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Cryoablation versus Partial Nephrectomy for Clinical T1b Renal Tumors: A Matched Group Comparative Analysis

Peter A. Caputo [a], *Homayoun Zargar* [a], *Daniel Ramirez* [a], *Hiury S. Andrade* [a], *Oktay Akca* [a], *Tianming Gao* [b], *Jihad H. Kaouk* [a,*]

[a] *Center for Laparoscopic and Robotic Surgery, Cleveland Clinic, Cleveland, OH, USA;* [b] *Department of Quantitative Health Sciences, Cleveland Clinic, Cleveland, OH, USA*

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Abstract

Background: The traditional treatment for a cT1b renal tumor has been radical nephrectomy. However, recent guidelines have shifted towards partial nephrectomy (PN) in selected patients with cT1b renal tumors. Furthermore, practitioners have extended the role of cryoablation (CA) to treat cT1b tumors in selected patients.
Objective: To evaluate the efficacy of CA compared to PN for cT1b renal tumors.
Design, setting, and participants: We performed a retrospective review of patients who underwent either renal CA (laparoscopic or percutaneous) or PN (robot-assisted) for a cT1b renal mass (>4 cm and ≤7 cm) between November 1999 and August 2014. To reduce the inherent biases of a retrospective study, CA and PN groups were matched on the basis of key variables: tumor size, Charlson comorbidity index (CCI), age, body mass index (BMI), American Society of Anesthesiologists (ASA) score, preoperative serum creatinine, preoperative estimated glomerular filtration rate (eGFR), gender, and solitary kidney. The matching algorithm was 1:1 genetic matching with no replacement.
Outcome measurements and statistical analysis: Survival analysis was performed only for patients diagnosed with renal cell carcinoma according to histopathologic evaluation of a tumor biopsy or resected tumor specimen. Recurrence-free, overall, and cancer-specific survival were analyzed using Kaplan-Meier survival curves. Survival outcomes were compared between groups using the log-rank test.
Results and limitations: A total of 31 patients were treated using CA and 161 using PN during the study period. After matching, there was no significant difference between the PN and CA groups for tumor size (4.6 vs 4.3 cm; $p = 0.076$), CCI (6 vs 6; $p = 0.3$), RENAL score (9 vs 8; $p = 0.1$), age (68 vs 68 yr; $p = 0.9$), BMI (30 vs 31 kg/m^2; $p = 0.2$), ASA score (3 vs 3; $p = 0.3$), preoperative creatinine (1.2 vs 1.4 mg/dl; $p = 0.2$), preoperative eGFR (63 vs 53 ml/min/1.73 m^2; $p = 0.2$), and proportion of patients with a solitary kidney (19% vs 32%; $p = 0.4$). The total postoperative complication rate was higher for PN than for CA (42% vs 23%; $p = 0.10$). There was no significant difference in percentage eGFR preservation between PN and CA (89% vs 93%; $p = 0.5$). The rate of local recurrence was significantly higher for CA than for PN ($p = 0.019$). There was no significant difference in cancer-specific mortality ($p = 0.5$) or overall mortality ($p = 0.15$) between the CA and PN groups.
Conclusions: Patients treated with CA for cT1b renal tumors had a significantly higher rate of local cancer recurrence at 1 yr compared to those treated with PN. Until further studies are performed to clearly define the role of CA in cT1b renal tumors, CA should be reserved for patients with imperative indications for nephron-sparing surgery who cannot be subjected to the risks of more invasive PN.

* Corresponding author. Center for Laparoscopic and Robotic Surgery, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195, USA. Tel. +1 216 4442976; Fax: +1 216 4457031.
E-mail address: kaoukj@ccf.org (J.H. Kaouk).

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Patient summary: We evaluated the efficacy of renal cryoablation compared to partial nephrectomy for clinical T1b renal tumors. The cryoablation and partial nephrectomy groups were matched to provide a better comparison. We concluded that renal cryoablation had a higher rate of local cancer recurrence.

1. Introduction

Over the last decade there has been a sharp increase in the detection of incidental renal tumors attributed to the ubiquitous use of abdominal imaging in current medical practice. As the incidental detection of renal masses has increased, so has our knowledge of the natural history of the disease. This knowledge has led to adoption of nephron-sparing techniques such as partial nephrectomy (PN) and focal ablative therapy options for the treatment of renal cell carcinoma (RCC). The treatment algorithm for cT1b renal tumors is still evolving and the treatment options available to practitioners are expanding. The traditional treatment for a cT1b renal tumor has been radical nephrectomy. However, guidelines have recently shifted towards PN, and state that if a cT1b renal tumor is amenable to PN, it is the treatment of choice in select patients [1,2]. Furthermore, since the introduction of renal cryoablation (CA) in the late 1990s, practitioners have extended the role of CA to treat cT1b tumors in select patients. A recent study reported similar oncologic outcomes for cT1b renal masses treated by PN and CA [3]. The use of CA as a possible oncologically equivalent treatment option for the management of cT1b renal masses must be considered with utmost care and should not be considered oncologically equivalent to PN until further studies are performed. Our objective was to evaluate the efficacy of CA compared to PN for cT1b tumors with respect to oncologic survival outcomes.

2. Patients and methods

2.1. Data acquisition

We reviewed our prospectively maintained CA and PN databases approved by the institutional review board. Patients included for analysis underwent either renal CA (laparoscopic or percutaneous) or PN (robot-assisted approach) for a cT1b renal mass (>4 cm and ≤7 cm and no imaging concerns regarding more advanced disease) between November 1999 and August 2014.

Our technique for CA (both laparoscopic and percutaneous) and robotic PN have previously been described [4–6]. Of note, the technique for all laparoscopic CA procedures was a Tru-Cut (Medline Industries, Mundelein, IL, USA) needle biopsy; the biopsy technique for all percutaneous CA procedures was fine needle aspiration.

CA was used for patients with comorbid medical conditions for whom, at the discretion of the physician, the risk of surgery outweighed the benefit of PN. Furthermore, CA was indicated for patients unwilling to accept the risks for PN.

Renal cross-sectional contrast-enhanced imaging was performed at 3, 6 and 12 mo and then annually thereafter in the CA group. Tumor recurrence in the CA group was defined as an area of new contrast enhancement within a previous completely treated ablation site appearing >3 mo after treatment. If a contrast-enhancing lesion in the ablation zone was found at the first 3-mo imaging check, this was considered incomplete treatment or early post-treatment changes and not tumor recurrence [7]. The PN group underwent renal cross-sectional contrast-enhanced imaging within 3–12 mo after surgery, and annually thereafter. Tumor recurrence in the PN group was defined as a new contrast-enhancing lesion found within or abutting the surgical resection bed for the ipsilateral kidney.

To evaluate renal functional outcomes, the Modification of Diet in Renal Disease formula was used to calculate the estimated glomerular filtration rate (EGFR). Preservation of eGFR was calculated using preoperative and postoperative eGFR values.

2.2. Statistical analysis

2.2.1. Baseline comparison between CA and PN groups

Key baseline variables (tumor size, Charlson comorbidity index, age, body mass index [BMI], American Society of Anesthesiologists [ASA] score, preoperative serum creatinine, preoperative eGFR, gender, and solitary kidney) were compared between the CA and PN groups. The nonparametric Wilcoxon rank sum test was used to calculate p values for continuous variables, and a χ^2 test was used for categorical variables. The χ^2 or Wilcoxon rank sum test was used to compare covariate differences before and after matching to show that matching improved the balance between the two treatment groups.

2.2.2. Matching by key baseline variables

To reduce differences between groups due to selection bias and confounding, we performed a matched analysis. Matching was based on key baseline variables (tumor size, Charlson comorbidity index, age, BMI, ASA score, preoperative serum creatinine, preoperative eGFR, gender and solitary kidney). RENAL scores were not included in the matching algorithm. The matching algorithm was 1:1 genetic matching with no replacement, which automatically finds a balance using a genetic search algorithm to determine the optimal weight for each covariate within the matching algorithm. Genetic matching maximizes the balance of observed covariates between groups, and is a generalization of propensity score and Mahalanobis distance matching. Further details regarding genetic matching have been reported by Sekhon [8].

2.2.3. Analysis of oncologic outcomes

Survival analysis was performed for those diagnosed with RCC on histopathologic evaluation of tumor biopsy or resected tumor specimens. Recurrence-free survival, overall survival, and cancer-specific survival were analyzed using Kaplan-Meier survival curves. Survival outcomes were compared between the CA and PN groups using the log-rank test.

All statistical analyses were performed in R (R Project for Statistical Computing, Vienna, Austria).

3. Results

A total of 31 patients were treated using CA and 161 patients were treated using PN during the study period. Key baseline

Table 1 – Baseline characteristics for patients in the study group

	Cryoablation	PN	*p* value
Patients (*n*)	31	161	
Tumor size (cm)	4.3 (4.2–4.7)	5.0 (4.5–5.6)	<0.001
Charlson comorbidity index	6.0 (5–7)	4.0 (3–5)	<0.001
RENAL score	8.0 (6–9)	9.0 (8–10)	0.007
Age (yr)	68 (64–76)	61 (52–68)	0.001
Body mass index (kg/m^2)	30.6 (26.3–37.4)	30.6 (26.6–35.4)	0.5
ASA score	3 (3–3)	3 (2–3)	0.004
Preoperative creatinine (mg/dl)	1.40 (1.00–1.80)	0.93 (0.79–1.12)	<0.001
Preoperative eGFR (ml/min/1.73 m^2)	53.4 (39.6–72.6)	84.3 (68.5–97.5)	<0.001
Gender			0.2
Female	6 (19)	53 (33)	
Male	25 (81)	108 (67)	
Solitary kidney			<0.001
No	21 (68)	151 (94)	
Yes	10 (32)	10 (6.2)	

PN = partial nephrectomy; ASA = American Society of Anesthesiologists; eGFR = estimated glomerular filtration rate.
Data are presented as median (interquartile range) for continuous variables and as *n* (%) for categorical variables.

patient and tumor characteristics are listed in Table 1. The CA group consisted of patients who were treated with both laparoscopic (*n* = 25, 81%) and percutaneous (*n* = 6, 19%) approaches. All key variables except BMI and gender were significantly different at baseline between the two groups.

After 1:1 matching, the balance of the key variables was checked, and the results show that a good balance between the matched groups was achieved for all matched variables. There was no significant difference between the groups for tumor size, Charlson comorbidity index, RENAL score, age, BMI, ASA score, preoperative creatinine, preoperative eGFR, gender, and proportion of patients with a solitary kidney. Table 2 lists the preoperative variables for the matched cohorts. The range for year of treatment was 1999–2012 for the CA group and 2007–2014 for the PN group.

The total postoperative complication rate was higher for PN patients (*n* = 13, 42%) than for the CA group (*n* = 7, 23%; *p* = 0.10). Of the seven total complications in the CA group, one (3.2%) was Clavien grade 1, five (16%) were grade 2, and one (3.2%) was grade 4. Of the 13 total complications in the PN group, four 4 (13%) were Clavien grade 1, five (16%) were grade 2, and four (13%) were grade 3a (Table 3).

There was no significant difference in percentage eGFR preservation between the CA and PN groups (93% vs 89%; *p* = 0.5). The proportion of those diagnosed with RCC after histopathologic examination was lower in the CA than in the PN group (71% vs 90%; *p* = 0.085). The median follow up was 30.1 mo for the CA group and 13.0 mo for the PN group (*p* = 0.008; Table 3).

Survival analysis was calculated for patients diagnosed with RCC. Of the 22 patients diagnosed with RCC in the CA group, five (23%) experienced recurrence. Among the 28 patients diagnosed with RCC in the PN group, there were no recurrences. The rate of local recurrence was significantly higher along the curve for CA compared to PN (*p* = 0.019). There was no significant difference in rates along the curve for cancer-specific mortality (*p* = 0.48) and overall mortality (*p* = 0.155) between the CA and PN groups (Figs. 1–3). Tumor characteristics for those diagnosed with RCC are listed in Table 4.

Table 2 – Baseline characteristics for patients in the matched groups

	Cryoablation	PN	*p* value
Patients (*n*)	31	31	
Tumor size (cm)	4.3 (4.2–4.7)	4.6 (4.3–4.9)	0.076
Charlson comorbidity index	6 (5–7)	6 (5–7)	0.3
RENAL score	8 (6–9)	9 (7–10)	0.10
Age (yr)	68 (64–76)	68 (64–76)	0.9
Body mass index (kg/m^2)	30.6 (26.3–37.4)	29.7 (25.0–34.6)	0.2
ASA score	3 (3–3)	3 (3–3)	0.3
History of RCC	7 (23)	3 (9.7)	0.16
Preoperative creatinine (mg/dl)	1.40 (1.00–1.80)	1.21 (1.00–1.43)	0.2
Preoperative eGFR (ml/min/1.73 m^2)	53.4 (39.6–72.6)	62.6 (52.1–72.4)	0.2
Gender			>0.9
F	6 (19)	7 (23)	
M	25 (81)	24 (77)	
Solitary kidney	10 (32)	6 (19)	0.4

PN = partial nephrectomy; ASA = American Society of Anesthesiologists; RCC = renal cell carcinoma; eGFR = estimated glomerular filtration rate.
Data are presented as median (interquartile range) for continuous variables and as *n* (%) for categorical variables.

Table 3 – Perioperative variables for the matched groups

	Cryoablation	PN	*p* value
Patients (*n*)	31	31	
Follow-up length (mo)	30.1 (13.2–64.0)	13.0 (3.19–19.2)	0.008
eGFR preservation (%) [a]	93 (79–111)	89 (78–103)	0.5
eGFR follow-up (mo)	6.0 (3.0–12)	9.63 (2.1–12)	0.8
Complications	7 (23)	13 (42)	0.10
Clavien grade			0.11
0	24 (77)	18 (58)	
1	1 (3.2)	4 (13)	
2	5 (16)	5 (16)	
3a	0 (0.0)	4 (13)	
4a	1 (3.2)	0 (0.0)	
Histology			0.085
Benign	6 (19)	2 (6.5)	
Nondiagnostic	1 (3.2)	0 (0.0)	
Oncocytoma	2 (6.5)	1 (3.2)	
Renal cell carcinoma	22 (71)	28 (90)	

PN = partial nephrectomy; eGFR = estimated glomerular filtration rate.
Data are presented as median (interquartile range) for continuous variables and as *n* (%) for categorical variables.
[a] eGFR determined from postoperative creatinine measured within 12 mo after date of procedure.

Five patients (23%) in the CA group experienced local recurrences. Of these, one was treated with laparoscopic radical nephrectomy and had no further recurrence. Two patients who experienced recurrence were observed. The other two patients with recurrence were treated with repeat CA; one had no further recurrence, while the other experienced local recurrence in the CA zone again and was observed.

Four patients (13%) in the CA group experienced incomplete treatment. Of these, two were retreated with renal CA and experienced no tumor recurrence, and the other two patients were observed and required no further intervention. When calculating survival curves, incomplete treatment was not considered a recurrence event. One patient (3.2%) in the PN group had a focally positive surgical margin. The final pathology for the tumor was oncocytoma, and the patient did not experience tumor recurrence.

Within the CA group, five patients experienced local recurrence, of whom four underwent laparoscopic CA and one had percutaneous CA. One patient who had received laparoscopic CA suffered cancer-specific mortality. Six patients suffered all-cause mortality, of whom five and one had received laparoscopic and percutaneous CA, respectively.

The median number of probes used per CA case was two; the probe size used was 2.4, 3.8, or 4.6 mm.

Before matching, the event rate in the initial group of 161 PN patients was four local recurrences, one renal cancer-specific death, and five all-cause mortality events.

4. Discussion

The treatment algorithm for cT1b renal tumors has changed over the last few decades to favor the nephron-sparing PN

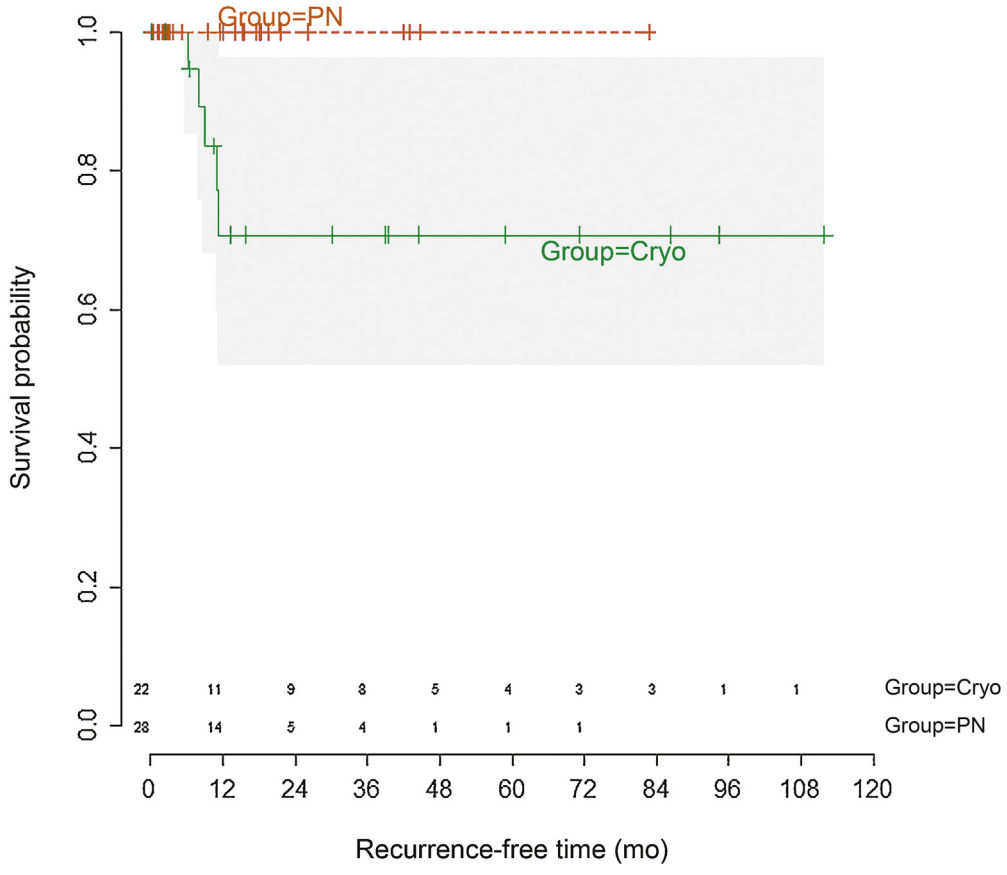

Fig. 1 – Recurrence-free survival. Cryo = cryoablation; PN = partial nephrectomy.

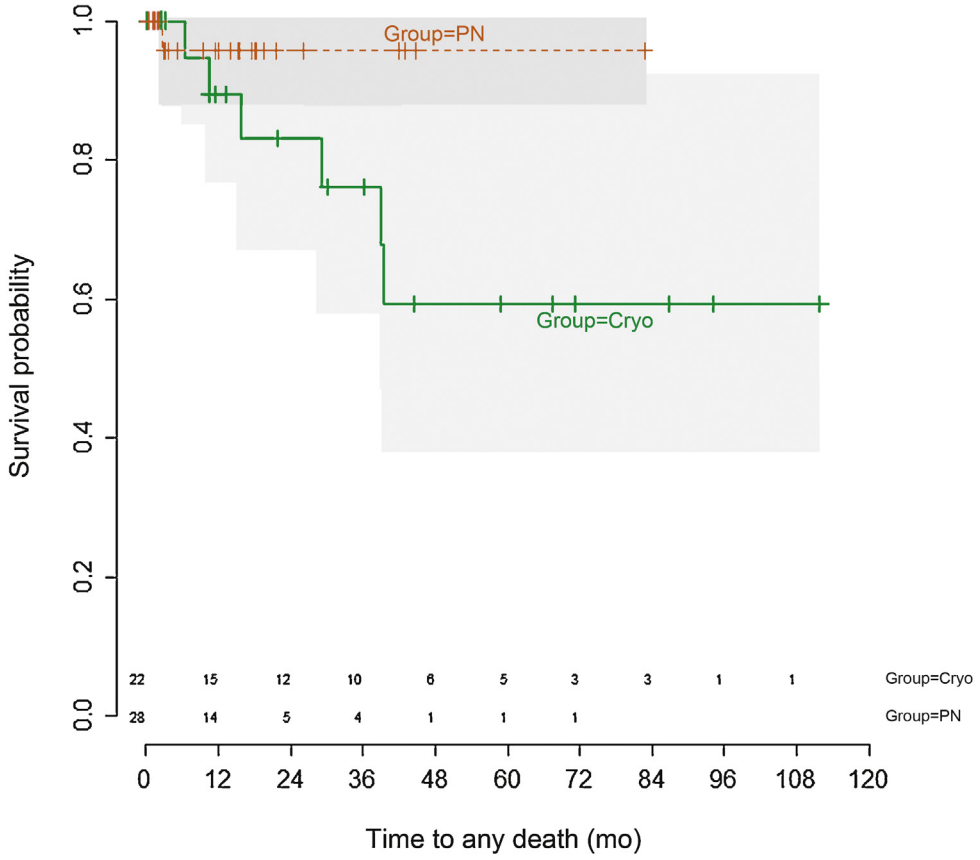

Fig. 2 – Overall survival. Cryo = cryoablation; PN = partial nephrectomy.

approach, reserving the traditional treatment of radical nephrectomy for complex tumors not amenable to PN [1,2]. To follow this trend of nephron-sparing approaches, practitioners have extended the role of CA to treat cT1b tumors in selected patients. Thompson et al [3] reported similar oncologic outcomes for PN and CA of cT1b renal masses, with 3-yr local recurrence–free survival of 96% and 97%, respectively. However, multiple studies do not reach the same conclusion. A systematic review and cumulative analysis by Klatte et al [9] revealed a higher risk of local recurrence for CA than for PN (relative risk [RR] 5.24, 95% confidence interval [CI] 2.67–10.28). Similarly, a meta-analysis by Kunkle et al [10] identified a higher risk of local recurrence for patients treated with CA compared to those treated with PN (RR 7.45, 95% CI 2.24–6.92). Of note, the analyses by Klatte et al and Kunkle et al did not subcategorize patients into groups based on clinical T stage, and most of the patients had tumors of <4 cm in size.

Thompson et al [3] compared a subset of patients with cT1b renal masses treated with CA and PN and found no significant difference in local recurrence–free survival or metastasis-free survival. However, the authors did find a significant difference in overall survival between the CA and PN groups (74% vs 93%). This difference in overall survival is probably due to the greater age (74.9 vs 60.5 yr) and Charlson comorbidity index (2.2 vs 1.2) in the CA compared to the PN group according to the authors. By contrast, we found a significant difference in local recurrence–free survival, while Thompson et al did not. We suggest that the discrepancy between the two studies can be explained by the matching process applied to the patients in our study, so that our groups represent a more homogeneous population. There are a few points to discuss that make a direct comparison of these two studies imperfect. First, our study population did not exclude patients with previously diagnosed RCC or genetic syndromes, while Thompson et al excluded such patients. Furthermore, our study included patients who had laparoscopic CA and percutaneous CA, while Thompson et al only included percutaneous CA. Finally, while our study had significantly longer follow-up in the CA group, Thompson et al had significantly longer follow-up in the PN than in the CA group (4.4 vs 1.9 yr).

We compared oncologic and functional outcomes between patients treated with either CA or PN for a cT1b renal tumor. To best control for selection and informational bias, each group was matched on the basis of key variables known to influence outcomes. Table 2 lists the key variables for the groups and shows that the matching process was successful in creating similar groups. Our series revealed that CA was inferior to PN with regard to recurrence-free survival ($p = 0.019$). We did not find a significant difference between CA and PN in the rate of cancer-specific survival ($p = 0.5$) or overall survival ($p = 0.15$). With regard to renal functional outcomes, the percentage eGFR preservation was

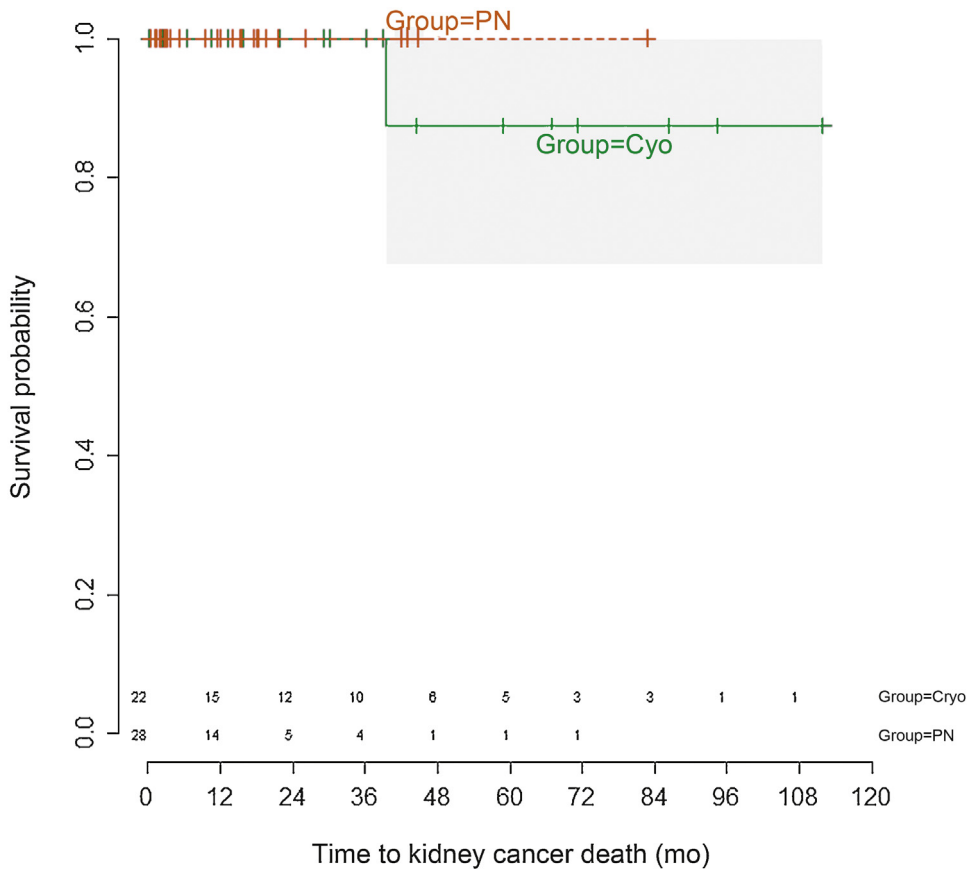

Fig. 3 – Cancer-specific survival. Cryo = cryoablation; PN = partial nephrectomy.

similar for CA and PN (93% vs 89%; $p = 0.57$). The CA group did have a lower incidence of postoperative complications compared to the PN group (23% vs 42%; $p = 0.10$), but the difference was not statistically significant. This difference in complication rate might become statistically significant for a larger sample size. Given that there was no significant difference in cancer-specific mortality or all-cause mortality between the groups, it could be suggested that the higher rate of postoperative complications following PN should be considered an indication for CA in selected patients.

Table 4 – Tumor characteristics for the renal cell carcinoma subset

	CA	PN	*p* value
Histology, *n* (%)			0.4
Clear cell	17 (77)	23 (82)	
Papillary	1 (4.5)	5 (18)	
Not specified[a]	4 (18)	0 (0.0)	
Grade, *n* (%)			0.6
1	1 (4.5)	1 (3.6)	
2	7 (32)	11 (39)	
3	5 (23)	13 (46)	
4	0 (0.0)	2 (7.1)	
Not specified[a]	9 (41)	1 (3.6)	

[a] Biopsy diagnosis of RCC without histologic subtyping or grading

Histopathologic examination revealed fewer patients with RCC in the CA group than in the PN group (71% vs 90%; $p = 0.085$). It is unclear if the discrepancy represents a truly lower RCC rate in the CA group, as the lower RCC rate may indicate the presence of a sampling error associated with diagnostic capabilities for a single renal tumor biopsy. A recent study by Abel et al [11] showed that a single tumor biopsy in larger renal masses was inferior to a multiple biopsy technique with respect to the rate of nondiagnostic biopsies and the accuracy in detecting aggressive pathologic features. However, if the difference in RCC rate between the groups is truly lower in our CA group, our data may underestimate the true difference in oncologic efficacy between CA and PN for cT1b tumors.

The median follow-up was significantly shorter for the PN group (13.0 mo) than for the CA group (30.1 mo). This discrepancy is one of the limitations of our study. However, the numbers of patients at risk on our survival curves at 12 mo are similar, and we believe a true comparison can be made for this length of follow-up. Nevertheless, we recognize that for follow up longer than 12 mo we may be underestimating the event rates in our PN group.

It should be noted that the cohorts compared with regard to our survival outcomes of interest are in fact subsets of the entire matched groups. Thus, instead of paired survival analysis, we performed survival analysis for two groups

using the log-rank test. This estimate should still be unbiased assuming missing at random, with very minimal loss of efficiency when treating paired survival data as grouped data.

Our study does have limitations and caution is required when drawing conclusions from populations with small sample sizes combined with the low event rates for local cancer recurrence and cancer-related death. However, despite the small sample size, we were able to detect statistically significant differences between the groups with regard to our outcomes of interest. Furthermore, CA techniques have evolved over the period of our study and percutaneous CA has largely replaced the laparoscopic approach. Considering the potential better visualization of the ice ball during computed tomography–guided percutaneous cryotherapy compared to the ultrasound-guided laparoscopic approach, better long-term results might be achieved using the percutaneous approach. Given that our long-term results mainly represent outcomes for laparoscopic CA, these outcomes might not be a true reflection of the current practice for CA, and this should be kept in mind when interpreting our results. Other limitations include the retrospective nature of our study; although key variables such as age, renal function, and comorbidity were controlled for by the matching process, it is possible that selection bias or confounders inherent to retrospective studies exist for which we did not control. There was a higher proportion of patients with a solitary kidney in the CA group before and after matching and, although controlled for in the matching process, this could lead to further selection bias. Further, there was a disparity in follow-up between the groups, with only half of patients in the PN group followed for longer than 12 mo.

5. Conclusions

Patients treated with CA for cT1b renal tumors had a higher rate of local cancer recurrence than patients treated with PN. Until further studies are performed to clearly define the role of CA in cT1b renal tumors, CA should be reserved for patients with imperative indications for nephron-sparing surgery who cannot be subjected to the risks of more invasive PN.

Author contributions: Peter A. Caputo 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: Caputo, Kaouk, Zargar.
Acquisition of data: Caputo, Akca, Andrade, Ramirez.
Analysis and interpretation of data: Gao, Caputo.
Drafting of the manuscript: Caputo, Zargar.
Critical revision of the manuscript for important intellectual content: Zargar, Kaouk.
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