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Published in:
Clinical Journal of Sport Medicine

DOI:
10.1097/JSM.0000000000000332

Effectiveness of Shockwave Treatment Combined With Eccentric Training for Patellar Tendinopathy: A Double-Blinded Randomized Study

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Objective: To evaluate the effectiveness of a combined treatment of focused shockwave therapy (ESWT) and eccentric training compared with sham-shockwave therapy (placebo) and eccentric training in participants with patellar tendinopathy (PT) after 24 weeks.

Design: Randomized controlled trial.

Setting: Sports medicine departments of a university hospital and a general hospital in the Netherlands.

Participants: Fifty-two physically active male and female participants with a clinical diagnosis of PT (mean age: 28.6 years; range, 18-45) were randomly allocated to the ESWT (n = 22) or sham shockwave (n = 30).

Interventions: Extracorporeal shockwave therapy and sham shockwave were applied in 3 sessions at 1-week intervals with a piezoelectric device. All participants were instructed to perform eccentric exercises (3 sets of 15 repetitions twice a day) for 3 months on a decline board at home.

Main Outcome Measures: The Victorian Institute of Sport Assessment-Patella (VISA-P) scores (primary), pain scores during functional knee loading tests, and Likert score (secondary) were registered at baseline and at 6, 12, and 24 weeks after the start with the ESWT or sham-shockwave treatment.

Results: No significant differences for the primary and secondary outcome measures were found between the groups. In the ESWT/eccentric group, the VISA-P increased from 54.5 ± 15.4 to 70.9 ± 17.8, whereas the VISA-P in the sham-shockwave/eccentric group increased from 58.9 ± 14.6 to 78.2 ± 15.8 (between-group change in VISA-P at 24 weeks −4.8; 95% confidence interval, −12.7 to 3.0, $P = 0.150$).

Conclusions: This study showed no additional effect of 3 sessions ESWT in participants with PT treated with eccentric exercises. The results should be interpreted with caution because of small sample size and considerable loss to follow-up, particularly in the ESWT group.

Key Words: sports, tendinopathy, patellar, knee, eccentric, ESWT

(*Clin J Sport Med* 2017;27:89–96)

INTRODUCTION

Patellar tendinopathy (PT) is a common sports injury causing pain most commonly at the origin of the patellar tendon at the inferior pole of the apex patellae as well as physical dysfunction. It is caused by an overload of the knee extensor mechanism. Patellar tendinopathy is often chronic and difficult to treat.[1] In the last decade, eccentric training has evolved to be a standard treatment method for PT with 50% to 70% chance of improvement at 3 to 6 months of follow-up.[2,3] Until now, professionals involved in sports medicine have been searching for new treatment modalities to more effectively treat chronic tendinopathies. Since the early 90s, extracorporeal shockwave therapy (ESWT) has been used for treatment of tendinopathies.[4,5] It is theorized that ESWT produces a regenerative and tissue-repairing effect and inhibits pain receptors.[5,6] van Leeuwen et al[7] reviewed the effect of ESWT in PT. Their review showed ESWT to be a safe and promising intervention; however, most studies had limitations in methodological quality. Therefore, it is hard to draw firm conclusions about its overall effectiveness.[7] Recently, combined treatment approaches are being applied. The literature suggests that a combined therapy of eccentric loading and shockwave is more effective than eccentric loading alone in chronic Achilles tendinopathy[8] and chronic PT after a 3-month follow-up.[9] It is interesting to examine whether the positive outcome of combined therapy also lasts at long-term follow-up.

The aim of this randomized controlled study [PATELLAr tendinopathy Sham and Shockwave (PATELLASS) study] is to

Submitted for publication April 23, 2015; accepted January 14, 2016.

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The authors report no conflicts of interest.

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determine the effectiveness of a combined treatment of eccentric training and ESWT compared with eccentric training and sham shockwave (placebo) in participants with PT during a 24-week follow-up. We hypothesized that participants treated with this combined approach of eccentric training and ESWT will improve significantly more in Victorian Institute of Sport Assessment-Patella (VISA-P) scores than participants treated with eccentric training and sham-shockwave therapy at 24-week follow-up.

METHODS

Study Design

The PATELLASS study is a multicenter randomized and placebo-controlled trial conducted at the sports medicine departments of a university hospital [University Medical Center Utrecht (UMCU), Utrecht, the Netherlands] and a general hospital [Medical Center Haaglanden (MCH), Leidschendam, the Netherlands]. Participants were randomized to either eccentric exercises in combination with ESWT (ESWT group) or eccentric exercises in combination with sham-shockwave therapy (placebo group). Participants and outcome assessors were blinded to the designated intervention at all time during follow-up at 6, 12, and 24 weeks. The physical therapists providing the shockwave treatment were not blinded to the intervention because they had to adjust the shockwave device to "true" or "sham" treatment. These physical therapists were not involved in the follow-up of the participants.

Participants

Study participants were recruited from general practitioners, sports medicine, and physical therapy practices. A digital letter was sent to potential referring physicians and physical therapists to inform them about the study. They were asked to refer eligible participants to the sports medicine departments of the UMCU or MCH. All participants who matched the inclusion and exclusion criteria and were willing to participate in the study were included.

Inclusion criteria were the presence of PT in participants active in sports at least once a week and an age between 18 and 40 years. Patellar tendinopathy was diagnosed by sports medicine physicians based on the following clinical findings: (1) history of knee pain located in the patellar tendon or its patellar insertion related to activity, (2) recognizable palpation tenderness of the patella tendon or its insertion on the patella, (3) symptoms present for over 8 weeks, and (4) the VISA-P score less than 80 at baseline. During loading, the pain had to remain isolated to the circumscript part of the tendon or tendon bone junction and not spread to whole patellar region (to distinguish between PT and patellofemoral pain). In case of bilateral complaints, the most painful knee was included.

Exclusion criteria were (1) acute knee or acute patellar tendon injury, chronic inflammatory joint diseases [(rheumatoid) arthritis] or signs or symptoms of other (co-) existing knee pathologies, (2) using immunosuppressive or corticosteroid medication in the last 6 months, (3) previous knee surgery (on the anterior cruciate ligament or the patellar tendon), (4) a local (corticosteroid) injection of the knee in the past month, (5) contraindications for ESWT treatment (eg, pregnancy, malignancy, coagulopathy), or (6) participants who received ESWT before (ie, these participants are not blinded to the ESWT treatment).

Intervention

Shockwave Treatment

The focused ESWT and sham-shockwave treatments were provided by two independent physical therapists (at 2 different locations in the Netherlands). Both physical therapists are qualified and experienced in application of ESWT. The device was placed on the most painful spot with the knee extended. Extracorporeal shockwave therapy was applied in 3 sessions at 1-week intervals with a Piezoelectric ESWT device (Swiss PiezoClast; Electro Medical Systems, Nyon, Switzerland) using 1000 pulses in a frequency of 4 Hz and an energy density level of 0.2 mJ/mm^2. The energy density was gradually increased during the session. There is still considerable controversy in ESWT protocols with respect to the number of sessions and dosage. Manufacturers of comparable low–medium dose energy devices consistently recommend between 3 and 5 sessions.[4] Current treatment protocol was chosen because of the usability and tolerance in the study of Peers.[9]

The sham-shockwave treatment procedure for the control group was nearly the same as the ESWT treatment and was administered with the same device, in 3 sessions at 1-week interval, using 1000 pulses in a frequency of 4 Hz and an energy level 1.[9,10] Transmission gel was applied between the focusing pad and the skin of the participants, but not between the applicator and focusing pad. In this way, shockwaves were hardly conducted and had a maximum energy density level of 0.03 mJ/mm^2.[10] The participants were told that the treatment could be painful but that there is an interindividual variation in pain perception. By pressing the applicator to the painful spot, the participants experienced some pain. They also heard the repetitive pulses generated by the shockwave device, but were unaware of the dosage.

Eccentric Training

All participants were instructed by trained physical therapists on how to perform the eccentric exercises on a decline board of approximately 25 degrees at home. Each training session had to be completed twice daily, with 3 sets of 15 repetitions being performed at each session, during 12 weeks.[11] The exercises were performed without warming up. The downward (eccentric) component was performed with the affected leg, and the upward (concentric) component was performed with both legs. Participants were instructed to complete the exercises with the trunk upright. They were advised not to exceed a pain level of 4 on a numeric rating scale (NRS) for pain (0 = no pain to 10 = worst pain ever) during the eccentric training sessions. When pain decreased to NRS <4, the participants were instructed to add load in a backpack. If pain increased to >5, the participants were

TABLE 1. Mean ± SD and Ranges of Baseline Characteristics

	ESWT (n = 22)	Sham Shockwave (n = 30)	*P*	Total Group (n = 52)	Lost to Follow-up at 24 Weeks (n = 11)
Age, yrs	30.5 ± 8.0 (18-45)	27.3 ± 5.2 (18-40)	0.083	28.6 ± 6.7 (18-45)	30.2 ± 6.6 (21-41)
Male, %	63.6	80.0	0.189	73.1	63.6
BMI	23.9 ± 3.5 (19.9-32.3)	23.4 ± 2.4 (18.1-27.0)	0.492	23.6 ± (18.1-32.3)	24.5 ± 3.8 (20.3-32.2)
Hours of sports per week	4.5 ± 3.8 (0-16)	4.1 ± 2.7 (0-8)	0.673	4.3 ± 3.2 (0-16)	4.7 ± 4.2 (0-16)
Mean VISA-P ± SD	54.5 ± 15.4 (21-78)	58.9 ± 14.6 (20-80)	0.298	57.1 ± 14.9 (20-80)	57.7 ± 13.7 (38-80)
Duration of symptoms in weeks	65.1 ± 72.7 (12-312)	99.4 ± 126.3 (12-500)	0.260	84.9 ± 107.4 (12-500)	91.5 ± 108.6 (12-312)
Primary sport	7 Running	8 Cycling/spinning			
	6 Soccer	6 Soccer			
	1 Athletics	4 Running			
	1 Basketball	4 Tennis/squash			
	1 Badminton	2 Athletics			
	1 Fitness	1 Badminton			
	1 Field hockey	1 Field hockey			
	1 Korfball	1 Skating			
	1 Triathlon	1 Volleyball			
	1 Gymnastics	1 Kickboxing			
	1 Aerobics	1 Unknown			

BMI, body mass index.

instructed to perform the exercise with less weight or temporarily adjust the amount of repetitions.

Furthermore, they were allowed to perform sport at a pain level not exceeding NRS 4. No restrictions were given for adjuvant physical therapy treatment, but it was not encouraged. Adjuvant treatment was registered at follow-up.

Outcome

The primary outcome measure was the validated Dutch translation of the VISA-P questionnaire, which quantifies the pain and activity level and is specifically designed for evaluating outcome in PT.[12,13] The VISA-P score ranges from 0 to 100 (0 = no activity/maximum pain and 100 = maximum activity/no pain).

Secondary outcome measures were pain scores during functional knee loading tests, as rated verbally by a NRS for pain on a scale of 0 to 10 (0 = no pain and 10 = worst pain ever). The pain was scored during 10 single-leg decline squats, during 3 single-leg jumps, and during 3 single-leg maximal vertical jumps of the affected leg.[10] Satisfaction was rated on a 6-point Likert scale at follow-up assessments (1: completely recovered; 2: much better; 3: a little better; 4: unchanged; 5: worse; and 6: much worse).

Follow-up measurements were performed at 6, 12, and 24 weeks after the start with the ESWT or sham-shockwave treatment. Side effects, adverse reactions, and the compliance to eccentric exercises were recorded.

Sample Size, Randomization, and Blinding

The sample size was estimated based on the difference in VISA-P scores between symptomatic and asymptomatic participants, with a clinically relevant difference in VISA-P scores of 15 points. Baseline scores of 64 points were expected in symptomatic participants with an SD of 19 points.[14] With a power of 80% and an alpha of 5%, 28 athletes per group were needed to detect a clinically relevant difference.

The allocation to treatment took place after baseline assessment by the sports medicine physician. Randomization (simple randomization procedure) was performed using sealed identical nonopaque envelopes containing cards with "A" or "B" on it. An independent nurse at each of the locations was responsible for preparation and execution of this procedure. Slightly more envelopes per location were prepared as was calculated in the power analysis, because we intended to include more participants than strictly needed. After opening the envelope, the card with "A" or "B" on it was handed over to the physical therapist on that location. The 2 care providers (physical therapists) providing the (sham-) shockwave treatment were the only ones who knew the representation of "A" or "B." Allocation information was withheld from the participants and the outcome assessors for the duration of the data collection (24 weeks).

Statistical Methods

Baseline characteristics and outcome measures at follow-up were tabulated using descriptive statistics (mean and SDs, numbers, and percentages). Independent sample t-tests were used to assess the difference between baseline characteristics and the number of exercise sessions between the groups. Differences between categorical data were assessed by the χ^2 test. Repeated-measures analysis was used to assess the difference on the primary and secondary outcome variables between the groups over time. Analyses were performed following the intention-to-treat principle (both mean value substitution and last observation carried forward were performed; results for mean value substitution were given). Two-sided P values of <0.05 were considered

significant. All statistical analyses were performed using IBM SPSS Statistical software package version 20 (SPSS Inc, Chicago, Illinois).

Ethical Considerations

The Medical Ethical Committee of the UMCU and MCH approved the study protocol before its start (protocol number 10/202/C). All participants were fully informed about the nature of the trial and its rationale. All participants provided written informed consent.

RESULTS

Study Participants

Fifty-two athletes were randomized into the ESWT or sham-shockwave group. Baseline characteristics are presented in Table 1, showing no significant group differences. Baseline characteristics and VISA-P scores (56.7 ± 13.6 vs 57.6 ± 17.0 points) were not significantly different between the 2 locations either. During follow-up, 7 athletes (31.8%) in the ESWT group and 4 athletes (13.3%) in the placebo group were lost to follow-up (see flow diagram of the study, Figure 1). All participants completed the 3 sessions of ESWT or sham-shockwave treatment. The mean baseline VISA-P scores were 55.9 ± 15.4 for the group that completed the study protocol and 57.7 ± 13.7 for the lost-to-follow-up group ($P = 0.871$).

The mean number of eccentric exercise sessions per week (maximum of 14) for the ESWT and placebo group was 10.1 ± 4.5 and 9.8 ± 3.8 sessions at 6 weeks ($P = 0.753$) and 8.7 ± 4.2 and 6.1 ± 5.2 sessions at 12 weeks ($P = 0.065$), respectively.

Because of the low number of reported cointerventions in both groups, the possible influence of cointerventions on the primary outcome (VISA-P) was not further examined.

Primary Outcome Measure

The mean baseline VISA-P scores were 54.5 ± 15.4 for the ESWT group and 58.9 ± 14.6 for the placebo group ($P = 0.298$). Both groups improved over time to 70.9 ± 17.7 and 78.2 ± 15.8 at 24 weeks, respectively ($P = 0.150$) (Figure 2). The mean changes in VISA-P scores from baseline according to treatment group are shown in Table 2. The results show a significant effect for time ($P = 0.000$), but no interaction effect for treatment × time ($P = 0.740$). Analyses of the primary outcome, both with and without imputation of missing data, did not alter the outcome. The results were similar for both mean value substitution and last observation carried forward (data of the mean value substitution are presented).

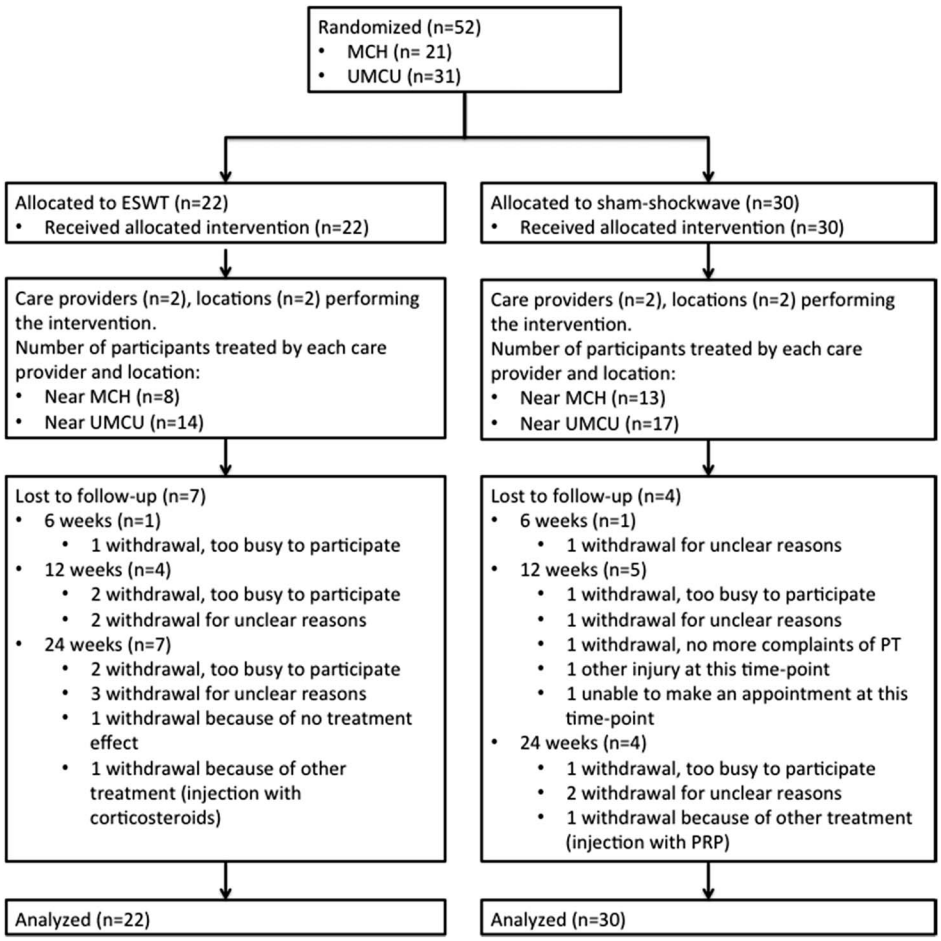

FIGURE 1. Flow diagram of study participants.

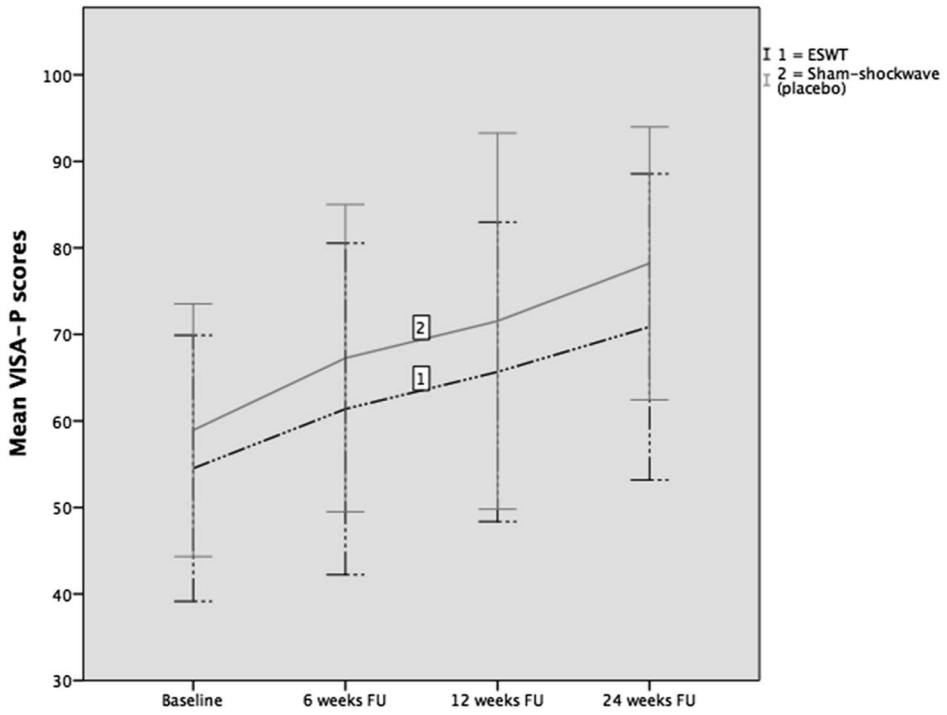

FIGURE 2. Mean VISA-P scores (SD) at baseline, 6, 12, and 24 weeks in ESWT and sham-shockwave group (placebo). FU, follow-up.

Secondary Outcome Measure

The mean NRS scores at baseline and follow-up are presented in Table 2. Both groups significantly improved over the study period. No significant differences were found between the ESWT and the sham-shockwave group (except for pain during 3 maximal vertical jumps at 6 weeks, in favor of the sham-shockwave group).

The Likert scores for patient satisfaction are presented in Table 3, showing no significant differences between the 2 groups at 6, 12, and 24 weeks ($P = 0.127$, $P = 0.755$, and $P = 0.928$ respectively). Sixty-seven percent in ESWT and 69% in the sham-shockwave group reported good outcomes after 24 weeks (much better or completely resolved). No complications were reported after ESWT or sham-shockwave treatment.

TABLE 2. Primary and Secondary Outcome Measures at Baseline, 6, 12, and 24 Weeks in ESWT and Sham-Shockwave Group (Placebo)

	ESWT (n = 22)				Sham Shockwave (n = 30)			
	Baseline, Mean (SD)	Week 6, Mean (SD)	Week 12, Mean (SD)	Week 24, Mean (SD)	Baseline, Mean (SD)	Week 6, Mean (SD)	Week 12, Mean (SD)	Week 24, Mean (SD)
VISA-P score (0-100)	54.5 (15.4)	61.4 (19.2)	65.7 (17.3)	70.9 (17.7)	58.9 (14.6)	67.3 (17.8)	71.5 (21.7)	78.2 (15.8)
Pain during 10 decline squats (0-10)	4.1 (2.4)	3.3 (2.4)	2.0 (1.5)	1.8 (1.8)	4.7 (2.5)	3.1 (2.7)	2.9 (2.5)	2.2 (2.3)
Pain during 3 single-leg jumps (0-10)	3.3 (2.6)	3.5 (2.9)	2.4 (1.7)	1.8 (1.8)	3.2 (2.7)	2.3 (1.8)	2.3 (2.2)	1.9 (1.9)
Pain during 3 maximal vertical jumps (0-10)	2.8 (2.9)	3.3 (2.3)	2.1 (1.7)	1.6 (1.9)	3.8 (2.4)	2.0 (2.0)	2.2 (2.0)	1.5 (1.9)

	Between-Group Difference (95% CI), Week 6	Between-Group Difference (95% CI), Week 12	Between-Group Difference (95% CI), Week 24
VISA-P score (0-100)	−1.4 (−9.0 to 6.2)	−3.0 (12.3 to 6.3)	−4.8 (−12.7 to 3.0)
Pain during 10 decline squats (0-10)	0.8 (−0.6 to 2.2)	−0.4 (−1.5 to 0.8)	0.4 (−1.0 to 1.9)
Pain during 3 single-leg jumps (0-10)	1.0 (−0.3 to 2.4)	−0.1 (−1.4 to 1.2)	−0.2 (−1.6 to 1.2)
Pain during 3 maximal vertical jumps (0-10)	2.2 (0.9 to 3.4)*	0.6 (−0.6 to 1.8)	1.2 (−0.2 to 2.5)

*$P < 0.05$.
CI, confidence interval.

TABLE 3. Likert Scores, Frequencies (Percentage)

	ESWT			Sham Shockwave		
Likert Score	**n = 21; 6 wk**	**n = 18; 12 wk**	**n = 15; 24 wk**	**n = 29; 6 wk**	**n = 25; 12 wk**	**n = 26; 24 wk**
1: completely recovered	—	—	2 (13.3)	—	2 (8.0)	5 (19.2)
2: much better	6 (28.6)	6 (33.3)	8 (53.3)	9 (31.0)	9 (36.0)	13 (50.0)
3: a little better	8 (38.1)	5 (27.8)	2 (13.3)	14 (48.3)	5 (20.0)	5 (19.2)
4: unchanged	7 (33.3)	4 (22.2)	2 (13.3)	3 (10.3)	5 (20.0)	2 (6.7)
5: worse	—	3 (16.7)	1 (6.7)	3 (10.3)	3 (12.0)	1 (3.3)
6: much worse	—	—	—	—	1 (4.0)	—

DISCUSSION

The present randomized controlled trial (RCT) showed no favorable effects of a combined treatment of eccentric loading and ESWT over a treatment approach with eccentric loading and sham shockwave in participants with PT during a 24-week follow-up period. Victorian Institute of Sport Assessment-Patella and pain scores significantly improved over the study period, but there was no treatment effect between the groups over time. Sixty-seven percent in the ESWT group and 69% in the placebo group reported distinct improvement of symptoms.

One study investigated the effect of eccentric training combined with ESWT for chronic PT. In the thesis of Peers,[9] 21 participants with PT for over 3 months, who were treated with eccentric exercises and ESWT, improved significantly more in VISA-P scores at 12-week follow-up compared with the 20 participants treated with eccentric exercises and sham shockwave. The change in VISA-P scores of the ESWT group was 19 at 6 weeks and 17 at 12 weeks. These results obviously differ from the findings in our study, in which the increase in VISA-P score is much less, despite identical ESWT energy density levels and sessions. However, the device was different from ours and their focus area was the tendinosis zone of the patellar tendon instead of the most painful spot.[9] Furthermore, the VISA-P baseline values were lower in the Peers study (46.5 for the ESWT group and 53.8 for the sham-shockwave group) compared with ours. This might have influenced the results, as it seems that ESWT is more effective in more advanced stages of late dysrepair or degenerative tendinopathy (representing lower baseline VISA-P scores).[10,15] Mani-Babu et al[16] recently published a review that compared the effect of ESWT with other conservative treatment options in lower extremity tendinopathies. Six studies for PT could be included; 3 RCTs, 2 prospective studies, and 1 retrospective study. The 3 RCTs showed mixed effects. In the study by Taunton et al[17] with 20 participants, the ESWT group improved significantly more in VISA-P scores than the sham-shockwave group. In the RCT conducted by Zwerver et al, athletes (N = 62) were randomized between ESWT and sham-shockwave treatment. The athletes were allowed to continue to practice sports during the treatment. Although the VISA-P score in both groups improved over time (end of follow-up after 22 weeks), no significant differences were found between the groups ($P = 0.82$).[10] The baseline VISA-P scores were higher (60.9 ± 12.6) compared with this study. In the Wang et al[18] randomized study, ESWT was compared with a mixture of conservative treatments (including eccentric exercises for the patellar tendon). A large difference in VISA-P score was found in favor of the ESWT group ($P < 0.05$), with almost no progression in the control group after a follow-up ranging from 10 to 48 months. The baseline VISA-P scores were however much lower than those in this study. Again, this might have influenced the results in favor of ESWT. The prospective and retrospective studies all showed a generally positive effect of ESWT on the improvement of the VISA-P score.[19–21] Based only on the RCTs, conflicting evidence is available that ESWT is more effective than other conservative treatments for chronic PT. This could be a major reason for the lack of difference between the groups in our study. Other factors that could explain the discrepancies between the outcomes of the RCTs are the differences in study population (athletes vs patients; different baseline VISA-P scores; various stages of tendinopathy) and differences in instrumental settings of the shockwave device (differences in focal depth and number and intensity of pulses). This makes it hard to compare the results.[5]

Reviews on eccentric training for PT generally show a positive effect on VISA-P over time.[22,23] However, in several studies, for example by Frohm et al and Young et al, the increase in VISA-P after 12 weeks of eccentric training is larger compared with our study (approximately 20-40 VISA-P points compared with our 10-point increase in the group that received eccentric training and sham shockwave).[24,25] Possibly, the variations in study populations may account for the differences. The Young study only analyzed elite volleyball players (N = 17), whereas this study examined recreational athletes from various sports. The etiological factors for PT, including amount of tendon loading, are most likely not the same in both populations, which will possibly influence the outcome as well. Moreover, the athletes in the Frohm study (N = 20) were frequently supervised during their exercises and during their return-to-sports after an initial 6 weeks of rest, whereas athletes in our study performed the exercises unsupervised at home. This guidance might have positively influenced participants' compliance to the exercises and sport advice.

Limitations

Results of this study should be interpreted with some caution. There was a large loss to follow-up; 31.8% in the ESWT and 13.3% in the sham-shockwave group at 24 weeks.

However, this difference in lost to follow-up percentage was not significant between the groups and no significant differences were found for baseline characteristics and VISA-P scores between participants lost to follow-up and participants who completed the full 24-week follow-up period, irrespectively of the treatment group. This makes attrition bias less likely in this study.

The fact that the physical therapists (who performed the treatments) were unblinded could have influenced the results. This may have lead to a possible different interaction with the participants or a possible influence on the administered treatment and consequently the outcomes. Analyses of the primary outcome measure VISA-P between the 2 different locations did however not show differences after 12 and 24 weeks of follow-up (with similar baseline VISA-P scores of 56.7 ± 13.6 and 57.6 ± 17.0 points). We therefore do not expect biased results by the fact that the interventions were performed by 2 (unblinded) caregivers.

The power analysis before the start of the study revealed that 56 patients in total were needed to detect a clinically relevant difference in the VISA-P score of 15 points. Because of a limited inclusion period, we included a slightly less number of 52 participants, which is still a high number for PT study. For this reason, the chance of a type II error slightly increased. A recently published study of Hernandez-Sanchez et al[26] shows that a minimal clinically important difference for the VISA-P score among athletes with PT is 13 points. This is close to the clinical relevant change of 15 points that we defined. The VISA-P SD in our homogenous group of 52 athletes was however lower (SD 14.9) than expected a priori (SD 19). A poststudy power analysis based on the lower SD shows that with a power of 80% and an alpha of 5%, 22 athletes per group would have been sufficient to detect a clinically relevant difference in VISA-P scores. This retrospectively corresponds to the amount of participants included in this study, but is not enough to correct for the amount of lost to follow-up.

A complete case analysis of the primary outcome, excluding the lost-to-follow-up participants from both groups, as well as an analysis with imputation of the missing data [according to the intention-to-treat principle (mean value substitution and last value carried forward)], did not alter the outcome of the study. The higher number of participants lost to follow-up in the ESWT group could perhaps be explained by the too intense treatment combination. But, as stated before, with the exact same treatment protocol as Peers,[9] in their study only 4% of the participants were lost to follow-up. In the other study on tendinopathy (Achilles) in which eccentric training was combined with ESWT, the lost to follow-up percentage was 12%. The reasons for withdrawal from the study are not sufficient enough to explain the high percentage. Therefore, it remains largely unknown why our randomized double-blinded study suffered from a high percentage lost to follow-up and therefore an increased risk of a type II error.

CONCLUSIONS

There is no additional effect of ESWT over sham shockwave (placebo) in participants with chronic PT treated with eccentric exercises. The primary (VISA-P) and secondary outcome measures (pain scores during functional tests and Likert scores) did not differ significantly between the groups during the 24-week follow-up period. Because of low power of the study caused by a high percentage of participants lost to follow-up, particularly in the ESWT group, these conclusions should be interpreted with caution.

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