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THE REFRACTORY OVERACTIVE BLADDER: SACRAL NEUROMODULATION VS. BOTULINUM TOXIN ASSESSMENT (ROSETTA)

Hypothesis / aims of study

Sacral neuromodulation and onabotulinumtoxinA are treatments for refractory urgency urinary incontinence (UUI). The objective of this study was to compare change from baseline in mean daily urgency urinary incontinence episodes (UUIE) over a 6-month period in women treated with these two therapies.

Study design, materials and methods

We performed a randomized trial of women with refractory UUI comparing sacral neuromodulation versus intradetrusor injection of 200 U onabotulinumtoxinA. The primary outcome was change from baseline in mean daily UUIE over a 6-month period measured with a monthly 3-day diary. Secondary outcomes included quality of life, satisfaction, and adverse events.

Results

A total of 386 women were randomly assigned; 369 were treated, and 364 were available for the primary outcome analyses. In both the intention to treat and clinical responder, primary outcome analyses, the onabotulinumtoxinA group reported significantly greater mean reduction in UUIE per day compared to the neuromodulation group. (Figure) In the onabotulinumtoxinA group, 20% had complete UUI resolution as compared to 4% in the sacral neuromodulation group, (p=0.0002). (Table) Urinary tract infections were higher in the onabotulinumtoxinA group (35% vs.11%, p<0.001). Self-catheterization was required in 8% and 2% of the onabotulinumtoxinA group at one and six months, respectively and neuromodulation device revisions/removals occurred in 3%.

Figure: Change in urgency urinary incontinence episodes per month by treatment group. Intention-To-Treat Population (Overall p values < 0.01); Clinical Responder Population (overall p values = 0.01). Note error bars represent 95% confidence intervals for mean change in UUI episodes

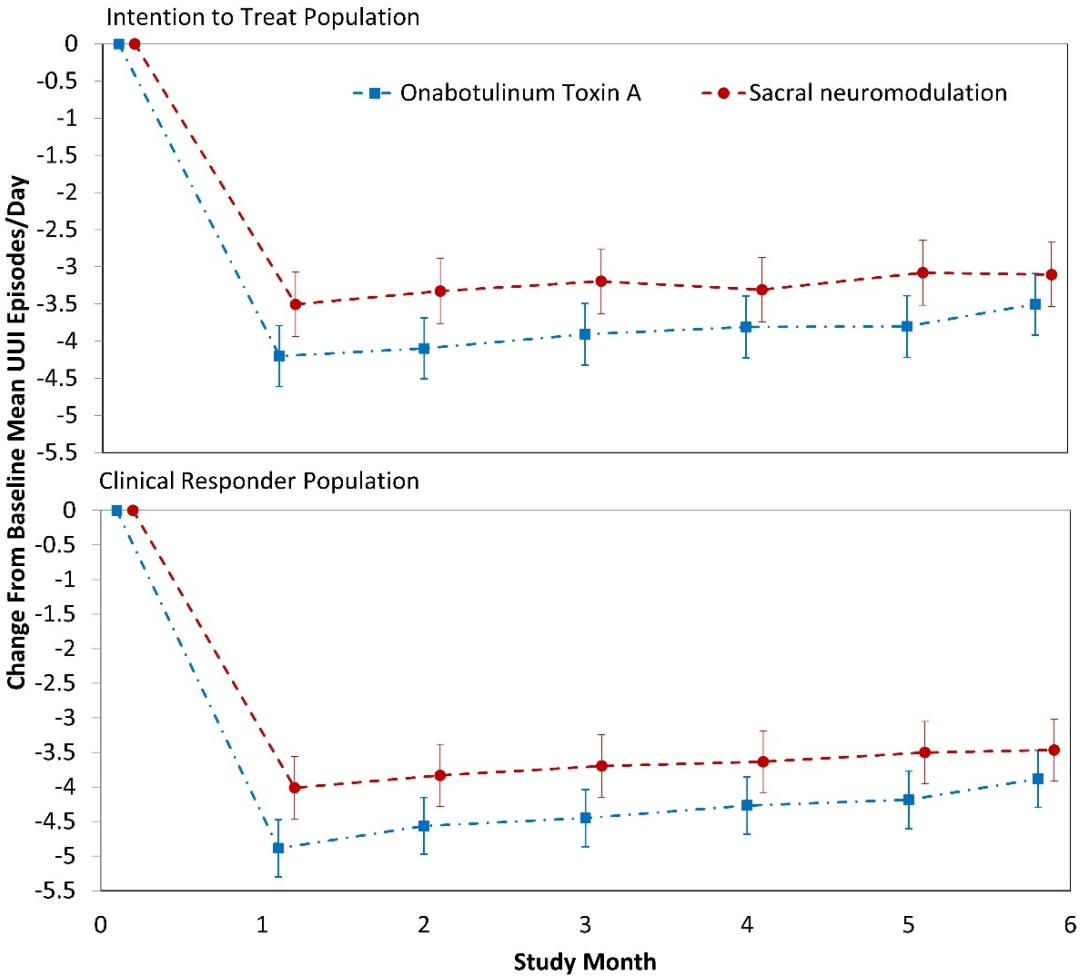

Table: Outcomes in Intention-To-Treat population

	Onabotulinum group (N=190)	Neuromodulation group (N=174)	p
UUIE/day at Baseline (mean)	5.4±2.7	5.2±2.7.	0.5
Reduction in UUIE / day (mean)	**-3.89**	**-3.25**	**0.01**
Complete resolution of UUIE[d]	**35/178 (20%)**	**6/166 (4%)**	**0.0002**
Improvement in symptom bother (OABq-SF) (adjusted mean) ∞	**-46.7**	**-38.6**	**0.002**
Satisfaction with treatment (OAB SATq) (adjusted mean) ¥	**67.5**	**59.7**	**0.01**
Endorsement with treatment (OAB SATq) (adjusted mean) ¥	**76.2**	**65.2**	**0.0015**
Patient global impression of improvement (PGI-I) in bladder leakage*	71%	67%	0.73
Patient global impression of improvement (PGI-I) in bladder function*	68%	69%	0.61

[d] represents individuals completing at least 4 follow up diaries over 6 months who had complete resolution of UUIE on all their diaries
∞ Values for the Overactive Bladder Questionnaire Short Form (OABq-SF) are changes from baseline in the adjusted mean scores for months 1 to 6.
¥ Values for the Overactive Bladder Satisfaction questionnaire (OAB-SATq) range from 0-100 and includes five subscales; treatment satisfaction, side effects, treatment endorsement, convenience, and patient preference, with higher scores reflecting better satisfaction
*Response of better, much better, very much better

Interpretation of results

The onabotulinumtoxinA group was significantly more likely to experience a greater mean reduction in UUIE per day and complete resolution of UUI; in addition, report greater improvements in overactive bladder symptom bother, and have higher satisfaction and endorsement scores with the assigned treatment. There were no group differences in patient global impression of improvement in bladder leakage or in bladder function.

Concluding message

Compared to sacral neuromodulation, intradetrusor injection of 200 U of onabotulinumtoxinA resulted in greater reduction in mean daily episodes of UUI and was more likely to result in complete resolution of UUI and higher satisfaction albeit with an increased risk of urinary tract infections and need for transient catheterization.

Disclosures

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