Benefits of Thoracic Thrust Manipulation when Applied with a Multi-Modal Treatment Approach in Individuals with Mechanical Neck Pain: A Pilot Randomized Trial

Samannaaz S Khoja1, David Browder2, Daniel Daliman3 and Sara R Piva1*

1Department of Physical Therapy, School of Health and Rehabilitation Science, University of Pittsburgh, USA
2Texas Physical Therapy Specialists, Austin, USA
3Physiotherapy Associates, Mesa, USA

Corresponding Author: Piva SR, Department of Physical Therapy, University of Pittsburgh, Bridge side Point 1, 100 Technology Drive, Suite 210, Pittsburgh, PA, 15219, USA, Tel: 4123836712; Fax: 4126485970; E-mail: spiva@pitt.edu

Received Date: August 29, 2015; Accepted Date: September 29, 2015; Published Date: October 01, 2015

Abstract

Objectives: Mechanical neck pain is generally treated with a multimodal approach that includes electro/thermal modalities, exercise and non-thrust manual therapy to the neck. Recent studies reported beneficial effects of thoracic thrust manipulation (TTM) but evidence for additive effects of TTM over multimodal neck program (MNP) is limited. The purpose of this pilot study was to assess the supplementary effects of TTM on pain and disability when applied in addition to a MNP to treat mechanical neck pain.

Methods: Twenty-two eligible subjects (age: 38 ± 11 years, BMI: 25 ± 5 Kg/m2, 68% female) were randomized to receive MNP only or MNP+TTM for a maximum of 12 sessions. Outcomes were assessed at baseline and at 6 weeks follow up, and consisted of the numeric pain rating scale (NPS), Neck Disability Index (NDI), Global Rating of Change, duration of care, and neck active range of motion (AROM).

Results: At 6 weeks both groups showed similar improvement in pain and disability that were clinically important. The NPS improved 2.9 points in the MNP+TTM group and 2.7 points in MNP group. The NDI reduced 14.6% in MNP+TTM and 11.8% in MNP. Increases in neck range of motion were small and similar in both groups. The percentage of subjects who improved in the global rating of change was 60%. Both groups reported similar duration of care (40 and 33 days in the MNP and MNP+TTM respectively).

Conclusion: TTM does not appear to provide additional benefits over the MNP on the outcomes of pain, disability, neck range of motion, duration of care or global perception of change.

Keywords: Thoracic manipulation; Neck pain

Introduction

Neck pain affects around 30-50% of adults and is associated with activity limitation, absence from work, and a high economic burden [1-4]. Neck pain due to an unidentifiable patho-anatomic origin is termed as mechanical neck pain, which usually presents with stiffness around the cervical and shoulder region, and pain that is reproducible on cervical movements [5,6]. Mechanical neck pain is generally treated conservatively, and common modes of intervention include electro/thermal therapeutic agents, exercise, soft tissue techniques and manual therapy. Cervical thrust manipulation is an effective form of manual therapy that reduces mechanical neck pain and improves range of motion [7-9], but at the same time also exposes the patients to rare but severe complications related to vertebral artery injury [10-15]. To avoid the potential complications related to thrust techniques, indirect techniques directed to the thoracic spine, such as thoracic thrust manipulation (TTM), are often used by clinicians to treat mechanical neck pain. TTM is thought to produce a hypoalgesic effect on the spine by inhibiting descending pain pathways, such as the periaqueductal grey matter [16]. Studies have demonstrated that TTM appears to increase neck movement, and reduces neck pain and disability, without the exposure to potential adverse events reported during cervical thrust manipulations [17-24].

Evidence to support the benefits of TTM has been communicated in some studies. The immediate effect of TTM has been demonstrated in studies that compared a single session of TTM to sham manipulation, non-thrust mobilization, or no intervention, and reported superior improvements in pain and neck range of motion in those who received TTM [16,20-23]. Similar short-term benefits of TTM applied over multiple sessions have also been reported. Gonzalez-Iglesias and colleagues conducted two clinical trials that compared subjects who received either electro/thermal modalities (infrared lamp and transcutaneous electrical nerve stimulation) alone to those who received electro/thermal modalities supplemented with 3 treatment sessions of TTM; one trial reported treatment effect at 1-week follow-up [19] while the second reported treatment effects at 2-and 4-week follow ups [18]. Both trials reported clinically significant improvements in pain and neck disability favouring TTM [18,19]. Long term effects of TTM up to 6 months has also been reported in studies. Lau and colleagues compared the effects of infra-red radiation over the painful area to infra-red radiation supplemented by TTM over...
8 weeks (2x/week), and reported significant improvements in pain and disability at 8-week, 3-month and 6-months follow-up periods in the group that received TTM combined with infra-red radiation [17]. Cleland and colleagues compared the effects of 2 TTM sessions combined with exercise to exercise alone, and reported that TTM combined with exercise improved pain and disability more effectively than exercise alone at 1 week, 4 weeks, and 6-month follow-ups [24]. Six of the studies discussed above [18-20,22-24] were also included in a recent systematic review that demonstrated small to large effect sizes (0.38 to 4.03) for improvement in pain and self-reported function across the individual studies [6].

While the current literature demonstrates beneficial effects of TTM, it is important to note that majority of the studies on the effectiveness of TTM have used comparisons with interventions of limited effectiveness such as sham manipulation, electro/thermal agents, or using a single mode of treatment such as exercise alone or mobilization alone. As per the current evidence-based guidelines, a multimodal treatment approach improves neck pain to a greater extent than does a single mode of intervention [5,25,26] and represents what is commonly utilized in clinical practice. However, evidence pertaining to the effectiveness of TTM when added to a multimodal program (i.e., combination of electro/thermal therapeutic agents, stretching and strengthening exercises, and non-thrust manual therapy to the cervical spine) is limited. We are aware of only one study that investigated the effectiveness of TTM combined with non-thrust cervical manual therapy. Masaracchio and colleagues compared the effects of TTM combined with non-thrust cervical mobilization against non-thrust cervical mobilization alone, applied twice over a one-week period and reported superior improvements in pain and disability in those who received TTM [27]. While the study demonstrates that TTM supplemented benefits, the study only assessed the effects of two treatment sessions, which is considerably shorter than the duration of care for mechanical neck pain treatment in clinical practice. Comparing the effectiveness of TTM with a multimodal approach is clinically relevant and may help guide clinicians in selecting interventions for patients with neck pain. As the benefits of MNP supplemented by TTM are currently understudied, the aim of this pilot study was to explore the differential benefits of a multimodal neck program (MNP) supplemented with TTM compared to MNP alone. We hypothesized that the MNP+TTM group would demonstrate less disability and pain as compared to the MNP group.

Methods

Study participants

The study was a pilot randomized clinical trial. Participants were recruited from two outpatient physical therapy clinics—Will ford Hall Medical Centre, San Antonio, TX and Centre for Rehab Services Hermitage, Hermitage, PA. Participants who were fluent in English, between 18 and 65 years of age, and presented with clinical features consistent with mechanical neck pain, and consented to participate were included in the study. Mechanical neck pain was defined as chief complaints of pain and/ or stiffness in the neck or shoulder girdle region which was reproducible with neck movements. Subjects were excluded if their chief complaint of pain could not be reproduced by neck movement. Subjects were also excluded if they had history of tumour in the spine, spine compression fracture, osteoporosis and metabolic disorders such as rheumatoid arthritis, and prolonged steroid use. Additional exclusion criteria included neurological signs such as decreased deep tendon reflexes, muscle weakness and sensory deficits, surgery to the cervical or thoracic spine in the prior 6 months, and pregnancy. This study was approved by the Institutional Review Boards of Will ford Hall Medical Centre and the University of Pittsburgh. All subjects signed a consent form prior to participate in this research study.

This pilot study was powered based on a large treatment effect (F-statistic=0.63), and it was determined that 11 subjects per group would provide 80% power to detect the large treatment effect between groups at an alpha level of 0.05. Thus, 22 subjects were randomized into two groups of 11 subjects each. Four subjects (one from the MNP+TTM group and three from the MNP group) did not complete the study. One subject from the MNP+TTM group and one from the MNP group discontinued therapy after three visits without providing reasons. The remaining two subjects from the MNP group dropped after completing 2 weeks of therapy. Figure 1 represents the participant flow diagram along with reasons for drop-outs.

Outcome measures

Eligible subjects underwent a baseline testing session followed by 6 weeks of physical therapy treatment. The primary outcomes were pain, disability, and subject’s perceived change in health status assessed after 6 weeks of intervention. Secondary outcomes were neck range of motion and duration of care. The outcomes were also measured at 2 and 4 weeks during the intervention phase, in order to describe the trajectory of change in the outcomes during intervention and to capture improvements in the subjects who fully recovered and were discharged prior to the 6-week time point.

Pain was assessed using the 11-point numeric pain rating scale (NPS). The NPS is a valid, reliable and well-known measure of pain intensity [28,29]. The minimum clinically important difference (MCID) of the NPS in subjects with neck pain is a 2-point decrease in pain [30]. Subjects reported their current, worst and least amount of pain in the last 24 hours. These values were then averaged for data analysis. Disability caused by neck dysfunction was measured by the Neck Disability Index (NDI). NDI is a self- reported valid questionnaire that has been widely administered in neck trials for almost two decades [22,24,26,31-35]. It consists of 10 items, of which 7 address activity limitation, 2 address pain, and one addresses concentration. Each item is scored from 0 to 5 and the total score is expressed as a percentage; higher scores indicate greater disability. The MCID for the NDI in subjects with mechanical neck pain is a decrease in 10% of its scores [36]. Each subject’s perceived change in health status was measured by a 15-point Global Rating of Change (GRC) scale at 2, 4, and 6 weeks. The global rating of change ranges from 15 (“a very great deal better”) to 8 (“about the same”) to 1 (“a very great deal worse”). Intermittent descriptors of improving are assigned values from 9 to 15, and of worsening are assigned values from 1 to 7 [37]. A score of 12 and above represents a moderate improvement in health status, and is generally used as a cut-off for clinically important improvement [37]. Data on the NPS and the GRC were also collected at every treatment session to determine the criterion for discharge. The criteria for discharge the patients before the end of the 12 sessions included the absence of neck pain on the NPS and/or the rating of “a very great deal better” on the GRC during any treatment session.
Neck active range of motion (AROM) and duration of care were the secondary outcomes. Neck AROM was measured using a gravity goniometer. Neck flexion, extension, and side bending to the left and right were measured in sitting. The subjects were instructed to sit erect and look straight ahead. The goniometer was placed on their head in the sagittal plane for flexion and extension. Instructions to "try to touch the chin to the chest" were given for measuring flexion and to "bend backwards" for extension. Side bending to left and right was measured by placing the goniometer on the head in the frontal plane and instructions to "try to touch the ear to the shoulder" on each side were given. Rotation to both sides was measured in supine. The goniometer was placed in the transverse plane, on the midline of the participant’s forehead and instructions to "rotate the head to the left and right" were given. Measures of AROM have demonstrated good reliability. The intra-class correlation coefficient values for AROM measurement using these techniques ranged from 0.78 to 0.91 [38]. In addition, duration of care was calculated based on the total number of treatment visits for each subject before their discharge, as well as the number of days from randomization until discharge.

Randomization

Randomization was stratified by severity of pain (<7 or ≥ 7 points on the NPS) and site, and assigned in blocks of 4 subjects with equal allocation for each group. The principal investigator (SRP) used a random-number generator to obtain the randomization schedule and prepared sequentially numbered sealed opaque envelopes containing cards with intervention assignment. Baseline assessment of outcome measures was conducted prior to randomization. After baseline examination, the treating physical therapist opened the envelope with group assignment. Subjects were assigned to MNP or MNP supplemented with TTM (MNP+TTM). Intervention was initiated immediately after randomization. To ensure blinding during follow up assessments, each of the two participating clinics had a tester therapist who was blinded to the subject’s allocation and performed the range of motion tests. Self-reported questionnaires (NPS, NDI and demographics) were administered by the clinical front desk staff, and subjects completed the questionnaires in the waiting room prior to seeing the treating therapist.

Interventions

The interventions were delivered by experienced physical therapists credentialed in manual therapy practice. The treating physical therapists were trained in the study treatment procedures, and were instructed to record the interventions delivered to the subject during each session. Subjects in both intervention groups participated in a maximum of 12 treatment sessions, scheduled twice per week for 6 weeks. During intervention, the subjects were instructed to maintain their usual level of physical activity and to avoid activities that exacerbated their symptoms.
Multimodal neck program (MNP). All subjects in the study, regardless of group assignment, received the MNP. This program consisted of 3 components: electro/thermal therapeutic agents, active exercises, and manual therapy to the neck. Therapeutic agents included one of the following applied to the neck: transcutaneous electrical nerve stimulation, heat, or ultrasound. Active exercises consisted of neck range of motion, chin tucks and isometric strengthening exercises for neck flexion, extension, and lateral bending. Manual therapy for the neck consisted of soft tissue techniques (myofascial release or massage over the neck and shoulder girdle region) and oscillatory lateral glides for the cervical spine. The physical therapists had to adhere to the 3 components of the intervention. The therapist could choose the intervention to be used in each of the 3 components in a pragmatic way according to patient’s presentation. The therapist had to select: a) one of the therapeutic agents, b) the sequence of active exercises, and c) the manual therapy technique to be used. Each of the three components of the MNP intervention was performed for at least 7 minutes and no longer than 15 minutes. This flexibility was intended to keep the study intervention at par with clinical practice. Thrust (low amplitude high velocity) technique to the cervical spine was not allowed.

Thoracic Thrust Manipulation (TTM): Subjects assigned to the MNP+TTM group received TTM in addition to the MNP. The manipulation consisted of regional thoracic techniques performed during each treatment session (Appendix). The manipulation was performed with the subject supine or sitting, depending on therapist preference. The thoracic region to be manipulated was decided based on location of the most painful area and/or stiffness in the thoracic region. In absence of pain or stiffness in the thoracic region, the mid-thoracic area was manipulated. In addition to the TTM, the subjects were instructed to perform the Wing Arm Exercise a couple of times a day at home to maintain thoracic range of motion (Appendix).

Data analysis

Subject characteristics and baseline outcome measures were described using mean (standard deviation) or median (25-75 quartiles) for continuous data and frequencies for categorical data. Distribution of data was assessed using the Shapiro-Wilk test. Due to pilot nature of the study, all analyses were exploratory, with the main premise being to help interpret the findings with respect to clinical important changes we calculated the percentage of subjects who improved above the MCIDs for the NPS and NDI. Additionally, the trajectory of improvement in pain and disability for each group was observed using line graphs with average changes and their respective 95% CI at 2, 4 and 6 weeks.

The percentage of subjects in each group who reported a score of 12 and above [37] (moderate improvement in health status) on the GRC was also calculated at each follow-up. Duration of care was assessed as number of days from randomization till discharge and the number of PT sessions attended. A per-protocol analysis in subjects who completed the study was conducted. SPSS 22.0 (SPSS Inc. Chicago, IL) was used for all analyses.

Results

Baseline subject’s demographic and biomedical characteristics by group are displayed in Table 1, and demonstrated no visible differences between groups. According with the daily intervention records, the therapists treating the patients were compliant with delivery of interventions as outlined in the protocol. In both groups, the average compliance rate across the 12 visits for both groups was greater than 90% in each intervention component.

Table 2: Baseline demographics and biomedical characteristics. Variables are expressed as Mean ± Standard Deviation unless specified.

The within-group and between-group differences in outcome measures with their 95% CI are reported in Table 2. The within-group changes demonstrated clinically meaningful improvements for pain and disability in both groups. Between-group differences in outcomes at 6 weeks were small and are reflected by the small effect size indices for pain, disability and range of motion (Cohen’s d range: 0.04-0.3), with the exception of neck extension which showed a moderate effect size (0.55). Pairwise comparisons for within-group changes using the Wilcoxon signed-rank test demonstrated significant improvements in pain and disability in both groups, significant improvement in right side bending and right rotation in the MNP+ TTM group, and significant improvement in left side bending and rotations on both
In terms of clinical relevance of the findings, the average magnitude of improvement in pain and disability exceeded the MCID of the NPS and NDI, indicating that both groups experienced clinically important improvement in these outcomes. The NPS reduced 2.9 points in the group that received TTM, while it reduced 2.7 points in the group that did not receive TTM. The NDI score reduced 14.6% in the group that received TTM and 11.8% in the group that did not receive TTM. In addition, we calculated the percentage of subjects who improved above the MCID for the NPS and NDI at 6 weeks. We observed that 70% of those in the MNP+TTM group and 75% of those in the MNP group had clinical important improvements in pain. For disability, around 60% of subjects in each group improved above the MCID for the NDI. On the other hand, for range of motion measures, although a significant time effect was observed for changes in cervical extension, left side bending and rotations on both sides, the magnitude of changes were small and lower than the established minimum detectable changes for these measures. Right rotation in the MNP+TTM group improved 13 degrees and was the only movement that improved beyond its minimal detectable change [38].

In terms of clinical relevance of the findings, the average magnitude of improvement in pain and disability exceeded the MCID of the NPS and NDI, indicating that both groups experienced clinically important improvement in these outcomes. The NPS reduced 2.9 points in the group that received TTM, while it reduced 2.7 points in the group that did not receive TTM. The NDI score reduced 14.6% in the group that received TTM and 11.8% in the group that did not receive TTM. In addition, we calculated the percentage of subjects who improved above the MCID for the NPS and NDI at 6 weeks. We observed that 70% of those in the MNP+TTM group and 75% of those in the MNP group had clinical important improvements in pain. For disability, around 60% of subjects in each group improved above the MCID for the NDI. On the other hand, for range of motion measures, although a significant time effect was observed for changes in cervical extension, left side bending and rotations on both sides, the magnitude of changes were small and lower than the established minimum detectable changes for these measures. Right rotation in the MNP+TTM group improved 13 degrees and was the only movement that improved beyond its minimal detectable change [38].

![Figure 2](image-url)
Similar results for all the studied outcomes. The percentage improvement in pain scores relative to baseline for the MNP+TTM group was 11 and in the MNP group was 12. An intention-to-treat analysis including the 4 drop outs showed very similar results for all the studied outcomes.

Discussion

The current study is unique as it investigated whether a multimodal treatment approach to the neck when supplemented with TTM would provide additional benefits when compared to multimodal neck treatment alone. The study findings demonstrated that both MNP supplemented by TTM and MNP alone improved pain and disability in subjects with mechanical neck pain in a similar fashion after a 6-week intervention period. These results are supported by the small between-group effect sizes (d<0.3), similar average improvement on NPS and NDI, and equivalent percentage of subjects achieving clinically relevant improvements on outcomes of pain and disability at 6 weeks. Although previous trials reported superior benefits of TTM on pain and disability, these studies also compared TTM to interventions that have limited effectiveness in improving neck pain when applied in isolation [5,26,39,40] such as no intervention [20] sham manipulation [22,23] electro/thermal therapy, [17-19] or exercise alone[24]. In contrast, our trial tested the additive effects of TTM when used as a supplement of a multimodal intervention that included electro/thermal agents, exercises and non-thrust cervical spine manual therapy, which is a more clinically relevant comparison since such multimodal interventions are commonly used in clinical practice and are beneficial for patients with neck pain [5].

Both intervention groups in the current study demonstrated improvements similar to previous reports in studies that used TTM [22-24] or MNP [26,39] to treat mechanical neck pain. If we calculate the percentage improvement in pain scores relative to baseline for the current study, pain scores reduced 58% in those in the MNP+TTM group, and 47% in those in the MNP group. These results are comparable to studies that explored the short term effects of TTM compared to sham/non-thrust manipulation and demonstrated between 30% and 60% improvement in pain from baseline [22-24]. Disability scores reduced equally in both groups by 40% relative to baseline, which is also similar to previous study that observed about 45% reduction in disability in those who received TTM [22]. Current study findings are also comparable to previous studies that reported the benefits of MNPs over placebo and practitioner care [26],[39]. Previous studies demonstrated between 50% to 70% improvement of pain and between 43% to 63% improvement of disability in those who received non-thrust manual therapy techniques, electro/thermal modalities and active exercises directed at the neck [26],[39]. Thus when comparing our study findings to previous studies we observe similar improvements when TTM is combined with MNP to TTM or MNP alone; this seems to indicate that when thoracic manipulation is used, treatment to the neck region may not be necessary, or vice versa. Thus, these observations add perspective on the appropriate usage of TTM to treat mechanical neck pain, and are not intended to discourage the use of TTM.

The larger average improvements in NPS and NDI scores at 2 weeks in the MNP+TTM group compared to MNP alone suggests that thoracic manipulation can initially accelerate recovery in those with neck pain. Similar findings have been demonstrated in previous studies that showed improvements in pain and disability after 1-4 sessions of TTM [20-23]. We are only aware of one other study in mechanical neck pain that consisted of similar intervention and comparison arms as our current study, and reported immediate benefits of the arm that contained TTM [27]. Masaracchio and colleagues compared the benefits of TTM provided with non-thrust cervical manual therapy to non-thrust cervical manual therapy alone, on outcomes of pain (NPS) and disability (NDI) [27]. Both intervention arms also included active neck range of motion exercises. The study had a relatively short duration (one week); subjects underwent baseline testing, two treatment sessions and follow up assessment. Clinically relevant improvements in pain (decrease in NPS by 2.8 points) and disability (per cent scores of NDI decreased by 16%) in those that received TTM in addition to exercise and cervical mobilization compared to those that received only mobilization and exercise (mean decrease in NPS by 1.5 points, and per cent score of NDI by 7.4%). Although our improvements at 2 week follow up were smaller in magnitude they followed a similar pattern that favoured the treatment arm with TTM: MNP+TTM group mean decrease in NPS by 1.6 points and in NDI per cent scores was 10.2%, while in the MNP group mean decrease in NPS scores was 0.2 points, and no improvement in NDI scores. These differences between the groups in the current study faded with time, and by 6 weeks both groups had similar magnitudes of improvement in pain and disability scores. While TTM seems to accelerate recovery, it did not significantly reduce the overall duration of care, as both groups showed no significant difference in time to discharge or in number of PT sessions.

The study is not free of limitations. The small sample size may limit the ability to detect statistically significant differences between the groups, however, the non-significant between-group findings are supported by small effect sizes (d<0.3). The negative findings are further supported by the considerable overlap of the within-group 95% CI for both NPS and NDI, and by the observation that the between-group 95% CI was reasonably symmetric around 0 (zero) for NPS and NDI. Furthermore, both groups showed similar magnitudes of change and similar rates of subjects that improved beyond the MCIDs for pain and disability, indicating that clinically relevant changes were similar irrespective of treatment group. In summary, even though definitive conclusions cannot be inferred by this study, the results indicate that...
TTM may not provide additional benefits when a multi-modal intervention is already being used to treat mechanical neck pain.

Conclusions

Results of this study indicated that TTM did not provide additional benefits above that of a 6 week of MNP that included non-thrust manual therapy, active exercises, and electro/thermal modalities to the neck. Both groups demonstrated clinically important improvements in pain, disability, and perceived health status at 6 weeks follow up period. Neck range of motion and duration of care were also similar in both groups. We believe the results may assist clinicians to understand the potential role of TTM in patients with neck pain.

References


