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Sequential activation of ground pads reduces skin heating during radiofrequency ablation: Initial in vivo porcine results

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Abstract

***Purpose*: Radiofrequency (RF) ablation is a common treatment modality for inoperable liver cancer. Skin burns below ground pads during RF ablations are increasingly prevalent, hindering the development of higher-power RF generators capable of creating larger ablation zones.**

***Materials and Methods*: 9 RF ablations (n=4 simultaneous, n=5 sequential) were performed with 300W for 12 min via two internally cooled cluster electrodes placed in the gluteus maximus of domestic swine. Three ground pads placed on the animal's abdomen were activated either simultaneously, or sequentially where activation timing was adjusted to equilibrate skin temperature below each pad. Temperature rise at each pad was compared. Ablation zone dimensions were determined via MRI.**

***Results*: Maximum temperature rise was significantly higher with simultaneous activation than with sequential activation (21.4 vs 8.1 ºC, p<0.01). Ablation zone diameters during simultaneous and sequential activation were 6.9±0.3 and 5.6±0.3,,respectively.**

***Conclusion*: Sequential activation of multiple ground pads resulted in significantly lower skin temperatures during high-power RF ablation.**

I. INTRODUCTION

Radiofrequency (RF) ablation has been successfully utilized as a minimally invasive treatment for primary and metastatic liver tumors, as well as tumors in kidney, lung, bone, and adrenal gland tissue [1]. Since the introduction of RF ablation for tumor treatment, the inability to create large ablation zone volumes without multiple power applications has been a major limitation. While current commercial systems have allowed the creation of larger coagulation zones (4-6 cm) than initial systems (~1.5 cm) due in part to an increase in maximum generator power (250W vs 50W), recent studies have shown the possibility of obtaining even larger coagulation zones by using higher power levels (up to 1000W) [2, 3].

During RF ablation, dispersive electrodes (or "ground pads") serve as the return path for applied RF current. Current clinical systems typically employ two or four ground pads placed on both thighs connected in parallel to the RF generator. An important consequence of the use of increased power during RF ablations is the corresponding increase in current density (and thus heating) at the leading edge of ground pads, since current preferentially flows to the nearest edge of the most proximal pad(s) (the "leading edge effect") [4, 5]. The incidence of skin burns in recent studies ranges from 0.1 to 3.2 % for severe skin burns (2^{nd} or 3^{rd} degree) and from 5 to 33 % for 1^{st} degree burns[6-8]. However, two recent studies argue that the incidence of skin burns after RF ablation may be under-reported [8, 9].

To date, efforts to reduce ground pad burns have primarily focused on increasing total ground pad area by adding additional pads. However, further improvement to clinical grounding systems in this fashion is impractical because there is no available skin surface to place additional ground pads equidistant from the active electrode (a requirement due to the leading edge effect). Without modification to existing clinical grounding strategies, the incidence of skin burns during RF ablation procedures will likely increase as RF generator power continues to increase.

Two recent studies [10, 11] demonstrated in computer simulations and ex vivo gel phantom studies that in the case of three ground pads at different distances from the active electrode, sequential activation of collinear ground pad subsets leads to lower maximum temperatures at the ground pads than if all pads are connected simultaneously. The purpose of this *in vivo* porcine study is to evaluate the performance of a similar sequential activation algorithm in comparison to the grounding method in which all pads are activated simultaneously in an *in vivo* porcine model.

II. MATERIALS AND METHODS

Animals, Anesthesia, and Procedures

Preapproval for all animal experiments was obtained from the Institutional Animal Care and Use committee. A total of 9 domestic swine (mean weight ~47 kg) were used in this study. After anesthetization, two internally cooled cluster electrodes (Valleylab ACTC 1525, Boulder, CO) with an exposed length of 2.5 cm were placed in the animal's gluteus maximus (one cluster electrode on each side) approximately equidistant from the leading edge of the proximal ground pad. This placement provided similar distance between the proximal ground pad and active electrode as in clinical procedures. We used two simultaneously activated cluster electrodes because we found in preliminary experiments that one cluster electrode led to rapid impedance rises at the higher power levels (compared to current devices) used in this study. The cooling water circulated through the cluster electrodes was kept at ~0 °C during all procedures using an ice water bath.

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Three ground pads with integral leading-edge temperature sensors (Thermopads, Angiodynamics, Queensbury, NY) were placed collinearly on each animal's shaved abdomen such that the adhesive region of each pad abutted the adhesive region of the adjacent pad. For the purpose of our study, the proximal pad represented the two or four pads that are currently placed equidistant from the active electrode in clinical RF ablation procedures. The middle and distal pads represented the addition of ground pad area further from the cluster electrodes (since clinically there is no skin area available for additional equidistant ground pads) to accommodate higher power application; this would be analogous clinically to 6 or 12 total ground pads (3 pads on one or both sides of each thigh).

One RF ablation was performed per animal using one of the ground pad activation algorithms described in the Experimental Groups section. After each ablation was completed, the ground pads were removed and pictures were taken of any skin burns. After the animals were euthanized, the gluteal muscle tissues containing the ablation zones were excised and placed in 10% neutral buffered formalin for fixation.

Experimental Groups

A total of 9 ablations (one per animal) were performed in this study. In group 1 (control), 4 ablations were performed in which all three ground pads were activated simultaneously for the duration of the procedure. In group 2, 5 ablations were performed with sequential activation of subsets of the ground pads with the same applied power (300W) as in group 1 A diagram showing the activation cycle for the sequential algorithm used in group 2 is shown in Figure 1.

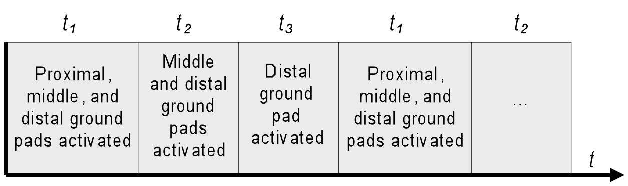

Figure 1: Timing diagram for sequential activation algorithm. During power application, skin heating occurs primarily at the leading edge of the activated ground pad that is nearest to the active RF electrode (ie, the proximal pad during t_1, the middle pad during t_2, and the distal pad during t_3).

Figure 2 shows a block diagram of the ground pad activation control system used in this study. A high-power RF generator (500W, PDX-500, AEI, Fort Collins, CO) supplied RF power at a frequency of 325 kHz. A custom program (Labview, National Instruments, Austin, TX) running on a laptop PC was used to ramp up the applied RF power from 50W initially to the set power over a period of 30 s, after which constant set power was applied for the remainder of each 12 min ablation. During power application, a data acquisition device (34970A, Agilent, Santa Clara, CA) continuously measured the applied RF voltage. The control program used this measured voltage and the applied power to calculate impedance and to implement an impedance control algorithm; if the calculated impedance exceeded 150% of the initially measured impedance at any point, the program turned off power application for 10 s, and reapplied power at 80% of the previous magnitude. In all groups, the temperature signals from the temperature sensors at the leading edge of each ground pad were filtered to reduce noise and recorded at a sampling rate of 100 Hz using a second data acquisition device (DAQCard-6036E, National Instruments, Austin, TX). The applied RF current was calculated by dividing the applied power by the applied voltage.

In the group 2 ablations, the control program continuously updated the activation time periods for each ground pad subset based on the temperatures recorded by the leading edge temperature sensors, with the goal of equilibrating temperatures at each pad. The switching between pad subsets was performed by a custom relay circuit, which interfaced with the control program via digital signals from the Agilent data acquisition device.

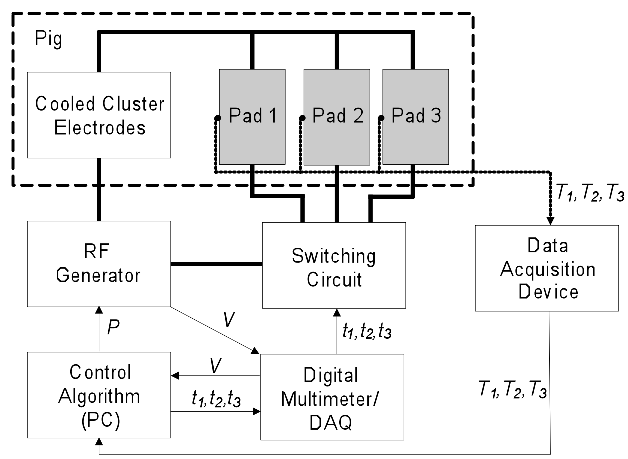

Figure 2: Diagram of ground pad activation control system. A control algorithm on the PC regulated the generator output power *P*. A digital multimeter/DAQ measured the applied voltage *V* and relayed it to the control algorithm for calculation of current and impedance. A second data acquisition device recorded the temperatures (T_1, T_2, T_3) at the leading edge of each ground pad. During the group 1 procedures, all 3 ground pads were activated for the entire ablation. During the group 2 ablations, the control algorithm adjusted the switching periods (t_1, t_2, and t_3) via the digital multimeter/DAQ to keep leading edge temperatures equal between pads.

Temperature rise analysis

The recorded temperature data from each procedure were analyzed to determine the temperature rise at each ground pad. The differences in average temperature rise were compared amongst the three pads using one-way ANOVA within each group, and the differences in average temperature rise for each pad between groups 1 and 2 were compared using Student's t-test. Statistical significance was designated as $p < 0.05$.

Ablation zone and RF current measurement
Ablation zone dimensions were determined via MR imaging of the fixed muscle samples orthogonal to the RF electrode. Imaging was performed using a 1.5T MR system (Magnetom Avanto, Siemens Medical Solutions, Erlangen, Germany). A plastic container including the fixed muscle samples was placed in a 4-element head matrix coil. Initial 3D gradient echo localizers were used to locate samples. Subsequently, high-resolution T2-weighted fast spin-echo imaging was performed. The scans were analyzed to determine the ablation zone maximum transverse diameter and axial diameter, with the extent of the "white zone" (hyperintense region in the MR images) demarcating the ablation zone boundary. A previous study comparing the extents of this region in MR images to histological results demonstrated that the former is effective in predicting the extent of necrosis during RF ablation [12]. Axial and maximum transverse ablation zone diameters were compared using Student's t-test. We also reported the measured current during each trial and impedance values measured 15 s after initial power application. Statistical significance was designated as $p < 0.05$.

III. RESULTS

Comparison of temperature rise
In group 1, the temperature rise at the leading edge of the proximal ground pad was significantly higher then the other two pads after 12 minutes (Table 1). In group 2, the temperature rise was not significantly different between the three pads (p=0.5). The temperature rise at the proximal pad was significantly higher in group 1 than in group 2, while the temperature rise at the middle and distal pads was significantly higher in group 2 than in group 1. The maximum temperature rise after 12 minutes was significantly higher in group 1 than in group 2 (21.4 vs 8.1 ºC).

Group	Proximal pad temperatures, °C		
	Initial	Final	Rise
1	32.2 ± 0.6	53.6 ± 4.2†	21.4 ± 3.6†
2	32.9 ± 0.5	41.0 ± 1.0*	8.1 ± 1.1**
	Middle pad temperatures, °C		
	Initial	Final	Rise
1	33.7 ± 0.4	35.3 ± 0.6†	1.6 ± 0.6†
2	34.0 ± 0.7	41.7 ± 1.1^{+}	7.7 ± 1.0^{+}
	Distal pad temperatures, °C		
	Initial	Final	Rise
1	33.7 ± 0.1	34.7 ± 0.5†	1.0 ± 0.3†
2	34.0 ± 0.6	41.2 ± 1.0^{+}	7.2 ± 0.9^{+}

Table 1: Measured temperatures at each ground pad after 12 min RF ablations. Note: Values are means ± standard deviations
* $p < 0.05$ (t-test vs. Group 1), ** $p < 0.01$ (t-test vs. Group 1)
$^{+}$ $p < 0.001$ (t-test vs. Group 1), † $p < 0.001$ (Group 1 ANOVA)

Comparison of measured electrical parameters and ablation zone dimensions
Resection of each ablation zone in its entirety was difficult due to the large size of the zones and the heterogeneity of muscle tissue. Therefore, we only included the measurements of 8 ablation zones (n = 4 for each group) in our statistical analysis. The average applied power was not different between group 1 and 2 (p=0.99). However, the RMS current applied in group 2 was significantly lower than in group 1. Correspondingly, the maximum transverse diameter of the group 2 ablation zones was also significantly lower than group 1 (5.6±0.3 vs 6.9±0.3, p< 0.01). However, there was no significant difference in the axial diameters of the ablation zones (5.6±0.8 vs 5.6±0.5). There was also no significant difference in initial impedance (with all 3 pads activated) between the two groups (p=0.79) (Table 2). An impedance rise was observed during power application in one case in both groups 1 and 2.

	I_{RMS} (A)	P (W)	Z, 3 pads (Ω)	Z, 2 pads (Ω)	Z, 1 pad (Ω)
1	3.4 ± 0.1	292 ± 3	32 ± 2^{+}	NA	NA
2	3.0 ± 0.1*	292 ± 7	30 ± 2^{+}	37 ± 3	45 ± 2

Table 2: Measured electrical parameters during 12 minute RF ablations
Note: Values are means ± standard deviations. All impedance values represent initial impedance (15 s).
* $p < 0.05$ (t-test vs. Group 1)
$^{+}$ $p = 0.79$ (t-test)

IV. DISCUSSION

Higher RF generator power will likely be required in future monopolar RF tumor ablation systems to create larger ablation zones that fully treat large tumors. Two recent studies showed that even with current commercial RF electrodes, larger ablation zones could be created if higher RF power was used [2, 3]. However, existing ground pad technology is currently a limiting factor for further increase in RF generator power for clinical tumor ablation devices. Potential methods to reduce skin heating include increasing the ground pad area, or - as employed in the current study – increasing the number of ground pads. We compared two methodologies of activating these additional pads: (1) simultaneous activation, in which all pads are continuously active, and (2) sequential activation via the algorithm shown in Fig. 3. While only 3 pads were used in this study, note that the results can be extended to multiple thighs as clinically used; ie three pads could be placed on each thigh and activated according to the algorithms described above.

In this study, we performed ablations with up to 300 W for 12 min, which is higher power than currently used clinically (200-250W). As may be expected, the simultaneous activation of three collinear ground pads (ie at varied distances from the active electrode) produced heating primarily at the most proximal ground pad, since the majority of applied current is still dispersed there. Therefore adding additional ground pad area further from the active electrode does not provide significant benefit over the currently clinically used arrangement if all of the pads are simultaneously activated. The goal of this study was to investigate whether the use of a sequential activation algorithm with this ground pad configuration could reduce skin heating during ablation in contrast with simultaneous activation.

The sequential activation algorithm resulted in considerably lower maximum skin temperature at the leading edge of the pads (Table 2). Leading edge temperatures at all three pads were successfully equilibrated in the group 2 ablations, whereas in the group 1 ablations only the proximal pad experienced significant heating (Table 2).

During the time periods when only one or two pads were activated with the sequential algorithm, the impedance increased (Table 2). This increase occurred because the distance between the cluster electrodes and the closest activated ground pad increased, and because the overall activated ground pad area was reduced. Therefore, since we applied constant power from the RF generator, less average current was applied in the group 2 ablations, resulting in smaller ablation zone transverse diameters (5.6 vs. 6.9 cm).

The limitations of this study include the reduced number of measurements obtained due to difficulties in excising the ablation zones, which may affect the accuracy of our comparisons.

V. CONCLUSION

The benefit of using multiple ground pads on each thigh during monopolar RF ablation was investigated via two different activation algorithms. While simultaneous activation provided little reduction of skin heating, sequential activation more effectively utilizes the additional pad area and considerably lowers skin temperatures. In addition, the sequential activation algorithm would eliminate the need to place all ground pads equidistant from the active RF electrode, since pad activation times are automatically adjusted to keep all pads at the same temperature. This method would therefore allow the placement of ground pads on currently unused areas of the patient's skin (eg back, or additional pads on thighs as in the current study), thereby reducing maximum skin temperatures and allowing the use of higher RF generator power.

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