Botox May Beat Neural Stimulation for Urge Incontinence, But Has Risks

EMBARGOED FOR RELEASE until 11 a.m. (ET) on Tuesday, October 4, 2016

DURHAM, N.C. -- When women suffer from bladder incontinence, the urge to urinate can come on suddenly and sometimes uncontrollably, leading to leakage. Patients looking for relief can initially opt for first- and second-line therapies such as drinking fewer liquids or caffeinated beverages, pelvic floor muscle training, and medication.

If those treatments prove inadequate however, patients may seek more invasive options, including a form of nerve stimulation called sacral neuromodulation (an implanted device sold as InterStim), or a bladder injection of botulinum toxin, which is sold as Botox.

A head-to-head comparison of sacral neuromodulation and botulinum toxin led by a Duke Health researcher shows that Botox provides more daily relief for women, but might also be associated with more adverse events.

The findings are to be published Oct. 4 in the Journal of the American Medical Association (JAMA).

An injection of botulinum toxin in the bladder muscle works to address urgency urinary incontinence by relaxing the overactive bladder muscles that cause the condition. A sacral neuromodulation implant does the same thing by sending electrical pulses to nerves in the spine.

“Urgency urinary incontinence is common, with 17 percent of women over age 45 and 25 percent of women over age 75 suffering from it,” said Cindy L. Amundsen, M.D., the study’s lead author and the Roy T. Parker Professor of Obstetrics and Gynecology at Duke University School of Medicine. “That’s why it’s important for both patients and health care providers to have information that can guide their choice between these two therapies.”

The study involved 381 women from nine U.S. medical centers who recorded at least six urgency incontinent episodes over three consecutive days and had not improved with other treatments.

The participants were randomly assigned to either receive sacral neuromodulation or a 200-unit injection of botulinum toxin. After a trial period to test their responsiveness to the therapies, 364 women were enrolled and followed for six months after treatment.
The study team analyzed the number of urgency incontinent episodes on monthly “bladder diaries.” Participants who received botulinum toxin saw their number of daily urgency incontinent episodes decrease by 3.9 on average versus 3.3 on average in the sacral neuromodulation group. The difference was statistically significant.

Botulinum toxin participants also reported a greater reduction in bothersome symptoms, higher satisfaction with treatment, and a greater likelihood of endorsing the treatment.

Additionally, among participants who completed at least four monthly diaries, a higher percentage of botulinum toxin participants saw at least a 75-percent reduction in or complete resolution of urgency incontinent symptoms.

However, the Botox patients also had three times the rate of urinary tract infections. Some botulinum toxin participants also required intermittent self-catheterization, although at lower rates than reported in previous studies using this dose.

For the sacral neuromodulation participants, the most common adverse event was removal or revision of the implant during the six months. This occurred at a low rate, similar to previous studies.

“This study is valuable because it is the first randomized trial comparing the efficacy of two FDA-approved, third-line therapies in a severely affected population,” Amundsen said. “The information should help guide care.”

While the study did not compare the cost of the two treatments, Amundsen noted that patients who receive botulinum toxin may require additional injections as part of continued treatment. Additionally, the study only takes Botox into account and no conclusions can be drawn for other botulinum toxin preparations that may be used to treat urgency incontinence.

In addition to Amundsen, co-authors include Holly E. Richter, Shawn A. Menefee, Yuko M. Komesu, Lily A. Arya, W. Thomas Gregory, Deborah L. Myers, Halina M. Zyczynski, Sandip Vasavada, Tracy L. Nolen, Dennis Wallace, and Susan F. Meikle.

The study was funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH Office of Research on Women’s Health at National Institutes of Health 3316 (U01 HD41249UIO, HD41261U10, HD41267, U10 HD054215U10-HD41267-11, U10-HD069013, U10-HD054214-06, U10-HD054215-06, U10-HD041267-I2, U10-HD069025-01, U10-HD069010, U10-HD054136, U10-HD05424I, and U10-HD04I250-11).

One co-author reported financial relationships with the commercial makers of both InterStim and Botox. Full disclosures are available in the study’s manuscript.

###