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Partial nephrectomy vs cryoablation for T1a renal cell carcinoma: A comparison of survival benefit stratified by tumour size

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ABSTRACT

Objective: We compared the impact on survival outcomes of partial nephrectomy (PN) and cryoablation (CA) for patients diagnosed with T1a renal cell carcinoma (RCC).

Patients and Methods: Among patients diagnosed between 2004 and 2014 in the Surveillance, Epidemiology and End Results program, we identified histologically confirmed T1aN0M0 RCC treated with PN (n = 17644) or CA (n = 868). Propensity score matching (PSM) was performed. Kaplan-Meier method, Cox proportional hazards model were used to calculate cancer specific mortality (CSM) and overall mortality (OM) in the unmatched and matched cohort, and in subgroups based on tumour size (< 2 cm, 2-3 cm, 3-4 cm). Sensitivity analyses were performed.

Results: A total of 18512 patients were identified: PN (93.88%) and CA (6.12%). In the propensity-score matched cohort, for tumours ≤ 2 cm, the CA and PN groups had similar CSM (HR: 1.41, 95% CI: 0.32–6.31, p = 0.65) and OM (HR 0.97, 95%CI: 0.47–2.01, p = 0.93). For tumours 2-3 cm, CA was associated with similar CSM (HR 1.64, 95%CI: 0.67–4.03, p = 0.28) but higher OM (HR 2.05, 95%CI: 1.35–3.11, p < 0.001), compared with PN. For tumours 3-4 cm, CA was associated with increased CSM (HR: 3.76, 95% CI: 1.62–8.69, p = 0.002) and OM (HR 2.17, 95%CI: 1.48–3.18, p < 0.001).

Conclusion: For RCC ≤ 2 cm, PN and CA are equal in survival outcomes. For RCC 2-4 cm, PN may have a possible advantage over CA.

1. Introduction

The incidence rate of kidney cancer is rising in most countries, and it's mainly attributable to an increase in stage T1a renal cancer that is presumably curable [1,2]. Stage T1a renal cancer now makes up 48–66% of all renal tumours that are diagnosed [3,4]. Historically, surgery has been the standard treatment of stage T1a RCC [5,6]. Survival outcomes of active surveillance are controversial in several studies [7–9]. Most population-based analyses showed a significantly lower cancer-specific mortality (CSM) is associated with surgical treatment [6].

Partial nephrectomy (PN), a nephron-sparing treatment, is now the benchmark for treatment of T1a RCC [5,6]. PN can be performed, either using an open, pure laparoscopic- or robot-assisted approach, based on surgeons' expertise and skills [6]. For organ-confined renal cancer, PN is associated with similar CSM [10–12], as well as lower overall mortality (OM) [13,14] compared with radical nephrectomy. However, PN rates have plateaued at around 40% of all localized RCC treatments [15,16].

Cryoablation (CA), recommended by European Association of Urology as an alternative treatment for cT1a renal tumour in high-risk surgical patients [17], is performed, either with a percutaneous or a laparoscopic-assisted approach with the latter being increasingly favoured. Since the initiation of ablation surgeries for small renal masses in the 1990s, the number of ablations performed has been steadily increasing and has reached a plateau of approximately 7% of all T1 RCCs treated in the USA [18]. CA is an ideal minimally invasive modality due to superior renal function outcomes and low rates of complications. A recent systematic review looked through the available data and demonstrated a lower rate of recurrence-free survival was associated with

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CA compared with extirpative surgeries, but emerging studies suggested that patients treated with CA might have comparable survival outcomes in the intermediate term [19]. Prospective studies investigating oncological results with long-term follow up are needed.

Studies were conducted to compared open, laparoscopic or robotic PN with percutaneous or laparoscopic cryoablation, of which the oncological outcomes were mixed. Some studies showed no difference in OM and CSM [20,21], while others suggested a significant benefit of the PN techniques [22–25]. However, there's no RCT comparing survival outcomes between different ablation methods or with PN.

The survival benefit for patients with RCC is the primary goal of RCC treatments. We aim to compare survival outcomes of PN and CA in this population-based analysis using data from Surveillance, Epidemiology, and End Results (SEER) program.

2. Material and methods

2.1. Study population

We identified consecutive adult patients (age at diagnosis ≥ 18 years old) with first diagnosed T1aN0M0 RCC who had PN or CA as the primary treatment between 1 January 2004 and 31 December 2014 in the National Cancer Institute's SEER database. SEER program database collected parameters regarding demographic characteristics, tumour characteristics, the course of treatment, and survival outcomes. We conducted this study accordance with the SEER research data use agreement.

The International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3) site code was restricted to C64.9 to identify patients with kidney cancer. TNM status was classified according to the American Joint Committee on Cancer (AJCC) 6th edition. Surgery codes were 30, 13 for PN and CN respectively in kidney cancer in the SEER program. We excluded patients with bilateral cancer, other malignancy, and those who underwent radiation therapy. A flowchart of the SEER query and exclusions can be seen in Fig. 1.

2.2. Covariates

Baseline characteristics were adjusted for in analyses, including demographical characteristics (sex, marital status, age, race, region, and year of diagnosis) and tumour characteristics (histologic subtype, grade, tumour laterality, tumour size). Tumour sizes are recorded as the largest dimension or diameter of the primary tumour. And they are recorded in millimeters from 1983 onwards.

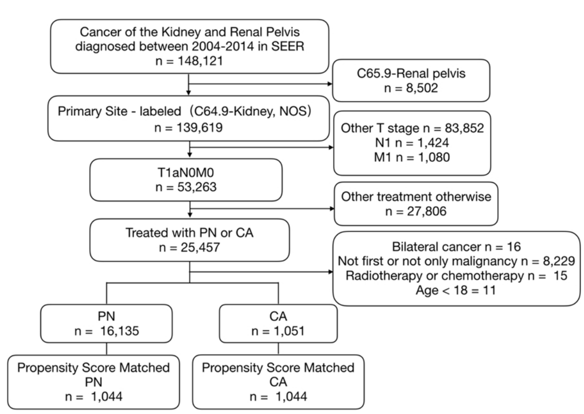

Fig. 1. Patients selection process. SEER = Surveillance, Epidemiology and End Results. RCC = Renal Cell Carcinoma; PN = Partial Nephrectomy; CA = Cryoablation.

2.3. Outcomes

We estimated CSM and OM of T1a RCC diagnosed between January 2004 and December 2014 by underlying cause-of-death information from state death certificates, with follow-up till December 2015.

2.4. Statistical analysis

For baseline characteristics, categorical variables were expressed as frequency with its proportion. Pearson's chi-square test was used to determine any statistical difference between proportions of the two groups. We compared CSM and OM of two treatment groups by using the unadjusted Kaplan-Meier curves with the log-rank test followed by Cox regression models adjusting for all demographic and tumour characteristics. Subset analyses were conducted by stratifying patients by tumour size. To confirm the results, we performed a secondary analysis using propensity score matching (PSM) since two treatment groups differed significantly in some of the baseline characteristics.

Propensity scores were estimated in multivariable logistic regression models, where the dependent variable was the primary procedure (CA vs PN). The independent variables for the PSM included all available patient and disease characteristics except for grade and histological subtype. We applied the greedy matching method within specified calliper distances to match patients in two treatment groups with the matching ratio of 1:1 using a calliper equal to 0.05. Covariate balance between treatment groups was examined by standardized difference, with a value less than 0.10 considered balanced [26]. The same statistical analyses mentioned above were conducted in the matched cohort and the tumour size subgroups of it.

Because the percentage of missing data was less than 1%, no imputation was performed.

2.5. Sensitivity analysis

To test the robustness of our results, we conducted 3 sensitivity analyses. Firstly, Cox regression with the competing risk model was performed in the unmatched and matched cohort. Second, the inverse-probability-of-treatment weighting (IPTW) method was used, which made the distribution of risk factors equal to that in total patients [26]. And the standardized mortality ratio weighting (SMRW) method was also utilized, which made the distribution of risk factors equal to that in the CA group [27]. The two weighting methods focused on treatment effects in different standard populations. Covariates for each model were identical to those in the PSM described above. Third, we conducted an analysis in which tumour grade, histological subtypes, and all the other baseline characteristics were included as independent variables for PSM.

All the analyses were performed with the statistical software packages R (http://www.R-project.org, The R Foundation) and EmpowerStats (http://www.empowerstats.com, X&Y Solutions, Inc., Boston, MA). A p value < 0.05 was considered statistically significant.

3. Results

3.1. Baseline patient characteristics

A total of 17,186 patients who were diagnosed with first RCC and treated with PN (93.88%) or CA (6.12%) between 2004 and 2014 were identified. In the unmatched cohort, compared with patients underwent PN, those underwent CA were older ($p < 0.001$), more likely to be unmarried ($p = 0.020$), white ($p = 0.016$), diagnosed in the most recent years ($p < 0.001$), and from the Pacific Coast ($p < 0.001$). There were also significant differences in the tumour characteristics (histologic subtypes, grade, and tumour size) between patients who received CA compared with those who received PN (all $p < 0.001$) (Table 1).

Table 1
Baseline characteristics of unmatched cohort and matched cohort. PN = partial nephrectomy; CA = cryoablation.

	Before matching			After matching		
	PN N = 16,135	CA N = 1051	P-value	PN N = 1044	CA N = 1044	P value
Age			< 0.001			0.680
< =50	31.2	9.4		10.9	9.4	
> 50, < =60	29.1	20.3		20.3	20.3	
> 60, < =70	26.7	30.6		30.6	30.6	
> 70	13	39.7		38.2	39.7	
Sex			0.739			0.790
Female	40.3	39.8		40.4	39.8	
Male	59.7	60.2		59.6	60.2	
Marital status			0.020			0.592
Married	63.6	60		61.3	60	
Unmarried	36.4	40		38.7	40	
Year of diagnosis			< 0.001			0.822
2004–2007	20.4	15.6		15.4	15.6	
2008–2011	38.5	40.7		39.6	40.7	
2012–2014	41.1	43.7		45	43.7	
Race			0.016			0.461
White	81.9	85.3		83.6	85.3	
Black	10.6	8.8		9.2	8.8	
Others	7.6	5.9		7.1	5.9	
Region			< 0.001			0.538
Pacific Coast	43.7	50.7		50.6	50.7	
East	43.4	29.8		31.5	29.8	
Others	13	19.5		17.9	19.5	
Tumour laterality			0.933			0.600
Left	48.1	48		46.8	48	
Right	51.9	52		53.2	52	
Histologic subtype			< 0.001			< 0.001
Clear Cell	60.2	40.2		60.2	40.2	
Non-Clear Cell	39.8	59.8		39.8	59.8	
Grade			< 0.001			< 0.001
Grade I/Grade II	70.1	39.8		68.1	39.8	
Grade III/Grade IV	17	2.8		18.6	2.8	
Unknown	12.9	57.5		13.3	57.5	
Tumour Size			< 0.001			0.973
< 2 cm	27.6	21.5		21.4	21.5	
2–3 cm	39.7	45.9		45.5	45.9	
3–4 cm	32.7	32.6		33.1	32.6	

3.2. Unmatched cohort

Log-rank tests and Cox proportional hazards model adjusted for sex, marital status, age, year of diagnosis, race, histologic subtype, grade, region, tumour laterality, tumour size and tumour extension showed similar results in survival analysis. The CA group has a higher CSM and OM versus the PN group (HR 3.06, 95% CI 2.06–4.56; $p < 0.01$; HR 2.04; 95% CI 1.69–2.47; $p < 0.01$).

In subset analyses, the results of Kaplan-Meier method and Cox regression showed that CSM and OM were similar between PN and CA group for tumours < 2 cm in Cox regression (HR 1.94, 95% CI 0.59–6.35, p = 0.27; HR 1.01, 95% CI 0.56–1.83, p = 0.98, respectively). For tumours 2–3 cm, the CA group has a higher CSM and OM (HR 2.41, 95% CI 1.16–5.02, p = 0.02; HR 2.09, 95% CI 1.53–2.85, $p < 0.01$) in Cox proportional hazards model. For tumours 3–4 cm, the CA group has higher CSM and OM (HR 3.84, 95% CI 2.28–6.48, $p < 0.01$; HR 2.45, 95% CI 1.86–3.21, $p < 0.01$, respectively) (Figs. 2 and 3, Table 2).

3.3. Propensity-score matched cohort

The propensity score-matched cohort included 1051 patients in each group. After propensity score balancing, covariate balance was achieved for all included variables except for histological subtype and grade. (Table 1) In the matched cohort, the CA group has a higher CSM and a higher OM (HR 3.22, 95% CI 1.66–6.26, $p < 0.01$; HR 2.14, 95% CI 1.58–2.90, $p < 0.01$, respectively).

In subset analyses, for tumour < 2 cm, the mortality caused by RCC or all causes was similar between CA and PN group (HR 1.41, 95% CI 0.32–6.31, p = 0.65; HR 0.97, 95% CI 0.47–2.01, p = 0.93, respectively). For tumours 2–3 cm, the CA group has a similar CSM (HR 1.64, 95% CI 0.67–4.03, p = 0.28) but a higher OM (HR 2.05, 95% CI 1.35–3.11, $p < 0.01$). For tumours 3–4 cm, the CA group has a higher CSM and OM (HR 3.76, 95% CI 1.62–8.69, $p < 0.01$; HR 2.17, 95% CI 1.48–3.18, $p < 0.01$, respectively) (Table 3).

3.4. Sensitivity analysis

In competing risk model, CA yields a higher CSM (before PSM: HR 3.17, 95% CI 2.21–4.55, $p < 0.001$; after PSM: HR 2.07, 95% CI 1.14–3.77, p = 0.02). And the subset analysis by size using competing risk model suggest CA equals PN for tumour < 2 cm (before PSM: HR 1.62, 95% CI 0.49–5.34, p = 0.42; after PSM: HR 1.20, 95% CI 0.22–6.52, p = 0.83) and tumour 2–3 cm (before PSM: HR 2.56, 95% CI 1.32–4.97, p = 0.005; after PSM: HR 0.82, 95% CI 0.20–3.26, p = 0.78). But the CA group has a higher CSM for tumour 3–4 cm (before PSM: HR 4.69, 95% CI 2.95–7.47, $p < 0.001$; after PSM: HR 3.59, 95% CI 1.52–8.47, p = 0.004) (Tables S1 & S2).

In IPTW and SMRW model, CA is associated with a higher CSM (IPTW: HR 3.72, 95% CI 2.76–5.00, $p < 0.001$; SMRW: HR 3.67, 95% CI 2.70–5.00, $p < 0.001$) and a higher OM (IPTW: HR 2.05, 95% CI 1.76–2.38, $p < 0.001$; SMRW: HR 2.02, 95% CI 1.73–2.36, $p < 0.001$) in Cox proportional hazards model adjusted for sex, marital status, age, year of diagnosis race, histologic subtype, grade, region,

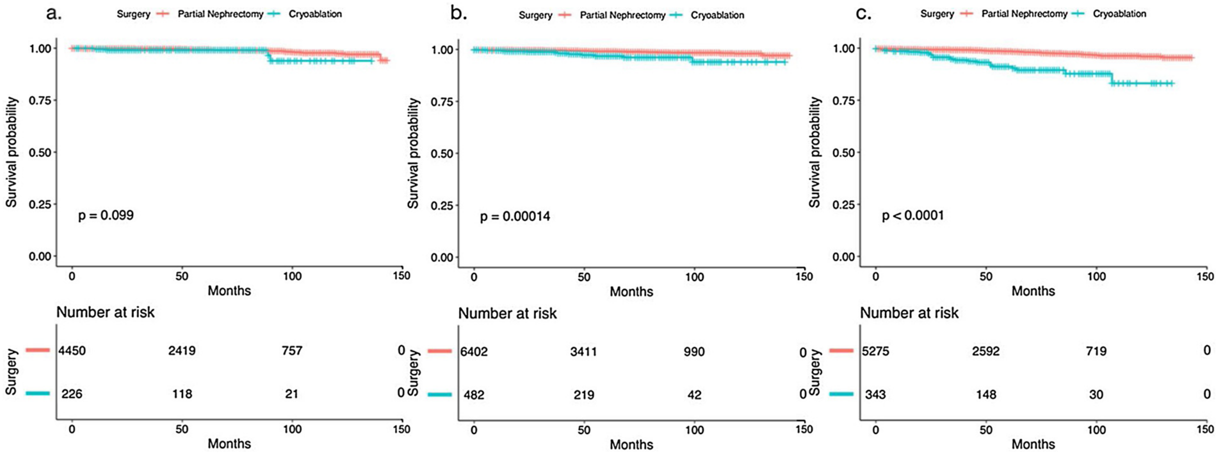

Fig. 2. Cancer-specific survival graph by the type of surgery for tumours < 2 cm (a), 2–3 cm (b), and 3–4 cm (c) in the unmatched cohort.

tumour laterality, tumour size and tumour extension. In subset analysis by size of IPTW model, CA is not inferior to PN for tumour < 2 cm regarding CSM (IPTW: HR 2.10, 95% CI 0.83–5.31, p = 0.12; SMRW: HR 1.97, 95% CI 0.74–5.26, p = 0.18) or OM (IPTW: HR 1.32, 95% CI 0.79–2.20, p = 0.28; SMRW: HR 1.34, 95% CI 0.79–2.27, p = 0.27). However, CA yields increased CSM and OM for tumour 2–3 cm and 3–4 cm (Tables S3 & S4).

In the propensity-score matched analysis in which tumour grade, histological subtypes, and all the other baseline characteristics were included as independent variables for PSM, CA was still associated with increased risk of CSM (HR: 3.85, 95% CI: 1.66–8.91, $p < 0.01$) and OM (HR 2.17, 95%CI: 1.48–3.18, $p < 0.001$) for tumour 3–4 cm (Table S5).

4. Discussion

In this retrospective cohort of T1a RCC, we found that PN and CA are equal for T1aN0M0 RCC less than 2 cm. For those between 2–4 cm, CA is likely to be associated with a higher risk of CSM and OM.

Oncological outcomes have been mixed among studies comparing CA and PN. In two recently published SEER-based cohort, Adam et al [28] and Minzhi et al [29] exploited the SEER-medicare linked database, which only recruited patient aged over 65. However, our data showed that the mean age for PN and CA group were 56 and 66, respectively. The results could be biased if all patients under 65 were excluded. In a recent single-institution retrospective study, Thompson et al. included clinical T1a RCC treated by CA or PN with the median tumour size of 2.8 and 2.4 cm in two treatment group respectively, found that CA is associated with a higher OM for clinical T1a RCC [30]. But they did not analyze the survival of patients based on tumour size. Dena et al. 29 compared thermal ablation with PN and found thermal ablation equals PN for tumours < 2 cm, which is similar to what we have found comparing CA and PN. Our and Dena's studies suggest

Table 2
Associations of the type of surgery with CSM or OM in the subset of patients with T1a RCC after further adjustment for demographic and tumour characteristics in the unmatched cohort.

Outcomes	HR[a] (95% CI)	p value
Cancer-Specific Mortality		
All-sized T1a RCC	3.06 (2.06, 4.56)	< 0.001
< 2 cm RCC	1.94 (0.59, 6.35)	0.27
2–3 cm RCC	2.41 (1.16, 5.02)	0.02*
3–4 cm RCC	3.84 (2.28, 6.48)	< 0.001***
Overall Mortality		
All-sized T1a RCC	2.04 (1.69, 2.47)	< 0.001***
< 2 cm RCC	1.01 (0.56, 1.83)	0.98
2–3 cm RCC	2.09 (1.53, 2.85)	< 0.001***
3–4 cm RCC	2.45 (1.86, 3.21)	< 0.001***

CSM = cancer-specific mortality; OM = overall mortality; RCC = renal cell carcinoma; HR = hazard ratio; CI = confidence interval; CA = cryoablation; PN = partial nephrectomy.
[a]HR represents the association of CA versus PN with outcome. HR > 1 indicates an increased risk of outcome in patients receiving CA.
* $p < 0.05$.
*** $p < 0.001$.

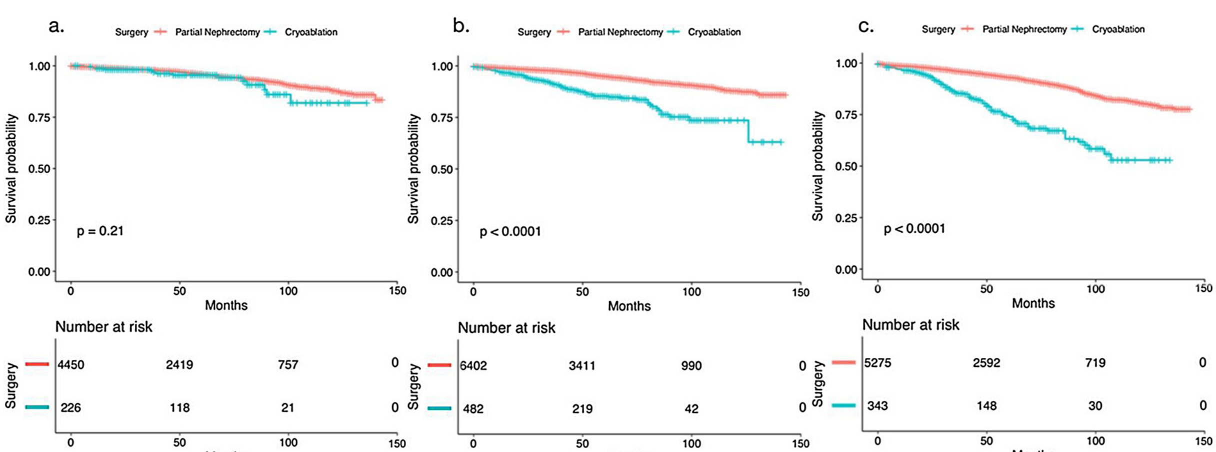

Fig. 3. Overall survival graph by the type of surgery for tumours < 2 cm (a), 2–3 cm (b), and 3–4 cm (c) in the unmatched cohort.

Table 3
Associations of the type of surgery with CSM or OM in the subset of patients with T1a RCC after further adjustment for demographic and tumour characteristics in the propensity-score matched cohort.

Outcomes	HR[a] (95% CI)	p value
CSM		
All-sized T1a RCC	2.44 (1.40, 4.26)	0.002
< 2 cm RCC	1.41 (0.32, 6.31)	0.65
2–3 cm RCC	1.64 (0.67, 4.03)	0.28
3–4 cm RCC	3.76 (1.62, 8.69)	0.002**
OM		
All-sized T1a RCC	1.90 (1.47, 2.47)	< 0.001***
< 2 cm RCC	0.97 (0.47, 2.01)	0.93
2–3 cm RCC	2.05 (1.35, 3.11)	< 0.001***
3–4 cm RCC	2.17 (1.48, 3.18)	< 0.001***

CSM = cancer-specific mortality; OM = overall mortality; RCC = renal cell carcinoma; HR = hazard ratio; CI = confidence interval; CA = cryoablation; PN = partial nephrectomy.
** $p < 0.01$.
*** $p < 0.001$.
[a] HR represents the association of CA versus PN with outcome. HR > 1 indicates an increased risk of outcome in patients receiving CA.

ablation surgeries have comparable oncological outcomes with PN for small renal mass < 2 cm.

Additionally, Lehman et al [31] and Kim [32] et al reported that tumour size as a key metric for incomplete ablations, the risk for complications following CA, and local recurrence, which can account for why CA leads to a higher CSM and OM for patients with a larger RCC. Studies [33–35] were conducted to identify cut-offs in tumour size as the predictor of peri-operative complications. And these cut-offs varying from 3.0 to 3.5 cm. No study identified the cut-off for CSM and OM.

To our knowledge, this is the first study that uses SEER database to compare CA with PN for T1a RCC. We stratified the patients by tumour size and explored survival benefit in each subgroup. Although the PN group were younger and healthier than the CA group, we adjusted for baseline characteristics which could potentially bias the comparison in Cox proportional hazards model and competing risk model and performed PSM. We also used two additional weighting methods (IPTW and SMRW) in the sensitivity analysis to test the robustness of our findings.

This study is not without limitations. SEER database doesn't differentiate approaches of surgeries such as percutaneous, laparoscopic and robotic-assisted approaches. Additionally, in order to include patients of all ages, we used overall SEER database rather than Medicare-linked one, thus failed to collect information about preexisting conditions and Charlson Comorbidity Index score. Despite the limitations, this is the first study to compare survival outcomes of PN and CA. We found CA and PN yield equal survival outcomes for patients with RCC less than 2 cm. However, PN yields superior survival outcomes for RCC larger than 2 cm.

Given the retrospective nature of this study, we interpret our results with caution. Further prospective studies are warranted to investigate the optimal cut-offs of tumour size for choosing which surgery to perform. We envision that an ideal randomized clinical trial would do subgroup analysis of tumour size and minimize selection bias of patients' dispositions like comorbidities and tumour complexity.

5. Conclusion

For RCC ≤ 2 cm, PN and CA are equal in survival outcomes. For RCC 2–4 cm, PN may have a possible advantage over CA.

Author contributions

Author 1: Xinyang Liao: Performed the analysis, Wrote the paper.
Author 2: Shi Qiu: Collected the data, Wrote the paper.
Author 3: Wanyu Wang: Contributed data or analysis tools, Wrote the paper.
Author 4: Xiaonan Zheng: Other contribution.
Author 5: Kun Jin: Contributed data or analysis tools.
Author 6: Shiyu Zhang: Other contribution.
Author 7: Yige Bao: Wrote the paper.
Author 8: Lu Yang: Conceived and designed the analysis, Wrote the paper.
Author 9: Qiang Wei: Conceived and designed the analysis, Wrote the paper.

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Conflicts of interest

The authors declare that there are no conflicts of interest.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.canep.2019.02.016.

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