ENGLISH BOTULINUM TOXIN A: EVALUATION OF URODYNAMICS BEFORE AND AFTER STANDARDIZED INJECTION REGIME IN IDIOPATHIC AND NEUROGENIC DETRUSOR OVERACTIVITY NON RESPONSIVE TO PHARMACOLOGICAL TREATMENT

Hypothesis / aims of study
It is acknowledged that Botulinum toxin A injection (IIBAI) is the second line treatment in neurogenic and idiopathic detrusor overactivity non responsive to pharmacological treatment, despite its off-label use in Germany. Its effect in these pathologies has been proven on a high evidence level and it is generally accepted. However, despite several working groups showed, that IIBAI does not induce vesicorenal reflux (VUR), there are still the acceptance, that IIBAI does induce VUR. Beside the evaluation of urodynamic findings after IIBAI has not been published yet.

Study design, materials and methods
From 2002 till 2007, 63 patients with neurogenic detrusor overactivity and 144 patients with idiopathic detrusor overactivity non responsive to pharmacological treatment received IIBAI. All patients underwent a full urological examination with conventional videourodynamic before. The standardized application of IIBAI (250 IE Dysport® in idiopathic, 500 IE Dysport® in neurogenic detrusor overactivity) was performed in local anaesthesia after standardized regime (7 locations in the detrusor muscle, 3 in the trigonal area). Videourodynamic was performed 6 weeks after IIBAI for evaluating results.

Results

<table>
<thead>
<tr>
<th></th>
<th>Idiopathic detrusor overactivity (n=144)</th>
<th>Neurogenic detrusor overactivity (n=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum cystometric capacity</td>
<td>+190.9 ml [± 78.5] *</td>
<td>+460.7 ml [± 131.4] *</td>
</tr>
<tr>
<td>Incontinence episodes</td>
<td>-4.3 [± 1.3] *</td>
<td>-6.3 [± 2.5] *</td>
</tr>
<tr>
<td>Max. flow rate</td>
<td>-1.2 ml/s [± 7.3]</td>
<td>-1.9 ml/s [± 2.7]</td>
</tr>
<tr>
<td>No OAB syndrome left</td>
<td>128</td>
<td>58</td>
</tr>
<tr>
<td>Pads/d</td>
<td>2.7 [± 3.6] *</td>
<td>3.3 [± 1.7] *</td>
</tr>
<tr>
<td>Changes in detrusor pressure at max. flow rate</td>
<td>-18.2 cmH2O [± 7.2] *</td>
<td>-22.8 cmH2O [± 10.6] *</td>
</tr>
</tbody>
</table>

Side effects:
- Urinary retention
- Post void residual (PVR)
- Induced vesicoureteral reflux

Morphological changes
- Contractile detrusor
- Acontractile detrusor

Mean duration of effect
- 4.9 months [± 1.2]
- 5.7 months [± 2.2]

Specialties
- X

Changes in detrusor pressure at max. flow rate
- -18.2 cmH2O [± 7.2] *
- -22.8 cmH2O [± 10.6] *

*: p< 0.05

Interpretation of results
IIBAI is effective in neurogenic and idiopathic detrusor overactivity. It reduces incontinence episodes, OAB and use of pad highly significantly. Detrusor pressure at maximum flow gets cut down significantly.

Interestingly IIBAI does not paralyze the detrusor completely in idiopathic detrusor overactivity, patients are still able to void with PVR below 50 ml.

In neurogenic detrusor overactivity, IIBAI induce excessive PVR and urinary retention, which is clinically wanted.

Concluding message
This study is the first study which evaluates prospectively the effect of botulinum toxin A on urodynamics after standardized injection regime. It also could be shown, that Botulinum toxin A does not induce VUR.

Patients with idiopathic detrusor overactivity are still able to void with PVR below 50 ml by injection of 250 IE Dysport®.

References
Available from authors on request

Specify source of funding or grant
None

Is this a clinical trial?
Yes

Is this study registered in a public clinical trials registry?
No

What were the subjects in the study?
HUMAN

Was this study approved by an ethics committee?
Yes

Specify Name of Ethics Committee
Ärztekammer des Saarlandes

Was the Declaration of Helsinki followed?
Yes

Was informed consent obtained from the patients?
Yes