

Abstract

Hypothesis / aims of study

Artificial urethral sphincter (AUS) is the gold standard as a treatment for severe stress urinary incontinence (SUI) after radical prostatectomy. The number of AUS implantations has been increasing in Japan since the remedy was provided by medical insurance in 2012. Even though the AUS is implanted, symptoms of SUI worsen again and revision surgery is required because of urethral atrophy, urethral erosion, mechanical failure, and so on. Previous reports indicated that approximately 30-50% of patients have experienced treatment failure during follow-up^{1,2}. However, there are few reports focusing on long term patient reported outcome after surgery. Therefore, we conducted a prospective study into how quality of life (QOL) reported by patients with AUS implantation changes before and after the surgery over time.

Study design, materials and methods

Fifty-eight patients underwent AUS implant surgery in our institute from 2007 to 2018, 11 of whom have been followed for more than 4 years after primary surgery without revision in our institute continuously. Patients were filled out the questionnaire of ICIQ-SF (International Consultation on Incontinence) and KHQ (King Health Questionnaire) before, 1 year and 4 more years after primary surgery. For ICIQ-SF, patients were asked to rate answers on a Likert scale with a maximum possible score on the first 3 questions of 5, 6 and 10, respectively. KHQ consists of 9 items scored on a scale of 0 to 100 with 0 representing the best condition and higher scores indicating worse conditions. The Wilcoxon signed rank test was used to compare changes in total scores of ICIQ-SF and each KHQ domain at the points before vs 1 year and more than 4 years after surgery.

Results

Fifty-eight patients underwent AUS implantation (all devices were AMS 800™), 8 of whom had revision of AUS (median time of revision surgery was 35.5 months after first surgery). The reasons for treatment failure were mechanical failure, urethral atrophy and urethral erosion in 4 cases, 3 cases and 1 case, respectively. Eleven of 50 patients (non-revision group) had been followed continuously for more than 4 years in our institute. The median age of the 11 patients and follow-up months after AUS implantation were 77 years old and 52 months, respectively. Regarding ICIQ-SF, total score deteriorated at the point of 4 years after surgery after having improved significantly at 1 year after surgery ($p=0.017$) (Figure 1). Six of 9 domains of KHQ improved significantly at a year after surgery. In addition, 2 domains (Role limitation score and Social limitation score) have significance at 4 years after surgery compared to these before surgery (Figure 2). On the other hand, the score of General health perceptions turned worse after having improved at 1 year after surgery.

Interpretation of results

The increase of ICIQ-SF total score during long term follow-up means that the efficacy of AUS was attenuated over time. However, all patients but 8 have been relatively satisfied with the efficacy of their device for a long time; these 8 patients due to device failure at a median of 35.5 months after surgery. The reasons for device failure are categorized as mechanical issues, urethral atrophy, urethral erosion and device infection. In addition, previous reports indicated that treatment failure is likely to occur mostly during the first 3 years after surgery. These results suggest that patients who avoid infection, urethral erosion and atrophy in the first 3 years after primary surgery could keep relatively better long-term QOL affected by urinary dysfunction. Five of 11 patients answered "Not Applicable" in the domain "Personal relationship". This is the reason why the domain did not improve significantly during follow-up in this study. We presume that SUI does not cause severe problems in their relationship with their partner, because Japanese senescence patients are generally sexually inactive.

Concluding message

The long term QOL after AUS implantation more than 4 years after surgery is satisfactory. The treatment failure could worsen patient QOL until 3 years after primary surgery, resulting in requirement of revision. On the other hand once the patients avoid treatment failure by some causes such as mechanical failure, infection, urethral erosion and atrophy until three years after surgery, they could enjoy better outcomes.

Methods and Materials

- Fifty-eight patients underwent AUS implant surgery in our institute from 2007 to 2018, 11 of whom have been followed for more than 4 years after primary surgery without revision in our institute continuously.
- Patients have filled out the questionnaire of ICIQ-SF (International Consultation on Incontinence) and KHQ (King Health Questionnaire) before, 1 year and 4 more years after primary surgery.
- For ICIQ-SF, patients were asked to rate answers on a Likert scale with a maximum possible score on the first 3 questions of 5, 6 and 10, respectively.
- KHQ consists of 9 items scored on a scale of 0 to 100 with 0 representing the best condition and higher scores indicating worse conditions. The Wilcoxon signed rank test was used to compare changes in total scores of ICIQ-SF and each KHQ domain at the points before vs 1 year and more than 4 years after surgery.

Discussion

- The increase of ICIQ-SF total score during long term follow-up means that the efficacy of AUS was attenuated over time.
- However, all patients but 8 have been relatively satisfied with the efficacy of their device for a long time; these 8 patients due to device failure at a median of 35.5 months after surgery.
- The reasons for device failure are categorized as mechanical issues, urethral atrophy, urethral erosion and device infection. In addition, previous reports indicated that treatment failure is likely to occur mostly during the first 3 years after surgery.
- These results suggest that patients who avoid infection, urethral erosion and atrophy in the first 3 years after primary surgery could keep relatively better long-term QOL affected by urinary dysfunction.
- Five of 11 patients answered "Not Applicable" in the domain "Personal relationship". This is the reason why the domain did not improve significantly during follow-up in this study.
- We presume that SUI does not cause severe problems in their relationship with their partner, because Japanese senescence patients are generally sexually inactive.

Introduction

- Artificial urethral sphincter (AUS) is the gold standard as a treatment for severe stress urinary incontinence (SUI) after radical prostatectomy.
- Even though the AUS is implanted, symptoms of SUI worsen again and revision surgery is required because of urethral atrophy, urethral erosion, mechanical failure, and so on.
- Approximately 30-50% of patients have experienced treatment failure during follow-up^{1,2}. However, there are few reports focusing on long term patient reported outcome after surgery.
- The aim of this study is to clarify how quality of life (QOL) reported by patients with AUS implantation changes before and after the surgery over time.

Results

Table 1 Patient Characteristics

N		11	
Age	(Now)	77	(47-84)
Follow-up	(Months)	52	(41-72)
Incontinence etiology	Radical prostatectomy	11	-100%
Charlson Comorbidity Index		0	(0-2)

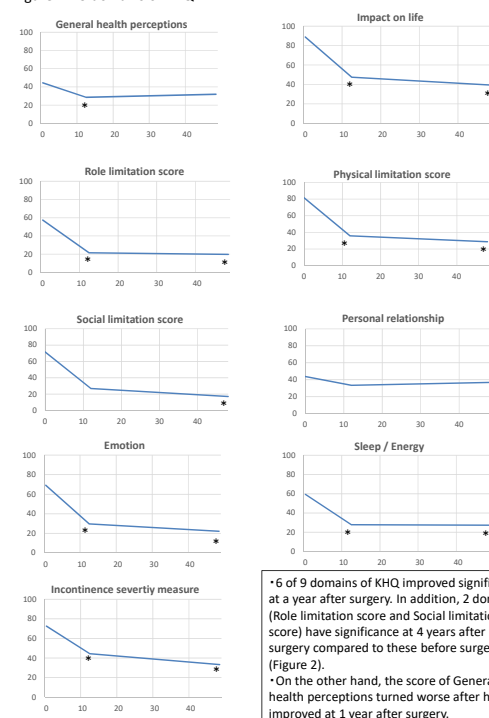
• 58 patients underwent AUS, 8 of whom had revision of AUS (median time of revision surgery was 35.5 months after first surgery).
• 11 of 50 patients (non-revision group) had been followed continuously for more than 4 years in our institute.

Figure 1 ICIQ-SF total score



• Total score deteriorated at the point of 4 years after surgery after having improved significantly at 1 year after surgery ($p=0.017$)

Figure 2 9 domains of KHQ



• 6 of 9 domains of KHQ improved significantly at a year after surgery. In addition, 2 domains (Role limitation score and Social limitation score) have significance at 4 years after surgery compared to these before surgery (Figure 2).
• On the other hand, the score of General health perceptions turned worse after having improved at 1 year after surgery.

*: Significant difference to before surgery

Conclusions

- The long term QOL after AUS implantation more than 4 years after surgery is satisfactory. The treatment failure could worsen patient QOL until 3 years after primary surgery, resulting in requirement of revision. On the other hand, once the patients avoid treatment failure by some causes such as mechanical failure, infection, urethral erosion and atrophy until three years after surgery, they could enjoy better outcomes.

References

- 1 Long-term outcomes after primary failures of artificial urinary sphincter implantation. Wang R, McGuire EJ, He C, Faerber GJ, Latini JM. Urology. 2012 Apr;79(4):922-8.
- 2 Long-term durability and functional outcomes among patients with artificial urinary sphincters: a 10-year retrospective review from the University of Michigan. Kim SP, Sarmast Z, Daignault S, Faerber GJ, McGuire EJ, Latini JM. J Urol. 2008 May;179(5):1912-6.