

Clinical paper

Medtronic provides the following synopsis of a clinical publication involving Emprint™ ablation system with Thermosphere™ technology.

TITLE Multi-institutional analysis of outcomes for Thermosphere™ microwave ablation treatment of colorectal liver metastases: the SMAC study

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BACKGROUND AND AIMS

Oncological guidelines endorse the use of locoregional treatments such as image-guided ablation techniques in the management of colorectal liver metastases (CLM). Radiofrequency ablation (RFA) is the most widely investigated image-guided ablation technique, but microwave ablation (MWA) has gained popularity among interventional radiologists. Compared to RFA, MWA may produce larger ablation zones over a shorter period of time. The Thermosphere™ technology was developed to overcome the issue of unpredictability associated with MWA and produce reliable spherical ablation zones.¹⁻³ The aim of this study was to investigate the safety and effectiveness of MWA with Thermosphere™ technology (T-MWA) of CLM and factors affecting local tumor progression-free survival (LTPFS).

STUDY DESIGN

This multi-institutional retrospective study in Italy included 132 patients (86 males and mean age 65.1 years) with 213 CLM (median size at ablation 1.4 cm). All patients underwent T-MWA treatment between January 2015 to September 2019. Chemotherapy before ablation (CBA) was administered in 70 patients (112 out of 204 CLM). A total of 150 ablation procedures were performed by experienced interventional radiologists using the 2450-MHz/100-W Emprint™ microwave ablation system with Thermosphere™ technology. Mean time from detection to ablation was 160.6 days +/- 158.8 days. Technical success was assessed immediately after the procedure, by means of contrast-enhanced CT or ultrasound. Median follow-up period was 19 months (range 6-55 months).



The following terminology and reporting criteria for tumor ablation were used to determine ablation endpoints:

- Technique efficacy was defined as absence of pathological enhancement at the ablation zone (residual tumor) on imaging (CT or MRI) at 1 month after ablation.
- Local tumor progression (LTP) was defined as appearance of foci of vital disease at the edge of the ablation zone at any of the follow-up time points.
- Intra-segment progression was defined as appearance of metastases within the same segment as the ablation area, at a minimum distance of > 1cm from the ablated index lesion.
- Intrahepatic progression was defined as appearance of metastases in any liver site outside of the ablation area.
- Complications were classified according to SIR classification.

KEY POINTS

- Primary efficacy of 95.7% (204/213 nodules) was achieved.
- LTP was observed in 58/204 CLM (28.4%) during the follow-up period. Six-, twelve-, and eighteen-month LTPFS were 88.2%, 75.8%, and 69.9%, respectively.
- Intrahepatic progression was observed in 79/132 patients (59.8%) during the follow-up period. Six, twelve, and eighteen months, intrahepatic progression-free survival rates were 65.8%, 56%, and 36.8%, respectively.
- Of the 150 procedures, 6 (4%) complications were observed with 3 being classified as major (pleural effusions managed with drainage placement). No related deaths or biliary complications were noted.
- Twelve- and twenty-four-month overall survival were 98.3% and 89.9%, respectively.
- Multivariate analysis found that lesion size at ablation, minimum margin size, the number of lesions, and intra-segment progression were statistically significant factors affecting LTPFS.
- CBA modified the kinetic growth of the lesion. At time of diagnosis, lesion size was slightly higher in CLM receiving CBA, whereas at time of ablation, size was higher in chemo-naïve CLM. Ablation margins in the CBA group were significantly smaller than those in the chemo-naïve group. CBA was found not to significantly impact LTPFS.

CONCLUSION

T-MWA is a safe and effective treatment for CLM with no biliary complications reported in more than 200 ablated lesions. LTPFS is affected by lesion size at ablation, number of lesions, minimal ablation margin, and intra-segment progression. CBA modifies kinetics growth of the lesions but deteriorates ablation margins and does not significantly impact local tumor progression-free survival.

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****THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION****