Percutaneous Microwave Tumor Ablation Is Safe in Patients with Cardiovascular Implantable Electronic Devices: A Single-Institutional Retrospective Review

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ABSTRACT

The risk of electromagnetic interference between microwave (MW) ablation and cardiac implantable electronic devices (CIEDs), ie, pacemakers and defibrillators, has not been fully evaluated. Fourteen MW ablations (kidney, n = 8; liver, n = 5; lung, n = 1) were performed in 13 patients with CIEDs in normal operating mode. Electrocardiography tracings, cardiovascular complications, tumor size, tumor-to-CIED distance, and tumor-to-device lead distance were recorded. Mean tumor size was 2.9 cm, mean tumor-to-CIED distance was 26.4 cm (range, 9–30 cm), and mean tumor-to-lead distance was 12.1 cm (range, 3.5–20 cm). No device-based cardiovascular complications or class C or higher complications per Society of Interventional Radiology criteria were identified. MW ablation appears to be safe in select patients with CIEDs.

ABBREVIATIONS

CIED = cardiac implantable electronic device, ECG = electrocardiography, MW = microwave, RF = radiofrequency

Percutaneous microwave (MW) ablation is an increasingly accepted minimally invasive treatment option for various tumor types in an array of organ systems (1,2). Multiple studies (3,4) have shown MW ablation to be safe with few complications, even in close proximity to the heart. However, in patients with cardiovascular implantable electronic devices (CIEDs), ie, pacemakers and defibrillators, there is concern over potential electromagnetic interference from ablation devices (5–7). For radiofrequency (RF) ablation, these concerns have led the 3 largest cardiac device manufacturers (Medtronic, Boston Scientific, and St. Jude Medical) to recommend deactivating tachyarrhythmia detection and activating asynchronous pacing for pacemaker-dependent patients (8–10).

Theoretically, MW ablation should have less risk because of the rapid absorption of the electromagnetic field by tissue surrounding the antenna and the lack of electrical current flow in tissue (11). Despite the theoretical advantages of high-frequency MW devices in patients with CIEDs, clinical safety data are limited. A previous study (12) demonstrated no CIED-related complications during thermal ablations. However, the data are limited given the small number of MW procedures included and the fact that, before the procedure, the CIEDs were changed to automatic pacing and defibrillator modes were turned off if present (12). Therefore, in the present study, ablations were performed at a single institution without CIED inactivation or alterations from normal functioning

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mode. The purpose of this retrospective study was to evaluate the safety of MW ablation with a single 2.45-GHz system in a cohort of patients with CIEDs undergoing treatment of liver, kidney, or lung tumors without device inactivation or alterations from normal functioning mode.

MATERIALS AND METHODS

Patient Inclusion

This study was approved by the institutional review board and complied with the Health and Insurance Portability and Accountability Act. All patients with a CIED who underwent MW ablation at a single institution were identified through a retrospective review of an ablation database from 2011 through January 2018. A total of 13 patients were identified who had undergone 14 MW ablation procedures. One patient underwent ablation of 2 liver tumors in separate procedures. A review of anesthesia records, including continuous electrocardiography (ECG) tracings, and progress notes were completed for all procedures to identify any changes in ECG activity, cardiovascular status, or device complications during or immediately after the procedure.

Patient Characteristics

The patients included 8 men and 5 women with a mean age of 72 years (range, 39–86 y). The indications for the CIEDs included heart failure in 6 patients, atrial or ventricular arrhythmias in 4 patients, and complete heart block in 3 patients. The CIED device types included 7 pacemakers, which included 4 from Medtronic (Dublin, Ireland), 1 from Boston Scientific (Marlborough, Massachusetts), and 2 from St. Jude Medical (St. Paul, Minnesota), as well as 6 combination pacemaker/implantable cardioverter-defibrillators, with 3 from Medtronic, 2 from Boston Scientific, and 1 from St. Jude Medical (Table 1).

Table 1. Patient Characteristics

Characteristic	Value
Patient sex	
Male	8
Female	5
Patient age (y)	
Mean	72
Range	39–86
Indication for implanted cardiac device	
Heart failure	6
Atrial or ventricular arrhythmia	4
Heart block	3
Implanted cardiac device type	
Pacemaker	7
Pacemaker/ICD	6
Implanted cardiac device manufacturer/type	
Medtronic	7
Adapta	1
Advisa	1
Consulta	1
Evera	1
Virtuoso	1
Unspecified	2
Boston Scientific	4
Incepta	1
Confient	1
Essentio	1
St. Jude Medical	3
Accent	1
Fortify Assura	1
Zephyr	1

ICD = implantable cardioverter-defibrillator.

Imaging Review

Contrast-enhanced computed tomography (CT) or magnetic resonance images obtained before the procedure were reviewed for measurements of tumor size. The immediate postprocedural contrast-enhanced CT scan was used to measure the ablation zone and the minimum distance from the closest MW antenna tip to the implanted cardiac device and leads. All measurements were made in consensus with a radiology trainee and attending radiologist with 9 years of experience. Tumor size and ablation zone size were defined as the single longest dimension measured in axial, sagittal, or coronal reconstructions.

MW Ablation Technique

All 14 percutaneous MW ablation procedures were performed under general anesthesia with continuous ECG monitoring. In addition, all implanted cardiac devices remained in normal operating mode during the procedures without any programming or other mitigation strategies. The MW ablation system consisted of a 17-gauge gas-cooled antenna and 2.45-GHz generator with peak output of 140 W (Certus 140; Ethicon, Madison, Wisconsin). Placement of the MW antenna was completed under ultrasound (US; Vivid E9; GE Healthcare, Waukesha, Wisconsin) or CT fluoroscopy (Optima CT 660; GE Healthcare) guidance, with noncontrast CT performed to confirm needle positioning before ablation. During the 13 intraabdominal procedures, real-time US monitoring was used to determine the adequacy of tumor and margin coverage by the ablation zone. The single lung MW ablation was monitored with intermittent CT fluoroscopy for evaluation of adequate coverage. All but 1 ablation were completed at maximum power (65 W, 95 W, or 140 W) for the given type and number of antennas. The 1 outlying procedure was completed for 2 minutes at maximum power (65 W) followed by 2 minutes of treatment at 45 W. The average ablation treatment time was 6.6 minutes (range, 4–12 min).

All procedures were performed by 1 of 6 board-certified radiologists with an average of 11 years of experience in tumor ablation (range, 5–20 y). The decisions regarding number of MW antennas, instillation of intraperitoneal fluid

(hydrodissection), output power, and duration of treatment were all at the discretion of the performing radiologist. A contrast-enhanced CT scan of the treated region was obtained immediately following the procedure to ensure coverage of the tumor and to evaluate for complications. All patients were admitted for overnight observation, which is standard practice at the study institution and occurs irrespective of the presence of a CIED.

Electronic Medical Record Review

The electronic medical records of each patient were reviewed (Epic; Epic Systems, Verona, Wisconsin). Continuous ECG tracing recording during the procedure and in the postanesthesia care unit were reviewed to evaluate for any alterations in cardiac rhythm or other cardiac complications. Additionally, progress notes were reviewed for any deviations from baseline cardiac rhythm recorded during the overnight observation. Reportable alterations included bradycardia (heart rate less than 60 beats per minute), tachycardia (heart rate greater than 100 beats per minute), atrial arrhythmia (atrial fibrillation, flutter, or paroxysmal supraventricular tachycardia), and ventricular arrhythmia (ventricular tachycardia or fibrillation). The Society of Interventional Radiology (SIR) classification system was used to grade any procedure-related complications noted on posttreatment imaging or clinical documentation (13).

RESULTS

Tumor Characteristics

Patients treated with MW in the present study had malignancies located in the liver (n = 5), kidney (n = 8), or lung (n = 1). The tumors within the liver included 1 hepatocellular carcinoma, an intrahepatic cholangiocarcinoma, and 3 hepatic metastases (from an ovarian granulosa cell tumor and a neuroendocrine carcinoma). The patient with metastatic neuroendocrine carcinoma to the liver had 2 metastatic lesions treated during 2 separate procedures. All 8 tumors within the kidney were renal cell carcinoma. The single treated lung tumor was an adenocarcinoma. The mean longest dimension of the treated tumors was 2.9 cm (range, 1.3–4.0 cm). A summary of tumor characteristics is provided in **Table 2**.

Table 2. Tumor Characteristics

Characteristic	Value
Tumor location	
Liver	5
Kidney	8
Lung	1
Tumor size (cm)	
Mean	2.9
Range	1.3–4.0

Ablation Results

The mean antenna-to-device distance for all procedures was 26.4 cm, with a range of 8.5–35.0 cm. Specifically, mean antenna-to-device distances were 26.5 cm for liver ablations, 28.5 cm for kidney ablations, and 8.5 cm for the single lung ablation. The mean antenna-to-lead distance was 12.1 cm, with a range of 3.5–20.0 cm. Mean antenna-to-lead distances were 10.7 cm for liver ablations, 13.3 cm for kidney ablations, and 10.0 cm for the single lung ablation. An example case and measurement is presented in the **Figure**.

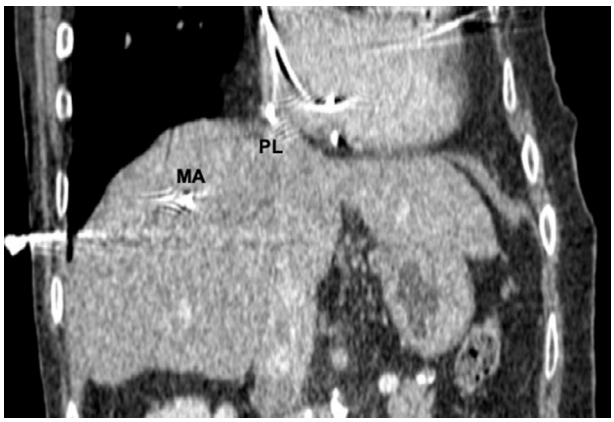

Figure. Example case of an 81-year-old woman who underwent MW ablation of a 3.7-cm intrahepatic cholangiocarcinoma in close proximity to the patient's pacemaker leads (*PL*) without complication (MA = microwave antenna).

The MW ablation procedures had a 100% technical success rate. The mean longest dimension of the ablation size was 3.6 cm (range, 1.6–6.7 cm). The treated patients had a mean follow-up imaging time of 16 months (range, 0–32 mo). The rate of local tumor progression for the treated tumors was 0% in the limited cohort.

There were no device-based complications and no complications of SIR class C or more severe during any of the 14 ablations. There were 2 cardiac events that were deemed unrelated to the implanted cardiac devices. One patient undergoing a kidney ablation had a short episode of bradycardia noted by the anesthesiologist during placement of the first MW antenna before the application of energy. The procedure was immediately stopped, and a consultation from a cardiac electrophysiologist was obtained; the bradycardia was considered normal within the patient's cardiac device settings. The procedure was completed without further incident. In a second patient undergoing ablation of a liver metastasis, minimal ST-segment elevation was identified in the ECG tracing by the anesthesiologist, with maximum ST elevations of 1.4 mm in lead II and 2.4 mm in lead V. No observable change was noted in the degree of ST-segment elevation during the delivery of energy from the MW ablation. The procedure was completed without further incident, and a cardiology consultation was obtained. The minimal ST-segment elevation persisted after completion of the procedure. Three consecutive troponin measurements were negative, and the patient was monitored

Table 3. Ablation Results

Outcome	Value
Antenna-to-device distance (cm)	
Mean	26.4
Range	8.5–35.0
Liver ablation (cm)	26.5
Kidney ablation (cm)	28.5
Lung ablation (cm)	8.5
Antenna-to-lead distance (cm)	
Mean	12.1
Range	3.5–20.0
Liver ablation (cm)	10.7
Kidney ablation (cm)	13.3
Lung ablation (cm)	10.0
Device-based complications	0
Technical success (%)	100
Longest dimension of ablation zone (cm)	
Mean	3.6
Range	1.6–6.7
Imaging follow-up time (mo)	
Mean	16
Range	0–32
Local recurrence rate (%)	0

for 24 hours after the procedure, without further ST elevation. A summary of ablation results is shown in **Table 3**.

DISCUSSION

The number of patients with CIEDs has been increasing in recent years (14). These devices remain susceptible to electromagnetic interference from a range of technologies, including medical devices such as RF generators (5–10). The results of the present study demonstrate that MW ablation can be safely performed in patients with CIEDs without the need for inactivation or program mitigation. Technically successful MW ablations were completed in the liver, kidney, and lung without complications in all 14 procedures, with antennas as close as 8.5 cm to the CIED and 3.5 cm to the CIED lead. Importantly, no programming changes were needed for any of the CIEDs, and all 6 defibrillators remained on throughout the procedures without discharging or other adverse events. These results are increasingly important, as more patients with significant cardiac disease are experiencing longer lifespans with the help of CIEDs, and minimally invasive treatments such as percutaneous tumor ablation are attractive options for this vulnerable patient population (15).

Previous studies (5–7,16,17) have raised specific concerns over potential electromagnetic interference from ablation devices. Specifically, RF ablation has been shown to have potential interactions with CIEDs (5–7). Recent case reports (16,17) have demonstrated direct interference of a CIED during RF ablation, including irregular pacing and intermittent runaway pacing during RF ablation of an adrenal metastasis and electrical reset of a pacemaker during RF ablation of a lung tumor. Pacemaker reset can result in high-output ventricular pacing and has the potential to cause failure of the device's internal inappropriate pacing inhibition from sensed external electric activity (16,17). These concerns have led to suggestions of a 5-cm safety margin from the ablation antenna to the CIED or its leads (17). However, the present study demonstrated the ability to complete MW ablations safely as close as 3.5 cm from the CIED lead.

Data regarding the safety of MW ablation in CIED patients are limited. Skonieczki et al (12) evaluated the use of ablation in patients with CIEDs, but only 7 of the 22 cases were performed with MW, and all of the pacemakers were changed to automatic pacing and defibrillators switched off during the actual ablation procedure. No other study of MW ablation in patients with CIEDs was identified in the literature. Unlike the previous study (12), the present investigation was completed without any adjustments to the CIEDs and included twice the number of MW ablation procedures.

MWs are a portion of the electromagnetic spectrum between 300 MHz and 300 GHz, and clinical ablation devices operate at 915 MHz or 2.45 GHz (11). During MW ablation, there is concern that the cardiac device or its lead may act as an antenna when placed within the electromagnetic field produced during the procedure. However, the higher frequencies associated with MW should theoretically decrease the risk of interactions, as CIEDs are engineered to reject frequencies outside their operating range. Additionally, at 915 MHz and 2.45 GHz, the electromagnetic field is restricted to approximately 2–4 cm radially around the antenna, which limits the volume of tissue in which CIEDs would even be exposed to electromagnetic energy (11).

In contrast to MW, most clinical RF devices operate between 375 and 500 kHz, increasing the risk of electromagnetic interference with the CIED, as CIEDs have been shown to be more susceptible to electromagnetic interference from low-frequency magnetic fields (18). RF devices also produce a current flow between the conducting electrode (treatment device) and dispersive electrode (grounding pads). Improper placement of the grounding pads can lead to electrical current passing through or near the CIED or its leads even if the treatment electrodes are at an appropriate distance.

There are several limitations to the present study. The relatively small sample size limits the ability to extrapolate the findings to all populations, particularly as the study group included only 1 lung tumor. Another limitation is that the mean distances from the MW antennas to the CIED device and leads were relatively large (closest distances were 8.5 cm and 3.5 cm away from the CIED and leads, respectively). As the penetration of the MW electromagnetic field is on the order of 2–4 cm, there were not enough cases in the present series to evaluate the safety of cases in which the leads or CIED overlap the expected field. Theoretical concerns with CIED devices or leads in close proximity to MW antennas include creation of a current in metallic objects and the unknown tolerance of devices to the high temperatures created by MW fields. These concerns may best be studied in a live animal model. All patients were

treated with a specific MW device operating at 2.4 GHz, and it is possible that results obtained with other antenna designs, frequency spectra, or power levels may be different. However, because electromagnetic field penetration is limited in tissues, it is anticipated that the results would hold for other MW devices in a similar patient population. An additional limitation is the lack of a full ECG evaluation of each CIED before and after the ablation procedure. Although continuous ECG tracings were reviewed to identify any device-based complications during or immediately after the procedure, it is possible that there may have been alterations in CIED function that were not uncovered in the absence of ECG alteration.

In conclusion, percutaneous MW ablation for the treatment of tumors in the liver, kidney, and lung with a single MW device appears to be safe for use in selected patients with CIEDs without device inactivation or alteration from normal functioning mode.

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