Radiofrequency Ablation Alone versus Radiofrequency Ablation Combined with Chemoembolization in Unresectable Hepatocellular Carcinoma

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Objective: *To determine the effectiveness of the treatment in unresectable hepatocellular carcinoma between radiofrequency ablation (RFA) alone and combination of RFA and transcatheter arterial chemoembolization (TACE).*
Material and Method: *Forty-six patients with 57 hepatic nodules smaller than 5 cm in maximum diameter were treated with RFA alone in 37 nodules and combined RFA with TACE in 20 nodules. RFA electrode size was varying from 2 to 5 cm diameter. The chemotherapeutic drugs in TACE were mixture of flurouracil with lipiodol and mitomycin-C with lipiodol. The residual tumor, local recurrent, and tumor progression was evaluated by dynamic enhanced CT or MRI study of the liver after treatment.*
Results: *Local response in RFA alone and combined treatment were 97.3% and 70%, respectively. Recurrence rate in RFA alone and combined treatment were 6.9% and 20%, respectively. The average ablative margin visualized on post RFA images were 0.7 cm and 0.4 cm in RFA alone and combined treatment, respectively. Complication rate was 0.07% and all of complications were minor complication.*
Conclusion: *For small unrespectable HCC nodules, RFA ablation alone is the effective treatment, Additional TACE may not be necessary if RFA is performed completely under controlling the important factors, especially ablated margin.*

Keywords: *Radiofrequency ablation, Transcatheter arterial chemoembolization, Combined therapy, Hepatocellular carcinoma, Treatment outcome*

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Hepatocellular carcinoma (HCC) is one of the most common primary hepatic malignancies worldwide[1]. Chronic hepatitis B and C, mostly in the cirrhotic stage, are responsible for the great majority of cases of HCC. The geographic areas at the highest risk are South-East Asia and sub-Saharan Africa[2]. The current curative treatments of HCC are surgical resection, liver transplantation and imaged guided ablation treatment. The surgical resection seems to be the treatment of choice which is considered the first-line therapy, however, the resection rate is only in the range of 10% to 37%, even in the centers with extensive experience in hepatic resection for HCC[3]. The major improper reasons are multifocal lesions and inadequate residual normal liver. Transcatheter arterial chemoembolization (TACE) is a well-known procedure in treating HCC, which is proper for multifocal lesion and variable size of tumor. This treatment is standard of choice in treatment of unresectable hepatocellular carcinoma. Recently, percutaneous ablation treatment has been widely used for treatment of small HCC such as percutaneous ethanol injection (PEI) and radiofrequency ablation (RFA)[4-6]. RFA has been reported to be better than PEI in a higher rate of tumor necrosis and survival rate[5,6]. The efficacy of RFA is known as superior to TACE in less invasiveness, more preservation of normal liver tissue, low recurrent rate, and shortening hospitalization days. Recently, a few researches discussed the role of combination treatment of the TACE and local treatment such as RFA or percutaneous ethanol injection, but no one could demonstrate the significant effectiveness.

RFA combined with TACE is a treatment option for local tumor control, which has been reported to be effective in a small number of HCC less than 3 cm[7,8]. The purpose of the present study was to give retrospective assessment of effectiveness of

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combined RFA and TACE with RFA alone in the treatment of small and medium-size HCC (less than 5 cm).

Material and Method

Patients

The present retrospective study was approved by the institutional review board. The informed consent was obtained from all patients before the procedure of treatment. Eighty-three patients with 107 HCC nodules between January 2006 and December 2007 underwent RFA. Among them, 57 nodules of unresectable HCC smaller than 5 cm in maximum diameter in 46 consecutive were recruited in the present study. Of these patients, TACE was performed in 11 patients before radiofrequency ablation and six patients after radiofrequency ablation. RFA was performed in 29 patients. Patients who were treated with hepatectomy or evidence of distant metastases or severe coagulopathy were excluded from the present study. Primary outcome was evaluated in rate of viable tumor by pattern of arterial enhancement and others associated factors.

Clinical background

Forty-six HCC patients were evaluated by imaging modalities, such as dynamic CT of liver. The diagnostic criteria for HCC by imaging were based on pattern of enhancement; arterial enhancement and delayed washout in portal venous phase. The alpha-fetoprotein level equal or more than 20 μg/L was also additional criteria in atypical pattern of tumor enhancement. All of these patients give obtained clinical information: age, gender, hepatitis profile, presence of ascites, Child-Pugh classification of cirrhosis, sizes and location of tumors, number of masses, serum biochemical parameters (alanine amino-transferase, aspartate aminotransferase, albumin, total bilirubin, platelet count, and prothrombin time), and serum tumor markers (alpha-fetoprotein).

Procedure for radiofrequency ablation

All of HCC nodules were performed with LeVeen CoAccess Electrode System (Boston Scientific radiofrequency generator), which consists of a core needle with multiple small umbrella-shaped electrodes. The electrodes were intended for coaxial placement within the insulated cannula; 15 cm long, 18 to 20 gauge. Selecting an electrode diameter size depends on the size of the tumor that ideally engulfs or extends beyond the target tissue at least 0.5 cm. All patients were treated with intravenous sedation by anesthesiologist while the cardiovascular and respiratory systems were continuously monitored. The procedure was performed until impedance of the target lesion reached maximum value and echogenic cloud occupied the entire tumor area. Repeated ablation was performed at the same target lesion to ensure the accomplishment of the ablation by changing in radial position of umbrella-shaped electrodes.

Procedure for transcatheter arterial chemo-embolization (TACE)

The modified Seldinger technique with local anesthesia was used to access right common femoral artery. The chemotherapeutic agents mixed with iodized oil (Lipiodol) were injected through the hepatic artery. The authors used fluorouracil (5-FU) and mitomycin-C emulsion as the chemotherapeutic agent mixed with lipiodol 10 ml. Gelfoam embolization was performed in some patients. In combined treatment, TACE were performed either before or after RFA treatment. The interval between two treatments was performed within 30 days.

Imaging acquisition and evaluation

All the patients were performed with pre- and post-treatment imaging; dynamic CT of the liver. Post-treatment images were obtained at 4 weeks and every 4 to 8 weeks after RFA or TACE treatment. CT acquisition was performed by using 64-slice MDCT (Lightspeed VCT, GE medical systems, Milwaukee, WI) covering entire liver with the following protocol: 64 x 1.25 mm collimation, reconstruction at 1.25 mm and 7.5 mm slice thickness without overlap. The scanning was obtained on pre-contrast, during arterial phase (30 seconds after contrast injection) and portal venous phase (80 seconds after contrast injection). A 100-ml bolus of 370 mgI/ml iopromide (Bayer Schering Pharma AG, Berlin, Germany) followed by 30 ml of normal saline at flow rate 4 ml/sec.

Efficacy and follow-up

All the pre- and post-treatment images were consensus evaluated by two interventional radiologists on picture archiving and communication system (PACs). The radiologists were blinded in history and laboratory findings. The response of treatment was assessed in viability of tumor according to pattern of enhancement. The viable tumors were defined as peritumoral arterial enhancement after contrast medium injection on dynamic CT study. Other therapeutic

responses were also evaluated by percent of tumor necrosis in RFA group and pattern of iodized oil accumulation in CT images. Tumor necrosis was estimated in five grades according to percent RFA defect; grade I (0-24%), II (25-49%), III (50-74%), IV (75-99%), and V (100%) necrosis. According to the study of Hyo Soon Lim, et al[9], Iodized oil accumulation within the tumor was classified into 4 types: type I, homogeneous accumulation, type II, partial defect in the tumor; type III, faint accumulation; and type IV, no or slight accumulation. The pattern and distribution of iodized oil in tumor was useful for assessing the therapeutic effects of TACE. A greater amount of accumulation of iodized oil within tumor indicated a greater area of necrosis. Other data including tumor size, duration for first post-treatment imaging, size of RFA defect, and complication of treatment were also collected. The margin of ablated lesion was also collected, which was defined as the half value of RFA ablated size minus pretreated tumor size. The last follow-up imaging was recruited to evaluate viable tumor, which is suggested of tumor recurrence. The time between dates of treatment to the dates of last imaging was recorded.

Statistical analysis

The statistical analysis was calculated with Student's t test for normality continuous data, and Mann-Whitney U-test for non-normality continuous data to test for significance of difference between averages size of the tumor and post-ablation. The Chi-square test and Fisher's exact test were analyzed the categorical data. Data were expressed as mean $\pm$ standard deviation. All analysis was calculated with SPSS version 11.5. P-value of less than 0.05 was set for statistical significant.

Results

Patients

Seventeen consecutive patients underwent combination treatment and 29 consecutive patients underwent RFA for the treatment of HCC. Tumor characteristics are similar between two patient groups such as age, number of tumor, hepatitis profile, liver function on initial staging and ascites, which are no statistically significant ($p > 0.05$).

Among the 57 nodules, the TACE was combined with RFA in 20 nodules (17 patients) and RFA alone was performed in 37 nodules (29 patients). Average tumor size of the combined treatment group was 2.5 ± 0.9 cm (ranged 0.7-4.3 cm), whereas in RFA alone was 1.9 ± 0.9 cm (ranged 0.4-4.0 cm) (Table 1). The chemotherapeutic agents in all patients of combined treatment were mixture of 5-FU and Mitomycin-C except one patient used only 5-FU alone. Ten nodules were embolized with gelfoam, while the others were only chemoinfusion.

Immediate response

All hepatic nodules treated by RFA were 57 nodules in 46 patients. Tumors were located in the left lobe 17 nodules, and the right lobe 40 nodules. All of these nodules were seen under ultrasonographic guidance. The electrode size using in these nodules were various diameter size from 2.0-5.0 cm, but during real-time performance, the diameter of RFA needle tip was expanded approximately to the size of the nodule. The ranging of RFA defect was varying from 1.3-6.1 cm (average 3.3 ± 0.9 cm) (Table 1).

The average size of ablation area of the combined treatment group was 3.2 ± 0.8 cm (ranged 1.3 to 4.6 cm). Two ablated lesions were smaller than the pretreatment nodule and the first follow-up study also showed peripheral enhancement indicated viable tumor. Margin of combined treatment nodules was 0.4 ± 0.5 cm (ranged 0.8 to 1.4 cm).

Thirty-seven nodules were treated by RFA alone in 33 sessions. Average size of ablation area in RFA along group was 3.3 ± 0.9 cm (ranged 1.6 to 6.1 cm). No statistical significant difference in ablation area was seen in both groups of patients. However, the margin of tumor ablation in RFA alone (0.7 ± 0.4 cm)

Table 1. Immediate response of hepatocellular carcinoma after RFA alone and combined RFA with TACE

Characteristic	Combined RFA + TACE (20 nodules)	RFA alone (37 nodules)	p-value
Tumor size in longest diameter (cm)	2.5 ± 0.9	1.9 ± 0.9	<0.05
RFA defect size (cm)	3.2 ± 0.8	3.3 ± 0.9	0.68
Margin of ablated area (cm)	0.4 ± 0.5	0.7 ± 0.4	<0.05
Complete tumor ablation	14	35	<0.05
Incomplete tumor ablation	6	2	<0.05

was statistically significant ($p < 0.05$) larger than combined treatment group (0.4 ± 0.5 cm). Tumor necrosis of combined treatment was found in grade 1, 3, 4, and 5 in 5%, 5%, 20%, and 70% of nodules, respectively. Complete ablation seen on first follow-up imaging in the combined treatment was 14 in 20 (70%). The tumor necrosis in RFA alone group was found in grade 2, 3, and 5 was 2.7%, 2.7%, and 94.6% of nodules, respectively (Table 2).

The average size of ablation area in RFA combined treatment group was 3.2 ± 0.8 cm (ranged 1.3-4.6 cm). In the first follow-up study, the residual viable tumor was detected in six of 20 nodules (30%). The most common pattern of iodized oil accumulation in the present study was type IV (no or slightly accumulation) found in 11 patients from 20 patients (55.0%) in the combined treatment group.

Long-term follow-up

Follow-up time was varying between 29-766 days, average follow-up time of the total nodules 283.2 ± 176.6 days. At six months after treatment, 29 nodules in RFA alone group and five nodules in combined treatment group were evaluated for tumor recurrence. One lesion in RFA alone group showed residual tumor from first follow-up study and this patient survived to follow-up more than 6 months. The recurrent nodules were found two from 29 nodules (6.9%) in RFA alone group (Fig. 1), which presented recurrence at six-month follow-up. In combined treatment group, there was only one from five nodules (20%) which showed recurrence after six-months follow-up (Table 3).

Complication

No serious immediate complication after treatment in both groups was found. The minor complication was seen in the first follow-up study on CT in four cases, including hematoma at the puncture site one case, subcapsular hematoma two cases, and bile duct injury one case. All of these cases had no need for specific treatment and no need for longer hospital administration. All patients could tolerate the treatment until the end of the procedure.

Discussion

In the present study, the authors analyzed the tumor necrosis and recurrent rate of small-size HCC undergoing RFA alone or RFA with TACE (combined treatment). The authors found that complete tumor necrosis or grade 5 necrosis was the most common (86%) in all HCC nodules. Concordantly, several studies[10, 11] showed complete tumor necrosis after single session of RFA highly to 80 to 90% in HCC smaller than 3 to 5 cm. The authors found that HCC nodules that were treated by RFA alone, had a very high success rate in complete tumor response (94.6%), while the combination group had a lower success rate (70%), thus RFA was the possible important factor for tumor viability in combined treatment. The authors also found that ablated margin in combination treatment was significantly smaller than the RFA group and the

Table 2. Percentage of tumor necrosis immediately after radiofrequency ablation*

Tumor necrosis (grading)	Combined RFA + TACE (20 nodules)	RFA alone (37 nodules)
Grade 1 = 0-24 %	1 (5%)	0
Grade 2 = 25-49%	0	1 (2.7%)
Grade 3 = 50-74%	1 (5%)	1 (2.7%)
Grade 4 = 75-99%	4 (20%)	0
Grade 5 = 100%	14 (70%)	35 (94.6%)

* p-value among all nodules is not significant (p-value = 0.05)

Table 3. Tumor recurrence at long term follow-up

Characteristic	Combined RFA + TACE	RFA alone	p-value
Recurrent nodule	1/5 (20%)	2/29 (6.9%)	0.39
Duration of last follow-up (day)	178.6 ± 104.5	339.7 ± 182.7	<0.05

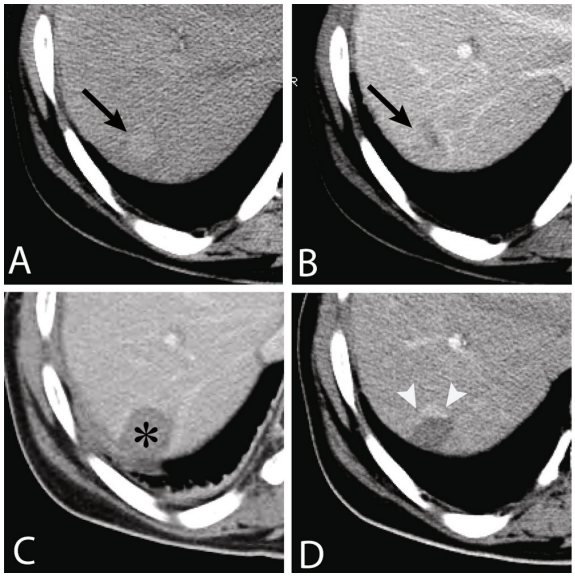

Fig. 1 Recurrent tumor in a 51-year-old man treated HCC with radiofrequency ablation (RFA) alone. A, axial contrast-enhanced CT scan during arterial obtained before RFA shows an enhanced 1.8 cm HCC node (arrow) at postero-superior portion of right lobe of liver (segment VII). B, axial contrast-enhanced CT scan during portal venous phase of this nodule shows heterogeneous portal venous washout (arrow). C, axial contrast CT scan during portal venous phase obtained 1 hour after RFA shows complete ablation of tumor (asterisk) without residual tumor. D, follow-up 6 months of axial contrast-enhanced CT scan during early portal venous phase shows recurrent tumor at anterior rim (arrowheads) of the previous ablated area

margin of ablated area of combination group was less than 5 mm. Concordant with Nakazawa et al[12], the absence of an ablative margin of at least 5 mm in single HCC less than 3 cm significantly correlated with local tumor progression. Difficult locations for RFA include subcapsular tumor, perivascular region, and centrally located tumor proximity to major bile ducts[13] was also an influence factor for local recurrence. The authors found that seven incomplete ablated nodules in combined treatment accounted for subcapsular lesions in five nodules. The subcapsular nodules were technical difficulty in both RFA and TACE treatment. The RFA was difficult to place the needle in the proper position without complication or respiratory motion during the procedure. The TACE was also difficult to perform due to being unable to adequate superselect into the target tumor for injection of chemotherapeutic agent.

Sutherland et al[14] revealed local recurrent tumor at post RFA lesion varied from 3 to 33 months. The authors evaluated recurrent rate at six-months after treatment due to study time limitation. After treatment at 6 months, more than 50% of combination treatment was excluded to perform other treatment, thus the sample size was too small for recurrent rate evaluation. Contrary to the combination group, there was exclusion in only 24% of cases in RFA alone group. This authors showed lower rate of tumor recurrence in RFA alone than the combined treatment. Recent studies[13,15] revealed local recurrence at the post RFA lesion was not infrequent, and its incidence ranges from 5.7% to 39%. The authors showed also a similar result. The recurrence rate was 6.9% in RFA alone group (Fig. 1), which was the acceptable rate.

Several literatures showed a varied result of tumor recurrence in combined treatment. Randomized controlled trial of Akamatsu et al[16] studied transcatheter arterial embolization (TAE) prior to percutaneous tumor ablation in patient with HCC. They found no recurrence tumor in TAE/RFA group. Another randomized controlled trial[7] conducted in HCC larger than 3 cm that found the local recurrence 80% in TACE group, 81% in RFA group and 59% in TACE-RFA group and the recurrences in the TACE-RFA group was significantly lower than the other groups. According to the literature reviews, several studies showed combined TACE-RFA trended to be superior than RFA alone especially in expandable ablated area more than using RFA alone. However, most of them studied in the large tumor, larger than 3 to 5 cm. The authors showed also recurrent tumor in combined treatment, which had no significant difference in recurrence rate to RFA alone group. This might be due to several factors. The tumors in the present study were the small nodules and these are difficult to superselect for chemoembolization, therefore the effective of TACE might not be adequate. One review study[17] revealed nodular HCC lesion ≤ 3 cm, good treatment results had been reported with the use of RFA alone. Shibata et al[18] also reported that combined TACE and RFA have an equivalent effectiveness for the treatment of small HCC (< 3 cm) and RFA alone. Considering that chemoembolization was associated with increased cost and patient discomfort, it might be reasonable to restrict combined use of chemoembolization to non-nodular HCC lesions if tumor size was ≤ 3 cm. In small nodules, the authors supposed that the effectiveness of RFA was the important factor for complete tumor response

and recurrence rate. TACE might not be necessary if RFA can be performed completely.

The present study showed a low complication rate (0.07%) and all had minor complications. Concordant with the study of Akahane et al[19], that demonstrates minor complications of RFA about 0.82% in each treatment[19].

The present study was retrospective study. Two groups of HCC lesion are not randomly selected to perform the treatment; therefore, size of the tumor in combined treatment is slightly larger than RFA alone group. Moreover, combined treatment in the present study was performed in tumor with difficult location, particularly subcapsular location. The sample size in both groups was also limited. The local recurrence evaluation was limited at 6 months, because many cases in combined treatment were excluded to perform other treatment options.

Conclusion

Radiofrequency ablation is the effective treatment in local response and recurrence rate for unresectable small HCC nodules less than 5 cm. Additional TACE may not be necessary if RFA is performed completely under controlling the important factors, especially ablated margin.

Potential conflicts of interest

None.

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การศึกษาผลการรักษาผู้ป่วยมะเร็งตับที่ไม่สามารถผ่าตัดได้และเป็นก้อนขนาดเล็กด้วยวิธีการใช้คลื่นวิทยุความถี่สูงเพียงอย่างเดียวและการรักษาด้วยวิธีใช้คลื่นวิทยุความถี่สูงร่วมกับการฉีดสารเคมีบำบัดเข้าทางหลอดเลือดแดงตับ

ทนงชัย สิริอภิสิทธิ์, ประพันธ์ ศิวะสัตยานนท์, ตรงธรรม ทองดี

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพในการรักษามะเร็งตับที่ไม่สามารถผ่าตัดได้และเป็นก้อนขนาดเล็ก ระหว่างการรักษาโดยการจี้เผาด้วยความร้อนจากคลื่นวิทยุความถี่สูง (Radiofrequency Ablation (RFA)) เพียงอย่างเดียว และการรักษาโดยวิธีการ RFA ร่วมกับการฉีดยาเคมีบำบัดเข้าสู่หลอดเลือดแดงตับ (transcatheter arterial chemoembolization (TACE))*

วัสดุและวิธีการ: *ผู้ป่วย 46 ราย ที่มีก้อนมะเร็งตับขนาดเล็กกว่า 5 เซนติเมตร จำนวนรวม 57 ก้อน โดยก้อนมะเร็งจำนวน 37 ก้อน ได้รับการรักษาด้วยวิธีการ RFA เพียงอย่างเดียว และก้อนมะเร็งจำนวน 20 ก้อน ได้รับการรักษาด้วย RFA ร่วมกับการรักษาด้วยวิธีการ TACE ซึ่ง RFA ใช้เข็ม ขนาด 2-5 เซนติเมตร และ TACE ใช้ยาเคมีบำบัด คือ fluorouracil ร่วมกับ lipiodol และ mitomycin-C ร่วมกับ lipiodol การวัดผลการรักษาประเมินโดยใช้การตรวจด้วย CT เพื่อดูเซลล์มะเร็งที่เหลืออยู่, การกลับเป็นซ้ำ และการดำเนินโรคของก้อนมะเร็ง*

ผลการศึกษา: *การถูกทำลายของเซลล์มะเร็งตับในกลุ่มผู้ป่วยที่รักษาด้วยวิธี RFA เพียงอย่างเดียว และกลุ่มที่รักษาด้วยวิธี RFA ร่วมกับ TACE มีค่าเป็น 97.3% และ 70% ตามลำดับ การกลับเป็นซ้ำของมะเร็งตับ ในกลุ่มผู้ป่วยที่รักษาด้วยวิธี RFA เพียงอย่างเดียว และกลุ่มผู้ป่วยที่รักษาด้วยวิธี RFA ร่วมกับ TACE มีค่าเป็น 6.9% และ 20% ตามลำดับ ค่าเฉลี่ยระยะขอบความกว้างของรอยจี้เผาก้อนมะเร็งภายหลังที่ได้รับการรักษาด้วย RFA มีค่า 0.7 เซนติเมตร และ 0.4 เซนติเมตร ในกลุ่มที่รักษาด้วยวิธี RFA เพียงอย่างเดียว และกลุ่มที่รักษาด้วยวิธี RFA ร่วมกับ TACE ตามลำดับ อัตราการเกิดภาวะแทรกซ้อนเป็นชนิดที่ไม่รุนแรงและมีค่าประมาณ 0.07%*

สรุป: *การรักษาก้อนมะเร็งตับขนาดเล็กด้วยวิธีการ RFA ที่ทำได้อย่างสมบูรณ์เพียงอย่างเดียว ได้ผลเพียงพอต่อการรักษา โดยอาจจะไม่จำเป็นต้องให้รักษาเพิ่มเติมด้วยวิธีการ TACE และปัจจัยที่มีผลต่อการรักษาที่สำคัญคือระยะขอบความกว้างของรอยจี้เผาก้อนมะเร็งภายที่ได้รับการรักษาด้วย RFA*