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Original Article

SAFE: Multi-institutional study of time to complications after robot-assisted partial nephrectomy, selection of a population eligible for outpatient management (UroCCR 90)

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ABSTRACT

Introduction: The average hospital length of stay after robotic-assisted partial nephrectomy (RAPN) is 3 days, with a current trend towards outpatient cases, although no population has been identified. The main objective of the study was to analyze the time to onset of post-operative complications, identify risk factors for significant early complications in order to define a population eligible for outpatient case.

Material and method: The study included 3342 patients with clinically localized renal tumors who underwent RAPN surgery between 2010 and 2021. The primary endpoint was the occurrence of significant complications (SC) (Clavien Dindo > 2 [CD]). A CS-free survival analysis was performed. A multivariate logistic regression model was fitted to predict the risk of early significant complications (ESC) after RAPN.

Results: The rates of total complications and SC were 14.99% and 3.59% respectively. Median time to SC was significantly longer at 3 days [3.9–5.7] versus 2 days [2.4–3] for total complications ($P = 0.012$). The majority of complications occurred within the first 72 h, and the risk factors for early SC (< 72 h) (ESC) were clamping time ($P = 0.04$) and ASA > 2 score ($P = 0.007$). Analysis of survival without ESC showed a significant impact of clamping time ($P = 0.043$) on complication-free survival.

Conclusion: Using standard preoperative variables, we were able to determine that the only factor influencing the occurrence of postoperative ESC was ASA score > 2 and thus define it as a primary eligibility criterion for an indication of outpatient RAPN subject to a clamp time of less than 20 mins.

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RÉSUMÉ

Introduction et objectifs: La durée moyenne d'hospitalisation après une néphrectomie partielle assistée par robot (RAPN) est de 3 j, avec une tendance actuelle vers les cas ambulatoires, bien que la population susceptible d'être traitée en ambulatoire n'ait pas été identifiée. L'objectif principal de l'étude était d'analyser le délai d'apparition des complications postopératoires afin d'identifier les facteurs de risque de complications précoces significatives et de définir ainsi une population éligible à un traitement ambulatoire.

Matériel et méthodes: Nous avons inclus 3342 patients atteints de tumeurs rénales cliniquement localisées et ayant bénéficié d'une RAPN entre 2010 et 2021. Le critère d'évaluation principal était la survenue de complications significatives (SC) (grade Clavien-Dindo > 2). Nous avons effectué une analyse de survie sans SC. Nous avons ajusté un modèle de régression logistique multivarié pour prédire le risque de complications significatives précoces (ESC) après RAPN.

Résultats: Les taux de complications totales et de SC étaient respectivement de 14,99% et de 3,59%. Le délai médian jusqu'à la SC était significativement plus long, à savoir 3 j (intervalle 3,9–5,7) contre 2 j (intervalle 2,4–3) pour les complications totales ($p = 0{,}012$). La plupart des complications sont survenues dans les 72 premières heures, et les facteurs de risque d'ESC (< 72 h) étaient le temps de clampage ($p = 0{,}04$) et un score ASA (American Society of Anesthesiologists) > II ($p = 0{,}007$). L'analyse de la survie sans ESC a montré un impact significatif du temps de clampage ($p = 0{,}043$) sur la survie sans complication.

Conclusion: En utilisant des variables préopératoires standard, nous avons déterminé que le seul facteur qui influence la survenue d'une ESC postopératoire est un score ASA > 2. Nous le définissons donc comme le principal critère d'éligibilité pour la RAPN ambulatoire lorsque le temps de clampage est < 20 mins.

1. Introduction

Kidney cancer is the sixth most common cancer in men and eighth in women, with around 65,150 new cases and 13,680 deaths per year in 2013. There has also been an increase in the incidental discovery of smaller, earlier-stage renal masses due to the greater accessibility of imaging. This trend has increased indications for minimally invasive surgery such as robot-assisted partial laparoscopic nephrectomy (RAPN), with over 9,000 procedures performed annually in France since 2011 [1]. This technique not only offers a lower conversion rate, but also better nephron sparing and shorter hospital stays [2], all the more so when coupled with the implementation of a RAAC [3] protocol, notably with the absence of post-operative drainage [4].

The combination of these factors has made it possible to imagine a RAPN procedure, which is still mostly performed in conventional hospitalization with an average length of stay (LOS) of 3 days [5], with discharge the following day [6–9] or even as an outpatient procedure [10–12]. However, no tool currently exists to define an ideal target population for such an approach.

The main aim of our study was therefore to analyze the time to onset of specific postoperative complications of RAPN and to identify factors predictive of their onset, particularly early (< 72 h), in patients with renal tumors who have undergone RAPN, with the aim of identifying patients who can be deferred from in-hospital monitoring and therefore most likely to be eligible for safe outpatient surgery.

2. Method

2.1. Inclusion and exclusion criteria

We retrospectively analyzed all patients who underwent RAPN between 2010 and 2021 from a prospectively maintained national multicenter database of 3474 patients (UroCCR). This study was submitted as a UroCCR project (NCT03293563), approved by the IRB and granted CNIL authorization number DR-2013-206.

All patients received oral and written information on the objectives and methodology of the UroCCR project, and written consent was obtained. The time of occurrence of the complication was recorded retrospectively by clinical research associates, interns or surgeons at each center, based on the date of the examination that led to its diagnosis.

Excluded were procedures involving associated adrenalectomy [34], lymphadenectomy [22] or metastasectomy [6], as well as cases requiring conversion [32], totalization [16] or stopping the procedure [5]. In all, we studied 3342 patients with clinically localized renal tumors who had undergone RAPN surgery.

2.2. Judging criteria

The primary endpoint was the occurrence of significant complications corresponding to a Clavien-Dindo complication (CD) > 2 (SC). The time to onset of a complication was recorded and treated according to its early onset, defined as less than 72 h, and the significance of the complication.

Pre-, intra- and postoperative data analyzed included: Age, gender, BMI, anticoagulant or antiplatelet agent use, ASA score, preoperative creatinine serum level, tumor size, RENAL score classified as low, moderate or high risk, surgical approach, operative time, clamping time, blood loss, intraoperative blood transfusion, multiple lumpectomy, type of renal suture, use of haemostatic agents, occurrence of intraoperative complications including proximal organ wounds (vascular, digestive, pleural, excretory tract, liver, spleen), presence of toxic fat, occurrence of postoperative complications or transfusion, and death. Post-operative complications were distinguished according to their medical character (renal failure, pneumopathy, urinary tract infection, unspecified sepsis, behavioural disorders, ileus, acute urine retention, thrombosis, isolated fever, anemia, pain, nausea, other) or surgical (urinary fistula, lodge hematoma, wall abscess, pneumothorax, wall hematoma, pleurisy, arteriovenous fistula, acute obstructive renal failure, pseudoaneurysm, other). The need for revision surgery was recorded and detailed (excretory tract drainage, hemostasis, abscess drainage, totalization, embolization, other).

2.3. Statistical analysis

A descriptive analysis of postoperative complications was performed for early and ultra-early significant complications at day 0, as well as a univariate analysis of risk factors for early significant complications (ESC). Numerical variables were expressed as mean (± SD) and discrete outcomes as absolute and relative frequencies (%). We created 2 groups according to the occurrence or non-occurrence of an ESC. Group comparability was assessed by comparing baseline demographic data. Normality and heteroscedasticity of continuous data were assessed with the Shapiro-Wilk and Levene tests respectively. Continuous results were compared using the unpaired Student's *t*-test, Welch's *t*-test or Mann-Whitney U-test, depending on the distribution of the data. Discrete results

were compared using the chi-square test or Fisher's exact test. The alpha risk was set at 5% and two-tailed tests were used.

A multivariate logistic regression model was fitted to test the association between the occurrence of significant early complications. Based on our univariate analysis, we included variables with a threshold $P < 0.2$. The final model was chosen following a principle of parsimony in the inclusion of covariates. Thus, the following variables were analyzed: ASA score [dichotomized as low (ASA I–II) or high (ASA III–IV)], clamp time, operative time, blood loss and tumor size. Data were checked for multicollinearity using the Belsley-Kuh-Welsch technique. Heteroscedasticity and normality of residuals were assessed by the White test and the Lilliefors test respectively.

A Kaplan Meier curve analysis of significant complication-free survival was performed, as well as a multivariate Cox analysis of the occurrence of ESC.

A *P*-value of 0.05 was considered statistically significant. Missing data were imputed the mean for numerical variables and the most frequent modality for discrete variables. Patients with missing data for other variables were excluded from the analysis.

Statistical analysis was performed with EasyMedStat A *P*-value of 0.05 was considered statistically significant. Missing data were imputed the mean for numerical variables and the most frequent modality for discrete variables. Patients with missing data for other variables were excluded from the analysis.

3. Results

3.1. Study population

Our study included 3342 patients, whose characteristics are detailed in Table 1.

3.2. Descriptive analysis

Median hospital stay was 3 days [3.4–3.6], with 98% of patients discharged within 10 days. The total complication rate was 14.81%, with 3.59% significant complications. The early complication rate for all CDs combined was 11.06%. The rate of significant early complications was 2%, with 0.36% occurring on D0. The median time to complications was 2 days [2.5–3], with a median of 2 days [2–2.6] for medical complications and 3 days [4.3–5.6] for surgical complications. More than half (57%) of significant complications occurred within the first 72 h (Fig. 1), with a median time to onset of 3 days [3.9–5.7] and a time to surgical or radiological revision of 5 days [5.5–8.1].

At D0, the 12 significant complications (0.36%) were classified into five medical complications and seven surgical complications. Medical complications included two septic shocks with a urinary origin, leading to the patient's death, and pulmonary complications, one PAO and one COPD decompensation requiring a stay in intensive care, and one acute renal failure with hyperkalemia requiring dialysis sessions. Surgical complications all required revision surgery for six compartmental hematomas, including three hemorrhagic shocks and one (8.3%) pneumothorax.

In this population, the proportions of ASA I, II, III and IV groups were 0%, 63.6%, 27.3% and 9% respectively, and 25.2%, 57.6%, 16.8% and 0.3% among patients with no complication at D0 ($P = 0.006$). The median clamping time was also significantly longer in this population, at 22 mins (IQR 6.2) and 23.5 (IQR 12) in the case of revision surgery, compared with 15 (IQR 10) for patients with no complications at D0. The rate of intraoperative complications was also higher, with 25% (OR = 12.2; CI(3.3; 46); $P = 0.004$) and 42.9% (OR = 27.6; CI (6.1; 125.3); $P < 0.001$) in case of revision surgery versus 2.6% in the rest of the population.

In our study, significant complications were mainly loge hematomas (34%), false aneurysms (22.5%), urinary fistulas (15%), arteriovenous fistulas (9.2%), wall hematomas (5.8%), wall abscesses (4.2%), acute obstructive renal failure (2.5%), pneumothorax (0.8%), and others (15.8%). Surgical revision consisted of embolization in 32.5% of cases,

Table 1
Patient demographics.

Variable	*n*	Median	CI 95%
Age	3342	62	59,42-60,28
Sexe	Women: 1162(34.8%) Men: 2180 (65.2%)		
BMI	3197	26.40	27.04-27.42
Tumoral size	2752	3.40	3.85-4.15
Pre-operative creatinemia	2680	80	82.88–84.85
ASA Score	I: 808 (25.18%) II: 1851 (57.68%) III: 539 (16.80%) IV: 11 (0.34%)		
Operative approach	Transperitoneal: 2943 (91.11%) Retroperitoneal: 287 (8.89%)		
Anticoagulant/ antiaggregant therapy	321 (9.71%)		
Clamp	2851 (86.76%)		
Length of hospital stay	3242	3	3.41-3.65
Post-operative complications	Total:495 (14.81%) Medical: 378 (11.31%) Surgical: 198 (5.92%)		

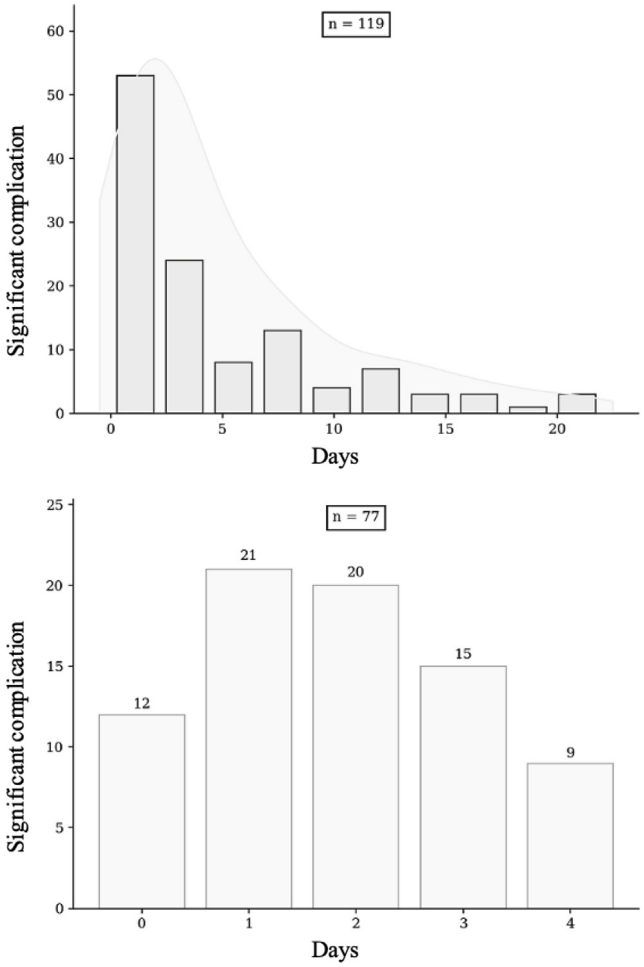

Fig. 1. Histogram of time to significant complication.

placement of a JJ catheter in 20%, hemostasis surgery in 10%, totalization in 7.5%, abscess drainage in 2.5%, and other types of revision in 15.8%.

3.3. ESC analysis

Among the 2% of patients with ESC, the proportions of ASA I, II, III and IV groups were 21.9%, 48.4%, 28.1% and 1.6% respectively, and 25.2%, 57.9%, 16.6% and 0.3% for others ($P = 0.032$) (Fig. 2).

Median operative time was longer in ESC patients with 162 mins (IQR 78) vs. 141 (IQR 74) in other patients (CI = [−49.3;−9.1]; $P = 0.002$) with median clamping time also significantly longer in ESC patients with 21.5 mins (IQR 10) vs. 15.0 (IQR 10) (CI = [−8.9;−2.4]; $P < 0.001$). Intraoperative blood loss was greater in the ESC group with 200 mL (IQR 300) vs. 150.0 (IQR 250) (CI = [−156.6;16.9]; $P = 0.008$), with a higher intraoperative transfusion rate in the ESC group (6.06% vs. 1.7%) (OR = 3.72; CI [1.31; 10.59]; $P = 0.029$). The ESC group also had more intraoperative complications (8.82% vs. 2.6%) (OR = 3.62; CI [1.53; 8.61]; $P = 0.01$), with significantly more vascular wounds (2.94% vs. 0.4%) (OR = 7.59; CI [1.7; 34.3]; $P = 0.036$) and hemorrhage (4.41% vs. 0.89%) (OR = 5.15; CI [1.5; 17.3]; $P = 0.026$). Median tumour size was 4.0 cm (IQR 2.5) in patients in the ESC group and 3.4 (IQR 2.1) in the others (CI = [−1.8;0.3]; $P = 0.013$).

There was no significant difference in age, gender, preoperative creatinine level, BMI, anticoagulant or antiaggregant use, approach, off-clamp rate, multiple lumpectomies, capsular and parenchymal suturing, use of hemostatic agents, non-vascular proximal organ wounds (digestive, pleural, excretory tract opening), presence of toxic fat and RENAL score.

In multivariate analysis, clamping time (OR = 1.03, [1.0; 1.1], $P = 0.04$) and ASA > 2 score (OR = 2.25, [1.2; 4.1], $P = 0.007$) were associated with higher rates of ESC. Operative time (OR = 1.0, [1; 1.01], $P = 0.5$), blood loss (OR = 1.0, [1.0; 1.0], $P = 0.5$), tumor size (OR = 1.1 [0.9; 1.3], $P = 0.1$) were not significantly associated with ESC rates.

Determining a cut-off point for the significance of clamping time by means of an ROC curve enabled us to highlight two thresholds, 14.5 (Se 0.72, Sp 0.55) and 21 mins (Se: 0.5, Sp: 0.8). In multivariate analysis, the use of a 20-minute cut-off (OR = 2.27, [1.3; 3.96], $P = 0.0039$) was associated with higher rates of early complications (Fig. 3).

3.4. Survival analysis

Analysis of significant complication-free survival (Fig. 4) confirms a predominantly early onset within the first 72 h.

Analysis of ESC-free survival (Fig. 5) also revealed a trend in favor of ASA > 2 score (HR 1.9; $P = 0.08$) on significant complication-free survival, while clamping time had a significant impact on significant complication-free survival (HR: 1; $P = 0.043$).

4. Discussion

4.1. External validity

In our study, the rate of significant complications was similar to that reported in the literature, with a total complication rate of 14.81% and 3.59% for significant complications [2,13]. The incidence of hemorrhagic complications, estimated at 3.62%, was also comparable to that reported

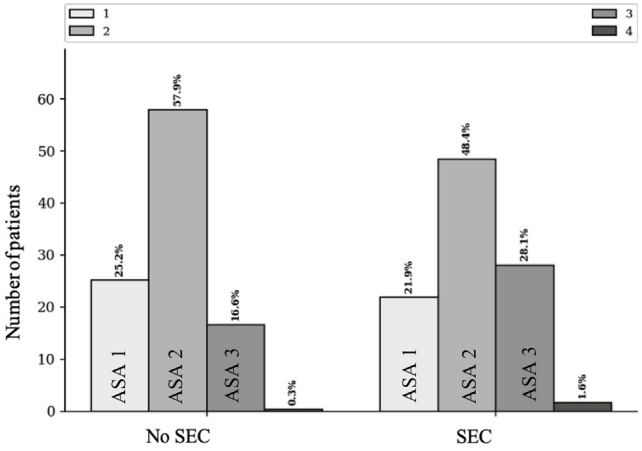

Fig. 2. Histogram of ASA Score distribution.

in the literature, which varies from around 1 to 5% [14]. Like Potretzke et al., we also found an incidence of 0.8% of urinary leakage, which is in the low range of the literature review carried out in the same study, which estimated the incidence at between 0.6 and 3.0% based on the results of 13 studies published between 2008 and 2015 [15]. The results of our study indicate a predominantly early onset of the 3.59% of significant complications, mainly occurring within the first 72 h. However, the rate of significant complications at D0 was only 0.36%. To our knowledge, this is the first detailed description of the time to onset of major complications after RAPN in such a large population.

4.2. Main results of the study

The major risk factors for significant early complications in our study were ASA score and clamping time. These two parameters can be considered a reflection of the patient's general condition and the complexity of the lumpectomy.

Indeed, the ASA score is an important risk factor for post-operative medical complications, including mortality, whatever the type of procedure [16]. Richstone et al retrospectively analyzed 335 cases of partial nephrectomy to determine the relationship between clinico-biological factors and bleeding complications, and found that the incidence of bleeding complications was 2.9 times higher for patients with ASA class > 2 [17]. The ASA score was also found to increase post-operative hospital stay (0.015) [18]. We can therefore deduce that the patient's general condition is one of the key factors in the post-operative period. The use of the less subjective Charlson score (CCI) in other post-operative studies confirms this hypothesis.

In the study by Brandao et al, CCI was found to be the only factor significantly associated with a higher 30-day readmission rate, with a 2.77-fold higher probability of readmission in the case of CCI > 5 (95% CI = 1.10–6.94; $P = 0.03$). [19]. Similarly, in Larson et al, the CCI was higher (mean 2.2, 3.1 and 3.8; $P < 0.001$) in patients with the longest hospital stay [20]. The use of this more reproducible score could be worth evaluating to condition accessibility to outpatient management.

In our study, clamping time had an impact on significant complication-free survival and was associated with a higher risk of developing ESC.

variable	modality	odds ratio	p-value
intercepte		0.00797 [0.00403;0.0158]	6.14e-44
ASA Score		2.14 [1.19;3.84]	0.0106
Clamp >20min		2.27 [1.3;3.96]	0.00394
Blood loss		1.0 [0.999;1.0]	0.589
Tumoral Size		1.13 [0.965;1.31]	0.132

Fig. 3. Risk factor of ESC.

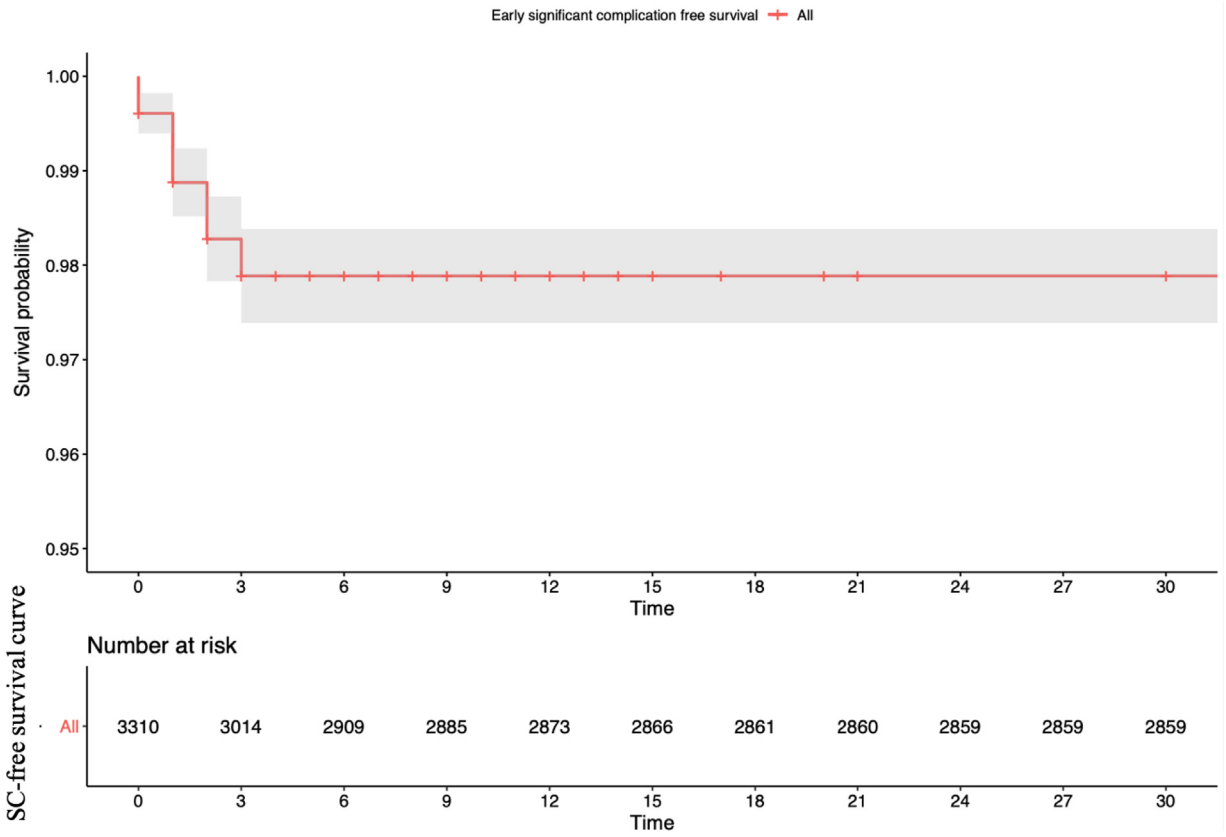

Fig. 4. SC-free survival curve.

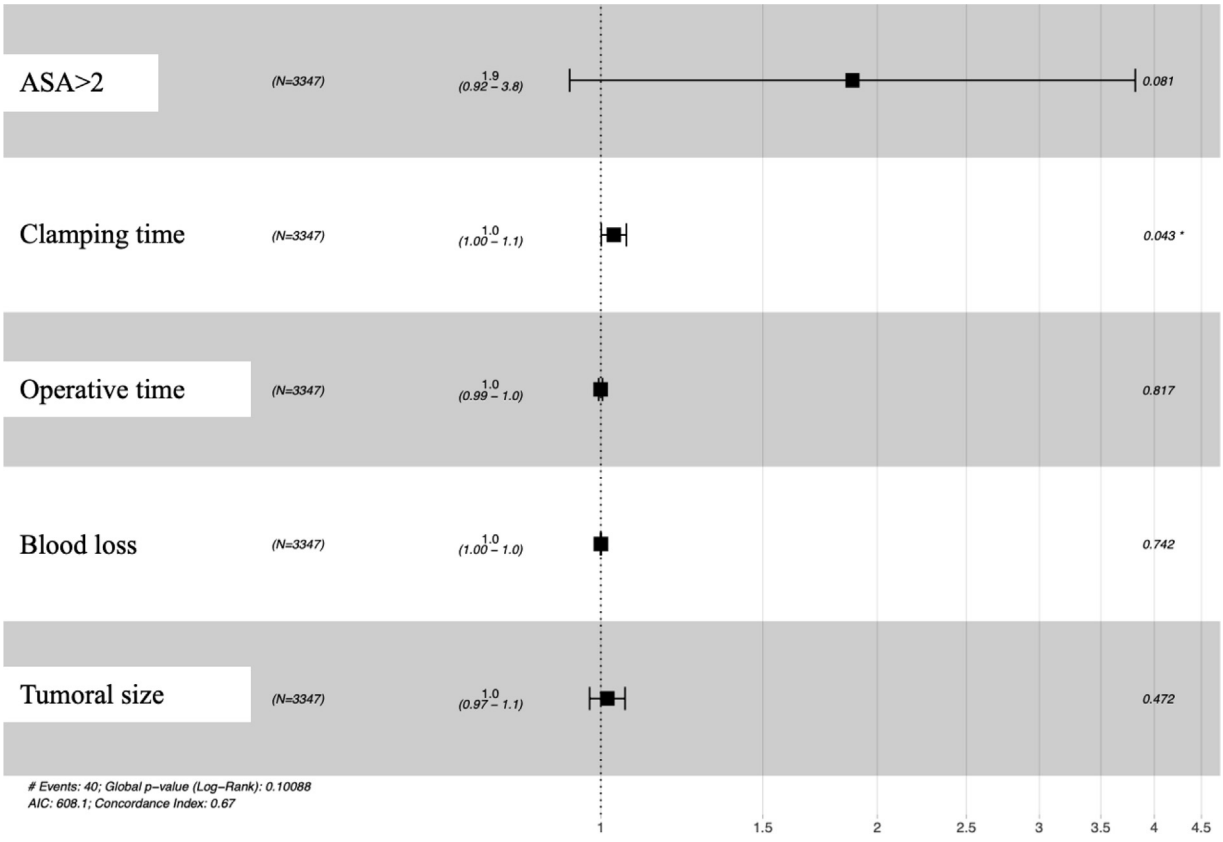

Fig. 5. Association between the length of stay and the severity of complication/Cox hazard model for ESC-free survival.

Clamping time is an important factor in partial nephrectomy, particularly for short- and long-term renal function. Two clamping time cut-offs were of particular interest in our study (14.5 and 21 mins).

In the literature, similar cut-off times are found in the prediction of postoperative renal failure in the more or less long term. R Houston Thompson et al described a cut-off time of 25 mins as a risk factor for acute and chronic renal failure [21]. Becker et al also found a similar cut-off of 20 mins in their review of the literature [22] to be associated with an adverse impact on renal function. However, to the best of our knowledge, no link between clamping time and the occurrence of significant early post-operative complications has ever been described.

4.3. Internal validity

Our study has certain limitations; it includes a large collection of data from 20 different centers with the inherent biases associated with large retrospective studies. Although the database is maintained prospectively, the collection of the time of occurrence of complications was done retrospectively on the basis of the dates of performance of complementary examinations attesting to them. The data were collected by surgeons or interns at each center, or even directly by clinical research associates, which may have had an impact on the quality of the data. In addition, certain key variables such as surgical experience or center size were not assessed in our study. Yet we know that surgical experience is a major factor impacting post-operative outcomes [25]. In addition, clamping time is strongly associated with surgeon experience, tumor size and complexity predicted by morphometric scores. Among these factors, increasing surgical experience is the most important factor impacting clamping time [23]. It would therefore have been interesting to include it in our multivariate analysis.

4.4. Highlights of the results

According to our study, the determination of the surveillance period could be based solely on the assessment of the patient's general condition, according to his or her comorbidities, and on the technical difficulty defined by the surgeon. Thus, any patient with an ASA < 3 score could be eligible for outpatient management if the surgeon considers that the surgical complexity allows it. Ambulatory management could therefore be implemented on the basis of these criteria, with low risk for the patient. However, to date, there is still no specific reimbursement coding for RAPN, and as reimbursement for LAPN has not been upgraded since 2015, the financial attractiveness of outpatient management remains low[1]. However, some medico-economic studies tend to show that integrating outpatient care into a dedicated care pathway could improve its cost-effectiveness [24]. In addition, the growing number of studies confirming the benefits of robotics on post-operative follow-up, and the absence of prejudice for the patient from a reduction in the period of hospital surveillance, could lead to a reappraisal of this therapeutic approach.

However, other factors also influence the need for hospitalization, such as nursing care, pain control, postoperative ileus, and assistance with mobility. Shortening hospital stay would likely require efforts at addressing these needs in the outpatient/home setting. In our study, the length of stay was associated with medical and surgical complication with a median stay of 3 days (2–4) versus 6 days (4–8) in the complication group even for the non significant complication (CD < 3). However there was a correlation between the severity of complication according to clavien dindo scale and the length of stay (Fig. 5).

4.5. Future prospects

On the basis of these results, it would be interesting to carry out a prospective study to confirm the feasibility of ambulatory surgery based on simple patient selection using clinical assessment scores for patient comorbidities, such as the CCI. In addition, it would be relevant to include the surgeon's clinical assessment of potential technical difficulty. In our study, although tumour size was significant in univariate analysis, only clamping time was significant in multivariate analysis. Considering that it is a reflection of technical difficulty, surgeon assessment appears to be the best predictor of perioperative outcome, and seems to outperform conventional scores according to Khene et al. [26].

5. Conclusion

The time to onset of significant complications was predominantly early, within 72 h, confirming the need for three days' in-hospital monitoring. However, using standard preoperative variables, we were able to determine that the only factor influencing the occurrence of postoperative ESC was ASA score > 2 and thus define it as a primary criterion for eligibility for an indication of outpatient RAPN subject to a clamping time of less than 20 mins.

Disclosure of interest

The authors declare that they have no competing interest.

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