

A comparative study of treatment interventions for patellar tendinopathy: a secondary cost-effectiveness analysis

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Abstract

Objective: To compare the cost-effectiveness of three patellar tendinopathy treatments.

Design: Secondary (cost-effectiveness) analysis of a blinded, randomised controlled trial, with follow-up at 10 and 22 weeks.

Settings: Recruitment was performed in sport clubs. The diagnosis and the intervention were carried out at San Jorge University.

Participants: The participants were adults between 18 and 45 years ($n=48$) with patellar tendinopathy.

Interventions: Participants received percutaneous needle electrolysis, dry needling or sham needling, all of which were combined with eccentric exercise.

Main outcome measures: Costs, quality-adjusted life years and incremental cost-effectiveness ratio were calculated for each group.

Results: The total cost per session was similar in the three groups: €9.46 for the percutaneous needle electrolysis group; €9.44 for the dry needling group; and €8.96 for the sham group. The percutaneous needle electrolysis group presented better cost-effectiveness in terms of quality-adjusted life years and 96% and 93% probability of being cost-effective compared to the sham and dry needling groups, respectively.

Conclusion: Our study shows that percutaneous needle electrolysis has a greater probability of being cost-effective than sham or dry needling treatment.

Keywords

cost and cost-analysis, dry needling, electrolysis, patellar ligament, quality of life

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Introduction

Patellar tendinopathy (PT) is a pathology that affects the patellar tendon and produces decreased functionality and increased pain in the anterior part of the knee associated with tenderness to palpation in the lower pole of the patella.¹ This condition sometimes presents changes in the tendon tissue, such as increased tendon thickness, neovascularisation, and increased cellularity with incompletely healed tendon micro-ruptures and altered collagen distribution.^{2–6}

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In the general population, the prevalence of PT is 14%; it affects 8.5% of amateur athletes⁷ and an even greater proportion of professional athletes. Tendinopathies are an area of great interest, since it is estimated that 45% of professional volleyball athletes and 32% of basketball athletes have PT.^{8–10}

Nowadays, the available evidence about which type of exercise is the most indicated for the treatment of PT is inconclusive, but it is known that exercises and control/administration of loads are fundamental for the treatment.¹¹ Over the years, eccentric exercise (EE) has been postulated as one of the most beneficial interventions for the prevention and treatment of PT,^{12–16} although new training protocols (such as those using high resistance at low speed) seem to give very good results.¹⁷ In physiotherapy, minimally invasive treatments, such as percutaneous needle electrolysis (PNE) and dry needling (DN), are being increasingly used based on research showing them to be effective for the treatment of tendinous injuries,^{18,19} although recent studies have shown that adding minimally invasive techniques does not provide any additional benefit over only performing an EE programme.¹⁹

In addition, there are few studies on the cost-effectiveness of minimally invasive therapies.^{20–22} One of them compared the cost-effectiveness of two different minimally invasive treatments for plantar heel pain provoked by myofascial trigger points and concluded that PNE had a better cost-effectiveness ratio than DN. Another study, performed in patients with lateral elbow tendinopathy, compared the cost-effectiveness of PNE with other surgical treatments and concluded that treatment with PNE combined with EE and stretching constitutes a treatment with a very acceptable cost-effectiveness ratio.²⁰ However, to our knowledge, there are no studies comparing the cost-effectiveness of different minimally invasive treatments in the case of tendinopathies. Therefore, the aim of this study was to evaluate the cost-effectiveness of an EE programme when performed alone or combined with DN and PNE, assessed in terms of quality-adjusted life years (QALYs).

Methods

Study design

A randomised controlled trial (RCT) was carried out between March 2018 and March 2020 to compare the effectiveness of three different physiotherapy protocols applied in three intervention groups of patients with PT: PNE, DN and sham needling.¹⁹ Randomisation was performed as a 1:1:1 block stratification. This study followed the standards of the Declaration of Helsinki for good clinical practice and was prospectively registered at ClinicalTrials.gov on 15 July 2015 (NCT02498795). The Aragon Ethics Committee evaluated and authorised the

project (reference no. PI15/0017). This cost-effectiveness study is a secondary analysis of this RCT.¹⁹

Participants

Patient recruitment was carried out by means of informative campaigns targeted at different sports clubs and federations.

Inclusion criteria

In order to be included in the study, participants had to: (1) have had anterior knee pain located on the inferior pole of the patella for at least 3 months while practicing sports; (2) be aged between 18 and 45 years old; (3) practice some kind of sports at least three times a week; and (4) score < 80 on the Victorian Institute of Sport Assessment-Patellar questionnaire (VISA-p).^{19,23}

Exclusion criteria

The exclusion criteria for the study were as follows: (1) knee surgery within the previous 6 months; (2) chronic joint diseases; (3) injection of corticosteroids in the patellar tendon in the last 3 months; (4) contraindications to needling; (5) use of medication 48 h before (e.g. non-steroidal anti-inflammatory drugs); and (6) any other concomitant treatment for PT.

Intervention conditions

First, patients received information on the study procedure and the interventions to be performed and signed the informed consent. All of them were randomised to the corresponding groups.

The therapists in charge of assessments (MPL) and data analysis (DF) were blinded as well as the patients. An interview was conducted at the end of the study by email to verify blinding of the patients. In the first session, patients were asked to fill in their baseline data and sociodemographic variables through an interview. In addition, they completed a quality of life (QoL) questionnaire (SF-36) and received an explanation of the EE programme that they should perform at home daily. This programme consisted of three sets of 15 repetitions of single-leg squats on a decline board twice a day, and speed was increased if the participants were pain free.²⁴ The resting time between each set was decided by each participant according to their needs. It was indicated that exercise could achieve five points on a numerical pain rating scale^{25,26} and, if it was higher, the exercise should be stopped and the investigator, before trying again 24 h later, following the same rules.

For all the interventions, the participants were placed in a supine position with a pillow below the knee (approximately 20° of knee flexion). The area was cleaned before the intervention with an antiseptic solution (70% propan-2-ol,

Skin-Des). All interventions (PNE, DN and sham needling) were combined with EE. Each participant received four treatment sessions, once every 2 weeks over 8 weeks.

DN and PNE interventions. The DN intervention consisted of three needle insertions lasting 3 s each, following the recommendations of clinical practice published by other authors in recent studies.^{27,28} The needles used were 0.25 mm × 25 mm (APS, Agupunt, Barcelona, Spain), which were inserted until they reached the target area in the patellar tendon (1.5–2.0 cm) at an angle of 45 degrees.¹⁹ The procedure was ultrasound (US)-guided to ensure the specificity of application to the injured area and to guarantee that the procedure was safe for the patient. The PNE intervention was exactly the same as the DN, except for the addition of a galvanic current (EPI®, Cesmar Electro-medicina, Barcelona, Spain) with an intensity of 3 mA (and voltage 16–18 V) during the 3 s that the procedure lasted.

Sham needling. A sham needle was placed over the treatment area, simulating the same procedure as in the other two groups. The physiotherapist performing the interventions placed high importance on the entire intervention experience, as cognitive influences that extend beyond mimicking of tactile sensations are recommended to create a believable simulation.

Costs

The economic evaluation was conducted from the perspective of a hospital, clinic or health centre. Direct health care costs such as the needling material (sterile gauze, antiseptic solution, US gel, needles),^{29,30} the US and PNE device³¹ and the staff (physiotherapist)²¹ were calculated. The cost of both US and PNE devices was assessed considering the average cost of the equipment (5 or 10 years of amortisation of the equipment cost), the average number of uses per year, and the cost of maintenance, following the guidelines of the Spanish Society of Ultrasound (SEUS) in the case of the US and the approximate cost of the equipment according to market distributor prices.³²

The cost of the physiotherapist was estimated by calculating the average cost of a physiotherapy session according to the staff costs in four representative regions of Spain (Aragón,³³ Castilla y León,³⁴ Madrid³⁵ and Basque Country).³⁶

Outcomes

QoL was measured with the SF-36 questionnaire, which covers the following eight dimensions: physical function, physical role, body pain, general health, vitality, social function, emotional role and mental health. The scores of the eight dimensions of the SF-36 are arranged in such a

way that the higher the value registered, the better the corresponding health status. The SF-36 is a useful scale for evaluating the burden of very diverse diseases, detecting the health benefits produced by a wide range of different treatments and assessing the health status of patients.³⁷ SF-36 values were transformed to QoL values using SF-6D scores,³⁸ then QALYs were estimated for each subject using area under the curve analysis. QALY is a measure of health status, which considers both quantity and quality of life. To perform the economic analysis based on the QALYs, three comparisons were made: PNE versus DN versus sham.

Statistical analysis

To analyse the uncertainty of QALY, the probabilistic bootstrapping method was applied. To summarise uncertainty, this study analysed the proportion of bootstrap replications that are below and to the right of the cost-effectiveness threshold line. Then, the incremental cost-effectiveness ratio (ICER) was represented in relation to possible values of the cost-effectiveness threshold in the acceptability curve.³⁹ The ICER represents the economic value of the intervention, compared with its alternative.⁴⁰

Results

A total of 48 patients, aged 32.5 ± 7.14 years (mean \pm SD), were included in the final economic analysis (Table 1).

Costs

The calculations used in this study to determine the costs of treatments are displayed in Table 2.

Regarding the PNE group, there was an additional cost due to the equipment. The cost of the physiotherapist remained the same in the three groups and varied according to the costs analysed for each region, between €4.10 in Castilla y León and €19.00 in Madrid. Total direct costs, compared to the sham treatment, were €2.46 more expensive with PNE and €2.39 with DN.

Quality-adjusted life years

The mean change in QALY during the study corresponded to +0.038 for PNE, +0.013 for DN and +0.016 for the sham intervention.

A bootstrap technique was used to calculate the probability of each alternative being cost-effective (Table 3).

The results were promising in the case of PNE, since it presented a 93% probability of being cost-effective against DN (24% dominant) at 22 weeks (Figure 1).

PNE was also favourable when compared with the sham needling treatment, with 96% probability of being cost-effective against sham, but not dominant, mainly due to the difference in price (Figure 2).

Table 1. Baseline characteristics of participants.

	PNE (n = 16)	DN (n = 16)	Sham (n = 16)	p value
Gender (male)	14 (88%)	13 (81%)	15 (94%)	0.565
Age (years)	31.1 ± 7.33	33.2 ± 7.97	32.7 ± 6.1	0.684
Height (m)	1.77 ± 0.107	1.76 ± 0.092	1.78 ± 0.059	0.823
Weight (kg)	80.6 ± 17.39	74.5 ± 11.62	78.6 ± 9.77	0.427
Duration of symptoms (months)	16.9 ± 10.3	19 ± 28.4	18.4 ± 16.3	0.952

PNE: percutaneous needle electrolysis; DN: dry needling.
Values are expressed as mean ± SD or number of patients (%).

Table 2. Costs.

		PNE (n = 16)	DN (n = 16)	Sham (n = 16)
Sanitary consumables (session) €	Latex gloves	0.09	0.09	0.09
	Needles	0.08	0.08	0.08
	Disinfectant	0.54	0.54	0.54
	Sterile US gel	0.04	0.04	0.04
	Sterile US cover	0.14	0.14	0.14
		0.89	0.89	0.89
US equipment (session) €		0.05 ± 0.02	0.05 ± 0.02	0.05 ± 0.02
PNE equipment €		0.02 ± 0.01	–	–
Physiotherapist mean (session) €		8.45 ± 6.12	8.45 ± 6.12	8.45 ± 6.12
Average total cost per session €		9.46 ± 0.8	9.44 ± 0.07	8.96 ± 0.42
Total (4 sessions) €		37.85 ± 0.30	37.78 ± 0.29	35.85 ± 1.70

PNE: percutaneous needle electrolysis; DN: dry needling; US: ultrasound.

The threshold that is used to evaluate the implantation of a therapeutic alternative is usually €25,000;⁴¹ however, in our study, PNE was cost-effective against DN and sham in values much lower than this threshold (Figure 3).

Discussion

We aimed to analyse the cost-effectiveness of three different treatments for PT. Cost-effectiveness studies are the best tool when using a good efficacy marker, such as the patient's QoL, if they evaluate all the costs involved. In our study, our patients' baseline characteristics were homogeneous and their compliance with home exercise (single-leg eccentric squat) was excellent for all groups, with all participants completing their sets of exercises, allowing us to assess the variation that is exclusively due to treatment. The SF-36 questionnaire is, in our opinion, the best tool, despite having a wide variety of questionnaires such as the 5-level version of the EQ-5D (EQ-5D-5L), as it gives greater sensitivity for this type of ailment that is not related to

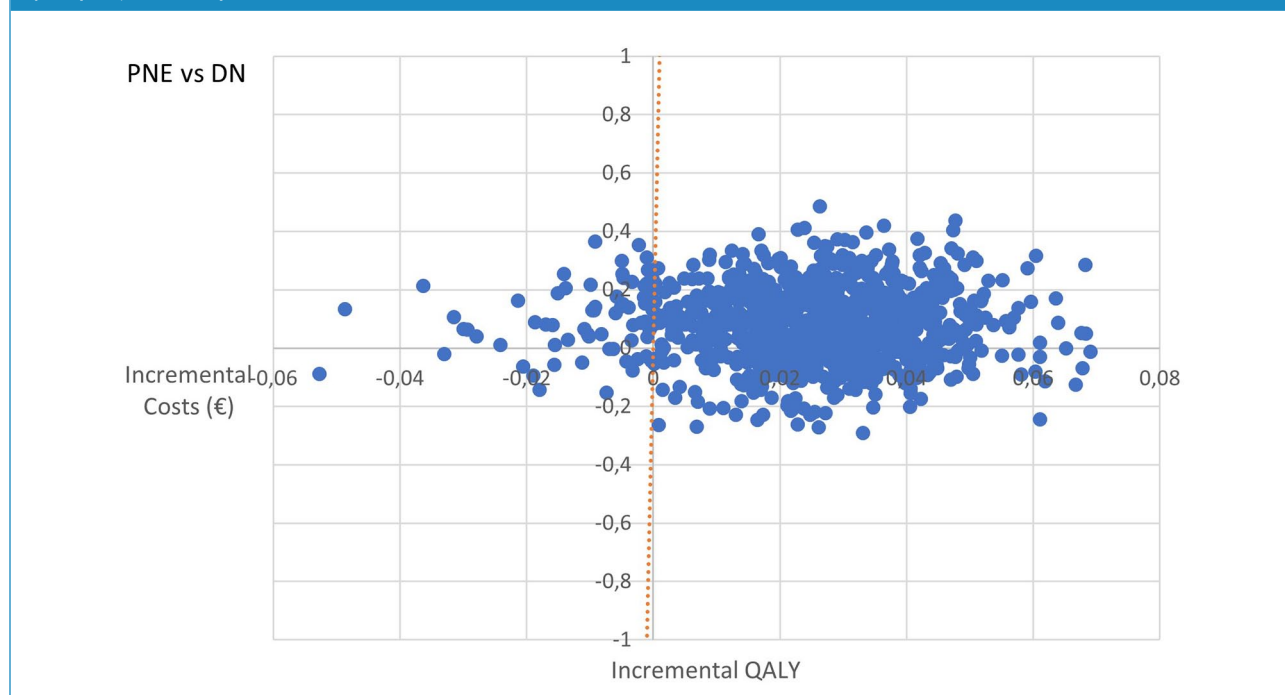
relatively serious states of health.³⁸ The analysis shows that there was a certain gain of QALYs in the groups, with greater importance in PNE.

Regarding costs, equipment and staff were considered for the cost-effectiveness analysis as they are the ones that most influence the costs of a clinic or a health centre. Equipment presented many difficulties for the analysis due to the great variety of prices of US equipment (from €3000 to €60,000) and maintenance, and PNE equipment (from €1000 to €3000). Despite this, our results showed that there was no major difference in material costs between groups. In the case of staff costs, the time spent by the physiotherapist does not have a stipulated fixed price and it was necessary to determine the variability of costs according to different regions. Our costs were cheaper than in the study published by Minaya et al., who determined a cost per session of €60 for the treatment of chronic lateral epicondylalgia with PNE.²⁰ In the case of our study, we assessed that the cost for the health centre would be €9.46 ± 0.8 based on publicly published costs. The lack of information on the

Table 3. Cost-effectiveness results per treatment group.

		PNE	DN	Difference PNE versus DN	Sham	Difference PNE versus sham	Difference DN versus sham
Deterministic analysis	Costs (€)	37.85 ± 0.30	37.78 ± 0.29	+0.076	35.85 ± 1.70	+2.004	+1.928
	QALY	0.038 ± 0.043	0.013 ± 0.052	+0.025	0.016 ± 0.025	+0.022	-0.003
	ICER (€/QALY)			3.04		89.34	-757.41
Probabilistic analysis	Costs (€)	37.85 ± 0.07	37.78 ± 0.10	+0.074	35.89 ± 0.86	+1.956	+1.877
	QALY	0.038 ± 0.011	0.013 ± 0.013	+0.025	0.015 ± 0.006	+0.022	-0.003
	ICER (€/QALY)			2.88		91.71	-167.53
	% Cost-effective			93.0%		96.0%	30.8%

PNE: percutaneous needle electrolysis; DN: dry needling; ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year.

Figure 1. Incremental cost-effectiveness plane for percutaneous needle electrolysis (PNE) versus dry needling (DN). QALY: quality-adjusted life year.

description of its costs prevented us from making more comparisons. Another cost-effectiveness study by Arias-Burúa et al.⁴² assessed the inclusion of DN in an exercise programme for subacromial pain syndrome; however, we did not consider the cost section to be very plausible considering that there was a difference of more than €10,000 in the control group due to absenteeism and that data comparisons were not possible.

The cost-effectiveness analysis performed after bootstrapping revealed that the PNE group had a clear advantage over the DN and sham groups at 22 weeks. To our

knowledge, there are no other publications that have analysed the cost-effectiveness of these techniques in patients with PT. However, other studies showed similar results in the comparison of PNE versus DN in the treatment of plantar heel pain,²¹ with PNE having an 83% probability of being cost-effective against DN, similar to our study that showed a probability of 93%. In the case of the comparison of DN versus sham needling, we observed that the results were not in favour of DN as suggested by Arias-Burúa et al.,⁴² who found DN to be dominant over control in subacromial pain syndrome. The differences in results between

Figure 2. Incremental cost-effectiveness plane for percutaneous needle electrolysis (PNE) versus sham needling. QALY: quality-adjusted life year.

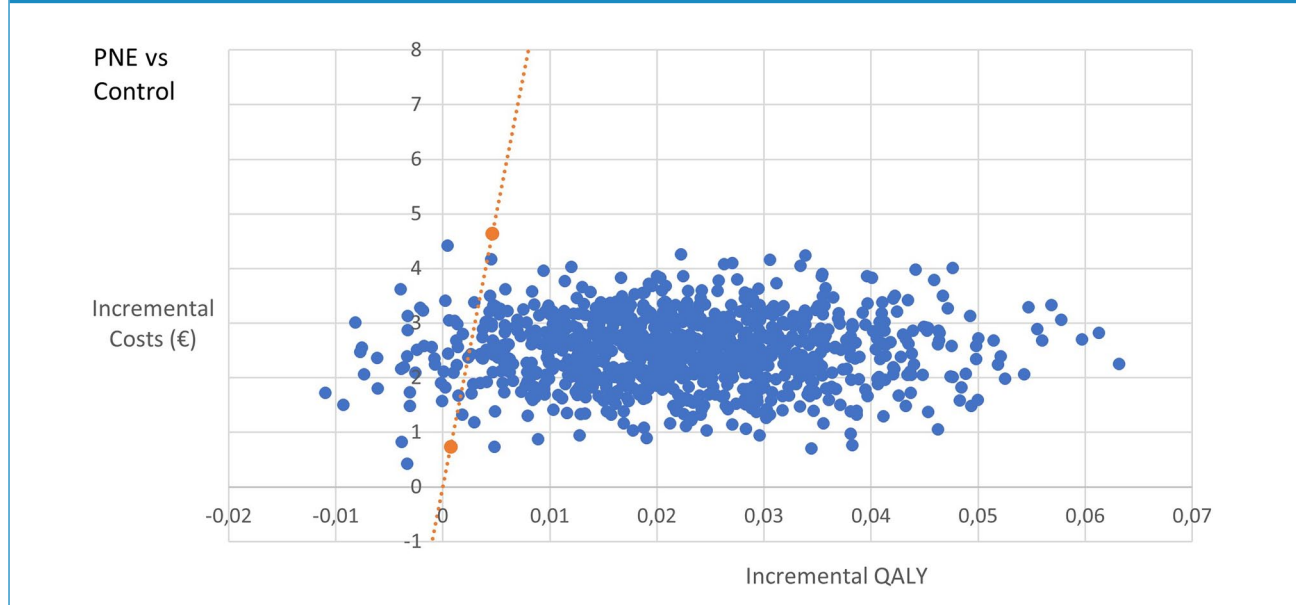
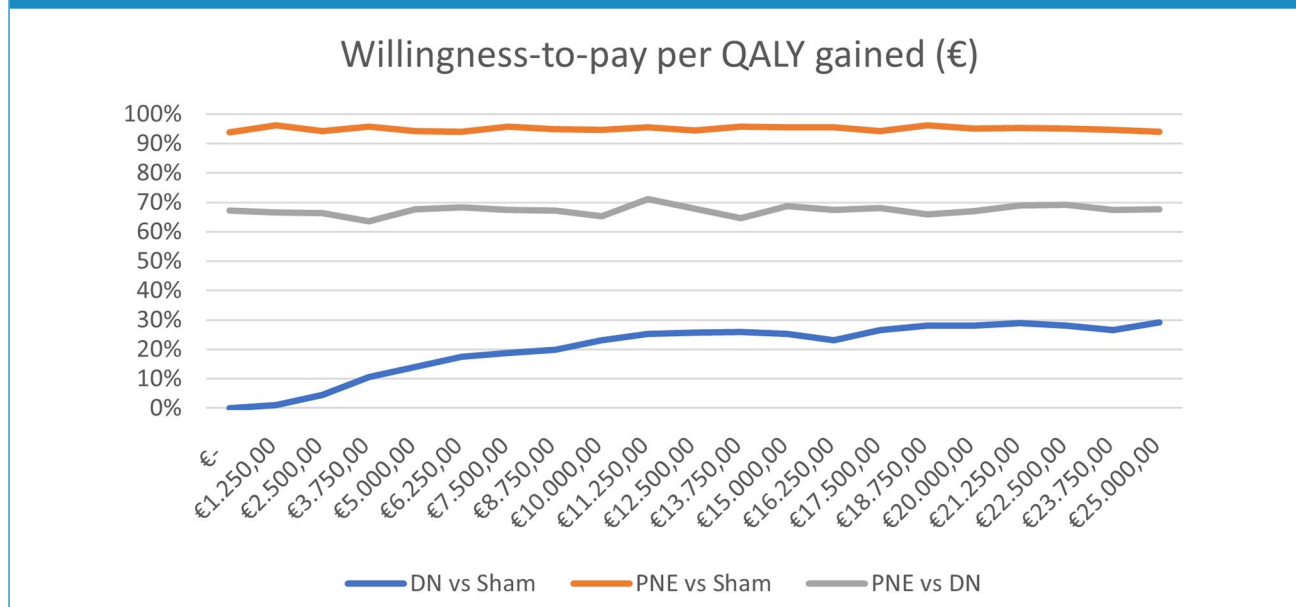


Figure 3. Cost-effectiveness acceptability curve. QALY: quality-adjusted life year.



our studies may be due to differences in ailments or the type of analysis performed.

On the one hand, our study has some limitations and, therefore, the results should be interpreted with caution. The primary study had a relatively small sample size, which impedes generalisation of the results or the performance of sub-analysis by sport or gender, among others. Moreover, there is a lack of studies with which to compare our results. On the other hand, the study has also strengths,

such as being the first (to our knowledge) to follow a strict methodology in the cost-effectiveness analysis of PNE and DN.

Conclusion

The comparative cost-effectiveness analysis translated into a 93% probability that PNE was cost-effective compared to DN and 96% compared to sham needling. Further studies

are necessary to verify the possible benefits of the DN technique for PT.

Declaration of conflicting interests

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