LETTER TO THE EDITOR

CONSERVATIVE TREATMENT OF SACROILIAC JOINT PAIN WITH EXTRACORPOREAL SHOCKWAVE THERAPY

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To the Editor,

The largest axial joint in the body is the sacroiliac joint (SIJ) (1). The anatomy and C-shape of sacroiliac (SI) allow to ensure the stability and to cope with the shearing forces, vertical load and movement. On the other hand, several muscles (including the piriformis, biceps femoris, gluteus maximus and minimus, erector spinae, latissimus dorsi, and iliacus muscles), as well as the thoracolumbar fascia, guarantee the mobility of the SIJ.

The SIJ may be affected by pathologic disorders, presenting as low back, sacral, pelvic, gluteal, or general hip pain. There are conservative treatment options which include medication optimization, physical therapy, therapeutic injection and radiofrequency ablation (2). With regard to medical and physical therapy interventions, different options are available: prolotherapy, radiofrequency ablation, repetitive exercises, manual joint mobilization, manipulation, bracing, massage, patient education, aerobic conditioning, general therapeutic exercise and electrotherapeutic modalities such as heat, ultrasound, electrical stimulation, intraarticular SIJ steroid injections, and ablation of the dorsal ramus of L5 as well as the S1-S3 dorsal rami innervating the SIJ. Currently, there are no guidelines nor management plans for this dysfunction; physicians usually refer to it as low back pain (LBP) and physiotherapists treat the pain as LBP. Extracorporeal shockwave therapy (ESWT) is a physical stimulation used in different areas such as urology, plastic and muscular-skeletal pathologies (3-5). ESWT has proved to be effective in treating musculoskeletal disorders due to its angiogenic, analgesic and anti-inflammatory effects. Starting from this assumption and considering the biological effects of the therapy, the aim of this study is to verify the effect of ESWT on low back pain induced by sacroiliac joint dysfunction.

MATERIALS AND METHODS

A prospective randomized study was designed in order to assess the clinical efficiency of ESWT for sacroiliac joint pain. The study was conducted according to the Declaration of Helsinki and the guidelines for Good Clinical Practice. The study was approved by the local Ethics Committee. Prior informed consent to participate in the study was given by all subjects. All subjects' medical

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history was examined for exclusion and inclusion criteria.

Study subjects

Thirty patients were enrolled from our Orthopedic Unit and randomized into two groups. Fifteen subjects (ESWT group) received ESWT, while the other fifteen (exercise group) were treated with an exercise protocol. All the patients enrolled in the study were taking nonsteroidal anti-inflammatory drugs (NSAIDs) or pain killing drugs, and these therapies were interrupted at the beginning of the study, 2 weeks before the start of therapy. Inclusion criteria were: age >18 years, SI pain diagnosis of at least 2 months based on clinic and provocative tests, and diagnosed SIJ dysfunction due to degenerative sacro-ileitis or SIJ disruption, Oswestry Disability Questionnaire (ODQ) ≥ 18%, and Visual Analogic Scale (VAS) ≥ 5. The SIJ was identified as the main pain generator using the following criteria: i) pain close to the posterior superior iliac spine and the patient could point with a single finger to the location of pain (Fortin Finger Test); ii) at least 3 positive findings out of 5 provocative physical examination maneuvers for SIJ pain [including pelvic compression, thigh thrust, flexion abduction external rotation (FABER), distraction, and Gaenslen's test]; and iii) at least 50% pain reduction on fluoroscopically guided injection of local anesthetic into the joint (SIJ block). Patients were excluded from the study if they reported contraindications to ESWT (cancer or current or previous infections of the affected area, a cardiac pacemaker, or pregnancy, epilepsy, coagulation disorders due to pathologies or drugs). Furthermore, patients were excluded for the following reasons: severe back pain due to other causes (e.g., known hip or spine conditions), diagnosed sacral pathology of other origin, recent (<1 year) major trauma to the pelvis, metabolic bone disease (osteoporosis or other bone conditions), any chronic rheumatologic, neurologic or psychiatric condition that could interfere with physical therapy, infection, or suspected drug abuse. The protocol did not allow interventional procedures (e.g., SIJ steroid injections, radiofrequency ablation of the lateral branches of sacral nerve roots) during the previous and the following 6 months. Each patient was evaluated on recruitment (T0), 1 month (T1), 3 months (T2), 6 months (T3) and 1 year (T4).

Sample size

The present study aimed to verify the equality of VAS score means in the two treatment groups: ESWT *vs* exercise therapy. To test this hypothesis, significance level (alpha) was set at 0.050 and a 2-tailed test was used. We proposed a sample size of at least 11 patients for each group of treatment. With this sample size and assuming between two groups a mean difference of 1.5 points and a common within-group standard deviation of 1.3, the study had to have power of 82% to yield a statistically significant result.

Baseline assessments included a detailed medical history and physical examination. Clinical results were evaluated using visual analogic scale (VAS) and Oswestry Disability Questionnaire (QDQ) at the time of recruitment (T0) and at the follow-up (FU) visits at 1 and 3, 6 and 12 months (T1, T2, T3, T4, respectively). At baseline, patients were randomized 1:1 to receive ESWT or exercise therapy. Treatments were allocated according to a sequential randomization list generated using Stata MP12 statistical software. Patients were randomized into an ESWT group (3 sessions, 1 per week) or an Exercise group (2 sessions per week for 8 weeks).

ESWT group

ESWT was applied using an electromagnetic generator (Minilith SL1, Storz Medical, Tägerwilen, Swiss) equipped with in-line ultrasound-guidance (Aloka SSD 900, Aloka Co., Ltd. Tokyo, Japan), and was administered once per week for three sessions, in accordance with guidelines (6). The patient was placed in a prone position (Fig. 1). Under ultrasound guidance, the depth of the probe was adjusted so as to treat structures, which represented the main affected sides in SIJ. The sacrum was flat and wide, leaving space to position the probe along SIJ (between SIJs and the foramina). At the same time, its length and orientation potentially could make all the joint components, such as nerve roots, ligaments, and muscles, well exposed. The probe was oriented perpendicular to the posterior SIJ line, and moved up and down along the joint line (Fig. 2). Coupling gel was used between the shockwave head and low back region. No local anesthesia was needed. We used a low-medium energy level (0.03 mJ/mm2), which was consistent with patient pain tolerance levels, during the treatment. At each treatment session, 2000 impulses were applied. Repetition frequency of shockwave pulses was 4 Hz.

Exercise group

All participants in the Exercise group received

individual treatment sessions of 50 min, generally 2 times per week, for a total of 8 weeks that focused on mobilization and stabilization exercises for control and stability (7). Each patient was followed by a physical therapist and instructed to conduct 8 exercises. In each session all exercises were included. The treatment progression followed a pragmatic approach and was determined by the clinical improvement revealed by a physiotherapist. The first four exercises were unilateral and were reproduced for each side. These exercises were developed to restore good triplanar pelvic and hip position and maintain it during movement: #1 exercise "bridging", #2 exercise "adductor ball squeeze", #3 exercise "abdominal marching" and #4 exercise "reverse curl-ups". The following two exercises were prescribed to facilitate elongation of posterior ligaments and carried out in side-lying position: #5 exercise "a scissor slide" and #6 exercise "a knee-to-knee". The last two exercises were performed in a supine hook lying position and were prescribed for muscle activation: #7 exercise "basic bridge exercise" and #8 exercise "bilateral adductor ball squeezes". The plan of treatment included an average of one to three sets of exercises, consisting of 8-10 repetitions.

Statistical analysis

The compiled forms were put into a database using Excel software and analyzed with STATA MP15 software. Continuous variables were expressed as mean ± standard deviation and range otherwise as median, interquartile range and range, instead categorical variables were expressed as proportions. The Skweness and Kurtosis test was used to evaluate the normality of continuous variables. For the not normally distributed variables a normalization model was built up, using the logarithmic function. The Student's *t*-test for independent data (parametric) was used to compare normal or normalized continuous variables between the two groups. The ANOVA test for repeated measurements was used to compare normal or normalized continuous variables between groups and times.

The Wilcoxon Rank-Sum (non-parametric) test was used to compare the non-normalizable continuous variables between groups, the Friedman test (non-parametric) was used to compare them between several times, and the Wilcoxon signed-rank test (not parametric) was used to compare them between individual times. The chi-squared test and the Fisher exact test were used to compare the categorical variables between groups.

Univariate linear regression was used for each individual outcome to evaluate the association between VAS at T2, Oswestry Disability Questionnaire at T2 (both continuous variables normally distributed or normalizable) and the corresponding variable at T0, age, gender, BMI, tobacco habit (yes/no), the articulation side concerned, previous physiokinesitherapy (yes/no); Student's *t*-test and the correlation coefficient, with a 95% confidence interval (95% CI), were calculated. A multivariate linear regression model was constructed for each outcome, using as determinant the group variable adjusted for those variables associated with the single outcome in the univariate regression; the correlation coefficients were calculated, with 95% confidence interval (95% CI) and the *t*-student test.

To evaluate the association between the number of positive tests at the T2 objective examination (non-normalizable continuous variable) and the respective variable at T0, age, gender, BMI, tobacco habit (yes/no), the affected joint side, previous conservative treatment (yes/no), the univariate non-parametric regression was used; the observed estimate was calculated, with 95% confidence interval (95% CI) and the z-score test.

A non-parametric multivariate regression model was constructed for each outcome, using as determinant the group variable adjusted for those variables associated with the single outcome in univariate regression; Observed Estimates (Obs. Est.) were calculated, indicating 95% confidence interval (coef.) (95% CI) and the z-score test. A p-value <0.05 was considered significant for all the tests.

RESULTS

The average age was 62.6±11.8 (43.0 – 82.0) years old and the BMI was 163.4±7.5 (150.0–179.0) kg/m^2. In 53.3% of patients the SI pain was localized on the right side, in the remaining 46.7% on the left. No adverse effects were noted during the performed procedures. By comparison of the two groups, there were no statistically significant differences in relation to the epidemiological, anthropometric and clinical evaluations at recruitment (Tables I).

We found a statistically significant difference in the comparison of the number of positive tests at the physical examination between times in the total

Table I. *Average, standard deviation and range of number of positive tests at physical examination, of VAS scale and of the Oswestry Disability Questionnaire score, for follow-up and groups.*

Time	ESWT group	Exercise group	Total	z	p
n. positive test at physical examination					
T0	3.9±0.9 (3.0 – 5.0)	4.0±0.8 (3.0 – 5.0)	3.9±0.9 (3.0 – 5.0)	0.4	0.657
T1	3.0±1.3 (0.0 – 5.0)	2.9±0.7 (2.0 – 4.0)	2.9±1.0 (0.0 – 5.0)	0.4	0.720
T2	2.5±1.2 (0.0 – 5.0)	2.7±0.5 (2.0 – 3.0)	2.6±0.9 (0.0 – 5.0)	0.5	0.645
T3	2.2±1.0 (0.0 – 4.0)	2.3±0.6 (2.0 – 4.0)	2.3±0.8 (0.0 – 4.0)	0.1	0.908
T4	2.1±1.7 (0.0 – 7.0)	2.3±0.6 (1.0 – 3.0)	2.2±1.3 (0.0 – 7.0)	1.2	0.216
VAS					
T0	7.5±1.3 (6.0 – 10.0)	7.0±1.3 (5.0 – 9.0)	7.3±1.3 (5.0 – 10.0)	0.9	0.382
T1	5.6±1.4 (4.0 – 8.0)	6.1±1.4 (3.0 – 8.0)	5.9±1.4 (3.0 – 8.0)	1.1	0.251
T2	3.9±2.0 (0.0 – 8.0)	5.6±1.9 (3.0 – 8.0)	4.8±2.1 (0.0 – 8.0)	2.0	0.045
T3	3.8±2.3 (0.0 – 8.0)	5.1±2.0 (2.0 – 8.0)	4.5±2.2 (0.0 – 8.0)	1.4	0.153
T4	3.8±2.0 (0.0 – 7.0)	4.4±2.0 (2.0 – 8.0)	4.1±2.0 (0.0 – 8.0)	0.6	0.528
Oswestry Disability Questionnaire (0-100)					
T0	38.9±9.3 (18.0 – 50.0)	41.3±13.6 (18.0 – 74.0)	40.1±11.5 (18.0 – 74.0)	0.0	0.967
T1	28.7±14.4 (0.0 – 48.0)	35.5±16.2 (10.0 – 74.0)	32.1±15.5 (0.0 – 74.0)	0.8	0.442
T2	22.9±14.4 (0.0 – 48.0)	33.9±17.8 (10.0 – 74.0)	28.4±16.8 (0.0 – 74.0)	1.6	0.100
T3	19.7±14.4 (0.0 – 40.0)	28.3±14.5 (8.0 – 58.0)	24.1±14.9 (0.0 – 58.0)	1.5	0.142
T4	18.1±11.5 (0.0 – 38.0)	26.3±15.4 (8.0 – 58.0)	22.2±14.0 (0.0 – 58.0)	1.4	0.157

The evaluation times are at recruitment (T0) and 1, 3, 6 and 12 months later (T1, T2, T3, T4). Statistical analysis is reported.

sample (Fr = 54.8; p = 0.000) and in the ESWT group (Fr = 17.6; p = 0.000); there was also a statistically significant difference of VAS between FUs (F = 36.5; p = 0.000) and in the interaction between FUs and group (F = 4.0; p = 0.005); there was a statistically significant difference of ODQ score between the FUs (F = 33.6; p = 0.000; Table II).

There were no statistically significant differences in the comparison of outcomes between groups and different FUs (p> 0.05). The comparison between different FUs for each outcome is described in Table II. By the univariate analysis we observed a statistically significant association between the number of positive tests at T2 and at T0 (Obs. Est. = 0.5; 95% CI = 0.2-0.9; z = 2, 6; p = 0.010); between VAS at T2 and group (coef. = - 1.7; 95% CI = -3.1 - -0.2; t = 2.4; p = 0.025); between ODQ at T2 and at T0 (coef. = 1.2; 95% CI = 0.8-1.5; t = 7.2; p = 0.000); between ODQ at T2 and age (coef. = 42.2; 95% CI = 12.8 - 71.6; t = 2.9; p = 0.006). There were no statistical associations between the outcomes and the determinants in the analysis (p> 0.05).

By multivariate analysis a statistically significant association was found between ODQ at T2 and ODQ at T0 (coef. = 0.99; 95% CI = 0.70-1.29; t = 6.9; p = 0.000), the age (coef. = 2.2; 95% CI = 7.7-42.7; t = 3.0; p = 0.007) and group (coef. = - 9.5; 95% CI = - 15.8 - -3.2; t = 3.1; p = 0.005); there was a statistically significant difference between the number of positive tests at T2 and at T0 (Obs. Est. = 0.5; 95% CI = 0.1-0.9; z = 2.4; p = 0.017), whilst there was no statistical association between the number of positive tests at T2 and group (ESWT/exercise) (Obs. Est. = -0.1; 95% CI = -0.7-0.5; z = 0.2; p = 0.829). The population did not undergo other therapeutic interventions during FU nor they did adopt changes in occupational behavior.

DISCUSSION

The results of our experience supported that SW could be useful in management of SIJ pain. We found an improvement in clinical tests, pain and disability

Table II. *Comparison of individual outcomes at different follow-up times*

Comparison	Positive test		VAS		ODQ	
	test	p	test	p	test	p
T0 *vs* T1	z=4.3	0.000	t=5.8	0.000	t=5.8	0.000
T0 *vs* T2	z=4.6	0.000	t=6.2	0.000	t=6.3	0.000
T0 *vs* T3	z=4.7	0.000	t=6.9	0.000	t=6.9	0.000
T0 *vs* T4	z=4.4	0.000	t=7.5	0.000	t=9.1	0.000
T1 *vs* T2	z=2.5	0.012	t=3.8	0.001	t=2.8	0.008
T1 *vs* T3	z=3.4	0.001	t=4.2	0.000	t=3.5	0.002
T1 *vs* T4	z=3.0	0.003	t=5.5	0.000	t=5.3	0.000
T2 *vs* T3	z=2.5	0.012	t=1.7	0.107	t=2.5	0.017
T2 *vs* T4	z=2.5	0.011	t=3.0	0.005	t=3.7	0.001
T3 *vs* T4	z=1.1	0.290	t=1.7	0.094	t=2.1	0.048

Statistical analysis is reported for results of clinical evaluation, pain score (VAS) and disability (Oswestry Disability Questionnaire, QDS) of all the population of the study.

in the population enrolled at the different FUs. At T2 we found a statistically significant difference in the SW group for VAS and Oswestry Disability.

The rationale of this application in SI joint pain is modulating the joint inflammation, reducing the activation of nociceptors, resetting the osteo-articular imbalance and relaxing the muscles involved locally. On the basis of these biological hypotheses, shockwave therapy has been used in the treatment of low back pain and sacro-ileitis (8-10). In low back pain, the ESWT is responsible for the reduction of pain, functional recovery and sensory and motor conduction deficit recovery of peripheral nerves (8-10). To date, in the only work published on the application of shock waves in SIJ pain, the treated group showed a significant reduction of pain at 4 week post-treatment, whilst a trend to improvement in disability was recorded, but it was not significant (11). In our case study, the control group presented an improvement trend at the different FUs. It showed a clinical and functional improvement, even though it was not statistically significant. This result is consistent with the literature, suggesting that exercises only in SI joint pain treatment may have limited benefit, if not integrated in multidisciplinary treatment, for example with pharmacological or instrumental therapy (12).

In conclusion, our work suggests that ESWT is efficient for the treatment of sacro-iliac pain, but the treatment represents a challenge for the clinician. Subsequent studies can verify the effectiveness of a combined treatment of shockwave therapy and therapeutic exercise, allowing to combine the bio-stimulatory effects of physical therapy to the action of stabilization exercises for SIJ.

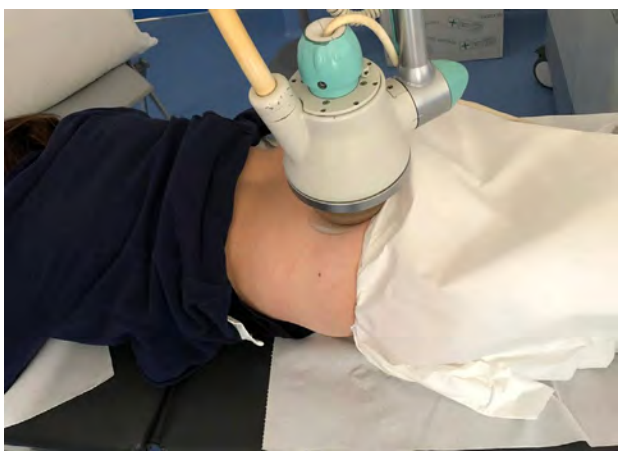

Fig. 1. *The patient's position and placement of the probe during ESWT.*

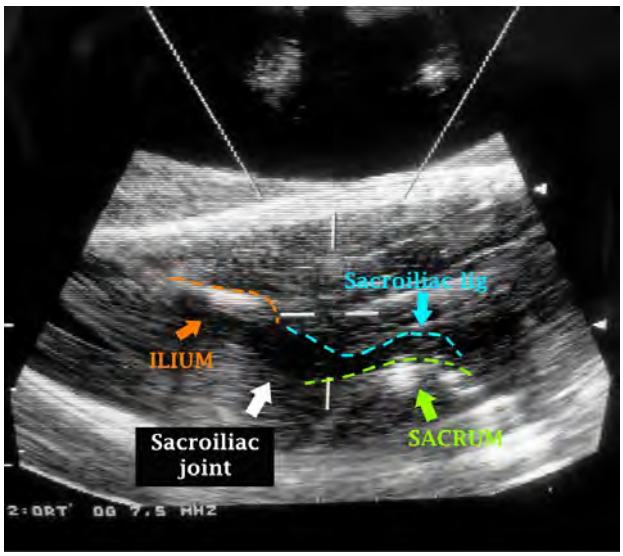

Fig. 2. *Identification of the sacroiliac joint under ultrasound guidance: in transverse projection it is an interruption of the hyperechoic profile of the bone cortex, corresponding to the joint space between the sacrum and the ileum.*

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