

Research article

A randomised, placebo-controlled, clinical trial for the short-term effectiveness of manipulative therapy and acupuncture on pain caused by mechanical thoracic spine dysfunction

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Introduction: A randomised, assessor-blinded, placebo-controlled trial was used to compare the short-term effectiveness of manipulative therapy and acupuncture on the pain caused by mechanical thoracic spine dysfunction and on the pressure pain threshold.

Subjects and Methods: The research sample consisted of 114 female patients aged 20–60 years. The primary complaint of these subjects had been pain in the thoracic spine area. After completing a questionnaire and undergoing a clinical examination, 114 subjects were diagnosed with mechanical thoracic spine dysfunction and these were randomised into the final study groups. Five persons dropped out the trial and thus the remaining 109 subjects were randomly divided into the manipulation group ($n = 37$), the acupuncture group ($n = 35$), and the placebo group (interference-electrotherapy with suction cups without electricity; $n = 37$). The subjects were treated four times with a 1-week follow-up assessment. The measurements of VAS and pressure pain threshold were taken on three occasions (baseline, before the second treatment and one week after the last treatment). The whole intervention took 4 weeks.

Results: The VAS measurement performed one week after the last treatment indicated that manipulative therapy was superior to placebo (P -value 0.01). The intra-group results of the VAS measurements between the first and the last measurement revealed clinically significant pain reductions in all three groups. Pressure pain threshold values had increased in both the manipulation group and in the acupuncture group, whereas in the placebo group they had decreased, though the differences were not statistically significant.

Conclusions: This trial suggests that manipulative therapy is more efficient than placebo in treating the pain caused by mechanical thoracic spine dysfunction when measured one week after the last treatment. In contrast, there was no significant difference between the effect of acupuncture and placebo.

Keywords: Acupuncture, Manipulative therapy, Mechanical dysfunction, Thoracic spine

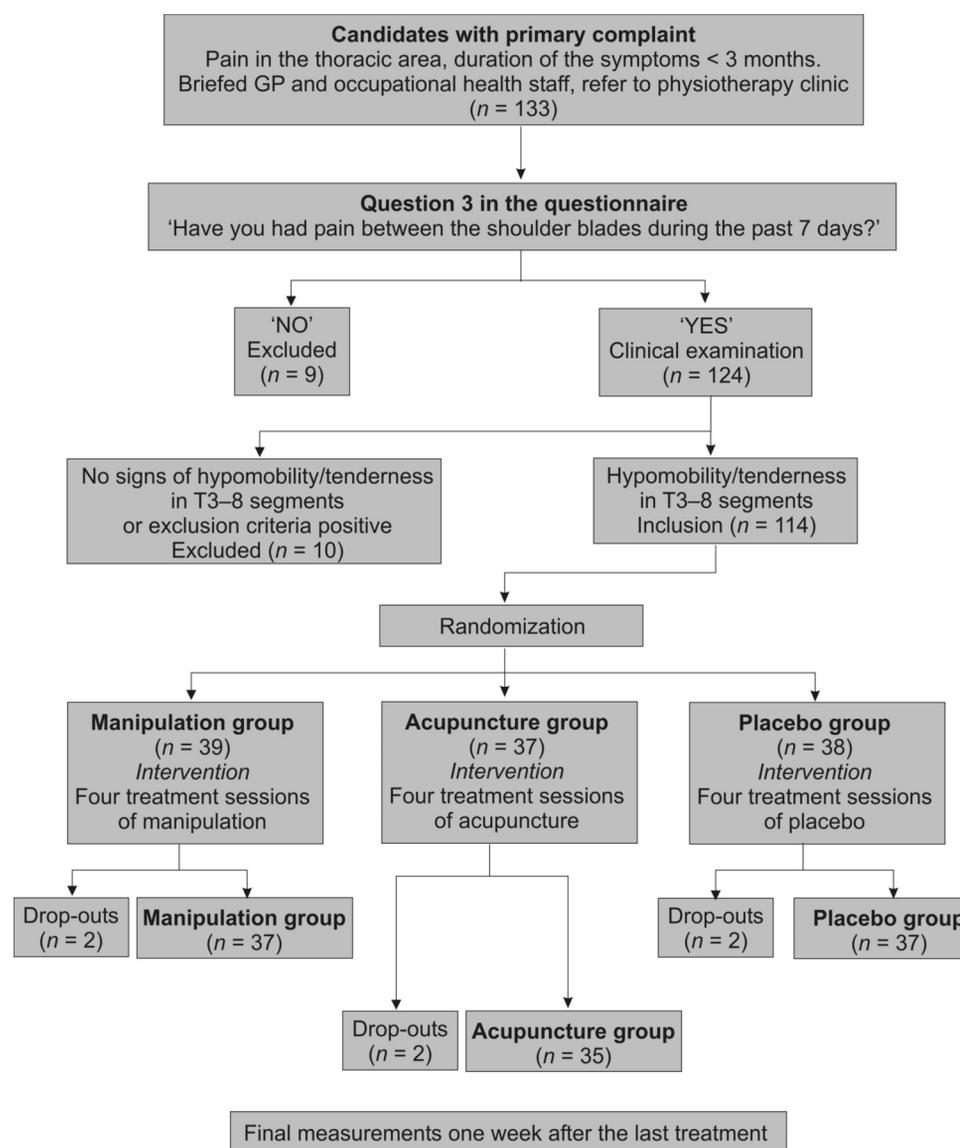
Introduction

According to two national surveys conducted in France and Finland, problems in the neck and shoulder area are very common in western societies. Not only are they discomforting to the individual, but they also are costly for society due to sickness absences and related benefits. In Europe, the prevalence of neck pain is almost as

high as the prevalence of low back pain, with ranges of 7.3–40% being reported.^{1,2} In North America, a cross-sectional study also revealed a high prevalence of neck pain, to the extent that 4.6% of the adult population was significantly disabled by this symptom.³

The role of the thoracic spine has rarely been studied epidemiologically. There is a lack of evidence both on the prevalence of upper back or thoracic pain and for upper back pain treatments. However, there is clinical evidence that, in addition

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Scheme 1 Progression of participants through the evaluation process including withdrawals

to evoking local pain in the thoracic area, it can also cause radiating pain along the intercostal nerves, and may be involved in the T4-syndrome, evoking crown headache and numbness of the hands.^{4,5} Two fluoroscopic studies have indicated that an injection given into thoracic zygapophyseal joint can reduce local and referred pain in the thoracic area.^{6,7} More research in this area is needed to clarify which treatment methods are effective against the pain caused by mechanical dysfunction.

Professionals using manual therapy (OMT-physiotherapists, chiropractors, osteopaths) not only use a variety of mobilisation treatments but also manipulative therapy (high velocity thrust, HVT) to try to ease thoracic segmental hypomobility in their clinical work. There is little in the current literature to confirm the effectiveness of thoracic spine thrust manipulation. There is only

one pilot study of the effect of manipulative therapy on the pain caused by mechanical thoracic spine dysfunction. Its results indicated that manipulative therapy could ease pain better than placebo treatment.⁸ The short-term benefit of manipulative therapy on spinal pain has been claimed in several systematic reviews to be at least moderate.^{9–12} However, the pain reduction achieved with manipulative therapy for lumbar and cervical pain does not seem to be any better than conventional treatment methods when evaluated by rigorous trial data.^{9,13}

Acupuncture is widely used when treating pain of the locomotor system although the claims of its efficacy are conflicting. Most systematic reviews have concluded that acupuncture is not the first-choice treatment for easing the symptoms of acute low back pain.¹⁴ There is one systematic review stating that there is evidence to suggest that



Figure 1 Facet-traction manipulation

acupuncture does have a role in the treatment of recurrent headaches.¹⁵ Three randomised trials have indicated some beneficial effects of acupuncture on cervicogenic pain.¹⁶⁻¹⁸

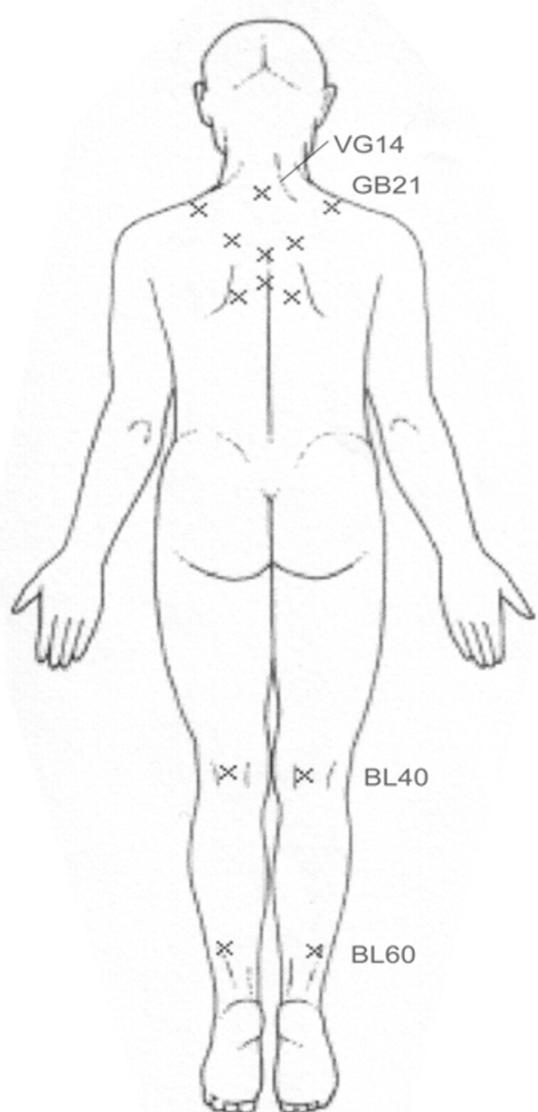


Figure 2 Acupuncture treatment for dysfunction in T4 segment

The aim of this randomised, controlled trial was to compare which of the two treatments, manipulative therapy or acupuncture, is more efficacious in reducing the pain caused by mechanical thoracic spine dysfunction. Within this trial, only the short-term effectiveness of these two conservative treatments is assessed (Scheme 1). In an extensive search through many medical databases, no similar kinds of studies were found.

Subjects and Methods

A prospective, randomised, placebo-controlled trial was performed to compare the effect of manipulative therapy and acupuncture on the pain caused by mechanical thoracic spine dysfunction and on the changes in the pressure pain threshold.

The subjects and the therapist were unblinded to the treatment method but the assessor who conducted the measurements was blinded. Subjects were divided into treatment groups with a simple randomisation procedure. Two individuals not involved in the trial performed the randomisation before the baseline measurements started. Randomisation was made on paper with the randomisers blindfolded. One randomiser chose mixed digits while the other randomiser recorded the results. The numerals 0, 1 and 2 represented the manipulation group, 3, 4 and 5 the acupuncture group and numerals 6, 7 and 8 the placebo group.

The change in VAS measurements was used as the primary outcome. The power calculations were based on the achievement of a 50% pain reduction as assessed by VAS in the treatment groups compared with a pain reduction of 20% in the placebo group. A significance level of $\alpha = 0.05$ and power of 0.80 were used. The calculations estimated that at least 35 subjects would be needed in each treatment group. The anticipated standard deviations for VAS were 1.5 and 3.0 for PPT, respectively.

Participants

The research sample consisted of female patients aged 20–60 years who sought help from a private physiotherapy clinic primarily because they had experienced problems in the thoracic area during the period of September 1998 to May 2001. They had been referred for evaluation by their local general practitioners (GPs) and occupational health staff, who had been informed about this research project in writing. Only female subjects were included in the study. The duration of the symptoms had to be less than 3 months prior to the study. In all, 114 subjects out of the 133 patient sample with mechanical thoracic spine dysfunction were randomised to the final study with 19 subjects

Table 1 Comparability of treatment groups at baseline

	Manipulation (n = 37)	Acupuncture (n = 35)	Placebo (n = 37)
Age (years)	43.6 (1.66)	42.2 (1.50)	41.7 (1.58)
VAS 1 (0–10)	5.2 (1.99)	4.8 (1.76)	5.2 (1.86)
PPT 1 (kg/cm ²)	7.2 (3.08)	7.6 (2.72)	7.8 (2.72)
Symptom onset, average weeks	7.4 (2.07)	8.8 (2.78)	7.7 (2.43)
Physical activity: very active	16	15	15
Physical activity: moderate	19	20	19
Physical activity: none	2	1	2

PPT, pressure pain threshold measurement (SD).

Table 2 Mean changes of treatment groups at different measuring times

	Manipulation (n = 37)	Acupuncture (n = 35)	Placebo (n = 37)
VAS 2 (0–10)	3.8 (1.66)	4.2 (1.75)	4.7 (1.80)
PPT 2 (kg/cm ²)	7.4 (2.79)	7.0 (2.94)	7.0 (2.67)
VAS 3 (0–10)	2.0 (2.14)	2.5 (1.85)	2.9 (1.68)
PPT 3 (kg/cm ²)	8.4 (2.51)	8.1 (2.72)	7.7 (2.98)

VAS 2 and PPT 2 are measurements conducted after the first treatment. VAS 3 and PPT 3 are measurements conducted 1 week after the last treatment (SD).

excluded on the basis of their response to the questionnaire or the clinical examination. The questionnaire included a question: 'Have you experienced pain between the shoulder blades during the past 7 days?', which was a critical evaluative question. The questionnaire included a body diagram. Those subjects answering 'no' were excluded from the next phase, *i.e.* clinical examination. Those participating in the clinical examination had to have had hypomobility and/or tenderness between the T3–T8 segmental area. The subjects were assessed in the sitting position palpating the symptomatic segments in order to define the reduced segmental range of motion. There is published evidence that an experienced manual therapist can reliably palpate the hypomobile segment.^{19,20}

There were three exclusion criteria: (i) the primary subjective problem was some pain other than thoracic pain (headache, neck pain *etc.*); (ii) a contra-indication to manipulation or acupuncture; and (iii) not having experienced pain in the thoracic area within the last 7 days. A total of five persons dropped out of the experiment.

Interventions

The subjects were treated four times receiving their treatments within 3 weeks. The last measurement was taken 1 week after the final treatment session and thus the entire intervention lasted for 4 weeks. The use of analgesics was forbidden during the intervention. It was also not permitted to undertake any other treatment modalities during the interventions. All the treatments were carried out by one experienced physiotherapist specialised

in orthopaedic manual therapy and who also was qualified to perform acupuncture.

The manipulation technique used in the experiment was high-velocity thrust called facetraction manipulation, *i.e.* the supine subject holds her arms crossed against her chest and the therapist performs a thrust while keeping a fixation on the segment below the treatment target (Fig. 1).

The therapist was instructed to manipulate as many segments between the area T3–T8 as considered necessary. The treatment time lasted 10–15 min. This technique is widely used among OMT-physiotherapists and osteopaths. This technique is demonstrated in Kaltenborn's textbook of manual therapy techniques.²¹

Acupuncture was given to points GB21, GV14, GV9–12, BL13–18 l.a., BL60 l.a. Points GV9–12 were used so that needling occurred at a segment above, and to a segment below, the symptomatic segment. The duration of treatment was 30 min (Fig. 2). The needling procedure was chosen during a consultation with an acupuncture instructor and pain specialist Jukka-Pekka Kouri MD in January 1999.

The control group was treated with placebo. Subjects were naive to their treatment and they had provided informed consent. The expressions of the treatment methods within the agreement form were 'manipulative therapy', 'acupuncture (needling)' and 'physical modality', the latter referring to the placebo treatment. The placebo treatment was interference-electrotherapy with suction cups in place but without electricity. The effect of intermittent sucking varied between 0–0.2 bar. Each treatment lasted for 20 min. The treatment method mimics the kind of electrotherapy given during a physiotherapy consultation.

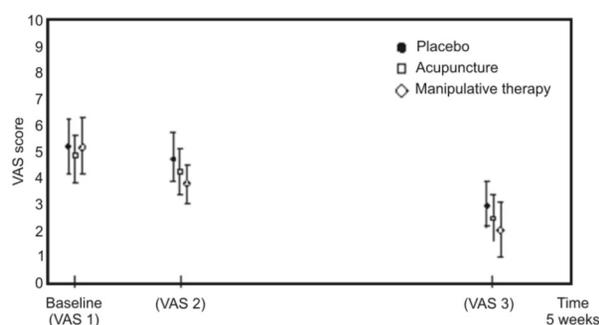


Figure 3 The results of VAS values with SEM, between the groups at different measuring times

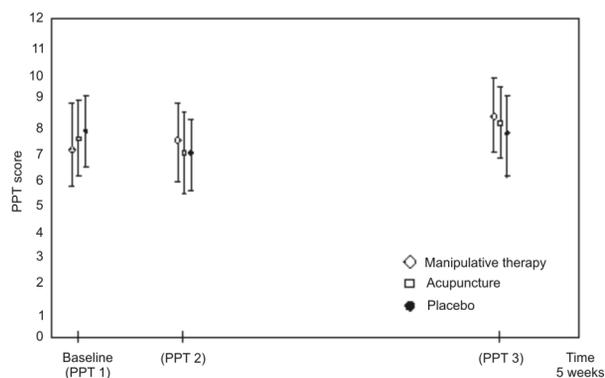


Figure 4 The results of PPT values with SEM, between the groups at different measuring times

Outcome measures

The measurements were taken at the baseline, before the second treatment and 1 week after the last treatment. All the measurements were done by the same experienced physiotherapist, who was specialising in orthopaedic manual therapy during the study period. The assessor was blinded to the treatment protocol.

The subjects filled in a symptom form with advice on how to use the VAS procedure.

The pressure pain threshold measurement was taken from three different points on the symptomatic side of the thoracic spine: one segment above the most symptomatic segment and one segment below that segment. The contact point was on the paraspinal muscles. The pressure was raised 1 kg/s until the subject said 'now' at the cut-off-point for discomfort. The average of the three-point measurement was recorded as the result of the pressure pain threshold measurement. The application of the three-point measurement was influenced by the knowledge of the significant overlap within the symptoms of the thoracic spine zygapophysial joint pain patterns.⁷ The subject was orally informed of the threshold-feeling and practised this once using her arm muscles before the measurement.²²⁻²⁴

The satisfaction with the treatment was examined in the final measurement with three-point patient global impression of change, a modification of the standard seven-point global impression of change (PGIC). This modification was done because satisfaction with the treatment was not the primary outcome measure. The categories were: treatment 'helped remarkably', 'helped to some extent' and 'did not help'.

Statistical analysis

The data were analyzed statistically with SPSS for Windows, v.11.0.0 (SPSS Inc., 1989–2002).

The distributions of VAS measurements were non-normal as tested with the Shapiro–Wilk test and, therefore, non-parametric tests were used. Friedman's test to a repeated measures was used for the VAS and pressure pain threshold measurements with Bonferroni correction being applied.

The satisfaction to the treatment was analyzed with the Kruskal–Wallis test with Bonferroni correction.

Results

A total of 133 subjects were screened for potential eligibility. Four had experienced no pain between the shoulder blades within the last 7 days and 15 had no hypomobility or else had tenderness between the segments T3–T8, but manipulative therapy or acupuncture was contra-indicated and, therefore, these 19 potential subjects were excluded prior to the randomisation.

The remaining 114 subjects were randomised for the final study. A total of five persons dropped out of the experiment. The reasons for discontinuation were dissatisfaction with the treatment, use of other treatment modality, other sickness and one suspected prolapsed disk. Two persons each from the manipulation and acupuncture groups and one person from the placebo group discontinued and thus the remaining 109 subjects were subdivided into the manipulation group ($n = 37$), with an age range of 20–60 years (average, 43 years), the acupuncture group ($n = 35$), 24–56 age range (average, 42 years) and the placebo group ($n = 37$), age range 23–59 years (average, 41 years). Prior to the start of the experiment, the averages in the VAS-information form were: manipulation 5.2 (4.2–6.2), acupuncture 4.8 (3.9–5.7) and placebo 5.2 (4.3–6.1). These did not differ significantly from each other (Table 1). Baseline variables were sufficiently similar to indicate there was no difference between the groups at baseline (Table 1).

The second measurement was taken before the second intervention in order to determine the

immediate response to the treatment. VAS values were reduced in all the treatment groups, but there was no statistical significance between the three groups. The pressure pain threshold value had increased only in the manipulation group, but this was not statistically significant.

In the measurement performed 1 week after the last treatment, the averages of the VAS-information form were: manipulation 2.0 (1.0–3.1), acupuncture 2.5 (1.4–3.4) and placebo 2.9 (2.1–3.7). In the comparison of manipulation against placebo, the *P*-value was 0.01, which is a statistically significant value (Fig. 3). The intragroup comparison revealed clinically important pain reductions in all three treatment groups when the baseline and final measurements were compared: manipulation group 5.2–2.0, acupuncture 4.8–2.5 and placebo 5.2–2.9 since it has been estimated that a difference of > 2 points in numeric rating scale would represent a clinically important change in acute pain outcome measures.²⁴

The pressure pain threshold value had increased in both the manipulation and the acupuncture

groups but, in contrast, it had declined in the placebo group though the differences were not statistically remarkable. The intragroup analyses of pressure pain threshold values revealed that the pain threshold had increased by 12.0% in the manipulation group, by 5.0% in the acupuncture group whereas there was a decline of 1.0% in the placebo group when the differences between baseline and last measurements were compared.

In all, 64.9% of the persons in the manipulation group, 48.6% in the acupuncture group but only 18.9% in the placebo group stated that the treatment had eased the pain 'remarkably'. The satisfaction with the treatment method achieved statistical significance (*P*-value 0.01) when the manipulation and placebo groups were compared.

Discussion

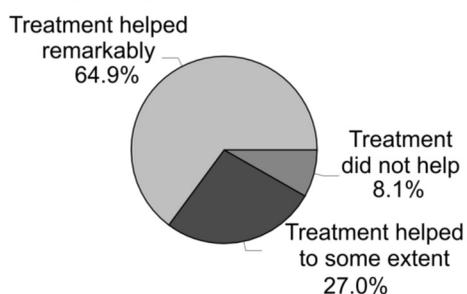
This randomised, controlled trial was conducted with the purpose of investigating the short-term effectiveness of manipulative therapy and acupuncture on pain caused by mechanical thoracic spine dysfunction. According to the results of this trial, manipulative therapy seems to be an effective way to treat patients with thoracic spine pain. There are some indications that it does ease the pain very quickly, and here, at least after four treatments, the difference compared to placebo was statistically significant. The effect of acupuncture in treating patients with thoracic spine pain was not so obvious.

Mechanical spine dysfunction was determined in this trial by combining the subject's own assessment of the primary symptom in the thoracic area with the manual therapy-based signs in the same segmental area. The palpation skills of assessing a restricted joint motion in the thoracic area were considered to be only moderate.^{19,20} This study was not designed to measure the reliability of assessing mechanical joint dysfunction. The same therapist performed all the treatments which makes the results less generalisable than if they had been collected via a multicentre study design.

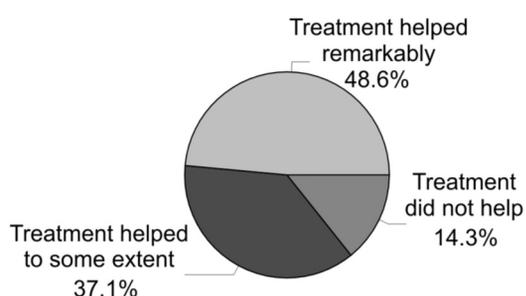
The VAS measurement is considered to be reasonably accurate in clinical research.²⁵ The percentage pain intensity difference of 33% and the absolute difference of > 2 points in numeric rating scale has been determined to be a clinically important change in acute pain outcome measures.^{24,26,27} This trial showed that 27 out of a total of 37 subjects (72.9%) in the manipulation group, 24 of 35 (68.5%) in the acupuncture group and 23 of 37 (62.1%) in the placebo group surpassed this clinically important change in VAS.

The secondary outcome, pressure pain threshold value, increased in the manipulation and

Manipulation group (n = 37)



Acupuncture group (n = 35)



Placebo group (n = 37)

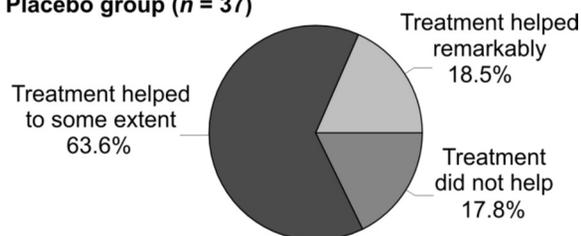


Figure 5 Patient satisfaction with the treatment

acupuncture groups, but did not change in the placebo group. However, these differences were not statistically or clinically significant. In chronic neck pain, both acupuncture and manipulative therapy have been shown to have a significant effect compared to placebo treatment.^{28,29} Many trials have highlighted the major interindividual variations in PPT in symptomatic subjects and the moderate negative association between PPT and pain intensity.^{23,30} One study indicated that mid-thoracic tenderness in the T4- and T6-segments is not a normal phenomenon found in asymptomatic subjects.³¹ Pressure pain threshold values are believed to increase in a caudal direction from the cervical to the lumbar area.^{23,31}

The confounding variables within this trial were occupational environment, physical activity and analgesic medication or other treatment modalities during the intervention. All these factors were enquired into at the baseline questionnaire and the use of analgesics was forbidden during the intervention. It was also not permitted to undertake any other treatment modalities during the interventions. In fact, the use of other modalities was the reason for the drop-out of three subjects.

This trial has certain limitations because only visual analogue scale, pressure pain threshold and patient satisfaction were measured and analyzed. Some sort of disability or functional assessment would have provided valuable clinical information. For example, the global impression of change would have been a better choice to measure patient satisfaction with the treatment. The 10-min difference between the different individual treatment times is one weakness of this trial. There were deficiencies in randomisation method; a computer-based method should have been used instead of the method used in this trial. Within this study, there were economical limitations as both researchers conducted the study during their daily work as private practitioners. A multicentre study design would have increased the financial cost though it might have enabled longer intervention and follow-up periods.

Considering the generalisability of the results of this trial to other reports. These studies have claimed that manipulative therapy is not significantly more efficacious in pain reduction than acupuncture, and the same conclusion has been presented with the systematic reviews when manipulative therapy has been compared with other treatment modalities.^{9,13} In the cervical spine area, it has been shown that both manipulative therapy and exercise therapy are effective at alleviating a cervicogenic headache.³² According to

a randomised controlled trial, a combination of exercise and spinal manipulation was found to be more beneficial to the patients with chronic neck pain than spinal manipulation alone.³³ The results of this study where the efficacy of manipulative therapy was compared to placebo are similar those described the pilot study of Schiller.⁸

The conclusion of the results of acupuncture treatment for mechanical spine dysfunction was similar to the systematic reviews. Although subjective pain was eased and pressure pain threshold values increased, the differences compared to placebo were not statistically significant. The study protocol demanded that the symptom had not lasted longer than 3 months. It is possible that the effect of acupuncture is clearer in treating more chronic or more intense pain. It has been speculated that qualitative verbal rating scales, which express a more subjective change in the pain and global complaints, might reveal longer lasting benefits of acupuncture.¹⁷ In professional publications, there has been a debate about whether traditional pain measurements in randomised controlled trials are relevant if one wishes to evaluate the efficacy of acupuncture.³⁴

There seems to be a spontaneous recovery tendency with these acute or subacute mechanical dysfunctions as evidenced by the rather good result obtained with placebo. Some other placebo, such as ultrasound without electricity, would have been a possible substitute for the method used in this study. It was claimed in a chiropractic study by Schiller⁸ that one reason for drop-out of the subjects from the study was that the subjects in the placebo group were not really naive to ultrasound without electricity. There is a possibility that the placebo treatment chosen may have a slight somatosensory effect, though no clear explanation can be provided. As in almost all physiotherapeutic studies, it is not possible to blind the therapist.

There is a lack of evidence both on the prevalence of upper back or thoracic pain and for upper back pain treatments. Further research in this area is needed to understand better which treatment methods are effective against the pain caused by mechanical dysfunctions. In future studies, these individual treatment modalities should be combined with other treatments, especially exercise therapy, to mimic the real treatment procedure. Furthermore, more long-term follow-up periods should be used.

Conclusions

The measurements made at the baseline indicated that all the treatment groups were comparable with each other.

The immediate response to a single treatment revealed some evidence that manipulative therapy would be more efficient than acupuncture in relieving the pain and elevating the pressure pain threshold, but there was no statistical significant difference between the groups.

The measurement taken one week after the last treatment demonstrated that manipulative therapy was significantly superior to the placebo ($P < 0.01$) when measuring the feelings of pain with VAS. The VAS values were reduced also in the acupuncture and placebo groups; the extent of the decline was not statistically significant. The intragroup results of the VAS measurements between the first and the last measurement displayed a clinically significant pain reduction in all three groups. Pressure pain threshold values had increased in both the manipulation and the acupuncture groups, whereas it had declined in the placebo group though the differences were not statistically significant. The satisfaction with the treatment was more positive in the manipulation and acupuncture groups than in the placebo group, revealing statistically significance in the comparison of manipulation with placebo ($P < 0.00$).

This trial suggests that manipulative therapy is more efficacious than placebo in treating the pain caused by mechanical thoracic spine dysfunction when measured 1 week after the last treatment. There was no significant difference between the effect of acupuncture and placebo.

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