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ORIGINAL ARTICLE

Is 3D laparoscopic off clamp simple enucleation a feasible alternative for clinical T1 renal tumors? Outcomes from a single center experience

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Summary

Purpose: *To evaluate the safety of 3D laparoscopic off clamp simple enucleation (SE) of kidney tumors versus standard laparoscopic on-clamp partial nephrectomy (PN) in terms of perioperative, oncological and functional outcomes.*

Methods: *All patients that underwent 3D laparoscopic nephron sparing surgery (NSS) in our department for clinical T1 tumors between January 2019-September 2020 were included. Of the total of 84 patients, 38 (45.24%) underwent SE (SE group) and 46 (54.76%) PN (PN group). Perioperative data was collected and analyzed. Oncological outcomes were evaluated by the positive surgical margin (PSM) rate and follow-up at 6 months after surgery.*

Results: *Mean age, gender, tumor size, PADUA score and length of hospital stay were comparable between the two groups. Estimated intraoperative blood loss (284.21 ml vs 151.52 ml, p=0.0001) and hemoglobin drop (p=0.0001) were significantly lower for the PN group. Patients that underwent SE showed a better preservation of renal function (eGFR drop of 4.4 ml/min vs 1.78 ml/min, p=0.75). No significant differences were found regarding the PSM, although the PSM rate was lower in the SE group when compared with the PN group (2.63% vs 4.34%, p= 0.07).*

Conclusion: *Off-clamp simple enucleation of renal masses is feasible by laparoscopic approach and has produced comparable oncologic outcomes with standard on-clamp partial nephrectomy, with an incremental advantage for the preservation of renal function.*

Key words: *3D laparoscopy, off-clamp, simple enucleation, partial nephrectomy, renal tumor, outcomes*

Introduction

The detection rate of renal cancer, and especially of small renal masses (SRM) has increased during the last years due to the widespread use of abdominal ultrasound and computed tomography [1].

Nephron sparing surgery (NSS) techniques have been developed in order to preserve the maximum amount of normal renal parenchyma while respecting the principles of oncologic surgery [2,3]. Simple enucleation (SE) consists of developing the surgical plane between the normal renal parenchyma and the renal mass with its pseudocapsule, using blunt dissection. The procedure can be performed with or without clamping of the renal vessels [4,5]. Partial nephrectomy (PN), that entails the excision of the tumor with a safety margin of

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normal renal tissue, is still considered to be the standard approach for clinical T1 renal tumors, when technically possible [6,7].

The ideal surgical treatment of SRM entails the tumor removal with negative surgical margins, a maximum preservation of renal function without perioperative complications. In order for these points to be achieved, several surgical and ischemia techniques have been described. The enucleation of SRM without ischemia has been proposed as an alternative to resection or standard partial nephrectomy. Data from the literature has shown a maximum renal function preservation of zero ischemia enucleation (32.0% vs 20.7% of patients that developed acute kidney injury after PN vs SE, p=0.01), with similar recurrence rates (3.2% of patients, 95% CI:2.0-5.0%) when compared with standard partial nephrectomy [4,8].

The interruption of renal blood supply by clamping the renal artery during partial nephrectomy has been shown to produce ischemic lesions and have an impact on the postoperative renal function. A cut-off duration of 20 to 25 min of ischemia time has been reported in order to avoid renal function impairment after partial nephrectomy [9]. Several strategies for reducing the ischemia time have been described in the literature. Selective vascular/parenchymal clamping has been shown to reduce the normal kidney parenchyma that is subjected to ischemic lesions. Another technique for reducing the ischemia time is represented by early unclamping, that entails the removal of the vascular clamp after the resection of the kidney mass but before completing the renorrhaphy. Moreover, on-demand clamping, where the vascular clamp is applied on the renal artery if there is persistent bleeding in the operating field during resection, is considered to be another option for reducing ischemic trauma to the kidney [10].

The off-clamp enucleation aims to ensure the best results in terms of renal function preservation, by avoiding completely the renal ischemia. SE by robotic assisted laparoscopic surgery is considered to be the preferred approach for SRM in many high volume centers, shorter ischemia time and lower complication and conversion to open surgery rates being associated with robotic surgery [11,12]. However, due to the increase in the level of experience in laparoscopy, 3D visualization and development of laparoscopic specialized instruments, more complex cases of renal masses can be approached by laparoscopic enucleation [13].

The aim of this study was to assess the feasibility and safety of laparoscopic off-clamp SE as compared to PN in terms of surgical, oncological and functional outcomes.

Methods

From January 2019 to September 2020 data from all patients (n=84) that underwent 3D laparoscopic NSS for clinical T1 renal tumors was prospectively collected. Exclusion criteria were represented by refuse to sign informed consent and presence of synchronous metastasis.

The 2009 American Joint Committee on Cancer TNM system was used for all tumors staging. The Preoperative Aspects and Dimensions Used for Anatomical (PADUA) classifications of renal tumors score was reported in all cases for preoperative planning and predicting the risk of surgical and medical postoperative complications after NSS [14].

Patient characteristics and perioperative data including age, tumor size, PADUA score, renal function, operative time, blood loss, complications, hospitalization days were collected and analyzed. Preoperative and postoperative creatinine clearance was calculated using the Cockcroft-Gault Equation [15].

All 3D laparoscopic procedures began by attempting simple enucleation; in cases where it was not technically feasible, we performed standard partial nephrectomy. Of the total of 84 patients, 38(45.24%) underwent SE (SE group) and 46 (54.76%) PN (PN group). Simple enucleation was performed without clamping of the renal artery, by blunt dissection of the plane between the tumor pseudocapsule and normal parenchyma. Partial nephrectomy was performed with temporary clamping of the renal artery using laparoscopic Bulldog clamp and warm ischemia time was recorded. The surgical approach (transperitoneal or retroperitoneal) was chosen according to surgeon preference with regards to tumor localization. Renorraphy was performed in single-layer for all patients using absorbable sutures and sliding-clip technique. In case of renal artery clamping, the Bulldog was released after the renorraphy was complete. Perioperative complications were reported according to the Clavien-Dindo classification [16].

This study was approved by the local ethics committee and conducted in line with the Declaration of Helsinki. Informed consent was given and collected from all of the patients enrolled.

Statistics

Statistical analyses were performed using the IBM Statistical Package for the Social Sciences (SPSS v.26, IBM Corporation, Armonk, New York, USA). For comparison of continuous variables of the two groups, the Student's T-test was performed. For comparison of categorical variables of the two groups, the Pearson's chi-square test was used. Statistical significance was set at $p<0.05$.

Results

Demographics and perioperative data are listed in Table 1.

The two study groups were similar in terms of mean age, gender, tumor size, PADUA score of renal tumors and hospitalization days. The mean operative time was shorter for the SE group when compared to the PN group (158.42 min vs 169.9 min, p=0.048). Estimated intraoperative blood loss and Δ HB were significantly lower for the PN group when compared to the SE group (p=0.0001). The postoperative renal function evaluated by creatinine clearance calculated with the Cockcroft-Gault Equation and Δ eGFR revealed that patients from the SE group recorded a lower drop of median postoperative eGFR when compared with the PN group (p=0.93). The mean WIT for the PN group was 18.78 min.

In the SE group, 57.89% of cases were performed by retroperitoneal approach and 42.11% by transperitoneal approach. In the PN group, the retroperitoneal and transperitoneal approach were performed in 58.7% and 41.3% of the cases, respectively. The overall incidence of perioperative complications was similar between the two groups (7.89% for the SE group and 8.7% for the PN group, p=0.72). 14.28% of the patients reported at least one perioperative complication, according to the Clavien-Dindo classification. Most of the complications were Clavien-Dindo grade 1 and 2. Clavien-Dindo grade 3 complication was reported in one case from the PN group, where surgical re-intervention for drainage of postoperative urinoma

Table 1. Descriptive analysis of demographics and perioperative characteristics of patients who underwent NSS for clinical T1 renal tumors

	SE group	*PN group*	*p value*
Age, mean (SD)	58.8 (12.04)	57.2 (12.8)	0.54
Gender, n (%)			
Male	26 (68.42)	30 (65.22)	0.32
Female	12 (31.58)	16 (34.78)	
cT, n (%)			
1a: <4 cm	31 (81.58)	35 (76.09)	0.47
1b: 4.1- 7 cm	7 (18.42)	11 (23.91)	
PADUA score, n (%)			
Low risk: 6-7	29 (76.32)	31 (67.39)	0.12
Intermediate risk: 8-9	7 (18.42)	10 (21.74)	
High risk: >/=10	2 (5.26)	5 (10.87)	
Op. time (min), mean (SD)	158.42 (33.65)	169.9 (17.55)	0.048
EBL(ml), mean (SD)	284.21 (86.10)	151.52 (62.4)	0.0001
Hospitalization (d), mean (SD)	3.55 (1.32)	3.72 (2.03)	0.3
WIT(min), mean	0	18.78	-
Preop. HB (g/dL), mean (SD)	14.57 (1.12)	15.1 (1.08)	0.03
48h HB (g/dL), mean (SD)	13.15 (1.27)	14.53 (1.19)	0.0001
Δ HB (g/dl), mean (SD)	1.42 (0.61)	0.57 (0.51)	0.0001
Preop. eGFR (mL/min), mean (SD)	73.31 (16.70)	84.23 (21.46)	0.012
48h eGFR(mL/min), mean (SD)	71.53 (16.14)	79.83 (21.17)	0.93
Δ eGFR (mL/min), mean (SD)	1.78 (0.56)	4.4 (0.29)	0.75

SD: standard deviation; cT: clinical tumor stage; n: number of patients; d: postoperative days; WIT: warm ischemia time; HB: hemoglobin; Δ HB: difference between preop. HB: and 48h HB; EBL: estimated intraoperative blood loss; eGFR: estimated glomerular filtration rate calculated using the Cockcroft-Gault Equation; Δ eGFR: difference between preop. eGFR and 48h eGFR; Op. time: operative time.

Table 2. Histology results of patients with clinical T1 renal tumors who underwent NSS

Histology	*SE group n (%)*	*PN group n(%)*	*p value*
AML	3 (7.90)	1 (2.17)	-
CCC	27 (71.05)	35 (76.09)	0.274
Cr	2 (5.26)	2 (4.35)	-
Onc	4 (10.53)	3 (6.52)	-
Pap	2 (5.26)	5 (10.87)	-

AML: angiomyolipoma; CCC: clear cell carcinoma; Cr: cromophobe; Onc: oncocytoma; Pap: papillary was necessary. There were no Clavien-Dindo grade 4 or 5 complications. The complications rate was not found to be influenced by the type of surgical approach (retroperitoneal or transperitoneal, p=0.470).

Pathological staging in the SE group was pT1a in 86.84% and pT1b in 13.16% of the cases, whereas in the PN group 79.09% of cases were pT1a and 23.91% were pT1b. The PSM rate was lower for the SE group when compared with the PN group (2.63% vs 4.34%, p=0.07). For the SE group, Fuhrman nuclear grade 1-2 was identified in 85.19% of cases and grade 3-4 in 9.42%. For the PN group, Fuhrman nuclear grade 1-2 was identified in 82.73% of cases and grade 3-4 in 10.65%. Unclassified nuclear grade was reported in 5.39% for SE group and 6.62% of cases for the PN group, respectively. The histological subtypes are listed in Table 2. At 6 months follow-up, in our cohort of 84 patients no evidence of local recurrence or distant metastases was identified on contrast-enhanced computed tomography studies.

Discussion

In our study, we found that 3D laparoscopic SE for clinical T1 renal tumors has comparable surgical, pathological and oncological outcomes and an improved preservation of renal function when compared to standard PN. Mid and long-term oncological outcomes of SE (evaluated by positive surgical margins, local recurrence or distant metastasis) are considered to be a point of discussion in the current literature. In addition, the impact of SE versus standard PN on renal function is not currently clearly defined.

A multicenter comparative study on more than 1500 patients of standard partial nephrectomy and simple enucleation was conducted by Minervini et al in 2011. PSM rate was shown to be higher in the PN group, but no difference between 5 and 10-year cancer specific survival was found (93.9% and 91.6% after PN; 94.3% and 93.2% after SE) [17]. In our study, we found similar results regarding the PSM rate between the two groups, although the results are hampered by the short follow up. Another prospective multicenter study conducted by Minervini et al. on more than 500 patients evaluated the impact and feasibility of different surgical techniques during PN. They found that operating time, WIT, EBL and hospitalization days were similar when comparing SE with PN. Clavien-Dindo grade 2 complications were more frequently recorded after PN when compared with SE. In addition, the PSM rate was higher for the PN group, a result which was consistent with the findings of Longo et al in their multicenter dataset matched-pair comparison, also similar with our findings [8,18,19]. Another meta-analysis by Xu et al revealed shorter operative time, hospitalization days, less blood loss, complications rate and reduced renal function impairment of SE vs PN (p<0.002) with no differences in terms of WIT, PSM and recurrence rates, results which were consistent with the findings of other reviews and meta-analyses in the literature [20-22].

Regarding the minimally invasive approach, Vartolomei et al evaluated the mid-term oncological outcomes of robot assisted PN on 123 patients from a single center. Follow up included clinical examination, blood tests and urine analysis, computed tomography or magnetic resonance imaging of the thorax and abdomen at 3,9 months after surgery and annually for 5 years. The authorss have shown that PN (robot-assisted) for clinical T1 renal tumors is a feasible, safe and efficient treatment, with over 90% 5-year disease-free survival, cancer-specific survival and 5-year overall survival [23]. Another study on minimally invasive partial nephrectomy conducted by Bertolo et al, that included approximately 2000 patients, reported no difference in the overall survival, recurrence and metastasis-free survival when comparing off-clamp and on-clamp robotic partial nephrectomy [24].

When comparing the 3D laparoscopic with the robot-assisted approach for PN, Zhao et al found that the robotic system can provide a decreased WIT but no difference in EBL, conversion to open surgery, PSM rate and long term recurrence rate were reported [25]. Although laparoscopic PN can prove to be a technically difficult procedure, the use of 3D magnified view in laparoscopy has proven to reduce the gap between this approach and the robot-assisted PN. In this perspective, the authors have reported a PSM rate of 3.0 vs 1.0%, operating time of 188.2 vs 171.9 min for the laparoscopic vs robot-assisted approach, results which were similar with our findings regarding the 3D laparoscopic SE. Gu et al also compared the laparoscopic vs robot-assisted approach in PN and found no significant difference in PSM rate, perioperative complications and renal function impairment (p>0.05), with a shorter WIT(< 25 min) for the robotic approach (p<0.001) [26].

As far as preservation of renal function after partial nephrectomy is concerned, Dong et al showed in a retrospective study that tumor enucleation (TE) provides potentially better renal function preservation when compared with standard partial nephrectomy (SPN), with a median glomerular filtration rate preservation of 101% for TE and 84% for SPN (p<0.0001) [27]. These results are similar with our findings that suggest the fact that simple enucleation for renal tumors allows for maximum renal function preservation when compared with SPN, without altering the oncological outcomes. Similar results regarding the preservation of renal function after tumor enucleation were found by Mari et al. The authors evaluated the functional outcomes of clamp less robot assisted simple enucleation of clinical T1 renal tumors and concluded that off-clamp enucleation provides better preservation of early perioperative renal function, with similar complication and positive surgical margin rate, when compared with on-clamp minimally invasive PN [28]. Wang et al found in a retrospective analysis of 337 cases that elevated baseline eGFR, higher WIT and increased nephrometry score were independent predictors of renal function impairment (immediately postoperative reduction of eGFR by 23.8%, after one year 15.5% decline of eGFR) [29].

Limitations of this study include the small sample size, the lack of randomization and long-term outcomes. A lack of standardization on reporting the postoperative renal function following minimally invasive PN is noted in current literature.

Conclusions

Off-clamp SE is possible by laparoscopic approach and has proven comparable oncologic outcomes with standard on-clamp PN, with an incremental advantage for the preservation of renal function. Whenever feasible, the surgeon should aim for off-clamp simple enucleation of cT1 renal masses.

Conflict of interests

The authors declare no conflict of interests.

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