

Ultrasound-Guided Sclerosis of Neovessels in Patellar Tendinopathy

A Prospective Study of 101 Patients

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Background: A randomized controlled study has shown promising clinical results after treatment with sclerosing injections in a group of patients with patellar tendinopathy, but no study has investigated medium- or long-term outcome in a large and unselected group of patients.

Purpose: To investigate if sclerosing treatment would affect the level of patellar tendon pain and knee function after 24 months in a large group of patients with patellar tendinopathy.

Study Design: Case series; Level of evidence, 4.

Methods: This prospective study recruited patients with a clinical diagnosis of jumper's knee and visible neovascularization corresponding to the painful area on power Doppler ultrasound. They received up to a maximum of 5 ultrasound-guided sclerosing injections using polidocanol at 4- to 6-week intervals. Knee pain and function were recorded using the Victorian Institute of Sport Assessment-Patella (VISA-P) score before treatment and 6, 12, and 24 months after the first injection.

Results: In total, 101 patients (15 women and 86 men) with 120 tendons were included and given from 1 to 5 sclerosing injections (mean [SD], 2.5 [0.9]). The patients reported a significantly improved VISA-P score from baseline (mean, 39; 95% confidence interval [CI], 36-42) to the 24-month follow-up (mean, 65; 95% CI, 60-70) (range, 21-100; $P < .001$, paired t test). However, a VISA-P score of >95 points was reported in only 22 cases (20%), whereas 37 cases (36%) reported a VISA-P score of <50 at 24 months.

Conclusion: Sclerosing treatment with polidocanol resulted in a moderate improvement in knee function and reduced pain in a heterogeneous group of patients with patellar tendinopathy. Nevertheless, few of the patients were cured, and the majority still had reduced function and substantial pain after 24 months of follow-up.

Keywords: jumper's knee; sclerosing treatment; polidocanol; neovascularization

Patellar tendinopathy is an insertional tendinopathy most commonly affecting the patellar tendon's origin on the

inferior pole of the patella^{5,8-10} and affects athletes in many sports and at all levels of participation.

Effective treatment options are needed, and recently, sclerosing injections have become increasingly popular. However, the widespread clinical acceptance may have superseded scientific evidence.^{11,15,16,19} Since the pioneering study by Öhberg et al¹⁸ in 2002 on the Achilles tendon, a number of studies have investigated the effect of sclerosing therapy at several tendon sites (Achilles,^{3,4,7,14,17,20,24} patellar,^{2,11} lateral epicondyle,^{25,26} and supraspinatus¹). Most of the studies report optimistic results, but all studies have methodological limitations, particularly related to study size and/or short duration of follow-up.¹²

Three randomized controlled trials (RCTs) have compared patients receiving polidocanol injections to those receiving placebo injections, the first on 20 patients with Achilles tendinopathy,³ one on 42 cases of patellar tendinopathy,¹¹ and one on 34 cases of lateral epicondylitis.²⁵ The majority of patients reported reduced pain, but in all of these studies, the patients in the placebo group crossed over to polidocanol treatment after 3 to 4 months.

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The first study investigating the effects of sclerosing injections on patellar tendinopathy was a prospective case series, a pilot study on 15 tendons that were followed up for 6 months.² Twelve of the patients included were satisfied with treatment and reported markedly reduced visual analog scale (VAS) pain scores during tendon loading activity, from a mean of 81 to 10.²

The only RCT available on the patellar tendon included 33 elite athletes with 42 affected tendons, where the patients were randomized to immediate or delayed polidocanol injections (crossover after 4 months).¹¹ The study reported significantly improved pain and function (Victorian Institute of Sport Assessment–Patella [VISA-P]) scores in the polidocanol group and no change in the placebo group before crossover. At the 12-month follow-up, the self-reported VISA-P score had improved from 54 to 77, but it should be noted that only 6 of 33 patients were pain free during activity.¹¹

Appropriately designed RCTs on sports-related tendinopathy are notoriously difficult to conduct; the challenge is to recruit (elite) athletes to studies where they risk being assigned to a placebo group for long periods of time. Also, although RCTs are considered the superior study design, one limitation is that the external validity may be low. Therefore, there is a need for prospective studies following a large group of patients who are representative of the general patient population in the longer term. Thus, the aim of the present study was to investigate the outcome of sclerosing injections with polidocanol on tendon pain and knee function in 100 consecutive patients with patellar tendinopathy.

METHODS

Design

This prospective study recruited patients from 2 clinics: 1 private sports medicine clinic and 1 public hospital. Patients with patellar tendinopathy and neovascularization received up to a maximum of 5 ultrasound-guided injections at 4- to 6-week intervals. The cost of each procedure was 1500 NOK in the private clinic. The treatment stopped when they were symptom free or if there was no improvement in pain and function score after 3 injections. Pain and function was recorded before treatment and 6, 12, and 24 months after the first injection.

The study was approved by the Regional Committee for Research Ethics and the Norwegian Medicines Agency. The patients were insured through the Drug Liability Association.

Patient Recruitment

After a clinical screening examination, the patients were asked to complete a questionnaire detailing their anthropometric details, the history of their knee pain, any treatment, sporting profile, and activity level. Patients who fulfilled the clinical inclusion criteria was asked to sign a written consent form and invited to an ultrasound screening.

Inclusion Criteria

To be included in the study, the patients had to have a clinical diagnosis of patellar tendinopathy and neovascularization on a power Doppler ultrasound examination corresponding to the painful area.

The following diagnostic criteria were used to identify patients with patellar tendinopathy^{11,13}:

- History of pain in the patellar tendons or the patellar insertion in connection with training or competition
- Tenderness to palpation corresponding to the painful area

Patellar tendinopathy symptoms had to be present for a minimum of 3 months, and both knees were included if the patient has bilateral problems.

Ultrasound Examination

Patients who fulfilled the clinical inclusion criteria and completed the consent form went through an ultrasound examination and received the initial sclerosing injection treatment. The ultrasound examinations were performed by 1 physician in 1 clinic (TT) and 2 in the other (SH, HH), using high-resolution gray-scale ultrasound with the aid of power Doppler (Philips EnVisor HD; Philips Medical Systems, Andover, Massachusetts). A linear multifrequency probe (8-13 MHz) was used and the pathological changes in the painful thickened patellar tendon registered on a standard form. Color Doppler was used to diagnose the neovascularization, and both knees were examined. Digital images were stored even if the contralateral tendon was symptom free.

Initial Ultrasound-Guided Sclerosis Treatment

Polidocanol (Aethoxysklerol [10 mg/mL], Inverdia AB, Solna, Sweden) was used as the sclerosing agent. The active substance is an aliphatic nonionized nitrogen-free surface anesthetic. Before the treatment, the skin was washed with a solution of chlorhexidine and alcohol. Polidocanol was then injected with a 0.7×50 -mm needle. As polidocanol is also a local anesthetic, there was no need for anesthesia before the injection.

Injections were given against the vessels entering the patellar tendon from the ventral side of the tendon. The injection was performed dynamically; linear high-resolution ultrasound ensures injection into or close to the vessels. The ultrasound probe was held on the ventral side of the patellar tendon parallel with or transverse to the fibers. It was necessary to use power Doppler to identify these small vessels and thereby make it possible to place the tip of the needle into or close to the vessels entering the patellar tendon. When the tip of the needle was positioned correctly, a small amount of polidocanol was gradually injected until all vessels were closed. Altogether, up to 2 mL was injected into each knee (maximum dose 4 mL per patient per treatment session), and it was possible to observe the immediate effect of the injection on ultrasound.

After each injection, we registered the amount of fluid injected into each tendon.

In case of complications during injection treatment, standard emergency equipment with oxygen and defibrillator was available in the treatment room. Complications that occurred as a consequence of the injections would also be recorded.

Follow-up and Further Sclerosing Treatment

The procedure was the same for all patients after each injection treatment session. The first 2 weeks after treatment, the patients were asked to reduce their level of training (no jumping or weightlifting; only pain-free training allowed). After that, the patients could train as much as their pain allowed them to. They were allowed to take anti-inflammatory (nonsteroidal anti-inflammatory medications [NSAIDs], Cox-2 inhibitors) or pain medication without restrictions.

The patients were scheduled for follow-up visits in the laboratory every 4 to 6 weeks until they were satisfied (or until they had been given a maximum of 5 injections). They first completed a pain and function score and were then reexamined using ultrasound. All knees that were symptomatic at baseline were examined, regardless of symptoms. Patients with an unsatisfactory result and who had persistent neovascularization were offered a new sclerosing injection.

The patients were asked to complete mail-in questionnaires after 6 (if they were unable/unwilling to come for a follow-up visit), 12, and 24 months. The patients were allowed to seek other treatment if they were not satisfied with the results of the sclerosing injections.

Treatment Evaluation

Outcomes measured over the study period were knee pain and function using VISA-P score.²¹ This self-recording questionnaire, designed specifically to quantify knee function and pain in patients with patellar tendinopathy, assesses symptoms, simple tests of function, and the ability to play sport. The maximum VISA-P score for an asymptomatic, fully performing individual is 100 points, and the theoretical minimum is 0. The VISA-P score has been shown to be a reliable and valid measure.²¹ The patients also reported if they had received additional treatment during the follow-up period.

Statistics

To test the principal null hypothesis that there was no difference in VISA-P score from baseline to 24-month follow-up, we used a paired *t* test. Within-group changes over time were analyzed using analysis of variance (ANOVA) for repeated measures. Between-group changes were compared using unpaired *t* tests and ANOVA, as appropriate. We used a significance level of 5%, and results are presented as the means with their 95% confidence intervals (CIs) or SD, as appropriate.

TABLE 1
Patient Characteristics at Baseline^a

	Patients (n = 101)
Age, y	27 ± 10 (17-58)
Height, cm	182 ± 7 (165-197)
Weight, kg	81 ± 11 (58-110)
No. of female/male patients	15/86
No. of bilateral symptoms	19
Duration of symptoms, mo	17 ± 22 (3-180)
Total amount of training, h/wk	12.5 ± 5.6 (3-34)
Baseline Victorian Institute of Sport Assessment-Patella (VISA-P) score	39 ± 17 (2-76)

^aValues are presented as mean ± SD (range) unless otherwise indicated.

RESULTS

After a clinical screening and ultrasound examination at the clinics involved, 111 patients (15 women and 96 men) with 131 painful tendons were included to receive sclerosing injections (ie, 20 patients with bilateral problems). Ten patients (n = 11 tendons) had to be excluded from the analyses because they did not report any outcome at any of the 6-, 12-, or 24-month follow-ups. This means that the final sample consisted of 101 patients (n = 120 tendons; 19 patients had bilateral problems). The sports groups represented were football (n = 40), handball (n = 20), volleyball (n = 8), running/athletics (n = 10), ice hockey/bandy (n = 6), badminton/squash (n = 3), ballet (n = 2), bicycle motocross (n = 1), biking (n = 1), ski jumping (n = 1), karate (n = 2), orienteering (n = 1), basketball (n = 1), and snowboarding (n = 1); 4 patients did not register type of activity. The baseline characteristics and training history for the patients are shown in Table 1.

The patients were given from 1 to 5 (mean [SD], 2.5 [0.9]) sclerosing injections (1 injection; 17 tendons, 2 injections; 44 tendons, 3 injections; 49 tendons, 4 injections; 7 tendons, 5 injections; 3 tendons). Of the 101 patients included, 79 (n = 92 tendons) were followed up at 6 months, 75 (n = 88 tendons) were followed up at 12 months, and 95 (n = 112 tendons) were followed up at 24 months. Six patients (n = 8 tendons) were lost to follow-up at 24 months, 4 because they could not be reached and 2 because they declined the invitation to take part. Between the 6-month and 24-month follow-ups, 22 patients (n = 22 tendons) underwent knee surgery. In addition, 15 patients (n = 20 tendons) received shockwave therapy during the follow-up period, 5 (n = 6 tendons) received corticosteroid injections, 6 (n = 6 tendons) received electrotherapy, and 3 (n = 3 tendons) reported using nonsteroidal anti-inflammatory drugs.

The mean VISA-P score at baseline for the 10 patients who had to be excluded was 35 (95% CI, 32-38; *P* = .20 compared to the 101 patients included).

Patients followed up at 24 months (n = 95) reported a significantly improved VISA-P score from baseline to the 24-month follow-up (*P* < .001, paired *t* test) (Figure 1). An ANOVA for repeated measures of patients with VISA-P

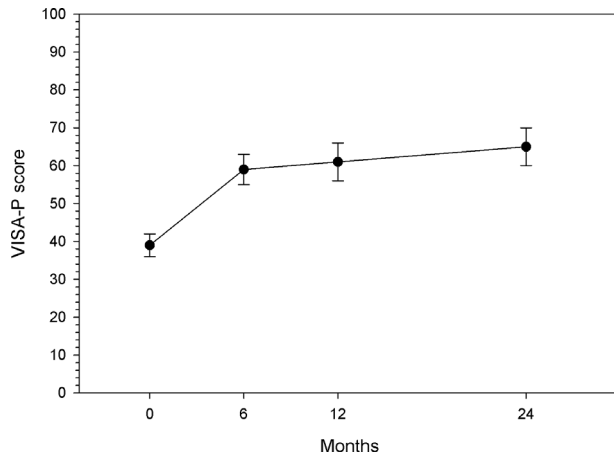


Figure 1. Victorian Institute of Sport Assessment–Patella (VISA-P) score (mean, 95% confidence interval) for all included patients at baseline ($n = 101$) and at 6 ($n = 79$), 12 ($n = 75$), and 24 ($n = 95$) months.

scores recorded at all follow-ups ($n = 67$ tendons) showed that there was a significant change with time ($P < .001$). The greatest improvement in VISA-P score during the follow-up period was from baseline to the 6-month follow-up. There was no further improvement in VISA-P score from 6 months to the 12-month or 24-month follow-up. A VISA-P score of >95 points was reported in 14 cases (16%) at the 12-month follow-up and in 22 cases (20%) at the 24-month follow-up.

There was no difference in outcome when we excluded the patients who underwent surgery. Figure 2 shows the separate VISA-P scores for the 22 patients who underwent knee surgery between the 6- and 24-month mark ($n = 22$ tendons) and the remaining 80 patients ($n = 98$ tendons). For the subgroup that underwent surgery, there were no improvements in VISA-P score at any follow-up visit (baseline vs 6 months: $P = .86$; baseline vs 12 months: $P = .54$; baseline vs 24 months: $P = .052$, paired t tests) (Figure 2). The remaining patients reported an improved VISA-P score from baseline to the 6-month follow-up ($P < .001$, paired t test) but no further improvement in VISA-P score to the 12-month follow-up ($P = .48$, paired t test). There was an improvement in VISA-P score from the 6-month follow-up to the 24-month follow-up ($P = .006$, paired t test) but no difference in VISA-P score from 12 to 24 months ($P = .053$, paired t test).

To examine whether VISA-P score at baseline was a predictor of outcome, we also separated the patients into 3 tertiles according to their VISA-P score at baseline. However, as shown in Figure 3, there were no differences between the 3 groups in VISA-P score at 6 months ($P = .18$, ANOVA), 12 months ($P = .79$, ANOVA), or 24 months ($P = .24$, ANOVA). However, this means that patients in the 2 lowest tertiles increased their VISA-P scores from baseline to 6 months ($P < .001$ for group 1, the lowest tertile; $P < .001$ for group 2, the middle tertile, paired t test), whereas there was no change for group 3, the highest tertile ($P = .10$).

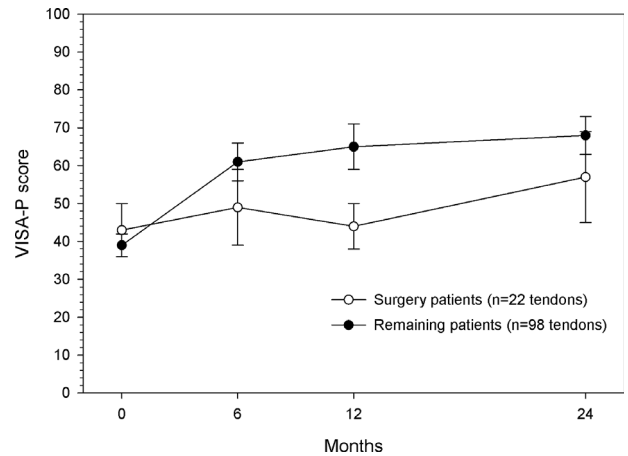


Figure 2. Victorian Institute of Sport Assessment–Patella (VISA-P) score (mean, 95% confidence interval) for patients who went through knee surgery ($n = 22$ tendons) and patients who did not ($n = 98$ tendons, surgery patients excluded) at baseline and at 6, 12, and 24 months.

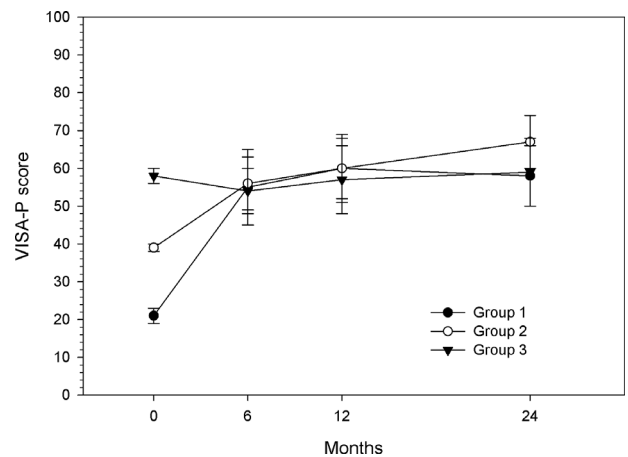


Figure 3. Victorian Institute of Sport Assessment–Patella (VISA) score (mean, 95% confidence interval) for patients separated into tertiles according to their VISA-P score at baseline ($n = 101$).

There was no relationship between age, sex, height, weight, duration of symptoms, or amount of training and VISA-P score at 12 or 24 months, nor was there any difference in VISA-P at 12 or 24 months between the 2 clinics.

None of the patients reported adverse events or side effects after sclerosing injections.

DISCUSSION

This prospective case series shows that sclerosing injections with polidocanol in patients with patellar tendinopathy resulted in a statistically significant improvement in knee function and reduced pain 24 months after start of treatment. Still, it should be noted that the improvement

was moderate, and a substantial proportion of patients were not fully satisfied; as many as 36% of patients reported a VISA-P score at 24 months of <50 and only 20% a VISA-P score of >95.

A methodological limitation of a prospective case series is that the effects observed cannot be compared with those of a matched control group. In other words, we cannot know if the effects observed can be attributed to the treatment or simply reflect the natural history of the injury. However, interpretation is less of a problem when there is no effect of treatment or, as in the present study, only a limited improvement in outcome. The data clearly show that sclerosing therapy does not represent a quick fix or cure-all for patients with patellar tendinopathy.

The main strengths of the current study are the sample size and the external validity of the findings. A randomized clinical trial is generally the preferred study design, but external validity can be compromised by the ability to recruit a representative sample. We believe that the patients we included were highly representative of the population likely to seek sclerosing treatment, as there were no other clinics in Norway offering such treatment during the inclusion period. Also, only 6 of the included patients (8 tendons) were lost to follow-up after 24 months. We have also used a reliable and valid measure to quantify knee function, the VISA-P score.²¹

A potential confounder is that patients were not limited in what other types of treatment they could receive during the follow-up period, such as surgery, shockwave therapy, corticosteroid injections, various forms of electrotherapy, and NSAIDs. Notably, as many as 22 patients underwent arthroscopic knee surgery, and these patients were included in the data analysis using an intention-to-treat model. However, it should be noted that, even if the patients who went through knee surgery were excluded, there was no difference in outcome. Unfortunately, we were not able to record the type of surgery (ie, whether they underwent tendon or nontendon surgery) or the final diagnoses (ie, whether concomitant injuries were found). However, as can be seen in Figure 2, there was no improvement in knee function from baseline to 24 months in this subgroup.

In the RCT investigating the effect of sclerosing treatment in patients with patellar tendinopathy,¹¹ the patients included were a homogeneous group of elite athletes who were still competing at a high level despite pain and limited function. The present study included a more heterogeneous group, ranging from elite athletes to recreational athletes, where most patients were not fully able to take part in training or competition. This is also reflected in their baseline VISA-P scores, which were higher in the RCT (54) than in the present study (39). The 2 studies show a significant and similar improvement in pain and function score. However, the patients in the present study reported a considerably lower VISA-P score after treatment (61 at 12 months) compared with patients in the RCT (77 at 12 months). Age, weight, height, duration of symptoms, and activity level (amount of training reported at baseline) were not associated with outcome. However, as can be seen in Figure 3, it appears that treatment benefit

was limited to patients with lower pain and function score at baseline (ie, the 2 lowest tertiles).

Although several other nonoperative therapeutic options have been proposed, few RCTs are available to inform treatment choice for patients with patellar tendinopathy. Eccentric exercises have the most evidence, and the majority of the studies suggest that eccentric training has a positive effect,²² although patients should be removed from sports-specific activity during treatment.²³ Bahr et al⁶ compared eccentric training to open tendon surgery followed by eccentric training in an RCT on patients with severe symptoms (baseline VISA-P score: 30), similar to the patients included in the present study. They reported no benefit from open tendon surgery beyond that seen from eccentric training alone. However, both groups reported an improved VISA-P score from baseline to the 12-month follow-up.⁶ Nevertheless, few patients were cured, as an end point VISA-P score of 70 still indicates reduced function and substantial pain, similar to the results in the present study.

CONCLUSION

Sclerosing treatment with polidocanol resulted in a moderate improvement in knee function and reduced pain in a heterogeneous group of patients with patellar tendinopathy. Nevertheless, few of the patients were cured, and the majority still had reduced function and substantial pain after 24 months of follow-up.

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