JOURNAL OF BIOLOGICAL REGULATORS & HOMEOSTATIC AGENTS Vol. 32, no. 2, 385-389 (2018)

LETTER TO THE EDITOR

EXTRACORPOREAL SHOCKWAVE THERAPY *VERSUS* EXERCISE PROGRAM IN PATIENTS WITH LOW BACK PAIN: SHORT-TERM RESULTS OF A RANDOMISED CONTROLLED TRIAL

A. NOTARNICOLA[1,2], G. MACCAGNANO[1], M.F. GALLONE[3], L. MASTROMAURO[4], F. RIFINO[1], V. PESCE[1], I. COVELLI[1] and B. MORETTI[1,2]

[1]*Orthopedics Section, Department of Medical Sciences of Basis, Neurosciences and Organs of Sense, Faculty of Medicine and Surgery, University of Study of Bari, General Hospital, Bari, Italy;* [2]*Course of Motor and Sports Sciences, Department of Medical Sciences of Basis, Neurosciences and Organs of Sense, Faculty of Medicine and Surgery, University of Study of Bari, Bari, Italy;* [3]*Department of Biomedical Sciences and Human Oncology, Faculty of Medicine and Surgery, University of Study of Bari, General Hospital, Bari, Italy;* [4]*Centro Polivalente di Riabilitazione Frangi, Segesta-Korian, Acquaviva delle Fonti, Bari, Italy*

Received September 20, 2017 – Accepted January 23, 2018

The physiotherapy treatment of low back pain (LBP) with physical stimulation offers different possibilities of application. Until now, the physical therapies used in LBP are laser therapy, ultrasonotherapy and currents. We conducted a clinical trial in order to verify whether shockwave therapy, which is very effective in treating tendinopathies and fracture consolidation delays, leads to clinical and electromyographic improvement in patients affected by LBP. We randomized thirty patients affected by LBP treated with shock waves (shockwave group) or a standard protocol characterized by rehabilitative exercises (control group). At one and three months, the patients treated with shockwave therapy showed clinical improvement measured by VAS scales (p=0.002; p= 0.02), and disability evaluated with Roland scales (p=0.002; p=0.002) and Oswestry (p=0.002; p=0.002). At three months, the patients treated with shock waves, showed a significant improvement in terms of values of amplitude of the sensory nerve conduction velocity (SNCV) of the plantar medialis nerve (left: p=0.007; right: p=0.04), the motor nerve muscular conduction (MNCV) of the deep peroneal nerve (left: p=0.28; right: p=0.01) and recruitment of motor units of finger brevis extensor (left: p = 0.02; right: p=0.006). In the control group, there was a trend to increase the clinical and electromyographic results without statistical significance. The preliminary results suggest a good applicability of shockwave therapy in the treatment of LBP, in accordance with the anti-inflammatory, antalgic, decontracting effects and remodeling of the nerve fiber damage verified in previous studies conducted on other pathological models. Future research will allow us to verify the integration of this therapy into a rehabilitation protocol combined with other physical therapies.

To the Editor,

The prevalence of low back pain in the adult is 37% (1). New studies permit to increase our knowledge about the different components responsible for low back pain (LBP) symptomatology (2). The arthritis and disc degeneration can start a local inflammatory process. There emerges a mechanical compression of root and radiculopathy. The spinal

Key words: shock wave, electromyographic exam, low back pain

Mailing address:
Dr Angela Notarnicola,
Orthopedics Section, Department of Medical Sciences of Basis,
Neurosciences and Organs of Sense, Faculty of Medicine and Surgery,
University of Study of Bari, General Hospital,
Piazza Giulio Cesare 11, 70124 Bari, Italy
Tel./fax.: +39 080 5592938
e-mail: angelanotarnicola@yahoo.it

0393-974X (2018)

DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.

muscle becomes hypertonic, causing pain due to development of atrophy and fat degeneration of muscle fiber. Furthermore, chronic pain may cause central neuroplasticity. The LBP treatment is multidisciplinary, as multiple treatments can be administered simultaneously or in series (3-5). The shock waves (SW) represent innovative treatment of LBP. This therapy is characterized by anti-inflammatory, anti-oedema, decontracturant, antalgic, neuro-modulation and neurotrophic effects (6, 7). In lumbar pain these actions are able to manage the various pathological components. In the literature two preliminary trials have compared the SW protocol and exercises with a thermotherapy protocol and exercises in LBP treatment (8, 9). The results showed a progressive clinical improvement over time, with better outcomes in patients treated with extracorporeal shockwave therapy (ESWT).

The present study aimed to examine three goals based on the aforementioned information: i) to determine the effectiveness of ESWT without exercise for the patients with low back pain; ii) to compare this treatment with the exercises performed alone; iii) to analyze the effects, not only with subjective pain degree (VAS) and disability (Roland Morris Disability Questionnaire and Oswestry Low Back Pain Disability Questionnaire), but also by electromyographic values of the affected muscles and nerves of the lower limb. By improving the knowledge of this therapy we will be able to prescribe an efficacious SW therapy integrated with rehabilitation protocol for the patient with LBP.

MATERIALS AND METHODS

Thirty patients were recruited from our Orthopedic Unit. The study was approved by the local Ethics Committee. Prior informed consent to take part was given by all participants. Inclusion criteria were age >18 years old, a diagnosis of chronic low back pain or low back pain and leg pain lasting at least 12 weeks, made on the basis of clinical symptoms and instrumental tests, and a functional VAS score >/=4; computed tomography (CT) or nuclear magnetic resonance (MRI) documented discopathy or disk hernia. Patients were excluded from the study if they had contraindications to SW therapy. Furthermore, they were excluded if they had the presence of active vertebral fractures, a history of previous spine surgery, rheumatic diseases such as rheumatoid arthritis, infections and systemic diseases that could affect pain perception (diabetes, etc) or local injections (local anesthetic and/or corticosteroids; O2O3, etc) or physiotherapy administered within the previous 4 weeks. At the recruitment the study protocol included the collection of medical history and clinical visit, as in our previous experience (10). Clinical results were evaluated using visual analogic scale (VAS), Roland Morris Disability Questionnaire and Oswestry Low Back Pain Disability Questionnaire at the time of recruitment (T0) and at the follow-up (FU) visits at 1 and 3 months (FU) (T1 and T2). All subjects had an electromyography study carried out by an electromyographer blinded to the subjects' treatment. The work by Dillingham and colleagues (11) showed that the electromyography study of the legs was able to detect 94-98% of subjects with a radiculopathy. At T0 and T2, each patient was evaluated by electroneuromyographic exam in order to record the sensitivity nerve conduction velocity (SNCV) of the plantar medialis nerve (the data were expressed as amplitude in microVolts), of the motor nerve muscular conduction (MNCV) of deep peroneal nerve motor and the recruitment of the muscular motor units of the finger brevis extensor (the data were expressed as amplitude in milliVolts).

In the SW group, ESWT was administered with an electromagnetic generator equipped with in-line ultrasound guidance (Minilith SL1, Storz, Swiss), during three sessions (1 session per week). Under ultrasound guidance, the depth of the probe was adjusted to treat muscular structures, which represent the main affected sides in LBP, mainly the quadratus lumborum muscle, the gluteus maximus muscle, the gluteus medius muscle, the gluteus minimus muscle, and the piriform muscle. We used a low-medium energy level (0.03 mJ/mm2), which was consistent with the patient pain tolerance level, during the treatment. We administered 2000 impulses. In the control group, all participants received individual exercise treatment sessions of 50 min, generally 5 times per week, for a total of 4 weeks.

All information was collected in a spreadsheet and data were analyzed using Stata MP12 statistical software. The proportions in the three treatment groups were compared using *chi*-squared test. For the evaluation of functional score variation over the time in each single treatment group, median scores were compared using Wilcoxon sign-rank test and comparing two times at a time (T0 *vs* T1; T1 *vs* T2). In order to evaluate differences between the two treatment groups with regard to functional scores measured at single time of follow-up, median scores were compared using Wilcoxon-Mann-Whitney test for independent samples. For each test we considered a value of $p<0.05$ as statistically significant. The z-value was the value of the statistical test. The data were not normally distributed.

RESULTS

In the study, 30 patients were recruited and randomized to the two groups. Six patients (2 in the SW group and 4 in the exercise group) dropped out of the study. At the last follow-up we analyzed 24 patients: 13 in the SW group (6 males and 7 females), and 11 in the control group (6 males and 5 females). The average age was 61.8±14.2 years (exercise group: 54.4±10.3 years, SW group: 68.2±14.3 years). As regards epidemiological characteristics and clinical features, the two groups were homogeneous. Weight, height and Body Mass Index (BMI) were 75.5±13.2 kg, 166±7.5 cm and 27.4±4.5 kg/cm2, respectively. 8.3% of the population were smokers. The Lasegue and Wasserman tests were positive in 50% and 25% of the recruited population, respectively. 16.7% of patients presented a sensitivity alteration, 29.2% were characterized by a deficit of one or more tendon-bone of reflexes at the lower limb, and 4.2% had a modification of the muscular tone of the lower limb muscle.

Clinical-functional data and electromyography

Regarding the VAS scores at recruitment, the two groups were not homogeneous, with a higher value in the group treated with SW (T0: z=-3.15, p=0.002). At the two consequent follow-ups, a reduction emerged of the values for both groups, which was statistically significant in the SW group (T0-T1: z = 3.1, p=0.002; T1-T2: z=2.4, p=0.02).

Regarding the Roland scores, at T0 the two groups were homogeneous. There was a progressive reduction of disability at the two following follow-ups which was statistically significant only in the SW group (T0-T1: z=3.1, p=0.002; T1-T2: z=3, p=0.002). At T2 there was a significant difference between the two groups in favor of the SW group (z=2.82; p=0.005).

With regard to the Oswestry score, at T0 the two groups were homogeneous. There was a progressive reduction of disability, which was statistically significant for the SW group (T0-T1: z=3.15, p=0.002; T1-T2: z=3.13, p=0.002). At T2 by comparison of the two groups, the SW group showed better values than the exercise group (z=2.73, p=0.006).

At T0, the analysis of the electromyographic evaluation detected that the MNCV amplitude of the deep peroneal nerve, finger brevis extensor was homogeneous between the two treatment groups for the lower left limb (z=1.48, p=0.14), whilst we observed higher values in the SW group for the lower right limb which were statistically significant (z=-2.4, p=0.01). At T2 there emerged a significant increase in the SW group for both lower limbs (left: z =-2.38, p=0.02, right: z=-2.76, p=0.006).

At T0, regarding the value of MNCV of deep peroneal nerve, we did not detect any statistically significant differences between the two groups (left: z=-0.46, p=0.64; right: z=-1.65, p=0.10). At T2 there emerged a significant increase of the values in the SW group on the right (z=-2.55, p=0.01), but not on the left (z=-1.08, p=0.28).

At T0 the value of amplitude of SNCV of the plantar medialis nerve showed higher values in the exercise group (left: z=2.06, p=0.04; right: z=2.69, p=0.007). At T2 we detected a significant improvement in the SW group (left: z=-2.69, p=0.007; right: z=-2.06, p=0.04).

DISCUSSION

The results of this study show that SW could be useful in management of low back pain, allowing a clinical improvement and a functional electromyographic recovery. The rationale of this application in LBP is to modulate the inflammation and involvement of the muscular-nervous structures involved locally. We verified an improvement in the clinical and functional pain and disability score already at the end of the treatment and T2, which was statistically significant in the SW group. Furthermore, in the SW group, the electromyographic values also demonstrated a significant recovery of SNCV of the plantar medialis nerve, the MNCV of the deep peroneal nerve and the recruitment of the muscular motor units of the finger brevis extensor. The analysis of the results highlighted the clinical-functional improvement and neuro-muscular properties in LBP according to the effects of SW. The *in vivo* studies on the animal model of SW stimulation on the sciatic nerve allowed to analyze the electro-neuro-myographic effects (12). The evaluations carried out within 14 weeks showed a reduction of motor nervous conduction (61% of reduction). After a muscular nerve traumatic event, the SW application was able to guarantee the regeneration of the damaged nerve and recovery of muscular function (13). A first SW model application for nerve fiber disorders is carpal tunnel syndrome. In carpal tunnel syndrome, the application of SW compared to placebo (12) and orthosis treatment (14) determined a significant recovery of disability and nervous function and pain remission, persistent at 12 weeks. The comparison of SW application and neurotrophic administration in carpal tunnel syndrome treatment showed similar results (15).

These results are due to the different effects of SW which are responsible for decreasing muscular tension and improving local perfusion in muscle contracted areas. Furthermore, the clinical effects are related to the decrease of algogenic substance production and inhibition of muscular nociceptors. This selective effect is responsible for decreasing metabolic demand.

In conclusion, due to the biological effect of shock waves and our clinical experience, ESWT may represent a new strategy in the treatment of low back pain. Further research will able to verify the effectiveness of integrated protocol of this therapy combined with therapeutic exercises.

ACKNOWLEDGEMENTS

The authors thank Brian John Molloy B.A. for language revision.

REFERENCES

1. Schmidt-Wilcke T, Leinisch E, Gänssbauer S, Draganski B, Bogdahn U, Altmeppen J, May A. Affective components and intensity of pain correlate with structural differences in gray matter in chronic back pain patients. Pain 2006; 125(1-2):89-97.
2. Beattie PF. Current understanding of lumbar intervertebral disc degeneration: a review with emphasis upon etiology, pathophysiology, and lumbar magnetic resonance imaging findings. J Orthop Sports Phys Ther 2008; 38(6):329-40.
3. Haldeman S, Dagenais S. A supermarket approach to the evidence-informed management of chronic low back pain. Spine J 2008; 8(1):1-7.
4. Notarnicola A, Maccagnano G, Tafuri S, Gallone MF, Moretti L, Moretti B. High level laser therapy for the treatment of lower back pain: clinical efficacy and comparison of different wavelengths. J Biol Regul Homeost Agents 2016; 30(4):1157-1164.
5. Fiore P, Panza F, Cassatella G, et al. Short-term effects of high-intensity laser therapy versus ultrasound therapy in the treatment of low back pain: a randomized controlled trial. Eur J Phys Rehabil Med. 201; 47(3):367-73.
6. Iannone F, Moretti B, Notarnicola A, Moretti L, Patella S, Patella V, Lapadula G. Extracorporeal shockwave increase interleukin-10 expression by human osteoarthritic and healthy osteoblasts in vitro. Clin Exp Rheumatol 2009; 27(5):794-9.
7. Moretti B, Iannone F, Notarnicola A, Lapadula G, Moretti L, Patella V, Garofalo R. Extracorporeal shockwave down-regulate the expression of interleukin-10 and tumor necrosis factor-alpha in osteoarthritic chondrocytes. BMC Musculoskelet Disord 2008; 9:16.
8. Notarnicola A, Maccagnano G, Gallone MF, Covelli I, Tafuri S, Moretti B. Short term efficacy of capacitive-resistive diathermy therapy in patients with low back pain: a prospective randomized controlled trial. J Biol Regul Homeost Agents 2017; 31(2):509-515.
9. Lee S, Lee D, Park J. Effects of extracorporeal shockwave therapy on patients with chronic low back pain and their dynamic balance ability. J Phys Ther Sci 2014; 26(1):7-10.
10. Han H, Lee D, Lee S, Jeon C, Kim T. The effects of

extracorporeal shockwave therapy on pain, disability, and depression of chronic low back pain patients. J Phys Ther Sci 2015; 27(2):397-9.
11. Dillingham TR, Lauder TD, Andary M, et al. Identifying lumbosacral radiculopathies: an optimal electromyographic screen. Am J Phys Med Rehabil 2000; 79:496-503.
12. Wu YT, Ke MJ, Chou YC, et al. Effect of radial shockwave therapy for carpal tunnel syndrome: A prospective randomized, double-blind, placebo-controlled trial. J Orthop Res 2016; 34(6):977-84.
13. Mense S, Hoheisel U. Shockwave treatment improves nerve regeneration in the rat. Muscle Nerve 2013; 47(5):702-10.
14. Raissi GR, Ghazaei F, Forogh B, Madani SP, Daghaghzadeh A, Ahadi T. The effectiveness of radial extracorporeal shockwave for treatment of carpal tunnel syndrome: A Randomized Clinical Trial. Ultrasound Med Biol 2017; 43(2):453-460.
15. Notarnicola A, Maccagnano G, Tafuri S, Fiore A, Pesce V, Moretti B. Comparison of shockwave therapy and nutraceutical composed of Echinacea angustifolia, alpha lipoic acid, conjugated linoleic acid and quercetin (perinerv) in patients with carpal tunnel syndrome. Int J Immunopathol Pharmacol 2015; 28(2):256-62.