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ONABOTULINUM TOXIN A VS RESINIFERATOXIN IN THE TREATMENT OF WET OVERACTIVE BLADDER PATIENTS: A CLINICAL AND URODYNAMIC PROSPECTIVE ANALYSIS.

Hypothesis / aims of study

Overactive bladder (OAB), is defined by the International Continence Society as urgency, with or without incontinence, usually accompanied by frequency and nocturia, in the absence of obvious bladder pathology. Previous studies have suggested that neurotoxins such as resiniferatoxin (RTX) and onabotulinum toxin A (OnabotA) can be used in patients refractory to oral anticholinergics. Therefore, we prospectively compared the efficacy of a single bladder instillation of resiniferatoxin, 100 nM, versus a bladder wall injection of 100 U of OnabotA in the treatment of OAB symptoms. Our primary objective was the reduction in the number of incontinence episodes; secondary objectives were the effect in urinary frequency, cystometric capacity, evaluation of post void residual urine, and OAB quality of life score (OABq).

Study design, materials and methods

A total of 34 female patients with refractory wet OAB, were treated RTX (17 patients) or OnabotA (17 patients) and prospectively analysed during a year. The decision to treat with OnabotA or RTX was made by the patients' preference. Patients were evaluated before treatment with history and physical examination, blood and urine analysis, 3 day bladder diary, Quality of Life Questionaires (OABq), urodynamic studies (cystometrogram, urofluxometry, post-void residual). Exclusion criteria were previous exposure to OnabotA and RTX. All these items were repeated at each subsequent visit done at week 12, and week 24 after treatment. Results are presented as mean (Percentil 25;Percentil 75). Student's T test was used for statistical significance and value of $p<0.05$ was considered significant.

RTX was purchased to Sigma and prepared immediately before bladder instillation, as an 100 nM concentration solution using 100 ml of a 10% alcoholic solution as vehicle. OnabotA was purchased to Allergan, and 100 U diluted in 30 ml of saline and injected in the bladder wall in 30 injection points (3,3 U/ml). All patients gave signed informed consent.

Results

A total of 34 female patients were analysed; 17 were treated with RTX, and another 17 with OnabotA. Mean age was 59,5 (48;71) years in the OnabotA group and 63 (41;69) years in the RTX group. Detrusor hyperactivity was present in 11 and in 5 patients treated with OnobotA and RTX respectively. However, in terms of incontinence episodes and urinary frequency, both groups were identical. Table 1 presents the results at base line, week 12 and 24 after treatment, for both populations.

		Baseline	**Week 12**	**Week 24**
Incontinence (episodes/day)	**BonT/A**	**3** (2;4,75)	**0** (0;1) †	**0** (0;1) †
	RTX	**3,5** (1,75;5,25)	**2,5** (1;5) †	**3** (1,75;4,25)
Frequency (episodes/day)	**BonT/A**	**11**(8,25; 14)	**6** (5;9) †	**5,5** (5;6) †
	RTX	**9,5** (8; 16,5)	**8,5** (7;9) †	**10** (8;12,75)
MCC (ml)	**BonT/A**	**363** (315,75; 421,5)	**490** (426,5;569) †	**501** (435,75;582) †
	RTX	**450,5** (300;500)	**558,5** (372;620) †	**490,5** (327;545)
PVRUrine (ml)	**BonT/A**	**0** (0;0)	**47,5** (35,25;56,75) †	**34** (25;40,5) †
	RTX	**0** (0;57,5)	**38,5** (22,5; 52,25)	**27** (16;37,25)
OAB QoL score (%)	**BonT/A**	**29,2** (11,8;50,6)	**45,9** (18,9; 66,8) †	**39,4** (16;59,7) †
	RTX	**12,4** (7,4; 27,6)	**15,7** (9,45;34,05) †	**14,2** (8,5;31,45) †

Table 1: MCC – maximum cystometric capacity; PVRUrine – post void residual urine; OAB QoL – Overactive Bladder Questionair Quality of Life score. † $p<0.05$.

Interpretation of results

In a population of OAB wet patients, OnabotA is effective in abolishing urinary incontinence episodes and reducing urinary frequency, increasing quality of life and improving bladder capacity, and this effectiveness is maintained by, at least, 6 months. RTX, although inducing a significant reduction of incontinence episodes, did not cure urinary incontinence, and caused a modest improvement in urinary frequency and quality of life. The effect lasted 3 months.

Concluding message

In patients with OAB wet, RTX does not seem to be effective enough to constitute an alternative to OnabotA.

Disclosures

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