

# Outcomes of robot-assisted simple enucleation of renal masses

## A single European center experience

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### Abstract

The aim of this study was to assess the ability of pre- and intraoperative parameters, to predict the risk of perioperative complications after robot-assisted laparoscopic simple enucleation (RASE) of renal masses, and to evaluate the rate of trifecta achievement of this approach stratifying the cohort according to the use of ischemia during the enucleation.

From April 2009 to June 2016, 129 patients underwent RASE at our Institution. We stratified the procedures in 2 groups: clamping and clamp-less RASE. After RASE, all specimens were retrospectively reviewed to assess the surface–intermediate–base (SIB) scoring system. Patients were followed-up according to the European Association of Urology guidelines recommendations. All pre-, intra-, and postoperative outcomes were prospectively collected in a customized database and retrospectively analyzed.

A total of 112 (86.8%) patients underwent a pure RASE and 17 (13.2%) had a hybrid according to SIB classification system. The mean age was 61.17 years. In 21 patients (16.3%), complications occurred, 13 (61.9%) were Clavien 1 and 2, while 8 were Clavien 3a and b complications. Statistical significant association with complications was found in patients with American Society of Anesthesiology (ASA) score 3 (44.5%,  $P=.04$ ), longer mean operative time (OT) 195 versus 161.36 minutes ( $P=.03$ ), mean postoperative hemoglobin (Hb) 10.1 versus 11.8 ( $P<.001$ ), and mean  $\Delta$ Hb 3.59 versus 2.18 ( $P<.001$ ). In multivariate logistic regression, only longer OT and  $\Delta$ Hb were statistical significant predictive factors for complications. In sub-group analysis, clamp-less RASE was safe in terms of complications (14.1%), positive surgical margins (1.3%), and mid-term local recurrence (1.3%). Although in this approach there is higher EBL ( $P=.01$ ), this had no impact on  $\Delta$ Hb ( $P=.28$ ). A clamp-less approach was associated with a higher rate of SIB 0 (71.8% vs 51%,  $P=.02$ ), higher trifecta achievement (84.6% vs 62.7%,  $P=.004$ ), and better impact on serum creatinine (mean 0.83 vs 0.91,  $P=.01$ ).

RASE of renal tumors is a safe technique with very good postoperative outcomes. Complication rate is low and associated with ASA score  $>3$ , longer OT, and  $\Delta$ Hb. RASE is suitable for the clamp-less approach, which allows to perform easier the pure enucleation (SIB 0) and to obtain higher rates of trifecta outcomes.

**Abbreviations:** ASA = American Society of Anesthesiology, BMI = body mass index, EAU = European Association of Urology, EBL = estimated blood loss, NSS = nephron sparing surgery, OT = operative time, PADUA = preoperative aspects and dimensions used for an anatomical, PN = partial nephrectomy, PSM = positive surgical margins, RASE = robot-assisted simple enucleation, RCC = renal cell carcinoma, SE = simple enucleation, SIB = surface–intermediate–base, SM = surgical margin, WIT = warm ischemia time.

**Keywords:** complications, partial-nephrectomy, renal cell carcinoma, robot-assisted simple enucleation, trifecta

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## 1. Introduction

Despite the nephron sparing surgery's (NSS) concepts are well known, no overall accepted consensus yet exists regarding the optimal width of normal parenchyma that should surround the tumor to both avoid local recurrence and loss of renal function.<sup>[1–5]</sup>

In order to further increase the amount of normal renal tissue spared during NSS, tumor simple enucleation (SE) was proposed as a minimal partial nephrectomy (PN).<sup>[11]</sup> The presence of a continuous, fibrous capsule composed of dense connective fibrous tissue surrounded by healthy tissue with a median thickness of 1 mm represents the pathologic rationale, which allows avoiding the tumor-surrounding healthy tissue removal without undermining the oncological radicality.<sup>[2–5]</sup> As a result, tumor SE should not be in contrast with the European Association of Urology (EAU) guidelines which state the maintenance of a “minimal” tumor-free surgical margin (SM), sufficient to avoid local recurrence, without specifying its exact thickness.<sup>[6]</sup>

Tumor SE is performed in an avascular plane (if the perforating vessels for the tumor are excluded), allowing to carry out the procedure also without clamping the renal artery, hence without ischemia.<sup>[3,4,7]</sup> Nonetheless, as shown for open surgery, dimension, anatomical aspects of the tumor as well as vascular variants of the renal blood supply may increase the procedure complexity and difficulty, with a possible impact on the complication rate in a robot-assisted approach, too.

For a better comparison of different surgical techniques, the achievement of trifecta outcome was described<sup>[8]</sup> as the simultaneous obtainment of negative SMs, renal function preservation, and no urological complications.

The aim of this study was to assess the ability of pre- and intraoperative parameters (including the preoperative aspects and dimensions used for an anatomical (PADUA) scoring system), to predict the risk of perioperative complications after robot-assisted laparoscopic simple enucleation (RASE) of renal masses, and to evaluate the rate of trifecta achievement of this approach stratifying the cohort according to the use of ischemia during the enucleation.

## 2. Methods

SE was first performed in our Divisions in November 2011 and it accounts for 38% (129) from all the robotic NSS procedures done between April 2009 and June 2016 in our department (342 in total). The preoperative diagnostic workup included contrast enhanced computer tomography (CT) scan, blood analyses, and anesthesiology evaluation (including American Society of Anesthesiology [ASA] score) in order to draw out patients suitable to undergo this type of surgery using the robot-assisted laparoscopic approach. A mass biopsy was performed anytime imagistic information (contrast enhancement features and growth rate)<sup>[9]</sup> could not rule out for sure the malignant nature of the mass: it was the case of 45 (34.9%) patients. All tumors were scored according to the PADUA scoring system.<sup>[10]</sup>

After having received Institutional Review Board approval, we carried out the retrospective chart review of the 129 patients who underwent RASE. We stratified RASE in 2 groups, clamping and clamp-less RASE, at our institutions during the considered period.

### 2.1. Patient selection

All treatment options available in our institutions, including surveillance or percutaneous tumor ablation, were discussed with

the patients. Patients receiving (and accepting) surgical indication were first evaluated if eligible for robotic surgery. After more than 2 years of experience with robot-assisted “classic PN,”<sup>[11]</sup> simple tumor enucleation was adopted as an alternative NSS technique and preferred to the “classic PN” every time that after the kidney preparation, the mass revealed easily to be approached. Successively, larger and more complex (i.e., higher renal score) tumors underwent enucleation; in all cases, the intention was to perform the procedure without clamping the artery unless the case was judged at a risk of bleeding or if relevant blood loss (BL) occurred during the procedure and (deferred) artery clamping was however required.

Tumor histology was performed according to the 2004 World Health Organization criteria<sup>[12]</sup> and grade classification followed the Fuhrman scheme. Surgical staging was according to the tumor, node, metastasis system.<sup>[13]</sup> Disease relapse was defined as any local recurrence (retroperitoneal or renal fossa) or distant metastasis biopsy-proven renal cells carcinomas RCCs. Recurrences in contralateral kidney were considered as second primaries. All specimen were retrospectively reviewed to score the thickness of healthy parenchyma visually evident on the superficial surface of the tumor according to the surface–intermediate–base (SIB) scoring system,<sup>[14]</sup> confirming that in all cases enucleation was performed (SIB score sum 0–1).

### 2.2. Surgical technique

All procedures were performed using the transperitoneal approach with da Vinci *Si* system. First, the renal pedicle was dissected out and the artery well exposed to enable prompt clamping in case of excessive bleeding during tumor excision, in case of clamp-less intention. Intraoperative ultrasound was performed in all cases. After having had dissected out the kidney and swept the perinephric fat away from the tumor, the capsule was sharply incised (using the monopolar scissors coagulation) circumferentially or hemi-circumferentially (Fig. 1A) starting from the passage between lesion and the healthy renal tissue. Once the tumor pseudo-capsule was seen and reached, the tumor was enucleated by blunt dissection, with no visible rim of normal parenchyma. The development of the cleavage between the tumor and the healthy tissue was performed in 2 different manners: the classic way,<sup>[11]</sup> surrounding the mass and conducting the dissection until the deepest part of the tumor is reached and detached from the tumor bed or according to our previously described “beer-bottle-opener technique”<sup>[15]</sup> using blunt dissection and adequate traction. The cleavage plane between tumor and healthy tissue is thus reached, starting from the hemi-circumferential capsule incision (Fig. 1B) and developed toward the deepest part of the tumor; the dissection is carried out under direct vision (Fig. 1C) and perforating vessels, clipped. After the deepest part of the tumor bed is reached, the cleavage plane is developed toward the posterior half-circumference and finally the tumor completely excised (Fig. 1D).

3/0 poliglecaprone running sutures secured with resorbable Lapra-Ty clips were used for closure of the renal medulla. Re-approximation of the cortical parenchyma was performed with 2/0 polyglactin simple mattress sutures, secured with sliding Weck Hem-o-lok clips and reinforced with Lapra-Ty clips (Ethicon, Cincinnati, OH).

After renal reconstruction, hemostasis was again ensured with careful inspection of the surgical bed under low insufflations pressure. The specimen was extracted, the gross margins of the tumor were inspected, and the specimen was sent to the pathology laboratory for permanent section.



**Figure 1.** Our technique for SE. (A) Half-circumference capsule incision; (B) once reached the tumor surface, the cleavage is developed by blunt dissection; (C) the visual control of the tumor bed; (D) the enucleation is concluded by cutting the posterior attachment with the capsule (dotted line). SE = simple enucleation.

Intraoperative features as well as postoperative complications were recorded and scored according to the Clavien system. Overall operatory time (OT) (as surrogate of the procedure difficulty), EBL, hemoglobin (Hb) loss, creatinine level (between preoperative and latest recorded follow-up, median 25 months) and nutritional status (body mass index [BMI]) were also recorded.

Patients were followed according to the guidelines recommendations<sup>[16]</sup> and institutional protocol, including clinical examination, laboratory blood tests (hemogram, renal function examination), urine analysis, CT scan (thorax and abdomino-pelvic) or abdominal MRI, and chest x-ray, at 3 and 9 months after surgery and afterwards annually for 5 years and every 2 years thereafter.

Three types of analysis were carried out: the correlation between patients characteristics (such as PADUA score, ASA score, and BMI) and complications after RASE; the correlation between intraoperative parameters (such as OT and blood loss) and complication rates; and outcomes of clamp-less RASE were compared with those of clamping RASE, including the simultaneous achievement of the 3 goals of NSS, that is, negative SMs, functional preservation, and complication-free recovery, known as trifecta outcome.<sup>[17]</sup>

### 2.3. Statistical methods

Associations of postoperative complications with categorical variables were assessed using the chi-square tests, while differences in means of continuous variables were analyzed using the *t* test. Logistic regression analysis was performed to assess the association of predictive factors with complications. Sub-group analyses according to clamping technique were also done. All *P* values were 2-sided, and statistical significance was defined as a *P* < .05. Statistical analyses were performed using Stata 11.0 statistical software (Stata Corp., College Station, TX).

## 3. Results

### 3.1. Patients characteristics and association with complications after RASE

A total of 129 patients underwent RASE in our tertiary department. Out of these, 112 (86.8%) had a pure SE and 17 (13.2%) had hybrid SE according to SIB classification system. The mean age was 61.17 years and most of them were males (67.4%). Complications were experienced by 21 patients (16.3%), 13 (61.9%) patients had Clavien 1 and 2 complications (8 (61.5%) had anemia, 2 (15.4%) hematoma, and 1 (7.7%) hematuria, atrial fibrillation, and chylous ascites), and 8 patients had Clavien 3a and b complications (5 urinary fistulas and 1 had tumor bed bleeding, hemicolectomy, and trocar port bleeding, respectively). The mean tumor diameter revealed on CT scan was 33.79 mm, in concordance with mean histological diameter of the tumor, that is, 33.62 mm, but with higher mean diameter in patients who experienced complications, that is, 37.54 mm on CT scan. Most patients had tumors on the right side (74, 57.4%), but complications were more frequent in patients with tumors on the left side (18.2%, *P* = .61). Complications were not associated with PADUA score nor with PADUA complexity classification (*P* = .14 and .09, respectively), instead we noticed higher complication rates in patients with PADUA score >8 and in those classified as high complex with 42.9% patients with complications.

Complications were more frequent and a statistical significant association was found in patients with ASA score 3 (44.5%, *P* = .04). Complications were also associated with a longer mean OT (195 vs 161.36 min, *P* = .03), mean postoperative Hb (10.1 vs 11.8, *P* < .001), and mean ΔHb. (3.59 vs 2.18, *P* < .001), but were not associated with mean estimated blood loss (EBL) (*P* = .67) (Table 1).

**Table 1****Association of clinic-pathologic and functional parameters with complications in 129 patients who underwent RASE.**

Parameter	All cohort	No complications	Complications	P value
Age (mean), y	61.17	60.7	63.6	.22
Gender				
Female	42 (32.6)	34 (80.9)	8 (19.1)	.55
Male	87 (67.4)	73	13 (14.9)	
Diameter CT (mean)	33.79	33.01	37.54	.19
Diameter histology (mean)	33.62	33.27	35.38	.57
Side				
Left	55 (42.6)	45	10 (18.2)	.61
Right	74 (57.4)	63 (85.1)	11 (14.9)	
PADUA score				
6	43 (33.3)	39 (90.7)	4 (9.3)	.14
7	43 (33.3)	36 (83.7)	7 (16.3)	
8	24 (18.6)	19 (79.2)	5 (20.8)	
9	12 (9.3)	10 (83.3)	2 (16.7)	
10	3 (2.3)	1 (33.4)	2 (66.6)	
11	2 (1.6)	2 (100)	0	
12	2 (1.6)	1 (50)	1 (50)	
PADUA complexity				
Low	86 (66.7)	75 (87.2)	11 (12.8)	.09
Intermediate	36 (27.9)	29 (80.5)	7 (19.5)	
High	7 (5.4)	4 (57.1)	3 (42.9)	
ASA score				
1	75 (58.1)	63 (84)	12 (16)	<b>.04</b>
2	45 (34.9)	40 (88.8)	5 (11.2)	
3	9 (7)	5 (55.5)	4 (44.5)	
BMI (mean)	26.68	26.73	26.43	.73
OT (mean), min	166.83	161.36	195	<b>.03</b>
EBL (mean), mL	265.24	272	230	.67
pT stage				
Benign	19 (14.7)	14 (73.7)	5 (22.3)	.67
1a	71 (55)	60 (84.5)	11 (15.5)	
1b	21 (16.3)	18 (85.7)	3 (14.3)	
2a	2 (1.6)	2 (100)	0 (0)	
3a	10 (7.7)	8 (80)	2 (20)	
Unclassified	6 (4.7)	6 (100)	0 (0)	
Fuhrman grade				
0	19 (14.7)	14 (73.7)	5 (22.3)	.69
1	17 (13.2)	14 (82.3)	3 (17.7)	
2	73 (56.6)	62 (84.9)	11 (15.1)	
3	13 (10.1)	12 (92.3)	1 (7.7)	
unclassified	7 (5.4)	6 (85.7)	1 (4.3)	
SIB				
0	82 (63.6)	68 (82.9)	14 (17.1)	.88
1	30 (23.2)	26 (86.7)	4 (13.3)	
2	17 (13.2)	14 (82.3)	4 (17.7)	
CKD baseline				
Stage 0–1	102 (79)	86 (84.3)	16 (15.7)	.72
Stage 2–3	27 (21)	22 (81.4)	5 (18.6)	
CKD				
Stage 0–1	103 (79.8)	87 (84.4)	16 (17.6)	.64
Stage 2–3	26 (20.2)	21 (80.8)	5 (19.2)	
eGFR baseline (mean)	70.11	69.56	72.94	.27
eGFR (mean)	68.94	68.41	71.71	.23
Serum Cr baseline (mean)	0.90	0.89	0.94	.31
Serum Cr (mean)	0.86	0.85	0.90	.36
ΔCr (mean)	-0.03	-0.03	-0.04	.83
Hb baseline (mean)	14.03	14.1	13.7	.23
Hb postop. (mean)	11.54	11.82	10.1	<b>&lt;.001</b>
ΔHb (mean)	2.41	2.18	3.59	<b>&lt;.001</b>
LOS (mean), d	4.74	4.52	5.85	<b>&lt;.001</b>

ASA = American Society of Anesthesiologist score; BMI = body mass index, CKD = chronic kidney disease, Cr = creatinine, CT = computer tomography, EBL = estimated blood loss, eGFR = estimated glomerular filtration rate, Hb = hemoglobin, LOS = length of stay, OT = operation time, PADUA = Preoperative Aspects and Dimensions Used for an Anatomical classification, RASE = robot-assisted simple enucleation, SIB = surface-intermediate-base.

Bold values signify statistically significant.

### 3.2. Parameters that predicts complications after RASE

In univariate analysis high PADUA complexity (odds ratio [OR] 5.11,  $P=.04$ ), longer OT (OR 1,  $P=.03$ ), and  $\Delta$ Hb. (OR 1.94,  $P<.001$ ) were statistical significant predictive factors for complications. In multivariate logistic regression, only OT and  $\Delta$ Hb retain a statistical significant value as independent predictors of complications after RASE (Table 2).

### 3.3. Safety of clamp-less RASE compared with clamping RASE

When we performed subgroup analysis according to clamping approach, we noticed that clamp-less RASE is safe in terms of PADUA score, PADUA complexity of tumors, ASA score of patients, OT, complications (14.1%), positive surgical margins (PSM) (1.3%), and mid-term local recurrence (1.3%). Instead, in these approaches, patients may lose more blood ( $P=.01$ ), but with a low rate of postoperative blood transfusion (8.9%,  $P=.02$ ) and with no impact on  $\Delta$ Hb. ( $P=.28$ ) and with a slightly lower length of hospital stay (4.47 vs 5.15 mean days,  $P<.001$ ). The clamp-less approach was associated with a higher rate of SIB 0 achievement (71.8% vs 51%,  $P=.02$ ) and with higher trifecta achievement (84.6% vs 62.7%,  $P=.004$ ). The clamp-less approach was found to have a better impact on serum creatinine too (mean 0.83 vs 0.91,  $P=.01$ ), but with no statistical significance as far as estimated glomerular filtration rate at last follow-up was concerned (Table 3).

## 4. Discussion

Tumor SE should be considered as an attempt aimed to improve the results of PN by decreasing at minimum the amount of healthy renal tissue to be removed.<sup>[6,18]</sup> Moreover, by conducting the dissection through the natural cleavage, which is an avascular plane, the renal artery clamping might be omitted or eventually deferred.<sup>[8,12]</sup>

Even if in his paper Ficarra et al<sup>[10]</sup> observed that in multivariate analysis PADUA scores were independent predictors of the occurrence of any grade of complications, they also draw the attention on a major limit of their study, that is, the lack of laparoscopically treated patients in his series.

Unfortunately, none of the various analysis of the results of the group of Florence, both in open or in robotic surgery, take into account an attempt to validate this renal score in this peculiar setting.<sup>[3-5,7]</sup> They only concluded that the robotic approach can achieve better surgical results by reducing the need for clamping, warm ischemia time (WIT), EBL, and length of stay, mainly due to a clearly lower complication rate.<sup>[7]</sup>

In our series, overall complication rate was similar to previously mentioned experiences (16.3%), despite that our cohort included patients with higher mean diameter and higher PADUA score.

Ours seems the first study testing the value of the PADUA renal score in predicting the complication occurrence in this setting (i.e., robotic SE) (Table 2), and we noticed that only OT and  $\delta$ Hb are independent predictive factor for predicting complications. In case of OT more than 195 minutes, one should carefully manage the patient as it has a higher risk of complication occurrence, same as the loss of 3.5 point of postoperative Hb increase with 2-fold the risk of complications.

Also, patients with high PADUA complexity score might experience higher rates of complications with an OR of 8.5. On the other hand, Serni et al<sup>[18]</sup> in a cohort of 96 patients with high complex PADUA score tumors reported a high complication rate of 26.1% and included only 20 patients with RASE, thus, it seems that the robotic approach might not be fit for high PADUA score tumors.

The main criticism against tumor SE is the higher risk of PSMs as a result of conducting the dissection in the natural cleavage plane.

The need of a safety margin during PN was arbitrary chosen in 1950 by Vermooten<sup>[19]</sup> and its thickness became a debated issue as many studies demonstrated that the “safety” should be guaranteed by as less as 1 mm of healthy tissue surrounding the tumor and even by SE.<sup>[1]</sup> This more extensive NSS approach, avoiding the tumor-surrounding healthy tissue removal, was first performed and advocated by Carini et al<sup>[1]</sup> in open surgery. The group of Florence first provided the pathologic rationale of this minimal PN, describing the presence a continuous, fibrous capsule composed of dense connective fibrous tissue surrounded by healthy tissue with a median thickness of 1 mm with signs of chronic inflammation.<sup>[2]</sup> As a result, SE should not contrast the EAU requirement of a “minimal healthy tissue layer” sufficient to

**Table 2**

**Univariate and multivariate logistic regression for predicting complications in 129 patients that underwent RASE.**

Variable	Univariate			Multivariate		
	OR	CI	P value	OR	CI	P value
Gender	0.74	0.28–1.96	.55	0.4	0.12–1.34	.13
Age (cont.)	1.03	0.98–1.08	.22	1.03	0.97–1.1	.23
PADUA complexity		Ref.			Ref.	
Intermediate	1.64	0.58–4.65	.94	0.99	0.24–4.08	.99
High	5.11	1.00–25.97	<b>.04</b>	8.5	0.87–82.2	.06
Side	0.78	0.3–2	.61	0.68	0.21–2.25	.53
Diameter CT (cont.)	1	0.97–1.03	.56	0.97	0.93–1.01	.27
OT (cont.)	1	1–1.01	<b>.03</b>	1.01	1–1.02	.04
EBL (cont.)	0.99	0.99–1	.67	0.99	0.99–1	.051
ASA score		Ref.			Ref.	
2	0.65	0.21–2	.45	0.46	0.12–1.8	.51
3	4.2	0.98–17.94	.053	1.66	0.23–11.82	.61
Delta Hb (cont.)	1.94	1.36–2.74	<b>&lt;.001</b>	2.32	1.43–3.76	.001

ASA=American society of anesthesiologist, CI = confidence interval, CT=computer tomography, EBL=estimated blood loss, Hb=hemoglobin, OR = odds ratio, OT=operation time, PADUA=Preoperative Aspects and Dimensions Used for an Anatomical classification.

Bold values signify statistically significant.

**Table 3****Patients characteristics and association with clinic, pathologic, and functional parameters in the 2 groups (clamp-less and no-clamp-less).**

Parameter	All cohort, n = 129	Group 1 clamping, n = 51	Group 2 clamp-less, n = 78	P value
Age (mean), y	61.17	60.47	61.62	.52
Gender				
Female	42 (32.6)	15 (35.7)	27 (64.3)	.53
Male	87 (67.4)	36 (41.4)	51 (58.6)	
Diameter CT (mean)	33.79	35.92	32.39	.18
Diameter histology (mean)	33.62	34.23	33.21	.71
Side				
Left	55 (42.6)	24 (31.2)	31 (68.8)	.41
Right	74 (57.4)	27 (36.5)	47 (63.5)	
PADUA score				
6	43 (33.3)	13 (30.2)	30 (69.8)	.21
7	43 (33.3)	22 (51.2)	21 (48.8)	
8	24 (18.6)	9 (37.5)	15 (62.5)	
9	12 (9.3)	3 (25)	9 (75)	
10	3 (2.3)	1 (33.4)	2 (66.6)	
11	2 (1.6)	1 (50)	1 (50)	
12	2 (1.6)	2 (100)	0 (0)	
PADUA complexity				
Low	86 (66.7)	35 (68.6)	51 (65.4)	.46
Intermediate	36 (27.9)	12 (23.6)	24 (30.7)	
High	7 (5.4)	4 (7.8)	3 (3.9)	
ASA score				
1	75 (58.1)	31 (60.8)	44 (56.4)	.78
2	45 (34.9)	16 (31.4)	29 (37.2)	
3	9 (7)	4 (7.8)	5 (6.4)	
BMI (mean)	26.68	27.17	26.36	.22
OT (mean), min	166.83	159.58	171.57	.31
EBL (mean), mL	265.24	151.41	339.66	<b>.01</b>
Transfusions	9.3%	9.8%	8.9%	<b>.02</b>
pT stage				
Benign	19 (14.7)	11 (57.8)	8 (42.2)	.16
1a	71 (55)	25 (35.2)	46 (64.8)	
1b	21 (16.3)	9 (42.9)	12 (57.1)	
2a	2 (1.6)	1 (50)	1 (50)	
3a	10 (7.7)	5 (50)	5 (50)	
Unclassified	6 (4.7)	0 (0)	6 (100)	
Fuhrman grade				
1	17 (15.4)	7 (41.2)	10 (58.8)	.31
2	73 (66.4)	27 (41.1)	46 (58.9)	
3	13 (11.8)	5 (38.5)	8 (61.5)	
Unclassified	7 (6.4)	1 (14.3)	6 (85.7)	
SIB				
0	82 (63.6)	26 (31.7)	56 (68.3)	<b>.02</b>
1	30 (23.2)	18 (60)	12 (40)	
2	17 (13.2)	7 (41.2)	10 (58.8)	
PSM no. %	2 (1.55)	1 (1.9)	1 (1.3)	.09
Complications	17%	21.6%	14.1%	.27
Trifecta	76%	62.7%	84.6%	<b>.004</b>
Local rec.	0.8%	0%	1.35%	.42
CKD baseline				
Stage 0–1	102 (79)	39 (76.5)	63 (80.8)	.55
Stage 2–3	27 (21)	12 (23.5)	15 (19.2)	
CKD				
Stage 0–1	103 (79.8)	40 (78.4)	63 (80.8)	.74
Stage 2–3	26 (20.2)	11 (21.6)	15 (19.2)	
eGFR baseline (mean)	70.11	68.70	71.03	.31
eGFR (mean)	68.94	68.05	69.52	.48
Serum Cr baseline (mean)	0.90	0.90	0.90	.97
Serum Cr (mean)	0.86	0.91	0.83	<b>.01</b>
ΔCr (mean)	-0.03	0.01	-0.006	<b>&lt;.001</b>
Hb baseline (mean)	14.03	14.08	13.99	.72
Hb postop. (mean)	11.54	11.71	11.43	.34
ΔHb (mean)	2.41	2.24	2.52	.28
LOS (mean), d	4.74	5.15	4.47	<b>.003</b>

ASA=American society of anesthesiologist score, BMI=body mass index, CKD=chronic kidney disease, Cr=creatinine, CT=computer tomography, EBL=estimated blood loss, eGFR=estimated glomerular filtration rate, Hb=hemoglobin, LOS=length of stay, OT=operation time, PADUA=Preoperative Aspects and Dimensions Used for an Anatomical classification, PSM=positive surgical margins, SIB=surface-intermediate-base.

Bold values signify statistically significant.

guarantee the surgical radicality and to avoid local relapse.<sup>[6]</sup> The same group proposed the SIB score in order to standardize the terminology to describe the NSS technique and to facilitate outcome assessments and comparisons of surgical series.<sup>[14]</sup>

Nevertheless, in the open series,<sup>[1,3]</sup> they report no PSM, and in their robotic experience, the PSM reported rate was 2.8%.<sup>[7]</sup> In our series, the rate was lower (1.5%) even if there are at least 2 major differences between the 2 series: the percentage of benign lesions (17.7% vs 14.7%) and the percentage of clamp-less procedures (33.9% vs 60.5%). In fact, we choose this approach mainly to be performed without clamping or with a deferred pedicle clamping.

The use of trifecta outcome further contributes to better define and compare different surgical approaches. As previously shown, trifecta outcomes improved in the robotic and laparoscopic approach due to the reduction of PSM and zero ischemia approach.<sup>[17,20]</sup> RASE further contributes in improving the trifecta rate achievement.

The question if the PSM rate may be a satisfactory, oncologic surrogate endpoint is still a matter of debate: some studies have demonstrated no association between SMs status after PN of small renal masses and recurrence of RCCs,<sup>[21,22]</sup> while others suggest that in high-risk tumors, PSM might actually have a clinical significance,<sup>[23]</sup> in a very recent meta-analysis,<sup>[24]</sup> the authors while arguing a noninferiority of SE compared with the standard PN, note an association between PSM rate and disease recurrence.

As shown before in the robotic SE published series, the rate of procedures performed without WI is clearly higher,<sup>[7]</sup> than in open setting.<sup>[3]</sup>

Zero ischemia was also associated with lower serum creatine at last follow-up. Despite some reports doubt about the renal function benefit of 0 ischemia surgery, as its clinical consequence should be little or inconsistent,<sup>[25]</sup> we firmly believe that avoiding (where possible) renal pedicle clamping may show important advantages on renal function preservation as was shown in a similar cohort of 49 patients in a multi-institutional study.<sup>[26]</sup> Excluding the potential effect of an unknown (as unpredictable) WIT on the renal function, the decision for an off-clamping approach should gradually determine (depending also on the surgeon's expertise) to avoid the dissection of the vascular pedicle elements which will translate in lower OT and thus a decreased risk of blood loss.

Limitations of this study include those inherent to a single-institution, retrospective study, even if a mid-term follow-up. Another bias of the study may refer to the OT, which might be influenced by the learning curve of the surgeons and the fact that our department is a teaching institution in which residents and young specialists learn robotics. Although multiple patient and tumor factors were included in our multivariable analysis, unmeasured confounders and competing risk factors for complications were not evaluated for in this analysis. As a result, prospective, multicentric, and long-term follow-up studies are required to confirm the promising published data.

## 5. Conclusions

RASE of renal tumors is a safe technique with very good postoperative outcomes. Complication rate is low and associated with ASA score >3, longer OT, and  $\Delta$ Hb. RASE is suitable for the clamp-less approach, which allows to perform the pure enucleation (SIB 0) easily and to obtain higher rates of trifecta outcomes.

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