1

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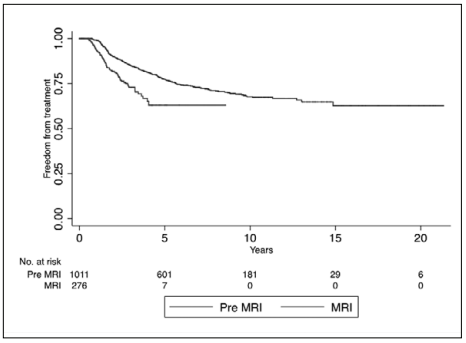
Introduction: Multiparametric MRI (mpMRI) has led to improved detection of clinically significant prostate cancer and is now increasingly used in active surveillance (AS) patients. However, most AS cohorts in the literature were described prior to widespread use of mpMRI. Our investigation compares outcomes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



2

Identifying Gene Expression to Predict Biochemical Recurrence Following Radical Prostatectomy

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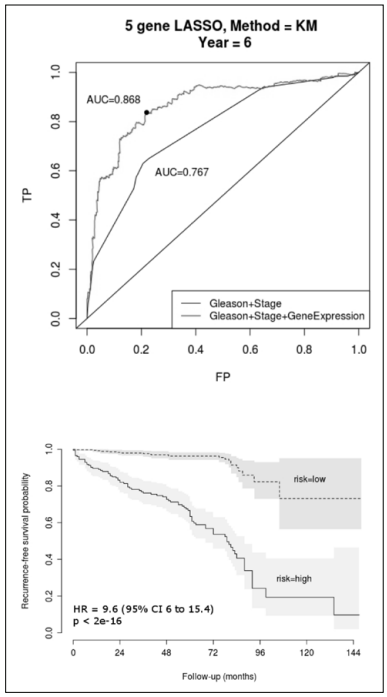
Introduction: Identification of novel biomarkers associated with high risk prostate cancer or biochemical recurrence can drive improvement in detection, prognosis, and treatment. The current understanding of prostate cancer genomes is still emerging, and studies can be limited by small sample sizes and 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 0.868 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.



3

ARCHES — Efficacy of Androgen Deprivation Therapy with Enzalutamide or Placebo in Metastatic Hormone-Sensitive Prostate Cancer: Prostate-Specific Antigen Results

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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 (NCT02677896), 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: 1150 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 rPFS overall, regardless of baseline PSA level (Table). 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 + ADT pts vs. 85.9% 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 predictive 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.

Results	ENZA + ADT	PBO + ADT	HR (95% CI)
Median baseline PSA, no. (ng/mL)	572 (5.36)	574 (5.07)	-
rPFS: overall population, no. (median, mo)	574 (NR)	576 (19.4)	0.39* (0.30-0.50)
rPFS: baseline PSA ≤ median, no. (median, mo)	293 (NR)	305 (NR)	0.37* (0.26-0.54)
rPFS: baseline PSA > median, no. (median, mo)	279 (NR)	269 (16.7)	0.41* (0.29-0.58)
Time to PSA progression, no. (median, mo)	574 (NR)	576 (NR)	0.19* (0.13-0.26)
Time to castration resistance, no. (median, mo)	574 (NR)	576 (13.9)	0.28* (0.22-0.36)
PSA reduction from baseline, no. (%) ≥ 50% ≥ 90%	 533 (92.9) 418 (72.8)	 327 (56.8) 173 (30.0)	 - -
PSA undetectable (< 0.2 ng/mL) rate, no. (%)	348 (68.1*)	89 (17.6)	-

*P < .0001; †Pts with detectable PSA at baseline.
Abbreviations: ADT, androgen deprivation therapy; CI, confidence interval; ENZA, enzalutamide; HR, hazard ratio; NR, not reached; PBO, placebo; PSA, prostate-specific antigen.

4

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

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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 nmCRPC, PSA doubling time ≤ 10 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 a ≥ 50% decline, of a ≥ 90% decline, and a decline to undetectable levels below the limit of quantification (Table). Median treatment duration was 18.4 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.

Baseline Characteristic	Enzalutamide + ADT (n = 933)	Placebo + ADT (n = 468)
Age, median, y	74	73
PSA doubling time < 6 mo, no. (%)	715 (76.6)	361 (77.1)
Serum PSA, ng/mL	11.1	10.2
Endpoint		
Patients with baseline PSA values, no. (%)	933 (100)	467 (99.8)
Patients with ≥ 1 postbaseline assessment, no. (%)	887 (95.1)	439 (93.8)
Confirmed PSA response > 50%, no. (%)	712 (76.3)	11 (2.4)
P value	< .0001	
Confirmed PSA response ≥ 90%, no. (%)	522 (55.9)	2 (0.4)
P value	< .0001	
Confirmed PSA response to undetectable level, no. (%)	90 (9.6)	0
P value	< .0001	
Time to first use of cytotoxic chemotherapy, median (95% CI), mo	NR (38.1-NR)	39.7 (38.9-41.3)
HR (95% CI)	0.38 (0.28-0.51)	
P value	< .0001	
CFDS, median (95% CI), mo	39.6 (37.7-NR)	38.9 (30.9-41.3)
HR (95% CI)	0.40 (0.31-0.52)	
P value	< .0001	
CFS, median (95% CI), mo	38.1 (37.7-NR)	34.0 (30.3-39.7)
HR (95% CI)	0.50 (0.40-0.64)	
P value	< .0001	

Abbreviations: ADT, androgen deprivation therapy; CI, confidence interval; NR, not reached.

5

Need for Intervention and Survival in a Cohort of Patients on Active Surveillance for Prostate Cancer

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Introduction: Active surveillance has become an accepted management strategy for very low risk, low risk, and select cases of favorable intermediate risk localized prostate cancer. Long term data will be critical to continued understanding of which patients are suitable for this strategy and when patients should transition to treatment. We update and investigate long-term follow up in our active surveillance cohort.

Materials & Methods: Under IRB approved protocol, a retrospective cohort study of 1291 men diagnosed with localized prostate cancer was performed at a single tertiary-care center from 1996-2016. In 2008 our group agreed on the following AS guidelines: Gleason ≤ 6 (Gleason 7 in select patients with low volume), ≤ 3/12 cores positive with ≤ 20% in each core, and PSA < 10. Our follow-up protocol includes: PSA/DRE every 4-6 months x 3 years, then annually. Mandatory confirmatory 12 core biopsy is performed at 12-18 months with subsequent biopsies at the discretion of the treating physician. In 2014 multiparametric MRI and fusion biopsy became integrated into our practice. Survival analyses were conducted using the Kaplan-Meier method.

Results: The study cohort consisted of 1291 men with a median age at diagnosis of 66.8 (IQR, 60.8-71.9 years). Median follow-up was 6.4 years (Range, 0.1-22.1 years). The median PSA at diagnosis was 5.1 ng/mL (IQR, 4.0-6.9 ng/mL) with 91% having a PSA < 10 ng/mL. Overall, 97.2% (1255/1291) of patients were Gleason 6 or lower, and 2.8% (36/1291) were Gleason 7. 92.4% (1193/1291) were stage T1c. At the time of analysis, 1155 (89.5%) men were alive and 136 (10.5%) died. Cancer specific survival was 98.8% at 10 years. Freedom from intervention was 68% at 5 years, 57% at 10 years, and 52% at 15 years. 455 men underwent definitive treatment with radical prostatectomy (41.1%), radiation therapy (47.3%), brachytherapy (11.4%) or focal therapy (0.2%). Reasons for intervention included: 74% pathologic progression, 9% PSA progression, 10% patient preference, 1% DRE progression, 3% radiographic progression and 4% other.

Conclusions: Approximately half of men on AS are treated by 10 years with the most common reason being pathologic progression. Active surveillance appears to remain a safe and established management strategy without a negative impact on the patient's ultimate care.

6

Multimodal Therapy for Patients with High-Grade, High-Risk Prostate Cancer with Long-Term Follow up

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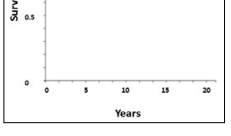
Introduction: High-risk prostate cancer requires a multimodal approach to treatment. Surgery has played an increasing role for these patients although long-term follow-up and experience with neoadjuvant therapy, a basic tenet of cancer treatment, remains limited. Here we report our experience with neoadjuvant hormonal ablation followed by surgery and postoperative radiation with greater than 20-year follow-up.

Materials & Methods: From 1990-2012, 82 patients with clinically organ-confined prostate cancer underwent multimodal therapy (MMT) consisting of neoadjuvant hormonal ablation followed by radical retropubic prostatectomy and postoperative radiation. High-risk prostate cancer was defined preoperatively as a Gleason Score 8-10 or PSA > 20. Patients with negative surgical margins were observed initially and treated with salvage XRT in the instance of recurrence. Adjuvant and salvage CSS were compared. Median follow-up for these patients is 10 years, ranging from 6 to 29 years.

Results: The MMT protocol was well tolerated in all 82 patients with no treatment-related discontinuation of therapy. Final surgical pathology revealed stage pT3-T4 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%) 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 58/82 (71%) patients with Gleason 8-10 cancers, cancer-specific survival for patients undergoing MMT at 10, 15 and 20 years was 54/58 (93%). Overall survival at 10, 15 and 20 years was 47/58 (81%), 46/58 (79%), and 42/58 (72%) respectively. Freedom from biochemical recurrence was at 38/58 (66%), 33/58 (57%) 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.



7

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 PCa, 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 pathology, 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 1.14-5.26, 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.

8

Is Gadolinium Really Necessary? Moving from Multiparametric to Biparametric Prostate MRI

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Introduction: Multiparametric magnetic resonance imaging (mpMRI) has been increasingly incorporated into prostate cancer care. Traditionally, mpMRI (mpMRI) combines T2-weighted (T2W), diffusion-weighted (DWI), and dynamic contrast-enhanced (DCE) sequences. Recent data have challenged routine use of DCE, since these images are only helpful for peripheral zone (PZ) lesions with equivocal DWI findings. Our objective was to determine how often DCE MRI provided actionable information among men undergoing prostate mpMRI.

Materials & Methods: We performed a retrospective review of our prostate MRI database from January 2012 through January 2018. PIRADS v2 was used as standard. Patients were characterized as active surveillance (AS), biopsy naïve (BN), or prior negative biopsy (PNB). DCE sequences were considered actionable if a PZ lesion deemed PIRADS 3 on DWI was upgraded to PIRADS 4 based on contrast-enhancement. Cost data were obtained from the Medicare Physician Fee Schedule Search.

Results: 153 patients (124 AS, 15 BN, 14 PNB) were included. Median age was 64 (IQR 58-64) years and the median PSA was 7.0 (IQR 5.0-11) ng/ml. Median PSA density was 0.15 (IQR 0.11-0.23 ng/ml/cc). One hundred twenty-seven PIRADS 1, four PIRADS 2, five PIRADS 3, fourteen PIRADS 4, and three PIRADS 5 lesions were identified. DCE provided actionable information in 4 men (2.6%). Eliminating DCE sequences would have saved $121.99 per MRI or $18,664.47 for the entire cohort (Table 1) at the risk of needing to repeat MRI imaging in 4 men.

Conclusions: DCE sequences provide little additional information over T2W and DWI in the vast majority of men undergoing prostate MRI. Routine use of DCE may represent low value care.

Table 1. Cost analysis of multiparametric versus biparametric prostate MRI

MRI pelvis with and without contrast	$476.75
MRI pelvis without contrast	$354.76
Cost differential per MRI	$476.75 - $354.76 = $121.99
Cost differential for entire cohort	$121.99 * 153 = $18,664.47

9

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 698,728 men with PCa treated with RP including 380.201 (54.41%) with PLND. Mean age at diagnosis was 62.6. PLND was omitted (Nx) 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 higher odds of 30-day readmission (adjusted OR: 1.52, 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

Variable	Odds ratio	95% CI	P value
Age at diagnosis	0.99	0.99-1.00	0.160
Median Income	0.96	0.92-1.00	0.105
Education	0.968	0.927-1.012	0.158
Distance to hospital	1.00	0.99-1.00	0.212
Race	1.12	0.86-1.46	0.370
Type of Hospital	0.95	0.88-1.02	0.199
Government Insurance	1.13	1.04-1.22	0.003
Facility Region Location	0.986	0.97-0.998	0.028
Capra Score			
0	Omitted	Omitted	Omitted
1	0.18	0.12-0.27	< 0.001
2	0.41	0.33-0.51	< 0.001
3	Ref.	Ref.	Ref.
4	1.59	1.33-1.89	< 0.001
5	3.63	3.17-4.16	< 0.001
6	5.26	4.59-6.03	< 0.001
7	9.01	7.83-10.3	< 0.001
8	10.19	8.60-12.09	< 0.001
9	11.65	8.86-13.77	< 0.001
10	19.05	13.80-26.30	< 0.001
LN count			
1-10	Ref.	Ref.	Ref.
11-20	3.13	2.90-3.37	< 0.001
21-30	5.07	4.50-5.73	< 0.001
> 30	6.58	5.38-8.05	< 0.001

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Impact of Second Generation Neoadjuvant Hormone Therapy on Radical Prostatectomy Outcomes

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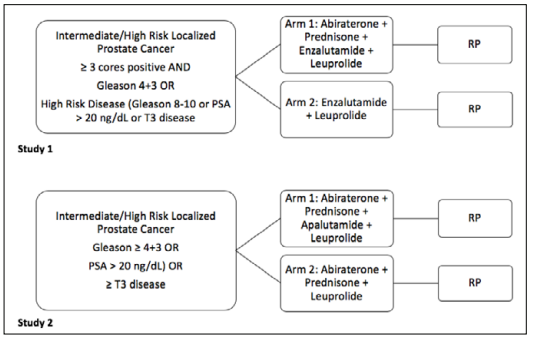
Introduction: Phase II trials have shown that intense neoadjuvant androgen deprivation therapy (NeoADT) with abiraterone or enzalutamide combined with luteinizing hormone-releasing hormone (LHRH) analogues demonstrate favourable pathologic response in prostate cancer. There are currently phase III trials 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. Thirteen 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 regain 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 1 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 potency at 1-year post-RP compared to 12% of those with higher residual disease (P < 0.001). ypT0 patients had similar continence rates as patients with higher residual disease with only 1 patient using more than 1 pad per day in each group.

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.

Figure 1. Neoadjuvant Androgen Deprivation Therapy Protocol



11

Associations of Rurality and Disease Outcome in Urologic Malignancy

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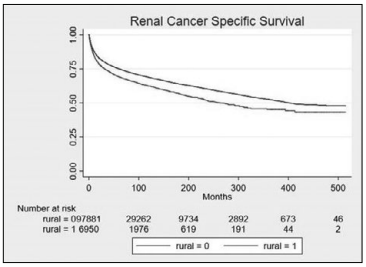
Introduction: Patients residing in rural regions have comparatively worse outcomes for many cancers. However there is less known about treatment and outcome for patients with urologic cancers. The objective of this study is to evaluate differences in treatments and outcomes among patients with urologic 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 older at cancer diagnosis (mean 70 ± 12.1 vs. 67.41 ± 12.7) and more frequently of white race (97.1% vs. 82.46%) vs. urban counterpart. Patients residing in rural counties were less likely to undergo definitive treatment with surgery for stage 1 or stage 2 disease ($p < 0.001$). In multivariable Cox regression, rural status was associated with greater risk of cancer-specific death in kidney cancer (HR: 1.1, 95% CI: 1.02-1.24; P value: 0.03) but was not seen in other cancers (Figure 1). After categorizing the population based on % of rurality, adjusted kidney cancer-specific death increased among most rural populations: 15% rurality or more (HR: 1.16, 95% CI: 1.05-1.27; P: 0.03), 40% rurality or more (HR: 1.31, 95% CI: 1.15-1.49; $P < 0.001$) and 70% or more (HR: 1.32, 95% CI: 1.05-1.67; P value: 0.01).

Conclusions: There are notable differences in cancer incidence, treatment and outcome for patients residing in rural areas. Rural status was associated with poorer cancer-specific survival for kidney cancer but was not seen in other genitourinary malignancies, independent of stage at diagnosis and treatment received. Further research is warranted to understand the factors underlying these differences in outcome.



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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 PI-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 PI-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 PI-RADS 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 1.59, 95%CI 1.03-2.47, $p = 0.03$), 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 1.88-5.72, $p < 0.001$) 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 (PI-RADS 4 or 5). By contrast, men with a P4 lesion and an additional low-grade lesion (PI-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. Willscher Award Eligible

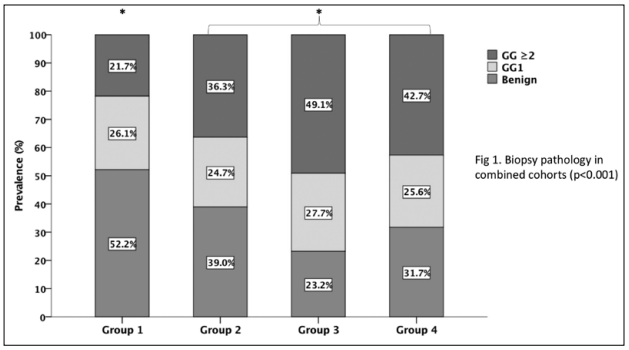

Fig 1. Biopsy pathology in combined cohorts (p<0.001)

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Independent Contributions of MRI Fusion and Systematic Prostate Biopsies to Detect Clinically Significant Prostate Cancer: A Multi-Institutional Review

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Introduction: MRI fusion biopsies are being increasingly utilized to both diagnose and manage prostate cancer. However, the added benefit of fusion biopsies compared to systematic biopsies varies greatly in the literature. We compare the clinically significant cancer detection rates (≥ Grade Group 2 (GG 2)) between 3 separate institutions (A, B, C) performing concurrent targeted and systematic biopsies.

Materials & Methods: MRI fusion biopsies performed at each institution over similar time periods were identified. Fusion biopsies were performed with the UroNav system at two institutions (A, C) and the BioJet system at the other. Patient demographics, clinical information, MRI/TRUS results, and pathology results were collected. Chi square comparisons of proportions were used for statistical analysis (MedCalc).

Results: 256, 76, and 202 men underwent MRI fusion biopsies at institutions A, B, and C respectively with demographics and overall cancer detection rates as shown (Table 1). There were more men on active surveillance at Institution A ($p < 0.0001$); age at biopsy, PSA, number of cores obtained, and cancer detection rates were similar across institutions. The rate of ≥ GG 2 prostate cancer detected by targeted biopsies but missed by systematic biopsies was 5.5%, 18.4%, and 7.4% at institutions A, B, and C with an overall rate of 8.0%. The rate of systematic biopsies detecting ≥ GG 2 prostate cancer missed by targeted biopsies was 9.8%, 2.6%, and 7.0% with an overall rate of 7.3% (Table 2). Using the presence of ≥ GG 2 cancer on any biopsy as the presumed incidence, the sensitivity of targeted biopsies to detect ≥ GG 2 cancer is 66.2%, 93.75%, and 85.4% respectively. Targeted biopsies are statistically less sensitive at Institution A v B ($p = 0.006$) and A v C ($p = 0.009$) but similar at B and C ($p = 0.370$). The sensitivity of random biopsies to detect ≥ GG 2 cancers is 81.1%, 56.25%, and 81.7%. Random biopsies were statistically more sensitive at Institution A v B ($p = 0.015$) and C v B ($p = 0.010$) but similar at A and C ($p = 0.910$). Comparing the sensitivity of random and targeted biopsies within each institution demonstrates only Institution B has a higher detection rate with targeted biopsies ($p = 0.002$). Institution A approached statistical significance in favor of random biopsies ($p = 0.061$), and there was no difference at Institution C ($p = 0.700$).

Conclusions: The value of targeted and systematic biopsies to detect ≥ GG 2 prostate cancers varied widely between 3 institutions. Limits of this study include its retrospective nature, an unequal distribution of total patients, an unequal distribution of patients with prior prostate cancer, equipment variability, and user variability. It stresses the importance of all institutions to critically examine their own outcomes. Overall, MRI fusion biopsies uniquely identified 8.0% of ≥ GG 2 prostate cancers while systematic biopsies uniquely identified 7.3% indicating that both methods significantly contribute to risk stratification.

Table 1. Demographics and overall prostate cancer detection at three institutions

	Institution A	Institution B	Institution C
# Active Surveillance (%)	157 (61.3%)	23 (30.3%)	61 (30.2%)
# PCa Naïve (%)	95 (37.1%)	48 (63.2%)	139 (68.9%)
# Prior PCa	4 (1.6%)	5 (6.6%)	2 (1.0%)
# Total biopsies	256	76	202
# Positive biopsies (%)	169 (66.0%)	53 (69.7%)	134 (66.3%)
Median age (range)	65y (40y-83y)	66y (51y-80y)	68y (51y-82y)
Median PSA (range)†	5.9 (0.4-99.4)	6.3 (0.4-31.0)	6.1 (0.7-31.0)

Overall sample = 534 patients across 3 institutions. †PSA units are ng/mL.
PCa: prostate cancer

Table 2. Overall detection rates† of clinically significant‡ vs. non-clinically significant prostate cancer using targeted and systematic biopsies

		Systematic Biopsies		
		No PCa	GG 1 PCa	≥GG 2 PCa
Targeted Biopsies	No PCa	179 (33.5%)	89 (16.7%)	20 (3.7%)
	GG 1 PCa	15 (2.8%)	63 (11.8%)	19 (3.6%)
	≥GG 2 PCa	15 (2.8%)	28 (5.2%)	106 (19.9%)

†Overall sample = 534 patients across 3 hospitals; ‡Clinically significant defined as grade group ≥2.
PCa: prostate cancer; GG: grade group

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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% (25) from systematic biopsy ($p < 0.001$). Among patients with GG3 on biopsy (46), 57% (26) were downgraded to GG2 prostate cancer on final prostatectomy pathology. There were higher rates of downgrading when regarding targeted biopsy (47%) compared to systematic biopsy (17%) ($P = 0.01$). Among patients with GG4 and GG5 (47), 74% (35) were downgraded on final prostatectomy pathology. There were higher rates of downgrading when regarding targeted biopsy (68%) compared to systematic biopsy (34%) ($P = 0.001$). On multivariable regression analysis adjusted for clinical, radiologic, and pathologic factors, targeted biopsy Gleason GG (GG3-5 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.

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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, 1-2 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 (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 2.59. 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 (32%) 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 (59%), while a rising serum PSA (64%) was the most likely reason for progression in the NSAS group ($p = 0.006$). 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 in the SAS group (25%) and RP was the second 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.

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4Kscore and mpMRI, in Combination, Safely Reduces Prostate Biopsy Rates

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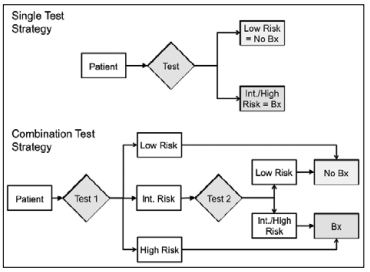
Introduction: mpMRI and biomarkers have emerged as popular alternatives prior to prostate biopsy (Bx). We investigate a combination of the 4Kscore Test and mpMRI to improve diagnostic performance, and potentially further reduce Bx rates compared to the individual tests alone.

Materials & Methods: A retrospective, five-center study of 407 men who underwent a 4Kscore, mpMRI, and Bx. mpMRI results were reported with PIRADS and categorized as low (PIRADS 1-2), intermediate (PIRADS 3) and high (PIRADS 4-5). The 4Kscore Test is reported as a continuous percent probability of diagnosing high-grade GG2 or higher cancer (HG): categorized into low (< 7%), intermediate (8-32%), and high (> 33%) risk. The primary endpoints evaluated potential Bx reduction, sensitivity, negative predictive value (NPV), and undetected HG cancers when utilizing Single Test or Combination Test strategies for Bx decision-making. Either test was evaluated independently, versus both tests in sequence. Single Test men were stratified with low risk results, avoiding Bx, and intermediate or high risk, poceeding to Bx. Combination Test, high-risk patients by the first test would receive a Bx and low risk would not. Intermediate risk patients, the second test would be used for determining if a Bx would occur (Fig. 1).

Results: The study includes 407 men: 114 were discovered with HG cancer. Using 4Kscore or MRI alone, resulted in a 25-27% biopsy reduction, with 8-12 men having undetected HG. Combination strategies yielded higher specificities, leading to larger biopsy reductions in the range of 38-41%, while 11-15 men had an undetected HG. Sensitivity and NPV did not appreciably differ between strategies (Table 1). Similar results were observed in those with a total PSA of 2-10 ng/mL and 3-10 ng/mL.

Conclusions: 4Kscore Test and mpMRI, in conjunction, enhances prostate Bx decision making could further reduce Bx rates, while improving specificity for high-grade cancer, with minimal changes to NPV and sensitivity.

Test	Bx Reduction (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Undetected GG2+ Ca (vs. biopsy all)
4Kscore (Single Test)	24.8	93.0	31.7	34.6	92.1	8
mpMRI (Single Test)	27.0	89.5	33.4	34.3	89.1	12
4Kscore = Test 1 mpMRI = Test 2 (Combination Test)	41.0	88.6	52.6	42.1	92.2	13
mpMRI = Test 1 4Kscore = Test 2 (Combination Test)	37.6	86.8	47.1	39.0	90.2	15



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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 multiparametric MRI and were scored using PIRADS v.2. 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 GG≥2. Patients at the NA setting were matched to academic setting controls using Mahalonobis-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 a 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. Secondary analysis of imaging and pathology characteristics was performed using weighted samples t-tests for continuous variables and pearson chi-square for discrete variables.

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 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 or template-directed cores (Table 1). On average, lesions were given lower PIRADS 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.

*Max K. Willscher Award Eligible

Figure 1. Standardized mean differences and variance ratios before and after matching

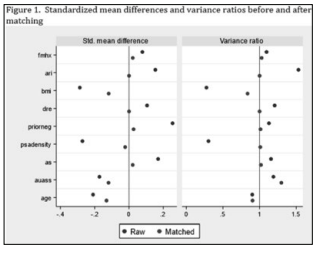
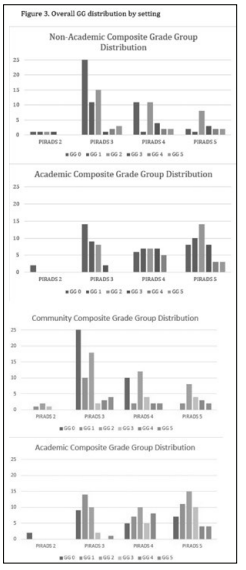


Table 1. Effect of non-academic setting on FB outcome

Treatment effect of NA setting	Effect	Std Error	P>|z|	95% CI	
Overall csPCa detection	3.93% increase	6.72%	0.58	-0.10	0.17
csPCa by FB cores	7.68% increase	6.86%	0.24	-0.06	0.22
csPCa by Template cores	8.32% decrease	6.81%	0.25	-0.22	0.06
Upgrade due to FB cores	0.88% increase	3.97%	0.99	-0.08	0.08
Upgrade due to template cores	1.37% increase	6.63%	0.92	-0.12	0.14
csPCa missed by template cores	7.86% increase	5.09%	0.11	-0.02	0.19
csPCa missed by FB cores	9.84% decrease	5.78%	0.07	-0.22	0.01



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MRI Membranous Urethral Length Does Not Predict Early Return to Continence Following Robotic-Assisted Radical Prostatectomy

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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 continence as 0 pads and early vs. late continence as ≤ 3 months vs. > 3 months. Cohort two defined continence as 0-1 pads and early vs. late continence as ≤ 2 months vs. > 2 months. Univariate analysis was conducted using analysis of variants (AVONA) 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 ($p = 0.63$). On bivariate analysis, smaller prostate size was 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 status, total days of post-operative catheter placement, pathologic stage, and Gleason score were also evaluated. On multivariate analysis, none were independently associated with early return to continence. For cohort two, MUL was again not predictive of early continence ($p = 0.960$). 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 ($p = 0.015$) were both predictive of late return to continence. On multivariate analysis, again, no 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.

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Combination of Multiparametric MRI-Ultrasound Fusion and Systematic Prostate Biopsy Results in Optimal Concordance with Final Surgical Pathology

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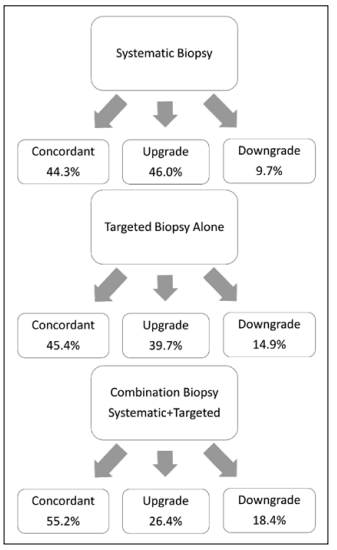
Introduction: Accurately predicting the Gleason score (GS) on radical prostatectomy (RP) with prostate biopsy is important for risk stratification and selecting patients for active surveillance. Multiparametric MRI (mpMRI) is useful for detecting clinically significant disease, but the exact concordance 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, 174 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) 1.25, 95% confidence interval (CI) 1.08-1.44, P = 0.003] and targeted biopsy (RR 1.22, 95% CI 1.08-1.37, P = 0.002) for predicting concordance with surgical pathology. There was no significant difference in concordance rates between systematic and targeted biopsy alone (P = 0.90). The relative risk of upgrade on surgical pathology with combination biopsy was significantly lower when compared to systematic (RR 0.58, 95% CI 0.48-0.70, P < 0.001) or targeted biopsy alone (RR 0.67, 95% CI 0.57-0.79, P < 0.001).

Conclusions: Combination (targeted and systematic) biopsy is associated with the highest concordance rate between biopsy and RP when compared with systematic or targeted biopsy alone. 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.



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Does Post Prostatectomy Decipher Score Predict PSA Recurrence and Impact Care?

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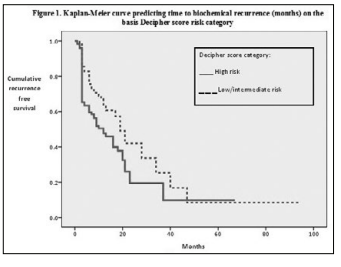
Introduction: Decipher score (GenomeDx Biosciences) is a genomic classifier that predicts the 5-year risk of metastasis after radical prostatectomy (RP). Decipher score may also be used to guide the timing of adjuvant vs. salvage radiotherapy. We examined the ability of Decipher to predict biochemical recurrence (BCR) and to impact clinical decision making.

Materials & Methods: We identified post-RP Decipher tests ordered for adverse pathology between 1/1/14 and 8/31/18. BCR was defined as a PSA > 0.02 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 > .02 and < .20 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 (58.6%) had Gleason Grade Group 4+3 or higher and most (70.7%) had stage 3 disease or higher. Median (IQR) follow-up was 12.0 (6.6, 18.8) 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 (59.5%) than those with non high-risk scores (20%; p = .001). This relationship was significant independent of pre-operative 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 early 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.



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Laboratory Testing Following Robotic Assisted Laparoscopic Radical Prostatectomy Does Not Change Clinical Management

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Introduction: Robotic assisted laparoscopic radical prostatectomy (RALP) has evolved into a safe and efficacious procedure with excellent outcomes. Routinely, laboratory tests are conducted following RALP. In this study, we evaluated the necessity of laboratory tests in patients undergoing RALP and any associated clinical value.

Materials & Methods: Data was gathered retrospectively from records of patient between the ages of 40-80 that underwent RALP for prostate cancer in our institution between 3/29/2015 - 12/31/2017. Patients were included if they had RALP with or without lymph node dissection, preoperative laboratory testing performed within 30 days of surgery and again one day post- operatively. Patients were excluded if they had a concurrent procedure. The following laboratory values were reviewed: Hemoglobin, platelets, white blood cells, calcium, sodium, potassium, chloride and creatinine. Post-operative tests results were considered abnormal if they were outside our organization's standardized normal range.

Results: 156 patients met all above-mentioned criteria. 4 patients had abnormal laboratory values post-operatively (leukocytosis). After careful review of their medical records we found that all 4 patients were a-febrile, did not receive antibiotic treatment and were discharged the following day without any change in their clinical management. None of these patients had any post-operative complications, unplanned visits to ED or readmissions within 90 days.

Conclusions: In our retrospective observational study, we found no evidence of a clinical need to perform laboratory tests in uncomplicated patients undergoing RALP. Such unnecessary tests increase the chances of infection, increase costs and pose a burden on the healthcare system. There may still be a need to perform tests in patients that complicated intraoperatively or that have co-morbidities that predispose them for post-operative complications.2

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A Multi-Institutional Assessment of Multimodal Analgesia in Penile Implant Recipients Demonstrates Dramatic Narcotics Reduction

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Introduction: Increasing regulations are being placed on providers in an effort to combat the growing opioid epidemic in the United States. Although implantation of an inflatable penile prosthesis (IPP) is associated with significant post-operative pain, there have been few rigorous attempts at describing non-opioid based pain management strategies for implant recipients. Here, we present results of a multi-institutional assessment of a multimodal analgesic (MMA) regimen in patients (pts.) undergoing IPP surgery to a matched cohort of pts treated with a traditional opioid-based (OB) regimen.

Materials & Methods: We performed a multicenter comparison of pts. undergoing IPP implantation by high-volume implanters whose pain was managed using a recently described, novel MMA protocol (Table 1) to a matched, historic cohort of pts. managed via an OB protocol. Patients were excluded if they underwent any additional procedure or had a history of narcotic dependence. Both groups were compared with respect to visual analog pain scale (VAS), and opioid usage (total morphine equivalents, TME) in the post-anesthesia care unit (PACU), post-operative days (POD) zero and one, and in immediate post-discharge period. Narcotics usage on discharge and follow up were assessed and compared between both groups.

Results: 91 pts. were eligible for final analysis: 53 (58%) in MMA arm and 38 (42%) in the OB arm. There were no differences between groups with regards to age, race, BMI, or medical comorbidities. VAS was significantly lower in the MMA group in PACU (mean 1.1 vs. 2.9, $p = 0.002$), POD0 (mean 2.8 vs. 4.7, $p = 0.001$), and POD1 (mean 3.02 vs. 4.00, $p = 0.04$). Patients in the MMA group used fewer narcotics in the PACU (mean 1.6 vs. 4.3 TME, $p = 0.002$), POD0 (mean 5.8 vs. 13.8 TME, $p < 0.001$), and POD1 (mean 10.8 vs. 25.1 TME, $p = 0.001$). Despite being discharged with substantially fewer narcotics (mean 14.9 vs. 51.3 tabs, $p < 0.001$), a smaller proportion of MMA pts. required narcotic refills (7.5% vs. 47.4%, $p < 0.001$). No pts. in either group experienced significant medication-related side-effects.

Conclusions: To our knowledge, this is the first multicenter pain management investigation in penile implant recipients. The use of a multimodal analgesic protocol not only demonstrates excellent durability in significantly reducing post-operative pain but further reduces inpatient and outpatient narcotic usage without any discernable side-effects.

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Compliance Rates for Post-Vasectomy Semen Analysis Using Laboratory Versus Home-Based Tests

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Introduction: Vasectomy is a common urologic procedure. Post-vasectomy semen analysis (PVSA) is an important test to ensure successful sterilization. Compliance rates are reported around 50%. FDA approved home-based sperm antigen semen tests might improve PVSA compliance when done in the privacy and convenience of home with the immediate gratification of the knowing the results. Current AUA guidelines recommend visual laboratory inspection of the post-vasectomy semen 8-16 weeks following the procedure. This study explores differences in compliance rates between lab-based and home-based PVSA.

Materials & Methods: We conducted a retrospective chart review of patients who underwent vasectomy by one of three surgeons between May 2017 and June 2018. Patients were excluded if they had undergone prior vasectomy or vasectomy reversal. Following vasectomy, two surgeons prescribed laboratory-based PVSA and the third prescribed home-based PVSA (SpermCheck). Patients were considered to be compliant if they completed PVSA within the 8-16 week post-vasectomy time frame recommended by the AUA.

Results: Two hundred and two patients underwent vasectomy in the capture period. One hundred and twenty-five patients comprised the lab-based PVSA cohort and 77 patients in the SpermCheck cohort. The patients in each group were similar in terms of age (39.2 vs. 39.9, $p = 0.497$) and prior children (2.38 vs. 2.41, $p = 0.804$). The compliance rate for lab-based PVSA was 60.2% and for SpermCheck was 80.4% ($p = 0.020$). The rate of negative semen analysis was equivalent between the two groups (94.2% vs. 96.0%, $p = 0.482$).

Conclusions: Utilization of a home-based semen analysis showed a higher rate of PVSA compliance compared with a traditional lab-based test. Compliance rates for the lab-based PVSA cohort is similar to that reported in the literature. Use of an at-home testing kit may increase compliance with PVSA by means of convenience and reduced stigma surrounding semen analysis, and improved compliance will ideally reduce unintentional pregnancies. As a small retrospective cohort, this study expands the conversation about the role of home-based testing within the AUA guidelines.

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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 (PP) 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.

Materials & Methods: We conducted a retrospective review of 716 diabetic patients undergoing primary PP (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 immunosuppression, 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 7.5% ± 1.5, respectively. Most PP were inflatable (98.6%). Devices used were AMS 700 (43.2%), AMS Ambicor (0.1%), Coloplast Titan (55.3%), 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 explantation and revision rates with PBG levels ($p = 0.567$ and 0.517, respectively), nor with HbA1c levels ($p = 0.219$ and 0.160, 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.

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Cutting the Cord: A National Survey on Urology Resident Vasectomy Training

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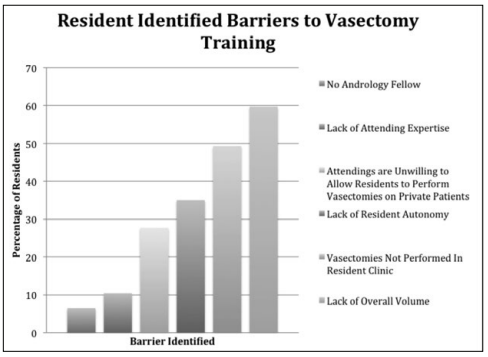
Introduction: Vasectomy is one of the most common in office procedures performed by urologists. Vasectomy is generally performed under local anesthesia while the patient is awake in a urology clinic. This makes the procedure technically challenging and difficult to teach to urology residents. There has been limited research on resident training in vasectomy. Nguyen et al[1] 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), 37% of Uro 2's, 10.7% of Uro 3's and 10.7% 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 highlighting areas for improvement 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.

[1]Nguyen 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 Procedure. *J Urol* 2008;180(4):1451-1454. Doi:10.1016/j.juro.2008.06.047.



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The Use of Penile Computed Tomography Cavernosogram (CTC) in the Evaluation of Peyronie's Disease

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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, is 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. Intralesional 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 iodinated 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 exceeding previous clinical assessment was frequently identified. Corporal 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.

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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 data 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 + Cephalosporin (Cefazolin), while 321 (53.2%) received prophylaxis that differed from guidelines. The number of infections in the AUA guidelines group was 17 (6.0%) vs. 6 (1.9%) for the non-AUA guidelines group, $p = 0.008$. The number of explantations in the AUA guidelines group was 23 (8.2%) vs. 6 (1.9%) in the non-AUA guidelines group, $p < 0.001$. There was no significant difference in revision rates between the two groups ($p = 0.360$). On further analysis, the infection rate for patients treated with Gentamicin + Vancomycin (7.73%) dropped significantly when a Quinolone (1.04%) was added to the regimen, $p = 0.001$. Similar reductions were seen with explantation (9.6% to 1.0%, $p < 0.001$) and revision (8.2% to 3.1%, $p = 0.028$) rates. Out of the 23 recorded infections, 14 (60.9%) of them grew a positive culture with at least one isolated organism and 6 (42.9%) of them grew multiple species. Overall, 9 (64.3%), 6 (42.9%), 4 (28.6%), and 3 (21.4%) of the cultures grew gram-positive, gram-negative, anaerobic bacteria, and fungi, respectively.

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 most commonly prescribed antibiotic regimen of Gentamicin + Vancomycin. The AUA guidelines should be amended to reflect findings of this and other device infection related studies.

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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. Resultant 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 PVI irrigation, demonstrating a reduction in postoperative infectious complications, table 2. Conclusion: Urologists should consider utilizing dilute PVI irrigation during salvage procedures, 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.

Irrigant	Cytotoxicity	activity	Animal	Summary
Povidone-iodine	Rabenberg 2002	Rabenberg 2002	Gilotra 2015	Most in vitro studies show cytotoxicity at subclinical concentrations (0.001%-1%) to various cell lines including fibroblasts. Activity against gram positive organisms as well as biofilm formation demonstrated. PVI irrigation in rabbit model of prosthetic joint infection showed significant reduction in bacterial burden. Conflicting evidence on causing tissue inflammation and reduced healing. Significant cytotoxicity at concentration as low as 0.03% and at all bactericidal concentrations. Animal studies showed impairment to healing and increased tissue inflammation. Cytotoxicity at subclinical concentrations noted (>0.002%), to various cell lines including fibroblasts. Antimicrobial activity to gram positives, gram negatives, and even biofilm formation in some studies superior to PVI.
	Liu 2017	Udowsik 2016	Hasiolo 2016	
	van Meurs 2014	van Meurs 2014	Cheng 2015	
	Schaumberger 2010	Schmidt 2018		
	Sawada 2018	Zhaden 2018		
Hydrogen Peroxide	Rabenberg 2002	Rabenberg 2002	Hasiolo 2016	
	van Meurs 2014	van Meurs 2014	Cheng 2015	
	Schaumberger 2010			
	Sawada 2018			
Chlorhexidine	van Meurs 2014	van Meurs 2014	Penn-Barwell 2012	
	Liu 2018	Schwentner 2011		
	Sawada 2018	Smith 2215		
		Schmidt 2018		
		Zhaden 2018		

*Mulcahy salvage utilizes half strength povidone-iodine (5%) and half strength hydrogen peroxide (1.5%)

Table 1: Review of preclinical data on the solutions of interest. Publications are separated by their findings on in-vitro cytotoxicity, antibacterial activity, and results in animal models. Studies shaded in green denotes a favorable cytotoxic profile, antibacterial activity, or effect on wound healing. Studies with findings of cytotoxicity, inadequate antibacterial activity, and impairments to wound healing are shaded in red.

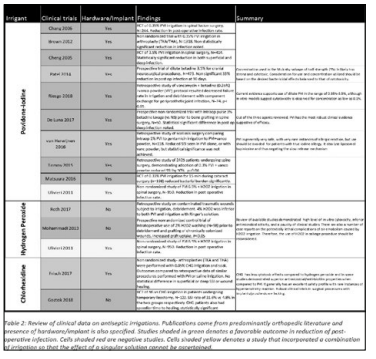

Table 2: Review of clinical data on antiseptic irrigations. Publications come from predominantly orthopedic literature and presence of hardware/implant is also specified. Studies shaded in green denotes a favorable outcome in reduction of post-operative infection. Cells shaded red are negative studies. Cells shaded yellow denotes a study that incorporated a combination of irrigation so that the effect of a singular solution cannot be ascertained.

28

Assessment of Novel Extended Manual Modeling Demonstrates Safe and Effective Reduction of Residual Penile Curvature During Penile Prosthesis Implantation

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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 have opted towards other surgical options for treating concomitant ED and PD. Comparison was made of outcomes in patients undergoing a variant of the original technique ('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 who underwent EMM were compared to a matched 1:2 cohort of NAS patients. 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°; $p < 0.0001$). An example patient is seen in Figure 1. There was no difference between EMM and NAS cohorts with respect to operative time (93.8 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 rear-tip extender (1.1 cm vs. 1.8 cm; $p = 0.006$). 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.

30

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, 1,083,176 Medicare beneficiaries had 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 exists 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.

P1

The Use of Urethral Slings to Treat Incontinence in Elderly Women: Is it Safe?

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Introduction: Urethral slings are a durable treatment for stress urinary incontinence. However, there is a paucity of data on the use of slings in the very elderly. Here, we sought to evaluate the use of urethral slings to treat incontinence in female octogenarians.

Materials & Methods: The Premier Hospital Database (2003-2015) was queried using International Classification of Diseases (ICD-9) procedural codes (CPT) codes for urethral sling procedures. Slings were classified by type (retropubic, transobturator or single incision). Advanced age was defined as ≥ 80 years old. Prolonged length of stay (pLOS, ≥ 1day), prolonged operative time (pOT, ≥ 90 minutes), major post-operative complications, sling type, and excess cost (≥ $5397) were analyzed. Each threshold represents ≥ 75thpercentile. Chi-squared and logistic regressions were used for analysis.

Results: A total of 143,474 women who underwent urethral sling placement were identified, with a median age of 55 years (25-85). Of these, 59,212 were ≥ 80 years old (41.3%). There was no association between advanced age and sling type ($p = 0.142$). Sling placement was associated with an overall post-operative complication rate of 0.35% (503/143,474). Age ≥ 80 was associated with a higher rate of major post-operative complications (OR 5.99, 1.72% vs. 0.29%, $p < 0.0001$), pOT (27.2% vs. 20.3%, $p < 0.0001$), pLOS (32.7% vs. 21.6% $p < 0.0001$), and excess cost (35.5% vs. 24.6%, < 0.0001). When controlled for pOT and Charleson Comorbidity Index (CCI), age was still associated with increased rate of major complications (OR 3.44, $p < 0.0001$).

Conclusions: While octogenarians are more likely than younger women to experience major complications after sling placement, the observed rate was only 1.7%. In our nationally-representative sample, age >= 80 was also associated with pOT, pLOS, and excess cost. Thus, urethral sling should be considered for well-selected octogenarians suffering from stress incontinence, but every effort should be made to medically optimize these patients pre-operatively, and patients should be counseled appropriately on their increased risk.

P2

Intravesical Botulinum Toxin Injections for Detrusor Overactivity in Patients Suffering from Multiple Sclerosis; Appropriate Clinical Practice for Retaining this Population

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Introduction: Multiple sclerosis (MS) is a progressive demyelinating disease affecting the central nervous system which is frequently related to voiding dysfunction and a wide range of urinary complications. Detrusor overactivity (DO) is the most frequently reported urodynamic abnormality. DO is often associated with an overactive bladder, defined by urgency, possibly associated with urge incontinence, daytime frequency, and nocturia. When DO is refractory to antimuscarinic medication, botulinum toxin-A (BTX-A) injections may be a reasonable alternative to improving bladder function. Muscle fiber paralysis occurs within the first few days of injection, and toxin effects in the detrusor muscle generally last 6 to 12 months. Clinically, intradetrusor injection of BTX-A has been found to decrease urinary incontinence and improve quality of life. BTX-A is an ideal therapy due to its effectiveness and long duration of action, relative ease of administration, easy learning curve, reproducibility of results on repeated administration, and low incidence of complications. There is a reported prevalence of 72% of MS patients requesting re-treatment with BTX-A.[1] This study was conducted to assess adherence among MS patients who initiated BTX-A injection therapy with intent to identify the patient characteristics, comorbidities, or complications related to treatment cessation.

Materials & Methods: After IRB approval, a retrospective chart review of patients who had been identified through a multidisciplinary MS care center were analyzed. Patients received at least 1 BTX-A detrusor injection treatment between August 2016 and October 2018. BTX-A treatment consisted of multiple trigone-sparing detrusor muscle injections consisting of 200 to 300 units of BTX-A under cystoscopic guidance.

Results: A total of 276 BTX-A treatments were performed on 76 patients. There was a preponderance of females (69% vs. 31%) and mean patient age was 53.1 years (range 28 to 86). Of those patients, 13 received 1 injection (17%), 12 received 2 treatments (16%), and 51 received 3 or more treatments (67%). The median time between successive treatments was 7.6 months (SD 2.4). Of the patients who failed to return for subsequent treatment, the primary reasons reported for nonadherence were urinary retention requiring CIC, progression to alternative treatment (i.e. sacral nerve stimulation), or infectious complications. The majority of patients who received multiple injections reduced or even stopped taking anticholinergic drugs.

Conclusions: Poor patient adherence is an important area to consider in outcomes research and healthcare cost. Despite substantial sequelae, there is limited research substantiating best practices for engaging and retaining the MS population. Appreciating the high adherence rate to treatment with BTX-A will hopefully underscore the importance of thorough education efforts, exploring questions and patient misperceptions, and providing for treatment adherence. We may conclude that patients prematurely discontinue therapy for a number of possible reasons that include the treatment failure or complication, the cost (financial or personal), dosing frequency and expectations of treatment. The route of administration of medication is also a factor which influences adherence.

1. Khan S, Game X, Kalsi V, et al. Long-term effect on quality of life of repeat detrusor injections of botulinum neurotoxin-A detrusor overactivity in patients with multiples sclerosis. *J Urol* 2011;185:1344-1349.

P3

The Role of Anesthesia in Urinary Retention Following Mid Urethral Sling

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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 25 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 preoperative 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 preoperative 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

Variable	Passed void trial	P value
Scopolamine		**0.048**
Yes	15/25 (60%)	
No	50/57 (87.7%)	
Surgical approach		**0.005**
Retropubic	23/36 (63.9%)	
Transobturator	42/46 (91.3%)	
Paralytic (rocuronium/vecuronium)		0.16
Yes	30/42 (71.4%)	
No	35/40 (87.5%)	
Preoperative antidepressants		**0.03**
Yes	21/22 (95.5%)	
No	44/60 (67.7%)	

P4

Green Light Laser Enucleation of the Prostate (GLEP) with Lasting Outcomes: Longer-Term Follow-up

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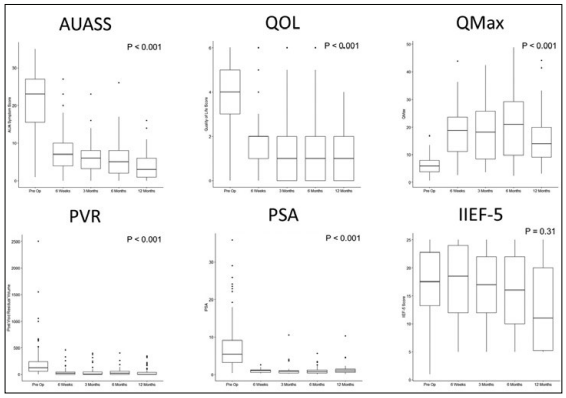
Introduction: The short-term safety and efficacy of the Green Light Laser Enucleation of the Prostate (GLEP) has been reported previously. Theoretical advantages of GLEP include improved hemostasis due to the absorption spectrum of 532nm laser, better tissue handling due to the side-firing laser fiber, 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 prostates.

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 stricture 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.

	Patient and Perioperative Characteristics
Number of Patients	148
Age at Surgery (years)	70.5 ± 7.4
ASA Score	2.3 ± 0.5
PSA (ng/mL)	9.1 ± 22.0
Prostate Volume (cc)	143.7 (range 40-570)
>80cc	129 (86.0%)
Catheter Dependent	48 (33.8%)
Pre-Operative Prostate Medications	
Patients on a-blocker	114 (77.0%)
Patients on 5-ARI	63 (42.6%)
Patients on Anti-Coagulation	
Aspirin	68 (45.9%)
Plavix	2 (1.4%)
Coumadin	6 (4.1%)
Xarelto/Apixaban	5 (3.4%)
Applied Energy (kJ)	116.74 ±180.8
Lasing Time (minutes)	29.49 ±15.57
Procedure Time (minutes)	134.04 ± 55.32
Pathology	
Benign	141
Gleason 3+3	4
Gleason 3+4	3
Specimen Weight (grams)	73.7 ± 53.8
Discharge POD 1	73.6%
Void trial on POD 1	74.3%
Passed Initial Void Trial	91.2%



Poster Session I: Incontinence/Overactive Bladder/BPH/ Female/Reconstruction

P5

Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms (LUTS) Due to Benign Prostatic Hyperplasia (BPH): Durable 4-Year Results from Randomized Controlled Study

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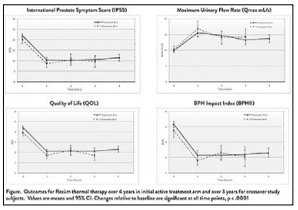
Introduction: A randomized controlled trial of water vapor thermal therapy was conducted to treat moderate to severe LUTS/BPH and to determine minimal important differences in International Prostate Symptom Scores (IPSS) associated with perceptible changes in quality of life (QOL).

Materials & Methods: Total 188 subjects in active arm: 135 men ≥ 50 years old, IPSS ≥ 13, maximum flow rate (Qmax) ≤ 15 ml/s and prostate volume 30 to 80 cm^3 treated with Rezūm® System thermal therapy were followed 4 years; subset of 53 men, requalified for crossover from control to active treatment were followed 3 years.

Results: IPSS, QOL, Qmax and BPH Impact Index improved ~50% and remained consistently durable throughout 4 years, p < .0001 (Figure); crossover subjects had similar sustained outcomes. At 4 years surgical retreatment rate was 4.4%, BPH medication resumption rate was 5.2%. Sexual function was preserved. IPSS and QOL scores strongly correlated; a mean IPSS change corresponding to a 1-point QOL improvement is ~ -5 points for IPSS 13-19, -8.2 for IPSS 20-26, -11.7 for severest LUTS of IPSS 27-35.

Conclusions: Rezūm thermal therapy provides effective symptom relief and improved QOL with durability over 4 years, has limited impact on sexual function and is applicable to all prostate zones with procedures performed under local anesthesia in an office setting.



P6

Comparison of Transabdominal and Transrectal Ultrasound for Sizing of the Prostate

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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 Imagining (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. PUS and TRUS were compared by calculating the Pearson correlation coefficient and interclass correlation coefficient (ICC), and agreement between modalities assed 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/m^2, 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 ± 4.8) cm^3 and by TRUS (64 ± 4.9) cm^3. The mean of the volume differences, Vol_{PUS} - vol_{TRUS}, was (-0.2 ± 2.2) cm^3, with 161 (60%) patients having a ≤ 10mL 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 95% limits of agreement were 34/-35 cm^3. When analyzed by prostate size, limits of agreement for prostates < 40 cm^3 and > 100 cm^3 are +14/-22 cm^3 and +65/-58 cm^3, 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.

P7

En Bloc Enucleation of the Prostate

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Introduction: Lower urinary tract symptoms (LUTS) are a common constellation of symptoms classically associated with bladder outlet obstruction from prostatic hyperplasia. Several medical and surgical options exist for management of bladder outlet obstruction secondary to prostatic hyperplasia. In this surgical video, we discuss the indications, techniques, and step-by-step procedure to perform a Greenlight photovaporization and enucleation of the prostate (PVEP).

Materials & Methods: A 72-year-old male was admitted for an episode of acute urinary retention complicated by urosepsis. He was referred to urology for follow up evaluation with a catheter in place. Prior to his episode with urinary retention, the patient reported an IPSS 27 with QoL 5. He had a 132 cc prostate as confirmed on TRUS.

Results: The accompanying video illustrates the following principles: proximal and distal limits of dissection, the technique for adenoma dissection and enucleation, morcellation of the specimen, and use of the Greenlight laser system. On a 1 month follow-up visit, the patient reported IPSS 2, QoL 0, with a PVR 13 cc. No readmissions or ED visits. No incontinence and no change in erectile function.

Conclusion: The accompanying video illustrates the principles for evaluation and surgical management of prostatic hyperplasia and bladder outlet obstruction using the Greenlight laser system to perform a photovaporization and enucleation of the prostate in safe, controlled manner.

P8

Cost-Effectiveness Analysis of Autologous versus Allograft Pubovaginal Slings

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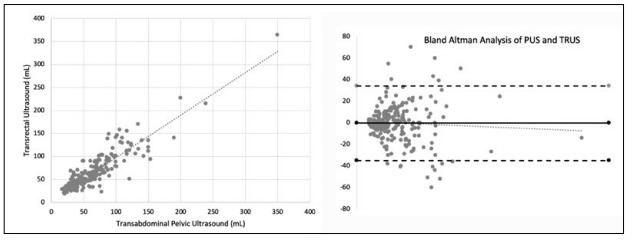
Introduction: Pubovaginal slings are considered the gold standard in the treatment of stress urinary incontinence when considering clinical outcomes. When considering sling material, there are numerous options available to the surgeon and patient with notable differences in durability, success rates, and cost. Autologous fascial slings harvested either from the rectus fascia or the fascia lata have the best long-term outcomes, but with improvements in processing, allograft material may approach in efficacy. In the literature, the assumption has been that allograft slings are more costly, but no analysis has been done to support this assertion.

Materials & Methods: A decision analysis model was constructed to compare the cost-effectiveness of cadaveric (allograft) and autologous pubovaginal slings. Clinical outcomes and complication data was obtained from published studies. Cost data was obtained from a conglomeration of healthcare claims data from health plans, plan administrators, and medicare using the FairHealth Consumer database. Expected value calculations with Markov modeling and sensitivity analysis was used to determine the superior sling material based on overall cost-effectiveness inclusive of equipment, time, secondary costs from complications, and re-interventions. The model was analyzed over a 5 year period and a perspective of cost to society was adopted.

Results: Decision analysis modeling demonstrated that on a per-procedure basis, autologous and allograft pubovaginal slings incur an expected cost of $8635 and $9717, respectively. The primary driver of increased cost of allograft pubovaginal slings is the increased re-operation rates in comparison to autologous slings. However, varying costs of operating room time, regional cost discrepancies, and individual success rates are critical variables in altering cost-effectiveness.

Conclusions: Our decision analysis model demonstrates superior cost-effectiveness for autologous pubovaginal slings compared to allograft-based slings. The cost-savings are primarily due to superior clinical outcomes despite longer operative times. Based on this analytical modeling, surgeons can aim to utilize their own loco-regional outcomes and cost data to determine the most cost-effective approach in their specific practice.



P9

Testing for Racial Sampling Bias in the National Cancer Database: Does the NCDB Adequately Represent Racial Minorities with Genitourinary Cancers?

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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 2004-2015 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 or Pacific Islander (API), which are all significantly lower (p =< 0.0001 for all). The capture rates for black, NANA, and API renal cancer diagnoses are each significantly lower than that of white patients (p =< 0.0001 for all), with 73.25% of white vs. 71.67% of black, 39.20% NANA, and 63.5% of API renal cancer diagnoses captured. This difference remained when looking at black male renal cancer patients (p =< 0.0001), but not in females (p = 0.5997). The capture rate was higher for black than white female patients with bladder cancer (p =< 0.0001). However, all NANA and API bladder cancer patients had significantly lower capture rates than their white counterparts (28.34% and 56.16% respectively, p =< 0.0001 for both). No difference was found for penile (p = 0.5153) and testis 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 and 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.

Table 1

	White Capture Rate	Black Capture Rate	Asian or Pacific Islander Capture Rate	Native American/Alaska Native Capture Rate
Prostate	**57.12%** (1,126,439/1,971,925)	**53.19%** (192,786/362,429)	**50.23%** (24,651/49,077)	**29.55%** (2,937/9,939)
Renal (All)	**73.25%** (394,074/537,996)	**71.67%** (52,015/72,574)	**63.50%** (8,273/13,028)	**39.20%** (2,146/5,475)
Renal (Male)	**72.87%** (245,577/337,023)	**70.10%** (30,523/43,544)	**63.41%** (5,282/8,330)	**37.58%** (1,232/3,278)
Renal (Female)	**73.89%** (148,497/200,973)	**74.03%** (21,492/29,030)	**63.67%** (2,991/4,698)	**41.60%** (914/5,475)
Bladder (All)	**63.26%** (480,723/759,961)	**64.34%** (28,199/43,826)	**56.16%** (7,505/13,364)	**28.34%** (717/2,530)
Bladder (Male)	**62.57%** (362,138/578,811)	**62.04%** (18,131/29,226)	**56.08%** (5,644/10,064)	**27.79%** (530/1,907)
Bladder (Female)	**65.46%** (118,585/181,150)	**68.96%** (10,068/14,600)	**56.39%** (1,861/3,300)	**30.02%** (187/623)
Penile	**82.78%** (10,607/12,813)	**83.44%** (1,305/1,564)	**71.56%** (239/334)	**45.95%** (51/111)
Testis	**66.80%** (60,556/90,664)	**65.43%** (2,139/3,269)	**56.09%** (1,100/1,961)	**35.63%** (310/870)

*Patients for whom the race was unknown or unspecified were excluded from table

P11

A Comparison of Pre- and Post-Operative Bladder/Bowel Symptoms Among Patients Undergoing Complete Surgical Endometriosis Resection

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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. Referral diagnoses/chief complaints at the time of initial presentation were assessed for the 46 patients without a prior biopsy-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 (23.9%), abdominal pain (23.9%), dysmenorrhea (19.6%), urinary frequency (15.2%), and dysuria (15.2%). Time from initial presentation to surgery was, on average, 185.6 days (13-1140) for the 71.7% of patients who presented to a gynecologist for their initial appointment, 255.8 days (55-1081) for the 13% who saw both a urologist and gynecologist at their initial visit, and 785 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 55% 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.

P10

ProTouch Laser Enucleation of the Prostate: A Retrospective Analysis of the First 77 Cases

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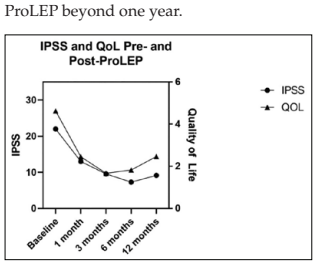
Introduction: The ProTouch (1470 nm) laser is a novel diode laser for use in endoscopic enucleation of the prostate. ProTouch laser enucleation of the prostate (ProLEP) may provide similar outcomes to traditional HoLEP with the additional benefit of improved hemostasis and tissue vaporization.

Materials & Methods: This is an IRB approved single surgeon chart review of 77 patients (average age 69.9 ± 9.9 years) who underwent ProLEP (10/16-3/19). Pre-operative, intra-operative, and post-operative variables were collected and analyzed.

Results: Average prostate gland size was 92.4g (range: 27-290g) by pelvic ultrasound and average pre-operative International Prostate Symptom Score (IPSS) (on medical therapy) was 22.3 ± 6.9. Post-operative IPSS was significantly reduced at 1, 3, 6, and 12 months [12.9 ± 9.3, 9.5 ± 8.1, 7.3 ± 5.0, 9.2 ± 6.0 (p-value < 0.0001)]. Quality of life (IPSS bother scale) was significantly improved from baseline (4.7 ± 1.2) at 1, 3, 6 and 12 months [2.5 ± 1.9, 1.7 ± 1.6, 1.8 ± 1.5, 2.5 ± 1.9 (p-value < 0.0001)]. Average pre-operative Q_{max} was 9.1 ± 4.5 cc/sec with significant post-operative improvement at 1, 3 and 6-months [27.2 ± 11.3 cc/sec, 15.1 ± 11.1 cc/sec, 20.8 ± 6.6 cc/sec (p-value < 0.05)]. 25 patients (32.5%) were catheter dependent prior to surgery, 19 of whom had indwelling catheters while the remaining 6 performed daily clean intermittent catheterization. All patients were voiding spontaneously at 1-month post-procedure. Average operative time was 130.7 minutes and average EBL was 51.8 mL. An average of 30.4g of prostatic tissue was resected during the ProLEP procedure, with an average of 34.2% of total prostatic tissue mass resected. Thirty-eight patients (49.4%) were discharged from the recovery room, with 72 patients (93.5%) being discharged on or before POD#1. 53 patients (68.8%) had their catheters removed on or before POD#1. 14 patients (18.2%) experienced intra-operative or post-operative complications, 8 of whom required re-catheterization for post-operative acute urinary retention. Urethral false passage occurred in 1 patient, 2 patients required antibiotics for a UTI, and 1 patient underwent cystoscopy for persistent hematuria. Two patients returned to the operating room for clot evacuation and fulguration. No patients received a blood transfusion. All of the complications were Clavien-Dindo IIIb classification or less (Clavien I - 64.3%, Clavien II - 14.3%, Clavien IIIa - 7.1%, Clavien IIIb - 14.3%). No patients required repeat surgery.

Conclusions: To our knowledge, this study is the first to investigate ProLEP for the treatment of LUTS in men with BPH. Our data suggest that ProLEP is indeed a safe and effective alternative to TURP. Further studies are required to investigate the outcomes of ProLEP beyond one year.



*P12

Predictors of Index Surgical Care Setting during Penile Prosthesis Surgery: Impact on Perioperative Outcomes and Cost

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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 the 1,894 patients undergoing index PP, 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. 0: 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 0.57, 95% CI 0.33-0.99; $p = 0.05$), 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 34.16, 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.

*Max K. Willscher Award Eligible

Table 1. Predictors of outpatient PP procedure, multivariable analysis.

		Odds Ratio	p-value	95% CI
Age		1.00	0.99	0.97-1.03
Charlson Comorbidity Index Score (CCI)	0	reference		
	1	**0.66**	**0.013**	**0.46-0.91**
	≥2	**0.43**	**<0.001**	**0.28-0.64**
Payer	Medicare	reference		
	Medicaid	**0.28**	**0.008**	**0.11-0.71**
	Private	1.58	0.086	0.94-2.67
	Uninsured	0.90	0.87	0.26-3.16
Race	White	reference		
	Black	**0.57**	**0.048**	**0.33-0.99**
	Hispanic	1.07	0.83	0.57-2.00
	Other	0.59	0.22	0.25-1.37
Income	<40,000$	reference		
	$40,000-$50,999	1.29	0.22	0.86-1.94
	$51,000-$65,999	1.00	1.00	0.58-1.73
	≥66,000	1.16	0.60	0.66-2.01
% < high school education in patient zip code	<9.7%	reference		
	9.7-11.6%	0.84	0.63	0.43-1.68
	11.7-12.9%	1.16	0.66	0.60-2.22
	≥13%	0.96	0.91	0.43-2.13
Patient residence	Urban	reference		
	Small Metro	**3.14**	**0.012**	**1.29-7.70**
	Micropolitan	**13.09**	**<0.001**	**3.1-55.12**
	Rural	3.95	0.11	0.75-20.93
State	New York	reference		
	Florida	**34.16**	**<0.001**	**9.54-122.3**

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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

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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

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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 rates of bladder cancer diagnosis.

Results: Over the four-year period there was a weighted population of 298,120,000 Americans. The prevalence of HPV positive serology was as follows: HPV18 - 5.5%, HPV16 - 13.2%, HPV11 - 6.4%, HPV6 - 17.4%. There were 443,948 bladder cancer cases. Among cases compared to controls there was a higher prevalence of male gender (80% vs. 53%, $p = 0.0056$), Caucasian race (93% vs. 66%, $p = 0.001$), and HPV6 positive serology (18.1% vs. 17.6%, $p = 0.0005$). There was no difference among the other three HPV types. On logistic regression controlling for race, gender, and smoking status, increasing body weight (OR 1.01, $p < 0.0001$) and HPV6 positivity (OR 1.9, $p < 0.0001$) were associated with increased odds of bladder cancer diagnosis while increasing age (OR 0.89, $p < 0.0001$) and HPV11 positivity (OR 0.23, $p < 0.0001$) were protective.

Conclusions: Prior research has shown that there is likely a relationship between HPV and bladder cancer, but this relationship has previously been incompletely defined. In this large, nationally representative database, we describe a significant association of HPV6 positive serology with a diagnosis of bladder cancer and, similar to prior studies, we demonstrate that this association is likely associated with younger age at diagnosis. This finding is striking and might affect future investigation into the pathophysiologic basis of this relationship.

*Max K. Willscher Award Eligible

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Fascial Anastomosis Suspension Technique (FAST) During Open Retropubic Radical Prostatectomy: A Novel Method to Improve Early Postoperative Recovery of Urinary Continence

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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 Thuroff et al in 1992; 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 toward 1, 3, 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 on both 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. Continence results were evaluated in terms of number of pads per day and according to the International Consultation on Incontinence Questionnaire (ICIQ) score at 24 and 48 hours and at 4 weeks postoperatively. Continence was defined as the need of 0-1 pad per day.

Results: Continence rate (CR) for group 1 and group 2 was 15% Vs. 40% at 24 hrs; 20% vs. 50% 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 striated sphincter, and a further stabilisation of posterior urethra within the pelvic diaphragm, while avoiding the potential obstructive complications on urinary flow related to sling compression.

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

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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 80 cases of RARC with ICIC from 2013-2018 (Table), excluding cases with intracorporeal neobladder, nephroureterectomy, and non-cancer indications. Two-attending 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 (30% Q1 vs. 10% Q4), any complications (70% Q1 vs. 45% Q4), and hospital readmission (45% Q1 vs. 20% Q4) decreased significantly. Total operative time, initially shorter with two attendings (mean 471 min in Q1), was relatively consistent throughout the series (mean 504 min). Mean ileal conduit time (defined as ICIC 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.

Perioperative outcomes, complications and times of RARC with ICIC

Variable	Q1 (n=20)	Q2 (n=20)	Q3 (n=20)	Q4 (n=20)	Total (n=80)
Attending co-surgery (%)	17 (85)	14 (70)	6 (30)	9 (45)	46 (57.5)
Estimated blood loss (cc)	328	373	368	316	346
Kengh of stay (days)	7.8	9.5	9	6.9	8.3
Minor complications (Clavien 1-2) (%)	8 (40)	12 (60)	11 (55)	7 (35)	38 (47.5)
Major complications (Clavien 3-5) (%)	6 (30)	2 (10)	4 (20)	2 (10)	14 (17.5)
Hospital readmission rate (%)	9 (45)	7 (35)	6 (30)	4 (20)	46 (57.5)
Total operative time (min)	471	503	52	515	504
Ileal conduit time (min)	219	236	221	214	222
Trainee console time (min)	33	57	62	50	51

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Early Stable Disease after Cytoreductive Nephrectomy is a Benchmark for Long Term Outcomes

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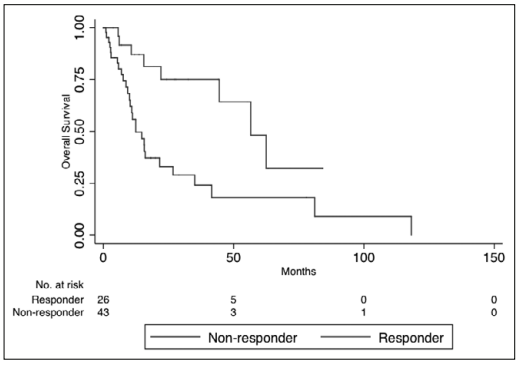
Introduction: The role of cytoreductive nephrectomy (CN) is controversial in the targeted therapy era. Results from the CARMENA and SURTIME trials question the role of CN when more effective systemic treatments are available. However, patient selection is key and a good response from surgery can delay 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 progression of 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 metastatectomy. 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 56.5 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.



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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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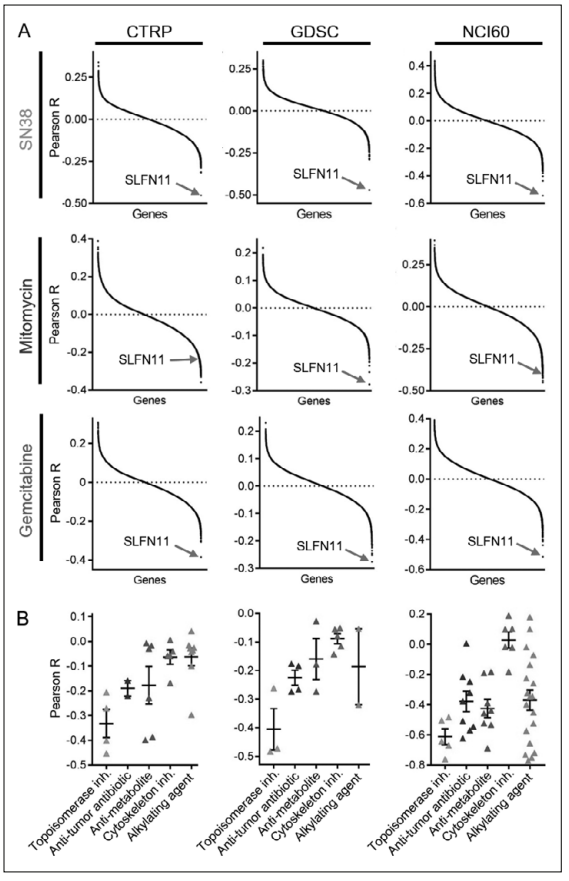
Introduction: Precision medicine seeks to integrate data from a patient's cancer to effectively tailor anti-cancer therapy. DNA-damaging chemotherapies have been successfully used to treat urologic cancers, but tend to be associated with significant toxicities. Thus, the identification of biomarkers 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 Schlafen 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.



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Comparison of Intra- and Post- Operative Outcomes of Straight Laparoscopic, Hand-Assisted Laparoscopic, and Robotic-Assisted Laparoscopic Partial Nephrectomies for Small Renal Masses at a Single Institution

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Introduction: Partial nephrectomy has become the standard operative procedure for the treatment of small renal masses. Due to a decrease in morbidity with similar long-term outcomes, the minimally invasive compared to open approach has become the preferred surgical technique. This surgery can be performed via Straight Laparoscopy (SL), Hand-Assisted laparoscopy (HA), or Robotic-Assisted laparoscopy (RA). The purpose of this study was to compare the intra- and post-operative outcomes of these techniques at a single-institution.

Materials & Methods: A single-institution retrospectively review of intra- and post-operative outcomes in minimally invasive partial nephrectomy cases between 2012 and 2018 was performed. Statistical analysis included a linear regression model adjusting for age, gender, demographics, size of tumor on pathology, and RENAL nephrometry score to investigate differences in estimated blood loss (EBL), operative time (OT), length of stay (LOS), and warm ischemia time (WI). We used a chi square analysis to investigate differences in post-operative complications (up to 30 days), demographics, and gender, and analysis of variances (ANOVA) to check for differences in positive margin rate, RENAL nephrometry scores, and age among the three different surgical techniques.

Results: A total of 164 cases were reviewed. 36, 65, and 63 surgeries were performed using the SL, HA, and RA technique, respectively. In our study, the SL technique was more popular in the early years (67% between 2011-2013) and RA in the later years (92% between 2014-2018, and 48% between 2017-2018). There were no differences among the cohorts in regards to age, gender, intra-operative complications, and positive margin rates ($p > 0.05$). The HA technique had a higher RENAL nephrometry score (mean of 1.38) compared to RA and SL (1.2 and 1.4, respectively) ($p < 0.05$). There were no differences in EBL in the SL, HA, and RA techniques (193, 291, and 259 min, respectively) ($p > 0.05$). OT was longer for RA (229 min) compared to SL and HA (187 and 198 min, respectively) ($p < 0.05$). WI time for HA (19.6 min) was shorter than for SL and RA (21.3 and 25.3 min, respectively) ($p < 0.05$). LOS was longer for HA (3.1 days) when compared to SL and RA (2.4 and 2.3 days, respectively) ($p < 0.05$). HA and SL had a higher overall incidence of Clavien-Dindo grade 3 and 4 post-operative complications compared to RA (15.3% vs. 13.8% vs. 1.5%, respectively) ($p < 0.05$).

Conclusions: Our study demonstrates that at our tertiary care center, the RA approach is beginning to be used more frequently and is starting to overshadow traditional SL. The RA technique had a low incidence of post-operative complications, but the HA technique was used in more anatomically complex cases. We did not measure renal function pre and post-operatively, however, given the shorter WI time seen with the HA technique it can be better suited for patients looking for greater preservation of their renal function. More prospective studies comparing the three techniques are needed to validate our results.

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Assessing the Learning Curve for Robotic Assisted Laparoscopic Intracorporeal Urinary Diversion- Initial Experience and Outcomes

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Introduction: Robotic assisted radical cystectomy with intracorporeal urinary diversion is a relatively new surgical technique for management of patients requiring bladder removal, with potential advantages relating to postoperative recovery, wound complications, and cosmesis. We sought to study the outcomes of our early experience with this procedure performed at a community medical center.

Materials & Methods: We reviewed a prospectively maintained database of a single surgeon series of 35 consecutive robotic assisted radical cystectomies with extended pelvic lymph node dissection and intracorporeal urinary diversion (RC/ICUD). Time to return of bowel function, hospital length of stay, estimated blood loss, and 90-day postoperative complications were assessed. Cases were subsequently stratified into 3 consecutive time periods to assess for change in operative time. Patients were placed on a standardized ERAS protocol.

Results: 29 patients underwent ileal conduit urinary diversion, while 6 underwent construction of an ileal neobladder. Average follow up interval was 12 months (1-42 months). Median total operative time for RC/ICUD was 459 minutes (range 266-665 min). Median operative time for ileal conduit patients was 430 minutes (range 266-635 min) and for neobladder patients was 533 minutes (range 479-665 min). For ileal conduit patients, the first 10 cases had a median operative time of 514 minutes. The next 10 cases had a median operative time of 456 minutes, and the most recent 9 cases had a median operative time of 331 minutes. Median EBL was 150 cc (range 25-800 cc). Median length of stay was 6 days (range 3-14 days). Median time to flatus was 3 days (range 1-7 days). Median time to first bowel movement was 4 days (range 2-7 days). 24 patients (68%) experienced a complication. 4 of the 35 patients (11%) experienced Clavien > 2 complication. There were no high grade bowel complications or wound infections.

Conclusions: Our initial experience with intracorporeal urinary diversion supports the feasibility of this technique as a minimally invasive option for patients undergoing cystectomy, with a similar safety profile to open urinary diversion. Median operative time improved with experience. Further study is needed to clarify the benefits of intracorporeal diversion.

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Institutional Review of Open Versus Laparoscopic Partial Nephrectomy for Surgical Treatment of Renal Cell Carcinoma

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Introduction: Laparoscopic partial nephrectomy (PN) is a widely performed, minimally-invasive alternative to open PN. We compared pre-, peri- and post-operative factors in patients undergoing either open or laparoscopic PN for treatment of renal cell carcinoma (RCC).

Materials & Methods: Under IRB approved protocol we interrogated our institutional RCC database for all patients who underwent either open or laparoscopic PN for RCC from 1997-2018. Patients with benign pathology on surgical pathology were excluded from this analysis. Open versus laparoscopic technique decision was at the discretion of the treating urologic surgeon. Laparoscopic cases include both pure laparoscopic and robotic assisted laparoscopic techniques. Outcomes analyzed included intra-operative parameters, pathologic outcomes, post-operative complications and disease local recurrence rates.

Results: The study cohort consisted of 732 patients with a median age of 59 at the time of surgery for RCC (IQR, 50-67) and a total of 760 unique PN cases (187 open and 573 laparoscopic). 48 (8.4%) of the laparoscopic cases were performed with robotic assistance and were not analyzed separately. The median size of the tumor on imaging was 2.6 cm (IQR, 2-3.9 cm) for open procedures and 2.45 cm (IQR, 1.8-3.4 cm) for laparoscopic. Surgical pathology for open PN revealed 150 (75.4%) pT1a, 32 (16.4%) pT1b, 3 (1.5%) pT2, 13 (6.7%) pT3a. For laparoscopic PN, surgical pathology revealed 458 (78.2%) pT1a, 90 (15.4%) pT1b, 4 (0.7%) pT2, 34 (5.8%) pT3a. The mean surgery time was 213.6 minutes (SD 65.0) for open procedures and 208.8 minutes (SD 74.1) for laparoscopic procedures (p = 0.433). When vascular clamping was used, the mean ischemic time was 20.6 minutes (SD 9.0) for open procedures compared to 22.0 (SD 7.4) minutes for laparoscopic procedures (p = 0.025). Mean estimated blood loss was 400 cc (SD 401) and 248 cc (SD 267) for open and laparoscopic procedures respectively (p = 0.001). Positive margins occurred in 10/187 (5.3%) of open PN vs. 19/573 (3.2%) of laparoscopic PN. Risk of any post-operative complication for open PN was 29.9%, with a 5.3% risk of Clavien grade 3a-4a complications. For laparoscopic PN, the risk of any complication was 15.4% and 3.5% for Clavien grade 3a-4a complications. Local recurrence rates were 2.1% for open procedures and 2.8% for laparoscopic procedures.

Conclusions: Laparoscopic partial nephrectomy is an effective, minimally-invasive surgical option for curative treatment of RCC with comparable surgical oncologic outcomes and an apparent lower complication risk. The statistically significant difference in ischemic time of 1.4 minutes is of unlikely clinical significance and we are currently investigating functional outcomes.

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Active Surveillance Stone Protocol Reduces Endourologic Interventions

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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 surgery. 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, 2018. 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 MSC and UP 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, 0.61; p-value =< 0.001).

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 rate 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 evaluate additional factors that may affect stone burden and incidence of surgical treatments over a longer period of follow up.

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The Utility and Value of Immersive Virtual Reality Simulation for Percutaneous Nephrostomy Tract Access and Surgical Training

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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 clearance and is a difficult technique to master. Current methods to train urologists in PCNL access are 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 PCNL tract access.

Materials & Methods: Urology and interventional radiology (IR) residents and attendings were recruited to evaluate an immersive VR simulator for percutaneous tract access acquisition (Table 1). Using a head mounted display (Oculus Rift) and a robotic arm (Marion Surgical), participants were instructed to establish percutaneous access into the lower pole calyx in the prone position in a VR operating room (Figure 1). A Likert type scale (1 = not at all, 5 = extremely, and 1 = poor, 5 = excellent) was used to record the participant's VR experience. Additionally, the robotic arm recorded kinematics parameters (economy of motion; cumulative time, path length, and velocity).

Results: Almost all (95%) of the participants rated the VR simulation as a realistic experience. The realism of instrument handling (2.7/5), targeting (3.4/5), haptic feedback (2.4/5) and overall realism (3.25/5) were rated as slightly to somewhat realistic (Table 1). The image quality (4.1/5), brightness (4.3/5), resolution (3.95/5), delay (4.05/5), overall comfort (3.9/5) and overall performance (3.95/5) were rated as very good. The usefulness of the simulator for hand-eye coordination (3.8/5), usefulness as a rehearsal tool (3.8/5), and likelihood to recommend it to colleagues for training (3.6/5) were rated as very good. There were no significant differences between the novices and experts for their VR experience nor economy of motion (cumulative time, path length, and velocity). Subjectively, participant's comments included that the VR simulator was a great practice module, was realistic and great for 'warm up' prior to surgery.

Conclusions: Immersive VR simulation for PCNL access is a unique platform for surgical education which was rated favorably amongst participants. The training platform was unable to differentiate between novices and experts. Further technical improvements to haptic feedback, fluoroscopic control and subsequent procedural steps are warranted. It is likely that future iterations of this technology will help train urologists in PCNL access.

Demographics (n = 20)				
Age (year)	35 (26 - 66)			
Gender (male)	65%			
Participants Attendings Residents	6 (IR = 2, Urology = 4) 14			
Virtual Reality Experience (1 = not at all, 5 = extremely)				
	Total (n=20)	Novice (n=17)	Expert (n=3)	p
Realistic (yes)	95%	94.1%	100%	
Realism of instrument handling vs. live surgery	2.7	2.6	3.3	0.57
Realism of targets (i.e. calyx, collecting system, etc.)	3.4	3.2	4.3	0.24
Realism of haptic feedback	2.4	2.2	3.3	0.20
Overall realism	3.25	3.3 3.7	3.0	0.77
Usefulness for hand-eye coordination	3.8		4.3	0.49
Useful rehearsal tool	3.8	3.6	4.3	0.44
Likelihood to recommend	3.6	3.5	4.3	0.40
Image Control (1 = poor, 5 = excellent)				
	Total (n=20)	Novice (n=17)	Expert (n=3)	p
Quality	4.1	4.1	4.3	0.51
Brightness	4.3	4.3	4.3	0.94
Resolution	3.95	3.9	4.3	0.46
Delay in image display (5 = no delay)	4.05	4.1	4.0	0.92
Overall comfort	3.9	3.9	4.0	0.87
Overall performance	3.95	3.9	4.3	0.46
Economy of Motion				
	Total (n=20)	Novice (n=17)	Expert (n=3)	p
Cumulative time (s)	180	174	214	0.55
Path length (cm)	273	275	261	0.87
Average velocity (cm/s)	.0019	.020	0.015	0.36

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

Figure 1. Virtual Surgery Simulator (a) VR simulator set up and use (b) fluoroscopic image with target access (c) virtual operating room seen by participant

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Impact of a Multidisciplinary Kidney Stone Prevention Clinic

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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.

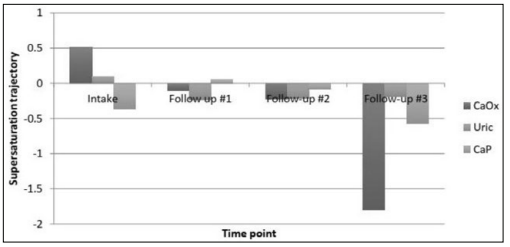
Results: 77 patients were followed over an average of 1.76 follow up visits (275 ± 143 days). Of the 63 surveys completed, 100% of patients found their visit with the RD helpful and 98.4% would recommend the clinic to friends/family. Of the 46 records with consecutive 24-hour urine studies, significant reductions were observed in the supersaturation profiles 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 (-.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.

Table 1. Change in stone supersaturation and supersaturation trajectory.

Stone Risk [Ref. Range]	Change in Value	95% CI	Change in Trajectory	95% CI
Calcium Oxalate [6-10]	-0.343 (p=0.57)	-1.49 to 1.45	-1.271 (p=0.24)	-3.47 to 0.93
Uric Acid [0-1]	-0.301 (p=0.001)	-0.119 to -0.482	-0.371 (p=0.027)	-0.045 to -0.697
Calcium Phosphate [0.5-2]	-0.642 (p=.042)	-0.025 to -1.258	0.139 (p=.79)	-0.951 to 1.229

Figure 1. Change in supersaturation profile from most recent 24-hour urine collection



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Creation and initial implementation of the D.I.R.E.C.T Pathway (Delayed Imaging to Reduce Excessive Computed Tomography) for the Evaluation of Patients with Suspected Renal Colic

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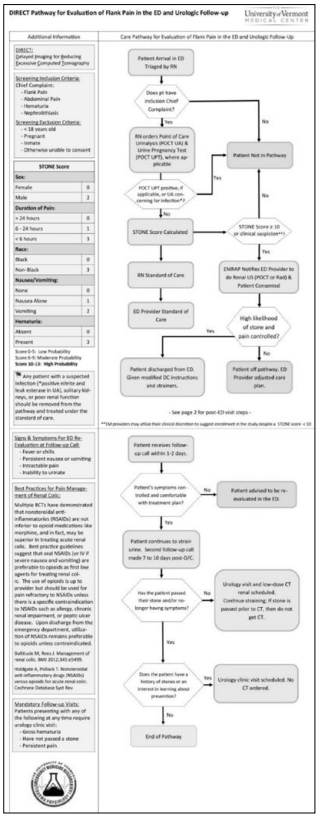
Introduction: Computed tomography (CT) remains the standard of care for the evaluation of acute renal colic and its use has significantly increased over the past 2 decades. Concerns, however, exist regarding radiation exposure and cost. Ultrasonography has been proposed as an alternative initial imaging approach. While shown to be safe, urologists often require the additional anatomic information provided by CT to help guide patient management. Considering that the majority of ureteral stones (~80%) will pass without intervention, obtaining a CT initially on every patient with a suspected stone may not be necessary. We propose an ED algorithm using initial ultrasonography for patients with high suspicion of uncomplicated ureterolithiasis that provides a mechanism for appropriate outpatient urologic follow-up with CT imaging if necessary.

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 judgement 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.



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Dusting is Efficacious and Safe with a 30-Watt Laser

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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 costs 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 200 nm laser (27.4%) and 365 nm laser (72.6%). Mean operative time of URSL cases dusting the stones (mean size 52.85 mm^2) was 35.4 minutes. Mean operating time of URSL cases using basketing of stones (mean size 50.69 mm^2) 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 mm^2) 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 mm^2) 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 costs 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.

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Informing the Management of Asymptomatic Nephrolithiasis: Markov Decision Analysis for the 1cm Renal Stone

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Introduction: The management of incidentally discovered, asymptomatic renal stones is controversial. While some choose watchful waiting, others recommend pre-emptive surgical treatments. Of surgical options, shock wave lithotripsy (SWL) is considered the least invasive and has purported highest initial postoperative quality of life (QOL), although it has inferior stone-free rates (SFR) compared with ureteroscopy with basket extraction of fragmented stones (URS-B). More recently, ureteroscopy with laser "dusting" (URS-D), generating very fine fragments left in situ to pass, has enjoyed growing acceptance as it reduces the need for a ureteral stent and thus may offer improved QOL. Literature, though suggests inferior SFR compared with URS-B. We performed decision analysis to assess quality adjusted life-years (QALY) associated with each treatment option.

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. Toll-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

Figure 1. Markov Decision Tree, Global View

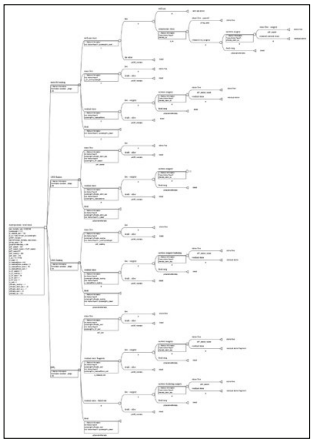
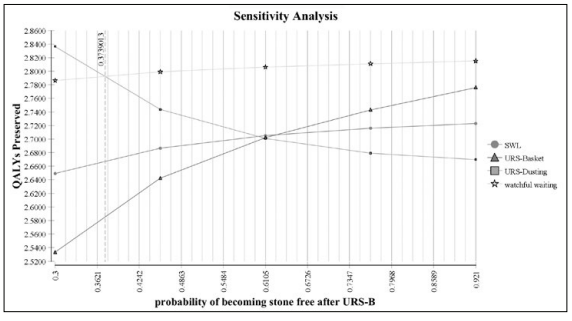


Figure 2. URS-B, one-way sensitivity analysis



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The Effect of Holmium Laser Fiber Bending Radius on Power Delivery During Flexible Ureteroscopy

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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 Lumenis Pulse 30H Holmium Laser, a standard mirror, a collection fiber with a 400 µm core diameter, a Thorlabs Amplified Si Photodetector, and a Tektronix MSO702004 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 deionized water. The laser was fired at 0.3 J/5 Hz without 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 pulse peak power did not vary significantly at any bending radius or number of turns measured. The Oscilloscope is accurate within 2% of measurement. Because our experiment compared two values, any measured power output difference of less than 4% was within the margin of error. At the tightest radius measured, the 365 µm fiber was measured as transmitting 1.6% less power than baseline - within the 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 undergo without breakage. Endourologists can trust that laser output will be stable during ureteroscopy regardless of stone location.

Bending Radius and Number of Turns	RMS of Pulse Peak Power (au)	Standard Deviation (au)
Baseline	0.7745	0.0046
1.7 cm	0.7624	0.0038
1.9 cm	0.7622	0.0039
3cm	0.7652	0.0039
3.5cm	0.7683	0.0048
6cm	0.7720	0.0032
8cm	0.7728	0.0054

Table 1. Power outputs and bending radii, 365 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.

Bending Radius and Number of Turns	RMS of Pulse Peak Power (au)	Standard Deviation (au)
Baseline 1	0.3000	0.0019
0.5cm	0.3051	0.0049
1.3cm	0.3053	0.0019
1.8cm	0.3068	0.0019
3.4cm	0.3110	0.0022
6cm	0.3113	0.0022
7.6cm	0.3127	0.0022
Baseline 2	0.3120	0.0025
1.3 cm 2R	0.3183	0.0025
1.3 cm 5R	0.3120	0.0022
1.3 cm 10R	0.3039	0.0026

Table 2. Power outputs and bending radii, 200 µm laser fiber. "Number of Turns" refers to the number of times the laser fiber was fully wrapped around the cylindrical object before measurement. No variation in RMS was statistically significantly different from baseline.

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

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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 45. 52.5% of stone formers were male, 91% white, and 47.6% were in the Southern US. The incidence of stone occurrences was 0.6% (177/33,961 individuals, weighted to represent population of 1,923,322/296,185,002 individuals). By 2015, the mean age was 51.7, with 52% male, 83% white, and 38.2% in the southern US. The overall incidence of stone occurrences increased to 0.9% (247/35,427 individuals, weighted to represent population of 2,810,497/321,423,251 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.

48

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

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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 urology 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 1096 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 was associated with greater odds of urology follow-up in univariate and multivariate analyses ($p < .0001$, Table 1). The 18-29 year age group demonstrated the lowest odds of follow up (0.47, 95% CI 0.32-0.68, Table 2). Female gender predicted urologic follow-up as well. There were no significant differences in follow-up based on income, ethnicity, and insurance type (government vs. private).
Increasing age, female gender, African American race, and a 4-year college degree predicted increasing odds of following up with a PCP (Table 2). Again, there were no significant differences seen based upon ethnicity, income level, and insurance type.

Conclusion: Increasing age is associated with higher rates of urologic follow-up after an ED visit for nephrolithiasis. In addition, women and patients with higher education levels are more likely to seek follow-up after an ED visit for nephrolithiasis. Incorporating these factors when scheduling patients for return visits and enhancing outreach to younger patients, who are less likely to follow up, may improve rates of return and ultimately decrease kidney stone related morbidity.

Table 1. Univariate analysis findings

	Follow up with Urology (%)	P Value	Follow up with PCP (%)	P Value
Age (years) -18-29 -30-39 -40-49 -50-59 -60-69 -70-79 -80+	36.1 42.9 45.9 54.9 59.9 62.5 69.0	< .0001	15.0 34.4 39.7 35.4 46.2 51.8 44.8	< .0001
Sex Female Male	50.2 48.8	0.0468	39.2 32.0	0.0001
Race Asian African American Caucasian Other	59.5 46.1 50.6 39.3	0.0099	20.2 45.5 34.4 32.1	< .0001
Ethnicity Hispanic Non-Hispanic	50.3 49.1	0.0475	36.6 34.0	-
Education Level Less than high school High school or GED Associate or some college 4-year degree or higher	54.8 45.6 38.2 55.5	0.0012	36.6 31.5 27.5 39.6	0.0056

Table 2. Odds Ratios of Follow-up

	Follow up with Urology-OR (95% CI)	Follow up with PCP-OR (95% CI)
Age (years) -18-29 vs. 50-59 -30-39 vs. 50-59 -60-69 vs. 50-59 -70-79 vs. 50-59	0.47 (0.32- 0.68) 0.61 (0.41- 0.92) - -	0.32 (0.21- 0.51) - 1.57 (1.06- 2.32) 1.96 (1.09- 3.53)
Female vs. Male	1.31 (1.01- 1.71)	1.73 (1.31- 2.28)
Asian vs. Caucasian	2.02 (1.22- 3.34)	-
African American vs. Caucasian	-	2.30 (1.57-3.36)
Hispanic vs. non-Hispanic	1.55 (1.01- 2.39)	-
Associate vs. 4-yr degree	0.55 (0.39- 0.77)	0.68 (0.47- 0.98)
High school vs. 4-yr degree	0.62 (0.44- 0.86)	0.54 (0.37- 0.77)

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Nephrolithiasis is Associated with Depression in US Adults: an NHANES Analysis

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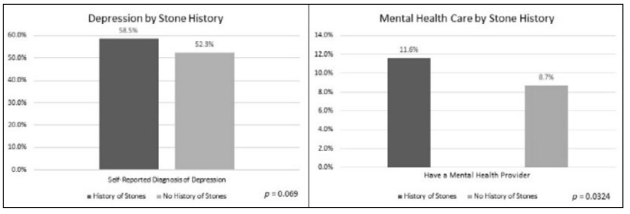
Introduction: Depression and anxiety have been associated with increased number of opioid prescription refills among those managed with opioids for myriad problems including nephrolithiasis. Furthermore, depression and anxiety are independent risk factors for opioid abuse. Given frequent use of opioids in treating nephrolithiasis, we sought to determine the prevalence of anxiety and depression among stone formers.

Materials & Methods: We conducted a population-based survey analysis of the National Health and Nutrition Examination Surveys (NHANES) from 2013-2016. We included all adults and examined sociodemographic factors including responses to survey questions regarding history of nephrolithiasis, anxiety, depression, and overall health status.

Results: In an analysis representing nearly 117,000,000 US adults, there was a 9.1% prevalence of nephrolithiasis. While 20% of the population denied any anxiety symptoms, 47% reported occasional symptoms, 18% reported weekly, and 16% reported daily anxiety. Half of the population denied depression symptoms while 40% reported occasional symptoms, 6.5% reported weekly, and 4.3% reported daily. Nine percent of the population seeks regular mental health care. Among the total population, 14% report excellent health, 60% report very good/good, and 18% report fair/poor. When stratified on a history of nephrolithiasis vs. none, there were higher rates of anxiety and depression symptoms, but these were not significant (83% vs. 80.5% p = 0.3370, 58.5% vs. 52.3%, p = 0.0690). However, those with nephrolithiasis had significantly higher rates of treatment by mental health providers (11.6% vs. 8.7%, p = 0.0324) and reported worse health status (26% fair/poor vs. 18%, p < 0.0001). On logistic regression controlling for age, race, BMI, and gender, patients with nephrolithiasis had higher rates of depression with an OR of 3.2 (1.03, 9.77) for daily, 2.06 (1.13, 3.75) for weekly, and 1.32 (0.96, 1.82) occasionally compared to never (p = 0.0463 overall). Patients with nephrolithiasis also reported overall lower health scores (p < 0.0001).

Conclusions: A diagnosis of nephrolithiasis is associated with higher rates of depression, mental health care, and perceptions of lower reported health status. Providers should be vigilant for signs and symptoms of depression and anxiety in those they see for kidney stones. In light of the increased risk of comorbidities including opioid abuse, mental health referral should be pursued for those stone formers reporting symptoms of depression and anxiety.



P14

Characterization of U.S. Urology Resident Opioid Prescription Patterns

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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 were significant regional differences in resident prescription patterns following URS, PCNL, and TPP (p < .008) but not for SWL (p = .067). Those sections that 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 < 0.006, 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 narcotics prescriptions after urologic surgery are improving, residents may benefit from additional training, best practice policies, and/or society guidelines.

Table 1. Average Number of Opioid Pills Prescribed Per Procedure by Regional AUA Section

AUA Section	URS	SWL	PCNL	TPP
Northeastern	0.67*	1.33	8.78	1.44*
New England	4.00	3.86	8.57*	2.57
New York	7.71	1.14	12.14	4.29
Mid-Atlantic	5.00	4.00	13.00	7.60
Southeastern	11.29*	7.57	17.57	11.38*
North Central	8.92	5.59	14.97	8.14
South Central	10.54	5.31	20.85*	11.08
Western	6.69	2.19	13.62	5.38

*Maximum and minimum averages varied significantly compared with average of all remaining sections combined; p< .006

P13

George Langstaff (1780-1846): Surgeon, Pathologist, Museum Curator, and the First to Observe Prostate Cancer during Post-Mortem Examination

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Introduction: George Langstaff was an English surgeon and pathologist in the early 1800s. Here, we review his early life and the contributions he made to our early understanding of prostate cancer.

Materials & Methods: Using PubMed, and Google Scholar, a comprehensive literature review was conducted to investigate Dr. Langstaff's early life and work in the field of prostate cancer. We also reviewed his paper published in Medico-Chirurgical Transactions in 1817, which is notable as the first gros anatomic description of prostate cancer.

Results: George Langstaff was born in Richmond, Yorkshire, England in 1780, and died in London on August 15th, 1846. After training at St. Bartholomew's Hospital, Dr. Langstaff received his diploma from the Royal College of Surgeons in 1804, and worked as a surgeon in the parish of St. Giles Cripplegate church, and later was appointed as a surgeon to the parish workhouse in 1813. As a surgeon and a pathologist in the workhouse, he had access to numerous post-mortem specimens, from which he established a museum. His drawings of these specimens were later published in the ten-volume catalogue raisonné, which included illustrations of 2380 normal and abnormal human specimens. Notably, he published a paper including six cases of "Fungus Haematodes" in Medico-Chirurgical Transactions in 1817. He used this term to describe tumors which would bleed due to 'fungus-like' growth if situated on the external part of the body. In his case of "Fungus Haematodes in the Urinary Bladder, Liver, and Lungs", Dr. Langstaff described a 68-year old man who presented with pain in his bilateral flanks and hypogastric region, lower urinary tract symptoms, and hematuria. Dr. Langstaff noted an enlarged prostate on digital rectal examination, and moderate membranous urethral obstruction. On post-mortem examination, Dr. Langstaff found an ingrowing tumor in the bladder. He recounted the origin of the bladder tumor as "… from the prostate gland, chiefly from the middle, or third lobe." He observed the tumor extending laterally from posterior part of the bladder to the ureteral orifices. He also found that the prostatic urethra was almost obstructed due to the tumor, and he detected several lesions with similar "fungoid" nature in both the liver and lungs.

Conclusions: George Langstaff had a meticulous approach to investigating post-mortem specimens and is likely the first person to describe metastatic prostate cancer from a gross anatomic perspective.

Poster Session II: General Urology/Best Practices

P15

A Retrospective Evaluation of a Novel Perioperative Opioid Sparing Protocol for Patients Undergoing Robotic Assisted Laparoscopic Surgery

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Introduction: The over prescribing of opioid analgesics by health care providers has significantly contributed to the opioid epidemic. The number of individuals addicted to prescription pain medications and the gateway these medications provide to illicit drug use is profound. Over 11 million people abused prescription opioids and more than 40% of all opioid overdose deaths involved a prescription opioid in 2016. Providers were inaccurately educated that patients who have had surgery cannot over utilize these medications, and superior pain control in the post-operative period could improve healing. We now recognize that a multifactorial approach to pain control is far more effective and can enhance earlier recovery after surgery. The negative effects of opioids on cognition, respiratory effort, gastrointestinal and urinary function, and their addictive potential are now common knowledge. Our study purpose is to provide a retrospective evaluation of a non-opioid perioperative regimen for robotic assisted laparoscopic prostatectomy and partial/total nephrectomy patients.

Materials & Methods: This study design was a retrospective chart review between patients who received an opioid sparing packet and those who did not. Data was collected from the medical records of 55 consecutive patients who had a robotic assisted laparoscopic surgery performed by the same surgeon at the same facility. Patient data was collected from the inpatient medical record as well as outpatient 7 day post-operative phone calls. The patients length of stay, analog pain scores, number of narcotic tablets utilized in the post-operative period, and the presence of a narcotic prescription at discharge were collected. The statistical significance threshold was set at p-value 0.05 using 95% confidence intervals (CIs). All data was analyzed using Microsoft Excel 2010 software. A paired T-test assuming equal variances was used to compare the differences in length of stay, average pain scores on post day 0, 1 and 2, pain scores 7 days post-op, average oral milligram morphine equivalents and number of narcotics prescriptions.

Results: Of 16 traditional patients that did not receive an opioid sparing pathway, 7 (43.75%) were discharged with a narcotic prescription compared to 2 (5.13%) of 39 patients on the opioid sparing pathway that were discharged with a narcotic prescription ($p < 0.001$). There was no statistically significant difference for the non-opioid sparing versus the opioid sparing patients in hospital length of stay or average analog pain scores on post-operative day 0, 1 and 2. The difference in total oral milligram morphine equivalents was (45.69 vs. 29.86, $p = 0.14$) in patients with no history of opioid abuse. Average pain score at home was statistically significant (5 vs. 1.8, $p < 0.001$) but the sample size in the non-opioid sparing group was low (n=4) compared to the opioid sparing group (n = 30).

Conclusions: This novel opioid sparing perioperative regimen can result in the same post-operative pain control and 95% fewer narcotic prescriptions being written at the time of discharge. By decreasing the number of patients requiring narcotics post operatively and decreasing the total number of narcotic prescriptions written, there is the potential to have a positive impact on the opioid epidemic.

P16

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 evidential 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 statement's 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 (155/516 = 30%) of statements were "Expert Opinion," meaning a recommendation was made without sufficient data to even establish an evidence grade. The lowest rates of evidential 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. Urologic training 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.

P17

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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Introduction: During active surveillance (AS) for localized prostate cancer, after the diagnostic biopsy (DxBx), a confirmatory biopsy (Bx1) is typically performed within 1-2 years. Grade/volume reclassification between DxBx and Bx1 occurs in about 20% of cases and is more often due to differences in prostate sampling completeness or biopsy technique rather than true cancer progression. Prior single center studies have demonstrated higher re-classification rates when patients had their DxBx at a tertiary site as opposed to a community urology setting. We analyzed the Canary PASS (Prostate Cancer Active Surveillance Study), a large prospective AS cohort at 10 academic centers, to determine if patients who had DxBx at an off-site practice were at higher risk of reclassification than those having their DxBx at a PASS-site.

Materials & Methods: Out of 1648 participants in PASS, 983 had DxBx with Gleason score ≤ 3+3=6 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 DxBx (on-site vs. off-site) was associated with reclassification after controlling for age, the ratio of positive cores on DxBx, BMI, prostate size, PSA, and DxBx-Bx1 time interval. We used Fisher's exact test to compare rates of definitive prostate cancer treatment by DxBx location.

Results: Of 519 men who had off-site DxBx and on-site Bx1, 102 (19.7%) had grade/volume reclassification compared to 72 (18.6%) out of 399 patients who had on-site DxBx and on-site Bx1. After controlling for potential confounders, location of DxBx was not associated with grade/volume reclassification. Uropathologic re-review occurred in approximately half (52%) of off-site DxBx, and was not significantly associated with grade reclassification. Participants with an off-site DxBx were more likely to elect definitive treatment than participants with an on-site DxBx (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 confirmatory biopsy at academic institutions. These findings support the continued safety of active surveillance in all urologic practice settings.

P18

Recent Trends in Receipt of Palliative Care for Men with Metastatic Prostate Cancer

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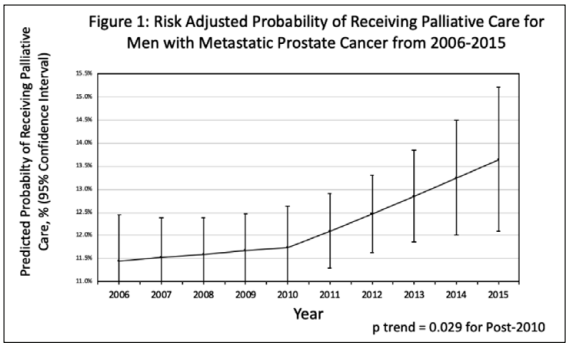
Introduction: Appropriate use of palliative care can prolong life and may reduce over-use of inappropriate end-of-life care. The past decade has seen several factors that may increase palliative care use the publication of a seminal 2010 paper showing a survival benefit for palliative care in metastatic 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 200462015.

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 from 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 palliative care in each study year increased significantly over the study period ($p < 0.001$). However, on our risk-adjusted analysis the association between year and receipt of palliative care was only significant post-2010 ($p = 0.029$). Advanced age and higher comorbidity score also increased the estimated probability of receiving palliative care ($p < 0.01$ for both). The risk-adjusted probabilities in each year are summarized in Figure 1 and ranged from 11.5 (95% CI 10.5-12.4) in 2006 to 13.7 (95% CI 12.1-15.2) in 2015.

Conclusions: 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.



	ALL	USA	Non-USA
Completed the survey	204	76	129
Years in practice (IQR)	13.29 (6.75, 20)	11.52 (6.5, 15)	14.29 (6.75, 20.25)
Perform routine follow up imaging	91.67%	97.30%	88.37%
US	76.60%	91.90%	67.20%
KUB	44.70%	45.90%	44.30%
CT	39.60%	50%	32.80%
How long after surgery do you perform imaging (in weeks)?			
4-6 weeks	53.92%	69.74%	44.96%
6-8 weeks	39.22%	55.26%	30.23%
4-8 weeks	71.08%	90.79%	59.69%
Low dose CT imaging quality is similar to SP	78.43%	77.63%	78.29%
Would not use low dose CT scan on obese patients	48.53%	30.26%	59.69%
Identified 30 BMI as cutoff for streak effects	12.25%	19.74%	7.75%
Estimated correctly the radiation exposure in:			
Standard Protocol CT	39.22%	52.63%	31.01%
Low Dose CT	36.27%	50.00%	27.91%

P19

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

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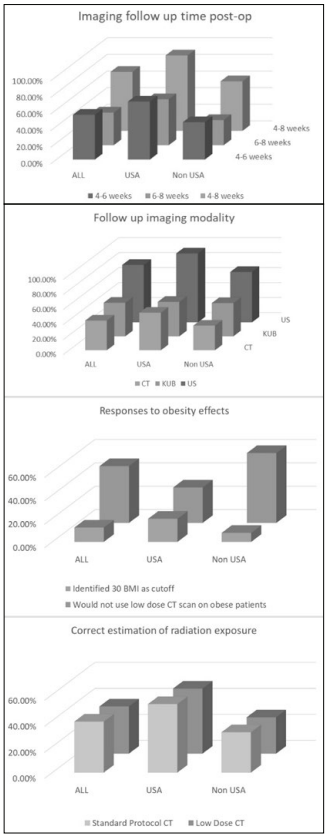
Introduction: Nephrolithiasis patients undergo repeated imaging studies throughout their lives, exposing them to large doses of radiation, potentially leading to secondary malignancies. Studies have found that effective dose of radiation exceeded the recommended levels in up to 20% of nephrolithiasis 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/m^2. 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.

Conclusions: Our data reveals that urologists worldwide need better education on radiation exposure from diagnostic studies. Additionally, there appears to be a knowledge deficit with the timing and utilization of low dose CT. This deficit appears larger outside than within USA. Current guidelines appear to be discretionary, not supported with enough evidence and do not take into account the utilization of low-dose CT. Clear evidence-based guidelines may help alleviate these knowledge gaps and undue radiation exposure to nephrolithiasis patients.



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 tamsulosin, tylenol, and pyridium. Patients with an allergy to NSAIDs or CKD stage II or greater were excluded from the non-opioid pathway as they were unable to be prescribed NSAIDS. Frequency of postoperative adverse events including visits to the emergency room (ER) for stent-related symptoms, stent-related clinic 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 or both were ineligible for the non-opioid pathway and excluded, and 32 were excluded for having other concurrent procedures such as cystolitholapaxy. 300 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 patients 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 90% of patients can be discharged 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 pain 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

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Introduction: Opioid analgesics 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 panel. 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. Willscher Award Eligible

P22

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

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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 52353, 52356 and DRG code 669 as well as PCNL CPT codes 50080, 50081 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 $3457 in 2015 to $4027 in 2018, while inpatient reimbursement increased 15% from $9430 in 2015 to $10867 in 2018. Annual URS case volume at our institution increased 100% from 222 in 2013 to 443 in 2016. Annual gross reimbursement for ureteroscopy procedures is expected to reach $3.12 million in 2018. Medicare reimbursement for outpatient PCNL increased 139% from $3457 in 2015 to $8254 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 78% from 77 in 2013 to 137 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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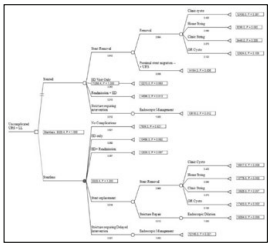
Introduction: Current guidelines suggest ureteral stent placement may be omitted in select patients. Complication and re-operative rates are known to be higher for stentless ureteroscopy (URS). The purpose of this study is to assess the cost-effectiveness of stentless vs. stented URS laser lithotripsy 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 practice patterns 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 increased costs to the healthcare system. Although stent omission is not recommended for every patient, careful stratification and selection of stone patients may enable surgeons to improve cost-effectiveness of URS lithotripsy.



P24

Ureteral Stenting After Routine Ureteroscopy: Is Earlier Stent Removal Feasible?
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Introduction: Ureteroscopy is a standard treatment option for urinary tract calculi. Common protocol is to place an internal ureteral stent after ureteroscopy for up to one week. The minimal length 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 difference 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 urinary tract calculi 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 (26.5%), 80 in group 2 (35.9%), and 84 in group 3 (37.7%). 218 (97.8%) 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 statistical difference between groups (p value = 0.667), and Cox regression showed no association between duration of stent placement and unplanned visits, when adjusted for sex, age, and the presence of impacted stones (p value = 0.674). 18 (8%) patients (3 (1.3%) in group 1, 8 (3.6%) in group 2, and 7 (3.1%) in group 3) had an unplanned visit during the 30-day post-operative period, including pre- and post-stent removal. Cox regression showed no association between duration of stent placement and unplanned visit, adjusted for sex, age, and presence of impacted stones (p value = 0.610).

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 required to further define optimal duration of stent placement.

P25

Factors associated with Patient No-Show Appointments in Community Urology Practice
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Introduction: Patient no-show appointments may contribute to suboptimal health outcomes, limited access, and contribute to a loss of budgeted revenue in physician practices. In employed models, patient no-shows may also adversely affect physician productivity and incentive compensation. Identifying and understanding factors associated with patient no-shows is an important first-step process of informing the development of interventions designed to optimize patient health outcomes, improve access, and maximize provider productivity and revenue. The purpose of this evaluation is to describe factors associated with patient no-shows in a large community urology practice in Southern New England.

Materials & Methods: A review of this evaluation by an institutional review board determined that it entailed an analysis of de-identified data for performance improvement, and human subject research was not indicated. This evaluation analyzed patient demographic, payor, provider, and scheduling data reported through Greenway Prime Suite practice management software for office-based appointments scheduled to occur during May 2018-January 2019 among 5 physicians and 1 nurse practitioner. Appointment outcomes were categorized as complete or patient no-show. Patient no-shows were defined as scheduled appointments the patient did not attend without prior notification of the practice. All other appointment statuses were excluded from analysis. Additional factors included in analysis were categorized according to variables and outcomes of interest. Cohort means were compared using independent two-sample, two-sided t-tests. A p-value of .05 was considered statistically significant. Associations were measured using risk ratios (RRs) that were evaluated for significance using 95% confidence intervals (CIs). All data were analyzed using Microsoft Office-based software.

Results: 894 (11.4%) of 7,836 scheduled appointments resulted in patient no-shows. Patients generating no-shows were younger (64.7 vs. 68.1 years; $p < .001$) and more likely to identify no primary care provider (PCP) (RR: 3.31; 95% CI: 2.91-3.76) or secondary insurance coverage (RR: 1.18; 95% CI: 1.03-1.35) at the time of registration. Ninety-four (71.8%) of 131 appointments scheduled for self-paying patients resulted in patient no-shows. Self-paying patients were at highest risk of generating a no-show compared to all other patient-payor arrangements (RR: 6.91; 95% CI 6.09-7.84). Provider-specific no-show rates ranged from 2.3% to 16.1%. General urology physicians were more likely to experience patient no-shows compared to physicians with urologic oncology subspecialty training (RR: 5.53; 95% CI: 3.67-8.32). Patients generating no-shows were scheduled further in advance compared to patients generating complete appointments (54.7 vs. 38.4 days; $p < .001$), and were more likely to be scheduled at the main hospital-based office location compared to satellite office locations (RR: 1.40; 95% CI: 1.23-1.60). Appointments scheduled for less than 30 minutes were also more likely to generate no-shows when compared to appointments scheduled for 30 minutes or more (RR: 1.40; 95% CI: 1.15-1.71). Routine 3-6-month follow-up appointments were most likely to generate no-shows compared to all other appointment types (RR: 1.84; 95% CI: 1.61-2.10).

Conclusions: Interventions for reducing patient no-shows should focus on younger patients, uninsured and underinsured patients, patients without PCPs, patients seeking care from general urologists, and patients scheduled for routine 3-6 month follow-up appointments.

P26

Chasing the Pack: Association Between Urology Hospital Rankings and Surgical Outcomes
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Introduction: Patients value hospital rankings when making decisions about their healthcare. Rankings, such as the U.S. News and World Report (USNWR) integrate safety, outcome, and reputation metrics, however it is unknown whether these rankings are robust to surgery type, or if meaningful differences exist within top performing strata. Therefore, we aimed to study the associations of USNWR ranking and outcome measures using national registry data.

Materials & Methods: We used the Vizient clinical database, a hospital registry representing care at 97% of academic medical centers and over six million inpatient visit submissions, to analyze outcomes for urologic surgeries from 2014 through 2018. We compiled the following hospital outcomes on mortality, length of stay (LOS), 30-day readmissions, LOS index (observed/expected ratios), case mix index and patient safety and adverse event composite (PSI-90) for radical prostatectomy (RP), cystectomy (RC) and radical nephrectomy (RN). We studied the associations of USNWR "Top 50 Hospitals" and outcome by surgery type and in aggregate. In addition, we examined the relative differences in outcome and rank order within quintiles of ranking.

Results: We identified a total of 20,888 including 8,385 RP, 7,486 of RN and 5,017 of RC during the study period. Case volume was significantly higher in the top 10 hospitals for RP, RC, and RN compared to 11-20 that were the second group with highest volume (1,700 more cases for RP, 1,806 for RN and 490 for RC; $P < 0.001$). Hospital LOS was significantly lower in the upper quintile for RP ($P < 0.001$) and RN ($P < 0.001$) but not in RC. Adjusting for expected ratios, LOS index was not different in RP among the different tiers but was lower for RN. 30-day readmission in upper quintile was significantly lower in RP only compared to 41-50 but similar to 11-40 institutions There was not significant variation in mortality between groups or procedures. Bottom ranking positions were negatively correlated with surgical volume (RP rho: -0.50, $P < 0.001$; RN rho -0.41, P 0.005; RC rho: -0.42, P 0.0013) and positively correlated with mean LOS for RP (rho 0.45, P 0.002) and RC (rho 0.48, P 0.001). No other significant differences were found for the other variables. Comparing outcomes individually by hospitals, no significant differences or trends were found favoring top hospitals for LOS, mortality, costs, readmissions or PSI-90.

Conclusions: USNWR ranking of top urology programs was associated with better measures of patient outcome including mortality, readmission, and length of stay when grouped by quintiles and remained consistent across major cancer surgery types. There were no significant differences in outcome within deciles of rank, suggesting that categories of performance rather than ordinal position may be sufficient to describe hospital quality.

P27

Kidney Stones in Black Women in the United States: Data from the Black Women's Health Study
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Introduction: Nephrolithiasis is a common urologic condition and a significant source of patient morbidity and healthcare expenditure. There has been an increase in the prevalence of kidney stones in the United States in recent years, especially 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 questions 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 ($P < 0.0001$), 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 ($P < 0.0001$). The 2,570 sub-study participants in 2017 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% completed 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 gallstones. These data are consistent with hypotheses relating lifestyle-associated risk factors with nephrolithiasis and also confirm reports of lower rates of metabolic evaluation among African American patients despite respondents' multiple 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.

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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 pathology on RNU samples 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 validation using 71 additional UTUC biopsy samples. In total, 39 high grade (HG) and 32 LG samples were analyzed using ROC curves and logistic regression to establish a predictive miRNA model corresponding to final pathological grade and invasion after RNU. Kaplan-Meier survival analysis was performed comparing statistically significant miRNA to pathologic grade and invasion from both 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 32.1% and specificity 97.3% with AUC 0.65.
Survival analysis for miR-146b (HR 3.77, $p = 0.002$) and 223-3p (HR 6.16, $p < 0.001$) were compared to biopsy invasion (HR 2.97, $p = 0.032$) and biopsy HG (HR 1.18, $p = 0.721$). In combination, miR-146b and miR223-3p were associated with median survival of 13 months ($p < 0.001$) compared to 54 months for biopsy invasion ($p = 0.006$) and 87 months for biopsy HG ($p = 0.017$).

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.

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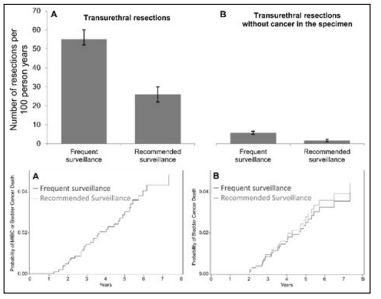
Introduction: Surveillance recommendations for patients with low-risk non-muscle-invasive bladder cancer (NMIBC) are based on limited evidence. Our objective was to add to the evidence by assessing outcomes after frequent versus recommended cystoscopic surveillance.

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 (5.7 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.



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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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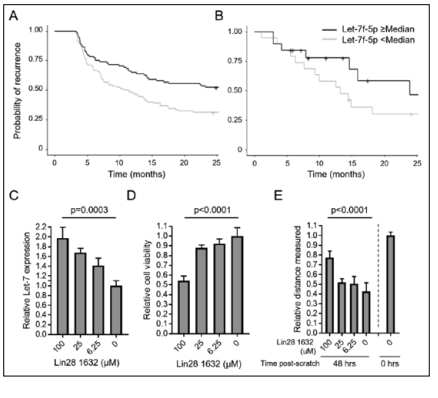
Introduction: Among patients diagnosed with non-muscle invasive bladder cancer (NMIBC), 50% to 75% experience recurrences within 6 to 12 years of diagnosis, and 10% to 30% of tumors progress to muscle-invasive disease. The need to screen for these events every 3-6 months by cystoscopy makes bladder cancer one of the most expensive malignancies. Non-coding RNAs, particularly the microRNAs (miRNAs), have emerged as useful prognostic biomarkers in cancer. The objective of this study was to identify reproducible prognostic miRNAs in resected non-muscle invasive bladder tumor tissue that are predictive of the recurrent tumor phenotype as potential biomarkers and molecular therapeutic targets.

Materials & Methods: Two independent cohorts of NMIBC patients from the New Hampshire Population Cohort and Dartmouth Hitchcock Medical Center were analyzed using a biomarker discovery (n = 178) and validation (n = 38) approach, respectively. We isolated tumor tissue RNA and assessed expression of ~800 miRNAs, and performed recurrence free survival (RFS) analyses using a multivariable model adjusted for sex, age, multiplicity, tumor size, stage, and grade. Urine and plasma samples were obtained from available patients from the validation cohort and analyzed for miRNA expression. To assess the therapeutic potential of targeting Lin28, a known negative regulator of Let-7f-5p, Lin28 primers and small molecule inhibitor Lin28 1632 were obtained and assayed using RT-PCR, cell viability, and scratch assays in NMIBC cell line HTB-2.

Results: miRNA Let-7f-5p showed the strongest association with recurrence across both the NH population cohort ($p = 0.039$) and the DHMC cohort ($p = 0.065$). Survival analyses stratified by median Let-7f-5p expression confirmed longer RFS in the patients with high Let-7f-5p for both discovery and validation cohorts ($p = 0.011$ and 0.065; Figure 1A/B). Let-7f-5p was found to have potential clinical utility as a biomarker, and levels in urine and plasma were both found to be significantly correlated with levels in tumor tissue ($p = 0.0004$ and 0.014, respectively). Finally, inhibition of Lin28 with Lin28 1632 significantly increased levels of Let-7f-5p expression ($p = 0.0003$; Figure 1C) and led to significant inhibition of viability and migration of HTB-2 cells (both $p < 0.0001$; 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 Lin28, a negative regulator of Let-7f-5p, represents a novel therapeutic opportunity in NMIBC.



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Outcomes of Pathologic Upstaging of Clinical T1b and T2 Renal Cell Carcinoma
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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 imaging 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 305 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 months for RN ($p = 0.7703$). 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 even in patients with pathological upstaging. When technically achievable, partial nephrectomy should be considered for these larger clinically localized renal masses.

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

Table 1. Clinical outcomes of clinical T1b and T2 renal cell carcinoma treated by partial nephrectomy and radical nephrectomy.			
	Partial Nephrectomy	**Radical Nephrectomy**	**P-value**
Patients (n)	149	305	-
Tumors (n)	152	310	-
Median follow-up (mos, [IQR])	25.9 [18.8, 31.3]	45.1 [37.2, 50.1]	-
Clinical T1b (n, %)	142 (46.7)	162 (53.3)	-
Clinical T2 (n, %)	10 (6.3)	148 (93.7)	-
Tumor size (cm, median [IQR])	5 [4.4, 5.5]	6.8 [5.3, 9]	< 0.001
RCC histology			
Clear cell	106 (69.7)	246 (79.4)	0.023
Papillary	31 (20.4)	33 (10.6)	0.004
Chromophobe	15 (9.9)	30 (9.7)	0.948
Collecting duct	0 (0)	1 (0.3)	0.483
Upstaged (%)	10 (6.7)	122 (40.0)	< 0.001
cT1b to pT3a	10	52	< 0.001
cT2 to pT3a	0	67	0.004
Positive margins (%)	7	0	0.222
Local recurrence (%)	10 (6.7)	24 (7.8)	0.653
Development of distant metastasis (%)	10 (6.7)	40 (13.1)	0.04
RCC recurrence (local or distant) (%)	18 (12.1)	50 (16.4)	0.222
Median time to relapse (mos, [IQR])	13.6 [7.0, 54.9]	11 [5.9, 40,2]	0.7703
Deaths (%)	9 (6.0)	53 (17.4)	0.001
Deaths from RCC (%)	4 (2.7)	27 (8.8)	0.016
Deaths in upstaged patients (%)	4 (40.0)	29 (23.8)	0.267
RCC deaths in upstaged patients (%)	3 (30.0)	18 (14.8)	0.198

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Rate of Upstaging in Variant Histology Nonmuscle Invasive Bladder Cancer: Is There Evidence to Support the AUA Guidelines "Expert Opinion"?
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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, then, 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 22,722 cases of bladder cancer were included. A total of 21,855 (96%) cases were urothelial, and 867 (4%) 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 "Expert Opinion" set forth in the AUA Guidelines for non-muscle invasive bladder cancer and lend further data for timely cystectomy in this high-risk population.

Rates of Up/Downstaging			
Histology	**Upstaged**	**Same Stage**	**Downstaged**
Urothelial	2,552 (11.7%)	18,147 (83.0%)	1,156 (5.3%)
Adenocarcinoma	77 (30.8%)	161 (64.4%)	12 (4.8%)
Small Cell	34 (43.6%)	39 (50.0%)	5 (6.4%)
Spindle Cell	43 (44.8%)	44 (45.8%)	9 (9.4%)
Squamous Cell	154 (49.9%)	148 (47.4%)	10 (3.2%)
Signet Ring Cell	24 (61.5%)	13 (33.3%)	2 (5.1%)
Micropapillary	37 (40.2%)	46 (50.0%)	9 (9.8%)

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The Impact of Low- Versus High-Intensity Surveillance Cystoscopy on Surgical Care and Cancer Outcomes in Patients With High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

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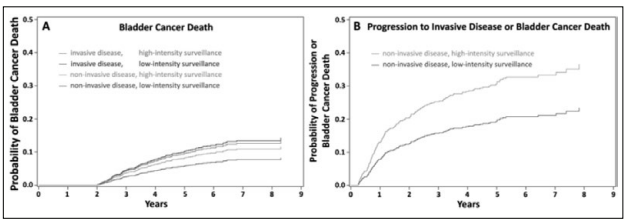
Introduction: Surveillance guidelines for NMIBC are based on expert opinion and informed by limited evidence. We have previously found that about one third of patients with high-risk NMIBC undergo fewer surveillance cystoscopies than recommended (i.e., low-intensity surveillance). Our objective was to assess the association of low- vs. high-intensity cystoscopic surveillance with outcomes, including the frequency of transurethral resections, bladder cancer death, and progression of disease.

Materials & Methods: Retrospective national cohort study of patients diagnosed with high-risk (high grade Ta, T1, or carcinoma in situ) NMIBC from 2005 to 2011 within the Department of Veterans Affairs with follow-up through 2014. Patients were categorized by number of surveillance cystoscopies over two years following diagnosis into low- (1-5) vs. high-intensity (6 or more) surveillance. Propensity score adjusted Poisson regression was used to assess the association of low-intensity cystoscopic surveillance with frequency of transurethral resections (overall and resections with or without cancer in the specimen). Propensity score adjusted competing risks regression was used to assess the association of surveillance intensity with risk of bladder cancer death or progression to invasive disease, stratified by whether patients were diagnosed with non-invasive or invasive disease.

Results: Among 1,542 patients, 520 (33.7%) underwent low-intensity cystoscopic surveillance. Those receiving low-intensity surveillance over 2 years following diagnosis underwent a median of 4 cystoscopies, compared to a median of 7 for high-intensity surveillance. Patients undergoing low-intensity surveillance had fewer transurethral resections overall (37 vs. 99 per 100 person years; $p < 0.001$), resections with cancer in the specimen (28 vs. 77 per 100 person years, $p < 0.001$), and resections without cancer in the specimen (7.5 vs. 16 per 100 person years; $p < 0.001$). Low vs. high-intensity surveillance was not associated with risk of bladder cancer death among patients with non-invasive (cumulative incidence 5.8% vs. 8.3% at 5 years, $p = 0.27$) or with invasive disease at diagnosis (cumulative incidence 10.3% vs. 9.6% at 5 years, $p = 0.75$, Figure Panel A). Among patients with non-invasive disease, low-intensity surveillance was unexpectedly associated with a decreased risk of progression or bladder cancer death (cumulative incidence 20% vs. 31% at 5 years, $p = 0.003$, Figure Panel B).

Conclusions: Patients with high-risk NMIBC undergoing low- vs. high-intensity cystoscopic surveillance underwent fewer transurethral resections, but did not experience an increased risk of bladder cancer death. In fact, they had a lower risk of progression. These findings suggest that less intensive surveillance might be reasonable for patients with high-risk NMIBC. However, patients who underwent low-intensity surveillance likely had more favorable bladder cancer, because urologists used clinical information not available in our data to inform their decision making. Thus, these observational data provide a strong rationale for a prospective randomized study to assess whether the frequency of surveillance can be decreased among patients with high-risk NMIBC.



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Renal Mass Biopsy for Cystic Renal Masses: Can We Challenge the Dogma?

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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 a 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 felt not 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 (0-2 cm: 18.8%, 2-4 cm: 48.0%, 4-7 cm: 37.8%, > 7 cm: 50.0%; $p = 0.001$). Independent predictors of a diagnostic renal cystic 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-mass diameter ratio greater than 0.45 was significantly associated with a diagnostic biopsy ($p = 0.027$). Inclusion of only masses with a nodule-to-mass 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-mass 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.

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The Impact of Insurance Status on Outcomes for Bladder Cancer

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Introduction: Health disparities in the United States are closely linked to patients' ability to afford care. Bladder cancer is known to impart a substantial financial burden upon diagnosed individuals. We sought to determine the association between insurance status and clinical outcomes in bladder cancer.

Materials & Methods: We used the Surveillance, Epidemiology, and End Results (SEER) database and the National Cancer Database (NCDB) to identify men and women aged < 65 years who were diagnosed with bladder cancer from 2007 to 2014. With SEER, we evaluated the association between insurance status (private insurance, Medicaid insurance, and lack of insurance) and diagnosis with muscle-invasive bladder cancer as well as bladder cancer-specific survival. NCDB was used to identify those with localized muscle-invasive bladder cancer and evaluate the association between insurance status and receipt of neoadjuvant chemotherapy (among those who underwent radical cystectomy) as well as post-diagnosis delay of any treatment (surgery, radiation, or chemotherapy) > 3 months. Analyses were controlled for age, sex, race, year of diagnosis, income, education, geographical region, clinical TNM stage, and histologic type.

Results: There were 29,525 individuals in the SEER cohort and 6,069 in the NCDB cohort. Multivariable analyses (with private insurance holders as the reference group) demonstrated that uninsured individuals were nearly twice as likely to receive a diagnosis of muscle-invasive bladder cancer (OR: 1.90; 95% CI: 1.70-2.12). Medicaid-insured individuals had similarly increased odds of receiving this diagnosis (OR: 2.03; 95% CI: 1.87-2.20). Uninsured patients were also more likely to die of bladder cancer (adjusted hazard ratio [AHR]: 1.49; 95% CI: 1.31-1.71), as were those with Medicaid coverage (AHR: 1.61; 95% CI: 1.46-1.79). Uninsured patients were less likely to receive neoadjuvant chemotherapy (OR: 0.76; 95% CI: 0.59-0.97) and more likely to experience a delay in treatment (OR: 1.50; 95% CI: 1.22-1.83). These outcomes were similar for Medicaid-insured patients.

Conclusions: Individuals lacking insurance and those with Medicaid coverage are more likely to be diagnosed with muscle-invasive bladder cancer as well as die from the disease; they are also less likely to receive guideline-directed care. Expanding high-quality insurance coverage may help to reduce the burden of this disease.

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Premature Termination of Genitourinary Cancer Trials: Assessing Trial Efficiency Using Novel Algorithms

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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. Of trials reported as "completed," 84% met at least 75% of their anticipated accrual goal.

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 1: Associations with Premature Termination for Reasons Unrelated to Toxicity or Efficacy

Variable	OR	95% CI	P value
Anticipated Accrual	1.0002	0.998-1.002	0.82
Multicenter Trial	0.82	0.57-1.17	0.27
Site Locations			
International Only	Reference		
USA Only	2.53	1.67-3.88	<0.001
Both USA and International	0.56	0.28-1.06	0.08
Sponsor			
Other	Reference		
Industry	0.92	0.62-1.37	0.69
US Government	0.69	0.10-3.17	0.66
NIH	0.70	0.42-1.17	0.18
Cancer Type			
Bladder	Reference		
Kidney	0.86	0.48-1.55	0.61
Penile	0.74	0.03-6.99	0.81
Prostate	0.55	0.33-0.93	0.02
Testicular	0.42	0.09-1.49	0.21

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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

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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 16,837 (42.3%) 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.

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Workplace Absenteeism Following Robotic and Open Kidney Surgery

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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. Three study periods were established relative to the date of surgery: baseline (-380 to -15 days), perioperative (-14 to +28 days), and postoperative (+28 to +352 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 = 0.003), 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 0.2-17.6) fewer days of work relative to their 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.

MarketScan Radical and Partial Nephrectomy Absenteeism Subsample 2012-2017

	Radical Nephrectomy			Partial Nephrectomy		
	Open (n=274)	Robotic (n=47)	p-value	Open (n=159)	Robotic (n=163)	p-value
Sex (%)			0.55			0.70
Male	66.5	61.7		66.7	68.7	
Female	33.6	38.3		33.3	31.3	
Mean Age (SD)	52.1 (7.0)	54.3 (6.7)	0.06	51.2 (8.1)	50.3 (9.5)	0.33
Age Group (%)			0.003			0.06
18-34	0	4.3		2.8	9.8	
34-44	16.8	2.1		17.4	12.3	
45-54	36.8	34.0		40.3	40.5	
55-64	46.5	59.6		39.6	37.4	
Comorbidities (%)			0.47			0.85
0	0	0		0	0	
1	12.9	6.4		12.5	14.7	
2	19.4	21.3		21.5	21.5	
≥3	67.7	72.3		66.0	63.8	
Geographic Region (%)			0.29			0.36
Northeast	12.9	14.9		21.5	22.7	
Northcentral	29.0	34.0		24.3	32.5	
South	48.4	34.0		38.2	31.3	
West	9.7	17.0		16.0	13.5	
Residence (%)			0.66			0.17
Rural	8.4	6.4		10.4	6.1	
Urban	91.6	93.6		89.6	93.9	
Health Plan Type (%)			0.84			0.23
Less Restrictive	66.5	68.1		59.0	65.6	
More Restrictive	33.6	31.9		41.0	34.4	
Baseline Days Absent (Mean)	20.2	26.2	0.38	24.2	19.5	0.31

Differences in perioperative/postoperative days absent between patients undergoing robotic versus open radical and partial nephrectomy, adjusted for baseline absenteeism and for all covariates

	Radical Nephrectomy			Partial Nephrectomy		
	Open (n=274)	Robotic (n=47)	p-value	Open (n=159)	Robotic (n=163)	p-value
Periop/Postop Days Absent (Mean)	68.7	59.5	0.29	57.9	44.4	0.004
Difference in Periop/Postop Days Absent - Baseline Adjusted (95% CI)	-	-13.1 (-28.1 to 1.8)	0.08	-	-12.1 (-20.8 to -3.4)	0.007
Difference in Periop/Postop Days Absent – Fully Adjusted (95% CI)	-	-15.1 (-26.8 to -3.3)	0.01	-	-8.9 (-17.6 to -0.2)	0.04

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Characteristics and Clinical Outcomes of a Multi-Institutional Observational Patient Cohort Who Underwent Anastomotic Posterior Urethroplasty by a Combined Robotic Transabdominal and Open Transperineal Approach

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Introduction: Urethral strictures occurring between 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 anastomotic posterior urethroplasty by a combined robotic transabdominal and open transperineal surgical approach between 1/2012 and 12/2018 was performed. We reviewed patient demographics, medical history, etiology, and previous endoscopic treatment. Urethroplasty success was anatomic and based upon atraumatic passage of a 17Fr flexible cystoscope. 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 anastomotic posterior urethroplasty 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 tobacco smoking history. 66.7% of the cohort (n = 10) had a history of prostate cancer, and 6.7% of the cohort (n = 1) had a history of urothelial cancer. All patients with a history of prostate cancer were treated with radiation therapy: 20% (n = 2) brachytherapy, 60% (n = 6) eternal beam radiation therapy (EBRT), and 20% (n = 2) combination brachytherapy and EBRT. Of 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 urethroplasty by a combined robotic transabdominal and open transperineal approach is associated with a low rate of 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.

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Urothelial Cell Carcinoma of the Bladder in Pediatric Patients: A Systematic Review of Case Reports & Case Series

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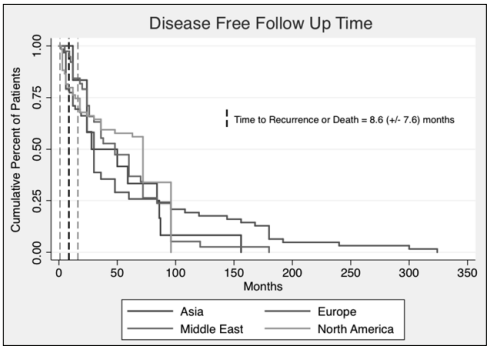
Introduction: Urothelial cell carcinoma (UCC) of the bladder is exceedingly rare in pediatric patients. Limited data is available to guide management in this population.

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, 32.6% 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 TaN0M0 (88.2%). 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; 2.64-15.81) 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.

*Max K. Willscher Award Eligible



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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 Charlson Comorbidity Index (CCI) and Frailty Index (FI) were used to investigate the relationship between pre-operative comorbidity and immediate complications following urethroplasty with buccal 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 buccal grafting were identified, performed between the years 2007 and 2015. Each patient's CCI was calculated based on ICD 9 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. Weighted multivariate logistic regression was utilized 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 buccal graft. The average age was 48.7 +/- 16.4 (range 18-90 years). 67.5% of the patients were white. Mean BMI was 30.5 +/- 6.7 (range 17.5-65). 16.4% 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 I, 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 buccal 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.

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

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Introduction: 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 and intraoperative clinical variables and the postoperative outcomes of ABP patients who elect to undergo BPR.

Materials & Methods: The institutional database of a single reconstructive urologist was retrospectively reviewed for ABP patients who underwent BPR between 7/2011 and 12/2018. We reviewed preoperative demographics, medical history, associated urinary and sexual dysfunction, and previous treatment, as well as intraoperative time, estimated blood loss (EBL), and surgical techniques. Postoperative outcomes included residual urinary, sexual, and infectious BPR symptoms; wound complications; BPR failure; and death. Wound complications reviewed included hematoma, dehiscence, cellulitis, and surgical site infections. BPR failure was defined as recurrent ABP requiring repeat BPR.

Results: 48 ABP patients underwent BPR between 7/2011 and 12/2018. Mean follow-up was 345.3 (range 0-2173) days. Mean age at presentation was 54.9 (range 27.0-82.1) years. Mean weight and BMI were 294.1 (range 206.0-492.0) lbs and 42.8 (range 28.0-72.1), respectively. 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 dilation, 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. 58.3% (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 BPR. 89.6% (n = 43), 60.4% (n = 29), and 62.5% (n = 30) of the cohort reported urinary dysfunction, sexual dysfunction, and skin or urinary infection reasons for pursuing BPR, respectively. Mean BPR surgical time was 181.4 (range 41-364) min; mean EBL was 84.3 (range 10-700) mL. BPR included escutcheonectomy, penile skin graft, and penile scar release with z-plasty in 52.1% (n = 25), 60.4% (n = 29), and 10.4% (n = 5) of the cohort, respectively. Escutcheonectomy mean area was 229.6 (range 37.5-462.5) cm^2 and mean weight was 713.6 (range 82.5-3600) g; mean skin graft area was 167.2 (range 20-900) cm^2. 8.3% (n = 4) patients had a concurrent urethral procedure at the time of BPR. Postoperatively, 16.7% (n = 8), 0% (n = 0), and 10.4% (n = 5) of the cohort reported residual urinary dysfunction, sexual dysfunction, and skin or urinary infection symptoms, respectively. Clavien grade I-II complications occurred in 18.8% (n = 9), whereas Clavien grade III-V complications occurred in 12.5% (n = 1 operative hematoma, n = 4 BPR failures requiring reoperation, n = 1 death within 30 postoperative days) of the cohort. Mean time to repeat BPR was 334.8 (range 152-529) days.

Conclusions: BPR results in significant improvement in urinary dysfunction, sexual dysfunction, and skin and urinary infection symptoms, with a low risk of buried penis recurrence. Most complications are minor and rarely require operative intervention.

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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 Ukranian 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 Si, 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.