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Review

Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review

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HIGHLIGHTS

- ESWT is likely a safe treatment for PF.
- No complications are expected at one-year follow-up.

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ABSTRACT

Background: Extracorporeal shockwave therapy (ESWT) seems to be an effective treatment for plantar fasciitis (PF) and is assumed to be safe. No systematic reviews have been published that specifically studied the complications and side effects of ESWT in treating PF. Aim of this systematic review is therefore to evaluate the complications and side effects of ESWT in order to determine whether ESWT is a safe treatment for PF.

Methods: For this systematic review the databases PubMed, MEDLINE, Cochrane and Embase were used to search for relevant literature between 1 January 2005 and 1 January 2017. PRISMA guidelines were followed.

Results: Thirty-nine studies were included for this review, representing 2493 patients (2697 heels) who received between 6424 and 6497 ESWT treatment sessions, with an energy flux density between 0.01 mJ/mm^2 and 0.64 mJ/mm^2 and a frequency of 1000–3800 SWs. Average follow-up was 14.7 months (range: 24 h - 6 years). Two complications occurred: precordial pain and a superficial skin infection after regional anaesthesia. Accordingly, 225 patients reported pain during treatment and 247 reported transient red skin after treatment. Transient pain after treatment, dysesthesia, swelling, ecchymosis and/or petechiae, severe headache, bruising and a throbbing sensation were also reported.

Conclusion: ESWT is likely a safe treatment for PF. No complications are expected at one-year follow-up. However, according to the current literature long-term complications are unknown. Better descriptions of treatment protocols, patient characteristics and registration of complications and side effects, especially pain during treatment, are recommended.

1. Introduction

Plantar fasciitis (PF) is the most common cause of heel pain and accounts for up to 15% of all foot symptoms requiring medical care [1–3]. It is associated with significant morbidity, resulting in activity limitations for the affected patients [4–7]. PF accounts for approximately 1% of all patient visits to orthopaedic surgeons in the United States.[4]

The aetiology of PF is poorly understood [2,8]. PF is thought to be caused by biomechanical overstress of the insertion of the plantar fascia on the calcaneal tuberosity [2]. Discussion of its biomechanical aetiology usually involves the windlass mechanism and an increased tension of the plantar fascia during gait [2]. Mechanical

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overload, irrespective of whether it is the result of biomechanical deviations, obesity, or work habits of prolonged standing and running, may contribute to the symptoms. This makes it more likely to be a chronic degenerative process than acute inflammation [2].

Diagnosis can be made with reasonable certainty on the basis of clinical assessment alone.[5] PF is characterised by pain at the calcaneal origin of the plantar fascia that is usually worse with the first steps in the morning or after a period of inactivity. The pain becomes worse by extended duration of weight bearing. Additional to these findings, there is localised tenderness during palpation at the insertion of the fascia during physical examination [9,10].

The standard treatments of PF are conservative measures that include insoles, shoe modification, physical therapy, stretching exercises, night splints and nonsteroidal anti-inflammatory drugs (NSAIDs) [1,3]. After failure of these conservative treatments, corticosteroid injections can be given [1,3]. For intractable cases, surgical procedures like fasciotomy are performed [1,3]. An alternative non-invasive treatment can be Extracorporeal Shock Wave Therapy (ESWT), which is used in various forms of tendinopathy, including PF [2,8,11].

Shockwave treatment is commonly used in the management of tendon injuries and there is increasing evidence for its clinical effectiveness [12]. There is a paucity of fundamental (in vivo) studies investigating the biological actions of shockwave therapy. Destruction of calcifications, pain relief and mechanotransduction-initiated tissue regeneration and remodelling of the tendon are considered to be the most important working mechanisms [12]. A shockwave is a special, non-linear type of pressure wave with a short rise time (around 10 μs) [13,14]. There are two types of shockwave therapy for the generation and application on human tendons: focused shockwave therapy (FSWT) and radial shockwave therapy (RSWT). Focused shockwaves are characterised by a pressure field that converges at a selected depth in the body tissues, where the maximal pressure is reached [11,14]. FSWT can be generated using three methods: electrohydraulic, electromagnetic and piezoelectric [11,14]. The difference between the three methods of generation is the time at which the shockwave forms [15]. Radial shockwaves are characterised by a diverging pressure field, which reaches maximal pressure at the source, and they are not generated in water [14].

When applying ESWT several important variables should be taken into account. Next to the type of ESWT, variety may occur in the amount of shockwaves given (SWs), number of treatment sessions and in-between intervals, administration of anaesthesia and energy flux density (EFD, in mJ/mm^2). EFD refers to the concentrated SW energy per unit area and is a term used to reflect the flow of SW energy perpendicularly to the direction of propagation; it is taken as one of the most important descriptive parameters of SW dosage [16]. Low-energy ESWT is an EFD of $\leq$0.12 mJ/mm2, and high-energy ESWT is > 0.12 mJ/mm^2 [16,17].

The heterogeneity of systems (FSWT vs. RSWT), treatment protocols and study populations, and the fact that there seem to be responders and non-responders, continue getting in the way of giving firm recommendations on an optimal shockwave therapy approach [12].

Many studies have investigated the effectiveness of ESWT in treating PF. Studies published before 2005 show variable outcomes. This may have been due to the limited experience of the healthcare providers who performed the ESWT and/or the shockwave devices they used. The literature now shows a decade-old trend. Recent systematic reviews and meta-analyses show ESWT to be an effective treatment with success rates between 50% and 94% [2,16,18].

Efficacy of ESWT for PF has been established in the current literature and assumptions about patient safety have been made in several studies over the past ten years [11,19]. The 2010 guideline of the American College of Foot and Ankle Surgeons described it to be a safe treatment for PF [20]. However, little has been published about the complications and side effects of ESWT. There are indeed known complications that occurred for other indications during ESWT. For example, two cases of osteonecrosis in the humeral head after ESWT have been described after treating tendons of the shoulder [21,22].

Patient safety in ESWT for PF should be evaluated, and fascia ruptures, osteonecrosis and damage to nerves or other structures must be taken into account. More insight into side effects like pain, which might interfere with treatment course and compliance, is also important.

To our knowledge there are no systematic reviews that specifically focus on the complications of ESWT in treating PF. Hence this study aims to systematically review which complications and side effects of ESWT have been reported and how often in order to determine whether ESWT is a safe treatment for PF.

2. Methods

This systematic review was conducted using the recommendations of the Cochrane Adverse Effects Methods Group about systematic reviews of adverse effects, and it was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (see Fig. 1 for flow diagram) [23,24].

2.1. Inclusion and exclusion criteria

The databases PubMed, MEDLINE, Cochrane and Embase were used to search for relevant literature. Studies were pre-selected based on the following inclusion criteria: humans; date of publication between 1 January 2005 and 31 December 2016; full text available in English, German or Dutch; the title or abstracts suggested a study about patients with PF treated with ESWT. Conference publications, letters to authors, notes, systematic reviews and meta-analyses were excluded.

2.2. Search strategy

Using a PICO (P: patients with plantar fasciitis, I: ESWT, C: −, O: side effects and complications), the following search was conducted with filters for articles from the year 2005: *((((extracorporeal shockwave therapy) OR eswt) OR shockwave therapy)) AND ((((plantar fasciitis) OR heel spur) OR heel pain) OR plantar fasciopathy)*. We also performed expanded searches with the terms 'complications', 'side effects' and 'adverse effects'.

2.3. Study selection and data extraction

Two reviewers completed the same search in the databases and article extraction independently. A pre-selection was made by screening titles and abstracts of the studies. Next, eligibility was assessed by reading the full text to determine whether side effects and/or complications were mentioned. Articles that described side effects and/or complications were included. Search results were compared afterwards and disagreements were settled by discussion, with the possibility to consult a third reviewer in case of uncertainties.

Complications were defined as: unexpected or uncomfortable symptoms during or after treatment that did not resolve within two weeks, or a treatment-caused unintended and undesirable event or condition that requires extra medical care or which affects the patient's health and functioning for a period of time, with or without irreparable damage. Side effects were defined as