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Trifecta Outcomes to Assess Learning Curve of Robotic Partial Nephrectomy

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ABSTRACT

Background and Objectives: The learning curve for achieving desirable perioperative outcomes in robot-assisted partial nephrectomy (RAPN) has not been well studied. Information is available regarding "trifecta" outcomes of no complications, no positive margins, warm ischemia time (WIT) of ≤25 minutes, and a ≤15% decrease in postoperative glomerular filtration rate (GFR). This study was conducted to assess the impact of the learning curve on surgical outcomes in patients undergoing RAPN.

Methods: We reviewed 131 consecutive patients who underwent RAPN by a single, fellowship-trained surgeon from October 2007 through June 2015. Patients were divided into 4 subgroups, and mean perioperative values were compared. The learning curve was evaluated as the time it took the surgeon to attain a trifecta outcome.

Results: Means for the RENAL Nephrometry Score, procedure length, WIT, and estimated blood loss (EBL) were 5.3 ± 1.2, 172.1 ± 43.5 minutes, 22.7 ± 7.0 minutes, and 267.2 ± 341.8 mL, respectively. Significance was noted for differences in WIT (P = .50), postoperative creatinine (P = .006), postoperative estimated (e)GFR (P = .40), and percentage change in creatinine (P = .023). The learning curve for achieving positive outcomes was noted in >61–90 cases after 66–80 months of performing minimally invasive partial nephrectomy surgeries at a rate of 20 cases per year.

Conclusion: RAPN is a safe, feasible procedure with slightly better surgical outcomes than laparoscopic partial nephrectomy (LPN). In the hands of an experienced surgeon, the learning curve for achieving trifecta outcomes can involve a significant number of cases over several years.

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INTRODUCTION

Nephron-sparing surgery (NSS) has become the favored treatment method for patients with small renal tumors.[1] In the past, most surgeons would elect to perform a complete removal of the diseased kidney. However, with an increased understanding of the impact of kidney resection on renal function, NSS has become the gold standard. Specifically, the procedure has been shown to minimize the chances of developing postoperative renal insufficiency—a risk factor for increased morbidity and mortality.[2,3] Although NSS has clear benefits for the patient, it is a more challenging procedure for the surgeon because of its reconstructive nature and the increased risk of intraoperative bleeding and postoperative complications.[2,4]

In the past decade, use of laparoscopy has substantially increased, because its minimally invasive nature results in shorter hospitalizations and decreased perioperative blood losses. Specifically, laparoscopic partial nephrectomy (LPN) has been shown to offer advantages, such as shortened operative length, decreased blood loss, and increased postoperative renal function, when compared to open partial nephrectomy.[5] As an NSS, LPN is not without its challenges, and studies have shown it to be a difficult procedure with a lengthy learning curve.[6] Consequently, most surgeons require extensive repetition to achieve the type of perioperative outcomes that make laparoscopic technique favorable to open surgery. Therefore, robot-assisted technology was introduced in hopes of shortening the learning curve associated with laparoscopy. Advocates of robot-assisted surgery cite enhanced visualization, greater manual dexterity and flexibility, and tremor reduction as advantages that can help make any procedure less challenging.[7] Several studies have shown that surgeons can achieve better perioperative outcomes in kidney surgery when treating tumors with robot-assisted partial nephrectomy (RAPN), a technically easier procedure than LPN.[8,9]

The trifecta outcome is a novel concept introduced by Hung et al[10] that offers a strict definition of desirable surgical outcomes. According to the literature on radical prostatectomy, it has recently been adopted and assessed in several partial nephrectomy reports and is becoming the benchmark for stellar operative outcomes for NSS. There have been minor disparities in the way different reports define trifecta outcomes, but all studies rely on the following 3 criteria: negative surgical margins, minimal renal function decrease, and absence of complications in patients. Some studies have included warm ischemia time (WIT) in their definition of trifecta because of its inverse relationship with postoperative renal function. Thus, trifecta in most studies is defined as no complications, negative surgical margins, WIT of ≤25 minutes, and a ≤15% decrease in postoperative estimated glomerular filtration rate (eGFR).[11,12] There is only limited information on the learning curve associated with achieving desirable perioperative outcomes in RAPN, but there are no data on the length of time or the number of cases that it actually takes a surgeon to achieve trifecta outcomes.

In this study, we assessed the impact of the learning curve on perioperative outcomes in a consecutive series of patients who had undergone RAPN. In addition, we defined the number of cases a surgeon would have to perform to reach trifecta outcomes of no complications, negative surgical margins, WIT of ≤25 minutes, and a ≤15% postoperative eGFR decrease for RAPN.

METHODS

After obtaining institutional review board approval, we retrospectively reviewed data for 131 patients who underwent RAPN by a single surgeon at our institution from October 2007 through June 2015. The surgeon had completed a fellowship in robotics and laparoscopic surgery, and thus had prior experience in RAPN. The cases analyzed in the study were collected from the time the surgeon became an independent physician after completing the fellowship. All procedures were performed with the da Vinci Si Surgical System (Intuitive Surgical, Sunnyvale, California, USA) and were performed with a standard robotic technique.

All procedures were performed with a similar standardized surgical approach. After the colon was resected and the tumor located, the renal hilum was dissected to unveil the renal vasculature, and the exposed tumor was dissected and removed. Last, the cortex was coagulated with electrocautery to maintain hemostasis.

To measure the learning curve for RAPN, we adopted a protocol from studies describing the learning curve of robotic prostatectomy.[13,14] Each case was assigned a consecutive number. For each case, we recorded demographic, perioperative, pathological, and follow-up data. Operative time was defined as the time from first incision to completion of skin closure, excluding docking and undocking of the robot. WIT was defined as the time from initial vascular clamping until the removal of the final arterial clamp. Any complication from admission to first follow-up was included in the overall complication variable. Serum creatinine was recorded before and on the first day after RAPN. The RENAL Nephrometry Score is a tool used to grade renal tumors according to complexity before surgical decision making and to ensure that tumor complexity did not change with consecutive patients.[14] The learning-curve was defined as the number of cases it took to reach the trifecta outcomes of no complications, negative surgical margins, WIT of ≤25 minutes, and a ≤15% postoperative eGFR decrease for RAPN.

Renal function outcomes were calculated by using serum creatinine measurements to approximate the GFR. The eGFR was calculated by using the condensed Modification of Diet in Renal Disease (MDRD) equation.[15,16] The percentage changes in renal function were calculated with a standard equation for both serum creatinine and eGFR.

Continuous variables were reported as means with their respective standard deviation (SD), and categorical variables were reported as frequencies with their respective percentages. To assess the impact of the surgeon's experience on perioperative outcomes, we divided the cases into 4 subgroups of at least 30 consecutive cases. To compare these groups, we used the paired-sample *t* test. For all statistical analyses, results reaching $P \leq .05$ were considered statistically significant. All data were analyzed with the SAS v 9.4 software (SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

Clinical Parameters and RENAL Nephrometry Score

The clinical characteristics of all 131 patients are summarized in **Table 1**. The average age of the patients was 60 ± 12.7 years. The average tumor size was 3.7 ± 2.3 cm. Preoperative creatinine fell within healthy limits, with a value of 1.0 ± 0.3 mg/dL and correlated with a preoperative eGFR of 76.9 ± 21.9 mL/min/1.73 m^2. The average length of stay was 4.3 ± 4.7 days, with an average fol-

Table 1.
Clinical Characteristics of 131 Consecutive Patients

Variable	n*
Mean age	60.0 (SD = 12.7)
Gender	
Male	67 (51)
Female	64 (49)
Race	
Caucasian	64 (49)
Hispanic	10 (7)
African American	20 (15)
Asian	6 (5)
Unknown	31 (24)
Mean BMI	29.2 (SD = 6.9)
ASA classes 1/2	62 (51)
ASA classes 3/4	59 (49)
Mean tumor size (cm)	3.7 (SD = 2.3)
Mean preoperative creatinine (mg/dL)	1.0 (SD = 0.3)
Mean preoperative GFR [MDRD] (mL/min per 1.73 m^2)	76.9 (SD = 21.9)
Mean length of stay (days)	4.3 (SD = 4.7)
Mean time to follow-up (days)	39.1 (SD = 92.4)

Data are n (%), unless otherwise indicated. ASA classes, American Society of Anesthesiology Classification System.

low-up period of 39.1 ± 92.4 days. **Table 2** shows no significant difference in body mass index (BMI) or length of stay (LOS) between consecutive patients (*P* = .842 and = .610, respectively).

The RENAL Nephrometry Score information is summarized in **Table 3**. The average RENAL score for all patients was 5.3 ± 1.2. When broken down by case, the metric was 5.7 ± 1.1 for the first 30 cases, 5.2 ± 1.3 for the second 30 cases, 5.2 ± 1.0 for the next 30 cases, and 5.1 ± 1.4 for the final cases. There was no significant difference in interpatient nephrometry scores of the consecutive patients (*P* = .43).

Tumor Pathology

Tumor pathology data are summarized in **Table 3**. Of the 131 patients, 84 had pathology results confirming the presence of renal cell carcinoma (RCC); 47 had benign tumors consisting of 5 with angiomyolipoma, 11 with oncocytoma, 23 with benign cysts, and 8 with other diagnosis consisting of neuroendocrine tumors and adeno-

Table 2.
Correlation of Surgeon Experience with Perioperative Outcomes

Surgeon Experience Cases	BMI	Procedure Length (min)	WIT (min)	EBL (mL)	LOS	Overall Complications, n	Postoperative Creatinine (mg/dL)	Postoperative GFR [MDRD] (mL/min per 1.73 m^2)	Change in Creatinine (%)	% Change in GFR (mL/min)
1 to 30	28.2 (6.2)	187.3 (46.3)	25.3 (6.4)	276.8 (347.2)	4.2 (3.1)	3	2.2 (2.7)	59.0 (37.0)	121	−24
31 to 60	28.4 (7.5)	173.5 (38.2)	21.8 (6.3)	317.7 (336.3)	3.8 (3.5)	2	3.3 (4.2)	48.3 (31.5)	223	−26
61 to 90	29.7 (6.4)	173.8 (48.9)	19.2 (7.3)	314 (454.2)	3.8 (2.9)	0	1.2 (0.6)	70.5 (25.4)	27	−7
91+	29.7 (7.1)	162.4 (40.4)	22.6 (7.8)	199.2 (248.7)	5 (6.9)	0	1.4 (1.2)	66.7 (33.3)	48	−9
All Cases	29.2 (6.9)	172.1 (43.5)	22.7 (7.0)	267.2 (341.8)	4.2 (4.7)	5	2.0 (2.6)	61.5 (32.8)	101	−16
P	0.842	0.207	0.050	0.489	0.610	-	0.006	0.040	0.023	0.257

Data are means (SD), unless otherwise indicated.

Table 3.
Correlation of Surgeon Experience with Pathology Data

Surgeon Experience (n Cases)	RENAL Nephrometry Score*	Benign Tumor	RCC	pT1A	pT1B	>pT2A
1 to 30	5.7 (1.1)	13 (43)	17 (57)	10 (59)	4 (29)	3 (12)
31 to 60	5.2 (1.3)	11 (37)	19 (63)	14 (74)	1 (5)	4 (21)
61 to 90	5.2 (1.0)	7 (23)	23 (77)	14 (61)	5 (22)	4 (17)
91+	5.1 (1.4)	16 (400	25 (60)	16 (64)	3 (12)	6 (24)
All cases	5.3 (1.2)	47 (36)	84 (64)	54 (64)	13 (15)	17 (20)
P	0.430	0.723	0.398	0.663	0.298	0.339

Data are n (%), unless otherwise indicated. *Means (SD).

mas. Of the patients who presented with RCC, 67 (80%) had T1 tumors consisting of 54 with a T1a classification and 13 with a T1b classification. Seventeen patients (20%) had a T2a or greater classification. There was no significant difference for benign tumor status *(P* = .723), RCC status (*P* = .398), T1a classification (*P* = .663), T1b classification (*P* = .298), or T2a or greater classification (*P* = .339).

Operative Time

The operative time data are summarized in **Table 2**. Overall, the average operative time for all patients in the study was 171.1 ± 43.5 minutes. The operative time for cases 1–30, cases 31–60, cases 61–90, and cases 91+ were 187.3 ± 46.3, 173.5 ± 38.2, 173.8 ± 48.9, and 162.4 ± 40.4 minutes, respectively. The differences between the groups were not significant (*P* = .207).

WIT

The WIT is summarized in **Table 2**. The average WIT for all patients in the study was 22.7 ± 7.0 minutes. The time for cases 1–30, 31–60, 61–90, and 91+ were 25.3 ± 6.4, 21.8 ± 6.3, 19.2 ± 7.3, and 22.6 ± 7.8 minutes, respectively. The differences between the groups were significant (*P* = .05).

Outcomes and Complications

EBL was averaged for all patients in the study at a value of 267.2 ± 341.8 mL (**Table 2**). The first 30 cases had an average blood loss of 267.8 ± 347.2 mL followed by 317.7 ± 336.3 mL for the next 30 cases. Cases 61–90 had an average blood loss of 314 ± 454.2 mL followed by 199.2 ± 248.7 mL for the last cohort of consecutive patients. The differences between the groups were not significant (*P* = .489). Cases 1–30 had the highest frequency of perioperative complications (3 patients) followed by cases 31–60 (2 patients). No complications were noted for any patient in the remaining groups.

Renal Function

Postoperative creatinine was an average of 2.0 ± 2.6 mg/dL for all patients in the study. Specifically, cases 1–30 and 31–60 showed higher creatinine, with averages of 2.2 ± 2.7 mg/dL and 3.3 ± 4.2 mg/dL, respectively, when compared to the other cases. Cases 61–90 had an average postoperative creatinine of 1.4 ± 1.2 mg/dL, followed by 2.0 ± 2.6 mg/dL for all remaining cases, resulting in an eGFR of 59.0 ± 37, 48.3 ± 31.5, 70.5 ± 25.4, and 66.7 ± 33.3 ml/min/1.73 m^2 for each patient group, respectively. Both postoperative creatinine (*P* = .006) and postoperative GFR (*P* = .04) showed significant differences between group means. Furthermore, the percentage change in creatinine level was highest for cases 1–30 and cases 31–60 with percentages of 121% and 223%, respectively. The differences among groups for percentage change in creatinine were significant (*P* = .023).

Learning Curve

The surgeon in this study conducted roughly 20 robotic partial nephrectomies per year. It took >61–90 RAPN cases over the course of 66–80 months for the physician to reach trifecta outcomes of zero complications, negative surgical margins, WIT of ≤25 minutes, and a ≤15% decrease in postoperative eGFR.

DISCUSSION

Robot-assisted surgical technology can help the surgeon overcome the complexity of traditional nonrobotic laparoscopic surgery. Experienced surgeons performing RAPN can show instant proficiency after their first few cases without jeopardizing patient outcomes. However, similarly to LPN, RAPN is not without its own learning curve. In this study, the learning curve associated with achieving trifecta outcomes of zero complications, no negative margins, WIT of ≤25 minutes, and a ≤15% decrease in postoperative eGFR was within 61–90 cases over the course of 66–80 months.

The literature still lacks a universal definition of the learning curve for RAPN. Without a strict definition of a learning curve, it is difficult to evaluate a surgeon's initial experience with this technique. The ideal metric should encompass aspects of the surgeon's technical ability and the patient's postoperative health. WIT has been shown to be an important consideration in evaluating surgical outcomes of NSS. Most studies show WIT of ≤25 minutes is associated with better patient outcomes.[17,18] Likewise, postoperative GFR and perioperative complications can give insight into the health of a patient after renal surgery. Several studies have been published promoting the metric known as the trifecta outcome as a validated benchmark of assessing the surgeon's capacity in performing RAPN.[11,12,19] Thus, we believe the trifecta outcome is one way of overcoming the lack of a learning-curve definition, because it encompasses both the surgeon's ability and the patient's postoperative condition.

Our initial experience outcomes were similar to those published in the RAPN literature. In most of the RAPN initial experience studies, WIT is ≤30 minutes, and procedural length is ≤250 minutes.[17,20–23] In the 131 patients in this study, we report an average WIT of 22.7 ± 7.0 minutes and an average procedural length of 172.1 ± 43.5 minutes. Despite similar perioperative results, our mean tumor size of 3.7 ± 2.3 cm was greater than that of most patients reported in those studies (≤3 cm). Postoperative renal function has also been an important variable across RAPN outcome studies. Koon et al[24] found that their study population mean postoperative eGFR, when calculated with the MDRD equation, was 76.8 ml/min/1.73 m^2. In a similar study, Veeratterapillay et al[25] found the mean 1-day postoperative eGFR to be 80.8 ± 27 ml/min/1.73 m^2 with a percentage change of −12.2 ± 17 from the preoperative eGFR.[25] These studies showed slightly different results in regard to postoperative renal function. We found a mean 1-day postoperative eGFR of 61.5 ± 32.8 ml/min/1.73 m^2 with an average percentage change of −16%. We hypothesize that our lower postoperative eGFR was the result of larger mean tumor size. We believe that resecting more tumor mass inevitably causes a larger decrease in postoperative eGFR.

There are limited data on initial single-surgeon experience with NSS, and only a few studies stratify consecutive patients into groups and compare group means. In a study published by Gill et al[26] the learning curve of a single surgeon performing LPN was assessed. They divided patients into 3 groups of at least 275 patients each and found median WIT of 32 minutes in the first 2 groups before dropping to 14 minutes in the last group. On closer examination, they found that intergroup tumor complexity increased in the 3 groups. Thus, they were able to conclude that WIT decreased with surgeon experience, irrespective of increasing tumor complexity. Significance was cited for mean EBL, mean operative time, and mean WIT across the 3 groups. In another study, Hanzly et al[27] separated 116 consecutive LPN and 116 consecutive RAPN into 4 quartiles. They then compared these 4 quartiles across surgical technique and found a shorter learning curve in RAPN when compared with LPN. They based these results on the fact that RAPN had shorter OR times and WITs. It is no secret that robot-assisted surgery, although costly, is likely easier to adopt than laparoscopic surgery. Features such as enhanced 3D display and tremor reduction in robotic surgery allow physicians to obtain better operative outcomes in a shorter time when compared to the time required for laparoscopic surgery.

Only a few studies have assessed the learning curve of RAPN and provided an estimate of the number of cases needed to exceed the learning curve. Haseebuddin et al[28] separated patients into 2 groups: tumor size <2 cm and ≥2 cm. They defined the learning curve as the time it took for minimal variations in both operative time and WIT. Their reported learning curve for RAPN was 16 cases to reach minimal variation in operative length and 26 cases to reach minimal variation in WIT. In addition, in the study most similar to our current one, Mottrie et al[29] defined the learning curve for RAPN as the time it took a surgeon to reach mean WIT <20 minutes and console time <100 minutes. They found the learning curve to be >30–40 cases. Unlike our study, which shows significance between groups for WIT, postoperative creatinine, postoperative eGFR, and percentage change in creatinine, significance was cited in Mottrie et al for WIT, console time, and percentage of pelvicaliceal repair between consecutive case groupings. Both of these studies have shorter RAPN learning curves than that in our present study, which showed the learning curve to be 61–90 cases or more. A possible reason for the different results has to do with the way we centered the learning curve on the strict, yet validated, trifecta outcome.

The previous studies have several limitations. In Haseebuddin et al,[28] there was no clear definition of the learning curve; instead, they relied on a weak "minimal variation" parameter. Most surgeons will note a decrease in outcome variation with increased surgical volume, but this does not necessarily indicate mastery of the technique. The study by Mottrie et al[29] has been scrutinized for selection bias and its weak constraints for a learning-curve definition. Editorial comments from Nadu[30] cited the failure of Mottrie to include complication rates in their learning-curve definition as a significant limitation in their study. Furthermore, Nadu warned of the possibility that researchers had selected patients with favorable outcomes. Both studies fail to include a metric to assess the complexity of each case, and that could be a major confounder, as case complexity may decrease with consecutive cases, and the later cases are likely to have better perioperative outcomes. Thus, it is difficult to conclude whether better outcomes were a result of improved surgical ability or decreased case complexity. Our study addresses and accounts for all the aforementioned limitations. To start, we have a clear definition of the learning curve that has been cited in the literature as a desirable goal for all surgeons performing RAPN. In addition, we have stratified our groups by the RENAL Nephrometry Score, to assess whether there were any significant changes in case complexity over consecutive cases. In this study, the RENAL Nephrometry Score was ~5 for all groups ($P = .43$). Thus, case complexity did not skew our results.

Our study is not without limitations. We recognize the limitations associated with a retrospective design. There is also a limitation in the calculation of the RENAL Nephrometry Score. All patients in the study had computed tomographic images, but the same radiologist did not review all of the scans. In addition, ours was a single-center, single-surgeon study. The individual nature of the results can limit its universality and applicability to real-world clinical practice. The findings are not to be used as a strict definition of the learning curve associated with RAPN. Instead, the findings suggest that RAPN requires a substantial learning curve over several years to gain proficiency.

CONCLUSION

RAPN is a safe, effective treatment modality for small renal masses. It has been shown that it offers surgical outcomes that are better than LPN and is a technically easier procedure to master. In our study, we defined the number of cases that is needed for a kidney surgeon to become proficient in performing RAPN and attain trifecta outcomes. We found that the goal can be reached after >61–90 cases at a rate of 20 cases per year.

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