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Long-term outcomes of CT-guided percutaneous cryoablation of T1a and T1b renal cell carcinoma

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PURPOSE
We aimed to evaluate the long-term outcomes of computed tomography-guided percutaneous cryoablation (PCA) for biopsy-confirmed renal cell carcinoma (RCC).

METHODS
This was a single-center, retrospective study investigating all patients treated with PCA between January 2010 and February 2019 for RCC tumors. Primary outcome measures included overall survival (OS), disease-free survival (DFS), progression-free survival (PFS) and cancer-specific survival (CSS). Secondary outcome measures included kidney function, complications, technical success, hospital stay, procedural time, and the identification of factors affecting the primary outcomes.

RESULTS
Fifty-three consecutive patients with 54 lesions (T1a: 49/54; T1b: 5/54) were included. Mean tumor diameter was 28.0±8.5 mm and mean R.E.N.A.L. score was 7.2±2.0. Technical success was 100% (54/54 lesions) after two reinterventions for incomplete ablation. Mean follow-up time was 46.7±28.6 months (range, 3–122 months). Local recurrence was noted in 5 patients (9.2%). According to Kaplan-Meyer analysis, OS was 98.2%, 94.2%, 71.2%, and 58.2% at 1, 3, 5, and 8 years. One patient (1.9%) died of cancer and CSS was 95.8% at 8 years. DFS was 100.0%, 95.5%, and 88.6%, and PFS was 100%, 94.3%, and 91.0%, at 1, 2, and 5 years. Clavien–Dindo grade II complication rate was 7.8% (5/64 procedures). There were no complications classified as grade III or greater. Mean creatinine increase was 7.1±6.3 μm/L (p = 0.31). No patient advanced to dialysis during follow up. Mean procedural time was 163±45 min. Median hospital stay was 2.0 days (IQR, 1–2.5 days). Diabetes was the only independent predictor of decreased OS (hazard ratio 4.3, 95% CI 0.043–0.914; p = 0.038).

CONCLUSION
PCA for stage T1a and T1b RCC provides favorable long-term oncological and renal function preservation outcomes, with acceptable complication rates.

Renal cancer has been listed as the 14th most common malignancy worldwide accounting for 2.2% of all cancers, while in Europe it represents 3.5% of all newly diagnosed cancers with an estimated incidence of 136 500 new cases in 2018 (1, 2). Renal cell carcinoma (RCC) is the most frequent renal cancer, which most commonly affects men between ages of 50 and 70 years, although its incidence in younger population has been steadily increasing over the years. It has been reported that in 2018, approximately 54 700 patients died of kidney and renal pelvis malignancies in Europe, a percentage representing 2.8% of all oncologic deaths (1–3).

Although surgery remains the gold standard treatment for localized RCC and partial nephrectomy (PN) is indicated for T1 renal masses (<7 cm), percutaneous, minimally invasive, nephron-sparing, curative modalities (image-guided, thermal ablation) are continuously gaining ground as valid alternatives to surgery, especially for high surgical risk patients and in cases in which PN is not technically feasible (4). Specifically, the two more recent meta-analyses have reported similar oncological outcomes between thermal ablation and surgical treatments for localized renal masses, while complication and renal function outcomes favored the thermal ablation groups (5, 6).

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Percutaneous cryoablation (PCA) is another efficient minimally invasive ablative modality for the treatment of localized T1a and T1b RCCs, demonstrating a particularly favorable safety profile and extremely favorable oncological 5-year outcomes, comparable to those of PN and thermal ablation (7–9). Advantages of the cryoablation over thermal ablative methods include the possibility of intraprocedural, real-time visualization of the ablation zone, less urothelial injury and more uniform ablation (9, 10). Long-term, oncological data following PCA for the treatment of RCC remain limited, while over 5-year outcomes are missing. We sought to evaluate the long-term outcomes of computed tomography (CT)-guided PCA performed in our institution for the treatment of RCC.

Table. Demographical data, lesion characteristics and procedural details

Age (years), mean±SD (range)	71±13 (22–87)
Female sex, n (%)	28 (52.8)
Diabetes, n (%)	13 (24.5)
Cardiac disease, n (%)	12 (22.6)
Chronic kidney disease, n (%)	17 (32.1)
Stroke/TIA, n (%)	4 (7.5)
Hypertension, n (%)	32 (60.4)
Preoperative creatinine (μm/L), mean±SD	91.53±35.04
Tumor size (mm), mean±SD	28.0±8.5
R.E.N.A.L. score, mean±SD	7.2±2.0
Exophytic location, n (%)	10 (18.5)
Central location, n (%)	2 (3.7)

SD, standard deviation; TIA, transient ischemic attack.

Methods

Institutional review board approval was not required for this retrospective study. This was a single-center, single-arm, retrospective study investigating the immediate and long-term clinical and radiological outcomes of CT-guided PCA for the treatment of RCC in consecutive patients treated in the Department of Radiology between January 2010 and February 2019. The Department's electronic databases were thoroughly searched and clinical, laboratory and imaging files were recorded and analyzed. The decision to proceed with PCA over other treatment modalities was taken within a multidisciplinary team meeting and was based on tumor stage, clinical status, major comorbidities and patient preference, as recommended by International Guidelines (11). The study included biopsy-proven, stage T1a and T1b, N0, M0 cases treated with PCA and at least 1-year available imaging and clinical follow-up. Patients were not included in the study if baseline and follow-up laboratory tests and contrast-enhanced CT were not available for review. All patients were evaluated by a urologist, received formal consultation regarding the treatment options and signed an appropriate written informed consent form regarding the risks and benefits of PCA, prior to the procedure. Patients' demographical data, lesion and procedural details are analytically reported in the Table.

Main points

- Percutaneous cryoablation (PCA) is another efficient minimally invasive ablative modality for the treatment of localized T1a and T1b renal cell carcinomas (RCCs). Long-term, oncological data following PCA for the treatment of RCC remain limited, while over 5-year outcomes are missing.
- In this series, the 8-year overall patient survival and cancer-specific survival were 58.2% and 95.8%, respectively.
- No patient advanced to dialysis during follow up and no complications classified as grade III or greater were noted.
- Diabetes was the only independent predictor of decreased overall survival.
- PCA for stage T1a and T1b RCC provides favorable long-term oncological and renal function preservation outcomes, with acceptable complication rates.

Procedure

The procedure has been analytically described in previously published studies (7–10). In brief, patients were admitted to the Urology ward the day prior to the procedure and blood tests including full blood count, coagulation profile (prothrombin time, activated partial thromboplastin time, international normalized ratio) and estimated glomerular filtration rate (eGFR) were obtained. All ablations were performed under general anesthesia. A modified World Health Organization interventional radiology check list was carried out and the side of renal tumor was always marked on the skin to enhance patient safety. The patient was then transferred onto the CT table on a Montreal mattress, in a prone position with the arms held above the head and an initial CT scan of the area of interest was performed to plan the access site and route of entry. IceRod® or IceSphere™ (Boston Scientific) 17 G cryoablation needles were used. If necessary, multiple adjacent needles were placed to ensure an "ice ball" overlapping coverage extending at least 5 mm beyond the lesion. Carbon dioxide or hydrodissection were utilized when appropriate. If not already available, biopsy was performed following the placement of cryoneedles. Once optimal position of the needles was secured, freeze-thaw cycles were applied as follows: 10–12 minutes of freezing, 5–6 minutes of passive thaw, 1 minute of active thaw, 10 minutes freezing, 5–6 minutes of passive thaw followed by 3 minutes of active thaw, while CT scans to assess ice ball were obtained at regular 4-minute intervals. After the procedure, patients were taken to the interventional theatre recovery suite for monitoring and were subsequently sent to the ward for overnight surveillance. In the absence of hematuria or other complications, day case discharge was decided for selected patients satisfying the local day case discharge policy.

Endpoints, definitions and follow-up

Primary and secondary outcome measures were defined according to international reporting standards and guidelines (11, 12). Primary endpoints were: (a) overall survival (OS), defined as the time of patient survival calculated from the date of first PCA session regardless of the cause of death; (b) disease-free survival (DFS), defined as the interval between the PCA and the date that the patient survived without any radiological findings of RCC; (c) progression-free sur-

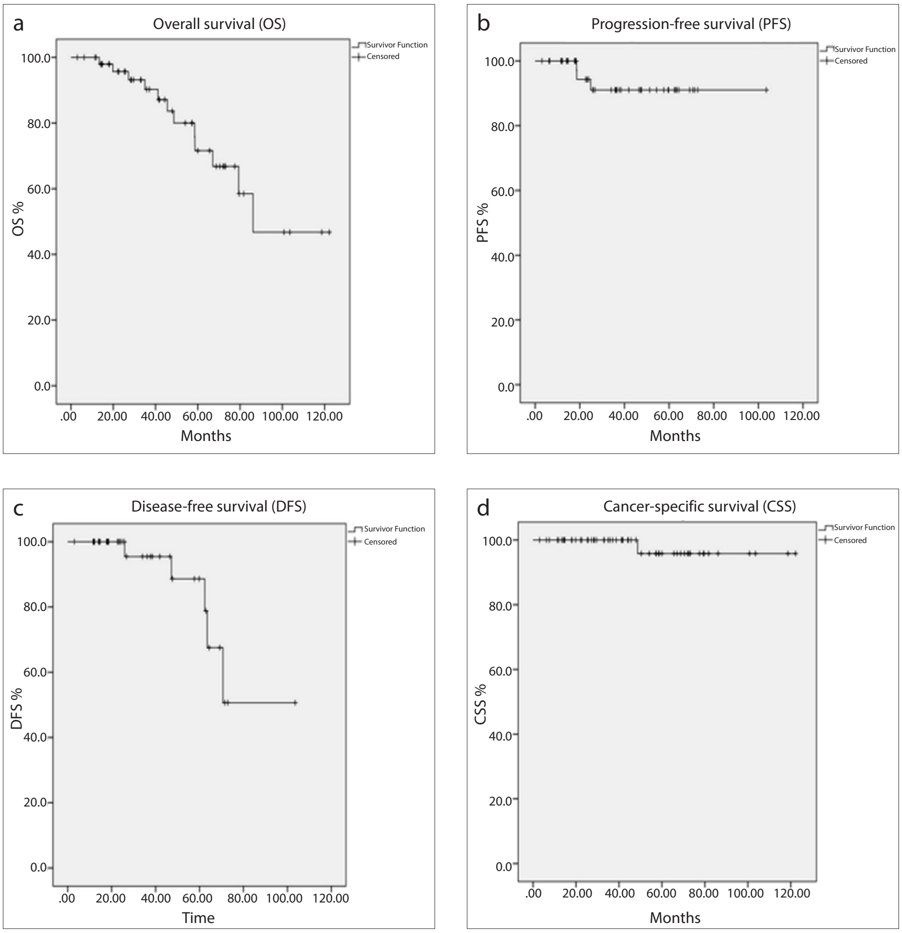

Figure 1. a–d. Kaplan-Meier plots of patients' **(a)** overall survival, **(b)** progression-free survival, **(c)** disease-free survival, and **(d)** cancer-specific survival.

vival (PFS), defined as the time period after PCA during which the patient was alive with documented viable RCC tissue but without progression of the disease (e.g., local lesion enlargement and/or new lesion and/or metastasis); (d) cancer-related survival (CSS) rate, defined as the percentage of patients who did not die of RCC within the follow-up period. Secondary outcome measures included: (a) local recurrence, defined as the presence of viable tumor in the ablation zone after at least one negative follow-up CT study; (b) kidney function assessed by pre- and the last available post-procedural plasma creatinine levels and clinical notes; (c) primary technical success, defined as the lack of remaining viable tumor in the ablation zone on subsequent follow-up imaging; (d) technical success, defined as the absence of viable tumor after additional PCA session; (e) hospital stay; (f) procedural time (overall occupancy of the CT room); (g) the identification of factors affecting the primary outcomes and adverse events classified according to the surgical Clavien–Dindo system (13). Procedural time was defined as the time period starting with the patient entering the CT room and finishing when the patient was leaving the CT room.

The department's follow-up protocol included thin-section, contrast-enhanced, unenhanced arterial and portal-venous phase CT at 3, 6, 12 months and yearly thereafter. All radiological studies were reviewed by experienced radiology consultants not involved in the PCA procedures. In the presence of viable tumor at any follow-up CT, the decision regarding further treatment was taken in the multidisciplinary team meeting. Routine urologic clinic follow-up visits and laboratory tests were also performed at 1, 6, 12 months and annually subsequently.

Statistical analysis

Discrete variables are reported as counts and percentages. Continuous variables are reported as median and interquartile range (IQR) in parentheses or as mean ± standard error (SE) in cases in which data are deriving from normal distributions according to the Kolmogorov–Smirnov goodness-of-fit test. For variables that passed the normality test, the unpaired Student t test was used to determine the significance of difference, while the Mann–Whitney U test was used for qualitative variables and for non-parametric testing of continuous variables not deriving from normal distributions. All primary endpoints (OS, DFS, PFS and CSS) were estimated using the Kaplan–Meier method and results are reported only for SE <10% to establish the statistical validity of the outcomes. A multivariable Cox proportional-hazards stepwise regression model was used to identify the presence of possible factors affecting outcomes during the total follow-up period. Dependent variables analyzed in the multivariable model were diabetes mellitus, dialysis, hyperlipidemia controlled with drugs, history of stroke/transient ischemic attack, cardiac disease (history of myocardial infarction, stable or unstable angina, drug-compensated congestive heart failure, poorly controlled arrhythmia, poorly compensated chronic heart failure), hypertension under drug therapy, T stage (T1a or T1b), lesion location (hilar or not), lesion type (>50% exophytic or endophytic), and R.E.N.A.L. score (low, intermediate, high). The covariates examined included OS, DFS, PFS, and recurrence. The Cox multivariable analysis outcomes are expressed as hazard ratios with 95% confidence intervals (95% CI). All statistical analysis was performed using the SPSS/PASW software (version 21.0, 2012; IBM). The threshold of statistical significance was $p < 0.05$.

Results

In total, 53 consecutive patients (28 female, 52.8%; mean age, 71±13 years; age range, 22–87 years) and 54 lesions were included in the study. The majority of lesions treated were T1a (49/54, 90.7%) and the rest were T1b (5/54, 9.3%). The mean tumor diameter was 28.0±8.5 mm (range, 15–53 mm). The mean R.E.N.A.L. nephrometry score was 7.2±2.0. The median complexity of the lesions classified according to the R.E.N.A.L. score was intermediate (27/54, 50%), while 6 tumors (11.1%) were classified as high complexity lesions. Primary technical success was 96.3% (52/54 lesions). Patients' demographics are analytically reported in the Table. Technical success was 100% (54/54 lesions) after two

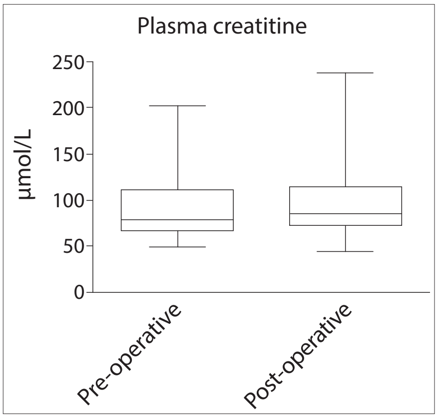

Figure 2. Box-plot representation of pre- and post-procedural values of plasma creatinine levels.

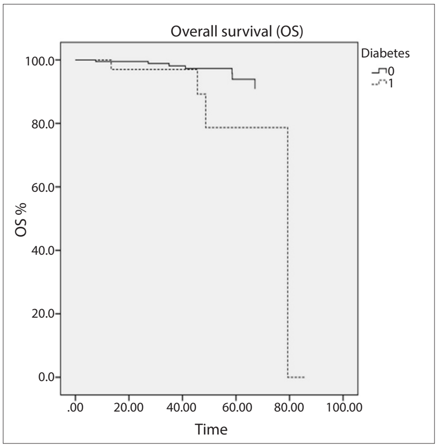

Figure 3. Cox multivariable regression analysis plot demonstrating overall survival in subjects with and without diabetes.

reinterventions for incomplete ablation discovered at initial follow-up imaging. Mean follow-up duration was 46.7±28.6 months (range, 3–122 months). Local recurrence was noted in 5 patients (9.2%). In total, 64 procedures were performed including 2 for incomplete ablation and 7 for local recurrence. In one patient 3 reinterventions were performed due to recurrence, while in one patient with recurrence, surveillance without further treatment was decided and the patient demonstrated residual disease without progression throughout the follow-up period. In total, 11 patients died during the follow-up period (11/53, 20.7%). According to Kaplan–Meyer analysis estimated OS was 98.0%, 90.3%, 71.6%, and 46.8% at 1, 3, 5, and 8 years (Fig. 1a). At 1, 2 and 5 years, DFS was 100.0%, 95.5% and 88.6%, while PFS was 100%, 94.3% and 91.0%, (Fig. 1b, 1c). One patient (1.7%) died of cancer (metastatic RCC) and CCS was 95.8% at 8-year follow-up (Fig. 1d). In the remaining patients who did not die of RCC, deaths were attributed to cardiovascular events (8 cases) and pneumonia (2 cases). The overall adverse event rate was 20.3% (13/64 procedures). Of those, 7.8% (5/64 procedures) were classified as Clavien–Dindo grade II and included four urinary tract infection (4/64; 6.2%) successfully treated with antibiotics and one case of large retroperitoneal hematoma with active extravasation at CT angiography (1/64; 1.5%), which resolved without further sequelae. This patient underwent selective renal artery digital subtraction angiography, but no signs of active bleeding or pseudoaneurysm were noted and embolization was not performed. The patient was transfused, remained stable with no signs of bleeding and was discharged after a total of 6 days. The remaining 5 adverse events were classified as Clavien–Dindo grade I and included 2 cases of pneumothorax which resolved without drainage (2/64; 3.0%) and 6 cases of self-resolved small perinephric hematomas (6/64; 9.4%). There were no procedure-related deaths or any adverse events requiring intervention or resulting in permanent sequelae. Patients not previously on dialysis did not require dialysis during the follow-up period. Mean plasma creatinine increase was 7.1±6.3 μm/L and was not statistically significant (pre-procedural median creatinine value 79. μm/L [IQR, 49.00–110.0 μm/L] versus post-procedural median creatinine value 85.00 μm/L [IQR, 44.00–114.3 μm/L]; $p = 0.31$) (Fig. 2). Mean procedural time was 163±45 minutes. Median hospital stay was 2.0 days (IQR, 1.0–2.5 days; range, 1–6 days). According to the multivariable Cox regression model, diabetes was the only factor negatively affecting OS (hazard ratio 4.3, 95% CI 0.043–0.914; $p = 0.038$) (Fig. 3). The remaining primary outcome measures (DFS, PFS, and CSS) were not influenced by any factor according to the multivariable analysis.

Discussion

This retrospective single-center study provides additional data on 5-year oncological outcomes of percutaneous CT-guided cryoablation in patients with T1a/b RCC, confirming the long-term safety and effectiveness of the method. The 5-year OS was 71.6%, similar to the 78.8% reported in the largest published series of 220 patients by Breen et al. (9). Similarly the 5-year DFS and recurrence rates were comparable to those reported in previously published series (7, 9, 14, 15).

Interestingly, the estimated overall survival rate decreased from 71.6% at 5 years to 46.8% at 8 years. The authors speculate that this outcome is correlated with the old age (mean age at the time of treatment was 71 years) and severe comorbidities of the specific population investigated, which included patients with chronic kidney disease (32.1%), diabetes (24.5%), cardiac disease (22.6%) and stroke/TIA (8%). Indeed, according to multivariable analysis, overall survival was negatively influenced only by diabetes and not by cancer-related factors, such as T stage, recurrence, R.E.N.A.L. complexity score, or lesion location. Analogously, factors influencing cancer-specific endpoints (DFS, PFS, and CSS) were not identified. On the other hand, the 8-year cancer-specific survival was 95.8%, further supporting the effectiveness of PCA in an elderly population with significant comorbidities and unfavorable long-term prognosis. Similarly, very high CSS rates have been previously observed, ranging between 85.7% at 2 years and 100% at 3 years for specifically T1b lesions and 100% for mixed T1a/b lesions (7, 15, 16).

With regard to the technical aspects of the procedure, the primary technical success rate of 96.3% was again comparable to that reported in the literature, which ranges between 95.6% and nearly 100%. Nevertheless, this should be expected as mean tumor diameter was smaller than 3 cm, which is the recommended cutoff value for percutaneous treatment according to the recent consensus of the European Association of Urology, and only 11.1% of the lesions were of high complexity according to the R.E.N.A.L. score. In the two cases of suboptimal ablation noted at 1 month follow-up, lesion diameters were 41 and 33 mm, with high and intermediate complexity scores, respectively. The remaining four T1b lesions were adequately ablated at a single session.

Thermal ablation is an established minimally invasive treatment option for small renal masses (5). However, very optimistic outcomes following cryoablation were recently provided by different studies, while meta-analysis reported effectiveness rates of 90% and 89%, for radiofrequency ablation and cryoablation, respectively (17).

In this series, the technical success rate was nearly 97%, while no ureteric strictures were identified during flexible ureteroscopy, without the positioning of pre-procedural ureteric stents. Interestingly, no major complications were noted as most adverse events were urinary tract infections requiring antibiotic therapy and prolonging hospitalization, mainly classified as Clavien–Dindo grade I or II. As a result, median hospitalization time was 2 days. Notably, the safety of the PCA procedure is also supported by the fact that plasma creatinine levels were not significantly affected and no patient required dialysis.

Nevertheless, it should be highlighted that similar outcomes are also reported following radiofrequency ablation and MWA and given the high technical and clinical success and low complication rates achieved by all thermal ablation treatment modalities, only large, multicenter, randomized trials, designed to include a large number of patients (at least 900) could provide meaningful data regarding the superiority of cryoablation versus other thermal ablation treatments (18–22). Finally, future prospective randomized studies comparing cryoablation versus PN are absolutely necessary, as data on local recurrence-free survival and cancer-specific survival remain contradictive, while the reported superior overall survival rates achieved by PN could be attributed to selection bias (23).

Limitations of this study include the single-center design, which certainly affects the reproducibility of the outcomes and the single-arm design which does not allow comparisons between PCA and other minimally invasive treatment options. Also, some cases and data could have been missed during the retrospective search of the Department's electronic archives. Moreover, due to the small number of patients analyzed, the statistical validity of the results including the multivariable analysis, is limited. Additionally, the small number of T1b cases herein treated precludes any meaningful comparison of effectiveness between the subgroups of T1a and T1b.

In conclusion, in this series of patients suffering from T1a and T1b biopsy-proven RCC, CT-guided percutaneous cryoablation provided favorable long-term oncological and renal function preservation outcomes with acceptable complication rates. These results further support the safety and effectiveness of cryoablation in small renal tumors and indicate the necessity of large comparative randomized studies between available percutaneous minimally invasive treatment options.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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