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ORIGINAL ARTICLE

Long-term subjective continence status and use of alternative treatments by women with stress urinary incontinence after collagen injection therapy

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Abstract This study examined subjective continence status and use of subsequent alternative therapeutic procedures at long-term follow-up after collagen injection for stress incontinence (SI) in women. Seventy women who underwent collagen injection for SI were identified by retrospective chart review and surveyed by mail questionnaire for subjective continence status, daily pad usage pre- and post-treatment, and use of anticholinergics and alternative procedures. Questionnaire responders' versus non-responders' mean age, follow-up, and pad usage were compared. Thirty-three women (47%) responded on questionnaires. Of the 33, 50% were dry or subjectively improved at long-term follow-up and 91% had not chosen an alternative invasive treatment after collagen injection. Chart review showed responders were not significantly different from non-responders in mean age (65.9 vs. 69.2 years), pad usage (0.6 vs. 0.8 pads/day), or follow-up (4.5 vs. 4.3 years). Collagen injection, a minimally invasive treatment for SI, appears to benefit a significant number of women.

Keywords Bladder · Collagen injection therapy · Incontinence · Stress · Women

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Introduction

Urinary incontinence is a common medical problem affecting over 25 million people in the United States. Stress urinary incontinence (SUI) is an involuntary loss of urine without detrusor activity. It has been classified as type I, II and III [3]. In type I and II SUI, the bladder neck and the proximal urethra are closed at rest and descend with increase in abdominal pressure, defined as urethral hypermobility. In type III SUI, commonly referred to as intrinsic sphincter deficiency, the bladder neck is open at rest.

Treatment of SUI has varied from conservative treatment such as pelvic floor muscle reeducation to invasive procedures such as retropubic urethropexy and pubovaginal sling. Transurethral injection of bulking agents such as collagen has been used to treat patients with intrinsic sphincter deficiency, as outlined by Medicare policy followed by private insurers. Collagen injection has recently been concluded to be effective in patients with urethral hypermobility [2]; however, and is a viable option in patients who are not able to or are not willing to undergo surgery. It can be done in the office with local anesthetic and has no permanent complications.

The long-term effectiveness of collagen injection in patients with intrinsic sphincter deficiency has varied from 43 to 77%, and can require more than one injection [1, 5, 6]. Because most patients require multiple and repeated injections, with only limited effectiveness, collagen injection has not been regarded as the gold standard of treatment for SUI.

The purpose of our study was to examine the long-term subjective improvement of the patients who elect to have this treatment. More importantly, the objective of the survey was to determine how many of the patients who underwent collagen injection had sought alternative treatments for their incontinence at long-term follow-up.

Methods

One hundred and six female patients underwent collagen injection to treat urinary incontinence from 1993 to 1999. All the patients were classified as type I, II or III SUI based on clinical examination and urodynamic findings by a single urologist (JSW). The charts were reviewed for previous anti-incontinence surgeries. Contigen (Bard) was injected submucosally at the bladder neck. Institutional review board approval was obtained for this questionnaire study.

Addresses of 81 patients were available and questionnaires were sent to these patients. The questions asked the patients to indicate the amount of leakage since the collagen injection, the number of pads the patient currently wears per day, whether they have undergone any surgery since the collagen injection, and whether they take any anticholinergics. Eleven of the patients were found to be deceased or not at the available address. Seventy patients either did or did not reply. Their charts were reviewed for the mean follow-up time and the post-injection continence status (based on reported number of pads per day). If the patient underwent multiple injections, the number of pads after the last injection was considered the indicator of post-injection continence status. These patients were divided into two groups: one that returned the questionnaire (R) and one that did not (NR). Their age, the mean follow-up time, and the post-injection continence status were compared to determine whether the two groups differed. These data were assessed at the most recent clinic visit for both groups except for the post-collagen number of pads used. In the R group, the number of pads reported in the survey was analyzed. In the patients who returned the questionnaire, the numbers of pads used pre-operatively and currently were compared. Their subjective continence status, the number of patients who underwent alternative procedures and the number of patients who reported using anticholinergics were assessed.

Results

The 106 patients who underwent collagen injection were classified as the following types: I, 22 (21%); II, 32 (30%); and III, 52 (49%). Sixteen patients (15%) had detrusor instability based on urodynamic studies and physical exam by one surgeon (JSW). Thirty-four of the patients (32%) underwent anti-incontinence surgery before collagen injection.

Eleven letters were returned secondary to patients' death or wrong addresses. Of the other 70 patients, 33 patients (47%) replied (Group R) and 37 (53%) did not (Group NR). Between the R and NR groups, no significant differences were found in age (65.9 and 69.2 years old), post-injection continence status based on the post-collagen number of pads used (0.6 and 0.8 pad per day), or the number of years post-injection (4.5 and 4.3 years).

Of the 33 patients in Group R, 3 (9.1%) subsequently had undergone alternative procedures, two a "sling procedure" and one a Raz urethropexy. The majority of patients in Group R, a total of 30, did not proceed to more alternative treatments.

Of the 30 Group R patients who did not undergo alternative procedures after collagen injection, 3 (10%) reported they never leaked, 12 (40%) reported leaking less than before the collagen, 8 (26.7%) reported leaking the same amount as before the collagen, and 7 (23.3%) reported leaking more since the collagen (Table 1). There was no significant difference in the average number of pads used in Group R pre-injection and post-injection (3 vs. 2 per day, respectively). Eight Group R patients (24.2%) reported using supplemental anticholinergics after the collagen treatment.

Discussion

Urethral collagen injection is an acceptable therapy for women with SUI. Several studies have evaluated the effectiveness and the longevity of the treatment. The longest period of follow-up reported in the literature is 24 months [4]. Although the outcome of the treatment is assessed in a very subjective way, the average follow-up period for the patients in our survey is over 4 years. In addition, no other study has quantified the number of patients who wish to seek alternative treatment after collagen therapy. Because of the morbidity associated with the available alternative treatments (i.e., surgery), many of our patients who failed the collagen treatment did not choose to have further treatments.

There are several shortcomings in our study, which are inevitable in survey-based studies. First, the questionnaire response rate was very low, possibly because most of the patients were elderly and may have been deceased at the time we conducted the survey. Second, the follow-up is not a comprehensive follow-up and many of the patients who did not respond to our survey may have sought other treatments. Third, the assessment of the outcome was subjective and did not employ other objective tools currently available.

Table 1 Long-term subjective results after collagen injection in patients who did not undergo alternative treatments

Result	No. of patients (%)
Never leak	3 (10%)
Leak less than before the collagen	12 (40%)
Leak the same amount as before the collagen	8 (26.7%)
Leak more since the collagen	7 (23.3%)

Despite the deficiencies of the study, assessment at an average of over 4 years after collagen injection indicated that half of the patients had improvement or cure. In contrast to the rate of subjective improvement we found; however, the numbers of pads pre- and post-injection were not different. The subjective improvement rather than the objective improvement may account for the fact that so few of our patients sought more invasive treatments.

Some of the patients who had not elected to undergo more invasive procedures at the time of this survey may eventually do so. Because our follow-up period is fairly long; however, we can confidently say that patients who have chosen minimally invasive therapeutic procedures for their incontinence usually do not seek more invasive procedures for their problem, even if they have persistent symptoms. Moreover, we found that the majority of patients who sought additional therapy after collagen injection elected to receive less invasive medical therapy for overactive bladder (anticholinergics) rather than any other surgical therapy for their incontinence.

Conclusions

Urethral collagen injection is an acceptable first line of therapy for women with SUI. Of the patients who choose this therapy, most have not elected to undergo more invasive surgeries for their urinary incontinence even several years after the collagen injection. Moreover, subjective outcome assessment after a long-follow-up period indicates that approximately half of the patients do not leak or are improved with this therapy.

References

1. Benshushan A, Brzezinski A, Shoshani O et al (1998) Periurethral injection for the treatment of urinary incontinence. Obstet Gynecol Surv 53:383
2. Bent AE, Foote J, Siegel S et al (2001) Collagen implant for treating stress urinary incontinence in women with urethral hypermobility. J Urol 166:1354
3. Blaivas JG, Olsson CA (1988) Stress incontinence: classification and surgical approach. J Urol 139:727
4. Gorton E, Stanton S, Monga A et al (1999) Periurethral collagen injection: a long-term follow-up study. BJU Int 84:966
5. Kim YH, Kattan MW, Boone TB (1997) Correlation of urodynamic results and urethral coaptation with success after transurethral collagen injection. Urology 50:941
6. Smith DN, Appell RA, Winters JC et al (1997) Collagen injection therapy for female intrinsic sphincteric deficiency. J Urol 157:1275