5-Year Longitudinal Followup after Retropubic and Transobturator Mid Urethral Slings

Kimberly Kenton,*,† Anne M. Stoddard,‡ Halina Zyczynski,§ Michael Albo,§ Leslie Rickey,‖ Peggy Norton,§ Clifford Wai,§ Stephen R. Kraus,¶ Larry T. Sirls,** John W. Kusek,§ Heather J. Litman,§ Robert P. Chang†† and Holly E. Richter‡‡

From Northwestern University, Chicago, Illinois (KK), New England Research Institutes, Watertown (AMS, RPC), and Boston Children's Hospital, Boston (HJL), Massachusetts; University of Pittsburgh, Magee-Women's Research Institute, Pittsburgh, Pennsylvania (HZ); University of California San Diego, San Diego, California (MA); Yale University, New Haven, Connecticut (LR); University of Utah, Salt Lake City, Utah (PN);University of Texas Southwestern, Dallas (CW), and University of Texas Health Sciences Center at San Antonio, San Antonio (SRK), Texas; William Beaumont Hospital, Royal Oak, Michigan (LTS); National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland (JWK); and University of Alabama at Birmingham, Birmingham, Alabama (HER) for the Urinary Incontinence Treatment Network

Purpose: Few studies have characterized longer-term outcomes after retropubic and transobturator mid urethral slings.

Materials and Methods: Women completing 2-year participation in a randomized equivalence trial who had not undergone surgical re-treatment for stress urinary incontinence were invited to participate in a 5-year observational cohort. The primary outcome, treatment success, was defined as no re-treatment or self-reported stress incontinence symptoms. Secondary outcomes included urinary symptoms and quality of life, satisfaction, sexual function and adverse events.

Results: Of 597 women 404 (68%) from the original trial enrolled in the study. Five years after surgical treatment success was 7.9% greater in women assigned to the retropubic sling compared to the transobturator sling (51.3% vs 43.4%, 95% CI −1.4, 17.2), not meeting prespecified criteria for equivalence. Satisfaction decreased during 5 years but remained high and similar between arms (retropubic sling 79% vs transobturator sling 85%, p=0.15). Urinary symptoms and quality of life worsened with time (p <0.001), and women with a retropubic sling reported greater urinary urgency (p=0.001), more negative impact on quality of life (p=0.02) and worse sexual function (p=0.001). There was no difference in the

Abbreviations and Acronyms

KM = Kaplan-Meier

MESA = Medical, Epidemiological and Social Aspects of Aging

MUS = mid urethral sling

QOL = quality of life

SUI = stress urinary incontinence

Accepted for publication August 14, 2014.

Study received institutional review board approval at each participating clinical site.

Supported by NIH NIDDK 1U10 DK60379-01.

* Correspondence: 250 E Superior St., Suite 05-2370, Prentice Women's Hospital, Northwestern University Feinberg School of Medicine, Chicago, Illinois 60611 (telephone: 312-472-3874; FAX: 312-472-3690; e-mail: kimberly.kenton@northwestern.edu).

† Financial interest and/or other relationship with the National Institutes of Health.

‡ Financial interest and/or other relationship with Proctor and Gamble, Johnson & Johnson, GlaxoSmithKline and Bristol-Myers Squibb.

§ Nothing to disclose.

‖ Financial interest and/or other relationship with Pfizer, UpToDate and NIH.

¶ Financial interest and/or other relationship with SUFU, Drugs & Aging, BMC Urology, Allergan and Laborie Medical.

** Financial interest and/or other relationship with Johnson & Johnson and AMS.

†† Financial interest and/or other relationship with New England Research Associates.

‡‡ Financial interest and/or other relationship with Society of Gynecologic Surgeons, Pelvalon, Kimberly Clark and UpToDate.

Editor's Note: This article is the fourth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 378 and 379.

0022-5347/15/1931-0203/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2014.08.089
Vol. 193, 203-210, January 2015
Printed in U.S.A.

proportion of women experiencing at least 1 adverse event (p=0.17). Seven new mesh erosions were noted (retropubic sling 3, transobturator sling 4).

Conclusions: Treatment success decreased during 5 years for retropubic and transobturator slings, and did not meet the prespecified criteria for equivalence with retropubic demonstrating a slight benefit. However, satisfaction remained high in both arms. Women undergoing a transobturator sling procedure reported more sustained improvement in urinary symptoms and sexual function. New mesh erosions occurred in both arms over time, although at a similarly low rate.

Key Words: urinary incontinence, stress; suburethral slings

Mid urethral slings are the most commonly performed surgeries for women with stress urinary incontinence. Approximately 200,000 SUI surgeries are performed annually in the United States, increasing 27% from 2000 to 2009.[1,2] Most of this increase is attributed to sling procedures.[3] Insufficient information is available regarding the long-term success and safety of MUS procedures as most previous clinical trials reported outcomes only at 1 to 2 years, and did not include physical examinations in the followup.

Failure rates increase with time for most SUI procedures.[4,5] Whether this is due to surgical failure or the natural history of incontinence with aging is unclear. Complications of SUI surgery, including urgency urinary incontinence, urinary tract infections and mesh related problems, may have a long-term impact on patient satisfaction and QOL. The Food and Drug Administration issued warnings about the use of mesh for prolapse and SUI surgery due to a lack of information regarding longer term outcomes. Mesh related complications can occur up to 5 years postoperatively.[5,6] Few prospective studies report long-term outcomes after MUS in a comparative fashion using validated symptom and QOL questionnaires and physical examination, which are essential for evaluating mesh complications.[5,7–9] Even fewer randomized trials compare continence outcomes and mesh complications between retropubic and transobturator slings with followup longer than 2 years.[10]

We previously reported 1 and 2-year outcomes of a randomized equivalence clinical trial of retropubic and transobturator MUS in women with SUI.[11,12] We report 5-year outcomes including treatment success, satisfaction, urinary symptoms, QOL and adverse events in women who completed the TOMUS (Trial of Mid-urethral Slings) and were enrolled in this observational cohort study.

METHODS

Study Design

Details of design and 1-year (primary outcome) and 2-year outcomes of the randomized equivalence trial of retropubic and transobturator MUS have been published (NCT00325039).[11,12] Women completing the trial who did not undergo surgical re-treatment for SUI were invited to participate in the observational study to assess 5-year treatment success, satisfaction, symptom specific distress, QOL and adverse events of MUS. Institutional review boards at each participating institution approved the observational followup study protocol. Participants provided written consent for participation in followup.

Outcomes

The primary outcome of treatment success was defined as no re-treatment for SUI (behavioral, pharmacological, pessary or surgical) and no self-reported SUI symptoms on the MESA questionnaire.[13] An answer of never or rarely to all stress specific questions was considered negative symptoms. Secondary outcomes included the Urogenital Distress Inventory and the Incontinence Impact Questionnaire.[14] Women also completed the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire[15] to assess sexual function, the Patient Global Impression of Improvement[16] to assess overall improvement, and 1 item satisfaction question, "How satisfied or dissatisfied are you with results of bladder surgery related to urine leakage?". Possible responses were completely satisfied, mostly satisfied, neutral, mostly dissatisfied and completely dissatisfied. Completely and mostly satisfied were reported as satisfied. Neutral, mostly dissatisfied and completely dissatisfied were reported as not satisfied.

Pelvic examinations were performed at annual visits to assess for visual and palpable evidence of mesh exposure, and to associate patient symptoms with physical findings. Prolapse was assessed using the Pelvic Organ Prolapse Quantification system.[17] Participants who were not seen in-person could mail in the completed questionnaires.

Adverse events were defined as deviation from normal postoperative followup and severity grade determined with modified Clavien-Dindo classification, which is based on level of therapy required to treat an event.[18] Nonserious adverse events (grades I and II) did not require surgical, endoscopic or radiological intervention. Serious adverse events required such intervention (grade III), were life threatening (grade IV) or resulted in death (grade V). Several adverse events were collected during the cohort study such as mesh exposure (mesh visualized in the vagina), mesh erosion (mesh erosion after primary healing into a nearby organ), vesical and urethral-vaginal fistulas, and recurrent urinary tract infections defined as 3 or more in 1 year.