

**DEPARTMENT OF UROLOGY  
AMERICAN UROLOGICAL ASSOCIATION  
ANNUAL MEETING 2020**



**Accepted Abstracts**

*Colleagues, as we have seen, COVID-19 has brought many changes to our daily and professional lives. One of these was transitioning the 2020 American Urological Association annual meeting to a virtual format. Consistent with our history of clinical excellence and contributions to the field of Urology, we had a number of presentations and educational sessions at this year's meeting. To help highlight everyone's efforts, this compendium of AUA 2020 abstracts from the Cleveland Clinic team was assembled. Please take a look at what our department has been up to and learn from the findings of your colleagues' research.*

## Cleveland Clinic AUA Footprint

CLINICAL TOPIC	NUMBER OF ABSTRACTS			
	POSTER	PODIUM	VIDEO	TOTAL
Education	1	–	–	1
Endourology/Stones	7	–	–	7
Female	7	1	1	9
Men's Health	7	3	–	10
Minimally Invasive Surgery	6	3	4	13
Oncology	5	10	–	15
Grand Totals	33	17	5	55

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## Education

### TRENDS IN OPEN AND MINIMALLY INVASIVE CASE LOGS AND COMFORT LEVEL AMONG US UROLOGY RESIDENTS

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#### Introduction and Objective

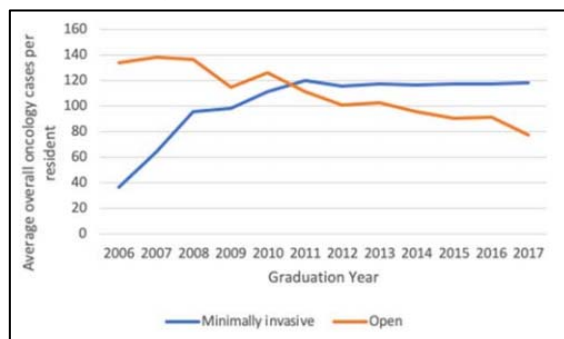
Urologists' use of minimally invasive surgery (MIS) has increased rapidly in the last decade. In reaction to this, the Urology RRC set required minimums of MIS cases for residents to complete prior to graduation. No such guidelines exist for open surgery, though the ability to perform these procedures open remains essential for occasional situations where conversion to open is necessary. In this descriptive study, we evaluate the change in proportion of MIS and open oncologic cases logged by graduating US urology residents, along with the relative comfort level of graduating residents in performing these surgeries.

#### Methods

Combined ACGME case logs were queried for common urologic oncologic cases logged by residents graduating in 2006-2017 from five academic institutions. Logs were searched for radical prostatectomy (RPx), radical and partial nephrectomy (PNx), and radical cystectomy, and were characterized as open or MIS. In addition, surveys regarding the relative comfort level of performing RPx and PNx, open vs MIS, were sent to 24 graduating or recently graduated residents from five institutions. Descriptive statistics were employed to characterize rate of change.

#### Results

From 2006-2017, the percentage of open cases downtrended significantly by an average of -2.9% per year or 57 fewer open oncologic cases per graduate over the course of training. This represented a change from 77.6% to 38.9% open cases over



this timeframe. Among 16 residents who returned completed surveys 81.25% (13/16) felt more comfortable doing a robotic in lieu of open RPx, 2 felt equally comfortable with either approach, and only one felt more comfortable performing an open RPx. Half of respondents felt more comfortable doing a

robotic PNx, 25% felt equally comfortable using either approach, and 25% felt more comfortable performing an open PNx.

#### Conclusions

In the last decade the proportion of open urologic oncology procedures has declined, and graduating residents now feel more comfortable performing these procedures robotically than they do open. We anticipate the number of open cases will continue to decrease as the remaining attendings who perform a significant number of open cases retire. Given this context, it may be worthwhile for the Urology RRC to consider establishing minimum case numbers for principal open urologic oncology procedures.

Source of Funding: NA

## Endourology/Stones

### NEPHROLITHIASIS DISPARITY IN PEOPLE WITH DISABILITIES: DATA FROM THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

Marlie Elia\*, Smita De, Manoj Monga, Cleveland, OH

#### Introduction and Objective

Mounting evidence in many medical disciplines demonstrates that people with disabilities (PWD) face significant health disparities. To our knowledge, no prior epidemiological studies of urologic disease have examined this population. This study seeks to describe the prevalence of nephrolithiasis within PWD, and its associations with known nephrolithiasis risk factors.

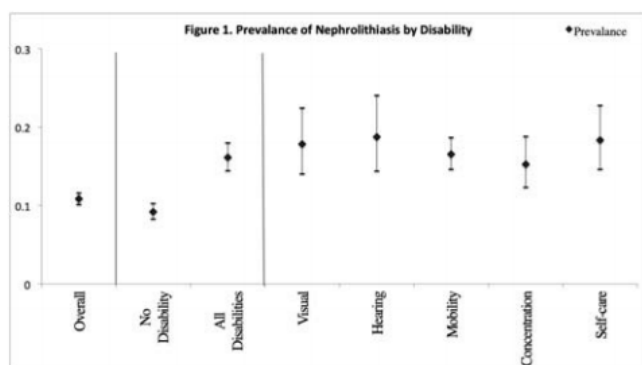
#### Methods

We analyzed the National Health and Nutrition Examination Survey (NHANES), a nationally representative cross-sectional by the Centers for Disease Control. Questions on disability status and history of kidney stones were included in the 2013-2016 cycles for 11,488 adults over the age of twenty. 85 subjects (0.7%) were missing data and were excluded from the analysis. Disability was assessed in regards to impairments in five domains: hearing, vision, concentration, mobility, and self-care. Age-adjusted proportions were produced by the direct method and Taylor series linearization was used for estimates of variance. Univariate analysis and multivariate logistic regression was used to assess the association of nephrolithiasis history in PWD in relation to known correlates to nephrolithiasis. Covariates were chosen a priori based on associations to nephrolithiasis reported in the literature.

#### Results

Of people with a history of stones, PWD account for an estimated 34.7% (CI: 30.5-39.1%) of the US population of non-institutionalized adults over the age of twenty, which equals 36,394,097 people. Figure 1 demonstrates the prevalence of stones by disability domain. 16.1% (CI 95%: 14.4-18.0) of PWD

have a history of nephrolithiasis. PWD have significantly elevated odds of nephrolithiasis history (un-adjusted OR: 1.90 95% CI: 1.54-2.35). After adjusting for age, gender, race, diabetes, hypertension, and obesity, odds of stone history remain elevated in PWD overall (adjusted OR: 1.46 95% CI: 1.17-1.83) and in every disability domain except for self-care.



## Conclusions

Odds of stone history are significantly elevated in PWD. These odds vary by disability type and persist after adjustment for multiple known risk factors in all disability domains except for self-care. Further research is necessary to explore these novel results and ensure that any specialized needs of this population are met.

Source of Funding: N/A

## FUNCTIONAL ANALYSIS OF THE URINARY TRACT MICROBIOME OF CALCIUM OXALATE STONE FORMERS

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### Introduction and Objective

Individuals with urinary stone disease (USD) are more likely to take antibiotics in the past and harbor a functionally less diverse microbiome than those with no history of the disease. The urinary tract microbiome of USD patients exhibits greater levels of dysbiosis than the gut microbiome. Therefore, the objective of the current study was to determine what microbial functions of the urinary tract are associated with calcium oxalate (CaOx) formers to understand how the microbiome may contribute to the onset of CaOx stones.

### Methods

Two groups of patients, either with no history of USD or an active episode of CaOx stones, were recruited with five patients in each group. The metabolic potential of the urinary tract microbiome was quantified through comparative shotgun metagenomics from clean catch urine samples. Functional differences between groups were assessed through non-parametric t-tests of the normalized abundances of full-length genes, which were annotated through Prodigal and KEGG pathways. Additionally, draft genomes were extracted from the data to aid in future mechanistic studies.

## Results

Shotgun metagenomics revealed that individuals with CaOx stones had a urinary tract microbiome distinct from those with no history of USD. CaOx stone formers were functionally less diverse than controls, corroborating previous metabolomic studies. Reduced functions of stone formers included oxalate metabolism, previously thought to be relegated to the gut microbiome, as well as transmembrane transport, proteolysis, and oxidation-reduction processes. A total of 17 draft genomes were extracted from the data, primarily from the *Lactobacillus* genus, which are thought protect against USD and urinary tract infections.

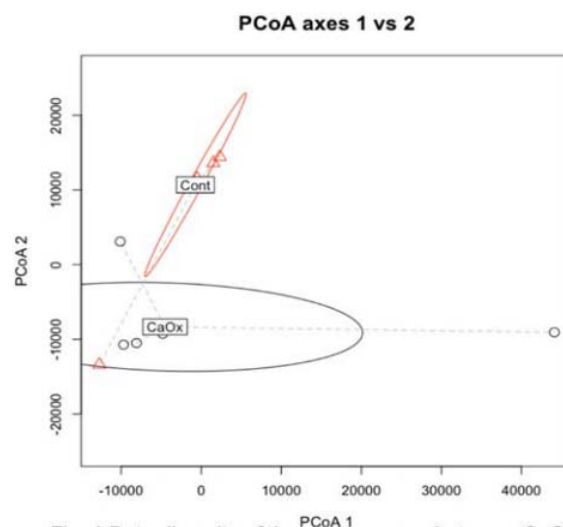


Fig. 1 Beta diversity of the metagenome between CaOx patients and controls with no history of USD are distinct.

## Conclusions

Our prospective clinical study shows that individuals with USD harbor a distinct urinary tract microbiome. Surprisingly, USD patients harbored lower levels of oxalate-degrading genes, which suggests oxalate metabolism may continue in the urinary tract and play a role in inhibiting CaOx stone formation. Additional functions reduced in CaOx stone formers, such as proteolysis and oxidation-reduction processes overlap with known mechanisms of stone formation and thus may also play important roles for the onset of USD.

Source of Funding: Lerner Research Institute

## PREDICTING THE POSTOPERATIVE OUTCOME OF PERCUTANEOUS NEPHROLITHOTOMY WITH MACHINE LEARNING SYSTEM: SOFTWARE VALIDATION AND COMPARATIVE ANALYSIS WITH GUY'S STONE SCORE AND THE CROES NOMOGRAM

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### Introduction and Objectives

To validate the output of a machine learning-based software as an intelligible interface for predicting multiple outcomes after percutaneous nephrolithotomy (PCNL). We compared



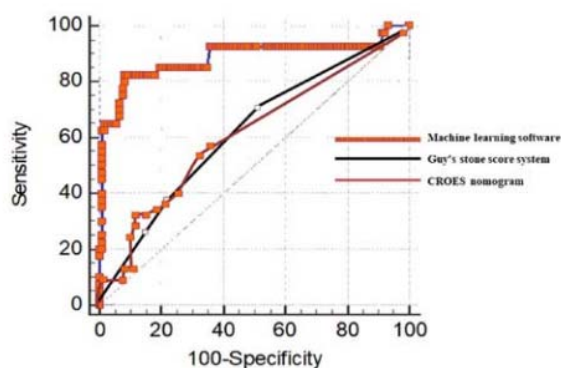
the performance of this system with Guy's stone score (GSS) and the Clinical Research Office of Endourological Society (CROES) nomogram.

## Methods

Data from 146 adult patients (87 males, 59%) who underwent PCNL at our institute were used, and preoperative variables and postoperative outcomes were recorded. Stone-free status was determined by computed tomography scan postoperatively. Preoperative data were consecutively imported into the software and its output was extracted. To validate the system, accuracy of the software for predicting each postoperative outcome was compared to the actual outcome. Similarly, preoperative data were analyzed with GSS and CROES nomograms to determine stone-free status as predicted by these nomograms, and the predictive performance of these two systems was calculated. A receiver operating characteristic (ROC) curve was generated for each scoring system, and the area under curve (AUC) was calculated and used to assess the predictive performance of the nomograms versus ANN software. RESULTS: Overall stone-free rate (SFR) was 72

## Results

Overall stone-free rate (SFR) was 72.6% (106/146). Forty of 146 patients (27.4%) were scheduled for Forty-two ancillary procedures (shock wave lithotripsy (SWL) (n=31) or repeat PCNL (n=11)) to manage residual renal stones. Overall, the machine learning system predicted the PCNL outcomes with an accuracy ranging between 80% and 95.1%. A higher GSS grade and lower CROES nomogram score were significantly associated with lower SFR ( $p=0.01$  and  $p=0.03$ , respectively). When ROC curves were plotted for each predictive model for stone-free status, the area under the ROC curve for ANN software (0.915) was significantly larger than the AUC for GSS (0.615) or CROES nomograms (0.621) ( $p<0.001$ ) (Figure 1).



**Figure 1.** Receiver operating characteristic (ROC) curve for stone-free status. The area under the ROC curve for the machine learning software (0.915) was significantly larger than the area under curve for Guy's gradings (0.615) and CROES (0.621) nomograms. CROES: Clinical Research Office of Endourological Society.

## Conclusions

At the internal institutional level, the machine learning-based software was a promising tool for recording, processing and predicting outcomes after PCNL. Validation of this system

against an external dataset is highly recommended before its widespread application.

*Source of Funding:* Shiraz University of Medical Sciences.

## WISCONSIN QUALITY OF LIFE MACHINE LEARNING ALGORITHM FOR PREDICTING QUALITY OF LIFE IN KIDNEY STONE PATIENTS

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## Introduction and Objective

The Wisconsin Stone Quality of Life (WISQOL) questionnaire, a quality of life (QOL) measurement tool designed specifically for kidney stone patients was recently validated. Using the WISQOL score as the gold standard of the model, we built the WISQOL Machine Learning Algorithm (WISQOLMLA) to predict patients' QOL based on demographic, symptomatic, and clinical data collected for the validation of the WISQOL.

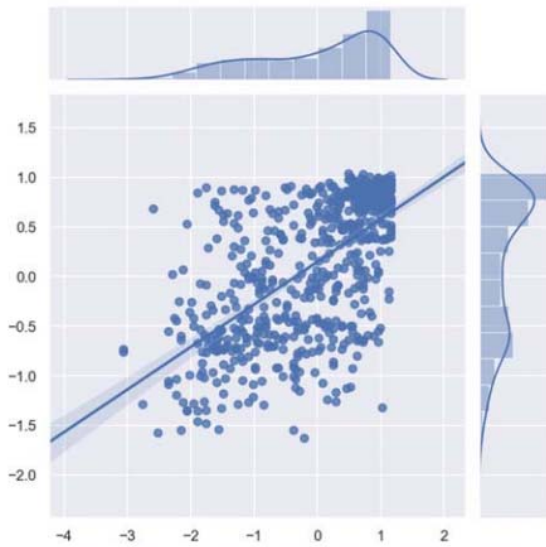
## Methods

Using gradient boosting and deep learning models implemented in Python, QOL scores for all 3206 patients were predicted. We also stratified QOL scores by quintiles. The dataset was split using a standard 70/10/20% training/validation/testing ratio. Per usual machine learning practice, categorical variables were numerically discretized. Variables were then standardized to mean of 0 and standard deviation of 1 to aid model convergence. Regression performance was evaluated using Pearson's correlation ( $r$ ). Classification was evaluated with area under the ROC curve (AUC).

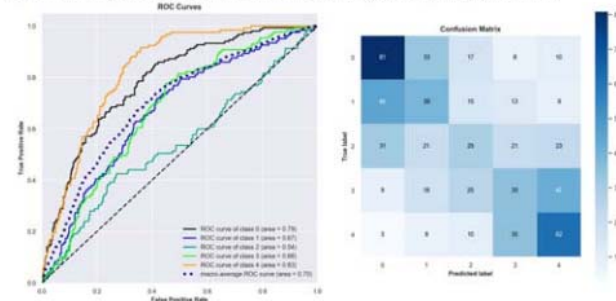
## Results

Gradient boosting obtained a test correlation of 0.622 (Fig. 1). Deep learning obtained a correlation of 0.592. Multivariate regression only achieved a correlation of 0.4375. Quintile stratification on all WISQOL patients obtained an average test AUC of 0.70 for the 5 classes. The model performed best in distinguishing between lowest (0.79) and highest quintile (0.83) (Fig. 2). Feature importance analysis showed that the model correctly weights in symptomatic status, BMI, age as well as other medical and demographic features to estimate QOL.

**Figure 1 Out-of-sample correlation between QOL estimates and WISQOL total score ( $r = 0.622$ )**



**Figure 2. Out-of-sample ROC curves for quintile stratification (AUC = 0.78) and corresponding confusion matrix**



## Conclusions

Harnessing the power of the WISQOL questionnaire, WISQOL-MLA can accurately predict a stone patient's QOL from readily available clinical information and outperforms linear models. Future endeavors include scaling the tool as an aid to urologists that don't have the resources to collect precise QOL scores via questionnaire.

*Source of Funding:* No funding source.

## REGIONAL DIFFERENCES AND THE IMPACT ON STONE-RELATED QUALITY OF LIFE: RESULTS FROM THE NORTH AMERICAN STONE QUALITY OF LIFE CONSORTIUM

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## Introduction and Objective

Urolithiasis is associated with a decreased health-related quality of life. The Wisconsin Stone Quality of Life (WISQOL)

questionnaire is a validated instrument to evaluate Stone-Related Quality of Life (SRQOL) in patients with kidney stones. Our objective was to assess the correlation between geographical location and SRQOL in the North American Stone Quality of Life Consortium.

## Methods

A total of 2308 patients from 14 institutions who completed the WISQOL questionnaire were categorized into 4 populations by their geographical locations: West (W), Midwest (MW), South (S), and Northeast (NE). The WISQOL questionnaire is a 28- question survey that quantifies SRQOL using a Likert-type scale according to the following domains: social function, emotional function, stone-related impact, and vitality (total score range 0-140). Demographic and clinical data, as well as WISQOL domain and total scores were analyzed.

## Results

Populations did not differ by age, gender, number of comorbidities, nor age at enrollment. In group W, more patients had stones at the time they completed the WISQOL, and their body mass index was lower compared to other groups (Table 1). Upon univariate analysis, population W exhibited a lower SRQOL within each domain and a lower overall SRQOL compared to the other geographical populations ( $p < 0.001$ ) (Table 2). After controlling for statistically significant covariates through multivariate analysis, residing in the West was a significant independent predictor of a lower SRQOL ( $p < 0.001$ ). Residing in the Northeast was a significant independent predictor for a higher SRQOL ( $p = 0.017$ ) compared to the rest of the cohort.

Variable	West (N=607)	Midwest (N=433)	South (N=612)	North East (N=656)	P	Pairwise Comparison	Total (N=2308)
Average Age	53 ± 14.7	54.2 ± 14.5	53.8 ± 14.4	52.7 ± 14.0	0.2	NA	53.5 ± 14.4
Gender, N (%)							
Male	329 (54.2)	217 (50.1)	325 (53.1)	313 (47.7)	0.09	NA	1184 (51.3)
Female	278 (45.8)	216 (49.9)	287 (46.9)	343 (52.3)			1124 (48.7)
Ethnicity, N (%)							
African American	13 (2.1)	13.3 (3.0)	29 (4.7)	13 (2.0)		W:MW ( $p < 0.001$ )	68 (2.9)
Asian	87 (14.3)	6 (1.4)	11 (1.8)	11 (1.7)		W:S ( $p < 0.001$ )	115 (5.0)
Hispanic/Latino	56 (9.1)	5 (1.2)	38 (6.2)	22 (3.4)	<0.01	W:NE ( $p < 0.001$ )	121 (5.2)
White	400 (65.9)	400 (92.4)	511 (83.5)	601 (91.6)		MW:S ( $p < 0.001$ )	1912 (82.8)
Other	26 (4.3)	2 (0.5)	8 (1.3)	9 (1.4)		S:NE ( $p < 0.001$ )	45 (1.9)
NA	25 (4.1)	7 (1.6)	15 (2.5)	0			47 (2.0)
Employment, N (%)							
Employed	370 (61.0)	244 (56.4)	345 (56.4)	496 (74.6)		W>S ( $p = 0.04$ )	1455 (63.0)
Retire/Unemployed	210 (34.6)	151 (34.9)	256 (41.8)	146 (22.2)	$p < 0.01$	NE>W ( $p < 0.001$ )	763 (33.1)
NA	27 (4.4)	38 (8.8)	11 (1.8)	14 (2.1)		NE>S ( $p < 0.001$ )	90 (3.9)
Average number of comorbidities	1.7 ± 1.6	1.9 ± 1.7	1.8 ± 1.6	1.9 ± 1.9	0.05	NA	1.8 ± 1.7
Patients with metabolic syndrome	27 (4.4)	19 (4.4)	39 (6.4)	29 (4.4)	0.3	NA	114 (4.9)
Average BMI (kg/m <sup>2</sup> )	28.5 ± 6.8	30.5 ± 7.5	30.5 ± 7.4	30.7 ± 7.8	<0.01	MW>W ( $p < 0.001$ )	30.0 ± 7.4
						NE>W ( $p < 0.001$ )	
						S>W ( $p < 0.001$ )	
Average age at onset	41.0 ± 16.9	43.2 ± 16.1	40.5 ± 16.2	39.3 ± 15.8	0.07	NA	41.2 ± 16.9
Stones Events, N (%)							
One	154 (25.4)	92 (21.2)	155 (25.3)	111 (16.9)		W:MW ( $p = 0.02$ )	512 (22.2)
Multiple	382 (62.9)	259 (59.8)	428 (69.9)	416 (63.4)	<0.001	W:S ( $p < 0.01$ )	1485 (64.4)
NA	71 (11.2)	82 (18.9)	29 (4.7)	129 (19.7)		S>W ( $p < 0.001$ )	311 (13.3)
Had ever undergone stone removal surgery, N (%)							
Yes	381 (63.0)	289 (66.4)	439 (71.7)	478 (72.9)	<0.01	W:NE ( $p = 0.001$ )	1581 (68.5)
No	226 (37.0)	150 (34.6)	173 (28.3)	178 (27.1)		MW:NE ( $p = 0.002$ )	727 (31.5)
Had ever stones upon completion of survey, N (%)							
No	131 (21.6)	137 (31.6)	148 (24.2)	191 (29.1)	<0.001	W:MW ( $p < 0.01$ )	607 (26.3)
Yes	366 (60.3)	221 (51.0)	335 (54.7)	321 (48.9)		W:NE ( $p < 0.001$ )	1243 (53.9)
NA	110 (18.1)	75 (17.3)	129 (21.1)	144 (22.0)			458 (19.8)
Had symptoms at time of survey, N (%)							
No	300 (49.4)	264 (61.0)	318 (52.0)	395 (60.3)	<0.001	W:MW ( $p < 0.01$ )	1277 (55.3)
Yes	242 (39.9)	140 (32.3)	249 (40.7)	211 (32.2)		W:NE ( $p < 0.01$ )	842 (36.5)
NA	65 (10.7)	29 (6.7)	45 (7.4)	50 (7.7)		S:NE ( $p = 0.01$ )	189 (8.2)

Variable	West (N=607)	Midwest (N=433)	South (N=612)	North East (N=656)	P	Pairwise Comparison	Total (N=2308)
Domain 1 (social, max: 40)	34 (21-40)	38 (31-40)	37 (28-40)	39 (32-40)	<0.01	NE>S (p<0.001) MW>W (p<0.001) NE>W (p<0.001) S>W (p<0.001)	37 (28-40)
Domain 2 (emotional, max: 35)	23 (14-31)	29 (21-34)	28 (18-34)	30 (23-34)	<0.01	NE>S (p<0.001) MW>W (p<0.001) NE>W (p<0.001) S>W (p<0.001)	28 (19-34)
Domain 3 (stone-related impact, max: 40)	28 (18-36)	32 (25-38)	31 (21-37)	34 (25-39)	<0.01	MW>S (p<0.001) NE>S (p<0.001) MW>W (p<0.001) NE>W (p<0.001) S>W (p<0.001)	31 (22-38)
Domain 4 (vitality, max: 15)	10 (6-14)	12 (8-15)	11 (7-14)	12 (8-15)	<0.01	MW>W (p<0.001) NE>W (p<0.001) S>W (p<0.001)	11 (7-15)
Total WISQOL score (max: 140)	109 (69-125)	120 (99-138)	119 (81-135)	122.5 (98.75-134)	<0.01	NE>S (p<0.001) MW>W (p<0.001) NE>W (p<0.001) S>W (p<0.001)	115 (86-131)

## Conclusions

Geographical region was independently associated with SRQOL. Patients residing in the West exhibited a significantly lower SRQOL compared to other populations whereas patients residing in the Northeast had a significantly higher SRQOL.

*Source of Funding:* none

## ACUTE KIDNEY INJURY AND PERCUTANEOUS NEPHROLITHOTOMY: FREQUENCY AND PREDICTIVE FACTORS

Juan Fulla\*, Juan Calle, Marlie Elia, Henry Wright, Ina Li, Manoj Monga, Cleveland, OH

### Introduction and Objective

Percutaneous Nephrolithotomy (PCNL) is the treatment of choice for patients with large and complex stones. Although it is typically considered a well-tolerated procedure with a low risk of major complications, the risk of acute kidney injury (AKI) has not been reported. Our objective was to assess the frequency of AKI in patients undergoing PCNL and to identify independent predictors of AKI during hospitalization.

### Methods

We performed a retrospective review of percutaneous nephrolithotomy cases performed within our hospital system between January 2014 and June 2019. Demographic, laboratory, and intraoperative data were obtained. Perioperative AKI was defined as 1) Increase in serum creatinine by  $\geq 0.3$  mg/dL ( $\geq 26.5$  micromol/L) within 48 hours, or 2) Increase in serum creatinine to  $\geq 1.5$  times baseline. Multivariable logistic regression analysis was performed to determine factors influencing AKI. A Mann-Whitney U test was used to compare quantitative variables with non-normal distribution. A p value of 0.05 was considered significant.

### Results

A total of 566 patients were included. The patients mean age was  $58 \pm 14.4$  years. The frequency of AKI was 4.4% (n=25). The risk factors for AKI after PCNL were having a baseline creatinine  $> 1.54$  ng/dL (p=0.03, odds ratio [OR] = 2.66, confidence interval [CI] = 1.07-6.6), and a preoperative hemoglobin of less than 10.6 g/dL (p=0.02, odds ratio [OR] = 2.47, confidence interval [CI] = 1.09-5.5). Conversely, having a baseline creatinine level  $< 1.2$  mg/dL was found to be

protective (p=0.02, odds ratio [OR] = 0.4, confidence interval [CI] = 0.18-0.89). No significant relationship was found between age, gender, body mass index, smoking status, hypertension, diabetes, or operative time and the risk of AKI. Patients without AKI had a median hospitalization of 2 days, while those with an AKI were hospitalized for a median of 3 days, and this difference was statistically significant (p < 0.001).

## Conclusion

Perioperative AKI occurs in 4.4% of patients undergoing PCNL. Preoperative hemoglobin and serum creatinine can identify those at increased risk, in whom it may be important to avoid nephrotoxic agents.

*Source of Funding:* None

## PREDICTIVE FACTORS FOR KIDNEY STONE RECURRENCE IN TYPE 2 DIABETES MELLITUS

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### Introduction and Objective

The presence and severity of type 2 diabetes mellitus (DM) are associated with kidney stone disease. However, the factors related to stone recurrence in DM patients has not been established. In this study, we determined the predictive factors for stone recurrence in DM patients.

### Methods

A cross-sectional analysis of stone recurrence was conducted from January 2013 to August 2019 by using our database of DM patients diagnosed with stone disease between 2002 and 2012. The patients were divided into 2 groups according to stone disease status: recurrent stone and non-recurrent stone. Baseline characteristics were compared and logistic regression was done to access which variables could predict a stone recurrence.

### Results

There were 1,617 DM patients with stone disease, 1,244 (77%) did not have a stone recurrence and 373 (23%) had a stone recurrence. Of these patients with recurrent stone, 40% had asymptomatic stones, 43% required emergency department visits, and 45% required a surgical intervention. Median time to recurrence was 64 months. Multivariable analysis revealed age (odds ratios [OR] 0.973, 95% confidence interval [CI] 0.961-0.985), insulin therapy (OR 0.564, CI 0.399-0.798), HbA1c (OR 1.093, CI 1.007-1.186), urine pH (OR 0.799, CI 0.674-0.947), and stone with calcium oxalate and uric acid composition (OR 1.775, CI 1.303-2.418 and OR 2.312, CI 1.316-4.063, respectively) as significant predictors for stone recurrence.

Table 1. Baseline patient characteristics by recurrent stone status				
	Recurrent (N=373)	Non-recurrent (N=1244)	Total (N=1617)	P
Age (y), median (Q1,Q3)	70 (63,78.5)	74 (66,82)	73 (64,81)	<b>&lt;0.001</b>
Gender (male)	240 (64.3)	774 (59.8)	984 (60.9)	0.130
BMI (kg/m <sup>2</sup> ), median (Q1,Q3)	32.5 (28.5,38.3)	31.9 (28.3,36.6)	32 (28.3,36.9)	0.071
Previous GFR (mL/min/1.73m <sup>2</sup> ), median (Q1,Q3)	102.8 (71.9,140.9)	93.0 (57.0,128.4)	96.1 (59.2,130.2)	<b>&lt;0.001</b>
Current GFR (mL/min/1.73m <sup>2</sup> ), median (Q1,Q3)	78.7 (51.0,114.7)	68.4 (48.0,140.1)	71.8 (45.6,106.3)	<b>0.001</b>
CKD stages, N (%)				
Stage 1	146 (39.1)	419 (33.8)	565 (35.0)	0.066
Stage 2	108 (29.0)	299 (24.1)	407 (25.2)	0.069
Stage 3	93 (24.9)	386 (31.1)	479 (29.7)	<b>0.026</b>
Stage 4	20 (5.4)	92 (7.4)	112 (6.9)	0.210
Stage 5	6 (1.6)	44 (3.5)	50 (3.1)	0.85
Insulin therapy, N (%)	49 (13.1)	258 (20.7)	307 (19.1)	<b>0.001</b>
HbA1c (%), median Q1,Q3	7.1 (6.3,7.9)	6.8 (6.2,7.7)	6.9 (6.2,7.7)	<b>0.014</b>
Urine pH, mean ± SD	5.7±0.7	5.8±0.8	5.8±0.8	<b>0.001</b>
Stone composition, N (%)	(N=110)	(N=218)	(N=328)	
Calcium oxalate	80 (72.7)	162 (74.3)	242 (73.8)	0.861
Uric acid	22 (20.0)	36 (16.5)	58 (17.7)	0.530
Calcium phosphate	7 (6.4)	15 (6.9)	22 (6.7)	>0.999
Struvite	1 (0.9)	5 (2.3)	6 (1.8)	0.668
Follow-up period (y), median (Q1,Q3)	9 (7,11)	10 (8,12)	10 (7,12)	<b>&lt;0.001</b>
Abbreviations: y, year; Q, quartile; BMI, body mass index; kg, kilogram; m, meter; min, minute; GFR, glomerular filtration rate; CKD, chronic kidney disease; HbA1c, glycated hemoglobin; SD, standard deviation.				
P-values are derived from Mann-Whitney U test or T-test for continuous variables, and Chi-square test for categorical variables.				
Bold values indicate P ≤ 0.05.				

Table 2. Multivariable analysis comparing patients with recurrent stone to those without recurrent stone			
	OR*	CI	P
Age (y)	0.973	0.961-0.985	<b>&lt;0.001</b>
Gender (male)	0.815	0.633-1.048	0.111
BMI (kg/m <sup>2</sup> )	1.012	0.994-1.030	0.198
Current GFR (mL/min/1.73m <sup>2</sup> )	0.997	0.993-1.000	0.064
Insulin therapy	0.564	0.399-0.798	<b>0.001</b>
HbA1c (%)	1.093	1.007-1.186	<b>0.033</b>
Urine pH	0.799	0.674-0.947	<b>0.010</b>
Stone composition			
Calcium oxalate	1.775	1.303-2.418	<b>&lt;0.001</b>
Uric acid	2.312	1.316-4.063	<b>0.004</b>
Calcium phosphate	1.891	0.742-4.818	0.182
Struvite	0.725	0.083-6.364	0.771
Abbreviations as in Table 1.			
*OR (odds ratio) and CI (95% confidence interval) for a 1-unit change in this factor.			
P-values are derived from binary logistic regression.			
Bold values indicate P ≤ 0.05.			

Conclusions

The stone composition and insulin therapy are strong predictors for kidney stone recurrence in DM patients, while HbA1c and urine pH are modifiable factors.

Female—Infection

ANTIBIOTIC-RESISTANT UROPATHOGENS FORM BIOFILMS PREDOMINANTLY ON DISTAL AND LUMINAL ASPECTS OF CATHETERS AND ARE INHIBITED BY A NOVEL CETYLPYRIDINIUM CHLORIDE-BASED FORMULATION

Glenn Werneburg\*, Cleveland, OH; Nadine Henderson, Stony Brook, NY; Raymond Rackley, Cleveland, OH; Anh Nguyen, Stony Brook, NY; Daniel Shoskes, Cleveland, OH; Amanda Le Sueur, Anthony Corcoran, Aaron Katz, Mineola, NY; Jason Kim, Annie Rohan, David Thanassi, Stony Brook, NY

Introduction and Objective

Urinary catheter biofilms promote bacterial resistance to antibiotics and host cell defenses. Biofilm formation is critical for the pathogenesis of catheter-associated UTI. Here we sought to determine the bacterial composition and antibiotic resistance patterns of bacterial biofilms, as well as their

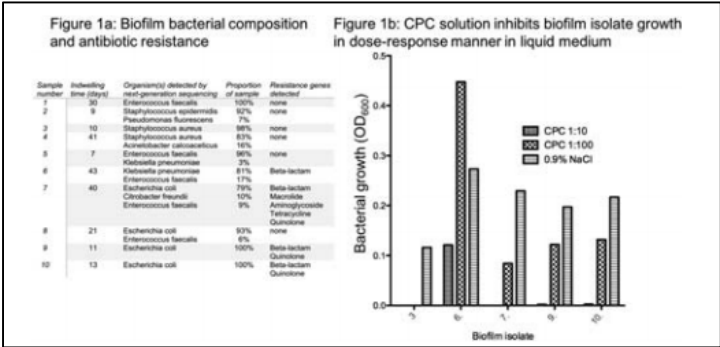
locations on catheters over time. Further, we aimed to test a novel antiseptic formulation, containing cetylpyridinium chloride (CPC) as the active product ingredient combined with pro-adherence factors, for growth inhibition of the biofilm bacterial isolates in liquid medium.

Methods

Urinary catheters were collected following removal from patients, were sectioned and stained for biofilms using crystal violet, and spectrophotometry was used for quantitation. Viability was confirmed via growth in liquid culture, and next generation sequencing via the MicroGenDX platform was employed. Five isolates were cultured, normalized, and subcultured in the presence of the 1:10 or 1:100 antiseptic formulation, or a normal saline control, and growth was measured with spectrophotometry.

Results

Thirty-three urinary catheters were included in the study. Biofilm formation increased as a function of time up to 5 weeks. Biofilms predominated on the luminal, balloon, and distal (p=0.034 vs. proximal end) portions of catheters. Uropathogenic bacteria were detected in 10 of 10 samples analyzed using next-generation sequencing (Figure 1a). Genes conferring bacterial resistance to multiple antibiotics were detected in isolates. Relative to the normal saline control, the CPC formulation consistently inhibited growth of the bacterial isolates in a dose-dependent manner (Figure 1b).



Conclusions

Biofilms were composed of uropathogenic bacteria, which were often resistant to common antibiotics. A novel antiseptic formulation inhibited growth of biofilm isolates in a dose-response manner. Biofilm reduction techniques including routine antiseptic irrigation warrant further investigation, as they are well-positioned to target the luminal-predominant biofilms identified in our study and thus may reduce the risk of CAUTI.

Source of Funding: NIH T32GM008444 and F30AI112252 (GTW), R01GM062987 (DGT), AACN-Sigma Theta Tau Critical Care Award (AJR)



## Female—OAB

### INTRAOPERATIVE PREDICTORS OF SACRAL NEUROMODULATION IMPLANTATION & TREATMENT RESPONSE - RESULTS FROM THE ROSETTA TRIAL

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#### Introduction

Few data exist on intra-operative stimulation responses in Sacral Neuromodulation (SNM) for Overactive Bladder (OAB). This study tested hypotheses that lower intra-op amplitudes with stronger motor and/or sensory responses were associated with successful test stimulation, as well as fewer urgency urinary incontinence episodes (UUIE) after implant.

#### Methods

As part of the prospective, randomized, multicenter ROSETTA trial, intra-op details of SNM stage 1 were collected: responsive electrodes, amplitudes, and strength of motor and sensory response (Likert scale). Surgeons were instructed to achieve intra-op motor or sensory response at amplitudes < 5V on = 2 electrodes. Participants with stage 1 success (= 50% reduction in UUIE on 3- day diary) received a stage 2 implant. Demographics, baseline OAB symptoms, and therapy response were recorded in the primary trial. An intra-op amplitude-response score for each electrode was calculated, ranging from 0 (no response at high amplitude) to 90 (maximum response at 1 V). Statistical methods included Fisher's exact test, as well as logistic and linear regression.

#### Results

Of 161 women with intra-op data, 141 (88%) had a positive motor or sensory response at < 5V on = 2 electrodes; 139 (86%) had stage 1 success, while 22 (14%) did not. Demographics, baseline symptoms, and surgery duration did not differ by stage 1 result. Stage 1 success did not differ by number of electrodes with intra-op motor and/or sensory response, average amplitude at responsive electrodes, or minimum amplitude producing responses. Relative to other electrodes, a best amplitude-response score for pelvic bellows at electrode 3 was associated with stage 1 failure (11/ 22 [50%] vs 36/138 [26%];  $p=0.0409$ ). This was the strongest predictor of Stage 1 response in stepwise and LASSO logistic modeling. Similarly, in a linear model of Stage 1 percent improvement in daily UUIE, a best amplitude-response score for pelvic bellows at electrode 3 was associated with lower percent improvement (mean  $\pm$  standard deviation =  $66\% \pm 31$ ,  $N=47$  vs  $79\% \pm 25$ ,  $N=113$ ,  $p=0.008$ ). After stage 2, mean daily UUIE reduction at 24 months was less for patients with an intra-op sensation response at electrode 3 (mean  $\pm$  SD =  $-2.5 \pm 2.2$ ,  $N=115$ ) than without ( $-5.0 \pm 3.2$ ,  $N=22$ ,  $p=0.005$ ). No intra-op variables predicted change in UUIE at 6 months.

#### Conclusions

Intraoperative data during stage 1 sacral neuromodulation show a limited ability to predict trial stimulation outcome, but were constrained by small sample size. Future research into optimal stimulus parameters is needed.

*Source of Funding:* NICHD PFDN

### LONG TERM CLINICAL RESULTS ON TREATMENT OF URINARY URGENCY INCONTINENCE WITH THE AXONICS RECHARGEABLE SACRAL NEUROMODULATION SYSTEM

Howard B Goldman\*, Cleveland, OH; Rebecca McCrery, Omaha, NE; Kevin Benson, Sioux Falls, SD; Chris Taylor, Harrison, AR; Osvaldo Padron, Tampa, FL; Bertil Blok, Rotterdam, Netherlands; Stefan de Wachter, Edegem, Belgium; Andrea Pezzella, West Columbia, SC; Felicia Lane, Orange, CA

#### Introduction and Objective

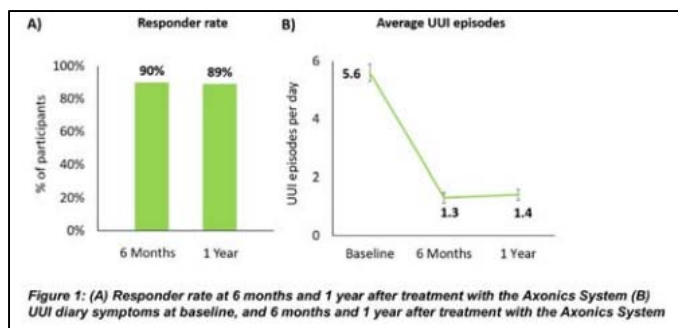
Sacral neuromodulation (SNM) is a guideline-recommended treatment for certain types of urinary dysfunction and fecal incontinence. The Axonics System is a miniaturized, rechargeable SNM system designed to provide therapy for at least 15 years. The long life of the Axonics System is expected to significantly reduce surgeries associated with surgical replacement of non-rechargeable systems. The ARTISAN-SNM study is a pivotal study designed to treat patients with urinary urgency incontinence (UUI). Clinical results at 1-year are presented.

#### Methods

The ARTISAN-SNM study protocol was approved by Ethics Committees at all sites. 129 participants with UUI across 19 centers in the US and Europe were implanted with the Axonics System in a single, non-staged procedure. Efficacy data was collected using a 3-day bladder diary, a validated quality of life questionnaire (ICIQ-OABqol), and a participant satisfaction questionnaire. Therapy responders were identified as participants with  $\geq 50\%$  reduction in urgency leaks compared to baseline. An as-treated analysis was performed in all implanted participants.

#### Results

At 1 year, 89% of all implanted participants were therapy responders ( $p<0.0001$ ; Fig 1A). UUI episodes per day reduced from 5.6 0.3 (average standard error) at baseline to 1.4 0.2 ( $p<0.0001$ ; Fig 1B). Of the responders, 77% had  $\geq 75\%$  reduction in UUI episodes and 29% were dry. Eighty-one (81) study participants had at least 1 large leak per day at baseline. At 1 year, 74% of these participants had a 100% reduction in the large leak episodes. ICIQOABqol scores improved by 34 points as compared to baseline, and the improvement was clinically and statistically significant ( $p<0.0001$ ). Ninety-six percent (96%) of the participants responded that the recharging duration and frequency were acceptable and 93% were satisfied with their SNM therapy. No serious device-related adverse events were reported. Revisions and device-related explants occurred in approximately 3% of participants.



## Conclusions

The Axonics System showed sustained safety and efficacy at 1 year for treatment of UII. Participants reported that recharging frequency and duration of their SNM system was acceptable.

*Source of Funding:* Axonics Modulation Technologies. Note: The term Axonics is trademarked.

## PREDICTIVE FACTORS OF PNE SUCCESS IN A CONTEMPORARY SERIES: A SINGLE INSTITUTION EXPERIENCE

Neil J. Kocher\*, Samir Derisavifard, Jessica Rueb, Michele Fascelli, Raymond Rackley, Courtenay Moore, Sandip Vasavada, Howard Goldman, Cleveland, OH

## Introduction and Objective

Peripheral nerve evaluation (PNE) permits a trial of sacral neuromodulation to determine candidates for permanent system implant in a single operation. Prefluoroscopy PNE success rates with unipolar leads are quoted at 40- 50%, whereas staged procedures with tined quadripolar leads have an estimated 77% success rate. With the availability of in-office fluoroscopy and improved technique over time, more contemporary data on PNE success rates appear limited. This study determined predictive factors toward PNE screening success and persistent functional response following full system implant.

## Methods

A retrospective review of PNE patients at a large academic center from 2015-2019 was performed. All unipolar leads were placed percutaneously in-office utilizing fluoroscopy by one of four FPMRS fellowship-trained providers. Patients with urgency-frequency, urge incontinence, and/or fecal incontinence were included, while those with chronic urinary retention were excluded. Rates of full system implant after successful PNE trial and continued improvement at >1-month following permanent implant were reviewed. Multivariable logistic regression determined predictors of PNE success and continued functional success at follow-up.

## Results

102 PNE patients were included. 78 patients (76.5%) were PNE responders (>50% symptom improvement). On multivariate analysis, patient predictors of PNE success included younger

age ( $p=0.014$ ), urge incontinence ( $p=0.021$ ), fecal incontinence ( $p=0.017$ ), and absence of a neurologic diagnosis ( $p=0.04$ ). PNE factors associated with satisfactory screening included presence of bellows and plantar toe flexion ( $p=0.038$ ), and perineal sensation ( $p=0.027$ ) (Table). 68 of the 78 PNE responders (87.2%) had a successful working implant at >1-month follow-up. Absence of a neurologic diagnosis was predictive of successful implant on long-term follow-up ( $p=0.013$ ).

Patient Factors	PNE Response	PNE No Response	$p^*$
Age, mean	64.2 (SD 16.3, range 24-87)	71.4 (SD 12.6, range 39-89)	0.014
Gender, n (% Female)	66 (84.6)	21 (87.5)	0.14
BMI	29.7 (SD 5.4)	28.6 (SD 5.6)	0.12
ASA, median	3	2.5	0.16
Hx CAD, n (%)	13 (16.7)	3 (12.5)	0.36
Hx CHF, n (%)	2 (2.6)	1 (4.2)	0.44
Hx HTN, n (%)	47 (60.3)	13 (54.2)	0.25
Hx HLD, n (%)	34 (43.6)	10 (41.7)	0.81
Hx COPD, n (%)	7 (9.0)	0 (0)	0.30
Hx DM, n (%)	21 (26.7)	2 (8.3)	0.21
Hx CVA, n (%)	8 (10.3)	3 (12.5)	0.42
Hx OSA, n (%)	22 (28.2)	3 (12.5)	0.71
Hx Neurologic Dx, n (%)	5 (6.4)	8 (33.3)	0.04
Hx UII, n (%)	69 (88.5)	19 (79.9)	0.021
Hx FI, n (%)	11 (14.1)	0 (0)	0.017
Current Smoker, n (%)	4 (5.1)	0 (0)	0.27

PNE Factors	PNE Response	PNE No Response	$p^*$
Bilateral leads, n (%)	72 (92.3)	23 (95.8)	0.37
At Least Bellows, n (%)	67 (85.9)	21 (87.5)	0.41
At Least Toe Plantar Flexion, n (%)	63 (80.8)	20 (83.3)	0.056
Bellows and Toes, n (%)	63 (80.8)	19 (79.2)	0.038
Sensation, n (%)			
Rectal	20 (25.6)	9 (37.5)	0.027
Perineal	55 (70.5)	11 (45.5)	
None	3 (3.8)	4 (16.7)	

## Conclusions

This contemporary series of PNE patients revealed screening rates equivalent to staged implant. Predictors of PNE success included younger age, urge incontinence, fecal incontinence, and absence of a neurologic diagnosis. Conversion from successful screening test to permanent implant may not be the ideal outcome and evaluation for persistent improvement should be considered as an indicator of successful screening.

*Source of Funding:* None

## STIMULATION OUTPUT AND IMPEDANCE OVER 6 MONTHS WITH A CONSTANT CURRENT SACRAL NEUROMODULATION SYSTEM

Stefan de Wachter\*, Edegem, Belgium; Rebecca McCrery, Omaha, NE; Kevin Benson, Sioux Falls, SD; Chris Taylor, Harrison, AR; Osvaldo Padron, Tampa, FL; Bertil Blok, Rotterdam, Netherlands; Andrea Pezzella, West Columbia, SC; Howard B Goldman, Cleveland, OH; Felicia Lane, Orange, CA

## Introduction and Objective

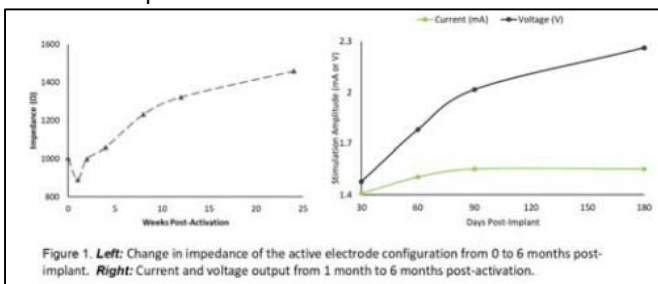
Neuromodulation systems can deliver electrical stimulation output either as constant voltage (CV) or constant current (CC). As tissue impedance changes, CC systems adjust their output to deliver consistent current, while a CV system allows the current output to vary with impedance, which may impact stimulation efficacy. The ARTISAN-SNM study was designed to evaluate the safety and efficacy of the Axonics System, a constant current SNM system, for the treatment of urinary urgency incontinence (UUI). A summary of the stimulation output and impedance over the first 6 months of SNM therapy is provided.

## Methods

129 participants with UUI across 19 centers were implanted with the Axonics neurostimulator and quadripolar tined lead in a non-staged procedure. Participants were programmed postoperatively or within 2 weeks of implant. At 6 months, 125 participants were available. Stimulation parameters and impedance data were recorded at each study visit. Impedance at the active stimulation electrode is reported, and output voltage was calculated using the Ohm's law (Voltage = Impedance \* Current).

## Results

Across the 125 participants, active electrode impedance increased from 1,004 U ( $\pm 310$ ) at activation to 1,460 U ( $\pm 355$ ) at 6 months, an average increase of 42%. Stimulation current increased from 1.1 mA ( $\pm 0.5$ ) at activation to 1.6 ( $\pm 0.8$ ) at 6 months, and the stimulation voltage increased from 1.1 V ( $\pm 0.8$ ) to 2.3 V ( $\pm 1.2$ ). Stimulation output current increased by 45%, while the stimulation output voltage increased by 109%. A sub-analysis was performed in 78 participants that remained on the same active electrode configuration from 1 month to 6 months (Fig. 1); 68% of these participants experienced a 50% increase in output voltage, including 24% experiencing a >75% increase compared to activation.



## Conclusions

Electrode impedance increases significantly in the first 6 months of SNM therapy. Stimulation with a constant current SNM system results in a modest increase in stimulation current while stimulation output voltage increases by a significantly greater degree. Constant current SNM systems may require less patient or clinician adjustment of therapy than voltage-controlled systems.

*Source of Funding:* Axonics Modulation Technologies. Note: The term Axonics is trademarked.

## PREVALENCE OF ABNORMAL IMPEDANCE IN SACRAL NEUROMODULATION DEVICES AND IMPLICATIONS FOR PRACTICE: A CASE-CONTROL STUDY

Michele Fascelli\*, Jessica Rueb, Samir Derisavifard, Neil Kocher, Courtenay Moore, Raymond Rackley, Sandip Vasavada, Howard Goldman, Bradley Gill, Cleveland, OH

## Introduction and Objective

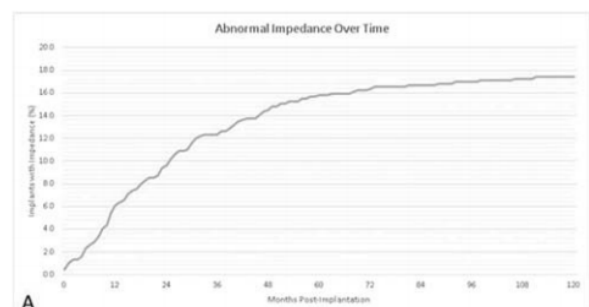
Impedance changes over time, or "impedance drift", in neuromodulation can influence the need for device reprogramming, lead revision, and battery replacement. Abnormal electrical impedance (AEI) has been understudied with respect to impact on sacral neuromodulation (SNM). This study assessed SNM longevity in individuals with and without AEI and its impact on revisions.

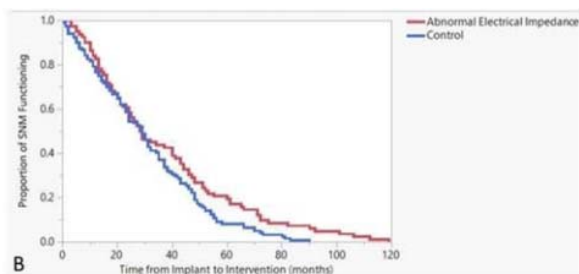
## Methods

Patients with one or more SNM interrogations in the office were identified. Those implanted from 2003 to present were included. Follow-up within the first 10 years of device implantation was analyzed. Patients with AEI were identified as cases and the remaining patients who underwent device interrogation were controls. Time intervals collected included: implant to device interrogation encounter, device interrogation to revision, and original implant to revision. Revision included surgical interventions for the lead and/or pulse generator. Device longevity, or time from original implant to revision, was analyzed by Kaplan-Meier analysis.

## Results

Of 710 patients with device interrogations, 132 (18.6%) were 'cases' and had an AEI within the first 10 years of follow-up (Figure 1A). Of these, 11 (1.5%) were short circuits (4,000U). The remaining 578 patients were 'controls' and had normal impedances. Amongst patients with AEI, 41% (N=50/121) underwent revision, 58% (N=70/121) received device reprogramming, and 0.8% (N=1/121) pursued removal. Operative intervention was avoided in 54% (N=38/70) of the patients undergoing reprogramming. A 21% (N=121/578) revision rate was noted in the control group. Device longevity did not differ between cases and controls with regard to time from implant to revision ( $p=0.24$ , Figure 1 B). Interval from implant to device interrogation (AEI: 27.6 vs control: 23.3 months,  $p=0.16$ ) nor interval from SNM interrogation to revision (AEI: 7.6 vs control: 9.8 months,  $p=0.24$ ) differed between cases and controls. Cases with AEI that underwent reprogramming achieved a mean additional 17.3 months of device longevity prior to revision.





## Conclusions

The prevalence of AEI in SNM increases with duration of follow-up, however device reprogramming can avoid surgical revision in many cases.

*Source of Funding:* None

## Female—PFD

### PELVIC FLOOR CHEMODENERVATION OFFERS BENEFIT TO PATIENTS UNDERGOING PHYSICAL THERAPY FOR HIGH TONE PELVIC FLOOR DYSFUNCTION: A PROSPECTIVE COHORT TRIAL

Samir Derisavifard\*, Jessica Lloyd, Cleveland, OH; Mia Swartz, Kirkland, WA; Julie LaCombe, Bellevue, WA; Howard Goldman, Cleveland, OH

#### Introduction and Objective

Therapeutic options for the management of painful high-tone pelvic floor dysfunction (HTPFD) are limited. We sought to determine whether the addition of pelvic floor chemodenervation to an established regimen of pelvic floor physical therapy (PFPT) for HTPFD improves patients' subjective outcomes.

#### Methods

Subjects were recruited from an FPMRS practice. Inclusion criteria included a 6 month history of PFPT-refractory HTPFD. Exclusion criteria included pregnancy or any contraindication to onabotulinumtoxinA (BTX-A) injection. Pelvic floor BTX-A injections were offered following a standard template at either 50, 100, or 150 units. Following injection, patients continued PFPT and were followed for 12 months. Patient reported outcome measures were assessed with visual analog scale (VAS) pain indices of non-menstrual pelvic pain and dyspareunia, Patient Global Impression of Severity (PGI-S), the Pelvic Floor Distress Inventory (PFDI), and the Female Sexual Function Index (FSFI). The Patient Global Impression of Improvement (PGI-I) was also assessed following intervention. Appropriate statistical analyses were used to compare changes in survey responses over time.

#### Results

Twenty patients were enrolled. Of these, 40, 25, and 35% underwent injection with 50, 100, and 150 u, respectively. The average age was 42.8 years (range: 22-78) and BMI was 24.7

(SD: 6.1), with 90% of the subjects being Caucasian and 55% tolerating vaginal penetration prior to BTX-A injection. PGI-S scores showed significant improvement at 2 weeks through 12 months (baseline: 3.01 vs. 2.0-2.1,  $p < 0.01$ ). VAS rated pelvic pain showed >50% improvement at all follow up points; peak improvement was at 3 months (baseline 4.9 vs. 1.6,  $p < 0.01$ ). VAS rated dyspareunia showed significant improvement at 3 through 12 months following injection (baseline: 6.9 vs 2.2-3.4,  $p = 0.038-0.045$ ). No significant changes (favorable or unfavorable) were noted with FSFI results. No major adverse events were documented.

## Conclusions

The addition of pelvic floor BTX-A to a PFPT regimen is effective in significantly reducing HTPFD-related pelvic pain and dyspareunia while improving health-related quality of life. Peak efficacy was noted 3 months after injection, and no detriment was seen to existing urinary, defecatory, or other sex-related complaints. Further study is needed, but the addition of pelvic floor BTX-A injection appears to be a promising adjunctive treatment for this clinically-challenging condition.

*Source of Funding:* SUFU Chemodenervation Grant

## Female—Prolapse

### DISTAL LEVATOR PLICATION: AN ADJUNCT FOR ANTERIOR PREDOMINANT PELVIC ORGAN PROLAPSE REPAIR

Jessica Rueb\*, Copley, OH; Michele Fascelli, Neil Kocher, Cleveland, OH; Samir Derisavifard, Howard Goldman, Cleveland, OH

#### Introduction and Objective

Levator myorrhaphy was first described as a constricting technique in 1961 with wide levator ani midline plication to which the vaginal cuff was affixed. This was considered for patients who did not intend to be sexually active and reported low morbidity. Our technique of distal levator plication (DLP) is a reconstruction of the levator ani complex proximal to and at the vaginal introitus. This approach is preferred for minimal posterior prolapse wherein traditional colpocleisis would be difficult. We seek to describe our technique.

#### Methods

Here we describe DLP in an 85-year-old female status post total abdominal hysterectomy who presented with symptomatic pelvic organ prolapse. Exam demonstrated a stage 3 cystocele and the vaginal cuff was within two centimeters of the hymen. She no longer was interested in sexual activity. After anterior colporrhaphy and apical suspension, DLP is performed. A rectangular area of posterior vaginal epithelium is excised to expose the fibromuscular layer, extending from the hymenal ring to 2-3 cm proximal. The levator ani are plicated with 0-PDS to create a muscular ridge



overlying the distal portion of rectum and perineum prior to recreating the perineal body.

Age (yrs, median, range)	77 (59-81)
Ethnicity (% , n)	
Caucasian	96 (22)
Black	0 (0)
Other	4 (1)
BMI (kg/m <sup>2</sup> , mean, SD)	29.8 (5.2)
Smoking History (% , n)	
Current	0 (0)
Former	35 (8)
Never	65 (15)
SUI treated concomitantly (% , n)	65 (15)
POP Q (median, range)	
Ba	3.5 (0-6)
Bp	-1 (-3-1)
C	
Prior Surgery for Prolapse (% , n)	
Yes	13 (3)
No	87 (20)
ASA (% , n)	
2	61 (14)
3	39 (9)
4	0 (0)
Postoperative Pain Issues (% , n)	39 (9)
Postoperative UTI (% , n)	17 (4)
De novo urgency (% , n)	4 (1)
No. of Voiding Trials (% , n)	
1	70 (16)
2	26 (6)
3	4 (1)
Other complications (ED visits, readmissions, bleeding, wound complications (% , n)	0 (0)

## Results

All compartments are well supported and the end result is a narrowed genital hiatus, accommodating approximately one to two finger breadths. Post-operatively, vaginal packing is removed in the recovery unit, the patient is discharged home on post-operative day (POD) 0, and outpatient voiding trial is performed on POD two.

## Conclusions

In our experience, DLP combined with anterior and apical repairs results in a greater than 95% symptomatic resolution.

*Source of Funding:* None

# Female—SUI

## TELEMEDICINE OPTIMIZES EARLY POST-OPERATIVE FOLLOW UP AFTER SYNTHETIC MID-URETHRAL SLING (MUS): A RANDOMIZED MULTI-INSTITUTIONAL CONTROL TRIAL

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## Introduction and Objective

The female stress urinary incontinence (SUI) American Urological Association (AUA) guidelines state physicians should communicate with patients in the early postop period after MUS. If asymptomatic, however, patients may not need to be seen in the office. We assessed whether telemedicine based follow up (TBFU) is equivalent to office based follow up (OBFU) in the early post-operative period after routine MUS with regards to unplanned events and patient reported outcomes.

## Methods

This is a prospective, international, multi-institutional, intention-to-treat, randomized control trial. All patients had documented SUI or stress-predominant mixed urinary incontinence. Patients were randomized 1:1 to 3-week postoperative OBFU or TBFU; patient-requested crossover between groups was permitted. OBFU at 3-5 months was recommended for all. The primary outcome was the rate of unplanned events by follow up method. Secondary outcomes included rate of patient satisfaction, crossover, and compliance with 3-5 month OBFU. Appropriate statistical analyses were performed with significance set at  $p < 0.05$ .

## Results

We included 237 patients enrolled from 5 sites (TBFU:121 vs. OBFU: 116). Average age was 56 years (Range: 34-87), and BMI was 26.3 (STD: 4.5). The majority of the sample was White (48%) or Asian (46%). No differences in demographics or medical comorbidities were noted between the study groups ( $p$ : 0.09-1.0). Comparing TBFU to OBFU, no differences were noted in unplanned events – hospital admission, emergency department visit, or unplanned office visit or call (14% vs. 12.9%,  $p=0.85$ ) or adverse medical events (9.9% vs. 8.6%,  $p=0.82$ ). TBFU and OBFU patients were equally “very satisfied” with their surgical outcomes (71.1% vs. 69%,  $p=0.2$ ). Predictors of satisfaction included non-White ethnicity ( $p < 0.01$ ; OR: 3.2, 95%CI: 1.4-7.4) and no college-level education ( $p < 0.01$ ; OR: 7.4, 95% CI: 1.77-31). Sixteen (13.2%) TBFU patients requested crossover to OBFU; age  $> 65$  was predictive of crossover ( $p=0.048$ ; OR: 3.3, 95% CI: 1.1-9.9). TBFU patients were more compliant with 3-5 month OBFU (90.1% vs. 79.3%,  $p=0.04$ ).

## Conclusions

After MUS placement, TBFU is a safe, feasible patient communication option in the early postop period. With TBFU patients report no difference in satisfaction compared to OBFU but had greater compliance with 3-5 month follow up. Older patients were more likely to cross over from TBFU to OBFU.

*Source of Funding:* None

## Men's Health—BPH

### HEALTH INFORMATION SOUGHT ON BPH e ARE NEWER THERAPIES REPLACING THE OLD?

Rebecca Campbell\*, Daniel Shoskes, Bradley Gill, Cleveland, OH

#### Introduction and Objective

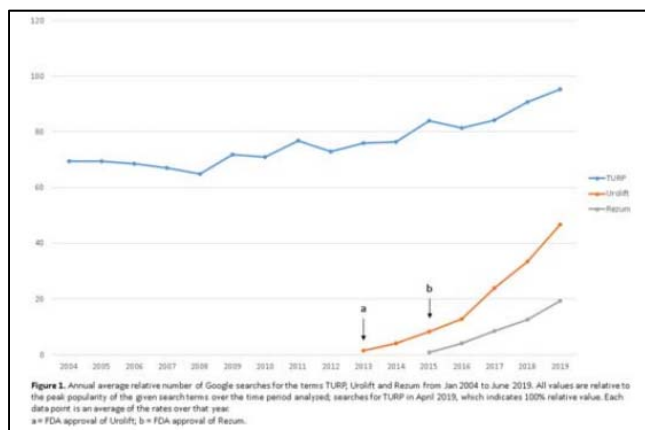
The Urologic Disease in America project found the prevalence of benign prostatic hyperplasia (BPH) grew over time (24.5% in 2004 to 28% in 2013 – a 14.3% increase). Given the introduction of minimally-invasive office-based BPH procedures over the last decade, it is unknown how public interest in such newer treatments has evolved. This study assessed how interest in Rezum and Urolift has varied over time relative to that in TURP, according to population-level web search patterns.

#### Methods

Publicly available population-level Google search patterns (<http://google.com/trends>) were used to compare internet queries for “TURP”, “Rezum” and “Urolift” in the United States over the last 15 years (the full time period available on Google Trends) and since FDA approval of each new BPH therapy in 2015 and 2013, respectively. Interest in each therapy was further examined at both the state and metropolitan area levels. Finally, related queries to each search term were assessed to identify ‘how’ patients seek BPH information on the internet. All data was analyzed relative to the most frequently searched term for the given queries, over the time period of interest; this data point was set at a value of 100.

#### Results

Along with the Urologic Disease in America findings of BPH prevalence, search queries of “TURP” increased 31% from 2004 to 2019. Since 2013, interest in Urolift has steadily increased 33-fold, corresponding to a 1.4% up to 46.7% increase, relative to TURP, since its FDA approval. Similarly, interest in Rezum increased 21-fold since its 2015 FDA approval – a 0.92% up to 19.3% increase, relative to TURP. There were no consistently identified regions of the United States with greater interest in these BPH therapies; similarly, when stratified by metropolitan areas, no clear pattern emerged.



#### Conclusions

Although Rezum and Urolift are gaining popularity, each only garners one-fifth to one-half of the queries TURP does. Interest in all BPH therapies has increased over time, in line with the rising prevalence of the condition, with Urolift approximately 2.5-times more searched than Rezum after being FDA approved 2 years prior. This approach to analyze search terms may help uncover the unmeasured burden of disease on patients who have not yet seen a physician, as well as gauge the impact of direct to consumer medical marketing.

Source of Funding: None

## Men's Health—ED

### COMPARISON OF LOW INTENSITY SHOCKWAVE FOR VASCULOGENIC ERECTILE DYSFUNCTION USING ELECTROHYDRAULIC VS ELECTROMAGNETIC RADIAL SHOCKWAVE GENERATORS

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#### Introduction and Objective

Low intensity shockwave therapy (LSWT) has emerged as a novel treatment of arteriogenic erectile dysfunction (ED). Part of the difficulty of comparing results in the literature is the use of multiple different machines and protocols. Even controlling for total energy applied, the shape of the waveform depending on the shock generator is different and might produce variable biologic effects. The purpose of this study is to compare outcomes of LSWT for men with ED between devices that generate either electrohydraulic spark waves or electromagnetic radial waves.

#### Methods

A retrospective chart review compiled the outcomes of men who had LSWT for ED either using the TRT Urogold 100 (electrohydraulic generation) or the Zimmer enpuls Pro (electromagnetic radial generation). All men received 6 weekly treatments. On the Urogold 100, we used a total of 3000 shocks at 0.09 mJ/mm<sup>2</sup> and for the Zimmer we used 10,000 shocks at 15 Hz and 90 mJ energy (both are standard protocols for each respective device). Given the higher frequency of the Zimmer device, total treatment times were equivalent. There were 6 treatment sites: one at each crus of the penis and 2 on the shaft bilaterally. SHIM score assessed erectile function before and 6 weeks after therapy. Men also self-reported erectile hardness on a scale of 0 (no change), 1 (firm enough for penetration) or 2 (completely firm). Data was compared with paired or unpaired t test, Chi squared or Kruskal-Wallis as appropriate and significance set at p<0.05.

#### Results

24 men were treated with the Urogold and 23 with the Zimmer device. Both groups were equivalent in age (61.3 vs 60.5 years) and duration of ED symptoms (61 vs 72 months). Starting SHIM score was also similar (9.3 ±4.2 vs 8.7 ±4.8, p=0.67). Following

treatment there was a clinically and statistically significant increase in SHIM scores with both machines. For the Urogold mean SHIM increased from 9.3 to 15.5 ( $p<0.001$ ) and for the Zimmer mean SHIM increased from 8.7 to 15.8 ( $p<0.0001$ ). Self-reported erectile hardness for the Urogold was 0: 46%, 1: 21% and 2: 33%. For the Zimmer it was 0: 29%, 1: 38%, 2: 33%. Differences between these proportions were not significant by Chi squared ( $p=0.36$ ). There were no reported side effects with either machine.

### **Conclusions**

In our patient population, LSWT was effective for arteriogenic ED in the majority of patients and there was no significant difference in outcomes between an electrohydraulic and an electromagnetic radial device.

*Source of Funding:* None

## **Men's Health—Infection**

### **DETECTION OF BACTERIA BY NEXT GENERATION SEQUENCING IN MEN WITH CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME: INCIDENCE, CORRELATION TO CONVENTIONAL CULTURE AND IMPACT ON SYMPTOMS**

Nicholas Farber\*, Paige Gotwald, Daniel Shoskes, Cleveland, OH

#### **Introduction and Objective**

Chronic prostatitis/ Chronic pelvic pain syndrome (CPPS) is a syndrome that shares clinical features with urinary infections and a certain subset of patients improve with antibiotics. However, traditional cultures of urine and expressed prostatic secretions often fail to identify an organism. Next-generation sequencing (NGS) analyzes microbial DNA and can identify organisms that fail to grow in traditional cultures. We sought to compare traditional cultures with NGS in men with CPPS and examine the impact on symptoms and treatment response.

#### **Methods**

25 men with a clinical diagnosis of CPPS underwent both traditional cultures and NGS (MicroGen Dx) of urine and expressed prostatic secretions (EPS). NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) and UPOINT domains were evaluated. Patients with negative traditional cultures and positive NGS were offered antibiotic therapy.

#### **Results**

Urine cultures were negative in all CPPS patients, while 8% (2/25) had a positive EPS culture. NGS identified these organisms in one patient and failed to detect it in the other. In culture negative patients, NGS identified at least one organism in EPS in 70% (16/23), though only 30% (7/23) were for established uropathogens. Patients with positive and negative NGS had similar mean NIH-CPSI scores of  $23.3 \pm 6.8$  and  $20.5 \pm 6.9$ , respectively ( $p=0.44$ ). Organisms of questionable pathogenicity in EPS found by NGS included vaginal flora (*Prevotella* spp., *Sneathia amnii*), anaerobes, and fungi. In the

subset of 6/25 (24%) men with systemic symptoms suggestive of infection, all had negative EPS cultures but NGS identifying a uropathogen in 50% (3/6). 4 were treated with antibiotics based on the sensitivity gene panel but only 1 patient (25%) resolved their symptoms.

### **Conclusions**

NGS detected a variety of microorganisms not found by conventional culture in urine and EPS. In men with systemic symptoms suggestive of infection, NGS found a pathogen missed by culture in 50%. The presence of vaginal flora, anaerobes, and yeast is novel but the clinical significance is unclear and the value of prolonged antimicrobial treatment of these organisms is not proven. Based on our data, NGS may help identify pathogenic organisms in men with CPPS who have symptoms suggestive of true infection, however men should still be offered multimodal therapy based on their clinical phenotype to maximize the chance for symptom resolution.

*Source of Funding:* None

### **CLINICAL AND PATHOLOGIC RELEVANCE OF A PROSTATE MRI DIAGNOSIS OF "PROSTATITIS"**

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#### **Introduction and Objective**

Non-malignant abnormalities in the peripheral zone are common in prostate mpMRI. Such findings include decrease in T2-weighted signal, decrease in diffusion coefficient or enhancement in a diffuse or linear pattern. These abnormalities are often reported as "prostatitis" and lead to patient anxiety and treatment referral. However, the relationship between these MRI findings and clinical prostatitis is unknown. We investigated the relationship between MRI evidence of prostatitis with clinical symptoms and pathology.

#### **Methods**

Retrospective review of patients undergoing prostate mpMRI (2016-2017) was performed, and patients were divided into two groups based on the presence of either "prostatitis" or "inflammation" in the radiology report. Patients with prior prostate cancer treatment were excluded. Clinical characteristics included age, PSA, biopsy/ intervention history, lower urinary tract symptoms (LUTS), pain, use of urologic medications for LUTS, urinary findings of pyuria or leukocyte esterase positivity), prostate volume, and PIRADS score. Pathologic finding of inflammation on either prior biopsies or biopsy within 6 months was also recorded. Groups were compared using chi-square for dichotomous variables and t-tests for continuous variables and t-tests for continuous variables.

#### **Results**

104 patients were identified with "prostatitis/inflammation" and 119 without. Report of any LUTS was high in both groups (57% and 60% for prostatitis and no prostatitis respectively,  $p=0.69$ ), though report of moderate/severe LUTS (physician

description or IPSS of 8-19 and 20+) was more common in the no prostatitis group (8% vs 17%,  $p=0.038$ ). Use of urologic meds was similar between the two groups (66% and 55% for prostatitis and no prostatitis respectively,  $p=0.074$ ). Any biopsy finding of inflammation was more common in the prostatitis group (57% vs 35%  $p=0.002$ ). Reports of pelvic/perineal pain, chronic dysuria, or urinary findings of inflammation/infection were uncommon in both groups (<5% for pain/dysuria and <10% for urinalysis findings in both groups).

### **Conclusions**

MRI findings of prostatitis may be associated with a pathologic finding of inflammation on biopsy, however, such findings did not correlate to reported LUTS, pelvic pain or use of urologic medications. While mpMRI findings of prostatitis may indicate NIH Category IV prostatitis, there is no evidence of correlation with categories I, II or III prostatitis nor with symptomatic LUTS and patients should be reassured that further investigation or treatment is not warranted.

*Source of Funding:* none

## **SGLT2-INHIBITOR USAGE AND INCIDENCE OF FOURNIER'S GANGRENE**

JJ Zhang\*, Kristina Gam, Shannon Wu, Kenneth Angermeier, Cleveland, OH

### **Introduction and Objective**

In May 2019, the Food and Drug Administration (FDA) issued a Black Box Warning against sodium-glucose cotransporter-2 inhibitor (SGLT2) anti-hyperglycemic medications, citing a limited case series on the incidence of Fournier's gangrene (FG) after SGLT2-inhibitor initiation. We sought to further investigate the risk of SGLT2-inhibitors in a population of FG patients.

### **Methods**

Patients who were diagnosed with FG at a large academic institution between 2009-2019 were retrospectively queried. Baseline patient characteristics, medication records, and measures of disease severity were compared between SGLT2-inhibitor users and non-users. Statistical analyses were performed using Pearson's chi-squared and Mann-Whitney with significance defined as  $p<0.05$ .

### **Results**

Of 285 patients, 51 were excluded for inaccurate diagnosis or incomplete records. Median age at diagnosis was 58 (IQR 48-66) with BMI 33.8 (27.2-40.2), Charlson Comorbidity Index (CCI) of 3 (IQR 1-5) and HgbA1c of 7.9 (IQR 6.1-10.5). 60.3% were type II diabetics and 3.4% were type I diabetics. 32.9% were insulin-dependent at diagnosis, and 94.4% underwent operative management. In total, 4 patients (1.7%) were taking SGLT2 inhibitor medication at or prior to FG diagnosis, and 69 (29.5%) were taking a different oral anti-hyperglycemic class. Median age of SGLT2-inhibitor users was 55.5 (IQR 27-69) with 75% male predominance. Median time to onset of FG after

SGLT2-inhibitor initiation was 33 months. SGLT2-inhibitor use was significantly associated with higher HgbA1c at FG diagnosis, with median HgbA1c 12.6 vs. 7.8 for non-users ( $p=0.031$ ). Insulin-dependence and CCI were associated with increased number of admissions for FG ( $p=0.015$ ,  $p=0.001$ ). Usage of SGLT2-inhibitors or any other oral anti-hyperglycemic class was not associated with number of FG admissions or surgeries. There was no significant difference between SGLT2-inhibitor users and non-users in age at diagnosis, CCI, BMI, number of operations, or number of FG admissions.

### **Conclusions**

Incident Fournier's Gangrene after SGLT2 inhibitor initiation is rare in our patient population at a large academic institution. Insulin dependence, rather than usage of any oral anti-hyperglycemic class, was associated with increased FG admissions. SGLT2-inhibitor users were associated with significantly higher HgbA1c compared to non-users, indicating a potential role of poor Diabetes control in the development of FG rather than a medication-induced pathogenesis. The FDA Black Box warning against SGLT2-inhibitors is poorly supported by literature and requires additional validation.

*Source of Funding:* None

## **Men's Health—Infertility**

### **FOLLICLE STIMULATING HORMONE PREDICTS IMPROVEMENT IN SEMEN PARAMETERS WITH CLOMIPHENE CITRATE IN MEN WITH INFERTILITY**

Nicholas Farber, Scott Lundy\*, Stephanie Njemanze, Sarah Vij, Cleveland, OH

### **Introduction and Objective**

Clomiphene citrate (clomid) is a selective estrogen receptor modulator commonly utilized for empiric medical therapy in the setting of idiopathic male infertility. Although clomid is frequently prescribed to improve sperm parameters, it is unknown which sub-populations derive benefit and which fail to improve on this medication. Therefore, we sought to investigate the effect of treatment with clomid on semen parameters and define predictors of success and failure.

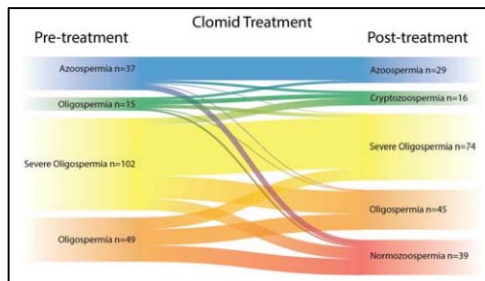
### **Methods**

We performed a single institution retrospective review of all men with a diagnosis of infertility who were prescribed clomid. History and physical examination data were collected. Pre- and post-treatment hormonal and semen parameters were assessed. Exclusion criteria included normozoospermia or incomplete data. Primary outcome was a change in World Health Organization (WHO) sperm concentration categorization (e.g. severe to moderate oligospermia). Binary logistic regression assessed predictors of WHO category upgrade. Fitted binomial distributions were used to generate Receiver Operating Characteristics.



## Results

203 men were analyzed. Median sperm concentration increased after starting clomid, from 1.88 million/mL to 3.6 million/mL ( $p=0.001$ ). All mean hormone levels significantly increased after treatment. There were no significant changes in sperm DNA damage, total antioxidant capacity, or oxidation-reduction potential. 74 men (36%) experienced an upgrade in WHO sperm concentration category, while 24 men (12%) downgraded (Figure 1). On logistic regression, follicle stimulating hormone (FSH) was inversely related to WHO upgrade (OR 0.858,  $p=0.012$ ). A pre-treatment FSH < 3.45 IU/L is 85% sensitive and 37% specific for concentration upgrade. No other variables analyzed (LH, testosterone, varicocele) were predictive of upgrade. The presence of varicocele was protective against downgrading ( $p=0.006$ ).



## Conclusions

In men prescribed clomid, lower pretreatment FSH was predictive of WHO sperm concentration category upgrade. FSH level should be considered in the clinical decision making when starting patients on clomid for idiopathic infertility. Sperm concentration downgrade is an uncommon (12%) but real risk, and the presence of varicocele appears protective against downgrading.

Source of Funding: None

## PROLACTIN TO TESTOSTERONE RATIO PREDICTS PITUITARY ADENOMAS IN MALE PATIENTS WITH MILD HYPERPROLACTINEMIA

Anup Shah\*, Bryan Naelitz, Darren Bryk, Nicholas Farber, Daniel Shoskes, Betul Hatipoglu, Sarah Vij, Cleveland, OH

### Introduction and Objective

Mild hyperprolactinemia often prompts pituitary magnetic resonance imaging (pitMRI) in men presenting with hypogonadism; however, the clinical yield of this test is low. We sought to identify a combination of lab results that more accurately predicts clinically significant MRI findings in patients with mild hyperprolactinemia and reduce unnecessary pitMRIs.

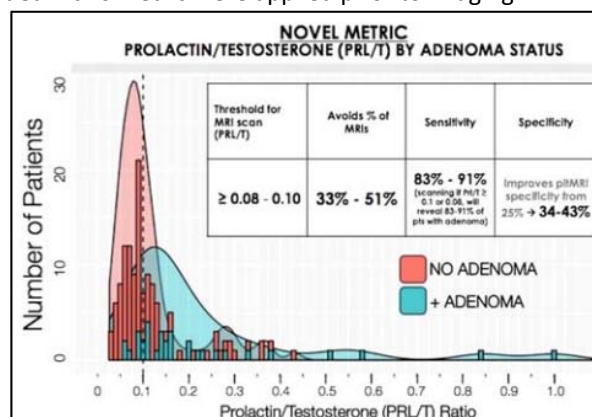
### Methods

Male patients with mild hyperprolactinemia (15-50 ng/mL) who presented with erectile dysfunction, low libido, hypogonadism, or infertility who had undergone pitMRI were included. Those with a prior diagnosis of prolactinoma, hormonal or dopaminergic therapy, or incomplete data were excluded. Symptoms, age, prolactin (PRL), body mass index (BMI), testosterone (T), luteinizing hormone (LH), follicle-

stimulating hormone (FSH), thyroid-stimulating hormone (TSH), creatinine (SCr), all medications, and MRI findings were collected. Means of continuous variables were compared with the Wilcoxon-Rank Sum test, and categorical variables were compared with Fisher Exact or Chi-squared tests. Fitted binomial distributions were used to generate Receiver Operating Characteristics (ROCs).

## Results

141 men met inclusion criteria. Pituitary adenomas were identified in 35 patients (24.8%) with a median adenoma size of 4 mm (range 1.2 – 38 mm). The ratio of PRL (ng/mL) to T (ng/dL) (PRL/T) outperforms PRL or T alone in predicting positive pitMRI findings (Area Under the Curve (AUC) 0.77 vs 0.70, 0.70 respectively). A PRL/T ratio cutoff >0.1 identified adenomas ( $p < 0.001$ ) with high sensitivity (83%, 29/35 adenomas identified). 51% of pitMRIs could have been prevented if this metric were applied prior to imaging. A PRL/T ratio cutoff of >0.08 identified adenomas with higher sensitivity 91% (32/35), and 33% of pitMRIs could have been avoided if this metric were applied prior to imaging.



## Conclusions

To our knowledge, this study of pitMRI findings among men with hypogonadism and mild hyperprolactinemia is the largest of its kind. The use of PRL/T ratio in lieu of prolactin or testosterone alone retains high sensitivity for identifying patients with prolactinoma (83-91%) and may reduce unnecessary MRIs by up to 51%.

Source of Funding: None

## FRESH MICRODISSECTION TESTICULAR SPERM EXTRACTION RESULTS IN A HIGHER RETRIEVAL RATE OF SPERM ACCEPTABLE FOR INTRACYTOPLASMIC SPERM INJECTION COMPARED TO FROZEN-THAWED MICRODISSECTION TESTICULAR SPERM EXTRACTION

Darren J. Bryk\*, Scott Lundy, Nicholas Farber, Neel Parekh, Cleveland, OH; Nayna Desai, Beachwood, OH; Edmund Sabanegh, Sarah C. Vij, Cleveland, OH

### Introduction and Objective

Most studies report similar intracytoplasmic sperm injection (ICSI) outcomes in fresh and frozen-thawed (FT) microdissection testicular sperm extraction (mTESE).

However, men who do not make it to ICSI, due to poor post-thaw results, are not included in these studies. We hypothesized that fresh mTESE results in a higher rate of obtaining sperm acceptable for ICSI compared to FT mTESE.

## Methods

We retrospectively reviewed all patients with non-obstructive azoospermia who underwent mTESE at a tertiary care institution from April 2007 to October 2019. The primary endpoint was rate of obtaining sperm usable for ICSI, which was defined as motile sperm at the time of fresh mTESE or post-thaw motile sperm after FT mTESE. Fisher's exact test was used to compare fresh and frozen-thawed mTESE results.

## Results

One hundred and three men with 121 mTESEs were included. Table 1 compares sperm retrieval rates for fresh and FT mTESE. The surgical sperm retrieval rate (including both motile and immotile sperm) in FT mTESE was 36/94 (38.3%). Motile sperm was noted in 31/94 (33.0%) FT mTESEs, but post-thaw motile sperm was identified in 17/94 (18.1%). Of the 27 fresh mTESEs, 3 (11.1%) found no sperm—2 couples pursued egg freezing and no further records noted for the third; all 24 fresh mTESEs where motile sperm was found proceeded to ICSI. Seven patients had a FT mTESE followed by a fresh mTESE based on poor post-thaw results as assessed by an embryologist. Of these, 6/7 (85.7%) had motile sperm retrieved but 1/7 (14.3%) had post-thaw motility; all 7 (100%) had motile sperm on fresh mTESE acceptable for ICSI. In the entire cohort, fresh mTESE yielded significantly higher retrieval rates of motile sperm acceptable for ICSI compared to FT mTESE ( $p < 0.001$ ).

	Fresh (N=27)	Frozen-Thawed (N=94)
Surgical Sperm Retrieval (N, %)	24 (88.9)	36 (38.3)
Motile Sperm Retrieval (N, %)	24 (88.9)	31 (33.0)
Post-Thaw Motile Sperm (N, %)	N/A	17 (18.1)

## Conclusions

Our data suggests that there is a percentage of men whose decision to undergo FT mTESE precluded their ability to proceed with an ICSI cycle based on the results of that operation. Patients should be adequately counseled on the likelihood that FT mTESE may result in successful sperm retrieval but inability to proceed to ICSI.

*Source of Funding:* None

## MICRODISSECTION TESTICULAR SPERM EXTRACTION PRACTICE PATTERNS FOR MALE INFERTILITY PROVIDERS: WHAT ARE THE BARRIERS TO PERFORMING FRESH VERSUS FROZEN?

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## Introduction and Objective

Reproductive urologists' practice patterns related to microdissection testicular sperm extraction (microTESE) are unknown. We surveyed providers that perform this operation to better understand practice patterns and barriers.

## Methods

A 22-question anonymous survey was emailed to reproductive urologists who are members of the Society for Study of Male Reproduction. Descriptive statistics and chi-squared analysis comparing fresh and frozen microTESE were performed. Using logistic regression analysis, we determined significant predictors of performing fresh microTESE for non-obstructive azoospermia (NOA).

## Results

A total of 208 surveys were sent with 76 responses received (response rate 36.5%). A majority of respondents are fellowship trained (86.8%) and work in academia (60%). Most (63.2%) perform frozen microTESE for NOA, while 44.7% perform fresh. MicroTESE is performed most often at non-fertility surgical centers (59.2%). An on-site andrologist is present for real-time tissue evaluation for 57.7% of these respondents. The most common reported barriers to performing microTESE are cost (44.7%), scheduling difficulties (34.2%), and andrologist availability (15.8%). There are no significant differences between the identified barriers and urologists' preference for performing fresh vs. frozen microTESE on chi-squared analysis. The majority (87.5%) of those performing microTESE at a fertility surgical center prefer fresh, while only 12.1% of those at non-fertility surgical centers prefer fresh ( $p < 0.001$ ). On univariable logistic regression analysis, those who perform microTESE at a fertility surgical center are >50 times more likely to use fresh sperm (OR 50.8, 95% CI 4.9-527.7,  $p = 0.001$ ) vs those at a non-fertility surgical center.

## Conclusions

There are wide variations and a variety of barriers among reproductive urologists' practice patterns related to microTESE. Frozen microTESE is performed more commonly than fresh, most often at non-fertility surgical centers, and most urologists do not have an onsite andrologist present to evaluate the sample in realtime. Urologists who perform microTESE at a fertility surgical center are more likely to perform them fresh. Location-specific factors appear to be a primary determinant as to whether microTESE is done fresh or frozen.

*Source of Funding:* None.

## Men's Health—Testosterone

### PREVENTING UNNECESSARY PITUITARY MRIS IN HYPOGONADAL AND INFERTILE MEN WITH HYPERPROLACTINEMIA: COST SAVINGS USING A NOVEL PROLACTIN TO TESTOSTERONE RATIO

Nicholas Farber\*, Anup Shah, Bryan Naelitz, Darren Bryk, Neel Parekh, Betul Hatipoglu, Daniel Shoskes, Sarah Vij, Cleveland, OH

#### Introduction and Objective

Hyperprolactinemia is a common laboratory finding in a population of men with symptomatic hypogonadism or infertility. If serum prolactin (PRL) is above the upper limit of normal on two laboratory analyses, current practice is to recommend further workup with a pituitary magnetic resonance imaging (pitMRI) study to assess for a pituitary adenoma. However, this practice pattern may lead to unnecessary healthcare costs secondary to the overutilization of pitMRI. Recent data has suggested serum prolactin:testosterone (PRL/T) ratio may predict pitMRI findings. We sought to examine the cost savings associated with utilizing combinations of serum PRL and serum PRL/T to predict pitMRI positive findings and obviate the need for unnecessary pitMRI.

#### Methods

We performed a retrospective review of all men < 75 years old with infertility or symptomatic hypogonadism who had mild hyperprolactinemia (15-55 ng/ml) and underwent pitMRI at a tertiary care center. Exclusion criteria included a prior pituitary adenoma or symptoms concerning for a pituitary abnormality (e.g. visual changes, galactorrhea). pitMRI findings were reviewed. Baseline clinicodemographic (symptoms, age, BMI, medications) and laboratory variables (PRL, T, LH, FSH, SCr) were collected. Receiver Operating Characteristics and Area Under the Curve metrics were created from fitted binomial distributions. A cost analysis was performed based on the institutional cost of a pitMRI.

#### Results

136 men met inclusion criteria. Pituitary adenomas were found on pitMRI in 35 men (25.7%). Of the various combinations of serum PRL and PRL/T, PRL/T > 0.10 had greatest specificity while PRL/T > 0.08 OR PRL > 25 had the greatest sensitivity (Table 1). Cost savings were significant for all combinations (Table 1).

Sensitivity/Specificity of Imaging Cutoffs for Obtaining pitMRI and Cost Savings			
Indication for pitMRI	# Adenomas Correctly Captured (Sensitivity)	# Without Adenoma Avoiding MRI (Specificity)	Cost Savings (\$)
PRL/T > 0.10	29/35 (82.9%)	65/101 (64.4%)	132,080
PRL/T > 0.01 OR PRL > 25	33/35 (94.3%)	48/101 (47.5%)	97,536
PRL/T > 0.08 OR PRL > 25	35/35 (100%)	32/101 (31.7%)	65,024

#### Conclusions

The combination of serum PRL and PRL/T correctly predicts the vast majority of pituitary adenomas in patients with mild hyperprolactinemia. Further, this laboratory combination avoids a substantial proportion of unnecessary pitMRIs, resulting in a significant healthcare cost savings. Future clinical guidelines should consider incorporating a screening threshold using serum PRL and PRL/T prior to ordering pitMRI for mild hyperprolactinemia.

Source of Funding: None

## MIS—Bladder

### RECURRENCES AFTER ROBOT-ASSISTED RADICAL CYSTECTOMY: RESULTS FROM THE INTERNATIONAL ROBOTIC CYSTECTOMY CONSORTIUM

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#### Introduction and Objective

There have been concerns about higher incidence of local recurrence after robot-assisted radical cystectomy (RARC) compared to its open counterpart. We sought to report and detail recurrences following RARC utilizing a multinational database.

#### Methods

A retrospective review of the International Robotic Cystectomy Consortium (IRCC) database was performed (3296 patients, 28 institutions, from 14 countries). Data were reviewed for demographics, perioperative, pathologic and oncologic outcomes. Recurrence rates and patterns were analyzed. Kaplan Meier curves were used to depict recurrence-free (RFS), local recurrence-free (LRFS), and distant recurrence-free survival (DRFS). Multivariate stepwise Cox regression models were used to identify variables associated with RFS, LRFS, and DRFS.

#### Results

Out of 1976 patients with complete data, 498 (25%) relapsed. Mean age was 68±11 years, with a median follow up of 26 months. Distant recurrences were observed in 18% of patients and local recurrences in 12%. Early oncologic failure (within 3 month) occurred in 7%. Port site recurrence occurred in one patient and peritoneal carcinomatosis in 23 patients (1%). The

most common sites of local and distant recurrence were the pelvis and lungs, respectively (Table 1a).

Table 1a. Pathologic outcomes and sites of disease relapse						
Recurrence Site	1 Mo.	3 Mo.	6 Mo.	12 Mo.	24 Mo.	All
LOCAL RECURRENCE, N (%)						
Pelvis	1 (0.4)	24 (10)	50 (22)	76 (33)	94 (41)	99 (20)
Vagina	0	0	1 (0.4)	1 (0.4)	3 (1)	3 (0.6)
Rectum	0	1 (0.4)	3 (1)	5 (2)	12 (5)	14 (1)
Perineum	0	3 (1)	7 (1)	10 (4)	11 (5)	12 (2)
Urethra	1 (0.4)	1 (0.4)	2 (0.9)	4 (2)	8 (1)	9 (2)
Penile	0	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	3 (0.6)
Neobladder/Conduit	0	3 (1)	4 (2)	5 (2)	6 (3)	7 (1)
Kidney	1 (0.4)	2 (0.9)	5 (2)	9 (4)	13 (6)	17 (3)
Multiple Local	0	5 (2)	11 (5)	18 (8)	24 (10)	31 (6)
Unidentified site	1 (0.4)	3 (1)	16 (7)	31 (13)	41 (18)	49 (10)
DISTANT RECURRENCE, N (%)						
Nodal	2 (0.6)	21 (6)	37 (10)	63 (18)	78 (22)	93 (19)
Lung	0	12 (3)	33 (9)	59 (17)	77 (22)	104 (21)
Liver	1 (0.3)	11 (3)	20 (6)	37 (10)	46 (13)	58 (12)
Bowel	0	0	0	2 (0.6)	2 (0.6)	4 (0.8)
Brain	1 (0.3)	1 (0.3)	3 (0.9)	8 (2)	9 (3)	12 (2)
Abdominal wall	0	0	4 (1)	8 (2)	11 (3)	12 (2)
Multiple distant	0	0	0	0	0	35 (7)
Unidentified site	2 (0.6)	8 (2)	32 (9)	62 (17)	85 (24)	108 (22)
Peritoneal carcinomatosis	0	5 (2)	11 (5)	16 (7)	19 (8)	23 (5)
Post-site recurrence	0	0	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.2)

Multivariate regression models identified pN+ status and  $\geq$ pT3 as predictors of RFS, LRFS and DRFS ( $p < 0.01$ ) (Table 1b).

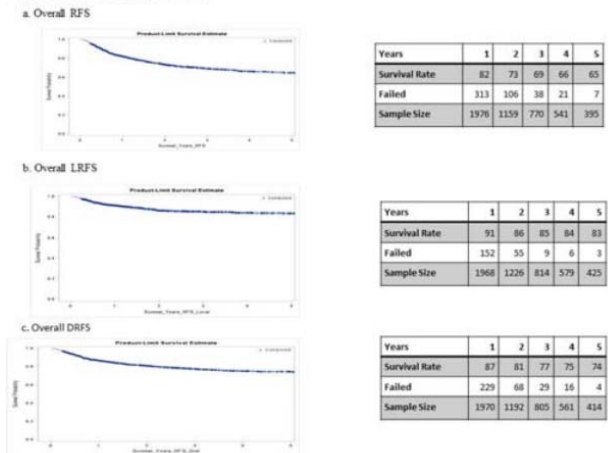
Table 1b: Multivariable stepwise Cox proportional hazards modeling predictors of survival			
	Hazard Ratio	95% CI	P
RFS			
Black race	1.88	1.07–3.29	0.03
Preoperative hydronephrosis	1.36	1.02–1.81	0.04
Blood transfusion	1.74	1.23–2.46	<0.01
$\geq$ pT3	3.27	2.51–4.27	<0.01
pN+ve	2.47	1.89–3.23	<0.01
LRFS			
$\geq$ pT3	4.48	3.13–6.40	<0.01
pN+ve	2.12	1.54–2.91	<0.01
Positive surgical margin	1.60	1.06–2.41	0.02
DRFS			
Preoperative hydronephrosis	1.56	1.13–2.15	<0.01
Blood transfusion	1.67	1.12–2.50	0.01
$\geq$ pT3	3.27	2.37–4.49	<0.01
pN+ve	2.56	1.87–3.52	<0.01
CI – Confidence interval			

The 5-year RFS, LRFS, and DRFS were 65%, 83%, and 74%, respectively (Figure 1).

## Conclusions

Recurrence patterns and rates after RARC seem comparable to open series. Disease stage remains the main predictor of recurrence following RC.

Figure 1: Overall RFS, LRFS, and DRFS



Source of Funding: Roswell Park Alliance Foundation

## OUTCOMES OF ROBOT-ASSISTED RADICAL CYSTECTOMY IN NORTH AMERICA VS EUROPE: RESULTS FROM THE INTERNATIONAL ROBOTIC CYSTECTOMY CONSORTIUM

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## Introduction and Objective

Utilization of robot-assisted radical cystectomy (RARC) has increased over the last decade. We sought to compare the outcomes between North American and European institutions.

## Methods

We reviewed our prospectively maintained International Robotic Cystectomy Consortium database (2006-2019). Patients were divided according to the site of the institution (North America vs Europe). Data were reviewed. Kaplan Meier (KM) curves to depict recurrence free survival (RFS), disease specific survival (DSS), and overall survival (OS). Cochran-Armitage trend test used to investigate significant trend of NAC and intracorporeal urinary diversion (ICUD) over time.

## Results

We identified 2957 patients, of which 1909 (65%) were in North America. North American patients were older (68 vs 66 years,  $p < 0.001$ ), had higher BMI (28 vs 27,  $p < 0.01$ ), included more patients with ASA  $\geq 3$  (63% vs 27%,  $p < 0.01$ ). European patients were more likely to receive ICUD (67% vs 44%,  $p < 0.01$ ), continent urinary diversion (26% vs 19%,  $p < 0.01$ ), shorter operative time (368 vs 393 mins,  $p < 0.01$ ), and longer



## INITIAL EXPERIENCE WITH SINGLE PORT ROBOTIC PYELOPLASTY THROUGH A SMALL PFANNENSTEIL ABDOMINAL INCISION: TECHNICAL CONSIDERATIONS

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### Introduction and Objective

To present the feasibility and technical aspects of single port robotic pyeloplasty through pfannenstiell abdominal incision using the da Vinci SP® surgical system.

### Methods

Between May and June 2019, 3 patients (1 male) with documented ureteropelvic junction (UPJ) obstruction underwent Single port robotic pyeloplasty through a small pfannenstiell abdominal incision. Patients were positioned on lateral decubitus position and access to the peritoneal cavity was made through a 1-1.5 inch lateral pfannenstiell incision. The GelPOINT Mini advanced access platform (Applied Medical, Rancho Santa Margarita, CA) was used for trocar insertion to accommodate a 25 mm multichannel robotic port, a 12-mm accessory laparoscopic port and a nasogastric tube as a suction tube. After docking the da Vinci SP® robotic system, access to the UPJ segment was made by minimal reflection of colon in cephalad direction, parallel to the ureter. Classic dismembered pyeloplasty over a stent was done but no drain was placed in any patients. The trocar site was closed at the end of procedure.

### Results

Mean patients' age was 60 years. All cases were completed successfully without any intraoperative complications. Operative time ranged between 146 and 183 minutes. Postoperative course was uneventful and patients were discharged a few hours after the surgery (Mean hospital stay: 9 hours). In-hospital opioid usage ranged between 1.6 and 7.6 morphine milligram equivalent in total. Patients remained symptom free after stent removal and during their short-term follow-up period ranged between 4-5 months.

### Conclusions

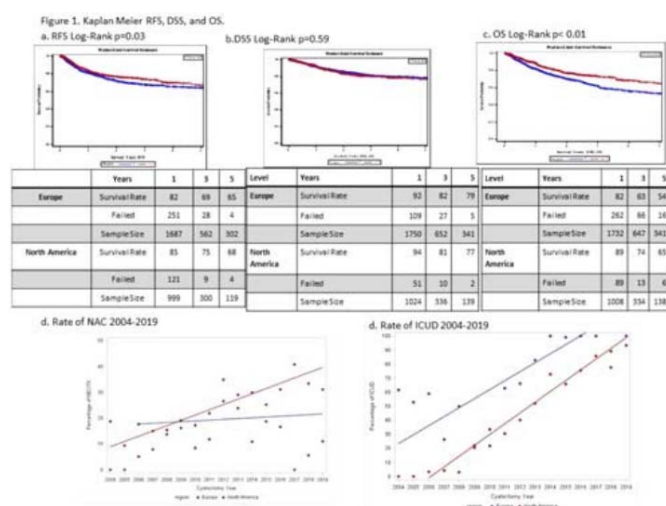
The multiquadrant surgery feature of the da Vinci SP® robotic system enables surgeon to do pyeloplasty through a small pfannenstiell abdominal incision. Through this access point, dissection is parallel to the course of ureter with minimum colon mobilization. Moreover, this small lower abdominal access point may be associated with promising cosmetic, postoperative pain and morbidity outcomes and short hospital stay. Studies including larger sample size and long-term functional data are required for further assessment of this surgical approach.

Source of Funding: none

hospital stay (12 vs 7 days,  $p<0.01$ ). North American patients had more overall complications (60% vs 55%,  $p=0.02$ ) and 90-day mortality (4% vs 2%,  $p<0.01$ ). North American patients had a higher  $\geq pT3$  ( $p<0.01$ ), positive margins ( $p=0.03$ ), and  $pN+ve$  ( $p=0.05$ ). North American patients had more recurrences (24% vs 19%,  $p<0.01$ ), and distant recurrences (18% vs 14%,  $p=0.02$ ) (Table 1).

Variable Name	North America	Europe	All	P
No of patients (%)	1909 (65)	1048 (35)	2957	—
Age at cystectomy, mean $\pm$ SD	68 $\pm$ 11	66 $\pm$ 11	67 $\pm$ 11	<0.01
Sex, Males, N (%)	1470 (78)	757 (72)	2227 (76)	<0.01
Body mass index, mean $\pm$ SD (kg/m <sup>2</sup> )	28 $\pm$ 6	27 $\pm$ 5	28 $\pm$ 6	<0.01
ASA $\geq$ 3, N (%)	1075 (64)	202 (27)	1277 (52)	<0.01
Operative time min, mean $\pm$ SD	393 $\pm$ 119	368 $\pm$ 94	383 $\pm$ 110	<0.01
Intracorporeal urinary diversion, N (%)	728 (44)	697 (67)	1425 (53)	<0.01
Continent urinary diversion, N (%)	361 (19)	272 (26)	633 (22)	<0.01
Inpatient stay in days, median (IQR)	7 (6, 10)	12 (8, 15)	8 (6, 13)	<0.01
$\geq pT3$ , N (%)	667 (40)	334 (32)	1001 (37)	<0.01
$pN+$ , N (%)	383 (23)	176 (20)	559 (22)	0.05
Positive surgical margins, N (%)	129 (9)	50 (7)	179 (8)	0.03
Any complications, N (%)	910 (60)	500 (55)	1410 (58)	0.02
High grade complications, N (%)	372 (26)	226 (25)	598 (26)	0.36
Reoperations with 30 days, N (%)	96 (5)	50 (5)	146 (5)	0.79
Death 0-90 days, N (%)	71 (4)	20 (2)	91 (3)	<0.01
Any recurrence, N (%)	461 (24)	204 (19)	665 (22)	<0.01
Any distal recurrence, N (%)	337 (18)	150 (14)	487 (16)	0.02
Any local recurrence, N (%)	212 (11)	101 (10)	313 (11)	0.24

There was a significant increase in NAC utilization among North American compared with European institutions ( $p<0.01$ ), and significant increase of ICUD among both ( $p<0.01$ ) (Fig1a). KM curves showed a significantly higher RFS ( $p=0.03$ ) and OS ( $p<0.01$ ) but similar DSS ( $p=0.59$ ) rates for European compared to North American patients at 5 years (Fig1b).



### Conclusions

Utilization of NAC has significantly increased among North American institutions, but remained stable over time among European institutions.

Source of Funding: Roswell Park Alliance Foundation

# INITIAL EXPERIENCE WITH SINGLE-PORT ROBOTIC RETROPERITONEAL PARTIAL NEPHRECTOMY USING A PURPOSE-BUILT SINGLE-PORT SURGICAL SYSTEM: TECHNICAL DETAILS

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## Introduction and Objective

To present the feasibility and technical details of robot-assisted single port partial nephrectomy with a retroperitoneal approach, using da Vinci SP® platform.

## Methods

Between April and July 2019, 2 patients (1 male) with renal mass (both right side) underwent robot-assisted single port retroperitoneal partial nephrectomy. Both patients had organ confined disease with lower pole 24 and 25 mm renal masses (Nephrometry score: 4p and 6p). Patients were positioned in 90 degree flank position and a 30 mm transverse incision was made between the 12th rib and the iliac crest at the level of the mid axillary line. The retroperitoneal space is initially identified and created by digital exploration, followed by balloon dilation to create an appropriate working space. The inner ring of the alexis wound retractor was inserted in the retroperitoneal space, and the GelPOINT Mini advanced access platform (Applied Medical, Rancho Santa Margarita, CA) was assembled. A 25 mm multichannel robot port and a 12-mm accessory laparoscopic port were passed through the GelPOINT and the da Vinci SP® Surgical System (Intuitive Surgical, Sunnyvale, CA) was docked. Standard partial nephrectomy with early unclamping technique and renorrhaphy in two layers was performed. The specimen was extracted through the trocar site and no drain was placed.

## Results

Patients' age was 58 and 78 years. Both cases were completed successfully without any need for conversion, blood transfusion or intraoperative complications. Operative times were 155 and 240 minutes, with warm ischemia times of 26 and 29 minutes. Postoperative course was uneventful and patients were discharged after 26 and 42 hours of hospital stay. In-hospital analgesia included exclusively nonsteroidal anti-inflammatory drugs. Histopathological examination of specimens showed a 21 mm clear cell renal cell carcinoma and a 26 mm benign papillary adenoma, both with negative margins.

## Conclusions

Single-port partial nephrectomy through retroperitoneal approach is feasible in selected patients by Using da Vinci SP® platform is feasible. This system has features such as double-jointed articulating robotic instruments and the articulating camera that allow to optimize the work in a smaller environment such the retroperitoneal space. With avoiding violation of the peritoneum, promising results regarding pain control, the need for opioid usage and postoperative recovery can be expected. Further comparative studies with larger

sample and long-term follow-up data are recommended to corroborate these initial findings.

Source of Funding: none

# ONCOLOGIC OUTCOMES AFTER ROBOT-ASSISTED PARTIAL NEPHRECTOMY IN THE IRON STUDY: RESULTS FROM A LARGE, GLOBAL, MULTICENTRIC ANALYSIS OF PATIENTS WITH CLINICALLY LOCALIZED KIDNEY CANCER

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## Introduction and Objective

Despite its wide adoption, there is a paucity of data on oncologic outcomes after robot-assisted partial nephrectomy [RAPN] and no predictive models. The aim of the study was to investigate predictors of adverse oncologic outcomes in renal cell carcinoma [RCC] patients treated with RAPN in a large, multicentric, global analysis.

## Methods

1,623 patients diagnosed with a renal mass and elected for RAPN at 9 high volume European, North American or Asian Institutions were prospectively assessed in a central dataset. Adverse oncologic outcomes consisted of local recurrence [LR; namely RCC in the resection bed], systemic progression [SP; namely RCC outside of the kidney] and clinical relapse [CR; namely any of LR or SP]. KaplanMeier [KM] plots were used to depict adverse oncologic outcomes rates. Cox-regression multivariable models were used to compute the risk of adverse oncologic outcomes in the preoperative setting (Model A - clinical predictors and overall population) and in the postoperative setting (Model B - pathological predictors and confirmed RCC only).

Predictors	Cox regression analysis predicting LR		Cox regression analysis predicting SP		Cox regression analysis predicting CR	
	HR	95% CI	P	HR	95% CI	P
CLINICAL						
Age at diagnosis, yrs	1.02	(0.99-1.05)	0.1	0.98	(0.95-1.01)	0.3
Gender, female v male	0.88	(0.16-0.87)	<b>0.02</b>	0.43	(0.19-0.94)	<b>0.03</b>
Clinical tumor size, mm	1.22	(1.03-1.44)	<b>0.01</b>	1.16	(0.96-1.39)	0.1
PADUA score	1.22	(0.99-1.49)	0.05	1.26	(1.04-1.55)	<b>0.01</b>
Year of surgery, yrs	0.85	(0.74-0.97)	<b>0.02</b>	0.87	(0.75-1.00)	0.06
C index	<b>0.82</b>			<b>0.77</b>		<b>0.77</b>
B. Post-operative model						
PATHOLOGICAL						
Age at diagnosis, yrs	1.00	(0.97-1.04)	0.5	0.97	(0.94-1.00)	0.09
Gender, female v male	0.42	(0.18-0.97)	<b>0.04</b>	0.52	(0.23-1.14)	0.1
Pathological tumor size, mm	1.21	(1.04-1.41)	<b>0.01</b>	1.21	(1.03-1.41)	<b>0.01</b>
Tumor grade, G <sub>1-2</sub> v G <sub>3-4</sub>	2.45	(1.25-4.79)	<b>&lt;0.001</b>	3.19	(1.64-6.17)	<b>&lt;0.001</b>
Surgical margins, R1 v R0	4.44	(1.89-8.56)	<b>&lt;0.01</b>	1.78	(0.59-5.36)	0.3
Year of surgery, yrs	0.85	(0.74-0.98)	<b>0.03</b>	0.86	(0.74-0.99)	<b>0.04</b>
C index	<b>0.83</b>			<b>0.83</b>		<b>0.78</b>

## Results

KM derived 2-year rates of LC, SP and CR were 2.3, 2.5 and 4.5% after a median follow-up of 24 months, respectively, in the overall population. The same figures resulted 2.7, 2.9 and 5.4% after a median follow-up of 25 months, respectively, in 1,324 (82%) patients with confirmed RCC. In the preoperative setting, male gender, larger tumour, higher PADUA score and

former year of surgery were associated with higher risk of adverse oncologic outcomes at multivariable analysis (Model A). In the postoperative setting, male gender, larger tumour, higher tumour grade, positive surgical margins and former year of surgery were associated with higher risk of adverse oncologic outcomes at multivariable analysis (Model B). C-index ranged from 0.77 to 0.83.

## Conclusions

Despite generally RAPN is associated with good cancer control, for the first time, it is possible to estimate the risk of adverse oncologic outcomes such as LC, SP and CR after RAPN with optimal predictive accuracy. In the preoperative setting, the proposed model can support clinicians in the choice for the best therapeutic option, while in the postoperative setting it can support clinicians at proper follow-up planning.

**Source of Funding:** On behalf of the ERUS Scientific Working Group, the YAU working group on robot-assisted surgery and the YAU working group on kidney cancer. This study is supported by a restricted research grant from Intuitive. The sponsor had no role in data collection, management, analysis or interpretation.

## TRIFECTA ACHIEVEMENT AFTER PARTIAL NEPHRECTOMY HELPS PREDICTING LONG TERM ONCOLOGIC AND FUNCTIONAL OUTCOMES: A MULTICENTER STUDY

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## Introduction and Objective

The best follow-up (FU) strategy following partial nephrectomy (PN) for localized renal cell carcinoma (RCC) remains unclear, being an intensive imaging-based strategy unlikely to impact on survival. Similarly, the optimal schedule for assessing eventual onset of chronic kidney disease (CKD) is a matter of debate.

## Methods

A multicenter database including 1807 patients was queried for "robotic PN", "non-metastatic clear cell RCC" at the 4 participating institutions within the study period (2006–2018). Baseline demographic, clinical, pathologic, perioperative, oncologic and functional outcomes data were collected. Mayo Recurrence Risk Score (MRRS) was calculated. A composite outcome (ROME's) was proposed to include no Recurrences, no Overall Mortality and eGFR not significantly impaired (absence of newly onset stage≥3CKD [or IV-V in case of baseline stage 3]). Chi-square and Mann-Whitney tests compared categorical and continuous variables. Uni/multivariable Cox regression analyses assessed predictors of ROME's nonachievement and cancer recurrence (CR); risk-

classes were developed accordingly. Kaplan-Meier (KM) method was used to estimate predictive role of these risk classes on the same two outcomes computed at 12, 24, 36, 48, 60 months after PN.

## Results

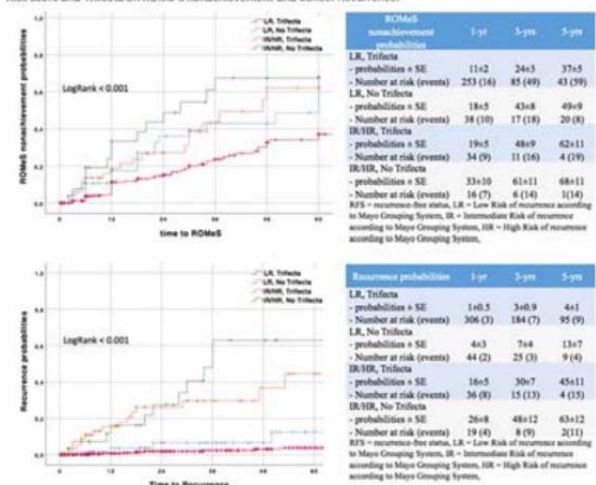
Overall, 633 patients were included in the analysis (Tab1); 81% (n=16) achieved Trifecta and 85% (n=540) were low-risk MRRS. At multivariable analysis (Tab2), age ( $p<0.001$ ), ASA score ( $p=0.016$ ), Trifecta ( $p=0.038$ ) and MRRS ( $p=0.026$ ) predicted ROME's nonachievement while only MRRS was an independent predictor of CR ( $p<0.001$ ) and ROME's nonachievement ( $p<0.001$ ) (Fig1).

	Overall N=633	No ROMEs N=133 (21%)	ROME's N=500 (79%)	p
Age, years	60 (51-68)	66 (57-73)	58 (49-66)	<0.001
Male Gender, n (%)	413 (65%)	96 (72%)	318 (64%)	0.106
Body mass index	29.4 (26-33.6)	31.2 (26.3-32.9)	29.4 (26.2-34.8)	0.654
ASA score ≥3, n (%)	327 (52%)	80 (60%)	247 (49%)	0.050
eGFR at baseline, mL/min	86 (72.7-104.9)	73.8 (64.6-82.9)	91.2 (77.8-107.8)	<0.001
eGFR at discharge, mL/min	77.6 (61.4-96)	60.9 (48.5-79.7)	82.1 (66.6-98.1)	<0.001
Off-clamp approach, n (%)	354 (56%)	74 (56%)	280 (56%)	0.904
Ischemia time†, min	19 (14-24)	23 (15-28)	19 (14-23)	0.014
TRIFECTA, n (%)	516 (81%)	92 (69%)	424 (85%)	<0.001
Mayo Recurrence Risk Group, n (%)				
Low Risk	540 (85%)	95 (72%)	443 (89%)	<0.001
Intermediate/High	95 (15%)	38 (28%)	57 (11%)	

Data are presented as median (IQR)  
†data are calculated on patients undergoing on-clamp partial nephrectomy  
ASA= American Society of Anesthesiologists, eGFR = estimated glomerular filtration rate

ROME's nonachievement	Univariable Analysis				Multivariable Analysis			
	CR	95% CI		p	CR	95% CI		p
		Lower	Higher			Lower	Higher	
Age	1.043	1.026	1.061	<0.001	1.037	1.019	1.055	<0.001
Male gender	1.200	0.798	1.804	0.381	—	—	—	—
Body mass index	1.012	0.981	1.045	0.454	—	—	—	—
ASA score ≥3	1.952	1.332	2.861	0.001	1.619	1.418	1.916	0.016
TRIFECTA	0.478	0.322	0.709	<0.001	1.574	1.274	2.026	0.038
Intermediate/High risk group	2.217	1.478	3.325	<0.001	0.605	0.388	0.941	0.026
Recurrence	Univariable Analysis				Multivariable Analysis			
	CR	95% CI		p	CR	95% CI		p
		Lower	Higher			Lower	Higher	
Age	1.033	1.005	1.063	0.022	1.025	0.996	1.056	0.089
Male gender	1.668	0.794	3.504	0.177	—	—	—	—
Body mass index	0.939	0.826	1.069	0.342	—	—	—	—
ASA score ≥3	1.013	0.524	1.955	0.970	—	—	—	—
TRIFECTA	0.295	0.155	0.562	<0.001	0.640	0.322	1.273	0.204
Intermediate/High risk group	14.450	7.458	27.997	<0.001	12.6	6.3	25.089	<0.001

Figure 1: Kaplan-Meier analyses to investigate the predictive role of the Mayo Recurrence Risk Score and Trifecta on ROME's nonachievement and Cancer Recurrence.





Conclusions

Achieving Trifecta at discharge is a significant predictor of maintaining successful outcomes in the long-term; together with MRRS, it may help defining cost-effective FU strategies.

Source of Funding: None.

COMBINED ASSESSMENT OF LONG-TERM FUNCTIONAL AND ONCOLOGIC OUTCOMES AFTER ROBOT-ASSISTED PARTIAL NEPHRECTOMY: THE ROME'S SCORE

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Introduction and Objective

We assessed the predictive role of a newly trifecta after RAPN on a comprehensive outcomes assessment (ROME's) defined as: no Recurrence, no Overall Mortality, absence of eGFR significant reduction.

Methods

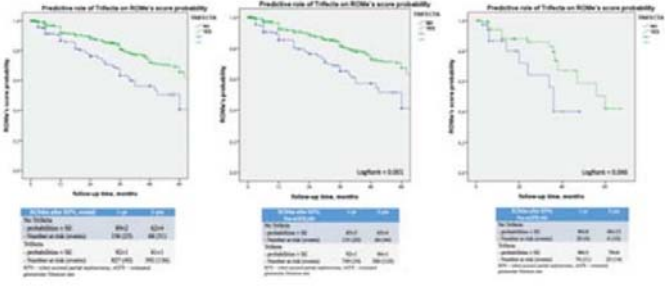
A multicenter database including 2105 patients was queried for patients with renal masses who underwent RAPN at 8 institutions (Sept 2006–Sept 2017). Baseline demographic, clinical, pathologic, perioperative, oncologic and functional outcomes data were collected. The newly trifecta included: negative margins, no severe complications, and ≤30% postoperative eGFR reduction. The ROME's included no Recurrences, no Overall Mortality and baseline eGFR not significantly reduced (defined as absence of newly onset CKD stage IIIa or IV-V when baseline eGFR was ≥ or < 60 mL/min/1.73m<sup>2</sup>). Chi-square and Student-t test were used to compare categorical and continuous variables. Kaplan-Meier method was performed to investigate the predictive role of Trifecta on ROME's achievement. Survival outcomes were computed at 12, 24, 36, 48, 60 months after surgery and the log-rank test was applied to assess statistical significance between groups.

Results

1434 patients were included (Tab.1). Trifecta was achieved in 1185 (83%) patients. ROME's was achieved by 1192 (83%) patients: they were significantly younger (p<0.001), thinner (p=0.002), with lower ASA scores (p<0.001), higher baseline eGFR (p<0.001), and less complex tumors (p=0.001). On Kaplan-Meier analysis (Fig.1), Trifecta was significantly associated with a higher probability of achieving the ROMEs (p<0.001); in a stratified analysis trifecta was significantly associated with ROMEs either when RAPN was performed in elective (p<0.001) or in imperative settings (p<0.046).

Table 1. Patients' characteristics and outcomes after RPN, according to Trifecta achievement				
	Overall N=1434	No ROMEs N=242 (17%)	ROME's N=1192 (83%)	p
Age, years	61±11.8	65.5±9.7	60±11.9	<0.001
Male Gender, n (%)	954 (67)	166 (68)	788 (66)	0.455
Body mass index	28±5.9	29±6.7	28±5.6	0.002
ASA score ≥3, n (%)				
1-2	932 (65)	113 (47)	819 (68)	<0.001
3-4	502 (35)	129 (53)	373 (32)	
Clinical tumor size, cm	4.2±2.6	4.5±2.3	4.3±2.7	0.396
Ischemia time, min	12.3±11.2	13.4±12.7	12±10.9	0.100
Operative time, min	159±60.7	165.7±77	158±57	0.127
Complications CD≥3, n (%)	43 (3)	10 (4)	33 (2)	0.112
Preop eGFR, mL/min/1.73m <sup>2</sup>	89.3±26	75.8±20	92±26	<0.001
RENAL score, n (%)				
≤ 6	731 (51)	99 (41)	632 (52)	0.001
7-9	559 (39)	99 (41)	460 (39)	
≥ 10	144 (10)	44 (18)	100 (9)	
Data are presented as median ± SD ASA= American Society of Anesthesiologists, eGFR= estimated glomerular filtration rate				

Figure 1. Kaplan-Meier analyses to investigate the predictive role of trifecta on ROMEs achievement according to Pre-eGFR



Conclusions

ROME's provides a comprehensive summary of long-term outcomes after NSS. Achieving the newly defined Trifectath is a significant predictor of maintaining successful outcomes during follow-up.

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DEVELOPMENT OF A NOMOGRAM TO PREDICT ACHIEVEMENT OF TRIFECTA OUTCOMES AFTER ROBOTIC PARTIAL NEPHRECTOMY FOR CT1-2 RENAL TUMORS

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Introduction and Objective

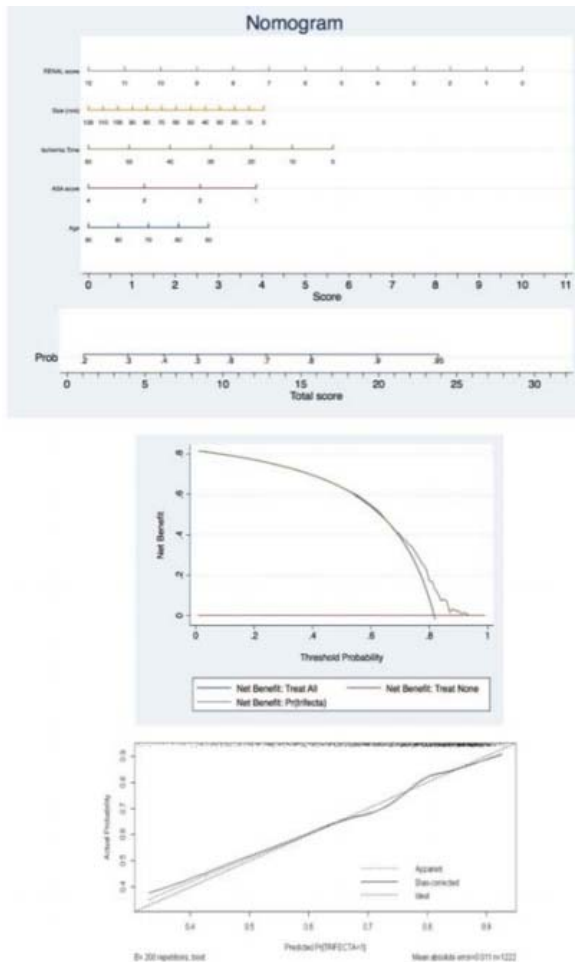
Robot-assisted partial nephrectomy (RPN) is an established and widely performed surgical procedure. The two trifecta outcomes available in Literature are limited by reproducibility of subjective assessment of parenchymal volume loss and by inapplicability in off-clamp procedures, respectively. In this study, we proposed a combination of three standardized and reproducible postoperative criteria (Trifecta) to optimize



outcomes reporting after RPN and we developed a nomogram to predict probability of achieving trifecta.

## Methods

We defined "trifecta" as the combination of negative margins, absence of severe (Clavien>2) perioperative complications and perioperative eGFR reduction < 30%. A total of 2105 consecutive patients who underwent RPN for cT1-2 renal tumors were used to generate a nomogram predicting probability of achieving trifecta outcomes. The discrimination accuracy was measured by concordance index (CI). Calibration plot was generated with 200 bootstrap resampling. A decision curve analysis was performed to assess the net benefit of the model.



## Results

Overall, 2105 patients were included in the analysis. The trifecta was achieved in 1605 (78.6%) patients. On multivariable logistic regression analysis, age, ASA score, tumor size, RENAL nephrometry score and duration of warm ischemia time were significant predictors of trifecta achievement. The developed nomogram had a 0.69 CI (Figure 1A) and was perfectly calibrated (Figure 1B). On decision curve analysis, the net benefit of using the nomogram to predict trifecta was evident for probabilities higher than 70% (Figure 1C).

## Conclusions

This newly defined trifecta is an easy and reproducible system specifically designed to provide a comprehensive summary of global results of perioperative and long term oncologic and functional outcomes. Estimating the probability of achieving trifecta is significantly increased by the use of the nomogram for probabilities higher than 70%.

*Source of Funding:* none

## THE IRON STUDY: INVESTIGATION OF ROBOT-ASSISTED VERSUS OPEN NEPHRON-SPARING SURGERY

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## Introduction and Objective

The aim of the study is to investigate clinical outcomes after robot assisted [RAPN] or open surgery partial nephrectomy [OPN] in a very large, multicentric, global analysis.

## Methods

3,468 patients diagnosed with a cT1-2 cN0 cM0 renal mass elected for RAPN or OPN at 9 high-volume European, North American or Asian Institutions were prospectively assessed in a central database. The outcomes of the study were perioperative complications, renal function and cancer control. Regression analysis and propensity-score matching were used to account for all measurable potential confounders with special attention to key determinants of clinical outcomes invariably neglected in previous investigations, such as tumour complexity and surgical experience.

## Results

After accounting for all measurable potential confounders, relative to OPN, RAPN was associated with lower rate of any intraoperative (5.7 vs 9.3%) or postoperative (18 vs 33%) complications (Table 1). After stratification according to complication severity or type, relative to OPN, RAPN was associated with lower rate of Clavien-Dindo  $\geq 2$  (12 vs 20%), Clavien-Dindo  $\geq 3$  (4 vs 6.1%), haemorrhagic (6.4 vs 9%) and urinary leakage-related (0.8 vs 4.6%) complications. Conversely, relative to OPN, RAPN was associated with longer ischemia time (16 vs 15 min), lower postoperative estimated glomerular filtration [eGFR] (76 vs 78 mL/min) but similar 1-year eGFR (71 vs 68 mL/min). No difference was recorded with respect to the rate of positive surgical margins (4.3 vs 5.1%) or local recurrence (1.6 vs 2.1%), systemic progression (1.8 vs 4.5%) and cancer specific mortality (0.8 vs 2.4%) at a median follow-up of 32 months. These observations were confirmed

also after accounting for individual items defining tumour complexity and surgical experience.

**Table 1. Clinical outcomes of 3,468 patients treated with robot-assisted (RAPN) and open partial nephrectomy (OPN) for a cT1-2 renal mass at high-volume European, North American or Asian Institutions, 2004-2018**

Outcome	OPN (N=1063)	RAPN (N=2405)	RAPN v OPN OR-EST-HR (95% CI)	P
<b>MORBIDITY AND COMPLICATIONS</b>				
Intraoperative complications <sup>1</sup>	99 (9.3)	139 (5.7)	0.39 (0.22-0.68)	<0.001
Overall complications <sup>1</sup>	355 (33)	435 (18)	0.29 (0.12-0.60)	<0.001
Clavien-Dindo complication ≥ 2 <sup>2</sup>	215 (20)	279 (12)	0.37 (0.24-0.57)	<0.001
Clavien-Dindo complication ≥ 3 <sup>2</sup>	65 (6.1)	97 (4.0)	0.29 (0.12-0.60)	<0.001
Estimated blood loss (mL) <sup>2</sup>	180 (100-350)	150 (100-300)	-140 (-163 to -115)	<0.001
Operative time (min) <sup>2</sup>	120 (100-163)	150 (120-200)	+31 (+26 to +36)	<0.001
Length of stay (d) <sup>2</sup>	6 (5-7)	4 (3-5)	-2 (-2 to -1)	<0.001
Hemorrhagic complication <sup>1</sup>	96 (9.0)	155 (6.4)	0.43 (0.25-0.72)	<0.01
Urinary leakage <sup>1</sup>	49 (4.6)	21 (0.8)	0.05 (0.01-0.3)	<0.01
<b>FUNCTIONAL OUTCOMES</b>				
Ischemia time (min) <sup>2</sup>	15 (8-21)	16 (11-22)	+4.3 (+3 to +5)	<0.001
Postop eGFR (mL/min/1.73m <sup>2</sup> ) <sup>2</sup>	78 (63-93)	76 (60-89)	-6 (-8 to -4)	<0.001
1-yr eGFR (mL/min/1.73m <sup>2</sup> ) <sup>2</sup>	68 (55-87)	71 (56-88)	-1 (-2 to +1)	0.5
<b>PATHOLOGIC OUTCOMES</b>				
Pathological size (mm) <sup>2</sup>	3 (2.1-4)	3 (2.4-1)	0.7 (-0.2 to 1.7)	0.1
Malignancy <sup>1</sup>	834 (78)	1920 (80)	1.06 (0.77-1.45)	0.7
pT3-pT4 <sup>1</sup>	51 (4.7)	107 (4.4)	0.90 (0.46-1.76)	0.8
G3-G4 <sup>1</sup>	191 (18)	550 (23)	0.83 (0.58-1.20)	0.3
Positive surgical margins <sup>1</sup>	55 (5.1)	103 (4.3)	0.53 (0.27-0.99)	0.05
<b>5-YEAR ONCOLOGIC OUTCOMES</b>				
Local recurrence <sup>3</sup>	23 (2.1)	40 (1.6)	1.88 (0.97-3.63)	0.06
System progression <sup>3</sup>	48 (4.5)	44 (1.8)	0.83 (0.49-1.41)	0.5
Clinical progression <sup>3</sup>	71 (6.6)	79 (3.2)	1.00 (0.67-1.49)	0.9
Cancer-specific mortality <sup>3</sup>	26 (2.4)	20 (0.8)	1.01 (0.41-2.42)	0.9

Data are presented as frequency and proportion for categorical variables and as median and interquartile range for continuous variables

<sup>1</sup>Logistic regression models (adjustment variables: age, Charlson Comorbidity index, gender, eGFR—pre, clinical size, tumor size, PADUA score, year of surgery and institution)

<sup>2</sup>Linear regression models (adjustment variables: age, Charlson Comorbidity index, gender, eGFR—pre, clinical size, tumor size, PADUA score, year of surgery and institution)

<sup>3</sup>Cox-regression models (adjustment variables: clinical size, PADUA score and year of surgery)

## Conclusions

Morbidity is lower after RAPN relative to OPN. Early renal function preservation is inferior after RAPN relative to OPN, but no difference is observed at long term follow-up. Oncologic outcomes are similar after either treatment modality. The global setting of the study, the very large study cohort, the thorough clinical data collection, the relatively long follow-up and the inclusion of contemporary patients treated in the post dissemination era of RAPN are unique strengths of the study and support the validity of the conclusion.

**Source of Funding:** On behalf of the ERUS Scientific Working Group, the YAU working group on robot-assisted surgery and the YAU working group on kidney cancer. This study is supported by a restricted research grant from Intuitive. The sponsor had no role in data collection, management, analysis or interpretation.

## MIS—Pediatrics

### PEDIATRIC TRANSMESENTERIC ROBOTIC SINGLE PORT DISMEMBERED PYELOPLASTY

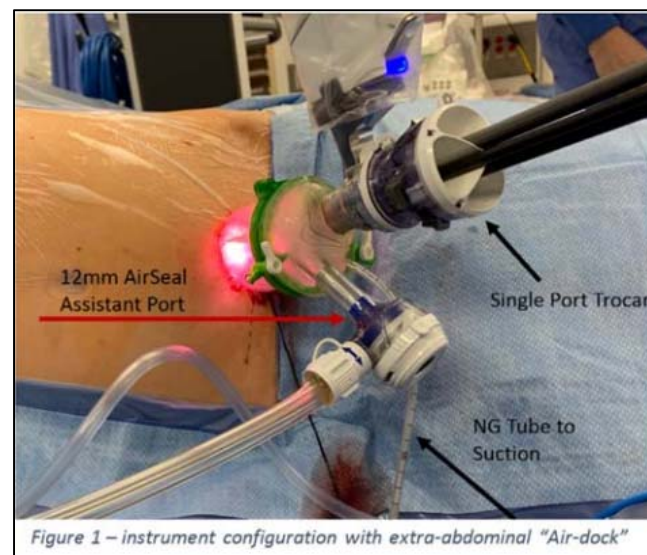
Prithvi Murthy\*, Juan Garisto-Risco, Benjamin Abelson, Audrey Rhee, Jihad Kaouk, Cleveland, OH

#### Introduction and Objective

Standard robotic pyeloplasty has been shown to improve convalescence and post-operative pain requirements in children. Single port robotic surgery using the DaVinci SP platform (Intuitive Surgical, Sunnyvale, CA) may further these benefits. Herein we present a case of a pediatric transmesenteric robotic single port dismembered pyeloplasty.

## Methods

A 14 year old male with history of bilateral extravesical ureteral reimplantation at age 3 presented to our clinic with acute onset left sided flank pain. Ultrasound, CT urogram and MAG3 renal scan were consistent with high grade left sided obstruction. The patient and family were counseled on management and he was consented for left robotic pyeloplasty. The surgery was performed entirely through a 3cm incision on the left lateral aspect of the patient's prior Pfannenstiel incision. Instruments were placed extra-abdominally via the GelPOINT Mini advanced access system (Applied Medical, Rancho Santa Margarita, CA) as shown in Figure 1.



## Results

Operative time was 165 minutes. Estimated blood loss was 30cc. The patient was discharged on post-operative day one after foley catheter removal. He did not require any home-going narcotics. His stent was removed 4 weeks post-operatively. He did not experience any wound related complications, and his incision at 1 month is shown in Figure 2.

Ultrasound at 2 months demonstrated complete resolution of his prior hydronephrosis, and he remains asymptomatic.

## Conclusions

The single port robotic platform is an alternative minimally invasive option for pediatric pyeloplasty. Extraabdominal instrument placement and use of the "mini-Pfannenstiel" incision lengthen the operative field and may facilitate single port robotic surgery in smaller children. Larger series will be required to elucidate patient benefits.

**Source of Funding:** None



## MIS—Prostate

### SALVAGE FOCAL CRYOTHERAPY OFFERS SIMILAR SHORT-TERM ONCOLOGICAL CONTROL AND IMPROVED URINARY FUNCTION COMPARED TO SALVAGE WHOLE GLAND CRYOTHERAPY RADIATION RESISTANT/ RECURRENT PROSTATE CANCER

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#### Introduction and Objective

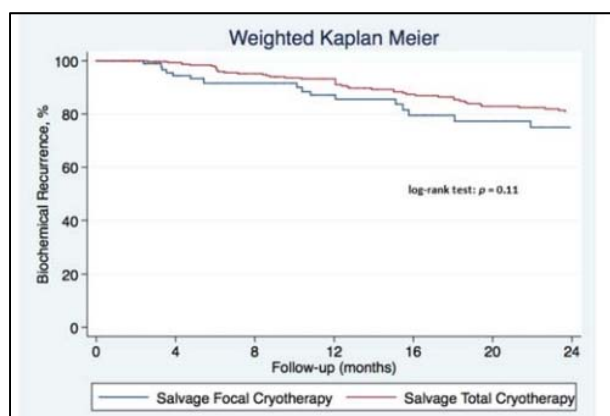
The treatment of radiation-persistent prostate cancer remains a challenge and should be tailored to the individual patient. We aim to compare short-term oncological and functional outcomes of salvage focal cryotherapy (SFC) to salvage total cryotherapy (STC) for radiation persistent/ recurrent prostate cancer.

#### Methods

We queried the COLD registry for men who underwent SFC and STC of the prostate for radiation persistent/recurrent disease. Propensity score weighting was used to match age at time of treatment, pre-salvage therapy PSA, Gleason sum, and pre-salvage cryotherapy androgen deprivation therapy status. Primary outcome was progression-free survival (PFS).

#### Results

A total of 385 men with biopsy-proven persistent/ recurrent prostate cancer after primary radiotherapy were included in the study. Median follow-up, age, PSA and Gleason sum pre-salvage cryotherapy was 24.4 months (1st/3rd quartile: 9.8/60.3), 70 years (1st/ 3rd quartile: 66/74), 4 ng/dl (1st/3rd quartile: 2.7/5.6) and 7 (1st/3rd quartile: 6/8), respectively. After propensity score weighting, patients who were treated with STC did not have a significant difference test in PFS compared to patients treated with SFC on weighted log-rank test (79.8% vs. 76.98%,  $p=0.11$ ). SFC was associated with a lower probability of post-treatment transient urinary retention (5.6% vs 22.4%,  $p<0.001$ ). There were no significant differences in rectal fistula (1.4% vs 3.8,  $p=0.30$ ), new onset urinary incontinence within 12 months (9.3% vs 15.1%,  $p=0.19$ ) or new-onset erectile dysfunction within 12 months (52.6% vs 59.6,  $p=0.47$ ) in the SFC vs STC group, respectively.



Variable	Unweighted patient cohort			Weighted patient cohort		
	Salvage focal cryotherapy N=72 (%)	Salvage whole gland cryotherapy N=313 (%)	P	Salvage focal cryotherapy (%)	Salvage whole gland cryotherapy (%)	P
Age, years						
<60	8 (11.1)	27 (8.6)	0.03	15.3	8.2	0.37
61-70	23 (31.9)	140 (44.7)		32.0	44.1	
71-80	41 (56.9)	146 (46.7)		52.6	47.6	
PSA, ng/mL						
≤1	2 (2.8)	6 (1.9)	<0.01	2.9	2.0	0.45
1-1.99	12 (16.7)	37 (11.8)		16.2	11.8	
2-4.99	32 (44.4)	168 (43.7)		43.2	51.9	
5-9.99	26 (36.1)	102 (32.6)		37.7	32.2	
Unknown	0 (0)	14 (3.72)				
Gleason Score						
≤6	31 (45.6)	107 (34.2)	0.46	36.9	35.4	0.73
7	26 (18.2)	108 (34.5)		38.0	34.6	
≥8	5 (7.4)	84 (26.3)		16.6	25.9	
Unknown	6 (8.8)	14 (4.5)		8.5	4.1	
ADT						
Yes	19 (26.4)	98 (31.3)	0.85	29.0	30.4	0.18
No	52 (72.2)	209 (66.8)		69.2	67.8	
Unknown	1 (1.4)	6 (1.9)		1.8	1.8	

PSA = prostate specific antigen; ADT = androgen deprivation therapy

#### Conclusions

STC has similar 2-year oncological outcome compared to SFC in the radiation- persistent/recurrent disease population, but patients who underwent SFC have a lower urinary retention rate compared to STC.

*Source of Funding:* WPT is supported by the Ruth L. Kirschstein NRSA Institutional Research Training Grant (T32- CA093245).

### OUTPATIENT EXPERIENCE WITH EXTRAPERITONEAL SINGLE-PORT ROBOTIC RADICAL PROSTATECTOMY

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#### Introduction and Objective

The da Vinci SP® surgical platform has allowed for the development of novel surgical techniques for radical prostatectomy. Robotic-assisted laparoscopic radical prostatectomy is usually followed by an overnight hospital stay. This study assesses the safety and feasibility of extraperitoneal single-port robotic radical prostatectomy as an outpatient procedure.

#### Methods

60 consecutive patients with clinically localized prostate cancer underwent extraperitoneal single-port robotic radical prostatectomy by a single high-volume surgeon. Local anesthesia was used intraoperatively to infiltrate the rectus fascia as well as the skin. Minimal intraoperative fluids and in-hospital opiates were used as part of an outpatient enhanced recovery protocol. Patients were discharged the day of surgery if they were ambulatory, tolerating a regular diet and had controlled pain, regardless of surgical start time or case order. All patients were offered the option to stay overnight even if meeting these milestones. Patient data was collected prospectively in an institutional review board-approved database and evaluated retrospectively.

#### Results

All surgeries were completed in an extraperitoneal fashion with bilateral pelvic lymph node dissection. Mean operative time was 198 minutes with mean estimated blood loss of 179 mL. There were no intraoperative complications and no patients received a blood transfusion. 73% of patients were

discharged on the date of surgery with a median length of stay of 4.2 hours. Final pathology revealed positive margins in 14 patients; however, 8 of these patients had pT3a disease, 5 had gleason 4+5 or 5+4 = 9 disease at final pathology and 4 of these patients were pN1. While 53% of patients were discharged with an opiate prescription, the discharge prescribing practice was changed during the series with only 10% of the last 30 patients in the series receiving opiate prescriptions at discharge. There were no emergency room visits for postoperative pain control. 7 patients had Clavien 3a complications (6 symptomatic lymphoceles requiring drainage and 1 urinoma requiring drainage). Of the patients with available 4-6 week follow up, 49% were requiring 0-1 pads per day (n=41).

## Conclusions

Extraperitoneal single-port robotic radical prostatectomy can be performed safely as an outpatient procedure without the need for postoperative opiates in the majority of patients.

*Source of Funding:* None

## SINGLE-PORT ROBOT-ASSISTED PERINEAL RADICAL PROSTATECTOMY AND PELVIC LYMPHADENECTOMY USING THE SP SURGICAL SYSTEM

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## Introduction and Objective

With the advent of purpose-built single-port robotic technology, we have adapted perineal prostatectomy to be performed with the Da Vinci SP® surgical system (Intuitive Surgical, Sunnyvale, CA). We report our clinical results and discuss technical aspects of the single-port trans-perineal robot assisted radical prostatectomy (SP-RAPP) with pelvic lymph node dissection.

## Methods

Between October 2018 and June 2019, 21 patients underwent SP-RAPP in our center by a single surgeon. Patients who had multiple previous abdominal surgeries or inability to tolerate pneumoperitoneum were included. The patient was positioned in exaggerated dorsal lithotomy with 15 degree of Trendelenburg. A 2.5 cm semicircular incision was made in the perineum between the ischial tuberosities. After dissection of the subcutaneous tissues, the mini advanced access platform (GelPoint, Rancho Margarita, CA) was placed on the perineum. The robot was docked between the legs and operation was performed with steps of standard perineal prostatectomy.

## Results

The median age of the patients was 63.9 (IQR 47- 69) and median body mass index was 28.9 (IQR 22.6-40.1) kg/m<sup>2</sup>. Preoperative median prostate specific antigen value was 6.35 (IQR 5.1- 9.3) ng/mL and 17 patients (80.9%) had previous major abdominal surgeries. Median operative time was 262 (IQR 171-327) minutes and estimated blood loss was 50 (IQR 30-700) cc. Median length of stay was 23.35 (IQR 5.2-76.3)

hours. Lymphadenectomy was done in 12 patients (57%) and bilateral nerve sparing was possible in 12 patients (57%). Median pain score was 2.5 (IQR 0-8) at discharge and median postoperative catheterization time was 12.5 (IQR 7-23.2) days. Median follow-up period was 6.7 (IQR 4.3-8.7) months and at 3 months of follow-up, all patients were continent. In this period, 8 post-operative complications were reported (5 cases of anastomotic leakage: prolonged urethral or suprapubic catheter; 2 cases of bladder neck contracture: managed by endoscopic dilation; one AKI: managed by conservatively).

	SP (N=21)
Age (years)	63.9 (IQR 47–69)
BMI (kg/m <sup>2</sup> )	28.9 (IQR 22.6–40.1)
Charlson Comorbidity Index	4 (IQR 2–4)
PSA (ng/mL)	6.35 (IQR 0.98–51.9)
ASA Score	3 (IQR 2–3)
Previous Abdominal Surgery	17/21 (80.9%)
Biopsy Pathological Gleason	
6	5 (23.8%)
7 (3+4)	7 (33.3%)
7 (4+3)	6 (28.5%)
8	2 (9.5%)
Undifferentiated	1 (4.7%)*
NCCN Risk Group	
Low Risk	3 (14.3%)
Intermediate	15 (71.4%)
High Risk	3 (14.3%)
Operative time (min)	262 (IQR 171–327)
Estimated blood loss (mL)	50 (IQR 30–700)
Length of stay (hours)	23.35 (IQR 5.2–76.3)
Nerve Sparing	12/21 (57%)
Lymphadenectomy	12/21 (57%)
Pain Score at Discharge	2.5 (IQR 0–8)
Postop urethral catheterization time (days)	12.5 (IQR 7–48)
Specimen Weight (grams)	29.6 (IQR 16.5–68)
Surgical Pathology Gleason	
6	1 (4.9%)
7 (3+4)	11 (52.3%)
7 (4+3)	7 (33.3%)
8	2 (9.5%)
9	0
pT Stage	
T2	11 (52.4)
T3a	7 (33.3%)
T3b	3 (14.3%)
Complication	7 (33%)
Vesicourethral stricture	2
Anastomosis site leakage	5

\*radiation effect

## Conclusions

SP-RAPP is an option for prostate cancer removal in patient with complex surgical history or inability to tolerate pneumoperitoneum. Additional studies involving more patients and long-term follow-up are required.

*Source of Funding:* none



# Oncology—Bladder

## OUTCOMES OF NON-MUSCLE INVASIVE BLADDER CANCER AFTER ROBOT-ASSISTED RADICAL CYSTECTOMY: RESULTS FROM THE INTERNATIONAL ROBOTIC CYSTECTOMY CONSORTIUM

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### Introduction and Objective

Pathological reclassification is not uncommon after robot assisted radical cystectomy (RARC). We sought to report upstaging at the final pathology among patients who underwent RARC for non-muscle invasive bladder cancer (NMIBC).

### Methods

We reviewed our prospectively maintained database from the International Robotic Cystectomy Consortium (3926 patients, 28 institutes) between 2003-2019. Upstaging was defined as  $\geq$  pT2 at final pathology from initial pathology < pT2. Multivariate regression models were fit to investigate variables associated with upstaging. Kaplan Meier (KM) curves were used for DSS, RFS, and OS. Multivariate Cox regression models were used to identify predictors of RFS, DSS and OS. Cochran-Armitage test to identify trends for upstaging over time.

### Results

Out of 3926 patients, 881 had RARC for NMIBC. Upstaging occurred in 288 patients (33%): upstaged to pT2 (48%), pT3 (36%), and pT4 (16%). Patients who upstaged were older (70 vs 67 years,  $p=0.02$ ) and more likely have cN+ (10% vs 2%,  $p<0.01$ ). They had higher pN+ (29% vs 4%,  $p<0.01$ ), higher positive margins (9% vs 4%,  $p=0.02$ ), higher high grade complications (93% vs 72%,  $p<0.01$ ), and were more likely to receive adjuvant treatment (22% vs. 5%,  $p<0.01$ ). Upstaged patients had more recurrences (33% vs. 12%,  $p<0.01$ ), both distal (25% vs 8%,  $p<0.01$ ) and local (14% vs 3%,  $p<0.01$ ). They had higher 90-day mortality (4% vs 2%,  $p=0.05$ ).

Upstaging was significantly associated with ASA $\geq$ 3 (OR 2.44; 95% CI 1.55-3.84;  $p<0.01$ ), cN+ (OR 8.16; 95% CI 2.57-25.99;  $p<0.01$ ), pTa (OR 0.41; 95% CI 0.22- 0.78;  $p<0.01$ ) and cystectomy era 2014-2019 vs 2005-2008 (OR 0.48; 95% CI 0.27-0.87,  $p=0.02$ ). KM curves showed a statistically worse RFS (54% vs 84%;  $p<0.01$ ), RFS (71% vs 95%,  $p<0.01$ ), and OS 41% vs 80%,  $p<0.01$ ), for patients who upstaged at 5 years (Fig 1a). Upstaging has decreased from 38% in 2003 to 26% in 2019 (Fig 1b).

Variable Name	No Upstage	Upstaged	All	P
No of patients (%)	593 (67)	288 (33)	881	<0.01
Age at cystectomy, mean (IQR)	67 (61,74)	70 (60,77)	68 (61,75)	0.02
Sex, Males, N (%)	118 (20)	52 (18)	170 (19)	0.59
Body mass index, mean $\pm$ SD (kg/m <sup>2</sup> )	28 $\pm$ 6	28 $\pm$ 6	28 $\pm$ 6	0.22
cT1, N (%)	340 (57)	193 (67)	533 (61)	0.02
cT2, N (%)	102 (17)	48 (17)	150 (17)	0.02
cTa, N (%)	113 (19)	34 (12)	147 (17)	0.02
cN+, N (%)	4 (2)	17 (10)	21 (5)	<0.01
Operative time min, mean $\pm$ SD	397 $\pm$ 108	379 $\pm$ 106	390 $\pm$ 107	0.01
Intracorporeal urinary diversion, N (%)	269 (48)	150 (55)	419 (50)	0.05
Ileal conduit, N (%)	406 (69)	224 (78)	630 (72)	0.05
Inpatient stay in days, median $\pm$ SD	10 $\pm$ 7	12 $\pm$ 11	11 $\pm$ 9	0.02
pT2, N (%)	—	138 (48)	138 (16)	—
pT3, N (%)	—	104 (36)	104 (12)	—
pT4, N (%)	—	46 (15)	46 (5)	—
pN+, N (%)	22 (4)	76 (29)	98 (12)	<0.01
Positive surgical margins, N (%)	20 (4)	20 (9)	40 (6)	0.02
Postop adjuvant treatment, N (%)	26 (5)	55 (22)	81 (11)	<0.01
Any recurrence, N (%)	70 (12)	96 (33)	166 (19)	<0.01
Any distal recurrence, N (%)	45 (8)	72 (25)	117 (13)	<0.01
Any local recurrence, N (%)	19 (3)	41 (14)	60 (7)	<0.01
Any urological recurrence, N (%)	20 (3)	13 (5)	33 (4)	0.45
Death 0-90 days, N (%)	9 (2)	11 (4)	20 (2)	0.05

Variable	Odds Ratio	95% CI	P
cTa	0.41	0.22-0.78	<0.01
ASA $\geq$ 3	2.44	1.55-3.84	<0.01
Preoperative N+	8.16	2.67-25.99	<0.01
Cystectomy era 2014-2019 vs 2005-2008	0.48	0.27-0.87	<0.01

Figure 1a. Kaplan Meier RFS, DSS, and OS.

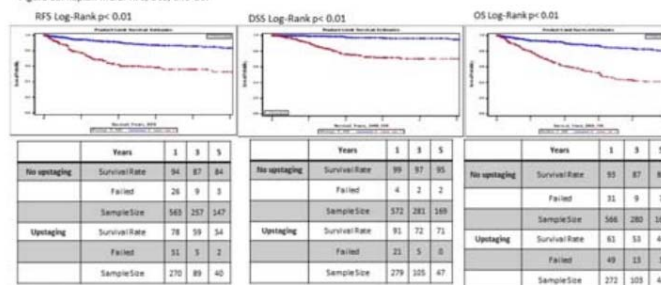
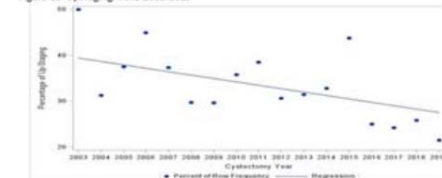


Figure 1b: Upstaging Trend 2003-2019



### Conclusions

Pathological upstaging is common after RARC for NMIBC but has shown a decrease over time.

Source of Funding: Vattikuti Foundation

## A MULTI-INSTITUTIONAL EVALUATION OF RESCUE THERAPY WITH INTRAVESICAL GEMCITABINE AND DOCETAXOL FOR NON-MUSCLE INVASIVE BLADDER CANCER AFTER BCG FAILURE

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## Introduction and Objective

After the recurrence of NMIBC following BCG therapy, risk stratified management directs patients toward radical cystectomy, clinical trial enrollment, and off-label use of intravesical chemotherapy. Many patients remain unfit for or unwilling to have major extirpative surgery. The identification of efficacious and safe alternatives to radical cystectomy is of paramount importance. We report the findings of a large, multi-institutional cohort of patients receiving intravesical Gemcitabine and Docetaxol after BCG failure.

## Methods

Participating institutions reviewed all patients treated with an induction course of sequential intravesical Gem/Doce for recurrent NMIBC between June 2009 and May 2018. Maintenance therapy was continued based on individual institutional protocols. Surveillance for recurrence was carried out per AUA guidelines. Recurrence and survival probabilities were plotted using the Kaplan-Meier methods and Cox regression models were used to evaluate the effect of patient, disease, and treatment variables on outcomes.

## Results

276 patients with a median follow-up of 22.9 months and a median number of 2 prior intravesical therapy induction courses were identified and included in the analysis. Only 3.3% of patients were unable to tolerate the full induction course of therapy. High grade RFS was 65% at 1 year and 52% at 2 years. Progression free survival was 97% and 93% at 1 and 2 years, respectively. On Cox regression analysis, clinical stage, number of prior BCG failure, BCG failure categorization, and treating institution did not impact disease recurrence. The addition of maintenance therapy was significantly associated with recurrence free survival (HR 2.37, 95% CI 1.36-4.11,  $p < 0.01$ ). Sixteen percent of patients underwent cystectomy at a median of 11.3 month from starting therapy. Bladder cancer specific mortality was 1% at 1 year and 5% at 2 years. There was no difference in outcome between patients with CIS and those with no CIS.

## Conclusions

In this multi-institutional review of a pretreated patient population with moderate follow-up, the intravesical administration of Gemcitabine and Docetaxol is safe, well tolerated, and efficacious in preventing recurrence in patients with recurrent, NMIBC after BCG failure. BCG failure number and category, clinical T stage, and the presence of CIS did not impact treatment success while the administration of maintenance therapy significantly improved RFS. Prospective and mechanistic research is warranted.

*Source of Funding:* John & Carol Walter Family Foundation

## Oncology—Kidney

### A SIMPLIFIED EQUATION TO ESTIMATE NEW BASELINE RENAL FUNCTION AFTER RADICAL OR PARTIAL NEPHRECTOMY: DEVELOPMENT AND VALIDATION

Diego Aguilar Palacios\*, Brigid Wilson, Mustafa Ascha, Sunah Song, Molly E. DeWitt-Foy, Steven C. Campbell, Robert Abouassaly, Cleveland, OH

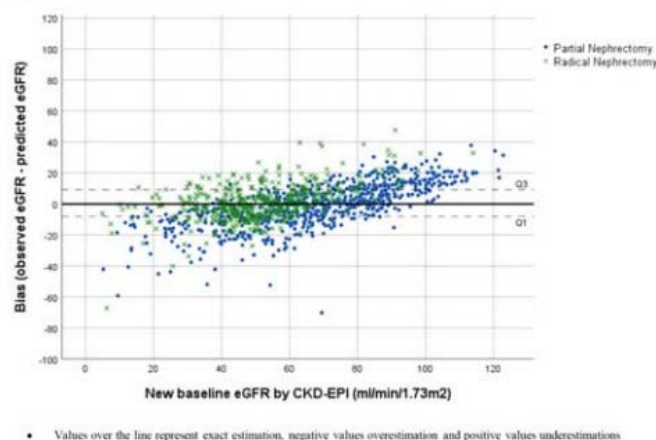
## Introduction and Objective

Preoperative estimation of new baseline glomerular filtration rate (GFR) after renal surgery for RCC has important clinical implications. Here we develop and externally validate an equation to estimate postoperative new baseline GFR.

## Methods

A cohort of 8080 kidney cancer patients undergoing partial or radical nephrectomy (2005 -2015) in the veteran's affair national health system was identified. All patients had both preoperative and new baseline GFR estimations by CKD-EPI. New baseline GFR was defined as the last GFR value 1-12 months after surgery. Patients with preoperative end-stage renal disease were excluded. Multivariable linear regression was used to create an equation to predict new baseline GFR using two-thirds of the cohort. The simplest equation with highest  $R^2$  was selected and tested. The equation was then internally validated in the remaining third of the cohort. For external validation, a cohort of 1121 patients from an outside tertiary care center was used. Correlation ( $R^2$ ), bias (median of observed GFR – predicted GFR), accuracy (percentage of predicted GFR values within 30% of observed GFR) and precision (interquartile range of observed GFR – predicted GFR) of equation were examined.

Figure 1. External validation.



## Results

Per multivariable analysis new baseline GFR =  $18.10 \pm$  preoperative GFR ( $\times 0.70$ ) – 17.89 (if radical nephrectomy) – 1.40 (if hypertension) – 2.20 (if diabetes).  $R^2$ /bias/accuracy/precision of equation were 0.64/-1.06/80/-8.7-7.4 and 0.64/0.87/79/-8.1-9.1 in the internal and external validation cohorts, respectively.

## Conclusions

Our analysis provides a simplified equation to predict postoperative new baseline renal function after renal surgery in kidney cancer patients that is highly accurate and externally validated.

*Source of Funding:* Merit Pilot Award #PPO 17-216, VA Grant

## SPLIT RENAL FUNCTION IN PATIENTS WITH RENAL MASSES: UTILITY OF PARENCHYMAL VOLUME ANALYSIS VERSUS NUCLEAR RENAL SCANS

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### Introduction and Objective

To evaluate the utility of parenchymal volume analysis (PVA) for estimation of split renal function (SRF) in patients with renal masses needing surgical management. Estimation of SRF is important in many patients with renal masses for deciding about partial versus radical nephrectomy and estimating the risk for developing severe chronic kidney disease. For potential renal donors PVA is used to estimate SRF, but the utility of this approach in the more complex renal mass patient population has not been defined.

### Methods

All patients from our center (n=374) with renal tumors and a normal contralateral kidney managed with partial nephrectomy (2010-2018) with preoperative/postoperative nuclear-renal scans (NRS) and cross-sectional imaging were analyzed. Parenchymal volumes were measured by freehand scripting or software analysis. Ipsilateral estimated glomerular filtration rate (eGFR) values based on SRF from NRS versus those based on PVA were evaluated by Pearson correlation. Concordance between different methods of estimation of ipsilateral eGFR values were analyzed by Bland-Altman plots.

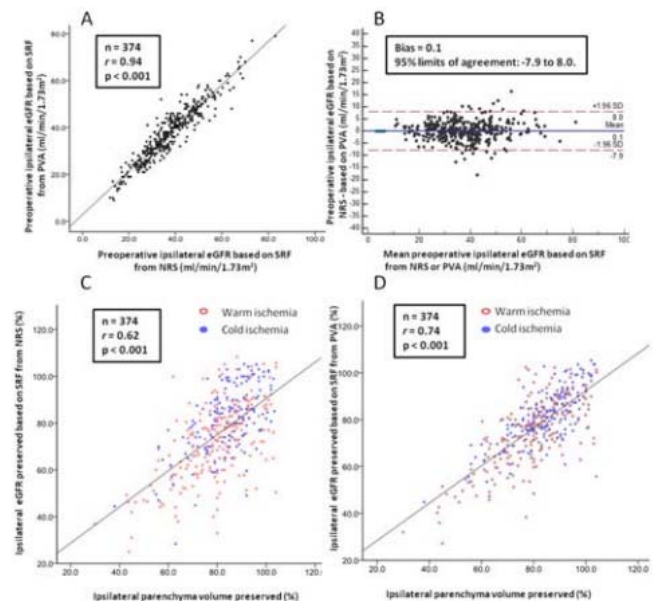
### Results

Median age and tumor size were 62 years and 3.4cm, respectively. The median preoperative ipsilateral parenchymal volume and eGFR were 181cm<sup>3</sup> and 36.9mL/min/1.73m<sup>2</sup>, respectively. Parenchymal volumes estimated by freehand scripting versus software analysis correlated strongly ( $r=0.98$ ,  $p<0.001$ ). Preoperative ipsilateral eGFRs based on SRF from PVA versus NRS were strongly correlated ( $r=0.94$ ,  $p<0.001$ )(Figure 1A-B). Ipsilateral eGFR saved after partial nephrectomy correlated strongly with parenchymal volume preserved (all  $r>0.60$ )(Figure 1C-D); however, the correlation was much stronger when ipsilateral eGFRs were based on SRF from PVA rather than NRS (z-statistic=3.15,  $p=0.0016$ ).

### Conclusions

Parenchymal volume analysis (PVA) has utility for estimation of split renal function in patients with renal masses who are candidates for partial nephrectomy, even though this population is older and more comorbid than renal donors, and

the tumor(s) can complicate the analysis. PVA can be obtained by software analysis from preoperative cross-sectional imaging and thus readily incorporated into routine clinical practice.



*Source of Funding:* None.

## HOSPITAL-LEVEL QUALITY INDICATORS FOR KIDNEY CANCER SURGERY: A VETERAN'S AFFAIR NATIONAL HEALTH SYSTEM VALIDATION OF CONCEPT

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### Introduction and Objective

Validation and implementation of quality indicators (QIs) for oncological surgical care is imperative in national health care systems. However, QIs must be adjusted for significant case-mix variations among hospitals and to capture disparate patient outcomes. Here, we explore and validate a compound quality score (CQS) as a metric for hospital-level quality of care in kidney cancer patients.

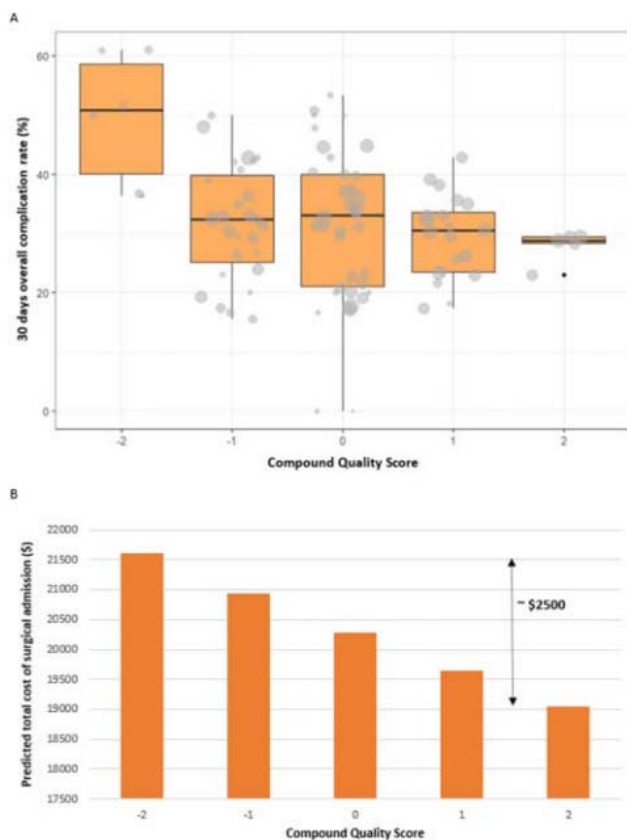
### Methods

Kidney cancer patients (n=8233) treated at the VA (2005-2015) were identified. Two previously described and validated process QIs were explored: the proportion of patients with a) T1a tumors undergoing partial nephrectomy; and b) T1-T2 tumors undergoing minimally invasive radical nephrectomy. Demographics, comorbidity, tumor characteristics and treatment year were used for case-mix adjustment using indirect standardization / multivariable regression models. The predicted vs observed ratio of cases was calculated to generate each QI score. CQS represents the sum of both QIs scores. Ninety-six hospitals were benchmarked by CQS and patient-level outcomes were regressed on CQS levels to assess

for length of stay (LOS), 30 days complications/readmission, 90 days overall mortality and total cost of surgical admission.

## Results

CQS identified 25, 33 and 38 hospitals with higher, lower and average performance, respectively. Total CQS score was independently associated with LOS [ $\beta = -0.04$ ,  $p < 0.01$ , predicted LOS 0.84 days shorter for CQS = 2 vs. CQS = -2], 30 days surgical complications [OR = 0.88,  $p < 0.01$ ] or 30 days medical complications [OR = 0.93,  $p < 0.01$ ] and total cost of surgical admission [ $\beta = -0.014$ ,  $p < 0.01$ , predicted 12% lower cost for CQS = 2 vs. CQS = -2]. No association was found between CQS and 30 day readmissions or 90 days mortality (all  $p > 0.05$ ), although low event rates were observed (8.9% and 1.7%, respectively).



## Conclusions

Variability in quality of surgical care at a hospital-level can be captured with the CQS among kidney cancer patients. CQS is associated with length of stay, post-operative complications and total cost of surgical admission. Quality indicators should be used to identify, audit and implement quality improvement strategies across health systems.

Source of Funding: Merit Pilot Award #PPO 17-216, VA Grant

## PARTIAL NEPHRECTOMY FOR PATIENTS WITH SEVERE CKD: IS IT WORTHWHILE?

Diego Aguilar Palacios\*, Jianbo Li, Furman Mahmood, Robert Abouassaly, Steven C. Campbell, Cleveland, OH

## Introduction and Objective

Partial nephrectomy (PN) is prioritized over radical nephrectomy (RN) in patients with CKD whenever feasible. However, we hypothesized that some patients with severe CKD might rapidly progress to end stage renal disease (ESRD), in which case the morbidity that can be associated with PN would not be justified.

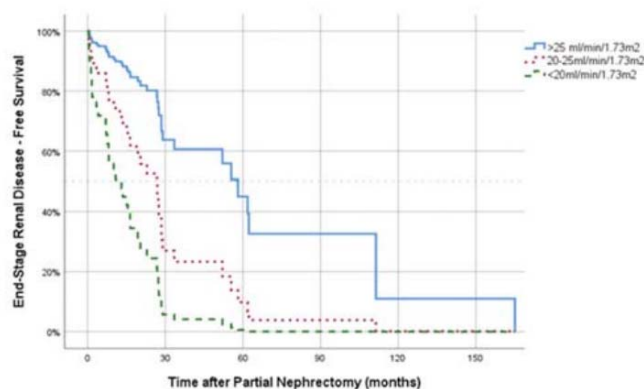
## Methods

Retrospective review of all 62 patient with stage IV CKD undergoing PN (1999-2015) was performed to evaluate preoperative/intraoperative factors and postoperative outcomes. ESRD was defined as postoperative initiation of permanent dialysis or  $eGFR < 15 \text{ mL/min/1.73m}^2$ . Survival analyses were used to evaluate factors associated with time to progression to ESRD.

## Results

Median age was 67 years, 71% of patients were male and 84% were Caucasian. Comorbidities included hypertension (94%), cardiovascular disease (53%), diabetes (32%), and tobacco use (58%), and median preoperative  $eGFR$  was  $23 \text{ mL/min/1.73m}^2$ . Open PN was performed in 45 patients (73%). Benign pathology was found in 10 patients (16%) and 7 had locally-advanced disease (11%). Unfavorable perioperative outcomes occurred in 15 patients (24%) defined as 90 day-mortality (3%), postoperative Clavien complication  $\geq IIIb$  (14%), or positive surgical margin (12%). Median time to progression to ESRD was only 27 months, and only 14 months in patients with preoperative  $GFR < 20 \text{ mL/min/1.73m}^2$ . In contrast, median time to progression to ESRD was 58 months in patients with preoperative  $GFR > 25$ . On multivariable analysis African-American race [HR: 2.55 (1.10-5.95)], preoperative  $eGFR$  20-25 or  $< 20$  [HR: 2.59 (1.16-5.84) and 5.03 (2.03-12.44), respectively] and minimally invasive approach [HR: 2.05 (1.01-4.19)] were independently associated with progression to ESRD.

Figure 1. Kaplan-Meier curves for end-stage renal disease – free survival stratified by preoperative GFR.



## Conclusions

Our data suggest that patients with stage IV CKD undergoing PN tend to have substantial comorbidities and are at risk for unfavorable perioperative outcomes and rapid progression to ESRD. Alternate strategies such as renal mass biopsy for



oncologic risk stratification, active surveillance, or RN (either upfront or after progression to ESRD) may be more appropriate, particularly if PN is high complexity and African-American or when preoperative GFR<25.

*Source of Funding:* None

## DOES REDUCED RENAL FUNCTION PREDISPOSE TO CANCER-SPECIFIC MORTALITY DUE TO RCC?

Diego Aguilar Palacios\*, Emily Zabor, Furman Mahmood, Brigid Wilson, Robert Abouassaly, Steven C. Campbell, Cleveland, OH

### Introduction and Objective

A recent publication in European Urology reported an association between reduced renal function following nephrectomy and increased cancer-specific mortality (CSM) in kidney cancer patients, suggesting that partial nephrectomy (PN) should be prioritized whenever feasible. We hypothesized that this association might be related to confounding factors such as tumor characteristics rather than a direct effect of functional differences.

### Methods

Retrospective review of 1396 patients undergoing PN/RN (1999-2008) for clinically localized RCC (no apparent venous or lymph node involvement and M0) was performed. Benign tumors were excluded. All patients were required to have preoperative and new baseline GFR estimations by CKD-EPI. New baseline GFR was defined as the average of GFR values 1-12 months after surgery. Associations of preoperative and new baseline GFR with CSM were investigated in a Cox regression analysis adjusting for tumor-related parameters.

### Results

Median age was 60 years and 64% were male. Comorbidities included HTN (52%), CKD (21%), DM (18%) and cardiovascular disease (18%). PN was performed in 867 patients (62%). Median preoperative/new baseline GFR levels were 80/60 mL/min/1.73m<sup>2</sup>, respectively. Median tumor diameter was 3.5 cm, 70% of cases were clear cell, 39% high grade, 26% had histologic necrosis and 2% sarcomatoid features. Pathology revealed stage T3a or greater in 18% and positive margins in 3%. Median follow-up among survivors was 10.2 years (IQR=3-13). Overall survival was 88%/73% and CSM-free survival was 96.2%/93.6% at 5/10 years, respectively. On multivariable analysis increased age [HR 1.03, p= 0.02], increased tumor size [HR 1.26, p<0.01], tumor grade III/IV [HR 2.78, p<0.01], and clear cell histology [HR 3.02, p<0.01] were associated with increased hazard of CSM. Neither preoperative GFR nor new baseline GFR, treated as time-dependent, were associated with CSM on MVA (p=0.6 and 0.9, respectively).

### Conclusions

Our data confirm that CSM for RCC is primarily associated with aggressive tumor characteristics, and do not support oncologic protection related to greater preservation of renal function although further research will be required. The relative

indications for PN/RN remain unclear, particularly for tumors with increased oncologic potential and high tumor complexity.

Multivariable analysis for factors associated with kidney cancer-specific mortality			
	HR	95% CI	P
Age	1.03	1.01, 1.06	<b>0.020</b>
Sex			0.6
Female	—	—	
Male	1.13	0.68, 1.88	
Tumor size*	1.26	1.20, 1.32	<b>&lt;0.001</b>
Histology			<b>&lt;0.001</b>
Other	—	—	
Clear cell carcinoma	3.02	1.49, 6.14	
Tumor grade			<b>&lt;0.001</b>
I/II	—	—	
III/IV	2.78	1.56, 4.94	
Pre-op eGFR (per 10 units)	1.04	0.90, 1.19	0.6
New baseline eGFR (per 10 units)	1.01	0.85, 1.21	0.9
*Tumor stage was also a significant and independent predictor of CSM but was not added to this model due to very strong collinearity with tumor size.			

*Source of Funding:* none

## THE IMPACT OF CASE ORDER ON POSITIVE SURGICAL MARGINS FOR PROSTATE CANCER: A MULTI-INSTITUTIONAL ANALYSIS

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### Introduction and Objective

Our aim was to evaluate whether sequential surgeries result in worse outcomes, such as positive surgical margins (PSM), in patients undergoing robotic-assisted laparoscopic prostatectomy (RALP), by comparing the second surgery to the first.

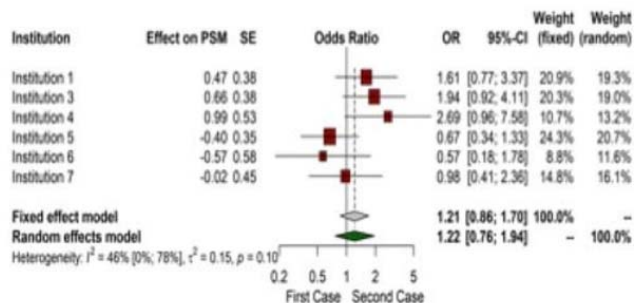
### Methods

We retrospectively analyzed 898 RALP cases (449 sequential pairs) across eight institutions, from 1/1/2015-07/1/2018. Pooling the data across eight institutions, we calculated odds ratio (OR) and 95% confidence intervals (95% CI) using multivariable logistic regression models, adjusting for age, BMI, PSA, Grade, Tumor Involvement, EPE, and SVI, modeling PSM as the dependent variable, and case sequence as the independent variable of interest. Due to potential heterogeneity between institutions, we then conducted a meta-analysis to calculate a random-effects OR.

### Results

A total of 898 RALP cases were included in this study, across 8 institutions. There were no differences between the first and

the second cases of the day in PSA (6.2 ng/mL vs 6.3 ng/mL) total lymph node yield (12.0 vs. 11.0), seminal vesicle invasion (49% vs 52%), operative time (216.0 mins vs 220.0 mins), BMI (28.4 kg/m<sup>2</sup> vs 28.6 kg/m<sup>2</sup>), prostate volume (45.1 g vs 45.2 g) and positive surgical margin rate (n=121 vs n=135). The second case of the day more likely to have higher prostatic involvement (p=0.02), as well as higher blood loss (p=0.25). In multivariable models, there were no differences in positive surgical margin (PSM) between the first and the second cases of the day. However, SVI (OR 1.92), EPE (OR 2.05), tumor involvement (OR 1.03), PSA (OR 1.02) as well as individual institution were statistically significantly associated with an increased risk of positive surgical margin.



## Conclusions

Data from our multi-institutional study suggests no statistically significant difference in lymph node yield, operative time, or PSM between the first and the second RALP of the day. Despite the lack of statistical significance by conventional parameters, there is a strong trend for increased rate of PSM in the second prostatectomy of the day in select patients. Disease specific factors such as EPE, SVI, PSA, tumor involvement as well as institutional experience are all associated with increased risk for positive surgical margin.

Source of Funding: None.

## Oncology—Prostate

### PREDICTORS ASSOCIATED WITH A PROLONG HOSPITAL STAY AFTER SINGLE-PORT ROBOTIC RADICAL PROSTATECTOMY: A COMPARATIVE ANALYSIS OF OUTPATIENT VERSUS INPATIENT CARE

Alireza Aminsharifi\*, Guilherme Sawczyn, Soodong Kim, Clark A. Wilson, Juan Garisto, Jihad Kaouk, Cleveland, OH

#### Introduction and Objective

At our institute with recent implementation of single-port robotic prostatectomy using da Vinci SP® system (Intuitive Surgical, Sunnyvale, CA), a significant amount of patients were discharged a few hours after their surgery without need for hospital admission. In the present study, we present analyze and compare the perioperative characteristics of patients receiving outpatient versus inpatient care after single-port robotic prostatectomy. Moreover, to our knowledge, this is

the first ever reported comparative trial to examine the predictors of inpatient care after single-port robotic prostatectomy.

#### Methods

Between February 2019 and June 2019, data on 61 patients underwent single-port radical prostatectomy were categorized into two groups: Patients received outpatient care (Group I [n=8]: discharged from the recovery room on postoperative day 0) and those with inpatient care (Group II [n=13]: patients stayed ≥24 hours after the surgery). Demographics and perioperative data were recorded and analyzed between the two groups. Multivariable binary logistic regression was used to determine the factors associated with inpatient care.

#### Results

During the study period, most patients (48/61: 78.7%) were discharged a few hours (Median: 4.2 hours) after the surgery (outpatient care: Group I), while others (Group II) received inpatient care (Median hospital stay: 32 hours p <0.00001). The operative time was significantly shorter in patients with outpatient prostatectomy (p=0.003). More than 90% of patients in this group were operated through extraperitoneal approach (p=0.002). Pain score at the time of discharge was similar in both groups, however, the rate of narcotic administration was significantly greater in patients with inpatient care (61.5% versus 22.9%, p=0.01). Moreover, the amount of narcotics per patient (if administered) was also significantly greater in this subgroup (p=0.008) With multivariable regression analysis, a longer operative time (odds ratio [OR]: 1.15 95% CI 1.10-1.29, p=0.026) as well as a higher dose of administered narcotic after the operation (OR: 1.25 95% CI 1.04-1.49, p=0.018) were significant predictors of an increased odds of inpatient care after single-port robotic prostatectomy.

#### Conclusions

A safe transition to outpatient care protocol is feasible after implementation of single-port robotic prostatectomy. A longer operative time and the amount of received narcotic after the procedure were the most significant predictors of prolong hospital stay after single-port robotic prostatectomy in this study. Both predictors can be improved with modifications in surgical techniques, intraoperative and postoperative pain management protocols. Interventional trials for development of outpatient protocols after single-port robotic surgery although difficult to undertake would be highly advisable.

Source of Funding: None.

## COMPARISON OF MICRO-ULTRASOUND AND MULTIPARAMETRIC MRI IMAGING FOR PROSTATE CANCER: A MULTICENTRE PROSPECTIVE ANALYSIS

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### Introduction and Objective

This study aims to compare the sensitivity, specificity, NPV and PPV of mpMRI with the novel high-resolution micro-ultrasound imaging modality. This approach offers the benefits of simplicity, a single intervention for imaging and biopsy, leveraging the low cost of ultrasound. Micro-ultrasound may be used to image suspicious lesions and target biopsies in real-time with or without additional MRI-based targets.

### Methods

Data from 9 sites was aggregated, totaling 866 subjects presenting for ExactVu micro-ultrasound guided biopsy with available mpMRI studies. Samples in all subjects were taken from mpMRI targets and micro-ultrasound targets, with up to 12 systematic samples filled in. Various strategies were used for mpMRI target sampling including cognitive fusion with micro-ultrasound, separate software-fusion systems, and software-fusion using the microultrasound FusionVu system. Clinically significant cancer was considered any Gleason Sum > 6 and targeted samples were taken for PI-RADS > 2 or PRI-MUS<sup>1</sup> > 2 lesions.

### Results

Overall, 39% of all biopsy cases were positive for clinically significant PCa. mpMRI demonstrated 89% sensitivity and NPV of 77%. Compared to mpMRI, micro-ultrasound sensitivity (95%) and NPV (87%) were higher. Micro-ultrasound was less specific (21% vs 23% for mpMRI) with similar PPV (44% vs 43%). The aggregate effect demonstrates higher sensitivity for csPCa with micro-ultrasound compared to mpMRI ( $p < 0.01$ ).

### Conclusions

Micro-ultrasound is an attractive option for screening and targeted biopsy. Sensitivity and NPV appear superior to MRI, but specificity is mildly reduced. Further larger-scale studies are required for validation of these findings.

### References

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Source of Funding: None

## TREATMENT INTENSIFICATION AND OUTCOME IN HIGH-RISK PROSTATE CANCER: A MULTI-INSTITUTIONAL CONSORTIUM ANALYSIS

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### Introduction and Objective

External beam radiotherapy (EBRT) with androgen deprivation therapy (ADT), EBRT with a brachytherapy boost (EBRTpBT) with ADT, and radical prostatectomy (RP) with or without postoperative therapy are standard of care options for NCCN high-risk prostate cancer (HRPCa). Treatment intensification has been associated with improved outcomes, but the comparative effectiveness of these treatments remains unclear and analyses are complicated by the heterogeneity of outcomes within HRPCa. The goal of this study was to compare prostate cancer-specific mortality (PCSM) outcomes for patients receiving maximal treatments across modalities.

### Methods

Individual patient data were for 9775 patients who received definitive treatment for HRPCa between 2000-2013 across multiple institutions. Unfavorable HRPCa was defined by the presence of any primary Gleason grade 5, cT3b-4,  $\geq 50\%$  cores positive on biopsy, or  $\geq 2$  NCCN high risk features. Maximal treatment was defined as follows: RP with adjuvant radiotherapy (Max RP), EBRT with  $\geq 2$  years ADT (Max EBRT), and EBRT+BT with  $\geq 1$  year ADT (Max EBRT+BT). Fine-Gray competing risks regression models with the inverse probability of treatment weight were used to evaluate PCSM outcomes across groups. Propensity scores included age-at-treatment, initial PSA, clinical T stage, and Gleason grade group as covariates.

### Results

Median follow-up was 6.1 years. 7551 patients were classified as having favorable ( $n=2185$ ) and unfavorable ( $n=5366$ ) HRPCa. Among favorable HRPCa patients, proportions of maximal therapy receipt were as follows: 31/1525 (2.1%) RP, 123/384 (32%) EBRT, and 33/276 (11.9%) EBRT+BT. For unfavorable HRPCa, these proportions were: 201/3016 (6.6%) RP, 663/1573 (42.1%) EBRT, and 201/777 (25.8%) EBRT+BT. Patients with unfavorable HRPCa had significantly higher rates of PCSM than those with favorable HRPCa ( $p < 0.01$ ). No significant differences in PCSM were identified when comparing types of maximal treatment.

Treatment Comparison	Favorable HRPc sHR	Unfavorable HRPc sHR
Max EBRT vs Max EBRT+BT	Unstable*	1.44 (0.82-2.52)
Max EBRT vs Max RP	0.26 (0.006-10.48)	0.80 (0.43-1.52)
Max EBRT+BT vs Max RP	Unstable*	0.56 (0.28-1.13)
sHR=subdistribution hazard ratio		
*unstable estimate due to low event rates		

## Conclusions

In this large multi-institutional study, we identified favorable and unfavorable subgroups of HRPc with significantly different PCSM outcomes. No significant differences in PCSM were appreciated between maximal treatments. Unfortunately, these maximal treatments are underutilized across all modalities.

Source of Funding: None

## THE ISOPSA ASSAY IS SENSITIVE FOR BIOPSY-IDENTIFIED CRIBRIFORM PATTERN 4 GLANDS AND INTRADUCTAL CARCINOMA OF THE PROSTATE

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## Introduction and Objective

IsoPSA is a novel structure-based serum assay that measures the relative concentration of PSA isoforms altered by disrupted cellular processes. IsoPSA-based early detection protocols may reduce the number of unnecessary biopsies performed, as IsoPSA has an improved specificity compared to serum total PSA. If the IsoPSA Assay is to be used for the early detection of prostate cancer, it must not miss potentially lethal cancers, including cribriform pattern 4 glands and intraductal carcinoma of the prostate (CC and IDC). Here we report on the sensitivity of IsoPSA for detecting CC and IDC.

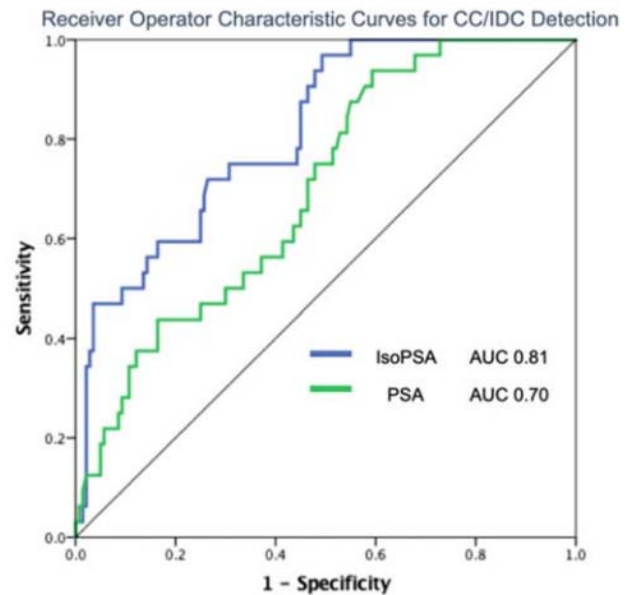
## Methods

A genitourinary pathologist re-reviewed biopsies of men that underwent prostate biopsy as part of a previously published prospective IsoPSA validation cohort. Men were designated for biopsy by typical screening indications. All patients underwent total PSA and IsoPSA testing. The previously established cutoff of IsoPSA K  $\geq 8.5$ , which corresponds to a 17% likelihood of possessing high-risk prostate cancer, was used to determine whether men would have been biopsied by an IsoPSA-based early detection protocol. The primary outcome was the sensitivity of the IsoPSA Assay for CC/IDC containing tumors. The discriminatory power of serum total PSA and IsoPSA were compared by receiver operating characteristic curves.

## Results

172 men underwent prostate biopsy, 58.7% (101/ 172) of whom were diagnosed with prostate cancer. Of men with prostate cancer, 31.7% (32/101) possessed biopsy-identified CC/IDC. The IsoPSA Assay was 100% sensitive for identifying these potentially lethal cancers, 100% (32/32) had an IsoPSA K  $\geq 8.5$ . The area under the curve for IsoPSA was 0.81 compared to 0.70 for serum total PSA (figure 1). 29.1% (50/172) of

patients had an IsoPSA K  $< 8.5$  and may have been spared prostate biopsy.



## Conclusions

IsoPSA, a novel structure-based assay for PSA isoforms, is highly sensitive for tumors containing biopsy-identified CC/IDC. A reduction in unnecessary biopsies resulting from use of IsoPSA will not result in an increase in missed aggressive, potentially lethal subtypes of prostate adenocarcinoma.

Source of Funding: None

## CLINICAL UTILITY OF PSA DENSITY AND PI-RADS FOR DEFERRING BIOPSY FOR THE DETECTION OF CLINICALLY SIGNIFICANT PROSTATE CANCER

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## Introduction and Objective

We sought to identify PSA density (PSAD) and Prostate Imaging-Reporting and Data Systems (PI-RADS) category cut-offs that would allow deferring biopsy in men with suspicion for clinically significant prostate cancer (csPca).

## Methods

Our institution's prostate MRI registry (n=1718) was queried for patients who had MRI-guided biopsy (MRI-GB) and/or systematic biopsy (SB) performed after prostate MRI between January 2013 and October 2018 (n=676). Patients in the diagnostic group (either biopsy naïve or with prior negative biopsy) and patients with PCa on active surveillance (AS) were considered eligible. PSA, PSAD, and PI-RADS category were entered into logistic regression models for predicting csPca (grade group [GG]  $\geq 2$ ) at biopsy. Receiver operating characteristic (ROC) analysis was performed to assess model accuracy and results were stratified by biopsy indication and PI-RADS categories.



## **Results**

Logistic regression models that combined PSAD and PI-RADS categories had the highest ROC's in both the diagnostic and AS groups (AUC=0.830 and 0.778, respectively). For diagnostic group patients with PSAD  $\leq 0.15$ , csPCa was found in 6/89 (6.7%) of negative MRI patients (i.e. PIRADS  $\leq 2$ ), 4/90 (4.4%) of PIRADS 3 patients, and 59/159 (37%) of PIRADS 4-5 patients. If a PSAD cutoff of  $\leq 0.15$  and PIRADS  $\leq 3$  MRI were used in combination as criteria for biopsy deferral, only 10/526 (1.9%) of patients would have had csPCa missed on subsequent biopsy, while sparing 134/526 (25.4%) men of biopsies in which no cancer was found and sparing 35/526 (6.7%) men of biopsies in which insignificant cancer was found. Among patients in the AS group with a negative MRI, 0/22 (0%) and 3/8 (37.5%) had csPCA if the PSAD was  $\leq 0.15$  and  $>0.15$ , respectively

## **Conclusions**

For the diagnostic group of patients undergoing prostate biopsy, PSAD cut off  $\leq 0.15$  is useful for deferring biopsy only in patients with PIRADS  $\leq 3$ . Confirmatory biopsy in patients should be strongly considered before enrolling patients in AS even in the setting of a negative MRI if the PSAD is  $> 0.15$ .

## **RISK STRATIFICATION FOR EQUIVOCAL PI-RADS 3 RESULTS: CAN MICRO-ULTRASOUND HELP DETERMINE WHICH MEN TO BIOPSY?**

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## **Introduction and Objective**

Reducing unnecessary prostate biopsy procedures is an important clinical goal to reduce pain and anxiety for the patient, as well as the risk of infection and overtreatment. Multiparametric (mpMRI) has been proposed as an effective strategy to reduce the need for a prostate biopsy both in the initial and in the repeat biopsy setting. However, indeterminate or equivocal findings at mpMRI can pose a diagnostic challenge. We aimed to determine whether micro-ultrasound could help to further stratify the need for a prostate biopsy in patients with PIRADS 3 lesion at mpMRI.

## **Methods**

This study was based on a retrospective series of patients presenting with at least one PI-RADS 3 lesion at mpMRI at one of 7 international sites. All patients were imaged with micro-ultrasound using the ExactVu™ (Exact Imaging, Markham, Canada) system, and the presence of suspicious lesions was determined and graded according to the PRI-MUS™ (Prostate risk identification using micro-ultrasound)1 protocol. Maximum PRI-MUS score for each subject was used to determine whether the case was non-suspicious on micro-

ultrasound (PRI-MUS 1 or 2), equivocal (PRI-MUS 3), or suspicious (PRI-MUS 4 or 5). All patients with a suspicious (PRI-MUS  $>2$ ) lesion were subjected to a micro-ultrasound guided targeted biopsy. In addition, mpMRI targeted biopsies on PI-RADS 3 lesions were also obtained either with a cognitive or with a fusion biopsy technique according to each center protocol.

## **Results**

144 subjects were included. Overall prostate cancer detection rate for PI-RADS 3 subjects was 48% (69/144), while 20% (29/144) of patients were diagnosed with a clinically significant prostate cancer defined as a ISUP Grade Group (GG)  $> 1$  tumor. PRI-MUS was able to provide significant risk stratification in this population, with non-suspicious micro-ultrasound imaging reducing the risk of finding GG $>1$  cancer by more than half to 5% (1/19). Equivocal micro-ultrasound provided little additional information with a GG $>1$  detection rate of 14% (5/35), while suspicious micro-ultrasound imaging resulted in a significant 17% relative increase in GG $>1$  detection rate to 26% (29/90,  $p=0.02$ ).

## **Conclusions**

Micro-ultrasound imaging and PRI-MUS protocol findings appear to provide useful additional information in the case of equivocal mpMRI results. When combined with other clinical risk indicators such as PSA, PSA density and family history, it may be possible to better advise patients on the necessity of a biopsy using this data.

*Source of Funding:* None.

## **A 17-GENE GENOMIC ASSAY AS A PREDICTOR OF OUTCOMES IN AFRICAN AMERICANS WITH PROSTATE CANCER**

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## **Introduction and Objective**

Adoption of prognostic molecular assays for prostate cancer (PCa) requires evidence of robust performance in different racial groups, especially in African Americans (AA), who have worse outcomes than Caucasian Americans (CA). Retrospective analysis was conducted to assess the performance of the Oncotype DX Genomic Prostate Score® (GPS™) test in AA versus CA.

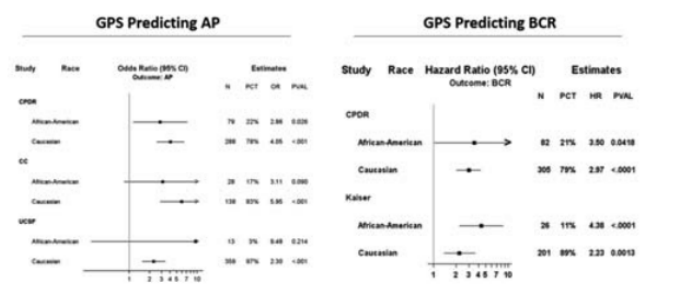
## **Methods**

Compared GPS results (scale 0-100 units (u)) and gene group scores in biopsies from 201 AA and 1144 CA with clinically localized PCa from 6 independent study cohorts (Ctr for Prostate Disease Research (CPDR); Veteran Healthcare Admin (VA); Cleveland Clinic (CC); Kaiser Permanente N. CA (Kaiser); UC San Francisco (UCSF); North Carolina-Louisiana Prostate Cancer Project (PCaP)). Four cohorts had outcome data after radical prostatectomy (RP): adverse pathology (AP): CC, CDPR,

& UCSF; biochemical recurrence (BCR): CPDR & Kaiser. In cohorts with AP and BCR, the association of GPS test with outcomes were compared. AP was defined as high-grade (Gleason  $\geq 4+3$  or any pattern 5) and/or non-organ-confined disease (pT3). Binary logistic regression models were used for AP. BCR was defined as 2 successive PSA levels  $>0.2$  ng/ml or initiation of salvage therapy. Cox proportional hazards models were used to evaluate the association of GPS test and race with time to BCR.

Results

Percent of AA in each cohort ranged from 3-57% (15% overall). Although each cohort had different baseline risk distributions and percentages of AA, median and interquartile ranges of GPS results and gene group expression patterns were similar between AA and CA in each cohort. In univariable analyses, GPS test was predictive of AP and BCR in AA and CA subsets (Figure). In a multivariable model with GPS test and clinical/pathological features including race, GPS test was significantly associated with AP (UCSF: OR/20 GPS  $u=1.93$ , 95% CI 1.26-2.98,  $p=0.002$ ; CPDR: OR/20  $u=2.63$ , 95% CI 1.69-4.18,  $p<0.001$ ) and BCR (CPDR: HR/20  $u=3.16$ , 95% CI 2.05-4.80;  $p<0.001$ ; Kaiser: HR/20  $u=2.13$ , 95% CI 1.41- 3.22,  $p<0.001$ ). In multivariable models, race was not a statistically significant predictor of either endpoint.



Conclusions

GPS assay is similarly predictive of outcomes in AA and CA PCa and appropriate for improving risk stratification in AA with newly diagnosed PCa.

Source of Funding: Genomic Health, Inc. and Department of Defense (for PCaP).