UPDATE EVIDENCE BASED REVIEW

EXTRA-CORPOREAL SHOCK WAVE THERAPY (ESWT) IN TREATMENT OF SELECTED MUSCULOSKELETAL CONDITIONS

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Important Note

This evidence-based review summarises information on the effectiveness of Extracorporeal Shockwave Therapy in treatment of selected musculoskeletal conditions. It is not intended to replace clinical judgement, or be used as a clinical protocol. A reasonable attempt has been made to find and review papers relevant to the focus of this report. It does not claim to be exhaustive. This document has been prepared by staff of the ACC, Evidence Based Healthcare Advisory Group. The content does not necessarily represent the official view of ACC or represent ACC policy.

EXECUTIVE SUMMARY

Background

This evidence-based review examined the research evidence assessing efficacy of ESWT in treatment of selected musculoskeletal conditions.

Efficacy of ESWT applications have been evaluated for the following conditions:

- Calcific Rotator Cuff Tendinopathy (CRCT)
- Non-calcified shoulder syndrome
- Chronic Achilles tendinopathy
- Lateral and medial elbow tendinopathy
- Patella and knee injury
- Osseous non-union and delayed union

Search strategy

The relevant databases were searched in May - July 2007. These included Medline, Embase, EBM reviews, PEDro, Proquest, CINAHL, DARE, Google Scholar. Secondary sources, such as websites of insurance companies, were viewed for their coverage position. The search was limited to the English language publications, human studies, and the years of publishing from 2004 to July 2007.

Selection criteria

Due to paucity of research all studies involving use of shock wave therapy for the abovementioned musculoskeletal conditions were selected. The papers evaluated in the EBH review 2004 were subsequently excluded.

Outcome measures

The common outcome measures assessed in all the studies were pain reduction and functional improvement in the affected area. More specific outcome measures were assessed separately for each condition.

Main results

No universal conclusion has been reached on overall effectiveness of ESWT for management of musculoskeletal disorders. Efficacy of the treatment was considered separately for different pathologies, with results and recommendations specific to each condition.

CRCT is the only pathology where the evidence from the clinical trials supports ESWT use. All six original trials examined in this review reported some therapeutic benefits for CRCT.

In respect to elbow tendinopathy, two original studies and three systematic reviews provide conflicting results. Both studies indicate some therapeutic benefits for elbow tendinopathy, however methodological robustness of these studies is questionable. Conversely, the balance of conclusions from the systematic reviews appears to suggest little or no effectiveness of ESWT in treatment of lateral elbow tendinopathy.

Likewise, in regard to chronic Achilles tendinopathy the studies reported conflicting results. Two studies demonstrated a significant benefit from shock wave applications, and one study showed no additional therapeutic value from this treatment. Systematic reviews alluded to the lack of evidence on ESWT effectiveness for treatment of this condition.

Very few and low level of evidence studies have been published on therapeutic value of shock waves for non-calcified shoulder tendinopathy, medial elbow tendinopathy, patella and knee injury, non-union and delayed union.

Conclusions

The results of the review indicate that ESWT is an effective treatment option for CRCT.

In regard to Achilles tendinopathy and lateral epicondylopathy current evidence is conflicting and insufficient for determining therapeutic benefit of ESWT.

In respect to non-calcified shoulder syndrome, medial epicondylitis, patella and knee injury, non-union and delayed union, paucity of studies does not allow firm conclusions to be drawn.

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BACKGROUND

In October 2001 and in November 2004 ACC completed two reports examining effectiveness of ESWT in treatment of plantar fasciitis, lateral epicondylitis, non-union of bone fracture and calcified tendinopathy of the shoulder. The update report of November 2004 concluded that ESWT was effective in treatment of plantar fasciitis. The review also considered ESWT use in treatment of bone non-union, lateral epicondylitis and calcifying tendonitis of the shoulder. However evidence published at the time of the review did not allow the reviewers to determine effectiveness of ESWT for these conditions.

Subsequent to the earlier EBH reports, ACC has been asked to re-consider evidence of ESWT effectiveness in relation to the following medical conditions:

- Calcified tendinopathy and non-calcified shoulder syndrome
- Rotator cuff syndromes
- Lateral and medial epicondyle injuries
- Achilles tendon injuries
- Patellar tendon and knee injuries

For consistency with the 2004 evidence-based review, in addition to the above conditions this paper has also considered ESWT application for treatment of osseous non-union.

We recommend that in making purchasing decisions both evidence-based reports will be taken into consideration.

OBJECTIVES

The purpose of this report is to provide an update on efficacy of ESWT in treatment of selected musculoskeletal conditions in order to inform purchasing decisions.

REVIEW METHODOLOGY

The studies pertaining to use of shock waves in treatment of the identified musculoskeletal conditions were appraised by scrutinising their design, population under study, interventions and outcomes. Evaluated papers were assigned a score according to the SIGN criteria (36) (Appendix 2). The appraisal of each paper was compiled into the evidence tables (Appendix 1).

SEARCH STRATEGY

The following databases and search engines have been searched for relevant literature:

- Ovid Medline, including Ovid Medline(R) In-Process & Other Non-Indexed Citations and Ovid Medline(R)
- EMBASE
- EBM reviews – ACP Journal Club
- EBM reviews – Cochrane Central Register of Controlled Trials
- EBM reviews – Database of Abstracts of Reviews of Effects
- EBM reviews Full Text – Cochrane DSR, ACP Journal Club, and DARE
- All EBM reviews – Cochrane DSR, ACP Journal Club, DARE, and CCTR
- PEDro
- Proquest
- CINAHL
- The York Database of Abstracts and Reviews of Effectiveness (DARE)
- References to relevant research listed in the referenced articles
- Google Scholar
- Website of the insurance company Cigna was viewed for its coverage position[1].

Key words used: Extra-corporeal shock wave therapy, shock wave therapy, shock waves, high energy shock waves, ESWT, Achilles tendon, rotator cuff, tendinopathies, non-union, fracture, delayed union, patella, knee, epicondylitis, elbow, lateral epicondylitis, tennis elbow, epicondyalgia, tendonitis and tendinosis.

[1] http://www.cigna.com

The search was conducted from the year 2004. The papers appraised in the 2004 EBH review were excluded from this supplementary report. The search was limited to human studies and to the papers published in English, hence relevant papers published in other languages (Chinese, German, French) were not included in this review. However the English abstracts of these papers, if available, have been acknowledged (12, 30).

A number of new clinical trials on efficacy of ESWT have been carried out since the previous evidence-based review. Comparison between the clinical trials is difficult because of significant variations in treatment protocols. Study inclusion criteria, amount of energy delivered, frequency and timing of shock waves delivery, the choice of site for focusing shock waves and use of anaesthetics vary considerably between the studies, making the comparison problematic.

EXTRACORPOREAL SHOCK WAVE THERAPY TECHNOLOGY

Over the past decade extracorporeal shock wave therapy has emerged as an alternative treatment option for tendon pathologies refractory to conventional non-surgical treatments. This therapy involves application of shock waves that are sound waves generated by an underwater high-voltage spark. The waves are then focused at the target area with the help of an elliptical reflector or acoustic lens. The precise mechanism of shock waves' therapeutic properties has not been established, and it is believed that shock waves stimulate the healing process by inducing neovascularisation and ossification (21). The energy at the point of application is called energy density, measured in joules per area. The total energy received at treatment is determined by the number of impulses and the energy density. Shock waves are generated by electro-hydraulic, electromagnetic or piezoelectric methods.

ESWT treatment protocols have not yet been standardised, with significant diversity between the studies in dosages, frequency of applications, density of energy and total energy applied. Other variations in technique include the treatment site and use of anaesthetic injections prior to shock wave application. With regard to the former, the issue is whether shock waves should be directed at the point of maximal tenderness or guided by radiological or ultrasound imaging

(34). In respect to the latter, the limited evidence suggests that use of anaesthetic injection may hinder ESWT therapeutic effect (13).

In New Zealand this treatment is provided by Health Compass Ltd based in Auckland. This treatment provider is using an OrthoSpec™ electro-hydraulic device[2].

Classification of shock waves energy level

The amount of ESWT energy is measured in energy flux density per square unit mJ/mm^2. The energy level is commonly categorised into three groups by an energy flux density (2):

- low energy extracorporeal shock with an energy flux density below 0.08 mJ/mm^2
- medium energy ESW from 0.08 mJ/mm^2 to 0.28 mJ/mm^2
- high energy ESW from 0.28 mJ/mm^2 to 0.60 mJ/mm^2

RESULTS

The studies have been examined separately for each musculoskeletal condition under review.

Pain relief and improvement functional ability were considered as a common outcome measure and an indication of therapeutic benefit(s). Pain reduction in the study group was regarded as significant when VAS score was reduced by over 50% compared with the control group.

CALCIFIED ROTATOR CUFF TENDINOPATHY (CRCT)

Calcific (also referred to as calcifying and calcified) tendonitis or tendinopathy of the rotator cuff is a common medical condition characterised by presence of crystalline calcium phosphate in any tendon of the rotator cuff. For consistency of terminology, this report refers to this condition as calcific rotator cuff tendinopathy (CRCT). Calcification of the rotator cuff does not always result in clinical manifestations, with reports of 3-20% prevalence of asymptomatic calcific

[2] ***www.kompasstechnologies.co.nz***

deposits in the rotator cuff in the general population (41). Clinical manifestations of CRCT are chronic shoulder pain and shoulder dysfunction.

It is important to note that aetiology of this condition is not known (19, 30). A general consensus among the orthopaedic specialists is that CRCT is not caused by trauma (41).

Conventional treatment of CRCT is conservative therapy with the use of subacromial steroid injection, oral non-steroid anti-inflammatory drugs, physiotherapy (19). For about 90% of patients this therapy is effective. When conservative therapy fails to improve the symptoms, the next available treatment is needle extraction or bursoscopic excision of calcific deposits. Efficacy of needle extraction varies, and the procedure carries a risk of tendon injury. Arthroscopic excision is effective in 80-90% of cases resistant to conservative therapy (2). ESWT is contemplated for CRCT resistant to conservative therapy and prior to using surgical interventions.

The literature search detected six original studies and two systematic reviews.

Original studies

Six original studies on use of ESWT in treatment of CRCT have been identified (2, 8, 18, 28, 30, 34). Five studies were designed as randomised controlled trials. These studies used different study design, with single- or double-blinded studies introducing convincing evidence in support of this treatment.

The sample size of the studies varies from 43 to 135 participants. The population under study are patients experiencing long-standing symptoms of CRCT. The common inclusion criteria are failure of conservative therapy to settle the symptoms, and Type I and Type II calcific deposits verified radiologically.

Patients with systematic diseases, coagulation disorders, osteoarthritis, neurological abnormalities, infectious diseases, tumours, rotator cuff tear were excluded from the studies. Pregnancy was also a common exclusion criterion.

The studies used various degrees of energy flux density of ESWT application, from low-energy at 0.15 mJ/mm^2 to the highest energy level tolerated by patients, up to 0.45 mJ/mm^2.

The regime of applications varied from a single administration (18) to up to 5 sessions of weekly administration (28). The shocks were applied every 4-7 days (8) or 6-weekly (28).

The measured outcome was similar across all the studies. It included changes in shoulder function measured by the Constant and Murley scale, pain relief assessed by VAS score, and radiological resolution of calcific deposits.

Consistent results of all the studies indicate that ESWT is an effective and safe method of CRCT treatment.

The efficacy of ESWT in treatment of CRCT of the shoulder was assessed in the study by Pleiner et al (30). This double-blinded study used two different energy flux density applications without pre-treatment analgesia for the treatment and control groups at an interval of two weeks. The treatment group received an application of 2x2000 impulses of 0.28mJ/mm^2, the control group was treated with the application of 2x2000 impulses of <0.07 mJ/mm^2. The results suggested a significantly greater improvement in shoulder function and slightly higher, non-significant disintegration of calcific deposits in the treatment group compared with the control group. However this did not correspond with pain relief. The overall impression of the results was that use of shock-wave therapy was beneficial for improving shoulder function, as well as for reduction of calcific deposits. However it did not result in shoulder pain reduction.

Similar to the Pleiner's study, therapeutic value of high-energy shock waves was highlighted by the results of the clinical trial by Albert et al (2). This prospective randomised trial compared treatment outcome for two groups receiving low-energy and high-energy ESWT. Eighty patients with chronic shoulder pain resistant to conservative treatment were randomly allocated into treatment group receiving high-energy impulses and control group receiving low-energy shocks. The assessed outcomes comprised shoulder function assessed by the Constant and

Murley score, pain relief and radiological findings on resorption of the calcific deposits. The results demonstrated superior improvement in shoulder function and pain relief in the treatment group. Total or subtotal resorption of the calcific deposits was achieved in 15% in the treatment group and 5% in the control group.

A 15-point increase in the Constant and Murley score was achieved in 50% in the treatment group and in 20% in the control group. Pain relief was more marked in the treatment group but it was not considered to be statistically significant. The authors concluded that no significant clinical improvement was observed after treatment with low-energy ESWT, and that the clinical outcome was markedly better with high-energy ESWT. The procedure was well tolerated, with minimal adverse reactions, such as skin petechia and haematoma in the site of the application. The study conclusion supported the use of high-energy ESWT in treatment of CRCT.

In line with the above studies, a prospective RCT by Krasny et al demonstrated shoulder pain reduction and disintegration of calcific deposits (18). The study compared results for two groups of 40 patients with long-standing painful calcific tendinopathy of the supraspinatus[3]. All the patients were due to undergo arthroscopic removal of the calcificates within 6 months after commencement of the study. Group 1 was treated with ultrasound-guided needling[4] and subsequent high-energy shock wave therapy. Group 2 received high-energy shock wave therapy only. The ESWT treatment comprised one session of 2500 impulses of shock waves with an energy flux density of 0.36 mJ/mm^2. The results indicated a dissipation of calcific deposits and a significant reduction in shoulder pain.

Peters et al concluded that ESWT resulted in improvement of symptoms and resorption of calcium deposits in the treatment groups (28). The study randomised 90 patients into 3 groups to receive either ESWT or sham treatment. Two treatment groups received ESWT at one of two energy levels: low-energy at 0.15 mJ/mm^2 or high-energy at 0.44 mJ/mm^2. No changes were observed in the group receiving sham treatment. Some improvements in the shoulder function and resorption of calcific deposits were reported in the group receiving low-energy

[3] Supraspinatus muscle is one of four muscles forming the rotator cuff muscle
[4] Repeated puncture of a deposit with a needle carried out under local anaesthesia

treatment. Significant improvements in pain relief, shoulder function and complete or partial calcificates resorption were noted in the group receiving high-energy ESWT. At the 6 month follow up the latter group had no recurrence of pain and no calcifications were observed. No side effects apart from small haematomas were reported, and the treatment was well tolerated with no anaesthesia used during the applications of shock waves.

A prospective study by Cosentino et al assessed effectiveness of ESWT for a sample of 135 patients with chronic calcifying tendonitis of the supraspinatus (8). There was no comparison group and all patients received four treatments with an interval of 4-7 days, consisting of 1200 shocks with a frequency 120 shocks per minute. The energy flux density commenced at 0.03 mJ/mm^2 and was increased to 0.28 mJ/mm^2 in subsequent sessions. No methods of pain relief, such as analgesics, local anaesthetics or NSAIDs[5] were used in conjunction with the ESWT. Shoulder function Constant and Murley score, pain relief and changes in calcific deposits were assessed prior to the start of the treatment, after the last session and at 3 and 6 month follow up.

The authors reported a significant shoulder pain relief and a significant improvement in the shoulder function. Pain reduction, as measured by the Constant and Murley score, was reported as achieved at 140% at the end of the therapy. However this figure appears to be flawed as pain cannot be reduced beyond 100%. A scrutiny of the study results suggests that although pain reduction was significant (a 53% reduction in the mean pain score), it did not achieve the suggested figure. At one month after the end of the sessions partial resorption of the calcific deposits was observed in 44.5% of cases, and complete resorption in 22.3%. The study concluded that ESWT was safe and effective in treatment of CRCT, and that it should be considered as an alternative therapy.

All the previous studies identified significantly better outcome following the application of high-energy ESWT. Therapeutic value of low-energy ESWT was questioned (2, 28).

[5] Non-Steroid Anti-Inflammatory Drugs

A study by Sabeti-Aschraf et al deduced significant improvement in shoulder function, pain relief and dissipation of calcific deposits following treatment with low-energy ESWT (34). Albeit in this study the energy flux density was 0.08 mJ/mm^2, the figure that according to the classification is also considered to be a medium-energy level (2).

The study compared two ways of focusing shock waves. Both groups received low-energy shock waves administered 3 times in weekly intervals. In Group 1 the site of administering was identified as the point of maximum tenderness revealed by palpation. In Group 2 shock waves were focused on the calcific deposit identified with the assistance of a radiographically-guided, 3-dimentional computer-assisted navigation device. The study reported significant therapeutic benefits for both groups, however the results were significantly better in the Group 2.

The key results of the CRCT studies are summarised in the Appendix 3.

Systematic review

The search yielded two systematic reviews pertaining to use of ESWT for problems associated with the rotator cuff (14, 15).

Evaluation of the interventions for rotator cuff pathology compared effectiveness of surgical and conservative treatment options for the tendinopathy (14). The review examined 64 studies on treatment of rotator cuff pathology from 1966 to May 2003. The paper refers to three studies on application of ESWT, and describes their results as inconsistent, with two studies suggesting significant improvements following high-energy ESWT, and one study indicating similar improvements for the treatment and placebo groups. The systematic review concludes that out of all options available for treatment of rotator cuff tendonitis, there is sufficient evidence in support of benefits of electrotherapy, steroid injections, exercise therapy and acupuncture. However the results of studies on success of ESWT in treatment of this condition are inconsistent, hence it is not possible to establish its effectiveness. It is worthwhile to note that two of these studies were appraised in the 2004 evidence-based report.

A systematic review by Harniman et al examined efficacy of ESWT in treatment of CRCT and non-calcific tendinopathy (15). The summary of the review suggests moderate evidence of effectiveness of high-energy ESWT in treatment of CRCT.

It is important to emphasise that both papers on systematic review were published in April – June 2004, and further studies have been published since their publication (2, 18, 28, 34).

To sum up, all the original studies reported positive effects of high-energy ESWT in treatment of CRCT. Although not all the studies detected disintegration of calcific deposits, most of them agree that ESWT resulted in improvement in shoulder function and in reduction of shoulder pain. Scrutiny of the reported results, as summarised in the Table 2 (Appendix 3) suggests that the results demonstrate:

a) moderate efficacy in improving shoulder function as measured by Constant and Murley score;
b) equivocal efficacy in pain relief as measured by VAS score;
c) moderate efficacy in resorption of calcific deposits in comparison with sham treatment.

NON-CALCIFIC ROTATOR CUFF TENDINOPATHY

No original studies were identified in respect to this condition. The only reference found in the reviewed papers is a remark regarding moderate evidence of ESWT being not effective in treatment of non-CRCT (15). The systematic review by Harniman et al appraised two RCTs and concluded that moderate evidence suggested no effect of low energy shock waves on non-calcific rotator cuff tendinopathy.

LATERAL & MEDIAL ELBOW TENDINOPATHY

Lateral and medial elbow tendinopathy is considered to be a correct term for describing several medical conditions associated with pathological changes in the elbow tendons (38). Lateral epicondylitis, tennis elbow, epicondylalgia, tendonitis and tendinosis are the terms often used to describe the pathology related to lateral

elbow. It is the most commonly diagnosed elbow condition and affects about 1-3% of the population at large (16).

Epicondylalgia is treated with steroid injections, physiotherapy, acupuncture, exercises, glyceryl trinitrate patches and NSAIDs. Conservative treatment appear to provide short-term benefits and most effective treatment for this condition is not established (17). However treatment with glyceryl trinitrate patches (GTN) emerges as possibly the most effective therapy up to date (27). Failure of conservative therapies for persistent epicondylitis can be an indication for arthroscopic or open surgery. ESWT is considered as a treatment option for epicondilylagia resistant to conservative treatment.

Current evidence on the ESWT clinical benefits is conflicting. Two publications on the original studies and three papers on systematic review in relation to lateral epicondylitis were found. No studies were detected in respect to medial epicondyle dysfunction.

Original studies

A prospective cohort study by Melegati et al compared two techniques of focusing shock waves on the affected areas (25). The trial included 41 patients with long standing lateral epicondylitis. The patients were randomly allocated to two treatment groups. Group 1 received shock waves focusing on the lateral side of the elbow with the ultrasonographic probe on the lateral epicondyle. Group 2 received the same treatment but focused on the back of the elbow. Medium-energy shock waves were applied in 3 weekly sessions, and pain relief and elbow function were measured at baseline and at 6 months after the treatment. The study results suggested improvement in elbow function and pain relief for both groups at 6 months after the treatment as compared with the baseline values. No difference in outcome was noted between the treatment groups. The authors' conclusion was that ESWT improved self-reported elbow function measured by Total Elbow Scoring System (TESS) but the therapy did not eliminate the epicondylalgia.

The results of a double-blind randomised controlled trial by Pettrone & McCall indicated that ESWT without local anaesthesia is effective in management of

chronic lateral epicondylitis (29). The sample of 114 patients was randomised into treatment group receiving low-energy shock waves and control group receiving sham treatment. The outcome measurements comprised pain relief, changes in upper extremity function and activity, patients' subjective impression of their disease state and grip strength. The results assessed at 12 weeks after the treatment noted significant improvements in the treatment group in comparison with the placebo patients.

Pain reduction, improvement in functional score and activity score and changes in subjective perception of the disease state were significantly greater in the ESWT group. The improvements noted at 12 weeks were maintained in almost all of the treatment group participants who were followed for 12 months. The study reported ESWT as an effective treatment for chronic lateral epicondylitis resistant to conservative treatment.

Systematic review

Three papers on systematic review came to conflicting conclusions.

A systematic review by Buchbinder et al examined in-depth ten clinical trials assessing effectiveness of shock wave therapy in treatment of lateral elbow pain (4). The review included 9 trials that randomised 1006 participants to ESWT or placebo and one trial that randomised 93 patients to ESWT or steroid injection. Statistical analysis of the data from all the reviewed trials detected no significant benefit of ESWT over placebo. The results of the review summarised the findings as 'Platinum' level evidence of little or no effectiveness from using ESWT for managing pain and improving function in patients with lateral elbow pain.

The review highlighted that all examined trials reported improvement in the outcome in treatment and control groups, and suggested that the observed effects may be due to self-limiting natural history of epicondylalgia.

It is important to note that appraisal of seven out of ten studies was included in the 2004 EBH report, and one paper (29) assessed in this review.

A systematic review by Stasinopoulos and Johnson selected seven high quality RCTs to be scrutinised in respect to efficacy of ESWT in treatment of tennis elbow (37). The review alluded to the conflicting results and highlighted methodological limitations common for the reviewed studies. The review summarised that the study results vary from no therapeutic effects arising from shock waves applications to improvement in function and pain relief. Three out of five studies comparing ESWT with sham treatment did not demonstrate ESWT effectiveness, with the other two trials indicating that ESWT was more effective at the end of treatment and at the follow up. One study suggested improvement in pain and function for two treatment groups compared with the baseline values. A comparison of effectiveness between steroid injection and ESWT suggested a better clinical outcome from the steroid injection. The review recommendation was that in order to establish absolute and relative effectiveness of ESWT more well designed randomised controlled studies are needed.

With one exception, all the studies reviewed in the Stasinopoulos paper were previously assessed in the EBH 2004 review.

A systematic review and meta-analysis by Bisset et al examined clinical trials on physical interventions applied in management of lateral epicondylalgia, such as non-electrotherapeutic interventions (exercise, acupuncture, orthotics etc) and electrotherapeutic methods (laser, ESWT, electromagnetic field etc) (3). The review concluded that ESWT was not beneficial in the treatment of tennis elbow. The paper stated that because of poor methodological quality of the eight studies found through the literature search, only two studies were included in the meta-analysis. One study reported no difference in outcome measures for treatment and placebo groups. Likewise, another double blind RCT noted no therapeutic effects of ESWT in comparison with the control group. Meta-analysis of both studies suggested no added benefit over placebo for the ESWT group. Both studies examined in the Bisset review were appraised in the 2004 EBH report.

Interventional procedure guidance published by the National Institute for Health and Clinical Excellence of NHS Scotland refers to evidence on ESWT effectiveness in treatment of elbow tendinopathy as '***conflicting***', and suggests that current evidence indicate little benefit over placebo response (10).

Similarly, updated clinical policy from Aetna insurance company concludes that the overall impression from the studies was of no additional benefit for ESWT over placebo treatment (1).

In summary, the systematic reviews arrive at conflicting conclusions, with two papers suggesting no added benefits from ESWT application, and one paper indicating that ESWT was an effective treatment method, however its effectiveness needs to be validated further through robust clinical trials.

ACHILLES TENDINOPATHY

Achilles tendon injury is a relatively common pathology with the pain, swelling and tenderness usually experienced in the relatively hypovascular area 2 to 6cm above the insertion of the tendon into the calcaneus. Tendon injuries can be acute or chronic. Aetiology of chronic tendinopathy is not fully understood, and it is considered to be a degenerative rather than inflammatory condition (22).

A significant number of patients with chronic tendinopathy do not respond well to conventional conservative therapies (26). Hence other treatment options, such as eccentric loading of the calf muscle, glyceryl trinitrate patches (GTN)(27) and ESWT, have been tried as emerging methods of managing this condition.

Original studies

Out of three papers identified through the literature search two studies demonstrated a significant benefit of ESWT use in treatment of chronic Achilles tendinopathy (13, 33). One study did not indicate any additional benefit from ESWT in comparison with conventional treatment (9). However a direct comparison of the studies results is devoid of significance due to different treatment protocols used in these trials.

An observer-blinded randomised controlled study by Rompe et al compared three different treatment methods for non-insertional Achilles tendinopathy (33). Low-energy ESWT was compared with an eccentric calf muscle loading exercise

programme and wait-and-see approach. ESWT treatment was given in 3 sessions at weekly intervals, with the energy flux density equal to 0.1 mJ/mm^2. Seventy five patients with long standing symptomatic tendinopathy resistant to conservative therapy were randomly allocated to three equal size groups. Group 1 completed a supervised eccentric loading exercise programme. Group 2 received 3 sessions of low-energy ESWT. Group 3 did not receive any active intervention apart from use of analgesics and NSAIDs when necessary for pain relief.

The results, such as VAS score, general assessment and pain assessment, were recorded at a 4-month follow up. The results demonstrate a significant improvement in function and pain relief for the Group 1 and Group 2, with no improvement in the Group 3. Both, eccentric loading training and ESWT, were effective in management of the Achilles tendinopathy, with no significant difference in the results between these treatment groups. Group 3 did not show any clinical improvement.

One of the criteria used in assessment of the results was success of treatment on Likert scale as perceived by patients. A slightly higher number of patients in Group 1 compared with Group 2 rated the results of the treatment as a '***success***' (15 versus 13). A majority of patients in Group 3 graded the treatment outcome as a '***failure***'.

Overall, the trial demonstrated that eccentric calf muscle training and low-energy ESWT achieved comparable results, and that these results were significantly better than the outcome of the wait-and-see approach.

A similar conclusion was reached in a prospective cohort study, albeit unlike in the previous trial the study applied high-energy ESWT (13). Furia et al compared the results for three groups of patients: a treatment group with two subgroups and a control group that received conventional conservative treatment. Within the treatment group the patients were randomly allocated for treatment with ESWT and a local anaesthesia field block, and for management with ESWT and methods of pain relief other than local anaesthesia.

The treatment group received a single application of 3000 shocks at 0.21 mJ/mm^2 energy flux density. Assessment of pain relief and changes in functional capacity at 1, 3 and 12 months subsequent to the treatment demonstrated significant improvement in the treatment group in comparison with the group that received conservative treatment with conventional methods (physiotherapy, NSAIDs, shoe ware modifications etc). The treatment subgroup that did not receive a local anaesthestic field block achieved better results, hence it was inferred that local anaesthesia may inhibit efficacy of ESWT.

While overall conclusion of the study was the achievement of significant therapeutic benefits from shock waves application, the authors emphasised that this trial used a particular protocol. Hence the study results could not be generalised to other ESWT protocols and devices.

In conflict with the previous results were the findings of a randomised controlled trial comparing effects of medium-energy ESWT with placebo (9). Costa et al compared the outcome of shock waves application to the point of maximum tenderness with the effects of applying shock waves through a bubble wrap, hence preventing shock waves from reaching the tendon. The treatment was carried out in three sessions, with a monthly interval. This publication was the only study that reported a serious complication subsequent to the ESWT application as two patients had an Achilles tendon rupture two weeks after commencement of treatment.

Rompe criticised the treatment method used in the study as it did not comply with the protocol that was considered to be effective in his study (32). Rompe refers to the following prerequisites for achieving therapeutic benefits:

1. Application of 1500-2000 low-energy flux density waves
2. Focus of shock waves on the site of maximal discomfort
3. No use of local anaesthesia
4. Application of 3-4 treatments at weekly intervals
5. A follow up for at least 3 months after the last session

As Costa's study did not comply with the points 1 and 4, Rompe argued that the applied treatment was ineffective, and that the study showed how not to treat patients with Achilles tendinopathy rather than indicated ineffectiveness of ESWT in general.

From the conflicting results of these two RCTs it is problematic to draw a definite conclusion on ESWT benefit.

Systematic review

Cochrane Bone, Joint and Muscle Trauma group in the review of treatment options for acute and chronic Achilles tendinopathy did not include ESWT trials (24). McLauchlan and Handoll evaluated randomised and quasi-randomised trials of treatment interventions in adults with Achilles tendonitis. This review included 9 trials on effectiveness of low dose heparin, NSAIDs, heel pads, topical laser therapy and peri-tendonous steroid injection. However ESWT was not considered in this review as a treatment option for Achilles tendinopathy. The omission of this therapy from the conventional treatment option was not explained in the report. It could indicate that shock wave therapy was not considered to be one of the mainstream treatment options for this condition.

In summary, with the limited and conflicting evidence it is problematic to draw definite conclusions on effectiveness of ESWT in treatment of chronic Achilles tendinopathy. A small number of studies, a limited number of patients involved in the trials, and different treatment protocols used in the trials do not allow the reviewer to form a final opinion on benefits of this therapy. The balance of evidence appears to indicate that repetitive low-energy shock waves are effective in reducing pain associated with Achilles tendonopathy. However this conclusion can be questioned because of paucity of research in this area.

PATELLA TENDONITIS & KNEE INJURIES

No publications on use of ESWT in treatment of patella tendonitis and knee injuries have been found.

NON-UNION AND DELAYED UNION

A thorough search of various databases found very few publications related to application of ESWT in treatment of non-union and delayed union fracture.

Four observational studies and two papers on literature review provided low level of evidence on effectiveness of the treatment.

The results of two case studies did not produce convincing evidence in support of ESWT effectiveness. Both studies involved a small number of patients, no control group and the overall number of patients who benefited from the treatment was equal to the number of cases where no beneficial effect from shock waves was detected. Ciampi et al refer to a single patient successfully treated with high-energy shock waves (6). In a case series involving five patients by Chooi and Penafort, two patients benefited from the treatment, and in three cases the results were described as '***disappointing***' (5).

A Japanese study designed as a case series of five patients reported good bone consolidation in the athletes with chronic stress fracture after use of high-energy ESWT (39). All five cases developed radiographic union, hence the authors concluded that shock waves therapy is an effective method of treatment for stress fractures.

A study commissioned by a manufacturer of the ESWT equipment Health Tronics showed beneficial results from treatment with high-energy shock waves for the non-union or delayed union of the proximal fifth metatarsal (40). Twenty eight patients with fractures in metaphyseal-diaphyseal cortical regions that were not making adequate progress towards fracture healing were treated with 1 application of 2000 high-energy shocks. At the 12-week, 6 and 12 months follow up the patients were assessed in respect to pain and radiographic evidence of healing. Patients with 50% pain relief and healed or partially healed on radiographs fracture site were considered as '***success***'**.** At 12 weeks 15 out of 23 patients were graded as '***success***', at 6 months 16 out 20 subjects were assigned to this category, and at 12 months in 13 out of 14 patients beneficial outcome was recorded. While the overall impression of this study was that ESWT can be effective in treatment of

non-union and delayed union, the results of the study need to be verified by further clinical trials.

A comprehensive review of the current treatment options for aseptic non-union of femoral shaft diaphysis indicates that the effect of shock waves on the bone is poorly understood (20). Lambiris et al refer to scarce research on this pathology, and conclude that further clinical studies are necessary for determining effectiveness of this therapy.

Therefore, albeit the published studies appear to suggest therapeutic benefits of shock waves application for treatment of non-union, these studies were observational and included a small number of patients. These results have not been verified by high quality robust clinical trials. Paucity and low grade of evidence did not allow the reviewer to establish that this treatment was effective in facilitation of osteogenesis subsequent to bone fracture.

DISCUSSION

Several studies reported encouraging results for use of ESWT for CRCT. However for other reviewed musculoskeletal conditions the results were either conflicting or non-existent.

Methodological quality

Methodological quality of the examined studies varied from a single case study to double blind RCTs. Due to dearth of research on ESWT in treatment of the selected musculoskeletal conditions all the studies have been selected for this review.

Study population, inclusion and exclusion criteria

Studies looking at ESWT in treatment of CRCT, Achilles tendinopathy and lateral epicondylitis applied similar inclusion and exclusion criteria. Patients with long-standing symptomatic tendonitis resistant to conventional therapies were selected for the studies. For patients with CRCT of the rotator cuff, the size and quality of the calcific deposits was an additional selection criterion.

Malignant disease, coagulation disorders, pregnancy, acute or systematic infection of bones and joints, cardiac pacemakers, degenerative changes around application sites, infections, endocrine and peripheral vascular disease were the common exclusion criteria.

Comparison

It is not possible to make a generic conclusion for all musculoskeletal conditions on effectiveness of shock wave therapy. A comparison between studies is problematic due to significant variations in treatment protocols and different study designs. Furthermore, reported variables differ between studies, and VAS score is rarely reported making inter-study comparison of pain relief impossible.

The following key issues that hinder cross-studies comparison have been identified:

- Studies applied different methods of shock wave generation (electrohydraulic, electromagnetic or piezoelectric).
- The treatment protocols have not been standardized, with dosage and frequency of ESWT markedly varying between the studies.
- Measured outcomes and statistical analysis significantly differed.
- Different areas were used for shock waves applications: some studies target calcific deposits, while others direct shock waves to areas of maximal tenderness.
- Anaesthetic injections were used in some studies but not used in others, hence adding to confounding factors.
- A follow up period ranged from short term recordings to long term observations.

The impression from the examined studies is that an optimal protocol for ESWT application has not been established. For CRCT the dosage of shock waves application ranges from 1000 impulses at 0.08 mJ/mm^2 (34) to 2500 impulses at 0.45 mJ/mm^2 (2). Frequency of administering ESWT varied from 3-4 sessions weekly (8, 34) to 2 sessions fortnightly (2, 30).

The optimal target for shock waves application has not been determined yet. A majority of studies identified a point of application from patients' subjective feedback on the point of maximal tenderness. However a single study suggested that focusing shock waves with ultrasound on calcific deposits produced more significant therapeutic benefits (34).

Anaesthesia was not used in a majority of trials that applied high energy shock waves. Two trials on rotator cuff tendinopathy used a combination of oral analgesics given pre- and post-procedure and contact anaesthetic patch (2) or intra-acromial analgesic injection (18). Furia used a local or regional anaesthesia prior to administering ESWT, and suggested that use of a local anaesthetic block may inhibit the effectiveness of shock waves (13).

A period of follow up is important as it provides valuable information on longevity of therapeutic effects. In respect to monitoring the outcomes, the length of a follow up period varied from 4 weeks (8) to 12 months (29).

Two papers on systematic review of ESWT in management of chronic tendinopathies suggest that this method is effective for some conditions (31, 35).

The overview of ESWT in treatment of chronic tendinopathies indicates that no clear consensus exists on clinical indications for this treatment (35). The article alludes to three categories of medical conditions:
1 – shock therapy appears to be effective, such as CRCT;
2 –the evidence of shock wave therapy effectiveness is inconclusive, such as lateral epicondylitis;
3 – no evidence of ESWT effectiveness, such as non-calcified shoulder tendon pathologies.

An overview of the current treatment methods used in managing chronic tendinopathy alluded to ESWT as generally effective treatment of calcifying tendinopathy (31). The section on treatment of Achilles tendinopathy suggests that eccentric loading is an emerging treatment for the condition. In the context of treatment specific to Achilles tendon pathology ESWT was not regarded as an effective treatment.

Positions of other insurance companies in respect to funding this treatment for musculoskeletal conditions vary, with several insurance providers referring to ESWT as experimental, investigational and with unproven effectiveness for these conditions (1, 7, 23).

With regard to Achilles tendinopathy and lateral epicondylitis, the evidence is conflicting. At the best this treatment appears to be effective for short term relief of symptoms. The cost of treatment needs to be weighted against the temporary alleviation of symptoms.

SAFETY OF ESWT

ESWT is considered to be a non-invasive treatment with low complication rates. It is thought that high-energy shock waves carry more risks of adverse effects than low-energy shock waves. Animal studies reported potential side effects arising from misdirection of shock waves to neurovascular structures that could result in nerve or vascular injury (15). However no reports of such an injury in human trials have been found.

Most common reported adverse consequences include transient erythema (21%), petechial rash and small haematomas (3.0%) in the site of shock wave application (4). Other reported complications include muscle pain (4.8%) and temporary or permanent nerve damage resulting in hyperesthesia or paraesthesia. Few serious adverse outcomes were reported, these included rupture of the Achilles tendon in two patients and avascular osteonecrosis of the humerus head in one instance (9, 11).

LIMITATIONS OF THIS REVIEW

A significant limitation of this review is that a number of non-English publications have not been considered. It has excluded several original studies and systematic reviews in Chinese and German. To address this limitation an acknowledgment has been made in respect to these studies in the instances when an abstract in English was available.

CONCLUSIONS AND RECOMMENDATIONS

In light of new studies published after the 2004 EBH review, there is now sufficient evidence to establish some ESWT benefits in treatment of CRCT. However for non-calcified tendon pathologies the evidence does not suggests effectiveness of shock wave therapy.

In regard to lateral epicondylitis and Achilles tendinopathies, albeit weight of evidence appears to indicate that this treatment may be beneficial for these conditions, lack of high quality clinical trials and small numbers of patients involved in the trials do not allow the reviewer to conclusively determine ESWT efficacy at this time.

There is insufficient evidence in support of use of ESWT for treatment of non-union and delayed union.

Because of paucity of information in respect to medial elbow tendinopathy, patellar tendonitis and knee injury no definite conclusions regarding the indications or expected outcome of ESWT can be made.

Clinical implications

All the trials involving ESWT for musculoskeletal conditions included patients with long standing symptoms, following failure of conservative treatments to resolve these conditions. Therefore when recommendations on referral of ACC claimants are made, it needs to be noted that a referral should be made only subsequently to unsuccessful management by conventional therapies.

Rotator cuff tendinopathies

The evidence supports use of ESWT in treatment of CRCT. However no evidence was found in support of ESWT application in treatment of non-calcific shoulder tendinopathy.

The reviewed studies commonly used the following selection criteria:

- CRCT with Type I and Type II calcific deposits

- Symptomatic tendinopathy for over 3 months
- Tendinopathy resistant to conservative treatment.

These criteria need to be applied when referring to ESWT therapy patients with CRCT.

Lateral and medial elbow tendinopathy

The original studies as well as the systematic reviews provide conflicting evidence on effectiveness of ESWT in treatment of lateral elbow tendinopathy On balance, the lack of convincing high quality evidence regarding ESWT effectiveness does not support its use in treatment of epicondylalgia.

No evidence has been found in support of effectiveness of ESWT in treatment of medial epicondylitis.

Achilles tendinopathies

Paucity of research and conflicting evidence do not allow the reviewer to form a final opinion on effectiveness of ESWT in treatment of Achilles tendinopathies. In addition to the evidence-based review of 2004 this updated review found two studies suggesting beneficial results. However in a combination with the conclusion of the 2004 report, it appears to be insufficient evidence up to date to determine effectiveness of shock waves therapy in treatment of chronic Achilles tendinopathy. This conclusion needs to be re-considered if new clinical evidence in support of this treatment is published.

Patella tendon and knee injury

No publications were found in regard to these conditions.

Non-union and delayed union

No high quality clinical trials have been published. The publications are descriptive and provide low level of evidence which is insufficient to establish effectiveness of ESWT in treatment of non-union and delayed union.

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