A systematic review of thrust manipulation combined with one conservative intervention for rotator cuff and related non-surgical shoulder conditions

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Objective: To determine effects of thrust manipulation plus one conservative intervention for non-surgical shoulder pain and disability due to rotator cuff dysfunction.

Methods: This review followed PRISMA guidelines. The databases searched were PubMed, PEDro, ICL, CINAHL, and AMED. Included were randomized trials with at least one group assigned to receive thrust manipulation and one adjunct conservative therapy. The Objectif : Évaluer les effets de la manipulation avec impulsion associée à une intervention conservatrice pour traiter la douleur à l'épaule ne nécessitant pas d'intervention chirurgicale et l'incapacité causée par une pathologie de la coiffe des rotateurs.

Méthodologie : La présente revue a été réalisée conformément aux lignes directrices PRISMA. Les bases de données interrogées sont PubMed, PEDro, ICL, CINAHL et AMED. Sont compris dans la revue des essais avec répartition aléatoire réalisés avec au moins un groupe de sujets devant subir une manipulation avec impulsion et une thérapie conservatrice d'appoint. On a utilisé l'échelle PEDro pour évaluer la qualité de la

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PEDro scale was used to assess methodological quality and GRADE for analysis.

Results: The search yielded 2088 articles with one meeting eligibility criteria. The trial examined thrust manipulation with exercise compared to sham. Statistically significant improvements in pain and disability were reported within but not between groups. Evidence quality according to the PEDro scale was good; GRADE was moderate.

Conclusion: Few trials have been conducted studying thrust manipulation plus another conservative intervention for rotator cuff conditions rendering available evidence of thrust manipulation plus exercise insufficient to determine effects of this combined treatment.

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KEY WORDS: chiropractic, thrust manipulation, manual therapy, rotator cuff, shoulder

Introduction

Shoulder pain is a prevalent condition with a lifetime occurrence of 1 in 3 people.¹ In the U.S., patients with rotator cuff disease comprise the majority (65%) of shoulder pain-related visits to physicians^{2,3}, and the incidence of rotator cuff conditions is expected to increase in an aging population of active patients with a low tolerance for dysfunction or physical restrictions^{3,4}. Rotator cuff conditions are typically diagnosed as tendinopathy which includes external or internal impingement, tendinitis, tendinosis with degeneration, and partial-thickness tendon tears.⁵

It is important to use and further develop non-surgical interventions for rotator cuff conditions to reduce risk and cost.⁶⁻⁸ Systematic reviews have been conducted evaluating manual therapies (including manipulation) for shoulder pain and conditions such as rotator cuff disease, and several have reported a moderate level of evidence supporting effectiveness.⁹⁻¹¹ However, some reviews have included studies with limitations such as *méthodologie et la méthode GRADE pour analyser la littérature.*

Résultats : La recherche a permis de repérer 2 088 articles dont un satisfaisant les critères d'admissibilité. L'essai visait à comparer les effets de la manipulation avec impulsion associée à des exercices à ceux d'un traitement fictif. Des améliorations significatives sur le plan clinique de la douleur et de l'incapacité ont été signalées à l'intérieur des groupes, mais non pas entre les groupes. La qualité des preuves était bonne selon l'échelle PEDro; la qualité de la méthode GRADE était moyenne.

Conclusion : Il existe peu d'essais sur la manipulation avec impulsion associée à une intervention conservatrice pour traiter les pathologies de la coiffe des rotateurs; par conséquent, les données probantes sur la manipulation avec impulsion associée à des exercices sont insuffisantes pour évaluer les effets de ce traitement associatif.

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MOTS-CLÉS : chiropratique, manipulation avec impulsion, coiffe des rotateurs, épaule

small randomized controlled trials without statistical differences between intervention groups or lacking the analyses or power to detect differences, and case reports and series.¹²⁻¹⁵ Additionally, previous systematic reviews do not adequately isolate the clinical effect of single or multiple conservative interventions (defined as those without medications, injections, or surgery) for shoulder conditions. This is particularly problematic for manual therapists including doctors of chiropractic because they often use multimodal treatments, combining therapies such as manipulation, mobilization, exercise, and massage.16,17 Without this knowledge, clinicians must ask important questions for each patient with shoulder pain such as: How many treatment interventions should be employed? What combinations of treatments are most effective? and What treatment combinations are ineffective or counterproductive? Though they generally endorse many conservative therapies, former systematic reviews don't answer these questions. Thus, clinicians must make

Inclusion	Exclusion
Randomized controlled trials	• Studies involving thrust manipulation under anesthesia
Studies including human participants of any ageStudies with the following interventions: thrust	• Studies including pharmaceuticals or injections included in treatment protocols
manipulation plus one conservative therapy in at least one study group	Studies lacking procedural descriptions of treatmentsStudies including a single intervention
 Studies reporting a confirmed diagnosis of or systematic diagnostic procedures categorizing shoulder symptom(s) as a rotator cuff or related 	• Studies including manipulation plus 2 or more conservative treatments
disorder	Studies involving participants requiring surgical evaluation or post-surgical conditions

Table 1. Article eligibility criteria.

important intervention choices for common shoulder conditions without the support of strong scientific evidence.

Recently, Minkalis et al. performed a systematic review of thrust manipulation as a solitary treatment for shoulder pain and related disorders.¹⁸ The review identified only a few studies using spinal or extremity thrust manipulation alone for the treatment of shoulder impingement syndrome. Due to the paucity of evidence, the review concluded there is insufficient data to support or refute thrust manipulation as a singular intervention for shoulder pain and disability. Thrust manipulation was not significantly more effective than sham. However, patients receiving thrust manipulation consistently reported reduced pain suggesting there is a mild therapeutic benefit. Given the small therapeutic effectiveness of this individual treatment, it is reasonable to question whether combining it with another intervention can contribute to an additive or synergistic effect. Therefore, the next logical question in this line of research should ask whether adding an additional conservative therapy to thrust manipulation demonstrates greater therapeutic effect. The purpose of this systematic review is to evaluate clinical trial evidence to determine the effectiveness of thrust manipulation plus one conservative intervention for the non-surgical management of shoulder pain and/or dysfunction associated with the rotator cuff.

Methods

This systematic review was conducted and reported ac-

cording to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Literature search

The electronic databases PubMed, Physiotherapy Evidence Database (PEDro), Index to Chiropractic Literature (ICL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Allied and Complementary Medicine Database (AMED) were searched from inception to May 2017. The search strategies were developed with a health sciences librarian and an example strategy is included in Appendix 1. References from articles that met the eligibility criteria and systematic reviews retrieved during the electronic search were hand-searched for studies potentially missed initially. The WHO International Clinical Trials Registry Platform (www.who.int/ictrp/ en/) and U.S. National Institutes of Health (https://clinicaltrials.gov/) were also searched to identify unpublished trials to evaluate the presence and magnitude of publication bias. This approach is consistent with the updated method guideline for systematic reviews published by the Cochrane Back and Neck Group.¹⁹

Eligibility criteria

Articles published in any language in peer-reviewed journals were screened for eligibility and included based on the criteria outlined in Table 1. Thrust manipulation was defined as high-velocity low-amplitude (HVLA) or Grade V mobilization, characterized by a single thrust directed to a specific joint and often resulting in an audible cavi-

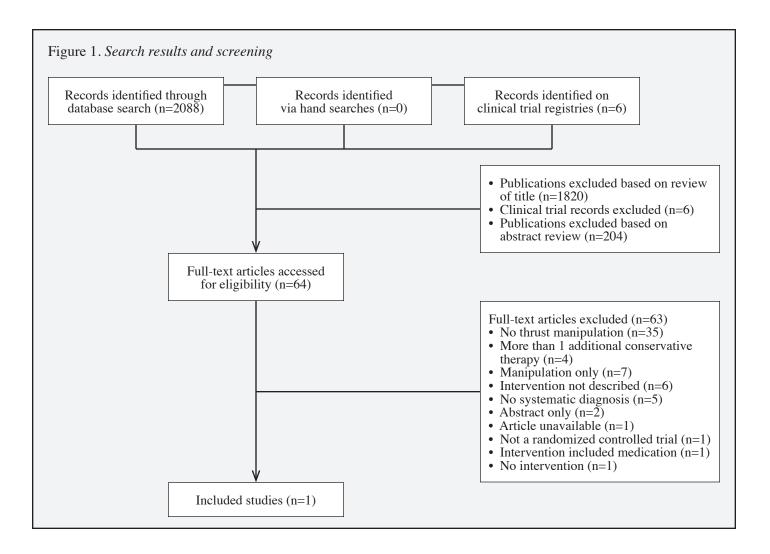


Table 2.

Characteristics of the included study for treatments for the management of rotator cuff or related disorders.

Autho & Yea		Diagnostic confirmation procedures	Intervention	Comparison	Treatment frequency	Data collection	Outcome Measures	Results	Conclusion
Riley et al. 2015 ²⁶	n=88 Mean age 49, both groups Mean duration 6 mo	Shoulder pain $\geq 2/10$ but $\leq 8/10$; at least 1 positive Hawkins- Kennedy, Neer Impingement, painful resisted abduction, or painful resisted external rotation at 0^{0} of abduction with elbows bent to 90^{0}	Group 1: TTM, ^a positive message and home exercise program Group 3: TTM, neutral message and home exercise program	Group 2: STM, ^b positive message and home exercise program Group 4: STM, neutral message and home exercise program	1 treatment	Pre, immediate post-treatment and 1-week follow-up	NPRS ^c (1-10) SPADI ^e (0-130)	Pre-post mean change present pain combined group': 1.76 (0.99- 2.54)*; pain with AROM ^d combined group: 1.36 (0.63-2.10)** Pre-post mean change combined group: 8.74 (6.00-11.49)**	No statistically significant differences between treatments or type of message

^aThoracic thrust manipulation; ^bScapular thrust manipulation (sham); ^cNumeric Pain Rating Scale; ^dActive range of motion; ^cShoulder Pain and Disability Index (higher score reflects more disability); ^{*}Inferential statistical analysis was done with TTM vs STM, messaging and treatment allocation as the grouping variable; ^{**}Means (95% confidence interval)

tation.²⁰ The manipulation could be directed to one of the shoulder joints, a cervical or thoracic spine joint, or a combination of the three. Conservative treatment was defined as manual therapy, electrotherapy, cryotherapy, heat therapy and exercise. Procedures including medication (e.g., prescriptions, over-the-counter, and injections) or surgery were ineligible.

Study selection and data extraction

Two independent reviewers (AM and KD) conducted article screening and determined eligibility. First, titles and abstracts were screened, and those that were irrelevant were excluded. Abstracts which appeared to meet review criteria were recorded and the full-text version of the article was retrieved. A final review of eligibility was performed and results were recorded in an Excel spreadsheet. Reviewers agreed on eligibility status of all but 4 articles initially; discussion between the 2 reviewers resulted in consensus.

A priori, we designated pain and function or disability outcomes as the primary outcomes of interest as these are clinically relevant and reported in most clinical trials studying conservative interventions for musculoskeletal conditions. The primary author (AM) extracted study characteristics/data from the included articles. Another author (CH) performed a secondary evaluation of the data extraction. Consensus agreement was reached through personal discussion.

Critical appraisal

The eligible study was assessed (AM) for its methodological quality using the PEDro scale. The score was consistent with the scoring for this study as listed in the PEDro database. The PEDro scale has been validated as a measure of the methodological quality of clinical trials²¹ assessing internal validity and sufficient statistical information for interpretability. The tool uses an 11-point scale based on items from the Delphi list developed by Verhagen *et al.*²² The first point pertains to external validity and is not counted toward the overall score, leaving a possible total score of 10. If the trial did not report on a particular PEDro criterion, it was scored as if the criterion was not met. Methodological quality scores are interpreted as follows: 9 to 10 is considered excellent, 6 to 8 is good, 4 to 5 is fair, and 3 or below represents poor quality.²³

Evaluation of the strength of evidence

A quality analysis for the strength of evidence was performed on the included article by 2 reviewers (AM and KD) using the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) approach.²⁴ This approach represents the level of confidence one can have in the estimate of treatment effect to support a recommendation. The GRADE tool evaluates factors such as study methodology, consistency and precision of results and the directness of the treatment comparisons. After developing an overall summary of quality by considering GRADE factors, a judgment is made to assign a study with 1 of 4 possible categories: high, moderate, low and very low. Once each study has been categorized, a recommendation is generated from a reflection of all available evidence for each trial. Four elements are then considered to generate the strength of the recommendation: the magnitude of the difference between the desirable and undesirable consequences of the treatment, quality of the supporting evidence, certainty about patient values and preferences, and costs associated with compared management options.25

Results

Figure 1 shows the study selection process from the initial database searches to final article inclusion. A total of 2088 citations were retrieved from the literature search, of which 1820 were excluded after title screening. Abstract review excluded 204 articles. A review of the remaining 64 full-text articles resulted in identifying one clinical trial that fulfilled inclusion criteria. The 63 studies excluded and reasons for exclusion are reported in Appendix 2. The most common reason for exclusion was due to thrust manipulation being absent from the study intervention (n=35). Searching the 2 trial registry platforms resulted in 6 trials; however, published results were not available for any of these studies. Five trials' descriptions were explicit enough on the registry to determine their ineligibility. An attempt to contact the principal investigator for the 6th potentially eligible trial was made, but elicited no response. Important characteristics of the included study are shown in Table 2.

Outcomes

Riley *et al.*²⁶ evaluated the effectiveness of a single thrust manipulation for patients with diagnoses consistent with supraspinatus tendinosis and/or impingement. The auth-

	Riley <i>et al</i> . 2015 ²⁶
Random allocation	\checkmark
Concealed allocation	
Baseline comparability	\checkmark
Subject blinding	
Therapist blinding	
Assessor blinding	✓
Follow-up	\checkmark
Intention-to-treat	
Between-group analysis	✓
Point estimates and variability	\checkmark
Total	6/10

Table 3. PEDro scale criteria and scoring.

ors measured present pain using a Numerical Pain Rating Scale (NPRS) and disability using the Shoulder Pain and Disability Index (SPADI). These measures were obtained pre-treatment, immediately post-treatment and one week post-treatment. The thrust manipulation applied to the thoracic spine was compared to a sham thrust manipulation applied to the scapula. Both interventions included a home exercise program. For both outcomes, statistically significant changes were found in all groups from baseline to short-term follow-up, but did not meet the minimum clinically important change threshold. Also, no statistically significant differences were found between the groups.

Methodological quality

The included study scored 6/10 on the PEDro instrument leading to a quality classification of 'good.' The sources of potential bias included: failure to conceal allocation, unblinded subjects and therapists, and no descriptions of an intention-to-treat analysis. Table 3 reports criteria used to score the included article and results.

GRADE

Based on the GRADE measure, the trial included in this systematic review was classified as having a 'moderate' strength of evidence. The moderate classification is based on limitations concerning the inability to calculate relative risk and absolute effects (as a result of imprecision). Also, further research is likely to have an important impact on confidence of the estimate of effect.

The strength of a recommendation for the use of thrust manipulation combined with exercise was not classified. Even though a moderate-quality rating was given, the evidence came from a single clinical trial reporting a single intervention session with no between-group differences. There was uncertainty between benefit and burden due to the lack of adverse event reporting for thrust manipulation and exercise. Although it is likely the benefits outweigh the risks for this clinical approach, the magnitude of the benefit is unknown. There is potential variability in patient's values and preferences regarding the importance and safety of exercise and thrust manipulation, and patient attitudes may change the perceived effect. Cost effectiveness of the interventions is also unknown. Patients may be willing to receive the interventions in light of uncertain benefit; however, a recommendation of any strength is not appropriate given the available evidence.

Discussion

This systematic review sought to evaluate clinical trial evidence studying thrust manipulative therapy applied to the shoulder, cervical or thoracic spine combined with one additional conservative intervention for the treatment of rotator cuff disorders.

One randomized controlled trial with a good methodological rating and a moderate quality rating met the eligibility criteria. The study included a single treatment session, which is not typical of how thrust manipulation is delivered or recommended. Because most management plans involve multiple sessions of thrust manipulation, using a single treatment session substantially limits the clinical interpretation of findings regardless of the magnitude of effect.^{27,28} Additionally, scapular manipulation (labeled as a sham) was delivered as a HVLA thrust similar to the "active" treatment described in the upper to mid-thoracic spine. Thus, the sham treatment may not have differed enough from the active intervention both in its mode or anatomical region of application to be physiologically distinct. Both groups received an exercise intervention that could have been responsible for improved outcomes.²⁹ Previous studies suggest adding manipulation with exercise is more optimal than when the treatments are provided exclusively.30-32

The limitations of the included study underscore the

need for high-quality studies with well described interventions, rigorously collected safety data, and pragmatic treatment schedules to understand the clinical effects of combined conservative interventions for patients with rotator cuff disease. This systematic review identified an important knowledge gap regarding the use of combined conservative treatments for rotator cuff or associated disorders. Because this gap exists, clinicians are unable to obtain research-based guidance to inform specific treatment strategies for patients suffering from common shoulder conditions.

A possible limitation of this systematic review is that some studies may have been missed despite a guided literature search and hand searching references. Also, a grey literature search (e.g., conference abstracts or graduate projects) was not conducted. However, studies available in the grey literature are difficult to systematically assess in terms of methodology. Validated appraisal tools require details in reporting that are typically lacking in these publications. Further, based on the search of the trial registries, the overall number of trials relative to possibly unpublished material suggests there is a low risk for publication bias in this study. Another limitation is that we cannot provide conclusions regarding tolerance or safety of treatments due to the fact that no adverse events were reported in the included study.

Though there was one study included, it was of good quality according to the PEDro scale and moderate according to GRADE. Nevertheless, it had significant methodological and pragmatic limitations, which prevent the ability to interpret findings and apply them to clinical settings. Additional clinical trial data is very likely to have an important impact on the estimate of the treatment effect and future recommendations for treatment.

Conclusion

This review identified one moderate-quality clinical trial reporting the efficacy of thrust manipulation plus one conservative intervention for a rotator cuff condition (shoulder impingement). Neither the clinical effectiveness of thrust manipulation plus exercise nor the relative contribution of individual therapies could be sufficiently evaluated to warrant clinical recommendations. We propose that clinical trials be conducted to study thrust manipulation plus an additional intervention to definitively determine the effectiveness of these treatments over a ser-

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ies of visits as used in clinical settings. Articles presenting clinical trial results from studies involving manipulation should follow the most recent guideline on reporting³³, provide rationale for therapy use, detailed descriptions of intervention techniques, and quantitative data including both short and long-term clinical outcomes and comprehensive safety data.

Authors' contributions

AM and KD conducted the literature search as well as the screening and selection of the included articles. AM completed the data extraction as the primary reviewer and CH evaluated the extraction as secondary reviewer. AM, RV, KD and CL prepared the manuscript. RV, CL, and CH oversaw the design of the study. All authors read and approved the final manuscript.

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A systematic review of thrust manipulation combined with one conservative intervention for non-surgical shoulder conditions

Appendix 1. Search terms used for PubMed

((((clinical trial[Publication Type]) OR random*) OR ((((single or double) near (blind* or mask*))))) OR placebo*)) AND ((((("Shoulder Impingement Syndrome"[Mesh] OR shoulder impingement syndrome)) OR ("Rotator Cuff"[Mesh] OR "rotator cuff"))) AND (((((((((("Manipulation, Chiropractic"[Mesh] OR chiropractic manipulation))) OR ("Musculoskeletal Manipulations"[Mesh] OR (musculoskeletal manipulation))) OR ("Manipulation, Spinal"[Mesh] OR (spinal manipulation))) OR exp physical therapy techniques) OR exp rehabilitation) OR "Ultrasonography, Interventional"[Mesh]) OR ((rehabilitat* or physiotherap* or physical therap* or manual therap* or ultrasound or ultrasonograph* or TNS or TENS or shockwave or electrotherap* or mobili*))) OR mobilization) OR "Physical Therapy Modalities"[Mesh])) NOT exercise)

Author	Reason for exclusion
Kukkonen ³⁴	Intervention not described
Bialoszewski ³⁵	No thrust manipulation
Taheriazam ³⁶	Intervention included NSAIDS/injections
Winters ³⁷	No thrust manipulation
Bennell ³⁸	No thrust manipulation
Holmes ³⁹	No thrust manipulation
Coombes ⁴⁰	Intervention not described
Rahme ⁴¹	No thrust manipulation
Atkinson ⁴²	Manipulation only
Munday ⁴³	Manipulation only
McCreesh ⁴⁴	No thrust manipulation
Lenker ⁴⁵	No thrust manipulation
Ginn ⁴⁶	No thrust manipulation
Littlewood ⁴⁷	No thrust manipulation
Surenkok ⁴⁸	No thrust manipulation
Coronado ⁴⁹	Manipulation only
vanRensburg ⁵⁰	More than one additional conservative therapy
Knebl ⁵¹	No thrust manipulation
Bergman ⁵²	No description of diagnostic procedure
Bergman ⁵³	No description of diagnostic procedure
Bergman ⁵⁴	No description of diagnostic procedure
Winters ⁵⁵	Manipulation only
Riley ⁵⁶	Intervention not described
Moosmayer ⁵⁷	No thrust manipulation
Eslamian ⁵⁸	No thrust manipulation
Delgado-Gil ⁵⁹	No thrust manipulation
Rhon ⁶⁰	No thrust manipulation
Kromer ⁶¹	Intervention not described
Heredia-Rizo ⁶²	No thrust manipulation
Vas ⁶³	No thrust manipulation
Cook ⁶⁴	No thrust manipulation
Walther ⁶⁵	No thrust manipulation
Kardouni ⁶⁶	Manipulation only
Kukkonen ⁶⁷	Abstract only
Kukkonen ⁶⁸	No thrust manipulation

Appendix 2. Articles excluded at full-text review.

Author	Reason for exclusion
Millar ⁶⁹	No thrust manipulation
Garrison ⁷⁰	No thrust manipulation
Kachingwe ⁷¹	No thrust manipulation
Conroy ⁷²	No thrust manipulation
Kromer ⁷³	No thrust manipulation
Harshbarger ⁷⁴	No thrust manipulation
Kaya ⁷⁵	No thrust manipulation
Aytar ⁷⁶	No thrust manipulation
Harris ⁷⁷	No intervention
Negahban ⁷⁸	No thrust manipulation
Dickens ⁷⁹	No thrust manipulation
Littlewood ⁸⁰	Intervention not described
Boorman ⁸¹	No thrust manipulation
Hall ⁸²	Abstract only
Redman ⁸³	Article unavailable
Bang ⁸⁴	More than one additional conservative therapy
Vinuesa-Montoya ⁸⁵	More than one additional conservative therapy
Lirio ⁸⁶	No thrust manipulation
Apeldoorn ⁸⁷	Intervention not described
Camargo ⁸⁸	No thrust manipulation
Haik ⁸⁹	Manipulation only
Kahlenberg ⁹⁰	Not a randomized controlled trial
Pekyavas ⁹¹	No thrust manipulation
Go ⁹²	No description of diagnostic procedure
Kardouni ⁹³	Manipulation only
Lambers ⁹⁴	No thrust manipulation
Mintken ⁹⁵	No description of diagnostic procedure
Wright ⁹⁶	More than one additional conservative therapy