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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 (χ^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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Uncited reference

Cleland et al., 2007; Kanlayanaphotporn et al., 2009; Shum et al., 2013.

Keywords

Sham; Rotator cuff; Thoracic spinal manipulation; Validity

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., 2013) 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 $n = 157$ 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).

2.3. Measurements

2.3.1. Perceived effects and believability—Prior to the treatment, participants answered 3 questions about their perception of the assigned treatment based on the labels of the assigned treatment. The 3 questions were: "Would you expect the effects of the treatment you will receive to: 1- decrease shoulder pain, 2- increase shoulder motion, 3- improve the use of the shoulder", with yes or no response options to each question. Post-treatment, participants completed the same questions about the perceived effects of the randomly assigned treatment they just received. Each answer was assigned a point value; 0 = no, 1 = yes, with a maximum of 3 points indicating maximum positive perceived effects of treatment. To assess believability of the sham comparators, the participants were asked post-treatment whether they believed they received the active form of treatment or a placebo form of treatment (a look-alike inactive treatment).

2.3.2. Shoulder AROM – flexion and internal rotation—Maximum active shoulder flexion was measured with participants seated in a chair with a fixed back. An Acumar™ digital inclinometer was placed along the long axis of the mid-humerus with the elbow in extension and the shoulder in neutral rotation. Participants were asked to keep their back firmly against the chair back and raise their arm as far as they could, going as far as they could regardless of the onset of pain. Shoulder maximum active internal rotation was measured in supine with the arm was positioned at 90° of humeral abduction and the elbow in 90° of flexion. The inclinometer was placed parallel to the mid-forearm, and starting in a

neutral position of humeral rotation and were asked to actively internally rotate their arm as far as they could regardless of the onset of pain. AROM measures were taken twice and averaged for final data analysis.

Test-retest reliability (inter-session) was established for the digital inclinometer measures on $n = 10$ participants. For flexion AROM, reliability was excellent [$ICC_{(3,2)} = 0.95$; SEM = 1.01°; $MDC_{90} = 1.42°$]. For shoulder internal rotation AROM, reliability was excellent [$ICC_{(3,2)} = 0.94$; SEM = 1.41°; $MDC_{90} = 1.99°$]. A change in shoulder AROM from pre-treatment to post-treatment would be considered meaningful if it was greater than the MDC of 1.42° for shoulder flexion and 1.99° for shoulder internal rotation.

2.4. Interventions

2.4.1. Manipulation group—A standardized treatment package of SMT was applied to the lower, middle, and upper (cervicothoracic junction) thoracic spine. Techniques used in prior clinical trials investigating the effects and outcomes of thoracic SMT in patients with shoulder pain were selected for use (Boyles et al., 2009; Strunce et al., 2009; Mintken et al., 2010), specifically, high-velocity low-amplitude thrusts applied at the end of the joint motion after the patient exhaled. For the cervicothoracic junction manipulation, the participants were seated and the thrust was provided as an axial (cephalad) distraction; and for the middle and lower thoracic spinal manipulation the participants were prone, and the thrust was directed in the posterior to anterior direction. Each regional technique was applied 2 times, for a total of 6 thoracic SMT doses, taking approximately 6 min.

2.4.2. Sham-manipulation group—The sham-SMT was performed with same patient body positioning as the SMT. The therapist followed the patient through the same spinal joint range of motion, but no manipulative thrust was delivered. The clinician applied minimal pressure and slid their hands across the skin to mimic the manipulative thrust. A total of 6 doses, 2 at each of the upper, middle and lower thoracic spine which took approximately 6 min, were delivered to mimic the treatment of the SMT group. This sham-SMT was validated as plausible and believable as an active treatment in participants free of shoulder pain (Michener et al., 2013).

Sample size estimates were determined for the primary aim of believability. An *a priori* power analysis for a Chi-square test, setting the expected test proportion at 0.50, significance at 0.05, and a standard proportion (those believing the active treatment to be active) set at 0.70 indicated $n = 23$ participants per group needed for 80% power.

3. Data analysis

Means, standard deviation and frequencies were calculated for all descriptive variables. To determine if the believability as an active treatment was different between the active SMT and the sham-SMT comparator group, the believability ratings (sham, look-a-like/active) of the active SMT group and the sham-SMT group were compared using a chi-square analysis, $\alpha = 0.05$. Perceived effects of treatment were examined by comparing the perceived effects of treatment at pre-treatment and post-treatment using independent *t*-tests, two-tailed with $\alpha = 0.05$. We performed additional testing to demonstrate the equivalence of pre-treatment and

post-treatment values of perceived effects (Garrett, 2005). No literature exists to suggest an *a priori* tolerance level for the equivalence testing for perceived effects of sham treatments based on a 4-point scale. Generally 2 points on an 11-point scale patient-rated scale represents a significant change (Salaffi et al., 2004). Based on those data, we extrapolated a similar ratio of significant change of 0.73 points on a 4-point scale of perceived effects. The *a priori* level for equivalence testing was therefore set at 0.73. To examine the effect on shoulder AROM, repeated measures ANOVAs were used to compare AROM of flexion and internal rotation between groups (SMT, sham-SMT) over time (pre and post-treatment), α = 0.05, with Tukey's Honestly Significant Difference post-hoc testing for change over time. Analyses were performed using SPSS 20.0 statistical software (SPSS Inc., Chicago, IL, USA).

4. Results

Patient (n = 56) with subacromial impingement syndrome participated in this study, with an even allocation of participants in the two treatment groups. There were no differences in patient demographics or characteristics between treatment groups (Table 1). There were no reports of subject adverse events with SMT or sham-SMT, as no participants reported an increase in NPRS of 2/ 10 or greater.

4.1. Believability

The percentage of participants who believed they received an active intervention in the SMT group (78.6%) and the sham-SMT group (60.7%) was not different between groups (χ^2 = 2.19, p = 0.15). Table 2 contains the descriptives for believability and perception of effects.

4.2. Perceived effects

Differences or lack thereof in perceived effects between treatment groups were assessed in 2 ways. First, there were no significant differences for perceptions of effects between SMT and sham-SMT groups at pre-treatment (t = 0.12, p = 0.90) and at post-treatment (t = 0.40, p = 0.69). We also performed equivalency testing, to test the hypothesis that the groups had the same perceived effects, specifically using a t distribution at 95% confidence indicated with a sample size of n < 30 per group. At pre-test, the mean difference in perceived effects between the SMT and sham-SMT was −0.03 [(95%CI = −0.60, 0.54), pooled SD = 1.07]. At post-test, the mean difference was 0.11 [(95%CI = −0.41, 0.62), pooled SD = 0.96]. The 95%CI of the perceived effect scores fell entirely within the *a priori* hypothesized equivalence range of ± 0.73, indicating statistically equivalent means between groups.

4.3. Shoulder flexion and internal rotation AROM

The descriptives for shoulder AROM measures are presented in Table 3. Comparison between groups over time for shoulder flexion AROM revealed no significant main effect [$F_{(1,54)}$ = 1.73; p = 0.20], nor a significant interaction [$F_{(1,54)}$ = 0.50, p = 0.48]. Internal rotation AROM had no significant interaction [$F_{(1,54)}$ = 0.02; p = 0.90], but there was a main effect for group [$F_{(1,54)}$ = 27.51; p < 0.001]. Tukey's HSD post-hoc testing revealed a significant increase in internal rotation over time within the SMT group [mean difference =

6.49° (95%CI = 3.20°, 7.17°) $p = 0.04$], but no significant difference over time for internal rotation motion in the sham-SMT group ($p = 0.62$).

5. Discussion

The sham-SMT investigated in this study is plausible for use as an inactive comparator to SMT delivered to the thoracic spine in patients with subacromial impingement syndrome of the shoulder. The sham-SMT was demonstrated to be believable as an active treatment, and had equal perceived effects on improving shoulder pain, motion and functional use of the shoulder. Moreover, we showed that the sham-SMT has an inert effect on shoulder range of motion. A prior study (Michener et al., 2013) reported that the same sham-SMT delivered to the thoracic spine was plausible and had an inert effect on shoulder range of motion, but only in participants free from shoulder pain. We have furthered this work, by validating the thoracic spine sham-SMT in patients with shoulder pain. Future clinical trials can use this sham-SMT to investigate the effects and outcomes of SMT in patients with shoulder pain.

Thoracic SMT may enhance patient-rated outcomes when used in the treatment of patients with shoulder pain. Thoracic SMT as a stand-alone treatment has demonstrated improvements patient-rated outcomes and shoulder range of motion in patients with shoulder pain (Boyles et al., 2009; Strunce et al., 2009; Mintken et al., 2010). However, not all patients improved with SMT. It is unclear as to when SMT should be used to treat patients with shoulder pain.

Elucidating the mechanisms of SMT may provide information that clinicians could use to enable treatment decision-making of SMT. Two predominant theories of SMT actions are biomechanical and neurophysiological. (Pickar, 2002; Bialosky et al., 2009; Herzog, 2010) Thoracic SMT has shown to alter muscle activity and induce central nervous system hypoalgesia (Cleland et al., 2004; Bishop et al., 2011). Evidence does not support meaningful biomechanical changes in passive mechanical stiffness or thoracic spinal motion after thoracic SMT. (Campbell and Snodgrass, 2010; Muth et al., 2012) Moreover, studies of vertebral motions during SMT have demonstrated only transient effects (Gal et al., 1997; Colloca et al., 2006), which limits the applicability of the biomechanical model of SMT. Future work is needed to characterize the mechanisms of thoracic SMT, in order to facilitate guidelines for the appropriate clinical use of SMT.

Perceived beneficial effects of SMT were assessed by asking patients their perception of effects at two time points, with only a verbal description of the treatment at pre-treatment, and then again after familiarity with the treatment at post-treatment. Neither group was given more than a label of the group they were assigned to, “spinal manual therapy” or “spinal range of motion,” prior to receiving their assigned treatment protocol. Both the SMT and sham-SMT group in this study received similar levels of therapist interaction, identical patient positioning and identical positioning of the therapist’s hands. We hypothesized that patients receiving a similar intervention would perceive both treatments as equal in terms of effects of treatment on shoulder pain, motion, and functional use. The results demonstrated that for traditional difference testing with *t*-tests and equivalence testing, the groups demonstrated equal levels of perceived effects of their assigned treatment both before and

after the treatment was administered. Believability as an active treatment was assessed after treatment, and the percentage of patients that reported that received an active treatment were not significantly different. The sham-SMT, as delivered in this study has demonstrated adequacy as a sham comparator in patients with shoulder pain.

The sham-SMT did not result in any changes in shoulder flexion or internal rotation AROM over time. This supports our hypothesis that the sham-SMT will have no effect on shoulder AROM, providing support for an inert effect. Future studies should determine if the sham-SMT has no other biomechanical or neurophysiological effects. Interesting, the SMT group demonstrated an increase of 6.49° in shoulder internal rotation over time, indicating that the SMT can affect shoulder motion. The improvement of 6.49° is greater than the MDC of 1.99° for this internal rotation measure.

The ideal placebo will be replicate as closely as possible all aspects of the active intervention, except have an inert effect. It will have similar perceived effects and believable as an active treatment. A variety of sham lumbar manipulative techniques have been proposed, but no consensus on a viable sham technique has been reached (Hancock et al., 2006). In this current study, the thoracic sham-SMT closely replicated the SMT with the same patient positioning and clinician hand positioning but with very minimal pressure. The thoracic SMT was demonstrated to be both plausible with respect to perceived effects, believed as an active treatment, and an inert effect on shoulder range of motion. However, there other placebo effects of the sham that were not investigated such as changes in peripheral and central nervous system sensitization. There are other potential shams, such as sham-ultrasound. Sham-ultrasound was not used in this study because it was found not to be plausible when compared to SMT, but only in participants without shoulder pain (Michener et al., 2013). We did not assess the effects of SMT on thoracic spine posture or mobility, which has been demonstrated to alter shoulder AROM. Additionally, muscle activity or activation was not assessed, which would more comprehensively assess the inert effects of the sham-SMT. Cavitations were not assessed in the SMT group, and therefore outcomes of the SMT were not examined in relationship to the presence of cavitations. Finally, we did not asses the validity of multiple sham-SMT treatment sessions, which may impact the plausibility of this sham-SMT.

This study provides evidence of plausibility for a thoracic spine sham-SMT as a comparator to SMT in patients with subacromial impingement syndrome. The sham-SMT was demonstrated to be believable as an active treatment, have equal perception of beneficial effects of the sham-SMT as compared to the active SMT, as well as having no effect on shoulder AROM. This comparator can be considered for use in clinical trials investigating the effects and outcomes of SMT in patients with shoulder pain.

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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.

Table 2

Believability and perception of effects for the spinal manipulative therapy (SMT) and sham-SMT.

	SMT group (*n* = 28)	Sham-SMT group (*n* = 28)	Statistic
Belief of treatment group, n (%)			
Active	22 (78.6%)		$\chi^2 = 2.19$, $p = 0.15$
		17 (60.7%)	
Placebo (look-like inactive)	6 (21.4%)		
		11 (39.3%)	
Perception of effects, pre–treatment			
Sum of 3 questions[a] (SD)	1.93 (1.27)		$t = 0.12$, $p = 0.90$
		1.96 (0.88)	
Perception of effects, post–treatment			
Sum of 3 questions[a] (SD)	2.18 (1.02)		$t = 0.40$, $p = 0.69$
		2.07 (0.98)	

[a]Perception of effects: 0–3, 3 = maximum positive perception of effects.

Table 3

Effects on shoulder active range of motion for spinal manipulative therapy (SMT) and sham-SMT groups.

	Shoulder active range of motion			
	Flexion (degrees)		Internal rotation (degrees)	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
SMT Group	172.54 (8.71)	173.61 (7.80)	46.88 (11.72)	53.37 (10.43)[a]
Sham-SMT Group	168.96 (9.22)	169.32 (9.35)	45.68 (12.42)	47.91 (14.95)

[a] Significant change from pre-treatment to post-treatment ($p = 0.04$).