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Comparison of the Effect of On-Clamp vs. Off-Clamp Partial Nephrectomy on Renal Function: A Retrospective Analysis

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Abstract

Objective: Partial nephrectomy (PN) suggests a better renal reserve and comparable oncologic results than radical nephrectomy. Zero-ischemia PN is a technique to avoid the deleterious effects of ischemia on renal parenchyma cells. We aimed to determine the factors affecting the postoperative renal function of patients with clinical T_1 tumor who either underwent zero-ischemia or ischemic PN through the open or robotic approach.
Materials and Methods: The medical records of all cases with preoperative normal serum creatinine levels who underwent either on-clamp or off-clamp PN through an open or robot-assisted laparoscopic approach for T_1 tumors between January 2008 and December 2018 at our center were analyzed retrospectively.
Results: In total, 90 patients (i.e., 15 robotic off-clamp, 15 open off-clamp, 30 robotic on-clamp, and 30 open on-clamp PN) were included in the study. Although the decrease in the absolute estimated glomerular filtration rate (eGFR) was significantly higher in the robotic PN procedure, the percentage of decrease in the eGFR was similar between the open and robotic surgeries. According to Spearman's correlation analysis, preoperative eGFR was the only parameter that was significantly associated with a decrease in the eGFR (r=0.546, p<0.001).
Conclusion: Our findings regarding the results of renal function tests are inadequate to state that either the robotic or open zero-ischemia PN is superior to their ischemic counterpart. Besides the operative time, warm ischemia time, estimated blood loss, and excised healthy renal parenchyma cells must be considered while predicting the long-term renal function after PN.
Keywords: Creatinine, glomerular filtration rate, ischemia, laparoscopy, partial nephrectomy

Introduction

Nephron sparing surgery, also known as a partial nephrectomy (PN), has developed into a standard treatment for clinical T_1 tumors (1). Based on the long-term follow-up data, PN suggests comparable oncologic and better renal function test results when compared with a radical nephrectomy (2). The current PN techniques, whether open or minimally invasive (such as laparoscopy or robotic approach), frequently comprise clamping off the renal artery, which allows a bloodless operative field to view the tumor with an adequate parenchymal margin and to complete the reconstruction precisely. Clamping off the main renal artery leads to ischemia in the injury that can cause postoperative renal dysfunction. Many studies have reported that the deterioration of the renal function after a limited warm ischemia time of under 30 min is temporary and is reversed spontaneously. Gill et al. (3) reported that even this reversible ischemia may lead to damage, especially in elderly patients or those who have chronic kidney disease (CKD) or pre-existing medical comorbidities. Zero-ischemia PN is a technique to eliminate iatrogenic ischemia. The off-clamp technique could be performed without any hilar clamping, whereas the on-clamp technique includes the clamping of the hilum, where the renal artery is clamped with or without the vein, for reducing the blood supply to the renal parenchyma cells. Superficial and small renal masses could be removed without clamping (3). Smith et al. (4) reported the efficacy of the open off-clamped PN and its usefulness for the preservation

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of the renal function in general without specifically looking at tumor complexity.

The adequate long-term renal function after PN is relevant for three factors: preoperative function, the volume of the preserved nephrons, and warm ischemia time (5,6). This study aimed to determine the factors affecting postoperative renal function in patients with clinical T_1 tumor who underwent either zero-ischemia or ischemic PN via the open or robotic approach.

Materials and Methods

The Ethics Committee of University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital approved the study (approval number: 2019/101). The medical records of all patients with preoperative normal serum creatinine levels who underwent either on-clamp or off-clamp PN through an open or robot-assisted laparoscopic approach (The Da Vinci Surgical System, Intuitive Surgical, Inc., Sunnyvale, CA, USA) for T_1 tumors between January 2008 and December 2018 at our center were analyzed retrospectively. All consecutive patients having a follow-up of at least 18 months with complete data available were included in the study. Patients with solitary kidney, CKD, and bilateral or multiple tumors and patients on the learning curve were excluded from the study. The type of the surgery was decided based on the additional cost of robotic surgery, surgical expertise, and patient's preference. All patients were classified into four groups according to the type of surgery: Group 1, robotic off-clamp PN; group 2, open off-clamp PN; group 3, robotic on-clamp PN; and group 4, open on-clamp PN. All patients provided written informed consent.

Most open procedures were performed through a retroperitoneal approach. All robotic procedures and a few difficult open procedures were performed via the transperitoneal approach. In the robotic groups, under general anesthesia, the patient was placed to the full side position at 60°. A Veress needle was used to create a 15 mmHg pneumoperitoneum. An 8 mm camera port was placed at the level of the rectus muscle lateral to the umbilicus level. Under direct vision, 8 mm robotic trocars, one in the subcostal and one in the lower quadrant, were placed at the level of the camera port. Depending on the tumor location, a 12 mm assistant port was placed at least 1 cm below the robotic port location. In both open and robotic on-clamp procedures, after the isolation of the renal artery, the renal artery was controlled using a bulldog clamp. In the off-clamp groups, in case of excessive bleeding during tumor excision, the renal artery was dissected and identified with a vessel loop to ensure rapid hilar control. The tumors were resected with an appropriate parenchymal margin instead of enucleation in all cases. Following tumor resection using cold scissors, the tumor bed was sutured using a 2-0 Vicryl (Ethicon, Somerville, NJ, USA) for hemostasis of the vessels and closure of the collecting system. Thereafter, parenchymal hemostasis was achieved by approximating both edges using continuous 3-0 V-Loc (Covidien, Mansfield, MA, USA) sutures. In the robotic groups, the tumor bed was examined under low insufflation pressure to achieve hemostasis after renal reconstruction. The tumor excision and renal reconstruction were completed without cooling in all cases.

All patients were evaluated with an abdominal multi-slice computed tomography or magnetic resonance imaging before surgery. The studied parameters included patients' demographic data, tumor size and location, renal nephrometry score, operation features, preoperative and postoperative imaging studies, and preoperative and postoperative serum biochemical analysis. The RENAL score was determined by two urologists (EG, NK) as previously described (7). In brief, the RENAL score includes five critical anatomical components of the renal mass: (R)adius (maximal tumor diameter), (E)xophytic/endophytic properties, (N)earness of the deepest portion of the tumor to the collecting system or sinus, (A)nterior/posterior location, and (L)ocation relative to the polar line. The eGFR of patients was measured using the modification of diet in the renal disease formula. The renal function was assessed before the surgery and postoperatively at 3, 6, 12, and 18 months. The percent change in eGFR was calculated as follows:

eGFR=(postoperative eGFR - preoperative eGFR)/preoperative eGFR × 100

The absolute eGFR was calculated as follows:

Absolute eGFR=postoperative eGFR - preoperative eGFR

Statistical Analysis

IBM Statistical Package for the Social Sciences Statistics for Mac v. 21.0 (IBM SPSS Corp., Armonk, NY, USA) was used for the statistical analysis. The mean ± standard deviation has been used to express the quantitative measurements. The numbers and percentages have been provided for quantitative measurements. The normal distribution of the continuous variables was tested using the Shapiro-Wilk test. Mann-Whitney U test was used for comparing the means between the nonnormally distributed groups. Means of more than two normally distributed and non-normally distributed groups were compared using analysis of variance and Kruskal-Wallis tests, respectively. The frequency of the categorical variables was compared using Pearson's chi-square test. $P<0.05$ was considered statistically significant. Logistic regression analysis was used to identify the predictive factors for a decrease of >20 in eGFR.

Results

A total of 90 patients, of whom 45 were males and 45 were females, were included in the study. The distribution of the patients was as follows: 15 robotic off-clamp PN, 15 open off-clamp PN, 30 robotic on-clamp PN, and 30 open on-clamp PN. The average age of the patients was 52.5±12.1 years. Patient characteristics are provided in Table 1. The mean follow-up time of the patients was 40.1±27.7 months. Our cohort was generally healthy, and 87.8% of the patients had an American Society of Anesthesiologists score of 1 or 2. The mean tumor size was 40.7±15.8 mm. The mean preoperative eGFR was 100 mL/min/1.73 m^2. The mean RENAL score of the masses was 7.1±1.9. The mean operative time and the perioperative estimated blood losses were 183±49.2 min and 193.1±134 mL, respectively. The percentage of the patients with minor (Clavien-Dindo grade 1 and 2) complications was 18.8%. Of the 6 minor complications, 2 were postoperative urine leakage that were resolved with a ureteral stent placement, and 4 were postoperative fever that

Table 1. Comparison of the patient demographics, characteristics, and operation features according to the type of surgery

Variables	Open off-clamp PN group	Robotic off-clamp PN group	Open on-clamp PN group	Robotic on-clamp PN group	p-value
Number of patients (group number)	15 (1)	15 (2)	30 (3)	30 (4)	
Mean age ± SD, years	50.2±14.3	51.4±14.0	56.6±8.7	50.1±12.4	0.162*
Gender, n (%)					0.003**
Male Female	4 (26.7) 11 (73.3)	3 (20) 12 (80)	17 (56.7) 13 (43.3)	21 (70) 9 (30)	1 vs. 4 0.006 2 vs. 3 0.020 2 vs. 4 0.002
ASA score					0.149**
ASA 1	4 (26.7)	3 (20.0)	14 (46.7)	7 (23.3)	
ASA 2	7 (46.7)	10 (66.7)	13 (43.3)	21 (70.0)	
ASA 3	4 (26.7)	2 (13.3)	3 (10.0)	2 (6.7)	
Preoperative GFR	82±19.9	121.6±44.7	92.3±14.8	106±31.5	0.006¥ 1 vs. 2 0.002 1 vs. 4 0.021
Tumor size, (mm)	29.4±5.2	30.6±5.9	57.3±11.6	34.9±12.7	<0.001¥ 1 vs. 3 <0.001 2 vs. 3 <0.001 3 vs. 4 <0.001
RENAL score	6.9±0.7	6.1±0.8	9.2±1.2	5.7±1.6	<0.001¥ 1 vs. 3 <0.001 1 vs. 4 <0.008 2 vs. 3 <0.001 3 vs. 4 <0.001
EBL, (mL)	359.3±140.7	240±90.8	73.6±48.3	206±94.4	<0.001¥ 1 vs. 3 <0.001 1 vs. 4 <0.006 2 vs. 3 <0.001 3 vs. 4 <0.001
OT, (min)	194±29.7	233±24.7	141.1±37.6	194.5±44.6	<0.001* 1 vs. 2 <0.003 1 vs. 3 <0.001 2 vs. 3 <0.001 2 vs. 4 <0.004 3 vs. 4 <0.001
Warm ischemia time, (min)	NA	NA	22.3 ± 5.3	17 ± 3.5	<0.001†
Complications, n (%)	4 (26.7)	2 (13.3)	5 (16.7)	6 (20)	0.798**
Follow-up (months)	92.5±13.2	38±10	26.4±14.7	28.7±16.2	<0.001* 1 vs. 2 <0.001 1 vs. 3 <0.001 1 vs. 4 <0.001 2 vs. 3 0.022
GFR at the 18-month follow-up	63.3±17	82.6±21.1	72.8±11.8	78.7±18.7	0.01*
Absolute GFR change	18.6±10.4	39±30	19.5±5.4	27.3±16.8	0.041¥
Percent GFR change (%)	22.4±10.3	28±15.1	21±4.1	24.7±7.6	0.083

PN: Partial nephrectomy, ASA: American Society of Anesthesiologists, eGFR: Estimated glomerular filtration rate, NA: Not applicable, SD: Standard deviation, *One-Way Analysis of Variance, **Pearson chi-square, ¥Kruskal-Wallis test, †Mann-Whitney U test & to present the post-hoc analysis results, the groups were numbered

were resolved with antipyretics. The mean postoperative nadir eGFR was 80.4±22.2 mL/min/1.73 m^2, which represents an absolute and a percent decrease of 19.6±17.1 mL/min/1.73 m^2 and 18.4%±11.1%, respectively. The longest operative time was observed in the off-clamp robot-assisted laparoscopic PN group (233±24.7 min) (Table 1).

Age and preoperative eGFR were found to be similar between the patients who underwent off-clamp (n=30; p=0.357) and on-clamp PN (n=60; p=0.739). The operative time, estimated blood loss, and percent of eGFR decrease was higher in the off-clamp PN, whereas the RENAL score and tumor size were higher in the on-clamp PN group.

The mean preoperative eGFR and operative time were significantly higher in the robotic PN, whereas the RENAL score and tumor size were significantly higher in the open PN. Although the absolute eGFR decrease was significantly

Table 2. Univariate analysis and logistic regression test to predict perioperative estimated glomerular filtration rate decrease of >20

	Univariate			Multivariate		
	OR	95% CI	p-value	OR	95% CI	p-value
Age (years)	0.992	0.956-1.028	0.648			
Gender (female)	1.000	0.416-2.403	1.000			
ASA 3	0.583	0.131-2.606	0.480			
Preoperative GFR	1.030	1.007-1.053	0.010	1.051	1.010-1.530	0.006
Tumor size	1.008	0.980-1.037	0.560			
RENAL score	0.951	0.762-1.185	0.653			
EBL	1.001	0.998-1.005	0.430			
OT	1.005	0.996-1.014	0.272			
Warm ischemia time	1.009	0.967-1.054	0.667			
Complications	0.657	0.222-1.944	0.448			
Follow-up	1.003	0.987-1.019	0.742			
GFR at the 18-month follow-up	1.007	0.990-1.024	0.428			
Absolute GFR change	1.476	1.235-1.765	<0.001			
Percent GFR change	1.011	0.998-1.090	0.946			
Operational method (on-clamp OPN and RPN)	1.249	0.498-3.136	0.636			

ASA: American Society of Anesthesiologists, eGFR: Estimated glomerular filtration rate, EBL: Estimated blood loss, OT: Operation time, OPN: Open partial nephrectomy, RPN: Robotic partial nephrectomy, CI: Confidence interval, OR: Odds ratio

higher in the robotic PN, the percent of eGFR decrease was similar between the open and robotic surgeries. No statistically significant difference was observed in percent eGFR decrease between on-clamp and off-clamp robotic PN groups (p=0.43).

Thirty patients had an eGFR decrease of 20%. In a logistic regression analysis, the preoperative eGFR was found to be the sole predictor of eGFR decrease of >20 [p=0.006, Exp (B)=1.051]. However, the operative time, age, ischemia duration, estimated blood loss, RENAL score, and tumor size were not statistically significant (p=0.085, p=0.633, p=0.842, p=0.120, p=0.361, and p=0.141, respectively). According to Spearman's correlation analysis, preoperative eGFR was found as the only parameter that was significantly associated with the percent decrease in eGFR (r=0.546, p<0.001) (Table 2).

Discussion

The extended use of different radiological imaging methods has led to the gain of several small renal masses being detected incidentally in recent years. Further, there is an increased demand for PN for treating the small renal masses. The hilar vascular clamping provides bloodless surgical field results in renal warm ischemic injury. Warm ischemic injury has a deleterious effect on kidney function (8). To overcome this issue, off-clamp PN with zero ischemia has been proposed. PN could be performed with either open or robotic techniques. Although the oncologic outcomes of the two techniques are similar, robotic PN offers faster recovery after surgery, shorter hospital stays, and favorable cosmetic results. Nowadays, robotic PN is considered not only for T_1, but also for T_2 tumors (9).

Gill et al. (10) used the selective vascular dissection technique that was first described as the robotic off-clamp technique. In a study by Kaczmarek et al. (11), the authors introduced the total off-clamp robotic PN technique in 49 patients after at least 12 months of follow-up and reported excellent functional outcomes. In their propensity score-matched analysis, Simone et al. (12) reported that off-clamp PN offers 100% preservation of the preoperative GFR in the postoperative period. They also reported that on-clamp PN is associated with a 7.3-fold higher risk of developing CKD and longer operation time compared with off-clamp PN. In our study, unlike Simone et al. (13), a 21% reduction in eGFR was detected in off-clamp robotic PN at the 18-month follow-up. This may be due to the longer follow-up period. Furthermore, no significant difference was observed in the absolute and percentage eGFR decrease in patients who underwent ischemic or nonchemic robotic PN. The only independent parameter predicting eGFR reduction was preoperative eGFR. Additionally, the operation time was statistically longer in the off-clamp robotic PN group, which may be associated with bleeding at the surgical site or difficulty in parenchymal suturing.

In a study by Smith et al. (4), the functional kidney results of 116 patients who underwent on-clamp open PN and 192 patients who underwent off-clamp open PN were compared. The mean warm ischemia time of patients in the on-clamp PN group was reported to be 23 min. The rate of the percent decrease in eGFR of patients in the off-clamp PN group was statistically lower than the on-clamp PN group (9.8% vs. 12.3%, p=0.037). Furthermore, tumor size, estimated blood loss >200 mL, a Carlson comorbidity index >5, and warm ischemia time longer than 22 min were associated with higher postoperative eGFR decline rate (4). Demirel et al. (14) determined that tumor grade, PADUA score, and C-index were valuable parameters predicting renal dysfunction after partial nephrectomy. In a meta-analysis by Liu et al. (8) comparing the effects of off-clamp and on-clamp PN, the authors concluded that off-clamp PN enables better preservation of the kidney reserves than on-clamp PN. Additionally, off-clamp PN represents oncologic outcomes that are comparable with superior renal functional outcomes. The complication rate was reported to be significantly lower in patients who underwent off-clamp PN than those who underwent on-clamp PN (12.5% vs. 18%). Each of the five studies constituting the meta-analysis showed better renal functional outcomes based on changes in the eGFR in patients who underwent off-clamp PN (8). In contrast with the aforementioned studies and meta-analysis, in our study, the percentage of eGFR reduction was determined as 22.4%±10.3% in off-clamp open PN and 21%±4.1% in on-clamp open PN, and we could not find evidence of superiority of off-clamp PN over on-clamp PN. In addition to warm ischemia time, the operative time and amount of bleeding may play a role in the decrease in eGFR after PN. Further, preserved renal parenchyma is vital in maintaining renal function after PN. In this study, the largest tumor diameter was observed in open PN with ischemia. This situation could lead to similar percentage of eGFR changes in all four groups.

The robotic off-clamp PN could be performed in many ways, and one of those ways is to excise the tumor without the identification/isolation of the renal hilum, called the purely off-clamp PN. In a study conducted by Simone et al. (13), the purely off-clamp robotic PN was found to be a safe surgical procedure with comparable surgical outcomes and minimal effect on renal function. In our study, we preferred to identify the renal hilum in case of an adverse event. Besides not using the renal hilum isolation, renorrhaphy could be avoided with the use of off-clamp PN. Laparoscopic PN performed without hilar clamping and renorrhaphy has been used effectively, especially in small-peripheral tumors with low nephrometry scores (15). In our study, renorrhaphy was not performed in any case.

The utility of the off-clamp PN is uncertain. We preferred this technique in patients with solitary T_1 tumors, which could be excised in <15 min warm ischemia time. The intraoperative bleeding in off-clamp cases is expected to be higher than in on-clamp ones, which may play an indeterminate role in the alterations in postoperative renal function. To decrease intraoperative blood loss during zero-ischemia PN, manipulations, such as pharmacologically induced hypotension during surgery, have been proposed (6). Our strategy was to keep the blood pressure within the normal limits to avoid renal perfusion injury. A drawback of the zero-ischemia technique could be the possibility of under-visualization during tissue resection because of bleeding, which affects the evaluation of the surgical margin. We suggest using a cold scissor during tumor resection instead of energy to better visualize and avoid tumor violation. The amount of normal parenchyma preserved during PN mainly affects renal function restoration; this should be considered when zero-ischemia robotic PN is planned because similar parenchymal preservation could be performed with <15 min warm ischemia time. Although the impact of short warm ischemia time is reversible, the excised parenchyma is irrecoverable (5).

Study Limitations

Our study also has limitations. Primarily, this study was conducted retrospectively. The study population was relatively small , and data were from a single institution although the follow-up period was sufficient (>18 months). No residual functional volume data were available. Further studies on nuclear imaging modalities, such as scintigraphy, are required to improve the quality and scientific merit of our findings.

Conclusion

Our findings regarding renal functional outcomes were insufficient to propose whether the robotic or open zero-ischemia PN is superior to the ischemic counterpart. Besides warm ischemia time, estimated blood loss, operative time, and excised healthy renal parenchyma must be considered while predicting long-term renal function following PN.

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Ethics

Ethics Committee Approval: The Ethics Committee of University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital approved the study (approval number: 2019/101).

Informed Consent: All patients provided written informed consent.

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Authorship Contributions

Critical Review: F.A.A., Supervision: F.A.A., Concept: E.G., N.K., Design: E.G., N.K., Data Collection or Processing: F.A., E.S., Analysis or Interpretation: F.A., E.S., Literature Search: N.K., K.G.Ş., Writing: E.G., K.G.Ş.

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