1

Association of Topiramate use with Current Stone Activity -- A Population Based Analysis

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Background: It is recognized that topiramate use may affect risk of stone disease. While demonstrated in single institution retrospective studies, large nationally based evaluations are absent. Furthermore, the suspected increased odds of stone disease have remained unquantified. We thus leveraged the nationally representative National Health and Nutrition Examination Survey (NHANES) to perform a population-based assessment of the association of current topiramate use on occurrence of stones presenting within the year immediately preceding survey participation.

Methods: We utilized the 2017-2020 (Pre-COVID-19) NHANES data to assess the association between current topiramate use and incidence of kidney stones. The dependent variable was the question "In the past 12 months have you passed a kidney stone?" from the Computer-Assisted Personal Interview section of the NHANES, and independent variable was the use of topiramate or phentermine-topiramate as reported on the Prescription Medications subsection of the Sample Person Questionnaire Interview. Covariates were only included if they showed significant association with topiramate use on univariate analysis. Participants under 20 years of age were excluded due to the lack of survey data on this demographic. Weights and strata provided by NHANES were employed and analyses were performed using survey package for STATA v14.

Results: 843 participants met analysis criteria, weighted to represent a nationally representative population of 23,064,066 noninstitutionalized US adults. Logistic regression was used to analyze the relationship between the incidence of kidney stone passage in the last 12 months and current topiramate use. It was found that current topiramate use was associated with a statistically significant 8.1-fold increase in the odds of stone passage in the last 12 months (OR: 8.1, 95%CI [1.04-63.06], p = 0.046). None of the investigated demographics or pharmaceutical covariates (age, diabetes status, body mass index, or concomitant use of diuretics, proton pump inhibitors or H2-blockers) demonstrated statistically significant association with topiramate use and thus were not included as covariates.

Conclusion: Our results demonstrate that odds of a stone within the last 12 months is increased significantly with topiramate use. Additionally, we provide the initial quantification of the strength of this association, with an estimated 8-fold increase in odds of stone formation. These findings can provide physicians with important data and improve risk counseling for patients considering topiramate use.

2

Contemporary Natural History of Observed Staghorn Calculi

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Background: The AUA Guidelines recommend removal of staghorn calculi in patients who are able to withstand surgical intervention. Older data report that non-operative, conservative management of staghorn calculi is associated with worse patient outcomes. The 10-year mortality for patients with staghorn stones who chose observation was 4 times higher than those that elect surgery (28% vs. 7.2%). Up to 30-70% of patients who refuse surgical intervention may develop life-threatening renal failure or sepsis from a urinary source within 6 years. However, given the frequent asymptomatic nature of staghorn calculi, some patients decline surgical intervention and, instead, choose observation. Given that the data on natural history of observed staghorn stones was reported over 40 years ago and may not represent present-day outcomes, we sought to update the existing evidence base by conducting a retrospective cohort study of patients who opted observation of their staghorn calculi.

Methods: A retrospective review of patients diagnosed with a staghorn calculus at our institution between 2007 and 2020 with a minimum of 1 year follow up. Patients were identified using the ICD-9 code 592 and confirming a diagnosis of a staghorn stone on CT scan. A staghorn stone was defined as a branching renal stone occupying the renal pelvis and 1 or more calyces. Data was collected regarding stone-related complications and the interval timeframe from diagnosis to complication.

Results: A total of 192 patients were diagnosed with a staghorn stone between 2007 and 2020. Fifty-seven (29.7%) patients fully met inclusion criteria with an average follow up of 3.8 ± 2.7 years. At the time of staghorn diagnosis, 12 (21%) patients declined intervention and elected for observation with a mean follow up of 4.4 ± 4.0 years. Of those who opted observation, 25% developed sepsis at a mean of 18 ± 10.4 months, 16.7% required urgent stent placement at a mean of 24 ± 0 months, and 8.3% progressed to renal failure at a mean of 6.0 ± 0 months. None of these patients required urgent nephrostomy tube placement. The overall mortality rate was 25% for this cohort at a mean of 4.7 ± 1.2 years (range 3.6-6 years), with no deaths due to sepsis but rather competing causes including malignancy.

Conclusions: Historic data suggests that the incidence of complications from untreated staghorn stones is relatively high; however, these studies are outdated. Our data indicates that patients who elect observation of staghorn stones have a lower risk of stone-related complications than previously reported. In our series, no mortality was directly attributable to staghorn calculi but rather competing causes. This data provides a contemporary update on anticipated natural history of staghorn in selected patients who decline surgical intervention and may allow more informed counseling.

3

Distressed Communities with High Risk Stone Formers May Benefit More from Multidisciplinary Kidney Stone Clinic Model

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Background: Recent studies have shown disparities in the management and outcome of patients with kidney stones based on their socioeconomic status (SES). Adverse markers on the 24-hour urine collections have been associated with a lower SES. A multidisciplinary kidney stone clinic (MSC) is an emerging approach that provides an individualized care especially to high-risk stone formers by a team of urologist, nephrologist, and dietitian in a single encounter. The goal of this study is to evaluate whether the MSC approach is effective in promoting socioeconomic equity among these patients. Our hypothesis is that the patients with a lower SES will be more responsive to the MSC approach and demonstrate a greater improvement in the 24-hour urine parameters than those with a higher SES.

Methods: A retrospective review of patient records from an MSC affiliated with a single academic medical center was conducted. Patient demographics such as age, insurance status, and distressed communities index score (DCI) along with 24-hour urine volume, pH, sodium, and calcium were collected. Growth curve modeling within generalized mixed effects modeling was used. Regression coefficients were standardized so that they can be interpreted like a correlation coefficient and directly compared to each other.

Results: A total of 192 patients who completed an average of 3.01 24-hour urine collections (SD = 3.14) were included. They were treated at the MSC for 1.91 years (SD = 3.01). A summary of patient characteristics is in Table 1. In patients with a high DCI and Medicare/Medicaid, there was a significant increase in urine volume ($\beta = 0.16$, $p = 0.0146$) and decrease in urine calcium ($\beta = -0.10$, $p = 0.0488$) throughout the duration of their treatment, irrespective of age. However, younger patients with a high DCI and Medicare/Medicaid had a significant decrease in sodium ($\beta = -0.12$, $p = 0.0157$), compared to older patients with identical DCI and insurance status ($\beta = 0.14$, $p = 0.0076$). All patients had a significant increase in urine pH throughout the duration of their treatment ($\beta = 0.12$, $p = 0.0288$).

Conclusions: Among patients who were treated at the MSC, those with a high DCI and Medicare/Medicaid had a significant improvement in urine volume, pH, sodium, and calcium, but the effect of age on these parameters was unclear. These results suggest that an MSC model may address the socioeconomic inequities that exist in the management of kidney stones possibly by providing highly streamlined and individualized care to these patients. Therefore, urologists should consider increasing the accessibility of MSC to their patients. However, it is necessary to further investigate this relationship by analyzing a complete 24-hour urine panel in a more diverse population over a longer duration of treatment. An additional experimental manipulation and a control group could strengthen the validation of these findings.

Table 1. Sample Characteristics at First 24 Hour Metabolic Urinalysis Kit

Measure	Mean	SD	Skew	Kurtosis	% Missing
Distressed Communities Index	44.50	27.93	0.66	-0.96	0.00
Age (years)	49.40	15.78	-0.08	-0.79	0.00
Urine Volume (mL/day)	1734.10	796.04	0.61	-0.34	1.56
Urine pH	6.35	0.64	0.05	-0.92	11.98
Urine Calcium (mg/day)	208.93	138.53	1.83	5.07	5.73
Urine Sodium (mg/day)	151.78	72.55	1.17	2.34	9.90
Kits completed (kits)	3.01	3.14	2.08	4.05	0.00
Treatment duration (years)	1.91	3.01	2.39	6.93	0.00
Measure	**Status**	**N**	**%**		
Insurance	Medicare/Medicaid	34	17.71		
	Private insurance	158	82.29		

Note: Patient health characteristics are reported at baseline. The exceptions are kits completed and treatment duration, which represents the number of kits

4

Urinary Thiosulfate Level in Stone Forming Versus Non-Stone forming Pregnant Females

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Background: Renal colic is the most common cause of non-obstetric hospitalization in the pregnant patient. Pregnancy is associated with multiple metabolic changes, including increased excretion of urolithiasis promoters including sodium, calcium, and uric acid. Prior study has established increased urinary calcium chelators in the third trimester of pregnancy. This phenomenon is thought to be a physiologic protective mechanism against the urolithiasis promoters. One such example is urinary citrate, which increases and decreases with urinary calcium level at different stages of pregnancy. Thiosulfate is a chelating agent that has also been associated with protective effect against calcium stone formation in animal models. Our study measured urinary thiosulfate on a controlled diet during third trimester and the postpartum period and sought to assess whether exogenous thiosulfate could serve as a viable lithogenic protective agent.

Methods: We recruited a cohort of pregnant patients between year 2014-2019, and collected 24-hour urine samples with IRB approval. The urine samples were collected from patients on a standardized diet at third trimester, post-partum, and post-lactation stages. Patients were identified as new stone formers during pregnancy or non-stone formers based on review of history. Urinary thiosulfate and other chemical components at various stages of pregnancy were analyzed.

Results: We recruited a total of 14 pregnant patients without history of stones prior to gestation. In order to control for dietary-induced variation in urine chemistry, all patients were placed on a standardized diet for the day before and day of each collection. Twenty-four hour urine was submitted third trimester (n = 14), post-partum (n = 12), and post-lactation (n = 6) stages. A total of 4 patients had new stone formation during pregnancy. Urinary calcium was noted to be increased in the third trimester ($p = 0.01$) with corresponding increase in the urinary citrate ($p = 0.02$). However, there was no statistical difference ($p = 0.97$) of urinary thiosulfate across third trimester (13.89 mEq, IQR 9.1-19.71), post-partum (13.87 mEq, IQR 8.6-20.5), and post-lactation (14.53 mEq, IQR 7.7-20.9) stages. Stratified analysis showed no statistically significant difference in thiosulfate level between stone former versus non-stone formers.

Conclusions: Unlike urinary citrate and calcium, endogenous urinary thiosulfate does not change significantly from the third trimester of pregnancy to post-partum stage in our cohort of patients on a standardized diet. Our observation does not support urinary thiosulfate as a lithogenic protective factor or utilization of exogenous thiosulfate as a strategy to prevent stone formation.

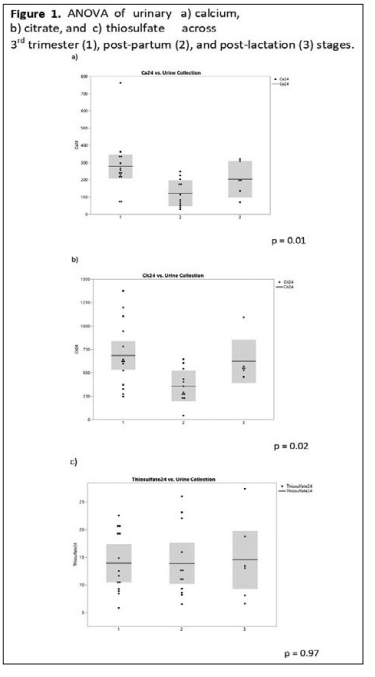

Figure 1. ANOVA of urinary a) calcium, b) citrate, and c) thiosulfate across 3rd trimester (1), post-partum (2), and post-lactation (3) stages.

5

Differential 24h Urine Findings in Predominantly Calcium Oxalate Monohydrate Stones

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Background: Calcium oxalate monohydrate (COM) stones are among the most commonly encountered. Debate continues whether selective or empiric medical therapy is preferable. The American College of Physicians has recommended empiric pharmacologic monotherapy including thiazide for those with active stone disease despite increased fluid intake without 24hour urine testing. However, it is unclear whether such empiric therapy can adequately target underlying abnormalities in a diverse group of patients. We assessed baseline 24hour urine parameters in those with COM-containing stones.

Methods: We collected data on adult patients from 2011-2022 who were evaluated for nephrolithiasis at a single institution and had complete 24 hour urine analysis evaluation. A complete 24 hour urine included measurements for pH, total volume, calcium, oxalate, citrate, uric acid, sodium, potassium and creatinine. We excluded patients less than 18 years of age. Data was analyzed using STATA v 14.0. Continuous variables were expressed as mean with standard deviation.

Results: Of the 541 patients, 274 were female (50.1%). The mean age of the patients was 55 years (standard deviation of 14.8 years). The mean BMI was 29.7 (standard deviation of 8). From this cohort, 232 consecutive patients with COM containing stones and 24h urine collections were subsequently analyzed. Those with predominant (> 80%) COM had significantly lower 24hour urine calcium (mg/d) than those with mixed CaOx (179 vs. 228, p = 0.0009) on initial 24 hour urine. Furthermore, this group had higher 24hour urinary oxalate (mg/d) than those with mixed CaOx (39 vs. 34, p = 0.03).

Conclusions: COM stones are characterized by lower urinary calcium and higher urinary oxalate than those with mixed calcium oxalate stones. As such, predominant COM stones represent a discrete phenotype which may not benefit from empiric treatment with calcium-lowering measures such as thiazide. Empiric thiazide treatment of COM stone formers in the absence of documented hypercalciuria may pose unnecessary expense as well as exposure to potential side effects.

6

Development and Utilization of a Novel EMR-Based Care Pathway for Nephrolithiasis Management in the ED

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Background: Patients with nephrolithiasis account for more than 2 million Emergency Department (ED) visits in the United States each year. Recently, there has been an increase in patients with nephrolithiasis. Coupled with the influx of COVID-19 patients in the ED, it is imperative to triage and treat these patients with nephrolithiasis in a timely manner. We designed an electronic medical record (EMR) integrated pathway to augment timely assessment, triage, and best practice management of patients with nephrolithiasis based on clinical presentation and imaging characteristics. The objective of this study is to describe the development and utilization of our EMR-based Care Pathway for nephrolithiasis in the ED.

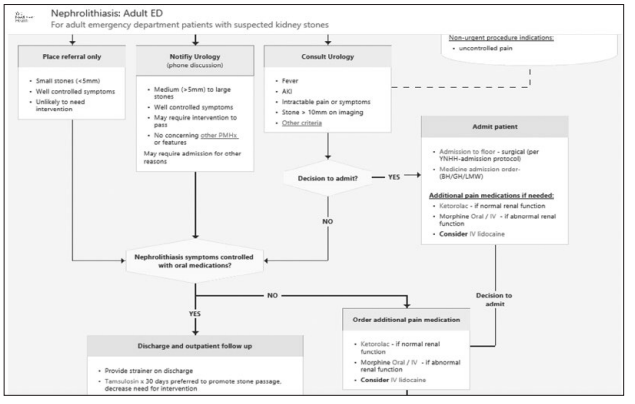
Methods: Our hospital system is composed of a university-based academic center with multiple hospitals and outpatient centers. To standardize and ensure best practice care, our system utilizes Care Signature Pathways through the EMR, which synthesize evidence, expert consensus, and clinical decision support at the point of care. The Nephrolithiasis Pathway, developed based on AUA guidelines and multispecialty reviews, is intended to meet specific goals including decreasing ED length of stay for uncomplicated non-obstructive kidney stones, increasing the number of low dose CT imaging for patients, and increasing the number of patients being discharged with a 28-day prescription of tamsulosin. It was developed with multidisciplinary stakeholders including ED, Urology, IR and Radiology providers.
The pathway begins with the identification of potential patients with nephrolithiasis with STONE score, initial diagnostic tests, pain control, rapid identification of infection and patients with suspected sepsis. The pathway then suggests imaging recommendations and based on patient factors including stone size, symptoms, presence of infection/AKI, recommends type of urologic evaluation either referral, notifying urology, consulting urology and admission. For patients ready for discharge, the pathway provides medical recommendations, follow up and return criteria (Figure 1). The pathway includes information on risk factors, indications for IR consult, US findings for nephrolithiasis, and management for suspected sepsis.

Results: The Care Pathway was utilized a 195 times from September 3, 2021-February 12, 2022 at 8 different hospitals or care centers (Table 1). The majority of usage was in the ED (171; 87.7%). A total of 79 providers utilized the Pathway with the majority being physicians (50; 63.2%). The pathway was involved in the care of 129 patients with an average age of 47, and 58.9% were males (53 women, 41.1%). A total of 35 Urology referrals were placed through the pathway with 21 new 28-day prescriptions of tamsulosin ordered.

Conclusions: An EMR-integrated Nephrolithiasis care pathway has been readily utilized in the ED and may augment triage and best practice management of patients presenting with stone disease. Further studies and larger usage are needed to validate these findings.

Table 1. Utilization of Care Pathway

Encounters	195
ED	171 (87.7%)
Medicine/Peds	16 (8.2%)
Urology	6 (3.2%)
Other	2 (0.9%)
Provider	79
Student	1 (1.3%)
RN	3 (3.8%)
PA	20 (25.3%)
APRN	5 (6.3%)
MD	50 (63.3%)
Patients	129
Age	47.2 (2-98)
Male	76 (58.9%)
Female	53 (41.1%)
Outcomes	
Referrals	35
Flomax	21



7

Obstructing Ureteral Calculi and Presumed Infection: Impact of Antimicrobial Duration and Time from Decompression to Stone Treatment in Developing Urosepsis

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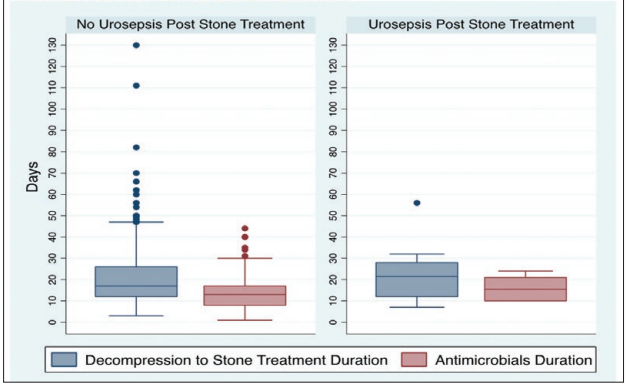
Background: Obstructive urolithiasis with associated urinary infection is a urologic emergency requiring urinary tract decompression to decrease the risk of urosepsis. Initial management after decompression requires tailored antibiotic treatment, although the duration of antibiotics required and the amount of time to wait until proceeding with definitive stone surgery is unknown. Traditionally, longer periods of time were recommended to optimize urinary sterilization before invasive treatment. This subjects the patient to the potential side effects of prolonged antibiotic use and whether this increased duration of antibiotics results in improved clinical outcomes is unknown. Our goal is to review the clinical outcomes of patients requiring urgent decompression and identify associated risk factors for the development of complications after definitive stone management with specific focus on the timing and antibiotic usage between the initial and definitive intervention.

Methods: A retrospective review of patients who were diagnosed with obstructive urolithiasis with a presumed infection and underwent urgent decompression with a ureteral double J stent or percutaneous nephrostomy (PCN) at our institution between 2012-2018 was performed. Demographic, infection and antimicrobial data, and initial admission to stone treatment characteristics were collected. Factors associated with developing urosepsis post stone treatment were analyzed.

Results: Of 872 patients who underwent urgent decompression of obstructive urolithiasis during this period, 346 (39.7%) underwent definitive stone management at our institution, and 215 (62.3%) of these were performed for presumed infection and included in our analysis. The median age was 63 years old (Interquartile (IQR) 52-72). 159 (74%) were female and 80 (37.2%) were diabetics. 71 (33%) had fevers, 138 (64.2%) had a positive urine culture, 54 (25.1%) had a positive blood culture, and 98 (45.6%) had urosepsis at the initial presentation. 179 (83.3%) underwent stent placement and the rest had a PCN placed by interventional radiology. The median antimicrobials duration post decompression was 13 days (IQR 8-18). The median duration from decompression to stone treatment was 17 days (IQR 12-27). 175 (81.4%) patients underwent ureteroscopy (URS) with laser lithotripsy/stone extraction and the rest underwent percutaneous nephrolithotomy (PCNL). 8 (4.6%) patients developed urosepsis post URS and 2 (5%) post PCNL. No factors were associated with developing urosepsis post stone treatment on univariate and multivariate logistic regression analyses.

Conclusions: This study demonstrates that in patients requiring urgent decompression for obstructing urolithiasis and suspected infection, the time between initial intervention and final stone treatment as well as the length of antimicrobial exposure did not impact rates of postoperative urosepsis. This highlights the importance of maintaining high clinical suspicion for prolonged use of antibiotics, to prevent overtreatment and possible exacerbation of antimicrobial resistance.

Figure 1: Decompression to stone treatment and antimicrobial durations for patients who did and did not develop urosepsis post stone treatment



8

Perinephric Fat Stranding is not Associated with Elevated Serum Creatinine in Patients with Acutely Obstructing Ureteral Stones

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Background: Previous literature has reported an association between perinephric fat stranding (PFS) and elevated serum creatinine in patients with acutely obstructing ureterolithiasis. Our aim was to further explore a potential association between severity of PFS and changes in serum creatinine from baseline.

Methods: Patients who presented to the emergency department with acutely obstructing ureterolithiasis between January 2018 and October 2018 were retrospectively reviewed. Data collected and reviewed included demographics such as sex and age, serum creatinine on presentation and baseline values, computed tomography (CT) imaging, and urinalysis and culture findings. A radiologist blinded to serum creatinine data then reviewed all CT images and graded the degree of hydronephrosis and PFS for each patient. Subjects were split into two groups based on degree of PFS and differences between groups in regards to the aforementioned variables were assessed via paired t-test, chi-squared test, and univariate and multivariate analysis.

Results: We identified 141 subjects of whom 114 had imaging consistent with none-mild PFS, Group 1, while 27 had findings consistent with moderate-severe PFS, Group 2. Group 1 had a mean age of 56 years old vs. Group 2 which was significantly older at 65 years (p = 0.01). The majority of subjects (77%) in Group 2 had an average duration of disease <24 hours which was a significantly higher percentage than Group 1 in which 50% had symptoms lasting <24 hours (p = 0.01). Group 2 had a significantly larger mean stone size (10.1 vs. 7.3 mm, p<0.01). No significant correlation could be found between PFS and degree of hydronephrosis, baseline creatinine, presenting creatinine, or change in creatinine from baseline. Multivariate analysis showed that a 1 year increase in age increased the odds of having moderate-severe PFS relative to none-mild by 3.5% (OR = 1.04, p<0.05) while a 1 mm increase in stone size increased the odds of having moderate-severe PFS relative to none-mild by 13.7% (OR = 1.14, p = 0.01).

Conclusions: Although increased PFS was found to correlate with increased age and stone size, no significant correlation was found between PFS and baseline creatinine, presenting creatinine, or change in creatinine from baseline. Given our findings, PFS likely has poor predictive value in assessing degree of renal function impairment in the case of acutely obstructing calculi.

Table 3: Univariate and multivariate logistic regression analyses for factors associated with urosepsis post stone treatment

	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Age	1.01 (0.97-1.06)	0.436	1.004 (0.96-1.06)	0.863
Female	1.96 (0.53-7.22)	0.311	1.81 (0.48-6.89)	0.384
Diabetes	2.66 (0.73-9.71)	0.140	2.87 (0.74-11.02)	0.125
Urosepsis on first presentation	0.79 (0.22-2.87)	0.717	0.47 (0.11-2.06)	0.320
Antibiotics duration	1.04 (0.97-1.11)	0.325	1.06 (0.97-1.17)	0.193
Decompression to stone treatment duration	1.003 (0.97-1.03)	0.840	0.98 (0.94-1.04)	0.663

OR = Odds Ratio, CI = Confidence Interval

9

Comparing the Costs and Benefits of Open vs. Robotic Simple Prostatectomy
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Background: With the rise of robotic surgery, there has been much debate on the cost/benefit of robotic vs. open surgery. However, most studies examining the outcomes and costs of robotic surgery have been done in the context of robotic-assisted laparoscopic radical prostatectomy (RALP). While urologic robotic surgery has expanded to other procedures such as cystectomies and simple prostatectomies, the cost/benefit of such robotic approaches has not been as well studied. In this analysis, we sought to examine the monetary costs, hospital resource utilization, and short-term complications of robotic vs. open simple prostatectomy in a national cohort.

Methods: We performed a retrospective cohort study of adult men undergoing elective open and robotic simple prostatectomy from 2008 to 2017. The data were abstracted from the Premier Hospital Database, a national hospital discharge dataset representing approximately 20% of non-federal hospital discharges in the United States. We assessed for an association between surgical approach (open vs. robotic) and postoperative outcomes including surgical complications, operating room time, need for blood transfusion, length of stay, readmissions and overall costs. All multivariable regression models were controlled for clinical, demographic and hospital factors.

Results: A total of 7,781 men in the study cohort underwent a simple prostatectomy during the study period of which 7,069 (90.85%) were open and 712 (9.15%) were robotic. There were no differences between the surgical approaches for 90-day minor (Clavien grade 1-2) and major (Clavien grade 3-5) complications although the open approach was more commonly associated with blood transfusion (OR: 1.47, 95% CI: 1.11 to 1.94, $p = 0.007$). The robotic approach was associated with a longer median operating room time (+105 min, 95% CI: 97 to 113 min, $p < 0.0001$), a shorter hospitalization (-1 day, 95% CI: -1.14 to -0.86 days, $p < 0.0001$), and a higher odds for 90-day readmission (OR: 1.26, 95% CI: 1.04 to 1.54, $p = 0.021$). The 90-day cost was significantly higher for robotic simple prostatectomy (+US$4,448, 95% CI: $4,011 to $4,886, $p < 0.0001$).

Conclusions: In the largest known cohort of simple open vs. robotic prostatectomies, the 90-day cost of robotic prostatectomy was significantly higher despite the shorter hospital length of stay—likely due to higher equipment costs and longer operative times—with no differences in major or minor complications.

10

Prostate Cancer Screening Behaviors Among U.S. Immigrants: a Cross-sectional Analysis Using the NHIS database
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Background: Immigrants constitute 14% of the U.S. population, but structural barriers and immigrant-specific characteristics make this group especially vulnerable to poor healthcare access. Prior research demonstrates U.S. immigrants have low rates of guideline-concordant breast and colorectal screening. Furthermore, male patients with limited English proficiency are more likely to be diagnosed with advanced stage genitourinary cancers. The shared decision-making model of prostate specific antigen (PSA) screening poses a unique challenge to immigrants, especially those with barriers to longitudinal care and English proficiency. Together, these data suggest that immigrants may experience significant inequity in access to and receipt of high-quality prostate cancer screening. The goal of this study was to characterize screening behaviors among U.S. immigrants and to identify specific mechanisms to enhance guideline-concordant PSA-based screening for U.S. immigrants.

Methods: Data was obtained from the National Health Interview Survey (NHIS). Descriptive statistics were used to characterize the sociodemographic features of immigrants versus the U.S.-born population. Complex samples logistic regression was performed to assess the relationship between immigrant-specific characteristics including region of birth, citizenship status, length of residence within the U.S., English language proficiency, and history of PSA screening.

Results: Immigrants were less likely than the U.S.-born population to have been screened for prostate cancer (aOR = 0.76; 95% CI = 0.65-0.88). Citizenship status, length of residence in the U.S., and English proficiency were directly linked to increased rates of PSA screening. There was significant variability in PSA screening for immigrants based on region of origin with Asian immigrants having the lowest rate of PSA screening. Increasing annual physician visits and expanding interpreter services were identified as modifiable mechanisms to improve prostate cancer screening among the U.S. immigrant population. Among U.S. immigrants, seeing a physician within the last 12 months led to a nearly three-fold increase in the odds of receiving screening for prostate cancer (aOR = 2.81; 95% CI = 2.11-3.72). English language proficiency led to a two-fold increase in the odds of receiving screening for prostate cancer (aOR = 1.97; 95% CI = 1.41-2.76).

Conclusions: This study demonstrated that immigrants have low rates of prostate cancer screening compared to the native-born U.S. population. Though the prevalence of prostate cancer overdiagnosis implies that universal PSA screening is not inherently desirable, the disproportionately low rate of PSA testing among U.S. immigrants is demonstrative of an approach to cancer prevention that does not adequately meet the needs of this marginalized population. Improving healthcare utilization and language services can make urologic cancer screening more equitable for U.S. immigrants.

11

Risk Stratification Using a Polygenic Risk Score Improves PSA Screening Efficiency: an Analysis of the PCPT Cohort

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Background: Prostate-specific antigen (PSA) based prostate cancer (PCa) screening reduces PCa related mortality, however, universal PSA screening (UPS) leads to unnecessary interventions, complications, and actions for many men who will, ultimately, never be diagnosed with PCa. Genetic risk-stratification, using a polygenic risk score (PRS), may play a role in better targeting PSA screening and improving screening efficiency (e.g. number of screening events required to detect PCa). Using data from the placebo arm of the PCa Prevention Trial (PCPT), we compared the screening efficiency of several risk adapted and non-risk adapted hypothetical screening models.

Methods: Efficiency was assessed by determining the number of screening events that each screening model would generate and what percentage of overall and high grade cancers would be diagnosed. In the UPS model all men are screened. In the family history (FH) model, only men with a FH of PCa would be screened. Finally, the PSA > 1 and > 1.5 models would only screen those men with PSAs greater than those thresholds. The PRS was derived using an algorithm involving weighted odds ratios of 29 PCa-associated single nucleotide polymorphisms previously identified. In the PRS adapted model, screening would not be performed in below average risk men. The PSA cutoff for biopsy for the models was determined using a biopsy detection rate of 40% for overall PCa. All models had annual screening events except PRS average risk patients who were screened every 3 years.

Results: 3986 PCPT participants who were in the placebo arm and had genetic data were included in the analysis: 1316 (33.0%) < 60, 2140 (53.7%) 60-69, and 530 (13.3%) > 70 years old at study entry. Overall and age stratified results are shown in the table. Amongst all the different models with the different age strata, the PRS risk adapted model was the most efficient, with fewest screening events and largest proportion of cancers detected. The efficiency was greatest in younger men, compared to UPS there were 5,356 fewer screening events, while capturing 13% more high grade tumors, and declines with age. Even so, in men > 70, the PRS risk adapted model required. half as many screening events to capture a comparable proportion of high grade cancers as the next best model (PSA > 1).

Conclusions: In this unique dataset, a risk adapted screening approach using a PRS was the most efficient model to minimize screening events and maximize the detection of high grade PCa.

Table:

Age	UPS	FH+ PSA >2.5	PRS	PSA >1	PSA >1.5
<60 years					
Screening events	8321	1021	2965	4020	1856
% any PCa	21.2%	13.1%	31.4%	20.5%	16.3%
%HG PCa	38.3%	19.1%	51.1%	38.3%	31.9%
60-69 years					
Screening events	13276	1343	4571	7212	4104
% any PCa	25.3%	11.0%	33.4%	23.8%	20.6%
%HG PCa	34.2%	13.2%	43.9%	30.7%	24.6%
>70 years					
Screening events	3195	292	1056	2056	1211
% any PCa	24.5%	11.9%	29.6%	23.9%	20.1%
%HG PCa	42.9%	17.1%	42.9%	40.0%	28.6%

Abbreviations: FH, family history; HG, high grade; PCa, prostate cancer; PRS, polygenic risk score; PSA, prostate specific antigen

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Comparison of High-resolution Micro-ultrasound and Conventional Ultrasound in MRI-ultrasound Fusion Biopsy for Diagnosis of Clinically Significant Prostate Cancer

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Background: High-resolution micro-ultrasound (microUS) is a novel technology that permits the visualization of lesions suspicious of prostate cancer. The present study aimed to assess the utility of MRI-ultrasound fusion targeted biopsy in detecting clinically significant prostate cancer using high-resolution microUS versus conventional ultrasound.

Methods: We performed a retrospective analysis of 62 patients who received ExactVu microUS-guided biopsy at a single institution from October 2021 through March 2022 (case group). Targeted biopsies (TB) were taken from multiparametric MRI targets (Prostate Imaging-Reporting and Data System [PI-RADS] ≥ 2), followed by a 12-core systematic biopsy. We also included a historical control group of 100 men who underwent MRI-US fusion biopsy using the Artemis device at the same institution between January 2019 and February 2020. The rates of cancer detection (any cancer and grade group (GG) ≥2) or missed cancer by TB were compared between the case (MRI-microUS fusion biopsy) and control (MRI-US fusion biopsy) groups.

Results: In men undergoing MRI-microUS fusion biopsy (case group), detection rates of any cancer and GG ≥ 2 were similar between SB and TB (any cancer: 69.3% vs. 62.9%, p = 0.38; GG ≥ 2: 48.3% vs. 46.7%, p = 1.00, Table 1). Moreover, detection rates of any cancer and GG ≥ 2 using TB were comparable between MRI-microUS and MRI-US fusion biopsy groups (p > 0.05, Table 1). In addition, the rate of missed GG ≥ 2 on TB was similar between MRI-microUS and MRI-US fusion groups (p > 0.05). On multivariate analysis of all studied men, biopsy-naïve status vs. prior negative biopsy (OR 25, p = 0.008), PSA density (OR 2.13 per 0.1 unit increase, p < 0.001), and PI-RADS score 5 vs. 3 (OR 8.03, p < 0.001) were significant predictors in the detection of GG ≥ 2 (Table 2). However, MRI-US fusion method (microUS or conventional ultrasound) was not associated with the detection of GG ≥ 2 (p > 0.05).

Conclusions: Our results suggest that microUS-guided biopsy of MRI targets is comparable to MRI-US fusion biopsy using conventional ultrasound, given similar cancer detection and missing rates. Due to the equivalency between conventional ultrasound and microUS in the setting of MRI fusion, our analysis has shifted to evaluating conventional ultrasound vs. microUS in the absence of MRI guidance.

Table 1. Distribution of prostate cancer detected and missed using each biopsy method per study group

		SB	TB	P value (TB vs. SB)
Cancer detected	*Any cancer*			
	MRI-microUS	43/62 (69.3%)	39/62 (62.9%)	0.38
	MRI-US	68/100 (68%)	68/100 (68%)	1.00
	P value*	0.86	0.50	
	GG≥2			
	MRI-microUS	30/62 (48.3%)	29/62 (46.7%)	1.00
	MRI-US	38/100 (38%)	44/100 (44%)	0.23
	P value*	0.19	0.73	
Cancer missed	*Any cancer*			
	MRI-microUS	4/62 (6.4%)	8/62 (12.9%)	0.38
	MRI-US	6/100 (6%)	6/100 (6%)	1.00
	P value*	0.91	0.12	
	GG≥2			
	MRI-microUS	6/62 (9.3%)	7/62 (11.2%)	1.00
	MRI-US	12/100 (12%)	6/100 (6%)	0.23
	P value*	0.59	0.23	

*Comparison between case (MRI-microUS) and control (MRI-US) groups

Table 2. Logistic regression models for the prediction of csPCa

	Univariate		Multivariate	
Variable	*OR (95% CI)*	*P value*	*OR (95% CI)*	*P value*
Age	1.04 (1.006-1.09)	0.02	1.02 (0.97-1.07)	0.43
African-American	1.44 (0.58-3.56)	0.42		
Biopsy status				
Biopsy naïve	1.00 (Ref)	-	1.00 (Ref)	
Prior negative biopsy	0.08 (0.01-0.70)	0.02	0.04 (0.004-0.44)	**0.008**
Active surveillance	0.95 (0.46-1.96)	0.89	0.95 (0.41-2.20)	0.91
PSA density	1.92 (1.33-2.76)	<0.001	2.13 (1.38-3.28)	**<0.001**
Maximum PI-RADS				
2-3	1.00 (Ref)		1.00 (Ref)	
4	3.21 (1.43-7.18)	0.004	2.42 (0.99-5.93)	0.053
5	8.8 (3.33-23.21)	<0.001	8.03 (2.53-25.49)	**<0.001**
Biopsy method				
Micro-ultrasound	1.00 (Ref)			
Conventional US	0.72 (0.38-1.36)	0.31		

Comparison of MRI/Ultrasound-fusion Trans-rectal and Trans-perineal Biopsy in the Detection of Clinically Significant Prostate Cancer: a Non-inferiority Study

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Background: Transrectal ultrasound (TRUS)/MRI-fusion biopsy has been shown to increase diagnostic yield compared to the conventional TRUS 12-core template methodology. Currently, Transperineal (TP) prostate biopsy is gaining increased clinical interest as a safe and effective approach to sample the prostate gland with less risk of infection and bleeding than TRUS biopsy. However, compared to (TRUS)/MRI fusion, the diagnostic efficacy of TP/MRI fusion biopsy—measured via cancer detection rate (CDR)—is not fully understood. Thus, this study seeks to better elucidate the effectiveness of TP/MRI fusion as a contemporary biopsy approach through comparing cancer detection rates between software-based TRUS/MRI- and TP/MRI-fusion prostate biopsy.

Methods: MRI/US Fusion prostate biopsies performed between 2019 and 2022 using either a TRUS- with UroNav (TRUSUN) or TP- with UroNav (TPUN) approach were analyzed. Patient characteristics including demographics, PSA, prostate volume, DRE status, highest PI-RADS lesion on MRI and final biopsy pathology were collected. Overall CDR, clinically significant Cancer Detection Rate (csCDR), and clinically significant cancer detection rate in target lesion only (csCDRt) were compared between the two biopsy approaches. Statistical analysis was performed using chi-squared and t-tests as appropriate.

Results: A total of 123 TRUSUN and 41 TPUN prostate biopsies were performed. Analysis of the total dataset showed no significant differences in baseline patient characteristics between the two groups, including age, race, smoking status, family history, diabetes, prostate volume, BMI, purpose of biopsy, PSA, and DRE findings. There were no significant differences in overall cancer detection rates between TRUSUN and TPUN approaches (p = .13). This was also the case in clinically significant cancer detection as well as clinically significant cancer detection in the target lesion only (p = .82 and .99, respectively). This remained true when stratified by Prostate Imaging-Reporting and Data System (PI-RADS) lesion designation, except for the PI-RADS 3 group, in which TRUSUN outperformed TPUN biopsy in detecting clinically significant prostate cancer (p = .001). On subgroup analysis of the PI-RADS 3 group, there were no significant differences in patient characteristics that may account for this.

Conclusions: In statistically similar patient cohorts, TPUN as compared to TRUSUN prostate biopsy showed statistically similar rates of overall CDR, csCDR and csCDRt. While a lower detection rate in those with PI-RADS 3 was noted, this is likely due to a relatively small sample size of just 5 patients with PI-RADS 3 lesions who underwent TPUN biopsy. While further data is needed to better refine these conclusions, these data suggest that the diagnostic utility gained via utilization of US/MRI-fusion in transrectal biopsy may be maintained when applied to a transperineal approach, thus bolstering the current supporting evidence for the continued adoption of TP biopsy into urologic clinical practice.

Table 1. Patient demographics and characteristics of those undergoing TRUSUN and TPUN biopsy.

Characteristic	TRUS Fusion	TP Fusion	p value
Total	122	41	
Age, yrs			.65
Mean (SD)	67 (6.89)	66 (7.43)	
Range	50 - 82	50 - 79	
Race			.17
White (%)	101 (82.8)%)	38 (92.7%)	
Black (%)	5 (4.1%)	2 (4.9%)	
American Indian (%)	0 (0%)	0 (0%)	
Asian (%)	2 (1.6%)	0 (0%)	
Unknown (%)	12 (9.8%)	1 (2.4%)	
Body Mass Index (kg/m^2)			.87
Mean (SD)	29.1 (4.86)	29.9 (5.56)	
Smoking Status			.24
Current	13 (10.6%)	1 (2.4%)	
Former	29 (23.7%)	12 (29.3%)	
Never	77 (63.1%)	28 (68.3%)	
Family History of Prostate Cancer			.76
Yes (%)	31 (25.4%)	8 (19.5%)	
No (%)	67 (54.9%)	20 (48.8%)	
Unknown (%)	24 (19.7%)	13 (31.7%)	
Purpose of Biopsy			.74
Cancer Screening (%)	96 (78.70%)	33 (80.5%)	
Active Surveillance (%)	26 (21.3%)	8 (19.5%)	
DRE Findings			.25
Normal (%)	86 (70.5%)	23 (56.1%)	
Abnormal (%)	32 (26.20%)	16 (39.0%)	
Unknown (%)	0 (0.0%)	1 (2.4%)	
PSA (ng/mL)			.52
Mean (SD)	9.2 (7.4)	8.3 (6.2)	
Range	0.5 - 45.4	2.4 - 38.3	
Prostate Volume (cc)			.21
Mean (SD)	58.8 (40.2)	48 (23.0)	
Range	14 - 301	17 - 122	
Highest PI-RADS Lesion			.24
PI-RADS 3 (%)	20 (16.4%)	5 (12.2%)	
PI-RADS 4 (%)	56 (45.9%)	25 (61.0%)	
PI-RADS 5 (%)	46 (37.7%)	11 (26.8%)	

Table 2. Comparative cancer detection rates between TRUSUN and TPUN biopsy approaches.

	Cancer Detection Rate		
Analytic Category	TRUSUN	TPUN	p value
Overall, Any Grade	78 (64.5%)	40 (77.5)	.13
Clinically Significant	61 (50.4%)	21 (52.5%)	.82
Clinically Significant In Target Lesion Only	70 (57.4%)	23 (57.5%)	.99
PI-RADS 3	2 (10%)	0 (0%)	.001
PI-RADS 4	31 (55.4%)	13 (52%)	.78
PI-RADS 5	37 (80.4%)	10 (90.9%)	.41

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Provider-level and Regional Variation in Robotic-assisted Laparoscopic Prostatectomy Volume

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Background: There is a well-established relationship between surgical volume and perioperative and oncological outcomes for robotic-assisted laparoscopic radical prostatectomy (RALP). [1] However, there is limited recent evidence regarding variation in surgical volume at the surgeon and regional level.[2] In this study, we evaluated variation in RALP volume among Medicare patients to better understand recent practice patterns and inform discussions on centralization of care.

Methods: Using publicly available Medicare data (https://data.cms.gov/) we determined the number of RALPs (CPT 55866) performed by urologists in the United States from 2014-2019. Providers were grouped into 4 United States regions by state: West, Midwest, Northeast, and South. The data were analyzed descriptively and using a multiple linear regression model with region fixed effects to determine the difference in provider RALRP volume across regions. Data were censored for provider volume < 11 cases / year due to privacy concerns.

Results: During the study period, there were 1058 distinct providers performing RALP in Medicare patients. Mean surgical volume per provider per year was 21.09 (SD 16.46, IQR 11). The highest and lowest surgical volume per provider were 306 and 11 cases, respectively (**Figure 1**). There were significant regional differences in RALP volume per physician with highest volume in the Northeast (**Figure 3A**), despite outlying high volume providers (**Figure 1**). There was an increasing number of RALPs performed over time, but no change in procedures per physician per year (**Figure 2/3**).

Conclusions: In recent Medicare data, there is wide variation in RALP volume at the provider and regional level. While this is a subset of overall surgical practice, these data elicit questions regarding the frequency of lower volume surgery and the consideration of centralization to improve outcomes. [3] Further research is needed to determine how to centralize surgical treatment of prostate cancer most effectively.

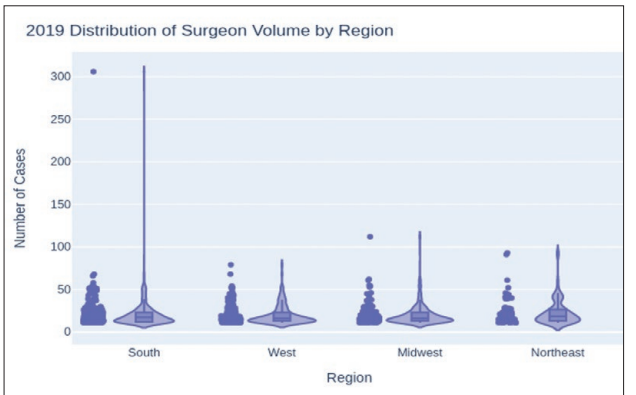

Figure 1: Distribution of urologist surgeon volume by region

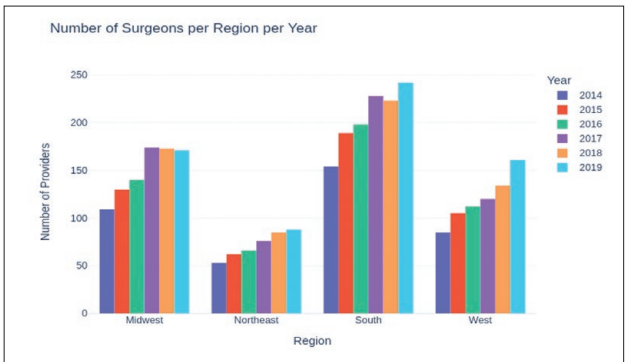

Figure 2: Number of Urologists in each region from 2014 to 2019

Figure 3A: Mean Number of Procedures per Physician in each Region and Year

	Midwest	Northeast	South	West
2014	18.62	24.25	20.75	21.55
2015	18.16	27.53	20.52	21.50
2016	18.84	25.35	21.17	22.87
2017	19.0	24.87	20.90	21.44
2018	19.32	26.11	21.71	21.72
2019	20.15	23.10	21.21	20.16

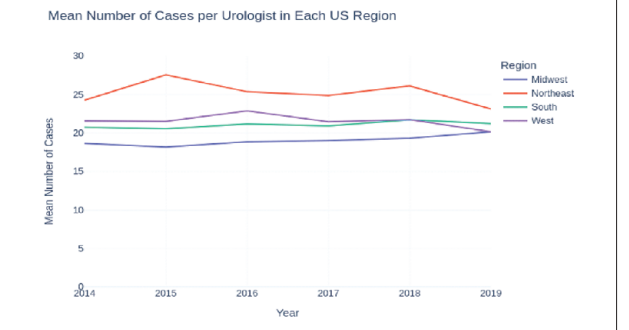

Figure 3B: Mean Number of Procedures per Physician in each Region and Year

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The Effect of a Bladder Peritoneal Flap on Lymphocele Formation after Robotic Radical Prostatectomy

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Background: Numerous series suggest that utilizing a slightly varied bladder peritoneal flap fixation technique lowers the rate of lymphocele formation after radical prostatectomy yet randomized prospective studies are lacking. Here we report on the results of a randomized clinical trial evaluating the effect of this technique on lymphocele formation after robotic radical prostatectomy.

Methods: Men (ages 18-89) undergoing robotic assisted radical prostatectomy with standard bilateral extended pelvic lymph node dissection (RARP/PLND) by a single surgeon were randomized 1:1 into two groups: one group underwent the creation of a bladder peritoneal advancement flap and the other underwent RARP/PLND as standard of care. Group assignment was revealed to the surgeon at the conclusion of the node dissection. All patients underwent an assessor-blinded pelvic ultrasound 3-12 months postoperatively to assess for lymphocele formation. Primary outcomes were rates of lymphocele formation and complications (Clavien ≥ 3). Length of stay (LOS), number lymph nodes removed, lymphocele volume, and continence at 6 months were secondary outcomes. An a priori power calculation was performed based on an estimate of 50% incidence of lymphoceles for the non-flap group and an assumption that the intervention will reduce the incidence of lymphoceles to 33%. Two interim analyses were conducted for safety and sample size using the O'Brien-Fleming method for alpha sharing and a desired sample of 134 per group was planned to achieve 80% power. Enrollment was stopped for efficacy after the second analysis. In this third interim analysis conducted for the purpose of dissemination, a significance level of .0184 was applied. The study was registered on ClinicalTrials.gov (NCT03567525).

Results: No demographic differences were observed. The flap group had significantly fewer lymphoceles at follow-up relative to the no flap group (Table 1) but the groups did not differ on any other outcome.

Conclusions: Prior retrospective studies have suggested that various bladder peritoneal advancement flaps lead to a decreased rate of symptomatic lymphocele formation. This prospective randomized trial supports the implementation of this simple modification for RARP/PLND.

Table 1. Comparisons between flap and no flap groups on age, D'Amico risk and outcomes of interest

	Flap N=106	No Flap N=98	p
Median age (IQR)	63 (59-68)	64 (58-69)	.56
D'Amico risk stratification (n,%)			.450
Low	1 (0.9)	0 (0.0)	
Medium	75 (70.8)	75 (76.5)	
High	30 (28.3)	23 (23.5)	
Any lymphocele (n,%)	4 (3.8)	14 (14.3)	<.01
Symptomatic lymphocele (n,%)	1 (0.9)	1 (1.0)	.95
Median lymphocele volume in Cc^3 (IQR)	105.0 (38.25-1759.5)	78 (37.25- 143.0)	.67
Median nodes removed (IQR)	15 (11.00- 19.25)	16 (12.00-21.00)	.40
Any other complication ≥ Clavien 3 (n,%)	1 (0.9)	1 (1.0)	1.0
Median length of stay (IQR)	1 (1-1)	1 (1-1)	.93
Continent at 6 months (n,%)	84 (83.2)	81 (83.5)	.94

Note: Categorical variables were analyzed using Chi-square or Fisher's exact test as appropriate. Continuous variables were analyzed by T-tests or Wilcoxon Ranked Sum Tests, depending on underlying distributions. IQR, interquartile range

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Patient Expectations after Robot-Assisted Laparoscopic Prostatectomy

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Background: In prior studies, prostate cancer (PC) patients undergoing robot-assisted laparoscopic prostatectomy (RALP) were more likely to be regretful and dissatisfied than those who underwent open radical prostatectomy. The degree of urinary incontinence and postoperative erectile dysfunction were predictors of regret. We hypothesize that there exist discrepancies between patients' expectations and their actual outcomes and that these discrepancies are associated with decisional regret. In this study, we aim to understand patients' expectations of recovery, how their expectations differ from reality, and if such discrepancies predict being regretful of undergoing RALP.

Methods: The Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) is a 16-item questionnaire assessing PC patients' health-related quality of life (HRQOL) at the point of care. A higher EPIC-CP score indicates worse HRQOL. Sixty-one subjects between 2019 to 2021 were prospectively enrolled in this IRB-approved study. Prior to surgery, we had subjects estimate their 3- and 12-month post-operative HRQOL by completing "predictive" EPIC-CP questionnaires - these represented patients' expectations. The subjects then underwent RALP, and completed EPIC-CP 3- and 12-months after surgery, which constituted their actual HRQOL outcomes. We then used the Wilcoxon Rank Sum Test to evaluate whether there were statistically significant differences between the anticipated and actual recovery for each HRQOL domain at 3- and 12-months post-surgery. The Decision Regret Scale, a validated five-item questionnaire used to measure the level of regret, was completed by participants at 12-months. We used Fisher's Exact Test to assess whether a worse-than-anticipated recovery was associated with regret.

Results: At 3-months, the mean HRQOL was better than what subjects expected (mean expected - observed EPIC-CP scores were significantly higher in the urinary incontinence, urinary irritation/obstruction, vitality, and hormonal domains; see Table 1). At 12-month post-operatively, however, discrepancies between expectations and reality in the prior-mentioned HRQOL domains were no longer significant, and subjects' sexual HRQOL was worse than they had anticipated (mean expected - observed EPIC-CP sexual scores was -2.43; $p < 0.01$; Table 1). In other words, on average, subjects expected their sexual HRQOL to be better than it actually was 12 months post-operatively. We found that subjects who experienced a worse-than-anticipated recovery at 12-months were more likely to regret undergoing RALP ($p = 0.042$).

Conclusions: Discrepancies between subjects' HRQOL expectations and actual outcomes are common after RALP. At our institution, 3-month HRQOL outcomes were better than subjects' expectations. However, many subjects expected their sexual HRQOL recovery at 12-months to be further along than their actual outcome. The discrepancy between expectations and reality was associated with decisional regret, highlighting the importance of pre-treatment patient counseling in accurately adjusting patient expectations. Strategies to reduce these discrepancies may include the use of validated decision aids and should be the subject of further study.

Table 1: Expected vs. Actual EPIC-CP Scores

	3-month EPIC-CP Score					12-month EPIC-CP Score				
Functional Domains	n	Expected Mean (Sd)	Actual Mean (Sd)	Mean Diff	p-value †	n	Expected Mean	Actual Mean	Mean Diff	p-value †
Urinary Incontinence	61	3.69 (2.51)	2.60 (2.23)	1.10	<0.01*	24	1.42 (1.64)	1.75 (1.36)	-0.33	0.37
Urinary Irritation/Obstrction	62	3.31 (2.62)	1.79 (2.08)	1.52	<0.01*	24	1.00 (1.25)	1.17 (1.37)	-0.17	0.43
Bowel	60	0.85 (1.75)	0.82 (1.53)	0.03	0.49	20	0.15 (0.67)	0.50 (1.79)	-0.35	0.33
Sexual	59	6.90 (2.70)	7.08 (2.91)	-0.19	0.72	21	3.90 (2.30)	6.33 (3.35)	-2.43	<0.01*
Vitality or Hormonal	58	1.78 (2.06)	1.12 (1.73)	0.66	0.01*	19	0.74 (1.48)	1.05 (1.68)	-0.32	0.43
Overall EPIC-CP Score	56	16.59 (8.83)	13.52 (7.33)	3.07	0.01*	18	7.39 (5.50)	11.06 (7.57)	-3.67	0.03

†: Wilcoxon Rank Sum Test; n: Unit of observation - Participant completed questions in the section; Sd: Standard Deviation;
Mean Dff: Mean Differences = Expected EPIC-CP Scores - Actual EPIC-CP Score;
Mean Dff < 0: Recovery worse than expected, Mean diff > 0: Recovery better than expected
*: p-value < 0.05, results are statistically significant

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Impact of Family History and Germline Genetic Risk Variants on Long-term Outcomes of Active Surveillance-eligible Prostate Cancer

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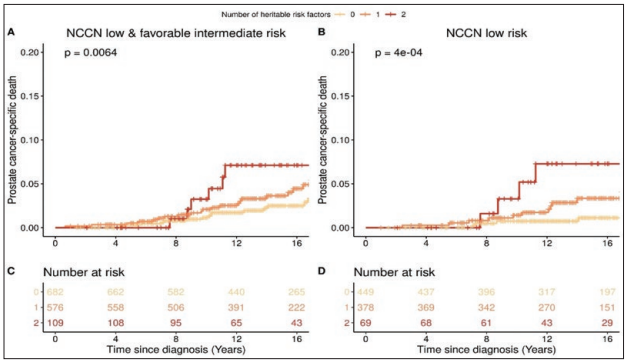
Background: A family history of prostate cancer (PCa) and BRCA/DNA repair gene-associated cancers are risk factors for developing prostate cancer. In the last decade, > 260 PCa-associated single nucleotide polymorphisms (SNPs) have been identified through large-scale genome-wide association studies that strongly stratify lifetime risk of prostate cancer. Few studies have examined the prognostic value of family history or PCa germline risk variants in patients with favorable-risk PCa eligible for active surveillance (AS). Here, we evaluate the impact of a positive family history and germline risk SNPs on outcomes on AS-eligible patients.

Methods: In a prospective cohort of 39,427 U.S. men in the Health Professionals Follow-up Study, 1,367 were diagnosed with clinically favorable-risk (NCCN very low-, low-, or favorable intermediate-risk) PCa from 1986 to 2016 and underwent genome-wide SNP genotyping. During the 30-year follow-up, 263 patients experienced disease recurrence and 52 patients died of PCa. A polygenic risk score was derived from 269 SNPs associated with development of PCa. Two loci associated with PCa survival were also assessed. Multivariable Cox proportional hazards models were used to estimate the association between family history of prostate, breast, or pancreatic cancer, germline risk SNPs, and PCa recurrence or death through 2019.

Results: The median follow up time from diagnosis was 14.1 years. A family history of prostate, breast, or pancreatic cancer was observed in 494 (36%) patients. Men with a positive family history had an 83% greater risk of PCa-specific death (95% CI 1.06-3.17, p = 0.03), and greater than that of men with a family history of PCa alone. The polygenic risk score was not associated with either PCa recurrence or death. However, focusing on 2 loci on 8q24 and 19q13 with the strongest evidence in the literature for association with PCa aggressiveness, we observed a significant association between rs2735839 on 19q13 and PCa-specific death (HR 1.81, 95% CI 1.04-3.17, p = 0.037). Using a risk score giving one point each to a positive family history and rs2735839 risk allele, each point of the heritable risk score was associated with a 72% increased risk of PCa-specific death (95% CI 1.16-2.54, p = 0.006).

Conclusions: Our study found that patients with AS-eligible PCa with a family history of prostate, breast, or pancreatic cancer or a 19q13 germline risk allele had elevated risks of PCa-specific death. These findings have implications for how germline genetic risk should be factored into AS selection criteria.



18

Overall Survival in Patients with Metastatic Hormone-sensitive Prostate Cancer (mHSPC) Treated with Enzalutamide + Androgen Deprivation Therapy by High or Low Disease Volume and Progression to mHSPC (M0 at Diagnosis) or *de novo* mHSPC (M1 at Diagnosis): *Post Hoc* Analysis of the Phase 3 ARCHES Trial

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Background: In ARCHES (NCT02677896), enzalutamide (ENZA) + androgen deprivation therapy (ADT) improved radiographic progression-free survival, overall survival (OS), and other key secondary endpoints vs. placebo (PBO) + ADT for patients with mHSPC (also known as metastatic castration-sensitive prostate cancer). Final OS results confirmed a long-term survival benefit with ENZA + ADT (hazard ratio [HR] 0.66; 95% confidence interval [CI] 0.53, 0.81; p < 0.0001). We present *post hoc* analyses of OS by disease volume and progression to M1 HSPC after initial diagnosis with localized disease (M0) or presentation of de novo mHSPC at initial diagnosis (M1).

Methods: Patients with mHSPC (N = 1150) were randomized 1:1 to ENZA (160 mg/day) + ADT (n = 574) or PBO + ADT (n = 576), stratified by disease volume and prior docetaxel use. After unblinding, 180 (31.3%) PBO + ADT-treated patients crossed over to open-label ENZA + ADT. High disease volume was defined per CHAARTED criteria. Medical profiles of patients assessed as MX/unknown metastasis at initial diagnosis (n = 213) were further reviewed centrally and adjudicated as having either M0 or M1 disease. Median OS and HRs were estimated by Kaplan-Meier methods and Cox proportional hazards, respectively.

Results: Median treatment duration was 40.2 months (mo) for ENZA + ADT and 13.8 mo for PBO + ADT. Inclusive of crossover, 401 (69.6%) PBO + ADT patients had subsequent life-prolonging therapy. OS benefits with ENZA + ADT were seen in all disease volume and M0/M1 populations at a similar magnitude to the overall population (**Table**). Median OS was not reached in most populations except PBO + ADT patients with high disease volume (45.9 mo; 95% CI 40.1, not estimable [NE]) or high disease volume and M1 disease (43.4 mo; 95% CI 36.4, 49.7) and ENZA + ADT patients with high disease volume and M0 disease (54.2 mo; 95% CI 54.2, NE). Due to the *post hoc* nature of the analysis, results should be interpreted with caution.

Conclusions: Our *post hoc* analysis demonstrates consistent long-term survival benefit with ENZA + ADT vs. PBO + ADT across patients with mHSPC with high and low disease volumes and M0 or M1 disease at initial diagnosis, despite substantial treatment crossover and subsequent therapy use in PBO + ADT patients.

Table:

Population	ENZA + ADT· E/n (%)	PBO + ADT· E/n (%)	HR· (95% CI)
Overall	154/574 (26.8)	202/576 (35.1)	0.66 (0.53, 0.81)
Low disease volume	35/220 (15.9)	46/203 (22.7)	0.66 (0.43, 1.03)
High disease volume	119/354 (33.6)	156/373 (41.8)	0.66 (0.52, 0.83)
M1	127/448 (28.3)	170/442 (38.5)	0.63 (0.50, 0.79)
M0	24/117 (20.5)	31/129 (24.0)	0.71 (0.41, 1.21)
Low disease volume + M1	26/151 (17.2)	34/133 (25.6)	0.65 (0.39, 1.08)
Low disease volume + M0	8/63 (12.7)	12/67 (17.9)	0.63 (0.26, 1.54)
High disease volume + M1	101/297 (34.0)	136/309 (44.0)	0.63 (0.48, 0.81)
High disease volume + M0	16/54 (29.6)	19/62 (30.6)	0.77 (0.39, 1.50)

·As randomized; ·HR < 1 favors ENZA + ADT; HR > 1 favors PBO + ADT.
E = events

Funding: This study was sponsored by Pfizer and Astellas Pharma, the co-developers of enzalutamide.

Acknowledgments: Medical writing and editorial support funded by the sponsors were provided by Jake Stoddart, MRes, and Jane Beck, MA, from Complete HealthVizion.

P1

Utilization of Telemedicine in Cancer Patients, an Analysis of the National Health Interview Survey Data in the COVID-19 Era

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Background: With recent advances in digital communications technology and the backlog of cancer care resulting from the COVID-19 pandemic, the demand for telemedicine has skyrocketed. The latest evidence suggests that high-quality oncological care can be delivered by means of telemedicine, with some caveats. Against this backdrop, we sought to analyze the use of telemedicine among cancer survivors, hypothesizing that its use may be higher for certain oncological conditions relative to others.

Methods: We conducted a cross-sectional study on cancer patients using data between July and December 2020 in the National Health Interview Survey (NHIS). We utilized an affirmative answer to *"Have you EVER been told by a doctor or other health professional that you had Cancer or a malignancy of any kind?"* to identify patients with cancer history. We used the question *"In the past 12 months, have you had an appointment with a doctor, nurse, or other health professional by video or by phone?"* to identify telemedicine recipients. Survey-weighted multivariable Poisson regression analysis adjusted for potential confounders was conducted to estimate risk ratios (RR) for receipt of telemedicine, and a two-way interaction between currently receiving treatment and cancer type was assessed for any effect modification.

Table 1: Respondent with a history of cancer demographics and characteristics factored by receipt of virtual care using the National Health Interview Survey between July and December 2020

Variables	Total		Receipt of Virtual Care		
	Weighted Mean (Std. dev.)	[95% CI]	Weighted Mean (Std dev)	[95% CI]	Weighted Prevalence [95% CI]
Age (continuous)	65.55 (13.77)	[64.96, 66.13]	65.89 (13.77)	[64.73,67.05]	0.44 [0.42,0.47]
	N (Weighted%)	Population weighted estimation in million	N (Weighted%)	Population weighted estimation in million	Weighted Prevalence [95% CI]
Currently receiving treatment for cancer					
No	2101 (88)	10.815	934 (83)	4.558	0.42 [0.39, 0.45]
Yes	288 (12)	1.497	181 (17)	0.907	0.61 [0.53, 0.68]
Total	2389 (100)	12.312	1115 (100)	5.465	0.44 [0.42, 0.47]
Cancer Type					
Breast cancer	340 (14)	1.667	143 (12)	0.647	0.39 [0.32, 0.46]
Colorectal cancer	74 (4)	0.478	32 (4)	0.2	0.42 [0.26, 0.59]
Cervical/ovarian/uterine cancer	163 (8)	0.979	75 (8)	0.447	0.46 [0.37, 0.55]
Lung cancer	44 (2)	0.238	23 (2)	0.117	0.49 [0.31, 0.67]
Lymphoma cancer	54 (2)	0.304	29 (3)	0.161	0.53 [0.37, 0.68]
Thyroid cancer	54 (3)	0.351	35 (4)	0.235	0.67 [0.47, 0.82]
Skin cancer (incl melanoma)	811 (32)	3.997	346 (28)	1.52	0.38 [0.34, 0.42]
Prostate cancer	211 (9)	1.074	101 (10)	0.543	0.51 [0.42, 0.59]
Other or multiple cancers	638 (26)	3.224	331 (29)	1.597	0.50 [0.45, 0.54]
Total	2389 (100)	12.312	1115 (100)	5.465	0.44 [0.42, 0.47]
Gender					
Female	1403 (57)	6.978	673 (57)	3.138	0.45 [0.42, 0.48]
Male	986 (43)	5.334	442 (43)	2.327	0.44 [0.40, 0.48]
Total	2389 (100)	12.312	1115 (100)	5.465	0.44 [0.42, 0.47]
Educational Attainment					
Incomplete school or Highschool degree	716 (40)	4.9	275 (35)	1.888	0.39 [0.34, 0.43]
Associate or Bachelor"s degree	1211 (45)	5.522	601 (48)	2.619	0.47 [0.44, 0.51]
Master's degree	350 (12)	1.44	179 (13)	0.731	0.51 [0.44, 0.57]
Professional and Doctoral degree	106 (3)	0.399	58 (4)	0.21	0.53 [0.41, 0.64]
Total	2383(100)	12.261	1113(100)	5.448	0.44[0.42,0.47]
Race/Ethnicity					
Non-Hispanic White	2083 (83)	10.175	959 (81)	4.408	0.43 [0.41, 0.46]
Non-Hispanic Black	134 (7)	0.853	74 (9)	0.465	0.55 [0.44, 0.65]
Hispanics	102 (7)	0.818	50 (7)	0.379	0.46 [0.34, 0.60]
Non-Hispanic Asians	27 (2)	0.233	15 (2)	0.133	0.57 [0.35, 0.77]
Others	43 (2)	0.233	17 (1)	0.08	0.34 [0.20, 0.52]
Total	2389 (100)	12.312	1115 (100)	5.465	0.44 [0.42, 0.47]
Receipt of treatment that weakens the immune system					
No	2161 (92)	11.179	959 (87)	4.716	0.42 [0.39, 0.45]
Yes	207 (8)	1.03	141 (13)	0.676	0.66 [0.57, 0.73]
Total	2368 (100)	12.209	1100 (100)	5.392	0.44 [0.42, 0.47]
General Hlth Status					
Poor	152 (7)	0.832	93 (9)	0.484	0.58 [0.49, 0.67]
Fair	376 (18)	2.161	228 (23)	1.273	0.59 [0.52, 0.65]
Good	795 (34)	4.176	386 (34)	1.882	0.45 [0.40, 0.50]
Very Good	756 (30)	3.745	309 (26)	1.425	0.38 [0.34, 0.42]
Excellent	309 (11)	1.394	98 (7)	0.397	0.28 [0.22, 0.35]
Total	2388 (100)	12.308	1114 (100)	5.461	0.44 [0.42, 0.47]
Family Income					
$0 to $34,999	691 (27)	3.283	334 (27)	1.476	0.45 [0.40, 0.50]
$35,000 to $49,999	321 (13)	1.632	145 (14)	0.756	0.46 [0.39, 0.54]
$50,000 to $74,999	429 (17)	2.086	194 (17)	0.917	0.44 [0.38,0.50]
$75,000 to $99,999	302 (13)	1.591	140 (12)	0.658	0.41 [0.35, 0.49]
$100,000 or greater	646 (30)	3.72	302 (30)	1.658	0.45 [0.40, 0.50]
Total	2389 (100)	12.312	1115 (100)	5.465	0.44 [0.42, 0.47]
Health Coverage					
No	52 (4)	0.505	10 (1)	0.062	0.12 [0.06, 0.24]
Yes	2336 (96)	11.801	1105 (99)	5.403	0.46 [0.43, 0.48]
Total	2388 (100)	12.306	1115 (100)	5.465	0.44 [0.42, 0.47]
Urbanization level of residence					
Non-metropolitan	430 (18)	2.169	165 (15)	0.844	0.39 [0.33, 0.45]
Medium and small metropolitan	825 (32)	4.001	352 (29)	1.558	0.39 [0.35,0.44]
Large fringe metropolitan	566 (25)	3.096	282 (25)	1.371	0.44 [0.39, 0.50]
Large central metropolitan	568 (25)	3.046	316 (31)	1.692	0.56 [0.50, 0.61]
Total	2389 (100)	12.312	1115 (100)	5.465	0.44 [0.42, 0.47]

CI – confidence interval. The survey's response rate was 48.9%. Respondents who reported ever being diagnosed with cancer were included in the analysis, respondents who answered no, refused to answer, were not certain, or did not know were excluded from the analysis. Respondents who reported multiple cancers were grouped with other cancers, and all other cancer types were from participants reporting one cancer

Results: We Identified 2,389 individuals with a cancer history, representing a weighted population of 12.312 million. The prevalence of telemedicine utilization was 44% (see Table1). Relative to breast cancer survivors, we found that PCa was a significant predictor of receipt of telemedicine (RR: 1.39, 95% CI: [1.06-1.81], P = 0.02), (see Table2). A significant interaction was found between those currently receiving treatment for cancer and cancer type P_{int} < 0.01; marginal probability analysis showed that patients currently receiving PCa treatment were more likely to receive telemedicine in comparison to those not on treatment, with an adjusted risk difference of 0.18, (95% CI[0.01-0.35], P = 0.04) (see Table 3).

Conclusions: Our study suggests that telemedicine appointments were widely used among cancer survivors in 2020, with PCa survivors more likely to use telemedicine compared to other malignancies. Such findings may point to wider adoption of telemedicine among urologists, as suggested by other studies, or that PCa care lends itself better to telemedicine, compared to other malignancies. Future studies should focus on understanding the dynamics of such patient- and provider-level factors.

Table 2: Survey Complex Weighted Poisson regression for the outcome of receiving virtual visits in patients with cancer history in the National Health Interview Survey between July and December 2020

	Risk Ratio	[95% CI]	P >t
Currently receiving treatment for cancer			
No	Ref	-	-
Yes	1.26	[1.1-1.44]	< 0.01
Cancer Type			
Breast cancer	Ref	-	-
Colorectal cancer	1.28	[0.86-1.91]	0.23
Cervical/ovarian/uterine cancer	1.36	[1.06-1.73]	0.01
Lung cancer	1.23	[0.84-1.80]	0.28
Lymphoma cancer	1.51	[1.05-2.18]	0.03
Thyroid cancer	1.94	[1.46-2.59]	< 0.01
Skin cancer (including melanoma)	1.16	[0.94-1.42]	0.16
Prostate cancer	1.39	[1.06-1.81]	0.02
Other or multiple Cancers	1.35	[1.11-1.65]	< 0.01
Age (continuous)			
	1.00	[1.00-1.01]	0.97
Gender			
Female	Ref	-	-
Male	0.88	[0.78-1.01]	0.07
Educational Attainment			
Incomplete school or Highschool degree	Ref	-	-
Associate or Bachelor"s degree	1.30	[1.15-1.48]	< 0.01
Master's degree	1.45	[1.20-1.74]	< 0.01
Professional and Doctoral degree	1.60	[1.27-2.03]	< 0.01
Race/Ethnicity			
Non-Hispanic White	Ref	-	-
Non-Hispanic Black	1.03	[0.85-1.24]	0.75
Hispanics	0.96	[0.75-1.23]	0.76
Non-Hispanic Asians	1.03	[0.67-1.60]	0.88
Others	0.86	[0.56-1.32]	0.48
Receipt of treatment that weakens the immune system			
No	Ref	-	-
Yes	1.20	[1.03-1.4]	0.02
General Health Status			
Poor	Ref	-	-
Fair	1.12	[0.92-1.37]	0.27
Good	0.87	[0.71-1.06]	0.16
Very Good	0.72	[0.58-0.89]	< 0.01
Excellent	0.54	[0.40-0.72]	< 0.01
Family Income			
$0 to $34,999	Ref	-	-
$35,000 to $49,999	1.03	[0.86-1.25]	0.73
$50,000 to $74,999	1.00	[0.85-1.19]	0.97
$75,000 to $99,999	0.93	[0.76-1.13]	0.45
$100,000 or greater	0.99	[0.83-1.16]	0.86
Health Coverage			
No	Ref	-	-
Yes	3.75	[1.63-8.6]	< 0.01
Urbanization level of residence			
Non-metropolitan	Ref	-	-
Medium and small metropolitan	1.01	[0.84-1.21]	0.92
Large fringe metropolitan	1.19	[0.99-1.44]	0.06
Large central metropolitan	1.39	[1.16-1.67]	< 0.01
Two-Way interaction between Currently receiving treatment for cancer and Cancer type was statistically significant (P_{int} < 0.01)			

Table 3. Marginal mean predicted probability of receiving virtual visits with the adjusted risk difference between those Not currently receiving treatment for cancer and for those currently receiving treatment for cancer for each cancer type

	Currently receiving treatment for cancer			
	No	Yes		
	MPP* [95% CI]	MPP* [95% CI]	ARD* [95% CI]	P>t
Cancer Type				
Breast cancer	0.35 [0.29-0.42]	0.34 [0.17-0.50]	-0.02 [-0.21-0.17]	0.85
Colorectal cancer	0.43 [0.26-0.59]	0.68 [0.36-0.99]	0.24 [-0.10-0.59]	0.17
Cervical/Ovarian/Uterine cancer	0.45 [0.37-0.54]	0.60 [0.33-0.87]	0.14 [-0.14-0.42]	0.33
Lung cancer	0.36 [0.19-0.52]	0.67 [0.40-0.94]	0.35 [0.002-0.70]	0.05
Lymphoma cancer	0.48 [0.29-0.67]	0.80 [0.53-1.07]	0.32 [0.001-0.64]	0.05
Thyroid cancer	0.66 [0.50-0.81]	0.48 [0.27-0.70]	-0.18 [-0.41-0.06]	0.14
Skin cancer (including Melanoma)	0.38 [0.34-0.43]	0.59 [0.45-0.73]	0.20 [0.07-0.33]	**< 0.01**
Prostate cancer	0.46 [0.36-0.56]	0.64 [0.49-0.80]	0.18 [0.01-0.35]	**0.04**
Other or multiple cancers	0.47 [0.42-0.53]	0.51 [0.42-0.60]	0.04 [-0.07-0.14]	0.50
*Mean Predicted Probability *Adjusted Risk difference				

P2

Disparities in the Attributable Bladder Cancer Risk Due to Smoking

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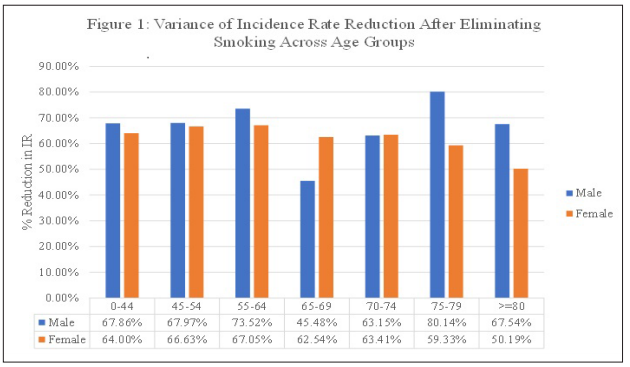
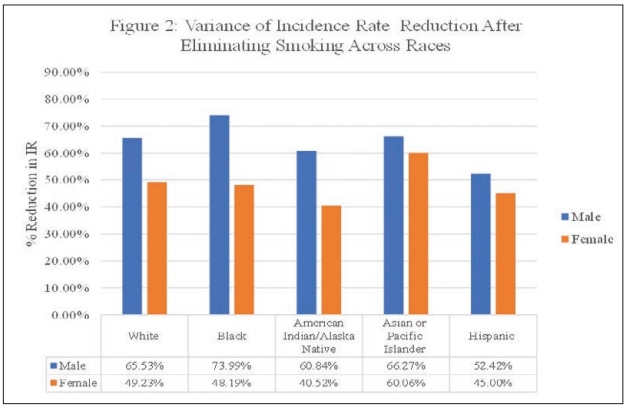
Background: Cigarette smoking is a well-established risk factor for bladder cancer (BC). In addition, strong underlying disparities have been described regarding both the incidence and management of bladder cancer related to patient characteristics. We hypothesized that disparities in the prevalence of smoking may contribute to observed disparities in the incidence of BC. To address this question, we evaluated the proportion of BC incidence that is attributable to smoking and the attributable burden of disease, by sex, race, and age.

Methods: We estimated the proportional reduction in the incidence of BC that would be expected if smoking was eradicated in the US, i.e., no one had ever smoked. The prevalence of smoking (current, former, never) was obtained from the Behavioral Risk Factor Surveillance System (BRFSS) [2017]. The relative risk of smoking and BC were obtained from a recent meta-analysis of 83 observational studies and the incidence rate of bladder cancer was obtained from the Surveillance, Epidemiology, and End Results (SEER) Program in 2018. The incidence rate was standardized to the 2018 US population from the Census. The variance of the standardized incidence rate (SIR) was calculated to capture the burden of BC attributable to smoking.

Results: Almost half (41.5%) of new BC cases in the US population can be attributed to smoking. By removing smoking, more than 10,663 cases of BC may be eliminated. Across all ages and races, more BC cases were eliminated by the removal of smoking among males than females; however, males still had a substantially larger incidence rate of BC compared to females. Across different races, the variance of SIR reduced the most for the black populations among males (74%) and Asian or Pacific Islander for females (Figure 1). When examining across age groups, those aged 75-79 among males (80 %) and those aged 55-64 (67%) among females had the greatest reduction (Figure 2).

Conclusions: Using population-based estimates for smoking prevalence and BC incidence, we observed disparities in the BC attributable to smoking, with greater burdens in males compared to females; black males and Asian females compared to other races, and males aged 75-79 years and females aged 55-64 years compared to other age groups.





P3

"Cystectomy... What Bugs You?" Creation of an Institutional Antibiogram

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Background: Radical cystectomy, the preferred treatment for non metastatic muscle invasive bladder cancer, is associated with high rates of post operative morbidity and mortality. Studies estimate up to a 60% 90 day complication rate. Most research studies show infections account for 30-40% of these complications. To improve morbidity and readmission rates following radical cystectomy, a post cystectomy discharge pathway was created. We set out to create an institution specific antibiogram to identify most common causative organisms to target as a way to specifically decrease genitourinary infection related complications.

Methods: We assessed 216 patients who underwent cystectomy from 2015 to 2021 at Maine Medical Center. Of the170 patients who had any post op complications, 82 (37.9%) patients developed an infection of the genitourinary tract and 32 of those resulted in readmission. Of the 84 total readmissions, 38% were readmitted with a uropathogen as suspected source. We extracted uropathogens from our patient data set and analyzed the 84 causative organisms and sensitivity patterns, where available, to create an antibiogram specific to our institution.

Results: The most common causative organisms of urinary tract infection following radical cystectomy at our institution were *Enterococcus faecalis* (n = 14), *Escherichia coli* (n = 12) and *Klebsiella spp* (n = 12). This was followed by *Enterobacter spp* (n = 8), *Pseudomonas aeruginosa* (n = 8), *Staphylococcus aureus* (n = 8), *Staphylococcus, coagulase negative spp* (n = 6), *Serratia Marcecens* (n =4), Yeast (n= 4) *Citrobacter spp* (n = 3), *Enterococcus faecium* (n = 2), *Proteus mirabilis* (n=1), *Streptococcus spp* (n = 1) and unidentified (n = 1). Sensitivities to above organisms do vary but analysis of trends do reveal oral antibiotics that can be used to target the most common organisms. The organisms that are most likely to be pathogenic are the bacterial enteric pathogens. When focusing on those organisms, we find 70.3% sensitivity to levofloxacin and 50% sensitivity to trimethoprim/sulfamethoxazole. See antibiogram attached.

Conclusions: This institutional antibiogram will help inform implementation of a post-operative antibiotic protocol aimed at decreasing readmission rates. For the post cystectomy discharge pathway the above analysis warrants use of a low dose levofloxacin (250mg daily) as first line agent to prevent infection until the ureteral stent is removed. Second line use of trimethoprim / sulfamethoxazole 800/160mg daily can be utilized where there is allergy or contraindications to the quinolone class (i.e. history of aortic aneurysm or tendinopathy). There are concerns about antibiotic resistance in this population. However, it is worthwhile to utilize a short course of commonly prescribed antibiotics to reduce infection that has historically occurred in over a third of cystectomy patients.

P4

Robotic Versus Open Radical Cystectomy for Urothelial Carcinoma of the Bladder

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Background: The comparative effectiveness of robotic-assisted (RARC) versus open radical cystectomy (ORC) in the management of urothelial carcinoma of the bladder (UCB) remains uncertain. Limited randomized trial evidence suggests similar perioperative outcomes and 2-year progression-free survival, but long-term survival outcomes and real-world data are lacking. We therefore evaluated the comparative effectiveness of RARC and ORC using a nationwide oncology dataset.

Methods: We conducted observational analyses designed to emulate the completed RAZOR trial using the NCDB. Specifically, we identified adults age 37-89 years with Charlson 0-1 diagnosed with cT1-4 cN0-1 cM0 UCB from 2010-2015 and treated with RARC or ORC with LND at a hospital performing an average of > 10 RCs per year. We then examined the associations of surgical approach with perioperative outcomes and overall survival (OS) using propensity score methods with stabilized inverse probability of treatment weights (sIPW), with Cox models further adjusted for imbalanced pathologic features (pT and pN stage).

Results: A total of 3,493 patients were included in the cohort, of whom 2,492 (71%) underwent ORC and 1,001 (29%) underwent RARC. Median follow-up was 29.5 months. After sIPW reweighting, pre-treatment baseline characteristics were well-balanced. After adjustment, RARC was associated with a statistically significant but clinically insignificant higher lymph node (LN) yield (median 20 vs. 18 LNs; $p < 0.01$) and shorter length of hospitalization (median 7 [IQR 5-8] vs. 7 [IQR 6-10]; $p < 0.01$), but there were no differences in positive surgical margins (8% vs. 8%; $p = 0.64$) or 30-day readmissions (10% vs. 9%; $p = 0.80$). After adjustment, there was no difference in OS between RARC and ORC (Figure 1; 5-year OS 57% vs. 55%; $p = 0.28$; HR 0.93, 95%CI 0.80-1.07). OS treatment effects were similar when examined across cT stage, cN stage, and age.

Conclusions: In observational analyses designed to emulate the completed RAZOR trial, RARC was not associated with statistically significant differences in positive surgical margins, 30-day readmissions, or OS compared to ORC.

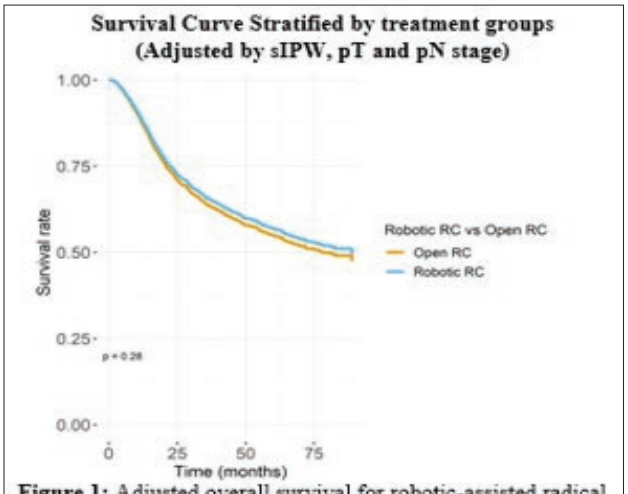

Figure 1: Adjusted overall survival for robotic-assisted radical cystectomy (RARC) and open radical cystectomy (ORC).

P5

Elevated CRP after Radical Cystectomy is Associated with Infectious, Wound, and Anastomotic Complications

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Background: Radical cystectomy (RC) is a highly morbid procedure with frequent infection related complications and readmissions. CRP is a non-specific inflammatory marker often used to guide patient management, with reported indications in the post-operative period. We hypothesized that a markedly elevated CRP several days after RC may be a sub-clinical indicator of complication risk due to infection, wound breakdown, or anastomotic leak.

Methods: Our prospectively maintained database included CRP starting May, 2020. For 66 consecutive patients, 58 had CRP measured POD#4. Fever or leukocytosis (WBC > 11.0) after POD#4 was also recorded. Complications were graded and classified by the MSKCC system. CRP was compared between patients with 30d Infectious/wound/anastomotic leak (I/W/A) complications and those without. ROC analysis was used to determine the optimal cutoff for elevated CRP. Multivariable analysis was performed to find factors associated with I/W/A complications.

Results: Median CRP for patients with I/W/L complications was 136.4 vs. 54.7 for those without (Figure 1). No significant differences in demographics were seen between groups. CRP performed well on ROC analysis for I/W/A with an AUC = 0.864 and a CRP of 93 chosen as a cutoff for being elevated based on Youden's index (Figure 1). Adjustment for disease burden, postop fever, leukocytosis, treatment type, and demographic characteristics showed only elevated CRP was independently associated with I/W/A complications (OR23.98, 95%CI 3.16-182.03, $p = 0.002$, Table 1).

Conclusions: Preliminary data suggests that CRP elevation on POD#4 can be a sub-clinical marker of future I/W/A complications within 30 days following RC. This association independent of other markers of infection including leukocytosis and fever (which was rare). There should be high suspicion of I/W/A complication for patients with an elevated CRP and modified discharge pathways or closer follow-up may be one a future strategy to try and prevent or reduce this morbidity.

Table 1. Multivariable analysis of factors associated with infectious, wound, or anastomotic leak complication after radical cystectomy.

		OR (95%-CI)	p=
Elevated CRP		**23.98 (3.16-182.03)**	**0.002**
Leukocytosis (WBC >11.0k)		3.88 (0.67-22.36)	0.129
Sex		0.11 (0.01-1.08)	0.058
Age	<50	0 (0-0)	0.595
	51-59	0.27 (0.01-8.67)	0.457
	60-69	0.3 (0.01-6.14)	0.431
	70-79	0.08 (0-2.34)	0.14
	>80	0.58 (0.01-32.11)	0.788
ASA ≥3		0.94 (0.08-11.69)	0.962
BMI >30		0.89 (0.17-4.76)	0.896
Smoking status		0.69 (0.09-5.09)	0.714
Case type	(open/robotic)	0.37 (0.05-2.95)	0.35
Neoadjuvant chemotherapy		4.06 (0.52-31.74)	0.181
Fever*		***	***

* Too few events for reliable inclusion in model

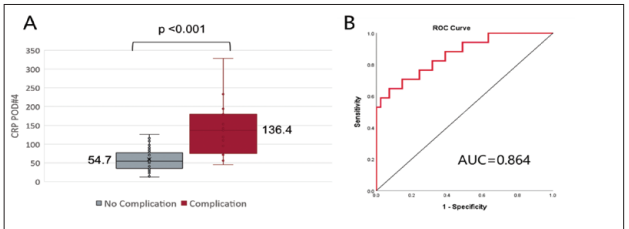

Figure 1. (A) Patients with infectious, wound, or leak complications after radical cystectomy (red) have elevated CRP on post-operative day 4 compared to patients without that class of complication (gray). Median value shown. (B) Receiver operator curve for CRP prediction of infectious, wound, or anastomotic leak complications.

P6

Short-term Outcomes in Radical Cystectomy Patients with History of Prior Pelvic Radiation

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Background: Radical cystectomy (RC) remains the standard of care for muscle-invasive bladder cancer as well as subsets of non-muscle invasive bladder cancer. Radiation to the pelvis for malignancy treatment may predispose patients who later need RC for bladder cancer to worse outcomes. Recently, there has been conflicting data on this topic. We thus sought to investigate the short-term outcomes in RC patients with a history of prior pelvic radiation in our cohort.

Methods: After obtaining IRB approval, we retrospectively reviewed patients with bladder cancer undergoing RC at our institution compared to those with bladder cancer and history prior pelvic radiation also undergoing RC. Pearson Chi Square test was used to assess categorical variables. Wilcoxon rank sum-test was used to assess continuous variables. Linear or binary logistic regression was used to calculate odds ratios listed as point estimates as well as 95% confidence intervals. Kaplan-Meier method with stratified-log rank was used to compare time-to-event.

Results: 342 patients met inclusion criteria from 2018 through 2021. 47 (13.7%) received prior prostate radiation. The prior radiation group had longer median length of primary stay compared to RC at 8.0 days and 6.0 days respectively ($p = 0.012$). The radiation group also had more overall complications at 53.2% compared to 35.9% for the RC group ($p = 0.024$). There was no significant difference between the groups in operative time, estimated blood loss, 30-day re-admission or 30-day mortality.

Conclusions: Patients undergoing RC with prior pelvic radiation are at higher risk of overall complications and longer length of stay in the hospital. Patients should thus be counseled accordingly. Longer follow-up will elucidate if this translates to worse overall survival.

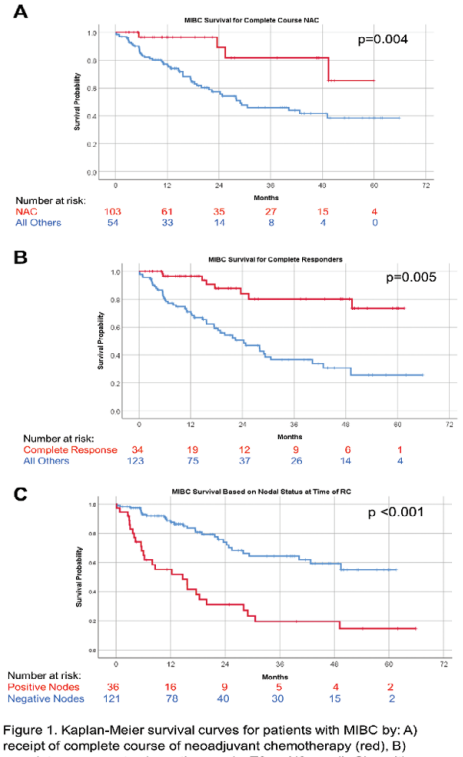

Figure 1. Kaplan-Meier survival curves for patients with MIBC by: A) receipt of complete course of neoadjuvant chemotherapy (red), B) complete response to chemotherapy (ypT0, ypN0 – red), C) positive lymph nodes at time of radical cystectomy (red)

P7

Early Survival Outcomes after Neoadjuvant Chemotherapy for Muscle Invasive Bladder Cancer

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Background: Neoadjuvant chemotherapy (NAC) should be offered to eligible patients with non-metastatic muscle invasive bladder cancer (MIBC) prior radical cystectomy (RC). Multiple studies have demonstrated an overall survival benefit when neoadjuvant chemotherapy is used, although the absolute survival benefit is relatively modest. Our academic center provides most cystectomy care in a rural state and approximately two thirds of patients receive a full treatment course of NAC prior to cystectomy. We sought to examine our early overall survival outcomes based on receipt of NAC.

Methods: Patients with MIBC who underwent RC from 2015-2021 in our database were identified. Demographics, treatment variables, surgical pathology, length of follow up, and vital status were recorded. Kaplan-Meier and Cox Regression controlling for sex, age, Charleston comorbidity index, organ confined disease, and nodal status were performed in SPSS.

Results: 158 patients with MIBC underwent cystectomy from 2015-2021. 65.8% (104/158) received a full course of NAC with most having cisplatin-based therapy (95.1%). Younger patients were more likely to receive NAC and < 20% of octogenarians received NAC ($P < 0.001$). Complete response rate was 32.7%. Median overall survival for MIBC patients improved with a NAC to 45.4 months (95%CI 39.3-51.5) versus 28.0 months (95%CI 21.7-34.3, $p = 0.004$, figure 1). Those with complete response (CR) to NAC had an OS of 52.0 months (95%CI 43.3-58.7) compared to 36.4 months (95%CI 30.9-41.9, $p = 0.005$) if not receiving NAC or without complete response. For all MIBC patients, positive lymph nodes (+LNs) were associated with worse overall median survival of 21.3 months (95%CI 13.5-29.1) versus 44 months (95%CI 39.0-49.1, $p < 0.001$). Median follow up for the cohort was 15.0 months [IQR 7.5-29.0]. Overall, NAC did not improve survival when controlling for other factors by Cox Regression analysis. CR appeared to improve prognosis but was not statistically significant and limited by a limited number of the cohort reaching the survival end point. Non-organ confined disease [OR 1.99 (1.03-3.86), $p = 0.041$] and +LNs [OR 2.91 (1.64-5.15), $p < 0.001$] were the most significant factors and associated with worse outcomes regardless of NAC receipt (figure 2).

Conclusions: We found improved survival for MIBC with NAC prior to RC, but this benefit is not maintained when controlling for other factors and likely reflects a selection bias of healthier patients being more likely to receive NAC. CR, and locally advanced or +LNs at time of surgery are more likely to predict survival outcomes. Factors predicting response to NAC (i.e. genetic/genomic markers) are needed to guide who may benefit from NAC.

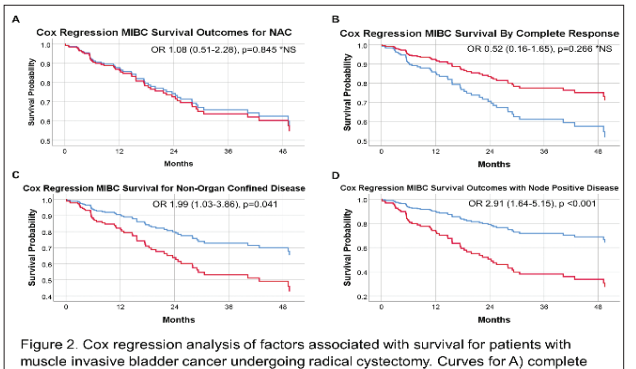

Figure 2. Cox regression analysis of factors associated with survival for patients with muscle invasive bladder cancer undergoing radical cystectomy. Curves for A) complete course of neoadjuvant chemotherapy (blue), B) complete response to NAC (blue), C) Non-organ confined disease (red), D) positive lymph nodes at radical cystectomy (red).

P8

Safety and Efficacy of Stereotactic MRI-guided Adaptive Radiation Therapy for Localized Kidney Tumors

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Background: To assess the safety, feasibility as well as short term oncologic and renal functional outcomes of stereotactic MRI guided adaptive radiotherapy (SMART) for localized kidney cancer in non-surgical candidates.

Methods: Single institution experience of patients undergoing MRI guided radiation therapy with daily plan adaptation for localized kidney cancer from 2020-2021. Patients were treated to a dose of 4000cGy over 5 fractions. Prior to each fraction, a pre-treatment MRI was obtained to allow for re-contouring of tumor and organs-at-risk. Patients were treated using an MR guided gated breath hold technique. Adverse events were classified according to the Common Terminology Criteria for Adverse Events (CTCAE) guideline version 5.0.

Results: Our cohort includes 12 patients with median age 75 years, median tumor diameter 4.75 cm, and median RENAL Nephrometry score 7. In terms of staging, 5 were cT1a, 5 were cT1b, 1 was cT2a, and 1 was cT3a. In total, 67.7% of patients had baseline Stage III CKD or worse renal function, and median Charlson Comorbidity index was 8. Histologic subtypes were 58.3% RCC, 25% papillary RCC, and 16.7% not reported. There was a total of 11 adverse events (AE) within 90 days: 10 were grade 1 for fatigue, nausea, vomiting, and diarrhea; there was one grade 2 AE for nausea (Table 1). No grade 3 or higher events were observed. The median baseline eGFR was 56.5 mL/min/1.73m^2, with median change in eGFR of -10 mL/min/1.73m^2 and the median change in tumor diameter was -0.5 cm at 7.5 months (IQR 2.25 - 12.25 months) of follow-up, with no local or distant progression. No SMART-related hospital admissions occurred (Figure 1).

Conclusions: SMART is a safe outpatient treatment option with low toxicity, limited decline in renal function, and high rates of local tumor control. For patients who are not surgical candidates, SMART may be an effective therapy for localized kidney cancer, especially for those less suitable for ablative therapies due to larger tumor size, close proximity to the collecting system, and use of anticoagulation.

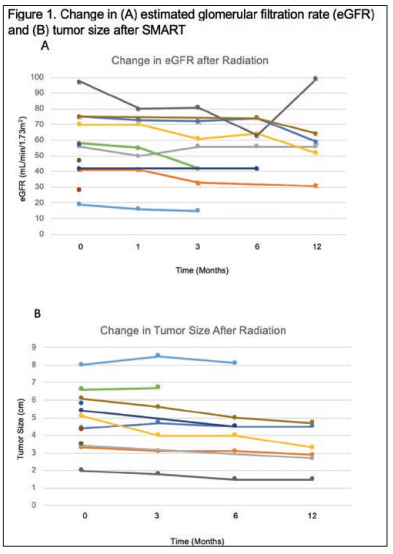

Figure 1. Change in (A) estimated glomerular filtration rate (eGFR) and (B) tumor size after SMART

Table 1: 90-day Adverse events after MGRT

Adverse Event (<90 days)	Grade 1	Grade 2	Grade 3	Total
Fatigue	6	0	0	6 (50%)
Dysphagia	0	0	0	0 (0%)
Esophageal pain	0	0	0	0 (0%)
Esophagitis	0	0	0	0 (0%)
Dyspepsia	0	0	0	0 (0%)
Abdominal pain	0	0	0	0 (0%)
Bloating	0	0	0	0 (0%)
Nausea	2	1	0	3 (25%)
Vomiting	1	0	0	1 (8.3%)
Diarrhea	1	0	0	1 (8.3%)
Constipation	0	0	0	0 (0%)
Radiation dermatitis	0	0	0	0 (0%)

P9

Evaluation of Artificial Intelligence Algorithm for Automated Prostate Lesion Detection and Classification on mpMRI using African American Patient Cohort

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Background: The objective of this study is to evaluate a novel, deep-learning artificial intelligence (AI) algorithm for automated prostate cancer detection and classification on multi-parametric magnetic resonance imaging (mpMRI) using a cohort of African American (AA) men.

Methods: A retrospective review of AA patients with mpMRI and biopsy within 9 months of imaging was conducted. Biopsied lesions with Gleason Grade 3 or greater were deemed cancerous. PSA, mpMRI images, pathology and radiology readings were packaged and analyzed using the algorithm. The study sample was split into two test cohorts and analyzed sequentially to assess if machine learning improved performance. Receiver operator curve (ROC) area was used to evaluate algorithm and radiologist performance in correctly detecting cancerous prostate lesions using biopsy data as the "gold standard" classifier.

Results: Sixty-eight AA men were included in the study, 27 in Test Cohort 1 and 41 in Test Cohort 2. In Test Cohort 1, AUC (95% confidence interval [CI]) for radiology and algorithm were 0.648 (0.46, 0.84) and 0.591 (0.48, 0.71), respectively. In Test Cohort 2, AUC (95% CI) for radiology and algorithm were 0.531 (0.38, 0.68) and 0.605 (0.48, 0.73), respectively. Across the Total Cohort, AUC (95% CI) for radiology and algorithm was 0.578 (0.47, 0.69) and 0.600 (0.51, 0.69), respectively (Figure 1).

Conclusions: We conclude that compared to radiologist reports, this novel AI algorithm demonstrates non-inferiority in detecting cancerous prostate lesions in AA men. Additionally, the improved AUC across test cohorts is suggestive that machine learning improves algorithm performance.

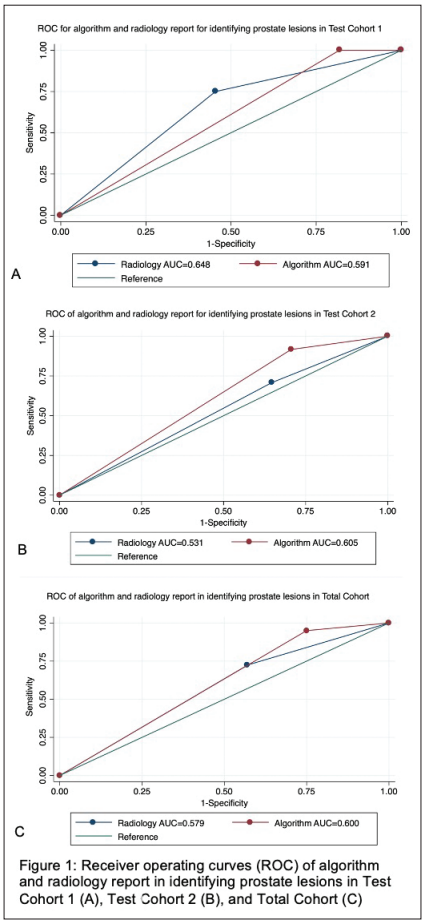

Figure 1: Receiver operating curves (ROC) of algorithm and radiology report in identifying prostate lesions in Test Cohort 1 (A), Test Cohort 2 (B), and Total Cohort (C)

P10

Access to Definitive Treatment and Survival for Intermediate-risk and High-risk Prostate Cancer at Hospital Systems Serving Health Disparity Populations

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Background: Socioeconomic and racial disparities in prostate cancer (PCa) can be attributed to patient-level and physician-level factors. However, there is growing interest in investigating the role of the facility of care in driving cancer disparities. Therefore, we sought to examine the receipt of guideline-concordant definitive treatment, time to treatment initiation (TTI), and survival for men with PCa receiving care at hospital systems serving health disparity populations (HSDPs).

Methods: We conducted a retrospective analysis of the National Cancer Database (2004-2016) among men with intermediate-risk or high-risk PCa eligible for definitive treatment. The primary outcomes were receipt of definitive treatment and TTI within 90 days of diagnosis. The secondary outcome was survival. We defined HSDPs as minority-serving hospitals - facilities in the highest decile of proportion of Non-Hispanic Black (NHB) or Hispanic cancer patients - and/or high-burden safety-net hospitals - facilities in the highest quartile of proportion of underinsured patients. We used mixed-effect models with facility-level random intercept to compare outcomes between HSDPs and non-HSDPs among the entire cohort and among men who received definitive treatment. We evaluated interactions between HSDP status and race for each of the outcomes.

Results: The cohort included 821,931 men with intermediate-risk or high-risk PCa. We included 968 non-HSDPs (72.2%) and 373 HSDPs (27.8%) facilities. Treatment at HSDPs was associated with lower odds of receipt of definitive treatment (aOR 0.64; 95% CI 0.57-0.71; $p < 0.001$), lower odds of TTI within 90 days of diagnosis (aOR 0.74; 95% CI 0.68-0.79; $p < 0.001$), and worse survival (aHR 1.05; 95% CI 1.02-1.09; $p = 0.003$). However, no difference was found in survival among patients who received definitive treatment ($p = 0.1$). NHB men at HSDPs had also worse outcomes than NHB men treated at non-HSDPs as well as NHW men treated at HSDPs (Table 1).

Conclusions: Patients treated at HSDPs were less likely to receive timely definitive treatment and had worse survival. NHB men have worse outcomes than NHW at HSDPs. NHB men with PCa remain largely disadvantaged since they are more likely to be treated at hospitals with worse outcomes and have worse outcomes than other patients at those same institutions.

Table 1: Interaction between race (NHW, n = 634,917 and NHB, n = 119,166) and patient treated at non-HSDP (n = 603,346) versus HSDP facilities (n = 150,737)

	Definitive Treatment		TTI within 90 days		Survival		Survival among men who received definitive treatment	
	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
NHB at HSDP vs. NHW at HSDP	0.68 (0.66-0.71)	< 0.001	0.74 (0.72-0.76)	< 0.001	1.17 (1.12-1.23)	< 0.001	1.13 (1.07-1.19)	< 0.001
NHB at HSDP vs. NHB at non-HSDP	0.65 (0.58-0.73)	< 0.001	0.76 (0.70-0.82)	< 0.001	1.07 (1.00-1.14)	0.05	1.04 (0.97-1.12)	0.22

P11

Increased Utilization of Ambulatory Robot Assisted Laparoscopic Prostatectomy during COVID-19 Pandemic: Results from a State Administrative Database

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Background: Robot-Assisted Laparoscopic Prostatectomy (RALP) is a gold standard procedure for localized prostate cancer. There have been increased reports of RALP being performed in ambulatory setting with same day discharge—which has been shown to provide similar efficacy compared to a traditional overnight hospitalization. With the outbreak of COVID-19 leading to high hospital bed demand, there has been increased interest in ambulatory prostatectomy. We therefore sought to analyze the utilization of ambulatory RALP before and during COVID pandemic using a large state administrative database.

Methods: We identified men who underwent RALP within the State Inpatient Database and the State Ambulatory Surgery Database in California between 2018 and 2020, which provided a representative sample of surgeries performed in a state in various care settings. California was chosen as a highly populous state with a combination of urban, rural patients in a number of different health systems. Relative patient demographic and clinical parameters were recorded. Univariate and Multivariate analyses were performed to investigate the clinical and demographic metrics that associates with ambulatory RALP utilization prior to and during the first waves of COVID-19 pandemic.

Results: During study period, 10612 men underwent RALP in inpatient setting, while 6774 underwent RALP at ambulatory surgical centers. Univariate analysis showed patients who received RALP in ambulatory surgical centers are more likely to be older (66 vs. 64, $p < 0.0001$), Non-Hispanic white (61.7% vs. 57.9%, $p < 0.0001$), residing outside of metropolitan area (28.2% vs. 30.8%, $p < 0.0001$). Patients who received RALP after the first wave of COVID in March 2020 were more likely to receive the procedure in ambulatory setting (53.8% vs. 33.5%, $p < 0.0001$). No difference was found in Charlson Comorbidity Index between groups (63.3% vs. 62.9%, $p = 0.634$). Multivariate analysis showed that patients who received RALP after the first wave of COVID were 2.31 times more likely to receive the procedure at an ambulatory center instead of inpatient setting ($p < 0.0001$). Patients covered by Medicare insurance is 1.54 times more likely to receive an ambulatory RALP compared to those with private insurance ($p = 0.010$).

Conclusions: While the factors underlying the shift towards outpatient robotic prostatectomy are likely complex, our comparison of a study period immediately prior to and during the first waves of the COVID-19 revealed that outpatient prostatectomies increased by 20.3% pre and post-pandemic with a more than two-fold increase in adjusted odds of outpatient RALP following the initial wave of the COVID-19 pandemic. Such association could be potentially explained by the limited hospital beds from the pandemic, encouraging more efficient use of space and resources. While further studies are warranted to investigate its long-term outcomes, the observed increasing uptake of RALP in ambulatory setting could potentially improve the accessibility and cost efficacy in COVID era.

Table 1. Multivariable Logistic Regression for men undergoing RALP at Ambulatory Settings in Reference to Inpatient Settings.

		Odds Ratio	95% CI	p-value
Age		0.9923	0.9779, 1.0069	0.2979
Insurance Status				
Private	ref			
Medicare		1.536	1.1066, 2.1319	0.0103
Medicaid		0.7011	0.3250, 1.5123	0.3652
Self-pay		0.8366	0.4338, 1.6133	0.5944
Race				
Non-Hispanic White	ref			
Non-Hispanic Black		1.1816	0.8970, 1.5564	0.2352
Hispanic		0.8711	0.5479, 1.3849	0.5595
Other		0.9924	0.7974, 1.2351	0.9456
Median Household Income				
Quartile 1 (wealthiest)	ref			
Quartile 2		1.0842	0.8678, 1.3545	0.4765
Quartile 3		0.959	0.7189, 1.2793	0.776
Quartile 4 (poorest)		0.7479	0.5185, 1.0789	0.1202
Urban-Rural Status				
Large metro area, >=1,000,000	ref			
Small metro area, >=1,000,000		1.4647	0.8897, 2.4113	0.1335
Micropolitan		2.9041	1.3633, 6.1861	0.0057
Rural		1.3997	0.7255, 2.7005	0.3159
CCI				
1	ref			
>=2		0.9729	0.8669, 1.0919	0.6409
COVID-19 Timeline				
Before first wave (3/2020)	ref			
After first wave		2.3162	1.7632, 3.0427	<0.0001

19

Efficacy and Safety of a Novel Gene Therapy (URO-902; pVAX/*hSlo*) in Female Patients With Overactive Bladder and Urge Urinary Incontinence: Results From a Phase 2a Trial

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Background: URO-902 is an investigational gene therapy for overactive bladder (OAB) and consists of a plasmid vector that expresses the α subunit of the large-conductance Ca^{2+}-activated K^+ channel in the detrusor to reduce bladder hypercontractility. We report interim results from a phase 2a trial assessing the safety and efficacy of URO902 in OAB.

Methods: This was a prespecified, 12-week interim analysis of a 48-week multicenter, randomized, double-blind, placebo-controlled, dose-escalation study (NCT04211831). Women aged 40–79 years with OAB and urge urinary incontinence (UUI) who were not adequately managed with oral OAB medications were randomly assigned to receive single-dose URO-902 24 mg, URO-902 48 mg, or placebo administered by intradetrusor injection via cystoscopy under local anesthesia. Safety was assessed by adverse events (AEs) and postvoid residual (PVR) urine. Exploratory endpoints included change from baseline (CFB) to week 12 in mean daily micturitions, urgency episodes, UUI episodes, and quality of life (QoL) measures.

Results: Of the 80 patients randomized, 68 completed week 12, and 74 were included in the intent-to-treat population. Mean (SD) age was 64.7 (7.1) years, and 13.5% had prior treatment with onabotulinumtoxinA. At week 12, URO-902 24 and 48 mg were associated with clinically relevant improvement vs. placebo in mean daily micturitions (LS mean CFB, –2.5 and –3.0 vs. –1.0, respectively), urgency episodes (–2.4 and –3.4 vs. –1.2), UUI episodes (–2.4 and –2.6 vs. –2.3), OAB questionnaire symptom bother score (–24.1 and –25.3 vs. –11.2), and proportion of patient global impression of change responders (40.9% and 57.7% vs. 30.8%) (Table). Treatment-emergent AEs occurred in 45.5% of patients receiving URO-902 24 mg, 46.2% receiving 48 mg, and 50.0% receiving placebo. The most commonly occurring AE (24 mg/48 mg/placebo) was urinary tract infection (0%/15.4%/3.8%). One patient (48-mg arm) had asymptomatic elevated PVR urine volume at week 2 (resolved spontaneously, did not require catheterization).

Conclusions: In this phase 2a trial of women with OAB and UUI, a single dose of URO-902 24 or 48 mg was associated with clinically relevant improvement in efficacy and QoL endpoints and was safe and well tolerated.

Table. Change from Baseline at Week 12 in Efficacy and Quality of Life Endpoints (ITT-E Population*)

Outcome	URO-902 24 mg (N=22)	URO-902 48 mg (N=26)	Placebo (N=26)
Micturitions			
Mean (SD) baseline	9.8 (1.6)	10.8 (2.7)	11.5 (2.7)
LS mean (95% CI) change from baseline	–2.5 (–3.5 to –1.4)	–3.0 (–4.0 to –1.9)	–1.0 (–2.0 to 0.1)
LS mean difference (95% CI) vs placebo	–1.5 (–2.9 to –0.2)	–2.0 (–3.3 to –0.6)	–
Nominal *P* value vs placebo	0.0297	0.0044	–
Urgency episodes			
Mean (SD) baseline	7.4 (2.8)	8.4 (3.1)	9.3 (3.4)
LS mean (95% CI) change from baseline	–2.4 (–3.9 to –0.8)	–3.4 (–4.9 to –1.9)	–1.2 (–2.7 to 0.3)
LS mean difference (95% CI) vs placebo	–1.2 (–3.1 to 0.7)	–2.2 (–4.0 to –0.4)	–
Nominal *P* value vs placebo	0.2060	0.0176	–
UUI episodes			
Mean (SD) baseline	5.3 (3.3)	4.3 (2.4)	5.9 (3.9)
LS mean (95% CI) change from baseline	–2.4 (–3.4 to –1.4)	– 2.6 (–3.6 to –1.6)	–2.3 (–3.3 to –1.2)
LS mean difference (95% CI) vs placebo	–0.1 (–1.4 to 1.2)	–0.4 (–1.7 to 0.9)	–
Nominal *P* value vs placebo	0.8564	0.5690	–
OAB-q symptom bother score			
Mean (SD) baseline	67.6 (20.9)	72.4 (16.6)	67.5 (22.9)
LS mean (95% CI) change from baseline	–24.1 (–34.5 to –13.7)	–25.3 (–35.3 to –15.2)	–11.2 (–21.6 to –0.8)
LS mean difference (95% CI) vs placebo	–12.9 (–25.4 to –0.4)	–14.1 (–26.3 to –1.9)	–
Nominal *P* value vs placebo	0.0431	0.0246	–
PGI change responders†			
Week 12 responders, n (%)	9 (40.9)	15 (57.7)	8 (30.8)
CMH difference (95% CI) vs placebo	11.2 (–15.4 to 37.9)	28.1 (3.4 to 52.8)	–
Nominal *P* value vs placebo	0.4093	0.0256	–

CMH, Cochran-Mantel-Haenszel; ITT-E, intent-to-treat exposed; LS, least squares; OAB-q, overactive bladder questionnaire; PGI, patient global impression of change; UUI, urgency urinary incontinence.

*Defined as all patients who were randomized and treated.

†Defined as a patient who answered "much better" or "moderately better" on the PGI change. A patient with a missing PGI change response was considered as nonresponder.

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Trauma History in Chronic Pain Syndromes

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Background: Physical and emotional trauma is unfortunately a common occurrence in the United States and long term effects of trauma have been discussed extensively in the literature. The CDC alongside Kaiser Permanente conducted a study published in the American Journal of Preventive Medicine in 1998 known as "The Adverse Childhood Experiences Study" (ACE Study) that demonstrated what had long been suspected, that there is an association between adverse childhood experiences (ACEs) and health and social problems across a lifetime. A history of trauma has been more specifically linked to those with chronic pain syndromes, which often leads to extensive medical referrals to specialists and is often challenging to treat due to the poorly understood etiology of their symptoms and can be frustrating for both the provider and patient. Dr. Van Der Kolk writes in his book *The Body Keeps the Score*, that "children who have developed in the context of ongoing danger, maltreatment, and inadequate caregiving systems are ill-served by the current diagnostic system, as it frequently leads to no diagnosis, multiple unrelated diagnoses, an emphasis on behavioral control without recognition of interpersonal trauma and lack of safety in the etiology of symptoms, and a lack of attention to ameliorating the developmental disruptions that underlie the symptoms." Chronic pain syndromes are commonly seen in our urology practice, and it is unclear how many of these patients have undergone appropriate screening and treatment for past trauma prior to being referred to us. We hypothesize that most patients will have not been asked about trauma history prior to being referred to a Urologist for their chronic pain.

Methods: We did a retrospective chart review of patients seen by 3 specific providers in our practice for chronic pelvic pain over the past 3 years. This included 80 patients. We excluded pediatric patients and any patients who were found to have a somatic explanation for their pain upon urologic evaluation such as cancer, UTI or nephrolithiasis. There were 47 patients remaining who were included in our study. The following data was collected: reason for urologic referral, a mental health diagnosis documented in their problem list (including anxiety, depression, PTSD) and mention of trauma history listed in their referral.

Results: Of the 47 patients, 82% were female, 26 had a medical diagnosis of PTSD, anxiety, or depression, 18 had significant trauma documented elsewhere in their medical chart (such as detailed mental health, trauma, abuse, or PTSD history). Only 9 patients had trauma history documented in urology referral.

Conclusion: Many patients with significant trauma are evaluated in our urology office for chronic pain without a trauma history ever being considered as part of the etiology of the pain. These patients subsequently undergo a urological evaluation and often leave the office without an explanation for their pain. We must consider trauma as a risk factor for patients with chronic pain in order to treat the patient in a more holistic fashion and assure they get the multidisciplinary care that they need.

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Comparing OnabotulinumtoxinA Injections and Sacral Neuromodulation for Treatment of Overactive Bladder

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Background: After failing more conservative treatments, patients with overactive bladder seek third-line therapies for their urinary symptoms. Two such treatments are intradetrusor onabotulinumtoxinA injections and sacral neuromodulation. We compared the patient profiles and success rates of these two therapies to determine whether successful treatment correlated with certain types of patients. We also identified patients who received both types of treatment to assess for factors that may have affected treatment outcomes.

Methods: We conducted a single-institution retrospective chart review of patients with overactive bladder who received either onabotulinumtoxinA injection, sacral neuromodulation, or both from 2005 to 2021. We compared age, sex, type of diagnosis, and success rates based on initial treatment modality. Success was defined as patient satisfaction with onabotulinumtoxinA injection and successful second-stage implantation for sacral neuromodulation. For patients who received both types of treatment, we investigated reasons for failing the first treatment and success rate of the second treatment.

Results: For initial therapy, 249 patients had onabotulinumtoxinA injections and 202 patients had sacral neuromodulation. Patients who received onabotulinumtoxinA injections were more likely to be older (70.2 vs. 67.1 years, $p = 0.02$) and female (74% vs. 70%, $p = 0.02$) than those who received sacral neuromodulation as initial therapy. Urge incontinence was the most common diagnosis (56.8%). There was no significant difference between the proportions of urge incontinence diagnosis in the onabotulinumtoxinA and sacral neuromodulation groups. The overall success rate for both treatments was 78.9%. There was no significant difference between the success rates of the two groups. Finally, there were 14 patients who received both therapies. Four patients received onabotulinumtoxinA first, and 10 patients received sacral neuromodulation first. Reasons for crossover included limited effectiveness, short-lived effects of onabotulinumtoxinA, and side effects of lower extremity muscle twitching with sacral neuromodulation.

Conclusions: Older female patients were more likely to have onabotulinumtoxinA as initial treatment. Success rates for onabotulinumtoxinA and sacral neuromodulation were similar, and there was no difference in patient diagnosis. The majority of patients who tried both treatments had success with the second treatment modality, which reflects the need for an individualized approach to treatment of overactive bladder.

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Trends in Urinary Retention Requiring Catheterization Following OnabotulinumtoxinA Treatment for Non-Neurogenic Overactive Bladder

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Background: Intradetrusor onabotulinumtoxinA injections are an effective treatment for overactive bladder (OAB) and urinary incontinence. Clinical trial data have demonstrated that 6% of patients with non-neurogenic OAB develop postoperative retention. We sought to investigate risk factors and patterns of catheterization in non-neurogenic patients at our institution.

Methods: We performed a single-institution retrospective chart review of patients who received onabotulinumtoxinA injections for non-neurogenic OAB between 2005 to 2021 by two fellowship trained urologists. We determined the rate of post-operative urinary retention requiring catheterization. Determination for catheterization was made by the discretion of the provider and not by a post-void residual (PVR) threshold. We also analyzed the demographic, medical history, and treatment data to determine predictive factors and trends in catheterization.

Results: Of 168 patients who received intradetrusor onabotulinumtoxinA injections, 16 required postoperative catheterization (9.5%). Patients with a history of a midurethral, pubovaginal, retropubic, or transobturator sling were significantly more likely to require postoperative catheterization (43.8% vs. 9.6%, $p = 0.00128$). Gender, history of urinary tract infection, and history of fecal incontinence, constipation, or irritable bowel syndrome were not significant predictors. For those patients with retention, 10 patients required catheterization for < 16 weeks, 4 patients for 17-36 weeks, and 3 patients for > 36 weeks (up to 75 weeks). Eight patients required a catheter at treatment 1, 4 patients at treatment 2, 1 patient at treatment 3, 2 patients at treatment 4, and 1 patient at treatment 5. Finally, of twelve patients where follow-up PVR was available, 2 had a PVR between 150 to 200 mL, 3 had a PVR between 200 to 300 mL, and 7 had a PVR between 300 to 400 mL.

Conclusions: Nearly 1 in 10 non-neurogenic patients receiving onabotulinumtoxinA treatment required postoperative catheterization, a higher rate than what is reported in the current literature. A significant number of patients who had previous sling surgery required catheterization. While the majority of catheterization length was less than four months, some patients experienced prolonged catheterization alongside continued treatment. Further investigation is required to better understand risk factors for catheterization in non-neurogenic patients receiving onabotulinumtoxinA treatment for OAB.

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Residency Applicant Demographics and Their Association with Rank-List Status: A Seven-Year Analysis of a Single Institution's Diversity, Equity, and Inclusion Initiatives in Recruitment

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Background: There is widespread consensus that the urologic community must become more representative of the national patient population. That is, as urology—and medicine in general—has historically been a white-male dominated field, recent efforts have focused on transitioning formal medical education into a more inclusive and diverse field, with the objective of further diversifying healthcare. Together, these efforts are formally termed Diversity, Equity, and Inclusion (DEI) initiatives. This study seeks to evaluate recruitment and applicant ranking trends within our single institution's urology residency program over the past seven application cycles to determine the success of our recruitment efforts in increasing DEI within our program.

Methods: Applications to our urology residency program over the past seven application cycles (2016-2022) were collected from the Electronic Residency Application Service (ERAS), and demographic characteristics including self-reported sex and race/ethnicity were recorded in a REDCap database. Odds ratios (OR) for applicant ranking (binary yes vs. no) were calculated using logistic regression and were adjusted for sex, race/ethnicity, and year of application. All analyses were conducted with Stata version 17.0 (Stata Corp., College Station, TX, USA).

Results: In total, our single institution reviewed 1,965 applications over the past seven application cycles. Of these applicants, 60% where male, 24% were female, and 16% did not report their sex. The greatest fraction of applicants self-identified as White (46%), while Asian (23%), Hispanic (7%), Black (5%) and Other/Undisclosed (17%) made up smaller fractions. American Indian applicants made up the least represented minority group at 0.3% (Table 1). Female applicants had significantly higher odds of being ranked compared to male applicants (OR 2.61, $p < 0.001$). In contrast, race/ethnicity and year of application were not significantly associated with odds of being ranked (Table 2).

Conclusions: The results of this study show female applicants having higher odds of being ranked at our institution compared with their male counterparts. We attribute these findings to our intentional commitment to DEI initiatives in residency recruitment. However, race/ethnicity was not significantly associated with odds of being ranked, suggesting that our efforts towards increasing racial and ethnic diversity within our program have not yet resulted in a statistically significant change in our ranking practices. Therefore, while some progress has been made toward our DEI goals, further efforts should be focused on identifying interview and ranking practices that are working against our achievement of racial and ethnic DEI within our academic urology residency program.

Table 1. Demographics and Baseline Characteristics of Urology Residency Program Applicants between 2016-2022

Demographic Variable	Applicant Number
Total Applicants (n)	1965
Sex	
Male, n, (%)	1175 (60)
Female, n, (%)	476 (24)
Undisclosed, n, (%)	314 (16)
Race/Ethnicity	
White, n, (%)	913 (46)
Black, n, (%)	108 (5)
Hispanic, n, (%)	145 (7)
Asian, n, (%)	460 (23)
American Indian, n, (%)	6 (0.3)
Other/Undisclosed, n, (%)	333 (17)
Ranked Applicants (n)	219
Sex	
Male, n, (%)	117 (53)
Female, n, (%)	66 (30)
Undisclosed, n, (%)	36 (17)
Race/Ethnicity	
White, n, (%)	85 (39)
Black, n, (%)	6 (3)
Hispanic, n, (%)	11 (5)
Asian, n, (%)	44 (20)
American Indian, n, (%)	0 (0)
Other/Undisclosed, n, (%)	73 (33)

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Evaluating Video Quality, Understandability, and Actionability of YouTube Content for Gender Affirming Surgery: Metoidioplasty

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Background: With the rise of social media platforms, consumer-style web-based health information has become more accessible to patients. The objective of this study was to analyze the quality, understandability, and actionability of metoidioplasty content on social-media platform YouTube.

Methods: A YouTube search for "Metoidioplasty" was conducted, and the first 50 relevant video results were analyzed. Videos greater than 30 minutes in length, non-English speaking, or exclusively showing a surgical procedure were excluded. Each video was characterized by speaker and presenter demographics, channel/video statistics, and clickbait. Completeness was calculated based on what percentage of the categories of anatomy, treatment options, outcomes, benefits, and risks were discussed. A complete video discussed all five topics. Calculated scores for validated DISCERN and PEMAT metrics were the primary outcome variables and were used to quantify the quality, actionability, and understandability. Cutoffs of DISCERN ≥ 3 and PEMAT 75% were used to differentiate between "poor" versus "good/sufficient." Multivariate and univariate logistic regressions were performed to assess associations and impact of variables on primary outcome variables (alpha < 0.05).

Results: Of the videos analyzed, 29% (n=13) were good quality, 49% (n = 22) had good understandability, 13% (6) had good actionability. Patients/consumers were the most common content publishers (n = 35, 78%) and speaker/narrator (n = 35, 78%). Twenty percent (n=8) were complete. Of all the video characteristics analyzed, there was a statistically significant association between completeness and good actionability (OR, 0.64; 95%CI, .012, 6.94; p = 0.05).

Conclusion: Informational videos available to transgender patients interested in metoidioplasty on YouTube have overall poor quality, actionability, and understandability. In the videos that were complete, content creators were less likely to suggest actionable steps viewers can take to learn more about metoidioplasty. The information that is available to patients on social media influences the patients' ability to make informed decisions on options for gender affirmation. As such, it is essential for physicians to be aware of the quality of content and source of their patient's information. At this time, it is unclear whether the overall lack of high quality videos and a lack of videos published by accredited physicians and hospitals are attributed to a lack of created content or to preferential display of patient-centered content curated by YouTube's internal algorithm.

Table 2. Odds of applicant ranking by sex, race/ethnicity, and year of application.

Demographic Variable	Odds Ratio (95% CI)	p-value
Sex		
Male	1 (ref)	
Female	2.61 (1.80, 3.79)	<.001
Race/Ethnicity		
White	1 (ref)	
Black	0.49 (0.19, 1.26)	.14
Hispanic	0.68 (0.30,1.56)	.37
Asian	0.84 (0.55, 1.29)	.42
Other/Undisclosed	0.64 (0.19, 2.14)	.47
Year of Application	1.02 (0.92, 1.13)	.69

CI = Confidence Interval

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The Artificial Urinary Sphincter and the Octogenarian

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Background: The artificial urinary sphincter (AUS) is the gold standard in surgical management of stress incontinence. While AUS can confer significant long-term quality of life improvements, the duration of AUS efficacy and complication rate can vary significantly between patients and is dependent, at least partly, on patient-related risk factors. Previous studies have identified several factors which would predispose to complications, including certain medical comorbidities as well as exposures such as pelvic radiation. However, little is known about how these factors specifically impact older patients. In this study, we sought to assess the duration of AUS efficacy and complications in AUSs implanted in patients over the age of 80.

Methods: A retrospective review of all AUS placements placed at a single institution between January 1st, 2011 and January 1st, 2021 in patients over the age of 21 was performed. The lifespan for each AUS was measured as the number of days between date of implantation and date of revision, explantation, or the study end date. We compared the lifespans of 1st, 2nd, and 3rd AUS in patients above and below 80 years old. We also evaluated the prevalence of medical comorbidities in these two age groups. Data was analyzed using t-tests and logistic regression.

Results: 97 patients met study criteria and were included in the analysis. Across all implanted AUSs, the mean AUS lifespan was 1015 days in patients over 80 versus 1821 days in patients under 80 ($p = 0.02$). Patients who were over the age of 80 at time of implantation were more likely to have an AUS with a lifespan of under one year when compared to patients below the age of 80 at time of implantation ($p = 0.001$). On multivariate analysis, age above 80 ($p = 0.01$), history of radiation ($p = 0.02$), and lower BMI ($p = 0.0003$) were associated with an AUS lifespan of under one year, whereas diabetes ($p = 0.29$), hypertension ($p = 0.34$), smoking status ($p = 0.76$), and coronary artery disease/peripheral vascular disease ($p = 0.60$) were not (Table 1).

Conclusions: Short AUS lifespans of <1 year were statistically more likely to occur in men over the age of 80, compared to those under 80. On multivariate analysis, history of radiation and decreased BMI were also found to be associated with an AUS lifespan of under one year. There was a trend towards shorter mean lifespan of AUS for men over the age of 80 whether initial or redo AUS, though this did not reach statistical significance. Further study is needed with larger sample size to further elucidate this relationship. Our findings emphasize the importance of consideration of age when deciding on stress incontinence management.

Table 1. Results of Logistic Regression.

Univariate			
	> 80 years old	< 80 years old	p-value
AUS Lifespan < 1 year	10 (40%)	20 (13.6%)	0.001
Multivariate			
	OR (95% CI)		p-value
Age > 80 years old	1.26 (0.28, 2.23)		0.01
BMI	-0.06 (-0.09, -0.02)		0.0003
Diabetes	-0.55 (-1.57, 0.46)		0.29
Hypertension	-0.45 (-1.40, 0.49)		0.35
Smoking Status	0.18 (-0.98, 1.35)		0.76
CAD/PVD	0.23 (-0.63, 1.09)		0.60
Prior Radiation	1.13 (0.16, 2.11)		0.02

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Self-administered Nitrous Oxide (SANO) During Transrectal Prostate Biopsy to Reduce Patient Anxiety and Pain: A Double-Blinded Prospective Randomized Controlled Trial

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Background: More commonly used outside of the US, nitrous oxide is gaining traction in the ambulatory setting as a method to decrease peri-procedural anxiety and pain. When used as a single agent at concentrations <50%, nitrous oxide is classified as minimal sedation, and does not require the presence of anesthesia personnel, NPO status, an escort home. The effects of nitrous have near-immediate onset and rapid offset (3-5 minutes), thus providing a promising option for many urologic outpatient procedures including outpatient prostate biopsies, which in this era of active surveillance for prostate cancer are significantly increasing in frequency. Although lidocaine block provides sufficient analgesia, it does not directly address the anxiety provoked by prostate biopsies. Our ongoing study seeks to determine whether self-administered nitrous oxide (SANO) decreases anxiety and pain perception in patients undergoing transrectal prostate biopsy.

Methods: This is an interim analysis of an ongoing single-center prospective randomized double-blind controlled trial comparing SANO versus oxygen placebo in patients undergoing transrectal prostate needle biopsy. Baseline and post-procedure pain levels were evaluated using the Baseline Pain Index (BPI) and the Visual Analog Scale for Pain (VAS-P). Anxiety levels were measured using the Visual Analog Scale for Anxiety (VAS-A), the State-Trait Anxiety Inventory (STAI), and the Situational Pain Catastrophizing Scale (SPCS). Operator ease was measured by surveying the blinded Urologist on difficulty of transrectal probe insertion, maintenance of positioning, and perceived tolerance of the procedure by the patient. Vital signs were recorded before, during, and after the procedure, and patients were screened for peri-procedural complications that may be related to SANO.

Results: An interim analysis was conducted on the initial 38 patients (19 SANO, 19 oxygen placebo) enrolled in our study. Decrease in anxiety, measured by VAS-A, was significantly higher in the SANO group vs. oxygen placebo (1.3 vs. 0.63; $p = 0.04$). Pain perception, as measured by VAS-P, was also lower in the SANO group, though this did not reach statistical significance (0.79 vs. 1.68; $p = 0.1$). With regards to operator ease, operating Urologists reported transrectal probe insertion was better than expected in the SANO group (53% vs. 21%), with better patient maintenance of position (53% vs. 16%), and improved patient tolerance of the procedure as perceived by the Urologist (53% vs. 26%). Procedure time was slightly longer in the SANO group, though this did not reach statistical significance (11.1 vs. 10.2 min).

Conclusions: In our interim analysis, patients receiving SANO during transrectal prostate biopsy had significantly lower anxiety and demonstrated a trend towards lower pain perception. Blinded Urologists scored superior operator parameters in the SANO group, with minimal increase in procedural time. These encouraging results support the incorporation of SANO to improve patient experience of care during prostate biopsies and may be a particularly promising option in those patients with a history of anxiety or apprehension surrounding invasive procedures.

Does a 5-item Frailty Index Predict Surgical Outcomes of Endoscopic Surgical Management for Benign Prostatic Obstruction?

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Background: The 5-item frailty index (5i-FI), an index of reduced physiological reserve, predicts surgical outcomes of urological and non-urological procedures. We sought to assess whether the 5i-FI is a predictor of surgical complications of endoscopic surgery for benign prostatic obstruction (BPO) and examine whether the type of endoscopic surgery predicts complications.

Methods: The National Surgical Quality Improvement Program was queried for patients who underwent transurethral resection of the prostate (TURP), photo-vaporization of the prostate (PVP), and laser enucleation of the prostate (LEP) between 2009-2019. The 5i-FI was calculated by giving a point for each of 1) chronic obstructive pulmonary disease or pneumonia, 2) congestive heart failure, 3) dependent functional status, 4) hypertension, and 5) diabetes. The endpoints were any complication, major complications (Clavien-Dindo 3), length of stay (LOS) ≥2 days, and readmission within 30 days of surgery. A multivariable logistic regression was run to assess the predictors of each outcome adjusting for the surgical approach, 5i-FI, and patient demographics. Then, we conducted a multinomial logistic regression to examine which baseline patient characteristics predicted the surgical approach. Significant predictors were included in the inverse probability treatment weighting (IPTW) propensity score to evaluate the independent effect of the surgical approach on complications.

Results: The cohort included 38,399 (62.6%) TURP, 19,121 (31.2%) PVP and 3,797 (6.2%) LEP. Baseline characteristics and outcomes across BPO treatments are reported in Table 1. We found that 5i-FI ≥ 2 was associated with 50%, 63%, 31%, and 65% increased risk for any complication, major complication, LOS ≥ 2, and readmission, respectively (Table 1). In comparison to TURP, PVP and LEP had a safer surgical profile (Table 2). Despite decreased odds of surgical complications with LEP, frail patients were less likely to receive LEP (OR 0.83; 95%CI [0.75-0.92]; p < 0.01) (Table 3). We also found that age, race, obesity, 5i-FI, history of bleeding diathesis (including anticoagulation within 30 days of surgery), among others, predicted the type of BPO surgery received (Table 3). After IPTW adjustment, LEP had the lowest weighted risk for any complication (6.29; 95%CI 5.48-7.20), major complication (2.30; 95%CI 1.83-2.89), and readmission (3.80; 95%CI 3.18-4.53) (Table 4). PVP had the lowest risk of LOS ≥ 2 (5.98; 95%CI 5.63-6.34).

Conclusion: The 5i-FI is an independent predictor of surgical complications after endoscopic BPO surgery, and LEP had the lowest risk of complications after weighting for baseline patient characteristics. Thus, preoperative frailty assessment could improve risk stratification prior to BPO surgery.

Table 1: Comparison of baseline characteristics and surgical outcomes across BPO treatment modalities (TURP, PVP, LEP)

Variables	Treatment			p-values
	TURP (38,399)	PVP (19,121)	LEP (3,797)	
Baseline Characteristics				
5i-FI score				
Score 0	12,894 (33.8%)	6,330 (33.1%)	1,454 (38.3%)	< 0.001
Score 1	16,708 (43.5%)	8,492 (44.4%)	1,628 (42.9%)	
Score ≥ 2	8,707 (22.7%)	4,299 (22.5%)	715 (18.8%)	
Age				
< 60	4,081 (10.6%)	1,981 (10.4%)	445 (11.7%)	< 0.001
60 – 69	12,558 (32.7%)	6,073 (31.8%)	1,432 (37.1%)	
70 – 79	14,361 (37.4%)	7,160 (37.4%)	1,403 (36.9%)	
≥ 80	7,398 (19.3%)	3,907 (20.4%)	517 (13.6%)	
Race				
White	22,608 (58.9%)	13,011 (68.1%)	3,008 (79.2%)	< 0.001
Black	2,309 (6%)	943 (4.9%)	185 (4.9%)	
Hispanic	2,354 (6.1%)	811 (4.2%)	125 (3.3%)	
Other	11,128 (29%)	4,356 (22.8%)	479 (12.6%)	
ASA classification				
1-2	18,158 (47.4%)	9,004 (47.2%)	2,037 (53.7%)	< 0.001
≥ 3	20,132 (52.6%)	10,088 (52.8%)	1,759 (46.3%)	
Obesity				
No	26,097 (68%)	12,931 (67.6%)	2,462 (64.8%)	< 0.001
Yes	12,302 (32%)	6,190 (32.4%)	1,335 (35.2%)	
Bleeding Diathesis				
No	37,335 (97.2%)	18,301 (95.7%)	3,684 (97%)	< 0.001
Yes	1,064 (2.8%)	820 (4.3%)	114 (3%)	
Surgical Outcomes				
Total operative time				
< 60 min	24,392 (63.5%)	12,470 (65.2%)	965 (25.4%)	< 0.001
60 – 120min	12,198 (31.8%)	5,868 (30.7%)	1,749 (46.1%)	
> 120 min	1,809 (4.7%)	783 (4.1%)	1,083 (28.5%)	
Length of Stay				
0 day	7,478 (19.5%)	13,274 (69.4%)	1,105 (29.1%)	< 0.001
1 day	20,938 (54.3%)	4,642 (24.3%)	2,116 (55.7%)	
> 2 days	9,983 (26%)	1,205 (6.3%)	576 (15.2%)	
Clavien-Dindo				
Grade 1-2	2,060 (5.4%)	956 (5%)	153 (4%)	< 0.001
Grade 3	639 (1.7%)	205 (1.1%)	53 (1.4%)	
Grade 4	519 (1.3%)	317 (1.7%)	34 (0.9%)	
Grade 5	104 (0.3%)	45 (0.2%)	4 (0.1%)	
Readmission	1,877 (4.9%)	906 (4.7%)	148 (3.9%)	0.023

Table 2: Predictors of complications (any complication, major complication, extended LOS, and readmission) adjusting for baseline characteristics, frailty index, and endoscopic surgical modality (TURP, PVP, and LEP)

Predictors	Outcomes							
	Any Complication		Major Complication		LOS ≥ 2 days		Readmission	
	OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value
Treatment								
TURP	Ref	-	Ref	-	Ref	-	Ref	-
PVP	0.92 (0.86-0.98)	0.01	0.90 (0.81-0.99)	0.05	0.18 (0.17-0.19)	< 0.01	0.98 (0.91-1.07)	0.69
LEP	0.66 (0.57-0.75)	< 0.01	0.65 (0.52-0.82)	< 0.01	0.50 (0.45-0.55)	< 0.01	0.81 (0.68-0.97)	0.02
FI Score								
0	Ref	-	Ref	-	Ref	-	Ref	-
1	1.15 (1.07-1.24)	< 0.01	1.16 (1.03-1.31)	0.02	1.03 (0.97-1.08)	0.38	1.20 (1.09-1.33)	< 0.01
≥2	1.50 (1.37-1.63)	< 0.01	1.63 (1.42-1.85)	<0.01	1.31 (1.23-1.39)	< 0.01	1.65 (1.48-1.85)	< 0.01
Race								
White	Ref	-	Ref	-	Ref	-	Ref	-
Black	1.15 (1.02-1.30)	0.03	1.16 (0.96-1.40)	0.13	1.14 (1.04-1.25)	< 0.01	1.16 (0.99-1.36)	0.07
Hispanic	1.05 (0.93-1.20)	0.43	0.87 (0.70-1.09)	0.24	1.01 (0.92-1.12)	0.81	0.97 (0.81-1.17)	0.78
Others	1.14 (1.06-1.22)	< 0.01	1.13 (1.01-1.25)	0.03	2.48 (2.36-2.60)	< 0.01	1.27 (1.16-1.38)	< 0.01
Age								
< 60	Ref	-	Ref	-	Ref	-	Ref	-
60-69	0.98 (0.88-1.10)	0.76	0.96 (0.80-1.15)	0.66	1.14 (1.05-1.24)	< 0.01	0.83 (0.72-0.97)	0.02
70-79	1.10 (0.98-1.22)	0.11	1.17 (0.98-1.41)	0.08	1.39 (1.28-1.51)	< 0.01	1.02 (0.88-1.17)	0.84
≥80	1.50 (1.33-1.69)	< 0.01	1.47 (1.21-1.78)	<0.01	1.92 (1.76-2.10)	< 0.01	1.40 (1.20-1.63)	< 0.01
Obesity								
No	Ref	-	Ref	-	Ref	-	Ref	-
Yes	0.98 (0.92-1.05)	0.61	0.98 (0.89-1.09)	0.73	0.91 (0.86-0.95)	< 0.01	0.93 (0.86-1.02)	0.11
ASA Score								
ASA ≤ 2	Ref	-	Ref	-	Ref	-	Ref	-
ASA ≥ 3	1.28 (1.20-1.37)	< 0.01	1.41 (1.27-1.57)	< 0.01	1.25 (1.19-1.31)	< 0.01	1.70 (1.55-1.86)	< 0.01
Operative time								
< 60 min	Ref	-	Ref	-	Ref	-	Ref	-
60-120 min m	1.22 (1.15-1.30)	< 0.01	1.10 (0.99-1.22)	0.07	1.43 (1.36-1.50)	< 0.01	1.01 (0.93-1.10)	0.73
> 120 min	1.73 (1.54-1.94)	< 0.01	1.74 (1.46-2.08)	< 0.01	2.35 (2.15-2.56)	< 0.01	1.23 (1.04-1.44)	0.01
Bleeding Diathesis								
No	Ref	-	Ref	-	Ref	-	Ref	-
Yes	1.87 (1.65-2.11)	< 0.01	1.94 (1.61-2.32)	< 0.01	1.59 (1.42-1.78)	< 0.01	1.98 (1.70-2.30)	< 0.01
Year of operation	1.02 (1.01-1.03)	< 0.01	1.04 (1.02-1.06)	< 0.01	0.92 (0.90-0.92)	< 0.01	1.07 (1.06-1.09)	< 0.01

Table 3: Multinomial logistic regression to assess the predictors of receipt of different BPO surgery modalities (TURP vs. PVP vs. LEP) in function of baseline patient characteristics

Baseline Characteristics	BPO Treatment Modalities				
	TURP	PVP		LEP	
		RRR (95% CI)	p-value	RRR (95% CI)	p-value
Frailty Index					
1	Reference	1.02 (0.98-1.07)	0.29	0.92 (0.85-0.99)	0.04
> 2	Reference	1.00 (0.95-1.06)	0.86	0.83 (0.75-0.92)	< 0.01
Race/Ethnicity					
Black	Reference	0.73 (0.67-0.79)	< 0.01	0.59 (0.50-0.69)	< 0.01
Hispanic	Reference	0.60 (0.56-0.66)	< 0.01	0.38 (0.32-0.46)	< 0.01
Others	Reference	0.70 (0.68-0.73)	<0.01	0.31 (0.28-0.34)	< 0.01
Age					
60-69	Reference	0.98 (0.92-1.05)	0.60	1.07 (0.96-1.20)	0.22
70-79	Reference	1.01 (0.95-1.08)	0.69	0.96 (0.86-1.08)	0.51
≥ 80	Reference	1.06 (0.99-1.34)	0.12	0.74 (0.65-0.86)	< 0.01
Obesity					
Yes	Reference	1.02 (0.98-1.06)	0.29	1.12 (1.04-1.39)	< 0.01
ASA Score					
ASA > 3	Reference	0.96 (0.92-0.99)	0.03	0.78 (0.72-0.84)	< 0.01
Bleeding Diathesis					
Yes	Reference	1.51 (1.37-1.66)	< 0.01	1.12 (1.04-1.21)	< 0.01
Year of surgery					
	Reference	0.94 (0.94-0.95)	< 0.01	1.10 (1.09-1.12)	< 0.01

Table 4: Unadjusted and weighted proportions for any complications, major complications, extended LOS, and readmission with endoscopic BPO surgeries (TURP, PVP, and LEP)

Surgical Outcomes	TURP		PVP		LEP	
	Unadjusted	Weighted	Unadjusted	Weighted	Unadjusted	Weighted
Any complications	8.65 (8.37-8.94)	8.63 (8.34-8.91)	8.0 (7.59-8.36)	8.0 (7.58-8.40)	6.28 (5.52-7.14)	6.29 (5.48-7.20)
Major complications	3.28 (3.11-3.47)	3.28 (3.11-3.47)	2.97 (2.73-3.22)	2.93 (2.69-3.20)	2.45 (1.98-3.02)	2.30 (1.83-2.89)
LOS > 2	26.0 (25.6-26.4)	25.6 (25.2-26.0)	6.30 (5.97-6.66)	5.98 (5.63-6.34)	12.9 (11.8-14..0)	12.4 (11.3-13.7)
Readmission	4.89 (4.68-5.11)	4.83 (4.62-5.04)	4.74 (4.44-5.05)	4.52 (4.22-4.84)	3.86 (3.27-4.56)	3.80 (3.18-4.53)

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Same-day Discharge after HoLEP: A Safety and Feasibility Study to Address Hospital Capacity Stressors in the COVID 19 Era

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Background: Holmium Laser Enucleation of the Prostate (HoLEP) is an increasingly popular contemporary surgical procedure to address lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). The typical post-operative pathway involves catheterization and weaning of continuous bladder irrigation overnight for a void-trial and hospital discharge on post-operative day (POD) one. Inpatient capacity constraints on hospitals due to COVID-19 surges have forced the delay or cancellation of many in-patient elective operations, thus resulting in the delay of care and frustration for patients with bothersome LUTS or retention. There has been an increased desire in the urologic community to investigate means to continue surgical care under these intermittent constraints. As such, this study seeks to investigate the safety and feasibility of same-day discharges after HoLEP, in hopes of addressing patient demand for the operation, while not contributing to further inpatient hospital burden.

Methods: Patients at a single tertiary care center who were awaiting a delayed HoLEP procedure were selected as meeting pre-defined study criteria and were offered a HoLEP with planned same-day discharge. Inclusion criteria were prostate size less than 150 grams, American Society of Anesthesiologists (ASA) Physical Status Score less than or equal to 3, no peri-operative anticoagulation/anti-platelet medication other than aspirin, no major medical comorbidity, and first-start surgical scheduling. These patients underwent attempted out-patient HoLEP, and patient demographics, medical history, procedure details and outcomes were analyzed. Patients not meeting the above criteria were delayed or underwent HoLEP with POD-1 discharge when hospital capacity allowed.

Results: From 11/08/2022 - 2/16/22, 13 patients met criteria to undergo a scheduled out-patient HoLEP. All surgeries were performed by a single surgeon (JAM) with resident assistance. The median patient age was 71.6 years and median prostate size was 96 grams. Of these 13 patients, 12 (92%) were safely and successfully discharged the afternoon of their operation, while 9 (75%) were offered and successfully completed a void trial prior to POD-0 discharge. The median resection time was 62 minutes and median resection weight was 72 grams. The median post-void residual change (PVR) change was -197cc, and median post-operative PVR was 5cc. Zero patients experienced intra-operative or peri-operative complications.

Conclusions: In the current COVID-19 era of volatility in hospital capacity constraints, it is necessary to minimize the capacity burden of elective urologic procedures. While the standard HoLEP post-operative pathway includes an overnight hospital admission, these data suggest that carefully selected patients can safely and feasibly undergo a void trial and discharge on the day of surgery, thus allowing for the timely care and treatment of this select group of patients, while not impacting in-patient hospital capacity.

Table 1. Characteristics of patients undergoing attempted same-day discharge after HoLEP.

Patient Characteristic	Value
Total (n)	13
Age (yrs)	
Median	71.6
Mean (SD)	72.5 (6.4)
Range	59 - 80
Body Mass Index (Kg/m^2)	
Median	27.8
Mean (SD)	27.9 (3.1)
Smoking History (n)	
Active	1
Former	4
Never	8
ASA Status	
Median	2
Range	2 - 3
Prostate Size, (g)	
Median	96
Mean (SD)	96.3 (17.5)
Range	60 - 125
Pre-operative Post-void Residual, (cc)	
Median	200
Mean (SD)	207.2 (180.3)
Range	12 - 525
PSA (ng/mL)	
Median	6.8
Mean (SD)	6.4 (3.8)
Range	1.1 - 14.6
Pre-operative Alpha Blocker (n)	11 (92%)
Pre-Operative 5-a Reductase Inhibitor (n)	3 (31%)
Pre-operative Anticoagulation/Antiplatelet (n)	1 (8%)
Pre-operative Retention Requiring Catheter (n)	6 (46%)

Table 2. Operative results and outcome measures for patients undergoing same-day discharge after HoLEP.

Operative Variable	Value
Resection Time (min)	
Median	62
Mean (SD)	62.5 (13.2)
Range	50 - 85
Morcellation Time (min)	
Median	6
Mean (SD)	6.4 (3.4)
Range	3 - 14
Resection Weight (g)	
Median	72
Mean (SD)	62.5 (26.4)
Range	29 - 96
Median Blood Loss (cc)	
Median	100
Mean (SD)	86.5 (24.2)
Range	25 - 100
Length of Hospitalization (hr)	
Median	7
Mean (SD)	7.6 (4.6)
Range	3 - 22
Length of Catheterization (hr)	
Median	8
Mean (SD)	25.8 (39.1)
Range	3 - 144
PVR Change (cc)	
Median	(-) 197.5
Mean (SD)	(-) 188.3 (156.3)
Range	(-) 465 - (-) 8
Hct Change (%)	
Median	(-) 3
Mean (SD)	(-) 2.8 (1.7)
Range	(-) 5.1 - 0
Successful POD-0 Discharge (n)	12 (92.3%)
Successful POD-0 Void Trial Prior to POD-0 Discharge (n)	9 (75.0%)

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Lack of Diversification in BPH Procedures Among Urologists in New England

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Background: There are diverse procedures available for surgical management of benign prostatic hypertrophy (BPH), with significant overlap in clinical indications but scarce comparative data. It is unclear whether providers focus or diversify their surgical BPH practices, and how practice patterns trend over time with the advent of new technologies. This information can guide patients seeking BPH care, and help urologists anticipate practice trends as new technologies emerge. In this study, we examined practice patterns in New England (NE) to assess whether urologists favor certain BPH procedures and to determine temporal trends in their surgical practice.

Methods: A retrospective analysis of BPH procedures for urologists in NE states from 2014-2019 was conducted using publicly available Medicare data. The number of cases performed per provider was collected, including transurethral resection of prostate (TURP) (CPT 52601), Greenlight laser vaporization (52648), Urolift (52441), Rezum (53854), and Holmium laser enucleation (HoLEP) (52649). Data were analyzed for 2019 regarding practice patterns by surgeon and state. Multivariate time series analysis was used to evaluate deterministic trends (i.e., average increases or decreases) and stochastic associations (i.e., correlations across procedures) over time, to document the composition of urology procedures being used. Changes in the rates of procedures used and providers performing procedures were estimated. Note that low rates of procedures (< 11) were censored for privacy reasons.

Results: 93 Medicare providers performing BPH procedures in 2019. 90% performed one type, while 10% performed two, and 0% performed more than two different types of procedures (Table 1). There was variation in preference for certain procedures by state (Table 1). Longitudinal associations retrieved from 2014-2019 were highly significant and negative (in all cases, $p < 0.01$; in most cases, $p < 0.0001$), indicating providers did not increase practice diversity over time. Provider and practice trends displayed a concurrent increase in the use of Rezum and HoLEP and a decrease in TURP and Greenlight, suggesting a shift in procedure type (Figure 1). Rezum utilization remained low and nearly constant.

Conclusions: New England Urologists tend to prefer one type of procedure for BPH in Medicare patients, chiefly TURP or Greenlight. Longitudinal analysis suggests that the emergence of newer procedures does not increase the diversity of practice for providers over time. Further study is needed on whether providers should focus on a specific procedure or diversify, what volume of procedures is needed to maintain competence, and how to ensure patients are appropriately counseled given the diversity of options for surgical management of BPH.

Figure 1a) Temporal trends in procedure and provider utilization from 2014-2019

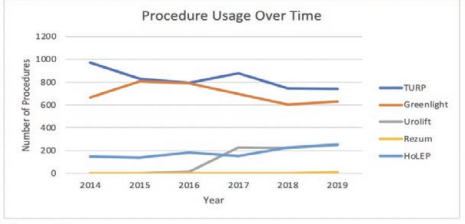
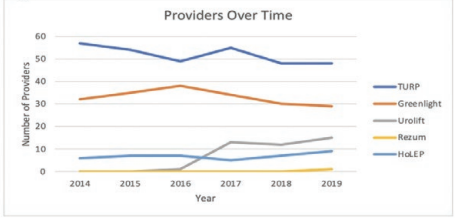


Figure 1b.



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Antibiotic Prophylaxis Practice Patterns in Patients Undergoing Transurethral Resection or Vaporization of the Prostate with Preoperative Catheterization

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Background: Patients undergoing transurethral resection of prostate (TURP) or Greenlight vaporization of the prostate (GLPVP) will often have an indwelling catheter or be on clean intermittent catheterization (CIC) prior to surgery. Urinary colonization is common in these patients and the optimal utilization of antibiotic prophylaxis prior to undergoing one of these procedures is unclear. We investigated antibiotic prophylaxis practice patterns at our institution for patients undergoing these procedures as well as infectious complications.

Methods: A single-institution, retrospective review was performed to identify patients who underwent a TURP or GLPVP from 2020-2021. Presence of a preoperative indwelling catheter or CIC regimen, preoperative urine cultures and antibiotics prescribed, and 30-day re-presentation secondary to a urinary tract infection (UTI) were recorded. Statistical analysis was performed using the chi-squared test.

Results: In total, 128 patients who underwent a TURP or GLPVP were identified. 50 patients (39.1%) had an indwelling catheter or were performing CIC preoperatively. Patients with an indwelling catheter or on CIC were more likely to have a positive preoperative urine culture (58.0% vs. 15.4%; $p < 0.01$). They were also more likely to be treated with antibiotics preoperatively (68.0% vs. 19.2; $p < 0.01$) even with a negative preoperative urine culture (28.6% vs. 4.6%; $p > 0.01$). Patients with positive urine cultures were likely to be treated with antibiotics preoperatively (96.6% for patients with an indwelling catheter or on CIC vs. 100% without; $p = 0.51$). Postoperative antibiotic prescribing rates were similar between the two groups (28.0% vs. 26.8%; $p = 0.89$). 2 patients (4%) with an indwelling catheter or on CIC were readmitted within 30 days with a UTI versus no readmissions for patients without an indwelling catheter or on CIC ($p = 0.08$). There was no difference in 30-day readmission rates with a UTI in patients with an indwelling catheter or on CIC who were placed on preoperative antibiotics versus those who were not (2.9% vs. 6.3%; $p = 0.58$).

Conclusions: Patients with an indwelling catheter or on CIC are more likely to be treated with antibiotics preoperatively prior to undergoing a TURP or GLPVP, even with a negative preoperative urine culture. The benefit of antibiotic prophylaxis in patients with an indwelling catheter or on CIC remains unclear. Infectious disease consultation generally suggests perioperative prophylaxis only in these patients, though our practice patterns demonstrate more aggressive use of preoperative antibiotics. This issue warrants further attention in prospective studies to determine the optimal balance between effective prophylaxis and good antibiotic stewardship.

1a) Number of Providers Performing N Types of Procedures in 2019

	1 type of procedure	2 types of procedures	3 types of procedures	4 types of procedures	5 types of procedures
Connecticut	11	1	0	0	0
Maine	11	0	0	0	0
Massachusetts	48	4	0	0	0
New Hampshire	7	3	0	0	0

1b) Types of Procedures Favored by Urologists by State

	Providers favoring TURP	Providers favoring Greenlight	Providers favoring Urolift	Providers favoring Rezum	Providers favoring Holep
Connecticut	8	2	2	0	0
Maine	2	5	1	0	3
Massachusetts	28	14	6	0	4
New Hampshire	3	5	2	0	0
Rhode Island	2	1	0	0	1
Vermont	2	1	1	0	0

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Lower Rates of Continued and De Novo BPH Medication Usage after the Prostatic Urethral Lift (PUL) Compared to TURP and PVP Demonstrated in US Healthcare Claims Analysis

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Background: The effect of minimally invasive and surgical BPH treatments on medication usage is largely unknown. This analysis assesses rates of preoperative, postoperative, and continued BPH medical therapy after Prostatic Urethral Lift (PUL), TURP, and photo-vaporization of the prostate (PVP) by analyzing US healthcare claims.

Methods: A representative sample of the commercial and Medicare claims from 2015-2020 included 40,267 patients who underwent outpatient PUL, TURP, and PVP. Duration and rate of BPH medication usage were calculated, including odds ratios to assess the likelihood of de novo and continued medication use following each surgical procedure of interest in comparison to PUL.

Results: For patients with records of BPH medical therapy who then underwent surgical treatment, a larger proportion stopped medication after PUL (66%) compared to TURP (60%) and PVP (58%). Compared to TURP and PVP, fewer PUL patients began de novo medication after their procedure (TURP 19%, PVP 20%, PUL 13%). The medication class used most commonly prior to surgery and continued postoperatively was alpha-blockers. Compared to PUL, odds ratios estimated 58% and 39% increased likelihood of continued medication usage following PVP and TURP, and odds ratios of 65% and 51% for de novo medication usage after PVP and TURP compared to PUL.

Conclusions: Despite the inaccuracies inherent to working with this large database, this analysis suggests that more patients continued to take BPH medication or began new BPH medications following treatment with TURP and PVP compared to PUL. More investigation is required to determine if these findings are due to over-performance of PUL or underperformance of PVP and TURP against expectations for improvement.

	PVP	TURP	PUL
Total patients that underwent procedure	11,158	22,021	7,088
- With medical records for BPH medication	3,162 (28.3%)	5,803 (26.4%)	1,497 (21.1%)
Prior Med Usage: n of prior usage (% of patients with med records)	2,533 (80.1%)	4730 (81.5%)	1,301 (86.9%)
	n (% prior med(s) users)	n (% prior med(s) users)	n (% prior med(s) users)
5-ARI	749 (29.6%)	1,306 (27.6%)	328 (25.2%)
α-blocker	2,230 (88.0%)	4,111 (86.9%)	1,115 (85.7%)
Combination	64 (2.5%)	100 (2.1%)	32 (2.5%)
Anti-cholinergic	389 (15.4%)	787 (16.6%)	221 (17.0%)
Beta-3-agonist	360 (14.2%)	572 (12.1%)	225 (19.6%)
PDE5-inhibitor	361 (14.3%)	653 (13.8%)	293 (22.5%)
- Stopped Upon Procedure: n of stopped usage (% of prior med users)	1,467 (57.9%)	2,860 (60.5%)	858 (65.9%)
Avg duration prior to procedure (first med record to procedure)	*68d*	*70d*	*127d*
- Continued After Surgery: n of continued usage (% of prior med users)	1,066 (42.1%)	1,870 (39.5%)	443 (34.1%)
Avg duration post-procedure (procedure to final med record)	*260d*	*200d*	*222d*
	n (% continued med(s) users)	n (% continued med(s) users)	n (% continued med(s) users)
5-ARI	309 (29.0%)	504 (27.0%)	99 (22.3%)
α-blocker	790 (74.1%)	1,414 (75.6%)	306 (69.1%)
Combination	17 (1.6%)	27 (1.4%)	10 (2.3%)
Anti-cholinergic	246 (23.1%)	491 (26.3%)	122 (27.5%)
Beta-3-agonist	267 (25.0%)	395 (21.1%)	159 (35.9%)
PDE5-inhibitor	206 (19.3%)	346 (18.5%)	129 (29.1%)
Odds Ratio for Continued Usage (vs. PUL)	1.58	1.39	--
De Novo Med Usage: n of de novo usage (% of patients with med records)	629 (19.9%)	1,073 (18.5%)	196 (13.1%)
Avg time from procedure to first med record	*123d*	*94d*	*150d*
Avg duration of de novo usage	*51d*	*36d*	*30d*
	n (% de novo med(s) users)	n (% de novo med(s) users)	n (% de novo med(s) users)
5-ARI	110 (17.5%)	204 (19.0%)	23 (11.7%)
α-blocker	302 (48.0%)	501 (46.7%)	76 (38.8%)
Combination	3 (0.5%)	4 (0.4%)	0 (0.0%)
Anti-cholinergic	297 (47.2%)	674 (62.8%)	136 (69.4%)
Beta-3-agonist	348 (55.3%)	485 (45.2%)	139 (70.9%)
PDE5-inhibitor	160 (25.4%)	253 (23.6%)	58 (29.6%)
Odds Ratio (vs. PUL)	1.89	1.63	--

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Hypertension Dampens Early Diuresis Pattern of Nocturnal Polyuria Syndrome

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Background: Nocturnal polyuria syndrome, nocturnal polyuria without an identifiable cause, has been demonstrated to be associated with a high rate of early nocturnal diuresis, hypothesized to be due to a blunting of the natural surge of antidiuretic hormone in early sleep. Conversely, hypertension is thought to cause nocturia via a rise in nocturnal natriuresis, rather than free-water clearance. The effect of hypertension on this early nocturnal diuresis pattern of the nocturnal polyuria syndrome has not been studied.

Methods: We performed a retrospective analysis of voiding diaries collected from adult male patients treated for lower urinary tract symptoms at a Veterans Affairs urology clinic. We included only the first diary entry with ≥2 nocturnal voids recorded for each patient with a contemporaneous blood pressure reading taken within 30 days of the date of the diary. We then compared the volume of the first nocturnal void to the average nocturnal voided volume of the remaining nocturnal voids, the late nocturnal average voided volume, in patients with or without a hypertensive blood pressure reading. A subgroup analysis of patients without obstructive sleep apnea, congestive heart failure, chronic kidney disease, diabetes insipidus, edema, or who were currently on diuretics, and who met two different definitions for nocturnal polyuria, nocturnal urine production ≥ 90 ml/hour and nocturnal polyuria index ≥ 0.33, was also performed.

Results: 241 diaries were included from 82 patients with non-hypertensive blood pressure readings and 159 patients with hypertensive blood pressure readings. The first nocturnal voided volume differed significantly from the late nocturnal average voided volume for the overall sample (200 mL [120-300 mL] vs. 183 mL [130-250 mL], p = 0.003) and for non-hypertensive patients (200 mL [148-300 mL] vs. 182 mL [130-250 mL], p < 0.001), but not for hypertensive patients (180 mL [100-300 mL] vs. 188 mL [128-258 mL], p = 0.430). When isolating for the subgroups of patients with nocturnal polyuria syndrome, non-hypertensive patients exhibited the characteristic pattern of early diuresis, but hypertensive patients did not record a difference between the first nocturnal voided volume and the late nocturnal average voided volume (see Table).

Conclusions: Hypertension appears to dampen the early diuresis rate pattern found in patients with nocturnal polyuria syndrome. This has broad potential implications for understanding how to manage nocturnal polyuria, as this suggests that a complex interplay exists between distinct pathophysiologic processes that may each contribute to the etiology of nocturia.

Table. Subgroup analysis of patients with nocturnal polyuria syndrome.

	NPS by **NUP ≥ 90 ml/h**	NPS by **NPi ≥ 0.33**
Hypertensive		
n	47	64
FNVV in ml, median (IQR)	250 (150-350)	183 (120-298)
LNAVV in ml, median (IQR)	240 (167-313)	170 (129-251)
p-value	0.184	0.319
Non-Hypertensive		
n	23	25
FNVV in ml, median (IQR)	275 (150-400)	200 (150-360)
LNAVV in ml, median (IQR)	204 (175-250)	180 (136-210)
p-value	0.009	0.002

Abbreviations: NPS is nocturnal polyuria syndrome. NUP is nocturnal urine production in milliliters/hour. NPi is Nocturnal Polyuria index. FNAVV is first nocturnal voided volume in milliliters. LNAVV is late nocturnal average voided volume in milliliters. IQR is interquartile range.

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Integration of Telehealth at Multidisciplinary Stone Clinic Increases Patient Adherence to Kidney Stone Prevention Visits

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Background: Recent studies have found that the implementation of the telehealth model has helped to improve access to specialty care, such as high-risk obstetrics and rheumatology outpatient clinics, by reducing the rate of missed appointments. However, little is known about the impact of telehealth on multidisciplinary kidney stone clinics (MSCs). An MSC is a relatively novel approach that provides individualized care, especially to high-risk stone formers, by a team made up of urologists, nephrologists, and dieticians, all in a single patient encounter. The goal of this study is to evaluate whether the implementation of telehealth improved patient adherence to their scheduled appointments with the MSC integrated care team.

Methods: A retrospective review of the patient records of a single MSC was performed to identify patient appointments at a single academic institution from 2018 to 2021. Scheduling and appointment data was collected and analyzed from the records. Date of the appointment, appointment type (in-person or virtual), and whether the patient showed or did not show to the appointment were recorded. If the visit was scheduled as a virtual encounter, patient adherence was measured as completion of the telephone visit and follow up scheduled. Two separate time intervals were analyzed: A pre-COVID-19 time interval from February 2018 to February 2020 and a post-COVID-19 interval from March 2020 to October 2021. Patient adherence to scheduled appointments prior to and after March 2020 were compared. Statistically significant differences between the experimental groups were determined using a two-sample t-test.

Results: A total of 1,065 patient encounters at the MSC were included in the analysis. 531 visits were recorded in the pre-COVID-19 interval and 534 visits in the post-COVID-19 interval. After March 2020, there was a significant increase in the scheduled appointments that were remote (+64.7%, $p < 0.001$). Additionally, there was a significant increase in patient adherence to scheduled appointments from 87.9% prior to March 2020 to 96.1% after March 2020 (+8.2%, $p < 0.001$).

Conclusions: Amongst the patients who were treated at the MSC, there was a significant increase in adherence to scheduled appointments, which coincided with a significant increase in the percentage of telehealth appointments following the start of the COVID19 pandemic in March 2020. These results suggest that telehealth could potentially increase access to the integrated MSC model for chronic kidney stone formers. However, further studies are necessary to expand this analysis to a more diverse population and examine the long-term effects of the wide-scale implementation of telehealth on kidney stone prevention.

Summary of Patient Encounter Characteristics, Pre-COVID-19 Interval and Post-COVID-19 Interval

	Pre-COVID-19 Interval	Post-COVID-19 Interval
Sex	50.3% Male / 49.7% Female	57.5% Male / 42.5% Female
Number of visits	531	534
Percentage of remove visits	15.6%	80.3%
Percentage of visits completed	87.9%	96.1%

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7-year Outcomes of Regionalized Care for Fournier's Gangrene at a Tertiary Care Center

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Background: Fournier's gangrene (FG) is a necrotizing fasciitis affecting the genitalia or perineum. Due to the rarity of this disease and frequent need for multidisciplinary care, it has been suggested that regionalized care would improve patient outcomes. However, FG is a surgical emergency requiring expeditious surgical debridement and there is a paucity of data regarding the outcomes of patients transferred for management of this disease. Herein, we report on our experience with regionalized care for FG over a 7-year period and investigate the outcomes of patients who were transferred to our facility.

Methods: We performed a retrospective review of patients treated for FG at our tertiary care center from 2015 through 2021. Patients who underwent operative debridement and had evidence of a necrotizing soft tissue infection involving the genitalia or perineum were included. Patients were grouped based on transfer status. The primary outcome measure was mortality rate at 30- and 90-days. Secondary outcome measures included length of hospital stay, number of operative debridements, postoperative ICU admission, postoperative mechanical ventilation, and postoperative vasopressor requirement. Chi-squared tests and t-tests were used for statistical analysis and a p value of 0.05 was considered as statistically significant.

Results: A total of 136 patients were treated for FG at our center. 106 (77.9%) were male and 30 (22.1%) were female. Overall 30-day and 90-day mortality rates were equivalent at 5.1%. 33.8% of patients directly presented to our tertiary care center and 66.2% were transferred from outside facilities. Patients transferred from outside facilities did not have an increased risk of mortality (5.6% vs. 4.3%; $p = 0.76$), length of hospital stay (mean 14.4±14.5 days vs. 13.3 ± 10.5 days; $p = 0.65$) or number of operative debridements (1.83 vs. 1.70; $p = 0.51$). There were no differences in rates of postoperative ICU admission (72.2% vs. 67.4%; $p = 0.80$), mechanical ventilation (44.4% vs. 47.8%; $p = 0.71$), or vasopressor requirement (43.4% vs. 52.2%; $p = 0.33$).

Conclusions: Regionalized care is a safe and effective means for managing FG. Patients transferred from outside facilities did not have lower mortality rates or inferior outcomes compared to patients who presented directly to our center.

Outcomes of patients who directly presented compared to transfers

Outcome	Total	Directly Presented	Transferred	p-value
30-day mortality	7 (5.1%)	2 (4.3%)	5 (5.6%)	0.76
90-day mortality	7 (5.1%)	2 (4.3%)	5 (5.6%)	0.76
Length of stay, mean	16.7 days	13.3 days	14.4 days	0.65
Number of debridements	1.79	1.70	1.83	0.51
ICU admission	96 (70.6%)	31 (67.4%)	65 (72.2%)	0.80
Mechanical ventilation	62 (45.6%)	22 (47.8%)	40 (44.4%)	0.71
Postoperative vasopressor	63 (46.3%)	24 (52.2%)	39 (43.3%)	0.33

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Current Findings Regarding Perioperative Complications in Benign Scrotal Surgery

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Background: Benign scrotal surgery is a core component of urology practice. Patients commonly pursue these procedures for pain control, increased comfort, and improved aesthetics. The potential risks of benign scrotal surgery have not been well described in the literature, particularly in the general adult population. We sought to characterize patients at the greatest risk of morbidity and mortality after benign scrotal surgery.

Methods: A secondary data analysis was conducted of adults undergoing elective scrotal surgery for benign conditions using 2015-2020 American College of Surgeons National Surgical Quality Improvement data. Patients who experienced a postoperative complication, an unplanned procedure, or who died within 30-days of surgery were identified using the composite outcome "postoperative event". Multiple logistic regression was used to examine the association between patient characteristics and the odds of experiencing a postoperative event.

Results: The study consisted of 12,917 patients, of which 4.1% experienced a postoperative event. After adjustment, malnourishment (OR 4.1, 95% CI: 1.2 - 14.5) decreased functional status (OR 3.8, 95% CI: 2.0-7.1), bleeding disorders (OR 3.4, 95% CI: 2.2-5.4), age ≥ 40 years (OR 1.6, 95% CI: 1.2-2.0), chronic obstructive pulmonary disease, (COPD, OR 1.8, 95% CI: 1.2-2.6), smoking (OR 1.4, 95% CI: 1.2-1.8), diabetes (OR 1.3, 95% CI: 1.1-1.7) and increased body mass index (BMI, OR 1.1, 95% CI: 1.1-1.1) were identified as risk factors for a postoperative event. The risk of a postoperative event was 2.7%, 4.5%, and 11.2% for patients with none, 1 to 2, and > 2 risk factors, respectively.

Conclusions: Complications after benign scrotal surgery are not infrequent, but are also not as common as historically reported. Risk factors include malnourishment, decreased functional status, bleeding disorders, age, COPD, smoking, diabetes, and increased BMI. Our results can be used to counsel patients on their risk of negative outcomes following these procedures.

P12

Expression and Localization of miR-146a-5p and miR-142-3p in Urethral Submucosa of Patients with Lichen Sclerosus-Induced Urethral Stricture Disease

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Background: In a prior study, we identified microRNA (miRNA) characteristic of lichen sclerosus (LS) induced urethral strictures (US). For this study, we used in situ-hybridization (ISH) to further investigate miRNA expression levels and localization in tissue from patients with LS-induced and non-LS US. ISH is a technique that detects and localizes DNA or RNA sequences in tissue by using labeled complementary probes. The goal of this study was to assess whether expression and localization of specific miRNAs were different between LS-induced and non-LS US.

Methods: 10 LS-induced and 9 non-LS US tissue samples were selected for ISH based on pathological and clinical review. 8 unique miRNAs identified from our prior study were chosen for ISH analysis. Tissue microarrays were prepared using 2mm punches of the stricture area. 5µm sections were stained using heat induced epitope retrieval with miRNAscope HD reagents (ACDBio, Newark, CA). Semi-quantitative tissue staining was scored by a single genitourinary pathologist for epithelial and submucosal regions (0 = no detection, 1 = low, 2 = moderate, and 3 = high expression). Data analysis was performed using SPSS v. 27. Variables were compared by the Wilcoxon rank sum test with significance considered at $p < 0.05$.

Results: There was significant difference in expression of miRNAs 146a-5p ($p = 0.028$) and 142-3p ($p = 0.022$) in the submucosa of LS-induced versus non-LS US. Representative images demonstrating increased staining for these miRNA probes are shown in Figure 1. MiRNA 155-5p likely had higher expression in the submucosa of LS tissue, but these results were not statistically significant ($p < 0.08$). There was no significant difference in miRNA expression in the epithelia of these samples.

Conclusions: Using ISH, this study showed up-regulation of several miRNAs in the submucosa of LS-induced US. The genetics of urethral LS remain under-investigated, and so establishing a miRNA profile may allow for better characterization of LS in order to ultimately guide prognosis and treatment. Further, histologic evaluation of LS is often difficult and these markers may aid in pathologic diagnosis

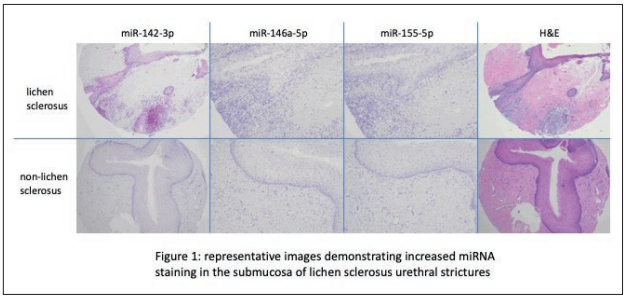

Figure 1: representative images demonstrating increased miRNA staining in the submucosa of lichen sclerosus urethral strictures

P13

The Absence of SRD5A2 Regulates the Heterotypic Cell-cell Communication in Prostate

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Background: Benign prostatic hyperplasia (BPH) is a heterogeneous disease that results from nonmalignant proliferation of both the prostate epithelial and stromal compartment. Steroid 5α reductase 2 (SRD5A2) is the predominant enzyme responsible for prostatic development and growth. We have shown that the expression of SRD5A2 is silenced in 30% of human adult prostate tissues by epigenetic regulation, and SRD5A2 is exclusively expressed in human and mouse prostatic stromal compartments. In SRD5A2 null (SRD5A2-/-) mice that were generated in our lab, the weight of the prostate gland decreased by ~50%. Here we wish to characterize the interacting signals between stromal cells and luminal epithelial cells (LE) in the absence of SRD5A2 by single-cell RNA sequencing (scRNA seq) analysis.

Methods: Prostatic single cells were digested from SRD5A2-/- mice and SRD5A2+/- littermate control mice. Unbiased scRNA seq with 10x genomics platform, followed by unsupervised clustering, was utilized to generate cell clusters based on differentially expressed (DE) gene profiles. The heterotypic cell-cell communication was analyzed using CellphoneDB2. Identified ligand-receptor pairs were validated by qPCR in human prostatic tissues collected from patients with BPH via transurethral resection of the prostate.

Results: Sixteen cell subpopulations were transcriptomically identified from 23,000 single cells. The cellular expression of SRD5A2 was exclusively identified in fibroblasts and myofibroblasts. The absence of SRD5A2 induced a significant decrease in luminal cells (53.2% vs. 31.8%) but an increase in stromal cells (11.3% vs. 18.0%). Analysis of significantly-changed ligand-receptor pairs indicated that stromal cells were among the most prolific interactors, and myofibroblasts were the most "outbound" cells both in SRD5A2+/- and SRD5A2-/- animals. Meanwhile, the fibroblasts in SRD5A2-/- mice had the most significantly increased weighted value (366 vs. 493), and LE1, one subset of LE cells, had the most significantly decreased weighted value (205 vs. 96) when compared with SRD5A2+/- control mice. Furthermore, the most significantly changed ligand-receptor pairs were identified, including WNT5A/PTPRK, TGFB2/TGFBR1, and (NRP1, NRP2, FLT1)/VEGFA, which regulate the stromal cell and LE communication. In human prostatic tissues, the expressions of WNT5A and PTPRK were significantly associated with SRD5A2 expression.

Conclusions: Our data suggest that the heterotypic cell-cell communication is substantially changed in the absence of SRD5A2. The stroma-niched signaling might serve as a therapeutic target for managing BPH patients who lack SRD5A2 expression.

P14

Radiographic Progression in the Absence of Prostate-Specific Antigen (PSA) Progression in Patients with Metastatic Hormone-Sensitive Prostate Cancer (mHSPC): *post hoc* Analysis of ARCHES

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Background: Enzalutamide (ENZA) + androgen deprivation therapy (ADT) significantly reduced the risk of radiographic progression and increased overall survival in men with mHSPC, regardless of baseline PSA levels (ARCHES; NCT02677896). This *post hoc* analysis investigated concordance between PSA progression and radiographic progression in patients with mHSPC.

Methods: Patients with mHSPC (n = 1150) were randomized 1:1 to ENZA (160 mg/day) + ADT or placebo (PBO) + ADT. The concordance between radiographic progression and PSA progression, as defined by Prostate Cancer Clinical Trials Working Group 2 (PCWG2) criteria, and between any rise in PSA above nadir was assessed.

Results: In total, 267/1150 patients in ARCHES had radiographic progression (ENZA + ADT, n = 79; PBO + ADT, n = 188). At radiographic progression, the median (range) PSA for ENZA + ADT-treated patients was 2.25 ng/mL (0-1062.3 ng/mL) and 17.47 ng/mL (0-1779.5 ng/mL) for PBO + ADT-treated patients. Most patients (67%) treated with ENZA + ADT did not have PCWG2-defined PSA progression at radiographic progression, compared with 57% of those treated with PBO + ADT (Table). The median absolute and percentage rise in PSA from nadir to radiographic progression was 0.77 ng/mL and 200%, respectively, with ENZA + ADT compared with 12.23 ng/mL and 367%, respectively, with PBO + ADT. Due to the *post hoc* nature of the analysis, results should be interpreted with caution.

Conclusions: In this *post hoc* analysis of ARCHES, we found frequent discordance between radiographic progression and PSA progression by PCWG2 criteria or any PSA rise over nadir in patients with mHSPC treated with ENZA + ADT. Thus, regular imaging is recommended to detect radiographic progression among patients treated with potent androgen receptor pathway inhibitors, such as ENZA + ADT, as serial PSA monitoring alone may not be sufficient to detect radiographic progression in many patients.

Table: Concordance of radiographic progression and increasing PSA

n (%)	ENZA + ADT (n = 79)	PBO + ADT (n = 188)
PSA progression[a] at time of radiographic progression[b]		
Yes	26 (32.9)	108 (57.4)
No	53 (67.1)	80 (42.6)
Any rise in PSA from nadir at time of radiographic progression[b]		
Yes	52 (65.8)	160 (85.1)
No	27 (34.2)	28 (14.9)

[a]PSA progression is defined as a ≥ 25% increase and an absolute increase of ≥ 2 ng/mL above the nadir, confirmed by a second consecutive value at least 3 weeks later; [b]Radiographic progression was assessed by independent central review or death (defined as death from any cause within 24 weeks from study drug discontinuation), whichever occurred first.

Funding: The study was sponsored by Pfizer and Astellas Pharma, the co-developers of enzalutamide.

Acknowledgments: Medical writing and editorial support funded by the sponsors were provided by Mashal Hussain, PhD, and Lauren Smith, BA (Hons), from Complete HealthVizion.

P15

Apamin Inhibits Renal Fibrosis via Suppressing TGF-β1 and STAT3 Signaling in Unilateral Ureteral Obstruction (UUO) Mice and in Renal Fibroblast

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Background: Renal fibrosis is a progressive and chronic process that influences kidneys with chronic kidney disease (CKD), irrespective of cause, leading to irreversible failure of renal function and end-stage kidney disease. Among the signaling related to renal fibrosis, transforming growth factor-β1 (TGF-β1) signaling is a major pathway that induces the activation of myofibroblasts and the production of extracellular matrix (ECM) molecules. Apamin, a component of bee venom (BV), has been studied in relation to various diseases. However, the effect of apamin on renal interstitial fibrosis has not been investigated. The aim of this study was to estimate the beneficial effect of apamin in unilateral ureteral obstruction (UUO)-induced renal fibrosis and TGF-β1-induced renal fibroblast activation.

Methods: Kidney fibrosis was induced by UUO surgery and renal fibroblast activation was induced by TGF-β1 treatment. To investigate the anti-fibrotic effect of apamin, we performed various histological staining and molecular biological methods.

Results: This study revealed that obstructive kidney injury induced an inflammatory response, tubular atrophy, and ECM accumulation. However, apamin treatment suppressed the increased expression of fibrotic-related genes, including α-SMA, vimentin, and fibronectin. Administration of apamin also attenuated the renal tubular cells injury and tubular atrophy. In addition, apamin attenuated fibroblast activation, ECM synthesis, and inflammatory cytokines such as TNF-α, IL-1β and IL-6 by suppressing the TGF-β1-canonical and non-canonical signaling pathways.

Conclusions: This study shown that apamin inhibits UUO-induced renal fibrosis *in vivo* and TGF-β1-induced renal fibroblasts activation *in vitro*. Apamin inhibited the inflammatory response, tubular atrophy, ECM accumulation, fibroblast activation, and renal interstitial fibrosis through suppression of TGF-β1/Smad2/3 and STAT3 signaling pathways. These results suggest that apamin might be a potential therapeutic agent for renal fibrosis.

P16

Alkaline Urine During Pregnancy is Associated with Increased Gastrointestinal Alkali Absorption

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Background: During pregnancy, there appears to be an increased risk of nephrolithiasis, in particular stones composed of calcium phosphate. The pathophysiology has been attributed to both hypercalciuria as well as alkaline urine during pregnancy, which predisposes to calcium phosphate precipitation. It has been proposed and widely accepted that alkaline urine during pregnancy is secondary to renal compensation of respiratory alkalosis. This is induced by increased minute ventilation related to the gravid uterus and increased maternal and fetal oxygen demands. However, this dogma has been challenged given that alkaline urine should be temporary and resolve once initial compensation has occurred. In this prospective study including pregnant women on a standardized diet, we sought to assess whether alkaline urine during pregnancy may alternatively be due to increased gastrointestinal alkali absorption (GIAA).

Methods: IRB approval was obtained for this prospective study. Women with singleton pregnancy presenting to the obstetrical department were offered participation. Subjects were all placed on a controlled, standardized diet after assessment of metabolic needs by an obstetrical. The standardized diet consisted of boost plus, boost breeze and unlimited water. Collections were obtained during the third trimester and while the patient was lactating. Subjects remained on the controlled diet for 48 hours: the 24 hours preceding urine collection and the 24 hours of the urine collection. GIAA was estimated from urine using the following equation: [(Na + K + Ca + Mg – (Cl + 1.8P)]. Statistical analysis were performed in STATA using T-test.

Results: Of the twenty participants currently enrolled in this study, after ensuring quality of collections by comparing 24 hour creatinine samples between individual patients, there were eleven patients who completed both pre- and post-partum 24 hour urine collections. There was no significant difference in known dietary-related factors including urinary volume, sodium, sulfate and urea nitrogen. Urinary pH was 6.6 pre-partum versus 5.95 post-partum ($p < 0.00001$). GIAA was 28.8 mEq pre-partum versus 11.3 mEq post-partum ($p = 0.00097$).

Conclusions: We have confirmed that, on a standardized formula diet, alkaline urine is observed acutely during pregnancy. Moreover, for the first time, we have demonstrated that this coincides with significantly augmented GI alkali absorption during pregnancy compared with early postpartum. This will allow improved understanding of the pathophysiologic underpinnings of stones in pregnancy.

P17

Opioid Use and Associated Patient Satisfaction with Pain Control after Common Urologic Surgeries?

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Objectives: Non-opioid postoperative pathways have been shown to be successful after various urologic surgeries. Success has been based on outcomes showing no increased utilization of healthcare resources when opioids are omitted in the postoperative setting (need for additional pain prescriptions, office calls for concerning symptoms, and ER visits). The patient perspective however has not been reported. Here we evaluate these important measures in patients undergoing endourologic procedures and robotic assisted radical prostatectomy (RARP).

Methods: A 2-phased study performed at an academic medical center included a retrospective review of prescribing patterns after 13 surgeries followed by a prospective patient telephone questionnaire. We present a secondary analysis of the 2 most common urologic surgeries included and describe patient reported outcomes including degree of pain control (very well/well/poor/very poor), satisfaction with pain control (very satisfied/satisfied/unsatisfied/very unsatisfied), and actual pain compared to expected pain (more than expected/as expected/less than expected). Opioid prescription and opioid use were recorded. Bivariate analyses were used to compare patients who did and did not use opioids in the RARP cohort while overall trends were reported for the endourologic procedures.

Results: Of the 68 patients undergoing endoscopic intervention, 14 (21%) were prescribed an opioid and 6 (9%) reported any opioid use. 58 (85%) reported their pain was very well or well controlled while 9 reported their pain was poorly controlled. 59 (87%) were satisfied or very satisfied with their pain control. 14 patients had more pain than they expected, 22 as expected, and 30 less than expected. (Table 1).
Fifty-three (93%) of the 57 patients undergoing RARP received an opioid prescription and only 23 reported any opioid use. All but one patient reported that their pain was well or very well controlled and almost all (54) of the patients were satisfied with their level of pain control. 36 (63%) reported their pain was less than expected while only 7 (12%) reported it was more than expected. Of the 23 patients requiring opioid use, 7 (30%) reported they were given more opioids than needed. (Table 2).

Conclusions: The majority of patients undergoing endourologic procedures do not use postoperative opioids and report favorable outcomes regarding their pain control. Similarly, after RARP, most patients do not use opioids even when they are prescribed, and are satisfied with their pain control. For the minority of patients who used opioids, the question remains whether they were used because they were given or because they were required for pain control. This challenge of identifying which patients require opioids after surgery requires additional future focus and remains a roadblock to a zero- opioid approach for all.

Table 1. **Patient Perspective of Cystoscopy/Endoscopy Patients**

		No Opioid Use N (%)	Any Opioid Use N (%)	P Value*	N missing
Cystoscopy / endoscopy patients (n = 68)		62	6		
How well pain controlled	Very well controlled	28 (46%)	2 (33%)	0.33	1
since surgery	Well controlled	26 (43%)	2 (33%)		
	Poorly controlled	6 (10%)	2 (33%)		
	Very poorly controlled	1 (2%)	0 (0%)		
How satisfied with pain	**Very satisfied**	**35 (57%)**	**2 (33%)**	**0.07**	**1**
control since leaving	**Satisfied**	**20 (33%)**	**2 (33%)**		
Discuss pain management	No	14 (23%)	1 (17%)	1.00	0
pre-op	Do not recall	1 (2%)	0 (0%)		
	Yes	47 (76%)	5 (83%)		
Actual pain compared to	More than expected	11 (18%)	3 (50%)	0.28	2
expected	As expected	21 (35%)	1 (17%)		
	Less than expected	28 (47%)	2 (33%)		
After surgery given instructions	Yes	56 (90%)	6 (100%)	1.00	0
on nonopioid pain manage					
Nonopioid med used	Yes	15 (52%)	4 (80%)	0.35	34
Acetaminophen	Yes	13 (21%)	3 (50%)	0.14	0
Ibuprofen	Yes	3 (5%)	2 (33%)	0.06	0
Use walking or exercise	Yes	15 (65%)	3 (60%)	1.00	40
After surgery, prescribed	Yes	8 (13%)	6 (100%)	<0.0001	0
opioid					
Prescribed right amount	Less than needed	0 (0%)	1 (17%)	0.07	55
of pain pills	Just the right amount	7 (100%)	3 (50%)		
	More than needed	0 (0%)	2 (33%)		
Prescription = "PRN"	Yes	5 (100%)	5 (83%)	1.00	57

P18

Impact of COVID-19 on Emergency Department Use for Genitourinary Injury

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Background: The COVID-19 pandemic brought unprecedented change to the United States (US) healthcare system. We investigated how the epidemiology of US emergency department (ED) usage for pediatric and adult genitourinary (GU) injuries changed during the COVID-19 pandemic.

Methods: We queried the National Electronic Injury Surveillance System for pediatric (≤ 17 years old) and adult (≥ 18 years old) injuries to the pubic region from March to December of 2019 (pre-COVID-19) and 2020 (COVID-19). Adult and pediatric data were probability-weighted to produce national estimates and analyzed separately. We compared demographic and injury characteristics across the two time periods by χ^2 test in SPSSv27.

Results: Over the entire study period, GU injury accounted for 1% of pediatric and 0.4% of adult ED visits. During COVID-19, GU injuries decreased in adults (23,387 vs. 28,090 cases) and children (19,684 vs. 26,857 cases). Compared to pre-COVID-19, there were significant differences in age, race, diagnosis, disposition, location of injury and product causing injury ($p < 0.01$, each). During COVID-19, there was a greater proportion of GU injuries in toddler and school age children; female children; White, Asian, and American Indian and Alaskan Native children; 24-34, 45-54, and 75-84 year olds; and Black and Asian adults. Proportion of GU avulsions, burns, and lacerations increased during COVID-19 for both adults and children. Cases treated and released increased during COVID-19 in children but decreased in adults.

Conclusions: COVID-19 decreased the volume of pediatric and adult GU injuries presenting to US EDs. Due to COVID-19-related concerns, patients may have altered health-seeking behaviors and avoided the ED unless they perceived a high severity of injury. Healthcare providers may have altered their care plans due to decreased capacity for non-COVID-19 related admissions.

Table 2. Patient Perspective of Prostatectomy Patients

		No Opioid Use N (%)	Any Opioid Use N(%)	P Value*	N missing
Prostatectomy patients (n = 57)		34	23		
How well pain controlled	Very well controlled	23 (70%)	10 (45%)	0.11	2
since surgery	Well controlled	10 (30%)	11 (50%)		
	Poorly controlled	0 (0%)	1 (5%)		
	Very poorly controlled	0 (0%)	0 (0%)		
How satisfied with pain	**Very satisfied**	**28 (82%)**	**14 (67%)**	**0.24**	**2**
control since leaving	**Satisfied**	**6 (18%)**	**6 (29%)**		
Discuss pain management	No	1 (3%)	2 (9%)	0.52	0
pre-op	Do not recall	4 (12%)	1 (4%)		
	Yes	29 (85%)	20 (87%)		
Actual pain compared to	More than expected	4 (12%)	3 (13%)	0.02	0
expected	As expected	4 (12%)	10 (43%)		
	Less than expected	26 (76%)	10 (43%)		
After surgery given instructions	Yes	34 (100%)	23 (100%)	--	0
on nonopioid pain manage					
Nonopioid med used	Yes	32 (94%)	21 (91%)	1	0
Acetaminophen	Yes	32 (94%)	20 (87%)	0.38	0
Ibuprofen	Yes	0 (0%)	2 (9%)	0.16	0
Use walking or exercise	Yes	34 (100%)	22 (100%)	--	1
After surgery, prescribed	Yes	30 (88%)	23 (100%)	0.14	0
opioid					
Prescribed right amount	Less than needed	0 (0%)	1 (4%)	0.01	8
of pain pills	Just the right amount	8 (31%)	15 (65%)		
	More than needed	18 (69%)	7 (30%)		
Prescription = "PRN"	Yes	28 (97%)	22 (96%)	1	5

*P value is based on Fisher"s exact test to compare patients who did and did not use opioids

P19

Decreased Utilization of Low-value Health Care Services during the COVID-19 Pandemic

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Background: Low-value health care is defined as care in which the potential to cause harm is greater than the potential benefits. We hypothesize that rationing of health care during the pandemic decreased the delivery of low-value services.

Methods: Data was retrieved from the Research Patient Data Registry and approved by Mass General Brigham Institutional Review Board. High-value care services were defined according to USPTF guidelines, while low-value care services were selected based on previous literature. The periods considered were of 3 months each and consisted of the study period during the pandemic year (Q4: March 2, 2020 to June 1, 2020) and periods preceding the onset of the pandemic (Q1: December 1, 2018 to March 1, 2019; Q2: March 2, 2019 to June 1, 2019; and Q3: December 1, 2019 to March 1, 2020). The numbers of services during each period (N_Q) were evaluated.
The 2020 ratio ($Y_{2020} = N_{Q4}/N_{Q3}$) represents the change due to the pandemic. To account for seasonality, the 2019 ratio in number of services ($Y_{2019} = N_{Q2}/N_{Q1}$) was used to illustrate relative service counts during a typical year. Y_{2020}-Y_{2019} less than zero reflects a reduction in the service during the pandemic year accounting for seasonality. The calculation was made for each service as well as by value of care and by type of care (cancer vs. non-cancer). The difference between $Y_{Low\text{-}value}$ and $Y_{High\text{-}value}$ is the difference-in-differences (DID) of ratios and illustrates the differential decline in services by value of care during the pandemic period. $Y_{High\text{-}value}$- $Y_{Low\text{-}value}$ greater than zero suggests that low-value care declined to a greater degree than high-value care.

Results: Demographic characteristics of 3,271,957 patients during the four time periods are obtained. Eighteen of the 21 identified services had a reduction in volume during the pandemic period. Reductions of both low-value and high-value care during the pandemic were evident overall. The DID in ratios of high-value care and low-value care was 0.08 ($p < 0.01$), suggesting a modest greater decline in low-value care as compared to high-value care during the pandemic. The reduction in low-value care relative to the decline in high-value care is most pronounced for cancer care with a DID in ratios of 3.39 ($p < 0.01$). All DID of ratios are presented in Table 1.

Conclusions: There was a reduction in both low-value and high-value care with a greater reduction in low-value services, especially for cancer care. The greater degree of reduction in low-value care and within the subdivision of low-value cancer care promisingly suggests that health care providers have appropriately emphasized higher-value care during the pandemic.

Table 1 - Difference-in-differences estimates of ratios of services delivered between the pre-pandemic period and pandemic period.

PROCEDURE	Ratio2019 (Q2/Q1)	Ratio2020 (Q4/Q3)	Difference in ratios	P-value*
HIGH-VALUE SERVICES				
Flu vaccine	0.343	0.194	-0.149	< 0.01
Tobacco cessation	2.444	1.231	-1.214	0.257
Cervical cancer screen	1.159	0.239	-0.920	< 0.01
Colorectal cancer screen	1.181	0.247	-0.935	< 0.01
LOW-VALUE SERVICES				
PSA testing for men over > 75	1.101	0.293	-0.808	< 0.01
Bone mineral density testing at frequent intervals	1.111	0.221	-0.889	< 0.01
Homocysteine testing for CV disease	1.142	0.427	-0.716	< 0.01
Hypercoagulability testing for patients with DVT	1.170	0.627	-0.543	< 0.01
CT of sinuses for uncomplicated acute rhinosinusitis	1.014	0.336	-0.678	< 0.01
Head imaging in evaluation of syncope	0.826	0.465	-0.362	0.002
Head imaging for uncomplicated headache	1.525	0.527	-0.998	< 0.01
EEG for headaches	0.727	1.000	0.273	0.704
Carotid artery disease screening in asymptomatic adults	1.175	0.494	-0.681	< 0.01
Carotid artery disease screening for syncope	1.078	0.330	-0.748	< 0.01
Stress testing for stable coronary disease	1.147	0.378	-0.769	< 0.01
Carotid endarterectomy in asymptomatic patients	1.308	0.162	-1.146	< 0.01
Arthroscopic surgery for knee osteoarthritis	0.714	0.333	-0.381	0.303
Cervical cancer screen (by age)	10.027	0.216	-9.811	< 0.01
Cervical cancer screen with ESRD	1.529	0.190	-1.339	< 0.01
Colorectal cancer screen in elderly patients	4.254	0.400	-3.854	< 0.01
Colorectal cancer screen in ESRD	2.067	0.583	-1.483	0.036
VALUE OF ALL SERVICES				
Difference in ratios of low-value care	1.177	0.353	-0.824	< 0.01
Difference in ratios of high-value care	0.974	0.231	-0.744	< 0.01
Difference-in-differences of ratios	-	-	0.080	< 0.01
VALUE OF CANCER SERVICES				
Difference in ratios of low-value cancer care	4.6117	0.2977	-4.314	< 0.01
Difference in ratios of high-value cancer care	1.1646	0.2406	-0.924	< 0.01
Difference-in-differences of ratios	-	-	3.390	< 0.01

** Wald statistic p-value for testing that Difference in ratios = 0.*

P20

Associations Between First Year and Early-Year Costs in Pediatric Spina Bifida Patients - A Longitudinal Machine-Learning Based Analysis

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Background: Spina bifida (SB) is a relatively common, chronic multi-system disorder that can present heterogeneously. SB patients often form lifelong relationships with healthcare providers given their need for long-term functional monitoring and, with severe disease, extensive medical and surgical interventions. Therefore, the disease carries a likely potential for high long-term costs, placing financial and resource strains on patients, providers, and healthcare systems. Our goal was to assess if machine learning (ML) algorithms could extrapolate early-year costs (EYCs) from first-year costs (FYCs) such that longer-term patient needs could conceivably be determined from their needs during the first year of life.

Methods: The Aetna database was used to access patient information from 2006-2019. The relevant ICD-9/-10 diagnosis codes and CPT codes were used to identify pediatric patients with SB status post initial myelomeningocele closure. Those included were required to have complete, continuous records from birth until age 5. Exclusion criteria included lapses in Aetna coverage and death before age 5. FYC and EYCs were determined using a K-nearest neighbors algorithm, with cluster number determined by within-group sum of squares. The predictive performance of the model was then assessed via accuracy, specificity, and sensitivity. Results are reported as means with 95% CI, and all analysis was performed using R.

Results: The Aetna database initially yielded 351 patients, of which 58 underwent further analysis after exclusion criteria were applied. From this, two clusters (high-cost group (HCG) and low-cost group (LCG)) were identified. Excluding surgical cost, the HCG demonstrated an average 5-year expenditure of $327,000, while the LCG spent $45,000. The median FYC was $22,000, serving as the threshold for extrapolative EYC analysis. Actual annual mean EYCs were found to be $55,546 for the HCG (aggregate mean = $222,183) and $11,138 for the LCG (aggregate mean = $44,550). When the ML algorithm was applied to FYC, the algorithm identified 24/29 HCG and 26/29 LCG members correctly, yielding a predictive accuracy of 0.86 (95% CI: 0.75-0.94), sensitivity of 0.89, and specificity of 0.83. Moreover, HCG patients were found to have increased facility, pharmacy, and service needs.

Conclusions: This is the first study to predict long-term costs in the SB population using a complete database. The ML algorithm is useful in identifying high-risk patients with increased disease severity who may require additional resources. This may offer benefit with respect to financial planning, resource allocation, policy making, and education.

P21

Clinical and Urodynamic Predictors of Hydronephrosis and Febrile UTIs in Neurogenic Bladder Children

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Background: Hydronephrosis and febrile urinary tract infections (fUTI) pose significant challenges for quality of life and are considered proxies for upper tract risks. The aim of this study is to identify clinical and urodynamic study (UDS) factors predictive of hydronephrosis and fUTI in children with neurogenic bladder.

Methods: UDS of neurogenic bladder patients from 2013-2019 were reviewed. Patients younger than 1 year old, studies with calibration issues, and bladder augmentation patients were excluded. Covariates included, age, sex, fUTI within 1 year, and UDS parameters such as detrusor leak point pressure (DLPP), maximal detrusor filling pressure (Pdetmax), post-void residuals (PVR >20% measured capacity), and vesicoureteral reflux (VUR) status. Multivariate logistic regression was performed using generalized estimating equations to adjust for repeat measurements.

Results: We included 518 studies of neurogenic bladder patients with a mean (SD) age of 10.9 (6.9) years. 42% were males, 21% had hydronephrosis, and 14% had fUTI within 1 year of UDS. After adjusting for age, sex, CIC, detrusor overactivity (Table 1A), hydronephrosis was significantly associated with recent febrile UTI history (OR = 2.0 (1.1-3.5), p = 0.02), high DLPP or Pdetmax (> 40 cmH2O, OR = 1.7(1.03-2.9), p = 0.039), elevated PVR (>2 0% capacity, OR = 2.5 (1.4-4.3), p < 0.01), and VUR (OR=2.1(1.2-3.7), p<0.01). After adjusting for age, sex, elevated PVR, CIC, detrusor overactivity, VUR, (Table 1B), fUTI was significantly associated with hydronephrosis (OR = 1.95, 95% CIC (1.11-3.44), p = 0.02) and high DLPP or Pdetmax (> 40 cm H20, OR = 2.10 , 95% CIC (1.03-4.289), p = 0.041).

Conclusions: In our cohort, higher bladder pressures (high DLPP or Pdetmax) were most significantly associated with upper tract changes proxies including hydronephrosis and febrile UTIs. Proper management of bladder pressure plays an essential role in neurogenic children. These results can help guide clinicians in identifying patients at higher risk of hydronephrosis and fUTI.

Table 1: Odds Ratio (OR) for Clinical and Urodynamic Predictors of Hydronephrosis (A) and Febrile UTI (B)

A

Patient characteristics	OR (95CI)	p value
Age at UDS (years)	1.01(0.97-1.05)	0.50
Sex (female=reference)	0.90(0.51-1.60)	0.72
recent fUTI	2.00(1.14-3.51)	0.02
DLPP or maximal filling pressure over 40cmH2O	1.73(1.03-2.93)	0.04
PVR over 20% measured capacity	2.47(1.43-4.27)	<0.01
CIC	0.42(0.23-0.76)	<0.01
Detrusor overactivity	1.13(0.65-1.95)	0.67
VUR	2.10(1.20-3.70)	<0.01

B

Patient characteristics	OR (95CI)	p value
Age at UDS (years)	0.968 (0.92-1.02)	0.21
Sex (female=reference)	0.968 (0.55-1.71)	0.91
Hydronephrosis	1.952 (1.11-3.44)	0.02
DLPP or maximal filling pressure over 40cmH2O	2.102 (1.03-4.29)	0.04
PVR over 20% measured capacity	1.341 (0.74-2.42)	0.33
CIC	1.264 (0.56-2.85)	0.57
Detrusor overactivity	0.5692 (0.30-1.08)	0.08
VUR	0.778 (0.42-1.45)	0.43

P22

Leaving No Stone Unturned: Factors Associated with Overturning Health Insurance Claim Denials

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Background: When managed care beneficiaries or providers of New York State (NYS) have claims denied, they may appeal the decision. Third-party reviewers then rule whether the denial should be upheld or overturned. This study aimed to be the first to describe rates of genitourinary (GU) external appeals in NYS and assess factors associated with successful appeals.

Methods: The NYS External Appeals database was retrospectively queried for "Genitourinary /Kidney Disorder" claims filed 2019-2021 and urological claims were isolated. Patient age group, gender, decision year, appeal reason, diagnosis, treatment, and reference to American Urological Association (AUA) were extracted. Diagnoses and treatments were categorized as seen in Table 1. Cases overturned, both in part and fully, were analyzed together. Annual appeal volume was analyzed by linear regression. Relationships between appeal decision and demographic factors were analyzed by χ^2 tests. Multivariate logistic regression analysis was done to identify factors related to overturns using SPSSv28.0.

Results: 408 GU cases were isolated, representing 70.6% of GU/kidney disorder appeals and 2.6% of all appeals. 161 (39.5%) denied claims were overturned by external review, which was lower than the overall rate (43.4%). Appeal volume increased annually, with overturned decisions increasing 244% by linear regression between 2019 and 2021 (m=29.5, p=0.068). 62 (15.2%) reviewers explicitly referenced AUA guidelines to justify their medical management decision. Appeals most commonly involved 40-59 year olds (32.4%), inpatient hospitalizations (63.5%) and infection diagnoses (32.4%) (Table 1).
Chi-squared analyses showed significant differences in overturn rate by gender, age group, diagnosis category, treatment type, and reference to AUA guidelines (Table 2). Multivariate logistic regression showed 20-39- and 40-59-year-olds had, respectively, 0.23 times and 0.34 times significantly lower odds of overturn than 0-19 year olds. Home health care (OR = 15.77), medications (OR = 18.75), and surgical services (OR = 47.72) denials had significantly higher odds of overturn by external review compared to inpatient hospital stays. Referencing AUA guidelines had 0.30 times lower odds of overturning denials, suggesting utilizing AUA guidelines may have prevented overtreatment or mistreatment (Table 3).

Conclusions: To our knowledge, this is the first study to examine GU insurance appeals in NYS and factors associated with successful appeals. Multivariate logistic regression showed age group, treatment type, and reference to AUA guidelines had significant associations with overturn rates. These findings will help serve as a reference point for urology advocacy groups engaging with insurance company decisions. These findings warrant further study to help patients not only medically, but financially as healthcare costs continue to rise.

Table 1. External Appeal Characteristics, 2019-2021.

Parameter, n (%)	2019 (n=98)	2020 (n=124)	2021 (n=186)
Gender			
Male	45 (45.9%)	57 (46.0%)	83 (44.6%)
Female	53 (54.1%)	67 (54.0%)	103 (55.4%)
Age group			
0-19	11 (11.2%)	11 (8.9%)	10 (5.4%)
20-39	22 (22.4%)	25 (20.1%)	26 (14.0%)
40-59	36 (36.7%)	38 (30.6%)	58 (31.1%)
60-79	27 (28.0%)	31 (25.0%)	44 (23.7%)
80+	2 (2.0%)	19 (15.3%)	48 (25.8%)
Appeal Reason			
Medical Necessity	94 (96.0%)	120 (96.7%)	174 (93.5%)
Formulary Exception	1 (1.0%)	3 (2.4%)	8 (4.3%)
Experimental/ Investigational	3 (3.0%)	1 (0.8%)	4 (2.2%)
Treatment			
Inpatient Hospitalization	87 (88.8%)	90 (72.6%)	89 (47.8%)
Home Health Care	1 (1.0%)	21 (16.9%)	61 (32.8%)
Medications	1 (1.0%)	3 (2.4%)	18 (9.7%)
Surgical Services	2 (2.0%)	3 (2.4%)	8 (4.3%)
Other	7 (7.2%)	7 (5.6%)	10 (5.4%)
Diagnosis Category			
Incontinence/LUTS	7 (7.2%)	28 (22.6%)	80 (43.0%)
BPH	7 (7.2%)	6 (4.8%)	12 (6.5%)
Oncology	7 (7.2%)	1 (0.8%)	4 (2.1%)
Infection	43 (43.9%)	49 (39.5%)	40 (21.5%)
Stones	24 (24.5%)	25 (20.2%)	30 (16.1%)
Sexual Dysfunction	2 (2.0%)	1 (0.8%)	7 (3.8%)
Congenital/Pediatric	0 (0.0%)	4 (3.2%)	3 (1.6%)
Iatrogenic/Stents and Nephrostomy Tubes	3 (3.0%)	2 (1.6%)	0 (0.0%)
Other	5 (5.0%)	8 (6.5%)	10 (5.4%)
Comorbidities			
No	73 (74.5%)	80 (64.5%)	135 (72.6%)
Yes	25 (25.5%)	44 (35.5%)	51 (27.4%)
Referenced AUA			
No	83 (84.7%)	104 (83.9%)	159 (85.5%)
Yes	15 (15.3%)	20 (16.1%)	27 (14.5%)
Decision			
Upheld	72 (73.5%)	74 (59.7%)	101 (54.3%)
Overturned	26 (26.5%)	50 (40.3%)	85 (45.7%)

Table 2. χ comparison between overturned and upheld GU service denials. Superscript [a] denotes significantly higher proportion between groups at a threshold of p<0.05.

Parameter, n (%)	Upheld (n=247)	Overturned (n=161)	p
Gender			0.015
Male	124 (50.2%) [a]	61 (37.9%)	
Female	123 (49.8%)	100 (62.1%) [a]	
Age Groups			<0.001
0 to 19	17 (6.9%)	15 (9.3%)	
20 to 39	60 (24.3%) [a]	13 (8.1%)	
40 to 59	94 (38.0%) [a]	38 (23.6%)	
60 to 79	60 (24.33%)	42 (26.1%)	
80+	16 (6.5%)	53 (32.9%) [a]	
Appeal Reason			0.815
Medical Necessity	236 (95.5%)	152 (94.4%)	
Formulary Exception	7 (2.8%)	5 (3.1%)	
Experimental/Investigational	4 (1.6%)	4 (2.5%)	
Diagnosis Category			<0.001
Incontinence/LUTS	36 (14.6%)	79 (49.1%) [a]	
BPH	17 (6.9%)	8 (5.0%)	
Oncology	7 (2.8%)	5 (3.1%)	
Infection	88 (35.6%)	44 (27.3%)	
Stones	66 (26.7%) [a]	13 (8.1%)	
Sexual Dysfunction	7 (2.8%)	3 (1.9%)	
Congenital/Pediatric	3 (1.2%)	4 (2.5%)	
Iatrogenic/Stents and Nephrostomy Tubes	3 (1.2%)	2 (1.2%)	
Other	20 (8.1%) [a]	3 (1.9%)	
Treatment			<0.001
Inpatient Hospitalization	202 (81.8%) [a]	64 (39.8%)	
Home Health Care	16 (6.5%)	67 (41.6%) [a]	
Medications	10 (4.0%)	12 (7.4%) [a]	
Surgical Services	3 (1.2%)	10 (6.2%) [a]	
Other	16 (6.5%)	8 (5.0%)	
Comorbidities			0.764
No	173 (70.0%)	115 (71.5%)	
Yes	74 (30.0%)	46 (28.5%)	
Referenced AUA			0.017
No	201 (81.4%)	145 (90.0%) [a]	
Yes	46 (18.6%) [a]	16 (10.0%)	

Table 3. Multivariate logistic regression of overturned GU service denials.

Parameters	OR (95%CI)	OR p-value
Gender; N (%)		0.131
Male	Ref	Ref
Female	1.48 (0.89 – 2.44)	0.131
Age Groups; N (%)		0.043
0 to 19	Ref	Ref
20 to 39	0.23 (0.09 – 0.60)	0.003
40 to 59	0.34 (0.14 – 0.79)	0.012
60 to 79	0.42 (0.17 – 1.05)	0.064
80+	0.41 (0.11 – 1.50)	0.178
Appeal Reason		0.659
Medical Necessity	Ref	Ref
Experimental/Investigational	1.36 (0.22 – 8.47)	0.744
Formulary Exception	0.44 (0.07 – 2.92)	0.395
Treatment; n (%)		<0.001
Inpatient Hospitalization	Ref	Ref
Home Health Care	11.29 (4.09 – 31.19)	<0.001
Medications	11.90 (2.39 – 59.31)	0.003
Surgical Services	28.26 (5.69 – 140.33)	<0.001
Other	1.99 (0.70 – 5.65)	0.195
Comorbidities		0.255
No	Ref	Ref
Yes	1.38 (0.79 – 2.40)	0.255
Referenced AUA		0.016
No	Ref	Ref
Yes	0.29 (0.11 – 0.79)	0.016

P23

Urologic Clinical Trials are Under-conducted in Low and Lower-middle Income Countries

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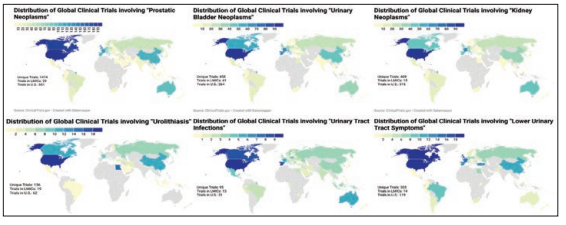
Background: Despite the global prevalence of disease, there is a significant disparity between the burden of disease and the host sites of clinical trials across the world. Prior studies have suggested that approximately 83% of all clinical trials being performed occur in twenty five countries.[1] There is a lack of knowledge regarding the distribution of clinical sites of ongoing clinical trials, especially in low and middle income countries (LMICs). In this study, we use publicly available clinical trial registries to analyze the distribution of urologic clinical trial sites.

Methods: We performed a search query on ClinicalTrials.gov for active clinical trials related to "prostatic neoplasms, urinary bladder neoplasms, kidney neoplasms, urolithiasis, urinary tract infections, and lower urinary tract symptoms." All phases of clinical trials were included. We did not exclude trials on the basis of specific age or gender recruitment criteria. Geographic analysis was performed by stratifying countries based on the World Bank classification by gross national income capita. Descriptive analysis was performed for the queried terms and graphically represented using choropleth maps.

Results: Using the ClinicalTrials.gov registry, the search terms were individually queried and the results were summarized in Table 1. The distribution of clinical trials sites were graphically represented using choropleth maps (Figure 1a-f). The query for prostatic neoplasms was the most populated on the registry, identifying a total of 1,474 clinical trials performed across 2,731 different trial sites and 65 different countries. Only 29 clinical trials (1.06%) were recruiting in LMICs. In contrast, for clinical trials related to non-oncologic urologic conditions, the query for "urolithiasis" identified 136 clinical trials across 139 trial sites of which LMICs comprised of 19 trial sites (13.67%), the query for "urinary tract infections" identified 95 clinical trials across 140 trial sites of which LMICs comprised of 13 trial sites (9.29%), and the query for "lower urinary tract symptoms" identified 303 clinical trials across 341 clinical trial sites of which LMICs comprised of 14 trial sites (4.10%.). Although limited, LMICs represented a higher proportion of non-oncologic urologic clinical trials as compared to their enrollment representation of urologic oncology clinical trials ($\chi 2 = 275.5$, $p < 0.001$).

Conclusions: A majority of urologic clinical trials are performed in high income countries. The disparity of clinical trial sites is greater for oncologic diseases as compared to non-oncologic diseases. Additional efforts are required to improve the number of clinical trials that are performed in LMICs.



P24

A Urology Fair Increases Medical Student Interest in Urology

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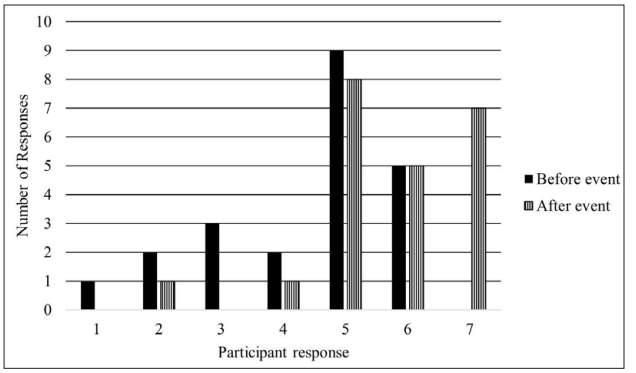
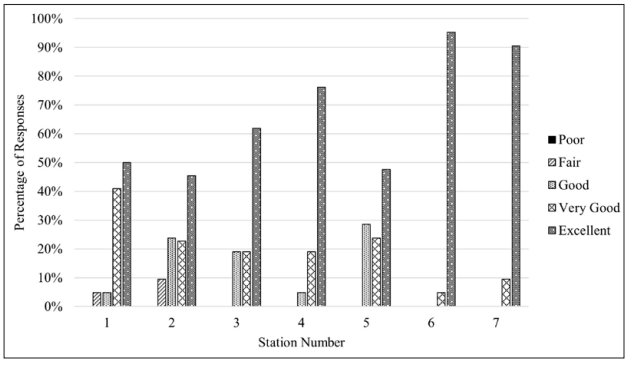
Background: The 2021 Urology Match compared to 2014 had increased number of urology residency positions, but a disproportionate increase in number of additional applicants. In 2020, urologists > 65 years old continued to be the largest percentage of the workforce (30%). This fact and the aging US population have led to estimations that workforce shortage will be as high as 46% by 2035. Therefore, increasing medical student interest in urology is one of the critical steps necessary to address the growing gap between available residency positions and applicants. The presence of a urology interest group (UIG) has been shown to significantly increase the number of urology applicants, specifically by creating and supporting interest and removing barriers for students. We examined the impact of a novel urology fair on medical student interest in urology.

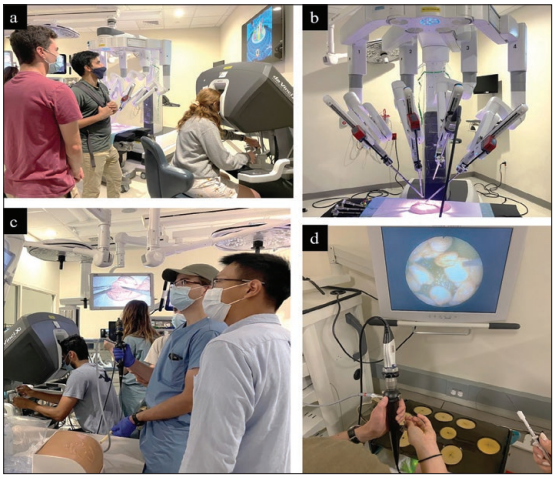
Methods: The 2021 Urology Fair was organized by the UIG of a medical school that is the primary teaching affiliate of an urban, tertiary, academic medical center. Medical students, residents, and faculty were involved in its preparation and execution. There were seven 20-minute stations including one-on-one with a resident, laparoscopy/suturing, flexible cystoscopy, ultrasound access/ureteroscopy, digital rectal exam/foley catheterization model, Da Vinci™ robotic simulator, and Da Vinci™ robotic animal model suturing. Student participants were asked to complete an online survey after the event.

Results: Twenty-two medical students attended the event and submitted an online survey. Nineteen (86%) students had never participated in a similar specialty fair and 16 (72%) were undecided about what field they wanted to pursue. Students who were "moderately likely" or "extremely likely" to consider matching into a surgical subspecialty increased from 5 (23%) before to 12 (55%) after the event. All stations at the event were rated as "very good" or "excellent" by the majority of students, ranging from 68% to 100%. The robotic simulator and animal model suturing stations were rated "excellent" in 20 (95%) and 19 (91%) responses, respectively. Twenty-one (95%) students indicated they wanted the event to be continued yearly, and 1 (5%) student was undecided.

Conclusions: A short, hands-on urology event increased medical student interest in urology. The Da Vinci™ robotic stations were the most well-received. An event based on our design that includes other surgical subspecialties may assist with increasing student interest earlier in medical school.







P25

Separating Fact from Fiction: Misconceptions About Urology Amongst Medical Students

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Background: The United States has an aging population with a changing burden of urologic diseases that affects both male and female patients. These trends make early exposure to urologic pathologies and a better understanding of urology imperative for physicians-in-training. This study aims to understand medical students' perspectives on their exposure to urology during medical school and potential strategies to increase that exposure.

Methods: An anonymous 16-question survey was administered via an online platform (REDCap 12.0.13) from January 8 2022 to February 25 2022 following approval by the Institutional Review Board. Eligible subjects were currently enrolled medical students in MD programs in the United States. A survey link was distributed via email. No incentive was provided for the completion of the survey.

Results: 178 medical students participated in the survey. Of the entire cohort, 30.3% could not explain what a urologist does. More than half of those surveyed (58.4%) learned about urology through medical school-related exposure, primarily interest-based groups. Free-text responses provided insights into students' understanding of the field and the need to increase exposure. Comments about the specialty and the role of a urologist included: "I may not know the exact line drawn between nephrologists and urologists", "my exposure to urology has been through renal and urogyn", "my school included no education on prostate health [what]soever, and I will graduate from medical school never been taught how to do a prostate exam", "urologists teaching some of our lectures during the 1st and 2nd-year curriculum would have been helpful, I never thought of it as a distinct field". Comments regarding the need for women in urology included: "I am wondering why we are concerned by a lack of female urologist/why there is a need when [the] majority of urology patients are male", "having an all-male patient population is [a] major turnoff for me". Comments regarding strategies to increase exposure to urology included: "urology is an under-emphasized topic in medical school", "increasing awareness of the specific examples/areas where women are needed in urology may help to increase recruitment. I think it's typically thought of as a specialty pertaining to the male reproductive system. Examples of cases in female patients that need urologists can help to increase awareness". Of the 87 students that responded to the free-text questions, 52.3% suggested ways to learn about a career in urology, 22.1% suggested including educational material in preclinical years, and 33.7% suggested clinical exposure.

Conclusions: A surprisingly high proportion of medical students (1 in 3) are unclear about the role of a urologist as a surgeon and how it is distinguished from other fields such as nephrology. In addition, free-text responses provided insights into students' misconceptions that urology is a medical field that only treats male patients and pathologies. Based on these perspectives, medical schools can address gaps in knowledge about urology by including more urology cases in the preclinical years, providing shadowing opportunities, offering a urology elective, and increasing opportunities to connect with a urologist during the surgery core clerkship.

P27

Association of May-Thurner Syndrome with Semen Parameters Among Men with Varicocele

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Background: May-Thurner Syndrome (MTS) is an anatomic variant condition in which the right common iliac artery (CIA) overlies and compresses the left common iliac vein (CIV). MTS has been associated with an increased risk of lower extremity deep vein thrombosis. Such iliac venous congestion may impair drainage of spermatic cord cremasteric and deferential veins. Though varicoceles are well known for their impact on fertility, it is not clear what effect MTS may have on fertility potential and semen parameters. We hypothesize that MTS may be an independent contributing factor to abnormal semen parameters in the setting of a left varicocele (Grade II/III or III/III). The objective of this study is to compare bulk semen parameters of men with varicoceles and MTS versus varicocele alone.

Methods: Men with a Grade II/III or III/III palpable left sided varicocele and baseline semen parameters were examined. Varicocele was confirmed by scrotal ultrasound demonstrating pampiniform venous dilation. In cases of recurrent varicocele after previous surgical repair, sustained reversal of pampiniform venous flow with Valsalva was demonstrated. Pelvic doppler ultrasounds were performed to determine whether MTS was present. MTS was diagnosed based on both >50% narrowing of the left CIV as it crosses under the right CIA and abnormal distal venous waveform. Baseline semen and hormonal parameters were analyzed with two sample t-tests.

Results: Of the 20 patients examined, 10 were found to have both a left varicocele and MTS. The results of our analysis are in Table 1. No differences were noted in age, sperm concentration, total motile count, FSH, or total testosterone. Men with a left varicocele and MTS presented with lower total motility than men without MTS.

Conclusions: In our initial cohort of men with left varicocele and semen analysis results, patients with concurrent MTS were found to have lower overall sperm motility. Further research is needed in larger cohorts to confirm these findings.

Table 1

	MTS (n = 10)	No MTS (n = 10)	p (two-sided)
Age (years)	29.3 ± 8.6	34.5 ± 6.8	0.15
Concentration (million/mL)	26.3 ± 17.0	22.22 ± 36.9	0.75
Total motility (%)	23.3 ± 11.7	42.23 ± 26	0.05
Total Motile Count (million)	14.3 ± 11.1	31.9 ± 68.7	0.43
Recurrent left varicocele	3	6	0.18
Total testosterone (ng/dL)	517 ± 146	551 ± 204	0.68
FSH (IU/L)	4.7 ± 3.0	7.7 ± 4.8	0.13

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Previous Use of Intracavernosal Injections is Associated with Higher Rates of Intraoperative or Postoperative Inflatable Penile Prosthesis Complications: A Large Multi-institutional Analysis

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Background: Intracavernosal injections (ICI) are a standard treatment for men with erectile dysfunction refractory to oral medications. ICI can be associated with corporal scarring which theoretically could make insertion of penile prosthesis more difficult. We sought to evaluate whether a history of ICI increased complications from inflatable penile prosthesis (IPP) using a large multi-institutional database.

Methods: A retrospective review was performed of IPPs from an international database of 16 expert implanters at 16 different institutions from 2016-2021. All primary and revision IPP cases were included. Patients with indeterminate of ICI history as well as those with indeterminate covariate history were excluded. Covariates investigated included Age, BMI, Diabetes Mellitus, hypertension, cardiac and/or peripheral vasculopathy, current smoking status, history of radiation and history of radical prostatectomy for prostate cancer. Outcomes assessed were intraoperative complications (proximal/distal perforation, proximal/distal corporal crossover, and urethral injury), postoperative non-infectious complications (erosion, hematoma formation, dehiscence, device malfunction, etc.) and postoperative infection. Patients were stratified by history of ICI and between-group differences in covariate risk factors were assessed with serial t-test or fisher's exact test as appropriate. Multivariate logistic regression analysis was used to assess for predictors of intraoperative complications, postoperative non-infectious complications and postoperative infection.

Results: A total of 3110 patients met inclusion criteria of which 914 (29.4%) had a history of ICI. On average, patients with a history of ICI tended to be older (62 vs. 63) and were more likely to have vasculopathy, as well as prior radical prostatectomy and/or radiation. On multivariate logistic regression, a history of ICI as well as current smoking and a history of radiation were all significant predictors of intraoperative complications (OR 2.08, p = 0.007, OR 2.02. p = 0.014, OR 2.27, p = 0.035 respectively. A history of ICI and patient age were both significant predictors of non-infectious postoperative complications (OR 1.37, p = 0.018, OR 1.02, p = 0.017 respectively). None of the investigated covariates were significant predictors of postoperative infection.

Conclusion: This large multi-institutional investigation supports the hypothetical notion that a history of ICI may predispose patients to increased risk in IPP surgery. Of note, patients with ICI history experienced intraoperative complications at over twice the expected rate when adjusted for confounders, and an association of similar magnitude was seen for patients who are current smokers and those with a history of radiation for prostate cancer. This is the largest study to date investigating the relationship between ICI history and complications during and after IPP placement. These results and the specific changes in complication risk may aid Urologists and their patients in both counseling and treatment of erectile dysfunction.

	ICI (n = 555)	No ICI (n = 766)	*p* value
Proximal Perforation	5 (0.9%)	5 (0.7%)	0.75
Distal Perforation	1 (0.2%)	4 (0.5%)	0.45
Proximal Crossover	1 (0.2%)	2 (0.3%)	1.00
Distal Crossover	4 (0.7%)	7 (0.9%)	0.76
Urethral Injury	1 (0.2%)	1 (0.1%)	1.00
Total Intraoperative Complications	12 (2.2%)	19 (2.5%)	0.85
Non-infectious Postoperative Complications	16 (2.9%)	17 (2.2%)	0.48
Infection	12 (2.2%)	25 (3.3%)	0.24

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Pharmacovigilance Analysis of Melanoma Adverse Events in Men Treated with Sildenafil for Erectile Dysfunction

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Background: Phosphodiesterase type-5 inhibitors are the first line of treatment for erectile dysfunction. In 2016, the Food and Drug Administration issued a warning regarding a possible association between phosphodiesterase type-5 inhibitors and melanoma. It is postulated that melanoma is associated with BRAF gene mutations resulting in the downregulation of the phosphodiesterase-type 5 pathway. In their latest update, the Food and Drug Administration stated that no action is necessary based on the available information. Therefore, we sought to conduct a pharmacovigilance analysis to examine the association between phosphodiesterase type-5 inhibitors and melanoma and to identify potential confounders.

Methods: We collected spontaneous adverse drug reactions for men who used sildenafil for erectile dysfunction captured in VigiBase (1968-2019), the World Health Organization's global database of individual case safety reports. Our primary endpoint was cutaneous or ocular melanoma. The disproportionality signal for melanoma with sildenafil use was reported using the reporting odds ratio (ROR), the odds of having the adverse event (melanoma) with the drug of interest (sildenafil) compared to the odds of the same event occurring with all other drugs in the database. The ROR was only reported if the empirical Bayes estimator, a more robust measure of association for rare events, met the threshold value for signal detection. We examined confounding by (1) indication, (2) dose, (3) age at report submission, (4) region, (5) stimulated reporting before and after 2014 when there was a sharp increase in awareness about the topic, (6) another phosphodiesterase type-5 inhibitor (tadalafil), (7) drugs prescribed for erectile dysfunction with different mechanisms of action (prostaglandin E1, testosterone, and papaverine), (8) drugs unrelated to erectile dysfunction but prescribed among the same age group (tamsulosin, metoprolol, and metformin), and (9) drugs associated with non-melanoma skin cancer (irbesartan and valsartan).

Results: We identified 11,250 reports of cutaneous and/or ocular melanoma, of which 763 (6.9%) were reported with sildenafil use among men. Among men who used sildenafil, most reports were among men 45-64 years of age (21.8%), originated from the Americas (99.6%), and were reported after 2015 (99.5%). We found a significant disproportionality signal of melanoma reports with sildenafil use for erectile dysfunction (ROR 90.0, 95%CI 80.6-100.4). More reports were recorded among men ≥45 years (ROR 34.8, 95%CI 30.8-39.3) and after 2014 (ROR 98.8, 95%CI 91.0-107.2). We also found a dose-response relationship with higher doses of sildenafil (≥ 50 mg) being associated with melanoma (ROR 12.3, 95%CI 9.5-15.9), but not lower doses. Similar trends were found for tadalafil across confounding variables. Other drugs with different mechanisms of action used for erectile dysfunction, drugs unrelated to the condition but prescribed among the same age group, and drugs associated with non-melanoma skin cancer did not meet the threshold for significance.

Conclusions: Herein, we found that phosphodiesterase type-5 inhibitors prescribed for erectile dysfunction are associated with cutaneous and ocular melanoma. While there may be confounding by age, region, dose, and stimulated reporting, our results support the need to keep sildenafil on the Food and Drug Administration's list of drugs with potential signals of serious risks.

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Single Time Point Total Testosterone to Predict 24-Hour Average Concentration of Total Testosterone in Hypogonadal Men Treated with an Oral Testosterone Undecanoate Softgel (JATENZO®)

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Background: In 2019, a novel, first-in-class testosterone (T) replacement therapy (TRT), oral testosterone undecanoate (TU) was approved by the U.S. FDA for the treatment of male hypogonadism. During clinical trials, dose adjustments were based on 24-hr average T concentration (Cavg) because single T measurements were considered less accurate. Subsequent, concordance analyses for this oral TU product have shown that a single total T value 6 hrs after the morning oral TU dose best corresponds to Cavg. Nonetheless, a conversion factor for T values obtained at other post-dose time points would be useful for healthcare providers (HCPs) and ease potential scheduling challenges for patients. Consequently, the relationship between other T sampling time points and Cavg was examined to determine if a reliable conversion factor could be derived to help HCPs monitor a patient's serum T concentration at times other than 6 hrs after oral TU administration.

Methods: Hypogonadal men, age 18-65 y/o, were recruited into a randomized, open-label, multicenter, dose-titration trial. Overall, 166 men were randomized into the oral TU arm. Dose titration was based on Cavg calculated from serial pharmacokinetic (PK) samples. There were three pre-designated PK visits, to individualize the appropriate TU dose and to achieve a eugonadal T Cavg at final study visit. Ratios between different timepoints and Cavg were determined for PK samples following morning drug administration.

Results: Overall, 87.3% (95% CI: 81.3%, 92.0%) of hypogonadal men had a final Cavg in the eugonadal range, with a mean serum total T = 488.7 ± 154.5 ng/dL (16.95 ± 5.37 nmol/L). Pooled values from all PK days demonstrated a linear relationship between T concentrations at 4, 6, and 9 hrs and Cavg ($p < 0.0001$). Visit and time of sampling interaction were not statistically significant ($p >> 0.50$), indicating consistency in results among PK visits and among sampling timepoints. A factor was derived to enable conversion of T values assessed at a time other than 6 hrs (post oral TU dose) into a close approximation of Cavg: 1/[1.870 - 0.14 x (hours after AM dose)]. Therefore, a sample drawn at 4 hrs after the morning oral TU dose would be multiplied by 0.75; while one drawn at 8 hrs would be multiplied by 1.33.

Conclusions: T Cavg can be approximated after morning JATENZO administration if a blood sample cannot be collected precisely 6 hrs thereafter.

Hours after Dose Oral TU Administration	Conversion Factor to Normalize T Value to C_{avg}
4	0.76
4.5	0.81
5	0.85
5.5	0.91
6	0.97
6.5	1.04
7	1.12
7.5	1.22
8	1.33
8.5	1.47
9	1.64

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Cardiometabolic Preventative Care in Men Presenting with Erectile Dysfunction

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Background: Men generally underutilize the healthcare system, as compared to women, with lower rates of preventative visits and higher rates of many chronic conditions. As a medical condition that often drives men to seek care, erectile dysfunction (ED) commonly has a vasculogenic etiology and may predict future cardiovascular events. We hypothesize that men presenting with ED as opposed to alternative diagnoses are less engaged with physical and mental preventative health, offering a potential opportunity to improve care.

Methods: Male patients presenting to a multidisciplinary men's health clinic were asked to complete a preventative care men's health checklist. A convenience sample of self-reported questionnaires for the year preceding the COVID pandemic (Mar 2019-Feb 2020) were collected and charts reviewed for demographics and visit information. Checklist and patient data were compared between men with a primary diagnosis of ED and men with other urologic diagnoses. Wilcoxon ranked sum tests were employed for nonparametric continuous data while Pearson's chi squared and Fisher's exact tests were used for categorical data. SPSSv26 was used for all statistical analyses with $p < 0.05$ considered significant.

Results: During the study period, 1,706 men completed a men's health checklist. A sample of 803 men with readily available electronic data was selected for inclusion, 120 (14.9%) of which had a primary diagnosis of ED. Median age was similar between ED and non-ED patients (62.0 vs. 64.2, $p = 0.08$). No significant difference in the frequency of ED diagnosis was noted across race ($p = 0.14$) or ethnicity ($p = 0.12$). Body mass index (BMI) was higher among men presenting with erectile complaints (28.7 vs. 27.5, $p = 0.003$) as well as self-reported rates of weight struggles (24.1% vs. 14.5%, $p = 0.009$). Over 94% of all men reported that they had seen their primary care physician within the recommended timeframe (1-2 years based on patient age) with similar rates between ED and non-ED groups ($p = 0.70$). Completion rates of recommended cardiometabolic screening including blood pressure assessment ($p = 0.79$), lipid panel ($p = 0.52$), and fasting glucose ($p = 0.53$) were likewise comparable. Men with ED were much more likely to self-identify as needing help with their mental health (16.8% vs. 6.4%, $p < 0.001$).

Conclusions: While the vast majority of men reported routine primary care evaluation, higher BMI and self-reported difficulties with weight were more common in men with ED compared to those with other urologic complaints. Mental health concerns, which can impact cardiometabolic risk, are more commonly reported by men with ED and warrant further exploration at individual and population levels.

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The Anatomic Diagnosis of Venous Leak Using CT Cavernosography

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Background: Penile duplex doppler ultrasound (DDUS) has been the gold standard for the evaluation of erectile hemodynamics since the 1980s, however anatomic detail and description is limited. CT cavernosography (CTC) is a new method for evaluating penile hemodynamics and provides a detailed anatomic view of the pathways of venous leak. To date, there has been no standardized anatomic description of penile venous leak erectile dysfunction (ED). The objective of this study is to evaluate patients with EDth erectile dysfunction usingwith CTC, describe anatomic variations of venous leak, and compare the diagnosis of venous leak ED on CTC to DDUS.

Methods: Retrospective review was performed for all patients with erectile dysfunction who underwent CTC and DDUS from July 2019 to October 2021. Patient demographics, laboratory data, erectile dysfunction history, imaging, and surgical history were collected. Subgroup analysis was performed on patients found to have venous leak on CTC as well as for patients who had also undergone DDUS. Venous leak on CTC was divided into three anatomical subgroups: superficial (entering the saphenous system), deep (entering the internal iliacs), and spongiosal leak (entering the corpus spongiosum of the urethra).

Results: 185 patients with erectile dysfunction underwent evaluation with CTC. 157 (84.9%) were found to have venous leak on CTC. Of this group, 69.4% (109/157) were found to have multiple anatomic types of venous leak, as displayed in Table 1.

Conclusions: CT cavernosography provides substantial anatomic detail regarding veno-occlusive disease in erectile dysfunction compared to DDUS alone. This is the first study to demonstrate multiple anatomic pathways of venous leak which suggests the complexity of veno-occlusive disease has been previously underestimated. A k. This study suggests that a significantly higher proportion of men will be found to have veno-occlusive disease using CTC compared to DDUS, and tand suggests the complexity of veno-occlusive disease has been previously underestimated. While further study is required, these preliminary results raise the possibility of occult venous leak in many men who might be best served by earlier surgical management.

Table 1: Anatomic Type of Venous Leak on CTC

Type of Venous Leak	N (% out of 157)	Type of Venous Leak	N (% out of 157)
Superficial Only	12 (7.6)	Superficial and Spongiosal	5 (3.2)
Deep Only	32 (20.4)	Deep and Spongiosal	4 (2.5)
Spongiosal Only	4 (2.5)	Superficial and Deep	59 (37.6)
		All three types	41 (26.1)

Table 2: Diagnosis of Venous Leak using CTC and DDUS

	(+) Venous Leak DDUS	(-) Venous Leak DDUS
(+) Venous Leak CTC	16 (25.8%)	36 (58.1%)
(-) Venous Leak CTC	5 (8.1%)	5 (8.1%)

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Predictors of Mental Health Concerns in a Men's Health Clinic

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Background: Mental health is increasingly recognized as a critical component of overall health status. Urologic diseases commonly impact patients' mental wellbeing, especially considering the sensitive nature of many male urologic conditions. Despite the need for mental health screening as a component of urologic care, most providers are ill prepared to recognize individuals at highest risk of mental illness. The current study is designed to tabulate rates of self-reported mental health struggles and identify factors differentiating men reporting such struggles among men presenting to a men's health clinic.

Methods: Each urologic patient presenting to a multidisciplinary men's health clinic was asked to complete a self-reported men's health checklist based on preventative health guidelines in addition to weight and mental health screenings. A retrospective sample of checklists completed between March 1, 2019 and February 29, 2020 was reviewed. Medical records were queried to supplement patient and visit information. The cohort was subdivided based on "yes" vs. "no" responses to the question asking if respondees were "struggling with mental health and in need of help." Clinical data and other checklist responses were compared between men reporting mental health struggles and those not reporting such struggles using Wilcoxon ranked sum tests and Pearson's chi-squared or Fisher's exact tests, as appropriate. SPSSv26 was used for all statistical analyses with $p < 0.05$ significance level.

Results: A sample of 803 men with available checklist data was selected from a total of 1,706 during the study period. After excluding 11 patients with missing responses to the mental health question, data from 792 unique patient checklists were included for analysis. Of those responding, 8.0% (n = 63) of patients identified as struggling with mental health and looking for help. There was a significant difference in the distribution of age with a lower median in the mental health struggles (MHS) group (59.7 vs. 64.2, $p = 0.03$). BMI was conversely higher in MHS (29.4 vs. 27.5, $p = 0.003$) with associated self-reported rates of weight struggles of 52.5% for MHS vs. 12.7% for non-MHS ($p < 0.001$). The three most common primary diagnoses were unevenly distributed ($p = 0.001$) with a higher rate of ED in the MHS group (47.6% vs. 23.5%), lower rate of prostate cancer (23.8% vs. 48.2%), and similar rates of benign prostatic hyperplasia (28.6% vs. 28.3%). Men in both groups reported high rates of compliance with recommended primary care follow up (94.7% vs. 97.8%, $p = 0.15$).

Conclusions: While a minority of men presenting to a men's health clinic reported mental health difficulties in need of attention, these men tended to be younger, have a higher BMI, and present with ED as a primary complaint. These factors should continue to be explored and kept in mind during patient encounters to better address the mental health needs of urologic patients.

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Adjuvant Dexamethasone and Dexmedetomidine in Bupivacaine Penile Nerve Block during Circumcision

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Background: Circumcision is one of the most common procedures performed by urologists in the United States. Surgeons often administer a perioperative penile nerve block with a long-acting local anesthetic to minimize pain and decrease postoperative opioid use. Recent studies in non-urologic surgical fields demonstrated that local nerve blocks combining a long-acting local anesthetic with either dexamethasone or dexmedetomidine have a faster onset and prolonged analgesia with minimal adverse effects. The purpose of this study is to evaluate the analgesic effectiveness of the addition of these adjuvant medications in penile nerve block performed during adult circumcision.

Methods: This is a retrospective, single institution, IRB-approved study of adult male patients undergoing circumcision from January 2019 to October 2021. Patients received an intraoperative penile nerve block prior to incision with either 0.5% bupivacaine (+/- 1% lidocaine) or a combination of 0.25% bupivacaine + 70mcg dexmedetomidine + 4 mg dexamethasone. The primary outcome was maximum pain score (Analog Pain Scale) in the post-anesthesia care unit (PACU). The secondary outcomes were intraoperative and postoperative opioid use (total morphine equivalents, TME). An additional analysis was performed to control for patients with diabetes.

Results: A total of 42 men (median 42 years old) underwent circumcision with a median duration of 33 minutes. Sixteen (38%) received 0.5% bupivacaine, 5 (12%) received 1:1 0.5% bupivacaine + 1% lidocaine, and 21 (50%) received the combination block. Fifteen (36%) patients had diabetes, and median hemoglobin A1c was 7.9%. Mean pain scores in PACU were not significantly different between the block groups. However, for non-diabetic patients, pain scores were significantly lower for the combination block group (0.46 vs. 1.6; $p < 0.05$). Intraoperative and postoperative opioid use was not significantly different between block groups, however, opioid use in the PACU was significantly lower in non-diabetic patients (0.7 vs. 4.0 TME, $p < 0.01$). Intraoperative bradycardia occurred in three patients, but none required intervention.

Conclusions: Intraoperative penile nerve blocks that combine long-acting local anesthetics with dexmedetomidine and dexamethasone can safely enhance immediate post-operative analgesia in non-diabetic patients undergoing circumcision. In patients with diabetes, the use of adjuvant non-opioid pain medications in the preoperative or intraoperative period may reduce opioid use postoperatively.

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Risky Business; The Use of Unregulated Phosphodiesterase Inhibitors in Healthcare Supplements

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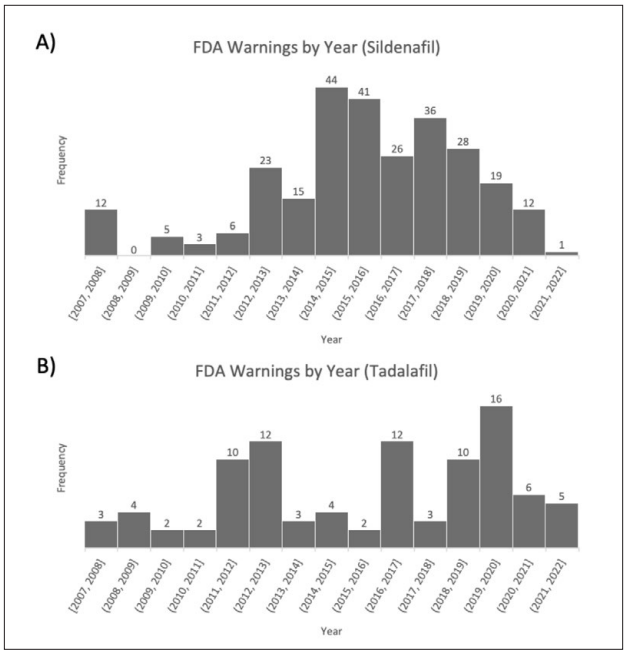
Background: Sildenafil and tadalafil are two Food and Drug Administration (FDA)-approved prescription drugs used to treat erectile dysfunction (ED). Though highly effective in the management of ED, they can cause adverse reactions due to their vasodilatory effects, and are contraindicated in men on nitrates. Lack of regulation of dose amounts can increase the risk of significant side effects. Additionally, the metabolism of PDE5i may be affected by other medications, leading to potential toxicity. In this study, we investigated reports of PDE5i in healthcare supplements unregulated by the FDA to characterize unmonitored exposure to these medications in the community.

Methods: The publicly available Food and Drug Administration's (FDA) "Health Fraud Data Base" (https://www.fda.gov/consumers/health-fraud-scams/health-fraud-product-database) includes unapproved products that have been subject to FDA health fraud related violations. The database was queried with keywords "sildenafil" and "tadalafil." Descriptive analyses were performed on the resulting returns.

Results: Between 2007 and 2021, there were 446 products identified by the FDA as containing either sildenafil, tadalafil, or both. The basis for FDA warnings ranged from "products marketed to cure, mitigate or treat disease" to the use of undeclared ingredients. 338 products (76%) were issued a public notification while 102 (23%) were recalled. Other FDA actions included safety alerts and news releases. 36% of products were identified as being imported items or international goods. There were 77 products readily available on US-company websites such as Amazon.com, Walmart.com, and Ebay.com.

Conclusions: Unregulated products containing PDE5i are commonly available to the United States public through mainstream consumer websites and in retail establishments. Products reported on the FDA website are likely a subset of a larger number of products in the community with unreported PDE5i. Urologists, other healthcare providers, and patients generally must be aware of the prevalence of pharmaceuticals within healthcare supplements and the hazards they present.



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Multicenter Comparison of Single Dilation Versus Sequential Dilation in Primary Inflatable Penile Prosthesis Placement

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Background: In primary implant patients without significant corporal fibrosis, penile implant surgical technique varies in implementation of either single dilation (SingD) or sequential dilation (SeqD). Vigorous debate exists regarding both methods, but there is no robust evidence supporting one technique over the other in the literature. We compared intraoperative complications and postoperative outcomes from a large international database of inflatable penile prostheses (IPP) performed by expert implant surgeons utilizing either approach.

Methods: IPP cases performed by six international implanters from 2016-2021 were identified. All primary implant cases were included, while revision cases, salvage operations, and patients with evidence of corporal fibrosis were excluded. Intraoperative complications and postoperative noninfectious outcomes were assessed between the two groups. These included proximal/distal perforation, cylinder crossover, and urethral injury.

Results: 2050 IPP cases were identified, and 1527 (75%) primary IPP cases with no evidence of corporal fibrosis (mean age 60 ± 10) were included. SingD was performed in 906 (59%) of cases while SeqD was performed in 619 (41%) of cases. There were no differences between groups with respect to demographic variables. Cylinder length was longer in the SeqD group vs the SingD group (18.1 cm ± 3 vs. 19.2 cm ±2 $p < 0.001$). There were 9 (0.6%) intraoperative complications in total, all of which were in the SeqD group ($p = 0.123$). Of these intraoperative complications, 6 (67%) patients sustained a distal crossover while 1 (11%) experienced a distal perforation and 1 (11%) had a proximal crossover. Postoperatively, 75 (89%, $p < 0.01$) of complications were in the SeqD group and 9 (11%) in the SingD group. Of these postoperative complications, there were 21 (28%) erosion events, 14 (67%) of which were in the SeqD group vs. 7 (33%) in the SingD group ($p = 0.02$).

Conclusions: In our international multicenter assessment of primary IPPs without corporal fibrosis performed by expert surgeons, patients undergoing sequential dilation appear to have an overall benefit in total cylinder length. Sequential dilation, however, may confer greater risk of postoperative complications, including corporal erosion.

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New Findings Regarding Independent Predictors of Poor Corporal Integrity in Penile Implant Recipients: A Multicenter International Investigation

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Background: Predictors of intraoperative corporal perforation and delayed cylinder complications in inflatable penile prosthesis (IPP) placement have not been well-delineated in the literature. We evaluated our retrospective multi-institutional database of IPP surgeries performed by expert implant surgeons to identify risk factors that are predictive of the development of these non-infectious complications.

Methods: IPP cases performed by six international implanters from 2016-2021 were identified. All primary and revision cases were included. Salvage cases for infection were excluded. Demographic characteristics, intraoperative variables, and postoperative outcomes were assessed. Poor corporal integrity (PCI) was defined as intraoperative corporal complications (proximal and/or distal perforation of the corpora, corporal crossover) or postoperative corporal complications (cylinder erosion, extrusion, impending erosion, or deformity). Risk factor analysis and stepwise linear regression were performed to identify predictors of PCI.

Results: A total of 2050 cases (mean age 61.3 ± 10), across 6 separate institutions were assessed. There were 57 (2.8%, mean age 64 ± 9, $p = 0.07$) cases of PCI. Intraoperative perforations comprised 29 (50.9%) of these complications, while the other 28 (49.1%) were either cylinder erosion, extrusion, impending erosion, or deformity due to PCI. The rates of diabetes ($p = 0.94$), vascular disease ($p = 0.388$), HTN ($p = 0.53$), smoking ($p = 0.064$), presence of corporal fibrosis ($p = 0.15$), history of ICI ($p = 0.60$) and history of priapism ($p = 0.34$) all had no statistically significant effect on corporal integrity. The only independent risk factor for PCI was a prior history of penile implant infection (OR 13.6, 95% CI 2.4-76.3, $p = 0.003$).

Conclusions: Our multicenter analysis found that prior history of penile implant infection is the lone independent risk factor for complications associated with poor corporal integrity in our series. Recognizing this risk factor preoperatively can allow for improved patient-specific counseling and changes in surgical strategy to potential prevent these complications.

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Patient Reported Outcome Measures following Hyperbaric Oxygen Therapy for Radiation Cystitis: Updated Results from the Multicenter Registry for Hyperbaric Oxygen Therapy Consortium

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Backgroound: Prior studies demonstrate hyperbaric oxygen (HBOT) is associated with reduced bladder bleeding interventions in hemorrhagic radiation cystitis. Previously, we demonstrated feasibility of collecting urine related patient reported outcome measures (PROMs) via the Multicenter Registry for HBOT. The purpose of this study is to evaluate change in urinary related PROMs before and after HBOT in a larger, updated cohort.

Methods: Prospectively collected data from 19 sites in the Multicenter Registry for Hyperbaric Oxygen Therapy Consortium were analyzed. Measures included a hematuria scale adapted from the RTOG/EROCT radiation scale for cystitis, Urinary Distress Inventory (UDI) and a question on hematuria severity and quantity. Data obtained on the first and last days of HBOT were compared using Wilcoxon rank sum test. Proportions were compared using chi-square tests.

Results: 213 patients had complete RTOG/EROTC hematuria data, 137 had UDI data and 130 had both. Patients were on average 70 (+/- 12) years old, 50/213 were diabetic, 80/213 are current or former smokers and 181/213 developed radiation cystitis due to prostate cancer related radiation treatment. Referral for HBOT occurred approximately 7.0 +/- 5.8 years following radiation. The average number of treatments was 36 +/- 11. RTOG/EROTC hematuria scores were significantly improved post HBOT (2.3 pre vs. 1.0 post, $p = 0.001$). UDI scores were significantly improved, post HBOT (35.8+/-26.4 vs. 26.6+/-22.7, $p < 0.01$).

Conclusions: In a novel, multi-institutional prospective data set, we demonstrate HBOT is associated with improved urine related PROMs for individuals undergoing HBOT for radiation cystitis. Continued expansion of the registry may provide more generalizable results and allow for analysis of factors leading to change in UDI scores.

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Urinary Comprehensive Genomic Profiling Predicts Clinical Recurrence in Patients Undergoing Surveillance for Urothelial Carcinoma

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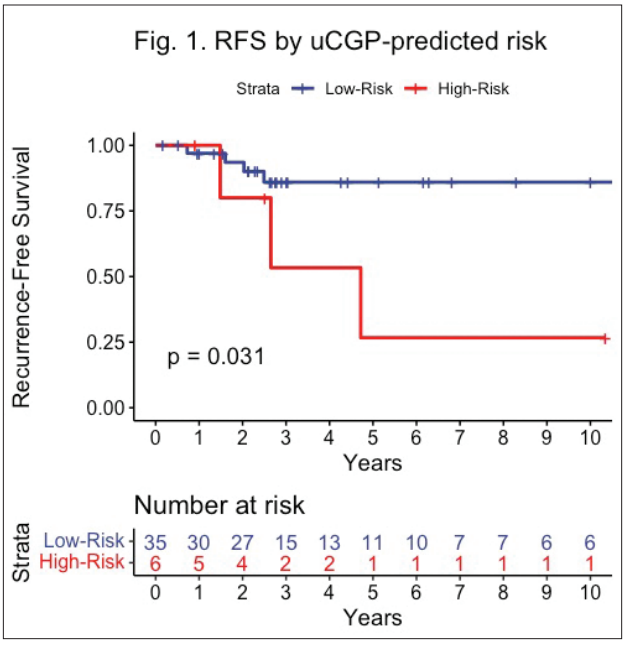
Background: Risk stratification of patients with urothelial carcinoma (UC) remains a major clinical challenge, with high rates of recurrence and disease progression. Urinary comprehensive genomic profiling (uCGP) has significant potential to aid in this endeavor.

Methods: uCGP was performed on blinded urine specimens collected at Massachusetts General Hospital prior to cystoscopy. 41 subjects with a history of UC but negative by surveillance cystoscopy at time of collection were analyzed. Urine DNA was sequenced and comprehensively profiled across 60 genes using the CLIA-validated UroAmplitude test (Convergent Genomics). Patients were predicted to be at high or low risk of recurrence using a machine learning algorithm based on genomic features. Cox proportional hazards models were used to estimate the association between risk predictions and recurrence-free survival.

Results: Stage and grade distribution of the primary tumor at diagnosis was Ta (73%), T1 (22%), T3 (2%), Tx (2%), with concomitant CIS in 10%; 41% low-grade (LG) and 59% high-grade (HG). Mean follow-up since specimen collection was 53.3 months. High recurrence risk was predicted in 15% (6 of 41) of subjects who had a positive UroAmplitude disease classification but negative cystoscopy. Among predicted high-risk patients, 50% had a clinical recurrence (mean time to recurrence 35.3 mo), all of which were HG. One notable high-risk patient with an initial TaLG tumor experienced a T4aHG recurrence with invasion into the prostate. uGCP-based recurrence prediction anticipated this clinical diagnosis by 17.8 months. Among 35 predicted low-risk patients, only 4 experienced recurrence (all TaLG; mean time to recurrence 20.5 mo). Recurrence-free survival was significantly worse in uGCP-predicted high-risk vs. low-risk patients (HR 4.5, 95% CI 1.01-20.2; Fig. 1). Among 10 subjects with no detectable mutations, no pathologically confirmed recurrence was observed (mean surveillance follow- up 45.3 mo).

Conclusions: uCGP can predict future recurrence of high-risk UC with substantial lead time. If validated with further studies, uCGP may provide a powerful way to risk-stratify patients and enable strategies for intensification (or deintensification) of UC management based on genomic risk.



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The Association of Baseline Frailty with Survival among Older Adults Undergoing Radical Cystectomy for Bladder Cancer

John Ernandez, BA[1], Sumedh Kaul, MS[2], Aaron Fleishman, MPH[2], Ruslan Korets, MD[3], Peter Chang, MD, MPH[3], Andrew Wagner, MD[3], Simon Kim, MD[4], Joaquim Bellmunt, MD, PhD[5], Nima Aghdam, MD[6], Aria Olumi, MD[3], Dae Kim, MD, MPH, ScD[7], Boris Gershman, MD[3]

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Background: Frailty is increasingly recognized as an important component of geriatric assessment in older adults and an important predictor of clinical outcomes. We hypothesized that baseline frailty is an independent predictor of survival for older adults undergoing radical cystectomy (RC) for bladder cancer. Herein, we examined the associations of a validated, claims-based frailty index (CFI) with survival in a large, population-based cohort.

Methods: Using the SEER-Medicare linked database, we identified older adults aged 66-89 years diagnosed with Tany Nany cM0 urothelial carcinoma of the bladder from 2000-2017 who underwent RC. Baseline CFI was calculated using a 12-month pre-diagnosis period. The associations of CFI with survival outcomes were assessed using the Kaplan-Meier method and Cox multivariable regression.

Results: A total of 5,916 patients were included in the study cohort, including 3,389 who were robust (CFI < 0.15), 2,247 who were pre-frail (CFI 0.15 to < 0.25), 232 who were mildly frail (CFI 0.25 to < 0.35), and 48 who were moderately-to-severely frail (CFI ≥ 0.35). Median follow-up was 37.0 (IQR 16.0-84.0) months. During follow-up, a total of 3,998 deaths occurred. Before adjustment, increasing level of frailty as reflected by the CFI was associated with worse cancer-specific survival, other-cause survival, and overall survival (Figure 1). In multivariable modelling, increasing CFI was independently associated with worse all-cause mortality, cancer-specific mortality, and other-cause mortality (Table 1).

Conclusions: Among older adults undergoing RC for bladder cancer, increasing baseline frailty as measured by the CFI was associated with worse survival outcomes, even after adjustment for patient and tumor characteristics. The CFI provides an objective assessment that can be used to improve decision-making in older adults with bladder cancer.

Figure 1: Overall survival (OS) stratified by CFI.

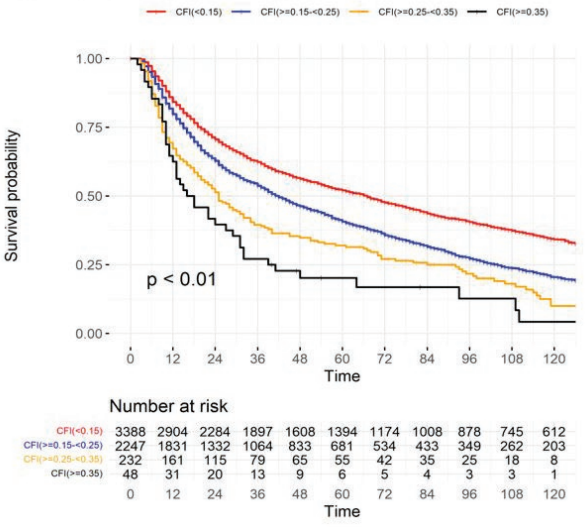

Table 1. Associations of CFI with all-cause mortality, cancer-specific mortality, and other-cause mortality.

CFI Modelling Strategy	Unadjusted HR (95% CI)	Fully Adjusted HR (95% CI)[1]	Fully Adjusted HR (95% CI)[1]
All-cause Mortality			
CFI (Continuous)	1.51 (1.43, 1.60)*	1.26 (1.17, 1.35)*	—
CFI (Discrete)			
CFI <0.15	—	—	—
CFI ≥ 0.15 to < 0.25	1.40 (1.31, 1.49)*	—	1.19 (1.11, 1.29)*
CFI ≥ 0.25 to < 0.35	1.96 (1.68, 2.28)*	—	1.41 (1.20, 1.67)*
CFI ≥ 0.35	2.70 (2.00, 3.66)*	—	1.54 (1.12, 2.12)*
Cancer-specific Mortality			
CFI (Continuous)	1.31 (1.22, 1.41)*	1.16 (1.05, 1.27)*	—
CFI (Discrete)			
CFI <0.15	—	—	—
CFI ≥ 0.15 to < 0.25	1.23 (1.14, 1.34)*	—	1.10 (1.00, 1.22)*
CFI ≥ 0.25 to < 0.35	1.55 (1.26, 1.89)*	—	1.27 (1.02, 1.59)*
CFI ≥ 0.35	2.26 (1.52, 3.36)*	—	1.45 (0.95, 2.20)
Other-cause Mortality			
CFI (Continuous)	1.88 (1.73, 2.05)*	1.45 (1.30, 1.61)*	—
CFI (Discrete)			
CFI <0.15	—	—	—
CFI ≥ 0.15 to < 0.25	1.68 (1.52, 1.87)*	—	1.34 (1.19, 1.52)*
CFI ≥ 0.25 to < 0.35	2.81 (2.24, 3.52)*	—	1.84 (1.43, 2.37)*
CFI ≥ 0.35	4.13 (2.55, 6.68)*	—	2.04 (1.22, 3.39)*

[1]Model adjusted for age, gender, marital status, Charlson index, smoking status, year of diagnosis, race, Hispanic origin, SEER registry, facility type, hospital bed size, NCI Center designation status, rurality, census tract poverty level, census tract income, census tract education level tumor grade, annual hospital cystectomy volume, receipt of neoadjuvant chemotherapy, T stage, pN stage, interaction term between T stage and receipt of neoadjuvant chemotherapy.
*Implies significance, $p < 0.05$

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Baseline Frailty and Perioperative Outcomes in Older Adults Undergoing Radical Cystectomy for Bladder Cancer

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Background: The perioperative morbidity of radical cystectomy (RC) is an important consideration for optimal decision-making in older adults with bladder cancer. Frailty, a component of geriatric assessment, has been associated with the morbidity of both surgical and non-surgical interventions in this patient population. Herein, we examined the associations between a validated, claims-based frailty index (CFI) and perioperative morbidity among a contemporary cohort of older adults undergoing RC for bladder cancer.

Methods: Using the SEER-Medicare linked database, we identified patients aged 66 to 89 years with Tany Nany cM0 urothelial carcinoma of the bladder diagnosed from 2000-2017 who underwent RC. Baseline frailty was assessed using the CFI, a validated deficit accumulation frailty measure, with a 12-month pre-diagnosis window. The associations of CFI with perioperative blood transfusion, prolonged hospitalization (defined as length of stay ≥90%-ile), and 90-day hospital readmissions were evaluated using logistic regression.

Results: A total of 5,916 patients formed the study cohort, including 3,389 who were robust (CFI < 0.15) and 2,527 who were pre-frail/frail (CFI ≥ 0.15). Overall, perioperative blood transfusion occurred in 1,499 (25%) of patients, prolonged hospitalization in 601 (10%) of patients, and 90-day readmission in 2,351 (40%) of patients. Before adjustment, increasing baseline CFI was associated with higher rates of perioperative blood transfusion, pLOS, and hospital readmission (Table 1). After multivariable adjustment, increasing level of frailty was independently associated with higher risks of prolonged hospitalization and 90-day hospital readmission, but not perioperative blood transfusion (Table 2).

Conclusions: The present study provides real-world, contemporary estimates of the perioperative morbidity of RC among older adults. Baseline frailty, as reflected by the CFI, was associated with increased risks of prolonged hospitalization and 90-day hospital readmission, even after adjusting for other patient and tumor characteristics.

Table 1. Rates of perioperative blood transfusion, prolonged hospitalization, and 90-day hospital readmission by baseline discrete CFI. Estimates represent frequency count (% rate).

CFI	Perioperative Blood Transfusion	Prolonged Hospitalization	90-day Hospital Readmission
CFI < 0.15	825 (24%)	273 (8%)	1,165 (34%)
CFI ≥ 0.15 to < 0.25	593 (26%)	275 (12%)	1,031 (46%)
CFI ≥ 0.25 to < 0.35	67 (29%)	43 (19%)	125 (54%)
CFI ≥ 0.35	14 (29%)	10 (21%)	30 (62%)
p-value	0.17	<0.01	<0.01

Table 2. Associations of CFI with perioperative outcomes.

CFI Modelling Strategy	Unadjusted OR (95% CI)	Fully Adjusted Continuous OR (95% CI)[1]	Fully Adjusted Discrete OR (95% CI)[1]
Perioperative Blood Transfusion			
CFI (Continuous)	1.21 (1.08, 1.35)*	0.96 (0.83, 1.10)	—
CFI (Discrete)			
CFI <0.15	—	—	—
CFI ≥ 0.15 to < 0.25	1.11 (0.99, 1.26)	—	0.88 (0.76, 1.02)
CFI ≥ 0.25 to < 0.35	1.26 (0.93, 1.69)	—	0.87 (0.62, 1.21)
CFI ≥ 0.35	1.28 (0.66, 2.35)	—	0.76 (0.38, 1.44)
Prolonged Hospitalization			
CFI (Continuous)	1.73 (1.50, 1.99)*	1.58 (1.32, 1.89)*	—
CFI (Discrete)			
CFI <0.15	—	—	—
CFI ≥ 0.15 to < 0.25	1.59 (1.33, 1.90)*	—	1.47 (1.19, 1.81)*
CFI ≥ 0.25 to < 0.35	2.60 (1.80, 3.66)*	—	2.19 (1.44, 3.27)*
CFI ≥ 0.35	3.00 (1.40, 5.86)*	—	1.94 (0.87, 3.98)
90-day Hospital Readmission			
CFI (Continuous)	1.74 (1.57, 1.93)*	1.36 (1.20, 1.55)*	—
CFI (Discrete)			
CFI <0.15	—	—	—
CFI ≥ 0.15 to < 0.25	1.62 (1.45, 1.81)*	—	1.28 (1.13, 1.46)*
CFI ≥ 0.25 to < 0.35	2.23 (1.71, 2.92)*	—	1.53 (1.13, 2.06)*
CFI ≥ 0.35	3.18 (1.78, 5.84)*	—	2.06 (1.13, 3.86)*

[1]Model adjusted for age, gender, marital status, Charlson index, smoking status, year of diagnosis, race, Hispanic origin, SEER registry, facility type, hospital bed size, NCI Center designation status, rurality, census tract poverty level, census tract income, census tract education level, tumor grade, annual hospital cystectomy volume, receipt of neoadjuvant chemotherapy, T stage, pN stage, interaction term between T stage and receipt of neoadjuvant chemotherapy.
*$p < 0.05$

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Radical Cystectomy Outcomes Based on Travel Distance in a Rural State
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Background: Radical Cystectomy (RC) is the standard of care for patients with non-metastatic muscle invasive bladder cancer (MIBC). Better outcomes are reported when RC is performed at high volume centers, which may lead to patients traveling further distances for care. We sought to exam the impact of travel distance on time to treatment (TTT) and clinical outcomes.

Methods: A prospectively maintained database of 220 patients undergoing RC from 2015-2021 was retrospectively reviewed. Distance traveled to treatment center by centroid of patient zip codes was classified as < 12.5 mi, 12.5-49.9 mi, and > 50 mi. Complications were graded and classified by the MSKCC system. Outcomes, TTT, and readmission to outside hospital (OSH) by distance traveled were compared.

Results: 114 patients with MIBC received neoadjuvant chemotherapy (NAC). There was no difference in TTT with NAC (p = 0.99) or time to consolidative surgery (p = 0.23) by travel distance (Figure 1). For 49 MIBC patients proceeding directly to surgery, time from diagnosis to RC was increased based on distance traveled (p = 0.04). There were no differences in overall complications, readmissions, 90d mortality, or length of stay (LOS) by travel distance when performing multivariable logistic regression including patient demographics and comorbidities (Table 1). All 32 patients readmitted to an OSH traveled >/= 12.5 mi (p < 0.001, Figure 2). For patients readmitted with low grade complications, most traveling >12.5 mi were managed at an OSH (p = 0.01, Figure 2). The majority of high-grade complications were readmitted to the treatment center (57.8%), although OSH readmission was still more frequent if traveling > 50 mi (Figure 2).

Conclusions: In a rural state with one high volume RC treatment center, many patients travel long distances for care. We saw an increase in time to treatment with increasing travel distance when surgery was the primary treatment, which was not seen when NAC was the initial treatment. We attribute this to surgery being performed at one center compared with NAC available at multiple sites in a wide geographic distribution. While low grade complications may be managed close to patients' homes, high grade complications often require readmission to initial treatment center. Statewide processes and collaboration defining complications that can be treated locally versus requiring return to treatment center may help to ameliorate the challenges associated with travel distance and recovering from radical cystectomy.

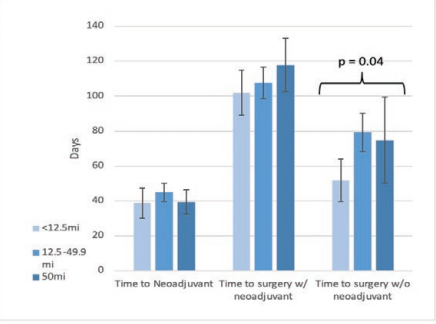
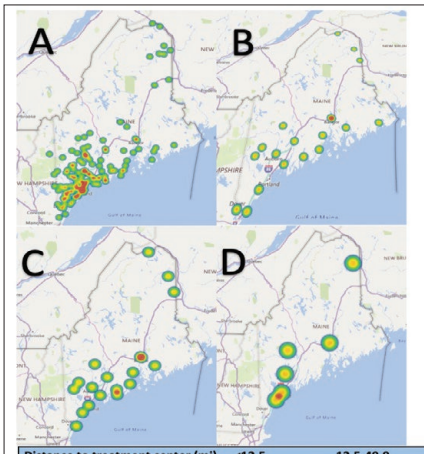


Figure 1. Time to initiation of neoadjuvant chemotherapy (NAC), time to consolidative surgery, and time to surgery without NAC based on distance traveled.



Distance to treatment center (mi)	<12.5	12.5-49.9	>50	p=
All Patients Readmitted to OSH (%) – MAP B				
Treatment Center	17 (100)	26 (57.8)	10 (43.5)	<0.001
OSH	0 (0)	19 (42.2)	13 (56.5)	
Patients Readmitted to OSH with low grade comp (%) - Map C				
Treatment Center	7 (100.0)	14 (46.7)	3 (30.0)	0.01
OSH	0 (0.0)	16 (53.3)	7 (70.0)	
Patients Readmitted to OSH with high grade comp (%) - Map D				
Treatment Center	10 (100.0)	12 (80.0)	7 (53.8)	0.03
OSH	0 (0.0)	3 (20.0)	6 (46.2)	

Figure 2. (Top) Heatmaps by patients' A) home zip code B) OSH readmissions C) low grade readmissions D) high grade readmissions. (Bottom) Readmission to OSH by complications.

Table 1. Effect of distance traveled to treatment center on complications, readmissions, and mortality by multivariable logistic regression analysis.

	Distance to Treatment Center (miles)		
	<12.5	12.5-49.9	>50
n =	54	103	63
Any Complication n (%)	44 (81.5)	81 (78.6)	48 (76.2)
Odds Ratio (95% CI)	ref	.642 (.232-1.77)	.512 (.172-1.52)
High Grade Complication n (%)	14 (25.9)	24 (23.2)	20 (31.7)
Odds Ratio (95% CI)	ref	.745 (.315-1.76)	1.29 (.501-3.30)
Readmission n (%)	17 (31.5)	45 (43.7)	23 (36.5)
Odds Ratio (95% CI)	ref	1.64 (0.76-3.55)	0.911 (0.38 - 2.19)
90 Day Mortality n (%)	3 (5.6)	7 (6.8)	2 (3.2)
Odds Ratio (95% CI)	ref	1.34 (.282-6.33)	0.53 (0.69-4.18)
Length of Stay >7d n (%)	15 (27.8)	34 (33.0)	20 (31.7)
OR (95% CI)	ref	1.69 (0.74-3.85)	1.20 (.477-3.04)

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Comparison Between Cytologic Processing Upper Urinary Tract Microbiopsies and Conventional Processing of Surgical Biopsies in Diagnosing Upper Tract Urothelial Carcinoma (UTUC)

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Background: We previously reported that cytologic processing of microbiopsies showed superior sensitivity for detecting high grade urothelial carcinoma (HGUC), compared with conventional processing. In this independent and larger cohort, we further evaluated the efficacy of cytologic processing of microbiopsies.

Methods: We reviewed the pathology database at a single institution for upper tract microbiopsies in which both surgical pathology and cytology processing were conducted concurrently from the same site. We excluded microbiopsies taken for non-urothelial diagnoses. Thirty-four patients had 64 paired microbiopsies. All microbiopsy specimens were collected from upper urinary tract including the ureter, renal pelvis and calyx using the Piranha 3F flexible ureteroscopic biopsy forceps. The same number of microbiopsies were taken for cytology and surgical pathology. The biopsy forceps was swirled in the cytorich red or formalin, and cleaned by swirling in normal saline between each biopsy. Holmium laser was used for hemostasis after both biopsies were complete if necessary. Cytologic processing involves making a cellblock from the visible fragments in the vial by pipetting directly to a Cellient cell block cassette. The rest of the supernatant is prepared into a ThinPrep for cytologic diagnosis. Surgical processing involves filtering the specimen through histology lens paper, folding the paper, processing in a standard tissue processor, and embedding the fragments in paraffin manually. McNemar's test was performed with Python and its Scipy package to compare the processing methods.

Results: When combined with both methods, 45 cases (70%) were diagnosed with urothelial carcinoma, whereas 41 (64%) cytologic specimens and 32 (50%) on the paired surgical biopsies were found to have urothelial carcinoma respectively. There was a statistically significant difference in diagnosing UTUC ($p = 0.039$). Cytologically processed microbiopsies had a sensitivity of 91%, while conventional processing has a sensitivity of 71%. 20 cases in this cohort were definitively diagnosed as high grade urothelial carcinoma by either method. 19 of these were diagnosed by cytological processing (95% sensitivity), and 8 were diagnosed by surgical processing (40% sensitivity). There was a statistically significant difference in diagnosing HGUC ($p = 0.002$). Furthermore, surgical processing resulted in 4 (6.25%) non-diagnostic samples with no tissue present for pathologic evaluation; Cytological processing resulted in only 2 (3.13%). Surgically processed biopsies resulted in 10 (15.6%) additional samples which were identified as being too scant of tissue, lacking in cells, or too denuded for adequate analysis and diagnosis.

Conclusions: Cytologic processing of upper urinary tract microbiopsies had a greatly improved efficacy in diagnosing Urothelial Carcinoma, particularly HGUC, as compared with the conventional surgical biopsy method. Improved sensitivity is likely related to the complete recovery of desquamated cells in the cytologic ThinPrep slide. Cytologically processed microbiopsies can add diagnostic information and guide clinical management. In light of these results, we strongly encourage the use of cytologically processed microbiopsies together with standard surgical biopsies.

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Utility of MRI-based Segmentation to Predict Parenchyma Volume Preservation after Partial Nephrectomy in Von Hippel Lindau Disease (VHLD)

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Background: Patients with von Hippel Lindau disease (VHLD) are at risk for multifocal, recurrent kidney tumors and cysts requiring multiple extirpative surgeries across their lifetime. This puts them at risk of developing kidney disease from volume loss secondary to partial or radical nephrectomy. Few studies have quantified renal volume preservation with pre- and post-operative MRI in a standardized manner. We sought to quantify the effect of partial nephrectomy on normal parenchyma volume loss, as well as its relationship to renal functional decline using MRI-based segmentation and volumetric analysis.

Methods: We identified VHLD patients undergoing partial nephrectomy from 2015-2021 with available pre- and post-operative MRI. Volume of renal tumors, cysts, and parenchyma of the operated kidney were acquired by semi-automated segmentation using ITK-SNAP of preoperative and postoperative MRI. Kidney parenchyma was defined as renal tissue not involved with tumors or cysts. Post-operative MRI and GFR were assessed after 3 months. eGFR was calculated using creatinine-based CKD-EPI 2021 equation. % parenchyma preserved was determined by 100*(post-operative parenchyma volume/preoperative parenchyma volume). % preoperative GFR preserved was obtained by 100*(post-operative GFR/preoperative GFR), Volumetric data was extracted using PyRadiomics library. Statistical analysis was conducted on StataSE 17.

Results: 82 patients (54 males with median age 48 years) were analyzed with median 3 (IQR: 2-5) tumors and 5 (IQR: 0-13) cysts per renal unit undergoing surgery. Post-operative MRI follow-up time was at median of 280 days (IQR: 238-405) post-nephrectomy. Median parenchyma volume loss was 46.3 cc (IQR: 27.6-66.3). Median preoperative GFR was 70 mL/min/1.73 m^2 (IQR: 58-89), and postoperative GFR was 65 (IQR: 52-81). On linear regression, % parenchymal preservation positively correlated with % preoperative GFR preserved after 3 months ($r = -0.641$, $p < 0.001$). On multivariate analysis, preoperative parenchyma volume ($p < 0.0001$), number of masses ($p = 0.044$), preoperative proteinuria ($p = 0.005$) and hypertension ($p = 0.019$) were predictors of postoperative GFR 3 months after nephrectomy . BMI ($p = 0.004$), age ($p = 0.001$), cyst volume ($p = 0.025$), cyst number($p < 0.0001$), and number of masses ($p = 0.042$) were predictors of post-operative parenchyma volume of the surgical unit.

Conclusions: These findings suggest that renal volume loss offers novel insight into renal function after surgery. Patients with VHL undergo medical imaging throughout their lifespan for tumor staging and assessment of recurrence. These initial findings support a novel imaging-based approach in the assessment and prediction of renal disease after resection of complex renal masses.

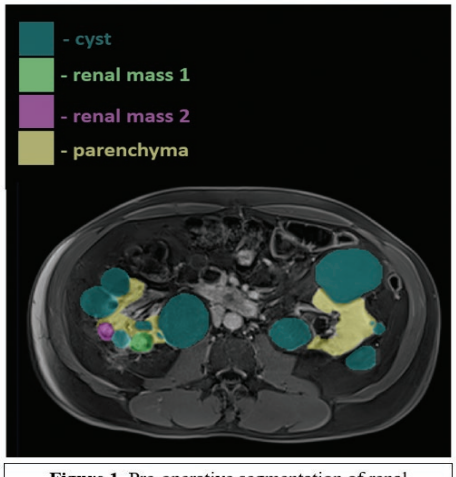

Figure 1. Pre-operative segmentation of renal parenchyma, tumors, and cysts via ITK-SNAP for determining the volumetric parameters

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Ileal Conduit versus Continent Urinary Diversion in Radical Cystectomy: An Analysis of 30-day NSQIP Outcomes

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Background: Continent urinary diversion at the time of radical cystectomy can provide patients with a more cosmetically pleasing and functionally normal lower urinary tract, but potentially at the cost of worse perioperative outcomes. The purpose of this study was to quantify the short-term burden associated with continent diversion relative to ileal conduit creation.

Methods: Patients who underwent radical cystectomy in 2019 and 2020 were identified in the American College of Surgeons National Surgical Improvement Program database using current procedural terminology codes. Patients were grouped by type of urinary diversion performed: ileal conduit versus continent diversion (neobladder or cutaneous pouch). Multiple logistic regression was used to examine the association between type of urinary diversion and 30-day outcomes, including post-operative complications, all-cause readmissions, and mortality.

Results: Of 4,951 patients who underwent radical cystectomy, 714 underwent continent diversion (14.4%). These patients were significantly younger (61.8 vs. 69.6 years, $p < 0.01$) and less likely to have diabetes (14.2% vs. 20.2%, $p < 0.01$), malnourishment (1.8% vs. 4.0%, $p < 0.01$), or a history of prior pelvic radiation (5.2% vs. 13.1%, $p < 0.01$) or surgery (45.8% vs. 51.5%, $p < 0.01$). A greater proportion of continent diversion patients experienced a post-operative complication (54.6% vs. 47.4%, $p < 0.01$) or readmission to the hospital (30.3% vs. 20.2%, $p < 0.01$). After adjustment, continent diversion patients had 1.5 (95% CI 1.2-1.8) and 1.8 (95% CI: 1.5-2.2) the odds of experiencing a post-operative complication or readmission to the hospital, respectively. Mortality did not differ between continent and ileal conduit urinary diversion patients (0.8% vs. 1.7%, $p = 0.1$).

Conclusions: Compared to ileal conduit creation, continent urinary diversion is associated with a greater likelihood of post-operative complications and readmission to the hospital within 30 days of surgery. Cystectomy patients seeking continent diversion should be thoroughly counseled on the increased short-term morbidity associated with this specific type of diversion.

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Cumulative Impact of Serial Partial Nephrectomy for the Treatment of Recurrent Renal Masses

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National Cancer Institute, Urologic Oncology Branch, Bethesda, MD, USA

Background: Reoperative partial nephrectomy (RePN) offers several advantages for the treatment of recurrent, multifocal renal masses. RePN has been previously demonstrated to be technical feasibility and delay the need for renal replacement therapy. However, there is still inherent complexity and known risks to repeat nephrectomy. We studied the largest known population of repeat partial nephrectomies in order to characterize likelihood of intra- and post-operative complications, as well as renal functional outcomes.

Methods: We performed a retrospective query of an institutionally maintained registry of nephrectomies for renal carcinoma conducted from 1976-2021. Demographic data, serum creatinine (SCr) and protein dipstick results were assessed within one week prior to surgery, and postoperative function assessments were conducted within 180 days after surgery. SCr was used to calculate eGFR using CKD-EPI 2021. Surgical history was established using both institutional and extrainstitutional data to determine number of previous partial nephrectomies per renal unit with the following nomenclature: "P1" was defined as the first nephrectomy on a surgically naïve kidney. All following repeat partial nephrectomies on the same renal unit were assigned "P2", "P3", "P4", and "P5". Post-operative complications were determined from Clavien-Dindo Classification System criteria.

Results: 1,140 institutional partial nephrectomies were evaluated within the period of 1989 and 2021. 178 extra-institutional surgeries were evaluated across 96 outside institutions between 1976 and 2021. Of these, 363 (93.3%) of reoperative cases were conducted within our institution. Of 1,008 cases with available pre- and post-operative GFR at a median follow up time of 117 days (IQR: 93-173), we observed a step-wise decline in GFR with an average GFR decline of 6.1 with each subsequent nephrectomy on the same renal unit ($p < 0.001$)). With each subsequent nephrectomy, both surgical duration ($p < 0.001$) and, estimated blood loss ($p < 0.001$) increase. On multivariate analysis, the number of tumors removed (Coef: -0.23, SE: 0.077, $p = 0.003$), largest tumor removed (Coef: -0.66, SE: 0.26 , $p = 0.011$), age (Coef: -0.215, SE: 0.048, $p < 0.0001$), total previous partial nephrectomies (Coef: -1.13, SE: 0.42, $p = 0.008$), presurgical GFR (Coef: 0.75, SE: 0.028, $p < 0.0001$), pre-operative proteinuria (Coef: -6.84, SE: 1.9, $p < 0.0001$) and solitary kidney (Coef: -7.3, SE: 1.8, $p < 0.001$) were predictors of post-surgical GFR. On multivariate analysis, number of tumors removed (OR: 1.07, SE: 0.059, $p < 0.0001$), number of previous partial nephrectomies on the same renal unit (OR: 2.06, SE:0.32, $p < 0.0001$) and open surgical approach (OR:4.9, SE:3.8, $p = 0.041$) were predictive of surgical complication.

Conclusions: These are the first-described findings that quantitatively describe serial nephrectomy on functional outcomes with long-term post-surgical follow-up. RePN conveys increasing surgical morbidity in terms of renal function decline as well as increased post-operative surgical complications. Additionally, intraoperative blood loss and surgical duration increase with subsequent surgery. Together, these impacts must be fully appreciated when counseling patients, particularly those with recurrent tumor syndrome.

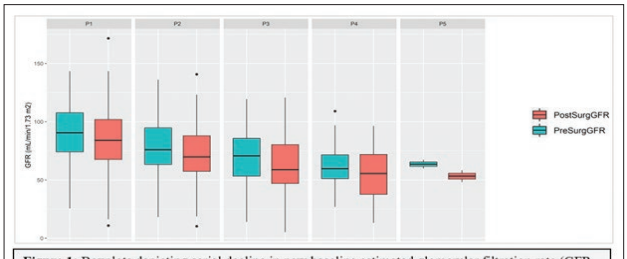

Figure 1: Boxplots depicting serial decline in new baseline estimated glomerular filtration rate (GFR with IQR) before ("PreSurgGFR") and after ("PostSurgGFR") partial nephrectomy. "P1" was defined as the first nephrectomy on a surgically naïve kidney. All following repeat partial nephrectomies on the same renal unit were assigned "P2", "P3", "P4", and "P5".

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Surgical Outcomes after Cytoreductive Nephrectomy Following Neoadjuvant Immunotherapy for Metastatic Renal Cell Carcinoma

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Background: Immunotherapy has caused a paradigm shift in the treatment of metastatic renal cell carcinoma (RCC) with remarkable tumor responses and prolonged patient survival. Much effort has focused on the oncologic outcomes of these patients, but there has yet to be an analysis of surgical outcomes and complication rates in patients treated with neoadjuvant immunotherapy followed by cytoreductive nephrectomy (CN). Case reports have shown conflicting results regarding safety and feasibility of CN following systemic immunotherapy. Our goal is to determine the feasibility of CN following immunotherapy for patients with metastatic RCC. We propose that CN is safe following neoadjuvant immunotherapy and that neoadjuvant treatment decreases the size of the renal mass prior to surgery.

Methods: We queried an institutional database for all cytoreductive nephrectomies completed between the years of 2019-2021 by 4 urologic surgeons at our single institution. These patients were selected for those who underwent neoadjuvant treatment for metastatic disease. Various demographic, surgical, and follow-up data were collected for the patient cohort. Surgical data collected included operative time, estimated blood loss, tumor size, and final pathology. Follow-up data collected included length of stay, readmission rates, and death rates. Primary outcome was the renal mass size comparison at time of therapy initiation and at time of nephrectomy. Secondary outcomes include estimated blood loss (EBL) and 30-day readmission rate.

Results: 15 patients were found that met the inclusion criteria. Neoadjuvant treatments most-commonly included concurrent treatment with ipilimumab and nivolumab (n = 9, 60%) and nivolumab alone (n = 3, 27%). Other regimens included cabozantinib/nivolumab, pembrolizumab/axitinib, and lenavatinib/everolimus combination therapy. The most common site of metastasis was lung (n = 10, 67%). Other sites included bone and brain. Median age at time of CN was 61 years-old. Mean renal mass size at time of therapy initiation was 11.0 cm and mean renal mass size at time of nephrectomy was 8.8 cm (p = 0.11). Six cases involved IVC thrombectomy, seven nephrectomies were completed open, and eight were completed laparoscopically. The difference between EBL for open vs. laparoscopic approaches was 785 cc vs. 207 cc, respectively (p = 0.06). There were no 30-day readmissions and only one patient died at time of most recent follow-up.

Conclusions: Neoadjuvant immunotherapy prior to CN is being increasingly used for the treatment of metastatic renal cell carcinoma. Our data shows a decrease in the mean size of the renal mass at time of nephrectomy following immunotherapy, making surgery more feasible and possibly less technically challenging. The fact that the 30-day readmission rate is zero emphasizes the short-term safety of this approach. A further analysis of the data could determine whether there are "responders" and "non-responders" in the patient cohort, as there are some patients whose tumors may respond favorably to neoadjuvant therapy and some whose tumor growth is refractory to treatment. Further subgroup analysis may shed light on the surgical differences between these groups. Additionally, future studies with larger cohorts of patients comparing upfront CN with neoadjuvant immunotherapy followed by CN may further discern the added value of systemic therapy prior to surgery in metastatic RCC.

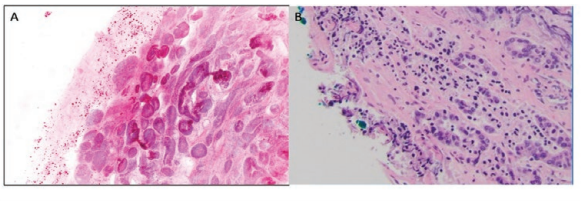

Figure 2:
A) NLM image of radical prostatectomy with frank adenocarcinoma at the inked margin.
B) H&E image of radical prostatectomy with frank adenocarcinoma at the inked margin.

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Feasibility of Nonlinear Microscopy Technique for Evaluating Prostatectomy Margins in Real Time

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Background: Treatment of prostate cancer with radical prostatectomy can have significant side effects including urinary incontinence and erectile dysfunction. Nerve sparing radical prostatectomies (NS-RP) help reduce these effects but come with a risk of compromising oncologic outcomes. Intraoperative margin evaluation using frozen section during RP has been shown to improve nerve-sparing rates and decrease positive surgical margins (Schlomm et al 2012) but is time and resource-intensive and has not been widely adopted. Nonlinear microscopy (NLM) is a novel technology that can quickly image fresh surgical specimens at adjustable depths and produce digital images resembling standard hematoxylin and eosin (H&E) histology. We have previously demonstrated the ability to accurately differentiate prostate cancer from benign glands using NLM (Cahill et al 2020). We describe a new method to evaluate RP margins using NLM, present preliminary data on feasibility and compare NLM with paraffin embedded H&E staining.

Methods: NS-RP or non NS-RP was performed per standard of care. The specimen is inked with different tissue marking dyes combined with fluorescent plastic beads that enable the inks to be visualized under NLM. The neurovascular bundle, if present on the prostate, was dissected off ex vivo to simulate nerve-sparing and this margin inked separately. The specimen was then grossed into standard whole mount slices (Figure 1). Pathology staff were previously trained in NLM slide preparation and cancer identification. Margins were evaluated using NLM, and the tissue subsequently processed for standard paraffin embedded H&E (Figure 2). After an initial trial period of 3 patients, the timing of the NLM process was recorded to assess intraoperative feasibility.

Results: 23 participants were included in the analysis. NLM evaluation correctly identified 7 cases with positive margins and 10 with negative margins. In 5 cases, tumors closely approached the margin and were cautiously deemed equivocal by NLM. All of these cases were ultimately negative on paraffin-embedded H&E. 1 case was falsely negative by NLM, but focally positive on H&E. The average time for NLM processing (inking, grossing, and evaluation) was 36 minutes. Transportation from the operating room to the NLM unit required an additional 6 minutes.

Conclusions: This study suggests the feasibility of RP margin evaluation using NLM without compromising final H&E margin status. Although not objectively analyzed, the team subjectively improved tissue handling and visualization of cellular architecture to determine margin status and we expect our times and accuracy to improve as we optimize workflow. This postoperative RP margin evaluation has helped develop a clinical roadmap for future prospective evaluation of prostate margins during RP using NLM, with the goal of increasing nerve spare RP rates and decreasing positive surgical margins without increasing operative times.

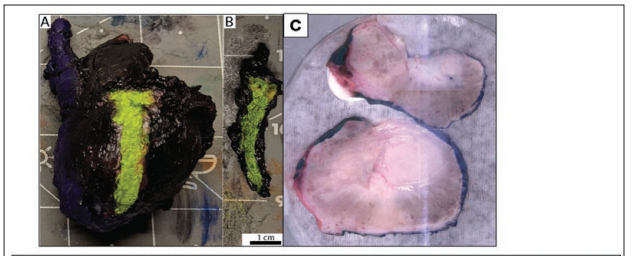

Figure 1. Gross images of inking and breadloaf
A. Radical prostatectomy specimen. Yellow = neurovascular bundle margin inked after resection.
B. Neurovascular bundle dissected off, corresponding surface to the main resection is also inked yellow.
C. Gross white light image of tissue in specimen holder. Orange ink was used for this neurovascular margin.

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Intraprostatic Ethanol Injection Using a Porous Needle in an Acute and Chronic Canine Study, Heart-Beating Cadaveric Organ Donors, and a Murine Xenograft Model of Human Prostate Cancer

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Background: Over the last 10 years, focal therapies have been developed with a goal of eradicating localized prostate cancer, while limiting side effects and complications associated with whole organ therapies. Provided that targeted intraprostatic drug delivery techniques will be developed, intraprostatic injection of a therapeutic agent could develop into an alternative nonmorbid treatment that would halt the progression and delay or eliminate the need for radical prostatectomy or whole organ radiation. We aimed to develop a safe, efficacious, and precise method for intraprostatic injection and establish correlation between the volume of the injectate and the volume of infiltrated area of the prostate.

Methods: We performed intraprostatic injection of 96% ethanol using a needle which has a segment of its wall made of a capillary membrane with hundreds of pores. The intraprostatic injection was performed in an acute and chronic canine experiment, in heartbeating cadaveric organ donors, and in a murine xenograft model of human prostate cancer (PCa). Whole mount sections of the prostates were used for 3D reconstruction of the necrotic lesions.

Results: In the acute experiments, ethanol injection resulted in lesions of well delineated coagulative necrosis with significant alteration of native histological architecture including shrinkage of cell nuclei and disruption of glandular columnar epithelium. In both healthy human and canine prostates, the prostatic pseudocapsule and neurovascular bundle remained intact without evidence of disruption. There was a linear correlation between administered volume of ethanol and the necrotic lesion volume. Regression analysis demonstrated strong correlation in the acute canine and xenografts of human PCa experiments ($R2 = 0.85$ and $R2 = 0.85$ respectively), and moderate correlation in the cadaveric organ donor experiment ($R2 = 0.48$). A formula was calculated for each experiment to estimate the relationship between the injected volume and the volume of infiltrated prostate tissue area.

Conclusions: This study proposes a new method that would allow for effective and predictable tissue distribution of injectate in the prostate, while limiting side effects. In the acute experiments, we documented well delineated areas of coagulative necrosis. Four weeks post injection, ablation of prostate tissue was documented. In both instances, EtOH injection did not cause any disruption to the prostatic pseudocapsule or evidence of injury to the periprostatic anatomical structures. Through varying the volume of the agent injected and use of needles with a different length of the porous segment, the infiltrated tissue could be adjusted allowing for targeted focal treatment. With the development of PCa therapeutics, alternative targeted therapies could be delivered using a similar injection protocol, achieving enhanced outcomes, and preventing complications.

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Multi-institutional Assessment of Performance Metrics for MRI-targeted Transperineal Prostate Biopsy

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Background: MRI-targeted biopsy (TB) combined with systematic biopsy has emerged as the optimal strategy for prostate cancer detection in the United States. Actionable Intelligence Metric (AIM) and Reduction Metric (ReM) have previously been defined in a transrectal prostate biopsy cohort to assess deliverables of TB. AIM measures the value add of TB over systematic biopsy alone for prostate cancer detection. ReM measures the ability of TB to detect prostate cancer in the absence of a systematic template. These metrics have not yet been applied in the transperineal prostate biopsy (TP-B) setting. We assessed the performance of AIM and ReM in men undergoing TP-B.

Methods: Patients with prostate lesions on MRI who underwent concurrent TB and systematic TP-B tracked in prospectively maintained databases in two academic centers were included. Cognitive fusion was used to obtain 1-4 TBs of each identified lesion. Actionable intelligence metric (AIM) = [higher Grade Group (GG) on TB (minimum GG ≥ 2) relative to TP-B] ÷ [total pts with GG ≥ 2] (i.e. % for whom TB offered actionable data over systematic TP-B). Reduction metric (ReM) = 1 - [all pts with higher GG on TP-B (minimum GG ≥ 2) relative to TB ÷ total pts undergoing biopsy] (i.e. % of men in whom systematic TP-B could have been avoided). AIM and ReM were compared among groups based on indication for biopsy and PI-RADS lesion on MRI. Differences between proportions were determined using a chi-squared test. A $p < 0.05$ was considered statistically significant.

Results: 120 men (median age 66y, IQR 60.3-70y; median PSA 9.2ng/ml, IQR 5.7-13.6 ng/ml; median prostate volume 43 cm^3, IQR 31.3-62.5 cm^3) were included: 46 biopsy naïve (BN), 31 men with prior negative biopsy (PNB), and 43 men on an active surveillance (AS). From this cohort, 13 men had MRI demonstrating highest PI-RADS lesion severity of 3, 60 had highest PI-RADS of 4, and 47 had highest PI-RADS of 5. Overall AIM and ReM for the cohort was 21.4% and 78.3%; 15.4% and 80.4% for BN, 15.8% and 67.7% for PNB, and 32.0% and 83.7% for AS. There was no significant difference between the AIM or ReM values based on indication for biopsy ($p = 0.275$, $p = 0.234$). AIM and ReM were 25.0% and 76.9% for patients with PI-RADS 3 lesions; 25.9% and 81.7% for patients with PI-RADS 4 lesions; 17.1% and 74.5% for PI-RADS 5. There was no difference in AIM ($p = 0.682$) or ReM ($p = 0.663$) based on PI-RADS score.

Conclusions: AIM and ReM remain useful tools to evaluate and compare deliverables of TB in the TP-B setting. TB adds value over systematic biopsy alone in 15-21% of patients. ReM values suggest that omitting systematic biopsy misses clinically significant cancers in up to 25% of patients. Combined TB and systematic biopsy remain the optimal approach for finding clinically significant prostate cancers in the TP-B setting. Findings are limited by moderate sample size. Further validation in a larger cohort is planned.

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Disparities in Prostate Cancer Specific Mortality Between Black and White Men According with The Type of Definitive Treatment

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Background: One factor implicated in racial/ethnic differences in prostate cancer survival is the disparity in access to high quality cancer care. There are evidence for both different patterns of treatment between racial and ethnic groups and also differences in quality within treatment types (less access to high volume surgeons among Black men receiving prostate cancer surgery, but also a tendency for Black men to choose radiation over surgery). Whether differences in prostate cancer specific mortality are predominantly within or between treatment types is not known. We therefore designed a study to assess the effect of race on prostate cancer specific survival according to the type of treatment.

Methods: Data on non-Hispanic Black and non-Hispanic White men diagnosed with localized intermediate- and high-risk prostate cancer in the Surveillance, Epidemiology and End Results (SEER) dataset from 2004 and 2015 was abstracted. Patients were followed up to December 2018. Multivariable logistic regression analysis was used to test the association between race and treatment type according to prostate cancer risk group. Univariable and multivariable time-to-event analyses, with the interaction term between race and treatment, were performed to assess whether the effect of race differed in different treatments for prostate cancer.

Results: Overall, 71,716 (79.7%) White men and 18,294 (20,3%) Black men were included in the study (Table 1). Black men were less likely to be treated with radical prostatectomy (OR: 0.46, CI: 0.44 - 0.48, $p < 0.001$), and more likely to be managed with radiotherapy (OR: 1.99, CI: 1.91-2.09, $p < 0.001$). Regarding race-based differences in treatment, the greatest disparity in treatment choice was observed among high-risk patients—where white men were 18.8%% less likely to receive surgery. Although Black men had worse unadjusted cancer-specific survival ($p = 0.037$), this difference disappeared after adjusting for treatment (aHR: 1.07, CI: 0.96-1.19, $p = 0.21$) (Table 2) and the interaction between race and treatment was not significantly associated with prostate cancer specific survival ($p_{int} = 0.594$), suggesting there was no race-based differences in the different treatments. Within each treatment group there was no significant survival difference between Black and White men treated with radical prostatectomy ($aHR_{for\ RP}$:1.01, CI: 0.78-1.32, $p = 0.913$) and with radiotherapy ($aHR_{for\ RT}$:1.07, CI:0.94-1.21, $p = 0.268$). A significantly higher mortality was found for radiotherapy compared to surgery (aHR: 1.67, CI:1.51-1.85, $p < 0.001$).

Conclusions: While these results come with the intrinsic limitations of retrospective research, our findings support the conclusion that white and Black men treated with the same modality can achieve similar prostate cancer outcomes. Differences in treatment (rather than differences in quality of care *within* treatment categories) may be more important for race-based differences in prostate cancer survival.

Table 1. Clinical and demographics characteristics

	White Men 71,716 (79.7%)	Black Men 18,294 (20.32%)	p-value
Age (years)	65 (60-69)	62 (57-67)	< 0.001
cTstage			< 0.001
cT1c	47,941 (66.85%)	14,192 (77.58%)	
cT2	20,648 (28.79%)	3,504 (19.15%)	
cT3	2,956 (4.12%)	545 (2.98 %)	
cT4	171 (0.24%)	53 (0.29%)	
PSA (ng/dL)			< 0.001
<10	50,128 (54.89%)	10,924 (38.19%)	
10-20	13,360 (17.7%)	4,181 (16.7%)	
>20	5,308 (27.41%)	2,451 (44.82%)	
Biopsy Gleason Score (GS)			0.001
GS6	1,128 (11.32%)	2,019 (11.04%)	
GS7	3,365 (66.99%)	12,389 (67.72%)	
GS8	9,788 (13.65%)	2,572 (14.06%)	
GS9	5,344 (7.45%)	1,232 (6.73%)	
GS10	426 (0.59%)	82 (0.45%)	
Positive Biopsy Cores, n 1-34-67-9>10	19,791 (38.11%)18,433 (35.49%) 8,358 (16.09%) 5,354 (10.31%)	4,680 (34.97%) 4,512 (33.72%) 2,430 (18.16%) 1,760 (13.15%)	< 0.001
Prostate cancer Risk Group			< 0.001
Intermediate-Risk	61,092 (85.19%)	15,381 (84.08%)	
High-Risk	10,624 (14.81%)	2,913 (15.92%)	
Treatment			< 0.001
Radical Prostatectomy	41,013 (57.19%)	8,016 (43.82%)	
Radiotherapy	30,703 (42.81%)	10,278 (56.18%)	
Follow-up, (months)	71 (50-91)	68 (48-89)	< 0.001

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Safety and Pathologic Findings of Robotically Assisted Super-Extended Pelvic Lymph Node Dissection for Prostate Cancer

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Background: The extent of pelvic lymph node dissection for prostate cancer varies greatly between surgeons and centers, and the therapeutic benefit remains to be determined. Here we examine the safety and pathologic findings when performing a super-extended pelvic lymph node dissection for high risk prostate cancer and we compare these outcomes to patients who underwent extended pelvic lymph node dissection.

Methods: We retrospectively queried an IRB approved prospectively maintained database to identify cases of robotic assisted radical prostatectomy (RARP) with lymph node dissection performed by a single surgeon between May 2016 and September 2021. An extended pelvic lymph node dissection (ELND) included external iliac, internal iliac, and obturator lymph nodes. Patients with NCCN high/very high and higher unfavorably intermediate (eg high volume Grade Group 3 with PSA approaching 20) risk prostate cancer patients were offered a super-extended pelvic lymph node dissection (sELND) which also included the common iliac, aortic bifurcation, and pre-sacral lymph nodes. We compare ELND and sELND with regards to perioperative parameters, length of stay, complications, and pathologic findings.

Results: 733 patients had RARP with lymph node dissection. 572 patients underwent ELND and 161 patients underwent sELND (Table 1). Robot time was longer for the sELND group ($p < .001$). As sELND was offered to higher risk patients, the number of salvage prostatectomies, PSA, age, and D'Amico risk were higher in the sELND group. Length of stay and complications were similar between the two groups. As expected, the sELND group had a higher rate of lymph node metastasis ($p < .001$). 13.7% of patients in the sELND group had positive nodes in the common iliac, aortic bifurcation, or pre-sacral chains. 3.1% of patients had positive nodes uniquely in these chains with negative external iliac, internal iliac, and obturator nodes.

Conclusions: A subset (13.7%) of high risk prostate cancer patients have positive nodes outside of the ELND template. Patients with positive nodes uniquely in the super-extended template (3.1%) would have been understaged had an ELND been performed. sELND for high risk prostate cancer is feasible and safe. Further studies are needed to determine clinical benefit.

Table 1.

	ELND	sELND	p
n	572	161	
Salvage prostatectomy	3 (0.5%)	4 (2.5%)	0.045
Age	64 (IQR: 59-68)	65 (IQR: 61-69)	0.034
BMI	28.5 (IQR: 25.8-32.1)	28.0 (IQR: 25.8-31.1)	0.474
PSA prior to surgery	6.1 (IQR: 4.6-8.7)	8.7 (IQR: 5.2-16.1)	<0.001
D'Amico classification			<0.001
Low	5 (0.9%)	0 (0.0%)	
Intermediate	435 (76.2%)	10 (6.3%)	
High	131 (22.9%)	150 (93.8%)	
Robot time	168 (IQR: 133-196)	194 (IQR: 166-215)	<0.001
EBL	200 (IQR: 100-300)	175 (IQR: 50-300)	0.031
LOS	1 (IQR: 1-1)	1 (IQR: 1-1)	0.831
Any complication	85 (14.9%)	23 (14.3%)	0.856
Clavien ≥ III complications	20 (3.5%)	10 (6.2%)	0.125
Lymph leak/lymphocele	8 (1.4%)	3 (1.9%)	0.714
DVT/PE	10 (1.7%)	5 (3.1%)	0.340
Rate of lymph node metastasis	43 (7.5%)	60 (37.3%)	<0.001

Note: ELND, extended pelvic lymph node dissection; sELND, super-extended pelvic lymph node dissection; BMI, body mass index; PSA, prostate-specific antigen; EBL, Estimated blood loss; LOS, length of stay; DVT/PE, deep vein thrombosis/pulmonary embolism

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Establishment and Evaluation of a Multidisciplinary Virtual Prostate Cancer Clinic

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Background: In order to facilitate patient safety in the era of COVID-19, Hartford Healthcare (HHC) piloted a nurse navigator-guided multidisciplinary virtual visit cancer clinic (MDVV). We evaluated the first year of the MDVV in terms of patient retention, quality metrics, and feedback from patients and providers.

Methods: Fifty-three patients with newly diagnosed or progressive prostate cancer were enrolled in the MDVV from August 2020 - August 2021. Patients had virtual consultations with a multidisciplinary team consisting of a urological oncologist, a radiation oncologist and a medical oncologist, and were guided through the visit by a nurse navigator. The goal was to help patients understand their diagnosis and treatment options and prepare them to take the next steps towards their treatment goals. Immediately after the consultation, the nurse navigator administered a 7 item satisfaction survey (Table 1). Providers were also asked to complete an anonymous survey focused on collaborative care, communication and efficiency of the program. We reviewed medical records to determine the proportion of patients who stayed at HHC for their prostate cancer treatment for the MDVV cohort vs. patients who completed traditional prostate cancer consults from October to December 2019. We also compared the cohorts on rates of multi- specialty consultations and adherence to NCCN imaging guidelines.

Results: A total of 51 of the 53 MDVV patients (96%) were treated at HHC; in the non-MDVV cohort 44 patients (88%) were treated at HHC ($p = .15$). The median score for patient satisfaction on all 7 domains was 1 (strongly agree). Provider satisfaction was rated as high by all participating providers. While 100% of the MDVV cohort received multidisciplinary consultation before treatment, only 14/50 traditional cohort patients (28%) received the same ($p < .001$). 100% of MDVV patients underwent imaging according to NCCN guidelines, compared with 33/50 (66%) of traditional patients ($p < .001$).

Conclusions: The MDVV approach seems to be an effective means of offering safe, in-home consultation to patients newly diagnosed with prostate cancer, leading to high satisfaction among patients and providers. This format also improves access to multidisciplinary consultation and, in this cohort, increased adherence to imaging guidelines.

Table 1.

Patient experience survey

Patients are asked to rate each item on a Likert Scale (1 to 5)

1 = Strongly Agree……3 = Neutral……..5 = Strongly Disagree

Time

1. This multidisciplinary visit optimized the time that I spent in the virtual clinic.
2. The time spent with each clinician enabled me to get a clear understanding of my diagnosis and allowed me the ability to participate in decision making and/or next steps.
3. The clinicians were punctual and I felt my time was valued.

Visit flow

4. The nurse navigator communicated the flow of the appointment so I felt informed about whom I was meeting with and what was going to be discussed.
5. During the transitions between clinicians I felt the provider handoffs accurately represented the key points from the previous consultation.
6. The physicians involved showed cooperation and worked towards a shared goal; while including me in decision making.
7. If accompanied, that person felt engaged by the providers (i.e., they could ask questions and help the patient as intended).

Overall

8. I felt listened to throughout this process.
9. I would recommend this multi-disciplinary virtual visit to other patients.

Comments: _____

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Outpatient Single Port Robotic Radical Prostatectomy: Outcomes of 157 patients and Analysis of Learning Curve

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Background: Robot-assisted radical prostatectomy (RARP) has been a standard of care in the management of prostate cancer since the early 2000's. With four articulated instruments, RARP greatly reduced postoperative recovery times and blood loss compared to open prostatectomy. In 2018, the USFDA approved the da Vinci single-port (SP) system, in which four instruments are still utilized, but enter via a single-site access trocar. Herein, we report the largest case series for SP-RARP to date. Our primary aim is to analyze the peri-operative and short-term outcomes of this procedure. Our secondary aim is an assessment of the learning curve with this new platform.

Methods: A total of 157 patients underwent SP-RARP by two surgeons who have completed over 3000 multiport robotic surgeries. For one surgeon, the first seven cases were done via a transperitoneal approach. The remaining cases used a preperitoneal approach. IRB-approved prospectively collected data was used. Basic demographic pre-operative variables and peri-operative outcomes were analyzed.

Results: Median patient age and PSA were 63 years and 6.3 ng/mL prior to treatment (IQR 4.7-8.2 ng/mL). Average prostate weight was 47 g. The median operating time was 195 min (IQR 165-221.25 min) with a median EBL of 100 mL (IQR 100-200 mL). The operating times of each surgeon are shown in Figure 1. Surgeon 1 stabilized their operating time around case #56, and Surgeon 2 stabilized around case #26 (Figure 1). Surgeon 2 used the transperitoneal approach for the first seven cases. There were no intraoperative complications. There were six total post-operative complications (3.8%) and four (2.5%) were high grade according to the Clavien-Dindo scale for surgical complications (IIIa or higher). The overall positive margin rate was 28% (26%, 36%, and 40% for T2, T3a, and T3b tumors respectively). 110 patients went home same day, 45 stayed one night at the hospital, with only two patients requiring to stay in the hospital for more than one night (70%, 29% and 1% respectively).

Conclusions: This case series analysis confirms the safety and efficacy of SP RARP with acceptable short-term outcomes. There is a significant learning curve for this new modality due to reduced flexibility of the instruments and diminished surgical field. The initial learning curve may be shortened by using the transperitoneal approach. Same day discharge appears to be an early benefit of the SP platform.