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Validation of a sham comparator for thoracic spinal manipulation in patients with shoulder pain

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ABSTRACT

The evidence to guide use of spinal manipulative therapy (SMT) for patients with shoulder pain is limited. A validated sham comparator is needed to ascertain the unique effects of SMT. We investigated the plausibility of a thoracic sham-SMT comparator for SMT in patients with shoulder pain. Participants ($n = 56$) with subacromial impingement syndrome were randomized to thoracic SMT or a sham-SMT. An examiner blinded to group assignment took measures pre- and post-treatment of shoulder active range of motion (AROM) and perceived effects of the assigned intervention. Treatment consisted of six upper, middle and lower thoracic SMT or sham-SMT. The sham-SMT was identical to the SMT, except no thrust was applied. Believability as an active treatment was measured post-treatment. Believability as an active treatment was not different between groups ($\chi^2 = 2.19$; $p = 0.15$). Perceptions of effects were not different between groups at pre-treatment ($t = 0.12$; $p = 0.90$) or post-treatment ($t = 0.40$; $p = 0.69$), and demonstrated equivalency with 95% confidence between groups at pre- and post-treatment. There was no significant change in shoulder flexion in either group over time, or in the sham-SMT for internal rotation ($p > 0.05$). The SMT group had an increase of 6.49° in internal rotation over time ($p = 0.04$). The thoracic sham-SMT of this study is a plausible comparator for SMT in patients with shoulder pain. The sham-SMT was believable as an active treatment, perceived as having equal beneficial effects both when verbally described and after familiarization with the treatment, and has an inert effect on shoulder AROM. This comparator can be considered for used in clinical trials investigating thoracic SMT.

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1. Introduction

Subacromial impingement syndrome associated symptoms arise from injury to one or more structures in the subacromial region – the rotator cuff and biceps tendon, bursae, and labrum. The causes of mechanical compression or excessive tendon loading are multifaceted. (Schellingerhout et al., 2008; Seitz et al., 2011; Braman et al., 2014) Thoracic spine mobility loss and 'slouched' posture (Theisen et al., 2010; Kalra et al., 2010) has been shown to reduce shoulder motion and decrease subacromial space dimensions. Thoracic spinal manipulative therapy (SMT), a low-amplitude high-velocity spinal thrust, is a treatment used to theoretically improve thoracic motion deficits. However, evidence does not support spinal motion changes after thoracic SMT (Campbell and Snodgrass, 2010; Muth et al., 2012). More recently, thoracic SMT has been shown to have neurophysiological effects of increased shoulder muscle performance and central nervous system hypoalgesia (Cleland et al., 2004; Bishop et al., 2011).

In patients with subacromial impingement syndrome, systematic reviews (Michener et al., 2004; Kromer et al., 2009) report short-term beneficial patient-rated outcomes with the use of manual therapy to the thoracic spine and shoulder. Three randomized clinical trials (Winters et al., 1997; Bang and Deyle, 2000; Bergman et al., 2004) delivering a package of manual therapy that included manipulation and mobilization of both the spine and shoulder girdle reported greater reductions in shoulder pain and disability with manual therapy treatment as compared to exercise only, subacromial injection only, or a combined approach of usual care (wait-and-see, injection, or physiotherapy). When thoracic SMT was used as a stand-alone treatment in a total of $n = 157$

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patients with shoulder pain (Boyles et al., 2009; Strunce et al., 2009; Mintken et al., 2010), there were immediate and short-term improvements in pain, shoulder range of motion and global rating of improvement. Without a control or comparator group for SMT that is comparable in physical contact and time spent with the patient, it is difficult to determine if the positive outcomes are solely attributable to SMT. The mechanisms and benefits of thoracic SMT in patients with shoulder pain are unclear.

To isolate the effects of SMT, it must be studied as a single intervention and control for non-specific effects with the use of a valid sham comparator. The lack of a sham comparator has limited the applicability of SMT studies without control of potential confounders such as passage of time, healthcare provider interaction, and perceived effects of the intervention. Without a comparator, effects may be falsely attributed to SMT. A sham comparator needs to be believable as an active and effective treatment. Moreover, an ideal sham will be inert, but otherwise replicate as closely as possible all other aspects of the intervention to be perceived as a beneficial active intervention.

A thoracic spine sham-SMT procedure has been reported as believable as an active treatment and to have perceived benefits (Michener et al., 2013). However, this prior study used only healthy participants. The aim of this study was to determine if a sham-SMT described previously (Michener et al., 2013) is a plausible sham comparator for SMT in patients with shoulder pain related to subacromial impingement syndrome. Three hypotheses were investigated. First, we hypothesized that the percentage of patients believing they received an active intervention will not be different between those receiving the sham-SMT as compared to the active SMT. Second, perceived beneficial effects will be no different between the groups at pre-treatment and post-treatment. Lastly, we hypothesized the SMT would improve shoulder range of motion, while the sham-SMT would cause no change in shoulder motion indicating an inert effect of the sham-SMT.

2. Methods

A prospective pre-post randomized controlled double-blind study design was used to assess the plausibility of a sham comparator for thoracic SMT. Ethics approval was obtained prior to the start of the study from Virginia Commonwealth University Internal Review Board (HM13182).

2.1. Participants

Patients with shoulder pain were recruited from local physical therapy and orthopedic surgeon clinics, and the community from November 2012 through April 2013. Patients were diagnosed with subacromial impingement syndrome and meeting the inclusion and exclusion criteria were asked to participate in the study. Inclusion criteria was pain >6 weeks, pain ≥2/10 on an 11-point scale, 18–60 years of age, and positive on 3 of 5 tests of the clinical examination for subacromial impingement syndrome: 1) Hawkins test, 2) Neer test, 3) pain arc test, 4) Jobe/Empty Can test–pain or weakness, 5) resisted shoulder external rotation test–pain or weakness (Michener et al., 2009). Patients were excluded if they previously had surgery of the shoulder, cervical spine, or thoracic spine; had a primary complaint of neck or thoracic pain; signs of cervical nerve root involvement; reproduction of shoulder or arm pain with cervical rotation to the ipsilateral side, axial compression, or Spurling's Test; signs of central nervous system involvement; contraindications to manipulative therapy such as osteoporosis, metastatic disease, or systemic arthritis; and primary diagnosis of adhesive capsulitis or shoulder instability. Patients ($n = 72$) were screened, and $n = 16$ did not meet the inclusion and exclusion criteria. Participants ($n = 56$) were randomly assigned to either a SMT treatment group ($n = 28$) or a sham SMT group ($n = 28$). Participants had an average age of 31.7 years, and were a little less than half female (Table 1).

2.2. Procedures

All participants were provided verbal and written explanation of study procedures and signed an informed consent approved by XXXX University Internal Review Board prior to participation. Participants were told the purpose of the study was to examine the effects of different spinal treatments, and they could receive an active treatment or look-alike placebo treatment. Participants were randomized to the SMT or sham-SMT group using a computer generated randomization list created in blocks of 2, 4, and 6. Prior to the delivery of the assigned treatment, participants were told they were randomized to either 'spinal manual therapy' (SMT) or 'therapist-assisted range of motion' (sham-SMT) in order to blind them to their group assignment as the active or inactive treatment.

Prior to treatment, participants completed an intake questionnaire consisting of health screening questions, demographics, and symptom history. Participants also completed a baseline numeric pain rating scale (NPRS), range 0–10 (0 = no pain, 10 = worst possible pain) and the Pennsylvania Shoulder Score (Penn) (Leggin et al., 2006), a shoulder-specific patient-rated outcome with the score range of 0–100 (100 = full shoulder function, no pain and fully satisfied with shoulder use). Next, shoulder active range of motion (AROM) of flexion and internal rotation were measured using a digital inclinometer. Prior to treatment delivery, participants were asked about their perception of the effects of their assigned treatment that was described only as the label given to the treatment of 'manual therapy' or 'spinal range of motion'. Post-treatment, participants underwent the same measures as pre-treatment of shoulder range of motion and perception of effects of the treatment they received. Additionally, they were asked their belief of which treatment group they were assigned of an 'active form of treatment' or 'placebo form of treatment (look-alike inactive treatment)'. The examiner who performed the pre-treatment and post-treatment measurements was blinded to treatment group assignment. A second person, a licensed physical therapist delivered the sham-SMT and SMT treatments. The treating clinician was blinded to the pre- and post-treatment measurements. Adverse event of increased pain was recorded if there was an increase of 2 or more points in pain on an 11-point NPRS, based on clinically meaningful change in pain in patients with shoulder pain (Mintken et al., 2009; Michener et al., 2011).

Table 1
Patient demographics and characteristics.

Characteristic	Total ($n = 56$)	SMT group ($n = 28$)	Sham-SMT group ($n = 28$)	*P* value
Age, yrs (SD)	31.7 (12.1)	30.9 (11.9)	32.5 (12.4)	0.62
Male gender, *n* (%)	30 (53.6%)	12 (42.9%)	18 (64.3%)	0.11
Dominant shoulder, *n* (%)	33 (58.9%)	14 (50%)	19 (67.9%)	0.17
Height, cm (SD)	175.3 (10.3)	172.7 (9.6)	177.8 (10.6)	0.07
Weight, kg (SD)	80.2 (16.9)	77.7 (17.1)	82.8 (16.5)	0.26
BMI (kg/m2)	26.2 (5.8)	26.1 (6.0)	26.4 (5.8)	0.86
Symptom duration (month)	37.7 (55.5)	38.5 (61.4)	36.8 (50.0)	0.91
Penn, points (SD)	71.2 (11.5)	71.3 (10.9)	71.1 (12.3)	0.94
NPRS, points (SD)	3.6 (1.4)	3.5 (1.3)	3.6 (1.4)	0.70

NPRS = Numeric Pain Rating Scale, 0–10 points, 0 = no pain.
Penn = Pennsylvania Shoulder Score, 0–100 points, 100 = full shoulder function, no pain, full satisfied with shoulder use.