Original Research

Clinical Experience of Percutaneous Radiofrequency Ablation Using an arfa RF ABLATION SYSTEM® in Various Organs

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Abstract

Purpose: To evaluate the feasibility, safety, and efficacy of radiofrequency (RF) ablation using an ablation system (arfa RF ABLATION SYSTEM®; Japan Lifeline Co. Ltd.) for treating solid tumors in various organs.

Material and Methods: Between October 2019 and August 2021, 80 patients (29 women, 51 men; median age, 70.0 yr) underwent 107 RF ablation sessions using the ablation system to treat 151 tumors in the liver (n = 86), lung (n = 51), adrenal gland (n = 4), pleura (n = 4), bone (n = 3), lymph node (n = 2), and kidney (n = 1). The maximum tumor diameter was 2-40 mm (median, 11 mm). This study evaluated technical success (defined as the completion of planned RF ablation), technique efficacy (defined as the complete tumor ablation on follow-up images), and adverse events. Local tumor progression in 146 curatively treated malignant tumors was evaluated.

Results: The technical success rate was 100% (107/107). Ablation zones in two tumors were insufficient. Therefore, the primary technique efficacy rate was 98.1% (105/107). Grade 3 hepatic infarction (1.6%, 1/64) and grade 4 pleuritis (3.4%, 1/29) occurred respectively after liver and lung RF ablation. During the median follow-up period of 10.2 months (Interquartile range, 4.2 and 16.4 months), local tumor progression developed in two tumors (1.4%, 2/146).

Conclusions: The arfa RF ABLATION SYSTEM® is a feasible, safe, and effective RF ablation device for managing solid tumors in various organs.

Key words: feasibility, radiofrequency ablation, interventional oncology

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Introduction

Since the introduction of radiofrequency (RF) ablation as a minimally invasive therapeutic option for managing solid tumors, it has been applied to treat solid tumors in various organs. Its utility has been established [1-4].

Currently, RF ablation systems of two types are available: monopolar and bipolar. Of these, monopolar RF ablation systems are the most used RF ablation systems in clinical settings. Electrode designs used for monopolar RF ablation systems are divided into straight internally cooled electrodes and multitined expandable type needle electrodes. The differences in the efficacy and safety between the different RF devices have not been identified so far [1-3, 5-7] Among them, the Cool-tip RF System® (Medtronic USA, Inc., MN, USA) was the first approved monopolar RF ablation system with a straight internally cooled electrode in Japan in 2004.

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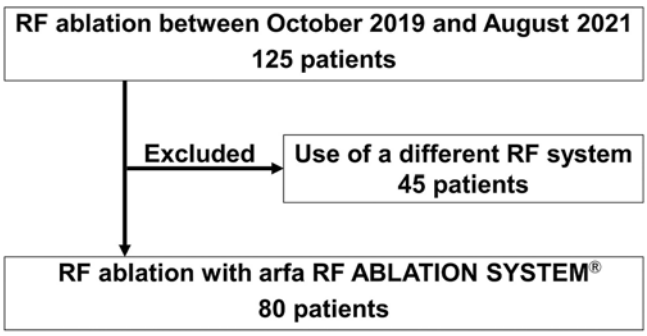

Figure 1. Flow diagram of the study population.

An RF ablation device has recently become commercially available in Japan: the arfa RF ABLATION SYSTEM® (Japan Lifeline Co., Ltd., Tokyo, Japan). This device is also a monopolar RF ablation system with a straight internally cooled electrode. Although one study reports the ablation area and safety of RF ablation using arfa RF ABLATION SYSTEM® for hepatocellular carcinoma (HCC) [8], no previous study reported the safety and efficacy of this system for other organs and diseases.

This study evaluated the feasibility, safety, and efficacy of RF ablation using the arfa RF ABLATION SYSTEM® for treating solid tumors in various organs.

Material and Methods

Subjects

The relevant institutional review board approved this retrospective study. Because of the study's retrospective nature, written informed consent to participate in this study was not deemed necessary. Instead, informed consent was obtained in the form of an opt-out on the website.

Between October 2019 and August 2021, 125 consecutive patients underwent RF ablation to treat various solid tumors. Among them, 80 patients who received RF ablation using the arfa RF ABLATION SYSTEM® were included in this study (**Fig. 1**). Those 80 patients underwent 107 RF sessions to treat 151 tumors. Those patients included 51 men (63.8%, 51/80) and 29 women (36.3%, 29/80) with a median age of 70.0 yr (interquartile range (IQR), 58.5 and 74.8 yr). Of them, 79 patients (98.8%, 79/80) received RF ablation as a curative treatment of malignant (95%, 76/80) and benign (3.8%, 3/80) tumors. The remaining one patient (1.3%, 1/80) was administered RF ablation as a palliative treatment. The most frequent sites for RF ablation were the liver (59.8%, 64/107 sessions) followed by lung (27.1%, 29/107 sessions), adrenal gland (3.7%, 4/107), pleura (3.7%, 4/107), bone (2.8%, 3/107), lymph node (1.9%, 2/107), and kidney (0.9%, 1/107). The maximum tumor diameter was 2-40 mm (median, 11 mm). **Table 1** presents details of the patient and tumor characteristics in the respective RF ablation sessions.

Table 1. Patient and Tumor Characterstics, and RF Ablation Procedures in Each Session.

Characteristics	No. (%) of RF ablation sessions
Patient characteristics	
Sex	
Male	64 (59.8%)
Female	43 (40.2%)
Age	
> 70 yrs	49 (45.8%)
≤ 70 yrs	58 (54.2%)
Treatment intent	
Curative	105 (98.1%)
Palliative	2 (1.9%)
Tumor characteristics	
Primary or metastasis?	
Primary	60 (56.1%)
Metastasis	47 (43.9%)
Size	
> 3 cm	3 (2.8%)
≤ 3cm, > 2cm	16 (15.0%)
≤ 2cm, > 1cm	50 (46.7%)
< 1cm	38 (35.5%)
Location and disease	
Liver	64 (59.8%)
Hepatocellular carcinoma	52 (48.6%)
Metastasis from colorectal cancer	8 (7.5%)
Metastasis from nasopharyngeal cancer	4 (3.7%)
Lung	29 (27.1%)
Metastasis from colorectal cancer	14 (13.1%)
Metastasis from sarcomas	8 (7.5%)
Metastasis from renal cell carcinoma	5 (4.7%)
Metastasis from hepatocellular carcinoma	1 (0.9%)
Metastasis from lung carcinoma	1 (0.9%)
Adrenal grand	4 (3.7%)
Metastasis from renal cell carcinoma	3 (2.8%)
Adrenal adenoma	1 (0.9%)
Pleura	4 (3.7%)
Malignant pleural mesothelioma	4 (3.7%)
Bone	3 (2.8%)
Osteoid osteoma	2 (1.9%)
Metastasis from lung carcinoma	1 (0.9%)
Lymph node	2 (1.9%)
Metastasis from colorectal cancer	1 (0.9%)
Metastasis from renal cell carcinoma	1 (0.9%)
Kidney	1 (0.9%)
Renal cell carcinoma	1 (0.9%)
RF ablation procedure	
Ablated tumors per session	
1	69 (64.5%)
2	32 (29.9%)
3	6 (5.6%)
Puncture number	
1 or 2	70 (65.4%)
3 or more	37 (34.6%)
Ancillary procedures	
TAI, TAE, and TACE	61 (57.0%)
Biopsy	2 (1.9%)
Hydrodissection	1 (0.9%)

Data are number of RF ablation sessions. Numbers in parentheses are percentages.

RF, radiofrequency; TAI, transcatheter arterial infusion; TAE, transcatheter arterial embolization; TACE, transcatheter arterial chemoembolization

Pretreatment workup

Before RF ablation, all patients underwent routine physical examinations, laboratory tests, and radiologic imaging studies. Imaging studies included chest radiography, abdominal MR imaging, PET, and thoracic, abdominal, and pelvic computed tomography (CT). The diagnoses were established mainly based on imaging findings. Four of the 80 patients (5.0%) underwent a percutaneous biopsy was performed to confirm the index tumor diagnosis.

RF ablation procedure

RF ablation procedures were conducted in an inpatient setting. Patients were administered local anesthesia using 1% lidocaine (Xylocaine®; AstraZeneca KK, Osaka, Japan) and moderate sedation with intravenous dexmedetomidine (Dexmedetomidine Intravenous Syringe®; Nipro Corp., Osaka, Japan) and fentanyl citrate (Fentanyl Injection®; Terumo Corp., Tokyo, Japan). Operators were eight interventional radiologists with 4-32 yr (median, 18 yr) of experience in interventional procedures. The arfa RF ABLATION SYSTEM® was used for all patients included in this study (**Fig. 2a** and **2b**). This system comprised a generator and an internally cooled electrode with a variable active tip length of 5-30 mm (**Fig. 2b**). Electrode placement was performed under real-time CT fluoroscopic guidance (**Fig. 3**). The active tip length of the electrode was chosen according to the tumor size and location and adjacent organs. In principle, the active tip length of the electrode was 1 cm more than the maximum tumor diameter. After the electrode was connected with a generator, RF energy was applied with 10 W for lung tumors and 40 W for other tumors with chilled water circulation within the electrode, except for osteoid osteomas. Then, because of a greater than 30% impedance increase of the ablated tissue from the baseline, the RF power was increased by 10 W every 30 s until the generator stopped delivering RF energy three times. A bone biopsy needle (Osteo-site®; Cook Medical Japan G.K., Tokyo, Japan) was introduced into the lesion for osteoid osteomas. The RF electrode was introduced through the bone biopsy needle. RF energy was applied with the manual control mode without cooling. The electrode temperature was maintained at 90℃ for 5 min [9]. Tract ablation was performed routinely when the electrodes were withdrawn. During tract ablation, internal cooling was stopped, and the RF energy was manually controlled to maintain the electrode temperature above 80℃. Overwrapping ablation was performed when an operator considered it necessary. RF ablation was performed for three or fewer lesions within one RFA session. **Table 1** presents details of the RF ablation procedures.

For 45 RF sessions designated to treat hepatocellular carcinoma (HCC), hepatic artery infusion chemotherapy using miriplatin-iodized oil suspension (MIRIPLA®; Dainippon Sumitomo Pharma Co., Ltd., Osaka, Japan) was administered immediately before RF ablation. Arterial injection of iodized oil (Lipiodol®; Guerbet Japan K.K., Tokyo, Japan) was done immediately before the ablation of two adrenal tumors in two sessions and a renal tumor in one session. Arterial embolization with trisacryl gelatin microspheres (Embosphere®; Nippon Kayaku Co. Ltd., Tokyo, Japan) or degradable starch microspheres (Spherex®; Yakult Co. Ltd., Tokyo, Japan) was administered immediately before RF ablation for metastatic liver tumors in 11 sessions.

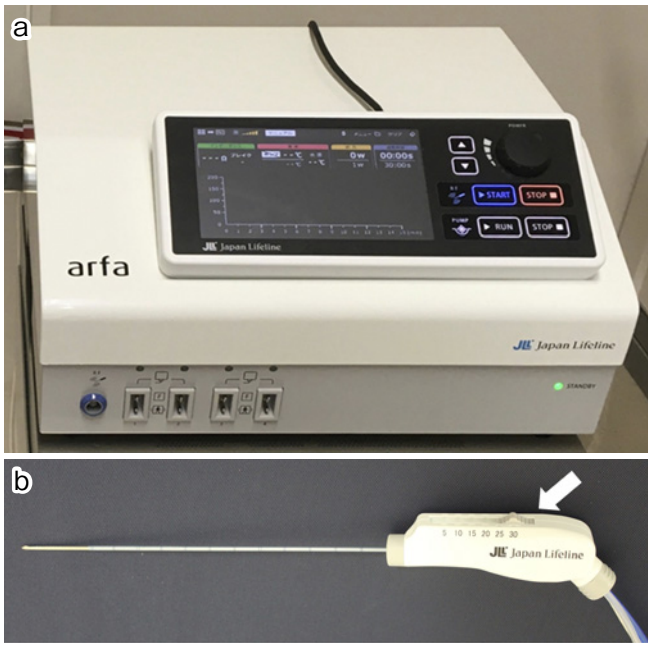

Figure 2. arfa RF ABLATION SYSTEM®
a. Generator
b. Internally cooled electrode of arfa RF ABLATION SYSTEM®. The length of the current-carrying part can be changed by shifting the electrode grip lever (white arrow).

Follow-up

Plain CT images were obtained from all patients immediately after the planned RF ablation procedure. If there were immediate complications, such as pneumothorax and bleeding, the required treatments were provided. After the procedure, patients were instructed to remain in bed with monitoring of vital signs done every 4 hr for 24 hr. Routine physical examinations were done every day during the hospital stay. Laboratory tests were done the next day and 3-5 days after RF ablation. Chest radiographs were obtained 3-5 hr later and on the next day from patients who underwent RF ablation for lung tumors and patients treated using a transthoracic approach. All patients but those with osteoid osteoma underwent contrast-enhanced CT or MR imaging within 5 days after RF ablation to evaluate the ablative zone. Eight patients had contraindication against using contrast materials, including poor renal function (n = 7) and allergy to contrast material (n = 1). The ablative zone was evaluated in those patients by non-contrast-enhanced CT (n = 7) or MR imaging (n = 1). In patients with osteoid osteoma, bone radiographs were obtained the next day and 1 week after RF ablation. The patient was discharged if no

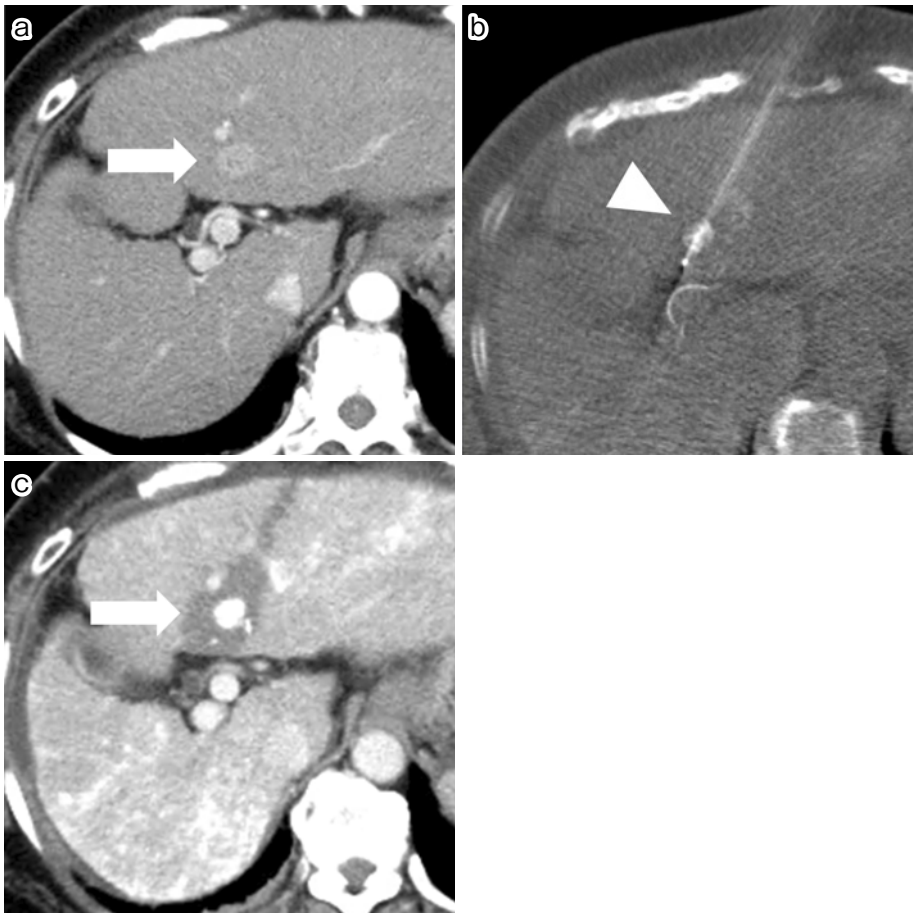

Figure 3. A man in his 70s underwent radiofrequency (RF) ablation with an arfa RF ABLATION SYSTEM® for treating hepatocellular carcinoma (HCC).
a. A HCC measuring 14 mm located in segment 2 (arrow).
b. The tumor was ablated by RF electrode with 20 mm active tip length (arrowhead).
c. Axial CT images acquired 2 days after RF ablation showed non-enhanced areas surrounding the index tumor (arrow).

difficulty was found from follow-up imaging and laboratory data returned to the baseline level. Follow-up was performed on an outpatient basis. The follow-up protocol included a routine physical examination and laboratory tests every month, with CT or MRI obtained every 3-4 months.

Assessment

This study evaluated the feasibility, safety, and efficacy of RF ablation using the arfa RF ABLATION SYSTEM® for various organs.

Technical success was defined as successful RF electrode placement in the index tumor and the accomplishment of ablation procedures under the planned protocol [10]. The definition of technique efficacy was set according to the index tumor location as follows: complete disappearance of tumor enhancement and coverage of index tumors by the ablative area in liver and kidney tumors, complete disappearance of tumor enhancement in pleural, adrenal, and lymph node tumors, and complete coverage of tumors by the ablative area (solid or ground glass opacity) in lung tumors [10, 11-14]. In patients with osteoid osteoma, relief of pain symptoms (visual analog scale score decreased by ≥2 points without analgesic administration) at 24 hr after RF ablation was defined as technique efficacy [9]. Primary technique efficacy was defined as accomplishing the criteria above after the initial RF session. The assisted technique efficacy was defined as the accomplishment after repeated RF sessions. Complications were defined according to the Common Terminology Criteria for Adverse Events (ver. 5.0) [15]. Any patient death within 30 days of RF ablation was designated as a grade 5 adverse event. A grade 3 or higher adverse event was defined as a major complication. Grade 1 and 2 adverse events were defined as minor complications. Common procedural side effects, including periprocedural pain, fever, and transient elevation of liver enzyme levels, were avoided from the evaluation. For this study, technical success, technique efficacy, and complications were evaluated on an RF session basis.

Local tumor progression was also evaluated in patients who received RF ablation as a curative treatment for malignant tumors (76 patients with 146 tumors). Local tumor progression was defined as the appearance of a growing tumor

Table 2. Complications.

Complication	CTCAE grade				
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Overall (*n*=107)	43.0% (46/107)	10.3% (11/107)	0.9% (1/107)	0.9% (1/107)	0%
Liver (*n*=64)	39.1% (25/64)	7.8% (5/64)	1.6% (1/64)	0%	0%
Fever	31.3% (20/64)	6.3% (4/64)	0%	0%	0%
Subcapsular hematoma	9.4% (6/64)	0%	0%	0%	0%
Pneumothorax	6.3% (4/64)	1.6% (1/64)	0%	0%	0%
Liver infarction	0%	0%	1.6% (1/64)	0%	0%
Pleural effusion	1.6% (1/64)	0%	0%	0%	0%
Hemothorax	1.6% (1/64)	0%	0%	0%	0%
Billirary hemorrhage	1.6% (1/64)	0%	0%	0%	0%
Blood pressure elevation	0%	1.6% (1/64)	0%	0%	0%
Lung (*n*=29)	62.1% (18/29)	20.7% (6/29)	0%	3.4% (1/29)	0%
Fever	3.4% (1/29)	3.4% (1/29)			
Pneumothorax	41.4% (12/29)	17.2% (5/29)	0%	0%	0%
Hemothorax	6.9% (2/29)	0%	0%	0%	0%
Pleurisy	0%	3.4% (1/29)	0%	3.4% (1/29)	0%
Pulmonary hemorrhage	6.9% (2/29)	0%	0%	0%	0%
Pleural effusion	3.4% (1/29)	0%	0%	0%	0%
Subcutaneous emphysema	3.4% (1/29)	0%	0%	0%	0%
Pleura (*n* = 4)	25% (1/4)	0%	0%	0%	0%
Fever	25% (1/4)				
Adrenal grand (*n*=4)	25% (1/4)	0%	0%	0%	0%
Retroperitoneal hemorrhage	25% (1/4)	0%	0%	0%	0%
Bone (*n*=3)	0%	0%	0%	0%	0%
Lymph node (*n*=2)	0%	0%	0%	0%	0%
Kidney (*n*=1)	100% (1/1)	0%	0%	0%	0%
Fever	100% (1/1)				

CTCAE, Common Terminology Criteria for Adverse Events

on follow-up CT or MR imaging. Follow-up imaging was conducted using a contrast agent, except for eight patients who had contraindication against using contrast materials as described above. Local tumor progression was evaluated on a tumor basis.

Results

Technical success and technique efficacy

Technical success was achieved in all RF sessions (100%, 107/107). The primary technique efficacy rate was 98.1% (105/107). The ablation zones were insufficient in 2 RF sessions to treat 2 HCC, and both were ablated completely during an additional RF ablation session. Therefore, the assisted technique efficacy rate was 100% (107/107).

Complication

Major complications occurred in two sessions (1.9%, 2/107): a grade 3 liver infarction requiring blood products after liver RF ablation (1.6%, 1/64) and a grade 4 aseptic pleurisy requiring admission to an intensive care unit after lung RF ablation (3.4%, 1/29). Minor complications occurred in 52 RF sessions (48.5%, 52/107). **Table 2** presents details of those complications.

Local tumor progression

During the median follow-up period of 10.2 months (IQR, 4.2 and 16.4 months), there was local tumor progression in one liver tumor (1.2%, 1/86) and one lung tumor (2.0%, 1/51). The 1-year cumulative local tumor progression rates of liver and lung tumors were, respectively, 1.5% (95% confidence interval (CI), 0%-4.3%) and 2.7% (95% CI, 0%-7.9%).

Discussion

Results of this study indicated that RF ablation using the arfa RF ABLATION SYSTEM® was feasible, safe, and effective for the management of solid tumors in various organs at least in a short-term follow-up. This generic RF ablation device is non-inferior to more commonly used RF ablation devices, such as the Cool-tip RF System®.

In earlier studies examining more than 100 cases, the major complication rates after liver and lung RF ablation using the Cool-tip RF System® were reported respectively as 0%-3% and 0.4%-10.2% [16-23]. In the present study, the respective major complication rates after liver and lung RF ab-

lation were 1.6% and 3.4%. Those were similar to results obtained for the Cool-tip RF System®. The electrode of the arfa RF ABLATION SYSTEM® has a variable active tip mechanism, so theoretically, an excessive ablative zone can be avoided. Such an RF electrode design might be partially attributed to this study's limited major complication rate.

The primary technique efficacy rate in this study was 98.1%. Moreover, the 1-year local tumor progression rates were 1.5% and 2.6% for liver and lung tumors. In earlier studies, 1-year local tumor progression rates after RF ablation using a Cool-tip RF System® were reported as 1.4%-15% for the liver and 10.1%-16.5% for lung tumors [17, 20, 22, 24, 25]. Therefore, the results of this study suggest that the local control efficacy of RF ablation using the arfa RF ABLATION SYSTEM® is not inferior to that provided by a Cool-tip RF System®. Another explanation for the excellent local control efficacy observed in this study may be partly attributed to the relatively small size of the index tumors.

No major complication was found after RF ablation for tumors located in the pleura, adrenal gland, bone, lymph node, or kidney. Those findings suggest that RF ablation using the arfa RF ABLATION SYSTEM® can be performed safely for tumors in those organs. However, further evaluation with an examination of a more significant number of cases is necessary.

Several limitations exist in this study. The small number of patients and retrospective nature with no control arm might be apparent limitations. Especially, the number of patients who received RF ablation other than liver and lung was small in this study. However, there is no available data about the RF ablation using arfa RF ABLATION SYSTEM® for those patients. Therefore, those patients' results were also included in this study. The short follow-up period is another limitation of this study. Therefore, the possibility remains that uncommon and delayed adverse events were not detected. The adjunctive technique was used for most of the liver tumors in this study, which might affect the efficacy of RF ablation. Despite these limitations, the results of this study suggest that similarly to the Cool-tip RF System®, the arfa RF ABLATION SYSTEM® is a useful ablation device for managing solid tumors in various organs.

In conclusion, RF ablation using the arfa RF ABLATION SYSTEM® was found to be feasible, safe, and effective for treating solid tumors in various organs.

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Preparation of first draft of manuscript; Naoya Kinota

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