Short term reoperation rates after artificial urinary sphincter placement in pediatric patients

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Introduction: *Artificial urinary sphincters (AUS) have demonstrated good functional outcomes in pediatric populations. We sought to examine the nationwide short term reoperation rates in pediatric patients after AUS placement.*

Materials and methods: *An observational cohort study was designed utilizing claims from the Truven MarketScan Commercial Claims and Encounters database from 2007 to 2018. Patients under 18 years of age undergoing an AUS procedure were identified using CPT and ICD9/10 codes. Reoperations included any removal, replacement, or AUS placement codes which occurred after the initially identified placement code. Follow up time was the amount of time between AUS placement and the end of MarketScan enrollment.*

Results: *From 2007-2018, we identified 57 patients under the age of 18 who underwent AUS placement and after excluding 8 for concurrent AUS complication procedure codes and 4 for follow up < 60 days, the final cohort included 45 patients. The median age was 13 years (IQR 9-16 years) at the time of AUS placement, and the median follow up time after AUS placement was 787 days (IQR 442-1562 days), approximately 2.2 years. Total reoperation rate was 22%. Reoperations included 40% device removals (4/10) and 60% replacements (6/10). Neither gender (p = 0.70) nor age (p = 0.23) was associated with need for reoperation. Patients who had a concurrent bladder surgery had a higher rate of undergoing reoperation (50% vs. 12%, p = 0.007).*

Conclusions: *The rate of reoperation after AUS placement approached 1 in 4 in pediatric patients. These data may be instrumental for providers and parents in counseling and decision-making regarding risks of prosthetic implantation.*

Key Words: artificial urinary sphincter, incontinence, pediatric, reoperation, device

Introduction

For children with incontinence secondary to neuropathic bladders who fail conservative management, artificial urinary sphincter (AUS) placement may be a treatment option. The most common underlying condition causing neuropathic bladder in children who undergo AUS placement is myelomeningocele, but device placement has also been used in children with epispadias, sacral agenesis, VACTERL syndrome, and spinal cord injury among others.[1-3] Since the AUS cuff is placed at the bladder neck in children, it has not been as successful in conditions like bladder exstrophy or ectopic ureteroceles because of the higher risk of cuff erosion.

Use of AUS in pediatric populations has been demonstrated to have good functional outcomes with high rates of continence since it was first employed in children in the 1970's. In the earliest studies, reoperation rates for either revision or removal were reportedly between 38%[4] and 59%.[5] Additionally, the majority of children who underwent a revision required more than one operation.[2,5] For patients who maintained their AUS, daytime continence exceeded 80%.[4-6]

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However, the largest studies of AUS placement in children typically include more than one AUS model and were published over 20 years ago.[2,4,5,7] In 1987, American Medical Systems (AMS) released an update on the AMS-800 model which improved on prior models by providing a narrow-back cuff design and provided the component connection updates and pressure-regulating reservoir balloon which are still utilized today.[8,9] Since then, studies have demonstrated a reduction in post-implantation device complications[10] and the AMS-800 model has become ubiquitous in use. Thus, studies including patients who underwent AUS placement before 1987 may have outcomes which differ from a modern cohort of patients who receive only the current model. The purpose of this study was to examine the frequency of short term reoperative procedures after AUS placement in a contemporary national pediatric cohort. We hypothesized that due to device updates and surgeon experience, reoperation rates today have improved since the 1980's.

Materials and methods

We performed an observational cohort study using claims from the Truven MarketScan database from 2007 to 2018 which were the earliest and latest years available to our research team. This database contains information from US employer-based commercial healthplans of over 240 million patients. It does not include patients with public (such as Medicaid) or no insurance. Each patient in the MarketScan database is assigned a unique identification number so that their medical care can be tracked longitudinally.

Patients under 18 years of age were included and AUS procedures were identified using Common Procedural Terminology (CPT) codes and International Classification of Disease, Ninth revision clinical modification (ICD-9-CM) and ICD-Tenth revision CM and Procedural Coding System (ICD-10-PCS) codes. Since the CPT codes do not differentiate between urethral and bladder neck device placement and distinction by ICD code did not occur until 2015 with ICD-10 codes, we did not make this distinction in our cohort, understanding that the majority of pre-adolescent children would have had the cuff placed at the bladder neck. The primary outcome of interest was reoperative procedures, which were defined as any device removal or device replacement after the initial AUS implant procedure. The follow up period was defined as the amount of time between initial AUS placement and when the patient's Marketscan enrollment ended. Patients without continuous follow up (due to any lapse or change in insurance coverage) were censored at the time when the first enrollment period ended. Patients with < 60 days of follow up were excluded. Individuals with procedures or diagnoses for complications of AUS at the time of initial placement were also excluded, as we could not verify whether this procedure was an initial placement or revision surgery.

Data were analyzed using SAS v9.4 (Cary, NC, USA). Continuous variables such as age and follow up time were summarized as medians with inter-quartile ranges (IQR); proportions were expressed as percentages. Binary logistic regression was used to evaluate the association between baseline variables and outcomes. This study was deemed exempt by the Institutional Review Board.

TABLE 1. **Patient characteristics for those who have met inclusion criteria**

# patients	**45**
Age (median, IQR)	13 years (IQR 9-16 years)
Gender	71% male (32/45) 29% female (13/45)
Comorbidities	Spina bifida 62% (28/45) Bladder exstrophy 2% (1/45) Chronic kidney disease: 4% (2/45)
Simultaneous procedures	Mitrofanoff 18% (8/45) Mitrofanoff + bladder augmentation 4% (2/45) Bladder augmentation 2% (1/45) Suprapubic tube 2% (1/45) Cystorrhaphy with revision of ureterostomy 2% (1/45)
Median follow up (median, IQR)	20 mo (IQR 12-44 months)

Results

Over the 12-year study period, we identified 57 patients under the age of 18 who underwent AUS placement. Of these, 8 were excluded due to concurrent AUS complication procedure codes. An additional 4 patients were excluded due to follow up of < 60 days after the initial device placement.

The final cohort of 45 patients had a median age of 13 years (IQR 9-16 years) at the time of initial AUS placement, Table 1. The majority of patients (71%, 32/45) were male, and most (62%, 28/45) had a diagnosis of spina bifida. One patient had a diagnosis of bladder exstrophy (2%, 1/45). Two patients had a diagnosis of chronic kidney disease (CDK) prior to AUS placement and no patient developed a diagnosis of CKD after AUS placement during the follow up period. An appendicovesicostomy placement was performed in 22% of patients simultaneously with the AUS placement, Table 1. The median follow up time after AUS placement was 787 days (IQR 442-1562 days), approximately 2.2 years.

Reoperation occurred in 22% of patients (10/45) within the follow up period. The median time to second operation was 136 days (IQR 46-512 days), approximately 4.5 months, Figure 1. Three patients (7%) had a reoperation within 60 days of initial placement; two of which were removals. Overall, reoperations included 40% device removals (4/10) and 60% replacements (6/10). Neither gender (p = 0.70) nor age (p = 0.23) were associated with need for reoperation. Patients who had a concurrent bladder surgery (augmentation, mitrofanoff, cystorrhaphy) at the time of AUS placement had a higher rate of undergoing reoperation (50% vs. 12%, p = 0.007). The majority of patients (91%, 35/39) had an AUS in place at the time of their last Marketscan claim. Patients with a diagnosis of spina bifida were more likely to have a reoperation than patients without a spina bifida diagnosis (32% vs. 6%, p = 0.040), however this association was non significant on multivariate regression with age and gender as additional covariates (p = 0.10).

There were 4 patients who subsequently had a diagnostic code for device malfunction/failure (ICD-9 996.39) without a CPT code for device reoperation. This occurred at a median 67 days after AUS placement (IQR 59-74).

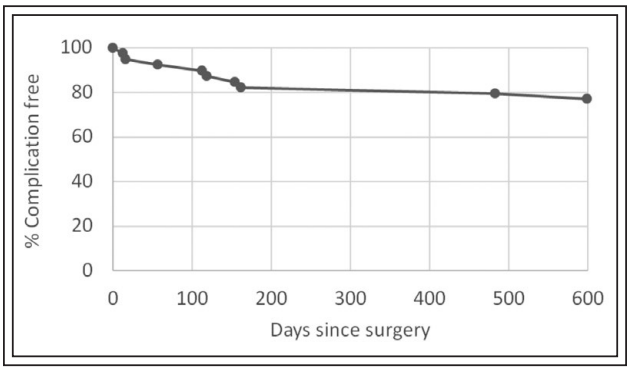

Figure 1. Proportion of patients who are reoperation-free by time in days after the initial AUS placement.

Discussion

In this retrospective nationwide cohort study of pediatric patients undergoing AUS placement with continuous follow up during the years 2007-2018, we found a reoperation rate of almost one in four patients. These data suggest that rates of overall reoperations (replacements and removals) have improved since the 1980s, though reoperations are still common within a short term follow up period.

The earliest published studies about AUS outcomes in pediatric populations include patients who received implants as early as 1977, and they reported reoperative rates as high as 60%.[2,5,7] During this time period before 1987, several different AMS AUS models were commonly used before the final edition of the AMS-800 model became standard. One study of 107 children with mean follow up time > 5 years reported device removal rates near 20% and a mean operational life of 56 months (4.7 years) for the device.[5] To identify whether patient population characteristics impacted reoperation rate, centers published data on subsets of patients. One study of 22 non-spina bifida patients with a mean follow up time of 6 years reported a reoperation rate of 36%, with a removal rate of 14%.[11] In another study of patients undergoing AUS placement with simultaneous or staged augmentation, urethral device erosion occurred in 33% (5/15) patients.[12] Our device removal rate (9%), replacement rate (13%), and total reoperation rate (22%) appear to be improved from these previously published studies, though this may be attributed to our shorter median follow up time. Thus, with longer follow up time it is likely that reoperation rates would increase. In a 2022 retrospective, European single-institution study examining long term outcomes of AUS placement in 71 patients with congenital neuropathic bladder (median age 14.5, median follow up time 17.2 years), authors found that 32% required subsequent surgical revision. Furthermore, they reported a device removal rate of 6% due to infection or erosion, and replacement rate of

25% all due to balloon reservoir malfunction. Median time to replacement at their center was 12 years, which is significantly greater than our finding of 4.5 months to reoperation.[13] The differences in rates may be attributed to surgeon experience in AUS implantation at their single reference center in Europe, in contrast to our study which captured operations that occurred throughout many centers in the United States by any surgeon.

We identified a national reoperation rate of 22% after AUS placement in children with employer-based health insurance. This number is closer to the rate seen in adult populations where reoperation rates tend to fall between 20%-25%.[14,15] However, the median time to second surgery in our cohort was about 4.5 months compared to adults who require secondary surgery for infection/erosion at a median time of 2 years.[16] Clearly, pediatric patients undergoing AUS placement differ in many ways from their adult counterparts due to anatomy, urinary physiology, comorbidities, and bladder function. Often times, children with an AUS will still require chronic intermittent catheterization (CIC) compared to adults where CIC is not routinely used. Performing CIC could impact reoperation rates by introducing bacteria into the urine or cause urethral mucosal injury. Another point to consider is that for these adolescents, the cuff alone, even if AUS device is no longer cycling, may provide adequate resistance to maintain continence in the post-pubertal male, with a relatively low risk of late erosion. This may explain why several patients in this study developed a diagnostic code for device malfunction but did not have documentation of a reoperation.

This study is strengthened by its inclusion of patients from across the country from any hospital, including community and academic centers, as this helps remove single institution or surgeon bias. Consequently, these results may be more applicable to the general pediatric population undergoing AUS placement especially those with employer-based insurance. Furthermore, Marketscan relies on insurance claims so it captures patients who underwent a reoperation at a different institution than the initial placement which single institutional studies may omit.

This study has several limitations. First, the Marketscan population is limited to patients who receive healthcare under employer-based insurance, thus excluding those who rely on public insurance or those who are uninsured, which limits the generalizability of our findings. Patients with spina bifida make up the largest group of pediatric patients receiving AUS placements and over half of children with spina bifida are on public insurance.[17] A nationwide study looking at reoperation rates after primary hypospadias repair found that nearly 1 in 2 patients undergoing distal repair had noncommercial insurance, and these patients were 26% more likely to undergo reoperation compared to privately insured patients (OR 1.26, $p < 0.04$).[18] There are many factors that may explain differential surgical outcomes between privately insured and publicly insured patients, though this is outside the scope of this paper. Our final cohort was 45 patients, which is a small sample however AUS placement in children is an uncommon procedure. Another limitation is that we do not have access to patient demographics such as race and socio-economic status or detailed follow up data including continence rates, bladder function or satisfaction. The database itself relies on proper billing and coding, which is subject to human error. Furthermore, because diagnostic coding may not include infectious status or device malfunction, we do not know for certain the particular reasons for device removal or replacements (whether it was due to device infection, erosion, or other complications). Finally, the study is limited by short follow up time and because of this, our findings likely underestimate the nationwide reoperative rate amongst all pediatric patients undergoing AUS placement. However, these data provide important information about the short term (less than 3 year) success rate of the operation.

Given these limitations, this study's reoperative rate after AUS placement of 22% likely represents a "best case scenario" in that it applies to privately insured patients at a median follow up time around 2 years. Notably, many patients underwent reoperation within 6 months after their initial device placement. Currently, very few of these procedures are being done in the United States, and the lack of surgeon exposure to this operation during training may partially explain this high reoperation rate. With these data, pediatric urologists can provide updated, transparent preoperative counseling before AUS placement.

Conclusion

To our knowledge, this is the first population-based attempt to assess postoperative outcomes of AUS placement in children using insurance-claims based data. We demonstrate that the estimated national rate of undergoing an AUS replacement or removal was almost one in four for privately-insured patients, with a significant proportion of reoperations occurring in the first 6 months after surgery. Given that our data only includes those covered by employer-based insurance, our data likely represents a "best case scenario" after

AUS placement in children. The true reoperation rate on a national level is likely greater than our findings. These data may be instrumental for providers and parents both in counseling and in decision-making regarding the risks of prosthetic implantation. □

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