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ORIGINAL ARTICLE

Cryoablation of renal cell carcinoma for patients with stage 4 or 5 non-dialysis chronic kidney disease

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Abstract

Purpose To evaluate the safety and efficacy of cryoablation for renal cell carcinoma (RCC) in patients with stage 4 or 5 non-dialysis chronic kidney disease (CKD).

Materials and methods This retrospective multicenter study included patients with maximum tumor diameter ≤ 4 cm, estimated glomerular filtration rate (eGFR) < 30 ml/min/1.73 m^2, in whom cryoablation was performed percutaneously with curative intent between July 2011 and May 2016.

Results Of 541 patients who underwent renal tumor cryoablation, 17 (3.1%; 4 women, 13 men; mean age 70.1 ± 10.6 years) with stage 4 or 5 non-dialysis CKD were included in this study. The pre-cryoablation eGFR was 22.5 ± 6.3 ml/min/1.73 m^2. The mean tumor diameter was 2.8 ± 0.7 cm. No Grade 3 or higher adverse events occurred post-cryoablation. The eGFR at each time point was significantly lower than that before treatment. One patient required hemodialysis initiation at 21 months post-procedure. None of the patients showed residual RCC at their last follow-up.

Conclusion Cryoablation of RCC is safe in patients with stage 4 or 5 non-dialysis CKD and yields treatment results comparable to those in patients without CKD. This treatment could be completed without the early initiation of hemodialysis after the procedure.

Keywords Chronic kidney disease · Cryoablation · Renal cell carcinoma · Kidney · Stage 4

Introduction

There has been a global increase in the number of patients with renal cell carcinoma (RCC) [1]. Additionally, due to advances in medical imaging, RCC is also more frequently incidentally detected [2, 3]. Although surgical resection is a mainstay of the treatment of renal tumors, percutaneous cryoablation is a minimally invasive treatment that is increasingly used for renal tumors [4–6]. Patients with various comorbidities, including chronic kidney disease (CKD), may

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also be candidates for this treatment, and several authors have reported the impact of this treatment on renal function. The preservation of renal function is crucial, particularly for patients with CKD, as well as for local tumor control.

Although several authors have described the effects of cryoablation of RCC in patients with various stages of CKD [7, 8], the literature has not focused on the results obtained for patients with stage 4 or 5 non-dialysis CKD (severely impaired renal function, preparing for renal replacement therapy) thus far. In this study, we retrospectively evaluated the safety and efficacy of cryoablation for the treatment of RCC in patients with stage 4 or 5 non-dialysis CKD.

Materials and methods

This study was conducted by the Japan Image-guided Ablation Group. Each institutional review board approved this retrospective multicenter study and waived the requirement for obtaining informed consent to use the patients' medical data.

Inclusion and exclusion criteria

RCC was diagnosed by percutaneous biopsy, or by imaging when a newly developed tumor or progressively enlarging tumor was present on computed tomography (CT) or magnetic resonance imaging (MRI) (Fig. 1a). Patients who met the following inclusion criteria were included in this study: (1) cryoablation treatment was initially performed between July 2011 and May 2016, at one of the three institutions; (2) the maximum tumor diameter was ≤ 4 cm, and ablation was performed with curative intent; (3) the estimated glomerular filtration rate (eGFR), obtained within 1 month before cryoablation, was < 30 ml/min/1.73 m^2. The following patients were excluded: (1) patients who used a drug that can affect renal function, such as anti-cancer drugs, within 1 month after cryoablation, except for non-steroidal anti-inflammatory drugs for pain relief or for antipyresis after the procedure and antibiotic agents used for infection control; (2) patients who had untreated RCCs after cryoablation; (3) patients who underwent transcatheter arterial embolization prior to cryoablation; (4) patients who underwent dialysis.

Cryoablation procedure

The cryoablation procedure was performed on an inpatient basis. All procedures were performed under moderate sedation and local anesthesia. All cryoablation sessions were performed percutaneously using an argon and helium-based cryoablation system (CryoHit, Galil Medical, Youknum, Israel) with cryoprobes (Ice-Rod or Ice-Seed, Galil Medical). The cryoprobe selection and the number and array of cryoprobes depended on each institution's policy.

The placement of a 17-gauge cryoprobe was performed under CT fluoroscopy (Aquilion PRIME, Aquilion 64, or Asteon, Canon Medical Systems, Otawara, Japan) or MRI (AIRIS II, Hitachi, Tokyo, Japan) guidance. If the tumor was adjacent to a non-target organ, such as the colon, water with or without contrast media was infused to displace the organ away from the expected ablation zone (i.e. hydrodissection). After the placement of the cryoprobes at the target site, cryoablation was performed in two freeze cycles, separated by more than 2 min of passive thawing

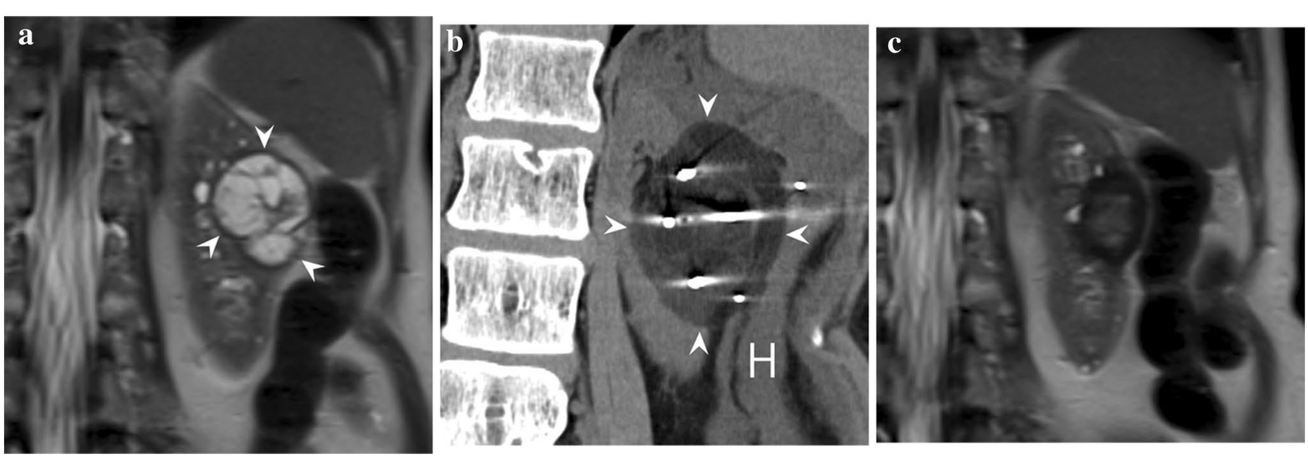

Fig. 1 A 63-year-old woman with chronic kidney disease stage 5 (pre-treatment estimated glomerular filtration rate [eGFR]: 11.8 ml/min/1.73 m^2). Unenhanced coronal T2-weighted magnetic resonance imaging (MRI) demonstrates a left renal tumor (arrow head) of 3.6 cm in diameter (**a**). Coronal reconstructed computed tomography image immediately after cryoablation demonstrates four cryoprobes and an ice-ball (arrowhead) covering the tumor circumferentially. Water density (H) shows injected saline displacing the colon (not shown) (**b**). Coronal T2-weighted MRI obtained 12 months after cryoablation demonstrates regression of the ablation zone without local tumor progression (**c**)

[9]. During or immediately after the freezing, we confirmed that the low-attenuation area on CT or low-signal-intensity area on MRI (i.e., the ice-ball) involved the tumor with an adequate (≥ 6 mm from tumor margin) circumferential ablation margin, whenever possible (Fig. 1b). If the ablation zone was not sufficient to treat the entire tumor, additional freeze and thaw cycles were performed after repositioning the cryoprobes. Completion of placement of both cryoprobes and performing freeze and thaw cycles as planned were considered as defining initial success. Later, each tumor was evaluated using imaging modalities to evaluate the initial efficacy.

Data collection

The medical charts of the 17 patients were carefully reviewed. The images obtained pre- and post-treatment were recorded, and it was also noted whether contrast medium was used. The eGFR was calculated using the following formula: eGFR (ml/min/1.73 m^2) = 194 × SC $r^{-1.094}$ × $age^{-0.287}$ × 0.739 (if female) [10]. The change in eGFR at each time point, compared to that before cryoablation, was defined as eGFR decrease. The percentage of eGFR decrease was defined as the eGFR decrease rate. Adverse events that occurred during and after the procedure, local tumor progression (LTP), distant metastases, and survival were also evaluated. Each adverse event was evaluated according to the Common Terminology Criteria for Adverse Events, version 4.0. Additionally, the R.E.N.A.L. nephrometry (RENAL) score [11] was calculated based on CT or MRI images. Each tumor was classified as low (4–6 points), intermediate (7–9 points), or high (10–12 points).

Statistical analyses

Change in eGFR before and 3 months after the procedure was compared using a paired Student's *t* test. Multiple variables related to the patients and tumors were assessed to determine their impact on the eGFR decrease rate. The patient-related variables were as follows: age (> 75 years or ≤ 75 years), sex (male or female), solitary kidney (yes or no), and eGFR before cryoablation (≥ 20 or < 20 ml/min/1.73 m^2). The tumor-related variables were as follows: maximum tumor diameter (≥ 3.5 cm or < 3.5 cm) and RENAL score. Each variable was compared using an unpaired Student's *t* test. A *P* value of < 0.05 was considered to indicate a statistically significant difference. Statistical Package for the Social Science version 22.0 software (IBM Corp., Armonk, NY, USA) was used for the statistical analyses.

Results

From July 2011 to May 2016, 541 patients underwent cryoablation of renal tumors in three participating institutions. Of these, 17 patients (3.1%; 4 women, 13 men; mean age 70.1 ± 10.6 years; range 55–92 years) met the inclusion criteria and were included in this study. The mean eGFR of the patients before cryoablation was 22.5 ± 6.3 ml/min/1.73 m^2 (median 24.5, range 11.8–29.6 ml/min/1.73 m^2).

Cryoablation was the initial treatment for RCC in 11 of 17 (65%) patients and the secondary treatment after surgery (radical nephrectomy alone in five and partial nephrectomy followed by radical nephrectomy in one patient) in the remaining 6 (35%) patients. Images were obtained before cryoablation by CT (*n* = 17), MRI (*n* = 16), or ultrasonography (*n* = 4). CT with contrast enhancement was performed in four of 17 (24%) patients, and MRI with contrast enhancement was performed in none of the patients (0%). None of the four patients administered contrast medium developed contrast nephropathy. RCC was histologically confirmed in 12 patients (10 clear cell carcinomas, one papillary RCC, and one oncocytic RCC).

The patients' comorbidities or previous medical histories were as follows: cancers other than RCC (*n* = 9; colorectum and prostate in 2, and stomach, lung, urinary bladder, ureter and thyroid in 1), hypertension (*n* = 5), diabetes mellitus (*n* = 3), myocardial infarction (*n* = 1), angina pectoris (*n* = 1), atrial fibrillation (*n* = 1), abdominal aortic aneurysm (*n* = 1), and psoriasis (*n* = 1).

The mean tumor diameter was 2.8 ± 0.7 cm (median 2.8, range 1.7–3.8 cm). The RENAL score was low in seven tumors, intermediate in nine, and high in one. The median number of cryoprobes used was three (range 2–4). The additional freeze and thaw cycles with repositioning the cryoprobes were performed in two (12%) of 17 cryoablation sessions. The median total freezing time was 30 min (range 22–50 min). Hydrodissection was performed in seven (41%) of 17 cryoablation sessions, to displace the colon. Additionally, a ureteral stent was placed before and during cryoablation in one patient to avoid ureteral freezing injury because of the proximity of the RCC to the ureter. Thus, technical success was achieved in all 17 (100%) sessions.

No Grade 3 or higher adverse event occurred during or after the procedure. Grade 2 and Grade 1 periprocedural pain occurred in one (6%) and three (18%) of 17 patients, respectively. Hemorrhagic adverse events (perirenal hematoma or hematuria; Grade 1) occurred in 16 (94%) patients. The only other adverse event was fever (Grade 1), which occurred in 2 (12%) patients. Freezing injury of the adjacent organ, such as the colon and ureter, and skin ulcers did not occur.

For evaluating local tumor progression, the imaging modalities periodically used were CT and MRI in 7

Table 1 Results of estimated glomerular filtration rate (eGFR), eGFR decrease, and eGFR decrease rates at each time point

Time point	# of patients	eGFR (ml/min/1.73 m^2)	*P* (paired *t* test)	eGFR decrease (ml/min/1.73 m^2)	eGFR decrease rate (%)
Pre-CA[a]	17	22.5 ± 6.3	Ref.	Ref.	Ref.
1 day	17	20.8 ± 6.5	0.008	1.7 ± 1.8	7.1 ± 7.4
3 days	13	19.3 ± 6.6	0.06	1.3 ± 2.3	7.0 ± 8.8
1 month	14	19.1 ± 6.2	0.002	2.8 ± 2.6	12.9 ± 11.4
3 months	16	20.0 ± 7.0	0.005	2.2 ± 2.6	10.6 ± 11.9
6 months	16	19.8 ± 7.4	0.005	2.6 ± 3.4	12.8 ± 15.0
12 months	14	18.2 ± 7.2	0.0002	4.1 ± 3.2	20.3 ± 18.1
24 months	11	17.2 ± 8.0	0.0007	5.0 ± 4.0	24.3 ± 18.4

[a]Cryoablation

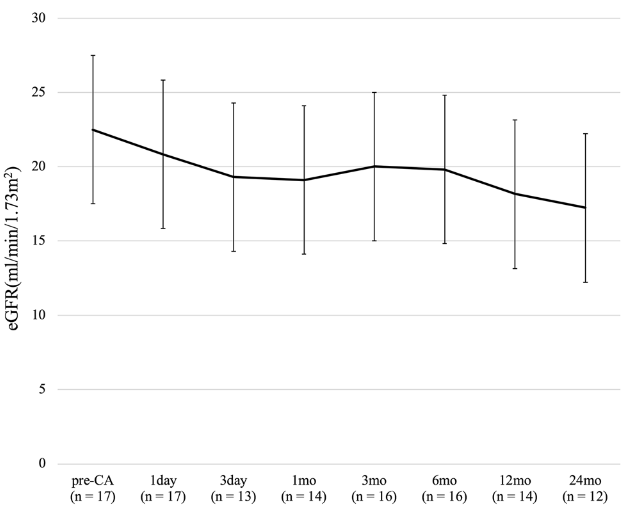

Fig. 2 Change in estimated glomerular filtration rate (eGFR) after cryoablation

Table 2 Univariate analyses of the effect of variables on eGFR decrease rate

Variables	Category	# of patients	eGFR[a] decrease rate (%)	*P*
Age (years)	≥ 75	7	4.8 ± 13.8	0.07
	< 75	9	15.1 ± 7.1	
Sex	M	13	10.4 ± 10.0	0.92
	F	3	11.1 ± 16.9	
Radical nephrectomy	Yes	5	10.8 ± 6.4	0.94
	No	11	10.5 ± 14.0	
Maximum diameter (cm)	≥ 3.5	10	12.3 ± 7.7	0.70
	< 3.5	6	9.8 ± 13.1	
eGFR[a] (ml/min/1.73 m^2)	≥ 20	9	9.2 ± 12.2	0.59
	< 20	7	12.4 ± 11.0	
RENAL score[b]	Low	7	9.2 ± 9.7	0.67
	Intermediate and high	9	11.7 ± 13.7	

[a]Estimated glomerular filtration rate

[b]R.E.N.A.L. nephrometry score

(41%), MRI alone in six (35%: Fig. 1c), or CT alone in four (24%) patients. No contrast enhancement was used in any of these examinations.

The serial changes in eGFR, eGFR decrease, and eGFR decrease rate are shown in Table 1. Although the mean eGFR decreased gradually after cryoablation until 1 month, it had slightly recovered by 3 or 6 months, and then gradually decreased thereafter (Fig. 2). The eGFR at each time point was significantly decreased as compared to that before cryoablation. The effect of each variable on eGFR decrease rates at 3 months after cryoablation is summarized in Table 2. None of the variables demonstrated statistically significant effects. One patient required maintenance dialysis at 21 months after cryoablation. In this patient, the initial tumor diameter was 3.5 cm, and the eGFR value before cryoablation was 17.1 ml/min/1.73 m^2 and that after treatment at 1 day, 3 days, 1 month, 3 months, 6 months, and 12 months was 16.9, 16.0, 14.4, 12.9, 10.7, and 6.8 ml/min/1.73 m^2, respectively.

For the 17 included patients, the median follow-up period after the first ablation session was 30 months (mean 30 ± 13 months; range 7–60 months). LTP occurred in two (12%) of 17 patients (3 and 13 months after cryoablation, respectively). In both tumors, LTP was diagnosed on serial unenhanced MRI. The locally progressed tumors were successfully treated by repeated cryoablation, and LTP did not occur thereafter. None of the 17 patients developed distant metastasis from RCC or de novo RCC in the kidney. One patient developed hepatocellular carcinoma 9 months after renal cryoablation, which was successfully treated with radiofrequency ablation, and another patient developed metastatic bone tumors from unknown primary origin (squamous cell carcinoma) at 30 months and died at 36 months after cryoablation. The remaining 16 patients are still alive, without any residual RCC.

Discussion

High-stage CKD is a critical condition for any patient, regardless of the presence of comorbid RCC. A systemic review showed that non-dialysis CKD was associated with an increased risk of all-cause and cardiovascular death in most studies [12]. Reduced eGFR was an independent risk factor for death. Furthermore, the risk of death increased in accordance with the CKD stage. Go et al. reported that the risk of death, cardiovascular events, or hospitalization of patients with CKD stage 4 was 3.2, 2.8, or 2.1 times greater than that of patients with eGFR of ≥ 60 ml/min/1.73 m^2, respectively [13]. In the natural course of non-dialysis CKD at stage 4 or 5, the mean decrease in eGFR has been reported as 2.3–2.65 ml/min/1.73 m^2 per year [14, 15]. O'Hair et al. reported that the median annual decrease in eGFR was lower for older patients than for younger patients [15]. The risk of having to initiate dialysis in stage ≥ 4 CKD patients has been estimated to be 24–40% within the first 2 years, in cohort studies. Therefore, stage 4 or 5 non-dialysis CKD patients with RCC will unavoidably require the initiation of dialysis in the near future.

A patient with T1a RCC is typically a good candidate for surgical resection, especially for partial nephrectomy. Partial nephrectomy has advanced since the beginning of this century, and is now the standard treatment for early-stage RCC. It can provide oncologic outcomes similar to that obtained with radical nephrectomy [16, 17]. Although, recently, laparoscopic operation or robotic-assisted surgery has been developed for partial nephrectomy, treatment of RCC remains challenging in a difficult clinical context, such as patients with a solitary kidney or severe CKD. The reported eGFR decrease rate after partial nephrectomy was 2.4–11.3% in the short term [18, 19] and 6.2–12.5% by the last follow-up [7, 20].

Few reports have focused on cryoablation of RCC in patients with stage 4 or 5 CKD. Actually, only 17 of 541 (3.1%) patients met the inclusion criteria of the current study. Wehrenberg-Klee et al. reported renal functional outcomes after ablation treatment in patients with CKD. Although they evaluated 48 patients with CKD, 12 of 48 (25%) patients had CKD at stage 4 or 5 and the detailed results of these patients were not described [8]. In the current study, the eGFR decrease at 3 months after the procedure was 2.2 ± 2.6 ml/min/1.73 m^2 and the eGFR decrease rate was 10.6 ± 11.9%. Although the eGFR decrease rate was comparable to that previously reported [4–6], the absolute value of the eGFR decrease was small, because the baseline value was quite low. In general, renal functional outcomes for partial nephrectomy and cryoablation are comparable [7, 18, 20]. Even in a large systemic review, categorical renal functional outcomes of patients with CKD stage ≥ 4 were obtained in 6% of partial nephrectomy and only in 1% of tumor ablation articles [7]. In this study, the eGFR at each time point after cryoablation was significantly decreased. This deterioration was consistent with the effect of cryoablation and the natural course of advanced stage CKD [12, 13]. Indeed, the eGFR decrease at 1 month was believed to be mainly due to the treatment, but it was unclear how much the natural course was responsible for the decrease after 1 month.

Although LTP in the present study occurred in 13% of the cases, which is higher than the figure previously reported [4–6], no residual tumor was seen at the last follow-up. This result is very important, because, if these patients will require initiation of dialysis in the near future, no surgery other than vascular access surgery would be required at dialysis onset. Compared to other ablative modalities, the visible ablation zone (i.e., the ice-ball) is a markedly beneficial feature of cryoablation, as it allows readjustment of cryoprobes to ensure complete ablation. Georgiades et al. have reported that the recommended margin for cryoablation of RCC is 6 mm [21]. Although the ablation margin was deemed to be sufficient in each case in the present study, the operators could try to minimize the ablation zone to preserve renal function as much as possible. Consequently, the ablation margin might have been insufficient in two cases. In contrast, the use of iodized contrast medium for CT or gadolinium contrast medium for MRI is generally contraindicated because of the risk of contrast-induced nephropathy [22] or nephrogenic systemic fibrosis [23]. Therefore, all the follow-up images of CT or MRI were performed without contrast enhancement. This had a negative impact on image evaluation for LTP, as small enhancing foci cannot be detected after cryoablation. Two cases of LTP in this series were detected on MRI without contrast enhancement. We believe that serial follow-up and meticulous comparison of morphology are important for early detection of LTP, even if images are obtained without contrast enhancement.

The RENAL nephrometry score was developed for scoring renal mass characteristics on cross-sectional imaging [8]. Its correlation with surgical outcomes of partial nephrectomy has been evaluated [23, 24]. In terms of cryoablation for RCC, it has been reported that the RENAL score was associated with the risk of post-procedural complications, rather than with the risk of recurrence [25–27]. In the current study, the RENAL score was not associated with the eGFR decrease rate, and no adverse event (CECAE Grade ≥ 3) occurred after the procedure.

This study had several limitations. First, it had a retrospective design; second, we investigated a small number of patients; third, not all the tumors were histologically confirmed; and fourth, we used various imaging modalities for treatment guidance and outcome evaluation.

In conclusion, cryoablation of RCC in patients with stage 4 or 5 CKD is safe and yields treatment results comparable to those of the previous reports which consisted of the patients without CKD. This treatment could be completed without the early initiation of hemodialysis after the procedure.

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Compliance with ethical standards

Conflict of interest Hideo Gobara and Takao Hiraki received funding from Okayama Prefecture, JPSS and AMED. Other authors have no conflict of interest to declare.

Ethical statement Each institutional review board approved this retrospective multicenter study and waived the requirement for obtaining informed consent to use the patients' medical data. All procedures performed were in accordance with the ethical standards of the institutional research committees and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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