

Role of Clinical and Surgical Factors for the Prediction of Immediate, Early and Late Functional Results, and its Relationship with Cardiovascular Outcome after Partial Nephrectomy: Results from the Prospective Multicenter RECORD 1 Project

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Purpose: We sought to determine the predictors of short-term and long-term renal function impairment after partial nephrectomy.

Materials and Methods: Clinical data on 769 consecutive patients who underwent partial nephrectomy were prospectively recorded at a total of 19 urological Italian centers from 2009 to 2012 in the RECORD 1 (Italian Registry of Conservative Renal Surgery) Project. We extracted clinical data on 708 of these patients who were alive, free of recurrent disease and with a minimum 2-year functional followup.

Results: Of the patients 47.3% underwent open, 36.6% underwent laparoscopic and 16.1% underwent robot-assisted partial nephrectomy. The median baseline estimated glomerular filtration rate was 84.5 ml/minute/1.73 m² (IQR 69.9–99.1). Immediate (day 3 postoperatively), early (month 1) and late (month 24) renal function impairment greater than 25% from baseline was identified in 25.3%, 21.6% and 14.8% of cases, respectively. Female gender and the baseline estimated glomerular filtration rate were independent predictors of immediate, early and late renal function impairment. Age at diagnosis was an independent predictor of immediate and late impairment. Uncontrolled diabetes was an independent predictor of late impairment only. Open and laparoscopic approaches, and pedicle clamping were independent predictors of immediate and early renal function impairment. Overall 58 of 529 patients (11%) experienced postoperative cardiovascular events. Body mass index and late renal function impairment were independent predictors of those events.

Conclusions: Surgically modifiable factors were significantly associated with worse immediate and early functional outcomes after partial nephrectomy while clinically unmodifiable factors affected renal function during the entire followup. Late renal function impairment is an independent predictor of postoperative cardiovascular events.

Key Words: kidney, nephrectomy, robotic surgical procedures, postoperative complications, cardiovascular system

Abbreviations and Acronyms

BMI = body mass index
CKD = chronic kidney disease
CVe = cardiovascular event
DMT2 = diabetes mellitus type 2
eGFR = estimated glomerular filtration rate
OPN = open PN
PN = partial nephrectomy
RAPN = robot-assisted PN
RF = renal function
RN = radical nephrectomy
WIT = warm ischemia time

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To date PN has been the standard treatment of localized renal tumors.¹ When preserving the normal parenchyma is feasible, conservative treatment offers equivalent oncologic results² with better preservation of RF³ compared to RN.

Thus, RF preservation represents a distinct goal of PN. Ischemia time has been historically associated with RF impairment and recommendations support that WIT should be limited to 20 to 25 minutes.^{4,5} Even so, in the last decade several other clinical unmodifiable factors (preoperative renal function, surgical indication, patient age, gender and tumor nephrometry features) and surgical modifiable factors (off clamp or selective clamp procedure, surgical technique and approach) were found to be associated with early and late RF impairment.⁶ These different aspects are often interconnected and the impact on RF is progressively hidden by compensatory hypertrophy from the contralateral and the operated kidney.^{5,7,8} Therefore, many controversies persist and this remains an important area of investigation. In this scenario a better understanding of the role of clinical comorbidities, tumor related features and surgical factors to predict the RF outcome might provide more accurate indications for patient counseling to define a personalized treatment strategy.⁹

In the current study we investigated predictors of short-term and long-term RF evolution, and accounted for possible confounders using a national collaborative project which generated a prospectively compiled, Internet based, comprehensive PN data set.

MATERIAL AND METHODS

The RECORd (Italian Registry of Conservative Renal Surgery) Project is a 4-year prospective, observational, multicenter study promoted by LUNA (Leading Urological No profit foundation Advanced research) of SIFU (Società Italiana di Urologia). Overall 769 consecutive patients underwent PN for a renal tumor at a total of 19 Italian urological institutions from January 2009 to December 2012.¹⁰ An online case report form was generated and centrally controlled to limit missing or wrong data inputs and send timely alerts in case of ignored followup visits.

Uncontrolled DMT2 was defined as patients with glycated hemoglobin (HbA1c) values between 7.5% and 11.0%. The surgical indication was defined as elective—localized unilateral renal cell carcinoma with a healthy contralateral kidney, relative—localized unilateral renal cell carcinoma with the coexistence of comorbidities such as diabetes, hypertension or lithiasis that could potentially affect kidney function in the future, and imperative—bilateral or multiple tumors, moderate to severe chronic kidney disease or neoplasm involving an anatomically or functionally solitary kidney.

Tumor anatomy was thoroughly described according to the location on the longitudinal and transverse planes, and the degree of exophyticity. Renal function was measured as serum creatinine and eGFR using the MDRD (Modification of Diet in Renal Disease) formula at baseline, day 3, and months 1, 6, 12 and 24 after surgery. Patients were treated with OPN, laparoscopic PN or RAPN as well as simple enucleation or standard PN according to surgeon and center preferences.

For the current study we extracted data on 708 patients who were alive, free of disease recurrence and with a minimum 2-year functional followup. Overall 42 patients (5.4%) were excluded from analysis because of recurrence at the time of data analysis, and 19 (2.5%) were excluded because they received surgical or medical therapy for progression.

The functional outcome was measured as an imperative or a relative reduction in eGFR and a decrease in eGFR greater than 25% from baseline. We chose the eGFR decrease greater than 25% from the baseline threshold according to the definition of progression to CKD in the NICE (National Institute for Health and Care Excellence) guidelines.¹¹ Based on results at the different time points the imperative and relative eGFR declines at postoperative day 3, and months 1 and 24 were adopted as study end points and defined as immediate, early and late RF impairment, respectively.

CVe was defined as new onset of myocardial infarction up to 3 weeks after surgery managed by medical treatment, coronary artery disease, unstable angina requiring hospitalization and medical treatment, transient ischemic attack and stroke, a heart failure event, coronary syndrome requiring percutaneous transluminal coronary angioplasty or peripheral artery disease requiring intervention.

Parametric and nonparametric continuous variables are reported as appropriate. Logistic univariable and multivariable regression analyses were done to identify predictors of functional renal impairment. A multivariable Cox proportional hazards regression model of CVe was fitted. Discrimination was evaluated by the ROC AUC and the Harrell concordance index as appropriate. Statistical significance was considered at $p < 0.05$ and all reported p values are 2-sided. Analyses were done with STATA®, version 14.1.

RESULTS

Table 1 summarizes the baseline features of the cohort. Median preoperative eGFR was 84.5 ml/minute/1.73 m². Preoperative eGFR was within the range of normality (CKD stage 1) in 39% of patients. A 12.9% rate of baseline CKD stage 3 or greater was observed. A clampless procedure was used in 37.6% of patients. Hilum clamping was done in the remaining 442 patients (62.4%) with a median WIT of 17 minutes (IQR 13–22).

Supplementary table 1 (<http://jurology.com/>) shows postoperative and followup outcomes. Median functional followup was 27 months (IQR 25.5–29.5).

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