

Article Summary: Effect of Ablation Confirmation Software on Microwave Ablation Efficacy and Outcomes. *Lescher J. et al. Presented at CIRSE 2020 Annual Conference*

Objective: The NEUWAVE™ Ablation Confirmation (AC) software is a post-processing software tool that facilitates evaluation of antenna placement and a quantitative assessment of margins during percutaneous microwave ablation (MWA). The purpose of this study was to assess technical performance and procedural outcomes for MWA of liver tumors in which the AC software tool was used.

Study Design: This was a single-center retrospective study that was approved by the Institutional Review Board. All ablations were performed between November 2016 and June 2018. MWA procedures were performed using the NEUWAVE System with Ablation Confirmation software for ablating liver tumors. AC was used for antenna position confirmation, repositioning, and/or ablation zone confirmation. Preprocedural, intraprocedural and follow up imaging was reviewed for tumor size, technical success, local tumor progression (LTP), and follow-up time.

Key Findings:

- Average (\pm standard deviation) tumor diameter was 2.2 cm \pm 1.0 cm for primary liver tumors and 1.3 cm \pm 0.9 cm for secondary liver tumors.
- Technical success was 100%.
- The median follow up time was 15.8 months for primary tumors and 22.5 months for secondary tumors.
- Probe position checks on AC were associated with repositioning of the probes in 23% of primary liver tumors and 20% of secondary liver tumors.
- The study found LTP rates as summarized in the table below:

	Primary Liver Tumor	Secondary Liver Tumor
Local Tumor Progression (LTP) Rate	4.5%	4.0%
Number of Patients	2 / 44	1 / 25

Conclusion:
MWA of liver tumors using the NEUWAVE System and AC software exhibited 100% technical success, and improved procedural outcomes which compare favorably with those reported in the literature.

Study Summary: 3D Assessment of Ablation Zone Margins with NeuWave Ablation Confirmation (AC) Software: A Feasibility Study.

Kamarinou NV, et al. Abstract presented at the Society of Interventional Oncology Annual Meeting, 31 January - 3, February 2020, New Orleans, Louisiana, USA

Objective: The accurate measurement of the minimal ablation margin (MM) is essential for improving ablation outcomes. A 10 mm ablation zone (AZ) margin has been shown to provide the best local tumor control, whereas a MM under 5mm is highly predictive of local tumor progression (LTP). The objective of this study was to determine the feasibility of measuring AZ margins in 3D with the NeuWave Ablation Confirmation (AC) software and to evaluate its role as an intraoperative real-time assessment tool during metastatic liver tumor ablation.

Study Design: This was a single center retrospective study. 23 patients with 29 lesions treated by microwave ablation (MWA) between October 2014 and September 2017 were reviewed. In all cases, the MM, calculated as the smallest distance between the tumor edge and the ablation margin, was measured in 3D and 2D. AC software was used to assess the MMs in 3D, by drawing the target tumor and then AZ in a pre and a post-ablation CT image slice and applying preset tissue contraction algorithms. A conventional 2D method was also employed to calculate the MM by comparing the distances of the index tumor (pre-ablation imaging) and the AZ (post-ablation imaging) from intrahepatic landmarks on CT images. A blinded faculty interventional radiologist examined the 3D MM measurements and provided feedback on whether he would recommend additional ablation should he have this information intraoperatively.

Results:

- A 3D assessment of margins was completed in 26/29 (89%) tumors.
- In three cases, the 3D minimal margin could not be evaluated due to errors in image registration attributed to changes in the position of the operating table.
- The 2D method did not detect any MM < 5 mm.
- The 3D assessment identified MM size < 5 mm in 9/26 ablated lesions with LTP noted in 8/9 lesions at 12 months.
- **The sensitivity and specificity of AC software for predicting LTP was 100% (8/8) and 94.4% (17/18), respectively.**
- Additional ablation would have been offered in 3/8 cases if AC software was available on the day of the procedure; tumor location precluded further ablation for the remaining 5 cases.

Conclusion: The NeuWave™ Ablation Confirmation (AC) software can be used to measure ablation zone margins in 3D and can detect minimal ablation margin size under 5 mm with higher sensitivity compared to standard 2D technique. It is a quick and user-friendly method that can be used intraprocedurally as an immediate ablation zone assessment tool to optimize the procedure.

INDICATIONS FOR USE:

The NeuWave™ Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors. The NeuWave™ Microwave Ablation System and Accessories are not indicated for use in cardiac procedures. The system is designed for facility use and should only be used under the orders of a clinician.

Abstract Summary: An Evaluation of Use of Ablation Confirmation Software on Percutaneous Microwave Ablation of Liver Tumors

P. Laeseke, et al. RSNA Abstract. 2017

Objective: Imaging post-processing tools may facilitate accurate probe placement and quantify ablative margins during thermal ablations. The purpose of this study was to quantify the impact of antenna placement and post-procedure margin evaluation utilizing post-processing software during percutaneous microwave ablation of liver tumors.

Design: From October 2015 to January 2017, 33 patients with 43 liver tumors underwent 33 sessions of percutaneous microwave ablation utilizing ultrasound and CT guidance. All procedures were performed by one of five experienced operators using the NEUWAVE™ System with Ablation Confirmation Software. Using CT images acquired pre-procedure, after antenna placement and post-ablation, post-processing software (Ablation Confirmation Software) was used to evaluate antenna placement and determine whether the target tumor and an adequate ablative margin was achieved. The number of times that use of Ablation Confirmation Software led to a change in antenna position or additional ablations was determined. Chi-squared tests were used to analyze whether Ablation Confirmation Software related changes depended on tumor size or number of antennas used. Technical success was also quantified.

Key Findings:

- Technical success was achieved in 100% of tumors in a single session
- The use of Ablation Confirmation Software led to repositioning of the antennas in 18.6% (8/43) of tumors
- The likelihood that Ablation Confirmation Software led to a change in antenna position was significantly higher for larger tumors (> 3 cm, $p=0.03$) and tumors treated with 3 antennas ($p=0.03$)
- Inadequate ablative margins on Ablation Confirmation Software led to additional ablation on 7% (3/43) of tumors
- Mean tumor diameter was 2.5 cm (range 0.7 to 6.0 cm)
- Median follow-up was 5 months (range 0 to 12 months)

Conclusion: Ablation Confirmation software changed how percutaneous microwave ablations of liver tumors were performed in approximately 20% of cases with the greatest impact seen for larger tumors or tumors ablated with multiple antennas.

INDICATIONS FOR USE:

The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors. The Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures. The system is designed for facility use and should only be used under the orders of a clinician.