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# Clinical Trial Protocol for ACCURATE: A CCafU-UroCCR Randomized Trial: Three-dimensional Image-guided Robot-assisted Partial Nephrectomy for Renal Complex Tumor (UroCCR 99)

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**Abstract**

*Background and objective:* Renal cancer often requires nephron-sparing surgery for optimal patient outcomes. Despite advances in imaging and robot-assisted surgery, there is a need to enhance surgical precision and renal preservation. This trial evaluates the effectiveness of three-dimensional image-guided robot-assisted partial nephrectomy versus standard methods in improving surgical outcomes.

*Clinical trial design and timeframe:* This trial is a prospective, 1:1 randomized, single-blind phase 3 superiority study conducted across 14 centers within the French Network for Research on Kidney Cancer, aiming to enroll 694 patients over 36 mo.

*Endpoints:* The primary endpoint is a composite trifecta score, including negative surgical margins, no complications, and renal function preservation (estimated glomerular filtration rate >90% at 1 mo). The secondary endpoints include oncological outcomes, conversion rates, perioperative parameters, and economic evaluation.

*Data sources and statistical analysis plan:* Data are collected via the UroCCR database. Logistic regression will analyze the primary endpoint, and various regression methods will address the secondary outcomes. Economic evaluations involve incremental cost-utility and cost-effectiveness ratios.

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*Strengths and limitations:* Strengths include the multicenter design and robust randomization. Limitations involve variability in surgeons' experience with the new three-dimensional technology and logistical challenges in technology adoption.
*Patient summary:* This clinical trial is designed to evaluate a new surgical technique for treating kidney tumors called three-dimensional (3D) image-guided robot-assisted partial nephrectomy. This study aims to determine whether this new method is more effective and safer than the current standard robot-assisted surgery by improving surgical precision and preserving kidney function. Kidney tumors require precise surgical removal to ensure the best outcomes for patients both during and after surgery. While robotic assistance has improved many surgeries, use of advanced 3D imaging during these procedures might enhance the surgeon's ability to operate with greater accuracy, potentially leading to better patient outcomes and fewer complications. Participants in the trial will undergo surgery using either the conventional robotic-assisted method or the new 3D image-guided technique. The method used for each participant will remain undisclosed to maintain the study's integrity. All participants will receive the highest standard of care, and their progress will be monitored closely throughout the trial. This study hopes to demonstrate that the 3D image-guided method can improve surgical precision and outcomes for patients undergoing kidney tumor removal. If successful, this technique could set a new standard for kidney surgery and improve the overall care patients receive in the future. The addition of 3D reconstruction to the surgery carries very little extra risk. If any technical issues occur, the surgeons can switch back to the regular method without affecting safety. The 3D technology we use, Synapse 3D, is approved and used in hospitals worldwide, ensuring that its safety is well proven by existing evidence.


## 1. Introduction

Renal cell carcinoma (RCC), with 14 000 new cases annually in France, is the third most common adult urological tumor [1]. The rise in RCC incidence, mainly due to improved imaging technologies and incidental detections [2], underscores the need for precise, organ-preserving treatments. Nephron-sparing surgery, particularly partial nephrectomy, has become the gold standard for renal tumors under 4 cm [3,4], offering oncological outcomes comparable with radical nephrectomy while preserving renal function [5,6], important for preventing cardiovascular morbidity [7] and improving overall survival.

The adoption of minimally invasive surgery, especially the Da Vinci robotic surgical system, has transformed partial nephrectomy by allowing the management of more complex tumors compared with conventional laparoscopy, without compromising oncological safety [8,9]. Innovations focus on reducing perioperative risks, maximize healthy renal parenchyma preservation, and limit renal ischemia.

A promising advancement is the use of advanced preoperative imaging combined with three-dimensional (3D) modeling obtained from Synapse 3D software (Fujifilm, Tokyo, Japan) for enhanced intraoperative navigation, known as three-dimensional image-guided robotic-assisted partial nephrectomy (3D-IGRAPN) [10]. This technique integrates a virtual anatomical map into the surgical console's view using the Tile-Pro, enabling precise dissections to improve the quality of nephron-sparing surgery.

Our study addresses a pivotal gap in current surgical oncology by assessing the efficacy of 3D-IGRAPN for complex renal tumors. The use of 3D virtual models promises improvements in zero-ischemia techniques and perioperative outcomes, representing a significant advancement in surgical practices.

Previous research suggests the potential of 3D modeling to improve surgical planning and execution [10–14], but a comprehensive and systematic evaluation through randomized controlled trials is lacking. This study seeks to provide robust evidence for the role of 3D-assisted navigation as a critical tool for RCC surgery.

## 2. Patients and methods

### 2.1. Study design and setting

This prospective, single-blind, 1:1 randomized controlled phase 3 superiority trial evaluates a novel surgical technique within the French Network for Research on Kidney Cancer, UroCCR (www.uroccr.fr). It involves 14 centers, leveraging a diverse patient cohort for a comprehensive evaluation. This study adheres to the Declaration of Helsinki and Good Clinical Practice as per ISO14155:2020 standards. Ethical approval for was obtained from CPP Est 1 (September 9, 2022) and the UroCCR Scientific and Ethical Committee (January 21, 2023), under ID-RCB: 2022-A01659-34. It is registered with the US National Library of Medicine Trial Registry (NCT05572216), and the research network is registered under NCT03293563.

### 2.2. Population and enrollment

Eligible participants are those, aged over 18 yr, scheduled for robot-assisted partial nephrectomy (RAPN) using the Da Vinci robotic system for renal tumors of moderate to high complexity (RENAL nephrometry score ≥7 [15]). Candidates must provide written informed consent for both UroCCR and the ACCURATE trial. Exclusions are limited to those with contraindications to RAPN or computed tomography (CT) contrast agents. There are no restrictions on tumor size, number of tumors, or hereditary or syndromal RCC. The study aims to enroll 694 patients over 36 mo.

### 2.3. Randomization and blinding

Participants are randomized 1:1 into two groups:

1. The 3D-IGRAPN group: RAPN with a 3D model for preoperative planning and intraoperative navigation
2. Conventional RAPN group: standard RAPN

Centralized randomization is managed within the UroCCR database via the ACCURATE research tab, using variable-sized blocks to maintain allocation concealment and prevent a bias. This occurs between the inclusion visit and at least 24 h before surgery. Stratification by center and RENAL nephrometry score ensures balanced distribution between groups. Patients remain blinded to their group allocation throughout the study.

### 2.4. Intervention

For preoperative 3D modeling, 3D-IGRAPN utilizes Synapse 3D software (Fujifilm), enhancing intraoperative navigation via the Da Vinci TilePro (Fig. 1). The preoperative workflow includes semiautomatic CT-scan segmentation of the tumor and key renal structures (arteries, veins, and excretory tract) relevant for tumor resection (Fig. 2). The standard RAPN uses the Da Vinci system with a conventional approach, allowing for transperitoneal and retroperitoneal approaches based on case requirements.

### 2.5. Surgical workflow and follow-up

Routine preoperative assessments include high-quality quadriphasic contrast-enhanced CT scans and creatinine measurements to ensure surgical readiness. Postoperative monitoring for complications, based on Clavien-Dindo classification, occurs immediately and continues until discharge (typically within 48 h), with follow-ups at 1, 6, 12, 24, and 60 mo. Follow-ups include renal function assessments, imaging, and quality of life evaluations using EQ-5D-5L (Supplementary material). Patients-reported outcomes measures are collected via the UroConnect digital application, and all data are stored in the UroCCR database.

Pathological evaluations are performed by expert pathologists from the Carare network, a consortium supported by the French National Cancer Institute. These pathologists are recognized for their expertise in renal tumors, ensuring reliable surgical margin assessments. Their blinded evaluations reduce the bias in the randomized trial.

Oncological follow-up protocol complies with French Association of Urology guidelines, involving clinical, biological, and radiological surveillance based on patient UISS risk group. Radiological follow-up includes contrast-enhanced imaging of the abdomen, pelvis, and chest.

### 2.6. Outcome measures

The primary endpoint is a composite trifecta score [16] at 1 mo after surgery, which combines negative surgical margins, the absence of severe complications (Clavien-Dindo >2), and preservation of renal function (postoperative estimated glomerular filtration rate maintaining >90% of the baseline value according to the Chronic Kidney Disease Epidemiology Collaboration formula, in ml/min). Each component of the trifecta score will also be explored individually.

The secondary endpoints are oncological safety (recurrence-free and overall survival at 6 mo, 1 yr, and 5 yr, and time to event), proportion of conversion rates to radical nephrectomy, and proportion of ischemia-free procedures. Intraoperative parameters such as the resection technique (recorded as enucleation, enucleoresection, or conventional resection), mean blood loss (ml), and surgical ergonomics measured by NASA-TLX (Supplementary Fig. 1) are also considered, along with the incremental cost-utility ratio (ICUR; defined as the additional cost per quality-adjusted life year gained over a 12-mo period). Additionally, patient-reported outcome measures are assessed using the EQ-5D-5L questionnaire to capture the impact on patients' quality of life after surgery. Details regarding the measurement of all primary and secondary outcomes are outlined in Table 1.

### 2.7. Data measurement and economic evaluations

Demographic data, biological parameters (eg, creatinine in µmol/l and hemoglobin in g/dl), intraoperative features, and postsurgical outcomes are systematically recorded in the UroCCR database to ensure data integrity and study reproducibility. Preoperative imaging is centrally reviewed by a specialist radiologist at the coordinating center for consistent assessment of RENAL scores, ensuring standardized evaluations across all trial sites.

Economic evaluations focus on resource allocation, covering hospitalizations, and necessary consultations.

### 2.8. Statistical analysis and economic evaluations

Sample size calculations are based on expected trifecta satisfaction rates of 45.1% for the conventional RAPN group and 55.7% for the 3D-IGRAPN group, supported by existing literature [10,17–19]. The hypothesized difference is 10.6%, but we argue that the minimal clinically relevant difference between groups should be set at 5%.

To achieve 80% power at a 0.05 significance level, a sample size of 694 patients is required. The analysis adheres to the intention-to-treat principle, whereby all participants are analyzed according to their initial randomization group, regardless of protocol deviation. In order to stay true to the intention-to-treat principle, primary endpoints were analyzed after multiple imputation with chained equations, with 50 iterations due to expected missing data under 30% [20].

A logistic regression model will be used to analyze the primary endpoint, incorporating group assignment and stratifying variables. Each component of the trifecta score

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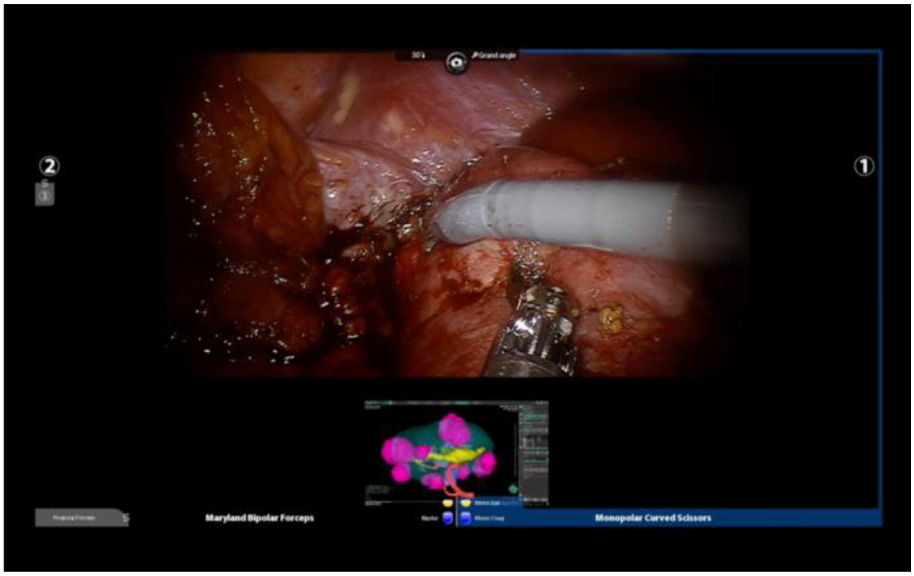


**Fig. 1 – Console view of 3D-IGRAPN with implementation of the 3D model on the robot's TilePro. 3D = three-dimensional; 3D-IGRAPN = three-dimensional image-guided robot-assisted partial nephrectomy.**

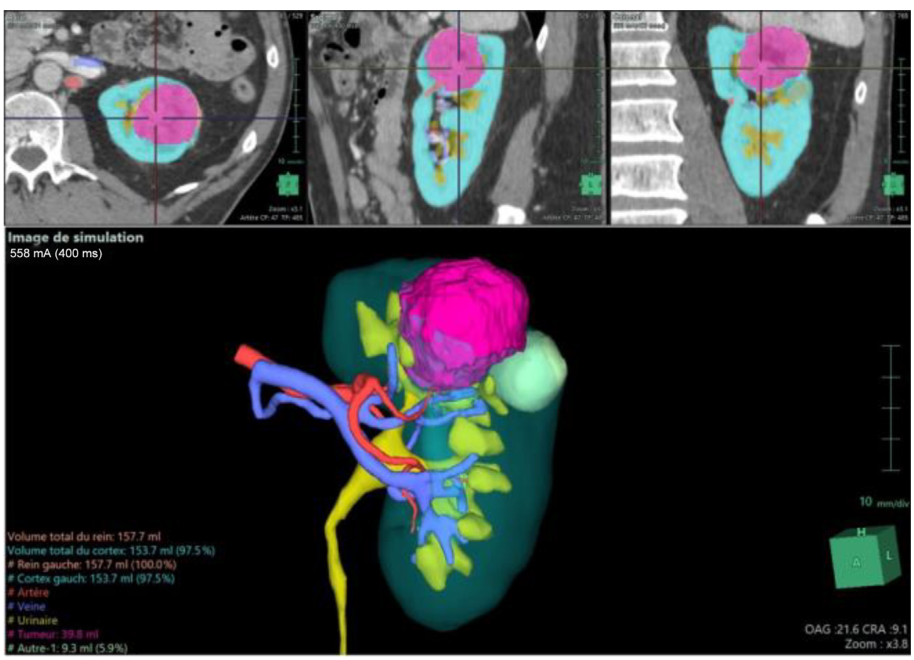


**Fig. 2 – Three-dimensional reconstruction by segmentation of the preoperative CT scan using Synapse 3D software (Fujifilm). CT = computed tomography.**

will similarly be analyzed individually using the same logistic regression methodology.

Secondary endpoints explored through regression models will adjust covariates as in the primary endpoint analysis:

1. Binary outcomes with logistic regression
2. Continuous outcomes with linear regression
3. Time-to-event outcomes with Cox proportional hazards models

For the economic endpoint, an ICUR will be calculated. The uncertainty surrounding the ICUR will be explored using a nonparametric bootstrap method (10 000 replicates) and an acceptability curve. If a survival difference at 12 mo exists, the incremental cost-effectiveness ratio will also be reported.

Quantitative variables will be described with mean, standard deviation, median, and interquartiles. They will be compared between groups using the Student *t* test or the Wilcoxon test, depending on normality. Qualitative variables will be described using frequencies and percentages, and will be compared using Fisher's exact test. The alpha risk is set at 5% for all analyses. No interim analyses are planned.

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**Table 1 – Timeline for outcome measurement**

| Time point | Inclusion | Surgery | Follow-up | | | | |
|---|---|---|---|---|---|---|---|
| | Between 3 mo and 1 d before surgery | D0 | 1 mo | 6 mo | 12 mo | 2 yr | 5 yr |
| Patient information | × | | | | | | |
| Consent (UroCCR and ACCURATE study) | × | | | | | | |
| Randomization | × | | | | | | |
| Clinical examination | × | × | × | × | × | | |
| Laboratory tests [a] | × | × | × | × | × | | |
| Imaging tests [b] | × | | | × | × | × | × |
| Trifecta | | | × | | | | |
| EQ-5D-5L (quality of life) | × | | × | × | × | | |
| Collection of adverse events | × | × | × | × | × | × | × |
| NASA-TLX scale | | × | | | | | |
| OS and DFS | | | | × | × | × | × |

CT = computed tomography; D0 = day 0; DFS = disease-free survival; MRI = magnetic resonance imaging; OS = overall survival.
[a] Laboratory tests: creatinine (in µmol/l for glomerular filtration rate estimation in ml/min) and hemoglobin (in g/dl).
[b] Imaging tests: quadriphasic CT scan (postoperative MRI if the patient is contraindicated for a CT scan).

## 3. Strengths and limitations

This clinical trial protocol presents several strengths that underscore its potential impact on urological oncology. Its multicenter, randomized controlled trial design ensures high evidence level and enhances generalizability of the results. The focus on 3D-IGRAPN addresses a crucial innovation in surgical techniques, aiming to improve patient outcomes through enhanced precision and nephron preservation. Centralized randomization in the UroCCR database ensures methodological rigor minimizing the allocation bias, while stratification by center and RENAL nephrometry score ensures balanced participant distribution.

However, there are limitations to consider. Variability in surgeon experience with 3D technology might affect outcome consistency, and integration of 3D models into RAPN can be a gradual process that may extend beyond the 2-yr enrollment period. Additionally, the technological demands may present logistical and economic challenges, potentially limiting broader adoption. In addition, ongoing training for surgical teams is necessary due to the reliance on advanced technology.

The trial uses single blinding, as double blinding is impractical given that the same clinician conducts both surgery and follow-up, potentially introducing a bias.

While the primary composite endpoint is rigorous, it is one of many and does not solely determine surgical success. Alternative metrics and long-term outcomes provide additional insights and are acknowledged within the study framework.

## 4. Discussion

Recent advancements in imaging technologies have impacted kidney cancer treatment significantly, improving diagnosis accuracy and surgical indications. Integration of 3D virtual models for preoperative planning and intraoperative guidance represents a transformative leap in improving the precision and efficacy of RAPN.

Porpiglia et al [11] have shown that 3D models improve selective clamping rates and a better understanding of vascular anatomy, demonstrating a clinical impact in reducing ischemic burden to preserve renal function.

Zanon et al's [12] systematic review supports the use of 3D imaging virtual planning in solid organ nodule resection, including the kidney, reducing operation time and blood loss, thereby enhancing surgical efficiency and outcomes.

Similarly, Michiels et al [10] have found that the 3D-IGRAPN technique enhance trifecta satisfaction significantly while reducing blood loss and major complications, underscoring the procedural safety of these techniques in maintaining nephron-sparing approaches and minimizing conversions to radical or open surgeries.

Further supporting this, Amparore et al [13] have demonstrated that 3D virtual models protect renal function substantially during minimally invasive partial nephrectomies, as indicated by a smaller drop in effective renal plasmatic flow, especially in high PADUA risk cases. These models allow for better estimation of kidney perfusion zones, facilitating accurate selective clamping [21] and mitigating postoperative renal function decline.

Finally, a large meta-analysis conducted by Piramide et al [14] aligns with these findings, indicating a significant reduction in global ischemia rates. However, while these techniques have increased enucleation frequency and decreased blood loss, they did not demonstrate a notable advantage in long-term oncological or functional outcomes, indicating the need for further research.

Despite the promising results, the adoption of 3D imaging in routine clinical practice is challenged by technological and practical hurdles. While state-of-the-art technologies such as HA3D [11] offer even more refined guidance, these currently require resources such as in-room engineers, which limits their applicability in broader clinical settings. However, the 3D-IGRAPN method, utilizing the Synapse 3D software and Da Vinci TilePro, provides a more autonomous workflow, reducing reliance on continuous technical support and allowing wider adoption in clinical settings.

This study aims to fill a gap in the literature by providing robust evidence from a prospective randomized trial on the perioperative and functional benefits of 3D image guidance in RAPN. By optimizing surgical precision and reducing renal parenchymal loss, we hypothesize that this technique

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will enhance renal function outcomes and establish new standards for the safe and effective management of complex renal tumors.

### 4.1. Benefit-risk assessment

The anticipated clinical benefits of 3D-IGRAPN are significant, particularly in improving the safety and functional outcomes of RAPN. The technology addresses the challenges of tumor complexity, promoting organ preservation and long-term renal function, and mitigating complications from chronic kidney insufficiency.

From a risk perspective, integration of 3D reconstruction poses minimal additional risks. The procedure remains adaptable to conventional methods if technical difficulties arise. With the CE marking approval and established clinical use of Synapse 3D, the approach is backed by evidence supporting its safety.

### 4.2. Expected implications

The successful adoption and validation of 3D-IGRAPN could have transformative implications. Demonstration of clinical superiority might establish image-guided surgery as the standard for complex renal tumors, potentially supplanting conventional RAPN techniques. As technology advances, integration of intuitive imaging and fusion methodologies could further improve surgical outcomes and efficiency.

This study will significantly impact clinical and academic domains, demonstrating how the advanced imaging technologies can redefine surgical oncology. The results could spur further exploration of 3D-guided surgical techniques across different tumor types and anatomical locations. With a multicentric design and large scale, this study is poised for high-impact publication, encouraging broader adoption and influencing surgical guidelines. The flexibility of incorporating various imaging software solutions into this paradigm will allow adaptability as advancements continue in this rapidly evolving field.

Our trial explores the integration of 3D models in surgery, offering insight into their broader presurgical impacts. Based on previous work using 3D models for patient counseling, we have noted improved understanding and reassurance by simplifying complex anatomy and procedures for patients [22]. This foundational work supports two ongoing trials—Rein-3D PRINT-Anxiety (UroCCR 113; NCT06035211) and Rein-3D PRINT-Personalize (UroCCR 114; NCT06379698)—within the RHU Digital Urology 3D project (https://digital-urology-3d.fr), further exploring the role of these models in reducing anxiety and enhancing communication in patient care.

By visually articulating the patient's unique condition, 3D models offer powerful tools for patient counseling and informed decision-making, enhancing therapeutic education, managing expectations, and supporting active patient participation in their health care journey. Widespread validation and adoption of 3D modeling tools could standardize patient-centered communication, setting new benchmarks for patient empowerment and satisfaction in clinical practice.

## 5. Conclusions

This protocol outlines a pioneering clinical trial to assess the effectiveness of 3D-IGRAPN versus conventional techniques. Using a multicenter, randomized controlled trial design, it seeks to provide evidence on whether advanced 3D imaging improves surgical precision and outcomes in renal tumor treatment. The anticipated results could inform clinical practice and potentially shift nephron-sparing surgery protocols. Adherence to ethical standards and comprehensive data collection will ensure the results' reliability and relevance to broader urological oncology practices.

## 6. Clinical trial in context

### 6.1. Evidence gap

Renal tumor surgery has traditionally faced challenges in balancing surgical safety and the preservation of renal function, especially for complex renal masses. While robotic assistance has recently increased the indications and feasibility of partial nephrectomy, the incorporation of advanced imaging technologies to guide these procedures remains underexplored. The evidence supporting the use of 3D image-guided techniques in enhancing surgical outcomes is limited, presenting a significant gap in the current clinical and research landscape.

### 6.2. Trial design

This multicenter, randomized controlled trial is designed to assess the efficacy and safety of 3D-IGRAPN versus conventional robotic techniques. This study employs centralized randomization, stratified by center and RENAL nephrometry score, ensuring methodological rigor and the potential for broad applicability of results.

### 6.3. Potential added value for clinical practice

The trial aims to establish whether 3D-IGRAPN significantly improves surgical precision, reduces complications, and enhances postoperative outcomes compared with conventional methods. Positive findings could facilitate the adoption of 3D image-guided surgeries as a new standard in nephron-sparing procedures, thereby improving patient care and surgical success rates.

### 6.4. Potential impact on clinical research

Should the trial demonstrate significant benefits of 3D image-guided techniques, it could open new avenues for research into their application across various types of surgeries. This trial could serve as a catalyst for further studies aiming to integrate advanced imaging technologies into surgical practices, potentially revolutionizing the approach to complex surgical procedures in oncology and beyond.

***Author contributions:*** Gaëlle Margue had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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***Ethics statement*:** This research was approved by the CPP Est 1 (September 9, 2022) and the Scientific and Ethical Committee of the UroCCR network, registered under NCT05572216, in line with the Declaration of Helsinki and Good Clinical Practice.

## Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euo.2025.03.012.

## References

[1] Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 2021;71:209–49.
[2] Turner RM, Morgan TM, Jacobs BL. Epidemiology of the small renal mass and the treatment disconnect phenomenon. Urol Clin North Am 2017;44:147–54.
[3] Ljungberg B, Albiges L, Abu-Ghanem Y, et al. European Association of Urology guidelines on renal cell carcinoma: the 2022 update. Eur Urol 2022;82:399–410.
[4] Bigot P, Barthelemy P, Boissier R, et al. French AFU Cancer Committee guidelines—update 2022–2024: management of kidney cancer. Prog Urol 2022;32:1195–274.
[5] Kunath F, Schmidt S, Krabbe LM, et al. Partial nephrectomy versus radical nephrectomy for clinical localised renal masses. Cochrane Database Syst Rev 2017;5:CD012045.
[6] Scosyrev E, Messing EM, Sylvester R, Campbell S, Van Poppel H. Renal function after nephron-sparing surgery versus radical nephrectomy: results from EORTC randomized trial 30904. Eur Urol 2014;65:372–7.
[7] Miller DC, Schonlau M, Litwin MS, Lai J, Saigal CS. Urologic Diseases in America Project. Renal and cardiovascular morbidity after partial or radical nephrectomy. Cancer 2008;112:511–20.
[8] Ingels A, Bensalah K, Beauval JB, et al. Comparison of open and robotic-assisted partial nephrectomy approaches using multicentric data (UroCCR-47 study). Sci Rep 2022;12:18981.
[9] Long JA, Yakoubi R, Lee B, et al. Robotic versus laparoscopic partial nephrectomy for complex tumors: comparison of perioperative outcomes. Eur Urol 2012;61:1257–62.
[10] Michiels C, Khene ZE, Prudhomme T, et al. 3D-Image guided robotic-assisted partial nephrectomy: a multi-institutional propensity score-matched analysis (UroCCR study 51). World J Urol 2023;41:303–13.
[11] Porpiglia F, Checcucci E, Amparore D, et al. Three-dimensional augmented reality robot-assisted partial nephrectomy in case of complex tumours (PADUA ≥10): a new intraoperative tool overcoming the ultrasound guidance. Eur Urol 2020;78:229–38.
[12] Zanon M, Altmayer S, Watte G, et al. Three-dimensional virtual planning for nodule resection in solid organs: a systematic review and meta-analysis. Surg Oncol 2021;38:101598.
[13] Amparore D, Pecoraro A, Checcucci E, et al. Three-dimensional virtual models' assistance during minimally invasive partial nephrectomy minimizes the impairment of kidney function. Eur Urol Oncol 2022;5:104–8.
[14] Piramide F, Kowalewski KF, Cacciamani G, et al. Three-dimensional model–assisted minimally invasive partial nephrectomy: a systematic review with meta-analysis of comparative studies. Eur Urol Oncol 2022;5:640–50.
[15] Kutikov A, Uzzo RG. The R.E.N.A.L. nephrometry score: a comprehensive standardized system for quantitating renal tumor size, location and depth. J Urol 2009;182:844–53.
[16] Hung AJ, Cai J, Simmons MN, Gill IS. "Trifecta" in partial nephrectomy. J Urol 2013;189:36–42.
[17] Bertolo R, Garisto J, Dagenais J, et al. Transperitoneal robot-assisted partial nephrectomy with minimum follow-up of 5 years: oncological and functional outcomes from a single institution. Eur Urol Oncol 2019;2:207–13.
[18] Beauval JB, Peyronnet B, Benoit T, et al. Long-term oncological outcomes after robotic partial nephrectomy for renal cell carcinoma: a prospective multicentre study. World J Urol 2018;36:897–904.
[19] Andrade HS, Zargar H, Caputo PA, et al. Five-year oncologic outcomes after transperitoneal robotic partial nephrectomy for renal cell carcinoma. Eur Urol 2016;69:1149–54.
[20] Jakobsen JC, Gluud C, Wetterslev J, Winkel P. When and how should multiple imputation be used for handling missing data in randomised clinical trials—a practical guide with flowcharts. BMC Med Res Methodol 2017;17:162.
[21] Amparore D, Piramide F, Checcucci E, et al. Three-dimensional virtual models of the kidney with colored perfusion regions: a new algorithm-based tool for optimizing the clamping strategy during robot-assisted partial nephrectomy. Eur Urol 2023;84:418–25.
[22] Bernhard JC, Isotani S, Matsugasumi T, et al. Personalized 3D printed model of kidney and tumor anatomy: a useful tool for patient education. World J Urol 2016;34:337–45.

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