Manual Therapy 16 (2011) 419–433

Contents lists available at ScienceDirect

Manual Therapy

journal homepage: www.elsevier.com/math

Systematic Review

Evidence for effectiveness of Extracorporal Shock-Wave Therapy (ESWT) to treat calcific and non-calcific rotator cuff tendinosis – A systematic review

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ARTICLE INFO

Article history:
Received 7 September 2010
Received in revised form
1 February 2011
Accepted 7 February 2011

Keywords:
Shoulder impingement syndrome
Tendinosis
Therapy
Review

ABSTRACT

Extracorporeal shock-wave therapy (ESWT) is suggested as a treatment alternative for calcific and non-calcific rotator cuff tendinosis (RC-tendinosis), which may decrease the need for surgery. In this study we assessed the evidence for effectiveness of ESWT for these disorders. The Cochrane Library, PubMed, Embase, Pedro, and Cinahl were searched for relevant systematic reviews and RCTs. Two reviewers independently extracted data and assessed the methodological quality.

Seventeen RCTs (11 calcific, 6 non-calcific) were included. For calcific RC-tendinosis, strong evidence was found for effectiveness in favour of high-ESWT versus low-ESWT in short-term. Moderate evidence was found in favour of high-ESWT versus placebo in short-, mid- and long-term and versus low-ESWT in mid- and long-term. Moreover, high-ESWT was more effective (moderate evidence) with focus on calcific deposit versus focus on tuberculum major in short- and long-term. RSWT was more effective (moderate evidence) than placebo in mid-term.

For non-calcific RC-tendinosis, no strong or moderate evidence was found in favour of low-, mid- or high-ESWT versus placebo, each other, or other treatments.

This review shows that only high-ESWT is effective for treating calcific RC-tendinosis. No evidence was found for the effectiveness of ESWT to treat non-calcific RC-tendinosis.

1. Introduction

Shoulder impingement syndrome (SIS) is the most frequently reported specific diagnosis in patients with CANS (Complaints of the Arm, Neck and/or Shoulder) (Huisstede et al., 2007; Feleus et al., 2008). Of those visiting their GP with a new episode of CANS, 33% are diagnosed with SIS (Feleus et al., 2008). Work-related factors associated with the occurrence of SIS are highly repetitive work, forceful exertion in work, awkward postures, and high psychosocial job demand (van Rijn et al., 2010). The consequences of SIS are functional loss and disability. Pathology of SIS is considered to be the principal cause of pain and symptoms arising from the shoulder. In general, the diagnosis SIS relates more to a clinical hypothesis as to the underlying cause of the symptoms than to definitive evidence of the histological basis for the diagnosis or the correlation between structural failure and symptoms (Lewis, 2009).

Some patients with SIS have calcific tendinosis, a reactive calcification that affects one of the rotator cuff tendons, which leads to the characteristic impingement symptoms (Sabeti-Aschraf et al., 2005). In the last 20 years extracorporeal shock-wave therapy (ESWT) has been used to treat soft tissue pain in the vicinity of bone structures (Chow and Cheing, 2007). The non-invasive ESWT is achieved through acoustic waves associated with a sudden rise in pressure generated by electrohydraulic, piezoelectric and electromagnetic devices resulting in release of low-, medium- or high-energy extracorporeal shockwaves (Uhthoff and Sarkar, 1989; Ogden et al., 2001). ESWT is currently applied to treat chronic enthesiopathies such as epicondylitis, plantar heel spur, and calcifying rotator cuff tendinosis (RC-tendinosis) (Gerdesmeyer et al., 2002). The exact mechanism by which ESWT relieves tendon-associated pain is still unclear. The theoretical benefits are the stimulation of tissue healing (Schmitz and DePace, 2009). and the breakdown of calcification (Loew et al., 1995). Of those with a calcific RC-tendinosis, the supraspinatus tendon is most affected (80%) followed by the infraspinatus tendon (15%) and subscapularis tendon (5%) (Bosworth, 1941; Molé et al., 1997; Bianchi and Martinoli, 2007). For these patients, ESWT is supposed to be successful. Moreover, ESWT is suggested to play a role in the management of non-calcific

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1356-689X/$ – see front matter
doi:10.1016/j.math.2011.02.005

RC-tendinosis, especially in those who have had repeated non-surgical treatment failures (Chung and Wiley, 2002).

The purpose of this study is to present an evidence-based overview of the effectiveness of ESWT for the management of calcific and non-calcific RC-tendinosis. This information can be helpful to further optimize the quality of care for patients with these disorders. Further, it can support developing and updating evidence-based protocols and clinical guidelines and it will identify gaps in our scientific knowledge and therefore can give direction to future research on calcific and non-calcific RC-tendinosis.

2. Methods

2.1. Search strategy

This study was part of a literature study concentrating on evidence for effectiveness of non-surgical and surgical interventions for SIS. A search of relevant studies was performed in the Cochrane Library, PubMed, Embase, Pedro and Cinahl up to October 2010. Keywords related to the disorder and interventions were included in the literature search. See Appendix I for the complete search strategy.

2.2. Inclusion criteria

Systematic reviews and RCTs were included if they fulfilled all of the following criteria: (a) patients with SIS were included, (b) SIS was not caused by an acute trauma or any systemic disease as described in the definition of CANS, (c) an intervention for treating SIS was evaluated, (d) results on pain, function or recovery were reported, and (e) a follow-up period of at least two weeks was reported. There were no language restrictions.

ESWT can be subdivided in low-, medium- and high-energy extracorporeal shockwaves.(Albert et al., 2007) There is no universal agreement concerning the thresholds of these subdivisions. For the present study, we defined shockwaves $\leq$0.11 mJ/mm^2 as low-ESWT, between 0.12 and 0.28 mJ/mm^2 as medium-ESWT, and $>$0.28 mJ/mm^2 as high-ESWT (Albert et al., 2007; Loew et al., 1999).

2.3. Study selection

Two reviewers (BH, LG) independently applied the inclusion criteria to select potentially relevant studies from the title, abstracts and full-text articles respectively. A consensus method was used to solve disagreements concerning inclusion of studies, and a third reviewer (B) was consulted if disagreement persisted.

Table 1
Methodological quality assessment: sources of risk bias.

A.	1. Was the method of randomization adequate?
B.	2. Was the treatment allocation concealed?
C.	Was knowledge of the allocated interventions adequately prevented during the study?
	3. Was the patient blinded to the intervention?
	4. Was the care provider blinded to the intervention?
	5. Was the outcome assessor blinded to the intervention?
D.	Were incomplete outcome data adequately addressed?
	6. Was the drop-out rate described and acceptable?
	7. Were all randomized participants analysed in the group to which they were allocated?
E.	8. Are reports of the study free of suggestion of selective outcome reporting?
F.	Other sources of potential bias:
	9. Were the groups similar at baseline regarding the most important prognostic indicators?
	10. Were co-interventions avoided or similar?
	11. Was the compliance acceptable in all groups?
	12. Was the timing of the outcome assessment similar in all groups?

2.4. Categorization of the relevant literature

Relevant articles are categorized as follows: *Systematic reviews* describe all (Cochrane) reviews; *Recent RCTs* contains all RCTs published after the search date of the systematic review on the same intervention; *Additional RCTs* describes all RCTs concerning an intervention that has not yet been described in a systematic review.

2.5. Data extraction

Two authors (LG, RS/BH) independently extracted the data from the included articles. A consensus procedure was used to solve any disagreement between the authors. Results were reported in short-term ($\leq$3 months), mid-term (4–6 months), and long-term ($>$6 months).

2.6. Methodological quality assessment

Two reviewers (LG, MR) independently assessed the methodological quality of each RCT using the 12 quality criteria of Furlan et al. (2008) (Table 1). Each item was scored as "yes", "no", or "don't know/unsure/unclear". 'High-quality' was defined as a "yes" score of $\geq$50%. A consensus procedure was used to solve disagreement between the reviewers.

2.7. Data synthesis

A quantitative analysis of the studies was not possible due to heterogeneity of the outcome measures. Therefore, we summarized the results using a best-evidence synthesis (van Tulder et al., 2003).

The article was included in the best-evidence synthesis only if a comparison was made between the groups (e.g. treatment versus placebo, control or another treatment) and the level of significance was reported. The results of the study were labeled 'significant' if 1 of the 3 outcome measures on pain, function, or recovery reported significant results.

The level of evidence was ranked as follows:

1. Strong evidence for effectiveness: consistently[1] positive (significant) findings within multiple high-quality RCTs.
2. Moderate evidence for effectiveness: consistently[1] positive (significant) findings within multiple low-quality RCTs and/or one high-quality RCT.
3. Limited evidence for effectiveness: positive (significant) findings within one low-quality RCT.
4. Conflicting evidence for effectiveness: provided by conflicting (significant) findings in the RCTs ($<$75% of the studies reported consistent findings).
5. No evidence found in favour of the effectiveness of the intervention: RCT(s) available, but no (significant) differences between intervention and control groups were reported.
6. No systematic review or RCT found.

3. Results

3.1. Characteristics of the included studies

The initial literature search resulted in 5 systematic reviews from the Cochrane Library. Via PubMed 5 reviews and 159 RCTs, via

[1] $\geq$75% of the trials reported the same findings.