Published in final edited form as:

AJR Am J Roentgenol. 2012 March ; 198(3): W260–W265. doi:10.2214/AJR.11.6503.

High-Powered Gas-Cooled Microwave Ablation: Shaft Cooling Creates an Effective Stick Function Without Altering the Ablation Zone

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Abstract

OBJECTIVE—The purpose of our study was to validate the ability of a new gas-cooled microwave device to secure antennas into tissue before ablation via shaft cooling and to verify that such cooling does not compromise the intended ablation.

MATERIALS AND METHODS—The force required to extract several types of applicators from ex vivo bovine liver before and after ablation was measured. Six groups were compared: cooled needle and multitined radiofrequency electrodes, secured and unsecured cryoprobes, and gas-cooled microwave antennas ($n = 6$ each). Ablations were next created in in vivo porcine livers for 2 and 10 minutes ($n = 6$ each) using the gas-cooled microwave system at 140 W. Extraction force was again measured before and after ablation and compared between groups using analysis of variance with post hoc Student t tests. Histologic analysis of the ablation zone was performed to evaluate cellular necrosis along the antenna shaft.

RESULTS—Ex vivo, the secured cryoprobe and microwave antenna required significantly more force to remove than unsecured radiofrequency, cryoprobe, and microwave applicators ($p < 0.05$, all comparisons). The multitined radiofrequency electrode and cooled radiofrequency electrode required significantly more force to remove after ablation than before ablation ($p = 0.006$ and 0.02 , respectively). In vivo, the secured antenna required significantly more force to remove before ablation than after ablation at both 2 ($p < 0.0001$) and 10 minutes ($p < 0.0001$). There was no histologic evidence of cell preservation along the antenna shaft.

CONCLUSION—The gas cooling used in this microwave device can effectively secure antennas into tissue without altering ablation shape or reducing the intended thermal damage.

Keywords

cryogenic cooling; microwave ablation; thermal ablation

Imaging-guided thermal tumor ablation is rapidly gaining acceptance for the treatment of tumors in liver, lung, kidney, and bone [1]. Although early clinical results are promising, substantial improvements in ablation devices are needed to decrease local failures, complications, and treatment times. Treatment of tumors by microwave ablation has many theoretic advantages when compared with radiofrequency ablation and cryoablation, including higher temperatures and faster tissue heating, but heating of the antenna shaft and supply cables has been a fundamental limitation to power delivery and overall effectiveness [2–5]. Some manufacturers have partially overcome this limitation by internally or externally water-cooling the antenna, but this has been at the cost of increased shaft diameter and complexity [6, 7]. Recently, a microwave ablation system has been introduced that can produce and handle very high amounts of power (140 W) in a small diameter antenna (17 gauge) because of the use of a novel gas-cooling mechanism.

Along with highly efficient cooling of the antenna shaft, an additional benefit of gas cooling is the ability to produce a small freeze zone near the radiating tip of the antenna to decrease the likelihood of applicator migration after placement. Applicator migration can have serious consequences and has been reported previously during ablation in the liver, lung, and breast [8–11]. With the introduction of a gas-cooled microwave system that can be secured by a small freeze zone near the radiating tip, two questions must be answered before clinical use: How effective is the freeze zone for securing the antenna in tissue, and does the freeze zone result in a suboptimal ablation zone shape, either by preserving or ablating tissue along the antenna shaft?

The purpose of this study was to examine the implications of gas cooling on microwave ablation procedures. We first measured the amount of force required to extract the gas-cooled antenna from tissue when secured in place. A gross and histologic examination of the ablation zone created by the gas-cooled microwave system was then performed to determine whether the freeze zone influenced the overall ablation shape, particularly along the antenna shaft.

Materials and Methods

Device Selection

Four ablation applicators were chosen for ex vivo testing, representing a spectrum of devices clinically available in the United States: internally cooled radiofrequency electrodes (1.5-mm diameter, Cool-tip, Covidien), multitined expandable electrodes (2.3-mm diameter, Starburst Xli, AngioDynamics), cryoprobes (1.7-mm diameter, Endocare), and a prototype gas-cooled microwave antenna (1.5-mm diameter, Certus 140, NeuWave Medical). The microwave system consists of a triaxial antenna [12] with carbon dioxide gas cooling just proximal to the radiating segment, producing an approximately 1.0-cm freeze zone with a target temperature of -10°C (Fig. 1).

Ex Vivo Force Measurements

Bovine liver was used for all ex vivo testing. Entire livers were allowed to warm to room temperature ($18\text{--}22^{\circ}\text{C}$) before being sectioned into $8 \times 6 \times 6$ cm blocks to permit devices to be inserted for a depth of at least 6 cm. Blocks of tissue that included large vessels were avoided during sectioning.

A digital force gauge (Model 475044, Exttech) was hung above the tissue sample from a movable stand with manual control of stand height. The ablation applicator was then attached to the force gauge and inserted at least 6 cm through the acrylic plate into the tissue block (Fig. 2). Each sample was positioned underneath an acrylic plate to prevent tissue motion during applicator extraction. The stand was elevated by rotating the handwheel on

the test stand, and the resulting withdrawal force was recorded. Measurements of the force required to withdraw applicators before ablation were obtained from each group ($n = 36$ total, 6 per group). The six ex vivo groups included a radiofrequency electrode, a multitined expandable electrode with the tines deployed, a cryoprobe with and without the stick function initiated, and the gas-cooled microwave antenna with and without the stick function initiated.

Applicators were then inserted back into the tissue. Ablation was initiated according to the manufacturer's suggested protocol to create ablation zones approximately 3 cm in diameter (Appendix 1). Postablation measurements of the force required to withdraw applications were collected immediately at the end of power application ($n = 36$ total, 6 per group). Samples were sectioned once along the axis of insertion and digitally scanned (Perfection V200 Photo, Model J231C, Epson).

In Vivo Experimental Methods

Approval for the in vivo study was obtained from our institutional research animal care and use committee, and all husbandry and experimental studies were compliant with the National Institutes of Health Guide for Care and Use of Laboratory Animals. Two female domestic swine (mean weight, 65 kg) were sedated with 7 mg/kg of intramuscularly administered tiletamine hydrochloride and zolazepam hydrochloride (Telazol, Wyeth) and 2.2 mg/kg of xylazine hydrochloride (Xyla-Ject, Phoenix Pharmaceuticals). Endotracheal intubation was performed, facilitated by 0.05 mg/kg of atropine. Once sedated, anesthesia was induced and maintained with inhaled isoflurane [13]. The liver of each animal was surgically exposed with a midline incision to allow more accurate applicator placement. Because the radiofrequency and cryoablation devices in this study have already been extensively characterized, only the gas-cooled microwave device was tested in vivo to minimize the use of live animals.

Preablation extraction force measurements were performed ($n = 6$) on the gas-cooled microwave antenna using the same setup and techniques as in the ex vivo study, with an acrylic plate holding the liver in place and extraction performed using the force gauge attached to a moving vertical stand. Ablations were then performed for 2 ($n = 6$) and 10 minutes ($n = 6$), as described in Appendix 1. Extraction force measurements were again obtained after ablation. Animals were then euthanized with an IV overdose of pentobarbital sodium and phenytoin sodium (Beuthanasia-D, Schering-Plough) [13].

Sample Preparation

The livers were removed en bloc and ablation zones sectioned along the antenna axis. Fresh unfixed slices of liver 3 mm in thickness were immersed in a solution of nitro blue tetrazolium (NBT, MP Biomedicals) at 100 mg/100 mL and Sorensen phosphate buffer, pH 7.4, until a blue color developed in the untreated liver at room temperature. The stained ablation zones were measured, photographed, and immersed in buffered formalin for fixation. Samples were then sent for analysis. Sections for histologic examination were embedded in paraffin wax, sectioned, and stained with H and E.

Statistical Analysis

Descriptive statistics were calculated for each group. One-way analysis of variance was used to analyze the ex vivo pre- and postablation groups separately. Tukey post hoc t tests were used to compare the ex vivo preablation groups to each other and the postablation results to each other. Additionally, the ex vivo pre- and postablation results for each applicator design were compared with each other using Welch corrected t tests. Pre- and postablation data from the in vivo studies was analyzed by Welch corrected t tests with a correction by the

Holm method for multiple comparisons. Statistical analyses were performed using R software (R Foundation for Statistical Computing), and p values of less than 0.05 were considered to indicate a statistically significant difference.

Results

Ex Vivo Extraction Force Measurements

The force necessary to remove probes from ex vivo tissue are summarized in Table 1. When compared with all other applicator types, the greatest force was required to remove cryoprobes with the stick function initiated before ablation ($p < 0.05$). Both the stuck cryoprobes and microwave antennas required significantly more force to extract than either the radiofrequency electrodes or the unstuck cryoprobes and microwave antennas ($p < 0.05$, all comparisons). Surprisingly, the force required to withdraw the multitined radiofrequency electrode before ablation was not statistically greater than the force required to withdraw any of the unsecured needlelike applicators ($p > 0.05$).

The multitined expandable radiofrequency electrode required significantly more force to remove postablation than the cool-tip radiofrequency electrode, cryoprobe (unstuck), and gas-cooled microwave antenna (unstuck) ($p < 0.05$, all comparisons). There were no significant differences in the force required to remove the remainder of the applicators ($p > 0.05$, all comparisons). Finally, the multitined expandable radiofrequency electrode, cooled radiofrequency electrode, unsecured cryoprobe, and unsecured microwave antenna required significantly more force to remove postablation than preablation ($p = 0.0058, 0.0198, 0.004$, and 0.029 , respectively). Conversely, stuck cryoprobes and microwave antennas required significantly more force to remove preablation than postablation ($p = 0.001$ and < 0.0001 , respectively).

In Vivo Extraction Force Measurements

In vivo force measurements were similar to ex vivo results (Table 1). The stuck microwave antenna required significantly more force to extract preablation than postablation (unstuck) at both 2 ($p < 0.0001$) and 10 minutes ($p < 0.0001$). Additionally, significantly more force was required to remove the applicator after a 10-minute ablation compared with a 2-minute ablation ($p = 0.011$). All results remained significant even after correction for multiple comparisons using the Holm method (before to 2 minutes after ablation, $p = 0.00016$; before to 10 minutes after ablation, $p = 0.00017$; and 2 minutes after ablation to 10 minutes after ablation, $p = 0.011$).

Pathology

Histologic analysis showed changes consistent with ablated tissue along the active portion of the antenna, including the tissue in the region surrounding the stick zone. Histologic changes included hemolysis of erythrocytes, hepatocytes with indistinct cell borders, cytoplasmic vacuolation, nuclear pyknosis, and Kupffer cell loss. There was no change in the pattern of the ablation zone near the freeze zone on samples stained with either NBT or H and E. Specifically, the proximal border of the ablation zone remained in a smooth uninterrupted arc—that is, there was no extension of the ablation zone along the probe shaft or indenting of the ablation zone by the freeze zone (Fig. 3).

Discussion

The results of this study show that gas-cooled microwave antennas can be more effectively secured in tissue than multitined or internally cooled radiofrequency electrodes but not to the same degree as cryoprobes. The amount of force necessary to remove a stuck microwave

antenna appears adequate to prevent probe migration during routine clinical use. Additionally, the multitined expandable radiofrequency electrode, cooled radiofrequency electrode, unsecured cryoprobe, and unsecured microwave antenna required significantly more force to remove postablation than preablation. This effect is likely caused by the contraction of tissue around the applicator as tissue is heated and, in the case of cryoablation, to freezing of tissue to the applicator during ablation.

Migration of unsecured probes before or after ablation can have devastating consequences, with the potential to cause track seeding; burns to the body wall; and, most important, undertreatment of tumors if the probe backs out prematurely [2]. Movement of unsecured applicators has been reported during pulmonary ablation because of respiratory motion [8, 9]. Applicator migration has also been reported during radiofrequency ablation of the liver and even during treatment of relatively motionless structures, such as the breast [10, 11]. In addition to preventing probe migration, the small stick zone (< 1.0 cm) on the microwave antenna does not appear to have a deleterious effect on the shape of the ablation zone, with no evidence of preservation of tissue within the ablation zone or tissue destruction proximally along the shaft outside the ablation zone. The histologic results are similar to the necrotic zone for previously studied prototypes that used water cooling or no cooling at all [14–16].

Several current ablation devices have applicators that are intrinsically secured in tissue. Multitined expandable radiofrequency electrodes (e.g., StarBurst Xli, AngioDynamics and LeVeen, Boston Scientific) attempt to mechanically secure the electrode into place by extension of the tines, and cryoprobes are frozen into tissue by controlling the input gas flow (Cryocare, Endocare). To date, heat-based ablation systems are either unsecured or use mechanical means, such as extension of the tines into tissue, to be secured. The gas-cooled microwave system used in this study would be the first heat-based ablation system to include a nonmechanical feature to secure applicators in tissue. The gas-cooled microwave system takes advantage of the Joule-Thompson phenomenon to allow the formation of a small ice ball just proximal to the radiating segment, which secures the antenna in place. The advantages of a nonmechanical solution include simplicity, ease of insertion, no need for tines that can potentially penetrate vulnerable structures (e.g., subdiaphragmatic probe placement with damage to lungs or heart on prong deployment), smaller needles, and speed. Additional advantages include less risk of probe movement; distortion of tine geometry and tissue, particularly when deploying tines through hard tumors or cirrhotic liver; and less risk of nontarget ablation related to the inherent lack of control associated with tine deployment.

Although microwave ablation has many theoretic advantages compared with other thermal ablation modalities, a major limitation has been the inability to apply large amounts of power through small-gauge antennas [12, 13]. This limitation has resulted in underpowering of microwave systems, with relatively small ablation zones and undesirably large antenna diameters [6, 7, 17]. Without cooling, the antennas used in this study are unable to handle more than perhaps 20 W of power at 2.45 GHz, and uncooled prototypes using larger-diameter coaxial cables are unable to deliver more than 70 W [13, 15]. Therefore, gas cooling increased power delivery by at least twofold, resulting in larger ablations than possible with early prototypes.

Water-cooled antennas have also been shown to improve power delivery and therefore increase ablation zone size [6, 7, 14]. Recent studies comparing cooled and uncooled antennas have noted an increase in ablation size and improvement in ablation shape with cooled designs [18]. However, the greater viscosity of water can limit its flow through small-diameter antennas. Many water-cooled systems require increased antenna diameters (~13–15 gauge) to accommodate the necessary volumetric flow rates. As shown in this

study, pressurized CO₂ gas has low viscosity and is an effective cryogen, making it suitable for cooling even 17-gauge antennas. Temperatures along the antenna shaft in this study were kept below 41°C during maximum power delivery by controlling the CO₂ flow rate. This control is performed automatically by the system software.

Gas cooling was also simpler to set up and to use when compared with water-cooled prototypes in previous studies because of the lack of pumps, water lines, and cooled IV bags. The cooling line is integrated into the applicator connection so that only one physical connection was required to set up the system. Gas also inherently eliminated the risk of contamination by the cooling water. In addition, the system used a power distribution module that attaches to the bedside from where the antennas originate to further simplify workflow and reduce setup complexity. The disadvantages of gas cooling are primarily related to the increased technical complexity and expense necessary to precisely deliver gas in a dynamic thermal environment. However, this is most relevant for manufacturing and not apparent to the end-user. The cost of the system evaluated in this study is similar to existing radiofrequency ablation systems.

There are some limitations to our study. First, the prototype microwave system used in this study was close but not identical to the commercially available product in the following ways: The system was controlled using LabView software (version 8.6, National Instruments) rather than the final version of the proprietary system software, and the microwave antennas were prototypes that have since been modified to provide more power at the tip. However, no changes have been made to the physical dimensions of the antennas or the stick function.

An additional limitation is that force measurements were not collected during the ablation to follow the effectiveness of the stick function as the ablation progressed. Unsecured applicators are most vulnerable to migration before ablation, when it may be necessary to manipulate patient position to facilitate imaging or introduce additional applicators. Applicator migration can also occur during ultrasound imaging, during CT because of bed motion, or because of inadvertent force on the applicators or supply cables. Our data suggest that tissue contraction caused by high-temperature thermal ablation increases the force required to extract the applicator. Further studies characterizing the stick function as ablation proceeds would be of interest.

Other limitations to this study include the use of normal porcine liver rather than a tumor model. Large-animal tumor models are available but are highly complicated and expensive to produce and are unlikely to have changed the results of this study. Finally, for the in vivo portion of the study, the antennas were placed after the liver was surgically exposed, not percutaneously. Thus, the effect of traversing the body wall, which may increase the extraction force for all applicators, was not taken into account. The reason for the use of an open surgical model was to obtain the maximum number of ablations per liver, reducing the number of live animals necessary for statistical significance.

In summary, the stick function associated with the prototype gas-cooled microwave system used in this study appears to effectively secure the antenna into tissue without preserving tissue adjacent to the antenna or distorting the shape of the ablation zone when compared with other ablation devices. Further testing of this system appears warranted, particularly because the effectiveness of the gas cooling allows the delivery of large amounts of power (140 W) through a small diameter antenna (17 gauge). Increased power delivery combined with an effective stick function could potentially increase the ability to treat large tumors quickly with microwave ablation while decreasing the complications associated with antenna placement.

Acknowledgments

We express our deepest gratitude to Lisa Sampson for all her assistance with this study.

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APPENDIX 1: Device-Specific Ablation Techniques

Multitined Expandable Applicator

A StarBurst electrode (RITA model 1500 radiofrequency generator, AngioDynamics) was used as the model for deployable radiofrequency devices. Ablations followed the manufacturer's recommendations for creating a 3-cm ablation zone except for an initial complete prong deployment to measure the maximum force necessary to remove the electrode. Ablations were 5 minutes in duration after allowing the electrode to heat to a target temperature of 105°C. Heating to target temperature took between 3.1 and 3.5 minutes at 150 W.

Internally Cooled Needle Electrode

The Covidien Cool-tip radiofrequency system was chosen as the model of single needle (nondeployable) radiofrequency ablation electrode. All ablations were performed with a 17-gauge internally cooled electrode (Cool-tip, Covidien) with a 3-cm exposed tip using a 200-W maximum generator that adjusts energy supply to the tissue on the basis of tissue impedance [16]. Ablation time was 12 minutes.

Cryoablation

Cryoablation was performed using a 1.7-mm-diameter percutaneous cryoprobe (PERC-17, Oblong Ice, Endocare) cooled by argon gas. The ablations were 10 minutes in duration. Applicator temperatures reached −98°C. Cryoablation applicators could not be removed immediately after ablation; therefore, force measurements were collected until a minimum of 20 lbs (9 kg) of force was applied to the applicator.

Microwave Ablation, Gas Cooled, Stick Function

The microwave system used for this study was a prototype Certus 140 (NeuWave Medical) that generates a maximum of 140 W from each of three power amplifiers for a maximum total output of 420 W. The Certus antenna has a 17-gauge diameter and is based on a triaxial design tuned for liver to minimize reflected power and maximize power deposition [12, 13]. The cooling system uses CO₂ gas that reaches approximately −10°C when expanded just proximal to the active radiating portion of the antenna using the Joule-Thomson phenomenon [19]. The temperature is constantly monitored at the tip and an active feedback loop used to regulate the gas flow. The subzero temperatures that result at the distal part of the applicator allow the applicator to be “stuck” in place. Ablations were performed for 10 minutes at 140 W, resulting in approximately 70 W at the applicator tip.

Fig. 1. Photograph shows gas-cooled microwave antenna with freeze zone illustrated by formation of ice ball (*arrow*) created by placing antenna into water with stick function initiated.

Fig. 2. Photograph shows experimental set-up. Force measurements to withdraw applicators were collected by attaching applicators to force gauge (*asterisk*), which was attached to movable stand (*arrow*), then elevating force gauge out of tissue sample.

Fig. 3.

Gas-cooled microwave ablation.

A, Photograph of gas-cooled microwave antenna with resulting ablation zone shows no indentation of ablation shape caused by cooling of shaft (*box*) and no alteration of ablation zone around area of freeze zone (*circle*).

B and **C**, Photomicrographs (**B** corresponds to circle in **A**, and **C** corresponds to box in **A**) of H and E-stained tissue from ablation zone along antenna track (*asterisks*) created by gas-cooled microwave device show complete ablation of tissue along antenna shaft. Most proximal edge of ablation zone is indicated by arrow in **C**.

TABLE 1

Force Required to Withdraw Applicators From Ex Vivo Bovine Livers and In Vivo Porcine Livers

Tissue Type	Applicator	Preablation Force (N)	Postablation Force (N)	<i>p</i>
Ex vivo	Expandable radiofrequency	2.9 ± 0.4	8.8 ± 3.2	0.0058
Ex vivo	Cooled radiofrequency	2.2 ± 0.6	3.5 ± 1.0	0.0198
Ex vivo	Cryoablation (unsecured)	1.7 ± 0.5	3.5 ± 1.0	0.004
Ex vivo	Cryoablation (secured)	52.4 ± 17.4	3.5 ± 1.0	0.001
Ex vivo	Microwave-unsecured	1.1 ± 0.3	4.4 ± 2.7	0.029
Ex vivo	Microwave-secured	18.3 ± 1.6	4.4 ± 2.7	< 0.0001
Ex vivo	Analysis of variance <i>p</i>	< 0.0001	0.0003	
In vivo	Gas-cooled microwave (secured): 2-min ablation	16.5 ± 3.1	1.2 ± 0.5	< 0.0001
In vivo	Gas-cooled microwave (secured): 10-min ablation	16.5 ± 3.1	2.0 ± 0.4	< 0.0001

Note—A total of six unpaired samples were used in the preablation and postablation groups. Except for *p* values, data are mean ± SD.