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Kidney Cancer

Two-year Follow-up for Oncological, Functional, and Quality-of-Life Outcomes in the Randomized ROBOCOP II Trial of Robot-assisted Versus Conventional Open Partial Nephrectomy

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Abstract

Background and objective: Robot-assisted partial nephrectomy (RAPN) is increasingly used to treat renal cell carcinoma (RCC), but randomized data comparing long-term outcomes to those after open partial nephrectomy (OPN) remain limited. Our aim was to compare oncological, renal function, and health-related quality of life (HRQOL) outcomes at 2 yr for patients who underwent RAPN versus OPN.

Methods: This single-center phase 2 randomized controlled trial included 50 patients with suspected localized RCC who were randomized 1:1 to RAPN or OPN. After 2-yr follow-up, we assessed overall survival (OS), recurrence-free survival, renal function, and HRQOL, including chronic postoperative pain and flank bulge. Analyses were conducted on an intention-to-treat basis.

Key findings and limitations: All but one patient completed oncological and renal follow-up, and 47 provided HRQOL data. At 2 yr, overall survival was 100%, with one lymph-node recurrence in the RAPN group. The adjusted mean estimated glomerular filtration rate did not differ between the groups (OPN 74.1 ml/min/1.73 m², 95% confidence interval [CI] 69.7–78.5; RAPN 75.8 ml/min/1.73 m², 95% CI 71.3–80.1; *p* = 0.59). HRQOL at 2 yr remained high, with no significant difference in changes from baseline between the two groups. Chronic postoperative pain at the operative site (44% vs 0%; *p* = 0.001) and flank bulge (32% vs 0%; *p* = 0.007) were significantly more common in the OPN group versus the RAPN group.

Conclusions and clinical implications: RAPN and OPN yielded excellent long-term outcomes. RAPN offers advantages in terms of postoperative morbidity without compromising renal function or QOL.

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ADVANCING PRACTICE

What does this study add?

This randomized controlled trial provides the first prospective 2-yr comparison of robot-assisted versus open partial nephrectomy with a focus on oncological outcomes, renal function, and patient-reported quality of life. The results demonstrate that robotic surgery leads to fewer long-term complications such as chronic wound pain and flank bulge, while maintaining excellent cancer control and kidney function. These findings highlight potential advantages of robotic surgery in long-term recovery and postoperative morbidity.

Clinical Relevance

In the present randomized study, the authors found that both open and robot-assisted partial nephrectomy provide comparable oncological outcomes as well as outcomes in health related quality of life. Patients with robot-assisted partial nephrectomy had significantly less postoperative pain as well as flank bulging compared to open surgery at 2 year follow-up. These data further support the use of robot-assisted partial nephrectomy as treatment option of first choice whenever technically feasible and available. Associate Editor: Christian Gratzke.

Patient Summary

Our study compared results at 2 years after two types of surgery (robot-assisted keyhole surgery and open surgery) for removing kidney tumors. Both approaches were equally effective in curing the cancer and preserving kidney function. However, patients who had robotic surgery were less likely to have long-term wound pain or bulging at the surgical site.

1. Introduction

Partial nephrectomy (PN) is the gold standard for the treatment of small renal masses. Over the past decade, robot-assisted PN (RAPN) has gained widespread popularity, replacing open PN (OPN) in many centers. The European Association of Urology (EAU) guidelines on renal cancer recommend that the choice between open, pure laparoscopic, and robot-assisted approach should be based on the surgeon's expertise and skills [1]. The ROBOCOP II trial randomized patients to RAPN or OPN. The rationale and detailed study characteristics were published in the study protocol [2]. Perioperative outcomes up to 90 d after surgery revealed fewer complications in the RAPN group, as reflected by a significantly lower mean Comprehensive Complication Index (OPN 14, standard deviation [SD] 16; RAPN 5, SD 15; $p = 0.008$). In addition, RAPN was associated with lower blood loss, opioid use, and postoperative pain scores both at hospital discharge and 30 d after surgery. However, OPN was associated with shorter overall operating time and shorter warm ischemia time (WIT) [3,4]. Most recently, 30-d data from the OpeRa trial yielded similar results [5].

Beyond these early outcomes, 2-yr follow-up was conducted for patients randomized in the ROBOCOP II trial. Here we report oncological and functional outcomes, as well as health-related quality of life (HRQOL), following RAPN and OPN.

2. Patients and methods**2.1. Study design**

As previously described, ROBOCOP II was a single-center, investigator-initiated, phase 2 randomized controlled trial (RCT) comparing OPN and RAPN in patients with suspected localized renal cell carcinoma [2]. The trial received ethics committee approval (reference 2020-542N)

and was registered on ClinicalTrials.gov (NCT04534998). ROBOCOP II involved multiple surgeons and used an unblinded design. A total of 50 patients were block randomized in a 1:1 ratio via a web-based computer tool with varying block lengths of four and six to undergo either OPN or RAPN. The trial was conducted at the Department of Urology and Urological Surgery, University Medical Center Mannheim, Germany, and was monitored by the Study Center of the German Society of Surgery.

The perioperative results and short-term HRQOL outcomes have previously been published [3,4]. Here we report 2-yr results for oncological outcomes, long-term kidney function, and HRQOL.

Eligible patients were adults (≥ 18 yr) scheduled for elective PN for localized renal tumors, with RAPN and OPN approaches both deemed feasible by all surgeons on the basis of preoperative imaging. Participants had to be capable of understanding the study and providing written informed consent, and preoperative computed tomography (CT) or magnetic resonance imaging (MRI) of the abdomen was required. Exclusion criteria included a solitary kidney, cognitive or legal vulnerability (eg, dementia), a need for emergency intervention, concurrent second surgery, the presence of multiple kidney tumors, or a second malignancy rendering PN clinically unnecessary.

In the RAPN group, surgery was performed via a transperitoneal robotic approach. After establishment of pneumoperitoneum and placement of trocars (4 robotic, 1 assistant), the kidney was mobilized and the tumor was localized. The renal vessels were dissected, and the renal artery was routinely clamped before excision. Tumor excision was typically performed via tumor enucleation or enucleoresection, with the aim of preserving as much healthy parenchyma as possible. Renorrhaphy was then performed using a sliding-clip or barbed suture technique.

In the OPN group, all patients underwent surgery through a standardized flank incision via a retroperitoneal approach. The renal hilum was exposed and the artery was clamped in all cases. Tumor removal was likewise performed via either enucleation or enucleoresection, following the same principles of parenchymal preservation. The renal defect was closed with two-layer continuous renorrhaphy using absorbable sutures. No blinding of surgeons, patients, caregivers, or outcome assessors was performed. There was no patient or public involvement.

2.2. Outcomes

2.2.1. Survival and oncological outcomes

Overall survival was assessed by contacting all patients or their primary care physicians via telephone 2 yr after PN. Oncological follow-up for patients with malignancy was based on the German kidney cancer guidelines and was routinely organized by each patient's primary care physician. The imaging reports were acquired by study personnel and no centralized review was performed. For patients with low-risk tumors (pT1a/b and grade 1/2 and R0), surveillance includes clinical examination, laboratory tests, and abdominal ultrasound at regular intervals up to 5 yr, with CT of the chest at 12, 24, and 48 mo, and abdominal CT at 3, 24, and 48 mo. For patients with intermediate-risk tumors (pT1a/b and grade 3 or R1), follow-up is extended to 9 yr. CT of the chest and abdomen is performed at 3, 12, 24, 48, 84, and 108 mo.

2.2.2. Renal function

Renal function was assessed as the estimated glomerular filtration rate (eGFR) using the Chronic Kidney Disease-Epidemiology Collaboration formula taken from laboratory reports provided by primary care physicians.

2.2.3. Persistent wound-related symptoms

Chronic postoperative pain in the area of the surgical access site was assessed via telephone interview by study personnel. Patients were explicitly asked if they were experiencing chronic postoperative pain or numbness in the area of the incisions. If a patient answered that they were experiencing pain, they were asked to rate the pain on a numeric rating scale (NRS) ranging from 0 (no pain) to 10 (excruciating pain) both at rest and on exertion, and to describe the pain from a range of options (burning, pulling, electrifying, stabbing, other) [6]. Patients were also asked if they had developed a flank bulge in the surgical area. If the answer was "yes", the patient provided photographic documentation that was confirmed and assessed by the study team.

2.2.4. HRQOL

HRQOL was assessed using the Kidney Disease QOL-Short Form (KDQOL-SF) questionnaire and the European Organization for Research and Treatment of Cancer (EORTC) QOL questionnaire-Core 30 (QLQ-C30) [7,8]. These questionnaires allow self-assessment of general (QLQ-C30) and kidney-specific (KDQOL-SF) HRQOL. Depending on patient preference, the questionnaires were mailed for manual completion or filled out using an online form.

2.3. Statistical analysis

Group baseline characteristics were compared using the mean value and SD or the median value and interquartile range for continuous variables, and the frequency and percentage for categorical variables. All analyses were performed in an intention-to-treat fashion and included all randomized participants. Kaplan-Meier analysis was performed for survival outcomes, with follow-up starting on the date of surgery. As overall survival was 100% and event rates were very low, no formal testing was performed. Patients who did not experience an event were censored at their last follow-up. For longitudinal assessment of eGFR and HRQOL, linear mixed-effects model analyses were performed using the *lmer* function from the *lme4* package in R v2024.04.2+764. Models included a patient-specific random intercept to account for correlation of repeated measurements within individuals, fixed effects for treatment group, time points, and their interaction, as well as covariates for sex, age, and baseline values. Treatment group comparisons at each time point were based on estimated marginal means using the *emmeans* package. For HRQOL, between-group differences were quantified as the adjusted mean difference (AMD) at each follow-up time point rather than simple unadjusted

change scores. Outcomes assessed only at 2-yr follow-up (wound-related symptoms) were analyzed using cross-sectional Fisher's exact tests. Deidentified data and the statistical analysis plan can be shared on reasonable request. There were no changes to the initial trial protocol [2]. As this was a feasibility trial, no formal sample-size calculation was performed.

2.4. Funding

The study received support from the Dietmar Hopp Foundation (<https://dietmar-hopp-stiftung.de/startseite.html>). The funding body had no role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or in the preparation, review, or approval of the manuscript.

3. Results

Overall, follow-up data were obtained for all 50 randomized patients who had undergone OPN or RAPN between June 2020 and November 2021. Two patients refused to take part in the HRQOL surveys, and one patient returned an empty questionnaire. For one patient, follow-up for oncological outcomes and kidney function was not possible; however, long-term wound-related complications were assessed via a telephone interview. Thus, survival outcomes were available for 50 patients, oncological follow-up was available for 40 out of 41 patients with kidney cancer, kidney function data were available for 49 patients, data on persistent wound-related symptoms were available for 50 patients, and a completed HRQOL questionnaire was obtained from 47 patients. Baseline characteristics of the patients are presented in Table 1.

3.1. Survival

At last follow-up, all patients were alive. Therefore, no statistical comparison of overall survival was performed. Of the 41 patients with malignancies (RAPN = 20; OPN = 21), only one patient in the RAPN group had experienced recurrence in the form of lymph node metastasis, and one patient in the OPN group did not have information on radiological staging and was treated as censored after 1 mo for analysis of progression-free and recurrence-free survival. The results are presented in Table 1 and Figure 1.

3.2. Kidney function

Data on kidney function at 2 yr were available for all but one patient. There was no significant difference in adjusted mean GFR at 2-yr follow-up between the groups (OPN: 74 ml/min/1.73 m², 95% CI 70–79; RAPN: 76 ml/min/1.73 m², 95% CI 71–80; AMD –2 ml/min/1.73 m², 95% CI –8 to 4; *p* = 0.6). Changes from baseline at the different time points are shown in Figure 2.

3.3. HRQOL

HRQOL data were available for 47 patients at 2-yr follow-up. Of these, two patients had not completed the baseline questionnaires. Therefore, data for the change from baseline to 2-yr follow-up were available for 45 patients.

Table 1 – Patient characteristics and overall and oncological survival

Parameter	OPN (n = 25)	RAPN (n = 25)
Median age, yr (IQR)	64 (54–71)	65 (58–71)
Female, n (%)	7 (28)	6 (24)
Kidney cancer (n)	21	20
Tumor stage (n)		
T1a	17	14
T1b	4	6
Mean tumor size, cm (standard deviation)	2.9 (1.2)	3.0 (1.3)
Median glomerular filtration rate, ml/min/1.73 m ² (IQR)	87 (66; 95)	74 (65; 81)
Oncologic outcomes		
Median follow-up for overall survival, mo (IQR)	23 (23–25)	24 (23–24)
Deaths at last follow-up (n)	0	0
Recurrence at last follow-up among malignant cases (n)	1	0
Progression at last follow-up among malignant cases (n)	1	0

IQR = interquartile range; OPN = open partial nephrectomy; RAPN = robot-assisted partial nephrectomy.

3.3.1. Chronic postoperative pain and flank bulge

No patients in the RAPN group and 44% of those in the OPN group experienced chronic pain in the surgical area (risk difference [RD] -0.44, 95% CI -0.21– -0.67; *p* < 0.001). No patients in the RAPN group and 32% in the OPN group experienced flank bulge (RD -0.32, 95% CI -0.1– -0.54; *p* = 0.004). Some 8% of patients in the RAPN group and 36% in the OPN group experienced numbness in the surgical area (RD -0.28, 95% CI -0.02– -0.54; *p* = 0.037; Fig. 2A). Pain levels were only recorded if patients stated that they experienced pain. As no patient in the RARP group reported pain, no between-group comparison of pain levels was possible.

In the OPN group, the mean NRS pain score was 1.7 (95% CI 0.3–3.1) at rest and 3.9 (95% CI 2–5.8) on exertion.

3.3.2. EORTC QLQ-C30

Linear mixed-effects model analysis revealed no significant difference in mean overall QLQ-C30 score between the two groups at 2 yr (RAPN: 86, 95% CI 79–94; OPN: 85, 95% CI 76–93; mean difference 2, 95% CI -9 to 13; *p* = 0.7; Fig. 3). Global QOL scores exceeded 75 on the scale from 0 to 100, which reflects a high level of patient-reported wellbeing (Supplementary Table 1) [9].

3.3.3. KDQOL-SF

While there were significant differences in KDQOL-SF scores between the groups at discharge (energy/fatigue; overall health; pain; burden of kidney disease) and at 30 d (physical role functioning) favoring RAPN, at 2-yr follow-up there were no significant differences between the groups for either kidney disease-specific domains (Fig. 4) or KDQOL-SF-36 core dimensions (Supplementary Table 2 and Supplementary Fig. 1).

4. Discussion

In this RCT comparing OPN and RAPN for renal masses, 2-yr follow-up data showed 100% survival in both groups and similar recurrence- and progression-free survival. HRQOL was generally high, with comparable changes from baseline in the two groups. The incidence rates for chronic postoperative pain and numbness in the surgical area and flank bulge were significantly higher in the RAPN group.

While this RCT was not powered to examine long-term survival or HRQOL outcomes and thus our results should

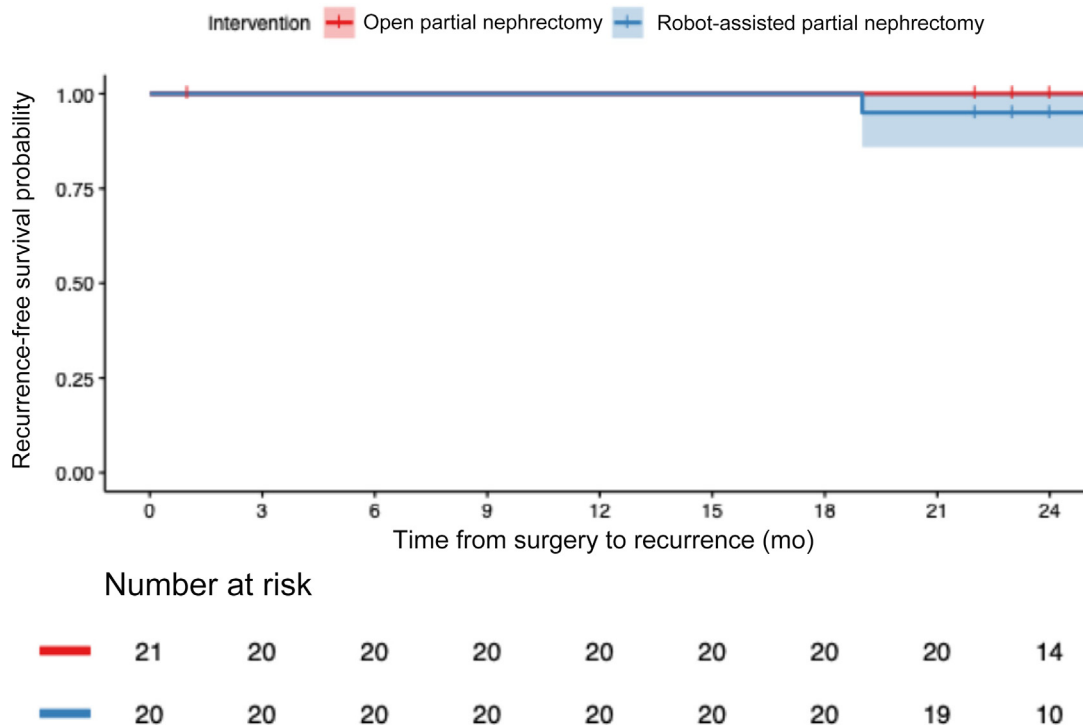


Fig. 1 – Recurrence-free survival (identical to progression-free survival).

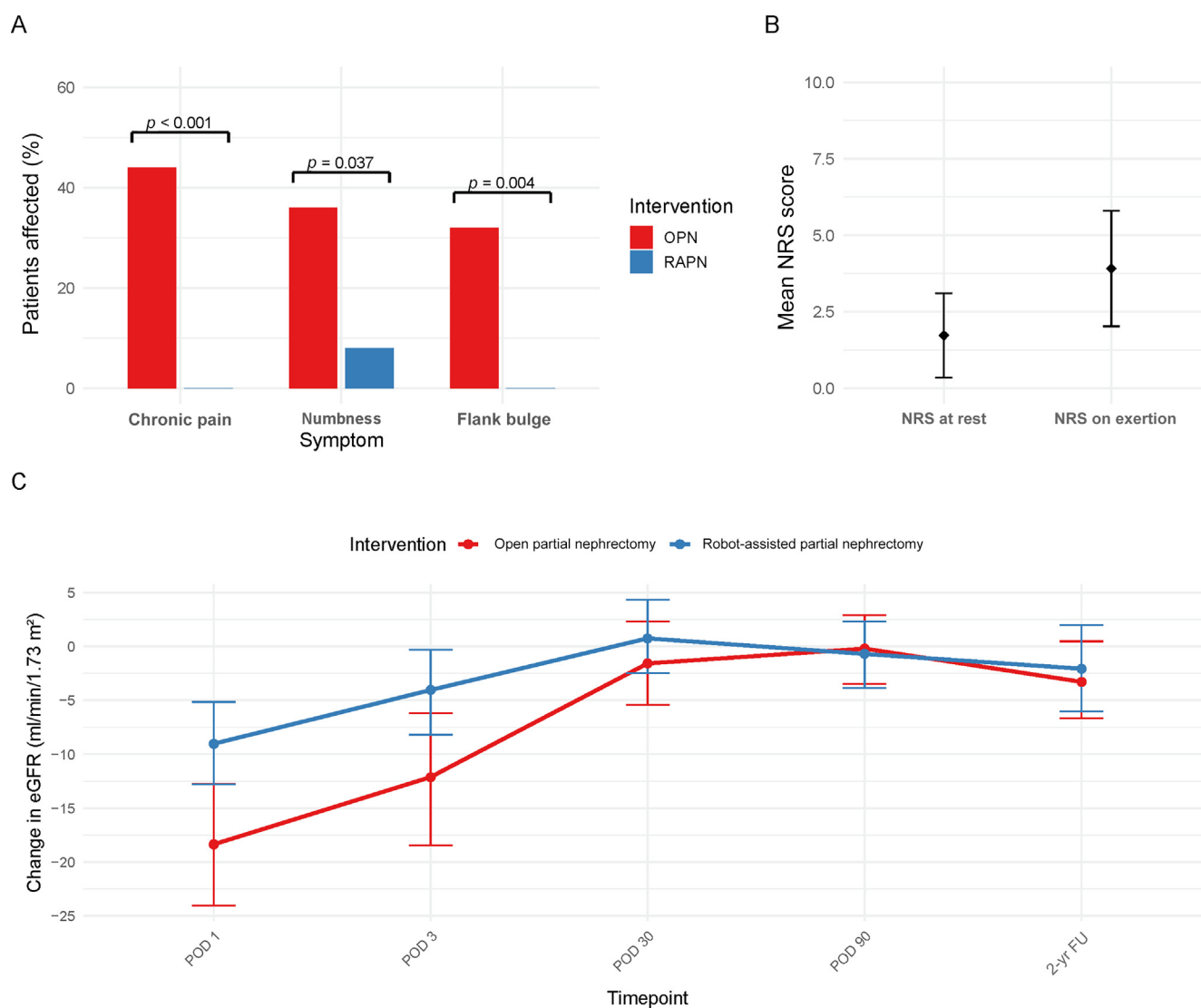


Fig. 2 – (A) Long-term postoperative complications at 2 yr (Fisher’s exact test for comparison between groups). (B) Chronic postoperative pain in the OPN group at 2 yr. NRS scores were only acquired for patients who reported chronic pain, due to this, so there are no data for the RAPN group. Error bars represent the 95% confidence interval. (C) Kidney function in terms of the adjusted mean change in eGFR from baseline. Error bars represent the 95% confidence intervals. OPN = open partial nephrectomy; RAPN = robot-assisted partial nephrectomy; eGFR = estimated glomerular filtration rate; POD = postoperative day; FU = follow-up, NRS = numeric rating scale (0–10).

be seen as explorative, differences in the incidence of chronic postoperative pain in the wound area, flank bulge, and numbness in the wound area between the two groups are striking. The differences for all three outcomes exceed 25% and should probably be viewed as clinically relevant. The 95% CIs for two outcomes are $\geq 10\%$, which can be interpreted as a minimal clinically relevant difference (MCRD). For numbness, the 95% CI also includes a difference of $< 5\%$, which is probably not clinically relevant.

As the QLQ-C30 and KDQOL-SF questionnaires were not specifically developed for assessment of postoperative outcomes, it is not surprising that no differences in general pain scores were observed, as these tools focus more on general assessment of pain and its interference with daily life. For pain on exertion, among the 11 patients who were experiencing pain, seven reported NRS scores > 3 points, indicating significant pain, while two patients reported NRS scores of 8 and

9, indicating severe pain. These HRQOL data are unique in the literature and support common clinical knowledge that while both RAPN and OPN have excellent clinical outcomes, RAPN is associated with faster recovery and less pain in the smaller wound area. Inkiläinen et al [10] assessed abdominal wall morbidity after OPN and found that 18% of patients experienced postoperative pain and 35% reported abdominal wall asymmetry, with obese patients generally at higher risk. In a study that examined chronic postoperative pain after open nephrectomy, patients with high anxiety scores and multiple comorbidities and comorbidity-related disabilities were at higher risk of experiencing chronic postoperative pain [11]. These findings are in line with our data and are important when counseling patients who are deciding on whether to undergo OPN or RAPN.

It is reassuring that no significant differences in general HRQOL (QLQ-C30 and KDQOL-SF) between OPN and RAPN

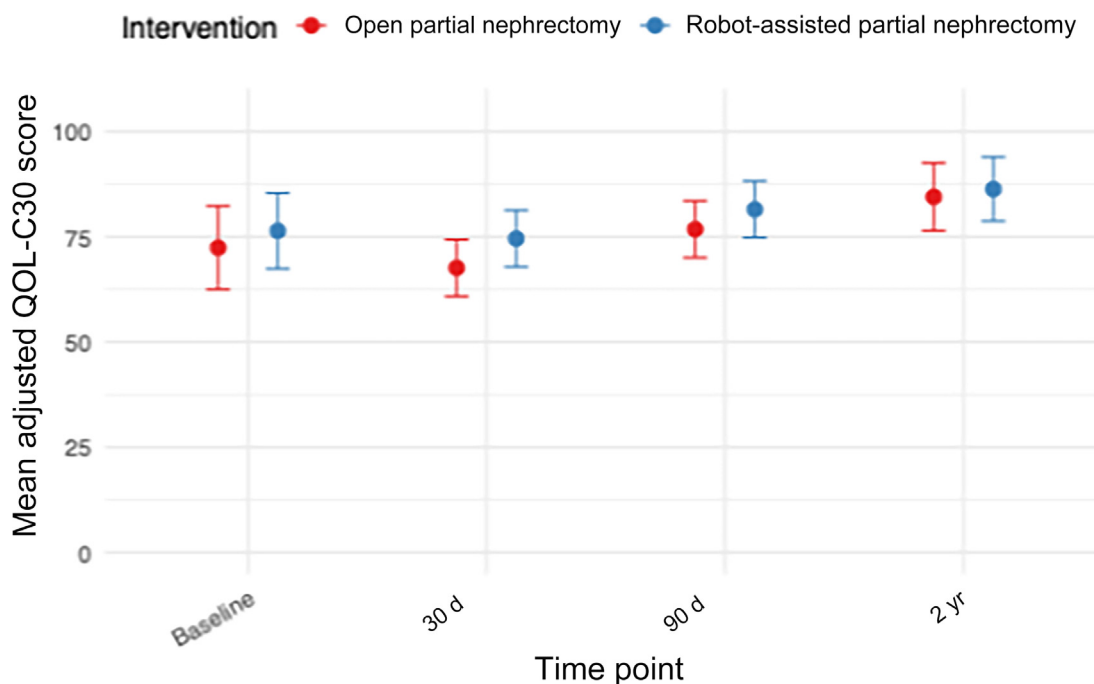


Fig. 3 – Adjusted mean Quality of Life-Core 30 (QOL-C30) overall scores. Error bars represent the 95% confidence interval.

became apparent at 2-yr follow-up. While it is generally accepted that the MCRD is between 5 and 10 points, and the trial was not powered to show differences in this range, the mean HRQOL differences between the two approaches did not cross this threshold at 30 d after surgery. Even so, the 95% CI for some domains crossed the 10-point difference level in both directions, which indicates the possibility of clinically meaningful differences in HRQOL.

An interesting finding in the 2-yr analysis is the absence of significant changes in long-term renal function, even though there had been a significant difference in WIT favoring OPN (OPN 8.7 min, SD 7.1; RAPN 15.4 min, SD 7.0; difference -6.7 min, 95% CI -10.7 to -2.7 ; $p = 0.001$). While the eGFR decrease in the initial postoperative period was greater in the OPN group (AMD in change from baseline for OPN vs RAPN: -9.1 ml/min/ 1.73 m² on postoperative day 1, $p = 0.0033$; -7.5 ml/min/ 1.73 m² on postoperative day 3, $p = 0.0165$), this can probably be attributed to the operative approach and could have concealed a real GFR decrease in the RAPN group because of tissue damage due to longer ischemia. Trials assessing off-clamp PN were not successful and resulted in a recommendation against off-clamp PN from the EAU [12], and this procedure is not performed at our institution. This supports a growing body of evidence indicating that for patients with preserved baseline renal function, modest differences in WIT, such as the one observed here, do not result in long-term clinically meaningful renal impairment.

4.1. Limitations

As already mentioned, this trial was not designed to measure differences in long-term outcomes such as recurrence-free or overall survival. The nonspecific HRQOL scores should therefore be interpreted with caution, as the

power for measurement of differences was low. However, oncological follow-up was nearly complete and only a few patients missed the HRQOL assessment, so attrition bias can be considered low and these results can be taken as a baseline for future trials. An additional limitation of this study is the indirectness of outcome data collection. Overall survival, postoperative pain, and QOL were assessed via patient self-reporting, while recurrence-free survival and renal function were based on imaging and laboratory reports obtained from external primary care providers. No centralized imaging review was conducted. While this approach reflects real-world practice, it may introduce variability in data quality and limit the consistency of outcome assessments.

4.2. Strengths

To date, this is the only RCT to report long-term oncological and HRQOL outcomes in this setting. Recent results from the OpeRa study revealed similar short-term outcomes as in ROBOCOP II, with 1-yr QOL outcomes available; however, longer-term results are still lacking and will add important information [5]. To the best of our knowledge, these are the only two trials that have prospectively assessed HRQOL after PN and provide very important insights into the postoperative course for these patients.

5. Conclusions

The trial results confirm that both RAPN and OPN offer excellent oncological control for small renal lesions and support the EAU guidelines on this topic. However, RAPN provided clear advantages in terms of postoperative pain and wound-related morbidity, without compromising renal function or HRQOL at 2 yr. RAPN was associated with lower

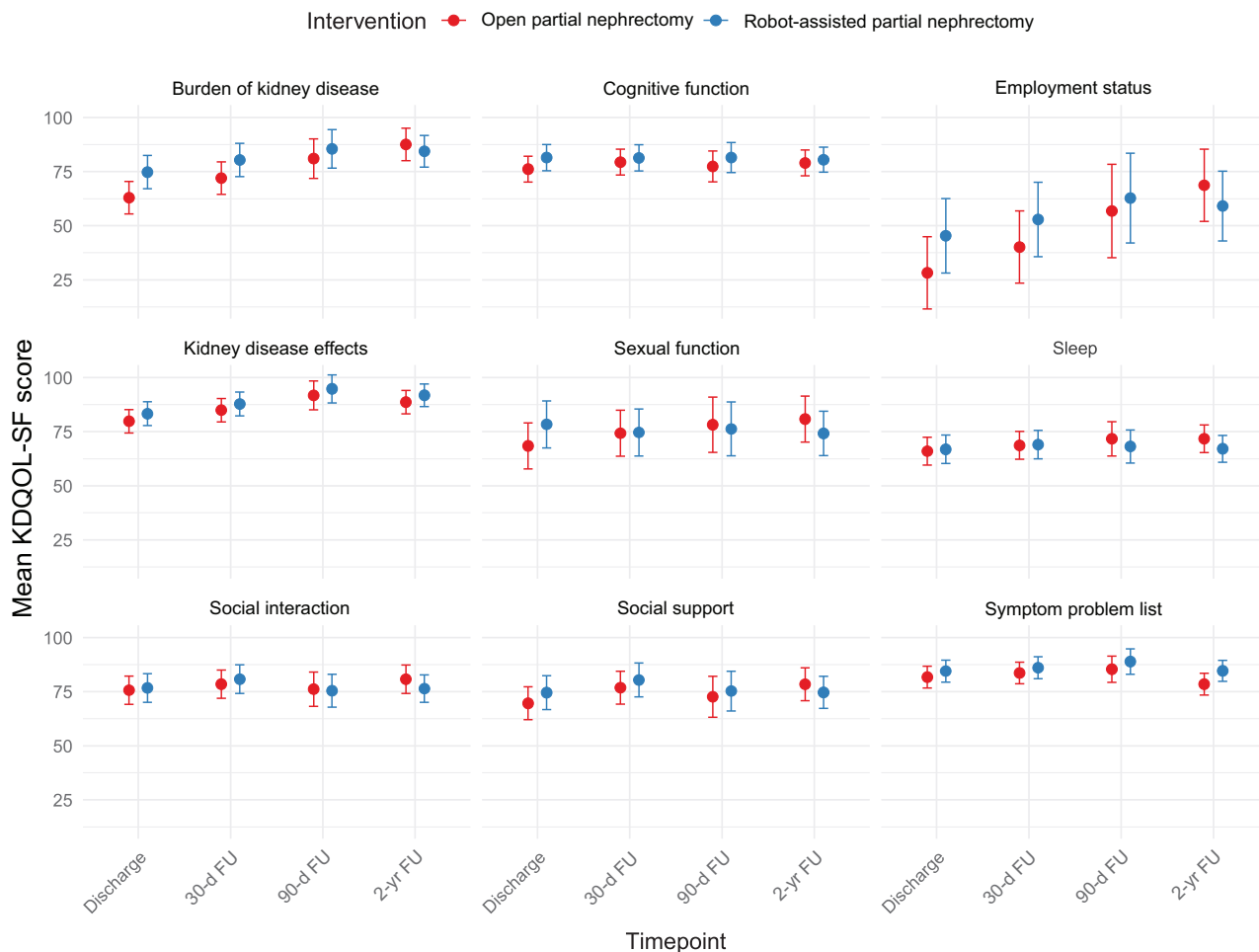


Fig. 4 – Adjusted mean scores for Kidney Disease Quality of Life-Short Form (KDQOL-SF) disease-specific domains. Error bars represent the 95% confidence interval; FU = follow-up.

blood loss, surgical complication rates and in-hospital opioid use, better postoperative kidney function recovery and short-term postoperative HRQOL, and less frequent wound pain and flank bulge at 2 yr. OPN was associated with slightly shorter operating time and WIT. In patients with localized kidney tumors suitable for both OPN and RAPN, RAPN should be the surgical approach of choice.

Author contributions: Karl-Friedrich Kowalewski 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.

Study concept and design: Haney-Aubert, Kowalewski, Michel.

Acquisition of data: Gottstein, Sidoti Abate, Menold, Neuberger, Westhoff.

Analysis and interpretation of data: Haney-Aubert, Gottstein, Sidoti Abate.

Drafting of the manuscript: Haney-Aubert, Kowalewski, Neuberger.

Critical revision of the manuscript for important intellectual content: Nuhn, Westhoff, Honeck, Michel, Kriegmair.

Statistical analysis: Haney-Aubert, Kowalewski.

Obtaining funding: Haney-Aubert, Kowalewski.

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Supervision: Kriegmair, Michel, Honeck, Nuhn.

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Appendix A. Supplementary data

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