Prostatic artery embolization compared to trans-urethral resection of the prostate and prostatic urethral lift: A real-world population-based study

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Article

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Abstract

Background There are growing interests for minimally invasive surgical techniques (MISTs) for the treatment of benign prostatic hyperplasia (BPH) associated lower urinary tract symptoms (LUTS). Prostatic artery embolization (PAE) uses selective angioembolization of prostatic arteries, thereby reducing size to improve LUTS/BPH. However, real-world data comparing surgical outcomes between MISTs and tissue resective techniques is lacking. We assessed the differences in surgical outcomes between PAE, transurethral resection of the prostate (TURP), and prostatic urethral lift (PUL) in a real world-population for LUTS/BPH.

Methods We present an observational population-based study of 12,902 men with BPH in New York State who received PAE, TURP, and PUL in outpatient and ambulatory surgery settings from 2014 to 2018. For short-term outcomes, we report 30-day and 90-day risks of readmission to inpatient and emergency room (ER) with/without complications and compared them across groups using Chi-square tests and mixed effect logistic regressions. For long-term outcomes, we report surgical retreatment and stricture rates using Kaplan Meier failure curves and compared them using Log rank tests and Cox regression models.

Results Of 12 902 men, 335 had PAE, 11 205 had TURP, and 1 362 had PUL. PAE patients had the highest 30-day (19.9%) and 90-day (35.6%) risks of readmission to inpatient or ER ($p<0.01$). Non-specific abdominal pain was the main diagnosis associated with 30-day and 90-day readmissions to inpatient or ER after PAE (14.3% and 26.8%, respectively). After 2 years of follow-up, PAE patients had the highest retreatment rate of 28.5% (95%CI: 23.7%-34.2%) compared to TURP (3.4% (95%CI: 3.1%-3.8%)) and PUL (8.5% (95%CI: 5.6%-12.9%)) ($p<0.001$).

Conclusion In a real-world population, PAE was associated with the most frequent 30-day and 90-day readmission to inpatient or ER and the highest retreatment rate among all surgical techniques even when controlled for individual patient comorbidities and surgical volume.

Introduction

Benign prostate hyperplasia (BPH) is a frequently diagnosed condition among aging men and is associated with lower urinary tract symptoms (LUTS) secondary to bladder outlet obstruction (BOO) (1). Trans-urethral resection of the prostate (TURP) is considered the gold standard for surgical management of symptomatic BPH for prostate volume of < 80cc (2). Newer minimally invasive surgical techniques (MISTs) have been introduced with the aim of reducing perioperative complications while maintaining procedure efficacy. Among these emerging techniques, prostatic urethral lift (PUL) and prostatic artery embolization (PAE) are being offered. PUL can be offered in an outpatient setting and consists in retracting obstructing prostatic lobes using mechanical implants under local anaesthesia (3). Moreover, PAE prevents prostate tissue growth and promotes smooth muscle and epithelial cell apoptosis in the prostatic transition zone through artery embolization. PAE was initially developed to treat hematuria, but studies have demonstrated relief in BPH associated LUTS following PAE (4, 5). Few studies have assessed surgical effectiveness of PAE compared to validated BPH surgical procedures such as TURP and PUL in a real-world setting. As such, we sought to assess differences in surgical outcomes between PAE, TURP and PUL.

Material And Methods

Data Source

We assessed the New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) data. Within SPARCS, patient data for inpatient stays, ambulatory and outpatient surgery visits as well as emergency department admissions in New York state (NY) was collected. Proper de-identification was ensured to maintain patient confidentiality.

Patient population

Our study population consisted of adult patients treated with TURP, PUL, or PAE for BPH in an outpatient surgical setting in NY between 2014 and 2018. We chose 2014 as the beginning of our study period because PUL and PAE can be identified using CPT codes in SPARCS since 2014. Water vapor therapy of the prostate (Rezum) was excluded from the study due to the overlapping codes with transurethral needle ablation (TUNA) of the prostate. Treatment indications were in accordance with the American Urology Association (AUA) clinical practice guidelines (6). Procedures were identified with Healthcare Common Procedure Coding System (HCPCS) codes (TURP: 52601, 52612, 52614; PUL: 52441, 52442, C9739, C9740; PAE: 37242, 37243) and the International Classification of Diseases (ICD), 9th and 10th revision procedure codes (TURP: 60.29, 0VB07ZZ, 0VB08ZZ). Patients with refractory hematuria as an indication for PAE were also included as many patients treated with PAE for LUTS/BPH will have hematuria and commonly coded together. Patients were excluded from the analysis if they had a history of prostate cancer, if they had any prior BPH procedure, if they received more than one BPH procedure at the index procedure date, and if they were not NY state residents. Institutional review board approval was obtained.

Characteristics and Outcomes

Baseline characteristics included age, race and ethnicity (white, black, Hispanic, others), type of insurance (Medicare, Medicaid, commercial insurance, others), index procedure year (2014-2015, 2016-2018), comorbidities (congestive heart failure, chronic pulmonary disease, hypertension, diabetes, coronary artery disease, peripheral vascular disease, obesity, anemia, depression, chronic kidney disease), prior Foley catheter insertion, and facility volume. The facility volume was calculated as the number of TURP, PUL or PAE carried out within 1 year prior to the procedure date and was categorized based on tertiles. We also summarized the comorbidity counts as a surrogate of patients' overall wellbeing.

Our primary outcomes were 30-day and 90-day readmissions to inpatient or ER, long-term reoperation, and long-term stricture development. Reoperations encompassed any subsequent BPH-related surgeries, including TURP, PUL, PAE, Rezum, transurethral needle ablation, transurethral microwave thermotherapy, Aquablation, transurethral incision, laser coagulation, laser vaporization, laser enucleation, and cryotherapy. For secondary outcomes, we evaluated 30-day and 90-day readmissions to inpatient or ER associated with each of the following complications: acute urinary retention (AUR), urinary tract infection (UTI), hematuria (7-9) and other non-specific abdominal pain, as well as 30-day and 90-day readmissions to inpatient and 30-day and 90-day readmissions to ER separately. Readmissions associated with other non-specific abdominal pain were defined as readmissions without AUR, UTI, or hematuria. We utilized ICD9 and ICD10 diagnosis codes to identify stricture, AUR, UTI, and hematuria. Reoperation was identified using a combination of CPT-4, ICD9 and ICD10 codes.

Statistical analyses

Baseline characteristics were analyzed using the Wilcoxon Rank-sum test for age and the Chi-square test for categorical variables. We examined short-term events in the TURP, PUL, and PAE groups separately and compared them across groups using Chi-squared tests. An unadjusted mixed-effects logistic regression was performed to examine the crude association between procedure type and short-term outcomes with a random intercept accounting for the clustering within each facility. For reoperation and stricture, we used a Kaplan Meier analysis to estimate the event rates at 6 months, 1 year, and 2 years after the index surgery and compared them with the Log rank test across groups. Unadjusted marginal Cox models with a robust sandwich estimator were performed comparing the risks of long-term events of the PUL group and the PAE group to those of the TURP group separately while accounting for the facility cluster. A marginal cox model estimates the average effect of treatment on outcomes over the study period. In the multivariable modeling, we adjusted for age, race and ethnicity, type of insurance, index procedure year, comorbidities, prior foley insertion, and facility volume categories. All analyses were completed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results

Baseline characteristics

Among the 12 902 men meeting the inclusion and exclusion criteria, 11 205 were treated with TURP, 1 362 were treated with PUL, and 335 were treated with PAE. Mean age at the surgery was 69.7, 69.4 and 70.2 years for TURP, PUL and PAE respectively ($p>0.05$). There was a higher proportion of black men in the PAE group (13.1%) compared to the TURP group (6.9%) and the PUL group (5.5%). Hypertension was the most common comorbidity across all study groups (n=6 656 (59.4%), n=578 (42.4%), n=235 (70.1%)). Men treated with PAE were more likely to have comorbidity count of ≥ 2 (n=218 (65.1%)) compared to those with TURP (n=5 049 (45.1%)) and those with PUL (n=473 (34.7%)). PUL patients were more likely to be treated at a high-volume center compared to those treated by TURP or PAE. Men receiving TURP were more likely to have a Foley catheter insertion prior to their surgery (n=2 458 (21.9%)) compared to those with PUL (n=132 (9.7%)) or PAE (n=37 (11.0%)) ($p<0.01$) (**Table 1**).

Short term outcomes

Within 30 days, PAE was associated with the highest readmission rate to inpatient or ER compared to TURP and PUL (TURP vs UTI vs PAE: 13.9%; 10.6%; 19.9%, p<0.01). However, TURP was associated with the highest 30-day readmission rate to ER of 10.8% compared to 8.9% and 8.4% for PUL and PAE respectively (p=0.05). Within 90 days, PAE was associated with the highest readmission rate to inpatient or ER compared to TURP and PUL (20.1%; 16.4%; 35.6%, p<0.01). For TURP, PUL, and PAE, the most frequent diagnosis associated with the 90-day inpatient or ER readmission was non-specific abdominal pain (8.4%; 8.3%; 26.8%, p<0.01) (**Table 2**).

After adjusting for covariates, the odds of 30-day readmission to inpatient was 2.81 (95%CI:1.85-4.27) times greater for patients receiving PAE compared to those receiving TURP (p<0.001). The odds of 30-day readmission to inpatient or ER with non-specific abdominal pain was 2.70 (95%CI:1.84-3.96) times greater following PAE compared to the odds following TURP (p<0.001). There was no significant difference in the risks of 30-day readmission to inpatient or ER or readmission to ER only between PUL and TURP and between PAE and TURP. PUL patients had a 50% (CI95%:0.32-0.80) lower risk of 30-day readmission to inpatient only and a 58% (CI95%:0.22-0.77) lower risk of 30-day readmission to inpatient or ER with a UTI compared to TURP patients (p<0.01) (**Table 2**).

The odds of 90-day readmission to inpatient or ER was 1.71 (CI95%:1.28-2.29) times greater after PAE compared to TURP (p<0.001). The odds of 90-day readmission to inpatient or ER with non-specific abdominal pain was 3.08 (CI95%:2.24-4.23) times greater after PAE compared to TURP (p<0.001). There was no significant difference in the risk of 90-day readmission to ER only between PAE and TURP. There was no significant difference in the risk of 90-day readmission to inpatient or ER or readmission to ER only between PUL and TURP. However, PUL patients had a 32% (OR 0.68, 95%CI:0.48-0.96) lower risk of 90-day readmission to inpatient only compared to TURP patients (p<0.05). PUL patients had a 47% (OR 0.53, CI95%:0.33-0.85) lower risk of readmission to inpatient or ER with a UTI compared to TURP patients (p<0.01). There was no significant difference in the risk of 30-day or 90-day readmission to inpatient or ER with AUR, hematuria or a UTI between PAE and TURP (**Table 2**).

Long term outcomes

Patients treated with PAE had the highest cumulative risk of reoperation at 6 months, 1 year and 2 years compared to those treated with PUL and those with TURP (6 months: 23.7%; 1-year: 26.5%; 2-year: 28.5%, p<0.001). After TURP, patients had the lowest cumulative risk of reoperation at 2 years with 3.4% (CI95%:3.1%-3.8%). At 2 years of follow-up, no PAE patients developed stricture. TURP was associated with the highest cumulative risk of stricture development at 2 years with 1.2% (CI95%:1.0%-1.4%) compared to PUL with 0.3% (CI95%:0.1%-1.4%) (p<0.05) (**Table 3**).

In the multivariable analysis, PAE patients had an adjusted HR for reoperation of 11.33 (CI95%:8.54-15.02) compared to TURP patients (p<0.001). PUL patients had an adjusted HR for reoperation of 2.23 (CI95%:1.62-3.08) compared to TURP patients (p<0.001). After adjusting for covariates, no difference in stricture development was found between PUL and TURP (**Table 3**).

Discussion

Growing interest in MISTs for the management of BPH associated LUTS has led to the study of PAE as an alternative to traditional resection procedures. Points of interest for PAE are mainly centered around overcoming the morbidity associated with invasive procedures. Angioembolization is performed under local anesthesia, doesn't require discontinuing anticoagulants and allows for potentially quicker post-procedure recovery (4, 5). Despite a growing body of evidence supporting PAE, there remains controversy about its real-world applications. Our study aims to provide insight on PAE performance compared to other surgical procedures in a larger, multi-centric and population-based observational analysis. We demonstrated that PAE had the highest readmission and reoperation risks when compared to TURP and PUL.

PAE exhibited the highest risk of 30-day readmission to inpatient or ER (20%) and the highest risk of 30-day readmission to inpatient only (13.1%) among all surgical procedures ($p < 0.01$). These results remain consistent when looking at 90-day readmission to inpatient or ER (35.6%), inpatient only (26.1%) and ER only (18.0%) for PAE ($p < 0.05$). To the best of our knowledge, no previous studies have reported 30-day or 90-day readmission rates for PAE. Compared to other MISTs, our 90-day ER readmission rate (18.0%) for PAE is similar to previously reported data from Garden et al for Rezūm with 17.9% (10). After adjusting for covariates, our study demonstrated that PAE had a 71% higher risk of 90-day readmission to inpatient or ER compared to TURP ($p < 0.001$). While there are no statistically significant higher odds of readmissions in the ER, PAE patients were 1.8 times and 2.1 times more likely to be readmitted inpatient compared to TURP patients after 30 days and after 90 days, respectively ($p < 0.001$). For PAE, non-specific abdominal pain was the main complication at 30-days (14.3%) and 90-days (26.8%) compared to TURP and PUL ($p < 0.01$). These results are similar to data reported by Abt et al in which 33% of PAE patients exhibited temporary pain and irritation within 90-days (11). However, our study results contrast with previous findings showing that abdominal pain after PAE was rather minimal or did not occur more frequently than after TURP (12). Compared to TURP, PAE was not associated with 30-day readmission with urinary retention, hematuria or UTI. Uflacker et al. recorded that among these, the most frequent were acute urinary retention (8%), rectalgia and/or dysuria (9%) and transient hematuria (4%) (12). Similarly, Shim et al. recorded acute urinary retention (9%), hematuria (3%), post-embolization syndrome (4%), but only 0.7% risk of pelvic pain (13) As such, there is inconsistency between our results and scientific literature, in which abdominal pain does not seem to be commonly found as a complication of PAE. This can be explained by a difference and lack of consistency in outcome definitions, as "non-specific abdominal pain" is an umbrella term that could potentially include or be a result of other outcomes we did not monitor, such as post-embolization syndrome. These results may reflect a lack of patient counseling on expected post-embolization syndrome and its appropriate management in the "real world.".

Within 6 months, PAE patients had 24% rates of requiring reoperation, compared to 1.5 and 2.2% for TURP patients and PUL patients, respectively ($p < 0.01$). Additionally, the observed 2-year risk of reoperation for PAE was 28.5% while TURP and PUL exhibited 3.4% and 8.5% 2 year risk of reoperation, respectively ($p < 0.01$). We observed that after two years, PAE patients are 10 times more likely to get reoperation than TURP patients when adjusted for covariates ($p < 0.001$). Our results are worse than data from Abt et al who reported 21% at 2 years although this could be attributed to the fact patients with hematuria were included in the study (11). Our results reflect more conservative risks of reoperation for PAE than what was previously published. These findings could be explained by our large sample size of PAE patients which included patients with hematuria and not being treated only for BPH which could offer a more accurate assessment of reoperation risks. Additionally, our study utilized a population-based design with a real-world population which reflects actual clinical aspects thus leading to more conservative reoperation risks (14).

Our study shows that a higher proportion of black ethnic men were treated with PAE compared to TURP and PUL. Men treated with PAE had a higher comorbidity count than men treated with PUL or TURP. PAE patients had significantly more congestive heart failure, chronic pulmonary disease, hypertension, diabetes, coronary and peripheral vascular disease and anemia, while TURP patients were more likely to have had prior foley insertion ($p < 0.01$). This is consistent with previous guidelines recommending PAE as a safe alternative to surgical gland ablative methods for patients with a higher comorbidity count or contraindications to surgery and anesthesia (15).

Our study also examined the cumulative risk of urethral stricture. No stricture events were recorded within our PAE cohort. Other studies have shown similar outcomes (16). This is expected considering artery embolization procedures doesn't involve instrumentation in the lower urinary tract, therefore preventing urethral scarring. Results obtained when comparing stricture events between PUL and TURP were non-significant (HR = 0.35 (0.07, 1.68)).

Taken together, our results show that readmission and reoperation is more likely with PAE compared to TURP or PUL. The adverse events profile of PAE is mainly characterized by non-specific abdominal pain, which is inconsistent with existing literature. TURP and PUL have a more similar adverse event profile, including approximately < 1% cumulative risk of stricture. Overall, our study corroborates pre-existing knowledge that PAE is relatively effective but not superior to other treatment modalities. Careful patient counseling with respect to the outcomes and patient selection of PAE is required when selecting treatment options.

Advantages of our study include a large real-world cohort of PAE patients with longitudinal follow-up. Additionally, risks of reoperation and readmission rates of surgical procedures are very accurate in our study due to the administrative and billing nature of the SPARCS database. However, our study is limited by administrative data used in this study did not report clinical features such as patient prostate gland size, presence of active urinary retention, if BPH related medications were restarted after treatment as well as number of sutures inserted during PUL treatment. Lack of stratification according to these clinical variables could have impacted our study outcomes. Lower procedure volume of PAE could have negatively impacted our results leading to an overestimation of retreatment rates. Also, we could not assess if clinicians treating patients with PAE for refractory hematuria were planning a staged surgical procedure leading to higher reported retreatment rates. Despite these limitations, we believe that our study results represent more conservative surgical outcomes expected after PAE treatment in a real-world setting. Patients seeking relief of their BPH associated LUTS should therefore be counseled about reintervention when selecting surgical procedures.

Conclusion

In a real-world population, PAE exhibited the highest risk of 30-day and 90-day readmission to inpatient or ER and the highest retreatment rate for all surgical techniques when controlled for individual patient comorbidities and surgical volume.

Declarations

Conflicts of Interest

NB is a consultant and investigator for Boston Scientific, Olympus, and PROCEPT BioRobotics. BC is a consultant and investigator for Boston Scientific and Olympus. KCZ is a consultant for Boston Scientific, and PROCEPT BioRobotics. DE is a consultant and investigator for PROCEPT BioRobotics. All other authors report no relevant conflicts of interest.

Compliance with Ethical Standards Research involving Human participants

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Informed consent: Not applicable.

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Zheng X: data collection, data analysis, manuscript writing

Oumedjbeur K: manuscript writing

Mao J: data collection, data analysis, manuscript editing

Zorn KC: Manuscript editing

Elterman D: manuscript editing

Bhojani N: manuscript editing

McClure T: manuscript editing

Te A: manuscript editing

Kaplan S: manuscript editing

Sedrakyan A: project development

Chughtai B: project development, manuscript editing

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Tables

Tables 1 to 3 are available in the Supplementary Files section.

Figures

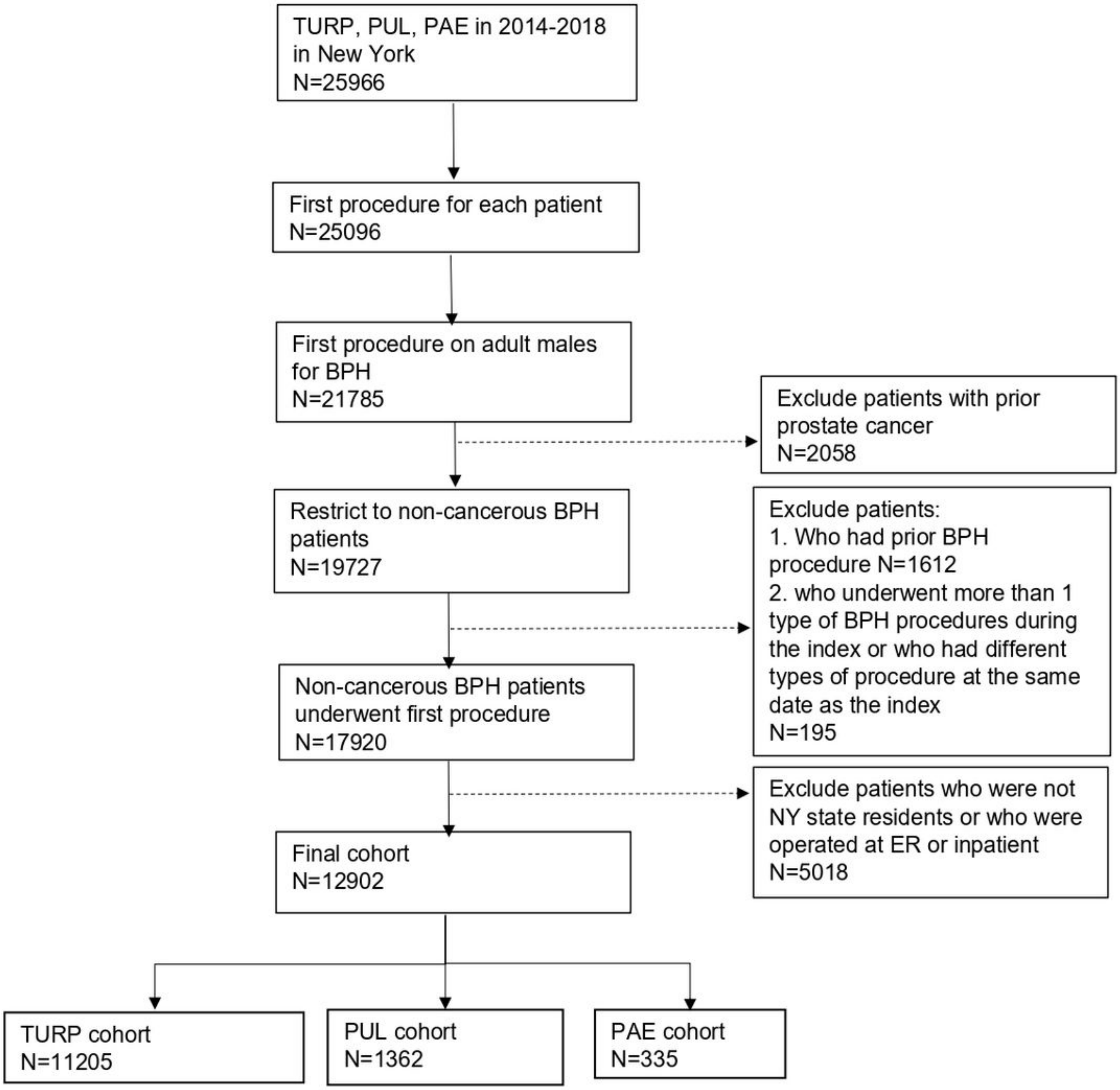
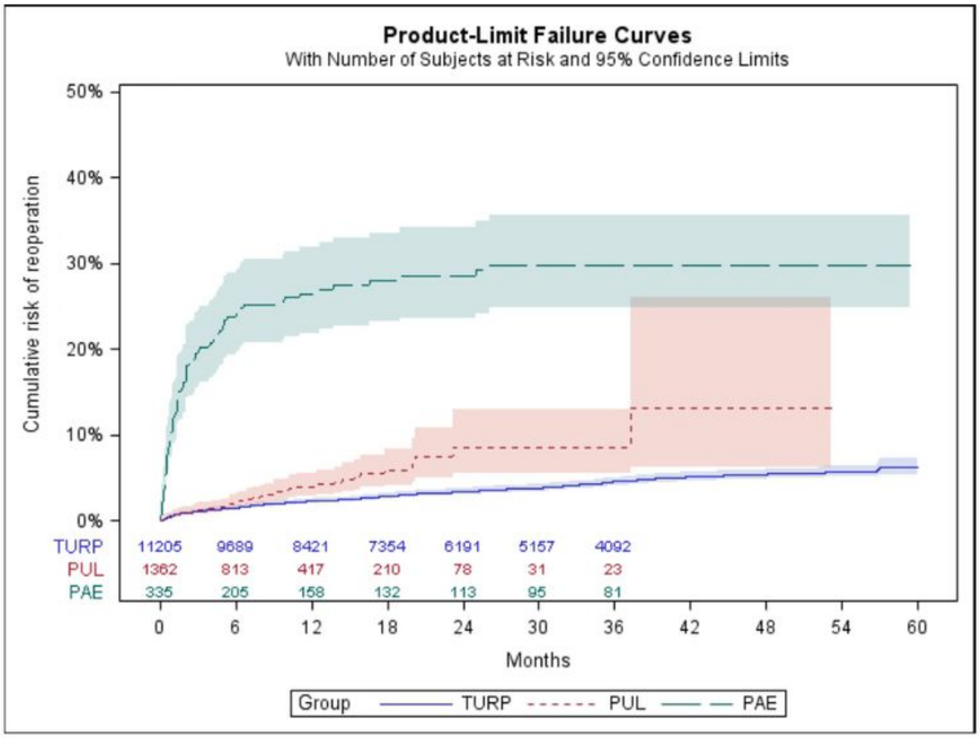


Figure 1

Flow chart for cohort selection



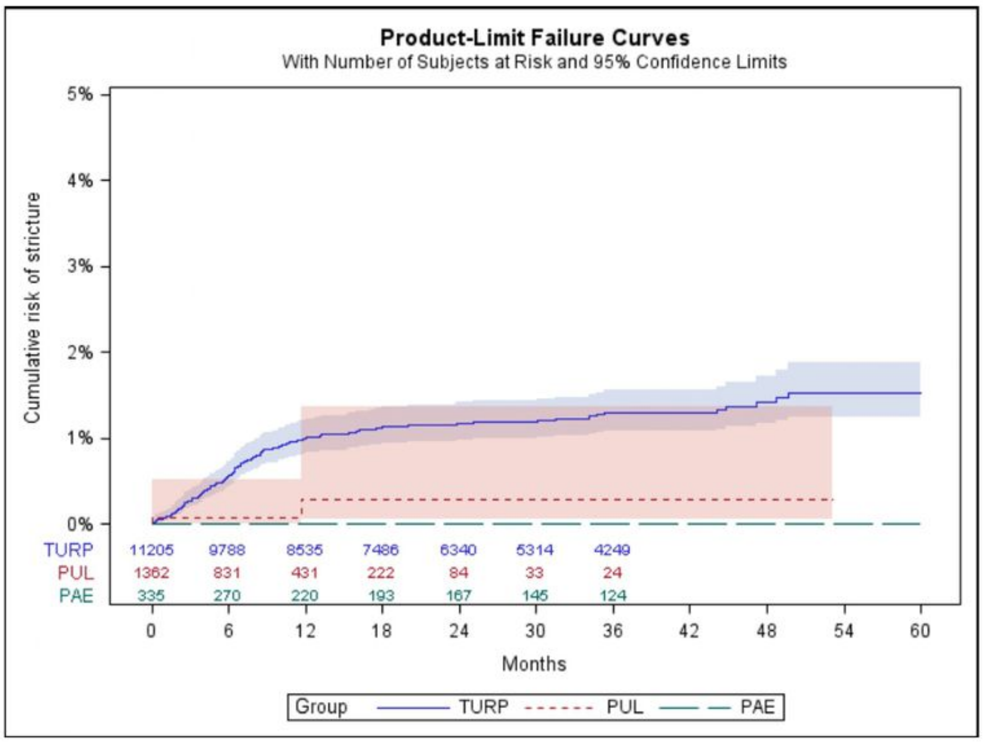


Figure 2

Failure plot of reoperation (top) and stricture (bottom) by procedure type

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- table1.xlsx
- Table2.xlsx
- table3.xlsx