

# Antispastic therapy with botulinum toxin type A in patients with traumatic spinal cord lesion

## Botulinumtoxininjektion als antispastische Therapieoption bei Patienten mit traumatischer Rückenmarksläsion

### Abstract

**Objectives:** The purpose of this study was to determine the effect of botulinum toxin injections for the treatment of spasticity after traumatic spinal cord injury.

**Methods:** 9 patients were included in this prospective designed study, with a follow-up of at least 2 years. All patients suffered from a massive spasticity after traumatic spinal cord lesion. Conservative treatment options did not show satisfying results. All patients were injected a maximal dose of 2,000 units of botulinum toxin A in no more than 6 skeletal muscle groups. Clinical control examinations were performed after 2 weeks and after at least 2 years.

**Results:** 6 patients reported a good or very good result. One patient offered increasing difficulty in walking for a short time after injection. 2 patients showed no beneficial effects. One patient experienced a modest temporary general weakness for 3 days. After 2 years, 3 patients showed improved function with persistent reduction of spasticity. In the other cases, the beneficial effect lasted for an average of 9 months.

**Conclusion:** Botulinum toxin A injection seems to be an effective complementary therapy option in the treatment of spasticity of paraplegic patients with complete deficit of their motor function (ASIA A and B) and a spastic distribution pattern, effecting only a limited number of muscle groups. Caution has to be recommended for incomplete paretic patients, who are able to walk.

**Keywords:** botulinum toxin, spasticity, traumatic spinal cord lesion

### Zusammenfassung

**Fragestellung:** Ziel dieser Arbeit war es, den Effekt von Botulinumtoxininjektionen bei der Behandlung therapieresistenter Spastiken nach traumatischen Rückenmarksläsionen zu evaluieren.

**Methode:** Es handelt sich um eine prospektive klinische Studie, die insgesamt 9 Patienten mit spastischer Paraplegie/Paraparese nach traumatischer Rückenmarksläsion erfasst. Alle 9 Patienten wiesen ausgeprägte therapieresistente Muskelspastiken auf. Allen Patienten wurden bis zu 2.000 Einheiten von Botulinumtoxin A in nicht mehr als 6 Muskelgruppen injiziert. Eine klinische Nachuntersuchung erfolgte nach 2 Wochen und nach mindestens 2 Jahren.

**Ergebnisse:** Sechs Patienten berichteten über ein gutes oder sehr gutes Ergebnis und zeigten sich zufrieden. Bei einem Patienten fiel eine Schwäche der angrenzenden Muskulatur auf, wodurch seine Mobilisation im Alltag negativ beeinflusst wurde. Bei 2 Patienten ließ sich keine wesentliche Spastikreduktion nachweisen. Ein Patient entwickelte eine generalisierte Schwäche, die sich spontan nach 3 Tagen zurückbildete. Von den übrigen 6 Patienten wiesen 3 Patienten nach 2 Jahren eine unveränderte zufriedenstellende Spastikreduktion auf, ohne dass eine erneute Therapie erforderlich war. Die übrigen 3 Patienten gaben an, dass der Effekt ca. 9 Monate angehalten hatte. Bei der 2-Jahreskontrolle

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wiesen diese eine Spastiksymptomatik entsprechend der vor der Behandlung auf.

**Fazit:** Die Studie zeigt, dass die Injektion von Botulinumtoxin A eine wirkungsvolle Therapie therapieresistenter Spastiken mit Beteiligung selektiver Muskelgruppen nach traumatischer Rückenmarksläsion (ASIA A und B) darstellen kann. Mit Vorsicht sollten die Injektionen bei denjenigen Patienten angewendet werden, die eine inkomplette Lähmung aufweisen und Fußgänger sind.

**Schlüsselwörter:** Botulinumtoxin, Spastik, traumatische Rückenmarksläsion

## Introduction

Different therapy strategies are used to reduce spasticity in patients with traumatic spinal cord lesions. These options consist of conservative management, including physiotherapeutic and pharmacological approaches, as well as surgical techniques. Botulinum toxin plays an important role in the treatment of spasticity of different causes [1]. By locally injecting botulinum toxin, an isolated skeletal muscle inhibition and improved muscle kinematics can be achieved. Thus, botulinum toxin injection is a treatment option of particular interest in cases of localized spasticity [1], [2], [3].

The purpose of this study is to evaluate the effect of botulinum toxin injections in patients with spasticity caused by traumatic spinal cord injuries and to determine favourable patients' characteristic.

## Materials and methods

The study included 9 male patients (mean age 40 y  $\pm$  16 y), suffering from a none-acute traumatic lesion of the spinal cord and chronic spastic paraplegia (Table 1). Eight patients had a complete spinal cord lesion, defined as American Spinal Injury Association (ASIA) impairment scale type A [4]. One patient showed an incomplete neurologic deficit, defined as ASIA type C. All of them offered an increased spasticity state of 3 to 4 on the Ashworth scale modified by Bohannon and Smith [5], [6]. All patients underwent a combination of physiotherapeutic and oral antispastic therapy for at least three months without satisfying success. Major spasticity affected not more than six general muscle groups of the lower limbs. All patients underwent botulinum toxin A injections in the affected muscle groups with a dilution of 100 U/ml under ultrasonographic control. The maximum general injection dose was limited to 2,000 U. After the injection, all patients underwent intensive physiotherapy of the affected muscles for three days to improve the Botox distribution. All patients underwent clinical control examinations after 3  $\pm$  2 weeks and 34  $\pm$  3 months after botulinum toxin injections.

## Statistics

A descriptive analysis was performed.

## Results

Six of the nine patients were satisfied or very satisfied after botulinum toxin injection and offered a clear reduction of spasticity in the treated muscle groups to a state of two or less on the Ashworth scale modified by Bohannon and Smith, with an average reduction of 1.9 states after two weeks (Figure 1). Five of them reported reduced difficulties during mobilisation including transfers to the wheel chair as well as getting dressed or undressed. The patient with incomplete motor function deficit showed a relevant reduction of the adductor spasticity. However, he had increasing problems in walking due to additional muscle weakness for three months and regaining muscle strength over a period of another three months afterwards. Another patient reported a temporary general weakness after injection, which fully recovered after three days. Two patients experienced no benefit regarding their spasticity level.

The effect of the botulinum toxin injections started after two to five days and reached a peak after an average of two weeks. No signs of infection or allergic reaction were recordable, particularly at the side of injection. At the final evaluation, three patients had persistent low spasticity at the affected muscle groups of state two or less of the Ashworth scale modified by Bohannon and Smith. Three patients regained spasticity to a slightly lower level ( $\leq 3$ ) compared to the initial level of spasticity (Figure 1). The beneficial effect lasted for at least seven months and decreased subsequently in all of them.

## Discussion

Several studies showed the beneficial effect of botulinum toxin to adults and children in cases of spasticity and demonstrated it to be safe even after repeated injections [7], [8]. However, Bakheit et al. described dose-dependent side-effects in 7% of the patients [9]. The side-effects consisted of focal or generalized muscle weakness and urinary incontinence in about 1% of patients. All other reported adverse events were less common and included pain at the site of the injection, fatigue, somnolence, influenza-like symptoms, fever, and purpuric skin rash. Similarly, one of our patients (11%) complained of mild

Table 1: Patient population

Pat	Age	Level of neur def	ASIA	Spastic: initial	Muscle groups involved (side)	Inj units	Spastic: 2 weeks	Effect duration	Adverse effect
1	45	L1	A	4	Hip flex+add (bil)	2,000	1	9 months	None
2	31	L2	A	4	Knee flex; Ankle sup+plant fl (bil)	1,500	1+	7 months	None
3	32	L1	A	4-	Hip flex; Knee flex; Ankle plant flex (l)	800	1	≥35 months	None
4	20	L1	A	4	Hip flex+add; Knee flex; Ankle sup+plant fl (bil)	2,000	4	None	None
5	77	L1	C	3	Hip add; Knee flex (bil)	1,200	2-	8 months	Mobility ↓
6	39	C7	B	3	Hip add; Knee fl; Ankle plant fl (bil)	2,000	3-	6 months	Initial gen weakness
7	28	Th 12	A	3	Hip add (bil)	1,000	1+	≥26 months	None
8	47	L1	A	4	Hip flex+add; Knee flex (bil)	2,000	4	None	None
9	41	L2	A	3	Anke sup+plant fl (bil)	2,000	1	≥25 months	None

Pat: patient; neur def: neurologic deficit; Inj units: units of botulinum toxin injected; C: cervical spine; Th: thoracic spine; L: lumbar spine; Flex: flexion; Add: adduction; Sup: supination; Plant fl: plantar flexion; gen: general

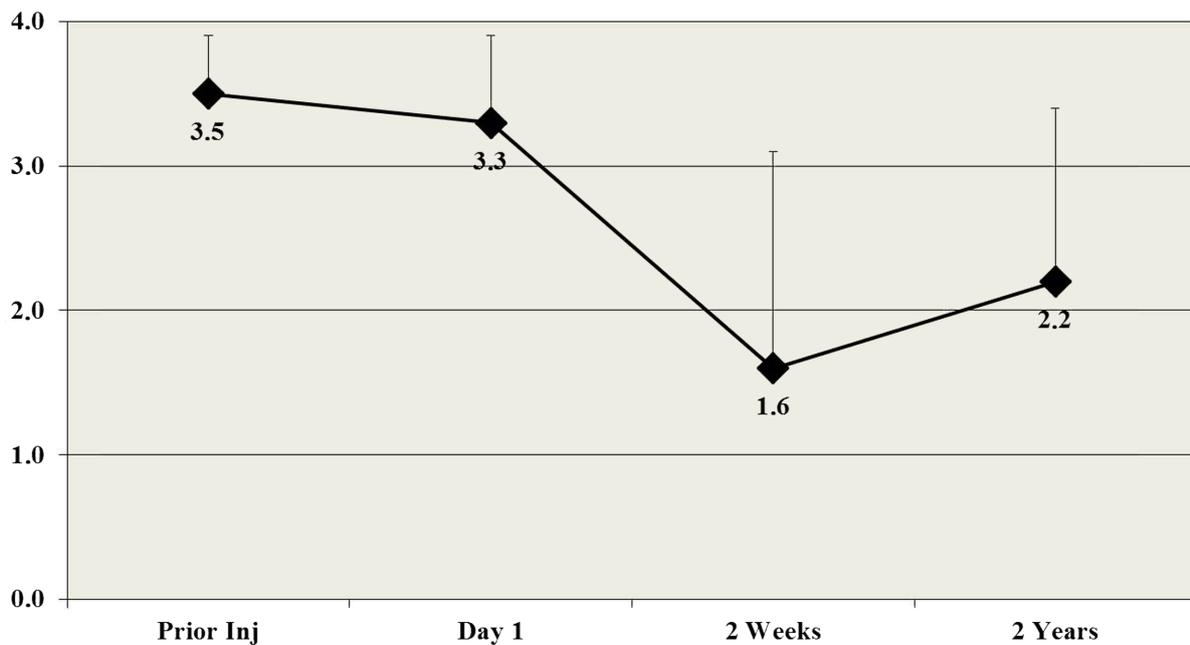


Figure 1: Depicts the course of spasticity, defined by the Ashworth Scale modified by Bohannon and Smith, on the day prior injection, the day afterwards, after two weeks, and after two years. The mean values and the standard deviation are presented. (Inj: Injection)

systemic weakness after injection, lasting for three days. Adverse effects were recorded after administering doses of more than 1,000 U in children and more than 2,000 U in adults [9]. Therefore, our maximal dose of administration was 2,000 U for each adult patient.

The encouraging results of our study are consistent with other studies that showed beneficial effects of botulinum toxin injections in the therapy of spasticity [1], [2], [3], [10]. Similarly, two case reports showed a positive effect of botulinum toxin injections in patients with spinal cord injury and ulcers caused by spasticity [11], [12].

In our study population, 6 of 9 of the patients presented with a significant reduction in their spasticity, reported a better quality of life, and were satisfied or very satisfied. Two of our patients did not benefit from the therapy. One of these patients showed a diffuse pattern of spasticity that affected six functional muscle groups of the upper and lower leg. Thus, this patient seemed to be a poor candidate for this treatment strategy based on the restricted maximal dose of botulinum toxin. Furthermore, this therapy has to be seen very critically in incomplete paretic patients (ASIA C), particularly in those who are

able to walk. These patients are commonly dependent on maximum strength of all functional muscle groups at their lower limb. Thus, botulinum toxin injection causes weakness of certain muscle groups, which might lead to temporary immobilisation as seen in one of our cases.

The strong limitation of this study is its limited patient group, including only nine patients and only one patient with incomplete motor function deficit (ASIA C). Thus, certain patients' characteristics which might cause limited effectiveness of botulinum toxin injections, such as diffuse spasticity pattern or incomplete motor function deficit are based on single cases only. Thus, the statistics was based on descriptive analysis only. Additionally, the level of spasticity was based on the Ashworth scale modified by Bohannon and Smith that is purely observer dependent, which might lead to bias.

Nonetheless, this study includes a very selective patient collective with beneficial effects in the majority of the cases. Future studies are warranted to further evaluate the effects of botulinum toxin and the safety profile of it in the treatment of patients with spasticity after traumatic spinal cord injury.

## Clinical messages

- Botulinum toxin injection for the treatment of spasticity after traumatic spinal cord lesion has the potential of a very promising treatment strategy.
- It seems to be particularly effective in patients with complete lower limb motor function deficit and spasticity pattern limited to few muscle groups.
- Caution has to be recommended in incomplete paretic patients, who are still able to walk, in order to avoid immobilizing effects.
- Further studies are necessary to find parameters, which might affect the antispastic therapy with botulinum toxin.

## Notes

### Competing interests

The authors declare that they have no competing interests.

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**Please cite as**

Spiegl UJ, Maier D, Gonschorek O, Heyde CE, Bühren V. Antispastic therapy with botulinum toxin type A in patients with traumatic spinal cord lesion. *GMS Interdiscip Plast Reconstr Surg DGPW*. 2014;3:Doc14. DOI: 10.3205/iprs000055, URN: urn:nbn:de:0183-iprs0000558

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**Published:** 2014-12-10

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