

Issues in Emerging Health Technologies

Extracorporeal shock wave treatment for chronic plantar fasciitis (heel pain)

Summary

- ✓ **Electrohydraulic, electromagnetic, or piezoelectric devices are used to translate energy into acoustic waves during extracorporeal shock wave treatment (ESWT) for chronic plantar fasciitis (or heel pain). These waves may help to accelerate the healing process via an unknown mechanism.**
- ✓ **ESWT, which is performed as an outpatient procedure, is intended to alleviate the pain due to chronic plantar fasciitis.**
- ✓ **Results from randomized controlled trials have been conflicting. Six trials reported data that favour ESWT over placebo or conservative treatment for efficacy outcomes, while three trials showed no significant difference between the ESWT group and the placebo group.**
- ✓ **The lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed in this bulletin does not support the use of this technology for this condition.**

The Technology

Shock waves are sound waves that are characterized by a rapid increase in pressure. They are produced using a generator and then focused at the target tissue using an elliptical reflector or an acoustic lens.¹ The energy at the focal point, which is called the energy density, is measured in joules per area (mJ/mm^2). Low energy density is $<0.2 \text{ mJ}/\text{mm}^2$, whereas high energy density occurs at $0.2 \text{ mJ}/\text{mm}^2$ to $0.4 \text{ mJ}/\text{mm}^2$. The number of impulses and the energy density define the total energy of a treatment.

Electrohydraulic, electromagnetic, or piezoelectric methods can be used for shock wave generation and delivery. These methods involve the conversion of electrical energy into mechanical energy through the generation of shock waves that are focused on a specific region of tissue and transmitted to the patient through a coupling gel. This is believed to provide analgesia and stimulate the healing process.²

The plantar fascia is a band of connecting tissue on the sole of the foot. Plantar fasciitis (heel pain) is a common condition with clinical features that include heel pain and tenderness upon weight bearing, and the associated limitation of physical activity. Recent clinical attention has been focused on the role of ESWT, an outpatient procedure, in the treatment of chronic plantar fasciitis that is unresponsive to conventional conservative therapies.

Regulatory Status

Health Canada licensed SONOCUR[®] Basic (Siemens), Epos Ultra[®] (Dornier MedTech), and Orthospec[™] (Medispec) for marketing in Canada, in July 1999, July 2004, and March 2005 respectively.³

Patient Group

It is estimated that 10% of the general population are affected by plantar fasciitis at some time during their lives. Approximately 10% of cases are recalcitrant to conservative treatment.^{4,5} Potential candidates for ESWT treatment have long-standing plantar fasciitis (>6 months in duration) that has not responded to conservative therapies.

Current Practice

Conservative measures for plantar fasciitis include the application of ice, rest, activity modification, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injection, dexamethasone iontophoresis (delivery of a corticosteroid through

the skin using an electrical charge), and non-weight-bearing or walking casts. Surgery may be used when these modalities fail. ESWT, which has been suggested for patients who do not respond to conventional conservative therapies, is positioned at the end of the conservative treatment spectrum.⁶

The Evidence

Randomized controlled trials (RCTs) published from 2000 to 2006 were reviewed. Eight RCTs compared ESWT with placebo (1,185 participants),⁷⁻¹⁴ one compared ESWT with conservative treatment (149 participants),¹⁵ and one compared ESWT with corticosteroid injection (125 participants).¹⁶ Among the eight trials comparing ESWT with placebo, one used a high energy level,⁸ four used low energy levels,^{9-11,13} two used multiple energy levels,^{7,12} and one trial did not indicate the energy level that was used.¹⁴ The main outcomes that were measured were pain, function, and adverse effects. All studies measured efficacy at multiple points in time ranging from one month to six years post-treatment.

The trials reported conflicting results regarding the clinical effectiveness of ESWT. Five RCTs with 659 participants^{7,8,11,13,14} showed statistically significant reductions in heel pain, and four trials showed statistically significant improvements in function in the ESWT group relative to placebo ($p < 0.05$). Among the mild to moderate adverse events that were reported, pain during and shortly after treatment was the most common.

Three RCTs involving 526 participants showed no significant effects for ESWT, relative to placebo, with respect to pain or function.^{9,10,12} The side effects reported during and after treatment included skin reddening, pain, local swelling, and hematomas. There was no evidence to show that there was a beneficial effect of ESWT on quality of life.

One trial (149 participants) with methodological limitations reported that ESWT is more beneficial than conservative treatment such as NSAIDs, orthotics, physiotherapy, and local cortisone injection. In this study, the ESWT group had significantly better pain and function scores compared with the control group ($p < 0.001$).¹⁵

Results from one randomized trial with 125 participants suggest that corticosteroid injection is more efficacious in reducing pain and tenderness, and more cost-effective, than ESWT ($p < 0.05$).¹⁶ This study included patients with a less chronic or more acute manifestation of plantar fasciitis (at least six weeks duration) compared to those in other trials (three to six months duration).

Among the five trials that reported favourable results for ESWT compared to placebo, four were supported by the manufacturers of the devices,^{7,8,13,14} and in the fifth trial, the authors received financial benefit from their research.¹¹ Among the three trials indicating that there were no benefits from using ESWT for plantar fasciitis,^{9,10,12} two declared that they had received financial assistance from the manufacturers.^{10,12} The trial comparing ESWT to conservative treatment did not receive funding from the manufacturers,¹⁵ while the trial comparing ESWT to corticosteroid injection did not indicate the funding source.¹⁶

The reported energy density range of ESWT in orthopedic practice is 0.01 mJ/mm² to 0.28 mJ/mm². None of the 10 RCTs that were included compared the effect of using different energy levels.

One recent meta-analysis,¹⁷ which excluded a 2006 RCT,⁷ found that the pooled estimates for morning pain at 12 weeks favoured ESWT, even though confidence intervals in five out of the six included RCTs crossed the no-effect line. The effect size, however, was very small. Moreover, when the authors removed from the meta-analysis the two trials of poorest quality (i.e., greatest sources of bias), the result was no longer significant. This supports the authors' conclusion that the use of ESWT for plantar heel pain in clinical practice is not supported by the evidence.

Adverse Effects

No systemic or local complications, or device-related problems, were reported in the studies that were examined in this review.

Administration and Cost

Treatment protocols for ESWT depend on the energy category.¹⁸ When high-energy machines are

used, the treatment course usually consists of one treatment of 1,000 pulses to 1,500 pulses with an optional additional treatment. With high-energy therapy, at least a local anesthetic is required, and imaging technology is used to locate the treatment area. When low-energy machines are used, the treatment course consists of three treatments of 2,000 pulses to 3,000 pulses with an optional two additional treatments. No anesthesia is required for low-energy therapy, and the treatment area is located based on the patient's feedback regarding the area of most discomfort.

One specialist practice in Australia estimated that treatment with ESWT costs A\$600 to A\$800, compared to A\$60 to A\$70 for corticosteroid injection.¹⁶ A 1998 Austrian cost estimate showed that ESWT is cheaper than arthroscopic surgery or open surgery; and is less expensive than other conservative therapies that continue for >6 weeks.¹⁹

The Canadian list price of the SONOCUR Basic unit is approximately C\$100,000 (Bert Stadler, Siemens Canada, Edmonton: personal communication, 2006 Nov 8). The Orthospec unit costs about C\$200,000 (Lui Mattiazzi, Osis Medical, Toronto: personal communication, 2006 Oct 15). The cost of the Epos Ultra unit was unavailable.

Concurrent Developments

Coblation fasciotomy, in which radiofrequency energy is used to cut the fascia tissue and relieve pressure, is being investigated.²⁰

Rate of Technology Diffusion

ESWT has been used in orthopedic practice over the past 10 years. The conflicting results regarding its clinical effectiveness and the pressures on reimbursement agencies has limited its diffusion in some countries. The increase in the number of applications for the reimbursement of costs related to ESWT for orthopedic indications and the unlimited expansion of the indications for this therapy led to a re-evaluation of ESWT in Germany in 1999 and the conclusion that "neither the benefit, nor the medical necessity, nor the efficiency" of this therapy had been proven.¹⁹ In Switzerland, after a

1998 assessment of ESWT, the Commission of Health Insurers decided to exclude ESWT in their cost catalogue.¹⁹

Implementation Issues

None of the studies reviewed in this bulletin evaluated the dose-response relationship between the energy level received by the patient and the clinical outcome.

Although a substantial body of literature exists, there is no clear evidence to support the use of ESWT in the management of chronic plantar fasciitis.

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