To the Editor:

Plantar fascial fibromatosis is characterized by solitary or multiple nodes causing painful thickening of the plantar fascia and stiffness in the toes. Conservative management includes high-energy shockwaves (SWs), whereas low-intensity focused extracorporeal SWs were never investigated yet. We report 2 cases of plantar fibromatosis treated with low intensity extracorporeal SWs to evaluate whether a low-energy flux density may have comparable results to high-energy SWs, and any change in terms of nodule dimensions and consistency may be detected. Each patient was treated with 4 sessions of low-energy focused SWs and was evaluated by clinical and ultrasound (US) examination at baseline (T0), immediately after treatment (T1), and after 3 months (T2) and 6 months (T3). At baseline and at each follow-up visit, visual analog scale (VAS), the subscales of Foot Function Index (FFI), and adverse effects were recorded. Both patients presented decreased pain and functional outcomes, lasting until 6 months. Softening of the nodules and plantar fascia was noted. There were no modifications in the size of nodules by US evaluation. No adverse effects were observed.

These preliminary results suggest that low-energy focused SWs may be considered as a valid therapeutic option for the conservative management of patients affected by plantar fibromatosis and in recurrences after surgical treatment.

INTRODUCTION

Plantar fascial fibromatosis is a rare, benign disease characterized by marked nodularity and thickening of the plantar fascia. Described for the first time in 1894 by Dr. Georg Ledderhose, the disease also has been referred to as Morbus Ledderhose (ML) disease. This disorder is frequently associated with Dupuytren and Peyronie disease, is more common in males, and may occur at any age, with the greatest prevalence at the fourth and fifth decades.

Morbus Ledderhose disease can be diagnosed by palpation of painful solitary or multiple nodules and cords, mainly affecting the medial part of the plantar fascia, which have generally a very slow growth and rarely produce severe deformities in the foot.

Although a genetic base has been emphasized by few studies, several other factors have been hypothesized as cofactors in the pathogenesis of ML, including postural problems with excessive load on the foot, direct trauma, diabetes, gout, obesity, inappropriate footwear, and the association with some sports. Nevertheless, its pathogenesis remains incompletely understood.

The disease is characterized by 3 developmental phases: a first phase with high proliferative cellular activity, a subsequent acquisition of myofibroblastic characteristics and start of tissue contraction, and a final phase characterized by few mature fibroblasts embedded in a dense matrix.

Clinical manifestations include development of fiber nodes or cords under the plantar fascia, sharp pain in the foot, difficulty in putting on shoes and walking. Plantar thickening may cause stiffness in the toes; differently from Dupuytren’s contracture, flexion of fingers is uncommon, because the digital expansions of plantar aponeurosis are absent on the first toe and very thin on the other toes. Ultrasound or magnetic resonance imaging is useful to confirm diagnosis, especially when surgery is indicated to define dimensions and depth of nodules. The treatment remains symptomatic. In early stages, conservative therapy including stretching, orthotics, nonsteroidal anti-inflammatory drugs, physiotherapy, and collagenase Clostridium histolyticum injections is applied, whereas with disease progression irradiation of the plantar surface, local cortisone injections, and SW therapy have been proposed. Cryosurgery has been indicated as an additional option to reduce the size ofLedderhose nodes, although it is not always successful in reducing pain.

Operative treatment is indicated in case of persistent pain or failure of conservative treatment. The standard procedure includes a partial or subtotal fasiculectomy of the plantar aponeurosis; however, the recurrence rate is high.

Extracorporeal SW therapy (ESWT) is a relatively recent therapeutic option in the treatment of many musculoskeletal disorders, particularly in tendinopathies and nonunion fractures.

Furthermore, there is a general consensus on the role of ESWT in chronic plantar fasciopathy (PF), in which focused SWs are recognized as an effective tool for pain relief and functional outcomes, despite the variability in the proposed protocols for the treatment of PF (i.e., device, energy, and frequency), whereas the use of radial SW therapy remains controversial.

The role of ESWT in the tendon metabolism has been partially related to the stimulation of extracellular matrix biosynthesis by tenocytes because of transforming growth factor b1 and insulin like growth factor 1 overexpression. These findings suggest that tendon tissue can convert SW stimulation into biochemical signals.

To our knowledge, only 1 study investigated the potential effects of high-energy focused ESWT on pain reduction in plantar fibromatosis, reporting good clinical results on 6 patients.

We report 2 cases of ML treated with low-intensity focused ESWT. Our primary aim was to verify if, using a different device with an ultrasonographic targeting probe and applying a low-energy flux density, we would have comparable clinical results and, second, if any change in terms of nodule dimensions and consistency could be detected.

METHODS

Clinical examination included VAS (0–10), FFI, and US evaluation of the plantar fascia. The FFI is a self-administered index consisting of 23 items divided into 3 subscales: pain (FFI-p), disability (FFI-d), and activity (FFI-a). Both total and subscale scores have been demonstrated to be reliable, consistent, and valid. Ultrasound evaluation and measurements were performed using a linear 12.5-MHz probe (Avius; Hitachi Medical, Tokyo, Japan).

All assessments and US evaluation were performed at baseline (T0), immediately at the end of the treatment (T1), and after 3 months (T2). At 6 months (T3), all questionnaires were replicated by a telephone interview.

Low-energy ESWT was applied by an electromagnetic SW system with ultrasonographic targeting (MODULITH SLK; Storz Medical, Tägerwilen, Switzerland) with the following parameters: 1 session per week for 4 consecutive weeks, 1600 shots, at frequency of 3 Hz and energy flux density accordingly to the patient’s tolerance with a maximum peak of 0.20 mJ/mm².

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TABLE 1. Foot Function Index Scores for both patients at each evaluation

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<tr>
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<th>FFI - pain</th>
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<th>FFI - disability</th>
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<th>FFI - activity</th>
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<tr>
<td></td>
<td>Case 1 LF</td>
<td>Case 1 RF</td>
<td>Case 2</td>
<td>Case 1 LF</td>
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<tr>
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<td>0</td>
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<td>37</td>
<td>6</td>
<td>3</td>
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<tr>
<td>T3</td>
<td>12</td>
<td>1</td>
<td>2</td>
<td>20</td>
<td>5</td>
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The FFI score is divided in pain, disability and activity subscores. In Case 1 there was a worsening in pain and disability subscores in the left foot (LF) at T1, while there is a marked improvement in T2 and T3 evaluations. In the right foot (RF) of Case 1 and in Case 2 all scales improved immediately after treatment.

**Patient 1**

The patient was a 61-year-old man with multiple small plantar nodules on both feet, which caused medial plantar pain and stiffness of the first toe. He had not attempted any therapeutic action before ESWT.

At baseline, the left foot showed higher pain and disability scores than the right side (respectively, FFI-p, 33 and 24; FFI-d, 60 and 47; FFI-a, 20 and 6; VAS, 6 and 4) (Tables 1 and 2).

After treatment, the right foot had a decrease in all scores at T1 (FFI-p, 16; FFI-d, 38; FFI-a, 5; VAS, 2) and almost a complete recovery at T2 (FFI-p, 0; FFI-d, 6; FFI-a, 0; VAS, 0) with stable results at the 6-month follow-up.

On the other hand, the left side showed little worsening pain and functional outcomes at T1 (FFI-p, 44; FFI-d, 73; VAS, 7), whereas the follow-up at T2 resulted in a remarkable decrease in all subscales (FFI-p, 9; FFI-d, 37; FFI-a, 6; VAS, 2); the repetition of questionnaires after 6 months showed durable effectiveness in pain reduction (FFI-p, 12; VAS, 1) and a further improvement in function (FFI-d, 20; FFI-a, 2).

Immediately after treatment and during the whole observational period, he noted softening of the nodules and decrease in first-toe rigidity.

**Patient 2**

A 30-year-old man presented to the outpatient clinic with a recurrence 1 year after a partial fasciectomy on his right foot, consequently to an ML diagnosis. He showed a very painful area corresponding to a subcutaneous node (20 × 6 × 14 mm), and he excluded a new surgical intervention.

After being treated, the questionnaires provided a progressive decrease in all scores with a complete recovery at T2: FFI-p (25, 16, and 0, respectively, at T0, T1, and T2), FFI-d (19, 13, and 3), FFI-a (3, 2, and 0), and VAS (7.4, and 0) (Tables 1 and 2).

By US evaluation, we did not detect a reduction in the dimensions of the lesion at T1 and T2, although a softer consistency was reported by the patient and confirmed by palpation.

After 6 months, the telephone interview showed a very slight increase in pain scores (FFI-p 2, VAS 1) and stable benefits on functional outcomes.

**DISCUSSION**

Plantar fasciopathy is the most common cause of heel pain. Despite a different etiopathogenesis, ML and PF share some characteristics, such as the predominance of a medial pain distribution and the association with mechanical factors such as postural problems with excessive load on the foot, inappropriate footwear, and sports practice.

Furthermore, clinical suspicion of PF should be confirmed by diagnostic US, which may reveal the coexistence of a plantar fibroma; these findings suggest that probably ML is frequently associated to PF and overall underestimated.9

In patients affected by chronic PF, ESWT has shown pain relief and functional outcomes improvement in the short term,6 with an increasing evidence of efficacy for both focused and second-generation radial SWS and a failure rate lower than surgery.10,11 Moreover, SWS mimic various mechanical loading conditions inducing a biochemical response of tendon fibroblasts, which are the major mechanoresponsive cells in the tissue accelerating the repair process.12

Recently, Knobloch and Vogt3 investigated the effects of high-energy ESWT in 6 patients (5 men, 58 ± 4 years old) treated using a Storz Duolith SD1 without anesthesia (2000 impulses, 3 Hz, 1.25 mJ/mm²) for 2 sessions with a week interval. Three patients were operated on before. Visual analog scale score was 6 ± 2 at baseline and 2 ± 1 after 14 days. At 3-month follow-up, pain was 1 ± 1. Softening of the nodules was noted by all patients, and no adverse effects were registered.5

Our first purpose was to evaluate whether, using a different device with an ultrasonographic targeting probe and applying lower energy, the results in terms of pain decrease were comparable; in fact, some authors indicate that high-energy ESWT for PF should be performed with local anesthesia.3

Because there is no standard procedure for PF, but the majority of the studies suggest 3 to 5 low-energy ESWT applications for PF,6,7 we provided 4 sessions of treatment, maintaining the week intervals and frequency of the aforementioned study, but energy flux density was modulated according to the patient’s tolerance with a maximum peak of 0.20 mJ/mm². Therefore, the total amount of energy was much lower. Confirmation by US scan allows proper positioning of the device, in order to direct the focus on the surface of the nodule. In our cases, pain relief lasted for at least 6 months, and both patients improved in the disability and activity scores, showing great functional recovery.

Our secondary aim was to investigate whether any change on node morphology occurred after the treatment detected by US and clinical evaluation. Although we were not able to find any difference in the dimensions, remarkable softer consistency of nodules and plantar fascia was appreciated, reported by patients and confirmed by palpation.

Similarly, Knobloch and Vogt3 found a softening of the plantar fibromas in all
and fibroblasts, thus possibly counteracting matosis; in fact, SWs induce mechanical modifications on penile angulation. Studies show contradictory results of variations in Peyronie disease; however, the results did not lead to definitive conclusions. Current European guidelines for the treatment of Peyronie disease indicate that ESWT may be used to reduce painful symptoms, whereas it is not recommended to correct plaques or penile deviations; the existing studies show contradictory results of variations on penile angulation.

We speculate that ESWT when applied within a correct timing may be useful to modify the progression of plantar fibromatosis; in fact, SWs induce mechanical and biochemical responses on tendon tissue and fibroblasts, thus possibly countering the myofibroblastic maturation and tissue contraction. However, our observation is limited to a very small sample, and further studies are requested to confirm the present findings.

**CONCLUSIONS**

Our results, limited to 2 patients, suggest a possible role of low-energy focused ESWT in the conservative treatment of painful plantar fibromatosis (Ledderhose disease), but need to be confirmed by well-designed studies, with a larger sample size and a long-term follow-up assessment.

Despite beneficial effects on pain and functional recovery, we had no evidence of a reduction in the dimensions of the nodules.

**REFERENCES**