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ORIGINAL ARTICLE

Late complications and 5 years outcomes of robotic partial nephrectomy in France: prospective assessment in the French Kidney Cancer Research Network (UroCCR 10)

Gaëlle Margue[1] · Alexandre Ingels[2] · Karim Bensalah[3] · Nicolas Doumerc[4] · Christophe Vaessen[5] · Morgan Roupret[5] · François Audenet[6] · Arnaud Mejean[6] · Franck Bruyere[7] · Jonathan Olivier[8] · Hervé Baumert[9] · Constance Michel[9] · Philippe Paparel[10] · Bastien Parier[11] · Philippe Sebe[12] · Jean-Alexandre Long[13] · Hervé Lang[14] · Thierry Lebret[15] · Jean-Jacques Patard[16] · Jean-Christophe Bernhard[1]

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Abstract

Purpose To describe the practice of robotic-assisted partial nephrectomy (RAPN) in France and prospectively assess the late complications and long-term outcomes.

Methods Prospective, multicenter (n = 16), observational study including all patients diagnosed with a renal tumor who underwent RAPN. Preoperative, intraoperative, postoperative, and follow-up data were collected and stored in the French research network for kidney cancer database (UroCCR). Patients were included over a period of 12 months, then followed for 5 years.

Results In total, 466 patients were included, representing 472 RAPN. The mean tumor size was 3.4 ± 1.7 cm, most of moderate complexity (median PADUA and RENAL scores of 8 [7–10] and 7 [5–9]). Indication for nephron-sparing surgery was relative in 7.1% of cases and imperative in 11.8%. Intraoperative complications occurred in 6.8% of patients and 4.2% of RAPN had to be converted to open surgery. Severe postoperative complications were experienced in 2.3% of patients and late complications in 48 patients (10.3%), mostly within the first 3 months and mainly comprising vascular, infectious, or parietal complications. At 5 years, 29 patients (6.2%) had chronic kidney disease upstaging, 21 (4.5%) were diagnosed with local recurrence, eight (1.7%) with contralateral recurrence, 25 (5.4%) with metastatic progression, and 10 (2.1%) died of the disease.

Conclusion Our results reflect the contemporary practice of French expert centers and is, to our knowledge, the first to provide prospective data on late complications associated with RAPN. We have shown that RAPN provides good functional and oncologic outcomes while limiting short- and long-term morbidity.

Trial registration NCT03292549.

Keywords Hemostasis · Kidney cancer · Partial nephrectomy · Robotic surgery

Introduction

The incidence of renal cell carcinoma (RCC) is increasing worldwide [1], with a majority of small renal masses incidentally diagnosed on cross-sectional imaging [2]. European guidelines recommend performing partial nephrectomy (PN) for the management of localized RCC when technically feasible [3]. Nephron-sparing surgery (NSS) allows comparable oncologic outcomes and better preservation of renal function compared with radical nephrectomy [4], and the development of robotic surgery has drastically reduced the perioperative morbidity of PN [5, 6].

The number of robotic-assisted partial nephrectomies (RAPN) performed each year has increased exponentially [7]; in France, 160 RAPN were registered in 2010 compared to over 1500 in 2015 [8]. In the hope to get this technique being recognized and reimbursed by the national health insurance, it was therefore essential to assess patient characteristics, as well as operative and clinical outcomes, for this expanding procedure.

Extended author information available on the last page of the article

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The objective of the Robotic Partial Nephrectomy (RoPaN) study was to form a large prospective cohort to describe the practice of RAPN in France, and to assess the late complications as well as long term outcomes.

Methods

Study design

We conducted a prospective, observational study including all patients who underwent RAPN in 16 French tertiary centers. Preoperative, intraoperative, postoperative, and follow-up data were collected prospectively after written informed consent and stored in the French research network for kidney cancer database, UroCCR (CNIL DR 2013-206; NCT03293563). Patients were included over a period of 12 months, then followed for 5 years with specific assessment of long-term complications at the three follow-up visits within the first year (Supplementary Fig. 1). The study was authorized and approved ethically by the Advisory Committee on Data Management in Health Research, and was registered on the US National Library of Medicine Trial Registry (NCT03292549).

Study population

All adults patients diagnosed with a renal tumor and scheduled for a RAPN were included in the cohort. There were no exclusion criteria.

Outcomes

The objectives were to describe the characteristics of patients undergoing RAPN and the surgical techniques and to assess peri- and postoperative morbidity, long term functional and oncologic outcomes. Patient data included age, sex, American Society of Anesthesiology (ASA) score, body mass index (BMI), solitary kidney, chronic kidney disease (CKD), and tumor characteristics (size, bilateral/multifocal status, cystic component, complexity according to PADUA [9] and RENAL [10] scores). Surgical data included operative time, type of clamping, warm ischemia time (WIT), blood loss, hemostasis procedure (e.g., suture, hemostatic agent used, early unclamping, etc.), approach used (transperitoneal vs. retroperitoneal), and conversion to open surgery. The percentage of surgeries meeting the trifecta [11] criteria (absence of perioperative complications, negative margins, and WIT < 25 min) was also documented. Morbidity was assessed in terms of per- and postoperative transfusion rates, medical or surgical complication rates (graded according to Clavien-Dindo score (CDS)), and length of hospital stay. Late morbidity was recorded at 1–3, 6, and 12 months postoperatively. Pathology results were reported (including margins, TNM stage, histological subtype, International Society of Urologic Pathologists (ISUP) grade) and functional outcomes were assessed by measuring the serum creatinine level and estimating the glomerular filtration rate (GFR) according to the Modification Diet in Renal Disease (MDRD) formula pre- and postoperatively (at hospital discharge and at 3, 6, and 12 months postoperatively). We also recorded any CKD upstaging at any follow-up. Finally, we assessed the long-term oncologic and functional outcomes 5 years after the surgery.

Statistical analysis

Quantitative variables are reported as mean ± standard deviation or median (interquartile range). The Mann–Whitney test was used to compare non-normally distributed continuous variables. All tests were bilateral with an α-risk of 5%.

Results

Patients and tumors characteristics

A total of 466 patients were included over a 1-year period (from March 2015 to March 2016), representing 472 RAPN (Table 1). Two-thirds of patients were male, and the mean age was 61.5 ± 12.2 years. Most tumors (73.8%) were cT1, with a mean size of 3.4 ± 1.7 cm. The median PADUA score was 8 [7–10] and median RENAL score was 7 [5–9], indicating mostly moderate complexity NSS tumors (Table 2). Nephron-sparing surgery was performed for an elective indication in 80.3% of cases, mostly using a transperitoneal approach (86.7%) (Table 1). The mean operating time was 157.2 ± 65.6 min. Clamping was used in most surgeries (94.4%), principally of the main renal artery (76.0%).

Morbidity

The mean estimated blood loss was 272.2 ± 385.4 mL, with 18 patients (3.8%) requiring transfusion. Intraoperative complications occurred in 32 patients (6.8%), and conversion to open surgery was required in 20 RAPN (4.2%). In the population of patients who required conversion to open surgery, the mean tumor size was 4.5 ± 2.1 cm, and the median RENAL score was 9 [6–9]. Early postoperative surgical complications (within the hospital stay) were experienced in 26 patients (5.5%) (Table 3). These were severe (CDS ≥ 3) in 11 patients (2.3%). The mean hospital stay was 4.2 ± 2.9 days. Lastly, two patients (0.4%) died within the first month postoperatively.

Regarding late complications, 48 patients (10.3%) had one or more surgical complication in the 12 months

Table 1 Patient and surgical characteristics (n = 466 patients)

Patients	n = 466
Age at surgery (years), mean ± SD	61.5 ± 12.2
Male/female, n (%)	299 (64.2)/167 (35.8)
ASA ≥ 3, n (%)	61 (12.9)
BMI > 25, n (%)	283 (60.8)
Solitary kidney, n (%)	11 (2.4)
Surgeries	**n = 472**
Indication, n (%)	
Elective	376 (80.3)
Relative	33 (7.1)
Imperative	55 (11.8)
Operative time (min), mean ± SD	157.2 ± 65.6
Clamping, n (%)	442 (94.4)
Main renal artery	356 (76)
Segmental artery	56 (12)
Pedicular	27 (6)
Early unclamping, n (%)	283 (60.5)
Warm ischemia time (min), mean ± SD	16.8 ± 8.9
Estimated blood loss (mL), mean ± SD	272 ± 385
Ureteral stent, n (%)	56 (12)
Hemostatic agent, n (%)	92 (20)
Approach, n (%)	
Transperitoneal	409 (87)
Retroperitoneal	60 (13)
Conversion to open surgery, n (%)	20 (4.2)
Conversion to radical nephrectomy, n (%)	5 (1.1)

SD standard deviation, *ASA* American Society of Anesthesiology, *BMI* body mass index

post-surgery after discharge from hospital, mostly within the first 3 months and mainly comprising vascular, infectious, or parietal complications (Table 3).

Functional and oncologic outcomes

The mean GFR decreased significantly postoperatively compared to preoperatively, with an average GFR loss of 6.2 ± 15.9 mL/min at 3 months. Fifty-two patients (11.2%) had CKD upstaging at discharge, 15 (3.2%) at 3 months, 16 (3.4%) at 6 months, 21 (4.5%) at 12 months, and 29 (6.2%) at 5 years (Table 4).

Overall, 484 tumors were removed, and pathology reports showed 91 benign lesions (18.8%). Among the 393 malignant lesions, 66.7% were clear cell RCC and 4.6% had positive margins (Table 2).

After 12 months of follow up, three patients (0.8%) experienced a local recurrence and two (0.5%) a contralateral recurrence (mean time 8.2 ± 1.5 months). Five patients (1.3%) were diagnosed with metastatic progression (mean time 8.8 ± 4.1 months), and the overall mortality rate was 0.9%.

After 5 years of follow-up, 21 patients (4.5%) experienced a local recurrence and eight (1.7%) had a contralateral recurrence (mean time 35.1 ± 25.11 months). Twenty-five patients (5.4%) were diagnosed with metastatic progression (mean time 35.4 ± 24.9 months). Twenty-five patients (5.4%) died during follow-up, including 10 (2.1%) related to RCC.

Discussion

Robot-assisted PN has become the gold standard in the management of small renal masses and the number of RAPN performed each year is increasing exponentially. While early studies indicated the need for careful case selection [12, 13] and restricted indications to patients with low comorbidity and small, uncomplicated tumors, RAPN is now being offered to larger populations. Indeed, development of the robotic approach for NSS appears to significantly decrease its morbidity [5, 5] and is therefore particularly beneficial

Table 2 Tumor characteristics and pathology outcomes

Tumors	n = 484
Size (cm), mean ± SD	3.4 ± 1.7
Bilaterality, n (%)	26 (5.4)
Multifocality, n (%)	17 (3.5)
Cystic, n (%)	95 (19.6)
Hilar localization, n (%)	96 (19.8)
RENAL score, median (IQR)	7 (5–9)
RENAL, n (%)	
Low [4–6]	177 (36.6)
Intermediate [7–9]	165 (34.1)
High [10–12]	57 (11.8)
NR	85 (17.5)
PADUA score, median (IQR_2)	8 (7–10)
PADUA, n (%)	
Low [6–7]	160 (33.1)
Intermediate [8–9]	127 (26.2)
High [10–13]	109 (22.5)
NR	88 (18.2)
Benign pathology, n (%)	91 (18.8)
Malignant tumors	n = 393
Margins, n (%)	
Positive	18 (4.6)
In contact	28 (7.1)
TNM stage, n (%)	
pT1a	278 (70.7)
pT1b	78 (19.8)
pT2a	6 (1.5)
pT3a	31 (7.9)
ISUP grade, n (%)	
I	28 (7.1)
II	208 (52.9)
III	90 (22.9)
IV	18 (4.6)
NR	49 (12.5)
Pathology subtype, n (%)	
ccRCC	262 (66.7)
Papillary type I	51 (13.0)
Papillary type II	17 (4.3)
Chromophobe	35 (8.9)
Others	28 (7.1)

RENAL Radius, Exophytic/endophytic properties, Nearness of tumor to the collecting system or sinus in millimeters, Anterior/posterior Location relative to polar lines nephrometry scoring system, *IQR* interquartile range, *PADUA* Preoperative Aspects and Dimensions Used for an Anatomical classification of renal tumors, *TNM* Tumor, Node, Metastasis, *ISUP* International Society of Urologic Pathologists, *ccRCC* clear cell renal cell carcinoma

for older [15] and comorbid patients, as well as those with more complex tumors. This is well reflected in contemporary French practice within the centers included in our study, with almost 13% of patients presenting with an ASA ≥ 3 score, 12% of tumors being of high complexity according to the RENAL score, and indications for imperative and relative NSS in 12% and 7% of patients, respectively (including 2.4% of single kidneys and 5.6% of bilateral tumors).

Our study also confirms the safety of RAPN, with early medical and surgical complication rates of 15% and 5.5%,

Table 3 Morbidity

Surgeries	n = 472
Perioperative transfusion, n (%)	19 (4.0)
Intra-operative complications, n (%)	32 (6.8)
Early post-operative complications, n (%)	
Medical	71 (15.0)
Surgical	26 (5.5)
Major ($CDS_1 \geq 3$)	11 (2.3)
Surgical revision, n (%)	10 (2.1)
Hospital stay (days), mean ± SD	4.2 ± 2.9
Trifecta, n (%)	318 (67.4)
Late complications following hospital discharge	**n = 466**
Death within 30 days after surgery, n (%)	2 (0.4)
Complications within 1 year, n (%)	48 (10.3)
Within 3 months	35 (7.5)
3–6 months	6 (1.3)
6–12 months	12 (2.6)
Type of complications, n (%)	
Vascular	12 (2.6)
Infectious	11 (2.4)
Parietal	8 (1.7)
Others	17 (3.6)

CDS Clavien–Dindo score, *SD* standard deviation

Table 4 Functional outcomes

	Preoperative	At discharge	3 months	6 months	12 months	5 years
GFR according to MDRD formula (mL/min), mean ± SD	84.7 ± 32.7	78.0 ± 23.8	78.0 ± 22.5	78.2 ± 22.3	77.1 ± 21.5	73.3 ± 20.1
Change in GFR compared to preoperative (mL/min), mean ± SD	–	− 6.8 ± 31.5	− 6.2 ± 15.9	− 6.1 ± 15.78	− 6.6 ± 16.5	− 8.9 ± 14.5
CKD upstaging compared to preoperative, n (%)	–	52 (11.2)	15 (3.2)	16 (3.1)	21 (4.5)	29 (6.2)

GFR glomerular filtration rate, *MDRD* Modification Diet in Renal Disease, *SD* standard deviation, *CKD* chronic kidney disease

respectively, including major complications in 2.3% of patients. These results are consistent with published retrospective cohorts, which found complication rates between 15 and 24% [16–21], with major complications in < 4% of patients. These rates are considerably lower than those observed in open surgery; for example, in a retrospective multicentric study comparing 560 open surgeries and 1409 RAPN [6], Ingels et al. reported a complication rate of 17.9% for the robotic approach (of which 2% were major), compared to 34.9% (5.5% major) for the open approach ($p < 0.0001$), as well as a shorter mean hospital stay (4.2 vs. 7.1 days). The length of stay was similar in our study. The increased safety provided by the robotic approach has allowed the recent implementation of new care pathways [22], with Enhanced Recovery After Surgery protocols and even outpatient surgery [23] in selected patients, which will considerably reduce hospital stays in future cohorts. To our knowledge, our study is the first national prospective cohort with follow-up over 5 years that has aimed to evaluate the long-term complications of RAPN. We have established that the morbidity of RAPN is acceptable, with an additional 10.3% of late complications occurring between hospital discharge and the first year, mostly in the first three months after surgery.

When considering the rate of conversion to open surgery, the literature shows rates between 1.1 and 1.6% [11, 15, 21]. It is higher in our population. This can partly be explained by the predominance of patients with tumors of intermediate complexity (median RENAL score of 7). In addition, these conversions occur in patients with larger tumors (mean size of 4.5 cm) and high complexity (median RENAL score of 9).

Functional outcomes in our study are consistent with those found in the literature [21, 24]. In the retrospective cohort by Khalifeh et al. [25], there were an average GFR loss of 8% three years after surgery, compared to 8.9% at 5 years in our study. These values are very acceptable, with < 5% of patients presenting with CKD upstaging at the 1-year follow up. Regarding the quality of the procedures, evaluated by the Trifecta, the robotic approach seems to allow good results with, in our series, 67.4% of the procedures fulfilling the criteria. This rate is higher than those observed in the literature, usually between 45 and 54% depending on the studies [15–17, 26].

Finally, although the oncologic safety of RAPN has been debated, it is no longer in question and several authors have reported good oncologic outcomes [24, 26, 27]. In the retrospective study conducted by Andrade et al. [16], including 115 patients undergoing RAPN, the five-year cancer-free survival rate was 97.8%. In the cohort of 278 RAPN studied by Bertolo et al. [17] the median follow-up was 46 months, during which 10.1% of patients died, 1.8% related to the disease; 3.6% of patients experienced recurrence at five years and 3.2% had become metastatic. Our cohort had slightly higher, but still acceptable, recurrence and metastatic progression rates at five years of 6.2% and 5.4%, respectively, while the disease-related mortality was similar at 2.1%.

The multicentric nature of our study, while reflecting French practice in its entirety, also leads to limitations in the interpretation of perioperative morbidity. Surgical techniques, the expertise of surgeons, and volume of activity vary between centers and may therefore have an impact on complication rates. As the patients were enrolled and operated on more than five years ago, we could discuss the relevance of our study in contemporary practice. However, if we consider more recent retrospective cohorts, such as the one by Ingels et al. [6], the characteristics of the enclosed patients and the results are similar to those of our series, and therefore our findings are still relevant.

With the rapid evolution of robotic surgery, many technologies have been developed in recent years. Mini ultrasound probes inserted through the trocars help to identify tumor margins and localize endophytic tumors [28]. Three-dimensional (3D) models of the kidney, vascularization, and the tumor are made from preoperative computed tomography scans and allow planning and guidance of robot-assisted surgery, introducing the concept of 3D Image-Guided Robot-Assisted Partial Nephrectomy (3D-IGRAPN) and further decreasing the complication rates of NSS [29]. More recently, augmented reality technology that merges the 3D model and the intraoperative robotic view is being developed [30]. It is likely that these innovations will change the characteristics of RAPN patients and outcomes in the years to come.

Conclusions

Our national, multicenter, prospective, observational study reflects the practice of RAPN in France and is, to our knowledge, the first to provide data on late complications associated with RAPN. As RAPN has become the gold standard for managing small renal masses, our series confirms the very good functional and oncologic outcomes of this surgery, while limiting short- and long-term morbidity.

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Author contributions Manuscript editing writing: GM, JCB. Data collection and management: GM, AI, KBND, CV, MR, FA, AM, FB, JO, HB, CM, PP, BP, PS, JAL, HL, TL, JJP, JCB. Protocol development: JCB. Data analysis: GM, JCB.

Data availability The data that support the findings of this study are stored in the UroCCR database and available on request.

Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethical approval This study was performed in line with the principles of the Declaration of Helsinki. The study was authorized and approved ethically by the Advisory Committee on Data Management in Health Research, and was registered on the US National Library of Medicine Trial Registry (NCT03292549).

Informed consent Informed consent was obtained from all individual participants included in the study.

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Authors and Affiliations

Gaëlle Margue[1] · Alexandre Ingels[2] · Karim Bensalah[3] · Nicolas Doumerc[4] · Christophe Vaessen[5] · Morgan Roupret[5] · François Audenet[6] · Arnaud Mejean[6] · Franck Bruyere[7] · Jonathan Olivier[8] · Hervé Baumert[9] · Constance Michel[9] · Philippe Paparel[10] · Bastien Parier[11] · Philippe Sebe[12] · Jean-Alexandre Long[13] · Hervé Lang[14] · Thierry Lebret[15] · Jean-Jacques Patard[16] · Jean-Christophe Bernhard[1]

✉ Gaëlle Margue
gaelle.margue@chu-bordeaux.Fr

[1] Service d'urologie, Urology Department, Bordeaux University Hospital, CHU de Bordeaux, Place Amelie Raba Leon, 33000 Bordeaux, France

[2] Urology Department, Henri Mondor University Hospital, APHP, Paris, France

[3] Urology Department, Rennes University Hospital, Rennes, France

[4] Urology Department, Toulouse University Hospital, Toulouse, France

[5] Urology Department, Pitié-Saplétrière Hospital, APHP, Paris, France

[6] Urology Department, European Georges Pompidou Hospital, Paris, France

[7] Urology Department, Tours University Hospital, Tours, France

[8] Urology Department, Lille University Hospital, Lille, France

[9] Urology Department, Saint Joseph Hospital, Paris, France

[10] Urology Department, Lyon Sud University Hospital, Lyon, France

[11] Urology Department, Bicêtre University Hospital, Le Kremlin-Bicêtre, France

[12] Urology Department, Hospital Group Diaconesses Croix Saint-Simon, Paris, France

[13] Urology Department, Grenoble Alpes University Hospital, Grenoble, France

[14] Urology Department, Strasbourg University Hospital, Strasbourg, France

[15] Urology Department, Foch Hospital, Paris Saclay University, Suresnes, France

[16] Urology Department, Mont de Marsan Hospital, Mont de Marsan, France