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INTERFACES CIENTÍFICAS

THE EFFECT OF THE FIRST INTRADETRUSOR BOTULINUM TOXIN INJECTION ON FUNCTIONAL INDEPENDENCE, QUALITY OF LIFE, PAIN AND SPASMS IN INDIVIDUALS WITH SPINAL CORD INJURY[1]

O EFEITO DA PRIMEIRA INJEÇÃO INTRADETRUSORA DE TOXINA BOTULÍNICA NA INDEPENDÊNCIA FUNCIONAL, QUALIDADE DE VIDA, DOR E ESPASMOS EM INDIVÍDUOS COM LESÃO MEDULAR

LA PRIMERA INYECCION DE TOXINA BOTULÍNICA EN EL DETRUSOR Y SU EFECTO EN LA INDEPENDENCIA FUNCIONAL, LA CALIDAD DE VIDA, EL DOLOR Y LOS ESPASMOS EN SUJETOS CON LESION DE LA MEDULA ESPINAL

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1 Artigo baseado na dissertação intitulada: "O efeito da toxina botulínica intradetrusora sobre a capacidade funcional, qualidade de vida, dor e espasmos nos indivíduos com trauma raquimedular", defendida no Programa de Pós-Graduação em Reabilitação e Desempenho Funcional da Universidade Federal dos Vales do Jequitinhonha e Mucuri. 2020.

ABSTRACT

After a spinal cord injury (SCI) practically all patients experience neurogenic bladder dysfunction. The botulinum toxin type A is a procedure for treating urological complications in these patients. The objective this study was to analyze whether individuals with traumatic SCI have improved functionality, quality of life (QoL), pain, and spasms after the first application of intradetrusor botulinum toxin type A. A prospective longitudinal observational study was developed with twenty patients with traumatic SCI followed up in a rehabilitation center. The patients were evaluated before, one and four months after the first application of intradetrusor botulinum toxin type A. The instruments used were: Spinal Cord Independence Measure III (SCIM III) and Qualiveen-SF, to assess functionality and QoL, respectively; Numeric Rating Scale for pain assessment and the Penn Scale to assess the spasms. Descriptive and inferential ($p < 0.05$) statistics were performed. Of the patients evaluated, 90% were men, and 80% had paraplegia. In the first month after applying botulinum toxin type A, there was improvement in the domain related to sphincter control of SCIM III ($p=0.02$). There was no statistically significant difference in the QoL, pain intensity, frequency and severity of spasms before application of botulinum toxin and after 1 and 4 months ($p>0.05$). The first application of intradetrusor botulinum toxin type A interfered positively functional independence related to sphincter control in the first month after application, but did not influence the pain, spasm and QoL.

KEYWORDS

Botulinum Toxin Type A; Neurogenic Urinary Bladder; Recovery of Function; pain; spasm.

RESUMO

Após uma lesão medular (LM), praticamente todos os pacientes apresentam disfunção neurogênica da bexiga. A toxina botulínica tipo A é um recurso utilizado para o tratamento de complicações urológicas nesses pacientes. O objetivo deste estudo foi analisar se indivíduos com LM traumática apresentam melhora na funcionalidade, qualidade de vida (QV), dor e espasmos após a primeira aplicação de toxina botulínica intradetrusora tipo A. Um estudo observacional longitudinal prospectivo foi desenvolvido com vinte pacientes com LM traumática, acompanhados em um centro de reabilitação. Os pacientes foram avaliados antes, um e quatro meses após a primeira aplicação de toxina botulínica intradetrusora tipo A. Os instrumentos utilizados foram: Spinal Cord Independence Measure III (SCIM III) e Qualiveen-SF, para avaliar a funcionalidade e a QV, respectivamente; Escala de Avaliação Numérica para avaliação da dor e Escala Penn para avaliação dos espasmos. Foram realizadas estatísticas descritivas e inferenciais ($p<0,05$). Dos pacientes avaliados, 90% eram homens e 80% apresentavam paraplegia. No primeiro mês após aplicação da toxina botulínica tipo A houve melhora no domínio relacionado ao controle esfincteriano do SCIM III ($p=0,02$). Não houve diferença estatisticamente significativa na QV, intensidade da dor, frequência e gravidade dos espasmos antes da aplicação da toxina botulínica e após 1 e 4 meses ($p>0,05$). A primeira aplicação de toxina botulínica tipo A intradetrusora interferiu positivamente na independência funcional relacionada ao controle esfincteriano no primeiro mês após a aplicação, mas não influenciou na dor, no espasmo e na QV.

PALAVRAS-CHAVE

Toxina Botulínica Tipo A. Bexiga Urinária Neurogênica. Recuperação da Função Fisiológica. Dor. Espasmo.

RESUMEN

Después de una lesión de la médula espinal (LME), prácticamente todos los pacientes experimentan disfunción neurogénica de la vejiga. La toxina botulínica tipo A es un recurso utilizado para tratar las complicaciones urológicas en estos pacientes. El objetivo de este estudio fue analizar si los individuos con LME traumática presentan mejoras en la funcionalidad, calidad de vida (CV), dolor y espasmos después de la primera aplicación de toxina botulínica tipo A en el detrusor. Se desarrolló un estudio observacional longitudinal prospectivo con veinte pacientes con LME traumática monitoreada en un centro de rehabilitación. Los pacientes fueron evaluados antes, uno y cuatro meses después de la primera aplicación de toxina botulínica tipo A en el detrusor. Los instrumentos utilizados fueron: Spinal Cord Independence Measure III (SCIM III) y Qualiveen-SF, para evaluar funcionalidad y CV, respectivamente; Escala de Calificación Numérica para evaluar el dolor y Escala de Penn para evaluar

los espasmos. Se realizó estadística descriptiva e inferencial (p<0,05). De los pacientes evaluados, el 90% eran hombres y el 80% presentaba paraplejía. En el primer mes después de la aplicación de la toxina botulínica tipo A, hubo mejora en el dominio relacionado con el control de esfínteres del SCIM III (p=0,02). No hubo diferencias estadísticamente significativas en la CV, la intensidad del dolor, la frecuencia y la gravedad de los espasmos antes de la aplicación de la toxina botulínica y después de 1 y 4 meses (p>0,05). La primera aplicación de toxina botulínica tipo A en el detrusor interfirió positivamente con la independencia funcional relacionada con el control de esfínteres en el primer mes después de la aplicación, pero no influyó en el dolor, los espasmos y la calidad de vida.

PALABRAS-CLAVE

Toxina Botulínica Tipo A; Vejiga Urinaria Neurogénica; Recuperación de la Función; Dolor; Espasmo.

1 INTRODUCTION

The spinal cord injury (SCI) may cause significant changes in the affected individual. The motor, sensory, and autonomous functions are affected; complete or partial impairment may occur, and it may be permanent or temporary, depending of the lesion; the traumas comprehend major cause of SCI (FEKETE *et al*., 2020; FALEIROS *et al*., 2023).

Individuals with SCI may experience several health-related difficulties; they may suffer from complications secondary to trauma, such as urinary incontinence, neuropathic pain, spasticity, contractures, respiratory changes, among other signs and symptoms. On the psychosocial spectrum, the consequences are related to depression, anxiety, financial difficulty and with social life (FOONG-CHOMCHEAY *et al*., 2019; SHARON *et al*., 2023).

It is essential to point the urinary tract disorders among the complications of SCI, they have been an important cause of these individuals' mortality and present a high level of comorbidities, resulting in significant financial costs and harm the quality of life (QoL) (THAPA *et al*., 2018; KREBS *et al*., 2021; CHEN *et al*., 2023). After a SCI, practically all patients experience neurogenic bladder dysfunction of varying severity (THAPA *et al*., 2018; KREBS *et al*., 2021; CHEN *et al*., 2023; PELOSI *et al*., 2023). The possible implications are recurrent urinary tract infection, possible progression to sepsis, urinary retention, chronic vesicoureteral reflux, and hydronephrosis, causing renal failure due to high intravesical pressure (THAPA *et al*., 2018; KAVANAGH *et al*., 2019).

The adequate treatment for the neurogenic bladder is the possible means for reducing these patients' morbidity and mortality. Botulinum toxin type A emerged as an additional procedure for treating urological complications in patients with SCI, have demonstrated its effectiveness and safety to treat neurogenic detrusor overactivity (CHEN *et al*., 2019; COOLEY; KIELB, 2019; CHEN *et al*., 2023).

The neurogenic detrusor overactivity causes incontinence, recurrent urinary tract infections, and interferes negatively with the QoL (HUANG *et al.*, 2016; MYERS *et al.*, 2019; TATE *et al.*, 2020). Studies on the effects of botulinum toxin A focus on the doses and techniques of application and the repercussion on the function of the bladder and QoL of patients with SCI (HUANG *et al.*, 2016; CHEN *et al.*, 2019; MYERS *et al.*, 2019).

It is known nonetheless that the bladder overactivity is one of the factors that may intensify the spasticity in people with SCI and, associated with it, possible worsening pain and functionality (PALAZÓN-GARCIA *et al.*, 2019; SHAW; SAULINO, 2020). Moreover, common urinary tract infections in individuals with neurogenic detrusor overactivity result in several signs and symptoms in patients with SCI, including increased pain and spasms (AMARAL *et al.*, 2019). There is a lack of information about the interference of a treatment for neurogenic detrusor overactivity in these variables, that are frequently seen during the neurofunctional rehabilitation these patients.

This study aimed to answer whether the first application of intradetrusor botulinum toxin type A as treatment of refractory neurogenic bladder improves the functional independence, QoL, neuropathic pain, and spasticity of individuals with traumatic SCI.

2 METHODS

2.1 DESIGN AND PARTICIPANTS

A prospective longitudinal observational study was carried out, with a four-month follow-up, in a national reference rehabilitation unit. Convenience sample, composed of patients with cervical and thoracic traumatic SCI, aged 18 years or over, of both sexes, with medical indication (elevated detrusor pressures/lack of response to the use of oral medication at maximum dose/**urodynamic** study) for the first surgical procedure for injection with intradetrusor botulinum toxin type A (rehabilitation unit protocol: 200 units distributed in 30 points in the bladder, performed in the same way for all patients – after identifying the bladder trigone, which was spared, the bladder was divided into quadrants, and a line application was performed) between May and September 2019.

The exclusion criteria were patients with other neurologic diseases and did not agree on participating in the research. The study was approved by Research Ethics Committee of Association of Social Pioneers / SARAH Network (CAAE: 05178818.3.0000.0022).

2.2 PROCEDURES

The first meeting was at the preoperative consultation. The second evaluation was a month after the procedure, via telephone, previously arranged with the patient during the first consultation. The third encounter was four months after applying intradetrusor botulinum toxin when the patient returns for assessment with the urologist. In each evaluation, the patient answered the following research instruments: the Spinal Cord Independence Measure - Version III (SCIM - III) (RIBERTO *et al.*, 2014), the Qualiveen Short-Form (Qualiveen SF) (D'ANCONA *et al.*, 2009), the Numeric Rating Scale (NRS) (ANDRESEN *et al.*, 2016) and the PENN Spasms Frequency Scale (MILLS *et al.*, 2018).

2.3 MEASURES

The SCIM-III assesses the capacities and performance in the daily living activities of individuals with SCI and detects the improvement concerning its functionality. The scale is divided into three domains: self-care (scores range from 0-20), respiration and sphincter management (scores range from 0-40), and mobility (scores range from 0-40). The total SCIM-III scores range from 0-100, and the highest scores are equivalent to a greater level of functional independence (RIBERTO *et al.*, 2014). The Qualiveen SF assesses the impact in the QoL caused by the bladder dysfunction. It was specific and valid for the patients of this study (D'ANCONA *et al.*, 2009).

It was composed of eight items distributed in four domains: discomfort with limitations, frequency of limitations, fears, and feelings related to urinary problems. The patients answered questions on a scale from 0 (no impact) to 4 (high impact). The NRS was utilized for classifying the neuropathic pain intensity. The patient evaluated the intensity of the pain on a score range of 0 to 10 (0: no pain and 10: extreme pain; mild pain: 1-4, moderate pain: 5-6 and severe pain: 7-10) (ANDRESEN *et al.*, 2016). The PENN Spasms Frequency Scale was utilized to evaluate the frequency and severity of whole body muscular spasms.

The scale can be used to characterize an individual's spasticity and measure the response of treatment. The PENN scale features two core steps. On the first, the patient classifies the frequency of spasms during the last seven days, on a scale of five levels, ranging from zero (without spasms) to four (spasms that occur more than ten times an hour). If the first step equals zero, the patient does not proceed to the next step. The second step of the scale consists of three levels and assesses the severity of the spasms (MILLS *et al.*, 2018).

2.4 STATISTICAL ANALYSIS

The data were analyzed using the software GraphPad Prism, version 5.0 (GraphPad Software Inc., USA). To characterize the sample, descriptive statistics were performed, composed of frequency, central tendency, and variability. For inferential statistics, the normality of all variables was verified with the Shapiro-Wilk test. The analysis of variance (ANOVA) for repeated measures and Tukey's post hoc were used for parametric variables, and Friedman's test and Dunn's post hoc were used for non-parametric variables ($p < 0.05$).

3 RESULTS

3.1 SAMPLE CHARACTERISTICS

Twenty patients participated in the study, with an average age of 34 ± 7 years old (minimum age: 23 and maximum: 48), the majority were male (90%), with paraplegia (80%); all underwent the first application of intradetrusor botulinum toxin type A. No adverse effects were observed on the procedure and the BT. Sample characteristics are represent in Table 1.

Table 1 – Characteristics of the patients

Variables	N	(%)
Sex		
Male	18	(90%)
Female	2	(10%)
Education		
Elementary School Completed	3	(15%)
Incomplete Elementary School	1	(5%)
High School Graduate	8	(40%)
Incomplete High School	3	(15%)
Higher Education/ College Degree	2	(10%)
Incomplete Higher Education	3	(15%)
Currently Working		
Yes	10	(50%)
No	10	(50%)
Neurological Level		
C4 – C8	4	(20%)
T1 – T6	6	(30%)
T7 – T12	10	(50%)
AIS		
A	15	(75%)
B	3	(15%)
D	2	(10%)

AIS: ASIA (American Spinal Injury Association) Impairment Scale.
Source: Research Data.

3.2 FUNCTIONAL INDEPENDENCE AND QUALITY OF LIFE

Table 2 shows that there was no difference in self-care and mobility domains of the SCIM III, however was identified a crucial difference in respiration and sphincter management domain ($p = 0.02$) and that despite the decrease in the score in all domains of the Qualiveen SF questionnaire, after applying the intradetrusor botulinum toxin, there was no significant difference in the QoL of individuals between the three assessment moments.

Table 2 – Data on functional independence and quality of life before and after application of intradetrusor botulinum toxin

Variables	Pre-application of BT	1st-month post application of BT	4th-month post application of BT
SCIM-III			
Self-care	18.35 ± 3.81	17.35 ± 5.57	17.35 ± 5.57
Respiration and sphincter management	26.26 ± 4.86	27.31 ± 4.72*	26.79 ± 4.66
Mobility	16.37 ± 3.65	16.37 ± 3.65	16.37 ± 3.65
Total	60.98 ± 6.43	61.03 ± 6.54	60.51 ± 6.55
Qualiveen SF			
Discomfort with limitations	2.15 ± 1.04	2.00 ± 1.21	2.00 ± 1.21
Fears related to urinary problems	3.30 ± 0.95	3.10 ± 1.19	3.10 ± 1.18
Feelings related to urinary problems	3.50 ± 0.86	3.37 ± 1.14	3.37 ± 1.14
Frequency of limitation	3.20 ± 1.02	3.15 ± 1.15	3.15 ± 1.15
Total	3.04 ± 0.55	2.91 ± 0.88	2.91 ± 0.88

BT: botulinum toxin; SCIM III: Spinal Cord Independence Measure (highest scores are equivalent to a greater level of functional independence); Qualiveen SF: Qualiveen Short-Form (0: no impact – 4: high impact in the quality of life).
*Statistics difference between pre-application of botulinum toxin and the 1st month post-application ($p = 0.02$); Results expressed as mean ± standard deviation.
Source: Research Data.

3.3 PAIN INTENSITY AND SPASMS

At the pre-application of the intradetrusor botulinum toxin, 50% of the patients reported pain, and the severe intensity was the most prevalent (33%). After applying the botulinum toxin, the percentage of patients with pain intensity from 7 to 10 decreased in the first and fourth months after the application. Among the assessed individuals, 55% presented frequent spasms (scores 3 to 4 on the PENN Spasms Frequency Scale). A month after the procedure, the presence of frequent spasms was 40%, and in the fourth month, 45%. The frequency of moderate and severe spasms decreased in the first month after applying botulinum toxin, and this reduction was maintained in the fourth month after treatment.

However, there was no significant difference in the variables spasms and pain between the pre and post-application (first and fourth months) of intradetrusor botulinum toxin type A (Table 3). The mean pain found in the three moments (pre-application; 1st-month and 4th-month post application of botulinum toxin) was respectively: 3.44 ± 0.90; 2.44 ± 0.78 and 2.94 ± 0.79 (p>0.05). The mean frequency of spasms in the three moments was: 2.65 ± 0.27; 2.12 ± 0.28 and 2.29 ± 0.26 (p>0.05).

Table 3 – Data on pain intensity and spasms before and after application of intradetrusor botulinum toxin

Variables	Pre-application of BT	1st-month post application of BT	4th-month post application of BT
NRS	**N (%)**	**N (%)**	**N (%)**
0	9 (50%)	11 (55%)	9 (50%)
1-4 (mild)	2 (11%)	5 (28%)	3 (17%)
5-6 (moderate)	1 (6%)	0 (0%)	3 (17%)
7-10 (severe)	6 (33%)	3 (17%)	3 (17%)
Total*	18 (100%)	18 (100%)	18 (100%)
PENN	**N (%)**	**N (%)**	**N (%)**
Frequency of spasms			
0	3 (15%)	3 (15%)	3 (15%)
1	4 (20%)	8 (40%)	6 (30%)
2	2 (10%)	1 (5%)	2 (10%)
3	7 (35%)	6 (30%)	7 (35%)
4	4 (20%)	2 (10%)	2 (10%)
Total	20 (100%)	20 (100%)	20 (100%)
Spasm Severity			
Mild	6 (35%)	10 (59%)	10 (59%)
Moderate	7 (41%)	4 (23%)	4 (23%)
Severe	4 (24%)	3 (18%)	3 (18%)
Total	17 (100%)	17 (100%)	17 (100%)

NRS: Numeric Rating Scale; *: two patients did not respond; PENN: Penn Spasm Frequency Scale; 0: no spasms; 1: mild spasms induced by stimulation; 2: infrequent full spasms occurring less than once per hour; 3: spasms occurring more than once per hour; 4: spasms occurring more than 10 times per hour.
Source: Research Data.

4 DISCUSSION

This is the first study to evaluate the effect of the surgical procedure for injection with intradetrusor botulinum toxin type A on functional independence, pain, and spasms in patients with traumatic SCI. Our results confirmed the improvement in the domain of functional capacity concerning sphincter control after the surgical procedure for the injection with intradetrusor botulinum toxin type A. However, there was no improvement in the quality of life, pain reduction, or spasms.

Concerning the study sample, the higher prevalence of males is consistent with studies on SCI (BYCHKOVSKA *et al.*, 2022; FALEIROS *et al.*, 2023; PELOSI *et al.*, 2023; CONTI *et al.*, 2023). The individuals' average age was 34 years old, compatible with others research (KANNA *et al.*, 2022; FALEIROS *et al.*, 2023). Of the study patients, the majority presented paraplegia, similar to those found in the literature (BYCHKOVSKA *et al.*, 2022; FALEIROS *et al.*, 2023; CONTI *et al.*, 2023).

We did not identify significant statistical differences in the QoL after the treatment with the botulinum toxin type A. In a similar study, in which individuals with SCI were subject to the first application of botulinum toxin type A and the QoL and the bladder function were assessed before and after the treatment, was verified that an improvement of the urinary incontinence and a positive impact on the QoL (HUANG *et al.*, 2016). Nevertheless, besides the intradetrusor injection, there was a simultaneous application on the external urethral sphincter and the utilized method to evaluate the QoL was the Incontinence-Specific Quality-of-Life Instrument, a non-specific instrument for individuals with neurologic dysfunction. The Qualiveen SF, utilized in this study, is a measure of QoL of people with neurogenic overactive bladder with strong reliability, validity and responsiveness (USMAN ALI *et al.*, 2024).

Spasticity and pain are common and incapacitating after an SCI. In this study, 85% of the individuals reported having spasms, and 20% classified it as severe, according to the frequency and gravity of the PENN Scale. Similar data were described in a cross-sectional study that used the PENN scale to describe the frequency and severity of spasms, 77% of individuals with SCI reported having spasms, and 17% rated these spasms as severe (HØGHOLEN *et al.*, 2018).

In our study, 50% of the individuals reported some level of pain. Of this total, 33% categorized it as severe, a result close to the study by Andresen *et al.* 2016, who found 28.1% of individuals with SCI with severe pain. The pain on the SCI contributes to QoL's decrease, limiting the daily life activities and social integration (ANDRESEN *et al.*, 2016). Infections of the urinary tract and spasticity have a direct influence on the pain in patients with a SCI (CAMERON *et al.*, 2011).

As bladder overactivity is one of the factors that can intensify spasticity in individuals with SCI and the spasticity can interfere with activities of daily living, levels of pain, and more functional problems (PHADKE *et al.*, 2013; PALAZÓN-GARCÍA *et al.*, 2019), in addition to evaluating the influence of botulinum toxin type A on spasticity, we analyzed the pain and the functional independence of these individuals.

When analyzing the impact of applying the intradetrusor botulinum toxin over the spasms, we have observed a decrease in the percentage of frequency, most evident one month after the treatment, and in the severity of the spasms. The percentage of pain intensity described by patients according to the NRS scale was also modified with the application of botulinum toxin. However, no significant diffe-

rence was found concerning the variables spasms and pain using the intradetrusor botulinum toxin type A. Few studies analyze the influence of intradetrusor botulinum toxin over spasticity and pain. In a multicentre trial carried out in patients submitted to the application of intradetrusor and sphincteric botulinum toxin, it was verified that 89% of the patients were satisfied and felt better from the bladder pain (HUANG *et al*., 2016).

The SCIM-III scale utilized in this study was built explicitly to assess the SCI's functional capacity. This scale also has a related domain for the bladder function, making it an ideal instrument for functional evaluation after SCI in studies that analyze urinary control (MARITZ *et al*., 2022). In our study, the gain in functionality was observed only in this specific domain. There was an improvement in the item related to sphincter control, in this item, the worst result is the use of the indwelling catheter and the best is to be continent without using drainage instruments. It is essential to highlight the importance of caring for bladder dysfunction to achieve urological continence to prevent complications such as vesicoureteral reflux, urinary tract infections, and improved QoL (PANICKER *et al*., 2015; PANICKER, 2020).

This study presented some limitations. The reduced number of individuals was due the inclusion only of patients over 18 years old, with traumatic SCI, without other impairments that influenced urinary control and that never had received intradetrusor botulinum toxin injection. It is known the importance of the social context for the individuals of this study, including the relation between the urinary control and the participation of patients with SCI (CAMERON *et al*., 2011). This variable was not included in the present study due to the grand number of assessments, we prioritize variables that commonly interfere in the neurofuctional rehabilitation of these patients, recommend that future studies assess the participation of individuals with SCI who perform the procedure with intradetrusor botulinum toxin.

5 CONCLUSION

There was an improvement in functional independence domain related to sphincter control, one month after the first application of intradetrusor botulinum toxin type A in individuals with traumatic SCI and neurogenic detrusor overactivity. The treatment did not influence the QoL, the pain, and the spasticity of the patients.

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