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Immediate effect of activator trigger point therapy and myofascial band therapy on non-specific neck pain in patients with upper trapezius trigger points compared to sham ultrasound: A randomised controlled trial

Anja Blikstad, Hugh Gemmell *

Anglo-European College of Chiropractic, 13-15 Parkwood Road, Bournemouth BH5 2DF, UK

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KEYWORDS

Chiropractic;
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Summary

Objective: To determine the immediate effect of activator trigger point therapy (ATrPT) and myofascial band therapy (MBT) compared to sham ultrasound (SUS) on non-specific neck pain, cervical lateral flexion and pain pressure threshold of upper trapezius trigger points.

Design: Randomised, placebo-controlled clinical trial.

Setting: Anglo-European College of Chiropractic (AECC) in Bournemouth, England.

Subjects: Forty-five subjects between 18 and 55 years of age with non-specific neck pain of at least 4 on an 11-point numerical rating scale (NRS), an upper trapezius trigger point (TrP) and decreased cervical lateral flexion to the opposite side of the active upper trapezius TrP were recruited from the AECC student body.

Methods: The subjects were randomly assigned to one of three treatment groups: activator trigger point therapy, myofascial band therapy or sham ultrasound (control group). Neck pain level was determined using a numerical rating scale, degree of lateral flexion (LF) was determined using a cervical range of motion (CROM) goniometer and pain pressure thresholds (PPT) were measured with a pain pressure algometer. All subjects attended one treatment session and outcome measures were repeated within 5 min after treatment.

Results: A one-way ANOVA indicated there was no statistically significant difference between the groups at baseline in age, pain level, lateral cervical flexion or pain pressure threshold ($p > 0.05$). For the primary outcome measure of pain reduction the odds of a patient improving with activator trigger point therapy was 7 times higher than a patient treated with myofascial band therapy or sham ultrasound (95% CI:

* Corresponding author. Tel.: +44 1202 436268; fax: +44 1202 436312.
E-mail address: hgemmell@aecc.ac.uk (H. Gemmell).

1.23–45.03). The number needed to treat (NNT) with activator trigger point therapy for one patient to improve was 3 (95% CI: 1.4–10.6).

Conclusion: Activator trigger point therapy appears to be more effective than myofascial band therapy or sham ultrasound in treating patients with non-specific neck pain and upper trapezius trigger points.

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Introduction

It has been suggested that mechanical neck pain has a lifetime prevalence of 45–54% in the general population,^{1–3} and up to 30% of men and 50% of women experience neck pain in the course of a lifetime.⁴ Saringovallis and Hollins⁵ estimated that the occurrence of neck pain at any given point of time is between 13.4 and 22.2%. It has further been reported that 14% of neck pain patients are at risk of their pain becoming chronic which, makes neck pain very expensive in terms of absenteeism from work and in terms of healthcare costs.⁶

Frequently, non-specific neck pain is caused by a mechanical or myofascial problem.⁷ Evidence exists to suggest that active myofascial trigger points (TrPs) are common in patients presenting with non-specific neck pain.^{3,8} Gemmell et al.⁹ reported the effect of myofascial band therapy (MBT) in a tennis player with a mild ankle sprain and enthesiopathy of the anterior ankle ligaments. Prior to treatment, the patient was unable to play tennis or compete in tournaments. Treatment consisted of firm thumb pressure at the implicated enthesiopathy and a stroking pressure along the longitudinal myofascial bands of the involved muscle. After two treatments, the patient showed a 100% improvement, without relapse during a nine-month follow-up period, and he was able to return to sports. However, this study only reports a single case and it is uncertain whether the same outcome would be seen in other patients with a myofascial band. Therefore, the effect of treatment in patients with non-specific neck pain is unknown.

The activator-adjusting instrument (AAI) has been used as a treatment method by chiropractors mostly as a joint fixation adjusting method.¹⁰ However, to date, no research has been done to determine the effect of the AAI in treating myofascial TrPs.

Both MBT and activator trigger point therapy (ATrPT) have been used by the second author (HG) with anecdotal success in patients with non-specific neck pain. However, no study has investigated the effect of ATrPT, and there is a lack of research on MBT in the treatment of non-specific neck pain. Comparing the effect size of each treatment will help clinicians determine if one or both treatments are appropriate for their individual patients. There-

fore, the purpose of this study was to determine the immediate effect of ATrPT and MBT on non-specific neck pain in subjects with upper trapezius trigger points, compared to sham ultrasound (SUS).

Methods

This study was a randomised, placebo-controlled clinical trial. The study was conducted at the Anglo-European College of Chiropractic (AECC) in the UK and approval for the study was obtained from the AECC Research Ethics Sub-Committee. Data collection occurred over three weeks during the 2006 autumn term at the AECC.

Subjects

Subjects for the study were recruited from the student body of the AECC. Subjects were admitted into the study if they met the following criteria:

- Male or female between 18 and 55 years of age.
- Unilateral or bilateral neck pain that had lasted for at least 4 weeks, but no longer than 12 weeks.
- Neck pain could extend to the shoulder region and upper arms.
- Neck pain of at least 4 on an 11-point numerical rating scale (NRS).
- Presence of an active trigger point in the upper trapezius muscle (an active upper trapezius TrP was defined as a tender nodule in a taut band that referred pain in a pattern specific for upper trapezius TrP₁ or TrP₂).⁸
- Decreased cervical lateral flexion (LF) to the opposite side of the active upper trapezius TrP.

Subjects with any of the following were excluded:

- Specific neck pain (radiculopathy, systemic disease, etc.).
- Blood coagulation disorder.
- Currently taking anticoagulants (e.g. warfarin).
- Long-term steroid use.

Each subject read a Study Information Sheet and signed an Informed Consent Form before enrolment

in the study. Forty-five subjects from the AECC student body were randomly assigned to the three groups. The randomisation scheme was generated by using the web site Randomization.com (<http://www.randomization.com>). To ensure equal numbers in the groups, subjects were randomised in blocks of three. Sealed opaque envelopes were prepared containing the assigned treatment and numbered consecutively. Subjects were allocated to the next available envelope number.

Interventions

A detuned Medi-Link Systems ultrasound machine from Electro-Medical Supplies (Greenham) Ltd. was used as the sham control. The subject was informed that pulsed ultrasound was going to be used and he/she should not feel any sensation of heat or pain, and if this was felt to let the clinician know and the machine would be turned down. Since this was a sham procedure, such adjustment made no difference. Ultrasound lotion was applied over the TrP and the ultrasound head was moved slowly over the upper trapezius muscle in the region of the TrP for 2 min. The machine's integrated timer was used to alert the clinician when 2 min had elapsed.

Myofascial band therapy consisted of firm thumb pressure in a slow stroking motion from the lateral shoulder to the mastoid process along the upper trapezius muscle and through the active TrP for 1 min (Fig. 1).

The AAI is a hand held device that delivers controlled and reproducible forces. The design of the activator allows the force to be delivered on to a very specific point.¹¹ The Activator IV features force settings ranging from 1 to 4. Activator trigger point therapy involved placing the Activator IV perpendicular over the trigger point using a force setting of 3 (170 N). The trigger point was treated with the Activator IV using 10 thrusts at a rate of one thrust per second (Fig. 2).



Figure 1 Myofascial band therapy.

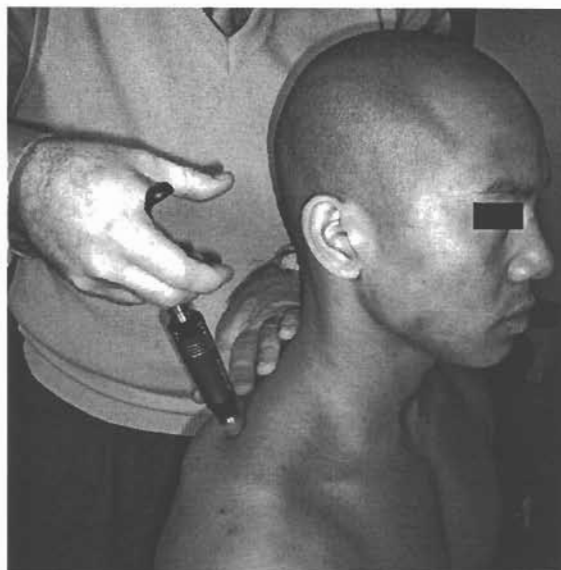


Figure 2 Activator trigger point therapy.

Outcome measures

The primary outcome measure was an 11-point numerical rating scale. The NRS was used to measure the subjects' self-reported neck pain before and after treatment. The NRS has been shown to have concurrent and predictive validity as a measure of pain intensity.^{12,13} A decrease of 2 points has been shown to indicate clinical improvement.^{14,15} Therefore, a reduction of 2 or more points on the NRS was used to indicate improvement.

A pain pressure algometer (PPA) was used to measure pain threshold in the subjects' upper trapezius trigger points. A PPA is a hand held device that can measure deep tenderness and pressure pain thresholds in muscles, bone and ligaments. It consists of a gauge that is attached to a hard rubber tip of one centimetre in diameter. The dial gauge is calibrated in kg/cm^2 and ranges from 1 to 10 kg/cm^2 . The force recorded was the amount of pressure that caused pain in the subject; this is called the pain pressure threshold (PPT). Inter-examiner reliability of the PPA is good to excellent (intra-class correlation (ICC) = 0.75–0.89).^{16,17} It is also suggested that reliability is enhanced when one examiner takes all measurements.¹⁷ As a secondary outcome measure we used an increase of at least 1 kg/cm^2 on PPT to represent clinical improvement. This was based on studies that showed a mean difference between right and left upper trapezius muscles on PPA of 0.05 kg/cm^2 and a side to side difference exceeding 2 kg/cm^2 suggested clinically significant tenderness.^{16,18}

The cervical range of motion (CROM) goniometer was used to measure lateral cervical flexion. Inter-

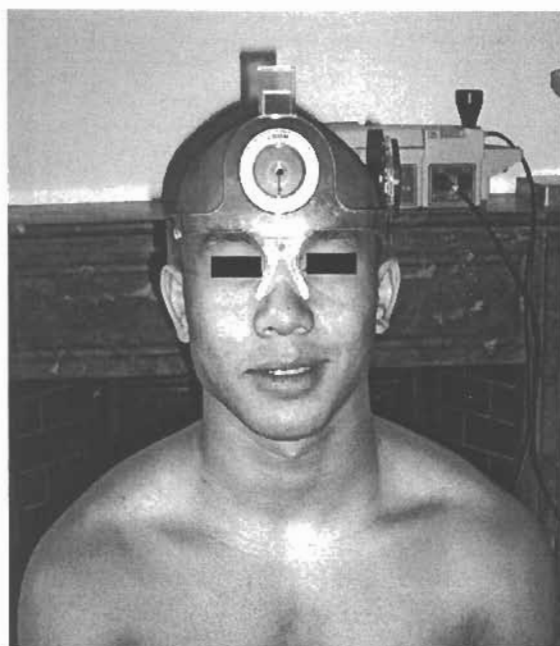


Figure 3 CROM device used for measuring lateral cervical flexion.

examiner reliability of the CROM device for measuring lateral cervical flexion is good to excellent (ICC = 0.73–0.89).^{19,20} Conventional radiography has been used as a gold standard for determining the validity of the CROM, and results have shown it to be a valid device²¹ (Fig. 3). In a prior study of upper trapezius trigger point treatment²² an increase in lateral cervical flexion of 5° was found to be significant after treatment. Therefore, we used an increase on lateral cervical flexion of 5° to represent clinical improvement.

Procedure

The subject entered the treatment room and completed the pain scale. If the subject met the selection criteria he/she was asked to read the Informed Consent Form and to sign it. The examiner then measured the subject's TrP sensitivity using the pressure algometer. A TrP located in the area of TrP₁ or TrP₂ was

marked with a cross using a skin-pencil and PPT of the active upper-trapezius TrP was then measured. If there was more than one active trigger point, the most painful/tender trigger point was used as the signal point. In order to measure PPT the rubber tip of the PPA was placed over the cross signifying the TrP location and the patient was instructed to indicate when the sensation changed from pressure to pain. The pressure was steadily increased at a rate of 1 kg/cm²/s as recommended by Fischer.²³ Cervical lateral flexion was then determined by the use of a CROM. This was strapped to the subject's head and the subject was asked to sit up straight and first laterally flex their head to the right (degrees of lateral flexion was recorded) and then laterally flex their head to the left (degrees of lateral flexion was recorded).

The examiner then exited the room and the treating clinician entered. The clinician opened the next consecutively numbered envelope and delivered the assigned treatment. To mask the examiner to treatment assignment, the clinician set the timer on the ultrasound machine for each subject, placed ultrasound lotion over the trigger point and then wiped it off for each subject, the AAI was placed on the clinician's hand and 10 thrusts were delivered for those subjects not in the activator group, and each subject was kept in the treatment room for 3 min. The clinician advised each subject not to discuss anything about the treatment with the examiner. The clinician then left the room and the examiner entered and conducted the post-treatment tests within 5 min of treatment.

Data analysis

Data analysis was conducted using INSTATTM for Windows. Clinically significant improvement was determined using an odds ratio and number needed to treat (NNT) with 95% confidence intervals.

Results

Forty-five subjects were randomly assigned, 15 to the MBT group, 15 to the activator group and 15 to

Table 1 Baseline characteristics of the groups

	Activator (n = 15)	Myofascial band (n = 15)	Sham ultrasound (n = 15)
Age (S.D.)	23.9 (±3.925)	22.6 (±2.384)	24.9 (±5.44)
Number of males	4	9	7
Mean numerical rating scale (S.D.)	4.6 (±0.6325)	4.6 (±0.5071)	4.7 (±0.9612)
Mean left lateral flexion (S.D.)	41.5 (±9.102)	38.5 (±6.424)	39.9 (±7.469)
Mean right lateral flexion (S.D.)	43.7 (±8.836)	40.2 (±5.102)	41.8 (±6.625)
Mean pressure point threshold (S.D.)	3.4 (±1.803)	3.2 (±0.8367)	3.8 (±1.710)

Table 2 Number of subjects improved with treatment based on reduced pain

	Activator	Myofascial band	Sham US
Number improved	8	2	2
Group size	15	15	15
Improved (%)	53.3	13.3	13.3

the sham ultrasound group. Baseline data for the groups are shown in Table 1. There was no baseline difference between the groups in age ($p = 0.26$), level of pain ($p = 0.90$), pain pressure threshold ($p = 0.54$), left cervical lateral flexion ($p = 0.57$) or in right cervical lateral flexion ($p = 0.40$).

For the primary outcome measure of pain reduction, the number of patients that improved in each treatment group is shown in Table 2. The absolute risk reduction (ARR) was calculated to be 40. The number needed to treat (NNT) is a measure of the number of patients that must be treated in order for one patient to improve. Number needed to treat is calculated as $1/ARR$ and it was found to be 2.5, which was significant (95% CI: 1.4–10.6). This means that for one patient (treated with ATrPT) to improve, 3 patients must be treated. The odds ratio was 7.4, which was significant (95% CI: 1.226–45.025). This means that patients treated with ATrPT are 7 times more likely to improve than a patient treated with MBT or SUS.

On the secondary outcome measure of Cervical left lateral flexion, the odds ratio for ATrPT was 4.0, but this was not significant (95% CI: 0.8761–18.263). As the odds ratio was not significant, the NNT for ATrPT was not calculated. For MBT the odds ratio was 1.3, which was not significant (95% CI: 0.3004–5.917). Therefore, the NNT was not calculated. The number of subjects improved is shown in Table 3.

For the secondary outcome measure of right lateral cervical flexion the NNT and odds ratio for ATrPT could not be calculated as the number improved in the ATrPT group was equal to the number in the SUS group (6). The NNT and odds ratio for MBT was also not calculated as the SUS group had a greater number of subjects that improved. The number of subjects improved is shown in Table 4.

Table 3 Number of subjects improved with treatment based on increased left lateral cervical flexion

	Activator	Myofascial band	Sham US
Number improved	10	6	5
Group size	15	15	15
Improved (%)	66.7	40.0	33.3

Table 4 Number of subjects improved with treatment based on increased right lateral cervical flexion

	Activator	Myofascial band	Sham US
Number improved	6	5	6
Group size	15	15	15
Improved (%)	40.0	33.3	40.0

For the secondary outcome measure of PPT, the odds ratio for ATrPT was 3.5, but this was not significant (95% CI: 0.6913–17.721). The NNT was, therefore, not calculated. For MBT the odds ratio was 2.0, but this was not significant (95% CI: 0.3804–10.515). The NNT was not calculated due to a non-significant odds ratio. The number of subjects improved is shown in Table 5.

Discussion

We have used clinical improvement with confidence intervals to determine the effectiveness of the two treatments as compared to sham treatment as statistical significance can be inferred from confidence intervals; however, in addition, these intervals give the largest and smallest effects that are likely given the observed data. Statistical significance testing determines if the data are compatible with the concept of no difference between the groups. What matters to a clinician is not the size of the significance, but what the effect size is. In this way decisions as to whether a particular treatment applies to an individual patient seen in real life may be made.

The number needed to treat in the ATrPT group was small (NNT = 2.5), which suggests that only three patients need be treated with ATrPT for one patient to improve. Furthermore, an odds ratio of 7.4 suggests that a patient treated with ATrPT has a seven times greater chance of improving after one treatment than a patient treated with MBT or SUS. However, due to the small sample size and wide confidence intervals, estimates of the effect size may be imprecise and more data should be collected before anything definite can be said about the effect size.

Table 5 Number of subjects improved with treatment based on increased pain pressure threshold

	Activator	Myofascial band	Sham US
Number improved	7	5	3
Group size	15	15	15
Improved (%)	46.7	33.3	20.0

Fischer²³ stated that normal PPTs in healthy subjects with non-impaired upper-trapezius muscles were 5.4 kg/cm² in males and 3.7 kg/cm² in females. This does not quite correlate with the results from the present study which showed mean baseline PPTs of 3.965 kg/cm² in the male subjects and 3.068 kg/cm² in the females. Taking into consideration that Fischer studied the PPT over normal muscle in healthy subjects, our results are likely due to soreness and pain over muscles with active TrPs. In the present study, PPT values were only obtained unilaterally from the right or left upper trapezius. Measurements from opposite sides of the body are highly reproducible and it is considered unnecessary to measure soft tissue PPT bilaterally.²³ In cases of suspected unilateral pathology, PPTs can be used to compare differences from side to side.²⁴ The current study was conducted on symptomatic students, which may explain the low baseline PPT values, likely to be caused by tight upper trapezius muscles with presence of TrPs and cervical spine manipulable lesions due to poor posture while studying.

Previous studies have described the use of various physical modalities in the treatment of non-specific neck pain.^{8,22,25-29} However, to the investigators' knowledge this is the first study to determine the effectiveness of ATrPT and MBT on non-specific neck pain. Only a few treatment interventions for neck pain have been studied and evaluated scientifically²⁷ and it is uncertain whether most studies address the actual pathological entity or some other processes of the problem. Thus, it is difficult to determine if our results are important or only significant to this particular study.

The present study included a sham control group, who also received hands-on intervention. This strengthens the evidence of effectiveness because the placebo effect, which should not be underestimated,³⁰ was accounted for. However, although clinically significant results were found for ATrPT, future research into the long-term effects of this treatment is warranted.

There is some evidence to suggest a correlation between transient increase in pain during treatment and increased therapeutic effect.⁸ It is possible that post-treatment evaluation of pain (NRS) may have occurred too soon after treatment. Some of the subjects expressed difficulty in rating their exact level of pain immediately after treatment due to post-treatment soreness. The patient is also more likely to recall the previous level of pain, which may affect the results.³¹ The fact that the examiner was female may have influenced the results as males have been found to report significantly less pain in front of a female examiner than a male examiner.³² A follow-up session in order to measure long-term

effectiveness of treatment would possibly have altered the results. Some of the participants complained it was too soon after treatment to feel a difference and some found it difficult to rate their current level of pain because the analgesic effect of treatment was masked by post-treatment soreness.

The mechanism behind ATrPT has not yet been investigated. It is possible that a quick impulse located to the centre of the TrP reduces its height and thus lengthens the TrP resulting in a disruption of the sarcolemmal membrane. As a consequence of this, the length of all sarcomeres normalise and the balance between hypercontracted and over-stretched sarcomeres is restored. If the contraction knot is reduced, less energy is needed to maintain the contraction of the sarcomeres. The energy crisis theory is responsible for the release of substances that sensitise adjacent nociceptors.³³ Thus, a release in overall muscle tension may result in decreased pain and disability.

Conclusion

The results suggest that activator TrPT to an upper trapezius TrP has an immediate effect in reducing pain in patients with sub-acute non-specific neck pain.

Competing interests

No competing interests declared.

Authors' contributions

HG developed the concept for this research. HG and AB designed the study. AB and HG analysed the data. HG and AB wrote the first draft of the manuscript and both authors approved the final version.

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