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Original Research

The Effects of Botulinum Toxin Injections on Plantar Flexor Spasticity in Different Phases After Stroke: A Secondary Analysis From a Double-Blind, Randomized Trial

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Abstract

Background: There are no guidelines on the ideal time to inject botulinum toxin type A (BT-A) for lower leg spasticity in stroke patients. An early injection may produce unwanted weakness, interfering with gait recovery.
Objective: To evaluate whether the outcomes after BT-A injection for plantarflexion spasticity can be different according to stroke chronicity.
Design: A secondary analysis study from a double-blinded, randomized trial with group reclassification according to stroke chronicity.
Setting: Two rehabilitation centers.
Participants: Stroke participants (n = 40) with plantar flexor spasticity, treated with BT-A (200 units) into the gastrocnemius muscle.
Methods: Outcome parameters were reanalyzed serially using 2-way repeated measures of analysis of variance (ANOVA), at baseline and 2, 4, and 8 weeks postinjection. Subjects were reclassified into 3 groups: early, within 6 months (n = 12); middle, between 6 months and 1 year (n = 14); and late, between 1 and 2 years from stroke onset (n = 12).
Main Outcome Measures: The Modified Ashworth Scale, clonus scale, 10-m walking test, ABILOCO, and the Functional Ambulation Category.
Results: The 2-way repeated measures of ANOVA showed improvement in gait and spasticity after injection in the 3 groups. Significant improvement in the Modified Ashworth Scale ($P < .001$) was observed, starting from the post−2 week injection period. Improvement of gait as assessed by the functional measurement ABILOCO and the Functional Ambulation Category ($P < .001$) were observed in all 3 groups, mostly at the post−8 week injection period.
Conclusions: Our serial measurements of the outcome parameters indicated that BT-A could be expected to lead to consistent improvement in both the muscle tone and gait quality in those with plantar flexor spasticity regardless of stroke chronicity, including those injected as early within the first 6 months.
Level of Evidence: IV

Introduction

Lower limb spasticity, especially chronic ankle plantar flexor spasticity, is associated with equinovarus deformity, causing reduced foot clearance and circumduction of the affected leg during gait [1,2]. It can also cause asymmetric weight bearing and inefficient gait patterns. These factors have contributed to the justification of focal treatments with botulinum toxin type A (BT-A) aiming to reduce spasticity of the plantar flexor muscles, namely, the gastrocnemius, soleus, and tibialis posterior muscles. The BT- A−injected gastrocnemius muscle, in particular, has been shown to increase the range of motion in the ankle, and prevent equinovarus deformity with plantar flexor spasticity, in previous randomized controlled trials [1-6].

Latest evidence now advocates early active management with BT-A as an appropriate component of subacute rehabilitation post-stroke [7,8]. Recent studies have shown injection within the initial stages of post-stroke

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recovery to be safe and beneficial to prevent the development of disabling contracture in the upper extremity [9-11]. Stroke recovery is most robust within the first 6 months, and one may postulate that early BT-A may help prevent the formation of abnormal muscle activity and the acquisition of spastic motor patterns. However, unintended weakness after injection may occur when motor recovery is still incomplete, and this could be detrimental when subjects are at their peak of motor training. To perform BT-A injection safely during these early stages in those with emerging patterns of spasticity without deterring gait recovery is clinically challenging.

On the contrary, BT-A treatment at late stages of recovery can also be problematic. As spasticity becomes chronic, secondary changes that include stiffness, contracture, and fibrosis of surrounding muscles or soft tissues may ensue [12]. Also, as adults with stroke enter their chronic stage, they may exhibit fixed patterns of spastic gait, using the increased extensor tone with compensatory adaptive patterns. These changes associated with chronic stroke may make spasticity unresponsive to treatment.

It is not known whether the outcome after BT-A injection may vary according to when these injections are performed after stroke; thus, there is still a lack of consensus on the appropriate time window for BT-A injection to the lower extremities. In fact, despite many studies on the efficacy of BT-A to treat plantarflexion spasticity, most studies have been focused on chronic patients [13-16]. In contrast, evidence that supports early use is still limited in number [17].

Past trials of BT-A injection to treat lower extremity spasticity had included many subjects with various onset duration; therefore, were unable to provide consensus on the optimal time of treatment. Some recent studies [18-20] were successful in showing positive outcomes after early BT-A injection to treat lower extremity spasticity. For example, a study by Fock et al. [19] made a direct comparison between early and late injections in traumatic brain injury patients, and recent studies [18,20] showed that BT-A as early as within 3 months of stroke was useful. Though comparisons had been made to a placebo control group, direct comparisons of BT-A injection to those at their later stages of recovery have not been available in these previous trials [18,20]. In fact, a direct comparison between those with early versus late intervention and whether they show disparate effects after injection are yet to be made.

The authors had previously undertaken a dual-center, double-blinded, randomized, prospective clinical trial of BT-A with the intent to compare the efficacy of different injection sites to the gastrocnemius muscle to treat plantarflexion spasticity [4]. The results of the original study were negative, with both groups showing improvement with no differences according to injection site. This secondary analysis from the original clinical trial was undertaken to investigate whether the response of BT-A in reducing plantar flexor spasticity and improving gait can be different according to stroke chronicity, focusing on time of injection since stroke onset.

We thus aimed to determine if those who had received early injection within the first 6 months since stroke onset showed disparate results from those who received later treatment. We also aimed to determine whether the effects of BT-A in reducing plantar flexor spasticity and improving gait were similar across subjects with different stroke chronicity, without gait deterioration; even in those injected early within the first 6 months after stroke onset.

Methods

Participants

The authors had previously performed a dual-center double-blinded, randomized clinical trial using BT-A for lower limb spasticity following stroke to investigate the effect of different injection sites to the gastrocnemius muscle [4]. Briefly, a total of 40 persons with hemiparetic stroke with ankle plantar flexor spasticity and post-stroke duration within 2 years had been recruited in the previous trial. All subjects were required to complete the 10-meter walk test (10-MWT) with or without assistance or assistive tools. Participants with previous chemodenervation including BT-A treatment or cognitive dysfunction, who could not give informed consent before the procedure, had been excluded. Stratified block randomization was used, and recruited eligible subjects had been allocated into 2 groups. One group had received the injection at 2/10th and 3/10th of calf length, which was the zone with the greatest density of intramuscular endings, hence the location where the effects of BT-A would be most potent. This was compared to a group that received injection at conventional sites at and below the midbelly of the gastrocnemius. BT-A injections were done by physiatrists; with more than 5 years of experience in spasticity management, who were also blinded to the participants' allocation. Outcome measurements had been carried out by 2 other blinded physiatrists. The results from the original clinical trial had shown that both groups showed improvement of spasticity and ambulatory gains, with no intergroup differences.

Time since stroke onset was selected as a factor that may affect the outcome, and for this secondary analysis, the participants were regrouped according to stroke chronicity depending on time since stroke onset: those within 6 months (early group), between 6 and 12 months (middle group), and between 1 and 2 years (late group). Serial outcome measures were reanalyzed across the second-, fourth-, and eighth-week follow-up. The ethical boards of our institution approved the design and objectives for the secondary analysis of this study. All subjects

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