Extracorporeal shock wave therapy in the treatment of trochanteric bursitis: the ASSERT database

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Summary

***Introduction*: This study aimed to determinate the effectiveness of extracorporal shock wave therapy (ESWT) in the treatment of trochanteric bursitis (TB) in both the short and long term.**
***Methods*: The participants of this study were recruited by different clinicians of the National Health Service (NHS) and private sector centres in the United Kingdom. Data were collected in a web-based database [Assessment of the Effectiveness of Extracorporeal Shock Wave Therapy (ESWT) for Soft Tissue Injuries (ASSERT)]. The 40 participants (mean age 56.35 ± 13.90 y) were treated using a standardized ESWT protocol. At baseline and again at 3, 6, 12 and 24 months following ESWT treatment, the participants were evaluated with the Visual Analogue Scale (VAS) for pain perception, the Lower Extremity Functional Scale (LEFS) for functional limitation assessment, and the 6 scores of EuroQol-5D questionnaire (EQ-5D) for quality of life.**
***Results*: There was a significant improvement over time in 2 of the 8 analysed scores that were VAS (*p*=0.0006) and the Pain/Discomfort score of EQ-5D (p=0.0003).**
***Conclusion*: ESWT showed beneficial effects on the pain relief in TB over a 24-month follow-up period. Level of evidence: IV.**

KEY WORDS: extracorporeal shock wave therapy, longitudinal study, trochanteric bursitis.

Introduction

Trochanteric bursitis (TB) or greater trochanteric pain syndrome (GTPS) as it frequently referred to, most commonly occurs in sedentary people between the ages of 40 to 60 years[1-5]. It has been described as the second most important diagnosis of hip problems seen in primary care[6]. However, as the aetiology is multifactorial it can affect patients of all ages. TB is initially treated conservatively using an array of treatments: rest, anti-inflammatory medication, ice and heat, stretching, physiotherapy, ultrasound and injection of local corticosteroid if all the aforemended fail[1,7-13]. However, despite local corticosteroid being touted as the most effective conservative treatment the evidence has found it to be ineffective over time and provides no benefit in the mid-long term[14]. In patients refractory to conservative treatments, surgical options such as supratrochanteric fasciotomy or trochanteric bursectomy may be used. Shockwave therapy is a well recognised treatment for patients with recalcitrant tendinopathies[15-26] and has been shown to be safe and effective in treating TB[14,27]. However, researchers in the field have called for additional studies to validate the use of ESWT for TB[14,27]. Such studies can be performed using large database analyses[28]. Indeed, the National Institute for Health and Care Excellence (NICE) identified that the evidence on the efficacy and safety of ESWT for

refractory greater trochanteric pain syndrome is limited in quality and quantity and recommends that the procedure should only be used with special arrangements for clinical governance, consent and audit or research[29]. The Assessment of Effectiveness of ESWT for Soft Tissue Injuries (ASSERT) is one such database, the aim of which is to determine the effectiveness of ESWT in patients suffering from selected soft tissue injuries in both the short and long term[30].
This study evaluated the effectiveness of ESWT in patients with chronic TB enrolled in ASSERT over 24 months considering different aspects, namely the reduction of the clinical severity of symptoms, the relief of pain, and the improvement of the quality of life.

Materials and methods

The ASSERT database was used to collect information on the effectiveness of ESWT across the United Kingdom. The ESWT machines were standardised and a standardised treatment protocol, together with standardised baseline measurements and outcome measures and time points in centres across the United Kingdom, were adopted to aid validity[30].

Recruitment

Participants were recruited from both the National Health Service (NHS) and private sector centres in the United Kingdom. Clinicians recruited participants presenting with trochanteric bursitis, and for whom ESWT was indicated as the treatment choice.

Participants

Participants were included if they were over the age of 18, had a diagnosis of TB confirmed by the recruiting clinician; undergone a course of conservative therapy which had not been effective in relieving symptoms; been recommended to receive ESWT at one of the recruiting centres; not been diagnosed with inflammatory arthropathy; and demonstrated the ability to give informed consent.
There were 43 participants (8 males; 35 females) enrolled and a total of 40 participants (7 males and 33 females) met all the inclusion criteria and were considered for analysis (Tab. I).
This study has been designed and conducted in accordance with the principles of the Declaration of Helsinki and it has been approved by the Local Ethics Committee (11/LO/0253). A written informed consent was obtained by each participant[31].

Use of ESWT machine

Standardisation of the machine and the process of administration of ESWT had been agreed to ensure consistency, reproducibility and generalisability of the results. All clinicians using the Swiss DolorClast device (Electro Medical Systems SA, Nyon, Switzerland) and Stortz devices (Stortz Medical AG, Tägerwilen, Switzerland) received training and certification to ensure adherence to the protocol. All clinicians followed a standardised method of administration of ESWT[32]. This included delivering an initial 500 "warm-up" impulses at a low air pressure (1.5 bar of air pressure). This reduces the pain which patients experience during treatment. Based on patient feedback, the clinician then increased the air pressure to 2.5 bar or above. The total dose of impulses remained constant at 2500 per session, with one session a week for three planned consecutive weeks, with a maximum gap between two consecutive treatments of two weeks.

Database

The ASSERT database is a web based system (www.assert.org.uk) from which the clinician received a study number for each participant[30]. Only unidentifiable information with the patients' study number was entered into the database. Sensitive data are held on secure servers. Following informed consent, the clinician recorded the following information: (1) Diagnosis: this was formulated on clinical grounds and some clinicians also used imaging to confirm the diagnosis; (2) Area treated/condition presented with; (3) Date of presentation of symptoms; (4) Date of treatment of ESWT; (5) Code for clinicians centre; (6) Centre where treatment was administered; (7) Previous treatments prior to consultation; (8) Side treated; (9) Dates when ESWT was administered; (10) Baseline scores recorded: EuroQol questionnaire scores (EQ-5D)[33], Visual Analogue Scale for pain (VAS)[34], and Lower Extremity Functional Scale[35]; (11) Follow-up scores at 3, 6, 12 and 24 months post treatment; (12) Satisfaction: rated poor, satisfactory, good or excellent; (13) Time to effective treatment; (14) Recurrence of the condition; (15) Complications; and (16) Adverse events.

Baseline and follow-up assessments

After having obtained written informed consent, the treating clinician undertook baseline assessments. The follow-up assessments were instead performed after 3, 6, 12 and 24 months' post treatment. The co-

Table I. Sample of participants.

	n	Age (y)	Number of previous treatments
Participants enrolled	43 (8 males and 35 females)	55.26 ± 14.57	1.93 ± 0.97
Participants considered for the analyses	40 (7 males and 33 females)	56.35 ± 13.90	2.03 ± 0.90

ordinators of ASSERT undertook all follow-up assessments via email, telephone or post.

Outcome assessment

The EQ-5D[33], the VAS for pain[34] and the Lower Extremity Functional Scale (LEFS)[35] were completed by the participants of the study.

The EQ-5D is a standardised measure of health status developed by the EuroQol Group to provide a simple, generic measure of health for clinical and economic appraisal. For the present study, the version 3L (EQ-5D-3L) was used. This is a simple questionnaire composed of 5 items with a 3-point scale answer for each item, and designed for completion by the person being treated. Each one of the 5 items respectively investigates 5 dimensions of the quality of life, namely (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort, and (5) anxiety/depression. A score from 1 (best score) to 3 (worst score) is assigned for each dimension. The EQ-5D also includes a scale, named EQ-5D Thermometer Scale, that allows obtaining a global score to generally describe the quality of life of the patient. It consists in a vertical line, 100 mm in length, anchored by 2 word descriptors at each end, which are "the worst health you can imagine" and "the best health you can imagine". Patients are asked to mark on the line the point which they feel represents their perception of their current health status. The score ranges from 0 (worst health status) to 100 (best health status), and it is computed by measuring the distance (in mm) between the end of the line marked with "the worst health you can imagine" and the mark on the line indicated by the patient.

The VAS for pain is very similar to the EQ-5D Thermometer Scale, but it focuses only on the pain perceived by the patient, not on the overall quality of life. It consists in a horizontal line, 100 mm in length, which asks the patients "How severe is your pain today?". The line is anchored by 2 word descriptors at each end, which are "no pain" and "very severe pain". Also in this case, patient to mark on the line the point which they feel represents their current perception of their pain intensity. The score, from 0 (no pain) to 100 (very severe pain), is computed as the measurement of the distance (in mm) between the end of the line marked with "no pain" and the point on the line indicated by the patient.

LEFS consists of 20 items, each with a maximum score of 4. The total possible score of 80 indicates a high functional level, whereas the minimum possible score is 0 and it indicates a severe functional limitation. Clinicians can also be reasonably confident that change on the LEFS of greater than 9 scale points is a true change[35].

Statistical analysis

A Linear Mixed Model analysis (LMM) with maximum likelihood method was used in order to evaluate the significant effects over time produced by ESWT in the treatment of the TB. To perform the LMM analysis, one fixed factors were considered that was Time factor (fixed factor: T0 *vs* T3 *vs* T6 *vs* T12 *vs* T24) to investigate differences over time. The VAS and the LEFS scores, as well as the 6 scores of the EQ-5D were considered as dependent variables for the analysis. If two or more of the follow-up datasets were missing the patient was excluded.

The age and the number of previous treatments were considered as covariates of the analysis to verify if these factors could have influenced the VAS, LEFS and EQ-5D scores over time.

Due to the multiple dependent variables, the Bonferroni correction was used adjust the *p*-value. The Bonferroni correction indicates an adjusted *p*-value <0.006 for significance.

When a significant effect over time was detected, Bonferroni post-hoc analysis (adjusted for multiple comparison) was used to perform comparisons in pair among the different time of assessments.

All the analyses were performed with the statistical software SPSS 20 (IBM Corporation, Chicago, IL, USA).

Results

There was a significant reduction over time of the VAS score ($F_{4,76}$=5.456; p<0.0006).

There were no significant modifications over time ($F_{4,70}$=2.874; p<0.029, not significant after Bonferroni correction) for the LEFS scores.

Concerning the EQ-5D questionnaire domains, only the EQ-5D Pain/Discomfort score was modified over time with a significant reduction ($F_{4,73}$=6.122; p<0.0003), whereas the other scores did not report significant modifications with no changing over time in the EQ-5D Anxiety/Depression ($F_{4,70}$=1.140; p<0.345), in the EQ-5D Mobility score ($F_{4,72}$=1.901; p<0.120), in the EQ-5D Usual Activities score ($F_{4,73}$=2.926; p<0.027, not significant after Bonferroni correction), in the EQ-5D Self-Care (the participants referred the same score in all their respective time-point assessments so F was not computable due the absence of variance; p<1.000), and in the EQ-5D Thermometer Scale ($F_{4,71}$=0.227; p<0.923)

The involvement in previous treatment and the age of the patients seems to not have produced significant influences on all the analysed dependent variables (not significant p<0.006 values for all the variables).

All the data are reported as Means ± SD in Table II with the results of the post-hoc analysis.

Discussion

The main result of this study was that the VAS score of the participants showed a significant reduction at all the time-point assessments, significantly lower than that of the baseline score. This indicates that the ESWT produced a beneficial effect in relation to pain reduction after only 3 months, and that this beneficial

Table II. Results relative to the effects over time with the post-hoc analyses outputs.

Tests		T0	T3	T6	T12	T24	Overall significance in time	Comparisons in pair - significance
		Means ± SD (N)	Means ± SD (N)	Means ± SD (N)	Means ± SD (N)	Means ± SD (N)		
VAS	Scores	48.25 ± 23.39 (28)	32.83 ± 26.37 (29)	32.43 ± 30.98 (21)	24.31 ± 24.25 (13)	26.45 ± 29.01 (11)	*p*=0.0006	T0 *vs* T3, T6, T12, T24
	Difference with baseline score		-15.42	-15.82	-23.94	-21.80		
LEFS	Scores	44.07 ± 17.35 (27)	51.42 ± 21.45 (26)	49.55 ± 25.89 (20)	61 ± 17.35 (12)	54.6 ± 20.55 (10)	Not significant	-
	Difference with baseline score		7.35	5.48	16.93	10.53		
EQ-5D Anxiety/Depression	Scores	1.36 ± 0.56 (28)	1.27 ± 0.45 (26)	1.45 ± 0.69 (20)	1.17 ± 0.39 (12)	1.20 ± 0.42 (10)	Not significant	-
	Difference with baseline score		-0.09	0.09	-0.19	-0.16		
EQ-5D Mobility	Scores	1.68 ± 0.48 (28)	1.46 ± 0.51 (26)	1.35 ± 0.49 (20)	1.50 ± 0.52 (12)	1.40 ± 0.52 (10)	Not significant	-
	Difference with baseline score		-0.22	-0.33	-0.18	-0.28		
EQ-5D Pain/Discomfort	Scores	2.21 ± 0.42 (28)	1.81 ± 0.49 (26)	1.85 ± 0.81 (20)	1.83 ± 0.72 (12)	1.50 ± 0.53 (10)	*p*=0.0003	T0 *vs* T3, T6, T12, T24
	Difference with baseline score		-0.41	-0.36	-0.38	-0.71		
EQ-5D Usual Activities	Scores	1.89 ± 0.42 (28)	1.65 ± 0.63 (26)	1.50 ± 0.69 (20)	1.58 ± 0.67 (12)	1.50 ± 0.53 (10)	Not significant	-
	Difference with baseline score		-0.24	-0.39	-0.31	-0.39		
EQ-5D Self-Care	Scores	1.07 ± 0.26 (28)	1.08 ± 0.27 (26)	1.05 ± 0.22 (20)	1.00 ± 0.00 (12)	1.00 ± 0.00 (10)	Not significant	-
	Difference with baseline score		0.01	-0.02	-0.07	-0.07		
EQ-5D Thermometer Sc.	Scores	70.14 ± 22.63 (28)	66.69 ± 22.79 (26)	70.25 ± 25.81 (20)	71.92 ± 21.33 (12)	72.00 ± 22.91 (10)	Not significant	-
	Difference with baseline score		-3.45	0.11	1.77	1.86		

p-value for significance after Bonferroni correction is <0.006.

effect was maintained for all the 24 months of observation. The same positive effect was observed also for the EQ-5D Pain/Discomfort scores, which showed similar results to the VAS scores. No significant results were obtained in any of the other outcome scores. However, it is possible to note that the baseline scores of the other EQ-5D scores (Tab. II) were substantially low, and they remained low for all the duration of the follow-up. The EQ-5D Thermometer Score was already high at the baseline assessment, with a mean of 70, which remained static through out the follow-up points indicating that perhaps TB does not impact on the global health so much as the pain aspect.

Another clinically important finding concerns the time necessary to obtain significant benefits on health status and pain relief. In fact, there was a significant improvement three months after the last session of ESWT in VAS, EQ-5D Pain/Discomfort which is in contrast to previous research which identified effectiveness at mid-term and longer-term follow-up[14,27] and this is re-confirmed in the present study where the significance continues through 24 months. Given these results, ESWT can be considered a valid and effective method for the treatment of TB. Another important finding was that although the LEFS Score did not reach significance at any follow-up points the Minimally Clinical Important Difference (MCID) was reached at both 12 and 24 months. The MCID of the LEF Score is 9 points. Clinicians can be confident that a change of greater than 9 scale points is not only a true change but is also a clinically meaningful functional change[35]. The mean change in the scores were 16.93 and 10.53 at 12 and 24 months respectively meaning that it takes this amount of time to see the true benefit of the treatment.

The results of the present study are in accordance with previous randomised studies[14,27] and a recent meta-analysis performed in 2018[36] confirming that ESWT is safe and effective in the non-surgical management of TB. However, the literature also reported that larger sample and high-quality clinical trials and systematic reviews are necessary to demonstrate the efficacy of ESWT in the treatment of TB[27] and that data should be collected on diagnosis, outcomes, baseline measures, confounding factors, and treatment applied[36]. In this respect, the ASSERT database plays an important role. In fact, ASSERT aimed to collect high quality and relevant data about the effectiveness of ESWT in patients with TB in a pragmatic and systematic manner to improve the quality of outcomes and ensure the quality and cost effectiveness of ESWT. ASSERT can monitor the outcomes achieved by practitioners and identify where these fall below an expected performance to inform best practice and additional training requirements.

Inconsistent evidence exists regarding the short term effectiveness of ESWT for TB as reporting Furia et al. who reported “no change”[27] at 1-month whereas Rompe et al.[14] report clinical significance. However, Furia et al.[27] only administered one session of ESWT compares to the standardised three administered by Rompe et al.[14] At 3.6 and 12 months both studies reached clinical significance a result we did not find in ASSERT. However, as MCID was reached at 12 and 24 months if we had bigger numbers (only had 40 participants) then significance may have been reached.

The present evidence[14,27,36] however clearly indicates ESWT as an effective therapy for the management of TB. No analysis is perfect, and we acknowledge that many other variables such as the amount of energy employed, high *vs* low intensity shock wave treatment, radial *vs* focused shock wave treatment, the methods of localization of the shock waves, the number of shocks, and the number of sessions must also be considered when evaluating the efficacy of ESWT. Nevertheless, we point out that the protocol used to administer extracorporeal shock wave treatment in the ASSERT is based on the evidence produced by Level I studies[32]. Nevertheless, we acknowledge that more high-quality and well-conducted studies are necessary. A database such as ASSERT could be a valid method for the systematic collection of large amount of data and for the standardization of procedures to obtain strong evidences in this field.

Concerning the limitations, this study is not a randomised controlled trial. However, Level I studies have been conducted in the present field, and have shown that ESWT is safe and effective in the management of the condition at hand.[14,27] The NICE suggested that the effectiveness of ESWT in “real life” would have needed to be evaluated in a pragmatic fashion, using standardised protocols and well validated clinically relevant outcome measures. The ASSERT protocol is NICE compliant, and satisfies the requirements set out by NICE[29].

The fact that many different clinicians were involved in the treatment, after appropriate certified training and standardisation of the protocol, and that the effects of treatment were evaluated by independent individuals, increases the generalizability of the present findings, and, in this respect, should be considered a major strength of the present study. Also, all patients previously had failed a variety of conservative management means, and this was a major criterion to be recruited in the present study[27].

In conclusion, when administered in a standardised fashion to an unselected population of patients suffering from trochanteric bursitis, ESWT therapy is safe and effective in alleviating symptoms of pain for up to 24 months.

Compliance with ethical standards

Conflict of interest

All Authors declare no conflict of interest.

Funding

The ASSERT database has been developed and established through funds provided by Industry (Spectrum Technology UK) and ESPRC grants.

Acknowledgements

We thank Mr Jim Westwood and Mr Chris Schiel from Spectrum Technology for their support. Mr Nathan Bentley of twotwentyseven London Ltd – a creative digital agency developed the ASSERT platform following the direction of Professor Nicola Maffulli and Mrs Gayle Maffulli.
We thank all the clinicians recruiting participants onto the ASSERT database and the participants of ASSERT. Professor Nicola Maffulli developed the concept of ASSERT.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent
Informed consent was obtained from all individual participants included in the study.

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