Urogynecology Digest

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OnabotulinumtoxinA vs sacral neuromodulation on refractory urgency urinary incontinence in women: a randomized clinical trial

Amundsen CL, Richter HE, Menefee SA, et al. JAMA. 2016;316(13):1366–1374.

This was a multicentre open-label randomized trial (February 2012 to January 2015) at 9 US medical centres involving 381 women with refractory urgency urinary incontinence. The objective was to assess whether onabotulinumtoxinA is superior to sacral neuromodulation in controlling refractory episodes of urgency urinary incontinence. Study eligibility required women to have refractory urgency urinary incontinence, defined as persistent symptoms, despite at least one supervised behavioural or physical therapy intervention and the use of a minimum of two anticholinergics (or an inability to tolerate the medication or contraindications to use of the medication). To be included, women needed a minimum of six urgency incontinence episodes on a baseline 3-day diary. Exclusion criteria were relevant neurological diseases, a history of using either of the study interventions, or a postvoid residual of more than 150 mL. Participants were randomized to cystoscopic intradetrusor injection of 200 U of onabotulinumtoxinA ($n = 192$) or sacral neuromodulation ($n = 189$). The primary outcome measure was a change from baseline mean number of daily urgency urinary incontinence episodes

over 6 months. Secondary outcomes included a change from baseline in urinary symptom scores in the Overactive Bladder Questionnaire Short Form (SF), Overactive Bladder Satisfaction questionnaire, and adverse events. Baseline characteristics were similar in the two groups.

Participants treated with onabotulinumtoxinA showed greater improvement in the Overactive Bladder Questionnaire SF for symptom bother, treatment satisfaction, and treatment endorsement than treatment with sacral neuromodulation. There were differences in convenience, adverse effects, and treatment preference. Urinary tract infections were more frequent in the onabotulinumtoxinA group. The need for self-catheterisation was 8 and 2% at 1 and 6 months in the onabotulinumtoxinA group respectively. Neuromodulation device revisions and removals occurred in 3%. Although the improvement in the onabotulinumtoxinA group was statistically significant, it is of uncertain clinical importance.

The main strengths are the randomized trial design, large sample size, and use of validated questionnaires. As a single injection of one formulation of botulinum toxin A was investigated, no conclusions can be reached on other botulinum toxin preparations or the effect of multiple injections of onabotulinumtoxinA compared with sacral neuromodulation therapy. Furthermore, this trial compared two active treatments, preventing any determination of a placebo effect.

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