EUROPEAN GUIDELINES

FOR THE MANAGEMENT OF CHRONIC

NON-SPECIFIC LOW BACK PAIN

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O Airaksinen	JI Brox	C Cedraschi
J Hildebrandt	J Klaber-Moffett	F Kovacs
AF Mannion	S Reis	JB Staal
H Ursin	G Zanoli	

On behalf of the COST B13 Working Group on Guidelines for Chronic Low Back Pain

Contributors:

JAN HILDEBRANDT (CO-CHAIR)   Anaesthesiologist/Algesiologist (DE) Chair + Chapters *Multidisciplinary treatment, Pharmacological procedures (antidepressants, opioids, antiepileptic drugs, capsicum plasters), Injections and nerve blocks, Radiofrequency and electrothermal procedures, Spinal Cord Stimulation*

HOLGER URSIN (CO-CHAIR)   Biological and Medical Psychology (NO) Chair + Chapter *Cognitive behavioural therapy*

ANNE F. MANNION (EDITOR)   Physiologist/Clinical Researcher (CH) Editor + Chapters *Exercise therapy, Manual Therapy (manipulation/mobilization), Physical treatments, Brief educational interventions,*

OLAVI AIRAKSINEN   Rehabilitation Physician (FI) Chapters *Patient assessment (imaging, electromyography), Pharmacological procedures (NSAIDs, muscle relaxants)*

JENS IVAR BROX   Physical Medicine (NO) Chapters *Definition, epidemiology, patient assessment (physical examination and case history), Physical therapy, Manual Therapy (manipulation/mobilization)*

CHRISTINE CEDRASCHI   Psychologist (CH) Chapters *Cognitive behavioural therapy, Brief educational interventions*

JENNIFER KLABER-MOFFETT   Rehabilitation/Physiotherapist (UK) Chapters *Exercise therapy, Manual Therapy (manipulation/mobilization), Brief educational interventions*

FRANCISCO KOVACS   General practitioner (ES) Chapters *Manual Therapy (manipulation/mobilization), Neuroreflexotherapy, Traction, Acupuncture*

SHMUEL REIS   General practitioner (IL)

BART STAAL   Epidemiologist/Physiotherapist (NL) Chapters *Physical treatments, Manual Therapy (Massage), PENS, Back schools, Brief educational interventions*

GUSTAVO ZANOLI   Orthopaedic Surgeon (IT) Chapter *Surgery*

MEMBERS WHO PARTICIPATED IN THE FIRST MEETINGS

LUC BROOS	Physical Medicine	(BE)
IRENE JENSEN	Psychologist	(SE)
MARTIN KRISMER	Orthopaedic surgeon	(AT)
CHARLOTTE LEBOEUF-YDE	Epidemiologist	(DK)
WILHELM NIEBLING	General practitioner	(DE)
JOHAN VLAEYEN	Psychologist	(BE)

ADDITIONAL CONTRIBUTORS TO THE GUIDELINES DOCUMENT

STAFF AND STUDENTS OF DEPT. OF BIOL & MED PSYCH AND HALOS/UNIFOB	University of Bergen, Norway	Administrative and technical assistance.
DAVID O'RIORDAN	Schulthess Klinik, Zürich	Assistance with summaries and quality rating of exercise trials; assistance with literature management
EMMA HARVEY	University of Leeds	Assistance cross-checking the SRs/RCTs on exercise
JO JORDAN KATHERINE DEANE	Chartered Soc Physio, UK Uni Northumbria, UK	Assistance with summaries and quality rating for additional exercise trials

Objectives

The primary objective of the European evidence-based guidelines is to provide a set of recommendations that can support existing and future national and international guidelines or future updates of existing back pain guidelines.

This particular guideline intends to foster a realistic approach to improving the treatment of common (non-specific) chronic low back pain (CLBP) in Europe by:

1. Providing recommendations on strategies to manage chronic low back pain and/or its consequences in the general population and in workers.
2. Ensuring an evidence-based approach through the use of systematic reviews and existing evidence-based guidelines, supplemented (where necessary) by individual scientific studies.
3. Providing recommendations that are generally acceptable to a wide range of professions and agencies in all participating countries.
4. Enabling a multidisciplinary approach, stimulating collaboration between the various players potentially involved in treatment, thus promoting consistency across countries in Europe.
5. Identifying ineffective interventions to limit their use.
6. Highlighting areas where more research is needed.

Target population

The target population of this guideline on diagnosis and treatment of chronic non-specific low back pain comprises individuals or groups that are going to develop new guidelines (national or local) or update existing guidelines, and their professional associations that will disseminate and implement these guidelines. Indirectly, these guidelines also aim to inform the general public, people with low back pain, health care providers, health promotion agencies, industry/employers, educationalists, and policy makers in Europe.

When using this guideline as a basis, it is recommended that guideline development and implementation groups should undertake certain actions and procedures, not all of which could be accommodated under COST B13. These will include: taking patients' preferences into account; performing a pilot test among target users; undertaking external review; providing tools for application; considering organisational obstacles and cost implications; providing criteria for monitoring and audit; providing recommendations for implementation strategies (van Tulder et al 2004). In addition, in the absence of a review date for this guideline, it will be necessary to consider new scientific evidence as it becomes available.

The recommendations are based primarily on the available evidence for the effectiveness and safety of each treatment. Availability of the treatments across Europe will vary. Before introducing a recommended treatment into a setting where it is not currently available, it would be wise to consider issues such as: the special training needs for the treating clinician; effect size for the treatment, especially with respect to disability (the main focus of treatments for CLBP); long-term cost/effectiveness in comparison with currently available alternatives that use a similar treatment concept.

Guidelines working group

The guideline group on chronic, non-specific low back pain was developed within the framework of the COST ACTION B13 'Low back pain: guidelines for its management', issued by the European Commission, Research Directorate-General, department of Policy, Co-ordination and Strategy. The guidelines Working Group (WG) consisted of experts in the field of low back pain research. Members were invited to participate, to represent a range of relevant professions. The core group

consisted of three women and eight men from various disciplines, representing 9 countries. None of the 11 members believed they had any conflict of interest.

The WG for the chronic back pain guidelines had its first meeting in May 2001 in Amsterdam. At the second meeting in Hamburg, in November 2001, five sub-groups were formed to deal with the different topics (patient assessment; medical treatment and invasive interventions; exercise and physical treatment and manual therapy; cognitive behavioural therapy and patient education; multidisciplinary interventions). Overall seven meetings took place, before the outline draft of the guidelines was prepared in July 2004, following which there was a final meeting to discuss and refine this draft. Subsequent drafts were circulated among the members of the working group for their comments and approval. All core group members contributed to the interpretation of the evidence and group discussions. Anne Mannion played a major role in editing (language and content) the whole document in the final stages. The guidelines were reviewed by the members of the Management Committee of COST B13, in Palma de Mallorca on 23rd October 2004. The full guidelines are available at: www.backpaineurope.org

References
1. van Tulder MW, Tuut M, Pennick V, Bombardier C, Assendelft WJ **(2004)** Quality of primary care guidelines for acute low back pain. Spine, 29(17): E357-62.

Summary of the concepts of diagnosis in chronic low back pain (CLBP)

- **Patient assessment**
  Physical examination and case history:
  The use of diagnostic triage, to exclude specific spinal pathology and nerve root pain, and the assessment of prognostic factors (yellow flags) are recommended. We cannot recommend spinal palpatory tests, soft tissue tests and segmental range of motion or straight leg raising tests (Lasegue) in the diagnosis of non-specific CLBP.
  Imaging:
  We do not recommend radiographic imaging (plain radiography, CT or MRI), bone scanning, SPECT, discography or facet nerve blocks for the diagnosis of non-specific CLBP unless a specific cause is strongly suspected.
  MRI is the best imaging procedure for use in diagnosing patients with radicular symptoms, or for those in whom discitis or neoplasm is suspected. Plain radiography is recommended for the assessment of structural deformities.
  Electromyography:
  We cannot recommend electromyography for the diagnosis of non-specific CLBP.
- **Prognostic factors**
  We recommend the assessment of work related factors, psychosocial distress, depressive mood, severity of pain and functional impact, prior episodes of LBP, extreme symptom reporting and patient expectations in the assessment of patients with non-specific CLBP.

Summary of the concepts of treatment of chronic low back pain (CLBP)

- **Conservative treatments**:
  Cognitive behavioural therapy, supervised exercise therapy, brief educational interventions, and multidisciplinary (bio-psycho-social) treatment can each be recommended for non-specific CLBP. Back schools (for short-term improvement), and short courses of manipulation/mobilisation can also be considered. The use of physical therapies (heat/cold, traction, laser, ultrasound, short wave, interferential, massage, corsets) cannot be recommended. We do not recommend TENS.
- **Pharmacological treatments**: The short term use of NSAIDs and weak opioids can be recommended for pain relief. Noradrenergic or noradrenergic-serotoninergic antidepressants, muscle relaxants and capsicum plasters can be considered for pain relief. We cannot recommend the use of Gabapentin.
- **Invasive treatments**:
  Acupuncture, epidural corticosteroids, intra-articular (facet) steroid injections, local facet nerve blocks, trigger point injections, botulinum toxin, radiofrequency facet denervation, intradiscal radiofrequency lesioning, intradiscal electrothermal therapy, radiofrequency lesioning of the dorsal root ganglion, and spinal cord stimulation cannot be recommended for non-specific CLBP. Intradiscal injections and prolotherapy are not recommended. Percutaneous electrical nerve stimulation (PENS) and neuroreflexotherapy can be considered where available. Surgery for non-specific CLBP cannot be recommended unless 2 years of all other recommended conservative treatments — including multidisciplinary approaches with combined programs of cognitive intervention and exercises — have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease.

Overarching comments
- In contrast to acute low back pain, only very few guidelines exist for the management of CLBP.
- CLBP is not a clinical entity and diagnosis, but rather a symptom in patients with very different stages of impairment, disability and chronicity. Therefore assessment of prognostic factors before treatment is essential.
- Overall, there is limited positive evidence for numerous aspects of diagnostic assessment and therapy in patients with non-specific CLBP.
- In cases of low impairment and disability, simple evidence-based therapies (i.e. exercises, brief interventions, and medication) may be sufficient.
- No single intervention is likely to be effective in treating the overall problem of CLBP of longer duration and more substantial disability, owing to its multidimensional nature.
- For most therapeutic procedures, the effect sizes are rather modest.
- The most promising approaches seem to be cognitive-behavioural interventions encouraging activity/exercise.
- It is important to get all the relevant players onside and to provide a consistent approach.

Summary of recommendations for further research
In planning further research in the field of chronic non-specific low back pain, the following issues/areas requiring particular attention should be considered.

Methodology
- Studies of treatment efficacy/effectiveness should be of high quality, i.e. where possible, in the form of randomised controlled trials.
- Future studies should include cost-benefit and risk-benefit analyses.

General considerations
- Studies are needed to determine how and by whom interventions are best delivered to specific target groups.
- More research is required to develop tools to improve the classification and identification of specific clinical sub-groups of CLBP patients. Good quality RCTs are then needed to determine the effectiveness of specific interventions aimed at these specific risk/target groups.
- More research is required to develop relevant assessments of physical capacity and functional performance in CLBP patients, in order to better understand the relationship between self-rated disability, physical capacity and physical impairment.
- For many of the conservative treatments, the optimal number of sessions is unknown; this should be evaluated through cost-utility analyses.

Specific treatment modalities
Physical therapy
Further research is needed to evaluate specific components of treatments commonly used by physical therapists, by comparing their individual and combined use. The combination of certain passive physical treatments for symptomatic pain relief with more "active" treatments aimed at reducing disability (e.g. massage, hot packs or TENS together with exercise therapy) should be further investigated. The application of cognitive behavioural principles to physiotherapy in general needs to be evaluated.

Exercise therapy
The effectiveness of specific types of exercise therapy needs to be further evaluated. This includes the evaluation of spinal stabilisation exercises, McKenzie exercises, and other popular exercise regimens that are often used but inadequately researched. The optimal intensity, frequency and duration of exercise should be further researched, as should the issue of individual versus group exercises. The "active ingredient" of exercise programmes is largely unknown; this requires considerably more research, in order to allow the development and promotion of a wider variety of low cost, but effective exercise programmes. The application of cognitive behavioural principles to the prescription of exercises needs to be further evaluated.

Back schools, brief education The type of advice and information provided, the method of delivery, and its relative effectiveness all need to be further evaluated, in particular with regard to patient characteristics and baseline beliefs/behaviour. The characteristics of patients who respond particularly well to minimal contact, brief educational interventions should be further researched.

Cognitive-behavioural therapy
The relative value of different methods within cognitive-behavioural treatment needs to be evaluated. The underlying mechanisms of action should also be examined, in order to identify subgroups of patients who will benefit most from cognitive-behavioural therapy and in whom components of pain persistence need addressing. Promising predictors of outcome of behavioural treatment have been suggested and need further assessment, such as treatment credibility, stages of change, expectations regarding outcome, beliefs (coping resources, fear-avoidance) and catastrophising.
The use of cognitive behavioural principles by professionals not trained in clinical psychology should be investigated, to find out how the latter can best be educated to provide an effective outcome.

Multidisciplinary therapy.
The optimal content of multidisciplinary treatment programmes requires further research. More emphasis should be placed on identifying the right treatment for the right patient, especially in relation to the extensiveness of the multidisciplinary treatment administered. This should be accompanied by cost-benefit analyses.

Pharmacological approaches
Only very few data exist concerning the use of opioids (especially strong opioids) for the treatment of chronic low back pain. Further RCTs are needed. No studies have examined the effects of long term NSAIDs use in the treatment of chronic low back pain; further studies, including evaluation of function, are urgently required. RCTs on the effectiveness of paracetamol and metamicol (also, in comparison with NSAIDs) are also encouraged. The role of muscle relaxants, especially in relation to longer-term use, is unclear and requires further study.

Invasive treatments
Patient selection (in particular), procedures, practical techniques and choice of drug all need further research. In particular, more high quality studies are required to examine the effectiveness of acupuncture, nerve blocks, and radiofrequency and electrothermal denervation procedures.

Surgery
Newly emerging surgical methods should be firstly examined within the confines of high quality randomized controlled trials, in which "gold standard" evidence-based conservative treatments serve as the control. Patients with failed back surgery should be systematically analysed in order to identify possible erroneous surgical indications and diagnostic procedures.

Methods not able to be recommended
It is possible that many of the treatments that '***we cannot recommend'*** in these guidelines (owing to lack of/conflicting evidence of effectiveness) may indeed prove to be effective, when investigated in high quality randomized controlled trials. Many of these treatment methods are used widely; we therefore encourage the execution of carefully designed studies to establish whether the further use of such methods is justified.

Non-responders
The treatments recommended in these guidelines are by no means effective for all patients with CLBP. Further research should be directed at characterising the sub-population of CLBP patients that are not helped by any of the treatments considered in these guidelines.

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Chronic LBP

Summary of evidence and recommendations

Chapter 2: Low back pain definitions and epidemiology

- The lifetime prevalence of low back pain is up to 84%.
- After an initial episode of LBP, 44-78% people suffer relapses of pain occur and 26-37%, relapses of work absence.
- There is little scientific evidence on the prevalence of chronic non-specific low back pain: best estimates suggest that the prevalence is approximately 23%; 11-12% population are disabled by low back pain.
- Specific causes of low back pain are uncommon (<15% all back pain).

Chapter 3: Patient assessment, and prognostic factors

C3 (A1-3) Patient assessment

Diagnostic triage, case history and physical examination

Summary of evidence
- Studies do not enable a valid evaluation of diagnostic accuracy of the straight leg raising test (level B).
- No single test has a high sensitivity and specificity for radiculopathy, ankylosing spondylitis or vertebral cancer (level B).
- There is conflicting evidence that spinal palpatory tests are reliable procedures to diagnose back pain (level C)
- Pain provocation tests are the most reliable of the palpatory tests (level B)
- Soft tissue tests are unreliable (level A)
- Regional range of motion is more reliable than segmental range of motion (level A)
- Intraexaminer reliability is better than interrater reliability for all palpatory tests (level A)
- As palpatory diagnostic tests have not been established as reliable and valid, the presence of the manipulable lesion remains hypothetical (B)

Recommendation
We recommend that diagnostic triage is carried out at the first assessment and at reassessment in patients with chronic low back pain to exclude specific spinal pathology and nerve root pain.

We recommend the assessment of prognostic factors (yellow flags) in patients with chronic low back pain. The validity and relevance of these factors are discussed in the section on prognostic factors.

We cannot recommend spinal palpatory and range of motion tests in the diagnosis of chronic low back pain.

C3 (A4) Imaging
Summary of evidence
- There is moderate evidence that radiographic imaging is not recommended for chronic non-specific low back patients (level B).

- There is moderate evidence that MRI is the best imaging procedure for use in patients with radicular symptoms, or for those in whom discitis or neoplasm is strongly suspected (level B).

- There is moderate evidence that facet joint injections, MRI and discography are not reliable procedures for the diagnosis of facet joint pain and discogenic pain (level B)

- SPECT and scintigraphy may be useful for diagnosing pseudoarthrosis after surgery for spinal fusion, in suspected stress fractures in the evaluation of malignancy, and in diagnosing symptomatic painful facet joints (level C).

Recommendation
We do not recommend radiographic imaging for chronic non-specific low back patients.

We recommend MRI in patients with serious red flags and for evaluation of radicular symptoms. Plain radiography is recommended for structural deformities.

We do not recommend MRI, CT, or facet blocks for the diagnosis of facet joint pain or discography for discogenic pain.

C3 (A5) Electromyography (EMG)
Summary of evidence
- There is conflicting evidence that surface EMG is able to differentiate patients with non-specific CLBP from controls and for monitoring rehabilitation programmes (level C).

- There is limited evidence that fear-avoidance is associated with increased muscle activity on lumbar flexion (level C).

- There is conflicting evidence for the usefulness of needle EMG in patients with lumbar spinal stenosis and spinal radiculopathies (level C).

Recommendation
We cannot recommend the use of electromyography as a diagnostic procedure in chronic non-specific low back pain.

C3 (B) Prognostic factors
Summary of evidence
- There is strong evidence that low work place support is a predictor of chronicity in patients with acute back pain (level A).
- There is strong evidence that in the worker having difficulty returning to normal occupational duties at 4-12 weeks the longer a worker is off work with LBP, the

lower the chances of ever returning to work; and that most clinical interventions are quite ineffective at returning people to work once they have been off work for a protracted period with LBP (level A).

- There is moderate evidence that psychosocial distress, depressive mood, severity of pain and functional impact and extreme symptom report, patient expectations, and prior episodes are predictors of chronicity (level B).
- There is moderate evidence that shorter job tenure, heavier occupations with no modified duty, radicular findings, are predictors of chronicity (level B).
- There is moderate evidence that no specific physical examination tests are of significant prognostic value in chronic non-specific LBP (level B)

Recommendation
We recommend that work related factors, psychosocial distress, patient expectations, and extreme symptom reporting are assessed in patients with chronic low back pain.

Chapter 4: Physical treatments

C4 (A) Interferential therapy
Summary of evidence
- There is no evidence for the effectiveness of interferential therapy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
- There is limited evidence that interferential therapy and motorized lumbar traction plus massage are equally effective in the treatment of chronic low back pain (level C).

Recommendation
We cannot recommend interferential therapy as a treatment for chronic low back pain.

C4 (B) Laser therapy
Summary of evidence
- There is conflicting evidence that laser therapy is effective for chronic low back pain with regard to pain improvement (level C).
- There is limited evidence that there is no difference in effectiveness between laser therapy, laser therapy and exercise and exercise (level C)

Recommendation
We cannot recommend laser therapy for the treatment of patients with chronic low back pain.

C4 (C) Lumbar supports

Summary of evidence
- There is no evidence for the effectiveness of lumbar supports compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
- There is no evidence for the effectiveness of lumbar supports compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend the wearing of a lumbar support for the treatment of non-specific chronic low back pain.

C4 (D) Shortwave diathermy

Summary of evidence
- There is no evidence for the effectiveness of shortwave diathermy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
- There is no evidence for the effectiveness of shortwave diathermy compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend shortwave diathermy as a treatment for chronic low back pain.

C4 (E) Therapeutic ultrasound

Summary of evidence
- There is limited evidence that therapeutic ultrasound is not effective in the treatment of chronic low back pain (level C).
- There is no evidence for the effectiveness of therapeutic ultrasound compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend therapeutic ultrasound as a treatment for chronic low back pain.

C4 (F) Thermotherapy

Summary of evidence
- There is no evidence for the effectiveness of thermotherapy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
- There is no evidence for the effectiveness of thermotherapy compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend thermotherapy/heat as a treatment for chronic low back pain.

C4 (G) Traction
Summary of evidence
- There is limited evidence that lumbar traction is **not** more effective than sham traction (level C).
- There is no evidence for the effectiveness of lumbar traction compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend lumbar traction as a treatment for chronic low back pain.

C4 (H) Transcutaneous electrical nerve stimulation (TENS)
Summary of evidence
There is strong evidence that TENS is not more effective than placebo or sham TENS in the treatment of chronic low back pain (level A).
There is moderate evidence that TENS is not more effective than vertebral axial decompression, acupuncture, PENS, or electroacupuncture in the treatment of chronic low back pain (level B).

Recommendation
We do not recommend TENS for the treatment of chronic low back pain.

Chapter 5: Exercise therapy

Summary of evidence
- There is moderate evidence that exercise therapy is more effective in the reduction of pain and/or disability, at least in the short-term, than passive treatments intended/considered to be control treatments by the authors of the respective RCTs (level B).
- There is strong evidence that exercise therapy is more effective than "GP care" for the reduction of pain and disability and return to work in at least the mid-term (3-6 months) (level A).
- There is strong evidence that exercise therapy alone is not more effective than conventional physiotherapeutic methods in the treatment of chronic LBP (level A).
- There is conflicting evidence regarding the effectiveness of exercise as compared with intensive multidisciplinary programmes (level C).
- There is strong evidence that strengthening/reconditioning exercises are no more effective than other types of exercises in the treatment of chronic LBP (level A).
- There is limited evidence in each case that: there are no differences between aerobic exercises, muscle reconditioning or physiotherapy exercises in relation to pain or disability up to 12 months after treatment; there are no significant differences between the effects on pain reduction of carrying out just 4 exercise therapy sessions as opposed to 8 sessions; aerobic exercises are superior to lumbar flexion exercises in terms of pain immediately after the programme; a home exercise programme with individualised exercises is more effective than one using general exercises; a combined exercise and motivational programme shows a significantly larger decrease in pain and disability up to 12 months post-treatment than does exercise alone (each, level C).
- There is conflicting evidence regarding the effectiveness of programmes involving mainly trunk flexion exercises as compared with those involving mainly trunk extension (level C).

- There is moderate evidence that individually supervised exercise therapy is not more effective than supervised groups exercise (level B).
- There is strong evidence that the changes in pain and disability reported after various types of exercise therapy are not directly related to changes in any aspect of physical performance capacity (level A).

Recommendation
We recommend supervised exercise therapy as a first-line treatment in the management of chronic low back pain.

We advocate the use of exercise programmes that do not require expensive training machines. The use of a cognitive-behavioural approach, in which graded exercises are performed, using exercise quotas, appears to be advisable. Group exercise constitutes an attractive option for treating large numbers of patients at low cost. We do not give recommendations on the specific type of exercise to be undertaken (strengthening/ muscle conditioning, aerobic, McKenzie, flexion exercises, etc.). The latter may be best determined by the exercise-preferences of both the patient and therapist.

Chapter 6: Manual therapy

C6 (A) Manipulation/mobilisation
Summary of the evidence
- There is moderate evidence that manipulation is superior to sham manipulation for improving short-term pain and function in CLBP (level B).
- There is strong evidence that manipulation and GP care/analgesics are similarly effective in the treatment of CLBP (level A)
- There is moderate evidence that spinal manipulation in addition to GP care is more effective than GP care alone in the treatment of CLBP (level B).
- There is moderate evidence that spinal manipulation is no less and no more effective than physiotherapy/exercise therapy in the treatment of CLBP (level B).
- There is moderate evidence that spinal manipulation is no less and no more effective than back-schools in the treatment of CLBP (level B).

Recommendation
Consider a short course of spinal manipulation/mobilisation as a treatment option for CLBP.

C6 (B) Massage
Summary of evidence
- There is limited evidence in each case that massage is more effective than: sham procedures; remedial exercise and posture education; relaxation therapy (for pain relief); acupuncture (long-term pain relief and function); self-care education (for short-term pain relief and improvement of function); and general physical therapies (for mid-term pain relief (each, level C)).
- There is limited evidence that massage and spinal manipulation are equally effective for pain relief, but that massage results in less functional improvement than spinal manipulation (each level C).
- There is limited evidence that there is no difference between massage and transcutaneous muscle stimulation with regard to improvements in either pain or

function (level C). There is limited evidence that massage is less effective than TENS in relieving pain (level C).

- There is limited evidence that there is no difference in the effectiveness of massage and the wearing of a corset (level C).
- There is limited evidence that a combined treatment of massage with remedial exercises and education is better than massage alone, remedial exercises alone or sham laser therapy for short-term pain relief and improved function (level C).
- There is limited evidence that therapeutic acupuncture massage is more effective than classical massage (level C).

Recommendation
We cannot recommend massage therapy as a treatment for chronic low back pain.

Chapter 7: Back schools and brief educational interventions/advice to promote self-care

C7 (A) Back schools
Summary of evidence
- There is conflicting evidence for the effectiveness of back schools with regard to pain, functional status and return to work, compared with waiting list controls or 'placebo' interventions (level C).
- There is moderate evidence that back school is more effective than other treatments examined (simple advice, exercises only, manipulation) with regards to pain and functional status in the short-term (level B). There is moderate evidence for no difference between back schools and these other treatments with regard to their long-term effects on pain and functional status (level B).

Recommendation
Consider back schools where information given is consistent with evidence-based recommendations for short-term (<6 weeks) pain relief and improvements in functional status. We do not recommend back schools as a treatment for chronic low back pain when aiming at long-term effects (>12 months).

C7 (B) Minimal contact/brief educational interventions to promote self-care
Summary of evidence
- There is moderate evidence that brief interventions addressing concerns and encouraging a return to normal activities are better than usual care in increasing return to work rates (level B).
- There is moderate evidence that brief interventions encouraging self-care are more effective than usual care in reducing disability (up to 6 months) but not pain (level B).
- There is limited evidence that Internet-based discussion groups/educational interventions are more effective than no intervention in reducing disability (level C).
- There is conflicting evidence that Internet-based discussion groups/educational interventions are more effective than no intervention in reducing pain (level C).
- There is strong evidence that brief interventions provided by a physiotherapist, or a physician and physiotherapist, and encouraging a return to normal activities, are as effective in reducing disability as routine physiotherapy or aerobic exercise (level A)

- There is limited evidence that brief self-care interventions are as effective as massage or acupuncture in terms of reducing pain and disability (level C).

Recommendation
We recommend brief educational interventions, which can be provided by a physiotherapist or a physiotherapist and physician, and which encourage a return to normal activities, to reduce sickness absence and disability associated with CLBP.

We do not give recommendations on the specific type of brief educational intervention to be undertaken (face-to-face, Internet-based, one-to-one, group education, discussion groups, etc.). The latter may best be determined by the available resources and the preferences of both the patient and therapist.
The emphasis should be on the provision of reassurance and positive messages that encourage a return to normal activities.

Chapter 8: Cognitive-behavioural treatment methods

Summary Evidence
- There is strong evidence that behavioural treatment is more effective for pain, functional status and behavioural outcomes than placebo/no treatment/waiting list control (level A).
- There is strong evidence that a graded activity programme using a behavioural approach is more effective than traditional care for returning patients to work (level A).
- There is limited evidence that there is no difference between behavioural therapy and exercise therapy in terms of their effects on pain, functional status or depression up to 1 yr after treatment (level C).
- There is limited evidence that in patients with chronic LBP and evidence of lower lumbar disc degeneration there is no difference between the effects of cognitive-behavioural therapy and spinal fusion in terms of disability 1 yr after treatment (level C).
- There is moderate evidence that the addition of cognitive behavioural treatment to another treatment has neither short nor long term effects on functional status and behavioural outcomes (level B).
- There is strong evidence that there is no difference in effectiveness between the various types of behavioural therapy (level A).

Recommendation
We recommend cognitive-behavioural treatment for patients with chronic low back pain.

Chapter 9: Multidisciplinary treatment

Summary of evidence
- There is strong evidence that intensive multidisciplinary biopsychosocial rehabilitation with a functional restoration approach reduces pain and improves function in patients with chronic low back pain (level A).

- There is moderate evidence that intensive multidisciplinary biopsychosocial rehabilitation with a functional restoration approach is more effective than outpatient non-multidisciplinary rehabilitation or usual care with respect to pain (level B).

- There is strong evidence that intensive multidisciplinary biopsychosocial interventions are effective in terms of return to work, work-readiness (level A).

- There is strong evidence that intensive physical training ("work hardening") programs with a cognitive-behavioural component are more effective than usual care in reducing work absenteeism in workers with back pain (level A).

Recommendation
We recommend multidisciplinary biopsychosocial rehabilitation with functional restoration for patients with chronic low back pain who have failed monodisciplinary treatment options.

Chapter 10: Pharmacological procedures

C10 (A) Antidepressants

Summary of evidence
- There is strong evidence that noradrenergic and noradrenergic-serotonergic antidepressants are effective in relieving pain in patients with chronic low back pain (level A).
- There is moderate evidence that activities of daily living (function, disability) are **not** improved by antidepressants (level B).

Recommendation
Consider the use of noradrenergic or noradrenergic-serotonergic antidepressants as co-medication for pain relief in patients with chronic low back pain without renal disease, glaucoma, pregnancy, chronic obstructive pulmonary disease and cardiac failure.

C10 (B) Muscle relaxants
Summary of evidence
- There is strong evidence that benzodiazepines are effective for pain relief (level A) and conflicting evidence that they are effective for relieving muscle spasm (level C).
- There is conflicting evidence that non-benzodiazepines are effective for pain relief (level C) and that they are **not** effective for the relief of muscle spasm.

Recommendation

Consider the use of muscle relaxants (benzodiazepines) for short-term pain relief in chronic LBP, but use them with caution due to their side effects (drowsiness, dizziness, addiction, allergic side-effects, reversible reduction of liver function, gastrointestinal events). As they do not appear to exert their effect by reducing muscle spasm, other pain relieving drugs with fewer serious side-effects should be considered first.

C10 (C) NSAIDs

Summary of evidence
Most studies have examined the effectiveness for up to 3-month periods of time. There is strong evidence that NSAIDs are effective for the relief of chronic low back pain (level A).

Recommendation
We recommend NSAIDs for pain relief in patients with chronic low back pain. Because of the side-effects, NSAIDs should only be used for exacerbations or short-term periods (up to 3 months).

C10 (D) Opioids

Summary of evidence
- There is strong evidence that weak opioids relieve pain and disability in the short-term in chronic low back pain patients (level A).
- There is limited evidence that strong opioids relieve pain in the short-term in chronic low back pain patients (level C).

Recommendation
We recommend the use of weak opioids (e.g. tramadol) in patients with non-specific chronic low back pain who do not respond to other treatment modalities. Due to the risk of addiction, slow-release opioids are preferable to immediate-release opioids, and should be given regularly (around the clock) rather than as needed.

C10 (E) Antiepileptic drugs (Gabapentin)

Summary of evidence
- There is limited evidence that gabapentin is not effective for the relief of chronic low back pain (level C).

Recommendation
We cannot recommend the use of gabapentin in patients with non-specific chronic low back pain.

C10 (F) Capsicum pain plasters (capsaicin)

Summary of evidence
- There is strong evidence that capsicum pain plaster is more effective than placebo for short term (3 weeks) treatment (level A).

Recommendation
Consider capsicum pain plasters for short-term symptomatic pain relief in chronic low back pain.

Chapter 11: Invasive procedures

C11 (A) Acupuncture

Summary of evidence
- There is conflicting evidence that acupuncture is better than a sham procedure in the treatment of chronic low back pain (level C).
- There is moderate evidence that acupuncture is not more effective than trigger point injection and TENS (level B).
- There is limited evidence that acupuncture is less effective than massage and spinal manipulation (level C).
- There is limited evidence in each case that acupuncture is similar to self-care education, and better than training of proper posture and motion in accordance with Bruegger concepts (level C).
- There is limited evidence that the addition of acupuncture improves the results of standard GP treatment (defined as exercise, NSAIDs, aspirin and/or non-narcotic analgesics) or conventional treatment (defined as physiotherapy, exercise, back school, mud packs, infrared heat therapy and diclofenac) (level C).

Recommendation
We cannot recommend acupuncture for the treatment of chronic low back pain.

C11 (B) Injections and nerve blocks

C11 (B1) Epidural corticosteroids and spinal nerve root blocks with steroids

Summary of evidence
There is no evidence for the effectiveness of epidural corticosteroids in patients with non-radicular, non-specific low back pain (level D).

Recommendation
We cannot recommend the use of epidural corticosteroids in patients with non-radicular, non-specific low back pain.

C11 (B2) Facet injections

Summary of evidence
There is no evidence for the effectiveness of intraarticular injections of steroids or facet nerve blocks in patients with non-specific low back pain (level D).

Recommendation
We cannot recommend the use of intraarticular injections of steroids or facet nerve blocks in patients with non-specific chronic low back pain.

C11 (B3) Intradiscal injections

Summary of evidence
There is moderate evidence that local intradiscal injections (glucocorticoid or glycerol) are not effective for chronic low back pain (level B).

Recommendation
We do not recommend the use of intradiscal injections for the treatment of chronic low back pain.

C11 (B4) Intramuscular injections of botulinum toxin

Summary of evidence
There is limited evidence that Botulinum toxin is effective for the treatment of chronic low back pain (level C)

Recommendation
We cannot recommend the use of Botulinum toxin for the treatment of chronic non-specific low back pain.

C11 (B5) Sacroiliac joint injections

Summary of evidence
There is limited evidence that injection of the sacroiliac joint with corticosteroids relieves sacroiliac pain of unknown origin for a short time (level C).

Recommendation
We cannot recommend the use of sacroiliac joint injections with corticosteroids for the treatment of non-specific chronic low back pain.

C11 (B6) Sclerosant injections (prolotherapy)

Summary of evidence
There is strong evidence that local injections with sclerosants (prolotherapy) in the ligaments of the back are not effective for non-specific chronic low back pain (level A).

Recommendation
We do not recommend the injection of sclerosants (prolotherapy) for the treatment of non-specific chronic low back pain.

C11 (B7) Trigger point injections

Summary of evidence
There is conflicting evidence for the short-term effectiveness of local intramuscular or ligament (lig. ilio-lumbale) infiltration with anaesthetics in chronic low back pain (level C).

Recommendation
We cannot recommend the use of trigger point injections in patients with chronic low back pain.

C11 (C) Neuroreflexotherapy

Summary of evidence

- There is strong evidence that NRT is more effective than a sham procedure in providing pain relief up to 30-45 days (level A)
- There is limited evidence that NRT is more effective than a sham procedure in improving return to work (level C).
- There is limited evidence that the addition of NRT to standard medical care provides better outcomes than standard care alone with respect to short-term (up to 60 days) pain relief and disability, and for subsequent drug treatment, healthcare utilisation and sick leave up to 1 year later (level C).
- Only minor and rare adverse events have been reported.

Recommendation

Consider NRT for patients with moderate or severe (≥3 points on a VAS) low back pain.

C11 (D) Percutaneous electrical nerve stimulation (PENS)

Summary of evidence

- There is moderate evidence that PENS is more effective than sham PENS in the treatment of chronic low back pain (level B).
- There is conflicting evidence that PENS is more effective than other treatments in the treatment of chronic low back pain (level C).
- There is conflicting evidence that PENS treatments with 30 minutes duration of electrical stimulation, with an alternating frequency of 15 and 30 Hz, and with needles probes positioned along the involved nerve roots at dermatomal levels corresponding to the patients' pain symptoms are more effective than PENS treatments with other treatment characteristics (level C).

Recommendation

Consider PENS for symptomatic pain reduction in patients with chronic non-specific low back pain.

C11 (E) Radiofrequency (RF) and electrothermal denervation procedures

C11 (E1) Radiofrequency (RF) facet denervation

Summary of evidence

- There is conflicting evidence that RF denervation of the facet joints is more successful than placebo for eliciting short-term or long-term improvements in pain or functional disability in mechanical chronic low back pain (level C). Proper selection of the patients (successful diagnostic blocks) and an optimal technique may be important to achieve better results.
- There is limited evidence that intra-articular denervation of the facet joints is more effective than extra-articular denervation (level C).

Recommendation

We cannot recommend RF facet denervation for patients with non-specific chronic low back pain.

C11 (E2) Intradiscal Radiofrequency Thermocoagulation (IRFT) and Intradiscal Electrothermal Therapy (IDET)

Summary of evidence
- There is conflicting evidence that procedures aimed at reducing the nociceptive input from painful intervertebral discs using either IRFT or IDET, in patients with discogenic low back pain pain, are not more effective than sham treatments (level C).
- There is limited evidence that RF lesioning of the ramus communicans is effective in reducing pain up to 4 months after treatment (level C).

Recommendation
We cannot recommend the use of intradiscal radiofrequency, electrothermal coagulation or radiofrequency denervation of the rami communicans for the treatment of either non-specific or "discogenic" low back pain.

C11 (E3) Radiofrequency (RF) lesioning of dorsal root ganglion

Summary of evidence
There is limited evidence that radiofrequency lesions of the DRG are not effective in the treatment of chronic LBP (level C).

Recommendation
We cannot recommend the use of RF lesioning of the dorsal root ganglion to treat chronic low back pain.

C11 (F) Spinal cord stimulation

Summary of evidence
There is no evidence on the effectiveness of spinal cord stimulation in patients with non-specific chronic low back pain (level D).

Recommendation
We cannot recommend the use of spinal cord stimulation for the treatment of chronic non-specific LBP.

C11 (G) Surgery

Evidence Summary
- There is limited evidence that in selected patients with severe CLBP and degenerative changes at L4-L5 or L5-S1 level, who have failed to improve with conservative treatment, surgery is successful in relation to improvements in functional disability (Oswestry) and pain up to 2 years after treatment when compared to traditional non-specific conservative treatment in Sweden (level C)
- There is moderate evidence that surgery is similar to a combined program of cognitive intervention and exercises provided in Norway or UK in improving functional disability (Oswestry) (level B)
- There is strong evidence that demanding, expensive and higher risk surgical techniques are not better than the most straightforward and least expensive surgical technique of posterolateral fusion without internal fixation (level A)
- There is conflicting evidence on the cost-effectiveness of surgery: it appeared to be slightly more cost-effective than (or equal to) traditional non-specific conservative treatment in Sweden, but twice as expensive as a combined program of cognitive intervention and exercises provided in UK, for which similar clinical results had been obtained (level C)

- The complication rate after surgery has been reported to be around 17-18% (6 to 31% depending on technique) with a 6-22% re-intervention rate.
- In the trials examined, 4-22% of patients allocated to the non-surgical treatment arms also underwent surgery.

Recommendation

We cannot recommend fusion surgery for CLBP unless 2 years of all other recommended conservative treatments have failed and combined programs of cognitive intervention and exercises are not available in the given geographical area. Considering the high complication rates of surgery, as well as the costs to society and suffering for patients with failed back surgery, we strongly recommend that only carefully selected patients with severe pain (and with maximum 2 affected levels) should be considered for this procedure.

Chapter 1. Methods

Literature search
The recommendations for treatments are based on a systematic review of systematic reviews and randomized clinical trials on chronic low back pain (CLBP).

The following databases were searched for systematic reviews published before November 2002: Cochrane, Medline, Health Star, Embase, Pascal, Psychoinfo, Biosis, Lilacs and IME (Indice Medico Espanol). The general search strategies used are shown in the Appendix.
Where a Cochrane review was found for a given procedure, this formed the basis for putting together the recommendations for that procedure.

Additional RCTs (i.e. those possibly not included in the previously identified systematic reviews) were identified from electronic searches that covered a time period from January 1995 up to November 2002.
Other "additional studies" (both SRs and RCTs) were identified from the working group's personal knowledge of the literature, especially for papers published after November 2002.

Methodological quality of the studies
The methodological quality of a systematic review (SR) identified by the search was assessed using the Oxman & Guyatt index (Oxman and Guyatt 1991). SRs were rated from 0 to 7: SRs rating as 4 (or lower) were those for which it was difficult to rule out major flaws (= low quality); SRs with a rating of 5 or higher were considered to be "high quality".

Additional relevant RCTs, not previously included in the latest systematic reviews, were also assessed for their methodological quality, using criteria related to the internal validity of the trial (van Tulder et al 1997). One point was awarded for each condition that was fulfilled. If a trial achieved a score of 5 or more out of 10, it was considered "high quality".

Checklist for methodological quality of therapy studies
1)   Adequate method of randomisation
2)   Concealment of treatment allocation
3)   Withdrawal/drop-out rate described and acceptable
4)   Co-interventions avoided or equal
5)   Blinding of patients
6)   Blinding of observer
7)   Blinding of care provider
8)   Intention-to-treat analysis
9)   Compliance
10)   Similarity of baseline characteristics

Where additional RCTs were used to supplement the evidence derived from an existing Cochrane Review, the rating scheme of the corresponding Cochrane review (which sometimes differed slightly from that above, depending on the date of the review and the treatment modality in question) was used to provide consistency in assessing the overall evidence for a given treatment modality.

The additional RCTs were identified from the systematic electronic search (of papers up to November 2002), from the working group's personal knowledge of the literature

(for papers between November 2002 and the time of submission of this document), and (as a final check that nothing of importance had been overlooked) from a final search of Medline only, for all additional RCTs or systematic reviews since November 2002.

The evidence levels for the treatments were classified according the following classification:

Level A (Strong Evidence): Generally consistent* findings provided by (a systematic review of) multiple high quality randomised controlled trials (RCTs)
Level B (Moderate Evidence): Generally consistent findings provided by (a systematic review of) multiple low quality RCTs
Level C (Limited or Conflicting Evidence): One RCT (either high or low quality) or inconsistent findings from (a systematic review of) multiple RCTs
Level D (No Evidence): No RCTs

(*consistent findings were considered as those for which ≥75% studies showed a similar result)

Evaluation of the studies: criteria for inclusion/exclusion
Systematic reviews or RCTs involving individuals who were not, at the time, suffering from CLBP and for whom the intervention in question was being examined within the context of "secondary prevention" were not included (these are discussed separately in the "prevention" guidelines). Similarly, studies in which most of the patients had acute pain were excluded, even if some subacute and CLBP patients had taken part (unless the results for the chronic LBP patients were given separately). Those studies in which predominantly subacute and/or chronic LBP patients took part were included.

Furthermore, unless explicitly stated, studies on patients with CLBP with a select and uniform pathology (e.g. *all* with spondylolysis/spondylolisthesis, *all* with post-operative pain) were excluded. Although we concede that (i) these are not universally-accepted diagnoses/indications, (ii) they are not necessarily the cause of the chronic pain, and (iii) in *any* group of patients with non-specific pain these same pathologies/indications may also exist, we felt that the inclusion of homogeneous groups of *only* these patient types may limit the generalisability of the results.

It is rare for studies to include homogeneous groups of patients with *just* back pain and no leg pain, or groups in which *all* patients have *both* back and leg pain. The majority of studies are carried out on groups of patients "with non-specific back pain and/or leg (radiating) pain". Although this may appear to be a heterogeneous collective, unless the leg pain is of a radicular nature (an exclusion criteria in most studies), then the symptoms of both back and leg pain are in actual fact still most accurately covered by the term "non-specific chronic LBP".

Studies in which patients with mixed complaints were grouped (e.g. with respect to either the location of the chronic pain e.g. back and/or neck, back and/or general musculoskeletal pain, or its diagnosis e.g. non-specific LBP and/or chronic whiplash associated disorder) were also excluded, unless the results for the CLBP patients were given separately.

We have not examined treatment combinations (unless explicitly stated, e.g. for multidisciplinary treatment) i.e. the recommendations are given in relation to single treatments.

Treatment effectiveness was based on the outcome variables pain, disability, return to work, and use of health care resources. If a procedure was not effective with regards to any of these, it was felt not to be clinically relevant, even if it elicited changes in other outcome variables e.g. range of motion, strength, etc. We were unable to pass comment on effect sizes for each of the treatments, or the achievement of what might be considered "clinically relevant changes". In keeping with the approach used in most of the Cochrane Reviews, the evidence was, instead, compiled in relation to the achievement of statistically significant differences in treatment outcomes.

Recommendations given for each treatment
Based on the strength of evidence for the effectiveness of each treatment, in combination with various other "known concerns" (such as cost-effectiveness, safety, side-effects, and general provisos regarding the evidence itself e.g., duration of effect, breadth of effect for different outcomes, number of different studies/research groups addressing the problem, etc.) recommendations were made. Consensus was reached in formulating the final recommendations for each treatment. Although no formal grading scheme was applied during this procedure, and the recommendations were simply based on group discussion of all relevant factors, they fitted to the following overall scheme (devised a posteriori to provide further clarification to the reader):

- **"recommended"** (level A/B evidence of effectiveness in relation to sham treatments, treatments considered in the RCTs to be control treatments, or usual care; especially if level A/B evidence that better than/as good as other "potentially effective" treatments; and no "known concerns")
- **"consider using"** (level A/B evidence of effectiveness in relation to sham treatments, treatments considered in the RCTs to be control treatments, or usual care, but with some "known concerns"; or level A/B evidence that better than/as good as other "potentially effective" treatments and without "known concerns")
- **"we cannot recommend"** (level C/D evidence regarding effectiveness in relation to sham treatments, treatments considered in the RCTs to be control treatments, or usual care; with/without "known concerns")
- **"we do not recommend"** (level A/B evidence that not more effective than sham treatments, treatments considered in the RCTs to be control treatments, or usual care; with/without "known concerns").

Organisation of the work
Sub-groups were firstly formed to deal with the different topics. The searches for the SRs were carried out by three people (FK, JBS, CL), and the abstracts were categorised into their respective topic categories (AFM) for consideration by each sub-group. The sub-groups carried out their own searches for additional RCTs, and a later "top-up" search (in Medline only) was carried out by AFM for studies published after November 2002. Information was exchanged amongst the whole group regarding studies identified from their knowledge of the literature.
One or more members of each sub-group reviewed the evidence relating to the topic to which they had been assigned, and wrote a first draft. All drafts were discussed, revised, edited, and refereed by several members of the working groups.
All members of the Working Group have read and accepted the statements in these guidelines.

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Chapter 2: Chronic low back pain: definitions and epidemiology

Definitions

Low back pain is defined as pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain. In these guidelines, chronic low back pain is defined as low back pain persisting for at least 12 weeks, unless specified otherwise. This means that we deal with cases that may be characterised as subacute back pain, cases that have lasted for very long periods of time, and cases of recurrent pain in which the current episode has lasted for approximately 12 weeks. It also means that the type of patients being considered range from those who continue to function well inspite of pain to those who are severely incapacitated by persistent back pain. We do not deal specifically with repeated, short bouts of pain.

A simple and practical classification, which has gained international acceptance, is to divide low back pain into three categories – the so-called "diagnostic triage" (Waddell 1987):

- Specific spinal pathology
- Nerve root pain/radicular pain
- Non-specific low back pain

The recommendations are given in relation to "non-specific" chronic low back pain, i.e. low back pain that is not attributable to a recognisable, known specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or cauda equina syndrome).

Epidemiology

Low back pain in general

Six systematic reviews on the epidemiology of low back pain were identified (Balague et al 1999, Bressler et al 1999, Ebbehoj et al 2002, Hestbaek et al 2003, Pengel et al 2003, Walker 2000). Two of these specifically focused on children (Balague et al 1999, Ebbehoj et al 2002) and one on the elderly (Bressler et al 1999). None of the reviews gave specific prevalences for acute, recurrent, chronic, or non-specific low back pain. The high number of patients with recurrent pain often makes it difficult to distinguish between acute and chronic pain. There is a lack of standards for severity, location, and comorbid conditions.

One systematic review identified 56 population prevalence studies of low back pain (Walker 2000). Thirty studies were of acceptable quality. Point prevalence of low back pain ranged from 12-33%, 1-year prevalence from 22-65% and lifetime prevalence from 11-84%. Another systematic review included 12 studies that specifically examined the prevalence of back pain in the elderly (> 65 years) (Bressler et al 1999). It was concluded that the prevalence is not known with certainty but is not comparable with that in the younger population.

The two reviews on LBP in schoolchildren and adolescents reported a prevalence approaching that reported for adults (Balague et al 1999, Ebbehoj et al 2002). The cumulative (lifetime) prevalence was between 30% and 51% for subjectively rated morbidity and 14%-43% for objectively rated morbidity. The average annual incidence of LBP was estimated to be approximately 16%, with 50% of cases reporting recurrence, and 8% a chronic evolution (Balague et al 1999).

Low back pain fluctuates over time with frequent recurrences or exacerbations (van Tulder et al 2002).Two systematic reviews reported on the prognosis, long-term course or epidemiology of low back pain (Hestbaek et al 2003, Pengel et al 2003). One SR included 36 studies (Hestbaek et al 2003) and one included 15 studies (Pengel et al 2003). The first review reported that, after a first episode of low back pain, the proportion of patients who still experienced pain after 12 months was on average 62% (range 42-75%), the percentage of patients sick-listed after 6 months was 16% (range 3-40%), the percentage who experienced relapses of pain was 60% (range 44-78%), and the percentage who had relapses of work absence was 33% (range 26-37%) (Hestbaek et al 2003). The second review concluded that rapid improvements in pain (mean reduction 58% of initial scores), disability (58%), and return to work (82% of those initially off work) occurred in the first month after an initial episode of LBP. Further improvement was apparent until about three months. Thereafter levels for pain, disability, and return to work remained almost constant. 73% of patients had at least one recurrence within 12 months (Pengel et al 2003).

Two studies made a specific attempt to investigate the epidemiology of chronic LBP (Andersson et al 1993, Cassidy et al 1998). One involved a survey of a sample of 2184 Canadian adults between 20 and 69 years of age and revealed that, in the 6 months preceding the survey, nearly 50% of respondents had experienced low intensity/low disability low back pain, 12.3% high-intensity/low-disability low back pain and 11% high-disability low back pain (Cassidy et al 1998). A further study carried out on a random sample of 15% of the population aged 25-74 in two Swedish primary health care districts reported that the prevalence of chronic low back pain lasting longer than 3 months was 23% (Andersson et al 1993).

Specific causes of back pain
It is frequently reported that low back pain symptoms, pathology and radiological findings are poorly correlated. Pain is not attributable to specific pathology (as defined earlier) or neurological encroachment in about 85% of people (Deyo 1988). Clinicians should be aware of the incidence and characteristics of specific back pain. About 4% of people seen with low back pain in primary care have compression fractures and about 1% have a neoplasm (Deyo et al 1992). An observational study in more than 7000 women > 65 years reported that 5% developed at least one vertebral fracture in 4 years (Kado et al 2003).
The spondylarthropathies and spinal deformities commonly involve the whole spine. Spondylarthropathies have been reported to occur at a rate of 0.8 to 1.9% of the general population (Saraux et al 1999).
The prevalence of scoliotic deformities that appear as a rib prominence upon forward bending is reported to be between 1 and 4% (Dickson et al 1980, Span et al 1973, Strayer 1973). Kyphotic deformities such as Mb. Scheuerman are reported to occur in 1.5 % of the general population (Sorensen 1964).
Spinal infections are rare, and chronic spinal infections are particularly rare. Infectious diseases of the spine should be considered if the patient has fever, has had previous surgery, has a compromised immune system, or is a drug addict.

Spondylolysis and spondylolisthesis are often classified as non-specific low back pain because a considerable proportion of patients with such anatomic abnormalities are asymptomatic (Soler and Calderon 2000). The anatomic incidence is about 5% (Wiltse et al 1976). Spondylolisthesis is usually classified from grade 0 (spondylolysis) to grade 5 (spondyloptosis). The onset of symptoms often coincides with the adolescent growth spurt (Barash et al 1970).
To the best of our knowledge, the prevalence of lumbar radiculopathy has never been examined. In one large epidemiological study, the one-year incidence of

cervical radiculopathy was 83/100 000 (Radhakrishnan et al 1994); the incidence of lumbar radiculopathy is probably much higher.

Back and leg pain after surgery represent a major problem addressed at specific conferences for failed back surgery. Failure rates range from 5-50%. Based on a failure rate of 15%, it was estimated that 37500 new patients with failed back surgery syndrome would be generated annually in the US (Follet and Dirks 1993). One of the causes that is consistently reported in the literature includes poor patient selection (Goupille 1996, Van Goethem et al 1997). This means that patients with non-specific back pain are operated on for radiologically diagnosed disc bulging, herniation or degeneration, which turn out not to be responsible for their pain. Given the considerable personal suffering for patients and the costs to society, more efforts should be directed towards prevention of this situation. This is not solely the responsibility of the surgeons (Koes 1998).

Summary
- The lifetime prevalence of low back pain is up to 84%.
- After an initial episode of LBP, 44-78% people suffer relapses of pain occur and 26-37%, relapses of work absence.
- There is little scientific evidence on the prevalence of chronic non-specific low back pain: best estimates suggest that the prevalence is approximately 23%; 11-12% population are disabled by low back pain.
- Specific causes of low back pain are uncommon (<15% all back pain).

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Chapter 3   Patient assessment, and prognostic factors

C3 (A) Patient assessment

Most patients with chronic low back pain should have had a thorough history taking and a clinical examination in the acute and subacute stage. A thorough clinical examination should be repeated in the chronic stage. The primary purpose of the examination is the repeat screening for 'red flags', to assess "yellow flags" and to make a specific diagnosis. It is, however, well accepted that even in chronic low back pain it is often not possible to arrive at a diagnosis based on detectable pathological changes. Several systems of diagnosis have been suggested, in which low back pain is categorised based on pain distribution, pain behaviour, functional disability, clinical signs, etc. However, none of these systems of classification have been adequately validated.

The simple and practical classification of low back pain into three categories (specific spinal pathology, nerve root pain/radicular pain, and non-specific low back pain) sets the priority in the clinical examination procedure, including the history-taking and physical examination. The first priority is to make sure that the problem is of musculoskeletal origin and to rule out non-spinal pathology. The next step is to exclude the presence of specific spinal pathology. Suspicion of the latter is aroused by the history and/or the clinical examination and can be confirmed by further investigations. Serious red flag conditions like neoplasm, infection, and cauda equina syndromes are extremely rare (Carragee and Hannibal 2004). The examiner should have the clinical knowledge and skill to diagnose serious spinal pathology and structural deformities. The next priority is to decide whether the patient has nerve root pain. The patient's pain distribution and pattern will indicate that, and the clinical examination will often support it. If that is not the case, the pain is classified as non-specific low back pain.

The examination serves other important purposes besides reaching a "diagnosis". Through a thorough history taking and physical examination, it is possible to evaluate the degree of pain and functional disability. This enables the health care professional to outline a management strategy that matches the magnitude of the problem. Finally, a careful initial examination serves as a basis for providing the patient with credible information regarding diagnosis, management and prognosis and may help to reassure the patient. This information should be given in a common language understandable to the patient. Preferably, the information should be given consecutively during the clinical examination and when evaluating imaging. Terms like "positive" findings for significant pathology are hard to accept and understand for the patient. Concepts such as instability, disc displacement, slipping of the vertebra (spondylolisthesis) and hypo- and hypermobility, that refer to mechanical disorders that are not readily definable or not verified by experimental or clinical studies, should be avoided.

Psychosocial 'yellow flags' are factors that increase the risk of developing or perpetuating chronic pain and long-term disability, including work-loss associated with low back pain (Kendall et al 1997). The validity and relevance of these factors are discussed in the section on **prognostic factors**. Identification of 'yellow flags' should lead to appropriate cognitive and behavioural management. Examples of 'yellow flags' include:

- Inappropriate attitudes and beliefs about back pain (for example, the belief that back pain is harmful or potentially severely disabling, or a high expectation from passive treatments rather than the belief that active participation will help),

- Inappropriate pain behaviour (for example, fear-avoidance behaviour and reduced activity levels),
- Work related problems or compensation issues (for example, poor work satisfaction)
- Emotional problems (such as depression, anxiety, stress, tendency to low mood and withdrawal from social interaction) (Kendall et al 1997).

C3 (A1) Diagnostic triage
Evidence from scientific studies
Although there is general consensus on the importance and basic principles of differential diagnosis, no scientific studies have actually been carried out to evaluate the effectiveness of the diagnostic triage system recommended in most guidelines.

Clinical guidelines
All guidelines propose some form of diagnostic triage in which patients are classified as having: (a) possible specific spinal pathology e.g. tumour, infection, inflammatory disorder, fracture, cauda equina syndrome (where the clinician is alerted to these by the presence of 'red flags', such as: patient aged <20 or >55 years old, non-mechanical pain, thoracic pain, history of cancer, steroid use, structural changes, general unwellness, loss of weight, diffuse neurological deficit); (b) nerve root pain; or (c) non-specific low back pain.

Comments
Individual red flags do not necessarily link to a specific pathology, but indicate a higher probability of an underlying condition that may require further investigation. Multiple red flags need further investigation. Screening procedures for diagnoses that benefit from urgent treatment should be sensitive. Red flags have not been evaluated comprehensively in any systematic review. A recent study of 33 academic and 18 private practice settings (altogether 19,312 patient files) reported an incidence of spinal tumours of 0.69% and 0.12%, respectively (Slipman et al 2003). Patients with spinal pain caused by neoplastic disease who presented to musculoskeletal physiatrists were an average age of 65 years and reported a relatively high likelihood of night pain, aching character of symptom manifestation, spontaneous onset of symptoms, history of cancer, standing and walking provoking symptoms, and unexplained weight loss. In addition, the pain intensity level ranged widely, with an average VAS score of 6.8. (Slipman et al 2003). If there are no red flags, one can be 99% confident that serious spinal pathology has not been missed. It has been shown that, with careful clinical assessment revealing no red flags, X-rays detect significant spinal pathology in just one in 2500 patients (Waddell 1999).

C3 (A2) Case History
Evidence
One systematic review of 36 studies evaluated the accuracy of history-taking, physical examination and erythrocyte sedimentation rate in diagnosing low back pain. The review specifically examined the accuracy of signs and symptoms in diagnosing radiculopathy, ankylosing spondylitis and vertebral cancer (van den Hoogen et al 1995). The review found that few of the studied signs and symptoms seemed to provide valuable diagnostics. No single test seemed to have a high sensitivity and high specificity for radiculopathy; the combined history and the erythrocyte sedimentation rate had relatively high diagnostic accuracy in vertebral cancer; getting out of bed at night and reduced lateral mobility seemed to be the only moderately accurate items in ankylosing spondylitis.

Comments

The combination of history, signs and tests needs further evaluation. For example, the combination of back pain, spinal deformity (scoliosis or kyphosis) and elevated SR suggest further evaluation because spondylodiscitis is suspected (see imaging for further evaluation)

Although these signs and symptoms are not specific, high sensitivity is more important in order to detect patients with serious pathology that have a good prognosis when they are given the appropriate treatment.

C3 (A3) Physical Examination
Lasegue (passive straight leg raise) test
Definition of the procedure

The passive straight leg raise test (PSLR) requires a firm level couch, with a supine, relaxed patient with trunk and hips without lateral flexion. The practitioner should ensure that the patient's knee remains extended, with the foot in the vertical plane. The affected leg is supported at the heel and the limb gently elevated. The angle of leg elevation at the onset of pain and the site of pain is recorded. If the PSLR is unilaterally limited, induces unilateral symptoms, or is bilaterally limited to less than 50°, then each leg should be raised in turn to the onset of pain, lowered a few degrees (to reduce pain) and, in turn, the ankle dorsiflexed, the hip medially rotated, and the neck flexed. Symptom reproduction by one of these tests would be interpreted as a positive PSLR outcome, suggesting increase root tension.

Results of search

Two systematic reviews were identified (Deville et al 2000, Rebain et al 2002). The review of Deville et al included 17 studies; all were surgical case-series at non-primary care level and evaluated the diagnostic value of the Lasegue (or "straight leg raising") test for disc herniation. The review of Rebain et al included 20 studies.

Additional trials

No additional trials were found.

Quality assessment of the evidence

The systematic review was of high quality.

Evidence

In the review of Deville et al was found that the pooled diagnostic odds ratio for straight leg raising was 3.74 (95% CI 1.2 – 11.4); sensitivity was high 0.91 (0.82-0.94), but specificity was low 0.26 (0.16-0.38) (Deville et al 2000). The pooled diagnostic odds ratio for the crossed straight leg raising test was 4.39 (95% CI 0.74 – 25.9); with low sensitivity 0.29 (0.23-0.34) and high specificity 0.88 (0.86-0.90). The authors concluded that the studies do not enable a valid evaluation of diagnostic accuracy of the straight leg raising test. This does not imply that such tests are not useful as a screening procedure, but that the straight leg test is not sufficient to make the diagnosis of radiculopathy. A methodological weakness in many studies was that disc herniation was selected as outcome. Given the high number of disc herniations in asymptomatic persons, a large number of false negatives (in terms of herniation) might in fact have been true negatives in terms of herniation-related symptoms.

In the review of Rebain et al, the sensitivity of the test (0.8) was also far greater than its specifity (0.4) (Rebain et al 2002). The authors concluded that there remains no standard PSLR procedure, and no consensus on interpretation of the results. The PSLR is apparently simple to carry out and interpret. It is regarded as one of the diagnostic standards and is widely used. Until there is a standard procedure for

carrying out and interpreting the PSLR, with known reliability and validity, clinicians and researchers should treat the test with caution. More research is needed into the clinical use of the PSLR, its intraobserver and interobserver reliability, the influences of age, gender, diurnal variation, psychosocial factors, and its predictive value in lumbar intervertebral disc surgery.

Spinal palpation and motion tests
Definition of the procedure
In addition to history taking, the physical examination, and possibly also diagnostic imaging and laboratory tests, spinal palpation tests are sometimes used to determine whether manipulative therapy is indicated and/or to evaluate the effectiveness of an intervention. These tests essentially involve the assessment of symmetry of bony landmarks, quantity and quality of regional and segmental motion, paraspinal tissue abnormalities, and tenderness on provocation. The achievement of an accurate palpatory assessment depends to a large extent on the validity and reliability of the specific palpatory tests used.

Results of search.
Two systematic reviews (SR) were retrieved on the reliability of spinal palpation in the diagnosis of lumbar, thoracic and neck pain (Seffinger et al 2004) and lumbo-pelvic pain (Hestbaek and Leboeuf-Yde 2000). The review of Seffinger et al (2004) included a total of 49 articles in relation to 53 studies. Only those dealing with lumbar spinal tests (n=22 papers) were considered here: **1.** intra and interexaminer reliability for motion palpation tests (Bergstrom and Courtis 1986, Binkley et al 1995, Boline et al 1988, Grant and Spadon 1985, Inscoe et al 1995, Lindsay et al 1994, Maher et al 1998, Mastriani and Woodman 1991, Mootz et al 1989, Phillips and Twomey 2000, Rhudy et al 1988, Richter and Lawall 1993, Strender et al 1997) **2**. intraexaminer and interexaminer reliability for pain provocation tests (Boline et al 1988, Boline et al 1993, Hsieh et al 2000, Maher and Adams 1994, McCombe et al 1989, Nice et al 1992, Richter and Lawall 1993, Strender et al 1997, Waddell et al 1982) and **3.** intraexaminer and interexaminer reliability for soft tissue tests (Binkley et al 1995, Boline et al 1988, Byfield and Humphreys 1992, Downey et al 1999, Hsieh et al 2000, McKenzie and Taylor 1997).
The review of Hestbaek and Leboeuf-Yde (2000) evaluated the reliability and validity of chiropractic tests used to determine the need for spinal manipulative therapy of the lumbo-pelvic spine.

Additional trials
No additional trials were found.

Quality assessment of the reviews
Both SRs were of high quality. In the review of Seffinger (2004), of the 22 papers it included, 14 were rated as high quality and 8 low quality. No correlation was found between quality score and outcome.
Conclusion of the SRs
The majority of lumbar spinal palpatory diagnostic tests demonstrated low reliability. Data from higher quality studies showed acceptable reliability (Kappa value = 0.40 or greater) only for the following spinal palpatory diagnostic procedures: intraexaminer lumbar segmental vertrebral motion tests; interexaminer pain provocation test at L4/L5 and L5/S1; interexaminer lumbar paraspinal trigger points. There were mixed reliability results for interexaminer lumbar segmental vertrebral motion tests. Many trials did not show a high degree of reliability. In the studies that used kappa statistics, a higher percentage of the pain provocation studies demonstrated acceptable reliability (64%), followed by motion studies (58%), landmark studies

(33%) and soft tissue studies (0%). Among motion studies, regional range of motion was more reliable than segmental range of motion. Overall, intraexaminer reliability was better than interexaminer reliability. Paraspinal soft tissue palpatory tests had low interexaminer reliability, even though they are one of the most commonly used palpatory diagnostic procedures in clinical practice, especially by manual medicine practitioners.

The level of clinical experience of the examiners did not improve the reliability of the procedure. Contrary to common belief, examiners' consensus on procedure used, training just before the study, or use of symptomatic subjects, did not consistently improve reliability of spinal palpatory diagnostic tests.

Hestebaek and Leboef-Yde concluded that only tests for palpation of pain had acceptable results (Hestbaek and Leboeuf-Yde 2000). Motion palpation tests were not reliable. Palpation for muscle tension, palpation for misalignment, and visual inspection were undocumented, unreliable, or not valid.

Summary of evidence

- Studies do not enable a valid evaluation of diagnostic accuracy of the straight leg raising test (level B).
- No single test has a high sensitivity and specificity for radiculopathy, ankylosing spondylitis or vertebral cancer (level B).
- There is conflicting evidence that spinal palpatory tests are reliable procedures to diagnose back pain (level C)
- Pain provocation tests are the most reliable of the palpatory tests (level B)
- Soft tissue tests are unreliable (level A)
- Regional range of motion is more reliable than segmental range of motion (level A)
- Intraexaminer reliability is better than interrater reliability for all palpatory tests (level A)
- As palpatory diagnostic tests have not been established as reliable and valid, the presence of the manipulable lesion remains hypothetical (B)

Recommendation

We recommend that diagnostic triage is carried out at the first assessment and at reassessment in patients with chronic low back pain to exclude specific spinal pathology and nerve root pain.

We recommend the assessment of prognostic factors (yellow flags) in patients with chronic low back pain. The validity and relevance of these factors are discussed in the section on prognostic factors.

We cannot recommend spinal palpatory and range of motion tests in the diagnosis of chronic low back pain.

C3 (A4) Imaging

Definition of procedure

Imaging in patients with chronic low back pain serves two purposes: to evaluate patients with red flags or radicular pain; and to plan surgical techniques in those for whom surgery is being considered. In primary care settings, the most common spine imaging tests are plain radiography, computed tomography (CT), magnetic resonance imaging (MRI), and bone scanning. Other tests (myelography, discography, and positron emission tomography) are usually ordered by specialists

before surgical intervention and were therefore not reviewed. In general, referral for imaging should be based on a specific indication.

Plain Radiography

Low cost and ready availability make plain radiography the most common spinal imaging test. The anteroposterior and lateral views demonstrate alignment, disc and vertebral body height, and gross assessment of bone density and architecture; however, soft tissue structures are not evaluated extensively by these views. Oblique views show the pars interarticularis in profile and are useful for diagnosing spondylolysis when clinical suspicion of this disorder exists. Other special views include flexion and extension views to assess instability, and angled views of the sacrum to assess sacroiliac joints for ankylosing spondylitis. Several investigators have recommended discontinuing the use of routine oblique and spot lateral views because they do not provide adequate clinically relevant findings (Bigos et al 1994).

Computed Tomography (CT)

Computed tomography continues to play a vital role in spinal imaging. Computed tomography uses X-rays to generate cross-sectional images of the spine. Although spine images can be obtained only in the frontal or slightly off-frontal plane, sagittal and coronal reconstructions can be made. Computed tomography can accurately depict the foraminal and extraforaminal nerve root because surrounding fat provides natural contrast.

Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging offers several advantages over CT for spinal imaging, but is more expensive. Soft tissue contrast is better, which allows the different parts of the disc (the nucleus pulposus and annulus fibrosus) to be distinguished from one another and allows visualization of the ligaments. Magnetic resonance imaging also offers better visualization of the vertebral marrow and the contents of the spinal canal. It does not rely on reconstructed images because the sagittal and coronal images can be obtained directly. Finally, MRI uses no ionizing radiation.

A disadvantage of MRI is that it cannot be used to visualize cortical bone directly.

Bone Scanning (SPECT)
Bone scanning involves intravenous injection of radioactive compounds that adhere to metabolically active bone. Since 1971, technetium-99m–labeled phosphate complexes have been the agents of choice. The primary objective of bone scanning is to detect occult fractures, infections, or bony metastases and to differentiate them from degenerative changes

Results of search
Systematic reviews
Five systematic reviews were retrieved (Boos and Lander 1996, Jarvik and Deyo 2002, Littenberg et al 1995, Saal 2002, van Tulder et al 1997). All were high quality.

One review included 672 articles (from 1985 to 1995) that focused on the development or application of imaging modalities for lumbar spinal disorders (Boos and Lander 1996). The review concluded that the vast majority of studies evaluated imaging only at the technical efficacy level. Articles assessing imaging on a higher level of efficacy (e.g. diagnostic and therapeutic impact, patient outcome and cost-benefit analysis) were sparse. The review recommended that the spine specialist be very critical in his interpretation of such studies when attempting to apply the findings in clinical practice.

In another review, which sought to examine the causal relationship between radiographic findings and nonspecific low back pain, two reviewers independently scored the methodologic quality of all relevant studies using a standardized set of criteria (van Tulder et al 1997). Degeneration, defined by the presence of disc space narrowing, osteophytes, and sclerosis, turned out to be associated with nonspecific low back pain, but odds ratios were low, ranging from 1.2 to 3.3. Spondylolysis and spondylolisthesis, spina bifida, transitional vertebrae, spondylosis and Scheuermann's disease did not appear to be associated with low back pain. The review concluded that there is no firm evidence for the presence or absence of a causal relationship between radiographic findings and non-specific low back pain.

A review on the diagnostic accuracy of imaging for patients with low back pain in primary care settings (Jarvik and Deyo 2002) reached similar conclusions to those of the1994 US guidelines (Bigos et al 1994). For adults younger than 50 years of age with no signs or symptoms of systemic disease, symptomatic therapy without imaging is appropriate. For patients 50 years of age and older, or those whose findings suggest systemic disease, plain radiography together with simple laboratory tests can almost completely rule out underlying systemic diseases. Advanced imaging should be reserved for patients who are being considered for surgery or those in whom systemic disease is strongly suspected.

Another review examined studies of diagnostic tests commonly used in the evaluation of chronic low back pain, with a focus on invasive techniques, such as discography (Saal 2002). The conclusion of the review was that there are inherent limitations in the accuracy of all diagnostic tests. The authors emphasised that any tests used to diagnose the source of a patient's chronic low back pain require accurate determination of the abolition or reproduction of the patient's painful symptoms.

One review considered the clinical effectiveness of SPECT bone imaging for low back pain (Littenberg et al 1995). Only 3 reports provided a gold standard reference test (diagnostic test) and allowed the calculation of sensitivity and specificity for SPECT. The review concluded that there was weak evidence that SPECT is useful in:

1. Detecting pseudarthroses after failed spinal fusion
2. Evaluating back pain in the young child, the adolescent (spondylolysis, osteoid osteoma), and the young adult (stress fractures associated with anorexia or hormonal disturbances)
3. Distinguishing benign from malignant lesions in cancer patients.
SPECT has not been sufficiently studied in the detection of other disorders. The decision to use SPECT in most patients with CLBP is not supported by clinical trials. Its effect on clinical management and cost-effectiveness is unknown.

Additional studies
A recent review reported that 73% and 69% of discs with a high intensity zone (HIZ) were positive on discography in symptomatic and asymptomatic individuals respectively (Carragee and Hannibal 2004). These studies suggest that HIZ is not pathognomonic for discogenic illness in patients with non-specific CLBP (see **Comments**). Multiple studies by Carragee et al. (summarised and referenced in (Carragee and Hannibal 2004)) have suggested that discography is an unreliable indicator of a chronic LBP patient's primary cause of illness. The problems of making a reliable diagnosis are related to: the high number of painful disc injections in asymptomatic individuals; the finding that painful injections are related to abnormal psychometric testing, such as somatisation and emotional distress, and to litigation; and the finding that patients with non-spinal pain are reported to have painful injections (see **Comments**).

In one study, 2108 consecutive adult patients were entered into the CLBP bone scintigraphy database to examine the diagnostic benefit of bone SPECT, together with planar flow study, blood pool and delayed three-phase imaging (Kanmaz et al 1998). The study concluded that, when used to examine adult patients with CLBP, SPECT detects significantly more scintigraphic abnormalities than does planar imaging. The addition of a flow study and blood pool imaging as part of these LBP examinations improved sensitivity and specificity. However, the clinical utility of this procedure could not be confirmed; there were no documented changes in treatment planning because of these positive findings. In a smaller study it was suggested that SPECT scan might enhance the identification of patients benefiting from facet joint injection (Dolan et al 1996).

The role of radiography in primary care patients with low back pain of at least 6 weeks duration was studied in a randomised (unblinded) controlled trial with 421 patients, described in two papers (Kendrick et al 2001a, Kendrick et al 2001b). The use of lumbar spine radiography prior to treatment in primary care was not associated with improved functioning, reduced pain or improved overall health status after treatment, and was associated with an increase in GP workload. Participants receiving X-rays were more satisfied with their care, but were not less worried or more reassured about serious disease causing their low back pain. A subsequent paper by the same group on the cost-effectiveness of radiography, showed that only when a 1-point increase in satisfaction is valued at more than 50 pounds sterling can it be claimed that radiography is cost-effective in these terms (incremental net monetary benefit mean = 116 pounds sterling, 95% CI 7-225 pounds sterling). It concluded that radiography is likely to be cost-effective only when satisfaction is valued relatively highly. Strategies to enhance satisfaction for patients with low back pain without using lumbar radiography should be pursued (Miller et al 2002).

A recent randomized controlled study analysed the clinical and economic consequences of replacing spine radiographs with rapid MRI in primary care patients (Jarvik et al 2003). Although physicians and patients preferred the rapid MRI, substituting rapid MRI for radiographic evaluations in the primary care setting

offered little additional benefit to patients (in terms of the subsequent pain and disability levels 12 months after the original examination), and increased the costs of care. One further recent study (van den Bosch et al 2004) pointed out that the prevalence of degenerative changes was high in older patients, but the therapeutic consequences of diagnosing these abnormalities were minor, which does not justify the radiation exposure.

In one study, plain radiographs and flexion-extension radiographs of 215 patients with clinically suspected lumbar spine instability were analysed (Pitkanen et al 2002). Posterior and anterior sliding instability were strongly associated with various plain radiographic findings (anterior: with degenerative spondylolisthesis, spondylolytic spondylolisthesis; posterior: with retrolisthesis, traction spurs and spondylarthrosis). The authors concluded that flexion/extension radiographs are thus only indicated for preoperative planning.

Other studies have evaluated decision making (Gillan et al 2001), radiography in primary care (Kerry et al 2002, Kerry et al 2000), early imaging (Gilbert et al 2004a, Gilbert et al 2004b), and diagnosing cancer (Hollingworth et al 2003, Joines et al 2001). Hollingworth et al concluded that there is currently not enough evidence to support the routine use of rapid MR to detect cancer as a cause of LBP in primary care patients (Hollingworth et al 2003).

Safety
Adverse effects
Lumbar radiography and in particular computed tomography may be harmful because they expose the gonads to ionizing radiation, especially with oblique views or repeated exposures. The ionizing radiation associated with one conventional lumbar radiograph is equivalent to that of 15 radiographic examinations of the thorax or the average ionizing radiation experienced from all other sources for 8 months (2 mSV) (Gron et al 2000). This is of particular concern in younger female patients.

Imaging identifies many abnormalities that are unrelated to back symptoms; the abnormalities are equally prevalent in persons with and without back pain (van den Bosch et al 2004). Examples include spondylolysis, facet joint abnormalities, some congenital anomalies, Schmorl's nodes, herniated discs, disc dehydration ("black discs"), disc protrusion, and mild scoliosis (Cobb angle < 10°).

Comments
1.   In general, referral for imaging should be based on specific indication. The referral should include information that a) documents that imaging is indicated, and b) clearly indicate the specific pathology suspected or the question to be evaluated. The latter is important for choosing the best imaging modality and for the assessment of the images.
2.   In primary care patients, the presence of a lytic or blastic lesion on plain radiographs was 60% sensitive and 99.5% specific for cancer. This suggests that plain radiography is not a good screening procedure for cancer and metastases. Sensitivity was 70% and specificity 95% for compression fractures (Deyo and Diehl 1988). In one study the sensitivity varied from 0.83 to 1.00, and specificity from 0.85 to 0.96. This indicates that MRI is a good, but not perfect method to detect spinal metastases (Kosuda et al 1996). In one study on planar imaging and SPECT, estimates of sensitivity ranged from 0.74 to 0.98 (Jarvik and Deyo 2002). Radiographs may be adequately sensitive, but their ability to distinguish acute from old compression fractures is poor. Osteophytes or vertebral body fusion suggest an old compression fracture (i.e. sequela from an acute fracture). Magnetic resonance

imaging is more specific because it identifies marrow edema or hematoma associated with an acute fracture (Yamato et al 1998).

In one study, computed tomography and MRI had a high sensitivity and low specificity for herniated discs of (Jarvik and Deyo 2002).

A metaanalysis showed that for spinal stenosis the sensitivity of CT imaging ranges from 0.7 to 1.0 and the specificity ranges from 0.8 to 0.96 (Kent et al 1992).

In one study, MRI was shown to be more accurate than plain radiography or bone scanning; sensitivity was 0.96 and specificity was 0.92 (Modic et al 1985).

3.   MRI and discography are commonly used in the diagnosis of non-specific low back pain when common degenerative changes are suspected to cause discogenic pain. Studies of MRI have revealed that high proportions of asymptomatic individuals (up to 80%, depending on the "MRI-abnormality" in question) have such changes (Boden et al 1990, Jarvik et al 2001, Jensen et al 1994, Rankine et al 1999, Savage et al 1997, Stadnik et al 1998, Weishaupt et al 1998) and some of these increase with age (Savage et al 1997). Among symptomatic subjects, MRI findings of mild to moderate neurologic compression, disc degeneration or bulging, and central stenosis were not found to correlate with severity or symptoms (Boden et al 1990, Jarvik et al 2001).

The presence of a high intensity zone (HIZ) in T2-weighted MRI has been purported to be highly specific for discogenic pain and indicative of internal disc disruption (IDD) (Aprill and Bogduk 1992, Yoshida et al 2002), although typical pain provocation upon discography and signs of disc disruption in the post-discography CT are required to consolidate the diagnosis. Much controversy surrounds both the diagnosis and management of IDD: some maintain that IDD is the main source of discogenic (non-radicular) pain, accounting for up to 40% of the cases with non-specific back pain (Schwarzer et al 1995a), whilst others question the importance of IDD and the relevance of the HIZ (high specificity but very low sensitivity in relationship to pain) (Carragee et al 2000, Smith et al 1998). Importantly, even the proponents of IDD concede that no clinical tests exist for its diagnosis (Schwarzer et al 1995a).

4.   The zygapophysial (facet) joint may be a source of low back pain, but the existence of a "facet syndrome" is controversial (Schwarzer et al 1994a). One study concluded that pain relief after facet joint blocks does not correlate with facet arthrosis (Schwarzer et al 1995c). Another study concluded that there remains no standard test with which to establish the validity of facet blocks of any type in making a diagnosis of facet joint pain (Schwarzer et al 1994b). Reproducibility of the facet joint blocks is low; the specifity is only 65%. Approximately 30% of patients undergoing lumbar facet joint blocks report complete relief of their pain after subcutaneous injection of physiological saline (Schwarzer et al 1995b).

Summary of evidence

- There is moderate evidence that radiographic imaging is not recommended for chronic non-specific low back patients (level B).

- There is moderate evidence that MRI is the best imaging procedure for use in patients with radicular symptoms, or for those in whom discitis or neoplasm is strongly suspected (level B).

- There is moderate evidence that facet joint injections, MRI and discography are not reliable procedures for the diagnosis of facet joint pain and discogenic pain (level B)

- SPECT and scintigraphy may be useful for diagnosing pseudoarthrosis after surgery for spinal fusion, in suspected stress fractures, in the evaluation of malignancy, and in diagnosing symptomatic painful facet joints (level C).

Recommendation

We do not recommend radiographic imaging for chronic non-specific low back patients.

We do recommend MRI in patients with serious red flags and for evaluation of radicular symptoms. Plain radiography is recommended for structural deformities.

We do not recommend MRI, CT, or facet blocks for the diagnosis of facet joint pain, or discography for discogenic pain.

C3 (A5) Electromyography (EMG)

Definition of procedure

For clinical purposes, needle EMG is used with neurography to distinguish, for example, between diabetic neuropathy and radiculopathy. Surface EMG has not been established as a diagnostic procedure, but is commonly used in experimental and clinical studies of patients with non-specific chronic low back pain, in order to examine global trunk muscle activation or muscle fatigue characteristics.

Needle EMG is the primary source for providing information on the paraspinal muscles in clinical practice. Immediately after nerve damage, needle EMG can detect a dropout of motor units ("decreased recruitment"). If the lesion is incomplete, motor unit changes (increased amplitude and duration, increased complexity of motor unit waveforms) occur in the subsequent weeks, indicating axonal sprouting and repair. Thus, increased motor unit complexity implies previous injury. Selective activation of paraspinal muscles in order to observe individual motor units is challenging. Reliable motor unit estimates require isolation of 10 to 20 motor units per muscle, and there are only limited data on the normal configuration of paraspinal motor units (Travlos et al 1995).

The role of the paraspinal muscles for the stabilisation and movement of the spine was assessed in some of the earliest kinesiology studies using surface and wire electromyography (EMG) (Floyd and Silver 1955). The absence of "flexion-relaxation" (electrical silence in the paraspinal muscles when in full trunk flexion) was introduced as a characteristic particularly associated with the presence of CLBP. In the 1980s, surface electromyography (SEMG) with power spectral analyses was developed for use in the objective evaluation of back muscle fatigue (De Luca 1993). Most commonly, the rate of decline of the mean or median frequency of the SEMG

power spectrum (and occasionally the increase in the average EMG amplitude) was used as an index of muscle fatigability (De Luca 1993).

Results of search
4 systematic reviews dealing with EMG and low back pain were identified (Fisher 2002, Mohseni-Bandpei et al 2000, Pullman et al 2000, van Dieen et al 2003).

Quality assessment of evidence
The reviews were all of high quality.

Systematic reviews
One review article concluded that needle EMG is the best established of the available electrophysiological techniques for evaluating radiculopathies and can define the presence of these lesions (Fisher 2002). The value of these studies is limited by the fact that only motor fibers are monitored, the specificity (for radiculopathy) of the physiological abnormalities measured, and the requirement that these abnormalities involve multiple muscles in a specific distribution. Needle EMG may be least sensitive as a diagnostic tool in patients with lumbar spinal stenosis where electrophysiological evaluation arguably could be most helpful for clinical management (Fisher 2002).

In one review (Mohseni-Bandpei et al 2000) thirty of the 38 studies reported differences in surface EMG (SEMG) measures (e.g. higher or lower levels of activation; henceforth classified as "positive" studies) for CLBP patients, compared with controls, when tested in one or more postural positions. Eight studies found no difference in SEMG between people with CLBP and controls. Ten of the 12 studies that monitored rehabilitation programmes reported positive results (i.e. changes moving in the direction of "normal"), while 2 studies found no change in SEMG after rehabilitation. This review stated that there is a need for further research on the classification of various subgroups of LBP patients using surface EMG and the identification of individuals at risk of developing LBP.

Pullman and colleagues concluded that surface electromyography is to be considered unacceptable as a clinical tool in the diagnosis of low back pain at this time (Pullman et al 2000). Surface electromyography is considered an acceptable tool for assessment of muscular dysfunction in patients with chronic low back pain.

Another review concluded that the findings on trunk muscle recruitment in CLBP patients (as assessed with surface electromyography) fit neither the pain–spasm–pain model, nor the pain-adaptation model (van Dieen et al 2003). The changes observed are task-dependent, related to the individual problem and hence highly variable between and probably within individuals.

Additional studies
After the review of De Luca (De Luca 1993) on the use of surface EMG power spectral changes for distinguishing between the back muscle fatigability of normal controls and CLBP patients, large numbers of experimental and clinical studies followed, often with inconsistent findings: in some studies, CLBP patients were more fatigable than controls, whilst in others, they were less fatigable; some patients showed an increased fatigablity after exercise rehabilitation, whilst others showed a decreased fatigability; and the accurate classification of "patients" and "normal controls" using the procedure as described in the early studies could not always be reproduced (Elfving et al 2003, Mannion et al 1997, Mannion et al 2001a, Mannion et al 2001b, Mohseni-Bandpei et al 2000).

A recent study showed that pain-related fear shows a significant inverse correlation with lumbar flexion and direct correlation with the EMG amplitude in full flexion in chronic low back patients (i.e. pain-related fear is related to the presence of the flexion-relaxation phenomenon) (Geisser et al 2004). The authors concluded that pain-related fear is directly associated with musculoskeletal dysfunction (reduced range of flexion, increased surface EMG amplitude in full flexion) observed in people with chronic low back pain, and that these abnormalities may be involved in the development and maintenance of chronic low back pain.

Intramuscular wire EMG studies (most commonly of the deep trunk muscles, internus oblique, transversus abdominus, and multifidus) have been carried out to investigate the spine's stability/motor control mechanisms during various tasks and have reported dysfunction in patients with chronic low back pain (Hodges 2003, Hodges and Moseley 2003). However, the relationship between these dysfunction (as potential diagnostic tools) and patient-orientated clinical parameters, such as pain and disability, remains poorly investigated.
Conflicting with the conclusion of Fischer (Fisher 2002), in a recent study it was concluded that paraspinal denervation observed by electromyography may be a better marker than MRI findings for symptomatic spinal stenosis (Haig 2002).

Comments
The general consensus at present appears to be that the test procedures have no clear relevance to clinical diagnostics although they may still be useful in experimental studies and/or in the rehabilitation environment for examining mechanisms of back muscle function/dysfunction.

Summary of evidence
- There is conflicting evidence that surface EMG is able to differentiate patients with non-specific CLBP from controls and for monitoring rehabilitation programmes (level C).
- There is limited evidence that fear-avoidance is associated with increased muscle activity on lumbar flexion (level C).
- There is conflicting evidence for the usefulness of needle EMG in patients with lumbar spinal stenosis and spinal radiculopathies (level C).

Recommendation
We cannot recommend the use of electromyography as a diagnostic procedure in chronic non-specific low back pain.

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C3 (B) Prognostic factors

In connection with patients with back pain, prognostic factors refer to all variables that are predictive of future events such as repeated/continued back pain, disability, return to work, costs, etc. Prognostic studies include both clinical studies of variables that are predictive of future events and epidemiological studies of aetiological risk factors. Ideally, in studies of prognostic factors, all patients should have received the same treatment or been in a randomised trial (Altman 2001).

The purpose of studies of prognostic factors is not just to predict disease more accurately or parsimoniously, but also to guide clinical decision-making, improve understanding of the disease process, improve design of clinical trials and to define risk groups.

Systematic reviews

Five SRs on risk factors were identified (Goldberg et al 2000, Hartvigsen et al 2000, Leboeuf-Yde 2000a,b, Lings and Leboeuf-Yde 2000). These studies were excluded because they evaluated risk factors for first-time back pain, which was evaluated in the prevention guidelines.

One SR was identified that included only patients with acute low back pain (Pengel et al 2003). However, this study was included because its purpose was to describe the course of acute low back pain and sciatica and to identify clinically important prognostic factors for the subsequent resolution or persistence of pain. The study did not reveal any specific prognostic factors, reported that the methodology of most papers was poor, and concluded that prognostic factors should be assessed separately for patients in and out of work, respectively.

Six systematic reviews on prognostic factors for chronicity were identified (Borge et al 2001, Hoogendoorn et al 2000, Hunter 2001, Pincus et al 2002, Shaw et al 2001, Waddell and Burton 2001). Four papers included mixed populations of acute, subacute and chronic pain patients (Hoogendoorn et al 2000, Pincus et al 2002, Shaw et al 2001, Waddell and Burton 2001). Two papers included only patients with chronic low back pain (Borge et al 2001, Hunter 2001).

One of the systematic reviews covered back pain in the occupational setting (Waddell and Burton 2001). Thirty-four systematic reviews, 28 narrative reviews, 22 additional relevant studies and 17 previous guidelines were included. Among the evidence statements given, the authors concluded that in the worker having difficulty returning to normal occupational duties at 4-12 weeks: there is strong epidemiological evidence that the longer the length of absence from work due to CLBP, the lower the chances of ever returning to work, and that most clinical interventions are quite ineffective at returning people to work once they have been absent for a protracted period with CLBP; there is moderate evidence that changing the focus from purely symptomatic treatment to a "back school" (or multidisciplinary) type of rehabilitation, can produce faster return to work, less chronic disability and less sickness absence; and there is moderate evidence that temporary provision of lighter or modified duties facilitates return to work and reduces time off work (Waddell and Burton 2001). The authors also highlighted that individual and work-related psychosocial factors play an important role in persisting symptoms and disability, and influence response to treatment and rehabilitation. Workers' own beliefs that their low back pain was caused by their work and their own expectations about inability to return to work are particularly important.

One systematic review of 25 publications (18 cohorts) evaluated psychological predictors of chronicity/disability in prospective cohorts of low back pain patients (Pincus et al 2002). Increased risk of chronicity (persisting symptoms and/or

disability) as a result of psychological distress, depressive mood, and to a lesser extent somatisation, emerged as the main finding. The authors highlighted the need to clarify the role of other potentially important psychological factors, in particular fear avoidance and coping strategies, through rigorous prospective studies (Pincus et al 2002).

One systematic review of 13 studies evaluated psychosocial factors at work and in one's private life as risk factors for chronic low back pain (Hoogendoorn et al 2000). Insufficient evidence was found for an effect of a high work pace, high qualitative demands, low job content, low job control, and psychosocial factors in private life. Strong evidence was found for low workplace social support and low job satisfaction as risk factors for back pain. However, the possibility that these risk factors may have been influenced by other confounding factors led the authors to conclude that there is evidence for an effect of work-related psychosocial factors on low back pain, but the evidence for the role of *specific* factors has not yet been established (Hoogendoorn et al 2000).

Prognostic factors predicting extended disability following acute occupational LBP were evaluated in one systematic review of 22 studies (Shaw et al 2001). Significant prognostic factors included low workplace support, personal stress, shorter job tenure, prior episodes of LBP, heavier occupations with no modified duty, delayed reporting, severity of pain and functional impact, radicular findings and extreme symptom report.

No systematic reviews have been carried out on psychological predictors of prognosis (in relation to either natural history or treatment) in patients who already have chronic low back pain.

One systematic review that evaluated the prognostic value of physical examination findings in 10 studies reported that there is no satisfactory answer to the question of whether some physical examination tests have a prognostic value in the conservative treatment of low back pain (Borge et al 2001).

One systematic review of 6 studies evaluated medical history (Hunter 2001). It was concluded that there is moderate evidence that a history of similar pain and a longer duration of previous pain each predict the recurrence but not duration of subsequent pain episodes; limited evidence that a history of similar pain predicts poorer outcomes after recurrent injury; and limited evidence that a longer time off work before treatment predicts poorer activity and poorer participation outcomes after recurrent injury.

Additional studies
A prospective population-based study investigated prognostic factors for return to work in a cohort of 328 employees sicklisted for 3-4 months because of low back pain (van der Giezen et al 2000). One year after the first day of sick leave, 198 employees had returned to work. The most important predictors of being at work in the final multivariate model were a positive subjective evaluation of the health status (OR 1.53) and a better job satisfaction (OR 1.26). These variables had a significantly larger impact on work status than more physical aspects of disability and physical requirements of the job.

One cohort longitudinal study involving 192 subacute and 61 chronic compensated workers with low back injuries tested a multivariate predictive model of occupational low back disability (Schultz et al 2002, 2004). The study found that positive expectations of recovery and perception of health change were the key psychosocial

predictors of return-to-work 3 months after study's inception and of number of days lost due to low back disability within 18 months after the injury. However, only a small subsample (<30%) of the eligible chronic sample agreed to participate in the study, and the results thus raise questions concerning the generalisability of the results.

A prospective cohort study investigating risk factors associated with the transition from acute to chronic occupational low back pain (Fransen et al 2002) included 854 new cases of work-related back injury; 3 months after the initial claim, 204 individuals were still receiving compensation payments. A combined multiple regression model of individual, psychosocial and workplace risk factors showed that poor perceived general health status (OR 1.9) was a significant predictor of chronicity while job dissatisfaction and poor workplace relationships did not identify workers at risk of developing chronic occupational disability.
The two aforementioned studies (Fransen et al. 2002, Schultz et al 2004) both involved a selected population (workers suffering a low back injury and receiving compensation payments) and the generalisability of the results to other populations needs further investigation.

A subanalysis of a randomised clinical trial compared patient expectations and treatment effect in 135 chronic low back pain patients receiving either massage or acupuncture (Kalauokalani et al 2001). Patient expectation regarding treatment benefit was found to be associated significantly with clinical outcome. As compared to patients with lower expectations, participants with higher expectation ratings for the treatment received had a fivefold greater likelihood of improved function after adjustment for sociodemographics, health status, and physical factors (95% CI 1.9-15.4., p=0.002). The patients with high expectations for a specific treatment had significantly better functional outcomes if they actually received that treatment (p=0.03; R^2=0.35).]

One additional prospective study (N=159) aimed to determine the prognostic value of a comprehensive medical assessment for the prediction of return-to-work status in subacute low back work-injured patients (Hunt et al 2002). A full medical assessment was carried out at baseline and a repeat examination was performed 3 months later, when return-to-work status was determined. The authors were unable to identify any medical variables (medical history subscales, physical examination subscales, and lumbar range-of-motion tests) that accounted for significant proportions of variance in return to work. They suggested that injured workers' subjective interpretations and appraisals may be more powerful predictors of the course of post-injury recovery than are exclusively medical assessments.

A randomized study compared manipulation, exercise and physician consultation to physician consultation alone in 204 patients with chronic low back pain. Severe affective stress predicted poor response to manipulation (OR 3.8 (95% CI 1.3 to 10.8)). Over 25 days sick leave during previous year (OR 19.6 (3.8 to 102.5)), poor life control 9.4 (1.9 to 47.0), and generalized somatic symptoms predicted outcome from physician consultation at 1 year (Niemisto et al 2004).

Summary of evidence
- There is strong evidence that low work place support is a predictor of chronicity in patients with acute back pain (level A).
- There is strong evidence that in the worker having difficulty returning to normal occupational duties at 4-12 weeks the longer a worker is off work with LBP, the lower the chances of ever returning to work; and that most clinical interventions are quite ineffective at returning people to work once they have been off work for a protracted period with LBP (level A).

- There is moderate evidence that psychosocial distress, depressive mood, severity of pain and functional impact and extreme symptom report, patient expectations, and prior episodes are predictors of chronicity (level B).
- There is moderate evidence that shorter job tenure, heavier occupations with no modified duty, radicular findings, are predictors of chronicity (level B).
- There is moderate evidence that no specific physical examination tests are of significant prognostic value in chronic non-specific LBP

Recommendations
Assess work related factors, psychosocial distress, patient expectations, and extreme symptom reporting in patients with chronic low back pain.

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11. Leboeuf-Yde C **(2000b)** Body weight and low back pain. A systematic literature review of 56 journal articles reporting on 65 epidemiologic studies. Spine, 25(2): 226-37.
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Chapter 4: Physical treatments

C4 (A) Interferential therapy

Definition of the procedure
Interferential current is an electrophysical agent that is commonly used by physiotherapists. It can be described as the application of a medium frequency alternating current modulated to produce low frequencies up to 150 Hz (Hurley et al 2001). The supposed effects of interferential therapy are pain relief, based on the Gate control theory (Melzack and Wall 1965), and an increase of the blood flow to the tissues.

Results of search
Systematic reviews
No SRs were found on the effects of interferential therapy in the treatment of chronic low back pain.

Additional trials
Two trials were found (Hurley et al 2001, Werners et al 1999). One study concerned acute LBP and was therefore excluded (Hurley et al 2001). The second compared the effects of interferential therapy with those of motorized lumbar traction and massage (combined) (Werners et al 1999).

Quality assessment of the evidence
The trial was rated as high quality.

Effectiveness
Effectiveness of interferential vs. sham/placebo treatments
No studies were found on this issue.
There is no evidence for the effectiveness of interferential therapy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).

Effectiveness of interferential vs. other treatments
One high quality trial found a significant reduction in pain and disability after interferential therapy and after motorized lumbar traction plus massage, with no difference between groups for the extent of the improvements (Werners et al 1999). There is limited evidence that interferential therapy and motorized lumbar traction plus massage are equally effective in the treatment of chronic low back pain (level C).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for interferential therapy.

Comments
None

Summary of evidence
There is no evidence for the effectiveness of interferential therapy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
There is limited evidence that interferential therapy and motorized lumbar traction plus massage are equally effective in the treatment of chronic low back pain (level C).

Recommendation
We cannot recommend interferential therapy as a treatment for chronic low back pain.

References
1. Hurley DA, Minder PM, McDonough SM, Walsh DM, Moore AP, Baxter DG **(2001)** Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation. Arch Phys Med Rehabil, 82(4): 485-93.
2. Melzack R, Wall PD **(1965)** Pain mechanisms: a new theory. Science, 150(699): 971-9.
3. Werners R, Pynsent PB, Bulstrode CJ **(1999)** Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting. Spine, 24(15): 1579-84.

C4 (B) Laser therapy

Definition of the procedure
Laser therapy is a therapeutic non-invasive modality that is supposed to have analgesic effects, anti-inflammatory effects, effects on nerve regeneration, and effects on regeneration of muscular and bone tissues (de Bie et al 1998). Wavelength, dosage and dose-intensity are reported to determine the magnitude of the effects.
Lasers with different wavelengths are used in the treatment of musculoskeletal disorders. The wavelengths vary from 632 to 904 nm. The physical properties of the interaction between laser light and tissue can be distinguished in the processes of absorption and scattering. By means of absorption, light energy will transformed into another form of energy which results in warmth dissipation (de Bie et al 1998). By scattering, the direction of light propagation will be changed. Absorption and scattering are dependent on the wavelength and determine the loss of laser energy into the irradiated tissue. The electromagnetic energy that is applied to the body tissues by means of laser therapy is thought to stimulate or inhibit biochemical, physiological and proliferative activities in the cell (de Bie et al 1998). In general, controversy exists with regard to the appropriate treatment parameters for the different treatment indications.

Results of search
Systematic reviews
Two SRs were found (Bjordal et al 2003, de Bie et al 1998) that were not specifically aimed at assessing the evidence for laser therapy in chronic low back pain. One SR aimed at reviewing the effectiveness of 904 nm laser therapy in various musculoskeletal disorders (de Bie et al 1998). It included one trial on the effects of laser therapy for chronic low back pain (Klein and Eek 1990). The other SR reviewed the effects of low level laser therapy with location-specific doses for pain from chronic joint disorders (Bjordal et al 2003) and included three other relevant trials on the effects of laser therapy in chronic low back pain patients (Basford et al 1999, Soriano and Rios 1998, Toya et al 1994).

Additional trials
One additional trial was found (Gur et al 2003).

Quality assessment of the evidence
The two SRs (Bjordal et al 2003, de Bie et al 1998) and the four trials they contained (Basford et al 1999, Klein and Eek 1990, Soriano and Rios 1998, Toya et al 1994) were all rated as high quality. The additional study (Gur et al 2003) was rated as low quality.

Effectiveness
Effectiveness of laser therapy vs sham procedure
The SRs did not separately assess the effectiveness of laser therapy in chronic low back pain. Therefore, the results of the four individual trials are examined here, in order to then summarise the evidence.
One study compared 904 nm laser therapy with placebo laser (Klein and Eek 1990). There were no statistically significant differences in pain improvements between the groups.
One study compared 830 nm laser therapy with placebo laser and reported statistically significant improvements in health status in favour of the laser group when compared with the placebo group (Toya et al 1994). However, no results were reported for pain, functional status or work absenteeism.
A further study compared 904 nm laser therapy with placebo laser and also reported statistically significant improvements in health status in favour of the laser group

when compared with the placebo group (Soriano and Rios 1998). Results regarding pain, functional status and work absenteeism were also lacking in this study.

One study compared NdYag laser therapy (1064 nm) with a placebo laser and found statistically significant differences in pain improvements between the groups (Basford et al 1999).

The two trials that reported pain measurements (Basford et al 1999, Klein and Eek 1990) were both triple blinded (patient, therapist and observer). One of them did (Basford et al 1999) and the other one did not (Klein and Eek 1990) report statistically significant differences between the groups in favour of laser therapy.

There is conflicting evidence that laser therapy is effective for chronic low back pain with regard to pain improvement (level C).

Effectiveness of laser therapy vs. other treatments
One low quality trial found that there was no difference between laser, laser therapy and exercise and exercise alone in terms of pain and function (Gur et al 2003)

There is limited evidence that there is no difference in effectiveness between laser therapy, laser therapy and exercise and exercise (level C)

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for interferential therapy.

Comments
The application of laser therapy in the aforementioned trials was heterogeneous with respect to wavelength, dose-intensity and dosage. Future studies on the effects of laser therapy should apply similar treatment parameters in order to increase the homogeneity among studies.

Summary of evidence
There is conflicting evidence that laser therapy is effective for chronic low back pain with regard to pain improvement (level C).
There is limited evidence that there is no difference in effectiveness between laser therapy, laser therapy and exercise and exercise (level C)

Recommendation
We cannot recommend laser therapy for the treatment of patients with chronic low back pain.

References
1. Basford JR, Sheffield CG, Harmsen WS **(1999)** Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain. Arch Phys Med Rehabil, 80(6): 647-52.
2. Bjordal JM, Couppe C, Chow RT, Tuner J, Ljunggren EA **(2003)** A systematic review of low level laser therapy with location-specific doses for pain from chronic joint disorders. Aust J Physiother, 49(2): 107-16.
3. de Bie RA, Verhagen A, de Vet HCW, Lenssen T, van den Wildenberg FAJM, Kootstra A, Knipschild PG **(1998)** Efficacy of 904 nm laser therapy in musculoskeletal disorders. Physical Therapy Reviews, 3: 1-14.

4. Gur A, Karakoc M, Cevik R, Nas K, Sarac AJ **(2003)** Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain. Lasers Surg Med, 32(3): 233-8.

5. Klein RG, Eek BC **(1990)** Low-energy laser treatment and exercise for chronic low back pain: double-blind controlled trial. Arch Phys Med Rehabil, 71(1): 34-7.

6. Soriano F, Rios R **(1998)** Gallium Arsenide Laser Treatment of chronic low back pain: a prospective randomised and double blind study. Laser Therapy, 10: 175-80.

7. Toya S, Motegi M, Inomata K, Ohshiro T, Maeda T **(1994)** Report on a computer-randomized double-blind clinical trial to determine the effectiveness of the GaAlA (830 nm) diode laser for attenuation in selected pain groups. Laser Therapy, 6: 143-8.

C4 (C) Lumbar supports

Definition of the procedure
Lumbar supports (in this document considered synonymous with braces or orthoses) are used in industry to prevent back injuries and also as a treatment for people with low back pain. Several potential mechanisms of action of lumbar supports are reported in the literature that may support their use in the treatment of low back pain. They are supposed to: (1) correct deformity; (2) limit spinal motion; (3) stabilize the lumbar spine; (4) reduce mechanical loading; and (5) provide miscellaneous effects such as massage, heat or placebo (1).

Results of search
Systematic reviews
Two SRs were found by the electronic literature search (Jellema et al 2001, Koes and Hoogen 1994). In one SR, the evidence was summarised for bed rest and orthoses for back pain (Koes and Hoogen 1994). In a more recent Cochrane review, the effects of lumbar supports for prevention and treatment of chronic low back pain were assessed (Jellema et al 2001). This review was used as the starting point in formulating these recommendations. The review included six RCTs (Coxhead et al 1981, Doran and Newell 1975, Hsieh et al 1992, Million et al 1981, Penrose et al 1991, Valle-Jones et al 1992), but only one used a patient population with chronic low back pain (> 6 months duration of complaints) (Million et al 1981). The remainder used either mixed populations (both acute and chronic) or populations that were not clearly defined and these studies were therefore not considered further. The study on CLBP patients compared the effects of corsets with and without lumbar supports (Million et al 1981). However, as only subjectively-rated "global improvement" was recorded (and no relevant outcomes such as pain, disability, quality of life or return to work), this study was also not considered further.

Additional RCTs
No additional trials were found.

Quality assessment of the evidence
The two SRs were rated as high quality

Effectiveness
Effectiveness of lumbar supports vs. sham/placebo
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of lumbar supports compared with sham/placebo treatments in the treatment of chronic low back pain (level D).

Effectiveness of lumbar supports vs. other treatments
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of lumbar supports compared with other treatments in the treatment of chronic low back pain (level D).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Adverse effects of lumbar supports which have been reported in the literature are: skin lesions, gastrointestinal disorders, muscle wasting, higher blood pressure and higher heart rates (Calmels and Fayolle-Minon 1996, Jellema et al 2001, McGill 1993).

Subjects (indications)

Not having shown evidence of effectiveness, it is not possible to define indications for the use of lumbar supports.

Comments
None

Summary of evidence
There is no evidence for the effectiveness of lumbar supports compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
There is no evidence for the effectiveness of lumbar supports compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend wearing a lumbar support for the treatment of non-specific chronic low back pain.

References
1. Calmels P, Fayolle-Minon I **(1996)** An update on orthotic devices for the lumbar spine based on a review of the literature. Rev Rhum Engl Ed, 63(4): 285-91.
2. Coxhead CE, Inskip H, Meade TW, North WR, Troup JD **(1981)** Multicentre trial of physiotherapy in the management of sciatic symptoms. Lancet, 1(8229): 1065-8.
3. Doran DM, Newell DJ **(1975)** Manipulation in treatment of low back pain: a multicentre study. Br Med J, 2(5964): 161-4.
4. Hsieh CY, Phillips RB, Adams AH, Pope MH **(1992)** Functional outcomes of low back pain: comparison of four treatment groups in a randomized controlled trial. J Manipulative Physiol Ther, 15(1): 4-9.
5. Jellema P, van Tulder MW, van Poppel MN, Nachemson AL, Bouter LM **(2001)** Lumbar supports for prevention and treatment of low back pain: a systematic review within the framework of the Cochrane Back Review Group. Spine, 26(4): 377-86.
6. Koes BW, Hoogen HMMvd **(1994)** Efficacy of bed rest and orthoses of low back pain. Eur J Phys Med Rehabil, 4: 86-93.
7. McGill SM **(1993)** Abdominal belts in industry: a position paper on their assets, liabilities and use. Am Ind Hyg Assoc J, 54(12): 752-4.
8. Million R, Nilsen KH, Jayson MI, Baker RD **(1981)** Evaluation of low back pain and assessment of lumbar corsets with and without back supports. Ann Rheum Dis, 40(5): 449-54.
9. Penrose KW, Chook K, Stump JL **(1991)** Acute and chronic effects of pneumatic lumbar support on muscular strength, flexibility and functional impairment index. Sports Train Med Rehabil, 2: 121-9.
10. Valle-Jones JC, Walsh H, O'Hara J, O'Hara H, Davey NB, Hopkin-Richards H **(1992)** Controlled trial of a back support ('Lumbotrain') in patients with non-specific low back pain. Curr Med Res Opin, 12(9): 604-13.

C4 (D) Shortwave diathermy

Definition of the procedure
Continuous and pulsed forms of shortwave diathermy are applied by physiotherapists in the treatment of soft tissue disorders and arthritis (Kitchen and Partidge 1992). The treatment consists of the application of shortwave electromagnetic radiation with a frequency range from 10 to 100 MHz. The hypothesized working mechanism of this therapeutic application is the heating of tissues and the stimulation of tissue repair (Kitchen and Partidge 1992).

Results of search
Systematic reviews
No SRs were found on the effects of diathermy in the treatment of chronic low back pain.

Additional trials
One additional trial was found which used sub-thermal shortwave diathermy as a control treatment in investigating the effectiveness of exercises and traction (Sweetman et al 1993). However, as no relevant outcomes such as pain, disability, quality of life or return to work were used, this study was not considered further.

Effectiveness
Effectiveness of shortwave diathermy vs. sham procedure
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of shortwave diathermy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).

Effectiveness of shortwave diathermy vs. other treatment
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of shortwave diathermy compared with other treatments in the treatment of chronic low back pain (level D).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for shortwave diathermy.

Comments
None

Summary of evidence
There is no evidence for the effectiveness of shortwave diathermy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
There is no evidence for the effectiveness of shortwave diathermy compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation

We cannot recommend shortwave diathermy as a treatment for chronic low back pain.

References

1. Kitchen S, Partidge C **(1992)** Review of shortwave diathermy continuous and pulses patterns. Physiotherapy, 78: 243-52.
2. Sweetman BJ, Heinrich I, Anderson JAD **(1993)** A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment. Journal-of-Orthopaedic-Rheumatology, 6: 159-66.

C4 (E) Therapeutic ultrasound

Definition of the procedure
Ultrasound equipment consists of a generator and transducer. The generator produces electromagnetic energy with a frequency of 0.5 to 3.5 MHz, which is converted by the transducer to mechanical energy with similar frequency and intensity of up to 3 W/cm^2 (Van der Windt et al 2003). According to laboratory research, the application of ultrasound may result in an increase in cellular metabolic rate and increased visco-elastic properties of collagen tissue (Maxwell 1992).Ultrasound causes a rise in temperature which is assumed to be a mediating mechanism for tissue repair, the enhancement of soft tissue extensibility, promotion of muscle relaxation, augmentation of blood flow, and alleviation of inflammatory reactions of soft-tissue (Van der Windt et al 2003).

Results of search
Systematic reviews
One SR was found, which was part of the evidence review by the Philadelphia Panel on selected rehabilitation interventions (Philadelphia Panel 2001).

Additional trials
No additional trials were found.

Quality assessment of the evidence
The included SR was rated as high quality.

Effectiveness
Effectiveness of therapeutic ultrasound vs. placebo
The SR included only one trial from 1960 on the effects of ultrasound for chronic low back pain compared to a placebo group (Roman 1960). There was no difference in pain improvement between the ultrasound group and a placebo group. No results were presented for return to work or functional status.
There is limited evidence that therapeutic ultrasound is not effective in the treatment of chronic low back pain (level C).

Effectiveness of therapeutic ultrasound vs other treatment
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of therapeutic ultrasound compared with other treatments in the treatment of chronic low back pain (level D).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for therapeutic ultrasound.

Comments
None

Summary of evidence
There is limited evidence that therapeutic ultrasound is not effective in the treatment of chronic low back pain (level C).
There is no evidence for the effectiveness of therapeutic ultrasound compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend therapeutic ultrasound as a treatment for chronic low back pain.

References
1. Maxwell L **(1992)** Therapeutic ultrasound. Its effects on the cellular and molecular mechanisms of inflammation and repair. Physiotherapy, 78: 421-6.
2. Philadelphia **(2001)** Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for low back pain. Phys Ther, 81(10): 1641-74.
3. Roman MP **(1960)** A clinical evaluation of ultrasound by use of a placebo technic. Phys Ther Rev, 40: 649-52.
4. Van der Windt DAWM, Van der Heijden GJMG, Van der Berg SGM, Ter Riet G, De Winter AF, Bouter LM (2003) Ultrasound therapy for acute ankle sprains. (Cochrane Review). In The Cochrane Library, Issue 4. John Wiley & Sons, Ltd.: Chichester, UK.

C4 (F) Thermotherapy / heat

Definition of the procedure
The application of heat is thought to have beneficial effects on blood circulation and muscle stiffness. By these mechanisms it may result in relaxation, pain relief and improvement in functional disability.

Results of search
Systematic reviews
Two systematic reviews were found: one was part of the evidence review by the Philadelphia Panel on selected rehabilitation interventions (Philadelphia 2001) and the other was part of a review on traction for low back pain (van der Heijden et al 1995). No trials were found in either review that had examined the effects of thermotherapy (alone) for chronic low back pain.

Additional trials
No additional trials were found.

Quality assessment of the evidence
The included SRs were rated as high quality.

Effectiveness of thermotherapy vs sham/placebo procedures
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of thermotherapy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).

Effectiveness of thermotherapy vs. other treatments
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of thermotherapy compared with other treatments in the treatment of chronic low back pain (level D).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for thermotherapy.

Comments
None

Summary of evidence
There is no evidence for the effectiveness of thermotherapy compared with sham/placebo treatments in the treatment of chronic low back pain (level D).
There is no evidence for the effectiveness of thermotherapy compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend thermotherapy/heat as a treatment for chronic low back pain.

References
1. Philadelphia **(2001)** Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for low back pain. Phys Ther, 81(10): 1641-74.
2. van der Heijden GJ, Beurskens AJ, Koes BW, Assendelft WJ, de Vet HC, Bouter LM **(1995)** The efficacy of traction for back and neck pain: a systematic, blinded review of randomized clinical trial methods. Phys Ther, 75(2): 93-104.

C5 (G) Traction

Definition of the procedure
Lumbar traction is applied by putting a harness around the lower rib cage and a second one around the iliac crest, and applying a force aiming at separating both harnesses. The applied force must be at least 25% of the body weight (weaker forces are considered as placebo). The duration and level of exerted traction can be varied in a continuous or intermittent mode (van der Heijden et al 1995).

Different types of traction exist: manual traction (i.e. traction exerted by the therapist, using the patient's head, arms or legs), motorised traction (i.e. traction exerted by a motorised pulley), suspension (i.e. traction exerted by gravitational forces, through the body weight of the patient), and bed-rest traction (i.e. traction by a pulley and weights) (van der Heijden et al 1995).

Results of search
Systematic reviews
One systematic review (SR) was found (van der Heijden et al 1995) .
Among the 17 RCTs included in the review, 16 were excluded for the following reasons:

- 3 focused on cervical traction (British 1966, Goldie and Landquist 1970, Zylbergold and Piper 1985)
- 5 included only acute low back pain patients (Coxhead et al 1981, Larsson et al 1980, Mathews et al 1987, Pal et al 1986, Walker et al 1982)
- 2 did not provide information on the duration of pain (Mathews and Hickling 1975, Reust et al 1988)
- 4 focused specifically on prolapsed lumbar disk, and not on common low back pain (Ljunggren et al 1984, Weber 1972, 1973, Weber et al 1984)
- 1 used only "global treatment effect" as the outcome measure (Bihaug 1978)
- 1 examined combination treatments (intermittent motorized traction and isometric abdominal exercises vs hot packs and rest vs hot packs, massage and mobilisation) and also used only "global treatment effect" as the outcome measure (Lidstrom and Zachrisson 1970)

The remaining RCT were used as the basis for formulating these recommendations (van der Heijden et al 1970).

Additional trials
No additional trials were found.

Quality assessment of the evidence
The systematic review was of high quality. The one relevant RCT on CLBP that it included was of high quality (van der Heijden et al 1970).

Effectiveness
Effectiveness of traction vs. a sham procedure
The RCT compared motorized traction with sham traction and did not find any significant differences between the treatments for any of the outcome measures examined (van der Heijden et al 1970).
There is limited evidence that lumbar traction is **not** more effective than sham traction (level C).

Effectiveness of traction vs other treatments
Unknown (no studies were found on this issue)
There is no evidence for the effectiveness of lumbar traction compared with other treatments in the treatment of chronic low back pain (level D).

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
The SR did not review studies on safety of lumbar traction, but cited case reports suggesting that there is danger of adverse effects in heavy traction (lumbar traction with forces exceeding 50% of the total body weight) (van den Hoogen et al 1995). Those risks include increased blood pressure and respiratory constraints due to the traction harness, and a theoretical potential increase of nerve impingement in cases of medial or distal disk protrusion.

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for lumbar traction.

Comments
None

Summary of evidence
There is limited evidence that lumbar traction is **not** more effective than sham traction (level C).
There is no evidence for the effectiveness of lumbar traction compared with other treatments in the treatment of chronic low back pain (level D).

Recommendation
We cannot recommend lumbar traction as a treatment for chronic low back pain.

References
1. Bihaug O **(1978)** Autotraksjon for ischialgpasienter; en kontrollert sammenlikning mellom effekten av Auto-trakjson-B or isometriske ovelser ad modum Hume endall eg enkins. Fysioterapeuten, 45: 377-9.
2. British **(1966)** Pain in the neck and arm: a multicentre trial of the effects of physiotherapy, arranged by the British Association of Physical Medicine. Br Med J, 5482: 253-8.
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4. Goldie I, Landquist A **(1970)** Evaluation of the effects of different forms of physiotherapy in cervical pain. Scand J Rehabil Med, 2(2): 117-21.
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6. Lidstrom A, Zachrisson M **(1970)** Physical therapy on low back pain and sciatica. An attempt at evaluation. Scand J Rehabil Med, 2(1): 37-42.
7. Ljunggren AE, Weber H, Larsen S **(1984)** Autotraction versus manual traction in patients with prolapsed lumbar intervertebral discs. Scand J Rehabil Med, 16(3): 117-24.
8. Mathews JA, Hickling J **(1975)** Lumbar traction: a double-blind controlled study for sciatica. Rheumatol Rehabil, 14(4): 222-5.
9. Mathews JA, Mills SB, Jenkins VM, Grimes SM, Morkel MJ, Mathews W, Scott CM, Sittampalam Y **(1987)** Back pain and sciatica: controlled trials of manipulation, traction, sclerosant and epidural injections. Br J Rheumatol, 26(6): 416-23.
10. Pal B, Mangion P, Hossain MA, Diffey BL **(1986)** A controlled trial of continuous lumbar traction in the treatment of back pain and sciatica. Br J Rheumatol, 25(2): 181-3.
11. Reust P, Chantraine A, Vischer TL **(1988)** [Treatment of lumbar sciatica with or

without neurological deficit using mechanical traction. A double-blind study]. Schweiz Med Wochenschr, 118(8): 271-4.

12. van den Hoogen HM, Koes BW, van Eijk JT, Bouter LM **(1995)** On the accuracy of history, physical examination, and erythrocyte sedimentation rate in diagnosing low back pain in general practice. A criteria-based review of the literature. Spine, 20(3): 318-27.

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C4 (H) Transcutaneous electrical nerve stimulation (TENS)

Definition of the procedure
Transcutaneous electrical nerve stimulation (TENS) is a therapeutic non-invasive modality, which is primarily applied for pain relief. This technique consists of electrical stimulation of peripheral nerves via skin surface electrodes. The development and application of TENS was based on the Gate control theory of pain (Melzack and Wall 1965). According to this theory, the stimulation of the large afferent fibers may cause the inhibition of the small nociceptive fibers by the activation of the inhibitory interneurones in the substantia gelatinosa of the spinal cord dorsal horn (Jette and Delitto 1997, Melzack and Wall 1965, Milne et al 2001). By the application of TENS, these neuro-regulatory peripheral and central effects would modulate the transmission of pain.

In clinical practice various types of TENS applications are used, which are different with regard to intensity and electrical characteristics (Brosseau et al 2002, Jette and Delitto 1997, Milne et al 2001):
1) high frequency (40-150 Hz, 50-100 usec pulse width, moderate intensity);
2) low frequency (1-4 Hz, 100-400 usec pulse width, high intensity);
3) burst frequency (1-4 Hz with high internal frequency, 100-250 usec pulse width, high intensity)
4) hyperstimulation (1-4 Hz, 10-500 msec pulse width, high intensity).

Results of search
Systematic reviews
Three SRs were found by the electronic literature search ((Brosseau et al 2002, Milne et al 2001) and (Philadelphia Panel 2001, van Tulder et al 1999)).

Additional RCTs
Five additional RCTs were found. One of these compared the effects of TENS with vertebral axial decompression (VAX-D) (Sherry et al 2001); two made a comparison between TENS and percutaneous electrical nerve stimulation (Hsieh and Lee 2002) (Yokoyama et al 2004); and one compared TENS with electroacupuncture (Tsukayama et al 2002). One RCT was excluded because it specifically assessed the effects of TENS in patients with multiple sclerosis who had low back pain (Al-Smadi et al 2003).

Quality assessment of the evidence
The three SRs were rated as high quality ((Brosseau et al 2002, Milne et al 2001) and (Philadelphia Panel 2001, van Tulder et al 1999)). Among the four additional RCTs that were included (Hsieh and Lee 2002, Sherry et al 2001, Tsukayama et al 2002, Yokoyama et al 2004), no effects were reported in favour of TENS; as this lack of effect did not change the general pattern of no effectiveness that was shown by the SRs, no rigorous quality assessment of these trials was carried out.

Effectiveness
Effectiveness of TENS vs sham/placebo procedures
Three SRs included studies comparing TENS versus a sham procedure or placebo. The Philadelphia panel stated that they had found good evidence of no clinically important benefit with TENS (Philadelphia 2001). The conclusion of the Cochrane review was that the meta-analysis (based on 5 RCTs) suggests that TENS is not more effective in reducing pain and improving functional status than sham or placebo (Brosseau et al 2002, Milne et al 2001).

The Cochrane review on the effectiveness of acupuncture (van Tulder et al 1999) included one trial which compared three treatments: acupuncture, TENS and placebo TENS (Lehmann et al 1986). There was no difference in effects between the two reference groups (TENS and placebo TENS) (Lehmann et al 1986).

There is strong evidence that TENS is not more effective than placebo or sham TENS in the treatment of chronic low back pain (level A).

Effectiveness of TENS vs. other treatments
One low quality trial included in the Cochrane review on the effectiveness of acupuncture reported that neither TENS nor placebo TENS groups were as effective as acupuncture (Lehmann et al 1986). The additional trials that compared other types of treatment with TENS also did not report effects in favour of the TENS groups (Hsieh and Lee 2002, Sherry et al 2001, Tsukayama et al 2002).
There is moderate evidence that TENS is not more effective than vertebral axial decompression, acupuncture, PENS, or electroacupuncture in the treatment of chronic low back pain (level B).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for TENS.

Comments
Despite the lack of effects of TENS reported in the scientific literature there are arguments for more research on the effects of TENS, perhaps in combination with interventions that aim to improve disability in chronic low back pain:
1. The five studies that were included in the Cochrane SR showed a trend towards a greater pain reduction in the TENS group compared to the placebo group.
2. The characteristics of the device parameters of the TENS application were heterogeneous among the studies included and in some cases not even reported. These application characteristics (optimal frequency-intensity, application techniques, duration of treatment and site of application) may be critical in order to achieve treatment effects. Due to the small number of studies and lack of reporting it was not possible to separate studies according to these criteria.

Summary of evidence
There is strong evidence that TENS is not more effective than placebo or sham TENS in the treatment of chronic low back pain (level A).
There is moderate evidence that TENS is not more effective than vertebral axial decompression, acupuncture, PENS, or electroacupuncture in the treatment of chronic low back pain (level B).

Recommendation
We do not recommend TENS for the treatment of chronic low back pain.

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Chapter 5: Exercise therapy

Definition of procedure
"Exercise therapy" was defined as any programme in which, during the therapy sessions, the participants were required to carry out repeated voluntary dynamic movements or static muscular contractions (in each case, either "whole-body" or "region-specific"; and either with or without external loading), where such exercises were intended as a treatment for low back pain. The exercise was to have been supervised or "prescribed" (van Tulder et al 2003).

Systematic reviews and RCTs in which exercises represented part of a back school or multidisciplinary treatment program were excluded (these are covered separately in their own categories). However, systematic reviews or RCTs in which exercises were the main component of a therapy otherwise referred to as "physiotherapy" were included.

In some previous SRs (van Tulder and Koes 2003, van Tulder et al 2003) the terms "*active*" and "*inactive*" treatments have been used to (roughly) indicate "index" and "control/placebo" treatments. We felt that their chosen nomenclature could confuse, especially within the context of exercise therapy. In these recommendations we will attempt to specifically name the particular interventions under investigation, and in forming sub-categories for the evidence rating we will use the term *"passive treatments considered/intended by the authors to be a control treatment"* instead of the term "inactive". Nonetheless, the reader should bear in mind that categorising such treatments together does not necessarily differentiate between the effects of being put in a waiting list control group (which could have a nocebo effect) and being given hot packs and traction (which might have a powerful placebo effect). The whole issue of developing appropriate control/placebo treatments in relation to musculoskeletal treatment programmes remains to be resolved.

Results of search
Systematic reviews
The various searches returned a total of 16 hits regarding **reviews** of exercise therapy for chronic back pain (Abenhaim et al 2000, Brox et al 1999, Colle et al 2001, Daniels and Denner 1999, Ebenbichler et al 2001, Evans and Richards 1996, Faas 1996, Hilde and Bo 1998, Koes et al 1991, Maher et al 1999, Miltner et al 2001, Mior 2001, van Tulder and Koes 2003, van Tulder et al 1997, van Tulder et al 2003). Two additional SRs were identified from the working group's knowledge of the literature (Kool et al 2004, Liddle et al 2004).
4 of these reviews (Colle et al 2001, Daniels and Denner 1999, Ebenbichler et al 2001, Mior 2001) were not systematic reviews and/or did not deal with the effectiveness, cost-effectiveness or safety of exercise therapy and were therefore excluded.

Additional RCTs
4 older trials were identified that had not been included in the two main reviews (van Tulder and Koes 2003, van Tulder et al 2003), but had been considered in other systematic reviews (Callaghan 1994, Klein and Eek 1990, Reilly et al 1989, Sweetman et al 1993). Two were not considered further in producing these guidelines: one included no comparison of exercise per se with another treatment (only exercise with laser versus exercise with placebo laser (Klein and Eek 1990); and the other reported no pain or disability scores (Sweetman et al 1993). N.B. the systematic reviews (van Tulder and Koes 2003, van Tulder et al 2003) included two trials that we chose to exclude, as they did not focus on the treatment of non-specific CLBP as defined in the introduction: one concerned prevention not

treatment (Soukup et al 1999); and the other examined only patients with a specific homogeneous pathology of spondylysis/spondylolisthesis (O'Sullivan et al 1997).

Using the search criteria described in the introduction, 24 new RCTs were identified that had not been included in or had been published subsequent to the two reviews (Aure et al 2003, Bendix et al 2000, Descarreaux et al 2002, Ghoname et al 1999, Gur et al 2003, Hagen et al 2000, Hemmila et al 2002, Horneij et al 2001, Hsieh et al 2002, Jousset et al 2004, Klaber Moffett et al 1999, McIlveen and Robertson 1998, Moseley 2002, Muller et al 2001, Niemisto et al 2003, Penttinen et al 2002, Petersen et al 2002, Preyde 2000, Rasmussen-Barr et al 2003, Rittweger et al 2002, Staal et al 2004, Storheim et al 2003, Tritilanunt and Wajanavisit 2001, UK BEAM trial team et al 2004).

8 of the RCTs were subsequently excluded in producing these recommendations: one used a crossover design in which it was difficult to extract the effects of exercise therapy alone and only the immediate short term effects were considered (Ghoname et al 1999); in two studies, exercises were combined with manipulation (Aure et al 2003, Niemisto et al 2003) or manual therapy and education (Moseley 2002); another concerned prevention, not treatment (Horneij et al 2001); two were rather more back school/education than exercise therapy and are therefore considered in the back school recommendations (Hsieh and Lee 2002, Penttinen et al 2002); in one, the patient group was poorly defined (and may actually have been secondary prevention), the study was very low quality study, and only "global quality of life" was measured, immediately after the treatment (Muller et al 2001); one was considered to represent "advice/recommendations to remain active" rather than an exercise therapy treatment as such (Hagen et al 2000).

Quality assessment of SRs
Of the 12 reviews (Abenhaim et al 2000, Brox et al 1999, Evans and Richards 1996, Faas 1996, Hilde and Bo 1998, Koes et al 1991, Kool et al 2004, Liddle et al 2004, Maher et al 1999, Miltner et al 2001, van Tulder and Koes 2003, van Tulder et al 1997, van Tulder et al 2003), two were sufficiently up to date and of high enough methodological rigour to be categorised as high-quality systematic reviews and to be used as the basis for forming these recommendations: one was a Cochrane review (van Tulder et al 2003), and the other a shortened, regularly updated summary of the Cochrane's main findings (van Tulder and Koes 2003). The first SR (van Tulder et al 2003) included 23 trials on non-specific CLBP or a mixture of non-specific chronic/sub-acute LBP (Bentsen et al 1997, Bronfort et al 1996, Buswell 1982, Deyo et al 1990, Elnaggar et al 1991, Frost et al 1995, Frost et al 1998, Hansen et al 1993, Hemmila et al 1997, Johannsen et al 1995, Kendall and Jenkins 1968, Lidstrom and Zachrisson 1970, Lindström 1994, Lindstrom et al 1992a, Lindstrom et al 1992b, Ljunggren et al 1997, Manniche et al 1993, Manniche et al 1988, Manniche et al 1991, Martin et al 1986, O'Sullivan et al 1997, Risch et al 1993, Snook et al 1998, Torstensen et al 1998, Turner et al 1990, White 1966, 1969). The second SR (van Tulder and Koes 2003)included a further 13 papers reporting on 8 RCTs (Bendix et al 1998, Bendix et al 1995, Franke et al 2000, Friedrich et al 1998, Hildebrandt et al 2000, Kankaanpaa et al 1999, Kuukkanen and Malkia 2000, Mannion et al 2001a, Mannion et al 1999, 2001b, Mannion et al 2001c, Soukup et al 1999, Soukup et al 2001). All other SRs were scrutinised for any additional RCTs not covered by these two reviews. Further, some of the other reviews highlighted or addressed a number of important issues regarding the recommendations for exercise based on evidence found in the literature and these reviews were therefore taken into consideration in attempting to formulate the final recommendations in a useful manner. For example, a high quality SR that emphasised the potential importance of the type and dose of exercise was considered worthy of mention (Hilde and Bo 1998).

Quality assessment of additional trials

The RCTs finally included in examining the strength of evidence, along with their quality ratings are listed in Table 1. This includes all those trials that we considered relevant from the two main SRs (van Tulder and Koes 2003, van Tulder et al 2003), from other systematic reviews (not previously included in the two main SRs), from our search for additional RCTs, and from the working group's knowledge of the literature.

Table 1. List of all RCTs used in compiling the evidence for the effectiveness of exercise therapy in CLBP.

Authors and reference	Total score (out of 9)*	Quality rating
Aure 2003	6	high
Bendix 1995, 1998	6	high
Bendix 2000	4	low
Bentsen 1997	4	low
Bronfort 1996	7	high
Buswell 1982	0	low
Callaghan 1994	2	low
Descarreaux 2002	3	low
Deyo 1990	7	high
Elnaggar 1991	4	low
Franke 2000	3	low
Friedrich 1998	5	high
Frost 1995, 1998	6	high
Gur, 2003	3	low
Hansen 1993	5	high
Hemmila 1997, 2002	6	high
Hildebrandt 2000	6	high
Johanssen 1995	0	low
Jousset 2004	7	high
Kankaanpaa 1999	2	low
Kendall & Jenkins 1968	1	low
Klaber-Moffett 1999	5	high
Kuukkanen 2000	2	low
Lidström & Zachrisson 1970	2	low
Lindstrom 1992a,b, 1994	7	high
Manniche 1988, 1991	6	high
Mannion 1999, 2001a, b, c	8	high
Martin 1986	0	low
McIlveen and Robertson 1998	6	high
Moseley 2002	4	low
Peterson 2002	4	low
Preyde 2000	5	high
Rasmussen 2003	3	low
Reilly 1989	4	low
Risch 1993	3	low
Rittweger 2002	3	low
Snook 2003	6	high

Staal 2004	8	high
Storheim 2003	5	high
Torstensen 1998	7	high
Tritilanunt &Wajanavisit 2001	4	low
UK BEAM trial, 2004	7	high
Turner 1990	2	low
White 1966	3	low
White 1969	2	low

* using grading system of van Tulder et al 1997; ≥5 points = high quality

Effectiveness versus passive treatments intended/considered by the authors of the RCT to be control treatments (hot packs plus rest, semi-hot packs plus sham traction, waiting list control group, transcutaneous electrical stimulation (TENS), sham TENS, detuned ultrasound or short wave therapy).
Six RCTs from the earlier Cochrane review (van Tulder et al 2003) (searches up to 1999) were included (Deyo et al 1990, Hansen et al 1993, Lidstrom and Zachrisson 1970, Martin et al 1986, Risch et al 1993, Turner et al 1990). One of the two high quality trials reported a larger decrease of pain (but not function) for stretching and relaxation exercises than for TENS or sham TENS (Deyo et al 1990),whilst the other high quality trial reported a significantly better overall treatment effect for strengthening/muscle reconditioning exercises compared with semihot packs plus sham traction, but no difference in pain intensity between the two
treatments (Hansen et al 1993). The results of these two studies were considered to be conflicting with respect to pain reduction. The results of the 4 lower quality studies (Lidstrom and Zachrisson 1970, Martin et al 1986, Risch et al 1993, Turner et al 1990) were also inconsistent for pain, functional status or overall improvement (two in favour of exercise, two showing no difference from "ineffective treatment").
Four recent additional RCTs showed more favourable results for exercise therapy compared with control/placebo/'ineffective' treatments: in one low quality study (N=59), back muscle reconditioning exercises for 3 months were superior to an "ineffective" treatment (4 sessions of massage/thermal therapy) as regards pain intensity and functional disability (Kankaanpaa et al 1999); in a high quality study (N=95), exercises in water ('hydrotherapy') were superior to waiting list control with regard to short-term clinically relevant improvements in functional status (McIlveen and Robertson 1998); a high quality study (N=107) showed that light remedial exercises were statistically better than sham low-level laser therapy with regard to function 1 month after treatment (Preyde 2000); and a low quality study (N=86) showed that a 3 month home exercise programme (aimed at strength, endurance and flexibility) resulted in a more lasting improvement in pain and function, up to 12 months after treatment, compared with control treatment (no physical exercises) (Kuukkanen and Malkia 2000).

In summary, three of the four high quality trials showed superior results for exercise therapy in relation to pain or function/disability (at least in the short-term), whilst one showed no superiority for exercise with regards to pain, but did show that the "overall treatment effect" was more favourable after exercise therapy. Four out of six low quality studies showed a favourable result for exercise therapy (with respect to either pain or disability, at least in the short-term).

There is moderate evidence that exercise therapy is more effective in the reduction of pain and/or disability, at least in the short-term, than passive treatments intended/considered to be control treatments by the authors of the respective RCTs (level B).

Exercise versus "GP care"

One high quality study (Lindström 1994, Lindstrom et al 1992a, Lindstrom et al 1992b) and one low quality study (White 1969) included in previous systematic reviews compared exercises with GP care. Both reported better outcomes for the exercise groups with regards to return to work. Of the additional trials, one (high quality) (N=187) found aerobic exercise to be better than GP care with regard to pain 12 months after treatment and with regard to function/disability 6 and 12 months after treatment (Klaber Moffett et al 1999). Another high quality RCT (N=93) found that, immediately after treatment, an exercise programme (including cardiovascular, strength, and flexibility exercises, body awareness, and relaxation) was not better than GP care with regards to four prospectively measured pain outcomes and disability, although patients in the exercise group reported a greater reduction in pain intensity, retrospectively, and were more satisfied with their care (Storheim et al 2003). A high quality RCT (N=222) showed that Cesar therapy (postural training) resulted in more patients reporting an improvement in back symptoms at 6 months (but not 12 months) compared with GP care (Hildebrandt et al 2000). Another high quality RCT (N=134) showed that graded activity was more effective than usual care in reducing the number of days of absence from work because of low back pain in the 6 and 12 months after treatment (Staal et al 2004). Another high quality RCT (N=1334) that included primary care patients with subacute and chronic back pain showed that "stay active GP care" together with general exercise therapy (as used in previous studies (Frost et al 1995, Klaber Moffett et al 1999)) resulted in significantly greater improvements in disability after 3 months, but not 12 months, compared with "stay active GP care" alone (the GPs had been previously trained in the active management of CLBP). However, the compliance with the exercise programme was quite poor.

There is strong evidence that exercise therapy is more effective than GP care for the reduction of pain and disability and return to work in at least the mid-term (3-6 months) (level A).

Exercise versus physiotherapeutic treatments
In the following trials, physiotherapeutic treatment often comprised a mixture of any of the following, administered at the discretion of the treating physiotherapist: manual therapy, massage, mobilisation, hot/cold packs, shortwave diathermy, ultrasound, TENS, traction. The physiotherapy treatments administered often included an exercise component.

Three high quality RCTs of exercise vs "conventional physiotherapy" (Hansen et al 1993, Hemmila et al 1997, Torstensen et al 1998) were included from the earlier Cochrane review (van Tulder et al 2003). These did not show any significant treatment group differences with regard to pain intensity, functional status, overall improvement or return to work. One additional high quality trial (N=148) did not show any difference between aerobic exercise or muscle reconditioning and 'modern, active physiotherapy' (i.e. mainly exercises, but supplemented where necessary with other physical therapy procedures) (Mannion et al 2001b). In one high quality RCT (N=98) light remedial exercise (stretching and encouragement to undertake aerobic exercise) did not differ from massage with respect to short-term improvements in function, and both were inferior to a combined programme of exercise *and* massage with regard to short-term improvements in pain and function (Preyde 2000). An additional low quality RCT (Rasmussen-Barr et al 2003) (N=47) compared manipulation with stabilising exercises and reported that the latter were more effective than manual treatment in terms of improvements in pain, general health and functional disability (3 months after treatment) and in terms of the need for recurrent treatment (in the 12 months following the study treatment) (Rasmussen-Barr et al 2003). However, drop out rates were high at the longer-term follow-up, and at this

point the differences in the reduction of pain intensity and disability (ODI) were not significantly different between the groups. Another high quality RCT (N=1334) showed that manipulation but not general exercise therapy showed significantly greater improvements in disability after 12 months than did "best GP care", although no direct statistical comparison of manipulation and exercise was carried out (UK BEAM trial team et al 2004).

There is strong evidence that exercise therapy alone is not more effective than conventional physiotherapeutic methods in the treatment of CLBP (level A).

Exercise (outpatient) versus intensive multidisciplinary treatment
One high quality RCT (N=123) included in the systematic review (van Tulder et al 2003) found that a full time intensive 3 week multidisciplinary programme was more effective than outpatient exercise in improving pain and function (at 4 and 24 months) but not return to work (Bendix et al 1998, Bendix et al 1995). A more recent low quality RCT from the same research group (N=127), however, found that intensive multidisciplinary treatment and exercise therapy showed no significant differences in the resulting improvements in pain and function — only the global rating of "overall improvement" was better in the group of patients receiving the intensive treatment (Bendix et al 2000). An additional high quality trial (N=86) on patients with an average sick-leave of 6 months in the last 2 years found that the mean number of sick-leave days was significantly lower in the functional restoration group, but there was no significant difference in the intensity of pain, the quality of life, functional indexes, psychological characteristics, the number of contacts with the medical system, or the drug intake (Jousset et al 2004).

There is conflicting evidence regarding the effectiveness of exercise as compared with intensive multidisciplinary programmes (level C).

Exercise versus various other treatments (back school, cognitive therapy, limiting early morning flexion, laser therapy)
One high quality RCT (N=81) provided limited evidence (level C) that aerobic exercise therapy shows improved outcomes on pain and functional status compared with back-school education (Frost et al 1995, Frost et al 1998). A low quality RCT (N=96) provided limited evidence (level C) that aerobic exercises with operant-conditioning behavioural therapy results in better outcomes on pain and function immediately post-treatment compared with aerobic exercises or operant-conditioning behavioural therapy alone, but that all treatments are similarly effective after 6 and 12 months (Turner et al 1990). One high quality RCT (N=93) provided limited evidence (level C) that cognitive therapy and exercise therapy do not differ significantly from each other with respect to their effects on disability and pain, and neither treatment reduces sickness absence; however, cognitive therapy and not exercise therapy was significantly better than GP treatment with regard to disability (Storheim et al 2003). One high quality RCT (N=85) provided limited evidence (level C) that exercises are less effective than the practice of 'limiting the amount of early morning lumbar flexion', with regard to pain and functional status (Snook et al 2002, Snook et al 1998). One low quality trial (N=75) provided limited evidence (level C) that exercise therapy, laser therapy, and laser therapy combined with exercise all led to significant post-therapy improvements in pain and disability, with no difference between the groups (Gur et al 2003).

Relative effectiveness of different types of exercise
Muscle reconditioning/strengthening exercises versus other types of exercise
Four RCTs from the previous SRs compared some type of muscle reconditioning/ strengthening exercises with other types of exercises (Bronfort et al 1996, Hansen et al 1993, Johannsen et al 1995, Manniche et al 1988, Manniche et al 1991). Of

the 3 high quality trials (Bronfort et al 1996, Hansen et al 1993, Manniche et al 1988, Manniche et al 1991), one reported better outcomes regarding pain and functional status for an intensive, dynamic strengthening programme than with mild exercise (Manniche et al 1988, Manniche et al 1991). The other two reported no difference between strengthening/reconditioning exercises and conventional general physiotherapy exercises (Hansen et al 1993) or stretching exercises (Bronfort et al 1996). One other study reported no significant differences between intensive muscle reconditioning (for back muscle endurance) and co-ordination training in terms of the improvements in pain and disability (Johannsen et al 1995).

Four additional trials were identified comparing reconditioning/strengthening exercises with other types of exercise. One high quality RCT (N=148) reported no difference between muscle reconditioning exercises and either aerobic or physiotherapy exercises (Mannion et al 1999, 2001b) with regard to improvements in pain up to 1 year after treatment. Disability was significantly more reduced after 6 months in the muscle reconditioning and aerobics groups than in the active physiotherapy, but the difference had disappeared by 12 months, at which time all groups showed a similar significant reduction from baseline values (Mannion et al 1999, 2001b). A low quality study (Kuukkanen and Malkia 2000) (N=86; not truly randomised, but controlled trial) showed no significant difference in relation to the reduction in pain and disability between intensive reconditioning exercises using gym equipment (pulleys, bar-bells, plinths, etc.) and home exercises (no equipment, just using body weight exercises). A further low quality RCT (N=260) showed that muscle reconditioning exercises (similar to those used in previous studies (Manniche et al 1988)) gave similar results to McKenzie exercises in terms of improvements in pain and disability (Petersen et al 2002). In a low quality RCT (N=60), the improvements in pain and disability did not differ significantly between a group performing muscle reconditioning exercises (isodynamic lumbar extension, MedX) and a group carrying out whole body vibration exercises (eliciting muscle activity via stretch reflexes) (Rittweger et al 2002).

There is strong evidence that strengthening/reconditioning exercises are no more effective than other types of exercises in the treatment of CLBP (level A).

Aerobic exercises versus other types of exercise
One high quality RCT (N=148) provided limited evidence (level C) that there are no differences between aerobic exercises and either muscle reconditioning or physiotherapy exercises (Mannion et al 1999, 2001b) with regard to improvements in pain up to 1 year after treatment (see above). Disability was significantly more reduced after 6 months in the aerobics and muscle reconditioning groups than in the active physiotherapy, but the difference had disappeared by 12 months, at which time all groups showed a similar significant reduction from baseline values (Mannion et al 1999, 2001b). One low quality trial (N=72) provided limited evidence (level C) that a programme of aerobic exercises combined with health education is superior to lumbar flexion exercises and health education in terms of pain immediately after the programme (Tritilanunt and Wajanavisit 2001).

Flexion exercises vs other types of exercise
One low quality trial (Tritilanunt and Wajanavisit 2001) provided limited evidence (level C) that a programme of lumbar flexion exercises combined with health education is inferior to aerobic exercises with health education in terms of pain immediately after the programme (Tritilanunt and Wajanavisit 2001).

Flexion vs extension exercises (either stretching or muscle reconditioning)

Three small (N<60 patients), low quality trials compared trunk flexion and extension exercises (either stretching and/or strengthening) for CLBP. Two of these found no difference between the approaches in their effectiveness; both programmes elicited a similar reduction in pain (Buswell 1982, Elnaggar et al 1991). The third compared muscle reconditioning programmes for the trunk extensors and the trunk flexors and found that the flexor reconditioning programme was superior in terms of the number of patients who were symptom free after 3 months (Kendall and Jenkins 1968).

There is conflicting (level C) evidence regarding the effectiveness of programmes involving mainly trunk flexion exercises as compared with those involving mainly trunk extension.

Other considerations
Structure of exercise classes: group classes vs individual
One low quality RCT (N=190) found no significant differences between individual and group exercises for pain and disability 4 weeks after the end of treatment (in each case, the exercise groups also received massage therapy) (Franke et al 2000). A second, high quality RCT (N=148) of group aerobic exercises (10-12 participants per group) versus either small group (2-3 participants) reconditioning exercises or individual physiotherapy exercises found no significant differences between the treatments in the proportion of patients in each group reporting clinically relevant improvements in pain and disability up to 1 year later (N.B. all were exercise-based therapies, although the exact exercises carried out were not identical in each case) (Mannion et al 2001b).
There is moderate evidence (level B) that individually supervised exercise therapy is not more effective than supervised groups exercise.

Number of exercise sessions
One low quality RCT provided limited evidence (level C) that there are no significant differences between the effects on pain reduction of carrying out just 4 exercise therapy sessions (over two weeks) as opposed to 8 sessions (over 4 weeks) (Callaghan 1994).

General versus individualised exercise programmes
A very small (N=20) low quality RCT provided limited evidence (level C) that a home exercise programme with specific exercises (individualised, based on pre-assessment of patient) is more effective than a home exercise programme using general exercises (typical of those commonly prescribed in back schools) (Descarreaux et al 2002).

Exercise with motivation
One high quality trial (Friedrich et al 1998) provided limited evidence (level C) that a combined exercise and motivational programme shows a significantly larger decrease in pain and disability 4 and 12 months after the 4-week programme compared with exercise alone.

Relationship between changes in clinical symptoms (pain and disability) and improvements in performance (e.g. spinal range of motion, trunk strength) as a result of the exercise therapy.
If specific exercise programmes are designed to target a particular aspect of physical function, then it would seem to be important —especially in examining the effectiveness of *different modes of exercise*— to examine whether improvements in performance are related to improvements in symptoms. Only 7 studies from those listed in Table 1 examined whether improvements in objective indices of function, recorded after exercise therapy, were in any way related to changes in self-rated pain and disability/functional status (Elnaggar et al 1991, Hsieh and Lee 2002, Johannsen et al 1995, Kuukkanen and Malkia 2000, Mannion et al 2001a, Mannion et al 1999, Martin et al 1986, Rittweger et al 2002). Two studies found a weak negative relationship between changes in LBP severity/disability and changes in 3D spinal mobility in the sagittal plane (correlation coefficient, r, approx 0.2-0.4) (Elnaggar et al 1991, Mannion et al 1999). Using principal components analysis to group the various aspects of performance (trunk strength in 3 planes, endurance, EMG-determined back muscle fatigability, back extensor activation, trunk mobility in 3 planes) one study found no significant relationship between changes in any aspect of performance and changes in self-rated disability (Mannion et al 2001a). Two studies reported no relationship between gross spinal flexibility and either pain/disability at the start of the exercise programme or between changes in each after therapy (Hsieh and Lee 2002, Kuukkanen and Malkia 2000). One study found no correlation between the improvements in spinal mobility or back muscle strength and the reduction in either pain or disability (Johannsen et al 1995). A further study reported that the increase in trunk strength showed a moderate significant correlation with the decrease in functional impairment after exercise therapy (r=0.48), but changes in spinal mobility did not correlate with changes in either pain or functional impairment (Martin et al 1986). One study found no correlation between the gain in lumbar torque and pain relief or pain-related disability after exercise therapy (p>0.2) (Rittweger et al 2002).

There is strong evidence (level A) that the changes in pain and disability reported after various types of exercise therapy are not directly related to changes in any aspect of physical performance capacity.

Cost effectiveness
Few studies have examined the cost effectiveness of different treatments. One study reported that the relative costs of group aerobic exercises vs physiotherapy vs muscle reconditioning were in a ratio of approximately1:3:4, for similar clinical effectiveness, indicating that group aerobic exercise constituted the most cost-effective treatment (Mannion et al 1999, 2001b). However, no full economic evaluations have been published so far.

Safety
Adverse effects were reported in only few studies: two studies reported cardiovascular problems, apparently unrelated to the treatment programmes (coronary occlusion (Hansen et al 1993)) and myocardial infarction (Bronfort et al 1996); and one study reported an increase in back pain at the start of treatment (Manniche et al 1991).

Comments

1. The overall effectiveness of exercise therapy for CLBP may be overestimated: the studies on exercise have a certain bias because patients who do not like exercise are less likely to volunteer to participate.

2. At present, the influence of exercise intensity, frequency of therapy sessions, and programme duration on outcome remains largely unknown. Few studies have directly examined dose-response, and the sheer diversity of exercise programmes used in previous RCTs precludes the useful examination of pooled data e.g. in meta-analyses (Hilde and Bo 1998).

3. It is difficult to accurately characterise the exercise programmes used in some of the RCTs, as they involve a mixture of different exercise modes (stretching, aerobic exercises, muscle reconditioning). Further, it is questionable whether the categorisation of "flexion exercises" and "extension exercises" is justified, unless it is clear whether the direction of the exercise (flexion or extension) refers to the muscles being stretched or strengthened (e.g. trunk-flexion stretching exercises actually stretch the back and hip extensors; trunk-flexion strengthening exercises train the trunk flexors).

4. The cost-benefit ratio for group exercise classes and individual exercise sessions should be investigated more thoroughly, as this issue is highly relevant to the economics of CLBP.

5. The mechanisms of action by which exercise therapy appears to be an effective treatment for CLBP are presently unclear. There is little relationship between changes in clinical symptoms and changes in any "objectively measured" aspect of functional capacity (e.g. strength, flexibility, muscular endurance, etc.) This may explain the conclusion that there is no convincing evidence to endorse the use of one type of exercise over another in the treatment of CLBP.

6. All the exercise programmes investigated were done so within the confines of a research study and thus the individuals involved were under some sort of supervision/observation (even those in which the exercise sessions *per se* was unsupervised). There is currently no evidence to show whether simply prescribing exercise (e.g. just sending patients off to the local leisure centre to join an exercise class, or telling them to keep themselves fit and active) would be equally effective.

Summary of evidence

- There is moderate evidence that exercise therapy is more effective in the reduction of pain and/or disability, at least in the short-term, than passive treatments intended/considered to be control treatments by the authors of the respective RCTs (level B).
- There is strong evidence that exercise therapy is more effective than "GP care" for the reduction of pain and disability and return to work in at least the mid-term (3-6 months) (level A).
- There is strong evidence that exercise therapy alone is not more effective than conventional physiotherapeutic methods in the treatment of CLBP (level A).
- There is conflicting evidence regarding the effectiveness of exercise as compared with intensive multidisciplinary programmes (level C).
- There is strong evidence that strengthening/reconditioning exercises are no more effective than other types of exercises in the treatment of CLBP (level A).
- There is limited evidence in each case that: there are no differences between aerobic exercises, muscle reconditioning or physiotherapy exercises in relation to pain or disability up to 12 months after treatment; there are no significant differences between the effects on pain reduction of carrying out just 4 exercise therapy sessions as opposed to 8 sessions; aerobic exercises are superior to lumbar flexion exercises in terms of pain immediately after the programme; a home exercise programme with individualised exercises is more effective than one using general exercises; a combined exercise and motivational programme

shows a significantly larger decrease in pain and disability up to 12 months post-treatment than does exercise alone (each, level C).

- There is conflicting evidence regarding the effectiveness of programmes involving mainly trunk flexion exercises as compared with those involving mainly trunk extension (level C).
- There is moderate evidence that individually supervised exercise therapy is not more effective than supervised groups exercise (level B).
- There is strong evidence that the changes in pain and disability reported after various types of exercise therapy are not directly related to changes in any aspect of physical performance capacity (level A).

Recommendation
We recommend supervised exercise therapy as a first-line treatment in the management of chronic low back pain.

We advocate the use of exercise programmes that do not require expensive training machines. The use of a cognitive-behavioural approach, in which graded exercises are performed, using exercise quotas, appears to be advisable. Group exercise constitutes an attractive option for treating large numbers of patients at low cost. We do not give recommendations on the specific type of exercise to be undertaken (strengthening/muscle conditioning, aerobic, McKenzie, flexion exercises, etc.). The latter may be best determined by the exercise-preferences of both the patient and therapist.

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Chapter 6 Manual Therapy

C6 (A) Spinal manipulation/mobilisation

Definition of the procedure
Spinal manipulation is defined as a high velocity thrust to a joint beyond its restricted range of movement. Spinal mobilization involves low-velocity, passive movements within or at the limit of joint range (Brox et al 1999, Koes et al 1996). Most studies do not make a clear distinction between these two, because in clinical practice these two techniques are part of a "spinal manipulation package" that is often referred to as manual therapy (Harvey et al 2003).

For a discussion on differences between spinal manipulation and mobilisation techniques see (CMAJ Oct 2004)

Results of search
Systematic reviews
22 studies were retrieved through the electronic search (Abenhaim and Bergeron 1992, Anderson et al 1992, Assendelft et al 1992, 1996, Assendelft and Lankhorst 1998, Assendelft et al 2003, 2004, Bronfort 1999, Cassidy et al 1993, Cherkin et al 2003, Cooperstein et al 2001, Ernst 2001, Ernst and Harkness 2001, Ferreira et al 2002, Gatterman et al 2001, Koes et al 1996, Koes et al 1991, Leboeuf-Yde et al 1997, Pustaver 1994, Shekelle et al 1992, Shekelle et al 1998, Stevinson and Ernst 2002). 5 of these were considered to be individual/observational studies or non-systematic reviews and were hence excluded from further consideration (Bronfort 1999, Cooperstein et al 2001, Gatterman et al 2001, Leboeuf-Yde et al 1997, Shekelle et al 1998). The remaining 17 were systematic reviews or meta-analyses. A further 3 SRs were identified through the working group's knowledge of the literature (Brox et al 1999, Ottenbacher and DiFabio 1985, White and Ernst 2000). Of these total 20 SRS, two were excluded: one because it focused on the description of the manipulative method and not on the evidence of its effectiveness (Cassidy et al 1993) and another because it was related to acute and not CLBP (Pustaver 1994). Among the remaining 18 systematic reviews, one focused on an economic analysis of complementary medicine (including spinal manipulation) (White and Ernst 2000) and two on the safety of spinal manipulation (Ernst 2001, Stevinson and Ernst 2002). Thirteen focused on the effectiveness of spinal manipulation and/or spinal mobilization (considered as one and the same) vs. other procedures (some of them considered as being placebo) (Abenhaim and Bergeron 1992, Assendelft et al 1992, 1996, Assendelft and Lankhorst 1998, Assendelft et al 2003, 2004, Brox et al 1999, Cherkin et al 2003, Ferreira et al 2002, Koes et al 1996, Koes et al 1991, Ottenbacher and DiFabio 1985, Shekelle et al 1992); whilst two separated out spinal manipulation and spinal mobilization (Anderson et al 1992, Ernst and Harkness 2001).
The most up to date systematic review was an updated Cochrane review (Assendelft et al 2004) (same review as (Assendelft et al 2003)) which presented separate results for studies of CLBP.

Additional studies
Eight additional RCTs were identified (Aure et al 2003, Chiradejnant et al 2003, Hemmila et al 2002, Hurwitz et al 2002, Licciardone et al 2003, Niemisto et al 2003, Rasmussen-Barr et al 2003, UK BEAM trial team et al 2004b). Three of these were excluded from further consideration: two studies ("manual therapy" vs. "exercise therapy"), because the patients in the manual therapy group also received a substantial amount of exercise therapy, making the respective effects of the manual therapy and the exercise therapy difficult to ascertain (Aure et al 2003, Niemisto et al 2003); and a third ("folk-medicine bone-setting" vs "exercise therapy" vs

"physiotherapy"), because the treatment given in the "bone-setting" group was not comparable with the type of manual therapy (administered by medically qualified personnel) described in all the other trials used to form these recommendations (Hemmila et al 2002). Furthermore, the physiotherapy group in this trial also received manual therapy, and the descriptions of the treatments (especially the exercise therapy) were unclear and not consistent in the two papers published from the trial.

Quality assessment of the evidence
Systematic reviews
Six of the final 18 SRs were assessed as being of high quality (Assendelft et al 1996, Assendelft et al 2003, 2004, Brox et al 1999, Cherkin et al 2003, Koes et al 1991) and 12 as being of low quality (Abenhaim and Bergeron 1992, Anderson et al 1992, Assendelft et al 1992, Assendelft and Lankhorst 1998, Ernst 2001, Ernst and Harkness 2001, Ferreira et al 2002, Koes et al 1996, Ottenbacher and DiFabio 1985, Shekelle et al 1992, Stevinson and Ernst 2002, White and Ernst 2000). As one of these was also an up-to-date Cochrane review (Assendelft et al 2004)(same as (Assendelft et al 2003)), it was used as the basis for forming these recommendations. The quality ratings of the studies included in the Cochrane review followed a slightly different 10-point scheme than that described in the introduction to these guidelines, but was still based on the guidelines given by the Cochrane Collaboration Back Review Group (van Tulder et al 1997). Manipulation was compared with sham manipulation in three studies (scoring 7, 5, and 5 points respectively) (Ongley et al 1987, Triano et al 1995, Waagen et al 1986); compared with treatments considered to be "ineffective", such as traction, corsets, topical gels (based on the lack of evidence for their benefit or evidence for their harm in previous systematic reviews) in 5 studies (scoring 6, 8, 6, 3 and 3 respectively) (Gibson et al 1985, Koes et al 1992, Pope et al 1994, Postacchini et al 1988, Timm 1994); compared with GP care/analgesics in 5 studies (scoring 7, 7, 5, 8 and 3 respectively) (Andersson et al 1999, Bronfort et al 1996, Evans et al 1978, Koes et al 1992, Postacchini et al 1988); compared with physical therapy/exercise therapy in 4 studies (scoring 6, 8, 3 and 3 respectively) (Hemmila et al 1997, Koes et al 1992, Postacchini et al 1988, Skargren et al 1997); and compared with back schools in 3 studies (scoring 3, 3 and 5 respectively) (Herzog et al 1991, Postacchini et al 1988, Triano et al 1995).

Additional RCTs:
Using the same rating scheme as used by Assendelft et al (Assendelft et al 2004) the four additional RCTs identified by the authors' knowledge of the literature (Hurwitz et al 2002, Licciardone et al 2003, Rasmussen-Barr et al 2003, UK BEAM trial team et al 2004b) were scored 4, 4, 3, and 7 respectively.

Effectiveness
The Cochrane review carried out a series of meta-analyses to examine the effectiveness of manipulation vs the various other procedures (grouped as described above) for the outcomes pain and disability, in both the short-term (<6 weeks after randomisation; outcome measurement closest to 3 weeks) and long-term (<6 weeks after randomisation; outcome measurement closest to six months) (Assendelft et al 2004).

Effectiveness of manipulation vs. a sham procedure
Based on 3 studies (quality ≥ 5/10) (Ongley et al 1987, Triano et al 1995, Waagen et al 1986), the Cochrane review meta-analyses revealed that manipulation was superior to sham manipulation for short-term and long-term pain relief, and for short-term improvement in function (Assendelft et al 2004). The pooled difference in pain intensity (on a 0-100 mm VAS) was 10 mm (95% CI, 3-17mm) in the short-term and 19 mm (95% CI, 3-35 mm) in the long-term; short-term improvement in function on the 24-point Roland Morris Disability scale was 3.3 points (95% CI, 0.6 – 6.0). There were no significant benefits in relation to long-term function. The findings of the Cochrane review conflict somewhat with those of an earlier low quality systematic review of manipulation for various conditions, which concluded that serious methodological flaws in two of the studies on manipulation for back pain (also included in the Cochrane review) prevented any firm conclusions from being reached (Ernst and Harkness 2001). One additional RCT (quality, 4/10) compared manipulation with sham manipulation and with a "no additional intervention" control group (Licciardone et al 2003). All groups were allowed to continue with their usual or other back care for back pain (with the exception of manipulative therapy). Treatment was delivered by third- and fourth-year medical students in the process of completing an additional year of training devoted to osteopathic theory and practice (see **Comments** section). One month after the last treatment, the outcomes for manipulation and sham manipulation (each with additional access to usual care) did not differ, and both were better than the control treatment (usual care only) with regards to pain, physical functioning and satisfaction with care (Licciardone et al 2003).

There is moderate evidence (generally consistent findings; 3 out of 4 studies) that manipulation is superior to sham manipulation for improving short-term pain and function (level B).

Effectiveness of manipulation vs. treatments considered to be ineffective
Based on 5 studies (scoring 6, 8, 6, 3 and 3 quality points respectively) (Gibson et al 1985, Koes et al 1992, Pope et al 1994, Postacchini et al 1988, Timm 1994), the Cochrane review meta-analyses revealed that manipulation was superior to treatments considered to be "ineffective" (see earlier) for short-term pain relief and for short-term improvement in function (Assendelft et al 2004). The pooled difference in pain intensity (on a 0-100 mm VAS) was just 4 mm (95% CI, 0-8mm) and in function on the 24-point Roland Morris Disability scale, 2.6 points (95% CI, 0.5 – 4.8). There were no significant benefits in relation to long-term pain or function.

There is strong evidence that manipulation is superior to treatments considered to be ineffective for improving short-term pain and function (level A).

Effectiveness of manipulation vs. GP care or analgesics
Based on 5 studies (scoring 7, 7, 5, 8 and 3 respectively) (Andersson et al 1999, Bronfort et al 1996, Evans et al 1978, Koes et al 1992, Postacchini et al 1988), the Cochrane review meta-analyses revealed that spinal manipulation showed no statistically or clinically significant differences from general practitioner care or analgesics with regard to either short-term or long-term changes in pain and disability (Assendelft et al 2004).
One additional RCT (quality score 4) compared manipulation with usual medical care (instructions/recommendations on back care and exercise) (Hurwitz et al 2002) and found that the mean changes in low back pain intensity and disability of participants in the medical and chiropractic care-only groups were similar at each follow-up assessment (adjusted mean differences at 6 months for most severe pain, 0.27, 95% confidence interval, -0.32-0.86; average pain, 0.22, -0.25-0.69; and disability, 0.75, -0.29-1.79) (Hurwitz et al 2002).

There is strong evidence (level A) that manipulation and GP care/analgesics are similarly effective in the treatment of CLBP.

Effectiveness of manipulation plus GP care vs GP care only
One additional trial (quality rating, 4) showed that manipulation in addition to continued medical care was superior to continued medical care alone, with regards to pain, physical functioning and satisfaction with care 1 month after the last manipulation treatment (Licciardone et al 2003).
Another additional large trial (N=1334) (quality rating, 7), that included primary care patients with subacute and chronic back pain from all over the UK, showed that manipulation, when added to "stay active GP care", improved pain and disability significantly more than "stay active GP care" in both the short and long-term (up to 12 months) (UK BEAM trial team et al 2004b).

There is moderate evidence that spinal manipulation in addition to GP care is more effective than GP care alone in the treatment of CLBP (level B).

Effectiveness of manipulation vs. physiotherapy/exercise therapy
Based on 4 studies (scoring 6, 8, 3 and 3 respectively) (Hemmila et al 1997, Koes et al 1992, Postacchini et al 1988, Skargren et al 1997), the Cochrane review meta-analyses revealed that spinal manipulation showed no statistically or clinically significant differences from exercise therapy or physiotherapy with regard to short-term or long-term changes in pain and disability (Assendelft et al 2004).
N.B. The longer follow-up (Hemmila et al 2002) from one of these studies (Hemmila et al 1997) was excluded from our own considerations, as the manipulative therapy administered ("folk-medicine bone-setting") was not considered to be comparable with the type of manual therapy, administered by medically qualified personnel, described in the other trials.

An additional study (quality rating, 3) (Rasmussen-Barr et al 2003) compared manipulation with spine-stabilising exercises and reported that the latter were more effective than manual treatment in terms of improvements in pain, general health and functional disability (3 months after treatment) and in terms of the need for recurrent treatment (in the 12 months following the study treatment) (Rasmussen-Barr et al 2003). However, drop out rates were high at the longer-term follow-up, and at this point the differences in the reduction of pain intensity and disability (ODI) were not significantly different between the groups.

There is moderate evidence that spinal manipulation is no less and no more effective than physiotherapy/exercise therapy in the treatment of CLBP (level B).

Effectiveness of manipulation vs. back school
Based on 3 studies (scoring 3, 3 and 5 respectively) (Herzog et al 1991, Postacchini et al 1988, Triano et al 1995) the Cochrane review meta-analyses revealed that spinal manipulation showed no statistically or clinically significant differences from back school with regard to short-term or long-term changes in pain and short-term changes in disability (long-term disability was not studied in any of the RCTs) (Assendelft et al 2004).

There is moderate evidence that spinal manipulation is no less and no more effective than back-schools in the treatment of CLBP (level B).

The finding that spinal manipulation shows no difference from other conventionally advocated therapies (such as GP care, analgesics, exercise therapy, physiotherapy or back school) confirmed the general findings of all the earlier, high quality

SRs (Assendelft et al 1996, Assendelft et al 2003, Brox et al 1999, Cherkin et al 2003, Koes et al 1991).

Cost/effectiveness
One low quality SR focused on economic analysis of complementary medicine (including spinal manipulation). With regard to this procedure, it concluded that there is no convincing evidence that manipulative therapy for back pain improves cost/effectiveness of treatment or saves costs for the primary care provider (White and Ernst 2000).
One high quality SR, based on two RCTs, reported that the cost-effectiveness for manipulation was not better than for an educational booklet or physiotherapy (Cherkin et al 2003).
One high quality RCT carried out in the UK showed that manipulation, as carried out by chiropractors, osteopaths or physiotherapists, was more cost-effective than "stay active GP care" in terms of the use of healthcare resources in the following year (UK BEAM trial team et al 2004a).

Safety
Three SRs focused specifically on prospective studies on the safety of spinal manipulation (not mobilization) (Assendelft et al 1996, Ernst 2001, Stevinson and Ernst 2002). The studies they included may or may not have included patients with CLBP amongst all patients who were given spinal manipulations. One other review focused on effectiveness of both spinal manipulation and mobilization and gave some data on safety (Shekelle et al 1992). The SRs concur in stating that cervical manipulation (which is infrequently used by manipulators treating low back pain) has been linked with a greater number of complications and of a more serious nature than lumbar manipulation. The most serious side effects are vertebrobasilar accidents, disk herniation, and cauda equina syndromes. Estimates of the incidence of serious complications range from 1 per 2 million manipulations to 1 per 400 000 (Ernst 2001, Stevinson and Ernst 2002).
Minor, transient adverse effects occur in approximately half of all patients receiving spinal manipulation. Local discomfort, headache, fatigue and discomfort outside the area of treatment were the most frequent complaints. They appear the same day as the treatment or the day after, and disappear within 24-48 hours, although they may last longer in about one fifth of the patients (Ernst 2001, Stevinson and Ernst 2002).

Subjects (indications)
The patient populations described in the majority of trials were heterogenous but were often primary care patients who appeared to be moderately disabled with back pain but not sick-listed. No specific indications for spinal manipulation are known.

Comments

1.   The studies considered in the various SRs included patients with and without referred pain. All studies considered included a substantial proportion of "chronic" LBP patients, although definitions of CLBP were inconsistent across reviews.

2.   In many of the RCTs upon which the conclusions of the Cochrane review (Assendelft et al 2004) were based, the study sample included mixed populations of patients with subacute and chronic neck, thoracic and low back pain. Although this was not necessarily compatible with our own general criteria for these recommendations (see **Methods**, in the **Introduction**), it was difficult to tease out the studies only dealing with CLBP and this probably reflecting the treatments given in the clinics of chiropractors and manual therapists.

3.   The best systematic reviews stated that the general quality of RCTs on spinal manipulation is low, making it difficult to draw firm conclusions, although recent, additional trials appear to be of higher quality.

4.   Most of the manipulation/mobilisation treatments were administered by personnel that were considered "qualified" within their own medical specialty (osteopathy, chiropractic, manual medicine, physiotherapy), although the requirements for qualification differ markedly amongst these professions. The study that showed no difference between manipulation and sham manipulation was carried out by third and fourth year medical students in the process of completing an additional year of training devoted to osteopathic theory and practice (Licciardone et al 2003). The authors of the study conceded that "it was possible that the predoctoral fellows may not have had sufficient practical experience to provide the treatment with the same efficacy as more seasoned practitioners or to provide nontherapeutic sham manipulation". However, the failure to identify any difference between sham and real manipulation may also have arisen as a result of the small size of the control and sham groups. Further, the study had a relatively high drop-out rate, especially in the manipulation group.

In general, it would seem prudent to recommend that the treatment only be carried out by suitably qualified/trained practitioners within the given medical specialty.

5. The manipulative/mobilization treatments used in the RCTs to date were most commonly administered twice per week (range, 1-7 times per week), and most commonly for a period of 2-3 weeks (range, 2-9 weeks). There is no evidence to suggest that long-term manipulative treatment contributes any additional benefit.

6.   Most of the systematic reviews on effectiveness included RCTs on spinal manipulation *and* spinal mobilization, and in fact considered both as the same treatment. As such, it is impossible to determine the relative effectiveness of spinal manipulation or mobilization. Nonetheless, in practice, they are usually used together as part of a treatment package (Harvey et al 2003).

7. One recent study sought to examine whether a mobilisation technique selected by the treating physiotherapist is more effective in relieving low back pain than a randomly selected mobilisation technique. There was no suggestion that this was the case (Chiradejnant et al 2003).

Summary of the evidence

- There is moderate evidence that manipulation is superior to sham manipulation for improving short-term pain and function in CLBP (level B).
- There is strong evidence that manipulation and GP care/analgesics are similarly effective in the treatment of CLBP (level A)
- There is moderate evidence that spinal manipulation in addition to GP care is more effective than GP care alone in the treatment of CLBP (level B).
- There is moderate evidence that spinal manipulation is no less and no more effective than physiotherapy/exercise therapy in the treatment of CLBP (level B).
- There is moderate evidence that spinal manipulation is no less and no more effective than back-schools in the treatment of CLBP (level B).

Recommendation
Consider a short course of spinal manipulation/mobilisation as a treatment option for CLBP.

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C6 (B) Massage therapy

Definition of the procedure.
Massage can be defined as soft tissue manipulation using the hands or a mechanical device (Furlan et al 2002). Different techniques can be used, such as: effleurage, petrissage, friction, kneading, or hacking. Either a classical approach is used, or an approach in which the rules of massage from physical medicine are combined with those of acupuncture from neural therapy (treats one unique point with a special vibrating instrument that stimulates the acupuncture point superficially (but not with needle insertion)). In clinical practice, massage is often applied in combination with other therapies such as exercises and other interventions but sometimes also as a sole treatment.

Results of search
Systematic reviews
Two SRs were found that dealt with the effects of massage in low back pain patients (Ernst 1999, Furlan et al 2002). One of them was a Cochrane SR, which described the effects of massage in adults with acute, sub-acute and chronic (>12 weeks) low back pain (Furlan et al 2002). The latter SR formed the basis for this evidence review.

Additional trials
Two additional trials were found (Hsieh et al 2004, Walach et al 2003). In one, the effects of massage were compared with standard medical care in a group of patients with chronic pain (Walach et al 2003). However, this study was excluded from the evidence review because it was not clear from the publication what proportion of the study population had low back pain at the start of the study. In the second trial, acupressure was compared with physical therapy (consisting of either infrared light therapy, thermotherapy, electrical stimulation, exercise therapy or pelvic manual traction) (Hsieh et al 2004).

Quality assessment of the evidence
The two SRs were of a high quality.
The Cochrane SR included 7 RCTs that were reported in 8 publications (Cherkin et al 2001, Franke et al 2000, Hernandez-Reif et al 2001, Hoehler et al 1981, Hsieh et al 1992, Melzack et al 1983, Pope et al 1994, Preyde 2000). In these studies massage therapy was compared with a variety of treatments.
The additional trial (Hsieh et al 2004) was high quality.

Effectiveness
Effectiveness of massage versus sham procedure
One high quality RCT (according to the Cochrane Review) showed that massage was significantly better than sham laser therapy with regard to both pain and function up to 1 month after treatment (i.e. disability) (Preyde 2000).

There is limited evidence that massage is more effective than sham procedures in the treatment of chronic low back pain (level C).

Effectiveness of massage versus remedial exercises and posture education
One high-quality study reported that, immediately after treatment, massage therapy led to significantly greater disability and pain improvements compared with remedial exercise and posture education (Preyde 2000).

There is limited evidence that massage is better than remedial exercise and posture education in reducing short-term pain and improving function (level C).

Effectiveness of massage versus relaxation therapy
One low quality study reported significantly more pain relief after massage therapy in comparison to progressive relaxation therapy (Hernandez-Reif et al 2001).

There is limited evidence that massage is more effective than relaxation therapy for pain relief (level C).

Effectiveness of massage versus acupuncture
One high quality study compared 10 sessions (over 10 weeks) of either massage or acupuncture (Cherkin et al 2001). Patients in the massage group had better function scores than those in the acupuncture group, at both short-term (10 weeks) and long-term (52 weeks) follow-ups. Differences in pain scores in favour of massage were found only at the longer-term follow-up.

There is limited evidence that massage is more effective than acupuncture in reducing pain (long-term) and improving function (short-term and long-term) (level C).

Effectiveness of massage versus self-care education
One high quality study compared 10 sessions (over 10 weeks) of massage therapy with self-care education (Cherkin et al 2001). Patients in the massage group had more pain relief and better function scores at the short-term follow-up (i.e. 10 weeks). These differences were not maintained at long-term follow-up (i.e. 52 weeks).

There is limited evidence that massage is better than self-care education in reducing pain and improving function in the short term but not the longer term (level C).

Effectiveness of massage versus spinal manipulation
In one low quality study, the effectiveness of spinal manipulation was compared with that of massage therapy, where the latter was serving as a control treatment (Hoehler et al 1981). The manipulation group had better results in relation to pain reduction immediately after the first session, but the difference was not maintained at the longer term. One high quality trial (reported in two papers (Hsieh et al 1992, Pope et al 1994)) showed that spinal manipulation resulted in greater improvements in function compared with massage; there were no differences in pain improvements between the groups.

There is limited evidence that spinal manipulation and massage are equally effective in pain relief, and that spinal manipulation results in better function than massage (each level C).

Effectiveness of massage versus general physical therapies
One high quality study found that acupressure had a significant effect on pain compared with various physical therapies up to 6 months after treatment.

There is limited evidence that acupressure massage is more effective than general physical therapies for mid-term pain relief (level C).

Effectiveness of massage versus electrical stimulation
One high quality RCT showed no differences in pain and function scores between a massage group and a group receiving transcutaneous *muscle* stimulation (Hsieh et al 1992, Pope et al 1994).
Another high quality RCT showed that massage resulted in significantly less pain relief compared with TENS (Melzack et al 1983).

There is limited evidence that there is no difference between massage and transcutaneous *muscle* stimulation with regard to improvements in either pain or function (level C). There is limited evidence that massage is less effective than TENS in relieving pain (level C).

Effectiveness of massage versus corset
One high quality RCT, reported in two papers, compared massage to the wearing of a corset (Hsieh et al 1992, Pope et al 1994). No differences between the treatments were found for function or pain.

There is limited evidence that there is no difference in the effectiveness of massage and the wearing of a corset (level C).

Effectiveness of massage as a component of combined therapy
One high quality study showed that massage in combination with remedial exercises and education was better for pain relief than massage alone, immediately after treatment (Preyde 2000). The combination therapy was also better than remedial exercises only or sham laser therapy, in terms of both pain relief and improvement of function up to 1 month after treatment (Preyde 2000).

There is limited evidence that massage in combination with remedial exercises and education is better than massage alone, remedial exercises alone or sham laser therapy for short-term pain relief and improved function (level C).

Effectiveness of different types of massage vs each other
One high quality study compared the effectiveness of therapeutic acupuncture massage with classical massage (each combined with either individual medical exercises or group exercises) (Franke et al 2000).
Immediately after therapy, acupuncture massage showed significantly better effects for both disability and pain compared with classical massage.

There is limited evidence that therapeutic acupuncture massage is more effective than classical massage (level C).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for massage.

Comments
None

Summary of evidence

- There is limited evidence in each case that massage is more effective than: sham procedures; remedial exercise and posture education; relaxation therapy (for pain relief); acupuncture (long-term pain relief and function); self-care education (for short-term pain relief and improvement of function); and general physical therapies (for mid-term pain relief (each, level C)).
- There is limited evidence that massage and spinal manipulation are equally effective for pain relief, but that massage results in less functional improvement than spinal manipulation (each level C).
- There is limited evidence that there is no difference between massage and transcutaneous *muscle* stimulation with regard to improvements in either pain or function (level C). There is limited evidence that massage is less effective than TENS in relieving pain (level C).
- There is limited evidence that there is no difference in the effectiveness of massage and the wearing of a corset (level C).
- There is limited evidence that a combined treatment of massage with remedial exercises and education is better than massage alone, remedial exercises alone or sham laser therapy for short-term pain relief and improved function (level C).
- There is limited evidence that therapeutic acupuncture massage is more effective than classical massage (level C)**.**

Recommendation
We cannot recommend massage therapy as a treatment for chronic low back pain.

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Chapter 7 Back schools and and brief educational interventions/advice to promote self-care

C7 (A) Back schools

Definition of the procedure

A back school can be defined as an intervention that consists of an education and a skills program, including exercises, in which all lessons are given to groups of patients and supervised by a paramedical therapist or medical specialist (van Tulder et al 2004). The original 'Swedish back school', introduced in 1980, consisted of four sessions of 45 minutes (Forssell 1980). The content of the sessions included information on the anatomy and function of the back, discussion of the mechanical strain in different positions and teaching of the semi-Fowler position. Since then, the content of back schools has changed and is also very variable. An evaluation of back schools must, therefore, consider the content of the program.

Results of search
Systematic reviews

Four SRs were found (Cohen et al 1994, Koes et al 1994, Maier-Riehle and Harter 2001, van Tulder et al 2004); one of them was a Cochrane SR (van Tulder et al 2004). The Cochrane SR included 15 RCTs on the effects of back schools on chronic LBP and covered a search period up to December 1997. In May 2003 the Cochrane SR was updated and four additional RCTs were included (Heymans et al 2004). This updated Cochrane SR served as the starting point in formulating these recommendations. The review was based on 9 reports of 6 trials in which back schools had been compared with waiting-list controls or 'placebo' interventions (Dalichau et al 1998, Dalichau et al 1999, Glomsrod et al 2001, Keijsers et al 1989, Keijsers et al 1990, Lankhorst et al 1983, Linton et al 1989, Lonn et al 1999, Postacchini et al 1988) and 10 reports of 5 trials in which back schools had been compared with other conservative treatments (exercises, spinal or joint manipulation, myofascial therapy and instructions/advice) (Harkapaa et al 1989, Harkapaa et al 1990, Hurri 1989a, b, Julkunen et al 1988, Klaber Moffett et al 1986, Mellin et al 1990, Mellin et al 1989, Penttinen et al 2002, Postacchini et al 1988).

Additional RCTs

No additional trials were found.

Quality assessment of the evidence

The updated Cochrane SR was rated as high quality. Of the relevant trials that it contained, 3 were of high quality (Glomsrod et al 2001, Linton et al 1989, Lonn et al 1999) (one trial, two papers) (Klaber Moffett et al 1986) and the rest were of low quality.

Effectiveness
Effectiveness of back schools versus waiting-list controls or 'placebo' interventions for chronic low back pain

Six trials (Dalichau et al 1998, Dalichau et al 1999, Keijsers et al 1989, Keijsers et al 1990, Lankhorst et al 1983, Linton et al 1989, Lonn et al 1999, Postacchini et al 1988) (Glomsrod et al 2001), two of which were high quality (Linton et al 1989, Lonn et al 1999) and (Glomsrod et al 2001) (one trial, two papers), compared back schools with waiting-list controls or placebo interventions. One high quality trial reported statistically significant effects on pain at 6 weeks and 6 months after treatment in favour of a back school group compared with a waiting-list control group (Linton et al 1989). The other high quality trial reported a significantly earlier

return to work (reduction of sick leave days) for a back school treatment compared with no treatment (Lonn et al 1999) (Glomsrod et al 2001). The remaining trials reported a mixture of results (some positive, some negative).

There is conflicting evidence for the effectiveness of back schools with regard to pain, functional status and return to work, compared with waiting list controls or 'placebo' interventions (level C).

Effectiveness of back school versus other treatments for chronic low back pain
In comparing back school with various other treatments (such as simple advice, exercises only and manipulation), one high quality trial (Klaber Moffett et al 1986) and four low quality trials (Harkapaa et al 1989, Harkapaa et al 1990, Hurri 1989a, b, Julkunen et al 1988, Mellin et al 1990, Mellin et al 1989, Penttinen et al 2002, Postacchini et al 1988) showed effects in favour of the back school group for pain relief and functional status in the short term (< 6 weeks follow-up). Two low quality studies (Harkapaa et al 1989, Harkapaa et al 1990, Hurri 1989a, b, Mellin et al 1990, Mellin et al 1989) showed no differences in long-term outcomes (> 12 months follow-up).

There is moderate evidence that back school is more effective than other treatments examined (simple advice, exercises only, manipulation) with regards to pain and functional status in the short-term (level B). There is moderate evidence for no difference between back schools and these other treatments with regard to their long-term effects on pain and functional status (level B).

Cost-effectiveness
Unknown (no studies identified on this issue)

Safety
Unknown (no studies identified on this issue)

Subjects (indications)
As back schools are generally very heterogeneous in their content, it is not possible to strictly define ideal indications regarding the type of patient that will best benefit from this treatment.

Comments
Back schools often show a lot of overlap with other interventions such as functional restoration, work hardening, multidisciplinary rehabilitation, and graded activity. Furthermore, the labels that are assigned to these differing interventions do not necessarily indicate a correspondingly standardised or consistent content.
It should be noted that, for the purposes of this guideline, a back school was only considered to be such, if the content closely matched the definition of the procedure as given in the introduction.

Summary of evidence
- There is conflicting evidence for the effectiveness of back schools with regard to pain, functional status and return to work, compared with waiting list controls or 'placebo' interventions (level C).

- There is moderate evidence that back school is more effective than other treatments examined (simple advice, exercises only, manipulation) with regards to pain and functional status in the short-term (level B). There is moderate evidence for no difference between back schools and these other treatments with regard to their long-term effects on pain and functional status (level B).

Recommendation
Consider back schools where information given is consistent with evidence-based recommendations for short-term (<6 weeks) pain relief and improvements in functional status. We do not recommend back schools as a treatment for chronic low back pain when aiming at long-term effects (>12 months).

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C7 (B) Brief educational interventions to promote self-care

Definition of the procedure
Brief educational interventions (as distinct from back schools) include interventions that involve minimal contact with a healthcare professional (normally just one or two sessions), the use of self-management patient-led groups, the provision of educational booklets, and the use of Internet and e-mail discussion groups. The interventions aim to encourage active self-management and to reduce concerns. Some such interventions are described as 'mobilisation' in some studies, to indicate the attempt to encourage the patient to become more active; this should not be confused with the manual therapy treatment of spinal mobilisation.

Results of search
No systematic reviews on the topic were identified.
One general descriptive review was identified, which had a section covering "other educational interventions" for chronic LBP (Turner 1996). This included two low quality studies that investigated the provision of an educational booklet. One included a mixed population of primary care patients (Roland and Dixon 1989) and the other mainly acute patients (Cherkin et al 1996). They were therefore not considered further.

Additional studies
Twelve RCTs were identified through the search and the working group's knowledge of the literature (Buhrman et al 2004, Cherkin et al 2001, Frost et al 2004, Hagen et al 2000, Indahl et al 1998, Karjalainen et al 2004, Karjalainen et al 2003, Lorig et al 2002, Storheim et al 2003, Triano et al 1995, Von Korff et al 1998). One of these was excluded as it included an education programme rather than "brief" education (Triano et al 1995). One study was reported in two papers (Karjalainen et al 2004, Karjalainen et al 2003). Thus, ten RCTs were included.

Quality assessment of the evidence
Among the ten RCTs, four were high quality (Cherkin et al 2001, Frost et al 2004, Karjalainen et al 2004, Karjalainen et al 2003, Storheim et al 2003). Four others were low quality (Buhrman et al 2004, Lorig et al 2002, Moore et al 2000, Von Korff et al 1998). Two that used Zelen's design appeared to have high internal validity but using the Cochrane quality criteria were rated as low quality (Hagen et al 2000, Indahl et al 1998).

Effectiveness
Effectiveness of minimal contact/brief educational interventions vs usual care
Two trials investigated the effects of a light mobilisation (i.e. "activating") program comprising a physical examination and information and advice to stay active, as compared with usual care (Hagen et al 2000, Indahl et al 1998). Another trial, which included a 2 year follow up, evaluated a mini-intervention consisting of a detailed assessment of the patients' history, beliefs and physical findings by a physician and a physiotherapist, followed by recommendations and advice (Karjalainen et al 2004, Karjalainen et al 2003).

Two of these trials (one high and one low quality) reported statistically significant effects on sick leave reduction at 12 months (Hagen et al 2000) and at 2 years (Karjalainen et al 2004, Karjalainen et al 2003) in the groups receiving information and advice to stay active as compared with the groups receiving usual care. One trial (Indahl et al 1998) showed that light mobilisation and information increased return to work up to five years after the intervention.

A fourth trial, also carried out in Scandinavia, compared a brief cognitive intervention provided by a physician and a physiotherapist with usual care and with aerobic exercise (Storheim et al 2003). There was no difference between the treatments with regard to sick-listing.

There is moderate evidence that brief interventions addressing concerns and encouraging a return to normal activities are better than usual care in increasing return to work rates (level B).

One high quality trial (Karjalainen et al 2004, Karjalainen et al 2003) found no differences between a brief-education group and a usual care group in relation to pain, disability, and health-related quality of life, at 12 months and 2 years follow up. However, another high quality trial (Storheim et al 2003) found that, 18 weeks after inclusion into the study, patients receiving a brief cognitive intervention by a physician and physiotherapist improved significantly more in relation to disability, self-efficacy for pain, emotional distress, general health and life satisfaction, but not pain intensity, compared with usual care.

Two low quality studies carried out in the USA compared a short group education programme encouraging self-care with usual care in the primary care setting. One found that a lay-led self-management group intervention of 4 sessions was more successful than usual care supplemented by a book on back pain care in reducing disability at 6 months but not pain intensity (Von Korff et al 1998). The other found that a brief cognitive-behavioural group programme led by a psychologist and encouraging self-care reduced disability at 3 months and pain intensity at 6 months significantly more than usual care supplemented by a book on back pain care (Moore et al 2000).

There is moderate evidence that brief interventions encouraging self-care are more effective than usual care in reducing disability (up to 6 months) but not pain (level B).

Effectiveness of minimal contact (internet-based) interventions vs no intervention or waiting list control
Two trials evaluated internet-based brief interventions (Buhrman et al 2004, Lorig et al 2002). One examined the use of a closed, moderated, e-mail discussion group in people with chronic back pain having at least 1 outpatient visit in the past year, no "red-flag" symptoms, and access to e-mail (Lorig et al 2002). Participants also received a book and videotape about back pain. Controls received a subscription to a non-health-related magazine of their choice. It showed statistically significant improvements in pain, disability, role function, and health distress at one year after treatment. It also found a tendency towards a decline in physician visits. The other study evaluated a 6-week long internet-based cognitive-behavioural intervention with telephone support for patients with chronic back pain (Buhrman et al 2004). Improvements in control over pain, and coping strategies were found immediately after the intervention, but pain measures (pain diary reports and the MPI) did not improve with the intervention.

There is limited evidence that Internet-based discussion groups/educational interventions are more effective than no intervention, in reducing disability (level C).

There is conflicting evidence that Internet-based discussion groups/educational interventions are more effective than no intervention, in reducing pain (level C).

Effectiveness of minimal contact/brief educational interventions vs physiotherapy or exercise therapy

Two high quality trials were identified (Frost et al 2004, Storheim et al 2003) that compared a brief educational intervention with routine physiotherapy and with exercise, respectively.

One trial measured the effectiveness of routine physiotherapy compared with an assessment session and advice from a physiotherapist for patients with low back pain of more than six weeks' duration (N=286) (Frost et al 2004). There was no significant difference in disability at 12 months and the authors concluded that routine physiotherapy seemed to be no more effective than one session of assessment and advice from a physiotherapist. Another study compared a brief cognitive intervention with aerobic exercise of 45 sessions (Storheim et al 2003) and reported no significant differences between the treatments with regard to either disability or prospectively measured pain (although, retrospectively, the exercise group reported a greater pain reduction and were more satisfied with their care).

There is strong evidence that brief interventions provided by a physiotherapist, or a physician and physiotherapist, and encouraging a return to normal activities, are as effective in reducing disability as routine physiotherapy or aerobic exercise (level A)

Effectiveness of minimal contact/brief educational interventions versus other treatments

One high quality study (Cherkin et al 2001) compared the effectiveness of acupuncture, therapeutic massage, and self-care education for persistent back pain (N=262). Self-care intervention consisted of a book and 2 video-tapes (one on self-management and the other demonstrating exercises). After 1 year, self-care was no different from massage or acupuncture, in terms of pain and disability.

There is limited evidence that brief self-care interventions are as effective as massage or acupuncture in terms of reducing pain and disability (level C).

Cost-effectiveness

No full cost-effectiveness analyses alongside the trials were found. One high quality trial (Karjalainen et al 2004, Karjalainen et al 2003) reported lower costs from low back pain in the mini intervention group (A) compared with a mini intervention plus a work site visit (B) or usual care (C): A=4670 Euros, B=5990 Euros, C = 9510 Euros. (A vs. C, P = 0.04; and B vs. C, not significant). The average number of days on sick leave was 30 in A, 45 in B, and 62 in C (A vs. C, P = 0.03; B vs. C, not significant). The authors concluded that, despite a lack of significant effect on pain intensity and perceived disability, mini-intervention including proper recommendations and advice according to the "active approach" was able to reduce LBP-related costs.

Safety

Unknown (no studies were found on this issue)

Subjects (indications)

In particular, sick-listed people with a high perceived risk of not recovering may benefit from appropriate advice and information in a brief educational intervention provided by a physician and physiotherapist. It should be noted that many of the studies have been carried out with patients who were more at the subacute end of the subacute-chronic spectrum (especially the Scandinavian ones that provided moderate evidence that brief educational interventions addressing concerns and encouraging a return to normal activities are better than usual care in increasing return to work rates).

Comments

1. It is difficult to define how intense or how extensive a brief intervention should be. It may be that a stepped approach as recommended by Von Korff (2001), where patients are initially offered a minimal intervention to address their worries and concerns, is all that is needed for the majority, while more intensive interventions may be required for those with on-going activity limitations.

2. The brief/minimal interventions varied considerably in how they were applied, for example whether they were face-to-face or not (e.g. internet or a booklet). They also varied in content and delivery. One common factor appeared to be the focus on return to normal activities and work. More research is needed to investigate which approach is most effective for any particular group of patients.

3. "Return to work" is only relevant for populations who are all in paid employment but off sick on entry to the trial, as in four of the Scandinavian studies cited above. "Sickness absence" is a broader term, but is difficult to measure in mixed populations that include people who are not in paid employment. It is important to measure sickness absence wherever it is relevant.

4. Internet interventions, used as "minimal contact/brief educational interventions", are unlikely to reach all back pain populations e.g. older people, deprived people.

5. Individual beliefs and communication skills of the care provider, as related to active management, are likely to influence the credibility and the effectiveness of the delivery.

6. The option of brief or minimal contact interventions should be made more widely and explicitly available to patients, helping them to avoid more intensive and perhaps unnecessary treatments.

7. The use of brief or minimal contact interventions for chronic back pain appears to be a promising area for further research, particularly as this approach could result in significant cost-savings if it proves to be as effective as more intensive treatment.

Evidence Summary

*   There is moderate evidence that brief interventions addressing concerns and encouraging a return to normal activities are better than usual care in increasing return to work rates (level B).

*   There is moderate evidence that brief interventions encouraging self-care are more effective than usual care in reducing disability (up to 6 months) but not pain (level B).

*   There is limited evidence that Internet-based discussion groups/educational interventions are more effective than no intervention in reducing disability (level C).

*   There is conflicting evidence that Internet-based discussion groups/educational interventions are more effective than no intervention in reducing pain (level C).

*   There is strong evidence that brief interventions provided by a physiotherapist, or a physician and physiotherapist, and encouraging a return to normal activities, are as effective in reducing disability as routine physiotherapy or aerobic exercise (level A)

*   There is limited evidence that brief self-care interventions are as effective as massage or acupuncture in terms of reducing pain and disability (level C).

Recommendations
We recommend brief educational interventions, which can be provided by a physiotherapist or a physiotherapist and physician, and which encourage a return to normal activities, to reduce sickness absence and disability associated with CLBP.

We do not give recommendations on the specific type of brief educational intervention to be undertaken (face-to-face, Internet-based, one-to-one, group education, discussion groups, etc.). The latter may be best determined by the available resources and the preferences of both the patient and therapist.
The emphasis should be on the provision of reassurance and positive messages that encourage a return to normal activities.

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Chapter 8: Cognitive-behavioural treatment methods

Definition of procedure
Cognitive and behavioural methods involve procedures where changes in the cognitions and behaviours are the main aspect of the treatment offered. Psychological components may be involved in back school programmes and multidisciplinary treatment programmes, but these are dealt with in their own separate chapters.
Cognitive and behavioural interventions are commonly used in the treatment of chronic (disabling) low back pain. The main assumption of a behavioural approach is that pain and pain disability are not only influenced by somatic pathology, if found, but also by psychological and social factors (e.g., patient's attitudes and beliefs, psychological distress, and illness behaviour) (Waddell 1987).
Consequently, the treatment of chronic low back pain is not primarily focused on removing an underlying organic pathology, but at the reduction of disability through the modification of environmental contingencies and cognitive processes. In general, three behavioural treatment approaches can be distinguished: operant, cognitive and respondent (Turk and Flor 1984) (Vlaeyen et al 1995). Each of these focuses on the modification of one of the three response systems that characterize emotional experiences, that is behaviour, cognitions, and physiological reactivity.
Operant treatments are based on the operant conditioning principles of Skinner (Skinner 1953) and applied to pain by Fordyce (Fordyce 1976) and include positive reinforcement of healthy behaviours and consequent withdrawal of attention towards pain behaviours, time-contingent instead of pain-contingent pain management, and spouse involvement. The graded activity programme is one example of operant treatment for chronic low back pain (Lindstrom et al 1992a).
Cognitive treatment aims to identify and modify patients' cognitions regarding their pain and disability. Cognitions (the meaning of pain, expectations regarding control over pain) can be modified directly by cognitive restructuring techniques (such as imagery and attention diversion), or indirectly by the modification of maladaptive thoughts, feelings and beliefs (Turner and Jensen 1993).
Respondent treatment aims to modify the physiological response system directly, e.g., by reduction of muscular tension. Respondent treatment includes providing the patient with a model of the relationship between tension and pain, and teaching the patient to replace muscular tension by a tension-incompatible reaction, such as the relaxation response. Electromyographic (EMG) biofeedback, progressive relaxation and applied relaxation are frequently used (Turk and Flor 1984) (Vlaeyen et al 1995).
A large variety of behavioural treatment modalities are used for chronic low back pain, because there is no general consensus about the definition of operant and cognitive methods. Furthermore, behavioural treatment often consists of a combination of these modalities or is applied in combination with other therapies (such as medication or exercises). Although they may vary in aims and methods, cognitive and behavioural treatments have in common 1) the assumption that the individual's feelings and behaviours are influenced by his/her thoughts; 2) the use of structured techniques to help patients identify, monitor and change maladaptive thoughts, feelings and behaviours; 3) an emphasis on teaching skills that patients can apply to a variety of problems (Turner 1996).

Results of search
Systematic reviews
One systematic Cochrane review (search date 1999; 20 RCTs) was identified (van Tulder et al 2000, van Tulder et al 2004).

Additional studies
Four subsequent RCTs were identified (Brox et al 2003, Spinhoven et al 2004, Staal et al 2004, van den Hout et al 2003). One of these randomised patients with evidence of disc degeneration at L4-5 and/or L5-S1 to either lumbar fusion or a cognitive intervention with exercises. Another randomised airline workers sick-listed with back pain to a behavioural graded activity group or usual care (Staal et al 2004). The trial dealt with an exercise programme (and is accordingly dealt with in the section on Exercise Therapy) but it used behavioural therapeutic principles which aimed at helping sick-listed workers to unlearn pain behaviours through graded activity/exercise, i.e. operant-conditioning principles, and the study was therefore also included in this chapter. A further study (Spinhoven et al 2004) concerned a reanalysis of a previous RCT (Kole-Snijders et al 1999) included in the Cochrane review (van Tulder et al 2000, van Tulder et al 2004). In another, although the study was presented as describing a secondary preventive intervention, 67% of the study population were suffering from chronic LBP and 28% from subacute LBP at the time of investigation, and so the trial was still included (van den Hout et al 2003).

Quality Assessment
The Cochrane review (van Tulder et al 2000, van Tulder et al 2004) and additional trials (Brox et al 2003, Spinhoven et al 2004, Staal et al 2004, van den Hout et al 2003) were all considered high quality.

Effectiveness
Effectiveness of cognitive-behavioural treatment vs placebo, no treatment, or waiting list control
The review, which statistically pooled the data from 2 high quality RCTs (Nouwen 1983, Turner and Clancy 1988) and 5 low quality RCTs (Newton-John et al 1995, Stuckey et al 1986, Turner 1982, Turner et al 1990, Turner and Jensen 1993) (N=419 patients altogether) found that behavioural therapy significantly reduced pain intensity compared with no treatment, placebo, or waiting list control (pain: pooled effect size was 0.62, 95% CI 0.25 to 0.98; behavioural outcomes: pooled effect size was 0.40, 95% CI 0.10 to 0.70) (van Tulder et al 2000, van Tulder et al 2004)). It found that behavioural therapy did not significantly increase function (pooled effect size was 0.35, 95% CI -0.04 to +0.74).

There is strong evidence that behavioural treatment is more effective for pain, functional status and behavioural outcomes than placebo/no treatment/waiting list control (level A).

Effectiveness of cognitive-behavioural treatment vs traditional care
One high quality RCT (Lindstrom et al 1992b) identified by the review (van Tulder et al 2000, van Tulder et al 2004) showed that behavioural therapy statistically significantly increased the proportion of people who had returned to work after 12 weeks compared with traditional care (rest, analgesics, or unspecific physical treatment modalities). An additional high quality trial (Staal 2003, Staal et al 2004) showed that behavioural treatment statistically significantly increased return to work rates as compared with usual care (guidance and advice from the occupational physician and GP care), but had no effect on pain or function.

There is strong evidence that a graded activity programme using a behavioural approach is more effective than traditional care for returning patients to work (level A).

Effectiveness of cognitive-behavioural treatment vs other treatments
One low quality trial (Turner et al 1990) found no difference between behavioural therapy and exercise therapy in relation to pain or depression after 6 or 12 months.

There is limited evidence that there is no difference between the effects of behavioural therapy and exercise therapy in terms of pain, functional status or depression up to 1 yr after treatment (level C).

Effectiveness of cognitive-behavioural treatment vs fusion surgery
One additional, high-quality trial of patients with chronic low back pain and evidence of severe disc degeneration at L4-5 and/or L5-S1, randomized to either lumbar fusion or a cognitive intervention with exercises, found that there was no significant difference between the groups in relation to their improvement in the primary outcome measure, disability (Oswestry), at the 1-year follow-up (Brox et al 2003).

There is limited evidence that in patients with chronic LBP and lower lumbar disc degeneration there is no difference between the effects of cognitive-behavioural therapy and spinal fusion in terms of disability 1 yr after treatment (level C).

Effectiveness of cognitive-behavioural treatment as an adjunct to other treatments
The review identified six low quality RCTs (Altmaier et al 1992, Basler et al 1997, Nicholas et al 1991, 1992, Strong 1998, Turner et al 1990) that had compared behavioural therapy plus other treatments to those treatments alone (physiotherapy and back education, inpatient pain management programmes, and back exercises); there was moderate evidence that the addition of cognitive behavioural treatment to another treatment has neither short nor long-term effects on functional status and behavioural outcomes (level B).

There is moderate evidence that the addition of cognitive behavioural treatment to another treatment has neither short nor long term effects on functional status and behavioural outcomes (level B).

Effectiveness of different types of behavioural therapy vs each other
The review identified 7 RCTs (N=308) that together indicated no statistically significant difference between different types of behavioural therapy in functional status or pain (van Tulder et al 2000, van Tulder et al 2004). Two were high quality trials (Kole-Snijders et al 1999, Turner and Clancy 1988) and five were low quality trials (Nicholas et al 1991) (Bru et al 1994) (Turner 1982) (Turner and Jensen 1993) (Newton-John et al 1995).

A reanalysis of the data of a high quality RCT (Kole-Snijders et al 1999)(included in the Cochrane review) found no statistically significant difference between operant behavioural treatment associated either with cognitive coping skills training or group discussion in changes in pain beliefs (Spinhoven et al 2004). Catastrophising decreased and perceived control over pain increased at one year in both groups. However, the exact nature of the contribution of the treatment to these changes remained unclear. The subsequent RCT (84 people recently on sick leave with low back pain) compared problem-solving therapy versus group education (van den Hout et al 2003). All participants also received behavioural graded activity. The RCT found that problem-solving therapy significantly reduced total sick leave compared with group education between 6 months and 1 year after treatment (8.3 days at baseline to 18.5 days with problem solving vs 10.4 days at baseline to 37.9 days with group education, P < 0.05) (van den Hout et al 2003). However, at baseline, people in the problem-solving group had had fewer days sick leave and more had returned to work than people allocated to group education. The results of the RCT may, therefore, be confounded by these factors, and not due to differences in relative effectiveness of the treatments. The RCT found no significant difference between problem-solving therapy and group education in return-to-work rates at one year (return to normal work: 8.9% at baseline to 75% at 6 months and 85.4% at 12

months with problem solving vs 20.5% at baseline to 70.3% at 6 months and 62.9% at 12 months with group education (p-value not presented).

There is strong evidence that there is no difference in effectiveness between the various types of behavioural therapy (level A).

Cost-effectiveness
One study conducted a full economic evaluation of a behavioural treatment (Goossens et al 1998). The population consisted of patients with chronic pain including chronic low back pain. The study showed that adding a cognitive component to an operant treatment did not lead to significant differences in costs and improvement in quality of life when compared with the operant treatment alone. Economic endpoints were the costs of the programme and other health care utilisation, costs for the patient, and indirect costs associated with production losses due to low back pain. Compared with the common individual rehabilitation therapy the same effects could be reached at the same or lower costs with a short and intense standardised group programme (Goossens et al 1998).

Safety
Unknown (no studies found on this issue)

Subjects
In most trials included in the review, patients with severe, long-lasting chronic non-specific low back pain were recruited. Patients were usually not selected through screening for psychosocial factors.

Comments
1. One recent RCT examined the effectiveness of cognitive/behavioural treatment in chronic LBP patients who had persisting symptoms 6 weeks after disc surgery (Ostelo et al 2003). The study found no differences between the behavioural treatment and usual care (mixed physiotherapy techniques) at 1 year, for any of the clinical outcome measures (functional status or pain) (Ostelo et al 2003).

2. There is a problem with attempting to use a meaningful "sham" or "blind" control group in the RCTs, as this can provide a variably powerful placebo effect. This is especially problematic in evaluating psychological treatments. The procedures offered to the controls should also be monitored for "nocebo" effects, which may give false positive effects.

3. The results of the Cochrane review of behavioural treatment for chronic low back pain are similar to another systematic review of behavioural treatment for chronic pain, excluding headache, which showed that behavioural treatments are more effective than waiting list controls (Morley et al 1999). However, in contrast to the latter review, the Cochrane review did not find any differences when comparing behavioural treatment to alternative active treatments.

4. Most studies included in the Cochrane review and in the additional trials evaluated a cognitive-behavioural treatment consisting of various components that were applied in many different ways. At present, we know little about the actual or comparative value of different methods within cognitive-behavioural treatment. It is still unclear which type of behavioural treatment is the most effective. Similarly, subgroups of patients need to be better defined in order to address specific components of pain persistence such as excessive pain-related fear, increased muscle tone or environmental contingencies. This seems especially relevant now that the biopsychosocial model has been widely accepted and multimodal or multidimensional treatment programs (that may include cognitive-behavioural

treatment programs) are becoming more and more popular in the treatment of chronic (back) pain patients.

5. Health care providers' attitudes and beliefs about activity, including return to work, seem to be highly variable (Rainville et al 2000) and to influence their self-reported practice behaviours for back pain patients (Linton et al 2002). A survey of orthopaedic surgeons and family physicians indicated that their recommendations regarding the appropriate level of function for chronic low back pain may reflect personal attitudes of the physician and his/her perception of the severity of the symptoms (Rainville et al 2000). Along the same lines, a study on fear-avoidance beliefs in GPs and physiotherapists showed that those with high levels of fear-avoidance beliefs had an increased risk of believing sick leave to be a good treatment and not encouraging a return to activity, compared with those with low levels of fear-avoidance beliefs (Linton et al 2002).

6. Promising predictors of outcome of behavioural treatment have been suggested, such as treatment credibility (Kole-Snijders et al 1999), stages of change (Kerns et al 1997), patient profiles such as the multidimensional pain inventory (Turk et al 1998), the patient's own expectancy of the prognosis (Jensen et al 2000), and the patient's expectancy of the outcome of therapy (Kalauokalani et al 2001). Other important variables are the belief that the complaints would be worse with continued working or physical exercise, lack of personal control over the pain, catastrophising interpretations of pain, and whether or not the patient believes him or herself to be able to do something him or herself (Haldorsen et al 1998, Spinhoven et al 2004, Vlaeyen and Linton 2000); these may lead to fear of movement and fear-avoidance behaviours and thus, in turn, to inactivity, reduced mobility, increased disability, anger, anxiety and depression (Vlaeyen and Linton 2000). More research is still needed on possible underlying mechanisms to define subgroups of patients who may benefit most from behavioural treatments.

Summary Evidence
- There is strong evidence that behavioural treatment is more effective for pain, functional status and behavioural outcomes than placebo/no treatment/waiting list control (level A).
- There is strong evidence that a graded activity programme using a behavioural approach is more effective than traditional care for returning patients to work (level A).
- There is limited evidence that there is no difference between behavioural therapy and exercise therapy in terms of their effects on pain, functional status or depression up to 1 yr after treatment (level C).
- There is limited evidence that in patients with chronic LBP and lower lumbar disc degeneration there is no difference between the effects of cognitive-behavioural therapy and spinal fusion in terms of disability 1 yr after treatment (level C).
- There is moderate evidence that the addition of cognitive behavioural treatment to another treatment has neither short nor long term effects on functional status and behavioural outcomes (level B).
- There is strong evidence that there is no difference in effectiveness between the various types of behavioural therapy (level A).

Recommendations
We recommend cognitive-behavioural treatment for patients with chronic low back pain.

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Chapter 9: Multidisciplinary interventions

Definition of the procedure
Multidisciplinary treatment programs for chronic low back pain were originally based on a model of operant conditioning (Fordyce et al 1973). Because chronic LBP is believed to be associated with physical deconditioning effects, an exercise component is always included. Because many patients with chronic LBP have problems at the work-place and are relatively young (mean age in the most studies 42 years), there has been a strong belief in so-called work hardening or conditioning exercises, and these are included in the treatment in most trials.

The content of multidisciplinary treatment programmes usually consists of an extensive combination of physical, vocational, and behavioural components, and the modification of medication use. Commonly, such programmes are carried out for a considerable number of hours per week, sometimes even on an inpatient basis. The content of these programmes and the way they are labelled or described varies widely. For example, multidisciplinary biopsychosocial rehabilitation, rehabilitation programmes, behavioural programmes, back schools, or functional restoration (FR) programmes may all involve one or more of these components. True multidisciplinary treatment programs have to include medical (pharmacological treatment, education), physical (exercise), vocational and behavioural components and have to be provided at least by three health care professionals with different clinical backgrounds (physician, physiotherapist, psychologist).

Result of search
Systematic reviews
Five reviews of multidisciplinary treatment were retrieved through the search (Di Fabio 1995, Guzman et al 2001, Scheer et al 1997, Staal et al 2002, Teasell and Harth 1996), and an additional review was identified from the working group's knowledge of the literature (Schonstein et al 2003). The latter SR determined the effect on time lost from work of physical conditioning programs for workers with back and neck pain (see comments).

Four of these SRs were excluded because they concentrated on back schools (Di Fabio 1995) or return to work interventions (Staal et al 2002); included all interventions for industrial LBP without presenting results for multidisciplinary treatment separately (Scheer et al 1997); or were not systematic reviews (Teasell and Harth 1996).

The remaining two systematic reviews (both Cochrane reviews) were considered further (Guzman et al 2001, Schonstein et al 2003). These included 10 randomized, controlled trials (Alaranta et al 1994, Basler et al 1997, Bendix et al 1995, Bendix et al 1996, Harkapaa et al 1990, Jackel et al 1990, Lukinmaa 1989, Mitchell and Carmen 1994, Nicholas et al 1991, 1992).

Additional RCTs
13 papers described 11 further randomized trials (Altmaier et al 1992, Bendix et al 1998a, Bendix et al 1998b, Bendix et al 1997, Bendix et al 2000, Corey et al 1996, Haldorsen et al 2002, Haldorsen et al 1998, Jousset et al 2004, Keel et al 1998, Keller et al 1997, Rose et al 1997, Turner et al 1990).

One additional paper provided a health economic assessment of multidisciplinary treatment (Skouen et al 2002).

Quality assessment of the evidence
Systematic reviews

The two Cochrane reviews (Guzman et al 2001, Schonstein et al 2003) were of high quality.

Additional studies
Among the additional RCTs, six were of high quality (Altmaier et al 1992, Bendix et al 1998a, Bendix et al 1998b, Haldorsen et al 2002, Haldorsen et al 1998, Jousset et al 2004), and six were of low quality (Bendix et al 2000, Corey et al 1996, Keel et al 1998, Keller et al 1997, Rose et al 1997, Turner et al 1990).
One low quality trial (Turner et al 1990) was excluded because the treatment was not really multidisciplinary (was provided by just one healthcare professional).

Effectiveness
Effectiveness of multidisciplinary treatment versus sham procedures
No studies were found on this issue.

Effectiveness of multidisciplinary treatment programmes versus other treatments (e.g. standard rehabilitation programs, intense vs. less intense programs, vs outpatient physical programs, vs usual care)

One Cochrane systematic review (Guzman et al 2001) included ten trials evaluating 12 randomised comparisons (Alaranta et al 1994, Basler et al 1997, Bendix et al 1995, Bendix et al 1996, Harkapaa et al 1990, Jackel et al 1990, Lukinmaa 1989, Mitchell and Carmen 1994, Nicholas et al 1991,1992). Together, they randomised a total of 1964 patients with chronic low back pain.

The conclusions from the review were:
- There is strong evidence that intensive multidisciplinary biopsychosocial rehabilitation with functional restoration reduces pain and improves function in patients with chronic low back pain (level A).
- There is moderate evidence that intensive multidisciplinary bio-psycho-social rehabilitation with a functional restoration approach improves pain when compared with outpatient non-multidisciplinary rehabilitation or usual care (level B).
- There is contradictory evidence regarding vocational outcomes of intensive multidisciplinary bio-psycho-social intervention (level C).

Additional studies
Effectiveness of multidisciplinary treatment programmes vs controls
One study compared a multidisciplinary rehabilitation program (n=36) in an outpatient setting (2 hours treatment, three times a week for 6 weeks) with a control group of patients on a waiting list (these served as controls only for the immediate post-treatment effects) (Keller et al 1997). Although no psychologists were directly involved in the treatment, both the physicians and physiotherapists had received training in pain management by an experienced psychologist and were closely supervised by clinical psychologists to ensure a strict application of operant techniques for the modification of the patient's behaviour. At the end of the program pain frequency, pain intensity and disability caused by pain (scale of functional capacity) improved significantly in the treatment group only. Up to 6 months after treatment, patients in the treatment group continued to show beneficial effects in terms of pain intensity, pain frequency, posture, self-efficacy, well-being, strength and endurance, compared with their pre-treatment status.

Effectiveness of multidisciplinary treatment programmes versus less intensive programmes
Two trials were carried out by one research group (Bendix et al 1998a, Bendix et al 1998b, Bendix et al 1997). In the first trial, 132 patients were randomized to three

treatment programs: a) intensive 3-week multidisciplinary program ("functional restoration"; FR) 8 hours a day (n= 40), b) active physical training and back school twice a week for 6 weeks (n=28), c) psychological pain management and active physical training twice a week for 6 weeks (n= 34). The results were presented for the one-year follow up (Bendix et al 1997), 2-year follow up (Bendix et al 1998b), and five-year follow up (Bendix et al 1998a). At all follow up times the functional restoration program was superior to the other programs except in relation to the variables leg pain and medication use. After five years the superior effect of the FR program was less marked but still evident in some regards (more patients were working). In the second trial, a FR program (n=50) was compared with treatment as usual (n=49) (Bendix et al 1998a, Bendix et al 1998b): the patients in the FR group had significantly fewer sick leave days and health care contacts and more of them went back to work, but all other parameters (pain, function (activities of daily living scale), work ability) were not different between the groups.

In one additional low quality trial from the same research group (Bendix et al 2000), patients where treated with either FR (whole day for 3 weeks) (N=64) or intensive outpatient physical treatment of a lesser intensity than the FR program (1.5 hour sessions three times a week for 8 weeks) (N=74). At the one-year follow-up evaluation, overall global assessment but not working capability, sick leave (for those at work), healthcare contacts, pain, or self-reported activities of daily living were significantly better in the FR group. Another high additional study combined the effects of functional restoration versus 3 hours per week physical therapy: a randomized controlled study (Jousset et al 2004). It found that the mean number of sick-leave days was significantly lower in the functional restoration group. Physical criteria and satisfaction with the treatment were also better, but there was no significant difference in the intensity of pain, the quality of life and functional indexes, the number of contacts with the medical system or the medication intake.

In one trial, a FR program (6.5 hours a day for a maximum of 35 days) was compared with usual care (Corey et al 1996). 100 patients were treated in each group, but only half of them were back patients. Nonetheless, the results for the back patients and non-back patients were given separately. 18 months after treatment, the FR patients reported less pain and more improved sleep, and more of them were back to work compared with the control group. However, the follow-up included only in 74 patients with treatment and 64 controls.

One research group conducted two trials, one with 469 patients sick listed with treatment group (n=312) and a control group (normal GP care with no further advice) musculoskeletal pain divided into multimodal (n=312) and a control group (normal GP care with no further advice) (n=158) (Haldorsen et al 1998). The multimodal program lasted for 4 weeks. At one year, the treatment group had not returned to work at a higher rate but had an improved work potential, quality of life, and physical and psychological health. In this study, only 40-50% of the patients had LBP (the rest were shoulder/neck problems); however, the authors maintained that the location of the pain did not influence the overall results.

A further study compared an experimental inpatient group undergoing FR (n=243) in different Swiss rehabilitation clinics with inpatients who were treated as usual in the clinics (n= 168) (Keel et al 1998). There was a high drop out rate of 31.1%. The FR approach showed slightly but significantly better (p<o.o5) long-term results (impairment at work, hours worked a day, spatial distribution of pain, quality of life) than the traditional group.

Together these studies strengthen the evidence for the Cochrane review for the greater effectiveness of intensive multidisciplinary treatments compared with less

intensive treatments, especially in relation to return to work or work capacity (level A).

Effectiveness of group vs individual multidisciplinary treatment programmes
One study examined the differences in outcome between group programs (N=26) and individual treatment (n= 24) (Rose et al 1997). The second part of the study (with other patients n= 60) was concerned with identifying the optimum duration of treatment. The follow-up was 6 months. The study showed no differences between group or individual treatment and between 15-, 30-, or 60-hour programs.

Effectiveness of intensive physical conditioning ("work hardening") programs for workers with back and neck pain
A Cochrane systematic review evaluated the effectiveness of physical conditioning programs for workers with back and neck pain in reducing time lost from work (Schonstein et al 2003).
These programs aim to facilitate return to work, improve the status of workers performing modified duties, or enable the achievement of a higher level of function by increasing strength, endurance, flexibility, and cardiovascular fitness. Such programs simulate work or functional tasks in a supervised environment and may include workplace visits and ergonomic adaptations of the workplace. Sometimes the exercise part of simulated work is called "work hardening". So-called work hardening or work conditioning is also used for decreasing fear-avoidance behaviour (Vlaeyen and Linton 2000). A total of 21 published articles on 19 trials were included in the review. The authors stated that, unlike earlier reviews, they were able to perform a meta-analysis because they had obtained additional information and data from the authors of the original trials. Trials on treatment of subacute LBP were also included. The authors concluded that physical conditioning programs for chronic back pain patients can be effective in reducing the number of sick days lost due to back pain when compared with usual care. A closer analysis of the trials that showed positive results revealed that all had significant cognitive-behavioural components (such as teaching the patients that it was safe to move) combined with intensive physical training that included training of aerobic capacity, muscle strength and endurance, and coordination. All the trials with positive results included vocational interventions. All subjects included in trials that showed a treatment effect were either off work or on modified duties, with an explicit capacity to return to their previous jobs.

There is strong evidence that "work hardening" programs with a cognitive-behavioural component are more effective than usual care in reducing work absenteeism in workers with back pain (level A).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
All ten trials included in the Cochrane review (Guzman et al 2001), and also the additional studies described above, excluded patients with significant radiculopathy or other indications for surgery. In the Cochrane review, most subjects were workers selected from insurance listings (Alaranta et al 1994, Harkapaa et al 1989, Mitchell and Carmen 1994) or patients referred to pain centres (Basler et al 1997, Bendix et al 1995, Bendix et al 1996, Jackel et al 1990, Lukinmaa 1989, Nicholas et al 1991, 1992).

Multidisciplinary biopsychosocial rehabilitation or functional restoration (FR) is indicated if the ergonomic behaviour, work potential, quality of life, and physical and psychological health of a patient with chronic non-specific mechanical low back pain are substantially disturbed. Because of the high costs of treatment, a screening instrument addressing the prognosis of the individual patient (see (Haldorsen et al 2002)) is necessary to avoid under or over treatment. Treatment should be early in the course of disability.

Comments
1) In all studies, the treatment, patient characteristics, treatment modalities and treatment intensity varied substantially. It is at present unclear what the optimal content of multidisciplinary treatment programmes is and which health care professionals should be involved. More research is needed.

2) From a health care policy point of view it is not clear whether the benefits of these programmes outweigh their costs - these intensive programmes might result in a large drain on health care resources. However, assigning monetary values to quality of life issues such as pain and function, in order to complete cost-benefit analyses, is contentious and challenging. A crucial element in cost-benefit analyses concerns the savings in wage replacement costs achieved by treatment.

3) One study investigated 654 patients sick listed for at least 8 weeks with musculoskeletal pain (45% back pain, 34% neck/shoulder pain, 11% generalized muscle pain and 10% other musculoskeletal pain) (Haldorsen et al 2002). The patients were categorized into three groups differing in their prognosis score for return to work (good, medium, poor). They were then randomly assigned to three outpatients treatment programs (ordinary treatment, light multidisciplinary and intensive multidisciplinary). Patients in the different prognosis groups (see above) were equally randomized into the different treatment groups. Follow up was 14 months. The patients with a good prognosis for return to work did just as well with ordinary treatment as with the two more intensive treatments. The patients with a medium prognosis benefited equally from the two multidisciplinary programs, and the patients with a poor prognosis returned to work at a significantly higher rate (p<o.o5) after the intensive multidisciplinary program than did patients who received ordinary treatment or light multidisciplinary treatment.
The authors concluded that multidisciplinary treatment is effective concerning return to work, when given to patients who are most likely to benefit from that treatment.

4) The data from the study described above (Haldorsen et al 2002) were used to examine the cost-benefit ratio of multidisciplinary programs (Skouen et al 2002). However, as none of the three programmes had any effect on return to work for women, only men were examined in the analysis. Benefit was judged by return to work, in the 3 groups examined (control-treatment as usual, n=86; light multidisciplinary treatment, n=52; and extensive multidisciplinary treatment, n=57). The authors concluded that, for male patients, multidisciplinary treatment, especially the light program, could save a substantial amount of money. After subtracting costs,

the net productivity gains for society from light multidisciplinary treatment were about U.S. $ 852.000 for 57 male patients during the first 2 years.

5) There is a need for further trials to examine whether the effects of job status, in terms of the availability of the previous job or modified duties for workers with back pain, is also to be considered when reporting return-to-work outcomes. Further studies are also recommended to investigate whether men and women respond differently in relation to vocational outcomes.

6) Differences between studies in the effects concerning vocational outcomes most likely depend to a large extent on the healthcare and economic systems of the different countries.

Summary of evidence
- There is strong evidence that intensive multidisciplinary biopsychosocial rehabilitation with a functional restoration approach reduces pain and improves function in patients with chronic low back pain (level A).

- There is moderate evidence that intensive multidisciplinary biopsychosocial rehabilitation with a functional restoration approach is more effective than outpatient non-multidisciplinary rehabilitation or usual care with respect to pain (level B).

- There is strong evidence that intensive multidisciplinary biopsychosocial interventions are effective in terms of return to work, work-readiness (level A).

- There is strong evidence that intensive physical training ("work hardening") programs with a cognitive-behavioural component are more effective than usual care in reducing work absenteeism in workers with back pain (level A).

Recommendation
We recommend multidisciplinary biopsychosocial rehabilitation with functional restoration for patients with chronic low back pain who have failed monodisciplinary treatment options.

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Chapter 10   Pharmacological procedures

The treatment most commonly prescribed for back pain is medication; particularly nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and narcotic analgesics. In one longitudinal study of primary care patients with low back pain, 69% were prescribed nonsteroidal anti-inflammatory drugs, 35% muscle relaxants, 12% narcotics, and 4% acetaminophen; 20% received no medications (Cherkin et al 1998). Patients with more severe symptoms were more likely to receive narcotics or muscle relaxants. Patients with greater dysfunction were also more likely to receive narcotics. The efficacy of drug treatment for chronic back pain is less clear, partly because of the complexity of the mechanisms causing chronic pain and the greater role of social, psychological, and economic factors.

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C10 (A) Antidepressants

Definition of the procedure
Antidepressants have often been used as adjuncts in the treatment of chronic low back pain and other chronic pain syndromes with an effect distinct from their antidepressants properties. The most commonly studied have been the tricyclic antidepressants (noradrenergic and serotonin-noradrenergic antidepressants). The rationale for the use of these drugs is that they block the reuptake of neurotransmitters (e.g. norepineprhrine and serotonin) and so modulate pain sensations, although the antinociceptive actions are not completely understood. Selective serotonin reuptake inhibitors (SSRI), e.g. fluoxetine, paroxetine, citalopram, trazodone, have been available since 1988. As antidepressives they have a favourable side-effect profile compared with the traditional tricyclic antidepressants (Ansari 2000). Their analgesic properties are unclear and controversial.

Results of search
Systematic reviews
3 systematic reviews were found (Ansari 2000, Fishbain 2000, Salerno et al 2002). One of these (Ansari 2000) was excluded because it had only one study on low back pain (Goodkin et al 1990), which was already included in two other reviews.
The remaining two reviews included a total of 14 RCTs.

Additional studies
One additional systematic review (Staiger et al 2003) was identified.
One additional RCT was retrieved, but was excluded because it dealt with patients with chronic musculoskeletal pain in general, including both whiplash injuries and LBP (Schreiber et al 2001).

Quality assessment of the evidence
Systematic reviews
The three included reviews were of high quality (Fishbain 2000, Salerno et al 2002, Staiger et al 2003).

Randomised controlled trials included in the reviews
5 RCTs included in the reviews were of high quality (Alcoff et al 1982, Atkinson et al 1999, Atkinson et al 1998, Dickens et al 2000, Goodkin et al 1990) and the rest of low quality (Gardela 1991, Hameroff et al 1982, Hameroff et al 1984, Jenkins et al 1976, Pheasant et al 1983, Storch and Steck 1982, Treves et al 1991, Ward et al 1984, Ward 1986). Three studies dealt with selective serotonin reuptake inhibitors (Atkinson et al 1999, Dickens et al 2000, Goodkin et al 1990) and the others dealt with noradrenergic and serotonin-noradrenergic reuptake inhibitors. Five of these studies were excluded from further consideration, for the following reasons:

- one dealt mainly with specific back pain (radicular pain) and included only 5-6 patients with non-specific back pain (Storch and Steck 1982)
- one treated the patients with intravenous maprotilene and only for a short time (Treves et al 1991)
- one dealt with acute LBP only (Gardela 1991)
- two dealt with both neck and back pain together (Hameroff et al 1982, Hameroff et al 1984)

Effectiveness
Effectiveness versus placebo
One high quality review (Fishbain 2000) concluded that, of the 10 trials with serotonergic-noradrenergic reuptake inhibitors, seven (70%) reported the antidepressants to have an antinociceptive effect. For the five trials with noradrenergic reuptake inhibitors, four (80%) reported an antinociceptive effect. The two trials on selective serotonin reuptake inhibitors showed that the latter were not effective.
The second review (Salerno et al 2002) concluded that patients with antidepressants were significantly more likely to improve in pain severity than those taking placebo (0.41; 95%confidence interval, 0.22-0.61) but not in activities of daily living (0.24; 95% confidence interval, -0.21-0.69).

The third high quality review (Staiger et al 2003) reported that, among studies using antidepressants that inhibit norepinephrine reuptake (tricyclic or tetracyclic antidepressants), four out of five found significant improvements in at least one relevant outcome measure. Assessment of these agents' impact on functional measures produced mixed results. No benefit in pain or functional status was found in three studies of antidepressants that do not inhibit norepinephrine reuptake.

Effectiveness versus other treatments (only vs. other antidepressants)
Two high quality systematic reviews (Salerno et al 2002, Staiger et al 2003) concluded that noradrenergic-serotonergic and noradrenergic antidepressants are more effective than selective serotonin reuptake inhibitors (which seem to have no effect).

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
20% of the patients undergoing antidepressive therapy experienced an adverse reaction (placebo 14%), mainly drowsiness, dry mouth, dizziness and constipation (Salerno et al 2002). In many trials, the reporting of side effects was insufficient, so this percentage probably underestimates the degree to which they occurred.
Patients with renal disease, glaucoma, pregnancy, chronic obstructive pulmonary disease and cardiac failure should not be treated with antidepressants.

Subjects (indications)
Patients with chronic low back pain with or without depression. The benefit appears to be independent of depression status (Staiger et al 2003).

Comments
None

Summary of evidence
- There is strong evidence that noradrenergic and noradrenergic-serotonergic antidepressants are effective in relieving pain in patients with chronic low back pain (level A).
- There is moderate evidence that activities of daily living (function, disability) are **not** improved by antidepressants (level B).

Recommendation
Consider the use of noradrenergic or noradrenergic-serotonergic antidepressants as co-medication for pain relief in patients with chronic low back pain without renal disease, glaucoma, pregnancy, chronic obstructive pulmonary disease and cardiac failure.

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C10 (B) Muscle Relaxants

Definition of procedure
The term "muscle relaxants" is very broad and includes a wide range of drugs with different indications and mechanisms of action. Muscle relaxants can be divided into two main categories: antispasmodic and antispasticity medications. Antispasmodics decrease muscle spasm associated with painful conditions such as low back pain and can be subclassified into benzodiazepines and non-benzodiazepines.
Benzodiazepines (e.g. diazepam, tetrazepam) are used as anxiolytics, sedatives, hypnotics, anticonvulsants, and/or skeletal muscle relaxants.
Non-benzodiazepines (e.g. cyclobenzaprine, tolperisone, tizanidine, flupirtin) include a variety of drugs that can act at the brain stem or spinal cord level. The mechanisms of action with the central nevous system are still not completely understood.
Antispasticity medications (e.g. dantrolene, baclofen) reduce spasticity that interferes with therapy or function, such as cerebral pulsy, multiple sclerosis, and spinal cord injuries.

Results of search:
Systematic reviews
One systematic review was identified (van Tulder et al 2003b), which was also a Cochrane review (van Tulder et al 2003a).

Additional RCTs
No additional trials were found.

Quality assessment of evidence
Systematic reviews
The systematic review (van Tulder et al 2003a, b) was of high quality and included six RCTs dealing with chronic LBP: four of these were of high quality (Arbus et al 1990, Pratzel et al 1996, Salzmann et al 1992, Worz et al 1996) and two were of low quality (Basmajian 1978, Pipino et al 1991). One low quality study dealt with acute exacerbations of chronic low back pain (Casale 1988) and so this was not considered further.

Effectiveness
Effectiveness of antispasmodics vs. placebo
a) Benzodiazepines vs. placebo Two high quality trials (N=222) showed that tetrazepam 50 mg t.i.d. is more effective than placebo for short-term pain relief and overall improvement (Arbus et al 1990, Salzmann et al 1992). The pooled relative risk (RR) and 95% CIs for pain intensity were 0.82 (0.72 to 0.94) after 5-7 days' follow-up and 0.71 (0.54 to 0.93) after 10-14 days. The pooled RRs and 95% CIs for overall improvement were 0.63 (0.42 to 0.97) after 10-14 days' follow-up.

With regards to muscle spasm, one high quality trial (N=50) showed that in the short-term tetrazepam is more effective than placebo (Arbus et al 1990). Another trial (N=76 people) showed no difference between diazepam and placebo regarding the effects on muscle spasm (Basmajian 1978).

b) Non-benzodiazepines vs. placebo
One high quality trial (N=107) showed that flupirtin is more effective than placebo for patients with chronic LBP for short-term (after 7 days) pain relief and overall improvement, but not for the reduction of muscle spasm (Worz et al 1996).

One high quality trial (N=112) showed that tolperisone is more effective than placebo for short-term (after 21 days) overall improvement, but not for pain relief or reduction of muscle spasm (Pratzel et al 1996).

One low quality trial (N=76 people) showed no difference in short-term (after 18 days) reduction of muscle spasm between cyclobenzaprine and placebo (Basmajian 1978).

Effectiveness of antispasmodics vs. other treatments
Unknown (no studies were found on this issue)

Effectiveness of antispasticity medication vs. placebo
Unknown (no trials were found on this issue)

Effectiveness of antispasticity medication vs. other treatments
Unknown (no trials were found on this issue)

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
The studies examined indicate that muscle relaxants are associated with adverse events. Central nervous system events were more prevalent in patients on muscle relaxants, with the most common complaints being drowsiness, dizziness and addiction (van Tulder et al 2003b). All these side-effects were consistently reported for many of the benzodiazepines and non-benzodiazepines reviewed, with the exception of addiction for non-benzodiazepines. However, two high quality trials showed that neither flurpirtin (Worz et al 1996) nor tolperisone (Pratzel et al 1996) were associated with a higher incidence of adverse events compared with placebo. It is known that tolperisone can have severe allergic side-effects and that flurpirtin can induce reversible reduction of liver function.
For gastrointestinal events, the difference between muscle relaxants and placebo was not significant (van Tulder et al 2003b). The most common complaint was nausea.
The adverse effects of muscle relaxants, especially those involving the central nervous system, indicate that they should be used with caution.

Subjects (indications)
The studies included both chronic low back pain patients without any further specification (Arbus et al 1990, Salzmann et al 1992, Worz et al 1996) or chronic low back pain patients with muscle spasm (Basmajian 1978, Pipino et al 1991), undergoing short-term use of muscle relaxants.

Comments
1. Muscle relaxants are prescribed to relieve the pain that supposedly arises in connection with muscle spasm. The studies examined in these guidelines indicate that, whilst muscle relaxants appear to be effective for the short-term relief of pain, they have no effect on muscle spasm. The mechanism of action for these drugs, in relieving pain, remains unclear.
2. Trials are needed to examine whether muscle relaxants are as effective as analgesics or nonsteroidal anti-inflammatory drugs in the relief of pain.

Summary of evidence
- There is strong evidence that benzodiazepines are effective for pain relief (level A) and conflicting evidence that they are effective for relieving muscle spasm (level C).
- There is conflicting evidence that non-benzodiazepines are effective for pain relief (level C) and that they are **not** effective for the relief of muscle spasm.

Recommendation
Consider the use of muscle relaxants (benzodiazepines) for short-term pain relief in chronic LBP, but use them with caution due to their side effects (drowsiness, dizziness, addiction, allergic side-effects, reversible reduction of liver function, gastrointestinal events). As they do not appear to exert their effect by reducing muscle spasm, other pain relieving drugs with fewer serious side-effects should be considered first.

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C10 (C) Non Steroidal Anti Inflammatory Drugs (NSAIDs)

Definition of procedure
Non-steroidal anti-inflammatory drugs (NSAIDs) are the most frequently prescribed medications worldwide and are widely used for patients with low back pain. The rationale for using NSAIDs in the treatment of low back pain is based on their analgesic potential and their anti-inflammatory action.

Results of search
Systematic reviews
Two systematic reviews were retrieved (van Tulder et al 1997, van Tulder et al 2004), one of which was a Cochrane review (van Tulder et al 2004). Together the reviews included 51 studies on both acute and chronic low back pain patients.

Four of the 51 studies reported exclusively on chronic low back pain (Berry et al 1982, Hickey 1982, Vetter et al 1988, Videman and Osterman 1984). One study (Postacchini et al 1988) included a mixed population of acute and chronic low back pain patients, but because some analyses pertained only to chronic low back pain, this report was considered further. The other 46 studies did not adequately specify whether patients with acute or chronic low back pain were examined.
The studies of Berry, Hickey, Postacchini, Vetter, Videman (Berry et al 1982, Hickey 1982, Postacchini et al 1988, Vetter et al 1988, Videman and Osterman 1984) were used to formulate these guidelines.

Additional trials
Five recent papers describing 4 additional RCTs on COX2 NSAIDS vs placebo were identified (Birbara et al 2003, Ju et al 2001, Katz et al 2003, Katz et al 2004, Pallay et al 2004).
In addition, one trial was found comparing Doloteffin, a proprietary extract of Harpagophytum (a phyto-antiinflammatory drug), and rofecoxib (Vioxx), a selective inhibitor of cyclo-oxygenase-2 (COX-2) in the treatment of low back pain (Chrubasik et al 2003).

Quality assessment of evidence
Systematic reviews
Both systematic reviews were of high quality. Of the 5 relevant studies from the SRs, only one was of high quality (Hickey 1982) and the others were of low quality (Berry et al 1982, Postacchini et al 1988, Vetter et al 1988, Videman and Osterman 1984).

Additional trials
The four additional RCTs on COX2 inhibitors vs placebo, described in the five papers (Birbara et al 2003, Ju et al 2001, Katz et al 2003, Katz et al 2004, Pallay et al 2004), were all high quality.
The trial comparing Doloteffin and rofecoxib (Vioxx) was of high quality, but it used a very low dose (12.5 mg) of rofecoxib, and had a relatively small sample size (N=88) (Chrubasik et al 2003).

Effectiveness
Effectiveness of NSAIDs vs. placebo
One high quality study from the systematic review compared diflunisal vs. placebo, and reported better outcomes for the NSAID group in patients with chronic low back pain (Hickey 1982).

One low quality study from the systematic review compared diflunisal vs. placebo vs. naproxen sodium (Berry et al 1982). Naproxen was superior to placebo in relieving

global pain and, depending on the method of measurement, in relieving night pain and pain on movement. Diflunisal showed no significant differences from placebo.

Three additional papers from the same group summarised the results of two 4-week trials to compare rofecoxib 25 mg (N=228), rofecoxib 50 mg (N=233) and placebo (N=229) (Ju et al 2001, Katz et al 2003, Katz et al 2004). Both rofecoxib groups showed a significantly greater reduction in pain intensity (VAS) compared with the placebo group, after one week of treatment. Disability (Roland Morris) scores also reduced significantly. Both regimens were superior to placebo in eight of nine secondary endpoints. Fifty mg provided no advantage over 25 mg, although 25 mg had a slightly better safety profile. (N.B. see **Comments** section)

In another additional RCT (N=319) it was found that, compared with placebo, etoricoxib (60 mg and 90 mg) significantly decreased pain (by 12.9 and 10.3 points respectively, on a 0-100 VAS) and improved functioning after 12 weeks (by 2.24 and 2.06 points respectively on the 0-24 Roland Morris Disability Scale) (Birbara et al 2003).

A further trial (N=325) used a similar design to that of Birbara et al (2003) to study the effects of 3 months' treatment with either etoricoxib 60 mg, etoricoxib 90 mg or placebo; the improvements in disability and pain reduction were similar to those reported by Birbara et al (2003), with no differences between the dosages (Pallay et al 2004).

Effectiveness of NSAIDs vs. other treatments
One low quality study from the systematic review aimed to assess the effectiveness of adding vitamin B to an NSAID treatment by comparing diclofenac (50 mg) with a combined therapy of diclofenac (50 mg) and vitamins B1, B6, and B12 (thiamine nitrate, pyridoxine hydrochloride, and cyanocobalamine, resp.; in dosages of 50 mg, 50 mg, and 0.25 mg, respectively) in 256 patients (Vetter et al 1988). All parameters used as a measure of pain relief indicated significantly superior results with the B-vitamin supplemented therapy when compared with results obtained with diclofenac alone.

Two low quality studies from the systematic review compared different kinds of NSAIDs. In a 3-way, double-blind, cross-over study, diflunisal (500 mg twice daily) was compared with naproxen sodium (550 mg twice daily) and each was compared with placebo (Berry et al 1982). Whilst naproxen showed significantly better results than placebo, diflunisal did not, indicating that naproxen was superior to diflunisal. In the second study, patients received either indomethacin (25 mg t.i.d.) or piroxicam (20 mg in the morning; and a placebo at lunchtime and before dinner) for six weeks (Videman and Osterman 1984). The overall results of both treatment groups (with regard to pain and improvements in the ability to do everyday tasks) were similar.

One low quality study from the systematic review examined diclofenac vs. chiropractic manipulation vs. physiotherapy vs bed rest vs back school (Postacchini et al 1988). The greatest reduction in pain was found in the NSAID group, but the difference was not statistically significant. The intervention group sample sizes were also small in this study.

One high quality study showed no differences in the pain relief afforded by Doloteffin and rofecoxib (Chrubasik et al 2003).

Cost-effectiveness

Unknown (no studies were found on this issue)

Safety
No back pain specific studies examined the side-efffects of NSAIDs.
However, gastrointestinal complications (irritation, ulcers and bleeding) are generally
known side effects of NSAIDS that may lead to hospitalization. COX2 inhibitors have
been shown to have a better GI safety profile in osteoarthritis and rheumatoid
arthritis studies (Bombardier et al 2000, Silverstein et al 2000). However, one of
these drugs (rofecoxib) increases cardiovascular risk (myocardial infarction and
stroke) with long-term use (>18 months) (Topol 2004), and the drugs are presently
being evaluated for continued registration (November 2004).
None of the other NSAIDs, including other COX2 inhibitors, have been thoroughly
examined in relation to such serious long-term risks.

Subjects (indications)
The study populations examined were usually described as having lumbar
degenerative spondylosis.

Comments
1.   In many of the studies used to formulate these recommendations, the sample
size was low (N=37 (Berry et al 1982); N=30 (Hickey 1982); N=459, but in the
subgroup with chronic LBP N=81 (Postacchini et al 1988); N= 28 (Videman and
Osterman 1984)) and the follow-up was short (2-6 weeks).
2.   No RCTs have been carried out to compare NSAIDs and acetaminophen
(paracetamol) or metamizol in patients with chronic low back pain. In patients with
knee and hip pain due to osteoarthritis, NSAIDs have proven superior to
acetaminophen for improving pain but not function (Amadio and Cummings 1983,
Towheed et al 2003). However, in the studies reviewed, the size of the treatment
effect was modest and the mean trial duration was only six weeks (Towheed et al
2003, Amadio et al. 1983). Trials are required comparing NSAIDs with other
analgesics for chronic low back pain.
3.   Three recent studies showed that COX2 inhibitors are effective in the treatment
of LBP (Birbara et al 2003, Katz et al 2003, Pallay et al 2004); however, one of these
COX2 inhibitors (rofecoxib) has since been withdrawn from the market. (see **Safety**).

Summary of evidence
Most studies have examined the effectiveness for up to 3-month periods of time.
There is strong evidence that NSAIDs are effective for the relief of chronic low back
pain (level A).

Recommendation
We recommend NSAIDs for pain relief in patients with chronic low back pain.
Because of the side-effects, NSAIDs should only be used for exacerbations or short-
term periods (up to 3 months).

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C10 (D) Opioids

Definition of procedure
Oral or transdermal drug treatment with either weak opioids (e.g. tramadol, codeine, tilidin) or strong opioids (e.g. morphine, oxycodone, hydromorphone, fentanyl, buprenorphine) in patients with chronic non-specific low back pain.

Result of search
Systematic review
No systematic reviews were found.

Additional trials
8 RCTs were found (Hale et al 1999, Jamison et al 1998, Maier et al 2002, Mullican and Lacy 2001, Palangio et al 2000, Raber et al 1999, Ruoff et al 2003, Schnitzer et al 2000).

Four of these studies were excluded for the following reasons:
- One investigated only 45.6% LBP patients, and the results for these could not be separated our from those of all patients (Palangio et al 2000).
- One compared only tramadol immediate release versus sustained release capsules without control and had no follow up (Raber et al 1999).
- One compared only sustained and immediate release oxycodone with no control (Hale et al 1999).
- One investigated both chronic LBP patients and patients with osteoarthritis (only 24% with only chronic LBP only) (Mullican and Lacy 2001).

Quality assessment of the evidence
Of the included RCTs, four were of high quality (Maier et al 2002, Ruoff et al 2003, Schnitzer et al 2000) although one had a very small sample size (Maier et al 2002) and one had short treatment and follow-up periods (Schnitzer et al 2000).
The third study was of low quality (Jamison et al 1998).

Effectiveness
Effectiveness of opioids versus placebo
One high quality study (Schnitzer et al 2000) compared Tramadol (N=127) with placebo (N=127) for treating chronic patients with non-specific low back pain, showing that tramadol was highly significantly superior on all parameters (VAS pain scores, pain relief scores, pain description and disability).
One high quality study (Maier et al 2002) compared morphine with placebo for patients with either non-specific low back pain (N=12) or low back pain plus radicular pain (neuropathic pain associated with spinal stenosis, epidural fibrosis after disc surgery or arthrodesis) (N=12). It showed that, with regard to pain relief, morphine was superior to placebo in cases of neuropathic (radicular) pain (NNT 2-4 for 50% pain relief) but not in cases of severe non-specific low back pain (NNT 12 for 50% pain relief).
Another high quality trial (Ruoff et al 2003) compared a mixture of Tramadol (37.5 mg) and acetaminophen (paracetamol; 325 mg) (N=161) with placebo (N=157) for 3 months in patients with at least moderate (VAS pain > 40mm on a 0-100mm scale) chronic low back pain. Tramadol/acetaminophen significantly improved pain, disability (Roland Morris) and quality of life compared with placebo.

Effectiveness of opioids versus other treatments (naproxen)
One low quality study (Jamison et al 1998) compared three drug regimes: (i) an NSAID, naproxen (n=12); (ii) set-dose oxycodone (n=13); and (iii) titrated-dose oxycodone plus sustained-release morphine (n=11). All three medications significantly reduced pain and emotional distress (p<0.05) even in the long-term (28 weeks), but the opioid groups were significantly better than the naproxene group (p<0.001). All medications had little effect on activity and sleep.

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Side effects were moderate (mainly constipation, dizziness or sweating, but sexual impotence also in many cases) for long-term use of opioids. Most side effects (except constipation and impotence) subsided over time. In the studies examined, no cases of dependence were reported, but dependence on opioids is always possible.

Subjects (indications)
Patients with moderate to severe chronic non-specific low back pain who do not respond to analgesics or NSAIDs or experience side effects with these medications.

Comments
1. Only few data exist concerning the use of opioids (especially strong opioids) for the treatment of chronic low back patients, and further RCTs are needed.

2. Strong opioids should be used only if all other available therapeutic treatments for pain relief have failed.

Summary of evidence
- There is strong evidence that weak opioids relieve pain and disability in the short-term in chronic low back pain patients (level A).
- There is limited evidence that strong opioids relieve pain in the short-term in chronic low back pain patients (level C).

Recommendation
We recommend the use of weak opioids (e.g. tramadol) in patients with non-specific chronic low back pain who do not respond to other treatment modalities. Due to the risk of addiction, slow-release opioids are preferable to immediate-release opioids, and should be given regularly (around the clock) rather than as needed.

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C10 (E) Antiepileptic drugs (Gabapentin)

Definition of the procedure
The amino acid antiepileptic drug, gabapentin, is normally indicated for adjunctive use in the treatment of partial epileptic seizures. Recently it has also been used in pain treatment (mainly neuropathic pain). Possible mechanisms of action include biochemical effects enhancing the ratio of gamma-aminobutyric acid (GABA) to glutamate, ion-channel action, and/or enhancement of nonsynaptic GABA release.

Results of search
Systematic reviews
No systematic reviews were found on gabapentin for the treatment of non-specific chronic LBP.

Additional trials
One RCT was found on the effectiveness of gabapentin for the treatment of chronic LBP (McCleane 2001).

Quality assessment of the evidence
The RCT (McCleane 2001) was of high quality.

Effectiveness
Effectiveness of gabapentin vs. placebo
In the one RCT (McCleane 2001), 80 patients were randomized to groups receiving either gabapentin up to 1200 mg/day or placebo. 65 patients provided analyzable results. Pain was measured using a 0-10 NRS. Gabapentin failed to improve pain significantly compared with placebo.

Effectiveness of gabapentin vs. other treatments
Unknown (no studies were found on this issue)

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Side effects in the gabapentin group were comparable with those in the placebo group. Gabapentin has few and minor side effects, except for in patients with genetic lactose deficiency ("Lapp lactase deficiency").

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for the use of gabapentin.

Comments
Normally gabapentin is used in patients with neuropathic pain. In the one RCT that was identified, these patients were excluded from the study (McCleane 2001).

The dose of gabapentin that was used in this trial (up to 1200 mg/day) was low, but within recommended therapeutic doses. Higher doses were avoided since the author's experience was that these were not well tolerated by the patients. No data are available on the potential effectiveness of higher doses of gabapentin in chronic LBP.

Summary of evidence

There is limited evidence that gabapentin is not effective for the relief of chronic low back pain (level C).

Recommendation
We cannot recommend the use of gabapentin in patients with non-specific chronic low back pain.

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C10 (F) Capsicum pain plasters (capsaicin)

Definition of the procedure
Capsaicin, from chilli peppers, binds to nociceptors in the skin, causing excitation of the neurons and a period of enhanced sensitivity perceived as itching, pricking, or burning, with cutaneous vasodilatation. This is followed by a refractory period with reduced sensitivity and, after repeated applications, persistent desensitization. The desensitizing effect is fully reversible.

Results of search
Systematic reviews
One systematic review was retrieved (Mason et al 2004). This review dealt with topical capsaicin for the treatment of chronic pain in general (neuropathic and musculoskeletal pain). Only one trial of low back pain was included (Keitel et al 2001): 154 patients were randomized to placebo or local capsicum treatment.

Additional trials
One additional RCT was retrieved (Frerick et al 2003). 301 patients (148 with capsicum and 153 with placebo) completed the study and follow up. Outcome was measured by pain questionnaire, impairment of movement and disability.

Quality assessment of the evidence
The systematic review (Mason et al 2004) and the one relevant trial it included (Keitel et al 2001) were both of high quality. The additional trial (Frerick et al 2003) was also of high quality.

Effectiveness
Effectiveness of capsicum pain plasters vs sham procedure
A double-blind, randomised study compared capsicum plaster with a placebo for 3 weeks in 154 patients with chronic, non-specific back pain (Keitel et al 2001). The sum of 3 separate pain scales decreased more markedly in the capsicum group than in the placebo group (38.5% compared to 28.0%; p = 0.002) and the proportion of responders (i.e. individuals in whom pain was reduced by at least 30% of the baseline value) was also significantly higher for the capsicum group (60.8% vs 42.1% in the placebo group; p = 0.0219). A second study from the same group of authors, which involved 320 patients with chronic, non-specific back pain who were randomly assigned to capsicum plaster (N=160) or placebo plaster (N=160), produced similar results: after three weeks treatment, the compound pain sub-score was reduced by 42% and 31% (p=0.002) for capsicum and placebo plasters respectively, and responder rate was 67% versus 49% (p=0.002) respectively (Frerick et al 2003). The authors claimed that the superiority of the capsicum plaster was highly statistically significant and clinically relevant.

The authors of the systematic review reported that trials of capsicum plaster for musculoskeletal pain (in general) suggested moderate to poor efficacy (number needed to treat (NNT) was 8.1 for 50% pain reduction) (Mason et al 2004).
In the additional trial (Frerick et al 2003), NNT for 50% pain reduction was 9 (OR 2.1).

There is strong evidence that capsicum pain plaster is more effective than placebo for the short term (3 weeks) relief of pain (level A).

Effectiveness of capsicum pain plasters vs other treatments
Unknown (no studies found)

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Around one third of patients experienced local adverse effects (unpleasant burning, itching sensation).

Subjects (indications)
Patients with chronic low back pain with an intensity ≥5 on an 11-point scale.

Comments
Both trials were carried out by the same research group in Germany and both were sponsored by a drug company (Beiersforf AG).

Summary of evidence
There is strong evidence that capsicum pain plaster is more effective than placebo for short term (3 weeks) treatment (level A).

Recommendation
Consider capsicum pain plasters for short-term symptomatic pain relief of chronic low back pain.

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Chapter 11 Invasive procedures

C11 (A) Acupuncture

Definition of the procedure.
Acupuncture is defined as the insertion of needles (1 cm to 10 cm (Leake and Broderick 1998)) at specific points for the treatment or prevention of symptoms and conditions. Those specific points (i.e. "acupuncture points") are defined by their location (Shanghei 1960) and some specific characteristics: they coincide with the migration pathways of some radioactive tracers (Kovacs et al 2000, Kovacs et al 1992, 1993, Vernejoul et al 1985) and have special electrical characteristics (Kovacs et al 1992, 1993, Niboyet 1963). Stimulation of non-acupuncture points of the skin is also considered by some to be acupuncture (Leggett Tait et al 2002).

Alternative methods of stimulation exist. Moxibustion refers to the use of the herb Artemisia vulgaris (mugwort) which is burned over the acupuncture site for warming purposes (van Tulder et al 2004). Electroacupuncture refers to the technique of applying an electrical current to the inserted needles at various frequencies. Laser acupuncture refers to directing a laser beam at the acupuncture site. Fire needles involve inserting red-hot needles at an acupuncture point. Cupping is a technique by which a vacuum force is applied to acupuncture sites. Bloodletting refers to the pricking of the skin for the purpose of releasing blood. Acupressure refers to the manual stimulation of a point with pressure (Leggett Tait et al 2002).

For the purpose of this Guideline, only studies on acupuncture involving puncturing of the skin (either at acupuncture points or non-acupuncture sites) are considered. Studies on laser acupuncture, acupressure, and acupuncture-like TENS are covered by the recommendations of this Guideline dealing with laser, massage or PENS respectively.

Results of search.

Systematic reviews
Sixteen systematic reviews (Berman 2001, Brosseau et al 2002, Ernst 1998, Ernst and White 1998, Ezzo et al 2000, Flowerdew and Gadsby 1997, Gadsby and Flowerdew 2000, Leake and Broderick 1998, Leggett Tait et al 2002, Milne et al 2001, Reed 1996, Smith et al 2000, van Tulder et al 1999, van Tulder et al 2004, van Tulder et al 1997, White and Ernst 2000) were retrieved through the electronic search. Twelve were excluded for the following reasons:

- Four were actually not systematic reviews, but rather narrative reviews or proposals for future research on acupuncture (Berman 2001, Leake and Broderick 1998, Leggett Tait et al 2002, Reed 1996)
- Four focused on TENS (including acupuncture-like TENS) (Brosseau et al 2002, Flowerdew and Gadsby 1997, Gadsby and Flowerdew 2000, Milne et al 2001)
- One mixed acupuncture and laser-acupuncture (Smith et al 2000), which is not consistent with the definition of acupuncture that is being used in this Guideline.
- One focused on acupuncture for all kinds of chronic pain (not only back pain) and did not provide separate results for back pain (Ezzo et al 2000)
- One focused on the economic analysis of complementary medicine (not only acupuncture, although it included this procedure), and did not deal with

acupuncture for back pain (in fact, it included no studies on this subject) (White and Ernst 2000)
- One (van Tulder et al 1999) was a previous report of a lately updated Cochrane review (van Tulder et al 2004)
- One (Ernst 1998) was basically redundant with another review that had already been included (Ernst and White 1998)

The remaining three systematic reviews were included (Ernst and White 1998, van Tulder et al 2004, van Tulder et al 1997). They covered original studies published up to the first issue of 1997 (in the Cochrane Library) or up to the end of 1996 (in the rest of databases).

Among the three systematic reviews that were included, one included studies on both neck and back pain (Ernst and White 1998) and two included only studies on back pain (van Tulder et al 2004, van Tulder et al 1997).

Additional RCTs
An additional search on individual RCTs published after the period covered by the systematic reviews, led to the identification of 22 additional papers (Carlsson and Sjolund 2001, Ceccherelli et al 2003, Cherkin et al 2001, Franke et al 2000, Giles and Muller 1999, Grant et al 1999, Hogeboom et al 2001, Hsieh et al 2004, Kalauokalani et al 2001, Kerr et al 2003, Kittang et al 2001, Leibing et al 2002, MacPherson et al 1999, Meng et al 2003, Molsberger et al 2002, Sator-Katzenschlager et al 2004, Sprott 1998, Thomas et al 1999, Wang and Tronnier 2000, Wedenberg et al 2000, Wehling and Reinecke 1997, Yi-Kai et al 2000).

Fourteen of these studies were excluded for the following reasons:
- One dealt only with acute patients (Kittang et al 2001)
- Three didn't study the effectiveness of acupuncture, but compared different acupuncture techniques (electrical vs manual acupuncture) (Sator-Katzenschlager et al 2004) or focused on the consistency among different practitioners (Hogeboom et al 2001) or the correlation between the number of sessions and the therapeutical effect (Ceccherelli et al 2003)
- Two focused on "acupuncture massage" (i.e. massage on the "meridians" that unite acupuncture points) (Franke et al 2000) or acupressure (i.e. massage on acupuncture points) (Hsieh et al 2004) but did not involve needling
- One focused on patients with fibromyalgia, and not with back pain (Sprott 1998)
- One compared a treatment consisting of acupuncture and cytokine inhibiting natural herbs versus two other procedures (local anaesthetics and steroid injections) for sciatica, making it impossible to determine to what extent each of the two treatments given to the patients in the "acupuncture group" was responsible for the overall effects (Wehling and Reinecke 1997)
- Three were not randomized controlled trials (one was a short-term follow-up of a group of patients treated with acupuncture, with no comparison group (Yi-Kai et al 2000), the objective of the second one was to pilot procedures which were going to be used in a RCT (MacPherson et al 1999), and the third one presented the research protocol for a pragmatic study, but was not a research report (Thomas et al 1999)).
- One RCT included patients undergoing disc surgery (Wang and Tronnier 2000).
- Two reports (on pregnant women and elderly) did not provide information on the duration of pain (Grant et al 1999, Wedenberg et al 2000).

Among the remaining eight additional reports, two analyzed different aspects of the same study: the first one focused on the results of the study (Cherkin et al 2001), and the other one on the relationship between patients' expectations and those results (Kalauokalani et al 2001).

Among these eight reports, six dealt only with chronic patients (Carlsson and Sjolund 2001, Giles and Muller 1999, Kerr et al 2003, Leibing et al 2002, Meng et al 2003, Molsberger et al 2002), and two with subacute (> 6 weeks) and chronic patients (both papers corresponded to the same study) (Cherkin et al 2001, Kalauokalani et al 2001).

Quality assessment of the evidence.
Systematic reviews
Among the three systematic reviews which were included, two were of high quality (van Tulder et al 2004, van Tulder et al 1997), reaching the maximum possible score on methodological quality, and one was of low quality (Ernst and White 1998).

Additional RCTs
Among the eight additional RCTs that were identified, four were of high quality (Cherkin et al 2001, Kalauokalani et al 2001, Leibing et al 2002, Molsberger et al 2002) and four were of low quality (Carlsson and Sjolund 2001, Giles and Muller 1999, Kerr et al 2003, Meng et al 2003).

Effectiveness
Effectiveness of acupuncture vs. sham procedures or no treatment
Systematic reviews
The three systematic reviews all included studies comparing acupuncture versus a sham procedure or placebo (Ernst and White 1998, van Tulder et al 2004, van Tulder et al 1997). All three concurred in concluding that there is no evidence that acupuncture has an effect beyond the placebo effect. The two systematic reviews reaching the maximum methodological quality concluded that there is limited evidence that acupuncture is not more effective than placebo or sham acupuncture for the treatment of chronic low back pain (van Tulder et al 2004, van Tulder et al 1997).

No systematic review gave separate results for different outcome variables. Most studies that were included in the systematic reviews focused on pain, but some also included range of movement, global assessment by the physician, work status, disability, and patient's assessment of condition.

Additional studies
One high-quality RCT with a follow-up period of 9 months compared acupuncture to a sham procedure (Leibing et al 2002). No differences were found between the groups in terms of improvement of pain intensity or disability (Leibing et al 2002).

One high quality RCT compared: a) conservative treatment (defined as physiotherapy, physical exercise, back school, mud packs, infrared heat therapy and diclofenac 50 mg up to 3 times a day), b) conservative treatment plus real acupuncture and c) conservative treatment and sham acupuncture (defined as needle insertion to a depth of less than 1 cm in non-acupuncture points of the lumbar region). The percentage of patients showing a ≥50% reduction of pain was significantly greater in group b) than both in groups a) and c), although there were no differences in the intake of diclofenac (Molsberger et al 2002).

Two low-quality RCTs compared acupuncture and sham (disconnected) TENS (Carlsson and Sjolund 2001, Kerr et al 2003). One found differences in favour of acupuncture for pain, return to work, disturbance of sleep and analgesic intake (Carlsson and Sjolund 2001), while the other did not find differences in pain, length of pain relief post-treatment and satisfaction with treatment (Kerr et al 2003).

There is conflicting evidence that acupuncture is better than a sham procedure in the treatment of low back pain (level C).

Effectiveness of acupuncture vs. other procedures
Systematic reviews
Three systematic reviews compared the effectiveness of acupuncture with other treatments (Ernst and White 1998, van Tulder et al 2004, van Tulder et al 1997). The two high quality reviews concluded that acupuncture is not more effective than trigger point injection or TENS (van Tulder et al 2004, van Tulder et al 1997). The third systematic review, which was a low quality one, stated that acupuncture has proven to be superior to various control interventions (Ernst and White 1998). However, its results did not appear to support its conclusion.

Additional RCTs
Six RCTs compared acupuncture with other procedures (Cherkin et al 2001, Giles and Muller 1999, Kalauokalani et al 2001, Leibing et al 2002, Meng et al 2003, Molsberger et al 2002).

One high quality study compared acupuncture, sham-acupuncture and "active" physiotherapy (defined as training of proper posture and motion in accordance with Bruegger concepts (Bruegger 1990) and found that acupuncture was better than physiotherapy but not better than placebo-acupuncture, in terms of improvement of pain and disability (Leibing et al 2002).

One high quality RCT compared: a) conservative treatment (defined as physiotherapy, physical exercise, back school, mud packs, infrared heat therapy and diclofenac 50 mgs up to 3 times a day), b) conservative treatment plus real acupuncture and c) conservative treatment and sham acupuncture (defined as needle insertion to a depth of less than 1 cm in non-acupuncture points of the lumbar region). The percentage of patients showing a ≥50% reduction of pain was significantly greater in group b) than both in groups a) and c), although there were no differences in mobility (Schober's sign and finger to ground distance) nor in the intake of diclofenac (Molsberger et al 2002).

One high quality RCT compared acupuncture, massage and self-care educational material, and found that acupuncture provided results similar to those for self-care educational material, and worse than those for massage in terms of improvement of symptoms and disability (Cherkin et al 2001). Sub-group analysis of the data of that study showed that patients' expectations regarding each treatment were associated with its effectiveness (i.e., patients improved to a larger extent with those treatments that they believed were going to be more effective) (Kalauokalani et al 2001). One low quality RCT comparing spinal manipulation, non steroidal anti inflammatory drugs (NSAIDs) and acupuncture, found spinal manipulation to be better than the other two alternatives in terms of improvement of disability and pain (Giles and Muller 1999).

One low quality RCT compared: a) standard treatment (defined as any of the following treatments or their combinations, as prescribed by the general practitioner: home exercises, exercises with a physical therapist, non-steroidal anti-inflammatory drugs, aspirin, non-narcotic analgesics), with b) standard treatment plus electroacupuncture, in patients aged 60 yr and over. It found that the addition of acupuncture to standard treatment resulted in an improvement in disability (six weeks after treatment) and an improvement in pain (at 9 weeks, but not 6 weeks after treatment)(Meng et al 2003). Although the study was not able to demonstrate that expectations regarding treatment *per se* effected outcome, within the two

treatment groups the patients "impressions of acupuncture" influenced their outcome within the given treatment groups (positive impressions were associated with a more positive response in the acupuncture group, whilst negative impressions led to a more positive result in standard treatment).

There is moderate evidence that acupuncture is not more effective than trigger point injection or TENS for the treatment of low back pain (level B).

There is limited evidence that acupuncture is less effective than massage and spinal manipulation (level C).

There is limited evidence in each case that acupuncture is similar to self-care education and better than training of proper posture and motion in accordance with Bruegger concepts (level C).

There is limited evidence that the addition of acupuncture improves the results of standard GP treatment (defined as exercise, NSAIDs, aspirin and/or non-narcotic analgesics) or conventional treatment (defined as physiotherapy, exercise, back school, mud packs, infrared heat therapy and diclofenac) (level C).

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Systematic reviews
No papers focusing on the systematic assessment of adverse events derived from acupuncture were included in the systematic reviews.
One systematic review reported on the number (but not relative incidence) of complications from acupuncture for back and neck pain. Adverse reactions to acupuncture (Ernst and White 1998) included drowsiness/syncope/fainting (274 cases), hepatitis (127 cases), other infections (endocarditis, osteomyelitis, septicemia, perichondritis, etc.) (100 cases), increased pain (70 cases), pneumothorax (65 cases), and cardiac trauma (7 cases). However, the *proportion* of such events in all patients treated with acupuncture remains unknown.

Additional RCTs
Among the additional RCTs, only two provided information on adverse effects. One study comparing acupuncture, massage and self-care education stated that 11% of patients reported significant discomfort or pain during or shortly after acupuncture treatment (Leibing et al 2002). This rate was similar to that reported after massage (13%) (Leibing et al 2002).
One study comparing acupuncture and TENS stated that 10% of patients in the acupuncture group reported dizziness (Grant et al 1999).
One study on electroacupuncture stated that 21% of patients reported aching, 12.5% bruising and 4.2% light-headedness. An additional 4.2% of patients withdrew from the study because of pain (Meng et al 2003).

Subjects (indications).
Patients treated in the studies included subacute or chronic patients, with and without referred pain and with or without sciatica. Not having proven effective in the treatment of chronic LBP, it is impossible to define ideal indications for the use of acupuncture.

Comments:
1. There is some evidence suggesting that the proportion of patients improving in the sham acupuncture groups (i.e. superficial needling or needling at non-indicated points) is higher than the proportion improving with other "inert" placebo groups

(sham TENS, sugar pills or placebo acupuncture –in which no needles are inserted). This may be due to acupuncture triggering an especially powerful placebo effect, to chance, to an unknown confounder, to the fact that this evidence comes from indirect comparisons across studies performed in different settings and populations by different research groups, or to sham acupuncture not being a really physiologically inert placebo (Ernst and White 1998, Ezzo et al 2000).

2. There is lively debate among the acupuncture community to determine what procedures fall within the definition of acupuncture. The variability of techniques called acupuncture makes it difficult to assess its quality, and might lead to inappropriate pooling of different techniques within a systematic review. However, to date, no individual acupuncture technique has consistently shown effectiveness.

3. The quality of the vast majority of the RCTs was low, and their results are conflicting. Therefore, more thorough research is needed in this field.

4. In general, the evidence derived from additional RCTs is consistent with that of the systematic reviews in three respects:
    a) There is no consistent evidence that acupuncture provides anything more than a placebo effect in the treatment of low back pain.
    b) Acupuncture provides results that are comparable with (as effective as, slightly better or slightly worse) than those of other techniques that have not consistently shown effectiveness vs. a sham procedure. Therefore, it is not possible to rule out the notion that those studies are just comparing the size of the placebo effect triggered by different procedures.
    c) Adverse effects are potentially serious.

Summary of evidence
- There is conflicting evidence that acupuncture is better than a sham procedure in the treatment of low back pain (level C).
- There is moderate evidence that acupuncture is not more effective than trigger point injection and TENS for the treatment of low back pain (level B).
- There is limited evidence that acupuncture is less effective than massage and spinal manipulation (level C).
- There is limited evidence in each case that acupuncture is similar to self-care education and better than training of proper posture and motion in accordance with Bruegger concepts (level C).
- There is limited evidence that the addition of acupuncture improves the results of standard GP treatment (defined as exercise, NSAIDs, aspirin and/or non-narcotic analgesics) or conventional treatment (defined as physiotherapy, exercise, back school, mud packs, infrared heat therapy and diclofenac) (level C).

Recommendation
We cannot recommend acupuncture for the treatment of chronic low back pain.

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C11 (B) Injections and nerve blocks

Injections for low back pain include epidural corticosteroids (glucocorticoids) (with or without local anaesthetics), spinal nerve root blocks, facet blocks (intra-articular or block of the ramus dorsalis of the spinal nerves), sacro-iliacal joint blocks (injections into the sacro-iliacal joint or into the sacro-ilical ligaments), intradiscal injections, sympathetic blocks (at the lumbar sympathetic chain) and local injections (into muscles and/or ligaments). The procedures are defined under the different topic headings.

C11 (B1) Epidural Corticosteroids and Spinal Nerve Root Blocks with Steroids

Definition of procedure
Epidural injections are possible by caudal, sacral, sacral transforaminal, lumbar midline, paralumbar (lateral) and lumbar transforaminal approaches. They can be given "blindly" or with x-ray guidance (either by fluoroscopy or CT). Various glucocorticoids can be used, alone or in combination with a local anaesthetic or saline. The volume is usually in the 1 to 5 ml range, although some clinicians use 10 ml or more.
Spinal nerve root blocks, which aim at the same target, are normally carried out under fluoroscopy or CT guidance and are given either "periradicularly" (i.e. in the vicinity of the nerve root) or directly into the nerve root sleeve.
Different corticosteroids are used: mainly methyprednisolone, triamcinolone ore dexamethazone.

The procedure aims to target the high level of phospholipase A2 at the interface of the epidural space and the herniated disc material, believed to cause inflammation of the nerve root in lumbar spinal radicular pain.

Result of search
Systematic reviews
Seven systematic reviews were retrieved (Cannon and Aprill 2000, Koes et al 1999, McQuay et al 1997, Nelemans et al 2004, Rozenberg 1998, Tonkovich-Quaranta and Winkler 2000, Watts and Silagy 1995).
One SR (Koes et al 1999) was an updated version of a previous review by the same authors (Koes et al 1995).

All reviews included only trials of epidural steroids for radicular pain. There were no systematic reviews dealing with steroids for non-specific LBP without radicular pain.

Additional RCTs
Eight additional RCTs, published after the period covered by the systematic reviews or not included in them, were retrieved (Devulder et al 1999, Heavner et al 1999, Karppinen et al 2001a, Karppinen et al 2001b, Kraemer et al 1997, Lutze et al 1997, Riew et al 2000, Vad et al 2002). Seven of these RCTs dealt only with radicular pain, whilst one (Devulder et al 1999) dealt only with patients with failed back surgery syndrome.

Quality assessment
Four systematic reviews were of high quality (Koes et al 1999, Nelemans et al 2004, Rozenberg 1998, Watts and Silagy 1995) and three were of low quality (Cannon and Aprill 2000, McQuay et al 1997, Tonkovich-Quaranta and Winkler 2000).

Of the additional RCTs on radicular pain, four were of high quality (Karppinen et al 2001a, Karppinen et al 2001b, Riew et al 2000, Vad et al 2002), and three were of low quality (Heavner et al 1999, Kraemer et al 1997, Lutze et al 1997).

Effectiveness
There is no evidence for the effectiveness of epidural steroids for non-specific chronic low back pain (no RCTs were found on this issue) (level D).

Although we acknowledge that none of the SRs or the additional RCTs dealt with the main theme of these guidelines — non-specific LBP — the results of the studies carried out in relation to chronic radicular pain will be briefly discussed for the interested reader.

Effectiveness of corticosteroid injections vs. a sham procedure for radicular pain
Systematic reviews
One review addressed, in particular, some of the technical problems of injecting epidural corticosteroids (uncontrolled injections without X-ray guidance and the imprecise application of the steroid in relation to the target, the nerve root) (Cannon and Aprill 2000). The authors concluded that, although the literature does not resoundingly vindicate their use, epidural corticosteroids seem to have a favourable role in the non-operative treatment of true radicular pain, with the highest success being achieved when the corticosteroid can be delivered to the pathologic side, usually the disc-root interface.

One SR stated that convincing evidence is lacking on the effect of epidural injection therapy for low back pain and that there is a need for more, well designed explanatory trials in this field (Nelemans et al 2004).

A further review concluded that the effectiveness of epidural administration of corticosteroids has not been established (half of the studies showed positive, the other half negative results) and that the benefits, if any, seem to be of a short duration only (Koes et al 1999).

Another review, that included the same studies as Koes et al. (1999), came to the same conclusion, although they scored the studies in a different way, mostly with lower quality scores (Rozenberg 1998). There was no association between methodological score and outcome.

One SR stated that, based on the available studies, epidural corticosteroids may be an effective treatment for chronic radicular pain (Tonkovich-Quaranta and Winkler 2000). They concluded that their use is warranted in patients who have failed conservative therapy.

In an SR that included in nearly all the same studies as Koes et al. (1999), but statistically pooled the results of the trials, it was concluded that epidural corticosteroids effectively reduced lumbosacral radicular pain (Watts and Silagy 1995). The pooled odds ratio was 2.61 (95% confidence interval 1.90-3.77) for short-term (60 days) pain relief. For long-term pain (up to 12 months) the OR was 1.87 (95% CI 1.3-2.68).

One SR (McQuay et al 1997) compared two previous reviews that had included the same studies (Koes et al 1995, Watts and Silagy 1995) and stated that the number needed to treat (NNT) for short term improvement (1-60 days) and 75% relief was just under 7.3, with 95% confidence intervals from 4.7 to 16; for 50% relief, the NNT was just under 3. From the 5 trials that measured the long-term improvement (12 weeks up to a year) the NNT for a pain-relief of 50% was about 13, with 95% confidence intervals from 6.6 to 314. This means that for every 13 patients treated with epidural steroids, one patient will obtain more relief in the long-term than he/she would have with the control treatment (placebo or local anaesthetic).

The main difference between the two previous reviews concerned the pooling of the results of individual trials: in one (Koes et al 1995) (and its update (Koes et al 1999)), it was decided that the studies were too heterogeneous to perform a meta-analysis; in the other, all data were used to estimate the overall pooled odds ratio that showed that the treatment is effective (Watts and Silagy 1995).

In conclusion, although all three reviews were of high quality, the studies that they included had very small sample sizes; some trials also had serious methodological flaws and some had inadequate outcome measures. Studies were also heterogeneous with respect to the injection volume used, the control treatment, outcome criteria, time at which outcome was assessed, average symptom duration at the time of treatment and indications for the injection. Furthermore, one main problem with all the trials was that the injection was not carried out under either fluoroscopic or CT guidance; it is well known that many injections do not reach their target (either the epidural space or the ventral part of this space close to the spinal ganglion) (Cannon and Aprill 2000, Kraemer et al 1997, Riew et al 2000). Even the highest quality RCT (Carette et al 1997) used a blind injection technique with high volume (10 ml).

Summary from SRs
The general conclusion from the systematic reviews is that there is conflicting evidence for the effectiveness of epidural/perineural corticosteroid injections for radicular pain (level C).

Additional studies
One RCT reported that the injection of a combination of methylprednisolone and bupivacaine at the affected nerve root had a better short-term effect than the injection of saline on leg pain, straight-leg raising and patient satisfaction in patients with subacute/chronic sciatica (Karppinen et al 2001a). However, these effects were not maintained beyond 4 weeks.

Another controlled trial showed that epidural perineural (lateral and ventral part of the epidural space) injections with steroids (N=24 patients) had a better effect (MacNab criteria: leg pain, back pain, return to work, ability to do sport) than saline injections (N=25 patients) in patients with lumbar radicular syndromes (Kraemer et al 1997). Follow up was 3 weeks and three months.

Effectiveness of corticosteroid injections vs. other procedures for radicular pain
Systematic reviews
The general conclusion from the systematic reviews is that there is conflicting evidence for the effectiveness of epidural/perineural corticosteroid injections for radicular pain compared with other procedures (level C).

Additional studies
One study reported that epidural perineural (lateral and ventral part of the epidural space) injections with steroids (N=40 patients) had a better effect (MacNab criteria: leg pain, back pain, return to work, ability to do sport) than conventional epidural injections (N=47 patients) in patients with lumbar radicular syndromes (Kraemer et al 1997). Follow up was 3 weeks and three months.

Another showed that CT guided injections of the nerve root (N=20 patients) were just as effective as fluoroscopic guided injections (N=20 patients) (Lutze et al 1997). Both patient groups improved significantly (p<0.05) as measured by % improvement in VAS pain (in both groups: 65% reported good to excellent results after one month, 42% of patients after 6 months).

In one RCT, selective nerve root injection with betamethasone and bupivacaine resulted in a better outcome (reduction in the number of patients going on to surgery) than did injection with bupivacaine alone (altogether N=55 patients) (Riew et al 2000).

In one RCT transforaminal epidural steroid injections had better results than trigger point injections. After an average follow-up period of 1.4 years, the group receiving transforaminal epidural steroid injections had a success rate of 84%, as compared with 48% for the group receiving trigger-point injections (P < 0.005) (Vad et al 2002).

The final RCT examined four treatments in patients with radiculopathy plus low back pain: a) hypertonic saline plus hyaloronidase (N=17); b) hypertonic saline (N=15); c) isotonic saline (N=17); d) isotonic saline plus hyaloronidase (N=10) – each in combination with corticosteroid and local anaesthetic (Heavner et al 1999). Each treatment had the same (generally positive) outcome (VAS pain difference).

Cost/effectiveness
Cost/effectiveness was not addressed in any of the systematic reviews. One trial among the additional RCTs (Karppinen et al 2001b) addressed the cost-effectiveness of periradicular steroid injections in patients with unilateral sciatica. In comparing steroid with saline injections it showed that 1 year after treatment, steroid seemed to have prevented operations for contained herniations, costing $12,666 less per responder in the steroid group (P < 0.01). For extrusions, steroid seemed to increase the operation rate, and the steroid infiltration was more expensive, costing $4445 per responder (P < 0.01).

In one study, although no formal cost-effectiveness analysis was carried out, it was shown that the subsequent operative rate was much lower in a group of patients receiving nerve–root injections with bupivacaine and betamethasone than it was in a group that received only bupivacaine P<0.004) (Riew et al 2000).

Safety
Systemic corticosteroids side effects: suppression of adrenocorticotropic hormone (ACTH) and Cushingoid symptoms (mainly if high doses of corticosteroid are used or the injections are given too often) (Abram and O'Connor 1996, Weyland et al 1992). Technical complications: accidental dural puncture (5% of the cases) with consequent postdural puncture headache; and epidural haematoma (very rare). Infectious complications: several cases of epidural abscess after epidural steroid injection have been documented, most of which occurred in diabetic patients; however, the incidence is very rare.
Neurological complications: neurological squeal (chemical meningitis) can occur after intrathecal application of steroids, mainly of depot-corticosteroids, probably due to polyethylene glycol in the vehicle (Nelson 1993), but also in cases of water-soluble corticosteroid (Devoize et al 1993). Arachnoiditis after epidural injection of steroids is very rare (Abram and O'Connor 1996).
The reported side effects are uncommon if the procedure is carried out under aseptic conditions and in consideration of the contraindications (local or systemic infection, bleeding diathesis, severe congestive heart failure and uncontrolled diabetes) (Rozenberg 1998).

Subjects (indications)
Not having shown evidence of effectiveness for **non-specific low back pain**, it is not possible to define indications for epidural corticosteroid injections.

Comments
1.   Epidural corticosteroid injections would only be considered for radicular pain, if a contained disc prolapse is the cause of the pain and if the corticosteroid is injected close to the target (nerve root).
2.   The injection should be X-ray guided and should aim at:
      a) The ventral part of the epidural space, near the spinal nerve root, or
      b) The spinal nerve root through a transforaminal approach.
3.   There is conflicting evidence that conventional epidural steroids (without X-ray guidance) are effective in radicular pain.

Summary of evidence
There is no evidence for the effectiveness of epidural corticosteroids in patients with non-radicular, non-specific low back pain (level D).

Recommendation
We cannot recommend the use of epidural corticosteroids in patients with non-radicular, non-specific low back pain.

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C11 (B2) Facet Injections

Definition of procedure
Facet block injections consist of the precise instillation of local anaesthetic and/or corticosteroid into a facet joint or around its nerve supply (ramus medialis of the ramus dorsalis). Fluoroscopic monitoring is necessary to check the position of the needle. Sometimes CT is used for this purpose. If a joint is anaesthetized through its nerve supply, at least two nerves (rami dorsales) should be blocked for each joint.

Result of search
Systematic review
Only one high quality review (Nelemans et al 2000) was retrieved and considered suitable for formulating these recommendations, although an additional low quality review (Manchikanti 1999) was considered to be of possible clinical value.
The Nelemans' review included three RCTs (Carette et al 1991, Lilius et al 1989, Marks et al 1992).

Additional RCTs
None were retrieved

Quality assessment of the evidence
Systematic review
The included SR was of high quality (Nelemans et al 2000). Two of the trials it included were of high quality (Carette et al 1991, Marks et al 1992) and one was of low quality (Lilius et al 1989).

From the clinical point of view:
a) One of the high methodological quality studies accepted a >50% reduction in pain after one single diagnostic block for applying the diagnosis of "pain coming from the facet joint" (Carette et al 1991). Since there is a false positive rate of 25%-36% with single blocks (Manchikanti 1999, Schwarzer et al 1994), this may have led to the inclusion of patients with pain that did not really derive any benefit from the facet joint.
b) The low quality study (Lilius et al 1989) did not use diagnostic blocks to establish the suspected diagnosis of facet pain and injected a volume of 8 ml, which is higher than recommended (Manchikanti 1999, Schwarzer et al 1994).

Effectiveness
Effectiveness versus sham procedures (intra-articular saline)
The high quality study in which one single diagnostic block was accepted for establishing the origin of pain (Carette et al 1997) compared intra-articular saline and intra-articular methylprednisolone. They did not find any significant difference between groups at the 1 and 3 month follow-up assessments. However, at six months the percentage of patients with notable improvement was significantly higher in the methylprednisolone group. Despite this latter finding the study concluded that the effectiveness of facet joint injections is small, because 11 of the 22 patients in the steroid group who reported substantial improvement at 6 months after injection reported no benefit at earlier evaluations. No pharmacological or biological explanation could be offered for the results.

The low quality study (Lilius et al 1989) compared three modes of injection: intra-articular injections with corticosteroid and local anaesthetic, intra-articular injection with saline only and pericapsular injection of corticosteroid and local anesthetic. They reported that mean scores for pain relief with methylprednisolone and/or bupivacaine were not superior to those for placebo (saline) injections.

Effectiveness versus other treatments
One high quality study (Marks et al 1992) compared intra-articular facet joint injections with facet nerve blocks, in each case using local anaesthetic (lidocaine) and steroid (methylprednisolone). There was no significant difference in the immediate response. The duration of response after facet joint injection was marginally longer than after facet nerve block (p< 0.05 1 month after infiltration), but for both groups the response was usually short-lived; by 3 months only 2 patients continued to report complete pain relief. The authors concluded that facet joint injections and facet nerve blocks may be of equal value as diagnostic tests, but neither is a satisfactory treatment for chronic back pain.

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
There is one report on septic facet joint arthritis (Levy et al 1993), but the rate of such an event is unknown and seems likely to be rare.

Subjects (indications)
There is no clear indication of the patients for whom the procedure would be useful. An important difficulty is the uncertainty surrounding the clinical definition (diagnosis) of facet joint syndrome and the necessity for confirming its existence before the injection is indicated. This cannot be proven by the clinical investigation.

Comments
1. Several possible causes of pain within the facet joints have been reported (Dreyfuss et al 1995). However, according to some authors (Schwarzer et al 1994), the reported prevalence of facet joint pain (ranging from 8% to 94%) seems to be a function of the size of the sample and the belief of the author. Within the context of these guidelines, facet joint pain is considered as one possible source for non-specific low back pain and not as a specific diagnosis.

2. Clinical practice does not usually meet recommended criteria. One study reported that the factors found to be predictive of a response to facet joint anaesthesia (defined as 75% decrease in pain severity), which can be viewed as a gold standard diagnostic test for facet joint syndrome, were different from the criteria generally used for the clinical diagnosis of this condition (Revel et al 1998).

3. Facet joint syndrome is very difficult to define clinically and facet nerve blocks have a very high placebo effect (Schwarzer et al 1994), so it is very difficult in practice to reliably select patients with indications for a facet joint injection.

4. It has not yet been determined whether the mechanism by which facet joint injection may alleviate pain involves a local anti-inflammatory effect of the glucocorticoid, the introduction of fluid into the joint space, or the puncture hole made in the joint capsule.

5. Intra-articular injections and nerve blocks are considered almost the equivalent for diagnostic and therapeutic purposes and the result is short-lived for both techniques.
6. There is moderate evidence that intraarticular corticosteroids are not effective in patients with pain of facet joint origin (level B).

Summary of evidence

There is no evidence for the effectiveness of intraarticular injections of steroids or facet nerve blocks in patients with non-specific low back pain (level D).

Recommendation
We cannot recommend the use of intraarticular injections of steroids or facet nerve blocks in patients with non-specific chronic low back pain.

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C11 (B3) Intradiscal Injections

Definition of procedure
Intradiscal injections (discography) are normally used to diagnose discogenic nonradicular pain (see section on **Diagnosis** for further details). In some studies intradiscal injections of steroids have been used to treat discogenic pain. The injection is applied by a posterior-lateral extradural approach. The rationale for the glucocorticoid intradiscal injection is the reduction of inflammation in the disc. The rationale for intradiscal glycerol for the treatment of so-called discogenic pain is the denervation of intradiscal nerve fibers (chemical neurolysis).

Result of search
Systematic Reviews
One systematic review (Nelemans et al 2000) included one study (Simmons et al 1992) of intradiscal injection of methylprednisolone for non-specific chronic LBP.

Additional RCTs
Two additional RCTs were retrieved (Khot et al 2004, Kotilainen et al 1997).

Quality assessment of the evidence
One of the additional RCTs was of high quality (Khot et al 2004). The RCT included in the systematic review (Simmons et al 1992) and one additional RCT (Kotilainen et al 1997) were of low quality.

Effectiveness
Effectiveness versus a sham procedure:
Unknown (no studies were found on this issue)

Effectiveness vs. other procedures
One small, low quality study compared intradiscal injections of methylprednisolone and of bupivacaine in patients with and without sciatica (with internal disc disruption or nonsequestered prolapsed discs; total N=25 patients) (Simmons et al 1992). There was no difference between the groups for short-term (after 14 days) pain relief.

In one high quality study (Khot et al 2004) patients with chronic (nonradicular) discogenic pain (N=120) were randomized to intradiscal saline or methyprednisolone injection. There was no significant difference in outcome (pain and Oswestry disability) between the groups at the 12- month follow-up (p=0.71).

The other small (total N=15 patients), low quality study compared intradiscal injections of glycerol and bupivacaine in patients with chronic low back pain in which discography had suggested one symptomatic disc (Kotilainen et al 1997). 73% of the patients showed clinical signs and symptoms of segmental instability of the lumbar spine. There was a good immediate response after the injection and after 14 days (self evaluation questionnaires), but after one month the effects had disappeared in both groups.

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Intradiscal injections can be potentially dangerous (infection: discitis or spondylodiscitis). The rate of occurrence of this event is unknown.
Intradiscal glucocorticoids bring about a progressive degeneration of the disc that is milder than that occurring after chemonucleolysis (Kato et al 1993).

Subjects (indications)
Not having shown effectiveness, it is impossible to define indications for local intradiscal injections. In addition, it is very difficult to diagnose discogenic low back pain.

Summary of evidence
There is moderate evidence that local intradiscal injections (glucocorticoid or glycerol) are not effective for chronic low back pain (level B).

Recommendation
We do not recommend the use of intradiscal injections for the treatment of chronic low back pain.

References
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C11 (B4) Intramuscular Injections of Botulinum Toxin

Definition of procedure:
Normally, intramuscular injection of Botulinum toxin is indicated in patients with dystonia or spasticity, and serves to reduce muscle tension and pain. Botulinum toxin not only inhibits the release of acetylcholine but also of neuropeptides such as substance P, which is known to have a key function in pain generation.

Result of search
Systematic Reviews.
No systematic reviews were retrieved.

Additional RCTs
One additional RCT was found (Foster et al 2001).

Quality assessment of the evidence
The study was of low quality.

Effectiveness
Effectiveness of Botulinum toxin vs. a sham procedure (injection with saline)
The study compared the injection of 200 units Botulinum toxin (40 units/site at five paravertebral intramuscular levels on the side of most discomfort) (N=15 patients) with the injection of saline at the same site (N=16 patients) (Foster et al 2001). The results for VAS pain and Oswestry disability showed that Botulinum toxin was superior to placebo at three and eight weeks after injection, but the statistical analysis was insufficient (p=0.009 for pain relief and p=0.011 for Oswestry score).

There is limited evidence (level of evidence C) showing the short-term effectiveness of Botulinum toxin in chronic low back pain.

Effectiveness of Botulinum toxin vs. other procedures
Unknown (no studies were found on this issue)

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Botulinum toxin can weaken the muscles if repeated injections are given over a long period of time (Foster et al 2001).

Subjects (indication)
Not having shown evidence of effectiveness, it is not possible to define indications for the use of botulinum toxin.

Comments
The mechanism of pain relief in patients with low back pain is unclear.
Botulinum toxin is expensive and has side effects.
For these reasons, and in spite of the positive results on effectiveness derived from a low quality RCT vs. placebo, botulinum toxin cannot be recommended for chronic low back pain. Further studies are needed.

Summary of evidence

There is limited evidence that Botulinum toxin is effective for the treatment of chronic low back pain (level C)

Recommendation

We cannot recommend the use of Botulinum toxin for the treatment of chronic non-specific low back pain.

References

1. Foster L, Clapp L, Erickson M, Jabbari B **(2001)** Botulinum toxin A and chronic low back pain: a randomized, double-blind study. Neurology, 56(10): 1290-3.

C11 (B5) Sacroiliac Joint Injections

Definition of procedure
Sacroiliac joint injections consist of the infiltration of local anaesthetic and/or corticosteroids into the sacroiliac joint. They can be performed without x-ray control, under CT-guidance or with fluoroscopic control. A controlled study of clinically guided injection (with no image guidance) showed that an intra-articular approach was achieved in only 22% of cases (Rosenberg et al 2000).

Result of search
Systematic review
No systematic reviews were retrieved.

Additional RCTs
Two randomized controlled studies were found (Luukkainen et al 2002, Maugars et al 1996). One of these was excluded, as it dealt specifically with sacroiliitis (Maugars et al 1996).

Quality assessment of the evidence
The remaining RCT was of low quality (Luukkainen et al 2002, Maugars et al 1996).

Effectiveness
Effectiveness of sacroiliac joint injections vs. a sham procedure (saline injection)
The one RCT compared "blind" peri-articular injections of lidocaine and isotonic sodium chloride vs. lidocaine and methylprednisolone (Luukkainen et al 2002). Their results showed that the injections containing corticosteroid were more effective in reducing pain one month after the injection.

Effectiveness of sacroiliac joint injections vs. other procedures
Unknown (no studies were found on this issue)

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (Indication)
The study stated that it included patients with sacroiliac pain. However, it is difficult to define such patients, as there are currently no reliable clinical tests available to confirm such a diagnosis (Dreyfuss et al 1996).

Comments
1. The sacroiliac joint can definitely be a source of low back pain. Stimulation of the joint by injection in subjects without pain produces pain in the buttock, the posterior thigh, the groin and the knee (Dreyfuss et al 1996) (see also Guidelines for Pelvic Girdle Pain).

2. Intra-articular injection can be given in the lower part of the joint with fluoroscopic guidance only. However, even at this location an accurate intra-articular injection, confirmed by contrast medium, is often difficult. It is not clear whether intra-articular spread is necessary to achieve effectiveness. Further, it is not clear if joint injections with corticosteroids are successful only in joints that are inflamed, or also in other conditions.

3. There is some suggestion that more reliable diagnostic tests for sacroiliac joint pain have been developed in recent years (Kokmeyer et al 2002, van der Wurff et al 2000)

Summary of evidence
There is limited evidence that injection of the sacroiliac joint with corticosteroids relieves sacroiliac pain of unknown origin for a short time (level C).

Recommendation
We cannot recommend the use of sacroiliac joint injections with corticosteroids for the treatment of non-specific chronic low back pain.

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C11 (B6) Prolotherapy (Sclerosant Injections)

Definition of procedure
Prolotherapy consists of injecting sclerosing substances into the ligaments of the lumbar spine (such as the supraspinous, intraspinous, posterior iliosacral and iliolumbar ligaments) and lumbodorsal fascia and apophysial joint capsules. Today, the most commonly used solution for these injections is a mixture of glucose, glycerine and phenol.

The rationale for their use is based on two premises: firstly, that laxity of the ligaments and fascia supporting the lumbar motion segments may be responsible for some cases of chronic low back pain and secondly, that the injection of substances which initiate an inflammatory response will strengthen these ligaments and consequently reduce back pain.

Result of search
Systematic Reviews
One SR (Nelemans et al 2000) included one study with sclerosants injected into ligaments (Ongley et al 1987).

Additional RCTs
Two additional RCTs were found (Dechow et al 1999, Klein et al 1993). These two papers referred to injections of sclerosants into ligaments, fascia and joint capsules of the back.

Quality assessment of the evidence
The study included in the SR was of low quality (Ongley et al 1987).
The two additional RCTs were of high quality (Dechow et al 1999, Klein et al 1993).

Effectiveness
Effectiveness versus a sham procedure (injection with lidocaine and saline)
One high quality RCT (Dechow et al 1999) compared the effects of three, once-weekly injections of either dextrose-glycerine-phenol or saline plus lidocaine into the ligaments of the L4-5 and L5-S1 lumbar motion segments. There were no differences between the groups (for McGill pain questionnaire, VAS pain, pain drawing, modified somatic perception questionnaire, modified Zung depression inventory, Oswestry disability scale, or physical investigation) at 1, 3 and 6 months.

The other high quality RCT (Klein et al 1993) compared a similar regimen of injections. 79 patients who failed to respond to previous conservative care were randomly assigned to receive a double blind series of six, once-weekly injections of either xylocaine/saline solution or xylocaine/proliferants (dextrose, 25%, glycerine, 25%, phenol, 2.4%) into the posterior sacroiliac and interspinous ligaments, fascia, and joint capsules of the low back from L4 to the sacrum. After 6 months, no relevant differences between the groups were observed for the improvement in Roland and Morris disability score, VAS pain, pain grid score, range of motion, or lumbar function assessed with the B-200 triaxial dynamometer (both groups improved to a similar extent).

Effectiveness vs. other procedures
The low quality study (Ongley et al 1987) compared a treatment involving forceful spinal manipulation and injection of dextrose-glycerine-phenol proliferant (six, once-weekly injections of 20 ml in 40 patients), with a treatment involving less extensive initial local anaesthesia and manipulation, and substitution of saline for proliferant (41 patients). The first group showed better results than the control group (Roland and Morris scale, Waddell scale, VAS pain, pain grid score) in all parameters (p=0.001)

after 1, 3, and 6 months, although with the combined treatments it was not possible to ascertain what the "active ingredient" was (manipulation or proliferant).

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indication)
Not having shown evidence of effectiveness, it is not possible to define indications for the use of sclerosants. It appears to be difficult to accurately identify patients with instability of the spine and pelvis or laxity of the ligaments.

Summary of evidence
There is strong evidence that local injections with sclerosants (prolotherapy) in the ligaments of the back are not effective for non-specific chronic low back pain (level A).

Recommendation
We do not recommend the injection of sclerosants (prolotherapy) for the treatment of non-specific chronic low back pain.

References
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4. Ongley MJ, Klein RG, Dorman TA, Eek BC, Hubert LJ **(1987)** A new approach to the treatment of chronic low back pain. Lancet, 2(8551): 143-6.

C11 (B7) Trigger Point Injections

Definition of procedure
Myofascial trigger points are defined as hyperirritable loci within a taut band of skeletal muscle. Trigger points are located in the muscle or its associated fascia. They are painful on compression and can evoke a reliable, characteristic referred pain with or without autonomic response.

It is proposed that an "active" trigger point causes pain, while a "latent" trigger point may restrict movement and weaken the affected muscle. The latent trigger point persists for years after recovering from injury (or in connection with degenerative disease of the joints and spine) and predisposes to acute exacerbation, fatigue, reaction to cold and damp surroundings, and emotional upset (Lou and Racz 1998).

The rationale or hypothetical mechanism for injection in the trigger points is the selective destruction of mature myocytes by local anaesthetic, saline infiltration or dry needling, or the "breaking of the reflex mechanism" of the pain, probably mainly by muscle relaxation.

Result of search
Systematic reviews
One systematic review was found (Nelemans et al 2000), which included 5 papers on trigger point injections (Collee et al 1991, Frost et al 1980, Garvey et al 1989, Hameroff et al 1981, Sonne et al 1985): three of these dealt with local injections into muscles (Frost et al 1980, Garvey et al 1989, Hameroff et al 1981), and two into ligaments (Collee et al 1991, Sonne et al 1985).

One of these studies concerned acute pain (Frost et al 1980) and another examined both lumbar <u>and</u> cervical triggerpoints (Hameroff et al 1981). These two were therefore not considered further.

Additional RCTs
No additional trials were found.

Quality assessment of the evidence
All studies were of low quality.

Effectiveness
Effectiveness versus a sham procedure (injection with saline)
One study (Collee et al 1991) compared trigger point injections (lig. iliolumbale) with 5 ml of lidocaine or isotonic saline, in patients with iliac crest pain. When both treatment groups were compared at day 14, the pain score was slightly but significantly lower in the lidocaine treated group and more patients in this group felt improvement (but this was not significant). Among those who improved with lidocaine, the beneficial effect continued for at least 2 months in more than 80% of patients.
One study that examined triggerpoint injections into a ligament (Sonne 1985) (lig. ileo-lumbale) included subacute and chronic LBP patients: 30 patients were randomly allocated to one of two treatment groups: (i) 5 ml lidocaine 1% mixed with methylprednisolone acetate, or (ii) isotonic saline. A maximum of three injections were given at one-week intervals. Pain (VAS), movement, and the patient's self-assessment were measured 14 days after treatment. Significant improvement s in pain (p<0.01) and patient self-assessment (p<0.05) but no changes in movement were recorded in the lidocaine/methylprednisolone group; no significant changes were recorded in the control group.

Effectiveness vs. other procedures

One study dealt with patients with subacute pain of 4 weeks duration (N=63) (Garvey et al 1989). Injection therapy into several myofascial tender points was of four different types: lidocaine, lidocaine combined with a steroid, acupuncture in the triggerpoint, and vapocoolant spray with acupressure. Results indicated that therapy without injected medication (63% improvement rate) was at least as effective as therapy with drug injection (42% improvement rate) (p=0.09 for the difference). The acupressure group showed the greatest response, but the difference was not significant. The authors concluded that direct mechanical stimulus to the trigger-point seemed to give symptomatic relief equal to that of treatment with various types of injected medication.

Cost/effectiveness

Unknown (no studies were found on this issue)

Safety

Unknown (no studies were found on this issue)

Subjects (indications)

Patients with trigger points in the back and pelvic muscles, or localized pain of muscular origin.

Comments

It has not yet been determined whether the mechanism by which intramuscular injection may alleviate pain involves the needling effect, the local anaesthetic, or the local anti-inflammatory effect of a glucocorticoid.

Summary of evidence

There is conflicting evidence for the short-term effectiveness of local intramuscular or ligament (lig. ilio-lumbale) infiltration with anaesthetics in chronic low back pain (level C).

Recommendation

We cannot recommend the use of trigger point injections in patients with chronic low back pain.

References

1. Collee G, Dijkmans BA, Vandenbroucke JP, Cats A **(1991)** Iliac crest pain syndrome in low back pain. A double blind, randomized study of local injection therapy. J Rheumatol, 18(7): 1060-3.
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3. Garvey TA, Marks MR, Wiesel SW **(1989)** A prospective, randomized, double-blind evaluation of trigger-point injection therapy for low-back pain. Spine, 14(9): 962-4.
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C11 (C) Neuro-Reflexotherapy

Definition of the procedure
Neuro-reflexotherapy intervention (NRT) is defined as the temporary implantation of epidermal devices (surgical staples (up to 90 days) and small metallic burins (which fall off after about 2 weeks)) in trigger points in the back at the site of clinically involved dermatomes in each case, and in referred trigger points located in the ear. The trigger points used in NRT are defined by their innervation and by physical examination and differ from those used for trigger point therapy injections (Kovacs et al 1993, Kovacs et al 1997, Kovacs et al 2002, Urrutia et al 2004). NRT is performed without anaesthesia, on an outpatient basis.
NRT interventions are not related to acupuncture. The zones of the skin chosen for the implants are defined by their innervation. They do not coincide with the points described in Chinese acupuncture texts or with the migration pathways of some radioactive tracers (as is typically the case for acupuncture points) (Kovacs et al 1993, Kovacs et al 1997, Kovacs et al 2002, Urrutia et al 2004). Similar to TENS, the purpose of NRT is to "deactivate" neurons assumed to be involved in the persistence of pain, neurogenic inflammation, and muscle dysfunction and contracture (Kovacs et al 1993, Kovacs et al 1997, Kovacs et al 2002, Urrutia et al 2004).

Results of search
Three papers (Kovacs et al 1993, Kovacs et al 1997, Kovacs et al 2002) and a Cochrane review (Urrutia et al 2004) were retrieved.

All three papers were RCTs. Two were double-blind randomized controlled clinical trials of NRT versus a sham procedure, consisting of the implantation of epidermal devices up to 5cm away from the appropriate target zones. Both studies focused on the effect of NRT for treating exacerbations of low back pain and had a short-term follow-up (up to 45 days) (Kovacs et al 1993, Kovacs et al 1997). The third study was a cluster randomized controlled trial in which physicians (i.e. clusters) were randomized, and which compared the standard GP treatment protocol with such a protocol supplemented with NRT. Its follow-up period for pain and disability was 60 days and for subsequent healthcare utilisation, one year (Kovacs et al 2002). Approximately 50% of the patients examined had had LBP for less than 17.5 days (control group) and 48 days (experimental group), indicating that many of patients were not strictly chronic according to the definition given in the introduction. All three studies were led by the same senior author, and were conducted in different Hospitals and Primary Care Centers belonging to the Spanish National Health Service.

Quality assessment of the evidence
The systematic review and the three RCTs were of high quality.

Effectiveness
Effectiveness vs. sham procedures
Two high quality studies showed a statistically significant reduction in the severity of pain, whether local or referred, in the NRT group, at the end of the follow-up period (30 and 45 days, respectively) (Kovacs et al 1993, Kovacs et al 1997). Quality of life was only assessed in one study, and showed a slightly more favourable result in the intervention group for the subscale "change in quality of life" of the COOP charts (Kovacs et al 1997) (N.B. this data is wrongly reported in the tables of both the original study (Kovacs et al 1997) and the Cochrane review (Urrutia et al 2004); data for control and intervention groups have been reversed.) There were no differences found for the variables "overall health" and "overall quality of life" (Kovacs et al 1997). One study did (Kovacs et al 1993) and one study did not (Kovacs et al 1997) find significant differences between the two groups in their ability to perform activities of

daily living (possibly because of the different ways used to assess this variable). In one study, the mean numbers of days off work due to an episode of LBP during follow-up was significantly lower in the NRT group (Kovacs et al 1993). A reduction in the consumption of drug treatment was observed in one RCT (Kovacs et al 1993) but not in the other (Kovacs et al 1997), possibly because in the latter its consumption was low at baseline.

Effectiveness vs. other treatments
One high quality study showed that the addition of NRT to standard medical care improved low back pain, referred pain, disability and return to work at 60 days follow-up. Additionally, it was associated with a reduction in the subsequent use of health resources (cost of drug treatment, visit to primary care physicians, and referral to several diagnostic procedures and to physiotherapy) over the year following treatment. No differences in quality of life –as measured by the EuroQol questionnaire- were found between groups (Kovacs et al 2002).

Cost/effectiveness
One high quality RCT studied the cost/effectiveness of adding NRT to standard medical care. Its results show that such an addition improves the cost/effectiveness of the management of low back pain (Kovacs et al 2002).

Cost/effectiveness ratios for low back pain, referred pain, disability, and quality of life were more favorable (not significant) for the NRT-treated group. A sensitivity analsysis showed that differences in favor of the NRT group persisted in the three assumptions of the best case, the worst case, and the average case. In addition, the cost-effectiveness ratio for lumbar pain and disability in the NRT group was better even when the worst-case assumption in this group was compared with the best-case assumption in the control group (Kovacs et al 2002).

Safety
In the RCTs in which NRT was compared to a sham procedure (Kovacs et al 1993, Kovacs et al 1997), adverse events included transient cutaneous discomfort (itching, irritation and redness) after insertion of the surgical staples in 4% to 13% of cases (7% to 11% in the sham group), and limited dermal infection in 0% to 2% of cases (0% to 3% in the sham group). Dermal infection was successfully treated with an antibiotic cream in less than 48 hours in all cases, and none of the patients required extraction of the staples before they were planned to be removed (Kovacs et al 1993, Kovacs et al 1997).

In the cluster randomized RCT, in which NRT was added to standard medical care, adverse events were enquired about and none were reported (Kovacs et al 2002).

Subjects (indications).
All of the RCTs included chronic patients with low back pain, with or without referred pain (Kovacs et al 1993, Kovacs et al 1997, Kovacs et al 2002), and two of them also included patients with acute (defined in the COST guidelines project as lasting for 6 weeks or less) and subacute LBP (6 weeks – 3 months). Only patients with a VAS pain score ≥ 3 were included.

Comments
All three RCTs were conducted in Spain. Availability of the procedure outside Spain is unknown. No data are available on the ease and time-frame needed to achieve the necessary level of expertise, although various different physicians participated in the Spanish RCTs, indicating that the administration of NRT can be learnt with adequate training. At present, the results are only valid where physicians with a special training in NRT are available.

Summary of evidence

- There is strong evidence that NRT is more effective than a sham procedure in providing pain relief up to 30-45 days (level A)
- There is limited evidence that NRT is more effective than a sham procedure in improving return to work (level C).
- There is limited evidence that the addition of NRT to standard medical care provides better outcomes than standard care alone with respect to short-term (up to 60 days) pain relief and disability, and for subsequent drug treatment, healthcare utilisation and sick leave up to 1 year later (level C).
- Only minor and rare adverse events have been reported.

Recommendation

Consider NRT for patients with moderate or severe (≥3 points on a VAS) low back pain.

References

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4. Urrutia G, Burton AK, Morral A, Bonfill X, Zanoli G **(2004)** Neuroreflexotherapy for non-specific low-back pain. Cochrane Database Syst Rev, (2): CD003009.

C11 (D) Percutaneous electrical nerve stimulation (PENS)

Definition of the procedure
Percutaneous electrical nerve stimulation (PENS) can be described as an analgesic therapy which uses acupuncture-like needle probes positioned in the soft tissues and/or muscles to stimulate peripheral sensory nerves at the dermatomal levels corresponding to the local pathology (Ghoname et al 1999a). PENS treatments may vary with respect to location, frequency and duration of the electrical stimulation.

Results of search
Systematic reviews
No systematic reviews were found on the effectiveness of PENS as a treatment for chronic low back pain.

Additional RCTs
Seven RCTs were found. Four of these were randomized crossover studies (Ghoname et al 1999a, Ghoname et al 1999b, Hamza et al 1999, White et al 2001) and the other three were parallel group RCTs (Hsieh and Lee 2002, Weiner et al 2003, Yokoyama et al 2004).
Three of the randomized crossover studies examined the effects of different treatment durations (Hamza et al 1999), different frequencies of electrical stimulation (Ghoname et al 1999b), and different montages (i.e. patterns of stimulation) (White et al 2001). The fourth one compared PENS with TENS and with flexion-extension exercises (Ghoname et al 1999a). The three parallel group RCTs compared the effects of PENS with TENS (Yokoyama et al 2004), one-shot PENS with TENS (Hsieh and Lee 2002) and PENS plus physical therapy with sham-PENS plus physical therapy (Weiner et al 2003).

Quality assessment of the evidence
One RCT was rated as high quality (Weiner et al 2003), and the others as low quality (Ghoname et al 1999a, Ghoname et al 1999b, Hamza et al 1999, Hsieh and Lee 2002, White et al 2001, Yokoyama et al 2004).

Effectiveness
Effectiveness of PENS vs sham/placebo procedures
One high quality RCT (Weiner et al 2003) and three low quality randomised cross-over studies (Ghoname et al 1999a, Ghoname et al 1999b, Hamza et al 1999) made a comparison of the effects of PENS and sham-PENS. The three studies showed significant effects on pain in favour of PENS compared with sham-PENS. The study population of the high quality RCT (Weiner et al 2003) consisted of adults aged 65 years and older, which somewhat limits the generalisability of the results to other populations and settings.

There is moderate evidence that PENS is more effective than sham PENS in the treatment of chronic low back pain (level B).

Effectiveness of PENS vs. other treatments
Three low quality studies compared PENS with TENS (Ghoname et al 1999a, Hsieh and Lee 2002, Yokoyama et al 2004). One study showed that PENS was significantly more effective for pain relief than TENS (Yokoyama et al 2004). Another compared one-shot treatment of PENS plus medication with one-shot treatment TENS plus medication and found no differences in effects (Hsieh and Lee 2002). The third compared PENS with TENS and with flexion-extension exercises and showed that PENS was significantly more effective in decreasing pain than either TENS or flexion-extension exercises (Ghoname et al 1999a).

There is conflicting evidence that PENS is more effective than other treatments in the treatment of chronic low back pain (level C).

Relative effectiveness of different modes of PENS application (duration, frequency, location)
Three low quality randomised cross-over studies compared differing modes of PENS application. One study compared electrical stimulation for four different time intervals (0, 15, 30 and 45 minutes) (Hamza et al 1999). The 30-minute and 45-minute durations of electrical stimulation produced similar hypoalgesic effects and were significantly more effective than either the 15-minute or 0-minute durations of electrical stimulation. Another study compared the use of different frequencies of PENS applied for 30 minutes, three times a week for 2 weeks: 4 Hz, alternating 15 Hz and 30 Hz, 100 Hz and sham-PENS (0 Hz) (Ghoname et al 1999b). Alternating 15 Hz and 30 Hz was the most effective PENS frequency for the reduction of pain. The third study compared PENS treatments with four different patterns of stimulation (montages) (White et al 2001). In all groups, patients received 30 minutes' PENS treatment with an alternating stimulation frequency of 15 and 30 Hz, which was applied three times a week for 2 consecutive weeks. The study showed that stimulation of the lower back and buttock along the involved nerve roots at the dermatomal levels corresponding to the patients' pain symptoms was more effective than stimulation at locations closer to the spinal column.

There is conflicting evidence that PENS treatments with 30 minutes stimulation duration, with an alternating frequency of 15 and 30 Hz, and with needle probes positioned along the involved nerve roots at dermatomal levels corresponding to the patients' pain symptoms are more effective than PENS treatments with other treatment characteristics (level C).

Cost-effectiveness
Unknown (no studies were found on this issue)

Safety
Potential side effects for PENS are fainting, bleeding, wound infection, or even pneumothorax (Hsieh and Lee 2002). It is not clear how often these side effects occur as a result of PENS treatments. For obvious reasons PENS should preferably be applied by skilled and experienced physicians.

Subjects (indications)
Symptomatic pain relief in patients with non-specific low back pain.

Summary of evidence
- There is moderate evidence that PENS is more effective than sham PENS in the treatment of chronic low back pain (level B).
- There is conflicting evidence that PENS is more effective than other treatments in the treatment of chronic low back pain (level C).
- There is conflicting evidence that PENS treatments with 30 minutes duration of electrical stimulation, with an alternating frequency of 15 and 30 Hz, and with needle probes positioned along the involved nerve roots at dermatomal levels corresponding to the patients' pain symptoms are more effective than PENS treatments with other treatment characteristics (level C).

Recommendation
Consider PENS for symptomatic pain reduction in patients with chronic non-specific low back pain.

References

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6. White PF, Ghoname EA, Ahmed HE, Hamza MA, Craig WF, Vakharia AS **(2001)** The effect of montage on the analgesic response to percutaneous neuromodulation therapy. Anesth Analg, 92(2): 483-7.

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Chapter 11 (E) Radiofrequency denervation and electrothermal denervation procedures

Radiofrequency procedures, first introduced in 1975 (Shealy 1975), involve the application of current flow from an active electrode to a dispersive ground plate. The body's tissue completes the circuit, creating an electrical field. This electrical field and ionic motion leads to the creation of frictional heat dissipation, causing local tissue heating.
Recently this procedure has been questioned and another RF-technique, called "pulsed RF (PRF)", has been introduced to avoid damage to nerve fibres. However, the latter is not included in this review since to date no RCTs are available for this procedure.

The rationale for the use of radiofrequency (RF) procedures and also for intradiscal electrothermal therapy in low back pain is the assumption that these treatments can relieve pain by destroying the nerves innervating the relevant structures causing the pain (joints and discs, or the spinal ganglion itself).

C11 (E1) Radiofrequency Facet-Denervation

Definition of procedure
Radiofrequency facet joint procedure (neurotomy) consists of applying an RF procedure to the facet joint in order to destroy the nerves that supply it.
The rationale for this procedure is based on the assumption that cutting the nerve supply to the facet joints at special target points (junction between superior border of the transverse process and the lateral aspect of the superior articular process) will alleviate the pain

Result of search
Systematic Review
Two systematic reviews of RCTs on radiofrequency facet denervation were retrieved (Geurts et al 2001, Niemisto et al 2003).
The Cochrane review (Niemisto et al 2003) was used to formulate these recommendations, as it was the more recent of the two SRs (including studies up to April 2002, and all those considered in the previous review).
The Cochrane review included 4 studies of facet denervation (Gallagher et al 1994, Leclaire et al 2001, Sanders and Zuurmond 1999, van Kleef et al 1999).

Additional RCTs
No additional trials were found.

Quality assessment of the evidence
The included SR (Niemisto et al 2003) was of high quality.
Among the three considered RCTs, two were of high quality (Leclaire et al 2001, van Kleef et al 1999) and two were of low quality (Gallagher et al 1994, Sanders and Zuurmond 1999).

Effectiveness
Effectiveness of radiofrequency facet-denervation versus sham procedures
One study investigated 15 patients with facet denervation (lesion of rami dorsales L3-L5) and a control group (16 patients) (van Kleef et al 1999). The control group received the same procedure but without use of radiofrequency current. Patients were selcted for neurotomy procedure after positive (at least 50% pain reduction) ramus dorsali diagnostic block with lidocaine. Before treatment and 8 weeks after the

treatment VAS pain, Waddell impairment scale, number of analgesics, Oswestry scale, quality of life and globalperceived effect (7-point scale) were monitored. The rate of success (reduction in VAS pain) was higher in the lesion group (odds ratio of effect was 3.33 unadjusted to the effect of a previous diagnostic nerve block and 9.53 adjusted to it). The difference between the adjusted and unadjusted odds ratios was mainly caused by controlling for outcome after the diagnostic block: patients who were pain free after a diagnostic block had better results. There was a significant (p<0.01 for adjusted difference, p<0.05 for unadjusted difference) reduction in the Oswestry scale and in the global perceived effect (p<0.05). The other scales didn't change significantly.

A similar study design was used in another study to investigate 41 patients (30 patients neurotomy, 11 sham lesion) who had firstly undergone a diagnostic block ("in and around the joints followed by pain relief for 10 hours") (Gallagher et al 1994). They reported a minor change (p=0.05) in patients in the facet neurotomy group with respect to pain (VAS) after one and 6 months and with respect to the McGill score only one month after the lesion.

One study investigated 70 patients (36 neurotomy, 34 placebo lesion) who had had a successful intraarticular diagnostic block ("significant pain reduction for 24 hours") with lidocaine/Triamcinolone (Leclaire et al 2001). Minor (p=0.05) positive and short-term (4 weeks) improvements were observed for disability (Roland and Morris scale), but there was no effect on pain (VAS) and Oswestry scale. After 12 weeks neither functional disability nor pain showed any improvement.

There is conflicting evidence that RF denervation of the facet joints is more successful than placebo for eliciting short-term or long-term improvements in pain or functional disability in mechanical chronic low back pain (level C). Proper selection of the patients (successful diagnostic blocks) and an optimal technique may be importat to achieve better results.

Effectiveness of radiofrequency facet-denervation versus other treatments
In one study, two types of facet denervation were compared: intra-articular (PIFD; N=17 patients) and extra-articular (PEFD; N=17 patients) (Sanders and Zuurmond 1999). Before and 3 months after the lesion, VAS pain, functional health (COOP/WONCA) and Oswestry disability (function) were recorded. The VAS scores before and after treatment were respectively: PIFD, 6.3 (2.0) and 1.5 (1.7); and PEFD, 5.7 (2.3) and 3.9 (2.8) (difference between groups for reduction in pain, p<0.01). The two functional scores were also significantly better (p<0.01) after PIFD than PEFD.

There is limited evidence that intra-articular denervation of the facet joints is more effective than extra-articular denervation (level C).

Cost effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)

Patients with chronic facet pain. However, in practical terms, these patients are very difficult to define because there are no clinical tests of facet joint pain and there are a high proportion of positive results to placebo from the prognostic blocks.

Patients selected for facet denervation should firstly have a diagnostic block, twice, with a very low volume of anaesthetic (0.5 ml) at the target location; they should show consistent results with at least 80 % pain relief (Dreyfuss et al 2000).

Comments

1. Facet denervation may be indicated for cervical pain more than for lumbar pain. In contrast to RF procedures at the cervical facets, it seems that technical problems limit denervation of the lumbar facets because it is difficult to place the electrode parallel to the nerve, as needed for denervation in the lumbar area. Additionally, lumbar mechanical pain is seldom of pure facet origin.

2. A non-randomized study has suggested that there must be at least 80% pain relief from a diagnostic block before permanent denervation is indicated, and selection has to be strict in order to get really good results (Dreyfuss et al 2000). This was not done in one of the trials included in formulating these guidelines (Leclaire et al 2001).

3. There is a need for further high quality RCTs with larger patient samples, careful pre-selection of patients with diagnostic blocks, longer follow-ups, and meaningful standardized outcomes.

Summary of evidence

- There is conflicting evidence that RF denervation of the facet joints is more successful than placebo for eliciting short-term or long-term improvements in pain or functional disability in mechanical chronic low back pain (level C). Proper selection of the patients (successful diagnostic blocks) and an optimal technique may be importat to achieve better results.
- There is limited evidence that intra-articular denervation of the facet joints is more effective than extra-articular denervation (level C).

Recommendation

We cannot recommend RF facet denervation for patients with non-specific chronic low back pain.

References

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C11 (E2) Intradiscal Radiofrequency Thermocoagulation (IRFT) and Intradiscal Electrothermal Therapy (IDET)

Definition of procedure
Radiofrequency (RF) lesions not only target the rami dorsales to relieve facet pain, but also aim to reduce the nociceptive input from painful intervertebral discs. Percutaneous intradiscal radiofrequency thermocoagulation (IRFT) has been used for this purpose. In this procedure a RF cannula is placed in the center of the disc and a lesion is then made here.

Intradiscal electrothermal therapy (IDET[TM]) consists of heating the outer annulus of the intervertebral disc. A flexible intradiscal catheter with a temperature controlled thermal resistive coil is passed through a trocar into the annulus of the disc and is heated to a temperature of 70 degrees centigrade. This procedure has been developed as an alternate treatment to spinal fusion for patients with unremitting pain hypothesised to be caused by internal disc disruption (IDD). Much controversy surrounds the diagnosis of IDD (Biyani et al 2003, Carragee and Hannibal 2004, Wetzel et al 2002) (also see **Diagnosis**).

The biological effect of IDET is not well understood (Bono et al 2004, Freeman et al 2003a, Kleinstueck et al 2003, Wetzel et al 2002). The aims of the procedure are to destroy nociceptors and induce modulation and shrinkage of collagen in the outer annulus.

To date, there is no clear consensus regarding the effects on neuronal deafferentation, collagen modulation, or spinal stability. One study on cadaveric specimens (Kleinstueck et al 2003) showed that, except for a very limited margin (1.2 mm) around the catheter, the temperature does not reach the required level to induce collagen shrinkage within the disc. Temperatures sufficient to ablate nerves were developed in some areas but were not reliably produced in clinically relevant regions, such as the posterior annulus. These results suggest that beneficial clinical outcomes may be critically dependent on probe placement or other unknown factors.

Another study on human cadaveric specimens (Bono et al 2004) detected temperatures sufficient for collagen denaturation and nociceptive ablation at distances greater than those reported in the study of Kleinstueck (Kleinstueck et al 2003). A further study investigated intradiscal electrothermal therapy (IDET) in an ovine model in which posterolateral annular tears were induced experimentally (Freeman et al 2003a). IDET delivered at 90° C consistently heated the posterior annulus and the nucleus to a temperature normally associated with coagulation of nociceptors and collagen contraction. However, IDET did not denervate the posterior annular lesion. Thermal necrosis was observed within the inner annulus and the adjacent nucleus from 6 weeks after IDET. The authors concluded that the reported benefit from IDET appear to be related to factors other than denervation and repair.

Results of search
Systematic reviews
No systematic reviews were found.

Additional studies
Three RCTs were retrieved (Barendse et al 2001, Ercelen et al 2003, Pauza et al 2004).
One prospective cohort study of IDETwith historical or non-interventional groups as controls (Karasek and Bogduk 2000) and three retrospective cohort studies (Cohen et al 2003, Davis et al 2004, Saal and Saal 2002) were also identified. The latter

studies, although uncontrolled, provided useful information to consider in forming these recommendations, but they were not considered in arriving at the level of evidence.
One RCT on radiofrequency denervation of the ramus communicans nerve for chronic discogenic pain was found (Oh and Shim 2004).

Quality assessment,
Three RCTs (Barendse et al 2001, Ercelen et al 2003, Pauza et al 2004) were of high quality and one (Oh and Shim 2004) was of low quality.

Effectiveness
Effectiveness of IRFT or IDET vs. a sham procedure
One RCT compared the effects of IRFT denervation (N=13 patients) and sham IRFT (same procedure but without the use of radiofrequency current ; N=15) on short-term pain relief physical impairment, disability and quality of life (Barendse 2001). There were no differences in outcome between the groups (no relevant improvements in either group). A later study sought to examine different durations of radiofrequency thermocoagulation (120s vs 360s) in an attempt to examine their influence on the effectiveness of this method (Ercelen et al 2003). The authors found no significant difference between the application of lesioning for two different time periods (both methods were associated with a significant reduction in pain 1 month after treatment, with the effect disappearing in each group by 6 months).

The other RCT compared the effects of intradiscal electrothermal therapy (IDET) (N=37 patients) with sham IDET (same procedure without heating) (N=27 patients) (Pauza et al 2004). Patients in both groups exhibited improvements in VAS pain, Oswestry disability and quality of life (SF-36); improvements in pain and disability were slightly but significantly better in the IDET group. The number needed to treat with IDET to achieve 75% relief of pain was five. 50% of patients experienced no appreciable benefit.

There is conflicting evidence that procedures aimed at reducing the nociceptive input from painful intervertebral discs using either IRFT or IDET, in patients with discogenic low back pain pain, are not more effective than sham treatments (level C).

Effectiveness of IRFT or IDET vs. other treatments
One study investigated the effectiveness of a different method for causing disc denervation in patients suffering from chronic discogenic back pain, namely RF lesioning of the ramus communicans, which innervates the posterior part of the disc (Oh and Shim 2004). The lesion group (n=26 patients with one symptomatic level) received RF thermocoagulationand the control group (n=23), a lidocaine injection at the same side. Both groups were failed IDET patients. 4 months after treatment, the improvement in pain was significantly greater in the RF lesion group than in the control group.

There is limited (level C) evidence that RF lesioning of the ramus communicans is effective in reducing pain up to 4 months after treatment.

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Some complications have been reported: burning sensations in the legs, which resolved after several weeks; herniation of a disc treated with the procedure and development of radicular pain, numbness and paresis, which resolved after several weeks (Cohen et al 2003); and discitis (Davis et al 2004).

Subjects (indications)

At this stage, it is impossible to define patients in whom the procedure would be indicated, since it has no proven effectiveness; further, the patient selection procedures are unclear.

Comments

1. A second, randomized, double blind, placebo controlled trial (with a similar design to that described above (Pauza et al 2004)) was recently published in the form of a peer-reviewed abstract (Freeman et al 2003b) after presentation at the Annual Conference of the Spine Society of Europe. The study reported no difference between IDET and sham IDET with respect to the number of patients showing a clinically relevant improvement in pain or disability (no significant improvements in either group). Although the study appeared to be of high quality, since it has not yet been published as a full paper, it is impossible to formally rate it.

2. Three retrospective studies on IDET revealed good results after 6 months (Cohen et al 2003), 6 and 12 months (Karasek and Bogduk 2000) and 24 months (Saal and Saal 2002). However, a more recent study revealed particularly poor results for the procedure, with only 39% patients reporting less pain 1 year after the procedure compared with their pre-IDET status; 50% were dissatisfied with their outcome and the percentage of patients on disability remained constant (Davis et al 2004).

Summary of evidence

- There is conflicting evidence that procedures aimed at reducing the nociceptive input from painful intervertebral discs using either IRFT or IDET, in patients with discogenic low back pain pain, are not more effective than sham treatments (level C).
- There is limited evidence that RF lesioning of the ramus communicans is effective in reducing pain up to 4 months after treatment (level C).

Recommendation

We cannot recommend the use of intradiscal radiofrequency, electrothermal coagulation or radiofrequency denervation of the rami communicans for the treatment of either non-specific or "discogenic" low back pain.

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C11 (E3) Radiofrequency Lesioning of Dorsal Root Ganglion

Definition of the procedure
Percutaneous radiofrequency consists of partially lesioning the dorsal root ganglion, in order to destroy nerves responsible for chronic refractory radicular pain. This procedure was developed as an alternative to surgical rhizotomy.

Results of search
Only one RCT was retrieved (Geurts et al 2003).

Quality assessment of the evidence
The RCT was of high quality.

Effectiveness
Effectiveness vs. a sham procedure
One high quality RCT showed that, after 3 months, there was no difference between groups receiving either radiofrequency lesions of the dorsal root ganglion (n=45) or sham radiofrequency lesions (identical procedure, but without current) (n=38) for the primary outcome "success" or "failure" (as measured by changes in VAS leg pain, changes in daily physical activities and changes in use of analgesics) or for any secondary outcomes (pain intensity, daily physical activities, use of analgesics, quality of life). Treatment was "successful" in seven of 44 patients (16%) who received the radiofrequency lesion compared with nine (25%) of 36 who received control treatment (difference p=0.43) (Geurts et al 2003).

Effectiveness vs. other treatments
Unknown (no studies were found on this issue)

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
This procedure was not shown to be effective, so it is impossible to define indications. In theory, its use would only make sense for patients with radicular pain.

Summary of evidence
There is limited evidence that radiofrequency lesions of the DRG are not effective in the treatment of chronic LBP (level C).

Recommendation
We cannot recommend the use of RF lesioning of the dorsal root ganglion to treat chronic low back pain.

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C11 (F) Spinal Cord Stimulation (SCS)

Definition of procedure
SCS consists of implanting epidural electrodes transcutaneously and connecting them to a generator, which is internalized during a second procedure if the test stimulation is successful.
SCS has been used for treatment of postoperative back pain (so-called failed back surgery syndrome; FBSS) for more than 30 years, mainly to treat chronic radicular pain (Burchiel et al 1996).

Result of search
Systematic reviews
No systematic reviews on SCS for non-specific chronic LBP were retrieved by the search.

Additional studies
No additional trials were found.

Effectiveness
Effectiveness vs. a sham procedure
Unknown (no studies were found on this issue)

Effectiveness vs other treatments
Unknown (no studies were found on this issue)

Cost/effectiveness
Unknown (no studies were found on this issue)

Safety
Unknown (no studies were found on this issue)

Subjects (indications)
Not having shown evidence of effectiveness, it is not possible to define indications for spinal cord stimulation.

Comments
1) One high quality systematic review on the effectiveness of spinal cord stimulation (SCS) in relieving pain and improving function in patients with failed back surgery syndrome or complex regional pain syndrome (CRPS) was found (Turner et al 2004). It contained three (uncontrolled) prospective case series studies of SCS for failed back surgery syndrome (Dario et al 2001, Kumar et al 2002, Ohnmeiss et al 1996), which were all of low quality.It concluded that the literature on SCS for FBSS is too sparse to be able to make definitive statements about its effectiveness in reducing physical disability, work disability, and medication consumption in chronic LBP.
2) Two case-series studies (20 patients with a follow up 24-84 months (Dario et al 2001) and 40 patients with a follow up 12 and 24 months (Ohnmeiss et al 1996)) concluded that patients with FBSS improve significantly after SCS with regard to leg pain, but not back pain (NRS) and disability.
3) The review reported a complication rate of 34.3% (mean across all studies with SCS for CRPS or FBSS) (Turner et al 2004). Superficial infection was reported at a rate of 4.5%; equipment failure, 10.2%; stimulator revision, 23.1%; and stimulator removal, 11.0%. The most common adverse event was a stimulator revision (additional operation), most frequently due to a need to reposition the electrodes. Battery replacement was another reason for stimulator revision, but not mentioned as complication. Serious side effects were not reported.

4) One low quality study examined the cost-effectiveness of SCS (Kumar et al 2002). Patients who were referred for SCS but did not undergo electrode internalisation were used as controls. This group was treated with conservative pain therapy. The surgical group consisted of 60 patients and the control group of 40 patients. The authors reported cumulative costs for SCS over a five-year period of $29.123 compared with $38.029 for medical therapy. The type of medical therapy administered was not mentioned.
5) There is clearly a need for trials on SCS versus modern multidisciplinary pain management or versus opioid treatment in patients with chronic LBP due to FBSS.

Summary of evidence
There is no evidence on the effectiveness of spinal cord stimulation in patients with non-specific chronic low back pain (level D).

Recommendation
We cannot recommend the use of spinal cord stimulation for the treatment of chronic non-specific LBP.

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Chapter 11 (G) Surgery

Definition of procedure
The rationale for the use of surgery in chronic low back pain is the assumption that spinal segments demonstrating degenerative changes on imaging can lead to mechanical pain.
Usually surgeons tend to reject the global definition of non-specific chronic low-back pain and attempt to identify subgroups in the CLBP group of patients with presumed, and in part clinically defined, symptoms elicited by a degenerated segment, often described as segmental pain, often the sequelae of a disc herniation. Definitions such as degenerative disc disease, facet joint degeneration, spinal instability — which are not universally recognized as diagnostic entities — were therefore acknowledged in searching for evidence to formulate these recommendations, as was the term used for the Cochrane review, "degenerative lumbar spondylosis" (Gibson et al 1999). Surgery performed for more specific conditions (tumours, trauma, radicular and myelopathic syndromes) was not taken into consideration.
The surgical procedures are usually aimed at obtaining a solid fusion between two or more vertebral segments. This can be performed with a posterior, anterior, or combined approach. The surgeon can also use different types of commercially available instrumentation (spacers, cages, screws, hooks and rods), and supplemental bone from the same patient or others, or, more recently, synthetic bone and growth factors, to promote bone formation and the achievement of solid fusion (arthrodesis). As in other fields of medicine, in recent years there has been a trend towards minimally invasive spine surgery, and some of the new techniques have been considered in other sections of the guidelines; many other variants will no doubt be presented in the near future, but they will need to firstly undergo the same rigorous scientific scrutiny as the traditional ones. Another type of surgery that is potentially indicated in degenerative disc disease, and hence worthy of consideration in this review on non-specific LBP, is disc replacement surgery.

Result of search
Systematic Reviews
One systematic review on surgery for back pain was found (Gibson et al 1999). The review included 16 trials, none comparing any form of surgery for degenerative lumbar spondylosis with natural history, placebo, or conservative treatment. Most of the trials also included patients with specific conditions that were simply grouped together because of the surgical technique (fusion). Another systematic review (de Kleuver et al 2003) investigated the rationale for total disc replacement or disc prosthesis (searched Medline (1966 to January 2002), Cochrane, Current Contents and Cinahl). It included nine case series with a total of 564 arthroplasties in 411 patients. As the review did not identify any controlled trials, it was not considered further in summarising the evidence for these guidelines.

Additional RCTs
27 additional studies, reporting 15 RCTs, were identified from the search and the working group's knowledge of the literature.
Three RCTs, written up in 4 papers compared surgery for CLBP with conservative treatment (Brox et al 2003, Fairbank et al 2005, Fritzell et al 2001, Keller et al 2004); two of these also addressed the comparison of three different surgical techniques for CLBP (Fritzell et al 2003, Fritzell et al 2002) or evaluated cost-effectiveness of lumbar fusion vs. nonsurgical treatment for CLBP (Fairbank et al 2005, Fritzell et al 2004).

Two RCTs comparing lumbar artificial disc replacement with fusion were reported in 6 studies (Delamarter et al 2003, Geisler et al 2004, McAfee et al 2003a, b, Zigler 2003, Zigler et al 2003).

The remaining 13 articles reporting on 10 RCTs addressed the comparison of different surgical techniques to achieve a spinal fusion (Andersen et al 2003, Boden et al 2002, Boden et al 2000, Burkus et al 2002a, Burkus et al 2002b, Christensen et al 2002b, Johnsson et al 2002, Ma et al 2001, Madan and Boeree 2003, McAfee et al 2002, Sasso et al 2004, Thomsen et al 1997, Zhao et al 2002).

Quality assessment of the evidence
Systematic reviews
The systematic review was a Cochrane Review and methodologically of high quality (Gibson et al 1999). None of the trials included in the review compared any form of surgery with natural history, placebo, or conservative treatment. Therefore, none of the RCTs included in the review are useful for the scope of this chapter.

Additional trials
The three RCTs comparing surgery with conservative treatment (Brox et al 2003, Fairbank et al 2005, Fritzell et al 2004, Fritzell et al 2001, 2002, Keller et al 2004) were of high methodological quality, although minor flaws (or at least reasons for concern) could be found in all three. The inclusion/exclusion criteria and the control groups used differed somewhat and these studies were therefore addressed separately in the effectiveness section.
The trials on disc replacement (Delamarter et al 2003, Geisler et al 2004, McAfee et al 2003a, b, Zigler 2003, Zigler et al 2003) were of low methodological quality, had several methodological flaws, and constituted — to a certain extent — the repeated publication of the same material.
The surgical fusion trials compared: 360° fusion vs. posterior fusion in 1 high quality study (Christensen et al 2002b); 2 types of 360° fusion in 1 low quality study (Sasso et al 2004); anterior vs. posterior fusion in 1 study (Ma et al 2001) (in Chinese, only abstract could be evaluated); instrumented vs. uninstrumented fusion in 1 high quality longer follow-up (Andersen et al 2003, Christensen et al 2002a) of a previously reported study (Thomsen et al 1997); BMP vs. autograft bone in 3 high quality studies (Boden et al 2002, Boden et al 2000, Johnsson et al 2002) and 1 low quality study (Burkus et al 2002a, Burkus et al 2002b); 1 vs. 2 BAK cages in 1 low quality study (Zhao et al 2002); GRAFT ligamentoplasty vs. anterior fusion in 1 low quality study (Madan and Boeree 2003); complete vs. partial discectomy prior to fusion in 1 low quality study (McAfee et al 2002).

Effectiveness of surgery vs natural history, ineffective or sham treatment (placebo)
None of the systematic reviews or the additional trials directly addressed the effectiveness of surgery in comparison with natural history, ineffective or sham/placebo treatments. However, we considered the Swedish Lumbar Spine Study (Fritzell et al 2001) in this section, because it explicitly used as a control group patients who were treated with different kinds of physical therapy that were not specifically designed for this kind of patient, but rather reflected the non-surgical treatment policy at the time. Moreover, as one of the inclusion criteria for the study was "unsuccessful non-surgical treatment efforts", assignment to a control group that involved further use of these previously unsuccessful non-surgical treatments could only at best be considered a placebo treatment (and at worst, a nocebo). We therefore considered this treatment to reflect the "*natural treatment history*" of the condition.

In the Swedish Lumbar Spine Study, at the 2-year follow-up 289 of 294 (98%) patients, including 25 who had changed groups, were examined (Fritzell et al 2001). Back pain was reduced in the surgical group by 33% (64 to 43), compared with 7% (63 to 58) in the non-surgical group (P=0.0002). Pain improved most during the first 6 months and then gradually deteriorated. Different indices of disability were used: Oswestry scores reduced by 25% (47 to 36) in the surgical group compared with 6% (48 to 46) in the non-surgical group (P=0.015); Million index scores by 28% (64 to 46) and 8% (66 to 60) (P=0.004) respectively, and General Function Scores by 31% (49 to 34) and 4% (48 to 46) (P=0.005) respectively. ZUNG depressive scores were reduced by 20% (39 to 31) in the surgical group compared with 7% (39 to 36) in the non-surgical group (P=0.123). In the surgical group, 63% (122/195) rated themselves as "much better" or "better" compared with 29% (18/62) in the non-surgical group (P<0.0001). The "net back to work rate" was significantly in favour of surgical treatment: 36% vs. 13% in the non-surgical group (P=0.002).

Effectiveness of surgery vs conservative treatment
In the Norwegian study (N=64), at the 1-year follow-up, 97% of the patients were examined, including 6 who had either not attended treatment or had changed groups (four patients randomised to lumbar fusion did not have surgery, and two patients randomised to cognitive/exercises did not attend treatment (Brox 2003). The Oswestry Disability Index was significantly reduced from 41 to 26 after surgery, compared with 42 to 30 after the cognitive intervention and exercises. The mean difference between groups was 2.3 (-6.7 to 11.4) (P = 0.33). Improvements in back pain, use of analgesics, emotional distress, life satisfaction, and return to work were not different. Fear-avoidance beliefs and fingertip-floor distance were reduced more after the conservative treatment, and lower limb pain was reduced more after the surgical treatment, in each case significantly. The success rate according to an independent observer was 70% after surgery and 76% after cognitive intervention and exercises.
In the UK Medical Research Council trial (N=349), at the 2-year follow-up there was no clinical or statistical difference in outcome (pain, Oswestry disability, quality of life, SF36 physical or mental components) between spinal fusion and an intensive 3-week (15 day) programme of exercise therapy, spine stabilisation exercises and education using cognitive-behavioural principals (Fairbank et al 2005). The surgery results paralleled those reported in the other two trials (Brox 2003, Fritzell et al 2001).

Effectiveness of different surgical treatments vs each other
In the comparison of the three techniques in the Swedish Lumbar Spine Study (Fritzell et al 2003, Fritzell et al 2002), the following groups were analysed: Group 1 (posterolateral fusion; n = 73), Group 2 (posterolateral fusion combined with variable screw placement, an internal fixation device; n = 74), and Group 3 (posterolateral fusion combined with variable screw placement and interbody fusion; n = 75). The "circumferential fusion" in Group 3 was performed either as an anterior lumbar interbody fusion (n = 56) or as a biomechanically similar posterior lumbar interbody fusion (n = 19). All surgical techniques were found to reduce pain and decrease disability substantially, but no significant differences were found among the groups. In all three groups, the patients rated the overall outcome similarly, as did the independent observer. The more demanding techniques in Groups 2 and 3 consumed significantly more resources in terms of operation time, blood transfusions, and days in hospital after surgery. In this high quality trial, there was no obvious disadvantage in using the least demanding surgical technique of posterolateral fusion without internal fixation.
In the disc replacement trials, changes in pain and Oswestry Disability Index were not significantly different between disc replacement and fusion surgery at the mid-

term follow-ups (Delamarter et al 2003, Geisler et al 2004, McAfee et al 2003a, b, Zigler 2003, Zigler et al 2003).

Cost-Effectiveness
In the Swedish Lumbar Spine Study (Fritzell et al 2004), the societal total cost per patient (with standard deviations in brackets) in the surgical group was significantly higher than in the non-surgical group: Swedish kroner (SEK) 704,000 (254,000) vs. SEK 636,000 (208,000). The cost per patient for the healthcare sector was significantly higher for the surgical group, SEK 123,000 (60,100) vs. 65,200 (38,400) for the non-surgical group. All treatment effects were significantly better after surgery. The incremental cost-effectiveness ratios (ICER), illustrating the extra cost per extra effect unit gained by using fusion instead of non-surgical treatment, were: for overall improvement, SEK 2,600 (600-5,900); for back pain, SEK 5,200 (1,100-11,500); for Oswestry, SEK 11,300 (1,200-48,000); and for return to work, SEK 4,100 (100-21,400). The authors concluded that for both the society and the healthcare sectors, the 2-year costs for lumbar fusion were significantly higher compared with non-surgical treatment but all treatment effects were significantly in favour of surgery. The probability of lumbar fusion being cost-effective increased with the value put on extra effect units gained by using surgery. It most be noted that although different surgical techniques had different costs, all were grouped together in this article: using the non-instrumented PLF as a reference, costs increased by 66% when instrumentation was added, and 103% if an interbody procedure was also performed. The cost-effectiveness of interventions for chronic conditions probably requires a longer-term analysis.

In the MRC trial, at the 2-year follow-up, the treatment costs of the surgery arm were approximately twice those of the conservative arm. The costs of conservative treatment depend on how many patients opt for surgery afterwards (22% in this trial).

Safety
No information regarding clinically relevant complications was provided in the Cochrane review.
In the Swedish Lumbar Spine Study (Fritzell et al 2001), the early complication rate in the surgical group was 17%. 7 patients (10%) in the conservative group subsequently underwent surgical treatment before the 2-year follow-up. In the analysis of the three surgical subgroups, the early complication rate was 6% in Group 1, 16% in Group 2, and 31% in Group 3 (for group definitions see earlier). There was no association between clinical outcome and complications on a group level. The re-intervention rate was 6% in the PLF group, 22% in the VSP, and 17% in the "360" group (P=0.020). The odds ratio for requiring a re-intervention after instrumented fusion compared with non-instrumented fusion was 4.0 (95% confidence interval, 1.3-11.9).
In the Norwegian study (Brox 2003), the early complication rate in the surgical group was 18%.
In the MRC trial (Fairbank et al 2005), no complication rate was reported for the surgical group.
In one of the disc replacement studies (disc replacement vs fusion), the number of patients with major, minor, or other neurological complications was equivalent in the two groups (Geisler et al 2004). There was a greater incidence of both major and minor complications in the BAK fusion group at 0 to 42 days postoperatively.

Subjects (indications)
The inclusion criteria for the three RCTs comparing surgery with conservative treatment were different, in particular regarding the duration for which the patients had to have shown no response to conservative treatment: in the Swedish Study this was 2 years, and in the Norwegian and UK studies, 1 year.

All studies included only patients with maximum 2 affected levels.
Some efforts have been made to characterise patients who might ultimately benefit from a spinal fusion prior to their actually undergoing surgery. Methods used include external fixators, bracing, provocative injections, pain drawings, dynamic x-rays, discography and other more common imaging techniques. The usefulness of most of these methods remains unproven. There is conflicting evidence on the use of external fixation (Axelsson et al 1999, 2003, Bednar and Raducan 1996), and the contradictory results do not therefore allow a formal recommendation on the use of this technique. However, given the invasiveness and the non-reversibility of surgical procedures, it is strongly encouraged that more studies are performed in this direction.

Comments
1.   Even though all three RCTs on surgery vs conservative treatment used the Oswestry Disability Index (ODI) as the primary outcome measure, combining the results of the three studies is not directly possible because they used very different non-surgical comparison groups, and had different selection criteria for indicating surgery. In fact the Swedish and the MRC study did not exclude previous disc surgery, as the Norwegian did (presented separately, in the form of an abstract (Brox 2003)), and the inclusion criteria for the MRC study were procedure-driven (*"patients being considered for surgical stabilisation"*), rather than based on a common "diagnosis". The fact that the Norwegian study reported a significant difference in post-treatment leg pain in favour of the surgical group is also a reason for concern. Among other explanations, this might indicate the presence of some specific cause of leg pain that was treated successfully surgically; this might, in turn, indicate a selection bias in a group of patients that were supposed to have non-specific CLBP. Discrepancies in the power calculations used and in the estimates of clinically relevant change scores for the ODI are also detectable in the three studies. The Swedish "non-specific conservative care" may reflect the natural history of the condition in that country, rather than a specifically designed treatment alternative. The other two studies used a more extensive combination of cognitive intervention and exercises for the conservative treatment. The Norwegian study showed significant improvements in fear avoidance beliefs and fingertip-floor distance after non-operative treatment, whilst lower limb pain was better in the surgical group.
2.   The trials that addressed the comparison of different surgical fusion techniques included patients with specific conditions that were grouped together because of the surgical technique (fusion), rather than the indication. Therefore it was difficult to decide whether they should be included in a review on CLBP. On the other hand, there is no a priori reason to believe that fusion performed for a specific cause would have a different technical evolution. As most of the trials of different surgical techniques are not identified by a systematic search on low back pain, we concede that the evidence retrieved for this chapter might not be systematic enough to make a definitive statement on the single comparisons. In general, however, high quality trials failed to demonstrate any positive effect of more demanding and expensive surgical techniques. The interested reader might look for the next update of Cochrane review, which should be published soon and should incorporate the new trials with the 11 trials already included in the paper published in 2000 (Gibson et al 1999). In the latter review, the authors stated that any attempt to interpret the combined results must be cautious and tentative, because of the heterogeneity in patient selection and implants used in the different trials.
3.   We are also aware of an ongoing protocol for a Health Technology Assessment on the same topic (as above) for the Spanish Health authorities, and of a large multicentre study comparing disc replacement vs. cognitive intervention and exercises, started in May 2004 in Norway. The studies published to date on disc replacement often comprise the same basic material presented in various smaller papers: the results of multicentre RCTs are split to produce numerous interim and

sub-group analyses. This is a cause for concern. Considering that the sample size of the originally planned study can be nearly 10 times greater than that of the studies that are ultimately published, we fear this publication strategy may end up with the widespread acceptance of this new technology before it has undergone proper evaluation.

Evidence Summary
- There is limited evidence that in selected patients with severe CLBP and degenerative changes at L4-L5 or L5-S1 level, who have failed to improve with conservative treatment, surgery is successful in relation to improvements in functional disability (Oswestry) and pain up to 2 years after treatment when compared to traditional non-specific conservative treatment in Sweden (level C)
- There is moderate evidence that surgery is similar to a combined program of cognitive intervention and exercises provided in Norway or UK in improving functional disability (Oswestry) (level B)
- There is strong evidence that demanding, expensive and higher risk surgical techniques are not better than the most straightforward and least expensive surgical technique of posterolateral fusion without internal fixation (level A)
- There is conflicting evidence on the cost-effectiveness of surgery: it appeared to be slightly more cost-effective than (or equal to) traditional non-specific conservative treatment in Sweden, but twice as expensive as a combined program of cognitive intervention and exercises provided in UK, for which similar clinical results had been obtained (level C)
- The complication rate after surgery has been reported to be around 17-18% (6 to 31% depending on technique) with a 6-22% re-intervention rate.
- In the trials examined, 4-22% of patients allocated to the non-surgical treatment arms also underwent surgery.

Recommendation
We cannot recommend fusion surgery for CLBP unless 2 years of all other recommended conservative treatments have failed and combined programs of cognitive intervention and exercises are not available in the given geographical area. Considering the high complication rates of surgery, as well as the costs to society and suffering for patients with failed back surgery, we strongly recommend that only carefully selected patients with severe pain (and with maximum 2 affected levels) should be considered for this procedure.

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POTENTIAL CONFLICTS OF INTEREST

WORKING GROUP 2 (CHRONIC LBP)

This declaration of potential conflicts of interest has been signed by the following members of the COST B 13 Working Group on European guidelines for chronic low back pain:

I have not received and will not receive any economic or other type of support for myself or my research that constitutes any conflict of interest for any statement in these guidelines.

I am not currently or have not been previously hired by or supported by any organisation that receives financial benefits from the promotion of any specific treatments discussed in these guidelines.

Olavi Airaksinen
Jens Ivar Brox
Christine Cedraschi
Jan Hildebrandt
Anne Mannion
Jennifer Klaber Moffett
Schmuel Reis
Bart Staal
Holger Ursin

Francisco M. Kovacs has given this declaration (May 4th 2005)

I have received and will receive support for my research that may constitute a conflict of interest for any statement in these guidelines.

I am currently and have been previously supported by any organisation that receives financial benefits from the use of specific treatments discussed in these guidelines.

The following clarification has been added:

From 1987 to 2005, I have received grants for my research from the Spanish National Health Service, other Spanish governmental organizations (Consellería de Salut i Consum, Consellería d'Innovació, and Consellería de Educació i Sports, del Govern de les Illes Balears, and Instituto Nacional de Migración y Servicios Sociales), not for profit organizations (Spanish Red Cross, Fundacion Kovacs, Spanish National Organization for the Blind (ONCE) and the Fundacion ONCE) and two commercial companies, although none linked to the surgical or pharmaceutical industry (Flex -a Spanish mattress company- and ENDESA -a Spanish electrical utility company-).

I have received support for reporting results from my research from all of the organizations cited above, as well as from other public and not for profit organizations (Fundacion Rubio, Instituto Municipal de Investigaciones Medicas, and several medical associations). For this purpose, twice I have received indirect support from the surgical industry, although for presentations not related to the procedures which are mentioned in the Guideline (one presentation on the Spanish version of the Roland-Morris Questionnaire, and one on COST B13).

As a clinician, I receive money to treat private patients (honoraria from them). In that clinical practice, I use or prescribe most of the technologies which are recommended in this Guideline.

I am the Chair of the Fundacion Kovacs, which is a non remunerated position. The Fundacion Kovacs (www.kovacs.org) is a not for profit Spanish organization, with its own funding, devoted to medical research, health care and the promotion of public health. It has no links with the surgical or pharmaceutical industry, and it is supervised and audited by the Spanish Ministry of Education and Science. The Foundation has funded and is funding research on several of the technologies which are mentioned in the Guideline. The Clinics of the Foundation receive money to treat patients both from public (National Health Service) and private (honoraria from patients) sources, and they use and prescribe most of the technologies which are recommended in this Guideline.

Gustavo Zanoli has given this declaration of potential conflicts of interest (May 2, 2005):

I have received and will receive economic or other type of support for myself or my research that constitutes conflict of interest for statements in these guidelines.

I am currently and have been previously hired by or supported by organisations that receive financial benefits from the promotion of specific treatments discussed in these guidelines.

In detail, I received grants from the government and Italian NIH for preparing recommendations in the past, I received grants and invitations from surgical and pharmaceutical companies for lecturing and counselling in the field of LBP, as a surgeon and LBP expert I receive money to treat patients both from public (salary from university Hospital) as well as private (honorarium form insurances, patients) sources.

Appendix

Search strategy for the systematic reviews

Literature search, conducted 11.12.2001

Databases
1. Cochrane
2. Medline
3. Health Star
4. Embase
5. Pascal
6. Psychoinfo
7. Biosis
8. Lilacs
9. IME (Índice Médico Español)

Search Strategy:

1. Cochrane: **#**-1 Back pain.

2. Medline and Health Star:
   a) sensitive strategy:
   #1 (back pain) AND systematic[sb]
   #2 (back pain) AND systematic[sb] Field: All Fields, Limits: Publication Date from 1990
   b) specific strategy: Adding:
   #3 (back pain) AND systematic[sb] Field: All Fields, Limits: Publication Date from 1990, Review

3. Embase: #1 Back pain. De (MESH)
   #2 Low back pain. De (MESH)
   #3 1 OR 2
   #4 Systematic
   #5 3 and 4 (Limitado por Review y publicaciones desde 1990)

4. Pascal, Psychoinfo and Biosis:
   #1 Back pain
   #2 Low back pain
   #3 1 OR 2
   #4 Systematic
   #5 3 AND 4 (limit to Publication type"Review" and Publication Date since1990)

5. **Lilacs:** #1 dolor de espalda. [DE]
   #2 (lumbago) O lumbalgia. [TI]
   #3 (dolor) Y espalda. [TI]
   #4 #1 O #2 O #3
   #5 (revisión) Y sistemática.
   #6 #4 Y #5

6. IME: #1 (dolor de espalda) O lumbago O lumbalgia. [DE]
   #2 (dolor de espalda) O lumbago O lumbalgia
   #3 revisión sistemática
   #4 #1 Y #3

#5 #2 Y #3

RESULTS

	Total hits		
Cochrane	12		
Medline and Health Star			
"Specific":	121	5	excluded
		20	redundant
"Sensitive"	273	121	redundant with Medline specific
		14	excluded
		10	redundant
Embase	13	1	redundant
Pascal, Psychoinfo and Biosis	14	2	redundant
Lilacs	0		
IME	0		

**Typical subgroup search
(e.g. results for physical treatments and exercise)**

Embase

No.	Records	Request
1	9163	back pain
2	74295	randomized trial
3	458	#1 and #2
4	81	exercise and #3
5	44	training and #3
6	14	traction and #3
7	0	bracing and #3
8	29	manipulation and #3
9	14	massage and #3
10	8	heat and #3
11	5	cold and #3
12	4	ultrasound and #3
13	7	tens and #3
14	0	electrotherapy and #3
15	3	diathermy and #3
16	4	laser and #3
17	9	manual therapy and #3
18	4	TNS and #3
19	1	interferential therapy and #3
* 20	163	#4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19

Psychinfo

Search History

#20 #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 (6 records)

#19 interferential therapy and #3 and (PY=1995-2002) (0 records)

#18 TNS and #3 and (PY=1995-2002) (0 records)
#17 laser and #3 and (PY=1995-2002) (0 records)
#16 diathermy and #3 and (PY=1995-2002) (0 records)
#15 electrotherapy and #3 and (PY=1995-2002) (0 records)
#14 manual therapy and #3 and (PY=1995-2002) (0 records)
#13 tens and #3 and (PY=1995-2002) (0 records)
#12 ultrasound and #3 and (PY=1995-2002) (0 records)
#11 cold and #3 and (PY=1995-2002) (0 records)
#10 heat and #3 and (PY=1995-2002) (0 records)
#9 massage and #3 and (PY=1995-2002) (0 records)
#8 manipulation and #3 and (PY=1995-2002) (0 records)
#7 bracing and #3 and (PY=1995-2002) (0 records)
#6 traction and #3 and (PY=1995-2002) (0 records)
#5 training and #3 and (PY=1995-2002) (0 records)
#4 exercise and #3 and (PY=1995-2002) (2 records)
#3 #1 and #2 (6 records)
#2 randomized trial and (PY=1995-2002) (352 records)
#1 back pain and (PY=1995-2002) (645 records)