

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome

Treating greater trochanteric pain syndrome using shockwave therapy

The greater trochanter is the bony bump on the outer side of the hip. This area may become painful following hip surgery or as a result of inflammation of the fluid-filled sac (bursa) that allows smooth motion between bones and tendons or muscles. Such inflammation (bursitis) is often caused by minor repetitive trauma or a direct injury.

In extracorporeal shockwave therapy, a machine is used to deliver sound waves to the painful area. It is not known exactly how this works, but it is thought that it might stimulate healing.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2010.

Procedure name

- Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome

Specialty societies

- British Orthopaedic Association
- British Hip Society
- British Society of Skeletal Radiologists.

Description

Indications and current treatment

Greater trochanteric pain syndrome is a disorder that affects the (lateral) side of the hip or hips. Greater trochanteric pain may be associated with inflammation of the trochanteric bursa (also known as trochanteric bursitis). The trochanteric bursa is a small fluid-filled sac that separates the greater trochanter of the femur and the overlying fascia lata to allow smooth movement. Greater trochanteric pain may also be associated with direct injury, tendon damage, infection, differences in leg length or hip-replacement surgery.

Greater trochanteric pain syndrome is usually managed conservatively with rest, physiotherapy, anti-inflammatory medication and corticosteroid injections. Surgical approaches such as supratrochanteric fasciotomy or bursectomy can also be used if conservative treatments fail to relieve the symptoms.

The mechanism by which shockwave therapy might have an effect on greater trochanteric pain syndrome is not well defined.

What the procedure involves

Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area. Ultrasound guidance may be used to assist with positioning of the device. The shockwaves are generated using electrohydraulic, electromagnetic or piezoelectric energy.

The patient is placed in the lateral decubitus position and ultrasound gel is applied to the skin overlying the greater trochanter and peritrochanteric region. Treatment protocols for ESWT vary according to the energy density and frequency of shockwaves. ESWT is delivered in a lateral to medial direction and may be applied in a series of treatments or a single session. Local anaesthesia may be administered to the patient before treatment because high-energy ESWT can be painful.

Instruments used to assess efficacy

A visual analogue scale (VAS) is used to measure pain on a scale from 0 to 10 (0 = no pain, 10 = severe pain). A 2-point change is considered to be clinically significant.

The Harris hip score was originally a hip replacement evaluation tool. This tool assesses pain, function and functional activities from 0 to 100. A 10-point change in score is considered to be clinically significant. Higher scores indicate improvement.

The Roles and Maudsley score is a subjective 4-point patient assessment of pain and limitations of activity (1 = excellent result with no symptoms following treatment; 2 = significant improvement from pre-treatment; 3 = patient somewhat improved; 4 = poor, symptoms identical or worse than pre-treatment).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome. Searches were conducted of the following databases, covering the period from their commencement to 22 April 2010 and updated 28 September 2010: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with refractory greater trochanteric pain syndrome (chronic greater trochanteric bursitis).
Intervention/test	Extracorporeal shockwave therapy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 295 patients from 2 non-randomised comparative studies^{1,2}.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome

Abbreviations used: IP; interventional procedures; NR, not reported; NS, not significant; RCT, randomised controlled trial; SWT, shock wave therapy; VAS, visual analogue scale									
Study details	Key efficacy findings				Key safety findings				Comments
Rompe JD (2009) ¹	Number of patients analysed: 229 (78 vs 75 vs 76)				<u>Adverse reactions until 1 month follow-up</u>				Follow-up issues:
Comparative study (sequential allocation)	Recovered /improved (patients who selected 1 [completely recovered] or 2 [much improved] on the Likert scale)					Shockwave group (n = 78)	Injection group (n = 75)	Home-training group (n = 76)	
International		1 month	4 months	15 months	No adverse reaction	46.1% (36/78)	44% (33/75)	64.5% (49/76)	Study design issues:
Recruitment period: not reported	A. Shockwave group (n = 78 at baseline, n = 73 at 4 months)	12.8% (10/78)	67.9% (53/78)	74.3% (58/78)	Increased pain for 1 day	10.2% (8/78)	10.7% (8/75)	9.2% (7/76)	
Study population: patients with persistent lateral hip pain who fulfilled the inclusion criteria below.	B. Injection group (n = 75 at baseline, n = 69 at 4 months)	74.7% (56/75)	50.7% (38/75)	48% (36/75)	Increased pain > 1 day	2.6% (2/78)	24% (18/75)	19.7% (15/76)	<ul style="list-style-type: none"> 2-centre study (orthopaedic outpatient clinics). Sequential allocation to treatment group (not formally randomised) but there were no significant differences in baseline characteristics between groups (including age, sex, duration of symptoms, use of analgesics and pain level during past week). Investigator did not know in advance which consultation hour each patient was assigned to. All patients advised to return slowly to previous levels of sports/recreational activity 6 weeks after start of treatment. Degree of recovery
n = 229 (78 vs 75 vs 76)	C. Home-training group (n = 76 at baseline, n = 71 at 4 months)	6.6% (5/76)	40.8% (31/76)	80.2% (61/76)	Radiating pain	3.8% (3/78)	9.3% (7/75)	6.6% (5/76)	
Age: shockwave group: 47 years, injection group: 50 years and home-training group: 46 years.	p value: A vs B	< 0.001	< 0.05	< 0.01	Skin irritation	33.3% (26/78)	2.7% (2/75)	NR	<ul style="list-style-type: none"> 2-centre study (orthopaedic outpatient clinics). Sequential allocation to treatment group (not formally randomised) but there were no significant differences in baseline characteristics between groups (including age, sex, duration of symptoms, use of analgesics and pain level during past week). Investigator did not know in advance which consultation hour each patient was assigned to. All patients advised to return slowly to previous levels of sports/recreational activity 6 weeks after start of treatment. Degree of recovery
Sex: shockwave group: 71% (55/78) female; injection group: 72% (54/75) female [reported as 75% in the paper - IP analyst] and home-training group: 70% (53/76) female [reported as 69% in the paper - IP analyst].	p value: A vs C	NS	< 0.001	NS	Swelling	2.6% (2/78)	9.3% (7/75)	NR	
Patient selection criteria: inclusions: local tenderness on palpation of greater trochanter, pain for more than 6 months and while lying on the affected side, positive resisted external rotation test and no radiological evidence of hip	p value: B vs C	< 0.001	NS	< 0.001	Other minor reaction	1.3% (1/78)	0	NR	<ul style="list-style-type: none"> 2-centre study (orthopaedic outpatient clinics). Sequential allocation to treatment group (not formally randomised) but there were no significant differences in baseline characteristics between groups (including age, sex, duration of symptoms, use of analgesics and pain level during past week). Investigator did not know in advance which consultation hour each patient was assigned to. All patients advised to return slowly to previous levels of sports/recreational activity 6 weeks after start of treatment. Degree of recovery
	<u>Mean pain scores</u>				Comparison of adverse reactions: Injection vs shockwave: p = NS Injection vs home training: p < 0.05 Home training vs shockwave: p < 0.05				
		Baseline	1 month	4 months	15 months	All adverse reactions described as mild.			
	A. Shockwave group (n = 78 at baseline, n = 73 at 4 months)	6.3 ± 4.1	5.6 ± 3.7	3.2 ± 2.4	2.4 ± 3.0				
	B. Injection group (n = 75 at baseline, n = 69 at 4 months)	5.8 ± 3.6	2.2 ± 2.0	4.5 ± 3.0	5.3 ± 3.4				
	C. Home-training group (n = 76 at baseline, n = 71 at 4 months)	6.2 ± 3.7	5.9 ± 2.8	5.2 ± 2.9	2.7 ± 2.8				
	p value: A vs B	NS	< 0.001	< 0.01	< 0.001				
	p value: A vs C	NS	NS	< 0.001	NS				
	p value: B vs C	NS	< 0.001	NS	< 0.001				
	<u>Return to previous levels of sporting/recreational activity at 4 months</u>								

Abbreviations used: IP; interventional procedures; NR, not reported; NS, not significant; RCT, randomised controlled trial; SWT, shock wave therapy; VAS, visual analogue scale																									
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<p>or knee joint disease. Exclusions: history of acute trauma, dysplasia, sciatica, hip deformities, internal hip rotation $\leq 20^\circ$ and presence of signs of general myofascial tenderness on palpation.</p> <p>Technique: standardised repetitive low-energy radial shockwave therapy (3 weekly sessions using Swiss DolorClast, 2000 pulses applied with pressure of 3 bar at 8 pulses per second, no local anaesthesia applied) vs single local corticosteroid injection (25 mg prednisolone) vs standardised home-training programme (including demonstration from physical therapist and written instructions. Exercises of 20 minutes to be done twice a day every day for 12 weeks).</p> <p>Follow-up: 15 months</p> <p>Conflict of interest/source of funding: none</p>	<p>Shockwave group: 64.1% (50/78) Injection group: 49.3% (37/75) Home-training group: 34.2% (26/76)</p> <p>(Shockwave vs injection: $p < 0.05$, shockwave vs home training: $p < 0.001$ and injection vs home training: $p = NS$)</p> <p><u>Additional treatment during 4-15 month follow-up</u></p> <table border="1"> <thead> <tr> <th></th> <th>Shockwave group (n = 78)</th> <th>Injection group (n = 75)</th> <th>Home-training group (n = 76)</th> </tr> </thead> <tbody> <tr> <td>No additional treatment</td> <td>61.5% (48/78)</td> <td>41.3% (31/75)</td> <td>39.5% (30/76)</td> </tr> <tr> <td>Physical therapy</td> <td>3.8% (3/78)</td> <td>17.3% (13/75)</td> <td>31.5% (24/76)</td> </tr> <tr> <td>Corticosteroid injection</td> <td>12.8% (10/78)</td> <td>22.7% (17/75)</td> <td>7.9% (6/76)</td> </tr> <tr> <td>Pain medication</td> <td>21.8% (17/78)</td> <td>18.9% (14/75)</td> <td>21.1% (16/76)</td> </tr> </tbody> </table> <p>Comparison of use of additional treatment: Injection vs shockwave: $p = NS$ Injection vs home training: $p < 0.01$ Home training vs shockwave: $p < 0.01$</p> <p>80.3% (61/76) of patients in the home-training group reported continuing with home training on their own.</p>				Shockwave group (n = 78)	Injection group (n = 75)	Home-training group (n = 76)	No additional treatment	61.5% (48/78)	41.3% (31/75)	39.5% (30/76)	Physical therapy	3.8% (3/78)	17.3% (13/75)	31.5% (24/76)	Corticosteroid injection	12.8% (10/78)	22.7% (17/75)	7.9% (6/76)	Pain medication	21.8% (17/78)	18.9% (14/75)	21.1% (16/76)		<p>assessed on 6-point Likert scale ranging from completely recovered to much worse).</p> <ul style="list-style-type: none"> Severity of pain over last week assessed on scale from 0 to 10 (0 = no pain and 10 = worst conceivable pain). <p>Other:</p> <ul style="list-style-type: none"> A placebo-controlled trial was denied by the institutional review board as patients had already suffered for more than 6 months.
	Shockwave group (n = 78)	Injection group (n = 75)	Home-training group (n = 76)																						
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Study details	Key efficacy findings			Key safety findings	Comments																																																							
<p>Furia JP (2009)²</p> <p>Non-randomised comparative study</p> <p>US</p> <p>Recruitment period: 2007–2008 Study population: patients with chronic greater trochanteric pain syndrome (moderate to severe pain located over the greater trochanter and peritrochanteric area, pain with resisted hip abduction and impaired function).</p> <p>n = 66 (33 vs 33)</p> <p>Age: SWT group: 51 years (mean); control group: 50.2 years (mean) Sex: SWT group: 66.7% (22/33) female; control group: 66.7% (22/33) female</p> <p>Patient selection criteria: inclusions: patients with an established diagnosis for 6 months for whom at least 3 types of traditional non-operative measures for a minimum of 6 months have failed. Exclusions: < 18 years old, rheumatoid arthritis, polyarthritis, local infection, pregnancy, bleeding disorders, tumours, prior hip surgery and unresolved hip, pelvis or lumbar vertebrae fractures. All patients had anteroposterior pelvic and lateral radiographs to rule out end-stage hip osteoarthritis.</p> <p>Technique: low-energy radial shockwave therapy (1 session using Swiss DolorClast, 2000 pulses applied with pressure of 4 bar equal to 0.18 mJ/mm², 10 shocks per second) vs control group (non-operative therapy).</p> <p>Follow-up: 12 months</p> <p>Conflict of interest/source of funding: none</p>	<p>Number of patients analysed: 66 (33 vs 33)</p> <p>VAS (mean pain score)</p> <table border="1"> <thead> <tr> <th></th> <th>SWT group (n = 33)</th> <th>Control group (n = 33)</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td>Baseline</td> <td>8.5 ± 0.9</td> <td>8.5 ± 0.9</td> <td>–</td> </tr> <tr> <td>1 month</td> <td>5.1 ± 0.9</td> <td>7.6 ± 1.0</td> <td>< 0.001</td> </tr> <tr> <td>3 months</td> <td>3.7 ± 0.8</td> <td>7.0 ± 0.8</td> <td>< 0.001</td> </tr> <tr> <td>12 months</td> <td>2.7 ± 0.9</td> <td>6.3 ± 1.2</td> <td>< 0.001</td> </tr> </tbody> </table> <p>p < 0.001 for each time point for SWT and control group compared with pre-treatment</p> <p>Mean Harris Hip score</p> <table border="1"> <thead> <tr> <th></th> <th>SWT group (n = 33)</th> <th>Control group (n = 33)</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td>Baseline</td> <td>49.6 ± 4.9</td> <td>50.4 ± 4.4</td> <td>–</td> </tr> <tr> <td>1 month</td> <td>69.8 ± 7.3</td> <td>54.4 ± 5</td> <td>< 0.001</td> </tr> <tr> <td>3 months</td> <td>74.8 ± 5.9</td> <td>56.9 ± 5.2</td> <td>< 0.001</td> </tr> <tr> <td>12 months</td> <td>79.9 ± 6.2</td> <td>57.6 ± 5.8</td> <td>< 0.001</td> </tr> </tbody> </table> <p>p < 0.001 for each time point for SWT compared with pre-treatment</p> <p>Mean Roles and Maudsley score</p> <table border="1"> <thead> <tr> <th></th> <th>SWT group (n = 33)</th> <th>Control group (n = 33)</th> </tr> </thead> <tbody> <tr> <td>Baseline</td> <td>4</td> <td>4</td> </tr> <tr> <td>1 month</td> <td>2.5</td> <td>3</td> </tr> <tr> <td>3 months</td> <td>2</td> <td>2.9</td> </tr> <tr> <td>12 months</td> <td>2</td> <td>2.9</td> </tr> </tbody> </table> <p>% of patients with excellent or good scores (1 or 2) after treatment was significantly greater in the SWT group than the control group at each time point (p < 0.001). In both the SWT and controls groups, no patient reported worsening of symptoms compared with baseline.</p> <p>Return to preferred sporting activity at pre-injury level SWT group: 76.5% (13/17) patients Control group: 66.7% (10/15) patients</p> <p>Return to occupation requiring extensive physical activity SWT group: 87.5% (7/8) patients Control group: 83.3% (5/6) patients</p>				SWT group (n = 33)	Control group (n = 33)	p value	Baseline	8.5 ± 0.9	8.5 ± 0.9	–	1 month	5.1 ± 0.9	7.6 ± 1.0	< 0.001	3 months	3.7 ± 0.8	7.0 ± 0.8	< 0.001	12 months	2.7 ± 0.9	6.3 ± 1.2	< 0.001		SWT group (n = 33)	Control group (n = 33)	p value	Baseline	49.6 ± 4.9	50.4 ± 4.4	–	1 month	69.8 ± 7.3	54.4 ± 5	< 0.001	3 months	74.8 ± 5.9	56.9 ± 5.2	< 0.001	12 months	79.9 ± 6.2	57.6 ± 5.8	< 0.001		SWT group (n = 33)	Control group (n = 33)	Baseline	4	4	1 month	2.5	3	3 months	2	2.9	12 months	2	2.9	<p>4 minor complications: 2 patients had pain during treatment which resolved after the procedure. 2 patients had transitory reddening of the skin that resolved without intervention.</p> <p>It is assumed that these complications were in the SWT group (not explicitly stated in the paper).</p>	<p>Follow-up issues:</p> <ul style="list-style-type: none"> • An additional 3 patients were treated in the SWT group but not reported (1 patients had concomitant Achilles tendinopathy and was excluded. There was insufficient follow-up data on 2 further patients). • Completeness of follow-up not reported at 1, 3 and 12 months. <p>Study design issues:</p> <ul style="list-style-type: none"> • Single centre study. All treatments performed by lead author. • Patients made an informed choice of treatment modality. • Control patients were selected from a cohort of 70 patients treated with non-operative therapy. The controls were matched for age and gender. • Non-operative therapy included anti-inflammatory medications, exercises, iontophoresis and corticosteroid/ local anaesthetic injection. <p>Study population issues:</p> <ul style="list-style-type: none"> • 51.5% (17/33) patients in the SWT group and 45.5% (15/33) patients in the control group participated in regular sporting activity 3–5 times per week. • No difference between groups for mean duration of symptoms (p = 0.4).
	SWT group (n = 33)	Control group (n = 33)	p value																																																									
Baseline	8.5 ± 0.9	8.5 ± 0.9	–																																																									
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Efficacy

Recovery/symptom improvement

A non-randomised comparative study of 229 patients (78 ESWT vs 75 single local corticosteroid injection vs 76 home training) reported an increased proportion of patients who had either completely recovered or had improved symptoms (assessed using a 6-point Likert scale, 1 = completely recovered and 6 = much worse) following ESWT at 1 month (13% [10/78]), 4 months (68% [53/78]) and 15 months (74% [58/78]) after treatment. In the corticosteroid injection group, 75% (56/75) reported complete recovery or improved symptoms at 1 month, which dropped to 51% (38/75) at 4 months and to 48% (36/75) at 15 months. The home-training group reported an increased proportion of patients who had either completely recovered or had improved symptoms following treatment at 1 month (7% [5/76]), 4 months (41% [31/76]) and 15 months (80% [61/76]).

Pain

The non-randomised comparative study of 229 patients reported significantly higher mean pain scores (measured on a visual analogue scale from 0 to 10; 10 indicates worst conceivable pain) in the ESWT (5.6) and the home-training groups (5.9) compared to the injection group (2.2, $p < 0.001$) at 1 month. However, the reverse was reported at 15 months with ESWT (2.4) and home-training (2.7) groups reporting significantly lower pain scores than the injection group (5.3, $p < 0.001$). All groups reported similar pain scores (range 5.8–6.3) at baseline¹.

A non-randomised comparative study of 66 patients (33 ESWT vs 33 non-operative therapy) reported significantly lower mean pain scores (measured on a visual analogue scale) in the ESWT group compared to the non-operative therapy group at 12-month follow-up (2.7 vs 6.3, $p < 0.001$). Both groups reported mean pain scores of 8.5 at baseline².

Harris hip score

The non-randomised comparative study of 66 patients reported significantly higher mean Harris hip scores (measured on a scale from 0 to 100; high scores indicate improvement) in the ESWT group compared to the non-operative therapy group at 12 month follow-up (79.9 vs 57.6, $p < 0.001$). The groups reported similar mean Harris hip scores at baseline (ESWT: 49.6 and non-operative therapy: 50.4, p value not reported)².

Roles and Maudsley score

The non-randomised comparative study of 66 patients reported a significantly higher proportion of patients with excellent or good scores (1 or 2 on the Roles

and Maudsley scale) in the ESWT group compared with the non-operative therapy group at 1, 3 and 12 month follow-up ($p < 0.001$)².

Return to sport/recreational activities

The non-randomised comparative study of 229 patients reported 64% (50/78) of the ESWT group, 49% (37/75) of the injection group and 34% (26/76) of the home-training group returned to previous sporting or recreational activity at 4 months (ESWT vs injection, $p < 0.05$ and ESWT vs home training, $p < 0.001$)¹.

The non-randomised comparative study of 66 patients reported 76% (13/17) of the ESWT group and 67% (10/15) of the non-operative therapy group returned to previous sporting activity at pre-injury level. The same study reported that 88% (7/8) of patients in the ESWT group and 83% (5/6) of patients in the non-operative therapy group returned to an occupation requiring extensive physical activity².

Safety

The non-randomised comparative study of 229 patients reported 46% (36/78) of the ESWT group, 44% (33/75) of the injection group and 65% (49/76) of the home-training group had no adverse reactions up to 1-month follow-up (injection vs home training $p < 0.05$ and home training vs ESWT $p < 0.05$). All adverse reactions were described as mild¹.

Pain related to the procedure

The non-randomised comparative study of 229 patients reported 2% (2/78) of the ESWT group, 24% (18/75) of the injection group and 20% (15/76) of the home-training group had increased pain for more than 1 day¹.

Skin irritation

The non-randomised comparative study of 229 patients reported 33% (26/78) of the ESWT group and 3% (2/75) of the injection group had irritated skin within 1 month of follow-up¹.

The non-randomised comparative study of 66 patients reported transitory skin reddening that resolved without intervention in 2 patients. It is assumed that these patients were in the ESWT group, but this is not explicitly stated in the paper².

Validity and generalisability of the studies

- The quantity of evidence was limited.

- One paper claimed to be a randomised controlled trial but did not randomise patients to the 3 study treatments. Patients in the comparative study of 66 patients chose their treatment group.
- The extracorporeal shockwave treatment protocols were different in the 2 available studies.
- No long-term data are available.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Extracorporeal shockwave therapy for refractory plantar fasciitis. NICE interventional procedures guidance 311 (2009) Available from www.nice.org.uk/guidance/IPG311
- Extracorporeal shockwave therapy for refractory Achilles tendinopathy. NICE interventional procedures guidance 312 (2009). Available from www.nice.org.uk/guidance/IPG312
- Extracorporeal shockwave therapy for refractory tennis elbow. NICE interventional procedures guidance 313 (2009). Available from www.nice.org.uk/guidance/IPG313

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Professor Nicola Maffulli (British Orthopaedic Society) and Mr David Silver (British Hip Society/British Society of Skeletal Radiologists)

- Both Specialist Advisers perform this procedure regularly.

- Both Specialist Advisers describe this procedure as the first in a new class of procedure with fewer than 10% of specialists engaged in this area of work (one of the Specialist Advisers also considers the procedure to be established practice).
- The Specialist Advisers thought that theoretical adverse events include pain, tendon rupture, haematomas and neuronal damage.
- Anecdotal adverse events: tenderness, bruising and haematoma.
- The Specialist Advisers considered key efficacy outcomes to be a degree of recovery measured on 6-point Likert scale, severity of pain measured on a VAS and improved function.
- The Specialist advisers recommended training in machine operation and administration of ESWT (given by the supplier).
- One Specialist Adviser states that there is controversy due to lack of robust data on efficacy, although the procedure is considered safe.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme sent 60 questionnaires to 1 trust for distribution to patients who had the procedure (or their carers). NICE received 30 completed questionnaires.

The Patient Commentators raised the following issues about the safety and efficacy of the procedure which did not feature in the published evidence or the opinions of Specialist Advisers, and which the Committee considered to be particularly relevant:

Thirty percent (9/30) of patients stated that they would not have ESWT again: 3 patients reported that the procedure had made their condition worse with increased pain and decreased mobility. The remaining 70% (21/30) of patients would recommend this procedure to others.

References

1. Rompe JD, Segal NA, Cacchio A et al. (2009) Home training, local corticosteroid injection, or radial shockwave therapy for greater trochanter pain syndrome. *American Journal of Sports Medicine* 37: 1981–90.
2. Furia JP, Rompe JD, Maffulli N. (2009) Low-energy extracorporeal shockwave therapy as a treatment for greater trochanteric pain syndrome. *American Journal of Sports Medicine* 37: 1806–13.

Appendix A: Additional papers on extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Souza AC, Arkader F, Rocket P et al. (2006) Shockwave therapy for the treatment of the trochanteric bursitis with tendinosis of the gluteus. Available from http://www.razova-vlna.eu/dokumenty/06_SWT_study.pdf	Case series n = 56 Follow-up = 180 days	Safety and efficacy of ESWT: Excellent: 41.1% Good: 48.2% Acceptable: 3.6% Poor: 7.1% Patients assessed with Roles and Maudsley score and VAS.	Not published in peer reviewed journal.
Peled E, Norman D, Levin D et al. (2006) Greater Trochanteric bursitis and EXWT. Israeli Orthopaedic Association (conference abstract). Journal of Bone and Joint Surgery 90 (Suppl. 3): 508	Case series n = 14 Follow-up = not reported	Conventional treatment (non-steroid anti-inflammatory drugs, physiotherapy, ultrasound and one steroid injection). failed in all patients. Patients received 6 courses of ESWT (1500 impulses) Mean duration of symptoms: 14.2 months. Mean VAS dropped from 7.9 to 1.6 (p = 0.001). No side effects except minimal local discomfort during session time.	Conference abstract

Appendix B: Related NICE guidance for extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome

Guidance	Recommendations
Interventional procedures	<p>Extracorporeal shockwave therapy for refractory plantar fasciitis. NICE interventional procedures guidance 311 (2009)</p> <p>1 Guidance</p> <p>1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory plantar fasciitis raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p>1.2 Clinicians wishing to undertake ESWT for refractory plantar fasciitis should take the following actions.</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG311publicinfo). • Audit and review clinical outcomes of all patients having ESWT for refractory plantar fasciitis (see section 3.1). <p>1.3 NICE encourages further research into ESWT for refractory plantar fasciitis. Future research should take the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anaesthesia use and the type of energy applied (see section 2.5). The studies should include validated outcome measures and be based on a minimum of 1-year follow-up. NICE may review the procedure on publication of further evidence.</p> <p>Extracorporeal shockwave therapy for refractory Achilles tendinopathy. NICE interventional procedures guidance 312 (2009)</p> <p>1 Guidance</p> <p>1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory Achilles tendinopathy raises no major safety concerns: there have been reports of occasional tendon rupture in treated patients, but this may also occur when the procedure has not been used. However, current evidence on efficacy of the procedure is inconsistent. Therefore, ESWT for refractory Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research.</p>

	<p>1.2 Clinicians wishing to undertake ESWT for refractory Achilles tendinopathy should take the following actions.</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy, and about its safety in relation to a possible risk of tendon rupture, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG312publicinfo). • Audit and review clinical outcomes of all patients having ESWT for refractory Achilles tendinopathy (see section 3.1). <p>1.3 NICE encourages further research into ESWT for refractory Achilles tendinopathy. Future research should take the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anaesthesia use and the type of energy applied (see section 2.5). The studies should include validated outcome measures and be based on a minimum of 1-year follow-up. NICE may review the procedure on publication of further evidence.</p> <p>Extracorporeal shockwave therapy for refractory tennis elbow. NICE interventional procedures guidance 313 (2009)</p> <p>1 Guidance</p> <p>1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory tennis elbow raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p>1.2 Clinicians wishing to undertake ESWT for refractory tennis elbow should take the following actions.</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG313publicinfo). • Audit and review clinical outcomes of all patients having ESWT for refractory tennis elbow (see section 3.1). <p>1.3 NICE encourages further research into ESWT for refractory tennis elbow. Future research should take the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anaesthesia use and the type of energy applied (see section 2.5). The studies should include validated outcome measures and be based on a minimum of 1-year follow-up. NICE may review the procedure on publication of further evidence.</p>
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Appendix C: Literature search for extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/09/2010	September, 2010
Database of Abstracts of Reviews of Effects – DARE (CRD website)	28/09/2010	n/a
HTA database (CRD website)	28/09/2010	n/a
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/09/2010	September, 2010
MEDLINE (Ovid)	28/09/2010	1950 to September Week 2 2010
MEDLINE In-Process (Ovid)	28/09/2010	September 27, 2010
EMBASE (Ovid)	28/09/2010	1980 to 2010 Week 38
CINAHL (NLH Search 2.0)	28/09/2010	n/a
Zetoc (for update searches only)	28/09/2010	n/a

MEDLINE search strategy

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	((shockwave* or shockwave*) adj5 therap*or treatment*) or lithotrip*).tw.
2	(ESWT or ESWL or ESWLS).tw.
3	exp High-Energy Shockwaves/
4	hesw.tw.
5	exp Lithotripsy/
6	lithotripsy.tw.
7	((high-energ* or (high adj5 energ*) or ultraso*) adj5 shock* adj5 wave*).tw.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	exp Hip/ or exp Hip Joint/
10	exp Bursitis/

11	9 or 10
12	(bursitis adj5 (hip* or coxa*)).tw.
13	bursitis.tw.
14	bursa*.tw.
15	trochant*.tw.
16	(adhesive adj capsuliti* adj5 (hip* or coxa*)).tw.
17	11 or 12 or 13 or 14 or 15 or 16
18	8 and 17