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Comparison of the effectiveness of botulinum toxin and saline solution on ankle function in patients with short gastrocnemius muscles: a controlled clinical trial

Comparación de la efectividad de la toxina botulínica y solución salina en la función del tobillo en pacientes con gastrocnemios cortos: ensayo clínico controlado

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Abstract

Introduction: the short gastrocnemius muscles are responsible for plantar pain and are a contributing factor in various pathologies, such as plantar fasciitis, hallux valgus, hallux limitus, metatarsalgia, and Achilles tendonitis. **Objective:** this study aims to compare ankle function changes following botulinum toxin versus saline solution injections in adults with non-spastic short gastrocnemius muscles. **Material and methods:** in this controlled clinical trial, adult participants diagnosed with short gastrocnemius muscles using the Silfverskiold test were randomized into two groups. The experimental group received intramuscular botulinum toxin injections, while the control group received saline solution injections. Demographics were recorded. Pre-intervention and 4-week post-intervention assessments included Maryland and American Orthopaedic Foot and Ankle Society (AOFAS) questionnaires. **Results:** the study included 18 patients, equally divided into two groups. Cavus feet were common. Baseline Maryland scores were 59.7 ± 4.4 in the experimental group and 58.8 ± 5.9 in the control group, increasing to 67.6 ± 4.3 and 60.5 ± 6.3 post-intervention, respectively (p = 0.01). AOFAS scores in the experimental group were 70.2 ± 9.6 at baseline and 81.5 ± 8.3 post-intervention, while the control group had scores of 73.0 ± 9.4 and 74.6 ± 9.0, with no statistically significant differences. **Conclusion:** botulinum toxin presents a viable treatment option for short gastrocnemius muscles, leading to improved functionality and symptom reduction in adults.

Keywords: gastrocnemius muscle, ankle joint, Maryland questionnaire, American Orthopaedic Foot and Ankle Society questionnaire, botulinum toxin, saline solution.

Level of evidence: II

Resumen

Introducción: *los gastrocnemios cortos son causantes de dolor plantar y es un factor contribuyente en diversas patologías, como la fascitis plantar, el Hallux valgus, el Hallux limitus, la metatarsalgia y la tendinitis de Aquiles.* ***Objetivo:*** *este estudio tiene como objetivo comparar los cambios en la función del tobillo tras las inyecciones de toxina botulínica frente a solución salina en adultos con músculos gastrocnemios cortos.* ***Material y métodos:*** *en este ensayo clínico controlado, se asignaron al azar adultos diagnosticados con músculos gastrocnemios cortos mediante la prueba de Silfverskiöld a dos grupos. El grupo experimental recibió inyecciones intramusculares de toxina botulínica, mientras que el grupo de control recibió inyecciones de solución salina. Se registraron datos demográficos y se aplicaron los cuestionarios Maryland y American Orthopaedic Foot and Ankle Society (AOFAS) previas a la intervención y cuatro semanas después.* ***Resultados:*** *el estudio incluyó a 18 pacientes, divididos equitativamente en dos grupos. Los pies cavos fueron comunes. Las puntuaciones basales en la escala Maryland fueron de 59.7 ± 4.4 en el grupo experimental y 58.8 ± 5.9 en el grupo de control, aumentando a 67.6 ± 4.3 y 60.5 ± 6.3 después de la intervención, respectivamente (p = 0.01). Las puntuaciones en la escala American Orthopaedic Foot and Ankle Society (AOFAS) en el grupo experimental fueron de 70.2 ± 9.6 al inicio y 81.5 ± 8.3 después de la intervención, mientras que*

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el grupo de control tuvo puntuaciones de 73.0 ± 9.4 y 74.6 ± 9.0, sin diferencias estadísticamente significativas. ***Conclusión:*** *la toxina botulínica se presenta como una opción de tratamiento viable para los músculos gastrocnemios cortos, lo que lleva a una mejora en la funcionalidad y la reducción de los síntomas en adultos.*

Palabras clave: *gastrocnemios, tobillo, escala Maryland, escala American Orthopaedic Foot and Ankle Society, toxina botulínica, solución salina.*

Nivel de evidencia: *II*

Introduction

The gastrocnemius muscle consists of two heads, one medial and one lateral, originating from the posterior portion of the medial and lateral femoral condyles respectively, before uniting into a single tendon with the soleus muscle tendon and inserting into the calcaneus, providing it with the property of being a biarticular muscle capable of pulley mechanisms.[1]

Short gastrocnemius muscles are present in one out of every five individuals.[2] The decreased length of the muscle bellies causes discomfort throughout the lower limb, from the lumbar spine to alterations in the foot. Increased tension occurs when both the knee and hip are in extension.[2] Diagnosis is purely clinical, using the Silfverskiöld test,[2,3] considered positive when the foot fails to achieve dorsiflexion greater than 10 degrees or presents a difference of more than 13 degrees with the knee extended and flexed, with the gastrocnemius muscles causing equinus contracture, which disappears upon relaxing the muscle bellies by flexing the knee.

Conservative treatment is based on stretching exercises to improve range of motion and reduce both pain and tension in knee and hip extension.[2,3] Surgical treatment aims to lengthen the muscle belly, with two approaches, proximal and distal. Proximal lengthening is usually preferred due to a lower risk of nerve injury and no immobilization requirement.[2] Currently, minimally invasive medial head release is proposed, showing good results with safety margins and no decrease in strength or complications, without requiring immobilization or post-procedure rest.[4] Botulinum toxin has been studied as a minimally invasive treatment for equinus contracture in both pediatric and adult populations.[5-7] Botulinum toxin application can lead to pain reduction three days post-injection and complete remission by twenty-one days, along with increased ankle dorsiflexion,[8] improving equinus contracture and reducing forefoot pressure, offering a cost-effective alternative to surgery with lower risks due to temporary flaccid paralysis. Combining it with surgical release of the medial head of the gastrocnemius has been observed not to alter gait or decrease strength.[9]

The objective of this study is to compare ankle functional changes following the application of botulinum toxin and saline solution in adult patients with short gastrocnemius muscles.

Material and methods

This study was approved by the local ethics committee under registration number 010917OT01. It is a prospective, longitudinal, comparative, randomized, and blinded study. Adult patients with gastrocnemius pathologies who attended the Traumatology and Orthopedics Department of the ISSSTE Regional Hospital «Dr. Manuel Cárdenas de la Vega» between May 1st and November 1st, 2017 were invited to participate. Adult patients of both genders, diagnosed with short gastrocnemius muscles using the Silfverskiold test, who were beneficiaries of the ISSSTE and agreed to participate by signing informed consent, were included. Patients with cutaneous lesions in botulinum toxin application or with atopy to it were excluded. Patients experiencing adverse effects to the administered medication or lost to follow-up during consultations were also eliminated. The study flowchart is shown in *Figure 1*.

Randomization

Patients who agreed to participate by signing informed consent and met inclusion criteria were enrolled. An Excel spreadsheet was created to maintain a list of these patients. Subsequently, a sequence of random numbers was generated in Excel to assign patients to either the intervention or control group. Patients assigned odd numbers were allocated to the control group, receiving 0.9% saline solution application along with gastrocnemius stretching exercises, while those assigned even numbers were placed in the experimental group, receiving

botulinum toxin injection alongside gastrocnemius stretching exercises.

Procedure

Demographic data and functional status were collected. To apply the intervention according to the group and maintain blinding of the patients, the solution for injection was prepared prior to the consultation, ensuring that patients had no knowledge of their group assignment. Treatment administration was exclusively performed by the authors. To do this, the belly of the medial gastrocnemius was located, and two injection points were selected, spaced between the popliteal fold and the Achilles tendon insertion directly into the muscle belly using insulin needles.[10] In the experimental group, 0.5 ml of botulinum toxin (Disport 500U) diluted in a 1:5 ratio with saline solution was injected at each point in both legs. In contrast, the control group received 0.5 ml of saline solution at each injection site. Additionally, isometric exercises for the gastrocnemius were prescribed.[11]

Outcome

The foot functionality was assessed twice by the same physician who administered the treatment using the *Maryland Foot Score* and the *American Orthopaedic Foot and Ankle Society* (AOFAS) scale score: pre-intervention and 4 weeks post-intervention.

The Maryland Foot Score,[12] ranges from 0 to a maximum of 100 points, with higher scores indicating greater patient satisfaction. Items on this scale assess pain, gait, functional activities, and cosmetic appearance.

The AOFAS scale,[13] comprises three subscales referencing pain, function, and alignment across nine items. A maximum score of 100 points on this scale indicates the absence of symptoms. For the pain subscale, the maximum score is 40 points, indicating no pain. Functionality has a maximum score of 50 points, representing complete function. Alignment offers a maximum score of 10 points, indicating good alignment.

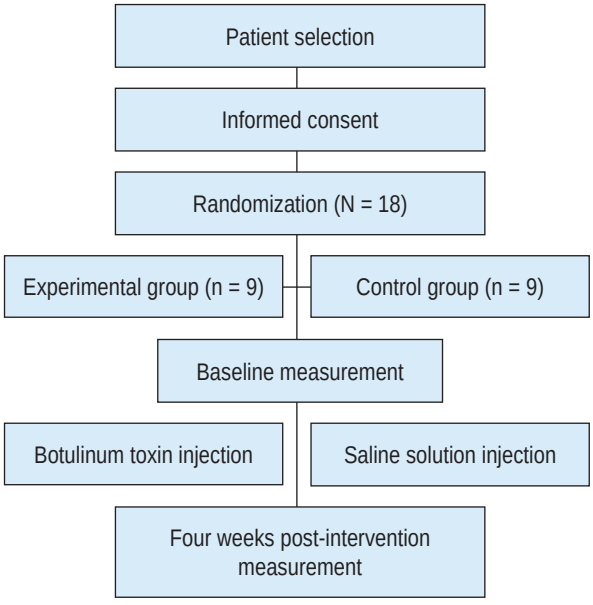

Figure 1: Study flowchart.

Sample calculation

A sample size calculation was conducted for the primary outcome of the study (Maryland scale) using the formula for estimating the mean in two populations, where the value of K was 7.9, $\alpha 1$ was 5, $\alpha 2$ was 5, $\mu 1$ was 60, and $\mu 2$ was 65. These numbers were based on means and standard deviations from a pilot study conducted at our health center (unpublished data). The result was 16 patients per group, with 80% power and 95% confidence in the primary outcome results.

Statistical analysis

A third-party, independent of the authors, was responsible for conducting the statistical analysis, without knowledge of the group allocation for each intervention. Categorical data were summarized using frequencies and percentages, while numerical data were presented as means and standard deviations. χ^2 tests were employed to compare groups concerning categorical variables. The independent samples t-test was utilized for analyzing numerical variables between two groups, and the paired samples t-test was used to compare pre- and post-intervention outcomes within the same group. Data were analyzed using SPSS v22, with a significance level set at $p < 0.05$.

Results

The consort flow diagram is shown in *Figure 2*. A total of 18 patients were included, evaluating a total of 36 feet, distributed into two groups with nine patients each. Demographic data are shown in *Table 1*.

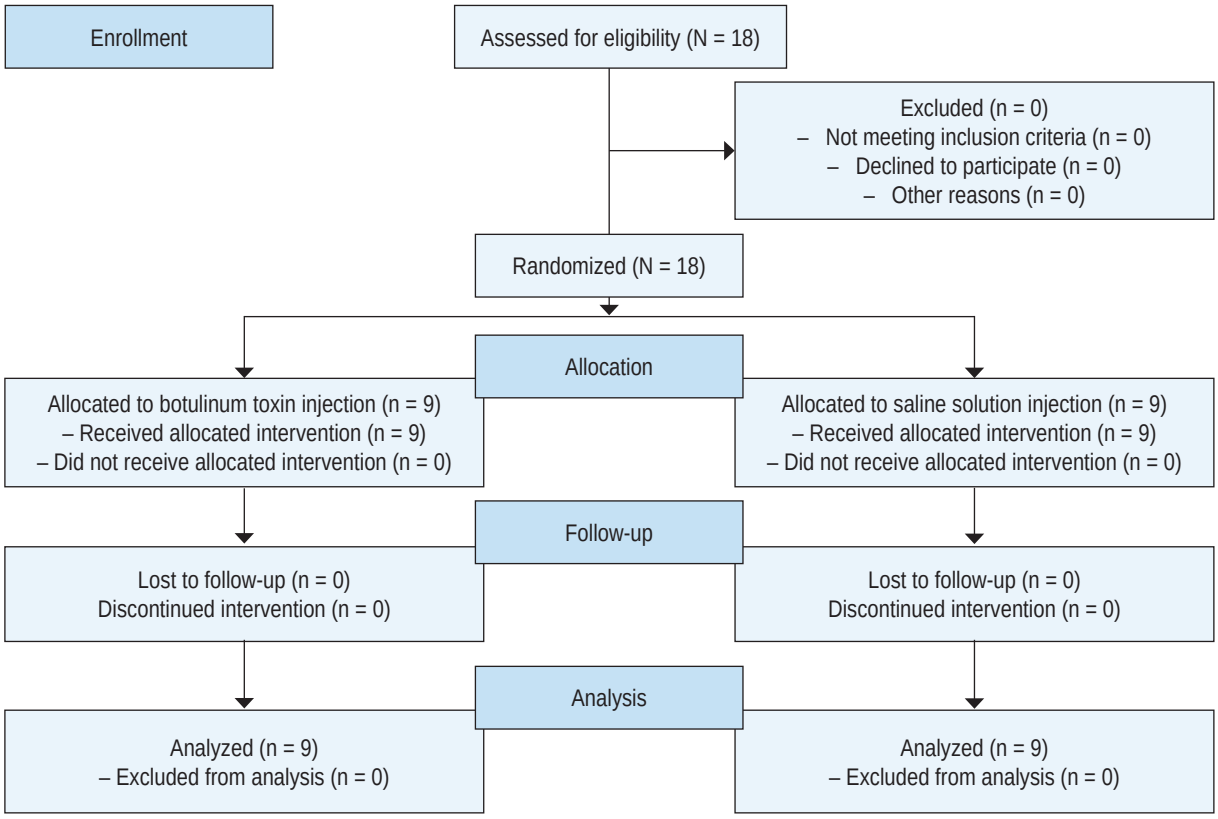

Figure 2: Adapted consort flow diagram.

At baseline, the experimental group scored 59.7 ± 4.4 on the Maryland scale, compared to 58.8 ± 5.9 in the control group, showing no statistically significant difference initially. However, post-intervention results were 67.6 ± 4.3 and 60.5 ± 6.3, respectively, indicating a statistically significant difference with p = 0.01 at this evaluation point. According to the AOFAS scale, baseline scores in the experimental group were 70.2 ± 9.6, increasing to 81.5 ± 8.3 post-intervention. In contrast, the control group presented scores of 73.0 ± 9.4 and 74.6 ± 9.0, respectively, with no statistically significant differences *(Table 2)*. No adverse effects were reported in either group.

Table 1: Demographic data by group. N = 18.

	Experimental	Control	p
Gender			1
Male	1	1	
Female	8	8	
Age, (SD)*	50 ± 8.4	54 ± 12.0	0.426
Cavus foot, n (%)	9 (100)	8 (88.9)	
Flat foot, n (%)	0	1 (11.1)	1

* Continuous variables are presented as mean and standard deviation, while categorical variables are presented as proportions.

Discussion

Short gastrocnemius can lead to reduced dorsiflexion, with subsequent tension and plantar pain,[14,15] being among the common reasons for seeking medical consultation. It has been demonstrated that botulinum toxin injections improve range of motion and decrease plantar pain. Moreover, it is a safe treatment for use in various musculoskeletal pathologies, as no adverse effects have been reported with botulinum toxin treatment.[5,6,16] In our intervention, no adverse events associated with botulinum toxin application were observed, confirming its safety as a treatment option. This study highlights that the use of botulinum toxin combined with stretching as an initial minimally invasive treatment yields positive results,

showing increased dorsiflexion and decreased pain and tension in the Achilles tendon.

The initial treatment for short gastrocnemius is conservative and ranges from oral NSAIDs administration, stretching, injections, and even suggests the use of a splint for 12 to 24 weeks.[17] The use of corticosteroids as a treatment for symptoms caused by short gastrocnemius has been controversial, as it presents advantages and disadvantages when compared with different minimally invasive treatments.[18] It has been shown that the combination of botulinum toxin injection in gastrocnemius and stretching produces a greater reduction in pain and an increase in function compared to corticosteroid injection.[3,19]

If conservative treatment fails to alleviate tension in the Achilles tendon, the next step is proximal release of the medial gastrocnemius. It is a surgical treatment with a satisfaction rate exceeding 80%, with very few reported post-surgical complications and usually relieving pain within the first 2 to 3 months.[17] For future research, the efficacy of proximal release of the medial gastrocnemius and stretching should be evaluated against the use of botulinum toxin injections and stretching. This would ascertain whether botulinum toxin as a minimally invasive treatment yields better results than proximal release of the medial gastrocnemius as a surgical treatment, as well as determine the degree of advantage over the surgical procedure and its safety.

Limitations of this study include the follow-up time, sample size, and adherence to treatment (stretching). Future research should seek strategies for good adherence to stretching exercises.

Conclusions

Botulinum toxin is a viable option for the pathology of short gastrocnemius, showing improvement in functionality and symptom reduction compared to saline solution in this study. Additionally, it presents few adverse effects when applied to patients with short gastrocnemius, making it a cost-effective and beneficial option.

Table 2: Intervention results. N = 18.

Outcome	Experimental*	Control*	p
Maryland basal scale	59.7 ± 4.4	58.8 ± 5.9	0.723
Maryland scale post-intervention	67.6 ± 4.3	60.5 ± 6.3	**0.013**
AOFAS basal scale	70.2 ± 9.6	73.0 ± 9.4	0.544
AOFAS scale post-intervention	81.5 ± 8.3	74.6 ± 9.0	0.115

* Continuous variables are presented as mean and standard deviation.

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Conflict of interests

None of the authors have a conflict of interest to disclose.