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

Michael E. Rezaee, MD, MPH1
Outcomes in High-risk Non-muscle Invasive Bladder Cancer (NMIBC): Implications for global BCG shortages. 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 11.1% vs. 58.7 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.

Materials & Methods: 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 < 0.05). The MIBC group was found to have an increased percentage of CD3+ T cells expressing NKG2A (p < 0.05, p < 0.10). 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 < 0.01, 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 than 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.
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 of 70.9 years and 28.9% 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/m² had significantly greater odds of parastomal hernia development. Significant opportunity exists to reduce morbidity associated with parastomal hernias in this population.

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.

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 -80°C. 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, 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, p = 0.02), while 2.84-2.82 ppm increased the risk of malignant pathology (OR 7158.67, 95% CI 3.27, 2.73x1012, p = 0.02), and the specific metabolites characterizing this region remain to be identified. Tissue 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 2.94-2.82 ppm ROI substantially increased the risk of RCC.

Introduction: Fat-poor angiomylipoma (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 pathology based on metabolomic profile 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 (cRCC) 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 -80°C. 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 cRCC 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 cRCC samples & 7 AML specimens. Candidate predictors of malignancy rather than AML based on FDR p-values include histidine, phenylalanine, phosphocholine, serine, alanine, glycine, N-acetylglutamate, and glycerophosphocholine. 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 2.99x106, 95% CI 3.27, 2.73x1012, p = 0.02). AMLs had lower EBL than ORC patients (mean: 500 vs. 850 mL, p < 0.0001), higher CCI (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), and LOS (OR = 1.05, 95% CI: 1.006-1.102, p = 0.043). Reduced risk of SSI in RARC may be mediated by a Bruker AVANCE spectrometer. Metabolomic profiles of RCC & adjacent benign renal tissues were compared, and false discovery rates (FDR) were used to account for multiple testing. Regions of interest (ROI) with FDR < 0.05 were considered potential predictors of cRCC 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.

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Conclusions: HRMAS-MRS identified many metabolites that may help differentiate fat-poor AML from cRCC. In particular, metabolites in the 3.5-4.5 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.
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 T3N0M0 grade 2 clear cell RCC. In the interim, he had undergone a large ventral hernia repair with placement of a large piece of intrabdominal 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.

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 SCC from 1993 to 2019 was 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.
Risk Factors for Multiple Intravesical Recurrences of Non-muscle Invasive Bladder Cancer

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Introduction: Currently available risk calculators such as 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 335 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 EORTC risk calculator were not significantly associated with multiple recurrence versus single recurrence, such as multifocal disease (OR 1.83, 95% CI 0.82 - 4.08), high-grade disease (OR 1.07, 95% CI 0.47 - 2.45), or T1 disease (OR 51, 95% CI 18 - 139), (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.

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. Fisher 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 = 0.035), as was large stone burden (a Seoul score >= 5 (OR 3.76; p = 0.046) or S.T.O.N.E score >= 9 (OR 3.52; 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 = 0.02), 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.
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 9-138, 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 STES 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 surgeon’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 definition was able to achieve the best STES. Further study to validate this metric against other operative time models is warranted.

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 infections after ureterorenoscopy. However, there are few studies in the literature which investigate this phenomenon 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 0.035” pressure sensor guidewire (CookTM, 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 pelvis 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.
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 = 83). 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. 73%, 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, 36% developed hydronephrosis, 19% passed spontaneously, 26.6% 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 for symptoms. Active surveillance is a viable option for asymptomatic renal stones, and these data may aid in patient counseling.

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 the setting of an urgent ureteroscopic (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 52322) 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 (URS obstruction, malignant obstruction, etc). Variables collected included Charlson Comorbidity Index (CCI), medical comorbidities, laboratory values, vital signs, and illness severity during initial presentation (QN of ICU, 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. Among average length of readmission was 4.7 days, and among patients who remained hospitalized at the time of the study, the average time to readmission was 9.2 days. Patients who were readmitted had a high rate of severe illness requiring ICU admission, pressor requirement, QSOFA score, bacteremia, 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 regarding their elevated risk.
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 a majority of urolithiasis patients 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 urolithiasis were excluded from admission to the CDU if any single criterion 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 urolithiasis and admitted via the SOP to the CDU (Table 2). The mean stone size was 4.6 mm (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 those 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 on more acute surgical consultation and management will evaluate the cost savings of this protocol as well as low follow-up rate (57.4%) as an area for quality improvement.
Inpatient Urologic Consultation is not Necessary to Ensure Follow up in Patients with Uncomplicated Ureterolithiasis

Meredith C. Wasserman, MD, MS, David W. Sobel, MD, Siddharth Marthi, BS, Edmond Godbout, PA, Chris Tucci, MS RN, Gyan Panek, MD, MS
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%). 26% 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). 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

<table>
<thead>
<tr>
<th>Establishment Urologist (22)</th>
<th>Urologic Consultation (25)</th>
<th>History of Nephrolithiasis (40)</th>
</tr>
</thead>
</table>

Table 1. Outcomes of discharged patients

<table>
<thead>
<tr>
<th>Patients discharged with ureterolithiasis (n = 141)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who followed up with a urologist</td>
<td>76</td>
<td>54%</td>
</tr>
<tr>
<td>Urologic consultation</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>History of nephrolithiasis</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Established urologist</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Patients who did not follow up with a urologist</td>
<td>65</td>
<td>46%</td>
</tr>
<tr>
<td>Urologic consultation</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>History of nephrolithiasis</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Established urologist</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Risk Factors for Polymicrobial Stones in Patients Undergoing PCNL

William C. Daly, BS1, Erin Santos, PA-CA2, Christopher Stockdale, MD2, Johann Ingimarsson, MD2
1Maine Medical Center Research Institute, Center for Outcomes Research and Evaluation, Portland, ME; 2Maine Medical Center Department of Urology, Portland, ME

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 December 2018. 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 3/3 (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 = 0.013), neurogenic bladder (OR 11.7; p = 0.017) and infected stone as indication (OR 9.98; p = 0.001) were all independently associated with polymicrobial stone. Limited upper or lower extremity mobility (OR 3.1; p < 0.001), neurologic disease (OR 8.95; p = 0.001) (specifically multiple sclerosis (MS) (OR 6.3, p = 0.043) and contractures (OR 5.5, p = 0.022) 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.
Significant Variability in Outpatient Opioid Prescriptions by Discharge Provider following Percutaneous Nephrolithotomy (PCNL)

Timothy K. O'Rourke, Jr, MD, David W. Sobel, MD, Nicole Thomasian, BS, Christopher Tucci, MS, RN, Gyan Pareek, MS, MD
Brown University/Rhode Island Hospital, Providence, RI

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 had 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.

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

David W. Sobel, MD, Timothy O'Rourke, MD, Alejandra Balen, MD, Marcelo Paiva, MPP, Martus Car, MD, Rachel Greenberg, MD, Rebecca Ortiz, BA, Philip Callery, PhD, Christopher Tucci, MS, Gyan Pareek, MD
Brown University, Providence, RI

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 (8%) 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. Coven 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 deferral 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

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Cost / Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiologist</td>
<td>$2,000.00</td>
</tr>
<tr>
<td>Surgical technician</td>
<td>$98.00</td>
</tr>
<tr>
<td>Circulating nurse</td>
<td>$168.00</td>
</tr>
<tr>
<td>Radiologic technologist</td>
<td>$120.00</td>
</tr>
<tr>
<td>Two PACU Nurses</td>
<td>$336.00</td>
</tr>
<tr>
<td>Operating room assistant (ORA)</td>
<td>$60.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$2,782.00</strong></td>
</tr>
</tbody>
</table>
A Multi-Institutional Experience Comparing Internal Urethrotomy with Intravesical Mitomycin C for Recurrent Bladder Neck Contractures in Radiated vs. Non-Radiated Patients

Alexander Rozanski, MD1, Lawrence Zhang, BA1, Daniel Holst, MD2, Steven Copacino, BA1, Alex Vanni, MD1, Jill Buckley, MD1
1Lahey Hospital and Medical Center, Burlington, MA; 2UC San Diego, San Diego, CA

Introduction: We have previously published our initial and intermediate-term experience with direct visual internal urethrotomy (DVIU) and intravesical 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 intravesical 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, and 44% 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 intravesical 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.

Introduction: One in 12 patients with BPH will require surgical management. TURP is the gold standard, but new technologies may provide superior outcomes with lower complication rates. The 1470nmDiode laser is a novel technology for use in endoscopic laser enucleation of the prostate (DiLEP). There is a paucity of data comparing bipolar laser enucleation to TURP (DiLEP vs. PVR and complications (Clavien-Dindo) were compared. Statistical analyses with STATA were conducted using independent Student’s t-test, 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. 60(48-88), p < 0.0001) and a greater proportion of median lobes (77% vs. 57%, p < 0.0001) (Table 2). Both groups had significant improvements in Qmax and PVR from baseline at postoperative time points (1, 3, and 12 months) with no significant difference between groups at any timepoint (Figure 1). DiLEP had a greater percentage of prostate tissue resected (36% vs. 27-47) vs. 31% (20-42), a shorter length of stay (16.9 hours (2.9-25) vs. 27.7 hours (24-33), p < 0.0001), and had longer operative times, but a lower overall complication rate (4.5%) vs. 8.7% (3.7-14). 53(46%) patients undergoing DiLEP were discharged from the PACU, as compared to none undergoing TURP. Catherization 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 overall 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

<table>
<thead>
<tr>
<th>Variable</th>
<th>TURP (n=207)</th>
<th>DiLEP (n=143)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>72 (61-86)</td>
<td>73 (61-89)</td>
<td>0.997</td>
</tr>
<tr>
<td>Race (%)</td>
<td>73 (36-92)</td>
<td>74 (38-92)</td>
<td>0.816</td>
</tr>
<tr>
<td>History of prostate cancer</td>
<td>35 (17-57)</td>
<td>36 (17-57)</td>
<td>0.786</td>
</tr>
<tr>
<td>History of TURP</td>
<td>68 (34-100)</td>
<td>69 (34-100)</td>
<td>0.836</td>
</tr>
</tbody>
</table>

Table 2: Preoperative and Operative Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>TURP (n=207)</th>
<th>DiLEP (n=143)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative PSA (ng/ml)</td>
<td>12.1 (3.5-40)</td>
<td>12.1 (3.5-40)</td>
<td>0.873</td>
</tr>
<tr>
<td>Preoperative PSA (ml)</td>
<td>20 (4-80)</td>
<td>20 (4-80)</td>
<td>0.870</td>
</tr>
<tr>
<td>Prostate Volume (ml)</td>
<td>50 (18-130)</td>
<td>50 (18-130)</td>
<td>0.876</td>
</tr>
<tr>
<td>Time from Symptom Onset</td>
<td>10 (0-30)</td>
<td>10 (0-30)</td>
<td>0.433</td>
</tr>
</tbody>
</table>

Table 3: Complication Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>DiLEP (n=143)</th>
<th>TURP (n=207)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Loss (%)</td>
<td>10 (0-70)</td>
<td>10 (0-70)</td>
<td>1.000</td>
</tr>
<tr>
<td>Operative Time (min)</td>
<td>133 (108-157)</td>
<td>54 (39-74)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Postoperative Catheter</td>
<td>24.1 (20-64)</td>
<td>22.1 (18-67)</td>
<td>0.013</td>
</tr>
<tr>
<td>PVR (ml)</td>
<td>25 (15-40)</td>
<td>25 (15-40)</td>
<td>0.876</td>
</tr>
<tr>
<td>Event Rate (%)</td>
<td>4.5% (3.7-14)</td>
<td>8.7% (3.7-14)</td>
<td>0.136</td>
</tr>
</tbody>
</table>

Figure 1: Median Qmax and PVR over time for each procedure, with values with statistical significance compared to preoperative TURP and DiLEP as indicated using horizontal red and blue dashed lines.
A Validation Study of a Simplified Acquired Buried Penis Repair Classification System: Perioperative Complications and Outcomes

Alexander Rozanski, MD, Lawrence Zhang, BA, Jaime Cavallo, MD, Alex Vanni, MD
Lahey Hospital and Medical Center, Burlington, MA

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 - excutomeancatomy; V - abdominal penileplasty. 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 are more likely to achieve successful outcomes. Further multi-institutional studies should be pursued to assess this classification system across different reconstructive centers.

Table 1. Patient Demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>Total number of patients (%)</th>
<th>Current study</th>
<th>Pilot study</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>5 (10%)</td>
<td>6 (12%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>II</td>
<td>2 (4%)</td>
<td>3 (6%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>III</td>
<td>21 (42%)</td>
<td>27 (54%)</td>
<td>22 (44%)</td>
</tr>
<tr>
<td>IV</td>
<td>29 (58%)</td>
<td>31 (62%)</td>
<td>28 (56%)</td>
</tr>
<tr>
<td>V</td>
<td>4 (8%)</td>
<td>4 (8%)</td>
<td>3 (6%)</td>
</tr>
</tbody>
</table>

Table 2. Perioperative Outcomes Based on Repair Complexity

<table>
<thead>
<tr>
<th>Category</th>
<th>BM (kg/m²) (median [IQR])</th>
<th>Tobacco use (%)</th>
<th>Diabetes mellitus (%)</th>
<th>Urethral stenosis (%)</th>
<th>Any complication (%)</th>
<th>High grade complication (%)</th>
<th>Successful repair (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>29 (26-33)</td>
<td>19 (10-25)</td>
<td>19 (10-30)</td>
<td>2 (0-10)</td>
<td>2 (0-10)</td>
<td>1 (0-3)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>II</td>
<td>47 (39-53)</td>
<td>20 (10-30)</td>
<td>24 (15-35)</td>
<td>4 (0-10)</td>
<td>4 (0-10)</td>
<td>0 (0-0)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>III</td>
<td>55 (45-65)</td>
<td>25 (15-35)</td>
<td>33 (20-40)</td>
<td>6 (0-10)</td>
<td>6 (0-10)</td>
<td>2 (0-0)</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>IV</td>
<td>62 (50-70)</td>
<td>19 (10-20)</td>
<td>30 (20-40)</td>
<td>8 (0-10)</td>
<td>8 (0-10)</td>
<td>3 (0-0)</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>V</td>
<td>65 (50-75)</td>
<td>20 (10-30)</td>
<td>35 (20-40)</td>
<td>10 (0-10)</td>
<td>10 (0-10)</td>
<td>1 (0-0)</td>
<td>1 (2%)</td>
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</tbody>
</table>

Conclusions: Utilizing this classification system as a predictor of perioperative outcomes, our study validates the pilot study findings. Patients requiring high complexity repairs are more likely to achieve successful outcomes. Further multi-institutional studies should be pursued to assess this classification system across different reconstructive centers.

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 Rezum are attractive minimally invasive treatment options for patients with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). PUL relies on a mechanical approach, using implants to create a continuous channel between the prostate’s lateral lobes, while Rezum relies on a 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 Rezum.

Materials & Methods: Clinical outcomes for the PUL group were obtained from published retrospective literature while those for the Rezum 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 Rezum 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 Rezum group (65.3 years, 17.2 points, 11.5 mL/s, 29.2 mL). The PUL 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 Qmax 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 Qmax (-43%) with maximum percent changes achieved at 3-month (-42%, -45%). The Rezum group saw gradual improvements in IPSS and Qmax, with maximum percent changes in IPSS (-37%) and Qmax (-44%) achieved at 6- and 12-month, respectively. Improvements in Qmax were durable to 12-month in the Rezum 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 Rezum group (117%) and at 6-month for the PUL group (36%).

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

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

Alexander Rozanski, MD, Lawrence Zhang, BA, Steven Copacino, BA, Alex Vanni, MD
Lahey Hospital and Medical Center, Burlington, MA

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 (MHSQ) 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 30.5 kg/m², 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 bulbous (6%). 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.
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 prostate hyperplasia (BPH) includes estimation of prostate volume 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 access 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 π/6). Correlation between MRI versus TRUS and PUS was calculated 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 into numerous other variables, including race, ethnicity, and size. Results: A total of 95 patients had MRI, TRUS, and PUS. Median age was 64, median BMI was 27 kg/m2, 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 PUS was 6.1 ± 15.5 cc and mean difference in volume estimate between MRI and TRUS 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 0.89 (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 vs. MRI and PUS vs. TRUS, respectively.

Conclusions: MRI may be considered clinically interchangeable with TRUS and PUS for prostate sizing at prostate volumes ≤ 50cc, as BA analysis 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 ±10 cc, 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.
Combination Robotic Simple Prostatectomy and HoLEP for Morbidly Enlarged Prostates > 400 g
Alison Levy, MD, David Canes, MD, Jessica Mandeville, MD, Lahey Hospital and Medical Center, Burlington, MA

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 (DVUI) (N = 1) in the same setting were excluded. One hundred and five patients were included. The median age was 71 years (interquartile range: IQR: 63-79), with a male gender:female ratio of 28:1. 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 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 months (IQR 2.4-14.5). PVR 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 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 = 0.43, 95% confidence interval 0.41 - 0.45, p = 0.10).

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.

Conservative Management of Radiation-induced Male Urethral Stenoses: Can Urethral Reconstruction be Safely Avoided?
Alexander Rozarski, MD, Lawrence Zhang, BA, Steven Copacino, BA, Alex Vanni, MD, Lahey Hospital and Medical Center, Burlington, MA

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 electrocardiogram (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 VI 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 multivariate 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 (75%), diabetes mellitus (35%), and diuretic use (46%). 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, [1.19-8.69], 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 = 0.019). No significant associations were observed between nocturia and p-QTc according to Model I (OR 1.51, [0.56-4.10], p = 0.410), Model II (OR 1.39, [0.53-3.81], 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.
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 methods; 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.

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

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Massachusetts General Hospital, Boston, MA

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 PSAd 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), number of prostate volume measurements was 2 (IQR 2-3). 414 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 +0.081 ng/mL/ml per year (IQR -0.02-0.10). 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 < 0.0001) [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, PSAd velocity 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.
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. 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 = 121,663)

<table>
<thead>
<tr>
<th>Year of Diagnosis</th>
<th>Odds Ratio (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>45-65</td>
<td>1.06 (1.05-1.07)</td>
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<tr>
<td>55-65</td>
<td>1.04 (1.03-1.05)</td>
<td>0.001</td>
</tr>
<tr>
<td>65-74</td>
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</tr>
<tr>
<td>75-84</td>
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<table>
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<th>Race</th>
<th>Odds Ratio (95% CI)</th>
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<td>White</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
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</tr>
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<td>Asian</td>
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<tr>
<td>Other</td>
<td>1.03 (1.02-1.04)</td>
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<table>
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<tr>
<th>Mean Family Income in County of Residence</th>
<th>Odds Ratio (95% CI)</th>
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<td>$40,000-62,899</td>
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<tr>
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<td>1.00 (0.99-1.01)</td>
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<table>
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<tr>
<th>Medicaid Expansion Status</th>
<th>Odds Ratio (95% CI)</th>
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<tbody>
<tr>
<td>Expansion</td>
<td>Ref</td>
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</tr>
<tr>
<td>Non-expansion</td>
<td>1.03 (1.00-1.06)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

* Estimated from American Community Survey, regarding patient’s county of residence. ** Wald test 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.
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 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 lesion 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 4.45 [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 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.

| Table 1: Univariable and Multivariable Logistic Regression Predicting GG Progression on AS Biopsy |
| Age at Diagnosis (y) | PIRADS 3 vs 0 | PIRADS 4 vs 0 | PIRADS 5 vs 0 |
| Odds Ratio (95% CI) | p-value | Odds Ratio (95% CI) | p-value | Odds Ratio (95% CI) | p-value |
| Age at Diagnosis (y) | 1.07 (1.04-1.11) | 0.005 | 1.35 (1.26-1.45) | 0.007 |
| PSA (ng/mL) | 1.10 (1.06-1.14) | 0.008 |
| PSA density (ng/mL) | 1.15 (1.04-1.26) | 0.175 |
| T Stage | 2.09 (1.80-2.41) | 0.000 |
| NCCN Risk Level | Low | 1.99 (1.82-2.17) | 0.000 |
| Intermediate | 1.18 (1.08-1.29) | 0.000 |

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

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1Lahey Hospital and Medical Center, Burlington, MA; 2Beth Israel Deaconess Medical Center, Boston, MA

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 (PPFT) 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 PPFT 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 PPFT 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 PPFT 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, 94/144 (65.2%) 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 1.25-6.25) 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.

*Max K. Willscher Award Eligible

Robotic Radical Prostatectomy

Douglas Dahl, MD, Rumpf, BS, Keyan Salari, MD, PhD, Matthew Wszolek, MD, Adam Feldman, MD, MPH, Jeffrey K. Twum-Ampofo, MD, Andrew Gusev, BS, Alberto C. Pieretti, MD, Florian Rumpf, BS, Reyan Salan, MD, PS, Matthew Wozolek, MD, Adam Feldman, MD, MPH, Douglas Dahl, MD

Is Repeat Prostate Biopsy Prior to Treatment Necessary for Active Surveillance Patients with Clinical and Radiographic Findings Suggesting Gleason Grade Progression?
Risk Stratification by Prostate Health Index Prior to MRI-Ultrasound Fusion Targeted Biopsy

Benjamin Press, MD, Ghazal Khajir, MD, Michael S. Leapman, MD, Preston Spreñkle, MD
Yale University School of Medicine, New Haven, CT

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 isofrm 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 (36.7 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

<table>
<thead>
<tr>
<th>phi Range</th>
<th>Probability of PSA</th>
<th>Probability of GG2-PSA</th>
<th>Probability of GG2-PSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 26.9</td>
<td>4% (15%)</td>
<td>23.08%</td>
<td>24.08%</td>
</tr>
<tr>
<td>27.0 - 35.9</td>
<td>36.64%</td>
<td>21.03%</td>
<td>29.79%</td>
</tr>
<tr>
<td>36.0 - 54.9</td>
<td>72.58%</td>
<td>35.50%</td>
<td>42.22%</td>
</tr>
<tr>
<td>55.0 - 83.02%</td>
<td>30.19%</td>
<td>32.82%</td>
<td>32.82%</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>PI-RADS</th>
<th>phi Range</th>
<th>Probability of PSA</th>
<th>Probability of GG2-PSA</th>
<th>Probability of GG2-PSA</th>
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<tr>
<td>1</td>
<td>0 - 12.5%</td>
<td>12.5%</td>
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<td>0.00%</td>
</tr>
<tr>
<td>2</td>
<td>27%</td>
<td>49.02%</td>
<td>35.20%</td>
<td>11.73%</td>
</tr>
<tr>
<td>3</td>
<td>15%</td>
<td>15.79%</td>
<td>15.79%</td>
<td>0.00%</td>
</tr>
<tr>
<td>4</td>
<td>56%</td>
<td>57.50%</td>
<td>40.00%</td>
<td>17.50%</td>
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<tr>
<td>5</td>
<td>16%</td>
<td>66.67%</td>
<td>66.67%</td>
<td>0.00%</td>
</tr>
<tr>
<td>6</td>
<td>0%</td>
<td>60.00%</td>
<td>33.33%</td>
<td>26.67%</td>
</tr>
<tr>
<td>7</td>
<td>1%</td>
<td>61.54%</td>
<td>36.77%</td>
<td>30.77%</td>
</tr>
<tr>
<td>8</td>
<td>3%</td>
<td>77.98%</td>
<td>33.33%</td>
<td>44.44%</td>
</tr>
<tr>
<td>9</td>
<td>5%</td>
<td>88.54%</td>
<td>23.53%</td>
<td>64.71%</td>
</tr>
<tr>
<td>10</td>
<td>10%</td>
<td>46.43%</td>
<td>22.22%</td>
<td>50.00%</td>
</tr>
<tr>
<td>11</td>
<td>15%</td>
<td>81.35%</td>
<td>24.73%</td>
<td>65.59%</td>
</tr>
</tbody>
</table>
**Free Hand Transperineal Prostate Biopsy Offers Equivalent Cancer Detection and Improved Antibiotic Stewardship Compared to Transrectal Ultrasound-Guided Prostate Biopsy**

Christian Schaffler, BS, Ryan Daigle, BS, Carl K. Gjertson, MD, Peter C. Albertsen, MD, Benjamin T. Rastau, MD
University of Connecticut School of Medicine, Farmington, CT

**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 free-hand 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 (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 59.9-75.9) than those undergoing TRUS-B (63y, IQR 58.0-69.0; p = .03). There were no significant differences in median prostate PNA 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 = 0.03). 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 < 0.001). 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 = 0.46). 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>
<thead>
<tr>
<th>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).</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUS-B (10 or 12-core)</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>Grade</strong></td>
</tr>
<tr>
<td>Benign</td>
</tr>
<tr>
<td>Grade Group 1</td>
</tr>
<tr>
<td>Grade Group 2</td>
</tr>
<tr>
<td>Grade Group 3</td>
</tr>
<tr>
<td>Grade Group 4</td>
</tr>
<tr>
<td>Grade Group 5</td>
</tr>
<tr>
<td>Any Cancer</td>
</tr>
<tr>
<td>Clinically Significant Cancer</td>
</tr>
</tbody>
</table>

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

Keyan Salari, MD, Jeffrey Twum-Ampofo, MD, Andrew Gusey, MD, Joshua Caldwell, MD, Eduard Nicaise, BS, David Kuppermann, MD, Dimitar Zlatey, MD, Douglas Dahl, MD, Jason Efstathiou, MD, Phil, Michael Blute, MD, Anthony Zietman, MD, Adam Feldman, MD, MPH
Massachusetts General Hospital, Boston, MA

**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 prostate 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 3.7-6.3). The vast majority of patients had grade group 1 (99%) and clinical stage T1 (98%) 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. Willacher Award Eligible*
Utilization and Outcomes of Serial Prostate MRI for Prostate Cancer Active Surveillance
Andrew Gusev, BA, Jeffrey Twum-Ampofo, MD, Alberto Pieretti, MD, Carl Ceraolo, BA, Florian Rumpf, BA, Alice Yu, MD, Keyan Salari, MD PhD, Douglas Dahl, MD, Adam S. Feldman, MD MPH
Massachusetts General Hospital, Boston, MA

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 a 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 22% 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] < 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 93 men with two negative MRIs experienced prolonged freedom from treatment, 88% and 83% at 5 and 10 years, compared to 76% 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] < 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. While a majority of men do not experience PIRADS score change on serial prostate mpMRI, those who have radiologic progression progress to treatment sooner.
**The Effect of Body Mass Index on Clomiphene Citrate Therapy Outcomes for Hypogonadal Men**

Alexander Flochacki, MD, MPH, Alexander Erbella, MD, Erin Burns, RN, Susan Parks, CMS, Nicole Rossetti, RN, Matthew Wosnitzer, MD

*University of Vermont Medical Center, Burlington, VT; Florida State University College of Medicine / Tallahassee Memorial Healthcare, Tallahassee, FL; Yale New Haven Health, Northeast Medical Group, Fairfield, CT*

**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 50 mg 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. **Table 1: BMI-stratified demographics and results of hypogonadal men on clomiphene citrate**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal</th>
<th>Overweight</th>
<th>Obese</th>
<th>Morbidly Obese</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>36 ± 8</td>
<td>35 ± 7</td>
<td>44 ± 10</td>
<td>62 ± 3</td>
<td>-</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24 ± 1</td>
<td>37 ± 1</td>
<td>44 ± 6</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Δ Total Testosterone (ng/dL)</td>
<td>19.0 [22.7, 32.9]</td>
<td>149 [100, 197]</td>
<td>142 [100, 169]</td>
<td>96.2 [76, 151]</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td>Δ Estradiol (pg/dL)</td>
<td>5.2 [1.8, 17.4]</td>
<td>5.0 [0.9, 30.8]</td>
<td>5.5 [0.36, 13.0]</td>
<td>9.2 [1.2, 27.4]</td>
<td>0.39</td>
</tr>
<tr>
<td>Δ PSA (ng/dL)</td>
<td>0.23 [0.0, 0.47]</td>
<td>0.04 [0.06, 0.14]</td>
<td>0.12 [0.03, 0.12]</td>
<td>0.09 [0.1, 0.25]</td>
<td>0.37</td>
</tr>
<tr>
<td>Δ Hematocrit (%)</td>
<td>1.2 [0, 2.6]</td>
<td>1.4 [0.8, 0.6]</td>
<td>0.1 [0.1, 0.2]</td>
<td>1.4 [0, 1.2]</td>
<td>0.13</td>
</tr>
</tbody>
</table>

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

Figure 1: BMI-stratified increase in total testosterone in men on clomiphene citrate. Note: Error bars represent 95% confidence interval.
Access to Male Fertility Preservation Information and Referrals at National Cancer Institute Cancer Centers

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1Beth Israel Deaconess Medical Center, Boston, MA; 2Frank H. Netter, MD School of Medicine, New Haven, CT; 3Johns Hopkins University, Baltimore, MD

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 = 0.73).

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.

<table>
<thead>
<tr>
<th>US Census Region (N)</th>
<th>Overall Fertility Information</th>
<th>Overall Sexual Health Information</th>
<th>Male Fertility Information</th>
<th>Referred to Specific Andrologist</th>
<th>Referred to andrologist</th>
<th>Referred to sperm banks</th>
<th>Average number of andrologists in 5-mile radius</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast (14)</td>
<td>50.00%</td>
<td>42.85%</td>
<td>42.85%</td>
<td>93.75%</td>
<td>76.53%</td>
<td>50.00%</td>
<td>2.2</td>
</tr>
<tr>
<td>Midwest (14)</td>
<td>76.53%</td>
<td>50.00%</td>
<td>50.00%</td>
<td>76.53%</td>
<td>76.53%</td>
<td>42.85%</td>
<td>0.8</td>
</tr>
<tr>
<td>South (22)</td>
<td>67.61%</td>
<td>33.33%</td>
<td>29.57%</td>
<td>76.19%</td>
<td>66.67%</td>
<td>71.43%</td>
<td>0.5</td>
</tr>
<tr>
<td>West (13)</td>
<td>66.67%</td>
<td>26.67%</td>
<td>26.67%</td>
<td>95.70%</td>
<td>80.00%</td>
<td>60.00%</td>
<td>6.6</td>
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</tbody>
</table>
Patient Desire for Disposition of Cryopreserved Sperm upon Death as a Surrogate Marker for Likelihood of Consent for Posthumous Sperm Retrieval
Dylan M. Bulley, BA1, Brooke A. Harnisch, MD1, Vikram Lyall, BS1, Michael E. Goltzman, MD1, Stanton C. Hareng, MD2
1University of Connecticut, Farmington, CT; 2Yale University School of Medicine, New Haven, CT

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 have consented. This 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, 2018 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 500 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 sperm to their partner 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 for sperm retrieval. The prior, depth of this information may be useful to guide physician-institution-patient decision making in these complex situations.

Table 1. Trends in Patient Preference of Transfer versus Discard of Sperm in the Event of Death

<table>
<thead>
<tr>
<th>Period</th>
<th>Mean Age</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>38.0 +/- 6.0</td>
<td>30.4 +/- 6.0</td>
<td>35.6</td>
</tr>
</tbody>
</table>

Race/Biology

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>323 (76.6%)</td>
<td>34 (12.7%)</td>
</tr>
<tr>
<td>Black</td>
<td>105 (43.1%)</td>
<td>20 (12.5%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>36 (32.1%)</td>
<td>12 (21.1%)</td>
</tr>
</tbody>
</table>

Etiology of Infertility

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male-Factor Infertility</td>
<td>150 (76.1%)</td>
<td>45 (10.7%)</td>
</tr>
<tr>
<td>Female-Factor Infertility</td>
<td>129 (79.4%)</td>
<td>25 (18.4%)</td>
</tr>
<tr>
<td>Combined Male-Female</td>
<td>31 (88.5%)</td>
<td>2 (6.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>32 (97.5%)</td>
<td>2 (6.0%)</td>
</tr>
</tbody>
</table>

Marital Status

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>203 (94.0%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Unmarried</td>
<td>10 (43.4%)</td>
<td>24 (10.6%)</td>
</tr>
<tr>
<td>No-Prior Children</td>
<td>107 (83.7%)</td>
<td>16 (12.9%)</td>
</tr>
<tr>
<td>Prior Children, Current Partner</td>
<td>79 (92.1%)</td>
<td>12 (1.4%)</td>
</tr>
<tr>
<td>Prior Children, Non-Partner</td>
<td>51 (85.5%)</td>
<td>5 (8.8%)</td>
</tr>
</tbody>
</table>

Occupation Classification

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Collar</td>
<td>115 (33.4%)</td>
<td>22 (6.4%)</td>
</tr>
<tr>
<td>White Collar</td>
<td>102 (42.7%)</td>
<td>35 (14.0%)</td>
</tr>
</tbody>
</table>

Insurance Status

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Insurance</td>
<td>102 (52.1%)</td>
<td>27 (13.0%)</td>
</tr>
<tr>
<td>No Insurance</td>
<td>28 (47.1%)</td>
<td>5 (8.2%)</td>
</tr>
</tbody>
</table>

Total

<table>
<thead>
<tr>
<th>Category</th>
<th>Transfer</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>342 (40.7%)</td>
<td>6 (0.7%)</td>
</tr>
</tbody>
</table>

*Statistical significance considered to be p < .05. Continuous variables assessed with independent sample t-test. Discrete variables assessed with chi-square or Fishers’ exact test
p value for multi-factor vs. female factor infertility patients
p value for Commercial vs. No Commercial
p value for Blue collar vs. White collar
p value for prior children vs. non-prior children
p value for patients with commercial insurance vs. all others

A Novel Evaluation of Medicare Reimbursement for Commonly Treated Sexual Medicine Conditions
Lael Reinstein, MD, MPH, Martin Gross, MD
Dartmouth Hitchcock Medical Center, Lebanon, NH

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 an8% 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 an8% 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.
Intraoperative Use of Vancomycin Paste during Penile Prosthesis Placement: Initial Outcomes

Priyanka Beareddy, MD, MPH,1 Maria D’Amico, MD,2 Shu Pan, MD,3 Nannan Thirumavalavan, MD,4 Brett Gross, MD3 Pedro J. Flacke, MD2,3 Ricardo Munarriz, MD5
1Boston University, Boston, MA; 2Northwell Health, Albert Einstein College of Medicine, Bronx, NY; 3Tufts University School of Medicine, Boston, MA; 4Lahey Hospital and Medical Center, Burlington, MA

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 surgery and device dependent improvements, innovative infection prevention measures are warranted. 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 prosthetic 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 infection-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 in all patients. To date, five patients have experienced adverse events: one recurred to doxycycline due to a positive intraoperative culture, one excised a large hematoma from the tip of the penis, one excised the corpora to effectively dilate the corpora, and one experienced a true infection requiring explant in order to effectively dilate the corpora.

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.

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

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1Boston University, Boston, MA; 2Northwell Health, Albert Einstein College of Medicine, Bronx, NY; 3Tufts University School of Medicine, Boston, MA; 4Montefiore Medical Center, Cleveland, OH; 5University of Rochester, Rochester, NY

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. Dilatation of the corpora both distally and proximally often require the use of caverrotomes. 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%), caverrotomes in 7 patients (20.6%), and a combination of both sharp excision and caverrotomes 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 caverrotomes or sharp corporal excision in order to effectively dilate the corpora.

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

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1Tufts University School of Medicine, Boston, MA; 2Lahey Hospital and Medical Center, Burlington, MA

Introduction: Patient-centered care focuses on maximizing patients’ physical and emotional well-being. A key aspect to delivering this includes education 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. An important 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.

Materials & Methods: Before the procedure, patients were informed about the role for CT in evaluating their condition. The method for CT 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 included: 1) how clear was the CT scan giving them a clear understanding of their condition and treatment options, 2) did they feel well-informed about the need for the CT scan (M = 4.7/5, SD = 0.8), and 3) how meaningful was the procedure, informedness about the procedure, impact of the CT on patient understanding of the disease process and treatment options, impact of the CT 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 concomitant 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 = 4.8/5, 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 phentolamine. 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.
Acute Changes in 24 Hour Lithogenic Urine Measures Intra and Peri Partum
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Dartmouth-Hitchcock Medical Center, Lebanon, NH

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 boosted 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. As noted in Table 1, we noted 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 mg pre-partum and 125.2 mg post-partum (p = 0.001). Urinary pH was 6.9 pre-partum and 5.9 post-partum (p < 0.001). Urinary hyper saturation of calcium phosphate (iCaP) was 2.1 pre-partum and 0.7 post-partum (p < 0.0001).

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

Association of Prior Pregnancy with 24-hour Urine Composition and Stone Risk
Vivian Paredes Bhushan, MS1, Marie-Therese Valovyska, MD1, Vernon M. Pais, Jr, MD2
1Dartmouth Geisel School of Medicine, Hanover, NH; 2Dartmouth-Hitchcock Medical Center, Lebanon, NH

Introduction: Pregnancy is associated with increased lifetime prevalence of nephrolithiasis. During pregnancy, purported changes in urinary milieu include hypercalciuma 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 of at time of 24 hour urine was 29.6 kg/m2. Previously gravid women were more likely to exhibit hypercalciuma than G0 women (56% 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 urinary calcium remained elevated in G3+ compared to G0 women (+0.049 mg and +94 mg/L, respectively, p < 0.05). Prior gravidity did not impart significant effect on most recent urine pH. There was no difference observed 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: 1.296, p = 0.034; 95% CI: 0.963-0.912).

Conclusions: Women with multiple pregnancies were more likely than G0 women to have hypercalciuma 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.
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 telephone calls, 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 had a low number of postoperative 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.

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.

Conclusion: 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.

Emergency Department Factors that Predict Prolonged Length of Stay after Stent Placement for Obstructing Urolithiasis and Infection
Alejandra Balen, MD, David Sobel, MD, Marcelo Paiva, MPP, Timothy O’Rourke, MD, Martus Cn, MD, Rachel Greenberg, MD, Rebecca Ortiz, BA, Philip Caffery, PhD, Christopher Tucci, MSN, Gyan Pareek, MS MD

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
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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1University of California San Diego School of Medicine, San Diego, CA; 2Maine Medical Center, Portland, ME; 3University of California San Diego Health, San Diego, CA

Introduction: Prostate cancer (PCa) 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 PCa 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 PCa 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 = 82591, 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 PCa risk SNPs could aid individualized screening recommendations within the African American population.

Kidney Stone Volume Measurement using Ultra-Low Dose Computed Tomography and New Software Solutions
Ohad Kott, MD,1 Thomas Yi, MD,2 Jorge Pereira, MD,3 David Grand, MD,2 Adib Karam, MD,2 Derek Merck, PhD,3 Scott Collins, PhD,3 Simone Thavanesan, MD,1 Gyan Pareek, MD,2
1Minimally Invasive Urology Institute, The Miriam Hospital, Providence, RI; 2The Warren Alpert Medical School of Brown University, Providence, RI; 3Mount Sinai Medical Center, Miami Beach, FL

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. Zioscan 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 Ortho 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 Zioscan 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 mm²/3. 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 Zioscan 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 Zioscan and Synapse reproducible and operator-independent both in SCT and UCT. Adoption of such tools may benefit patients and surgeons. Discussion on concordance rates in SSB between radiologist and software measurement warrant further research to determine the gold standard in SSB measurement.
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 alteration 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 Quagen QIAPEAK 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.

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 parainfluenza virus 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. 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 1000 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.
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 calculus 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 emergent cystoscopy and ureteral stent placements 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 = 49.6 [after hours], t(40) = 1.4, p = .16). No differences were detected in time from imaging diagnosis to OR [F(5,106) = 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 presented 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 requiring a salvage pubovaginal sling procedure to date. 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.

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 local inflammatory response. 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 (<12mo) or late-onset (>12mo) 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, transvesical excision has been performed in two patients, with two patients awaiting definitive operative intervention. 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. 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.

Table 1: Case Series of Patients with Bulking Agent Complications

<table>
<thead>
<tr>
<th>Inj ectable Agent</th>
<th>Presenting Symptoms</th>
<th>Timing of Presenting Symptoms</th>
<th>Time from Bulking Agent to Diagnosis</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collagen®</td>
<td>Dysuria, Urgency, Vaginal pain, Frequency</td>
<td>Early-Onset 2 Years</td>
<td>Transvaginal Open Excision</td>
<td></td>
</tr>
<tr>
<td>Macrophase®</td>
<td>Pelvic pain, Vaginal pain, Dyspareunia</td>
<td>Late-Onset 7 Years</td>
<td>Transvaginal Open Excision</td>
<td></td>
</tr>
<tr>
<td>Macrophase®</td>
<td>Low urgency, Vaginal pain, Nocturia</td>
<td>Early-Onset 4 Years</td>
<td>Transurethral Resection*</td>
<td></td>
</tr>
<tr>
<td>Coaptite®</td>
<td>Recurrent UTIs, Frequency, Urges incontinence</td>
<td>Early-Onset Unknown</td>
<td>N/A**</td>
<td></td>
</tr>
</tbody>
</table>

*Appearing Transvaginal Open Excision

**Appearing Transurethral Resection

Figures 1 & 2: Surgical Management of Urethral Bulking Agent Complications in Women.
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 3 (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 = 123]; Figure 1), urgency (3.4, vibegron [n = 152]; −3.2, tolterodine [n = 123]), and total incontinence (−2.5, vibegron [n = 125]; −1.9, tolterodine [n = 120]; 61.0% of 143 vibegron-treated patients had ≥ 75% reduction in UUI, and 40.8% became dry 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 in Older Women: Does Distance Matter?

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UMassMemorial Medical Center, Worcester, MA

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 antidepressive 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.
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 96 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). 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).

Table 1. Number of AUS reoperations undergone by patients

<table>
<thead>
<tr>
<th>Number of reoperations</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>24/31 (77.4)</td>
</tr>
<tr>
<td>1</td>
<td>5/31 (16.1)</td>
</tr>
<tr>
<td>2</td>
<td>1/31 (3.2)</td>
</tr>
<tr>
<td>3</td>
<td>1/31 (3.2)</td>
</tr>
</tbody>
</table>

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.

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 alkalized lidocaine versus lidocaine alone.

Materials & Methods: This 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 30 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.

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

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SUNY Downstate Health Sciences University, Brooklyn, NY, USA; 2Boston University, Boston, MA, USA

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 (500 mL divided by 24 hours) and Nocturnal MVV (NMVV) < 200 were employed as nocturnal proses 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 19 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 OR 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.

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 103°F and WBC of 15. Urimanly 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 gddalianum-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 masturbatory 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 penoscopical approach. Purulent material was encountered, washed out with triple antibiotic solution (vancomycin/zyomin/amphotericin), drains were placed and the incision was closed. His cultures grew Streptococcus anginosus and he was empirically treated with an oral antibiotic for several days. He was seen in clinic in follow up four weeks later where recurrent abscesses were noted. A culture sent to the office was negative for fungi. He visited a 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 when washed out and treated with calcium fluoride and vancomycin. He recovered for a total of 4 days before discharge home. He has been seen in clinic with complete recovery and no further infectious issues.

Conclusions: In addition to usage in the infected penile prostheses context, the Carrion cast may be applied to penile abscesses unrelated to prostheses.
Urolithiasis Management in the Early 1900s: Howard A. Kelly and the Wax-Tipped Ureteral Catheter

Introduction: Diagnosis of ureteral and renal calculi was revolutionized with medical implementation of X-ray in the early decades of the 1900s. Diagnosis of urolithiasis 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 arcoscopy 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 bongie, 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 ultrasonography, early innovations utilizing a wax-tip catheter were 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...were rendered unnecessary,..." Urolithiasis has 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 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 on the forefront of surgical technology and innovation.
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)

Michael T. Grant, MD
GreenLEP, while post procedural SUI is approximately 1.4% at 6 months.

The chief year. Significant improvements in IPPS, QOL, and PVR can be achieved 1 month after 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 prostate (>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: 35.5). Overall, patients who underwent GreenLEP experienced significant reductions in IPSS (22.4 vs. 6.4, p < 0.001), QOL (4.5 vs. 2.8, p = 0.04) 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 IPSS, QOL, and PVR can be achieved 1 month after GreenLEP, while post procedural SUI is approximately 1.4% at 6 months.

Poster Session I
**P10**

**Modulation of TRPV4 Channel Activity by ATP in Rat and Human Urinary Bladder**

Seneca D. Hutson, BSc1, Katarina Zvarova, MD, PhD2, Peter Zvara, MD, PhD2

1University of Vermont, Burlington, VT, USA; 2University of Southern Denmark, Odense, Denmark

**Introductions:** 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 rats undergoing radical cystectomy. Contractile response of the bladder tissue to strips containing detrusor muscle and urothelium from the bladder of adult female patients undergoing radical cystectomy. Contractile response of the bladder tissue to strips containing detrusor muscle and urothelium from the bladder of adult female patients undergoing radical cystectomy. Contractile response of the bladder tissue to strips containing detrusor muscle and urothelium from the bladder of adult female patients undergoing radical cystectomy.

**Results:** TRPV4 agonist (GSK101679A) 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 1 nM and reached a peak at 100 nM. This effect was significantly reduced by pretreatment with 1 µM TRPV4 antagonist (HC067047). ATP (1 mM) administered before GSK completely blocked the GSK effect. Adding 1-100 µM of ATP at the peak of GSK-evoked response increased the amplitude of phasic activity. A 1 mM 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 Ca2+-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 rat and human 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 of using ATP to modulate TRPV4 channel activity during bladder filling via negative feedback, thus contributing to the control of bladder sensory signaling.

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**P11**

**Estrogen Receptors Regulate Prostate Growth in Benign Prostatic Hyperplasia upon SRD5A2 Promoter Methylation**

Christina Sharky, BS, Sejun Liu, MD, Zongwei Wang, PhD, Aria F. Olumi, MD

**Introductions:** Steroid 5-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 methylated promoter in the promoter region. We have demonstrated that there is an “andrologic 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 epithelial 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 with ER expression.

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

**Conclusions:** ERα and ERβ co-localize in human benign prostatic tissue. Specifically, ERα is expressed in the nucleus of both the prostatic stroma and epithelium. 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.

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**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 180 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 amino and fatty acid metabolism 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.
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 instillations 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. 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.

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 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.

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.

*Max K. Willsher Award Eligible

WITHDRAWN

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 and family planning in the 1960s. Studies around the turn of the 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.

Established and Experimental Techniques to Improve Phalloplasty Outcomes: Optimization of a Hypercomplex Surgery
Erin Carter, MS1, Curtis Crane, MD2, Richard Santucci, MD3
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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 2% by technical optimization of the urethroplasty portion of phalloplasty. We use transcutaneous visual light spectroscopy (TvlasTM) 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 (FlosealTM) to eliminate the need for scrotal drains and limit scrotal hematoma. We continue to investigate the role of extracellular matrix nerve connection sheaths (AxoguardTM) to improve the efficiency of nerve regeneration and optimize postoperative function.

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 experimental techniques to further minimize urethral complications, enhance nerve regeneration, improve postoperative flap monitoring, control of postoperative bleeding, and manage flap donor site morbidity, 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.

Autologous Dermal Fat Graft Augmentation Glansplasty for Management of Transmasculine Neoglans 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 I: 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)

Evaluating a Rural Transgender and Gender Diverse Population and Interest in Genital Gender Confirming Surgery
Amanda R. Swanton, MD/PhD1, Ella A. Damiano, MD, John F. Nigriny, MD, Benjamin Bolot, DO, MS, John H. Turco, MD, William Bibhrle, III, MD, Rachel A. Moses, MD, MPH2
1Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA; 2The Crane Center for Transgender Surgery, Austin, TX, USA

Introduction: In addition to the multiple psychosocial and health disparities faced by transgender and gender diverse persons (TGGD) seeking hormonal and surgical treatments, 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 P44 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 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 18-40, 25% (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). Genetic 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.
Predicting Cancer Detection Rates from Multiparametric Prostate MRI: Refining the PI-RADS Categorization System

Aaron Fleishman, MPH, Ruslan Korets, MD, Michael Johnson, Francisco Ramos, BS

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, PI-RADS-IU) 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 consired 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 (cCDR; 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 cCDR was 26%. In multivariable regression models predicting CDR, number of prior biopsies (OR 0.18, 95%CI 0.10-0.32 for 1; OR 0.16, 95%CI 0.10-0.27 for 2+; OR 0.1, 95%CI 0.06-0.16 for 5 versus 0) were independently associated with CDR (Table 1). In multivariable models predicting cCDR, abnormal DRE (OR 2.75, 95%CI 1.22-6.09), solitary lesion on MRI (OR 2.42, 95%CI 1.35-4.58 versus 2+), PSA density (OR 1.04, 95%CI 1.00-1.09) and PI-RADS category (OR 3.3, 95%CI 1.03-10.7 for 3; OR 3.44, 95%CI 1.03-14.4 for 4; OR 3.54, 95%CI 1.15-2.88) and PI-RADS category (OR 5.39, 95%CI 1.43-29.1 for 4; OR 15, 95% CI 9.54-88.8 for 5 versus 3) were independently associated with CDR (Table 1). In multivariable regression models predicting CDR, number of prior biopsies (OR 0.18, 95%CI 0.10-0.32 for 1; OR 0.16, 95%CI 0.10-0.27 for 2+; OR 0.1, 95%CI 0.06-0.16 for 5 versus 0) were independently associated with CDR (Table 1). The bootstrap-adjusted c-index was 0.80 for the CDR model and 0.71 for the cCDR 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 associated with risk of malignancy in men undergoing MRI-targeted biopsy for elevated PSA.

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>CDR (OR, 95% CI)</th>
<th>cCDR (OR, 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-biopsy PSA, ng/mL</td>
<td>1.01 (0.93-1.09,1)</td>
<td></td>
</tr>
<tr>
<td>Abnormal DRE</td>
<td>2.75 (1.22-6.09)</td>
<td></td>
</tr>
<tr>
<td>Number of prior prostate biopsies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (vs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.18 (0.08-0.47)</td>
<td>0.16 (0.10-0.27)</td>
</tr>
<tr>
<td>2+</td>
<td>0.16 (0.10-0.27)</td>
<td>0.10 (0.06-0.16)</td>
</tr>
<tr>
<td>Number of lesions, 1 (for 2+)</td>
<td>1.00 (0.93-1.07)</td>
<td>1.00 (0.93-1.07)</td>
</tr>
<tr>
<td>PI-RADS Category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2.42 (1.35-4.58)</td>
<td>3.3 (1.03-10.7)</td>
</tr>
<tr>
<td>4</td>
<td>3.3 (1.03-10.7)</td>
<td>3.44 (1.03-14.4)</td>
</tr>
<tr>
<td>5</td>
<td>3.54 (1.15-2.88)</td>
<td>5.39 (1.43-29.1)</td>
</tr>
<tr>
<td>Prostate volume on MRI</td>
<td>1.02 (0.99-1.05)</td>
<td>1.00 (0.97-1.03)</td>
</tr>
<tr>
<td>PSA density (per 0.1 ng/mL increase)</td>
<td>1.75 (1.15-2.62)</td>
<td>1.04 (1.02-1.06)</td>
</tr>
</tbody>
</table>

Conclusion:

1. Our study demonstrates the potential for personalized risk-stratification beyond the PI-RADS categorization.

2. The bootstrap-adjusted c-index was 0.80 for the CDR model and 0.71 for the cCDR model.

3. In multivariable regression models predicting CDR, number of prior biopsies (OR 0.18, 95%CI 0.10-0.32 for 1; OR 0.16, 95%CI 0.10-0.27 for 2+; OR 0.1, 95%CI 0.06-0.16 for 5 versus 0) were independently associated with CDR (Table 1). In multivariable models predicting cCDR, abnormal DRE (OR 2.75, 95%CI 1.22-6.09), solitary lesion on MRI (OR 2.42, 95%CI 1.35-4.58 versus 2+), PSA density (OR 1.04, 95%CI 1.00-1.09) and PI-RADS category (OR 3.3, 95%CI 1.03-10.7 for 3; OR 3.44, 95%CI 1.03-14.4 for 4; OR 3.54, 95%CI 1.15-2.88) and PI-RADS category (OR 5.39, 95%CI 1.43-29.1 for 4; OR 15, 95% CI 9.54-88.8 for 5 versus 3) were independently associated with CDR (Table 1).
Poster Session II

P21

Transperineal Prostate Biopsy - Comparing Diagnostic Accuracy and Patient Reported Pain to Standard TRUS and MRI/US Fusion Biopsy techniques
Aaron Berkenwald, MD, Kristian Stensland, MD, Colette Osborne, MAS, Linda Tropjian, BS, Lori-lyn Price, MAS, Aliza Zolmitzadeh, MD, MEH, William Faust, MD
1Agency, Burlington, MA, USA; 2Tufts Medical Center, Boston, MA, USA

Introduction: Transperineal Prostate Biopsy (TPBs) using the PrecisionPoint system (Pernoo, 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 TPBs 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 pain for patients prior to biopsy, anesthetic block, biopsy and post-procedure. Mean NRS scores were compared using the ANOVA test. CDR and csCDR were compared between TPBs, TRUSBx and TRUS/MRI fusion biopsy using Fisher’s exact test.

Results: 316 patients met inclusion criteria for cancer detection. CDR for TPBs, 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 TPBs 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 groups 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 TPBs report similar levels of discomfort for all aspects of the procedure when compared to transrectal biopsies with the exception of anesthetic block. Procedural times were longer in the TPBx and TRUS/MRI fusion (2.5 vs. 3.0 and 3.1 respectively, p = 0.14). NRS pain scores were reported in 253 total biopsies. Mean patient reported NRS scores for TPBs 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 groups 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.

P22

Learning to Hit the Target: Improving Accuracy of Fusion Biopsy over Time at Maine Medical Center
Madeline Rutan, BA,1 William C. Daly, BA,2 Christine Gentile, MPH2, Moritz Hansen, MD,2 Matthew Havin, MD,2 Stephen Ryan, MD,2 Jesse D. Sammon, DO1
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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%, 32%, 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.

**Table 1:** TRUS, TRUS/MRI Fusion vs. P-values

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TRUS</th>
<th>TRUS/MRI Fusion</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (out of 10)</td>
<td>3.4 (2.2)</td>
<td>3.8 (2.6)</td>
<td>0.04</td>
</tr>
<tr>
<td>Anxiety Mod</td>
<td>2.8 (2.9)</td>
<td>2.8 (2.6)</td>
<td>0.802</td>
</tr>
<tr>
<td>Procedure</td>
<td>3.2 (2.2)</td>
<td>3.2 (2.2)</td>
<td>0.982</td>
</tr>
</tbody>
</table>

**Table 2:** Mean NRS scores for transperineal biopsy and 12-core biopsy

<table>
<thead>
<tr>
<th>Parameter</th>
<th>12-Core Biopsy</th>
<th>Transperineal Biopsy</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (out of 10)</td>
<td>3.4 (2.2)</td>
<td>3.9 (2.6)</td>
<td>0.04</td>
</tr>
<tr>
<td>Anxiety Mod</td>
<td>2.8 (2.9)</td>
<td>2.8 (2.6)</td>
<td>0.702</td>
</tr>
<tr>
<td>Procedure</td>
<td>3.2 (2.2)</td>
<td>3.2 (2.2)</td>
<td>0.982</td>
</tr>
</tbody>
</table>

**Figure:** Percentage of normal fusion biopsies with Gleason 6 or clinically significant (≥Gleason 3+4=7) prostate cancer
A Retrospective Evaluation of a Novel Perioperative Opioid Sparing Protocol for Patients Undergoing Robotic Assisted Laparoscopic Radical Prostatectomy or Nephrectomy

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South County Hospital, Wakefield, RI, USA

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.

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 that were 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.
The Impact of Residential Segregation on Prostate Cancer Treatment and Outcomes

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Boston University School of Medicine, Boston, MA, USA

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 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. White patients comparatively have a 42% decreased risk of presenting at advanced stage with increasing segregation, while white patients have a 20% increased risk of surgical resection with increasing segregation. 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).

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 PS-RADS category (Table 1). In IPW-adjusted logistic regression, there was no statistically significant difference in CDR (OR 1.03; 95% CI 0.85-1.29) 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 PS-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 (csCDR) for MRI-U/S fusion biopsy versus in-bore MRI-targeted biopsy for the overall cohort and stratified by PS-RADS category, adjusted for patient and MRI features. Numbers represent %.

<table>
<thead>
<tr>
<th>Biopsy Type</th>
<th>CDR Overall</th>
<th>CDR PS-RADS 3</th>
<th>CDR PS-RADS 4</th>
<th>CDR PS-RADS 5</th>
<th>csCDR Overall</th>
<th>csCDR PS-RADS 3</th>
<th>csCDR PS-RADS 4</th>
<th>csCDR PS-RADS 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI-U/S</td>
<td>41 (57.4)</td>
<td>2 (16)</td>
<td>3 (25)</td>
<td>5 (42)</td>
<td>33 (50.0)</td>
<td>0 (0)</td>
<td>2 (16)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>In-bore MRI</td>
<td>22 (34.9)</td>
<td>1 (8.3)</td>
<td>1 (8.3)</td>
<td>1 (8.3)</td>
<td>10 (14.7)</td>
<td>2 (16)</td>
<td>1 (8.3)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.83</td>
<td>0.98</td>
<td>0.98</td>
<td>0.98</td>
<td>0.86</td>
<td>0.98</td>
<td>0.98</td>
<td>0.98</td>
</tr>
</tbody>
</table>
Adenocarcinoma of a Continent Urinary Conduit: A Case Report and Review of the Literature

Michael E. Goltzman, MD1, Richard T. Kershen, MD2

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 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.


Poster Session II

The Relationship Between Health Literacy and Non-Recommended Screening for Prostate Cancer Relative to Other Malignancies
Madeleine Rutan, BA1, Jesse D. Sammon, DO, David-Dan Nguyen, DES2, Kerry L. Kilbridge, MD3, Peter Herzog, MPH4, Quoc-Dien Trinh, MD5

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 2015 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: 46.9% (CI 42.6%-51.1%; p = 0.002) and 67.3% (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%-50.6%; p < 0.001) of and low 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 1.53; CI 1.31-1.80; p < 0.001) and BCa (OR 8.21; CI 4.90-13.76; p < 0.001).

Conclusions: Patients with higher HL underwent 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.
Post-Prostatectomy Radiation with Long Term Follow-up: Outcomes and Changing Indications

Ghali Lemitri-Chlieh, MS, Alex Hennessy, MD, Ilene Staff, PhD, Peter Haddock, PhD, Max Jackson, BS, Joseph Tortora, MD, Alison Champagne, RN, Joseph Cusano, BS, Tara McLaughlin, PhD, Joseph Wagner, MD

Hartford Hospital, Hartford, CT, USA

Introduction: The criteria for adjuvant and salvage post-prostatectomy radiotherapy (ART and SRT, respectively) continue to be defined. 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, or (ii) Early SRT: rising PSA < 0.2 mg/mL or (iii) Traditional SRT: PSA ≥ 0.2 mg/mL prior to RT. Secondary recurrence was defined as a confirmed PSA ≥ 0.2 mg/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 = 0.021). Median time (in years) between surgery and last RT 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 = 0.021). 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.

P29

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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1Yale School of Medicine, New Haven, CT, USA; 2Tulane University, New Orleans, LA, USA

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 GG2 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 (72.3%) 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 FH-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). Conclusion: 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.

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

Table 1: Univariable and multivariable results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariable</th>
<th>Multivariable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>0.07</td>
<td>1.01</td>
</tr>
<tr>
<td>FH-RADS 4-5 vs 2-3</td>
<td>2.89</td>
<td>1.14</td>
</tr>
<tr>
<td>PSA density (per 0.1 unit)</td>
<td>1.83</td>
<td>1.49</td>
</tr>
</tbody>
</table>

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

3D-FUS (12.5%) 3.27 1.36-7.86 8.08 0.20 1.14 2.30 0.02