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RESEARCH ARTICLE

Multiple Perforations of the ECRB Tendon Using an Innovative Standardized, Reproducible Technique; A Cadaveric Study on Accuracy and Prospective Clinical Safety Assessment Pilot Study. No Adverse Effects in the First 122 Patients with Lateral Epicondylitis

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Abstract

Background: In LE (Lateral Epicondylitis) otherwise known as Tennis Elbow, the Extensor Carpi Radialis Brevis (ECRB) tendon is most commonly involved. In the majority of studies, injections are performed with a lack of standardization. The Instant Tennis Elbow Cure (ITEC) device has been developed to perform reproducible and standardized perforations by multiple needles. The goal of this pilot study was to estimate the accuracy of this ITEC device by means of a cadaveric study and to assess the clinical safety of this procedure.

Methods: Ten cadaveric arms were injected using the ITEC device. The location and depth of the ECRB tendon was measured by ultrasound imaging. The accuracy of the infiltration was assessed by locating the injected dye through dissection and arthrotomy of the cadaveric elbow.
A prospective clinical pilot study was conducted to assess the safety of the ITEC device in treating patients with chronic LE. An optional infiltration with an injection fluid was carried out?? Primary outcome measures were side effects and complications of the ITEC device occurring within a follow up period of 8 weeks after treatment.

Results: In all cadaveric elbows the injection fluid (in this case an injection fluid) was located at the ECRB tendon. In one cadaver, a minimal amount of dye was found intra-articular and in 3 cadavers a small quantity was located in the surrounding tissue of the ECRB tendon. 122 patients with LE were treated with the ITEC device. No adverse effects or complications were reported at 8-week follow up.

Conclusion: Treatment of LE using the ITEC device appears accurate and safe. It may improve future research since it is reproducible and it can be performed in a standardized way.

Level of evidence: IV

Keywords: Cadaver study, Injection therapy, Lateral epicondylitis, Pilot study, Tennis elbow

Introduction

Lateral epicondylitis (LE) of the elbow, otherwise known as Tennis Elbow, is a common condition in general practice, with an incidence of 4 to 7 per 1000 patients per year (1, 2). The etiology and pathophysiology of LE is still not exactly known. It is presumed to be an overload injury causing micro- and macroscopic lesions

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Table 1. Overview of injection therapies, volumes of the infiltrations and injection technique.

	Injectables			Volume	Injection technique
Kazemi et al 2010 (19)	AB 2cc + 2% lidocaine 1cc	methylprednisolone 20 mg + 2% lidocaine 1cc		3cc	Single shot. Manually performed. No ultrasound guidance described.
Ozturan et al 2010 (20)	AB 2cc + prilocaine 1cc	methylprednisolone acetate 1cc + prilocaine 1cc		2-3cc	5 tendon penetrations using 1 skin portal. Manually performed. No ultrasound guidance described.
Peerbooms et al 2010 (15)	PRP 3cc + bupivacaine hydrochloride 0.5% with epinephrine 1:200000	kenacort 40 mg/mL triamcinolon acetonide) + bupivacaine hydrochloride 0.5% with epinephrine 1:200000		3-4cc	1cc directly in tender part, and remaining 2-3 cc by peppering technique: a single skin portal and 5 penetrations of the tendon. Manually performed. No ultrasound guidance described.
Wolf et al 2011 (21)	Saline 2cc + lidocaine 1cc	Corticosteroid 2cc + lidocaine 1cc	AB 2cc + lidocaine 1cc	3cc	Injection under the extensor origin and injecting with multiple passes of the needle in a fanlike fashion in the area. Manually performed. No ultrasound guidance described.
Omar et al 2012 (14)	PRP	Corticosteroid		No info	No info, 1 injection. Manually performed. No ultrasound guidance described.
Dojode et al 2012 (22)	AB 2cc + 0.5% Bupivacaine 1cc	Corticosteroid 2cc + 0.5% Bupivacaine 1cc		3cc	Single injection. Manually performed. No ultrasound guidance described.
Krogh et al 2013 (13)	PRP 3-3.5cc	Saline 0.9% 3cc	Triamcinolon 40mg/mL 1cc + lidocaine 10mg/mL 2cc	10 -15 mL of lidocaine 10 mg/mL in the peritendon of common tendon origin + injection of 3-3.5cc	Ultrasound-guided injection technique. PRP and saline by peppering technique by making 1 skin portal and about 7 tendon perforations. The glucocorticoid injection was made with 1 skin portal, and the content was injected at the deepest aspects of the common tendon origin.
Jindal et al 2013 (23)	AB 2 cc + 2% lignocaine 1cc	40 mg methyl prednisolone acetate + 2% lignocaine 1cc		3cc	Single injection. Manually performed. No ultrasound guidance described.
Arik et al 2014 (24)	AB 2cc + 2% prilocaine hydrochloride 1cc	40 mg methylprednisolone acetate 1cc + 2% prilocaine hydrochloride 1cc		2-3cc	Single injection not specified. Manually performed. No ultrasound guidance described.
Gautam et al 2015 (25)	PRP 2cc	40 mg/ml methylprednisolone 2cc		2cc	peppering technique, not specified if the injection was performed with ultrasound guidance.

AB= Autologous blood, PRP= platelet rich plasma

in the common origin of the wrist and finger extensors, most commonly involving the Extensor Carpi Radialis Brevis (ECRB) tendon (3-5). Degenerative changes are seen characterized by hypercellularity, angiofibroblastic hyperplasia and neovascularization (4-6).

Besides non-surgical treatments such as non-steroidal anti-inflammatory drugs (NSAID), splinting, acupuncture and physiotherapy, injection therapy with multiple perforations of the ECRB tendon has become an accepted alternative treatment option for chronic LE, whether or not with an additional infiltration. Various substances have been described as injection fluid such as glucocorticoids, autologous blood (AB), platelet-rich-plasma (PRP), hyaluronic acid, a sclerosing agent called polidocanol, botulinum toxin and dextrose. However, despite numerous studies no consensus exists concerning the optimal treatment (7-17). In most comparative studies, injections are performed manually and 'blindly' without ultrasound guidance (12). A meta-analysis by Qian et al. on the effectiveness of AB and PRP versus corticosteroids confirms this statement and shows the variation in injection technique, injection volume and the lack of standardization described in current literature [Table 1] (14,15,18-25). This meta analysis only included studies on autologous blood products. When considering other injectables the variation in application will increase. In a recently published cadaveric study it was shown that manually performed injections of the ECRB tendon, without ultrasound guidance, lack accuracy and that only 30% of the injections were at least partially located at the ECRB tendon, whilst 60% of the injections were localized intra-articular (26). To our knowledge, there are no studies published which describe a standardized, reproducible injection technique using the same number, direction and depth of the needle perforation with an identical amount of injection fluid released with each perforation. The lack of standardized application of this procedure make a proper comparison difficult.

Recently, a device (ITEC; Instant Tennis Elbow Cure) has been developed that mimics the needle perforation performed by medical staff. It is designed to overcome the objections of manually and blindly performed injections and performs percutaneous, reproducible, standardized perforations by 12 needles.

The primary goal of this pilot study was to assess the accuracy of this ITEC device through a cadaveric study. A secondary goal was to assess the first clinical safety assessment of the ITEC device in 122 patients with LE with a focus on identifying potential adverse outcomes of this new standardized perforation technique.

Materials and Methods

The study consists of two parts; firstly a study on the accuracy of the ITEC device using cadaveric arms and secondly a pilot study concerning the first clinical safety assessment of the ITEC device in patients with LE.

ITEC Device

The ITEC (Instant Tennis Elbow Cure) device (CE 621544, ITEC Medical B.V. Enschede, the Netherlands) consists of a table with an attached injection arm, on which the arm of the patient can be accurately positioned [Figure 1]. The shoulder and elbow are positioned in a standardized way; with the arm 90 degrees flexed in the elbow and with 90 degrees abduction in the shoulder. At 90° of elbow flexion, the ECRB tendon runs straight from the lateral epicondyle to the wrist (27). An ITEC-injection disposable can be fixed in the injection arm. This sterile disposable contains a set of 12 injection needles (3x4) designed in accordance with the anatomic landmarks of the ECRB tendon. The effective length of the needles varies between 18-19mm. This variation in length and the number of needles is also based on the anatomical characteristics of the elbow (28-30). To assess local anatomy, an ultrasound study was performed on the dimensions of the ECRB tendon,

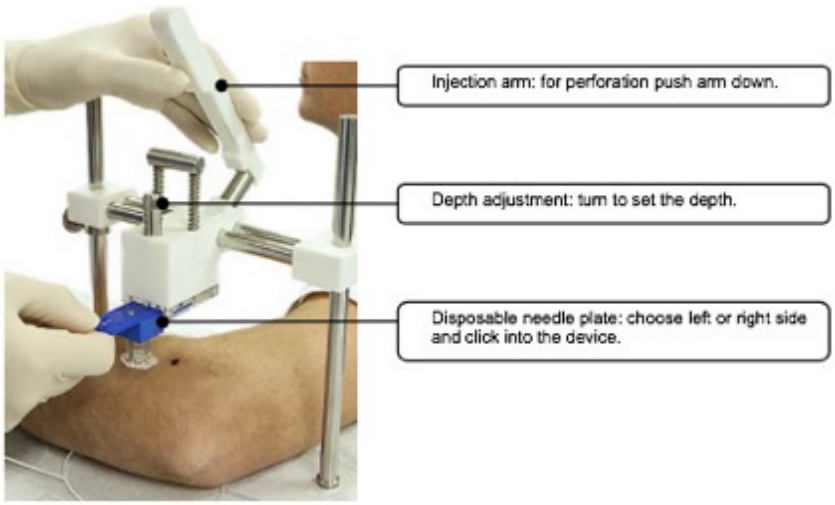

Figure 1. The ITEC (Instant Tennis Elbow Cure) device (CE 621544, ITEC Medical B.V. Enschede, the Netherlands). Image under copyright by ITEC Medical B.V. and published with their permission.

Figure 2. The ITEC disposable. Image under copyright by ITEC Medical B.V. and published with their permission.

taking into account the length and slope of the lateral epicondyle (31). A syringe can be attached optionally to allow injection with PRP, dextrose, AB or another preferred injection fluid [Figure 2].

The procedure is carried out as follows:

-Depth measurement from the skin to the middle of the ECRB tendon (M1) with an ultrasound probe (5-12 MHz phased array transducer type with Esaote MyLab Five ultrasound imaging system (Esaote Europe B.V. Maastricht, the Netherlands)) [Figure 3].

-Adjusting the depth of injection on the ITEC device.

-Positioning of the arm at 90 degrees elbow flexion and 90 degrees abduction in the shoulder.

-Placement of the set of disposable needles.

-Percutaneous perforation using the ITEC device; the perforation is performed by a single movement of the arm of the device.

Cadaveric study

A total of ten human fresh frozen cadaveric arms were used; 5 left and 5 right arms in 7 males and 3 females. The location of the origin of the ECRB tendon was marked and the depth of the tendon was measured (M2) by ultrasound imaging [Figure 3]. Perforation and infiltration of the ECRB tendon of the cadaveric arms was performed using the ITEC device according to the above-mentioned procedure [Figure 4]. The specimens were provided by the Department of Anatomy of the University Medical Center Utrecht, the Netherlands and were derived from bodies who had entered the department through a donation program. From these persons written informed consent was obtained during life that allowed the use of their entire bodies for educational and research purposes.

First two cadavers were used as a pilot to explore the most appropriate injection technique. Initially an infiltration with methylene blue was performed by an experienced orthopaedic surgeon, specialized in elbow pathology. After the infiltration, a dissection of the cadaveric elbow was undertaken to determine the location of the methylene in the soft tissue and an arthrotomy was performed to ascertain the presence/absence of methylene blue intra-articular. During dissection it was found that the methylene blue rapidly diffuses to the surrounding tissue. Therefore, the remaining cadavers were infiltrated with acrylic dye which diffused much more slowly into the soft tissue. The first two pilot arms were also used to determine how much dye was needed to infiltrate the entire insertion of the ECRB tendon, this proved to be 0.4cc. The remaining eight cadaveric arms were infiltrated with yellow acrylic dye by the same orthopaedic elbow surgeon and infiltrated with blue acrylic dye by an orthopedic resident. This resident had no experience with the ITEC device. In all perforations 0.4cc dye was infiltrated. The localization of the dye was again assessed by dissection and arthrotomy by the orthopaedic elbow surgeon and verified by the resident.

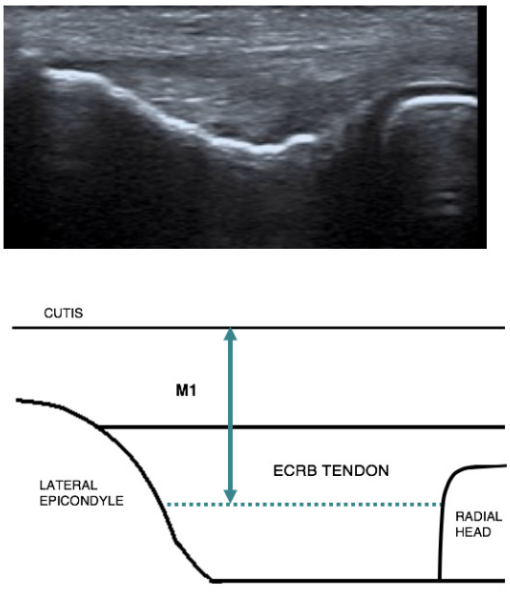

Figure 3. Ultrasound view and schematic view of the ECRB tendon. Dotted line = middle of the ECRB tendon. M1= length from the cutis to the middle of the ECRB tendon.

Clinical study

A prospective, phase I, pilot clinical study was conducted at the Amphia hospital (Breda, the Netherlands). Ethical approval was waived by the Dutch Medical Ethics Committee of Eindhoven (Maxima Medical Center). Patients with chronic (more than 3 months) lateral epicondylitis of the elbow, eligible for percutaneous release by needle therapy were evaluated from October

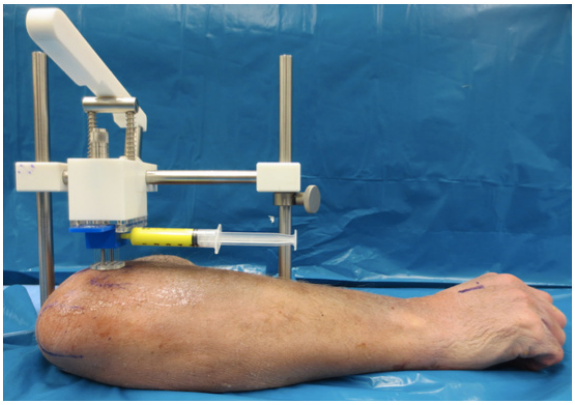

Figure 4. Set up of the cadaveric arms with the ITEC device.

2013 till June 2016. The eligibility for treatment was decided by the attending orthopedic surgeon. LE was diagnosed as follows: pain on the lateral site of the elbow during physical examination; pain during palpation of the lateral epicondyle and pain at the lateral epicondyle during dorsal flexion of the wrist (from a neutral position with a straight elbow) against resistance. Conventional radiographs of the elbow (AP and lateral) were made to exclude bony pathology.

All patients were treated with percutaneous needle therapy by the senior author using the ITEC device according to the above procedure. Before depth measurement, the skin was sterilized and an infiltration with a local anesthetic was applied subcutaneously (lidocaine 1%) at the affected elbow.

In addition to the perforations an optional infiltration with an injection fluid was carried out through the disposable needles. According to the patients' and physicians' preferences the injections consisted of AB, dextrose or perforation only.

Outcome measures

Primary outcome measures of the safety assessment study were complications and side effects of the ITEC device, this with a follow up of 8 weeks after treatment. Patients were followed up conforming to the national standards; including physical examination, assessment of infection, hematoma formation, possible nerve damage and instability. Informed consent was obtained from all patients.

Results

Cadaveric study

In the first two cadaveric elbows methylene blue was found in the ECRB tendon. No methylene blue was found intra-articular after arthrotomy. In all of the following 8 cadaveric elbows both the blue and the yellow dye were found in the ECRB tendon as intended. In one cadaveric arm, a minimal amount of blue dye was found intra-articular. In the remaining elbows no dye was seen after arthrotomy. In one arm a little amount of blue dye was also located subcutaneously. In two arms a small amount of yellow dye was located subcutaneously whereby in one case also a small amount of dye was found in the Extensor Carpi Radialis Longus (ECRL) tendon. The depth measurement (M1) of the ECRB tendon varied from 0.41 to 0.93 cm [Figure 3].

Clinical study

A total of 122 patients with chronic LE were treated with the ITEC device; 66 males and 56 females. Within the 8 week follow-up period there were no adverse effects or complications reported in this safety-assessment study.

Discussion

This study describes the first safety assessment of the ITEC device for the treatment of lateral epicondylitis of the elbow and its accuracy. The use of the ITEC device resulted in an accurate infiltration of the ECRB tendon in human cadaveric arms. The cadaveric study showed no difference in accuracy when the perforation was carried out by a highly experienced orthopaedic elbow surgeon or by a novice orthopaedic resident. In 122 consecutive patients with chronic lateral epicondylitis no adverse events or complications were reported after treatment with the ITEC device with an 8-week follow-up. Therefore, we state that the ITEC device is an accurate method in cadavers to perforate and infiltrate the ECRB tendon. The device is safe to use in daily clinical practice.

The ITEC device offers several advantages. Given the accuracy of the technique, potential significant health care efficiency gains could be made. Further research and clinical results are required. Because of the simple, standardized technique the ITEC device may also be suitable for nurse practitioners or general practitioners to employ in the treatment of patients. In current literature, there is a paucity of evidence from unbiased trials on the effectiveness of injection therapy in the treatment of LE (12,18). This is hypothesized to be caused by the lack of accuracy and standardization of the injection technique. Often the number of perforations and ml of fluid released is not determined which makes the comparison, even in well-designed RCT 's debatable.

This pilot study has several limitations. In the cadaveric study, the assessment of the localization of the injected dye after dissection and arthrotomy was not blinded. For practical reasons this was done by the same orthopedic surgeon and checked by the same resident who performed the infiltrations.

However, injection therapy with the ITEC device seems accurate. To demonstrate an advantage for daily practice randomized trial is required, comparing infiltrations with the device to manually performed injections. It must be taken into consideration that treatment with the ITEC device is more expensive than manual infiltration. A cadaveric study on manually performed injections for LE showed a lack of accuracy with only 30% of the injections located at the intended ECRB tendon (26). These results are, despite the limited accuracy, not directly translatable to clinical practice. It must be taken into account that the infiltrations were carried out on nonresponsive cadavers and based on bony landmark only. Injections in patients who are able to point out the most painful area might be more accurate.

It is not proven that perforation of the ECRB tendon itself is the best treatment or injection technique in the treatment of LE. Given the current concepts about the etiology of LE it is only hypothesized that the whole insertion of the ECRB tendon needs to be treated. By perforating the ECRB tendon it is thought that the needles break up scars or poke holes in the affected tendon so that bleeding occurs. These blood cells carry precursors, which eventually could develop into collagen to replace the damaged tendon.

Possible complications of this procedure are local infection, skin necrosis or nerve injury. If complications do occur, they are expected to present in the first weeks after treatment. Therefore, a follow-up of 8 weeks should be appropriate for thorough assessment.

In the cadaver study the methylene blue diffused quickly to the surrounding tissues and was therefore replaced

by acrylic dye. The quick diffusion and subsequent wide spread of methylene blue after injecting the ECRB tendon was confirmed by a cadaver study by Evans et all (32). In our study the injection with acrylic dye proved to diffuse more slowly, however, some minimal diffusion could not be prevented in 1 arm. In the first arm with acrylic dye a minimal amount of blue dye was found intra-articular. It is possible that this is caused by diffusion and not by the injection as the exploration was done very slowly. The two arms in which the yellow dye was partially located subcutaneously were both cachectic, which may have contributed to the localization of the dye. In the other arms the punctures of the needles were clearly visible in the subcutis without the presence of any dye.

In view of future research, the ITEC device may provide important opportunities. One of the limitations of the current literature is the fact that most studies report manual and blind injections, resulting in unreliable comparisons of treatment modems. Additionally, these studies are not standardized in relation to number of perforations and quantity of injection fluid. Since the ITEC device enables a standardized injection technique with a standard number of needles, fluid amount, depth and direction of the needles, it will be more reliable in comparing different injectables during trials.

In conclusion, treatment of lateral epicondylitis using the ITEC device seems accurate and safe. Using the new, standardized technique may improve future research due to it's accuracy, reproducibility and standardization. This device might also be suitable to be used by medical staff without experience in elbow surgery.

Treatment of LE using the ITEC device seems accurate and safe. It may improve future research since it is reproducible and it can be performed in a standardized way.

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