

Quality of life and patient satisfaction after artificial urinary sphincter

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Abstract

Background: We assessed satisfaction and quality of life (QOL) in men with artificial urinary sphincter (AUS) placement.

Methods: We identified 39 men who had AUS placement. A retrospective chart review was conducted. Validated questionnaires, including the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), Post-Operative Patient Global Impression of Improvement (PGI-I), Incontinence Impact Questionnaire-Short Form (IIQ-SF), and Urogenital Distress Index (UDI-SF), were used to measure patient-reported outcome. Global satisfaction was also assessed.

Results: At chart review, 34 of 39 questionnaires were assessed for QOL, satisfaction and surgical outcome. Follow-up ranged from 7 to 60 months (median = 24 months). Surgical revisions were required in 6 (17.6%) patients due to infection (1), erosion (1), combined infection and erosion (1), device failure (1) and second cuff placement (2). Quality of life was assessed using the IIQ-SF and UDI-SF, with mean scores of 15.4 and 24.8, respectively; these scores indicated a low negative impact on QOL. The ICIQ-SF mean score was 8.2, well below the worst possible score. The number of men using more than 1 pad per day dropped from 27 preoperatively to 10 postoperatively. Most patients (31/34) described their urinary condition as better, 2 had no change and 1 was worse. Most patients (31/34, 91.2%) would be willing to undergo the procedure again, 2 were undecided, and 1 would not. Similarly, 28 patients (82.4%) would recommend the procedure to a friend, 3 respondents would "with reservation," 1 respondent was undecided, and 2 would not recommend the AUS placement.

Conclusion: Treatment of urinary incontinence with the AUS has a positive effect on QOL with high patient satisfaction and reasonably low complication rates.

Introduction

Quality of life (QOL) considerations are integral to the treatment of stress urinary incontinence (SUI) in men. While SUI in men cannot be attributed to any one cause, the condi-

tion arises predominantly in patients who have undergone radical prostatectomy. In post-prostatectomy patients, SUI has an incidence of 8% to 77%.¹ In 2% to 33% of affected men, symptoms persist for more than 12 months causing up to 10% of this subset to seek surgical intervention.² Overall, leakage affects QOL enough to prompt 8% to 15% of patients suffering from post-prostatectomy incontinence to seek some form of treatment.³

Available surgical options for the treatment of SUI include injectables, adjustable balloon therapy, slings, and the artificial urinary sphincter (AUS); the AUS is considered the gold standard for treatment.

The AUS is regarded for its particularly high success rates, ranging from 59% to 90%, where success is defined as a continence status of 0 to 1 pads per day.⁴ While revision rates in the literature appear to be variable (between 17% and 32%), the durability of the AUS has been favourably measured by a "5-year revision-free rate" of 75%, as well as a "probability of device use for 9 years" of 84%.⁴

The AUS has also been associated with high patient satisfaction and a positive impact on health-related QOL. In the literature, satisfaction rates range from 87% to 90%, remaining high even in the setting of incomplete continence.⁴

Our study seeks to assess QOL and patient satisfaction in men who received AUS placement for the treatment of SUI at our specific institution.

Methods

Thirty-nine men who had undergone AUS placement at our institution between 2003 and 2008 were identified and asked to self-assess their postoperative QOL. The corresponding demographic and surgical information for these patients was obtained through a retrospective chart review.

To facilitate accurate assessment by patients, we used self-assessment instruments that have been validated in existing studies and amalgamated them into a patient survey (Appendix 1). This survey consisted of 4 existing instruments, the International Consultation on Incontinence

Questionnaire-Short Form (ICIQ-SF), Post-Operative Patient Global Impression of Improvement (PGI-I), Incontinence Impact Questionnaire-Short Form (IIQ-SF) and Urogenital Distress Index (UDI-SF).

In addition to assessing QOL, the patient survey measured patient satisfaction with AUS by incorporating an additional set of questions.⁵ Our survey also sought to determine the extent of protection required by patients against urinary leakage both before and after their procedure.

Beyond efforts to eliminate researcher bias, the survey was designed to be brief (32 questions) and simple to minimize errors stemming from low patient compliance.

Results

Of the 39 questionnaires mailed out, 3 were not returned, 2 were returned incomplete (wrong address) and 34 were returned completed. The ages of the men who responded ranged from 35 to 87, with a mean age of 70.6. The time of follow-up ranged from 7 to 60 months, with a median time of 24.0 months.

Of the 34 men who responded, most were incontinent as a result of undergoing radical prostatectomy with or without radiation (Table 1).

Revisions

The overall revision rate was 17.6% (6/34). Complications leading to revision included infection (1), erosion (1), or both (1), as well as device failure (1) (Table 2). Infections occurred 2 to 3 months postoperatively. A second cuff was implanted in 2 patients who were dissatisfied with their level of continence, despite having a well-functioning device and significant improvement from baseline.

All 34 men evaluated in this study had functioning devices at the time of reporting.

Quality of life

The QOL tools used included the ICIQ-SF, IIQ-SF, UDI-SF, and the PGI-I.

Possible ICIQ-SF scores range from 0 to 21, with 0 corresponding to the least possible negative impact on QOL, and 21 being the greatest.⁶ The median score among our patients at a median follow-up of 24 months was 7.0, indicating a low impact on QOL.

The IIQ-SF and UDI-SF scores range from 0 to 100, and again lower scores correspond with better QOL, while higher scores indicate worse QOL.⁷ The mean scores for the IIQ-SF and UDI-SF were 15.4 and 24.8, respectively.

The PGI-I questionnaire data indicate that most patients felt that their urinary condition had changed in a positive

Table 1. Causes of stress urinary incontinence amongst men in our study population

Cause	n
Radical prostatectomy alone	24
Radical prostatectomy plus radiation	6
Radiation plus salvage cryotherapy	2
Radiation alone	1
Pelvic fracture	1
Total	34

manner after the AUS placement (Fig. 1). Among the subset of men requiring a surgical revision, all 6 reported that their urinary condition had improved; 5 out of 6 felt their condition was "very much better" after surgery, and the remaining patient responded that his condition was "much better" following the procedure.

Patient satisfaction

Most patients (31/34) stated that they would have an AUS placed again, knowing what they know now (Fig. 2). Furthermore, most patients (31/34, 91.2%) would recommend the AUS to a friend with the same problem (Fig. 3). Of the 6 men who required revisions, 5 replied that they would be willing to undergo AUS placement again, while 1 would not. Similarly, 5 out of the 6 responded that they would recommend the procedure to a friend, whereas 1 said he would not.

Use of protection against leakage

There is a significant decrease in the usage of all forms of protection against urinary leakage after AUS placement in our study group (Fig. 4).

Discussion

The purpose of our study was to determine the effect of the AUS on the QOL of male patients suffering from SUI. We used 4 validated instruments: the IIQ-SF, ICIQ-SF, UDI-SF, and PGI-I. Of these instruments, the ICIQ-SF and the

Table 2. Revisions following initial artificial urinary sphincter placement

	Our series (n=34)	In the literature ⁴
Overall	6 (17.6%)	8-45%
Infection and erosion	3 (8.8%)	<8%
Infection	1 (2.9%)	
Erosion	1 (2.9%)	
Infection + erosion	1 (2.9%)	
Device failure	1 (2.9%)	0-53%
Second cuff placement	2 (5.9%)	3-9%

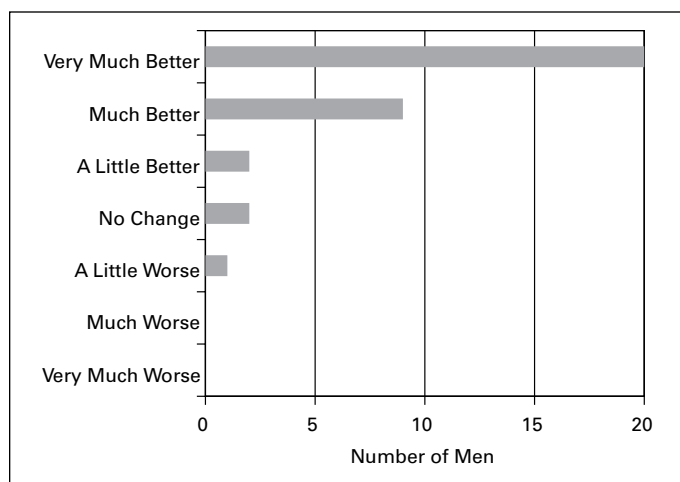


Fig. 1. Perception of urinary condition amongst men post-artificial urinary sphincter placement.

PGI-I have been validated for use in men in particular.⁸ The UDI-SF and the IIQ-SF were originally validated for use in women.⁷ Although the validity and reliability of the UDI-SF has not been assessed in men, the IIQ-SF has been tested in men and has demonstrated some validity.⁹ Regardless, the UDI-SF and the IIQ-SF have been used in the literature to assess QOL in men with incontinence.^{10,11,12}

Although the validity of each of the 4 instruments used in our survey has been separately established, the validity of using all of them as part of a larger comprehensive survey has not. We cannot accurately predict whether the assimilation of the questionnaires might have affected the individual results, and the literature is lacking to guide us in this regard. To preserve the validity of each instrument to the best of our ability, we designed our survey to maintain the integrity of each individual instrument by keeping it intact and administering it in full. Therefore, no additions or omissions were made, and all questions comprising each instrument were maintained in the order in which they had been originally validated. The results of each instrument were then tabulated separately as described in their original studies. By delivering our survey in this manner, we believe we were able to minimize any potential negative effects on validity.

Our study is limited by its retrospective nature, which may introduce recall bias among participants. Furthermore, preoperative QOL scores from our study population were not available for comparison to postoperative values, which limits our ability to directly determine the impact of treatment.

The IIQ-SF and UDI-SF have been used in other studies to quantify QOL in men with SUI. Haab and colleagues administered questionnaires, including the IIQ-SF and UDI-SF, to 15 patients with pure SUI after prostatectomy who were awaiting AUS insertion to act as the control group.¹⁰ The mean scores for this control group on the IIQ-SF and

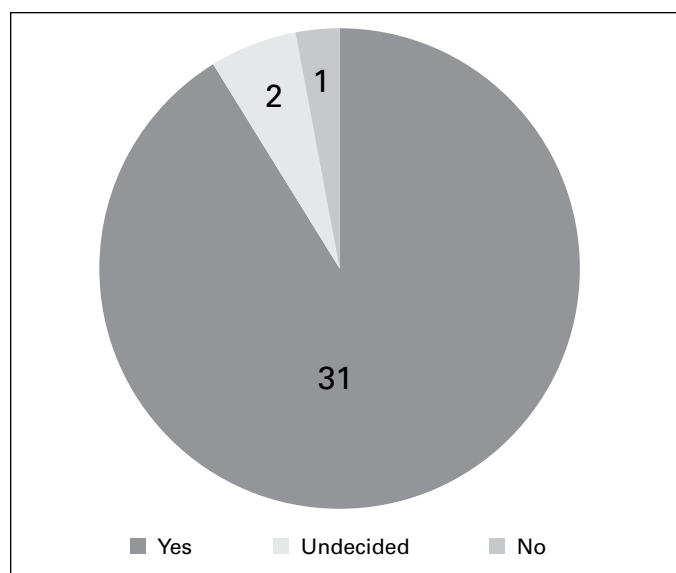


Fig. 2. Answers to the question: "Knowing what you know now, would you have an artificial urinary sphincter placement again?"

UDI-SF were 83 and 85, respectively. The authors compared the results of the control group to those of the study population ($n = 68$) and found a statistically significant difference between the 2 groups; QOL and distress, due to incontinence, were less affected in the treatment group.¹⁰ Postoperative scores on both tools reported by Haab and colleagues were comparable to scores we obtained in our patient population. Fleshner and Herschorn similarly compared the results of the IIQ-SF in patients who had undergone AUS insertion versus patients who had incontinence post-radical prostatectomy but no treatment, and also found that incontinence had a lesser impact on the patients who had received treatment by way of AUS insertion.¹¹ O'Connor and colleagues administered both tools preoperatively and postoperatively to patients post-radical cystectomy and orthotopic neobladder and also found a statistically significant decrease in patients' scores following AUS implantation.¹²

Since we were unable to make a direct comparison between preoperative and postoperative IIQ-SF and UDI-SF scores in our study cohort, we used the PGI-I question to assess how patients had felt their condition had changed postoperatively. Most of our patients felt that their condition had improved as a result of AUS implantation, with 29/34 (85.3%) reporting that they were "very much better" or "much better" after surgery.

The ICIQ-SF data collected from our patients further indicated that the impact of incontinence following AUS insertion was relatively small. Unfortunately, no other studies looking at QOL and AUS have used this particular tool. As a result, there are no values for comparison, and no way to quantify the change in symptoms postoperatively.

Along with considering QOL, we also were interested in

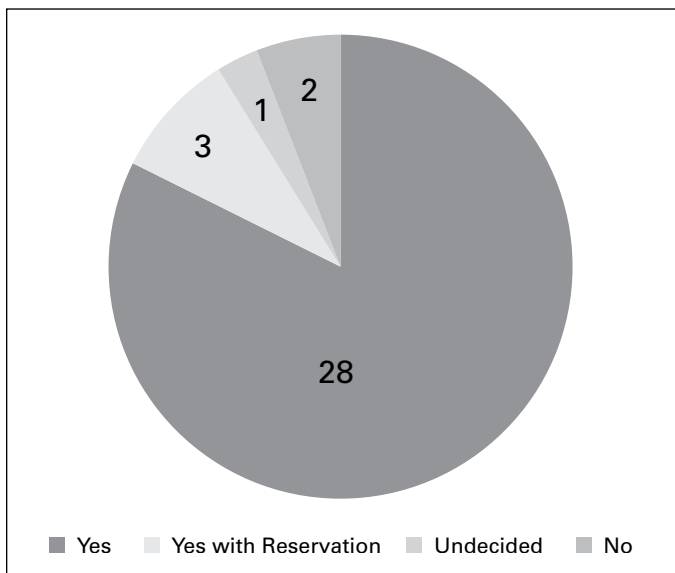


Fig. 3. Answers to the question: "Would you recommend the artificial urinary sphincter to a friend?"

assessing patient satisfaction with the device, and whether or not satisfaction was affected by the need for surgical revisions. Rates of satisfaction in our series were very high. More than 90% of patients were willing to undergo the procedure again and were willing to recommend the procedure to a friend. This is similar to the results reported by Litwiller and colleagues and slightly higher than what was reported by Haab and colleagues.^{5,10} Our revision rates were similar to those reported elsewhere in the literature.⁴ Our data demonstrated high satisfaction rates even among men requiring surgical revisions, most men reported feeling better off than they were prior to surgery and were satisfied overall.

Lastly, we attempted to quantify the improvement in continence by inquiring about protection usage. We noted that there was a decrease in the need for protection usage across all types of protection (pads, penile clamp, and condom catheters). Other studies have defined social continence or 'success' of the procedure as the need for protection not exceeding 1 pad per day.^{4,10} The most common form of protection used by our study cohort was pads, and the number of men using >1 pad per day prior to surgery dropped significantly. Postoperatively, only 29.4% of men were using >1 pad per day, meaning that 70.6% of men in our study achieved continence based on this definition. While the recording pad use as a determinant of continence suffers from the wide variability in pad types and individual behaviour, the observed changes in usage in our study points to a significant positive impact of AUS placement.

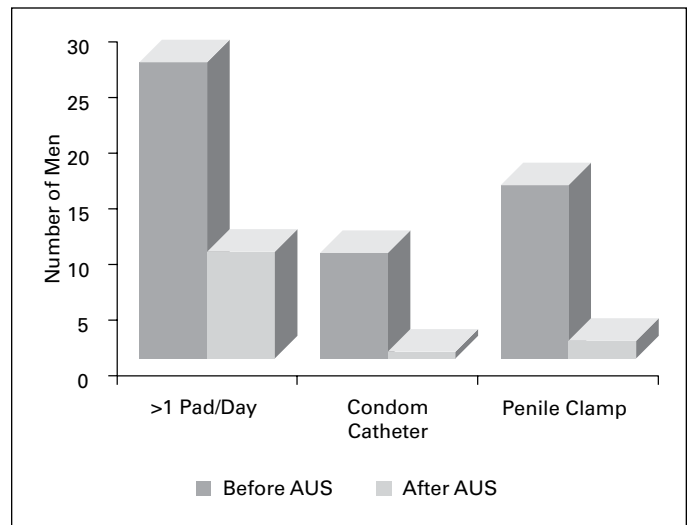


Fig. 4. Use of protection against leakage before and after artificial urinary sphincter insertion.

Conclusion

Insertion of the AUS has a strong positive impact on the QOL of men with SUI. We also observed high satisfaction rates with the procedure, even in men requiring revisions. Revision rates in this series are similar to those reported in the literature.

Competing interests: None declared.

This paper has been peer-reviewed.

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Appendix 1. Quality of life questionnaire

Questions 1-3 pertain to symptoms prior to artificial urinary sphincter (AUS) implantation, 4-32 pertain to symptoms after AUS implantation

1. Did you wear protective pads for urine leakage, if so, how many in 24 hours?
2. Did you ever use a penile clamp for protection?
3. Did you ever use a condom catheter for protection?
4. How often do you urinate during the day?
5. How many times per night do you wake up to urinate?
6. Do you ever leak urine? If so, how much?
7. Do you wear protective pads for urine leakage, if so, how many in 24 hours?
8. Do you ever use a penile clamp for protection?
9. Do you ever use a condom catheter for protection?
10. How often do you leak urine? (never, about once a week or less often, 2-3 times a week, about once a day, several times a day, all the time)
11. How much urine do you usually leak (whether you wear protection or not)? (none, a small amount, a moderate amount, a large amount)
12. Overall, how much does urine leakage interfere with your everyday life? (0=not at all, to 10=a great deal)
13. When does urine leak? Please circle all answers that apply to you. (never – urine does not leak, leaks before you can get to the toilet, leaks when you cough or sneeze, leaks when you are asleep, leaks when you are physically active/exercising, leaks when you have finished urinating and are dressed, leaks for no obvious reason, leaks all the time)

(Responses for questions 14-26: not at all, slightly, moderately, greatly)

Has urine leakage affected your ...

14. Ability to do household chores (cooking, housecleaning, laundry)?
15. Physical recreation such as walking, swimming, or other exercise?
16. Entertainment activities (movies, concerts, etc)?
17. Ability to travel by car or bus more than 30 minutes from home?
18. Participation in social activities outside your home?
19. Emotional health (nervousness, depression, etc)?
20. Feeling frustrated?
- Do you experience, and if so, how much are you bothered by ...
21. Frequent urination?
22. Urine leakage related to the feeling of urgency?
23. Urine leakage related to physical activity, coughing, or sneezing?
24. Small amounts of urine leakage (drops)?
25. Difficulty emptying your bladder?
26. Pain or discomfort in the lower abdomen or genital area?
27. Knowing what you know now, would you have an artificial urinary sphincter placement again? (yes, undecided, no)
28. Would you recommend the artificial urinary sphincter to a friend? (yes, yes with reservation, undecided, no)
29. Circle the one answer that best describes how your urinary tract condition is now, compared with how it was before you had the operation. (very much better, much better, a little better, no change, a little worse, much worse, very much worse)
30. Overall, how bothersome has any trouble with urination been during the last month? (not bothersome at all, bothers me a little, bothers me some, bothers me a lot)
31. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about it?
32. Feel free to take this opportunity to make any comments you may have.

Male stress urinary incontinence: assessing patient-reported outcomes

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Male stress urinary incontinence (SUI) is caused by intrinsic sphincter deficiency (ISD) from a variety of etiologies – prostatic surgery as the being the most common. SUI may sometimes be associated with overactive bladder symptoms. Based on the severity of symptoms and the associated level of bother, the patient may seek treatment. A treatment plan is elaborated after careful patient evaluation involving a combination of voiding diary, quality of life (QOL) questionnaires, flowmetry, urethrocystoscopy and urodynamics. The therapeutic options include conservative methods, such as pelvic floor exercises, or surgical modalities such as injectables, adjustable balloon therapy, slings and the artificial urinary sphincter (AUS). The success is defined by objective or subjective outcome measures.

This retrospective study presents a global assessment of patient satisfaction and QOL in 37 men at a follow-up of 7 to 60 months after AUS.¹ The investigators demonstrated an overall high QOL level based on a survey of patient-reported outcomes (PRO) composed of 4 questionnaires: International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), Post-Operative Patient Global Impression of Improvement (PGI-I), Incontinence Impact Questionnaire-Short Form (IIQ-SF) and Urogenital Distress Index (UDI-SF). Out of 34 patients, 31 would have an AUS placed again and recommend it to a friend with a similar problem. The authors concluded that the insertion of AUS positively impacted QOL and patient satisfaction.¹

The economic burden of male SUI has been steadily increasing in the last 2 decades, with most of the increase occurring in the ambulatory surgery setting.² Many patients are counselled for and chose a surgical intervention with hopes of cure. As incontinence is not a life-threatening, the patient must decide if the expected benefits outweigh the possible risks and complications of the surgery. His decision is therefore based on how severely his condition affects his QOL. It is crucial for

the surgeon to establish realistic expectations, because they are direct determinants of a patient's satisfaction following the intervention. Another consideration is the limited lifespan of a mechanical device, such as the AUS. The increasing risk of mechanical revision with long-term follow-up may significantly change patient satisfaction over time.³

The purpose of using PRO in incontinence research is to measure the impact of an intervention on the overall health status from a patient's perspective. In clinical trials, these tools are ideally administered before and after treatment in a prospective fashion. Despite the wide availability of QOL questionnaires, there is little consensus about their applicability to guide treatment decision.⁴ Due to the retrospective nature of this study, we cannot compare the preoperative and postoperative scores of the QOL questionnaires. However, the desire to undergo surgical treatment can be used as a surrogate of significant QOL impairment before the intervention. Future clinical studies should prospectively measure PRO and correlate them with objective outcomes in homogeneous populations of patients to avoid any possible bias.

Competing interests: None declared.

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