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Focused extracorporeal shock wave therapy for greater trochanteric pain syndrome with gluteal tendinopathy: a randomized controlled trial

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Abstract

Objectives: To investigate if focused extracorporeal shock wave therapy (f-ESWT) is an effective treatment in a population affected by greater trochanteric pain syndrome (GTPS).
Design: Randomized controlled trial, with blind outcome assessors.
Setting: Outpatients, University Hospital.
Subjects: A total of 50 patients affected by GTPS with gluteal tendinopathy.
Interventions: The study group was assigned to receive f-ESWT, the control group received ultrasound therapy (UST).
Main measures: We assessed hip pain and lower limb function by means of a numeric rating scale (p-NRS) and the Lower Extremity Functional Scale (LEFS scale), respectively. The first follow-up evaluation (2M-FUP) was performed two months after the first treatment session, the second (6M-FUP) was carried out six months later.
Results: The mean age of the population was 61.24 (9.26) years. A marked prevalence of the female sex was recorded (44 subjects, 86%). The statistical analysis showed a significant pain reduction over time for the study group and the control group, the f-ESWT proving to be significantly more effective than UST ($P < 0.05$) at the 2M-FUP (2.08 vs 3.36) and at the 6M-FUP (0.79 vs 2.03). A marked improvement of the LEFS total score was observed in both groups as well, but we found no statistical differences in the comparisons between groups.
Conclusion: Our findings support the hypothesis that f-ESWT is effective in reducing pain, both in the short-term and in the mid-term perspective. We also observed a functional improvement in the affected lower limb, but, in this case, f-ESWT showed not to be superior to UST.

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Greater trochanteric pain syndrome, tendinopathy, shock wave

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Introduction

Greater trochanteric pain syndrome (GTPS) is characterized by lateral hip pain, usually exacerbated by weight-bearing activities and by rolling over in bed. Traditionally, the diagnosis is based on clinical findings, pain to palpation in the greater trochanteric area being the most traceable sign at the physical examination. Thanks to an extensive use of sonography and magnetic resonance imaging in the last decade, gluteal tendinopathy has been recognized as a frequent cause, particularly in case of chronic trochanteric pain.[1–3] Nevertheless, there are still few scientific evidences about the optimal conservative therapy to be used. Efficacy on pain control of corticosteroid injection and non-steroidal anti-inflammatory drugs is proven but usually limited in time.[4–7] In the field of the classical physical therapies, including stretching and strengthening exercise, there is a lack of scientific evidence confirming a clinical efficacy, as well as in other tendinopathies.[4,5,8–11]

Among conservative therapies, extracorporeal shock wave therapy appeared to provide beneficial effects in various insertional tendinopathies,[12–14] the way of action being based on a mechano-transduction pathway, stimulating a regenerative biological activity.[15–17] The more established type of medical shock wave involves focused shock wave therapy. Focused shock wave systems are built to deliver mechanical energy in a small focal area at a settled depth in the subcutaneous tissues. Another form of treatment is radial shock wave therapy, producing unfocused waves, with a considerably lower peak-pressure and penetration.[12–14] To date, results from clinical studies showed better mid-term and long-term outcome for radial shock wave therapy, compared with other conservative treatments,[7,18] but the clinical efficacy of focused shock wave therapy, despite an extensive use in clinical practice, has yet to be proved in patients affected by GTPS.

The aim of this study is to investigate if focused extracorporeal shock wave therapy is an effective treatment, with respect to hip pain and lower limb function, in a population affected by GTPS with gluteal tendinopathy.

Methods

This study was conducted as a randomized controlled trial with blind outcome assessors. It was registered at clinicaltrial.gov (NCT03142971), it was approved by the local ethical board ('Area Vasta Pavia' Bioethics Committee: P-20120040185) and was drawn up in accordance with the CONSORT 2010 Statement Guidelines.[19]

All consecutive subjects, affected by GTPS and referred to our medical centre from 2013 to 2016, were screened for inclusion in an outpatient rehabilitative setting. The recruitment procedure, performed by a physical and rehabilitation medicine specialized physician, included a clinical examination of the affected hip, a neurological examination of the lower limbs, an X-ray of the pelvis and a sonographic examination of the gluteal tendons. Eligibility criteria were as follows:

- Unilateral hip pain of six weeks or longer duration;
- Pain to palpation in the greater trochanteric area and pain with resisted hip abduction at physical examination;
- Gluteal tendinopathy, in the absence of full-thickness tears, demonstrated at a sonographic examination of the gluteal tendons (see below for diagnostic criteria);
- No corticosteroid injections or other conservative therapies (except pharmacological pain treatments), since the onset of the current pain episode;
- No general contraindication to shock wave therapy (pacemaker, pregnancy, bleeding disorders

or anticoagulant drug usage, cancer in the focal area);
- No clinical signs of lumbar radiculopathy at physical examination;
- No hip osteoarthritis, diagnosed on the basis of clinical and radiographic findings, according to Altman et al.'s[20] criteria;
- No history of knee osteoarthritis;
- No previous fractures or surgery in the affected limb;
- No rheumatologic diseases;
- Adult age (18–80 years);
- Written consent.

We performed the sonographic examination of the gluteal tendons, with respect to morphology and echo-texture, in both longitudinal and transverse planes, referring to previous medical literature to properly define tendinopathy, partial and full-thickness tendon tears.[21] In particular, we recorded calcific tendinopathy in presence of hypoechoic changes in the fibrillar pattern of the tendon, associated to one or more focal areas of calcification. Non-calcific tendinopathy was recorded instead if hypoechoic changes in the fibrillar pattern were present but not associated to some foci of calcification. Subjects presenting trochanteric bursitis, in the absence of any sonographic sign of gluteal tendinopathy, were excluded.

Enrolled patients were then randomized to receive either focused extracorporeal shock wave therapy (study group) or ultrasound therapy (control group). The patients' allocation was performed by a computer-generated randomization list, using the command 'ralloc' of the STATA statistical software and by the use of prefilled envelopes, indicating which group each patient was allocated to. A clinician, blinded to the treatment allocation recorded, demographics, pain duration and localization (side of the pathology) and evaluated patients for outcome measures at baseline (the week prior to the treatment) and during the follow-up. Patients and clinicians performing treatments were not blinded to the treatment allocation.

As outcome measures, we analysed lateral hip pain by means of a pain-on-movement numeric rating scale (with a score range 0–10) and lower limb function. For practical reasons and in order to monitor the trend of moderate-to-severe pain over time, the proportion of patients reporting a numeric rating scale score $\geqslant 4$ was also considered.[22] Function was tested using the Lower Extremity Functional Scale, a self-administered questionnaire designed to measure functional performances of the lower limbs in relation with symptoms.[23] The Lower Extremity Functional Scale ranges from 0 (complete inability) to 80 (no functional limitation). We were particularly interested in item K and T, respectively investigating limitations in walking two blocks and rolling over in bed, both reflecting the most frequently reported limitation at the first medical examination. Outcome measures were repeated two and six months after the first treatment session.

We allowed the use of pharmacological pain therapies during the study protocol, specifically paracetamol 1000 mg or ibuprofen 400 mg daily for five days, in case of transient pain exacerbations. To better focus on pain-related functional limitations, we asked patients to avoid the intake of pain therapies, if pain was tolerable, the day we assess outcome measures only, at baseline and at both follow-up assessments. Each time they returned to the clinic for the follow-up, we recorded the drug assumption.

Patients in the study group were treated with focused extracorporeal shock wave therapy once a week for three consecutive weeks. At the beginning of each treatment session, with the patients lying in lateral decubitus position, the enthesis of the gluteus medius on the anterior part of the greater trochanter's lateral facet was targeted through a non-inline sonographic focusing, using a linear probe (7.5–12 MHz) connected to an ultrasound scanner (ESAOTE MYLAB FIVE, Genova and Florence, Italy). A device powered by a piezoelectric generator (PIEZOSON 100PLUS, Richard Wolf) was used for shock wave therapy. All patients received 1800 pulses (frequency = 4 Hz) of an energy flux density of 0.15 mJ/mm^2 with a perpendicular technique. At the first treatment session, the energy flux density was gradually increased from 0.05 to 0.15 mJ/mm^2 during the first 300 pulses. We placed a coupling gel between the probes and the skin.

Patients in the control group were treated with ultrasound therapy daily for 10 consecutive days. We used a mono-frequency ultrasound device (ROLAND, RT-20 series, frequency = 1 MHz). With the patients lying in lateral decubitus position, we treated an area of 5 cm^2, softly moving the probe around the most painful point of the greater trochanter at the clinical palpation. Ultrasound therapy was supplied in a continuous modality, with an intensity of 1.5 W/cm^2 in sessions of 10 minutes each. We placed a coupling gel between the probe and the skin.

Considering a percentage of patients with a pain numeric rating scale score $\geqslant 4$ equal to 70% in the ultrasound therapy group and a percentage equal to 30% in the focussed extracorporeal shock wave therapy group, with 23 patients per group, a power of 81% will be achieved. Fisher exact test with an alpha error equal to 5% was used to determine the sample size. Expecting a drop-out rate of 10%, the number of patients needed will be approximately 50.

Quantitative variables were described as mean and standard deviation if normally distributed (Shapiro–Wilk test), as median and interquartile range if not normally distributed; qualitative ones as counts and percentages. Univariate comparisons between two groups were performed with Student's *t*-test (or similar non-parametric tests) for quantitative variables; chi-square test or Fisher exact test were used to evaluate statistical associations between qualitative variables. Univariable and multivariable linear regression models for repeated data over time were used in order to compare pain numeric rating scale and Lower Extremity Functional Scale scores in the two treatment groups. Univariable and multivariable logistic regression models for repeated data over time were performed in order to analyse percentage differences of patients with pain numeric rating scale score $\geqslant 4$ between the two treatment groups. Post estimation tests were performed with Wald test. The main analysis was by 'Intention to Treat', considering subjects being analysed in the group to which they were allocated whether or not they had the treatment; an analysis 'Per Protocol', only considering patients who had the treatment that they were supposed to have, was also performed in order to get a more sensitive evaluation of the differences between the two groups. All tests were two-sided. A *P*-value <0.05 was considered statistically significant. Data analysis was performed with the STATA statistical software, version 14 (Stata Corporation, College Station, 2015, Texas, USA).

Results

The trial profile is synthetized in the flow diagram (Figure 1).

Data about basic demographics and outcome measures at baseline are shown in Table 1. We observed no statistical differences between groups at baseline, even for the outcome measures, and we recorded a sonographic evidence of calcific tendinopathy in 80% (40) of the patients, the remaining being affected by non-calcific tendinopathy.

All the participants in the study group felt the shock wave therapy unpleasant but tolerable. No assumption of painkillers, due to the discomfort of the shock wave therapy itself, was recorded. We observed no local side-effect. We recorded, at the follow-up at two months, a pain exacerbation in three subjects (two in the control group), who needed to assume paracetamol in two cases and ibuprofen in one. At the follow-up at six months, we recorded four pain exacerbations (three in the control group), respectively treated in two cases with paracetamol again (the same patients reported at the two months follow-up) and in two cases with ibuprofen. Between the follow-up assessments, two other subjects needed to assume ibuprofen for transient back pain.

Regarding 'Intention to Treat' analysis, the descriptive statistics of the outcome measures for the two groups at both follow-up assessments, together to the respective *P*-values for comparisons between groups at different observation times, are reported in Table 2. Outcome measure of the two groups at different observation times are also graphically shown in Figure 2(a) and (b), where *P*-values for comparisons within group and between groups are reported. For results of the 'Intention to Treat' between groups analysis and of the within group analysis see also Supplemental Tables 1a, 2a and

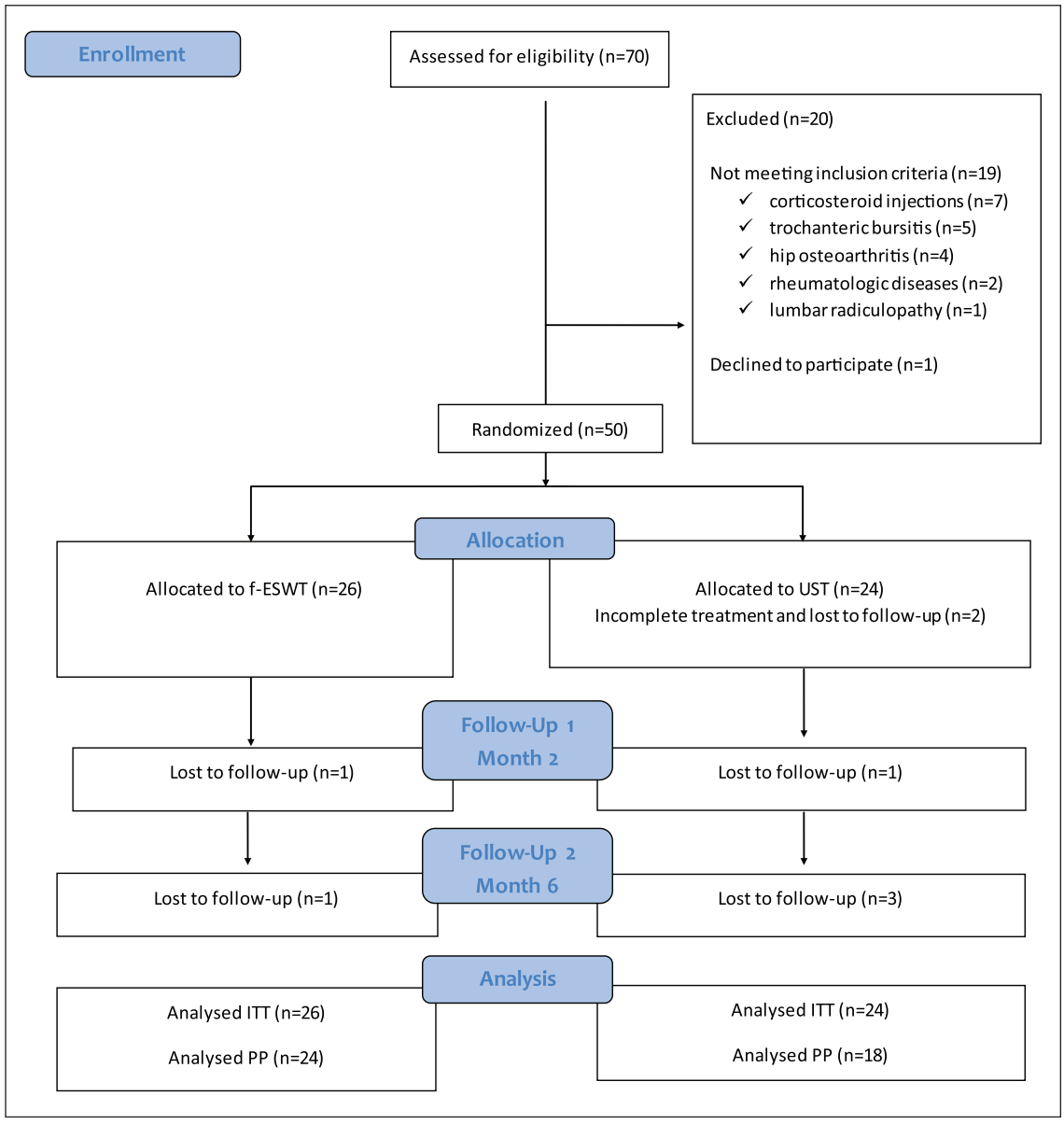

Figure 1. The Consort flow diagram of the study.
f-ESWT: focused extracorporeal shock wave therapy; UST: ultrasound therapy; ITT: intention to treat; PP: per protocol.

2d. Comparisons between groups, regarding pain-on-movement numeric rating scale values, were statistically significant at both follow-up assessments. In both groups, the number of patients reporting a pain numeric rating scale score ⩾4 reduced at both follow-up times compared to baseline. No statistical significance in the comparisons between groups was found for Lower Extremity Functional Scale total score; item K and T followed the same trend as total score. When adjusting for body mass index (BMI) and for pain duration, the results reported for the analysed outcomes did not change

Table 1. Demographic and clinical features at baseline, for the overall sample and for each group.

	Overall ($n=50$)	f-ESWT ($n=26$)	UST ($n=24$)
Gender, male, *n* (%)	7 (14)	5 (19.23)	2 (8.33)
Age, mean (SD) (years)	61.24 (9.26)	61 (9.18)	61.5 (9.52)
BMI, mean (SD) (kg/m^2)	26.3 (3.44)	25.69 (2.48)	26.96 (4.22)
Pain time, median (IQR) (months)	6 (3–12)	6 (3–12)	6 (3–12)
Pain localization – side, right, *n* (%)	19 (38)	10 (38.46)	9 (37.5)
p-NRS score, mean (SD)	5.03 (1.96)	5.12 (2.17)	4.93 (1.72)
p-NRS score $\geqslant 4$, *n* (%)	36 (73.47)	19 (73.08)	17 (73.91)
LEFS total score, mean (SD)	48.14 (18.43)	49 (19.17)	47.17 (17.94)
LEFS score–item K, mean (SD)	2.88 (1.11)	2.85 (1.22)	2.91 (1.00)
LEFS score–item T, mean (SD)	2.27 (1.06)	2.35 (1.09)	2.17 (1.03)

f-ESWT: focused extracorporeal shock wave therapy; UST: ultrasound therapy; BMI: body mass index; p-NRS: pain numeric rating scale; LEFS: lower extremity functional scale; item K: 'walking two blocks'; item T: 'rolling over in bed'; IQR: interquartile range.

Table 2. Outcome measures at follow-up (two and six months), for each group.

Outcome measures	f-ESWT	UST	*P*-value
p-NRS score at follow-up two months	2.08 (2.12)	3.36 (2.14)	0.020*
p-NRS score at follow-up six months	0.79 (1.28)	2.03 (2.09)	0.047*
p-NRS score $\geqslant 4$ at follow-up two months, *n* (%)	5 (20.83)	10 (47.62)	0.127
p-NRS score $\geqslant 4$ at follow-up six months, *n* (%)	1(4.35)	4 (22.22)	0.151
LEFS total score at follow-up two months	65.08 (11.16)	57.48 (11.91)	0.244
LEFS total score at follow-up six months	68.21 (11.49)	63.39 (13.03)	0.596
LEFS score – item k at follow-up two months	3.58 (0.58)	3.48 (0.51)	0.600
LEFS score – item k at follow-up six months	3.58 (0.65)	3.67 (0.59)	0.956
LEFS score – item t at follow-up two months	3.46 (0.83)	2.67 (1.02)	0.056
LEFS score – item t at follow-up six months	3.13 (0.99)	2.67 (0.97)	0.437

f-ESWT: focused extracorporeal shock wave therapy; UST: ultrasound therapy; p-NRS: pain numeric rating scale; LEFS: lower extremity functional scale; LEFS item K = 'walking two blocks'; item T = 'rolling over in bed'. Data are shown as mean (SD) if not otherwise specified.
*Comparisons between the two groups were statistically significant (*P*-value < 0.05).

considerably (Supplemental Tables 1b and 1c, 2b, 2c, 2e and 2f).

The 'Per Protocol' analysis showed results similar to the ones reported by the 'Intention to Treat' analysis, with the study group reporting a greater reduction of the pain-on-movement numeric rating scale score and a more relevant functional improvement than the control group. The comparisons between the two groups were not statistically significant at both follow-up times (Supplemental Figure 1a and 1b). Regarding the 'Per Protocol' analysis, the results of the regression analysis with the between-group comparisons for the outcome scores are reported in Supplemental Table 1d (see also Supplemental Table 1e and f for the comparisons adjusted for BMI and for pain duration), the line charts of the outcome measures are shown in Supplemental Figure 1a and 1b.

Discussion

Our findings support the hypothesis that focused extracorporeal shock wave therapy is effective in reducing greater trochanteric pain, both in the

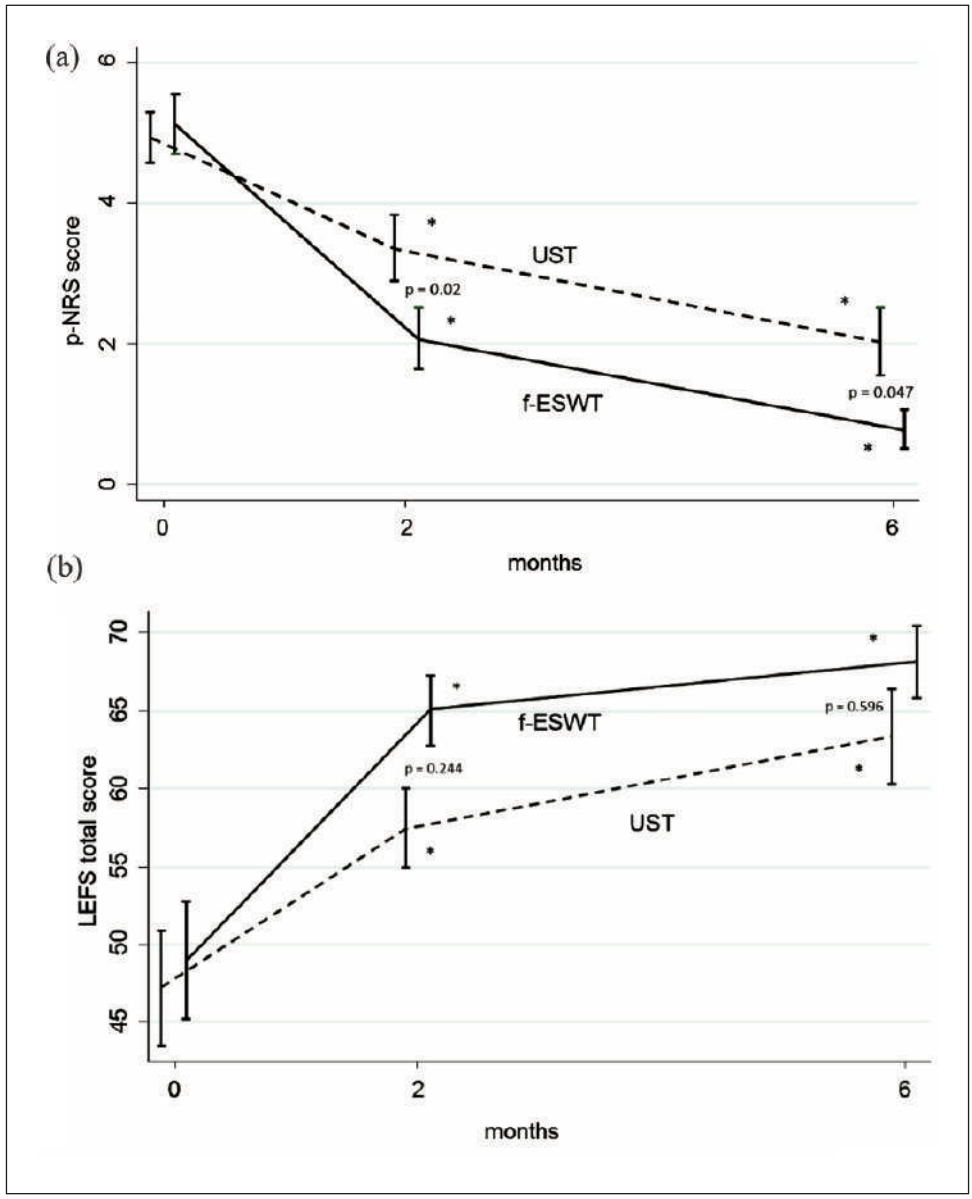

Figure 2. Line charts of the outcome measures for the ITT analysis ($n = 50$: f-ESWT = 26, UST = 24).
(a) line chart for p-NRS score (⊥ = standard error; *P*-values for the comparisons between groups at follow-up two and six months are reported. *Comparisons within group: f-ESWT: baseline to two months: $P < 0.0001$; two to six months: $P = 0.003$; UST: baseline to two months: $P < 0.006$; two to six months: $P = 0.004$).
(b) line chart for LEFS total score (⊥ = standard error; *P*-values for the comparisons between groups at follow-up two and six months are reported. *Comparisons within group: f-ESWT: baseline to two months: $P < 0.0001$; two to six months: $P = 0.022$; UST: baseline to two months: $P < 0.008$; two to six months: $P = 0.018$).
p-NRS: pain numeric rating scale; f-ESWT: focused extracorporeal shock wave therapy; UST: ultrasound therapy; LEFS: lower extremity functional scale.

short-term (two months) and in the mid-term (six months) perspective, in patients affected by gluteal tendinopathy. During follow-up, shock wave therapy proved to be significantly more effective than ultrasound therapy. We also observed an improvement in the affected lower limb function in the overall sample but without significant differences in the comparisons between groups.

Scientific evidences about the conservative treatment of GTPS were recently reviewed by Barratt et al.,[1] the authors showing a paucity of good quality research in this field. In the particular case of shock waves, only two trials indeed investigated their clinical efficacy in chronic trochanteric pain: a case–control study and a quasi-randomized trial.[18,7] Both studies showed a satisfying and stable outcome for radial shock wave therapy. In particular, Rompe et al.[7] concluded that radial shock waves were more effective, in the mid-term (four months) and in the long-term (15 months) perspectives, than corticosteroid injection and home training. Despite the extensive use of focused shock wave therapy in clinical practice, there was a lack of evidence about their efficacy in GTPS. This report is a first contribution to close this gap. In a randomized controlled trial, we assessed that focussed shock waves are also effective, in the short-term and in the mid-term perspectives, in reducing greater trochanteric pain. Our follow-up failed to assess the long-term outcome of the treatment. However, results from previous clinical studies in other tendinopathies showed that a clear improvement of symptoms, when achieved 3–12 weeks after focused shock wave treatment, was usually maintained at the one-year follow-up.[24–26]

GTPS is basically a clinical diagnosis, the pathophysiology still being not completely understood. In the past decades, lateral hip pain was suspected to arise from the inflammation of the trochanteric bursa, but histopathological studies revealed that isolated bursal distension is a rare report in the absence of a gluteus medius tendinopathy.[27–30] In the screened population, we found indeed only few cases of isolated trochanteric bursitis. We diagnosed GTPS using more detailed criteria than previous studies investigating the efficacy of radial shock wave therapy in this clinical condition: the use of sonography, associated to clinical findings, helped us to better identify subjects affected by gluteal tendinopathy, that is, the target of shock wave therapy. Sonography is actually considered a valid tool to diagnose gluteal tendinopathy, being very sensitive in identifying focal area of degeneration and foci of calcification. Compared to sonography, the major advantage in terms of differential diagnosis of magnetic resonance imaging is the skill to also assess for intra-articular pathology.[21,31,32]

For what regards focused shock wave treatment methodology, a detailed knowledge of the anatomy of the greater trochanter is essential for a correct focusing. Two reports provided a very detailed anatomical description of the multiple tendons' insertions on the greater trochanter, identifying the lateral facet as the wider insertional site of the gluteus medius and localizing the insertion of the gluteus minimus on the anterior facet, in anatomical contiguity with the insertion of the gluteus medius.[33,34] We chose, therefore, to deliver the focused shock wave therapy to the anterior part of the lateral facet, where the insertions of the gluteal tendons are closer. The main footprint of the gluteus medius tendon is rather wide, having a mean longitudinal dimension of 3.5 cm.[33] If we only consider the practical aim to treat the entire width of the insertional area of the gluteal tendons, radial shock wave therapy and ultrasound therapy are probably preferable to focused shock wave therapy. Moreover, a treatment protocol with ultrasound is usually cheaper than one with shock wave therapy. Conversely, in our opinion, focused shock waves are preferable if we take account of the depth of the greater trochanter, which is often located up to 3–4 cm beneath the level of the skin. The gluteal tendons, in fact, lie under a thick layer of soft tissues, which is usually greater than that associated with the tendons of the shoulder, elbow and so on. A sonographic guide is also essential to improve the shock wave focusing.

Patients enrolled in this study proved to be a representative sample of the population affected by GTPS. In 2007, a large cross-sectional population-based study found that BMI was not associated to

GTPS.[3] Our results reported for the analysed outcomes did not change as well, when adjusting for BMI. Regarding function, low levels of fulltime work participation and general function were found in a recent case–control study: the authors reported indeed a similar impairment in function (and quality of life) for patients affected by GTPS and for patients affected by severe hip osteoarthritis.[35] Comparing the average Lower Extremity Functional Scale total score of the overall sample at baseline with the maximum possible score, we also found a marked lower limb functional limitation (39.8% on average). Our results showed a statistically significant trend of improvement of the Lower Extremity Functional Scale total score over time for the study group and the control group. The lack of statistical evidence in favour of the shock wave group could probably be attributed to the relatively small number of patients enrolled. Lower Extremity Functional Scale is a specific tool that measures the overall function of the lower limb. Since 2015, a condition-specific outcome score, the Victorian Institute of Sports Assessment tendinopathy questionnaire for GTPS (VISA-G), is available to better assess GTPS-associated disability.[36] VISA-G was not available at the beginning of this study.

Our findings should be read in light of the following limitations. We enrolled a relatively small number of patients. It is indeed likely that the lack of statistical evidence in the 'per protocol' analysis could be attributed to the reduction of the sample during the follow-up, the number of patients lost being more in the control group than in the study group. Patients could not be blinded to the group assignment, but the influence of their expectations about the outcome was probably marginal, since both groups showed improvement over time. The lack of a longer follow-up (12 months) prevented further comparisons with the previously published literature and with the assessment of the long-term outcome of the treatment. The support of magnetic resonance imaging would have improved the assessment of gluteal tendinopathy and the exclusion of intra-articular pathology. Finally, for ethical reasons, we did not choose to plan a placebo-controlled trial, since we enrolled subjects suffering from chronic pain. Therefore, we opted for treating the control group with ultrasound therapy, a worldwide known physical therapy, commonly used to treat soft tissues, but the biological effects of ultrasounds are not yet completely understood, some in vitro studies supposing a regenerative role in the tendon repair process.[37] Besides, in the field of tendinopathies, limited evidences of good clinical outcome are reported for ultrasound therapy, despite the popularity of this therapeutic agent.[9,37–39]

In conclusion, this study showed that focussed extracorporeal shock wave therapy is an effective and safe option to treat GTPS in the clinical practice. Ultrasound therapy proved to be less effective to manage lateral hip pain, but it could be a valid alternative, for instance, in subjects who present contraindications to shock wave therapy.

Clinical Messages

- Focused extracorporeal shock wave therapy is effective in reducing pain and, probably, in improving lower limb function in greater trochanteric pain syndrome with gluteal tendinopathy.
- Ultrasound therapy showed to be less effective to reduce lateral hip pain, but it could be a valid alternative in subjects presenting contraindications to shock wave therapy.

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Supplemental Material

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