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Prospective Analysis of the Beneficial Effects of Intratissue Percutaneous Electrolysis (EPI) Combined with Eccentric Exercise in the Treatment of Chronic Achilles Tendinopathy

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Abstract

Achilles tendinopathy is a common injury but none treatment has been established as the gold standard. Intratissue Percutaneous Electrolysis (EPI) is an ultrasound-guided technique that achieves rapid regeneration of the tendon. The present study shows the functional capacity and pain relief obtained with EPI in combination with eccentric exercise in this pathology. A prospective study of 39 Achilles tendons between January 2010 and December 2012, followed up to three months, was carried out. Demographic variables were collected, and follow-up was performed with the Victorian Institute of Sport Assessment-Achilles (VISA-A) and the Foot and Ankle Disability Index for Sport (FADI) for functionality scores and the Visual Analog Scale (VAS) for pain. All patients received a weekly session of EPI with two weekly sessions of eccentric exercise. There were 33 males (84.6%) and 6 females (15.4%). The mean age was 42.6 years (range 25-64). It took an average of 5.9 ± 4 sessions for the healing process. Improvement was seen in all values under study, VISA-A went from 46.2 ± 17.8 to 88.1 ± 5.5 ($p < 0.001$), the FADI-Sport from 62.3 ± 24.3 to 112 ± 9.5 ($p < 0.001$), the VAS-Work score from 4.3 ± 2.8 to 0.9 ± 1.6 ($p < 0.001$), the VAS-ADL score from 4.8 ± 2.7 to 0.8 ± 1.2 ($p < 0.001$) and the VAS-Sport score from 8.8 ± 2.2 to 1.3 ± 1 ($p < 0.001$). There were no adverse events attributable to the EPI technique. The treatment of Achilles tendinopathy with Intratissue Percutaneous Electrolysis (EPI) in combination with eccentric exercise has been successful on the short term. There was an improvement in terms of pain and function with few treatment sessions required.

Keywords: Achilles; Electrolysis; EPI; Regeneration; Tendinopathy

Introduction

Achilles tendinopathy is a common injury that occurs predominantly in young patients with activities that are, by nature, highly demanding such as those involving running or jumping [1]. It also presents in elderly patients or in those who are overweight [2,3]. The origin of Achilles tendinopathy is multifactorial with intrinsic factors like dysmetria or malalignment of the lower extremities, ankle mobility deficits or forefoot deformities playing a significant role. Extrinsic factors also influence mechanical overload or

overuse of the tendon. Other factors such as advanced age, diabetes or rheumatic diseases also seem to have some relationship to it. This multifactor characteristic does not always make the results obtained with conventional treatment effective [4,5] and of the various treatments described for chronic Achilles tendinopathy, based on current evidence, none have been demonstrated to be the most effective [1-5]. Intratissue percutaneous electrolysis (EPI) is an ultrasound-guided technique [6,7] that produces a non-thermal electrochemical ablation that leads to rapid regeneration of injured tendon through the localized inflammation reaction obtained [8]. Different studies report promising clinical results with the EPI technique in the treatment of musculoskeletal pathologies, mainly tendinopathies [9-11]. This study provides an analysis of Achilles

tendinopathy treated with the combination of EPI and eccentric exercises. The working hypothesis is that intratissue percutaneous electrolysis obtains a significant improvement in terms of pain and function.

Patients and Methods

Prospective study carried out between January 2017 and December 2019 on a consecutive series of patients diagnosed with Achilles tendinopathy confirmed by high-definition Doppler color ultrasound (Figure 1) following the Musculoskeletal Ultrasound Technical Guidelines of the European Society of Musculoskeletal Radiology [12]. Inclusion criteria were age between 18 and 65 years, ultrasound confirmation of a chronic alteration of the tendon, insertional Achilles tendinopathy for more than 6 months, failed treatment with conservative physiotherapy and acceptance of treatment with EPI. Exclusion criteria included coagulopathy, pregnancy, active infectious process, cancer and previous surgery on the tendon under study or administration at least two months before receiving EPI treatment of fluoroquinolones, anticoagulants, corticosteroids or non-steroidal anti-inflammatories as well as the inability to complete the treatment program and follow up. All patients who met the inclusion criteria signed informed consent. Patients were enrolled in the study consecutively as they were referred from the outpatient clinic of the orthopedic surgeon in charge. The ethics committee of our institution approved the study.

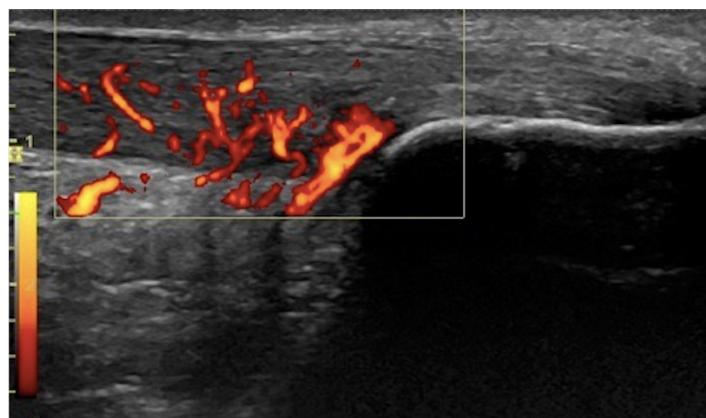


Figure 1: Achilles tendinopathy studied with high-definition color Doppler ultrasound. Longitudinal view reveals intensive hypervascularization (*) combined with hypoechoic zones. Important tendon thickening was detected.

To carry out Intratissue percutaneous electrolysis, patients are placed in the prone position with their feet at the tip of the gurney so that the Achilles tendon area was made easily accessible. The area was disinfected with isopropyl alcohol and the standard sterilization measures were taken for these types of procedures. Treatment with EPI was carried out using a specific approved EPI device (Epiadvanced, Barcelona, Spain), certified according to Directive 93/42/CEE. All patient's current intensity

was set at 3 mA during ten seconds (Figure 2). In all cases, the EPI procedure was performed guided by high-resolution Doppler ultrasound with a 6-15MHz linear probe by means of three punctures with a 0.3mm needle at the injured zone of the tendon. All patients received a weekly session of EPI combined with two weekly sessions of eccentric exercise consisting of three sets of ten repetitions at low velocity and without pain. Demographic variables as well as the functional assessment using the Victorian Institute of Sport Assessment-Achilles (VISA-A) and the Foot and Ankle Disability Index for Sport (FADI) validated questionnaires were collected from patients [13,2]. The VISA-A score goes from 0 to a theoretical 100 in asymptomatic patients, while the FADI-Sport scores between 0 and 136, this being the maximum score of asymptomatic patients. Pain assessment was performed using a Visual Analog Scale (VAS) divided into activities in daily life (ADL VAS-score), at work (Work VAS-score) and sport (Sport VAS-score) [2]. All questionnaires were done on the patient's first visit to the clinic and at three months follow-up.

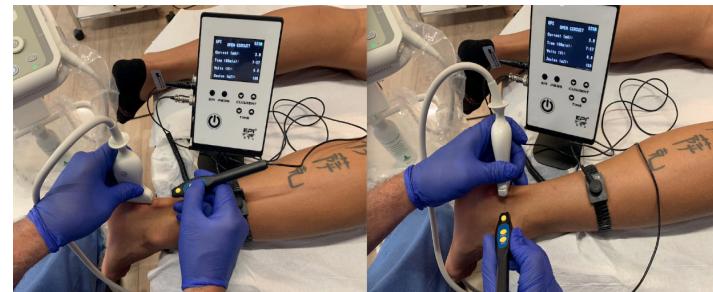


Figure 2: Intratissue percutaneous electrolysis (EPI) procedure with specific device. The 0.3 millimeters needle (arrow) was used to apply the EPI with high-resolution ultrasound guidance. Longitudinal (a) and transversal (b) views were used.

Statistical Analysis

The quantitative variables are described based on the mean and standard deviation. For categorical variables, the percentage and the number of cases have been provided. For categorical variables, the percentage as well as the number of cases has been provided. Inference was studied using the Fisher exact test or Chi-square, depending on the case. The comparison of quantitative variables (EVA, VISA-A and FADI) was done with a "t" test for related samples, without assuming the existence of homoskedasticity. The significance level was the usual 5% ($\alpha = 0.05$), bilateral approach. All the analyses were performed using the SPSS 19 (SPSS Inc., Chicago, Illinois) statistical package.

Results

During the period of the study, 39 patients were treated. Thirty-three patients (84.6%) were male and the remaining 6 (15.4%) were female. The mean age was 42.6 years (range 25-64). The mean body mass index was 25 (range 18.2 to 32.2). The

average time of evolution of the Achilles tendinopathy symptoms before consulting our clinic was 18.6 months (range 2-84) and the follow-up was up to three months for each patient. A statistically significant improvement was found in the value of the VISA-A. It went from a pre-treatment average of 46.2 ± 17.8 to a value 88.1 ± 5.5 ($p < 0.001$) at the end of treatment. The value of FADI-Sport, in its turn, presented a significant increase going from 62.3 ± 24.3 pre-treatment to a value of 112 ± 9.5 ($p < 0.001$) at the end of treatment (Table 1). Values of the Visual analogue scale showed a statistically significant improvement for both the VAS-Work score that went from 4.3 ± 2.8 pre-treatment to 0.9 ± 1.6 after treatment ($p < 0.001$), the VAS-ADL score of 4.8 ± 2.7 that went to 0.8 ± 1.2 at endpoint ($p < 0.001$) and VAS-Sport score that went from 8.8 ± 2.2 to 1.3 ± 1 at the final assessment ($p < 0.001$) (Table 1). No relationship was found between the functional values and pain values reported and the demographic variables studied ($p > 0.05$). The number of EPI sessions required was on average 5.9 ± 4 . No adverse events attributable to the EPI technique used during treatment were seen. There were no cases of regression of improvement in terms of pain or function reported.

	Baseline	3 months FU	p. value
VISA-A	46.2 ± 17.8	88.1 ± 5.5	$p < 0.001$
FADI	62.3 ± 24.3	112 ± 9.5	$p < 0.001$
VAS-Work	4.3 ± 2.8	0.9 ± 1.6	$p < 0.001$
VAS-ADL	4.8 ± 2.7	0.8 ± 1.2	$p < 0.001$
VAS-Sport	8.8 ± 2.2	1.3 ± 1	$p < 0.001$

Table 1: Functional and pain evaluation of the series during the follow-up

(VISA-A): Scores of Victorian Institute of Sport Assessment-Achilles; FADI: Foot and Ankle Disability Index for Sport; VAS: Visual Analog Scale ADL: Activities of Daily Life; work and sport. Values are expressed as mean \pm standard deviation.

Discussion

The present study shows the promising results obtained with EPI combined with eccentric exercise in the treatment of refractory Achilles tendinopathy at the three-month follow-up. It confirms our working hypothesis.

Functional improvement was assessed using VISA-A, a validated test for Achilles tendinopathy and the FADI-Sport for foot and ankle [14,15]. Pain was evaluated with the VAS score [2]. The good results obtained are based on the local effect obtained with EPI, an electrochemical therapy that induces a short local inflammatory response with a cathodic current flow that leads to the rapid regeneration of injured tendon [6-8]. The eccentric treatment has shown good results with a decrease in pain of 50% according to the visual analog scale and some increases of some 10-15 points in the value of the VISA-A questionnaire [13,16,17].

It should be noted that most authors using eccentric exercise for the treatment of tendinopathies use a similar protocol. It consists of 12 weeks of training with eccentrics with workouts of 3 series of 15 repetitions two or three times per day [16,18,19]. This does imply a long period of treatment with daily sessions.

The use non-steroidal anti-inflammatory drugs have reported poor symptom improvement [20]. Some authors showed good results with the use of the laser while others did not observe differences in the pain levels between shock wave therapy and the treatment simulated in their randomized controlled trial [21,22]. The use of ultrasound or a combination of ultrasound and Cyriax has reported improvement in pain values [23]. While some authors have seen some degree of improvement with shock wave therapy [3], others do not advocate the use of shock wave therapy for the treatment of patients with chronic Achilles tendon pain [24], including one article on the adverse effect of shock wave therapy [25]. No clear treatment protocol was extracted from the revision of the works consulted. While some studies used pulsed ultrasound, others used continuous ultrasound, radial shock or extracorporeal shock waves with a different number of sessions with doses ranging from 8Hz to 50Hz or diverse ranges of pulses from 2000 to 3000 administered per session [3,4,22-27]. Surgery has been marked as a treatment option when conservative treatment fails [28-30], but the results of it are not always good and it has a negligible complications rate [4,22,26]. The use of growth factors such as platelet-rich plasma has shown good results [31-34]. But more RCT are needed to determine its effectiveness and its use protocol.

The main strength of this study is in that it is the first investigation into the effectiveness of the EPI in the treatment of Achilles tendinopathy to be described in the literature. Promising results have been obtained using this technique. There was an average increase of the VISA-A by 41.9 points and the FADI-Sport by 49.7 points after treatment and significant improvement in the values of the VAS-ADL score, the VAS-Work score and the VAS-Sport score. This improvement was achieved with a low number of treatment sessions (a mean of 5.9 sessions). Another weakness of this study is the use of eccentric exercise combined with EPI. Despite this, it is a common limitation in studies done in this area [6,13,18,26,31-34]. The sample size presented ($n=39$) may also be considered a limitation of this study, although many of the existing works in the current literature employ similar number of participants [12,13,19,23,28-30,34-36]. A major limitation of this study is the lack of control group. The use of placebo for comparison with the control group may have reported stronger conclusions, but the majority of our patients are referred after failing with other treatments. Therefore, it is unlikely that a group of them would accept a placebo for a sufficient period of time. In conclusion the treatment of Achilles tendinopathy with Intratissue Percutaneous Electrolysis (EPI) in combination with eccentric exercise has been

successful on the short term. There was an improvement in terms of pain and function with few treatment sessions required.

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