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American Journal of Interventional Radiology

Technical Innovation *Interventional Oncology*

Use of ultrasound gel to mitigate risks of skin burns from non-actively cooled microwave applicators

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Received: 16 January 2024
Accepted: 19 March 2024
Published: 09 May 2024

DOI
10.25259/AJIR_3_2024

Quick Response Code:

ABSTRACT

The purpose of this study is to investigate the potential of using ultrasound gel to mitigate the risks of skin burn at the insertion site during microwave ablation (MWA) using non-actively cooled applicators. *Ex vivo* experiments in porcine tissue were conducted using two identical MWA systems. Five MWA scenarios were tested at different applicator insertion depths with an ultrasound gel layer applied at the applicator insertion sites: 8 cm insertion depth with and without 4 cm thick gel, 10 cm insertion depth with and without 2 cm thick gel, and 12 cm insertion depth without gel (reference). In all experiments, temperature elevations at the applicator insertion site on the tissue surface were recorded using thermal sensors in all experiments during 10-min MWA. The application of ultrasound gel and increasing applicator insertion depths resulted in measurable reductions in temperature elevations at the applicator insertion sites. For an insertion depth of 8 cm, the temperature elevations were 39.9 ± 4.7°C and 23.2±6.5°C without and with gel, respectively ($P < 0.001$). For an insertion depth of 10 cm, the temperature elevations were 20.8 ± 1.5°C and 14.4 ± 1.5°C without and with gel, respectively ($P < 0.001$). The maximal temperature elevations corresponding to an 8 cm insertion depth with gel were comparable with those corresponding to a 10 cm insertion depth without gel. Similarly, the maximal temperature elevations (12.2 ± 1.8°C) corresponding to 12 cm insertion depth without gel were comparable to those corresponding to 10 cm insertion depth with gel. Applying ultrasound gel at the applicator insertion site can significantly reduce temperature elevations at the tissue surface during MWA procedures.

Keywords: Microwave ablation, Skin burn risk mitigation, Ultrasound gel

INTRODUCTION

Image-guided microwave ablation (MWA) has been demonstrated to be a desirable treatment for localized tumors and has been especially suitable for treatments of tumors with strong vascular components or those located in proximity to vascular tissues.[1-3] Currently, image guidance is often achieved using either computed tomography or ultrasound. However, due to superior soft-tissue contrast provided by magnetic resonance imaging (MRI), MRI-guided MWA (MRgMWA) has been demonstrated to be advantageous in reducing procedural complications.[4] Further improvements in MWA safety and treatment outcomes can be achieved with real-time monitoring using MR thermometry.[5] As of today, MR thermometry monitoring of MRgMWA can be limited due to intermittent electromagnetic interference introduced by the action of the MWA system. As a result, few commercial MR-conditional MWA systems are available, and clinical MRgMWA treatments have only been performed at a few institutions.[4,6-12]

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The use of an MWA system (Avecure, MedWaves Inc., San Diego, CA) for MRgMWA has been demonstrated recently.[11,12] Due to an impedance mismatch between the MW applicator and tissues, a portion of the microwave energy could be reflected resulting in applicator shaft heating and potential skin burns. As a consequence, skin burns at the applicator insertion site are among the major potential risks of MWA treatments.[13,14] A clinical review of complications related to percutaneous MWA for liver tumors reported skin burns in 21 out of 583 (4%) cases performed with non-actively cooled applicators.[15] Integrating cooling components with microwave applicators is therefore very beneficial.[16,17] At present, however, there are no commercial MWA systems with cooled applicators designed for MRgMWA. The clinical system used in our study limits the risks of tissue heating along the applicator shaft by automatic adjustments of the output frequency and generator duty cycle to limit the maximal temperature elevation set by the user. Despite these strategies, significant temperature rises at the applicator insertion site may still occur, with risks increasing for shallower insertion depths.[18] Consequently, the manufacturer provided a set of recommended minimal insertion depths corresponding to each combination of applicator type, desired ablation zone size, and ablation duration. Shallower minimal insertion depths are still desirable, however, as they allow flexibility in applicator path planning and minimize procedural complexity and risks of complication.

This work aims to investigate the application of ultrasound gel, a material widely used in diagnostic ultrasound, at the applicator insertion site to reduce the undesired temperature rises at that site. If effective, this method could enable shallower insertion depths while minimizing risks of associated skin heating or skin burns during MWA treatments of tumors located in close proximity to patient skin.

MATERIAL AND METHODS

Ex vivo experiments in porcine muscle tissue were conducted using two identical MR-conditional MWA systems (Avecure, MedWaves Inc., San Diego, CA). Each system consisted of a microwave generator and a "large" applicator ("large" is a vendor-specific labeling of the applicator type) which is expected to deliver an ablation zone size of approximately 4.0 × 5.5 cm in 10-min ablation.[11,12,19] The maximal power allowed by the system (36W) was used and the maximal ablation temperature was set to 130°C (as measured using a built-in temperature sensor near the applicator tip). The automatically adjusted output frequency was between 902–928 MHz.

The experimental setup for one MWA system is illustrated in Figure 1. Five settings with different combinations of applicator insertion depth and ultrasound gel thickness were investigated: 8 cm insertion depth with and without a 4 cm thick layer of ultrasound gel (Aquasonic 100 ultrasound transmission gel, Parker Laboratories, Fairfield, NJ, USA); 10 cm insertion depth without and with a 2 cm gel, and 12 cm insertion depth without any ultrasound gel (8, 10, and 12 cm insertion depths are typical in clinical MRgMWA with use of "large" applicator). The combined insertion depth ("effective" insertion depth) of the applicators inside both tissue (8, 10, and 12 cm) and gel layers (4, 2, and 0 cm, respectively) was therefore 12 cm in all experiments. The motivation of applying ultrasound gel was not only to extend the effective insertion depth but to utilize its thermal properties for heat conducting and transferring. To better control the ultrasound gel thickness for quantitative analysis, a cylindrical tube (inner diameter 2.6 cm) surrounding the applicator shafts was used to contain the gel.

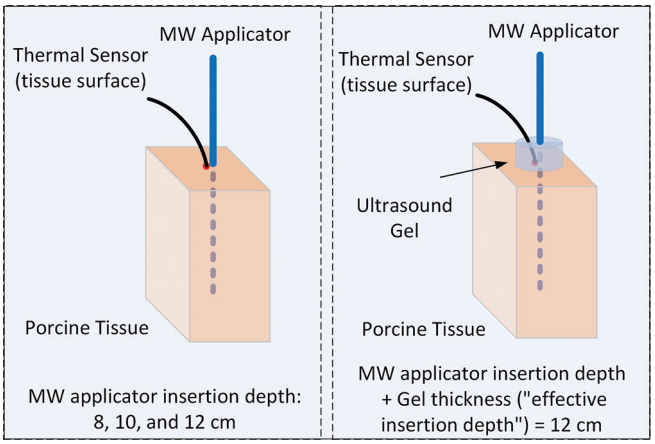

Figure 1: Schematic of the setup for *ex vivo* tissue experiments (left) without and (right) with ultrasound gel. (MW: microwave).

All experiments were performed in a clinical MRI room with the MRI scanner not active. During the experiments, the temperature histories on the tissue surface at the applicator insertion sites were continuously recorded by a fiber optic thermometer system (Qualitrol Omniflex-2, Fairport, USA), as shown in Figure 2. Fresh (i.e., not previously frozen) porcine muscle tissue was equally divided into tissue samples to be separately used for each insertion depth experiment. In ablations with 8 or 10-cm insertion depths, a pair of applicators (connected to separate MWA systems) was inserted into one sample, one with and the other without ultrasound gel applied on the tissue surface. To avoid any potential impact of overlapping treatment zones on the measured surface temperatures, the applicators were inserted in parallel with spacing >4 cm.[18] The size of each tissue sample was large enough to completely enclose the treatment zones. Each ablation experiment (10-min ablation) was repeated 3 times, for measurement statistics [Figure 2]. The ablation experiment with 12 cm insertion depth was only

performed without gel, as a reference. At the end of each ablation experiment, the porcine tissue was dissected along the applicators to inspect the treatment zones.

The mean tissue surface temperature elevations relative to the pre-ablation baseline (the pre-ablation baseline temperature was measured for about 2 min) were plotted against the ablation time and fitted using a linear model. The temperature change rates (*dT/dt:* °C/*min*) were computed and compared across the five experimental settings. To further demonstrate the efficacy of using gel for reducing skin temperature rise at the insertion site, the following statistical analyses were performed. A linear mixed model was used to estimate the temperature difference between the start and end time for each insertion depth and gel layer combination. In addition, "difference in differences" (DID) estimates were used to estimate the difference in temperature rises corresponding to ablations with versus without gel.[20,21] The insertion depth of 12 cm was not included in the analysis due to a lack of corresponding temperature measurements with gel. Least square estimates were reported, and the statistical significance level was set at 0.05. All analyses were done using Statistical Analysis System (SAS) 9.6 software (SAS Institute, Cary, NC).

RESULTS

Figure 3 shows the mean surface temperature changes for applicator insertion depths of 8 cm [Figure 3a], and 10 cm [Figure 3b]. The temperature changes for an applicator insertion depth of 12 cm were also plotted as a reference.

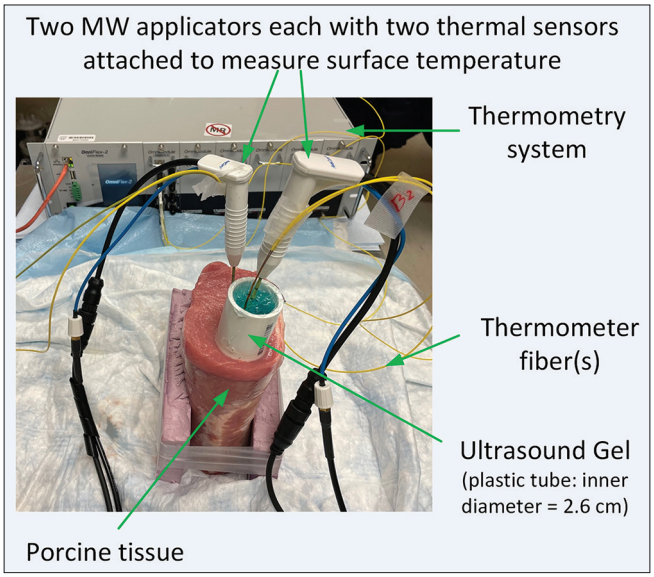

Figure 2: Porcine tissue experiment setup (components were indicated by green arrows). Two identical microwave applicators were used simultaneously with and without gel applied on the tissue surface. The temperature at the applicator insertion site on the tissue surface was continuously monitored during all microwave ablation procedures using temperature fibers/probes (yellow). (MW: microwave).

The mean temperature change curves could be roughly divided into two segments based on the observed trend in the curve. Through linear fit analysis, the average rates of surface temperature changes for 8 cm insertion depth, without and with gel, were calculated as 6.8 and 3.1°C/min during the first 4 min followed by 2.2 and 1.6°C/min. Similarly, for 10 cm insertion depth, without and with gel, the rates were 4.7 and 3.0°C/min during the first 2½ min followed by 1.1 and 0.8°C/min Corresponding to a reference 12 cm insertion, the rates of temperature changes were calculated as 0.15°C/min (after 2½ min) and 0.1°C/min (after 4 min). The results are summarized in Table 1.

The maximal tissue surface temperature rises measured at the end of 10-min ablations are summarized in Figure 4. With gel, the maximal tissue surface temperature rises were significantly reduced for both 8 and 10 cm insertion depths. On average, using gel resulted in a DID of 16.7°C reduction (95% confidence interval [CI] 9.9–23.5°C, $P < 0.001$) in temperature rise at 8 cm insertion (39.9 ± 4.7°C without gel vs. 23.2 ± 6.5°C with gel), and 6.4°C reduction (95% CI 4.4–8.4°C, $P < 0.001$) at 10 cm insertion (20.8 ± 1.5°C without gel vs. 14.4 ± 1.5°C).

The cut-open views of the porcine tissue after ablations with an insertion depth of 8 cm are displayed in Figure 5: (left) without gel and (right) with a 4 cm thick layer of gel. By visual inspection, the size of the thermal lesion was not affected by the application of the gel. Compared to thermal lesions generated without gel [Figure 5: left], no ablated tissue extended to the skin layer along the shaft when the gel was applied [Figure 5: right]. Since the tissue samples were cut in slightly different planes relative to the MW applicators, the quantitative comparison was not attempted.

DISCUSSION

Significant temperature rises at the tissue surface adjacent to the applicator shaft were observed during the MWA experiments using a non-actively cooled applicator. Although lower temperature rises are expected clinically in

Table 1: Rates of surface temperature change rates during 10-min MWA for different insertion depths with and without gel.

dT/dt (°C/min)	(0, 4.0) min	[4.0, 10.0] min	(0, 2.5) min	[2.5, 10.0] min
8 cm (w/o gel)	6.8	2.2	-	-
8 cm (w/ gel)	3.1	1.6	-	-
10 cm (w/o gel)	-	-	4.7	1.1
10 cm (w/ gel)	-	-	3.0	0.8
12 cm (w/o gel)	-	0.1	-	0.15

MWA: Microwave ablation, w/o: without, w: with

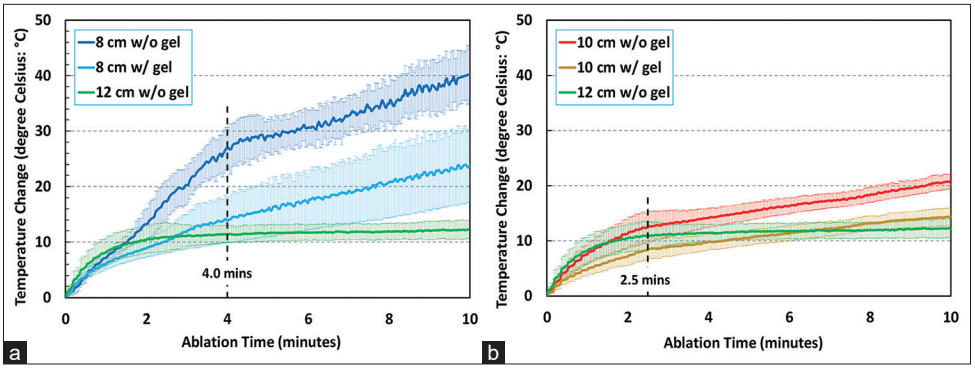

Figure 3: Mean surface temperature changes for microwave ablation with an insertion depth of (a) 8 cm and (b) 10 cm, both with and without gel; the temperature changes for an insertion depth of 12 cm were also plotted as a reference. Note: the vertical dashed lines represented the ablation time of 4.0 and 2.5 min where the mean temperature change curves were divided into two segments for 8 and 10 cm insertion depths, respectively. (w/o: without, w: with.)

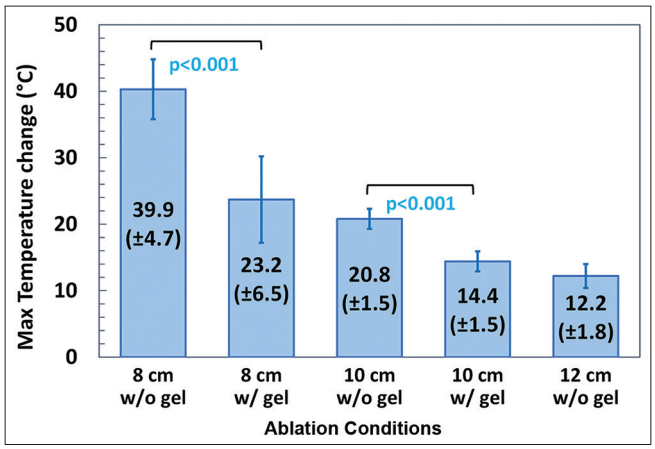

Figure 4: Comparison of the maximal tissue surface temperature rises for all five ablation conditions. (w/o: without, w: with.)

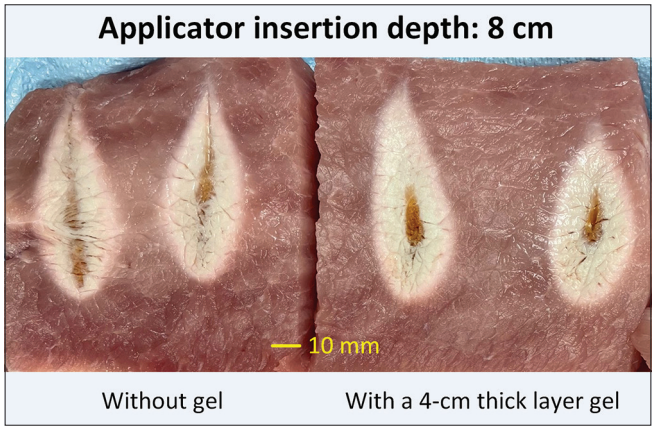

Figure 5: Subjective comparison of the treatment zones with and without a 4 cm thick layer gel for an insertion depth of 8 cm.

patients (due to continual heat dissipation caused by blood perfusion),[9,11,12] mitigation of temperature rises at the applicator insertion site is still desirable to limit potential risks of thermal burns. The results presented here are quite general (i.e., not limited to MRgMWA only) and may apply to other MWA systems using non-actively-cooled applicators.

Without the application of the ultrasound gel, the temperature rises at the tissue surface decreased with deeper applicator insertion depths. This is consistent with what has been reported previously.[18] Application of ultrasound gel consistently resulted in lower tissue surface temperature rises during ablations. When a 4 cm and 2 cm thick layer of gel were applied for insertion depths of 8 cm and 10 cm, respectively, the averaged maximal tissue surface temperature rises were reduced by 41.9% and 30.8%, as compared to the corresponding values without gel. Furthermore, the tissue surface temperature rises for an 8 cm insertion depth with the use of gel were comparable to those observed for a 10 cm insertion depth without gel (both had the same 12 cm "effective" insertion depth). As insertion depths of 8~10 cm have been used clinically with few reported heating incidences (vendor recommended minimal insertion depths: 8 cm for the "large" applicator used in this work), shallower insertion depths with the application of an additional layer of ultrasound gel may therefore be acceptable if needed.

This study is not without limitations. First, only the results of an MWA applicator with a "large" antenna have been shown here. The effectiveness of using ultrasound gel to reduce tissue surface temperature rises using other available antenna sizes (e.g., "medium," "small," and "mini") need to be investigated also. Second, the diameter of the applied cylindrical layer of gel was fixed to 2.6 cm in this work. The impact of varied diameters warrants future experiments. Third, the ultrasound gel thickness and diameter were controlled using a cylindrical tube surrounding the applicator shafts for investigation purposes. Although manageable, the use of such a tube is likely unnecessary in clinical practice as the ultrasound gel can stay in place well (clinical validation is needed). Fourth, the impact of ultrasound

gel application on the treatment zones at various applicator insertion depths was only visually evaluated. Quantitative evaluation of the treatment zones including MRI-thermometry to assess dynamic temperature changes within these zones is warranted in future studies. Fifth, although the study was performed on MWA applicators that were designed for operation in the MRI environment (MR-conditional), the contributions from MRI operation on the heating of the applicator insertion site were not assessed. Last, the underlying mechanisms for reducing the temperatures at the insertion site using ultrasound gel are still not fully understood. Improved heat conduction/dissipation and impedance matching with MWA applicators through skin-gel interface (as opposed to skin-air) likely plays a role, however, further theoretical and/or numerical simulation studies (incorporating various tissue types) are needed to investigate other possible contributing mechanisms.

CONCLUSION

Significant temperature increases were measured at the tissue surface during MWA due to the action of the MWA system/applicator. These undesired temperature increases and potential risks of patient injury can be effectively mitigated by a combination of maximized applicator insertion depth and application of ultrasound gel layer at the skin-applicator interface.

Ethical approval

The Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent is not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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How to cite this article: Ren L, Woodrum D, Gorny K, Felmlee J, Thompson S, Adamo D, *et al.* Use of ultrasound gel to mitigate risks of skin burns from non-actively cooled microwave applicators. Am J Interv Radiol. 2024;8:5. doi: 10.25259/AJIR_3_2024