Long-Term Quality of Life and Functional Outcomes among Primary and Secondary Artificial Urinary Sphincter Implantations in Men with Stress Urinary Incontinence

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Abbreviations and Acronyms

AUS = artificial urinary sphincter

PPD = pads per day

QOL = quality of life

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Purpose: There remains a paucity of data regarding subjective and functional outcomes after artificial urinary sphincter implantation. Therefore, we evaluated long-term differences in quality of life after primary and secondary artificial urinary sphincter surgery.

Materials and Methods: Men were invited to participate in a mail-in survey assessing artificial urinary sphincter status, patient satisfaction and urinary control. Patients with primary (467) and secondary (122) artificial urinary sphincter devices without an event were included in the study. Differences between the cohorts including quality of life (10-point scale, maximum 100) and functional outcomes were evaluated.

Results: Overall 229 (49%) patients with primary and 49 (40%) with secondary artificial urinary sphincters completed the survey at a median of 8.3 years. Patients with primary and secondary artificial urinary sphincter devices reported similar artificial urinary sphincter quality of life (score 74 vs 74). There were no significant differences in urinary continence outcomes including use of 1 pad or less daily (56% vs 55%), frequency of leakage 1 time or more per day (81% vs 71%) or degree of minimal leakage related bother (64% vs 55%). At less than 5 vs 10 or more years there was a significant reduction in artificial urinary sphincter quality of life (86 vs 73, p=0.007). Urinary continence also declined with time, including perceived urinary control (85% vs 53%, p=0.004), minimal leakage related bother (76% vs 59%, p=0.05) and use of 1 pad or less daily (67% vs 55%, p=0.07). On univariate analysis no clinical variables, including secondary revision, were associated with satisfaction or continence outcomes.

Conclusions: We noted a high level of artificial urinary sphincter quality of life, acceptable urinary control and no difference in functional outcomes between men undergoing primary or secondary artificial urinary sphincter surgery. However, the time related decline in satisfaction and continence highlights the need for patient counseling regarding long-term artificial urinary sphincter functional outcomes.

Key Words: urinary sphincter, artificial; male; urinary incontinence, stress; patient satisfaction; quality of life

ORIGINALLY introduced in 1972,[1] the artificial urinary sphincter remains the gold standard treatment option for men with moderate to severe stress urinary incontinence.[2] It has demonstrated acceptable durability

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with 5-year revision-free survival rates of 60% to 75%.[3–5] Nevertheless, there has been substantial variability in patient reported satisfaction[4,6–12] and urinary continence related outcomes.[3,4,6–10,12–15] In a recent pooled analysis the reported rate of social continence (1 pad or less daily) after AUS surgery was 79% (range 61 to 100),[2] and similarly, rates of satisfaction have varied from 73% to 91%.[6–12] Accordingly, given that the majority of published series have a limited sample size and followup duration, the long-term natural history of urinary control and satisfaction with implanted devices remain largely unknown.

Meanwhile, previous studies have demonstrated an increased risk of adverse outcomes among men undergoing AUS revision or secondary implantation surgery.[16–19] However, during the last decade there remains a paucity of data regarding differences in primary (first-time) and secondary AUS functional[11,16,17] and QOL related outcomes. Thus, we hypothesized that men undergoing secondary AUS surgery would have significantly worse QOL and urinary continence relative to primary implantations, and for both cohorts AUS related outcomes would decline with time. Therefore, to accurately risk stratify and appropriately counsel patients regarding postoperative expectations, we evaluated the long-term differences in urinary related QOL after primary and secondary AUS surgery.

MATERIALS AND METHODS

After institutional review board approval we identified 2,135 male AUS procedures performed at our institution from 1983 to the present. To accurately assess outcomes with extended followup the study was limited to patients with an intact AUS implanted before 2012. Thus, 1,802 patients were identified during this period. Patients were excluded from the study if they underwent salvage AUS placement after erosion/infection, AUS implantation for neurogenic bladder dysfunction, were less than 18 years old or declined research consent. Three surgeons performed the AUS implantations during the time frame of the study and all implanted devices were AMS 800™.

Clinical characteristics and details of the primary and secondary devices including reason for secondary device placement (mechanical vs nonmechanical failure) were assessed. After device placement patients were evaluated 6 weeks postoperatively for device activation. Thereafter, patients were followed via office evaluation on an as needed basis, as determined by continence or other device concerns. Details regarding device survival were obtained from last office examination, any available subsequent operative report, or written or telephone correspondence.

Men with AUS device implantation between 1983 and 2011 were invited to participate in a mail-in survey which served as their last documented date of followup. Accordingly at last followup there were 742 men with a first-time primary AUS and no secondary event, and 194 men with a secondary AUS and no tertiary event. Of these men 346 died, leaving 467 men with primary and 122 with secondary AUS devices eligible for analysis. A standardized questionnaire was used to assess device status (intact/revision/explanted), patient satisfaction with questions adapted from previous studies,[6,7] as well as urinary continence, adapted from the validated EPIC-UD (Expanded Prostate Cancer Index Composite urinary domain) (see supplementary Appendix, http://jurology.com/).[20] Given that urinary continence is highly correlated with QOL,[21] the patient reported change in urinary continence from baseline to after AUS implantation served as an index for overall AUS related QOL and satisfaction, and was assessed on a scale of 0 to 10 (much worse to much better). QOL scores were multiplied by 10 to convert to a scale of 0 to 100, with 100 representing the best situation.

Statistical analysis was performed using the SAS® software package. The Student t-test and chi-square cross table analysis were used to assess differences in cohorts, as well as temporal trends based on time from surgery to survey completion. Spearman rank correlations were used to investigate the relationship between AUS QOL score and reported urinary continence outcomes. Logistic and linear regression analyses were used to evaluate associations between clinical characteristics, including history of mechanical and nonmechanical failure, and perceived satisfaction and urinary continence. Statistical tests were 2-sided with $p < 0.05$ considered statistically significant.

RESULTS

Between 1983 and 2011, 1,082 (60%) primary AUS implantations and 321 (18%) secondary revisions were performed. Men who were alive and without a subsequent event at survey completion (467 primary and 122 secondary devices) formed the basis of this study. Of these men 229 (49%) with primary and 49 (40%) with secondary devices completed the survey. The etiology for revision surgery among secondary AUS implantations included 31 (63%) mechanical failures (6 single component replacement, 23 entire AUS revision and 2 repositioning without removal), 17 (34%) cases of urethral atrophy (4 entire AUS revision and 13 tandem cuff placement only) and 1 (2%) scrotal pump repositioning for pain.

Median patient age at surgery was 70 years (IQR 65–75). A total of 237 (85%) men underwent radical prostatectomy, 71 (26%) received radiation therapy and 22 (9%) received androgen deprivation therapy. When stratified by primary and secondary AUS surgery men undergoing primary device placement were more likely to have a history of transurethral prostate resection (18% vs 0%, p=0.02) and prior radiation therapy (28% vs 14%, p=0.05, table 1). There were no differences in other clinical characteristics including body mass index (28 vs 27 kg/m^2),