Chapter 8

No effect of extracorporeal shockwave therapy on patellar tendinopathy in jumping athletes during the competitive season: a randomised clinical trial

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Abstract

**Background:** Patellar tendinopathy (PT) is a common overuse injury among jumping athletes. No evidence-based treatment guidelines exist. Extracorporeal shockwave therapy (ESWT) appears to be a promising treatment but its effectiveness has not been studied in athletes with PT who have symptoms for 3 to 12 months and are still playing.

**Aim:** Aim of the TOPGAME study was to determine the effectiveness of ESWT on pain, symptoms and function in athletes with early symptomatic patellar tendinopathy who are still in training and competition.

**Study design:** Randomised controlled clinical trial

**Methods:** Athletes playing volleyball, basketball or handball with PT for 3 to 12 months were randomised into the ESWT or placebo group during the first half of the season. The ESWT group received 3 ESWT treatments while the placebo group received sham ESWT. In-season follow-up measurements were 1, 12 and 22 weeks after treatment. Primary outcome was severity of PT determined with the VISA-P questionnaire. Secondary outcome was pain on a VAS during ADL and sports and after performance of functional tests. Multilevel analyses were performed to determine differences between groups over time.

**Results:** 127 symptomatic athletes were invited to participate; 62 were eligible, gave consent and were randomised into the ESWT (n=31) or placebo group (n=31). Mean VISA-P scores before and 1, 12 and 22 weeks after treatment were 59.4 (±11.7), 66.8 (±16.2), 66.7 (±17.5) and 70.5 (±18.9) for the ESWT group and 62.4 (±13.4), 66.3 (±19.0), 68.9 (±20.3) and 72.7 (±18.0) for the placebo group. There was a significant effect for time (p<0.01) but no treatment x time interaction effect (p=0.82). Secondary outcome measures showed the same.

**Conclusions:** ESWT as monotherapy during the competitive season has no benefit over placebo treatment in the management of actively competing jumping athletes with patellar tendinopathy who have mild symptoms for less than 12 months.
Background

Patellar tendinopathy ("jumper’s knee") is a clinical condition of gradually progressive activity-related pain of the patellar tendon, most commonly at the insertion at the apex patellae. Prolonged repetitive stress of the knee extensor apparatus can lead to this common overuse tendinopathy in athletes from several different sports. The overall prevalence of patellar tendinopathy among elite and non-elite athletes is high and varies between 3 and 45%. In sports characterized by high demands on speed and power for the leg extensors, such as volleyball and basketball, a prevalence of 44.6% and 31.9% respectively has been reported. Patellar tendinopathy is one of the leading causes for athletes to consult physicians or physical therapists in sports medicine centres. It often contributes to the decision to quit an athletic career and also causes mild yet long-lasting symptoms after such a career. The overall high prevalence, the impact on sports performance and the chronic nature of the condition show that in some jumping sports patellar tendinopathy can have the same health impact as acute knee injuries.

There is no consensus on what is the most appropriate treatment for patellar tendinopathy. Several conservative treatment modalities (e.g. physical therapy, anti-inflammatory medication, rest, exercise) and different surgical procedures have been described. Overall, they have not been proven to be highly successful in relieving symptoms to such a degree that athletes can continue to participate in their sport at their full potential. New treatment modalities for patellar tendinopathy have recently been introduced, based on the finding that the pathology underlying chronic (patellar) tendinopathies is not inflammatory tendinitis but a degenerative tendinosis due to a failed healing response. Extracorporeal shockwave therapy (ESWT) is one of these new treatments which might enhance regeneration. In the last few years ESWT has also been used to treat patellar tendinopathy, and seems to be a safe and promising treatment for this condition. In most of the research on ESWT treatment for patellar tendinopathy, patients have been recruited on a referral-based specialist care setting. Moreover, ESWT is often only applied when other treatments have already failed. This means that most patients included in these studies have serious, chronic problems, generally to such extent that they had to stop playing sports entirely, or at least reduce their level of sports participation significantly. One can presume that patients in this stage have a decreased healing tendency and are possibly less responsive (more resistant) to all treatment modalities. To our knowledge, the effectiveness of ESWT has not been systematically investigated in athletes who have early symptomatic patellar tendinopathy and are still actively competing.

The aim of the current study was therefore to determine the effectiveness of ESWT on pain, symptoms and function, in athletes with patellar tendinopathy whose symptoms have lasted between 3 and 12 months and who are still in training and competition.
Methods/design

Design
The TOPGAME study (Tendinopathy Of Patella Groningen Amsterdam Maastricht ESWT) was a multi-centre randomised controlled trial with blinded participants and outcome assessors, using a two-group repeated measures design with a treatment period of 2 weeks and 22 weeks of follow-up (trial number NTR1408). We tested the hypothesis that ESWT is more effective than placebo ESWT in relieving pain and symptoms and improving function in athletes with early symptomatic patellar tendinopathy who are still in training and competition. An extensive description of the design of the TOPGAME study is published elsewhere. The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee (Number 2008/052) of University Medical Center Groningen (UMCG), the Netherlands.

Recruitment
Recruitment of participants for the TOPGAME study took place in May-November 2008 and was facilitated by the Dutch Basketball, Handball and Volleyball associations, who sent a generic informative e-mail to all their registered athletes (aged 18-35). Additional attention was also drawn to the TOPGAME study through advertisements in newspapers and websites and at tournaments. Athletes were invited to fill out an internet-based questionnaire on sports participation and current knee complaints, and were also asked if they would be willing to participate in the study. Athletes with a high likelihood of having patellar tendinopathy based on a description of their symptoms and the localization on a pain map received written information about the study and were contacted by mail or phone. They were invited for a consultation by one of the two sports medicine physicians of the study (FH, JZ), who examined all the athletes and clinically established the diagnosis of patellar tendinopathy using the criteria described below.

Participants
Male and female basketball, handball and volleyball players aged 18-35 who met the following criteria were included:

1. History of knee pain in the patellar tendon or its patellar or tibial insertion in connection with training and competition, and palpation tenderness at the corresponding painful area.
2. Symptoms for 3 to 12 months in the current season or in the second half of the previous season (January–May 2008).
3. VISA-P score < 80. The VISA-P (Victorian Institute of Sport Assessment - Patella) score is a short questionnaire measuring the severity of patellar tendinopathy by assessing pain, function and ability to play sports.

No imaging studies were done to confirm the clinical diagnosis since previous studies have demonstrated that, although ultrasound and MRI can increase the likelihood of the diagnosis, they are not conclusive. Athletes were excluded if they suffered from acute knee injuries or other (co-)existing knee pathology, used non-steroid anti-inflammatory drugs or fluoroquinolones, had knee surgery or injection therapy with corticosteroids in
the preceding three months or had contraindications for ESWT treatment (pregnancy, malignancy, use of anticoagulants, coagulopathy).

**Randomisation**
Participants were allocated randomly and blinded to an intervention group (patient-guided ESWT) or a control group (placebo treatment) by an independent statistician (EV) who was blinded for any baseline characteristics of the participants. Randomisation was done before the first treatment by means of a computer-generated randomisation list (SPSS 16, Chicago). The randomisation procedure took place at the team level, resulting in players from the same teams being allocated to the same group. While the different treatment methods within the study groups potentially have various immediately noticeable effects on the subjects (e.g. level of pain), this method of randomisation was chosen to keep the treatment allocation blinded to the subjects and to avoid spill-over of the intervention. The independent physical therapists who administered the ESWT or placebo treatment were informed by the statistician about the group allocation. Group allocation was concealed from the athletes and the outcome assessor at all times during the trial. To evaluate athlete blinding, athletes were asked at final follow-up to indicate which treatment they believed they had received (ESWT, placebo ESWT or don't know).

**Intervention**
ESWT treatment and placebo treatments were given by five experienced and independent physical therapists at four different (sports) medicine centres across the Netherlands. They received a specific training on how to apply the ESWT and placebo ESWT before the start of the study. In case of bilateral symptoms the worst knee was evaluated and treated.

**ESWT treatment**
ESWT was administered in three sessions at one-week intervals using a piezoelectric ESWT device (Piezowave, Wolf GmbH, Knittlingen, Germany). After explaining the treatment procedure to the athlete, the physical therapist palpated the patellar tendon to find the most painful spot. At this painful zone 2000 impulses at a frequency of 4 Hz were administered. The energy flux density was titrated according to individual pain tolerance up to a possible maximum of 0.58 mJ/mm² (level 20). Treatment started at level 5 (0.1 mJ/mm²). The athlete was told that treatment could be painful but that there is inter-individual variability in pain perception. After every 100 impulses the physical therapist asked the athlete, if he/she tolerated the treatment. If so, the therapist increased the energy flux density by one level, up to the aforementioned maximum level.

A transmission gel was applied between the applicator and the focusing pad (before the athlete entered the room) as well as between the focusing pad and the skin of the patient to optimize shockwave transmission to the patient. Pads with a focus of 5 or 10 mm were used, depending on the athlete’s body stature. No local anaesthesia was used, since Rompe and colleagues demonstrated that repetitive application of shockwaves is more effective without than with local anesthesia. The athlete was in supine position with a slightly flexed knee and shockwaves were focused on the painful zone in the tendon or insertion. The inferior pole of the patella was tilted to focus on the dorsal insertion of the
patellar tendon as well. This treatment protocol was chosen based on our previous experi-
ence with ESWT application in patients with chronic patellar tendinopathy.17

**Placebo treatment**
The treatment procedure for the athletes in the placebo group was the same, except that
no transmission gel was applied between applicator and focusing pad. In this way shock-
waves are not or hardly conducted. Measurements of energy density provided by the
manufacturer for this placebo set-up revealed negligible or only very low energy densities
of less than 0.03 mJ/mm² (Wolf GmbH, Knittlingen, Germany). The physical therapist
gave the same instructions and by pressing the focusing pad to the painful spot athletes
experienced some pain; the athletes in the placebo group also heard the repetitive im-
pulses of the ESWT device and even saw the physical therapist adjusting the level after
every 100 impulses, yet were unaware of the dosage administered.

**Concurrent sports participation and medical treatment**
No restrictions were given for either group with regard to sports participation or concur-
rent medical treatment. If the athlete experienced an increase in pain in the first 48 hours
after treatment he/she was advised to take acetaminophen up to a maximum dose of 3 dd
1000 mg for pain relief.

**Measurements**

**Baseline**
Collection of baseline data started in September 2008 and continued during the first half
of the competition season until December 2008. After informed consent the following
baseline measurements were carried out:

**Baseline questionnaire**
The baseline questionnaire covered demographic variables, hours of sports participation
and information about the injury and previous medical treatment.

**VISA-P questionnaire**
The primary outcome of the TOPGAME study was the self-reported VISA-P score.13
The VISA-P score is a simple, reliable instrument for measuring the severity of patellar
tendinopathy and is sensitive to small changes in symptoms. It was specifically designed
for patellar tendinopathy, rating pain, symptoms, simple test of function and the ability
to play sports. Six of the eight questions are scored on a scale from 0 to 10 points, with
10 representing optimal health. The maximum VISA score for an asymptomatic athlete
is 100 points. Validity and reliability of the Dutch translation of the VISA-P score have
been demonstrated recently.18

**VAS pain**
Secondary outcome parameters were ratings of pain on a Visual Analogue Scale (VAS)
during activities of daily living (ADL) and sports, and after performance of functional
tests: maximal jumping test, triple-hop test and single-leg decline squat (SLDS). In the
first test athletes performed a maximal countermovement jump three times using their
left or right leg or both legs, and pain was recorded immediately after. In the triple-hop test athletes performed three hops with both their right and left leg; total distance and pain were recorded. The SLDS test, in which the athlete performs a single-leg squat to 60° of knee flexion on a 25° decline board, was designed to preferentially load the patellar tendon. It was performed once, then pain was assessed and then nine consecutive single leg decline squats were done, followed by pain assessment.\textsuperscript{19,20} Assessors of the functional tests were medical and physical therapy students who had received specific training before the start of this study and who were unaware of the athletes’ group allocation. Athletes were instructed on how to perform the functional tests and there was one practice session before the real measurements took place.

**Follow-up**

All measurements were repeated 1, 12 and 22 weeks after the final treatment session, when athletes were still in competition. Side effects and adverse reactions/events as well as rate of overall treatment satisfaction were also recorded. Further, all athletes recorded their athletic activities and concurrent medical treatment on a weekly basis, using a web-based diary. Athletes were also asked if they had noticed improvement of symptoms and if they would recommend their treatment to family and friends.

**Sample size**

Sample size was calculated based on the VISA-P score. From a previous investigation a baseline score of 64 points was expected in symptomatic athletes (95 points in athletes without patellar tendinopathy), with a SD of 19 points.\textsuperscript{30} A 15-point difference in VISA scores between the treatment and placebo groups was considered to be clinically relevant. To detect a difference of 15 points on the VISA scale with an SD of 19, a power of 90% and an alpha of 5%, 34 subjects per group were needed.

**Statistical analyses**

Descriptive statistics (means and standard deviations, numbers and percentages) were used to describe the characteristics of the intervention and placebo groups and the outcome variables at the four measurement points. Multilevel analysis was used to assess the effect of the ESWT treatment and to determine whether there was a difference on the primary and secondary outcome variables between the two groups over time. This statistical technique takes into account the dependency of observations within subjects. Analyses were performed following the intention-to-treat principle (last observation carried forward). Differences were considered statistically significant at p < 0.05. All analyses were done using SPSS version 16 (SPSS, Chicago).
Chapter 8

Internet based questionnaire for basketball, handball and volleyball players
Screening for athletes with high likelihood for patellar tendinopathy

- Contacted, invitation for participation
  N=127
  - 11 did not react on invitation

- Appointment for baseline measurements
  N=116
  - 3 failed to attend baseline measurements

- Baseline measurements
  N=113
  - 30 did not meet the inclusion criteria:
    - 27 duration of symptoms
    - 17 other or concomitant knee problems
    - 3 previous ESWT treatment
    - 2 VISA > 80
    - 1 pregnant
  - 1 withdrawal because of travelling time

- Randomisation at team level
  N=62

- Allocated to ESWT group
  N=31
  - 3 ESWT treatments N=30
    - 1 withdrawal because of travelling time
  - Followed up at
    Week 1  N = 30
    Week 12 N = 30
    Week 22 N = 30
  - Included in intention to treat analysis
    N=31

- Allocated to placebo group
  N=31
  - 3 placebo treatments N=28
    - 1 withdrawal because of travelling time
    - 1 withdrawal for unclear reasons
    - 1 withdrawal because of other injury
  - Followed up at
    Week 1  N = 27
    Week 12 N = 27
    Week 22 N = 27
  - Included in intention to treat analysis
    N=31

Figure 8.1. Flow of participants throughout the trial and reasons for participant withdrawal
Table 8.1. Baseline characteristics for ESWT (n=31) and placebo control (n=31) groups

<table>
<thead>
<tr>
<th>Personal characteristics</th>
<th>ESWT-group N=31</th>
<th>Placebo-group N=31</th>
<th>Total group N=62</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>24.2 ± 5.2</td>
<td>25.7 ± 4.5</td>
<td>24.9 ± 4.9</td>
</tr>
<tr>
<td>Sex (men/women)</td>
<td>20/11</td>
<td>21/10</td>
<td>41/21</td>
</tr>
<tr>
<td>Height (m)</td>
<td>181.6 ± 10.0</td>
<td>181.6 ± 9.2</td>
<td>181.6 ± 9.5</td>
</tr>
<tr>
<td>Mass (kg)</td>
<td>80.1 ± 15.6</td>
<td>78.3 ± 13.1</td>
<td>79.2 ± 14.3</td>
</tr>
<tr>
<td>Training hours (h/wk)</td>
<td>3.4 ± 1.8</td>
<td>2.9 ± 1.4</td>
<td>3.1 ± 1.6</td>
</tr>
<tr>
<td>Clinical characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VISA-P at baseline</td>
<td>59.4 ± 11.7</td>
<td>62.4 ± 13.4</td>
<td>60.9 ± 12.6</td>
</tr>
<tr>
<td>Duration of symptoms (months)</td>
<td>7.3 ± 3.6</td>
<td>8.1 ± 3.8</td>
<td>7.7 ± 3.7</td>
</tr>
<tr>
<td>Unilateral/bilateral symptoms</td>
<td>18/13</td>
<td>13/18</td>
<td>31/31</td>
</tr>
<tr>
<td>Location of pain: proximal/midtenoid/distal (only for treated tendons)</td>
<td>29/1/1</td>
<td>27/2/2</td>
<td>56/3/3</td>
</tr>
</tbody>
</table>

**Results**

The flow of participants through the trial and reasons for participant withdrawal are shown in Figure 8.1. Of the 127 athletes who were contacted after completing the internet-based questionnaire, 63 met the inclusion criteria. One athlete decided not to participate because of travelling time, therefore in the end a total of 62 participants were randomised to either ESWT or placebo treatment.

Fifty-seven participants (92%) completed all treatments and measurements. The five who dropped out of the study had similar characteristics and baseline results compared to those with complete follow-up. There were no significant baseline differences between the ESWT and placebo groups for demographic and clinical characteristics (Table 8.1). Mean duration of symptoms was 7.3 ± 3.6 and 8.1 ± 3.8 months, respectively. Before the start of the study, 58% of the athletes in both groups had tried to reduce their symptoms by doing stretching exercises, reducing their training load and/or using a patellar strap.

All patients tolerated the treatment procedure well without side effects or adverse complications. The averages of mean and maximum energy density applied were 0.25 ± 0.07 mJ/mm² and 0.42 ± 0.17 mJ/mm², respectively.

**Primary outcome measure**

Mean VISA-P scores before and 1, 12 and 22 weeks after treatment are summarized in Table 8.2. The mean VISA-P scores for the ESWT and placebo group were 59.4 ± 11.7 and 62.4 ± 13.4 at baseline and increased over the study period by 11.1 ± 18.6 (20.9% ± 35.2)
and $10.4 \pm 15.5 (18.8\% \pm 30.6)$, respectively (Figure 8.2). There was a significant effect for time ($p<0.01$) but no treatment x time interaction effect ($p=0.82$).

**Secondary outcome measures**
VAS for pain during ADL, sports, during 1 and 10 single-leg decline squats, after 3 maximum single leg jumps and after the triple-hop test decreased during the follow-up period, but no significant differences were found between the ESWT and the placebo group. (Table 8.2)

One week after treatment significantly more athletes in the treatment group than in the placebo group reported that their symptoms had improved and evaluated the treatment as beneficial ($65\% \text{ vs. } 32\%, \chi^2=6.46 \ p=0.01$). One week after treatment more athletes from the ESWT group answered that they would recommend their treatment for this injury to family and friends ($84\% \text{ vs. } 52\%, \chi^2=7.38 \ p=0.01$).
Table 8.2. Main outcome measures at 1, 12 and 22 weeks in the ESWT and Placebo group

<table>
<thead>
<tr>
<th></th>
<th>Baseline mean (SD)</th>
<th>ESWT (n = 31)</th>
<th>Placebo (n = 31)</th>
<th>Difference (95% CI) at 1 week</th>
<th>Difference (95% CI) at 12 weeks</th>
<th>Difference (95% CI) at 22 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>VISA score (0-100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>59.4 (11.7)</td>
<td>66.8 (16.2)</td>
<td>66.7 (17.5)</td>
<td>3.6 (-3.2 to 10.4)</td>
<td>0.8 (-7.7 to 9.3)</td>
<td>0.7 (-8.0 to 9.4)</td>
</tr>
<tr>
<td>1 week</td>
<td>62.4 (13.4)</td>
<td>66.3 (19.0)</td>
<td>68.9 (20.3)</td>
<td>0.2 (-1.2 to 0.8)</td>
<td>-0.3 (-1.4 to 0.9)</td>
<td>0.2 (-1.0 to 1.4)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>70.5 (18.9)</td>
<td>68.7 (20.0)</td>
<td>72.7 (18.0)</td>
<td>1.6 (-1.6 to 4.9)</td>
<td>-0.2 (-1.6 to 1.3)</td>
<td>1.0 (-2.6 to 0.6)</td>
</tr>
<tr>
<td>22 weeks</td>
<td>-17</td>
<td>72.7 (18.0)</td>
<td>72.7 (18.0)</td>
<td>-0.5 (-1.8 to 0.7)</td>
<td>-0.5 (-1.8 to 0.9)</td>
<td>-0.2 (-1.6 to 1.2)</td>
</tr>
<tr>
<td>Pain during ADL (0-10)</td>
<td>2.9 (1.8)</td>
<td>2.7 (2.2)</td>
<td>2.3 (1.9)</td>
<td>-0.4 (-1.8 to 1.0)</td>
<td>-0.2 (-1.6 to 1.3)</td>
<td>-1.0 (-2.6 to 0.6)</td>
</tr>
<tr>
<td>Pain during sports</td>
<td>4.9 (2.3)</td>
<td>4.2 (3.1)</td>
<td>4.0 (3.0)</td>
<td>0.2 (-1.0 to 1.4)</td>
<td>-0.2 (-1.6 to 1.3)</td>
<td>-1.0 (-2.6 to 0.6)</td>
</tr>
<tr>
<td>Pain during 1 decline</td>
<td>3.5 (2.8)</td>
<td>3.5 (3.1)</td>
<td>3.0 (2.8)</td>
<td>-0.4 (-1.8 to 1.0)</td>
<td>-0.2 (-1.6 to 1.3)</td>
<td>-1.0 (-2.6 to 0.6)</td>
</tr>
<tr>
<td>squat on injured leg</td>
<td>4.6 (2.8)</td>
<td>4.1 (2.9)</td>
<td>3.8 (3.1)</td>
<td>0.2 (-1.0 to 1.4)</td>
<td>-0.2 (-1.6 to 1.3)</td>
<td>-1.0 (-2.6 to 0.6)</td>
</tr>
<tr>
<td>Pain during 10 decline</td>
<td>3.9 (2.6)</td>
<td>3.3 (2.6)</td>
<td>3.0 (2.9)</td>
<td>-0.4 (-1.8 to 1.0)</td>
<td>-0.2 (-1.6 to 1.3)</td>
<td>-1.0 (-2.6 to 0.6)</td>
</tr>
<tr>
<td>squats on injured leg</td>
<td>4.4 (2.5)</td>
<td>3.3 (2.5)</td>
<td>3.1 (2.8)</td>
<td>-0.3 (-1.3 to 0.7)</td>
<td>-0.3 (-1.6 to 0.7)</td>
<td>0.3 (-0.9 to 1.6)</td>
</tr>
<tr>
<td>Pain during 3 single-leg</td>
<td>4.4 (2.5)</td>
<td>3.3 (2.5)</td>
<td>3.1 (2.8)</td>
<td>-0.3 (-1.3 to 0.7)</td>
<td>-0.3 (-1.6 to 0.7)</td>
<td>0.3 (-0.9 to 1.6)</td>
</tr>
<tr>
<td>jumps on injured leg</td>
<td>4.4 (2.5)</td>
<td>3.3 (2.5)</td>
<td>3.1 (2.8)</td>
<td>-0.3 (-1.3 to 0.7)</td>
<td>-0.3 (-1.6 to 0.7)</td>
<td>0.3 (-0.9 to 1.6)</td>
</tr>
</tbody>
</table>
**Concurrent sports participation, treatment and pain medication**

There were no differences with regard to sports participation (number of training hours) and concurrent medical treatment between the ESWT and the placebo group during the follow-up period. There was no significant difference in the use of pain or anti-inflammatory medication between both groups.

**Success of blinding**

Both the outcome assessors and the athletes were blinded during the entire trial. Blinding appeared to be successful, since after the last evaluation 18 of the 30 (60%) athletes in the ESWT group guessed correctly that they had received real ESWT treatment, and 17 out of 27 (56%) athletes in the placebo group guessed correctly that they received placebo treatment.

**Discussion**

The main finding of this randomised placebo controlled study was that our patient-guided ESWT treatment procedure during the competitive season provided no benefit over placebo treatment in the management of actively competing jumping athletes with patellar tendinopathy with symptoms for less than 12 months. VISA-P scores reflecting symptoms, knee function and sports participation improved significantly in both the ESWT and the placebo group over the 22-week study period, yet no significant differences between the groups were found.

This is the first randomised controlled trial to evaluate the effectiveness of ESWT in a homogenous group of actively playing athletes with rather mild patellar tendon pain lasting 3 to 12 months. Unfortunately the number of 68 subjects calculated a priori was not achieved. Since inclusion, treatment and final evaluation had to be scheduled within one competitive season to rule out any effects of rest and recovery in the off-season period, the inclusion period was very limited. However, the homogenous group of 62 included athletes had a lower VISA-P standard deviation than expected a priori. A post-hoc power analysis shows that with this actual lower standard deviation the included number of participants should have been sufficient to detect the postulated difference.

There are some potential explanations for the absence of a beneficial ESWT effect in the TOPGAME study. This study was performed in athletes with rather mild symptoms lasting less than 12 months, while previous randomised clinical studies that found positive results of ESWT included mainly athletes with chronic severe patellar tendinopathy who were treated in a hospital-based setting after several conservative treatments had already failed. One can presume that the athletes in our study with a mean VISA score of 60 and mean duration of symptoms of 8 months were suffering from reactive tendinopathy or early tendon disrepair in the continuum of tendon pathology, as described by Cook. The baseline ultrasound images obtained from some of the subjects confirm this presumption. Patients in previous RCTs had much lower VISA-P scores (around 45 points) and a longer and more variable duration of symptoms (>14 months), therefore it is likely that their
patellar tendons were in a more degenerative stage of tendon disease. It seems thus possible that ESWT is not an effective treatment modality for mild patellar tendinopathy in the early stages of the disease.

Another explanation might be that athletes continued participating in their usual training and matches during the treatment and follow-up period and received no restrictions with regard to sports participation during the season. Bosch et al. (2009) demonstrated in ponies that even exposure of normal tendinous tissue to electrohydraulically generated shockwaves of 0.14 mJ/mm² leads to disorganization of the collagen network for up to six weeks. They advised restricting exercise in recently treated patients. It is possible that in our study the total load on the tendon due to the combination of both ESWT-induced collagen disorganization and the mechanical overload from training and matches was too high and there was insufficient time for recovery. This might have interfered with potential reparative effects of ESWT. A similar phenomenon was found in a study by Visnes et al. (2005), who could not detect an effect from a 12-week eccentric training program in a group of volleyball players with jumper’s knee who still trained and competed during the intervention period. Different results might have been found if athletes had been removed from training and matches, or if the intervention and follow-up period had been out of season. For example, Wang et al. (2007) found excellent results when athletes with chronic patellar tendinopathy were not allowed to perform heavy activities, including sports, 4-6 weeks after their ESWT treatment; however, improvement in their study might have been caused by this long period of rest in combination with ESWT treatment.

Other possible explanations for not finding a positive effect of ESWT could be the chosen ESWT protocol and treatment approach. To our knowledge there is no consensus on the most appropriate and effective ESWT treatment protocol. We decided to treat the athletes with piezoelectric-generated focused shockwaves, in three sessions of 2000 impulses at a weekly interval using a patient-guided approach to determine the increase of energy density and localization of treatment. This protocol was based on our previous experience and was tested in a pilot study. The total amount of energy and mean and maximum energy density in this study were higher than in previous studies on this topic. Although no local anaesthesia was used, it was well tolerated by the athletes and no side effects were reported, the energy density might have been too high. In animal studies it was demonstrated that electromagnetically- or electrohydraulically-generated shockwaves with energy densities above 0.5-0.6 mJ/mm² can give rise to oedema within the paratenon and can result in histological changes like fibroid necrosis, fibrosing of the paratenon and infiltration of inflammatory cells. The fact that some of our athletes received treatment in this high-energy density range could have influenced our results; however, it remains uncertain if the aforementioned damage also occurs after treating the human patellar tendon with piezoelectrically generated shockwaves. VISA-P scores improved during the follow-up period, so we believe that our treatment approach had no detrimental effects on the patellar tendons. We cannot rule out that the rather high energy density levels resulted in less beneficial effects than expected though. A limitation with regard to the treatment protocol was that the placebo group might have received a very minimal dose of ESWT. The energy density in studies that found ESWT to be effective were much higher than this minimal dose, so it is not plausible that this caused the improvement in our placebo group. On the other hand, it
might also be possible that especially very minimal doses of ESWT are effective in athletes with mild patellar tendinopathy of rather short duration when tendon degeneration has not occurred yet.

Furthermore, since we were interested in the effectiveness of ESWT alone we did not add other exercises or treatments to our intervention protocol, making sure a potential effect was caused by ESWT and not by other co-interventions. However, it is known that athletes with patellar tendinopathy can benefit from a more comprehensive rehabilitation program including pain management, reduction of load, and an exercise program to improve muscle tendon-function and to normalize the kinetic chain. Peers et al. (2003) demonstrated that a combination of ESWT and eccentric training was effective in patients with chronic patellar tendinopathy. This could also explain the difference between our results and positive results of ESWT in other studies.

Despite the fact that we have to conclude that ESWT appeared not to be effective in the TOPGAME study, considering the aforementioned explanations we still believe ESWT might be useful in the rehabilitation of athletes with patellar tendinopathy. Additionally, although in our study no significant differences between the groups were found for the VISA-P and VAS pain scores during the entire study period, most improvement in the ESWT group was recorded during the first week post-treatment. It was also remarkable that one week after the end of the treatment significantly more athletes from the ESWT group reported that their symptoms had improved and that they would recommend ESWT to family and friends as treatment for patellar tendinopathy. Previous animal studies demonstrated potential explanations for short-term (and long-term) pain relief. Hyperstimulation analgesia, destruction of unmyelinated nerve fibres and suppression of neurotransmitters Substance-P and Calcitonin Gene-related peptide have been described as underlying mechanisms for this antinociceptive effect of ESWT. ESWT thus seems to produce some short-term improvement of symptoms in this group of athletes with mild patellar tendinopathy lasting than 12 months. It can be hypothesized that symptoms further improved when athletes stopped playing and did additional exercises as part of a combined rehabilitation program.

Conclusions

The TOPGAME study demonstrates that ESWT as monotherapy during the competitive season has no benefit over placebo treatment in the management of actively competing jumping athletes with patellar tendinopathy with mild symptoms lasting than 12 months. It is possible that ESWT does not influence tendinopathy in this early stage of the disease, that the combined load of ESWT and continuation of training is too high and interferes with tendon regeneration, or that our treatment protocol needs to be adjusted. These findings do not conclusively mean that the use of ESWT in patellar tendinopathy should be ceased. Since athletes reported subjective improvement after one week, no detrimental effects were elicited and there is growing evidence for the effectiveness of treatment programs for tendinopathies combining ESWT and eccentric training. Further trials evaluating the most appropriate treatment strategy for each stage of patellar tendinopathy seem warranted.
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