Original Article

Perioperative and functional outcomes following robot-assisted partial nephrectomy: Descriptive analysis of Indian study group on partial nephrectomy database

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ABSTRACT

Introduction: There is an unmet need for high-quality data for Robot-assisted partial nephrectomy (RAPN) in the Indian population. Indian study group on partial nephrectomy (ISGPN) is a consortium of Indian centers contributing to the partial nephrectomy (PN) database. The current study is a descriptive analysis of perioperative and functional outcomes following RAPN.

Methods: For this study, the retrospective ISGPN database was reviewed, which included patients who underwent RAPN for renal masses at 14 centers across India from September 2010 to September 2022. Demographic, clinical, radiological, perioperative, and functional data were collected and analyzed. Ethics approval was obtained from each of the participating centers.

Results: In this study, 782 patients were included, and 69.7% were male. The median age was 53 years (interquartile range [IQR 44–62]), median operative time was 180 min (IQR 133–240), median estimated blood loss was 100 mL (IQR 50–200), mean warm ischemia time was 22.7 min and positive surgical margin rates were 2.5%. The complication rate was 16.2%, and most of them were of minor grade. Trifecta and pentafecta outcomes were attained in 61.4% and 60% of patients, respectively.

Conclusions: This is the largest Indian multi-centric study using the Indian Robotic PN Collaborative database to evaluate the outcomes of robot-assisted PN, and has proven its safety and efficacy in the management of renal masses.

Access this article online	
Quick Response Code:	Website: www.indianjurol.com
	DOI: 10.4103/iju.iju_443_23

Received: 13.11.2023, **Revised:** 16.02.2024,

Accepted: 03.03.2024, **Published:** 01.04.2024

Financial support and sponsorship: This work was supported by grants from Intuitive Surgical, California, US.

Conflicts of interest: Akhil Dahiya is an Intuitive Surgical, California, US employee. The other authors declare that the research was conducted without commercial or financial relationships that could be construed as a potential conflict of interest.

INTRODUCTION

The growing body of evidence suggests that partial nephrectomy (PN) is the standard treatment option for small renal masses.[1] The European Association of Urology recommends PN for localized T1 tumors as a standard treatment option.[2] Postoperatively, renal functions in these patients are preserved significantly better with PN than with radical nephrectomy (RN). Furthermore, cardiovascular morbidity and mortality risk are significantly lower after PN.[3,4] Moreover, the survival outcomes are comparable between the two approaches.[5-7] For localized T2 renal masses, PN is used more selectively wherever it is technically feasible.[2] However, the level of evidence is weak (3b) for the equivalence of oncological outcomes following PN versus RN in patients with T2 tumors.[2]

While PN can be done through an open or minimally invasive laparoscopic approach, robot-assisted PN (RAPN) has seen rapid adoption globally.[2,8,9] Although the choice of procedure in the real-world environment depends on the complexity of the tumor, comorbidities, and surgeon's experience, RAPN has shown consistent perioperative and oncological outcomes in managing localized renal tumors, irrespective of tumor complexity.[10,11] Complex renal masses, as determined by their size and location (endophytic, hilar, or cystic), have been safely and effectively managed by RAPN.[12]

With the improving adoption of RAPN in India, there have been some small-scale single-center and multicentric studies from India reporting perioperative outcomes following RAPN in patients with renal masses.[13] Largely, there is a need for robust and high-quality data for RAPN in our population. With this aim, the Indian study group on PN registry was conceived for patients with renal masses who underwent RAPN. The current study was designed to report perioperative and functional outcomes following RAPN. To our knowledge, this is the largest multicentric study from India assessing perioperative and functional outcomes following RAPN.

MATERIALS AND METHODS

A retrospective multicentric chart review was undertaken for patients who underwent RAPN utilizing the Da Vinci Surgical System Si, X, or Xi (Intuitive Surgical, Sunnyvale, CA, USA) between September 2010 and September 2022 across 14 centers in India. All patients above the age of 18 years who underwent RAPN for renal masses were included in this study. Patients were excluded if they had more than two masses requiring multiple PN on the same kidney, had a solitary or horseshoe kidney, or were scheduled for bilateral PN simultaneously. Patients were excluded if they had prior surgery at the affected kidney the previous year, except for endoscopic kidney stone surgery. Patients were also excluded from the analysis if they had missing data, especially on baseline variables such as age, tumor size, or tumor complexity. The study was conducted per the ethical principles specified in the most recent edition of the Helsinki Declaration and the applicable guidelines for good clinical practice. Each participating center obtained ethics committee permission, and the study was registered at the Clinical Trials Registry of India portal under registration number CTRI/2022/04/041924.

Demographic data, medical history, clinical characteristics, perioperative, functional, and oncological outcomes were collected from the patient's medical records.

- The following perioperative outcomes were collected from admission to discharge: Operating room (OR) time, estimated blood loss (EBL), warm ischemia time (WIT), length of hospital stay, hemoglobin (g/L), hematocrit (%), creatinine (mg/dL), estimated glomerular filtration rate (eGFR) (mL/min), intraoperative and postoperative complications, location of tumor, malignancy status, resection margins, pathological stage, and tumor size (mm)
- Chronic kidney disease (CKD) was defined as eGFR as estimated using a modification of diet in renal diseases (MDRD) equation <60 mL/min. For follow-up, eGFR was calculated using the MDRD equation, and no functional imaging was used to evaluate residual function
- Clavien–Dindo classification was used to grade complications[14]
- Trifecta was defined as WIT (<25 min) + negative surgical margin + no complication[15]
- Pentafecta: Trifecta + >90% preservation of eGFR and no stage upgrade of CKD at 12 months postoperatively[15]
- Acute kidney injury (AKI) was defined as a fall in eGFR ≥25% of the baseline.[16]

Continuous variables were expressed as mean with standard deviation or median with interquartile range wherever deemed appropriate. Categorical or nominal data were expressed as frequencies or percentages. The statistical analysis involved the utilization of the Student's *t*-test for independent samples to compare the mean of two groups. The comparison of categorical data was conducted using either the Chi-square or Fisher's exact tests, depending on which was deemed suitable for the analysis. Statistical analysis was performed using Stata IC 13.1 (Stata Corp LLC, Texas, USA).

RESULTS

Baseline characteristics of participants

Clinical data of patients who underwent RAPN were collected from participating centers during the specified time interval. In this study, 782 patients had complete

demographic, perioperative and pathological data and were included in the analysis. In this cohort ($n = 782$), the median age of patients was 53 years, and 69.7% were males. Tumor complexity, as defined by the renal nephrometry score, was deemed low, intermediate, and high in 45%, 40.7%, and 14.1% of the patients. A complete set of baseline patient and tumor characteristics are represented in Table 1.

The median operative time in the cohort was 180 min, and the median EBL was 100 mL. The mean WIT was 22.7 min, where 509 (65.1%) patients had a WIT of <25 min. Conversion to open surgery was required only in 3 (0.4%) patients. Of 782 patients, 127 (16.2%) had complications. Most of the patients had minor complications and only 20 patients had grade III complications. Blood transfusion was needed in 16 (2%) of the patients. At the same time, none of the patients experienced a Clavien–Dindo grade IV or V complication in the postoperative period. Positive surgical margin rates were 5.1%. Histopathology reports found malignant tumors in 736 (94.1) cases, and the mean tumor size was 38 mm, where approximately 298 (38.1%) of tumors had a size of 4 or more than 4 cm (T1b or T2 tumors). The perioperative outcomes are shown in Table 2. A subgroup analysis assessed various significant factors between patients having WIT ≤25 min and >25 min [Table 3]. Patients having the absence of CKD, low renal score, and malignant tumors on final histopathology were associated with ≤25 min WIT. Another subgroup analysis based on the renal score was performed. In it, a higher operative time and a higher WIT were significantly associated with a high renal score [Table 4].

Functional outcomes

Mean creatinine and eGFR at baseline were 0.93 mg/dL and 92.1 mL/min, respectively. In the immediate postoperative period (before discharge), the mean serum creatinine and eGFR were 1.04 mg/dL and 82.85 mL/min, respectively. At 90 days postsurgery, these values were 0.96 mg/dL and 89.49 mL/min, respectively. However, only 224 patient's data were available for the 90-day assessment. The postoperative creatinine and eGFR at 1 year of follow-up were 0.97 mg/dL and 90.4 mL/min, respectively (for 458 of 782 patients). AKI immediate postoperatively was seen in 169 (21.6%) patients. Trifecta outcomes were attained in 480 (61.4%) of the patients. Pentafecta outcomes were attained in 275/458 (60%) patients.

DISCUSSION

PN is the mainstay treatment for small renal masses but it has rapidly expanded the spectrum to large and more complex tumors.[1] Assessing the best approach for PN is mostly determined by completely removing the tumor, minimizing complications, and preserving renal function.[17] RAPN has several advantages, including a smaller incision, greater range of motion, and better vision, which can reduce

Table 1: Preoperative characteristics of patients included in the Indian Study Group on Partial Nephrectomy database

Variables	*n*=782, *n* (%)
Age (year), median±IQR	53±18
Sex, *n* (%)	
Male	545 (69.7)
Female	237 (30.3)
Weight (kg), mean±SD	73.22±13.61
Comorbidities, *n* (%)	
Hypertension	343 (43.9)
Diabetes	180 (23)
Chronic kidney disease	209 (26)
Others	56 (7.1)
Previous abdominal surgery (in the past 1 year), *n* (%)	8 (1)
Side, *n* (%)	
Left	391 (50)
Right	391 (50)
Tumor location, *n* (%)	
Anterior	306 (39.1)
Posterior	323 (41.3)
Hilar	31 (4)
Other	122 (15.6)
Hemoglobin (g/dL), mean±SD	13.20±1.81
Creatinine (mg/dL), mean±SD	0.92±0.42
eGFR (mL/min), mean±SD	93.11±28.92
RNS, *n* (%)	
Low	352 (45)
Intermediate	319 (40.7)
High	111 (14.1)
ASA classification, *n* (%)	
ASA I	219 (28)
ASA II	273 (34.9)
ASA III	121 (15.5)
ASA IV	2 (0.3)

eGFR=Estimated glomerular filtration rate, ASA=American Society of Anesthesiologist, IQR=Interquartile range, SD=Standard deviation, RNS=RENAL nephrometery score

Table 2: Perioperative outcomes of the Indian Study Group on Partial Nephrectomy database

Variables	*n*=782, *n* (%)
Operating room time (min), median (IQR)	180 (133–240)
Length of hospital stay (days), mean±SD	6.85±4.14
EBL (mL), median (IQR)	100 (50–200)
WIT (min), mean±SD	22.7±8.5
<25	467 (59.7)
>25	315 (40.3)
Postoperative complications (up to 90 days)	127 (16.2)
Grade 1	80 (62.9)
Grade 2	29 (22.8)
Grade 3a	13 (10.2)
Grade 3b	8 (6.2)
Grade 4/5	0
Creatinine (mg/dL), mean±SD (immediate postoperative period)	1.04±0.44
eGFR (mL/min), mean±SD (immediate postoperative period)	82.85±28.06
Conversion to open nephrectomy, *n* (%)	3 (0.4)
Malignant tumor on biopsy, *n* (%)	736 (94.1)
Pathological tumor size (mm), mean±SD	38.7±14.8
≤40	484 (61.9)
>40	298 (38.1)
Positive surgical margin (%)	40 (5.1)

IQR=Interquartile range, SD=Standard deviation, eGFR=Estimated glomerular filtration rate, EBL=Estimated blood loss, WIT=Warm ischemia time

Table 3: Subgroup analysis of various variables according to warm ischemia time included in this study

Variables	WIT ≤25 min (*n*=573)	WIT >25 min (*n*=209)	*P*
Age (year), mean±SD	53±13	52±13	0.281
Sex, *n* (%)			
Male	351 (61.2)	194 (92.8)	0.542
Female	222 (38.8)	15 (7.2)	
Weight (kg), mean±SD	72.7±13.6	72.4±13.4	0.784
Comorbidities, *n* (%)			
Hypertension	227 (39.6)	116 (55.5)	0.571
Diabetes	109 (19)	71 (33.9)	0.146
Chronic kidney disease	117 (20.4)	92 (44)	0.001
Hemoglobin (g/dL), mean±SD	13.1±1.8	13.2±1.7	0.670
Creatinine (mg/dL), mean±SD	0.91±0.42	0.93±0.41	0.495
eGFR (mL/min), mean±SD	93.40±28.21	92.5±30.24	0.705
RNS, *n* (%)			<0.001
Low	285 (49.7)	67 (32)	
Intermediate	174 (30.3)	145 (69.3)	
High	50 (8.7)	61 (29.1)	
Creatinine (mg/dL), mean±SD (immediate postoperative period)	1.04±0.49	1.04±0.32	0.918
eGFR (mL/min), mean±SD (immediate postoperative period)	83.25±27.16	82.10±29.71	0.567
Malignant tumor on biopsy, *n* (%)	472 (82.3)	201 (96.1)	0.047
Pathological tumor size (mm), mean±SD	37.31±14.78	41.53±14.55	<0.001
Positive surgical margin (%)	22 (3.8)	18 (8.6)	0.169

IQR=Interquartile range, SD=Standard deviation, eGFR=Estimated glomerular filtration rate, WIT=Warm ischemia time, RNS=RENAL nephrometery score

Table 4: Subgroup analysis comparing RENAL nephrometry score with various factors of the Indian Study Group on Partial Nephrectomy database

Variables	Low nephrometry score (*n*=352)	Intermediate nephrometry score (*n*=319)	High nephrometry score (*n*=111)	*P*
WIT (min), *n* (%)				
≤25	285 (80.9)	174 (54.5)	50 (45)	<0.001
>25	67 (19)	145 (45.4)	61 (54.9)	
Operative time (min)	186.6±72.1	202.3±84.7	216.4±94.1	<0.001
Intraoperative adverse events, *n* (%)	11 (3.1)	9 (2.8)	4 (3.6)	0.916
Conversion to RN, *n* (%)	2 (0.6)	1 (0.3)	0	0.676
Development of AKI, *n* (%)	70 (19.8)	77 (24.1)	22 (20.7)	0.362
Postoperative complications, *n* (%)	55 (15.6)	50 (15.6)	22 (19.8)	0.544

RN=Radical nephrectomy, WIT=Warm ischemia time, AKI=Acute kidney injury

the risk of damage to adjacent organs and postoperative complications.[12] A study by Garg *et al*. compared various tumor-related characteristics and outcomes following open, laparoscopic and robotic partial nephrectomies in 141 patients in a high-volume Indian center. They found the RAPN group to have lesser blood loss and lesser hospital stay as compared to the open approach.[18] In the past 10 years, multiple meta-analyses have reported the advantages of robotic-assisted surgery over other techniques in managing small renal masses.[19] A 2023 meta-analysis included comparative randomized and nonrandomized studies of open and robotic PN for highly complex renal masses.[20] This analysis reported better results for the robotic group regarding hospital stay, overall complications, and blood transfusion rate for the robotic arm. The authors reported no difference in positive surgical margin rates, ischemia time, and short-term kidney functions.[20] However, most clinical studies included in the above-cited meta-analyses, and other sources of clinical literature do not include clinical evidence for RAPN that originated from India.

Unlike the West, in India, there is no National or Commercial Databases of clinical outcomes for surgical procedures. To date, there has been only a single large-scale multicentric study from India that has evaluated RAPN outcomes, which included patients from just five centers.[13] Furthermore, that multicentric study was sliced out of a larger multinational database. The present collaborative effort aims to fill this gap in the literature and create a representative database of clinical outcomes for RAPN. The present study is the largest collaborative, multi-institutional study for any surgical procedure from India. Data for this study were collected from 14 public and private tertiary care institutes across India. The perioperative outcomes, i.e., WIT, complication rates, trifecta, and pentafecta outcomes, are comparable to published literature.[13] In the present study, we noted mean operating and WIT to be 180 min and 22.7 min. Overall complications and major complications rates were 16.2% and 2.5%, respectively. Positive surgical margins were noted in 5.1% of the patients. Trifecta and pentafecta outcomes were achieved in 61.4% and 60% of the patients.

The first multicentric analysis from India for RAPN was published in 2022 by Sharma *et al*.[13] The authors analyzed perioperative outcomes of 614 Indian RAPN cases from the Vattikuti collective quality initiative (VCQI) database. The baseline characteristics of patients in this analysis were comparable to our study in terms of mean age, male predominance, tumor size, tumor complexity, polarity, and baseline renal functions. Most of the perioperative outcomes were comparable in both these studies. We report a mean WIT of 22.73 min and a mean OR time of 180 min. The VCQI analysis reported a mean WIT of 23.0 min. The conversion rates and complication rates were also similar between the two datasets. In our study, the complication rate was 16.2%, most of which were low grade as per the Clavein–Dindo classification. The conversion rate to open surgery was just 0.4%. There was a difference in positive surgical margin rates, 5.1% in our study versus 10.3% in the VCQI database. One possible reason could be the inclusion of more robotic centers in the present study, which reflected the true outcome and diluted any surgeon-related or learning curve-related bias. The oncological outcomes could not be compared. Other than the VCQI database study, there are few single-centric retrospective studies, but the sample size in these studies is too small to compare outcomes with our study.[21-23] Regarding trifecta and pentafecta outcomes, Abdel Raheem *et al*. studied outcomes of RAPN in patients with PADUA scores >10 and reported trifecta achievement in 61% of patients.[24] They observed that in the patients with negative trifecta outcomes, the tumor size, operative time, and EBL were higher. Perioperative outcomes such as complications, blood loss, and margin-positive rates reported in the present study compare well to those reported in a systematic review and pooled analysis of perioperative outcomes following RAPN for moderate to complex renal masses.[1]

The transatlantic robotic nephron-sparing surgery study group's (TRoNeS) analysis of prospectively collected data from 635 RAPN cases matches our effort.[25] The mean patient age was 60.7 years, older than our study, and the mean preoperative tumor size was 33 mm, which is smaller than our mean size of 38 mm. This group reported a mean operative time of 156.3 min, a mean blood loss of 171 mL and a positive surgical margin rate of 3.8%.[25] We report a slightly longer operative time and a margin positivity of 5.1%. We attribute this difference to the fact that data for the TRoNeS study were collected from 3 high volume centers (vs. 14 in our study).

Limitations

The study incorporates the inherent limitations of a retrospective study. Homogenizing surgical techniques and treatment protocols in a multicentric setting are often impossible. Plus, the study has low-volume and high-volume RAPN tertiary care centers, and the learning curve of participating surgeons was not considered. There was short and irregular follow-up of patients across various centers, making it difficult to uniformly assess the functional and oncologic outcomes. Follow-up data might be prone to bias, as a majority of patients lack data for the same (at 3 months 224 patients and at 1 year 458 patients had follow-up functional data. There is a lack of data on complications (apart from Clavien–Dindo scoring) and reasons for conversion in the database. The techniques of renorrhaphy and enucleation were not homogeneous, and the detailed data on them were missing. The data on adjuncts for tumor identification, such as intraoperative ultrasound, indocyanine green, and frozen section, were missing.

CONCLUSIONS

With this collaborative effort, we have tried to create a database of clinical outcomes for RAPN in Indian patients. This collaboration has validated the value of robot-assisted surgeries for localized renal masses in Indian settings. Further studies from this registry are going to provide important data on our population.

Acknowledgments

The authors would like to thank Catalyst Clinical Services Pvt., Ltd., for their contribution regarding the conduct of the study, medical writing, and submission assistance.

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How to cite this article: Rawal S, Ganpule A, Singh G, Shrivastava N, Kishore TA, Dubey D, *et al*. Perioperative and functional outcomes following robot-assisted partial nephrectomy: Descriptive analysis of Indian study group on partial nephrectomy database. Indian J Urol 2024;40:121-6.