Disability and Rehabilitation

ISSN: 0963-8288 (Print) 1464-5165 (Online) Journal homepage: http://www.tandfonline.com/loi/idre20

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To cite this article: Bernardino Roca, María A. Mendoza & Manuel Roca (2016): Comparison of extracorporeal shock wave therapy with botulinum toxin type A in the treatment of plantar fasciitis, Disability and Rehabilitation, DOI: 10.3109/09638288.2015.1114036

To link to this article: http://dx.doi.org/10.3109/09638288.2015.1114036

Published online: 01 Mar 2016.

DISABILITY AND REHABILITATION, 2016
http://dx.doi.org/10.3109/09638288.2015.1114036

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RESEARCH PAPER

Comparison of extracorporeal shock wave therapy with botulinum toxin type A in the treatment of plantar fasciitis

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ABSTRACT

Objective To compare the efficacy of extracorporeal shock wave therapy (ESWT) with botulinum toxin type A (BoNT-A) in the treatment of plantar fasciitis (PF). **Design** Open label, prospective, randomized study. **Results** A total of 72 patients were included. In all participants the median (and interquartile range) of the visual analog scale (VAS) of pain result, when taking the first steps, was 8 (6–9) points before treatment and 6 (4–8) points after treatment ($p < 0.001$). In the group of patients that received ESWT, the median (and interquartile range) of improvement in the VAS of pain result, when taking the first steps, was 2 (1–4) points, and in the group of patients that received BoNT-A the same result was 1 (0–2) points ($p = 0.009$). In the group of patients that received ESWT, the median (and interquartile range) of improvement in the Roles and Maudsley scale of pain result was 1 (0–1) points, and in the group of patients that received BoNT-A the same result was 0 (0–1) points ($p = 0.006$). In a multivariate analysis use of ESWT and lower weight were associated with improvement of pain with treatment in at least one of the three VAS of pain scales used in the study. **Conclusion** ESWT was superior to BoNT-A in the control of pain in patients with PF.

➤ IMPLICATIONS FOR REHABILITATION

- Plantar fasciitis is characterized by pain at the calcaneal origin of the plantar fascia, exacerbated by weight bearing after prolonged periods of rest.
- Although studies comparing extracorporeal shock wave therapy or botulinum toxin type A to placebo suggest a superiority of the first one, no reliable data exist about it.
- Extracorporeal shock wave therapy was superior to botulinum toxin type A in the control of pain in patients with PF.

ARTICLE HISTORY
Received 4 May 2015
Revised 17 October 2015
Accepted 26 October 2015
Published online
15 February 2016

KEYWORDS
Botulinum toxin type A (BoNT-A); extracorporeal shock wave therapy (ESWT); plantar fasciitis (PF); visual analog scale (VAS) of pain

Introduction

Plantar fasciitis (PF) is characterized by pain at the calcaneal origin of the plantar fascia, exacerbated by weight bearing after prolonged periods of rest.[1] The condition is generally regarded as benign, but is very common in the general population, tends to persist for many months, and in some cases produces considerable disability.[2–3]

The main pathologic abnormalities in PF are degenerative changes at the plantar fascia enthesis. Processes such as deterioration of collagen fibers, fibroblast proliferation, increased secretion of abnormal ground substance, and increased vascularity are considered to be involved in the pathophysiology of the condition.[4,5] But there are studies suggesting that inflammatory changes [6] and strain of posterior muscles of the lower limb [7] may also play a role in the development of the disease, at least in some cases.

Treatment options for PF include biomechanical approaches such as taping or footwear modification, physiotherapy techniques such as stretching exercises, local ice application, electrotherapy, cortisone or blood derivative injections, systemic non-steroidal anti-inflammatory agents, and surgery.[1,3] Nevertheless, the efficacy of all those treatments to relieve the symptoms of PF is only modest.[4] For that reason, more studies in this area are clearly needed.

Extracorporeal shock wave therapy (ESWT) is a lithotripsy derivative that is being extensively used in the management of tendinopathies.[1] The therapy consists

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of sound waves that are directed to affected tissues. The proposed mechanisms of action include: stimulating blood flow for a beneficial immune and inflammatory response, reinjuring tissues to stimulate healing, and shutting down the neuronal pain pathways through the pulses hitting the affected nerves.[8] Recent studies have demonstrated the efficacy of this therapy in a variety of conditions,[9] and the US Food and Drug Administration (FDA) has approved it for the treatment of PF.

Injection with botulinum toxin type A (BoNT-A) is also being increasingly used in the management of several conditions that consist of muscle spasm or pain. The substance blocks presynaptic acetylcholine reuptake, and in this way produce weakness of the muscles, which reduces tension in tissues and improves pain. A direct analgesic action, due to inhibition of the release of neurotransmitters involved in nociceptive neural pathways, is also possible.[10] The toxin is now first-line therapy in many conditions that manifest with dystonia or spasticity. And at least two recent randomized studies have also demonstrated some effectiveness in the treatment of PF.[11–13]

In order to increase knowledge in the field, we undertook this study to compare the last two modalities of treatment of PF, i.e. ESWT and BoNT-A, in patients that had not responded to first-line therapy for the condition. In a review of the literature, we found no other studies that directly compared both modalities of treatment in PF or other conditions. Therefore although studies comparing ESWT or BoNT-A to placebo suggest a superiority of the first one, no reliable data exist about it, and for that reason we planned this study.

Methods

Design, setting and ethics

This was an open label, prospective, randomized study, to compare the efficacy of ESWT and BoNT-A in the treatment of PF, in patients that had not responded to physiotherapy and electrotherapy.

The study was carried out in the Department of Physical Therapy and Rehabilitation of the University General Hospital of Castellon, Spain. The centre is a public institution belonging to the National Health Service, ruled by the Valencia Health Agency, and affiliated with the Jaume I University.

The study project was approved by an interdisciplinary committee of the University General Hospital of Castellon. The study was carried out in compliance with the ethical principles for medical research involving human subjects set forth in the Declaration of Helsinki of 1964, and subsequent updates.[14] Every patient gave written informed consent to participate in the study. During the analysis of data codes were used, instead of patient's personal details.

Patients

Participants were enrolled in the study from September 2011 through June 2013. They were included if they met all the following criteria: age older than 15 years; diagnosis of PF made by a physician officially certified as Specialist in Physical and Rehabilitation Medicine; symptoms of PF of at least 6-month duration; lack of response to physiotherapy and electrotherapy applied during a minimum of 4 weeks; and informed consent to participate in the study. And patients were excluded if they presented any of the following criteria: pregnancy, desire to become pregnant or breastfeeding if the patient was a woman; cognitive disorder; disease or malformation with symptoms overlapping with those of PF; PF previously treated with ESWT, BoNT-A, injected corticosteroids, surgery or other invasive procedures; pacemaker use; wound or infection in the foot affected by PF; coagulation disorder; hypersensitivity to BoNT-A; neutralizing antibodies against BoNT-A; and hypersensitivity to lidocaine.

When a patient presented with PF simultaneously in both feet, only the more painful one was chosen for the study. For that purpose pain was assessed with a visual analog scale (VAS) [15] when taking the first steps in the morning after prolonged rest. If both feet gave identical score of pain, one foot was randomly chosen, with the help of Research Randomizer, a software available at http://www.randomizer.org: the programme was arranged to choose between two possible results, 1 or 2; when the programme gave as a result 1 the left foot was chosen and when the programme gave as a result 2 the right foot was chosen. When a patient, after inclusion in the study, presented with PF in the contralateral foot, only the first episode of PF was considered for the study. In both cases, the episode of PF not included in the study was treated in the same way as the included one.

Participants were randomly distributed in two groups of the same size, with the help of Research Randomizer, a software available at http://www.randomizer.org; a total of 80 allocations, 40 for each group were made. The investigator who generated the random number sequence had no contact with participants throughout the study. One group of patients received ESWT, and the other group received BoNT-A for the treatment of PF.

The same day of enrollment in the study patients were randomized and received the study treatment. A first follow-up visit was planned for 1–2 months later.

Treatments

Patients in one group received ESWT, generated by a Piezoson 100® (Richard Wolf, GmbH, Knittlingen, Germany). The target area was the site of maximum local tenderness, found through palpation. Patients were given 3000 focused shock waves with a flux intensity of 12 mJ/mm^2, at a pressure of 64 mPa and at a frequency of 4 Hz, in just one session. The time of administration was approximately 15 min. The treatment was administered as recommended by the manufacturer of the generator.

Patients in the other group received injected BoNT-A (Botox, Allergan Inc., Irvine, CA, USA). The injection was performed at two sites. Using the method described by Babcock et al.,[13] 100 U of BoNT-A were diluted in 1 mL of normal saline, and one half of the solutions was injected in the insertion of the plantar fascia in the calcaneus and the other half in the area of maximal tenderness between one inch (2.5 cm) distal to the talar insertion of the plantar fascia and the midpoint of the plantar arch, both sites found through palpation.

Throughout the study period, participants were recommended to make daily stretching exercises of the muscles of the calf and the arc of the foot, as show at http://www.mayoclinic.com/health/medical/IM02897, and they were allowed to take any medications needed for conditions other than PF. In the follow-up visit, 1–2 months after enrollment, physicians could prescribe any treatment considered adequate for PF.

Study variables

The following variables were recorded from every patient on enrollment: gender; age; main activity, consisting of sport or other; affected foot, right or left; calcaneus spur, present or not in imaging studies; duration of symptoms of PF; weight; height; pain assessment in the affected foot with the VAS (0–10 points, with 10 being the most intense pain),[15] in the following situations: (a) taking the first steps in the morning after prolonged rest, (b) doing daily activities, and (c) doing exercise; pain assessment in the affected foot with the Roles and Maudsley scale (1–4 points, with 4 being the most intense pain);[16] European Quality of Life scale, consisting of: (a) six standardized measurements (each of them 0–2 points, with 2 being the worst health state), and (b) a complement consisting of a VAS (0–100 points, with 0 being the worst health state);[17] Foot Health Status Questionnaire, consisting of 13 standardized measurements (1–5 points each one, with 5 being the worst health state);[18] plantar fascia thickness, measured at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border, mean of two ultrasound measurements, each one made by one of the two examiners that completed that task in the study, both of them remained blinded for the treatment that patients received;[19] and prescribed treatment, ESWT or BoNT-A.

The following variables were recovered from every patient in the follow-up visit: time elapsed between enrollment and follow-up visits; pain assessment in the affected foot with the VAS (0–10 points, with 10 being the most intense pain) [15] in the following situations: (a) taking the first steps in the morning after prolonged rest, (b) doing daily activities, and (c) doing exercise; pain assessment in the affected foot with the Roles and Maudsley scale (1–4 points, with 4 being the most intense pain);[16] plantar fascia thickness, mean of two ultrasound measurements, each one made by a different explorer, at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border;[19] side effects of the study treatments, ESWT and BoNT-A.

Statistics

To relieve symptoms of PF, one meta-analysis suggests 60% efficacy of ESWT when compared to placebo [20] and one study suggests 25% efficacy BoNT-A when compared also to placebo.[11] Therefore, we estimated that we needed 66 patients, 33 in each group, to find a difference of 35% in efficacy to relieve symptoms of PF between both groups of treatment, with a power of 90%, and a level of significance of $p = 0.05$, one-tailed.

We reported discrete variables as absolute values and frequencies, and continuous variables as mean and standard deviation, if normally distributed, and as median and interquartile range, if not normally distributed. We used the Kolmogorov–Smirnov test, histograms and Q-Q plots to assess normality of variables. For bivariate analysis we used the following tests, as needed, chi square (χ^2); Student's *t*-test, of independent or paired samples; Mann–Whitney *U* test; Wilcoxon signed ranks; and Kruskal–Wallis *H* test. For multivariate analysis, we used a logistic regression. We imputed missing values with the automatic imputation model available in the software IBM SPSS Statistics version 22. In all analyses, we used a level of significance of $p = 0.05$, one tailed. We chose the one-tailed approach because published studies comparing ESWT or BoNT-A to placebo suggest a superiority of the first one.

Results

Patients

Of a total of 103 patients that were attended at the study centre during the study period with the

diagnosis of PF, 29 (28.2%) responded to first-line therapy with physiotherapy and electrotherapy, and were not included in the study. The other 74 (71.8%) met all the inclusion criteria, gave informed consent to participate in the study, and were randomized to receive ESWT or BoNT-A. By chance both groups consisted of 37 patients. But just before initiating treatment one patient in each group decided to withdraw from the study. Therefore 72 patients, 36 in every group, completed the study and were available for analyses (Figure 1). All data from all participants were available except for all four measurements of plantar fascia thickness belonging to the follow-up visit of one patient. Those data were randomly imputed, and no difference was found between the values of those variables before and after imputation ($p > 0.950$ for all four measurements).

A total of 16 patients (22%) suffered PF in both feet, 12 of them simultaneously and 4 of them sequentially. Of those 16 patients, 9 (56%) belonged to the ESWT group and 7 (44%) to the BoNT-A group ($p = 0.571$). As planned, only one of those episodes of PF, of every patient, was included in the study. The unincluded episode was treated in the same way as the included one.

Tables 1–3 summarize baseline characteristics of participants. In all cases results of both groups of treatment are reported and compared. Three participants, one male and two female, had the practice of sport as their main daily activity. One of them, a man, belonged to the ESWT group, and two of them, one man and one woman, belonged to the BoNT-A group.

Overall response to treatment

Table 4 summarizes clinical data of all patients in the study, independently of the treatment group. A comparison is made between overall results before and after treatment.

Response to every type of treatment

Table 5 summarizes the clinical response to every one of the two treatments used in the study.

Throughout the study period participating patients reported no symptoms suggestive of being side effects of ESWT or BoNT-A.

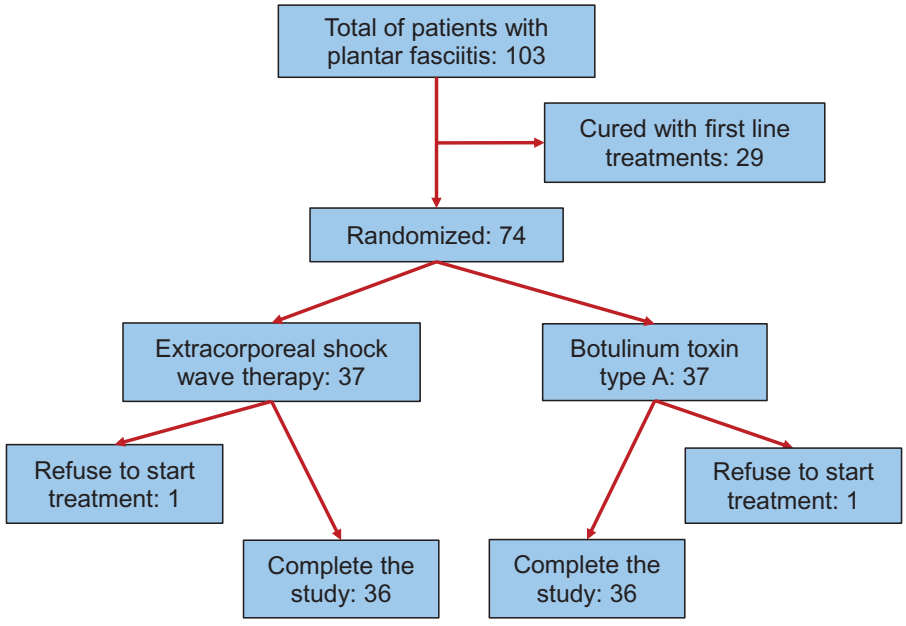

Figure 1. Study patients flow-chart.

Table 1. Epidemiologic data of the study patients.

	ESWT[a] ($N = 36$)	BoNT-A[b] ($N = 36$)	p
Gender female, number (percentage), for each treatment group	28 (77.8)	25 (69.4)	0.422
Age, years, mean ± standard deviation	50.4 ± 9.5	54.4 ± 13.3	0.144
Weight, kg, mean ± standard deviation	77.0 ± 13.0	81.4 ± 14.2	0.176
Height, m, mean ± standard deviation	1.63 ± 0.08	1.62 ± 0.08	0.815
Body mass index, kg/m^2, mean ± standard deviation	29.0 ± 4.8	30.9 ± 5.4	0.117

[a]ESWT, received extracorporeal shock wave therapy.
[b]BoNT-A, received treatment with botulinum toxin type A.

Table 2. Baseline clinical data related to plantar fasciitis of the study patients.

	ESWT[a] ($N = 36$)	BoNT-A[b] ($N = 36$)	p
Affected foot, right, number of patients (percentage), for each treatment group	20 (55.6)	19 (52.8)	0.813
Presence of calcaneal spur, number of patients (percentage), for each treatment group	30 (83.3)	26 (72.2)	0.257
Duration of symptoms of plantar fasciitis before initiating the study treatment, months, median (interquartile range)	12 (10–22)	12 (7–18)	0.152
VAS[c], when taking the first steps after prolonged rest, points, median (interquartile range)	7 (6–9)	8 (6–9)	0.291
VAS[c], during daily activities, points, median (interquartile range)	7 (5–8)	7 (6–8)	0.638
VAS[c], during exercise, points, median (interquartile range)	8 (6–9)	8 (7–9)	0.425
Roles and Maudsley scale of pain[d], points, median (interquartile range)	4 (3–4)	3.5 (3–4)	0.388
Plantar fascia thickness[e], mean ± standard deviation	6.1 ± 1.3	6.3 ± 1.5	0.692

[a]ESWT, received extracorporeal shock wave therapy.
[b]BoNT-A, received treatment with botulinum toxin type A.
[c]Visual analog scale for assessment of pain, from 0 to 10 points, with 10 being the most intense pain.
[d]From 1 to 4 points, with 4 being the most intense pain.
[e]Mean of two ultrasound measurements, each one made by a different explorer, at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border.

Table 3. Baseline quality of life data of the study patients.

	ESWT[a] ($N = 36$)	BoNT-A[b] ($N = 36$)	p
EQ-5D[c],[17] median (interquartile range)	5 (4–6)	6 (4–7)	0.417
EQ-5D complement[d],[17] median (interquartile range)	60 (40–78)	60 (50–75)	0.937
Foot Health Status Questionnaire[e],[18] median (interquartile range)	43 (39–48)	43 (39–47)	0.826

[a]ESWT, received extracorporeal shock wave therapy.
[b]BoNT-A, received treatment with botulinum toxin type A.
[c]European Quality of Life scale, consisting of the sum of six standardized measurements, each of them from 0 to 2 points, with 2 being the worst health state.
[d]Consisting of a VAS, from 0 to 100 points, with 0 being the worst health state.
[e]Consisting of the sum of 13 standardized measurements, from 1 to 5 points each one, with 5 being the worst health state.

Table 4. Clinical data at baseline, before treatment, and at follow-up visit, after treatment, in all patients of the study, independently of treatment received.

	Before[a] ($N = 72$)	After[b] ($N = 72$)	p
VAS[c], when taking the first steps after prolonged rest, points, median (interquartile range)	8 (6–9)	6 (4–8)	<0.001
VAS[c], during daily activities, points, median (interquartile range)	7 (5–8)	6 (4–7)	<0.001
VAS[c], during exercise, points, median (interquartile range)	8 (6–9)	6 (4–8)	<0.001
Roles and Maudsley scale of pain[d], points, median (interquartile range)	4 (3–4)	3 (2–3)	<0.001
Plantar fascia thickness[e], mean ± standard deviation	6.2 ± 1.4	5.9 ± 1.3	0.087

[a]Before treatment.
[b]After treatment.
[c]Visual analog scale for assessment of pain, from 0 to 10 points, with 10 being the most intense pain.
[d]From 1 to 4 points, with 4 being the most intense pain.
[e]Mean of two ultrasound measurements, each one made by a different explorer, at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border.

Table 5. Time elapsed from baseline visit to follow-up visit, and response of pain and plantar fascia thickness to every treatment used in the study.

	ESWT[a] ($N = 36$)	BoNT-A[b] ($N = 36$)	p
Time elapsed between baseline and follow-up visits, days, median (interquartile range)	36 (31–59)	38 (32–58)	0.592
VAS[c], when taking the first steps after prolonged rest, points of difference between the first and the second visit, median (interquartile range)	2 (1–4)	1 (0–2)	0.009
VAS[c], during daily activities, points of difference between the first and the second visit, median (interquartile range)	1 (0–2)	0 (0–2)	0.363
VAS[c], during exercise, points of difference between the first and the second visit, median (interquartile range)	1 (0–2)	1 (0–2)	0.204
Patients who noticed improvement of pain in at least one of the three modalities of VAS[c], number (percentage) for every treatment group	31 (86.1)	23 (63.9)	0.029
Roles and Maudsley scale of pain[d], points of difference between the first and the second visit, median (interquartile range)	1 (0–1)	0 (0–1)	0.006
Plantar fascia thickness[e], difference between the first and the second visit, mm, mean ± standard deviation	0.20 ± 0.77	0.33 ± 0.71	0.460

[a]ESWT, received extracorporeal shock wave therapy.
[b]BoNT-A, received treatment with botulinum toxin type A.
[c]Visual analog scale for assessment of pain, from 0 to 10 points, with 10 being the most intense pain.
[d]From 1 to 4 points, with 4 being the most intense pain.
[e]Mean of two ultrasound measurements, each one made by a different explorer, at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border.

Multivariate analysis

A logistic regression analysis, with the method forward stepwise (conditional), was carried out to try to find factors associated with clinical response to treatment, in terms of control of pain.

The dependent variable was improvement of pain (or not) in at least one of the three modalities of VAS of pain used in the study. The independent variables were: gender; age; affected foot; calcaneus spur, present or not; duration of symptoms of PF; weight; height; baseline pain assessment in the affected foot with the VAS of pain score, in the three situations described in Method; baseline pain assessment in the affected foot with the Roles and Maudsley scale score; baseline European Quality of Life scale score; baseline Foot Health Status Questionnaire score; baseline plantar fascia thickness; and prescribed treatment, ESWT or BoNT-A.

The regression model was significantly different from zero: $F = 15.02$, $p < 0.001$. Adjusted R^2 was = 18.0%, which means that independent variables were only slightly useful to predict the dependent variable. The only independent variables significantly associated with the dependent variable were "prescribed treatment" (coefficient 1.39, $p = 0.029$) and "weight" (coefficient −0.04, $p = 0.041$), which means that ESWT and low weight were positively associated with improvement of pain.

Discussion

The clinical importance of PF has been commonly underestimated in the literature.[21] That explains, at least in part, the relatively low number of high-quality research studies available on the disease, and the limited knowledge about the authentic efficacy of the several modalities of treatment used in the condition.[22] Nevertheless, PF is very common in the general population, tends to persist for many months, and in some cases provokes considerable disability.

With our study we pursued to improve knowledge in PF treatment, and more specifically to compare ESWT and BoNT-A, two commonly used modalities of treatment for the disease. We believe that our study is the first one directly comparing those two types of treatment. In a review of the literature that included the database Medline, accessed through PubMed, available in the Internet at http://www.ncbi.nlm.nih.gov/pubmed/, using the search profile ("shock wave" OR ESWT) AND "botulinum toxin", we found no other studies that specifically compared both modalities of treatment in PF or in other diseases.

Therefore, our study provides new information on the treatment of PF that will be helpful to design the most suitable strategy in the treatment of the disease. We consider that the design of the study, relatively simple but at the same time robust, is appropriate to reach reliable conclusions.[23]

Among the study participants there was a predominance of middle-aged women, as in other similar studies.[1,24] Overweight and obesity, a well-known risk factor for PF,[1,2] was almost twice as common in the study patients than in the general population of the same geographic area.[25] And calcaneal spur was more prevalent among our patients than in those of other comparable studies.[26]

We excluded from our study the patients that had responded to first-line therapy with physiotherapy and electrotherapy. But only about one fourth of all patients treated of PF in our centre during the study period were excluded for that reason. That reflects the limited efficacy of first-line treatments in PF.[4]

Also remarkable among the study patients is the long duration of symptoms and the relatively high punctuations in the pain scales used, which emphasize the clinical relevance of the disease in many patients.

The overall results of the study, independently of the treatment used, showed a significant response of symptoms, as measured with different pain scales. That is remarkable, because patients had failed to improve with first-line therapies. These results are in general comparable to those found by other authors that have compared diverse treatments of PF with placebo.[11,19,20,27–32]

Nonetheless this study had not been designed to assess the overall efficacy of treatments, as there was no placebo group. Moreover, the simple effect of time might explain, in part, the improvement in symptoms, as PF is a self-limiting condition that spontaneously disappears with time. Therefore these results must be interpreted with care.

Regarding thickness of plantar fascia, we found a tendency to diminish after treatment, but the difference between baseline and follow-up visits was not significant. Other authors have found a significant difference in that measurement, with similar numbers of patients that in our study.[28,29]

The most important finding in our study, according with the employed design, was the superiority of ESWT over BoNT-A in the treatment of PF, in terms of control of pain. In two of the five pain scales used a significant difference was found, and in the other three scales a tendency in favour of ESWT was also found.

As there are no other studies in the literature directly comparing ESWT with BoNT-A, our results can be considered as the clearest available evidence of the superiority of one treatment over the other. Notwithstanding, there are published studies comparing

both ESWT or BoNT-A with placebo,[9,11–13,20] which allows to indirectly comparing both modalities of treatment. In those studies the magnitude of improvement of PF symptoms with ESWT seems to be higher than with BoNT-A, which would agree with our findings.

The multivariate analysis in our study disclosed an association of improvement in pain scores after treatment with two variables: ESWT use and lower weight. The association of improvement of pain with ESWT use agrees with the other results of our study. And the association improvement of pain with low weigh is congruent with the known influence of overweight in the pathophysiology of PF,[2,4] although we have found no other studies assessing the influence of baseline weight on the response to treatment in PF.

We believe that the main limitation of this study is the relatively small number of patients included. Probably this is the reason why we did not find differences between both groups of treatment in all the compared variables. Anyway, the fact that our study was carried out in just one centre has also advantages, such as the consistency of clinical management of patients, and therefore the lower chance of several kinds of bias.[33] Moreover, the number of participants in most other studies assessing treatments of PF is similar or lower to that in our study.

Another possible limitation of this study is the unavoidable subjectivity in the measurement of several used variables. That is especially evident with variables that depend on information provided by patients, as pain scales,[34] but also with variables that depend on information provided by researches, as plantar fascia thickness measurement.[35] In order to minimize those problems, we used several pain scales, and performed two measurements of plantar fascia thickness, each one made by one explorer.

Finally another limitation is the open design of the study, which substantially increase the possibility of bias, not only related to patients but also to researchers.[36] Anyway a double blind design of a study of this kind, as theoretically would be desirable, is almost unfeasible, taking into account the characteristics of the employed treatments.

With the available results, including those of our study, it seems particularly important to investigate on ESWT, as this kind of therapy is effective and safe in PF, but many uncertainties still exist regarding the type of shock waves to use, their optimal intensity, the best way of administering them, etc.[37]

Disclosure statement

The authors declare no conflicts of interest regarding this work.

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