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BOTOX® FOR IDIOPATIC OVERACTIVE BLADDER PATIENTS REFRACTORY TO ANTIMUSCARINIC THERAPY: A 53 PATIENTS RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL.

Hypothesis / aims of study

Our purpose is to tested the subjective efficacy and effect duration of the botulinum toxin type-A intradetrusor injection in the treatment of idiopatic urodynamically-proven detrusor overactivivity resistant to anticholinergic drugs treatment.

Study design, materials and methods

Between Febrary 2009 and December 2010, in a prospective study, 53 women with a mean age of 58,8 years (range 21-76) with idiopatic overactive bladder (urgency-frequency syndrome and/or urge-incontinence), resistant to anticholinergic drugs treatment, were enrolled in our double blind placebo controlled trial. Women were randomly assigned to receive injection of BTX-A or placebo in to bladder.

Under general anesthesia in 27 patients, 100 Units of BTX-A, diluited in 20 ml 0,9% saline solution, were injected under video-cystoscopy into the detrusor muscle, sparing the trigone to avoid iatrogenic reflux: 1 ml was injected at 20 sites. Remaining 26 patients received placebo (injection vehicle).

Before treatment, videocystouretroscopy, micturion diary, urodynamic and neurological status were perfomed in all patients of two arms.

Frequence of voids, number of incontinence episodes (number of pad), number of voids associated with urgency per 24 hours were perfomed at baseline, at 4 and 24 weeks after the treatment.

The IUSS and QoL was valutated in all patients.

Results

A significant improvement in bladder function in regarde to subjective symptoms and quality of life was seen in the 27 Botox®-trated patients after 1 to 3 weeks.

At 4 weeks we had no significative prolongation of micturion time (41 to 50 sec.).

A 50% reduction in frequency episode was observed in patients treated with botulinum toxin (from 17±4 to 6±2). In placebo arms we observed a reduction from 16±4 to 14±2.

In Botox® arm, at 24 weeks urgency disappeared and incontinence resolved in 93,75 % of cases since 2-3 weeks after botulinum toxin-A injection.. However in the 2 patient frequency decreased from 11±4 to 7±2 incontinence episodes. No significant reduction of leak frequency appeared in placebo arm.

No patient had urinary tract infection at 4-12-24 weeks follow-up visits. The patients reported no dysuria. A patient reported bladder pain for three days after the treatment, treated with anti-inflamatory therapy. An important reduction of number of nocturia episodes was observed (from 6,3 to 1,2 in the average).

There were no severe side effect (except a case of temporary partial urine retention that regressed with intermittent catheterization).

Interpretation of results

The treatment is well tolerated with minimal, short lasting side effects. BTX-A injection provide improvement in symtoms for at least 24 weeks after treatment. We propone to observe the patients for a more long period to evaluate the necessity of repeating the intradetrusor injection of BTX type-A. In fact in our study there are 3 patients who have improvement of bladder symptoms at 40 weeks after the date of treatment.

Concluding message

Our study demonstrates that intradetrusor injection is a promising treatment option for the management of non neurogenic bladder overactivity in whom treatments with anticholinergic drugs have no effect.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Because this treatment is in use in others hospitals in Italy**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**