

**Patient characteristics predicting treatment success of shockwave therapy combined with physical therapy in plantar fasciopathy:
An observational cohort study**

Master thesis

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Samenvatting

Inleiding: Schokgolf therapie wordt door fysiotherapeuten steeds frequenter toegepast bij de behandeling van fasciopathie plantaris, met wisselend succes. Het succes van shockwave therapie bij fasciopathie plantaris hangt af van verschillende factoren. Het doel van deze studie is daarom het identificeren van patiënt-karakteristieken die het behandelingsucces van schokgolf therapie gecombineerd met fysiotherapie bij fasciopathie plantaris kunnen voorspellen.

Methode: Een observationele cohort studie is uitgevoerd onder 54 participanten. De participanten werden wekelijks behandeld met 4 sessies radiale shockwave therapie volgens een gestandaardiseerd protocol, dat gepaard ging met fysiotherapie. Zes baseline karakteristieken (leeftijd, geslacht, duur van de klachten, pijn in rust, episode nummer en de aanwezigheid van calcificatie) werden onderzocht op hun voorspellende waarde voor behandelingsucces volgens de 7-punts Likert schaal, 6 weken na baseline. Data werd geanalyseerd door middel van een bivariate en multivariate logistische regressie analyse.

Resultaten: Volgens de 7-punts Likert schaal werden 44 participanten (81.5%) succesvol behandeld. Bivariate logistische regressie analyse liet significante associaties zien tussen behandelingsucces en geslacht, pijn in rust en duur van de klachten ($p < 0.2$). Multivariate logistische regressie analyse liet zien dat behandelingsucces 6 weken na baseline werd voorspeld door de duur van de klachten ($p < 0.05$). Patiënten met klachten korter dan 12 maanden hadden 4.5 keer zoveel kans op een succesvolle behandeling dan patiënten met klachten voor 12 maanden of langer.

Conclusie: Deze observationele cohort studie laat zien dat behandelingsucces van schokgolf therapie gecombineerd met fysiotherapie kan worden voorspeld door de duur van de klachten op baseline, waarbij patiënten met klachten korter dan 12 maanden meer kans hebben op een succesvolle behandeling dan patiënten met klachten langer dan 12 maanden. Het identificeren van voorspellende factoren kan klinici helpen met het determineren van patiënten die het meeste kunnen profiteren van een interventie.

Abstract

Introduction: Shockwave therapy is increasingly used by physical therapists for the treatment of plantar fasciopathy with varying success. The success of shockwave therapy in plantar fasciopathy depends on several factors. Therefore, the aim of this study is to identify patient characteristics predicting treatment success of shockwave therapy combined with physical therapy in plantar fasciopathy.

Methods: An observational cohort study was conducted of 54 participants. At weekly intervals participants were treated with 4 sessions of radial shockwave therapy using a standardized protocol accompanied by a physical therapy regimen. Six baseline characteristics (age, gender, duration of complaints, pain at rest, episode number and presence of calcification) were investigated for their prognostic ability on treatment success according to the 7-point Likert scale at 6 weeks follow-up. Data were analysed using bivariate and multivariate logistic regression analysis.

Results: According to the 7-point Likert scale 44 participants (81.5%) were treated successfully with shockwave therapy combined with physical therapy. Bivariate analysis showed significant associations between treatment success and gender, pain at rest, and duration of complaints ($p < 0.2$). Multivariate logistic regression analysis showed that treatment success at 6 weeks follow-up was predicted by duration of complaints ($p < 0.05$). Patients with complaints for less than 12 months are 4.5 times more likely to experience a successful treatment than patients with complaints for 12 or more months.

Conclusion: The present observational cohort study showed that treatment success of shockwave therapy combined with physical therapy can be predicted by duration of complaints at baseline, indicating that patients suffering for less than 12 months were more successfully treated than those with complaints over 12 months. Identification of predicting factors may help clinicians to determine which patients are most likely to benefit from an intervention.

Keywords: Plantar fasciopathy, plantar fasciitis, shockwave therapy, pain, prognostic factors.

1. Introduction

Plantar fasciopathy (PF), or more commonly named plantar fasciitis, is a painful and invalidating overuse injury of the plantar fascia, which spans between the medial calcaneal tubercle and the proximal phalanges of the toes (1). The diagnosis PF is made on clinical findings and typical symptoms are pain and tenderness on weight bearing, especially during the first few steps in the morning, the beginning of an activity, and during longer activities (1-5). The prevalence of PF has not been studied, but it is estimated that PF affects approximately 10% of the general population in the United States at some time during life time (6).

The aetiology of PF, with or without bony traction spur (heel spur), is not completely understood, and is probably multifactorial (1,5,7). Reduced ankle dorsiflexion, obesity, and work- or sports related weight bearing appear to be risk factors (3-5,8-10). In acute PF the mechanical overload of the plantar fascia triggers a local inflammatory response. New insights indicate that chronic complaints of collagenous tissue, like the plantar fascia, may be susceptible to a failed healing process leading to degenerative alterations, contracture of the fascia, shortening of foot muscles and periostitis (5,11).

Many conservative treatments are used to treat PF with variable success, including stretching exercises, taping, shoe inserts, cortisone injections, physical therapy, and night splints (4,5,12-14). The role of these treatments should be considered in the light of the self-limiting nature of PF, with 80% of patients experiencing reduction of complaints within 12 months, regardless of management (1). For patients who suffer from this condition for a long time, a surgical approach is one of the options. Reports of the results of these surgical treatments, including endoscopic and open fasciotomy, have generally been favourable (15). Unfortunately after surgery complications are not uncommon and patients are required to avoid weight bearing, which leads to a prolonged time for return to work or sports (7).

With the desire for a less invasive approach, shockwave therapy (SWT) has emerged as an alternative treatment for chronic PF. SWT has been recognised to stimulate soft tissue healing, to reduce calcifications and to inhibit pain receptors resulting in

pain relief. However, the exact working mechanism has to be established (16,17). The majority of studies on SWT in soft tissue overuse injuries, in particular the more recent investigations, show favourable results, although the exact scientific and clinical value of SWT is still subject to research (7,18).

The success of SWT in plantar fasciopathy depends on several factors. Controversy exists about methods of application and shockwave generation (focused or radial), energy level to be used, number and frequency of treatments, use of (local) anaesthesia and methods of localisation (19). Besides the controversy on treatment protocols, there is little knowledge about which patients are most likely to benefit from shockwave therapy. For example, Helbig et al. (2001) suggested that patients with chronic symptoms are more likely to benefit from SWT than patients with acute symptoms of PF (20). On the other hand, Ogden et al. (2002) suggested that a shorter period of symptoms was significantly associated with success of SWT (21).

Identification of predicting factors may help clinicians to determine which patients are most likely to benefit from an intervention (22). Therefore, the aim of this study is to identify patient characteristics predicting treatment success of shockwave therapy combined with physical therapy in plantar fasciopathy.

2. Patients & Methods

2.1 Study design

Between September 2010 and July 2011 an observational cohort study (The Impuls-NVMST study) was conducted to identify patient characteristics predicting treatment success of shockwave therapy combined with physical therapy in plantar fasciopathy. The study was designed at Maastricht University and undertaken at physical therapy practices in The Netherlands which are connected to the Dutch Association for Musculo-Skeletal Shockwave Therapy (Nederlandse Vereniging voor Musculo-skeletale Shockwave Therapie, NVMST). The medical ethical committee of Maastricht University Medical Centre+ approved the Impuls-NVMST study.

2.2 Study procedures

Inclusion, treatment and measurements of all participants were conducted by their physical therapist at the participating physical therapy practices. Signed informed consent was obtained from all participants before treatment. An overview of the procedures is given in Figure 1. All data (patient characteristics, treatment parameters and outcome measures) were entered in a digital patient file (Electronisch Patiënten Dossier, EPD). Data from this EPD were used by the researchers for analysis and to answer the research question.

2.3 Study population

To be eligible for the trial, participants had to be adults of at least 20 years of age and diagnosed with plantar fasciopathy with symptoms present for more than 3 months. Participants were excluded if one of the following conditions were present: rheumatic or other systemic inflammatory disease, diabetes mellitus or other metabolic disease, malignancies, substantial movement disorders or instability of the foot or ankle, previous surgery for plantar heel pain or corticosteroid injections of the foot in the past 6 weeks.

No sample size calculation was executed because daily clinical practice was studied in this observational cohort study.

2.4 Treatment

Patients were treated with shockwave therapy whether or not combined with physical therapy following a standardized protocol.

2.4.1 Shockwave therapy

Shockwave therapy consisted of 2 different shockwave therapy treatment options: treatment option A and B (Table 1). Treatment option A was applied in case calcification of the plantar fascia tendon was present at baseline. Calcification was assessed using ultrasound, if ultrasound equipment was available at the physical therapy practice. Treatment option B was applied if no calcification was present at baseline, or if not assessed.

Table 1. Shockwave therapy treatment options

	Treatment option A	Treatment option B
Type of shockwave therapy	Radial shockwave therapy	Radial shockwave therapy
Number of treatments	4 (1 session weekly)	4 (1 session weekly)
Number of shockwaves per treatment	2200	2200
Frequency of shockwaves (hertz)	10	10
Intensity of shockwaves (bars)	3.2	2.7

Treatment parameters were different for both treatment options. The shockwaves were applied on the most sensitive spot at the heel in a constant circular movement. Additionally, the regular head of the shockwave device should be changed for a D-actor head to treat the whole plantar fascia. Parameters for treatment with the D-actor head were the same for both treatment option A and B with a total of 2000 shockwaves, a frequency of 15 hertz and an intensity of 2.2 bars.

2.4.2 Physical therapy

If necessary, the treating physical therapist prescribed additional treatment. In that case, eccentric exercises of the calf muscles were executed at home 2 times a day in 3 series of 10-15 repetitions, with 1-3 minutes pause in between (both with bended and extended knee). Additionally, participants could massage the plantar fascia of their foot with a golf ball or drink bottle. If necessary, mobilisation of the metatarsophalangeal joint I (MTP I) and correction of the dynamics of the foot were done by the treating physical therapist.

2.4.3 Pain medication

It was advised not to use any pain medication during the trial. Whenever pain medication was used, it was registered in the EPD.

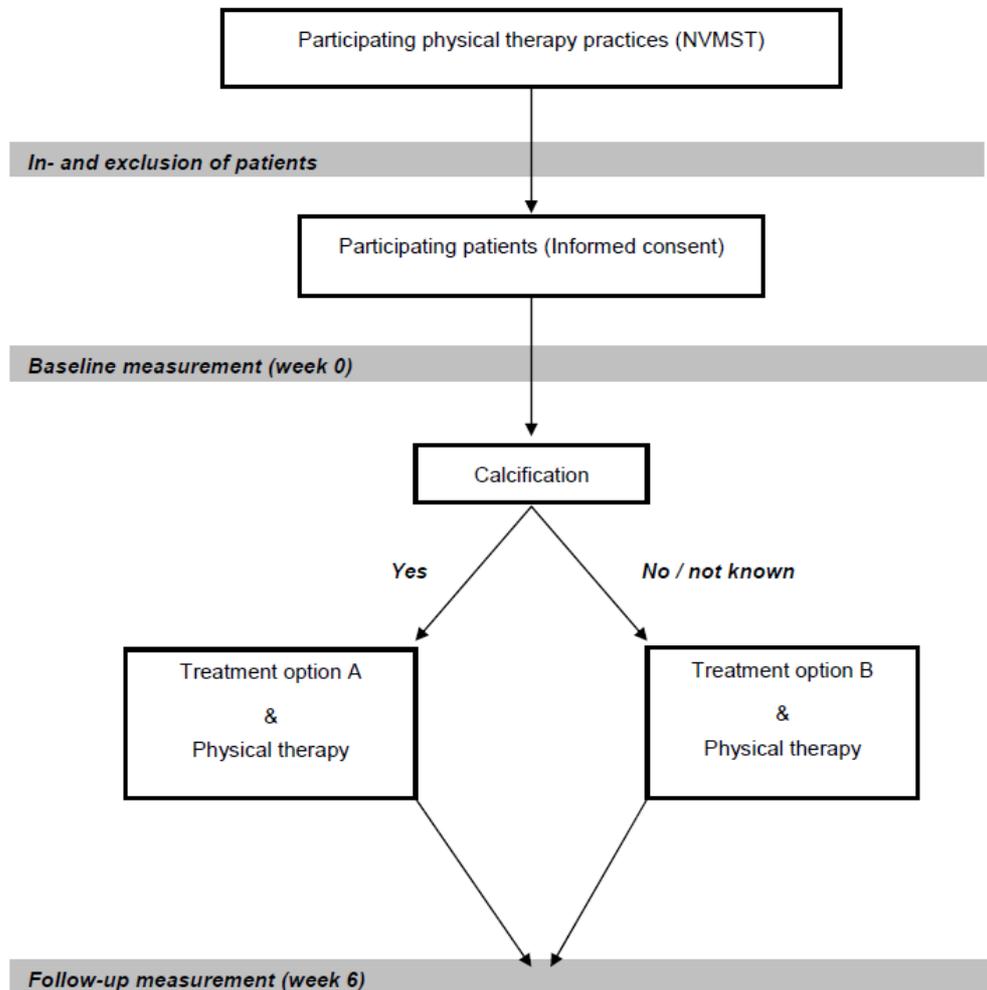


Figure 1. Flowchart

2.5 Treatment outcome (dependent variable)

The main outcome measure was treatment success at 6 weeks from baseline according to the 7-point Likert scale. The 7-point Likert scale is an easy and widely accepted global observational rating scale to evaluate the degree of recovery. The Likert scale consists of 7 items and can be rated on a 1 to 7 scale. In this study, treatment success rates were calculated by dichotomizing responses. Treatment was judged to be successful when participants reported themselves 'completely recovered', 'much improved' or 'somewhat improved' at 6 weeks from baseline.

Treatment was judged to be unsuccessful for participants who reported themselves 'same', 'worse', 'somewhat worse' or 'much worse' (Table 2).

Table 2. The 7-point Likert scale

Score	Description	Interpretation
1	Completely recovered	Successful
2	Much improved	Successful
3	Somewhat improved	Successful
4	Same	Unsuccessful
5	Worse	Unsuccessful
6	Somewhat worse	Unsuccessful
7	Much worse	Unsuccessful

2.6 Prognostic factors (independent variables)

Six potential prognostic factors were chosen by the investigators on clinical grounds and availability and included: age, sex, duration of the complaints (in months), pain score at rest (rated on a 100 millimetre VAS scale), episode number of complaints and presence of calcification (measured using ultrasound). All potential prognostic factors were baseline characteristics and were entered in the EPD before treatment.

2.7 Statistical analysis

Descriptive statistics were used to describe patient characteristics and treatment outcome. Univariate logistic regression was used to examine associations between possible prognostic factors (independent variables) and outcome (dependent variable). Independent variables showing a univariate association with the dependent variable ($p < 0.2$) were extracted as candidate variables to be used in the multivariate logistic regression analysis. Multivariate logistic regression was carried out using the Backward Stepwise (Likelihood Ratio) method $P_{in} < 0.05$; $P_{out} > 0.10$. Odds Ratio (OR), 95% Confidence Interval (CI) and p -value were calculated for each independent variable. Missing values in the analysis were replaced in accordance with the intention-to-treat principle by using last observation carried forward.

Statistical analyses were performed using the Statistical Package for the Social Sciences for Windows (version 16.0, SPSS Inc, Chicago, IL, USA). All p -values are two sided with significance level of 5%.

3. Results

3.1 Study population

The study population consisted of 54 participants with PF who all met the inclusion criteria. Baseline characteristics are presented in Table 3. Twenty-three patients were male (43%) and 31 were female (57%). The mean age of the study population was 53 ± 11.5 (range 30-78). Forty-five patients (83%) suffered from PF for the first time, 9 patients (17%) had a recurrent episode of PF. The duration of the symptoms ranged from 3 to 36 months, with a mean duration of 9.2 months. Pain was located at the origin of the plantar fascia at the calcaneus in most patients (65%); sometimes pain was felt at the fascia, underneath the foot. At baseline, the average pain score in rest was 51 ± 23.4 (range 8-90). Calcification was present in 21 patients (39%), in the other 33 patients calcification was not present or was not measured. At baseline, 36 patients (67%) participated in sports for at least 1 time per week. From these patients, the current percentage of sports participation at baseline compared to usual reached an average of 40% (range 0%-100%). At baseline, the percentage of overall functioning with PF, reached an average of 78% (range 25%-100%). The average percentage of paid work participation was 88% (range 0%-100%). The score regarding confidence in recovery at baseline scored an average of 74% (range 3%-100%).

3.2 Treatment and outcome measure

At 6 weeks follow-up 44 participants (81.5%) had a Likert score of 1, 2 or 3, which was initially defined as a successful treatment. Ten participants (18.5%) had a Likert-score of 4 or more and therefore had an unsuccessful treatment (Table 3). In 15 participants (28%), results at 6 weeks follow-up were missing and the 'last observation carried forward' (LOCF) method was used.

It is unknown in which participants only shockwave therapy was applied or when physical therapy or pain medication was applied as an additional treatment.

Table 3. Baseline characteristics (overall, and subdivided into successful and unsuccessful treatment).

	Overall (N=54)	Successful treatment (N=44)	Unsuccessful treatment (N=10)
Gender			
Male, N (%)	23 (43%)	21 (39%)	2 (4%)
Female, N (%)	31 (57%)	23 (43%)	8 (14%)
Age			
< 50 years, N (%)	21 (39%)	15 (28%)	6 (11%)
≥ 50 years, N (%)	33 (61%)	29 (54%)	4 (7%)
Pain score at rest			
< 50 mmVAS, N (%)	22 (41%)	16 (30%)	6 (11%)
≥ 50 mmVAS, N (%)	32 (59%)	28 (52%)	4 (7%)
Duration of complaints			
< 12 months, N (%)	38 (70%)	34 (63%)	4 (7%)
≥ 12 months, N (%)	16 (30%)	10 (19%)	6 (11%)
Episode number of complaints			
First episode, N (%)	45 (83%)	37 (69%)	8 (14%)
Relapse, N (%)	9 (17%)	7 (13%)	2 (4%)
Presence of calcification			
Yes, N (%)	21 (39%)	18 (34%)	3 (5%)
No, N (%)	33 (61%)	26 (48%)	7 (13%)

Abbreviation: VAS = Visual Analog Scale; mm = millimetre; N= number of patients.

3.3 Statistical analysis

3.3.1 Univariate analysis

The univariate analysis showed significant association between treatment success and gender, pain at rest, and duration of complaints at baseline ($p < 0.2$). A more liberal significance level was used to increase the power for true predictor selection. Other factors, including age, presence of calcification, and episode number had no significant impact on treatment success of SWT whether or not combined with physical therapy (Table 4).

Table 4. Univariate logistic regression analysis

	B	SE	OR (95% CI)	p-value
Duration of complaints (< 12 months)	1.50	0.73	4.50 (1.07-18.9)	0.04 **
Gender (male)	1.29	0.85	3.65 (0.70-19.2)	0.13 *
Pain score at rest (≥ 50 mmVAS)	0.97	0.72	2.63 (0.64-10.7)	0.18 *
Calcification (yes)	0.48	0.76	1.62 (0.37-7.10)	0.53
Age (≥ 50 years)	0.41	0.71	1.50 (0.37-6.06)	0.57
Episode number (first)	0.28	0.89	1.32 (0.23-7.59)	0.76

Abbreviation: B = Intercept; SE = Standard error of the mean; OR = Odds ratio; CI = Confidence interval.

* $P < 0.2$ (and therefore included in multivariate analysis); ** $P < 0.05$ (statistically significant).

3.3.2 Multivariate analysis

Gender, duration of complaints and pain were included in the multivariate analyses. The backward logistic regression analysis showed that only duration of complaints was a statistically significant prognostic factor for treatment success following SWT whether or not combined with physical therapy (Table 5). Participants with complaints for less than 12 months are 4.5 (odds = 4.50) times more likely to experience a successful treatment than patients with complaints for 12 months or more.

Table 5. Multivariate logistic regression analysis

		B	SE	OR (95% CI)	p-value
Step 1	Gender (male)	1.01	0.88	2.76 (0.49-15.5)	0.25
	Duration of complaints (< 12 months)	1.29	0.76	3.62 (0.82-16.0)	0.09
	Pain score at rest (≥ 50 mmVAS)	0.66	0.76	1.94 (0.43-8.66)	0.39
	Constant	0.72	0.73	2.05	0.32
Step 2	Gender (male)	1.11	0.87	3.03 (0.55-16.7)	0.20
	Duration of complaints (< 12 months)	1.36	0.75	3.91 (0.90-17.0)	0.07
	Constant	0.32	0.55	1.38	0.56
Step 3	Duration of complaints (< 12 months)	1.50	0.73	4.50 (1.07-19.0)	0.04 **
	Constant	0.61	0.51	1.83	0.23

Abbreviation: B = adjusted; SE = Standard error of the mean; OR = Odds ratio; CI = Confidence interval.

** $P < 0.05$ (statistically significant).

The model (with only the factor 'duration of complaints') correctly classified 81.5% of the patients: 100% of the successful treatment group and 0% of the non successful treatment group.

4. Discussion

The present study investigated patient characteristics predicting treatment success of shockwave therapy combined with physical therapy in plantar fasciopathy. The main results are that gender, pain in rest, and duration of complaints at baseline were bivariately associated to treatment success of shockwave therapy combined with physical therapy for plantar fasciopathy at 6 weeks follow-up ($p < 0.2$). The multivariate logistic regression model, however, identified only duration of complaints as a statistically significant factor ($P < 0.05$). According to the odds ratio, participants with complaints for less than 12 months are 4.5 times more likely to experience a successful treatment than participants with complaints for 12 or more months.

4.1 Comparison to other research

Few other studies have identified outcome predictors of shockwave therapy in plantar fasciopathy before. Here, we will only focus on patient-related outcome predictors; intervention-related predictors such as previous cortisone injections (23-25), different energy densities of SWT (26,27), different types of SWT (28), number of treatments (29) and the use of local anaesthesia (30) were not taken into account.

4.1.1 Duration of complaints

In the present study we found that participants with complaints for less than 12 months were significantly more likely to benefit from shockwave therapy (combined with physical therapy) than those who suffered longer. Four other studies investigated the prognostic value of duration of complaints with various results.

In accordance to the present study, Alvarez et al. (2003) found that patients were slightly more likely to have positive results if symptoms had been present for a shorter period of time (31). Patients with complaints for less than 24 months had better results on treatment outcome than those who had complaints for more than 24 months (31).

Auersperg et al. (2000) also found that the shorter the history of pain, the better the results of shockwave therapy in plantar fasciopathy (32). According to Auersperg results were the best in patients with a prior history less than 6 months (67,5% good or excellent results). Between 6 and 36 months of pain history, patients

had less than 60% good or excellent results, and with more than 36 months about 50% (32).

In contrast with the present study and the studies described above, Chuckpaiwong et al. (2009) found no significant association between duration of symptoms and treatment success (25). The differing in results can be explained by differences in study design. First of all, the study population in the study of Chuckpaiwong consisted of patients with complaints for 6 to 240 months, with an average of 30 months. This average is much higher than in our study. Moreover, we included patients with a minimum of 3 months of complaints, whereas Chuckpaiwong only included patients with complaints for 6 months or longer. Therefore Chuckpaiwong could possibly not detect a significant association between short duration of complaints and treatment success. Secondly, Chuckpaiwong used a 12 and 52 week follow-up period, whereas we only identified prognostic factors at 6 weeks. Possibly, dissimilar results are due to varying follow-up times, because treatment success may be different measured at different times after treatment. Third, Chuckpaiwong used focussed shockwave therapy to treat the study population. In our study we treated patients with radial shockwave therapy, which may have resulted in different effect on treatment success and therefore different results in outcome predictors.

Finally, Helbig et al. (2001) investigated the association between duration of complaints and treatment success and also reported no significant results (20). In contradiction with the present study, Helbig et al. found worst treatment results in those patients with pain for only 3 to 12 months. Patients who had symptoms for more than 35 months all achieved a good or very good results. Patient characteristics in Helbig were comparable with the patient characteristics in our study. The only explanation for the conflicting results compared to our study is the shockwave application; Helbig used focussed shockwave treatment whereas in the present study patients were treated with radial shockwave therapy. This might have had a different effect on treatment success and therefore different results in outcome predictors.

4.1.2 Age

Only one other study investigated the prognostic value of age in treatment success of shockwave therapy (25). Chuckpaiwong et al. (2009) found that having a higher age significantly negatively influenced SWT treatment outcome. This is in contrast to the

present study, where we did not detect age as a significant predictor of treatment success. We do not have an explanation for the difference in results, other than the difference in study design as described before.

4.1.3 Gender

Chuckpaiwong et al. (2009) also investigated gender as a possible prognostic factor of treatment success after SWT (25). Chuckpaiwong reported no statistical significant association between gender and SWT treatment outcome. This is consistent with the findings in our current study.

4.1.4 Calcification

Two studies investigated calcification as a prognostic factor of SWT treatment success. Both Lee et al. (2003) and Chuckpaiwong et al. (2009) found no correlation between presence and absence of calcification and eventual treatment outcome (25,33). This is consistent with the findings from our present study. However, an important limitation of our study is that we had to classify patients where no ultrasound had been done as 'no calcification present'.

4.1.5 Other factors

Other prognostic factors that we investigated in the present study (episode number and pain in rest at baseline) have, to our knowledge, not been investigated on their prognostic ability before. On the other hand, prognostic factors that *have* been associated with treatment outcome of SWT in plantar fasciopathy before, but which we did not investigate in our current study, are: Body Mass Index (BMI) (24,25), psychological issues (25), diabetes mellitus (25), plantar fascia thickness (25,34) and bilateral symptoms (25,35).

4.2 Strengths and limitations

The strength of the present study lies in its rigorous methods, which includes a detailed description of the methodology and the results, supported by extensive statistical analysis. Also, a few limitations concerning this study need to be considered. First of all, we investigated only a limited number of possible prognostic factors. The selection of factors was made on practical grounds, where we were dependent on a previously established study design. The second limitation is the small study population. Because the distribution among participants between the

successful and the unsuccessful treatment group was also skewed, the unsuccessful group was very small. As a result, we could have missed important prognostic factors. The third limitation of the present study is the follow-up period of only 6 weeks, because of a limited time schedule. Since previous studies found that the favourable effects of SWT may lag for some time in further improvements 3-6 months after the therapy is finished, a longer follow-up period is desirable (7,36-38). Finally, missing data at 6 weeks follow up (28%) and missing information about additional treatments could have influenced the accuracy of the present study.

4.3 Suggestions for further research

Prognostic research in large patient groups and with sufficient follow-up time is recommended for identification of more patient-related prognostic factors of shockwave therapy in plantar fasciopathy, so that SWT in the future can be applied selectively in patients who will benefit most. Besides patient-related factors, also intervention-related factors should be taken along because there is still no consensus about the most effective SWT treatment protocol in the management of PF. The most appropriate study-design would be a randomized placebo-controlled trial, because in that case both treatment success and prognostic factors can be studied and compared to a placebo group. Moreover, comparison with a placebo group would give more insight in the influence of the self-limiting nature of PF on treatment success and the associated prognostic factors.

5. Conclusion

The present observational cohort study showed that treatment success of shockwave therapy combined with physical therapy in plantar fasciopathy can be predicted by duration of complaints at baseline. Participants with complaints for less than 12 months are 4.5 times more likely to experience a successful treatment than participants with complaints for 12 or more months. Identification of predicting factors may help clinicians to determine which patients are most likely to benefit from an intervention.

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