Continence and Quality of Life Assessment after Artificial Urinary Sphincter Implantation

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Abstract

Background: Sphincter-related incontinence after radical prostatectomy, benign prostatectomy or due to neurogenic disease has a considerable negative impact on quality of life. Artificial urinary sphincter implantation is a mainstay therapeutic option for these patients.

Objectives: To assess patient satisfaction, subjective long-term continence and complications after AMS 800 artificial urinary sphincter implantation.

Methods: The medical records of 34 patients who underwent artificial urinary sphincter implantation for radical prostatectomy (n = 23), simple prostatectomy (n = 9) or neurogenic disease (n = 2) between 1995 and 2003 were studied retrospectively. Median follow-up was 49 months (range 3–102 months). Records were analyzed for urinary sphincter survival and complications. Quality of life and continence assessment was done by mailing an impact questionnaire.

Results: In 4 of the 34 patients (11.7%) the device was removed due to infection. One of the four had surgical revision elsewhere, and the other three were not interested in re-implantation of the device. Two patients (5.9%) underwent revisions due to mechanical failure. One patient died and three patients were not located. Twenty-seven out of a possible 30 patients (88%) completed the questionnaire; 22 (85%) achieved social continence (0–2 pads daily), and one patient had subjective difficulty activating the device. Subjective improvement and patient satisfaction was rated as 4.22 and 4.11, respectively (scale 0 to 5).

Conclusions: Artificial urinary sphincter implantation is an efficacious option for sphincter-related incontinence. This study documents the positive impact of artificial urinary sphincter implantation on quality of life with acceptable complications; these results are comparable to other published studies.

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Urinary incontinence has a significant negative impact on quality of life. Sphincter weakness incontinence may occur in patients after urologic operations or due to neurogenic diseases [1,2]. The incontinence rates following radical prostatectomy range from 3% to 60% depending mainly on continence definition [3]. A recent study demonstrated an overall incontinence rate of 18% after radical prostatectomy [4]. The incontinence rates after transurethral prostatic resection are reported to be 1.2% with mild stress incontinence and 0.5% with total incontinence [5].

The normal male urinary sphincter mechanism may be functionally divided into two separate units. The proximal sphincter consists of the bladder neck, the prostate and the prostatic urethra. This portion of the continence mechanism is removed during prostate surgery, leaving only the distal sphincter located at the membranous urethra to prevent urinary leakage. Sphincteric induced incontinence can result when physical damage occurs to the distal sphincter, its supporting structures or innervations during surgery. Concomitant detrusor hyperactivity may aggravate incontinence by induction of intermittent high pressure bladder contractions unopposed by the weak sphincteric tone. Most patients with surgery-induced incontinence suffer from intrinsic sphincter damage although many have concomitant detrusor hyperactivity [6].

Surgical options for correcting sphincter-related urinary incontinence are intra-urethral bulking agent injection, sling suspensory procedures, or artificial urinary sphincter implantation. Studies comparing collagen injection and artificial urinary sphincter implantation have shown the superiority of the latter [7]. Indeed, the artificial urinary sphincter has become the standard treatment for male sphincter incontinence. The artificial urinary sphincter consists of a cuff wrapped around a selected point of the bladder outflow, usually the bulbar urethra in men following prostatectomy. The cuff is connected to a pressure-regulating balloon positioned in the preperitoneal space. Between these two bodies there is a control pump that can be palpated through the skin in the scrotum. The system is fluid-filled and works hydraulically. The occlusive effect of the cuff on the urethra allows for continence and it is determined by the pressure-regulating balloon. The control pump, when squeezed, empties the cuff allowing normal micturition and later is refilled slowly to complete micturition.

Although the results of artificial urinary sphincter implantation have been reported before [8–15], only one (published more than a decade ago) focused on the Israeli experience [16]. Reported success and continence rates after artificial urinary sphincter implantation vary widely due to different study design, the relatively small number of patients, and the heterogeneous study population. Since the main goal of artificial urinary sphincter implantation is improvement in quality of life, assessing long-term patient satisfaction is the means to evaluate surgical success. To our knowledge no standardized validated questionnaire addressing quality of life issues after artificial urinary sphincter implantation exists to date. Some studies used a general prostate impact score questionnaire and added more specific questions [8], but in most cases the questionnaire was not validated [10,11,15]. We chose to use a questionnaire presented elsewhere [9] where it was validated in female incontinent patients and adapted to a male population. The other previously published Israeli study did not address quality of life and satisfaction issues [16]. We report on patient satisfaction,

subjective long-term continence and complications after implantation of the AMS 800 Artificial Sphincter (American Medical Systems, Minnetonka, MN, USA) at Rabin Medical Center.

Patients and Methods

All 34 men who underwent artificial urinary sphincter implantation at our institution between 1995 and August 2003 were identified and enrolled in the study. The mean age at implantation was 68 (range 54–85 years). Median follow-up was 49 months (range 3–102 months). Of the 34 patients, 23 had sphincter incontinence after radical retropubic prostatectomy for prostate carcinoma, 6 after transurethral resection of prostate, 2 after benign retropubic prostatectomy, and one patient after visual internal urethrotomy. In two patients the etiology was meningomyelocele, with sacral arc denervation causing sphincter incontinence. One of them had an artificial urinary sphincter implanted elsewhere and came to our center for revision. Pelvic radiation therapy was given previously in two patients, one for colon cancer and the other for prostate cancer. All patients had severe preoperative urinary leakage, documented by history, physical examination and video-urodynamic studies. Concomitant detrusor overactivity was demonstrated in 46% of the patients.

The AMS 800 artificial urinary sphincter was implanted in the bulbar urethra in all patients. The cuff was placed around the corpus spongiosum. We routinely used a 4.0 cm bulbar cuff, except in two patients in whom a 4.5 cm cuff was used. A 61–70 cm water pressure-regulating balloon was used. In two patients a penile prosthesis was inserted simultaneously. All patients were hospitalized overnight and discharged the following morning. Sphincters were deactivated for 4 weeks postoperatively.

The medical records of the implant recipients were obtained and reviewed for demographic data, surgery details, sphincter survival, and complications. Satisfaction and quality of life were assessed by a validated questionnaire that has been presented elsewhere [7], and is self-administered [see Appendix]. The questionnaire was translated to Hebrew and mailed to the patients. Telephone contact was attempted for patients who did not respond to the questionnaire.

Univariate analysis using the chi-square test was performed on clinical categorical variables to identify significant predictors of patient satisfaction. Multivariate analysis with the logistic regression model was done to detect independent predictors of outcome. A two-tailed value of P 0.05 was considered statistically significant.

Results

Of the 34 patients studied, 1 died and 3 could not be located. Overall, four patients (11.7%) had local infection and the device was explanted. Three were not interested in re-implantation of the device. One patient had his device removed due to infection and later on had a revision elsewhere.

A total of 27 men out of a possible 30 (88%) was available for evaluation by the questionnaire. After implantation 12 patients (44.4%) were dry, 9 patients (33.3%) used one pad daily, 2 patients (7.4%) used 2, and 4 patients (14.8%) used 3 or more pads daily [Table 1]. Surgical revision was performed in two patients, one for reservoir leakage and the other for mechanical failure. The mean time to revision was 14.5 months. One patient claimed to have difficulty operating the device. Of the responders 88.9% said they would undergo the operation again, and 81.4% said they would recommend it to a friend [Table 2]. When patients were asked about overall satisfaction and if they experienced less urinary leakage compared to before the surgery, they gave a rating of 4.11 and 4.22 (grade 0 to 5) on average, respectively.

Table 1. Degree of continence at follow-up

	No. (%)	Total no. (%)
No pads	12 (44.4)	12 (44.4)
1 pad/day	9 (33.3)	21 (77.8)
2 pads/day	2 (7.4)	23 (85.2)
More than 2 pads/day	4 (14.8)	4 (100)

Table 2. Patient satisfaction

	Yes (%)	Not Sure (%)	No (%)
Would you have an artificial sphincter placement again?	24 (88.9)	3 (11.1)	0 (0)
Would you recommend the artificial sphincter to a friend?	22 (81.5)	4 (14.8)	1 (3.7)

The etiology of incontinence or presence of concomitant detrusor overactivity did not correlate with sphincter survival or satisfaction rate. Patient satisfaction did not correlate significantly with degree of leakage, daytime or nocturnal frequency, or patient's age. The satisfaction rate correlated with willingness to recommend the surgery to a friend ($P = 0.001$) and marginally correlated with willingness to undergo having the surgery again ($P = 0.061$). The overall satisfaction rate correlated with the subjective improvement due to the surgery ($P < 0.05$).

Discussion

Artificial urinary sphincter implantation is currently the gold standard treatment for sphincter-related urinary incontinence. Over the years mechanical failure has decreased dramatically and has made this option more feasible. Four major device changes have been implemented: kink-resistant tubing, surface-treated cuff, sutureless tubing, and narrow backed cuff. These changes resulted in fewer mechanical failures as shown previously [9], and as demonstrated in our study in which there were only 2 (5.9%) mechanical failures.

Considerable variance exists in the medical literature regarding the definition of continence or "social continence." Some studies [13,14] defined "dry" as using two pads or less. Others used more strict criteria and defined socially continent patients as requiring up to one pad a day [9,11,15]. In our series, social continence was arbitrarily defined as using 0–2 pads daily, and our results, showing an overall 85% "social continence" rate, are comparable to other published studies. Our overall infection/erosion rate (11.7%) is marginally higher than other studies, ranging from 1.2 to 8.1% [8–15].

Patient satisfaction did not correlate with continence rate as no comparison was made between basic continence status and current status. The questionnaire did not address the change in pad status and urinary leakage, but the absolute value at the review date. The absence of correlation is not surprising. Currently, a prospective study is underway comparing the clinical variables before and after surgery. As expected, patients in our study who were satisfied with the surgical results were willing to recommend the procedure to a friend or to go through with it a second time. As shown previously [15] and again in our series, patients' age did not affect the satisfaction rate. Due to the small numbers we were not able to examine radiation therapy as a predictor of sphincter survival.

Our continence and satisfaction data are based mainly on mailed questionnaires, and completion by telephone contact when necessary. Since continence is essentially a quality of life problem, patient perception of the problem is the main issue and therefore justifies the use of a subjective questionnaire. Our questionnaire [see Appendix] was reproduced from another study [9] and translated to Hebrew. We preferred to use this specific questionnaire since, to the best of our knowledge, no simple validated questionnaire for this type of continence exists. The questionnaire was validated, albeit for female patients, and adapted for male patients. Its simplicity made it more appealing for mailing purposes. Although a long time elapsed between the surgery and the interview, we achieved a high response rate (88%), unusually high for a mailed questionnaire, which substantiates our results.

Conclusions

To our knowledge this is the largest Israeli study to address artificial urinary sphincter implantation and the first to specifically evaluate subjective satisfaction in patients who underwent artificial urinary sphincter implantation. In our series, the satisfaction rate and social continence rate remained high throughout the follow-up period. Although patients did not achieve complete continence, their satisfaction with the procedure did not decline. It seems that patient satisfaction depends not only on complete continence but also on the magnitude of improvement and the expectation of surgical outcome. Our results, using a validated questionnaire, are consistent with other published studies. The current study documents the positive impact and viability of artificial urinary sphincter implantation at the Rabin Medical Center, with an acceptable complication rate.

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Appendix: Survey Questionnaire

1. Do you ever leak urine? (never, once per month, once per week, daily)
2. How much leakage of urine do you have now? (none, very little, moderate, severe)
3. Do you wear protective pads for urine leakage? (yes, no).
   How many in 24 hours?
4. How often do you urinate during the day?
5. How many times per night do you wake up to urinate?
6. Have you had any major problem operating the device? (yes, no)
7. Knowing what you know, would you have an artificial sphincter placement again? (yes, no, not sure)
8. Would you recommend the artificial sphincter to a friend?
   (yes, no, not sure)
9. How much improved is your urinary leakage now compared to before your artificial urinary sphincter placement?
   (0 = not improved at all, 5 = extremely improved)
10. Overall, how satisfied are you with the results of your artificial sphincter placement?
    (0 = not satisfied at all, 5 = extremely satisfied)