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An Exploration into Patient Preference for Injectable Therapy over Surgery in the Treatment of Female Urinary Incontinence

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ABSTRACT

Objective: To explore patient preference for injectable therapy over open surgery in the treatment of urinary incontinence.
Material and Methods: Fifty-eight female patients presented for treatment of urinary incontinence. During the initial interview process, they were asked to quantify their preference for injectable therapy over surgery by specifying the lowest success rate they would accept and still try injectable therapy. The results were summarized and assessed in relation to patient age and history of previous urogynecologic surgery.
Results: The mean lowest acceptable success rate for all 58 surveyed patients was 34%, with 23 (40%) accepting a success rate of only 10%. Although not statistically significant, the data suggested that older patients may tend to accept lower success rates than younger patients (mean of 39% for patients aged less than 60 years compared to 22% for those aged 80 years or older). There was no difference in response based on history of previous urogynecologic surgery.
Conclusion: Patients appear willing to accept a relatively low success rate for injectable therapy compared to open surgery.

Key words: urinary incontinence, stress; injections; patient preference; survey
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INTRODUCTION

The treatment of female stress urinary incontinence includes multiple appropriate options ranging from pelvic floor rehabilitation to open surgical procedures. However, it is intuitive that patients will choose a less invasive treatment to minimize their convalescence. This explains the appeal of periurethral bulking agents. Unfortunately, the success rates of injectable therapies have been less than those obtained with surgical procedures (1,2). Nevertheless, a common perception is that patients, if offered injectable agents, will continue to be interested in this option and will be accepting its lower success rate. We attempted to explore this thought and to quantify the success rate of injectable therapy with a bulking agent that patients would consider acceptable.

MATERIALS AND METHODS

We interviewed 58 successive incontinent female patients newly presenting to the Department of Urology during a 6-month period. The patients were asked the following question orally by the attending urologist: “If it is determined that you may benefit from either surgical therapy, which is approximately 90% successful but requires postoperative convalescence, or an injectable therapy with a minimal postoperative convalescence, what is the

lowest success rate that you would accept and still try injectable therapy with an unspecified agent?" If patients had queries regarding the injectable therapy or surgery, every effort was made to respond in an unbiased and nonpersuasive manner. It was intimated that both procedures would be completed under general anesthesia. At the time of the questioning, the patients had not been categorized as having stress urinary incontinence, urinary urge incontinence, overactive bladder symptoms, or mixed urinary incontinence. Furthermore, patients were queried near the beginning of their consultation in order to limit potential physician bias and evaluation impact. The patients were asked to respond in increments of 10% success rates, ranging from 0% to 100% (i.e., a 10% success rate, a 20% success rate, etc.).

Wilcoxon's rank sum test was used to compare responses between patients with and without previous urogynecologic surgery, and Spearman's rank correlation test was used to investigate a possible association with age. The Institutional Review Board approved this study.

RESULTS

The patients' mean age was 70 years (range: 31-95 years). Eighteen patients (31%) had previous anti-incontinence or prolapse repairs: injectable therapy with carbon-coated zirconium oxide beads (2 cases), injectable therapy with collagen (3 cases), pubovaginal sling with autologous fascia (3 cases), suburethral sling with non-autologous material (1 case), Burch colposuspension (1 case), Marshall-Marchetti-Krantz urethropexy (2 cases), and pelvic prolapse surgery (6 cases).

The mean lowest acceptable success rate was 34%. Twenty-three of the 58 patients (40%) would accept a success rate of 20% or less and still undergo the minimally invasive procedure, whereas another 40% would require a success rate of 50% or greater. There was no evidence of any tendency for different responses in patients with a history of previous anti-incontinence procedure or pelvic prolapse surgery compared to those without ($P = 0.54$). Although not statistically significant, the data suggested that older patients may have a tendency to accept lower rates than younger patients (Spearman's rank correlation: -0.23; $P = 0.08$). The patient responses are displayed in Figure-1, by age and by history of previous surgery. Mean lowest acceptable success rates by age group were 39%, 38%, 35% and 22% for ages < 60, 60-69, 70-79 and 80 + years respectively.

Five of the 58 patients had prior experience with bulking agents. Three (two aged 79, one aged 75) had experience with injectable collagen and indicated that their lowest acceptable success rates were 10%, 30%, and 30%. The other two (aged 50 and 68) had experience with Durasphere injectable bulking agent (Advanced UroScience, Inc, St. Paul, Minnesota); their lowest acceptable success rate was 50%. These data provide no suggestion that patients with prior experience with injectable bulking agents differed in their preference levels from those without, but in view of the small numbers, no valid conclusion can be made from this sample.

COMMENTS

None of the available bulking agents, including bovine cross-linked collagen and carbon beads, have duplicated the success rates obtained with open anti-incontinence surgical procedures (1,3). However, injectable therapy has an inherent attractiveness, given its minimally invasive nature, ease of administration, and acceptable short-term results. Hence, injectable treatments continue to be offered either as first line or second line therapies or as the only medically tolerable procedure for patients who are infirm or fearful of surgery (3,4). Bulking agents are decried for their lack of comparable success rates, but the trade-off for the patient has been studied little.

Our results from this early exploratory study suggest that many patients are likely to accept a vastly lower success rate for injectable therapy over a more morbid open surgical procedure; for example, 19 of the 58 patients (33%) were willing to accept only a 10% chance of success (Figure-1). Although this result is initially surprising, it parallels the findings by Robinson et al. (5), who examined what

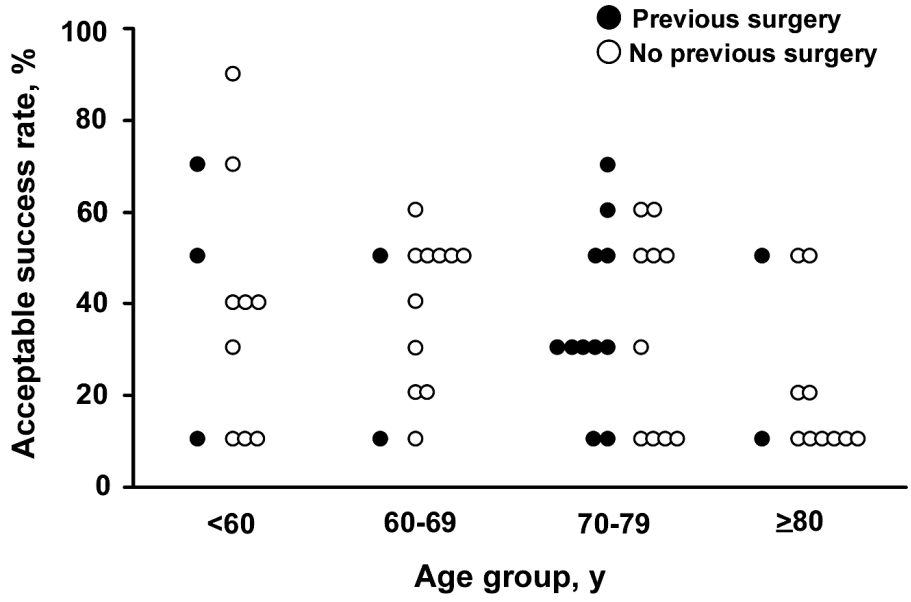

Figure 1 *– Patients' lowest acceptable success rates for injectable therapy among 58 patients with or without a history of previous urogynecologic surgery. The patients provided these rates in response to an initial interview question during evaluation for urinary incontinence.*

women perceive as a cure and, as we did in the present study, assessed patient tolerability of loss of efficacy if coupled with a reduction in morbidity. Those authors found that 38% of the women surveyed were willing to accept a minor operation if there was an 85% chance of a cure and that 57% would tolerate a 60% improvement rate if the intervention was only a clinical procedure (5). In addition, Karantanis et al. (6), in a study that analyzed women's preferences for treatment of stress urinary incontinence, noted that 66% of the women preferred pelvic floor treatment, 24% chose the tension-free vaginal tape (TVT) procedure, and 9% desired open colposuspension. Although Karantanis et al. did not include injectable therapy as a treatment option, their findings of a strong patient preference for less invasive therapies must be given an enhanced consideration in view that they used carefully written explanations and instructions to minimize potential bias. These findings above mirrored our conclusions that many patients prefer a minor procedure with a lower risk of complications but are also content to accept the accompanying trade-off of a lower success rate (5,6).

During the interview process, the study question was kept deliberately generic with regard to the specific injectable substance in order to eliminate potential patient bias based on experience or knowledge. Although the method of questioning did not involve a validated instrument, the query was simple, to the point, and suitable for an early exploration into this topic. In addition, we did not select patients to include or exclude based on type of incontinence because we wanted to explore general preference for therapies; after evaluation and surgical selection, the population would potentially be biased and possibly less representative of the unadulterated general population. The refining of the study group by evaluating first and asking second is a compelling idea, but we chose the alternative to avoid potential instillation of bias by the attending urologist concerning case specific therapeutic options. A potential weakness of the study is that the query was oral. A written form with descriptive and question

portions would have possibly limited potential bias even further.

Patients' perception of injection therapy as being nonsurgical may influence these results. This distinction between injection and operative procedures may be blurred and difficult to accept for a surgeon seeking an efficient end to a course of care; consequently, while reviewing options with the patient, a surgeon may present an unrecognized bias toward operative repair because of the current remarkable rapidity with which newer sling procedures are performed as opposed to the injectable therapeutic pathway that might entail repeated visits, injections, and ultimately an operative procedure in a moderate percentage of patients. A patient's preference should be understood as potentially different from the surgeon's. Robinson et al. (5) noted that only 23% of their study group found a major operation acceptable, even one that had an 85% cure rate, whereas Karantanis et al. (6) found that the women they studied preferred a TVT procedure over an open colposuspension by nearly 3 to 1.

If one accepts the tenet that few patients really want to have an elective surgical procedure, one may embrace injectable therapy as a definite step in the treatment of incontinence, regardless of success rates. Surgeons often abandon a procedure that is not perceived as being overly successful. However, perhaps instead of avoiding injectable therapy because of perceived ineffectiveness and potential inefficiency, one should remember the high degree of patient acceptance for an intervention that requires essentially no effort or assumed risk on the part of the patient. It will be of great future interest to see if these initial findings are mirrored in a large sample study in other voiding dysfunction studies, such as those involving diet and overactive bladder (7).

Although this exploration has concluded, it did alert us to the great preference of patients for therapies that are not surgical and piqued our interest into further inquiries of a similar nature. It may be of value to perform a study in the same manner as Karantanis et al. (6) to stratify patient preference for degrees of invasiveness, such as among injectable therapy, transobturator technique, and autologous fascial sling, and the reasons for same. We are currently in the early stages of formulating a written questionnaire to quantify patient preference in the reciprocal situation: how high a success rate has to be for a patient to choose an invasive operation. Although the permutations and criticisms of this question will be inspiring (i.e., minimally invasive vs. open surgery, transobturator vs. pubovaginal), the results will assist the entire field in the development of newer techniques and technologies.

CONCLUSION

Many patients are likely to accept a markedly lower rate of success with injectable therapy than with open surgery. There is no evidence that age and previous operative failure have a clinically significant effect on patients' desire to prefer injections. Injectable therapy is an option that is attractive to patients, as evidenced by their willingness to accept this form of treatment despite its potentially extremely low success rate.

CONFLICT OF INTEREST

None declared.

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