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FULL PAPER

Comparison of therapeutic efficacy and safety of radiofrequency ablation of hepatocellular carcinomas between internally cooled 15-G and 17-G single electrodes

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Objective: To compare the ablation volume, local tumour progression rate and complication rate of radiofrequency ablation (RFA) for small hepatocellular carcinomas (HCCs) using 15-G and 17-G single electrodes.

Methods: This retrospective study was approved by the institutional review board and informed consent was waived. We reviewed percutaneous RFA cases for HCCs using 15-G or 17-G electrodes without multiple overlapping ablations. A total of 36 pairs of HCCs matched according to tumour size and active tip length were included. We compared ablation volume and complication rate between the two electrode groups. Cumulative local tumour progression rates were estimated using the Kaplan-Meier method and compared using the log-rank test.

Results: Tumour size and ablation time were not significantly different between the 15-G and 17-G groups

($p = 0.661$ and $p = 0.793$, respectively). However, ablation volume in the 15-G electrode group was larger than that in the 17-G group ($14.4 \pm 5.4 \text{ cm}^3$ vs $8.7 \pm 2.5 \text{ cm}^3$; $p < 0.001$). No statistical difference in complication rates between the two electrode groups was found. The 10- and 20-month local tumour progression rates were not significantly different between the two groups (2.8% and 5.6% vs 11.1% and 19.3%; $p = 0.166$).

Conclusion: Ablation volume by the 15-G electrode was larger than that by the 17-G electrode. However, local tumour progression rate and complication rate were not significantly different between the two electrode groups.

Advances in knowledge: RFA of HCC using a 15-G electrode is useful to create larger ablation volumes than a 17-G electrode.

Radiofrequency ablation (RFA) is now considered to be one of the curative treatment modalities for the management of small hepatocellular carcinomas (HCCs).¹⁻⁵ There are various types of electrodes for RFA, including internally cooled electrodes, multi-tined electrodes and perfusion electrodes.^{6,7} Among them, an internally cooled electrode is frequently used because it is simple and easy to use. The ablation zone created by an internally cooled electrode is usually cylindrical in shape along the longitudinal axis of the electrode. Hence, the horizontal diameter of the ablation zone is relatively smaller than the longitudinal diameter. Therefore, an internally cooled electrode frequently requires overlapping ablations to achieve a sufficient ablative margin for large tumours (*i.e.* size $>2.5 \text{ cm}$). However, it is sometimes technically difficult to achieve a sufficient ablative margin under ultrasonography guidance since both the boundary of the index tumour and the active tip of the electrode are obscured by the echogenic zone generated by the previous ablation cycle. Therefore, it is ideal to achieve

a large ablation zone using a single electrode without multiple overlapping ablations.

Electrodes with a larger diameter have a larger contact surface with the surrounding tissue than smaller ones and thereby have a higher active electric field.⁸⁻¹⁰ This in turn delivers a larger amount of radiofrequency energy and thus produces a greater amount of heat around the active tip. Consequently, large electrodes create large ablation zones. However, to our knowledge, commercially available internally cooled electrodes are not large and are almost exclusively 17-G.^{11,12}

Recently, larger sized 15-G electrodes have been introduced and used for RFA of liver tumours in our institution. We have found that the 15-G electrode created a larger ablation volume than did the 17-G electrode, while the complication rate differed little. However, to our knowledge, there are no comparative data in the literature regarding the

therapeutic efficacy and complication rate after RFA between 15-G and 17-G single electrodes. Hence, the purpose of this study was to evaluate and compare the ablation volume, local tumour progression rate and complication rate after RFA of HCCs using 15-G and 17-G single electrodes.

METHODS AND MATERIALS

Study population

This retrospective study was approved by the institutional review board of our hospital, and the requirement for informed consent was waived. From October 2011 to November 2012, a total of 417 patients with 440 HCCs were treated with RFA in the radiology department of the Samsung Medical Center, Seoul, Republic of Korea. Study populations in this study are summarized as a flowchart in Figure 1. The inclusion criteria were as follows: (a) patients with HCCs treated by RFA and (b) patients who met the Milan criteria (a single HCC, 5 cm or smaller, or less than three HCCs, each 3 cm or smaller) and (c) RFA performed by a single ablation with a single electrode. Exclusion criteria were as follows: (a) patients having local tumour progression after previous RFA or chemoembolization, (b) patients not having immediate follow-up CT or MRI after RFA, (c) patients not having at least 12-month follow-up CT or MRI. There were 63 patients whose HCCs were ablated with a 15-G electrode, and 53 patients whose HCCs were ablated with a 17-G electrode. To conduct a matched-pair analysis, we attempted to match each case in the 15-G and 17-G groups, according to the same active tip length of the electrode and tumour size (within 2 cm) since these can affect the therapeutic outcomes of RFA. This resulted in a total of 36 matched pairs of HCCs. Finally, the 15-G electrode group consisted of 34 patients with 36 HCCs [28 males and 6 females (mean age, 61.4 years; range, 46–81 years)], whereas the 17-G electrode group consisted of 35 patients with 36 HCCs [28 males and 7 females (mean age, 60.7 years; range, 38–76 years)]. The diagnosis of the HCC was based on either

typical imaging features on CT or MR images³ ($n = 62$, 89.9%) or on histological confirmation by percutaneous biopsy ($n = 7$, 10.1%). The size of the HCCs was defined as the longest diameter of the tumour on ultrasonography images at the time of RFA procedures.

Radiofrequency ablation procedure

Before the RFA procedure, written informed consent was obtained from all patients. All RFA procedures were performed by one of three interventional radiologists (HR, HKL and MWL with 13, 13 and 8 years' experience, respectively, in the field of RFA of HCC, and each having >700 RFA cases of experience at the beginning of this study) under ultrasonography guidance (Logiq® E9; GE Healthcare, Milwaukee, WI). For local anaesthesia, 2% lidocaine hydrochloride (Lidocaine HCl INJ; Huons Co., Hwaseong, Republic of Korea) was injected at the puncture site. For pain control, 50 mg of pethidine hydrochloride (Samsung Pharmaceutical, Seoul, Republic of Korea) mixed with 50 ml of 5% dextrose in water was dripped intravenously. In addition, 100 µg of fentanyl citrate (Fentanyl Citrate Gu Ju INJ; GUJU Pharma, Seoul, Republic of Korea) mixed with 20 ml of normal saline was also injected intermittently one-quarter (25 µg of fentanyl citrate) at a time. Most patients were managed with conscious sedation while monitored anaesthesia care (MAC) was used in only 15.9% (11/69) of patients. MAC was preferred for index tumours located near portal vein branches, for which a patient is expected to have severe pain during the procedure.

We used 15-G or 17-G internally cooled length-adjustable electrodes (Proteus® RF Electrode; STARmed, Gyeonggi-do, Republic of Korea) with a 200-W RF generator (VIVA RF System; STARmed). In general, a 15-G electrode had a thicker calibre and rarely bent in the liver during insertion because it is

Figure 1. The flowchart depicts the process of selection of patients with radiofrequency ablation (RFA) for hepatocellular carcinomas. TACE, transcatheter arterial chemoembolization.

Figure 2. Photographs of 15-G (a) and 17-G (b) Proteus® electrode shafts (STARmed, Gyeonggi-do, Republic of Korea) with adjustable active tip under a compressor. To compare the stiffness of the two electrodes, we evaluated how well the electrodes bend by the same force using a compressor. With similar kilogram-force applied, the 15-G electrode bent less than the 17-G electrode, indicating that it is stiffer than the 17-G electrode. Arrows indicate the direction of force.

stiffer than a 17-G electrode (Figure 2). The type of electrodes and the length of the active tip were chosen based on size, location and geometry of the tumour as well as the preference of the radiologists. If needed, artificial ascites was introduced before the RFA procedure to improve the sonic window or to reduce the level of collateral thermal injury to the adjacent organ.^{13,14} In addition, fusion imaging (volume navigation, Logiq E9) was applied during the RFA procedure whenever needed to improve detection and localization of HCCs.¹⁵

Although the protocol for radiofrequency energy deposition followed the manufacturer's instructions, ablation time was decided at the operator's discretion based on tumour size, extent of echogenic zone on ultrasonography images during RFA and the patient's condition. If the index tumour was located adjacent to a dangerous structure and thus susceptible to collateral damage or the ablative margin seemed >5–10 mm during RFA and thus large enough to cover the entire tumour, operators did not perform aggressive treatment. In these cases, the operators terminated the RFA procedure even though the ablation time was less than 12 min, which is the manufacturer's recommended duration time. On the contrary, if the size of the echogenic zone was smaller than expected and overlapping ablation was infeasible owing to an unfavourable location of the tumour, RFA was maintained for more than 12 min. At the end of the RFA procedures, the electrode path was cauterized to prevent tract seeding or bleeding.

Assessment of ablation zones

Therapeutic outcomes of both electrodes were evaluated. The diameter and volume of the ablation zones (non-enhancing area on CT images) created after using the 15-G and 17-G electrodes were evaluated in random order by a board-certified abdominal radiologist (HJP, with 7 years' clinical experience) who was blinded to the type of electrode used for RFA (15 G vs 17 G), size of HCCs and radiological reports of immediate post-RFA CT

scans. Cases where the index tumours were located within 1 cm from the liver capsule or vessels >3 mm in diameter were excluded in this measurement, since the size and shape of the ablation zones are affected by these structures.¹⁶ Portal venous phase images of immediate post-RFA CT were used for quantitative analysis of the ablation zone. For volume measurement, maximum (Dmx) and minimum (Dmi) diameters were measured on an axial scan with the largest ablation area, whereas the vertical diameter (Dv) was measured from the most cranial to the most caudal border of the ablation zone. The volume of the ablation zone was calculated using the following formula: $\pi (Dv \times Dmx \times Dmi)/6$.¹⁰ The surrounding areas with benign periablation enhancement were not included in the measurement.

Follow-up after radiofrequency ablation and analysis of therapeutic efficacy

Liver CT or MRI was performed within 12 h following the RFA procedures to evaluate therapeutic efficacy and complications according to a standardization paper of image-guided tumour ablation.¹⁷ Technical success was defined as the index tumour being treated according to our treatment protocol and covered completely by the ablation zone, which means complete elimination of enhancing areas within the entire tumour on immediate follow-up liver CT or MRI. Technique effectiveness was defined by the absence of marginal nodular enhancements within the ablation zone on 1-month follow-up CT scans. If the RFA was considered technically effective on the follow-up CT scan performed 1 month later, liver CT was repeated every 3–4 months. Major complication was defined as any occurrence of events threatening the patient's life, leading to substantial disability and morbidity or demanding prolonged hospitalization. All other complications were considered minor. Local tumour progression was defined as the appearance of foci of untreated disease in tumours during follow-up that were previously considered to be completely ablated.

Table 1. Baseline characteristics of 69 patients with 72 hepatocellular carcinomas (HCCs)

Characteristics	15-G electrode (<i>n</i> = 34)	17-G electrode (<i>n</i> = 35)	<i>p</i> -value
Age (years)			
Mean $\pm$ SD	61.4 $\pm$ 8.6	60.7 $\pm$ 9.5	0.848 ^a
Range	46–81	38–76	
Sex: male/female	28/6	28/7	0.772 ^b
Child-Pugh: A/B	33/1	35/0	1.000 ^c
LC: yes/no	22/12	20/15	0.429 ^c
Aetiology of liver disease			0.479 ^b
HBV	26	23	
HCV	3	5	
Alcoholic	0	1	
Idiopathic	5	6	
Previous HCC treatment: yes/no	22/12	8/27	0.001 ^b

HBV, hepatitis B virus; HCV, hepatitis C virus; LC, liver cirrhosis; SD, standard deviation.

^aMann-Whitney test.

^b χ^2 test.

^cFisher's exact test.

Table 2. Characteristics of 72 hepatocellular carcinomas (HCCs) and treatment outcomes after radiofrequency ablation

Characteristics	15-G electrode (<i>n</i> = 36)	17-G electrode (<i>n</i> = 36)	<i>p</i> -value
Size of HCCs (cm)			
Mean $\pm$ SD	1.4 $\pm$ 0.2	1.3 $\pm$ 0.2	0.661 ^a
Range	1.0–2.0	1.0–2.0	
Tumour location ^b			
Subcapsular location	7 ^d	9	
Perivascular location	3 ^d	0	
Others	27	27	
Fusion imaging guidance: yes/no	16/20	19/17	0.479 ^c
Active tip length of electrodes			
2.0 cm/2.5 cm/3.0 cm	4/20/12	4/20/12	1.000 ^c
Ablation time (minutes)	8.7 $\pm$ 3.5 (3–18)	8.4 $\pm$ 2.5 (3–12)	0.793 ^a
Artificial ascites: yes/no	9/27	5/31	0.234 ^c
Ablation zone ^e			
Volume (cm ³)	14.4 $\pm$ 5.4 (7.6–9.4)	8.7 $\pm$ 2.5 (4.5–16.4)	<0.001 ^a
Dmx (cm)	3.3 $\pm$ 0.5 (2.6–4.5)	2.9 $\pm$ 0.5 (2.1–3.8)	0.008 ^f
Dmi (cm)	2.5 $\pm$ 0.3 (2–3.2)	2.2 $\pm$ 0.3 (1.6–2.8)	<0.001 ^f
Dv (cm)	3.2 $\pm$ 0.5 (2.4–4.0)	2.6 $\pm$ 0.5 (1.4–3.4)	<0.001 ^f
Follow-up (months)			
Mean $\pm$ SD	15.9 $\pm$ 2.4	16.4 $\pm$ 2.9	0.424 ^a
Range	12.6–20.2	12.1–20.6	
Technical success (%)	36/36 (100)	36/36 (100)	
Technical effectiveness (%)	36/36 (100)	36/36 (100)	
Complications (%)	2/36 (5.6)	3/36 (8.3)	1.000 ^g
Major complications (%)	1/36 (2.8)	0/36 (0)	1.000 ^g
Minor complications (%)	1/36 (2.8)	3/36 (8.3)	0.614 ^g

Dmi, minimum diameter of largest transverse ablation zone; Dmx, maximum diameter of largest transverse ablation zone; Dv, length from cranial to caudal border of ablation zone.

Values are presented as means $\pm$ SD where applicable.

Numbers in parentheses are ranges.

^aMann–Whitney test.

^bSubcapsular or perivascular location was defined when the tumour was abutting the liver capsule or hepatic vessels >3 mm in diameter, respectively.

^c χ^2 test.

^dOne case was located in both the subcapsular and perivascular areas.

^eIn terms of ablation zone, 9 out of 36 HCCs using the 15-G electrode and 9 out of 36 HCCs using the 17-G electrode were analysed after excluding lesions with subcapsular or perivascular location.

^fStudent's *t*-test.

^gFisher's exact test.

Statistical analysis

Continuous variables such as age, size of HCCs, ablation time, ablation volume and follow-up period between the 15-G and 17-G electrode groups were tested using Student's *t*-test or the Mann–Whitney test according to the normality assumption. Categorical variables such as sex, Child–Pugh classification, liver cirrhosis, aetiology of liver disease, previous HCC treatment, tumour location, fusion imaging guidance, use of artificial ascites and active tip length in each electrode were tested using Fisher's exact test or the χ^2 test. Technical success, technique effectiveness and complication rate were compared using

Fisher's exact test. Cumulative local tumour progression rates were estimated using the Kaplan–Meier method and compared using the log-rank test. A *p*-value <0.05 was considered statistically significant. All statistical analyses were performed with statistical software package IBM SPSS® v. 21.0 (SPSS Inc., Chicago, IL).

RESULTS

Baseline characteristics of the study population

The baseline patient characteristics of the 15-G and 17-G electrode groups are summarized in Table 1. There were no statistical

differences between the two groups except previous treatment history of HCC [transcatheter arterial chemoembolization (TACE) ($n = 11$), TACE + RFA ($n = 5$), resection + TACE + RFA ($n = 3$), resection ($n = 1$), resection + TACE ($n = 2$), and no history ($n = 12$) in the 15-G group vs TACE ($n = 3$), TACE + RFA ($n = 1$), resection ($n = 3$), resection + TACE ($n = 1$), RFA ($n = 1$), and no history ($n = 26$) in the 17-G group]. Tumour size and active tip length of electrodes were also not significantly different between the two groups (Table 2).

Ablation zones

Characteristics of the ablation zone and treatment outcomes are summarized in Table 2. 9 (25%) HCCs from each group were included for analysis of size of ablation zone, considering the distance from the liver capsule or hepatic vessels around the index tumour, which can affect the shape and size of the ablation zone. Although the total ablation times between the 15-G and 17-G electrode groups were not significantly different (8.7 ± 3.5 vs 8.4 ± 2.5 min; $p = 0.793$), three measured diameters and volume of ablation zone in the 15-G electrode group were significantly greater than those in the 17-G electrode group (Figures 3 and 4).

Therapeutic outcome

Technical success was achieved in all RFA procedures in a single treatment session. Technique effectiveness rates were also 100% in both groups. The major complication rate between the 15-G and 17-G groups was not significantly different (2.8%, 1/36 vs 0%, 0/36; $p = 1.000$). One patient in the 15-G group developed extensive portal vein thrombosis, which was classified as a major complication because the patient was hospitalized for up to 10 days after RFA, which was longer than initially expected. On retrospective review, the index tumour was abutting a portal vein branch. The minor complication rate was not significantly different between the two groups (2.8%, 1/36 vs 8.3%, 3/36; $p = 0.614$). They included one case with a small amount of haemorrhage in the 15-G group and pleural effusion ($n = 1$), haemobilia ($n = 1$) and subsegmental infarction ($n = 1$) in the 17-G group. None of those minor complications had clinical significance and subsequently required no treatment. The 10- and 20-month local tumour progression rates were not significantly different between the two groups (2.8% and 5.6% vs 11.1% and 19.3%; $p = 0.166$) (Figure 5).

DISCUSSION

In this study, the 15-G electrode created a larger ablation volume than the 17-G electrode although the ablation time was similar. Both the therapeutic efficacy and complication rate after RFA were not significantly different between the two electrode groups. However, the local tumour progression rate had a tendency to be lower in the 15-G group than in the 17-G group, although it did not reach statistical significance. If a larger study population was included, the local tumour progression rate between the two groups may have reached statistical significance. Based on the results of this study, it is likely that RFA using a 15-G electrode shows better performance than that using a 17-G electrode.

The results of this study are in close agreement with an old study by Goldberg et al.⁸ They evaluated the parameters affecting the size and distribution of an ablation zone produced by

Figure 3. Single hepatocellular carcinoma (HCC) treated with radiofrequency ablation (RFA) with a 15-G electrode in a 42-year-old female. (a) A single nodular HCC (arrow) measuring 2 cm was noted in Segment VI of the liver on the hepatobiliary phase of the liver MR image (repetition time/echo time, 3.1/1.5 ms; flip angle, 10°; matrix size, 256×256 ; bandwidth, 724.1 Hz per pixel; section thickness, 2 mm). (b) Axial portal phase CT image obtained immediately after RFA using a 15-G electrode with a 2.5-cm active tip for 10 min shows a large ablation zone (arrowheads) with no residual enhancing foci, suggestive of technical success. The measured ablation volume was 25.3 cm^3 . (c) Coronal portal phase CT image obtained immediately after RFA also shows a large round ablation zone (arrowheads).

Figure 4. Single hepatocellular carcinoma (HCC) treated with radiofrequency ablation (RFA) with a 17-G electrode in a 61-year-old male. (a) A small HCC (arrow) measuring 1.2 cm was noted in Segment VIII of the liver on the hepatobiliary phase of the liver MR image (repetition time/echo time, 3.1/1.5 ms; flip angle, 10°; matrix size, 256 × 256; bandwidth, 724.1 Hz per pixel; section thickness, 2 mm). (b) Axial portal phase CT image obtained immediately after RFA using a 17-G electrode with a 2.5-cm tip for 10 min shows a relatively small ablation zone (arrowheads), with ablation volume of 10.3 cm³. However, the tumour was covered with sufficient ablative margin, indicating technical success. (c) Coronal portal phase CT image obtained immediately after RFA shows a relatively small ovoid ablation zone (arrowheads).

(a)

(b)

(c)

Figure 5. Cumulative local tumour progression rate of 15-G and 17-G electrode groups after percutaneous radiofrequency ablation. mo, months.

radiofrequency electrodes and found that the extent of coagulation necrosis increased from 0.7 to 1.8 cm as the electrode diameter increased from 24 G to 12 G. Our results are also in line with recent studies using separable clustered electrodes, in which 15-G electrodes showed a larger ablation zone than 17-G electrodes under the same conditions.^{10,18} In the present study, there was no significant difference in ablation time between the 15-G and the 17-G groups (8.7 ± 3.5 min vs 8.4 ± 2.5 min; $p = 0.793$). This implies that a 15-G electrode can make a similar size ablation zone with shorter ablation time than a 17-G electrode. In other words, RFA using a 15-G electrode can reduce the overall ablation time. Another advantage of the 15-G electrode is that it is stiffer than the 17-G electrode (Figure 2). In general, the electrode path is affected by a stiff cirrhotic liver and the breathing motions of patients. Therefore, a stiff electrode would be useful for accurate electrode placement or repositioning during RFA procedures.

The complication rate did not differ between the 15-G group and the 17-G group in this study. However, portal vein thrombosis developed in the 15-G electrode group as a major complication after ablating an HCC abutting a portal vein branch. According to a recent study in which 15-G separable clustered electrodes were used,¹⁰ portal vein thrombosis developed in 3 (21.4%) out of 14 pigs. Although the exact reason is not known, a higher radiofrequency energy deposition of the 15-G electrode would be related to this complication. Since swine liver is thinner than human liver, the ablation zone is likely to contact a portal vein branch easily, thus it is susceptible to portal vein thrombosis. Therefore, human data with large series are needed to verify whether portal vein thrombosis occurs more frequently with 15-G electrodes or 17-G electrodes. Nevertheless, caution would be

necessary for RFA of HCCs abutting a portal vein with a 15-G electrode. On the contrary, given that the heat-sink effect is one of the limitations of RFA for tumours located close to portal veins,¹⁹ a 15-G electrode may overcome this limitation with its higher ablation performance. Further study is warranted to assess whether a 15-G electrode is useful to overcome the heat-sink effect.

Until now, the diameter of commercially available electrodes has ranged from 17 G to 14 G.^{6,7} However, to our knowledge, 17-G electrodes have been exclusively used for internally cooled electrodes. Although we do not know the exact reason why 17-G electrodes are most widely used for RFA of liver tumour, based on our results, we believe that the 15-G electrode can be an alternative to a conventional 17-G electrode for RFA of liver tumours with high performance and an acceptable complication rate.

Our study has several limitations. First, this study suffers from a selection bias since this was a retrospective study. The type of electrode used was determined by the radiologists who performed the RFA procedures depending on their preference, tumour size and patient condition. Although baseline characteristic of HCCs and RFA procedures were not different between the two groups, the lack of standardization for choosing an electrode may be a limitation of this study. Second, ablation time for a single ablation in most cases was shorter than the recommended 12 min. Since tumour sizes were small in both groups (1.4 ± 0.2 cm in the 15-G group, 1.3 ± 0.2 cm in the

17-G group), RFA was terminated before 12 min if the echogenic zone was considered large enough to achieve a sufficient ablative margin. Since most patients under conscious sedation have some degree of pain from prolonged RFA procedures, fulfilling the 12 min seems unnecessary if the echogenic zone is large enough. Furthermore, this issue may not affect our results significantly because the total ablation time was not different between the two electrode groups. Third, although patients with a follow-up period of at least 12 months after RFA were included in this study, the follow-up period was relatively short to determine the long-term therapeutic efficacy. However, instead of long-term therapeutic outcomes of RFA, we aimed to compare the size of the ablation zone, short-term therapeutic efficacy and the safety of RFA of HCCs using 15-G and 17-G single electrodes.

CONCLUSION

In conclusion, the therapeutic efficacy and complication rate were not significantly different between the two groups. However, RFA with a 15-G single electrode created a larger ablation volume than a 17-G electrode under similar ablation conditions. In addition, the 15-G group had a tendency for a lower local tumour progression rate than the 17-G group, although it did not reach statistical significance.

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