

## **BOTOX® FOR IDIOPATIC OVERACTIVE BLADDER PATIENTS REFRACTORY TO ANTIMUSCARINIC THERAPY.**

### 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 overactivity resistant to anticholinergic drugs treatment.

### Study design, materials and methods

Between February 2008 and December 2008, in a prospective study, 16 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, received injection of BTX-A into bladder.

Under general anesthesia, 100 Units of BTX-A, diluted 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.

Before treatment, videocystourethroscopy, micturition diary, urodynamic and neurological status were performed in all patients. Frequency of voids, number of incontinence episodes (number of pad), number of voids associated with urgency per 24 hours and number of episodes of nocturia per 24 hours were performed at baseline, at 4 and 24 weeks after the treatment.

### Results

A significant improvement in bladder function in regards to subjective symptoms and quality of life was seen in 15 patients after 1 to 3 weeks. There were no severe side effect (except a case of temporary partial urine retention that regressed with intermittent catheterization). At 4 weeks we had no significative prolongation of micturition time (41 to 50 sec.). At 24 weeks urgency disappeared in 15 of the patients and incontinence resolved in 93,75 % of cases since 2-3 weeks after botulinum toxin-A injection. In 15 patients urgency episodes decreased from 17±4 to 6±2. In 1 patient leak decreased from 11±4 to 7±2 incontinence episodes. No patient had urinary tract infection at 4-12-24 weeks follow-up visits. The patients reported no dysuria. A patients reported bladder pain for three days after the treatment, treated with anti-inflammatory therapy. An important reduction of number of nocturia episodes was observed (from 6,3 to 1,2 in the average).

### Interpretation of results

The treatment is well tolerated with minimal, short lasting side effects. BTX-A injection provide improvement in symptoms for at least 24 weeks after treatment. We propose 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

1. Experience with 100 cases treated with botulinum-A toxin injections in the detrusor muscle for idiopathic overactive bladder syndrome refractory to anticholinergics
2. Botulinum toxin injections for adults with overactive bladder syndrome
3. Short-term efficacy of botulinum toxin a for refractory overactive bladder in the elderly population

<b><i>Specify source of funding or grant</i></b>	<b>We have no interest conflict with the society that produce the botulinm toxin type-A..</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>the use of botulinum toxin type-A is already adopted in other urological treatment with the same procedure.</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>