Oral Communication

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Efficacy and Safety of Botulinum Toxin Treatment in the Early Management of Spasticity in Patients with Spinal Cord Injury (SCI)

Topic: Complications/Sequelae (ie Spasticity, Immobilization and Frailty)

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BACKGROUND

Spinal cord injury (SCI) is a relatively rare clinical condition, with an estimated global incidence ranging between 250,000 and 500,000 new cases per year. Nevertheless, the majority of affected individuals will develop spasticity at some point during the course of their lives, with prevalence estimates ranging from 65% to 78%, which is higher than in any other neurological condition. Spasticity following SCI is often highly disabling and represents a significant burden not only from an economic standpoint but, more importantly, in terms of care needs and functional limitations.

Currently available therapeutic options for spasticity are diverse and are selected based on the clinical, rehabilitative, and functional characteristics of each patient. These include systemic and local pharmacological treatments, interventional procedures, and surgical interventions. Among focal treatments, botulinum toxin has emerged as a valuable and well-established option for the management of spasticity, either as a standalone therapy or in combination with other rehabilitative strategies.

Despite this, the scientific literature specifically dedicated to the treatment of spasticity in SCI remains limited, and to date, no international guidelines tailored to this population have been published. As a result, the management of spasticity in SCI patients must often be inferred from recommendations developed for other central nervous system disorders. This applies not only to injection techniques and dosing regimens but also to patient selection and treatment timing. Furthermore, the technical documentation of currently available botulinum toxin formulations does not include spinal cord injury among the indicated conditions.

Based on these considerations, we hypothesize that early treatment—defined as within 12 months of the injury—of focal spasticity in patients with SCI may lead to better outcomes compared to delayed interventions. The objective of our study is therefore to evaluate the efficacy and safety of botulinum toxin treatment in a population of SCI patients treated in the acute phase, within one year of injury, compared to those treated after one year.

METHODS

A retrospective observational study was conducted on SCI patients followed at the Spasticity Unit of the Spinal Unit at the CTO Andrea Alesini Hospital in Rome. Patients were included if they were over 18 years of age, had a spinal cord injury of any etiology, and presented with focal spasticity suitable for treatment with botulinum toxin. Exclusion criteria included clinical instability, the presence of acute infections, and patient refusal to undergo treatment.

Ultrasound-guided injections were performed using onabotulinumtoxinA, abobotulinumtoxinA, or incobotulinumtoxinA, with dilution protocols in accordance with each manufacturer's technical guidelines and following the acquisition of informed consent.

The primary outcomes were the percentage change in the Modified Ashworth Scale (MAS) at the peak effect of the toxin after the first injection, which typically occurs around 30 days post-treatment, and the percentage change from baseline to the final injection peak. Adverse events were also monitored, including botulism, dysphagia, diplopia, infections at the injection site, and hematomas.

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Secondary outcomes included changes in the Spinal Cord Independence Measure (SCIM III) at the end of the observation period and the subjective perception of pain improvement reported at the final follow-up. Patients were consecutively enrolled between January 2022 and January 2024. Data collected included demographic information and clinical severity, including age, sex, time since injury at the time of first injection, etiology, neurological level of injury, ASIA Impairment Scale classification, and use of concomitant medications for spasticity. MAS was calculated as the sum of scores across the following muscle groups: pectorals, elbow flexors, triceps, wrist flexors, knee extensors and flexors, hip adductors, and ankle plantar flexors. Pain was evaluated using a binary questionnaire ("yes" or "no"), routinely administered during clinical assessments. Adverse events were recorded based on patient reports.

Statistical analysis was performed using IBM SPSS version 28. Group comparisons were conducted using Fisher's exact test for categorical variables and the Wilcoxon-Mann-Whitney test for continuous variables, with statistical significance set at a p-value of less than 0.05.

■ RESULTS

A total of 38 patients were enrolled in the study, with 14 assigned to the acute group and 24 to the chronic group. Among the acute patients, there were 12 males and 2 females, with a median age of 54 years (range 22 to 72; IQR 47.25-65). Ten patients presented with tetraplegia and four with paraplegia. One patient had a complete lesion classified as ASIA A, while the remaining 13 had incomplete injuries (3 ASIA B, 6 ASIA C, and 4 ASIA D). The median dose of botulinum toxin administered at the first treatment was 400 units (IQR 325-400), and 400 units (IQR 300-500) at the final injection. The median time from injury to first treatment was five months (range 3 to 12; IQR 3.25-8.75). MAS scores at baseline had a median of 17 (IQR 9-20.5), which decreased to 11.5 (IQR 11-17.75) at the first peak and to 7.5 (IQR 4-19) at the final assessment. SCIM III scores increased from a median of 42 (IQR 20.5-63.75) at baseline to 67.5 (IQR 25-86) at follow-up. Seven acute patients reported pain in the treated muscle groups, all of whom experienced improvement at the first evaluation and maintained this benefit at the final follow-up.

In the chronic group, there were 16 males and 8 females, with a median age also of 54 years (range 22 to 83; IQR 43-60.5). Fourteen patients had tetraplegia and ten paraplegia. Seven patients were classified as ASIA A, while 17 had incomplete injuries (4 ASIA B, 4 ASIA C, and 8 ASIA D). The median time from injury was 48 months. The median dose of botulinum toxin was 400 units at both the first and final treatments. Baseline MAS scores had a median of 18 (IQR 12.5-20.5), decreasing to 13 (IQR 11-17.5) at the first peak and remaining at 13 (IQR 11-16) at the final follow-up. SCIM III scores remained unchanged, with a median of 60 (IQR 26.5-70) at both assessments. Nine patients in this group reported neuropathic pain at baseline, seven of whom experienced improvement following the first treatment and maintained this benefit throughout the study period.

No statistically significant differences were observed between the two groups with respect to age, sex, level of lesion (tetraplegia versus paraplegia), etiology, drop-out rate, comorbidities, total toxin dose administered, or baseline MAS scores. However, a significantly greater reduction in MAS scores was observed in the acute group, with a median improvement of 32.5% after the first injection and 45.8% after the final treatment, compared to 14.3% and 18.9%, respectively, in the chronic group. The difference in MAS improvement between groups was statistically significant both after the first treatment ($p < 0.0001$) and at the final follow-up ($p = 0.014$). No statistically significant differences were observed in SCIM III outcomes between groups. All patients who reported baseline pain experienced subjective improvement at the first evaluation and maintained this improvement at the final follow-up, with no significant differences between acute and chronic groups.

In terms of safety, one patient in the acute group reported transient weakness and diplopia. Two patients in the chronic group developed injection-site hematomas, which resolved spontaneously within two to three days without further complications.

■ CONCLUSION

The findings of this study suggest that the use of botulinum toxin for the treatment of focal spasticity in the acute phase of SCI is both effective and safe, even when initiated as early as the third month following injury and with relatively high dosages. Early treatment appears to facilitate the rehabilitative process by eliminating spasticity-related barriers to motor learning, thereby allowing for more effective acquisition of new motor patterns. The more substantial reduction in MAS scores observed in the acute group may be attributed to the greater plasticity of spinal reflex circuits in the early post-injury phase, which can be favorably modulated through rehabilitative interventions.

Although improvements in spasticity did not translate into significant changes in SCIM III scores, this may reflect the fact that SCIM III assesses broader aspects of independence and daily functioning, which are more heavily influenced by lesion level and severity rather than focal spasticity alone.

This study has some limitations, including a relatively small sample size due to the low incidence of SCI, its monocentric design, and the absence of specific treatment guidelines for this population. Future multicenter studies are needed to increase statistical power and to enable subgroup analyses based on variables such as sex, specific motor outcomes, and treatment protocols. We hope that this study may serve as a starting point for the development of a dedicated multicenter research group focused on early spasticity management in SCI patients, analogous to those already established for other neurological conditions.

Statement of Disclosures

None