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Evaluation of Perioperative Outcomes and Renal Function after Robotic Assisted Laparoscopic Partial Nephrectomy Off/On Clamp: Comparison of cT1a versus cT1b Renal Masses

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ABSTRACT

Introduction: Partial nephrectomy (PN) is the standard of care for cT1a (<4 cm) renal masses. The American Urological Association Guidelines consider PN as an alternative to radical nephrectomy (RN) in renal masses cT1b (4-7 cm), especially when a preservation of renal function is needed. Our Aim of this study is to compare the perioperative and functional outcomes of Robotic Assisted Laparoscopic Partial Nephrectomy (RALPN) off/on clamp performed for cT1a vs. cT1b renal cell carcinoma (RCC).

Material and methods: RALPN was performed in 35 patients between October 2013 and January 2016 by a single surgeon in 2 community hospitals. They were divided in 4 groups: a) 20 patients with renal tumors < 4 cm (cT1a) vs. b) 15 patients with renal tumors >4-7 cm (cT1b), and these patients were subdivided C) 15 patients Off Clamp (no ischemia) RALPN vs. D) 20 patients On-Clamp (ischemia) RALPN. Patients demographic, perioperative outcomes and renal function are evaluated at 6 months.

Results: In all, 35 patients underwent RALPN no conversion to open. The patient's demographics and perioperative factors characteristics were similar among these 2 groups. Transfusion were more common in cT1b (13.3%) this difference was significant. The EBL was larger in the off-clamp RALPN cohort (350–415 vs. 55–75 mL). The percentage change in eGFR after 6 months in the cT1b on-Clamp RALPN was significantly (-9.5%) as compared to cT1a (-3.4%). This can be related to ischemia injury or renal parenchymal loss.

Conclusion: RALPN can be performed off-clamp in selected patients with cT1b (4-7 cm) renal tumors without compromising operative duration, length of stay, rates of positive margins, and postoperative complications. Careful, discussion with patients and anesthesia team about the increases of EBL and possible transfusion is recommended and decreases of the renal function by 9-10% at 6 months. Further studies with longer follow-up are needed to elucidate the impact of ischemia on long-term renal function and correlate it with tumor volume and renal parenchymal loss.

INTRODUCTION

Small renal masses (≤ 4 cm) account for 48-66% of newly diagnosed renal cell carcinomas (RCC) [1]. Partial nephrectomy (PN) is the standard of care for cT1a (<4 cm) renal masses. It offers equivalent oncologic outcomes; less renal function impairment and excellent overall survival results when compared to radical nephrectomy (RN). In fact, the American Urological Association (AUA) considers PN an alternative to RN, not only for cT1a but even for cT1b (4-7cm) tumors, especially if renal function preservation is required [2]. Although the open approach is the most popular technique when performing PN for cT1b tumors, laparoscopic PN (LPN) and robotic-assisted laparoscopic partial nephrectomy (RALPN) have been proposed as less invasive alternatives. LPN for cT1b renal tumors is a challenging and complex procedure, which requires advanced surgical skills even in the hands of experienced surgeons. RALPN has been developed and proposed as the natural evolution and simplification of LPN; it allows a more precise tumor excision and simplifies the reconstruction step of the procedure, especially when treating complex or large (cT1b) renal tumors. These benefits could translate into a reduction of the hilar clamping time (on clamp) or even allow a non-clamping procedure (off-clamp). Thus, minimizing the loss of healthy renal parenchyma and the associated renal function impairment.

However, a limited number of studies reporting results of RALPN on cT1b tumors are available in the literature and even less studies can be found comparing the outcomes between cT1a and cT1b masses (<4 cm vs. 4-7 cm). The objective of this study is to compare the perioperative and functional outcomes of RALPN on cT1a and cT1b renal tumors, as well as the differences between off-clamp and on-clamp techniques.

MATERIALS AND METHODS

Case Selection and Treatment Groups

RALPNs were performed by a single surgeon (Davila HH) between October 2013 and January 2016 on 35 patients. Of these patients, 20 had cT1a renal tumors (<4 cm) and 15 had cT1b tumors (4-7 cm). Cases were assigned to one of two treatment arms, off-clamp or on-clamp, depending on the characteristics of the patient and the tumor. Off-clamp RALPN was performed, when deemed feasible, after careful evaluation of preoperative imaging and intraoperative findings. In 15 patients, an off-clamp (no ischemia) technique was performed, whereas the other 20 received a conventional on-clamp RALPN. Patient's demographic and clinical information was added to a prospectively maintained database.

Perioperative Evaluation

Preoperative abdominal CT scans were reviewed before the surgery and used to assess tumor characteristics. The parameters evaluated included tumor type (solid or cystic), size, polar location (upper, central or lower) and growth pattern (exophytic, mesophytic, endophytic). Exophytic, mesophytic, and endophytic tumors were defined as: tumors with less than 1/3, 1/3 to 2/3, and more than 2/3 of their volume contained within the renal parenchyma, respectively [3]. R.E.N.A.L. Nephrometry scores were calculated for each tumor using the scoring system proposed by Kutikov et al. [4]. Patients with pathologically confirmed RCC were classified according to the clinical T-stage (cT1) using the 2002 American Joint Committee on Cancer TNM classification and results were analyzed separately.

The intraoperative variables analyzed included: renal warm ischemia time (WIT), estimated blood loss (EBL), operative duration and requirement of blood transfusion. Serial laboratory studies were performed on every patient and results of postoperative days 1 and 180 were recorded. The laboratory values analyzed included: the serum creatinine concentration (SCr), blood hemoglobin concentration (Hb) and blood hematocrit (Ht). For each patient, the estimated glomerular filtration rate (eGFR) was calculated using the serum creatinine concentration and the Cockcroft-Gault equation [5]. Lastly, patients' medical records were reviewed postoperatively to obtain information regarding complications, post-operative transfusion requirement and length of hospital stay (LOS).

Surgical Technique

Standard transperitoneal RALPN has been previously described [6]. We reviewed our off-clamp (no ischemia) outcomes. A standard pneumoperitoneum of 15 mmHg was used. All masses were removed by excision and hilar vascular clamps were removed in reverse order after renorrhaphy was complete. Tumor excision and enucleation were performed using the following: 1) monopolar scissors, 2) Maryland bipolar, 3) fenestrated pro-grasper and 4) blunt suction-dissection. Intracorporeal laparoscopic ultrasound was used intraoperatively to locate the tumors internal borders (endophytic portion) and to help demarcate the incision line. Hemostasis was achieved by placing Hem-o-Lock clips on visualized bleeding vessels. The renal hilum was dissected before excising the tumor and it was clamped when excessive intraoperative bleeding was encountered. When transfusions were required, 1 unit of packed red blood cells (500 ml) was administered. Off-clamp RALPN was performed on renal masses with varying degrees of complexity. The ease with which the technique was performed evolved accordingly to the surgeon's comfort with the procedure. Margin status was assessed by obtaining a renal parenchyma biopsy from the base of the operative bed after the excision.

Statistical Analysis

Results were analyzed using Chi-square and Kolmogorov–Smirnov tests for categorical and continuous variables, respectively. Continuous variables were reported using the mean value (and range), whereas categorical variables were reported as frequencies. A p-value (<0.05) was used as reference to indicate statistical significance. In order to identify preoperative and intraoperative variables that could predict postoperative renal function outcomes, linear regressions were used and adjustments were made for potential confounders.

RESULTS

The patients' demographic and preoperative characteristics did not vary significantly between the cT1a and cT1b groups **(Table 1)**. Both groups were comparable in age (61 vs. 59 yo), gender (65.4 vs. 60.1% male), white race frequency (77.3 vs. 80.3%), American Society of Anesthesiology (ASA) score (score 1 or 2 - 44.5 vs. 52%), body mass index (29.5 vs. 30.1 kg/m^2) and low RENAL Nephrometry Score frequency (58.2 vs. 60.3 mL/min).

The pathologic and perioperative outcomes were similar in both groups **(Table 2)**. Surgical times were not affected by the surgical assistant's experience. No procedures were converted to an open approach. No statistically-significant differences were observed in the frequency of clear cell RCC (13 vs. 8 cases) or frequency of tumors grade 1 or 2 (81% vs. 65%). Transfusions were more common in patients with cT1b tumors (13.3% vs. 0% $p>0.05$). There was one patient who had positive margins (cT1b), he was treated with an open PN 6 months after the initial surgery. There was no evidence of recurrence at 15 months follow-up. Patients' tumors assigned to the off-clamp and on-clamp groups were comparable on all the pathological and perioperative variables analyzed. Tumor location was comparable for both groups. The mean LOS was comparable between the off-clamp and on-clamp groups.

The mean preoperative eGFR in patients with cT1b tumors who received an off-clamp procedure was significantly lower than the rest of the patients (55.8 vs. 92.8 mL/min $p<0.05$). However, it did not result in a significant difference on the eGFR change 6 months after the off-clamp RALPN **(Table 3)**. The mean change in eGFR 6-months post-operatively **(Table 4)** was significantly lower in patients with cT1b tumors who had an on-clamp procedure (-9.5% $p<0.05$). One patient (cT1b) from the off-clamp group (2.85%) had to be converted to an on-clamp procedure due to severe intraoperative bleeding. The collecting system was entered in 5 patients in the off-clamp and 6 patients in the on-clamp groups, requiring additional pelvi-calyceal closure.

When comparing on-clamp and off-clamp RALPNs **(Table 5)**, no differences were observed between both groups in the preoperative or 6-month post-operative eGFR. As it was expected, the EBL was higher in the off-clamp group, this was found to be true both in univariate and multivariate analyses ($p<0.05$).

DISCUSSION

RALPN is a well-established approach for the treatment of small renal masses (<4 cm). The increased incidence of renal masses and the availability of robotic surgical systems has increased the number of RALPNs performed [7]. This approach change has allowed surgeons to extend the indications of RALPN to include larger and more complex tumors, like cT1b masses [8]. One of the most important issues that arise when performing PNs is the fact that the renal hilum is conventionally clamped in order to prevent excessive blood loss. The rationale for performing a RALPN instead of a conventional open approach is based on the benefits of the robotic approach, which include: a reduced ischemia (clamp) time (which translates into renal function preservation) and less perioperative complications, while still maintaining negative margins [8]. Several authors have described different techniques to decrease renal ischemic injury during PNs [9-16]. These include early unclamping (to significantly decrease the renal WIT), vascular control during microdissection (of renal vessels) and selective arterial clamping of tumor vasculature [17,18]. An alternative approach to reduce ischemia time is to perform an 'on-demand' clamping of the hilum, in cases where severe bleeding presents [19]. Janetschek et al. described an early series (25 cases) of off-clamp LPN on small (<2 cm) exophytic lesions, they reported a mean EBL of 287 ml, with ranges of: 20–800 ml [20]. Guilloneau et al. reported a comparative case series (28 cases) where off-clamp and on-clamp PN was performed for small renal tumors. Margins were negative in all patients but increased bleeding and longer operative duration were reported in the off-clamp group. These results are consistent with our study, where EBL was higher and transfusions were required more often in patients with off-clamp procedures for cT1b tumors **(Table 3)**.

Table 1. Patient's demographics and renal nephrometry scoring, comparison of cT1a vs. cT1b.

Age (Median)	**Tla (n=20)**	**Tlb(n=IS)**	**P-Value**
	61(33-78)	59 (45-79)	>0.05
Gender %			
Male	65.4	60.I	>0.05
Female	30.6	40.9	>0.05
Mean BMIKg/m2	29.5	30.I	>0.05
Race (%)			
White	77.3	80.3	>0.05
Black	11.5	13.6	>0.05
Other	11.2	6.1	>0.05
Comorbidities (%)			
Hypertension	59.7	63.I	>0.05
Diabetes	25.3	22.3	>0.05
Smoking	15	14.6	>0.05
Family History of RCC (%)	0	6.6	>0.05
Prior Abdominal Surgery (%)	35.5	28.5	>0.05

ASA (%)			
1or 2	44.5	52	>0.05
3 or 4	55.5	48	>0.05
Tumor size mean (cm)	3.1	5.8	>0.05
Laterality (%)			
Right	45.8	51.3	>0.05
Leh	53.6	48.7	>0.05
Bilateral	0.4	0	>0.05
RENAL Nephrometry Score (%)			
Low	58.2	60.3	>0.05
Medium	40	39.3	>0.05
High	1.8	0.4	>0.05

The effect of ischemia time on renal function has been extensively studied both clinically and in the laboratory setting. Ischemia time during off-clamp LPN has been compared to on-clamp LPN (<30 vs. >30 min) with regards to renal functional outcomes, results showed no significant differences in the postoperative change of serum creatinine concentration [21]. Porpiglia et al. also reported no significant differences between preoperative eGFR and eGFR 3 months after LPN in 18 patients with an ischemia time >30 min [22]. The use of hilar vessel clamps, a longer clamp time and a bigger EBL are factors that could predict a decreased postoperative eGFR [23].

When analyzing our results, we found no significant differences between groups in the postoperative change on renal function (measured as eGFR 6 months after the procedure). The only exception was patients with cT1b masses who had an on-clamp procedure; in this group, renal function was significantly lower than in the others. This result could be explained by the high tumor volumes (4-7 cm masses) and the associated loss of renal parenchyma to tumor tissue. Careful attention must be paid when interpreting this result due to the short follow-up time, since not enough time may have been allowed to recover renal function. The lower preoperative eGFR seen on the cT1b off-clamp group was interpreted as a selection bias, due to randomization not being performed when assigning patients to each treatment arm. However, this fact did not result in significant differences between any groups on the eGFR 6 months post-op. However, caution must be made when analyzing these results, as variations in muscle mass, hydration status and nutritional status can result in variations of SCr and consequently on the eGFR.

Table 2. Tumor pathology, perioperative outcomes and surgical times, comparison of cT1a vs. cT1b.

RCC (n) Pathology	Tla (n=20)	T b{n=lS)	P-Value
Clear Cell	13	8	>0.05
Pa pillary	5	3	>0.05
Chromo phobe	1	2	>0.05
Angiomyolipoma	0	1	NA
Oncocytoma	1	1	>0.05
Metastases	0	0	NA
Grade (%)			
1or 2	81%	65%	>0.05
3 or 4	19%	35%	>0.05
Peri-Operative Outcomes			
Median Operative Tim (min)	183	310	>0.05
Median EBL (ml)	75	120	>0.05
Median WIT (min)	18	23	>0.05
Prolonged WIT (min)	NA	28 (3)	NA
Number of Cases Zero ischemia	10	5	>0.05
Transfusion (%)	0	13%	<0.05
Positive Margins (%)	0	6.6 (n=1)	>0.05
Median LOS (days)	2.2	2.5	<0.05
Robotic Times			
Median DockingTime	28	30	>0.05
Median Console Time	155	185	>0.05
Median OR Time	192	225	>0.05
Median Anesthesia Time	183	215	>0.05
Surgical Assistant number of cases (n)			
A	15	8	>0.05
B	2	3	>0.05
C	3	4	>0.05

Table 3. Off-clamp RALPN, tumor characteristics, perioperative outcomes and renal function, comparison of T1a vs. T1b.

No Ischemia Time (Off clamp) (n)	Tla	Tlb	P-Value
	10	5	
Tumour Size, cm	2.8	5.2	>0.05
Tumour Location			
Upper Pole	3	3	>0.05
Mid Pole	2	0	>0.05
Lower Pole	5	2	>0.05
Depth of Penetration			
Endophytic	0	0	>0.05
Mesophytic	2	0	>0.05
Exophytic	8	5	>0.05
Operative Duration,min	165	185	>0.05
EBL,ml	350	415	>0.05
LOS	2.5	2.8	>0.05
Positive Margin	0	1	>0.05
Transfusions,number of patients	0	2	>0.05
Renal Function			
Mean preoperative eGFR ml/min	92.8	55.8	>0.05
Change eGFR at 6 months%	-3.5	-4.2	>0.05
Change Creatinine at 6 months mg/di	0.069	0.105	>0.05
Postoperative complications	0	0	NA

Table 4. On-clamp RALPN, tumor characteristics, perioperative outcomes and renal function, comparison of T1a vs. T1b.

Ischemia Time (On clamp) (n)	Tla	Tlb	P-Value
	10	10	
Tumour Size, cm	3.5	6.2	>0.05
Tumour Location			
Upper Pole	4	3	>0.05
Mid Pole	3	3	>0.05
Lower Pole	3	6	>0.05
Depth of Penetration			
Endophytic	2	1	>0.05
Mesophytic	3	2	>0.05
Exophytic	5	7	>0.05
Operative Duration,min	196	230	>0.05
EBL, ml	55	75	>0.05
LOS	2.1	2.5	>0.05
Positive Margin	0	0	>0.05
Tra nsf usions, number of patients	0	0	>0.05
Renal Function			
Mean preoperative eGFR ml/min	92.2	93.8	>0.05
Change eGFR at 6 months%	-3.4	-9.5	<0.05
Change Creatinine at 6 months mg/di	0.075	0.201	>0.05
Postoperative complications	0	0	NA

Table 5. Multivariate analysis of renal function comparing both surgical techniques (off-clamp and on-clamp RALPN).

	Off-Clam p		On-Clam p		P-Value
Off-Cla mp vs. On Clamp	Tla	Tlb	Tla	Tlb	
EBL, ml	350	415	55	75	<0.05
Mean Preoperative eGFR	92.8	55.8	92.2	93.8	>0.05
Cha nge eGFR at 6 Months	-3.5	-4.2	-3 .6	-9.5	>0.05
Cha nge Creatinine at 6 months mg/di	0.069	0.105	0.075	0.201	>0.05

Surgeon's autonomy is one of the main benefits of robotic surgery. Robotics allows the surgeon to control several instruments on 4 instrument arms. This in turn, translates into freedom from the surgical assistant. Surgeon's autonomy was recently evaluated during robotic assisted radical nephrectomy and results were similar to the ones seen in this study [24]. According to our results, surgical times are not affected by the assistant's experience, size of the tumor or surgical technique used (on-clamp or off-clamp).

In this study, off-clamp RALPN was performed in low complexity tumors with low RENAL Nephrometry scores. This may explain the low complication rate we encountered. Accurate selection of patients for off-clamp RALPN is of uttermost importance in order to achieve the desired results. However, we observed that as the surgical expertise of the team increases, more complex masses may be treated using this approach. Off-clamp LPN has shown to have equivalent oncological outcomes when compared to standard LPN [25]. In our study, there was only one positive surgical margin (no statistically-significant difference), suggesting that off-clamp RALPN allows complete tumor excision and does not compromise oncological control. Larger studies with longer follow-up periods are required to prove this hypothesis.

All procedures in our study were performed by a single surgeon, allowing a more uniform outcome comparison between the two operative techniques (on-clamp and off-clamp). The greatest limitation of this study was the presence of a selection bias; patients in each treatment arm were not randomly assigned to each group, on the contrary, treatment choice was made using preoperative and intraoperative findings.

CONCLUSION

Increasingly, attention has been focusing on strategies aimed at maximizing renal function by minimizing the ischemia time when performing PNs. RALPN is our preferred surgical approach for cT1 renal tumors (<7 cm) since it can be performed off-clamp (i.e., without ischemia) in select patients without compromising the operative or oncological outcomes. Off-clamp RALPN allows preservation of the traditional benefits of minimally invasive surgery while completely avoiding ischemia time; therefore, it provides the ultimate strategy for renal function preservation. This is especially relevant in patients with already-compromised renal function. Based on our analysis, we found on the T1b group an increase in EBL and possible blood transfusions and decreased of the renal function around 9% at 6 months after surgery. Larger studies with longer follow-up times and randomization of individuals to treatment arms are required to effectively evaluate the impact of intra-operative renal ischemia on long-term renal function. Renal function should be correlated with tumor size and other characteristics. Taking into account patient's and tumor's characteristics, selection criteria for routine off-clamp RALPN should be defined.

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None.

Conflicts of Interest

Authors have nothing to disclose.

Compliance with Ethical Standards

Ethical approval

All procedures involving human participants were performed in accordance with the ethical standards of the institutional and national research committees, the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individuals included in the study.

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