

Comparison of Ablation Volume Between Emprint[®] and Mimapro[®] Systems for Hepatocellular Carcinoma –A Preliminary Study

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Background: Microwave ablation (MWA) is a standard percutaneous local therapy for hepatocellular carcinoma (HCC). Next-generation MWA is reported to create a more spherical ablation zone than radiofrequency ablation (RFA). We compared the ablation zone and aspect ratio of two 2.45 GHz MWA ablation probes; Emprint[®] (13G) and Mimapro[®] (17G). We compared the ablation zone to the applied energy after MWA in patients with hepatocellular carcinoma (HCC). Furthermore, we investigated local recurrence.

Materials and Methods: We included 20 patients with HCC, with an average tumour diameter of 33.2 ± 12.2 mm, who underwent MWA using Emprint[®], and 9 patients who underwent MWA using Mimapro[®] with an average tumour diameter of 31.1 ± 10.5 mm. Both groups underwent the same ablation protocol using the same power settings. The images obtained after MWA showed the treatment ablation zone and aspect ratio, which were measured and compared using three-dimensional image analysis software.

Results: The aspect ratios in the Emprint[®] and Mimapro[®] groups were 0.786 ± 0.105 and 0.808 ± 0.122 , respectively, with no significant difference ($p = 0.604$). The ablation time was significantly shorter in the Mimapro[®] group than in the Emprint[®] group, and there was no significant difference in the frequency of popping or the ablation volume. There were no significant differences in local recurrence between the two groups.

Conclusion: There was no significant difference in the aspect ratios of the ablation diameter, and the ablation zone was almost spherical in both cases. Mimapro[®] at 17G was less invasive than Emprint[®] at 13G.

Keywords: hepatocellular carcinoma, microwave ablation, ablation zone

Introduction

Hepatocellular carcinoma (HCC) was the sixth most commonly diagnosed cancer and the third leading cause of cancer-related deaths worldwide in 2020.¹ The treatment policy in Japan is based on the consensus-based Clinical Practice Guidelines for HCC management proposed by the Japan Society of Hepatology.² Radiofrequency ablation (RFA) or surgical resection is recommended for patients with 1 to 3 tumours of ≤ 3 cm.² Microwave ablation (MWA) is a recent development in the field of tumour ablation that uses electromagnetic waves to establish a microwave near-field with direct tissue heating.

MWA is minimally invasive compared with conventional surgery and is easy to use for repeated treatment, achieving a high complete ablation rate. MWA is a good alternative treatment option for patients who are unwilling or unable to undergo surgery. The major advantages of ultrasound-guided MWA include real-time monitoring, accurate guidance and targeting of the tumour, minimal tissue trauma and damage, higher safety, and the ability to reach a larger target area than RFA.^{3,4}

However, early versions of MWA suffered from ablation zone predictability issues. New generations of MWA, including Emprint[®] (a 2450 MHz 100 W generator model) (Emprint[®] ablation system, Covidien/Medtronic, Minneapolis, MN, USA) and

Mimapro[®] (MTC-3C microwave generator and a 20-cm-long, 17G cooled-shaft electrode probe) (Mima-pro Scientific Inc. Nantong, China), are commonly used in Japan for MWA in patients with HCC and have recently helped address these issues.^{5,6}

Owing to the high risk of HCC recurrence, it is essential to ensure that the ablation zone is sufficient. In particular, it is important to be able to cauterise spherically. However, it is unclear whether there is a difference in the performance between the Emprint[®] and Mimapro[®] systems.

In this study, we compared the Emprint[®] and Mimapro[®] MWA systems regarding the ablation zone and local recurrence in patients with HCC.

Materials and Methods

Patient Population

In this study, we analysed patients who underwent percutaneous ultrasonography-guided MWA for HCC at our hospital from January 2017 to June 2022.

HCC was diagnosed using dynamic computed tomography (CT) or dynamic magnetic resonance imaging, or both, in accordance with the consensus-based Clinical Practice Guidelines for HCC.

All patient's conditions were discussed at a multidisciplinary tumour board meeting in which the decision to use US-guided MWA was made. Patients were included in this study if they (1) Were treated for HCC and (2) Were treated with either an Emprint[®] device or a Mimapro[®] device. The decision regarding which device to use depended on the operator.

Patients were excluded if (1) They were previously treated for MWA site recurrence, (2) There was an inability to separate the ablation zones of multiple tumours located close to each other, (3) They did not have contrast-enhanced CT (CE-CT) scans, (4) there was an unclear demarcation of the tumour on CE-CT, (5) There was missing energy data, and (6) They underwent simultaneous multi-probe ablations.

First, we assessed the electrode ablation zones of the Emprint[®] and Mimapro[®] systems. Next, we investigated local recurrence in patients who underwent MWA using the Emprint[®] MWA system (Emprint[®] group) and those who underwent MWA using the Mimapro[®] MWA system (Mimapro[®] group). After MWA treatment, patients were followed up every 6–8 weeks until June 2022.

MWA Procedure

MWA was performed using the Emprint[®] or Mimapro[®] MWA system with an antenna. All MWA sessions were conducted using a percutaneous approach under ultrasound guidance (LOGIQ E9 XD clear 2.0; GE Healthcare, Chicago, IL, USA). During MWA, patients underwent intravenous conscious sedation, and their vital signs were continuously monitored.

The output energy during MWA was gradually increased from 45 W for 60 sec to 60 W for 60 sec, 75 W for 60 sec, and then 100 W until the end of the treatment. Treatments were terminated when the ablation margin was included in the hyperechoic area on the ultrasound screen.

After ablation of the tumour, the antenna was slowly withdrawn (1 cm at a time), and MWA emission was continued at a power of 20 W until the antenna was pulled to just under the skin entrance site. This method allowed needle-tract cauterisation to prevent tumour seeding and minimise bleeding after ablation.

Follow-Up

The follow-up period was calculated starting from the beginning of MWA in all patients. Patients underwent CE-CT examinations 1 month after MWA, every 3 months in the first year, and every 6 months thereafter.

Local tumour progression was defined as the appearance of a tumour at the edge of the ablation zone.⁷

Furthermore, we determined the biggest and smallest diameters of the ablated zone.

Following a medical image analysis procedure (SYNAPSE VINCENT ver3.0.), a three-dimensional reconstruction of tumour volume was performed using volumetry.

Complications

Treatment complications were described according to the reporting standards of the Society of Interventional Radiology (SIR).⁸

Major complications were defined as events that led to substantial morbidity and disability that increased the level of care, resulted in hospital admission, or substantially lengthened the hospital stay (SIR classifications C–E). This included any case in which a blood transfusion or interventional drainage procedure was required. All other complications were considered minor.

Ethical Considerations

This study was approved by the Institutional Review Board of Saiseikai Niigata Hospital (No. E18-18) and conducted in accordance with the principles of the Declaration of Helsinki (as revised in 2013). Before participating in this study, written informed consent was provided by all patients.

Statistical Analyses

All statistical analyses were performed using EZR (version 1.54; Saitama Medical Center, Jichi Medical University), a graphical user interface for R (version 4.0.3; R Foundation for Statistical Computing, <https://www.r-project.org>, accessed on 10 January 2022). EZR is a modified version of R commander version 2.7–1 that includes statistical functions frequently used in biostatistics.⁹ Results were expressed as medians and interquartile ranges. Differences between the groups (continuous variables) were analysed using the Mann–Whitney *U*-test, whereas categorical data were analysed using Fisher's exact test. A two-tailed $p < 0.05$ was considered statistically significant.

Results

Patient Characteristics

Patient characteristics are shown in Table 1. The study population consisted of 21 males and 8 females. Age, aetiology, tumour diameter, and tumour location were not significantly different between the Emprint[®] and Mimapro[®] groups.

Comparison of Ablation Zone

The aspect ratios were 0.786 ± 0.105 and 0.808 ± 0.122 in the Emprint[®] and Mimapro[®] groups, respectively, with no significant difference ($p = 0.604$) (Table 2).

There was no significant difference in the ablation volume between the two groups ($p = 0.186$) (Table 2).

Popping Phenomena

There was no significant difference in the frequency of popping between the groups ($p = 0.396$) (Table 2).

Table 1 Clinicopathological Characteristics

Categories	Emprint [®] (n= 20)	Mimapro [®] (n= 9)	p-value
Age (years)	74.2 ± 6.8	69.1 ± 8.6	0.131
Sex (Male: Female)	15:5	6:3	0.642
Aetiology (HBV/HCV/Alc/NASH)	2/9/7/3	3/3/2/1	0.458
Tumour diameter (mm)	33.2 ± 12.2	31.1 ± 10.5	0.727
Location (S1/S2/S3/S4/S5/S6/S7/S8)	0/2/2/2/4/4/2/4	0/1/1/1/1/1/2/2	0.970

Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; Alc, Alcoholic; NASH, non-alcoholic steatohepatitis; S, segment.

Table 2 Ablation Outcome Parameters by Device

Categories	Emprint® (n= 20)	Mimapro® (n= 9)	p-value
Ablation time (min)	10.9 ± 3.0	6.8 ± 3.0	0.008*
Ablation volume (cm ³)	31.4 ± 17.7	28.2 ± 31.3	0.186
Ablation aspect ratio	0.786 ± 0.105	0.808 ± 0.122	0.604
Popping occurrence rate	5/20	4/9	0.396

Note: *Statistically significant.

Recurrence-Free Survival

During the follow-up period, local tumour recurrence occurred in 6 patients (20.6%) and did not occur in 23 patients (79.4%).

In the Emprint® group, local tumour recurrence occurred in 4 patients (20.0%). In contrast, local tumour recurrence occurred in 2 patients (22.2%) in the Mimapro® group. Recurrence-free survival was not significantly different between the groups. No significant difference was observed between the groups' local recurrence rates (Figure 1).

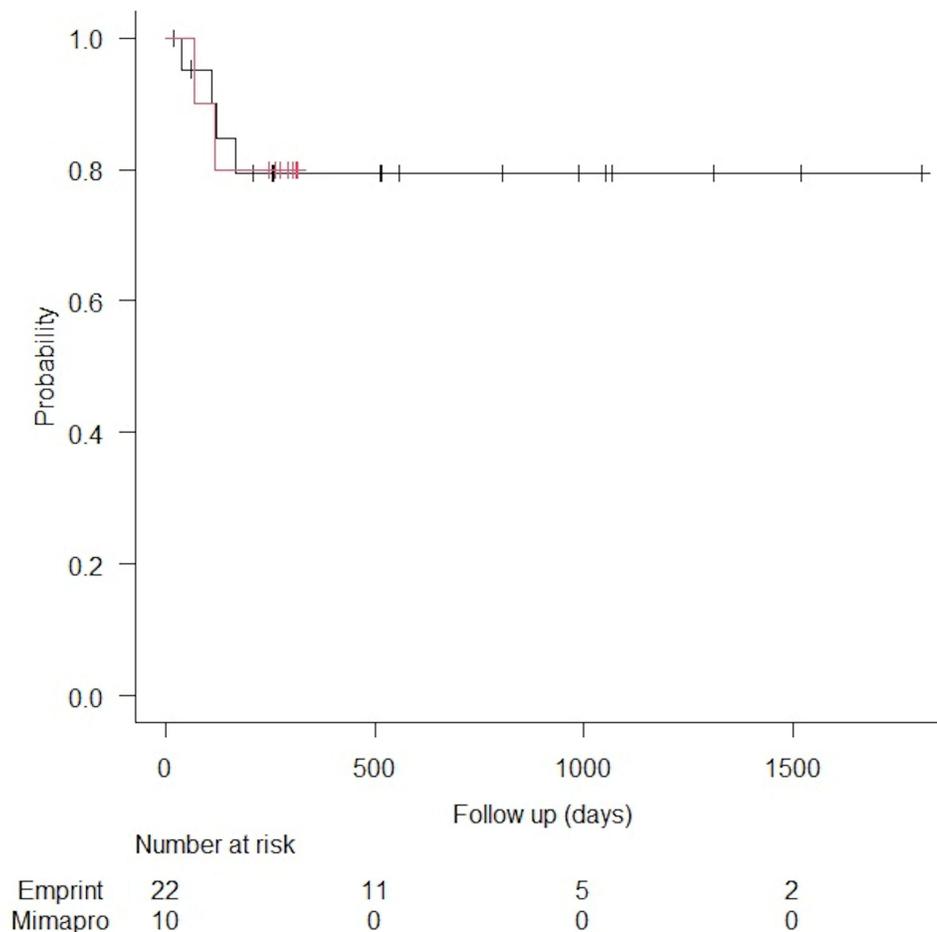


Figure 1 Kaplan–Meier curves depicting local tumour control over time based on microwave ablation devices. No significant difference was observed in the local recurrence rates between the groups.

Adverse Events

Ablation-related complications, including pain, fever, and fatigue, were observed in 50.0% (10/22) of patients in the Emprint[®] group and 33.3% (3/9) of patients in the Mimapro[®] group ($p = 0.403$); these symptoms were alleviated after symptom-mitigating treatment. No tumour seeding was observed along the MWA needle tracts. No ablation-related deaths occurred in our study.

Discussion

Treatment for hepatocellular carcinoma is expected to treat various tumour stages due to advances in systemic drug therapy, including immune checkpoint inhibitors^{10–13} and the position of MWA is also being discussed. However, during the course of systemic chemotherapy, ablation is expected as, well as resection as a conversion treatment.

In this context, more effective targeting of MWA, which has a higher possibility of local control than RFA among ablation, is important.

In this study, we evaluated patients with HCC who underwent MWA at our hospital. The Emprint[®] MWA and Mimapro[®] MWA systems were used. Patients in the Emprint[®] and Mimapro[®] groups were compared.

MWA is a thermal ablation modality based on increasing the temperature above the normal physiological threshold to kill cancer cells with minimal damage to surrounding tissues.^{14–19}

The aspect ratios of both the Emprint[®] and Mimapro[®] groups were similar to the clinical results of experiments with excised bovine livers, and nearly spherical ablation volumes were obtained. However, the Emprint[®] antenna probe is only 13G, whereas Mimapro[®] has three types: 14G, 17G, and 18G. In particular, 17G Mimapro[®] has approximately the same thickness as RFA and can cauterise more spherically than RFA. Next-generation MWA is less susceptible to heat sinks (blood flow in blood vessels) and may lead to a wider area of ablation than that expected from RFA.

While MWA was developed to overcome many of the issues of RFA, the initial systems suffered from the predictability of ablation zone issues.^{5,6,20–24}

Emprint[®] was developed as a new next-generation MWA system using thermosphere technology. MWA can create predictable spherical zones of ablation by incorporating thermal, field, and wavelength control technologies into the system.

Human data concerning MWA have shown good clinical outcomes. More data is necessary on the accuracy of the manufacturer-provided ablation zone model for predicting in vivo human results.

In this study, we compared Emprint[®] MWA (13G) and Mimapro[®] MWA (17G) as next-generation MWAs.

The aspect ratio was not significantly different between the Emprint[®] and Mimapro[®] groups; however, the Mimapro[®] gauge was thinner than the Emprint[®] gauge.

The ablation time was significantly shorter in the Mimapro[®] group, and there was no significant difference in the frequency of popping or the ablation volume. Furthermore, there were no significant differences in local recurrence between the groups.

The study's limitations included, firstly, inevitable selection biases in the study population owing to its retrospective nature, single-centre design, and small sample size. Secondly, the inability to assess therapeutic efficacy; thus, there is an urgent need for controlled clinical trials to compare this therapeutic modality with surgical resection or other percutaneous local treatments. Thirdly, a study on conversion after systemic chemotherapy has not been conducted. Fourthly, not only the systemic chemotherapy but also the therapeutic effect when used in combination with transarterial chemoembolization (TACE) has not been investigated at this time. Finally, the follow-up period was inadequate.

In conclusion, there were no significant differences in the ablation diameter and volume aspect ratios between the two groups, and the ablation zone was almost spherical in both cases.

Hence, irrespective of the 17G Mimapro[®] being thinner than the 13G Emprint[®], the same ablation volume was obtained. MWA using Mimapro[®] or Emprint[®] is expected to be useful as a minimally invasive technique in the future; nevertheless, long-term studies should be conducted.

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Author Contributions

All authors made a significant contribution to the work, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; they took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; agreed to submit to the current journal; and agreed to be accountable for all aspects of the work.

Disclosure

The authors have no conflicts of interest to declare in relation to this study.

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