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1. Städtisches Klinikum Neunkirchen

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 ackknowledged that Botulinumtoxin 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 into the trigonal area). Videourodynamics was performed 6 weeks after IIBAI for evaluating results.

Results

<u>ITS</u>		
	Idiopathic detrusor overactivity	Neurogenic detrusor overactivity
	(n=144)	(n=63)
Maximum cystometric capacity	+190.9ml[± 78.5]*	+460.7ml[± 131.4]*
Incontinence episodes	- 4.3[± 1.3]*	- 6.3[± 2.5]*
Max. flow rate	- 1.2 ml/s [± 7.3]	- 1.9 ml/s [± 2.7]
No OAB syndrome left	128	58
Pads /d	- 2.7 [± 3.6]*	- 3.3 [± 1.7]*
Changes in detrusor pressure at	-18.2cmH ₂ O[± 7.2] *	-22.6cmH ₂ O[± 10.6]*
max. flow rate		
Side effects:		
Urinary retention	1	56
Post void residual (PVR)	35.3ml[± 24.8]	650ml[± 198.1]
Induced vesicoureteral reflux	0	0
Morphological changes	Contractile detrusor	Acontractile detrusor
Mean duration of effect	4.9months [± 1.2]	5.7months [± 2.2]
Specialties	X	3/63 with preinjection reflux → no
		reflux after IIBAI

^{*:} 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.

It elevates significantly maximum cystometric capacity.

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 Botulinumtoxin 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