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Widespread Use of Multiparametric MRI in an Active Surveillance Cohort Results in Earlier Identification and Treatment of Clinically Significant Prostate Cancer

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Introduction: Multiparametric MRI (mpMRI) has led to improved detection of clinically significant prostate cancer and is now increasingly used in active surveillance (AS) patients. However, most AS cohorts in the literature were described prior to widespread use of mpMRI. Our investigation compares outcomes in AS in the pre- and post-MRI era at our institution.

Materials & Methods: We used an institutional database of 1291 men who started AS between September 1996 to December 2016. The cohort was divided into pre- and post-MRI era with the cutoff in July 2014, when mpMRI was routinely incorporated into our AS protocol. Clinical outcomes were compared using Wilcoxon Rank Sum and Chi-square tests. Treatment-free survival was analyzed using Kaplan-Meier plots. A multivariable Cox regression analysis was performed to control for baseline characteristics.

Results: In total, 276 men were included in the MRI era versus 1015 in the pre-MRI era. There was no significant difference in baseline PSA (p = 0.28) or Gleason Score (GS) (p = 0.21). Men in the MRI era were more likely to discontinue AS (Figure 1) and had a shorter time to treatment (2.5 vs. 5.9 years, P < 0.001). At 2 years, 18% of men in the MRI era had undergone treatment as compared 10% in the pre-MRI era. On multivariable analysis, men in the MRI era experienced earlier disease reclassification even after controlling for baseline characteristics (P = 0.003).

Conclusions: With widespread utilization of mpMRI, patients on AS are treated earlier. However, further follow up will be needed to see if this earlier identification and treatment of clinically significant disease ultimately results in a plateau in long-term treatment free survival.

Identifying Gene Expression to Predict Biochemical Recurrence Following Radical Prostatectomy

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Introduction: Identification of novel biomarkers associated with high risk prostate cancer or biochemical recurrence can drive improvement in detection, prognosis, and treatment. The current understanding of prostate cancer genomes is still emerging, and studies can be limited by small sample sizes and sparse clinical follow-up data. We utilized a large sample of prostate specimens to identify gene expression to predict biochemical recurrence following radical prostatectomy.

Materials & Methods: Between 2008 and 2011, patients undergoing radical prostatectomy at Hartford Hospital were consented to submit specimens for whole genome gene expression as part of the Total Cancer Care Consortium. RNA isolated from formalin-fixed paraffin-embedded prostates was hybridized to a custom Affymetrix microarray. Regularized (LASSO) Cox regression was performed with cross-validation to identify a gene expression signature that improves risk prediction. Recurrence was defined as post-operative PSA > 0.2 ng/mL or triggered salvage treatment. Model performance was assessed using time-dependent ROC curves (with area under the curve, AUC) and survival plots.

Results: Pre- and post-operative PSA data were available for 606 prostate specimens. Using the LASSO model, a 5 gene signature was identified that independently predicted biochemical recurrence above Gleason grade and tumor stage. The time-dependent ROC AUC for the 5 gene signature with Gleason grade and tumor stage was 0.866 compared to an AUC of 0.767 for Gleason grade and tumor stage alone (first figure below). Patients stratified into low and high risk groups based on the predictive model score displayed significant differences in their recurrence-free survival curves (second figure below). The predictive model was subsequently validated on two independent gene expression data sets. The model included genes (RHOU, MTX2, and ERP44) that have previously been implicated in prostate cancer biology.

Conclusions: Our unique 5 gene signature panel can improve prediction of biochemical recurrence over the use of classical pathological hallmarks alone. Further research should validate the 5 gene signature in more specific sub-populations of prostate cancer patients, including those with earlier biochemical recurrence.
ARCHES — Efficacy of Androgen Deprivation Therapy with Enzalutamide or Placebo in Metastatic Hormone-Sensitive Prostate Cancer: Prostate-Specific Antigen Results

**Introduction:** Potent androgen receptor inhibitor enzalutamide (ENZA) provides benefit in men with castration-resistant prostate cancer (CRPC). ARCHES, a multinational, double-blind, placebo (PBO)-controlled, phase 3 study (NCT02679996), examined the efficacy of ENZA with androgen deprivation therapy (ADT) in men with metastatic hormone-sensitive prostate cancer (mHSPC). As an important marker of prostate cancer, here we report prostate-specific antigen (PSA) results for ARCHES.

**Materials & Methods:** Patients (pts) with mHSPC were randomized 1:1 to ENZA (160 mg/day) + ADT or PBO + ADT, stratified by disease volume and prior docetaxel. Up to 3 months of ADT (≤ 6 months if with docetaxel), with no radiographic disease progression or rising PSA levels prior to day 1. PSA at initial diagnosis was not collected. Baseline PSA prior to study entry may reflect treatment prior to study entry. The primary endpoint was radiographic progression-free survival (rPFS) [scans assessed centrally] or death within 24 weeks of treatment discontinuation. Prespecified analyses included rPFS (overall and by baseline PSA levels), time to PSA progression, time to castration resistance, PSA undetectable rate, and PSA reduction from baseline. Treatment continued until disease progression or unacceptable toxicity.

**Results:** 1181 pts were randomized (ENZA + ADT, n = 574; PBO + ADT, n = 576). Baseline characteristics were balanced between groups; 91% had prior ADT. Overall median baseline PSA level was 5.21 ng/mL; median follow-up was 14.4 months. ENZA + ADT significantly improved time to PSA progression and time to castration resistance. The proportions of pts with undetectable PSA or a PSA reduction of ≥ 50% or ≥ 90% from baseline during the study were higher with ENZA + ADT. Adverse events were reported in 85.1% of ENZA plus ADT pts vs. 89.5% of PBO + ADT pts, with no unexpected adverse events.

**Conclusions:** ENZA + ADT significantly improved rPFS vs PBO + ADT in pts with mHSPC, regardless of baseline PSA level, suggesting the limitation of baseline PSA as a prognostic factor in this population, in which most pts received prior ADT. However, ENZA + ADT significantly improved PSA-related efficacy endpoints. Preliminary safety analysis appears consistent with the safety profile of ENZA in previous CRPC clinical trials.

**The PROSPER Trial: Prostate-Specific Antigen (PSA)- and Chemotherapy-Related Endpoints in Patients with Nonmetastatic Castration-Resistant Prostate Cancer Treated With Enzalutamide**

**Introduction:** Men with nonmetastatic castration-resistant prostate cancer (nmCRPC) are at high risk of developing metastatic CRPC (mCRPC). In previous clinical trials, enzalutamide improved overall survival and radiographic progression-free survival in men with mCRPC. The phase 3 PROSPER trial was designed with a primary endpoint of metastasis-free survival (MFS).

**Materials & Methods:** PROSPER is a randomized, double-blind, placebo-controlled, phase 3 multinational study (NCT02003924) in patients with asymptomatic mCRPC. PSA doubling time ≤ 30 months and PSA ≥ 2 ng/mL at screening. Patients were randomized 2:1 to enzalutamide 160 mg/day or placebo. The primary endpoint was MFS. Secondary endpoints included time to PSA progression, time to first use of new antineoplastic therapy, overall survival, time to first use of cytotoxic chemotherapy, chemotherapy-free disease-specific survival (CFDS), chemotherapy-free survival (CFS), and safety.

**Results:** In 1401 patients, baseline characteristics were well balanced between treatment arms (Table). Enzalutamide significantly reduced the risk of metastasis or death (hazard ratio [HR], 0.29; P < .0001), time to PSA progression (HR, 0.07; P < .0001), and time to first use of new antineoplastic therapy (HR, 0.21; P < .0001) vs. placebo. Enzalutamide treatment also significantly delayed the time to first use of cytotoxic chemotherapy, and prolonged CFDS and CFS (Table). A significantly greater proportion of patients receiving enzalutamide than those receiving placebo had confirmed PSA responses of ≥ 50% decline, of ≥ 90% decline, and a decline to undetectable levels below the limit of quantification (Table). Median treatment duration was 19.4 vs. 11.1 months with enzalutamide vs. placebo, respectively. Adverse events (AEs) were higher with enzalutamide than with placebo (any grade, 87% vs. 77%; grade ≥ 3, 31% vs. 23%; serious, 24% vs. 18%, respectively). 10% vs. 8% of men receiving enzalutamide vs. placebo, respectively, experienced an AE that caused treatment discontinuation.

**Conclusions:** For patients with nmCRPC and a rapidly rising PSA, enzalutamide resulted in a clinically meaningful and statistically significant reduction in developing mCRPC, as well as an increase in time to PSA progression and time to first use of new antineoplastic therapy (including chemotherapy), CFDS, and CFS. PSA responses were significantly greater in patients receiving enzalutamide than in those receiving placebo. AEs were generally consistent with the established safety profile of enzalutamide.
Multimodal Therapy for Patients with High-Grade, High-Risk Prostate Cancer with Long-Term Follow-up

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Materials & Methods: From 1990-2012, 82 patients with clinically organ-confined prostate cancer underwent multimodal therapy (MMT) consisting of neoadjuvant hormonal ablation followed by surgery and postoperative radiation with greater than 20-year follow-up.

Results: The MMT protocol was well tolerated in all 82 patients with no treatment-related discontinuation of therapy. Final surgical pathology revealed stage T3b T4 N0 M0 in 58/82 (71%), nodal involvement in 7/82 (9%). Distant metastatic disease was identified in 10/82 patients (12%). Cancer-specific survival for patients undergoing MMT at 10, 15 and 20 years was 78/82 (95%) and 77/82 (94%) respectively. Overall survival at 10, 15 and 20 years was 68/82 (83%) and 66/82 (80%) and 60/82 (73%) respectively. Biochemical recurrence was lower at 61/82 (74%) and 51/82 (62%) and 35/82 (43%) at 10, 15 and 20 years respectively. Of 82/82 (100%) patients with Gleason 8-10 cancers, cancer-specific survival for patients undergoing MMT at 10, 15 and 20 years was 54/82 (65%). Overall survival at 10, 15 and 20 years was 54/82 (83%) and 46/82 (59%) and 42/82 (52%) respectively. Freedom from biochemical recurrence was at 38/58 (66%), 33/58 (56%) and 24/58 (41%) at 10, 15 and 20 years respectively.

Conclusions: The MMT protocol for high-risk prostate cancer consisting of neoadjuvant hormonal therapy followed by surgery and post-operative radiation is an effective treatment strategy with excellent cancer-specific survival. Recurrence occurring primarily as a rising PSA as opposed to distant metastatic disease suggests limited morbidity as well among patients treated with this protocol.

Clinically-Insignificant Prostate Cancer (Gleason Grade Group 1) or Benign Pathology in PI-RADS 5 Lesions with Extraprostatic Extension on Multi-Parametric MRI

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Introduction: The clinical utility of extraprostatic extension (EPE) on multi-parametric magnetic resonance imaging (mpMRI) is unknown. We sought to investigate the rate of benign or clinically insignificant prostate cancer (cIPCa) in biopsy of PI-RADS 5 lesions with EPE, and to identify clinical and imaging parameters associated with these findings.

Materials & Methods: We retrospectively queried our institutional mpMRI-ultrasound fusion (targeted) biopsy database to identify patients with EPE detected on mpMRI along with a PI-RADS 5 lesion who underwent targeted biopsy between October 2014 and April 2018. mpMRI findings were assessed, including prostate and lesion volumes, and zonal location of the lesion (peripheral or transition). We measured the rate of benign or clinically insignificant cIPCa, defined as Gleason grade group (GG) 1, detected on the targeted biopsy of the lesion with EPE. Logistic regression and receiver operating characteristics curves with an area under the curve (AUC) were used to assess the ability of clinical and mpMRI characteristics to predict GG ≥ 2 prostate cancer on the targeted biopsy of those lesions.

Results: Of 300 PI-RADS 5 lesions that underwent targeted biopsy during the study period, 117 (39%) were associated with EPE on mpMRI. On targeted biopsy of those 117 lesions, 5 (4.3%), 14 (12%), and 98 (83.7%) lesions harbored benign pathohgy, GG1, and GG ≥ 2 prostate cancer, respectively. Benign or cIPCa was detected in 32% of lesions in the first quartile of prostate-specific antigen (PSA) density (< 0.13), 16.7% of lesions in the interquartile range of PSA density (0.13-0.30) and 3.1% of lesions with PSA density >0.30 (p = 0.003). Using a threshold of 0.13, PSA density was 82.6% sensitive and 42.1% specific for detecting GG ≥ 2 prostate cancer on PI-RADS 5 lesions with EPE. On multivariable analysis, PSA density (OR 2.5 per 0.1 decrease in unit, 95% CI 1.4:5.26, p = 0.02) was associated with an increased likelihood of benign or cIPCa in those lesions. Compared with lesion volume and PSA, PSA density had the highest discriminative ability for GG ≥ 2 prostate cancer in those lesions (AUC 0.71).

Conclusions: Clinically-insignificant findings (benign or cIPCa) were identified in a minority of PI-RADS 5 lesions with EPE. In this setting, patients with PSA density <0.13 could be more frequently detected with cIPCa on the targeted biopsy.
Clinical Risk Based Associations of Lymph Node Dissection and Detection Yield among Men Treated with Radical Prostatectomy for Prostate Cancer
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Introduction: Pelvic lymph node dissection (PLND) is recommended for men at risk for lymph node involvement at the time of radical prostatectomy (RP) yet is frequently omitted. We aimed to examine the probability of PLND based on clinical risk status, and to evaluate the impact of increasing lymph node yield on cancer detection rate across risk strata, with particular interest at the extremes of risk.

Materials & Methods: We queried the National Cancer Database to identify patients with clinically localized PCa who underwent RP as their primary treatment from 2004 to 2014. We extracted clinical and sociodemographic variables. Risk status was assessed using the Cancer of the Prostate Risk Assessment (CAPRA) score. We fit conditional logistic regression models to estimate likelihood of PLND and incremental value of increasing lymph node count by risk strata. As a secondary measure, we evaluated the association of PLND and increasing lymph node count with 30-day readmission.

Results: We identified 698,726 men with PCa treated with RP including 380,201 (54.4%) with PLND. Mean age at diagnosis was 62.6. PLND was omitted (Nxs) in 56.1%, 31.4%, and 24.7% of patients with low, intermediate, and high CAPRA-risk disease, respectively. Adjusting for clinical and pathologic factors, treatment in a community versus academic hospital (OR = 1.62, 95% CI 1.59-1.66, P < 0.001) and black race (OR = 1.13, 95% CI 1.09-1.17, P = 0.01) was associated with pNx status. Increasing lymph node count was independently associated with greater likelihood of detection of lymph node metastasis in all risk strata. In patients at the lowest spectrum of risk (CAPRA-0), greater reported lymph node yield remained associated with detection of metastasis (relative to 0-10, 11-20 nodes: OR: 3.28, 95% CI 3.06-3.53, P < 0.001; 20-30 nodes: OR: 5.77, 95% CI 5.16-6.45, P <0.001; > 30 nodes OR: 7.90, 95% CI 6.56-9.51, P < 0.001). In a multivariable model adjusted for clinical, pathologic, and demographic variables, reported lymph node counts greater than 30 were independently associated with detection of metastasis (relative to 0-10, 11-20 nodes: OR: 3.28, 95% CI: 1.02-2.25, P = 0.03).

Conclusions: Among men treated in the United States at Commission on Cancer accredited hospitals, PLND continues to be omitted in a substantial proportion of intermediate and high risk patients. Increasing lymph node yield was associated with greater odds of detecting lymph node metastasis in all groups of patients, including those at the lowest level of risk by clinical criteria.

### Table 1. Multiple variable model including predictors for N1 disease after RP + PLND

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<th>Variable</th>
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Impact of Second Generation Neoadjuvant Hormone Therapy on Radical Prostatectomy Outcomes
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Introduction: Phase II trials have shown that intense neoadjuvant androgen deprivation therapy (NeoADT) with abiraterone or enzalutamide combined with luteinizing hormone-releasing hormone (LHRH) analogues demonstrate favourable pathologic response in prostate cancer. There are currently phase III trials underway. However, the impact on surgical complication rates as well as the impact of therapeutic response on complication rates is unknown. The objective of this study is to assess complication rates and functional outcomes in patients who received NeoADT followed by radical prostatectomy (RP).

Materials & Methods: Between November 2014 and August 2018, 90 men with intermediate or high risk prostate cancer were enrolled in two clinical trials involving 6 months of intense NeoADT followed by RP (Figure 1). Data on surgical complications, pathology and self-reported functional outcomes were collected. Self-administered SHIM and EPIC questionnaires were used to assess post-operative erectile function. Comparison between nerve-sparing (NS) groups were performed using Fisher’s exact tests.

Results: Mean surgery time was 173 ± 42.2 minutes. Post-operative length of stay was 1 day in 87.8% of cases. Fifteen men (14.4%) experienced a post-operative complication; all except one were minor (≤ Clavien Grade II). We were able to perform bilateral or unilateral NS procedure in 24 (27%) and 36 (41%) cases respectively. NS did not result in higher positive margin rates (NS vs. non-NS, 13.3% vs. 13.8%, P = 1.0) possibly related to patient selection. Prior to surgery, 38% of men reported potency, 5% used assistance and 20% had erectile dysfunction. Pre-operative potency status was unknown for 37% of our cohort. At median time of 1-year post-RP, 24% of those who underwent unilateral or bilateral NS surgery regained mild to moderate erectile function on self-reported questionnaires, compared to 0% in those who did not receive NS surgery.

As for urinary incontinence, 62.7% (52/83) of men reported using zero pads per day at 6 months, and this increased to 71.9% (46/64) at 1 year. Additionally, 81% and 97% reported using one pad per day or less at 6 months and 1 year respectively. This was not significantly different between NS groups (P = 0.57).

Among ypT0 patients, 82% received NS surgery. 70% reported mild to moderate erectile function on self-reported questionnaires, compared to 0% in those who did not receive NS surgery.

Conclusions: Post-operative complication rates were low, even after aggressive NeoADT. Patients with complete pathologic response to NeoADT were more likely to receive NS surgery. Heterogeneity in patient selection.

Figure 1: Neoadjuvant Androgen Deprivation Therapy Protocol
Introduction: Patients residing in rural regions have comparatively worse outcomes for many cancers. However, there is less known about treatment and outcome for patients with urologic cancers. The objective of this study is to evaluate differences in treatments and outcomes among patients with urologic malignancies when coming from rural compared to metropolitan communities using national, population-level data.

Materials & Methods: We queried the Surveillance, Epidemiology and End-Results database to identify patients with urological cancers from 1973 to 2015. We compiled patient clinical, demographic, and outcome data, including rurality at the county level. Rural counties is defined as those with >50% population living in rural areas. We evaluated the association of rurality with treatment received, presence of advanced disease, and cancer-specific death using descriptive statistics and Cox proportional hazard models.

Results: We identified 992,536 patients including those with Kidney (112,477), Bladder (208,230), Prostate (637,005), penile (6,297) and testis cancer (28,527). Among all patients, 898,050 (90.4%) were male and 64,992 (6.55%) lived in rural counties. Overall, patients living in rural communities were more frequently of white race (97.1% vs. 82.4%) vs. urban counterpart. Patients residing in rural counties were less likely to undergo definitive treatment with surgery for stage 1 or 2 disease (p < 0.001). In multivariable Cox regression, rural status was associated with poorer cancer-specific survival for kidney cancer but was not seen in other genitourinary malignancies,

Conclusions: There are notable differences in cancer incidence, treatment and outcome among patients with urologic malignancies when coming from rural compared to metropolitan communities using national, population-level data.

Association between Tumor Multifocality on Multi-parametric MRI and Detection Rate of Clinically-Significant Prostate Cancer in Lesions with Prostate Imaging Reporting and Data System (PI-RADS) Score 4

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Introduction: Magnetic resonance imaging (MRI)/ultrasound fusion targeted biopsy of a lesion with prostate imaging reporting and data system (PI-RADS) score 4 (P4) is associated with a high positive predictive value (~45%) for clinically-significant prostate cancer. However, it is unknown if multifocality on multi-parametric MRI (mpMRI) could further risk stratify P4 lesions. We sought to assess the detection of the clinically-significant prostate cancer in P4 lesions stratified by tumor multifocality on mpMRI.

Materials & Methods: Using the MRI-ultrasound fusion prostate biopsy databases at two institutions, we identified patients with at least one P1-RADS 4 (P4) lesion on mpMRI who underwent targeted biopsy of those lesions. Each patient meeting the above criteria was grouped into one of four lesion MRI classifications - group 1 (an index lesion with P4 and an additional P4-RADS 2 or 3 lesion), group 2 (single lesion with P4), group 3 (two or more P4 lesions), or group 4 (a lesion with P4 and an index lesion with P4RADS 5). The rate of grade group (GG) ≥ 2 pathology on targeted biopsy of the P4 lesions was compared between the MRI classification groups. The clinical and radiological factors associated with finding GG ≥ 2 in P4 lesions were also evaluated.

Results: In a combined cohort, 645 patients with at least one lesion with P4 were identified. The studied MRI classification groups 1, 2, 3, and 4 included 184, 267, 112, and 82 men, respectively. For the combined cohorts, the rate of GG ≥ 2 biopsy pathology in the groups 1, 2, 3, and 4 was 21.7%, 36.3%, 49.1%, and 42.7%, respectively (p < 0.001, Figure 1). On multivariable analysis, age (OR 1.06, 95%CI 1.03-1.09, p < 0.001), clinical T2 (OR 1.39, 95%CI 1.03-1.87, p = 0.03), PSA density (OR 1.43 per 0.1 unit, 95%CI 1.22-1.67, p < 0.001), peripheral zone lesion (OR 1.62, 95%CI 1.01-2.59, p = 0.04), and MRI lesion group (group 2 vs. 1, OR 1.93, 95%CI 1.21-3.08, p = 0.006; and group 3 vs. 1, OR 3.28, 95%CI 1.86-5.72, p < 0.001) were significantly associated with the risk of GG ≥ 2 pathology on targeted biopsy of the P4 lesion.

Conclusions: Our data indicated that the rate of clinically-significant prostate cancer detection in P4 lesions located within peripheral zone might be increased with the presence of additional high-grade lesions on imaging (P4-RADS 4 or 5). By contrast, men with a P4 lesion and an additional low-grade lesion (P4-RADS 2 or 3) showed the lowest rate of aggressive pathology. Overall, detection of clinically-significant prostate cancer on biopsy of the P4 lesions might be influenced by tumor multifocality on imaging.

*Max K. Willacher Award Eligible
Impact of MRI-Ultrasound Fusion Prostate Biopsy on Pathologic Downgrading During Radical Prostatectomy

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Introduction: The discordance between Gleason grade at systematic prostate biopsy and radical prostatectomy is well established. The integration of MRI-ultrasound fusion improves the detection of clinically significant prostate cancer, but it is unknown if this approach over-estimates risk by directly sampling tumors. Therefore, we aimed to evaluate the concordance of MR fusion biopsy approaches and radical prostatectomy (RP) pathology.

Materials & Methods: We conducted a retrospective review of an institutional database of men undergoing MRI/US fusion biopsy between February 2013 and March 2018. We compared Gleason grade group (GG) of systematic 12-core, MRI/US targeted, and combined biopsy approaches with whole gland prostatectomy pathology. We evaluated rates of downgrading in the entire cohort, and among subsets of intermediate and high-risk cancer. Binomial logistic regression was utilized to identify clinical, radiologic, and pathologic features associated with downgrading of combined MRI/US fusion prostate biopsy pathology on radical prostatectomy.

Results: We identified 192 men who underwent MRI/US fusion biopsy and were treated with RP. The overall rate of downgrading at RP was 33%, including 29% (n = 55) based on Gleason grade from targeted biopsy, and 13% (n = 25) from systematic biopsy (P = 0.001). Among patients with GG3-4 biopsies, both were downgraded to GG2 prostate cancer on final prostatectomy pathology (P ≤ 0.001). There were higher rates of downgrading when regarding targeted biopsy (34%) compared to systematic biopsy (17%) (P < 0.001). On multivariable logistic regression analysis adjusted for clinical, radiologic, and pathologic factors, targeted biopsy Gleason (GG3 vs. GG1) remained the only variable significantly associated with downgrading on final pathology (P < 0.05).

Conclusions: Although MRI/US fusion biopsy improves detection of high grade cancer, a substantial proportion of patients were downgraded at radical prostatectomy. Further investigation is warranted to improve the concordance between biopsy and final pathology.

Active Surveillance for Localized Prostate Cancer after Long Term Follow Up

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Introduction: Active surveillance (AS) is the standard of care for low-risk prostate cancer as detailed in the EAU, AUA, and NCCN guidelines. The ProtecT trial has shown survival outcomes for low and intermediate risk prostate cancer to be excellent. Various criteria have been used to define men who are candidates for AS protocols, with some more restrictive than others. The purpose of this study was to determine whether men meeting more expansive selection criteria were less likely to remain on surveillance.

Materials & Methods: We retrospectively reviewed men monitored on AS by a single urologist at our institution between January 1990 and August 2018. We stratified men into “strict active surveillance” (SAS) and “non-strict active surveillance” (NSAS) categories. SAS was defined as Gleason 6 or less, PSA < 10 ng/mL, I2 positive biopsy cores, no core with >50% cancer, and PSA density (PSAD) < 0.15 ng/mL/g, based on the NCCN definition of “very low risk” prostate cancer. We analyzed progression to treatment, time to treatment, and overall duration of follow-up.

Results: We identified 155 men who underwent AS at our institution. We excluded men seen as second opinions or followed < 1 year. Of these, 100 men met SAS criteria while 55 did not meet (NSAS). Mean age at diagnosis was 65.6 years for the SAS group and 68.3 years for the NSAS group. Virtually all men were healthy with a mean Charlson Comorbidity Index of 2.95. Median duration of follow-up was 94 months. Men failed to meet SAS criteria primarily because of PSA > 10 (47%). In the SAS and NSAS groups, 32 men (52%) and 25 men (45%) ultimately underwent treatment. The median time to treatment was 46 and 39 months for the SAS group and NSAS group respectively. The median duration of follow-up was 90 months for the SAS group and 97 months for the NSAS group. Gleason upgrading was the most likely reason for progression in the SAS group (95%), while a rising serum PSA was the most likely reason for progression in the NSAS group (96%). The most common treatment modality was radical prostatectomy (RP) in the SAS group (66%), while androgen deprivation therapy (ADT) (44%) was the most common in the NSAS group (p = 0.007). External beam radiation therapy was the second most common treatment for the SAS group (25%) and RP was the most common treatment in the NSAS group (32%).

Conclusions: This analysis suggests that men meeting strict criteria for active surveillance are usually younger and progress to treatment because of a rising Gleason grade, while men undergoing active surveillance with more expansive selection criteria are often older and select hormonal therapy with evidence of disease progression.
Initial Experience of MRI-Fusion Biopsy in the Community Setting
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Introduction: The expanding role of MRI-fusion biopsy (FB) is well documented, however the reproducibility of outcomes during the initial experience of FB in the non-academic (NA) is unknown. We sought to determine if there are differences in the yield of clinically significant cancer on FB at an academic versus a NA setting.

Materials & Methods: We compared fusion-directed and template-directed biopsy cores for the first consecutive 125 FB patients at an academic to the first 125 consecutive FB patients at a NA setting. All patients underwent magnetic resonance imaging and were scored using PI-RADS v2. Specimens were graded according to the International Society of Urological Pathology (ISUP) criteria for Grade Group (GG). Clinically significant prostate cancer (csPCa) was defined as GG2. Patients at the NA setting were matched to academic setting controls using Mahalanobis-distance kernel matching. The following covariates were used: Prior negative biopsy, active surveillance, PSA density, abnormal DRE, family history of prostate cancer, age, use of 5-alpha reductase inhibitor, BMI, and composite AUA-SS. Patients with pre-existing csPCa or prior treatment were excluded from analysis. Standard errors and the 95% CI were calculated from 3,000 bootstrap samples to determine the effect of NA setting on FB outcomes.

Results: Of the 250 patients included, 219 patients were matched. There were significant baseline differences in frequency of prior negative biopsy and BMI. Matching reduced the difference in means for all covariates. Balance was confirmed by reduction in standardized mean differences and variance ratios (Fig. 1). There was no significant effect of NA setting on the proportion of FB-detected csPCa, the proportion of template-detected csPCa, the rate of upgrading from prior biopsy results, or in the proportion of csPCa missed by fusion-directed vs template-directed cores (Table 1). On average, lower PI-RADS scores were associated with lower PI-RADS ratings in the NA setting and template biopsies yielded lower GG diagnoses, however the maximum composite GG was not significantly different by practice setting (Figures 2, 3).

Conclusions: There was no significant effect of practice setting on the detection of clinically significant cancer in a sample-matched analysis of the first consecutive patients to undergo fusion biopsy.

MRI Membranous Urethral Length Does Not Predict Early Return to Continence Following Robotic-Assisted Radical Prostatectomy
Liz B. Wang, MD, Hersh H. Bendre, BS, David S. Wang, MD, Richard K. Bahayan, MD, Borna N. Bloch, MD, Mark H. Katz, MD
Boston Medical Center, Boston, MA

Introduction: Urinary incontinence following robotic-assisted radical prostatectomy (RARP) is a well-known complication, yet the mechanism of post-RARP incontinence is poorly understood. The urethral sphincter length may be an important predictor of recovery of continence and time to continence. The purpose of this study is to determine if membranous urethral length (MUL), measured via pre-operative T2-weighted magnetic resonance imaging (MRI), can predict time to continence post-RARP.

Materials & Methods: We performed a single-center retrospective cohort study of patients who underwent a RARP at our institution from 2013 to 2017. A total of 211 patients were identified, of which 101 had a pre-operative MRI. Of the 101 patients, 2 were excluded (lost to follow-up), and the remaining 99 were included.

The definition of continence and time to early continence were analyzed using 2 patient cohorts: Cohort one defined as 0 pads and early vs. late continence as ≤ 3 months vs. > 3 months (Table 1). Cohort two defined continence as ≥ 1 pads and early vs. late continence as ≤ 2 months vs. > 2 months. Univariate analysis was conducted using analysis of variance (ANOVA) for continuous variables and chi-squared test (N > 5) or Fisher’s exact test (N ≤ 5) for categorical variables. Significance was determined with p = 0.05.

Results: For cohort one, continence was achieved in 84 (85%) patients at the most recent follow-up visit. Mean time to continence was 3.93 months. Of the patients who were continent, 38 (45%) patients achieved early continence. Mean MUL was 13.3 mm for the early group and 13.7 mm for the late group, which was not statistically significant (p = 0.60). On bivariate analysis, all factors were independently associated with early return to continence (mean 32.8 grams for early vs. 38.2 grams for late, p = 0.04). Other factors such as age, race, BMI, history of diabetes, MRI findings, intra-operative nerve sparing, and lymph node dissection were also included. However, none were independently associated with early return to continence. For cohort two, MUL was again not predictive of early continence (p = 0.96). Higher BMI (p = 0.049) was associated with early return to continence. MRI finding of extension into the seminal vesicles (p = 0.02), and higher pathologic stage (p = 0.025) were both predictive of late return to continence. On multivariate analysis, none of the factors were associated with early return to continence.

Conclusions: The MUL was not a significant predictor of early return to continence after RARP in either cohort. However, smaller prostate size was correlated with early return to continence. Extension of disease into the seminal vesicles and higher pathologic stage may be associated with late return to continence. This knowledge may be useful to clinicians when counseling patients in regards to expectations for return to continence post-operatively.

Scientific Session II: Prostate II
Combination of Multiparametric MRI-Ultrasound Fusion and Systematic Prostate Biopsy Results in Optimal Concordance with Final Surgical Pathology
Alice Yu, MD, Tanner Yamany, MD, Nawar Hanna, MD, Eduoard Nicaise, BS, Arumarka Mottahed, MD, Mukebi Harisinghani, MD, Chin-Lee Wu, MD, Douglas Dahl, MD, Matthew Wszolek, MD, Michael Blute, MD, Adam Feldman, MD
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Introduction: Accurately predicting the Gleason score (GS) on radical prostatectomy (RP) with prostate biopsy is important for risk stratification and selecting patients for active surveillance. Multiparametric MRI (mpMRI) is useful for detecting clinically significant disease, but the exact concordance of GS between fusion biopsy and RP has not been well described in a clinical practice setting. The objective of this study is to assess whether systematic, targeted or combination (targeted + systematic) biopsy has better concordance with final surgical pathology.

Materials & Methods: In our institutional mpMRI-ultrasound fusion biopsy database of 570 men, 53 men who underwent targeted and systematic biopsy followed by RP GS on targeted, systematic and combination (targeted and systematic) biopsy were compared with GS on RP, and concordance was recorded. Concordance rates between biopsy types were compared with the McNemar test. Proportion of GS upgrade or downgrade at time of RP was also evaluated. Results: Concordance, upgrade, and downgrade rates are reported in Figure 1. Combination biopsy was superior to both systematic [Risk Ratio (RR) 0.25, 95% confidence interval (CI) 1.08-1.44, P = .003] and targeted biopsy (RR 1.22, 95% CI 1.08-1.37, P = .002) for predicting concordance with surgical pathology. There was no significant difference in concordance rates between systematic and targeted biopsy alone (P = .90). The relative risk of upgrade on surgical pathology with combination biopsy was significantly lower when compared to systematic (RR 0.56, 95% CI 0.48-0.70, P < .001) or targeted biopsy alone (RR 0.67, 95% CI 0.57-0.79, P < .001).

Conclusions: Combination (targeted and systematic) biopsy is associated with the highest concordance rate between biopsy and RP when compared with systematic or targeted alone biopsy. When the pathology is non-concordant, standard and targeted-alone biopsy are more likely to underestimate final RP pathology. These data support using a combination of targeted and systematic biopsy as standard practice when doing fusion biopsy.

Does Post Prostatectomy Decipher Score Predict PSA Recurrence and Impact Care? Christopher White, MD1, PhD2, Tara McLaughlin, PhD3, Joseph Tortora, MS, Kevin Pinto, BS, Alkay Gangakhedkar, BS, Alison Champagne, MPH1, Joseph Wagner, MD1
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Introduction: Decipher score (GeminiDe Biosciences) is a genomic classifier that predicts the 5-year risk of metastasis after radical prostatectomy (RP). Decipher score may also be used to guide the timing of adjuvant vs. salvage radiotherapy. We examined the ability of Decipher to predict biochemical recurrence (BCR) and to impact clinical decision making.

Materials & Methods: We identified post-RP Decipher tests ordered for adverse pathology between 3/1/14 and 9/30/18. BCR was defined as a PSA > 0.2 ng/mL. Decipher score was analyzed as both a continuous and categorical variable (high ≥60, low/intermediate <60). Kaplan-Meier analysis was used to examine the relationship between Decipher score and time to BCR (in months). Multivariate analysis with Cox Regression analyzed the relationships between Decipher score, pre-op PSA, pathologic Gleason, margin status and stage. We then focused on a subset of men with early BCR (eBCR, PSA >32 and <200 ng/mL) and categorized them into low/intermediate vs. high-risk Decipher score. Logistic regression was used to determine if those with high scores were more likely to get salvage treatment.

Results: A total of 208 patients underwent RP for prostate cancer with subsequent Decipher testing during the study period; 10 had no PSA follow-up. Of the 198 analyzed, 62%, 38% had high and low/intermediate risk Decipher scores, respectively and 51% had a BCR. The sample was characterized by unfavorable pathology. Over half (59.6%) had Gleason Grade Group 4+3 or higher and 70.7% had stage 3 disease or higher. Median (IQR) follow-up was 12.0 (6.6, 19.8) months. Decipher score was significantly associated with time to BCR (p = .02, Figure 1) but was not an independent predictor in multivariate analysis (p = .282). Among the 67 men with eBCR, those with high-risk Decipher scores were more likely to receive salvage treatment (59.3%) than those with non-high-risk scores (20%, p = .001). A significant independent predictor of higher PSA, Gleason Grade Group, margin status and stage (OR = 4.20, p = .03).

Conclusions: High decipher score is a significant predictor of BCR in this population of men with unfavorable pathology and is being incorporated into patient counseling to inform treatment decisions. Further research should focus on long-term outcomes for patients for whom Decipher score was used to guide treatment strategy vs. those for whom it wasn’t.
Immediate Preoperative Blood Glucose and Hemoglobin A1C Levels Are Not Predictive of Post-Operative Infections in Diabetic Men Undergoing Penile Prosthesis Placement

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Introduction: Recent reports have suggested that pre-operative diabetic control may be predictive of infection rates following penile prosthesis (IP) implantation. In this study, we sought to investigate whether immediate pre-operative serum blood glucose (PBG) levels were associated with PP infection rates in diabetic patients.

Methods & Materials: We conducted a retrospective review of 716 diabetic patients undergoing primary IP (inflatable and malleable) implantation from April 2003 to May 2018 across 15 institutions. PBG levels (within 6 hours of surgery) and Hemoglobin A1C (HbA1c) levels were recorded for each patient, along with clinical and demographic variables. Patients had a median follow up time of 7 months (range 0-157). Measured outcomes were rates of post-operative infection, revision and explantation. The impact of pre-operative glucose and HbA1c on post-operative infection rates was assessed using ANOVA and univariate analyses. The effects of age, diabetes type, diabetes related complications, body mass index, Charlson Comorbidity Index (CCI), history of immuno-suppression, previous radical prostatectomy, and PP type were adjusted for, using logistic regression models.

Results: Median age was 61 years (range 34-86). Median and mean pre-operative glucose levels were 134 mg/dL (range 54-344) and 143.3 mg/dL ± 45.9, respectively, and median and mean pre-operative HbA1c levels were 7.2% (range 4.8-15.2) and 7.3% ± 1.5, respectively. Most PP were inflatable (96.6%). Devices used were AMS 703 (42.3%), AMS Ambicor (0.1%), Coloplast Titan (35.5%), and Coloplast Genesis (1.3%). Surgical approach used was penoscrotal in 74.4%, subcoronal in 23.8%, and infrapubic in 1.8%. Post-operative infection, revision, and explantation rates were 3.8%, 5.9%, and 4.5%, respectively. There was no association between PBG levels and post-operative infection rates: continuous, p = 0.413; cut-off > 165 mg/dL, 75th percentile, p = 0.500; cut-off > 201 mg/dL, 90th percentile, p = 0.393. Additionally, there was no association between pre-operative HbA1c levels and post-operative infection rates: continuous, p = 0.430; cut-off > 6.5%, p = 0.611; cut-off > 8%, p = 0.241. Similarly, there were no associations between operation and revision rates with PBG levels (p = 0.567 and 0.537, respectively), nor with HbA1c levels (p = 0.194 and 0.165, respectively). On multivariate analysis, a higher CCI was a significant predictor of higher infection rates (p = 0.040).

Conclusions: In this large multi-institutional cohort of diabetic men undergoing PP implantation, neither PBG nor HbA1c were predictive of device infection. A higher CCI in diabetic patients predicts PP infection.
CUTTING THE CORD: A NATIONAL SURVEY ON UROLOGY RESIDENT VASECTOMY TRAINING

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Introduction: Vasectomy is one of the most common in office procedures performed by urologists. Vasectomy is generally performed under local anesthesia while the patient is awake in a urology clinic. This makes the procedure technically challenging and difficult to teach to urology residents. There has been limited research on resident training in vasectomy. Nguyen et al. demonstrated that supervised resident performance of in office vasectomy was safe and well tolerated by patients. To date, no other study on vasectomy training of urology residents exist. The aim of this study was to understand the current vasectomy training environment, including potential barriers to teaching this procedure.

Materials & Methods: An anonymous 18-question survey was e-mailed to the program coordinators of 135 ACGME accredited urology residencies in the United States. The survey was sent via SurveyMonkey and inquired about quantity, comfort and environment of vasectomy training in these programs as well as demographic data.

Results: Overall there were 115 residents respondents. Every AUA section and post-graduate year were represented. 65% of residents had performed ten or more vasectomies by the time they graduated from residency. Despite this, 69.7% of first year urology residents (Uro 1’s), 77% of Uro 2’s, 97.7% of Uro 3’s and 100% of Uro 4’s had performed <10 vasectomies. Additionally, 24.4% reported no training in pre and post op vasectomy counseling. A majority of the residents conducted vasectomies in the office versus the operating room. Despite this finding, a statistically significant percentage of resident respondents felt more comfortable performing vasectomies in the OR than in the office setting (89.6% vs. 66%, p = .001 ). Common barriers identified to vasectomy training are seen in Table 1. Overall, 76% of residents felt there was enough opportunity to perform vasectomies at their training program despite no formal vasectomy training program or simulation lab.

Conclusions: Despite the difficulty of teaching vasectomy in an office setting, a majority of residents feel comfortable doing an office vasectomy on their own. However, most urology residency programs have no formal training and residents are less comfortable performing vasectomies in the office when compared to the OR. Additionally, many residents receive no training on counseling. Barriers to training included volume, accessibility of the procedure and autonomy-all barriers that can be addressed at these institutions. Formal training programs in peri-operative counseling, vasectomy procedure and simulation lab could improve resident comfort and break down barriers to resident training.

2Nguyen CT, Hernandez AV, Gao T, Thomas AA, Jones JS. Office Based Vasectomy Can be Performed by Supervised Urological Residents With Patient Pain and Morbidity Comparable to Those of a Staff Surgeon.

MATERIALS & METHODS

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Introduction: The evaluation of Peyronie’s Disease (PD) relies on patient history and physical exam. The clinical assessment of plaque size and location on exam is qualitative, observer dependent and has been shown to be unreliable. Current AUA guidelines recommend an office intracorporal penile injection with or without penile color doppler ultrasound. Advanced imaging techniques play a limited role. Intracavernosal collagenase is the only FDA-approved medical treatment for PD. The benefit of this therapy is highly dependent upon pre-treatment evaluation and appropriate patient selection. Therapeutic benefit has been disappointing. Recent studies have demonstrated the utility for Computed Tomography Cavernosography (CTC) in the evaluation of penile anatomy and erectile dysfunction. Its use in the anatomic evaluation of PD has not been investigated or reported.

Materials & Methods: Men with documented PD underwent 3D CTC with concurrent intra-cavernosal injection (ICI). Patients were placed in the Philips IQon Spectral CT scanner and an injection of Trimix (papaverine 30 mg/cc, phentolamine 2 mg/cc, prostaglandin 20 mcg/cc) in the proximal base of the penis. The medication dose was determined by pre-existing erectile function. The dose was repeated until a 3 out of 4 erection was achieved (adequate for penetration) or the maximum dose (1cc) had been administered. A 20-gauge angio-catheter was inserted into the left subcoronal corpora after injection of lidocaine for local analgesia. The penis was then manually inflated using a 50% mixture of isosonicated contrast solution until maximum erection was achieved. 3D CT imaging was then obtained. A reversal dose of phenylephrine was administered if necessary, the catheter was removed, and a compressive dressing was placed. Images were processed using Philips software v4.7.5.43524.

Results: The procedure was uniformly well tolerated. Plaque size and location were underestimated by clinical assessment when compared to CTC. Extensive cavernosal disease was identified in locations inaccessible on physical exam. Precise measurement of the penile angulation in multiple planes was possible through three-dimensional software manipulation of the images. CTC revealed extensive fibrosis and/or atrophy of the underlying corpora cavernosa, identifying patients unlikely to respond to localized collagenase. In these cases, advanced imaging offered benefit in the process of patient counseling and therapeutic decision-making.

Conclusions: CTC is a valuable tool in the evaluation of Peyronie’s disease. CTC imaging provided enhanced pretreatment assessment of the location, size, and clinically unrecognized severity of disease. The procedure was well tolerated and demonstrated utility in clinical decision-making regarding disease management and patient education. Further prospective studies are needed to determine the role of CTC in the diagnosis and treatment of PD.
Adherence to the AUA Penile Prosthesis Antibiotic Prophylaxis Guidelines in Diabetic Patients is Associated with Significantly Higher Risks of Device Infection
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Introduction: The most devastating complication following penile prosthesis (PP) implantation is an infection requiring device explantation. Current AUA guidelines recommend antibiotic prophylaxis before PPI with an aminoglycoside and either a 1st/2nd generation cephalosporin or vancomycin. We conducted a multi-institutional study to examine infection rates in diabetic patients undergoing PP implantation with different prophylactic antibiotic regimens, and compared outcomes based on adherence to AUA guidelines.

Materials & Methods: Between April 2003 and May 2018, data was collected from 15 different institutions, and charts of 710 patients with diabetes receiving primary PP implantation were reviewed. Demographic including age, race, Body Mass Index (BMI), and type of diabetes were collected for each patient. Pre-operative antibiotic regimen was recorded for each patient and primary outcomes were post-operative infection, explantation, and revision rates. Patients had a median follow up time of 7 months (range: 0-157). Patients were included in the analysis only if they had complete information regarding perioperative antibiotics and outcomes. Univariate comparisons of proportions were completed for rates of infection, explantation, and revision between different antibiotic regimens.

Results: Overall, 603 patients had complete records and were included in this study. The total number of infections, explantations, and revisions for all patients included were 23 (3.8%), 29 (4.8%), and 33 (5.5%), respectively. The AUA prophylaxis guidelines were followed in 282 patients, 220 (36.5%) received Gentamicin + Vancomycin as prophylaxis and 62 (10.3%) received Gentamicin + Cefazolin (Cefazolin), while 321 (53.2%) received the two groups (p = 0.360). On further analysis, the infection rate for patients treated with the non-AUA guidelines group, p < 0.001. There was no significant difference in revision rates between the two groups (p = 0.826). An example patient is seen in Figure 1. There was no difference between EMM and NAS groups. There were no differences in age, race, BMI or medical comorbidity between cohorts. The mean pre-modeling curvature in the EMM group was 47.5° (range 30-90°) while post-modeling curvature improved to a mean of 11.7° (range 0-30°; p < 0.001). On further analysis, the infection rate for patients treated with Gentamicin + Vancomycin (7.3%) dropped significantly when a Quinolone (1.04%) was used. Overall, 58% of patients experienced a reduction in postoperative infectious complications, table 2. Question under utilizing dilute H2O2 as biofilm was observed in both PPI and CHG. Robust clinical evidence exists for dilute H2O2 irrigation, demonstrating a reduction in postoperative infectious complications, table 2. Compared with other antibiotics or biocidal agents, H2O2 irrigation offers a number of advantages, including its broad spectrum of activity and ease of use. In conclusion, H2O2 irrigation in the setting of penile prosthesis implantation appears to be both safe and effective.

Conclusions: Adherence to the AUA penile prosthesis antibiotic prophylaxis guidelines confers a higher rate of device infection in diabetic patients. The high rate of infection was noted in patients receiving the currently most prescribed antibiotic regimen of Gentamicin + Vancomycin. The AUA guidelines should be amended to reflect findings of this and other device infection related studies.

The Mulcahy Salvage Revisited: A Critical Appraisal of Antiseptic Irrigation
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Introduction: Penile prosthesis infection is a devastating complication to both patients and surgeons. It is most commonly managed with explantation (82.7%), which results in penile fibrosis and loss of penile size. The Mulcahy salvage protocol was introduced in 1996, consisting of: explantation, irrigation with antibiotic solution, hydrogen peroxide (1.5%), and betadine (5%), followed by reimplantation. The rationale for the irrigation solutions and concentrations has never been challenged nor investigated: Objective: To critically evaluate the cytotoxic and antimicrobial effects of antiseptic wound irrigation, and to derive an evidence based recommendation on the ideal concentration of clinical use.

Materials & Methods: A literature review was performed to investigate the effects of the different irrigation solutions: povidone-iodine (PVI), hydrogen peroxide (H2O2), and chlorhexidine (CHG). PUBMED search was used, focusing on publications from the past 15 years. Review articles were categorized according to their design, critically evaluated for cytotoxicity, antimicrobial activity, effects on wound healing, and clinical efficacy.

Results: Most in vitro assays demonstrate cytotoxicity of all three solutions at subclinical concentrations to cell lines including fibroblasts, table 1. H2O2 appeared to have the most harmful profile out of the three. Activity against gram positive organisms as well as biofilm was observed in both PVI and CHG. Robust clinical evidence exists for dilute H2O2 irrigation, demonstrating a reduction in postoperative infectious complications, table 2. Two recent cohort studies found similar results, while a third study found no benefit of the irrigation protocol. However, it is important to note that these studies used an arduous post-operative irrigation protocol, which has been used with success in other surgical disciplines. Use of H2O2 should be discouraged, given its potent cytotoxicity and lack of clinical efficacy. CHG may be a viable alternative but requires further evaluation.

Conclusions: Although many prosthetic urologists forgo manual modeling in cases of severe penile curvature, our contemporary series shows it to be both safe and effective. Further research is necessary to determine the optimal postoperative irrigation protocol.

Assessment of Novel Extended Manual Modeling Demonstrates Safe and Effective Reduction of Residual Perineal Curvature During Perineal Prosthesis Implantation
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1Dartmouth-Hitchcock Medical Center/Dartmouth-Hitchcock Keene, Keene, NH; 2Dartmouth-Hitchcock Medical Center, Lebanon, NH; 3Einstein Healthcare Network, Philadelphia, PA

Introduction: Described over 20 years ago, manual modeling is an effective strategy at reducing penile curvature in patients with erectile dysfunction (ED) and Peyronie’s Disease (PD) who undergo inflatable penile prosthesis (IPP) insertion. However, due to a lack of contemporary data and a historic 4% rate of urethral perforation, many for have opted towards other surgical options for treating concomitant ED and PD. Comparison was made of outcomes in patients undergoing a modified technique of ‘extended manual modeling,’ EMM with patients with no ancillary straightening (NAS) procedure.

Materials & Methods: All IPP cases from 2 high-volume implanters from Nov 2015 through Sept 2018 were reviewed. Patients with <30° of residual curvature after cylinder placement were included. Concomitant grafting and/or plication cases were excluded. EMM was performed by forcibly bending the erect penis in the direction opposite of the point of maximal curvature for 90-second intervals for as many cycles as necessary to achieve <30° curvature.

Results: Of 78 patients in the final analysis, 26 (33.3%) underwent EMM while 52 (66.6%) were in the NAS group. There were no differences in age, race, BMI or medical comorbidity between cohorts. The mean pre-modeling curvature in the EMM group was 47.5° (range 30-90°) while post-modeling curvature improved to a mean of 11.7° (range 0-30°; p < 0.001). An example patient is seen in Figure 1. There was no difference between EMM and NAS cohorts with respect to operative time (93.6 vs. 87.3 min, p = 0.53) or surgical approach (92% vs. 88.5% penoscrotal, p = 1.0). Both groups had similar cylinder length and reservoir volume, but patients in the EMM cohort had a smaller mean tip tip extent (1.1 cm vs. 1.8 cm; p = 0.086). No patient in either cohort experienced an intraoperative or postoperative complication at a mean follow-up of 19.9 months.

Conclusions: Although many prosthetic urologists forego manual modeling in cases of severe penile curvature, our contemporary series shows it to be both safe and effective. EMM may preclude the need for more time-consuming and complex surgical procedures.
Regional Variation in Penile Prosthesis Implantation among Medicare Patients Diagnosed with Erectile Dysfunction
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Introduction: Erectile dysfunction (ED) is a common and costly urologic condition with increasing prevalence as men age. Penile prosthesis implantation is an effective surgical treatment option for ED and is associated with high rates of patient and partner satisfaction. To date, limited research has been conducted to understand penile prosthesis utilization. The purpose of this study was to characterize penile prosthesis utilization and assess for regional variation in the use of this procedure in Medicare beneficiaries across the United States.

Materials & Methods: We examined penile prosthesis utilization (inflatable and semi-rigid implants) in Medicare beneficiaries with a diagnosis of ED for the years 2004 and 2014, the latter being the last year of complete International Classification of Disease, Ninth Revision data available. Adjusted utilization rates were calculated per 1000 beneficiaries accounting for age and race. Utilization rates were examined nationally and by hospital referral region (HRR).

Results: The national adjusted rate of penile prosthesis utilization was 5.0 and 3.7 per 1000 beneficiaries in 2004 and 2014, respectively. In 2014, 1,283,176 Medicare beneficiaries were identified with a diagnosis of ED. Significant variation was found in penile prosthesis utilization; up to a 12-fold difference was observed between HRRs (1.9/1000 in Norfolk, VA to 24.2/1000 in Miami, FL). Over 65% of HRRs performed zero or < 11 penile prosthesis surgeries per year and were censored from the study. The adjusted rate of penile prosthesis utilization was highest among men age 65 to < 70 (4.6 per 1000) and lowest among men greater than age 85 (0.9 per 1000).

Conclusions: Significant regional differences exist in the utilization of penile prostheses among Medicare beneficiaries, up to a 12-fold difference was found in our study. This variance may be explained by a combination of demand, urologist availability, and patient-specific factors. Additionally, over two-thirds of U.S. hospital referral regions perform few to zero implants per year. Penile prosthesis implantation in Medicare beneficiaries with ED likely depends on where these patients receive their urologic care.
The Role of Anesthesia in Urinary Retention Following Mid Urethral Sling
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Lahey Hospital and Medical Center, Burlington, MA

Introduction: Postoperative urinary retention is a known complication of mid urethral sling placement for stress urinary incontinence, occurring in 3-39% of cases. The use of certain perioperative medications may influence the risk of this complication. Antiemetics are commonly used to manage perioperative nausea, some of which also have anticholinergic properties. Additionally, muscle relaxants used for paralysis could impair detrusor function. The aim of this study was to investigate the association of perioperative medications with urinary retention in the perioperative period following mid urethral sling.

Materials & Methods: This was a retrospective cohort study of all women undergoing mid urethral sling placement for stress urinary incontinence by a single fellowship-trained urologic surgeon at one institution between March 2015 and June 2018, under approval by the Institutional Review Board. Recorded data consisted of preoperative demographics and clinical data including voiding function, surgical data, intraoperative anesthesia and perioperative medications, and postoperative voiding function. Both retropubic and transobturator approaches were included. Exclusion criteria included incomplete surgical or perioperative data. All patients underwent an active retrograde void trial in the recovery area on the day of surgery. Retention rates were compared with Fisher’s exact test.

Results: 82 patients were included, 17 (21%) of whom failed postoperative void trial. All of these women eventually passed a void trial, with no cases of permanent retention. A total of 21 patients received transdermal scopolamine and 40% of those patients receiving scopolamine failed the postoperative void trial (p=0.048). There was no statistically significant association between other antiemetics (Ondansetron, Promethazine) and urinary retention. Rate of retention was also higher in patients undergoing retropubic vs. transobturator approach (36% vs. 9%; p = 0.005). Administration of a muscle relaxant for anesthesia (rocuronium or vecuronium) was additionally associated with urinary retention (28% vs. 13% with muscle relaxant vs. no paralysis, respectively), though this association was not statistically significant (p = 0.16). Last, the rate of retention was lower in patients on preoperative perioperative antidepressants (p = 0.03).

Conclusions: Perioperative administration of transdermal scopolamine is associated with increased risk of urinary retention after mid urethral sling. This correlation is not seen with other common antiemetics and may provide a new avenue for minimizing postoperative complications. Retropubic approach, muscle relaxation, and absence of perioperative antidepressants may also correlate with higher rate of retention. Further studies are needed to elucidate these relationships.

### Effect of Perioperative Variables on Void Trial Success Rate

<table>
<thead>
<tr>
<th>Variable</th>
<th>Passed void trial</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scopolamine</td>
<td>0.048</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15/21 (71.4%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>30/41 (73.2%)</td>
<td></td>
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<tr>
<td>Surgical approach</td>
<td>0.005</td>
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<tr>
<td>Retropubic</td>
<td>27/59 (45.8%)</td>
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<td>Transobturator</td>
<td>3/66 (4.5%)</td>
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<tr>
<td>Paralysis (rocuronium/vecuronium)</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>30/42 (71.4%)</td>
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<tr>
<td>No</td>
<td>12/16 (75%)</td>
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Green Light Laser Enucleation of the Prostate (GLEP) with Lasting Outcomes: Longer-Term Follow-up
Tammer Yamany, MD, Carlos Mejia, BS, Kai Li, MD, Alan Yaghoubian, MD, Mahdi Zangi, MD, Bo Wu, MD, Shahin Tabatabaei, MD
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Introduction: The short-term safety and efficacy of the Green Light Laser Enucleation of the Prostate (GLEP) has been reported previously. Theoretical advantages of GLEP include improved hemostasis due to the absorption spectrum of 532nm laser, better tissue handling due to the side-firing laser fiber, better visualization of the prostate capsule, and more versatility with concomitant vaporization. We study the longer term (greater than 12 month) safety and efficacy of en-bloc GLEP with prostate morcellation using a side-firing laser for definitive management of symptomatic LUTS in patients with enlarged prostate.

Materials & Methods: We performed a retrospective analysis of the first 148 patients to undergo GLEP at our institution from 9/2014 to 8/2017. Primary outcomes were AUA symptom score, maximum flow rate, and post-void residual volume. Secondary outcomes were quality of life score, IIEF-5 score, and PSA. The technique for GLEP has previously been described.

Results: Patient and peri-operative characteristics can be found in Table 1. No intraoperative complications occurred. Median follow up time was 12 months. Primary and secondary outcomes can be found in Figure 1, with statistically significant improvement in all parameters (p < 0.001) except IIEF-5, which demonstrated no change (p = 0.31). The benefits of surgery are lasting with no significant change in primary or secondary outcomes from 6-8 week follow up to 12 month follow up. Complication rates included 1.4% blood transfusion, 6.1% clot retention, and 4.7% urinary tract infection. 10.8% of patients had stress urinary incontinence (SUI) at three months with 6.8% of patients having persistent SUI at 12 months. Among patients with SUI, the median number of pads per day used was 1 at 16 months. 2.7% of patients developed an anterior urethral structure that could be passively dilated with flexible cystoscopy. No patients required additional prostate debulking procedure in the time frame studied.

Conclusions: In experienced hands, GLEP is a safe and feasible option for management of large prostates with lasting outcomes beyond one year.
Comparison of Transabdominal and Transrectal Ultrasound for Sizing of the Prostate
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Nishant Garg, BS
Liz B. Wang, MD
Shawn E. Wason, MD
Philip V. Barbosa, MD
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Introduction: Prostate size is an important metric utilized in the management of many urologic diseases. Imaging to estimate prostate volume includes ultrasound (US), Computed Tomography (CT), and Magnetic Resonance Imaging (MRI); however, US stands apart as a fast, radiation-free, and cost-effective modality. Two methods of ultrasound used are transabdominal pelvic (PUS) and transrectal (TRUS) ultrasound, with the latter considered to be more accurate, but more invasive. This study aims to compare the accuracy of PUS to TRUS sizing and is the largest study to date to do so.

Materials & Methods: We performed a single-center, retrospective study of 244 patients with PUS and TRUS prostate sizing between January 1, 2012 and August 31, 2017. Prostate volume was derived from ellipsoid volume calculation using dimensions measured on US. TRUS was changed by calculating the Pearson correlation coefficient and interclass correlation coefficient (ICC), and agreement between modalities assessed using the Bland Altman analysis. This analysis was done for the whole sample population as well as for specific groupings according to BMI, prostate size, and time between exams.

Results: A total of 244 patients had both PUS and TRUS. Median age was 63 years old, median BMI was 28 kg/m², 50 (20%) were white, 120 (49%) were black, and 41 (17%) were Hispanic. Median PSA value prior to PUS was 7.6 ng/mL. Median time between each US modality was 31 days, with 126 (52%) patients having TRUS within 31 days. The average value obtained by PUS was (63 ± 4) cm³ and by TRUS (64 ± 4) cm³. The mean of the volume differences, VolPUS - VolTRUS, was (0.2 ± 2.2) cm³, with 161 (60%) patients having ≤ 10% difference between PUS and TRUS estimations. Pearson correlation coefficient was 0.90, and ICC was 0.93 overall and > 0.8 for all specific subgroups analyzed. Bland-Altman analysis showed 85% limits of agreement were 34/-35 cm³. When analyzed by prostate size, limits of agreement for prostates < 40 cm³ and ≥ 100 cm³ were 14/-22 cm³ and +65/-68 cm³, respectively.

Conclusions: There is strong correlation between PUS and TRUS, suggesting that PUS is a useful tool for measuring prostate volume. It is important to note, however, that the Bland-Altman analysis suggests that you cannot use PUS and TRUS interchangeably in all scenarios. Since PUS is non-invasive, it should be the preferred initial modality when the goal is estimating prostate size. However, if the prostate is very large or a specific volume would drastically change management decisions, one should consider utilizing additional imaging modalities.
Testing for Racial Sampling Bias in the National Cancer Database: Does the NCDB Adequately Represent Racial Minorities with Genitourinary Cancers? Kyle Michelson, BA\textsuperscript{1}, Danielle Gordon, BS\textsuperscript{5}, Tashzna Jones, BS\textsuperscript{5}, Thomas Monaghan, BS\textsuperscript{5}, Raymond Khang, MD\textsuperscript{1}, Matthew Smith, MD\textsuperscript{1}, Ponuru Prasad, BS\textsuperscript{5}, Hyezoo Kwon, BS\textsuperscript{5}, Nicholas Suss, BS\textsuperscript{5}, Andrew Winer, MD\textsuperscript{1}

\textsuperscript{1}UNY Dermatology Center, Department of Urology, Brooklyn, NY; \textsuperscript{2}Kings County Hospital, Department of Urology, Brooklyn, NY

Introduction: The National Cancer Database (NCDB) has provided data for countless studies in urologic oncology. However, no study has examined whether the NCDB equally represents genitourinary cancer patients of all races. Here we seek to delineate whether racial sampling bias is present in the reporting of primary genitourinary cancers in the NCDB by comparing it to the population-based United States Cancer Statistics (USCS) registry.

Materials & Methods: The NCDB registers cancer diagnoses at Commission of Cancer Centers, whereas the USCS covers the entire US population. The incidence of new diagnoses of primary urologic cancers stratified by race from 2010-2015 in the NCDB was compared to the same years in USCS in order to calculate a capture rate (percentage of diagnoses in USCS also represented in NCDB). Each race's capture rate was compared to that of white patients in order to determine statistical difference. Renal and bladder cancers were further stratified by sex. A chi-square test was performed to see if capture rates varied significantly by race.

Results: The NCDB captured 57.12% of the prostate cancer diagnoses for white patients found in the USCS (Table 1) versus 53.19% for black patients, 29.55% for Native American/Native Alaskan (NANA), and 50.23% for Asian Pacific Islander (API), which are all significantly lower (p < 0.0001 for all). The capture rates for black, NANA, and API renal cancer diagnoses were significantly lower than that of white patients (p < 0.0001 for all), with 73.25% of whites vs. 71.62% of black, 59.20% NANA, and 65.5% API renal cancer diagnoses captured. This difference remained when looking at black male renal cancer patients (p < 0.0001), but not in females (p = 0.9997). The capture rate was higher for black than white female patients with bladder cancer (p < 0.0001). All NANA and API bladder cancer patients had significantly lower capture rates than their white counterparts (28.34% and 56.36% respectively, p < 0.0001 for both). No difference was found for penile (p = 0.5153) and testsis cancer (p = 0.1024) in black patients, but the capture rate was lower for NANA and API patients for these cancers (p = 0.0001).

Conclusions: Black male patients in the USCS with prostate and renal cancers are less likely to be represented in the NCDB than white patients, whereas female black patients with bladder cancer are overrepresented. Native American/Native Alaskan and Asian Pacific Islander patients are universally underrepresented in the NCDB compared to white patients for all examined urologic cancers. It is vital to consider this sampling bias when interpreting NCDB-driven studies in urologic oncology.

A Comparison of Pre- and Post-Operative Bladder/Bowel Symptoms Among Patients Undergoing Complete Surgical Endometriosis Resection Rachael Mazzamurro-Romer, BA\textsuperscript{1}, Chung Hwa Yi, MD\textsuperscript{2}, Veronica Titaia, MD\textsuperscript{2}

\textsuperscript{1}Geisel School of Medicine at Dartmouth, Hanover, NH; \textsuperscript{2}Concord Hospital, Concord, NH

Introduction: We sought to determine the prevalence of bladder and bowel symptoms among patients presenting for surgical management of endometriosis and to assess the impact of complete laparoscopic endometriosis resection on those symptoms.

Materials & Methods: Retrospective chart review. Surgeries were performed by a single surgeon at one hospital from 1/2016-1/2018, with all patients receiving care at the hospital's integrated pelvic medicine clinic. Patient-reported pre-operative symptoms were assessed for 59 cases. Post-operative symptom improvement was assessed for the 56 patients who presented for follow-up. Referal diagnoses/chief complaints at the time of initial presentation were assessed for the 46 patients without a prior biops-confirmed diagnosis of endometriosis.

Results: Average age at the time of surgery was 25 years (15-42). Based on referral diagnoses/chief complaints at the time of initial presentation: 69.6% of patients had exclusively gynecologic complaints, 21.7% had both gynecologic and urologic complaints, and 8.7% had exclusively urologic complaints. The most common presenting complaints were pelvic pain (65.2%), dyspareunia (34.8%), endometriosis by history (25.5%), abdominal pain (25.9%), dysmenorrhea (19.6%), urinary frequency (15.2%), and dysuria (15.2%). Time from initial presentation to surgery was, on average, 358.6 days (13-1140) for the 71.7% of patients who presented to a gynecologist for their initial appointment, 258.8 days (55-1081) for the 13% who saw both a urologist and gynecologist at their initial visit, and 705 days (61-2753) for the 15.2% who presented to a urologist. At their pre-operative visit, 100% of patients endorsed pain symptoms, 72.9% bladder symptoms, and 44.1% bowel symptoms. The most common pre-operative symptoms were: dysmenorrhea (83.1%), dyspareunia (72.9%), pelvic pain (69.5%), urinary frequency (57.6%), urinary urgency (50.8%), and constipation (35.6%). 89.3% of patients with pre-operative pain symptoms, 53.7% with bladder symptoms, and 50% with bowel symptoms reported symptom improvement/resolution at their post-operative visit. Of patients with pathology-confirmed endometriosis, 91.1% had post-operative improvement in pain symptoms, 52.9% in bladder symptoms, and 35% in bowel symptoms, of patients with negative pathology, 80% had improvement in pain symptoms, 57.1% in bladder symptoms, and 25% in bowel symptoms.

Conclusions: Bladder/bowel symptoms are potential surrogate symptoms for endometriosis. Complete surgical resection of endometriosis results in improvement of pain, bladder, and bowel symptoms for the majority of patients.
Predictors of Index Surgical Care Setting during Penile Prosthesis Surgery: Impact on Perioperative Outcomes and Cost

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Brigham and Women’s Hospital/Harvard University, Boston, MA

Introduction: Penile prostheses (PP) are indicated in patients with refractory erectile dysfunction. PP insertion is traditionally performed as an inpatient procedure, but is now felt to be safe in the outpatient setting, which is more cost-effective. However, few studies have determined which patients undergo PP procedures in the outpatient setting. Thus, we sought to identify predictors of index PP care setting and perioperative outcomes and cost associated with inpatient versus outpatient procedures.

Materials & Methods: All-payer data from the 2014 Healthcare Cost and Utilization Project (HCUP) State Databases from Florida (FL) and New York (NY) were used to identify all patients undergoing index inflatable PP (IPP) or malleable PP (MPP) insertion. Patient demographics, regional data, total charges (converted to costs), and 30-day revisit rates were measured. Multivariable logistic regression adjusted for facility-level clustering was utilized.

Results: Of 1,894 patients undergoing index IPP, 387 (20.4%) received care in the inpatient setting compared to 1,507 (79.6%) in the ambulatory setting. The median cost associated with inpatient PP was $11,224.74 compared to $9,480.01 for outpatient PP (p < 0.001). Predictors of receiving care in the ambulatory setting included fewer comorbidities (CCI ≤ 2 vs. >3 OR 0.43, 95% CI 0.28-0.64; p < 0.001), payer status (Medicaid vs. Medicare: OR 0.28, 95% CI 0.11-0.71, p = 0.008), race (black vs. white: OR 0.37, 95% CI 0.23-0.60, p = 0.05), small metro area (small metro vs. large metro: OR 3.15, 95% CI 1.29-7.70; p = 0.01), and state of index procedure (FL vs. NY: OR 3.16, 95% CI 9.54-122.3; p < 0.001). There was no difference in 30-day revisit rates between inpatient or outpatient PP (8.0% vs. 6.23%, p = 0.21).

Conclusions: Both clinical and non-clinical factors predict the care setting of index PP procedure and inpatient PP is associated with higher procedural costs. Our findings may help providers better identify patients who should be considered for outpatient PP procedures.

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I Don’t Know What a Nomogram Is: A Mixed Methods Approach to the Creation of a Patient Decision Aid for Men with High-Risk Features Post-Prostatectomy

Jesse D. Sammon, DO, Christina R. Gentile, BS, Michael Kobut, PhD, Christopher Stockdale, MD, Moritz Hansen, MD, Paul Han, MD

Maine Medical Center, Portland, ME, USA

Introduction: Three large multi-institution RCTs have demonstrated that for men with extracapsular extension, seminal vesicle involvement, and/or positive surgical margins, after radical prostatectomy, adjuvant radiotherapy (ART) may have a favorable impact on biochemical and local recurrence rates. However there is conflicting evidence concerning the effect of ART on cancer specific and overall survival. Given limitations of existing data, and the risk of treatment related side effects, the decision to pursue ART is patient preference-sensitive.

Materials & Methods: A multidisciplinary work-group (Urologists, Radiation Oncologists, Medical Oncologists, Physician Assistants, Nurse practitioners, Oncology nurses) created an evidence-based decision aid (DA), based on a review of available literature and guided by International Patient Decision Aid Society criteria, to inform patients of the risks, benefits, and uncertainties of ART vs. early salvage RT for men with high-risk features following RP. Alpha testing included readability, plain language assessment and 3 iterative waves of qualitative usability interviews with prostate cancer patients recruited from a large metropolitan Urology group practice (n = 12). Three members of the study team conducted software-assisted coding and thematic analysis of transcribed interviews, focusing on participants’ reactions to the DA, points of confusion, and recommendations for improvement. Usability of the DA was measured using the NASA-TLX and system usability score.

Results: Prostate cancer patients reported favorable perceptions of the value of the prototype DA, but also identified several areas for improvement, including confusing terms and jargon. Patient feedback was used to iteratively revise the DA to maximize its understandability and usability. Patients also provided valuable input on their informational and emotional needs in dealing with prostate cancer. Quantitative measures suggested that the prototype DA had an acceptable level of usability.

Conclusions: A new decision aid for men with high-risk features following RP for PCa, iteratively designed with patient input, shows promising evidence of understandability and usability. Further research will assess the effectiveness of the DA in improving shared decision making for this subset of prostate cancer patients.

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Re-Examining an Old Trend: The Association of Human Papillomavirus and Bladder Cancer

Lael Reinstatler, MD, MPH, Kevin Shee, PhD, Kristian Stensland, MD, MPH, Lawrence Dagrosa, MD,1 John Seigae, MB, Einar F. Sverrisson, MD,2 Dartmouth Hitchcock Medical Center, Lebanon, NH, 1Leahy Clinic, Burlington, MA

Introduction: Exposure to the Human Papilloma Virus (HPV) is a recognized carcinogenic factor. Previous studies have shown a possible association between HPV and bladder cancer; however, associations with HPV serology have not been reported. In this study, we assessed the correlation between HPV positive serology and bladder cancer.

Materials & Methods: Using NHANES, a large nationally-representative population-based survey, we gathered clinical and demographic data on all patients with a diagnosis of bladder cancer from 2007-2010 and analyzed their HPV serology status. We assessed the association of positive serologic results for HPV18, HPV16, HPV11, and HPV6 on the risk of bladder cancer; however, associations with HPV serology have not been reported. In this study, we assessed the correlation between HPV positive serology and bladder cancer.

Results: Of 1,172 patients with a diagnosis of bladder cancer, 72 (6.1%) had positive serology for HPV18, 121 (10.3%) for HPV16, 75 (6.4%) for HPV11, and 130 (10.9%) for HPV6. The prevalence of HPV positive serology was as follows: HPV18 - 5.5%, HPV16 - 17.6%, HPV11 - 6.4%, and HPV6 - 11.6%.

Conclusions: This finding is striking and might affect future investigation into the pathophysiologic basis of this relationship.

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2019 NE-AUA Annual Meeting Abstracts
Fascial Anastomosis Suspension Technique (FAST) During Open Retropubic Radical Prostatectomy: A Novel Method to Improve Early Postoperative Recovery of Urinary Continence

Alessandra Ambu, MD, Stefano Gaetrico, MD, Marco Russo, MD, Mariateresa Carchedi, MD, Antonio Battaglia, MD, Giulio Bonvissuto, MD, Maurizio Bellina, MD
Ospedale degli Infermi di Rovigo - ASL TO3, Rovigo, Italy

Introduction: Postoperative urinary incontinence after radical prostatectomy (RP) may greatly affect patients' quality of life and may require a long time and further treatments to be addressed. We show our results with a novel technique for urethral suspension during RP, which is a modification of the technique originally described by JW Thrall et al in 1989; this latter considered the use of a single sling, harvested from the rectus muscle fascia, while we created one fascial limb on each side of the linea alba, then suturing both limbs to the vesico-urethral anastomosis, in order to suspend it and to avoid its downward dislocation.

Materials & Methods: From June 2017 to October 2017, 40 patients with localized prostate cancer underwent to open RP at our institution, with nerve-, bladder neck sparing technique. Our standard technique for the anastomosis includes an interrupted suture with 3 stitches on both sides (towards 11, 9, 7 on the left, and towards 1, 5 on the right), and a running suture on the posterior urethral plate. For the modified fascial anastomosis suspension technique (FAST), once the anastomosis is sutured, 2 limbs of rectus muscle fascia of the right and left sides of the linea alba are prepared, each 8 cm long and 1 cm wide, with a distal attachment; the free extremity is brought to the anastomosis and sutured to the stitch towards 7 on the left and to the stitch towards 5 on the right, under a mild perineal pressure to enhance the urethral suspension. In 20 patients (group 1) the standard vesico-urethral anastomosis was performed without additional procedures, while in 20 patients (group 2) a FAST was added to the standard vesico-urethral anastomosis.

Results: Continence rate (CR) for group 1 and group 2 was 15% vs. 40% at 24 hrs; 20% vs. 30% at 48 hrs, and 30% vs. 70% at 4 weeks respectively. No urinary obstructive complications were recorded in patients who received a modified anastomosis suspension technique.

Conclusions: Although on a small series of patients, our results show better early continence results for the patients who received a urethral suspension according to our technique, compared to patients who underwent RP according to a standard anastomosis technique without vesico-urethral anastomosis suspension. The mechanism on which early recovery of urinary continence following urethral suspension may be related, is basically unknown. Our hypothesis is that vesico-urethral anastomosis suspension created with 2 limbs of rectus muscle fascia may provide an additional support to the urethral stitiched sphincter, and a potential additonal support to the urethral striated sphincter, and a possible association and a good response from surgery can delay the use of cytotoxic agents and potentially improve survival. The objective of this study is to assess whether early responders to CN have better long-term outcomes.

Materials & Methods: Using a retrospective institutional database, 76 patients who underwent CN between September 2002 and January 2018 were identified. Those who had stable disease on their first evaluation within 6 months after surgery were considered responders. Non-responders demonstrated progressed disease defined as increased volume or new sites of metastasis. Survival analysis was conducted using Kaplan-Meier and log-rank tests.

Results: Median age was 61.0 years (IQR 52.8-70.5) in responders and 56.5 (IQR 52.1-70.9) in non-responders. Only 4 patients received systemic treatment before surgery, 2 in each group. At the time of surgery, 32 had lymph node dissection and 15 underwent concurrent metastectomy. After a median follow up of 11.6 months (IQR 5.2-29.3), 38 deaths were observed. Overall survival was significantly better in responders (P=0.002, Figure 1) with median survival of 36.5 months versus 12.4 months in non-responders. A good response to CN also delayed need for systemic treatment. Median time to start of systemic treatment was 26.1 months in responders compared to 2.5 months in non-responders (P=0.003).

Conclusions: A good early response to CN is associated with better overall survival. These findings suggest that some patients do benefit from surgery and future studies need to focus on how to better identify CN responders.

Building a Program in Robot-Assisted Radical Cystectomy with Intracorporeal Real Conduit

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Beth Israel Deaconess Medical Center, Boston, MA

Introduction: Robot-assisted radical cystectomy (RARC) with intracorporeal ileal conduit (ICIC) is primarily performed at very high-volume centers, and the prospect of integrating this surgery into routine practice can be daunting. Our objective is to describe a reproducible process by which to start a program in RARC with ICIC, and to report on our initial experience, including learning curve outcomes and integration of trainee teaching.

Materials & Methods: First, two fellowship-trained attending surgeons with prior RARC experience observed ICIC creation at a high-volume center. We identified and documented each case step, and referred to this document as needed before and during surgery. We prioritized attending co-surgery for initial cases. Trainee console participation was integrated per surgeon's discretion based on case times and patient safety. We prospectively recorded peri-operative outcomes, 90-day complications (Clavien-Dindo classification), individual case step times in minutes, and trainee participation. Outcomes were separated into quartiles to describe learning curve trends.

Results: We report on 88 cases of RARC with ICIC from 2013-2018 (Table), excluding cases with intracorporeal neobladder, nephroureterectomy, and non-cancer indications. Two/responding cases were the norm initially (78% Q1/Q2) and were less common over time (38% Q3/Q4). With increasing experience, the percent of subjects that experienced major (Clavien grade 3+) complications (33% Q1 vs. 10% Q4), any complications (70% Q1 vs. 45% Q4), and hospital readmission (43% Q1 vs. 20% Q4) decreased significantly. Total operative time, initially shorter with two attendings (mean 471 min in Q1), was consistently less than the mean of 504 min. Mean clinic time (defined as ICU to close) decreased from 236 min in Q2 to 214 min in Q4, allowing concomitant increases in resident/fellow robotic console time (33 min Q1 to 62 min Q3/50 min Q4).

Conclusions: Key elements for starting a program in RARC with ICIC include expert case observation, detailed step documentation/review, and initial two-attending co-surgery. This approach facilitates overcoming the learning curve while also incorporating trainee involvement.
A Comprehensive Pan-Cancer Gene Expression and Drug Sensitivity Analysis Reveals SLFN11 as a Marker of Sensitivity to DNA-Damaging Chemotherapy

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Introduction: Precision medicine seeks to integrate data from a patient’s cancer to effectively tailor anti-cancer therapy. DNA-damaging chemotherapies have been successfully used to treat urologic cancers, but tend to be associated with significant toxicities. Thus, the identification of biomarkers of response to chemotherapeutics may allow providers to limit treatment to only those patients who stand to clinically benefit. Here we have developed and implemented a comprehensive pan-cancer analysis integrating gene expression and drug sensitivity profiles to identify novel biomarkers of response to DNA-damaging chemotherapeutics.

Materials & Methods: Gene expression profiling and drug sensitivity analyses from the Cancer Cell Line Encyclopedia (CCLE) database (860 cell lines x 481 drugs), the Genomics of Drug Sensitivity in Cancer (GDSC) database (1065 cell lines x 266 drugs), and the National Cancer Institute 60 database (60 cell lines x 237 drugs) were correlated using Pearson’s method. 1-way ANOVA was used to compare relationship between chemotherapeutic classes. Human tumor gene expression and protein data was obtained from the Human Protein Atlas.

Results: The only gene found to be significantly correlated with drug sensitivity in correlation analysis for all 4 classes of chemotherapeutic agents in all 3 databases was SLFN11, or Schalten Family Member 11. Cancer cells with high SLFN11 gene expression were found to be highly correlated with sensitivity to DNA-damaging chemotherapeutic agents (Fig 1A; p < 0.0001). This relationship was not found for similar analyses performed for microtubule inhibitors (p > 0.05). When stratifying the analysis by chemotherapeutic class, SLFN11 expression was found to be an especially strong marker of topoisomerase inhibitor sensitivity (Fig 1B; p < 0.05 by 1-way ANOVA for each dataset). RNA sequencing and IHC for SLFN11 gene expression and protein, respectively, in human tumors showed highest levels of expression in renal cell tumors among all tumor types.

Conclusions: Using pan-cancer cell line gene expression profiling and drug sensitivity data, we have identified SLFN11 expression as a novel biomarker of sensitivity to DNA-damaging chemotherapeutics, particularly topoisomerase inhibitors, that is highly expressed in renal cell tumors.
Active Surveillance Stone Protocol Reduces Endourologic Interventions
Alejandra Baler, MD,1 Ohad Kott, MD,1 Osama Al-Alao, MD,1 Eric Jung, MD,2 Timothy O’Rourke, MD,1 Meredith Wasserman, MD,1 Christopher Tucci, RN,1 Jie Tang, MD,1 Coates Farese, MD,1 1Minimally Invasive Urology Institute, The Miriam Hospital, Department of Urology, The Warren Alpert Medical School of Brown University, Providence, RI 2Department of Medicine (Nephrology), The Warren Alpert Medical School of Brown University, Providence, RI

Introduction: Surgical management of nephrolithiasis (NL) is generally efficacious and well tolerated by patients, but is associated with risks including bleeding, perforation, infection, and those related to anesthesia. There is also a significant financial burden associated with surgical high-risk kidney stone formers make up less than 20% of the NL patient population, yet they account for over 80% of the surgical procedures. Our institution applies an active surveillance multidisciplinary approach to provide a close follow-up and treatment plan for high-risk kidney stone formers. We sought to compare the incidence of surgical intervention within the multidisciplinary kidney stone center (MSc) to the incidence of surgical intervention in a urology practice (UP) that uses a non-multidisciplinary approach. Both the MSc and the UP are affiliated with the same academic urology department, and therefore differ only by the treatment approach.

Materials & Methods: We identified 366 patients treated at the UP and 153 patients at the MSc with greater than 12 months of clinical follow-up between January 1, 2015 and September 1, 2019. Patients were excluded if they were treated at both centers. Patients were referred to the MSc if they had a total bilateral stone burden greater than 10mm, medical co-morbidities and previous stone surgery. We retrospectively reviewed patient records and calculated the annual incidence rate of surgical intervention for stone disease during the follow-up period. At the MSc, patients were seen every 3 months by a team that included a urologist, nephrologist, dietitian, nurse, and renal ultrasonographer. Patients met with all disciplines during every office visit. These providers worked in collaboration to form custom treatment plans focusing on improvement in quality of life, dietary changes, reduction in stone burden and prevention of surgical interventions.

Results: During follow-up, 230 out of 366 (62.8%) UP patients underwent surgical stone treatment compared to 45 out of 153 (29.4%) MSc patients. The cumulative incidence of surgical intervention for stone treatment among the UP and MSc group was 0.294 and 0.628, respectively. Multidisciplinary treatment resulted in a 53% decrease in the excess risk of incident surgical interventions compared to the UP group (Risk Ratio = 0.47, 95% CI: 0.36, 0.628, respectively). Multidisciplinary treatment resulted in a 53% decrease in the excess risk of incident surgical interventions compared to the UP group (Risk Ratio = 0.47, 95% CI: 0.36, 0.628, respectively). Multidisciplinary treatment resulted in a 53% decrease in the excess risk of incident surgical interventions compared to the UP group (Risk Ratio = 0.47, 95% CI: 0.36, 0.628, respectively). Multidisciplinary treatment resulted in a 53% decrease in the excess risk of incident surgical interventions compared to the UP group (Risk Ratio = 0.47, 95% CI: 0.36, 0.628, respectively). Multidisciplinary treatment resulted in a 53% decrease in the excess risk of incident surgical interventions compared to the UP group (Risk Ratio = 0.47, 95% CI: 0.36, 0.628, respectively).

Conclusions: This study demonstrates that MSc patients treated with an active surveillance multidisciplinary approach had a statistically significant lower incidence of surgical interventions compared to UP patients, despite being high-risk stone formers and prone to higher rates of surgical interventions. These results indicate that using an active surveillance multidisciplinary approach in the management of kidney stone disease may reduce incidence of endourologic interventions. Further study is required to validate additional factors that may affect stone burden and incidence of surgical treatments over a longer period of follow up.

The Utility and Value of Immersive Virtual Reality Simulation for Percutaneous Nephrostomy Tract Access and Surgical Training
Sehar Rasul, MD, Egor Parkhomenko, MD, David S. Wang, MD, Shaun E. Wasson, MD Boston University School of Medicine, Boston, MA

Introduction: Percutaneous nephrolithotomy (PCNL) is the gold standard for the removal of large kidney stones. Gaining renal access into the desired calyx is critical for successful stone retrieval and was the focus of training methods to train urologists in PCNL. Access is limited and include bench models, animal kidneys, live porcine models, and simulators. Immersive virtual reality (VR) technology with haptic feedback offers a potentially better training model for surgical learning and proficiency. We sought to evaluate the efficacy of a novel immersive VR simulator for percutaneous tract access.

Materials & Methods: We recruited 25 urologists, 19 nephrologists, 5 anesthesiologists, and 5 urology residents as participants. The VR simulator pre-registered and was divided into 3 stages: a) VR module, b) fluoroscopic control and subsequent procedural steps are warranted. It is likely that future iterations of this technology will help train urologists in PCNL access.

Table 1. Demographic, Virtual reality experience, image control, and economy of motion of an immersive virtual reality simulator for percutaneous nephrostomy tract access

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<tr>
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<td>15</td>
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<tr>
<td>Economy of Motion</td>
<td>Excellent</td>
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</table>
Impact of a Multidisciplinary Kidney Stone Prevention Clinic
Kevin Krughoff, MD, Cassandra Dehade, APRN, Kathy Barzynski, RD, Scott Fabozzi, MD
1Dartmouth-Hitchcock, Lebanon, NH; 2Concord Hospital, Concord, NH; 3Concord Hospital, Lebanon, NH

Introduction: There are several known benefits of a multidisciplinary approach to stone prevention, however the implementation of this model in the community setting has not been described. Our goal was to assess the feasibility of a stone prevention clinic in a community-based practice using responses to questionnaires, 24-hour urine parameters and routine imaging results.

Materials & Methods: Patients with recurrent stone disease, risk factors or comorbidities that place restrictions on their diet were enrolled in the stone prevention clinic. Appointments included a review of patient history, medications, dietary habits, stone analysis, lab work and 24-hour urine results. Patients were met with an APRN and Registered Dietitian (RD) who used this information to create personalized dietary and lifestyle plans. Patients were administered a questionnaire to determine how beneficial they felt the clinic was. Questionnaire results, stone risk parameters and imaging results were retrospectively reviewed for all consecutive patients referred to the clinic. Paired-samples t-tests were used to assess changes in individual 24-hour urine parameters across follow up visits. For patients with prior 24-hour urine data, difference-in-difference testing was used to assess change in stone supersaturation trends following enrollment.

Results: 77 patients were followed over an average of 1.76 follow up visits (275 ± 143 days). Of the 63 surveys completed, 100% of patients found their visit with the RD helpful and 98.4% would recommend the clinic to friends/family. Of the 77 patients enrolled, 20 had at least 2 24-hour urine samples available for analysis, lab work and 24-hour urine results. A significant decrease was seen in the trajectory of uric acid supersaturation for uric acid (-0.301 ± 0.089, p < 0.01) and calcium phosphate (-0.6416 ± 0.298 p = 0.04) (Table 1). A significant decrease was seen in the trajectory of uric acid supersaturation following enrollment (-0.371 ± 0.158, p = 0.02) (Figure 1). Follow up KUB and renal US showed no stone growth in 95% of patients.

Conclusions: The implementation of a multidisciplinary stone prevention model is feasible in the community setting. This is supported by positive feedback, significant reduction in stone risk parameters and lack of stone growth on routine imaging.

Materials & Methods: A prospective study was approved by the UVM IRB and an algorithm was developed defining patient eligibility, screening, diagnostic evaluation, discharge instructions, and follow-up supported through an internal grant at the University of Vermont (Figure 1). Through funding, a research coordinator was hired to organize workflow, collect data, and contact patients to arrange follow-up after the ED visit. Patient eligibility is determined by the STONE score and/or clinical judgment of the likelihood of the presenting symptoms being secondary to a stone. For those with a high suspicion, an ultrasound is obtained. If the presenting symptoms are controlled with no change in suspected diagnosis, the patient is discharged home with specific instructions and a urinary strainer. Follow-up phone calls occur at day 1-2 and day 7-10 post discharge. If there is no definitive stone passage and/or persistent symptoms, an outpatient urology visit is initiated that includes a reduced dose CT prior.

Results: The pathway began January 2019. To date, 5279 patients have been screened, 436 have met initial inclusion criteria, and 20 have been enrolled. The average STONE score of those enrolled was 9.6. Ten (50%) had a STONE score < 10. Thus far, 2 patients passed a stone after initial US and avoided CT. 6 patients had a CT after US, 3 while still in the ED. 10 patients had US alone (2 passed a stone, 1 to OR, 7 unable to be reached). Of the patients who could not be reached, review of the electronic health record did not reveal any ED return visits or CTs obtained. 3 patients are awaiting follow-up.

Conclusions: Our initial results show that through a coordinated effort between Urology and Emergency Medicine, our pathway is feasible to implement and initial results are promising regarding the reduction of upfront CT scans obtained. Patient follow up/compliance is one concern. The utility of the STONE score is another question as the majority of patients enrolled did not meet the criteria for likely ureterolithiasis. Future results are needed to evaluate the success of our pathway and determine whether this model can be expanded outside of our single center experience.
Introduction: It has been reported that 100-Watt lasers may shorten operative and lasing times leading to higher efficiency during ureteroscopic laser lithotripsy (URSL) and cost savings. At our institution, 30-Watt lasers are utilized for ureteroscopic cases. In this study, we sought to compare our institutions experience with 30-Watt lasers in the domains of cost-effectiveness and operating times to reported 100-Watt laser data from literature.

Materials & Methods: We identified 246 adult patients who underwent URSL at our institution between March 1, 2017 to September 1, 2017. Cases were included if their pre-operative stone burden was measured using standard non-contrast CT imaging and if post-operative imaging for residual stone burden assessment showed complete stone free status. All cases started with a similar stone fragmentation laser setting of 0.8 J and 8 Hz. Dusting cases followed with a 0.4 J and 25 Hz setting. Basketing cases included stone fragment extraction. We compared the operating time in our cohort to recently published data from the EDGE research group that compared dusting vs. basketing using a high-power holmium laser (Humphreys et al. J Urol. 2018 May).

Results: 101 patients met the inclusion criteria and were stone free post URSL. 39 cases used basketing with 200 nm laser (30.8%) and 365 nm laser (69.2%); 62 cases dusted the stones using 260 nm laser (27.4%) and 365 nm laser (72.6%). Mean-operative time of URSL cases dusting the stones (mean size 52.85 mm²) was 35.4 minutes. Mean operating time of URSL cases using basketing of stones (mean size 50.69 mm²) with 30-Watt was 50.4 minutes. Data from the EDGE research group depict mean operative time in URSL cases using dusting of stones (mean size 96.1 mm²) with 100 Watt is 35.9 minutes. No significant time difference was found when comparing mean operating times of the EDGE group study and our cohort. In addition, mean operative time of URSL cases using basketing of stones (mean size 63.3 mm²) with 100 Watt is 67.4 minutes.

Conclusions: In this study, ureteroscopic stone treatment using 30-Watt laser was efficacious and did not prolong operating time compared to dusting with a 100-Watt laser. Considering the price difference between the high and low power lasers, we estimate the yearly cost savings in our institution to be around $100,000. Operative time difference may be noticed in cases involving very large stone burden. However, when comparing the potential benefits of an expensive advanced laser, it is important to consider that actual time and cost savings may not be achieved, especially if operating time savings does not allow the addition of another surgical case to the schedule. In addition, basketing of kidney stones was found to prolong the operating time in our institution and therefore should be used in selected cases.

**Materials & Methods**: A Markov Model was constructed to represent potential outcomes for a single 1cm renal stone via each of the four possible interventions of interest (watchful waiting, URS-B, URS-D, and SWL) with TreeAge Pro software (Figure 1). The cohort was followed for 1 month cycles over three years. Tolls-penalties for receiving a stent and undergoing surgery were standardized and incorporated into each subtree when indicated. Probabilities, utilities, and toll-penalties were derived from existing literature as available and clinical extrapolation when no published data was available. In addition to overall preferred options, one-way sensitivity analyses were performed to determine threshold probabilities and utilities that may alter preferred options.

**Results**: Employing baseline published stone free probabilities, watchful waiting was the preferred intervention, preserving 2.82 QALYs over the three years. The remaining options had similar but decreasing QALYs – URS-B provided 2.78 QALYs, SWL provided 2.72 QALYs, and URS-D provided 2.67 QALYs. One-way sensitivity analysis was performed for the range of expected stone free probabilities for each intervention, as well as for the full range of potential disutility related to ureteral stents. URS-D was preferred when the probability of becoming stone free with URS-B dropped below 37% (Figure 2). Shock wave lithotripsy was preferred over URS-B when the probability of becoming stone free with URS-B dropped below 62%. As stents became progressively less bothersome, watchful waiting is preferred, followed by URS-B, SWL, and URS-D respectively.

**Conclusions**: When accounting for SFR and anticipated utilities of associated health states over a three-year period, watchful waiting is a preferred management decision for asymptomatic renal stones. However, these results are sensitive to both actual stone free rate and individual stent tolerance. These varying thresholds underscore the importance of shared decision making informed by surgeon-specific stone free rates and patient-specific stent tolerance.

*Max K. Willscher Award Eligible"
The Effect of Holmium Laser Fiber Bending Radius on Power Delivery During Flexible Ureteroscopy

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1 Boston University School of Medicine, Boston, MA; 2 Boston University Department of Electrical and Computer Engineering and BU Photonics Center, Boston, MA; 3 Boston University Department of Electrical and Computer Engineering and BU Photonics Center, Boston, MA; 4 Boston University Division of Materials Science and Engineering, Brookline, MA; 5 Boston University School of Medicine/Boston Medical Center, Boston, MA

Introduction: Holmium laser lithotripsy has become standard for ureteroscopic management of urinary tract stones. During flexible ureteroscopy, laser fibers may be subject to multiple sharp bends depending on stone location. It remains relatively unknown whether power delivery at the fiber tip changes due to fiber curvature. We evaluated whether bending angles affect the power output of a commonly used holmium laser.

Materials & Methods: We used a Lumetis Pulse 30H Holmium Laser, a standard mirror, a collection fiber with a 400 μm core diameter, a Thorlabs Amplified Si Photodetector, and a Tektronix MDO2000 Oscilloscope. Two commonly used laser fibers were used: a SlimLine™ SIS-365, and a Slimline™ 200 D F/L. The laser fiber and collection fiber were positioned in parallel, pointing downwards at a small mirror. The mirror and the fiber tips were then submerged in distilled water. The laser was fired at 0.3 Hz within any significant bend to establish a baseline. For subsequent testing, a portion of the laser fiber was horizontally and tightly wrapped around cylinders of varying radii. The fiber was wrapped one or more full revolutions around the cylinders, and the power output recorded over eight seconds. The peak values were used to calculate a Root-Mean-Square (RMS). Due to experimental setup variations, three baselines were taken. The smallest radii used are the smallest radii each fiber could achieve without breaking.

Results: The RMS of peak pulse power did not vary significantly at any bending radius or number of turns measured. The Oscilloscope is accurate within 2% of measurement uncertainty. At the tightest radius measured for the 200 μm fiber, the power output was measured as 1.7% more powerful than baseline - within uncertainty. After wrapping the 200 μm fiber 10 times at the smallest radius it would accept without breaking, the power was measured to be 2.6% lower than baseline, again within the 4% margin of error. In none of the cases did the fiber break or degrade. Measured power outputs are summarized in Tables 1 and 2.

Conclusions: We found no difference in peak power delivery in two different laser fiber types bent at various radii. Unless the laser fiber breaks, there will be no measurable difference in power delivery from bending alone under surgical conditions. This result was consistent to the smallest radius and highest number of turns the fiber could reliably manage of less than 4% was within the margin of error. At the tightest radius measured, the power output was 2.6% lower than baseline, within the 4% margin of error. Endourologists can trust that laser output will be stable during ureteroscopy regardless of stone location.

Beyond Prevalence: Incidence Rates for Kidney Stones in the United States

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1 Dartmouth Hitchcock, Lebanon, NH; 2 American Urological Association, Linthicum, MD

Introduction: It is well documented that the prevalence of nephrolithiasis is increasing in adults in the United States over time. Approximately 11% of men and 7% of women have reported a lifetime history of nephrolithiasis in cross sectional studies. However, the burden of acute management may be better assessed from annual incidence rates. This accounting of new stone events, however, is not as well described or understood.

Materials & Methods: The Medical Expenditure Panel Survey is a set of large-scale, healthcare utilization surveys of families, individuals, their healthcare providers, and employers, with surveys administered every 6 months for the duration of each individual’s 2 year panel. We queried the survey data of adult participants between 2005 and 2015, with analysis conducted with provided weights and strata to allow our findings to be representative of the civilian non-institutionalized US adult population. Those with diagnosed renal or ureteral calculi as noted by ICD 9 codes were included as our incident stone formers.

Results: In 2005, the mean age of stone formers was 42.5%. Of stone formers were male, 51% white, and 47% white in the Southern US. The incidence of stone occurrences was 0.6% for men and 0.4% for women. By 2015, the mean age was 51.7%, with 52% male, 83% white, and 38% in the Southern US. The overall incidence of stone occurrences increased to 0.9% (247,35.427, individuals). This increase in incidence from 2005 to 2015 was statistically significant, with a p-value of <0.01.

Conclusions: In this large-scale, nationally-representative analysis of adults in the United States, the incidence of stone occurrence annually is less than 1%. Nonetheless, incidence rates do appear to be increasing over time, rising from 0.6% in 2005 to 0.9% in 2015. This data may help to better anticipate need for urologic care for stone disease and may help direct resource distribution.

Who Will Follow Up? Predictors of Compliance with Nephrolithiasis Follow-up After Emergency Room Visits

Brandon S. Childs, MD, Roger B. Davis, ScD, Raslan Kores, MD, Peter L. Steinberg, MD
1 Lahey Hospital and Medical Center, Burlington, MA; 2 Beth Israel Deaconess Medical Center, Boston, MA

Introduction: Many patients with nephrolithiasis who present to the emergency department (ED) will spontaneously pass a kidney stone and have a low risk of future kidney stones; however, outpatient urolithiasis consultation may be of benefit, either to manage the inciting stone or reduce the risk of future stone events. A proportion of discharged patients fail to follow-up. Many of these patients are pain free and/or have passed their kidney stones, while others have barriers to attending their outpatient appointments, and are at high risk of repeat ED visits. We sought to identify factors predicting which patients will follow up with urology within 90 days of an index ED visit for nephrolithiasis.

Materials & Methods: Using data gathered from an urban academic center ED database from 2013 to 2018, we identified 1066 patients with kidney stones. Data was collected in regards to demographics and follow-up visits with urology and/or a PCP within 90 days. Univariate and multivariate regression analyses were conducted to identify factors associated with increased odds of following up.

Results: Increasing age, female gender, African American race, and a 4-year college degree predicted increased odds of following up with a PCP (Table 3). Conclusions: Increasing age was associated with greater odds of urologic follow-up after an ED visit for nephrolithiasis. In addition, men and patients with a BMI of 25.8% (286,650.002 individuals). By 2015, the mean age was 51.7%, with 52% male, 83% white, and 38% in the Southern US. The overall incidence of stone occurrences increased to 0.9% (247,35.427, individuals). This increase in incidence from 2005 to 2015 was statistically significant, with a p-value of <0.01.

Conclusions: In this large-scale, nationally-representative analysis of adults in the United States, the incidence of stone occurrence annually is less than 1%. Nonetheless, incidence rates do appear to be increasing over time, rising from 0.6% in 2005 to 0.9% in 2015. This data may help to better anticipate need for urologic care for stone disease and may help direct resource distribution.

Introduction: Holmium laser lithotripsy has become standard for flexible ureteroscopy. This study aimed to assess the impact of fiber bending on power delivery.

Methods: A laser fiber was bent at various radii and its power output was measured. The power was measured to be 2.6% lower than baseline, within the 4% margin of error. Measured power outputs are summarized in Tables 1 and 2.

Conclusions: We found no difference in peak power delivery in two different laser fiber types bent at various radii. Unless the laser fiber breaks, there will be no measurable difference in power delivery from bending alone under surgical conditions. This result was consistent to the smallest radius and highest number of turns the fiber could reliably manage of less than 4% was within the margin of error. At the tightest radius measured, the power output was 2.6% lower than baseline, within the 4% margin of error. Endourologists can trust that laser output will be stable during flexible ureteroscopy regardless of stone location.

Table 1. Power outputs and bending radii, 200 μm laser fiber. "Bending Radius" refers to the radius of the cylindrical object around which the laser fiber was wrapped for one full turn. No variation in RMS was statistically significantly different from baseline.

<table>
<thead>
<tr>
<th>Bending Radius Number of Turns</th>
<th>RMS of Pulse Peak Power [w]</th>
<th>Standard Deviation [w]</th>
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<td>Baseline</td>
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<td>0.0019</td>
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<tr>
<td>1.5 cm</td>
<td>0.7602</td>
<td>0.0019</td>
</tr>
<tr>
<td>3 cm</td>
<td>0.7602</td>
<td>0.0019</td>
</tr>
<tr>
<td>5 cm</td>
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<td>0.0019</td>
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<tr>
<td>7 cm</td>
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<td>Baseline</td>
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<td>1.5 cm</td>
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<td>5 cm</td>
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<tr>
<td>7 cm</td>
<td>0.7602</td>
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Table 2. Odds Ratios of Follow-up

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<th>Follow-up Variable</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
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<tr>
<td>Male vs. Female</td>
<td>0.47</td>
<td>0.32-0.68</td>
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<tr>
<td>Education</td>
<td>0.64</td>
<td>0.46-0.88</td>
</tr>
<tr>
<td>Income</td>
<td>0.64</td>
<td>0.46-0.88</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>0.64</td>
<td>0.46-0.88</td>
</tr>
<tr>
<td>Insurance Type</td>
<td>0.64</td>
<td>0.46-0.88</td>
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</table>

Table 3. Univariate analysis findings

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<tr>
<th>Follow-up Variable</th>
<th>Odds Ratio (95% CI)</th>
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</thead>
<tbody>
<tr>
<td>Male vs. Female</td>
<td>0.47 (0.32-0.68)</td>
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<tr>
<td>Education</td>
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<td>Insurance Type</td>
<td>0.64 (0.46-0.88)</td>
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</tbody>
</table>

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Kamyar Ghabili Amirkhiz, MD 1
1Yale School of Medicine, New Haven, CT; 2The James Buchanan Brady Urological Institute, Department of Urology, Johns Hopkins Medical Institutions, Baltimore, MD; 3University of Michigan, Ann Arbor, MI.

Characterization of U.S. Urology Resident Opioid Prescription Patterns
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1Boston University School of Medicine, Wellesley, MA; 2Boston University Medical Center, Department of Urology, Boston, MA

Introduction: Opioid abuse has become a national crisis. Interest in the prescription of post-operative opioids among urologists has peaked in recent years. Multiple studies have demonstrated a wide variation in the prescription of opioids by urologists. In the majority of urology practices, opioids are over-prescribed. Little is known, however, regarding opioid prescribing practices among urology residents. We sought to characterize these practices and to elucidate geographic differences in resident opioid prescriptions following common endourologic procedures.

Materials & Methods: An IRB approved, 21-question survey was distributed to urology residents at all urology programs in the US through the Society of Academic Urologists (SAU). The survey divided questions into 3 principle sections: demographic data (including AUA section), prescription patterns by endourologic procedure, and attitudes and policies surrounding opioid prescription. Endourologic procedures included ureteroscopy (URS), shockwave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL) and transurethral prostate procedures (TPP).

Results: A total of 115 (9%) respondents completed the survey. On average, residents prescribed 4.7 opioid pills following SWL, 7.6 following TPP, 8.0 following URS, and 14.7 following PCNL. Using ANOVA, there was a significant regional difference in resident prescription patterns following URS, PCNL, and TPP (p < .008) but not for SWL (p = .067). Those respondents who prescribed the most and fewest pills on average following each procedure were identified, and significant variation from all remaining sections combined was confirmed using Welch’s t-test (all p’s < .006, see Table 1). Providers who believed that prescribing more narcotic pills postoperatively would decrease patient calls and ED visits were more likely to prescribe narcotics following URS (r (112) = .34, p < .001). Nationally, 79% of residents reported that their opioid prescribing patterns had decreased compared with those one year prior and 69% of residents reported working at an institution that maintains an opioid prescription policy for patients following urologic surgery.

Conclusions: Opioid prescribing practices among U.S. urology residents varied by regional AUA section and resident attitudes influenced prescription patterns. The majority of residents reported that their opioid prescribing patterns have decreased in the past year and that they work at an institution that has an opioid prescription policy. While attitudes regarding narcotic prescriptions after urologic surgery are improving, residents may benefit from additional training, best practice policies, and/or society guidelines.

<table>
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<th>Procedure by Regional AUA Section</th>
<th>URS</th>
<th>SWL</th>
<th>PCNL</th>
<th>TPP</th>
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<td>1.33</td>
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<td>20.85</td>
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<tr>
<td>Minimum</td>
<td></td>
<td></td>
<td>2.19</td>
<td>11.62</td>
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<td>11.59</td>
<td>20.85</td>
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A Retrospective Evaluation of a Novel Perioperative Opioid Sparing Protocol for Patients Undergoing Robotic Assisted Laparoscopic Surgery

Joseph F. Gonzelli, MD,1 Hershy Cabrera, MD,1 Lisa Rameka, MD,1 Christina Procopaci, PharmD,2 David Krock, PharmD2

Vale, New Haven, CT; 2South County Hospital, Wakefield, RI; 3South County, Wakefield, RI; 4LIJ, Kingston, RI

Introduction: The over prescribing of opioid analogues by health care providers has significantly contributed to the opioid epidemic. The number of individuals addicted to prescription pain medication is at epidemic levels. The U.S. has approximately 9 million opioid users, and 2 million are addicted. The AUA and other professional urologic societies have published guidelines specifically targeting the perioperative period. There is limited evidence supporting the implementation of evidence-based strategies to decrease the number of prescriptions written in the perioperative period. In this study, we evaluated a novel opioid sparing protocol to determine its impact on pain scores and morphine equivalents in patients who underwent robotic surgery.

Methods: A prospective study was conducted from February 2017 to August 2017. All patients who underwent robotic assisted laparoscopic prostatectomy and partial/total nephrectomy were included. The novel opioid sparing pathway was introduced in September 2017. All patients received preoperative analgescics. An opioid sparing pathway was initiated when the patient arrived in the OR. This protocol included the use of intravenous ketorolac, fentanyl, and acetaminophen. Postoperative pain management was continued with these medications and as needed oral oxycodone and acetaminophen. The objective was to decrease the number of oral narcotics used in the study population.

Results: Of 180 patients included in the study, 99 patients underwent robotic assisted laparoscopic prostatectomy and 81 patients underwent partial/total nephrectomy. The novel opioid sparing protocol was implemented in 136 patients. Pain scores on post day 0, 1, and 2 days post-op were not statistically significantly different. Average oral oxycodone morphine morphine equivalents was 40 mg in the opioid sparing group compared to 70 mg in the traditional group. There was a significant decrease in the number of narcotics prescribed for the opioid sparing group compared to the traditional group. On day 3, average pain score was 2.8 in the opioid sparing group compared to 3.2 in the traditional group. The opioid sparing group had significantly lower narcotic requirements on day 3 compared to the traditional group.

Conclusions: This novel opioid sparing perioperative regimen can result in the same postoperative pain control and 50% fewer narcotic prescriptions being written at the time of discharge. By decreasing the number of patients requiring narcotics postoperatively and decreasing the total number of narcotic prescriptions written, there is the potential to have a positive impact on the opioid epidemic.

Effect of Diagnostic Biopsy Practice Location on Grade/Volume Reclassification in Active Surveillance for Prostate Cancer: A Multicenter Analysis from the Canary PASS Cohort

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1Beth Israel Deaconess Medical Center, Boston, MA; 2Fred Hutchinson Cancer Research Center, Seattle, WA; 3University of Washington, Seattle, WA; 4Seattle Children’s Research Institute, Seattle, WA; 5Stanford University, Stanford, CA; 6Emory University, Atlanta, GA; 7University of British Columbia, Vancouver, BC, Canada; 8University of Texas Health Science Center, San Antonio, TX; 9Urology of Virginia, Virginia Beach, VA; 10University of Michigan, Ann Arbor, MI; 11University of California, San Francisco, San Francisco, CA

Introduction: In this evaluation of a large multicenter AS cohort, a diagnostic biopsy practice location was not associated with significant differences in grade/volume reclassification on confirmitory biopsy at academic institutions. These findings support the continued safety of active surveillance in all urologic practice settings.

Materials & Methods: Out of 1485 patients in PASS, 983 had DXBs with Gleason score ≥ 3+3+3 and < 34% positive cores, and were evaluated for grade/volume reclassification in this study at Bx1. Participants who underwent prostate MRI were excluded from the analysis. Reclassification was defined as an increase of Gleason score ≥ 6 and/or increase to ≥ 34% of positive cores. We used multivariable logistic regression to evaluate our primary outcome: whether location of DXBs (on-site vs. off-site) was associated with reclassification after controlling for age, the ratio of positive cores on DXBs, BMI, prostate size, PSA, and DXBs-Bx1 time interval. We used Fisher’s exact test to compare rates of definitive prostate cancer treatment by DXBs location.

Results: Of 519 men who had off-site DXBs and on-site Bx1, 102 (19.7%) had grade/volume reclassification compared to 72 (18.6%) out of 399 patients who had on-site DXBs and on-site Bx1. After controlling for potential confounders, location of DXBs was not associated with grade/volume reclassification. Urologist re-review occurred in approximately 30% of DXBs-Bx1. Participants with an off-site DXBs were more likely to elect definitive treatment than participants with an on-site DXBs (37% vs. 29%, p = 0.01).

Conclusions: In this evaluation of a large multicenter AS cohort, diagnostic biopsy practice location was not associated with significant differences in grade/volume reclassification on confirmitory biopsy at academic institutions. These findings support the continued safety of active surveillance in all urologic practice settings.

Do AUA Guidelines Stand on the Shoulders of Giants, or Data?

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Introduction: Urologists and advanced practitioners rely on AUA Guidelines to steer clinical decision-making. In an era of evidence based medicine, it could easily be assumed that data exist for all scenarios presented in the guidelines. Understanding the limits of evidence support for the guidelines can aid in interpreting guidelines and identifying areas in which more generation of any level of data is direly needed. We analyzed the AUA Guidelines for reported levels of evidence to identify these gaps in data.

Materials & Methods: All available AUA Clinical Guidelines available from auanet.org were analyzed by two reviewers. Each guideline was assigned an evidence level was recorded. If a statement had multiple levels of evidence, the higher level was assigned for analysis purposes. In the event of disagreement from reviewers, assignment was made based on consensus. Analyses of data sufficiency were based on statements for which it would be possible for studies to be done and data to be generated, i.e. not “Clinical Principles.”

Results: A total of 636 guideline statements from 23 Clinical Guidelines were available. Of these, 516 were not “clinical principles.” Most statements were Grade C (207/516 = 40%). Very few statements were Grade A (31/516 = 6%). Nearly a third (159/516 = 30%) of statements were “Expert Opinion,” meaning a recommendation was made without sufficient data to even establish an evidence grade. The lowest rates of evidence guideline support were in stress urinary incontinence (12/17 = 70% Expert Opinion), medical therapy for stones (13/23 = 57% Expert Opinion), and localized renal cancer (12/22 = 55% Expert Opinion). There were no Expert Opinion statements for cryptorchidism, prostate cancer detection, or post-prostatectomy radiation guidelines.

Conclusions: Clinicians must understand the studies and data underpinning the AUA Guidelines, particularly as 30% of the guidelines are not based on published evidence. Understanding the evidence should equip urologists to understand and interpret data so that clinicians are able to apply evidence from outside the guidelines to clinical practice. Researchers should also look to the gaps in data support in the guidelines to generate new studies which will provide a stronger foundation to current clinical practices.
Recent Trends in Receipt of Palliative Care for Men with Metastatic Prostate Cancer

Alexander P. Cole, MD1, Sean Fletcher, MD2, Zara Cooper, MD2, Stuart Lipsitz, ScD2, Adam Kibel, MD2, Quoc-Dien Trinh, MD3

Introduction: Appropriate use of palliative care can prolong life and may reduce overuse of inappropriate end-of-life care. The past decade has seen several factors that may increase palliative care use. The publication of a seminal 2010 paper showing a survival benefit for palliative care in metastatic cancer, the passage of the Affordable Care Act, and increased reporting on end-of-life care in major lay publications. We designed a study to assess trends in palliative care in metastatic prostate cancer. We hypothesized that there would be a significant rise in use of palliative care from 2004-2015.

Materials & Methods: We abstracted data on men > 40 years of age, with metastatic prostate cancer within the National Cancer Database. The receipt of palliative care is determined by trained data abstractors at participating institutions in each study year. This includes medical, surgical, or radiation therapies performed with the explicit purpose of managing symptoms but not curing disease. Routine pain control is not included. A linear spline for a multilevel logistic regression model adjusted for comorbidities, age, and demographics, with a facility-level random intercept was used to estimate risk-adjusted probability of receiving in palliative care in each study year. Slopes pre and post-2010 were compared.

Results: Our study cohort consisted of 52,803 men with metastatic prostate cancer diagnosed between 2006-2015. The average age was 71.3 (95% CI 71.0-71.5). Of these men, 5,885 (16.1%) received palliative care. On a univariate analysis, the probability of receiving in palliative care in each study year increased significantly over the study period (p < 0.001). However, on multivariate analysis, the association between year and receipt of palliative care was only significant after 2010. Despite this apparently improvement only a small proportion of men with metastatic prostate cancer receive any palliative care.

Conclusion: In this study, we show that the proportion of men receiving palliative care for metastatic prostate cancer gradually increased from 2006 to 2015, however the association between year and receipt of palliative care was only significant after 2010. Despite this, apparently improvement only a small proportion of men with metastatic prostate cancer receive any palliative care.

Endourology Survey on Radiation Exposure Reveals a Need for Clear Guidelines for Post Ureteroscopy Imaging

Ohad Kott, MD1, Osama Al-Aalo, MD2, Jorge Pereira, MD3, Christopher Tuovi, RN1, Gyan Pareek, MD1

Introduction: Nephrolithiasis patients undergo repeated imaging studies throughout their lives, exposing them to large doses of radiation, potentially leading to secondary malignancies. Studies have found that effective dose of radiation exceeded the recommended levels in up to 20% of nephrolithiasis patients throughout the evaluation and follow up period. Currently, guidelines only suggest recommendations regarding postoperative imaging following ureteroscopic lithotripsy (URSL) and strategies to minimize radiation exposure. There are no recommendations on the frequency and modality of imaging utilized in stone formers. The latter varies and depends on practitioner discretion. As such, we sought to elucidate the common imaging practices following URSL and current knowledge of radiation exposure among endourologists.

Materials & Methods: A 15-item web-based survey was conducted among active members of the Endourological Society. The survey evaluated knowledge and perception of best practice and patient radiation exposure in post URSL imaging. The survey also collected clinical volume, training, experience and location of practice.

Results: 204 endourologists completed the survey with a mean of 13.29 years in practice (IQR 6.75, 20 years). Routine postoperative follow up imaging is regularly performed by 91.7% of respondents using the following modalities: Ultrasound (US) - 76.6%, X-ray (KUB) - 44.7%, computerized tomography (CT) - 39.6%. 53.92% of respondents reported performing follow up imaging between 4-6 weeks, while 39.22% cite between 6-8 weeks and 71.08% reported between 4-8 weeks. 78.43% of respondents consider the imaging quality of low dose CT scan similar to standard dose renal stone protocol CT (SP CT), 48.53% of respondents would not use low dose CT scan on obese patients while only 12.25% correctly identified that streak effect is significant for BMI > 30 kg/m². 39.22% of respondents estimated correctly the radiation exposure of SP CT scan while 36.27% of respondents estimated correctly the radiation exposure of a low dose CT scan. Clear evidence-based guidelines may help alleviate these knowledge gaps and undue radiation exposure to nephrolithiasis patients.

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Poster Session II: General Urology / Best Practices

**P20**

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

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Introduction: The opioid crisis continues to be a major focus in the United States. The contribution of physician prescribing patterns and the need for improvement in the medical community have been increasingly addressed in the literature. We have previously reported on the feasibility of implementing a non-opioid protocol for outpatient ureteroscopy (URS) with stent placement. Our initial experience demonstrated the success of a non-opioid approach for pain control and stent-related symptoms. In this study, we report our extended experience over a 26 month period.

Materials & Methods: Charts of patients who underwent URS with stent placement by a single surgeon from November 2016 to February 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 tamulosin, tylenol, and pyridium. Patients with an allergy to NSAIDS or CKD stage II or greater were excluded from the non-opioid pathway as they were unable to be prescribed NSAIDS. Frequency of postoperative adverse events including visits to the emergency room (ER) for postoperative symptoms, stent-related clinical telephone calls, and requests for prescription refills for pain medication were measured.

Results: Three hundred and sixty-three patients underwent URS with stent placement over the 26 month period. 31 with reported NSAID allergy or CKD stage II or greater were ineligible for the non-opioid pathway and excluded, and 32 were excluded for having other concurrent procedures such as cystolitholapaxy. 310 patients were included in the final analysis. A total of 271 patients were discharged without opioid medications (90.3%). 29 patients received opioids (9.7%). Of those discharged without an opioid, 216 received diclofenac and 24 received no pain medication (opioid or prescription NSAID). Both groups receiving opioids and non-opioids had a low number of postoperative visits to the ED for genitourinary-related concerns (2 patients receiving opioids [6.9%] and 23 patients without opioids [8.5%]). Telephone calls made to the urology clinic for concerning symptoms were made by 11 patients receiving opioids (37.9%) and 45 patients without opioids (16.6%). The number of pain medication refill requests was low for both groups: 13 patients receiving opioids (23.6%) and 11 patients without opioids (7.3%).

Conclusions: Our experience using a non-opioid pathway after URS and stent placement reveals that approximately 97% of patients tolerated the postoperative pain management without opioids. Patients had a low number of visits to the ED for postoperative genitourinary symptoms, a low number of telephone calls to the clinic, and requested few medication refills regardless of whether or not they received opioids on discharge. We hope our experience will encourage others to reduce opioid prescriptions in this population in the future.

**P21**

Incidence and Predictors of Repeated and Prolonged Opioid Prescriptions After Kidney Stone Event

Annah J. Vollstedt, MD*, William Meeks, MA*, Arsent Ngon, MA*, Brian Sites, MD, MS†, Vernon Pais, Jr., MD, MS‡
1Dartmouth Hitchcock Medical Center, Lebanon, NH; 2American Urological Association, Department of Data Management and Statistical Analysis, Linthicum, MD

Introduction: Analgesic opioids are often employed in the management of acute renal colic. However, prescription (Rx) opioids are recognized as the leading initial exposure for those suffering from chronic opioid use and abuse. We sought to determine the percent and characteristics of stone formers who were refilled an opioid prescription within 6 months of their incident stone event, as well as those who continued to have an opioid Rx one year after.

Materials & Methods: We assessed the cohort of US adults participating in the Medical Expenditure Panel Survey between 2005 and 2015. This nationally representative survey collects longitudinal data regarding medical diagnoses, encounters, and prescription drug use. Each participant is surveyed every 6 months over the course of 2 years. Those with an ICD-9 code for an incident kidney stone who also received an opioid Rx during the index 6-month period were included in the analysis. Patient characteristics were assessed for association with repeat opioid prescriptions within the same 6 months and for association with opioid use greater than 1 year after the incident stone.

Results: Of those stone formers receiving an opioid Rx, 49.8% received additional opioid prescriptions within the same 6-month period. Diabetes, lower income government insurance status, anxiety depression and alcohol-related disorders were significantly associated with additional opioid prescriptions within 6 months; Asian/Native Hawaiian/Pacific Islander survey participants were less likely to have additional opioids on univariate and multivariate analysis (p < 0.05). Of those receiving an opioid Rx, 21.8% were still filling an opioid Rx the following year. On multivariate analysis, both anxiety and depression each increased the odds of prolonged opioid use by > 50% (OR 1.5 and 1.6, respectively, p < 0.001).

Conclusions: Our nationally representative, longitudinal study reveals that of those stone formers receiving an opioid Rx, 50% received them repeatedly. Furthermore, over 20% have an opioid Rx one year later. Finally, we identified those stone formers who may be more susceptible to both repeated and prolonged opioid use. This information may be helpful when counseling our patients on both medical and peri-operative pain management of acute renal colic.

*Max K. Willems Award Eligible

**P22**

Economic Trends of Endourologic Surgery Reimbursement Demonstrates Increased Profitability for Healthcare Systems

Ohab Kott, MD, Christopher Tucci, RN, Gyan Pareek, MD
Minimally Invasive Urology Institute, The Miriam Hospital, Department of Urology, The Warren Alpert Medical School of Brown University, Providence, RI

Introduction: Nephrolithiasis afflicts 11% of the United States population. The utilization of endourological procedures for nephrolithiasis has increased in the past decade. Concurrently, the number of practicing urologists per capita is declining and practice trends are shifting towards large group practices and integration into large hospital systems. In these shifting settings, urologists need to know their value to a healthcare system. As such, we sought to evaluate the economic impact of endourological procedures on a healthcare system. By understanding these financial trends, urologists may better understand their downstream value and empower themselves during contractual negotiations.

Materials & Methods: We reviewed hospital records for ureteroscopy (URS) and percutaneous nephrolithotomy (PCNL) cases performed between January 1, 2013 - August 1, 2018. Medicare reimbursement data for the years 2013 - 2016 was reviewed for URS; CPT codes 52335, 52336 and DRG code 669 as well as PCNL; CPT codes 50885, 50881 and DRG code 660. We combined Medicare reimbursement data with a model developed to evaluate non-Medicare reimbursement.

Results: Medicare reimbursement for outpatient URS increased 16% from $3475 in 2015 to $4527 in 2018, while inpatient reimbursement increased 13% from $6940 in 2015 to $7067 in 2018. Annual URS case volume at our institution increased 10.6% from 551 to 609 in the same time period. Annual PCNL case volume at our institution increased 17.8% from 138 in 2014 to 163 in 2016. Annual gross reimbursement for URS procedures is expected to reach $3.12 million in 2018. Medicare reimbursement for outpatient PCNL increased 13% from $3457 in 2015 to $3824 in 2018. However, for inpatient cases it decreased 1% from $14067 to $13996 during the same time period. Annual PCNL case volume at our institution increased 7.8% from 77 in 2013 to 157 in 2016. Annual gross reimbursement for PCNL is expected to reach $2.24 million in 2018.

Conclusions: Our data demonstrates that approximately $6 million in reimbursement per year is being generated from endourological care alone at our institution. This figure does not include revenues generated downstream from endourological care like visits, diagnostic tests, consultations etc. It is critical for urologists to empower themselves with financial knowledge of their downstream value to the healthcare systems, especially during compensation discussions.

**P23**

Economic Evaluation of Stentless vs. Stented Uncomplicated Ureteroscopy and Laser Lithotripsy

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Introduction: Current guidelines suggest ureteral stent placement may be omitted in select patients. Complication and re-operative rates are known to be higher for stentless ureteroscopy (URS). The purpose of this study is to assess the cost-effectiveness of stentless vs. stented URS laser lithotripsy using a decision analysis model.

Materials & Methods: Expected value calculations with Markov modeling and sensitivity analysis were used to determine the optimal method based on overall cost-effectiveness inclusive of equipment, time, secondary costs from complications, emergency department visits, hospital readmission, and re-interventions. Data from randomized controlled trials and meta-analyses comparing stent placement and stent omission after routine URS laser lithotripsy were utilized to determine rates of emergency department visits, readmissions, re-interventions and patient outcomes among urologists. Cost of operating room disposables were obtained from manufacturers. Costs of emergency department visits, readmissions, immediate and delayed re-interventions were calculated based on published figures from the literature. Costs for billable procedures were determined using published data.

Results: Decision analysis modeling demonstrated that on a per-procedure basis, URS laser lithotripsy with and without ureteral stenting had average costs of $11,268 and $8,328, respectively (Figure 1). This represents an estimated savings of $2,940 per procedure without ureteral stent placement. The difference in cost for the 2 procedures was largely driven by the cost and method of ureteral stent removal. Sensitivity analysis shows that the cost difference can be minimized, but not eliminated, by increasing the rate of patient self-stent removal via string.

Conclusions: Our decision analysis model demonstrates superior cost-effectiveness for URS without stent placement with an estimated savings of $2,940 per procedure. The increased costs associated with higher complication rates for stentless URS do not add incremental costs to the healthcare system. Although stent placement is not recommended for every patient, careful stratification and selection of stone patients may enable surgeons to improve cost-effectiveness of URS lithotripsy.
Ureteral Stenting After Routine Ureteroscopy: Is Earlier Stent Removal Feasible? Stephen C. Hill, BA1, Alexander Boyko, BA2, Samir Metheb, BS·, Michelle Hsu, BS1, Mark Biebel, MD1, Mark H. Katz, MD1, Richard K. Babayan, MD2, Shaun E. Wason, MD1, David S. Wang, MD1

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Introduction: Ureteroscopy is a standard treatment option for urinary tract calculus. Common protocol is to place an internal ureteral stent after ureteroscopy to work on the tract for up to three weeks. The duration of time required for stenting after ureteroscopy is not well defined. Ureteral stents are associated with significant morbidity, including pain and discomfort. The objective of this study was to determine if there were any differences in postoperative unplanned clinic or ER visits based on duration of stent placement. We sought to determine if earlier stent removal was feasible.

Materials & Methods: This is a single-institution IRB approved retrospective review of 231 ureteroscopy cases with laser lithotripsy or basket extraction for ureteral tract calculus performed during 2018 by multiple surgeons. The main outcome measure was number of unplanned ED or outpatient visits within 30 days following surgery. Log rank test and Cox regression modeling (adjusted for sex, age, and presence of an impacted stone) were used to analyze if there were an association between unplanned visits and length of stent placement (number of days). The patients were separated into three groups based on stent duration: 1 (0-3 days), 2 (4-6 days), and 3 (>7 days).

Results: Of the 223 patients, there were 59 in group 1 (26.7%), 80 in group 2 (35.9%), and 84 in group 3 (37.7%). 218 (79.2%) were event free within the 30-day post-operative period. 5 (2.2%) patients had an unplanned visit after stent removal (2 in groups 1 and 2, 1 in group 3). There was no difference in duration of stent placement and unplanned visits, when adjusted for sex, age, and the presence of impacted stones (p-value = 0.674). 18 (8%) patients (13 (1.9%), 4 (1.5%), and 1 (0.6%) in group 1, 2, and 3, respectively) showed no association between duration of stent placement and unplanned visits, when adjusted for sex, age, and the presence of impacted stones (p-value = 0.630).

Conclusions: We found no difference in unplanned clinic or ER visits in patients based on the duration of stent placement following routine ureteroscopy. Stent removal after 3 days appears to be sufficient to minimize morbidity and complications after uncomplicated ureteroscopy. Further prospective studies are needed to further define optimal duration of stent placement.

Kidney Stones in Black Women in the United States: Data from the Black Women's Health Study Maria J. D'Amico, BA,1 Shaun Wason, MD,2 Lynn Rosenberg, ScD3, Yvette Cozier, DSc1

1Boston University School of Medicine, Boston, MA; 2Boston Medical Center, Boston, MA; 3Boston University School of Public Health, Boston, MA

Introduction: Nephrolithiasis is a common urolithic condition and a significant cause of patient morbidity and healthcare expenditure. There has been an increase in the prevalence of kidney stones in recent years in Southern United States and among Black and female patients. There are few epidemiologic studies of kidney stones focusing on black women. We present data on the prevalence, clinical characteristics, and diagnostic work up of women with self-reported kidney stones among participants in the Black Women's Health Study (BWHS).

Materials & Methods: The BWHS, initiated in 1995, is a prospective, epidemiologic study of 59,000 US black women (age 21-69) followed via biennial postal and web questionnaires. The 2005 questionnaire asked whether participants had ever been diagnosed with kidney stones as well as data on patient characteristics (age, education, geographic region, health behavior, medical factors (body mass index, type-2 diabetes, hypertension, high cholesterol, gallstones), and use of medical care. In 2017, a subset of BWHS participants (n = 2,570) completed a web-based questionnaire focusing on urinary tract health (e.g., urinary incontinence, UTI), including conditions regarding undergoing metabolic work-up, imaging and surgical procedures related to the diagnosis of kidney stones. Chi-square tests were used to compare characteristics between participants with and without a history of nephrolithiasis.

Results: Among the 43,179 participants who completed the 2005 survey, 836 (2%) reported ever being diagnosed with kidney stones. Women with and without a history of kidney stones were similar in terms of geographic location, education level, and health insurance coverage. Respondents with a history of kidney stones were more likely to be older (P < 0.001), to have smoked (P = 0.04), to be obese (P = 0.01), and to have been diagnosed with a comorbid condition (type-2 diabetes (P < 0.0001), hypertension (P = 0.01), hyperlipidemia (P < 0.0001), gallstones (P < 0.01)). The 2,570 sub-study participants in 20172 were slightly heavier, more educated, and more likely to reside in the Northeast than BWHS participants overall. Eight percent reported a history of kidney stones of which 40% experienced ≥ 2 stones in their lifetime, 32% had repeated episodes compared to patients with a metabolic work up, 70% had undergone a CT scan, and 29% had undergone a surgical procedure.

Conclusions: BWHS participants who reported a history of kidney stones were more likely to have other medical comorbidities, including key components of metabolic syndrome and other diseases. These data are consistent with the hypothesis that patients with kidney stones have increased risks factors with nephrolithiasis and also confirm reports of lower rates of metabolic evaluation among African American patients and the need for a better understanding of the risk factors for kidney stones. Further study is needed to establish the temporal sequence between nephrolithiasis and common comorbid conditions, including gallstones and diabetes, as well as to identify the barriers and facilitators of diagnostic work up of kidney stones in black women.
Using microRNA Expression from Biopsy Samples in Upper Tract Urothelial Carcinoma as a Predictive Model for Tumor Grade, Invasion and Survival

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Introduction: Radical Nephroureterectomy (RNU) is the gold standard treatment for Upper Tract Urothelial Carcinoma (UTUC). However, less invasive treatment modalities exist for low grade (LG), non-invasive tumors. Determination of tumor characteristics are currently based on endoscopic biopsies, which often result in insufficient tissue for accurate diagnosis. Molecular analysis of UTUC biopsies may enable practitioners to make more informed clinical decisions and avoid overtreating less aggressive tumors. We propose that analyzing microRNA (miRNA) expression patterns from UTUC biopsies to predict final pathologic grade and invasion on RNU may provide a framework for more effective diagnosis, and help predict survival.

Materials & Methods: Under an IRB-approved study, total RNA was extracted from formalin-fixed, paraffin-embedded UTUC biopsy samples from 64 patients who subsequently underwent RNU from 2005-2018 at three high-volume institutions. Twenty screening samples were profiled via miRNA RT-qPCR array for 752 unique miRNAs. Differentially expressed miRNAs were then validated using 71 additional UTUC biopsy samples. In total, 39 grade (LG) and 22 grade (HG) samples were analyzed using ROC curves and logistic regression to determine the ability of these miRNAs to predict final pathologic grade and invasion on RNU. Kaplan-Meier survival analysis was performed comparing statistically significant miRNA pairs in pathologic grade and invasion from both UTUC biopsy and RNU samples.

Results: Screening array analysis identified 26 miRNAs differentially expressed between LG and HG tumors (p < 0.05 and FDR < 0.1). Of these, four were up-regulated and 22 were down-regulated in the HG, invasive tumors. Hierarchical clustering analysis yielded two distinct groups with miRNA expression patterns corresponding to final RNU pathology (p = 0.029). Validation of these miRNA revealed correlation of miR-146b and 223-3p expression with invasive (p < 0.05) and HG tumors (p < 0.001). Predictive modeling of RNU invasion using miR-21-5p and 29c-3p in combination yielded sensitivity and specificity of 45.2% and 87.5% with a 0.74 AUC, compared to prediction from biopsy invasion sensitivity and specificity of 30% and 50%, respectively. Survival analyses for miR-146b (HR 3.77, p = 0.002) and 223-3p (HR 6.16, p < 0.001) were statistically significant correlation between specific miRNA expression and poor overall survival.

Conclusions: We present distinct miRNA expression profiles of UTUC biopsies that show a statistically significant correlation with RNU tumor invasion and grade. We further suggest the ability of these miRNA to predict final pathologic stage. Finally, we highlight a statistically significant correlation between specific miRNA expression and poor overall survival.

The Impact of Frequent Cystoscopy on Surgical Care and Cancer Outcomes Among Patients With Low-Risk Non-Muscle-Invasive Bladder Cancer

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Introduction: Surveillance recommendations for patients with low-risk non-muscle-invasive bladder cancer (NMIBC) are based on limited evidence. Our objective was to add to the evidence by assessing outcomes after frequent versus recommended cystoscopic surveillance.

Materials & Methods: This is a retrospective cohort study of patients diagnosed with low-risk (low grade Ta) NMIBC from 2005-2011 with follow-up through 2014 from the Department of Veterans Affairs. Patients were classified as having undergone frequent versus recommended cystoscopic surveillance (>3 versus 1-3 cystoscopies in the first 2 years after diagnosis). Using propensity score adjusted Poisson regression, we estimated the impact of frequent cystoscopy on the number of transurethral resections and on the number of resections without cancer in the specimen. We used competing risks regression to assess associations between frequent cystoscopy and the risk of progression to muscle-invasive bladder cancer (MIBC) or bladder cancer death.

Results: Among 1,042 patients, 798 (77%) had more frequent cystoscopy than recommended. In adjusted analyses, the frequent cystoscopy group had twice as many transurethral resections (55 versus 26 per 100 person years; p = 0.001, Figure 1A) and more than 3 times as many resections without cancer in the specimen (57 versus 1.6 per 100 person years; p = 0.001, Figure 1B). Frequent cystoscopy was not associated with time to progression to MIBC or bladder cancer death (3% at 5.0 years in both groups; p = 0.990, Figure 2A) or with time to bladder cancer death (3% at 5.4 years versus 3% at 5.1 years, p = 0.817, Figure 2B).

Conclusions: Frequent cystoscopy among patients with low-risk NMIBC was associated with twice as many transurethral resections and did not decrease the risk for bladder cancer progression or death. Frequent cystoscopy may lead to more incidental findings of abnormal appearing areas within the bladder, prompting additional biopsies. Overall, our findings support current guideline recommendations for less frequent cystoscopic surveillance among patients with low-risk NMIBC.

MicroRNA let-7f-5p is a Novel Biomarker of Recurrence and a Potential Therapeutic Opportunity in Non-Muscle Invasive Bladder Cancer

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Introduction: Among patients diagnosed with non-muscle invasive bladder cancer (NMIBC), 30% to 75% experience recurrences within 6 to 12 years of diagnosis, and 10% to 30% of progression events are invasive. Using ROC curves and logistic regression, we identified let-7f-5p as a potential predictive model for tumor grade, invasion and survival. Let-7f-5p expression levels were analyzed for 178 and 38 discovery and validation approach, respectively. We isolated tumor tissue RNA from two independent cohorts of NMIBC patients from the New Hampshire Population Cohort and Dartmouth Hitchcock Medical Center were analyzed using a biomarker population cohort and Dartmouth Hitchcock Medical Center were analyzed using a biomarker population cohort.

Results: Let-7f-5p levels of expression were assessed using RT-qPCR and validated using a known negative regulator of Let-7f-5p, Lin28. Let-7f-5p levels were significantly increased in patients with higher risk of progression, with increased levels of Let-7f-5p expression (p = 0.003, Figure 1C) and led to significant inhibition of viability and migration of HTB-2 cells (both p < 0.001, Figures 1D/E).

Conclusions: In this study, we have identified Let-7f-5p as a novel miRNA biomarker of recurrence in NMIBC tumors, and show that patients with high Let-7f-5p have longer RFS. We further show that targeting Let-28, a negative regulator of Let-7f-5p, represents a novel therapeutic opportunity in NMIBC.
Outcomes of Pathologic Upstaging of Clinical T1b and T2 Renal Cell Carcinoma

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Massachusetts General Hospital, Boston, MA

Introduction: Partial nephrectomy is the gold standard for the treatment of clinical T1a renal masses according to the American Urological Association guidelines, while the European Association of Urology extends their recommendations to also include T1b renal masses in order to maximize postoperative renal function and minimize metabolic and cardiovascular morbidity. In this study, we investigate the outcomes of clinical T1b and T2 renal cell carcinoma (RCC) treated by partial nephrectomy (PN) and radical nephrectomy (RN).

Materials & Methods: This was a retrospective single-institutional study of patients with clinical T1b and T2 renal masses undergoing either PN or RN from 2000-2017. Patients with metastatic disease on preoperative evaluation were excluded from the study. The rates of pathologic upstaging and clinical outcomes including margin status, local recurrence, distant metastasis, and survival were compared between the 2 treatment groups.

Results: There were 462 clinical T1b and T2 renal masses in 454 unique patients. The median follow-up of the whole cohort was 35.6 months. Partial nephrectomy was performed in 149 patients, and 313 underwent radical nephrectomy (Table 1). Ten tumors (6.7%), all cT1b, were upstaged to pT3a in the PN group, while 122 (40.0%) were upstaged in the RN group (p = 0.001). There was no statistically significant difference in the risk of positive margins or local recurrence, but there was an association of increased risk of metastasis in the RN group (p = 0.04). For the 18 patients who experienced an RCC recurrence, the median time to recurrence was 13.6 months for PN and 11.9 months for RN (p = 0.770). There were more deaths in the radical nephrectomy group (17.4% vs. 6.0% for PN), although in the survival analysis, the difference in overall survival between the 2 groups did not reach statistical significance (log rank p = 0.0601). In patients who had pathological upstaging, there was no associated increased risk of death from RCC or death from all causes between the partial and radical nephrectomy groups (p = 0.198 and p = 0.267, respectively).

Conclusions: There is a significant risk of pathologic upstaging in cT1b and larger tumors. However, when appropriately selected, partial nephrectomy for these tumors does not appear to compromise clinical outcomes and does not result in decreased survival compared to radical nephrectomy.

Table 1. Clinical outcomes of clinical T1b and T2 renal cell carcinoma treated by partial nephrectomy and radical nephrectomy.

<table>
<thead>
<tr>
<th>FG</th>
<th>Clinical</th>
<th>Radical</th>
<th>Pathologic</th>
<th>Partial</th>
<th>Radical</th>
<th>Pathologic</th>
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</thead>
<tbody>
<tr>
<td>Patients</td>
<td>149</td>
<td>313</td>
<td>122</td>
<td>157</td>
<td>40</td>
<td>28</td>
</tr>
<tr>
<td>Tumor size (mm)</td>
<td>46 (18-186)</td>
<td>78 (5-300)</td>
<td>87 (34-212)</td>
<td>108 (30-182)</td>
<td>113 (60-265)</td>
<td></td>
</tr>
<tr>
<td>Median follow-up, [IQR]</td>
<td>35.6 (27-57)</td>
<td>35.6 (27-57)</td>
<td>35.6 (27-57)</td>
<td>35.6 (27-57)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical T1a, n (%)</td>
<td>28 (28)</td>
<td>28 (28)</td>
<td>28 (28)</td>
<td>28 (28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower vs. Low median, [IQR]</td>
<td>114 (64-153)</td>
<td>281 (182-400)</td>
<td>38 (15-79)</td>
<td>281 (182-400)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCC staining</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Clear cell</td>
<td>160 (68.9)</td>
<td>280 (61.3)</td>
<td>160 (68.9)</td>
<td>280 (61.3)</td>
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<tr>
<td>Urothelial</td>
<td>9 (3.3)</td>
<td>17 (3.4)</td>
<td>9 (3.3)</td>
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<tr>
<td>Squamous cell</td>
<td>20 (7.6)</td>
<td>20 (7.6)</td>
<td>20 (7.6)</td>
<td>20 (7.6)</td>
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<tr>
<td>Adenoid cystic</td>
<td>4 (1.4)</td>
<td>4 (1.4)</td>
<td>4 (1.4)</td>
<td>4 (1.4)</td>
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<tr>
<td>Mixed</td>
<td>14 (5.3)</td>
<td>14 (5.3)</td>
<td>14 (5.3)</td>
<td>14 (5.3)</td>
<td></td>
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<tr>
<td>Metastatic disease, n (%)</td>
<td>39 (18.4)</td>
<td>39 (18.4)</td>
<td>39 (18.4)</td>
<td>39 (18.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease recurrence</td>
<td>39 (18.4)</td>
<td>39 (18.4)</td>
<td>39 (18.4)</td>
<td>39 (18.4)</td>
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<tr>
<td>Pathologic upstaging</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>pT2</td>
<td>14 (7.6)</td>
<td>108 (281)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT3a</td>
<td>156 (106, 285)</td>
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| Rates of Upstaging in Variant Histology Nonmuscle Invasive Bladder Cancer: Is There Evidence to Support the AUA Guidelines “Expert Opinion”? Kristian Stensland, MD, MPH, David Canes, MD, Harras Zaid, MD Lahay Hospital and Medical Center, Burlington, MA

Introduction: Non-urothelial variant bladder cancers may harbor more aggressive behaviors than pure urothelial cell carcinoma. As such, the AUA Guidelines on non-muscle invasive bladder cancer recommend consideration of timely cystectomy in patients with cT1 bladder cancer with variant histology, though this is provided as an “Expert Opinion”. The rationale for this recommendation is supposedly a high rate of upstaging at the time of cystectomy. However, the data on outcomes and upstaging for cT1 variant histologies are limited to small series. Herein, we sought to support this guideline statement with evidence from a large hospital based sample.

Materials & Methods: The National Cancer Database was queried for non-metastatic, cT1 cN0 bladder cancer patients diagnosed between 2006-2014. Cases were excluded if patients received neoadjuvant chemotherapy. Clinical staging was compared to pathologic staging for variant histologies and compared to conventional urothelial carcinoma. Variant histologies evaluated included the following: adenocarcinoma, small cell, spindle cell, squamous cell, signet ring cell, and micropapillary. Upstaging was defined as pathologic T2-T4 or pathologic node-positive disease. Rates of upstaging for each variant histology were compared to conventional urothelial carcinoma and the null hypothesis of no difference in upstaging tested by the chi-square test.

Results: A total of 22,872 cases of bladder cancer were included. A total of 21,855 (96%) cases were urothelial, and 116 (0.5%) were variant. The most common variant histology was SCC (n = 312), followed by adenocarcinoma (n = 250), spindle cell (n = 96), micropapillary (n = 92), small cell (n = 78), and signet ring cell carcinoma (n = 39). The rates of upstaging from clinical to pathologic staging were significantly higher for all 6 variant histologies evaluated compared to urothelial carcinoma, with rates ranging from 30.8% (adenocarcinoma) to 61.5% (signet ring cell carcinoma); see Table 1.

Conclusions: These data demonstrate significant rates of upstaging in cT1 bladder cancers with variant histologies, as high as 62%. The information provided here is in line with the AUA Guidelines for non-muscle invasive bladder cancer and lend further data for timely cystectomy in this high-risk population.
Renal Mass Biopsy for Cystic Renal Masses: Can We Challenge the Dogma?

Tammer Yamama, MD, Aisen O’Shea, MD, David Kuppermann, MD, Dimitar Zlatev, MD, Mukesh Harshinghani, MD, Ron Aronlimo, MD, Adam Feldman, MD, Massachusetts General Hospital, Boston, MA

Introduction: Renal mass biopsy (RMB) has been proven as a safe and effective method for diagnostic evaluation of small solid renal masses. However, routine biopsy of cystic renal masses has been advised against due to a high rate of non-diagnostic results. Diagnostic biopsy results may benefit clinical decision making when considering treatment options such as ablative therapy. Our objective is to identify predictive tumor and patient characteristics for a diagnostic biopsy of a complex cystic renal mass.

Materials & Methods: We performed a retrospective review of our database of 213 adult patients with cystic renal masses who underwent an RMB from 1998-2012. RMB was performed at the discretion of the urologist and patient. Any mass under consideration for ablative therapy was routinely biopsied. Core biopsies and fine needle aspirations (FNA) were performed. Non-diagnostic biopsies were considered biopsies with insufficient tissue or benign renal epithelial tissue not felt to be representative of the concerning lesion.

Results: A total of 213 cystic renal masses were biopsied from 1998-2012. 137 (64.3%) biopsies were non-diagnostic and 76 (35.7%) were diagnostic with 69 (32.4%) malignant and 7 (3.3%) benign neoplasms. There was no significant difference in age, gender, biopsy modality or imaging modality for biopsy in terms of diagnostic biopsy rates. The diagnostic rate increased with an increase in mass size (p = 0.2 cm: 18.8%, 2-4 cm: 46.0%, 4-7 cm: 57.8%, >7 cm: 90.0%; p = 0.003). Independent predictors of a diagnostic cystic renal mass biopsy included a mass diameter greater than 2 cm and differential contrast enhancement greater than 10 HU (p = 0.021 and <0.001, respectively). Inclusion of only masses larger than 2 cm with differential contrast enhancement greater than 10 HU improves the diagnostic rate to 65.7%. Among patients with a nodular component, a nodule-to-mask diameter ratio greater than 0.45 was significantly associated with a diagnostic biopsy (p = 0.027). Inclusion of only masses with a nodule-to-mask ratio greater than 0.45 improves the diagnostic rate to 85.7% from 41.9% for cystic masses with a nodular component.

Conclusions: Biopsy of cystic renal masses larger than 2 cm with differential contrast enhancement greater than 10 HU are more likely to result in a diagnostic biopsy result. Cystic masses with a larger nodule-to-diameter ratio are also more likely to result in diagnostic biopsy. Selective biopsy of cystic renal masses may benefit clinical decision making when considering available treatment options.
Premature Termination of Genitourinary Cancer Trials: Assessing Trial Efficiency Using Novel Algorithms

Kristian Stensland, MD, MPH1, Krystal DePorto, BS2, James Ryan, BS2, Matthew Galsky, MD3
1Lahey Hospital and Medical Center, Burlington, MA; 2Tufts University School of Medicine, Boston, MA; 3Icahn School of Medicine at Mount Sinai, New York, NY

Introduction: Cancer clinical trials fail to reach their planned primary endpoint at a reportedly high rate. Trials which fail prematurely do not contribute maximally to the knowledgebase, if at all, and divert patients from other trials. Optimizing the conduct of cancer clinical trials through improved trial planning, and identifying trials at higher risk of failing to complete, could streamline the trials enterprise and hasten the investigation of new treatments while minimizing patient and investigator burdens. We identified associations with premature termination in genitourinary cancer trials using novel data extraction algorithms.

Materials & Methods: We extracted clinical trial data from ClinicalTrials.gov for prostate, bladder, kidney, testicular, and ureteral cancers. We included only Phase 2-3 interventional trials started in 2007 or later that had completed or terminated. We designed data extraction algorithms to generate previously unavailable data points for trials, including sponsor and trial information, anticipated and actual accrual numbers (method previously validated and published), and site number and location. We then manually coded reasons for premature termination from the provided free text in the trial record. We considered "toxicity," "adverse events," or "interim analysis" to be appropriate reasons for trial termination as these reasons provide useful information. We identified associations with premature termination via a logistic regression model, with covariates as detailed in Table 1.

Results: A total of 747 trials were included. Of these, 231 (30.9%) terminated early, and 193 (25.8%) terminated for a reason other than toxicity/efficacy. The most common reason for termination was poor accrual (43.3%). On multivariable logistic regression, trials with sites outside the USA and prostate cancer trials were less likely to prematurely terminate. For termination as these reasons provide useful information. We identified associations with premature termination via a logistic regression model, with covariates as detailed in Table 1.

Conclusions: The rate of premature termination in genitourinary cancer trials is high, with more than 1 in 4 trials terminating prematurely for reasons other than toxicity or efficacy. Interventions are direly needed to optimize clinical trial conduct in order to decrease the drain on patient and investigator resources and hasten much-needed advances in genitourinary cancer care.

<table>
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<th>OR</th>
<th>95% CI</th>
<th>P value</th>
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<tr>
<td>USA Only</td>
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<td>1.67-3.88</td>
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<tr>
<td>Both USA and International</td>
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<td>0.28-1.09</td>
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<tr>
<td>Industry</td>
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<td>0.52-1.37</td>
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<tr>
<td>US Government</td>
<td>0.69</td>
<td>0.49-1.17</td>
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<tr>
<td>NH</td>
<td>0.70</td>
<td>0.63-1.17</td>
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<th>Cancer Type</th>
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<tr>
<td>Bladder</td>
<td>0.86</td>
<td>0.49-1.55</td>
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<td>Bladder</td>
<td>0.74</td>
<td>0.03-2.99</td>
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<td>Prostate</td>
<td>0.55</td>
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<tr>
<td>Testis</td>
<td>0.42</td>
<td>0.09-1.49</td>
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Contemporary Data on Incidence, Treatments and Outcomes of Tis, High-Grade Ta, and High-Grade T1 Non-Muscle Invasive Bladder Cancer Patients in the US

Jindin Song, PhD1, Mihaela V. Georgieva, PhD2, Iryna Bocharova, BA2, Eric Wu, PhD2, Amy Cao, PhD2, Sam Spigelman, MD2, Ashish M. Kamat, MD2, Amy Cao, MD2, Sam Spigelman, MD2
1Analysis Group, Inc., Los Angeles, CA; 2Analysis Group, Inc., Boston, MA
3Terry Pharmaceuticals, Parsippany, NJ; 4Department of Urology, Division of Surgery, University of Texas MD Anderson Cancer Center, Houston, TX

Introduction: Intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) therapy is the best treatment for patients with Tis, high-grade Ta, or high-grade T1 non-muscle invasive bladder cancer (NMIBC); for those who fail, options are limited other than radical cystectomy. This study examined SEER-Medicare data to provide a snapshot of the patterns of BCG use and outcomes in this patient population in the US.

Materials & Methods: We performed a retrospective analysis of the SEER-Medicare database to identify patients diagnosed with NMIBC between 2008 and 2015. Continuous enrollment in Medicare Parts A and B was required for ≤ 12 months prior to diagnosis and until death or end of Medicare claims availability (December 2016), whichever occurred first. Percentage of patients receiving BCG therapy was summarized. Proportions of patients who received cystectomy (partial or total) at 1, 3, and 5 years after BCG initiation were estimated among patients who received BCG using Kaplan-Meier analysis.

Results: Among the 54,444 patients diagnosed with bladder cancer, 39,789 (73.1%) had non-muscle invasive disease (Tis: 7.0%, Ta: 63.1%, T1: 29.9%) and 16,657 (24.3%) of the patients with NMIBC were Tis, high-grade Ta, or high-grade T1. Surprisingly, only slightly over half (56.5%) of these patients received at least one instillation of BCG therapy (median follow-up since first BCG was 37.2 months). The mean age at BCG initiation was 77.5 years (SD = 6.9), with 7,611 (80.0%) being male. The mean Charlson Comorbidity Index (CCI) score was 1.4 (SD = 1.7), with 5,797 (60.9%) of patients having CCI score ≥ 1. The most common comorbidities were diabetes (35.7%) and chronic pulmonary disease (33.7%). Approximately 4.4% of patients receiving BCG underwent cystectomy within 1 year of BCG initiation, 8.8% within 3 years, and 10.8% within 5 years.

Conclusions: In the contemporary era, approximately 40% of patients with NMIBC have Tis, high-grade Ta, or high-grade T1 disease at diagnosis. Only about half the patients receive BCG instillation therapy. Whether the low cystectomy rates seen at 1, 3, and 5 years after BCG initiation are due to comorbidity burden or other factors needs to be further studied.
Workplace Absenteeism Following Robotic and Open Kidney Surgery
Alexander P. Cole, MD1, Daniel Pucheril, MD1, Xi Chen, MS2, Prokhar Dasgupta, MBBS2, Quoc-Dien Trinh, MD3
1Brigham & Women’s Hospital, Harvard Medical School, Boston, MA; 2Faculty of Life Sciences, Kings College London, London, United Kingdom

Introduction: Robotic surgery is increasingly employed for the management of renal tumors. However, the perioperative cost of robotic surgery is greater than open surgery. Our objective was to investigate differences in workplace absenteeism between open and robotic approaches amongst patients undergoing radical (RN) and partial nephrectomy (PN).

Materials & Methods: Patients aged 18-64, undergoing open or robotic RN or PN from 2012-17, and having data on workplace absenteeism were identified within the Truven Health MarketScan® Database. This study period was established relative to the date of surgery: baseline (360 to -15 days), perioperative (+14 to +28 days), and postoperative (+28 to +52 days). The outcome of interest was the total number of days absent from work in the combined perioperative/postoperative period and was calculated by summing days absent for vacation, sick leave, and short-term disability. The propensity score for receiving robotic surgery was calculated based on demographic covariates. A multiple regression model determined the independent effect of surgical approach on absenteeism controlling for baseline absence and propensity score.

Results: In total, 203 and 308 patients met inclusion criteria for RN (156 open, 47 robotic) and PN (145 open, 163 robotic), respectively. Aside from the distribution of age groups (p = 0.018), baseline characteristics were statistically similar between open and robotic patients undergoing RN. There were no statistical differences between open and robotic patients undergoing PN. In the fully adjusted model, patients undergoing robotic RN and PN missed 15.1 (95%CI 3.3-26.8) and 8.9 (95%CI 2.1-17.6) fewer days of work relative to patients undergoing open counterparts, respectively.

Conclusions: Patients undergoing robotic kidney surgery return work sooner than patients undergoing open kidney surgery. The additional perioperative cost of robotic surgery may be offset by earlier return to work.

# Table

<table>
<thead>
<tr>
<th></th>
<th>Radical Nephrectomy</th>
<th>Partial Nephrectomy</th>
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<tr>
<td>Sex</td>
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<td>Female</td>
</tr>
<tr>
<td></td>
<td>66.5</td>
<td>61.7</td>
</tr>
<tr>
<td>p-value</td>
<td>0.06</td>
<td>0.12</td>
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<tr>
<td>Mean Age (y)</td>
<td>52.1 (17.0)</td>
<td>54.3 (16.7)</td>
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<tr>
<td>p-value</td>
<td>0.06</td>
<td>0.33</td>
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<tr>
<td>Age Group (%)</td>
<td>18-34</td>
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<td>4.3</td>
<td>6.1</td>
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<tr>
<td>p-value</td>
<td>0.03</td>
<td>0.28</td>
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<tr>
<td>Complications (%)</td>
<td>0.41</td>
<td>0.05</td>
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# Table

| Geographic Region (%) |   | 0.29               | 0.36               |
|                       | NorthEast           | 12.9                |
|                       | SouthEast           | 25.0                |
|                       | South               | 24.3                |
|                       | West                | 24.6                |
| Residence (%)         | Rural               | 4.4                 |
|                       | Urban               | 12.0                |
|                      | Health Plan Type (%) | 0.04               |
|                      | Less Resrictive      | 92.5                |
|                      | More Resrictive      | 7.5                 |
| Baseline Days Absent (Mean) | 0.26               | 0.31               |

Characteristics and Clinical Outcomes of a Multi-Institutional Observational Patient Cohort Who Underwent Anatomic Posterior Urethralplasty by a Combined Robotic Transabdominal and Open Transperineal Approach
Jaime A. Cavallo, MD1, MPH1, Alex J. Vanni, MD3, Gesalani Dy, MD2, Sabrina Stair, MD, MD1, David Canes, MD3, Lee Zhao, MD, MS2
1Lahey Hospital and Medical Center, Burlington, MA; 2New York University Langone Medical Center, New York, NY

Introduction: Urethral strictures occurring within the bladder neck and the bulbar urethra present a uniquely challenging reconstruction, especially when complicated by a prior history of radiation therapy. These patients are frequently managed a suprapubic tube or urinary diversion due to the complexity of reconstruction. Our objective is to review patency and incontinence outcomes of posterior urethral reconstruction treated by a combined robotic transabdominal and open transperineal approach.

Materials & Methods: A multi-institutional retrospective study of patients who underwent anatomic posterior urethralplasty by a combined robotic transabdominal and open transperineal surgical approach between 2011 and 2012 and 2018 was performed. We reviewed patient demographics, medical history, etiology, and previous endoscopic treatment. Urethral reconstruction success was anatomic and based upon urodynamic analysis of a 17Fr flexible cytoscope. Incontinence was defined as the use of >1 pad per day or procedures for incontinence.

Results: Between 1/2012 and 12/2018, a total of 15 patients underwent anatomic posterior urethralplasty by a combined robotic transabdominal and open transperineal approach at 2 institutions. Mean follow-up was 388 (range 10-1487) days. Mean age was 58.2 (SD 19.1) years, median Charlson Comorbidity Index was 4 (range 0-6) for these men. 40.0% of the cohort (n = 6) had a history of prostate cancer, 67.7% of the cohort (n = 10) had a history of urethral cancer. All patients with a history of prostate cancer were treated with radiation therapy: 20% (n = 2) brachytherapy, 60% (n = 6) external beam radiation therapy (EBRT), and 20% (n = 2) combination brachytherapy and EBRT. The patients with prostate cancer, 20% (n = 2) underwent salvage prostatectomy. Mean time from radiation therapy to diagnosis of posterior urethral stricture was 8.2 (SD 5.6) years. 86.7% (n = 13), 13.3% (n = 2), and 6.7% (n = 1) of the cohort underwent previous procedures for urethral stricture, bladder outlet obstruction, and other urologic disease, respectively. Obstructive voiding management at presentation was with a suprapubic catheter for 53.3% (n = 8) and intermittent catheterization for 13.3% (n = 2) of the cohort. Reconstruction required prostatectomy and corporal splitting in 40.0% (n = 6) and 6.7% (n = 1) of the cohort, respectively. Gracilis muscle flaps were used in 26.7% (n = 4) of the cohort. Postoperative hematoma, wound abscess, urinary leak, and PE/DVT each occurred in 6.7% (n = 1) of the cohort. Stricture recurrence occurred in 13.3% (n = 2) of the cohort. 26.7% (n = 4) of the cohort reported de novo erectile dysfunction at a mean of 104 (range 79-137) postoperative days after the index procedure. 46.7% (n = 7) of the cohort had pre-existing stress urinary incontinence (SUI), an additional 33.3% (n = 5) developed de novo SUI after the index procedure. 40.0% (n = 6) of the cohort underwent placement of an artificial urinary sphincter at a mean interval of 411 (range 105-1487) days after the index procedure.

Conclusions: Complex posterior urethralplasty by a combined robotic transabdominal and open transperineal approach is associated with a low rate of urethral stricture recurrence. Urinary incontinence is expected following this operation, and short-term results of AUS placement following reconstruction are encouraging. Further follow-up is needed to determine the long-term risk of urethral erosion in these high-risk patients.

# Table

| Differences in perioperative/postoperative days absent between patients undergoing robotic versus open radical and partial nephrectomy, adjusted for baseline absencess and for all covariates |   | 0.004               |
|----------------------------------------------------------------------|-------------------|
| Period/Patient Days Absent (Mean) | 68.7               |
| Difference in Period/Patient Days Absent (95% CI) | -13.1 (-26.1 to 1.8) |
| Difference in Period/Patient Days Absent (Fully Adjusted) (95% CI) | -15.1 (-26.9 to 3.3) |
Acquired buried penis (ABP) incurs significant health consequences including obstructive voiding, sexual dysfunction, and recurrent soft tissue and urinary tract infections. A paucity of data exists about the ABP population that pursues definitive treatment with buried penis repair (BPR). Our objective was to review the preoperative characteristics and postoperative outcomes of an observational patient cohort who underwent BPR.

Materials & Methods: We systematically searched MEDLINE, Cochrane Library and Google Scholar (through February 2019) for case reports and series to summarize data regarding presentation, evaluation, management, and follow-up for patients less than or equal to 18 years diagnosed with UCC of the bladder. Patient-level data was abstracted and logistic regression was used to identify factors associated with a combined outcome of recurrence-or-death.

Results: One hundred and two articles describing 243 patients from 26 countries met criteria. Average age was 12.5 years, 36.2% were female, 15.3% had medical comorbidities, and 13.2% had known risk factors for bladder cancer. Initial management was transurethral resection in 95.5% of patients, 12.1% required secondary intervention. Tumor subtype was papillary in 98.3%, 3.3% were muscle invasive, 93.4% were low-grade; the majority of patients were stage Ta/T1N0M0 disease. Mean time to recurrence-or-death was 8.6 months (SD 7.6) for 10.7%. Mean disease free follow-up without recurrence-or-death was 56.9 months (SD 54.2) for 89.3%. Patients with comorbidities, risk factors or family history (OR: 2.4, 95% CI: 1.02-5.58) or with greater than TaN0M0 disease (OR: 6.6, 95% CI: 2.64-15.61) had significantly greater adjusted odds of recurrence-or-death after initial treatment.

Conclusions: Based on pooled results, low-grade and stage UCC of the bladder in pediatric patients should likely be systematically monitored with renal/bladder ultrasound, urine analysis and cystoscopy for at least 3 years. Less aggressive surveillance is likely sufficient after this time period.

Characteristics and Clinical Outcomes of an Observational Patient Cohort Who Underwent Buried Penis Repair

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Introduction: Urothelial cell carcinoma of the bladder in pediatric patients: A systematic review of case reports & case series

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Conclusions: Based on pooled results, low-grade and stage UCC of the bladder in pediatric patients should likely be systematically monitored with renal/bladder ultrasound, urine analysis and cystoscopy for at least 3 years. Less aggressive surveillance is likely sufficient after this time period.

*Ken K. Willech Award Eligible

Safety of Urethroplasty in the Comorbid Population

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Introduction: It is well recognized that urethroplasty is a more durable treatment for urethral stricture disease than endoscopic management. The AUA guidelines even recommend that urethroplasty be offered to patients as initial treatment of even short strictures, and certainly preferred when a single attempt at endoscopic management has failed. However, many urologists may be hesitant to offer urethroplasty in patients with significant medical comorbidities. The Charlon Comorbidity Index (CCI) and Frailty Index (FI) were used to investigate the relationship between preoperative comorbidity and immediate complications following urethroplasty with bulbocavernous grafting. We hypothesized that even high-risk patients do well with this surgery.

Materials & Methods: Using the National Surgical Quality Improvement Program (NSQIP), patients with CPT codes for urethroplasty with bulbocavernous grafting were identified, performed between the years 2007 and 2015. Each patient’s CCI was calculated based on ICD9 codes. A FI score was also calculated for each patient by adding the number of FI conditions the patient had, again based on ICD 9 codes. 30-day complications were identified based on definitions in NSQIP and converted to Clavien-Dindo classification grades. Multivariate logistic regression was used to examine the association between post-operative complications and CCI as well as FI.

Results: There were a total of 646 patients identified who underwent urethroplasty with a bulbocavernous graft. The average age was 48.7 +/- 16.4 (range 18-90 years). 67.5% of the patients were male. Mean BMI was 31.9 +/- 6.7 (range 17.5-65.6). 16.6% of patients had smoked within the past year. 97.4% of the patients underwent general anesthesia for the surgery. The average pre-operative CCI was 1.9 +/- 1.8 (range 0-14). 60.2% of patients had no FI conditions, 24.9% had one, and 14.9% had two or more. Of the 646 patients, 2.9% had a urinary tract infection post-operatively, 0.9% had a superficial surgical site infection, 0.3% had a deep SSI, 0.2% required a transfusion intra- or post-op, 0.5% had a DVT requiring treatment, 0.9% had a wound disruption, 0.3% had an MI, and 0.2% had a PE. Zero patients experienced sepsis, stroke, acute renal failure or death. This constituted an overall complication rate of 6.8%.

As demonstrated above, for each post-operative complication recorded by NSQIP, less than 4% of the population exhibited the complication. Due to the low complication rates, models were only generated for UTI, Clavien-Dindo Grade 1, and overall complications. On multivariate logistic regression, after controlling for anesthesia type and race, there was no association between post-operative UTI (OR = 0.99; 95% CI: 0.76, 1.30; p = 0.96), Grade I (OR = 0.89; 95% CI: 0.69, 1.14; p = 0.36), or overall complication rate (OR 0.98, 95% CI: 0.82, 1.17; p = 0.82) and CCI scores. Similar results were observed for FI.

Conclusions: Urethroplasty with bulbocavernous grafting is a safe procedure with low complication rates, even in the comorbid population, and could therefore be considered a viable treatment option for stricture disease in this demographic.

Median Charlson Comorbidity Index was 3 (range 0-14). 22.9% (n = 11) of the cohort had a urethral stricture history, of which 14.6% (n = 7), 6.3% (n = 3), 2.1% (n = 1) had prior dilatation, direct vision internal urethrotomy, and urethroplasty, respectively. 10.4% (n = 5) of the cohort had a concurrent urethral stricture at the time of ABP evaluation. None of the penis was visible preoperatively for 52.1% (n = 25) of the cohort. 56.5% (n = 28) of the cohort had lichen sclerosus (LS) of the urethra or genital skin, 16.7% (n = 8) had genital lymphedema. 25% (n = 12) of the cohort had prior obesity-related surgery; 2.1% (n = 1) had prior dilation, direct vision internal urethrotomy, and urethroplasty, respectively. 24.9% had one, and 14.9% had two or more. Of the 646 patients, 2.9% had a urinary tract infection post-operatively, 0.9% had a superficial surgical site infection, 0.3% had a deep SSI, 0.2% required a transfusion intra- or post-op, 0.5% had a DVT requiring treatment, 0.9% had a wound disruption, 0.3% had an MI, and 0.2% had a PE. Zero patients experienced sepsis, stroke, acute renal failure or death. This constituted an overall complication rate of 6.8%.

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The History of the Use of Colonic Muscosa in Urethral Reconstruction

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Introduction: Oral mucosa graft urethroplasty was first described by the Ukrainian surgeon Kirill Sapezhko in 1894. It was his protégé, I. A. Thyrmos, who pioneered substitution urethroplasty with rectal mucosa and published its first use in 1902. We describe the poorly-known evolution of colonic mucosa use in urethral reconstruction to its modern-day resurgence.

Materials & Methods: PubMed and the Journal of Urology archives were both systematically queried for all published literature using the combination of search terms “colonic mucosa” or “rectal mucosa” and “urethroplasty” or “urethral reconstruction”. All resulting literature matches were reviewed to describe the chronologic history of colonic mucosa use in urethral reconstruction.

Results: Thyrmos’ initial description of rectal mucosa substitution urethroplasty in the Eastern scientific literature in 1902 failed to gain the attention of the Western scientific community for the greater part of a century. Brief mention of rectal mucosa as a “feasible but unproven option for urethral reconstruction” in an abstract from the 1918 Urologic Congress in Paris indicates international communication but lack of adoption of the concept. Descriptions of urethroplasty using colonic mucosa grafts did not appear again in the medical literature until Paul Mitofanoff of France published his experimentation with appendicular mucosa grafts in rats beginning in 1994. Between 2002 and 2009, Yue-Min Xu, Chongrui Jin, Rong Chen, Jie-Min St, and Chao Feng of China applied the concept of colonic mucosa substitution grafts to the dilemma of long-segment complex urethral reconstruction in which oral mucosa grafts would be inadequate in length or unavailable. Their preclinical studies in a dog model and subsequent clinical series achieved colonic mucosa grafts up to 21 cm in length but required concurrent bowel resection. In 2016, Alex Vanni and Leonard Zinman described the first minimally-invasive harvest of rectal mucosa graft up to 15 cm in length for long-segment urethral reconstruction using a transanal endoscopic microsurgical technique. This approach circumvented the need for bowel resection and minimized associated gastrointestinal morbidity. In patients with long-segment urethral stricture or limited availability of oral mucosa for substitution grafting, rectal mucosa remains a viable alternative graft with minimal donor site morbidity to achieve a functional outcome in complex urethral reconstruction.

Conclusions: The use of colonic mucosa in urethral reconstruction follows a historic trajectory that parallels that of oral mucosa in urethroplasty. In modern reconstructive urology, the advent of minimally-invasive tissue harvest techniques has caused rectal mucosa grafts to re-emerge as a viable alternative to oral mucosa grafts in complex urethral reconstruction.