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Does the inclusion of spinal manipulative therapy in multimodal treatment regimens result in better outcomes in chronic low back pain? A systematic review

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and Michael Ogonnia Ekwu**

Abstract

Low back pain (LBP) is the most common musculoskeletal disorder. It is costly, both health wise and socioeconomically. Spinal manipulative therapy (SMT) is a popular and well researched conservative management of chronic LBP. However, little is known about its role cum effectiveness as part of multimodal treatment regimens. The aim of this systematic review is to examine the evidence of the effectiveness of SMT as part of a multimodal regimen in the management of chronic LBP. Eligible studies were identified by searching Medline, Embase, PEDro, CINAHL, AMED, and the Cochrane Central Register of controlled trials. Randomized controlled trials (RCTs) on patients with chronic mechanical LBP were considered. Data from four RCTs (430 participants) were included in this review. All four had a low risk of bias. Three studies found a statistically significant improvement in pain and function at both short term and long term in the group that received SMT as part of a multimodal treatment regimen. Heterogeneity in the nature of the interventions that made up the treatment regimen, comparison interventions, duration of treatment and follow-up periods were identified. There is moderate quality evidence that the addition of SMT to multimodal treatment regimens for chronic LBP results in better outcomes in terms of pain and function as compared to other conservative interventions.

Keywords

Systematic review, low back pain, multimodal treatment regimes, manual therapy, spinal manipulative therapy

Introduction

Low back pain (LBP) is the most common musculoskeletal disorder.¹ It is costly, both health wise and socioeconomically.² Although the prevalence varies in different parts of the world, it is high enough to be considered a global problem. Louw et al. indicate a mean point prevalence of 32%,³ and a one year prevalence of 62% in Africa. As one of the most common reasons for seeking medical attention,⁴ and the highest outpatient physical therapy referral,^{5–7} LBP has been extensively studied. Current evidence shows that diverse factors may contribute to LBP. LBP is generally divided into two groups: mechanical and non-mechanical LBP.

Mechanical LBP forms the majority of all cases and can be defined as LBP that cannot be attributed to a recognized or known pathology.⁸ It is estimated that about 80% of the general population suffer from LBP once in their lifetime. However, it becomes chronic in only about 7–10% of cases.⁹

LBP is considered chronic if it persists for more than 12 weeks.¹⁰ Chronic LBP has been linked to both physical and psychological deconditioning that results in decreased physical performance, exacerbated nociceptive sensations, increasing anxiety levels, depression, impaired social functioning and work disability.¹¹ Patients with chronic mechanical LBP account for 75–90% of the socioeconomic cost of LBP;^{12,13} hence the need for optimal interventions to

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manage appropriately so as to lessen both the associated disability and economic burden.

Spinal manipulative therapy (SMT) is described as a 'hands-on' treatment directed towards the spine, which includes both manipulation and mobilization techniques.¹⁴ It is often used by physiotherapists, chiropractors, osteopaths and other health professionals who use non-invasive methods to rehabilitate musculoskeletal dysfunction. It has been shown to be an effective intervention for patients with chronic LBP even though it has received varied recommendations in clinical guidelines because of conflicting evidence underlying its usage in practice.^{14,15} Proposed effects of SMT include pain relief, increase in joint range of motion and stretching of soft tissue.^{16,17} As a single intervention, systematic reviews have shown SMT to be more effective than advice, back care education,^{18,19} placebo and electrotherapy. However, in clinical practice, it is highly unlikely that a patient who presents with chronic LBP will be treated with a single intervention. In actual clinical practice, a multimodal treatment regimen is often used during rehabilitation. Clinical trials have investigated the effect of multimodal treatments in managing chronic LBP inclusive of SMT. However, this has not been systematically reviewed. Therefore, this review was conducted to answer the following questions:

- How effective is SMT as part of a multimodal regimen in the management of chronic LBP?
- Is there a particular intervention that SMT works best with?

Methods

Eligibility criteria

Randomized controlled trials (RCTs) written in English that had adult patients between the ages of 18 and 65 with no gender restriction were considered for inclusion. Participants had to be diagnosed with chronic mechanical LBP, which was defined as symptoms located 'between the inferior margin of the twelfth rib and the inferior gluteal folds, with or without radiation to the lower extremity that had been present for 12 weeks or more.'²⁰ Patients with serious spinal pathologies such as inflammatory joint diseases, infections, metastases, osteoporosis, neoplasms or fractures were excluded. Studies that included pregnant women and patients who have had spinal surgery were also not considered for this review. Studies were considered if they included the following comparisons: SMT must have been administered as part of a multimodal treatment regimen such as SMT and electrotherapy or exercise. The comparison group must not have included SMT in their treatment, i.e. studies with SMT in both treatment arms were not included. The primary outcome measures considered were pain using either the Numeric Rating Scale or the Visual Analogue Scale (VAS) and back-related function (measured by either the Roland-Morris or Oswestry Disability Questionnaires).

Literature search

A computer-based search was performed up to September 2015 in six databases: Medline, Embase, CINAHL, AMED,

the Cochrane Collaboration's Register of Clinical Trials and PEDro.

The key search terms used were low back pain, sciatica, lumbago, manual therapy, SMT and mobilization. Search terms were appropriately combined for each database. The complete search strategy from Embase is shown in the Appendix.

Grey literature available electronically from clinical trials registers such as US Clinical Trials database and the World Health Organization International Clinical Trials Registry Platform (ICTRP) were also searched to locate any other relevant trial. In addition, a comprehensive examination of reference lists from retrieved articles was performed.

Study selection

The titles and abstract of each article was screened. Studies were eliminated if they did not meet the inclusion criteria. Full articles were obtained to assess if the study fulfilled the inclusion criteria.

Data extraction

Data were extracted from the selected studies (see summary in Table 2), specifically, the study design, study purpose, experimental and comparison interventions, number of subjects in each group, follow-up intervals and outcome measures used. The outcomes of interest were pain and back-related function.

Quality assessment

The included studies were critically appraised using the JBI-MASARI critical appraisal tool for RCTs.²¹ The JBI-MASARI critical appraisal tool for RCTs utilizes a 10-point scoring system to assess the methodological quality of RCTs. The individual trials were screened with the JBI-MASARI questions, and accorded a yes (Y), no (N) or unclear (?). Each yes was counted as one, while no and unclear were counted as zero. The maximum criterion was 10; high quality was meeting more than five criteria. Two investigators (OA and CM) independently assessed each study. If a disagreement in scores occurred, the investigators discussed the study's quality to reach a consensus on the final score. Table 1 shows the quality assessment of all the studies included in this review.

Data synthesis

The heterogeneity of the individual RCTs did not allow the results to be combined through meta-analysis; therefore, the results are described narratively.

Results

Study selection and description

The database search produced a total of 228 studies. The titles and abstracts were screened for relevance, and over 90% (204) were found not relevant to the review topic. 12 duplicates were highlighted and removed. 12 of these articles had a high probability of relevance. The full articles of these

Table 1. Methodological quality.

Authors, year	Was the assignment to treatment groups truly random?	Were participants blinded to treatment allocation?	Was allocation to treatment groups concealed from the allocator?	Were the outcomes of people who withdrew described and included in the analysis?	Were those assessing the outcomes blind to the treatment allocation	Were control and treatment groups comparable at entry?	Were groups treated identically other than for the named interventions?	Were outcomes measured in the same way for all groups?	Were outcomes measured in a reliable way?	Was appropriate statistical analysis used?	Total	Risk of bias
Niemisto et al., ²² 2003	Y	N	Y	?	Y	Y	Y	Y	Y	Y	8	Low
Mohseni-Bandpei et al., ²³ 2006	Y	N	Y	?	Y	Y	N	Y	Y	Y	7	Low
Rasmussen et al., ²⁴ 2008	?	Y	Y	Y	Y	N	Y	Y	Y	Y	8	Low
Balthazard et al., ²⁵ 2012	Y	?	Y	?	Y	?	Y	Y	Y	Y	7	Low

articles were then retrieved and assessed for inclusion. Four RCTs met the eligibility criteria, and made up the systematic review. The flow chart of the search process and study selection is provided in Figure 1.

The four RCTs that make up the review had a total of 430 participants, and investigated SMT as part of a multimodal treatment regimen for managing chronic LBP. The SMT techniques delivered in each study differed. The SMTs utilized includes lumbar manipulation (high velocity low amplitude thrust), passive accessory intervertebral movements (PAIVM) and muscle energy techniques. The ages of the participants ranged from 18 to 65 years. All of the studies had exercises as part of the multimodal treatment regimen. One of the studies compared a multimodal regimen to physician consultation, another to ultrasound therapy and two to exercise. All the studies were of high quality with a JBI-MASTARI score of 7–8 (Table 1).

All the studies had participants with duration of symptom onset of 3 months or more, indicating that the condition was chronic. The studies had variable timelines for outcome assessments and ranged from immediately post-intervention to 12 months after the start of the intervention. Table 2 shows the individual study characteristics.

Due to the heterogeneity of the interventions, comparison groups and follow-up periods, a meta-analysis of results was not performed. It has been recommended that a meta-analysis should only be carried out if statistical and clinical heterogeneity are at a barest minimum.^{26,27} Therefore, a narrative synthesis was carried out with the aim of describing and comparing the findings as regards the outcomes of interest. This is presented in Table 3.

The overall quality of evidence for pain and disability was rated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.²⁸ This is shown in Table 4.

Pain

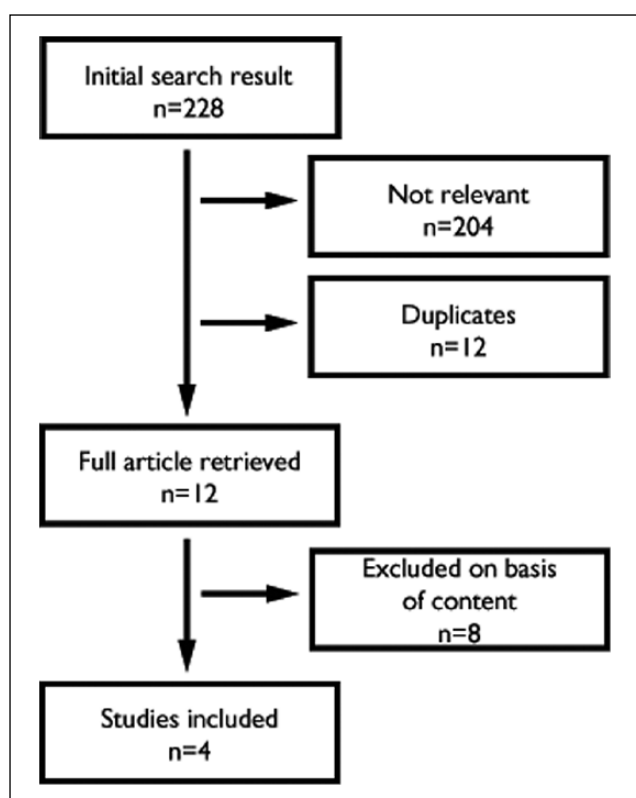
All the included studies reported pre-intervention and post-intervention pain values using the visual analogue scale. There was considerable variability among studies as regards time of follow-up, so the pain data were not collapsed for analysis. Of the four studies, three reported a statistically significant improvement in pain in favour of the group that had SMT as part of their treatment regimen. The study by Rasmussen et al. was the only study that reported no statistically significant improvement in terms of pain.²⁴ The authors compared SMT and extension exercises to extension exercises alone and reported no significant difference between the two groups at 4 weeks or 1 year ($p = 0.773$ and 0.776 respectively).

For short-term improvement, Niemisto et al. reported a significant improvement in pain in the group that had SMT;²² the reduction in pain was also significantly higher than that of the comparison group ($p < 0.001$). The study compared stabilizing exercises, physician consultation and SMT to physician consultation alone.²² Balthazard et al. also reported a significant reduction in pain immediately after treatment in the SMT group (SMT and active exercises) ($p = 0.032$);²⁵ this was also significantly higher ($p = 0.032$) than the comparison

Table 2. Characteristics of included studies.

Study, country	Population	Intervention	Control/comparison group	Follow-up	Outcomes
Niemisto et al., ²² Finland	n = 204 24–46 years LBP of up to 3 months duration	n = 102 SMT, exercises, and physician consultation	n = 102 Physician consultation Exercises	5 and 12 months	VAS OLBPQ
Mohseni-Bandpei et al., ²³ United Kingdom	n = 112 18–55 years LBP of >3 months duration	n = 56 SMT and exercise 2–7 sessions, average of 4	n = 56 Ultrasound therapy and exercise 3–11 sessions, average of 6	Immediate and 6 months	VAS OLBPDQ
Rasmussen et al., ²⁴ Denmark	n = 72 18–60 years LBP of >3 months duration	n = 35 Extension exercise, SMT	n = 37 Extension exercises	4 weeks and 1 year	VAS
Balthazard et al., ²⁵ Switzerland	n = 42 20–65 years LBP duration 12–26 weeks	n = 22 8 sessions of SMT, back care education, active exercises	n = 20 8 sessions of back care education and active exercises	3 and 6 months	VAS OLBPDQ

VAS: Visual Analogue Scale; OLBPDQ: Oswestry low back pain disability questionnaire; SMT: spinal manipulative therapy; LBP: low back pain.

**Figure 1.** Flow chart of study selection.

group (detuned ultrasound and active exercise). This improvement was sustained at the 3-month follow-up point.

Three of the studies reported long-term improvement.^{22,23,25} Niemisto et al. reported a statistically significant reduction in favour of SMT ($p < 0.001$) at 5 months follow-up.²² This improvement was sustained at 12 months follow-up period ($p < 0.001$) in favour of the SMT group. Mohseni-Bandpei et al. reported a significant increase at the 6 months follow-up period in favour of the SMT group

($p = 0.001$),²³ although both groups reported a significant improvement. Balthazard et al. also reported a significant reduction in pain at 6 months in the SMT group as compared to the comparison group (detuned ultrasound) ($p = 0.032$).²⁵

Disability (back-specific functional status)

Only three of the four reviewed studies reported pre-intervention and post-intervention disability values.^{22,23,25} They all made use of the Oswestry low back pain disability questionnaire. All the three studies reported a statistically significant improvement in functional status in favour of the SMT group (Table 2). Niemisto et al. reported a significant difference in function in the SMT group after treatment,²² at 5 months follow-up and at the end of the 1-year follow-up period ($p < 0.001$). The improvement was also significantly higher in the SMT group as compared to the comparison group ($p < 0.001$). Mohseni-Bandpei et al. showed a statistically significant improvement in functional improvement in the SMT group at 6 months follow-up (mean 8%, 95% CI 2–13, $p = 0.001$).²³ Balthazard et al. also reported a significant improvement in the SMT group immediately post treatment,²⁵ at 3 months and at 6 months follow-up periods ($p = 0.013$).

Discussion

Summary of main results

This systematic review sought to assess the effectiveness of SMT when used as part of a multimodal treatment regimen in the management of chronic mechanical LBP. The results of this systematic review indicate that SMT may be utilized in the management of chronic mechanical LBP as part of treatment regimens to reduce pain, and improve function. Three of the four included RCTs concluded that there was a statistically significant improvement in terms of pain and back-specific

Table 3. Comparison of findings for the outcomes of interest.

Study, outcome measure	Time	Pain score mean (SD or 95% CI)			Disability score mean (SD or 95% CI)		
		Group 1	Group 2	p-value	Group 1	Group 2	p-value
Niemisto et al., ²² VAS, OLBPQ	Immediate	59.5(21.2)	53.3 (21.2)	<0.001*	29.5 (9.7)	28.8 (8.7)	<0.001*
	5 months	25.2 (23.3)	36.1 (23.3)	<0.001*	14.9 (11.6)	18.6 (11.6)	<0.001*
	12 months	25.7 (23.3)	32.2 (23.3)	<0.001*	13.7 (11.6)	16.5 (11.6)	<0.001*
Mohseni-Bandpei et al., ²³ VAS, OLBPQ	Baseline	65 (19)	63 (19)	NS	30.8 (12.7)		NS
	6 months	37.9 (27.7–48.1)	22.8 (12.4–33.2)	0.001*	16.7 (11.1–22.3)	11.5 (5.6–17.3)	0.019*
Rasmussen et al., ²⁴ VAS (0–10)	Baseline	5 (3–6)	5 (3–6)	0.733			
	4 weeks	3 (1–4)	3 (1–4)	0.733			
	1 year	2 (1–3)	2 (1–3)	0.733			
Balthazard et al., ²⁵ VAS, OLBPQ	Baseline	53 (20)	65 (22)		30 (13)	32 (14)	
	Immediate	28 (11)	41 (29)		20 (15)	26 (15)	
	3 months	18 (17)	42 (32)	0.032*	16 (14)	26 (21)	0.013*
	6 months	23 (17)	38 (32)		16 (11)	26 (25)	

95% CI: 95% confidence interval; NS: not significant; *: statistically significant, i.e. $p > 0.05$; Group 1: Experimental group; Group 2: Comparison; VAS: Visual Analogue Scale; OLBPQ: Oswestry low back pain disability questionnaire.

Table 4. Summary of findings.

Does the inclusion of spinal manipulative therapy in multimodal treatment regimens result in better outcomes in chronic low back pain?

Patient or population: Patients with chronic neck pain

Setting: Hospital

Intervention: Spinal manipulative therapy (SMT) included in multimodal treatment regimens

Comparison: Any other conservative management

Outcomes	Impact	No. of participants (studies)	Quality of the evidence (GRADE)
Pain intensity (pain) assessed with: Visual Analogue Scale follow-up: range 4 weeks to 12 months	Three of the four included studies showed statistically significant reduction in pain in favour of the group that had SMT as part of their treatment regimen. One study reported no statistically significant reduction in pain levels in the multi-modal SMT group.	430 (4 RCTs)	⊕⊕⊕○ Moderate ^{a,b}
Disability (back-specific functional status) (disability) assessed with: Oswestry low back pain disability questionnaire follow-up: range 3 months to 12 months	All the studies reported statistically significant improvement in functional status in favour of the SMT group.	358 (3 RCTs)	⊕⊕⊕○ Moderate ^{a,b}

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

^aParticipants in majority of the studies were not blinded to treatment groups; ^bNarrative synthesis was conducted, estimates therefore not precise.

functional status both at short-term and at long-term follow-up.

Despite the high quality of the individual RCTs as graded by the JBI-MASTARI, this review can only provide moderate level evidence that the addition of SMT to treatment regimens for patients with chronic LBP is effective. The small number of studies, the considerable heterogeneity in the treatment regimens that SMT was combined with, and the differences in the nature of the SMT techniques applied contributed to this. Therefore, the result of this systematic review has to be considered with some caution.

All the studies had exercise as a part of the treatment regimen SMT was included in. This suggests that exercise may be a popular adjunct to SMT in clinical practice. However, the exercises varied in the four studies. The exercises included stabilizing exercises, back extension exercises (McKenzie), active mobility exercises and a computer generated set of exercises (PhysioTools, Finland). The only study that reported no additional benefit when SMT was added to back extension exercise was a high quality study with a low risk of bias.²¹ The disparity between this study and the other three studies may be linked to the difference in the SMT technique applied. This

may be supported by objections typically raised by clinicians as regards differentiating the type of manipulative therapy delivered (e.g. high-velocity low-amplitude manipulation versus mobilization) or the profession of the therapist (e.g. chiropractor versus manual therapist or physiotherapist).

The study by Mohseni-Bandpei et al.,²³ which carried out the same form of SMT (lumbar HVLA thrust) as the study by Rasmussen et al.,²⁴ reported significant improvement in the group that had exercises and SMT as compared to exercises alone. Both studies had a certified manual therapist delivering the thrusts. On the other hand, the study population in the two studies may have a role to play in the disparity seen in their results. Rasmussen et al. included participants with radicular pain,²⁴ while Mohseni-Bandpei et al. did not.²³ Therefore, the two studies did not have a homogenous population. Hence, there is a need to identify other subgroups in chronic LBP, besides using the duration of symptoms only. Moreover, recent work suggests that clinically important effects are observed when treatment is matched to the patient's signs and symptoms rather than provided to all patients with LBP.²⁹ Furthermore, recommendations from a UK consensus, which included senior researchers experienced in clinical trials for musculoskeletal conditions, include subgrouping patients.³⁰ Therefore, there is a need for future research in this area of LBP to focus on subgrouping patients to enhance treatment effectiveness.

This systematic review has also been able to show that SMT is effective as an adjunct to exercise in the management of mechanical chronic LBP. It showed that additional benefits accrued when SMT was added to exercise. However, the variation in the type of exercises in the different studies precludes determining the exercise SMT works best with as an adjunct.

The result of this review is in agreement with the review by Licciardone et al.,¹⁸ who pooled data from six studies and concluded that osteopathic manipulative therapy significantly reduces LBP. However the said review did not limit their review to studies on chronic LBP. A more recent review on SMT for chronic LBP concluded that there is no clinically relevant difference between SMT and other interventions for reducing pain.¹⁷ However, most of the studies in this review made use of single interventions,¹⁷ rather than multimodal treatment regimens as is usually seen in clinical practice.

Limitations

Only studies published in the English language were considered and this may have introduced a language bias. Also, experts in the field of spinal manipulation were not contacted to ascertain that no pertinent trial within the inclusion and exclusion criteria was unintentionally left out

Conclusion

The results from this systematic review suggests that there is moderate level evidence that the addition of SMT to treatment regimens in which exercise included is effective in reducing pain and improving function in chronic LBP. The methodological heterogeneity of included studies in terms of SMT techniques employed, the exercises SMT was combined

with and the small number of studies limits the strength of findings. Also, the nature of the evidence available makes it difficult to be specific about the exercise therapy the addition of SMT could work best with.

Declaration of conflicting interests

The authors declare that there are no conflicts of interest.

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Appendix

Embase search strategy

1. low back pain
2. sciatica.mp. or sciatica/
3. lumbago.mp.
4. lbp.mp.
5. 1 or 2 or 3 or 4
6. manipulation, spinal/ or manipulation, orthopedic/ or spinal manipulative therapy.mp.
7. mobilization.mp.
8. spinal manual therapy.mp.
9. 6 or 7 or 8
10. chronic.mp.
11. long term.mp.
12. 10 or 11
13. 5 and 9 and 12
14. limit 13 to (English language and 'all adult' and randomized controlled trial)