The role of Extra-Corporeal Shockwave Therapy (ESWT) plus rehabilitation for patients with chronic Greater Trochanteric Pain Syndrome (GTPS), a case series assessing effects on pain, sleep quality, activity and functioning

ABSTRACT:

Background: Greater Trochanteric Pain Syndrome (GTPS) is a common cause of lateral hip pain, most commonly affecting female patients aged 40-60, and which can have a significant impact on patients' quality of life. Extra-corporeal shockwave therapy (ESWT) alongside a structured rehabilitation programme has been shown in previous research studies to have a significant improvement in patient's levels of pain, although it is unclear if this then leads to improved level of global functioning or activity. This case series examines the change in a range of patient reported outcome measures (PROMs) following shockwave therapy as well as the frequency of self-reported side-effects.

Methods: Patients undergoing extra-corporeal shockwave therapy for Greater Trochanteric Pain Syndrome were identified from case logs from a single NHS clinic. Patients completed a range of validated patient-rated outcome measures at baseline and at subsequent follow-up appointments. These include measures of pain, and measures of local hip functioning (Oxford Hip Score - OHS, Non-Arthritic Hip Score - NAHS), global functioning (EQ-5D-5L), sleep quality (Pittsburgh Sleep Quality Index - PSQI), anxiety and depressive symptoms (Hospital Anxiety & Depression Scale - HADS), and activity levels (International Physical Activity Questionnaire - IPAQ.)

Results: 45 patients who completed ESWT for greater trochanteric pain syndrome were identified; with a median follow-up duration of 189 days. Side-effect incidence was low, with <10% reporting bruising, and no patients withdrew due to side-effects.

"Average" and "worst" self-reported pain values improved significantly from baseline at all time-periods studied; 6.3/10 and 8.2/10 to 3.8/10 and 5.4/10 at three-months respectively, correlating to an improvement of about a third. At three months 63% of patients were either satisfied or very satisfied, and 70% would recommend the procedure, these figures increased at six-months. Sleep quality, measures of local hip functioning, and depressive symptoms all improved consistently across different time-points, however activity levels and global health markers showed less evidence of improvement.

Conclusions: Extra-Corporeal Shockwave Therapy is known to be effective in patients with Greater Trochanteric Pain alongside a structured rehabilitation programme, and this case series is in keeping with the available evidence. This series demonstrates benefits across different areas of functioning. However, in this series physical activity levels did not increase even though pain decreases. As staying active has numerous health benefits further targeted intervention to address this alongside the reduction of pain may be required for optimal health outcomes.

The role of Extra-Corporeal Shockwave Therapy (ESWT) plus rehabilitation for patients with chronic Greater Trochanteric Pain Syndrome (GTPS), a case series assessing effects on pain, sleep quality, activity and functioning

Background

Greater Trochanteric Pain Syndrome (GTPS) is a common cause of lateral hip pain, with a incidence of 1.8/1000 patients per year in primary care,[1] and accounts for 20% of referrals to some orthopaedic spinal centres.[2] GTPS is commoner in women than men, and most commonly affects women in their 4^{th} and 5^{th} decade.[3, 4] Greater trochanteric pain is known to be commoner in patients with pre-existing low back pain, osteoarthritis of the knee (of either leg), and iliotibial band (ITB) pain, but conflicting evidence exists as to whether it is commoner in overweight or obese patients.[4, 5]

Greater trochanteric pain syndrome (GTPS) has held a range of alternative names over the last few decades, indicating the on-going confusion as to the pathological processes involved. These alternative terminologies have focussed on different anatomical structures (trochanteric bursitis, or gluteus medius tendinosis), or are region based (lateral hip pain, greater trochanteric pain.) Different structures have been postulated to be involved, with attention moving away from the bursae themselves, which had been the original focus, and more towards the tendons of the abductors and external rotators, especially gluteus medius.[4, 6, 7] This varied nomenclature can cause confusion to patients and clinicians alike, and for the purposes of this article the phrase “greater trochanteric pain” will be used, although the criticisms and limitations of this terminology are accepted.

Regardless of the terms used, this condition describes an area of reproducible pain over the area of the greater trochanter, which can spread to the buttock, or upper lateral thigh with occasional spread further down the leg, and which can mimic other conditions including nerve root impingement, spinal problems or hip joint pathologies.[2, 4] Examination typically reveals maximal tenderness in the posterolateral area of the greater trochanter, however the majority of clinical tests have been found to have limited sensitivity for greater trochanteric pain and are poorly able to differentiate this from other causes of lateral hip pain.[8] Identifying those patients with lateral hip pain who do not have particular problems putting on shoes & socks (which may help to differentiate between GTPS and osteoarthritis of the hip), or those whose lateral hip pain is reproduced by the FABERs test, are thought to be the most reliable clinical questions and assessments to discriminate GTPS from other hip pain sources.[8]

Imaging studies have confirmed tendinopathy of the gluteal muscles to be a common finding in patients with buttock, lateral hip and groin pain, with 88% patients with trochanteric symptoms having MRI evidence of gluteus tendinopathy compared to 50% of those with hip pain but without specific trochanteric symptoms; this difference was found to be significant.[6, 9] The absence of any peritrochanteric abnormalities on MRI makes greater trochanteric pain syndrome unlikely, however these changes occur in a high proportion of patients without trochanteric pain. Caution is therefore required in interpreting imaging results in this patient cohort and may be more useful in ruling out other conditions such as osteoarthritis of the hip, or tears of the gluteal tendons.[9]

Whilst many cases of greater trochanteric pain will settle with simple conservative management options, a study based in primary care has shown that after one year 36% of patients will still suffer with trochanteric pain, and at 5 years this remains 29% indicating the chronic nature of this condition.[1] Patients who received a corticosteroid injection had a 2.7-fold chance of recovery compared to those who did not.[1] However one randomised controlled trial that sought to examine the benefits of corticosteroid injection over usual care found a significant benefit favouring injections at 3 months, but by 12months there was no benefit.[10] In addition to being significantly more expensive, there appears to be no added clinical benefit in guided versus unguided corticosteroid injections, with both often being effective in the short and medium term, and 41%-47% patients still benefitting at three months.[11] Other conservative treatment options that have been shown to be effective include physiotherapy, non-steroidal anti-inflammatory drugs, and weight loss.[4] Surgery has been tried in recalcitrant cases and there have been a range of different techniques reported with surgery focussing on the bursa, the tendinopathy, or the ITB components of greater trochanteric pain syndrome, which highlights on-going uncertainties as to the underlying pathologies in this condition.[12-14]

Extra-Corporeal Shockwave Therapy (ESWT) can also be used to treat patients with trochanteric pain. This is the use of high-energy, inaudible, sound waves generated externally to the body and which are transmitted through the skin, and are often felt as vibrations. Whilst treatment doses vary, and there is case-control study showing benefits of a single-dose of ESWT in patients with GTPS,[15] ESWT is most

typically performed over three sessions at weekly intervals in order to promote a healing response alongside a structured rehabilitation programme. [3] This has a growing evidence base in the treatment of a number of different tendinopathy conditions, of which Greater Trochanteric Pain Syndrome may be one. Currently, there is limited evidence of benefit from the use of Extra-corporeal Shockwave Therapy (ESWT) specifically in patients with trochanteric pain, with the 2011 NICE guidance (IPG 376) highlighting that overall the evidence was inconclusive.[16] There is some case-series evidence which suggests benefit of ESWT [15], and one randomised control trial found that ESWT was better than physiotherapy or corticosteroid injection at four-months, at fifteen-months there were similar results from ESWT and physiotherapy, and that both were more effective than corticosteroid injections alone.[3] A subsequent systematic review looking at evidence in arrange of lower-limb tendon conditions has suggested that ESWT may be useful in managing patients with greater trochanteric pain syndrome as an alternative to other conservative treatments such as corticosteroid injection.[17] Table 1 displays the published studies involving ESWT for Greater Trochanteric Pain Syndrome, which remain limited in number.

Author / Year	**Type**	**Notes**	**number**	**Age**	**f/u**	**Result**	**Ref**
Mani-Babu 2014	Systematic Review	2 studies – 1 RCT, 1 case-control study	.	.	.	Probably effective	[17]
NICE	Review		.	.	.	Inconclusive	[16]

2011							
Rompe 2009	RCT	RCT: Home exercise programme (HEP) v corticosteroid injection (CS) v ESWT (3 sessions performed at weekly intervals)	229 pts	Mean 46-50	15 months	At 1-month CS > ESWT At 4 months ESWT > HEP / CS At 15 months HEP / ESWT > CS	[3]
Furia 2009	Case-control	Case control series: single-dose ESWT v "additional forms of non-operative treatment"	66 pts	.	12 months	Better outcomes in ESWT group	[15]

Table 1: Previous published studies investigating effectiveness of ESWT for GTPS

The side-effect profile from ESWT is favourable, with few serious side-effects reported in most papers across a range of conditions treated.[18] In a placebo-

controlled study of more than 270 patients, reported side-effects included transitory reddening of the skin (21%) which was harmless and did not lead to treatment cessation, pain (4.8%), and small haematomas (3%), in addition there was a possibility of ESWT triggering migraine or possible fainting.[19] The risk of haematoma was reported following the use of a non-MSK specific machine, and newer more MSK-specific ESWT devices, appear to have a safer side-effect profile.[19] Other reports of side-effects from the NICE guidance for lateral hip / trochanteric pain (IPG 376) report than in 2% of patients there was increased pain of more than 1 day following ESWT treatment, and skin irritation in 33% of patients at 1 month.[16]

This case series seeks to assess the frequency of side-effects seen and to quantify any changes in pain or other function measures following ESWT in an NHS clinic, and acts as an initial pilot study for further research in this area.

Methods

Patients with chronic Greater Trochanteric Pain Syndrome (GTPS) treated with Extra-Corporeal Shockwave Therapy (ESWT) have been treated by the authors within a single NHS Sports Medicine department in a secondary care hospital in the UK. In line with other hospital procedures, written consent forms are used to record consent before the first session of ESWT. Patients have sessions of ESWT performed by the same practitioner, once per week for three weeks. In keeping with routine use, the energy dose is controlled by the operator to a "maximal comfortably-tolerated" energy dose which was individual for different patients, and varied between sessions. Patients are given standardised post-procedural advice and are advised to avoid NSAIDs for the day of, and a few days after, each session of ESWT.

Before undergoing shockwave therapy, patients are taught to perform a structured home exercise programme including flexibility of the lower limb, lumbar mobilisation and range of movement, strengthening of the muscles around the hip including the gluteal muscles associated with GTPS, as well as core stability and proprioception exercises.[3, 20] These exercises are prompted at each of the subsequent clinic visits to promote adherence and facilitate progression. Patients are advised that these exercises can be uncomfortable, particularly to begin with, and are taught how to progress these. To support the use of the home exercise programme, patients are given written sheets discussing these exercises and reminding them of technique and how often these need to be performed for benefit.

- Data collection

Patients complete a structured questionnaire about their symptoms before treatment and at each subsequent follow-up visit. These outcome measures include questions about pain, as well as a range of validated Patient-Rated Outcome Measures (PROMs) which include questionnaires about sleep quality (Pittsburgh Sleep Quality Index – PSQI), global function (EQ-5D-5L), specific hip function (Oxford Hip Score – OHS, and the Non-Arthritic Hip Score – NAHS), as well as measures of anxiety and depression symptoms (Hospital Anxiety and Depression Scale – HADS). Lastly questionnaires are used to quantify levels of physical activity. These include the short-form (7-day recall) version of the International Physical Activity Questionnaire - IPAQ, and also two "vital signs" physical activity questions ("On how many days in the last week have you been at least physically active?" and "on how many minutes were you active for?" – multiplying these two figures together to give the number of active minutes in a week.)

These measures are all used to examine outcomes following the ESWT procedure. Table 2 displays information for each of the PROMs in use.

Outcome measure	**Assessing**	**Scale**	**Notes**
Oxford Hip Score (OHS)	Measure of hip-specific functioning	Range 0-48	Higher score indicates better self-rated hip functioning
Non-Arthritic Hip	Measure of hip-	Total NAHS	Higher score

Score (NAHS)	specific functioning	score, range 0-80	indicates better self-rated hip functioning
EQ-5D-5L	Global health status	Health score displayed, range 0-100%	Higher score indicates better self-rated global health
Hospital Anxiety & Depression Scale (HADS)	Measure of anxiety and depression symptoms	Anxiety & Depression sub-scales, each range 0-21	Lower score indicates fewer symptoms
International Physical Activity Questionnaire (IPAQ) – 7-day recall version	Assessment of physical activity undertaken in the previous 7 days	Scores of minutes of activity per week spent walking, in moderate activity, and in vigorous activity, and in hours of sitting on a weekday	Increased levels of physical activity, or lower levels of sedentary behaviour, are associated with significant health benefits.
Pittsburgh Sleep Quality Index (PSQI)	Sleep quality	Global PSQI score range 0-21	Lower score indicates better sleep quality

192 **Table 2: Patient-rated Outcome Measures (PROMs) used**

Typically, patients are followed up three-months following ESWT, with a proportion also seen at six-weeks where appointment availability allowed. Patients are then routinely followed up after the three-month point if clinically required.

The ESWT procedure is registered with the hospitals New Intervention Procedure Group (NIPAG) and data is recorded here in the format of a service evaluation project and audit; therefore formal NHS ethics permissions were not required.

- Statistical analysis

Data was recorded at baseline, and on an on-going basis at clinic follow-up and collated into an Excel spreadsheet (MS Excel from MS Office 2011, version 14.5.7) and analysed in SPSS (IBM SPSS Statistics, version 22). From this dataset the majority of the outcome measures are scale data. Comparisons were made between the baseline data and data from the six-week, the three-month, and where data was present the six-month follow-up appointments. As the sample sizes were small, the Shapiro-Wilk test was used to assess normality and as the majority of the data was found to be not normally distributed the majority of the analysis was performed with non-parametric tests, typically the Wilcoxon Signed-Rank Test to look at pre/post differences.

Results

A total of 46 patients who underwent Extra-Corporeal Shockwave Therapy (ESWT) for symptoms of trochanteric pain syndrome were identified from procedural logs. All patients were treated with a Chattanooga Intelect RPW rESWT machine using the manufacturer's standard settings for GTPS (20.0Hz, 2000 shocks per session, 3 treatment sessions at weekly intervals.) The energy intensity was controlled by the performing practitioner based on patient comfort. (The mean(SD) figures were ESWT1 = 2.37(0.27) bar, ESWT2 = 2.94(0.41) bar, and ESWT3 = 3.44(0.52) bar)

In addition to the ESWT treatment, all patients were given a structured home exercise programme to complete with written supporting material discussing progressing this as a part of their treatment.

45 patients completed all three treatment sessions of ESWT. A single patient withdrew from ESWT after their second session of treatment as she has been involved in a road traffic collision (unconnected with her trochanteric pain or the ESWT treatment) and was unable to attend the final treatment session due to her other injuries. The data for this patient was therefore removed from analysis.

At least one set of follow-up results were available for all of the 45 patients that completed ESWT. Normally patients are invited for follow-up at six-weeks, and three-months following ESWT, and depending on symptoms also some are seen at six-months. Not all patients attended for a six-week appointment post-ESWT due to appointment scheduling and patient availability, with results available for 28/45

patients (62%) at the six-week time point, and 44/45 (98%) at the three-month time-point, which is set as the primary outcome period.

Depending on the level on on-going symptoms at three-months, some patients also had a six-month follow-up appointment booked, whereas others were left with an open appointment for them to contact the department if there were problems or questions. In total there were 27/45 responses from patients at six-months (60%), however these figures may be skewed by the presence of on-going symptoms at three-months and may represent those with either poorer or slower outcomes.

- Patients

36 of the 45 patients (80%) who completed all three ESWT treatments for trochanteric pain were female, and the majority of both male and female patients were either overweight or obese. There was an average(SD) age of 60.9 (15.4) years, with the youngest patient being 20 and the oldest being 86 years old. There was a mean duration of symptoms of 43 months before trying ESWT, however this was skewed by two patients having symptoms for ten years prior to ESWT, with the median duration of symptoms being 30 months.

Table 3 displays the demographic information for the patients in this series. Figures displayed are mean(SD)

n=	Age	Height (m)	Weight (kg)	BMI (kg/m^2)	%BMI 25-30	%BMI 30+	Symptom duration

								(months)
Male	9	58.8 (16.4)	1.76 (0.09)	82.8 (15.4)	26.9 (4.7)	56%	11%	43.3 (28.9)
Female	36	60.3 (15.4)	1.60 (0.07)	75.9 (12.7)	29.6 (4.8)	31%	44%	43.2 (30.5)
All	45	60.0 (15.4)	1.64 (0.10)	77.4 (13.4)	29.0 (4.8)	36%	38%	43.2 (29.8)

Table 3: patient demographics

Before ESWT was conducted, all patients had been given a home exercise programme; 91% had received formal physiotherapy input, the remainder had been given exercises and exercise sheets from other consulting healthcare professionals. There was a wide-range of treatment given prior to ESWT, with an average of 3.0 corticosteroid injections given by other healthcare professionals to patients prior to referral for ESWT (range 0-8), with patients reporting an average of 3.6 weeks of benefit from their most recent injection (range 0-20 weeks). One patient had previously undergone surgery for their trochanteric symptoms one year prior to being referred for ESWT. All patients had either received an MRI or an ultrasound scan to examine the condition of the relevant muscles / tendons prior to ESWT as a part of the consideration of treatment process.

- Side-effects from ESWT

278 The incidence of side-effects following ESWT is previously discussed and this was
279 investigated within this case series. Overall incidence of side-effects in this series is
280 low with 7% and 9% of patients reporting bruising at the 2nd / 3rd ESWT treatments
281 respectively, all of which had settled by the six-week and three-month follow-up
282 periods. No patient withdrew due to side-effects. Table 4 displays the incidence of
283 side-effects from the NICE audit criteria for this case series.
284

	At 2nd Treatment *(n=45)*	At 3rd Treatment *(n=45)*	At six-weeks *(n=28)*	At three-months *(n=43)*	At six-months *(n=27)*
Is there any evidence of local skin reddening over the treatment site?	0%	0%	0%	0%	0%
Is there any local bruising or haematoma over the treatment site?	7%	9%	0%	0%	0%
Is there any evidence of other local skin / soft tissue damage?	0%	0%	0%	0%	0%
Is there any local	0%	0%	0%	0%	0%

numbness of the treated area?					
Is there evidence of rupture of the structure being treated?	0%	0%	0%	0%	0%
Does the patient report any increased stiffness or worsened mobility following ESWT?	0%	2%	0%	0%	0%

Table 4: Incidence of side-effects following ESWT treatment

- Pain scores

The proportion of patients reporting themselves as pain free (VAS = 0) or virtually pain-free (VAS of 0 or 1) at six-weeks was 7% and 11% respectively, at three-months the figures were 9% and 18% respectively, and at six-months was 19% and 33% respectively.

Overall there was an average reduction in pain as assessed by a 0-10 Visual Analogue Scale (VAS) from 6.3 at baseline, to 4.1 at six-weeks, 3.8 at three-months, and 3.5 at

six-months post-ESWT. These changes in pain from baseline were found to be significant at all time-points at six or more weeks. This improvement correlates to an average reduction of pain of about a third at all follow-up time points recorded.

Table 5 displays the self-reported values for "average" pain, self-reported "worst" pain and "stiffness" at baseline and follow-up appointments - all figures are mean(SD) and use a 0-10 visual analogue scale (VAS), with the significance of any changes seen being calculated from baseline values.

	At baseline	**Before 2nd ESWT**	**Before 3rd ESWT**	**At 6 weeks**	**At 3 months**	**At 6 months**
"Average Pain" (0-10)	6.3 (1.7)	6.4 (1.8)	6.0 (2.0)	4.1 (2.6) *	3.8 (2.7) *	3.5 (2.8) *
"Worst Pain" (0-10)	8.2 (1.2)	x	x	6.3 (2.5) *	5.4 (2.9) *	5.0 (3.1) *
"Average Stiffness" (0-10)	5.3 (2.8)	x	x	3.7 (3.1) *	3.3 (2.6) *	2.7 (3.0) *

Table 5: displaying baseline and follow-up pain and stiffness scores (all marked on a 0-10 Visual Analogue Scale)

These values are displayed in the Figure 1

Figure 1 – Displaying trend for self-reported "worst pain", "average pain" and 'average stiffness" (0-10 scales)

The changes in "average pain", "worst pain" and "stiffness" were all significantly improved from baseline at all of the follow-up appointments. Although a trend of continued improvement appears to be shown in this series, for the "average pain" and "average stiffness" the differences between the figures at six-weeks and subsequent follow-ups did not reach statistical significance. For the "worst pain" there was a statistically significant improvement in pain at 6-months compared to 6-weeks, but not 3-months. These suggest that the majority of the benefits seen occur in the first 6-weeks after ESWT, although benefits appear to continue beyond this point.

- Sleep disturbance

Sleep disturbance is a commonly reported symptom from patients with trochanteric pain syndrome, with pain sleeping on either the affected or the opposite side commonly reported. Sleep quality was assessed by means of the Pittsburgh Sleep Quality Index (PSQI), a patient self-reported questionnaire, at baseline and subsequent follow-up appointments. This questionnaire rates a number of domains of sleep quality and gives individual subs-scales as well as a global score which is displayed here for simplicity, with a lower score indicating better sleep quality overall.

The following table displays the average (SD) global PSQI results obtained at baseline and at follow-up.

	Baseline	6-weeks	3-months	6-months
PSQI (global)	10.9 (3.7)	9.7 (4.2) *	9.1 (3.7) *	9.0 (4.0) *

Table 6: displaying the global PSQI scores at baseline and at follow-up

The changes of global PSQI score from baseline to six-weeks, baseline to three-months and baseline to six-months, each of between 1.2 and 1.9 points, were all found to be significant ($p<0.05$). However, the changes from six-weeks to either three or six-months, and three-months to six-months, were not found to be significantly different.

- Local and global measures of function

A range of other patient-rated outcome measures (PROMS) were used to assess outcome including several hip-region PROMS including the Non-Arthritic Hip Score (NAHS) and the Oxford Hip Score (OHS). In addition, as a marker of overall level of health status the EQ-5D-5L was used, and markers of both anxiety and depression were obtained through the use of the Hospital Anxiety and Depression Scale (HADS).

Table 7 displays the mean(SD) scores for the different PROMs in use.

Outcome measure	Baseline	6-weeks	3-months	6-months

Non-Arthritic Hip Score (NAHS) - total	39.8 (12.7)	45.3 (17.2) *	50.3 (18.6) *	53.6 (19.8) *
Oxford Hip Score (OHS)	23.4 (9.0)	29.3 (10.5) *	31.9 (10.7) *	33.4 (11.1) *
EQ-5D-5L - %health	67% (15%)	72% (13%) *	73% (19%)	77% (15%) *
Hospital Anxiety & Depression Scale (HADS) – Anxiety sub-scale	7.4 (4.3)	6.7 (4.1)	6.0 (4.0)	5.1 (3.3) *
Hospital Anxiety & Depression Scale (HADS) – Depression sub-scale	5.5 (3.0)	4.1 (2.7) *	4.4 (3.6) *	3.7 (2.7) *

Table 7: displaying PROM data at baseline and follow-up appointments

Many of the differences in scores from either baseline to six-weeks, baseline to three-months, or baseline to six-months showed a significant change ($p<0.05$) as indicated above. The depression sub-scale of the Hospital Anxiety and Depression Scale (HADS) was significantly improved following ESWT all time points, whereas the anxiety sub-scale was only significantly different at the six-month follow-up time point. The overall health% as recorded by the EQ-5D was only improved significantly at six-weeks and six-months, but not at three-months, however the hip-specific

patient-rated measures (Oxford Hip Score and the Non-Arthritis Hip Score) were both significantly improved at all time periods studied.

- Activity levels

Patients with trochanteric pain syndrome often report that pain is a barrier to their physical activity, therefore it may be assumed that if pain is reducing then physical activity may increase. The measure this, the rates of physical activity were recorded by using both the short form (7-day recall) International Physical Activity Questionnaire (IPAQ) and also the "Vital signs" questions discussed previously. The results are as displayed in table 8.

Activity measure	Baseline	6-weeks	3-months	6-months
IPAQ – vigorous-level activity in minutes / week	108 (379)	108 (360)	98 (342)	83 (196) *
IPAQ – moderate-level activity in minutes / week	242 (666)	185 (461)	233 (630)	136 (243)
IPAQ – walking in minutes/ week	362 (576)	404 (690)	463 (652)	497 (621) *
IPAQ – number of hours spent sitting on a week day	4.3 (3.4)	4.8 (3.0)	4.7 (3.1)	5.0 (3.0)

"Vital signs"				
– minutes of at least moderate level of activity / week	119 (360)	68 (124)	95 (177)	80 (154)

Table 8: displaying activity values at baseline and at follow-up

The only measures of physical activity that changed significantly from baseline was decrease in the number of minutes of vigorous activity, and an increase in the number of minutes of walking (both as assessed by the short-form IPAQ) measured at six-months post-ESWT compared to baseline the clinical implications of which are unclear.

- Further intervention rates

From the data set available, there was a median follow-up duration of 189 days for this cohort, with a maximum of 315 days. 18% of patients required consideration of further intervention as a result of persisting symptoms following ESWT, most typically review for surgical intervention or further corticosteroid injection, with 82% of this case series not requiring further intervention during the time period studied.

- Overall satisfaction

Overall levels of satisfaction with treatment was assessed on a 5-part Likert scale, with 63% of patients being either "satisfied" or "very satisfied" at 3-months, and at 6-months this figure had increased to 75% In addition patients were asked if they would recommend the ESWT treatment to a friend or family member with the same symptoms on a four-part Likert scale. At 3-months 70% of patients would either

394 definitely or probably recommend the ESWT procedure, and at 6-months this figure
395 was 80% At all time points, 7% or less would not recommend the procedure. Tables 9
396 and 10 display the results from these two questions.
397

	6-weeks (n=18)	**3-months (n=40)**	**6-months (n=24)**
Very satisfied	39%	45%	50%
Satisfied	39%	18%	25%
Neutral	11%	28%	17%
Dissatisfied	6%	5%	4%
Very dissatisfied	6%	5%	4%

398 **Table 9: "On the basis of your results currently, how satisfied are you**
399 **with the results that you have had so far?"**
400
401

	6-weeks (n=20)	**3-months (n=43)**	**6-months (n=25)**
Yes, definitely	55%	49%	64%
Yes, probably	20%	21%	16%
Maybe	20%	23%	16%
No	5%	7%	4%

402 **Table 10: "On the basis of your results so far, would you recommend**
403 **this procedure to a friend or family member with the same symptoms?"**
404

Discussion

This case series demonstrates that the majority of patients report improvement in their symptoms. At three-months nearly two-thirds of patients are satisfied with the results of their treatment and 70% would recommend the treatment to a friend or family member with the same symptoms. The data from this case series, and the previous published work on this topic suggest that Extra-Corporeal Shockwave Therapy can be an effective treatment for a number of patients with recalcitrant Greater Trochanteric Pain Syndrome, which has not settled with other simple conservative measures, and one which is worth considering in care pathways, access permitting. Patients in this case series had a range of symptom duration and different treatments tried prior to referral for ESWT. There was no difference found in reported success or improvement in pain levels for those with symptoms of 18 months or less, compared to those with symptoms greater than 18 months suggestive that ESWT is worth considering in appropriate patients even with long-standing symptoms.

Causality of benefit cannot be proven from this case series design of study alone, but these findings of improvement are in keeping with other published literature. The figures at three-months are the primary end-point with the highest proportion of respondents and patients are typically seen at six-months only if they have on-going or slow resolving symptoms or other concerns. It is possible therefore that even with the figures appearing to have improved at six-months from the three-month period, although this did not necessarily reach statistical significance, these may underestimate health benefits due to selection bias, with patients that are doing well

not returning at six-months. The magnitude of benefits may be greater than seen here, and this is worth consideration in further research.

The side-effect profile reported in this case series shows that the incidence of side-effects from ESWT treatment for Greater Trochanteric Pain Syndrome is relatively low, with no patients in this series failing to complete treatment due to side-effects, and less than 10% reported bruising. This is a lower figure that quoted in other sources, and this may represent the use of a modern and specific ESWT machine.

This case series has demonstrated an overall average improvement of at least a third in symptoms of pain and stiffness as reported by the patients, as well as improvements in a wide range of other measures of function. The use of simple pain-scores is a very crude outcome measure, and this series has used a range of validated patient-rated outcome measures (PROMs) including specific measures of hip function, and also global measures of function. This holistic view of patient function goes far beyond the use of simple pain-rating tools and should be considered in further work to identify the most relevant outcome measures. Some measures of both local and general functioning have significantly improved, although not all reported benefits. Mood disturbance with both anxiety and depression features as assed by the Hospital Anxiety and Depression Scale (HADS) showed significant improvements at a number of time-periods. Sleep disturbance is an often-reported symptom of Greater Trochanteric Pain Syndrome, and this case series has demonstrated an improvement in sleep quality, as assessed by the PSQI questionnaire at all time-points following treatment. It is accepted that there may be confounding that exists between the various

outcome measures studied, further work may be required to examine these complex interactions in more detail. However, these outcome measures identify specific individual factors that are commonly reported by patients as problems, and it is encouraging to see improvements across a range of different domains.

Physical activity has many benefits to health, and musculoskeletal pain is an often reported barrier to physical activity. Whilst the subjects in this case series had a significant improvement in their pain levels and corresponding level of functioning, they did not report a consistent improvement in activity levels. If anything the amount of vigorous activity may have decreased at the six-month period, although the amount of walking appears to have increased. It is possible that the reduction in pain seen at the same time, may be influenced by this change in activity level. Despite the reduction in pain, and positive messages being given during the rehabilitation programme about the benefits of activity, further interventions are likely to be required to increase levels of activity in order to achieve optimal health benefits in the longer term.

Many of the benefits in the parameters studied improved from baseline to the six-week period in particular, and whilst some improved beyond this, for several these further changes did not reach statistical significance. This is suggestive that the most benefits are gained in the early period following treatment, and it is not clear from this case series when these benefits plateau, meaning that longer-term follow-up may be helpful in identifying final outcome points. A larger series may be able to investigate

this aspect in more detail, as this series was likely to be affected by a 60% review rate at six-months.

In summary this case series has demonstrated a significant improvement in both pain and a wide-range of different outcome measures in the period following extra-corporeal shockwave therapy and a structured rehabilitation programme. These include a wide range of measures of patent functioning indicating improvement in a range of the symptoms that commonly affect patients with Greater Trochanteric Pain Syndrome. Further work looking at specific benefits of the shockwave itself compared to rehabilitation alone would be useful to quantify this aspect of therapy, and potentially longer-term follow-up may be helpful to see where benefits plateau, which may avoid further interventions being done at a too early time-point, and allow better quality information to be given to patients about longer-term outcomes.

- **Abbreviations used**

ESWT – Extra-Corporeal Shockwave Therapy

GTPS – Greater Trochanteric Pain Syndrome

- **Ethics approvals**

This series is registered at the host NHS Trust as clinical audit. Formal NHS ethics approvals are not required as this constitutes usual treatment. No patient identifiable information is included.

- **Consent to publication**

Not applicable - No patient identifiable information is included.

- **Availability of data**

The raw data contained in this publication is not being made publically available at this time. This represents on-going clinical audit, data from this is are shared with the host trust audit team as per local policy.

- **Competing interest**

The authors have no potential conflicts of interest to declare

- **Funding**

No funding sources to declare. Clinical audit performed within employed role at host hospital trust.

- **Author contributions**

Both authors were involved in the clinical aspects of the cases in this manuscript. The corresponding author took the lead in data analysis and evaluation. The manuscript was prepared and checked by both authors.

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Fig 1 - displaying change in pain scores

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