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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Effect of lipiodol marking before CT-guided cryoablation on the outcome of sporadic renal cell carcinoma

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PURPOSE

This retrospective study evaluates the impact of preoperative lipiodol marking on the outcomes of computed tomography (CT)-guided cryoablation for histologically diagnosed sporadic renal cell carcinoma (RCC).

METHODS

This study analyzed the data of 173 patients who underwent CT-guided cryoablation for histologically proven sporadic RCC at a single institution between April 2014 and December 2020. The local control rate (LCR), recurrence-free survival rate (RFSR), overall survival rate (OSR), changes in renal function, and complications in patients with (n = 85) and without (n = 88) preoperative lipiodol marking were compared.

RESULTS

The 5-year LCR and 5-year RFSR were significantly higher in patients with lipiodol marking (97.51% and 93.84%, respectively) than in those without (72.38% and 68.10%, respectively) (*P* value <0.01, log-rank test). There were no significant differences between the two groups regarding the 5-year OSR (97.50% vs. 86.82%) or the deterioration in chronic kidney disease stage (12.70% vs. 16.43%). Grade ≥3 complications occurred in patients with lipiodol marking (n = 2, retroperitoneal hematoma and cerebral infarction in 1 patient each) and without (n = 5; urinary fistula in 2, colonic perforation in 2, urinary infection in 1).

CONCLUSION

Lipiodol marking before CT-guided cryoablation for sporadic RCC is a feasible approach to improving local control and RFS while mitigating the decline in renal function. Additionally, it may help reduce complications.

KEYWORDS

Ablation, cryoablation, computed tomography, kidney, oncology, tumor ablation

Renal cell carcinoma (RCC) ranks among the top 10 most common cancers, displaying higher prevalence in men than in women and often peaking between the ages of 60 and 70 years.[1,2] Advancements in diagnostic imaging modalities have led to a rising incidence of incidentally detected cases.[3,4] Although surgical resection remains the primary treatment, image-guided ablation techniques such as cryoablation and radiofrequency ablation are emerging as viable alternative therapies.[5-7]

Cryoablation for RCC has gained prominence as a minimally invasive treatment in recent years. Studies indicate its efficacy in providing high local control and preserving renal function to levels comparable to surgical resection. It is particularly applicable to elderly patients or those with comorbidities or multiple lesions.[8-12]

Presently, image-guided procedures dominate cryoablation for RCC, utilizing imaging equipment for lesion targeting and therapeutic area monitoring. Computed tomography

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(CT), magnetic resonance imaging (MRI), and ultrasonography serve as primary imaging modalities, with CT being the most practical. The treated area is visualized as a low-density "ice ball".[13-16]

A key limitation of CT-guided cryoablation is its poor soft-tissue contrast, which often makes it difficult to identify the lesion and distinguish it from the normal kidney.[17] This is particularly apparent in small-diameter or embedded lesions, which are common indications for cryoablation treatment. Although intravenously administered contrast improves visibility, the effect is transient and cannot be sustained throughout the time-consuming cryoablation procedure. To address these limitations, preoperative transarterial lipiodol marking has been developed as a preoperative (1 or 2 days) procedure to enhance lesion visibility.[18-21] Although this technique has shown promising efficacy in small case series, its superiority compared with cryoablation without lipiodol marking remains inadequately established.

Hence, this study aims to evaluate the mid- to long-term outcomes of lipiodol marking performed before cryoablation for RCC, comparing cases with and without lipiodol marking. The analysis includes an assessment of its impact on renal function and the incidence of complications.

Methods

Participants

This study obtained approval from the institusion's review board of Kyushu University Hospital and Medical Institutions (no: 21109-00), and the requirement for informed consent was waived. The indication for cryoablation for RCC was determined through discussions among radiologists and urologists while considering factors such as the patient's age, comorbidities, surgical history, and renal function. Cryoablation was especially considered for lesions that would be difficult to surgically resect. Patients were actively engaged in this decision-making process and provided explicit consent for the procedure.

Main points

- Lipiodol marking prior to computed tomography-guided cryoablation for sporadic renal cell carcinoma (RCC) improves local control.
- Renal dysfunction caused by lipiodol marking is clinically acceptable.
- Lipiodol marking prior to cryoablation for RCC may reduce complications.

During the period from April 2014 to December 2020, 336 renal tumors in 280 patients received cryoablation. Patients with sporadic RCC were selected, excluding those with prior RCC or treatment history, multiple lesions, or hereditary diseases such as Von Hippel–Lindau syndrome. Subsequently, out of 221 eligible cases, 173 cases with a histological diagnosis of RCC were included in this study (Figure 1). Lipiodol marking was performed in 85 cases before cryoablation and was not performed in 88 cases. Table 1 summarizes the patients' demographic data and tumor characteristics, revealing no statistically significant differences between the two groups in any variables.

Transarterial lipiodol marking

As described in a previous article,[22] transarterial lipiodol marking aimed to enhance tumor visibility before cryotherapy. Under local anesthesia, a 3- to 4-F sheath (Super Sheath, Medikit, Tokyo, Japan) was inserted through the femoral artery. Digital subtraction angiography of the renal arteries and branches was performed. Contrast media use was minimized in patients with impaired renal function and sometimes replaced with carbon dioxide for contrast enhancement. Feeding arteries were identified based on DSA findings and contrast-enhanced CT. Selective catheter insertion was performed into the feeding arteries, and lipiodol (Guerbet, France) was injected along with a small amount of gelatin sponge for embolization (Serescue, Nippon Kayaku, Tokyo, Japan). Unenhanced CT imaging confirmed lipiodol deposits in the lesion before completing the procedure.

Cryoablation procedure

Cryoablation was performed as described in a previous article.[22] Briefly, it was performed under local anesthesia using an interventional radiology-CT system (Aquillion One, Canon, Tokyo, Japan) and a cryoablation system (CryoHit, Galil Medical, Arden Hills, MN, USA). Cryoprobes (IceRod, IceSeed, Galil Medical) were inserted into the tumor, which was frozen in two 10-minute sessions. The ablation area extended with a 5-mm margin from the lesion. Needle biopsies were performed before or during cryoablation.

Follow-up

Post-cryoablation, the patients received inpatient care for several days, followed by outpatient consultations at 3 months post-procedure and every 6 months thereafter. These consultations aimed to assess complications and treatment efficacy, defining local recurrence as a residual or new lesion within or near the ablation area that visibly increased in size during the follow-up period. Further details on the follow-up protocol can be found in our previous article on cryoablation for RCC.[22]

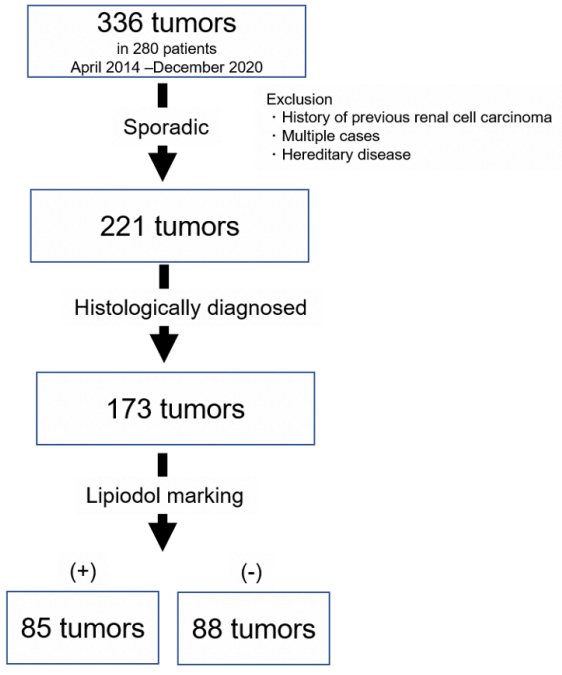


Figure 1. Selection of participants with cryoablation for sporadic renal cell carcinoma with histologic diagnosis.

Evaluations and statistical analysis

Demographic data in patients with sporadic RCCs treated by cryoablation were extracted and included age, sex, renal function [estimated glomerular filtration rate (eGFR), chronic kidney disease (CKD) grade], bilateral/unilateral kidney, presence of diabetes, anticoagulant/platelet medication, and history of other malignant diseases. The extracted characteristics of the tumor treated by cryoablation were size, location (right/left, exophytic/endophytic/hilum, upper/middle/lower, anterior/posterior/x), and histology (clear cell/papillary/chromophobe). The demographic data and tumor characteristics were compared between the groups with and without lipiodol marking using the Student's t-test for continuous variables (e.g., age, eGFR, tumor size).

The chi-square test was used for two categorical variables (e.g., sex, CKD grade, bilateral/unilateral kidney, presence of diabetes, anticoagulant/platelet medication, history of other malignant diseases, right/left). Furthermore, the Fisher–Freeman–Halton test was used for more than three categorical variables (e.g., exophytic/endophytic/hilum, upper/middle/lower, anterior/posterior/x) (Table 1). Local control was defined as no recurrence in the treated region as identified by CT or MRI after cryoablation.

Recurrence-free survival was defined as being alive without local recurrence in the treated area or distant metastasis by CT or MRI. Overall survival was defined as being alive with or without local recurrence or distant metastasis. The date of cryoablation was used as the starting point for the observation period. The local control rate (LCR), relapse-free survival rate (RFSR), and overall survival rate (OSR) of cryoablation for sporadic RCCs with or without preoperative lipiodol marking were obtained using the Kaplan-Meier method, followed by a log-rank test. Multiple Cox regression analyses of the LCR were performed to assess the effects of lipiodol marking, age, sex, bilateral/unilateral kidney, renal function, diabetes, anticoagulant/platelet medication, other malignant diseases, tumor size, tumor location, and histology.

For the evaluation of the change in renal function, a comparison of the ΔeGFR and downgrades in CKD stage between the two groups was analyzed using the Student's t-test and chi-square test, respectively. The common terminology criteria for adverse events (CTCAE), version 5, published by the US National Cancer Institute in 2017, was used to evaluate complications on a graded scale. The frequency of complications of CTCAE grade 3 or higher was also compared between the two groups using Fisher's exact test. For all statistical analyses, P values <0.05 were considered significant. All analyses were performed using JMP pro, version 15, software (SAS, Cary, NC, USA). Descriptive statistics are presented as mean ± standard deviation or median ± standard error, and frequencies are presented as percentages.

Table 1. Demographic data and tumor characteristics in all patients with sporadic renal cell carcinomas treated by cryoablation

	Lipiodol marking (+) (n = 85)	Lipiodol marking (-) (n = 88)	*P* value*
Demographic data			
Age, y (mean ± SD)	71.33 ± 11.22	71.20 ± 11.27	0.472
Sex, male/female (%)	60/25 (70.59/29.41)	68/20 (73.12/26.88)	0.316
Renal function			
eGFR mL/min/1.73 m^2 (mean ± SD)	60.92 ± 23.07	56.91 ± 22.02	0.244
CKD grade, 2/3/4/5 (%)	49/27/5/4 (57.65/31.76/5.88/4.71)	44/35/6/3 (50/39.77/6.82/3.41)	0.686
Kidney, bilateral/unilateral (%)	84/1 (98.82/1.18)	81/7 (92/04/7.95)	0.064
Diabetes, yes/no (%)	19/66 (22.35/77.65)	17/71 (19.32/80.68)	0.623
Anticoagulant/platelet drug, yes/no (%)	23/62 (27.06/72.94)	29/59 (32.95/67.05)	0.400
Other malignant diseases, yes/no (%)	27/58 (31.76/68.23)	30/58 (34.01/65.91)	0.745
Tumor characteristics			
Tumor size, mm (mean ± SD)	24.27 ± 7.47	26.08 ± 7.92	0.124
Tumor location			
Right/left (%)	39/46 (45.88/54.12)	47/41 (53.41/46.59)	0.322
Exophytic/endophytic/hilum (%)	48/31/6 (56.47/36.47/7.06)	41/39/8 (46.59/44.32/9.09)	0.428
Upper/middle/lower (%)	26/45/14 (30.59/52.94/16.47)	26/41/21 (29.55/46.59/23.86)	0.464
Anterior/posterior/x** (%)	35/41/9 (41.18/48.24/10.59)	37/43/8 (42.04/48.86/9.09)	0.947
Histology, clear cell/papillary/chromophobe (%)	79/5/1 (92.94/5.88/1.18)	82/6/0 (93.18/6.82/0)	0.578

*Categorical data: chi-square test for two variables and Fisher–Freeman–Halton test for more than three variables, continuous variable: Student's t-test. **Unclassifiable as a polar lesion. eGFR, estimated glomerular filtration rate; SD, standard deviation; CKD, chronic kidney disease.

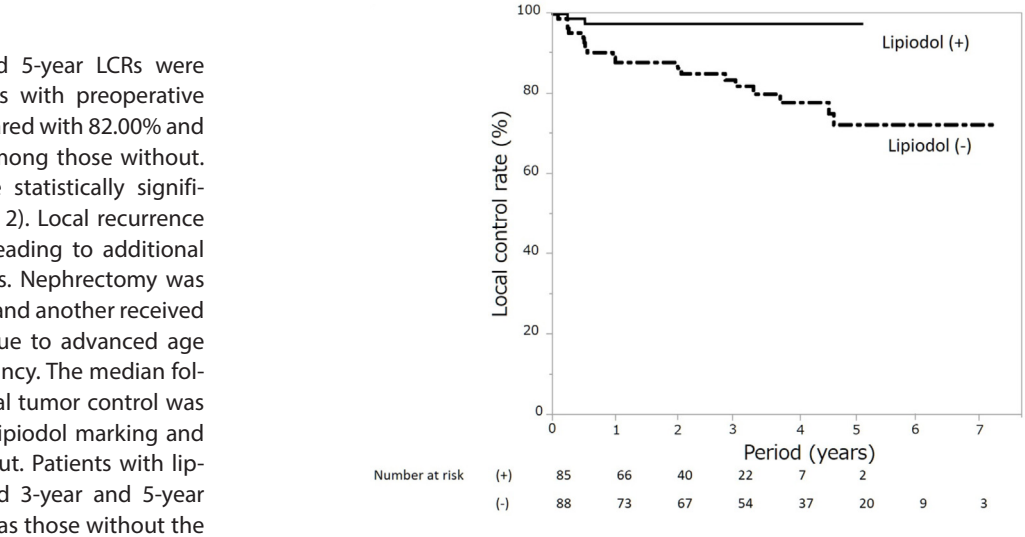
Results

Both the 3-year and 5-year LCRs were 97.51% among patients with preoperative lipiodol marking, compared with 82.00% and 72.38%, respectively, among those without. These differences were statistically significant ($P = 0.005$) (Figure 2). Local recurrence occurred in 20 cases, leading to additional cryoablation in 18 cases. Nephrectomy was performed in one case, and another received no further treatment due to advanced age and concurrent malignancy. The median follow-up duration for local tumor control was 2.01 ± 0.13 years with lipiodol marking and 3.12 ± 0.21 years without. Patients with lipiodol marking exhibited 3-year and 5-year RFSRs of 93.84%, whereas those without the marking had rates of 80.97% and 68.10%, respectively.

These differences were statistically significant ($P = 0.020$) (Figure 3). Four cases developed lung metastases. The 3-year and 5-year OSRs were both 97.50% for patients with lipiodol and 96.08% and 86.82%, respectively, for those without. However, these values did not constitute statistically significant differences (Figure 4). All deaths were attributed to diseases other than RCC. Multiple Cox regression analyses revealed significant effects of lipiodol marking ($P = 0.012$) and tumor size ($P = 0.045$) on the LCR (Table 2).

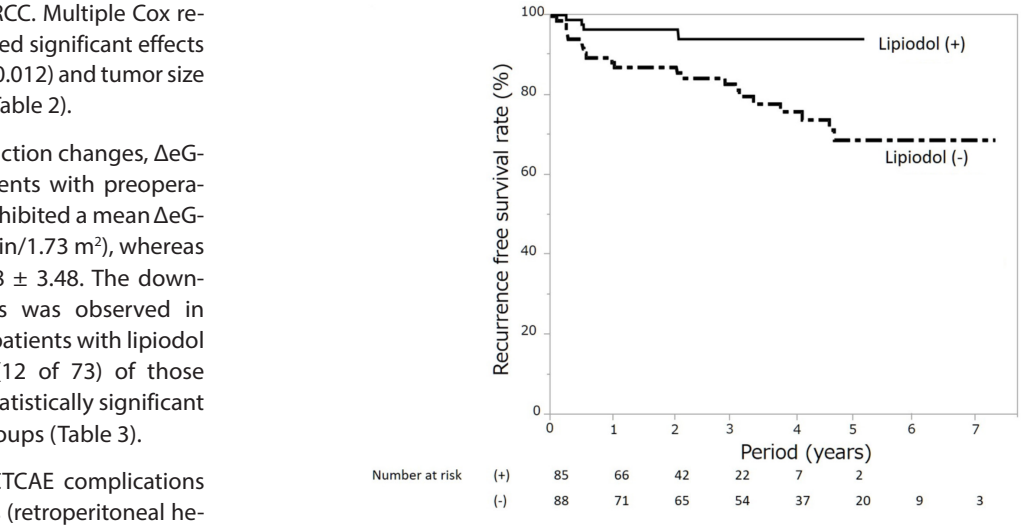
To evaluate renal function changes, ΔeGFR was calculated. Patients with preoperative lipiodol marking exhibited a mean ΔeGFR of 4.34 ± 8.08 (mL/min/1.73 m^2), whereas those without had 3.48 ± 3.48. The downgrading of CKD status was observed in 12.70% (8 of 63) of the patients with lipiodol marking and 16.43% (12 of 73) of those without, revealing no statistically significant differences between groups (Table 3).

Grade 3 or higher CTCAE complications occurred in only 2 cases (retroperitoneal hematoma in 1, cerebral infarction in 1) with lipiodol marking and 5 cases (urinary fistula in 2, colonic perforation in 2, urinary infection in 1) without. There was no statistically significant difference in the frequency of complications of CTCAE grade 3 or higher between the two groups (Table 4). The most common complications after cryoablation were fever, pain, and hematuria, almost all of which were grade 2 or lower.



	Period (years) median ± SE	LCR 3 years	LCR 5 years	*P* value
Lipiodol (+)	2.01 ± 0.13	97.51%	97.51%	0.005
Lipiodol (-)	3.12 ± 0.21	82.00%	72.38%	

Figure 2. The local control rate (LCR) of sporadic renal cell carcinomas treated by cryoablation with or without preoperative lipiodol marking. The LCR at 3 years was 97.51% with and 82.00% without preoperative lipiodol marking; at 5 years, those values were 97.51% and 72.38%, respectively. There was a statistically significant difference between them (log-rank test, $P = 0.005$). SE, standard error.



	Period (years) median ± SE	LCR 3 years	LCR 5 years	*P* value
Lipiodol (+)	2.01 ± 0.13	93.84%	93.84%	0.020
Lipiodol (-)	3.12 ± 0.21	80.97%	68.10%	

Figure 3. The recurrence-free survival rates (RFSRs) of all patients with sporadic renal cell carcinomas treated by cryoablation with or without preoperative lipiodol marking. The RFSRs at 3 years were 93.84% with and 80.97% without preoperative lipiodol marking; at 5 years, those values were 93.84% and 68.10%, respectively. There was a statistically significant difference between them (log-rank test, $P = 0.020$). SE, standard error; LCR, local control rate.

Discussion

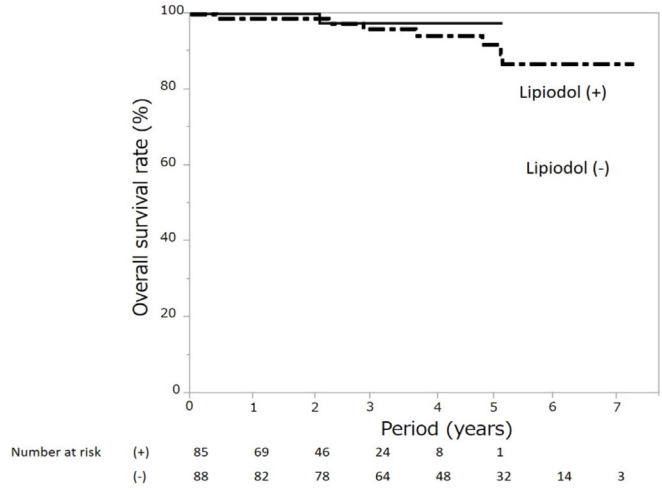
This retrospective study compared cryoablation outcomes, renal function changes, and complications in patients with and without lipiodol marking to clarify the usefulness of lipiodol marking prior to cryoablation for sporadic RCC. Despite its retrospective nature, no significant differences were observed in demographic data or tumor characteristics between groups, establishing the study as a reliable comparison. The LCR was significantly higher in patients with lipiodol marking than in those without. Previous reports have also reported the usefulness of lipiodol marking and effective short-term local control.[18-21] Moreover, there have been no reports of mid- to long-term treatment effects compared with groups without lipiodol marking, as in this study, and the results of this study further support the usefulness of lipiodol marking in the therapeutic effects of cryoablation.

The first factor that improves local control and other treatment effects is improved lesion visibility with lipiodol marking (Figure 5). CT has lower soft-tissue resolution than MRI, and RCCs with small tumor diameters and embedded lesions can be difficult to recognize through CT fluoroscopy.[19] The improved visibility of the lesion and more accurate puncture of the cryoprobe were obvious factors contributing to the improved outcome of the treatment.

In addition, the decrease in blood flow in the lesion may have been a factor affecting the treatment outcome. RCC is a tumor with abundant blood flow, and this heat sink is known to attenuate the freezing effect.[23] The small amount of embolic material in lipiodol marking is thought to induce a degree of ischemia in the lesion, and this may have reduced the heat sink effect and contributed to the therapeutic effect of cryoablation.

Transarterial lipiodol marking prior to cryoablation is associated with concerns regarding damage to the normal kidney and impaired renal function. In this study, there was no significant difference in change in renal function (eGFR) or CKD stage after cryoablation between the groups with and without lipiodol marking. Previous reports have also reported minimal deterioration in renal function when lipiodol marking was performed prior to cryoablation.[20] It is necessary to limit the use of contrast media in patients with severely impaired renal function and to be careful about the extensive injection of lipiodol into the normal renal parenchyma. However, lipiodol marking performed before cryoablation seems acceptable from the perspective of preserving renal function.

Complications were similar to those in previous reports, with most being minor (CTCAE grade 2 or lower) in groups with and without lipiodol marking.[8-10,18-21]



	Period (years) median ± SE	LCR 3 years	LCR 5 years	*P* value
Lipiodol (+)	2.01 ± 0.13	97.50%	97.50%	0.489
Lipiodol (-)	4.60 ± 0.18	96.08%	86.82%	

Figure 4. Overall survival rate (OSR) of all patients with sporadic renal cell carcinomas treated by cryoablation with or without preoperative lipiodol marking. The OSR at 3 years was 97.50% with and 96.08% without preoperative lipiodol marking; at 5 years, those values were 97.50% and 86.82%, respectively. There was no statistically significant difference between them (log-rank test, $P = 0.489$). SE, standard error; LCR, local control rate.

Table 2. Results of multiple Cox regression analysis of local control in patients with sporadic renal cell carcinomas treated by cryoablation

	HR (95% CI)	*P* value
Lipiodol marking (+/-)	0.145 (0.032, 0.657)	0.012
Age	1.385 (0.162, 11.866)	0.766
Sex	0.662 (0.209, 2.091)	0.482
Renal function		
eGFR	1.019 (0.969,1.071)	0.469
CKD grade	2.118 (0.378, 12.105)	0.870
Kidney	4.024 (0.589, 27.496)	0.156
Diabetes	1.941 (0.541, 6.966)	0.309
Anticoagulant/platelet medication	0.456 (0.136, 1.525)	0.203
Other malignant disease	0.552 (0.189, 1.613)	0.277
Tumor size	1.077 (1.002, 1.158)	0.045
Tumor location		
Right/left	0.435 (0.162, 1.169)	0.100
Exophytic/endophytic/hilum*	1.232 (0.240, 6.309) 1.935 (0.419, 8.941)	0.802 0.398
Upper/middle/lower*	0.610 (0.091, 4.094) 1.675 (0.283, 9.928)	0.611 0.570
Anterior/posterior*/X	0.374 (0.115, 1.225) <0.001 (0, 0)	0.104 1.000
Histology Clear cell/papillary*/other	2.884 (0.302, 27.505) 94.934 (0, 0)	0.357 1.000

*Reference category, *P* value of the Cox regression model: 0.022. HR, hazard ratio; eGFR, estimated glomerular filtration rate; CKD, chronic kidney disease; CI, confidence interval.

Table 3. Change of renal function 1 year after cryoablation for sporadic renal cell carcinomas

	Lipiodol marking (+)	Lipiodol marking (-)	*P* value*
ΔeGFR (mL/min/1.73 m^2) (SD)	Mean 4.34 (± 8.08)	Mean 3.48 (± 8.64)	0.547
Downgrade of CKD stage (n)	12.70% (8/63)	16.43% (12/73)	0.600

*ΔeGFR, Student's t-test, downgrade of CKD stage: chi-square test. eGFR, estimated glomerular filtration rate; CKD, chronic kidney disease; SD, standard deviation.

Table 4. Complications of common terminology criteria for adverse events grade 3 or above following cryoablation for sporadic renal cell carcinomas

Lipiodol (+) (n = 85)	Lipiodol (-) (n = 88)	*P* value*
Retroperitoneal hematoma: n = 1 Cerebral infarction: n = 1	Urinary fistula: n = 2 Urinary tract infection: n = 1 Colonic perforation: n = 2	
n = 2 (2.35%)	n = 5 (5.68%)	0.444

*Fisher's exact test.

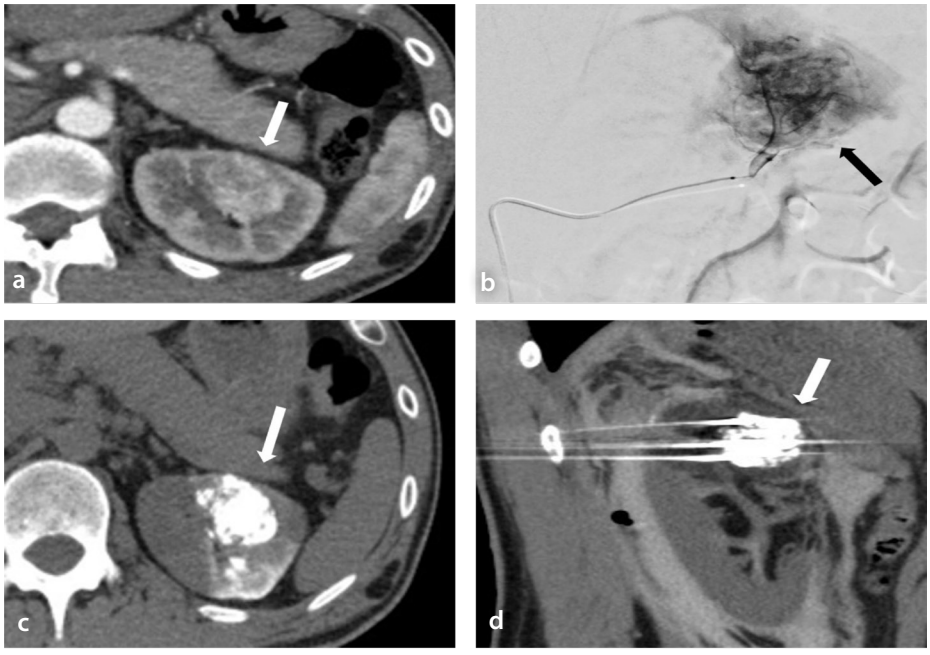


Figure 5. Cryoablation for a sporadic renal cell carcinoma of a 47-year-old man with preoperative lipiodol marking. **(a)** Contrast-enhanced CT showed an endophytic 3.3-cm mass at the ventral side of the left kidney (arrow). **(b)** Digital subtraction angiography from the upper branch of the left renal artery showed a hypervascular lesion representing the renal mass (arrow). **(c)** CT after transarterial lipiodol marking showed well-infused lipiodol in the renal mass (arrow). **(d)** CT-guided cryoablation was performed on the lipiodol-infused mass (arrow) using cryoprobes. After 4 years of follow-up, there was no recurrence, the ΔeGFR was 2, there was no decrease in CKD grade, and there were no grade 3 or higher complications. CT, computed tomography; eGFR, estimated glomerular filtration rate; CKD, chronic kidney disease.

The two complications that were grade 3 or higher in the group with lipiodol marking were an iliopsoas hematoma in a patient with severely impaired coagulation and a perioperative cerebral infarction in a patient on anticoagulation and platelet medication.

These events could have occurred regardless of whether or not lipiodol marking was performed. The two cases of intestinal perforation among the grade 3 or higher complications in the group without lipiodol marking may have been caused by the intestine entering the cryoablation area because the cryoprobes were inserted while the positional relationship between the lesion to be treated and the surrounding intestine was poorly visualized (Figure 6).

No intestinal perforation occurred in the group with lipiodol marking in this study, suggesting that lipiodol marking may reduce the risk of intestinal perforation. Although no statistically significant differences were found, our data suggest that improved lesion visibility may result in less frequent complications from cryoablation.

Transarterial lipiodol marking as a pretreatment for cryoablation for RCC is widely used in Japan,[18-20] but it is not well recognized in other countries. Selective catheterization of the target vessel by a transarterial approach, as well as infusion and embolization, is not a difficult procedure for many interventional radiologists and does not require special training. It should be more widely recognized as a method to improve the quality of cryoablation for RCC.

The limitation of this study is that it is a single-center, retrospective study. The number of cases was not sufficiently large. Although there have been reports on the efficacy of cryoablation treatment in larger patient populations,[8,11,12] there have been no reports on a larger group of participants in studies of lipiodol marking in cryoablation. Furthermore, cases with no tissue diagnosis on biopsy were excluded from this study. It was assumed that lesions that are difficult to diagnose by biopsy (small diameter, endophytic, hilum type, etc.) may not be easily treated by cryoablation, which may have affected the results of this treatment, the changes in renal function, and the occurrence of complications.

Finally, in the group with lipiodol marking, there was a concern that the lipiodol deposited in the lesions may interfere with the early detection of recurrent lesions by contrast-enhanced CT. In this study, the observation period for the group with lipiodol marking was shorter than that for the group without lipiodol marking, suggesting that further follow-up is needed.

Lipiodol marking prior to CT-guided cryoablation for sporadic RCC is a feasible approach to improve local control and RFS while lessening the decline in renal function, and it may be able to reduce complications.

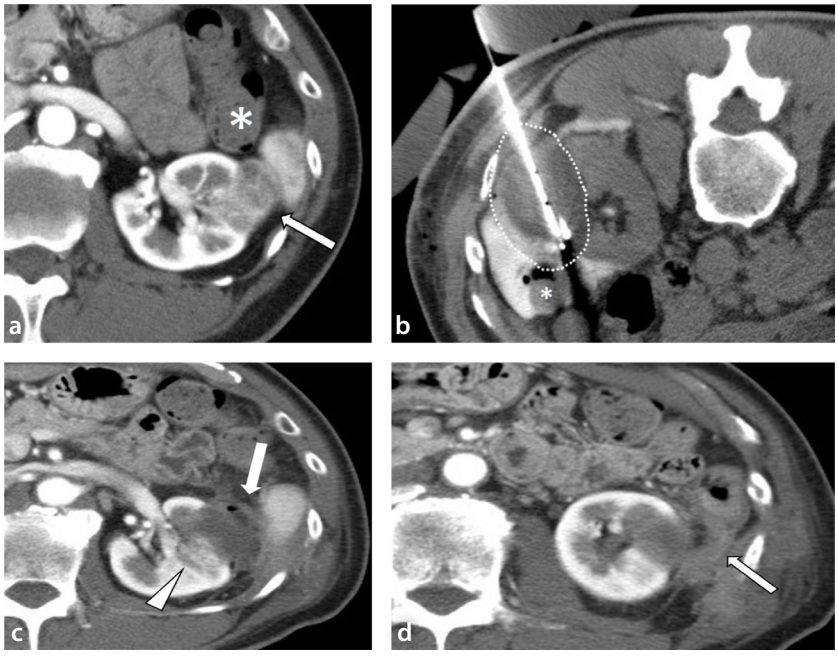


Figure 6. Cryoablation for a sporadic renal cell carcinoma of a 71-year-old man without preoperative lipiodol marking. **(a)** Contrast-enhanced CT showed an exophytic 2.9-cm mass at the anterolateral side of the left kidney (arrow). The mass and the descending colon (*) were in close contact. **(b)** CT-guided cryoablation was performed for the mass using cryoprobes with hydrodissection. However, part of the cryoablation area (dotted circle) extended over the colon (*). **(c, d)** Contrast-enhanced CT 1 month after cryoablation showed abscess formation (**c**, arrow) due to colon perforation (**d**, arrow), and part of the renal mass remained due to an insufficient cryoablation effect (**c**, arrowhead). Surgical resection was performed for the colon perforation, and additional cryoablation was performed for the residual lesions. CT, computed tomography.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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