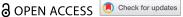




#### **ORIGINAL ARTICLE**



# Robot-assisted partial nephrectomy in complex renal tumors using the Versius platform: An initial but promising experience

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#### **ABSTRACT**

Background and objectives: The widespread utilization of robotic surgeries in urology encouraged several teams to explore the option of performing robot-assisted partial nephrectomy (RAPN), taking advantage of its magnified stereoscopic vision and the articulating instruments that facilitate tumor resection and the reconstructive steps of hemostasis and renorrhaphy. The implementation of the CMR Versius system in RAPN, especially in complex masses, has not been explored yet. Herein, we present our initial experience in performing RAPN in complex renal masses using this novel platform.

Methods: Between July 2022 and November 2023, thirty patients who had complex renal masses and were candidates for RAPN were enrolled in this study. Tumor complexity was assessed using the preoperative aspects of the dimension used for anatomic (PADUA) nephrometry scores. Perioperative data were prospectively collected and analyzed. 'TRIFECTA' was defined as free surgical margins, warm ischemia time (WIT)< 30 minutes, and no major complications (>Clavien-Dindo II).

Results: All cases were successfully completed with no conversion to radical, open, or laparoscopic surgery. The median PADUA score was 9.5 (8-11). The mean docking time, console time, and total operative time were  $9.17 \pm 0.91$ ,  $149 \pm 14.27$ , and  $177.17 \pm 29.53$  minutes, respectively. The mean WIT was  $26.67 \pm 3.66$  minutes. Surgical margins were free in all cases. TRIFECTA was fulfilled in 25/30 patients (83.33%). Five patients (16.66%) did not fulfill TRIFECTA; two patients had prolonged WIT > 30 minutes, two had prolonged WIT with prolonged urine leakage necessitating DJ stent insertion, and the fifth patient had only prolonged urine leakage and DJ insertion. None of the patients developed tumor recurrence or acute kidney injury during follow-up.

Conclusion: Performing RAPN with the CMR Versius platform is a feasible option in complex renal masses with slightly increased but accepted WIT and total operative time. It should be wisely restricted to well-experienced teams.

#### **ARTICLE HISTORY**

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#### **KEYWORDS**

Robotic; Versius platform; partial nephrectomy; nephron-sparing surgery

### Introduction

For decades, radical nephrectomy (RN) has been the gold standard for the management of renal tumors regardless of the stage of the tumor. In the recent era, nephron-sparing surgeries (NSS) have been evolving and favored over radical nephrectomy whenever technically feasible. For selected renal masses, NSS offers the same oncological control as RN without the risk of nephron wasting and subsequent impairment of renal functions [1].

The selection criteria of partial nephrectomy (PN) have widely expanded to include larger and more complex tumors, depending on the experience of the surgical team [2].

With the evolution and the widespread utilization of robotic surgeries in urology, several teams were encouraged to explore the option of performing roboticassisted partial nephrectomy (RAPN). In addition to the articulating instruments that offer generous degrees of flexibility that mimic the movements of the hand and wrist, the robotic surgeries are beneficial in that they have magnified stereoscopic vision that aids in in-depth perception. These important advantages helped in facilitating precise tumor resection and fastening the suturing steps during hemostasis and renorrhaphy [3].

The classic Da Vinci robotic system was developed by Intuitive Surgical in the early years of this millennium and remained monopolizing the robot market till the past few years. Recently, the patents of the Da Vinci systems started to expire, opening the way for many opponents to join the field as a step to reduce the costs and facilitate access to robotic surgeries [4].

One of these competitors is the CMR Versius robotic platform that has been introduced to the market and received the European CE Mark in March 2019. This new robotic system is flexible and multimodular, with robotic surgical arms mounted on separate portable bedside units (BSUs). Each robotic arm has 3 joints and carries a wristed instrument [5].

It is noteworthy that the data presented in the literature depend on studies conducted on RAPN done by the Da Vinci system. The implementation of the CMR Versius system in RAPN, especially in complex masses, has not been explored yet.

Herein, we present our initial experience in performing RAPN in complex renal masses using the CMR Versius platform.

#### **Patients and methods**

Between July 2022 and November 2023, thirty patients at Kasralainy Hospital, Cairo University, who had complex renal masses and were candidates for RAPN were enrolled in this study. CT chest, abdomen, and pelvis with IV contrast was done for all patients to confirm the diagnosis and to ensure organconfined disease with no secondary metastatic deposits (Figure 1). Baseline preoperative serum creatinine (sCr) was done for all patients. Estimated glomerular filtration rates (e GFR) were calculated using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula [6].

Tumor complexity was assessed using preoperative aspects of dimension used for anatomic classification (PADUA) nephrometry scores that were assessed preoperatively by the same two uroradiologists in all cases. Renal masses were classified according to this score as low risk (score 6-7), intermediate risk (8-9), and high risk (10-14) [7]. Only intermediate and high-risk cases were included in this study.

# Committee for proper selection

For proper selection and surgical planning, all cases were thoroughly reviewed and assessed preoperatively by a senior committee to avoid the inclusion of cases not amenable to NSS. The assessment was blindly done without knowing the approach through which NSS would be done, whether OPN, LPN, or RAPN.

Patients with solitary functioning kidneys, impaired kidney functions (eGFR <60 mL/min), previous upper abdominal surgery, or those who were medically unfit for pneumoperitoneum were excluded from the study. All patients' demographics, preoperative, intraoperative, and postoperative data were prospectively collected after ethical committee and institutional review board approval. A written informed consent was obtained from all patients before the procedure. All personal identifiers were removed, and data were analyzed anonymously.

All cases were done by a single surgeon who had previous extensive experience in laparoscopic partial nephrectomy (LPN) as well as good experience in this novel robotic platform.

# **Operative technique**

Under general anesthesia, the patients lie in a lateral decubitus position. All cases were done through a transperitoneal approach using three BSUs: a camera and two robotic arms, all introduced through 10 mm ports. A fourth 10 mm port was assigned to the bedside assistant, through which suction, bulldog clamps, and hemolok clips were introduced. On the

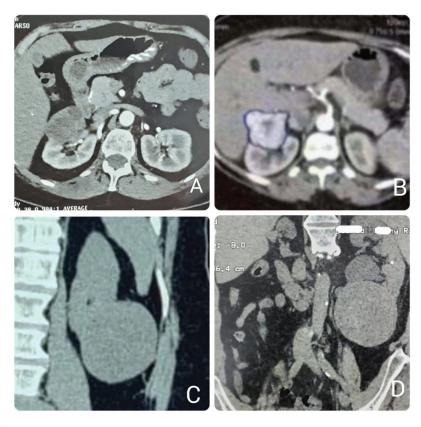


Figure 1. CT images for complex renal masses. A & B: Hilar tumors. C & D: Large lower polar mass.

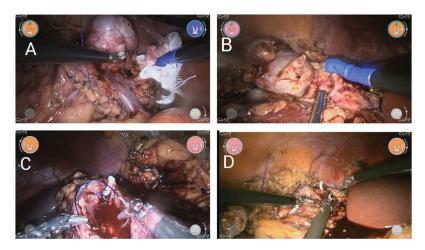


Figure 2. Operative steps. A: Full exposure of the tumor surface with its whole tumor circumference. B & C: Resection and enucleation of the tumor D: Hemostatic suturing of the tumor bed. E: Renorrhaphy using continuous transverse mattress sutures and sliding clip technique.

right side, a fifth 5 mm port was used for the introduction of the liver retractor. A 30° lens was used in all cases.

After reflection of the colon and exposure of the kidney, the renal pedicle was thoroughly dissected, the gerota's fascia and the prerenal fat were excised, and the tumor surface with its whole tumor circumference was fully exposed. (Figure 2A)

The renal pedicle was then controlled, starting warm ischemia. After proper resection and enucleation of the tumor (Figure 2B), continuous running suturing of the tumor bed is done using 2-0 barbed sutures (V-Loc, Covidien, Mansfield, MA). Any obvious bleeders or collecting system violation was sutured. (Figure 2C)

The renal pedicle was then released to end WIT, and a second layer of renorrhaphy was done using continuous transverse mattress sutures and sliding clip technique. (Figure 2D)

After checking hemostasis, the specimen was extracted through a 4-5 cm Abernathy incision. A tube drain was then inserted, and port sites and wounds were closed.

Docking time was calculated from the start of BSUs' distribution till instruments' insertion and ports' training. Total operative time represents docking time in addition to console time and the time spent for the specimen extraction and closure of wounds.

### Follow-up

All patients were monitored in the regular ward for vital signs, bowel movements, urine, and drain outputs. Hemoglobin (Hb) testing was done both right after surgery and the next morning. Serum Cr and eGFR were done before discharge. Foley's catheters were removed on the first postoperative day. Drains were removed in cases of nil output (<50 cc) for at least 24 hours, and the patients were discharged on the same day if vitally stable.

Patients who had prolonged drain output due to urinary leakage (more than 48 hours after surgery) were discharged with drains and monitored in the outpatient department. After one week, the drains were removed from patients whose urine leaks stopped spontaneously during follow-up appointments in the outpatient department. In case of prolonged urine leakage for more than two weeks, DJ stents were inserted.

The Clavien-Dindo grading system was used for complications assessment [8].

Patients came for regular visits in the outpatient clinic after one week to check the ports' site wounds, repeat sCr and eGFR, and decide the postoperative follow-up plan according to the histopathology report. Renal functions were particularly assessed before discharge and in the follow-up visits. According to Kidney Disease Improving Global Outcomes (KDIGO), acute kidney injury (AKI) would be deemed in case of either decreased urine output  $(\leq 0.5 \text{ ml/kg/hr for 6 hours})$ , rise of sCr  $\geq 0.3 \text{ mg/dl}$ within 48 hours, and/or 1.5-fold increase of sCr compared to the preoperative level within 7 days of surgery [9].

'TRIFECTA' was defined as free surgical margins, warm ischemia time (WIT)< 30 minutes, and no major complications (>Clavien-Dindo II).

Follow-up CT urography was done 3 months after surgery and then every 6 months in the first two years. (Figure 3)

### Statistical methods

The statistical package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA) was used for data entering and coding. As regards data summarization, the mean and standard deviation were used for quantitative variables; on the other hand,

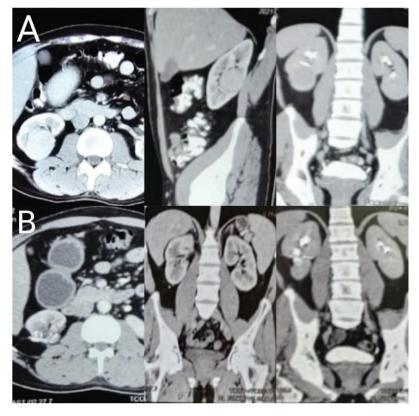


Figure 3. CT images of a patient who needed DJ stent insertion due prolonged urine leakage after RAPN. A: Preoperative images showing a posterior tumor which was more than 50% endophytic. B: Postoperative images after the DJ removal with free tumor bed & no extravasation of IV contrast.

frequencies (number of cases) and relative frequencies (percentages) were used for categorical variables.

#### Results

Thirty patients with complex renal tumors who underwent RAPN using the CMR Versius system were enrolled in this study. All cases were successfully completed with no conversion to radical, open, or laparoscopic surgery.

Patients' demographic and preoperative data are presented in Table 1. The median tumor size and PADUA score were 5 (2–8) and 9.5 (8–11), respectively. Details of the PADUA score are shown in Table 2. The mean docking time, console time, and total operative time were  $9.17 \pm 0.91$ ,  $149 \pm 14.27$ , and  $177.17 \pm 29.53$ minutes, respectively. The mean WIT was  $26.67 \pm 3.66$ minutes. Four patients (13.3%) had WIT >30 minutes, all of which had high-risk PADUA scores. Mean blood loss was  $154.33 \pm 67.19$  cc. Four patients (13.3%) needed intraoperative blood transfusion. The mean length of hospital stay (LOH) was  $2.37 \pm 0.49$  days.

As regards the postoperative course, five patients (16.67%) had prolonged urine leakage and were discharged with their drains. In two patients (6.67%), urine leakage stopped spontaneously, and the drains were removed after one week in the outpatient department. The other three patients (10%) had prolonged

leakage for more than two weeks and needed DJ insertion (Clavien-Dindo grade III b). There were no major complications of Clavien-Dindo> grade II in the other 27 patients (90%).

Surgical margins were free in all cases. Details of postoperative pathology are presented in Table 3. The mean sCr preoperatively, on discharge, and one week after discharge were  $0.96 \pm 0.08$ ,  $1.08 \pm 0.08$ , and  $1.02 \pm 0.07$  mg/dl, respectively. The mean eGFR pre-operatively, on discharge, and one week after discharge were  $85.37 \pm 14.55$ ,  $74.27 \pm 11.75$ , and  $79.67 \pm 13.52 \,\text{mL/min}/1.73 \,\text{m2}$ , respectively. The mean sCr rise was  $1.06 \pm 0.05$ -fold, and the mean eGFR loss was 6.52 ± 4.66%. None of the patients had a significant rise in sCr or a significant drop in

Table 1. Demographic data.

<u> </u>	
Age (Yrs.); mean ± s.d.	51.27 ± 12.96
Height (m); mean $\pm$ s.d.	$1.72 \pm 0.09$
Weight (kg); mean ± s.d.	$82.83 \pm 13.51$
BMI (kg/m [2]; mean $\pm$ s.d.	$27.96 \pm 3.71$
Sex, n (%)	18 (60.0%)
<ul><li>male</li></ul>	12 (40.0%)
• female	
Comorbidities; n (%)	14 (46.7%)
• No	2 (6.7%)
• cardiac	8 (26.7%)
<ul> <li>Hypertension</li> </ul>	6 (20.0%)
<ul> <li>Diabetes Mellitus</li> </ul>	
Side of surgery, n (%)	17 (56.7%)
Right	13 (43.3%)
● Left	

Table 2. Details of PADUA score.

Surface, n (%):	22 (73.3%)
<ul><li>Anterior</li></ul>	8 (26.7%)
<ul><li>Posterior</li></ul>	
Score For Tumor Size; n (%):	5 (16.7%)
<ul><li>1 (≤4 cm)</li></ul>	17 (56.7%)
• 2 (4.1–7 cm)	8 (26.7%)
• 3 (>7 cm)	
Score for Polar Location; n (%):	21 (70.0%)
<ul><li>1 (superior/inferior)</li></ul>	9 (30.0%)
• 2 (middle)	
Score for Renal rim; n (%):	20 (66.7%)
• 1 (Lateral)	10 (33.3%)
• 2 (Medial)	
Score for Renal sinus; n (%):	9 (30.0%)
<ul><li>1 (Not involved)</li></ul>	21 (70.0%)
• 2 (Involved)	
Score for Renal collecting system; n (%):	
<ul><li>1 (Not involved)</li></ul>	13 (43.3%)
• 2 (Involved)	17 (56.7%)
Score for Exophytic rate; n (%):	19 (63.3%)
• 1 (>50% exophytic)	11 (36.7%)
<ul> <li>2 (&gt;50% endophytic)</li> </ul>	0 (0.0%)
<ul> <li>3 (Totally endophytic)</li> </ul>	
PADUA risk; n (%):	15 (50.0%)
<ul> <li>Intermediate risk (8–9)</li> </ul>	15 (50.0%)
<ul> <li>High risk (10–14)</li> </ul>	

**Table 3.** Details of postoperative pathology.

post operative pathology; n (%):	24 (80%)
<ul> <li>clear cell RCC</li> </ul>	6 (20.0%)
<ul> <li>papillary cell RCC</li> </ul>	
Pathological (T) staging; n (%)	5 (16.7%)
• 1a	17 (56.7%)
• 1b	8 (26.7%)
● 2a	

eGFR nor had developed AKI within the first week postoperatively. The mean follow-up period postoperatively was  $15.8 \pm 4.63$  months. During the follow-up period, no patients developed tumor recurrence nor had a significant rise in sCr or drop in eGFR.

TRIFECTA was fulfilled in 25/30 patients (83.33%). Five patients (16.67%) failed the TRIFECTA; two had only prolonged WIT >30 minutes; two had prolonged WIT with prolonged leakage, for which DJ stents were placed; and the fifth patient had only prolonged urine leakage and DJ insertion. All five patients had high-scoring tumors.

## **Discussion**

Since their introduction, robotic surgeries have proved their growing role in assisting minimally invasive NSS and succeeded in bridging the gaps between open and laparoscopic partial nephrectomy (OPN& LPN) [3].

Several studies were held supporting the role of RAPN and proved its comparable outcomes to LPN and OPN.

Compared to LPN, RAPN has shown comparable pathological outcomes yet superior outcomes in terms of shorter WIT thanks to the significantly easier suturing steps. The 3-D magnified view and the wristed

flexible motion of the instruments account for facilitating these technically demanding steps [3].

Seeking an objective judgment in NSS, the term 'TRIFECTA' was developed to assess the overall outcome of such a procedure. Since first described by Hung et al. in 2013, many studies were designed to assess the fulfillment of this trifecta between different approaches [10].

Bravi et al. published a multicenter study on 2331 patients to assess the relationship between surgical approaches of NSS and the perioperative outcomes in terms of warm ischemia, pathological outcomes, postoperative complications, and acute kidney injury. They also assessed the probability of achieving the TRIFECTA for each surgical approach. Multivariate regression analysis showed that minimally invasive techniques had a lower rate of Clavien-Dindo ≥2 complications and almost half the risk of developing AKI when compared to open surgery. As regards WIT, LPN had longer ischemia time than OPN and RAPN. Surgical margin status did not differ among the three approaches. In renal tumors with PADUA scores < 10, RPN had higher rates of trifecta compared to PN and OPN. However, with higher-scoring tumors, the impact of the surgical approach on the perioperative outcomes might be limited [11].

In this current study, 83% of cases met the TRIFECTA. All of the cases had negative surgical margins with no reported recurrences in their follow-up periods. None of the patients with prolonged WIT developed AKI or even a significant drop in e-GFR. This may be attributed to the preoperative selection of cases in which all the enrolled patients had normal kidney functions and normal contralateral kidneys. This also points to the controversy of the accepted limit of WIT, especially in those with normal contralateral kidney and normal preoperative baseline kidney functions [12].

No cases were converted to OPN, LPN, or RN thanks to the meticulous preoperative selection of cases that were candidates for NSS.

Although it has become the management of choice for T1a renal masses, NSS is still controversial for the management of more complex renal tumors given the higher risk of longer ischemia time, bleeding, and collecting system violation [13].

With the improvement of surgical techniques and the advancement of surgical instruments and technology, many teams tried to expand the role of NSS to more complex renal masses [2].

Several studies were conducted to study the feasibility and safety of performing RAPN in complex renal masses.

A systemic review and meta-analysis were conducted by an Indian team to assess RAPN in moderately to highly complex renal masses. They reviewed the data of 2659 patients from 22 studies. They found that RAPN offers acceptable perioperative outcomes for moderately to highly complex renal masses, which was comparable to LPN and significantly superior to OPN in terms of complications rate, EBL, need for transfusion, and LOH [14].

However, most of the data in the literature is based on studies done on the Da Vinci robotic platform. Although many new approved robotic platforms are promising, data on RAPN using these platforms is still lacking.

In 2022, Weifeng Xu et al. published their prospective study to assess the performance of the novel robotic system (KD-SR-01) in RAPN. The study included seventeen patients. The mean docking time, WIT, and robotic operative time were 3.3, 16.9, and 68.6 minutes, respectively. LOH was 5 days. All cases were completed robotically with no conversion to radical nephrectomy. No major complications occurred. They concluded that performing NSS using the KD-SR-01 robot in the management of small renal masses was safe and technically feasible, with the need for further prospective comparative studies with the Da Vinci platform [15].

Andrea Gallioli et al. published their study in 2023 on ten patients who underwent RAPN using the Hugo™ RAS system. All cases were done transperitoneally. The median tumor size was 3 (2.2-3.7) cm, and the median PADUA score was 9 (8-9). The median docking time, console time, and WIT were 9.5 (9-14), 138 (124-162), and 13 (10-14) minutes, respectively. One major complication (Clavien-Dindo III a) occurred. Surgical margins were free in all cases. Preliminary results showed that performing RAPN using the Hugo™ RAS system is promising and can act as a cornerstone for future studies on this novel platform [16].

Another study was conducted by Francesco Chierigo and colleagues to describe their initial experience in RAPN with the Hugo™ RAS system. The study included ten patients with two retroperitoneal and eight transperitoneal cases. The median tumor size was 2.75 cm with a median PADUA score of 7 (7-9). The median docking time, console time, WIT, and total operative time were 20 (15-23), 136 (100-159), 16 (15-20), and 185 (170-232) minutes, respectively. Four complications were reported: one case of AKI, one with prolonged hospital stay due to chylous production in the drain, and two cases with pneumothorax. They pointed to the feasibility of RAPN with the novel HUGO RAS system and recommended future studies with larger case series and longer-term follow-up periods to compare with the Da Vinci platforms [17].

In 2022, the CMR Versius system was introduced in our institute. Performing RAPN was postponed until we gained experience, became familiar with the device, and mastered different robotic skills of dissection and reconstructive surgeries in nephrectomy and

pyeloplasty with this new platform. Starting with simple masses, we felt comfortable performing safe RAPN. This encouraged our team to try performing PN in more complex masses.

It is noteworthy that no patients with entirely endophytic masses amenable for NSS and fitting to our inclusion criteria presented to our institute to be enrolled during the period of this study. Patients with entirely endophytic masses who presented were either candidates for RN or did not meet the inclusion criteria of the current study.

In fact, completely endophytic renal masses, in particular, remain challenging in performing NSS even with the open approach. The conversion rate to RN is relatively higher than other renal masses due to the proximity to deep and large intra-renal vessels and the collecting system, causing a higher risk of intraoperative bleeding with difficult hemostasis, more difficult renorrhaphy, and a higher risk of postoperative potential complications [18,19].

So, we recommend future studies on endophytic masses to assess the performance of this platform in such challenging cases.

The main limitation of the current study is the small number of patients. This may be attributed to the scarcity of complex renal masses amenable for NSS despite being held in a large-volume tertiary center. Although the short-term follow-up period is also a limitation point in this study, the currently presented data meets the primary concern to assess the perioperative outcomes of RAPN in complex masses using this novel platform.

To the best of our knowledge, this is the first prospective series of RAPN done using the CMR Versius system, especially in high-score complex renal masses. Future research should be conducted to compare the outcomes of RAPN using the Versius platform to those of the other platforms.

# **Conclusion**

RAPN using the CMR Versius robotic system is safe and feasible, with favorable perioperative outcomes comparable to those published on other robotic platforms.

In complex renal masses, RAPN is a feasible option with relatively slightly increased but accepted ischemia time and total operative time. It can be safely done whenever technically feasible but should be limited and allocated to well-experienced teams in highvolume centers of excellence.

#### **Disclosure statement**

No potential conflict of interest was reported by the author(s).



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#### **Author contributions statement**

Mahmoud Abdelhakim contributed to the study conception and design as well as performing the surgical procedures. Material preparation, project administration, data collection, and analysis as well as manuscript writing were performed by Mohamed Abdelwahab. Both authors read and approved the final manuscript.

# **Data availability statement**

The data that support the findings of this study are available from the corresponding author upon reasonable request.

# Ethics approval and consent to participate

The Cairo University Research Ethics Committee (REC) reviewed and approved the study protocol (N-444-2023).

#### **Submission declaration**

This work has not been published previously, is not under consideration for publication elsewhere, its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and, if accepted, will not be published elsewhere, including electronically in the same form, in English or any other language, without the written consent of the copyright holder.

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