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COULD WE USE LESS INJECTION SITES OF ONABOTULINUMTOXINA IN RE-TREATMENTS WITH THE SAME EFFICACY? PRELIMINARY RESULTS OF A PILOT STUDY

Hypothesis / aims of study

OnabotulinumtoxinA (BTX) is used in the treatment of neurogenic (NDO) and idiophatic detrusor overactivity (IDO). In a recent study [1],similar efficacy and rates of adverse events were found using 1 to 3 injection sites, compared with standard technique (20-30 injection sites), in naïve NDO and IDO patients. Our purpose was to determine if re-treatment using less injections points, provides similar clinical efficacy, duration and adverse events compared with previous treatment.

Study design, materials and methods

This is a prospective, interventional, before and after, single center study. From January 2016 to March 2017, 34 NDO and IDO patients refractory to oral medication were included. Only patients who had been previously treated with BTX according to standard technique (20-30 puncture sites) and showed good clinical response were included. At the moment patients requested for repeating procedure, they were treated with the same BTX dose, but with three to four intradetrusor injection sites in retrotrigone region, depending on dose required. BTX injection was performed under local anesthesia or spinal anesthesia as an outpatient procedure. Pain during the procedure was evaluated using a visual analogue scale (score 0 to 10). Efficacy was measured using the Treatment Benefit Scale (TBS), and continence evaluated with bladder diaries and personal interview. Duration of effect was determined by patient reported return of symptoms and/or need of introducing additional oral drug treament. Adverse events were reported.

Results

We report the results of 15 patients with follow up available for more than 24 weeks (mean 37 weeks, 24-52). The mean (SD) age was 58,7 (14,7) years. Thirteen patients (87%) were females, six patients (40%) were neurogenic, five (33%) were in clean intermittent catheterization, all in neurogenic group. All the patients were incontinents. The procedure was performed under local anesthesia in fourteen patients (93%). Dose of BTX used were: 100 units in eight patients with 3 injection sites, 150 units in two patients with 3 injection sites, 200 units in three patients with 3 injections sites, 300 units in two patients with 4 injections sites. All the patients had VAS pain scale less than or equal to five. The TBS was greatly improved (1) in 40% (6 of 15 patients), improved (2) in 47% (7 of 15 patients), not changed (3) in 13% (2 of 15 patients), so 87% of patients improved. Twelve patients (80%) were continents after the procedure. Only two patients (13,3%) presented urinary tract infection (UTI) as adverse event. The mean duration of effect was 29 weeks compared with 36 weeks of previous procedure with no significant differences (p=0,157). No differences in efficacy, duration of effect and adverse events were found among IDO and NDO patients.

	All patients	**IDO**	**NDO**
N (%)	15	9 (60)	6 (40)
Female (%)	13 (87)	8 (89)	5 (83)
Age (mean, SD)	58,7 (14,7)	62,7 (12,6)	52,6 (16,6)
CIC (%)	5 (33,3)	0	5 (100)
Etiology NB (%)			
Spinal Cord Injury			2 (33)
Multiple Sclerosis			2 (33)
Spina Bifida			1 (17)
Motor neuron disease			1 (17)
Anesthesia (%)			
Local	14 (93)		
Spinal	1 (7)		
BTX dosage (%)			
100 U	8 (53,3)		
150 U	2 (13,3)		
200 U	3 (20)		
300 U	2 (13,3)		

Interpretation of results

Data about efficacy and safety of long-term BTX treatment in patients with overactive bladder, reported improvement in urinary symptoms on TBS of 74% to 83%, and UTI as adverse event in 13% to 17%, after repeated injections [2]. Long-term efficacy and safety with BTX treatment in patients with neurogenic detrusor overactivity reported that patients achieved a 50% or greater reduction in urinary incontinence in 87,6% to 92,1%, the UTI rate was 17,35 to 21,5% after repeated injections [3]. Our data about improvement on TBS (87%) and reduction in urinary incontinence (80%) was similar, with alike UTI rate (13,3%) as main adverse event. Tolerability of 3-4 injection sites with local anesthesia was acceptable, and duration of effect marginally lower compared to standard technique, but with no significant differences.

Concluding message

In this small pilot study on repeated treatments with BTX in IDO and NDO patients, we have found similar clinical efficacy and duration of effect using less puncture sites (3-4), compared to previous treatments using standard technique (20-30 puncture sites). We consider that treatment of BTX using three to four injections, may be an interesting option, with limited and expected adverse events. More studies are needed to confirm this findings.

References

1. 1. Avallone MA, Sack BS, El-Arabi A, Guralnick ML, O'Connor RC. Less Is More-A pilot study evaluating one to three intradetrusor sites for injection of OnabotulinumtoxinA for neurogenic and idiopathic detrusor overactivity. Neurourol Urodyn Internet. 2016 Jun cited 2017 Feb 26; Available from: http://doi.wiley.com/10.1002/nau.23052
2. 2. Nitti VW, Dmochowski R, Herschorn S, Sand P, Thompson C, Nardo C, et al. OnabotulinumtoxinA for the Treatment of Patients with Overactive Bladder and Urinary Incontinence: Results of a Phase 3, Randomized, Placebo Controlled Trial. J Urol Internet. 2017 Feb cited 2017 Feb 26;197(2):S216–23. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28012773
3. 3. Rovner E, Kohan A, Chartier-Kastler E, Jünemann K-P, Del Popolo G, Herschorn S, et al. Long-Term Efficacy and Safety of OnabotulinumtoxinA in Patients with Neurogenic Detrusor Overactivity Who Completed 4 Years of Treatment. J Urol Internet. 2016 Sep cited 2017 Mar 29;196(3):801–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27091236

Disclosures

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