Botox May Boost QOL in Overactive Bladder

Treatment with 100 U 'may be the best dose in terms of balancing efficacy and safety.'

BY SUSAN BIRK

CHICAGO — Patients with idiopathic overactive bladder refractory to anticholinergics reported significant improvements in health-related quality of life, symptom severity, and satisfaction for at least 24 weeks following treatment with botulinum neurotoxin type A in a randomized trial of 313 patients.

"Dose response was observed in main patient-reported measures, with Botox doses at or above 100 U consistently providing meaningful benefit as measured by improvements on these questionnaires," reported Dr. David A. Ginsberg and his colleagues in a poster at the annual meeting of the American Urological Association. "The benefit to patients was rapid, as early as 2 weeks, and was sustained for at least 24 weeks" at these doses.

Treatment with 100 U "may be the best dose in terms of balancing efficacy and safety" and lowering the risk of urinary retention as a possible side effect, Dr. Ginsberg of the University of Southern California in Los Angeles said in an interview.

Several earlier studies showed the drug's effectiveness in terms of urodynamics, but the present study offers some of the first objective data on changes in quality of life and patient satisfaction, he said. The use of Botox for overactive bladder is currently an off-label indication.

"One of the issues I think we've always had is, What is the best way to evaluate the efficacy in our therapies for overactive bladder? … What's very important are quality of life data. We do this [informally] every day in our practice. We ask patients … 'Are you feeling better?' But when we're doing studies, we don't really quantify this with quality of life evaluations," said Dr. Ginsberg, who disclosed that he is a consultant for Allergan Inc., which supported the multicenter, double-blind phase II study.

At baseline, participants (mean age, 58.8 years; 91% female) were having eight or more episodes of urge urinary incontinence per week with no more than one incontinence-free day, and an average of eight micturitions daily based on a 7-day voiding diary. Patients were randomized to receive Botox 50 U, 100 U, 150 U, 200 U, or 300 U or placebo intradetrusor injections. Patients received a single treatment of 20 injections under local anesthesia.

Health-related quality of life was assessed at baseline and at weeks 2, 6, 12, 18, 24, and 36 using the Incontinence Quality of Life questionnaire (I-QOL), the incontinence-specific King's Health Questionnaire (KHQ), and the Overactive Bladder–Urinary Incontinence Patient Satisfaction With Treatment Questionnaire (PSTQ). Global assessments of overall symptoms, activity limitations, and emotions related to overactive bladder since the last clinic visit were performed at the same intervals following treatment.

Significant improvements in incontinence-related QOL and urinary symptoms were found in all of the treatment groups, compared with the placebo group. "A clear dose-response relationship was observed for Botox at week 12, with mean increases from baseline in I-QOL total scores ranging from 29.8 in the Botox 50-U group to 39.7 in the 300-U group versus a mean increase from baseline of 17.9 in the placebo group," Dr. Ginsberg said. "This dose-response relationship was evident at all subsequent time points."

Global assessments of symptoms, QOL, activity limitations, and emotions were significantly more positive for up to 24 weeks in patients in all of the Botox treatment groups, compared with the placebo group, except in the group receiving the lowest Botox dose. At week 12, mean changes from baseline in patient satisfaction scores were significantly higher for the patients in the 100-U, 150-U, and 300-U groups.

Patient reports of side effects on the PSTQ did not differ between the placebo and Botox groups past week 12 of the study. Patients in the 200-U group had the highest incidence of postvoid residual urine of 200 mL or more. The proportion of patients with postvoid retention (PVR) of more than 200 mL were 0%, 12.5%, 14.5%, 20.0%, 28.8%, and 27.3% for the placebo and Botox 50-U 100-U, 150-U, 200-U, and 300-U groups, respectively.

A recent study of Botox in 81 patients with idiopathic overactive bladder (J. Urol. 2009;181:1773-8) reported that more than two of five patients required clean intermittent self-catheterization following treatment and concluded that "all prospective patients should be informed about this."

Dr. Ginsberg noted that patients in this study received Botox 200 U, an amount higher than what appears to be the optimal dose of 100 U.

"In addition, retention was defined as a PVR greater than 100 mL. Patients may very well have a PVR that high or higher, show improvement in regard to their [overactive bladder] symptoms, and not require intermittent catheterization to help empty their bladder," he said.

"I tell my patients there is about a 10%-20% risk that they might need [intermittent catheterization] to empty their bladder," he said. ■

Prolapse Surgery Possible Without Hysterectomy

BY SUSAN BIRK

CHICAGO — Uterus-sparing surgery was a safe alternative to concurrent hysterectomy for many women undergoing surgery for pelvic organ prolapse, based on mean follow-ups of 5 years.

Favorable outcomes can be achieved with uterine preservation, and women aged 40-60 years who are free of vaginal and uterine disease should know about this option, Dr. Elisabetta Costantini of the University of Perugia (Italy) and her colleagues wrote in a poster presented at the annual meeting of the American Urological Association. Leaving the uterus intact has been thought to introduce the risk for repeat surgery, yet none of the patients in this study required additional surgery.

Hysterocolposacropexy was performed in 47 women with symptomatic pelvic organ prolapse; 40 had abdominal procedures and 7 had laparoscopic procedures. Patients were followed up at 1, 3, 6, and 12 months after surgery and then yearly for a mean of 5 years (range, 12-141 months). Outcome measures included anatomical and physical examinations, assessments of urodynamics, and patient responses to questionnaires.

Sexual activity was maintained in 28 of 29 (96%) patients following surgery. None of the patients required repeat surgery for recurrent prolapse, and 83% reported long-term satisfaction with their procedures. However, anatomical examinations indicated cystocele of grade 2 or higher in six women (12.8%) and rectocele of grade 2 or higher in four (8.5%). Postoperative voiding symptoms persisted in 3 of 33 (9.1%) patients, and postoperative storage symptoms persisted in 6 of 32 (18.8%) patients. Two patients reported de novo urgency, and four patients showed de novo urinary incontinence (three with stress UI and one with urge UI). None of the patients developed pelvic neoplasms.

For younger patients, an option is to place only one posterior mesh; however, it is preferable for patients to plan not to conceive again, Dr. Costantini said during a press conference. "We should always advise them about the risks of pregnancy and delivery and the need for a long-term follow-up to rule out malignant disease." ■

Robotic Surgery May Be Effective For Endometrial Cancer Staging

BY ALICIA AULT

NEW ORLEANS — Robotic-assisted laparoscopy appears to be a safe and effective, minimally invasive alternative to traditional laparotomy for treating and staging endometrial cancer, according to a small retrospective study from one institution.

Although robotic surgery conferred the same or better benefits than traditional laparotomy, it was significantly more expensive: $40,298 vs. $27,320 for laparotomy.

Dr. John P. Judd of the Ochsner Medical Center in New Orleans and his colleagues compared patients who had robotic-assisted laparoscopic hysterectomy (RALH) with staging to those who had traditional laparotomy with staging.

The laparoscopic approach has many benefits, but it also means a limited range of motion, a significant learning curve, and the ability to see in two dimensions only, said Dr. Judd, who presented his results at the annual meeting of the Society of Gynecologic Surgeons. Robotic surgery offers three-dimensional views, enhanced knot tying and suturing, and the potential for a shorter learning curve.

In the Ochsner study, there were 14 patients in the robotic group and 50 in the traditional laparotomy group. They underwent exploratory laparotomy from July 2005 to February 2008. Patients in the robotic group had significantly less blood loss than those undergoing the traditional exploratory method—148 mL vs. 300 mL. And the total operating room time also was significantly less for the robotic procedure, at 192 minutes, compared with 314 minutes.

There was a shorter total procedure time, and the average postoperative stay was only 1.8 days for the robotic groups, compared with 3.5 days for the traditional approach.

Although robotic surgery conferred the same or better benefits than traditional laparotomy, it was significantly more expensive. The total charge for robotic surgery was $40,298, compared with $27,320 for traditional surgery, he said.

Dr. Judd concluded that the benefits outweighed the costs of the robotic surgery. However, he noted, prospective trials with more patients are needed to confirm the benefits.

Dr. Judd reported no disclosures. ■