Research paper

Cite as: Koonen L, van Amerongen M, Smulders K, Mangesius S, Cerna G, Klauser A, Mur E, Obradov M: Added value of ultrasound-guided percutaneous needle tenotomy over hydrodissection and physiotherapy in chronic lateral elbow tendinopathy: a pilot randomized controlled trial. J Ultrason 2023; 23: e358–e364. doi: 10.15557/JoU.2023.0040.

Submitted: 13.05.2023
Accepted: 24.08.2023
Published: 30.10.2023

Added value of ultrasound-guided percutaneous needle tenotomy over hydrodissection and physiotherapy in chronic lateral elbow tendinopathy: a pilot randomized controlled trial

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DOI: 10.15557/JoU.2023.0040

Keywords
physiotherapy; hydrodissection; lateral elbow tendinopathy; percutaneous needle tenotomy; ultrasound

Abstract

Aim of the study: There is no consensus on the most suitable non-surgical treatment of chronic lateral elbow tendinopathy. The aim of this pilot randomized controlled trial was to evaluate the size of effect of ultrasound-guided percutaneous needle tenotomy. **Material and methods:** Three intervention arms were formed: 1) percutaneous needle tenotomy, hydrodissection, and physiotherapy; 2) hydrodissection and physiotherapy; and 3) physiotherapy alone. Patients with chronic lateral elbow tendinopathy were randomized. Clinical endpoints included multiple questionnaires after three months: Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), Numeric Rating Scale (NRS) pain at rest and during activity, and EuroQol 5D-5L (EQ-5D-5L). **Results:** Thirty patients were included of 128 screened. The QuickDASH score improved in the percutaneous needle tenotomy and physiotherapy group, but not in the hydrodissection group. The NRS pain at rest and during activity improved more in the percutaneous needle tenotomy (resp. –2 and –2) and hydrodissection (resp. –3 and –3) groups than in the physiotherapy (resp. +1 and –1) group. The EQ-5D-5L improved similarly in all groups. **Conclusions:** Patients receiving percutaneous needle tenotomy and/or hydrodissection may show better results in terms of pain but not in their functional outcomes compared to those who received physiotherapy alone. The size of effect, however, is small, so a large sample size is needed for a future randomized controlled trial to further investigate these results.

Introduction

Lateral elbow tendinopathy (LET) affects about 3.4 per 1,000 patients[(1)]. The tendinopathy is presumably the result of repetitive strain of the hand, wrist, and elbow, in which the healing of subsequent microtears may not occur due to the poor vascularity of the tendon origins and continued injury[(2)]. Though self-limiting in 90% of the cases, the most effective treatment of refractory LET is still unknown[(3)].

Multiple treatment methods have been described in literature[(4)]. Conservative treatment is often long-term physiotherapy combined with NSAIDs[(5)]. Minimal invasive treatment may consist of shockwave, laser therapy or injections of various substances, for example, corticosteroids. The existing literature does not provide conclusive evidence for a preferred non-surgical method[(3)]. Surgical treatment options include open, arthroscopic or percutaneous release of the common extensor tendon origin, and an open technique repairing the origin of the extensor carpi radialis brevis tendon. Evidence in support of surgery is lacking[(6–8)].

In percutaneous needle tenotomy (PNT), multiple needle perforations are administered in the affected tissue. The underlying assumption is that the perforations cause an inflammatory response with neovascularization, which stimulate tendon healing[(9)]. A systematic review concluded that PNT may be an effective treatment, but none of the studies were controlled against a placebo or conservative treatment group[(9)].

PNT is performed after administering an anesthetic bolus. The mechanical effects of high-volume image-guided injection around the tendon (hydrodissection), together with neurotoxic and vasoconstrictive effects of the anesthetic, potentially have a beneficial effect; therefore, an effect of PNT can also be caused by hydrodissection[10]. Hydrodissection has shown conflicting results in chronic Achilles and patellar tendinopathy[11–17].

The aim of this pilot randomized controlled trial (RCT) was to evaluate the size of effect of the interventions for future sample size calculation. We hypothesized that the PNT group would improve more compared to the other groups due to the inflammatory response caused by the perforations. A placebo (sham) effect in the hydrodissection group and no effect of physiotherapy was expected because our study participants suffered ≥12 months from LET despite prior non-surgical management.

Materials and methods

Study design

A parallel multicenter pilot RCT (EudraCT No.: 2018-002822-22) was conducted between 31 October 2018 and 8 September 2021 in the Sint Maartenskliniek (Ubbergen, the Netherlands) and Medical University of Innsbruck (Innsbruck, Austria). Three treatment arms were used to isolate the effects of hydrodissection and physiotherapy: 1) PNT, hydrodissection and physiotherapy (PNT group); 2) hydrodissection and physiotherapy (hydrodissection group); and 3) physiotherapy alone (physiotherapy/control group)[18]. Patients were randomized in block sizes of three using an online randomization tool by the study nurse. Randomization was done in advance, so the patients were enrolled in their group depending on their study number. This guaranteed that clinical and sonographic information did not influence the randomization.

Approval of the bioethics commission was obtained (NL66032.091.18). Periodic scientific meetings took place between the principal investigators of the centers to discuss the logistics, recruitment, and results.

Participants

All patients with suspected LET, with symptoms persisting ≥12 months, referred by an orthopedic surgeon for diagnostic ultrasound, were screened for eligibility by the study nurse by checking the in- and exclusion criteria. (Tab. 1) The radiologist performing the diagnostic ultrasound checked the specific ultrasound in- and exclusion criteria to confirm the diagnosis. (Fig. 1 A and B)[19]. In each center, all the diagnostic ultrasounds and ultrasound-guided interventions were performed by the same radiologist. The radiologist in the Sint Maartenskliniek has 26 years' experience in musculoskeletal radiology, while the radiologist in the Medical University of Innsbruck – 20 years. After giving their informed consent, all eligible patients were randomized into the different study groups.

Interventions

Ultrasound-guided PNT and hydrodissection were performed according to the study protocol. The interventions were not blinded. The patients in the hydrodissection group received hydrodissection, followed by three months of physiotherapy. Hydrodissection was performed with an injection of 8–10 mL lidocaine 2% on the whole surface of the common extensor tendon (Fig. 1 C). The patients in the PNT group received PNT and hydrodissection, followed by three months of physiotherapy. PNT was performed with multiple (≥10) 21-gauge needle perforations of the affected tendons (Fig. 1 D). Patients receiving both PNT and/or hydrodissection, were advised two weeks relative rest after the procedure for the purpose of tendon healing and remodeling. The patients in the physiotherapy group started directly with physiotherapy. A structured exercise schedule was available with guidance by instruction videos or by a physiotherapist. Detailed procedural information can be found in the supplementary material.

Outcomes

The primary endpoint was the QuickDASH score[20]. QuickDASH measures the physical function and symptoms in people with musculoskeletal disorders of the upper limb. A QuickDASH score of 0

Tab. 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age between 18 and 65 years.	Surgery related to the lateral elbow tendinopathy, including needle aspiration of calcific deposits or prior percutaneous needle tenotomy.
≥12 months with pain in the elbow, unresponsive to conservative (non-surgical) treatment.	Systemic joint disease such as rheumatoid arthritis, etc.
Sonographically proven tendinopathy (hypervascularization, deep tendon calcifications, hypoechogenic tendon, erosive cortex).	Rupture of extensor tendons. Detachment of extensor tendons or tears in collateral ligament. Clefts >1 cm in extensor tendons.
Concordant pain during compression with a US probe in the region of extensor tendons.	Contraindication for lidocaine in accordance with the summary of product characteristics (second- or third-degree AV block without pacemaker, known hypersensitivity to other anesthetics of the amide type).
Able to give informed consent.	Pregnancy.
Able to perform the exercises according to the detailed exercise scheme.	Use of anti-inflammatory drugs, such as NSAIDs, steroids, methotrexate, anti-TNF, azathioprine in the period two weeks before and after the intervention.
	Use of anticoagulant drugs which will be bridged with acetylsalicylate acid around the procedure.
	Physical, emotional or neurological conditions that would compromise the patient's compliance with post intervention rehabilitation protocol follow-up.

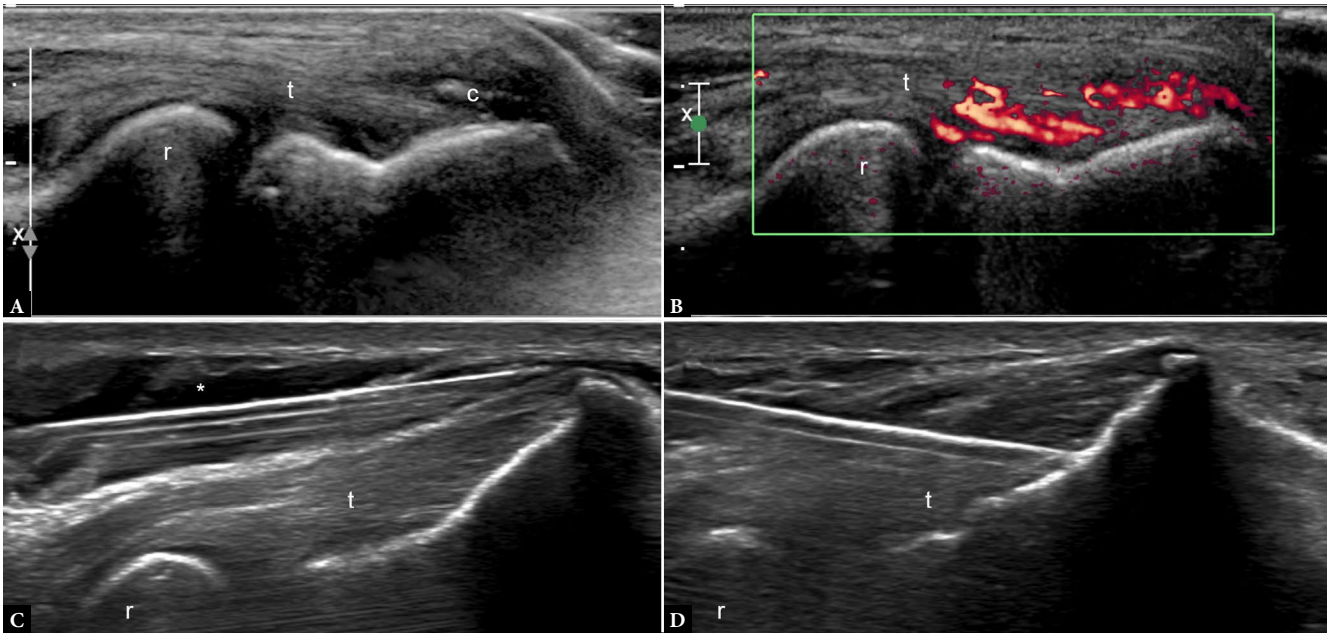

Fig. 1. *Ultrasound long-axis view showing the two interventions.* **A.** *pre-treatment with focal thickening, hypoechogenicity and calcifications (c) of the extensor tendon.* **B.** *pre-treatment with tendon hyperemia on color Doppler.* **C.** *Hydrodissection with injection of lidocaine (*) on the whole surface of the common extensor tendon.* **D.** *Percutaneous needle tenotomy with a 21G needle perforating the common extensor tendon. r – caput radi; t – common extensor tendon*

indicates no disability, while 100 indicates the most severe disability. Secondary endpoints included the EQ-5D-5L score, and NRS pain at rest and during activity[21,22]. The EQ-5D-5L measures health-related quality of life comprising five dimensions. Index values for EQ-5D-5L were calculated with the EuroQol tool. The value ranged from –0.205 (worst) to 1.0 (best). NRS pain was scored from 0 (no pain) to 10 (worst possible pain).

The primary endpoint regarding feasibility was the recruitment rate, measured in patient per center per month. The number of missing values and lost to follow-ups (LTFU's) were registered. Patients reported their experiences with the exercise schedule, such as adherence to the protocol, need for extra guidance, and general satisfaction.

Data collection

All groups were assessed pre-intervention (baseline) and at three months' follow-up. The patients received an email containing the outcome questionnaires, and provided information about the demographics, duration of symptoms, history of previous treatment, and experiences with the exercise schedule. Adverse events were monitored after the intervention, at six weeks' follow-up by phone, and at three months' follow-up. All data were collected by the study nurse using CastorEDC[23].

Statistical analysis

Data analysis was carried out in R software[24]. Median scores and range at baseline and at three months' follow-up were determined for each outcome. Changes over time were characterized as differences in median scores and their spread (given the small sample size). The differences in QuickDASH and NRS pain outcomes were related to the minimal clinically important improvement (MCII) of QuickDASH (15.91) and NRS pain (–2 or –33%) for each individual patient[25,26]. The analysis was done by the investigators, who were not blinded.

Results

Participants and feasibility

A total of 128 patients were assessed for eligibility (Fig. 2). Thirty patients (23%) were randomized in two years and ten months. This gives an average recruitment rate of 0.43 patients per center per month. The baseline characteristics are given below (Tab. 2). All patients received the intended treatment for which they were randomized.

Five patients were LTFUs, including two patients due to hospitalization for indications unrelated to the intervention (acute spinal disc

Tab. 2. Demographics and clinical characteristics

	PNT* (*n* = 11)	Hydrodissection (*n* = 9)	Physiotherapy (*n* = 10)
Mean age, years (95% CI**)	50.8 (44.4–57.2)	56.3 (53.9–58.7)	56.7 (52.3–61.1)
Gender (male / female)	9 / 2	6/3	7/3
Affected side = dominant hand	8	6	8
Mean duration of symptoms, weeks	73	103	80
* PNT – percutaneous needle tenotomy; ** CI – confidence interval			

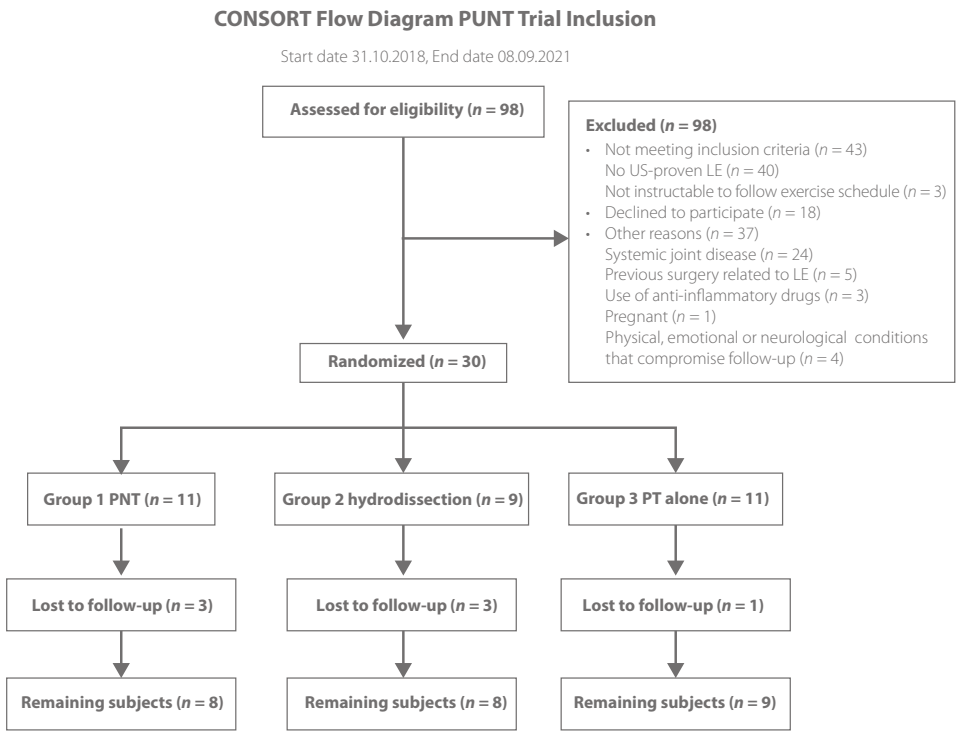

Fig. 2. *CONSORT Flow Diagram showing patient enrolment, allocation, and follow-up*

herniation and pacemaker implantation) and three patients who did not report a reason. We reported six (2%) missing values in the QuickDASH questionnaire and three (2%) missing values in the EQ-5D-5L questionnaire. One patient did not complete the questionnaires at three months. No adverse events or complications occurred. Two patients required extra guidance of a physiotherapist during the exercise schedule. Three patients did not perform all the exercises, and two patients were not satisfied with the exercise schedule.

Outcomes

Table 3 and Fig. 3 show the difference in median scores at baseline and at three months. The QuickDASH score improved in the PNT and physiotherapy group, albeit with a wide spread. The boxplot shows the wide interquartile range of QuickDASH in each treatment group and spread between each individual patient (Fig. 3 A). NRS pain at rest decreased in the PNT (–2) and hydrodissection group (–3), but increased in the physiotherapy group (+1). NRS pain during activity decreased in all groups (–2 vs –3 vs –1) (Fig. 3 B and C). EQ-5D-5L showed minimal differences in all groups (Fig. 3 D). Due to LTFUs and one patient who did not complete the questionnaires, the difference in endpoints against MCII was determined for seven (PNT), eight (hydrodissection), and nine (physiotherapy) patients (Tab. 3). More patients showed a MCII in NRS pain in the PNT and hydrodissection group than in the physiotherapy group. A similar number of patients showed MCII in QuickDASH between the groups.

Discussion

The current treatment of (chronic) LET includes a variety of therapeutic modalities without an established standard. This pilot study is

Tab. 3. Difference in median scores of QuickDASH and secondary endpoints. If available, compared to MCII**

Primary and secondary endpoints	PNT* (*n* = 11) Drop-out = 4	Hydrodissection (*n* = 9) Drop-out = 1	Physiotherapy (*n* = 10) Drop-out = 1
QuickDASH: Δmedian (min–max)	–18.2 (–45.5 – 29.3)	1.14 (–70.5 – 25.0)	–13.6 (–54.5 – 38.6)
ΔQuickDASH ≥MCII	4/7	3/8	4/9
NRS pain at rest: Δmedian (min–max)	–2 (–7 – 0)	–3 (–7 – –1)	1 (–3 – 4)
ΔNRS pain at rest ≥MCII	5/7	7/8	2/9
NRS pain during activity: Δmedian (min–max)	–2 (–7 – 0)	–3 (–9 – –0.5)	–1 (–6 – 2)
ΔNRS pain during activity ≥MCII	4/7	7/8	4/9
EQ-5D-5L: Δmedian (min–max)	0.11 (–0.03 – 0.35)	0.11 (–0.13 – 0.65)	0.06 (–0.19 – 0.67)
* MCII – minimal clinically important improvement; ** PNT – percutaneous needle tenotomy			

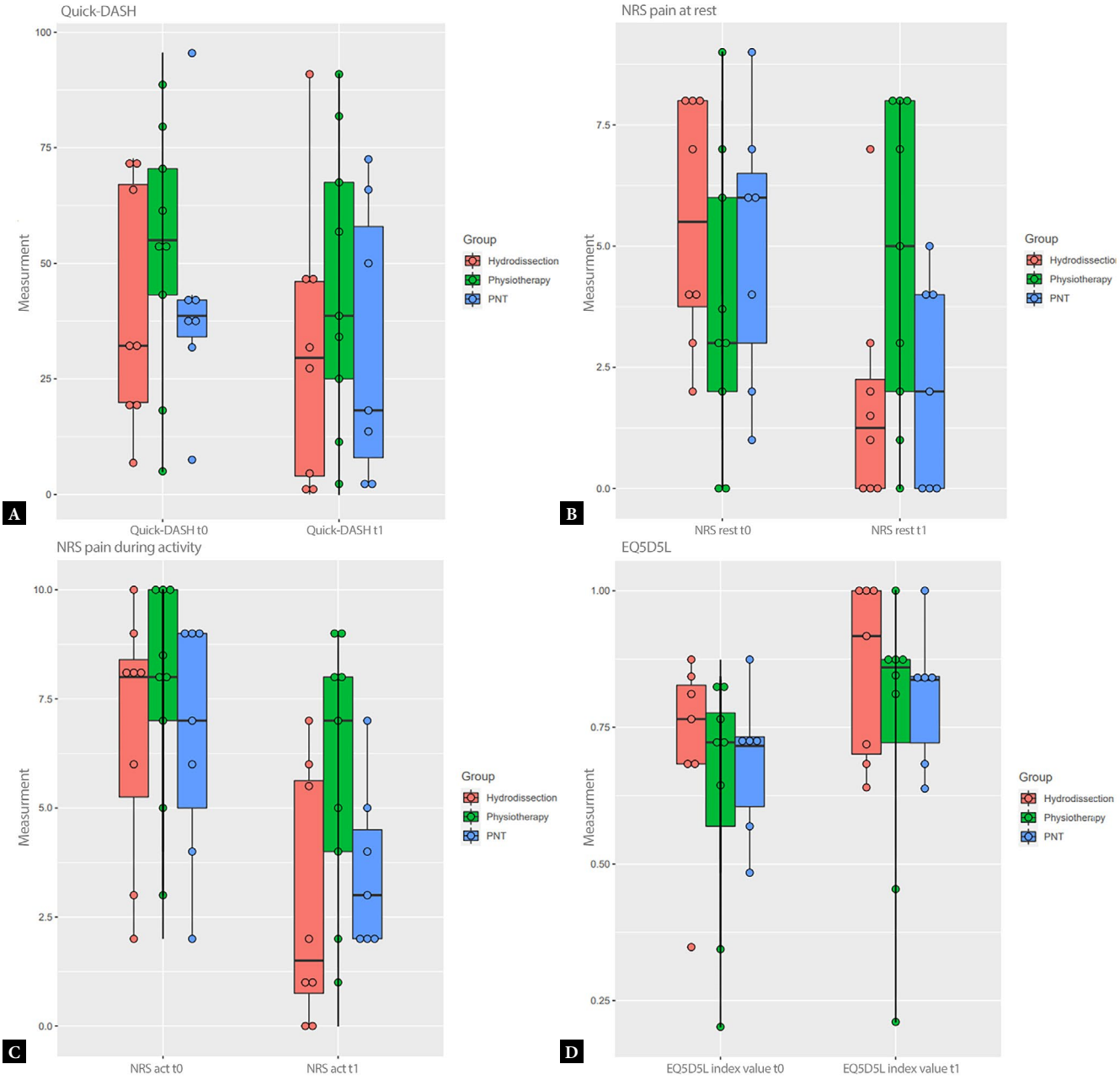

Fig. 3. *Boxplot showing median and interquartile ranges for each outcome in each treatment group for every individual patient at baseline (t0) and at three months' follow-up (t1).* **A.** *QuickDASH.* **B.** *NRS pain at rest.* **C.** *NRS pain during activity.* **D.** *EQ5D5L*

the first RCT to investigate the effect of PNT and/or hydrodissection against a conservatively managed control group.

The QuickDASH score improved in the PNT and physiotherapy groups, but not in the hydrodissection group. Combined with a similar improvement in the median EQ-5D-5L over all groups, improved functional outcomes were mainly associated with either PNT or physiotherapy. However, more interesting were the findings concerning the NRS pain scores as evaluated for all groups. NRS pain at rest and during activity improved for both the PNT and hydrodissection groups (resp. –2 and –2 for PNT; resp. –3 and –3 for hydrodissection). Similar improvement in NRS pain in the PNT and hydrodissection group is also reported in other literature, such as that shown in the dry needling group by Stenhouse *et al.* and in the hydrodissection group in chronic Achilles tendinopathy reported by Wheeler *et al.*[27,28] The physiotherapy group only showed an improvement of the Δmedian NRS score during activity (–1), however, an increased pain sensation at rest (+1). Although these differences are overlapping (Fig. 3), these trend differences might suggest a benefit to the intervention of both PNT and hydrodissection as added to physiotherapy alone. When the patients were analyzed individually, the same trend can be seen. More patients in the PNT and hydrodissection group showed a MCII in NRS pain than in the physiotherapy group, especially at rest. These results might be used

to advocate an ultrasound-guided intervention, but do not show any clear added value of PNT and hydrodissection over physiotherapy alone. Because of the small number of patients and wide spread of these outcomes, our results should be interpreted with caution for clinical implications, and a bigger sample size is needed to support the findings.

The most important feasibility issue was the low recruitment rate of 0.43 patients per center per month. We noticed that a lot of potential study participants were not willing to be randomized, probably because they were referred to the study center specifically for PNT. Also, the recruitment period was influenced by the onset of the COVID-19 pandemic. With the shown small size of effect in the current study, a large sample size is needed for future, sufficiently powered RCTs, possibly warranting a large multicenter study.

Our patients were mostly satisfied with the structured exercise schedule and guidance by online instruction videos or a physiotherapist. Most patients followed the exercise schedule fully at home without any extra guidance. Thus, this is a feasible method for a conservatively treated control group.

Strength and limitations of this study

The strength of our study is its randomized controlled design comparing three treatment groups and isolating the effect of PNT. Another strength was the strict patient selection process with precisely predefined clinical and radiological in- and exclusion criteria. The greatest limitation was our small sample size. Due to financial and logistic reasons, only two centers, instead of eight, were able to participate in the study. Thus, the study became a pilot trial with the main focus on the size of effect between the treatment arms for possible future sample size calculations. Another limitation is the drop-out of five patients. This may jeopardize validity, because the drop-outs were disproportionally divided over the groups with three LTFUs in the PNT group[29]. Finally, we did not perform a sham needle procedure in the physiotherapy group to blind all patients due to ethical considerations. This might have been useful to distinguish between a placebo effect or the effects of PNT and/or hydrodissection. However, we chose to use a conservatively managed (physiotherapy) group as our control group.

Conclusions

Patients with chronic LET may show better results in terms of pain reduction when treated with PNT and/or hydrodissection combined with physiotherapy than patients receiving physiotherapy alone. However, we could not find any added value of PNT over hydrodissection for the treatment of chronic LET. This pilot trial can be used for future research to demonstrate the efficacy of PNT and/or hydrodissection.

Conflict of interest

The authors do not report any financial or personal connections with other persons or organizations which might negatively affect the contents of this publication and/or claim authorship rights to this publication.

Acknowledgements

The authors would like to thank the research assistants Saskia Susan and Jolanda Rubrech-van As from the Sint Maartenskliniek Nijmegen and Karoline Volderauer from the Medical University Innsbruck for their assistance in data collection.

Author contributions

Original concept of study: LK, KS, AK, MO. Writing of manuscript: LK, MA. Analysis and interpretation of data: LK, MA, KS, MO. Final approval of manuscript: LK, MA, KS, SM, GC, AK, EM, MO. Collection, recording and/or compilation of data: LK, AK. Critical review of manuscript: MA, KS, SM, GC, AK, EM, MO.

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