

COMBINED TRANS- AND PERIURETHRAL INJECTIONS OF BULKING AGENTS FOR THE TREATMENT OF INTRINSIC SPHINCTER DEFICIENCY

Aims of Study

Urethral injections of purified bovine (GAX) collagen have gained widespread acceptance in recent years for the treatment of stress incontinence caused by intrinsic sphincter deficiency. The collagen is easy to use, is administered as an outpatient procedure, and is associated with rare complications. However, initial optimism has been tempered by poor durability and the frequent need for readministration, as the collagen is degraded by the body over time (1). In response to these concerns, carbon-coated zirconium oxide beads (Durasphere™) have been increasingly used because they are nonabsorbable and therefore, permanent. However, carbon-coated beads are fraught with their own problems, including difficulty of administration and reports of bead migration (2). Both collagen and carbon-coated beads have somewhat disappointing long-term results when used alone. We hypothesize that patients who have undergone combined injections of both collagen and carbon-coated beads will have improved subjective cure rates for stress incontinence caused by intrinsic sphincter deficiency and could potentially have a more durable response to treatment. The purpose of our study, therefore, is to compare the effectiveness of transurethral GAX collagen combined with periurethral carbon-coated bead (Durasphere™) injections to transurethral GAX collagen injections alone for the treatment of stress urinary incontinence caused by intrinsic sphincter deficiency.

Methods

An IRB approved retrospective cohort study was performed comparing outcomes for women who had undergone combined GAX collagen and Durasphere™ injections to women who had undergone GAX collagen injections alone for the treatment of Type III stress urinary incontinence from January 1999 to March 2003. Demographic data, symptoms of incontinence, urodynamic indices, number of injections required, urinary retention rates, and need for further surgical intervention were compared. Results for postoperative incontinence symptoms (dry, improved, no change, or worse) were compared at 2 weeks and 6 months follow up. Statistical analysis was performed using SPSS 11.5 (SPSS Inc., Chicago, Illinois). Data were analyzed using χ^2 , Student's t-test, and Fisher's exact test where appropriate. All t-tests were 2 sided. Odds ratios were calculated with 95% confidence intervals. Significance was defined as a P-value < 0.05. A sample size calculation showed that 24 patients in the combined injection group and 48 patients in the collagen alone group would be required to detect a 30% difference in cure rates with an alpha of .10 and a beta of 0.2.

Results

74 women were included in the study: 24 had combined GAX collagen/ Durasphere™ injections and 50 had GAX collagen injections alone. The groups did not differ by mean parity, hormonal status, body mass index, degree of urethral hypermobility, or urodynamic diagnoses. Mean age was older in the collagen alone group than the combined group (72 vs. 65 years, $p = .02$). The collagen alone group required a mean of 3.2 ± 1.2 vials of collagen and the combined group required a mean of 2.8 ± 1.2 vials of collagen and 2.9 ± 1.1 vials of Durasphere™ to achieve a negative intraoperative cough stress test. Postoperative urinary retention was more common in the combined group (33.3% vs. 2.0%, $p < .001$, OR= 6.8 (95% CI {1.1, 43.3}). The combined group underwent fewer subsequent anti-incontinence procedures after the index urethral injection than the collagen alone group (16.7% vs. 51%, $p = .005$), but mean follow up was shorter in the combined group than in the collagen alone group (22.8 ± 15.5 weeks vs. 66.3 ± 48.5 , $p < .005$). The percentages of patients improved or cured at 2 weeks and 6 months by injection type are presented below:

Table 1 – Outcomes of patient symptoms at 2 weeks and 6 months by injection type

Improved or cured	Combined weeks 2	Collagen weeks 2	Combined months 6	Collagen months 6
Overall incontinence	87.5%	84.0%	66.7%	51.1%
Stress incontinence	91.7%	84.0%	72.2%	55.3%
Urge incontinence	70.0%	79.6%	56.2%	63.0%

*No differences statistically significant

Conclusions

In our short follow-up, combined GAX collagen and Durasphere™ injections did not statistically significantly improve symptom outcomes compared to GAX collagen injections alone. Longer follow-up is needed.

References

1. Tschopp PJ, Wesley-James T, Spekkens A, et al. Collagen injections for urinary stress incontinence in a small urban urology practice: time to failure analysis of 99 cases. J Urol 1999;162:779
2. Pannek J, Brands FH, Senge T. Particle migration after transurethral injection of carbon coated beads for stress urinary incontinence. J Urol 2001;166(4):1350-3