Therapeutic Durability of the Male Transobturator Sling: Midterm Patient Reported Outcomes

Hanhan Li, Bradley C. Gill, Amy S. Nowacki, Drogo K. Montague,* Kenneth W. Angermeier,* Hadley M. Wood and Sandip P. Vasavada†,‡

From the Cleveland Clinic Lerner College of Medicine, Case Western Reserve University (HL, BCG, ASN, DKM, KWA, HMW, SPV), and Glickman Urological and Kidney Institute, Cleveland Clinic Foundation (DKM, KWA, HMW, SPV), Cleveland, Ohio

Purpose: The male transobturator AdVance™ sling is a viable option for mild to moderate post-prostatectomy incontinence. As this treatment is relatively new, our study provides an analysis of efficacy through patient reported outcomes and pad use.

Materials and Methods: A telephone survey and chart review were conducted on all patients receiving a sling before 2010 by either of 2 surgeons at a large academic institution. The survey included the Patient Global Impression of Improvement and Severity instruments, pad use characteristics before and after sling surgery, and items assessing durability of efficacy. Patient determined (subjective) success was very much or much better on the Patient Global Impression of Improvement without subsequent incontinence therapy. Quantitative success was defined as a decrease to 2 or fewer pads per day. We assessed therapeutic durability in a subanalysis of patients interviewed twice, first in a prior study.

Results: From initial office followup to 2 years, quantitative success decreased from 87.3% to 62.5% and pad use doubled from a mean ± SD of 0.8 ± 1.7 to 1.7 ± 2.5 pads per day. Patient determined success was 53.6% at 2 years. A subgroup of 25 patients interviewed at 7 and 29 months after sling surgery had quantitative success significantly decrease by 20% ($p = 0.03$), subjective success decrease by 4% ($p = 0.56$) and pad use significantly increase ($p = 0.01$) from 1.4 ± 2.2 to 2.3 ± 3.2 pads per day.

Conclusions: Most patients receiving the AdVance sling did see improvement in post-prostatectomy incontinence and a decrease in pad use, but in 20% of patients this benefit decreased with time. Nevertheless, patients remained satisfied and perceived the treatment as successful.

Key Words: prostatectomy; urinary incontinence, stress; suburethral slings; treatment outcome; patient satisfaction

Abbreviations and Acronyms

AUS = artificial urinary sphincter

PGI-I = Patient Global Impression of Improvement

PGI-S = Patient Global Impression of Severity

PPD = pad(s) per day

PPI = post-prostatectomy incontinence

SUI = stress urinary incontinence

Submitted for publication July 25, 2011.

Study received institutional review board approval.

Supplementary material for this article can be obtained at http://www.clevelandclinic.org/advanceslingjurol2012.

* Financial interest and/or other relationship with American Medical Systems.

† Correspondence: The Cleveland Clinic Foundation, Urological Institute A-100, 9500 Euclid Ave., Cleveland, Ohio 44195 (telephone: 216-445-0296; FAX: 216-445-7031; e-mail: vasavas@ccf.org).

‡ Financial interest and/or other relationship with Allergan, AMS and Pfizer.

See Editorial on page 1157.

STRESS urinary incontinence is a well-known complication of radical prostatectomy with an incidence varying from 7% to 33% depending on definition, time of measurement and age group.[1–3] With 5-year survival nearing 100%, prostate cancer has increased the demand to treat the accompanying quality of life issues, including SUI.[4–6]

When given a choice, most patients favor slings for PPI over the gold standard AUS, despite physician recommendations.[7] Patient preference and satisfaction when treating quality of life problems often create difficulties in defining success.[8] In this context we first reported patient determined outcomes of the AdVance sling.[9] At 1 year success rates ranged from 55% to

0022-5347/12/1874-1331/0
THE JOURNAL OF UROLOGY®

Vol. 187, 1331-1335, April 2012
Printed in U.S.A.
DOI:10.1016/j.juro.2011.11.091

77%.[10,11] As with all novel incontinence therapies, durability of treatment can only be determined with longer followup. In this study we assessed patient perceived success 2 years after sling placement and compared these outcomes with quantitative measures of pad use.

MATERIALS AND METHODS

After institutional review board approval, a chart review and telephone based survey were conducted on all patients receiving the AdVance sling by 2 surgeons at a large tertiary referral institution between May 2007 and December 2009. A total of 66 patients were identified, of whom 35 participated in our previous study.[9]

Chart review collected demographics (age, height, weight), comorbid conditions, SUI characteristics (etiology, duration, daily pad use, pad type, pad weight, urodynamic testing), and previous incontinence treatments. Operative reports were reviewed for simultaneous procedures and intraoperative complications. All AdVance procedures were performed as previously described.[9,12] Postoperative survey data were collected after patients returned to normal activities, and consisted of complications, pad use and subsequent incontinence therapy. Patients were given specific instructions to lift nothing heavier than a milk jug for approximately 6 weeks.

Patient recruitment for the telephone based survey was performed as previously described.[9] The surveys included 2 standardized instruments, the PGI-S and PGI-I, questions concerning current and prior pad use, whether the patient would recommend the surgery to a friend, an inquiry regarding complications following surgery, and whether efficacy was perceived to have changed with time. As before, verbal consent was obtained via telephone and information was gathered by an individual not involved with patient care.[9]

PGI-I responses of very much better or much better were considered subjective successes if no additional incontinence procedures were performed. All other PGI-I responses and receipt of subsequent incontinence treatment were considered subjective failures. Similar to previous studies, quantitative success included cure (0 PPD) and improvement (a decrease from pre-sling pad use to 1 or 2 PPD) after surgery.[13,14] Preoperative and postoperative pad use from chart review and telephone survey were used for analyses. Subjective durability was assessed by asking patients how their improvement has held up over time. Possible responses were much better, a little better, stayed the same, a little worse, much worse, or sling did not improve their urinary condition. Quantitative measures of durability were based on changes in pad use since undergoing sling surgery.

Statistical analyses were performed using JMP® 9. Descriptive statistics are reported as percentages, means with standard deviations or medians with quartiles (q1–q3) as appropriate. Patients lost to followup were analyzed as treatment failures and successes to give a range of possible outcomes. Fisher's exact tests and Pearson's chi-square tests were used for categorical variables, and paired t tests were used for continuous variables. Changes in pad use and success rates were analyzed in a subgroup of 25 patients who responded to the previous and current telephone surveys.[9] The Wilcoxon signed rank test was used for continuous variables and McNemar's tests for categorical values. To determine if surgeon operative experience might impact outcome, the first and last 10 telephone responders with charted baseline PPI less than 5 PPD were analyzed using the Wilcoxon rank sum and Fisher's exact tests with data from previous and current surveys.[9] Statistical significance was defined by $p < 0.05$ unless denoted otherwise.

RESULTS

Overall 66 patients (mean age 67 years, body mass index 27 kg/m^2) received the sling at a median 23 months after prostatectomy. Median baseline charted pad use was 2 (1–3) PPD. Most of the patients had SUI with 18.1% (12 of 66) having mixed urinary incontinence as assessed by patient reported preoperative symptoms. Nearly all of the patients (98.5%, 65 of 66) had radical prostatectomy as the etiology of incontinence. Documented approaches included open (30), laparoscopic/robotic (29) and perineal (1). Prior incontinence treatments included AUS (4), clamp (5), medications (20), periurethral collagen (7) and bone anchored sling (1). A history of radiation was present in 6.1% (4 of 66) of patients.

First office followup occurred at a median 1.3 (1.0–1.8) months after sling surgery with mean and median pad use of 0.8 (1.7) and 0 (0–1) PPD, respectively. Per records, 50.8% (32 of 63) of patients were cured and 36.5% (23 of 63) had improvement at first followup with 87.3% (55 of 63) reporting quantitative success. When adjusted for loss to followup, quantitative success was 83.3% to 87.9% when considering nonresponders as failures or successes, respectively.

Telephone surveys occurred at a median of 23.8 (16.9–28.4) months after surgery with 84.8% (56 of 66) reporting a mean and median pad use of 1.7 (2.5) and 1 (0–2) PPD, respectively. At this time 39.3% (22 of 56) were cured and 23.2% (13 of 56) showed improvement. Total quantitative success was 62.5% (35 of 56) and 53.0% to 68.2% when adjusted for loss to followup. Subjective success was 53.6% (30 of 56) and 45.5% to 66.7% when adjusted for loss to followup. When asked if they would refer the sling to a friend, 67.9% (38 of 56) of patients replied yes, 10.7% (6 of 56) replied maybe and 21.4% (12 of 56) replied no. Two patients cited procedure cost as a strong deterrent. PGI-I was significantly associated with PGI-S ($p < 0.0001$) and perceived durability of sling results ($p < 0.0001$). Most patients (67.9%, 38 of 56) reported durability of sling efficacy did not change or became worse with time. Specifically efficacy was much better (5), a little better (8), stayed the same