ORIGINAL PAPER

UROLOGICAL ONCOLOGY

Differences in pentafecta outcome between on-clamp and off-clamp robotic partial nephrectomy

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Citation: Fiorello N, Romei G, Tornabene G, et al. Differences in pentafecta outcome between on-clamp and off-clamp robotic partial nephrectomy. Cent European J Urol. 2026; 79: 84-89.

Article history
Submitted: Sep. 20, 2025
Accepted: Dec. 22, 2025
Published online: Mar. 26, 2026

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Introduction Robotic partial nephrectomy (RAPN) can be considered the gold standard for the treatment of localized renal tumors (cT1-T2a). The on-clamp approach is considered safer for complex tumors, but the off-clamp approach is constantly growing, offering advantages for renal function.

Material and methods We enrolled 517 patients underwent RAPN between 1/2020 and 12/2023 and we divided in two groups: A (on-clamp) and B (off-clamp). We analyzed the individual parameters of the pentafecta outcomes, so absence of complications, negative surgical margins (PSMs), and warm ischemia period shorter than 25’ or zero ischemia, >90% preservation of estimated glomerular filtration rate (eGFR) and no stage progression of chronic kidney disease (CKD) at 1-year follow-up, and finally the overall results.

Results The duration of surgery was significantly longer in group A (120' vs 90') (p <0.001). The median value for duration of warm ischemia was 16 minutes. Postoperative complications occurred in 22 cases (4.2%). Although the frequency of anemia was higher in Group B, in relation to the total number of procedures, no statistically significant difference was found (p = 0.36), neither for PSMs rate (p = 0.73). The achievement of pentafecta outcomes in group A and B was 79.7% and 91.2%, respectively (p ≤0.001). In patients who have undergone ischemia, the duration of clamping is correlated with the increase in postoperative creatinine (p <0.001).

Conclusions Off-clamp approaches show better results in pentafecta outcomes and to reduce the risk of increased creatinine in the post-operative course, although they require greater surgical skill but offer shorter execution times.

Key Words: renal cancer ‹› robotic surgery ‹› partial nephrectomy ‹› on-clamp ‹› off-clamp ‹› pentafecta outcomes

INTRODUCTION

Partial nephrectomy (PN) currently represents the gold standard treatment for T1 and in selected cases T2 renal tumors [1, 2]. The evolution of robotic surgery has allowed an increase in robot-assisted partial nephrectomy (RAPN) performed with optimal oncological outcomes and improved patient recovery [3–5]. The discussion in the literature on the on-clamp VS off-clamp approach is currently growing, without a clear prevalence of one of the two techniques [6, 7]. According to some authors, the on-clamp approach is considered safer without any evident disadvantage in maintaining long-term renal function [8]. Conversely, other authors see a clear advantage in the off-clamp approach, especially in preserving renal function in the long term, and therefore being able to perform it also in patients with chronic kidney disease (CKD) [9, 10]. Among the most used outcome scores in evaluating the surgical and oncological outcomes of RAPN is the “trifecta”, defined as the absence of complications,

doi: 10.5173/ceju.2025.0220

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negative surgical margins, and warm ischemia period shorter than 25 min or zero ischemia [11]. More recently, the "pentafecta" outcomes have also been proposed, which consists in an evaluation of long-term postoperative outcomes that include all of the three trifecta criteria in addition to >90% preservation of estimated glomerular filtration rate (eGFR) and no stage progression of CKD at 1-year follow-up [12].

MATERIAL AND METHODS

We enrolled retrospectively 517 patients underwent RAPN between 1/2020 and 12/2023 in a tertiary center for robotic surgery (Da Vinci Xi system), which includes 3 teams of urologists. All procedures were performed by urologists with moderate surgical experience (>100 procedures). Patient enrollment criteria included localized renal mass <7 cm (cT1) or tumors with maximum diameter between 7 and 10 cm (cT2a) with RENAL score <10. The enrolled patients had no contraindications to robotic surgery.
The exclusion criteria were represented by patients's general health conditions, therefore patients with ASA score 4, but also metastatic disease and a solitary kidney (especially this condition, where conservative surgical treatment of the kidney is foreseen, could determine an early worsening of renal function and therefore determine a bias). No patients received treatment prior to surgery (e.g., tumor embolization).
All procedures were performed using the transperitoneal approach.
For each procedure, the operative time, post-operative complications (Clavien–Dindo classification), surgical complexity (RENAL score), histological features and surgical margins (PSMs) were analyzed. The central objective of the study was to evaluate pentafecta outcomes, performing a comparative measurement between the groups: A (on-clamp) and B (off-clamp), looking for any correlations. The on-clamp procedure was always planned preoperatively according to surgical complexity. Off-clamp procedures on highly complex tumors (RENAL score 7–9) were decided intraoperatively and performed by urologists with extensive surgical experience (>200 procedures).
As mentioned in the introduction, pentafecta outcomes add to the trifecta (defined as the absence of complications, negative surgical margins, and a warm ischemia period shorter than 25 min or zero ischemia), changes in kidney function. eGFR was used as a proxy of renal function, and was calculated using the CKD-EPI equation [13]. The baseline eGFR was obtained almost immediately before surgery. For the last eGFR measurement, the serum creatinine nadir during a period of 1–6 months after surgery was used whenever available, and otherwise the nadir during postoperative hospital stay was used. For each patient, CKD was defined according to the national kidney Foundation kidney Disease Outcome Quality Initiative classification [14]. Upstaging of CKD was defined as a deterioration in one or more classes of CKD. Percentage eGFR change was calculated as ([last eGFR–baseline eGFR]/baseline eGFR).
Follow-up data were complete for all patients.

Statistical analysis

For multivariate statistical analysis we used the χ^2 test and integrated with multivariate logistic regression to adjust for confounders (tumor size, RENAL score, baseline renal function, surgeon experience), looking for statistically significant differences in the two groups regarding PSMs, postoperative morbidity (with greater attention to anemia), changes in creatinine levels and duration of procedures. The level of significance was established for p-value ≤0.05

Bioethical standards

Due to the nature of the study, the consent of the bioethics committee was not required.

RESULTS

Median value for age was 66 years (σ: 11.66, range: 19–88), for duration was 95 minutes (σ: 40.2, range: 30–285). In 8 cases the procedure was bilateral (1,5%). Median value for hospitalization was 3 days (σ: 0.98, range: 2–13).
Surgical complexity was stratified according to the RENAL score (illustrated in Figure 1).
In all cases, clamping was performed only on the artery and not also on the vein, involving only the main branch. The procedures on-clamp (group A) were 84 (16.2%), the median value for duration of warm ischemia was 16 minutes (σ: 8.21, range: 7–65).
Histology showed a prevalence for clear cell (the percentage is described in Figure 2).
Intraoperative complications occurred in 12 cases (laceration involving an artery, vein, or ureter) with concomitant surgical repair, without the need of retreatment.
Postoperative complications occurred in 22 cases (4.2%). Although the frequency of anemia was

higher in Group B, in relation to the total number of procedures, no statistically significant difference was found ($p = 0.36$).
The duration of the procedures was then analyzed in the two groups. Off-clamp had a median value of 90' (σ: 39.36, range 30–285) and the on-clamp group 120' (σ: 35.52, range 80–240). The difference in the two groups was statistically significant. ($p \leq 0.001$).
PSMs were evident in 5 procedures of group A (6%) in 17 procedures of group B (4.2%). Although the number of cases with PSMs is rather small, we did not find statistically significant differences between the two groups ($p = 0.73$).
The median values of preoperative creatinine levels in groups A and B were 1.11 (σ: 0.37, range: 0.45–2.5)

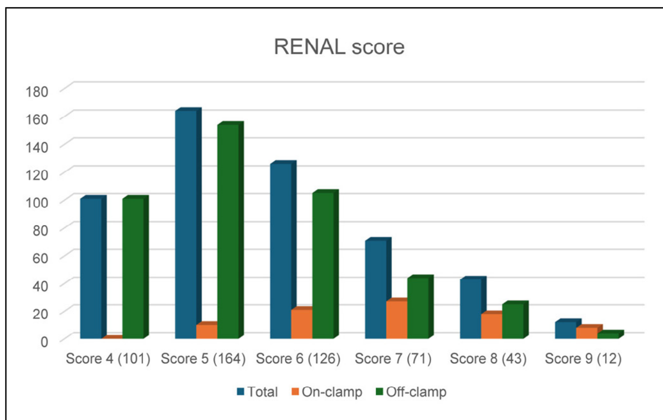

Figure 1. *The figure shows the distribution of the RENAL score between the two groups and overall. It is evident that as the surgical complexity increases, the proportion of on-clamp procedures increases.*

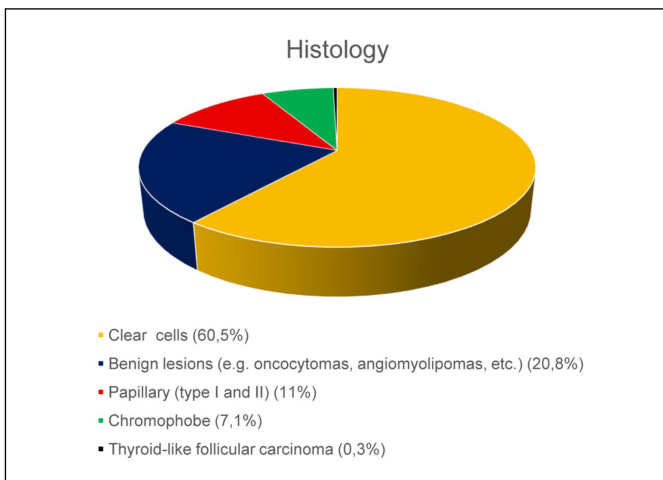

Figure 2. *The figure shows the percentage of histological variants in the procedures performed. It is interesting to highlight the high percentage of benign lesions that were not distinguishable on imaging before surgery.*

and 1.05 (σ: 0.39, range 0.41–2.71) mg/dl, respectively, while postoperative creatinine levels were 1.35 (σ: 0.35, range: 0.57–2.68) and 1.11 (σ: 0.36, range: 0.67–2.72). In patients who have undergone ischemia, the duration of clamping is correlated with the increase in postoperative creatinine ($p < 0.001$)
The maintenance of eGFR values was evaluated by measuring before the surgery and after one year, in accordance with the Pentafecta Outcomes criteria. Median value for preoperative eGFR in group A and B were 63 (σ:16.25, range 36–90) and 62 (σ:15.75, range: 29–90) ml/min/1.73 m^2, respectively, while median value for one-year eGFR were 64 (σ: 15.78, range: 37–90) and 65 (σ: 16.24, range: 31–90). We found no differences between the two groups and preservation >90% of eGFR was in 82 patients in group A (97%) and 424 in group B (98%). No patient had progression of CKD.
Finally, 67 patients of group A (79.7%) and 395 patients of group B (91.2%) achieved pentafecta outcomes across all fields, with significant differences ($p \leq 0.001$).
The overall results are described in Tables 1 and 2.

DISCUSSION

RAPN is the most widely used approach in the world for the removal of localized tumors of kidney [15]. The evolution of surgical technique has allowed performing surgery for more complex tumors (high nephrometric score or cT2) and to approach without clamping the peduncle, which until a few years ago seemed to be mandatory [16, 17]. The results of our study do not have such high numbers to draw extremely reliable conclusions, but it is sufficient to note that there is no difference between the two techniques. Furthermore, the off-clamp technique allows surgery to be performed even in complicated patients (patients with a single kidney, with CKD or who have undergone previous surgery) [18, 19]. The off-clamp technique perhaps requires greater surgical skill as more intraoperative bleeding may occur but, if correctly performed, it has no differences with the on-clamp approach.
Currently there is no evidence of a better approach, nor of significant differences even for large tumors [20–22]. There are some limitations to our study. First, it is a retrospective study, so an off-clamp approach was proposed in some patients more susceptible to progression to CKD. It would have been interesting to evaluate whether the on-clamp approach was actually harmful to renal function in these patients. The other main limitation is the evaluation of eGFR at one year, while it would be interesting to evaluate preservation over the years. Anyway,

the off-clamp approach is continuously growing and there is evidence in the literature of advantages in preserving renal function [23].
Actually, histology and tumor size showed no difference in all outcomes. We preferred to take into greater consideration the complexity of the tumor through the nephrometric score, although it does not always describe the surgical complexity (it can be due to previous surgery, data not included in the nephrometric scores). It is conceivable that the proportion of surgical complexity increases in group A, but where there was a comparison, possible only for excellent surgical performance, there were no differences.
One of the limitations of our study concerns the assignment to the off-clamp group. While for patients in group A, the on-clamp technique was planned preoperatively, the off-clamp technique of complex tumors was decided intraoperatively based on the surgeon's choice. This may represent a bias, even if both approaches offer advantages for extremely fragile patients [24].

Table 1. *Final results of group A. The final part shows the results related to the pentafecta outcomes*

Patient number (group A)	N = 84	Median value ±SD, %
Age	84	63 ±13.49
Operation time (minutes)	84	120 ±35.52
Warm ischemia time (minutes)	84	16 ±8.21
Right RAPN	43	51.2%
Left RAPN	40	47.6%
Bilateral RAPN	1	0.2%
RENAL SCORE 4	0	0%
RENAL SCORE 5	10	11.9%
RENAL SCORE 6	21	25%
RENAL SCORE 7	27	32.2%
RENAL SCORE 8	18	21.4%
RENAL SCORE 9	8	9.5%
Intraoperative complications	6	7.1%
Clavien–Dindo 1	0	0%
Clavien–Dindo 2	3	3.5%
Clavien–Dindo 3–4	0	0%
Preoperative plasmatic creatinine [mg/dl]	84	1.11 ±0.37
Post-operative plasmatic creatinine [mg/dl]	84	1.35 ±0.35
Preoperative eGFR ml/min/1.73 m²	84	63 ±16.25
Post-operative eGFR ml/min/1.73 m²	84	64 ±15.78
Clear cell RCC	56	66.6%
Papillary RCC (type 1–2)	6	7.2%
Chromofobe	6	7.2%
Benign lesions	16	19%
Rare variants	0	0%
Positive surgical margins (PSMs)	5	6%
Ischemia <25 minutes	74	88%
Post-operative complications (total number)	3	3.5%
Preservation of eGFR (>90%)	81	96%
No stage progression of CKD at 1-year	84	100%
Pentafecta outcomes achieved	**67**	**79.7%**

eGFR – estimated glomerular filtration rate; RCC – renal cell carcinoma; RENAL score – Radius, Exophytic/endophytic properties of the tumor, Nearness of tumor deepest portion to the collecting system, Anterior/Posterior, Location relative to the polar line; SD – standard deviation

Table 2. *Final results of group B. The final part shows the results related to the pentafecta outcomes*

Patient number (group B)	N = 433	Median value ±SD, %
Age	433	67 ±11.2
Operation time (minutes)	433	90 ±39.36
Warm ischemia time (minutes)	0	0%
Right RAPN	219	50.5%
Left RAPN	207	47.9%
Bilateral RAPN	7	1.6%
RENAL SCORE 4	101	23.3%
RENAL SCORE 5	154	35.5%
RENAL SCORE 6	105	24.3%
RENAL SCORE 7	44	10.2%
RENAL SCORE 8	25	5.8%
RENAL SCORE 9	4	0.9%
Intraoperative complications	6	1.3%
Clavien-Dindo 1	8	1.8%
Clavien-Dindo 2	9	2%
Clavien-Dindo 3-4	2	0.4%
Preoperative plasmatic creatinine (mg/dl)	433	1.05 ±0.39
Post-operative plasmatic creatinine (mg/dl)	433	1.11 ±0.36
Preoperative eGFR ml/min/1.73 m²	433	62 ±15.75
Post-operative eGFR ml/min/1.73 m²	433	65 ±16.24
Clear cell RCC	257	59.3 %
Papillary RCC (type 1–2)	51	11.8%
Chromofobe	31	7.2%
Benign lesions	92	21.3%
Rare variants	2	0.4%
Positive surgical margins (PSMs)	17	4.2%
Ischemia <25 minutes	433	100%
Post-operative complications (total number)	19	4.3%
Preservation of eGFR (>90%)	424	98%
No stage progression of CKD at 1-year	433	100%
Pentafecta outcomes achieved	**395**	**91.2%**

eGFR – estimated glomerular filtration rate; RCC – renal cell carcinoma; RENAL score – Radius, Exophytic/endophytic properties of the tumor, Nearness of tumor deepest portion to the collecting system, Anterior/Posterior, Location relative to the polar line; SD – standard deviation

In our study, there is a clear advantage in the duration of surgery, which allows us to schedule a greater number of interventions and therefore not to delay the treatment.

Finally, considering that obtaining the pentafecta outcome can be considered predictive for the maintenance of kidney health, the off-clamp approach, if correctly performed, can be considered safer in preserving kidney function. However, there are also other models to evaluate the impact of renal function after PN and predict postoperative acute kidney injury (AKI) and development of CKD, like RENSAFE (RENalSAFEty) [25]. Other studies instead consider preoperative eGFR, sex, ischemia technique, and postoperative eGFR percentage loss are the best predictors of eGFR percentage loss at 1 year after minimally invasive PN [26].

CONCLUSIONS

Currently, RAPN represents the gold standard treatment of localized renal tumors, with an increase in advanced indications. Off-clamp approaches show better results in pentafecta outcomes and to reduce the risk of increased creatinine levels in the post-operative course, although they require greater surgical skill, but offer shorter execution times.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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