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ONE OR TWO ULTRASONOGRAPHY-GUIDED BOTULINUM TOXIN A INJECTIONS IN THE TREATMENT OF REFRACTORY LATERAL EPICONDYLALGIA? A RETROSPECTIVE STUDY

Pierre-Loup Tabary[1], Jérémy Picard[2], Olivier Rémy-Néris[1], Gwenaël Cornec[1]

[1] Univ Brest, CHU Brest, INSERM UMR 1101 LaTIM, Brest, France
[2] Univ Brest, CHU Brest, INSERM UMR 1078 GGB, Brest, France

Corresponding author's e-mail: gwenael.cornec@chu-brest.fr

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ABSTRACT

Design: Retrospective cohort study evaluating the outcomes and safety of botulinum toxin A injections in refractory lateral epicondylalgia.

Participants: Seventy-nine patients (81 elbows) with refractory lateral epicondylalgia (persistent pain despite ≥6 months conservative treatment) treated between August 2022 and December 2023.

Interventions: All patients received an initial ultrasound-guided injection of 40 units of botulinum toxin A into the extensor carpi radialis brevis (ECRB). A second injection was offered in case of persistent symptoms, targeting the ECRB, extensor digitorum communis and/or supinator depending on standard provocative tests.

Main measures: Clinical outcome was categorised as 'poor', 'temporary', 'partial' or 'good' based on self-reported pain evolution. Patients no longer requesting care were classified in the 'good' category. Adverse events were systematically recorded.

Results: After the first injection, 20% (16/81) had a 'good' outcome. Among 51 elbows receiving a second injection, 47% (24/51) reached this category, yielding an overall rate of 49% (40/81). Favourable outcome was not significantly associated with sex, age, or number of muscles injected in univariable analyses. Transient motor weakness occurred in 34% (27/79) of patients; one patient experienced a persistent deficit lasting six months with functional impairment.

Conclusions: A second ultrasound-guided botulinum toxin A injection with individually tailored muscle targeting was associated with a favourable outcome in about half of patients insufficiently relieved after the first one. Randomised controlled trials are needed to evaluate the added benefit of a tailored muscle targeting strategy and ultrasound guidance in the management of refractory lateral epicondylalgia.

KEYWORDS

Botulinum toxin, chronic pain, lateral epicondylalgia

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INTRODUCTION

Lateral epicondylalgia, commonly referred to as "tennis elbow", is a frequent cause of elbow pain, with an estimated annual incidence of 1–3% in the western population[1]. Manual labourers are particularly at risk, with a reported prevalence of 7–14%[2]. Lateral epicondylalgia is often considered a self-limiting condition, with 80–90% of patients recovering within one year and an average duration ranging from 6 to 24 months[3], but it remains difficult to manage and is prone to recurrent episodes[4].

There is no consensus regarding management of lateral epicondylalgia[5–7]. Conservative treatment consists of a combination of rest, non-steroidal anti-inflammatory drugs, physical therapy, orthosis, extracorporeal shockwave therapies and injection therapies[8–11]. Refractory or chronic lateral epicondylalgia is usually defined by a duration of more than 6 months and failure of conservative treatment[12,13] and represents 10% of all cases[14]. Surgery remains an option but is associated with significant morbidity and variable outcomes[15,16].

Botulinum toxin A has emerged as an alternative, minimally invasive treatment[17,18]. Clinical trials have reported mixed results[19,20], with some randomised studies showing modest benefit[21–23] while some series suggested greater improvement[24,25]. Most published work has focused on single injections targeting the extensor carpi radialis brevis, with little data on the potential value of repeated treatment or multiple targets[26]. We hypothesised that a second injection, performed according to a tailored strategy (muscle selection adapted to clinical examination), would be associated with a higher rate of favourable clinical outcome than that observed after a single, non-tailored injection.

The present study aimed to evaluate the outcomes and safety of one or two ultrasound-guided botulinum toxin A injections in patients with chronic lateral epicondylalgia.

MATERIALS AND METHODS

This was a retrospective single-centre cohort study conducted in the Physical and Rehabilitation Medicine Department at a tertiary referral hospital. The study was performed in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki. It was approved by the "Comité de Réflexion Éthique de Territoire" — Territorial Ethics Reflection Committee — of Brest University Hospital (B2024CE.59). All patients received a letter informing them of the retrospective use of their clinical data and of their right to object, and none opposed. In accordance with French regulations governing retrospective research on routinely collected healthcare data, written informed consent was not required for this non-interventional study. Data were pseudonymised before analysis, patients being identified by a study number.

Population

All consecutive patients over 18 years old treated with ultrasound-guided botulinum toxin A (incobotulinumtoxinA) injection for refractory lateral epicondylalgia between August 2022 and December 2023 were eligible. Refractory lateral epicondylalgia was defined as persistent pain after 6 months, despite conventional management. There were no specific exclusion criteria other than age under 18 years old. Demographic and clinical characteristics were retrieved from electronic medical records.

Care pathway

All patients had been referred by a specialist (orthopaedic surgeon, rheumatologist, or sports physician) with a diagnosis of lateral epicondylalgia established by ultrasound and/or magnetic resonance imaging. All injections were performed by a single physician with 30 years of experience in ultrasound-guided injections. At baseline (V0), all patients were clinically assessed and received an ultrasound-guided injection of 40 units of incobotulinumtoxinA into the extensor carpi radialis brevis. Then, a follow-up assessment occurred 14 weeks (SD 4.6 weeks) after the first injection (V1). A second injection was proposed in case of persistent symptoms. The second injection targeted the extensor carpi radialis brevis, extensor digitorum communis, and/or supinator according to acute pain felt during standard provocative tests (respectively resisted wrist extension – Cozen's test, resisted third finger extension – Maudsley's test, and resisted supination) carried out as part of the physical examination. Any muscle painful on resisted contraction was injected. The total dose depended on the number of muscles injected: 40 units for the extensor carpi radialis brevis alone, 60 units if two muscles were injected (30 units each), and 90 units if three muscles were injected (30 units each). Treatment outcomes after the second injection were evaluated during a second follow-up visit (V2), mean 13 weeks (SD 5.4 weeks) after V1.

Outcome measures

The primary outcome was a patient-reported functional endpoint reflecting global satisfaction and cessation of care-seeking behaviour, previously used by Cogné et al. in a similar population[26]. According to medical records, clinical outcome was classified into four categories based on patient-reported pain evolution: 'poor', 'temporary', 'partial', and 'good' *(Table 1)*. Clinical outcome was defined as favourable only when patients met the criteria for the 'good' category, defined as explicitly stating that they were satisfied and no longer requested a treatment. Patients lost to follow-up were categorised as having a 'poor' outcome to limit attrition bias. Adverse events were also recorded and categorised as minor (no daily-life impairment) or major (daily-life impairment).

Statistical analysis

A descriptive analysis summarised patient characteristics, including missing data. Continuous variables were

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Category	Definition
Poor	No pain improvement reported
Temporary	Pain improvement reported, but not sustained at follow-up
Partial	Sustained pain improvement reported, but patient still requesting further treatment
Good	Patient no longer requesting treatment due to pain relief

Table 1. *Definitions of clinical outcome categories. Data source: patient self-report extracted from medical records at follow-up visits.*

presented as mean ± standard deviation (SD). Categorical variables were described as absolute and relative frequencies.

To assess factors associated with a favourable outcome after a second injection, univariable analyses were performed including age, sex, response to first injection, and number of muscles injected at the second session (1 or 2 vs 3). Associations were tested using Student's t test or Mann–Whitney U test for continuous variables and chi-square or Fisher's exact test for categorical variables, as appropriate.

All tests were 2-tailed and p values <0.05 considered statistically significant. Because of the sample size, trends with p values between 0.05 and 0.10 are reported and interpreted with caution. Data analyses were performed using Rstudio software version 2024.12.0.

RESULTS

Seventy-nine patients (81 elbows) were included. Baseline characteristics assessed at V0 are summarised in *Table 2*. The population was predominantly female (67%), with long-standing symptoms (89% lasting more than one year). Notably, most patients were on sick leave (61%) and nearly half had a recognised occupational disease (48%), reflecting the functional and socioeconomic burden of the condition in this refractory population.

After the first injection, 20% of cases (16/81) had a favourable outcome and 5 were lost to follow-up. Of the 60 elbows assessed at V1 with an insufficient outcome, 51 received a second injection and 9 declined. All patients who declined were women (9/9 vs 63%, p = 0.046) and tended to be older (mean 54 vs 49 years, p = 0.066) and more often had a 'poor' outcome after the first injection (7/9 vs 22/51, p = 0.076); the remaining two had a 'partial' outcome. Documented reasons for declining included referral for surgical opinion or reassessment for an alternative diagnosis (radial tunnel syndrome, carpal tunnel syndrome, or a rheumatological condition) in 4 cases, and personal choice in the remainder. Following a second injection, the overall rate of favourable outcomes was 49% (40/81). The distribution of clinical outcomes at each stage ('poor', 'temporary', 'partial', 'good') is displayed in *Figure 1* and *Table 3*.

Characteristic	Value (n = 79 patients)
Elbows treated, n	81
Age, years (mean ± SD)	50 ± 7
Women, n (%)	53 (67)
Symptom duration, n (%)	
>1 year	70 (89)
6-12 months	3 (4)
Missing	6 (7)
On sick leave, n (%)	48 (61)
Occupational disease recognition, n (%)	38 (48)

Table 2. *Participant baseline characteristics.*

Among the 51 elbows that received a second injection, 24 (47.1%) had a favourable outcome. In univariable analyses, clinical outcome was not significantly associated with age, sex, or number of muscles injected *(Table 3)*. A higher proportion of patients with a prior 'partial' outcome reached a favourable outcome after the second injection than those with a 'poor' or 'temporary' outcome (68.8% vs 37.1%), although this difference did not reach statistical significance ($\chi^2 = 3.23$, p = 0.072).

Transient extensor weakness was reported in 27 patients (34%); no patient experienced weakness twice. Among second injections, the occurrence of motor deficit was not significantly associated with the number of muscles injected (Fisher p = 0.920). One patient experienced a persistent extensor deficit lasting six months with functional impairment, which eventually resolved.

DISCUSSION

This retrospective study evaluated the outcomes and safety of one or two ultrasound-guided injections of botulinum toxin A in 79 middle-aged patients with refractory lateral epicondylalgia. The main finding was that nearly half of the patients had a favourable clinical outcome. A favourable clinical evolution was observed more than twice as frequently after the second injection, when muscle targeting was individually tailored by clinical examination, than what was observed after the first one. Because patients were not randomly allocated to a second injection, this observation should be read as an association rather than a demonstrated effect, and its interpretation is discussed further below.

It is believed that shielding the enthesis from excessive mechanical stress could provide favourable conditions for tendon repair[27,28]. Consistently, mechanical loading of the lateral epicondylar enthesis has been associated with ultrasonographic changes in other populations, and the onset of sports-related enthesopathy appears to depend on muscle contraction rather than on the overall amount of exercise[29]. A study of rabbit tendons after tenotomy suggests that botulinum toxin A injection could replace cast immobilisation, with better recovery of biomechanical

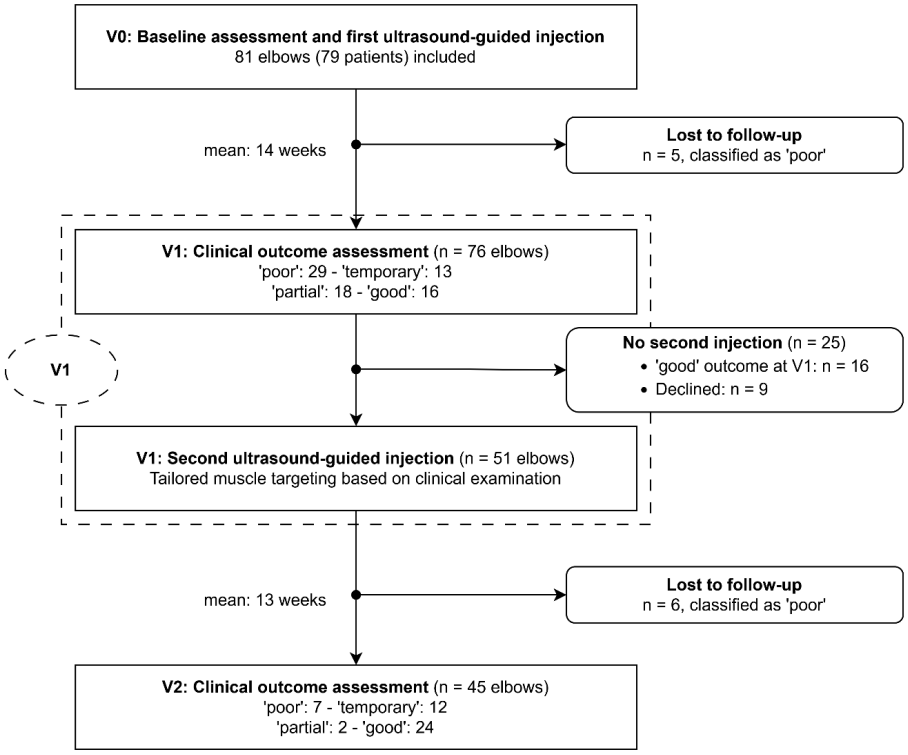


Figure 1. *Patient flow through the study and clinical outcome distribution at each follow-up visit.*

A) Distribution of clinical outcomes at each follow-up visit			
Clinical outcome	**V1 (After 1st injection)**	**V2 (After 2nd injection)**	
	n/81 (%)	n/51 (%)	
Poor	34 (42)	13 (25)	
Temporary	13 (16)	12 (24)	
Partial	18 (22)	2 (4)	
Good	16 (20)	24 (47)	
B) Factors associated with a 'good' outcome after the second injection.			
Factor	**'Good' outcome, %**	**Test statistic**	**p**
Age (years)	48.6 vs 49.7	t = 0.54	0.593
Sex (female vs male)	50.0 vs 42.1	$\chi^2 = 0.07$	0.798
Number of muscles injected (1–2 vs 3)	50.0 vs 45.2	$\chi^2 = 0.003$	0.960
Prior 'partial' vs 'poor/temporary' outcome	68.8 vs 37.1	$\chi^2 = 3.23$	0.072

Table 3. *Clinical outcomes and factors associated with a 'good' outcome.*

A) Patients lost to follow-up were classified as 'poor'. Nine patients declined a second injection.

B) Percentages compare the proportion reaching a 'good' outcome across subgroups. For age, values are mean age (years) in the 'good' versus the other categories combined. X^2 = chi-square test with Yates' continuity correction; t = Student's t-test.

properties such as maximal tensile strength[30]. This supports the idea that by inducing temporary paralysis, botulinum toxin A may reduce mechanical stress on the tendon insertion of the wrist extensors[31]. Song et al. observed in a systematic review that injection location is a source of heterogeneity in the current literature[32]. Injection location was often predetermined in the literature, using varying anatomical landmarks from one centimetre to one third of the length of the forearm from the tip of the lateral epicondyle[17,22,23]. This may be a limiting factor as several muscular structures have been shown to be involved in lateral epicondylalgia. The extensor carpi radialis brevis has been consistently identified as the main structure involved in lateral epicondylalgia, with biochemical evidence of glutamate accumulation in symptomatic tendons[33]. Anatomical studies have also emphasised the frequent involvement of the extensor digitorum communis[34,35]. In some cases, supinator or aponeurotic structures, particularly those related to radial nerve entrapment, may also contribute to symptoms[36]. This anatomical rationale may explain the clinical outcomes of the tailored injection strategy used in the present study.

To ensure correct localisation, injection was made under ultrasound guidance, which has rarely been done in randomised controlled trials, except by Lee et al.[22].

Beyond mechanical effects, experimental studies showed that botulinum toxin A inhibits the release of nociceptive neurotransmitters such as glutamate, substance P, and CGRP at peripheral nerve endings. More recently, it was shown that retrograde axonal transport may also contribute to central effects by modulating spinal sensitisation[37]. These mechanisms may partly explain why cumulative exposure after a second injection could have contributed to a higher rate of favourable outcome. The therapeutic value of repeated botulinum toxin injections remains underexplored in the literature. Creuzé et al.[38] found a short-term benefit of one low-dose botulinum toxin A injection in a randomised controlled trial. Building upon this work in a one-year follow-up study, Cogné et al.[26] found that multiple injections were frequently necessary before patients achieved sustained symptom relief and ceased requesting further treatment. These observations are consistent with our findings and suggest that several injections could be considered when the initial clinical outcome is insufficient or temporary.

Patient characteristics such as age and sex were not statistically associated with the primary outcome at V2. Patients experiencing partial but prolonged improvement after the first injection tended to have a better clinical outcome after a second one. This trend did not reach statistical significance, but it raises the hypothesis that prolonged partial response could be a predictor of favourable outcome after a second injection. The number of muscles treated was not significantly associated with the primary outcome at V2, although this result should be interpreted with caution given the limitations of subgroup analyses. These findings are hypothesis-generating and warrant prospective evaluation of tailored injection strategies in randomised controlled trials.

Transient weakness of finger and wrist extensors was the only adverse event. This effect, directly related to the pharmacological action of botulinum toxin A, was mostly mild and resolved spontaneously within weeks. Only one patient experienced prolonged weakness lasting up to six months, with a full recovery thereafter. The safety profile observed here was consistent with previous studies[39]. Thus, the risk-benefit ratio must be weighed by clinicians and patients must be informed of the risk of temporary weakness. Anticipating the temporary consequences of wrist and/or finger extensor weakness, with a wrist splint and sick leave if needed, could contribute to optimal treatment adherence.

Several limitations inherent to the retrospective, single-centre design must be acknowledged. The absence of a control group precludes any causal interpretation of the observed outcomes, which may reflect spontaneous resolution, regression to the mean, or placebo effects in addition to any pharmacological effect of botulinum toxin A. Retrospective data collection introduces possible reporting bias, and results obtained in a single tertiary referral centre with specific expertise in ultrasound-guided procedures and clinical examination may not be generalisable to other clinical settings. In addition, the decision to proceed with a second injection was not randomised but depended on persistent symptoms and patient willingness. Patients who declined were more often women, older, and more likely to have had a ‘poor’ rather than ‘partial’ initial response. This selective attrition may have favourably biased the observed success rate, since patients with a ‘partial’ initial response — who were more likely to benefit from a second injection — were over-represented in the second-injection group. The magnitude of this potential bias nevertheless appears limited, as retaining the nine patients who declined in the denominator still yields a favourable outcome in 40% (24/60) of cases after the second injection, approximately twice the rate observed after the first one. Regarding assessment, our primary outcome reflects a clinically meaningful patient-reported endpoint previously validated in a similar context[26]. To minimise bias, patients lost to follow-up (14%) were classified as having a ‘poor’ outcome. Nevertheless, this primary outcome remains a global self-reported impression. It could have been complemented by a standardised outcome measure such as the Patient-Rated Tennis Elbow Evaluation (PRTEE)[40], the absence of which may limit comparability with other studies. Although a favourable clinical outcome was found in 49% of patients overall at follow-up, it remains uncertain whether these benefits persist over the long term. Previous studies on corticosteroid injections for lateral epicondylalgia have shown that apparent short-term efficacy may be followed by poor outcomes at one year[5]. Longer follow-up studies are therefore needed to confirm whether the effects of botulinum toxin A are sustained over time.

In conclusion, a clinically meaningful improvement was observed in about half of the patients after one or two ultrasound-guided injections of botulinum toxin A. Future research should ideally take the form of a randomised controlled trial comparing a standardised single-target injection with an individually tailored, ultrasound-guided multi-target strategy, using validated multidimensional outcome measures such as the PRTEE, with at least one year of follow-up to account for the natural history of lateral epicondylalgia, and a prospective test of whether a partial response to a first injection predicts benefit from a second one. Botulinum toxin A may then offer a reasonable non-surgical option before resorting to surgery in refractory lateral epicondylalgia.

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