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A commentary by Mengnai Li, MD, PhD, is linked to the online version of this article at jbjs.org.

Focused Shockwave Treatment for Greater Trochanteric Pain Syndrome

A Multicenter, Randomized, Controlled Clinical Trial

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Background: Greater trochanteric pain syndrome (GTPS) is a condition of lateral hip pain. Its physiopathology remains unknown, and there is no consensus on optimal management. The aim of this study was to assess the effectiveness of electromagnetic-focused extracorporeal shockwave treatment (F-ESWT) in patients with GTPS.

Methods: This multicenter clinical trial included 103 patients with chronic GTPS randomly assigned to the treatment group, consisting of electromagnetic F-ESWT and a specific exercise protocol, or the control group, receiving sham F-ESWT and the same exercise protocol. Both groups were treated with 3 weekly sessions; the F-ESWT group received an energy flux density of 0.20 mJ/mm^2, whereas the control group received 0.01 mJ/mm^2. Patients were assessed at baseline and 1, 2, 3, and 6 months after treatment. A visual analogue scale (VAS) score for pain at 2 months was the primary outcome. The Harris hip score (HHS), Lower Extremity Functional Scale (LEFS), EuroQoL-5 Dimensions Questionnaire (EQ-5D), and Roles and Maudsley score were used as secondary outcomes. Complications were recorded.

Results: The mean VAS score decreased from 6.3 at baseline in both groups to 2.0 in the F-ESWT group versus 4.7 in the control group at 2 months; the 2-month score differed significantly between groups ($p < 0.001$). All secondary outcomes at all follow-up intervals were significantly better in the F-ESWT group, except for the LEFS score at 1 month after treatment ($p = 0.25$). No complications were observed.

Conclusions: F-ESWT in association with a specific exercise program is safe and effective for GTPS, with a success rate of 86.8% at 2 months after treatment, which was maintained until the end of follow-up.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Greater trochanteric pain syndrome (GTPS) is a common condition of lateral hip pain, evocable by palpation and exacerbated by a side-lying position and physical exercise[1-4]. It has an incidence rate of 1.8 to 5.6 per 1,000 subjects per year, is more frequent between the ages 40 and 60 years, and has a female-to-male preponderance of 4:1[1,3,5]. The relationship between GTPS and trochanteric bursitis[5-9], historically considered the same entity, has been reviewed in the literature, with treatments often targeting the bursitis[10,11]. The physiopathology of GTPS remains unknown; tendinopathy is the most frequent finding[2,3,6,12]. It has been associated with repetitive friction between the greater trochanter and the iliotibial band, causing microtrauma to the gluteal tendons at the insertion of the greater trochanter, leading to tendon degeneration[8]. Bird et al. demonstrated that the pathological findings in the gluteus medius and minimus tendons seen on magnetic resonance imaging (MRI) are important in defining GTPS and showed that trochanteric bursal distension was found in only 8.3% of patients[3]. Therefore, bursitis should be considered to represent an associated factor[6,8,9,13]. This change

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of paradigm renews the interest in the diagnostic and therapeutic approach to GTPS[14].

Recent systematic reviews of GTPS[10,14] and lower-limb tendinopathy[15,16] management have included the role of focused extracorporeal shockwave treatment (F-ESWT) and radial pressure waves[17,18], despite these being 2 different treatment modalities with varying levels of evidence[19]. Reviews on shockwave treatment recently confirmed the efficacy of F-ESWT for other tendinopathies[19-21]. Carlisi et al. demonstrated the effectiveness of piezoelectric F-ESWT in reducing the pain of GTPS at short and mid-term follow-up[22]. Seo et al. confirmed the positive effect of electrohydraulic F-ESWT for GTPS with a short-term success rate of 83.3%[23]. Both F-ESWT and radial pressure waves are effective therapeutic strategies for tendinopathies, with a grade-B level of recommendation for GTPS[19]. While radial pressure waves are suitable for treating large and superficial areas, F-ESWT technology allows the pressure waves to be concentrated deep inside the body[19], as in the case of gluteal tendons. The International Society for Medical Shockwave Treatment (ISMST) included GTPS in a list of clinical indications for F-ESWT based on evidence[24]. Biological patterns involved in the F-ESWT mechanism of action include anti-inflammation, neovascularization, anti-apoptosis, direct suppressive effects on nociceptors, chondroprotective effect, and tissue and nerve regeneration[19,25]. Several studies showed F-ESWT efficacy for tendinopathies[26,27]. Therefore, the aim of the study was to evaluate the effectiveness and safety of electromagnetic F-ESWT in patients with GTPS.

Materials and Methods

This multicenter, randomized, controlled clinical trial was registered in ClinicalTrials.gov (NCT03338465). It was conducted in 3 centers: 2 in Italy (Physical Medicine and Rehabilitation [PMR] Unit, Sant'Andrea Hospital, Sapienza University of Rome and Department of Orthopedics and Traumatology, Federico II University Hospital, Naples) and 1 in Spain (PMR Hospital Quirónsalud, Barcelona). The 140 consecutive patients referred to 1 of these 3 medical centers from November 2017 to January 2019 were screened for eligibility for enrollment in the study. The recruitment procedure included an initial screening visit, followed by a hip radiograph and a sonographic or magnetic resonance imaging (MRI) examination of the gluteal tendons and trochanteric bursa. Patients of either sex were eligible for inclusion if they (1) were ≥18 years old, (2) had unilateral pain in the greater trochanteric area for >3 months, (3) had pain while lying on the affected side, (4) had local tenderness on palpation of the greater trochanteric area, and (5) signed an informed consent form. The exclusion criteria were (1) signs, symptoms, and complementary studies indicating osteoarthritis, calcification, a tendon tear, or another cause of hip pain; (2) hip internal rotation of ≤20° or another range of motion of ≤10°; (3) previous hip surgery; (4) persistent low-back pain; (5) vascular, neurologic, or rheumatic disease; (6) neoplasia or local infection in the hip; (7) pregnancy; (8) severe coagulation disorders or anticoagulant therapy; (9) another nonoperative treatment for GTPS in the last 3 months, excluding analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs); and (10) previous shockwave treatment.

Of 140 patients assessed for eligibility, 103 with GTPS were enrolled and randomly assigned, using the Excel (Microsoft) RAND function, into 2 groups. Patients, assessors, data managers, statisticians, and study monitors were blinded to the treatment group allocation.

Treatment

An F-ESWT device (Duolith SD1 Ultra; Storz Medical) was used. Patients were treated in the lateral decubitus position, using a coupling ultrasound gel and an ultrasonic guide to concentrate the shockwaves on the greater trochanter area of the gluteus tendons enthesis. No local anesthesia was applied. Both groups were treated with 3 weekly sessions. At each session, 2,000 impulses were applied with a frequency of 5.0 Hz. The F-ESWT group received an energy flux density (EFD) of 0.20 mJ/mm^2, whereas the control group received 0.01 mJ/mm^2 (the lowest EFD of the device). The presence of the typical sound of the F-ESWT instrument during the treatment of both groups ensured the blindness regarding the group allocation. All of the patients received the same home-specific exercise program[17,28-30], to perform once a day for 24 weeks (see Appendix).

Outcome Measures

Patients were assessed at baseline and 1, 2, 3, and 6 months after the last session by clinicians blinded to the group allocation. The difference in the score on a visual analogue scale (VAS) for pain, ranging from 0 (absence of pain) to 10 (unbearable pain) points[31,32], at 2 months after the last treatment session was the primary outcome. The secondary outcomes included:

1. Harris hip score (HHS), which evaluates hip disability using questions about pain and daily life activities in the previous week and hip function and range-of-motion assessments. The scores range from 100 (no disability) to 0 (maximum disability)[33].
2. Lower Extremity Functional Scale (LEFS), a self-report questionnaire measuring the patients' initial function, ongoing progress, and outcome with regard to the lower extremity. The score ranges from 80 (very high function) to 0 (very low function)[34-36].
3. EuroQoL-5 Dimensions Questionnaire (EQ-5D), which evaluates patients' quality of life. It consists of a 5-dimension subjective assessment, with each item providing the option to choose a level of severity, graduated from 1 (absence of problems) to 3 (extreme limitation)[37].
4. Roles and Maudsley (RM) treatment satisfaction scale, which assesses pain and limitation of activity with a 4-point system (1 = excellent result; 2 = significant improvement; 3 = somewhat improved; and 4 = poor, with symptoms identical or worse than before treatment). The RM score has been widely used when reporting results of shockwave treatment[18,23].

Ethical Approval

The study was approved by the Independent Ethics Committee of Sapienza University of Rome (number 5143, protocol 219SA_2018) and of the Grupo Hospitalario Quirónsalud in Barcelona (reference Trocánter-Ondas_39_1.2). The research was conducted in accordance with the World Medical Association Declaration of Helsinki.

Statistical Analysis

Continuous variables are given as the mean and standard deviation (SD), while categorical variables are given as the frequency and percentage. The normality distribution of data was determined for each variable using graphical methods and the Shapiro-Wilk test. An a priori power analysis was conducted based on the difference between groups with regard to the mean VAS at the 2-month follow-up (the primary outcome). Assuming an alpha error of 0.05, a power of 0.90, a mean difference between groups of 2.0 points in the 2-month VAS score with an SD of 2.5, and a dropout rate of 20%, the estimated number of patients needed to be studied per group was 42. The estimated difference in the mean VAS score of 2 points between groups was based on previous intervention studies[18,22].

The unpaired Student t test was used to compare the group means for the scores for the secondary outcomes at the various follow-up time points. The Fisher exact test was used for noncontinuous variables.

Data analysis was carried out based on the intention-to-treat (ITT) approach. The significance level was $p < 0.05$. All analyses were conducted with IBM SPSS Statistics for Windows, version 21.

Results

Of 140 patients screened, 103 were allocated and treated according to the randomization in the study protocol

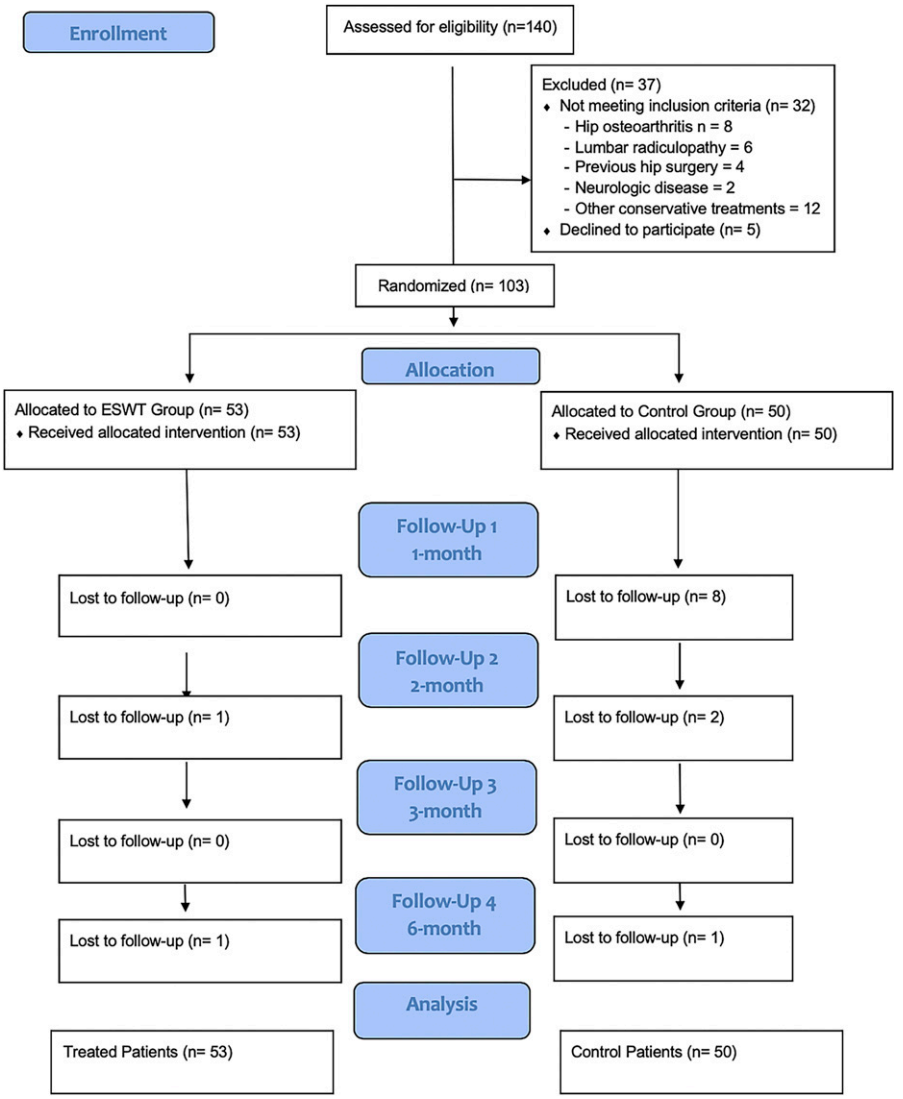

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flowchart of enrollment and analysis.

TABLE I Baseline Characteristics of Randomized Patients

	F-ESWT (N = 53)	Control (N = 50)	P Value
Age* *(yr)*	57.1 ± 12.9	55.6 ± 11	0.52
Sex: female†	42 (79)	32 (64)	0.08
Side: right†	30 (57)	28 (56)	0.95
Diagnosis†			0.74
Tendinopathy	29 (55)	29 (58)	
Bursitis	10 (19)	11 (22)	
Tendinopathy + bursitis	14 (26)	10 (20)	
VAS*	6.3 ± 1.8	6.3 ± 1.4	0.67
HHS*	65.0 ± 13.5	65.9 ± 11.2	0.71
LEFS*	50.3 ± 15.7	49.6 ± 13.1	0.82
EQ-5D*	0.53 ± 0.3	0.6 ± 0.2	0.28

*The values are given as the mean and SD. †The values are given as the number with the percentage in parentheses.

(Fig. 1). No significant intergroup differences were found at baseline assessment (Table I). During the follow-up, 13 patients (2 in the F-ESWT group and 11 in the control group) dropped out before the end of the study. Their missing responses were imputed as the last observation carried forward, using an ITT approach.

No complications were observed.

Primary Outcome Measure

The mean VAS score at 2 months was significantly better in the F-ESWT group (2.0 ± 2.1) than in the control group (4.7 ± 2.1; $p < 0.001$). The average difference of 2.7 points reached the hypothesized estimate for the power analysis calculation.

Secondary Outcome Measures

Between-group analysis showed significant differences in all of the secondary outcomes at all follow-up times in favor of the F-ESWT group (Tables II, III, and IV). The only exception was the LEFS score at 1 month, which improved in both groups without a significant difference between them ($p = 0.25$).

HHS

The mean pretreatment HHS was 65.0 ± 13.5 for the F-ESWT group and 65.9 ± 11.2 for the control group ($p = 0.71$). The F-ESWT group had greater improvement in HHS than the control group ($p < 0.01$ at 1 month and $p < 0.001$ at the other time points) (Table II).

LEFS

The mean pretreatment LEFS score was 50.3 ± 15.7 for the F-ESWT group and 49.6 ± 13.1 for the control group ($p = 0.82$). The magnitude of the change in the LEFS score was significantly greater for the F-ESWT group, except at 1 month ($p = 0.25$ at 1 month; $p < 0.003$ for the other time points) (Table II).

EQ-5D

The mean pretreatment EQ-5D health status score was 0.53 ± 0.31 for the F-ESWT group and 0.56 ± 0.24 for the control group ($p = 0.28$). The magnitude of the change in the EQ-5D score was significantly greater for the F-ESWT group ($p < 0.025$ at 1 month and $p < 0.001$ for the other time points) (Table II).

RM Score

The mean RM score was significantly better for the F-ESWT group compared with the control group ($p < 0.001$ at each time

TABLE II HHS, LEFS, and EQ-5D

	Mean ± SD		
	F-ESWT	Control	P Value
HHS			
Baseline	65.0 ± 13.5	65.9 ± 11.2	0.71
1 mo	80.0 ± 12.4	73.5 ± 12.2	<0.01
2 mo	88.5 ± 11.2	77.6 ± 12.6	<0.001
3 mo	90.4 ± 10.3	78.0 ± 11.7	<0.001
6 mo	91.0 ± 10.3	79.4 ± 12.5	<0.001
LEFS			
Baseline	50.3 ± 15.7	49.6 ± 13.1	0.82
1 mo	57.3 ± 14.8	54.0 ± 13.7	0.25
2 mo	65.7 ± 12.7	56.5 ± 14.6	<0.001
3 mo	67.6 ± 12.0	60.6 ± 10.4	0.003
6 mo	68.1 ± 11.0	60.6 ± 12.4	0.002
EQ-5D			
Baseline	0.53 ± 0.31	0.56 ± 0.24	0.28
1 mo	0.72 ± 0.22	0.62 ± 0.18	0.025
2 mo	0.82 ± 0.17	0.66 ± 0.22	<0.001
3 mo	0.85 ± 0.14	0.68 ± 0.15	<0.001
6 mo	0.83 ± 0.14	0.69 ± 0.15	<0.001

TABLE III RM Scores

	Mean ± SD	P Value
1 mo		<0.001
ESWT	2.26 ± 0.79	
Control	2.96 ± 0.76	
2 mo		<0.001
ESWT	1.81 ± 0.81	
Control	2.64 ± 0.87	
3 mo		<0.001
ESWT	1.64 ± 0.79	
Control	2.45 ± 0.73	
6 mo		<0.001
ESWT	1.59 ± 0.85	
Control	2.53 ± 0.77	

TABLE IV Percentage Distribution of RM Scores

	Excellent or Good* (%)	Fair or Poor† (%)
1 mo		
F-ESWT	64.2	35.8
Control	21.7	78.3
2 mo		
F-ESWT	86.8	13.2
Control	38.7	61.3
3 mo		
F-ESWT	84.9	15.1
Control	54.5	45.6
6 mo		
F-ESWT	88.5	11.5
Control	53.4	46.6

*RM score of 1 or 2. †RM score of 3 or 4.

point) (Table III). The percentages of patients with an excellent result (an RM score of 1) or significant improvement (an RM score of 2) were significantly greater in the F-ESWT group compared with the control group at each time point (64.2% versus 21.7% at 1 month, 86.8% versus 38.7% at 2 months, 84.9% versus 54.5% at 3 months, and 88.5% versus 53.4% at 6 months; $p < 0.001$ for all) (Table IV).

Discussion

GTPS is a clinical condition whose exact pathogenesis is still unknown and for which optimal treatment protocols have not been defined[5]. Nonsurgical therapy is the mainstay of managing GTPS and includes NSAIDs, physiotherapy, therapeutic exercises, shockwaves, platelet-rich plasma, or corticosteroid injections[14,38]. Surgical treatment is generally reserved for recalcitrant cases for which nonoperative management has failed[11,39-43]. Shockwave treatment recently gained a relevant position as a nonoperative treatment[15,16]. Grimaldi et al. emphasized the dearth of scientific evidence for both surgical and nonoperative management of GTPS[44,45]. In a recent systematic review, Barratt et al. confirmed the lack of high-quality research regarding the nonoperative treatments for GTPS[14].

On the other hand, research has provided evidence supporting ESWT and radial pressure waves for lower-limb tendinopathy[15]. In 2009, 2 different studies demonstrated the effectiveness of radial pressure waves for GTPS in the short and long term[17,18]. In a randomized controlled clinical trial, Rompe et al. found, at 4 and 15 months of follow-up, that radial pressure waves provided better results than corticosteroid injections and home exercises for patients with GTPS[17]. In a case-control study, Furia et al. demonstrated that patients with GTPS treated with radial pressure waves had better outcomes at 1, 3, and 12 months than those treated with other nonoperative treatments[18]. In a recent retrospective study, Seo et al. showed the effectiveness of electrohydraulic low-energy F-ESWT (EFD = 0.10 mJ/mm^2) for pain relief in patients with GTPS but its long-term effect appeared to decrease with time[23]. A randomized clinical trial by Carlisi et al. showed piezoelectric F-ESWT for GTPS to be more effective than ultrasound therapy for reducing pain at short-term and mid-term follow-up[22].

To our knowledge, the current multicenter, prospective, randomized clinical trial is the first study to evaluate the effectiveness of a focused electromagnetic device for GTPS and the first to include sham F-ESWT as a control. Our study showed early pain reduction and improvement on functional, quality-of-life, and treatment-satisfaction scales from the first month and throughout the follow-up period. Sixty-four percent of patients in the F-ESWT group showed an excellent or good result at 1 month, with the result improving to 86.8% at 2 months, compared with 21.7% and 38.7% at 1 and 2 months, respectively, in the control group. The 2 previous trials of F-ESWT in GTPS[22,23] showed some differences in comparison with our study. Our sample size is superior to those in the studies by Seo et al.[23] and Carlisi et al.[22], which included 18 and 50 patients, respectively. We used 3 treatment sessions for each patient and the same EFD continuously during the entire session. In contrast, Seo et al. applied 600 shocks at 0.10 mJ/mm^2 and a variable number of sessions, depending on the patients' recovery, and surprisingly up to 12 sessions, which is not a standard protocol approved by DIGEST (the German ESWT society)[46] or the ISMST. Carlisi et al. compared piezoelectric F-ESWT—3 sessions of 1,800 pulses with the first 300 shocks at 0.05 mJ/mm^2 and the rest at 0.15 mJ/mm^2—with ultrasound therapy. We considered it important to demonstrate the short-term and mid-term effectiveness of F-ESWT as patients want pain to be alleviated as soon as possible. Moreover, the use of sham F-ESWT allowed us to confirm the effectiveness of F-ESWT by comparing it with a control group. Surprisingly, 80% of the patients with GTPS in the study by Carlisi et al. showed calcific tendinopathy around the trochanter on ultrasound evaluation, which highlights the importance of applying F-ESWT instead of radial pressure waves for GTPS. Calcific tendinitis, which requires high energy levels, was an exclusion criterion in our study.

Imaging techniques demonstrated an underlying bursitis as a cause of GTPS in 21 (20%) of our 103 patients (Table I), in contrast to the 8.3% rate of bursitis seen on MRI in the study by Bird et al.[3].

The better global results in our study were influenced by the application of medium energy levels to our patients (to guarantee higher effectiveness from our technology), compared with low energy levels in the study by Seo et al.[23] and very low energy levels in the study by Carlisi et al.[22]. According to the RM score, 86.8% of the patients in our F-ESWT group showed excellent or good results at 2 months compared with 38.7% in the control group at the same time point. F-ESWT would be expected to have long-term satisfactory results based on 2-year follow-up results in previous studies of shockwave therapy for tendinopathies[45-47]. Clarification of underlying pathogenic mechanisms may aid in the development of a better management strategy for GTPS. A correct GTPS differential diagnosis

may facilitate selection of patients who will benefit the most from F-ESWT.

There are several limitations of this study. The first is the lack of follow-up of >6 months after the intervention. Second, since the control group received 3 F-ESWT sessions at the lowest EFD of the equipment it could be considered a quasi-placebo group. Third, we lacked exact data on patients' compliance with the home exercise protocol. Fourth, although women were more likely to be in the treatment group, a sample size of 103 patients may be not large enough to detect important differences in responses to the intervention between the sexes.

Further research is necessary to confirm the long-lasting effectiveness of F-ESWT for GTPS.

Conclusions

F-ESWT associated with a specific exercise program is safe and effective for GTPS, with a success rate of 86.8% at 2 months after treatment, which was maintained until the end of follow-up. Future high-quality randomized clinical trials are needed to elucidate the optimal shockwave treatment parameters for tendinopathies and to determine their long-term efficacy for patients with GTPS.

Appendix

Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F951). ■

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