

TREATMENT OF LOW BACK PAIN: CLOSING THE GAP BETWEEN RESEARCH AND PRACTICE

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INTRODUCTION

The vast majority of all adults in industrial countries will experience an episode of low back pain sometime during their life. Low back pain is one of the most frequent reasons for visiting primary care physicians, and a large variety of therapeutic interventions are available and commonly used. Many health care providers from a variety of professional backgrounds are involved in the management of low back pain. Messages that patients get are often not consistent as views and preferences may vary across professions. However, also patients have their own beliefs and preferences.

Deyo [3] suggested that several myths circulate about low back pain:

If you have a slipped or herniated disk you must have surgery. Surgeons agree about exactly who should have surgery.

X-ray and newer imaging tests (CT and MRI scans) can always identify the cause of pain.

If your back hurts, you should take it easy until the pain goes away.

Most back pain is caused by injuries or heavy lifting.

Back pain is usually disabling.

Everyone with back pain should have a spine x-ray.

Bed rest is the mainstay of therapy.

More myths exist about treatment of low back pain than the last one suggested by Deyo. For example, physiotherapists may strongly believe in the effectiveness of specific back exercises, ultrasound and massage; McKenzie therapists in McKenzie therapy; chiropractors in spinal manipulation; acupuncturists in acupuncture; psychologists in biofeedback and relaxation techniques; anesthesiologists in injections; and orthopedics in

corsets and traction. Patients may strongly believe in any of these treatments, depending on previous experiences and on various sources of information (e.g., newspapers, magazines, the Internet, family and friends, or health care providers).

Myths may disappear if patients and health care providers are aware of the facts. During the last two decades, there has been a vast increase in the number and quality of randomized controlled trials (RCTs) and systematic reviews evaluating the effectiveness of various conservative treatments for LBP. Or in other words, more and more facts have been provided. Subsequently, a number of clinical guidelines for the management of LBP in primary care have been developed in various countries world-wide in which the evidence from trials and reviews has been translated into clinically relevant recommendations, thereby closing the gap between research and practice.

The field of LBP research in primary care is an excellent example of evidence-based medicine. At present, more than 300 randomized controlled trials (RCTs) have been published evaluating all types of conservative or complementary treatments for low back pain that are commonly used in primary care. The establishment of the Cochrane Back Review Group in 1997 was an important step forward to promoting systematic collection, review, and synthesis of the LBP literature [1]. Within the framework of the Cochrane Back Review Group method guidelines have been developed and published to improve the quality of reviews in this field and to facilitate comparison across reviews and enhance consistency among reviewers [10].

The present paper summarizes the evidence from systematic reviews on the effectiveness of conservative and complementary treatments for acute and chronic low back pain.

METHODS

Systematic reviews were conducted of the available literature. Although there are some subtle differences in the methods used, in general these reviews included identification and selection of studies, assessment of the methodological quality of the trials, data extraction and data analysis.

Study selection.

Studies were selected in electronic databases such as Medline, Embase and PsycLit, and the Cochrane Controlled Trials Register using the search strategy recommended by the Editorial Board of the Cochrane Back Review Group [10]. Additional studies were identified through reference checking. Usually study selection was limited to trials published in English, Dutch, German and French, but in some reviews also trials published in other languages (for example Polish) were included.

Methodological quality assessment.

The methodological quality of RCTs was assessed by two reviewers independently. The criteria that were used all related to the internal validity of trials: 1) concealment of treatment allocation, 2) randomization procedure, 3) withdrawal/drop-out rate, 4) co-interventions, 5) blinding of patients, 6) blinding of observer, 7) intention-to-treat analysis, 8) compliance, 9) similarity of baseline characteristics, 10) blinding of care provider. A consensus method was used to resolve disagreements and a third reviewer was consulted if disagreements persisted. In some of the reviews the authors were contacted for additional

information if the article did not contain sufficient information on the methodological criteria. If the authors could not be contacted or if the information was no longer available, the criteria were scored as 'unclear'. Methodological quality assessment was pilot tested on similar trials outside the field of LBP.

Data extraction.

Two reviewers independently extracted the data on characteristics of the study population (e.g. age, gender, type and duration of LBP), the interventions (type, intensity, frequency and duration), and outcomes (mean and standard deviation or proportion) using a standardized form.

Data analysis.

Clinical homogeneity was evaluated by exploring the differences between the RCTs with regard to study population, types of exercises and reference treatments, and outcomes and measurement instruments. If studies were considered clinically homogeneous with regard to study populations, interventions and outcomes, they were analyzed as sub-group.

If the studies provided sufficient data, a quantitative meta-analysis was performed in which pooled estimates of effect were calculated. The random effects model was used in case of statistically heterogeneous data and the fixed effects model in case of statistically homogeneous data.

If studies did not provide sufficient data to enable statistical pooling, a qualitative analysis was performed using a rating system for levels of evidence. The rating system consisted of four levels of scientific evidence which are based on the quality and the outcome of the studies:

- 1) Strong evidence - provided by generally consistent findings in multiple high quality RCTs.
- 2) Moderate evidence - provided by generally consistent findings in multiple low quality RCTs.
- 3) Limited or conflicting evidence - only one RCT (either high or low quality) or inconsistent findings in multiple RCTs.
- 4) No evidence - no RCTs.

High quality studies were usually defined as RCTs, which fulfilled 5 or more of the validity criteria. Sensitivity analyses were performed exploring the results when high quality was redefined using other thresholds. Sub-group analyses were conducted for a) acute low back pain (12 weeks or less) and chronic low back pain (more than 12 weeks), and b) low back pain with radiation and low back pain without radiation.

RESULTS

Systematic reviews

At present, 10 systematic reviews on LBP have been published in the Cochrane Library (Issue 1, 2001) regarding conservative or complementary treatments: acupuncture [12], back schools [13], bed rest [5], behavioral treatment [16], exercise therapy [15], injection therapy [8], lumbar supports [17], massage [4], multidisciplinary biopsychosocial rehabilitation [6], and NSAIDs [14]. The evidence for other conservative interventions comes from other systematic reviews of conservative treatments for low back pain [2, 7, 11, 18]. The evidence is summarized below.

Results acute low back pain

There is strong evidence that NSAIDs relieve pain more than placebo. Advice to stay active speeds up symptomatic recovery and reduces chronic disability. There is strong evidence that muscle relaxants relieve pain more than placebo, but potential side-effects, including drowsiness, have been reported. There is also strong evidence that bed rest and specific back exercises (strengthening, flexibility, stretching, flexion and extension exercises) are not effective, i.e., these interventions were not more effective than no treatment, some type of placebo or sham treatment or waiting list controls. There is moderate evidence that analgesics and spinal manipulation are effective for pain relief. There is no evidence that other interventions (e.g. lumbar supports, traction, massage or acupuncture) are effective for acute low back pain.

Results chronic low back pain

There is strong evidence that exercise therapy, behavioral therapy, and multidisciplinary pain treatment programs are effective for chronic low back pain, and moderate evidence for the effectiveness of analgesics, NSAIDs, spinal manipulation, and back schools. There is no evidence that other interventions (e.g. antidepressants, steroid injections, acupuncture and EMG biofeedback) are effective. However, effects are usually small and short-term effects only. Sufficient evidence on long-term effects is lacking.

GUIDELINES FOR THE MANAGEMENT OF LOW BACK PAIN IN PRIMARY CARE

Many RCTs and systematic reviews in the field of low back pain in primary care have been published. Scientific evidence from these sources forms the basis of recommendations in clinical guidelines. Since publication of the US (AHCPR) guidelines in 1994 [2], various clinical guidelines on the management of low back pain in primary care have been issued. At present, guidelines exist in at least 11 different countries: Australia, Denmark, Finland, Germany, Israel, Netherlands, New Zealand, Sweden, Switzerland, United States, United Kingdom. In general, the evidence is quite clear and recommendations in these guidelines are quite consistent:

Reassure patients (favorable prognosis)

Advise to stay active

Prescribe medication if necessary (preferably time-contingent): 1) paracetamol, 2) NSAIDs

- Discourage bed rest
- Consider spinal manipulation for pain relief
- Do not advise back-specific exercises

However, there are some discrepancies between guidelines, for example with regard to exercises or spinal manipulation. The US, Swiss and German guidelines do consider exercises as a therapeutic option whereas other guidelines do not recommend exercise therapy for acute low back pain. The Danish guidelines specifically mention McKenzie exercises as a therapeutic option, whereas all the others do not. The Dutch, Australian and Israeli guidelines do not recommend spinal manipulation for acute LBP, whereas the other guidelines recommend considering spinal manipulation for pain relief.

DISCUSSION

Although some people may have strong preferences for specific treatments and strong beliefs about their effectiveness and several myths about treatment of low back pain may still exist, the evidence is quite clear (Table 1).

- Fact is that only few commonly used treatments for acute low back pain are supported by strong evidence: advice to stay active, NSAIDs and muscle relaxants.
- Fact is that only few commonly used treatments for chronic low back pain are supported by strong evidence: exercise therapy, behavioral therapy, multidisciplinary treatment programs.
- Fact is that some commonly used treatments for acute low back pain are likely to be ineffective: bed rest, specific back exercises, traction.
- Fact is that some commonly used treatments for chronic low back pain are likely to be ineffective: facet joint injections, traction.
- Fact is that the effectiveness of many commonly used treatments for low back pain still remains unclear: acupuncture, electromyographic (EMG) biofeedback, lumbar supports, physical agents and modalities, transcutaneous electrical nerve stimulation (TENS).

Scientific evidence shows that an active approach to low back pain patients is effective. Various national guidelines for the management of low back pain in primary care have recommended this active approach.

Differences in recommendations between guidelines may be due to incompleteness of the evidence, different levels of evidence, magnitude of effects, side effects and costs, differences in health care systems (organization / financial), or differences in membership of guidelines committees. More recent guidelines may have included more recently published RCTs and, therefore, may end up with slightly different recommendations. Recommendations in guidelines are not only based on scientific evidence, but also on consensus. Guideline committees may consider various arguments differently, such as the magnitude of the effects, potential side effects, cost-effectiveness, and current routine practice and available resources in their country. Especially as we know that effects, if any, are usually small and short-term effects only, interpretation of effect may vary among guideline committees. Other aspects, such as side effects and costs, may be given more weight by one committee but less by another. The constitution of the guideline committee

and the professional bodies they represent, may introduce bias – either for or against a particular treatment. For example, the Dutch guidelines were developed by and for general practitioners. As general practitioners are not trained to provide spinal manipulation, a recommendation for manipulation would mean a recommendation for a referral to a manual therapist or chiropractor. Given the weakness of evidence, the small effect on pain relief, and the alternatives that general practitioners have for pain relief (e.g., NSAIDs), the committee that developed the Dutch guidelines decided not to include a recommendation for spinal manipulation in the general practitioners' guidelines. In the US guidelines, which were multidisciplinary, in which chiropractors were actively involved in the guideline committee, and where patients have direct and easy access to chiropractors, a recommendation for spinal manipulation was included. This does not necessarily mean that one guideline is better than the other or that one is right and the other is wrong. It merely shows that when translating the evidence into clinically relevant recommendations more aspects play a role, and that these aspects may vary locally or nationally.

The development of clinical guidelines should ensure that patients are treated according to the best available evidence and should lead to optimal patient outcomes. Good clinical guidelines should involve priority setting when identifying the subject of the guidelines. Shekelle et al. stated that guideline committees should include individuals from all relevant disciplines or stakeholders; that evidence should be provided through systematically reviewing the relevant literature; that the evidence should be translated into clinically relevant recommendations taking into account patients' and physicians' views and preferences, the impact on resources and the feasibility of the interventions; and that good guidelines should also receive external review from an expert panel [9]. However, good guidelines are no guarantee for ensuring their use in daily practice. Changing physician behavior is very complex and involves enhancing knowledge; changing values, beliefs, attitudes, and perception; providing necessary skills and resources; and providing support and feedback. Development, publication and dissemination of guidelines are not enough to change behavior of health care providers. Development of effective implementation strategies is needed. Implementation of clinical guidelines will be a major challenge for the near future.

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