Original Article

Trifecta and pentafecta outcomes following robot-assisted partial nephrectomy in a multi-institutional cohort of Indian patients

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ABSTRACT

Introduction: The literature on studies reporting trifecta or pentafecta outcomes following robot-assisted partial nephrectomy (RAPN) in Indian patients is limited. The primary aim of this study was to report and evaluate the factors predicting trifecta and pentafecta outcomes following RAPN in Indian patients using the multicentric Vattikuti collective quality initiative (VCQI) database.

Methods: From the VCQI database for patients who underwent RAPN, data for Indian patients were extracted and analyzed for factors predicting the achievement of trifecta and pentafecta following RAPN. Trifecta was defined as the absence of complications, negative surgical margins, and warm ischemia period shorter than 25 min or zero ischemia. Pentafecta covers all the trifecta criteria as well as >90% preservation of estimated glomerular filtration rate (eGFR) and no stage upgrade of chronic kidney disease at 12 months.

Results: In this study, among 614 patients, the trifecta was achieved in 374 patients (60.9%) and pentafecta was achieved in 24.2% of the patients. Patients who achieved trifecta had significantly higher mean age (54.1 vs. 51.0 years, $P = 0.005$), body mass index (BMI) (26.7 vs. 26.03 kg/m^2, $P = 0.022$), and smaller tumor size (38.6 vs. 41.4 mm, $P = 0.028$). The preoperative eGFR (84.2 vs. 91.9 ml/min, $P = 0.012$) and renal nephrometry score (RNS) (6.96 vs. 7.87, $P \leq 0.0001$) were significantly lower in the trifecta group. Comparing patients who achieved pentafecta to those who did not, we noted a statistically significant difference between the two groups for tumor size (36.1 vs. 41.5 mm, $P = 0.017$) and RNS (6.6 vs. 7.7, $P = 0.0001$). On multivariate analysis, BMI and RNS were associated with trifecta outcomes. Similarly, only RNS was identified as an independent predictor of pentafecta.

Conclusions: RNS and BMI were independent predictors of the trifecta. At the same time, RNS was identified as an independent predictor of pentafecta following RAPN.

INTRODUCTION

Partial nephrectomy (PN) has become a standard treatment option for the management of small renal masses (SRM).[1,2] While a PN may be performed by an open or minimally invasive approach, robotic-assisted PN (RAPN) has gained popularity in recent times. To gauge various surgical modalities' efficacy and standardize reporting

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outcomes following PN, the achievement of trifecta has been proposed as a quality parameter.[3] Trifecta includes various factors assessing the adequacy of surgical resection (margin status), renal function preservation (warm ischemia time or estimated glomerular filtration rate [eGFR]), and safety of the procedure (complications).[3] Various definitions of trifecta have been proposed over a period of time, however, the basic premise remains the same.[4-7] Recently, pentafecta criteria were defined as the ultimate goal of RAPN, by adding long-term maintenance of preoperative renal function and absence of recurrence to the previously described trifecta parameters.[8]

Numerous studies have been published in the past two decades for identifying predictors of trifecta or pentafecta outcomes employing different surgical modalities and patient populations. However, data for the Indian patients are limited. Racial differences in renal cell carcinoma are well known.[9] However, outcomes in our population (clinically and pathologically) are not well defined. Differences in stage and grade of tumor for other cancers such as prostate are well known in our population.[10] Morphological and body habitus features of Indians are different from other races, which can impact surgical outcomes. For example, quality and thickness of perinephric fat can impact perioperative outcomes following RAPN. There is an lacuna in data available on trifecta and pentafecta outcomes in the Indian cohort of patients undergoing RAPN for renal masses. Hence, we aimed to determine trifecta and pentafecta using multi-institutional data of Indian patients who underwent RAPN from the Vattikuti collective quality initiative (VCQI) database. We also aimed to identify the factors predicting the achievement of trifecta and pentafecta outcomes using the same dataset. To the best of our knowledge, this is the first multicentric and largest study reporting results following RAPN on Indian patients.

MATERIALS AND METHODS

VCQI is a prospective multinational collaborative database for various robotic surgical procedures maintained by Vattikuti foundation [Supplementary File].[5,11-13] The data for patients who underwent RAPN at Indian centers was extracted for this study. Between October 2014 and March 2020, data for 3,801 patients who underwent RAPN was contributed to the database by all the VCQI participating centers. Of these 3,801 patients, 614 patients were operated at five Indian centers. All patients who had completed their 12-month follow-up were included in this study. The database allows follow-up creatinine, eGFR, and disease status to be entered at any time after surgery. For patients whose data were not available from the database, the database manager and participating centers were contacted for gathering the data. Patients with incomplete datasets were not included in the study. Data on demographic, operative, postoperative, and pathological variables were collected for each patient [Table 1].

Table 1: Descriptive analysis of the patients included in this study

Variables	*n*=614, *n* (%)
Age (median with range) years	54 (22–85)
Sex	
Male	422 (68.7)
Female	192 (31.3)
BMI (kg/m^2), mean±SD	26.4±4.1
Tumor size (mm), median (range)	40 (12–120)
Clinical symptoms	
Asymptomatic	473 (77)
Local	137 (22.3)
Systemic	4 (0.7)
Single kidney	25 (4.1)
Bilateral tumor	19 (3.1)
Tumor side	
Right	301 (49)
Left	313 (51)
Face of tumor	
Anterior	327 (53.3)
Posterior	213 (34.7)
Polar location of tumor	
Upper	229 (37.3)
Mid	201 (32.7)
Lower	184 (30)
RNS	7 (4–12)
Complexity stratification	
Low	226 (36.8)
Intermediate	286 (46.6)
High	102 (16.6)
Preoperative hemoglobin (g/dL), mean±SD	13.1±1.8
Preoperative creatinine (mg/dL), mean±SD	0.94±0.31
Preoperative eGFR (mL/min), mean±SD	87.8±30.7
Surgical access	
Transperitoneal	612 (99.7)
Retroperitoneal	2 (0.3)
Operative time (min), median (range)	
Missing (*n*=274)	180 (5–510)
WIT (min), mean±SD	23.0±9.1
Blood transfusion	18 (2.9)
Intraoperative complication	22 (3.6)
Conversion to open	0
Conversion to radical nephrectomy	1 (0.2)
Complications	97 (15.8)
Grade 1	64 (10.4)
Grade 2	19 (3.1)
Grade 3	13 (2.1)
Grade 4	1 (0.2)
At discharge, mean±SD	
Hemoglobin (g/dL)	11.8±1.6
Creatinine (mg/dL)	1.9±0.3
eGFR (mL/min)	78.4±29
Hospital stay (days) median (range)	4 (1–23)
Trifecta	374 (60.9)
Pentafecta (*n*=235)	57 (24.3)
CKD upgradation	58 (24.6)

SD=Standard deviation, BMI=Body mass index, WIT=Warm ischemia Time, eGFR=Estimated glomerular filtration rate, CKD=Chronic kidney disease, RNS=Renal nephrometry score

Preoperative eGFR was calculated using the modified diet in the renal disease equation. Complications were graded as per the Clavien–Dindo classification.[14] The absence of complications (up to 1 month postoperatively), negative surgical margins, and warm ischemia period shorter than 25 min or zero ischemia[15] constituted the trifecta. Pentafecta was a long-term postoperative outcome evaluation that

covered all the trifecta criteria as well as >90% preservation of eGFR and no stage upgrade of chronic kidney disease at 12 months postoperatively.[16]

Statistical analysis

We used the Kolmogorov–Smirnov and Shapiro normality tests to determine the normality of continuous data. On an independent sample, if the data were normally distributed, the Student's *t*-test was employed. For non-normally distributed variables, the Kruskal–Wallis test was utilized. Either the Chi-square test or Fisher's exact test was employed to analyze categorical variables. For the trifecta and pentafecta-attaining groups, multivariate regression analysis was done to identify predictors. All statistical tests were two-sided and performed with a significance level of $P < 0.05$. SPSS version 23 (IBM corporation, New York, USA) and Stata (version 16; StataCorp, College Station, TX, USA) were used for all statistical analyses.

RESULTS

Among the 614 patients included in this study, trifecta was achieved in 374 patients (60.9%). Among the 235 patients with follow-up eGFR available at 12 months following RAPN, pentafecta was achieved in 57 patients (24.2%). The median age and clinical tumor size of the patients were 54 years and 40 mm, respectively. Most patients were male (68.7%) and the mean body mass index (BMI) was 26.4 kg/m^2. Only 22.3% and 0.7% of the included patients had local or systemic symptoms respectively at presentation. The median renal nephrometry score (RNS) was 7 with most of the patients being in the low (36.8%) to intermediate (46.6%) category for tumor complexity. Descriptive analysis for rest of the baseline characteristics is provided in Table 1.

Patients who achieved trifecta were older (54.1 vs. 51.0 years, $P = 0.005$), had higher BMI (26.7 vs. 26.03 kg/m^2, $P = 0.022$), a smaller tumor size (38.6 vs. 41.4 mm, $P = 0.028$), and were largely asymptomatic at the time of clinical presentation (82.8% vs. 67.9%, $P \leq 0.001$). The preoperative eGFR was significantly lower in the trifecta group (84.2 vs. 91.9 ml/min, $P = 0.012$). RNS was also lower in the group achieving trifecta (6.96 vs. 7.87, $P \leq 0.0001$). There was no significant difference between the two groups in terms of gender, laterality, solitary units, tumor site, preoperative parameters (hemoglobin and creatinine), and surgical access [Table 2].

Table 2: Baseline comparison of patients achieving to those not achieving trifecta outcomes in the present study

Variables	Trifecta		
	Yes (*n*=374), *n* (%)	No (*n*=240), *n* (%)	*P*
Age (years), mean±SD	54.13±13.41	51.04±12.95	0.005
Sex			
Male	264	158	0.215
Female	110	82	
BMI (kg/m^2), mean±SD	26.78±4.31	26.03±3.66	0.022
Tumor size (mm), mean±SD	38.67±14.96	41.46±15.57	0.028
Clinical symptoms			
Asymptomatic	310 (82.8)	163 (67.9)	0.000
Local	61 (16.3)	76 (31.6)	
Systemic	3 (0.8)	1 (0.4)	
Single kidney	18 (4.8)	7 (2.9)	0.246
Bilateral tumor	14 (3.7)	5 (2.0)	0.246
Tumor side			
Right	175 (46.8)	126 (52.5)	0.167
Left	199 (53.2)	114 (47.5)	
Face of tumor			
Anterior	216 (57.7)	111.(46.2)	0.281
Posteriorj	131 (35.0)	82 (34.1)	
Polar location of tumor			
Upper	142 (37.9)	87 (36.2)	0.737
Mid	118 (31.6)	83 (34.6)	
Lower	114 (30.5)	70 (29.2)	
RNS	6.96±1.92	7.87±1.95	0.000
Complexity stratification			
Low	163 (43.6)	63 (33.3)	0.000
Intermediate	172 (45.9)	114 (47.5)	
High	39 (10.4)	63 (26.2)	
Preoperative hemoglobin (g/dL), mean±SD	13.13±1.72	13.09±1.96	0.790
Preoperative creatinine (mg/dL), mean±SD	0.94±0.29	0.93±0.35	0.695
Preoperative eGFR (mL/min), mean±SD	84.29±28.32	91.93±33.88	0.012
Surgical access			
Transperitoneal	374 (100)	238 (99.2)	0.077
Retroperitoneal	0	2 (0.8)	

SD=Standard deviation, BMI=Body mass index, eGFR=Estimated glomerular filtration rate, RNS=Renal nephrometry score

Comparing patients who achieved pentafecta to those who did not, we noted a statistically significant difference between the two groups for tumor size (36.1 vs. 41.5 mm, $P = 0.017$) and RNS (6.6 vs. 7.7, $P = 0.0001$). Patients achieving pentafecta outcomes were more likely to belong to the lower (49.1% vs. 28.6%) and intermediate complexity categories (47.4% vs. 49.4%), while the non-pentafecta cohort had more patients in the high complexity RNS category (21.9% vs. 3.5%). There were no significant differences between the two groups for other variables [Table 3].

Multivariate logistic regression analysis (MVA) was done to identify predictors of trifecta and pentafecta outcomes. On MVA, only BMI odds ratio (OR) 1.063, confidence interval (CI) 1.018–1.109, $P = 0.005$) and RNS (OR 0.772, CI 0.699–0.851, $P < 0.001$) were found to be associated with trifecta outcomes. Similarly, only RNS (OR 0.756, CI 0.623–0.917 $P = 0.005$) was identified as an independent predictor of pentafecta outcomes [Table 4].

DISCUSSION

PN has become a standard treatment option for SRM. Facilitated by advances in robotic surgery, many complex SRMs are now being taken up for PN to accomplish renal preservation while providing benefits of minimally invasive surgery to the patient. Achievement of trifecta and more recently, pentafecta have been described as potential quality indicators and objectives to strive for while performing a PN.[17] Rates of trifecta and pentafecta outcomes noted in the present study compare well with the literature on the topic. As per published literature, the trifecta achievement rates range from 58% to 81%,[3,15,18-21] while pentafecta has been studied only in a few studies and has been reported to have been achieved in 14%–40% of patients.[4,16,20,22] Numerous studies have identified predictors of trifecta outcomes in relation to different surgical modalities and patient populations. Perioperative variables such as tumor size,[23-29] nephrometry scores (RNS,[27,30,31] PADUA score,[27-29] C-Index,[27] Simplified PADUA REnal [SPARE][32]), surgical approach,[23,33] pelvicalyceal system involvement,[23] hospital volume,[34] hilar location,[16,24] intraoperative blood loss,[24,28,35] and the American Society of Anesthesiologists grading[23] have been identified as independent predictors of the trifecta. However, apart from tumor complexity, none of the other factors have been consistently shown to predict these outcomes.[36] In the present study, we noted tumor complexity, as judged by RNS, to be an independent predictor of both trifecta and pentafecta outcomes.

There is a relative lack of studies reporting RAPN outcomes in the Indian population. Tyagi *et al.*[16] compared the trifecta and pentafecta outcomes following RAPN in hilar versus nonhilar tumors in Indian patients.[16] The authors reported achieving trifecta outcomes in 34.1% of the hilar group patients compared to 58.5% in the nonhilar group ($P = 0.027$). Pentafecta outcomes were achieved in

Table 3: Baseline comparison of patients achieving to those not achieving pentafecta outcomes in the present study

Variables	Pentafecta		
	Yes (*n*=57), *n* (%)	No (*n*=178), *n* (%)	*P*
Age (years), mean±SD	53.63±13.55	52.53±13.09	0.593
Sex			
Male	38	111	0.557
Female	19	67	
BMI (kg/m^2), mean±SD	25.65±3.24	25.44±3.72	0.685
Tumor size (mm), mean±SD	36.12±13.88	41.49±16.57	0.017
Clinical symptoms			
Asymptomatic	39 (68.4)	117 (65.7)	0.708
Local	18 (31.5)	61 (34.3)	
Systemic	0	0	
Single kidney	2 (3.5)	6 (3.3)	0.960
Bilateral tumor	1 (1.7)	1 (0.6)	0.394
Tumor side			
Right	24 (42.1)	101 (56.7)	0.054
Left	33 (57.9)	77 (43.2)	
Face of tumor			
Anterior	27 (47.4)	75 (42.1)	0.977
Posterior	20 (35.1)	55 (30.9)	
RNS	6.6±1.7	7.7±1.9	0.0001
Complexity stratification			
Low	28 (49.1)	51 (28.6)	0.001
Intermediate	27 (47.4)	88 (49.4)	
High	2 (3.5)	39 (21.9)	
Preoperative hemoglobin (g/dL), mean±SD	13.17±1.84	13.08±1.90	0.777
Preoperative creatinine (mg/dL), mean±SD	0.90±0.41	0.88±0.25	0.738
Preoperative eGFR (mL/min), mean±SD	97.51±39.94	93.02±33.52	0.446

SD=Standard deviation, BMI=Body mass index, eGFR=Estimated glomerular filtration rate, RNS=Renal nephrometry score

Table 4: Multivariate logistic regression analysis to identify predictors of trifecta and pentafecta outcomes

Variables	Trifecta			Pentafecta		
	OR	Lower limit-upper limitof CI	*P*	OR	Lower limit-upper limitof CI	*P*
Age	1.011	0.997–1.026	0.132	1.008	0.981–1.036	0.547
Sex	0.903	0.626–1.304	0.586	0.923	0.474–1.797	0.813
BMI	1.063	1.018–1.109	0.005	1.004	0.916–1.101	0.934
Tumor size	1.001	0.989–1.014	0.853	0.993	0.970–1.017	0.575
Preoperative eGFR	0.994	0.988–1.000	0.055	1.006	0.996–1.016	0.249
RNS	0.772	0.699–0.851	0.000	0.756	0.623–0.917	0.005

CI=Confidence interval, BMI=Body mass index, eGFR=Estimated glomerular filtration rate, OR=Odds ratio, RNS=Renal nephrometry score

7% and 44% of hilar and nonhilar tumors, respectively in the same cohort. In another study from the same center and possibly on the same dataset, Sharma *et al.*[32] validated the SPARE nephrometry score to predict the trifecta and pentafecta outcomes post RAPN in the Indian population. The authors suggested that the SPARE nephrometry score's prediction accuracy was comparable to the existing RNS.[37] In another study by Mehra *et al.*,[38] authors reported trifecta outcomes in 73.1%, 64.3%, and 61.5% of the patients who underwent open PN, laparoscopic PN, and RAPN, respectively. Dias *et al.*,[39] in a single-center study of 108 patients who underwent RAPN, reported a trifecta rate of 67.6% and also noted the trifecta rate to improve with surgeon experience. In another similar study by Choudhary *et al.*,[40] trifecta outcomes were noted in 79.3% of the patients. In a matched analysis of RAPN with laparoscopic PN for complex renal masses, Garg *et al.*[41] reported trifecta and pentafecta rates of 66.6% and 46.6%, respectively, for RAPN. Compared to laparoscopic PN, RAPN had superior trifecta outcomes; however, pentafecta outcomes were comparable. However, all the above-mentioned studies are based on single-center experience and use varying definitions for trifecta outcomes. In contrast, our study presents data on a sizeable patient population from various high-volume fellowship training centers in the country. Trifecta and pentafecta outcomes reported in the present study align with Indian as well as international literature on the topic.

Limitations

While our study has the advantages of being multicentric and based on the largest Indian dataset, till date, it is not without its limitations. Limitations specific to VCQI database have been highlighted in previous studies.[42-44] First, due to a lack of stringent oversight, data entered may not be of consecutive patients and are prone to selection bias. Heterogeneity in surgical techniques and perioperative management of patients across different centers need to be considered. VCQI lacks data on imaging used to calculate tumor size and nephrometry scores. In addition, there is no provision for central radiology and pathology review. Data for operative technique employed such as tumor resection enucleation versus resection versus enucleoresection are missing. There is lack of data on intraoperative use of adjunctive techniques such as indocyanine green, intraoperative ultrasound, and frozen section use. It would also have been useful to know additional maneuvres or difficulties faced in the surgical management of patients who failed to achieve the trifecta and pentafecta outcomes. There is a lack of data on hilar or completely endophytic nature of tumors from the database. Finally, surgeon experience was not considered while studying the association of trifecta and pentafecta outcomes due to lack of data for the same from VCQI database. This is likely to have had a major impact on this outcome as has been shown by other studies previously. Finally, follow-up guidelines such as interval and imaging used could have been variable across the centers.

CONCLUSION

The present study showed that the rate of trifecta and pentafecta achievement after RAPN was 60.9% and 24.2%, respectively. Tumor complexity, as measured by RNS, is the predominant factor influencing the achievement of these favorable outcome parameters in Indian patients.

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SUPPLEMENTARY FILE

Supplementary File 1

Vattikuti Collective Quality Initiative Database

Vattikuti Collective Quality Initiative (VCQI) is a prospective multinational collaborative web-based database for various robotic surgical procedures maintained by Vattikuti Foundation.[7-9] For RAPN, data is added by 18 contributing institutions from 9 countries (United States, United Kingdom, India, Italy, Portugal, Belgium, Turkey, and South Korea). Five centers from India added data to this database. It is to be noted that all these five centers are high volume with fellowship training programs sponsored by the Vattikuti Foundation. For various perioperative variables, data are added to the system by each participating center.

Preoperative data

Baseline demographic data for each patient are collected such as age at the time of surgery, sex and body mass index. Other preoperative data included clinical tumor size (modality not specified), presenting symptoms (absent/local/systemic), solitary kidney, multifocal tumor, bilateral tumors, side of surgery (right/left), face of tumor (anterior/posterior), polar location of tumor (upper/mid/lower), and preoperative renal nephrometery score (not specified how and by whom it is estimated). The preoperative biochemical evaluation included hemoglobin, creatinine, estimated glomerular filtration rate (eGFR) as estimated by the modified diet in renal disease (MDRD) equation.

Intraoperative data

Operative data included surgical approach (retroperitoneal/transperitoneal), operative time, type of ischemia (warm/cold/none), ischemia time and blood loss. Data for IOAE were obtained by combining three domains separately reported in the Vattikuti database, i.e., intraoperative complications, conversion to radical nephrectomy/open surgery and intraoperative blood transfusion. Data for intraoperative complications are entered in a closed-end question with six options to select from. These included "Gross violation of tumor bed," " Major bleeding from the tumor bed," "Injury to major vessels," "Injury to abdominal organs," " conversion to open," and "others." Postoperative complications (up to 30 days following surgery) were recorded as per the Clavien–Dindo classification.

Postoperative variables

Discharge values for hemoglobin, creatinine, and eGFR were also recorded. Patients with at least one year of follow-up creatinine were reported for pentafecta outcomes.

Limitations of the database

1. Data to VCQI are contributed by different centers across the country. This may account for heterogeneity in surgical techniques, learning curves, and perioperative management of patients.
2. Lack of data on surgeon experience.
3. Data is lacking on the modality used for reporting tumor size and tumor complexity score. Furthermore, data on who calculated the RENAL nephrometery score is also lacking. Due to the retrospective and multicentric nature of the study, a central review of all the radiology was impossible.
4. There is a lack of data on operative details, such as the technique of resection enucleation versus resection versus enucleoresection. Details on clamping technique (selective, superselective, artery only or *en mass* clamping) and model of robot (Si, X, or Xi) is lacking.
5. Data precisely for hilar and completely endophytic tumors is also lacking from the database.
6. Lack of data on intraoperative use of adjunctive techniques such as indocyanine green, intraoperative ultrasound and frozen section.
7. Data is also lacking for the intraoperative repair of the pelvicalyceal system and type of renorrhaphy.
8. Follow-up guidelines employed may vary from center to center.

Contributing centers

1. Department of Urologic Oncology, Max Institute of Cancer Care, New Delhi*
2. King's College, London, King's Health Partners, UK
3. The Medicity Hospital, New Delhi, India*
4. Rajiv Gandhi Cancer Institute and Research Centre, New Delhi, India*
5. Humanitas Research Hospital, MI, Italy
6. Chennai Urology and Robotics Institute, Chennai, India*
7. Swedish Medical Center, Seattle, WA, USA

8. Henry Ford Hospital, Detroit, MI
9. ORSI Academy, Melle, Belgium
10. Central Ohio Urology Group and Mount Carmel Health System Prostate Cancer Program, Columbus, OH, USA
11. Yonsei University Health System, Seoul, South Korea
12. Peter MacCallum Cancer Centre, Royal Melbourne Clinical School, University of Melbourne Melbourne, Australia
13. Kokilaben Dhirubhai Ambani Hospital, Mumbai, India*
14. University of Miami Health System, Miami, Florida, USA
15. Urological Research Institute (URI), IRCCS Ospedale San Raffaele, Milan, Italy
16. Center for Robotic and Minimally Invasive Surgery, Hospital Da Luz, Luz Sáude, Portugal
17. San Luigi Gonzaga Hospital of Orbassano, Turin, Italy
18. Acıbadem M.A., Aydınlar University, Altuzinade Hospital, Department of Urology, Istanbul, Turkey

*Indian centers that contributed the data to the present study.