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The Impact of Partial versus Complete BCG Intravescial Therapy on Bladder Cancer Outcomes in High-risk Non-muscle Invasive Bladder Cancer (NMIBC): Implications for Global BCG Shortages

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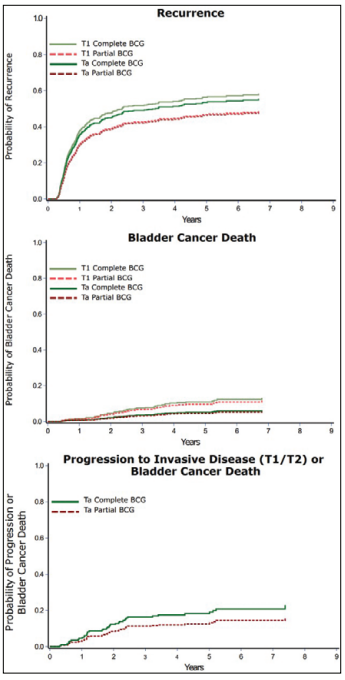
Introduction: Adjuvant intravesical Bacillus Calmette-Guérin (BCG) is used to reduce disease recurrence and progression in patients with high-risk non-muscle invasive bladder cancer (NMIBC). Unfortunately, repetitive global shortages of BCG have disrupted guideline-recommended intravesical therapy practices for many high-risk patients. BCG instillations have been rationed (i.e., partial induction), so at least those at highest risk for disease recurrence and progression can undergo BCG treatment. The impact of delivering fewer BCG instillations than currently recommended has not been thoroughly evaluated. The purpose of this study was to assess the association of partial vs. complete BCG induction with bladder cancer outcomes in patients with high-risk NMIBC.

Materials & Methods: This is a retrospective cohort study of Veterans who were diagnosed with high-risk NMIBC (high grade (HG) Ta, T1, or Carcinoma in Situ) between 2005 and 2011 who received at least one dose of adjuvant BCG during a 6 month intravesical therapy window after diagnosis. Patients were categorized into partial BCG induction (< 5 BCG instillations) versus complete BCG induction (>= 5 BCG instillations) groups. Propensity score adjusted regression models were used to assess the association of partial BCG induction with risk of disease recurrence and bladder cancer death, stratified by Ta vs. T1 disease. Associations with progression to invasive disease (T1/T2) or bladder cancer death were evaluated among those diagnosed with HG Ta disease.

Results: Among 540 patients with high-risk NMIBC, 114 (21.1%) received partial BCG induction, while 426 (78.9%) received complete BCG induction. This reflected a mean of 2.8 (SD 1.2) versus 6.0 (SD 0.8) induction doses per patient, respectively. Baseline patient characteristics did not differ significantly between groups. Partial vs. complete BCG induction was not significantly associated with increased risk of disease recurrence for patients with HG Ta (cumulative incidence ([CIn] 46.6% vs. 53.9% at 5 years, p = 0.38) or T1 (CIn 47.1% vs. 56.7 at 5 years, p = 0.19) disease. Similarly, partial vs. complete BCG induction was not significantly associated with increased risk of bladder cancer death for patients diagnosed with HG Ta (CIn 4.7% vs. 5.4% at 5 years, p = 0.87) or T1 (CIn 10.0% vs. 11.4% at 5 years, p = 0.77) disease. Among patients diagnosed with Ta disease, partial vs. complete BCG was not significantly associated with risk of progression to invasive disease (T1/T2) or bladder cancer death (CIn 13.1% vs. 19.0% at 5 years, p = 0.37; Figure Panel 1).

Conclusions: Patients with high-risk NMIBC who underwent partial BCG induction experienced similar bladder cancer outcomes compared to those who received complete BCG induction. These findings suggest that a reduced number of adjuvant BCG instillations in the induction period may be an alternative treatment strategy for some high-risk patients, particularly during global shortages of BCG.

Figure 1: Cumulative incidence plots showing the probability of disease recurrence, bladder cancer death, and progression to invasive disease (T1/T2) by BCG induction status.



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3

Urine Derived Lymphocytes Demonstrate Marked Differences in the Expression of Immune Checkpoint Molecules PD1 and NKG2A between Non-muscle Invasive and Muscle Invasive Bladder Cancer

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Introduction: Lymphocytes in the urine of patients with muscle invasive bladder cancer (MIBC) have been found to be representative of those in the tumor microenvironment. Given this relationship, we hypothesized that analysis of immune checkpoint molecules on these cells may reveal differences between the microenvironment of non-muscle invasive bladder cancer (NMIBC) and muscle invasive bladder cancer (MIBC). The checkpoint molecule PD1 is the target of numerous monoclonal antibody treatments for MIBC and its role in suppression of the immune response to cancer has been well studied. The novel checkpoint molecule NKG2A is an inhibitory receptor found on NK and T cells and NKG2A blocking monoclonal antibodies are currently in clinical trials for other cancer types. We sought to better understand the immune modulatory landscape of NMIBC and MIBC by studying urine derived lymphocyte expression of PD1 and NKG2A.

Materials & Methods: In this study, urine was obtained from patients diagnosed with bladder cancer prior to receiving treatment. Patients were sorted into disease groups based on the pathology results from staging cystoscopy (NMIBC n = 4, MIBC n = 6). Urine was collected via void at office visit or catheterization prior to cystoscopy or cystectomy. On the same day as collection, urine derived cells were isolated by centrifugation, treated with ACK lysis buffer for removal of erythrocytes, stained, and analyzed via flow cytometry. Statistical analysis between groups was calculated using unpaired 2-tailed student's t-test.

Results: There were significant decreases in the ratio of both NK cells and T cells to total urine cells for the MIBC group ($p < 0.05$, $p < 0.05$). The percentage of CD4+ and CD8+ T cells expressing PD1 was significantly higher in the MIBC group ($p < 0.05$, $p < 0.005$). The NMIBC group was found to have an increased percentage of CD8+ T cells expressing NKG2A ($p < 0.05$). Analysis of lymphocytes expressing both NKG2A and PD1 found a significant increase in this phenotype among CD4+ and CD8+ T cells in the MIBC group compared to NMIBC ($p < 0.05$, $p < 0.01$).

Conclusions: We conclude that it is feasible to detect differences in the urine lymphocyte composition and immune checkpoint profile between NMIBC and MIBC. Our analysis revealed increased expression of inhibitory marker PD1 on T cells from the urine of MIBC patients, suggesting the tumor microenvironment in MIBC is more inhibitory and contains more dysfunctional T cells then NMIBC. Conversely, the inhibitory receptor NKG2A, whose role in tumor immunology is still under investigation, was expressed by fewer CD8+ T cells in MIBC compared to NMIBC. However, CD4+ and CD8+ T cells expressing both PD1 and NKG2A were present in a higher proportion for the MIBC group. These differences may reflect disparities in the mechanism of immune modulation by the tumor microenvironment between these two diseases.

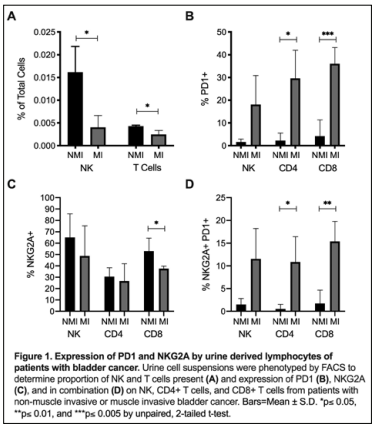

Figure 1. Expression of PD1 and NKG2A by urine derived lymphocytes of patients with bladder cancer. Urine cell suspensions were phenotyped by FACS to determine proportion of NK and T cells present **(A)** and expression of PD1 **(B)**, NKG2A **(C)**, and in combination **(D)** on NK, CD4+ T cells, and CD8+ T cells from patients with non-muscle invasive or muscle invasive bladder cancer. Bars=Mean ± S.D. *ps 0.05, **ps 0.01, and ***ps 0.005 by unpaired, 2-tailed t-test.

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Parastomal Hernia Development after Cystectomy and Ileal Conduit for Bladder Cancer: Results from the Dartmouth Ileal Conduit Enhancement (DICE) Project

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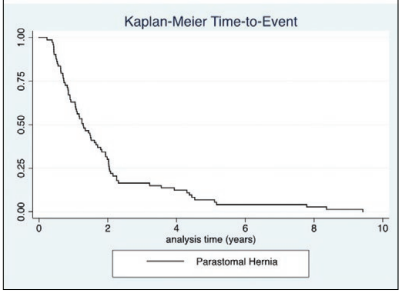
Introduction: Limited information exists regarding parastomal hernia development in bladder cancer patients. The purpose of this investigation was to describe the natural history of parastomal hernias and identify risk factors for hernia development in patients who undergo cystectomy with ileal conduit urinary diversion.

Materials & Methods: A retrospective cohort study was performed of bladder cancer patients who underwent cystectomy with ileal conduit urinary diversion between January 1st 2009 and July 31st 2018 at Dartmouth-Hitchcock Medical Center. The primary outcome of interest was the presence of a parastomal hernia as evident on post-operative cross-sectional imaging obtained for disease surveillance.

Results: A total of 107 patients were included with a mean age of 70.9 years and 29.9% being female. Parastomal hernias were identified in 68.2% of bladder cancer patients who underwent cystectomy with ileal conduit urinary diversion. 40% of patients with a parastomal hernia reported symptoms related to their hernia, while 12.5% underwent operative repair. After multivariate adjustment, patients with a post-op BMI > 30 kg/m^2 (Odds Ratio [OR]: 21.8, 95% CI: 1.6-305.2) or stage III or IV bladder cancer (OR: 18, 95% CI: 2.1-157.5), had significantly greater odds of parastomal hernia development. Fifty percent of parastomal hernias were identified 1.3 years from surgery, while 75% were identified by two years after cystectomy.

Conclusions: Parastomal hernias developed in over two-thirds of bladder cancer patients and occurred rapidly following cystectomy and ileal conduit urinary diversion. Greater post-operative BMI and bladder cancer stage were identified as significant risk factors for parastomal hernia development. Significant opportunity exists to reduce morbidity associated with parastomal hernias in this population.

Figure 1: Kaplan-Meier Curve Displaying Time-to-Parastomal Hernia Development



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Surgical Site Infection in Robot-assisted Radical Cystectomy vs. Open Radical Cystectomy

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Introduction: Radical cystectomy has a high incidence of complications due to the complex nature of the procedure. Little is known about the comparative risk of surgical site infection associated with robot-assisted radical cystectomy (RARC) vs. open radical cystectomy (ORC). Patients at our institution were analyzed to assess risk of developing SSI based on surgical approach.

Materials & Methods: All patients undergoing radical cystectomy with pelvic lymph node dissection for urothelial carcinoma of the bladder at a single institution from 2007-2017 were retrospectively reviewed. Data included age, sex, body mass index (BMI), Charlson Age-Adjusted Comorbidity Index (CCI), history of diabetes, surgical approach (RARC or ORC), urinary diversion type, length of operation, estimated blood loss (EBL), surgical site infection (SSI), and length of hospital stay (LOS). SSIs were defined using criteria outlined by the National Surgical Quality Improvement Program (NSQIP) that occurred at any point postoperatively. There were no exclusion criteria in terms of clinical or pathologic stage. Simple and multiple logistic regression models were fitted to the data to assess the role of perioperative factors on risk of surgical site infection. Independent variables that are correlated were excluded during variable selection in multiple regression analysis in order to satisfy the assumption of non-multicollinearity. Differences between the RARC and ORC patient cohorts were analyzed using Student's t-test or Wilcoxon rank sum test for continuous variables, and Pearson's Chi-squared test for categorical variables. Statistically significant differences were defined as $p < 0.05$.

Results: We identified a total of 232 patients (73 robotic, 159 open) who underwent radical cystectomy. SSI was significantly lower in RARC vs. ORC (14% vs. 29%, p = 0.01). RARC patients had lower EBL than ORC patients (mean: 500 vs. 850 mL, p < 0.0001), higher CCI (mean: 6.2 vs. 5.3, p < 0.05), and longer operative times (mean: 550 vs. 360 minutes, p < 0.0001). There was no significant difference in BMI (p = 0.93), diabetes (p = 0.58), urinary diversion type (continent vs. non-continent, p = 0.71), or LOS (p = 0.34) between surgical approaches. On simple univariate logistic regression, surgical approach (RARC vs. ORC, OR=0.40, 95% CI: 0.19-0.84, p = 0.016), EBL (OR = 1.0008, 95% CI: 1.0002-1.0014, p = 0.007), BMI (OR = 1.06, 95% CI: 1.002-1.125, p = 0.043), and LOS (OR = 1.05, 95% CI: 1.006-1.102, p = 0.026) were found to have significant correlation with risk of SSI. Diabetes, CCI, operative time, and urinary diversion method had no significant correlation with risk of SSI. Multivariate logistic regression including surgical approach (OR = 0.34, p = 0.008), LOS (OR = 1.06, p = 0.017), and BMI (OR = 1.07, p = 0.035) show that these variables have a significant relationship with SSI risk.

Conclusions: Patients who underwent RARC had a significantly lower SSI rate compared to those who underwent ORC. RARC patients experienced significantly lower EBL. Logistic regression analysis shows a strong relationship between surgical approach and SSI risk, suggesting a 60% reduction in SSI risk associated with RARC, as well as a strong relationship between EBL and SSI risk. Reduced risk of SSI in RARC may be mediated by lower EBL in RARC vs. ORC.

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Metabolomic Evaluation of Renal Cell Carcinoma and Fat-Poor Angiomyolipoma with Magnetic Resonance Spectroscopy

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Introduction: Renal cell carcinoma (RCC) is a metabolic disease, with the various subtypes exhibiting aberrations in different metabolic pathways. Metabolomics may offer greater sensitivity for revealing disease biology than evaluation of tissue morphology. In this study, we investigate the metabolomic profile of RCC using high resolution magic angle spinning (HRMAS) magnetic resonance spectroscopy (MRS).

Materials & Methods: Tissue samples were obtained from radical or partial nephrectomy specimens that were fresh frozen & stored at -80ºC. Tissue HRMAS MRS was performed by a Bruker AVANCE spectrometer. Metabolomic profiles of RCC & adjacent benign renal tissue were compared, and false discovery rates (FDR) were used to account for multiple testing. Regions of interest (ROI) with FDR < 0.05 were selected as potential predictors of malignancy. The Wilcoxon rank sum test was used to compare median MRS relative intensities for the candidate predictors. Logistic regression was used to determine odds ratios for risk of malignancy based on abundance of each metabolite.

Results: There were 38 RCC (16 clear cell, 11 papillary, 11 chromophobe) & 13 adjacent normal tissue specimens (matched pairs). Metabolic predictors of malignancy based on FDR include histidine, phenylalanine, phosphocholine, serine, phosphocreatine, creatine, glycerophosphocholine, valine, glycine, myo-inositol, scylla-inositol, taurine, glutamine, spermine, acetoacetate & lactate. Higher levels of spermine, histidine & phenylalanine at 3.15-3.13 ppm were associated with a decreased risk of RCC (OR $4x10^{-5}$, 95% CI $7.42x10^{-8}$, 0.02), while 2.84-2.82 ppm increased the risk of malignant pathology (OR 7158.67, 95% CI 6.3, $8.3x10^{6}$), and the specific metabolites characterizing this region remain to be identified. Tumor stage did not appear to affect the metabolomics of malignant tumors, suggesting that metabolites are more dependent on histologic subtype.

Conclusions: HRMAS-MRS identified many metabolites that may predict RCC. We demonstrated that those in the 3.14-3.13 ppm ROI were present in lower levels in RCC, while higher levels of metabolites in the 2.84-2.82 ppm ROI substantially increased the risk of RCC.

Introduction: Fat-poor angiomyolipoma (AML) can be difficult to differentiate from renal cell carcinoma (RCC) radiographically and may lead to biopsy or unnecessary intervention. *In vivo* platforms with the ability to identify tumor histology based on metabolic profiles may avoid unnecessary procedures & their complications. The metabolomics of AML have not been characterized, & research into this area may provide targetable molecules for large AMLs. In this study, we investigate the metabolomic profile of AMLs compared to clear cell RCC (ccRCC) using high resolution magic angle spinning (HRMAS) magnetic resonance spectroscopy (MRS).

Materials & Methods: Tissue samples were obtained from radical or partial nephrectomy specimens that were fresh frozen & stored at -80ºC. Tissue HRMAS MRS was performed by a Bruker AVANCE spectrometer. Metabolomic profiles of RCC & adjacent benign renal tissue were compared, and false discovery rates (FDR) accounted for multiple testing. Regions of interest (ROI) with FDR < 0.05 were considered potential predictors of ccRCC rather than AML. The Wilcoxon rank sum test was used to compare median MRS relative intensities for candidate predictors. Logistic regression was used to determine odds ratios for risk of malignancy based on abundance of each metabolite.

Results: There were 16 ccRCC samples & 7 AML specimens. Candidate predictors of malignancy rather than AML based on FDR p-values include histidine, phenylalanine, phosphocholine, serine, alanine, glutamate, glutathione, glycerophosphocholine, & glutamine. While an abundance of these metabolites is associated with higher risk of malignancy, the odds ratio was particularly high in the 3.5-3.49 ppm spectral region (OR $2.99x10^{6}$, 95% CI 3.27, $2.73x10^{12}$, p=0.033) in ccRCC samples.

Conclusions: HRMAS MRS identified metabolites that may help differentiate fat-poor AML from ccRCC. In particular, metabolites in the 3.5-3.49 ppm spectral region increased the risk of harboring RCC. Our findings may contribute to future *in vivo* studies to help identify which patients require intervention for malignancy & which may be observed for benign AML without requiring biopsy

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Robot-Assisted Laparoscopic Transdiaphragmatic Right Adrenalectomy
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Introduction: Multiple surgical approaches are available for consideration when an adrenalectomy is indicated by either open or laparoscopic means. We offer a video demonstration of a less utilized approach - a transdiaphragmatic adrenalectomy from a right sided approach with robotic assistance.

Materials & Methods: A 78 year-old male patient was found to have a solitary, biopsy-proven renal cancer metastasis to the right adrenal gland approximately nine years following right radical nephrectomy for T1bN0M0 grade 2 clear cell RCC. In the interim, he had undergone a large ventral hernia repair with placement of a large piece of intraabdominal mesh. Given the concerns for a hostile abdomen and retroperitoneum, the patient underwent a right sided adrenalectomy via a transdiaphragmatic approach with robotic assistance.

Results: The accompanying video illustrates the following principles; #1: Appropriate consideration of the various surgical approaches for an indicated adrenalectomy; #2: Patient positioning and port placement considerations; #3: Collaboration with anesthesiologists and thoracic surgeons comfortable with robotic surgical approaches; #4: The use of intraoperative ultrasound in guiding the surgical plan; #5: Consideration of the various helpful anatomic landmarks in the course of a transdiaphragmatic approach.

Conclusions: The accompanying video illustrates the principles and considerations for a robotic-assisted laparoscopic transdiaphragmatic approach to a right-sided adrenalectomy. Collaboration with thoracic surgery colleagues as well as a thorough understanding of the thoracic and retroperitoneal anatomy is crucial to success in this less utilized approach.

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Computer Generated vs. Human Generated R.E.N.A.L Nephrometry Score to Predict Surgical Outcomes in Renal Cell Carcinoma
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Introduction: R.E.N.A.L. nephrometry score is associated with pathological outcomes, complication rates and survival. Despite its success, widespread uptake has been limited by interobserver variability and time investment to generate scores. We developed an algorithm to produce a computer generated (CG) RENAL score, and compared this with human generated (HG) scores to predict RCC, high grade (Fuhrman 3-4), high stage (pT3-4) and tumor necrosis.

Materials & Methods: Retrospective review of 544 patients undergoing nephrectomy following CT for suspected RCC from 2010-2018. After manually delineating tumors on CT using an internally-made application, we developed an algorithm to automatically generate each RENAL score component. Each tumor was also manually, independently scored by one of five medical professionals. We used ROC curve analysis to quantify the discriminative ability of HG and CG RENAL scores.

Results: CT imaging was available for 195 patients. 183 (94%) had malignant tumors. Interobserver agreement between CG and HG RENAL scores was significant, but slight (kappa = 0.32, $p < 0.001$). However, CG score had good discriminative ability for cancer (AUC 0.76), greater than HG (0.67). CG (0.59) and HG (0.62) scores were comparable for high grade, whilst HG score (0.80) outperformed CG (0.62) scores for high stage. HG (0.74) also outperformed CG (0.63) score for tumor necrosis.

Conclusions: CG RENAL scores demonstrate significant agreement with HG RENAL scores and have similar ability to predict clinically important pathologic outcomes. These are promising results and, with further refinement, automated RENAL scores may be more reliable, cheaper, faster and potentially supersede human RENAL scoring in predicting post-operative outcomes.

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Long Term Outcomes of Organ Sparing Surgery for Penile Cancer at a Single Institution
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Introduction: Organ sparing surgery (OSS) for penile cancer has been shown to be a viable option for low-stage disease. However, recurrence rates are higher than non-OSS approaches, and there is limited long term follow-up within the literature. The objective of our study is to report our single institution experience with OSS for squamous cell carcinoma (SCC) of the penis over the last 26 years.

Materials & Methods: The charts of all patients at our institution undergoing OSS for penile SCC from 1993 to 2019 were retrospectively reviewed. Kaplan-Meier survival time to event analysis was conducted for recurrence. Patient and tumor characteristics were compared based on recurrence using bivariate analysis, and a Cox-proportional hazard model was used for survival analysis of time to event of recurrence. Model covariates included disease stage, tumor grade, presence of lymphovascular invasion, tumor size, age at diagnosis, and HPV status.

Results: 99 patients underwent OSS. Mean follow up was 54.9 months. Overall rate of recurrence was 30%. On a Kaplan-Meier analysis, T1 disease had a significantly higher rate of recurrence than Tis (47% vs. 24%, $p = 0.014$, fig. 1). On multivariate analysis, positive HPV status was the only predictor of disease recurrence (OR 5.50 [CI 1.06-28.4], $p = 0.042$). OSS patients underwent an average of 2.23 procedures. Approximately 85% of recurrences occurred in the first 5 years, with 60% occurring in the first 2 years (fig. 2). 11 patients (11.1%) progressed to partial penectomy with an average time to progression of 40 months. Only 1 patient (< 1%) progressed to total penectomy after 41 months.

Conclusions: Patients with T1 disease have a higher rate of recurrence compared to Tis. Positive HPV status is correlated with a higher risk of recurrence after OSS. Patients should be followed closely within the first 2 years of OSS with a minimum overall follow-up of 5 years. Patients undergoing OSS should be counseled preoperatively regarding possible additional procedures with an 11% progression rate to partial penectomy and a < 1% progression rate to total penectomy.

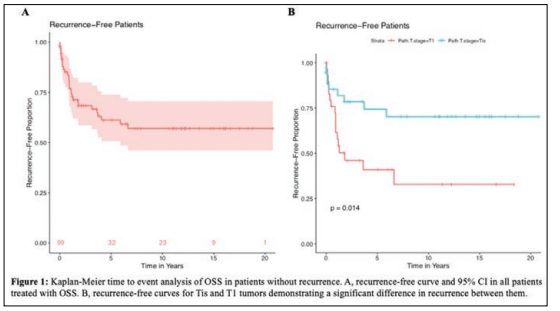

Figure 1: Kaplan-Meier time to event analysis of OSS in patients without recurrence. A, recurrence-free curve and 95% CI in all patients treated with OSS. B, recurrence-free curves for Tis and T1 tumors demonstrating a significant difference in recurrence between them.

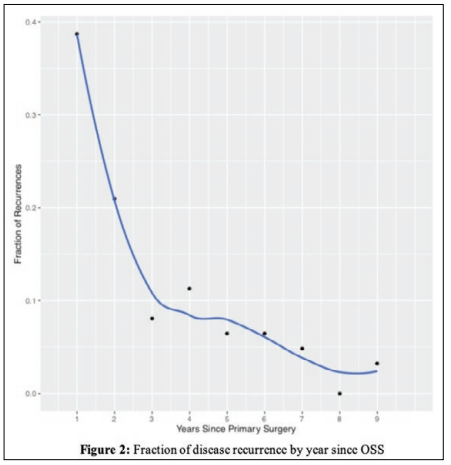

Figure 2: Fraction of disease recurrence by year since OSS

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Risk Factors for Multiple Intravesical Recurrences of Non-muscle Invasive Bladder Cancer

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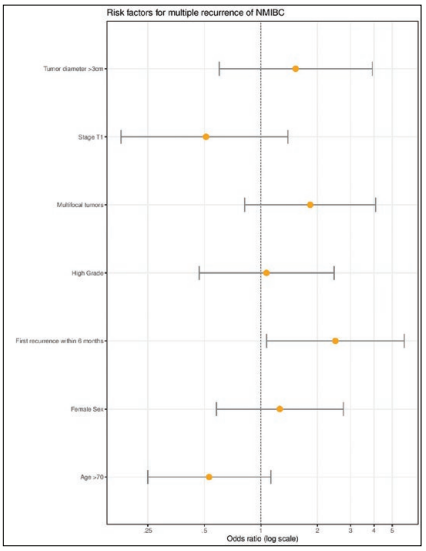
Introduction: Currently available risk calculators such are useful in identifying patients with non-muscle invasive bladder cancer (NMIBC) at risk for recurrence yet cannot identify patients who are at risk of multiple recurrence. Using an untreated cohort, we aimed to identify risk factors for multiple-recurrent disease in order to better risk stratify patients with NMIBC and aid clinical decision-making.

Materials & Methods: Our cohort consisted of 535 patients diagnosed with bladder cancer in Stockholm County between the years 1995-96. We included patients with pathologic Ta or T1 disease who were confirmed to have at least one recurrence of their disease during median follow up of 12 years. Patients were excluded if they underwent cystectomy after first recurrence of disease. Patients who received curative chemotherapy, curative radiation, or an intravesical agent such as BCG or mitomycin were excluded to eliminate the confounding effects of these treatments on disease recurrence. Of this cohort, we identified 136 with NMIBC who experienced a recurrence during the course of the study and met criteria for inclusion.

Results: The median age of the cohort at diagnosis was 72 years. 89 participants (65%) were male and 118 (88%) had pathologic Ta disease. 37 patients (27%) had high grade disease. Multiple recurrences were identified in 94 (69%) patients, versus 42 (31%) patients who experienced only a single recurrence. We found that patients with multiple-recurrent disease were more likely to experience their first recurrence within 6 months of their initial diagnosis (OR 2.49, 95% CI 1.07 - 5.79). Interestingly, many of the parameters included in the EROTC risk calculator were not significantly associated with multiple recurrence versus single recurrence, such as multifocal disease (OR 1.83, 95% CI .82 - 4.08), high-grade disease (OR 1.07, 95% CI .47 - 2.45), or T1 disease (OR .51, 95% CI .18 - 1.39), (Figure 1).

Conclusions: In this study of an untreated cohort of patients we compared the clinical characteristics of patients with multi- versus single-recurrent non-muscle invasive bladder cancer. We found that patients with multiple recurrences were more than two-and-a-half times as likely to have experienced a first recurrence within six months. This information is important for risk stratifying patients for intravesical treatment.



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Risk Factors for Sepsis Following PCNL

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Introduction: Post-operative sepsis is a rare, potentially devastating, risk of percutaneous nephrolithotomy (PCNL). Knowledge of pre-operative risk factors may identify which patients will benefit most from new management strategies.

Materials & Methods: Retrospective chart review was performed on 153 consecutive patients who underwent PCNL at Maine Medical Center between October 2016 and December 2018. Patient demographic factors, comorbidities, infection history, culture data, and stone factors were recorded. Post-operative sepsis was defined according to SIRS criteria for severe sepsis. Multivariate logistic regression was used to evaluate categorical variables as risk factors for sepsis. Fischer exact and student t tests were used to evaluate variables in patients with positive pre-op urine culture.

Results: 14 of 153 patients developed post-operative sepsis. Septic patients did not differ from others with regards age, gender, BMI, stone laterality, diabetes mellitus or renal function. Infected stone as an indication for PCNL was an independent predictor of sepsis (OR 5.66; p = 0.015), as was large stone burden (a Seoul score >= 5 (OR 3.76; p = 0.046) or S.T.O.N.E score >= 9 (OR 5.52; p = 0.018)). Patients with limited mobility (upper or lower body) were much more likely to become septic (OR 21.4; p = 0.002). Any positive pre-op culture was independently associated with sepsis (OR 13.7; p = 0.002), as were gram negative bacteria as a group (OR 5.7; p = 0.025) and specifically the proteus species (OR 10.6; p = 0.023). Such association was not found for gram positive bacteria. Among 45 patients with positive pre-op cultures, female gender (RR 3.9; p = 0.047), infected stone as an indication (RR 3.1; p = 0.047), limited lower (RR 3.5; p = 0.022) and upper (RR 3.4; p = 0.027) body mobility were all associated with post-op sepsis. Negative culture was protective against sepsis (OR 0.073; p = 0.002). Among patients with negative pre-op cultures, 2/109 (1.8%) had post-op sepsis, both with large complex stones (Seoul and S.T.O.N.E scores >=9).

Conclusions: Limited patient mobility and large stone burden are strong predictors of post PCNL sepsis. Positive pre-op urine culture, especially those with a gram-negative organism, also correlate with increased risk. Patients without these risk factors have low probability of sepsis, even before accounting for variation in intra-operative factors. Our results suggest a framework for risk-stratifying patients prior to surgery and the potential for more aggressive antimicrobial intervention in high risk patients, and less aggressive treatment in low risk patients.

12

Development of a Novel Metric to Preoperatively Estimate Flexible Ureteroscopy Operative Time: "The Stone Treatment Scale (STS)"

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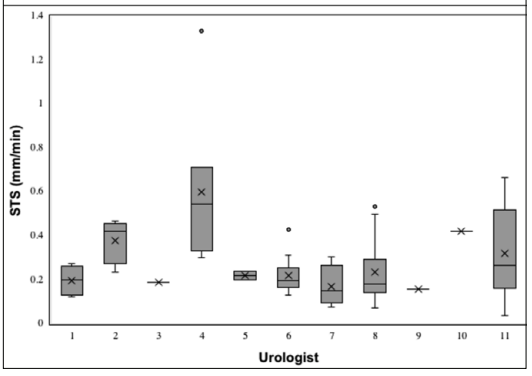
Introduction: As operating room (OR) time is a fixed commodity, new methods are needed to improve the accuracy of room time estimates to mitigate underutilization. We sought to develop a surgeon-friendly metric for flexible ureteroscopy and laser lithotripsy (URSLL) similar to prostate ablation rates by which urologists can better estimate case time for improved perioperative planning.

Materials & Methods: A retrospective review of all flexible URSLL procedures of calcium oxalate (CaOx) stones performed from December 2016 to April 2018 performed by 11 urologists at an academic institution was conducted. Patient characteristics, imaging, operative times, and outcomes were analyzed. Cases were included if preoperative computed tomography (CT) imaging was available and the patient was rendered stone free either by postoperative imaging or intraoperative surgeon interpretation. All cases were performed with a Lumenis Pulse 30H laser unit and dusting technique. Procedure length was measured by case start-to-case completion times. A novel measure of stone treatment efficiency was calculated for each case as stone burden treated (millimeter/operative time [minutes]). Differences between urologists were assessed through one-way analysis of variance (ANOVA).

Results: 69 CaOx flexible URSLL procedures were reviewed. 37 (54%) of patients were female; 60 (86%) of patients had postoperative imaging demonstrating stone-free status and 35 (51%) patients were declared visually stone free at completion of the case. The mean stone size was 9.2 mm (*R* 3-24, *SD* 4.53) and the mean operative time was 42 minutes (*R* 9-158, *SD* 27.7). The mean STES amongst all urologists studied was 0.3 mm/minute (*R* 0.38-1.33 *SD* 0.19) (Table 1). A significant difference between urologists was identified utilizing this novel metric of efficiency [$F(10,58) = 3.758$, $p = .006$] (Figure 1). The most efficient mean urologist STS in this series was 0.60 mm/minute and the least was 0.16.

Conclusions: The Stone Treatment Score (STS) can be a valuable metric for determining a urologist's efficiency to completely clear stone ureteroscopically within a set of technological constraints (laser power, technique). Operative scheduling may allow for more cases per operative day based on the efficiency a surgeon can achieve. This metric may be used to compare surgeon performance as well as create opportunities to improve perioperative planning and operating room utilization. The most efficient urologist by this metric in our study was a fellowship-trained endourologist. Further investigation as to factors associated with efficiency in the STS including assistant (resident or fellow) training year and experience. Further study to validate this metric against other operative efficiency estimates is warranted.

Figure 1 STS as a function of attending urologist



Descriptive Statistics			
N = 69 procedures	**Mean**	**Range**	**Standard Deviation**
Age (years)	58.0	31.27-82.29	13.38
Stone size (mm)	9.2	3-24	4.53
Procedure time (min)	42.4	9-158	27.74
Stone Treatment Score (STS) (mm/min)	0.3	0.04-1.33	0.20

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Renal Pelvis Pressures During Ureteroscopy Predict Pyelovenous Absorption in a Porcine Model

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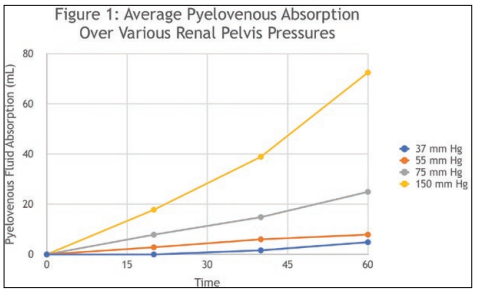
Introduction: Renal pelvis pressures and pyelovenous backflow during ureteroscopy are hypothesized to play a role in the development of infection after ureterorenoscopy. However, there are few studies in the literature which investigate this phenomon and the relationship between renal pelvis pressure, operative time, and pyelovenous backflow is poorly understood. Herein we present a pilot study of ureteroscopy in a swine model designed to evaluate these relationships.

Materials & Methods: In anesthetized pigs (n = 9; female; ~60 kg each), ureteroscopy was performed as follows: cystoscopy was performed to position a 0.018" pressure sensor guidewire (Comet™, Boston Scientific, Marlborough, MA) and standard guidewire. A flexible ureteroscope was then introduced into the renal pelvis and the position of the ureteroscope and the pressure sensor wire were confirmed. Infusion of irrigation fluid (5% ethanol in saline) at target renal pelvic pressures (37-150 mmHg) was maintained for 60 minutes using a pressure bag and instantaneous feedback from the pressure-sensing guidewire. Venous blood sampling was performed every 10 minutes. Each trial started with blood EtOH of 0 mg/dL. Volume of irrigant absorbed was determined with established equations utilizing animal blood EtOH, weight, and irrigation concentration.

Results: Fourteen (14) pig kidneys were used during the study. The average irrigation volume absorbed after 60 minutes of irrigation were 4.9, 7.9, 24.9, and 72.5 mL of fluid at renal pelvis pressures of 37, 55, 75, and 150 mm Hg, respectively ($P = 0.07$). At renal pelvis pressures of 55 mm Hg and above, pyelovenous backflow occurred as early as 20 minutes. At renal pelvis pressures of 37 mm Hg, pyelovenous backflow was not measured until at least 40 minutes of procedure time. Increasing renal pelvis pressures were associated with increases in fluid absorption for all pressures tested [Figure 1].

Conclusions: In this study of a swine model of ureteroscopy, increasing renal pelvis pressures during ureteroscopy were associated with increases in fluid absorption as well as more rapid fluid absorption. This model may be used in the future to better understand the relationship between renal pelvis pressure and pyelovenous backflow during ureteroscopy.



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Outcomes of Active Surveillance for Asymptomatic Renal Stones

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Introduction: A significant proportion of patients with asymptomatic nephrolithiasis pursue active surveillance with periodic imaging reassessment. While on surveillance, some patients will become symptomatic, but it is difficult to predict which patients will develop symptoms and over what time course symptoms will arise. We report the extended follow up outcomes of a cohort of patients with planned surveillance of asymptomatic renal stones.

Material & Methods: Medical records of patients with asymptomatic non-obstructing renal calculi who had declined initial surgical intervention and opted for active surveillance between 2008-2018 were retrospectively reviewed. Baseline demographics, stone size, number and location were collected. Cox proportional-hazards model was used to identify predictors of renal colic and to analyze clinical outcomes based on initial stone burden. Kaplan-Meier curve and log-rank test were used to examine event-free survival.

Results: A total of 110 patients (Male = 60, Female = 50) with 160 stones were followed for 71 ± 35 months (median = 85). Stone size of the cohort was 7.0 ± 4.2 mm (median = 6). Symptoms developed in 41.8% of patients, comprising 35.6% of stones in the entire cohort by 31 ± 24 months (median = 26). BMI ≥ 30 was associated with higher likelihood of symptom development (HR 1.91, CI 1.02-3.57, Table 1) and lower 5-year symptom free survival (50% vs. 71%, Figure 1). Age, gender, stone size, location, prior history of stones, and multiple renal stones were not associated with likelihood of symptom development. Clinical outcomes of the 160 stones are as follows: 12.5% triggered ER visit, 16.9% developed hydronephrosis, 1.9% developed silent hydronephrosis, 9.4% passed spontaneously, 20.6% underwent surgery for symptoms, and 18.8% underwent elective surgery without symptoms (Table 2). On univariate Cox analysis of the association between stone characteristics and clinical outcomes, non-lower pole stones had higher likelihood for spontaneous passage compared to lower pole stones (HR 4.63, CI 1.15-20.35). Stone size greater than or equal to 10 mm was associated with more surgical intervention (HR 2.11, CI 1.21-3.55) and lower 5-year surgery free survival (40% vs. 66%, Figure 2).

Conclusions: Over the course of 7-year median follow up for asymptomatic renal stones, most patients remain asymptomatic; a minority will spontaneously pass or require surgical intervention for symptoms. Those with higher BMI are more likely to develop symptoms, and stones ≥ 10 mm are associated with an increased odds of ultimately undergoing surgical intervention. Active surveillance is a viable option for asymptomatic renal stones, and these data may aid in patient counseling.

Figure 1. Symptom free survival of all patients stratified by BMI on presentation (log-rank test, p=0.04).

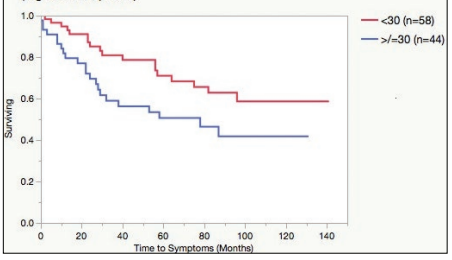
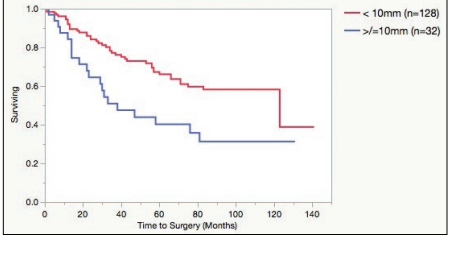


Figure 2. Surgery-free survival of all stones stratified by stone-size on presentation (log-rank test, p<0.01).



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Readmission After Ureteroscopy for Patients Stented Due to Febrile UTI with Obstructing Stone

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Introduction: Patients presenting with an obstructing ureteral stone and signs of infection represent a surgical emergency, requiring urgent decompression. Patients who have a ureteral stent placed in this setting often undergo ureteroscopy (URS) for definitive stone management following recovery. For these patients we postulated an increased risk for postoperative infectious complications and higher rates of readmission than those published in the literature for all-comers undergoing URS (2-7%).

Materials & Methods: A retrospective chart review was conducted at two hospitals associated with an academic medical center. After IRB approval, electronic medical records were reviewed from February 2012-June 2019. All patients who had a documented fever > 100.4° F and underwent a ureteral stent (CPT 52332) for obstructing stone were reviewed. Exclusion criteria included age < 18 years, lack of subsequent URS, time to URS > 6 months from stent placement, pregnancy, and non-stone indication for stent (UPJ obstruction, malignant obstruction, etc). Variables collected included Charlson Comorbidity Index (CCI), medical comorbidities, laboratory values, vital signs, and illness severity during initial presentation (QSOFA, ICU admission rates), as well as the use of access sheath, laser, and postoperative antibiotics at the time of definitive URS.

Results: 135 patients were included in the study, of whom 18 patients (13.3%) required unplanned admission within 30 days after URS. 13 of those patients (9.6%) were admitted for symptomatic UTI. Of these 13 patients, 23% became septic in the PACU, 23% required ICU admission, and 15% required postoperative vasopressors. Average time to readmission was 5.4 days for patients who were discharged home after URS. Average length of readmission was 3.7 days. A documented history of UTIs aside from the event prompting initial stent placement was a significant predictor of readmission following URS (p = 0.009). Female gender (p = 0.055), systolic hypotension <100 mmHg during initial presentation (p = 0.085), and a return visit for symptomatic UTI (p = 0.085) did not achieve significance. Age, CCI, diabetes, stone size, initial illness severity (ICU admission, pressor requirement, QSOFA score, bacteremia), stent dwell time, postoperative antibiotics, and stone composition did not impact readmission rates.

Conclusions: Patients who exhibit signs of infection coincident with an obstructing ureteral stone are at high risk of unplanned admission following URS for stone clearance. This risk is significantly increased for patients who have a prior history of recurrent UTIs. Patients who are readmitted have a high rate of severe illness requiring ICU-level care. Consideration should be given to closer post-operative follow-up or overnight monitoring for these patients, and they should be counseled appropriately about their elevated risk.

Unplanned admission <30 days for symptomatic UTI	No (122)	Yes (13)	Total Sample	P value
Age (years) at stent	61.1 (15.9)	59.8 (13.3)	61 (15.6)	0.786
Male	33.6%	7.7%	31.1%	0.056
CCI	2.94 (2.68)	2.77 (2.17)	2.93 (2.63)	0.822
Diabetic	29.5%	46.2%	31.1%	0.221
Prior UTI history	21.3%	53.8%	24.4%	**0.009**
Size of stone (mm)	7.27 (3.99)	6.67 (3.09)	7.22 (3.91)	0.611
ICU admission	20.5%	15.4%	20.0%	0.664
Pressors	10.7%	15.4%	11.1%	0.609
Bacteremic	31.1%	46.2%	32.6%	0.276
Tmax (°F) before stent	102.0 (1.3)	101.5 (1.1)	102 (1.3)	0.194
Systolic BP <100 mmHg	36.9%	61.5%	39.3%	0.085
QSOFA	0.84 (1.00)	1.31 (1.11)	0.89 (1.02)	0.12
Return for UTI between stent and ureteroscopy	8.2%	23.1%	9.6%	0.085
Sterile preop urine culture	61.5%	61.5%	61.5%	0.996
Time since stent (days)	42.8 (30.5)	47.9 (27.7)	43.3 (30.2)	0.564
Ureteral access sheath	42.6%	30.8%	41.5%	0.413
Laser use	63.1%	69.2%	63.7%	0.666
Operative time (min)	49.8 (34.2)	45.6 (27.0)	49.4 (33.6)	0.667
Post-op antibiotics	65.6%	84.6%	67.4%	0.166
Predominantly infectious stone (brushite, struvite)	31.1%	22.2%	30.4%	0.584
Categorical variables tested using Pearson"s chi squared analysis listed as %				
Nominal variables tested using independent t-test listed as mean (SD)				

Table 1. Association between baseline patient characteristic and symptom development.

		Became symptomatic	Remained Asymptomatic	HR
All Patients		46 (41.82%)	64 (58.18%)	(95% CI)
Gender				
F	50	21 (42.00%)	29 (58.00%)	
M	60	25 (41.67%)	35 (58.33%)	
Age				
< 65	82	35 (42.68%)	47 (57.32%)	
≥ 65	28	11 (39.29%)	17 (60.71%)	
BMI				
< 30	62	22 (35.48%)	40 (64.52%)	
≥ 30	45	23 (51.11%)	22 (48.89%)	1.91 (1.02-3.57)
Stone size				
< 10mm	83	35 (42.17%)	48 (57.83%)	
≥ 10mm	27	11 (40.74%)	16 (59.26%)	
Stone location				
Lower pole	58	23 (39.66%)	35 (60.34%)	
Non-lower pole	52	23 (44.23%)	29 (55.77%)	
History of stone				
No	16	6 (37.50%)	10 (62.50%)	
Yes	94	40 (42.55%)	54 (57.45%)	
Multiple stones				
No	34	15 (44.12%)	19 (55.88%)	
Yes	76	31 (40.79%)	45 (59.21%)	

Table 2. Percentage breakdown of asymptomatic stones by clinical outcomes and time to event.

		Became symptomatic	Remained Asymptomatic
All Stones		57 (35.63%)	103 (64.38%)
ER Visit			
No	140	37 (23.13%)	103 (64.38%)
Yes	20	20 (12.50%)	0 (0.00%)
Time (month)		37 ± 32 (28)	n/a
Hydronephrosis			
No	130	30 (18.75%)	100 (62.50%)
Yes	30	27 (16.88%)	3 (1.88%)
Time (month)		38 ± 26 (34)	36 ± 17 (30)
Spontaneous passage			
No	145	42 (26.25%)	103 (64.38%)
Yes	15	15 (9.38%)	0 (0.00%)
Time (month)		23 ± 17 (23)	n/a
Stone growth > 50%			
No	114	47 (26.25%)	67 (41.88%)
Yes	46	10 (6.25%)	36 (22.50%)
Time (month)		37 ± 41 (16)	47 ± 30 (43)
Surgical Intervention			
No	97	24 (15%)	73 (45.63%)
Yes	63	33 (20.63%)	30 (18.75%)
Time (month)		32 ± 22 (29)	34 ± 29 (24)

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24 hour Observation through Novel Stone Observation Pathway within Emergency Department Predicts Success of Outpatient Medical Expulsive Therapy

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Introduction: The incidence of nephrolithiasis continues to increase and safe emergency department management of acute renal colic is critical to patient outcomes. With the understanding that the majority of ureteral stones will pass spontaneously with outpatient medical expulsive therapy (MET), achieving pain control and treating associated symptoms to allow for safe discharge is paramount. In 2016 we developed a novel stone observation pathway (SOP) within our institution's Clinical Decision Unit (CDU) for patients with acute renal colic to have up to 24 hours of observation with the goal of a safe discharge on MET without requiring hospital admission or urologic consultation. The purpose of this study is to evaluate the safety and efficacy of the 24 hour observation model through a SOP for patients with acute renal colic.

Materials & Methods: A retrospective review of all patients admitted to the CDU utilizing the SOP from January 2016 to November 2019 was performed. Patients with ureterolithiasis were excluded from admission to the CDU if any single criteria from Table 1 was met. Patient characteristics, axial imaging, and follow up information were analyzed. Of note, it was assumed if a patient did not follow up with a urologist, they did not undergo surgical intervention for their ureteral stone. MET was considered successful if the patient did not return to the emergency department. Urologic consultation was not required during observation, however the urologist on call was alerted to patients with acute kidney injury, severe hydronephrosis, or calculi > 10 mm.

Results: 189 patients were diagnosed with uncomplicated ureterolithiasis and admitted via the SOP to the CDU (Table 2). The mean stone size was 4.6mm (SD +/- 1.9 mm). 148/189 (78%) patients were discharged within the 24 hour observation period and 42 patients were admitted for operative intervention (22%). 17 patients discharged from the unit returned to the emergency department for recurrent renal colic (9%) and 8 of these required admission for operative intervention (53%). 85 patients discharged from the unit followed up with a urologist (57%) and 30 of these patients ultimately required surgical intervention (22%). There were no readmissions for infection or sepsis.

Conclusions: 24 hour observation and discharge from a CDU in the emergency department using a SOP predicts success of outpatient MET. The protocol is both effective (< 10% readmission rate) and safe (0% readmission for UTI/pyelonephritis). Additionally, by avoiding admission to a urology service for observation, the urologist can focus efforts on more acute surgical consultation and management. Partnership between the divisions of urology and emergency medicine is critical for the success of the SOP. Future research will evaluate the cost savings of this protocol as well as low follow-up rate (57.4%) as an area for quality improvement.

Table 1: Stone Observation Pathway Exclusion Criteria

Exclusion Criteria
Temperature greater than 100.4 Farenheit
Heart rate greater than 110 beats per minute and persistent
Hypotension
Oxygen saturation less than 95%
Respiratory rate greater than 30 breaths per minute
Evidence of urinary tract infection or pyelonephritis
Altered mental status
Neurologic dysfunction (multiple sclerosis, paraplegia, etc)
Anuria
Pregnancy
Solitary kidney, polycystic kidney disease, renal transplant
End stage renal disease, hemodialysis
Indwelling catheter, stent or nephrostomy tube
Bedridden or nursing home patient
Active other admittable comorbid diagnoses
Attending discretion of unlikely discharge within a 24 hour period

Table 2: Outcomes of SOP patients

Patients admitted with renal colic (n = 189)	n	%
Patients discharged	148	78%
Patients admitted	42	22%
Patients returned to ER after discharge	17	9%
Patients who underwent intervention after return to ER	8	53%
Discharged patients who followed up with a urologist	85	57%
Discharged patients who required surgical intervention	30	22%

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Patterns of Opioid Prescription Post Ureteroscopy Among Members of the Endourological Society

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Introduction: Post-operative opioid prescription has been linked with persistent opioid use. Ureteroscopy (URS) is one of the most common urologic procedures, and therefore a potential area of focus to limit opioid prescribing among urologists. The aims of this study are to characterize national and international practice patterns of opioid prescription post URS and define reasons for opioid use in this setting.

Materials & Methods: We developed a survey directed to members of the Endourological Society. The survey was composed of 12-16 questions targeting practice patterns, frequency of opioid prescription post ureteroscopy, challenges faced when opioids are not prescribed and specific measures thought to be helpful to reduce the need for opioid prescriptions. The final survey was electronically distributed to 2000 Endourological Society members listed in the 2018-2019 Membership Directory. Accrual period was during May 2019.

Results: With a response rate of 8% (159/2000), the majority of respondents reported practicing urology for > 20 years (37.1%), and performing 10-20 ureteroscopies/month (45.3%). Around 40% of respondents were from the United States (US) and Canada. 66% completed a fellowship, 84% of which were endourology. 26% report routinely prescribing opioids and the majority do so less than 10% of the time (62.3%). 38% had no challenges when opioids were omitted. Measures felt to decrease the need for opioids were preoperative counseling, nonsteroidal anti-inflammatory drugs use, and use of adjunct medications. After adjusting for location, practice type, endourology fellowship completion, years of practice, and number of ureteroscopies/month, we found that respondents from the US and Canada were more likely to prescribe opioids routinely post URS, (Odds Ratio 87.5, P < 0.001, 95% Confidence Interval 17.3-443.5).

Conclusions: Among participants in our survey, nearly one quarter of urologists prescribe opioids routinely post URS, and US and Canadian urologists were more likely to prescribe routinely compared to the rest of the world. Despite proven feasibility of non-opioid management following URS, many urologists continue to prescribe opioids in this setting. We believe best practice guidelines by the American and Canadian Urological Associations should be considered to reduce opioid prescribing post ureteroscopy.

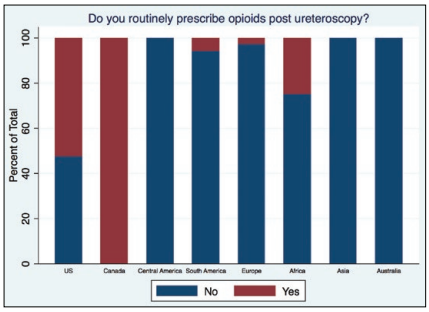

Table: Patient factors felt by participants to lead to the need for opioids post ureteroscopy, and measures that may decrease the need for opioids

	N(%)
Factors leading to the need for opioids*	
Patient with mental health diagnoses	32 (15.9)
Patients with substance abuse disorders	58 (28.9)
History of needing opioids for previous ureteroscopy	111 (55.2)
Measures that may decrease the need for opioids*	
Pre-op counseling and patient education	109 (21.1)
Post-op follow-up calls	47 (9.1)
Printed educational materials	67 (13)
NSAIDs use	116 (22.5)
Adjunct medications (Alpha-blockers, Anti-cholinergic, Phenazopyridine)	107 (20.8)
Protocol/culture change in not using opioids	70 (13.6)

*Participants were able to choose multiple choices

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Inpatient Urologic Consultation is not Necessary to Ensure Follow up in Patients with Uncomplicated Ureterolithiasis

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Brown University, Providence, RI

Introduction: The incidence of nephrolithiasis continues to increase and efficacious and safe emergency department management of acute renal colic is critical to patient outcomes. In 2016 we developed a novel Stone Observation Pathway (SOP) within our institution's Clinical Decision Unit (CDU) for patients with acute renal colic to have up to 24 hours of observation in order to control pain and treat associated symptoms with the goal of a safe discharge on MET without requiring hospital admission or urologic consultation. We found the overall follow-up rate was 54% prompting further investigation into factors that may affect this.

Materials & Methods: A retrospective review of all patients discharged from the CDU through the SOP for uncomplicated ureterolithiasis from January 2016 to November 2019 was conducted. Patient characteristics, axial imaging, and follow-up information were analyzed. Of note, it was assumed if a patient did not follow up with a urologist within our department, they did not follow up. Patients known to follow with an outside urologist were excluded from analysis. Inpatient urologic consultation was not required during observation, however the on-call urologist was alerted to patients with acute kidney injury, severe hydronephrosis or calculi > 10 mm. It was to the urologist's discretion if an inpatient consult was performed. Statistical analysis was performed using the chi-squared test.

Results: 141 patients with uncomplicated ureterolithiasis discharged from the CDU without intervention were included in the analysis. The mean stone size for all patients discharged was 4.1 mm (SD +/- 1.9 mm). Table 1 summarizes results and data analysis. 76 patients discharged from the CDU followed up with a urologist (54%). 28% of patients had a urologic consultation while under observation in the unit. Inpatient urologic consultation was not associated with follow-up rates (chi squared = 1.678, $p < 0.05$). Outpatient follow-up with a urologist was, however, associated with a prior stone history as well as prior care established with a urologist (chi squared = 0.0064, $p < 0.05$; chi squared = 0.0146, $p < 0.05$, respectively). Of note, 54 of 76 patients (71%) who followed up had never seen a urologist before and 40 of 61 patients (66%) with a history of nephrolithiasis followed up with a urologist.

Conclusions: Inpatient urologic consultation for patients admitted to a CDU with uncomplicated ureterolithiasis undergoing stone observation does not affect outpatient urologic follow-up rates. Additionally, patients with a history of nephrolithiasis were less likely to follow up suggesting these patients may be more comfortable with outpatient MET. Based on these results, in person consultation by a urologist is likely not necessary to ensure follow up in patients with uncomplicated ureterolithiasis and may represent an area to improve overuse of urgent inpatient specialty care.

Figure 1. Patterns in 76 patients who followed up with a urologist (n)

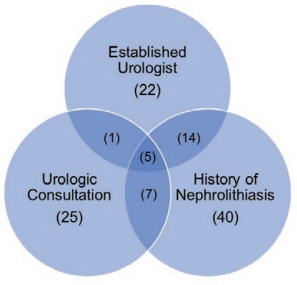

Table 1. Outcomes of discharged patients

Patients discharged with ureterolithiasis (n = 141)	n	%
Patients who followed up with a urologist	76	54%
Urologic consultation	25	
History of nephrolithiasis	40	
Established urologist	22	
Patients who did not follow up with a urologist	65	46%
Urologic consultation	15	
History of nephrolithiasis	21	
Established urologist	7	

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Risk Factors for Polymicrobial Stones in Patients Undergoing PCNL

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Introduction: Numerous studies have shown discordance between voided urine culture (UC) and stone culture (SC). This study sought to determine the correlation between polymicrobial stones and sepsis following percutaneous nephrolithotomy, and given poor concordance between UC and SC, other predicting factors for polymicrobial stones in patients undergoing PCNL.

Materials & Methods: Retrospective chart review was performed on 153 consecutive patients who underwent PCNL at Maine Medical Center between October 2016 and December2018. Patient demographic factors, comorbidities, infection history, culture data, stone factors and surgical factors were recorded. Sepsis was defined by SIRS criteria for severe sepsis. Multivariate logistic regression was used to evaluate categorical variables.

Results: 17 of 153 (11%) patients were found to have polymicrobial stones. Of those, 7 (41%) developed post-operative sepsis as compared to 3/33 (9%) in single organism stones and 4/103 (4%) in sterile stones. Presence of polymicrobial stone was significantly associated with post-op sepsis (OR 18, $p = 0.001$). Diabetes (OR 7.7; $p = 0.003$), neurogenic bladder (OR 11.7; $p = 0.001$) a history of urosepsis (OR 6.5; $p = 0.005$), stone diameter >= 26 mm (OR 3.8; $p = 0.026$), and infected stone as indication (OR 9.08; $p = 0.001$) were all independently associated with polymicrobial stone. Limited upper or lower extremity mobility (OR 31; $p < 0.001$), neurologic disease (OR 8.95; $p = 0.001$) (specifically multiple sclerosis (MS) (OR 6.3; $p = 0.040$)) and contractures (OR 55; $p = 0.002$) were associated with polymicrobial stones. While indication for PCNL because of infected stone, or having any positive pre-op urine culture had high specificity and negative predictive value for predicting polymicrobial stone, positive predictive value was low (0.27 and 0.19, respectively) (Table 1). However, combining these with information on DM, MS, spina bifida, ileal conduit or limited lower extremity mobility resulted in high positive predictive values, negative predictive value and specificity (Table 1).

Conclusions: Patients with polymicrobial stones have a substantially higher risk of post PCNL sepsis compared to stones with a single or no microbe species. There are a number of easily identifiable patient attributes significantly associated with polymicrobial stones. These allow for simple risk stratification to help identify PCNL patients at higher risk for polymicrobial stone and therefore sepsis and have implications for instituting modified treatment strategies such as broader peri-operative antibiotics. Further research is needed to study the effect of these strategies.

Additional Comorbidity	Positive Pre-op Urine Culture	Indication: Infected Stone
None	Sensitivity: 0.27 Specificity: 0.64 PPV: 0.19 NPV: 0.94	Sensitivity: 0.71 Specificity: 0.76 PPV: 0.27 NPV: 0.95
MS	Sensitivity: 0.12 Specificity: 0.99 PPV: 0.5 NPV: 0.90	Sensitivity: 0.12 Specificity: 0.98 PPV: 0.4 NPV: 0.90
DM	Sensitivity: 0.35 Specificity: 0.93 PPV: 0.38 NPV: 0.92	Sensitivity: 0.47 Specificity: 0.93 PPV: 0.47 NPV: 0.93
Ileal Conduit	Sensitivity: 0.24 Specificity: 0.99 PPV: 0.67 NPV: 0.91	Sensitivity: 0.24 Specificity: 0.96 PPV: 0.44 NPV: 0.91
Spina Bifida	Sensitivity: 0.24 Specificity: 0.96 PPV: 0.4 NPV: 0.91	Sensitivity: 0.24 Specificity: 0.96 PPV: 0.44 NPV: 0.91
Limited Lower Extremity Mobility	Sensitivity: 0.47 Specificity: 0.93 PPV: 0.47 NPV: 0.93	Sensitivity: 0.47 Specificity: 0.92 PPV: 0.42 NPV: 0.93

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Significant Variability in Outpatient Opioid Prescriptions by Discharge Provider following Percutaneous Nephrolithotomy (PCNL)

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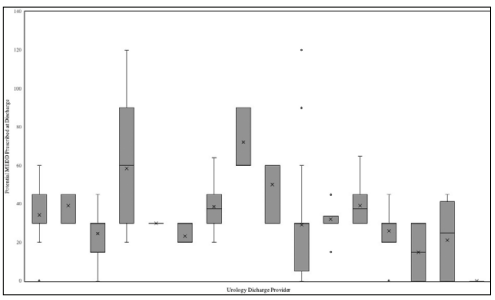
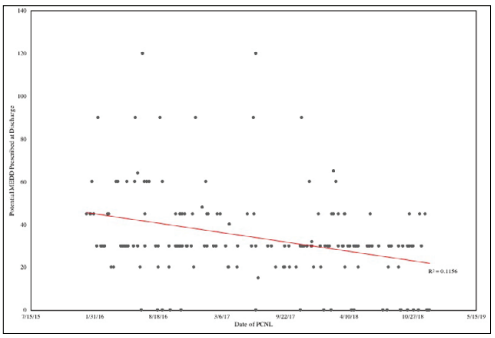
Introduction: Various initiatives throughout the United States have been implemented to limit and standardize opioid prescriptions at time of discharge following urologic surgery. Efforts have been made to standardize discharge prescriptions according to procedure via non-opioid care pathways. State-level legislation introducing limitations to opioid prescribing was passed in Rhode Island in an effort to curb over-prescription in 2016. We sought to characterize the discharge prescribing patterns of residents and advanced practice providers (APPs) following percutaneous nephrolithotomy (PCNL) at a single academic institution in Rhode Island.

Materials & Methods: All patients who underwent PCNL at a single institution from 2016-2018 were reviewed retrospectively. 163 patients were reviewed for a total of 182 discrete PCNL cases with associated hospital encounter and discharge. 16 urologic providers were responsible for each of these discharges (14 residents, 2 APPs). Prescriptions were stratified by provider to assess for differences as a function of discharging provider. All discharge opioid medications were converted to morphine equivalent daily dosing (MEDD) for standardization purposes. One-way analysis of variance (ANOVA) was performed to detect differences in potential MEDD prescribed at time of discharge between providers.

Results: Over the time interval studied, 161/182 (88.4%) PCNL cases were discharged home with an opioid analgesic. A statistically significant difference in opioid prescribing practices between the sixteen discharge providers was identified [$F(15,166) = 5.26$, $p < .0001$] (Figure 1). Additionally, a statistically significant decrease in MEDD prescribing over time was identified [$F(1,180) = 23.54$, $p < .0001$] (Figure 2). No differences in MEDD prescribed were observed for age and gender.

Conclusions: Significant variability existed in the opioid-prescribing practices of urologic providers following PCNL from 2016 to 2018, however, the overall MEDD prescribed has declined over time. This suggests that a standardized approach to prescribing opioids may be beneficial in limiting the number of prescriptions generated. Provider education should focus on typical and expected postoperative pain requirements for individual cases. Educating patients preoperatively on expectations pertaining to discharge prescriptions may prevent requests for additional opioid pain medications at the time of discharge. Partnering with state Department of Health and legislative bodies may be helpful in the global effort curb the opioid epidemic.





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The High Cost of Midnight Ureteral Stents for Obstructing Urolithiasis and Infection

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Introduction: Patients who present to the emergency department (ED) with obstructing urolithiasis and evidence of urinary tract infection often require ureteral stent placement after midnight. Overnight stenting requires operating room (OR) staff to be called in from home at many institutions, including our own. We sought to elucidate the workforce cost to perform stent placement after midnight when the call team is activated to mobilize the OR and complete the case.

Materials & Methods: Emergent cystoscopy and ureteral stent placement procedures performed in the OR at a single academic institution between May 2017 and December 2019 were reviewed retrospectively in an IRB-approved database. A cost analysis was performed to account for the minimal personnel required to be called into the hospital for the procedure including the anesthesiologist, surgical technician, circulating nurse, radiologic technologist, two post-anesthesia care unit (PACU) nurses, and an operating room assistant (ORA). Cost data were derived from median salary at our institution for call staff as well as specific fees from anesthesiology staff. The student's t-test was utilized to detect differences between groups.

Results: A total of 131 urgent stent placements were performed between May 2017 and December 2019. Of these, 18 (14%) procedures were performed between the hours of midnight and six o'clock AM. Ten patients (56%) stented after midnight demonstrated two, three or four systemic inflammatory response syndrome (SIRS) criteria upon presentation, while eight patients (44%) presented with zero or one SIRS criteria. Time from CT diagnosis to OR (minutes) in the presence of two, three or four SIRS criteria was not significantly different between the hours of 0600-2400 (49/59 [83%] patients; mean = 274.5, SD = 228.5) versus 0000-0600 (10/59 [17%] patients; mean =191.8, SD = 153.5); $t(19) = 1.4$, $p = .18$).The cost of calling in personnel after midnight was \$2,782.00 accounting for a mandatory 4 hours of overtime pay, not including post-call substitute staff the following morning. The mean operating room utilization time was 25 minutes (R 16-34, SD 6.0).

Conclusions: Patients presenting with obstructing urolithiasis and infection have high workforce costs associated with the need for decompression. At our academic institution without 24 hour staff for procedures performed outside of standard OR hours, the personnel cost of performing ureteral stent placement after midnight was \$2,782.00. Given that nearly half of the patients exhibited zero or one SIRS criteria at time of ED evaluation, further work is needed to determine which patients can safely be observed overnight with stent placement during daytime hours. In this series, potential deferment of clinically stable patients to stent placement the following morning could have produced a cost savings of \$22,256. Further study regarding the safety of stent placement outside of the OR (i.e., "bedside stenting") in the appropriate clinical context is also warranted.

Table 1: Personnel cost per case

Personnel:	Cost / Fee
Anesthesiologist	\$2,000.00
Surgical technician	\$98.00
Circulating nurse	\$168.00
Radiologic technologist	\$120.00
xppTwo PACU Nurses	\$336.00
Operating room assistant (ORA)	\$60.00
Total	**\$2,782.00**

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A Multi-Institutional Experience Comparing Internal Urethrotomy with Intralesional Mitomycin C for Recurrent Bladder Neck Contractures in Radiated vs. Non-Radiated Patients

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Introduction: We have previously published our initial and intermediate-term experience with direct visual internal urethrotomy (DVIU) and intralesional mitomycin C (MMC) for recurrent bladder neck contractures (BNC). This study highlights our continued durable results in addressing this challenging clinical problem and specifically focuses on success rates in radiated vs. non-radiated groups.

Materials & Methods: A retrospective review was performed of all patients who underwent DVIU with intralesional MMC for BNC between 2007 and 2019 at two institutions. Cold knife incisions were performed in a reproducible fashion followed by injection of 0.3 to 0.4 mg/ml MMC at each incision site. Patients with evidence of complete urethral obliteration, strictures of the entire posterior urethra, or less than 3 month follow-up were excluded. Success was defined as the ability to pass a 17-French cystoscope postoperatively without the need for catheterization or dilation.

Results: A total of 86 patients were included in our analysis. The vast majority (91%) had at least 1 prior DVIU, 55% had at least 1 prior dilation or required a specific dilation schedule, and 44% presented with an indwelling catheter or performed intermittent catheterization. At a median follow-up of 21 months, the overall success rate was 90% (65% after 1 procedure, 83% after 2 procedures, and 90% after 3 or more procedures). Non-radiated patients showed a significantly higher success rate compared to radiated patients (94% vs. 76%, p = 0.04) (Table 1). Of the 9 patients with cystoscopic failure, 5 had minimal urinary symptoms and pursued observation. Only 2 patients with a history of previous catheterization or urethral dilation required this postoperatively. Two patients underwent subsequent urinary diversion. Rigorous follow-up showed no long-term overall or MMC-specific complications.

Conclusions: Radical DVIU with intralesional MMC continues to prove to be a safe and durable treatment strategy for BNC from various etiologies, although success rates are exceptional in patients without a history of pelvic radiation.

Table 1

	Initial (median)	Final (median)	P-Value
Qmax (mL/s)	10.8	17.5	0.066
PVR (mL)	82	17	**0.003**
	Radiation	**No Radiation**	**P-Value**
# of patients	21	65	
stable bladder neck after 1 procedure	11	45	
% stable after 1 procedure	52.4%	69.2%	**0.04**
stable after 1 or 2 procedures	15	56	
% stable after 1 or 2 procedures	71.4%	86.2%	0.06
stable after any number of procedures	16	61	
% stable after any number of procedures	76.2%	93.8%	**0.04**

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A Retrospective Comparison of 1470$_{nm}$Diode Laser Enucleation and Bipolar Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Hyperplasia

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Introduction: One in 12 patients with BPH will require surgical management. TURP is the gold standard, but new technologies may provide similar outcomes with lower complication rates. The 1470$_{nm}$diode laser is a novel technology for use in endoscopic laser enucleation of the prostate (DiLEP). There is a paucity of data comparing bipolar TURP to 1470$_{nm}$DiLEP. We compared procedure efficacy, perioperative outcomes and complication rates between B-TURP and 1470$_{nm}$DiLEP.

Materials & Methods: This is an IRB-approved retrospective review of patients who underwent DiLEP (n:114; November 2016-February 2020) or TURP (n:194; January 2016-December 2018). Patients with history of prostate cancer and/or prior TURP were excluded from analysis. DiLEP was performed by a single surgeon, while TURP was performed by multiple surgeons. Prostate sizing was calculated via transabdominal ultrasound. Patient characteristics, peri-operative outcomes, treatment efficacy (Q_{max}, PVR) and complications(Clavien-Dindo) were compared. Statistical analyses with STATA were conducted using independent Student's t-tests, Fisher exact test, Wilcoxon rank-sum test, and Wilcoxon signed-rank test.

Results: Patients undergoing DiLEP had significantly larger prostates (92 ml (65.2-115) vs. 65(48-88), $p < 0.0001$) and a greater proportion of median lobes(77% vs.57%, $p = 0.01$; Table 2). Both groups had significant improvements in Q_{max} and PVR from baseline at all postoperative time points (1, 3, 6 and 12 months) with no significant difference between groups at any timepoint (Figure 1). DiLEP had a greater percentage of prostate tissue resected (36%(27-47) vs. 31%(20-42), $p = 0.001$) and a shorter length of stay (16.9 hours (2.9-25) vs.27.7 hours (24-33), $p < 0.0001$), but had longer operative times (133 minutes (108-157) vs. 54 minutes (39-74), $p < 0.0001$). 53(46%) patients undergoing DiLEP were discharged from the PACU, as compared to none undergoing TURP. Catheterization times were equivalent (24.5 hours (20-64) vs. 22.1 hours (18-67), p=0.13). Postoperative and < 30-day complications were similar in both groups (Table 3), however, DiLEP had significantly fewer complications >30 days post procedure and no grade IV complications.

Conclusions: DiLEP and TURP had similar efficacy for relieving obstruction and reducing PVR, however, when compared to TURP, DiLEP had longer operative times, but a lower > 30-day complication rate and a greater percentage of prostate resected. In addition, patients undergoing DiLEP had a shorter length of stay and just under half of patients were discharged home from the recovery room. These results support the non-inferiority of DiLEP relative to TURP for the surgical treatment of BPH.

Table 1: Demographic Variables

Variable	TURP (n = 194)	DiLEP (n = 114)	p-value
Age (Mean ± SD)	68.8 ± 8.5	69.5 ± 9.7	0.56[a]
Race (%)			
White	75 (39%)	57 (50%)	
Black	75 (39%)	34 (30%)	
Other/Unknown	43 (22%)	23 (20%)	0.25[b]
Ethnicity (%)			
Hispanic or Latino	51 (26%)	31 (27%)	
Not Hispanic or Latino	142 (73%)	83 (73%)	0.93[b]
BMI (kg/m^2) (Mean ± SD)	27.7 ± 4.9	28.2 ± 4.4	0.33[a]
ASA (%)			
1	2 (1%)	0 (0%)	
2	73 (38%)	52 (46%)	
3	90 (46%)	60 (53%)	
4	0 (0%)	1 (1%)	0.50[b]
Charlson Co-morbidity Index Median (IQR)	0 (0-2)	0 (0-2)	0.43[c]

[a]Unpaired t-test (for normally distributed variables)[b]Fisher's exact analysis [c] Wilcoxon rank-sum test (for non-normally distributed variables)

Table 2: Preoperative and Operative Variables

	TURP	DiLEP	p-value
Preoperative (baseline) Variables			
Variable			
Creatinine (Mean ± SD)	1.1 ± 0.4	1.1 ± 0.3	0.65[a]
Preoperative PSA (ng/mL) Median (IQR)	2.7 (1.2-5.4)	4.0 (1.9-5.6)	**0.05**[c]
Preoperative IPSS (n = 54 for TURP, n = 84 for LEP) (Mean ± SD)	21.9 ± 6.4	22.6 ± 7.8	0.49[a]
Preoperative QoL (n = 21 for TURP, n = 68 for LEP) (Mean ± SD)	4.9 ± 1.1	4.7 ± 1.1	0.38[a]
Preoperative Q_{max} (cc/sec)	8 (5-10)	9.2 (6.4 - 12)	0.54[c]
Preoperative PVR (cc) Median (IQR)	77 (40.5-200)	85.5 (23.5-207)	0.70[c]
Preoperative Prostate size (g) Median (IQR)	65 (48-88)	92 (65.2-115)	**< 0.0001**[c]
Median Lobe (%)			
Yes	111 (57%)	88 (77%)	
No	43 (22%)	10 (8.8%)	**0.001**[b]
Preoperative Catheter Use (%)			
None	141 (73%)	78 (68%)	
Indwelling Catheter	42 (22%)	30 (26%)	
Daily CIC	11 (5.7%)	6 (5.2%)	0.65[b]
Operative Outcomes			
Operative Time (min) Median (IQR)	53 (38-72)	133.5 (111-158)	**< 0.0001**[c]
Catheter Removal Time (hours) Median (IQR)	22.1 (18-62)	24.5 (20-64)	0.13[c]
% Prostate Resected Median (IQR)	31 (20-42)	36 (27-47)	**0.001**[c]
Length of Stay (hours) Median (IQR)	27.7 (24-33)	16.9 (2.9-25)	**< 0.0001**[c]

[a]Unpaired t-test (for normally distributed variables)[b]Fisher's exact analysis [c]Wilcoxon rank-sum test (for non-normally distributed variables)

Table 3: Complications

TURP Complications; % = percentage of total TURP patients (n = 194)				
Complication Grade	**Operative**	**D30**	**D30+**	**Total n (%)**
I	AUR (8) Vasovagal episode (3)	AUR (5) UTI (3)	AUR (5) UTI (4)	**28 (14%)**
II	Arrhythmia (1) Blood transfusion (3)	Urosepsis (2) Epididymitis (1)	Urosepsis (1)	**8 (4%)**
IIIa	0	Diagnostic Cystoscopy (1)	Diagnostic Cystoscopy (4) Urethral Stricture LA (3)	**8 (4%)**
IIIb	0	Clot evacuation GA (1)	Urethral Stricture GA (3) TUIBNC (3) Repeat TURP (2)	**9 (5%)**
IV	SICU for hyperglycemia (1) SICU for vasovagal (1) MICU for blood transfusion & fulguration (1)	SICU for blood loss anemia and clot retention (1)	0	**4 (2%)**
Total n (%)	**18 (9%)**	**14 (7%)**	**25 (13%)**	**57 (29%)**
DiLEP Complications; % = percentage of total DiLEP patient (n=114)				
I	False Passage (1) AUR (3)	AUR (1) UTI (2)	AUR (2)	**9 (8%)**
II	Urosepsis (1)	Seizure 2/2 UTI (1) Blood transfusion (1)	0	**3 (3%)**
IIIa	0	0	Diagnostic Cystoscopy (1)	**1 (1%)**
IIIb	Clot evacuation & fulguration (2)	0	Urethral Stricture GA (1)	**3 (3%)**
Total n (%)	**7 (6%)**	**5 (4%)**	**4 (4%)**	**16 (14%)**

D30 = Post-operative day 30; D30+ = Beyond 30 days post-operation; AUR = acute urinary retention; UTI = urinary tract infection; 2/2 = secondary to; LA = repair under local anesthetic; GA = repair under general anesthetic; TUIBNC = transurethral incision of bladder neck contracture

Figure 1: Median Q_{max} and PVR over time for each procedure, only values with voided volume>150cc were included. No significant difference between TURP and DiLEP at any timepoint using two-sample Wilcoxon rank-sum test.

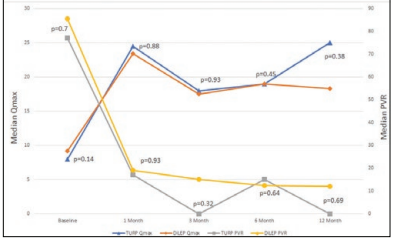
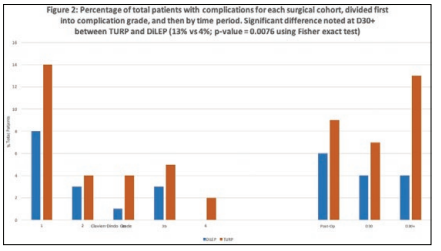


Figure 2: Percentage of total patients with complications for each surgical cohort, divided first into complication grade, and then by time period. Significant difference noted at D30+ between TURP and DiLEP (13% vs 4%; p-value = 0.0076 using Fisher exact test)



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A Validation Study of a Simplified Acquired Buried Penis Repair Classification System: Perioperative Complications and Outcomes

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Introduction: A recently published buried penis repair classification system has been proposed to better predict perioperative complications and outcomes (Pariser et al, 2018). Our objective was to validate this classification system at our reconstructive center and assess its utility in predicting patient outcomes.

Materials & Methods: Patients who underwent buried penis repair by a single surgeon between January 2012-December 2018 were included. The proposed classification system is as follows: Category I - penile unburying with local skin flap; II - skin graft; III - scrotal surgery; IV - escutcheonectomy; V - abdominal panniculectomy. High complexity was defined as category III or higher. Perioperative 90-day Clavien-Dindo complications were assessed. Failure was defined as the need for additional unburying surgery.

Results: Fifty patients underwent repair with 88% considered highly complex. Median body mass index (BMI) was significantly higher in the high complexity group (41 vs. 33 kg/m2, p = 0.004). Thirteen (26%) patients had urethral strictures with no association to surgical complexity (p = 0.17). In the high complexity group, 3 (7%) patients had high grade complications (Clavien ≥ 3). There were zero complications, low or high grade, in the low complexity group. At a median follow-up of 10.4 months, successful repair was achieved in 90%. All failures occurred in the high complexity group.

Conclusions: Utilizing this classification system as a predictor of perioperative outcomes, our study validates the pilot study findings. Patients requiring high complexity repairs have a higher BMI. High grade complications and failures only occurred in the high complexity group. Further multi-institutional studies should be pursued to assess this classification system and to refine important clinical variables and operative techniques to maximize patient goals and predict patient outcomes.

Table 1. Patient Demographics

	Current study	Pilot study
Total number of patients (%)	50	64
Age (years) [median (IQR)]	54 (42-64)	53 (42-63)
BMI (kg/m^2) [median (IQR)]	40 (35-46)	45 (38-53)
Tobacco use, current or former (%)	20 (40%)	16 (25%)
Diabetes mellitus (%)	15 (30%)	32 (50%)
Buried penis repair category (%)		
I	5 (10%)	3 (5%)
II	1 (2%)	17 (27%)
III	11 (22%)	7 (11%)
IV	29 (58%)	33 (52%)
V	4 (8%)	4 (6%)

Table 2. Perioperative Outcomes Based on Repair Complexity

	Low Complexity Repair (I-II) (n = 6)	High Complexity Repair (III-V) (n = 44)	P-value
BMI (kg/m^2) [median (IQR)]	33 (32-35)	41 (36-52)	**0.004**
Tobacco use (%)	3 (50%)	17 (39%)	0.67
Diabetes mellitus (%)	1 (17%)	14 (32%)	0.65
Urethral stricture (%)	3 (50%)	10 (23%)	0.17
Any complication (%)	0 (0%)	15 (34%)	0.16
High grade complication (%)	0 (0%)	3 (7%)	0.99
Successful repair (%)	6 (100%)	39 (89%)	0.99

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Real-world Evidence with the Prostatic Urethral Lift and Rezum: a Retrospective Cohort Study on the Efficacy and Durability in 12-month Clinical Outcomes

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Introduction: The Prostatic Urethral Lift (PUL) and Rezūm are attractive minimally invasive treatment options for patients with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia. PUL relies on a mechanical approach, using implants to create a continuous channel between the prostate's lateral lobes, while Rezūm relies on convective water vapor thermal energy to ablate the prostate's lateral and medial lobes. We report the first study analyzing 12-month real-world clinical outcomes between PUL and Rezūm.

Materials & Methods: Clinical outcomes for the PUL group were obtained from published retrospective literature while those for the Rezūm group were obtained by conducting a retrospective study. International Prostate Symptom Score (IPSS) and Quality of Life (QoL) were assessed at 1-, 3-, 6-, and 12-month while maximum flow rate (Qmax) was assessed at 3-, 6-, and 12-month. Statistically significant differences between groups and from baseline to follow-up were determined using a two-sample t-test and paired t-test, respectively.

Results: A total of 1413 patients were included in the PUL group and 219 patients were included in the Rezūm group. The PUL group had a higher mean baseline age (70.0 years), IPSS (19.0 points), Qmax (13.0 mL/s), and PVR (135.0 mL) when compared to the Rezūm group (63.3 years, 17.2 points, 11.5 mL/s, 29.2 mL, $P < 0.05$). The Rezūm group had a higher mean baseline QoL (4.3 points) when compared to the PUL group (4.0 points, $P < 0.01$). There were no significant differences in mean baseline prostate volume and PSA between the groups. Both groups saw significant improvements in IPSS and QoL as early as 1-month which remained durable to 12-month ($P < 0.01$). At 1-month, the PUL group saw rapid percent changes in IPSS (-39%) and QoL (-43%) with maximum percent changes achieved at 3-month (-42%, -45%). The Rezūm group saw gradual improvements in IPSS and QoL with maximum percent changes in IPSS (-37%) and QoL (-44%) achieved at 6- and 12-month, respectively. Improvements in Qmax were durable to 12-month in the Rezūm group ($P < 0.01$) and to 6-month in the PUL group ($P = 0.03$). Maximum percent change in Qmax was seen at 3-month for the Rezūm group (117%) and at 6-month for the PUL group (36%).

Conclusions: Real-world application of PUL and Rezūm showed significant and durable improvements in LUTS and QoL up to 12 months. PUL demonstrated rapid relief in LUTS with maximum improvements achieved in 3 months while Rezūm yielded gradual relief with maximum improvements achieved in 6 months, suggesting that cell necrosis from water vapor treatments with Rezūm requires a longer healing period. However, Rezūm demonstrated greater and more durable improvements in flow rates.

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Conservative Management of Lichen Sclerosus-induced Male Urethral Strictures: Can Urethral Reconstruction be Safely Avoided?

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Introduction: Lichen sclerosus-induced urethral stricture disease (LS-USD) creates surgical challenges for the reconstructive urologist due to the high risk of stricture recurrence and disease progression. We reviewed the outcomes of such patients at our institution to determine if conservative management can be an effective strategy.

Materials & Methods: We retrospectively identified patients with LS-USD who were managed with urethral balloon dilation or clean intermittent catheterization (CIC) +/- intraurethral steroids. Any patient who had an obliterative stricture, underwent urethral reconstruction as the primary means of USD treatment, or had less than 3 months follow-up was excluded. Primary outcome measures were urinary tract infection (UTI), acute urinary retention (AUR), serum creatinine, and uroflowmetry values. Secondary outcome measures were Sexual Health Inventory for Men (SHIM) and Male Sexual Health Questionnaire (MSHQ) scores.

Results: A total of 109 men met inclusion criteria between 2005-2019 with a median follow-up of 24 months (IQR 8-49). Median age was 52.2 years, body mass index was 35.5 kg/m^2, and Charlson comorbidity index was 1. Median stricture length on retrograde urethrogram was 10 cm (IQR 2-20). Stricture location was: meatus/fossa navicularis (33%), pendulous (9%), and bulbopendulous (58%). The most common urinary symptoms were slow flow (50%), sitting to void (25%), and spraying (23%). A total of 77 (71%) patients underwent subsequent urethral dilation. Median number of dilations per patient was 1 (IQR 1-3). CIC was utilized in 32% of patients, with 32% of this subgroup applying steroids intraurethrally via CIC. Uroflowmetry values and sexual health questionnaires showed no significant change between first and last visits (Table 1). Median serum creatinine at first and last visits remained unchanged at 1.0 mg/dL. Eight (7%) patients had an AUR episode requiring urgent treatment and 20 (18%) had a stricture-related UTI.

Conclusions: Although certain patients will desire or require urethral reconstruction, many patients with LS-USD, across a wide range of stricture lengths and locations, appear to be safely managed with urethral dilation or CIC +/- intraurethral steroids. Close observation is warranted due to the risk of stricture-related UTIs and AUR episodes.

Table 1. Uroflowmetry Values and Sexual Health Questionnaire Scores

Uroflowmetry

	Median	N	P-value
Qmax (first visit)	12.5	34	
Qmax (last visit)	10.9	34	0.24
Qmean (first visit)	7.2	23	
Qmean (last visit)	6.2	23	0.66
Post-void residual (first visit)	24	67	
Post-void residual (last visit)	17	67	0.08

Sexual Health Inventory for Men (SHIM)

	Median	N	P-value
First visit	23	17	
Last visit	23	17	0.76

Male Sexual Health Questionnaire (MSHQ)

	Median	N	P-value
First visit	17	25	
Last visit	17	25	0.76

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Comparison of Magnetic Resonance Imaging to Transabdominal and Transrectal Ultrasound for Sizing of the Prostate

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Introduction: Prostate size is an important factor when considering diseases of the prostate. AUA guidelines (2018) for surgical management of benign prostatic hyperplasia (BPH) now include consideration of prostate volume measurement prior to surgical intervention. Multiple imaging modalities exist to estimate size, including transabdominal pelvic ultrasound (PUS), transrectal ultrasound (TRUS), and cross-sectional imaging with computed tomography (CT) and magnetic resonance imaging (MRI). Ultrasound is a quick, inexpensive, and accessible imaging modality. MRI has been used increasingly in detection and diagnosis of prostate cancer and provides more accurate measurement of prostate size. This study seeks to compare PUS and TRUS to MRI in estimation of prostate size.

Materials & Methods: We performed a single-center, retrospective study of 95 patients with PUS, TRUS, and MRI prostate sizing between August 15, 2013 and June 20, 2017 with IRB approval. Prostate volumes were derived from ellipsoid volume calculation (length x width x height x $\pi/6$). Correlation between MRI versus TRUS and PUS was calculated through the Pearson coefficient (PC). Reliability between each of the three modalities was analyzed through intraclass correlation coefficient (ICC). Agreement was assessed using Bland-Altman (BA) analysis, which is a visual representation of how much of the data falls between clinically defined limits of agreement (LOA) that we defined as ±10 cc. Data was further stratified by numerous other variables, including prostate size.

Results: A total of 95 patients had MRI, TRUS, and PUS. Median age was 64, median BMI was 27 kg/m^2, and median PSA value prior to PUS was 7.1 ng/mL. Nineteen (20%) were white, 42 (44%) were black, and 21 (22%) were Hispanic. Mean difference in volume estimate between MRI and TRUS (Vol_{TRUS} - Vol_{MRI}) was (6.1 ± 15.5) cc, and mean difference in volume estimate between MRI and PUS (Vol_{PUS} - Vol_{MRI}) was (5.5 ± 16.6) cc. PC for MRI vs. TRUS and MRI vs. PUS was 0.80 and 0.74, respectively. The ICC for all three modalities was 0.90 (0.86-0.92). BA analysis for MRI vs. PUS and MRI vs. TRUS showed that for prostates ≤ 50cc, greater than 80% of the data fell within the LOA. These percentages decreased with increased prostate size to 39% and 42% for prostates > 50cc and ≤ 80cc and to 25% and 61% for prostates > 80 cc for MRI vs. PUS and MRI vs. TRUS, respectively.

Conclusions: MRI may be considered clinically interchangeable with TRUS and PUS for prostate sizing at prostate volumes ≤ 50cc, as BA analyses showed good agreement between imaging modalities in this range. PUS and TRUS remain good tests in initial assessment of prostate size. If minor changes in prostate size would drastically alter surgical management, we would not recommend US as the sole imaging choice. It is important to note that our conclusions are based on our LOA of ±10cc, and this may vary based on clinical scenario and provider comfort. When selecting modality for prostate sizing, one should consider all factors including the benefits and drawbacks of each type of imaging.

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Prostatic Urethral Lift: Does Age Matter?

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Introduction: Complex ureteral reconstruction for stricture disease with buccal mucosa graft (BMG) is reported in the urologic literature with a number of case series touting its success for long-segment ureteral strictures that would otherwise require an ileal ureter or autotransplant. To date, there are approximately 34 reported human cases of robotic-assisted buccal ureteroplasty. However, the prior reports have varying definitions of operative success. We sought to review our single-institution experience with robotic-assisted BMG ureteroplasties to complement the existing literature.

Materials & Methods: An institutional review board approved observational retrospective review of all robotic ureteroplasties performed with a BMG at our institution by two surgeons was undertaken. Patient demographics, operative characteristics, and post-surgical outcomes were recorded. Clinical failure of the ureteroplasty was defined as the need to perform any additional intervention on the ipsilateral collecting system secondary to refractory ureteral obstruction.

Results: A total of nine robotic BMG ureteroplasties were performed at our institution from 2015-2019. The stricture etiologies were iatrogenic endoscopic calculus treatment sequelae (n = 3), failed pyeloplasty (n = 3), idiopathic (n = 1), sequelae of nephrolithiasis (n=1), and iatrogenic ureteral injury during colorectal surgery (n = 1). All ureteroplasties were performed robotically, with six using an anterior onlay technique and three using an augmented anastomotic technique. Four of the patients had previously undergone a failed prior procedure for their stricture. The average ureteral stricture length in the cohort was 5.4 cm (4-7 cm). The stricture location was proximal for five cases while four cases were mid-ureteral. In seven cases the onlay graft was wrapped with an omental flap and in two cases the reconstruction was wrapped with only Gerota's fascia. With an average follow up of 15.6 months (1-23 months), three (33%) of the BMG ureteroplasties required an additional intervention secondary to clinical failure of the reconstruction. Two of these cases had previous open ureteral reconstruction attempts. Of the failed reconstructions (cases 4-6), one required short term placement of a nephrostomy tube, one has required a chronic ureteral stent, and one underwent an autotransplant.

Conclusions: The BMG ureteroplasty is an important addition to the armamentarium of surgical approaches for the management of ureteral stricture disease and is a viable treatment option for long segment ureteral strictures that would otherwise require an ileal ureter or autotransplant. Our small experience adds almost 25% case volume to the existing literature. Our success rate of 67% is notable lower than a previously reported multi-institutional review of 19 patients showing a 90% success rate published by Zhao et al (Eur Urol. 2017), but comparison is hindered by our limited case volume. We hope our experience encourages continued evaluation of this method as an efficacious option moving forward.

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The Robotic Buccal Mucosa Graft Ureteroplasty

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Introduction: Radiation-induced urethral stricture disease (R-USD) creates surgical challenges for the reconstructive urologist due to the high risk of stricture recurrence and postoperative urinary incontinence (UI). We reviewed the outcomes of such patients at our institution to determine if conservative management can be an effective strategy.

Materials & Methods: We retrospectively identified patients with R-USD who were managed with observation, endoscopic management, and/or clean intermittent catheterization (CIC). Any patient who had an obliterative stricture, underwent urethral reconstruction, or had less than 3 months follow-up was excluded. Primary outcome measures were urinary tract infection (UTI), acute urinary retention (AUR), serum creatinine, post void residual (PVR), and UI status. Secondary outcome measures were Urethral Stricture Surgery Patient-Reported Outcome Measure (USS PROM), Sexual Health Inventory for Men (SHIM), and Male Sexual Health Questionnaire (MSHQ) scores.

Results: A total of 61 men met inclusion criteria between 2007-2019, with a median follow-up of 23.4 months (IQR 8.4-40.3). Median age was 77.9 years, body mass index was 27.1 kg/m^2, and Charlson comorbidity index was 6. The indication for pelvic radiation was prostate cancer in 95% and colorectal cancer in 5%. The vast majority received external beam radiation (70%) or brachytherapy (28%). Of those with prostate cancer, 93% received radiation as primary therapy and 7% received adjuvant or salvage radiation. There were no salvage prostatectomies in this cohort. Median stricture length on urethrogram imaging was 2 cm (IQR 2-3). Stricture location was: bulbar (31%), bulbomembranous (49%), and prostatic (20%). The most common urinary symptoms were slow flow (57%), urgency/frequency (26%), and nocturia (21%). A total of 51 (83%) patients underwent subsequent urethral dilation and 20 (33%) underwent subsequent direct visual internal urethrotomy (DVIU). Median number of dilations and DVIUs per patient was 3 (IQR 1-7) and 1.5 (IQR 1-3), respectively. CIC was utilized in 39% of patients. Six (10%) patients had an AUR episode requiring urgent treatment and 27 (44%) had a stricture-related UTI. Median serum creatinine, PVR values, and questionnaire scores remained stable between first and last visits (Table 1). UI was reported in 49% of patients at first visit and 57% at most recent visit. Median number of pads per day minimally changed (1 vs. 2) and median number of diapers per day remained stable (1 vs. 1).

Conclusion: Although certain patients will desire urethral reconstruction, many patients with R-USD appear to be safely managed with conservative management with minimal effect on UI. Close observation is warranted due to the risk of stricture-related UTIs and AUR episodes.

Table 1

	Median	N
Creatinine (first visit)	1.1	47
Creatinine (last visit)	1.0	35
Post-void residual (first visit)	35	45
Post-void residual (last visit)	42	28

Urethral Stricture Surgery Patient-Reported Outcome Measure (USS PROM)

	Median	N
First visit	10	26
Last visit	6	7

Sexual Health Inventory for Men (SHIM)

	Median	N
First visit	5.5	14
Last visit	5	3

Male Sexual Health Questionnaire (MSHQ)

	Median	N
First visit	5	17
Last visit	5	5

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Combination Robotic Simple Prostatectomy and HoLEP for Morbidly Enlarged Prostates > 400g

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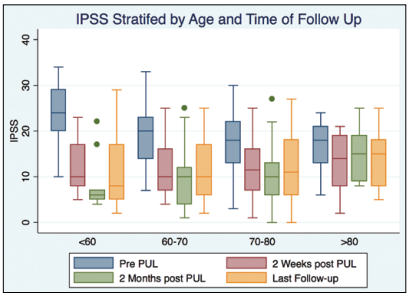
Introduction: Studies have established the effectiveness of Prostatic Urethral Lift (PUL) with relieving bladder outlet obstruction; however, predictors of success or failure with this new modality are not well documented. We sought to determine factors that may impact PUL outcomes.

Materials & Methods: A retrospective review of prospectively maintained Benign Prostatic Hyperplasia (BPH) database for patients who underwent PUL at University of Vermont Medical Center between 2017-2020 was performed. Demographic data, procedure characteristics, International Prostate Symptom Score (IPSS), and Post Void Residuals (PVR) pre and post PUL were collected. Associations between the change in IPSS score (IPSS pre PUL - IPSS post PUL) were analyzed.

Results: A total of 121 consecutive patients underwent PUL. Patients who did not have IPSS pre or post PUL (N = 13) or underwent median lobe Transurethral Resection of the Prostate (TURP) (N = 3) or Direct Vision Internal Urethrotomy (DVIU) (N = 1) in the same setting were excluded. One hundred and five patients were included. The median age was 71 years (interquartile [IQR] 63-77), with a median BMI of 28 (IQR 25-31). Most patients (76%) were on BPH medications pre PUL. Of those, 54 (67.5%) were able to stop taking BPH medications post PUL. 9.5% of patients had previous BPH surgeries and 2.9% of patients required chronic Foley or clean intermittent catheterization (CIC) pre PUL. Median number of sutures placed at PUL was 4 (IQR 4-5). Median follow up time post PUL was 3.3 months (IQR 2.4-14.5). IPSS decreased from a pre-operative median of 19 (IQR 13-23) to 11 (IQR 6-17), $p < 0.001$, while PVR decreased from 37 mL (IQR 10-116) to 35 mL (IQR 12-66), $p = 0.046$, respectively. In a multivariate regression analysis after adjusting for age, Body Mass Index, prostate volume, BPH medication at time of PUL or prior BPH surgery, prior chronic catheter or CIC, high median bar or lobe, number of sutures during PUL, median lobe transurethral incision, postoperative catheter due to retention, continued BPH medications on follow up, and follow up time, we found that increasing age is associated with less change in IPSS (Coef. Mean = -0.3, 95% confidence interval -0.4 - -0.1, $p = 0.010$).

Conclusions: Our results showed that even though PUL still has good effect in all ages, there was less change in IPSS in older patients. Although PUL is less invasive compared to other BPH surgical treatments, it may have less favorable outcomes specifically in patients older than 80 years. This may be due to bladder dysfunction from a more chronic obstructive process, and could potentially support earlier intervention for some patients. It may also sway surgeons toward performing TURP in older eligible patients. Regardless, we believe further study is needed to fully establish this relationship and to assess if the difference in efficacy is large enough to merit a change in clinical practice.



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Nocturia Independently Predicts Left Ventricular Hypertrophy and Left Atrial Enlargement among Patients with Cardiovascular Disease

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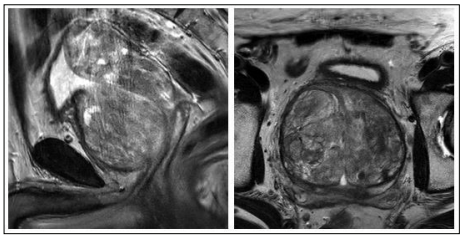
Introduction: Morbidly enlarged prostates > 400 g (MEP) due to benign prostatic hypertrophy (BPH) can result in significant lower urinary tract symptoms that are refractory to standard medical and surgical management. While the vast majority of large glands are amenable to either Holmium laser enucleation (HoLEP) or robotic simple prostatectomy (RSP), each of these procedures has drawbacks that limit effective management of MEPs. Namely, accessing the apex is difficult from the robotic approach; for HOLEP, base access and morcellation are challenging for glands of this size and perineal urethrostomy is often required. We sought to develop a safe procedure combining the strengths of HoLEP and RSP.

Materials & Methods: Patients with MEP and bothersome LUTS underwent a combined HoLEP and RSP procedure between 2017-2019. Patient charts were retrospectively reviewed.

Results: Three patients were identified with a mean prostate volume of 498 g (range 400-600 g) all of whom required self catheterization to empty their bladders preoperatively. Operative time ranged from 270-384 minutes. Mean drop in hematocrit was 8%. An average of 64% of the gland was removed (range 275-330 g). All patients were discharged on postoperative day 2 with a mean time to catheter removal of 10 days. One patient required an intraoperative blood transfusion and was found to have high risk prostate cancer in the specimen requiring further treatment. All patients were able to void at the time of follow up (mean 8.5 months) with a mean PVR of 64 cc. None of the patients have developed a urethral stricture and all have excellent continence.

Conclusions: Combined HoLEP and RSP is a safe procedure for MEP that may not be adequately treated by either procedure alone. By combining these approaches, the need for perineal urethrostomy and morcellation are obviated, endoscopic time is decreased, thereby potentially lowering the risk of urethral stricture formation, and apical dissection is substantially simplified.



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Conservative Management of Radiation-induced Male Urethral Strictures: Can Urethral Reconstruction be Safely Avoided?

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Introduction: Nocturia is a well-recognized, but poorly characterized, manifestation of cardiovascular disease. Multiple studies have reported associations between hypertension and the presence and severity of nocturnal voiding. Hypertension is associated with multiple cardiac abnormalities which independently heighten the risk for adverse cardiovascular outcomes, including left ventricular hypertrophy (LVH), left atrial enlargement (LAE), and prolonged QTc interval (p-QTc), However, the association between nocturia and these specific cardiac abnormalities is not well understood. This study aims to explore potential associations between nocturia and LVH, LAE, and p-QTc on electrocardiography (ECG).

Materials & Methods: Retrospective analysis of self-reported nocturnal voiding frequencies from 153 patients evaluated at an inner-city academic cardiology practice. Patient-reported nocturnal voiding frequency was recorded in the medical record at the time of routine clinical encounter. A nocturia database was compiled with institutional review board approval via a waiver of informed consent for retrospective analysis. ECGs concurrent with the clinical encounter were abstracted and evaluated according to current American Heart Association guidelines by a reviewer blinded to nocturia status. ECGs were assessed for the presence of LVH (using the Cornell and Sokolow-Lyon criteria), LAE (product of the amplitude and duration of the terminal negative component of the P wave in lead V1 measuring ≥ 1 mm by 1 mm or a total duration of the P wave ≥ 120 ms in the inferior leads), and p-QTc (≥ 460 ms in women and ≥ 450 ms in men). Three different multiple logistic regression models were used to predict LVH, LAE, and p-QTc based on nocturia status: Model I adjusted for age; Model II adjusted for age, sex, and race; Model III adjusted for age, sex, race, body mass index (BMI), hypertension, diabetes mellitus, and diuretic utilization.

Results: A total of 153 patients met the criteria for inclusion. The study sample was predominantly female (74%) and self-reported African-American race (90%), with a high prevalence of obesity (63%), hypertension (78%), diabetes mellitus (33%), and diuretic use (40%). Nocturia was present in 77% of study subjects, while LVH, LAE, and p-QTc were present in 44%, 41%, and 29% of study subjects, respectively. Nocturia predicted LVH according to Model I (OR 3.20, [1.18-8.69], $p = 0.022$), Model II (OR 3.17, [1.16-8.69], $p = 0.025$), and Model III (OR 2.99, [1.02-8.75], $p = 0.046$). Nocturia also predicted LAE according to Model I (OR 4.72, [1.56-14.30], $p = 0.006$), Model II (OR 4.71, [1.54-14.37], $p = 0.006$), and Model III (OR 4.24, [1.32-13.57], $p = 0.015$). No significant associations were observed between nocturia and p-QTc according to Model I (OR 1.51, [0.56-4.10], $p = 4.10$), Model II (OR 1.39, [0.51-3.81], $p = 0.517$), or Model III (OR 1.19, [0.41-3.49], $p = 0.747$).

Conclusions: LVH and LAE were both independently associated with nocturia in the outpatient cardiology setting. LVH is associated with reduced left ventricular compliance, whereas LAE reflects higher left ventricular preload, and both mechanisms likely predispose patients to sodium and water retention. Consistently, existing volume overload, particularly in conjunction with recumbency during sleep, would be expected to increase preload and cardiac output, lending to increased nocturnal urine production. Further investigation into nocturia as a marker of underlying cardiovascular disease is warranted.

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Evaluating the Outcomes of Active Surveillance in Gleason Grade Group 2 Prostate Cancer: Prospective Results from the Canary-PASS Cohort

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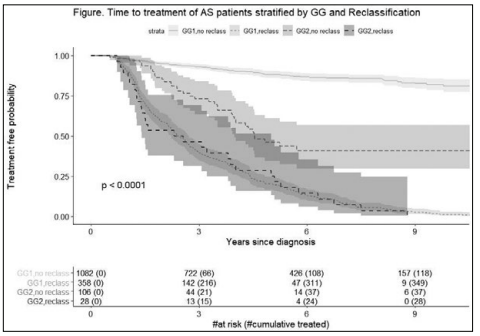
Introduction: The safety of Active Surveillance (AS) for grade group 2 (GG2) patients is debated. We sought to compare clinical outcomes of men with GG1 and GG2 prostate cancer undergoing AS in the Canary Prostate Cancer Active Surveillance Study (PASS) cohort.

Materials & Methods: Participants were prospectively enrolled in an AS study on protocol-directed follow-up at 10 centers nationwide. We included those who had GG1 or GG2 at diagnosis and at least one confirmatory biopsy. Patients were stratified according to GG at diagnosis and whether they were reclassified from initial biopsy. Time from diagnosis to treatment and time from definitive treatment to biochemical recurrence (BCR) were evaluated using Kaplan-Meier method; adverse pathology (AP) at Radical Prostatectomy (RP), defined as GG ≥ 3, ≥ pT3a, or pN1, was analyzed as interval censored data using Weibull regression.

Results: Between August 2008 and February 2019, 1574 patients met the eligibility criteria. At diagnosis, 1440 (91%) patients had GG1 and 134 (9%) had GG2, out of which 102 (76%) presented with single core of GG2. Patients with GG2 were older (66 vs. 62 years) and had shorter median follow-up (5.4 vs. 6.9 years) compared to GG1 patients. Reclassification rate at 5 years occurred in 36% of GG2 and 38% of GG1 patients. Overall, patients with GG2 had shorter time to treatment compared to patients with GG1 (median: 4.3 vs. 10.3 years $p < 0.0001$). Among those who were not reclassified, patients with GG2 had shorter time to treatment compared to GG1 (median: 4.55 vs. not reached), but had longer time to treatment compared to GG1 and GG2 who got reclassified (Figure). The risk of AP at RP was slightly higher for GG2 than for GG1 (hazard ratio: 1.37; 95% CI: 0.73-2.54). BCR within 3 years of treatment among those treated with surgery or radiation for GG2 was 10% and for GG1 was 13% ($p = 0.50$).

Conclusions: Most GG2 patients enrolled in this AS protocol had low volume GG2 disease. Adverse pathology after RP and BCR after definitive treatment are similar in low volume GG2 patients compared to GG1 patients. Our results show that AS patients with low volume GG2 will have a shorter time to treatment, and limited follow-up post-treatment suggest equal oncologic outcomes.



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PSA Density Velocity is the Most Important Predictor of Grade Group Progression During Prostate Cancer Active Surveillance

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Introduction: Active surveillance (AS) is an established option in the management of appropriately selected men with prostate cancer. Prostate-specific antigen density (PSAd) at diagnosis is an important predictor of disease progression, however change in PSAd over time, or PSAd velocity (PSAdv), has not been thoroughly assessed. We sought to investigate the prognostic impact of PSAdv in men on AS.

Materials & Methods: Within our institutional database of 1268 men enrolled in AS for prostate cancer between 1997-2016, we retrospectively identified patients with at least two PSA values and prostate volume measurements by radiologic imaging. PSAd was calculated as PSA divided by prostate volume on transrectal ultrasound (TRUS) or magnetic resonance imaging (MRI). PSAdv was calculated as the difference between two PSAd measurements divided by the time between them. The primary outcome was freedom from pathologic progression to grade group (GG) 2 or higher on any follow-up biopsy during AS. Logistic regression was used to determine clinical factors predictive of GG progression. A sensitivity and specificity analysis with receiver operator curve (ROC) was utilized to identify the optimal PSAdv threshold for distinguishing risk of GG progression. Using this cut-off point, survival analysis was conducted with the Kaplan-Meier method and log-rank test.

Results: 631 patients met criteria and were evaluated in this study. At diagnosis, median values were: age 64 years (IQR 59-69), PSA 5.1 ng/mL (IQR 4.0-6.8), PSAd 0.11 ng/ml/ml (IQR 0.08-0.16), percent of cores positive 8.3% (IQR 8.3-16.7), maximum single-core involvement 10% (IQR 5-20). The majority of patients had GG 1 (98%) and clinical stage T1c (94%) disease. During AS, median follow-up time was 5.7 years (IQR 4.0-8.3) and number of prostate volume measurements was 2 (IQR 2-3). 404 patients (64%) had PSAd values calculated using volumes only from TRUS, while the rest utilized both TRUS and MRI. Median time between PSA and prostate volume measurement was 37 days (IQR 19-61) and 16 days (IQR 1-39) for TRUS and MRI, respectively. Median PSA density velocity was +0.001 ng/ml/ml per year (IQR -0.02-0.03). 157 patients (25%) had GG progression on surveillance biopsy, with median time to progression 2.8 years (IQR 1.3-4.6). 241 patients (38%) progressed to treatment. On multivariable regression, PSAdv was the most significant predictor of GG progression ($p = 0.002$) [Table 1]. On sensitivity and specificity analysis, the optimal PSAdv cut-off value was determined to be 0.0055 ng/ml/ml/year. 269 patients in this cohort (43%) with PSAdv above this threshold had a significantly greater risk of GG progression during the course of surveillance ($p < 0.001$) [Figure 2].

Conclusions: In our analysis, PSAdv is the most significant predictor of GG progression on follow-up biopsy during the course of AS. It therefore represents an important adjunct measure for prognostication of outcomes for men during AS.

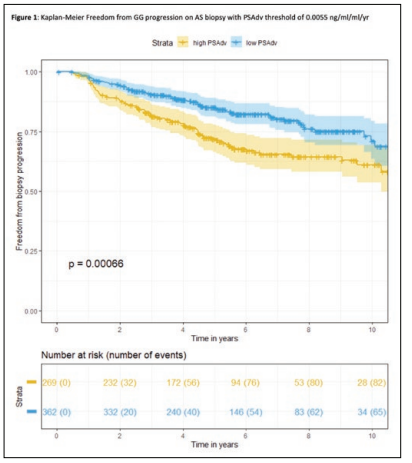

Table 1: Logistic regression predicting GG progression on follow-up biopsy during active surveillance

	Univariable		Multivariable	
	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Age (yr)	1.04 (1.01-1.07)	0.003	1.05 (1.02-1.08)	0.002
PSA (ng/ml)	1.00 (0.93-1.07)	0.93	–	
PSA density (ng/ml/cc)	12.36 (1.41-108.3)	0.02	43.38 (2.78-711.9)	.007
T Stage				
2	0.55 (0.18-1.32)	0.22	–	
NCCN Risk Level				
Low	1.57 (1.06-2.34)	0.02	0.99 (0.59-1.66)	0.98
Favorable Intermediate	0.71 (0.30-1.50)	0.40	–	
Diagnostic Biopsy				
Percent of cores positive	7.64 (1.12-50.8)	0.03	1.08 (0.09-11.74)	0.95
Max % core involvement	1.02 (1.01-1.03)	0.001	1.01 (1.00-1.03)	0.04
PSAdv (ng/ml/ml/year)	11.1 (2.11-77.5)	0.008	18.3 (3.08-132.7)	0.002

Baseline odds: T Stage compared to Stage 1, NCCN risks compared to Very Low

CI = confidence interval; PSA = prostate specific antigen; NCCN = National Comprehensive Cancer Network; PSAdv = PSA density velocity

Medicaid Expansion is Associated with Increased Utilization in Palliative Treatments for Metastatic Prostate, Lung, Colon and Breast Cancer in the United States

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Introduction: Policies to increase insurance coverage may influence receipt of palliative treatments for men and women with cancer. The 2010 Affordable Care Act restructured Medicaid eligibility and allowed for states to expand Medicaid coverage to those earning up to 138% of the federal poverty level, however not all states opted to expand Medicaid. We assessed whether state-level expansion of Medicaid insurance coverage following the 2010 Affordable Care Act was associated with increase in palliative treatments.

Materials & Methods: In this registry-based study, men and women aged 40-65, diagnosed with metastatic prostate, lung, colon and breast cancer from 2010-2016 were identified. The Medicaid expansion status of the state where each patient was diagnosed was the main exposure of this study. A multilevel mixed effect logistic regression model with a facility level random intercept to account for unmeasured hospital characteristics was used to assess for independent predictors of receiving palliative treatments. To assess whether trends differed based on Medicaid expansion status, an interaction term was fit combining both year and Medicaid expansion status of the state of diagnosis. The multilevel model was used to estimate probabilities of receiving palliative care for each year, for men and women in expansion and non-expansion states.

Results: The probability of receiving palliative treatments has increased from 2010 to 2016 in both expansion and non-expansion states. Patients treated in non-expansion states initially had a higher probability of receiving palliative treatments, however the rate of increase was greater in Medicaid expansion states ($p_{interaction}$ = 0.001) and by the end of the study the probability of receiving palliative treatments was greater in expansion states than in non-expansion states. The use of palliative treatments for patients with metastatic cancer, has increased from 2010 to 2016 with a greater increase in states which implemented Medicaid expansion.

Conclusions: Expansion in insurance coverage is associated with an increase in utilization of palliative care treatment.

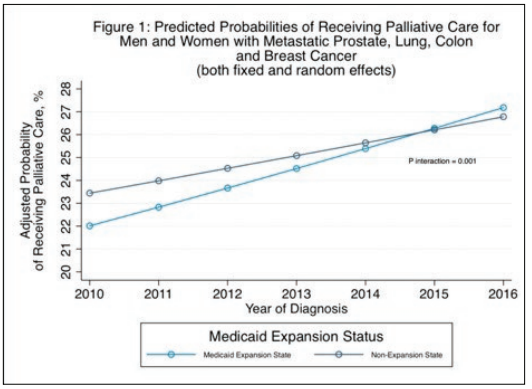

Table 1: Predictors of Palliative Treatments for Men with Metastatic Prostate, Lung, Colon and Breast Cancer on Multivariable Analysis with a Facility Level Random Intercept (N = 212,663)

	Odds Ratio (95% CI)	P value
Year of Diagnosis		
(per year)	1.06 (95% CI 1.05-1.06)	<0.001
Age Group		
36-40	*Ref*	
41-45	1.09 (0.94 –1.25)	0.25
46-50	1.11 (0.96 –1.27)	0.16
51-55	1.11 (0.97-1.27)	0.14
56-60	1.10 (0.93 – 1.26)	0.18
60-65	1.06 (0.93 – 1.22)	0.36
Race		
White	*Ref*	
Black Non-Hispanic	1.04 (1.00 – 1.07)	0.03
Hispanic	0.99 (0.94 – 1.06)	0.83
Asian	1.02 (0.95-1.09)	0.61
Other	1.07 (0.95 –1.20)	0.29
Unknown	0.78 (0.68 –0.90)	0.001
Charlson Comorbidity Index		
0	*Ref*	
1	1.03 (1.00 –1.06)	0.06
2	1.04 (1.00 –1.10)	0.05
≥ 3	1.04 (0.96 – 1.11)	0.23
Mean Family Income in County of Residence		
> \$63,000	*Ref*	
\$49,000-62,999	1.03 (1.00 –1.07)	0.06
\$38,000-47,999	0.99 (0.95 –1.02)	0.53
< \$38,000	1.03 (0.99–1.07)	0.12
Unknown	0.94 (0.77–1.16)	0.58
Medicaid Expansion Status		
Expansion	*Ref*	
Non-expansion	1.26 (1.10 –1.44)	0.001
Medicaid Non-Expansion*Year		
	0.98 (0.97 – 0.99)**	$P_{interaction}$ = 0.001

* Estimated from American County Survey, regarding patients' county of residence. ** Odds ratio corresponds to the difference in difference of odds ratio as you increase by one year in the non-expansion group versus increasing by one year in the expansion group.

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Is Repeat Prostate Biopsy Prior to Treatment Necessary for Active Surveillance Patients with Clinical and Radiographic Findings Suggesting Gleason Grade Progression?

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Introduction: Studies have described an increased risk of prostate cancer (PCa) grade group (GG) progression with presence of high-risk lesions or lesion progression on active surveillance (AS) MRI. Given the known risks of prostate biopsy, we investigate whether patients at high risk for GG progression may proceed to treatment without repeat biopsy.

Materials & Methods: We retrospectively reviewed our database of men on AS with localized PCa from 1996-2016. We identified men with Gleason Grade (GG) 1 disease on diagnostic biopsy, at least one prostate MRI, and at least one repeat prostate biopsy during AS. All MRIs were scored according to PIRADS version 2.0 and scores of 2 or less were considered to represent a negative MRI. Clinical and radiologic characteristics analyzed included age, PSA, PSA density (PSAd), index PIRADS score, PIRADS lesion size, and NCCN risk group. Univariate and multivariate logistic regression was used to identify factors associated with grade progression to GG 2 or higher on any subsequent surveillance biopsy.

Results: Of 1268 men evaluated in our AS database, 363 met criteria for this study. Median follow up time was 4.8 months (IQR 3.4-6.8). Median number of MRIs was 1 (Range 1-4). 42% of patients had no suspicious lesions on MRI, 13% had PIRADS 3, 30% had PIRADS 4, 15% had PIRADS 5 as their highest risk lesion. Of those with negative MRIs, 20% had GG progression on subsequent biopsy. For index MRI lesions of PIRADS 3, 4, and 5, the GG progression rates were 26%, 39%, and 62%, respectively ($p < 0.001$). For patients with PSAd > 0.15 and PIRADS lesions 3,4, or 5, GG progression rates were 45%, 32 %, and 71%, respectively ($p = 0.002$). On univariate analysis, age at diagnosis, PSAd, NCCN Risk Group (Low vs. Very Low), and PIRADS 4 and 5 lesions were predictors of biopsy GG progression [Table 1]. On multivariate logistic regression, PSAd as well as PIRADS 4 and PIRADS 5 on MRI remained significant predictors of GG progression. Compared to patients with negative MRIs, those with PIRADS 4 and PIRADS 5 lesion had increased risk of biopsy progression (OR 2.22 [95% CI: 1.17-4.21]) and (OR 4.55 [95% CI: 2.00-10.32]), respectively [Figure 1]. Analysis of PIRADS 4 and PIRADS 5 lesions by size demonstrated no difference in GG progression on follow up biopsy.

Conclusions: Patients on AS with PIRADS 3 and 4 lesions must have a confirmatory biopsy prior to consideration for surgery since a significant proportion of these patients may still be optimal for AS. GG 1 patients with PSAD > 0.15 and PIRADS 5 lesions may proceed to surgical treatment with omission of repeat biopsy; however, repeat biopsy should be performed prior to radiation to inform the need and duration of ADT.

Figure 1: Biopsy Grade Progression Free Survival

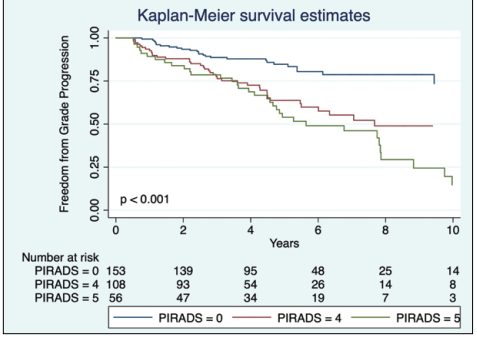

Table 1: Logistic regression predicting GG progression on follow up surveillance biopsy

	Univariable		Multivariable	
	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Age at diagnosis (yr)	1.07 (1.04-1.11)	<0.001	1.06 (1.02-1.10)	0.007
PSA (ng/mL)	1.07 (0.99-1.16)	0.08	-	
PSA density (ng/mL/cc)	276.5 (8.43-9065.1)	0.002	19.27 (0.34-1083.3)	.015
T Stage				
2	0.67 (0.26-1.73)	0.40	-	
NCCN Risk Level				
Low	1.70 (1.08-2.70)	0.02	1.31 (0.73-2.34)	0.36
Favorable Intermediate	1.70 (0.70-4.16)	0.24	-	
Highest PIRADS Lesion				
3	1.45 (0.67-3.12)	0.35	1.39 (0.58-3.28)	0.74
4	2.61 (1.50-4.55)	0.001	2.22 (1.17-4.21)	0.014
5	6.83 (3.49-13.38)	<0.001	4.55 (2.00-10.32)	<0.001

Baseline odds: T Stage compared to Stage 1, NCCN risks compared to Very Low, PIRADS scores compared to negative MRI

CI = confidence interval; PSA = prostate specific antigen; PIRADS = prostate imaging reporting and data system; MRI = magnetic resonance imaging; NCCN = National Comprehensive Cancer Network

*Max K. Willscher Award Eligible

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Using Preoperative Pelvic Floor Assessment to Predict Early Return of Continence after Robotic Radical Prostatectomy

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Introduction: While long-term urinary continence is eventually achieved in most patients who undergo radical prostatectomy, predicting when patients will become continent is challenging. The period of incontinence can be a source of uncertainty and distress for patients and may negatively impact quality of life. Prior studies aiming to predict return of post-operative continence have not evaluated patient-specific pelvic floor strength parameters. We evaluated the association of pre-operative pelvic floor physical therapy (PFPT) parameters with early return of urinary continence after robotic radical prostatectomy (RP).

Materials & Methods: We reviewed a prospectively maintained database of all patients undergoing RP. Patients were included if they underwent pre-operative PFPT consultation and completed 3-month patient-reported quality of life evaluation using EPIC-CP. All patients were evaluated by one of two therapists specializing in PFPT with biofeedback, who documented pelvic floor resting tone, pelvic floor working tone, pelvic floor endurance (defined as the ability to hold a 10-second pelvic floor muscle contraction), and dominant hand grip strength. We defined urinary continence as using 0 or 1 pad per day. We used multivariable logistic regression to evaluate the association of PFPT parameters with urinary continence at 3 months. We adjusted for other factors that could affect continence, including age, BMI, D'Amico risk classification, nerve sparing, and prostate volume.

Results: 144 men met inclusion criteria. Nerve-sparing was performed in 92.4% of patients. 89% of men had intermediate- or high-risk prostate cancer. At 3 months, 90/144 (62.5%) were continent, while 54/144 (37.5%) were not. On multivariable analysis, prostate volume (OR 0.98, 95% CI 0.96-1.00) and pelvic floor endurance (OR 2.70, 95% CI 1.23-6.25) were significantly associated with being continent at 3 months. Pelvic floor resting tone, working tone, and dominant hand grip strength were not associated with continence at 3 months. 56/76 (74%) men with good pelvic floor endurance were continent at 3 months, while only 34/68 (50%) men with poor endurance were continent ($p = 0.006$).

Conclusions: Pre-operative assessment of pelvic floor endurance is an objective measure that may allow more accurate prediction of early continence return after radical prostatectomy. Improved patient counseling could positively impact patient satisfaction and quality of life.

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Risk Stratification by Prostate Health Index Prior to MRI-Ultrasound Fusion Targeted Biopsy

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Introduction: Serum biomarkers that improve upon prostate specific antigen (PSA) for the prediction of prostate cancer, and may therefore help improve selection for prostate biopsy. Limited information exists to guide how these tools should be integrated in the context of prostate magnetic resonance imaging (MRI) in the MR-targeted biopsy era. We aimed to identify a biomarker threshold for the detection of GG2 or higher prostate cancer at MRI ultrasound fusion-targeted biopsy (MRF-TB).

Materials & Methods: Between June 2015 and July 2019, 192 men received biomarker testing with the prostate health index (phi), a measurement that combines %free PSA, total PSA, and the -2proPSA isoform of PSA, prior to undergoing MRF-TB at our institution. Findings on prostate biopsy (including Grade Group [GG]), PI-RADS, and phi were prospectively recorded. Cancer detection rates (CDR) at pre-determined phi ranges were evaluated. The interaction of PI-RADS and phi was also evaluated at phi level of 27 (previously reported and widely used cutoff) versus the phi cutoff value calculated at our institution.

Results: The median phi score was 51 (interquartile range 36-70). Sensitivity of phi for detecting any prostate cancer at a cutoff of 27 and 36 was 92.54% and 85.82%, respectively. Sensitivity of phi for detecting any GG2 or higher prostate cancer at a cutoff of 27 and 36 was 95.06% and 88.89%, respectively. In the subset of men with PSA between 4 and 10 ng/mL, CDR of GG2 and higher prostate cancer was significantly higher at a phi > 36 than < 36 (18.7 vs. 47.8%, p = 0.01) (Table 1). Among all men who obtained phi prior to MRF-TB, no men who had PI-RADS ≤ 3 and a negative phi were found to have GG2 or higher prostate cancer both at phi cutoffs of 27 and 36 (Table 2).

Conclusions: We evaluated the performance of the prostate health index among patients with suspicion of prostate cancer undergoing MRI ultrasound fusion biopsy. This analysis supports the use of a phi cutoff of ≤ 36 to avoid biopsy among patients whose prostate MRI has a low suspicion for prostate cancer.

Table 1

phi Range	Probability of PCa	Probability of GS6 PCa	Probability of ≥ GG2 PCa
0 - 26.9	46.15%	23.08%	23.08%
27.0 - 35.9	36.84%	21.05%	15.79%
36.0 - 54.9	77.78%	35.56%	42.22%
55.0+	83.02%	30.19%	52.83%

Table 2

PIRADS	phi Range	Probability of PCa	Probability of GS6 PCa	Probability of ≥ GG2 PCa
PIRADS < 3				
	phi ≤ 27	12.50%	12.50%	0.00%
	phi > 27	49.02%	35.29%	13.73%
PIRADS < 3				
	phi ≤ 36	15.79%	15.79%	0.00%
	phi > 36	57.50%	40.00%	17.50%
PIRADS = 3				
	phi ≤ 27	66.67%	66.67%	0.00%
	phi > 27	60.00%	33.33%	26.67%
PIRADS = 3				
	phi ≤ 36	60.00%	60.00%	0.00%
	phi > 36	61.54%	30.77%	30.77%
PIRADS > 3				
	phi ≤ 27	77.78%	33.33%	44.44%
	phi > 27	88.24%	23.53%	64.71%
PIRADS > 3				
	phi ≤ 36	46.43%	22.22%	50.00%
	phi > 36	81.55%	24.73%	65.59%

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The Impact of Pre-Treatment PSA on Risk Stratification in Men with Gleason 6 Prostate Cancer: Implications for Active Surveillance

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Introduction: The optimal treatment for men with Gleason 6 prostate cancer and a PSA above 10 ng/mL is uncertain. Although active surveillance is the preferred management strategy for men with low-risk disease, there are limited data to support the safety of active surveillance in men with favorable-intermediate risk disease due only to a discordant PSA above 10 ng/mL. We therefore evaluated the impact of pre-treatment PSA on risk-stratification in men with Gleason 6 prostate cancer.

Materials & Methods: We identified men aged 18-75 with cT1-2 cN0 cM0, pre-treatment PSA < 20 ng/mL, Gleason 6 prostate cancer diagnosed from 2010-2016 in the National Cancer Database (NCDB) who underwent radical prostatectomy. The primary outcomes were Gleason score upgrading to 7-10 and adverse pathologic features at prostatectomy (i.e., pT3a, pT3b, or pN1). The associations of patient and disease features with each outcome were evaluated using bivariate analyses as well as univariable and multivariable logistic regression. To evaluate for non-linear relationships between PSA and each outcome, we examined predicted marginal event rates standardized for baseline characteristics with PSA modeled using restricted cubic splines with four knots.

Results: A total of 79,036 patients were included in the cohort. Mean age at diagnosis was 59.5 (SD 6.8) years, and median pre-treatment PSA was 5.1 (IQR 4.1-6.8) ng/mL. At prostatectomy, Gleason score upgrading was identified in 49.7% of patients, including 41.2% with Gleason 3+4, 5.3% with Gleason 4+3, and 1.5% with Gleason 8-10. Adverse pathologic features were identified in 10.5% of patients, including 8.9% with pT3a disease, 1.4% with pT3b disease, and 0.2% with pN1 disease. In unadjusted analyses, patients with pre-treatment PSA ≥ 10 ng/mL had higher rates of Gleason core upgrading (58.8% vs. 47.9%, p < 0.001) and adverse pathologic features (19.7% vs. 10.0%, p < 0.001) compared to patients with a PSA < 10 ng/mL. In multivariable analyses that adjusted for patient and disease features, PSA ≥ 10 ng/mL was associated with statistically significantly increased risks of Gleason score upgrading (OR 1.47, 95% CI 1.39-1.55) and adverse pathologic features (OR 2.14, 95% CI 2.00-2.29). When modeled as a non-linear continuous covariate, PSA was associated with increased adjusted rates of Gleason score upgrading (Figure 1) and adverse pathologic features (Figure 2) without a clear dichotomization at a threshold of 10 ng/mL.

Conclusions: In this surgical cohort, higher pre-treatment PSA was independently associated with increased risks of Gleason score upgrading and adverse pathological features at prostatectomy in men with Gleason 6 prostate cancer. Flexible modeling of the relationship between PSA and each outcome did not support dichotomization at a threshold of 10 ng/mL. These results can be used to improve patient risk-stratification for active surveillance.

Figure 1: Predicated rates of Gleason score upgrading to 7-10 at prostatectomy, adjusting for baseline patient and disease characteristics, as a function of pre-treatment PSA modeled as a non-linear continuous variable using restricted cubic splines.

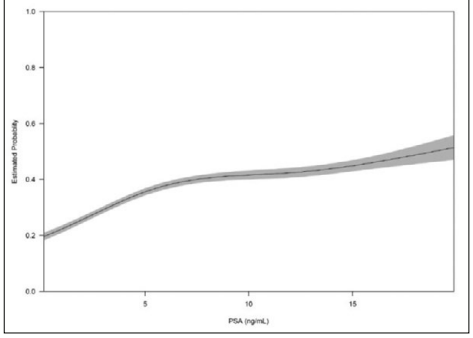
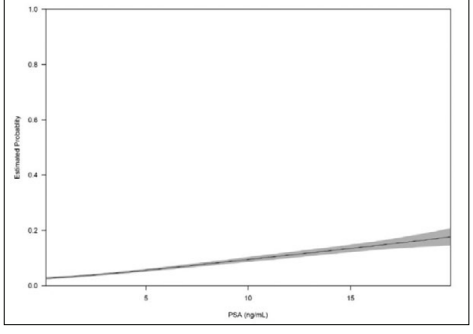


Figure 2: Predicated rates of adverse pathologic features at prostatectomy, adjusting for baseline patient and disease characteristics, as a function of pre-treatment PSA modeled as a non-linear continuous variable using restricted cubic splines.



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Free Hand Transperineal Prostate Biopsy Offers Equivalent Cancer Detection and Improved Antibiotic Stewardship Compared to Transrectal Ultrasound-Guided Prostate Biopsy

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Introduction: Transrectal ultrasound guided prostate biopsy (TRUS-B) is the gold standard for diagnosing prostate cancer. Due to the risk of infectious complications associated with TRUS-B, there has been increasing interest in transperineal prostate biopsy. We compared a prospectively collected cohort of freehand transperineal prostate biopsy (fTP-B) to an institutional cohort of TRUS-B patients. Differences in cancer detection and the amount of cancer within a given core were examined.

Materials & Methods: A historical cohort of patients who received TRUS-B from January 2017 to September 2018 (n = 170) was compared to a prospectively collected cohort of fTP-B patients (n = 101) from February 2019 through January 2020. TRUS-B patients underwent a 10 or 12 core biopsy and fTP-B patients underwent a 20-core biopsy. All TRUS-B patients were treated with prophylactic antibiotics while fTP-B patients received no prophylaxis. Biopsy core length and percent of total core were determined from the surgical pathology report. Positive cancer was defined as grade group 1 or higher, while clinically significant cancer was defined as grade group 2 or higher. Cancer detection rates were compared using chi-squared tests, and core length and percentage of core length were compared using student's T tests. A p value of < 0.05 was considered statistically significant.

Results: 271 patients were included (170 TRUS-B, 101 fTP-B). Men undergoing fTP-B were slightly older (Median 65.6y, IQR 59.9-79.6) than those undergoing TRUS-B (63y, IQR 58.0-69.0; p = .03). There were no significant differences in median prostate PSA before biopsy (TRUS-B 9.4 ng/mL, IQR 6.8-17.4 and fTP-B 9.4, IQR 6.7-13.4; p=0.82), PSA density (TRUS-B 0.36, IQR 0.16-0.38 and fTP-B 0.48, IQR 0.19-0.42, p = 0.27), or race (p = 0.52) between the cohorts. Clinically significant prostate cancer was more often diagnosed in men undergoing fTP-B (52/101, 51.5%) compared to TRUS-B (64/170, 37.6%; p = 0.01). This difference was attenuated when a 12-core template for fTP-B was derived from the original 20-core template (47/101, 46.5%; p = 0.15) Cancer core length was greater in TRUS-B (median 4.0mm, IQR 1.2-8.5) relative to fTP-B (median 2.8mm, IQR 1-6; p < .001). There was no difference between percentage core involvement with cancer between TRUS-B (median 40%, IQR 10-75) and fTP-B (median 30%, IQR 10-70, p = .06). There were no infections in the fTP-B group and 2 confirmed cases of UTI/sepsis in the TRUS-B group.

Conclusions: A 20 core fTP-B results in greater detection of clinically significant prostate cancer compared to 10-12 core TRUS-B. This difference was attenuated when biopsy techniques with similar core numbers were compared. Despite omission of antibiotics in all cases, there were no infections in the fTP-B group. While 2 cases of UTI/sepsis were confirmed in the TRUS-B group, accurate determination of the infection rate in TRUS-B was limited due to lack of adequate follow-up information. Further work in disseminating fTP-B should be explored since fTP-B offers at least equivalent cancer detection and enables superior antibiotic stewardship compared to TRUS-B.

Table 1: Distribution of cancer grade groups between transrectal (TRUS-B) and freehand transperineal (fTP-B) biopsy templates. Any cancer is defined as grade group 1-5, while clinically significant cancer is defined as grade group 2-5 (p value compared to TRUS-B control).

TRUS-B (10 or 12-core)		fTP-B (12-core)		fTP-B (20-core)	
Grade	Patients	Grade	Patients	Grade	Patients
Benign	70	Benign	24	Benign	19
Grade Group 1	36	Grade Group 1	30	Grade Group 1	30
Grade Group 2	24	Grade Group 2	12	Grade Group 2	15
Grade Group 3	13	Grade Group 3	10	Grade Group 3	11
Grade Group 4	14	Grade Group 4	13	Grade Group 4	13
Grade Group 5	13	Grade Group 5	12	Grade Group 5	13
Any Cancer	58.8%		76.2%; p<0.01		81.2%; p<0.01
Clinically Significant Cancer	37.6%		46.5%; p=0.15		51.5%; p=0.01

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The Prognostic Impact of a Negative Confirmatory Biopsy and mpMRI in Men on Active Surveillance for Prostate Cancer

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Introduction: Active surveillance (AS) is increasingly used in managing low-risk and favorable intermediate-risk prostate cancer. To mitigate the risk of unsampled higher risk disease, most institutional AS protocols call for a multiparametric MRI of the prostate (mpMRI) and a confirmatory prostate biopsy within 12-18 months following initial diagnostic biopsy. Here, we investigate whether the results of confirmatory biopsy and mpMRI impact the outcomes of men on AS.

Materials & Methods: We retrospectively reviewed our institutional database of men enrolled in AS between 1997-2019 who underwent a confirmatory biopsy within 18 months of diagnosis and ≥ 3 biopsies overall. Patients who progressed to treatment on the basis of their confirmatory biopsy were excluded. Biopsies containing prostate cancer were considered positive. Biopsies containing only benign prostatic tissue, prostatic intraepithelial neoplasia (PIN), or atypical small acinar proliferation (ASAP) were considered negative. A PI-RADS v2 score of 3 or higher was considered a positive mpMRI. The primary outcome was biopsy progression-free survival and secondary outcomes included grade- and volume-related biopsy progression-free survival, biochemical recurrence, and metastasis-free survival. Statistical analysis was conducted using the Kaplan-Meier method and Cox proportional hazards regression.

Results: Out of 1268 patients in our cohort, 470 met inclusion criteria for this analysis, with a median follow up of 7.2 years. At diagnosis, median age was 63 years (IQR 58-68) and median PSA was 4.9 ng/mL (IQR 3.7-6.5). The vast majority of patients had grade group 1 (99%) and clinical stage T1 (95%) disease. A total of 177 patients (38%) had a negative confirmatory biopsy. Of the 470 patients, 38% progressed to treatment, with biopsy (grade- or volume-based) progression the most common reason (87%). In univariate analysis, a negative confirmatory biopsy and a negative initial mpMRI were each significantly associated with improved biopsy progression-free survival, while age of diagnosis, involvement of > 20% of any core on diagnostic biopsy, and PSA density ≥ 0.15 were associated with greater risk of biopsy progression. In multivariate analysis, a negative confirmatory biopsy remained a significant predictor of grade-based (but not volume-based) biopsy progression-free survival (HR 0.54 [95%CI 0.31-0.95], $P = 0.03$), whereas mpMRI status was no longer a significant predictor. Neither confirmatory biopsy nor mpMRI status were associated with biochemical recurrence or metastasis-free survival.

Conclusions: A negative confirmatory biopsy is associated with a significantly lower rate of subsequent grade reclassification and progression to treatment among men on AS. This may serve as a useful tool for prognostication and help determine the intensity of interval biopsies for men on AS.

*Max K. Willscher Award Eligible

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Utilization and Outcomes of Serial Prostate MRI for Prostate Cancer Active Surveillance
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Introduction: Multiparametric Magnetic Resonance Imaging (mpMRI) is increasingly utilized in the diagnosis and risk stratification of men with prostate cancer (PCa). During Active Surveillance (AS) men often receive multiple MRIs, yet it is not well described how results of subsequent MRIs affect their outcomes. We investigated our AS cohort to assess the outcomes of men who underwent at least two prostate mpMRIs during their time on surveillance.

Materials & Methods: We retrospectively reviewed our institutional database of 1268 men enrolled in AS for localized PCa from 1996-2016. We identified men who underwent at least two prostate mpMRIs during the course of surveillance. MRIs without a reported Prostate Imaging Reporting and Data System (PIRADS) version 2.0 score were excluded. Radiologic progression was defined as new lesion (PIRADS ≥ 3) on a previously negative MRI or increase in PIRADS score of a previous lesion. Lesions with PIRADS score > 3 were defined as high-risk. Cox proportional hazards regression was used to identify factors associated with freedom from treatment. Survival analyses were conducted using Kaplan-Meier method and log rank test.

Results: The study cohort included 201 men. The majority of patients had GG 1 (97%) and clinical stage T1c (93%) disease. Median values were as follows: number of MRIs meeting criteria: 2 (range 2-3); follow up time: 5.1 years (IQR 3.7-7.7); time between MRIs: 2 years (IQR 1.5-2.8). On MRI 1, 10% of patients had PIRADS 3 lesions, 19% PIRADS 4, 6% PIRADS 5, while 65% were negative. Figure 1 demonstrates the distribution of PIRADS scores from MRI 2, arranged by initial lesion. Overall on repeat MRI, 62% of PIRADS scores did not change, while 27% increased and 11% decreased. Compared to lesions that remained the same, PIRADS increase was predictive of earlier progression to treatment (HR 3.9 [95% CI 2.2-6.9] p< 0.001), while PIRADS decrease did not have a significant effect. In 131 men with a negative initial scan, MRI 2 remained negative 63% of the time. This cohort of 83 men with two negative MRIs experienced prolonged freedom from treatment, 88% and 83% at 5 and 10 years, compared to 70% and 47% for those whom had at least one PIRADS ≥ 3 lesion [Figure 2]. Compared to a second negative MRI, a new development of a high-risk lesion, which occurred in 28% of initial negatives, was significantly predictive of subsequent progression to treatment (HR 5.7 [95% CI 2.8-11.6] p < 0.001).

Conclusions: While a majority of men do not experience PIRADS score change on serial prostate mpMRI, those who have radiologic progression progress to treatment sooner. Men with multiple negative MRIs have significantly prolonged freedom from treatment and may be candidates for an increased interval between surveillance MRI and biopsy.

Figure 1: Comparison of PIRADS scores on initial and repeat prostate MRI

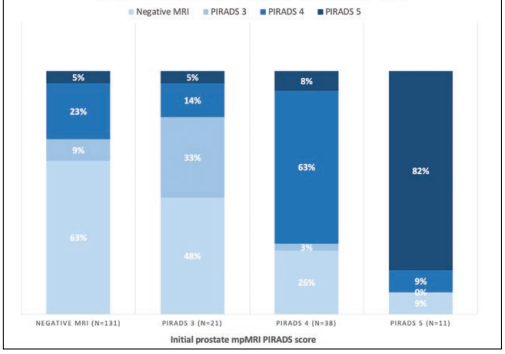
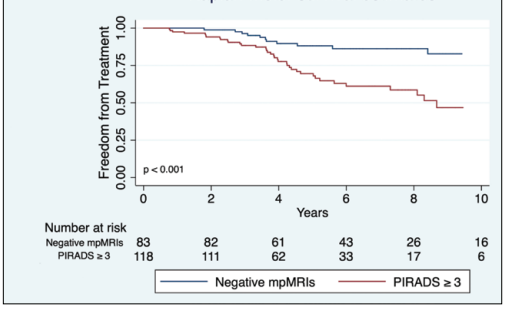


Figure 2: Treatment free survival



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Negative Combined Fusion-Systematic Biopsy Despite Presence of PIRADS 3, 4 or 5 Lesions: A Matter of False Positive Imaging or False Negative Biopsy?
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Introduction: MRI/Ultrasound fusion biopsy of the prostate has enhanced the detection of clinically significant prostate cancer (csPCa). However, the finding of a negative fusion and negative systematic biopsy in patients with suspicious lesion on MRI raises the question of either falsely positive imaging or a false negative biopsy. We investigate outcomes in this patient subgroup.

Materials & Methods: We retrospectively reviewed our database of patients undergoing MRI/transrectal US-guided fusion biopsy. All images were graded according to Prostate Imaginag Reporting and Data System (PIRADS) version 2.0. Patients underwent targeted biopsy (3-4 cores per target) followed by systematic 12-core double sextant biopsy within the same session. Patients with no prostate cancer (PCa) found on biopsies were followed. csPCa was defined as Grade Group (GG) ≥ 2 PCa and non- csPCa was defined as benign or GG1. MRI studies with PIRADS v2 score ≤ 2 were considered to have no MRI evidence of PCa.

Results: A total of 400 patients had at least one PIRADS ≥ 3 lesion and underwent fusion/systematic biopsy. Of these, 113 (28.3%)patients had no evidence of PCa on fusion or systematic biopsy. Mean follow-up was 32 months. 44 (39%) patients underwent repeat MRI and, of these, 24 (54%) had no suspicious lesion on repeat MRI. Initial PSA density (PSAd) was 0.12 for patients whose original PIRADS lesion disappeared, whereas it was 0.20 for patients with persistent lesions ($p = 0.03$). PSA, lesion size, and lesion grade did not correlate with disappearance of PIRADS lesion. 95% of patients with persistent PIRADS ≥ 3 lesions and 8.5% of those whose lesions disappeared proceeded to repeat biopsy. Of the 23 patients who underwent repeat biopsy, 16 (69.6%) had PCa and 11 (47.8%) had csPCa. Thus, of the 113 patients with an initial PIRADS ≥ 3 lesion and negative initial fusion/systematic biopsy, 9.7% (11) were subsequently found to have csPCa. The only predictor of csPCa on repeat biopsy was PSA change after initial negative fusion biopsy: +2.8 vs. -0.33 ng/mL at 1 year ($p = 0.01$) for csPCa and non-csPCa , respectively. PSAd at time of initial combined biopsy was nearly identical for patients with csPCa diagnosed on initial biopsy and those with csPCa diagnosed on repeat biopsy (0.252 vs. 0.245; $p = 0.88$).

Conclusions: In the setting of a negative initial fusion/systematic biopsy, at least 10% of patients will have csPCa. Both elevated PSAd and the persistence of a suspicious lesion on repeat MRI suggest a false negative initial biopsy for csPCa. However, low PSAd correlates with MRI lesion disappearance which likely represents falsely positive initial MRI.

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Efficacy and Safety of a New Oral Testosterone (TU) Formulation in Hypogonadal Men: Results from the 'inTUne' Trial
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Introduction: Oral delivery of testosterone (T) replacement therapy (TRT) has several potential advantages over currently available options. A novel formulation of oral TU was studied in two prior Phase 3 trials that demonstrated safety and efficacy. However, to further improve pharmacokinetic (PK) efficacy, a new dose titration algorithm was evaluated.

Materials & Methods: Hypogonadal men (diagnosis consistent with the Endocrine Society guideline of two morning serum T < 300 ng/dL and signs/symptoms with hypogonadism), age 18-65 y/o, were recruited into a 105 day, randomized, open-label, multicenter, dose-titration trial. Patients were randomized 3:1 to oral TU, BID (JATENZO®; n = 166) or a topical T product QD (Axiron®; n = 56). Dose titration was based on average T levels (C_{avg}) calculated from serial 24h pharmacokinetic (PK) samples. T was assayed by LC-MS/MS. Patients had two dose adjustment opportunities (on study day 21 and 56), which were based on plasma T levels (C_{avg}) calculated from multiple PK samples, prior to final PK visit. Safety was assessed by standard clinical measures, including ambulatory BP.

Results: 87% of patients in both groups achieved mean T C_{avg} in the eugonadal range. NaF-EDTA plasma T C_{avg} for oral TU group was 403 ± 128 ng/dL (~14 ± 4 nmol/L; mean ± SD) [serum T equivalent ~ 489 ± 155 ng/dL (17 ± 5 nmol/L)] and for topical T (Axiron®) was 391 ± 140 ng/dL (~14 ± 5 nmol/L). The overall safety profile of TU was similar to topical T. There were no deaths or T-related serious adverse events. Mean changes in HCT and PSA were similar in both treatment arms with HCT increase of 2-3% (absolute increase) and PSA increase of 0.2-0.3 ng/mL with no PSA values > 4 ng/mL. Final subject mean increase in systolic BP by cuff in the oral TU and topical T groups was 2.8 (± 11.84) and 1.8 (± 10.76), respectively.

Conclusion: A new oral TU formulation restored T to mid-eugonadal levels in hypogonadal patients. Both groups showed a modest change in HCT and PSA.

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Novel Mobile-Enabled Point-of-Care Testing for Comprehensive Male Fertility Assessment

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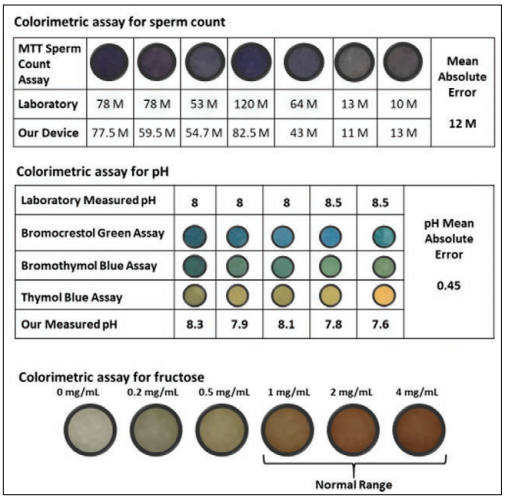
Introduction: Semen analysis remains the gold standard for male fertility testing. The current standard is for men to visit a laboratory and either deliver a fresh semen sample or collect a sample on site for analysis. This process, however, is uncomfortable for most men, time-consuming, and costly. We have developed a mobile-enabled paper-based device for home-based male fertility testing of sperm concentration, semen pH, and semen fructose concentration; allowing men to make their initial male fertility assessments in the comfort of their homes. Here we present validation data for our novel home male fertility colorimetric testing assay.

Materials & Methods: The testing device comprises a reservoir for sample loading, sample delivery microfluidic channels, and a paper layer pre-loaded with colorimetric reagents. Sperm count is quantified by measuring the colorimetric change of yellow tetrazolium dye to purple formazan by metabolically active sperms. The color change in each assay region is imaged and analyzed using a mobile phone application. Human semen samples were obtained from a local fertility clinic (Farmington, CT) and applied to our device without any sample preparation. Measured semen parameters were compared to standard semen analysis results by trained andrologists.

Results: Previous sensitivity testing of eight different sperm concentrations (utilizing ten semen samples) was performed to create a calibration curve with ($R^2 = 0.97$). Using the established calibration, the sperm concentration of seven new semen samples was evaluated in comparison to standard lab-based testing and a mean absolute error of 12M sperm was obtained. The pH sensitivity is increased by multiplexing of three pH indicators and their calibration curves have been determined and further tested in five semen samples with a mean absolute error of 0.45. The colorimetric fructose assay has been calibrated for concentrations ranging from 0 to 4 mg/mL ($R^2 = 0.98$).

Conclusions: Our preliminary clinical validation demonstrates the practicality of the proposed at-home diagnostic platform as a screening tool for male fertility assessment. Further testing is needed to define the sensitivity of the assays and user-friendliness of the platform. Furthermore, additional semen parameters, such as DNA fragmentation, are being targeted for future iterations of the platform.



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The Effect of Body Mass Index on Clomiphene Citrate Therapy Outcomes for Hypogonadal Men

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Introduction: Standard exogenous testosterone replacement therapy may lead to fertility decline or azoospermia, as they suppress the natural hypothalamus-pituitary-gonadal (HPG) axis necessary for endogenous testosterone production and spermatogenesis. For men with future fertility interest or male factor infertility, clomiphene citrate (CC) provides a fertility-sparing treatment option, by increasing endogenous testosterone production.

Materials & Methods: In a single male infertility clinic, our study retrospectively compared 100 consecutive men who were diagnosed with hypogonadism and treated by a single urologist with clomiphene citrate (CC) starting at 25 mg every other day and titrated to eugonadal total testosterone (TT) up to a maximal dose of 50mg daily. Increase in TT from baseline after three months of treatment measured treatment effectiveness. Additional outcomes were measured with change in prostate specific antigen (PSA), estradiol, and hematocrit (HCT) from baseline after three months of treatment.

Results: All BMI groups experienced an increase in TT (Figure 1), but patients with a normal BMI exhibited a greater increase in TT ($p < 0.01$). There was a minimal and non-significant change in PSA ($p = 0.37$), estradiol ($p = 0.59$), and HCT ($p = 0.13$). Results are summarized in Table 1.

Conclusions: CC increases TT less in overweight, obese, and morbidly obese men, while exhibiting minimal change in PSA, estradiol, or HCT in all BMI groups. Our study's findings suggest that CC may be a more effective treatment for hypogonadism in normal-weighted men compared to overweight and obese men.

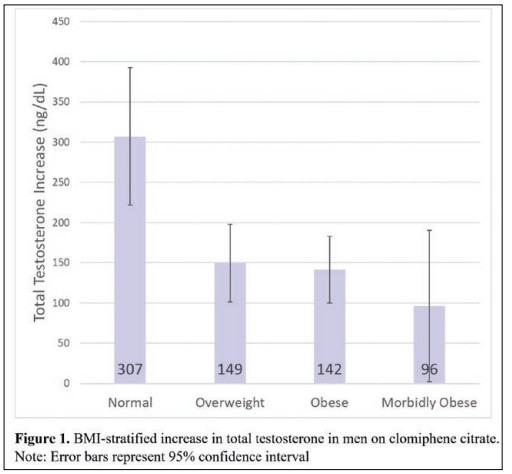

Figure 1. BMI-stratified increase in total testosterone in men on clomiphene citrate.
Note: Error bars represent 95% confidence interval

Table 1. BMI-Stratified demographics and results of hypogonadal men on clomiphene citrate

Parameter	Normal	Overweight	Obese	Morbidly Obese	p value
Age (years)*	36 ± 5	29 ± 7	44 ± 10	42 ± 3	-
BMI (kg/m²)*	24 ± 1	27 ± 1	34 ± 3	48 ± 6	-
Δ Total Testosterone (ng/dL) ‡	307 [221, 392]	149 [100, 197]	142 [100, 183]	96 [2, 191]	< 0.005
Δ Estradiol (pg/mL) ‡	6.2 [-1.9, 14]	5.6 [0.90, 10.0]	9.5 [5.58, 13.4]	8.2 [-1.2, 17.6]	0.59
Δ PSA (ng/mL) ‡	0.23 [0.01, 0.45]	0.04 [-0.06, 0.14]	0.12 [0.03, 0.12]	0.09 [-0.11, 0.29]	0.37
Δ Hematocrit (%)‡	1.2 [-0.3, 2.6]	-0.1 [-0.8, 0.6]	-0.1 [0.7, 0.5]	1.4 [-0.1, 2.9]	0.13

Notes: * means ± standard deviation; ‡ means and 95% confidence interval; N=100

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Angiographic Observations Derived From CT Cavernosography

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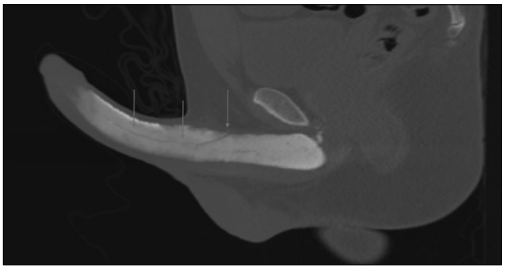
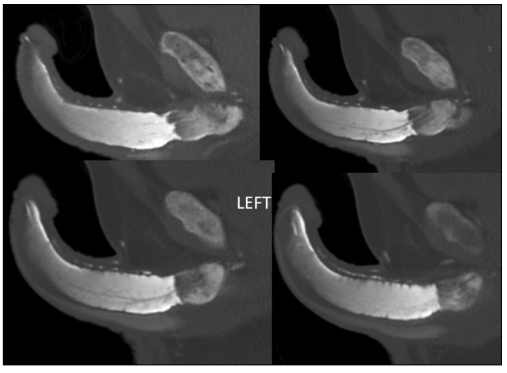
Introduction: Understanding penile arterial anatomy and its preservation is of interest to reconstructive and oncologic surgeons. Traditionally, the predominant cavernosal arterial supply is thought to be the cavernous artery (CA), originating from the internal pudendal artery (IPA). Penile duplex dopplers have demonstrated the existence of accessory cavernous arteries originating from the dorsal artery of the penis. Assessment of the arterial anatomy has been limited to imprecise doppler ultrasound and invasive fluoroscopic angiography. Herein we describe the ability of CTC to delineate heretofore undescribed arterial anatomy of the penis. We describe our observations on the importance of the contribution of the dorsal penile artery (DA) to the blood supply of the corpora cavernosa in men evaluated by CTC.

Materials & Methods: CTC images were reviewed from a sequential cohort of men. Briefly, a maximal erection is induced by intracavernosal injection (ICI) and inflation with 50% iodinated contrast media. A CT scan of the pelvis is then obtained. Imaging was reviewed to delineate the arterial anatomy with respect to the CA and DA perforators distal to the pubic symphysis.

Results: 14 men had imaging available for review collected between October 2019 and March 2020. The average age was 59.4 years and BMI 28.7; 7.1% of patients had cardiac disease or diabetes, while 14.2% had sleep apnea. Erectile dysfunction was the primary indication in 71.4%, 42.9% had comorbid penile curvature. 42% of men had an identifiable CA with a mean diameter of 1.95 mm. 78.6% of men had at least one identifiable perforating branch of the dorsal artery into the cavernosum, the average count being 2.83 (range 0-6). The mean penetrating angle was 51.8°. The mean distance from the pubic symphysis to the first, second, and third perforating arteries was 2.22 cm (range 0.3-7.3), 3.27 cm (range 1.0-5.3), and 3.95 cm (range 1.2-5.7), respectively, with a mean diameter of 1.76 mm.

Conclusions: This is the first time that CTC has been used to describe variability in penile arterial anatomy. Our results suggest that most men with ED have multiple accessory arteries penetrating the cavernosa distal to the pubic symphysis. These arteries, in aggregate, may provide major blood flow to the cavernosa. The results of this study have implications for the reconstructive and oncologic surgeon where DA's originating from the accessory pudendal arteries may be sacrificed. Additionally, these results may call into question the predictive value of penile dopplers where the exact artery that is being measured is uncertain. Penile arterial anatomy is more diverse than previously reported. Based on our CTC study, the corpora cavernosa receive significant blood supply from the dorsal arteries Limitations of this study include small sample size, observational nature, and lack of normal controls.





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Access to Male Fertility Preservation Information and Referrals at National Cancer Institute Cancer Centers

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Introduction: Future fertility and sexual function are critical quality-of-life issues for male cancer survivors. Access to subspecialists is not uniform throughout the United States. We sought to identify access gaps in male sexual health and fertility care at National Cancer Institute (NCI)-designated cancer centers (CC) across US Census Regions.

Materials & Methods: 64 NCI center websites (14 CC and 50 comprehensive CC) were examined for language related to male sexual health and fertility. A phone-based survey was used to establish CC referral patterns to andrologists and sperm banks. The Society for the Study of Male Reproduction (SSMR) membership directory was used to determine geographic locations for andrologists relative to each CC. Fisher exact test and ANOVA were used for categorical and continuous univariate comparisons, respectively. Multivariate logistic and linear regression were used to control for region and center type when assessing binary and continuous variables, respectively. Statistical significance was set to $p < 0.05$.

Results: Presence of information regarding fertility preservation, sexual health and male-specific fertility preservation was not associated with region ($p = 0.18$, 0.17, 0.48, respectively), while presence of fellowship-trained andrologists within 5 miles of a CC was associated with region, favoring the Northeast ($p = 0.014$). On logistic regression, centers whose websites discuss fertility were more likely to refer patients to sperm banks (OR 3.48 [1.11-12.29]). On linear regression, comprehensive CC were not more likely to have established referral patterns to andrologists or sperm banks, or be geographically closer to andrologists when compared to non-comprehensive CC ($p = 0.75$).

Conclusions: We demonstrate geographic differences in access to sexual health and fertility care at NCI-designated CC in the United States, with greater representation of andrologists in the Northeast. The association between online information regarding male fertility preservation and referral access to sperm banks suggests that certain centers may greater emphasize fertility and sexual health care compared to others. Our methods of data collection are tools readily available to patients and can be a focus of efforts to improve access to care in this population.

US Census Region (N)	Overall Fertility Information	Overall Sexual Health Information	Male Fertility Information	Referral to Specific Urologist	Referral to Andrologist	Referral to Sperm Bank	Average number of andrologists in 5 mile-radius
Northeast (14)	50.00%	42.85%	42.85%	85.71%	78.57%	50.00%	2.2
Midwest (14)	78.57%	56.25%	50.00%	78.57%	78.57%	42.86%	0.8
South (21)	47.61%	33.33%	28.57%	76.19%	66.67%	71.43%	0.5
West (15)	40.00%	26.67%	26.67%	85.71%	80.00%	60.00%	0.8

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Patient Desire for Disposition of Cryopreserved Sperm upon Death as a Surrogate Marker for Likelihood of Consent for Posthumous Sperm Retrieval

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Introduction: Decision-making regarding posthumous sperm retrieval can be ethically and legally challenging. Most cases do not clearly delineate in writing whether the deceased would consent for sperm retrieval. Therefore, decision making is guided by hospital policy or on a case-by-case basis. Patients who cryopreserve sperm are required to decide on disposition of their cryopreserved sperm should death occur while their sperm is in storage. Patients must decide between whether sperm should be "discarded per ASRM ethical guidelines" or "transferred to partner for his or her own family building efforts." The objective of this study is to evaluate patient preference on consents for sperm disposition in case of death based on age, etiology of infertility, race/ethnicity, marital status, prior paternity, occupation, or insurance status.

Materials & Methods: An IRB approved, retrospective chart review was conducted on patients who froze sperm from January, 2016 through October, 2019 at a single fertility center. We reviewed the disposition of cryopreserved sperm should death occur to a patient. Collected data included age, race/ethnicity, occupation, insurance status, marital status and duration of marriage, prior biological children, and cause of fertility. Patients were excluded if they were not trying to get pregnant at present, prior to cancer therapy, prior to starting gender affirming treatments, or not in a committed relationship.

Results: After review of 550 charts, 403 patients met criteria for inclusion. The mean age was 38.2 years +/- 6.7 (SD). Reasons for sperm cryopreservation were female factor (46.2%), male factor (34.7%), or combined factor (8.9%) infertility; a diagnosis was unknown or unspecified in 9.4% of patients. Overall, 84.9% of patients consented to transfer their sperm to their partner in case of death. Male-factor infertility and having commercial insurance were predictors of electing to transfer sperm; there was no difference in "transfer to partner" rates with age, race/ethnicity, marital status, duration of marriage, having prior children, or occupation (Table 1).

Conclusions: 84.9% of patients who cryopreserved sperm consented to transfer their sperm to their partners if death should occur. There does not appear to be a clear factor that would impact this decision, based on demographic information, prior children, or occupation. Since there is rarely written consent to perform posthumous sperm retrieval, this information is valuable in assessing whether most men who are married or in a committed relationship would consider proceeding in this fashion. This data may be useful to guide physician-institution-patient decision making in these complex situations.

Table 1. Trends in patient preferences of transfer versus discard of sperm in the event of death

Patient Characteristic	Transfer	Discard	p-value
Mean age	38.0 ± 6.6	39.1± 6.9	.255
Race/Ethnicity			
Caucasian	223/257 (86.8%)	34/257 (13.2%)	.466§
Non-Caucasian	105/125 (84.0%)	20/125 (16.0%)	
Black	36/43 (83.7%)	7/43 (16.3%)	
Hispanic	30/32 (93.8%)	2/32 (6.3%)	
Asian	38/49 (77.6%)	11/49 (22.4%)	
Reason for Cryopreservation			
Male-Factor Infertility	125/140 (89.3%)	15/140 (10.7%)	.019‡
Female-Factor Infertility	148/186 (79.6%)	38/186 (20.4%)	
Combined Male/Female	31/36 (86.1%)	5/36 (13.9%)	.061‡
Unspecified	35/38 (92.1%)	3/38 (7.9%)	
Marital Status			
Married	293/349 (84.0%)	56/349 (16.0%)	.228
Committed Relationship	47/52 (90.4%)	5/52 (9.6%)	
Mean # years married	5.81 ± 4.0	5.26 ± 3.6	.369
No Prior Children	197/233 (84.5%)	36/233 (15.5%)	.678§§
Prior Children, Current Partner	79/91 (86.8%)	12/91 (13.2%)	
Prior Children, Prior Partner	51/60 (85.0%)	9/60 (15.0%)	
Occupation Classification			
Blue Collar	115/137 (83.9%)	22/137 (16.1%)	.871
White Collar	192/227 (84.6%)	35/227 (15.4%)	
Commercial Insurance	297/344 (86.3%)	47/344 (13.7%)	.029*
Non-Commercial Insurance	18/25 (72.0%)	7/25 (28.0%)	
No Insurance	24/31 (77.4%)	7/31 (22.6%)	
Total	342/403 (84.9%)	61/403 (15.1%)	

Statistical significance considered to be $p < .05$. Continuous variables assessed with independent samples t-test. Dichotomous and categorical variables compared with Pearson's chi-squared test
† p value for male-factor vs. female-factor infertility patients
‡ p value for all infertility diagnoses
§ p value for Caucasian vs. Non-Caucasian
§§ p value for no prior children vs. any prior children
* p value for patients with commercial insurance vs. all others

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A Novel Evaluation of Medicare Reimbursement for Commonly Treated Sexual Medicine Conditions

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Introduction: Sexual medicine conditions commonly occur in Medicare patients. Medicare reimbursements are variable over time, and changes in Medicare compensation for sexual medicine disorders have not been previously described.

Materials & Methods: A review of provider utilization and Medicare reimbursement for common procedures in sexual medicine was performed via review of publicly available CMS (Centers for Medicare & Medicaid Services) data.

Results: From 2012-2016, utilization and reimbursement trends for medical and surgical management of Peyronie's disease, Erectile Dysfunction (ED), and Incontinence were examined. Over the time period, there was a 56% increase in providers for medical treatment of Peyronie's disease and a remarkable 86% increase in beneficiaries while the average submitted Medicare charge decreased by 10% and the average reimbursement remained stable. For the surgical treatment of Peyronie's, the number of providers remained the same and the number of beneficiaries increased slightly by 12%. Charges increased by 25% and reimbursement increased by 15% (Table 1). The medical treatment of ED saw an 8% increase in providers, a 10% increase in beneficiaries, a 5% decrease in submitted charges, and a 24% decrease in reimbursement. Surgical treatment of ED saw an 8% decrease in providers, a 5% decrease in beneficiaries, an 8% increase in submitted charges and a 33% increase in reimbursement. In the surgical treatment of male incontinence, a 17% decrease in providers was seen compared to a similar 20% decrease in beneficiaries with a 50% increase in submitted charges, and a 25% increase in reimbursement.

Conclusions: An assessment of CMS data indicates that there has been a robust increase in the treatment of Peyronie's disease with only a slight change in the reimbursement. This is in contrast to the management of ED which has seen an increase in medical management with a decrease in reimbursements compared to a decrease in surgical management with an increasing reimbursement. In the final category, male incontinence, there was a 20% decrease in both providers and beneficiaries with an increase in charges and reimbursement. These data are informative in that demand (as defined by providers and beneficiaries) does not seem to correlate with Medicare patterns of reimbursement.

Table 1. CMS Patterns for Treatment of Peyronie's Disease

Year	Number Providers	Number Beneficiaries	Average Charge	Average Payment
Medical Treatment of Peyronie's Disease				
2012	430	806	713.54	143.14
2013	381	676	602.82	138.90
2014	485	948	678.38	145.40
2015	626	1452	659.09	144.56
2016	675	1504	642.62	142.69
Surgical Treatment of Peyronie's Disease				
2012	451	1140	7444.30	1447.81
2013	468	1205	7274.93	1374.65
2014	390	1055	7085.55	1305.84
2015	408	1091	8062.18	1406.87
2016	450	1283	9347.80	1691.78

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Intraoperative Use of Vancomycin Paste during Penile Prosthesis Placement: Initial Outcomes

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Introduction: Penile prostheses are safe and effective treatment options in the management of severe vasculogenic ED. It is associated with high satisfaction rates in addition to low and acceptable complication rates. Penile prosthesis infection is rare (0.5% to 3%) but can be physically and emotionally devastating for the patient. Although these rates have decreased over the past years with surgeon and device dependent improvements, innovative infection prevention measures are welcome. Vancomycin paste has been used by cardiothoracic surgeons since at least 2007 in an effort to reduce sternal wound infections. Numerous studies have shown that the use of vancomycin paste has an excellent safety profile and has significantly reduced wound site infections, both deep and superficial. We have adopted its use to provide prolonged focal antibiotic exposure around the penile prosthesis pump, a location that is susceptible to the majority of penile prosthesis infections.

Objective: The aim of the study is to determine whether vancomycin paste can be safely used intraoperatively as an additional step for infection prevention during penile prosthesis placement.

Materials & Methods: A multi-institutional chart review of patients who underwent placement of a virginal inflatable penile prosthesis (IPP) with intraoperative use of vancomycin paste (3 gm) was conducted to determine initial outcomes. Adverse outcomes were of particular interest and were categorized in the following manner: penile prosthesis pump-related issues such as fibrosis, persistent pain, and difficult manipulation; as well as standard complications including infection, erosion, hematoma and complete device malfunction.

Results: From April 2019 to October 2019, 90 patients underwent virginal IPP surgery during which vancomycin paste (3 gm) was placed in the scrotum to encircle the pump. Surgical technique, use of irrigations, and drain placement remained consistent per routine protocol. To date, five patients have experienced adverse events, including deep wound infection, superficial wound infection, and scrotal hematoma. Of the five patients, only one experienced a true infection requiring explant, ultimately demonstrating an infection rate of 1.1%.

Conclusions: Vancomycin paste is a safe intraoperative infection prevention measure during IPP surgery. The infection rate within this cohort of patients is in congruence with what is found in today's literature. Nonetheless, no conclusions can be drawn regarding the ability of Vancomycin paste to prevent infections. Future prospective studies are necessary to further examine its efficacy.

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CT Cavernosography: a Patient-Centered Approach to Understanding Functional Penile Abnormalities

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Introduction: Patient-centered care focuses on maximizing patients' physical and emotional well-being. A key aspect to delivering patient-centered care is creating a partnership between the patient and practitioner and integrating both physician and patient knowledge through shared decision-making. Men with functional penile abnormalities are at higher risk of experiencing physical and emotional dissatisfaction. Interventions aimed at patient education may significantly improve patient quality of life and potentially affect response to treatment. CT cavernosography (CTC) is an emerging imaging technique that has been used to evaluate penile anatomy in conditions such as Peyronie's disease and erectile dysfunction. The aim of this study was to use a patient-reported outcome questionnaire to determine the efficacy of CTC in helping patients with functional penile abnormalities understand their condition and treatment options. We also assessed the pain attributed to the use of CTC and whether patients thought this was a valuable tool in the diagnosis of their condition when taking into account the discomfort of the test versus the information gained.

Materials & Methods: Before the procedure, patients were informed about the role for CTC in evaluating their condition. The method for CTC has been previously described. Briefly, a maximal erection was induced by combination of intracavernosal injection and inflation with 50% iodinated contrast media. A pelvic CT scan was then obtained. After the scan, images including 3D reconstructions were discussed with the patients and a 6-item questionnaire was administered for purposes of quality control. The 6 questions concerned pain associated with the procedure, informedness about the procedure, impact of the CTC on patient understanding of the disease process and treatment options, impact of the CTC on decision making, and value obtained from the CTC results. Patients rated the questions on a scale of 1-5 or 1-10.

Results: A total of 29 men aged from 22 to 71 years who underwent CTC for erectile dysfunction (45%), erectile dysfunction with comorbid penile curvature (34%), or other functional penile abnormalities (21%) between October 2019 and March 2020 were included. Patients reported feeling well-informed about the need for the CT scan (M = 4.8/5, SD = 0.8). They also reported that the CT scan gave them a clear understanding of their condition (M = 4.8/5, SD = 0.8) and helped them understand their treatment options (M = 4.7/5, SD = 0.8). Additionally, the scan helped them decide on their next treatments (M = 4.7/5, SD = 0.8). The average pain score attributed to the CTC was low (M = 2.9/10, SD = 2). Fifteen patients required either no pharmacologic reversal or a single dose of phenylephrine. Four patients had a prolonged erection after the procedure requiring corporal aspiration. After weighing the discomfort of the test versus the information gained, patients felt that the CTC was important in the diagnosis of their condition (M = 4.8/5, SD = 0.4).

Conclusions: The use of CTC in patients with functional penile abnormalities is associated with low pain, improved patient understanding of the disease and treatment options, and high patient satisfaction.

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Penile Prosthesis Placement in Patients with Corporal Fibrosis Secondary to Infection or Priapism: Outcomes and Complications

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Introduction: Corporal fibrosis can make the insertion of a penile prosthesis very challenging and is associated with high complication rates. Common causes of this pathology include prior infection, history of priapism, radiation therapy, poorly controlled diabetes, Peyronie's disease, etc. Dilation of the corpora both distally and proximally often require the use of cavernotomes, Rarely, sharp corporal excision may be necessary if the corporal fibrosis is severe.

Objective: The aim of this study was to investigate the outcomes and complications of penile prosthesis placement in patients with corporal fibrosis.

Materials & Methods: This is a single institution retrospective IRB approved study of 34 patients (mean age 52 years, range 31-74 years), with corporal fibrosis who underwent placement of penile prosthesis during a 16-year period.

Results: Etiologies of fibrosis included history of penile prosthesis infection (41.2%, 14/34), priapism (41.2%, 14/34), erosion of penile implant requiring explant (11.8%, 4/34), and poorly controlled diabetes (5.9%, 2/34). With regards to surgical techniques, sharp corporal excision was utilized in 5 patients (14.7%), cavernotomes in 7 patients (20.6%), and a combination of both sharp excision and cavernotomes in 17 patients (50%). In 5 patients (14.7%) where fibrosis was notable, the surgeons were able to dilate the corpora without the aforementioned specialized techniques, although more difficult. Complications included malpositioned prosthesis (8.8%, 3/34), distal erosion (2.9%, 1/34) and infection (2.9%, 1/34).

Conclusions: Penile prostheses can safely be placed in patients with severe corporal fibrosis. However, surgeons must be prepared to use cavernotomes or sharp corporal excision in order to effectively dilate the corpora.

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WITHDRAWN

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Acute Changes in 24 Hour Lithogenic Urine Measures Intra and Peri Partum
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Introduction: Urinary lithogenic changes during pregnancy have been hypothesized to contribute to both stone formation during pregnancy as well as long term increased stone prevalence in multigravid women. However, while short-term lithogenic changes during pregnancy have been postulated, such changes have never been demonstrated in a prospective fashion controlling for diet. Wide inter-person variation in food consumption can account for dramatic differences in 24 hour urinalyses and thus introduces potential confounding. We thus sought to define intrapartum 24 hour urine values and to assess the acute short term changes after completion of the pregnancy >= 6 weeks post-partum. To address potential dietary confounding and thus elucidate those changes intrinsic to the physiology of pregnancy, we utilized a standardized formula to control for dietary intake.

Materials & Methods: IRB approval was obtained for this prospective study. Women with singleton pregnancy presenting to the obstetrical department were offered participation. Those with gestational diabetes were excluded. Metabolic needs were assessed by an obstetrical dietitian and standardized diet was calculated based on each woman's metabolic requirements. The standardized diet consisted of boost plus, boost breeze and unlimited water. Vitamin supplements were held. Collections were obtained during the third trimester and follow-up urine was collected at 6 weeks or greater postpartum. Subjects remained on the controlled diet for 48 hours – the 24 hours preceding urine collection and continued for the 24 hours of the urine collection. Statistical analysis were performed in STATA using T-test.

Results: Of the twenty participants currently enrolled in this study, twelve have submitted a pre- and post-partum 24 hour urine collection. Post-partum collections analyzed in this study were done at any point after delivery, regardless of breast feeding and menstrual status. It was noted that there was no significant difference in known dietary-related factors of urinary volume, sodium, sulfate and urea nitrogen. Urinary calcium was found to be 302.5 pre-partum and 125.2 post-partum ($p = 0.001$). Urinary pH was 6.59 pre-partum and 5.93 post-partum ($p < 0.001$). Urinary super saturation of calcium phosphate (ssCaP) was 2.1 pre-partum and 0.7 post-partum ($p < 0.0001$).

Conclusions: Hypercalciuria and alkaline urine are observed acutely during pregnancy. By implementing a standardized formula diet, for the first time, we have demonstrated these changes are independent of self-selected diet and thus intrinsic to pregnancy. Abnormally elevated urinary super saturation of calcium phosphate during pregnancy further suggests that these changes may have clinical importance.

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Does CT scan after ultrasound change surgical planning for nephrolithiasis?
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Introduction: Ultrasound (US) is often used to diagnose nephrolithiasis, but it is less accurate than CT scan, potentially affecting surgical plans. We examined how often obtaining a CT scan after US changed the indicated management of nephrolithiasis, to see if risk factors that determine inaccurate US scans could be identified.

Materials & Methods: Approval was obtained through our institutional IRB. From those who presented to our health system over the past 3 years with suspected nephrolithiasis, we selected patients who had undergone a retroperitoneal US, and then a CT scan within 30 days. We recorded stone size and location for all studies. We recorded stone density and skin-to-stone distance for each CT scan. Using current AUA guidelines, we determined the indicated procedure based on findings of each imaging study: extracorporeal shockwave lithotripsy (ESWL), ureteroscopy (URS), or percutaneous nephrolithotomy (PCNL). We used Minitab software to perform all statistical analysis, i.e. general linear models and two-tailed Student's t-tests.

Results: 305 patients met inclusion criteria. Of these, the CT scan changed the indicated procedure 108 times (35.4%). 26 US studies indicated ESWL; CT changed 19 of these (73%). 129 US studies indicated URS; CT changed 62 of these (48%). 24 US studies suggested PCNL; CT changed 9 of these (37.5%). Using CT as the gold standard, 18 US studies were false positive for stones (sensitivity=0.72). 51 US studies were false negative for stones (specificity = 0.86). Average body mass index (BMI) was significantly lower in the patients with a false positive US as compared to those with a true positive US (26.59 versus 29.13 kg/m^2, $t(24) = 2.33$, $p = 0.029$). When comparing patients who had their indicated procedure changed by the CT scan to those who did not, there were no significant differences in age, BMI, or skin-to-stone distance. However, those who had their procedure changed had significantly lower density stones (566.1 versus 747.5 HU, $t(154) = 2.92$, $p = 0.004$). When patients were examined in subgroups based on what their indicated procedure was before and after the CT scan, there were also no significant differences based on age, BMI, or skin-to-stone distance. There was a significant difference based on HU, with stone density explaining 22.88% of the variation ($F(11,154) = 4.15$, p<0.001).

Conclusions: US has many advantages over CT, but cannot always be used in place of it. Our study demonstrates that a CT scan changes the indicated stone treatment in more than 1/3 of cases, and that lower-density stones are a risk factor for inaccurate US findings. US should be used with particular caution in those with a history of low-density stone types, and for ESWL surgical planning.

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Association of Prior Pregnancy with 24-hour Urine Composition and Stone Risk
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Introduction: Pregnancy is associated with increased lifetime prevalence of nephrolithiasis. During pregnancy, purported changes in urinary milieu include hypercalciuria and alkaline urine, which may predispose to calcium phosphate urolithiasis. Postpartum, it is unknown whether the cumulative number of pregnancies is associated with increased risk of these findings and calcium phosphate stone formation. We studied the effect of prior pregnancies on the urinary milieu and stone composition in a cohort of female stone formers.

Materials & Methods: With IRB approval, we performed a single-center retrospective review of stone patients treated between 2007 and 2017. We identified non-cystinuric, living female patients with complete 24-hour urinalyses and stone analyses who consented to a pregnancy history questionnaire. Linear regression was used to assess the association of pregnancy with urinary calcium, calcium phosphate supersaturation (SSCaP), and pH, comparing nongravid (G0) and previously gravid women. Pure stones were assigned to their respective category. Mixed stones were assigned to the category corresponding to their predominant crystal species. We additionally categorized stones containing > 10% calcium phosphate as "calcium phosphate-containing stones". Age, body mass index (BMI), and diabetes were adjusted for in the multivariate analysis.

Results: Of 116 who met inclusion criteria, 22 (19%) were G0 and 97 (81%) were previously gravid. Of those previously gravid, 15 (12.9%) were primigravid (G1), 26 (22.4%) secundigravid (G2), and 53 (45.7%) had three or more pregnancies (G3+). Mean age was 54.3 years, and did not differ significantly by history of pregnancy ($p = 0.9$). Mean years since last pregnancy was 24.6. Mean BMI at time of 24 hour urine was 29.6 kg/m^2. Previously gravid women were more likely to exhibit hypercalciuria than G0 women (50% vs. 22.7%, $p < 0.05$). Mean urine calcium was increased in G3+ women compared to G0 women (211.9 mg vs. 153.2 mg, $p < 0.05$). On multivariate analysis, both SSCaP and urine calcium remained elevated in G3+ compared to G0 women (+0.049 and +49 mg/d, respectively, $p < 0.05$). Prior gravidity did not impart significant effect on most recent urine pH. There was no difference in the odds of calcium oxalate stone formation among G0 women and previously gravid women, across all number of pregnancies. There was no difference observed in the odds of predominantly calcium phosphate stone formation of greater than 50% composition among G0 women and previously gravid women. However, compared with G3+ women, nulligravids were significantly less likely to have any calcium phosphate-containing stones (OR: 0.296; $p = 0.034$; 95%CI [0.096-0.912]).

Conclusions: Women with multiple pregnancies were more likely than G0 women to have hypercalciuria and elevated SSCaP, even decades after their last pregnancy. While these findings are suggestive of lasting effects, there was no proclivity in the formation of predominantly calcium phosphate stones, suggesting that pregnancy is only one of many factors contributing to nephrolithiasis.

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Continued Feasibility and Success of a Non Opioid Pathway for Postoperative Pain after Ureteroscopy

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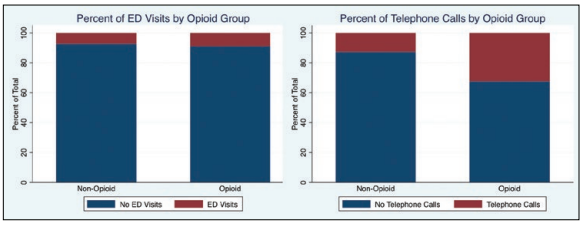
Introduction: The opioid crisis continues to be a major focus in the United States. The contribution of physician prescribing patterns and the need for improvement in the medical community have been increasingly addressed in the literature. We have previously reported on the feasibility of implementing a non-opioid protocol for outpatient ureteroscopy (URS) with stent placement. Our initial experience demonstrated the success of a non-opioid approach for pain control and stent-related symptoms. In this study, we report our extended experience over a 3 year period.

Materials & Methods: Charts of patients who underwent URS with stent placement by a single surgeon from November 2016 to November 2019 were retrospectively reviewed. During this time period, efforts were made to substitute opioid pain medications on discharge for either no prescription or Diclofenac, an NSAID. All patients received similar adjunct medications including Tamsulosin, Tylenol, and Pyridium. Patients with an allergy to NSAIDs or CKD stage II or greater were excluded from the non-opioid pathway as they were unable to be prescribed NSAIDs. Frequency of postoperative adverse events including visits to the emergency department (ED) for stent-related symptoms, stent-related clinic telephone calls, and requests for prescription refills for pain medication were measured.

Results: Four hundred and sixty-four patients underwent URS with stent placement over the 3 year period. 38 with reported NSAID allergy or CKD stage II or greater or both were ineligible for the non-opioid pathway and excluded, and 35 were excluded for having other concurrent procedures such as cystolitholapaxy. 391 patients were included in the final analysis. A total of 357 patients were discharged without opioid medications (91.3%). 34 patients received opioids (8.7%). Of those discharged without an opioid, 276 received Diclofenac and 81 received no pain medication (opioid or prescription NSAID). Both patients receiving opioids and non-opioids had a low number of postoperative visits to the ED for genitourinary-related concerns (3 patients receiving opioids [8.8%] and 26 patients without opioids [7.3%]). Telephone calls made to the urology clinic for concerning symptoms and prescription refills were made by 11 patients receiving opioids (32.4%) and 45 patients without opioids (12.6%).

Conclusions: More than 90% of patients were able to be discharged without opioids after URS and stent placement over a 3 year period without impact on ED visits, or clinic telephone calls. This was achieved through patient counseling and commitment to change practice patterns. We hope our experience will encourage others to take similar measures to decrease opioid prescriptions in this setting.



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Emergency Department Factors that Predict Prolonged Length of Stay after Stent Placement for Obstructing Urolithiasis and Infection

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Introduction: Infected obstructing ureteral calculi represent a surgical emergency and studies have shown that time to stent insertion correlates with hospital length of stay (LOS). This study sought to assess the factors present at time of emergency department (ED) presentation that were associated with increased LOS after emergent stent insertion for infected obstructing ureteral calculi.

Materials & Methods: A retrospective review of 131 patients stented for infected obstructing ureteral stones at a single academic institution between May 2017 and December 2019 was performed. Demographic data, ED presentation course, task-time analysis, LOS, and number of patients meeting Systemic Inflammatory Response Syndrome (SIRS) criteria by having two or more of the following criteria: fever > 38.0°C or hypothermia < 36.0°C, tachycardia > 90 beats/minute, tachypnea > 20 breaths/minute, leukocytosis >12*10^9/l or leukopenia < 4*10^9/l as a measure of severity of illness were obtained. Linear regression analysis was performed to characterize the relationship of the above factors and hospital length of stay.

Results: Patient characteristics are shown in Table 1. Mean LOS was 66.7 hours (R 5.7-243.8, SD 57.7). The mean time from presentation to operating room (OR) was 9.3 hours (R 3.3-48.6, SD 6.0). The elapsed time from presentation to OR did not affect LOS. 62 patients (47.3%) met SIRS criteria and LOS increased by 6.8 additional hours for each systemic inflammatory response syndrome (SIRS) criterion present during ED evaluation (t = 2.33, p = .02). Elevated serum lactate (t = 2.96, p= .004), serum creatinine (t = 2.8, p = .006), and presence of pyuria (t = 3.23, p = .002) were also correlated with increased LOS (6.9 hours, 5.9 hours, and 0.2 hours, respectively, for each rise in value). Correlations between ED factors and LOS are described in Table 2.

Conclusions: In patients presenting to the emergency department with obstructing urolithiasis and infection, presence of SIRS criteria, elevated serum lactate, creatinine and increased urine WBC count were all predictive of increased length of stay after stent placement. Time from presentation to stent insertion was not, however, significantly associated with length of hospital stay. These data question the true urgency of ureteral

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Genetically Defined Ancestry Reveals Unique Prostate Cancer Associated Polymorphisms in Men of African Ancestry: Analysis of the ELLIPSE Prostate Cancer Cohort

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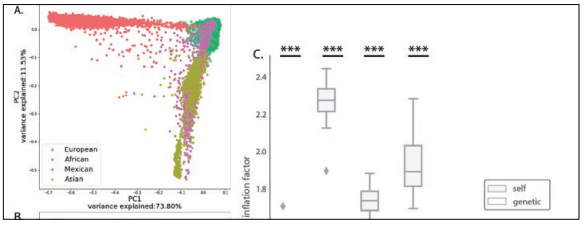
Introduction: Prostate cancer (PrCa) is the second leading cause of cancer death in U.S. men and while PSA screening can aid in detection, better tools are needed to stratify risk. Prior Genome-wide association studies (GWAS) using self-reported ancestry have identified PrCa associated Single Nucleotide Polymorphisms (SNPs), but the majority of these findings are specific to patients of European ancestry. We hypothesized that genetically defined ancestral groups would be a more accurate assessment of PrCa associated SNPs.

Materials & Methods: Genetic, phenotype, and self-identified ethnicity (European, African American, Latino, Asian) data was obtained from the ELLIPSE Prostate Cancer Meta-Analysis and Genotyping study (a case-control study of over 99,000 men). SNPs were imputed with the Michigan Imputation Server using the 1000 Genomes Project as the reference population. Genetic ancestry analysis was conducted using a merged identity-by-state matrix (ELLIPSE and HAPMAP study) and Principal Component Analysis (PCA). A k-means clustering model trained on HAPMAP data was used to determine that the ELLIPSE cohort best fit with 5 ancestral groups from the HAPMAP data: European n = 82551, African n = 6355, Mexican n = 1925, Indian n = 522 and Asian n = 291. Self-identified and genetically defined ancestral groups were compared with PCA. Genome-wide analysis were performed and SNPs passing the p-threshold of $5x10^{-8}$ were analyzed.

Results: Genetically defined ancestral groups better controlled for effects of population stratification than self-identified ancestral groups ($p < 3.47x10^{-9,}$ Figure 1). European and African ancestral groups were well-powered for analysis with numerous SNPs passing the p-threshold. Manhattan plot of the African ancestral group showed significant associations on chromosome 8, with multiple SNPs aligning with described loci in European populations. Unique SNPs were noted on chromosomes 6 and 11 (Figure 2). The Mexican, Indian and Asian ancestral groups were not sufficiently powered for analyses.

Conclusions: Patients in the ELLIPSE cohort have significantly better grouping when stratified by genetic ancestry compared to self-identified ancestry. Specifically, the cohort can be sorted into 5 ancestral groups that align with groups described by the International HAPMAP Project. Furthermore, GWAS using genetically identified ancestry uncovered SNPs specific to minority ethnic groups. Future characterization of these PrCa risk SNPs could aid individualized screening recommendations within the African American population.



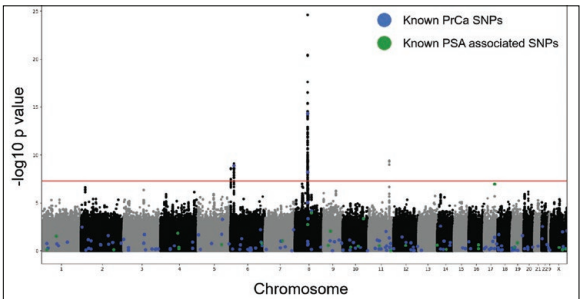


Figure 2. Manhattan Plot of PrCa associated SNPs in the African ancestry group. Several SNPs pass genome-wide significance threshold ($p<5x10^{-8}$). SNPs known to be associated with prostate cancer are labeled blue and SNPs known to be associated with PSA (prostate-specific antigen) are labeled green. The red line represents the p-threshold $5x10^{-8}$

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Kidney Stone Volume Measurement using Ultra-Low Dose Computed Tomography and New Software Solutions

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Introduction: Ultra-low dose computed tomography (UCT) is a promising alternative to standard dose CT (SCT) as imaging modality following nephrolithiasis treatment. Emerging software solutions allow easy stone size measurement including stone volume that provides clinically important information. This study evaluated two software solutions using UCT and SCT: Ziostation and Synapse.

Materials & Methods: 29 patients with nephrolithiasis who underwent nephrolithiasis treatment between October 2017-June 2019 were imaged using SCT immediately followed by UCT. Anonymized images were randomized to an Orthanc DICOM viewer prior to a blinded review by board-certified radiologist. Max stone diameters were measured in the axial and coronal planes, using standard electronic calipers. Radiologist stone volume was modeled as ellipsoids based on the max stone diameters. Stone volumes were compared to automated measurements by Ziostation and Synapse software and compared between doses. Stone location was recorded as upper/mid/lower pole or ureter. Site specific stone burden (SSB) was calculated as cumulative stone volume in each site. Radiation exposure was calculated from CT dose reports. SSB were considered concordant if < 30 mm^3. P-value of 0.05 was used as significance cutoff.

Results: 74 unique stones were identified in 29 patients. Mean exposure of UCT was significantly lower than SCT with 2.6 and 10.2 (mSv, $p < 0.01$) respectively. Overall radiologist measurement concordance rate was 90% between UCT and SCT, with no significant difference between doses ($p = 0.91$). SSB concordance rates within dose for Ziosoft and Synapse were 100% and 87% respectively.

Conclusions: No statistically significant difference was detected in SSB between UCT and SCT across all exams. UCT can be used for follow-up imaging post nephrolithiasis treatment exposing the patients to less radiation. Kidney stone volume measurement of post-operative SSB using Ziostation and Synapseis reproducible and operator-independent both in SCT and UCT. Adoption of such tools may benefit patients and surgeons. Discordance rates in SSB between radiologist and software measurement warrant further research to determine the gold standard in SSB measurement.

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Methylation of SRD5A2 Promoter Predicts a Better Outcome for Patients Undergoing Androgen Deprivation Therapy in Patients with Castration Resistant Prostate Cancer

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Introduction: Steroid 5-alpha reductase (SRD5A2) is a critical enzyme for prostatic development and growth. We have found that epigenetic modifications suppress expression of SRD5A2 in one-third of adult prostates, a condition associated with an androgenic to estrogenic switch in adult prostate tissues accounting for changes in hormonal milieu. Our objective is to demonstrate, in a well-defined subset of PCa patients, whether the SRD5A2 promoter methylation is associated with cancer progression during androgen deprivation therapy (ADT) in castration-resistant prostate cancer (CRPC).

Materials & Methods: 58 CRPC samples and 36 benign prostatic specimens were studied. The methylation status of CpG site(s) at SRD5A2 promoter regions was tested via Targeted Next-Gen Bisulfite Sequencing (tNGBS).

Results: Compared with benign prostatic tissue, CRPC samples demonstrated higher *SRD5A2* methylation in the whole promoter region (Local CRPC cohort: $P < 0.001$; Met CRPC cohort: $P < 0.05$). Hypermethylation of specific regions (nucleotides -434 to -4 [CpG# -39 to CpG# -2]) was associated with a better overall survival (11.3 ± 5.8 vs. 6.4 ± 4.4 years, $P = 0.001$) and progression free survival (8.4 ± 5.4 vs. 4.5 ± 3.9 years, $P = 0.003$) with cutoff value of 37.9%. The protein expression of *SRD5A2* was negatively correlated with the ratio of *SRD5A2* methylation both in the whole promoter region and in the specific region.

Conclusions: Our study demonstrates that SRD5A2 hypermethylation in specific promoter regions of SRD5A2, a condition that favors estrogenic as opposed to an androgenic milieu in the prostate, is significantly associated with better survival in CRPC patients who are treated with ADT. We show that a well-defined subset of prostate cancers with SRD5A2 methylation, specifically at CpG#: -39 to CpG#: -2, predicts better outcomes. Recognition of epigenetic modifications of SRD5A2, which affects the prostatic hormonal environment, may affect the choices and sequence of available therapies for management of CRPC.

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miRNA Expression Profile Predicts Local Invasion in cT1 Renal Cancer

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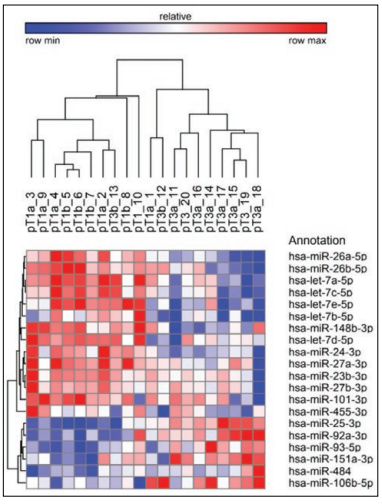
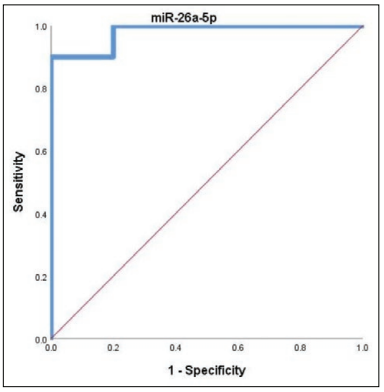
Introduction: Clinical staging of incidentally discovered renal masses largely relies on radiographic size criteria and gross invasion of venous structures or perirenal fat. However, early involvement of segmental veins or microscopic fat invasion in clear cell renal carcinoma (ccRCC) is not adequately detected on imaging leading to upstaging at the time of surgery. This has been estimated to occur in as many as 14% of patients with an associated 40% increase in mortality risk. Additionally, the incidence of pre-operative renal mass biopsy is increasing as active surveillance becomes more common. MicroRNA (miRNA) has been implicated as an early aberration identifiable in cancerous tissues. We therefore sought to identify alterations in miRNA expression profiles of clinical T1 (cT1) ccRCC which could predict pathologic upstaging to pT3 at the time of surgery.

Materials & Methods: Seventy eight age and Fuhrman grade matched patients with cT1 renal masses were identified who had undergone partial or radical nephrectomy for ccRCC at our institution, 40 pT1 and 38 pT3. Two patients were excluded due to synchronous tumours, and 2 patients were excluded due to the pre-operative presence of metastases. miRNA was isolated from the remaining patients using the Qiagen FFPE AllPrep RNA isolation kit. An array of 751 candidate miRNAs were screened via qRT-PCR using a balanced subset of 20 patient samples.

Results: miRNA screening identified 24 candidate miRNA with differential expression profiles between patients with pT1 and pT3 disease (Figure 1). 20 of these miRNA were previously identified as potential mediators of ccRCC progression while the remaining 4 have been implicated in other cancers including prostate, breast, colorectal, and lung. miR-26a-5p, -26b-5p, -24-3p, and -25-3p were the best predictors of pT1 versus pT3 disease (all p<.001, q<.05) with AUC >0.9. The ROC for miR-26a-5p is shown in Figure 2.

Conclusions: The differentiation of renal masses into subsets by probability of progression may aid in more appropriate and informed selection of patients for both surgery and active surveillance. As renal mass biopsy becomes more common, the development of novel techniques to examine factors influencing invasion may improve this selection process. We identified 24 candidate miRNA which could form a profile predictive of local invasion in ccRCC. Phase 2 of this study seeks to identify and validate a smaller subset of these miRNA as a predictive profile of pathologic upstaging, therefore creating a tool to aid in surgical decision making.





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Sendai Virus as a Novel Oncolytic Virus for Urothelial Carcinoma

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Introduction: The use of oncolytic viruses is an active area of investigation in the field of urologic oncology. Several clinical trials have been completed investigating recombinant adenovirus as a second-line treatment for non-muscle invasive bladder cancer after BCG-failure. Sendai virus is a murine paramyxovirus with no innate virulence in humans but with documented oncolytic activity and tumor cell specificity. Sendai virus treatment has been investigated in several murine solid tumor models, but to date has not been studied in bladder cancer.

Materials & Methods: We modified the genome of the Sendai virus to express green-fluorescent protein (GFP) as an indicator of successful viral infection. We then infected the urothelial carcinoma cell line 639V with Sendai virus at various titrations. Three days post-infection we performed a flow cytometric analysis to quantify oncolytic activity and changes in cell-surface protein expression. Finally, we infected primary urothelial carcinoma cells derived from pathologic T1, high grade urothelial tumor *in vitro*.

Results: At three-days post-infection, we observed GFP fluorescence in 639V cells exposed to the Sendai virus at titers greater than 1000 infectious units (IU). Successful viral infection, defined as a positive GFP-signal during cell acquisition via flow cytometry, directly correlated with increasing viral titer (Figure 1). Higher viral titers associated with increased 639V cell death. We observed upregulation of the immune checkpoint PD-L1, in addition to increased expression of the MHC class I proteins HLA-A, B, and C (Figure 2). We observed gross fluorescence of primary tumor cells 72-hours post-infection (Figure 3) using fluorescence microscopy.

Conclusions: Functionally wild-type Sendai virus was capable of both infecting and killing 639V urothelial carcinoma cells *in vitro*. Flow cytometric analysis revealed dynamic changes in expression of important surface proteins after infection, including PD-L1. These proof-of-concept experiments demonstrate the feasibility of Sendai virus as an alternative to adenovirus for the treatment of non-muscle invasive bladder cancer.

Figure 1: 639V cells exposed to GFP-expressing Sendai virus were analyzed 72 hours post-infection to determine successful infection and cell death. **A**: Values indicate the median fluorescence intensity (MFI) of 10000 639V cells at a given quantity of infectious units (IU). **B**: Cell death was determined using an amine viability dye. **C:** Histograms displaying MFI of HLA-A/B/C and PD-L1 of 639V cells 72-hours post exposure to Sendai virus, gated on live cells.

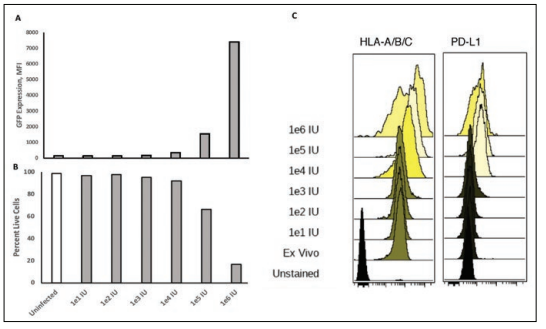
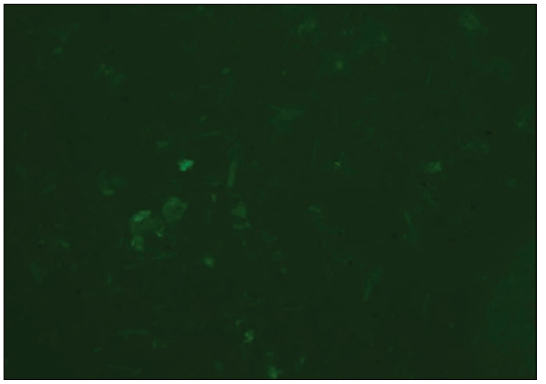


Figure 2: Gross fluorescence of Sendai-infected primary tumor cells derived from a pathologic T1, high-grade tumor after cystectomy, visualized using fluorescence microscopy.



65

Time to Operating Room is Significantly Longer if Emergency Department Presentation Occurs "After Hours" for Patients with Pyelonephritis and Obstructing Stones

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Introduction: Obstructive pyelonephritis secondary to obstructing ureteral calculi is considered a urological emergency. Patients with hemodynamic instability and signs of florid sepsis are emergently taken for ureteral stent or percutaneous nephrostomy tube placement. However, for patients without these presenting signs or symptoms but still in need of decompression, there is question as to the necessity of emergency surgery. We sought to explore time from diagnosis to operating room (OR) in patients with regard to the time of day and day of the week that the patient presented to the emergency department (ED) and its effect on hospital length of stay, a surrogate measure for clinical course and morbidity.

Materials & Methods: A retrospective review of all patients presenting to the ED with obstructive pyelonephritis secondary to obstructing ureteral calculi at a single academic institution between May 2017 and December 2019 was performed. Patient demographics, day of the week of presentation, as well as time of ED presentation and clinical course including times of imaging completion confirming diagnosis and time to OR were analyzed. Patients were categorized as having presented during "business hours" 6 AM - 6 PM or "after hours" 6 PM - 6 AM. Student's t-test and one-way analysis of variance (ANOVA) were utilized to detect differences between groups.

Results: A total of 131 patients with infected or septic stones who underwent urgent or emergent cystoscopy and ureteral stent placement were reviewed. Patients who presented to the ED during standard business hours were taken to the operating room on average more expeditiously (Mean = 250 minutes, SD = 220) than those who presented after hours (Mean = 406 minutes, SD = 207; $t(29) = 3$, $p = .005$). No significant difference in LOS was detected between these two groups (Mean = 69.8 hours, SD = 59.6 [business hours] versus mean = 53.1 hours, SD = 49.6 [after hours]; $t(40) = 1.4$, $p = .16$). No differences were detected in time from imaging diagnosis to OR [$F(6,106) = 0.99$, $p = .44$] nor length of stay [$F(6,122) = 1.88$, $p = .09$] based on the individual day of the week of ED presentation.

Conclusions: The time to operating room is significantly different based whether patients with pyelonephritis and an obstructing stone present to the ED during "business hours" or "after hours." Patients who presented to the ED "after hours" experienced a significant delay in time from diagnosis to arrival to the OR for definitive surgical management compared to those presenting during "business hours." Despite this, there was no difference in hospital length of stay between these groups, suggesting no significant impact on morbidity or clinical course in those deemed clinically stable for non-emergent stent placement. This suggests that in the appropriate clinical context stent placement may be performed non-emergently without significant effect on a patient's overall clinical course. Further studies should focus on the effect this may have on hospital and surgeon resources.

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Surgical Management of Urethral Bulking Agent Complications in Women

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Introduction: Urethral bulking agent (UBA) injection serves as a quick, minimally invasive method for the treatment of stress urinary incontinence (SUI) in women. When injected submucosally these agents restore continence via urethral coaptation. Though bovine collagen (Contigen™) served as the predominant injectable agent for years, a variety of synthetic agents including Macroplastique®, Durasphere® and Coaptite® have risen to prominence. Though widely utilized, there is only sparse data in the literature regarding potential complications of these agents. In this case series, we describe UBA complications in four patients requiring surgical management as well as the techniques utilized to resolve these complications.

Materials & Methods: This study entails a retrospective review of four patients presenting for evaluation and management of complications related to injection of UBAs to a single surgeon between 2016 and 2020. Presenting symptoms, diagnostic evaluation, surgical management and outcomes are reviewed. The presenting symptoms were described as either early-onset (< 12 mo) or late-onset (> 12 mo) according to first report.

Results: Patient characteristics and management strategies are presented in Table 1. The most common presenting symptoms included urinary urgency, vaginal pain and dyspareunia. In most cases, voiding dysfunction occurred early after the bulking therapy. In all cases, cystourethroscopy identified agent erosion or local inflammatory response (Figure 1); imaging was performed in 3 cases (1 MRI, 2 CT). To date, transvaginal excision has been performed in two patients, with two patients awaiting definitive operation. Patients undergoing transvaginal excision presented with vaginal pain and necessitated urethral reconstruction (Figure 2). Open excision of the UBA resulted in improvement or complete cure of symptoms. Both patients developed recurrent SUI, with one patient requiring a salvage pubovaginal sling procedure to date.

Conclusions: The majority of UBA complications, including urinary tract infection, hematuria, and urinary retention are considered mild and transient and may be managed with non-surgical interventions.[1] For patients in whom conservative management fails or for more severe complications (i.e. erosion, abscess, palpable mass and chronic pain) transurethral or transvaginal excision of bulking agent and associated granulomas should be considered. Though open excision is a major surgical endeavor, complete relief of symptoms can be achieved, albeit with a risk of de-novo SUI. Physicians should have a high level of suspicion for bulking agent erosion or granuloma development in all patients with a history of prior injection presenting with lower urinary tract symptoms and/or pain.

[1]De Vries AM, Wadhwa H, Huang J, Farag F, Heesakkers JPFA, Kocjancic E. Complications of Urethral Bulking Agents for Stress Urinary Incontinence: An Extensive Review Including Case Reports. Female Pelvic Med Reconstr Surg. 2018;24(6):392-398.

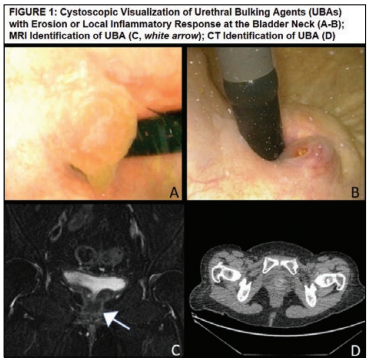

FIGURE 1: Cystoscopic Visualization of Urethral Bulking Agents (UBAs) with Erosion or Local Inflammatory Response at the Bladder Neck (A-B); MRI Identification of UBA (C, *white arrow*); CT Identification of UBA (D)

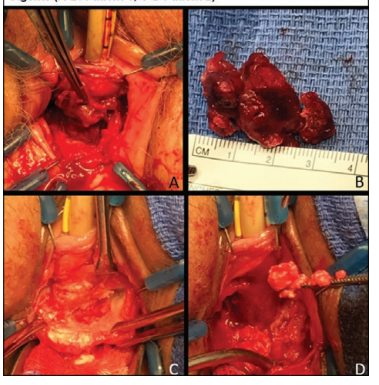

FIGURE 2: Transvaginal Open Excision of Urethral Bulking Agents (A-B: Patient 1; C-D Patient 2)

TABLE 1: Case Series of Patients with Bulking Agent Complications

Injectable Agent	Presenting Symptoms	Timing of Presenting Symptoms	Time from Bulking Agent to Diagnosis	Management
Collagen®	Dysuria, Urgency, Vaginal pain, Dyspareunia	Early-Onset	2 Years	Transvaginal Open Excision
Macroplastique®	Pelvic pain, Vaginal pain, Dyspareunia	Late-Onset	7 Years	Transvaginal Open Excision
Macroplastique®	Intermittency, Urgency, Nocturia	Early-Onset	4 Years	Transurethral Resection**
Coaptite®	Recurrent UTIs, Frequency, Urge incontinence	Early-Onset	Unknown	N/A**

**Awaiting Transvaginal Open Excision

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Once-Daily Vibegron 75 mg for Overactive Bladder (OAB): Double-Blind 52-Week Results From an Extension Study of the International Phase 3 Trial (EMPOWUR)

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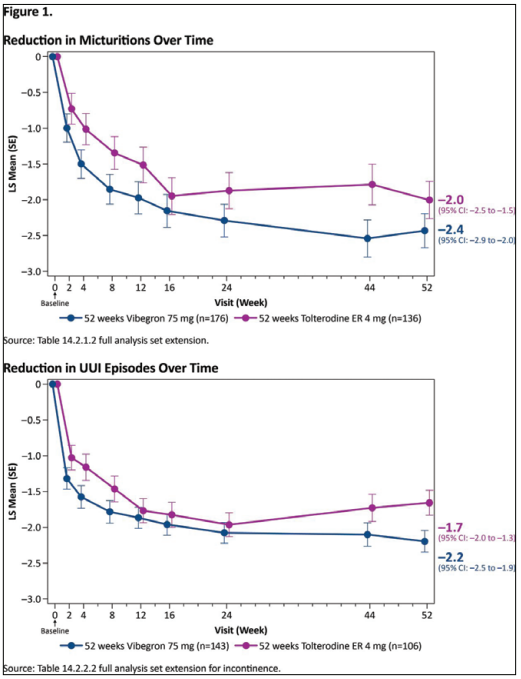
Introduction: Vibegron is a novel, oral, once-daily β3-adrenergic receptor agonist being investigated for overactive bladder (OAB) treatment. In the phase 3 randomized, double-blind, 12-week EMPOWUR trial (N = 1518), vibegron 75 mg statistically significantly improved primary OAB endpoints of daily micturitions and urge urinary incontinence (UUI) ($p < 0.001$ each) and key secondary endpoints vs. placebo; tolterodine extended-release 4 mg was active control. Vibegron tolerability was favorable. Results from the 40-week EMPOWUR extension are reported.

Materials & Methods: EMPOWUR enrolled adults aged ≥ 18 years with OAB wet (incontinence) or dry. The 40-week extension enrolled ~500 EMPOWUR completers. Those receiving vibegron or tolterodine in EMPOWUR continued; placebo patients received vibegron or tolterodine (1:1). The randomization was stratified by OAB type and sex. The primary endpoint was vibegron safety and tolerability. Key efficacy endpoints were changes from EMPOWUR baseline at week 52 in average daily micturitions, UUI, urgency, and total incontinence.

Results: Among 505 randomized, treated extension patients (n = 273, vibegron; n = 232, tolterodine), median age was 64.0 years (mean age: 61.1 years); 46.5% were aged ≥ 65 years; 78.2% were women; and 78.2% had OAB wet. Baseline characteristics and extension completion rates (vibegron, 85.8%; tolterodine, 84.1%) were similar. Adverse events (AEs) occurred in 62.6% of vibegron and 54.3% of tolterodine patients; 4 (1.5%) vibegron and 8 (3.4%) tolterodine patients discontinued study medication due to an AE. Key AEs (> 5% for vibegron) for vibegron and tolterodine, respectively, were hypertension (8.8% and 8.6%), urinary tract infection (6.6% and 7.3%), and headache (5.5% and 3.9%). One death (due to arteriosclerotic disease, judged not related to study drug by investigators or sponsor) occurred in the vibegron group. Among EMPOWUR vibegron and tolterodine patients receiving 52 weeks of active treatment, there was adjusted mean change from EMPOWUR baseline improvement at week 52 in all key OAB endpoints: micturitions (-2.4, vibegron [n = 152]; -2.0, tolterodine [n = 120]; Figure 1), UUI (-2.2, vibegron [n = 125]; -1.7, tolterodine [n = 91]; Figure 1), urgency (-3.4, vibegron [n = 152]; -3.2, tolterodine [n = 120]), and total incontinence (-2.5, vibegron [n = 125]; -1.9, tolterodine [n = 91]); 61.0% of 143 vibegron-treated patients had a ≥ 75% reduction in UUI, and 40.8% became dry (100% reduction) at week 52.

Conclusions: Consistent with the placebo-controlled EMPOWUR phase 3 study, vibegron demonstrated a favorable long-term safety profile in extension patients with OAB and showed durable improvements in micturitions, UUI, urgency, and total incontinence; 40.8% of wet patients became dry at week 52.

Figure Legend: Change from baseline least squares mean; 52-week groups only. Covariates included in the mixed model for repeated measures are study visit, treatment, treatment by study visit interaction, baseline, OAB type (micturitions only), and sex. Baseline value is computed using the run-in diary from the EMPOWUR 12-week study. LS = least square; UUI = urge urinary incontinence.



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Anovaginal Distance and UTI Frequency inOlder Women: Does Distance Matter?

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Introduction: Short urethral length and anovaginal distances are often cited as factors that increase a woman's risk of developing UTIs. However, little data exists to support either of these conclusions. Given the high prevalence of UTIs along with the severity of the associated sequelae, particularly in older patients, it is important to understand the multifactorial etiology of this disease. To determine how perineal anatomy may impact the development of recurrent UTIs, we measured anovaginal distance in post-menopausal women.

Materials & Methods: An IRB-approved, case-control study was performed in the department of Urology at an academic medical center. The selected patient population was women over 55 years of age. Patients were deemed ineligible for our study if they had any of the following: history of GU anatomic anomalies, > 1 kidney stone since menopause, history of gender affirmation surgery, current/recent urinary catheter use, history of colostomy, immunocompromised, active GU/gynecologic cancer, or current anticholinergic, SGLT-2 inhibitor, 1st generation antihistamine, or antipsychotic use. Eligible patients were identified through a pre-visit EMR review and were sorted into two study groups based on the presence or absence of recurrent UTIs, as defined by ≥ 3 culture-positive UTIs over the course of one year. Patients were consented appropriately and asked to complete a questionnaire regarding potential confounders, such as alcohol use and sexual activity. Anovaginal distance was measured from the posterior vaginal introitus to the anterior aspect of the anus. Measurements were taken using a Pop-Q exam stick (Marina Medical Instruments) that contained millimeter markings. Data was stored in the REDCap secure online system and analyzed using Microsoft Excel 2019.

Results: To date, the results from thirty-three patients have been evaluated. The mean anovaginal distance was 33.3 mm (SD: 8.3) for cases and 39.5 mm (SD: 6.3) for controls ($p = 0.02$). With the exception of sexual activity, which was significantly greater in the control group ($p = 0.03$), there was no difference in potential confounders across the two groups, including diabetes and BMI (Table 1).

Conclusions: Variations in perineal anatomy may contribute to the development of UTIs. This initial study demonstrates that women with recurrent UTIs have significantly shorter anovaginal distances than women without recurrent UTIs. These findings should be emphasized during clinical encounters, as behavioral modifications, such as front-to-back wiping and post-coital voiding, may be preventative for at-risk patients. Interestingly, sexual activity was also significantly greater in the control group, suggesting a secondary finding of unclear etiology. Although it is unlikely that sexual activity is protective, further research is needed to better understand the value of this outcome. As more data is collected, we hope to gain greater insight into how anatomy and sexual activity impact UTI risk.

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Single Surgeon Outcomes with Artificial Urinary Sphincter (AUS) implants in High-Risk Patient Population

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Introduction: Artificial urinary sphincter (AUS) implant is the gold standard treatment for stress urinary incontinence following management of prostate cancer, with post-prostatectomy incontinence (PPI) being the most common indication. Complications include device infection, urethral erosion, urethral atrophy, and device malfunction. Although certain factors have been linked to higher rates of complication and revision, prior literature has focused more on heterogeneous patient series versus higher-risk patients specifically. Thus, we sought to describe our experience with AUS in a high-risk patient population with regards to complication rates.

Materials & Methods: A retrospective chart review of patients who received AUS procedures over 2.5 years in a single surgeon's practice at a tertiary care center was performed. Inclusion criteria for high-risk patients included any of the following: prior anti-incontinence procedure, prior radiation treatment, history of bladder neck contracture and/or urethral stricture, urethral erosion and/or infection, and/or history of penile implant (prior or concomitant). Patients receiving a "virgin" AUS without meeting above criteria were excluded.

Results: A total of 53 AUS procedures in 43 male patients were initially identified. Of these, 41 AUS procedures in 31 patients met ≥ 1 inclusion criterion while 12 patients with primary implant and no other risk factors were excluded. Regarding inclusion criteria, 68.3% of cases (28/41) had ≥ 1 prior anti-incontinence procedure; 61.0% (25/41) had prior radiation treatment; 41.5% (17/41) had a history of bladder neck contracture and/or urethral stricture; 63.4% (26/41) met ≥ 2 inclusion criteria. Mean age was 71.0 ± 7.6 years, with the oldest patient being 90 years old at procedure time; mean BMI was 28.8 ± 3.3, with 39.0% (16/41) having BMI in the obese range; 65.9% (31/41) had current or former smokers; 7.3% (3/41) carried a diagnosis of coronary artery disease; 14.6% (6/41) carried a diagnosis of diabetes mellitus.
Regarding case type, 56.1% (23/41) were insertions, 24.4% (10/41) were revisions, 12.2% (5/41) were removal and replacements, and 7.3% (3/41) were removals; the number of AUS re-operations undergone by patients is summarized in Table 1. Mean operating time was 118.2 ± 32.5 min, and salvage procedure using dermal grafts were used in 17.1% (7/41). Mean length of post-procedure follow-up was 345 ± 252 days. Urethral atrophy was the most common complication in 22.0% (9/41), with a mean onset time of 400.6 ± 227 days. There were 4.9% of cases (2/41) with device infection/urethral erosion and 2.4% of cases (1/41) with device failure. Where listed, chart review showed that 45.5% of cases (15/33) were described as using one or fewer pads per day in postoperative follow-up.

Conclusions: Complication rates are comparable to those of prior literature, showing the feasibility of salvaging AUS in a highly complex patient cohort with a greater risk of complication and recurrent incontinence. Further follow-up of this cohort is warranted to better characterize complication rate and quality of life outcomes.

Table 1. Number of AUS reoperations undergone by patients

Number of reoperations	Number of patients (%)
0	24/31 (77.4)
1	5/31 (16.1)
2	1/31 (3.2)
3	1/31 (3.2)

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Sodium Bicarbonate to Augment Lidocaine's Intravesical Activity: A Randomized, Crossover Study

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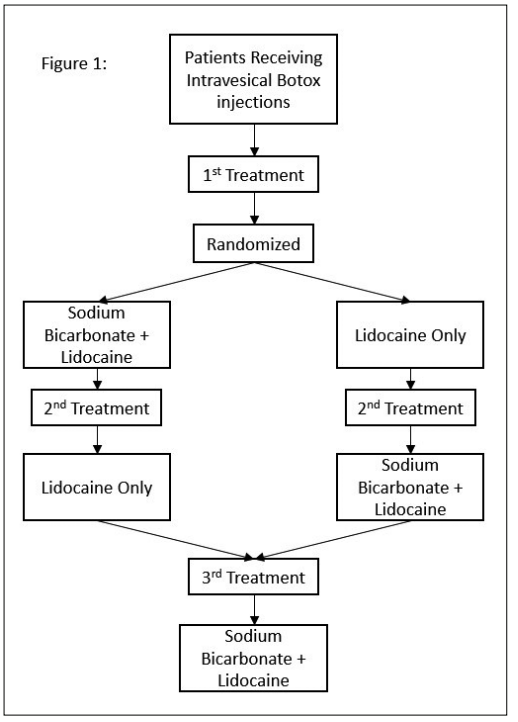
Introduction: There are multiple indications for intravesical botulinum toxin-A (BTX-A) injections. Local anesthetic has been used to improve discomfort experienced during intradetrusor injections. Alkalization of local anesthetic has improved its efficacy in other areas of the human body. We sought to study its effects in the naturally acidic environment of the bladder. The purpose of the study was to determine if there is a difference in pain perception during intradetrusor BTX-A injection when utilizing alkalinized lidocaine versus lidocaine alone.

Materials & Methods: This study was an IRB-approved, prospective, randomized controlled trial with a crossover design conducted by a single urologist in the office setting. Patients with indications for intravesical BTX-A injections and possessing the cognitive ability to report subjective pain scores were eligible. On the first procedure, patients were randomized to either the control or intervention group. Controls received 50 mL of 2% lidocaine alone, whereas the intervention group received a mix of 50 mL of 2% lidocaine with 5 mL of 8.4% sodium bicarbonate. On the second visit, 4-6 months later, participants would be switched to their opposite group to act as their own controls. On the third visit all patients received the intervention (Figure 1). Subjective pain, regarded as the primary outcome, was measured prior to the procedure, at time of first injection and throughout the procedure. Pain levels were assessed by identical pain questionnaires, including a qualitative measure of pain as per a visual analog pain scale (VAS). Demographic information was collected prior to intervention including age, sex, race, and prior analgesic use.

Results: Twenty-six of the 33 patients (13 men, 20 women; mean age: 59.5 years) received 2 procedures and 16 received a 3rd procedure . Of the 68 procedures, 26 were in the control arm and 42 intervention. Subjective pain score at first injection was significantly lower in the intervention arm (2.31 vs. 3.81; p = 0.028). Pain throughout the procedure was lower in the intervention arm although not significant (2.08 vs. 2.75; p = 0.258). There were no adverse events noted during the study.

Conclusions: In our cohort, those who received the sodium bicarbonate experienced less pain at first injection compared to those subject to lidocaine alone. Although subjective pain scores vary between patients, acting as their own controls limits this bias. With no adverse events and no significant alterations to the office-based procedure, we found sodium bicarbonate is an effective and cost-conscious augmentation to lidocaine instillation for intradetrusor BTX-A therapy. Buffering of lidocaine has a greater likelihood of achieving successful anesthesia which may promote further treatment adherence.

Figure 1:



P1

Nocturnal-Only Voiding Diaries: A Rational Alternative to 24-Hour Diaries for Patients with Nocturia?

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Introduction: The major etiologies underlying nocturia can be divided into excess urine production (i.e., nocturnal [NP] and global polyuria [GP]) or small bladder capacity (SBC). An assessment of voiding diary data from the hours of sleep alone can, in of itself, support a diagnosis of NP, but the generalizability of nocturnal urinary data to the 24-h period (e.g., in the diagnosis of GP or SBC) remains unclear. This study determines the sensitivity and specificity of nocturnal urinary parameters in diagnosing nocturia owing to GP and SBC.

Materials & Methods: Retrospective analysis of voiding diaries showing ≥ 1 nocturnal void(s) from men aged ≥ 18 years at an outpatient urology clinic. GP was defined as a 24-h urine volume > 3000 mL. SBC was defined as a 24-h Maximum Voided Volume (MVV) < 200 mL. Nocturnal urine production (NUP) > 125 mL/h (3000 mL divided by 24 hours) and Nocturnal MVV (NMVV) < 200 were employed as nocturnal proxies for GP and SBC, respectively.

Results: A total of 483 entries from 288 patients were included. Fifty-eight diaries demonstrated a 24-h urine volume > 3000 mL, and 110 diaries reported NUP > 125 mL/h, such that NUP > 125 mL/h was 71% sensitive and 84% specific for GP. Eighty-nine diaries reported a 24-h MVV < 200 mL, and 139 entries demonstrated a NMVV < 200 mL, corresponding to a 100% sensitivity and 87% specificity for SBC.

Conclusions: Beyond its intrinsic utility in diagnosing NP, nocturnal urinary data can predict diagnoses of GP and 24-h SBC with a fair degree of sensitivity and specificity. Nocturnal-only voiding diaries may represent a more patient-centered screening instrument in the initial evaluation of nocturia—particularly in the setting of patient nonadherence or when 24-h diaries are otherwise impractical.

P2

Nocturnal Urine Production is Central to the Pathogenesis of Nocturia in Patients with the Nocturnal Polyuria Syndrome

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Introduction: Fundamentally, nocturia is driven by a mismatch between nocturnal urine production (NUP) and bladder capacity, and the degree of discordance between these two variables strongly correlates with nocturia severity (Avulova, et al, Scand J Urol, 2015). By definition, patients with nocturnal polyuria [NP] in the absence of identifiable contributory comorbidities (termed the Nocturnal Polyuria Syndrome [NPS]) incur excess NUP, but bladder capacity in these patients remains poorly characterized. This study compares voided volumes (as a proxy for functional bladder capacity) in nocturia patients with vs. without NPS.

Materials & Methods: Retrospective analysis of voiding diaries showing ≥ 2 nocturnal void(s) from men aged ≥ 18 years at an outpatient urology clinic. Patients with secondary causes of NP (diuretic use, sleep apnea, heart failure, edema, kidney disease, and diabetes insipidus) were excluded. Included patients were divided into 2 cohorts by NP status (NUP > 90 vs. ≤ 90 mL/h). The number of nocturnal voids (NV), 24-h maximum voided volume (MVV), and nocturnal MVV (NMVV) were compared between groups using the Wilcoxon Rank-sum test to determine significance.

Results: Patients with (n = 49) vs. without (n = 60) NPS demonstrated greater NV (3 [2-4] vs. 2 [2-3] voids, $p = 0.030$), MVV (375 [300-480] vs. 208 [173-300] mL, $p < 0.001$), and NMVV (300 [260-460] vs. 180 [125-240] mL, $p < 0.001$).

Conclusions: Patients with vs. without NPS demonstrated more severe nocturia despite greater functional bladder capacity. Taken together, these results suggest that excess NUP (opposed to diminished bladder capacity) is the primary mechanism underlying the production-storage mismatch in NPS. Patients with nocturia owing to NPS may particularly benefit from behavioral/pharmacologic interventions targeting nocturnal urine volume.

P3

A Case Study Describing Successful Treatment of Recurrent Penile Abscesses using the Carrion Cast

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Introduction: The Carrion cast was first published in 2015 as a technique for treating infected penile prostheses. Here we describe a case report applying this procedure to a persistent penile abscess with success.

Materials & Methods: This is a case report.

Results: A 67-year-old gentleman without significant past medical history presented to an ER with penile pain and swelling. Upon presentation he had clinical signs of infection with a temperature to 103F and WBC of 15. Urinalysis was positive only for trace blood. Due to a contrast allergy, non-contrast CT scan of the pelvis was ordered which showed left greater than right penile swelling without discrete abscess or collection. He was observed on IV antibiotics without significant improvement for 48 hours when gadolinium-MRI was obtained. This revealed bilateral 8x1.5cm corporal abscesses. Upon further questioning, the patient revealed that three weeks prior to this event he had performed masturbation to include placing an earthworm and barbecue skewer per his urethra. Of note, the worm was removed intact. Once this history was obtained and based on persistent signs of infection, he was taken to the OR for washout via penoscrotal approach. Purulent material was encountered, washed out with triple antibiotic solution (vancomycin/zosyn/amphotericin), drains were placed and the incision was closed. His cultures grew streptococcus constellatus and he was transitioned to augmentin and discharged home several days later. He was seen in clinic in follow-up four weeks later where recurrent abscesses were suspected. Cystoscopy in the office was negative for fistula. He refused hospital admission given the Christmas Holiday but presented a day later for admission for IV antibiotics and repeat MRI which also ruled out a fistula and demonstrated recurrent bilateral abscesses. He was taken to the OR where the abscesses where washed out and calcium sulfate beads with vancomycin and tobramycin were instilled into both corporal spaces, as previously described by Dr. Carrion. Ultimately, he recovered from this second procedure, was discharged home, and has been seen in clinic with complete recovery and no further infectious issues.

Conclusions: In addition to usage in the infected penile prosthesis context, the Carrion cast may be applied to penile abscesses unrelated to prostheses.

P4

An Effective Foley Catheter Training Protocol for all Intern Residents

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Introduction: Bladder catheterization by means of foley catheter is a simple, effective medical intervention when utilized appropriately. Unfortunately, incorrect or improper usage is problematic. Catheter associated urinary tract infections (CAUTI) are a leading cause of nosocomial infections (> 30% of hospital acquired infections) and are associated with significant increases in patient morbidity and mortality as well as health care costs and hospital reimbursement. CAUTIs are associated with multiple catheterization attempts and poor technique which both stem from inadequate education. Given these reasons, Maine Medical Center had prior policies limiting foley catheter placement to properly trained nurses with an exception for urology and ob-gyn providers. There is also a lack of overall knowledge regarding foley catheterization. The Canadian Journal of Urology reports that 70% of foley catheter consults to an academic urology service did not need an adjunct device (wire, cystoscope, etc). The authors argue this creates higher costs to the healthcare system for poor appropriation of resources. Finally, a report from 2004 paper show approximately 50% of represented medical schools are not attaining the Association of American Medical College (AAMC) objective of rigorously teaching and evaluating technical procedures (including foley catheterization). Given these reasons, we developed a training program for foley catheterization for new intern residents.

Materials & Methods: We obtained institution review board approval. We then created a training program that incorporated the following learning materials: instructional videos, educational infographic, reference powerpoint slides, multiple choice test, and an in-person simulation using a pelvic model scored via a 10-point rubric. All educational materials were available on an online learning system. We trained all incoming interns who started on July 1 2019. The training was considered mandatory for all incoming interns. For the data collection component, we offered incoming residents an optional electronic survey prior to commencing their catheter training and again another optional paper survey immediately following the completion of their simulation component. Surveys contained a Likert scale confidence score and four question objective test that was scored from 0-100%.

Results: There were a total of 65 interns that participated in the foley catheter training. These 65 represented eight intern programs. 53 interns (response rate 81.5%) completed the pre-training survey and 60 interns (response rate 92.3%) completed the post-training survey. 94.2% of incoming residents reported some form of foley catheter training during medical school, but of these, only 34.7% had undergone formal simulation. Prior to our training 51.1% of respondents were confident in their ability to place a foley catheter and their objective test score was 50%. After our intervention there was a significant difference in pre and post training confidence levels and objective test scores, 3 (2-3) vs. 4 (4-4.75) [Median (IQR)] $p < 0.001$ and 50% (50-75) vs. 100% (100-100) $p < 0.001$ respectively. Mann-Whitney U test p-values reported.

Conclusions: Our data shows that interns are both lacking confidence and objective competence in placing foley catheters. We also demonstrate that our training protocol is a successful intervention by showing improvement in both metrics.

P5

Urolithiasis Management in the Early 1900s: Howard A. Kelly and the Wax-Tipped Ureteral Catheter

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Introduction: Diagnosis of ureteral and renal calculi was revolutionized with medical implementation of X-ray in the early decades of the 1900s. Diagnosis of urolithiases prior to X-ray was largely based on history and physical exam. Given the invasive nature of "cutting for stone" at that time, innovations aimed at improving diagnostic precision were needed. Dr. Howard Atwood Kelly, a gynecologist and member of the "Big Four" founders of the Johns Hopkins Hospital in Baltimore, Maryland along with William Halsted, William Welch, and William Osler is known for many contributions to surgery. Among some of his perhaps lesser known contributions include aerocystoscopy and ureteral catheterization utilizing wax-tipped catheters to improve the diagnosis of ureteral and renal stones in the late 19th century. His innovation in ureteral catheterization revolutionized the diagnosis of nephrolithiasis.

Materials & Methods: Historical textbooks and manuscripts were reviewed in an effort to characterize methods of diagnosing ureteral and renal calculi in the late 1800s and early 1900s with specific interest in Howard A. Kelly and the wax-tip catheter utilized for such purposes.

Results: Multiple references including those from Hugh Hampton Young, Guy LeRoy Hunner, Howard A. Kelly, and others were identified and reviewed to characterize early practice in wax-tip ureteral catheterization. The technique involved the creation of a "wax tip" associated with a silk renal catheter or rubber bougie, used to catheterize a ureter. Various methodologies were utilized to create the wax mixture. Dr. Young utilized "ordinary embedding paraffin," while Dr. Hunner, a colleague at Hopkins, utilized beeswax. Dr. Kelly reportedly utilized a mixture including dental wax and olive oil. The bladder, instilled with air, was inspected cystoscopically with direct visualization of the ureteral orifices. The wax-tipped catheters were passed proximally, twirled, removed, and closely inspected for scratch marks or defects suggestive of contact with a hard surface, that is, a stone. Occasionally stone fragments would become embedded in the wax—thus the procedure could potentially serve therapeutic purposes.

Conclusions: Although diagnosis of urolithiasis has been revolutionized by advanced imaging techniques including X-ray, computed tomography, and ultrasound, early innovations utilizing a wax-tip catheter were a significant advancement in management of nephrolithiasis in the 1890s and early 1900s. In 1926 Dr. Hugh H. Young commented on the importance of this innovation stating that with the diagnostic combination of X-ray and wax-tip ureteral catheterization "exploratory operations for kidney stone have become almost curiosities if not disgraceful." Urologists have been known for decades to be on the forefront of surgical technology and innovation. Important discoveries such as the wax-tip catheter are not only of historical interest but inspirational to those walking in the footsteps of the giants that came before.

P7*

Differential Expression of miRNA Involved in Biological Processes Responsible for Inflammation and Immune Response in Lichen Sclerosus Urethral Stricture Disease

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Introduction: The pathophysiology of Lichen Sclerosus (LS) urethral stricture disease (USD) is poorly understood. MicroRNA (miRNA) are non-coding genetic material involved in the regulation of gene expression. We sought to examine the pathophysiology of LS and non-LS USD by comparing miRNA expression profiles in men undergoing urethroplasty.

Materials & Methods: Total RNA was extracted from formalin-fixed, paraffin-embedded tissue samples from 13 LS urethral strictures and 13 non-LS urethral strictures collected from 2005-2017. The pathologic evaluation of strictures were based on histologic features considered diagnostic of LS. Representative portions of the FFPE block containing diagnostic areas foci of LS or non-LS strictures were selected by the pathologist for molecular evaluation. Each of these samples was profiled via miRNA RT-qPCR arrays for 752 unique miRNA. Statistical analyses were performed using SPSS v25. Gene Ontology (GO) analysis was performed using DIANA-mirPath v. 3.0.

Results: There were no significant differences regarding patient age, BMI, smoking history, or medical comorbidities between the LS vs. non-LS groups. Of the 143 miRNA detected for all samples, 27 were differentially expressed between the groups (false discovery p-value < 0.01). 15 of these miRNA each achieved an area under the curve (AUC) > 0.90 for discriminating between LS and non-LS strictures. MiR-155-5p specifically was found to be upregulated by 11 fold in LS vs. non-LS strictures ($p < 0.001$, AUC = 1.0).

Conclusions: To our knowledge this is a novel investigation into the pathophysiology of LS USD; no existing studies have evaluated the miRNA expression profiles in LS and non-LS USD. We have identified 18 distinct miRNA that differentiate USD caused by LS vs. other etiologies. The top eight differentially expressed miRNA have been linked to immune response processes as well as involvement in wound healing, primarily angiogenesis and fibrosis. Our models demonstrate excellent predictive value for distinguishing LS vs. non-LS USD samples and the differentially expressed miRNA identified in this study could potentially serve as biomarkers of LS.

*Max K. Willscher Award Eligible

P6

The Pioneering and Diverse Contributions of Leonard N. Zinman, M.D. to Urology

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Introduction: Few surgeons have contributed as broadly to the field of urology as the visionary Leonard N. Zinman, M.D. We sought to chronicle the pioneering and diverse contributions of Dr. Zinman to renovascular surgery, urologic oncology, and most notably as one of the founding fathers of reconstructive urology.

Materials & Methods: A systematic literature search for the published work of Leonard N. Zinman, M.D. was performed in Web of Science, Embase, Medline, Scopus, and Google Scholar. Data were abstracted from the literature search results.

Results: After completing his urologic training at the Massachusetts General Hospital, Zinman was recruited to the Lahey Clinic in 1964. Zinman collaborated with John Libertino, M.D. to describe a hepatorenal arterial bypass for use in patients with renovascular hypertension for whom an aortorenal bypass was not possible. Zinman and Libertino also introduced a reversible right colocystoplasty as a capacious reservoir with an antireflux mechanism for bladder replacement. Among his landmark contributions, Zinman was the first to apply the combined use of 5-fluorouracil and mitomycin with radiation therapy to the treatment of urethral squamous cell carcinoma. The Nigro chemoradiation protocol revolutionized the treatment of urethral squamous cell carcinoma from extirpative to genital-preserving therapy. Zinman pioneered the use of gracilis muscle interposition flaps in rectourethral fistula repairs, and gracilis muscle flaps as vascular beds for oral mucosa grafts in augmented urethroplasties. These innovative muscle flap applications converted previously irreparable fistulae and strictures requiring urinary diversion to reconstructable anatomy with excellent outcomes. Similarly, he significantly reduced the need for bladder neck reconstruction with the application of intralesional mitomycin C injections to endoscopic urethrotomy for recalcitrant contractures. He eliminated the need for bowel resection to procure rectal mucosa graft for urethral reconstruction by applying the transanal endoscopic microsurgery technique. He also described a novel urethral-preserving technique for the removal of Urolume stents. Zinman is a founding member of the Society of Genitourinary Reconstructive Surgeons, and is responsible for helping to define reconstructive urology as a urologic subspecialty.

Conclusions: As a urologist with mastery of reconstructive skills, an innovator with diverse landmark contributions to urology, and a leader who defined the field of reconstructive urology and educated generations of trainees, Leonard N. Zinman, M.D. has been one of the most valuable assets to the field of urology.

P8

From Focused Residency Training to Attending Practice: A Junior Attending's Experience with Greenlight Laser Enucleation of the Prostate (GreenLEP) on Large Prostates (> 80 cc)

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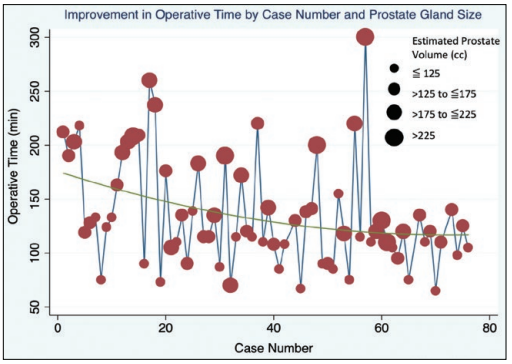
Introduction: GreenLEP is a relatively new endoscopic technique for the treatment of symptomatic benign prostatic hyperplasia. The procedure consists of transurethral en-bloc excision of the transitional zone of the prostate gland using a combination of mechanical dissection with a rigid scope and the Greenlight laser. Advanced endoscopic enucleation procedures such as GreenLEP and Holmium laser enucleation of the prostate (HoLEP) can be viewed as minimally invasive alternatives to open or robotic assisted simple prostatectomy for the treatment of large glands (> 80 cc). Over the past two decades widespread adoption of HoLEP has been hampered by a significant learning curve and the procedure is disproportionally utilized by urologists with exposure in fellowship training or who learned the procedure after years of experience with transurethral resection. There is limited data suggesting GreenLEP may have a softer learning curve than HoLEP but little is known about patient and procedural outcomes associated with GreenLEP on large prostates (> 80 cc) after structured mentorship in residency training and the transition to attending practice.

Materials & Methods: A retrospective cohort study of patients with prostates > 80 cc who underwent GreenLEP with a single attending surgeon after structured mentorship during residency training (6 months in chief year, 18 cases) was conducted at two academic institutions between November 2017 and January 2020. Paired t-test was used to assess differences in International Prostate Symptom Score (IPSS), Quality of Life (QOL) due to urinary symptoms, and post void residual (PVR) 1 month after GreenLEP. Multiple linear regression was used to identify predictors of operative time. Generalized estimating equations were used to estimate the post procedural odds of stress urinary incontinence (SUI) as a logistic function of time and covariates.

Results: A total of 73 patients were included with an average age of 68.9 years and estimated prostate volume of 147.8 cc (79-365 cc, SD 53.5). Overall, patients who underwent GreenLEP experienced significant reductions in IPSS (22.4 vs. 6.4, $p < 0.001$), QOL (4.5 vs. 1.4, $p < 0.001$) and PVR (442.5 vs. 54.4 cc, $p < 0.001$) at 1 month. An increasing number of cases performed was associated with decreasing operative time (β -0.76, $p < 0.001$, Figure 1), while larger estimated prostate volume was positively associated with increasing operative time (β 0.56, $p < 0.001$). Post procedural SUI was 15.3% at 1 month, and declined to 4.3% and 1.4% at 3 and 6 months, respectively. Age was the only variable associated with transient SUI ($p = .04$).

Conclusions: GreenLEP is a safe and effective surgical technique for prostates > 80 cc that can be successfully performed as a junior attending after structured mentorship during chief year. Significant improvements in IPPS, QOL, and PVR can be achieved 1 month after GreenLEP, while post procedural SUI is approximately 1.4% at 6 months.



P9

"I Only Want To See the Doctor" Comparison of Patient Satisfaction between Urology Physicians and Advanced Practice Providers

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Introduction: There is a projected national shortage of urologists in the coming decade. The American Urological Association supports the incorporation of advanced practice providers (APPs) into urologic practices. However, there has been limited research addressing the effect of increased utilization of APPs in the urologic setting and available research about patient satisfaction with APPs is mostly limited to primary care and non-surgical specialties. We are seeking to understand patient satisfaction with APPs in a urologic setting. The subspecialty nature of urologic practice leads us to believe that there may be measurable and meaningful differences in patient satisfaction.

Materials & Methods: We performed a retrospective assessment of patient satisfaction surveys administered over a 3 month period at a single high-volume academic urology practice in Maine. Patients were queried shortly after an encounter with one of 8 APPs or 8 physicians. Seven survey questions, relating specifically to patient satisfaction, were abstracted for analysis. These were derived from the Consumer Assessment of Healthcare Providers and Systems Clinician & Group Survey (CG-CAHPS). Responses to individual survey questions were assessed between provider category. The independent effect of provider type on patient satisfaction was assessed with multivariable analysis, controlling for available patient characteristics (age, race, gender, marital status).

Results: We analyzed responses from 1018 patient encounters. Patients seeing APPs (vs. a physician) tended to be older (79.9% of APP patient encounters were with patients over age 60, while 76.5% of physician encounters were with patients over age 60), more likely female (25.7% vs. 17.5%), non-white (4.1% vs. 2.5%), and less likely to be married or with a partner (69.1% vs. 74.6%). On univariable analysis there were no significant differences between APPS and physicians in any of the 7 metrics measuring patient satisfaction. Following adjustment for covariates, there were still no differences in patient satisfaction as demonstrated in the Table.

Conclusions: Despite the subspecialty nature of urologic practice, use of APPs is not associated with diminished patient satisfaction. While this finding suggests that patient satisfaction will not be reduced by increased utilization of APPs, more broadly, further research needs to clarify the most appropriate role for APPs within an outpatient urology practice. We plan further research to examine specific diagnoses and investigate the most appropriate role for outpatient urology APPs. Further, our study does not assess other clinically relevant patient outcomes, and more research needs to be done to examine the safety and efficacy of APP integration. Finally, it is important to examine our study's findings in a more broadly representative population as our patient population does not reflect the national averages. Nonetheless, given the impending national shortage of urologic physicians, our findings support the notion that APPs can be integrated into urologic care without decreasing overall patient satisfaction.

Table: Odds of maximal self-reported patient satisfaction with clinical encounter if seeing an APP vs. seeing a physician (the referent population), controlling for age, gender, race and marital status

	Odds Ratio	Confidence Interval 95%	P value
Did the provider explain things in a way that you could understand?	1.12	(0.77-1.63)	0.562
Did this provider involve you in decisions about your plan of care and/or medications?	1.16	(0.81-1.65)	0.419
Did this provider listen carefully to you?	1.14	(0.77-1.67)	0.518
Did this provider seem to know the important information about your medical history?	0.96	(0.69-1.33)	0.819
Did this provider show respect for what you had to say?	1.35	(0.94-1.96)	0.107
Was there good communication between the different doctors and nurses?	1.25	(0.86-1.82)	0.248
On a scale of 1-10 how likely would you be to recommend this provider to your family and friends?	1.35	(0.94-1.96)	0.942

1- referent score 1-3 out of 4

2- referent score 1-8 out of 10

P10

Modulation of TRPV4 Channel Activity by ATP in Rat and Human Urinary Bladder
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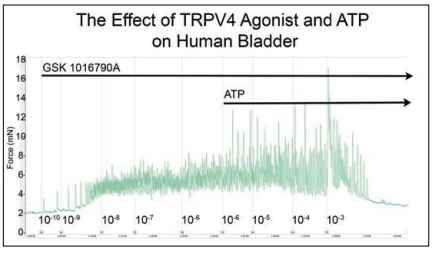
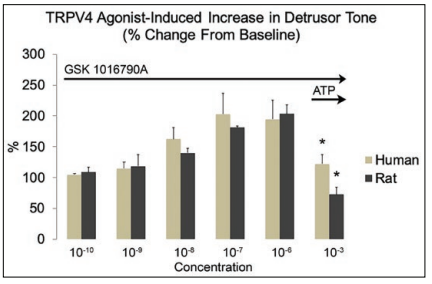
Introduction: Transient receptor potential V4 (TRPV4) channels involved in bladder sensory signaling represent a promising target for the treatment of bladder overactivity. Stretch-induced ATP release from the urothelium stimulates sensory nerve endings. Existing experimental evidence suggests that TRPV4 channels are likely involved in this process through activation of ATP release, although the exact mechanism of this effect needs further elucidation. In this study we investigated functional interaction between selective TRPV4 modulating drugs and ATP in rat and human bladder.

Materials & Methods: Bladder tissue was functionally assessed using *in vitro* myography. Experiments used full thickness strips from healthy rat bladder and partial thickness strips containing detrusor muscle and urothelium from the bladder of adult female patients undergoing radical cystectomy. Contractile response of the bladder tissue to TRPV4-modulating drugs (agonist - GSK1016790A, antagonist - HC067047) and their interaction with $P2X_{2/3}$ receptor agonist adenosine triphosphate (ATP) were evaluated in Ca-containing solution. Ca^{2+}-free solution was then used to demonstrate the reliance of these events on calcium.

Results: TRPV4 agonist (GSK1016790A) evoked dose-dependent increases in the baseline tone and amplitude of phasic contractions of muscle strips from both rat (n = 6) and human (n = 3) bladders. The response first developed at GSK concentration of 1nM and reached a peak at 100nM. This effect was significantly reduced by pretreatment with 1μM TRPV4 antagonist (HC067047). ATP (1mM) administered before GSK completely blocked the GSK effect. Adding 1-100μm of ATP at the peak of GSK-evoked response increased the amplitude of phasic activity. A 1mM dose of ATP, at the peak of GSK-evoked response, reversed the effect of GSK, returning the tone to baseline and completely abolishing phasic activity. In Ca^{2+}-free solution, both tonic and phasic responses to GSK were reduced by > 90%. These effects were observed in both rat and human tissue.

Conclusions: Our results show that TRPV4 increases tone and amplitude of phasic activity in bladder strips in both human and rat bladder, supporting its likely role in bladder overactivity. Lower concentrations of ATP potentiate TRPV4-induced phasic activity and higher concentrations of ATP completely inhibit all TRPV4 bladder effects. These observations point to the possibility that ATP may modulate TRPV4 channel activity during bladder filling via negative feedback, thus contributing to the control of bladder sensory signaling.





P11

Estrogen Receptors Regulate Prostate Growth in Benign Prostatic Hyperplasia upon *SRD5A2* Promoter Methylation
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Introduction: Steroid 5α-reductase type II (SRD5A2) is the predominant enzyme responsible for prostatic development and growth. We found that expression of SRD5A2 in the prostate is variable, and that one-third of prostate tissue samples from BPH patients do not express SRD5A2. We demonstrated that the absence of SRD5A2 expression is associated with *SRD5A2* methylation in the promoter region. We have demonstrated that there is an "androgenic to estrogenic switch" when SRD5A2 is absent in the prostate gland. Here we wished to identify if *SRD5A2* promoter methylation regulates estrogen receptor (ER) expression.

Materials & Methods: We used human prostatic stromal and epithelium cells, and prostate specimens that collected from patients who underwent transurethral resection of the prostate (TURP). ERα and ERβ histological expression was determined by immunohistochemistry. Genome DNA was extracted and SRD5A2 promoter methylation was determined with DNA methylation-specific PCR. The level of *SRD5A2* promoter methylation was correlated to ER expression.

Results: ERβ was expressed in both stroma and epithelial compartments, whereas ERα was mainly expressed in the basal epithelium. In cultured prostatic stromal and epithelium cells, ERβ only expressed in the nucleus. Six out of twenty-three patients were *SRD5A2* hypermethylation at the promoter region and had higher ERβ expression.

Conclusions: ERα and ERβ co-localize in human benign prostatic tissue. Specifically, ERβ is expressed in the nucleus of both the prostatic stroma and epithelial. *SRD5A2* promoter methylation is associated with the expression of ER. Targeting the estrogenic signaling may serve as an effective treatment strategy in subset of ER-sensitive BPH patients.

P12

Utilization of Capillary Electrophoresis Mass Spectrometry in the Development of a Metabolomic Signature for Prostate Cancer
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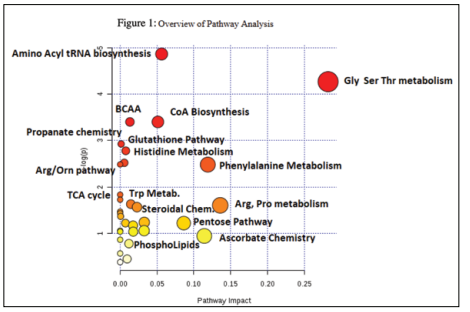
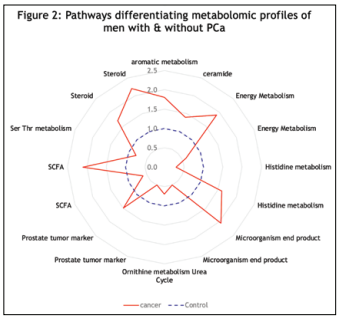
Introduction: Prostate cancer (PCa) pathogenesis is influenced by alterations in cellular metabolism. Metabolomics measures these biochemical changes to create global tissue metabolite profiles. Urinary studies are noninvasive and can potentially identify biomarkers for PCa. We used Capillary Electrophoresis Mass Spectrometry (CE-MS) to analyze urine from men undergoing prostate biopsy for suspicion of PCa to investigate their metabolomic profiles.

Materials & Methods: 150 urine specimens were prospectively collected from men undergoing prostate biopsy. After histopathologic evaluation of all biopsy cores was completed, 40 urine samples were selected for metabolomic investigation. 20 samples were taken from men with entirely benign prostate biopsies, and 20 from men with biopsy-proven PCa. An analysis of charged metabolites by CE-MS was performed as described (J Proteome Res. 2:488; 2003). Urinary metabolites were extracted from 100 μL urine by mixing with methanol containing 20 μM of internal standards. CE-MS experiments were performed with the Agilent CE system. Screening of potential biomarkers was performed with statistical protocols and pathway analyses. Metabolites with levels below the detection limit in all samples were excluded. Relative abundances of metabolites were normalized to levels of creatinine.

Results: CE-MS analysis produced thousands of features in the combined anionic and cationic modes. A volcano plot comparing p values against fold change identified 60 metabolites that were statistically different between urine samples of men with PCa and those of men without PCa. Pathway analysis of these using MetaboAnalyst (Metabolites 9:57; 2019) showed high activity in ceramide, short chain fatty acid (SCFA), branched chain amino acid, serine, threonine, and tryptophan metabolism. Figure 1 demonstrates the pathway analysis with fold change represented by color and vertical scale, and number of significant metabolites with size. Figure 2 graphically contrasts metabolomic profiles.

Conclusions: CE-MS analysis identified several metabolic pathways that were upregulated in urine of men with PCa. These metabolites are involved in steroid, aromatic, microorganism and SCFA processes and warrant targeted studies which are underway in our lab. If validated, they have potential to serve as non-invasive biomarkers for PCa diagnosis and therapeutics.





P13*

Ureteral Botulinum Toxin Attenuates Prostaglandin Expression in an Animal Model
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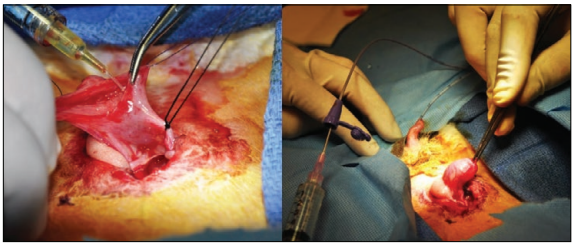
Introduction: Prostaglandin E (PGE) is associated with ureteral peristalsis and inflammation. Clostridium Botulinum toxin type A (BoNT-A) has been shown to impact several chemosensory mediators, however the impact on PGE is unknown. Our goal was to determine the effect of ureteral BoNT-A instillation on local PGE synthase expression in a novel animal model of ureteral inflammation.

Materials & Methods: Cystotomy and unilateral ureteral BoNT-A instillation with ipsilateral distal ureteral ligation was performed on 3 New Zealand white rabbits (2.4-2.8 kg). A fourth rabbit underwent 4 cc saline instillation to serve as a negative control. A fifth rabbit underwent direct periureteral BoNT-A injection in addition to ureteral instillation to serve as a positive control. Rabbits were survived for 7 days. Ureteral tissue was fixed in formalin and paraffin embedded. Ureteral sections underwent antigen retrieval followed by incubation with PGE synthase antibody and DAB HRP secondary.

RESULTS: All rabbits survived 7 days with one exception which was euthanized on post-operative day five following wound complications. PGE synthase was detected in ureteral tissue of all specimens. BoNT-A exposure was associated with a decrease in PGE synthase signal in a dose-dependent fashion, with direct injection showing the greatest decrease in signal.

Conclusions: The feasibility of an in-vivo study of ureteral BoNT-A instillation is demonstrated herein, with preliminary results showing attenuation of ureteral PGE synthase expression with BoNT-A exposure. The ability of BoNT-A to exert chemosensory and/or inflammatory modulating effects without direct injection is possible under conditions of inflammation.

Figure 1: Left - Midline cystotomy with ureteral instillation followed by distal ligation. Right - Urethral catheterization and cystorrhaphy leak test.



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WITHDRAWN

Figure 2: Native ureter stained for PGE synthase at 10X magnification.

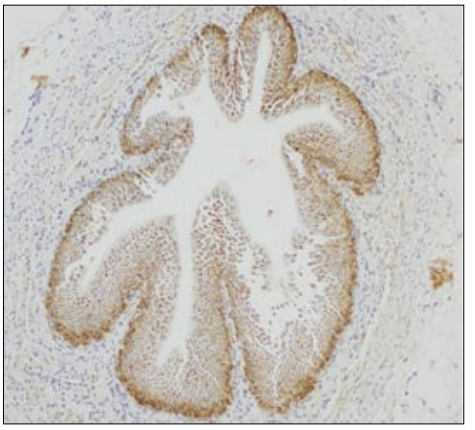
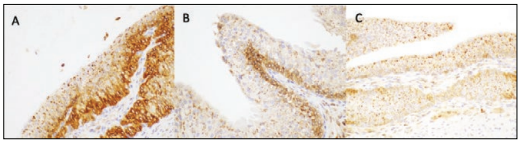


Figure 3: 40X magnification of ureter sections with distal ligation. A) No BONT-A exposure. B) 20U BoNT-A ureteral instillation. C) 5U BoNT-A ureteral instillation and 30U direct injection into periureteral tissue and bladder.



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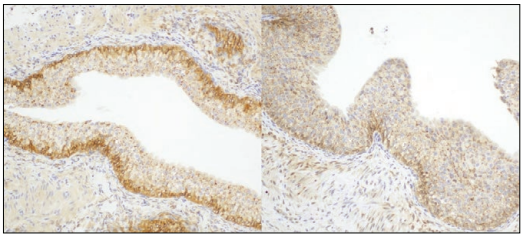

*Max K. Willscher Award Eligible

P15

The Evolving Focus on Surgeon Pregnancy by the Medical Community
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Introduction: Women surgeons have co-managed pregnancy and surgical practice for as long as they have been surgeons. We sought to chronicle the evolution of the medical community's focus on surgeon pregnancy by investigating thematic trends in the medical literature.

Materials & Methods: A systematic literature search using keywords was performed in Web of Science, Embase, and Medline for publications regarding physician pregnancy. Data regarding surgeon pregnancy in training and in practice were abstracted from the literature search results.

Results: Studies and narrative reviews regarding physician pregnancy began to populate the medical literature in the 1970s, paralleling a surge in medical school matriculation by women. Approximately fifteen years elapsed before the first studies of surgeon pregnancy emerged. The earliest studies focused on the effects of pregnancy on the field of specialty, practice type, and careers of women physicians. Multiple studies reported that female physicians who bore children were significantly less likely to hold academic positions commensurate with their experience level or ability, to have full-time employment status, and to achieve the work productivity of male physicians or female physicians who did not bear children. Early studies also consistently reported that male medical faculty and trainees were significantly more likely to hold negative views of female trainee pregnancy, the medical work environment toward pregnant trainees, and family-medical career balance. The medical community began to shift its focus toward medical workforce planning in the 1990s by evaluating the existence and comparative features of maternity leave policies for physicians in practice and in training. Beginning around the turn of the millennium, multiple studies report an increase in the birthrate among women surgeons in training, coined the "surgical residency baby boom". Studies in the new millennium began to report on the occupational hazards of procedural careers on pregnancy, including radiation exposure, hazardous substance exposures, and long work hours. Higher frequencies of infertility, assisted reproductive technology utilization, spontaneous abortion, preeclampsia, fetal growth restriction, preterm labor, and labor induction have been reported in female surgeons compared to age-matched female peers.

Conclusions: The medical community's focus on surgeon pregnancy has evolved substantially from a prioritization of the effects of surgeon pregnancy on colleagues and the pregnant surgeon's work productivity, to maternity leave policy advocacy, and ultimately to the occupational hazards of surgical practice on pregnancy.

P16

Established and Experimental Techniques to Improve Phalloplasty Outcomes: Optimization of a Hypercomplex Surgery

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Introduction: An increasing number of transgender and gender non-conforming patients are seeking genital gender-affirming surgeries across the US. Phalloplasty is the most complex of these surgeries, in that it combines many different smaller procedures into one or more stage(s). Each of these components have different risk profiles, and phalloplasty as a whole has a wide variety of possible complications. Some targets for improvement in outcomes concern urethral fistula/stricture, efficacy of reinnervation of the phalloplasty flap, postoperative flap monitoring, and donor site morbidity. In the setting of no established "gold standard", we sought describe interventions—some experimental, some established—that can be applied to improve outcomes of this ultracomplex surgery.

Materials & Methods: We reviewed the entirety of the English-language literature regarding established techniques for prevention of common complications after phalloplasty and complex flap surgery in general. We also identified promising reports on experimental techniques to further minimize urethral complications, enhance nerve regeneration, improve postoperative flap monitoring, control of postoperative bleeding, and manage flap donor site morbidity.

Results: Our high-volume phalloplasty group has achieved industry-low urethral complication rates of 22% by technical optimization of the urethroplasty portion of phalloplasty. We use transcutaneous visual light spectroscopy (Tstat™) monitoring for intraoperative decision-making and postoperative flap surveillance. We use collagen matrix sheets [Integra® Wound Matrix (Thin)] to improve aesthetic and functional outcomes at the flap donor site. We use thrombin-gelatin hemostatic matrix (Floseal™) to eliminate the need for scrotal drains and limit scrotal hematoma. We continue to investigate the role of extracellular matrix nerve connection sheaths (Axoguard™) to improve the efficiency of nerve regeneration to the flap. Further evaluation of dehydrated human amnion/chorion membrane allograft (Amniofix™) to decrease urethral fistula/stricture is planned.

Conclusions: One stage phalloplasty is a massive surgical endeavor (~ 200 RVUs per case) requiring several experienced surgeons working over 6-12 hours. Through a combination of surgical technique improvement and incorporation of promising new technology, we have attempted to optimize the results of this massive free-flap surgery. Ultimately, with continued innovation and sharing of improved surgical techniques, it may be possible to better standardize care and improve outcomes of this complicated and increasingly common surgery.

P18

Autologous Dermal Fat Graft Augmentation Glansplasty for Management of Transmasculine Neo-glans Atrophy following Penile Prosthesis Placement

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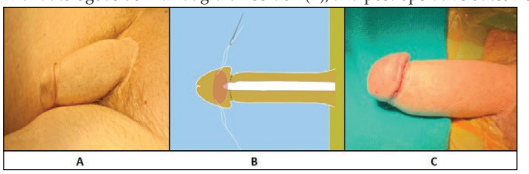
Introduction: Neo-glans atrophy is a described complication following penile prosthesis insertion in the transmasculine neophallus in which the neo-glans appears hypoplastic despite proper device fitting. This aesthetic result may cause patient dissatisfaction with the neophallus. Additionally, though long-term outcome data in this population is not available, the decreased tissue support between the device and skin may predispose to cylinder erosion. The purpose of this abstract is to describe a novel technique to address neo-glans atrophy which utilizes interposition of a full thickness dermal graft to correct the hypoplastic contour.

Materials & Methods: We provide a description of an autologous dermal fat graft tissue transfer to address neo-glans atrophy. Steps include harvest of the graft from a non-hair bearing area, graft preparation, development of the plane for tissue insertion without disturbance of the prosthetic device, and graft placement within the neo-glans.

Results: Autologous dermal fat graft neo-glansplasty has been demonstrated to be a feasible technique that improves cosmetic appearance of a hypoplastic neo-glans following penile prosthesis insertion (see Figure) and durably address neo-glans atrophy in this unique population.

Conclusions: Reconstructive urologists managing patients with neo-glans atrophy following penile prosthesis insertion may utilize this technique. Further work is needed to gather data on long term outcomes with this technique.

Figure 1: Appearance of transmasculine neophallus with penile prosthesis previously inserted that demonstrates neo-glans atrophy pre-operatively (A), intraoperative correction with autologous dermal fat graft insertion (B), and post-operative outcome (C)



P17

Evaluating a Rural Transgender and Gender Diverse Population and Interest in Genital Gender Confirming Surgery

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Introduction: In addition to the multiple psychosocial and health disparities faced by transgender and gender diverse persons (TGGD) seeking hormonal and surgical interventions, those living in rural areas face additional barriers to healthcare. The 2015 U.S. Transgender Survey revealed up to 25% of respondents had undergone genital gender confirmation surgery (GCS): 10% TGGD female and 2% of TGGD male respondents. Little is published regarding the transition related health care utilization for TGGD persons from rural areas. We sought to evaluate such a population.

Materials & Methods: This is a single center descriptive study evaluating a population of TGGD persons seeking gender related care in a rural academic hospital between September 2015 and February of 2020. The electronic medical record was reviewed to identify TGGD persons carrying ICD-10 and F64 CPT codes delineating "gender identity disorder" or "gender dysphoria". Patient variables including age, gender assigned at birth, use of hormones, history of GCS, and home zip code were abstracted through administrative data and retrospective chart review. Of those patients who had not previously undergone GCS, a granular chart review was performed to capture documented interest in pursuing GCS. Patient variables were tabulated using R, and comparisons were made using chi-squared tests. Zip codes were used to determine if patients resided in rural versus metropolitan locations.

Results: During this time period, 1466 patients were identified with gender identity CPT codes; 43 patients were excluded due to the patient being deceased or suspected coding errors. Of the 1423 patients included in the final analysis, 837 (59%) of patients were assigned female sex and 586 (41%) were assigned male sex at birth. Though most patients were between the ages of 18-60, 279 (20%) were younger than 18 and 45 (3%) were 65 or older. Hormone use was documented in 1036 (73%) of patients, including 588 (70%) TGGD males and 448 (76%) TGGD females ($p = 0.012$). Genital reconstruction was documented in only 42 (3%) of patients, including 6 (1%) TGGD males and 36 (6%) TGGD females ($p < 0.001$). Of those who had not received genital reconstruction, 100 (7%) patients had a documented interest in the medical record, including 21 (3%) TGGD males and 79 (14%) TGGD females ($p < 0.001$). The hospital drew patients from a large, multi-state region with 817 (57%) patients coming from rural zip codes.

Conclusions: A large number of TGGD persons from surrounding rural and metropolitan areas sought gender health care at this rural academic medical center, predominately adolescents and young adults, with a slightly higher proportion of TGGD males. The majority of patients receive hormone therapy. While a relatively small proportion have undergone genital gender confirming surgery, nearly 10% of patients had a documented interest in GCS which due to the limitations of the study, may be an under-estimation in this population. Further research is needed to determine transition related surgical healthcare needs of this population and to further develop rural comprehensive gender health programs.

P19

Predicting Cancer Detection Rates from Multiparametric Prostate MRI: Refining the PI-RADS Categorization System

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Introduction: The PI-RADS categorization represents the standardized method for assessing risk of prostate cancer in men undergoing multiparametric prostate MRI. However, there exists a substantial discrepancy in widely accepted cancer detection rates for each PI-RADS category as reported in seminal prospective studies (e.g., PROMIS, PRECISION) and cancer-detection rates (CDRs) observed in real-world clinical practice. We hypothesized that CDRs vary according to patient and MRI features beyond what is captured in the PI-RADS categorization. Herein, we examine the associations of clinical and radiographic features with CDRs and develop a predictive model to improve patient counseling and clinical management.

Materials & Methods: We identified men aged 18-89 with a diagnosis of elevated PSA or Gleason 6 prostate cancer on active surveillance and ≥ 1 PI-RADS 3-5 lesion on prostate MRI who underwent MRI-U/S fusion prostate biopsy in the office or in-bore MRI-targeted biopsy in Interventional Radiology. Only targeted biopsy cores were considered for MRI-U/S fusion biopsy. The associations of clinical and radiographic features with the per-lesion cancer-detection rate (CDR; Gleason 6-10) and clinically-significant cancer detection rate (csCDR; Gleason 7-10) were examined using multivariable logistic regression following a univariable screen at the $p < 0.10$ level. Patients with Gleason 6 prostate cancer on active surveillance were excluded from CDR analyses.

Results: Targeted biopsy was performed for 216 lesions in 169 patients, including MRI-U/S fusion biopsy in 130 lesions and in-bore MRI-targeted biopsy in 86 lesions. Median pre-biopsy PSA was 7.2 ng/mL (IQR 5.2-10.2). Thirty percent of lesions were in biopsy-naïve patients, while 29% were in patients on active surveillance for Gleason 6 prostate cancer. PI-RADS category was 3 in 17.1%, 4 in 51.9%, and 5 in 31.0% of lesions. Lesions were located in the anterior/transition zone in 58.8% of cases, and median lesion diameter was 13 mm (IQR 9-17 mm). Overall, the CDR was 48% and the csCDR was 26%. In multivariable regression models predicting CDR, number of prior biopsies (OR 0.18, 95%CI 0.06-0.47 for 1; OR 0.16, 95%CI 0.05-0.47 for 2+ versus none), PSA density (OR 1.75, 95% CI 1.15-2.88) and PI-RADS category (OR 5.39, 95%CI 1.43-29.1 for 4; OR 15.1, 95% CI 3.54-88.8 for 5 versus 3) were independently associated with CDR (Table 1). In multivariable models predicting csCDR, abnormal DRE (OR 2.75, 95%CI 1.22-6.19), solitary lesion on MRI (OR 2.42, 95%CI 1.13-5.48 versus 2+), PSA density (OR 1.04, 95%CI 1.00-1.09), and PI-RADS category (OR 3.30, 95%CI 1.03-13.7 for 4; OR 3.44, 95% CI 1.03-14.4 for 5 versus 3) were independently associated with csCDR (Table 1). The bootstrap-adjusted c-index was 0.80 for the CDR model and 0.71 for the csCDR model.

Conclusions: In this study, several clinical and radiographic features were independently associated with risk of malignancy in men undergoing MRI-targeted biopsy for elevated PSA. Such models can be operationalized to provide personalized risk-stratification beyond the PI-RADS categorization.

Table 1: Multivariable logistic regression for the outcomes of cancer detection rate (CDR) and clinically-significant cancer detection rate (csCDR).

	CDR aOR (95% CI)	csCDR aOR (95% CI)
Pre-biopsy PSA, ng/mL	--	1.01 (0.93,1.11)
Abnormal DRE	--	2.75 (1.22,6.19)
Number of prior prostate biopsies		
0 (ref)	--	--
1	0.18 (0.06,0.47)	--
2+	0.16 (0.05,0.47)	--
Number of lesions, 1 (vs 2+)	1.26 (0.53,3.04)	2.42 (1.13,5.48)
PI-RADS		
3 (ref)	--	--
4	5.39 (1.43,29.10)	3.30 (1.03,13.70)
5	15.10 (3.54,88.80)	3.44 (1.03,14.40)
Prostate volume on MRI	1.00 (0.99,1.01)	1.00 (0.99,1.01)
PSA density (per 0.1 ng/mL increase)	1.75 (1.15,2.88)	1.04 (1.00,1.09)

P20

Evaluating the AUA Guidelines: cT2b-c Grade Group 1 Prostate Cancer

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Introduction: The AUA and NCCN guidelines broadly stratify prostate cancers into low, intermediate (including favorable and unfavorable), and high risk groups to guide management. Included within the unfavorable intermediate risk category are patients with clinical T2b-c, grade group 1 (GG1) cancer with elevated PSA between 10-20. The AUA guidelines state that these patients "may not represent unfavorable risk disease", though little data exists to guide management here. Therefore, we aimed to assess whether the disease severity and outcomes of this subgroup more closely align with favorable or unfavorable intermediate risk prostate cancer.

Materials & Methods: The National Cancer Database was queried for all non-metastatic prostate cancer cases from 2010-2015. Patients were stratified into low, favorable intermediate, unfavorable intermediate, and high-risk groups by clinical T stage, GG, and PSA, according to the current AUA guidelines. Patients with GG1 clinical T2b-c disease were further separated into two distinct groups based on PSA (< 10 vs. 10-20). We compared 5-year overall survival (OS) using the Kaplan-Meier method and log-rank test for all patients, and stratified by treatment received (surgery or radiation). We then assessed associations with OS using a multivariable Cox proportional hazards model.

Results: A total of 482,378 cases were included, of which 31% were low, 25% favorable intermediate, 18% unfavorable intermediate, and 24% high risk. Men with cT2b-c, GG1, PSA < 10 comprised 1.67% (8065); cT2b-c, GG2, PSA 10-20 comprised 0.2% (1005). Patients with GG1, cT2b-c, PSA 10-20 disease had similar OSl at 5 years to the unfavorable intermediate-risk group regardless of treatment modality (surgery: 93.4% vs. 92.8%; radiation: 79.4% vs. 81.9%, both $p > 0.05$). In the multivariable model, the cT2b-c, GG1, PSA 10-20 risk factor had a similar effect on survival as the unfavorable intermediate group factor (HR 1.12, 95% CI 0.91-1.37, $p = 0.29$). In contrast, patients with cT2b-c, GG1, PSA < 10 had 5 year OS rates of 93%, comparable to men in the low-risk category (92.6%, $p = 0.14$) and significantly better than that of men in the intermediate favorable risk category (90%, $p < 0.001$). Survival was similar when stratified by treatment and on multivariable modeling.

Conclusions: Men with cT2b-c, GG1, PSA 10-20 disease have OS rates similar to those of men with unfavorable intermediate-risk disease regardless of treatment modality chosen. For men with PSA< 10 in this same strata, outcomes were similar to low risk disease and significantly better than the intermediate favorable risk group.

Figure 2: Cox proportional-hazards model for 5 year overall survival

Variable	HR (95% CI)	p value
Insurance Status		
Uninsured (base)	(reference)	
Private insurance/Managed care	0.72 (0.66-0.78)	< 0.001
Medicaid	1.13 (1.03-1.25)	0.012
Medicare	0.90(0.83-0.98)	0.016
Percent No High School Degree Quartiles (2012-2016)		
> 17.5% (base)	(reference)	
10.9-17.5%	1.04 (1.00-1.07)	0.026
6.3-10.8%	0.99 (0.95-1.02)	0.460
< 6.3%	0.91 (0.87-0.95)	< 0.001
Year of Diagnosis		
2010 (base)	(reference)	
2011	1.07 (1.04-1.11)	< 0.001
2012	1.07 (1.03-1.10)	< 0.001
2013	1.13 (1.08-1.17)	< 0.001
2014	1.19 (1.14-1.24)	< 0.001
2015	1.17 (1.11-1.23)	< 0.001
Age	1.05 (1.05-1.07)	< 0.001
Median Income Quartiles (2012-2016)		
< $40,227 (base)	(reference)	
$40,227-50,353	0.86 (0.84-0.89)	< 0.001
$50,354-63,332	0.82 (0.79-0.85)	< 0.001
>=$63,333	0.71 (0.68-0.74)	< 0.001
Charlson-Deyo Score		
0 (base)	(reference)	
1	1.45 (1.41-1.49)	< 0.001
2	2.15 (2.05-2.25)	< 0.001
3	2.86 (2.66-3.07)	< 0.001
Facility Type		
Community Cancer Program (base)	(reference)	
Comprehensive Community Cancer Program	0.95 (0.91-0.98)	0.003
Academic/Research Program	0.79 (0.76-0.82)	< 0.001
Integrated Network Cancer Program	0.93 (0.89-0.97)	< 0.001
Risk Category		
Low (base)	(reference)	
cT2b-c, GG1, PSA <10	1.10 (1.10-1.22)	0.070
Favorable intermediate	1.36 (1.32-1.41)	< 0.001
Unfavorable intermediate	1.60 (1.58-1.70)	< 0.001
cT2b-c, GG1, PSA 10-20	1.83 (1.49-2.25)	< 0.001
High	2.52 (2.45-2.60)	< 0.001
Risk Category		
Low	0.61 (0.59-0.63)	< 0.001
cT2b-c, GG1, PSA <10	0.67 (0.61-0.75)	< 0.001
Favorable intermediate	0.83 (0.80-0.86)	< 0.001
Unfavorable intermediate (base)	(reference)	
cT2b-c, GG1, PSA 10-20	1.10 (0.91-1.37)	0.285
High	1.54 (1.49-1.59)	< 0.001
Treatment Type		
No treatment (base)	(reference)	
Surgery alone	0.31 (0.30-0.32)	< 0.001
Radiation alone	0.56 (0.55-0.58)	< 0.001
Surgery and radiation	0.45 (0.42-0.48)	< 0.001

HR = hazard ratio; CI = confidence interval

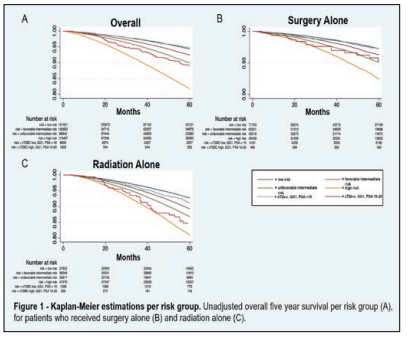

Figure 1 - Kaplan-Meier estimations per risk group. Unadjusted overall five year survival per risk group (A), for patients who received surgery alone (B) and radiation alone (C).

P21

Transperineal Prostate Biopsy - Comparing Diagnostic Accuracy and Patient Reported Pain to Standard TRUS and MRI/US Fusion Biopsy techniques

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Introduction: Transperineal Prostate Biopsy (TPBx) using the PrecisionPoint system (Perineologic, Cumberland, MD) allows for office based prostate cancer detection with the benefit of lower infectious complications when compared to Transrectal Prostate Biopsy (TRUSBx). We sought to evaluate our institutional experience, focusing on differences in pain experienced during TPBx vs. TRUSBx techniques, time of procedure, Cancer Detection Rate (CDR), clinically significant CDR (csCDR) and thirty-day complication rates.

Materials & Methods: After Institutional Review Board approval, a retrospective review of all consecutive patients undergoing prostate biopsy (June 2019-Feb 2020) at a single institution was performed. A 10-point Numerical Rating Scale (NRS) was used to record for pain during probe insertion, anesthetic block, biopsy and post-procedure. Mean NRS scores were compared using the ANOVA test. CDR and csCDR (defined as Gleason Grade Group 2 or higher cancer) was compared between TPBx, TRUSBx and TRUS/MRI fusion biopsy using Fisher's exact test.

Results: 316 patients met inclusion criteria for cancer detection. CDR for TPBx, TRUSBx and MRI fusion were 0.65, 0.47 and 0.67 (p = 0.005), while csCDR were 0.38, 0.30 and 0.44 respectively (p = 0.10). NRS pain scores were reported in 253 total biopsies. Mean patient reported NRS scores for TPBx vs. TRUSBx or TRUS/MRI fusion showed a significant difference during anesthetic injection only (3.9 vs. 2.7 and 2.8 respectively, p = 0.002). Notably, probe insertion scores were lower in the TPBx group vs. TRUSBx or TRUS/MRI fusion (2.5 vs. 3.0 and 3.1 respectively, p = 0.14). Procedural time was 13, 8.5 and 12.4 minutes respectively. The Transrectal groups had nine total 30-day complications including two sepsis events. The TPBx group had no 30-day complications reported.

Conclusions: Patients undergoing TPBx report similar levels of discomfort for all aspects of the procedure when compared to transrectal biopsies with the exception of anesthetic block (modest increase in pain). Procedural times were longer in the TPBx and TRUS/MRI fusion groups compared to standard TRUS. Both the CDR and csCDR were higher in the TPBx group versus the TRUSBx group, although no direct comparison was made. Additionally, TRUS/MRI fusion appears superior to both TRUSBx and TPBx in clinically significant cancer detection, however this cohort contained over twice as many patients on active surveillance. Finally, our study supports the assertion that TPBx has fewer infectious complications than standard transrectal approach.

TABLE 1	TRUS	TPBX	TRUS/MRI Fusion	P Values
n	94	106	116	
Age (mean (SD))	64.0 (6.5)	64.9 (8.3)	65.2 (7.2)	0.50
PSA (median [25th, 75thpercentile]	7.0[4.8, 9.8]	6.7[5.0, 10.4]	7.6[5.3, 10.3]	0.57
Purpose (n (%))				0.003
Cancer screening	81 (86.2)	93 (87.7)	83 (71.6)	
Active surveillance	13 (13.8)	13 (12.3)	33 (28.4)	
DRE (n (%))				0.16
Normal	67 (71.2)	86 (81.0)	94 (81.0)	
Abnormal	27 (28.8)	20 (19.0)	22 (19.0)	
Complication (n (%))				0.053
Grade I	2 (2.1)	-	5 (4.3)	
Grade II	-	-	2 (1.7)	
Cancer detection (n (%))				
No cancer	50 (53.2)	37 (34.9)	38 (32.8)	0.005
Gleason Grade ≥ 1	44 (46.8)	69 (65.1)	78 (67.2)	0.005
Gleason Grade ≥ 2	28 (29.8)	40 (37.7)	51 (44.4)	0.10

Table 2.

NRS scores (mean (SD))	TRUSN = 67	TPBx N = 93	TRUS/MRI Fusion N = 93	p-value
Probe insertion	3.0 (2.2)	2.5 (2.4)	3.1 (2.2)	0.14
Anesthetic block	2.7 (2.0)	3.9 (2.7)	2.8 (2.2)	0.002
Biopsy	2.3 (2.2)	3.0 (2.3)	2.9 (2.4)	0.11
Post-procedure	0.7 (1.2)	1.3 (1.9)	1.0 (1.6)	0.09
Procedural time (average minutes)	8.5	13.0	12.4	

P22

Learning to Hit the Target: Improving Accuracy of Fusion Biopsy over Time at Maine Medical Center

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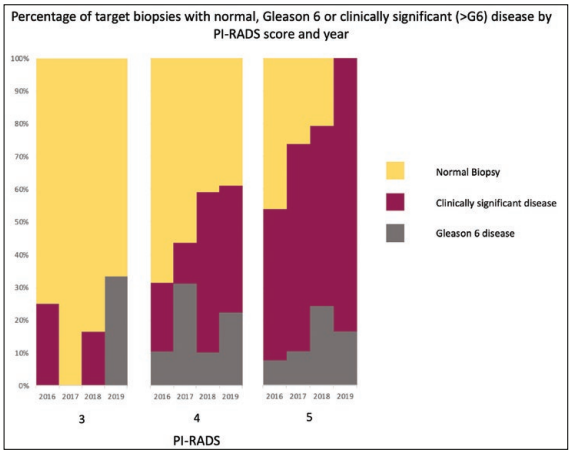
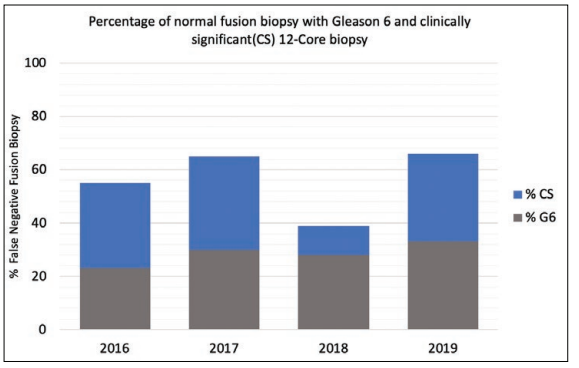
Introduction: Multiparametric MRI (mpMRI) and fusion biopsy technology has allowed for more accurate diagnosis of clinically significant prostate cancer (PCa) while helping to limit the overdiagnosis of non-significant disease. Little data exists, however, about the feasibility and success of implementation outside of large academic centers. This study sought to evaluate fusion biopsy adoption at Maine Medical Center for improvement over time and to discover meaningful areas for improvement.

Materials & Methods: Starting in 2016 data was collected for patients undergoing mpMRI at Maine Medical Center and subsequent biopsy with the Phillips Uronav system. We also collected urology specific and general demographic information. We analyzed this data with special focus on the probability of cancer detection (PCD) of PI-RADS 3, 4, 5 lesions, as well as the percentage of patients who had negative targeted biopsies but PCa on 12-Core biopsy (our "false negative" rate).

Results: Data from 224 patients was analyzed (179 underwent both fusion and 12-core biopsy, 10%, 52%, 37% PI-RADS 3, 4, 5 respectively). 49% underwent MRI as part of active surveillance protocol. Our overall PCD increased yearly, from 39% in 2016 to 67% in 2019. Most importantly, the positive predictive value (PPV) of PI-RADS 5 lesions has increased, from 54% in 2016 to 100% in 2019. Our overall "false negative" rate was 50%, our "false negative" rate for clinically significant disease (≥ Gleason 3+4=7) was 24.6% (range 11%-35% annually).

Conclusions: Our findings highlight the significant institutional learning curve associated with implementation of a fusion biopsy program at a large regional medical center. Our institution did not achieve desired outcomes immediately, but our results improved consistently over the study period. These outcomes highlight the importance of a rigorous iterative approach to quality improvement when implementing a fusion biopsy program.





P23

A Retrospective Evaluation of a Novel Perioperative Opioid Sparing Protocol for Patients Undergoing Robotic Assisted Laparoscopic Radical Prostatectomy or Nephrectomy

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Introduction: The over-prescribing of opioid analgesics by healthcare providers has significantly contributed to the national opioid epidemic. The purpose of this study is to evaluate the opioid-sparing effect of a non-opioid perioperative regimen in patients receiving either a robotic assisted laparoscopic prostatectomy or nephrectomy.

Materials & Methods: A retrospective cohort study was conducted between patients who received an opioid-sparing regimen and those who had not received this regimen. Patients enrolled in the treatment group received a perioperative blister-pack of medications to start three days prior to surgery and seven days postoperatively upon discharge. Average length of stay, numeric pain scores, quantity of opioids utilized in the inpatient post-operative period, the presence of an opioid prescription at discharge, and outpatient 7-day post-discharge phone calls were collected.

Results: Of the 97 patients included in the study, 12 patients out of 27 (44.4%) patients in the control group were discharged with an opioid prescription as compared to 2 of 70 (2.9%) patients in the treatment group. There were also significant differences in total oral milligram morphine equivalents utilized while inpatient (49.38 mg vs. 17.38 mg) in patients with no history of chronic opioid use, average length of stay (2.11 days vs. 1.49 days) and average outpatient pain scores seven days after discharge (3.73 vs. 1.67).

Conclusions: A non-opioid perioperative regimen can result in similar post-operative pain control and fewer opioid prescriptions being written at discharge. By decreasing the number of patients requiring opioids post operatively, there is the potential to have a positive impact on the opioid epidemic. The greatest impact being the reduction of opioid prescriptions prescribed upon discharge.

P24

Effect of Treatment Status on Affective Status of Patients with Prostate Cancer: A Pilot Study

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Introduction: Active surveillance (AS) has increasingly become the preferred option in the management of low-risk prostate cancer (PCa). This option potentially involves greater uncertainty and worry for patients, although little is known about the extent of this uncertainty. The goal of this exploratory study was to measure uncertainty, as well as anxiety and worry, among AS patients and in patients pursuing other treatment strategies.

Materials & Methods: We developed a patient survey consisting of 17 items designed to assess PCa patients' level of anxiety, uncertainty and of worry, which were measured using a 4-point Likert scale. We piloted the survey among all PCa patients seen at a multi-physician urology clinic between September and December 2018. For this initial study, we limited our analysis to the 6 items that focused on cancer specific worry and anxiety (Figure 1.). We combined these items into a 24-point summary score. We used descriptive statistics, ANOVA, and Mann-Whitney U tests to compare the survey responses of AS patients vs. patients receiving treatment as well as patients in other treatment groups.

Results: Cronbach's alpha for the six items was 0.90. A total of 253 patients returned complete surveys: 50 AS patients, 144 RP patients, and 59 patients in the process of deciding or who opted for another active treatment (Other). When compared to patients undergoing active treatment, patients undergoing AS had did not differ significantly in regards to worry about cancer progression or recurrence. Patients at a decision point and patients who were prior to treatment had significantly higher cancer worry scores than those not at a decision point or those post-treatment ($p < 0.001$ in both cases). Patients with no evidence of disease (NED) trended towards lower worry scores, but not to a significant degree ($p = 0.123$).

Conclusions: Patients undergoing AS did not have significantly more worry about cancer progression or recurrence. Patients prior to treatment or at decision points in their treatment were more worried that those that were not, which presents an opportunity for psychosocial intervention or further counseling to improve patient quality of life at these times.

Survey Item
How often do you think about the possibility that your cancer will grow or spread?
To what extent do you worry about your cancer coming back?
To what extent are you worried or anxious about the possibility your cancer will grow or spread?
To what extent are you afraid your cancer will grow or spread?
To what extent, when you think about the possibility of your cancer, do other unpleasant thoughts or images come to mind?
To what extent do you feel you worry excessively about the possibility your cancer will grow or spread?

P25

The Impact of Residential Segregation on Prostate Cancer Treatment and Outcomes

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Introduction: There are well-documented disparities in black-white prostate cancer outcomes. Prior studies have suggested that race-associated genetic variances, screening guidelines, and treatment disparities may contribute to worse prostate cancer outcomes in black patients. We sought to examine the effects of racial residential segregation on the diagnosis, management, and outcomes of black prostate cancer patients.

Materials & Methods: We obtained data on patients with prostate cancer from the Surveillance, Epidemiology, and End Results (SEER) program between 2005 and 2015 and limited to black and white patients within the 100 most populous participating counties. County demographics and socioeconomic characteristics were obtained from the 2013 5-year estimates of the American Community Survey (ACS). The racial index of dissimilarity (IoD) was used to assess the evenness with which white and black residents are distributed across census blocks within each county. Multivariable analyses were performed, predicting advanced stage at diagnosis (AJCC stage IV) in the overall cohort, and the resection of localized disease (AJCC stage I-II).

Results: When adjusting for SEER region and age at diagnosis, black patients have a 98% increased risk (RR 1.98, 95% CI 1.41, 2.76) of presenting at advanced stage with increasing segregation. White patients comparatively have a 42% decreased risk (RR 0.58, 95% CI 0.48,0.70) of presenting at advanced stage with increasing segregation. When evaluating surgery for stage I and II cancers, black patients have a 26% decreased risk (RR 0.74, 95% CI 0.64, 0.86) of surgical resection with increasing segregation, while white patients have a 20% increased risk (RR 1.20, 95% CI 1.12, 1.29).

Conclusions: Our data suggest that residential segregation has a significant impact on both black and white patients with prostate cancer. Black patients fare worse in higher levels of segregation with higher stage at diagnosis and lower likelihood of surgical resection, while white patients benefit from higher segregation with lower stage at diagnosis and higher likelihood of surgical resection. These findings underpin the importance of targeting structural racism and residential segregation when addressing black-white prostate cancer disparities.

P26

Comparative Effectiveness of MRI-U/S Fusion versus In-bore MRI-targeted Prostate Biopsy

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Introduction: MRI-targeted biopsy has emerged as a standard of care in the management of men with elevated PSA and prostate cancer on active surveillance. Although two main biopsy techniques exist - MRI-ultrasound fusion (MRI-U/S) and in-bore MRI-targeted biopsy - the optimal MRI-targeted biopsy technique has not been established. We therefore examined the comparative effectiveness of MRI-U/S fusion biopsy performed in the office and in-bore MRI-targeted biopsy performed in Interventional Radiology.

Materials & Methods: We identified men aged 18-89 with a diagnosis of elevated PSA or Gleason 6 prostate cancer on active surveillance who underwent MRI-U/S fusion prostate biopsy in the office or in-bore MRI-targeted biopsy performed in Interventional Radiology. MRI-U/S fusion biopsy comprised standard systematic (i.e., extended sextant) biopsies plus targeted biopsies, while in-bore MRI-targeted biopsy consisted only of targeted biopsies. The primary outcomes were cancer-detection rate (CDR; Gleason 6-10) and clinically-significant cancer detection rate (csCDR; Gleason 7-10). CDR and csCDR were compared across biopsy techniques using propensity-score adjustment for patient and MRI features using inverse probability of treatment weights (IPTW). In addition, the associations of biopsy technique with CDR and csCDR were evaluated, adjusted for patient and MRI features, using IPW-adjusted logistic regression.

Results: A total of 169 patients were included in the study, of whom 49 (29.3%) underwent biopsy for Gleason 6 prostate cancer on active surveillance. Overall 93 patients underwent MRI-U/S fusion biopsy and 76 underwent in-bore MRI-targeted biopsy. Median patient age was 67 years (IQR 62-71), median pre-biopsy PSA was 7.2 ng/mL (IQR 5.2-10.2), and 29.7% of men were biopsy-naïve. Before adjustment, the CDR was 66% and 43% (p = 0.014) for MRI-U/S and in-bore MRI biopsy, respectively, while the csCDR was 40% and 32% (p = 0.27). After propensity score adjustment, baseline characteristics were well-balanced. After propensity score adjustment, there was no statistically significant difference in overall CDR (57% vs. 55%; p = 0.83) or csCDR (35% vs. 37%; p = 0.86) for MRI-U/S and in-bore MRI biopsy, respectively. Similarly, there was no statistically significant difference in CDR or csCDR when stratified by PI-RADS category (Table 1). In IPW-adjusted logistic regression, there was no statistically significant difference in CDR (OR 1.03; 95% CI 0.81-1.29) or csCDR (OR 0.98; 95% CI 0.80-1.20) for MRI-U/S fusion compared to in-bore MRI-targeted biopsy.

Conclusions: In this study, MRI-U/S fusion prostate biopsy and in-bore MRI-targeted prostate biopsy were associated with no statistically significant differences in CDR or csCDR overall or when stratified by PI-RADS score. Additional studies are required to determine if specific lesion characteristics may modify treatment effects.

Table 1: Comparison of cancer detection rate (CDR) and clinically significant cancer detection rate (CDR) for MRI-U/S fusion biopsy versus in-bore MRI-targeted biopsy for the overall cohort and stratified by PI-RADS category, adjusted for patient and MRI features. Numbers represent # (%).

	MRI-U/S	In-bore MRI	p-value
CDR			
Overall	41 (57.4)	22 (54.9)	0.83
PI-RADS 3	2 (16)	1 (16.6)	0.98
PI-RADS 4	23 (66.7)	10 (47.6)	0.22
PI-RADS 5	16 (62.4)	11 (84.1)	0.19
csCDR			
Overall	33 (35.1)	25 (37.0)	0.86
PI-RADS 3	0 (0)	2 (15.2)	0.056
PI-RADS 4	17 (39.7)	18 (51.6)	0.45
PI-RADS 5	16 (44.9)	6 (26.0)	0.19

P27

Adenocarcinoma of a Continent Urinary Conduit: A Case Report and Review of the Literature

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Introduction: Colonic segments are routinely utilized by Urologists for bladder augmentation as well as urinary neobladder formation. Colonic adenocarcinoma is the third most common cancer diagnosed in the U.S. affecting roughly 4% of both genders.[1] While the increased risk of developing colonic adenocarcinoma is well known in patients who have undergone ureterosigmoidostomy, adenocarcinoma arising in an Indiana pouch is extremely rare.[2] We aim to report a case of adenocarcinoma in an Indiana pouch treated with trans-stomal endoscopic resection, and address the screening, diagnostic and treatment-related issues surrounding this rare disease including a review of the literature.

Materials & Methods: An extensive literature search on PubMed/MEDLINE was conducted. The keywords "Indiana pouch", "carcinoma", "adenoma", and "adenocarcinoma" were used to find case reports and case series. Data were gathered and tabulated in regard to age, sex, tumor pathology, presence or absence of metastatic disease, therapy, and outcomes.

Results: The patient is a 68-year-old man with a history of high-grade prostate cancer who underwent an aborted radical prostatectomy in 2009 due to extensive extra prostatic disease. He was subsequently treated with brachytherapy and external beam radiation therapy resulting in successful oncological control but suffered debilitating refractory lower urinary tract symptoms related to posterior urethral stenosis, mixed incontinence and retention. In 2017, he underwent a simple cystectomy with creation of an Indiana pouch. Two years after the procedure, the patient presented for surveillance pouchoscopy and was found to have a polypoid mass within his pouch (Figure 1A). He subsequently underwent endoscopic resection of this mass via a trans-stomal technique utilizing a cystoscope and a "hot" snare (Figure 1B). Pathologic investigation of the mass revealed a tubular adenoma with multifocal high-grade dysplasia/intramucosal carcinoma without invasion of the submucosa. Repeat endoscopic biopsy and pathologic investigation revealed no evidence of residual disease. Literature review revealed that adenocarcinoma was by far the most common tumor arising within the Indiana pouch (Table 1). While small tumors and/or polyps could be managed endoscopically, larger more extensive lesions required open resection and/or pouchectomy.

Conclusions: While large and/or invasive adenocarcinomas arising in an Indiana pouch may require partial or total resection of the pouch, small, non-invasive lesions may be managed endoscopically allowing pouch preservation. Given this fact, we advocate for regular (yearly) endoscopic surveillance of Indiana pouches as early detection of malignant lesions may enable less invasive management strategies and potentially better oncologic outcomes should a tumor or polyp be discovered. Adenocarcinoma continues to be a rare, but serious, complication of Indiana pouch urinary diversion.

1. Key Statistics for Colorectal Cancer. The American Cancer Society. https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html
2. Austen M, Kälble T. Secondary malignancies in different forms of urinary diversion using isolated gut. J Urol. 2004;172(3):831-8. f Urethral Bulking Agents for Stress Urinary Incontinence: An Extensive Review Including Case Reports. *Female Pelvic Med Reconstr Surg* 2018;24(6):392-398.

Table 1: Secondary malignancy in the colon as a continent urinary conduit (AC: Adenocarcinoma; HG-TVA: High-grade tubulovillous adenoma; TCC: Transitional cell carcinoma;Unk:Unknown)

Reference	Age/Sex	Tumor Pathology	Metastasis	Treatment	Results
Miyoshi et al, 1996	73/F	TCC	Locoregional: renal pelvis and ureter	Total resection and right nephroureterectomy	Unk
Gazzaniga et al, 2000	73/M	AC	No	Wide local excision	Unk
Lisle et al, 2000	76/M	AC	No	Total resection	Disease-free at 6 months
L'Esperance et al, 2001	72/F	AC	Distant: solitary liver lesion	Total resection with left nephrectomy and liver metastasectomy	Unk
Uesugi et al, 2002	71/M	AC	Locoregional: remote submucosal metastatic lesion	Total resection with right nephrectomy	Disease-free at 5 months
Komai et al, 2005	63/F	AC	Locoregional: renal pelvis, calyces; distant: lung	Total resection and chemotherapy	Deceased after 17 months from disease progression
Ho et al, 2007	66/F	AC	No	Unk	Unk
Ryoichi et al, 2007	76/F	AC	No	Endoscopic resection	Disease-free at 15 months
Raman et al, 2007	66/M	HG-TVA	No	Endoscopic resection	Unk
Jian et al. 2012	73/F	AC	No	Total resection	Disease-free at 3 years
Jian et al, 2012	78/M	AC	No	Total resection	Deceased after 3 months from surgical complications
Moyer et al, 2012	68/F	AC	No	Colon resection	Disease free at 24 months
Saba et al, 2013	80/M	AC	Distant: liver and lung	Chemotherapy	Deceased after 7 months from disease
Manka et al, 2015	42/F	HG-TVA	No	Local resection	Disease free at 6 months
Morgenstern et al, 2015	73/M	HG-TVA	No	Local resection	Unk
Bell et al, 2018	80/F	AC	No	Colon resection	Disease free at 4 months
Murray et al, 2018	66/M	AC	No	Endoscopic resection	Disease free at 36 months

P28

The Relationship Between Health Literacy and Non-Recommended Screening for Prostate Cancer Relative to Other Malignancies

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Introduction: Cancer screening risks overdiagnosis of indolent tumors, and subsequent intervention introduces cost and poor health outcomes. Shared decision making encourages screening choices that align with patient values; however, these conversations are difficult for patients with low health literacy (HL). We hypothesized that higher HL would support guideline-concordant screening. We sought to assess the effect of HL on non-recommended prostate cancer (PCa) screening relative to other cancers.

Materials & Methods: We examined the 2016 BRFSS, which includes HL modules. Respondents self-reported their ability to obtain and understand health information, resulting in 4 HL rankings. We assessed the effect of HL on non-recommended PCa screening and compared it to the effect on breast cancer (BCa) and cervical cancer (CC) screening. We calculated the population weighted proportion of patients in each HL category that underwent screening against USPSTF guidelines. The odds ratios of non-recommended screening for each malignancy was calculated, with the referent category of low HL.

Results: Individuals with higher HL exhibited higher rates of non-recommended screening for PCa and similar findings were seen for BCa and CC. Non-recommended PCa screening was performed in 27.4% (CI 23.7%-31.4%; $p < 0.001$) and 47.7% (CI 44.1%-51.3%; $p < 0.001$) of respondents with low and high HL, respectively. This compared favorably to BCa, which had the highest rates of non-recommended screening: 46.8% (CI 42.6%-51.1%; $p = 0.002$) and 67.7% (CI 64.2%-71.1%; $p = 0.002$) of respondents with low and high HL. Non-recommended CC screening was performed in 33.8% (CI 31.1%-36.5%; $p < 0.001$) and 48.4% (CI 46.3%-50.5%; $p < 0.001$) of low and high HL respondents. Individuals with high HL were significantly more likely than those with low HL to screen against recommendations for PCa (OR 1.73; CI 1.34-2.23; $p < 0.001$), CC (OR 1.533; CI 1.31-1.80; $p < 0.001$) and BCa (OR 8.213; CI 4.90-13.76; $p < 0.001$).

Conclusions: Patients with higher HL undergo increased rates of non-recommended PCa screening, contrary to our initial hypothesis. While this compared favorably to very high rates of non-recommended BCa screening in the high HL populations, the association was less pronounced in CC screening.

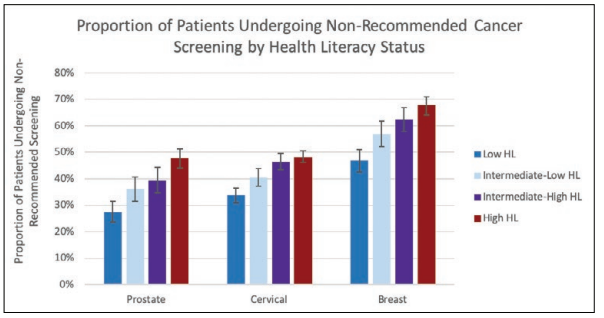
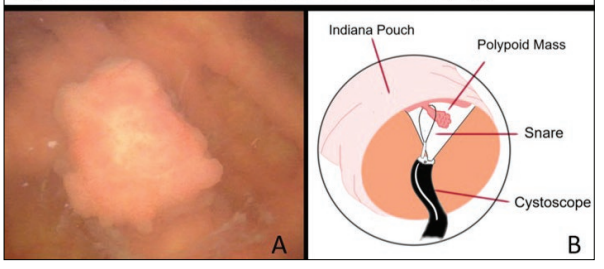


Figure 1: Direct Visualization of Polypoid Mass within an Indiana Pouch (A); Diagrammatic Representation of Trans-Stomal "Hot" Snare Technique (B)



P29

Post-Prostatectomy Radiation with Long Term Follow-up: Outcomes and Changing Indications

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Introduction: The criteria for adjuvant and salvage post-prostatectomy radiotherapy (ART and SRT, respectively) continue to be debated. While ASTRO/AUA guidelines recommend considering ART for patients with adverse pathologic findings, preliminary data from the RADICALS trial suggest that rates of biochemical progression-free survival do not differ between ART and early SRT. We examined the incidence of post-prostatectomy radiotherapy (RT) and the rate of secondary recurrences at our center to determine changing patterns in the administration of post prostatectomy radiation and outcomes.

Materials & Methods: We retrospectively identified patients who underwent radical prostatectomy (RP) and subsequent SRT or ART between Dec 1, 2003-Dec 31, 2013. Demographic, clinical, and pathological features were extracted. Patient groups were defined as either (i) ART: PSA < 0.2 ng/mL, treatment within 1 year post-RP, stable PSA, (ii) Early SRT: rising PSA < 0.2 ng/mL or (iii) Traditional SRT: PSA ≥ 0.2 ng/mL prior to RT. Secondary recurrence was defined as a confirmed PSA ≥ 0.2 ng/mL and above the post radiation nadir. The incidence and time to secondary recurrence, metastatic disease, and prostate cancer specific mortality were compared among the RT treatment groups.

Results: 3,570 patients underwent RP; 209 patients (5.9%) received post-RP RT. Of these 39 (18.7%), 29 (13.9%) and 141 (67.5%) underwent ART, early SRT and traditional SRT, respectively. Eight (20.5%), 4 (13.8%), and 40 (28.4%) of ART, early SRT, and traditional SRT groups received concurrent androgen deprivation therapy (p ns). Median time (in years) between surgery and last PSA was 7.06, with an interquartile range of 5.17-10.24. The incidence of ART and early SRT significantly increased from 2003-2007 to 2008-2013 (increasing from 8.6% to 25.0% and from 3.7% to 20.3%, respectively; p < 0.001). Outcome results are presented in Table 1. Overall, the groups differed significantly in rates of secondary recurrences (p = 0.037). These differences remained significant in multivariate analyses accounting for stage, PSA and Gleason Grade Group (p = 0.026). Similarly, multivariate analysis indicated that rates of metastasis differed significantly between the groups (p = 0.033) as did recurrence free survival when controlling for the same variables (p = .021). No differences were observed in prostate cancer specific mortality.

Conclusions: In accordance with ASTRO/AUA guidelines and results from studies like RADICALS, adjuvant RT and early SRT are being given with increased frequency at our institution. We feel the advent of hypersensitive PSA has contributed to the increased use of early SRT. According to ASTRO/AUA guidelines, "data from retrospective and prospective trials tend to support the notion that more favorable biochemical outcomes are associated with very low PSA values at the time RT is offered." Consistent with this premise, our secondary recurrence rate for early SRT (37.9%) was lower than traditional SRT (51.1%) but this was not significant. The impact and outcomes of changing post prostatectomy radiation treatment deserves further study.

Table 1. Outcomes across treatment groups

Outcome	Adjuvant (n=39)	Early Salvage (n=29)	Traditional Salvage (n=141)	P value (univariate)[3]	P value (multivariate)[4,5]
Secondary recurrence N (%)	11 (28.9)	11 (37.9)	71 (51.1)	.037	.026
Metastasis N (%)	6 (15.8)	4 (13.8)	41 (30.4)	.058	.033
Prostate cancer specific mortality N (%)	4 (10.8)	0 (0.0)	16 (12.3)	.140	.837
Recurrence free survival[1] median (IQR)	66.5 (23,83.3)	84.0 (75.5,112.0)	62.0 (37.0,98.0)	.125	.021
Metastasis free survival[1] median (IQR)	75.0 (48.0,89.3)	100.0 (80.0,117.3)	90.0 (62.0,126.0)	.239	.342
Prostate cancer specific survival[1] median (IQR)	111.0 (82.0,134.0)	111.5 (98.0,122.0)	133.0 (119.0,149.8)	.312	.939

[1] Time (in months) from date of radical prostatectomy to date of recurrence/metastasis or last PSA for non-event (note: not Kaplan-Meier censored data); [2] Time (in months) from date of radical prostatectomy to date of recurrence/metastasis or last contact for those alive (note: not Kaplan-Meier censored data); [3] Chi-square tests of proportion for occurrence, Kaplan Meier/Log Rank Test for time to event; [4] Multivariate models included diagnostic PSA, pathology stage, and pathology Gleason Grade Group; [5] Logistic regression was used to predict occurrence; Cox regression was used to predict time to event

P30

Association of High-Grade Prostatic Intraepithelial Neoplasia, Atypical Small Acinar Proliferation, or Perineural Invasion with the Risk of Upgrading in Active Surveillance Cohort in the MRI-Ultrasound Fusion Biopsy Era

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Introduction: The role of high-grade prostatic intraepithelial neoplasia (HGPIN), atypical small acinar proliferation (ASAP), or perineural invasion (PNI) on the risk of upgrading in subsequent MRI-ultrasound fusion biopsies has not been well studied. We aimed to determine if the presence of those pathological characteristics on prostate biopsy increases the risk of upgrading on subsequent MRI-ultrasound fusion biopsy for active surveillance (AS).

Materials & Methods: We retrospectively queried an institutional MRI-ultrasound fusion prostate biopsy database to identify men in AS for grade group (GG) 1 prostate cancer. Upgrading in AS cohort was defined as pathological progression from GG1 on initial biopsy to GG 2 or greater on subsequent biopsy between January 2013 and February 2019. Binary logistic regression was performed to identify clinical, radiological, and biopsy pathological features (HGPIN, ASAP, or PNI) associated with the presence of upgrading on surveillance biopsy.

Results: Our AS cohort included 127 men; 101 (79.5%) and 93 (73.2%) had region(s) of interest on initial and subsequent prostate MRIs, respectively, and therefore underwent MRI-ultrasound fusion biopsy. Among men on AS, 31 (24.4%) showed upgrading on subsequent biopsy. Although HGPIN was associated with upgrading among patients on AS in univariate analysis (p = 0.01), there was no independent significance in multivariable analysis (OR 3.84, 95%CI 0.60-24.63, p = 0.15). Age (OR 1.07, 95%CI 1.001-1.15, p = 0.04) and PI-RADS (4-5 versus 2-3, OR 2.89, 95%CI 1.14-7.35, p = 0.02) remained significantly associated with an increased risk of upgrading on subsequent biopsy in men on AS (Table 1).

Conclusions: No association was found between any of the studied pathological features (HGPIN, ASAP, or PNI) and upgrading on subsequent biopsy in AS cohort. Therefore, the presence of HGPIN, ASAP, or PNI on biopsy should not influence the management of men undergoing AS in the MRI-ultrasound fusion biopsy era.

Logistic regression models for the prediction of upgrading on subsequent biopsy in men on AS

	Univariate			Multivariate		
	OR	95%CI	P value	OR	95%CI	P value
ASAP	5.03	0.80-31.65	0.08	3.42	0.26-44.55	0.34
HGPIN	9.03	1.65-49.29	0.01	3.84	0.60-24.63	0.15
PNI	2.69	0.67-10.75	0.16			
More than 2 of above pathologic features	2.13	0.34-13.42	0.41			
Age	1.07	1.01-1.14	0.02	1.07	1.001-1.15	0.04
PI-RADS 4-5	3.27	1.36-7.86	0.008	2.89	1.14-7.35	0.02
PSA density (per 0.1 unit)	1.85	1.08-3.15	0.02	1.70	0.93-3.09	0.08