Trifecta outcomes of robot-assisted partial nephrectomy in solitary kidney: A Vattikuti Collective Quality Initiative (VCQI) database analysis

Sohrab Arora,[*] Ronney Abaza,[†] James M. Adshead,[‡] Rajesh K. Ahlawat,[§] Benjamin J. Challacombe,[¶] Prokar Dasgupta,[¶] Giorgio Gandaglia,[**] Daniel A. Moon,[††] TB Yuvaraja[ß], Umberto Capitanio[Δ], Alessandro Larcher,[**] Francesco Porpiglia,[‡‡]James R. Porter,[§§] Alexander Mottrie,[¶¶] Mahendra Bhandari,[*] Craig Rogers[*]

[*]Vattikuti Urology Institute, Henry Ford Hospital, Detroit, MI, USA

[†]Department of Urology, Ohio Health Dublin Methodist Hospital, Dublin, OH, USA

[‡]Hertfordshire and South Bedfordshire Urological Cancer Centre, Lister Hospital, Stevenage, UK

[§]Fortis Escorts Kidney and Urology Institute, New Delhi, India

[¶]MRC Centre for Transplantation, King's College London, London, UK

[**] Urology Clinic, San Rafaele Hospital, Milan, Italy

[††]Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia

[ß] Kokilaben Dhirubhai Ambani Hospital, Mumbai, India

[Δ] San Raffaele Hospital, Milan, Italy

[‡‡]San Luigi Gonzaga Hospital, University of Turin, Orbassano, Turin, Italy

[§§]Swedish Medical Center, Seattle, WA, USA

[¶¶]OLV Vattikuti Robotic Surgery Institute, Melle, Belgium

Corresponding Author:

Sohrab Arora

Vattikuti Urology Institute, Henry Ford Hospital, Detroit, MI, USA

Address: 2799 W Grand Blvd. Henry Ford Hospital K9, Detroit, MI, USA 48202

Email: sarora3@hfhs.org

Phone: +1(313)413-911

Conflicts of interest:

Conflicts of interest form attached

DR. SOHRAB ARORA (Orcid ID : 0000-0001-9903-9316)
DR. GIORGIO GANDAGLIA (Orcid ID : 0000-0002-5052-721X)
MR. DANIEL A MOON (Orcid ID : 0000-0002-1557-2584)
DR. UMBERTO CAPITANIO (Orcid ID : 0000-0001-9225-1795)
DR. FRANCESCO PORPIGLIA (Orcid ID : 0000-0001-8567-6795)
DR. CRAIG G. ROGERS (Orcid ID : 0000-0002-7781-6644)

Article type : Original Article

Article category: Robotics and Laparoscopy

Abstract:

Objectives: To analyze the outcomes of robot-assisted partial nephrectomy (RAPN) in patients with a solitary kidney in a large multi-institutional database.

Patients and Methods: A total of 2755 patients in the Vattikuti Collective Quality Initiative database underwent RAPN by 22 surgeons at 14 centers in nine 9 countries. Out of these patients, 74 underwent RAPN in solitary kidney between 2007 and 2016. A retrospective analysis of the functional and oncological outcomes was performed. Trifecta was defined as a warm ischemia time of less than 20 minutes, negative surgical margins, and no complications intraoperatively or within 3 months of follow up.

Results: All 74 patients underwent RAPN successfully with one conversion to radical nephrectomy. The median (interquartile range [IQR]) operative time was 180 (142-230) minutes. Early unclamping was used in 11 (14.9%) cases, while zero ischemia was used in 12 (16.2%) cases. Trifecta outcomes were achieved in 38/66 (57.6%) of the patients. Median (IQR) ischemia time was 15.5 (8.75-20.0) minutes for the entire cohort. Overall complication rate was 24.1% and the rate of Clavien-Dindo ≤2 complications was 16.3%. Positive surgical margins were present in four cases (5.4%). Median (IQR) follow-up was 10.5 (2.12-24.0) months. The median drop in estimated glomerular filtration rate at three months was 7.0 ml/min/1.72m^2 (11.01%).

Conclusion: Our findings suggest that RAPN is a safe and effective treatment option for select

renal tumors in solitary kidneys in terms of a trifecta of negative surgical margins, warm ischemia time less than 20 minutes, and low operative and perioperative morbidity.

Introduction

The gold standard treatment option for patients with a small renal mass is elective nephron sparing surgery (NSS). [1,2] The indication for NSS is imperative in case of solitary kidneys where a radical nephrectomy would make the patient anephric requiring hemodialysis or transplantation.

The goals of NSS in these patients are two-fold. The primary goal is oncological, i.e., the complete removal of the tumor, with the secondary goal being the preservation of maximal renal function. A 'trifecta' has been described for outcomes of NSS and includes negative surgical margins, warm ischemia time of less than 25 minutes, and no complications intraoperatively and up to three months postoperatively. [3,4]. Other studies have recommended a cutoff warm ischemia time of 20 minutes. [5,6]

Although open partial nephrectomy is the gold standard treatment for a tumor in a solitary kidney [7], robot-assisted partial nephrectomy (RAPN) is increasingly being used. [8,9] In fact, Patel et al showed that the availability of the surgical robot increases the utilization of NSS. [10] Combined with intraoperative ultrasonography, this treatment modality has the potential to spare a maximum amount of parenchyma, which is critical in solitary kidneys. Moreover, it has been found to be equally effective for endophytic, mesophytic, and exophytic tumors in terms of 'trifecta' outcome. [11]

In this study, we used the Vattikuti Collective Quality Initiative (VCQI) database to analyze the oncological and functional outcomes of RAPN in renal masses with a solitary kidney.

Patients and Methods

Data Source and patient cohort

VCQI is a collaboration of medical institutions from around the world with a focus on improving the quality of care in robotic surgery. A total of 2755 patients underwent RAPN by 22 surgeons at 14 centers in nine countries (India, United States of America, United Kingdom, Italy,

Belgium, Portugal, Australia, South Korea, and Turkey). Out of these 2755, RAPN on a solitary kidney was performed in 74 patients between 2007 and 2016. Ethical committee clearance for data collection was obtained at each participant center.

Definition of Variables

The variables used in this study were preoperative parameters, namely, age (patient's age in years on the date of surgery), gender (male/female), side of surgery (left/right), body mass index (kg/m^2), symptoms (absent, local or systemic), preoperative serum creatinine in mg/dL, Charlson Comorbidity Index [12], clinical stage (defined according to the American Joint Committee for Cancer as cT1a, cT1b, cT2) [13], tumor size (largest dimension of tumor on preoperative imaging in centimeters), PADUA score (Preoperative Aspects and Dimensions Used for an Anatomical classification) [14], RENAL score (radius, exophytic/endophytic properties, nearness of tumor to the collecting system or sinus in millimeters, anterior/posterior location relative to polar lines) [15], and estimated glomerular filtration rate (eGFR) calculated using the Cockroft-Gault formula. [16]

Operative variables used were the surgical approach used (retroperitoneoscopic/transperitoneal), total operative time (time from incision till the placement of the last skin suture), estimated blood loss in milliliters, and warm ischemia time (defined as the time from the clamping of the main renal artery until the unclamping in minutes in patients who had clamping without the use of regional hypothermia). The type of ischemia was coded as "zero ischemia" if no ischemia was used, and the use of regional hypothermia was coded as cold ischemia. Early unclamping was defined as the unclamping of the main renal artery after the inner renorrhaphy, but before the outer renorrhaphy.

Postoperative variables used included histological stage of the tumor determined according to TNM classification system (pT1a, pT1b, and pT2a), type (clear cell vs. non-clear cell vs. benign), tumor grade defined according to the Fuhrman criteria (grade 1, 2, or 3), and postoperative eGFR in $ml/min/1.73m^2$ at three months.

Follow-up and end points

Trifecta was defined as the combination of negative surgical margins, no complications intraoperatively and up to three months postoperatively [4], and either a warm ischemia (clamping of main renal artery with or without early clamping) time less than 20 minutes[6], or zero-ischemia where main renal artery was not clamped. The postoperative complications were

graded according to the Clavien-Dindo classification[17]. The oncological end point used was surgical margin status (positive surgical margin or negative) defined as the presence of tumor cells at the inked margin of resection. The functional endpoint used was the decrease in GFR defined as absolute and percentage decrease in GFR three months postoperatively compared to the preoperative value.

Statistical analysis

Frequencies and proportions were reported for categorical variables, while medians and interquartile ranges (IQR) were reported for continuously coded variables. All statistical tests were assessed with a significance level of $P \leq 0.05$ or CI not including zero. Statistical analysis was performed with SPSS version 21 (IBM Corp, Armonk, NY).

Results

A total of 74 patients underwent RAPN in a solitary kidney. Median follow-up was 10.5 months (IQR 2.12-24) with 11 patients having follow-up of more than two years. The descriptive characteristics of the cohort are summarized in Table 1.

The trifecta of negative surgical margins, warm ischemia time less than 20 minutes, and no complications was achieved in 38/66 (57.6%) patients who had data for all three variables (n = 66). Minimal ischemia techniques were used in 24 (32.4%) patients (early unclamp, selective clamp, zero ischemia, and cold ischemia).

While the majority had transperitoneal surgery, the retroperitoneoscopic approach was used in 10 (13.5%) of the cases. One patient with a cT1b tumor had a conversion to radical nephrectomy. None of the patients had conversion to open surgery. The operative and perioperative parameters are summarized in Table 2.

The median (IQR) postoperative eGFR at three months was 53 (35-62) ml/min/1.72m^2 with one patient having a postoperative eGFR less than 15 ml/min/1.72m^2 at three months. The median drop in eGFR at three months was 7.0 ml/min/1.72m^2 (11.01%). Two patients had acute renal failure, one of whom required temporary dialysis. Two patients had Clavien-Dindo grade 4 complications. One of them had pneumothorax requiring placement of a chest tube. The other had acute renal failure requiring dialysis.

The follow-up survival information was available in 43 cases, out of which 41 were alive and disease-free at a median follow-up of 10.5 months. None of the patients had a recurrence of cancer. Two patients died due to causes other than cancer.

Discussion

Renal mass in a solitary kidney is one of the absolute indications for NSS, whenever feasible. The gold standard approach for NSS in these cases has been open partial nephrectomy [7], but minimally invasive approaches like RAPN are being increasingly used [8,9]. RAPN has been shown to be safe and effective even for complex renal tumors. [18]. The advantages of robotic approach include better ergonomics, enhanced vision, and short learning curve. The present study evaluated the oncological and functional outcomes of RAPN in solitary kidney within the VCQI database. To our knowledge, this is the largest series of RAPN for tumors in solitary kidneys and adds to the growing volume of literature on this subject. Table 3 shows the results of our study in comparison with existing literature on robotic and laparoscopic partial nephrectomy in a solitary kidney.

Our study has several interesting findings. First, there was no conversion to open surgery even in tumors with high nephrometry scores. It has been shown previously that RAPN has a low conversion rate [8,19]. While our study confirms these reports for solitary kidneys, it is important to note that most of the institutions in this study were high-volume centers, and the findings must be seen in the context of surgeon experience. Although both renal function preservation and advantages of minimally invasive surgery are important, the former is of utmost importance in these patients, and a low threshold of conversion must be maintained, especially in larger tumors. Cold ischemia, either through an open or robotic approach should be considered in cases where longer ischemia times are expected to reduce the risk of acute kidney injury and its sequelae.

Second, the total complication rate in our study was 18/74 (24.1%), out of which Clavien-Dindo grade 1 and 2 complications were in 12 (16.3%) patients. This is higher than the 19.2% reported by Hillyer et al [8], and lower than the 33% and 40% reported by Panumatrassammee et al [20] and Zargar et al [9], respectively. Although there are no randomized controlled trials comparing open partial nephrectomy and RAPN, meta-analyses have shown that RAPN has a lower rate of complications when compared to open partial nephrectomy. [21,22] On the other hand, a similar

rate of complications between the two procedures was reported for solitary kidneys by Zargar et al. [9] This discrepancy could be due to the larger sample size of the meta-analysis.

The margins were positive in four patients (5.4%), which is similar to the 3.8%-6.7% reported in other reports. [8,9,20] This rate is higher than RAPN with normal contralateral kidney, as reported by Khalifeh et al. [4] This may reflect the attempt to preserve the maximum amount of parenchyma in a solitary kidney, which could lead to a resection closer to the tumor. This may also be due to gross violation of the tumor bed during surgery, which was present in three out of four cases with positive surgical margins in the present study.

The median warm ischemia time in our study, when the main renal artery was clamped, was 15.5 minutes with only eight patients (10.8%) having an ischemia time more than 25 minutes. This is similar to the 17-18.8 minutes reported in previous RAPN series. [8,9,19]

This data from 22 centers across the world show that the RAPN in a solitary kidney is a safe and effective procedure. However, the study is not devoid of limitations. The analysis was retrospective in nature which can lead to selection bias. There was no comparator arm, and the follow-up was short, despite the wide time span. The database does not have the reason and duration of solitary kidney, which may be an important predictor of outcomes in these patients. Multiple centers are a part of the VCQI database, and this design might lead to the inclusion of surgeons who are still in their learning curve, and there may be a considerable heterogeneity in surgical technique, although the latter might reflect a more real-life practice among various institutions. Another limitation is that the VCQI database doesn't have information about other forms of treatment, such as local ablation, open partial nephrectomy or prior biopsy. This may be a potential source of selection bias. The database is also limited in the amount of descriptive information about complications. Despite the limitations, the present study is one of the largest series on this subject in literature.

In conclusion, our findings suggest that RAPN is a safe and effective treatment option for select renal tumors in solitary kidneys in terms of a trifecta of negative surgical margins, low warm ischemia time, and low operative and perioperative morbidity.

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Figure Legends

No figures included in this manuscript

Conflict of Interest:

James R. Porter and Alexander Mottrie received honorarium from Intuitive Surgical, CA (USA). All other authors have no conflict of interest. Ronney Abaza reports grants from Conmed Inc., grants from Intuitive Surgical Inc., outside the submitted work; and Educational program support from Intuitive Surgical Inc.

Table 1. Descriptive statistics of 74 patients with solitary kidney who underwent robot assisted partial nephrectomy at multiple centers in the Vattikuti Global Quality Initiative in Robotic Urologic Surgery database between 2007 and 2016.

Variable	**Descriptive**
Age in years, median (IQR)	64 (56-72)
Sex, n (%)	
Males	56 (75.7)
Females	18 (24.3)
Body mass index (kg/m^2), median (range)	27.94 (15.10-46.79)
Symptoms, n (%)	
Incidentally detected mass	52 (70.3)
Local symptoms	4 (5.4)
Systemic symptoms	3 (4.1)
Charlson Comorbidity Index Median (IQR) (n=67)	2 (0-3)
Clinical stage, n (%) (n=70)	
T1a	54 (73)
T1b	13 (17.6)
T2a or above	3 (4.1)
Tumor size, cm, median (IQR) (n=70)	2.3 (1.8-3.7)
RENAL score (n=67)	
Median (IQR)	6.0 (5.0-9.0)
Low (4-6), n (%)	34 (45.9)
Moderate (7-9), n (%)	27 (36.5)
High (10-12), n (%)	6 (8.1)
PADUA score, median (IQR) (n=52)	8.0 (7.0-9.0)
Preoperative eGFR, ml/min/1.72m^2 (n=64)	61 (50-72)
Multiple tumors, n (%)	3 (4.1%)

eGFR, estimated glomerular filtration rate; IQR, interquartile range; PADUA, Preoperative Aspects and Dimensions Used for an Anatomical classification

Table 2. Operative and perioperative characteristics of 74 patients with solitary kidney who underwent robot assisted partial nephrectomy at multiple centers in the Vattikuti Global Quality Initiative in Robotic Urologic Surgery database between 2007 and 2016.

Operative time, minutes, median (IQR)	180 (142-230)
Estimated blood loss, ml, median (IQR)	150 (100-350)
Type of ischemia, n (%)	
Warm ischemia	50 (67.6)
Early unclamping	11 (14.9)
Zero ischemia	12 (16.2)
Cold ischemia	1 (1.4)
Ischemia time, minutes, median (IQR)	
For patients in whom main renal artery was clamped (n=50)	15.5 (8.75-20.0)
Ischemia time > 25 minutes, n (%)	8 (10.8)
Intraoperative complications	
Gross violation of tumor bed	3 (4.1)
Major bleeding from tumor bed	2 (2.7)
Injury to major vessels	3 (4.1)
Injury to abdominal organs	1 (1.4)
Histopathology, n (%)	
Clear cell RCC	43 (58.1)
Non clear cell RCC	17 (23.1)
Benign	12 (16.2)
Pathological stage, n (%)	
pT1a	52 (83.9)
pT1b	9 (14.5)
pT2a	1 (1.6)
Fuhrman grade (clear cell RCC), n (%)	

Grade 1	5 (8.9)
Grade 2	36 (64.3)
Grade 3	15 (26.8)
Surgical margin, n (%)	
Positive	4 (5.4)
Negative	70 (94.6)
Clavien grade of complications, n (%)	
Grade 1	5 (6.8)
Grade 2	7 (9.5)
Grade 3	3 (4.1)
Grade 4	2 (2.7)
Grade 5	1 (1.6)

IQR, interquartile range; RCC, renal cell carcinoma.

Table 3. Comparison of the present study with representative contemporary literature on partial nephrectomy in a solitary kidney

	Present study 2007-2016 (n=74)	Hillyer et al. [8] 2007-2012 (n=26)	Zargar et al. [9] 2007-2013 (n=30)	Panumatrassamee et al. [20] laparoscopic cohort* 2000-2012 (n=52)	Fergany, et al. [7] Open partial nephrectomy
Approach	Robotic	Robotic	Robotic	Laparoscopic	Open
Tumor size, cm, median (IQR)	2.3 (1.8-3.7)	4.3 (2.9-5)	2.8 (2.7)	2.8 (2.2-4.3)	Mean 4.18 ± 2.5
RENAL score, median (IQR) Low, n (%) Intermediate, n (%) High, n (%)	6.0 (5.0-9.0) 34 (45.9) 27 (36.5) 6 (8.1)	6.0 (5-7) 11 (42) 7 (26.9) 3 (12)	6 (2)	- 13 (25) 22 (42) 5 (10)	-
Operative time, min Mean ± SD Median (IQR)	- 180 (142-230)	- 210 (127-235)	174.9 ± 61.7 -	- 225 (180-270)	-
Estimated blood loss, ml, median (IQR)	150 (100-350)	225 (100-437)	200 (300)	250 (138-400)	-
Overall complications, n (%)	18 (24.1)	5 (19.2)	9 (30)	22 (42)	52 (13)
Positive surgical margins, n (%)	4 (5.4)	1 (3.8)	2 (6.7)	2 (4)	-
Warm ischemia time, min, median (IQR)	15.5 (8.75-20)	17 (12-28)	15 (9)	19 (15-34)	Mean 38.1 ± 20.9

Median follow-up, months, median (IQR)	10.5 (2.12-24)	6 (5-9.7)	7.8 (18.7)	15.6 (4.1-62.8)	Mean 43.7 ± 38.3
Percent decrease in eGFR, median (IQR)	-7 (16.3)	-15.8 (25.9)	-	-20 (42)	

eGFR, estimated glomerular filtration rate; IQR, interquartile range; SD, standard deviation

* Results from the laparoscopic cohort of the study