A systematic review of efficacy of McKenzie therapy for spinal pain

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Introduction

The McKenzie method is popular amongst physiotherapists as a management approach for spinal pain (Battie et al 1994, Foster et al 1999, Hurly et al 2000). The McKenzie method utilises an assessment process which aims to identify subgroups of patients within the non-specific spinal pain population whose symptoms behave in a similar way when subjected to mechanical forces. The classification into subgroups then directs treatment (McKenzie and May 2003). A key aspect of the McKenzie approach is that the patients receive individualised treatment based upon their clinical presentation.

At present the efficacy of McKenzie therapy is unclear. Many clinical trials that purport to evaluate McKenzie treatment provide treatment in a generic rather than individualised fashion, and include elements not part of the McKenzie approach. For example in the trial by Stankovic and Johnell (1990) all patients in the McKenzie group received the same treatment: extension exercise for two weeks then commencement of flexion exercise. Whilst extension is commonly the direction of movement that is prescribed, other patients are prescribed flexion or lateral movements (McKenzie and May 2003). In a trial by Delitto and colleagues (1993), which was described as using the McKenzie method, a sacroiliac joint manipulation procedure was part of the ‘McKenzie’ treatment whereas this treatment technique is not described in either the first or second edition of the McKenzie lumbar spine text (McKenzie 1981, McKenzie and May 2003). Accordingly some trials that appear to evaluate McKenzie therapy may not be valid indicators of the efficacy of the McKenzie method as described in McKenzie’s texts (McKenzie 1981, McKenzie 1990, McKenzie and May 2003).

While a number of narrative reviews (Rebbeck 2002, Maher et al 1999, Danish Institute for Health and Technology Assessment 1999) have concluded that the McKenzie method is effective for low back pain, the conclusions of systematic reviews are preferred as they theoretically provide less biased estimates of the effects of therapy. Additionally these existing reviews do not provide a quantitative analysis and so do not reveal information on the size of the treatment effect. Accordingly we felt it was appropriate to undertake a new review.

The aim of this systematic review was to investigate the efficacy of the McKenzie method of management of non-specific spinal pain. The specific questions to be investigated were:

1. What is the comparative efficacy of McKenzie therapy in relation to inactive treatment (placebo or sham) or no treatment?
2. What is the comparative efficacy of McKenzie treatment in relation to other standard therapies (including non-physiotherapy treatment)?

For this systematic review we chose to exclude studies with co-interventions so that the efficacy of McKenzie therapy could be investigated more clearly. Similarly, trials where the treatment was contrary to McKenzie principles were excluded.
Method

Criteria for considering trials for the review  To be included, a study had to fulfil several criteria. Only randomised or quasi-randomised controlled trials were accepted. There were no language restrictions. Subjects of all age groups and of either gender were included. Studies were included if the subject’s primary complaint was non-specific low back pain or neck pain with or without radiation to the extremities. Trials that recruited patients with the following specific spinal pathologies were excluded: cauda equina syndrome, cord compression, infection, fracture, neoplasm, inflammatory disease, pregnancy, any form of headache, whiplash-associated disorders, vertigo/dizziness, and vertebro-basilar insufficiency. Any duration of symptoms was allowed.

Trials of primary prevention, where the subjects were symptom-free at the time of the trial, were excluded. For the clinical trial to be included it needed to investigate the efficacy of the McKenzie method/McKenzie treatment in comparison to no treatment, sham treatment, or another treatment. Trials where McKenzie therapy was provided with a co-intervention were excluded.

Three criteria were used to describe the study regarding the McKenzie therapy. Studies were required to meet Criteria 1 and 2 to be included in the review:

- Trial specifies individualised patient treatment.
- Trial specifies treatment according to the McKenzie principles.
- Trial specifies that the treating therapists had formal training in the McKenzie method.

Trials were required to have reported at least one of the following outcome measures: pain, disability, quality of life, work status, global perceived effect, medication use, medical visits, or recurrence.

Identification and selection of studies  The following databases were searched up to September 2003: MEDLINE, EMBASE, DARE, CINAHL, PEDro, the Cochrane Register of Clinical Trials (CENTRAL), and the Cochrane Database of Systematic Reviews. Search words used were McKenzie therapy, McKenzie treatment, McKenzie method. Titles and abstracts of the search output were inspected by the primary author and clearly ineligible papers were deleted. Full copies of potentially eligible papers were retrieved and two reviewers independently screened these trials using the criteria described above. Members of the McKenzie Faculty were contacted, and the reference list of the McKenzie Institute was inspected to locate additional papers. Unpublished articles were included if they met the criteria for inclusion.

Studies meeting the eligibility criteria were assessed for methodological quality using the PEDro scale (Maher et al 2003). PEDro scores were extracted from the PEDro database and where an article had not previously been scored it was reviewed and scored by an experienced PEDro rater.

Data extraction  Data were independently extracted from each included study by two investigators using a standardised data extraction form. Disagreements were resolved by consensus.

In trials with more than two treatment groups, the treatment contrast thought to be of more relevance to current Australian physiotherapy practice was selected. In the Cherkin et al (1998) study the educational booklet vs McKenzie contrast was selected (rather than McKenzie vs chiropractic) and in the Kjellman and Oberg (2002) study the McKenzie vs general exercise contrast was selected (rather than McKenzie vs low dose ultrasound).

Data were extracted for ‘short term’, ‘intermediate’, and ‘long term’ follow-up based upon the criteria advocated by the Cochrane Back Review group (van Tulder et al 2003). Short term follow-up was defined as less than three months from randomisation, and if there were multiple eligible time points the time point closest to six weeks was chosen. Intermediate was defined as greater than three months and less than 12 months from randomisation. If there were multiple eligible time points the time point closest to six months was chosen. Long term was greater than or equal to 12 months. If there were multiple eligible end points we chose the time point closest to 12 months.

Data analysis  Pain and disability scores were transformed to a score ranging from 0 to 100. To describe the effect of treatment for individual studies we calculated the mean and 95% confidence interval for the between-group differences (Herbert 2000). Between-group differences in either end points or within-group change scores were used according to the data provided in each trial (Green et al 2001). Where numerical data were not provided they were interpolated from graphs provided. Where the standard deviation was not provided, we calculated it from the 95% confidence interval or standard error (Roberts 1991, Cherkin et al 1998, Gillan et al 1998) or if there were no data available to do this, we estimated it as one quarter of the range (Petersen et al 2002, Schenk et al 2003).

For continuous data we estimated the size of the treatment effect (the difference between group means) and its 95% confidence interval. For each trial that presented dichotomous data we estimated the size of the treatment effect as the relative risk, along with the 95% confidence interval. Trials with similar outcome measures and time points were grouped together for pooling. We used a random effects model to obtain pooled estimates of the difference between groups and ran a test of statistical heterogeneity of the trial outcomes. The analyses used algorithms taken from Fleiss (1993).

Table 1. Sources of references.

<table>
<thead>
<tr>
<th>Database searched</th>
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<td>McKenzie Institute reference list/McKenzie Faculty</td>
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Results

Twenty-four publications were retrieved with six trials eligible for inclusion in the review (Cherkin et al 1998, Gillan et al 1998, Kjellman and Oberg 2002, Petersen et al 2002, Roberts 1991, Schenk et al 2003). The yield from each database is shown in Table 1. The eighteen excluded papers and the reasons for exclusion are listed in Table 2. Fifteen studies were ineligible because they did not meet the inclusion criteria and three were excluded because we were unable to retrieve data (one author unable to be contacted, two authors contacted who stated they could not access original data). Five of the eligible trials studied patients with low back pain whilst one reported on neck pain (Kjellman and Oberg 2002).

Assessment of outcome From the low back pain trials, three provided data on changes in pain in the short term (Cherkin et al 1998, Petersen et al 2002, Schenk et al 2003) but none provided data beyond this. Five trials reported data on short-term disability (Roberts 1991, Cherkin et al 1998, Gillan et al 1998, Petersen et al 1998, Schenk et al 2003) whilst two reported data for intermediate disability (Cherkin et al 1998, Petersen et al 2002). No long-term pain or disability data were provided. Data on work absence between three and 12 months were provided in two studies (Cherkin et al 1998, Petersen et al 2002). The pain, disability, and work absence data were pooled. Data provided that were unable to be pooled because they were provided in a single trial included: reduced activity, number of recurrences (Cherkin et al 1998), number using pain medication, number visiting general practitioner, and global change (Petersen et al 2002) (Table 3).

In the study that recruited cervical patients (Kjellman and Oberg 2002) data were provided on changes in pain intensity, the number reporting continuous pain, and changes in disability in the short, intermediate, and long term. The number of patients seeking health care was also provided for the first six months and for the six to 12 month period.

Methodological quality of the individual trials The methodological quality of each trial is described in Table 4. The total PEDro scores ranged from four (Gillan et al 1998) to eight (Cherkin et al 1998). The most common methodological flaws were failure to blind the patient and the therapist (six out of the six trials), however this would be difficult to achieve in a trial evaluating McKenzie therapy. Failure to blind the assessor occurred in four of six studies and failure to explicitly use an intention to treat analysis occurred in four of six studies.

Treatment efficacy The effect sizes of the individual lumbar trials and pooled results are shown in Table 5. None of the tests for statistical heterogeneity was significant (all $p > 0.10$). At short term follow-up, for both pain and disability outcomes, the individual trial results mostly favoured McKenzie therapy. Both pooled results revealed a statistically significant, though small, between-group difference.
At intermediate follow-up the between-group differences of most individual studies and the pooled result for disability were small and not statistically significant. Work absence at the intermediate time point favoured McKenzie therapy but the effect was not statistically significant.

In the cervical study the McKenzie group had less pain and disability at short and intermediate follow-up however the effect sizes were small and not statistically significant. The effects on pain were: -8.0 (-21 to 5) and -2.0 (-15 to 11). The effects on the Neck Disability Index were: -5.0 (-13.2 to 3.2) and -2.0 (-10.7 to 6.7). The McKenzie group had fewer health care contacts in the following 12 months than the exercise groups (relative risk 0.86, 0.29 to 2.54) however the effect was not statistically significant.

**Sensitivity analysis** To determine if excluding trials where...
improved,’ and 28 points for ‘very much improved.’

improved,’ 17 points was the best cut-off for ‘much

improvement of 10 points most accurately detected patients

who considered themselves to be at least ‘minimally

improved,’ 17 points was the best cut-off for ‘much

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Accordingly an effect size of the order of 10 points, as we

found for pain in the short term, could be considered

worthwhile because it would be sufficient to move a patient

from ‘minimally improved’ to ‘much improved,’ or from

‘much improved’ to ‘very much improved.’

The long term effects of McKenzie therapy on pain outcomes

in patients with low back pain are uncertain because no study

provided data beyond three months. The data on disability

suggest that effect on disability reduction is not clinically

relevant because the upper estimate of the treatment effect,

reduction in disability of 4.5 points out of 100, is probably too

small to be judged as worthwhile by patients. However

judging what effect sizes for disability reduction are clinically

worthwhile is difficult because there is no study analogous to

Farrar et al (2000) for disability outcomes. The effect of

McKenzie therapy on work absence is unclear because only

two studies reported data for work absence, both measured

outcome at intermediate follow-up, and the individual studies

and the pooled result provide very imprecise estimates of the

effect.

We did not set a minimum quality score for inclusion in the

review but instead planned to look at the relationship between trial

quality and outcome. However because so few studies

were located it was judged not to be worthwhile to proceed with this analysis. All of the trials included for analysis scored above the minimum PEDro score of three set by Ferreira and colleagues in their review of spinal manipulative therapy (Ferreira et al 2002). Inspecting the individual quality items reveals that most studies fared less well on the validated quality items (randomisation, concealed allocation, blinding).

While it is hard to achieve therapist and patient blinding in trials of McKenzie therapy, blinding of assessors should be achievable. Concealed allocation is also achieved relatively easily, e.g. through the use of sealed opaque envelopes containing the allocation codes.

In general the studies suggest that McKenzie therapy is more effective than the comparison treatment at short term follow-up. The comparison treatments in the trials included NSAIDS, educational booklet, back massage and back care advice, strength training, and spinal mobilisation and general mobility exercises. We felt that it was appropriate to pool data from these trials because they are all considered contemporary treatments for spinal pain. With our strict inclusion criteria we have studies that are more homogeneous with regard to the experimental treatment than is usually the case in systematic reviews because we excluded trials where co-interventions were permitted and also those trials that did not provide McKenzie therapy consistent with McKenzie’s

Table 4. Methodological quality of trials (PEDro score).

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<th>Study</th>
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<td>Cherkin 1998</td>
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PEDro items: 1 Eligibility criteria; 2 Random allocation; 3 Concealed allocation; 4 Comparability at baseline; 5 Patient blinding; 6 Therapist blinding; 7 Assessor blinding; 8 At least 85% follow-up; 9 Intention to treat analysis; 10 Between-group statistical comparisons; 11 Point measures and measures of variability. Item 1 not included in PEDro score

Discussion

Using pre-defined selection criteria, most of the results from individual studies and the pooled results reveal that McKenzie therapy was statistically significantly more effective than other treatments in reducing pain and disability at short term follow-up. Our results suggest that McKenzie therapy provides on average 8.6 point greater short term pain reduction (pain measured on a 0 to 100 point scale) than other conservative treatments. The sensitivity analysis revealed a slightly greater effect of 11.4 points.

Given these results the issue is whether the greater pain reduction associated with McKenzie therapy, of the order of 10 points on a 0 to 100 point scale, is clinically worthwhile. Judging what is a clinically worthwhile effect is made difficult by the fact that there are little data available to inform the decision. In the 2001 study by Farrar et al, 2700 patients with chronic pain participating in trials of drug therapy were asked to rate their pain (originally on a 0 to 10 scale but transformed to 0 to 100 to allow comparison to our review) at baseline and follow-up. They also rated their global impressions of improvement at follow-up on the following scale: very much worse, much worse, minimally worse, no change, minimally improved, much improved, very much improved. Farrar et al (2001) reported that a pain improvement of 10 points most accurately detected patients who considered themselves to be at least ‘minimally improved,’ 17 points was the best cut-off for ‘much improved,’ and 28 points for ‘very much improved.’ Accordingly an effect size of the order of 10 points, as we found for pain in the short term, could be considered worthwhile because it would be sufficient to move a patient from ‘minimally improved’ to ‘much improved,’ or from ‘much improved’ to ‘very much improved.’

individualised treatment was not provided affected the results, a sensitivity analysis was conducted including the data from these trials (Nwuga and Nwuga 1985, Stankovic and Johnell 1990, Underwood and Morgan 1998). Two of the studies reported data on short-term pain (Nwuga and Nwuga 1985, Underwood and Morgan 1998), and one on short-term disability (Underwood and Morgan 1998) which were pooled with the other low back pain trials. Other data which could not be pooled were long-term pain and disability (Underwood and Morgan 1998), recurrence at one year and number on sick leave at one year (Stankovic and Johnell 1990). The pooling of these data with the other low back pain trials did not significantly alter the conclusion of the review, with the short-term pain effect increasing slightly to -11.4 (-17.2 to -5.6) and short-term disability increasing to -5.6 (-8.3 to -2.9) with both effects favouring McKenzie.

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texts. Finally, the pooled results and the individual trial results were very similar and none of the tests of statistical heterogeneity was significant.

Assessment for suitability prior to the provision of treatment is an essential element of the McKenzie method, with analysis of ‘directional preference’ the key to the management (McKenzie and May 2003). If a mechanical evaluation is not performed prior to commencing the study and suitability determined, those patients for whom the McKenzie method is not suitable will not have been detected. This approach is analogous to a manipulation trial excluding patients who have contraindications to manipulative therapy. Only one study in the review adopted this approach. In the Schenk et al (2003) trial potential subjects were screened and only those with derangement syndrome entered the trial. While the effects of treatment appeared larger than in other trials we feel that it would be premature to make a conclusion on this issue based upon one study.

Another characteristic of the McKenzie approach is that patients receive individualised treatment. There is some evidence provided recently that this approach to treatment is more effective than a generic treatment (Fritz et al 2003, Long and Donelson 2003). We investigated this, by conducting a sensitivity analysis including three trials that did not provide individualised treatment, but otherwise satisfied our inclusion criteria. The pooled results from the sensitivity analysis were similar to our original results where these trials were excluded. Further research is required to determine whether treatment is more effective when patients are sub-classified based on directional preference prior to randomisation and individualised treatment provided during the study.

In the studies reviewed, all the therapists who took part had received at least some training in the McKenzie method. In one study (Gillan et al 1998) the therapist providing the treatment had attained a Diploma in Mechanical Diagnosis and Therapy (360 clinical hours of training) and was a teacher of the McKenzie method. In the other four low back pain studies the majority of the therapists were credentialled in the McKenzie method (i.e. had undertaken a minimum of 98 hours training in the McKenzie method and passed an examination on the material). In the cervical study the therapists were not credentialled in the McKenzie method but had undertaken a minimum of 70 hours of training. Accordingly it is difficult to comment on the effect of level of therapist training.

Reviews of treatments for low back pain suggest that some treatments appear more effective for acute low back pain than for chronic low back pain. For example manipulative therapy is more effective in the acute phase (Ferreria et al 2002, Australian Journal of Physiotherapy 2004 Vol. 50 214).
Ferreira et al 2003) while exercise is more effective for chronic symptoms (van Tulder et al 2001). We did not initially set out to determine whether the efficacy of McKenzie therapy is related to the chronicity of symptoms, as McKenzie’s texts do not suggest that the therapy is more effective for a particular sub-group. We did attempt a post hoc investigation of this issue however there were insufficient trials in each stratum of symptom duration to permit this. While three studies investigated patients with acute low back pain (Gillian et al 1998, Roberts 1991, Cherkin et al 1998) only one study investigated patients with sub-acute acute symptoms (Schenk et al 2003) and only one investigated chronic low back pain (Petersen et al 2002).

In the studies reviewed no distinction was made between patients with back pain only and those with pain radiating into the lower limb. The proportion of patients with leg pain varied significantly, ranging from 70% (Roberts 1991) to 10% (Cherkin et al 1998) and this is of interest because the presence of leg pain at low back pain onset has been shown to be associated with poor outcomes (Carey et al 2000, Thomas et al 1999). The classification system recommended by the Quebec task force (Spitzer et al 1987) divides patients into different groups based upon the presence and extent of leg pain. Other systems of classifying patients with low back pain (e.g. Bigos et al 1994, Waddell et al 1996) divide patients with nerve root compromise into a separate classification from simple back pain. In two of the six trials, patients with nerve root compromise were excluded (Roberts 1991, Petersen et al 2002); in two more of the trials it was unclear whether these patients were excluded (Cherkin et al 1998, Gillan et al 1998), and in one trial patients with nerve root compromise were included. What is not yet clear from the literature is whether these patients with nerve root compromise or patients with radiating leg pain require different treatment from those with simple back pain. In this review there was no trial that recruited patients with only lumbar or cervical radiculopathy, therefore it is not possible to comment on its efficacy for this particular subgroup of patients. Further research is required in this area.

Conclusion

This review shows that for low back pain patients McKenzie therapy does result in a greater decrease in pain and disability in the short term than do other standard therapies. Making a firm conclusion on low back pain treatment effectiveness is difficult because there are insufficient data on long term outcome, or on outcomes other than pain and disability, and no trial has yet compared McKenzie to placebo or to no treatment. There are also insufficient data available on neck pain patients to determine the efficacy of the McKenzie method for cervical pain. Further research which addresses these issues is required.

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