

FIRST CLINICAL EXPERIENCE OF INTRAVESICAL ELECTROMOTIVE BOTULINUM TOXIN ADMINISTRATION FOR PAINFUL BLADDER SYNDROME TREATMENT.

Hypothesis / aims of study.

Some trials has shown efficacy of injections of botulinum toxin A into the bladder wall (submucosally) for treatment of Painful Bladder Syndrome.[1,2]. Disadvantages of this method: invasiveness, general anaesthesia, patients' fearing. On this reason, we decided to evaluate the possibility of intravesical electromotive incobotulinumtoxinA (Xeomin, Merz) administration. Electromotive drugs administration (EMDA) is widely used method of local drugs administration. Molecule of botulinum toxin A (BOTOX) is too heavy (900 kDa) but incobotulinumtoxinA (Xeomin) molecular weight is only 150 kDa. We've developed (in vitro) solution for electromotive incobotulinumtoxinA administration. The aim of this study – evaluate the clinical efficiency of electromotive Xeomin administration.

Study design, materials and methods

23 women, suffering of Painful Bladder Syndrome participated in study. Written informed consent was taken. Visual Analogue Scale and Voiding Diary (during 3 days) were filled before and after procedure. Mean age of patients was 38 ± 11 years. Mean Visual Analogue Scale (VAS) score was 6.3 ± 2.4 . Frequency was 23 ± 8 . Voiding volume was 87 ± 24 ml.

Patients were randomized divided on the two groups:

- 1) IncobotulinumtoxinA group (15 pts);
- 2) Saline group (8 pts).

For EMDA procedure in first group used solution: 200 U of Xeomin, 20 ml distilled water with 200 mcl 0.1 N HCl and 2 ml DMSO. In second group used saline, 25 ml.

We've used EMDA device (ELFOR, Nevoton, Russia), and catheter – electrode for intravesical EMDA (UroPhores, NMTC, Russia).

Duration of procedure was 20 minutes.

On 5th day after procedure all patients filled VAS and Voiding Diary (3 days).

Results

Group	VAS		Frequency		Voiding Volume	
	Before	After	Before	After	Before	After
IncobotulinumtoxinA (200 U)	6.3 ± 2.4	2.7 ± 1.1	23 ± 8	12 ± 4	87 ± 24 ml	134 ± 41 ml
Saline	6.3 ± 2.4	5.5 ± 2.1	23 ± 8	21 ± 6	87 ± 24 ml	95 ± 29 ml

Interpretation of results

In the incobotulinumtoxinA group all parameters significantly improved. There were absence of side effects.

Concluding message

Intravesical electromotive incobotulinumtoxinA (Xeomin, Merz) administration is a perspective method of treatment Painful Bladder Syndrome and, perhaps, overactive bladder. Further trials will necessary.

References

1. Botulinum toxin a has antinociceptive effects in treating interstitial cystitis. Smith CP, Radziszewski P, Borkowski A, Somogyi GT, Boone TB, Chancellor MB.
2. Botulinum A toxin intravesical injections in the treatment of painful bladder syndrome: a pilot study. Giannantoni A, Costantini E, Di Stasi SM, Tascini MC, Bini V, Porena M.

Disclosures

Funding: NMTC International **Clinical Trial:** Yes **Public Registry:** Yes **Registration Number:** Nizhegorodskiy State Medical University, **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Nizhegorodskiy State Medical University **Helsinki:** Yes **Informed Consent:** Yes