

Contents lists available at ScienceDirect

The Egyptian Journal of Radiology and Nuclear Medicine

journal homepage: www.sciencedirect.com/locate/ejrnm



Original Article

Radiofrequency ablation with monopolar cluster versus bipolar multipolar electrodes for the ablation of \geqslant 2.5 cm hepatocellular carcinoma



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ARTICLE INFO

Article history:
Received 4 February 2016
Accepted 29 August 2016
Available online 15 October 2016

Keywords: Radio frequency ablation Bipolar multipolar electrode Monoplar cluster electrode HCC

ABSTRACT

Purpose: To compare the effectiveness of radiofrequency ablation using a monopolar cluster and a bipolar multipolar electrode for the ablation of (\geq 2.5 cm) hepatocellular carcinoma.

Methods: 34 patients with a single HCC (mean size, 4.46 ± 2.3 cm; range, 2.5-7.4 cm) underwent percutaneous RFA with monopolar cluster (n = 18) or bipolar multipolar electrodes (n = 16). Technical success, technical effectiveness, major complications, and tumor progression were compared.

Results: Technical success was achieved in 83, 3%, and 81.3% of patients in the monopolar cluster and bipolar multipolar group respectively. Technical effectiveness was achieved in 87.5% and 94.4% of patients treated by monopolar cluster electrodes and bipolar multipolar electrodes, respectively (P = 0.591). No major complications were developed. Follow-up mean period was 21.4 months. The median local tumor progression rates were 17.7 and 22.7 months in the monopolar cluster and bipolar multipolar group respectively. On multivariate analysis, the use of a monopolar cluster electrode (P = 0.239) was risk factor for complication.

Conclusion: There were no differences in terms of complete ablation, local tumor progression, distant recurrence, and complication rates, but the overall survival regarding the distant recurrence and the life expectancy is better in bipolar multipolar electrodes compared to the monopolar cluster electrodes.

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1. Introduction

The success of the radiofrequency ablation (RFA) in the treatment of heptocellular carcinoma (HCC), which is equal or less to 3 cm [1], encouraged many of the pioneers of this science, and manufacturers, to try to ablate the larger tumors, and especially it is known necessarily impossible to subject patients with these diseases for surgery, or even for the treatment by chemoembolization to dangerous exposure to liver failure [2].

Because the complete ablation of a tumor requires safety margins, these performances are clearly insufficient for the proper treatment of a tumor target larger than 3 cm in a single application. Therefore, to ensure entire coverage of the targeted zone with monopolar devices, multiple overlapping RF ablations with successive positioning of the electrode are required [3]. Threatening the

Peer review under responsibility of The Egyptian Society of Radiology and Nuclear Medicine.

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success of the entire procedure, raises the need for a number of procedures to control, raising the rates of incidence of distant recurrence and raising the percentage of complications that you may encounter patients [4].

The manufactures in turn, have tended to develop the electrodes with the ability to ablate a large tumor size, by using the development in the designs of those electrodes [5,6].

In our study, we tried the comparison between the two types of these electrodes, representing a difference between them in the mode of action, and designs at that time, which will help us to reach a comprehensive vision in dealing with large HCC tumors in general. Although both of the electrodes had been used in previous studies, the comparison between them did not occur.

Electrodes used in the study differ in their mode of action and designs. The first is the monopolar cluster electrode [7], which requires ground pad, and the second is the bipolar multipolar electrode [8,9].

So, the role of this study is based on the measurement of the efficiency of each of the electrode to ablate a medium sized HCC

and measurement of the complications resulting from the use, so that researchers can take advantage of that study to target a larger number of patients with HCC.

2. Materials and methods

2.1. Study design

In accordance with a protocol approval by our institutional review board, radiology reports, laboratory, and medical records were retrospectively reviewed in all patients with HCCs, who initially managed by percutaneous RFA using monopolar cluster and bipolar multipolar devices. In compliance with local policy, no approval by an internal review board was required for this retrospective study. However, it was in accordance with common ethical guidelines and with the Declaration of Helsinki [10].

2.2. Patient selection

Between January 2012 and September 2014, 34 patients underwent percutaneous RF ablation for the treatment of HCC in our institution, 18 with the monopolar cluster device and 16 with the bipolar multipolar device. The location of the tumor was not a contraindication unless it was close to the colon or main bile ducts (<1 cm distance from tumor margin) on pretreatment imaging including triphasic enhanced computed tomography (CT) and/ or magnetic resonance (MR) imaging and ultrasound (US) examinations, all performed less than 1 month before treatment. All patients had a prothrombin time of at least 40% and a platelet count of at least 40,000/mL. We selected all patients in the monopolar cluster electrode group (n = 18) and multipolar internal cooled electrode group (n = 16) who met the following criteria: no more than one tumor, each equal or larger than 2.5 cm in greatest axial diameter; no detectable extrahepatic or intravascular spreading; and histologically proven Child-Pugh class A/B cirrhosis. According to the American Association for the Study of Liver Diseases practice guidelines [10], the diagnosis of HCC for patients with cirrhosis was based on noninvasive criteria: for tumors larger than 2 cm that showed a "washout" on the venous phase in addition to a typical hypervascular pattern on the arterial phase, only one dynamic imaging modality (CT or MR) was sufficient to noninvasively make the diagnosis of HCC, and if the serum α -fetoprotein (AFP) level was greater than 200 ng/mL in a tumor larger than 2 cm, noninvasive diagnosis of HCC was made regardless of enhancement pattern.

2.3. RF ablation

All RFA procedures performed percutaneously under ultrasound guidance. We used multiple electrode system during all procedures. Two types of electrodes were used with a 200-W radiofrequency generator: (1) Celon ProSurge Bipolar electrodes (Celon, Teltow, Germany) with 3 cm active tip were deployed. These electrodes are 1.8 mm in diameter and 15 cm or 20 cm in total needle length used to treat 16 patients. The electrodes were used with coolant pump to have internal cooling. No grounding pads were needed with this device. Two or three electrodes were deployed according to the tumor size and location, and (2) a single 15-cm, 17-gauge internal cooled electrode (Cool-tip; Radionics/Tyco, Burlington, Massachusetts) with a 3-cm distal active tip and thermistor. Sterile water at 4 °C was diffused into the internal lumen of the electrodes with a peristaltic pump to maintain a perfusion rate of 10–25 mL/min. Two 100-cm² grounding pads were applied to the skin of the patient's thighs used to treat 18 patients.

All electrodes were placed via the trans-hepatic approach and the ablation time depended on the perspective of the operator. Patients were discharged from the hospital the day after overnight clinical observation showed no complications.

2.4. Post treatment assessment and follow-up

According to our internal rules for the management of patients with cirrhosis who undergo liver interventional procedures, the patients remained hospitalized for at least 24 h after each procedure.

In all cases, early response was assessed with tri-phasic CT carried out 1 month after RF ablation. CT examinations with an initial unenhanced entire liver pass were followed by an arterial and portal phase of contrast material enhancement, interpreted reviewed by the operator. A tumor was considered to be entirely ablated when the ablation zone showed no inner or peripheral nodular or irregular enhancement on arterial-phase CT. A thin (<5 mm) regular periablational ring of enhancement visible on the arterial phase and persisting during the portal phase was considered a benign inflammatory response to thermal injury.

After each RF ablation procedure, in the case of residual tumoral tissue detectable on CT scan 1 month after the procedure, an additional RF ablation was attempted with the same RF devices if the patient still met the inclusion criteria required for the first procedure. Therefore, in practice, a complete treatment course could require a maximum of two RF ablation procedures separated by at least 1 month. If residual viable tumor persisted after the second RF ablation procedure (or the first procedure if a second RF procedure could not be attempted), the RF ablation treatment was considered incomplete.

After treatment, serum AFP determination, US, and triphasic spiral CT were performed every 3 months. During follow-up, complications, tumor progression, and death were recorded. For tumors considered completely ablated on CT examination performed 1 month after the last RF ablation procedure, local tumor progression was defined by the appearance of a nodular or irregular ring of enhancement in contact with the ablation zone or any thickening beyond 5 mm of the periablational ring detected at

Distant intrahepatic tumor progression was defined as the emergence of one or multiple tumor(s) not adjacent to the ablation zone.

2.5. Efficacy and complications

The rate of complete tumor ablation, the number of RF applications, and the number of sessions per tumor treatment were recorded for each group. The 1- and 2-year probabilities of local and distant tumor progression were computed. Patients were observed for any occurrence of adverse effects in line with the guidelines of the Society of Interventional Radiology [12].

2.6. Statistical analysis

Baseline characteristics were expressed in terms of patients and tumors. Comparisons between treatment with the monopolar cluster and bipolar multipolar electrodes were performed with the χ^2 test and Fisher exact test for categorical variables and the t test for continuous variables. The primary endpoint was defined as complete necrosis assessed on CT. The secondary endpoints were complication rate, local and distant tumor progression after 1 and 2 years, and death. The effect of the type of electrode on immediate response and local tumor progression was computed per nodule whereas distant tumor progression was computed per patient. Probabilities of outcomes were estimated by the Kaplan–Meier

method and compared with the log-rank test. Univariate and multivariate analysis was performed with the Cox proportional-hazards model. All statistical analyses were performed with STATA software (version 9.0; STATA, College Station, Texas).

3. Results

3.1. Patient characteristics

The characteristics of the patients and tumors in this study are summarized, in Tables 1 and 2. At the time of RFA, all patients had cirrhosis. Of the 34 patients, 13 patients were positive for hepatitis B virus, 15 patients were positive for hepatitis C virus, and six patients were mixed for both viruses At the time of RFA, all patients had cirrhosis. The tumor mean size of 34 patients was, 4.46 ± 2.3 cm; range, 2.5-7.4 cm. The mean tumor size was 4.57 ± 0.33 cm (median size, 4.15 cm; range, 3-7.2 cm) in the monopolar cluster group, and 4.35 ± 0.33 cm (median size, 4 cm; range, 2.5-7.4 cm) in the bipolar multipolar group. There were no practical differences between two groups in patient age, sex, positivity for hepatitis B or C virus, increase in serum α -fetoprotein, Child-Pugh score, median tumor size, or tumor location (i.e. subcapsular or non-subcapsular).

3.2. Technical success and effectiveness

No technical failures occurred, see Figs. 1 and 2. The rate of complete tumor ablation per tumor treated was 94.4% in monopolar cluster group and 87.5% in bipolar multipolar group. More than one RF application per procedure was performed in one of 18 cases in the cluster group (5.6%; range, 1–2 applications), and 1 of 16 cases in the bipolar multipolar group (6.25%; range, 1–2 applications, P = 0.013). More than one session was undertaken per treatment in one of 18 tumors (5.6%) in the monopolar cluster group, and one of 16 tumors (6.25%) in the bipolar multipolar group, see Fig. 3 (P = 0.013; Table 3). This means that the bipolar multipolar electrode requires a significant total number of applications and sessions to achieve a complete necrosis (see Figs. 4 and 5).

3.3. Tumor progression

The follow-up mean period was, 21.375 ± 1.07 months; range, 19-23 months. During follow-up, local tumor progression occurred in 3 (16.7%) of 18 patients in the monopolar cluster group and in 3 (18.75%) of 16 patients in the bipolar multipolar group. The average local tumor progression rates were 17.7 ± 1.6 months in the cluster type group and 22.7 ± 0.9 months in the bipolar multipolar

Table 1Baseline characteristics of 34 patients treated with RF ablation.

Characteristic	Total	BMG	MCG	P value
Patients	34	16	18	
Tumors	34	13	21	
Patient characteristics				
Sex (M/F)	24/10	9/7	15/3	0,088
Mean age (y) ± SD	67.34 ± 2	70.44 ± 3.05	64.58 ± 2.54	0.30
Etiology of cirrhosis				0,085
• HBV	13	3	10	
HCV	15	9	6	
HBCV	6	4	2	
Child-Pugh class				0,389
• A	28	14	14	
• B	6	2	4	
Esophageal varices				0,508
• Yes	16	8	8	
• No	18	8	10	
AFP				0,690
• 0 < AFP ≤ 20	20	11	10	
• 20 < AFP ≤ 200 mg	7	3	4	
• 200 mg < AFP	6	2	4	

Note.

HCV = hepatitis C virus.

HBV = hepatitis B virus.

HBCV = hepatitis B&C virus.

BMG = bipolar multipolar group.

MCG = monopolar cluster group.

AFP = α -fetoprotein.

Table 2Baseline characteristics of 34 HCCs treated with RF ablation.

Characteristic	Total	BMG	MCG	P value
Tumor characteristics				
Mean size ± SD (mm)	44,6 ± 2.3	43.5 ± 3.3	45.7 ± 3.3	0.58
Tumor location				0.25
 Right lobe 	23	9	14	
 Left lobe 	11	4	7	
Subcapsular tumor	7	2	5	1.00

Note.

BMG = bipolar multipolar group.

MCG = monopolar cluster group.

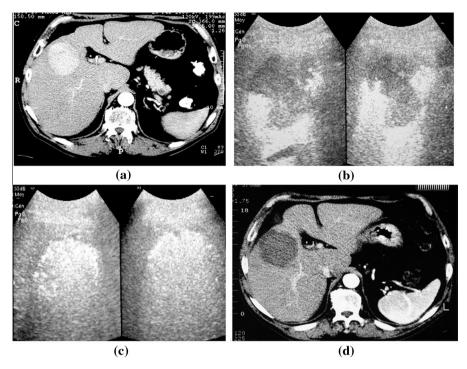


Fig. 1. A 62 years old man with 6 cm HCC successfully treated with bipolar multipolar radiofrequency (a) CT at arterial phase, (b) US transverse views at the beginning of RF energy deposition, (c) US transverse (on the left) and longitudinal (on the right) views at fee end of RF energy deposition, (d) CT at arterial phase performed 1 month after RF ablation procedure.

group. The average time of survival was better in case of bipolar multipolar group, compared to cluster group. However the log Rank (Mantel-Cox) was not decisive, P = 0.036.

3.4. Complications

The mean hospital stay durations in the monopolar cluster and bipolar multipolar groups were 1.06 days \pm 0.33 (range, 1–3) and 1.06 days \pm 0.25 (range, 1–2), respectively.

In the cluster group, one minor periprocedural complication occurred: a 1-day after ablation, one patient developed low grade fever that resolved after 5 days using paracetamol. In the bipolar multipolar group, two minor periprocedural complications occurred: 2 days after RF ablation, two patients developed ascites that resolved within 7 days after diuretic treatment.

3.5. Overall and disease-free survival rates

There were 8 (23.6%) deaths among the 34 patients during the follow-up period. The cause of death due to liver failure occurred in 2 patients treated with cluster electrode Distant tumor progression was the cause of death in 6 patients. Three patients were treated with monopolar cluster electrode and three patients with bipolar multipolar electrode.

Table 4 shows during follow-up period, death in the treated patients occurred in five (27.8%) of 18 patients in the cluster group, and in 3 (18.75%) of 16 patients in the bipolar multipolar group. The average death rates were 16.95 ± 1.9 months in the cluster type group and 23.7 ± 1.1 months in the bipolar multipolar group. The average time of survival (average time without death) was better in case of bipolar multipolar group, compared to cluster group, log Rank (Mantel-Cox) was, p = 0.004.

Table 5 explains the Kaplan–Meier analysis for factors associated with overall Survival.

4. Discussion

Despite the fact that a multiple-electrode RF ablation is a safe and effective procedure for ablation of medium sized HCC, caution dictates that RF ablation results be considered not as a whole but according to the technique used [13].

In this study, we compared two different systems of RF ablation, both of which used multiple electrodes. The first system with monopolar cluster electrode does not require precise parallel electrode placement because each electrode is electrically independent, and requires the use of ground pads. The later system was the bipolar multipolar electrode in which current flow is confined to tissue between electrodes and does not require the use of ground pads. In our study, even though the results were similar in terms of complete ablation, local tumor progression, distant recurrence, and complication rates, but the overall survival regarding the distant recurrence and the life expectance is better in case of bipolar multiple electrodes compared to the monopolar cluster electrodes.

As a whole, distant tumor recurrence may be explained by intrahepatic metastasis or the occurrence of new emerging tumors from the underlying chronic liver disease [14]. In patients with cirrhosis, after curative treatment of HCC, the incidence of distant tumor recurrence is estimated at 10–15% per year [15] and, at least in the case of successfully ablated small tumors, distant tumor recurrence seemed mainly to result from the occurrence of new independent tumors [15]. The distant tumor recurrence rate observed in our bipolar multiple electrode group is within the range reported in the literature after surgical resection [14,15] or percutaneous ablation [16]. On the other side, with the monopolar cluster electrodes, we observed a greater rate of distant tumor recurrence.

Clarification optimized for such an outcome, can be explained by Goldberg et al. [14] during the development of the cluster electrode; when multiple electrodes from the same power source are placed in close proximity, a weak current flows between the electrodes because they are at the same voltage. This factor

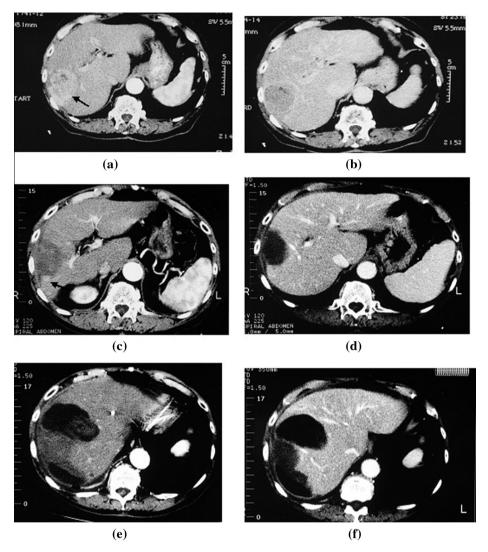


Fig. 2. (a) Arterial dominant phase axial CT scan obtained before ablation using monopolar cluster electrode shows hypervascular lesion (*arrow*) in posted or segment, right lobe. (b) Portal venous phase, the lesion appears hypo attenuating. (c) Enhanced CT scan obtained 1 month after ablation shows non-enhancing RFA area with peripheral enhancement (*arrow*) on arterial dominant phase. (d) Portal dominant phase axial CT scan does not show peripheral enhancement. (e) CT scan obtained after second session of ablation 1 month after c shows successful ablation with extensive ablated margin up to the crura of right diaphragm. Notice right pleural effusion, a common finding after ablation of lesion adjacent to diaphragm. (f) Portal dominant phase axial CT scan shows same findings as in e.

fundamentally limits the distance at which the electrodes can be separated owing to cool spots in the center of the ablation.

Commercially available cluster electrodes are limited by the weak current flow between electrode prongs. Attempting to increase the ablation zone size by setting the prongs further apart would cause increased irregularity in the shape of the induced coagulation, which is already a problem with these electrodes [17]. In addition, with cluster electrode system there is inability to distinguish viable tumor from necrotic tissue on immediate post ablation imaging. This resulted in premature termination of procedures before achieving adequate necrosis of the entire tumor and a surrounding ablative margin [18].

On the other side, with the bipolar multipolar electrode, the existence of the two electrodes on the same system prevents the occurrence of this gap, as each electrode can be a unit consistent with another electrode on the same or the parallel system, so six harmonic electrodes in the presence of two parallel systems can be noted [14].

Another shortcoming of monopolar cluster electrodes is the presence of the heat-sink effect if the index tumor is close to a large vessel (>3 mm) [18,14].

In the terms of complication, no major complication occurred in this series, and the minor complication rates appear to be similar between cluster and bipolar multiple-electrode systems.

When studying these types of multiple electrodes, we must be keep in mind the privacy of these electrodes in dealing with large tumors, which in turn means the large number of electrode placement and complications resulting either from the size of the tumor and its effect on the liver or from neighboring critical structures or the number of the electrode placement and the chance of distant tumor recurrence.

Placement of bipolar multiple electrodes in this study was not difficult compared with placing monopolar cluster electrode, which does not require precise parallel electrode placement. Placement of the first electrode generally took the longest because of the need to find a suitable window and approach, but subsequent placements were generally faster because the first electrode could be used as a guide needle.

To our knowledge, this is the first study to compare the safety and efficacy of RFA using monopolar cluster and bipolar multiple electrodes in patients with medium-sized HCCs.

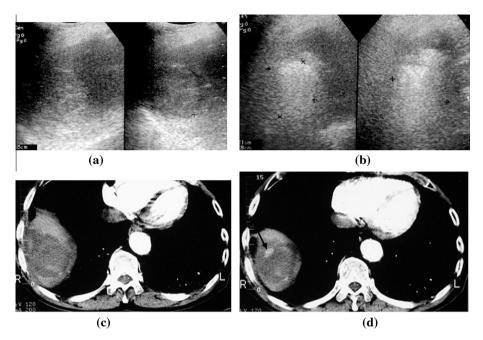


Fig. 3. A 68 years old man with 6.5 cm HCC incompletely ablated after 1 multipolar radiofrequency procedure:(a) US transverse (on left) and longitudinal (on right) views before treatment, (b) US transverse (on left) and longitudinal (on right) views just after the end of RF procedure, (c) CT at arterial phase performed 1 month after RF ablation procedure shows tumor almost completely ablated but (d) few cm above c, CT at arterial phase shows persistent of viable tumor (arrow) requiring complementary additional RF procedure.

Table 3Influence of type of electrode used on therapeutic response and course of treatment in 34 tumors treated with RF ablation.

	Total	BMG group	MCG group	P value
Complete ablation	31	14	17	0,455
Incomplete ablation	3	2	1	
No. of RF applications				0.013
1	32	15	17	
≥2	2	1	1	
No. of sessions				0.013
1	32	15	17	
2	2	1	1	

Note.

Values are presented as numbers of tumors where appropriate.

BMG = bipolar multipolar group.

MCG = monopolar cluster group.

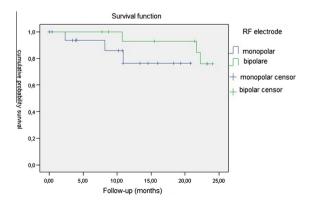


Fig. 4. Graph shows the average time of survival (average time without death) is better in the case of the bipolar multipolar electrode (23, 7 months), compared to fee cluster electrode (16, 9) months. Significant difference was noted between two groups. Log Rank (Mantel-Cox), p = 0.004.

The main limitation of this study was the absence of randomization, which may have introduced a bias. However, patients were selected only on the basis of objective criteria, both groups had similar baseline characteristics with regard to underlying cirrhosis and tumor characteristics, and both were treated over a short period of time by the same operator in the same center. The relatively small number of patients included in this study could also be considered a limitation. It is relevant that, in a secondary or tertiary center such as ours, many patients referred for RF ablation have larger tumors or are referred for local recurrences, which would violate the inclusion criteria because of the more advanced stage of their disease.

In conclusion, percutaneous RFA using bipolar multipolar electrodes is better in overall survival regarding the distant recurrence and the life expectance compared to the monopolar cluster electrodes.

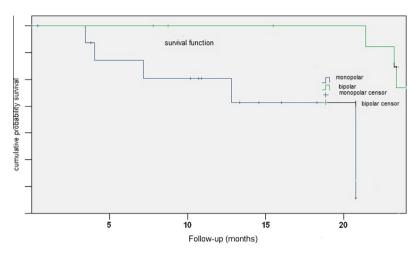


Fig. 5. Graph shows the average time of survival (average time without recurrence) is better in case of bipolar multipolar electrode (22.7 months), compared to cluster electrode (17.7 months). No significant difference was noted between the two groups (P = 0.036, log-rank test).

Table 4 Influence of type of electrode used on tumor progression (recurrence) and life at 2 years.

	Total	BMG group	MCG group	P value
No recurrence	28	13	15	0.611
Recurrence	6	3	3	
Live	26	13	13	0.693
Death	8	3	5	

Note.

Values are presented as numbers of tumors where appropriate.

BMG = bipolar multipolar group.

MCG = monopolar cluster group.

Table 5Kaplan–Meier analysis for factors associated with overall survival.

Variable	No. of living cases	P value age (y)
Etiology of cirrhosis		0.823
• HBV	11	
• HCV	13	
 MIXED 	4	
Complete ablation		0.006
• Yes	26	
• NO	0	
Recurrence		0.204
• BMG	13	
• MCG	15	
Death		0.004
• BMG	13	
• MCG	13	

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