UROGYNECOLOGY

Medium-term comparison of continence rates after rectus fascia or midurethral sling placement

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OBJECTIVE: The purpose of this study was to compare continence rates after placement of rectus fascia or midurethral slings.

STUDY DESIGN: We performed a retrospective cohort study of 242 women who underwent rectus fascia (n = 79) or midurethral (n = 163) sling procedures to treat urinary incontinence. Outcome was based on responses to validated questionnaires and need for interim treatment for incontinence. Survival free of incontinence was estimated using the Kaplan-Meier method. Associations between patient factors and survival free of incontinence were evaluated by fitting Cox proportional hazards models.

RESULTS: Women with rectus fascia slings were more likely to report any leakage of urine ($P = .04$) and were 13 times more likely to require urethrolysis ($P < .001$) than patients with midurethral slings. Patient satisfaction was lower in the rectus fascia sling group compared with the midurethral sling group ($P = .01$).

CONCLUSION: Midurethral slings appear to be more effective than rectus fascia slings and are less likely to cause postoperative voiding complications.

Key words: polypropylene, rectus fascia sling, tension-free vaginal tape, urinary incontinence

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Autologous rectus fascia slings (hereafter termed "autologous slings") have long been considered the standard procedure for management of stress urinary incontinence (SUI) because of their efficacy and durability.[1] Continence rates for this procedure exceed 75% at 6 years.[2] The main disadvantages with autologous slings, however, are prolonged operative time and increased morbidity associated with fascia harvest and postoperative voiding dysfunction.[3] Although xenografts and cadaveric allografts are used to overcome limitations associated with fascia harvest, these materials yield inferior results when compared with autologous fascia.[2,4]

Polypropylene midurethral slings, developed in the mid 1990s, revolutionized the treatment of SUI.[5] Sling placement is minimally invasive, and noncomparative trials showed that the long-term cure rates were similar to those of autologous slings.[1,2,6-8] The main shortcomings of midurethral slings are bladder perforation and mesh erosion, but both occur infrequently (< 5% of patients) and are remedied easily.[9]

Although midurethral slings theoretically are associated with less morbidity (requires no fascial harvest), no studies have shown that they are superior to the autologous sling. In a randomized clinical trial of 53 patients, Wadie et al[10] reported no difference in cure rates at 6 months for women treated with tension-free vaginal tape or autologous slings. Bai et al[11] observed no difference in cure rates at 3 and 6 months among 92 women with SUI who were randomized to undergo treatment with Burch colposuspension, autologous sling, or tension-free vaginal tape. However, women in the autologous sling group had a higher cure rate at 1 year ($P < .05$). Small sample sizes, nonstandardized follow-up care, lack of well-defined outcome criteria, masked outcome assessment, and short follow-up periods limit the interpretation of these studies.

To more rigorously compare the 2 procedures, we conducted a large, historical, cohort study of 242 women. We compared the medium-term urinary continence rates among women treated with an autologous sling or a midurethral sling. We hypothesized that women with an autologous sling would have lower incontinence rates than women treated with a midurethral sling.

Materials and Methods

This study was approved by the Mayo Clinic Institutional Review Board (Rochester, MN). Since the introduction of midurethral slings to our institution in 2002, the procedure has gained significant popularity. Nevertheless, 1 urolo-

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gist continued to use autologous slings as the primary operation for urinary incontinence. The continued use of autologous slings after the introduction of midurethral slings allowed comparison of 2 historical cohorts while minimizing the selection bias that would normally confound comparison of an uncontrolled series. Furthermore, the study design allowed us to compare surgical techniques that are difficult to assess prospectively.

We used a surgical database to identify all women who underwent placement of an isolated autologous sling or a midurethral sling without concomitant pelvic floor repairs from Jan. 1, 2000, through Sept. 30, 2005. Patient characteristics, history, physical examination findings, urodynamic test results, and operative reports were extracted from the electronic medical records. The medical records showed all clinical and surgical encounters, including phone conversations, at all Mayo Clinic sites in Rochester, MN, from 1993 to the present.

Patients were mailed validated questionnaires and asked to participate in the study. Eligible patients were at least 21 years old; had documented urinary incontinence (shown by urodynamics testing or preoperative examination); had undergone surgery for SUI or stress-predominant, mixed urinary incontinence (MUI); and had surgery at least 1 year before the study began. Patients with preexisting neurologic disease (eg, multiple sclerosis, spinal cord injury, or Parkinson disease), urethral diverticulectomy, urethral reconstruction, severe pelvic trauma or fracture, or concurrent pelvic organ prolapse repair were excluded.

Surgical procedures and catheter use

The rectus fascia was harvested through a Pfannenstiel incision. Permanent sutures were secured to the ends of a 10- × 2-cm strip of the rectus fascia and passed from the vagina to the abdomen using Stamey needles. The fascial strip was placed at the bladder neck/proximal urethra, and permanent sutures were tied loosely above the rectus fascia.

A polypropylene mesh kit (Uretex Urethral Support System; Bard Urological, Covington, GA) was used exclusively for patients in the midurethral sling group. The procedure was performed as described by Ulmsten and Petros[5] and as recommended by the manufacturer.

Suprapubic catheters were used for all patients. The suprapubic catheter routine was similar for patients in both groups.

Data extraction

To standardize comparisons between groups, MUI and SUI diagnoses were assigned during the review of the final clinical note before the index surgery. We used International Continence Society Standardization of Terminology[12] definitions for SUI (". . . complaint of involuntary leakage on effort or exertion or on sneezing or coughing") and MUI (". . . complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing"). Patients who reported urgency, with or without urge incontinence, were classified as having MUI.

The operative report for each surgery was reviewed to confirm the procedure(s) performed and to ascertain intraoperative complication(s) and estimated blood loss. Furthermore, hospital dismissal summaries and records of all patient contact from dismissal through the 6-week postoperative visit (including phone conversations and emergency department or office visits) were reviewed to determine the incidence of short-term complications.

Outcome assessment

Outcome data were obtained from responses to mailed questionnaires and from review of the electronic medical records. The following assessment tools were used: Incontinence Severity Scale (ISS),[13] the Patient Global Impression of Improvement questionnaire (PGII),[14] the Urinary Distress Inventory-6 (UDI-6), and the Incontinence Impact Questionnaire (IIQ-7).[15] Patients who responded "yes" to the question "Do you regularly leak urine?" were asked to estimate the month and year of symptom onset.

Three outcomes were assessed. Patients were considered to have "any incontinence" if they underwent a subsequent surgery for urine leakage after the index surgery or if they reported persistent leakage of urine at follow-up (eg, ISS score > 0). "Severe incontinence" was defined as an ISS score of 6 or higher.[13] The ISS is a global index that does not differentiate between stress- and urge-related leakage. Since patients were not expected to have improvement in urge-related symptoms after these procedures, "stress-specific incontinence" was determined by assessing how leakage usually occurred.

Patient satisfaction was defined as a response of "completely satisfied" or "somewhat satisfied" on a 5-point Likert scale (range, "completely satisfied" to "completely dissatisfied"). Strong improvement of urinary symptoms after surgery was measured by a response of "a great deal better" or "much better" in the PGII scale (a 7-point Likert scale with responses spanning from "a great deal better" through "a great deal worse"). Patients were considered to have clinically significant urgency or frequency, urge incontinence, or voiding dysfunction at follow-up if they indicated scores of 2 ("moderate") or 3 ("severe") to questions 1 ("frequent urination"), 2 ("urine leakage related to feeling of urgency"), or 5 ("difficulty emptying the bladder") of the UDI-6.

Statistical analysis

All analyses were performed using SAS version 8.2 (SAS Institute, Cary, NC). To compare baseline patient characteristics, we used the Wilcoxon rank-sum test for ordinal or continuous variables and the χ^2 test or Fisher exact test for categorical variables. We considered age, number of previous incontinence procedures, preoperative diagnosis (MUI vs SUI), body mass index (BMI), presence of intrinsic sphincter deficiency (ISD; defined as abdominal leak point pressure $\leq$ 60 cm H_2O), medical history, smoking history, and race. In addition, we summarized estimated blood loss during surgery, duration of catheterization, and intraoperative complication rates.

The cumulative incidence of incontinence (any, severe, and stress-specific incontinence) was calculated for each co-

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