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

<table>
<thead>
<tr>
<th>Group</th>
<th>VAS Before</th>
<th>VAS After</th>
<th>Frequency Before</th>
<th>Frequency After</th>
<th>Voiding Volume Before</th>
<th>Voiding Volume After</th>
</tr>
</thead>
<tbody>
<tr>
<td>IncobotulinumtoxinA (200 U)</td>
<td>6.3 ± 2.4</td>
<td>2.7 ± 1.1</td>
<td>23 ± 8</td>
<td>12 ± 4</td>
<td>87 ± 24 ml</td>
<td>134 ± 41 ml</td>
</tr>
<tr>
<td>Saline</td>
<td>6.3 ± 2.4</td>
<td>5.5 ± 2.1</td>
<td>23 ± 8</td>
<td>21 ± 6</td>
<td>87 ± 24 ml</td>
<td>95 ± 29 ml</td>
</tr>
</tbody>
</table>

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.

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