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Ultrasound-guided sclerosing treatment in patients with patellar tendinopathy (jumper's knee) – 44 month follow-up

ABSTRACT

Background: A randomised controlled study has shown good clinical results after treatment with sclerosing injections into the area with neovessels in patients with patellar tendinopathy, but no study has investigated medium- or long-term outcomes.

Purpose: To investigate the effect of sclerosing treatment 44 months (average, range: 42-47 months) after start of treatment.

Study Design: Case series

Methods: Patients with a diagnosis of jumper's knee and neovascularisation corresponding to the painful area were recruited and treated with ultrasound-guided sclerosing injections using polidocanol. Primary outcome was VISA score, and recorded before the start of treatment, after 12 months and 44 months after the start of the study period.

Results: Twelve of the 29 patients (14 tendons) who were followed up at 44 months had undergone arthroscopic surgery after sclerosing treatment, either to the patellar tendon (n=6) or for other intra-articular pathology (n=8). For patients who did not receive additional treatment after the sclerosing injections (n=23 tendons), VISA score was 55 (range: 28-71) at baseline and 81 (range: 39-100) at 12 month follow-up ($p<0.001$ vs. baseline).Their VISA score at 44 months follow-up was 89 (range: 73-100) ($p=0.047$ vs. 12 months) For patients who went through arthroscopic tendon surgery, VISA score was 53 (range: 39-71) at baseline and 71 before surgery (range: 48-98) ($p=0.14$ vs. baseline). Their VISA score at 44 months was 91 (range: 76-100, p=.0.16 vs. 12 months, $p=0.005$ vs. baseline). For patients who went through non-tendon surgery, VISA score was 45 (range: 15 to 69) at baseline and 57 (range: 32 to 95) before surgery ($p=0.29$ vs. baseline). Their VISA score at 44 months was 92 (range: 72-100 $p=0.006$ vs before surgery, $p<0.001$ vs. baseline).

Conclusion: Sclerosing treatment with polidocanol was effective for the majority of the patients. Nevertheless, one-third elected to seek additional treatment through arthroscopic surgery during the 44-month follow-up period.

Key terms: jumper’s knee; polidocanol; Color Doppler; tendon

INTRODUCTION

The exact causes of pain in tendinopathy are unclear, but may be related to increased vascularity in the tendon.[2;12] Studies have shown that neovascularisation is present in 60% to 80% of patients with chronic painful patellar tendinopathy,[5] and the presence of neovascularisation was associated with more tendon pain than in abnormal tendons without neovascularisation.[5;7] Based on the hypothesis that these vessels and their accompanying nerves are involved in the pain mechanism, a pilot study on sclerosing treatment for patients with Achilles midportion tendinopathy reported promising results.[11] This led to a randomized clinical trial investigating the effect of polidocanol injections in 20 patients with Achilles tendinopathy, demonstrating a significant short-term improvement compared to placebo injections.[1] In a study investigating the 2-year -term outcome after sclerosing treatment in Achilles tendinopathy, 38 of 42 patients reported treatment satisfaction.[10]

Based on the promising results in Achilles tendinopathy, we completed a randomized controlled trial of polidocanol injection therapy in elite athletes with patellar tendinopathy, where the patients were randomized to either immediate or delayed polidocanol injections.[6] The 12-month results have been described in detail and led us to conclude that knee function and pain improved significantly.[6] However, no study has investigated the medium- or long-term outcome after polidocanol treatment in patients with patellar tendinopathy. Therefore, in this paper we report on the activity levels, knee function and overall treatment satisfaction of the patients included in the randomized trial after 44 months.

METHODS

The randomized trial included 33 elite athletes (5 females and 28 males) with a mean age of 25 years (range: 17 to 42 years), mainly representing team handball (n=15), basketball (n=5), and football (soccer; n=6), with 43 tendons with neovascularisation. The team sport athletes

competed in the top two divisions of the respective Norwegian league, and in the individual sports the athletes represented a comparable level. The study protocol has been described in detail by Hoksrud et al.[6]

Athletes were invited to a clinical screening exam, and the following diagnostic criteria were used to identify patients with jumper's knee:[8] history of pain in the patellar tendon or the patellar insertion in connection with training or competition; tenderness to palpation corresponding to the painful area;[4] and symptoms from the patellar tendon for a minimum of 3 months. Patients who fulfilled the diagnostic criteria were invited to an ultrasound examination, including a color Doppler examination to assess neovascularisation. To be included in the study, subjects had to have a clinical diagnosis of jumper's knee, structural tendon changes and neovascularization corresponding to the painful area on the ultrasound examination, and a Victorian Institute of Sport Assessment (VISA) score (0-100 points) of less than 75 points.

The sclerosing treatment involved ultrasound-guided injections with the sclerosing agent Polidocanol (Aethoxysklerol [10 mg/mL], Inverdia AB, Stockholm, Sweden). The patients were scheduled for follow-up visits in the laboratory 3-5 weeks after each treatment and those who reported pain and reduced function were offered a new sclerosing injection if they had persistent neovascularization; no further injections were given if no vessels were seen on the ultrasound examination. During the treatment period (0-8 months in the group who received immediate injections, n=16; 4-8 months in the group receiving delayed treatment, n=17), patients received 0 to 5 sclerosing injections (mean: 3.1) with 3- to 5 week intervals (0 injections: 4 tendons, 1 injection: 6 tendons, 2 injections: 10 tendons, 3 injections: 10 tendons, 4 injections: 2 tendons, 5 injections: 11 tendons).

The primary outcome measure was knee function using VISA score.[14] Secondary outcome was overall satisfaction with treatment using a visual analog scale. For overall satisfaction, we

asked the patients to evaluate the sclerosing treatment on a scale from 0 to 10, where 0 represented very unsatisfied with treatment and 10 represented very satisfied with treatment. The outcomes were recorded at baseline, and 12 and 44 months after the first injection. At baseline and the 12-month follow-up the outcomes were recorded in writing and at 44 months by a telephone interview.

The study has been approved by the Norwegian Ethical Committee. Within-group differences were assessed with paired t-tests using a significance level of 5%, and the results are presented as the mean with their range or 95% confidence interval, as noted.

RESULTS

Of the 33 patients (43 tendons) who were included in the RCT and initially followed for 12 months, we were able to follow up with 29 patients (37 tendons) at 44 months (range: 42-47). The VISA score for the 4 patients (6 tendons) who did not participate in the final follow-up was excellent at 12 months (93, range 87-98).

Twelve of the 29 patients (14 tendons) who were followed up at 44 months had undergone arthroscopic surgery in the mean time, either to the patellar tendon or for other intra-articular pathology. In 6 cases (6 patients), tendon surgery was performed, in 7 cases (6 patients) debridement of minor retropatellar chondral defects was performed, and in 1 case, a plica medialis was resected. Of these, there were two patients with bilateral problems; one had non-tendon surgery performed on both knees, the other tendon surgery on one knee and non-tendon surgery on the other knee.

In all cases that went through tendon surgery, this was performed after the 12-month follow-up. In the 8 cases that went through non-tendon surgery, 5 surgeries were performed before the 12-month follow-up and 3 after the 12-month follow-up.

Of the 37 tendons that were followed up at 44 months, 24 were training and competing at the same level as before injury, while the activity level was reduced in 13 cases, 3 because of knee problems (Fig. 1).

VISA score

The patients who did not receive any additional treatment after the sclerosing injections (n=23 tendons) reported significantly improved VISA scores from baseline (55, range: 28 to 75) to the 12-month follow-up (81, range: 39 to 100) ($p<0.001$), and a further improvement in pain and function scores from the 12- to the 44-month follow-up (89, range: 73 to 100) ($p=0.047$) (Fig. 2).

Patients who went through arthroscopic surgery to the tendon (patellar tendon debridement, n=6 tendons) did not report a significant improvement in VISA score from baseline (53, range: 39 to 71) until before surgery (i.e. at 12 months; 71, range: 48 to 98) ($p=0.14$). Their VISA score at 44 months was 91 (range: 76 to 100, p=.0.16 vs. 12 months, $p=0.005$ vs. baseline) (Fig. 2).

For patients who went through non-tendon surgery (n=8 tendons), their VISA score was 45 (range: 15 to 69) at baseline and 57 (range: 32 to 95) before surgery (i.e. at 4 or 12 months ($p=0.29$ vs. baseline). They reported a significantly improved VISA score at the 44-month follow-up (92, range: 72 to 100) compared to baseline ($p<0.001$) and to their last score before surgery ($p=0.006$) (Fig.2).

Overall Treatment Satisfaction

Patients who did not receive other treatment after the sclerosing injection were equally satisfied with treatment at 12-month (7.9, range: 3 to10) and 44-month follow-up (8.2, range: 4 to10) ($p=0.30$, paired t-test). Patients who went through subsequent tendon surgery were more satisfied with treatment before surgery (i.e. at 12 months) (7.8, range 4 to10) compared to the

44-month follow-up (3.3, range: 2 to 5; p=0.001 vs. 12 months). Overall treatment satisfaction for patients who went through subsequent non-tendon surgery was 4.0 (range: 1 to 8) before surgery (i.e. at 4 or 12 months) and 5.8 (range: 3 to 10) at 44 months (p=0.13).

DISCUSSION

This follow-up study shows that injection treatment with polidocanol resulted in a significant improvement in knee function and reduced pain 44 months after the start of treatment in patients with patellar tendinopathy. However, it should be noted that in more than one-third of the cases, patients still elected to seek additional treatment through arthroscopic surgery during the follow-up period, either to the tendon itself (16%) or for other intra-articular pathology (22%). These results therefore show that, despite the group improvements documented, a significant proportion of patients were not fully satisfied. The long-term follow-up also shows that there was a subgroup of patients who turned out to have additional intra-articular pathology which may have contributed to their symptoms, even though a careful inclusion protocol which included ultrasound imaging was used.

It is perhaps not surprising that many of the patients sought out other treatment options. The average VISA score at 12-month follow-up for all patients included in the RCT was 77, which represented a significant improvement from their baseline score of 54.[6] Nevertheless, the scores ranged widely, from 32 to 100 at 12 months. The current trial is unique in that all patients were elite athletes, and it cannot be expected that they would be fully satisfied with a score of less than 90. However, in as many as 8 cases the 12-month VISA score was <50 and in 12 cases <60.

The pioneering work on sclerosing treatment was done on Achilles tendinopathy and the majority of patients included in clinical studies were recreational runners, typically aged 43 to 74 years,[11] and the treatment satisfaction and return to sport rates they report are not

necessarily valid in younger, elite athletes. Return to sport is not a reliable outcome in elite athletes, as they tend to continue to train and compete despite significant pain and loss of function. This can be seen from the cross-sectional study by Lian et al.,[9] which demonstrated that in 87 elite athletes with jumper's knee, who were competing at the national elite level in 9 different sports, the average symptom duration was 32 months and the average VISA score was 64. This can also be seen in the present study, where only 3 patients had retired from elite sports because of knee problems.

In other studies investigating the effects of sclerosing treatment in patients with tendinopathy, interpretation is also confounded by patients undergoing other treatment modalities, such as surgery, prior to final assessment. Although the results appear to be good, some of the tendons had undergone additional treatment at some point and treatment contamination may have affected the final outcome. One example is van Sterkenburg et al,[13] who retrospectively assessed the effects of sclerosing treatment on Achilles tendinopathy after 2.7 to 5.1 years follow-up. Although the results show that many patients improved, as many as 21 of the 40 tendons they were able to follow up had undergone additional treatment at some point; 15 tendons of these were treated operatively (open surgical debridement or Achilles tendoscopy).

In the present study, we wanted to prevent confounding by separating the patients into different groups, depending on whether they received additional surgical treatment or not. We have therefore divided the patients into three groups, one group who did not receive surgical treatment, one group who went through tendon surgery and one group who went through non-tendon surgery. All patients taken together, VISA scores improved, but patients who went through surgery did not report a significant improvement in VISA scores from baseline to before surgery. Their VISA scores likely explains why they elected to seek additional treatment. An interesting observation is that patients who went through tendon surgery were

less satisfied with sclerosing treatment after surgery (i.e. 44 months) compared with before surgery (i.e. 12 months), even if their knee function (VISA score) had improved significantly. The most likely explanation is that they attribute their improved function to surgical treatment and, consequently, were less satisfied with the sclerosing treatment than before.

The group of patients who went through non-tendon surgery also illustrates the difficulty with the diagnostic criteria for patellar tendinopathy.[3;4] We included patients based on a careful history and clinical examination and included an ultrasound exam requiring structural changes and neovascularization. Despite this, in 8 cases coexisting intra-articular conditions were revealed through subsequent arthroscopic surgery.

The current data also illustrate the difficulty of conducting controlled studies on elite athletes. Ideally, we would like to have long-term data from randomized trials to inform clinical decisions. In the present trial, we were able to randomize patients into immediate treatment or to a group receiving placebo injections during an initial 3-month period. However, it seems highly unlikely that elite athletes would be willing to accept placebo treatment for a sufficient period. For this reason, we may have to continue basing clinical decisions for tendinopathy on short-term outcomes or data from recreational athletes. When interpreting the data from the present study it should also be borne in mind that follow up at 44 month was done through a telephone interview, and that the sample size was limited.

In conclusion, this follow-up study shows that sclerosing treatment results in a mid-term improvement in knee function and pain in a group of young, elite athletes with patellar tendinopathy. However, few experience complete resolution of symptoms and as many as one-third elected to seek additional treatment through arthroscopic surgery during the 44-month follow-up period.

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Figure Legends:

Figure 1. Flowchart depicting treatments, follow-up and activity level.

Figure 2. VISA score (mean 95% confidence interval) for patients who did not receive additional treatment after sclerosing injections, patients who went through tendon surgery and patients who went through non-tendon surgery at baseline, 12 months and 44 months. For patients who went through non-tendon surgery, the 12-month follow-up was before surgery (i.e at 4 or 12 months).

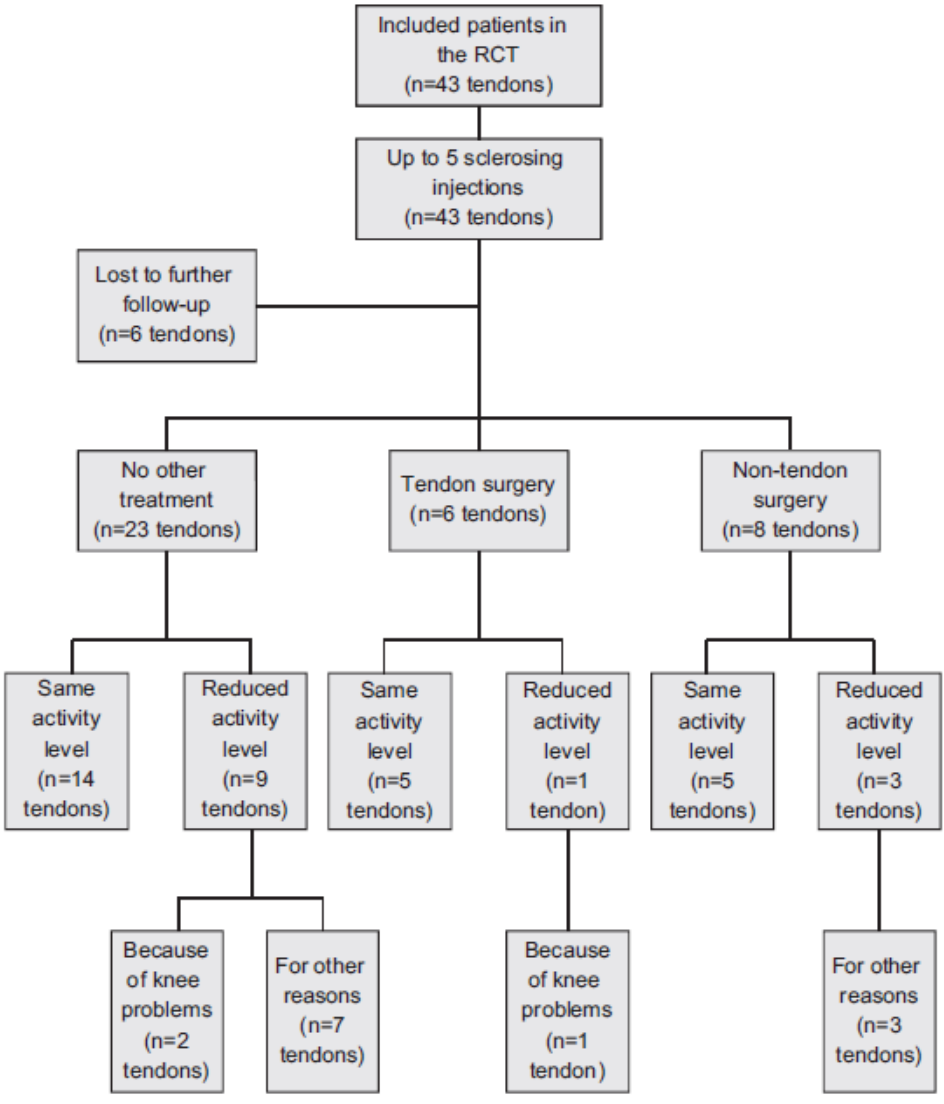

Figure 1. Flowchart depicting treatments, follow-up, and activity level.

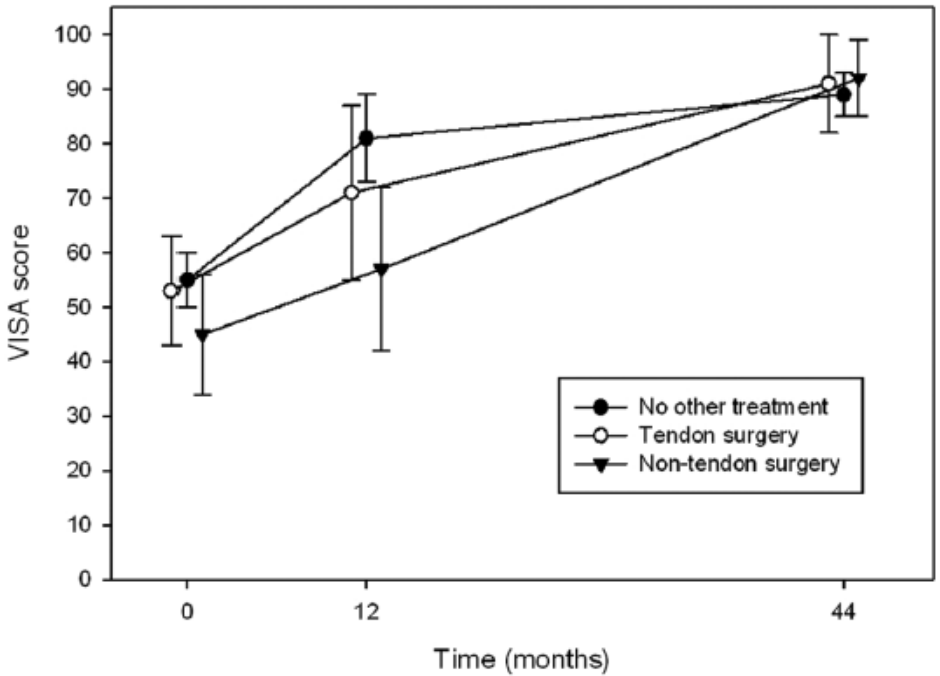

Figure 2. Victorian Institute of Sport Assessment (VISA) score (mean, 95% confidence interval) for patients who did not receive additional treatment after sclerosing injections, patients who went through tendon surgery, and patients who went through non–tendon surgery at baseline, 12 months, and 44 months. For patients who went through non–tendon surgery, the 12-month follow-up was before surgery (ie, at 4 or 12 months).