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# Off-clamp Versus On-clamp Robot-assisted Partial Nephrectomy: A Propensity-matched Analysis

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## Abstract

**Background:** Partial nephrectomy is the preferred treatment option for the management of small renal masses. On-clamp partial nephrectomy is associated with a risk of ischemia and a greater loss of postoperative renal function, while the off-clamp procedure decreases the duration of renal ischemia, leading to better renal function preservation. However, the efficacy of the off- versus on-clamp partial nephrectomy for renal function preservation remains debatable.

**Objective:** To compare perioperative and functional outcomes following off- and on-clamp robot-assisted partial nephrectomy (RAPN).

**Design, setting, and participants:** This study used the prospective multinational collaborative Vattikuti Collective Quality Initiative (VCQI) database for RAPN.

**Outcome measurements and statistical analysis:** The primary objective of this study was the comparison of perioperative and functional outcomes between patients who underwent off- and on-clamp RAPN. Propensity scores were calculated for age, sex, body mass index (BMI), renal nephrometry score (RNS) and preoperative estimated glomerular filtration rate (eGFR).

**Results and limitations:** Of the 2114 patients, 210 had undergone off-clamp RAPN and others on-clamp procedure. Propensity matching was possible for 205 patients in a 1:1 ratio. After matching, the two groups were comparable for age, sex, BMI, tumor size, multifocality, tumor side, face of tumor, RNS, polar location of the tumor, surgical access, and preoperative hemoglobin, creatinine, and eGFR. There was no difference between the two groups for intraoperative (4.8% vs 5.3%,  $p = 0.823$ ) and postoperative (11.2% vs 8.3%,  $p = 0.318$ ) complications. Need for blood transfusion (2.9% vs 0,  $p = 0.030$ ) and

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conversion to radical nephrectomy (10.2% vs 1%,  $p < 0.001$ ) were significantly higher in the off-clamp group. At the last follow-up, there was no difference between the two groups for creatinine and eGFR. The mean fall in eGFR at the last follow-up compared with that at baseline was equivalent between the two groups ( $-16.0$  vs  $-17.3$  ml/min,  $p = 0.985$ ).

**Conclusions:** Off-clamp RAPN does not result in better renal functional preservation. Alternatively, it may be associated with increased rates of conversion to radical nephrectomy and need for blood transfusion.

**Patient summary:** With this multicentric study, we noted that performing robotic partial nephrectomy without clamping the blood supply to the kidney is not associated with better preservation of renal function. However, off-clamp partial nephrectomy is associated with increased rates of conversion to radical nephrectomy and blood transfusion.

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## 1. Introduction

Partial nephrectomy (PN), wherever possible, is the preferred treatment option for the management of small renal masses [1,2]. Before resecting the tumor from the kidney, control of the hilar vessels is deemed necessary. Clamping the hilar vessels followed by cooling renal parenchyma to a low temperature (cold ischemia) was the standard practice during the open surgery era. However, with the increased adoption of minimally invasive surgical techniques, most PNs today are performed without cold ischemia (with warm ischemia) [2]. Clamping of the renal artery during tumor excision predisposes the kidney to the risk of ischemia (known as warm ischemia time [WIT]). It has been believed that a longer duration of ischemia results in a greater loss of postoperative renal function [3]. Furthermore, WIT has been identified as a predictor of short- and long-term renal function preservation [4–9].

Additional intraoperative maneuvers such as selective arterial clamping, early unclamping, and off-clamp PN have been proposed to reduce WIT. The theoretical premise of such additional maneuvers is that a decreased duration of renal ischemia should lead to better renal function preservation. However, the efficacy of off-clamp PN over on-clamp PN for renal function preservation remains debatable. Retrospective studies have reported inconsistent findings regarding renal function preservation [10–16]. The two prospective randomized controlled trials (RCTs) have reported no advantage for off-clamp PN over on-clamp PN for functional outcomes [10,11]. However, it is to be noted that these two RCTs were not without limitations. The first RCT by Anderson et al [10] was small and inadequately powered. At the same time, the second RCT by Antonelli et al [11] was limited by a large crossover of patients in either group. Therefore, with this study, we aimed to utilize the multicentric multinational Vattikuti Collective Quality Initiative (VCQI) database for robot-assisted partial nephrectomy (RAPN) to compare perioperative and functional outcomes following off- and on-clamp RAPN.

## 2. Patients and methods

VCQI is a prospective multinational collaborative database for various robotic surgical procedures maintained by Vat-

tikuti Foundation [17–19]. For RAPN, data are added by 18 contributing institutions from nine countries (USA, UK, India, Italy, Portugal, Belgium, Turkey, and South Korea). Ethics clearance was obtained from each participating institution. Owing to the multi-institutional nature of the database, patients without adequate data had to be excluded from the study. Data for demographic variables such as age, sex (male/female), and body mass index (BMI) were extracted for every patient. We also extracted data for clinical variables such as clinical tumor size, estimated glomerular filtration rate (eGFR) using the modified diet in renal disease equation, symptoms (absent/local/systemic), polar location of the tumor (upper/middle/lower pole), number (single/multiple), laterality (unilateral/bilateral), solitary kidney, and renal nephrometry score (RNS) (Supplementary material). Data for operative factors such as surgical access (retroperitoneal/transperitoneal), operative time, WIT, blood loss, intraoperative blood transfusion, need for conversion to radical nephrectomy (RN), and intraoperative complications were also extracted. Complications were graded as per the Clavien-Dindo classification [20]. The primary objective of this study was the comparison of perioperative and functional outcomes between patients who underwent off- and on-clamp RAPN. Kruskal-Wallis test was used for continuous variables. For categorical variables, chi-square or Fisher's exact tests were used. A propensity score model was developed to predict whether clamping was performed or not. We used five independent variables (age, sex, BMI, RNS, and preoperative eGFR) that could impact ischemia time for calculating propensity scores. Nearest neighborhood matching was performed for the off- and on-clamp groups using a caliper of 0.001. We performed 1:1 matching between the two groups, that is, off and on clamp. Statistical tests conducted were two sided, and a  $p$  value of  $<0.05$  was considered significant. The statistical tests were double sided and conducted using SPSS version 23 (IBM Corporation, New York, NY, USA) and Stata (version 16; StataCorp, College Station, TX, USA). Achievement of a  $p$  value of  $<0.05$  was used to define significance.

## 3. Results

From October 2014 to March 2020, the participating centers contributed the data of 3801 patients who underwent

RAPN. Data for off-clamp RAPN were contributed by 15 of the 18 participating centers. In this study, 2114 patients with complete data on the type of ischemia were included for the final analysis. Of these 2114 patients, 210 had undergone off-clamp RAPN and others on-clamp RAPN (Fig. 1). A comparison of patients who underwent off- and on-clamp RAPN has been shown in Table 1.

### 3.1. Overall analysis

#### 3.1.1. Before matching

The median age was significantly higher in the off-clamp group (62 vs 59 yr,  $p = 0.003$ ). The mean tumor size was significantly larger in the on-clamp group (35 vs 30.8 mm,  $p = 0.005$ ). The proportion of patients with solitary kidneys was significantly higher in the off-clamp group (6.2% vs 2.6%,  $p = 0.005$ ). The two groups were comparable for BMI, gender, tumor side, multifocality, and polar tumor location. The median RNS was significantly higher in the on-clamp group (7 vs 6,  $p \leq 0.001$ ). Two groups were comparable for preoperative hemoglobin and creatinine; however, eGFR was significantly higher in the on-clamp group (79 vs 75 ml/min,  $p = 0.023$ ).

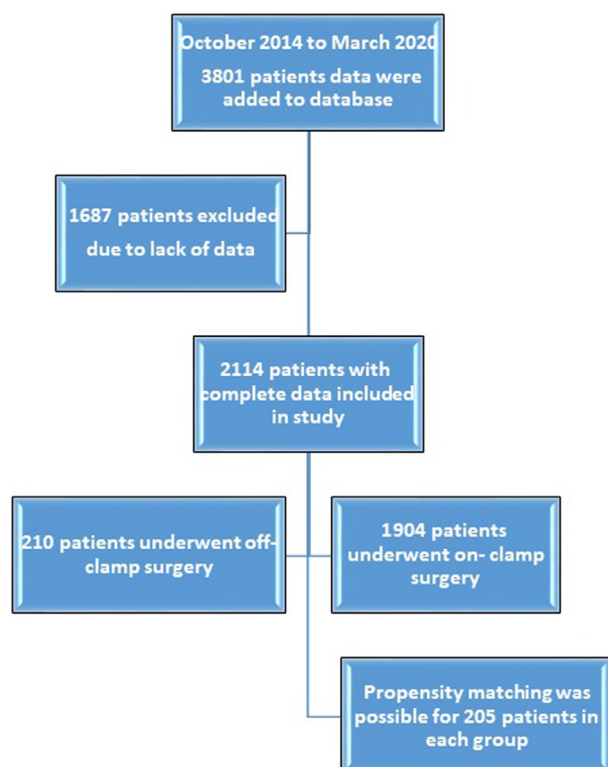
#### 3.1.2. After matching

Propensity matching was possible for 205 patients who underwent off-clamp RAPN with 205 patients who underwent on-clamp RAPN. The two groups were comparable for age, sex, BMI, tumor size, multifocality, tumor side, face of tumor, RNS, polar location of the tumor, surgical access and preoperative hemoglobin, creatinine, and eGFR

**Table 1 – Prematching comparison of patients undergoing robot-assisted partial nephrectomy with and without hilar clamping**

Variables	Hilar clamping		p value
	No (n = 210)	Yes (n = 1904)	
Age (yr), median (IQR)	62 (52–70)	59 (49–67)	<b>0.004</b>
Sex (male), n (%)	126 (60)	1264 (66.4)	0.064
BMI (kg/m <sup>2</sup> ), median (IQR)	27.4 (24.2–33.2)	27.3 (24.4–31.1)	0.3
Tumor size (mm), mean ± SD	30.8 ± 20	35.0 ± 18.5	<b>0.005</b>
Clinical symptoms, n (%)			
Asymptomatic	167 (79.5)	1582 (83.1)	
Local	37 (17.6)	297 (15.5)	0.15
Systemic	6 (2.85)	25 (1.4)	
Single kidney, n (%)	13 (6.2)	51 (2.67)	<b>0.005</b>
Multifocal, n (%)	9 (4.3)	98 (5.1)	0.6
Right-side tumor, n (%)	95 (45.2)	745 (39.12)	0.086
Face of tumor, n (%)			
Anterior	128 (61)	958(50.3)	<b>0.003</b>
Posterior	82 (39)	946 (49.7)	
Polar location of tumor, n (%)			
Upper	72 (34.2)	600 (31.5)	
Mid	75 (35.8)	735 (38.6)	0.6
Lower	63 (30)	569 (29.9)	
RENAL nephrometry score, median (IQR)	6 (5–8)	7 (6–9)	<b>&lt;0.001</b>
Preop hemoglobin (g/dl), mean ± SD	13.72 ± 1.62	13.85 ± 1.60	0.3
Preop creatinine (mg/dl), mean ± SD	1.04 ± 0.58	0.98 ± 0.36	0.13
Preop eGFR (ml/min), mean ± SD	75.1 ± 25.6	79.1 ± 23.88	<b>0.023</b>
Surgical access, n (%)			
Transperitoneal	186 (88.5)	1628 (85.5)	0.2
Retroperitoneal	24 (11.4)	276 (14.5)	

BMI = body mass index; eGFR = estimated glomerular filtration rate; IQR = interquartile range; SD = standard deviation.



**Fig. 1 – Flowchart depicting inclusion and exclusion of the patients from the study.**

(Table 2). However, the two groups were not comparable for the number of patients with solitary kidneys. The off-clamp group had a significantly higher number of patients with a solitary kidney (4.8% vs 2.9%,  $p = 0.026$ ). There was no difference between the two groups for intraoperative (4.8% vs 5.3%,  $p = 0.8$ ) and postoperative (11.2% vs 8.3%,  $p = 0.3$ ) complications. Need for blood transfusion (2.9% vs 0,  $p = 0.030$ ) and conversion to RN (10.2% vs 1%,  $p < 0.001$ ) were significantly higher in the off-clamp group. There was no difference between the two groups for blood loss and length of stay. The positive surgical margin rate was higher in the on-clamp group; however, the difference was not statistically significant (8.3% vs 3.9%,  $p = 0.07$ ). There was no difference between the two groups for immediate postoperative creatinine and eGFR. The median durations of follow-up in the off- and on-clamp RAPN were 19 and 17 mo, respectively. There was no difference between the two groups for creatinine and eGFR, at the last follow-up. The mean fall in eGFR at the last follow-up compared with baseline was comparable between the two groups (–16.0 vs –17.3 ml/min,  $p = 0.9$ ; Table 3).

## 4. Discussion

The major urological guidelines now recommend PN as a standard treatment option for managing small renal masses [1,2]. RAPN has superseded other methods as the preferred mode of surgery in recent times. Initial studies on PN had noted WIT to be an independent predictor of long-term

**Table 2 – Postmatching comparison of patients undergoing robot-assisted partial nephrectomy with and without hilar clamping for baseline characteristics**

Variables	Hilar clamping		p value
	No (n = 205)	Yes (n = 205)	
Age (yr), median (IQR)	62 (51.5–70)	61 (52–69)	0.7
Sex (male), n (%)	123 (60)	110 (53.6)	0.2
BMI (kg/m <sup>2</sup> ), median (IQR)	27.4 (24.1–33.0)	27.5 (24.7–32.1)	0.7
Tumor size (mm), mean ± SD	31 ± 20	33.4 ± 15.9	0.2
Clinical symptoms, n (%)			
Asymptomatic	162 (79)	163 (79.5)	
Local	37 (18)	40 (19.5)	0.4
Systemic	6 (3)	2 (1)	
Single kidney, n (%)	13 (4.8)	4 (2.9)	<b>0.03</b>
Multifocal, n (%)	9 (4.4)	12 (5.85)	0.5
Right side tumor, n (%)	93 (45.3)	76 (37.1)	0.088
Face of tumor, n (%)			
Anterior	125 (61)	107 (52.2)	
Posterior	80 (39)	98 (47.8)	0.073
Polar location of tumor, n (%)			
Upper	70 (34.1)	58 (28.3)	
Mid	73 (35.6)	75 (36.5)	0.4
Lower	62 (30.2)	72 (35.1)	
RENAL nephrometry score, median (IQR)	6 (5–8)	7 (5–8)	0.6
Preop hemoglobin (g/dl), mean ± SD	13.73 ± 1.63	13.58 ± 1.72	0.4
Preop creatinine (mg/dl), mean ± SD	1.03 ± 0.57	0.97 ± 0.31	0.2
Preop eGFR (ml/min), mean ± SD	75.6 ± 25.5	78.66 ± 25.8	0.2
Surgical access, n (%)			
Transperitoneal	182 (88.8)	174 (84.8)	0.2
Retroperitoneal	23 (11.2)	31 (15.2)	

BMI = body mass index; eGFR = estimated glomerular filtration rate; IQR = interquartile range; SD = standard deviation. Bold = statistically significant

**Table 3 – Postmatching comparison of patients undergoing robot-assisted partial nephrectomy with and without hilar clamping for perioperative outcomes**

Variables	Hilar clamping		p value
	No (n = 205)	yes (n = 205)	
Intraoperative transfusion, n (%)	6 (2.92)	0	<b>0.030</b>
Conversion to radical nephrectomy, n (%)	21 (10.2)	2 (0.97)	<b>&lt;0.001</b>
Complications, n (%)	23 (11.2)	17 (8.3)	0.3
I	10 (4.8)	5 (2.43)	
II	9 (4.4)	12 (5.85)	0.2
III	3 (1.46)	0	
IV	2 (0.97)	0	
Margin positive, n (%)	8 (3.9)	17 (8.29)	0.069
Blood loss (ml), median (IQR)	100 (50–200)	100 (50–200)	0.6
WIT (min), mean ± SD	0	18.9 ± 6.9	<b>&lt;0.001</b>
Length of stay (d), median (IQR)	3 (2–4)	3 (2–4)	0.9
Postoperative, mean ± SD			
Creatinine (mg/dl)	1.19 ± 0.69	1.19 ± 0.64	0.9
eGFR (ml/min)	63.3 ± 24.9	64.09 ± 21.7	0.7
Fall in eGFR (compared with baseline)	-12.3 ± 23.3	-14.5 ± 23.1	0.3
Last follow-up, mean ± SD			
Creatinine (mg/dl)	1.06 ± 0.62	0.98 ± 0.23	0.089
eGFR (ml/min)	59.59 ± 16.3	61.27 ± 15.3	0.3
Fall in eGFR (compared with baseline)	-16.03 ± 29.9	-17.3 ± 31.1	0.9
Median duration of follow-up (mo)	19 (1–96)	17 (1–80)	0.6

eGFR = estimated glomerular filtration rate; IQR = interquartile range; SD = standard deviation; WIT = warm ischemia time. Bold = statistically significant

renal function preservation [21]. This was the logic behind including WIT as one of the comprehensive outcome parameters of “trifecta” [22]. Herein, WIT served as a proxy marker for renal function preservation. Recent studies have reported somewhat contrary findings [10,11,23–25]. In a

recent study by Xiong et al [23], authors analyzed histopathology specimens of patients who underwent PN followed by RN for tumor recurrence. Normal renal parenchyma was examined at 5 mm away from the tumor in PN specimens and at remote sites in RN specimens. The

authors reported that the type and duration of ischemia did not correlate with the histological changes after PN. Hence, the old dictum of longer ischemia time leading to poor renal function preservation has been challenged. Therefore, the use of WIT as a proxy marker for renal function preservation has become controversial. Hence, this multicentric study aimed to study the impact of clamping (ie, warm ischemia) on perioperative and functional outcomes following RAPN compared with nonclamping (no ischemia).

We noted an apparent selection bias between the two groups from the overall analysis of this study (before matching). The two groups were statistically different for various patient-related (age and eGFR) and tumor-related (size and complexity) factors. Thus, patients who underwent off-clamp RAPN were older, and had smaller and lesser complexity renal masses. However, the two groups were comparable for all the perioperative outcomes except for the need for blood transfusion and conversion to RN (before and after matching). Rates of conversion to RN were prohibitively high in the off-clamp group (10% vs 0.5%,  $p < 0.0001$ ). Even after matching baseline characteristics, the conversion rates to RN and the need for blood transfusion remained higher in the off-clamp group. Much of the literature comparing off- and on-clamp PN for renal masses is limited to retrospective studies. Off-clamp RAPN has been associated with significantly higher blood loss in two studies [13,15]. In contrast to the current study's findings, a previous meta-analysis on the topic reported increased blood loss and lower complication rates with off-clamp RAPN [12]. However, blood transfusion rates, length of stay, and conversion to radical or open surgery were comparable in the two groups. The conversion rate to RN has not been reported explicitly in the previous retrospective studies. The rate of conversion to RN in the off-clamp cohort of our study is beyond the acceptable range. One could argue that long-term renal function could have been hampered by larger conversion to RN in the off-clamp group. Thus, from the results of this study, it is apparent that even in well-selected patients, off-clamp RAPN does not offer any functional advantages, and it is associated with prohibitively higher rates of conversion to RN. Owing to a lack of data on the cause for conversion to RN from the database, the plausible explanation for such heightened rates of conversion to RN remains unexplained.

Two RCTs reported no definite advantage of off-clamp RAPN over on-clamp RAPN in preserving renal function [10,11]. The largest RCT on the topic by Antonelli et al [11] reported no difference in the absolute variation in eGFR at 6 mo following surgery. Despite being powered adequately, this study was marred by a high crossover rate of patients in both groups. About 43% of the randomized patients were crossed over from off- to on-clamp RAPN at the discretion of the operating surgeon. In a smaller but randomized comparison of off- and on-clamp RAPN by Anderson et al [10], authors reported comparable perioperative and short-term (3 mo) functional outcomes between the two groups. Results from a retrospective comparison of off- and on-clamp RAPN have been variable. In their study of 41 off-clamp patients matched to 83 on-clamp patients, Rosen et al [15] reported no difference between the two

groups for a change in eGFR and chronic kidney disease (CKD) progression. Bertolo et al [26], in their study of 200 off-clamp and 400 on-clamp patients, noted a progressive decline in the difference in eGFR drop between the two groups up to 24 mo following surgery. Mari et al [14], in their retrospective study, reported a lower eGFR fall after off-clamp RAPN on postoperative days 3 and 30. However, there was no difference between the two groups at 6 mo and at the last follow-up visit. Simone et al [16] noted the probability of developing CKD stage 3b to be higher with on-clamp RAPN. Kaczmarek et al [13] reported a smaller drop in eGFR with off-clamp RAPN than with on-clamp RAPN (2% vs 6%,  $p = 0.008$ ). Finally, Huang et al [12], in their meta-analysis, noted off-clamp RAPN to be associated with higher renal function preservation (mean difference  $-3.17$ ,  $p = 0.012$ ) [12]. However, no difference in functional outcomes with respect to serum creatinine, eGFR, and fall in eGFR at the last follow-up was noted between the two groups in this study

#### 4.1. Limitations

Some limitations of this study are worth acknowledging. First, for this study, we have performed a retrospective analysis of a prospectively maintained database. Hence, the possibility of a selection bias cannot be ruled out. Data to VCQI are contributed by different centers across the country. This may account for heterogeneity in surgical techniques, learning curves, and perioperative management of patients. Data are also lacking for surgeon experience. Furthermore, data are lacking on the modality used for reporting tumor size and tumor complexity score. Furthermore, data on who calculated the RENAL nephrometry score are also lacking. Owing to the retrospective and multicentric nature of the study, a central review of all the radiology procedures was impossible. Nearly one-third of the patients had to be excluded due to a lack of data, which is an important limitation of this study. There is a lack of data on operative details, such as the technique of resection enucleation versus resection versus enucleoresection, and the use of adjunctive techniques such as indocyanine green, intraoperative ultrasound, and frozen section. The follow-up guidelines employed may vary from center to center. The propensity model used in the present study was matched only on the factors considered and did not attempt to balance on other measured factors not included in the propensity score model nor any unmeasured factors.

#### 5. Conclusions

Off-clamp, compared with on-clamp, RAPN is associated with significantly higher conversion rates to RN and the need for blood transfusion. Off-clamp RAPN does not offer any advantage in renal function preservation compared with on-clamp RAPN. Owing to a lack of generalizability of the findings of this propensity-matched analysis, further well-conducted randomized studies are needed.

**Author contributions:** Gagan Gautam had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design:* Sharma, Gautam, Shah, Ahluwalia.

*Acquisition of data:* Sharma, Gautam, Shah, Ahluwalia, Dasgupta, Challacombe, Bhandari, Rawal, Buffi, Porter, Rogers, Mottrie, Abaza, Rha, Moon, Yuvaraja, Capitanio, Maes, Porpiglia, Turkeri, Ahlawat, Parekh, Sivaraman.

*Analysis and interpretation of data:* Sharma, Gautam, Shah, Ahluwalia.

*Drafting of the manuscript:* Sharma, Gautam, Shah, Ahluwalia.

*Critical revision of the manuscript for important intellectual content:* Sharma, Gautam, Shah, Ahluwalia, Dasgupta, Challacombe, Bhandari, Rawal, Buffi, Porter, Rogers, Mottrie, Abaza, Rha, Moon, Yuvaraja, Capitanio, Maes, Porpiglia, Turkeri, Ahlawat, Parekh, Sivaraman.

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## Appendix A. Supplementary data

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