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Renal Functional and Perioperative Outcomes of Off-Clamp vs. Clamped Robot-Assisted Partial Nephrectomy: Matched Cohort Study

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Abstract

Objective—To evaluate the potential benefit of performing off-clamp robot-assisted partial nephrectomy (RAPN) as it relates to renal functional outcomes, while assessing the safety profile of this unconventional surgical approach.

Methods—Twenty-nine patients who underwent off-clamp RAPN for suspected renal cell carcinoma at Washington University between 3/2008 and 9/2011 (group-1) were matched to 29 patients with identical nephrometry scores and comparable baseline renal function who underwent RAPN with hilar clamping during the same period (group-2). The matched cohorts' perioperative and renal functional outcomes were compared at a mean 9-month follow-up.

Results—Mean estimated blood loss was 146.4 cc in group-1, versus 103.9 cc in group-2 ($p=0.039$). Mean hilar clamp time was 0 minutes in group-1 and 14.7 minutes in group-2. No perioperative complications were encountered in group-1; one Clavien-2 complication (3.4%) occurred in group-2 ($p=1.000$). At 9-month follow-up, mean eGFR in group-1 was 79.9, versus 84.8 ml/min/1.73m² preoperatively ($p=0.013$); mean eGFR in group-2 was 74.1, versus 85.8 ml/min/1.73m² preoperatively ($p<0.001$). Hence, eGFR declined by a mean of 4.9 ml/min/1.73m² in group-1, versus 11.7 ml/min/1.73m² in group-2 ($p=0.033$).

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Conclusions—Off-clamp RAPN is associated with a favorable morbidity profile and relatively greater renal functional preservation compared to clamped RAPN. Nevertheless, the benefit is small in renal functional terms and may have very limited clinical relevance.

Keywords

Robotic partial nephrectomy; Renal cell carcinoma; Off-clamp partial nephrectomy; Hilar clamping; Warm ischemia

Introduction

In view of evidence linking radical nephrectomy to suboptimal renal function, adverse cardiovascular events, and increased mortality,¹⁻⁴ the American Urological Association (AUA) guidelines now explicitly place partial nephrectomy (PN) as the standard of care for the management of T1a renal tumors and as an alternative treatment option for T1b tumors.⁵ Reflecting this paradigm shift, the use of PN has risen substantially at many centers of excellence over the past decade, approaching 90% for T1a tumors at some centers.⁶

With the rapid uptake of minimally invasive technology by the urologic community, laparoscopic PN and, more recently, robot-assisted partial nephrectomy (RAPN) have emerged as viable alternatives to open PN for the management of suspected renal malignancy. However, despite the increased utilization of minimally invasive PN, minimally invasive techniques for achieving renal hypothermia during renal hilar clamping have failed to achieve widespread clinical application. Hence, renal hilar clamping during minimally invasive PN is most commonly performed under “warm ischemia”.

While the negative impact of prolonged warm ischemia time (WIT) on renal function is well-established, the impact of short WIT is a subject of debate. We sought to evaluate the potential benefit of performing PN without renal hilar clamping as it relates to renal functional outcomes, while at the same time evaluating the safety profile of this unconventional surgical approach.

Materials and Methods

Washington University's Human Studies Committee approved the research protocol. A retrospective chart review identified 29 patients who underwent off-clamp RAPN for suspected renal malignancy at our institution between 3/2008 and 9/2011 (group-1). These patients were matched to a cohort of 29 control patients with identical nephrometry scores (standardized scoring system for quantifying renal tumor “complexity”⁷) and equivalent renal functional classification (as defined within the National Kidney Foundation Classification system⁸) who underwent RAPN with renal hilar clamping during the same period (group-2). The 29 control patients were selected from a prospectively maintained database of 135 patients who underwent RAPN with hilar clamping between 2008 and 2011. All cases were performed by two minimally invasive renal surgeons experienced in both the on-clamp and off-clamp technique. Importantly, patient matching was based strictly on tumor nephrometry score and preoperative renal functional classification and was blinded to the perioperative and renal functional outcome parameters evaluated in this study. All

patients demonstrated contrast-enhancing renal masses on preoperative CT/MRI. Indications for PN and selection of the off-clamp technique were based on tumor size and location, patient comorbidity/surgical risk, and patient and surgeon preference. All treatment options, including surveillance, were discussed with the patients.

Surgical Technique

A transperitoneal or retroperitoneal robotic approach was chosen depending on tumor location, patient surgical history, and surgeon preference. After dissecting out the kidney and sweeping the peri-nephric fat away from the tumor, intraoperative ultrasound was utilized to assess tumor depth and delineate the resection site. In the clamped RAPN group, the renal artery and vein were isolated and individually clamped using Bulldog clamps, and tumor excision was performed following administration of mannitol using cold scissors. In the off-clamp group, the renal hilum was dissected to enable rapid hilar control in case of excessive bleeding during tumor excision, which was performed without mannitol administration, hilar occlusion, or anesthetic blood pressure control using either electrocautery (at 50 Watts) or- in some of the earlier cases- the Habib-4X bipolar resection device (Angio Dynamics, Queensbury, NY). Bleeding vessels were controlled using monopolar or bipolar electrocautery during tumor excision, and the base of the resection was inspected and judiciously cauterized to ensure hemostasis. 2.0-Vicryl sutures were used for closure of the collecting system and/or large blood vessels at the resection base when indicated. 0-Vicryl simple mattress sutures were used to reapproximate the renal parenchyma, and the sutures were secured using sliding Weck clips; the Weck clips were reinforced with Lapra-Ty clips. The surgical bed was reinspected under low insufflation pressure to ensure hemostasis following renal reconstruction. The specimen was extracted and the gross margins of the tumor inspected prior to sending the specimen to Pathology for permanent section.

Postoperative Follow-up

Postoperative follow-up included monitoring of serum creatinine at 1 day, 1, 3, 6, and 12 months, and yearly thereafter.

Data Collection and Analysis

Patient data were compiled for specified demographic and clinical variables, tumor characteristics, perioperative outcomes, and renal functional outcomes following RAPN. (Table 1) Functional outcomes were assessed on the basis of postoperative changes in estimated glomerular filtration rate (eGFR), calculated using the CKD-EPI formula.⁹ Preoperative eGFR was compared to eGFR on last-follow-up to assess long-term changes in renal function following RAPN in each of the two matched patient cohorts. A comparison of postoperative changes in renal function between the matched patient cohorts was then performed. Of note, five matched patients from each cohort were excluded from the analysis of functional outcomes due to unavailable baseline and/or postoperative creatinine measurements.

Statistical analysis was performed using MedCalc-11.6 and SPSS-19. Continuous variables were compared using the paired t-test; categorical variables were compared using chi-square analysis. $P < 0.05$ (two-tailed) defined statistical significance.

Results

Table 1 compares patient and tumor characteristics as well as perioperative and functional outcomes in the two matched cohorts. Mean age was 60.8 years (SD=12.1) in group-1, compared to 60.0 years (SD=13.4) in group-2 ($p=0.767$). Mean American Society of Anesthesiologists (ASA) score was 2.3 (SD=0.7) in group-1 and 2.3 (SD=0.8) in group-2 ($p=0.865$). Mean age-adjusted Charlson Comorbidity Index (CCI) was 3.6 (SD=2.1) in group-1, versus 2.2 (SD=1.6) in group-2 ($p=0.010$). Mean tumor size was 2.3 cm (SD=1.2) in group-1 and 2.3 cm (SD=1.4) in group-2 ($p=0.983$). Mean nephrometry score was 5.7 (SD=1.9) in both groups.

Mean hilar clamp time was 0 minutes in group-1, versus 14.7 minutes (SD=6.2) in group-2. Mean operative time was 127.0 minutes (SD=37.9) in group-1, versus 123.8 minutes (SD=33.7) in group-2 ($p=0.721$). Mean estimated blood loss (EBL) was 146.4 cc (SD=99.2) in group-1 and 103.9 cc (SD=81.7) in group-2 ($p=0.039$). Perioperative complications, including blood transfusions, were encountered in 0/29 (0%) patients in group-1 and 1/29 (3.4%) patients in group-2 ($p=1.000$). All surgical margins were negative in group-1; 2/29 (6.9%) positive margins occurred in group-2 ($p=0.491$).

At a mean 9-month follow-up, mean eGFR in group-1 was 79.9 ml/min/1.73m² (SD=25.0), compared to 84.8 ml/min/1.73m² (SD=26.7) preoperatively ($p=0.013$); mean eGFR in group-2 was 74.1 ml/min/1.73m² (SD=21.1), compared to 85.8 ml/min/1.73m² (SD=21.3) preoperatively ($p < 0.001$). Hence, while both groups experienced a decline in renal function at 9-month follow-up, eGFR declined by a mean of 4.9 ml/min/1.73m² (SD=8.9) in group-1, versus 11.7 ml/min/1.73m² (SD=12.3) in group-2 ($p=0.033$).

Comment

With mounting evidence highlighting the importance of renal preservation¹⁻⁴ and documentation of the oncologic efficacy of PN,¹⁰ PN has emerged as the standard of care for the treatment of small renal masses.⁵ However, debate continues regarding the impact of variations in surgical technique on the extent of renal functional preservation following PN. In particular, while the negative impact of prolonged WIT on renal function is well-established, the impact of short WIT during renal hilar clamping remains a subject of contention. The historically safe duration of WIT, whereby full recovery of renal function could be expected, was commonly thought to be 30 minutes.¹¹⁻¹² More recently, some have asserted that considerably longer periods of WIT can be tolerated without significant impact on renal function. These assertions are based on studies in the porcine model demonstrating that renal pedicle clamping for 90 minutes is safe¹³⁻¹⁴ as well as retrospective clinical observations suggesting that ischemia for 40–55 minutes is well tolerated.¹⁵⁻¹⁶ Adopting the opposing view, others have contended that the cutoff defining “safe” WIT should be drawn

at 20 minutes.¹⁷⁻¹⁹ The latter view was recently supported by an international collaborative review of the literature.²⁰

While efforts to define an appropriate cutoff for WIT abound, a joint Cleveland Clinic/Mayo Clinic study is distinct in examining the impact of WIT as a *continuous variable* on renal functional outcomes. In this study, investigators identified 362 patients with a solitary kidney who underwent either open or laparoscopic PN and note that longer WIT was associated with a higher odds of acute renal failure and development of new-onset stage IV chronic kidney disease during follow-up. The authors conclude that when performing PN on a solitary kidney, “every minute counts when the renal hilum is clamped without hypothermic techniques.”²¹

In recognition of the potential impact that even limited WIT may have on renal function, variations in surgical technique have been attempted in an effort to minimize or eliminate WIT during PN. Some have adopted an “early unclamping technique,” whereby hilar vessels are clamped only during tumor resection and while suturing obvious vessels/collecting system at the resection base.²²⁻²⁴ Gill and colleagues were able to decrease their WIT for laparoscopic PN from 31.6 to 14.4 minutes using this technique.²² Others have performed “selective renal parenchymal clamping”; with this technique, the renal parenchyma is regionally clamped only in the area of the planned excision.²⁵ More recently, some surgeons have performed PN without any clamping of the renal hilum (often with medically induced hypotension during tumor excision) and have suggested that off-clamp PN can be safely performed in carefully selected patients.²⁶⁻²⁷

Despite considerable innovation by the urological community in minimizing WIT during PN, multiple studies have failed to demonstrate long-term improvement in renal functional outcomes after any modification of clamping technique or in the absence of renal hilar clamping.²⁸⁻³⁰ Herein, we examined the impact of the off-clamp technique on renal functional outcomes by comparing postoperative changes in eGFR in patients who underwent off-clamp RAPN with postoperative eGFR changes in a matched patient cohort who underwent clamped RAPN. Our study demonstrates that performing PN without renal hilar clamping may, in fact, provide a long-term advantage over the traditional clamping technique in terms of renal preservation. However, while this advantage is statistically significant, the benefit is small in renal functional terms and may have very limited clinical relevance. The clinical significance of this statistical advantage certainly requires further investigation before any definitive clinical application can be extrapolated from this study. We postulate that patients who may potentially derive the greatest clinical benefit from off-clamp PN are those with compromised baseline renal function. Conversely, it is less likely that patients with adequate renal reserve would benefit clinically from the off-clamp technique.

Our data suggest that patients undergoing off-clamp RAPN are not prone to increased complications compared to patients subjected to renal hilar clamping. Indeed, no perioperative complications were encountered in the off-clamp RAPN group. Despite a minor, though statistically significant, increase in blood loss associated with the off-clamp technique, mean EBL in the off-clamp group (146.4 cc) was clinically appropriate.

Furthermore, the increased EBL in the off-clamp RAPN group was not associated with an increased risk of blood transfusion (transfusion rate=0%) or positive surgical margin (positive margin rate=0%) in that group. Our data support the conclusion that the off-clamp technique in *select* patients can be performed safely. This conclusion is consistent with an earlier report from Johns Hopkins which demonstrated no difference in perioperative outcomes between off-clamp PN and PN performed with renal hilar clamping.¹⁶

Our study is limited in that renal functional outcomes are evaluated solely on the basis of post-operative changes in eGFR. Future studies may incorporate methods to evaluate split renal function, such as renal nuclear scans, as an additional means of assessing the relative impact of off-clamp versus clamped RAPN on renal functional outcomes. Also limiting this study is that it is a retrospective analysis largely based on chart review. Five matched patients from each cohort were excluded from the analysis of functional outcomes due to unavailable baseline and/or postoperative creatinine measurements; the potential impact of missing data on our overall outcomes is unknown. Another criticism of this study is that our indications to perform off-clamp RAPN were not strictly defined. The decision as to whether or not to perform hilar occlusion depended on lesion location and size, patient characteristics, and surgeon preference. Notably, our mean tumor size (2.3 cm in both groups) as well as our mean nephrometry score (5.7 in both groups) reflect generally smaller, less complex tumors. In consequence, our outcomes- especially those pertaining to intraoperative parameters- may not necessarily be applicable to larger, less accessible tumors. Furthermore, our sample size, while large enough to detect statistical differences in postoperative eGFR decline (our primary endpoint) as well as EBL between the two matched cohorts, may not have been adequate to detect subtle differences in other secondary outcomes between the two groups.

It is also important to note that although this study represents a matched cohort comparison of two surgical techniques, it is not possible to control for every potential confounding variable using a matched cohort study design. Despite considerable similarity between the two groups in the incidence of diabetes, hypertension and other factors that may impact renal functional outcomes, we take note of the fact that the mean CCI was higher in the off-clamp PN group compared to the group subjected to renal hilar clamping. We postulate that this particular difference in baseline patient characteristics does not alter the interpretation of our results, as increased comorbidity in the off-clamp group would be expected to bias *against* a more favorable outcome in that group; nevertheless, there may be other variables not controlled for in our matched analysis that could potentially impact renal functional outcomes in the two comparison groups. Although all RAPN cases were performed by two highly experienced minimally invasive renal surgeons, potential differences in surgical outcomes between these two surgeons may also introduce an element of bias into our results. Variations in surgical approach (transperitoneal versus retroperitoneal) as well as technique (resection with electrocautery versus the Habib resection device) between the two comparison groups may also bias our results. Furthermore, slight differences in mean length of follow-up between our two matched cohorts (284 days in group-1 versus 259 days in group-2) may result in “follow-up bias,” although it is not anticipated that eGFR in group-1 would be appreciably altered over the course of an additional month of follow-up. It is also

noteworthy that although widely utilized as a measure of tumor complexity, the R.E.N.A.L. nephrometry scoring system cannot capture intangible tumor characteristics which the surgeon might consider in determining surgical approach. Hence, equivalency of nephrometry scores between the two matched cohorts does not entirely eliminate the potential for bias in tumor selection between the groups.

A large randomized prospective study evaluating the impact of renal hilar clamping on renal functional outcomes, as determined by postoperative changes in eGFR as well as split renal function, would address the shortcomings of this study. However, given the considerable need for judicious patient selection when performing initial cases of off-clamp RAPN, a randomized trial is best reserved until more significant experience in this technique has been attained.

Conclusions

Off-clamp RAPN is associated with a favorable morbidity profile. While some renal functional decline is expected with or without renal hilar clamping following PN, the latter appears to result in relatively greater preservation of renal function. Nevertheless, the benefit is very small in renal functional terms and may have little clinical consequence. Further studies are needed to evaluate the clinical relevance of off-clamp PN.

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Abbreviations and acronyms

RAPN	Robot-Assisted Partial Nephrectomy
AUA	American Urological Association
PN	Partial Nephrectomy
WIT	Warm Ischemia Time

eGFR	estimated Glomerular Filtration Rate
ASA	American Society of Anesthesiologists
CCI	Charlson Comorbidity Index
EBL	Estimated Blood Loss
SD	Standard Deviation

Table 1

Comparison of patient and tumor characteristics as well as perioperative and functional outcomes in patients undergoing off-clamp RAPN (group-1) versus those undergoing RAPN with renal hilar clamping (group-2). RAPN= Robot-Assisted Partial Nephrectomy; BMI=Body Mass Index; ASA=American Society of Anesthesiologists; CCI=Charlson Comorbidity Index; WIT=Warm Ischemia Time; EBL=Estimated Blood Loss; sCr=serum Creatinine; eGFR=estimated Glomerular Filtration Rate; No.=Number; SD=Standard Deviation

	Group-1	Group-2	p-val.
<i>Patient Characteristics (n=29)</i>			
Mean age, years (SD)	60.8 (12.1)	60.0 (13.4)	0.767
BMI (SD)	30.2 (7.1)	29.0 (7.9)	0.498
Ethnicity			
No. Caucasian (%)	24/29 (82.8)	23/29 (79.3)	0.936
No. African American (%)	4/29 (13.8)	5/29 (17.2)	
No. Other (%)	1/29 (3.4)	1/29 (3.4)	
Mean ASA score (SD)	2.3 (0.7)	2.3 (0.8)	0.865
Mean age-adjusted CCI (SD)	3.6 (2.1)	2.2 (1.6)	0.010
<i>Tumor Characteristics (n=29)</i>			
Mean tumor size, cm (SD)	2.3 (1.2)	2.3 (1.4)	0.983
Mean nephrometry score (SD)	5.7 (1.9)	5.7 (1.9)	-
Tumor laterality			
Left (%)	18/29 (62.1)	15/29 (51.7)	0.426
Right (%)	11/29 (37.9)	14/29 (48.3)	
Tumor pathology			
No. RCC, Clear Cell (%)	14/29 (48.3)	18/29 (62.1)	0.785
No. RCC, Papillary (%)	6/29 (20.7)	5/29 (17.2)	
No. RCC, Chromophobe (%)	0/29 (0)	0/29 (0)	
No. Oncocytoma (%)	3/29 (10.3)	1/29 (3.4)	
No. Angiomyolipoma (%)	4/29 (13.8)	3/29 (10.3)	
No. Other (%)	2/29 (6.9)	2/29 (6.9)	
Tumor T-stage			
No. T1a (%)	21/29 (68.8)	22/29 (71.9)	0.520
No. T1b (%)	0/29 (0)	1/29 (0)	
No. benign/not applicable (%)	8/29 (31.3)	6/29 (25.0)	
<i>Perioperative Outcomes (n=29)</i>			
Surgical approach			
Transperitoneal (%)	18/29 (62.1)	29/29 (100.0)	<0.001
Retroperitoneal (%)	11/29 (37.9)	0/29 (0)	
Method of tumor resection			
No. using Habib resection device (%)	6/29 (20.7)	0/29 (0)	0.023
No. using electrocautery (%)	23/29 (79.3)	29/29 (100)	
Renorrhaphy			

	Group-1	Group-2	p-val.
No. undergoing single-layer repair (%)	21/29 (72.4)	12/29 (41.4)	0.017
No. undergoing two-layer repair (%)	8/29 (27.6)	17/29 (58.6)	
Mean operative time, minutes (SD)	127.0 (37.9)	123.8 (33.7)	0.721
Mean WIT, minutes (SD)	0 (0)	14.7 (6.2)	-
Mean EBL, cc (SD)	146.4 (99.2)	103.9 (81.7)	0.039
No. perioperative complications (%)	0/29 (0)	1/29 (3.4)	1.000
No. post-op transfusion (Clavien 2) (%)	0/29 (0)	1/29 (3.4)	
No. positive surgical margins (%)	0/29 (0)	2/29 (6.9)	0.491
Resection margin			
No. with 1-5 mm margin (%)	17/29 (58.6)	15/29 (51.7)	0.814
No. with margin 1mm (%)	6/29 (20.7)	8/29 (27.6)	
No. unspecified (%)	6/29 (20.7)	6/29 (20.7)	
<i>Renal Functional Outcomes (n=24)</i>			
No. with solitary kidney (%)	1/29 (3.4)	0/29 (0)	1.000
No. with diabetes mellitus (%)	2/24 (8.3)	3/24 (12.5)	1.000
No. with hypertension (%)	14/24 (58.3)	13/24 (54.2)	0.771
Mean age-adjusted CCI (SD)	3.3 (2.3)	2.1 (1.5)	0.045
Mean pre-op sCr (SD)	1.2 (1.6)	0.9 (0.2)	0.266
Mean sCr at last f/u (SD)	1.3 (1.7)	1.0 (0.3)	0.380
Mean pre-op eGFR, ml/min/1.73m ² (SD)	84.8 (26.7)	85.8 (21.3)	0.750
Mean eGFR at last f/u (SD)	79.9 (25.0)	74.1 (21.1)	0.194
Mean change in eGFR (SD)	-4.9 (8.9)	-11.7 (12.3)	0.033
Mean creatinine follow-up, days (SD)	284.2 (343.5)	258.6 (255.3)	0.791