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Research Article

A Pilot Study of the Botulinum Toxin Injection in the Psoas Major Muscles for Freezing of Gait in Parkinson's Disease Patients

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Abstract

Free Zing of Gait (FOG) is a common and very disabling parkinsonian symptom, which responds unsatisfactorily to medical treatment. 100 mg of Botulinum Toxin (BTX-A) was injected in an open-label fashion into the bilateral psoas major muscles of patients with Parkinson's disease (PD). The psoas major muscles are activated at the initiation of walking. Patient response was assessed subjectively using the FOG-Q scores and patients' self-reported satisfaction (worse, no change, or better [mild, moderate, remarkable]), one week after the injection and one month later.

Three of the five patients showed moderate satisfaction one week after the injection. It lasted more than one month and disappeared gradually. These findings indicate that BTX-A injection into the psoas major muscles can be useful for alleviating the symptoms of FOG in some PD patients. However, a double-blind placebo-controlled detailed study with larger sample size is needed to establish the efficacy of BTX-A injection in the psoas major muscles in the treatment of FOG.

Keywords: Parkinsonism; Hesitation; Botulinum toxin

Introduction

Freezing of Gait (FOG) is a common disabling form of gait difficulty in patients with Parkinson's disease (PD), often unresponsive to dopaminergic treatment. Botulinum Toxin Type A (BTX-A) has been attracting attention in ameliorating FOG [1]; however, the double-blinded randomized control studies have failed to prove a significant effect [2,3]. In these studies, BTX-A was injected into the lower extremity muscles. However, gait locomotion is initiated in the proximal rather than distal muscles [4]. FOG manifests as "hesitation" at the initiation of gait. Thus, BTX-A should be administered in the muscles that initiate gait, i.e., the psoas major muscles. The present study investigated the efficacy of BTX-A injections in the psoas major muscles in PD patients with medically refractory FOG as a pilot study.

Methods

The present study evaluated five patients with a clinical diagnosis of sporadic PD (Mean ± SD, Age: 74.4 ± 7.4 years, UPDRS part III 26.4 ± 3.2, Range of Hoehn-Yahr stage 3 to 4) based on the International Parkinson and Movement Disorder Society diagnostic criteria [5]. All patients suffered from severe FOG. BTX-A was injected at six points in the bilateral psoas major muscles (50 mg at each site): dorsally, 4 cm to 5 cm lateral to the midline between L2 and L3 and between L4 and L5; ventrally, in the distal portions beneath the inguinal ligament.

Patients' gait was video recorded before and after the injection. The degree of FOG was also assessed based on a questionnaire (FOG-Q) [6] before the injection and at one-week and one-month follow-ups. The present study was approved by the Ethics Committee at Neshige Neurology Clinic, with written consent from participants.

Results

After one week of the injection, four patients showed amelioration in hesitation severity and duration. Their short stepping, turning, and total gait time also improved (Video). In three patients, this improvement lasted more than a month. The FOG-Q score decreased over time in Pts. 1, 2, and 3, while it returned to baseline at one month in Pt. 4. Pt. 5 did not achieve a satisfactory outcome, and his FOG-Q did not improve at either one week or one month after the injection. In Pt. 1, the effectiveness lasted more than a month, followed by a gradual decline. In Pt. 2 and Pt. 3, the effectiveness lasted six months after the injection and diminished gradually.

Video: https://www.youtube.com/watch?v=hwRQsn9tg8s

Video: Time up & Go trial before and after the Botulinum Toxin Type A (BTX-A) injection into the psoas majors in Pt. 1.

Pt. 1 showed hesitation at gait initiation and turning before the injection. Three days after injection, the hesitation was improved.

Only one out of five cases showed EEG discharges consistent with the elevation of the lower limbs. The remaining four patients were not clear, mainly due to movement artifact (Table 1).

Discussion

The present study demonstrated an effect of BTX-A injections into psoas major muscle in some PD patients with FOG. As this was an open-label study, the improvement seen in some patients to the response to BTX-A treatment might be attributed to a placebo effect. This is because the symptoms of PD are easily influenced by mood and attention [7]. Their symptomatic improvement was high for

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Table 1: Patients' subjective assessment of BTX-A injection to the psoas major muscle.

	FOG-Q			Satisfaction	
	Before	1 week	1 month	1 week	1 month
Patient 1	21	20	18	Moderate	Moderate
Patient 2	17	13	12	Moderate	Moderate
Patient 3	19	11	11	Moderate	Moderate
Patient 4	18	15	18	Moderate	No
Patient 5	19	19	18	No	No

FOG-Q: Freezing of Gait Questionnaire
Lower numbers in FOG-Q indicates to be better.

more than one month after the injection and diminished gradually after that. This persistent nature of improvement of FOG symptoms and then gradual decline cannot be explained by the placebo effect. These observations suggest that the temporal association between the injection and the symptomatic course is likely an actual effect of BTX-A and not just a placebo response.

Although FOG mechanisms at the neuro-anatomical level remain unclear, the present results suggest that abnormal contractions in the psoas major muscles at gait initiation are likely causal at least in some PD patients. FOG likely shares a similar underlying mechanism as eyelid opening apraxia, which is responsive to BTX-A. This observation provided the rationale for the investigation of BTX-A in FOG which may be a spastic muscle dysfunction affecting the initiation of walking.

A recent open-label study of BTX efficacy in the proximal muscles also showed positive outcomes [9]. Walking starts with a movement of the center of gravity and raising of a knee, which activates the psoas major muscle [8]. Therefore, I injected the BTX-A into the psoas major muscle which may be a promising target for enhancing the effectiveness of BTX-A injections for FOG.

The reasons for inter-patient variability in response to BTX-A in the present study are unclear. From my knowledge, this has been a first study. There are many limitations. The psoas muscle is a deep-seated muscle, making precise injection technically challenging. Furthermore, no one knows where or how much BTX-A should be injected into the psoas major muscles to improve FOG.

Although this preliminary study has identified a potential application of BTX-A in some PD with FOG, the role of BTX-A in the treatment of FOG should be assessed in a double-blind cross-over precise study with a larger sample size. Until then, these preliminary findings should be interpreted with caution, which is of special importance in the highly subjective and variable symptom of FOG.

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