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Robotic Versus Laparoscopic Partial Nephrectomy: A Prospective, Randomized Trial Comparing Two Surgical Techniques

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Abstract

Purpose: To compare oncological, peri-, and post-operative outcomes of robot-assisted with those of laparoscopic partial nephrectomy.

Patients and Methods: Thirty patients with low- or moderate-complexity renal tumors (R.E.N.A.L. nephrometry scoring) were randomized in a single-blind manner and operated on by the robot-assisted (n=13) or laparoscopic (n=17) approach. The primary outcome was oncological safety, based on the Residual tumor (R) classification. Secondary outcome parameters were perioperative and postoperative results. The open-source R statistical software was used for statistical analysis.

Results: Oncological outcomes did not differ significantly between the two surgical methods (p=0.58). Operating time (p=0.105), ischemia time (p=0.884), overall length of hospital stay (p=0.664), postoperative pain, and preoperative and in-hospital renal function scores were similar. Creatinine levels differed significantly six months postoperatively (robotic: 0.9 mg/dl *vs*. laparoscopic: 1.1 mg/dl; p=0.014). Intraoperative blood loss was significantly greater in the laparoscopic group (400 ml *vs*. 168 ml; p=0.028), which was also reflected in postoperative hemoglobin levels (13.8 mg/dl *vs*. 12.5 mg/dl; p=0.012). Peri- or post-operative complications did not differ significantly (p=0.355). Subgroup analysis revealed significantly more frequent complications in patients with moderate-complexity tumors treated by laparoscopic surgery (p=0.021).

Conclusion: The oncological outcome in regard to the R status was similar in both groups. Intraoperative blood loss, postoperative renal function, and complications all benefited from robot-assisted surgery.

Trial registration: The study was registered on ClinicalTrials.gov (NCT03900364; 03/04/2019).

Keywords: Robotic surgery; Laparoscopy; Partial nephrectomy; Renal cell carcinoma; Nephrometry score

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Introduction

In the early 2000s, laparoscopic PN was established as an acceptable treatment alternative and provided oncological outcomes similar to those of open surgery [1]. Minimally invasive techniques have been developed continuously since this time. Robot-assisted PN, especially, has become increasingly popular. Recently published meta-analyses have reported the advantages of the robot-assisted technique in terms of conversion rates to open surgery and RN, shorter ischemia time, and shorter hospital stays [2-4]. However, there is no explicitly recommended surgical procedure (open, laparoscopic, or robot-assisted) for PN in patients with T1 renal tumors, due to the absence of prospective randomized controlled studies with long periods of follow-up.

The aim of this pilot study was to investigate, in a prospective randomized single-blind design, the oncological outcomes of robot-assisted and laparoscopic PN in patients with renal tumors of similar complexity. Secondary outcome parameters were perioperative aspects such as operating time, blood loss, ischemia time, peri- and post-operative complications, the dynamics of renal function, and postoperative pain.

Materials and Methods

After informed consent thirty patients were randomized prospectively at our clinic between

September 2018 and May 2020, to undergo either transperitoneal Robotic PN (RAPN, n=13) or transperitoneal Laparoscopic PN (LAPN, n=17). In order to ensure a comparable analysis, we divided the patients into two groups based on the R.E.N.A.L. nephrometry scoring system [5]: Patients with tumors of low complexity (n=20) and those with tumors of moderate complexity (n=10). The operations were performed by three experienced surgeons with high volumes of laparoscopic and robot-assisted procedures. The patients were randomized in a single-blind manner and did not know whether they would undergo laparoscopic or robotic surgery. The primary outcome parameter was the impact of the surgical procedure on the oncological outcome in terms of resection margins (R0, RX, R1). Secondary parameters were operative time, ischemia time, complications based on the Clavien-Dindo classification [6], intraoperative blood loss, Hb levels, the course of renal function in the six-month follow-up period, and the course of pain on the VAS score [7] during the hospital stay and six months postoperatively.

In fifteen patients a full-clamp partial nephrectomy has been performed, while eleven patients underwent an off-clamp technique.

Four patients (two each in the RAPN and LAPN groups) had to undergo nephrectomy intraoperatively, and were excluded from the statistical analysis regarding the development of postoperative renal function.

Our statistical analysis involved two steps. First, for comparing surgical methods all continuous variable data were checked for normal distribution (test of normality: Kolmogorov-Smirnov with Lilliefors significance correction, type I error =10%). Variables with normally distributed data were compared by use of the *t*-test for independent samples. For variables without normally distributed data and for variables measured on ordinal scales, the exact Mann-Whitney U test was used. Dichotomous variables were compared using Fisher’s exact test, and the remaining categorical variables by using the Chi-square test.

Second, we evaluated secondary endpoints based on surgical methods and tumor complexity. For this purpose, comparisons of continuous variables with normally distributed data without different variances (checked by the Levene test, type I error =5%) were performed using a parametric Analysis of Variance (ANOVA; post hoc tests by Hochberg's GT2 method). For comparisons of all other continuous variables and of variables measured on ordinal scales, a non-parametric analysis of variance (Kruskal-Walli’s test, followed by Nemenyi's multiple comparisons) was used. Categorical variable data were compared using the Chi-square test.

The type I error was not adjusted for multiple testing. Therefore, the results of inferential statistics are only descriptive. Statistical analysis was performed using the open-source R statistical software package, version 3.6.1 (The R Foundation for Statistical Computing, Vienna, Austria).

The study was approved by the Ethics Committee of Salzburg, Austria (415-E/2356/9-2018). All methods were performed in accordance with the CONSORT guidelines and research has been performed in accordance with the Declaration of Helsinki.

Results

Patient characteristics

Descriptive characteristics of the study population, including peri- and post-operative outcomes, are shown in Table 1. Patients in the RAPN and LAPN groups were similar in regard of age (59 years and 63 years), sex, BMI (29 kg/m^2 and 28 kg/m^2), preoperative Hb, creatinine and GFR levels (13.8 and 14.3 mg/dl; 0.8 and 1 mg/dl; 88.4 and 79.3 ml/min, respectively), and tumor complexity (8 low-complexity and 5 moderate-complexity renal tumors in the RAPN group; 12 low-complexity and 5 moderate-complexity renal tumors in the LAPN group). The mean tumor size was 2.4 cm in the RAPN group and 2.6 cm in the LAPN group. Ten of 13 patients in the RAPN group and 13 of 17 patients in the LAPN group had a histologically confirmed renal cell carcinoma. A complete list of histological findings is shown in the Supplementary Table 1. The mean duration of the hospital stay was 7 days in both groups.

Surgical margins

Statistical analysis revealed no significant difference between the RAPN group and the LAPN group in regard to positive resection margins (p=0.58).

Perioperative outcomes

The mean operating time and the mean ischemia time were similar in the RAPN and LAPN groups (respectively, 145 and 124 min, p=0.105; and 8.9 and 8.6 minutes, p=0.884). Intraoperative blood loss was significantly greater in the LAPN group (400 *vs.* 168 ml, p=0.028). Because of tumor location intraoperative conversion to nephrectomy was required in two patients each in the RAPN and LAPN groups (p>0.999).

Renal function

Preoperative renal function was similar in the two groups: Mean creatinine levels were 0.8 mg/dl and 1 mg/dl in the RAPN and LAPN groups, respectively (p=0.154). Postoperative creatinine levels also did not differ significantly during the hospital stay. However, 6 months post-surgery, we observed a statistically significant difference in renal function: Mean creatinine levels were 0.9 mg/dl in the RAPN group and 1.1 mg/dl in the LAPN group (p=0.014). GFR showed a continuous deterioration of renal function in the laparoscopy group, but without statistical significance.

Course of hemoglobin levels

Preoperative Hb levels were similar in both study groups: Mean values were 13.8 and 14.4 mg/dl in the RAPN and LAPN groups, respectively (p=0.796). The first complete blood count measured four hours post-surgery revealed a significant difference between groups (13.8 mg/dl for RAPN *vs.* 12.5 mg/dl for LAPN, p=0.012). Even on the day of discharge, Hb levels were lower in the LAPN group but no significant difference was noted between groups (12.9 mg/dl for RAPN *vs.* 11.7 mg/dl for LAPN, p=0.055). At the first follow-up investigation, which was usually performed 14 days after discharge, Hb levels were again similar in both groups (13.5 mg/dl for RAPN *vs.* 12.8 mg/dl for LAPN, p=0.295). In a subgroup analysis of the impact of the surgical procedure and tumor complexity, we did not see any difference between low-complexity nor moderate-complexity tumors operated by the robotic *vs.* laparoscopic procedure. But we noted a highly significant difference four hours postoperatively between low-complexity tumors operated by the robot-assisted procedure *vs.* moderate-complexity tumors operated by the laparoscopic procedure (14.1 mg/dl for RAPN *vs.* 11.7 mg/dl for LAPN, p=0.009; Table 2).

Postoperative pain

Postoperative pain on the VAS score revealed no significant difference between groups. Analogously, the need for painkillers was similar in both groups.

Table 1: Descriptive characteristics, including peri- and postoperative outcomes, stratified by surgical approach.

	Robotic (*N*=13; 43%)	Laparoscopic (*N*=17; 57%)	p Value
Age (year)	59 (37-80)	63 (38-81)	0.325
Sex			0.19
Male	8 (62%)	15 (88%)	
Female	5 (38%)	2 (12%)	
Body mass index, kg/m²	29 (17-38)	28 (21-38)	0.638
Tumor complexity (R.E.N.A.L. score)			0.705
Low complexity	8 (62%)	12 (71%)	
Intermediate complexity	5 (38%)	5 (29%)	
Side of lesion			>0.999
Right	7 (54%)	9 (53%)	
Left	6 (46%)	8 (47%)	
Operative time, min	145 (101-215)	124 (76-174)	0.105
Length of stay (days)	7.2 (6-10)	7.1 (5-13)	0.664
Ischemia time, min (*N*=26)	8.9 (0-28)	8.6 (0-25)	0.884
Estimated blood loss, ml (*N*=30)	168 (10-600)	400 (50-1600)	0.028
Mean size of tumor, cm (*N*=28)	2.4 (0,5-4)	2.6 (1-7)	0.709
Histology			>0.999
Renal cell carcinoma	10 (76,9%)	13 (76,5%)	
Benign tumor	3 (23,1 %)	4 (23,5%)	
Surgical margins (*N*=27)			0.58
R0	7 (58%)	12 (80%)	
RX	3 (25%)	2 (13%)	
R1	2 (17%)	1 (7%)	
Radical nephrectomy conversion (*N*=4)	2 (15%)	2 (12%)	>0.999
Peri/ postoperative complications	1 (8%)	4 (24%)	0.355
Major complications (Clavien Dindo > 2)	0 (0%)	4 (24%)	0.113
Hemoglobin level (mg/dl)			
Preoperative (*N*=30)	13.8 (7.3-16.7)	14.3 (13-16.4)	0.796
4 h postoperatively (*N*=29)	13.8 (11.6-15.9)	12.5 (10.4-15.2)	0.012
Discharge (*N*=27)	12.9 (9.9-15.5)	11.7 (10.1-14.5)	0.055
First follow-up (*N*=26)	13.5 (10.5-16.7)	12.8 (9.7-15.2)	0.295
Delta hemoglobin			
4 h postoperative – preoperative (mg/dl)	-0.59	-1.77	<0.001
Preoperative – 4 h postoperative (%)	-4.14	-12.26	<0.001
Discharge – preoperative (mg/dl)	-0.69	-2.52	0.005
Preoperative – discharge (%)	-2.6	-17.6	0.005
First follow-up – preoperative (mg/dl)	-0.33	-1.53	0.032
Preoperative – first follow up (%)	-0.76	-10.71	0.034
Creatinine level (mg/dl)			
Preoperative (*N*=30)	0.8 (0.3-1.1)	1 (0.7-1.5)	0.154
Post operative, day 1 (*N*=26)	0.9 (0.6-1.3)	1 (0.7-1.3)	0.344
Discharge (*N*=22)	0.9 (0.5-1.3)	1 (0.6-1.4)	0.163
6 months postoperatively (*N*=25)	0.9 (0.7-1.1)	1.1 (0.7-1.6)	0.014
Delta Creatinine			
Post operative, day 1 – preoperative (mg/dl)	0.1	-0.01	0.196
Preoperative – post operative, day 1 (%)	22.01	1.29	0.413
Discharge – preoperative (mg/dl)	0.1	0.05	0.71
Preoperative – discharge (%)	27.52	6.53	0.674
6 months postoperatively – preoperative (mg/dl)	0.1	0.11	0.614
Preoperative – 6 months postoperatively (%)	24.41	13.02	0.605
Glomerular filtration rate (ml/min)			
Preoperative (*N*=30)	87 (67-107)	79 (46-116)	0.198
Post operative, day 1 (*N*=26)	81 (49-101)	78 (52-97)	0.67
Discharge (*N*=22)	79 (50-111)	71 (46-97)	0.255
6 months postoperatively (*N*=25)	80 (67-94)	70 (47-100)	0.12
Post operative Pain (VAS)			
4 h postoperatively (*N*=30)	2.2	2.3	0.937
Day 1, 08:00 a.m. (*N*=30)	2.7	2.7	0.965
Day 1, 12:00 o'clock (*N*=30)	2.5	2	0.468
Day 1, 04:00 p.m. (*N*=30)	2.5	2.5	0.887
Day 2, 08:00 a.m. (*N*=30)	1.8	1.9	0.937
Discharge (*N*=30)	0.8	0.8	0.777
6 months postoperatively (*N*=25)	0	0.3	0.487
Painkillers (mg)			
Novalgin (*N*=25)	4750	4633	0.773
Paracetamol (*N*=25)	4889	3969	0.326
Dipidolor (*N*=23)	16	11	0.38

VAS: Visual Analog Scale; h: hours

Surgical complications

We noted five peri- and post-operative complications; four of these occurred in the LAPN group and one in the RAPN group (p=0.355). All four complications in the LAPN group were severe (Clavien-Dindo grade >2). No severe complication occurred in the RAPN group (p=0.113). A complete list of complications is provided in the Supplementary Table 1. In a subgroup analysis of tumor complexity and surgical methods (low-complexity robotic versus moderate-complexity robotic *vs.* low-complexity laparoscopic versus moderate-complexity laparoscopic), we noted a statistically significant difference for the combination of laparoscopic surgery and moderate-complexity tumors (p=0.021; Table 3).

Discussion

Perioperative outcomes of PN have been investigated in several studies. However, studies comparing RAPN with LAPN are scarce [8]. To date there is only one randomized controlled trial comparing RAPN *vs.* LAPN [9]. In the present investigation, 30 patients with renal tumors proven on radiological investigation underwent partial nephrectomy by the laparoscopic or the robotic procedure. In order to ensure that the operations were of comparable complexity, only patients with low-complexity and moderate-complexity tumors were included in the study. Patients were randomized in single-blind fashion and were unaware of the surgical method being used.

Neither of the two surgical methods was associated with a higher level of risk in regard to positive resection margins. This is in accord

Table 2: Subgroup analysis: Course of hemoglobin levels in regard to the impact of the surgical procedure and tumor complexity.

	Robotic & low NS (n=7)	Robotic & intermediate NS (n=5)	p Value
Hb 4 h postoperatively, mg/dl (SD)	14.1 (1.19)	13.4 (1.7)	0.873
Hb Change postoperatively - preoperative, mg/dl (SD)	-0.47 (0.38)	-0.76 (0.7)	0.926
	robotic & low NS (n=7)	**laparoscopic & low NS (n=12)**	
Hb 4 h postoperatively, mg/dl (SD)	14.1 (1.19)	12.9 (1.05)	0.217
Hb Change postoperatively - preoperative, mg/dl (SD)	-0.47 (0.38)	-1.38 (0.68)	0.074
	robotic & low NS (n=7)	**laparoscopic & intermediate NS (n=5)**	
Hb 4 h postoperatively, mg/dl (SD)	14.1 (1.19)	11.7 (0.79)	0.009
Hb Change postoperatively - preoperative, mg/dl (SD)	-0.47 (0.38)	-2.7 (1.34)	0.007
	robotic & intermediate NS (n=5)	**laparoscopic & low NS (n=12)**	
Hb 4 h postoperatively, mg/dl (SD)	13.4 (1.7)	12.9 (1.05)	0.976
Hb Change postoperatively - preoperative, mg/dl (SD)	-0.76 (0.7)	-1.38 (0.68)	0.463
	robotic & intermediate NS (n=5)	**laparoscopic & intermediate NS (n=5)**	
Hb 4 h postoperatively, mg/dl (SD)	13.4 (1.7)	11.7 (0.79)	0.158
Hb Change postoperatively - preoperative, mg/dl (SD)	-0.76 (0.7)	-2.7 (1.34)	0.08
	laparoscopic & low NS (n=12)	**laparoscopic & intermediate NS (n=5)**	
Hb 4 h postoperatively, mg/dl (SD)	12.9 (1.05)	11.7 (0.79)	0.292
Hb Change postoperatively - preoperative, mg/dl (SD)	-1.38 (0.68)	-2.7 (1.34)	0.531

SD: Standard Deviation; NS: Nephrometry Score; Hb: Hemoglobin; h: hours

Table 3: Subgroup analysis: Major complications in regard to the impact of the surgical procedure and tumor complexity.

	1 (*N*=8)	2 (*N*=5)	3 (*N*=12)	4 (*N*=5)	total	p Value
Clavien Dindo >2						**0.021**
Yes	0 (0%)	0 (0%)	1 (8%)	3 (60%)	4 (13%)	
No	8 (100%)	5 (100%)	11 (92%)	2 (40%)	26 (87%)	

1: Robotic and low complexity; 2: Robotic and intermediate complexity; 3: Laparoscopic and low complexity; 4: Laparoscopic and intermediate complexity

with previous prospective and retrospective studies and meta-analyses [2,3,10,11]. Furthermore, we registered no major difference in operating time or ischemia time. Previous studies have reported diverse data in regard to ischemia times; meta-analyses mention the superiority of robot-assisted partial nephrectomy [3,4,10-12]. However, large-scale prospective randomized studies will be needed to corroborate these data. In the meta-analyses published so far, heterogeneous factors such as surgical technique (transperitoneal or retroperitoneal access) have not been taken into account.

In the present investigation, however, we observed no significant difference in ischemia time. Therefore, the potential benefit of robot-assisted surgery in this regard is yet to be established. This is especially because the duration of ischemia is correlated with the restoration of renal function and an ischemia time in excess of 25 min is associated with a significant deterioration of GFR [13]. However, various studies, including randomized controlled trials and propensity-matched analysis, suggest that there is no difference in the long-term renal function outcomes between off-clamp and on-clamp techniques [14-16]. In the present investigation, the two groups had comparable levels of renal function preoperatively and during the entire hospital stay. However, six months postoperatively we noted a significant deterioration of creatinine levels in the LAPN group. The duration of ischemia cannot be regarded as the reason for the deterioration of renal function because the two groups did not differ significantly in this regard. One hypothesis for the deterioration in the LAPN group is that a smaller quantity of renal parenchyma was removed in the RAPN group. Previous investigations have shown that a significantly smaller volume of renal tissue is resected during robot-assisted PN [10,17], and this probably affects the preservation of renal function as strongly as the duration of ischemia [18,19].

Furthermore, we registered greater blood loss in the LAPN group, which is also reflected in the Hb levels measured 4 h postoperatively. Sims et al. discovered that greater blood loss reduces the secretion of AVP from the pituitary, which in turn has detrimental effects on mitochondrial function and renal function [20]. The occurrence of acute renal failure after pancreatic surgery was investigated in a retrospective study, and a significant association was noted between greater blood loss (>500 ml) and the development of postoperative renal failure [21]. In the long term, acute postoperative renal failure has a harmful effect on the recovery of renal function [22]. Thus, a further hypothesis to explain the difference in renal function between the two groups could be greater intraoperative blood loss in the LAPN group. Several studies have shown greater intraoperative blood loss in LAPN [23,24].

We were able to show, for the first time in a prospective setting, that neither of the surgical procedures was associated with a benefit in regard to postoperative pain. This is correlated with the results of a propensity-score matching analysis [25]. In the present study, the two groups required nearly equal quantities of analgesics, including opiates.

We registered no significant differences in terms of complication rate between the LAPN and RAPN group. However, our search of the published literature revealed diverse data in this regard. While

Supplementary Table 1: Patient characteristics of histology, complications and clamp technique.

	Robotic (N=13; 43%)	Laparoscopic (N=17; 57%)
Type of Histology		
ccRCC	9 (69%)	5 (29%)
RCC papillary	1 (8%)	6 (35%)
RCC chromophobe	0	2 (12%)
Oncocytoma	2 (15%)	2 (12%)
Renal cyst	1 (8%)	1 (6%)
Angiomiolipoma	0	1 (6%)
Clavien-Dindo complications		
0	12 (92%)	13 (76.5%)
1	0	0
2	1 (8%)	0
≥	0	4 (23.5%)
Type of postoperative complications		
Bleeding requiring surgery	0	2 (12%)
Bowel occlusion	0	1 (6%)
Venous thrombosis	1 (8%)	0
Ureteral injury	0	1 (6%)
Type of clamp technique		
Full-clamp	7 (54%)	8 (47%)
Off-clamp	6 (46%)	5 (29%)

ccRCC: Clear Cell Renal Cell Carcinoma; RCC: Renal Cell Carcinoma

the majority of retrospective studies and meta-analyses showed no difference in perioperative and postoperative complications [3,10,11,26,27], two large-scale trials and a level 2b meta-analysis did reveal significant differences [4,23,24]. Complications, especially severe complications, were less frequent after robot-assisted partial nephrectomy. A subgroup analysis of our data showed significant differences: More frequent severe complications were observed for moderate-complexity tumors operated on by the laparoscopic approach (Table 3). In addition, postoperative Hb levels differed significantly between patients who received laparoscopy for moderate-complexity tumors and those who received robot-assisted surgery for low-complexity tumors (Table 2). Three retrospective studies have compared LAPN and RAPN partial nephrectomy for moderate- and high-complexity tumors [28-30]. The results demonstrated the superiority of robotic surgery in regard to blood loss, operating time, risk of conversion to nephrectomy, and the preserved volume of renal parenchyma. Based on the findings of our subgroup analysis, further investigations are needed, particularly focusing on the comparison of laparoscopy *vs.* robotic surgery in more complex tumors.

The main limitation of the present study is its small sample size, which may have resulted in a potential bias in the subgroup analyses. Designed as a pilot study, its purpose was to obtain relevant data in a prospective randomized comparison. Currently, surgeons lack any clear published recommendation in favor of a specific procedure for partial nephrectomy because the studies published so far, largely retrospective in nature, have yielded similar results in regard to oncological safety and peri- as well as postoperative outcomes.

However, the results of a systematic review do correlate with our data: Advantages were noted for RAPN in regard to postoperative outcomes such as blood loss and renal function [31]. Further prospective randomized trials will be needed to confirm these conclusions and issue recommendations regarding a specific surgical procedure, considering tumor complexity if necessary.

A further limitation of the present study is the relatively short follow-up period of six months, which permits no statement about recurrence rates after the respective surgical procedures.

Conclusion

We observed no difference in the oncological outcomes of robotic and laparoscopic partial nephrectomy in regard to positive resection margins. In part, robotic partial nephrectomy was associated with significant advantages in terms of intraoperative blood loss and postoperative renal function. Further studies will be needed to confirm these data and issue explicit recommendations in favor of a specific surgical procedure for partial nephrectomy.

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