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SHOCKWAVE THERAPY SYSTEM FOR MUSCULOSKELETAL DISORDERS

HEALTH TECHNOLOGY ASSESSMENT SECTION

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EXECUTIVE SUMMARY

Introduction
Musculoskeletal disorders is the most common and disabling of medical disorders and the leading cause of work related disability among men and women 16-72 years old. Musculoskeletal disorders have substantial impact on quality of life. Extracorporeal shock wave therapy (ESWT) is an innovative non-invasive method for the treatment of localized musculoskeletal pain. ESWT was designed to administer a wide range of finely tuned low energy shock waves. Variable energy settings allow the patient to be treated with the energy level best suited for his or her medical condition. Certain brands of ESWT have been approved by Federal Drug Administration (FDA) United States for severe heel pain and lateral elbow pain.

Aims/objectives
To determine the safety, effectiveness and cost effectiveness of low (SWT) system for rehabilitation of musculoskeletal disorders

Results and conclusion
There was sufficient strong evidence to support the effectiveness of shock wave therapy for the treatment of shoulder calcific tendinitis. Evidence also showed that ESWT is more cost-effectiveness compared to surgery for shoulder calcific tendinitis. However, the evidence on effectiveness of ESWT in treating lateral elbow pain is still inconclusive. On the other, ESWT therapy for heel pain seems to bring only marginal gains over placebo or other therapy. Evidence also showed that ESWT is a safe treatment. Minor side-effects were reported with high –energy ESWT but all the side-effects were self limiting.

Recommendation
Shock wave therapy is recommended for the treatment of shoulder calcific tendinitis. As for other clinical indications more clinical research is warranted to establish its effectiveness. However, the limited scope of supportive evidence does not lend support for the purchase of shock wave therapy system for the treatment of just one specific condition which already has alternative conservative and surgical options of care locally.

Methods
Literature were searched through electronic databases which included Medline, Cochrane Library, Science Direct and general databases such as Google and Yahoo.

The search strategy used the terms, which were either used singly or in various combinations:
(shock wave therapy OR shockwave therapy OR extracorporeal shockwave therapy OR ESWL) AND (musculoskeletal disorders OR MSK OR musculoskeletal OR lateral epicondylitis OR tennis elbow OR plantar fasciitis OR heel pain OR shoulder calcific tendonitis OR shoulder calcific tendinitis). The search was limited to articles on human. There was no language limitation in the search. A critical appraisal of all relevant literature was performed using Critical Appraisal Checklist Project (CASP) checklists and the evidence graded according to the US/Canadian Preventive Services Task Force Level of Evidence (2001).

SHOCK WAVE THERAPY SYSTEM FOR MUSCULOSKELETAL DISORDERS

1. INTRODUCTION

Musculoskeletal disorders is also called ergonomic injuries and illnesses. The Federal Bureau of Labor Statistics (BLS) defined musculoskeletal disorders (MSDs) as injuries and disorders to muscles, nerves, tendons, ligaments, joints, cartilage, and spinal discs and do not include injuries resulting from slips, trips, falls, or similar accidents. It may include many kinds of sprain and strain, carpal tunnel syndrome, tendinitis, sciatica, and low back pain.

It is the most common and disabling of medical disorders and the leading cause of work related disability among men and women 16-72 years old. Musculoskeletal disorders have substantial impact on quality of life, use of healthcare resources and economy of the affected person as well as the country.

According to the Malaysian Burden of Disease and Injury Study, 2000, musculoskeletal disorders contributed 6% of Years Live with Disability (YLD) among males and 9% YLD among females. As a group, they contributed 2% of the total Disability Adjusted Life Years (DALYs). Osteoarthritis is the single most important contributor which contributed more than 50% of the cases.[1]

The estimated total economic cost to the United States due to musculoskeletal disorders was over $126 billion in 1988, second only to disease of circulatory system. Indirect costs incurred were from lost earnings and services such as job loss, early retirement, reduced working hours, stop working and reduced family income.

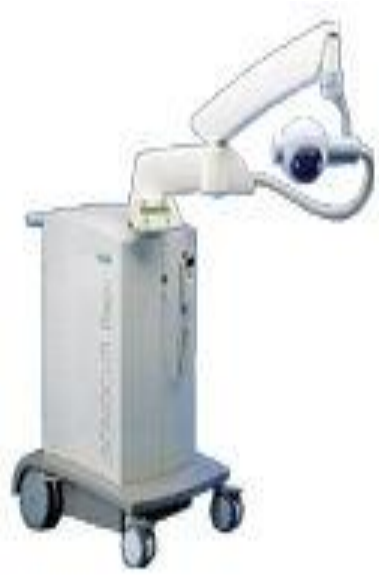
Various methods have been introduced to treat musculoskeletal disorders which include exercise, ultrasound, heat therapy, extracorporeal shock wave therapy and various other methods.

This review was requested by the Rehabilitation Unit, Medical Services Development Section, Medical Development Division, following a request to procure shock wave therapy system for rehabilitation units in Ministry of Health Malaysia hospitals.

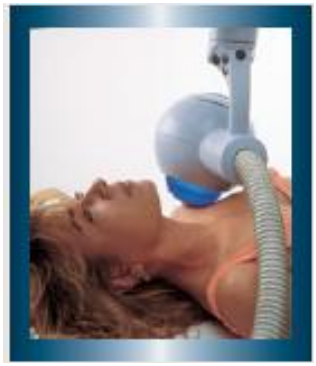
2. OBJECTIVES

To determine the safety, effectiveness and cost effectiveness of shock wave therapy system for rehabilitation of musculoskeletal disorders specifically for elbow pain, calcific tendinitis of the shoulders and heel pain.

3. TECHNICAL FEATURES



Extracorporeal **Shockwave Therapy**, or extracorporeal shock wave therapy is an innovative non-invasive method for the treatment of localized musculoskeletal pain. Shockwave Therapy was designed to administer a wide range of finely tuned low energy shock waves, which allows for anesthesia free treatment. Variable, energy settings allow the patient to be treated with the energy level best suited for his or her medical condition.



Extracorporeal shock wave therapy (ESWT) was introduced in the early 1990s as a spin-off of urological lithotripsy. Since then it has been applied to treat various musculoskeletal conditions too. In 1995, the German Society of Shock Wave Therapy stated in a consensus conference stated that extracorporeal shock wave therapy (ESWT) can be used to treat four orthopaedic conditions including tendinosis calcarea (calcific tendinitis), calcaneal spur (painful heel or plantar fasciitis), epicondylitis humeri radialis (lateral elbow pain) and pseudoarthrosis (false joint) and reimbursement by the compulsory health insurers was accepted. It was also introduced into routine care in 1995 in Switzerland and Austria.[2] In 2000, the Food and Drug Administration (FDA) in the US approved a ESWT device for the treatment of severe heel pain.[3] The FDA have subsequently approved two ESWT devices for the treatment of lateral elbow pain.[2] Other brands of ESWT have also been subsequently approved for heel pain and lateral elbow.

There are two types of ESWT machine available based on the energy level applied, namely high or low energy level. The high energy protocol consists of a single treatment of high energy shock waves (1300mJ/mm^2) which is painful and requires anaesthesia. Low energy protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied (e.g 1405mJ/mm^2 over three sessions).[4]

An articulating arm suspends the shock wave head so that it can be easily positioned and coupled to the patient on any body part. The coupling head allows for the focal point of the shock wave to be adjusted to various depths below the skin to exactly position the treatment energy in the best therapeutic location.

How It Works

Shockwave Therapy System is a sophisticated device in which a shock wave is generated at the base of the shock tube by an electromagnetic acoustic source. When a voltage pulse from

a capacitor reaches an aluminum membrane, the membrane is repelled causing a shock wave to course through a water filled generator. The shock wave moves through the water into an acoustic lens. The lens then focuses the energy of the shockwave on a concentrated point at a fixed distance from the lens.

Shockwave Therapy System administers a wide range of low energy shock waves, without the need for anesthesia. The articulating head of the Sonocur machine is placed onto the painful area and fine adjustments are made to focus the shock waves on the area of therapeutic focus.The treatment consists of initiating a preset number of pulses or shock waves. As the treatment progresses, a trained technician will graduate the energy level to therapeutic levels.

Indications

According to the manufacturer, Shockwave therapy system has been used to successfully treat hundreds of thousands of patients in Europe without significant complications. It is frequently used to treat the following common conditions:

- Tendinitis of the shoulder
- Tennis or Golfer's elbow (Lateral or Medial Epicondylitis)
- Tendintis of the Knee (Patellar tendinitis)
- Tendinitis of the Foot (Achilles tendinitis)
- Hell Spur (Plantar Facitis)

4. METHODOLOGY

4.1 SEARCH METHODS

Literature were searched through electronic databases which included Medline, Cochrane Library, Science Direct and general databases such as Google and Yahoo.

The search strategy used the terms, which were either used singly or in various combinations: (shock wave therapy OR shockwave therapy OR extracorporeal shockwave therapy OR ESWL) AND (musculoskeletal disorders OR MSK OR musculoskeletal OR lateral epicondylitis OR tennis elbow OR plantar fasciitis OR heel pain OR shoulder calcific tendonitis OR shoulder calcific tendinitis). The search was limited to articles on human. There was no language limitation in the search.

4.2 SELECTION OF STUDIES INCLUDED /EXCLUDED

Systematic reviews, meta-analysis and randomized clinical trials pertaining to safety, effectiveness and cost effectiveness of shockwave therapy for musculoskeletal disorders, lateral elbow pain, tennis elbow, lateral epicondylitis, lateral epicondylagia, plantar fasciitis, heel pain, calcific tendinitis of shoulder and chronic calcifying tendonitis of the rotator cuff were included in the review. Articles of shockwave therapy used for renal or ureteric calculi were excluded. Animal studies were also excluded.

A critical appraisal of all relevant literature was performed using Critical Appraisal Checklist Project (CASP) checklists and the evidence graded according to the US/Canadian Preventive Services Task Force Level of Evidence (2001).

Data were extracted and summarized in evidence table as in Appendix 3. The data were not pooled and only qualitative analysis was carried out.

5. RESULTS AND DISCUSSION

There were six systematic reviews and 10 randomized controlled trials (RCT) included in this review. The excluded studies were listed in Appendix 4.

5.1 EFFICACY/EFFECTIVENESS

5.1.1 Heel Pain

Plantar heel pain is a common condition which is estimated to affect 10% of runners, and to occur in a similar proportion of the general population at some time during life. Plantar heel pain is also known as plantar fasciitis, jogger's heel, tennis heel, calcaneodynia and in the past, gonorrheal heel.[5]

Crawford et. al. evaluated five randomized controlled trials in his review on extracorporeal shock wave therapy for plantar heel pain. He found that the results were equivocal. The results were not pooled. Ogden et. al. concluded that ESWT was more effective than placebo but only reported a mean difference of 6% (reduction in heel pain). Two trials by Rompe and Krishchek evaluated different doses of active treatment of ESWT. Rompe found that better outcomes were associated with higher dose of 3 x 100 impulses weekly, but in a smaller trial, Krischek did not detect a statistical difference between 3x100 impulses weekly or 3 x 10 impulses of ESWT weekly and is consistent with the findings of Buchbinder. Buchbinder compared 3x200-2500 impulses with 3x100 impulses given at weekly intervals and found no statistically significant differences in the degree of improvement in the two groups for any of the measured outcome namely: overall pain , pain in the morning and pain during activity, walking ability, Maryland Foot Score, Problem Elicitation Technique and SF36 at 6 and 12 weeks.[5 Level 1]

Cole *et.al.* in their evidence-based review of diagnosis and therapy of plantar fasciitis stated that there was no conclusive evidence to support the effectiveness of ESWT in reducing night pain, resting pain and pressure pain in the short term (from the two systematic reviews included in their review.[6 Level 1] Two well designed RCTs[7, 8 Level 1] published after the systematic reviews, did not found a significant difference between the treatment and the control groups three months after treatment. One RCT included 45 runners who had chronic heel pain for more than 12 months; found that three weekly treatments of ESWT significantly reduced morning pain in the treatment group at six and 12 months when compared with the control group.[6 Level 1]

Martin *et.al.* in their systematic review also concluded that for plantar fasciitis there was no evidence or inconclusive at best for low energy ESWT. However, high energy ESWT probably is effective.[4] Level 1

Three randomized controlled trials on plantar heel pain that were published after these systematic reviews were retrieved.

Rompe *et.al.* compared ESWT therapy for chronic plantar fasciitis with and without local anaesthesia and found that the application of local anaesthetics to the painful area prior to ESWT reduced the positive treatment effect. In his study, more patients who received ESWT without local anaesthesia achieved more than 50% reduction of pain (67% at 3 months, 60% at 12 months) compared to those who received ESWT with local anaesthesia (29% at 3 months, 24% at 12 months). The reduction was statistically significant, $p<0.01$.[9] Level 1

A multicentre randomized controlled trial comparing ESWT and placebo found that the mean change from baseline in investigator's assessment of heel pain (LOCF) was significantly greater in the ESWT group than that in the placebo group (difference = -0.94; p = 0.045; 95% CI -1.87 to -0.02). In the absence of a radiographically evident plantar calcaneal spur, the reduction in heel pain was statistically significantly greater for the ESWT group whereas in the presence of plantar calcaneal spur, the reduction in heel pain was not statistically significant**.**[10] Level 1

Gollwitzer *et.al.* compared ESWT and sham treatment in a RCT. They found that between-group difference in the composite heel pain visual analogue scale (VAS) score was not statistically significant but the Mann Whitney (MW) effect size showed at least medium size (relevant) superiority for the ESWT group. As for other outcome variables such as hell pain taking first steps of the day, while doing daily activities and during application of F-meter the results were all at least 20% greater for the ESWT group in comparison with the placebo group, and the observed superiority was relevant (MW effect size ≥ 0.6400).[11] Level 1

Based on the available evidence, ESWT therapy for heel pain seems to bring only marginal gains over placebo or other therapy and ESWT as applied should be done without LA in patients suffering from chronic heel pain.

5.1.2 Lateral elbow pain

Lateral elbow pain is one of the most common lesions of the arm. It is also known as tennis elbow, lateral epicondylitis, lateral epicondyalgia, rowing elbow, tendonitis of the common extensor origin and peritendonitis of the elbow. This injury is a major challenge, as it is difficult to treat, prone to recurrence, and may last for several weeks or months, with the average duration of a typical episode reported to be between six months and two years.

A Cochrane Systematic Review by Buchbinder *et.al.* on shock wave therapy for lateral elbow pain in 2005 included nine placebo controlled trials with a total of 1006 participants but the studies reported conflicting results.[2] Level 1Data from six of the trials could be pooled though some of the studies showed significant heterogeneity. Based upon this data, most of the

evidence supports the conclusion that ESWT is no more effective than placebo for lateral elbow pain. While three trials reported highly significant differences in favour of ESWT, these results became non-significant when combined with the results of the studies that reported no or minimal benefit of ESWT over placebo. Eleven of the 13 pooled analyses found no benefit of ESWT over placebo while 2 pooled analyses that did show a benefit included 2 positive trials. The positive pooled results were not supported by the results of four other individual trials that were unable to be pooled.[2 Level 1]

Another systematic review by Bisset *et.al.* on physical interventions for lateral epicondylalgia in 2005 included two studies by Haake(2002) and Speed C(2002) which fulfilled their quality requirements. These two studies have been included in the Buchbinder's Systematic Review above. The pooled analysis of this two studies also showed no significant treatment effect on continuous VAS (PVAS) (SMD 0.02; 95% CI -0.19 to 0.24) or global improvement (RR 1.01; 95% CI 0.78 to 1.57) four to six weeks after treatment.[12 Level 1]

The result of another systematic review which included seven studies in 2004, revealed conflicting findings about the effectiveness of ESWT in the management of tennis elbow. Five of the included studies were included in Buchbinder's systematic review and two of the them were included in Bisset's Systematic Review as well. The results were assessed by comparing the quality of studies (using Chalmer system) and the outcome. Two studies of satisfactory quality by Speed C in 2002 and Crowther A in 2002 and a high quality study By Haake m in 2002 revealed that ESWT was no more effective than sham therapy in treating tennis elbow. Positive effects of ESWT in the management of tennis elbow were shown by a satisfactory quality study (Rompe 1996) and a high quality study (Rompe 2004). A satisfactory quality study (Crowther A 2002) found that steroid injection was more effective than ESWT in the management of tennis elbow. A satisfactory study (Melegati 2004) comparing two techniques of ESWT (lateral and back) in the management of tennis elbow found no differences between them but improvement in relation to the baseline. The author suggested that further research with well designed RCTs is needed to establish its absolute and relative effectiveness.[13 Level 1]

Martin in his review also concluded that evidence on the effectiveness of ESWT in treating lateral epicondylitis is inconclusive.[4 Level 1]

Based on the evidence discussed, the effectiveness of ESWT in treating lateral elbow pain is inconclusive. Most of the evidence showed that ESWT was not more effective than placebo in treating lateral elbow pain, though there were some studies that showed the positive effects. Evidence also showed that steroid injection was more effective than ESWT. It is suggested that more clinical research is warranted to establish the effectiveness of ESWT in treating lateral elbow pain.

5.1.3 Shoulder Calcific Tendinitis

Calcific tendinitis of the shoulder is characterized by a reactive calcification that affects the rotator cuff tendons. Approximately 50% of patients with calcific tendinitis have shoulder

pain, particularly nocturnal discomfort.[14] The prevalence of calcification in the rotator cuff is reported to be between 2% and 20% in asymptomatic shoulder joints. The reported prevalence in patients with shoulder pain is up to 50%. The disorder is most common among people between 30 and 60 years of age.[15] Current treatment includes physiotherapy, nonsteroidal anti-inflammatory drugs, steroid injection, and surgical intervention to remove calcium deposits and decompress the subacromial space.[16]

Martin in his review concluded that for shoulder tendonitis, there was moderate evidence that low energy ESWT does not have any effect. There is moderate evidence that high energy ESWT has effect.[4 Level 1]

Pan *et.al.* in a RCT compared ESWT and TENS among 60 patients, they found that after 1 session (ESWT once, TENS 6 times), 2 sessions (ESWT twice, TENS 12 times) and at 12 week follow up, there were significant functional improvements in the Constant score and VAS score in both groups. Patients in the ESWT group had greater functional improvement and pain reduction than did those who had TENS therapy. The difference was significant at every point of assessment. The average change in the Constant score increased from 13.79 to 28.31 in the ESWT group and 3.52 to 11.86 in the TENS group. There was no significant difference found for Manual Muscle Test (MMT) in either group. As for sonographic outcome, the calcific plaques were still present in the shoulders of most patients at the end of treatment. Maximal diameters of calcific plaques showed a decrease after 2 treatment sessions and at 12 weeks follow up compared with baseline measurement. Patient with arc type calcification improved faster in response to ESWT compared to those with fragmented types of calcific deposits. For arc type cases, functional performance improved to a greater degree and more quickly in the ESWT group as compared with the TENs group after the first therapy.[14 Level 1]

The Constant score in ESWT group increased from 45 points at the beginning of a single blinded RCT study by Cosentino et. al. to 71 points at the end of treatment. It increased further to 74 points after a month and 76 points after 6 months. In the sham group, the score remain consistent, 48 points at the beginning of the study, 50 points at the end of the treatment, 46 points after a month and 44 points after 6 months. As for radiological outcome, one month after treatment partial resorption of the calcium deposits was seen in 14 (40%) patients and complete resorption was seen in 11 (31%) patients in ESWT group. The radiological disintegration was significant. In the sham group, the calcium deposits remained unmodified.[15 Level 1]

Hsu *et.al.* in a RCT involving 46 patients, compared ESWT and placebo. They found that, in the ESWT group, pain scale score decreased from 7.2 before ESWT to 3.7, 2.1, 1.6 and 1.3 at 6 weeks, 12 weeks, 6 months and 1 year respectively. In the control group, the pain scale scores persisted at the same high pre-treatment level. The difference between group and the difference in the ESWT group were statistically significant. The Constant score increased from 57.3 before ESWT to 74.3. 82.8, 85 and 88 weeks at 6 weeks, 12 weeks, 6 months and 1 year after treatment. In the control group the score was unchanged with time, from a score of 56.2 before therapy to 57.3, 54.3 and 56.8 at 6 weeks, 12 weeks and 6 months after treatment respectively. The overall results in the ESWT group were good to excellent in

87.9% of shoulders (29/33) and fair in 12.1% (4/33). In contrast, the results for the control group were fair in 69.2% of shoulders (9/13) and poor in 30.1% (4/13). In the ESWT group, calcium deposits were completely eliminated in 7 cases (21.2%) partially eliminated in 11 (36.3%) and unchanged in 15 (45.4%). Among control patients, calcium deposits were completely eliminated in no patient, partially eliminated in 2 (15.3%), and unchanged in 11(84.7%). The mean width of deposits decreased from 11.9 ± 5.4 mm to 5.5 ± 6.3 mm in the ESWT group. In the control group the mean width of deposits slightly reduced from 10.5 ± 6.4 mm to 9.8 ± 5.9 mm.[16 Level 2]

Gerdesmeyer *et.al.* in a multicentre RCT compared high energy ESWT with low energy ESWT and sham treatment in patients with chronic calcifying tendonitis of the rotator cuff. They found that both high energy and low energy interventions were superior to sham treatment. The mean change of Constant and Murley Scale (CMS) from baseline after 6 months was 31.0 (26.7 to 35.3) in the high energy group, 15.0(10.2 to 19.8) in low energy and 6.6 (1.4 to 11.8) in sham treatment. In secondary analysis, the high energy intervention appeared to be superior to the low energy interventions. As for VAS pain score, patients in the high energy group had significantly less pain than those in the low energy group, but both groups reported significantly less pain than those in the sham treatment 6 months after intervention. At 3 and 12 months after intervention, there was no significant differences in VAS score observed for the low energy compared to the sham treatment group. As for calcific deposit sizes**,** complete disappearance of the calcific deposit was observed in 60% of the patients in the high energy group after 6 months and in 86% after 12 months. In the low energy group, complete disappearance was observed in 21% and 37% respectively. In the sham treatment group, complete disappearance was observed in 11% after 6 months and in 25% after 12 months.[17 Level 1]

Cacchio *et.al.* in a RCT among 90 patients with radiographically verified calcific tendinitis of the shoulder found significant improvement of the University California-Los Angeles (UCLA) Shoulder Rating Scale in the treatment group as compared to the control group where the mean values increased from 10.25 ± 2.08 to 33.12 ± 2.94 in the treatment group and in the control group the mean value was 10.14 ± 1.96 before treatment and 11.28 ± 2.82 after treatment. The NNT to reach an excellent UCLA Shoulder Rating scale score was 1.09 one week after the last treatment session and 1.15 at the 6 month follow-up. The average calcification size showed a significant decrease after treatment in the treatment group, whereas no change was seen in the control group. Calcifications disappeared in 86.6% and were partially resorbed in six subjects in the treatment group.[18 Level 1]

There was good evidence to show that high energy ESWT is effective in the treatment of shoulder calcific tendinitis.

5.2 SAFETY

Four trials in Buchbinder *et.al.* systematic review reported no significant adverse effects in either treatment or control groups.[2 Level 1] One trial documented significantly more side effects in the ESWT group. However there were no treatment discontinuations or dosage adjustments related to side effects. Most frequents side effects reported were transitory

reddening of the skin, pain and small hematomas. Migraine occurred in four participants and syncope in three participants following ESWT. Chung *et.al.* reported mild adverse events in 11 of 31 participants in the ESWT and 13 of 28 participants in the placebo group. Among those received ESWT, the adverse events were nausea during therapy (3 participants), soreness after therapy (3 participants), and increased pain symptoms after therapy (4 participants). Other studies in the review reported similar mild side effects that resolved by final follow up.[2 Level 1]

There were more side effects reported by the therapy group (24 (18%)) in a randomized controlled multicentre trial compared to the placebo group (12 (9%)). Side effects reported were hematoma, nausea, dizziness, hair loss, and sleep disturbance.[7 Level 1]

Pan *et.al.* in a RCT comparing ESWT and TENS for shoulder pain found that 5 patients complained of soreness in the upper arm after ESWT, but this soreness subsided before their next visit. No other adverse event reported.[14 Level 1] Rompe *et.al.* found that all patients reported transient reddening occurred after low-energy shock wave application. Among patients receiving active ESWT without local anaesthesia, 24 of 45 patients reported pain during ESWT $\geq$ 5 on NRS compared 3 of 41 patients receiving active ESWT with local anaesthesia.[9 Level 1]

There was no serious adverse event encountered in Malay *et.al.* study. None in the placebo group reported any adverse events. Three participants in the active ESWT group reported one adverse event each. Two participants (1.7%) experienced bruising at the site of shockwave application on the heel and these incidents were considered to be device-related; one participant experienced local swelling that was determined to be unrelated to the device. Energy levels reached for these participants were reported to range from 4.5 to 7.[10 Level 1]

Gollwitzer *et.al.* found that the mean adverse reactions (ARs) reported in the ESWT group was 3.1, 2.7 and 3.0, respectively for the first, second and third visits respectively. For the placebo group the mean AR composite was 0.8, 0.9 and 1.2 which means that there were more side-effects with ESWT.[11 Level 1] Hsu *et.al.* in their study revealed local erythematous changes over shock application sites in 3 out of 33 ESWT patients (9.1%). No neovascular complications were noted.[16 Level 1]

Cosentino *et.al.* reported self limiting initial pain lasting for few minutes in the patients with chronic calcifying tendinitis of the shoulder receiving ESWT.[15 Level 1] Gerdesmeyer *et.al.* in their multicentre RCT among patients with chronic calcifying tendonitis of the rotator cuff found that in the high energy ESWT group, 20 patients reported moderate pain while 16 patients reported severe pain. Eight of them required intravenous analgesics during intervention. In the low energy ESWT group, moderate pain was reported by 22 patients and severe pain by five patients, two of them required intravenous pain medication. In the sham treatment group, 25 patients reported some sensation of pain while four patients had severe pain and one required additional intravenous pain medication. Petechiae, bleeding, hematoma or erythema were found directly after the treatment in 36 patients in the high energy group, 32 patients in the low energy group and eight patients in the sham treatment.[17 Level 1]

In conclusion, the evidence showed that ESWT is a safe treatment although there were mild, self limiting sides –effects reported.

5.3 COST EFFECTIVENESS

Rompe *et.al.* evaluated 79 patients randomized to arthroscopic surgery or ESWT at the end of two years. Direct medical costs were $2,970 more in the surgically treated group. This group also averaged more than 9 weeks of lost work time, compared to 2.5 weeks in the ESWT group. Indemnity costs in the surgical group were $9,240 per patient more than the ESWT group. Overall arthroscopy cost $12,000 more than ESWT.[19 Level II-1]

Haake *et.al.* revealed that the surgically treated patients cost more than 7 times as much as the ESWT-treated patients. Sixty patients were evaluated, half with surgery, half with two ESWT treatments each of 2000 impulses of the energy flow density 0.35 mJ/mm^2, administered one week apart. At follow-up, both treatments were equally effective. Direct medical costs averaged $4,298 (1 Dollar = 1 Euro) for the surgical group, while ESWT cost $875 on average. Lost work time cost $10,000 (range $2,400-$25,200). [20 Level II-1]

6. CONCLUSION

There was sufficient strong evidence to support the effectiveness of shock wave therapy for the treatment of shoulder calcific tendinitis. However, the evidence on effectiveness of ESWT in treating lateral elbow pain is still inconclusive. ESWT therapy for heel pain seems to bring only marginal gains over placebo or other therapy. ESWT as applied should be done without local anaesthesia in patients suffering from chronic heel pain.

Evidence showed that ESWT is a safe treatment. Minor side-effects reported using high – energy ESWT were self limiting.

In addition, evidence also showed that ESWT is more cost-effectiveness compared to surgery for shoulder calcific tendinitis.

7. RECOMMENDATION

Based on this review, shock wave therapy is recommended for the treatment of shoulder calcific tendinitis. As for other clinical indications more clinical research is warranted to establish its effectiveness.

However, the limited scope of supportive evidence does not lend support for the purchase of shock wave therapy system for the treatment of just one specific condition which already has alternative conservative and surgical options of care locally.

8. REFERENCES

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9. APPENDICES

9.1 Appendix 1- Levels of Evidence Scale

I	Evidence obtained from at least one properly designed randomized controlled trial.
II-I	Evidence obtained from well-designed controlled trials without randomization..
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III	Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE(Harris 2001)

9.2 Appendix 2 – Abbreviations

ESWT	Extracorporeal shock wave therapy
PVAS	Continuous Visual Analogue Scale
VAS	Visual Analogue Scale
SMD	Standardized Mean Difference
WMD	Weighted Mean Difference
FDA	Food and Drug Administration
RCT	Randomized Controlled Trials
SR	Systematic Review
TENS	Transcutaneous Electric Nerve Stimulation
MMT	Manual Muscle Test
CMS	Constant and Murley Scale
MW	Mann Whitney
LA	Local Anaesthetic
NNT	Number needed to treat
YLD	Years Live with Disability
DALY	Disability Adjusted Life Years
UCLA	University California-Los Angeles

9.4 Appendix 4 - Excluded studies

1. Ozkut AT, Kilincoglu V, Ozkan NK et. al. Extracorporeal shock wave therapy in patients with lateral epicondylitis. Acta Orthopaedica et Traumatologica Turcica. 2007;41(3):207-210. (Poor design)

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