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Ferreira R[1], D´Ancona C[2], Rassi M[3]

1. *Department of Urology, School of Medicine, State University of Campinas, UNICAMP, Campinas - Sao Paulo, Brazil and Rehabilitation Center Dr. Henrique Santillo - CRER, Goiania, Goias,Brazil,* ***2.*** *Department of Urology, School of Medicine, State University of Campinas, UNICAMP, Campinas - Sao Paulo, Brazil,* ***3.*** *Rehabilitation Center Dr. Henrique Santillo - CRER, Goiania, Goias,Brazil*

COMPARATIVE STUDY BETWEEN ORAL OXYBUTYNIN AND INTRADETRUSOR INJECTIONS OF BOTULINUM TOXIN TYPE A (BOTOX®) IN PATIENTS WITH BLADDER DYSFUNCTION FOLLOWING TRAUMATIC SPINAL CORD INJURY: URODYNAMIC RESPONSE AND EFFECT ON QUALITY OF LIFE.

Hypothesis / aims of study

Urinary incontinence (UI) is an aspect of bladder management in individuals with SCI. From the view of the SCI patients, it is a most unpleasant complication, which may disable the individuals socially (1). Assessment of the efficacy of treatments for UI, especially pharmacologic interventions, is often based on measurement of clinical and urodynamic parameters. Although these are relevant measures, direct measurement of the effect of treatment on Quality of Life (QOL) is particularly important because the relationship between subjective and objective responses to treatment and QOL changes is complex (2).The aim of this study was to evaluate the effect on QOL and urodynamic parameters of patients with spinal cord injuries treated with intradetrusor injections of botulinum toxin type A (Botox®) or oral oxybutynin.

Study design, materials and methods

This was a prospective and randomized study of 61 patients with SCI and detrusor overactivity. The subjects were allocated into two groups: patients in Group I (GI, n=28) underwent to intradetrusor injections of 300 U of botulinum toxin type A (Botox®), while patients in Group II (GII, n=33) received 5 mg of oxybutynin chloride three times daily. Urodynamic parameters such as maximum cystometric capacity (MCC), detrusor pressure at maximum cystometric capacity (Pdet.MCC) and compliance were evaluated. The QOL scores were obtained from the Medical Outcomes Study Short Form (SF-36), Qualiveen and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaires. The evaluations were performed before the patients were allocated to the different groups and after 1, 3 and 6 months. For statistical analysis, the chi-square test and Fisher's exact test were used to compare categorical variables between the groups. At the initial evaluation, the Mann-Whitney test was used to compare numerical variables between the two groups due to the lack of normal distribution. To compare longitudinal measurements between the two groups at the four evaluation moments, analysis of variance for repeated measures was used followed by Tukey's multiple comparison test. Statistical analysis was established at 5% ($p<0.05$).

Results

Of the 61 patients, 49 were male (80.3%). Median age was 32.0 years (range 19 to 61). After 6 months, the MCC increased significantly in patients in GI from 172.36 ± 33.53 mL to 461.61 ± 2139.38 mL, while in GII, the MCC increased from 167.64 ± 36.21 mL to 293.88 ± 69.49 mL ($p<0.001$). The Pdet.MCC decreased significantly in GI from 79.14 ± 21.80 cm H_2O to 30.39 ± 27.27 cm H_2O, while in GII, Pdet.MCC decreased from 79.58 ± 21.11 cm H_2O to 58.48 ± 19.11 cm H_2O, $p<0.001$. Compliance increased significantly in GI from 14.89 ± 3.15 mL/cm H_2O to 40.71 ± 24.10 mL/cm H_2O, while in GII, compliance increased from 14.74 ± 4.60 mL/cm H_2O to 21.61 ± 4.94 mL/cm H_2O, $p<0.001$. The scores obtained in the ICQI-SF questionnaire showed a significant reduction in patients in GI from 18.36 ± 2.06 to 7.93 ± 3.92, while in GII, ICQI-SF mean score decreased from 18.33 ± 1.78 to 15.00 ± 2.93 ($p<0.001$). Analysis of the SF-36 questionnaire scores showed a significant effect in patients in GI with respect to the general health, vitality and social functioning domains when compared to patients in GII ($p<0.001$). In the other domains, no statistically significant differences were found between the groups. The Qualiveen questionnaire showed significantly higher scores in GI compared to GII in all the domains evaluated ($p<0.001$).

Interpretation of results

Intradetrusor injections of 300 U of botulinum toxin type A (Botox®) provides significant improvement in urodynamic parameters such as maximum cystometric capacity, detrusor pressure at maximum cystometric capacity, compliance and QOL scores in patients with SCI compared with oral oxybutynin.

Concluding message

Treatment with intradetrusor injections of botulinum toxin type A (Botox®) results in a significant improvement in urodynamic parameters and in the Quality of Life of patients with detrusor overactivity due to spinal cord injuries compared to treatment with oral oxybutynin.

References

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Is this a Randomised Controlled Trial (RCT)?	**Yes**

What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethical Committte of Medical Sciences School, UNICAMP**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**