One-Year Follow-Up: Nonsurgical Approach Beneficial in SUI

Las Vegas — A nonsurgical approach to treating stress urinary incontinence that strengthens transurethral collagen by denaturing it with heat provided measurable durable improvement at 12 months, according to preliminary results from a multicenter clinical trial.

The study involved the use of the Renessa System, which was approved by the Food and Drug Administration in 2005 for the treatment of stress urinary incontinence (SUI) caused by hypermobility in women who have failed conservative care and are not candidates for surgical therapy.

“We have limited treatment options to offer women with stress urinary incontinence,” lead investigator Dr. Doug Brunk said in an interview after the study was presented during a poster session at a congress sponsored by the AAGL.

“Pelvic muscle exercises are safe but don’t work for everyone, and in practical terms, our patients are rarely compliant in the long run. Not all patients want surgery, whether it’s due to cost, time off work, or fear of anesthes- thesis and a procedure,” he said. “FDA-approved medications available to us to use for treating SUI. Renessa offers a safe option that will allow more than half of patients improvement or cure of their inconti- nence,” said Dr. Elser, who disclosed that she has been a paid consultant to Novasys Medical Inc., the manu- facturer of the Renessa System.

The system includes a small probe that the physician passes through the natural opening of the urethra. The probe heats multiple small treatment sites in the sub- mucosa of the bladder neck and upper urethra, dena- turing collagen in the tissue. Previous studies of the sys- tem have assessed its safety and initial success rates, but the current study is designed to evaluate patients at baseline and at 3, 6, 12, 18, 24, and 36 months follow- ing treatment.

Study participants included 136 women with stress urinary incontinence at 13 physician offices or ambu- latory surgery centers in the United States who had failed prior conservative treatment. Their average age was 47 years and they received pretreatment oral an- tibiotics. Of these, 29% underwent lidocaine injection.

The Renessa device was placed in the bladder and radiofrequency energy “was delivered in nine 1-minute increments, resulting in collagen denaturation of 36 cir- cumferential sites from the bladder neck to the proximal urethral submucosa,” according to the poster.

At each time point, patients answered questions on the Incontinence Quality of Life (I-QOL), the Urogen- ital Distress Inventory (UDI-6), the Patient Global Im- pression of Improvement (PGI-I) surveys, and under- went a 1-hour in-office stress pad weight test.

At baseline, the mean number of leaks per day was 2.9; the mean I-QOL score was 51.3 and the mean UDI-6 score was 52.7.

The researchers reported their 12-month results as in- tention to treat analysis because 63 of the 136 patients were lost to follow-up,” said Dr. Elser, a gynecologist who practices in Oak Lawn, Ill.

At 12 months, the mean number of leaks had dropped to 1.9 per day and 69% of patients reported a greater than 50% reduction in leaked volume on the stress pad weight test (a median reduction of 15.2 g from a baseline of 39.34 g).

“The stress pad test also indicated that 45% of women were dry. Of these, 29% had no leaks and 16% had less than 1 leak per day. This was quite promising,” Dr. Elser said.

The mean I-QOL and UDI-6 scores improved from baseline by 11.8 and 14.1 points, respectively. Results from the PGI-I indicated that 50% of patients deemed their incontinence to be “little,” “much,” or “very much” improved from baseline. No serious adverse events were reported at any time point.

Dr. Elser acknowledged that the number of patients completing the 12-month evaluation was a limitation of the study but the intent to treat analysis attempted to compensate for this.

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