

WHAT IS THE BEST DOSE FOR INTRAVESICAL BOTULINUM-A TOXIN INJECTION IN OVERACTIVE BLADDER TREATMENT? A PROSPECTIVE RANDOMIZED PRELIMINARY STUDY.

Hypothesis / aims of study

Botulinum-A toxin has emerged in the last three years as an attractive option to treat detrusor overactivity due to neurological and non-neurological etiologies. Although a significant number of studies have confirmed its effectiveness with doses from 200 to 300 units of Botox[®], there is a lack of studies defining the best dosages. The objective of this study is to determine the efficacy of two different dosages of intravesical Botox[®] injection for treatment of patients with detrusor overactivity.

Study design, materials and methods

We developed a simple blind, randomized study to test the effectiveness of 100 units and 300 units intravesical Botox[®] injection. Fourteen patients with a mean age of 33 y.o. (14 - 62 y.o.) were enrolled in this study. All but one suffer from neurogenic bladder (twelve due to spinal cord injury and one to neuroschistosomosis). The non-neurogenic one was considered with an idiopathic etiology after an exhaustive diagnosis exploration. Patients were submitted to complete urodynamic exam before and three months post-treatment. The dose (100u or 300u) was chosen by chance, immediately before the procedure. Cystoscopy was performed under general anesthesia with injection of 1 ml saline solution of Botox[®] in each of thirty points, homogeneously distributed in the bladder wall. Patients were kept on bladder irrigation with saline solution while bleeding and then discharged from the hospital. They were asked to perform clean intermittent catheterization four times a day, registering the residual volume. The outpatient follow up was done at 30, 60 and 90 days after the bladder injection.

Results

Eight patients received an injection of 100 units of Botox[®] and six of 300 units. In the first group, the bladder capacity before treatment was 144.6 ml (50 - 350 ml) and the maximum detrusor pressure during involuntary bladder contraction was 90.1 cmH₂O (47 - 120 cmH₂O). The second group (300u) had an average bladder capacity of 203.6 ml (160 - 290 ml) with a maximum detrusor pressure of 76.2 cmH₂O (33 - 102 cmH₂O). Previous to treatment, all of them were incontinent, using pads or some external device to collect urine. After Botox[®] injection, three patients who received 300 units of Botox[®] remained continent between catheterization lasting for a period of 2 to 7 months (still ongoing). The bladder capacity was improved to 431.0 ml (117 - 700 ml). In the group who received 100 units, two patients only referred got continence. The bladder capacity in this group remained unchanged (150.2 ml).

Interpretation of results

Although the relative small number of patients submitted to the study, better results seems to be obtained with the use of 300 U for intravesical injection in this situation, compared to 100 U. Since 2 patients submitted to 100 U became continent between catheterizations, more patients may allow identification criteria for its use.

Concluding message

The effective dose of Botox[®] to treat detrusor overactivity is still to be determined with larger series of patients. At this moment, we can conclude a tendency for 300 units, due to better results.