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Review

Complications of Percutaneous Cryoablation for Renal Tumors and Methods for Avoiding Them

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Percutaneous cryoablation of renal tumors is widely used because of its high efficacy and safety. This high safety can be attributed, at least in part, to the visibility of the ablated area as an "ice ball". This therapy has fewer complications (incidence, 0-7.2%) and is less invasive than surgery. Minor bleeding is inevitable in most kidney-related procedures, and indeed the most common complication of this therapy is bleeding (hematoma and hematuria). However, patients require treatment such as transfusion or transarterial embolization in only 0-4% of bleeding cases. Various other complications such as ureteral or collecting system injury, bowel injury, nerve injury, skin injury, infection, pneumothorax, and tract seeding also occur, but they are usually minor and asymptomatic. However, operators should know and avoid the various complications associated with this therapy. This study aimed to summarize the complications of percutaneous cryoablation for renal tumors and provide some techniques for achieving safe procedures.

Key words: cryosurgery, kidney neoplasms, carcinoma, renal cell, complication

Various percutaneous ablation therapies, such as cryoablation (CRA), radiofrequency ablation (RFA), and microwave ablation (MWA), have recently been used to treat patients with small renal cell carcinoma (RCC). They have shown excellent clinical results in terms of oncologic outcomes and safety. There are several reasons for the relative safety of CRA. In the clinical setting of image-guided CRA, the ablated area is visible as an "ice ball" under all modalities [1], such that operators can easily confirm the extent of the ablated area during the procedure. In addition, in the case of small renal masses, CRA is relatively painless and can be performed with significantly less sedation than RFA; one study found the mean fentanyl dose for 71 RFA and 65 CRA patients to be 236.4 μg and 172.3 μg, respectively; $p < .001$) [2]. Moreover, CRA is less likely to injure the collecting system: in a retrospective review of 67 cases in which the ice ball overlapped the renal sinus, no cases were complicated by collecting system injury [3]. Lastly, various techniques are available to reduce the risk of specific CRA complications. The purpose of this review is to summarize the potential complications of percutaneous CRA for renal tumors and provide some techniques to avoid them.

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Literature Review

Literature search. A literature search was performed in September 2021 using the following keywords in PubMed: "cryoablation or cryosurgery" and "renal mass or renal tumor or renal cell carcinoma" and "complication or safety." The search was limited to articles published after 2011. A total of 525 articles were identified, and the list of all electronically identified articles was manually examined to identify potentially relevant studies.

The following articles were excluded: i) non-English articles, ii) those with < 100 tumors, or iii) those with unknown results of percutaneous CRA only. Additionally, cited references from the selected articles and review articles retrieved in the search were assessed to identify significant manuscripts that had not been previously included. Of these, 37 articles that met the criteria were included in the review. The frequency of complications was cited from results at a single institution; in multi-institution reports, the results of the institution with the most tumors ablated were used (Table 1 [3-17]).

Imaging and sedation. Percutaneous CRA is always performed under image guidance. Computed tomography (CT) or magnetic resonance imaging are most frequently used as guidance modalities [1]. With CT guidance, a whole-body evaluation can be performed directly and easily after CRA. Post-ablation complications such as bleeding are better assessed on CT than on ultrasound [1]. Due to its high safety and minimal invasiveness, percutaneous CRA can be performed under conscious sedation on an outpatient basis [5,7]. Okhunov *et al.* retrospectively showed that there was no difference in treatment-related complications between 152 patients treated with CRA under local anesthesia with conscious sedation and 82 patients treated with general anesthesia (11.7% vs. 8.5%; $p = 0.454$) [18].

Complications. Various CRA-related complications may occur, including bleeding, ureteral or collecting system injury, bowel injury, nerve injury, skin injury, infection, pneumothorax, seeding, renal failure, cardiovascular and cerebrovascular events, and others [19]. However, most are usually minor and asymptomatic and do not require any therapy.

Frequency of all and major complications. The frequencies of any complication and of major complica-

Table 1 Complication rate of percutaneous renal cryoablation

	Author (reference number)/Year	Tumor/patient number	Mean tumor size (cm)	Study design	Complication classification used	Definition of major complication	Complication rate (%) All	Major	Bleeding with treatment	Urinary injury or obstraction with treatment	Pneumothorax with tube placement	Bowel injury with treatment	Pulmonary embolism
1	Rosenberg [3]/2011	129/107	2.2	Retrospective			N/A	0.8	0.8	N/A	N/A	N/A	N/A
2	Knox [4]/2020	297/277	2.5	Retrospective	SIR classification	≧C	N/A	3.0	1.0	N/A	N/A	N/A	0.3
3	Aoun [5]/2017	382/302	2.9	Retrospective	Clavien-Dindo	≧III	N/A	2.8	1.1	0.3	N/A	0.3	0.3
4	Breen [6]/2018	484/433	3.3	Retrospective	Clavien-Dindo	≧III	N/A	4.9	0.2	1.9	2.1	N/A	0.2
5	Georgiades [7]/2014	261/246		Prospective	CTCAE v.4.0	>2	N/A	5.7	1.5	1.1	0.8	N/A	N/A
6	McCafferty [8]/2021	201/201	2.8*	Retrospective	CIRSE classification	≧III	30.3	5.5	4.0	N/A	0.5	N/A	N/A
7	Cazzato [9]/2021	149/143	2.71	Retrospective	Clavien-Dindo	≧III	10.7	0.7	0.7	N/A	N/A	N/A	N/A
8	Patel [10]/2020	100/100	2.22	Retrospective	Clavien-Dindo	†	6.0	2.0	1.0	1.0	N/A	N/A	N/A
9	Pickersgill [11]/2020	328/308	2.7	Retrospective	Clavien-Dindo	≧II	8.1	N/A	2.6	0.6	N/A	0.3	0.6
10	Lim [12]/2020	185/180	2.85	Retrospective	Clavien-Dindo	≧III	3.2	2.2	0.5	0.5	0.5	N/A	N/A
11	Fraisse [13]/2019	177/177	2.59	Retrospective	Clavien-Dindo	†	15.8	1.7	N/A	0.6	0.6	0.6	N/A
12	Zargar [14]/2015	137/137	2.2*	Retrospective	Clavien-Dindo	†	7.27	0.7	N/A	N/A	N/A	N/A	0.7
13	Bhindi [15]/2017	618/565	3.0*	Retrospective	Clavien-Dindo	≧III	15.0	7.2	N/A	N/A	N/A	N/A	N/A
14	Blute [16]/2012	139/139	2.4	Retrospective	Clavien-Dindo	†	12.9	0	N/A	N/A	3.6 ‡	2.2 ‡	N/A
15	Hartman [17]/2014	114/114	2.5	Retrospective			N/A	N/A	N/A	N/A	N/A	N/A	2.6 §, 3.5‖

*Median; † We defined major complication as Clavien-Dindo ≧III; ‡ Observation; § Frequency within 30 days after cryoablation; ‖ Frequency within 365 days after cryoablation
N/A, not applicable; SIR, Society of Interventional Radiology; CTCAE, Common Terminology Criteria for Adverse Events; CIRSE, Cardiovascular and Interventional Radiological Society of Europe.

tions were 3.2-30.3% [8-14] and 0-7.2% [3-10, 12-16], respectively (Table 1). While different complication classifications were used, and the definition of major complications was not uniform across studies, most often they were defined by either the original authors or us as Clavien-Dindo grade [20] ≥ III. In the SIR quality improvement standards, Gunn *et al.* proposed that rates of major complications for T1a RCC exceeding 8% warrants a review of the operator's performance [19].

Risk factors for any and major complications have been reported. Risk factors for major complications have included patient age, tumor size, number of CRA probes, history of prior kidney surgery, RENAL score, and (MC)2 score [4, 5, 8, 15, 21, 22]. In addition to the aforementioned factors of major complications, comorbidity and upper pole location have been reported in all complications [10, 11, 15, 16, 23, 24]. Thus, percutaneous CRA must be performed more carefully when performing more CRA probe punctures in older patients with larger tumors.

There are inherent technical challenges and difficulties associated with percutaneous CRA in obese patients. However, obesity was not a significant factor for complications in retrospective studies [10, 25]. One study showed no significant difference in the rate of major complications in 161 obese ($p = 0.23$) or 39 morbidly obese patients ($p = 0.67$) compared with 189 non-obese patients [25]. Additionally, the RCC subtype did not significantly influence the rate of complications in a European multicenter retrospective study [21]. In a retrospective study comparing subtypes (130 clear cell RCCs vs. 43 papillary RCCs) from a single institution, 5.2% of patients with clear cell RCC experienced major complications ($p = 0.11$) [26].

Mortality. The mortality rate across studies was 0-1.6% [6, 25, 27], with only four deaths related to percutaneous CRA reported (Table 2). Breen *et al.* reported that one patient died of venous thromboembolism five days after discharge [6]. Schmit *et al.* reported that one patient died of urosepsis 30 days after CRA [25]. Buy *et al.* reported two fatal cases: one in which the patient died from cardiac infarction one day after CRA, and another in which the patient died from massive lung aspiration (Mendelson syndrome) two days after CRA [27].

Post-ablation syndrome. One prospective study showed that the incidences of fever (≥ 38.0°C), nausea, vomiting, and malaise were 40% (16/40), 20% (8/40), 20% (8/40), and 63% (25/40), respectively [28]. Most symptoms had begun by day 2 [28]. In another prospective study, Zhong *et al.* reported that 61% of patients (39/64) developed flu-like symptoms but only 9% of patients (6/64) developed post-ablation syndrome (defined as fever plus flu-like symptoms) [29].

Bleeding. The most common complication of percutaneous CRA is bleeding, including hematoma and hematuria. The kidney is a hypervascular organ, and the most common target RCCs (*e.g.*, clear cell RCC) are usually hypervascular. Minor bleeding is inevitable in most kidney-related procedures. However, the coagulation status of the patient needs to be controlled to avoid more extreme occurrences, such as the retroperitoneal extension of the hematoma [1]. Patients undergoing ablation must discontinue the use of coumadin and aspirin for at least 5 days prior and demonstrate a platelet count of more than 50,000/mL and an international normalized ratio of 1.5 or less immediately before the procedure [22]. Bleeding is usually asymptomatic, and patients require treatment such as transfusion or TAE in < 4% of bleeding cases [3-12] (Table 1). Patients with bleeding into the perirenal space were more likely to require intervention and admission than those with

Table 2 Summary of percutaneous CRA-related death

	Author (reference number)/Year	Tumor/Patient/Session number	Mortality rate (%)	Age/Sex	Comorbidity	Cause of death	Death date
1	Breen [6]/2018	484/433/473	0.2			Pulmonary embolism	5 days after discharge
2	Schmit [25]/2013	421/367/389	0.3	54/M	von Hippel Lindau disease, Chronic decubitus ulcers, Recurrent urinary tract infections	Urosepsis	30 days after CRA
3	Buy [27]/2013	120/95/122	1.6		Right coronary artery stenting	Cardiac infarction	1 day after CRA
4	Buy [27]/2013				Severe calcific aortic valve stenosis with cardiac insufficiency	Massive lung aspiration	2 days after CRA

CRA, cryoablation.

hemorrhage in the pararenal space or collecting system [30]. Bleeding was associated with advanced age, increased tumor size, increased number of CRA probes, central position, and malignancy [27, 30, 31].

One disadvantage of CRA is that bleeding complications are higher than those in heat-based ablation modalities (*i.e.*, RFA and MWA) with a theoretical coagulative advantage (radiofrequency and microwave technology are used as intraoperative thermocoagulative tools) in heat ablation [30]. In a study by Atwell *et al.*, the overall bleeding complication rate in 311 cases of percutaneous CRA was 7.4%, compared to only 1.2% in 254 cases of percutaneous RFA [31].

Ureteral strictures. Direct thermal injury to the ureter can be significantly reduced by various techniques such as hydrodissection, retrograde pyeloperfusion, and probe retraction [32]. Otherwise, urinary injury or obstruction can occur due to direct thermal injury, clots, and other factors in the clinical setting. Because of the use of protective measures, only 0-1.1% of cases of percutaneous CRA needed treatment for ureteral strictures [3-13] (Table 1). As a rare complication, Okawa *et al.* reported a case of ureteral obstruction by a sloughed tumor complicating CRA [33]. In cases with ureteral strictures, retrograde catheterization and the placement of a ureteric stent for irrigation are required [1]. However, surgical repair is rarely needed [5].

Pneumothorax. The frequency of pneumothorax is low. Pneumothorax requiring chest tube placement has been reported in 0-2.1% of cases [3-13], and mild pneumothorax requiring only observation was 3.6% [16] (Table 1). One reason for the frequency of this complication may be that an artificial pneumothorax before puncturing the cryoprobe is created in selected cases to avoid the transpulmonary route. In a prospective analysis of 171 tumors in 147 patients where pneumothorax was the most common complication, upper pole location was the single variable found to predict complications ($p = 0.006$) [24]. In CT-guided lung biopsy, the risk factors for pneumothorax requiring chest tube placement included longer transparenchymal distance and pulmonary emphysema [34]. In cases with distinct risk of percutaneous CRA-related pneumothorax, creating an artificial pneumothorax before puncturing the cryoprobe is advisable.

Bowel injury. In patients with RFA-related bowel injury, a post-ablation CT scan typically depicts wall thickening that may evolve into adhesions and perforation [35]. Gobara *et al.* reported that, in an 87-year-old man with a descending colon perforation, dynamic contrast-enhanced CT performed the morning after percutaneous CRA showed focal discontinuity in the mucosa and muscle layer enhancement and a marked thickening in the affected colon wall [36]. Even when displacement techniques (see below) are used, bowel injury can occur in cases, for example, when the ice ball becomes much larger than expected. Bowel sections contained in the ice-ball do not always require surgical treatment, with 2.2% of CRA cases having bowel injuries requiring observation [16] and 0-0.6% having bowel injuries requiring surgical resection [3-13] (Table 1).

Nerve injury. Nerve injury is a recognized complication of renal ablation, with a frequency of 0.6% (2/311 procedures) [31], 0.7% (1/153 procedures) [24], and 5.1% (6/117 procedures) [37]. If the ablation extends into the body wall or the psoas muscle, the intercostal, lumbar, genitofemoral, or lateral femoral cutaneous nerves may be injured [31]. If a dorsal approach for the CRA probe is required, Higuchi *et al.* have recommended hydrodissection or pneumodissection to lower the risk of freezing the intercostal, subcostal, and lumbar nerves whenever possible [37]. Puncture through the erector spinae muscle ($p < 0.01$) and not using hydrodissection or pneumodissection ($p = 0.01$) were identified as risk factors for abdominal wall pseudohernia [37]. The sequelae of such nerve injuries are usually temporary and resolve within 6 months in most patients [31, 37].

Thrombosis. Pulmonary embolism occurred in 0-3.5% of cases [3-17] (Table 1), but this complication is rarely fatal [27]. In a rat liver model, CRA induced a greater inflammatory and coagulative response than the other thermal ablation techniques, such as RFA or laser [38]. Although Hartmann *et al.* hypothesized that there might be a higher rate of thrombotic events in patients undergoing CRA, the incidence of thrombotic events in 114 patients treated with CRA was not significantly different ($p = 0.089$) from that of 105 patients undergoing partial nephrectomy in the same time period [17].

Seeding. Cancer seeding is rare, observed in 0% [3-16], 0.3% (1/311 procedures) [31], and 2.7% (2/74 procedures) of cases [39]. Rizzo *et al.* noted that one of the advantages of CRA is the lower morbidity due to lower risk of tumor seeding. They emphasized the importance of careful inspection of the perinephric fat, posterior abdominal wall, subcutaneous fat, and other tissues along the CRA probe tract during oncological surveillance to identify and treat possible cases of tumor seeding as early as possible [39].

Other rare complications. Some rare complications have been reported, such as acute catecholamine release [7], catecholamine crisis [40], urinothorax [41], acute gouty arthritis [42], and systolic blood pressure elevation during the perioperative period [43]. Acute catecholamine release and crisis were observed in 0.8% (2/265 procedures) [7] and 0.3% (2/588 procedures) of cases [40], respectively. Renal tumors in the upper pole may have a greater risk of pneumothorax and adrenal gland injury. In renal tumors of the upper pole, intraprocedural support by an anesthesiologist is recommended to facilitate prompt drug administration in case of catecholamine crisis [44].

Techniques to reduce the risk of complication. Operators perform various procedures before CRA (*e.g.*, transarterial embolization [TAE] [1,45] and ureteral stent placement [1,32,46,47]) and during CRA (*e.g.*, displacement, artificial pneumothorax [48], probe retraction [49], and skin protection [50]) to reduce the risk of complications.

TAE is performed to improve tumor localization on CT images (in some cases using iodized oil), to increase tumor ischemia, and to decrease the potential risk of procedural bleeding and dissemination (Figs. 1-3). Miller *et al.* reported that prior TAE using a coil significantly reduced complications [45]. Retrograde pyeloperfusion of warm saline via a ureteral stent is an efficacious option for ureteral protection during CRA for central lesions or lesions located on the medial side of the lower pole (Fig. 2) [1,46]. Zhao *et al.* reported that no ureter strictures or other severe clinical sequelae were observed after total or partial ice ball involvement of the ureter in six patients, including four patients with

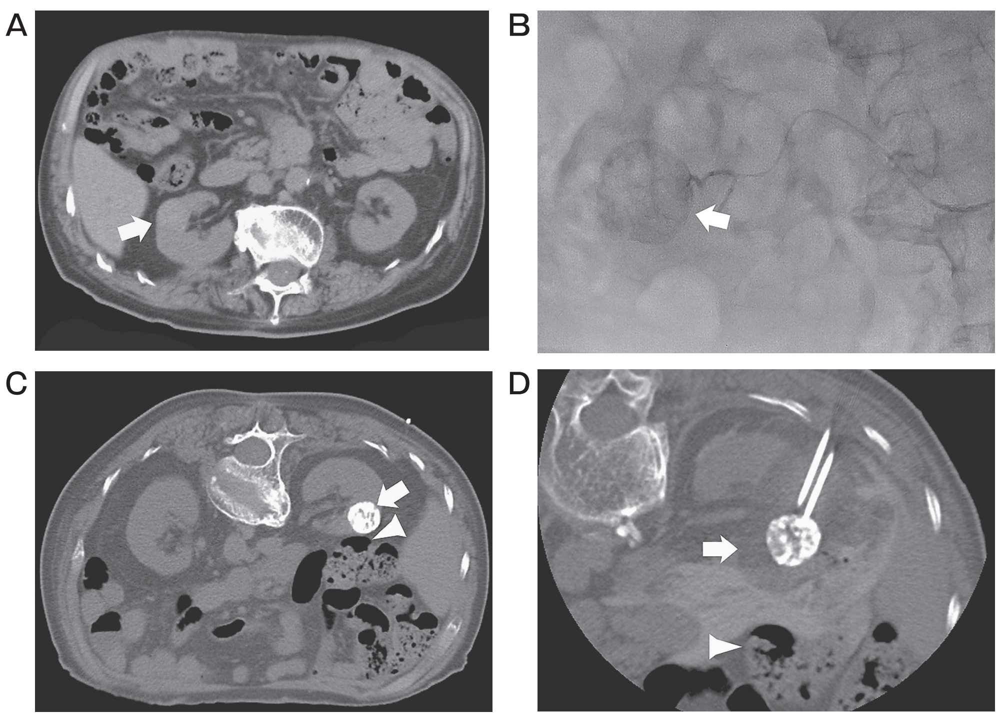

Fig. 1 A, Plain supine CT image of a 70-year-old man shows a biopsy-proven right clear cell RCC (arrow) 22 mm in diameter. This tumor shows slightly higher intensity than the renal parenchyma, but its boundaries are unclear; B, Angiogram shows a tumor stain (arrow). Super-selective intra-arterial embolization of the feeding artery to the tumor was performed using a 7 : 3 mixture of absolute ethanol and iodized oil; C, Plain prone CT image just before cryoablation shows a tumor (arrow) with very high intensity due to retention of iodized oil. The tumor is in contact with the ascending colon (arrowhead); D, Plain prone CT image during cryoablation shows the tumor surrounded by an ice ball (arrow). The ascending colon (arrowhead) is far from the tumor due to hydrodissection using saline with a 2% contrast medium.

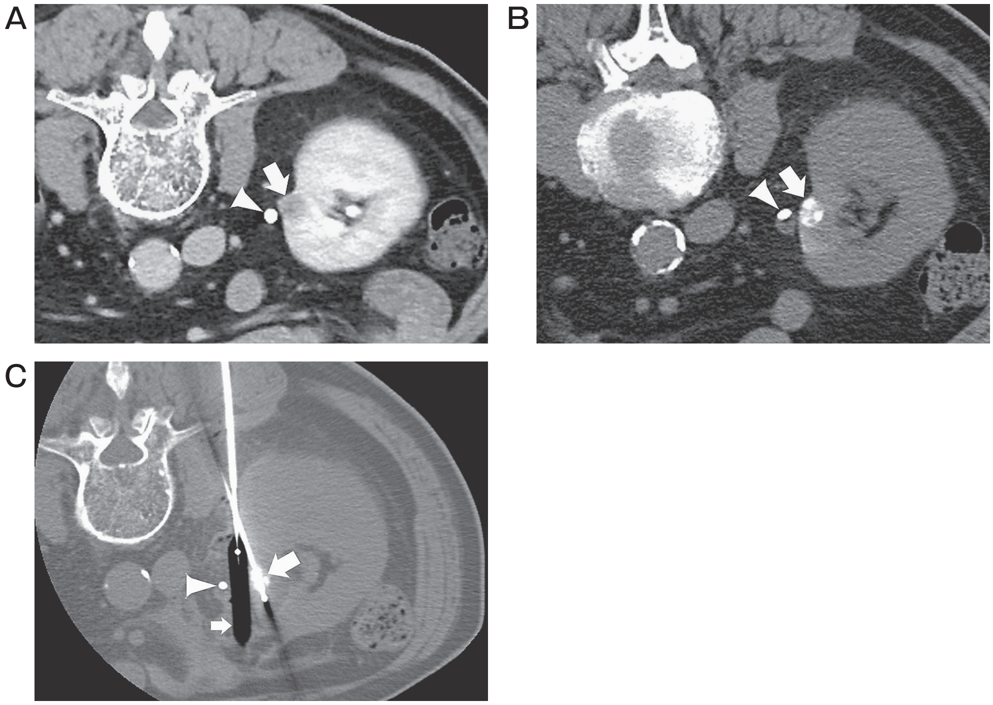

Fig. 2 A, Contrast-enhanced prone CT image of a 69-year-old man shows a biopsy-proven right clear cell RCC (arrow) 10 mm in diameter near the ureter (arrowhead); B, Plain prone CT image just before cryoablation shows the tumor (arrow) with very high intensity due to retention of iodized oil and also shows a placed ureteral stent (arrowhead); C, Plain prone CT image during cryoablation shows the tumor (arrow) penetrated by a cryoprobe and surrounded by the ice ball. The ureteral stent (arrowhead) is kept distant from the tumor by a dilated balloon (small arrow).

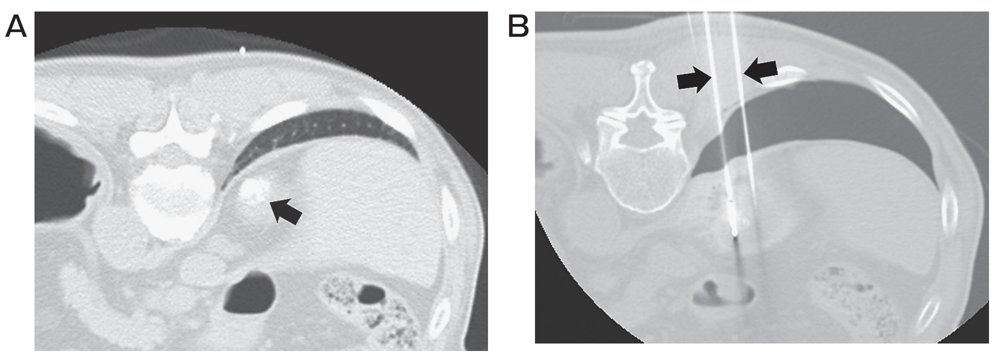

Fig. 3 A, Plain prone CT image just before cryoablation of a 73-year-old man shows a biopsy-proven right clear cell RCC (arrow) 13 mm in diameter with very high intensity due to the retention of iodized oil; B, Plain prone CT image during cryoablation shows cryoprobes (arrow) inserted via the thoracic cavity. The cryoprobes do not penetrate the lung parenchyma because of the creation of an artificial pneumothorax.

prior stent placement [47]. Multivariable analysis showed that patients who underwent pyeloperfusion or ureteric stent placement were significantly less likely to have complications [6].

In general, structures ≤10 mm from the tumor are considered candidates for displacement [51]. Displacement methods include hydrodissection (Fig. 1-D), pneumodissection, and balloon dissection (Fig. 2-C) [1, 32]. These techniques are usually safe. However, complications such as air embolization [52], massive percutaneous emphysema [53], and mediastinal emphysema [53] can occur rarely. When the target is located at the upper pole of the kidney, artificial pneumothorax is used at times to avoid damage to the intervening lung parenchyma (Fig. 3) [48]. In addition, skin protection, warm sterile gloves, gauze soaked in warm saline, or the hand of the operator may be placed over the skin during ablation to maintain a safe skin temperature [50].

Discussion

Percutaneous CRA for renal tumors is a safe procedure that rarely causes major complications. Some investigators have compared this therapy with others (*e.g.*, vs. RFA, MWA, surgery, and laparoscopic CRA), and found equal or greater safety of percutaneous CRA. CRA is usually performed by interventional radiologists percutaneously working collaboratively with urologists, or by urologists laparoscopically. In two retrospective studies comparing percutaneous and laparoscopic CRA (137 vs. 275 tumors [14] and 123 vs. 167 tumors [54], respectively), the overall and major complication rates were similar. In one study using prospectively collected data of 311 CRA and 254 RFA procedures, major complication rates did not differ significantly [31]. A meta-analysis with 44 CRA and 7 MWA studies showed that the MWA group reported significantly more complications than the CRA group (61.11% vs. 28%; $p=0.007$) [55]. In a retrospective study comparing 177 percutaneous CRA patients and 470 robot-assisted partial nephrectomy patients, the complication rate was significantly lower in the CRA group (28 [15.8%] vs. 104 [24.3%]; $p=0.029$), and the CRA and partial nephrectomy groups included 3 (10.7%) and 31 (30%) Clavien-Dindo grade III, and 0 (0%) and 9 (8.5%) grade IV-V injuries, respectively [13]. Using a meta-analysis of 17 retrospective studies comparing CRA and partial nephrectomy, CRA showed lower rates of overall and postoperative complications [56]. Although not specifically investigated in this review, CRA may also have less effect on renal function [56]. A large number of RCC patients appear to benefit from percutaneous CRA, and the use of this therapy is likely to increase further.

In conclusion, major complications rarely occur in percutaneous CRA for renal tumors, and this therapy is safe. However, operators must know how to avoid the various complications associated with this therapy.

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