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Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomised controlled trial

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Abstract

Extracorporeal shock wave therapy (ESWT) is an increasingly popular therapeutic approach to the treatment of a number of soft tissue complaints. Whilst benefit has been demonstrated in calcific tendinitis, evidence is lacking for benefit in the management of non-calcific rotator cuff disorders.

Aims: To perform a double-blind placebo controlled trial of moderate dose ESWT in chronic lateral epicondylitis.

Methods: Adults with lateral epicondylitis were randomised to receive either active treatment (1500 pulses ESWT at 0.12 mJ/mm^2) or sham therapy, monthly for three months. All were assessed before each treatment and one month after completion of therapy. Outcome measures consisted of visual analogue scores for pain in the day and at night.

Results: Seventy-five subjects participated and there were no significant differences between the two groups at baseline. The mean duration of symptoms was 15.9 and 12 months in the ESWT and sham groups, respectively. Both groups showed significant improvements from two months. No significant difference existed between the groups with respect to the degrees of change in pain scores over the study period. In the ESWT group the mean (SD, range) pain score was 73.4 (14.5, 38–99) at baseline and 47.9 (31.4, 3–100) at three months. In the sham group the mean (SD, range) pain score was 67.2 (21.7, 12–100) at baseline and 51.5 (32.5, 3–100) at three months.

At three months, 50% improvement from baseline was noted in 35% of the ESWT group and 34% of the sham group with respect to pain.

Conclusions: There appears to be a significant placebo effect of moderate dose ESWT in subjects with lateral epicondylitis but there is no evidence of added benefit of treatment when compared to sham therapy.

Keywords: Lateral epicondylitis; Elbow; Tennis; Shock wave; Treatment

Introduction

Lateral Epicondylitis (tennis elbow) is a common musculoskeletal complaint, and can result in significant pain, functional incapacity and time lost from work [24]. Although numerous therapies are advocated in the management of lateral epicondylitis, these can be ineffective [22]. As a result, new treatment options are being sought: these include extracorporeal shock wave therapy (ESWT).

Extracorporeal shock waves are single pressure pulses of microsecond duration that can be focused upon a site using ultrasound guidance. Over the past 30 years they have been utilised as a highly effective treatment of renal calculi. More recently ESWT has been used in the treatment of a number of musculoskeletal conditions, including lateral epicondylitis, at doses of 10–20% of those used in lithotripsy of renal calculi [1,2,4,5,8,9,11,18,23]. It has been suggested that shock waves may stimulate tissue healing, reduce calcification, inhibit pain receptors and cause denervation [1,2,4,5,9,11,23], although the precise effects have not been established. Despite the increasing popularity of this treatment modality, there are few randomised controlled trials of its use in specific musculoskeletal conditions. We report the

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first double-blind randomised controlled trial of ESWT in lateral epicondylitis.

Methods

Adult subjects with a clinical diagnosis of lateral epicondylitis were recruited in the out-patient clinic after assessment by a rheumatologist (CAS). Permission for the study was obtained from the Local Medical Ethics Committee and informed consent was obtained by all subjects prior to participation.

Inclusion criteria were: adults over the age of 18 years with unilateral lateral elbow pain for at least three months. All subjects had point tenderness at or near the common extensor tendon insertion at the lateral epicondyle and pain at the lateral epicondyle reproduced with resisted extension of the middle finger distal to the proximal interphalangeal joint [22].

Exclusion criteria were: additional elbow pathology including instability, arthritis or any local dermatological problem, generalised polyarthritis, neurological abnormalities, anticoagulant therapy, treatment to the affected area within the previous six weeks, pregnancy, diabetes, connective tissue or infectious disease, vasculitis or malignancy.

Subjects were assessed prior to treatment by a blinded observer. All subjects completed 10 cm visual analogue scales for elbow pain during the day and at night. All assessments were repeated prior to each treatment and one month after completion of therapy (i.e. three months from baseline).

Subjects were randomised to receive either ESWT (1500 pulses at 0.18 mJ/mm^2) or sham treatment, where the treatment head was deflated, no coupling gel was applied and standard contact with the skin was avoided. The machine makes a noise with every shock wave delivered and, in order to enhance the sham design, minimal energy pulses (0.04 mJ/mm^2) were generated, but contact with the region of interest was avoided [16,19–21]. No local anaesthesia was used. All treatments were applied using a Sonocur Plus Unit (Siemens), which generates mechanical shock waves using an electromagnetic generator.

Following the recommendations by Russo et al. [19], we used two parameters to focus the treatment upon the target area in the ESWT group. Firstly, ultrasonographic localisation of the region of interest was performed. Secondly, the focus was altered according to the site of maximum reproduction of local pain by the subject at initiation of treatment.

All subjects received three ESWT or sham treatments at monthly intervals. No other treatments were permitted during the study period. The primary end point was the final follow-up, three months from baseline (1 month after completion of treatment). Data was analysed on an intention to treat basis. A positive response was taken as a 50% improvement from baseline at three months.

Results

Seventy-five subjects were recruited to the study and their characteristics are detailed in Table 1. The sham group had a slightly shorter duration of symptoms and was a slightly smaller sample than the ESWT group but these differences were not statistically significant. There were no other differences at baseline.

Two patients in the ESWT group withdrew after 2 treatments due to worsening of symptoms. Two subjects in the sham group withdrew, the reasons for which were unclear. No other adverse effects were reported.

Both groups had significantly improved at the final follow up stage. Significant improvement with respect to pain was noted from two months onwards in both groups. The ESWT group showed a temporary increase in night pain after the initial treatment (Tables 2 and 3).

At three months, 14 (35%) of the subjects in the ESWT group and 12 (34%) of the subjects in the sham group showed a positive response (50% improvement from baseline) with respect to pain. Positive responses in

Table 1
Baseline characteristics of subjects in each group

Demographic details	Treatment $n = 40$	Placebo $n = 35$
Male/female	19/21	14/21
Mean age (range)	46.5 (26–70)	48.2 (31–65)
Mean duration of symptoms (range) (months)	15.9 (3–42)	12 (3–40)
Dominant arm affected	28	26
Previous treatments (number of subjects)		
Analgesics	15	13
NSAID	27	15
Injections	29	17
Physio	14	13

Other treatments prior to inclusion: splinting (five subjects), strapping (1), osteopathy (2), acupuncture (1), homeopathy (1).

Table 2
Visual analogue scale for pain in both groups during the study (mean (SD, range))

	Baseline	One month	Two months	Three months
ESWT	73.4 (14.5, 38–99)	65.9 (22.8, 20–100)	54.7 (27.1, 7–94)***	47.9 (31.4, 3–100)***
Sham	67.2 (21.7, 12–100)	61.1 (22.7, 24–100)	54.3 (28.5, 0–100)**	51.5 (32.4, 3–100)***

Paired non-parametric t test, compared to baseline.
**$p < 0.01$, ***$p < 0.001$.

Table 3
Visual analogue scale for night pain in both groups during the study (mean (SD, range))

	Baseline	One month	Two months	Three months
ESWT	40.4 (28.3, 0–98)	49.0 (26.6, 1–100)*	35.8 (28.3, 0–96)	33.5 (29.6, 0–93)
Sham	44.4 (32.1, 0–98)	33.7 (33.6, 0–100)	32.9 (33.9, 0–100)*	30.1 (35.7, 0–100)*

Paired non-parametric t test, compared to baseline.
*$p < 0.05$.

Table 4
Subjects with 50% improvement from baseline at three months

Group	ESWT	Sham	Fishers exact test
Pain	14 (35%)	12 (34%)	$P = 0.325$, RR = 1.361 (95%CI 0.749–2.474)
Night pain	12 (30%)	14 (43%)	$P = 1.0$, RR = 0.933 (95%CI 0.522–1.670)

night pain occurred in 12 (30%) and 15 (43%) in the ESWT and sham groups, respectively (Table 4).

No significant difference existed between the groups with respect to the degrees of change in the pain scores over the study period.

Discussion

ESWT is becoming increasingly popular as a therapeutic option in the treatment of a variety of musculoskeletal complaints, including lateral epicondylitis [1,2,4,5,8,9,11,18,23]. In 1996 over 66,000 treatments of ESWT were administered for musculoskeletal complaints in Germany, and since then ESWT has become increasingly popular worldwide. In the United States, the therapy has recently been approved for use in the treatment of chronic proximal plantar fasciitis [6,10]. Despite the growing enthusiasm for the use of ESWT in musculoskeletal conditions, there is a lack of double-blind randomised controlled trials that evaluate its effects in the management of specific conditions.

ESWT has been classified according to its energy levels, where low energy shock waves have a focal energy flux density (EFD) of less than 0.1 mJ/mm^2 and high energy waves an EFD of 0.2 mJ/mm^2 [13]. Whilst most of the reports to date of the use of ESWT in soft tissue lesions relate to the use of low energy shock waves, we have examined intermediate (medium) dose therapy.

The results of this study indicate a significant and sustained placebo effect of ESWT but there is no evidence of added benefit of treatment when compared to sham therapy. The placebo effect may explain the significant improvements noted by others in uncontrolled studies of ESWT in the treatment of soft tissue lesions [3,8,14,17]. It is not unreasonable that such a placebo effect can be noted, since pain, the cardinal symptom of musculoskeletal disorders, is the feature most responsive to a placebo effect [7,12]. A false impression of a placebo effect can arise due to regression to the mean [7,12] and spontaneous improvement cannot be specifically excluded.

In the only other randomised trial of low dose ESWT in chronic lateral epicondylitis, Rompe et al. evaluated 50 patients who were randomised to receive three treatments at weekly intervals of either 3000 impulses of 0.08 mJ/mm^2 or 30 impulses of 0.08 mJ/mm^2 (the 'control' group) [15]. The study does not appear to have been blinded and it is unclear as to whether data were analysed on an intention to treat basis. A significant improvement in pain and function was noted only in the 'treatment' group at three months follow up.

It may be argued that the control group in Rompe et al.'s study did not receive a reliable sham therapy. The form of sham therapy we used was carefully devised to ensure that no energy was delivered to the region of interest. Elements utilised by others were included [16,19,21], with additional measures to ensure this was a true sham therapy [21].

There is no consensus on appropriate ESWT doses and regimes and treatment parameters remain empirical. Although the technique is widely reported to be safe, there is a potential for haemorrhage and local soft tissue damage through cavitation and this appears to be more likely with high doses [1,23]. As we aimed to use a feasible regime with minimal side effects, a moderate dose regime was chosen, which avoided the need for administration of local anaesthetic or significant post treatment rest. In order to identify any significant side effects of treatment we used a wide dosage interval in comparison to those used by others (commonly one week). Significant adverse effects were not noted, in agreement with the experience of others [3,8–11,16,14,15,17,18].

The differences between different studies in the apparent efficacy of ESWT in different soft tissue complaints may be related to a number of factors, including study designs, differences in study populations, heterogeneity of treatment parameters such as shock wave intensity, focal energy, geometry of the shock wave focus, different placebos and different machine design. Such features need to be addressed in further rigorous studies of this therapy.

Conclusions

There appears to be a significant placebo effect of moderate dose ESWT in subjects with lateral epicondylitis but there is no evidence of added benefit of treatment when compared to sham therapy. The placebo effect may explain the significant improvements noted by others in uncontrolled studies [3,8,14,17]. The use of ESWT in alternative doses and/or different dosage intervals in the management of tendinopathies warrants

further research before it can be advocated for such conditions.

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