



Does tumour effraction during robotic partial nephrectomy have any impact on recurrence?

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Abstract

Objective To evaluate the impact of accidental surgical incision into the tumour (ASIT) on oncological outcomes in patients undergoing RPN for a malignant tumour.

Materials and methods A retrospective review of our prospectively maintained database was performed to identify all patients who underwent RPN for a localized RCC between June 2010 and July 2016. We stratified our cohort into two groups according to the presence of an ASIT. Perioperative data were compared between the two groups. Logistic regression analyses were used to assess the variables associated with ASIT. Recurrence-free survival was estimated using the Kaplan–Meier method and compared between groups with the log-rank test.

Results A total of 234 patients were identified. 32 (14%) ASIT were observed. Patients' characteristics were similar in the two groups. Most of intraoperative outcomes were comparable between the two groups, but patients in the ASIT group had greater EBL (475 vs. 300 mL; $p=0.01$). In multivariate analysis, tumour size ($p=0.02$), RENAL score ($p=0.02$), EBL ($p=0.05$) and low surgeon experience ($p=0.03$) were all predictive factors of ASIT. 15 (6%) of recurrences were observed over a median follow-up of 36 months. There was no difference in recurrence-free survival between the two groups ($p=0.57$).

Conclusions In our experience, accidental surgical incision into the tumour during RPN was a common event that did not appear to compromise oncological outcome.

Keywords Partial nephrectomy · Robotic surgical procedures · Recurrence · Complications · Survival

Introduction

Partial nephrectomy (PN) is the best option for the treatment of localized renal cell carcinoma (RCC) [1]. It provides optimal oncological control and better preserves renal function than radical nephrectomy [2]. In the last decade, the surgical approach has moved from open PN to laparoscopy mostly with robotic assistance [3]. The benefits of robot-assisted partial nephrectomy (RPN) have been widely reported: it

decreases surgical morbidity, analgesic requirements, length of hospital stay and convalescence [4, 5].

The primary objective of PN is to completely remove the tumour with negative margins. Typically, the tumour is sharply incised with a rim of normal renal parenchyma. The resection is usually carried out using cold scissors to better visualize the healthy parenchyma surrounding the tumour [6]. During this step of the intervention, an accidental surgical incision into the tumour (ASIT) can happen. Despite the fact that tumour recurrence after PN is a rare event and appears to be mainly related to tumour's stage and grade [7], one could assume that the risk is greater when ASIT occurs during RPN because of the pneumoperitoneum that may favour tumour cells dissemination and seeding. There is a body of evidence that suggests that tumour cell dissemination after tumour manipulation does occur and may contribute to tumour recurrence in some cases of laparoscopic surgeries [8, 9].

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The purpose of this study was to evaluate the impact of ASIT on oncological outcomes in patients undergoing RPN for a malignant tumour. We hypothesized that ASIT might increase the incidence of recurrence.

Materials and methods

Study design

After institutional review board approval, a retrospective review of our prospectively maintained database was performed to identify all patients who underwent RPN for a localized RCC between June 2010 and July 2016. All RPNs were performed by an expert surgeon or a senior surgeon or by fellows under the supervision of the expert surgeon. The presence of an ASIT was systematically mentioned in both operative and pathology reports. ASIT was defined as any accidental incision in the tumour or any accidental rupture of tumour surface during handling of the kidney and/or tumor. Patients were divided into two groups based on the presence of ASIT. Patients who had benign or cystic tumours, history of prior PN or radical nephrectomy, conversion to radical nephrectomy or open surgery and those with follow-up of < 1 years were excluded.

Surgical technique

All RPN procedures were performed through a transperitoneal approach. The Da Vinci[®] Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA) was used with a standard three-arm approach. The assistant surgeon was always a resident. Patients were placed in the flank position. A small incision was made at the umbilicus where a 12 mm port was inserted. Pneumoperitoneum was insufflated to a maximum pressure of 12 mmHg. A second 12 mm port was placed on the para rectal line, along with two 8 mm ports placed in the flank and in the hypochondrium. In case of right RPN, an additional 5 mm port was added below the xiphoid to retract the liver. Intraoperative laparoscopic renal ultrasound was systematically used before tumour resection to confirm its depth and limits. A Bulldog endoscopic clamp was used to clamp the renal artery. Excision of the tumour was always performed with cold scissors. During tumour excision, close observation of cut tissue was performed to identify any tumour violation. In this case, a complementary resection was performed. The early unclamping technique was used in the vast majority of cases. The renal reconstruction was made according to the sliding-clip renorrhaphy technique [10]. Haemostatic agents were never used and no drain was left postoperatively in place.

Covariates

Demographics, tumour and pathological characteristics were collected in an electronic database. Demographics included age, gender, American Society of Anesthesiologists (ASA) classification, body mass index (BMI), anticoagulant/antiplatelet treatments, performance of a preoperative biopsy, indications for nephron-sparing surgery [categorized as imperative (i.e., single kidney or preoperative eGFR < 60 ml/min) or elective (no imperative criteria)], the level of experience of the assistant surgeon ('Junior-level assistant' was defined as a resident in his/her 3 first postgraduate years. 'Senior-level assistant' was defined as a resident in his/her fourth or fifth postgraduate year) and surgeon experience's [subjectively categorized as low (< 60 cases) or high (> 60 cases)]. Tumours' characteristics included tumour size, tumour side, tumour position, RENAL nephrometry score [11] and Mayo adhesive probability score [12]. Pathologic data included stage, Fuhrman grade, surgical margins, histologic subtype, microscopic vascular invasion and sarcomatoid features.

Perioperative outcomes

The following variables were collected: operative time (OT), warm ischemia time (WIT), estimated blood loss (EBL), overall complication rate, major complication rate, positive surgical margins, absolute change in eGFR and length of hospital stay (LOS). Postoperative complications were graded using the Clavien–Dindo classification [13]. Major complications were defined as a Clavien score of 3 or higher. All outcomes were recorded within 30 days after the procedure.

Follow-up protocol

The oncologic follow-up schedule for patients at our institution comprised an outpatient visit at 1 month postoperatively, then every 6 months for 2 years and annually for at least three additional years. Follow-up consisted of a disease-specific history assessment, physical examination and contrast-enhanced computed tomography of the chest, abdomen, and pelvis. Disease recurrence was defined as the appearance of a tumoural mass in the resection bed or kidney fossa, regional lymph nodes, or metastasis in distant organs. All RCC recurrences or distant metastasis were confirmed by a biopsy.

Statistical analysis

Continuous variables were reported as medians and interquartile ranges (IQRs) and categorical variables were reported as proportions. Comparisons between groups were performed using χ^2 test and Fisher's exact test for discrete variables and Mann–Whitney test for continuous variables. Univariate and multivariate logistic regression analyses were used to assess the variables associated with ASIT. Multivariate models included covariates with a $p < 0.2$ in univariate analysis. Recurrence-free survival

was estimated using the Kaplan–Meier method and compared between groups with the log-rank test. Then, all patients were divided into two composite subgroups based on pathologic metrics as described by Shah et al. [14]: low-risk (pT1 and Fuhrman grade I–II) and high-risk (pT2–3 and/or Fuhrman grade III–IV). The relationship between ASIT and relapse risk was evaluated independently for these pathologic risk groups. Statistical analyses were performed using Stata 14.1 statistical software (Stata, College Station, TX, USA). All tests were two-sided with a significance level at $p < 0.05$.

Table 1 Baseline patient and disease characteristics

	Control	Accidental surgical incision into the tumour	<i>p</i>
No. pts (%)	202 (86)	32 (14)	
Median pts age at surgery (IQR)	62 (54–68)	66 (57–71)	0.16
No. male (%)	110 (54)	22 (69)	0.26
Median kg/m ² BMI (IQR)	26 (24–28)	26 (23–30)	0.76
Anticoagulant/antiplatelet treatments (%)	53 (26)	9 (28)	0.82
Surgeon experience (%)			0.005
Low (< 60 cases)	131 (65)	29 (90)	
High (> 60 cases)	71 (35)	3 (10)	
Median ml/min preoperative creatinine clearance/MDRD (IQR)	78 (68–74)	78 (65–114)	0.51
ASA classification (%)			0.78
1	39 (19)	6 (19)	
2	125 (62)	18 (56)	
3	38 (18)	8 (25)	
Indication for NSS (%)			0.12
Elective	176 (89)	25 (78)	
Imperative	26 (11)	7 (22)	
Median mm tumour size (IQR)	37 (25–50)	45 (30–56)	0.09
Tumour side (%)			0.55
Right	102 (51)	19 (59)	
Left	100 (49)	13 (41)	
Tumour position (%)			0.43
Anterior	78 (38)	8 (25)	
Posterior	81 (40)	13 (41)	
Hilar location (%)			0.34
Hilar	49 (24)	5 (16)	
No hilar	153 (76)	27 (84)	
Biopsy (%)	69 (34)	7 (22)	0.28
Median R.E.N.A.L score (IQR)	7 (4–9)	8 (5–9)	0.35
Median MAP score (IQR)	2 (0–4)	3 (0–4)	0.42
Assistant surgeon experience (%)			0.89
Junior	70 (35)	11 (34)	
Senior	132 (65)	21 (66)	

BMI body mass index, *ASA* American Society of Anesthesiologists, *NSS* nephron-sparing surgery; *MDRD* modification of diet in renal disease, *MAP* mayo adhesive probability

Results

Patients' and tumours' characteristics

We identified 234 patients who met the criteria for study inclusion. Patients' characteristics are summarized in Table 1. The total number of ASIT was 32 (14%). The groups were similar regarding ASA score, anticoagulant/antiplatelet treatments, BMI, indication for nephron-sparing surgery and level of assistant surgeon experience. Tumour tended to be bigger (45 vs. 37 mm) and more complex (RENAL score: 7 vs. 8) in the ASIT group, but these differences did not reach statistical significance ($p=0.09$ and $p=0.35$, respectively). Surgeons were less experienced in the ASIT group: 10% had done > 60 RAPNs vs. 35% in the control group ($p=0.005$).

Clear cell RCC was the most common histological subtype of RCC in both groups (69 vs. 78%). There was no statistically significant difference between the 2 groups regarding pathologic stages ($p=0.56$), Fuhrman grade (0.53), microscopic vascular invasion ($p=0.59$), sarcomatoid

features ($p=1$) and positive surgical margins ($p=0.07$) (Table 2).

Comparison of perioperative outcomes

Table 3 shows perioperative outcomes in each group. Most intraoperative outcomes including OT, WIT and early unclamping rate were comparable between the two groups. Patients in the ASIT group had greater EBL (475 vs. 300 mL; $p=0.01$), but this had no impact on the transfusion rate (17% vs 11%; $p=0.64$). The rates of overall complications and major complications were similar in both groups. There was no statistically significant difference in eGFR variation at 1 month (-4 vs -11 mL/min; $p=0.95$).

Predictors of accidental tumour incision

Results of univariate and multivariate analyses are shown in Table 4. In multivariate analysis, tumour size ($p=0.02$), RENAL score ($p=0.02$), EBL ($p=0.05$) and low surgeon experience ($p=0.03$) were all predictive factors of ASIT.

Table 2 Pathological characteristics and oncologic outcomes

	Control	Accidental surgical incision into the tumour	<i>p</i>
Histologic subtypes			0.49
Clear cell	140 (69)	25 (78)	
Papillary	36 (18)	5 (15)	
Chromophobe	26 (13)	2 (6)	
Fuhrman grade			0.53
1–2	133 (66)	21 (66)	
3–4	69 (34)	11 (34)	
Stage			0.56
1	163 (81)	26 (81)	
2	7 (3)	1 (3)	
3	32 (16)	5 (16)	
Microscopic vascular invasion			0.59
Yes	5 (2)	1 (3)	
No	197 (98)	31 (97)	
Sarcomatoid features			1
Yes	2 (99)	0 (0)	
No	200 (1)	32 (100)	
No. positive surgical margins (%)	8 (4)	4 (12)	0.07
Risk group stratification ^a (%)			0.95
Low-risk	116 (57)	18 (56)	
High-risk	86 (42)	14 (43)	
Median month follow-up	35.7 (21–43)	35.8 (23–49)	0.66
No. disease recurrence (%)	12 (6)	3 (9)	0.43
Local recurrences	9 (4.5)	2 (6)	
Metastatic progressions	3 (1.5)	1 (3)	

^aLow risk: pT1 and Fuhrman Grade I–II; high-risk: pT2–3a and/or Fuhrman Grade III–IV

Table 3 Perioperative and postoperative outcomes

	Control	Accidental surgical incision into the tumour	<i>p</i>
Median mins operative time (IQR)	150 (120–180)	180 (135–210)	0.12
Median mins WIT(IQR)	14 (10–19)	15 (10–20)	0.56
Median ml EBL (IQR)	300 (200–637)	475 (212–675)	0.01
No. early unclamping (%)	156 (77)	24 (75)	0.81
No. transfusions (%)	23 (11)	6 (17)	0.64
Median days length of stay (IQR)	4 (3–5)	4 (3–5)	0.67
No. overall complications (%)	70 (35)	11 (36)	0.94
No. major complications (%)	20 (10)	2 (7)	0.53
Median mL/min MDRD variation preoperatively/1 month postoperatively (IQR)	– 4 (– 8 to 0)	– 11 (– 15 to 1)	0.95

EBL estimated blood loss, *WIT* warm ischemia time

Table 4 Univariate and multivariate logistic regression analysis of factors associated with inadvertent surgical incision into a renal cell carcinoma

Variables	Univariate analysis			Multivariate analysis		
	Odds ratio	95% CI	<i>p</i>	Odds ratio	95% CI	<i>p</i>
Anticoagulant/anti-platelet treatments	1.08	(0.42–2.54)	0.85			
Indication for NSS				Reference		
Elective						
Imperative	2.26	(0.76–5.99)	0.13	2.18	(0.59–7.07)	0.22
Tumour size	1.02	(0.99–1.04)	0.01	1.04	(1–1.08)	0.02
RENAL score	1.57	(1.13–2.07)	0.001	1.23	(1.02–1.69)	0.02
Surgeons				Reference		
High (> 60 cases)	Reference					
Low (< 60 cases)	4.81	(1.61–20.69)	0.003	3.59	(1.11–16.17)	0.03
Estimated blood loss	1.12	(1.01–1.39)	0.02	1.01	(1–1.04)	0.05

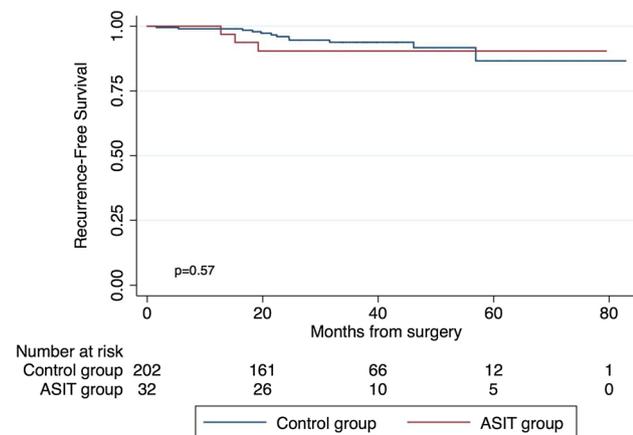


Fig. 1 Kaplan–Meier curve representing recurrence-free survival according to accidental surgical incision (ASIT) into a renal cell carcinoma during Robotic Partial Nephrectomy

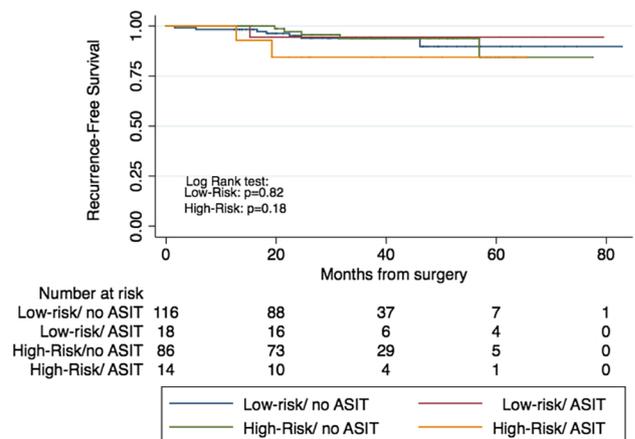


Fig. 2 Recurrence-free survival for localized renal cell carcinoma according to accidental surgical incision into the tumour (ASIT) by risk group stratification

Survival analyses

Median follow-up was 35.7 and 35.8 months in control and ASIT groups, respectively. There was a total 15 (6%) recurrences: 12 (6%) in the control group and three (9%) in the ASIT group. Figure 1 shows Kaplan–Meier curves of recurrence-free survival according to the presence of an ASIT. Using the log rank test, we did not find any difference between the 2 groups ($p=0.57$). We performed subgroup analysis stratified by stage and Fuhrman grade (pT1 and Fuhrman grade I–II vs. pT2–3 and/or Fuhrman grade III–IV) (Fig. 2) and did not find any difference regarding ASIT and control patients (high-risk: $p=0.18$ and low-risk: $p=0.82$).

Discussion

Removing the tumour with a free margin is the primary objective of RPN [15]. For that purpose, robotic surgeons usually complete tumour excision with a rim of normal parenchyma and use temporary arterial clamping to work in a bloodless field that provides an optimal vision. To preserve renal function, a maximum of non-neoplastic renal parenchyma should be spared and it has been shown that a minimal margin of renal parenchyma was enough to ensure oncological safety [16]. For that reason, surgeons tend to get as close as possible to the tumour during resection and in some cases (impaired conditions such as bleeding, lack of experience, complex tumour), an ASIT can occur.

Multiple prognostic factors have been studied for identifying patients at high-risk of recurrence, including tumour stage, nuclear grade, overall performance status, and molecular markers [17–20] but ASIT has not been specifically investigated as a potential predictor.

One could think that ASIT could promote tumour dissemination, but we did not find any association between the occurrence of an ASIT and local or metastatic recurrence. Interestingly, when the lesions were stratified into risk groups, ASIT was still not associated with recurrence. Several assumptions can be made to explain this finding: (1) warm ischemia induced by clamping of the renal artery might eradicate cells with high metabolic requirements, specifically cancer cells; (2) tumours in this study were relatively small and previous studies suggested that tumour size could be significantly associated with survival and recurrence, with local RFS decreasing significantly with each 1 cm increase in tumour size [21–23] (3) our follow-up might be too short to show any impact of tumour effraction.

Similarly, the impact of a positive surgical margin is debated. A review of 777 patients undergoing PN revealed an increased risk of recurrence in patients with a PSM and high-risk pathology. However, in the subgroup of patients with a tumour of low malignant potential, there was no

recurrence even in the case of a positive margin [24]. Higher rates of recurrence in case of a PSM were also reported by others [14] but many subsequent reports contradicted those results [25, 26]. Several large series reported that margin status did not have any impact on oncologic outcomes provided that follow-up was done appropriately [25, 26]. These publications and our results suggest that the risk of recurrence is mostly driven by tumour biology.

The incidence of ASIT was relatively common in our study and was associated with both surgeon's experience and tumour characteristics. A link between surgeon's experience and oncological outcomes has been suggested in many urological procedures [27, 28]. It makes sense to assume that surgeon's experiences can influence the incidence of accidental tumour effraction. The impact of tumour size could be explained by: (1) surgeons might have been more reluctant to incise a generous rim of adjacent renal parenchyma in cases of large tumours to preserve as much renal parenchyma as possible, (2) some large renal masses do not have a spherical shape and can send extensions which can be accidentally cut by the surgeon. Finally, we found an association between estimated blood loss and the occurrence of ASIT. We hypothesized that continuous and prolonged bleeding during the tumorectomy could impair the quality of the vision and maybe increase the risk of ASIT.

With the increased spread of robotic surgery to low volume surgeons [29], it is important to clarify the potential iatrogenic dissemination of tumour cells. We believe our results provide significant information, which may help surgeons decide what to do in case of an ASIT. There are several options: most of the surgeons usually do a re-resection of the tumour bed, while others choose to convert to radical nephrectomy and/or to an open approach. Although our follow-up is limited, our findings support the possibility to pursue the operation under laparoscopy provided the tumour is re-resected adequately. However, every decision should be taken according to many other parameters: the patient's characteristics, surgeon's experience and importance of tumour effraction. One would argue that, given similar oncological outcomes we observed in case of ASIT, re-resection could be avoided. However, the findings we report were obtained while performing those complementary resections and we think it is the best and safest way to do in such a situation.

There are some limitations to our work. First, it is a retrospective analysis at a single institution. Second, because of its retrospective design, the interpretation of ASIT could have been subjective. Third, there is a lack of consensus concerning the histopathological interpretation of ASIT because some pathologists do not consider ASIT as a positive margin, while others consider any tumour effraction as a positive margin. Indeed, in the absence of supporting data or specific studies on this issue, a consensus opinion was established in our department about the definition of PSM when ASIT

occurred. The margin was considered positive in case of ASIT only if there were tumour cells at the margin of the complementary resection, which had been confirmed microscopically. Another possible shortcoming is the relatively low number of patients in the ASIT group and the relatively short follow-up period. Lastly, the lack of statistical power due to the relatively limited number of disease recurrences undermines our findings considering the absence of statistical difference observed as large confidence intervals do not allow concluding to equivalence.

Conclusion

In our experience, accidental surgical incision into the tumour during RPN was a common event that was mainly influenced by surgeon experience and tumour size. Moreover, it did not appear to compromise oncological outcomes. Further studies with longer follow-up are needed to confirm these results.

Compliance with ethical standards

Conflict of interest The author declares that there is no competing interest.

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