

INCONSISTENT GRADING OF EVIDENCE ACROSS COUNTRIES: A REVIEW OF LOW BACK PAIN GUIDELINES

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ABSTRACT

Objective: The aim of this study was to report clinical treatment recommendations for low back pain (LBP) based on 5 international guidelines and best evidence from the Cochrane database of systematic reviews.

Methods: Five LBP guidelines available in English language were appraised, including 4 studies published since the seminal work by Koes et al (*Spine* 2001;26:2504-5213). The guidelines were examined for treatment recommendations concerning nonspecific LBP and guideline quality with application of the Appraisal of Guidelines for Research and Evaluation instrument. Secondly, a systematic literature search for reviews and randomized controlled trials was conducted using a modified version of the search strategy recommended by the Cochrane Back Review Group. Two systematic reviews were identified.

Results: According to best evidence from review of the Cochrane database of systematic reviews, there remains a lack of consensus regarding reported efficacy of spinal manipulative therapy for the treatment of nonspecific LBP. Furthermore, the guidelines reviewed in the present study have not changed significantly with respect to treatment recommendations for nonspecific LBP since the original review, and there is inconsistency between the guidelines regarding optimal time to introduce spinal manipulation to treat nonspecific LBP.

Conclusion: Treatment recommendations for nonspecific LBP, particularly spinal manipulation, remain inconclusive. Guideline developers need to consider guidelines in neighboring countries and reach consensus on how evidence is graded and incorporated into guidelines. Guidelines should continue to be regularly updated to incorporate new evidence and methods of grading the evidence. (*J Manipulative Physiol Ther* 2006;29:576-581.e2)

Key Indexing Terms: *Low Back Pain; Guidelines; Review Literature*

Low back pain (LBP) is a major health and economic problem with extremely high absenteeism costs to the economy.¹ Although most episodes of LBP are reported to be self-limiting,² the recommended treatment options are variable. Despite that expertise has improved in the sphere of LBP diagnosis and treatment, chronic disability arising from nonspecific LBP appears to be on the increase in Western society,³ and it is a major component of the general practitioner's consultations (prevalence of consulting rate).

This research critically appraised best evidence available in the Cochrane database of systematic reviews, available since 1999, to clarify uncertainty concerning treatment recommendations for nonspecific LBP and to also appraise the recommendations for treatment of nonspecific LBP in 5 LBP guidelines, 4 of which had been updated since the original study conducted by Koes et al.⁴

Discrepancies in treatment recommendations in current LBP guidelines would seem to reflect confusion with regard to best treatment. This was perhaps best shown in the findings from an international comparison of clinical guidelines for LBP, where LBP guidelines from 11 countries were compared, and treatment interventions considered effective for treatment of nonspecific LBP were presented.⁴

There was a question whether recommendations made by the authors of the original study had been addressed and whether subsequent reviewers of clinical guidelines had considered best evidence from the Cochrane database of systematic reviews, which was established after the research of Koes et al.⁴ Therefore, this recommendation became a key focus of this study. Spinal manipulative therapy (SMT) was chosen as an example of a therapeutic intervention because of its increasing popularity among patients with LBP. Clinical practice guidelines have been defined as, "...

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Table 1. Systematic reviews identified since the article by Koes et al⁴

Systematic reviews	Appropriate question	Methodology included	Literature search	Quality assessment	Homogeneity	Bias minimization	Direction bias	Study type	Relevance of review?
Assendelft et al ¹¹	1	1	1	1	1	+	—	RCT	No evidence that SMT is superior to other standard treatments for acute or chronic LBP
Bronfort et al ¹²	1	1	1	1	2	++	6	RCT	Recommendation can be made with some confidence that SMT and/or mobilization is a viable treatment option for LBP and neck pain.
Cherkin et al ¹³	1	1	3	3	3	+	—	RCT	Massage is effective for persistent back pain; SMT has small clinical benefits, which are equivalent to other standard treatments.
Ferreira et al ¹⁴	1	1	1	1	1	++	6	RCT	SMT produces slightly better outcomes than placebo; no treatment and short-wave diathermy for nonspecific LBP of <3-mo duration; SMT, exercise, and physiotherapy appear to produce similar outcomes in the first 4 wk of treatment.
Pengel et al ¹⁵	1	1	1	2	2	++	6	RCT	Review identified a major gap in the evidence for treatment interventions that are currently recommended in clinical practice guidelines; lack of uniform acknowledgment of and definition of subacute LBP in the guidelines as well as in the evidence

1, well covered; 2, adequately addressed; 3, poorly addressed; 4, not addressed; 5, not reported; 6, not applicable.
Direction of bias codes: ++, +, or —; if coded as + or —, it corresponds to the likely direction in which bias might affect the results.

systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.⁵

METHODS

The methods section comprises 2 parts, the first stage identified 5 LBP guidelines available in the English language and the Appraisal of Guidelines for Research and Evaluation (AGREE) guideline appraisal instrument (AGREE Collaboration, 2001)⁶ to appraise the quality of these guidelines, 4 of which were updated versions of the 11 guidelines appraised by Koes et al.⁴ The AGREE instrument was selected because it had been validated.

Search Strategy

Stage 2 identified systematic reviews and randomized controlled trials (RCTs), which were accessed through searches of the following electronic databases from 1999

to 2004: Cochrane Database of Systematic Reviews (Issue 1), MEDLINE, EMBASE, and DARE, using a modified version of the search strategy recommended by the Cochrane Back Review Group. The original search strategy proved to be too sensitive, identifying many studies unrelated to the topic under investigation and insufficient numbers related to it. Bibliographic sections of retrieved articles were also screened for studies, which might not have been otherwise identified in the search of the electronic databases.

A second more sensitive search was conducted of the following electronic databases from 2002 to 2004: the Cochrane Database of Systematic Reviews (Issue 2), MEDLINE, and EMBASE to retrieve RCTs and systematic reviews that had not been identified in the initial search. Again a modified version of the Cochrane Back Review Group search strategy was used, and search terms were modified to increase sensitivity of the search to include RCTs and systematic reviews from 2002 to 2004. The search strategy is presented in Appendix A.

Table 2. RCTs identified since the article by Koes et al⁴

Study	Method	Participants	Interventions	Outcomes	Results	Notes
Giles and Muller ¹⁶	RCT	115 Patients with uncomplicated LBP; duration: minimum of 13 wk; age: >17 y; treatment: at public hospital's multidisciplinary pain unit	Patients randomized to 1 of 3 intervention groups: 1. Medication 2. Acupuncture 3. Chiropractic spinal manipulation	Subjective measures: Oswestry questionnaire, Neck Disability Index, Short Form 36, Visual Analog Scale, pain frequency for all different spinal regions Objective measures: straight leg raise, lumbar range of motion, cervical range of motion	Patients with chronic spinal pain who received manipulation had greater short-term improvement than patients who had acupuncture or medication. However, study was small and needs to be evaluated with a larger study.	Main weakness of the study is that patients and treating clinicians could not be blinded. There were no data provided on the 12-mo follow-up questionnaires. The sample size was small.
Hurwitz ¹⁷	RCT	681 Ambulatory patients with LBP randomly assigned to 4 treatment groups	1. Medical care alone 2. Medical care with physical therapy 3. Chiropractic care alone 4. Chiropractic with physical modalities	a. LBP intensity b. LBP disability c. Medication use and disability days	After 6 mo of follow-up, both medical care and chiropractic care for LBP were comparable in effectiveness. Physical therapy may be marginally more effective than medical care alone for reducing disability in some patients, but possible benefits were small.	Well-designed study; blinding not possible; authors attempted to randomize patients in a well-designed manner to reduce bias; withdrawal and dropout cases were accounted for and described in detail.
Licciardone ¹⁸	RCT	91 Patients enrolled who met eligibility criteria (chronic LBP).	1. Osteopathic manipulation 2. Sham manipulation 3. Control group, no intervention, but allowed to continue with usual care for their LBP	1. Short Form 36 Health Survey 2. Visual Analog Scale 3. Roland-Morris Disability Questionnaire 4. Lost school/work days 5. Satisfaction with care	Osteopathic manipulation and sham manipulation appear to provide the same benefits when used in addition to usual care for treatment of chronic nonspecific LB P.	Study was not blinded. Randomization procedure was described fully. Withdrawal and dropout cases were accounted for.
Hsieh ¹⁹	RCT w/ assessor blinded	200 Patients who met eligibility criteria and ≥18 y of age, had LBP >3 wk but <6 mo duration for a current episode, or a pain-free period of at least 2 mo in the preceding 8 mo for recurrent LBP. Consented to treatment randomization	200 Patients randomized to a treatment group for 3 wk: 1. Back school 2. Joint manipulation 3. Myofascial therapy	1. Pain severity (Visual Analog Scale) 2. Activity level/function (Roland-Morris)	For subacute LBP, combined joint manipulation and myofascial therapy was as effective as joint manipulation or myofascial therapy alone. Back school was as effective as 3 manual treatments.	Sample size was small, which reduced the power of the study. There was no control group. Subacute LBP results only.

Data Extraction and Quality Appraisal

Five systematic reviews (Table 1) were reviewed, and data were extracted according to criteria outlined in the QUOROM statement for systematic reviewers.⁷ The quality of the extracted data were appraised and awarded scores, according to

the SIGN 50 checklist for systematic reviews and meta-analyses.⁸ The 4 RCTs (Table 2) identified were reviewed, and data were extracted according to methods recommended by the CONSORT Statement for reviewers of RCTs.⁹ Extracted data were appraised with a validated instrument.¹⁰

The AGREE Instrument

The AGREE instrument provides a framework for assessing the quality of clinical practice guidelines; this instrument is electronically available.⁶ The assurance of “quality,” in relation to a clinical practice guideline, implies that the care provider has confidence that the potential biases of guideline development have been addressed adequately and that the recommendations made are both internally and externally valid and can be implemented in the reality of the clinical practice setting. This process entails the assessment of benefits, harm, and costs involved in the dissemination and implementation of guideline recommendations. Hence, the AGREE instrument assesses the methods used for developing guidelines, content of the final recommendations, and the practical factors associated with their implementation. The instrument also assesses quality of reporting as well as the quality of some aspects of the recommendations made. Furthermore, it provides an assessment of the predicted validity of the guideline, but it does not assess the impact of the guideline on patient outcome.

RESULTS

The first search identified 2 major systematic reviews.^{11,12} The second more sensitive search identified 3 new systematic reviews¹³⁻¹⁵ and 4 RCTs.¹⁶⁻¹⁹

Updating Clinical Guidelines?

Overall, differences in treatment recommendations (concerning SMT) were subtle. The Swedish guideline, which had been updated since the earlier review by Koes et al,⁴ proposed the biggest change for the application of SMT in the treatment of LBP. The earlier version (2000) stated that SMT should be considered within the first 6 weeks (acute period) for patients who need additional help with pain relief or who are failing to return to normal activities. In contrast, the more recently updated guideline (2002) made no recommendation to use SMT as a treatment intervention for the acute phase of LBP, possibly because the guideline developers based their treatment recommendations on grade of recommendation “A,” which represents the highest level of evidence.

Apart from the Swedish guideline, very minor changes in treatment recommendations were apparent in the other 4 guidelines. However, the UK guideline was the only guideline to include subacute pain as a significant category or phase of LBP. The repercussions were clearly evident when one looks for example at the updated (2002) Swedish guideline, as treatment recommendations for SMT were based on level of evidence A. This meant that the treatment of acute LBP was excluded because evidence for this phase of LBP would have been based on grade of recommendation “B.” Meanwhile, the Danish guideline

(2000) based all of their treatment recommendations on a grade of recommendation B. However, the New Zealand guideline made treatment recommendations on grade of recommendation A. Yet, the Australian guideline (2003) made treatment recommendations based on level of evidence (I) and (II), which again departs not only from a level of evidence upon which to base treatment recommendations but also from a unanimous system of grading the evidence in the first instance.

DISCUSSION

Our study showed that there is insufficient evidence to suggest that the 5 LBP guidelines reviewed should be updated based on best evidence (1999-2004). Inconsistencies in the evidence suggest that there is continuing conflict of opinion regarding: efficacy of SMT for treatment of nonspecific or uncomplicated LBP; optimal time in which to introduce this treatment approach; whether SMT is useful for treatment of chronic LBP; and finally, whether subacute LBP actually exists as a separate category requiring a specific treatment approach in its own right. Furthermore, there are continuing inconsistencies in the evidence with respect to the potential economic advantages of using SMT because it has been stated that its effects are no better, or worse, than those reported in trials where usual medical care and other conventional methods have been used. However, such ambiguity could be explained by lack of a unanimous method of appraising the evidence, which could affect treatment recommendations made.

Koes et al⁴ suggested that there were no obvious clues as to why this variation presented; they suggested that these inconsistencies reflect the diverse settings, cultural practices, and socioeconomic influences in a country. Another likely contributing factor could have been representativeness of professional groups on the respective guideline committees, which, if not well balanced, could have affected decisions made regarding treatment recommendations. This may reflect,²⁰ “... professional autonomy relationships and the weight given to different forms of evidence.”

The most surprising finding, and a factor that casts some doubt on the reliability of the recommendations made, was that the levels of evidence and/or grades of recommendation used for formulating treatment recommendations varied so significantly between countries. This lack of standardization would seem to suggest a lack of consensus and adherence to the prescribed methodological rigor normally required for guideline development. Therefore, there would seem to be an urgent need to standardize how best evidence should be graded before formulating treatment recommendations for guideline development. At the present time, there appears to be a lack of consensus where different methods are used (grades of recommenda-

tion and levels of evidence), which is confusing and casts some doubt on whether a guideline can be trusted.

When it comes to appraising the evidence with regard to complementary medicine interventions such as SMT, perhaps the time has come to consider that the RCT is less able to show the efficacy of this particular intervention. Other research designs could be considered; perhaps one could suggest a fusion of qualitative and quantitative research designs, or a more pragmatic approach may be required, where clinical trials are conducted in the clinical setting itself, with patients receiving SMT in their usual treatment environment. A recent example of how this treatment intervention can be appraised is shown by the UK Beam Trial Team in 2004.²¹

CONCLUSION

In conclusion, this study showed that the treatment of LBP remains as ambiguous as before and that the way best evidence is being interpreted could play a large role in this. In the future, more rigid criteria will need to be put in place for guideline developers to help ensure that guideline recommendations concerning the efficacy of SMT for the treatment of LBP carry a reduced risk of bias and greater promise of reliability and validity. We recommend that future reviewers of clinical guidelines should examine the influence that studies excluded during systematic reviews may have on the direction of treatment effects and how this could impact recommendations made in guidelines. Furthermore, consensus needs to be reached with regard to which method should be unanimously used to grade the evidence, such that consistency of reporting will be achieved.

Practical Applications

- Treatment recommendations for LBP remain inconsistent.
- Consensus needs to be reached with regard to methodology used to grade evidence to improve consistency of reporting.
- The AGREE instrument is a useful tool to inform on guideline quality.
- Comparing guidelines across countries needs to take into consideration cultural and social influences on choice of treatment recommendations.

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APPENDIX A. SEARCH STRATEGIES

Cochrane Library (Issue 1, 2004)

1. Cochrane Database of systematic reviews for all completed reviews and protocols with low back pain in the title (15 completed reviews and 4 protocols retrieved)
2. Database of abstracts of reviews of effects (32 retrieved)
3. Health Technology Assessment Database (19 retrieved)

MEDLINE search

1. exp Low Back Pain/
2. systematic review.mp.
3. meta-analysis.pt
4. 1 and (2 or 3)
5. Limit 4 to yr = 1999-2004

EMBASE search

1. exp Low Back Pain/
2. systematic review.mp
3. (meta-analysis or metaanalysis).mp. [mp = title, abstract, subject headings, drug trade name, original title, device manufacturer, drug manufacturer name]
4. 1 and (2 or 3)
5. Limit 4 to yr = 1999-2004

Updated search strategies conducted in June 2004

A search conducted to identify new RCTs in MEDLINE, EMBASE, and the Cochrane Library since 2002 and for new systematic reviews in MEDLINE and EMBASE since 2002

Cochrane Library (Issue 2, 2004)

Searched for all RCTs on low back pain in the Cochrane Library published since 2002

1. (low:ti next back:ti next pain:ti)
 2. LOW BACK PAIN explode all trees (MeSH)
 3. (#1 or #2)
 4. #3 (2002 to 2004)
- MEDLINE

This is the search strategy recommended by the Cochrane Back Review Group. It proved to be too sensitive and retrieved too many.

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized controlled trials/
4. random allocation/
5. double-blind method/

6. single-blind method/
7. 1 or 2 or 3 or 4 or 5 or 6
8. limit 7 to animal
9. limit 7 to human
10. 8 and 9
11. 8 not 10
12. 7 not 11
13. clinical trials.pt.
14. exp clinical trials/
15. clin\$ with trial\$.tw.
16. placebos/
17. placebo\$.tw
18. random\$.tw.
19. exp research design/
20. 13 or 14 or 15 or 16 or 17 or 18 or 19
21. limit 20 to animal
22. limit 20 to human
23. 21 and 22
24. 21 not 23
25. 20 not 24
26. comparative study/
27. exp evaluation studies/
28. follow-up studies/
29. prospective studies/
30. (control\$ or prospective\$ or volunteer\$).tw.
31. Cross-Over Studies/
32. 30 or 21
33. exp Low Back Pain/
34. 32 and 33
35. limit 34 to yr = 2002-2004

Modified search strategy (used to identify RCTs in MEDLINE)

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized controlled trials/
4. random allocation/
5. double-blind method/
6. single-blind method/
7. 1 or 2 or 3 or 4 or 5 or 6
8. animal/
9. human/
10. 8 and 9
11. 8 not 10
12. 7 not 11
13. exp Low Back Pain/
14. 12 and 13
15. limit 14 to yr = 2002-2004

EMBASE Searches

As for MEDLINE, the recommended strategy for RCTs (below) was too sensitive.

1. Clinical Article/

2. exp Clinical Study/
3. Clinical Trial/
4. Controlled Study/
5. Randomized Controlled Trial/
6. Major Clinical Study/
7. Double Blind Procedure/
8. Multicenter Study/
9. Single Blind Procedure/
10. Crossover Procedure/
11. PLACEBO/
12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
13. allocat\$.ti,ab.
14. assign\$.ti,ab.
15. blind\$.ti,ab.
16. (clin\$ adj25 (study or trial)).ti,ab.
17. compar\$.ti,ab.
18. control\$.ti,ab.
19. cross?over.ti,ab.
20. factorial\$.ti,ab.
21. follow?up.ti,ab.
22. placebo\$.ti,ab.
23. prospective\$.ti,ab.
24. random\$.ti,ab.
25. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
26. trial.ti,ab.
27. (versus or vs).ti,ab.
28. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
29. 12 or 28
30. Human/
31. Nonhuman/
32. ANIMAL/
33. Animal Experiment/
34. 31 or 32 or 33
35. 30 and 34
36. 29 not 34

37. 29 and 35
38. 36 or 37
39. exp Low Back Pain/
40. 38 and 39
41. 38 and 39
42. limit 41 to yr = 2002-2004

Modified search strategy (used to identify RCTs in EMBASE)

1. Randomized Controlled Trial/
2. (random\$ adj3 trial).mp. [mp = title, abstract, subject headings, drug trade name, original title, device manufacturer, drug manufacturer name]
3. 1 and 2
4. low back pain.mp.
5. 3 and 4
6. limit 5 to (English language and yr = 2002-2004)

Searches for new systematic reviews

MEDLINE search for new systematic reviews

1. meta-analysis.pt.
2. meta-analysis.tw.
3. systematic review.mp.
4. exp Low Back Pain/
5. (1 or 2 or 3) and 4
6. limit 5 to yr = 2002-2004

EMBASE search for new systematic reviews

1. Meta Analysis/
2. meta-analysis.tw.
3. systematic review.mp.
4. exp Low Back Pain/
5. (1 or 2 or 3) and 4
6. limit 5 to yr = 2002-2004