

Chermansky C<sup>1</sup>, Wilson T<sup>2</sup>, Wallace D<sup>3</sup>, Vasavada S<sup>4</sup>, Nguyen J<sup>5</sup>, Myers D<sup>6</sup>, Komesu Y<sup>7</sup>, Honeycutt E<sup>3</sup>, Harvie H<sup>8</sup>, Gregory W T<sup>9</sup>, Amundsen C<sup>10</sup>

*1. Dept of Urology - University of Pittsburgh, 2. Dept of Urology - University of Alabama at Birmingham, 3. RTI International, 4. Dept of Urology - Cleveland Clinic Foundation, 5. Dept of Obstetrics and Gynecology - Southern California Kaiser Permanente, 6. Dept of Obstetrics and Gynecology - Brown University, 7. Dept of Obstetrics and Gynecology - University of New Mexico, 8. Dept of Obstetrics and Gynecology - University of Pennsylvania, 9. Dept of Obstetrics and Gynecology - Oregon Health Sciences University, 10. Dept of Obstetrics and Gynecology - Duke University*

## **TWO-YEAR OUTCOMES OF SACRAL NEUROMODULATION VERSUS ONABOTULINUMTOXINA FOR REFRACTORY URGENCY URINARY INCONTINENCE**

### Hypothesis / aims of study

Urgency urinary incontinence (UUI) is prevalent, and the utilization of third line therapy is increasing. We compared urgency urinary incontinence episodes (UUIE) over a 24-month period in women treated with either sacral neuromodulation (SNM) or intradetrusor onabotulinumtoxinA (BTX).

### Study design, materials and methods

381 eligible women were randomized to either SNM or 200 U BTX. Based on PGSC scores, reprogramming and revisions were evaluated in the SNM group, and two additional injections were allowed in the BTX group after 6 months. The primary outcome was change from baseline in mean daily UUIE over a 24-month period as measured by bladder diary. Secondary outcomes included no UUIE and >75% UUI reduction, quality of life, satisfaction, and adverse events.

### Results

293 had primary outcome data at 24 months. There was no difference in mean decrease in UUIE between the two groups over 24 months (Fig 1). The BTX group was significantly more likely to experience complete resolution of UUI and >75% reduction within the first year, but this difference was not seen at 24 months (Fig 2). No difference in overactive bladder symptom bother improvement was seen after 6 months; however, higher satisfaction (mean difference = -9.3, 95% CI= -15.2, -3.4) and treatment endorsement (mean difference = -10.49, 95% CI= -16.7, -4.1) were sustained to 24 months in the BTX group. There were no differences in other QOL measures. In the BTX group, 70% requested a 2nd injection (mean interval was 385 days SD ± 172) and 35% requested a 3rd (mean interval between 2nd and 3rd was 290 days SD ± 96). 1.8% chose to dose reduce. SNM revision and removals occurred in 3% and 9%, respectively. 30% of subjects in each group opted for additional medication or alternative study therapy. Recurrent urinary tract infections at 24 months were 27% in the BTX group and 10% in the SNM group, p = <0.0001.

### Interpretation of results

SNM and BTX resulted in similar reductions in mean daily UUIE at 24 months. BTX was more likely to provide complete resolution of UUIE in the first year compared to SNM. Higher satisfaction and treatment endorsement throughout 24 months was seen with BTX compared to SNM. Use of additional therapy was similar between the two groups, but UTI rates were higher following BTX.

### Concluding message

At 24 months, SNM and BTX resulted in similar reductions in mean daily UUIE. BTX was more likely to provide complete resolution of UUIE in the first year and higher satisfaction and treatment endorsement throughout 24 months. Use of additional therapy was similar, but UTI rates were higher following BTX.

Figure 1.

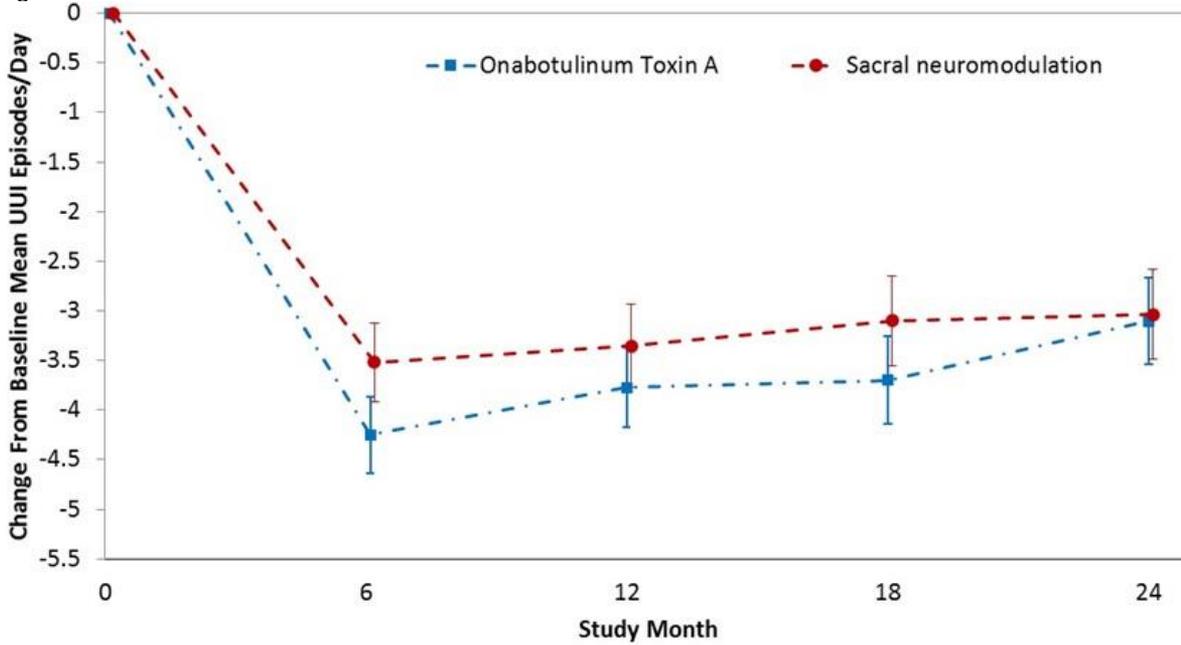
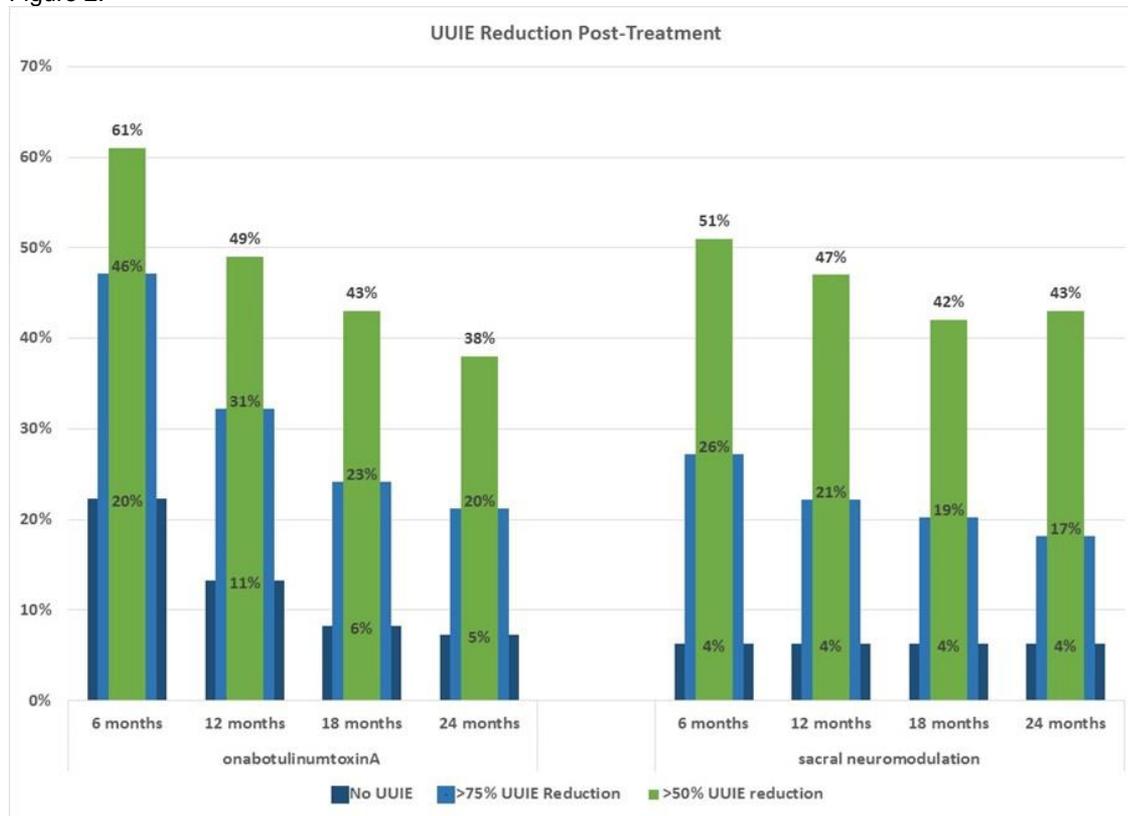


Figure 2.



**Disclosures**

**Funding:** Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institutes of Health Office of Research on Women's Health **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov number, NCT01502956 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** The institutional review board of each clinical site and the Data Coordinating Center of the Pelvic Floor Disorders Network approved the protocol. **Helsinki:** Yes **Informed Consent:** Yes