Day-case robotic-assisted partial nephrectomy: feasibility and preliminary results of a prospective evaluation (UroCCR-25 AMBU-REIN study)

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TOPIC PAPER

Day-case robotic-assisted partial nephrectomy: feasibility and preliminary results of a prospective evaluation (UroCCR-25 AMBU-REIN study)

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Abstract

Purpose Robotic partial nephrectomy (RPN) is a minimally-invasive technique used to treat renal tumors. A clinical pathway and prospective research protocol (AMBU-REIN) were specifically set up to establish and assess the routine use of day-case RPN.

Methods The AMBU-REIN study was conducted in the framework of the French research network on kidney cancer UroCCR (NCT03293563). We present our initial experience of patients treated using day-case RPN and released from our hospital on the same day, focusing on patient selection, safety and patient satisfaction using the EVAN-G validated questionnaire.

Results Between September 2016 and September 2019, 429 RPN were performed and 82 patients were consecutively selected for day-case RPN. Patients were managed using transperitoneal RPN with off-clamp tumorectomy for 66/82 cases. Mean tumor size was 2.7 ± 1.2 cm. There were no immediate severe postoperative complications; 7/82 patients were kept under observation overnight and discharged the following day. The follow-up at day 30 indicated postoperative complications, readmissions, and mortality rates of 1.2, 1.2, and 0%, respectively. Next-day patient satisfaction questionnaires indicated that patients were generally highly satisfied, with a mean ± standard deviation global score of 83.6 ± 10.3%. "Attention" was rated the highest overall (mean 94.8 ± 10.5%), while "pain management" scored the lowest (61.2 ± 20.5%).

Conclusions This prospective case series is the first to demonstrate the safety and feasibility of day-case RPN. For selected patients and through a dedicated, nurse-led clinical pathway, it provided a high level of patient satisfaction. Expected benefits on healthcare cost savings warrant further investigation.

Keywords Day-case surgery · Kidney cancer · Outpatient · Partial nephrectomy · Renal tumors · Robotic surgery

Introduction

The benefits of day-case surgery are well recognized for both patients and hospitals, resulting in quality and safety of care, high patient satisfaction, and cost savings (e.g., via reduced hospital stay and a reduction in inpatient beds)

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[1–3]. Advances in state-of-the-art techniques in imaging and surgical procedures, including robotic surgery, can facilitate treatment of patients as ambulatory cases. However, changing from conventional hospital stays to day-case surgery requires a change in mindset and organization of existing procedures and facilities with specific clinical pathways [2]. The French Ministry of Health recently announced an objective that 70% of surgical procedures would be outpatient cases by 2022. Such a change will require expanding day-case surgery to more complex surgeries. This must be supported by solid clinical evidence of the safety and benefits of day-case surgery, as well as guidelines regarding patient selection, patient information, discharge protocols, and general management.

Use of robotic assistance for partial nephrectomy (RPN) has progressively extended over the past few years and has become the new standard of care to treat renal tumors in a minimally-invasive fashion [4]. Compared with the open approach, RPN is associated with decreased bleeding, fewer transfusions, fewer postoperative complications, and shorter hospital stay [5]. Preliminary experience has demonstrated that discharge on postoperative day (POD) 1 or 2 is possible in most patients, and we have previously reported the first day-case RPN [6, 7]. The next step was to create a specific clinical pathway and protocol (AMBU-REIN) to establish the routine use of day-case RPN. We present our single center initial experience of patients treated using RPN and released from hospital on the same day. We focus on patient selection, patient satisfaction, and safety—all key factors that will help to promote the use of day-case RPN [6].

Methods

The AMBU-REIN protocol was labeled by the French National Cancer Institute (INCa) and the French Ministry of Health (DGOS) as part of national pilot experimentations on the development of day-case cancer treatment [8]. A specific clinical pathway with a dedicated nurse navigator and outpatient nurse involvement was set up (Fig. 1). Patients were proposed to enter the AMBU-REIN protocol at the discretion of the surgeon and anesthesiologist. The

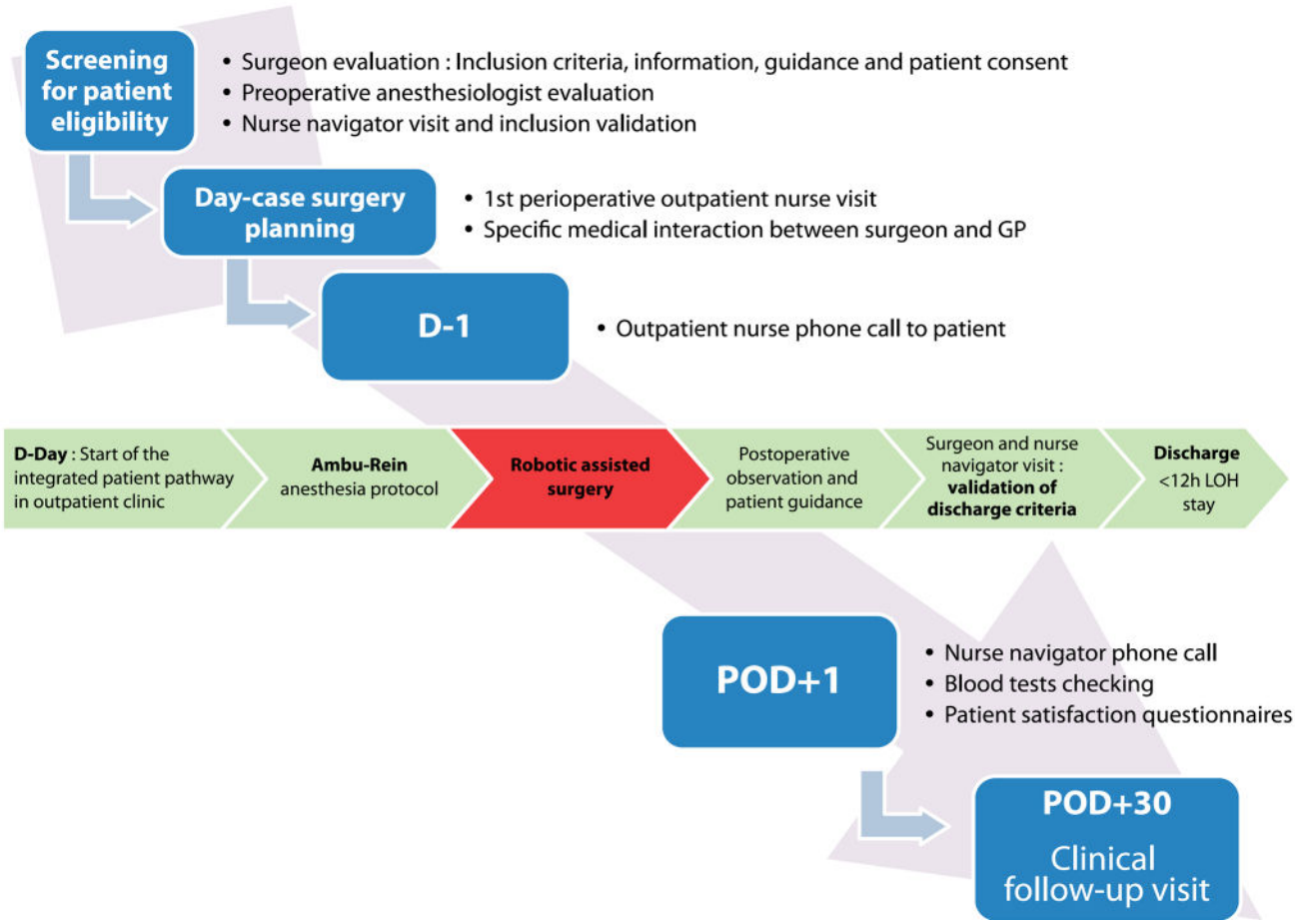

Fig. 1 Clinical pathway for day-case robotic partial nephrectomy (AMBU-REIN protocol)

inclusion in the AMBU-REIN protocol did not interfere with the indication or technical characteristics of the surgery itself. Preoperative exclusion criteria for day-case surgery were allergy to local anesthetics, severe renal insufficiency (glomerular filtration rate (GFR) < 30 ml/min), solitary kidney with moderate renal insufficiency (GFR < 60 ml/min), and pregnancy.

Pre-established criteria were decided for patients' exclusion from the day-case pathway in case of intraoperative blood loss > 300 ml, an operating time > 3 h, and/or an occurrence of a perioperative complication. This was considered as same-day discharge failure. Discharge was managed using the PADSS (Post-Anesthesia Discharge Scoring System) [9] and Aldrete score [10] higher than 9/10, as well as classical criteria for hospital discharge [1] (Online resource 1). A specific analgesic protocol was set up avoiding post-operative use of opioids and rapid shift to oral analgesia at H + 4 comprising systematic use of level 1 and 2 drugs.

All consecutive patients selected for day-case RPN were prospectively included in the AMBU-REIN protocol, with the aim of assessing its feasibility and safety as well as patient-reported outcomes. For this purpose, the clinical data reported for the AMBU-REIN study were collected within the framework of the UroCCR project (NCT03293563), which is IRB-approved and obtained the CNIL authorization number DR-2013-206. All patients received oral and written information about the objectives and methodology of the UroCCR project and AMBU-REIN study, and written consent was obtained. A complementary CNIL authorization for data analysis (number 2063345) was specifically obtained for the AMBU-REIN study. Collected data included demographics, patient and tumor characteristics, characteristics of the surgical procedure, and peri- and postoperative course, with follow-up until postoperative month 3.

Primary outcomes were same-day discharge failure, grade 3–5 postoperative complications, and postoperative day 30 readmissions. Secondary outcomes were patient satisfaction regarding the clinical pathway that was created, and was assessed on POD-1 using the validated EVAN-G questionnaire [11]. At the same time, additional questions were asked that specifically assessed patient-reported outcomes using visual analog scales from 0 to 10, such as pain, anxiety, fatigue, and ability to rest efficiently on the first night after surgery (Online resources 2 and 3). Finally, patients were asked to report their perception of encountered difficulties to fulfill everyday tasks once back home in comparison to what they had imagined before surgery.

Results are presented as mean ± standard deviation, median (range), or number of patients (%), as appropriate. The SPSS 22.0 (Chicago, Illinois) software was used for analysis.

Results

In total, 429 RPN were performed for a kidney tumor between September 2016 and September 2019 in our department. Among them, 82 patients (19.1%) (59 males, 23 females; mean age 55 ± 13 years) were consecutively selected for day-case RPN. Mean tumor size was 2.7 ± 1.2 cm and median (range) RENAL [12] and PADUA [13] scores were 7 (4–10) and 8 (6–12), respectively (Table 1). The proportions of low, moderate, and highly-complex tumors according to the RENAL and PADUA scores are reported in Fig. 2. Patients were managed using transperitoneal RPN with off-clamp tumorectomy for 66/82 cases (otherwise, the mean renal artery clamping time was 14 min). No preoperative foley catheter (except for three solitary kidneys) nor drain were placed. The mean operating time was 111 ± 39 min. Median (interquartile range) estimated blood loss was 100 (50; 175) ml. There were no immediate postoperative severe complications. Seven patients were kept under observation overnight and discharged the next day (Clavien Dindo Grade 1

Table 1 Patient and tumor characteristics and surgical outcomes

Characteristics	*n* = 82
Patient	
Gender, male/female	59/23
Age (years), mean ± SD	55 ± 13
ASA score, median (range)	2 (1–3)
BMI (kg/m^2), mean ± SD	26.2 ± 6.4
Tumor	
Tumor size (cm), mean ± SD	2.7 ± 1.2
RENAL[a] score, median (range)	7 (4–10)
PADUA[b] score, median (range)	8 (6–12)
Cystic lesions, *n* (%)	14 (17)
Imperative indication, *n* (%)	9 (11)
Surgery	
Surgery duration (min), mean ± SD	111 ± 39
Estimated blood loss (ml), median (IQ range)	100 (50; 175)
Off-clamp PN, *n* (%)	66 (80.5)
Positive surgical margins, *n* (%)	5 (6)
Overnight stay (SDD failure), *n* (%)	7 (8.5)
Grade 3–5 postoperative complications, *n* (%)	1 (1.2)
Postoperative readmissions (first 30 days), *n* (%)	1 (1.2)

IQ interquartile; *PN* partial nephrectomy; *SD* standard deviation, *SDD* same-day discharge

[a]The R.E.N.A.L. nephrometry score is a comprehensive standardized system for quantitating renal tumor size, location and depth (Kutikov A, et al. J Urol 2009;182:844–853); [b]Preoperative aspects and dimensions used for an anatomical (PADUA) classification of renal tumors in patients who are candidates for nephron-sparing surgery (Ficarra V, et al. Eur Urol 2009;56(5):786–793).

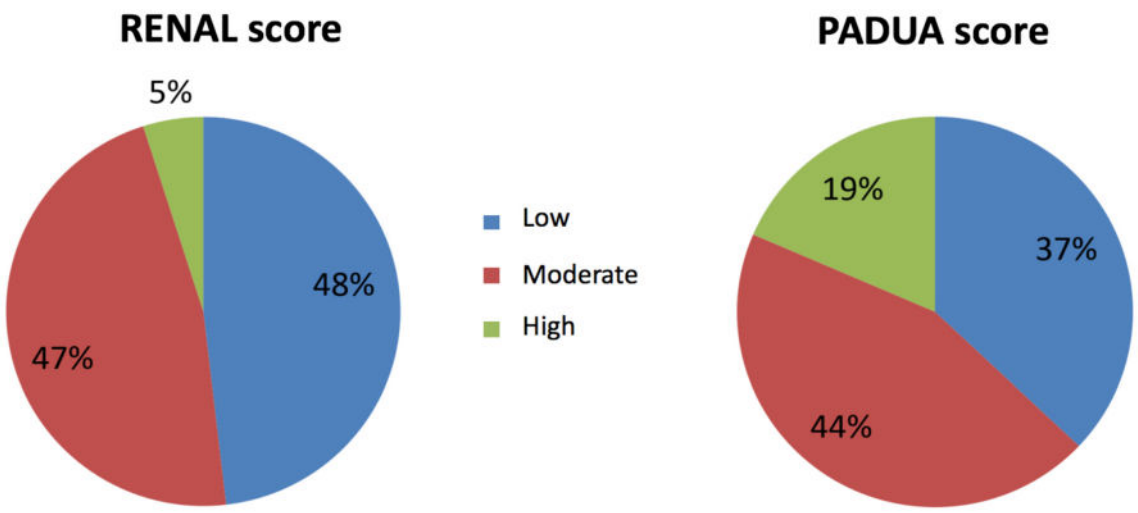

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Fig. 2 Tumor complexity according to RENAL and PADUA scores

complications): one patient for tramadol intolerance with hallucinations, two for uncontrolled pain, two for nausea, one for anxiety, and two for delayed resumption of natural voiding. All other patients (91.5%) were discharged on POD 0, with a hospital stay of less than 12 h. Follow-up at day 30 and postoperative month 3 indicated that postoperative complications, readmissions, and mortality rates were 1.2, 1.2, and 0%, respectively. One patient who had a left double tumorectomy was readmitted on postoperative day 4 for a subcapsular spleen hematoma (treated by selective arterial embolization) and a urinary fistula (treated by double J stenting) (Clavien Dindo grades 3b).

On POD-1, patient satisfaction regarding the perioperative period (assessed using the EVAN-G questionnaire) indicated that patients were generally highly satisfied, with a mean global satisfaction score of 83.6 ± 10.3% (Table 2). 'Attention' was rated the highest overall (mean 94.8 ± 10.5%), while 'pain management' scored the lowest (mean 61.2 ± 20.5%). The additional questions reported mean visual scale instantaneous evaluations for pain, anxiety, and fatigue at 4.3 ± 2.1, 2.3 ± 2.2, and 4.4 ± 2.3, respectively. A minority of patients (29%) reported more difficulties in achieving everyday tasks (Fig. 3) than they would have expected. Finally, 75% of patients said they

Table 2 Patient satisfaction questionnaire, results at postoperative day 1 ($n = 82$) (see Online resources 3 and 4 for questionnaires)

Parameters	Outcomes
Patient satisfaction (EVAN-G questionnaire scores[a]), % ± SD	
Comfort	76.4 ± 21.2
Attention	94.8 ± 10.5
Patient information	93.6 ± 10.2
Pain management	61.2 ± 20.5
Waiting	86.4 ± 21.0
Privacy	90.2 ± 10.4
Global satisfaction	83.6 ± 10.3
Additional questions[b], mean score ± SD	
Pain	4.3 ± 2.1
Anxiety	2.3 ± 2.2
Fatigue	4.4 ± 2.3
Rest	4.8 ± 2.6
Ready to do it again in an ambulatory setting? (Y), *n* (%)	61 (74.8)

SD standard deviation; *Y* yes

[a]Scored using a scale from 0 to 100; [b]scored using a visual scale from 1 ("None") to 10 ("Maximal"), as indicated

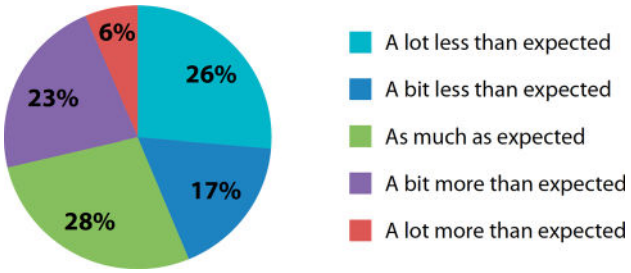

Fig. 3 Patient-reported outcomes on difficulties in achieving everyday tasks on postoperative day 1 compared to preoperative expectations

would go through the procedure as ambulatory cases again if they had to.

Discussion

Outpatient surgery rates in general have increased steadily over the past 25 years, with many advantages for patients (e.g., minimal disruption, faster recovery, increased patient satisfaction), hospitals (e.g., greater theater utilization, freeing-up of inpatient beds, reduced waiting lists, etc.), and healthcare funders (e.g., reduced costs) [1, 14]. Although day surgery is common for many urological procedures, it is currently not established for surgical management of renal tumors and especially partial nephrectomy. Official data from the French Technical Agency for Information on Hospitalization (ATIH—www.atih.sante.fr) reported that only 40 radical and partial nephrectomies were performed ambulatory in 2018 in France, among a total of 11,567 procedures (0.35%).

It is currently already possible to discharge the majority of patients on POD 1 or 2 using RPN, with low readmission rates [6, 7]. Indeed, as experienced for other urological fields or indications outside urology, in our experience establishing an Enhanced Recovery After Surgery (ERAS) protocol has been the first step before moving further to a specific clinical pathway for outpatient RPN [15–18]. Our report provides good evidence that RPN can be used to safely manage patients on a day-case basis, with discharge on POD 0. No immediate severe postoperative complications were experienced, allowing more than 90% of patients to be released on the same day, and the others on POD-1. One patient only presented major complications (Clavien grade 3b) within the 30-day postoperative period, and the patient was rapidly readmitted thanks to the emergency procedure (navigator nurse follow-up and 24/24 emergency phone number available for the patient).

However, patient selection is key for success and not all partial nephrectomies may be manageable as a day-case. Although we treated a range of tumor complexities, with more than 50% of tumors classified from moderate to high according to both RENAL and PADUA, the mean tumor size of 2.7 cm and patient age of 55 years reflect the underlying preoperative selection process. The pre-, intra-, and postoperative criteria we report here may ensure the safety of the procedure. Moreover, hospital and surgeon volume are known to greatly influence RPN outcomes [19]. In our center, the mean case load per year during the AMBU-REIN study period for RPN procedures was 143. Such a volume may also benefit from some of the favorable intraoperative outcomes reported (low blood loss, operating times that were often less than 2 h—63% of cases), as well as from the low postoperative morbidity. It may also play a substantial role in the ability for a multidisciplinary team, including surgeons, anesthetists, OR nurses, navigator nurse, outpatient-clinic nurses, to efficiently set up and run day-case protocols for complex surgeries. It is noteworthy that in our experience, the proportion of outpatient RPN remained stable around 19% throughout the 3-year duration of the study. Compared to other procedures, nephron-sparing surgery encompass a wide variety of situations according to tumor characteristics (size, location, complexity, multifocality), patient's renal function, and indication for conservative treatment (elective, relative, imperative) that may significantly impact on the perioperative course and risk of complications. Therefore, this proportion of outpatient RPN may not be easily increased in the future.

Using the validated EVAN-G questionnaire, we wanted to evaluate the whole clinical pathway and ascertain patient satisfaction. Satisfaction was high in most cases, although improvements must be made regarding pain management and patient comfort, which received the lowest EVAN-G scores. Based on this result, the oral analgesia protocol was recently modified with systematic use of level 2 drugs for at least 3 days and on-demand use of non-steroidal anti-inflammatories. The quality of patient information was rated 93.6/100, and it should be emphasized that patient information and guidance are essential for successful day-case surgery and patient compliance. We previously reported modern strategies to enhance patient preoperative education and surgical procedure understanding [20]. We strongly believe that this kind of initiative, combined with the central role of the navigator nurse, may be crucial in the development of day-case RPN [21]. The strong involvement of our navigator nurse in patient education and preoperative counseling was organized through dedicated consultation and phone call interactions (Fig. 1). This may certainly have contributed to the small proportion of patients being very negatively surprised regarding their early postoperative recovery (6%), as well as to the very low mean level of anxiety reported by the patients (2.3 ± 2.2). Patient-centered, nurse-led care coordination already benefit from the availability of numerous apps and mobile platforms integrated into clinical practice to

enhance the quality of postoperative follow-up and ease the implementation of day-case surgery [22, 23]. We currently plan to enhance the AMBU-REIN protocol and our patients' experience with a nurse-led care digital coordination.

Cost is always of concern, particularly with newer and more technologically-advanced procedures such as RPN. The combination of a short length of stay (compared with 10.1 days for open partial nephrectomy, as reported by Peyronnet et al. [5]), higher patient turnover through the day-case clinical pathway, better coordination, and few complications may represent a solution to offset the higher costs of robotic assistance. Siddiqi et al., although reporting on orthopedics, also emphasize the benefit of a preoperative patient-education protocol to decrease non-home discharge, unnecessary postoperative physician visits, and diagnostic testing—resulting, in their experience, an episode cost saving of 13% [24]. This may certainly apply to kidney surgery. A specific cost-consequence assessment with comparison of open partial nephrectomy, ERAS RPN, and day-case RPN regarding inpatient and post-discharge expenditure may fully explore the economic impact of innovative surgical care pathways.

To our knowledge, this prospective series is the first in the literature to report on the implementation of a dedicated protocol for day-case RPN, demonstrate its safety and at the same time confirm satisfactory patient experience through assessment of patient-reported outcomes. We could have imagined performing the same evaluation through a non-inferiority, open, randomized trial, with assignment of eligible patients to day-case RPN on a 1:1 basis to the AMBU-REIN pathway and conventional inpatient ERAS RPN. However, this methodology was not selected due to the small expected number of eligible patients, resulting in a long-lasting inclusion period. Finally, we also provided practical eligibility criteria and the example of a specific clinical pathway organization to help in its transferability. In so doing, the aforementioned trial could be designed in a multicenter fashion.

Conclusion

This prospective AMBU-REIN study is the first series to report on the safety and feasibility of day-case RPN. For selected patients, and through a dedicated nurse-led clinical pathway, it was demonstrated to provide a high level of patient satisfaction. Expected benefits on healthcare cost savings warrant further investigation.

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Author contributions Protocol/project development: JCB, SR, and SR. Data collection or management: SR, JCB, CM, ABDH, JG, GR, MGG, and GC. Data analysis: JCB, SR, AB, HB, PTF, KN, and JMF. Manuscript writing/editing: JCB.

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Compliance with ethical standards

Conflict of interest JCB declare to be proctor for Intuitive Surgical.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the research committee CPP Sud-Ouest et Outre-mer (approval DC 2012–108) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained.

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