Published in final edited form as:

J Vasc Interv Radiol. 2016 May ; 27(5): 631–638. doi:10.1016/j.jvir.2016.01.136.

Microwave versus radiofrequency ablation treatment for hepatocellular carcinoma: a comparison of efficacy at a single center

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Abstract

Purpose—To compare the efficacy and major complication rate of radiofrequency (RF) and microwave (MW) ablation for the treatment of hepatocellular carcinoma (HCC).

Materials and Methods—This retrospective study included 69 tumors in 55 patients treated by RF, and 136 tumors in 99 patients treated by MW between 2001 and 2013. All tumors were diagnosed as HCC by standard imaging criteria. Both RF and MW ablation devices comprised straight 17-gauge applicators. Overall survival and rates of local tumor progression were evaluated using Kaplan-Meier techniques with Cox proportional hazard models, as well as competing risk regression of local tumor progression.

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Presentation at SIR: Not presented at an SIR meeting

Conflicts of Interest:

- J. Louis Hinshaw- Shareholder Neuwave Medical
- Christopher L. Brace- Shareholder and consultant Neuwave Medical
- Fred T. Lee, Jr.- Shareholder, patent holder, and board director Neuwave Medical; patent holder and royalties- Covidien
- Meghan G. Lubner-Grant funding, Neuwave Medical, GE Medical, Philips
- Theodora A. Potretzke, Timothy J. Ziemlewicz, Shane A. Wells, Alejandro Munoz-del-Rio, Parul Agarwal- nothing to disclose

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Results—RF and MW cohorts were similar in age (mean: 62 [range 23-88] and 61 [44-82] yr, respectively; $p=0.22$), MELD (8.8 and 9.6, respectively; $p=0.24$), and tumor size (2.4 [0.6-4.5] cm and 2.2 [0.5-4.2] cm, respectively; $p=0.09$). Median length of follow-up was 31 months for RF and 24 months for MW. The rate of local tumor progression was 17.7% with RF and 8.8% with MW. The corresponding HR from Cox and competing risk models were 2.17 [95% CI: 1.04-4.50] ($p=0.04$) and 2.01 [0.95-4.26] ($p=0.07$), respectively. There was improved survival for patients treated with MW, although this was not statistically significant (Cox HR 1.59 [0.91-2.77]; $p=0.103$). There were few major (grade C) complications in either group (2 for RF, 1 for MW; $p=0.28$).

Conclusion—In this single center trial, treating HCC percutaneously with RF or MW ablation was associated with high primary efficacy and a durable response, with lower rates of local tumor progression noted after MW ablation.

Introduction

Thermal ablation is currently used in two predominant ways to treat hepatocellular carcinoma (HCC), both as a bridge to transplantation and as definitive therapy in patients who are unable or unwilling to undergo surgical resection or transplantation [1, 2]. In patients undergoing definitive therapy for HCC, there is increasing evidence to support ablation as first-line therapy, including several randomized controlled trials in which ablation compares favorably to surgical resection [3-5]. As a result, the BCLC guidelines, which are widely accepted in Europe and North America, now recommend ablation for treatment of very early or early HCC in patients who are not surgical candidates [2, 6].

Radiofrequency (RF) ablation has the longest history among thermal ablation methods, and most of the larger HCC trials were performed with RF [7, 8]. However, in recent years there has been increasing interest in microwave (MW) ablation due to potential physical advantages that are increasingly realized with modern high-powered devices. Whether the physical differences between RF and MW translate into better clinical outcomes remains an open question. While a few RF vs. MW case-series comparison studies are available, they are limited in general applicability as the MW equipment was either early first-generation (and may no longer be used), and/or is not available in Europe or the USA [9-11]. The choice of equipment is an important factor to consider due to important technical variables that distinguish even modern MW systems. Therefore, despite evidence suggesting equivalent outcomes with both RF and MW ablation for treatment of HCC, a comparison using modern MW ablation equipment currently available in the US and Europe is necessary to guide future clinical practice. Therefore, the purpose of this study is to compare the local treatment efficacy and major complication rate of a 17-gauge RF system and a 17-gauge MW ablation system for the treatment of hepatocellular carcinoma.

Materials and Methods

Patient Selection

This study was conducted under a waiver of informed consent from the Institutional Review Board and complied with the Health Insurance Portability and Accountability Act (HIPAA).

All subjects who underwent percutaneous radiofrequency or microwave ablation for HCC at a hepatic transplant center between 2001 and 2013 were identified for potential analysis. Patients were excluded if they had undergone combination treatment with transarterial chemoembolization (TACE) prior to ablation. At our institution TACE is performed in combination for those outside of the Milan criteria or when a solitary tumor over 3 cm is ill-defined on imaging. No patient with prior chemotherapeutic treatment for hepatocellular carcinoma was treated in the cohort. The study group included 69 tumors in 55 patients treated by RF ablation and 136 tumors in 99 patients treated by MW ablation. RF ablation was utilized in all patients treated before 2011. In January 2011 we began using MW ablation routinely. During 2011 RF was used in 3 cases by physician choice where the tumor was abutting the diaphragm or critical structures, otherwise from 2011 through 2013 all patients were treated with MW ablation. All patients were referred for ablation after an interdisciplinary discussion with hepatologists, hepatobiliary surgeons, transplant surgeons, oncologists, and radiologists. Liver dysfunction was categorized using the standard Model for End Stage Liver Disease (MELD) [12].

Ablation Procedures

All treatments were performed at a single center by one of seven board-certified abdominal radiologists with ablation experience ranging from 1-16 years. Each case was performed via a percutaneous approach with the patient under general anesthesia in a dedicated CT suite. Image guidance for electrode and antenna placement was provided by real-time ultrasound (Acuson Sequoia, Siemens, Mountain View, CA or Logiq E9, GE Medical Systems, Waukesha, WI) with CT utilized to confirm needle placement when necessary (Lightspeed Plus or Lightspeed Xtra, GE Medical Systems, Waukesha, WI).

Radiofrequency ablations were performed using an internally water-cooled electrode and generator with an impedance-based pulsing algorithm (Covidien Cool-Tip™, Boulder, CO) RF technology using either a single electrode, a cluster electrode, or multiple electrodes in switched mode (Cool-Tip Switching Controller™, Boulder CO). Microwave ablations were performed using a high-powered gas-cooled system with continuous in-phase output to up to three antennas (Certus 140, NeuWave Medical, Inc., Madison, WI).

All patients underwent an immediate post-ablation CT scan (Lightspeed Plus or Lightspeed Xtra, GE Medical, Waukesha, WI) including late arterial and portal venous phases that was performed with 80-150 mL of intravenous contrast if there were no contraindications. The ablation endpoint was identification of complete coverage of the tumor and a 5 mm circumferential margin. Achieving the ablation endpoint was defined as technical success [13, 14]. Patients were monitored for post-procedural complications during an overnight hospital admission and by nursing telephone contact 5-7 days post-procedure where any adverse events were documented in the medical record. Complications were classified according to the SIR classification of complications by outcome [15].

Patient Follow-up

Patients were evaluated every 3 months for 1 year and then at least every 6 months thereafter with either contrast-enhanced CT or contrast-enhanced MR imaging to evaluate for local

tumor progression (LTP) at the ablation site and for signs of delayed complications. LTP was determined according to standard reporting parameters [13]. Follow-up imaging was interpreted by subspecialty trained abdominal imagers. For the 18 patients (32.7%) who underwent RF and 20 patients (20.2%) who underwent MW who went on to liver transplantation, the latest available study prior to transplant was considered the final post-ablation follow-up. Date of death was determined by medical record review and search of public records for those lost to follow-up.

Statistical Analysis

Time-to-event outcomes were computed in months, based on differences between each event (LTP = local tumor progression, OS = overall survival) and ablation date. Kaplan-Meier actuarial survival estimates were obtained separately for each group and compared with a log-rank test. Since RF ablation had been available for approximately 14 years, whereas MW ablation had only been available for approximately 5 years at our institution, we used log-rank tests truncated at 48 months of follow-up. In patients with multiple ablation sessions, survival was determined from time of initial ablation and LTP was only considered on a per-ablation basis. That is, the two subjects whose LTP was retreated with ablation alone had their LTP count “reset” to zero at the time of their next ablation.

To better assess the differences in risk of experiencing an event (LTP) between groups, a Cox proportional hazard model with event type as a strata and patients as a cluster was fitted in order to obtain hazard ratios (HR) and their 95% confidence intervals (CI). Local tumor progression was obtained on a per tumor basis; all other outcomes were obtained on a per subject basis. Six patients received both kinds of ablations on separate tumors during separate sessions and are thus included in both the RF and MW ablation datasets, and considered as independent. Similarly, patients receiving the same kind of ablation (RF or MW) on multiple occasions were also considered as independent. There were 16 patients who underwent multiple RF or MW ablations, all for new tumor distant from the initially treated tumor. As an additional comparison of LTP between groups, Fine and Gray competing risk survival estimates were calculated with transplant and death as the other competing risk events in order to obtain HR and their 95% CI.

$P < 0.05$ (two sided) was the criterion for statistical significance. There was no adjustment of p values for multiple testing. All statistical graphics and computations were obtained in R 3.1.0 (R Core Team 2014).

Results

Patient population

The study population consisted of 154 patients (55 RF, 99 MW) with 205 tumors targeted for treatment with either RF ($n=69$) or MW ($n=136$) between 12/2001 and 3/2014. The population was predominantly male (121 vs. 33 male to female) with a mean age of 62 years. Patients receiving MW ablation had a slightly higher mean MELD score than those receiving RF ablation (9.6 vs. 8.8), but this difference was not statistically significant ($p=0.39$). Patient data is summarized in Table 1.

Tumors and follow-up

Mean tumor size was 2.2 cm in the RF group (range 0.6-4.5) and 2.1 cm in the MW group (0.5-4.2). When controlling for multiple tumors within a patient this was not statistically significant ($p=0.09$). The majority of tumors in both groups were less than 3 cm (76.5% in RF group and 86.8% of MW group). The follow up period was longer for patients receiving RF ablation due to the earlier introduction of RF ablation into our practice (median 31 months of follow-up versus 24 months).

Local Tumor Control

All ablations achieved technical success at the completion of the ablation procedure. The Cox hazard ratio for local tumor progression after RF ablation was 2.17 (95% CI 1.04-4.50, $p=0.04$), while the Fine and Gray hazard ratio was 2.07 (95% CI 0.95-4.26, $p=0.07$; Figures 1-2). The Fine and Gray hazard ratio of 6.00 for progression of tumors greater than 3 cm treated with RF ablation was notable, though not statistically significant ($p=0.08$). Progression data is listed in Table 2.

Overall survival

There was decreased survival for patients treated with RF as compared with MW ablation with hazard ratio of 1.59 (95% CI 0.91-2.77, $p=0.090$) (Figure 3).

Complications

There were no intraprocedural or immediate post-procedure deaths. There were few major (grade C) complications in either group. In the RF cohort, there were two complications (2/55, 3.6%) requiring specific interventions: a single small hemothorax requiring thoracentesis, and a single intraperitoneal hemorrhage requiring transfusions and urgent exploratory laparotomy at the direction of the referring surgeon. The patient who underwent thoracentesis recovered without sequela, while the patient with intraperitoneal hemorrhage is further discussed below. In the MW patients there was a single intra-procedural pneumothorax (1/99, 1.0%, $p=0.27$ RF vs. MW) requiring aspiration and a pleural blood patch. A chest tube was not required in this case and the patient was discharged per standard protocol without long-term sequela. There was 1 death within 30 days in each group. The patient in the RF cohort had intraperitoneal hemorrhage following the procedure which required transfusion and ultimately exploratory laparotomy to control. The recovery from the procedure and laparotomy was complicated by delayed transfusion reaction and subsequent hepatic failure leading to death approximately 30 days following the procedure. A patient in the MW cohort developed pneumonia for which they refused treatment resulting in sepsis and death approximately 1 week post-procedure.

Discussion

In this study, hepatocellular carcinoma patients with closely matched tumor sizes had an increased risk of local tumor progression when treated with RF compared with MW. This has important implications for interventional oncologists when choosing a modality for treating patients who are referred for and deemed appropriate to undergo thermal ablation. In

addition, there was improved overall survival in the MW cohort, although patient populations were heterogeneous.

Published rates of local tumor progression for both RF and MW vary widely by institution, tumor size, type of device, experience of the operators, and other variables. However, an interesting finding which supports the generalizable nature of our results is that the LTP rate in each separate limb of this study appears to track closely with the largest published experience for both RF and MW. A recent study by Kim, et al [16] of RF for the treatment of 1502 early stage HCC with a mean size of 2.2 cm and mean follow-up of 33 months (virtually identical to the 2.4 cm and 31 month median follow-up in this study) demonstrated a local tumor progression rate of 19.4%—very similar to the rate of 17.4% found in this study. The largest study to date of MW for treatment of HCC [17] included 1363 tumors with a mean size of 2.9 cm and mean follow-up of 17.3 months (vs. 2.2 cm and 24 month median follow-up in this study), and demonstrated an overall local tumor progression rate of 5.9%, slightly better than the 8.8% rate in this study, possibly related to shorter follow-up. However, neither of these single-modality studies had a comparison arm with any other ablation technology.

There have been only a small number of studies comparing RF and MW for the treatment of HCC, but no large randomized, controlled trials. Previous studies described the use of MW ablation equipment that is not available in Europe or the United States. Patients accrued prior to 2007 were likely treated by early devices that were associated with low power, short treatment times and relatively small ablation zones compared to more recent devices, and therefore may not be exactly applicable to the current suite of MW tools [9, 10, 18, 19]. There has been only one small randomized study comparing RF and MW. That study was limited to small HCC with very short follow-up (42 patients total, 5.1 months follow-up) and used MW technology only available in China. The results demonstrated larger MW ablation zones than RF, but no difference in local tumor progression rates. Sample size and follow-up interval was too short to make conclusions about survival [11]. In contrast, our study utilized a higher-power, 3rd-generation, MW ablation system and a multiple-applicator approach for RF and MW ablations when necessary [20]. The current study also is the largest series to date comparing systems available in North American and Europe.

There are several potential reasons for the lower local tumor progression detected with MW compared to RF in our study. Prior authors have demonstrated that modern MW ablation devices are able to heat continuously at a faster rate to generate greater temperatures than RF ablation systems [21]. Increased heating rates and internal temperatures overcome vascular perfusion more effectively. Water vaporization also leads to contraction of the treated tissue resulting in a larger effective margin than may be evident from imaging alone [22]. In addition, multiple antenna systems more efficiently distribute the applied energy throughout the tumor and margins [23-25]. These properties of MW ablation are particularly important for tumors > 3 cm, and for tumors adjacent to large blood vessels [26, 27].

Concerns about increased complications due to higher power MW systems creating larger ablation zones appear unfounded based on the results of this and prior studies [28, 29]. There were very few major complications overall, with no difference between groups. This

finding is concordant with a large multicenter study of complications after MW ablation in which the authors found that complications were not increased with MW ablation despite large ablation zones--perhaps due to "lessons learned" from the earlier RF era [28]. In addition, the use of intraprocedural monitoring and adjunctive strategies such as hydrodissection may allow for more aggressive ablations and have become commonly applied [30].

As with any retrospective study there are limitations related to heterogeneity of patient populations between the two groups. In this study, we utilized both the conventional Cox proportional hazard model that censors transplant and death, and the competing risk analysis of Fine and Gray, in which transplant and death are categorized separately. Slight differences between the outcomes of these analyses are likely due to factors such as underlying liver disease and the associated length of time to transplant or death.

The most important limitation to this study is that it is not a prospective randomized controlled trial (RCT) and due to the retrospective nature lacks a power analysis. However, a well-recruited RCT comparing RF and MW ablation is unlikely due to logistical constraints, thus a single center retrospective case series with comparable patient populations may be the most realistic option. Another limitation to the present study is the fact that most RF ablation patients were accrued prior to MW patients. This could bias the results as the operators could have benefited from the earlier experience with RF ablation. The longer follow-up after RF ablation may also have contributed to some bias. While both of these limitations are important, the operators for the RF arm of the study had prior experience with cryoablation and RF ablation, while the physicians in the MW arm included three new faculty members who had no prior ablation experience outside of residency/fellowship training. Both Kaplan-Meier and Fine and Gray analyses controlled for differences in follow-up intervals. The study is also limited in that only major complications were recorded and a full analysis of safety, particularly minor complications, could not be performed.

In summary, the results of this single center study demonstrate high primary efficacy and a durable response for both RF and MW ablation of hepatocellular carcinoma, with lower rates of local tumor progression noted after MW ablation. Major complications were low with both techniques. These results support consideration for the addition of MW ablation to the guidelines for treatment of very early and early hepatocellular carcinoma.

Acknowledgments

Scott Hetzel, MS- for statistical support

Financial Support: NIH Grant R01 CA142737

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Fig 1. Kaplan-Meier curves of Local Tumor Progression (LTP) for microwave ablation (MW, red) and radiofrequency ablation (RF, blue) demonstrating fraction of tumors free of LTP by time in months.

Fig 2.
Fine and Gray curves of Local Tumor Progression (LTP), transplant, and death for MW and RF treated tumors demonstrating fraction of tumors free of event by time in months.

Fig 3. Kaplan-Meier curves of Overall Survival (Death) for microwave ablation (MW, red) and radiofrequency ablation (RF, blue) demonstrating fraction of patients alive by time in months.

Table 1
Patient demographics and tumor size

	Radiofrequency (RF)	Microwave (MW)	p-value
Total patients	55	99	
Total tumors treated	69	136	
M/F	40/15	81/18	0.22
Mean age	62 y (23-88)	61 y (44-82)	0.24
MELD	8.8	9.6	0.39
BCLC Stage 0	6	16	0.37
BCLC Stage A	49	83	
Etiology of liver disease Hepatitis C	28	56	0.01
Hepatitis B	4	4	
Alcohol-induced	9	15	
Non-alcoholic steatohepatitis	2	3	
Hepatitis C and alcohol-induced	4	9	
Unknown or Other	8	12	
Mean tumor size	2.4 cm (95% CI 2.2-2.6)	2.2 cm (95% CI 2.0-2.3)	0.09
< 3 cm	53/69 (76.8%)	118/136 (86.8%)	
≥ 3 cm	16/69 (23.2%)	18/136 (13.2%)	0.08

Table 2

Follow up including local tumor progression (LTP), distant tumor progression (DTP), and complications.

	Radiofrequency (RF)	Microwave (MW)	Fine and Gray HR (95% CI, p-value)	Cox HR (95% CI, p-value)
Median follow up	31 mo. (1-148)	24 mo. (1-57)	-	
Local Tumor Progression	12/69 (17.4%)	12/136 (8.8%)	2.07 (0.95-4.26, p=0.07)	2.17 (1.04-4.50, p=0.04)
LTP for tumors < 3 cm	7/53 (13.2%)	11/118 (9.3%)	1.63 (0.69-3.85, p= 0.27)	1.82 (0.78-4.26, p= 0.11)
LTP for tumors ≥ 3 cm	5/16 (31.3%)	1/18 (5.6 %)	6.00 (0.80-44.9, p=0.08)	6.29 (0.68-58.0, p= 0.17)