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Extracorporeal Shock Wave Therapy for Achilles and Patellar Tendinopathy: Meta-Analysis and a Systematic Review of the Literature

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Abstract

Background: Sports related injuries such as lower limb tendinopathies can result in long-standing impairment of athletic performance. In recent years, treatment interventions like eccentric exercises, Platelet Rich Plasma (PRP) injections and Extracorporeal Shockwave Therapy (ESWT) have gained popularity among Physiotherapists and sports clinicians, but the evidence of their effectiveness is very limited.

Purpose: To investigate the effectiveness of ESWT on Achilles and Patellar tendinopathy.

Methods: A systematic review and meta-analysis was conducted using MEDLINE, EMBASE, AMED, CINAHL, PEDro and Cochrane databases and bibliographic searches from inception until April 2013 to identify randomized control trials comparing ESWT with other treatment methods.

Results: Of 306 titles screened, 9 papers, including 487 patients were included in this review. Meta-analysis showed no significant differences between the intervention and control group on the pooled VISA-A scores (p=0.59, 95% CI-15.02, 26.51) or load-induced pain (p=0.51, 95% CI-3.15, 1.56) for Achilles tendinopathy and no significant differences between the pooled VISA-P scores for patellar tendinopathy (p=0.27, CI-7.86, 27.87).

Conclusions: The meta-analysis did not demonstrate a statistically significant improvement in symptoms or load induced pain for ESWT compared to other treatments or control. Adequately powered, high quality studies with longer follow-ups are required.

Keywords: Shockwave; Tendinopathy; Extracorporeal shockwave therapy

Introduction

Sports related injuries are a constant and disturbing problem for both clinicians and athletes. Among these, overuse injuries may constitute 30-50% of all injuries [1]. Tendon injuries could be either acute or chronic in nature and the choice of treatment would depend on the specific pathology and diagnosis of the condition. Traditionally, emphasis was given on targeting inflammation. However, there has been considerable advancement in the management of tendon disorders in recent years. With the term 'tendinosis' and 'tendinopathy' replacing 'tendinitis' [2] treatment interventions like Eccentric exercises, Platelet Rich Plasma (PRP) and Extracorporeal Shockwave Therapy (ESWT) has gained popularity among sports clinicians in treating tendon related pathologies.

Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area of the body. Similar use of high energy sound waves is seen in lithotripsy for the breakdown of kidney or gall stones [3]. ESWT can be applied in different energy levels over one or more sessions and as high energy ESWT can be painful, is sometimes applied with anesthesia. ESWT is used in the treatment of musculoskeletal conditions such as chronic proximal plantar fasciitis [4] and lateral epicondylitis [5]. However, guidelines for its use in the UK currently recommend use limited to certain conditions or restricted to clinical trials (NICE 2009).

Previous systematic reviews [6] have identified a number of studies on ESWT for lower limb tendinopathies, however these reviews have been limited by the inclusion of relatively few studies with small numbers of patients, potential selection bias (limitedscope/databases/publication bias) and potential reporting bias. Consequently, current evidence to guide clinical practice is inconclusive. This systematic review attempts to address a number of these limitations in the question: 'Is Extracorporeal Shock Wave Therapy more effective than standard care or other interventions in improving pain and function in the management of Achilles and Patellar tendinopathies?'

Methods

We conducted a systematic review of the literature using standardised methods [7,8] Components of the research question were classified according the PICO acronym [9] P (Population)-adult humans with achilles and patellar tendinopathy; I (Intervention)-ESWT, which can be generated by different methods [10]. C

(Contrast)-compared to "standard care" or another intervention; O (Outcomes) of key interest was reduction in pain and increase in function measured at any time after treatment.

Literature search

We searched multiple databases: MEDLINE, CINAHL Plus, EMBASE, AMED, SPORTDiscus and PEDro, from their inception to April 2013. We also searched the Cochrane Trials Register, the ISI Web of Science, International Standard Randomised Control Trial Number (ISRCTN) register and the National Institute of Health (NIH) clinical trials register to identify unpublished studies. Medical Sub Heading (MeSH) terms and keywords including tendon* or tendin* and intervention-specific words shockwave* OR "shock wave*"were used (See search strategy Supplementary Data). Reference lists from articles were hand-searched to check for relevant articles not previously identified.

Eligibility criteria

We included all randomised control trials (RCT) comparing ESWT to other interventions reported in the English language. We included studies using Focused Shockwave (FSWT) and Radial Shockwave (RSWT) delivery methods, delivered with or without anaesthetic. Studies on both mid-portion and insertional tendinopathies were included. Exclusion criteria included non-human animal studies and studies involving anatomical structures other than tendon.

Selection of studies

Titles and abstracts from the search strategy were assessed by AP and in uncertain cases assessed by AN. A third reviewer (KP) acted as referee in cases of disagreement. Full-text versions of papers were obtained to confirm eligibility.

Data extraction

Extraction of published data on mean effects and standard deviations was performed by AP and confirmed by AN and KP.

Outcome measures

The two main outcomes of interest were function and tendinopathic pain, measured at any time point after the intervention.

We considered outcome in terms similar to the three main domains in the Victorian Institute of Sports Assessment (VISA) score: pain, functional status and the ability to undertake sports [11]. Visentini et al. considered these domains important in lower limb tendon pathology. 'VISA-P' (Patellar) was converted to a version for Achilles tendon symptoms 'VISA-A' (Achilles) while retaining validity and reliability by Robinson et al. [12].

A reduction in pain, typically recorded on the Visual Analogue Scale (VAS) [13] or Numerical Rating Scale (NRS) [14] whilst loading the tendon was considered a favourable outcome [15].

Secondary outcome measures

Functional objective measures like range of motion and strength were analysed where available. Other outcomes included a change in a tendon's structure or diameter (indicators of tendon pathology) measured using ultrasonography [16,17].

Methodological quality of the included studies

Included studies were assessed by AP for methodological quality and validity using the Physiotherapy Evidence Database (PEDro) 11-point rating scale [18,19]. The maximum score achievable on a PEDro scale is 10/10 as the first criterion, which measures the external validity of a trial, is not included in the final score. We classified studies as high quality (score of 6 or above) or low-quality (score below 6).

Analysis

Summary descriptions of the studies were tabulated. If aggregate data were considered suitable by the authors, we planned to carry out a meta-analysis using Review Manager 5.2. To produce forest plots, calculate summary effects sizes with 95% confidence interval (CI) for effect of ESWT on function and pain.

We identified a priori subgroups of interest as "patellar" and "Achilles" studies and those using Focused Shockwave (FSWT) and Radial Shockwave (RSWT) delivery methods. Our approach would be dependent on the risk of bias and estimated levels of heterogeneity being less than 70%. Results are reported in accordance with the Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA) guidance [20].

Results

Study selection

Study selection is shown in Figure 1 with nine studies meeting the inclusion criteria. Searching reference lists of key articles yielded one relevant study [21] not identified in the electronic search.

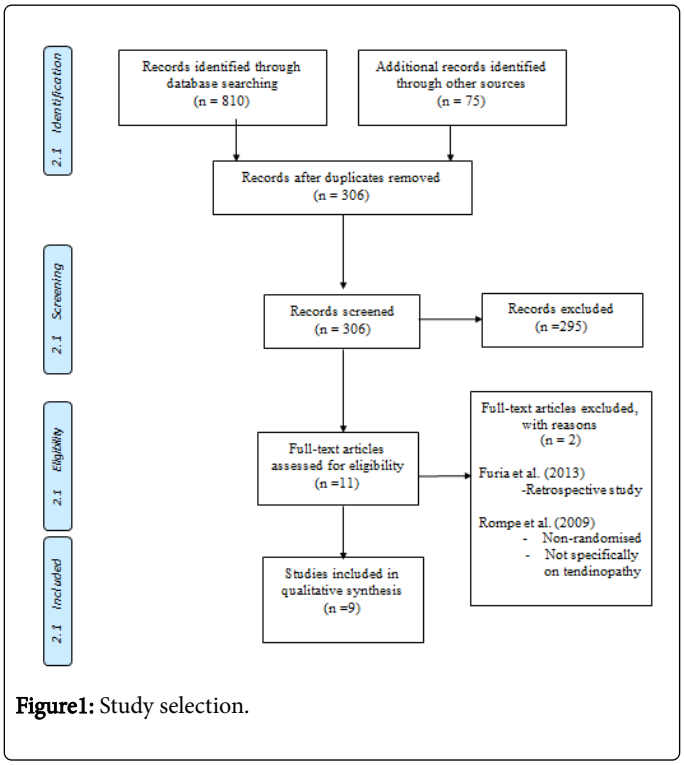

Figure1: Study selection.

Study characteristics

Table 1 and 2 describe study characteristics for the Achilles and patellar studies respectively. Generally, mean age in the Achilles studies was greater than the patellar studies, with most studies having more women than men. All studies included patients with symptoms of at least three months duration.

Autho, Year	Group	Number of Patients and Sex (M)	Mean Age (range ± SD)	Duration of symptoms	Number of sessions	Interval between ECSW sessions	Shockwave application and Energy level (mJ/mm^2) x Impulses	Co-interventions allowed during study period	Length of follow up	Significant differences in advantage of ESWT
Peers [21], 2003 (Insertional and non-insertional)	ESWT	20 (12)	45 (14)	>3 months	3	1 week	Focused 0.2×1000	Eccentric exercises at week 2	2,6 and 12 weeks	Yes at 12 weeks 2,6 weeks NR
	Placebo	19 (10)	44 (13)							
Costa et al. [22], 2005 (Insertional and non-insertional)	ESWT	22 (9)	58.7 (10.8)	>4 months	3	1 month	Focused 0.2×1500	None reported	12weeks and 1 year	No at 12 weeks 1 year NR
	Placebo	27 (12)	47.7 (13.5)							
Rompe et al. [24], 2007 (Non-insertional)	1.ESWT	25 (11)	51.2 (10.3)	>6 months	3	1 week	Radial 0.1×2000	Crossover was allowed after 16 weeks follow-up	16 weeks and 1 year	No at 16 weeks (1 *vs.* 2) Yes at 16
	2.EE	25 (9)	48.1 (9.9)							
	3.Wait and see	25 (9)	46.4 (11.4)	Twice/day, 12 weeks						weeks (1 *vs.* 3) 1 year NR
Rasmussen et al. [23], 2008 (Not-specified)	ESWT	24 (12)	49 (9)	>3 months	4	1 week	Radial 0.12 to 0.5×1500	Eccentric training and stretching	8 and12 weeks	No at 8 and 12 weeks
	Placebo	24 (8)	46 (13)							
Rompe et al. [35], 2008 (Insertional)	ESWT	25 (9)	40.4 (11.3)	>6 months	3	1 week	Radial 0.12×2000	Crossover was allowed after 16 weeks follow-up	16 weeks and 15 months	Yes at 16 weeks 15 months NR
	EE	25 (11)	39.2 (10.7)		Twice/day					
ESWT=Shock wave therapy, EE=Eccentric exercises, NR=Not reported										

Table 1: Randomised control trials comparing shock wave to other interventions for achilles tendinopathy.

Among the five Achilles studies, two studies included patients with both insertional and non-insertional tendinopathy [21,22]. Among these studies, Peers [21] was the only study that reported a separate analysis of both groups (insertional and non-insertional). Rasmussen, Christensen [23] did not specify the type or location of the Achilles tendinopathy.

Author	Group	Number of Patients and Sex (M)	Mean Age (range ± SD)	Duration of symptoms	Number of sessions	Interval between ECSW sessions	Shockwave application and Energy level (mJ/mm^2)xImpulses	Co-interventions allowed during study period	Length of follow up	Significant differences in advantage of ESWT
Taunton [36]	ESWT	10 (5)	(23-52)	>3 months	03-May	1 week	Focused 0.17×2000	None reported	12 weeks	Yes
	Placebo	10 (5)								
Peers [21]	ESWT	23 (19)	29 (8)	>3 months	3	1 week	Focused 0.2×1000	Eccentric exercises at week 2	2,6 and 12 weeks	Yes
	Placebo	22 (18)	31 (8)							
Wang et al. [26]	ESWT	29 (14) 33 knees	29.4 (10.5)	>6 months	01-Feb	4-6 weeks	Focused 0.18×1500	None	1,3,6 and 12 months	Yes except for diameter and appearance of the tendon
	Control group NSAID's,	24 (13) 25 knees	32.2 (10.4)		NR	NR				

	PT, EE, strapping									
Zwerver et al. [33]	ESWT	31 (20)	24.2 (5.2)	>3 months	3	1 week	Focused 0.5×2500	None	1,12 and 22 weeks	No
	Placebo	31 (21)	25.7 (4.5)							
Vetrano et al. [37]	ESWT	23 (20)	26.8 (8.5)	>6 months	3	48-72 hours	Focused 0.17 to 0.25×2400	Stretching, Strengthening exercises in both groups +Hydrotherapy	2,6 and 12 months	No
	PRP	23 (17)	26.9 (9.1)		2	1 week				
EE=Eccentric ex, NSAID=Non-steroidal anti-inflammatory drugs, PT=Physiotherapy, PRP=Platelet-rich plasma, NR=Not reported										

Table 2: Randomised control trials comparing shock wave to other interventions for patellar tendinopathy.

In the Achilles studies patients were requested to refrain for any other treatments like physiotherapy, insoles or non-steroidal anti-inflammatory drugs (NSAID's). Both studies by Rompe et al. permitted crossover at 16 weeks. Wang et al. and Zwerver et al. permitted participants in the treatment group to take analgesics post-application of ESWT as necessary. Taunton et al. did not report the use of any such medications.

The level of sport participation varied among the study samples. In the study by Costa, Shepstone [22], almost 79.5% of participants were involved in some sport, compared to only 30% of participants in the study by Rompe et al. [24]. Both Peers [21] and Rasmussen, Christensen [23] did not report participation in sport.

All five patellar studies recruited active sport participants with Zwerver et al. recruiting subjects who participated in sports with highly repetitive loading of the patellar tendon (basketball, volleyball and handball) and permitting subjects to train during the study period.

None of the Achilles or Patellar studies utilized local anaesthetic for the application of shock waves.

Report of Adverse Events

Adverse events were reported in the Achilles studies: Two older patients (62 and 65 years) in the study by Costa et al. [22] ruptured their Achilles tendon. This could be considered as a serious adverse event. Some subjects receiving ESWT had reddening of the skin after low-energy SWT (n=25) [24]. No adverse events were reported in the Patellar studies.

Quality of Studies

Table 3 summarizes the methodological quality of the included studies using the PEDro scale. Effective subject blinding was achieved in all studies apart from one [22] whereas, assessor blinding was achieved in all studies.

	1	2	3	4	5	6	7	8	9	10	11	Total Score
Achilles												
Taunton et al. (2003)	Yes	Yes	No	No	Yes	No	Yes	Yes	No	Yes	No	5/10
Peers (2003)-Achilles tendon	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	8/10
Peers (2003)-Patellar tendon	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	8/10
Costa et al. (2005)	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes	Yes	6/10
Wang et al. (2007)	Yes	No	No	Yes	No	No	Yes	Yes	No	Yes	Yes	5/10
Patellar												
Rompe et al.(2007)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/10
Rasmussen et al. (2008)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9/10
Rompe et al. (2008)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/10
Zwerver et al. (2011)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9/10
Vetrano et al. (2013)	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	7/10

1. Eligibility criteria specified 2. Random allocation 3. Concealed allocation 4. Baseline prognostic heterogeneity 5. Subject blinding 6. Therapist blinding 7. Assessor blinding 8. Outcomes obtained for >85% of initially allocated subjects 9. Intention to treat analysis 10. Between groups statistical comparisons reported 11. Point measures and measures of variability provided (PEDro, 1999).

Table 3: Methodological Quality of Included Trials.

Synthesis of Results

We conducted exploratory meta-analyses in an attempt to pool results for VISA-A, load induced pain and tenderness outcomes for Achilles and VISA-P outcomes for Patellar studies (Figure 2-5) however in all cases heterogeneity was considered to be high (I2 range 71% to 92%). An I^2 value of 75% and above is considered high and this in turn would affect the generalisibity of the findings of meta-analysis [25]. Pooled estimates were non-significant with confidence intervals crossing the line of no effect. These results must be considered as exploratory and interpreted with caution.

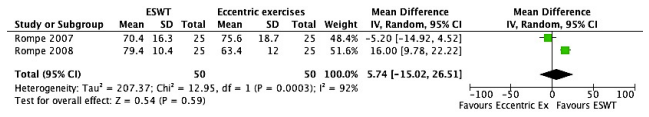

Figure 2: VISA-A at 16 weeks.

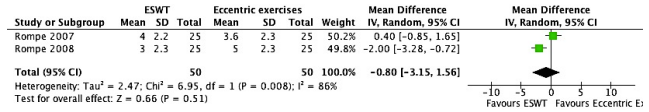

Figure 3: Load induced pain on Numerical rating scale (NRS) at 16 weeks.

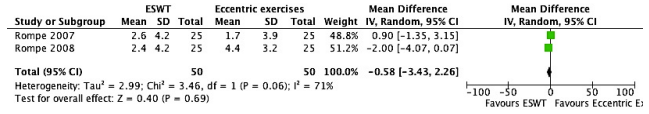

Figure 4: Tenderness at 3 kg on Numerical rating scale (NRS) at 16 weeks.

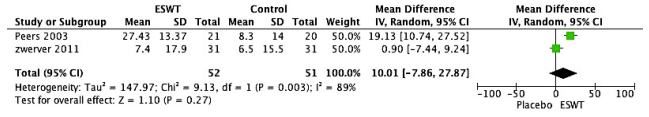

Figure 5: Improvement in VISA-P score at 12 week.

Tendon diameter on ultrasound scan was assessed in two studies [24,26] with contradicting results. To detect a significant difference in tendon structure post-treatment, a study might have to have a longer follow-up. Studies in the past that reported similar reduction in tendon thickness had a mean follow-up of more than three years [16,17] whereas studies included in this review had a mean follow-up of one year.

The studies on the Achilles tendinopathy did not report any statistically significant difference between groups with regards to functional objective measures whereas all Patellar studies included in this review reported functional improvement.

Discussion

These findings suggest that ESWT was not able to demonstrate a statistically significant improvement in VISA or load induced pain by meta-analysis compared to other treatments like eccentric exercises. Following meta-analysis, there were no significant differences between the intervention and control group on the pooled VISA-A scores (p=0.59, 95% CI-15.02, 26.51) or load-induced pain (p=0.51, 95% CI-3.15, 1.56) at 16 weeks for Achilles tendinopathy and no significant differences between the pooled VISA-P scores for patellar tendinopathy at 12 weeks (p=0.27, CI-7.86, 27.87).

Strengths and limitations of this study

Overall, the number of trials in this field is small and studies feature relatively small sample sizes. However, the included studies demonstrated reasonable quality with the PEDro score ranging from five to nine out of ten.

Our review was performed systematically and searched for both published and unpublished studies in a range of databases to try to provide a broad review of the trials of ESWT on lower limb tendinopathies. We included outcomes considered to be clinically relevant to healthcare providers and patients.

Our review has some limitations: Excluding studies published in languages other than English could lead to language bias. Additionally, study selection at the title and abstract stage was performed by one researcher (potentially resulting in selection bias) although they were supported by others to discuss uncertain cases and to confirm inclusion at full text stage. However within our resources every effort was made to minimise any systematic bias in this review.

Clinical implications

Interest and literature around ESWT is growing steadily and its use is established in in treating calcific tendinitis of the shoulder [27] and plantar fasciitis [28].

The included studies were heterogeneous in nature and therefore the results from the meta-analysis should be interpreted with caution. It remains largely unclear what parameters are the most important in using ESWT. Some studies utilised focussed and others radial ESWT. Intensities, interval between treatments and the total number of sessions also varied across the studies. Studies typically followed up subjects in the short to medium term and long-term effects are unclear. A systematic review on calcific tendinitis of the shoulder also

questioned the long-term effectiveness of ESWT [29]. Optimising the dose, delivery and timing of ESWT requires further investigation.

Furthermore, studies included in this review showed better results when eccentric exercises where introduced as co-interventions [21,23]. This finding is consistent with an earlier systematic review in chronic Achilles tendinopathy: by Al-Abbad and Simon [6]. Eccentric exercises might assist in maintaining the effects of ESWT in the long-term. However, this theory warrants further investigation.

None of the studies included in this review utilised anaesthesia for the application of ESWT. The use of anaesthesia has been seen to reduce the effectiveness of ESWT in previous studies [30-32].

Complications can occur with ESWT. These are reported as erythema and inflammation [24] and Achilles tendon rupture in older patients [22]. Longer term monitoring for safety in greater numbers of patients would provide further information on risks associated with the intervention.

Concurrent sports participation is another factor which may affect the effectiveness of ESWT. Subjects in the study by Zwerver et al. [33] continued to take part in sport during the treatment period and this could have neutralised the beneficial effects of ESWT. A similar non-effective treatment was seen when eccentric exercises were used to treat jumper's knee during a competitive season [34]. So a period of rest or restricting the subjects to minimal activities might be key in the successful treatment of tendinopathies.

Similarly, none of the studies reported economic evaluations, which should be considered to allow cost effectiveness decisions on treatment recommendations [35-37].

Recommendations

Considering the cost and investment required for a shock wave therapy machine and the findings of the review, careful consideration should be given to the implementation of such interventions. Other interventions like eccentric exercises may provide the same benefits as of ESWT. Where ESWT is already in use, increased number of sessions or co-interventions such as eccentric exercises might be required to maintain its long-term effectiveness. It may also be important to reduce loading of the tendon during the treatment phase by restricting the patient to lighter activities. Careful consideration also should be given when applying ESWT in older patients with degenerative tendons as it might lead to ruptures.

Conclusion

We produced a review that expanded upon previous reviews and addressed some methodological limitations. Studies were heterogeneous but taken overall, the findings suggest that ESWT was not able to demonstrate an improvement in outcomes compared to other available treatments such as eccentric exercises. Well-designed trials with optimised dosage and treatment protocols, adequate power, longer term follow-up and economic analyses are required to establish ESWT's long-term effectiveness and cost effectiveness.

Competing interests

None declared.

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