



A global, propensity-score matched analysis of patients receiving artificial urinary sphincters and the risk of complications, infections, and re-interventions

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Background: Artificial urinary sphincters (AUS) are the gold standard treatment for patients with stress urinary incontinence. However, risk factors for implant infection, complication, or re-intervention (removal, repair, replacement) are incompletely understood. We sought to understand the impact of various patient factors on the risk of device failure by leveraging a large, multi-national research database.

Methods: We queried the TriNetX database for all adult patients undergoing AUS. We evaluated the impact of age, body mass index, race, ethnicity, diabetes (DM), smoking history, history of radiation therapy (RT), history of radical prostatectomy (RP) and history of urethroplasty on select clinical outcomes. Our primary outcome was the need for re-intervention defined by current procedural terminology (CPT) codes. Secondary outcomes included overall device complication rate and infection rate defined by international classification of diseases (ICD) codes. Analytics were performed on TriNetX which calculated risk ratios (RR) and Kaplan-Meier (KM) survival. We evaluated our outcomes first on the entire population and then repeated analyses for each individual comparison cohort using the remaining demographic variables to perform propensity score matching (PSM).

Results: The overall rates of AUS re-intervention, complication and infection were 23.4%, 24.1% and 6.4%, respectively. KM analysis showed median AUS survival (no need for re-intervention) at 10.6 years and projected 20-year survival probability at 31.3%. Patients with a history of smoking or urethroplasty were at higher risk of AUS complication and re-intervention. Patients with DM or a history of RT were at higher risk of AUS infection. Patients with a history of RT were at higher risk of AUS complication. All risk factors besides race showed a difference in device removal itself.

Conclusions: To our knowledge, this represents the largest series to follow patients with an AUS. About one-quarter of AUS patients needed re-intervention. Multiple demographics place patients at increased risk of re-intervention, infection, or complication. These results can help guide patient selection and counseling with the goal of reducing complications.

Keywords: Stress urinary incontinence; artificial urinary sphincter; complications; re-intervention

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Introduction

Artificial urinary sphincters (AUS) are considered the gold standard treatment for men with stress urinary incontinence (SUI) (1), SUI is often iatrogenic after prostate or urethra surgery (2). AUS can be offered to almost all men with SUI due to its functional outcomes and high level of patient satisfaction (3-5), while alternative treatments, such as male slings (MS) or bulking agents (6), are often reserved for men with milder degrees of SUI (7).

Despite decades as the gold standard surgical option, some patients do poorly after AUS and even patients who initially do well often need additional revision surgery (8,9). It is therefore imperative for urologists to counsel their patients on the risks of AUS failure (10). Yet, risk factors for implant infection, complication or re-intervention (removal, repair, replacement) are incompletely understood and outcomes data are mostly limited to single institutional studies from high volume centers (11), with few studies coming from community based practice (12).

In this context, we sought to understand the impact of various patient factors on the risk of device failure and complications by leveraging a large, multi-national research database. By broadening our sample size, we aimed to discover the impact of various patient demographic factors on AUS outcomes in a diverse population which can help guide patient selection and counseling with the aim of improving outcomes for all.

Methods

We accessed the TriNetX electronic health record (EHR) data which is collected from its member healthcare organizations (HCOs) using an i2b2 data model. The

data used in this research is from the TriNetX Research Network that contains historical data from the EHR of over 100 million patients located in 69 HCOs (mostly from the United States) at time of analysis. TriNetX analyzes patient data up to 20 years prior to the date of analysis (2002–2022), therefore we excluded those undergoing the index event over 20 years ago, and includes data on demographics, medical diagnoses, procedures, lab values, vital signs and medications. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Given the de-identified nature of this dataset, our study was deemed exempt from Institutional Review Board approval and informed consent.

Our initial cohort included all adult (greater than or equal to 18 years old) men undergoing AUS surgery defined by Current Procedural Terminology (CPT 53445) which was set as our index event. Our primary outcome was the need for re-intervention at any point after implantation (CPT codes 53446, 53447, 53448, 53449) classification. Secondary outcomes included overall device complication rate, and specifically infection rate defined by International Classification of Diseases (ICD-10) codes (T83, T83.5, T83.8, T83.83, T83.84, T83.89, and T83.9 for all complications and T83.5 for infection). A full definition of each CPT and ICD code is included in [Table S1](#). If a HCO provided data in ICD-9-CM, a 9-to-10-CM mapping based on general equivalence mappings plus custom algorithms and curation to transform data from ICD-9-CM to ICD-10-CM was used by TriNetX. We assessed all outcomes as events that occurred starting day one after the index event. Potential patient risk factors, chosen based on previous literature on genitourinary implants and clinical experience (13), included in analysis were age, body mass index (BMI), race, ethnicity, diabetes (DM; ICD E08-E13), smoking history (ICD Z87.891, F17), history of radiation therapy (RT; ICD Z92.3), history of radical prostatectomy (RP; CPT 55840, 55866, 55845) and history of urethroplasty (CPT 53400, 53405, 53410, 53415, 53420, 53425).

We evaluated our outcomes first on the overall AUS population. We then performed subgroup analyses for each individual risk factor (i.e., patients with DM against patients without DM) and utilized all remaining variables for propensity score matching (PSM). All analyses were performed internally via TriNetX on demographic data which calculated risk ratios (RR) and Kaplan-Meier survival (KM) after PSM was performed with significance set at P values of <0.05. TriNetX has developed their own platform so that users can perform PSM directly on their website

Highlight box

Key findings

- Estimated 20-year device survival around 30%.
- AUS risk factors for device reintervention: urethroplasty, DM, smoking, radiation, prostatectomy.

What is known and what is new?

- Largest series of AUS to date.
- Longest estimate of device survival.

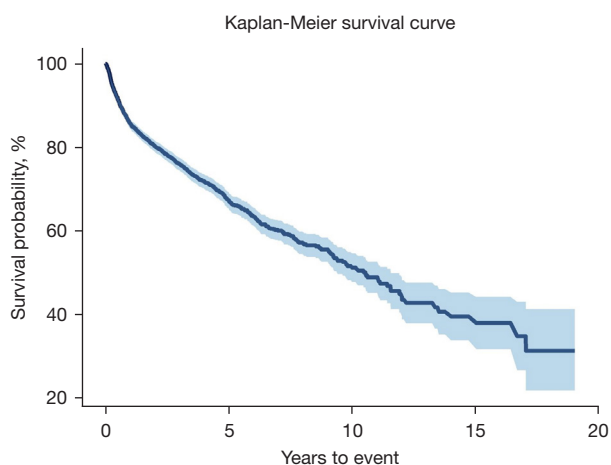
What is the implication, and what should change now?

- May help providers counsel patients and give better estimates of their outcomes after AUS.

Table 1 Risk of re-intervention, complication, or infection following artificial urinary sphincter

Risk factor	N before PSM	N after PSM	Re-intervention (CPT codes 53446, 53447, 53448, 53449)			Complication (ICD codes T83, T83.5, T83.8, T83.83, T83.84, T83.89, T83.9)			Infection (ICD code T83.5)		
			%	RR	P	%	RR	P	%	RR	P
Total population	4,729	–	23.4			24.1			6.4		
Diabetes	971	962	23.7			27.0			8.5		
No diabetes	3,364	962	21.0	1.13	0.16	23.1	1.17	0.07	5.7	1.48	0.02
Smoking	1,649	1,517	27.6			31.0			7.9		
No smoking	3,080	1,517	22.1	1.25	<0.01	25.6	1.21	<0.01	6.6	1.20	0.17
Black/AA	587	580	22.0			26.1			4.4		
Non-Black/AA	4,142	580	24.0	0.92	0.43	25.2	1.04	0.75	6.3	0.70	0.16
RT	778	769	23.3			26.6			8.3		
No RT	3,701	769	20.0	1.17	0.13	21.2	1.25	0.02	4.3	1.92	<0.01
RP	1,005	972	21.3			23.4			4.4		
No RP	3,718	972	24.3	0.88	0.12	25.4	0.92	0.34	7.8	0.56	<0.01
Urethroplasty	198	197	35.1			37.6			10.0		
No urethroplasty	4,531	197	24.2	1.45	0.03	23.3	1.62	<0.01	8.2	1.23	0.54

PSM, propensity score matching; CPT, current procedural terminology; ICD, international classification of diseases; AA, African American; RT, radiation therapy; RP, radical prostatectomy.

**Figure 1** Artificial urinary sphincter device Kaplan Meier survival curve.

which runs logistic regression based on user-specified variables of interest to obtain a list of propensity scores and then uses 1:1 greedy nearest-neighbor PSM to obtain the matched cohort (14). Sample sizes following PSM were nearer to the smaller of each pair of cohorts. Notably, when

less than 10 patients experience an outcome, TriNetX rounds the value to 10 to protect patient anonymity.

Results

Final analyses were run on September 22nd, 2022. After excluding women and patients who received an AUS over 20 years prior, we identified an overall cohort of 4,729 patients. Average age at surgery was 68.7 years with an average age at time of analysis being 74.1 years. The majority of patients were white (3,439, 77%) and not Hispanic or Latino (3,631, 81%). The overall rate of device re-intervention was 23.4% and the overall rate of complication and infection specifically was 24.1% and 6.4%, respectively. Kaplan Meier analysis showed median device survival (no need for re-intervention: CPT 53446-53449) of 10.6 years and projected 10- and 20-year survival probability at 51.7% and 31.3% (Figure 1).

The results for the various AUS cohort analyses are included in Table 1, including sample sizes before and after PSM. Patients were at a higher risk of re-intervention with a history of urethroplasty (35.1% vs. 24.2%; RR 1.45, P=0.03) or smoking (27.6% vs. 22.1%; RR 1.25, P<0.01). Patients

Table 2 Artificial urinary sphincter re-intervention, broken down into removal, removal and replacement (with or without an infected field) and repair

Risk factor	N before PSM	N after PSM	Removal (CPT code 53446)			Removal and replacement (CPT code 53447)			Removal and replacement through an infected field (CPT code 53448)			Repair (CPT code 53449)		
			%	RR	P	%	RR	P	%	RR	P	%	RR	P
Total population	4,729	–	9.7			12.9			0.6			4.1		
Diabetes	971	962	12.4			11.0			1.1			4.3		
No diabetes	3,364	962	8.2	1.51	<0.01	11.4	0.97	0.81	1.0	1.10	0.82	4.2	1.03	0.9
Smoking	1,649	1,517	14.1			13.8			0.66			4.4		
No smoking	3,080	1,517	8.3	1.69	<0.01	12.6	1.10	0.30	0.73	0.91	0.82	4.1	1.08	0.66
Black/AA	587	580	9.1			12.6			1.7			4.0		
Non-Black/AA	4,142	580	8.5	1.08	0.70	15.3	0.83	0.20	1.7	1.0	1.0	4.3	0.92	0.77
RT	778	769	13.0			10.0			1.3			4.2		
No RT	3,701	769	6.5	2.0	<0.01	11.2	0.89	0.44	1.3	1.0	1.0	5.1	0.82	0.39
RP	1,005	972	7.5			13.0			1.0			4.1		
No RP	3,718	972	10.7	0.71	0.02	13.4	0.97	0.76	1.0	1.0	0.99	4.3	0.95	0.81
Urethroplasty	198	197	18.8			16.7			5.1			8.8		
No urethroplasty	4,531	197	9.6	1.97	0.01	11.3	1.48	0.13	5.1	1.0	1.0	5.1	1.7	0.15

PSM, propensity score matching; CPT, current procedural terminology; AA, African American; RT, radiation therapy; RP, radical prostatectomy.

were at a higher risk of any complication with a history of urethroplasty (37.6% vs. 23.3%; RR 1.62, P<0.01), a history of RT (26.6% vs. 21.2%; RR 1.25, P=0.02), or a history of smoking (31.0% vs. 25.6%; RR 1.21, P<0.01). Patients were at a higher risk of infection with a history of RT (8.3% vs. 4.3%; RR 1.92, P<0.01) or DM (8.5% vs. 5.7%; RR 1.48, P=0.02) and lower risk with a history of RP (4.4% vs. 7.8%; RR 0.56, P<0.01). Race showed no difference in any primary outcome. A history of urethroplasty was associated with the highest RR for re-intervention and complication and RT was associated with highest RR for infection.

In Table 2, rates of AUS re-intervention are reported in further detail: removal rate (CPT 53446), removal and replacement rate (CPT 53447), removal and replacement through an infected field rate (CPT 53448), and repair rate (CPT 53449) individually. The overall rate of removal was 9.7%, removal and replacement 12.9%, removal and replacement through an infected field 0.6% and repair 4.1%, with some patients therefore needing multiple repeat interventions. Each risk factor besides race was associated with differences in device removal (DM 12.4% vs. 8.2%;

RR 1.51, P<0.01, smoking 14.1% vs. 8.3%; RR 1.69, P<0.01, RT 13.0% vs. 6.5%; RR 2.00, P<0.01, RP 7.5% vs. 10.7%; RR 0.71, P=0.02; urethroplasty 18.8% vs. 9.6%; RR 1.97, P=0.01). None of the subgroups showed a significantly increased risk for removal and replacement, removal and replacement through an infected field or repair alone.

Discussion

In this article, we present the largest sample, to our knowledge, of patients undergoing AUS. We leveraged a global database, TriNetX, and include up to 20 years of patient data. At 20 years, it's projected up to 70% of AUS patients will need some form of repeat intervention on their device, given not all patients have 20 years of data to report and some data would be censored. Of the evaluated patient risk factors, having a history of urethral surgery was associated with the highest risk of device complication compared to controls, and not surprisingly this also translated to having the highest risk of device re-intervention for AUS. Patients with DM had an increased

risk of infection compared to controls, perhaps not surprising given the relative immune dysfunction associated with DM (15). Although many of the potential risk factors studied are not modifiable, they may be helpful in counseling patients and setting expectations.

To better understand risks for re-intervention, we evaluated device removal, repair, and replacement (including through an infected field) individually. It becomes apparent that device removal is the large driver of disparities within our queried patient risk factors, risk of removal showed statistically significant differences between all but one patient comparisons. Smoking and history of urethroplasty both showed significant differences in risk of re-intervention and removal specifically, while history of DM and radiation do have significant differences in risk of removal but not re-intervention. A history of RP showed lower risk of device removal but again no overall significant difference in risk for device re-intervention. Our interpretation is that patients undergoing just removal are likely having their device removed for infection or urethral erosion. It is understandable that patients with the risk factors listed above are at higher risk for poor tissue healing and thus may be more susceptible to erosion or infection. Given that the incidence of removal and replacement through a sterile field combined with repair is higher than the incidence of purely removal, and the risk of infection as reported in *Table 1*, it follows that patients undergo re-intervention more commonly for mechanical than infectious considerations, which aligns with clinical practice.

Our study is unique in both its size and its length of follow up. We were able to project that about half of AUS patients would be free from re-intervention at 10 years and about 30% of patients would be free from re-intervention at 20 years. It is difficult to compare our 20-year projection to contemporary literature as most series do not extend to that timeframe. The longest series we were able to find included up to 15 years of follow-up at the Mayo Clinic, with two-fifths of patients free from re-intervention at their timepoint (11). There is more data to compare to regarding median device survival, however. We reported a median re-intervention-free survival of 10.6 years, similar to a series from Belgium which had a median revision-free survival of 10.8 years in 263 patients (16), while other groups report around one-third of patients having device failure around 10 years (3). It was thought that based on the data collection within TriNetX that there would be difficulty separating patients with purely non-infectious complications from

patients with any complications, which is why we did not include a non-infectious group. However, based on previous literature, having a non-infectious complication is more likely than an infectious one, similar to our results (3,11).

Given the wealth of data included in the TriNetX depository, we were able to evaluate the impact of multiple patient factors on device outcomes, with many similar patient factors in comparison to other studies in the literature (11,17-20). The effect of DM on the need for re-intervention has been reported, with one study out of Japan uniquely including data on physical performance status (21). We also include the impact of RT on device outcomes; however, one limitation is the inability to stratify within TriNetX based on purely pelvic radiation and our study population likely includes some patients with radiation elsewhere in the body. A previous study had found no difference in device survival at 1- and 5-years based on previous radiation treatment (18), which contrasts our findings of increased risk of device removal. In our study, we report the negative impact of smoking on device re-intervention and complication, which is contrary to a previous study by Godwin *et al.* (19). We found a similar risk of infection but higher risk of re-intervention or complication in patients receiving AUS after urethroplasty, which had been similarly reported from a multi-institutional group based in Germany and Egypt (17). With regards to race, we note no difference in outcomes which is consistent with previous data (20), but important context includes that African American men have previously been reported to receive surgical treatment for post-prostatectomy SUI at lower rates and with longer delays after prostatectomy (22).

Our study is not without limitations. The data within TriNetX reflects how the information is received from the HCOs, and like all registry studies, degrees of assumptions must be made regarding the quality, reliability and accuracy of this, and any, large, de-identified data set. Per TriNetX, once HCO data are transformed into the TriNetX proprietary data schema the data undergoes extensive data quality assessment that includes rejection of record that do not meet their quality standards. Further, some patients were likely lost to follow-up for various reasons including reestablishing care with an HCO outside of the TriNetX network. Additionally, we manually selected various patient risk factors to study and the various codes by which we identified patients corresponding to individual diagnosis or procedural groups. There is likely some inherent confounding since not all risk factors were able

to be to controlled. Further, our analyses were limited to generic ICD/CPT codes and we were unable to better assess specific surgical details such as approach taken (i.e., transcorporal *vs.* penoscrotal *vs.* perineal) or AUS cuff size selected. Likewise, we were unable to identify the specific etiology for the need of device re-intervention, which can have notable clinical differences if the revision was for a migrated scrotal pump versus an eroded pump, for example. There also may be an overlap between a device complication and an infection, such as if the device erodes. One surgeon may describe this as an infection, another may describe as a complication, and a third may describe as both, without an ability to distinguish between these scenarios based on the data in TriNetX. These factors may limit the applicability of our results. However, despite these limitations, we were able to provide the largest, and longest series of AUS patients, to our knowledge, and these strengths should be considered in light of the aforementioned limitations.

This study describes the largest collection of AUS patients to date and helps develop our understanding of how patients perform after this procedure. Large, multi-institutional datasets enable us to better collect real-world data representing a range of practice settings and expertise. This data is all de-identified and not under the control of the principal investigators, but the information discussed herein could be used to design prospective studies more accurately tailored to answer specific research questions. We reported the impact of patient factors such as previous history of smoking, prostatectomy, radiation, urethroplasty, but also the diagnosis of DM. Future work to discover more potentially modifiable patient comorbidities, like DM, would be helpful in designing studies to evaluate the impact of controlling medical comorbidities and how this may improve patient outcomes. Extending further, understanding how a history of prostate or urethral surgery alters anatomy could lead to new developments in surgical technique which may improve results for this population.

Conclusions

AUS remains the gold standard for patients with SUI with an overall high level of patient satisfaction. We described a relatively high risk of device failure and identified multiple patient factors associated with increased risk of device infection, complication, or need for re-intervention. Understanding which patient factors put patients at higher or lower risk of complications or the need for re-

intervention will help urologists properly counsel patients and set expectations. There are key limitations to our work, notably those inherent to any studies using large registry data, but these limitations do limit the applicability of our findings. However, despite this, the sample size and longitudinal nature of our study give it notable strengths. If patients are aware of their individual increased risk of complication, this should hopefully improve satisfaction even if a complication were to occur.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was deemed exempt from institutional review board and informed consent given the de-identified nature of the registry.

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Table S1 ICD and CPT codes and definitions

Code	ICD or CPT	Definition
53440	CPT	Sling operation for correction of male urinary incontinence
53442	CPT	Removal or revision of sling for male urinary incontinence
53445	CPT	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
53446	CPT	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir and cuff
53447	CPT	Removal and replacement of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff at same operative session
53448	CPT	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue
53449	CPT	Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
55840	CPT	Prostatectomy, retropubic radical, with or without nerve sparing
55866	CPT	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistant when performed
55845	CPT	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes
53400	CPT	Urethroplasty; first stage, for fistula, diverticulum, or stricture (eg Johanssen type)
53405	CPT	Urethroplasty; second stage (formation of urethra), including urinary diversion
53410	CPT	Urethroplasty, 1-stage reconstruction of male anterior urethra
53415	CPT	Urethroplasty, transpubic or perineal, one stage, for reconstruction or repair of prostatic or membranous urethra
53420	CPT	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53425	CPT	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; second stage
T83	ICD	Complications of genitourinary prosthetic devices, implants and grafts
T83.5	ICD	Infection and inflammatory reaction due to prosthetic device, implant and graft in urinary system
T83.8	ICD	Other complications of genitourinary prosthetic devices, implants and grafts
T83.83	ICD	Hemorrhage due to genitourinary prosthetic devices, implants and grafts
T83.84	ICD	Pain due to genitourinary prosthetic devices, implants and grafts
T83.89	ICD	Other specified complication of genitourinary prosthetic devices, implants and grafts
T83.9	ICD	Unspecified complication of genitourinary prosthetic device, implant and graft
E08-E13	ICD	Diabetes Mellitus
Z87.891	ICD	Personal history of nicotine dependence
F17	ICD	Nicotine dependence
Z92.3	ICD	Personal history of irradiation

ICD, International Classification of Diseases; CPT, Current Procedural Terminology.