

## **A DOUBLE BLINDED RANDOMIZED CONTROLLED TRIAL OF CONTINUOUS INTRAVENOUS KETOROLAC VERSUS PLACEBO FOR POSTOPERATIVE PAIN CONTROL FOLLOWING RENAL SURGERY**

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(Presentation to be made by Dr. Grimsby)

**Purpose:** Ketorolac is a powerful non-opioid analgesic, but has been associated with hemorrhage and renal impairment. The goal of this study was to evaluate the safety and efficacy of a novel continuous intravenous ketorolac infusion for pain control after renal surgery.

**Materials and Methods:** A double-blinded prospective randomized controlled trial was performed comparing a continuous infusion of ketorolac versus placebo in patients undergoing laparoscopic donor nephrectomy (LDN) or percutaneous ultrasonic nephrolithotomy (PNL). The primary outcome measures were the 24 hour differences in visual analog pain scores and in total narcotic consumption. Secondary outcomes were side effects and complications between groups. Data was collected and analyzed via commercially available software. The study was stopped after an interim analysis because the difference in mean pain scores between the two groups (0.6) was smaller than the 1 point set forth in the power calculations.

**Results:** A total of 128 patients underwent randomization. Mean morphine equivalents of supplemental analgesics used was 3 mg lower in the ketorolac treated patients. Over a 24 hour period, patients treated with continuous ketorolac had a larger decrease in mean pain score (1.0-1.1) versus placebo (0.5-0.6). Urine output and hemoglobin were lower in the ketorolac group but there was no statistically significant change in serum creatinine and no patient required a blood transfusion.

**Conclusions:** While the decreased use of narcotics was modest, the novel approach of providing a continuous steady state of ketorolac offers a safe and efficacious therapeutic option for post-operative pain control for patients undergoing renal surgery.

**Source of Funding:** None

## **RADIATION DOSES RECEIVED DURING RADIOFREQUENCY ABLATION AND CRYOABLATION TREATMENT OF SMALL RENAL TUMORS**

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(Presentation to be made by Dr. Richards)

**Objectives:** Percutaneous radiofrequency ablation (RFA) and percutaneous cryoablation (cryo) have been accepted as alternatives to surgical therapies in the treatment of small renal masses. These treatments require image guidance and the most commonly performed guidance modality is computed tomography which may subject patients to high radiation exposures. There have been no previous studies examining the radiation doses received by patients treated with RFA and cryo. The primary objective of this study is to analyze and compare the radiation exposures associated with these treatment modalities.

**Methods:** An institutional review board approved retrospective review of patients undergoing RFA or Cryo between 2004 and 2010 was performed. All patients with solitary renal tumors < 4.0 cm who were treated with either one of the percutaneous ablative techniques were identified. The time of the procedure, in minutes, was determined for each patient. Radiation dose was measured in mGy-cm and was recorded as the dose length product by the GE Lightspeed VCT scanner (16 slice). Data were analyzed using independent samples T-test and Pearson Chi-Square.

**Results:** Fifty-six patients with small renal masses were treated with a percutaneous ablation technique (24 RFA and 32 cryo). There was no difference between the groups in ASA score ( $p=0.33$ ), sex ( $p=0.19$ ) or age ( $p=0.55$ ). The mean procedure time for RFA and cryo was 61.4 and 89.4 minutes, respectively ( $p=0.001$ ). The mean number of probes between RFA and cryo was 1.3 and 3.4, respectively ( $p<0.001$ ). The mean number of CT scans between RFA and cryo was 10.9 and 16.4, respectively ( $p=0.002$ ). The mean DLP was analyzed for 41 patients who had dose reports available. The mean DLP (mGy-cm) for RFA ( $M=1460.77$   $SD=911.56$ ,  $N=13$ ) was significantly smaller than the DLP for cryo ( $M=2374.76$ ,  $SD=1666.21$ ,  $N=28$ ) using the two-sample t-test for unequal variances,  $p=0.03$ . Using conversion factors created by Huda et al, the effective doses of the ablative therapies in our study are 23.4 mSv for RFA versus 38.2 mSv for cryo.

**Conclusion:** Cryoablation resulted in significantly more radiation exposure, longer procedure times and a greater number of CT scans than RFA. Patients undergoing both percutaneous RFA and cryo are exposed to significant radiation exposures during treatment and this factor must be considered when selecting ablative strategies in young patients.

## **USE OF COMPUTED TOMOGRAPHY TO PREDICT RENAL TUMOR HISTOLOGY**

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(Presentation to be made by Dr. Kopp)

**OBJECTIVES:** Research in kidney tumor biology has identified distinct molecular pathways between histologic types of renal cell carcinoma (RCC). Diagnostic methods that differentiate RCC types will have an increasing role for targeted therapy. We investigated the use of multi-phase computed tomography (CT) with intravenous contrast to predict RCC histology.

**METHODS:** Retrospective cohort study of 141 patients with 4-phase CT for renal masses obtained between 10/2002 to 10/2010 confirmed by pathology [91 Clear Cell RCC (CC-RCC), 43 Papillary (Pa-RCC), 7 Chromophobe (Ch-RCC)]. Demographics and clinical characteristics were recorded. Imaging was interpreted by a radiologist (LA) who recorded tumor size, Hounsfield unit (HU) density measurements, tumor composition (homogeneous vs. heterogeneous), collecting system abutment, presence of tumor necrosis and cystic components. Data were analyzed within subgroups based on histology. Washout was calculated by the formula  $(\text{Mass Nephrographic HU} - \text{Mass Delayed HU}) / (\text{Mass Nephrographic HU} - \text{Mass Noncontrast HU})$  and used to calculate sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). Multivariate analysis (MVA) was conducted to identify factors predictive of histology.

**RESULTS:** Patient demographics were similar between groups except for significantly less tobacco use in the Ch-RCC group ( $p = 0.029$ ). Imaging demonstrated significant differences in median tumor size [CC-RCC 4.7 cm (range 2.8-7.2), Pa-RCC 2.7 cm (range 1.7-5.5), Ch-RCC 3.7 (range 3-8.5),  $p=0.008$ ], homogeneous composition (CC-RCC 6%, Pa-RCC 74%, Ch-RCC 86%,  $p<0.001$ ), collecting system abutment (CC-RCC 78%, Pa-RCC 47%, Ch-RCC 86%,  $p = 0.001$ ), and necrosis (CC-RCC 78%, Pa-RCC 21%, Ch-RCC 0%,  $p<0.001$ ). Washout value  $<0$  had a specificity and PPV of 100%, sensitivity of 50%, and NPV 78% for non-CC-RCC (Pa-RCC and Ch-RCC). Washout value  $\geq 0$  had sensitivity and NPV 100%, specificity 50%, and PPV 78% for CC-RCC. MVA demonstrated homogeneous composition was significantly associated with Pa-RCC (OR 63.9, 95% CI 8.1-507,  $p<0.001$ ).

**CONCLUSIONS:** Imaging characteristics may aid in distinguishing between different renal tumor histological subtypes. Washout value  $<0$  is highly specific for non-CC-RCC and washout value  $\geq 0$  is highly sensitive for CC-RCC. Homogeneous tumor composition is significantly associated with Pa-RCC. These findings may provide a further tool in clinical decision making. Additional investigation is requisite.

## **ACCURACY AND IMPLICATION OF PERCUTANEOUS RENAL BIOPSY IN THE MANAGEMENT OF RENAL MASSES**

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(Presentation to be made by Dr. Wuerstle)

**INTRODUCTION AND OBJECTIVES:** Percutaneous renal needle biopsy is gaining relevance and reemerging in clinical decision-making as the approach to management of renal masses is evolving. Particularly for small renal masses (SRMs) 4 cm or less, the clinical yield, determination of tumor histology, and prediction of final histologic subtype in biopsies for renal cell carcinoma may affect patient treatment options. We aim to characterize renal biopsy results in the recent decade, assess the accuracy of renal biopsy for predicting tumor histologic subtype and nuclear grade, and illustrate the role of renal biopsy in surgical versus nonsurgical management.

**METHODS:** A retrospective chart review was performed including patients in the Southern California Kaiser Permanente Medical Region that underwent either CT or ultrasound guided core percutaneous renal biopsy of a solid renal mass from January 2005 to December 2009. Patients were stratified by size of renal mass, comparing SRMs to larger renal tumors. Initial biopsy results including tumor histology and nuclear grade were evaluated and related to post-operative pathology specimens when surgery was performed.

**RESULTS:** The study included 126 patients (129 renal units with 132 biopsies). Sixty-three patients (50%) ultimately underwent surgery (23 partial and 40 radical nephrectomies). Patients who did not have surgical intervention tended to be older, average 68 years old versus 61 years old and had larger tumors 5.8 cm versus 5.2 cm. The overall sensitivity for detecting cancer (verified by final pathology) in our series was 75.4% with 100% specificity. The positive predictive value for patients who underwent surgery was 100% and negative predictive value 11.7%. When evaluating factors associated with renal biopsy's accuracy of predicting cancer, larger tumor size had an adjusted odds ratio of 2.20 (0.547, 8.878, 95% CI) and increasing number of biopsy samples >3 had an adjusted odds ratio of 2.50 (0.586, 10.694, 95% CI).

**CONCLUSIONS:** Percutaneous renal needle biopsy in the modern era has respectable sensitivity, excellent specificity and good concordance with final pathology. This modality can assist in clinical decision-making for renal masses, particularly for SRMs, as treatment options are expanding.

**SOURCE OF FUNDING:** Kaiser Permanente Southern California Regional Research Committee

## **UNDER-GRADING ON RENAL BIOPSY IN PATIENTS WITH <4CM RENAL MASSES UNDERGOING ABLATION**

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(Presentation to be made by Dr. Harris)

**Purpose:** Ablative techniques for small renal masses have emerged as less invasive options to the gold standard surgical excision with comparable early oncologic outcomes. We seek to determine whether differences exist in tumor grade between patients who undergo nephron sparing surgery (NSS) and ablation.

**Material and Methods:** Data was obtained using the Surveillance, Epidemiology and End Results database. Patients with solitary renal tumors <4cm treated with ablation or NSS and with RCC histopathology were identified. Tissue diagnosis in the ablation specimens was obtained from biopsy reports, whereas tissue from NSS specimens was determined from surgical pathology. Variables analyzed include year of diagnosis, age, sex, race/ethnicity, marital status, population density, education, poverty level, and tumor size. Stacked bar graphs were created to compare the distributions of grade and histology between the two groups. Multinomial logistic regression was used to determine factors independently associated with grade.

**Results:** 7,704 (87.4%) patients underwent NSS, 1,114 (12.6%) underwent either radiofrequency ablation or cryoablation. NSS patients are younger at diagnosis (age 59 vs. 68,  $p<0.0001$ , more likely married (70% vs. 64%,  $p<0.001$ ), and had smaller tumors (2.4cm vs. 2.6cm,  $p<0.0001$ ). No differences were seen in the distribution of histology between NSS and ablation groups. Tumor grade was significantly lower in tumors treated with ablation. Compared to grade 1 disease, those undergoing ablation are 30% less likely to have grade 2 ( $p<0.001$ ), 30% less likely to have grade 3 ( $p<0.001$ ), and 92% less likely to have grade 4 disease ( $p<0.01$ ) when compared to those having NSS.

**Conclusions:** There is a strong association between grade and treatment type in patients with small renal masses after controlling for baseline characteristics. As grade is determined by different modalities, we believe that this shows systematic under-grading in biopsy of small renal masses.

**Source of Funding:** None

# 1<sup>ST</sup> PLACE WINNER – JOSEPH F. McCARTHY / OLYMPUS PHYSICIAN ESSAY CONTEST

## POPULATION BASED COMPARATIVE EFFECTIVENESS OF NEPHRON SPARING SURGERY VERSUS ABLATION FOR SMALL RENAL MASSES

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(Presentation to be made by Dr. Whitson)

**Purpose:** To determine in a population based cohort if disease specific survival is equivalent in patients undergoing ablation versus nephron sparing surgery (NSS) for clinical stage T1a renal cell carcinoma (RCC).

**Materials and Methods:** Patients in the Surveillance, Epidemiology, and End Results database with RCC < 4 cm and no evidence of distant metastases were identified and included if they underwent ablation or NSS. Kaplan-Meier and Cox regression analyses were performed to determine if treatment type is independently associated with disease specific survival.

**Results:** Between 1998 and 2007, a total of 8,818 incident cases of RCC were treated with either NSS (7,704) or ablation (1,114). Median follow-up was 2.8 years (IQR 1.2-4.7) in the NSS group and 1.6 years (IQR 0.7-2.9) in the ablation group, although 10% of each cohort had follow-up beyond 5 years. 716 (8.1%) patients died during follow-up of which 110 (15%) were due to RCC – 91 (1.2%) in the NSS group and 19 (1.7%) in the ablation group. At 5 years, DSS survival was high after both NSS (98.2%) and ablation (94.4%), although this difference appears to increase over time. After multivariable adjustment, ablation was associated with a 2-fold greater risk of kidney cancer death than NSS (HR 1.9, 95% CI 1.1-3.3, p=0.02). Age, gender, marital status, and tumor size were also significantly associated with outcome. In the typical patient presenting with a small renal mass, the adjusted predicted probability of disease specific survival at 5 years was 98.3% with NSS and 96.6% with ablation.

**Conclusions:** After controlling for age, gender, marital status, and tumor size, the typical patient presenting with clinical stage T1a RCC who undergoes ablation rather than NSS has a 2-fold increase in the risk of kidney cancer death. However, at 5 years the absolute difference is small, and may only be realized by patients with long life expectancies.

**Source of Funding:** None

## **DOES TIMING OF CYTOREDUCTIVE NEPHRECTOMY IMPACT PATIENT SURVIVAL WITH METASTATIC RENALCELLCARCINOMA IN THE TYROSINE KINASE INHIBITOR ERA?**

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(Presentation to be made by Dr. Stroup)

**INTRODUCTION AND OBJECTIVES:** Metastatic renal cell carcinoma (mRCC) has been associated with a poor prognosis. While multimodal treatment with cytoreductive nephrectomy (CN) was established in the immunotherapy era, the role of CN in the setting of targeted therapy has been questioned. We sought to compare our experience of mRCC patients undergoing CN followed by adjuvant tyrosine kinase inhibitor (TKI) therapy vs. those undergoing neoadjuvant TKI therapy prior to planned CN.

**METHODS:** We performed a retrospective, multi-institutional analysis of patients with mRCC from 5/2005 to 8/2009. The cohort was divided between those undergoing CN with adjuvant TKI therapy (Group 1) vs. those undergoing neoadjuvant TKI therapy followed by planned CN (Group 2). Patient demographics, clinical variables, and oncological outcomes were compared.

Response to therapy was determined using Response Evaluation Criteria Solid Tumors (RECIST). Patients in Group 2 who did not respond to TKI therapy (i.e, disease progression) were not offered CN, and were treated with salvage systemic therapy. Primary outcome measures were disease-specific (DSS) and overall survival (OS).

**RESULTS:** Of 35 patients with mRCC, 17 in Group 1 underwent primary CN and adjuvant TKI therapy, while 18 in Group 2 underwent neoadjuvant TKI therapy prior to intended CN. Patient demographic and tumor characteristics were similar between Group 1 and Group 2, including; age (years): 57 vs. 55,  $p=0.554$ , BMI (kg/m<sup>2</sup>): 29 vs. 28,  $p=0.521$ , ECOG status 0-1: 82% vs. 67%  $p=0.443$ , mean tumor size (cm):  $9.2\pm 2.5$  vs.  $10.4\pm 4.4$ ,  $p=0.378$ , and median length of follow-up (mo): 29.9 vs. 25.4,  $p=0.219$ ]. On univariate analysis, DSS and OS were no different among groups,  $p=0.721$  and  $p=0.579$ . In Group 2, 11 had a favorable response and 7 progressed despite therapy. Response to neoadjuvant therapy was highly predictive of DSS, with 1/7 (14.3%) non-responders by RECIST surviving vs. 6/7 (90.9%) of responders surviving,  $p<0.001$ . Kaplan Meier analysis of DSS remained significant among patients who underwent primary TKI followed by nephrectomy vs. those undergoing primary CN followed by adjuvant TKI ( $p=0.028$ ) vs. primary TKI non responders prior to planned nephrectomy ( $p<0.001$ ).

**CONCLUSIONS:** Non-responders to neoadjuvant TKIs have a particularly poor prognosis. Responders to TKI therapy who underwent CN had better DSS than patients who underwent primary CN followed by TKI therapy. Further investigation is required to assess the role, timing, and sequencing of targeted therapy and CN in the treatment of metastatic RCC.

**Source of Funding:** None

## ESTIMATING THE RISK OF CHRONIC KIDNEY DISEASE AFTER NEPHRECTOMY

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(Presentation to be made by Dr. Ngo)

**Purpose:** Predictors of postoperative chronic kidney disease (CKD) after kidney cancer surgery are not well characterized. We sought to identify factors associated with chronic kidney disease after nephrectomy and to create a predictive model estimating the risk of CKD for use in clinical practice.

**Materials and Methods:** We identified 144 patients from the Stanford Cancer Center Database (SCCD) who underwent kidney cancer surgery between 2007 and 2010 with normal to near-normal preoperative renal function and at least 30 days of follow up. Radical nephrectomy was performed in 66% (N=95) of patients. New onset CKD (Stage 3 or higher) developed in 62.5% (N=90) of the cohort. Univariate logistic regression was used to screen for significant predictors of CKD. Multivariate models identified independent predictors of CKD and their corresponding odds ratios. Model performance was assessed using 10-fold cross-validation.

**Results:** Univariate predictors of post-operative CKD included increasing patient age (OR=1.27 per 5 years, 95% CI: 1.07-1.51), worsening preoperative eGFR (OR=0.70 per 10 ml/min, 95% CI: 0.56-0.89), and receipt of radical nephrectomy (OR=4.78, 95% CI: 2.08-10.99) and remained independent predictors in multivariate analysis. The resulting model had an area under the curve (AUC) of 0.798. The 10-fold cross-validation slightly attenuated the AUC to 0.774. From this final model, we generated a nomogram to predict the probability of CKD (Figures 1 and 2).

**Conclusions:** Increasing patient age, worsening preoperative eGFR, and surgical approach independently predicted CKD in patients undergoing nephrectomy in a robust, cross-validated predictive model. External validation of this model is needed before adoption in clinical practice.

Figure 1 – Risk of CKD by Preoperative eGFR.

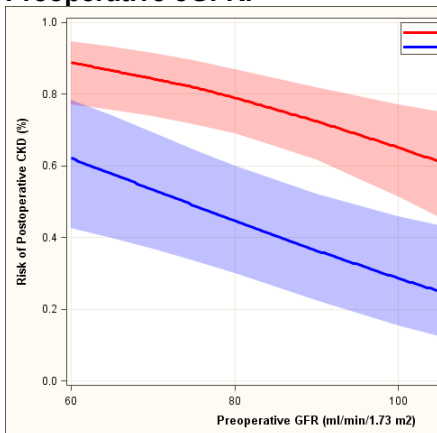
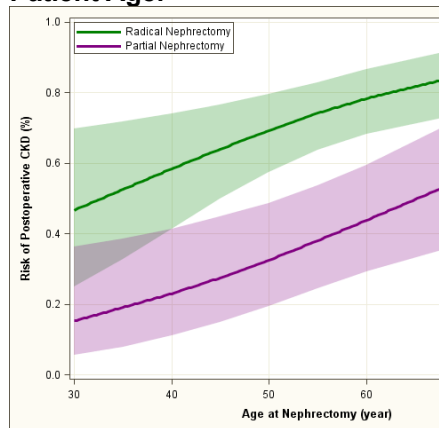


Figure 2 – Risk of CKD by Patient Age.



Risk of CKD as a function of GFR, keeping the age constant equal to the mean (57 years).

Risk of CKD as a function of age, keeping the preoperative GFR constant at the mean (85 ml/min/1.73 m<sup>2</sup>).

## **COMPARISON OF RATES AND RISK FACTORS FOR DEVELOPMENT OF ERECTILE DYSFUNCTION AFTER RADICAL OR PARTIAL NEPHRECTOMY**

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(Presentation to be made by Dr. Kopp)

**OBJECTIVES:** Nephron Sparing Surgery (NSS) has emerged as a preferred treatment option for small renal masses, comparing favorably with radical nephrectomy (RN) from the standpoint of oncologic efficacy and conferring superior renal functional preservation. Erectile function may be affected by declining renal function. We examined the incidence of and risk factors for development of erectile dysfunction (ED) in patients who underwent RN and NSS.

**METHODS:** Retrospective review of 432 patients (264 RN/168 NSS, mean age 58 years, mean follow-up 5.8 years) who underwent RN or NSS for renal tumors at two institutions from 1/1998 to 12/2007. Demographics and disease characteristics, metabolic parameters [estimated Glomerular Filtration Rate (GFR), serum creatinine, hyperlipidemia, diabetes mellitus (DM)], pre- and postoperative ED (Sexual Health Inventory for Men score <22) and response rate to 5-phosphodiesterase inhibitor therapy (5-PDEi) were recorded in sexually active men. Data were analyzed within subgroups based on treatment (RN vs. NSS). Multivariate analysis (MVA) was conducted to elucidate risk factors for development of de novo ED.

**RESULTS:** RN and NSS groups had similar demographics and comorbidities. Tumor size (cm) was significantly larger for RN (RN 7.0 vs. NSS 3.7,  $p < 0.001$ ). No significant differences were observed for preoperative eGFR, hyperlipidemia, and DM. Significantly more preoperative ED existed in NSS vs. RN ( $p = 0.042$ ). Postoperatively, significantly higher rates of de novo DM (11.4% vs. 4.2%,  $p = 0.015$ ), eGFR <60 mL/min/1.73m<sup>2</sup> (33.0% vs. 9.8%,  $p < 0.001$ ), and ED (29.5% vs. 9.5%,  $p < 0.001$ ) developed in RN vs. NSS cohorts, respectively. Overall response rate to 5-PDEi was 63% without significant difference between the two groups ( $p = 0.896$ ). MVA demonstrated RN (OR 3.56,  $p < 0.001$ ), hyperlipidemia (OR 2.32  $p = 0.014$ ), postoperative DM (OR 2.93,  $p < 0.001$ ), preoperative (OR 8.77,  $p < 0.001$ ) and postoperative (OR 2.64,  $p < 0.001$ ) eGFR <60mL/min/1.73m<sup>2</sup> were significantly associated with de novo ED.

**CONCLUSIONS:** Patients undergoing RN had significantly higher de novo ED compared to a contemporary, well-matched cohort undergoing NSS. RN, DM, and eGFR <60 were associated with development of ED. Further investigation on effects of nephron loss on ED is requisite.

## **2<sup>ND</sup> PLACE WINNER – MILEY B. WESSON / OLYMPUS RESIDENT ESSAY CONTEST**

### **VARIATION IN PREVALENCE OF AND RISK FACTORS FOR DEVELOPMENT OF DIABETES MELLITUS FOLLOWING RADICAL OR PARTIAL NEPHRECTOMY**

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(Presentation to be made by Dr. Kopp)

**OBJECTIVE:** Nephron Sparing Surgery (NSS) may have multiple metabolic benefits over radical nephrectomy (RN). We examined prevalence and risk factors for development of Diabetes Mellitus (DM) in patients undergoing NSS and RN.

**METHODS:** Retrospective review of 905 patients (mean follow-up 6.4 years) who underwent NSS or RN at two institutions from 7/1987-6/2007. Demographics, renal function and metabolic parameters [Body mass index (BMI), glomerular filtration rate (eGFR), proteinuria, serum creatinine] and history of preoperative and postoperative DM were recorded and analyzed between RN and NSS. Multivariate analysis (MVA) was conducted to elucidate risk factors for development of DM following surgery.

**RESULTS:** There were no significant differences with respect to mean follow-up, age, race, sex, or BMI. 610 patients underwent RN and 295 underwent NSS. Tumor size (cm) was significantly larger for RN (RN 7.0 vs. NSS 3.7,  $p < 0.0001$ ). Postoperatively, significantly more de Novo DM developed in the RN versus NSS cohort (RN 11.4 % vs. NSS 3.5%,  $p < 0.0001$ ). MVA demonstrated BMI  $> 30 \text{ kg/m}^2$  (OR 21.28,  $p < 0.0001$ ), history of HTN (OR 2.13,  $p = 0.0261$ ), preoperative eGFR  $< 60 \text{ mL/min/1.73m}^2$ , (OR 4.55,  $p = 0.0189$ ), preoperative proteinuria (OR 6.80,  $p = 0.0221$ ), postoperative eGFR  $< 60 \text{ mL/min/1.73m}^2$ , (OR 8.82,  $p < 0.0001$ ), postoperative proteinuria (OR 6.90,  $p < 0.0001$ ) and RN (OR 2.93,  $p = 0.0107$ ) as significantly associated with DM development.

**CONCLUSION:** RN had significant association with de Novo DM compared to NSS. BMI  $> 30 \text{ kg/m}^2$ , hypertension, preoperative eGFR  $< 60$ , preoperative proteinuria, postoperative eGFR  $< 60$ , and postoperative proteinuria were significantly associated with development of DM. Further investigation on effects of nephron loss on glucose metabolism is requisite.

**Source of Funding:** None

## **PANEL DISCUSSION**

### **Controversies and Management Options for Renal Ischemia During Partial Nephrectomy.**

**Moderator:  
Erik Castle, M.D.**

**Panelists:  
James Porter, M.D.  
Swedish Urology, Seattle, WA**

**&**

**Inderbir Gill, M.D.  
Chair, Department of Urology, Associate Dean for  
Clinical Innovation, USC**