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Functional and oncological outcome of percutaneous cryoablation versus laparoscopic partial nephrectomy for clinical T1 renal tumors: A propensity score-matched analysis

Takafumi Yanagisawa, M.D.[a,*], Jun Miki, M.D., Ph.D.[a], Kanichiro Shimizu, M.D., Ph.D[b], Wataru Fukuokaya, M.D.[a], Fumihiko Urabe, M.D.[a], Keiichiro Mori, M.D.[a], Hiroshi Sasaki, M.D., Ph.D[a], Takahiro Kimura, M.D., Ph.D.[a], Kenta Miki, M.D., Ph.D.[a], Shin Egawa, M.D., Ph.D.[a]

[a] *Department of Urology, The Jikei University School of Medicine, Tokyo, Japan*
[b] *Department of Radiology, The Jikei University School of Medicine, Tokyo, Japan*

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Abstract

Purpose: To evaluate the clinical trifecta of percutaneous cryoablation (PCA) vs. laparoscopic partial nephrectomy (LPN) for cT1 renal tumors.

Patients and methods: We retrospectively analyzed the records of patients who had undergone 2 types of nephron sparing surgeries (NSS) PCA or LPN for cT1 renal tumors between November 2011 and December 2019. The cohorts were matched by one-to-one propensity scores based on patient demographics, renal function, and tumor complexity. Perioperative and oncological outcomes and preservation of renal function following surgery were compared.

Results: After matching, a total of 180 patients who had undergone NSS for de novo renal tumors were evaluable: 90 for PCA and 90 for LPN. No statistically significant differences were noted among the measured baseline characteristics in the propensity score-matched cohorts. Overall perioperative complication rates were 5.5% in the PCA and 11.1% in the LPN groups ($P = 0.28$). The rate of eGFR preservation 1 to 3 months after surgery was significantly higher for PCA than for LPN (92.8 ± 11.5% vs. 88.5 ± 14.6%, $P = 0.03$). Median follow-up was 33 months for PCA and 18 months for LPN ($P < 0.001$). Three residual and 4 recurrent tumors were later diagnosed in the PCA group and 1 recurrent tumor in the LPN group. The 5-year local recurrence-free survival was lower for PCA than LPN (90.2% vs. 98.5%, $P = 0.36$). The 5-year metastasis-free survival rate was similar in both groups (98.4% vs. 100%, $P = 0.38$). The 5-year overall and cancer-specific survival rates were comparable in both groups (91.7% vs. 98.9%, $P = 0.53$, and 95% vs. 100%, $P = 0.55$, respectively).

Conclusions: Clinical T1 RCC patients are better treated with LPN if technically possible. Though PCA had a higher local recurrence rate, medium-term local control was not inferior to LPN. Additionally, PCA patients tended to retain renal function without severe complications. PCA appears to be a reasonable option for patients with high comorbidity at presentation.

Keywords: Renal cell carcinoma; Small renal mass; Percutaneous cryoablation; Laparoscopic partial nephrectomy

Abbreviations: eGFR, estimated glomerular filtration rate; CECT, contrast-enhanced computer tomography; CSS, cancer-specific survival; cT1, clinical T1; GFR, glomerular filtration rate; LCA, laparoscopic cryoablation; LCS, local control survival; LRFS, local recurrence-free survival; LPN, laparoscopic partial nephrectomy; MFS, metastasis-free survival; OS, overall survival; OPN, open partial nephrectomy; PCA, percutaneous cryoablation; PN, partial nephrectomy; RAPN, robot-assisted partial nephrectomy; RCC, renal cell carcinoma; RFA, radio frequency ablation; SRM, small renal mass

1. Introduction

LPN or robot-assisted partial nephrectomy (RAPN) has become the treatment of choice for cT1 renal tumors. Cryoablation is a widely accepted alternative, although many retrospective studies and systematic reviews have demonstrated the oncological priority of PN over ablation therapy [1−12].

Laparoscopic cryoablation (LCA) is currently being replaced by image-guided percutaneous cryoablation

*Corresponding author. Tel.: +81-4-7164-1111; fax: +81-4-7166-9374.
E-mail address: t.yanagisawa.jikei@gmail.com (T. Yanagisawa).

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(PCA), primarily because LCA requires general anesthesia and is associated with intraoperative difficulties in correctly identifying tumor margins [13]. Andrews et al. of Mayo Clinic recently compared outcomes of percutaneous radio frequency ablation (RFA) and PCA with those of partial nephrectomy (PN) for cT1 renal cell carcinoma (RCC), and noted no significant differences in 5-year local recurrence-free survival (LRFS) among the 3 procedures (PN: 97.7%, RFA: 95.9%, cryoablation: 95.9%) [14].

Recently, a systematic review of PN vs. cryoablation was published which demonstrated a strong preference for PN among oncologists. However, most of their comparisons were with LCA or a combination of LCA and PCA; only a few studies have compared PN vs. PCA only [1]. At Jikei University, we have experience with both PCA and LCA, and we note that PCA differs from LCA in a variety of technical areas, including method of anesthesia, type of indication, and level of invasiveness.

Suboptimal monitoring during ablation accounts for the high rate of local recurrence reported for LCA (11% −13.3%) compared to PN (0%) [2−12]. More advanced imaging guidance during PCA may provide better local control than LCA, theoretically leading to more optimized cancer control in the long term.

PCA is currently listed as an option in the guidelines. However, there is little high-quality supporting evidence in the literature and little real-world data comparing PCA and LPN/RAPN directly [15]. The objective of this study is to clarify the utility of PCA for cT1 renal tumors compared with LPN. We used a propensity score-matching methodology to minimize differences in patient background, such as age, comorbidities, and tumor complexity.

2. Patients and methods

2.1. Patients

Following approval by our institutional review boards (29-319 (8935)), we reviewed the records of 390 consecutive patients who had undergone PCA ($n = 139$) or LPN ($n = 251$) for de novo cT1 renal tumor at the Jikei University Kashiwa Hospital and the Jikei University Hospital between September 2011 and December 2019. Patients with benign tumors, diagnosed by biopsy or resection, were excluded. In total, 374 patients who had undergone PCA ($n = 133$) or LPN ($n = 241$) were eligible. No patients had synchronous metastasis or renal tumor accompanied by VHL disease.

Indication criteria for PCA at our hospital are: (1) Any cT1 tumor, irrespective of location and cystic type; (2) patient is able to maintain a prone position for at least 90 minutes; (3) patient has comorbidities or is considered a high risk for surgery, (4) patient prefers PCA even after demonstrating understanding that PCA is considered an alternative treatment. Patients were educated about the risks and benefits of both surgeries by the surgeons, who encouraged patients to choose LPN if they were candidates for that procedure.

All patients received plain and contrast-enhanced abdominal computed tomography (CECT) scans for RCC diagnosis and clinical staging in both groups. Supplementary magnetic resonance imaging (MRI) and abdominal ultrasonography were provided as needed for thorough evaluation of the tumor and also were preferred for image guidance in some PCA cases. Renal tumor biopsy was not routinely conducted when the tumor diameter was more than 3 cm and contrast provided by CECT was convincing for RCC.

3. Surgical and cryoablation techniques

LPN was performed using either a transperitoneal or retroperitoneal approach, as determined by tumor location, size, and the patient's physical characteristics. Tumors were generally excised under warm ischemia, which was accomplished by clamping only the main renal artery. Only one case could be performed without artery clamping, as a result of tumor location and size. If the urinary tract was opened, renal pelvic sutures were used. Parenchymal sutures were used in all patients, and hemostatic agents were applied before cortical closure.

PCA was performed under CT or MRI guidance. A cryoablation system (CryoHit, Galil Medical, Yokneam, Israel) and 17-gauge cryoneedles (IceRod, Galil Medical) were used [16]. For transcatheter arterial embolization, a mixture of absolute ethanol and iodized oil was used 2 or 3 days prior to CT-guided PCA to improve visualization of the renal mass [17]. In our hospital, we perform these procedures during the same admission. Cryoneedles were placed percutaneously to target the deposit of iodized oil on plain CT. The number of cryoneedles was determined by tumor diameter, and the needles were placed under local anesthesia. The ablation protocol consisted of a cycle of 15-minute freeze, 5-minute thaw, and 15-minute refreeze. Ice ball formation was monitored by imaging at 5-minute intervals during ablation. When a tumor was located near the intestinal tract, hydrodissection with an 18-gauge coaxial needle was utilized, and several milliliters of contrast medium mixed with saline was injected between the renal tumor and the intestine [18].

Perioperative complications were evaluated using the Clavien-Dindo classification. Bleeding, pneumothorax, or colon/intestinal injury after PCA, and ureteral injury, urinoma, or pseudoaneurysm after LPN, were stratified as technical complications.

4. Follow-up

Technique efficacy, residual unablated tumor, local tumor recurrence, and metastasis were assessed by plain CT or CECT and hematology at 1, 3, 6, and 12 months after treatment during the first year and every 6 months thereafter. PCA patients routinely received CECT. If ordinary CECT was unfeasible because of renal function issues

(3 cases in the PCA group), it was replaced by low-dose contrast medium CECT, MRI, and color Doppler ultrasonography. Renal function was postoperatively assessed by eGFR at 1, 3, 6, and 12 months, and postoperative eGFR preservation was calculated using the following formula:

(%eGFR preservation = postoperative eGFR / preoperative eGFR × 100)

The follow-up period ended at the patient's last outpatient visit.

We used standardized ablation therapy terminology from AhMed et al. [19]. The following terminology was defined to compare the 2 procedures: residual unablated tumor residue: any enhancing lesion residue noted at the initial 1-month postoperative imaging; local tumor recurrence: any enhancing lesion recurrence noted on imaging performed at 3 months or thereafter, or the appearance of a growing mass at that site in either group.

We compared overall survival (OS), cancer-specific survival (CSS), metastasis-free survival (MFS), and local recurrence free survival (LRFS) for LPN and PCA. Several patients underwent salvage PCAs for tumor residue or local recurrence, so we also evaluated local control survival (LCS) at the final follow-up in both groups. LRFS was defined as the time from LPN or PCA to any local recurrence. LCS was defined as the time from LPN or PCA to any local residue or recurrence after salvage PCA.

4.1. Statistical analysis

Continuous parametric variables were reported as mean ± standard deviation (SD). The chi-square test, Fisher's exact test, Student's *t* test, and the Mann-Whitney U test were used to compare features of each treatment. Two-sided $P < 0.05$ was considered to be statistically significant.

Propensity scores were calculated through logistic regression modeling based on the following covariates: Age, gender, Charlson's comorbidity index (CCI), the R.E.N.A.L nephrometry score, clinical T-stage, tumor diameter, and preoperative eGFR. Each patient underwent either PCA or LPN and was matched 1:1 with the nearest neighbor's propensity score, using the nearest neighbor matching algorithm without replacement [20]. We used a caliper size 0.2 times the standard deviation of the logistic regression model of the propensity scores to minimize treatment bias [21].

After matching, the Kaplan-Meier method was used to estimate OS, CSS, LRFS, MFS, and LCS. Log-rank tests were used for intertreatment comparisons. All statistical analyses were performed with Stata version 15.1 (StatCorp, LLC, College Station, TX) and R (The R Foundation for Statistical Computing, Vienna, Austria).

5. Results

5.1. Patient demographics

Preoperative data are shown in Table 1. The propensity score-matched cohorts consisted of 180 patients: 90 (50%) in the PCA group and 90 (50%) in the LPN group. Prior to matching, patients in the PCA group were older ($P < 0.001$) and had a higher incidence of cardiovascular disease ($P < 0.001$), higher CCI ($P < 0.001$), and lower baseline eGFR ($P < 0.001$) than the LPN group. No statistically significant differences were noted among the measured baseline covariates in the propensity score-matched cohorts (Table. 1).

5.2. Perioperative and histological data

PCA was performed successfully under local anesthesia in all cases. Mean operating time and mean length of hospital

Table 1
Patient demographics

Demographics	Before propensity score matching			After propensity score matching		
	PCA ($n = 133$)	LPN ($n = 241$)	*P* value	PCA ($n = 90$)	LPN ($n = 90$)	*P* value
Approach (intra/retro), No. (%)		160/81			58/32	
Age (y), Median (IQR)	73 (64−79)	61 (51−69)	<0.001	68.5 (61−76)	69.5 (63−75)	0.85
Gender, No. (%)						
Female	26 (20)	67 (28)	0.08	22 (24)	17 (19)	0.47
Male	107 (80)	174 (72)		68 (76)	73 (81)	
DM, No. (%)	34 (26)	48 (20)	0.24	20 (22)	27 (30)	0.31
HT, No. (%)	54 (41)	86 (36)	0.37	31 (34)	36 (40)	0.54
Cardiovascular disease, No. (%)	37 (28)	30 (12)	<0.001	21 (23)	21 (23)	1
Charlson's comorbidity index (CCI), Median (IQR)	2 (1−3)	0 (0−1)	<0.001	1 (1−2)	1 (0−2)	0.81
Baseline eGFR, ml/min/1.73m^2, Mean ± SD	58.2 ± 18.9	71.2 ± 17.5	<0.001	62.5 ± 18.6	63.2 ± 18.8	0.81
cTstage, No. (%)						
cT1a	111	207	0.55	78	77	1
cT1b	22	34		12	13	
Tumor size, mm, Mean ± SD	29.5 ± 9.6	27.7 ± 11.1	0.11	27.6 ± 9.7	28.8 ± 9.5	0.41
R.E.N.A.L Nephrometry score, Median (IQR)	6 (5−8)	6 (5−8)	0.47	6 (5−7)	6 (5−8)	0.65

DM = diabetes mellitus; eGFR = estimated glomerular filtration rate; HT = hypertension; Intra = intraperitoneal; IQR = interquartile range; LPN = laparoscopic partial nephrectomy; No. = number; PCA = percutaneous cryoablation; Retro = retroperitoneal; SD = standard deviation.

stay were significantly shorter for PCA than for LPN. Mean ischemic time for LPN was 21.2 ± 10.5 minutes (range, 0−73 minutes). Only one case needed too long WIT that of all the other patients was within 40 minutes. The patient had extremely soft and easy to collapse renal parenchyma owing to CKD, so we were forced to clamp renal artery 3 times owing to uncontrollable bleeding and perform parenchymal sutures many times. Perioperative complications were comparable between the 2 groups. Overall complication rates were 5.5% for PCA and 11.1% for LPN ($P = 0.28$). Rates of severe complication (Clavien grade ≧ Ⅲ) were 1.1% and 3.3%, respectively ($P = 0.62$, Table 2). Histological confirmation with pre-or intra-ablation renal biopsy was performed in 65 patients (72%) in the PCA group.

5.3. Preservation of renal function

After matching, the mean baseline eGFR was comparable in both groups (PCA 62.5 ± 17.3 ml/min/1.73m^2, LPN 63.2 ± 18.8 ml/min/1.73m^2, $P = 0.81$). The rate of eGFR preservation was significantly higher for PCA than for LPN at 1 to 3 months (PCA 92.8 ± 11.5, LPN 88.5 ± 14.6, $P = 0.03$, Table 3).

5.4. Oncological outcomes

Median follow-up was 26.5 months for PCA and 18 months for LPN ($P = 0.002$). Four patients died during the follow-up period. Cause of death was attributed to metastatic renal tumor in 1 and to intercurrent causes in the other 3. There were no perioperative deaths. One local recurrence was observed in the LPN group and was diagnosed as a positive surgical margin. The PCA group had 3 tumor residues (3.3%) and 4 local recurrences (4.4%). Salvage PCA was successful in all 7 patients. Metastasis developed in 1 patient in the PCA group; no metastatis occurred in the LPN group. No patients developed local recurrence and distant metastasis synchronously.

The 5-year LRFS was lower for PCA (90.2%, 95% confidence interval [CI]: 72.7−96.8) than for LPN (98.5%, 95%CI: 89.7−99.8, $P = 0.36$, [Fig. 1A]), but this difference was not statistically significant. The 5-year LCS after salvage PCA was the same in both groups (PCA 100% vs. LPN 100%). The 5-year MFS did not differ between the 2 ‘groups (PCA 98.4% vs. LPN 100%; $P = 0.38$, [Fig. 1B]). The 5-year OS was 91.7% (95%CI: 72.7−97.7) for PCA and 98.9% for LPN ($P = 0.53$, [Fig. 1C]). The 5-year CSS was 95.5% (95%CI: 69.5−99.3) and 100%, respectively ($P = 0.55$, [Fig. 1D]).

6. Discussion

Currently PCA, which does not require general anesthesia, is the least invasive NSS, but only a few studies have compared PCA and PN head to head to date [1,10−12]. We thus used our consecutive patient dataset with propensity score matching to compare outcomes for PCA and LPN

Table. 2
Operative and histological data

	PCA ($n = 90$)	LPN ($n = 90$)	P value
Operating time, minutes, Mean ± SD	89.4 ± 23.1	245.7 ± 65.3	<0.001
Blood loss, ml, Mean ± SD	-	153.3 ± 194.6	-
Perioperative transfusion, No (%)	0 (0)	3 (3.3)	0.25
Ischemic time, minutes, Mean ± SD	-	21.2 ± 10.5	-
Hospital stay, days, Mean ± SD	5.3 ± 5.3	8.8 ± 3.4	<0.001
Postoperative complications, No. (%)			
All	5 (5.5)	10 (11.1)	0.28
Technical	3(3.3)	8 (8.9)	0.21
Severe (Clavien grade ≧Ⅲ)	1 (1.1)	3 (3.3)	0.62
Clavien grade ≧ II	Hemopneumothorax (IIIa), 1 Atrium thrombosis (II), 1 Colon frostbite (II), 1 Congestive heart failure (II), 1	Bleeding→re-operation (IVa), 1 Ureter injury (IIIb), 2 Anemia→transfusion (II), 2 Pneumonia (II), 1 Ileus (II), 1	
Biopsy, No. (%)	70 (78)	6 (7)	<0.001
Histological confirmation, No. (%)	65 (72)	90 (100)	<0.001
RCC subtype, No. (%)			
Clear cell	60 (92)	76 (84)	0.21
Papillary	3 (3.3)	6 (6.7)	
Chromophobe	2 (2.2)	6 (6.7)	
Unclassified	0	2(2.2)	
Grade, No. (%)			
G1	28 (43)	32 (36)	0.35
G2	32 (49)	54 (60)	
G3	5 (7.7)	4 (4.4)	

LPN = laparoscopic partial nephrectomy; PCA = percutaneous cryoablation; SD = standard deviation.

Table 3
Preservation of renal function following treatment

eGFR changes, Mean ± SD	PCA	LPN	*P* value
Baseline eGFR, ml/min/1.73m^2	62.5 ± 18.6 (n = 90)	63.2 ± 18.8 (n = 90)	0.81
% eGFR preservation (POM 1–3)	92.8 ± 11.5 (n = 90)	88.5 ± 14.6 (n = 90)	0.03
% eGFR preservation (POM 6–12)	91.2 ± 13.6 (n = 81)	88.3 ± 15.2 (n = 71)	0.23

LPN = laparoscopic partial nephrectomy; PCA = percutaneous cryoablation; POM = postoperative months; SD = standard deviation.

and to better define the pragmatic applicability of these procedures.

In the present study, the 5-year OS, CSS and MFS were satisfactory, with no substantial differences between the PCA and LPN groups. Though the 5-year LRFS was lower for PCA (90.2% vs. 98.5%; P = 0.36) (Fig. 1A), the 5-year LCS was just comparable (PCA 100%, LPN 100%). These results suggest that salvage PCA can provide satisfactory

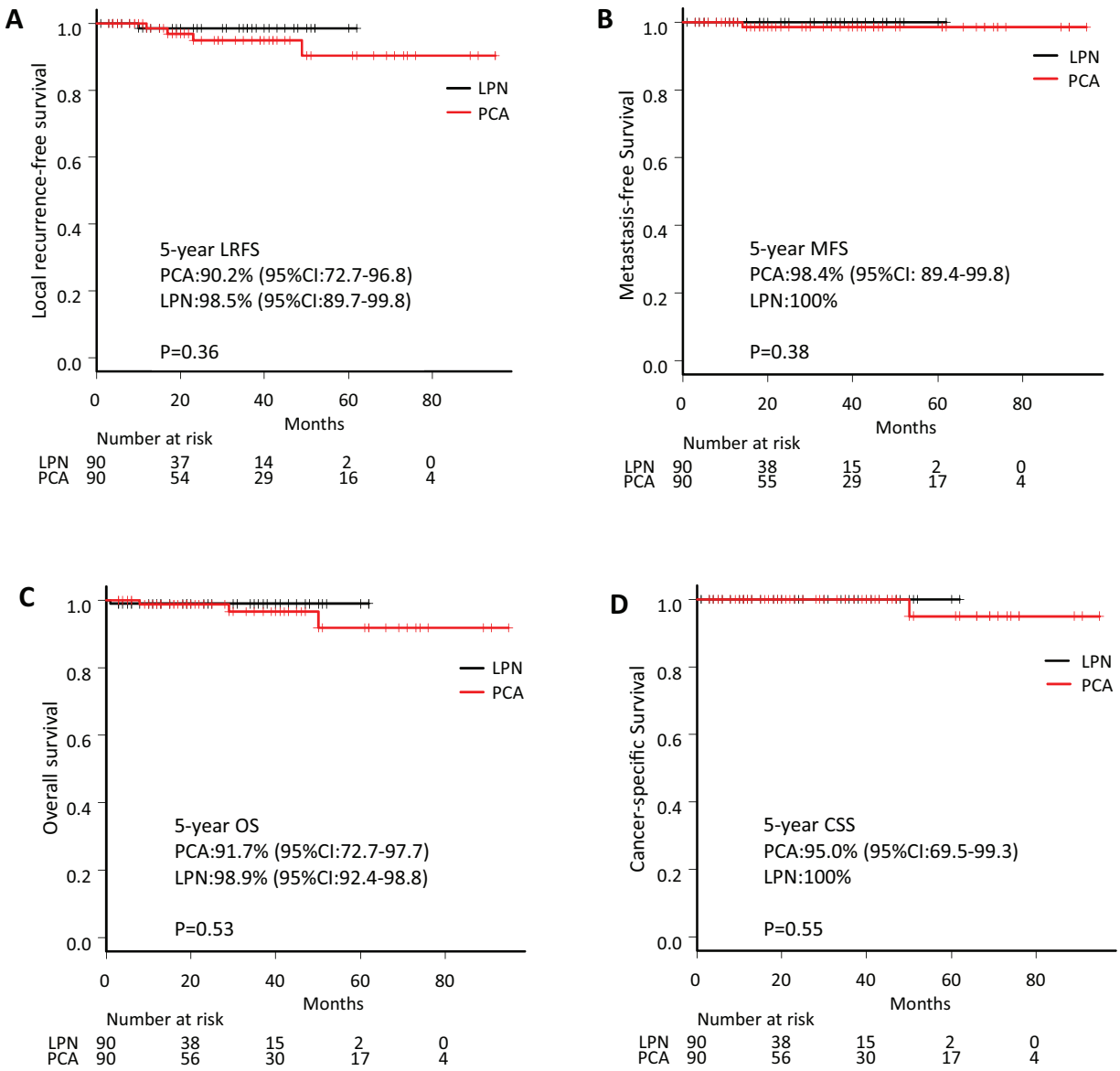

Fig. 1. Kaplan-Meier projection of local recurrence-free (A), metastasis-free (B), overall (C), and cancer-specific (D) survival.
PCA, percutaneous cryoablation; LPN, laparoscopic partial nephrectomy;
OS, overall survival; CSS, cancer-specific survival; LRFS, local recurrence-free survival; MFS, metastasis-free survival.

medium-term cancer control. The advantage of PCA is easier salvage ablation. The disadvantages include reduced cost-effectiveness and impaired patient well-being due to complications.

The 5-year MFS was nearly identical in the 2 groups. Metastasis occurs even in up to 6% of patients with cT1a RCC [22]. We observed only 1 metastasis (0.9%), occurring in the PCA group. However, the possibility of tumor dissemination via needle puncture is still a concern. Reassuringly, a high-quality study of renal tumor biopsies has concluded that such findings are anecdotal [23]. Since the effects of ablation on cancer microcirculation are still unclear, further studies and longer follow-up periods are necessary.

Previous reports and systematic reviews revealed a lower rate of complications with CA (almost LCA) than with LPN or RAPN [1,4,7,11]. In a large study from the Cleveland Clinic comparing LCA and RAPN, the rate of complications was lower for LCA (12% vs. 20%, $P = 0.01$) [4]. A meta-analysis showed that the risk of urologic and nonurologic complications was nearly 2-fold higher for LPN or RAPN than for LCA [7]. Additionally, some large single-institution studies have reported the incidence of PCA complications to range from 7.8% to 12.9% [24,25]. Another study showed no significant difference in overall complications between LCA and PCA, but significantly more severe complications in the LCA group (1.1% vs. 3.9%) [26]. In our study, the perioperative complication rates were 5.5% for PCA and 11.0% for LPN, respectively. While this difference was not significant ($P = 0.28$), the rate of complications was nearly 2-hold higher for LPN than PCA, consistent with findings from other studies. Severe complication rates (Clavien-Dindo $\geqq$ Ⅲ) were also higher in LPN group, but the difference was not statistically significant: 1.1% for PCA and 3.3% for LPN ($P = 0.62$).

One primary goal of NSS is the preservation of renal function. Previous reports and systematic reviews have shown superior renal function preservation with CA in comparison to PN [1,5,27]. In a high-quality comparison of 30 LCA and 48 LPN patients with solitary kidney, the LCA group showed a higher percentage of eGFR preservation at 3 months after treatment (92.7% vs. 85.5%) [5]. In the present study, eGFR in the PCA group was better preserved in postoperative months 1 to 3 (Table 3), suggesting that PCA may be a particularly good choice for CKD patients in whom preservation of renal function is essential [28].

6.1. Limitations

Renal tumor biopsy, which is recommended in the context of cryoablation, is not a routine practice at our institutions prior to PCA when tumors measure 3 cm or larger or when typical radiologic findings are obtained. Such biopsies were conducted in 65 patients (72%) in the PCA group who had histological confirmation of RCC (Table 2). In the LPN group, only 18 out of 251 patients were diagnosed with RCC by presurgical renal biopsy. Thus, the diagnosis of RCC with only CECT was endorsed by pathology in 96% of the LPN cases (223/233 patients).

Our study has several limitations. It is a retrospective study with a limited number of patients due to propensity score-matching. The follow-up period was short. For both groups of patients, multiple surgeons were involved. Oncological outcomes may have been overestimated in the PCA group due to possible contamination with benign tumors, since a renal tumor biopsy was not conducted in all patients. Our cryoablation protocol (two 15-minute freezing cycles, each followed by a 5-minute thawing cycle) is not widely used. Some experts used two 10-minute freezing cycles, each followed by a 10-minute thawing cycle [29]. However, some experts have used freezing cycles of 10 to 20 minutes, depending on tumor size [30]. We believed that the most important point is to perform 2 cycles of freezing and thawing and to cover the entire tumor with an iceball [30].

7. Conclusion

PN is the standard treatment for cT1 RCC because of its oncological outcome. In our study, though PCA had a higher local recurrence rate, the medium-term local control was not inferior to LPN. In addition, PCA was associated with better preservation of renal function and with patient safety without severe complications. PCA can be a minimally invasive treatment option for cT1 RCC.

Conflicts of interest

The authors declare no conflicts of interest associated with this manuscript.

Authors Contribution

TY contributed to protocol/project development, data collection and management, data analysis, and manuscript writing/editing. JM contributed to protocol/project development and manuscript editing. WF contributed to data analysis especially in propensity score matching. SK, FU, KM and HS contributed to data collection. TK contributed to manuscript editing. KM contributed to data management. SE contributed to manuscript editing.

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