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MP-09.01

Altered Expression of Sonic Hedgehog Pathway Intermediates in Renal Cell Carcinoma

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Introduction and Objectives: The sonic hedgehog (SHH) signal transduction pathway plays a central role in cell growth and differentiation during development. Its expression and activity have been shown to be aberrant in different kinds of cancer, but little is known about its role in kidney cancer. In the present study we analyzed expression of components of the SHH pathway in renal cell carcinoma.

Methods: Immunohistochemistry was performed on a commercial tissue microarray (TMA) containing 420 cores from 210 specimens obtained from partial or radical nephrectomy (US Biomax, Inc., Rockville, MD). All cores were clear cell carcinoma. The TMA was stained for the ligand sonic hedgehog, the receptor Smoothed and the receptor Patched. Staining intensity was graded from 0-3 by a pathologist (LF) in blinded fashion. A score was derived by multiplying the staining intensity by the percentage of surface area of the core with positive staining. These scores were normalized to the mean score of 28 cores of normal kidney on the TMA. The Kruskal Wallis test was used to compare staining score to pathologic stage and grade. There was no available clinical follow-up data. Expression of pathway intermediates was examined by Western blot in a single RCC cell line (CAKI-2) compared to a panel of bladder and prostate carcinoma cell lines.

Results: Sonic hedgehog ligand expression was low in normal kidney and increased by grade in RCC ($p < 0.001$). Patched expression also increased by grade in RCC ($p < 0.001$). Smoothed expression, in contrast, was highest in normal kidney ($p < 0.001$), decreased by 50% in low grade tumours, and increased again in intermediate and high grade tumours. Parallel but less pronounced changes were seen with tumour stage. All three components, as well as the ligand Indian hedgehog and the downstream effectors Gli-1 and Gli-2 were expressed at high levels in CAKI-2 when compared to prostate and bladder carcinoma cell lines, which is indicative of SHH pathway activity.

Conclusions: These results offer some preliminary indication that the regulation of the sonic hedgehog signaling pathway may be aberrant in renal cell carcinoma. Further investigations will be necessary to evaluate this pathway as a potential target for novel therapeutic agents.

MP-09.02

Nephron-Sparing Surgery for Renal Tumours in a Solitary Kidney

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Introduction and Objective: There is mounting evidence on the adverse effect of treatment induced renal function impairment on the survival of patients treated for renal tumours. Patients with solitary kidneys are clearly at risk for renal deterioration following even nephron-sparing surgery. We evaluate the effect of open partial nephrectomy on postoperative renal function in patients with a solitary kidney.

Materials and Methods: Of 145 consecutive patients who underwent partial nephrectomy at The Ottawa Hospital from 2002 to 2008, 17 had tumour in a solitary kidney. They underwent open partial nephrectomy with hilar clamping and surface renal cooling in all but one patient. Renal

surface cooling was achieved using ice-slush for 10-15 minutes. Renal function was estimated by calculating creatinine clearance (CrCl) using Cockcroft-Gault formula before and 3 months after the operation. 4 patients (23.5%) required short-term hemodialysis (HD) and only one patient (5.8%) required long-term HD. Univariate logistic regression analysis examining the effect of age at diagnosis, ischemia time, tumour size, preoperative CrCl, pre-existing diabetes mellitus and hypertension on 3 months post-operative CrCl and the need for short and long-term HD were performed.

Results: Mean patient age at diagnosis was 61.4 years with a mean follow-up period of 32.9 months. Mean tumour size was 2.86 cm and mean cold ischemia time was 39.7 minutes. Mean CrCl at baseline and 3 months post-operative were 72 and 61.8 ml/s respectively (p -value = 0.008). Postoperative CrCl was significantly affected by patient's age (p -value = 0.006) and baseline CrCl (p -value < 0.0001). Patient age, tumour size, ischemia time, baseline renal function and co-morbidity with diabetes or hypertension were not significant factors in determining the need for short or long-term HD.

Conclusions: Open partial nephrectomy results in a minor decrease in renal function in patients with a solitary kidney. This change in renal function although significant may not be clinically impactful. Patient age and preoperative renal function are important factors in predicting post-operative CrCl. The need for short and long-term HD was not determined by any preoperative or operative factor. Open partial nephrectomy should continue to be considered the treatment of choice in patients with tumours in a solitary kidney.

MP-09.03

A Classification Tree for Predicting Benign Histology in Renal Masses <5 cm Presumed to be Renal Cell Carcinoma

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Introduction and Objective: Most new renal masses are now diagnosed incidentally and frequently while still small in size. Most of these small renal masses (SRM) are treated with partial nephrectomy, procedure which has a significant amount of complications. Multiple series have reported a high proportion (up to 46%) of benign histology after surgical resection of these SRMs. There is a clear need for accurate prediction of benign disease. Multiple preoperative factors such as sex, age, tumour size and location have been implicated in the prediction of benign histology. We aimed to apply classification tree algorithms to discriminate between benign and malignant histology when SRMs are being evaluated preoperatively.

Methods: A classification tree was developed based on a cohort of 327 patients who underwent surgical management for presumed renal cell carcinoma <5 cm in largest diameter at our institution between July 1, 2001 and June 30, 2009. Age, sex, tumour size (largest bi-dimensional diameter in cm), tumour location (central vs. peripheral), degree of endophytic component (1-100%) and tumour axis location (according to the three renal axes) were used to develop the model.

Results: The overall incidence of benign disease was 11%. The classification tree partitioned the subjects into four disjoint sets differing in risk of benign histology based on a minimum of one and a maximum of three predictors: tumour location, degree of endophytic component and tumour size. As an example in one branch of the tree, patients who had periph-

eral tumours, with a >45% endophytic component, and a tumour volume of less than 4.9 cc had a 57.2% chance of having benign histology. Overall, patients who had central/hilar and peripheral tumours had a 6.4% and 20.4% chance of having benign histology, respectively. The cross-validated estimate accuracy of the model is 89.6% with a 95% CI (85.8, 92.7).

Conclusions: We demonstrate that we can predict benign disease using this model with an 89.6% accuracy. We observed that in this era of incidentalomas, tumour location and degree of endophytic component have a better predictive ability than tumour size when differentiating benign vs. malignant lesions. We believe that classification trees are easier to use in the clinical setting when compared with logistic regression models as they mimic the clinician's thought process. This classification tree will be validated with an external dataset.

MP-09.04 Predicting Growth Rate of Renal Masses on Active Surveillance as a Function of Patient and Tumour Characteristics

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Introduction and Objective: Active surveillance (AS) is the treatment of choice for patients with small renal masses (SRM) who are not surgical candidates, due to existing comorbidities or patient choice. It has been shown that most SRMs grow slowly, but there are some masses that grow rapidly, requiring treatment or progressing to metastatic disease. Patient and tumour characteristics related to this more aggressive behavior have been poorly studied. We report our analysis of a prospective cohort with a median follow-up of 35 months.

Methods: This study is based on a prospectively accrued cohort of 67 patients who underwent AS between July 1 2001 and June 30 2009 with a minimum follow-up time of 6 months. Age, sex, symptoms at presentation, tumour size at diagnosis (diameter in cm), tumour location (central/peripheral), degree of endophytic component (1-100%) and tumour consistency (solid/cystic) were used to develop a predictive model using Binary Recursive Partitioning Analysis.

Results: Median follow-up was 35 (9-96) months. Mean patient age was 74.1 (52-91) and 59.7% were male. There were 94% of the masses which were diagnosed incidentally; 58.2% of the masses had a peripheral location (41.8% central/hilar) with a mean endophytic component of 51.9%, and 88.1% of the masses were solid (11.9% cystic). Mean largest tumour diameter at diagnosis was 2.5 cm (range 0.8-5.4). One (1.5%) patient developed and died of metastatic disease while 11 (16.4%) went on to have surgery (all renal cell carcinoma). Seven (10.4%) patients died of other causes while 48 (71.6%) remain on AS. Average growth rate for the entire cohort was 0.22 cm/year. Binary recursive partitioning yielded a cut off point of 2.45 cm (95% CI 1.75, 2.65) for the diameter at diagnosis which optimally separated those masses with slower (0.17 cm/year) and faster (0.28 cm/year) growth rates. All other variables included in the model did not provide independent or additional prognostic information.

Conclusions: Based on this series of patients on AS with a mean follow-up time of 3 years we confirm that most renal masses grow slowly and carry a low metastatic potential. Two distinct growth rates are identifiable and can be predicted based on tumour size. Masses that are ≥ 2.45 cm in largest diameter at diagnosis grow faster than smaller masses. Although this data provides further insight into the natural history of untreated renal masses, it should not be extrapolated to a population of surgical candidates who tend to be younger and have a higher proportion of central lesions.

MP-09.05 The Rates of Metastatic Renal Cell Carcinoma are Decreasing Over Time: A Population-Based Analysis

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Introduction and Objectives: We assessed the rate of metastatic renal cell carcinoma (mRCC) at diagnosis in a large population-based tumour registry.

Materials and Methods: Between 1988 and 2006, 87842 patients were identified within 17 Surveillance, Epidemiology and End Results (SEER) registries with tissue-proven diagnosis of RCC of all stages. We examined the rates of mRCC at diagnosis throughout the study period. Multivariable logistic regression models examined the impact of year of diagnosis quartiles (1988-1992 vs. 1993-1997 vs. 1998-2002 vs. 2003-2006) on mRCC rates after adjusting for patient age, gender, race and socioeconomic status.

Results: The overall rate of mRCC was 19.1% and it decreased from 23.8% in the first year quartile to 16.5% over the study period (χ^2 trend: $p < 0.001$). The decrease in mRCC rates was more pronounced in females (-8.6%) than in males (-6.9%), in older individuals (-12.3% in ≥ 80 years) than in younger patients (-7.0% in < 50 years), in African-American (-9.7%) than in Caucasian patients (-7.3%), and in patients within the highest socioeconomic status quartile (-8.9%) relative to individuals within the lowest socioeconomic status quartile (-7.3%). In multivariable logistic regression models more advanced age ($p < 0.001$), male gender ($p < 0.001$), race other than Caucasian and African-American ($p = 0.02$) and lower socioeconomic status ($p < 0.001$) represented independent predictors of mRCC diagnosis. Finally, more contemporary year of diagnosis remained the foremost predictor of lower rate of mRCC at initial diagnosis ($p < 0.001$).

Conclusions: Our findings are highly encouraging and suggest that a larger proportion of patients will harbor curable or highly treatable stages of RCC. Conversely, an increasingly smaller proportion of mRCC will hopefully contribute to the overall RCC patient population. The increased use of imaging studies may represent an explanation for the observed results.

MP-09.06 The Rates of Partial Nephrectomy in Patients with Small Renal Masses are Increasing: A Population-Based Study

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Introduction and Objectives: Partial nephrectomy (PN) represents the treatment modality of choice for patients with small renal masses. We examined the rates of PN in patients with histologically proven small renal masses within a large population-based tumour registry.

Methods: Within the 17 registries from the Surveillance, Epidemiology and End Results database, between the years 1988 and 2006, we identified 20880 patients treated with either a partial or radical nephrectomy for T1aN0M0 histologically proven renal cell carcinoma. Trends, proportions, and multivariable logistic regression models were generated to assess the use of partial versus radical nephrectomy in this cohort.

Results: Overall, 30.1% of patients underwent a PN between 1988 and 2006. The annual rates of PN use increased from 7.0 to 42.1% throughout the entire study period (relative increase: 6.0%, chi-square trend: $p < 0.001$). For tumours smaller or equal to 2.0 centimeters, the use of PN increased from 14.0 to 58.3% (relative increase: 4.2%, chi-square trend: $p < 0.001$) vs. 5.1 to 35.5% (relative increase: 7.0%, chi-square trend: $p < 0.001$) in tumours sized between 2.1 to 4.0 centimeters within the study period. Of all patients who received a PN, most were Caucasian (84.0%) and male (63.0%). PNs were more frequent in patients aged between 60-69 years old (27.8%) and least common in octogenarians (3.9%). Metropolitan areas showed the highest rate of PN being per-

formed (91.0%). Additionally, most PN were performed in counties where the estimated median family income ranged between 45 to 75 thousand dollars (72.7%) vs. lower median family income counties (range 18 to 35 thousand dollars). Finally, most PNs were performed in the most contemporary year quartile (37.2%). Multivariable models revealed that males were 1.2 times more likely to undergo a PN relative to female gender vs. 1.2 times for Caucasians compared to African Americans and 2.3 times in patients aged less than 50 years old relative to octogenarians (all $p < 0.001$). Moreover, PN are 2.7 times more likely used in tumours sized less or equal to 2.0 centimeters relative to those larger than 2.0 centimeters ($p < 0.001$). Finally, PN was up to 4 times higher in more contemporary years ($p < 0.001$).

Conclusions: The rate of PN increased over the study period. As many as 48.1% of small renal masses less or equal to 2.0 centimeters were treated with PN. Only 24.4% of tumours sized from 2.1 to 4.0 centimeters were treated with a PN. Despite a clear increase in the rates of PN use over time, more emphasis needs to be placed on its benefit over radical nephrectomy to further encourage its use in clinical practice.

MP-09.07

Assessment of Mortality for Non-Cancer Related Mortality in Patients with Histologically Proven Small Renal Masses Managed Non-Surgically

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Introduction and Objectives: The National Comprehensive Cancer Network guidelines suggest the use of non-surgical management (NSM) of small renal masses in patients with multiple comorbidities and in those with limited life expectancy. We examined the rates of non cancer-related mortality (NCRM) in this category of patients.

Methods: Within the Surveillance, Epidemiology, and End Results database, we identified 1404 NSM patients for T1a renal cell carcinoma between the years 1988 and 2006. NCRM rates were assessed using the Kaplan-Meier and life table method.

Results: The overall 2-year NCRM survival rate was 67.9%. Between 1988 and 2004, the 2-year NCRM rates decreased from 37.3% to 29.1% (all log-rank $p \leq 0.01$). NCRM decreased from 27.3 to 25.2% in patients aged less than 50 years for the same time points (log-rank $p < 0.001$). In patients aged 80 years and older, NCRM rates for the same time points increased from 30.9 to 35.4% (log-rank $p = 0.2$). In males, the NCRM rates decreased respectively from 41.3 to 31.5% vs. 32.9 to 24.6% in females (all log-rank tests $p \leq 0.006$). Finally, NCRM rates decreased from 37.0 to 28.0% in Caucasians (log-rank $p = 0.005$). In African Americans, the rates remained relatively unchanged (39.1 to 38.4%, log-rank $p = 0.6$). NCRM was most commonly attributed to diseases of the heart (25.7%), lung cancer (9.9%), cerebrovascular diseases (4.3%), and other unspecified malignancies (5.2%).

Conclusions: Based on these results, older patients are more likely to die of NCRM than their younger counterparts. Similarly, males and African Americans are more prone to die of other causes than their female and Caucasian counterparts. The rate of NCRM rates have decreased in NSM patients for histologically proven small renal masses in renal cell carcinoma. This implies that the indication for NSM in these patients may have become less selective. Therefore, NSM may require a re-appraisal.

MP-09.08

Small Renal Mass Needle Core Biopsy: Outcomes of Non-Diagnostic Percutaneous Biopsy and Role of Repeat Biopsy

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Introduction and Objective: Percutaneous needle core biopsy is becoming established in the management of small renal masses ≤ 4 cm (SRMs). Numerous recent series have reported success rates of $\geq 80\%$ with excellent predictive accuracy. Indeterminate or non-diagnostic results con-

tinue to be a problem. We present the results of a large biopsy series with outcomes of the non-diagnostic biopsies.

Methods: A prospectively maintained database of patients undergoing renal mass biopsy was analyzed to determine the pathology and outcomes of SRM biopsies. Reports of "indeterminate" results included insufficient material, normal kidney or non-renal tissue. Repeat biopsy has recently been recommended and the correlation with the first biopsy as well as outcome were analyzed.

Results: Three hundred sixteen (316) biopsies were performed (SRM mean diameter 2.5 cm) between January 2000 and October 2009. Biopsy was diagnostic in 266 cases (84.2%) and non-diagnostic in 50 cases (15.8%). Among diagnostic biopsies, 203 (76.3%) were malignant, 95.1% of which were renal cell carcinoma (RCC). Histologic subtyping and grading of RCC was possible in 87.6% and 62.7% of cases, respectively. Twelve (12/50 or 24%) of the non-diagnostic biopsies were taken at the time of radiofrequency ablation. Four patients underwent surgical resection of the mass, and 23 were managed by active surveillance. Repeat biopsy was performed in 10 of the 50 non-diagnostic cases, and a diagnosis was possible in 9 (90%). Seven lesions were malignant, and 2 were oncocytic neoplasms. Larger tumour size and a solid nature were found to predict a successful biopsy. Minor complications were experienced in 10.3% of cases, with no major bleeding noted, and no seeding of the biopsy tract.

Conclusions: Percutaneous biopsy can be performed safely and accurately in the investigation of renal masses 4cm or less in size. In those cases in which the biopsy is indeterminate, repeat biopsy can be performed with similar accuracy, thus providing a diagnosis in the majority of patients.

MP-09.09

A Prospective Randomized Study of Pfannenstiel versus Expanded Port site Incision for Intact Specimen Extraction in Laparoscopic Radical Nephrectomy

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Introduction and Objective: Laparoscopic radical nephrectomy is evolving as the standard of care for cancerous renal masses. Upon complete dissection of the kidney, the specimen may be removed via muscle-splitting expansion of an expanded port site (EPS) or a Pfannenstiel (PFN) incision (non-muscle splitting). In a recent retrospective analysis, our group demonstrated a statistically significant reduction in hospital stay and narcotic use in patients who underwent PFN extraction. We present the results of a prospective randomized study investigating potential differences between PFN and EPS specimen extraction.

Methods: Based on a sample size calculation (power 90%, $p < 0.05$), a series of 97 consecutive patients (2005-2009) were randomized preoperatively to undergo either EPS or PFN specimen extraction after transperitoneal laparoscopic nephrectomy for renal malignancy. Postoperative follow-up (FU) occurred at 1 week, 6 weeks and 6 months with standardized questionnaires including a visual analog pain score, return to work, physical recovery, operative satisfaction, cosmesis satisfaction, and whether patients would repeat the operation, choose the same incision and recommend the same incision to others. Statistical analysis was conducted utilizing a two-tailed Student's t-test with two-sample unequal variance at each clinical encounter while a Fisher's exact test was employed at the 6 month visit for repeat operation, cosmesis and same incision.

Results: Target patient accrual was attained with 97 patients enrolled and 80 patients having completed 6 month FU: 44 EPS and 36 PFN. Wound infection occurred in 3 patients (2 PFN and 1 EPS). There were no statistically significant differences ($p < 0.05$) in pain scores, return to work, physical recovery, operative satisfaction and cosmesis at 1 week, 6 weeks and 6 months FU. At 6 months FU, there were no significant differences with respect to repeating the same operation, using the same incision and recommending the incision to others.

Conclusions: To our knowledge this is the first prospective randomized study comparing PFN and EPS specimen extraction in laparoscopic radical nephrectomy. Our FU results at 1 week, 6 week and 6 months did not reveal any statistically significant difference in pain scores, satisfaction, recovery or cosmesis.

5-STAR

MP-09.10

The Effect of Radical versus Partial Nephrectomy on Other-Cause Mortality in Patients with T1a Renal Cell Carcinoma: Results from the Surveillance, Epidemiology and End Results Database

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Introduction and Objective: Partial nephrectomy (PN) is frequently used. However, its rates could still be increased, especially in patients with T_{1a} renal cell carcinomas (RCC). The rationale for maximizing PN rates may reside in the protective effect of PN on non-RCC related events. We tested this hypothesis in a large population-based cohort.

Methods: Between 1988 and 2006, 23613 patients underwent a PN (n=7048; 29.8%) or a radical nephrectomy (RN) (n=16565; 70.2%) for pT_{1a}pN₀M₀ RCC within 17 Surveillance, Epidemiology and End Results (SEER) registries. Cumulative incidence plots addressed other-cause mortality (OCM) rates of PN vs. RN patients after accounting for cancer-specific mortality. Finally, multivariable competing-risks regression models addressed OCM after PN vs. RN after adjusting for age, gender, race, tumour size, histological subtype, tumour grade and year of diagnosis.

Results: Overall, cardiovascular disease, cerebrovascular disease and lung cancer were the three most frequent non-RCC related causes of death. In univariable analyses, RN was associated with a 1.52 (95% CI: 1.40-1.66; $p < 0.001$) increase in OCM relative to PN, which translated into a 5.01% and 8.63% absolute increase in mortality at 5 and 10 years after surgery respectively. In multivariable competing-risks regression models RN was still associated with a statistically significant increase in OCM rates relative to PN (HR: 1.29; 95% CI: 1.18-1.41; $p < 0.001$).

Conclusions: Patients treated with RN for T1a RCC have higher OCM rates than PN patients even after adjustment for various patient and tumour characteristics. In consequence, PN should be attempted whenever technically feasible in order to decrease non-RCC related deaths.

MP-09.11

Recurrence Rates Following Percutaneous and Laparoscopic Renal Cryoablation (RC) of Small Renal Masses (SRM): Does the Approach Make a Difference?

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Introduction and Objective: As the incidence of radiologic detection of renal masses increases, poor surgical candidates are often offered either percutaneous renal cryoablation (PRC) or transperitoneal laparoscopic renal cryoablation (TLRC). This multicentre experience compares PRC and TLRC.

Methods: Between 09/1998 and 02/2009, retrospective review of our PRC and TLRC experience was performed. Patients with a minimum 12 month follow-up were included for analysis. Post treatment surveillance consisted of laboratory studies and imaging at regular intervals. Treatment failure was considered if persistent mass enhancement or interval tumour growth was evident on radiography. Repeat biopsy and retreatment were recommended in the event of tumour recurrence.

Results: Sixty-one (67.2% male; 32.8% female) patients underwent PRC, having a mean body mass index (BMI) of 30.2 ± 6.4 kg/m². 81 (58.0% male; 42.0% female) patients underwent TLRC, having a mean BMI of 29.8 ± 6.6 kg/m² ($p = 0.770$). The average patient age was 69.1 ± 11.5 (PRC) and 65.7 ± 10.0 (TLRC) years ($p = 0.062$). The prevalence of comorbid conditions in the PRC and TLRC cohorts was: 21.3 ± 41.3% vs. 33.8 ± 47.6% diabetes mellitus ($p = 0.106$), 72.1 ± 45.2% vs. 78.8 ± 41.2% hypertension ($p = 0.366$) and 42.6 ± 49.9% vs. 58.8 ± 49.5% smoking history ($p = 0.058$), respectively. Mean tumour size was 2.7 ± 1.1 (PRC) and 2.5 ± 0.8 (TLRC) cm ($p = 0.153$). 76.4 ± 42.8% (PRC) and 60.3 ± 49.3% (TLRC) renal masses ($p = 0.052$) were biopsy-confirmed renal cell carcinoma. The mean follow-up was 31.0 ± 14.1 (PRC) and 39.8 ± 22.6 (TLRC) months ($p = 0.009$), with local tumour recurrence noted in 15.0 ± 36.0% (PRC) and 5.0 ± 21.9% (TLRC) of kidneys ($p = 0.044$), respectively. In the PRC cohort, disease-free survival (DFS) and overall survival (OS) were 93.3 ± 25.2% and 91.7 ± 27.9%, with 4 patients having evidence of disease at last follow-up. DFS and OS was 92.5 ± 26.5% and 93.8 ± 24.4% in the TLRC group, with 6 patients having evidence of disease at last follow-up. DFS ($p = 0.851$) and OS ($p = 0.639$) were similar.

Conclusions: In this multicentre study of well-matched PRC and TLRC cohorts, PRC had higher primary treatment failure rates than TLRC. However, a greater percentage undergoing PRC had biopsy-confirmed RCC. DFS and OS survival were similar in both groups. Additional follow-up is required to determine if the approach, either PRC or TLRC, truly affects the treatment outcomes.