

EFFICACY AND TOLERABILITY OF ONABOTULINUMTOXINA IN PATIENTS WITH OVERACTIVE BLADDER: FIRST MULTICENTRIC STUDY IN TURKISH POPULATION

Hypothesis / aims of study

To assess the efficacy, safety and effects on quality of life of onabotulinumtoxinA in patients with overactive bladder (OAB) who were refractory to anticholinergic treatment.

Study design, materials and methods

A total 80 patients older than 18 years with OAB symptoms who were unresponsive to conservative and medical treatments were included into this multicentric study. Patients with OAB symptoms were evaluated by 3-days voiding diary, incontinence quality of life questionnaires (I-QOL), uroflowmetry, postvoid residual urine volume both at baseline and 12th weeks of the study. Patients with increased urgency and at least one episode of urgency incontinence, increased daytime urinary frequency and/or nocturia were treated by onabotulinumtoxinA (Botox, Allergan) at a dose of 100 U dissolved in 20 mL of saline injected at 20 different points of bladder including trigone. Antibiotic prophylaxis was performed both at preoperative and postoperative period. Treatment benefit scale was completed by all patients at 12th week. Efficacy of treatment was also examined by the change from baseline in the mean number of urinary incontinence episodes, mean voided volume, change in frequency of micturition, mean and maximal bladder capacities and mean urgency episodes. Similarly, infection, hematuria, urinary retention and other treatment related adverse events were noted. Statistical analysis was performed using SPSS 18.

Results

The mean age of patients was 47.36±17.3 (18-87) years. Of the patients, 48 (60 %) were female whereas 32 (40%) were male. OnabotulinumtoxinA at a dose of 100 U significantly decreased urgency incontinence episodes, mean frequency of micturition and urgency episodes compared to pre-treatment. Similarly, mean bladder capacity and maximal bladder capacity were increased after treatment (Table 1). Incontinence Quality of Life scores were improved by 57.1 % compared to pre-treatment rate (p=0.0001). Of the patients, 52.5% and 30% reported well improvement and improvement, respectively on treatment benefit scale at the 12th weeks (Figure 1). Eighty percent of patients were reported that first onabotulinumtoxinA injection was still effective at 12th weeks and they did not request a repeat injection. Mean PVR increased slightly whereas maximum flow rate showed slight decrease at 12th weeks. However, there was no statistically significant difference compared to pre-treatment levels (p=0.391 , p=0.86). The most common adverse events were urinary tract infection, transient hematuria and urinary retention. Temporary urinary retention developed in three (3.75%) patients, urinary infection and transient hematuria were observed in 5 (6.25%) and 5 (6.25%) patients, respectively.

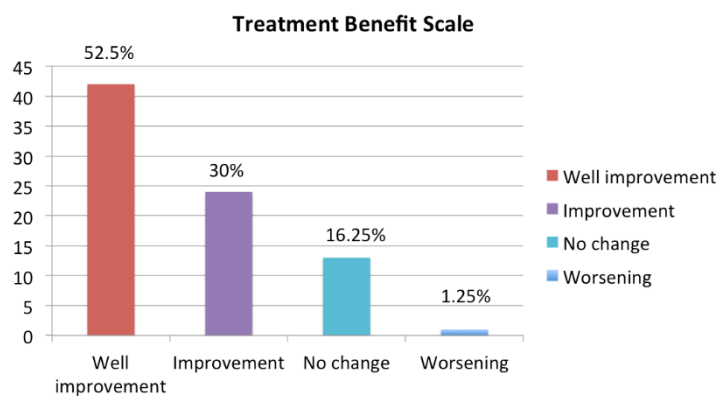
Concluding message

This is the first multicentric study conducted in a Turkish OAB patient group that showed clinically significant improvement with 100 U of onabotulinumtoxinA injection for treatment. Relatively low incidence of treatment emergent adverse events and a high ratio of treatment benefit make onabotulinumtoxinA injection a viable option for refractory OAB patients.

Table 1: Comparison of baseline and postoperative 12.weeks data

	Baseline (mean)	12.weeks (mean)	p
frequency (n)	14.98 ± 6.12	8.58 ± 4.63	0.0001
urge incontinence episodes (n)	7.6 ± 5.78	1.8 ± 2.86	0.0001
urgency episodes (n)	9.68 ± 5.6	2.88 ± 3.34	0.0001
bladder capacity (ml)	187.06 ± 93.59	242.71 ± 95.92	0.0001
maximal bladder capacity (ml)	279.68 ± 133.46	330.13 ± 123.82	0.0002

Figure 1: Treatment benefit scale at 12th week.



Disclosures

Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** University of Ondokuz Mayis **Helsinki:** Yes **Informed Consent:** Yes