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# TRANSURETHRAL RADIOFREQUENCY COLLAGEN DENATURATION (RENESSA®) FOR TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN: INTERIM UROGENITAL DISTRESS INVENTORY RESULTS OF A 36-MONTH STUDY

Hypothesis / aims of study

Transurethral radiofrequency collagen denaturation is approved by the FDA for the treatment of women with stress urinary incontinence (SUI) due to bladder outlet hypermobility. This nonsurgical procedure is performed in an office setting in about 30 minutes using local anesthesia, with most patients completing the procedure and leaving the physician's office within 1 hour. This clinical trial aimed to demonstrate its long-term effectiveness.

Study design, materials and methods

A 3-year prospective, single-arm, open-label study has thus far conducted patient evaluations at baseline and at 3, 6, 12, and 18 months following treatment at 13 physician offices or ambulatory surgery centers in the United States. Women with SUI due to bladder outlet hypermobility for at least 12 months who had failed prior conservative treatment were included. The study excluded women with urge or mixed urinary incontinence or who had prior definitive treatment (eg, incontinence surgery or bulking agents). Prior to the procedure, all patients received an oral antibiotic, an oral sedative if requested by the patient, and a local periurethral lidocaine injection. The procedure was then performed as previously described.[1,2] Efficacy assessments included patient completion of the Urogenital Distress Inventory (UDI-6),[3] a validated 6-question instrument that allows patients to rate how they experience symptoms on a scale from "not at all" to "greatly." If more than 2 questions were unanswered on any questionnaire, it was considered invalid. Longitudinal UDI-6 results up to 18 months are reported.

Results

In all, 139 women were enrolled (mean age, 47 years; age range, 26-87 years) and 136 women received treatment and were included in the intent-to-treat population. Approximately one third returned to normal daily activities within 1 day, while 91.9% of patients returned to normal activities within 2 days. Indwelling or intermittent catheterization was not required by any patient at discharge.

At baseline, the mean overall UDI-6 score was 52.5. At 6 months, 119 patients were evaluated. UDI-6 score improvement versus baseline was 17.6 points (*P*<.0001). Among 73 patients evaluated at 12 months, mean UDI-6 improvement was 14.1 points (*P*<.0001), and 62% of the women had improved UDI-6 scores. At 18 months, 59 patients were evaluated. Mean overall UDI-6 score improvement versus baseline was 13.2 points, with stress incontinence subscore improvement of 17.3 points.

**Table 1.** Change from baseline in mean UDI-6 scores in the intent-to-treat population (n=136) at 3, 6, 12, and 18 months.

| UDI-6 Measurement | Baseline | 3 mos | 6 mos | 12 mos | 18 mos | Mean Change at 18 mos* |
|---|---|---|---|---|---|---|
| Overall UDI-6 | 52.5 | 39.9 | 38.6 | 38.4 | 39.3 | −13.1 |
| Irritative Symptoms (Q1, Q2) | 51.5 | 41.4 | 36.9 | 36.3 | 37.6 | −13.8 |
| Stress Symptoms (Q3, Q4) | 83.0 | 64.7 | 65.1 | 65.6 | 65.7 | −17.3 |
| Obstructive/Discomfort (Q5, Q6) | 23.3 | 13.6 | 13.6 | 13.2 | 14.6 | −8.7 |

*All *P*<.0001 vs baseline except Obstructive/Discomfort score, *P*<.0004; P values based on paired Student *t* test. Decrease in scores indicates improvement.

Interpretation of results

Transurethral collagen denaturation showed measurable durable improvement, with no serious adverse events reported up to 18 months following treatment. This procedure is well tolerated, as evidenced by the finding that most patients returned to normal daily activities within 1 or 2 days. This nonsurgical procedure has demonstrated long-term effectiveness, as indicated by significant improvements in UDI-6 scores at all time points through 18 months.

Concluding message

Nonsurgical transurethral collagen denaturation is effective and well tolerated, and may allow women with SUI to avoid surgery or the burdensome compliance requirements of other nonsurgical therapies. Ongoing evaluation of this study population will further assess the long-term durability of this treatment.

References

1. Neurourol Urodyn 2006;25:331-335
2. Curr Med Res Opin 2007;23:1279-84

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| ***Specify source of funding or grant*** | **Study was sponsored by Novasys Medical, Inc.** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **No** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |

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|---|---|
| ***Specify Name of Ethics Committee*** | **CP-2639** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |