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Reliability assessment of a cooled intraesophageal balloon to prevent thermal injury during RF cardiac ablation: An agar phantom study

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Introduction: The use of a cooled intraesophageal balloon has recently been proposed to minimize the risk of thermal injury in the esophagus during radiofrequency ablation of the left atrium. However, the capacity of this device to adequately protect the esophagus under different procedural and anatomical conditions remains unknown.

Methods and results: An agar phantom-based model was built which provided temperature readings not only on the cooled balloon (T_b) but also at a hypothetical point between the esophageal lumen and myocardium at a distance of 2 mm ($T_{2\text{-mm}}$). RF ablations were conducted considering two anatomical factors (total distance between electrode and balloon and flow rate around electrode) and two procedural factors (angle and pressure between electrode and agar surface). The results show that most of the parameters studied have no significant influence on the temperature measured on the cooled balloon (T_b), the exception being variation of the flow rate, which was found to influence temperature. On the other hand, $T_{2\text{-mm}}$ was affected to a great extent by all the factors considered, the smallest influence being contact pressure. The results also suggest that when an intraesophageal balloon is employed, applied power is not a good predictor either of temperature on the balloon or of the temperature measured 2 mm away.

Conclusion: The results suggest that a cooled intraesophageal balloon provides effective thermal protection of the esophageal lumen. However, under certain circumstances the temperature reached at 2 mm away could possibly put at risk the integrity of the inner layers of the esophagus.

agar model, atrial fibrillation, cooling balloon, esophagus, radiofrequency ablation

Introduction

Since the first case of esophageal injury during radiofrequency (RF) ablation of the left atrium was reported in 2003 [1], several solutions have been proposed, including lower values for power and target temperature programs [2], monitoring esophageal temperature [3;4], monitoring pain during ablation [5], real-time imaging of the esophagus [6], mechanical esophageal deflection [7] and using other power sources to ablate [8-10]. In 2005, the authors proposed the use of a cooled intraesophageal balloon to minimize the risk of thermal injury in the esophagus, and assessed its feasibility by means of computer modeling [11]. Tsuchiya et al [12] later carried out a pilot clinical study using this type of device and their results suggested that the balloon provided a reduction of the temperature recorded in the esophageal lumen. However, a more recent preliminary study using this device in a dog model did not find any protector effect against thermal injury [13].

The capacity of a cooled balloon to protect the esophagus during RF cardiac ablation under different procedural and anatomical conditions (e.g. distance between electrode and esophagus) therefore remains unknown, and needs to be assessed with greater accuracy. Accordingly, we built a model based on an agar phantom, which provides temperature readings not only on the cooled balloon but also at a hypothetical distant point, i.e. between the simulated esophageal lumen and endomyocardium [14]. We then conducted RF ablations under different anatomical and procedural conditions, and so assessed the protection provided by an intraesophageal cooling balloon under different conditions.

Methods

An experimental model was built based on an agar phantom as tissue-equivalent material [14;15]. This modeling technique facilitates the precise positioning of very small temperature sensors (e.g. micro-thermocouples), and achieves reproducible conditions between ablations. Details on the phantom construction can be found in Rodriguez et al [15]. Figure 1 shows a diagram of the experimental set-up, including a cooled water-irrigated intraesophageal balloon (RPC-9 Abdominal Pressure Catheter 9F, Life-Tech, Stafford, TX, USA) identical to that employed in previous experimental and clinical studies [12;14]. The balloon was filled with fluid cooled to 5ºC at a flow rate of 25 mL/min. A hydraulic circuit (see Fig. 1) was set up to simulate blood flow and consequently removed heat from the agar and cooled electrode surfaces during ablation. A Stöckert roller pump (Shiley, Irvine, CA, USA) was employed to re-circulate the saline solution from the bath, which irrigated the phantom surface and the ablation electrode by means of an 18 mm diameter tube located 25 mm from the ablation catheter [15].

The different factors considered were two anatomical factors: distance between electrode and balloon and cooling around the electrode, i.e. flow rate of the hydraulic circuit; and two procedural factors: angle of contact between electrode and agar surface and pressure of the electrode on the agar surface. The control parameters were: distance of 6.5 mm between electrode tip and balloon surface (D = 2 mm in Fig. 1), catheter perpendicular to the surface of phantom (Φ = 90º), zero pressure applied on ablation catheter (P = 0 g), and a flow rate (F) in the hydraulic circuit to simulate blood flow of 1 L/min. The values of these parameters were varied as required to study the effect of each one on the temperature recorded on the esophageal cooled balloon (T_b in Fig. 1) and at a distance of 2 mm from the balloon ($T_{2\text{-mm}}$ in Fig. 1).

A methacrylate scaffold was designed to place the catheter axis precisely at a given angle to the phantom surface (Φ). Ablation experiments were conducted at angles of 90º, 45º and 0º. In all cases the tip of the ablation catheter was placed on the phantom surface at the intersection with the model axis (see Fig. 1). As Φ was reduced, the surface contact between electrode and agar scarcely increased, but this was obviously an inherent consequence, and hence was not quantified in any way. The scaffold also permitted a study of the influence of the pressure of the electrode on the agar surface by means of an extra weight (P) fixed to the catheter. Two values were considered: no extra weight (P = 0 g, control case) and P = 20 g. Increasing the pressure between electrode and agar induces penetration of the electrode into the agar (considered as ≈1 mm). The influence of flow rate (F) was studied at three different values: 0.5, 1.0 and 1.5 L/min. Finally, the effect of the distance between electrode tip and esophageal lumen was studied by building new phantoms in which the total distance between electrode tip and balloon surface was 4.5 mm (D = 0 mm in Fig. 1). In all the experiments, cooling was initiated inside the intraesophageal balloon two minutes prior to ablation, which is considered to be the optimum protocol [14].

Ablations were conducted with a Blazer II 7Fr/4 mm ablation catheter (Boston Scientific, Natiok, MA, USA). An ablation generator EPT-1000XP (EP Technologies, Sunnyvale, CA, USA) was utilized to deliver RF power between the ablation electrode and a 20×20 cm metallic plate located on the bottom of the bath. A constant temperature of 55ºC was programmed at the electrode tip, while limiting output power to 50 W. The duration of each ablation was 120 s in all the experiments. At the end of each ablation, the values of mean power delivered for the ablation period were recorded.

Ten ablations were conducted for each group and the analyzed variable was always the final temperature. We first checked that population distributions were normal (Shapiro-Wilk test) and then calculated the sample mean and constructed 95% confidence intervals for each variable, in order to compare the different groups graphically. In Figure 2, which contains the results, bars represent the final temperature mean and the error bars show 95% confidence intervals. This allows a straight statistical comparison between variables. The data in the text are expressed as mean ± standard deviation. The statistical analyses were performed with SPSS version 12.0 software (SPSS, Chicago, IL, USA).

Results

The protective effect of the intraesophageal cooling balloon was studied under different simulated conditions by varying anatomical and procedural factors. The studied variables were the final temperature reached at the two points mentioned above. Figure 2 shows the final temperature measured at T_b and $T_{2\text{-mm}}$ for the different cases considered. We observed that, in general, all the factors studied affected the temperatures measured at both points (T_b and $T_{2\text{-mm}}$), the effect being more pronounced at $T_{2\text{-mm}}$. This was obviously due to the distance from the cooling source.

Procedural factors: angle and pressure between electrode and agar surface

The first procedural factor assessed was the angle between electrode and agar. Reducing Φ from 90º to 0º produced an increase in both measured temperatures and applied mean power. When the angle was varied between 0º and 90º, the differences were always greater at $T_{2\text{-mm}}$ (≈11ºC) than T_b (≈4ºC). The decrease in temperature was only significant at $T_{2\text{-mm}}$ (see Fig. 2A) with values of 62.7±2.5ºC for Φ = 0º and 51.0±1.8ºC for Φ = 90º ($P < 0.05$). The applied mean power value significantly increased for Φ = 0º (38.0±2.7 W), differences between angles of 90 and 45º not being significant.

On the other hand, adding a 20 g weight to the catheter produced a slight decrease of the temperatures (see Fig. 2B) from 40.5±1.8ºC to 38.6±1.5ºC for T_b (not significant) and from 51.0±1.8ºC to 48.8±1.4ºC for $T_{2\text{-mm}}$ ($P = 0.05$). In this situation, the temperature sensor is buried in the agar, and is hence thermally protected from the cooling flow. This was evident by comparing the applied mean power in each case: 25.3±2.5 W for the no extra weight case (control) compared to 9.5±2.4 W for the weighted case (see Table 1) ($P < 0.05$). Here, wide variations in applied power did not cause much change in the temperature readings at either point.

Anatomical factors: flow rate and electrode-esophagus distance

Regarding the anatomical factors, the flow rate showed a significant effect on the temperatures recorded at both points. Briefly, the higher the convective cooling effect (due to higher flow rate), the higher the temperatures measured at a distance. Figure 2C shows that when flow rate was increased from 0.5 to 1.5 L/min the value of T_b significantly increased from 36.9±1.3ºC to 42.6±1.5ºC ($P < 0.05$), and $T_{2\text{-mm}}$ increased from 44.6±1.5ºC to 56.6±1.8ºC ($P < 0.05$). Likewise, the applied mean power also significantly increased from 25.8±3.8 W to 38.0±3.5 W (see Table 1) when flow rate was augmented.

Finally, as is shown in Fig. 2D, reducing total distance between the cooled balloon and electrode tip from 6.5 mm to 4.5 mm did not significantly affect T_b (42.2±1.8ºC vs. 43.2±1.9ºC). In contrast, $T_{2\text{-mm}}$ did increase significantly from 52.4±1.7ºC to 61.3±1.8ºC ($P < 0.05$) when the distance was reduced. In addition, no significant difference in applied mean power was observed between both distances (27.6±2.9 W vs. 28.3±2.8 W, see Table 1).

Differences between temperatures to prevent esophageal injury

We also measured (or estimated) the T_b values associated with a $T_{2\text{-mm}}$ value of 50ºC. Since it is possible to measure temperature inside the esophageal lumen (or on the balloon surface) in a clinical situation, but not 2 mm away, these values of T_b might provided useful information during ablation. Table 2 shows the difference between temperatures (i.e. T_b - $T_{2\text{-mm}}$) when $T_{2\text{-mm}}$ reaches 50ºC.

Discussion

The objective of our experimental study was to assess the reliability of a cooled balloon in avoiding thermal injury to the esophagus during RF catheter ablation under different simulated anatomical and procedural conditions. In general, our results suggest that the thermal protection offered by an intraesophageal cooled balloon could be effective, although it could fail under certain unfavorable anatomical and procedural conditions.

The intraesophageal cooling balloon with a coolant temperature of 5ºC gives adequate control of T_b and avoids hyperthermia (>45ºC) under most of the situations studied. The most important influence on T_b is flow rate. In fact, conditions of high flow rate cause T_b to rise, even when a cooled balloon is used. In contrast, $T_{2\text{-mm}}$ was always affected by varying the factors. Temperature measured at 2 mm was sometimes over 50ºC with certain anatomical and procedural factors. Electrode-agar pressure was the factor with least effect on $T_{2\text{-mm}}$.

In our study, the only factor that brought about a significant change in T_b was a variation in the flow rate. In particular, an increase in the convective cooling effect (i.e. flow rate) caused a sharp rise in the temperature readings. This is in total agreement with results recently obtained by Pilcher et al [16] in an ex vivo study using a large-tip catheter (10 mm). Form a clinical point of view, this result suggests that esophageal temperature could be significantly influenced by the flow rate at the target point, e.g. posterior left atrial wall vs. ostium of the pulmonary vein. In fact, Tangwongsan et al [17] found very different values of thermal convection coefficient in the inner atrium for different anatomical locations.

The anatomic distance between esophagus and electrode has been shown to be related to the increase in the esophageal temperature and thus with the risk of thermal injury [18;19]. However, one case of esophageal heating associated with an apparently long electrode-esophagus distance of 16 mm was also reported [4]. The discrepancy between the studies could be due to the effect of procedural and anatomical factors such as those considered in our study. Our findings suggest that when an intraesophageal cooling system is applied, the temperature in the esophageal lumen (T_b) of the simulated esophagus can be adequately controlled, even at short electrode-esophagus distances. Unfortunately, our results also suggest that with very short anatomic distances, $T_{2\text{-mm}}$ could rise higher than 50ºC, even when using a cooled balloon.

Our results also showed that increasing Φ from 0º to 90º caused a significant drop in

$T_{2\text{-mm}}$, and a significant decrease of the applied mean power. However, Φ has little effect on T_b. These results suggest that a very low Φ value (i.e. an electrode at a more acute angle) could produce temperatures >50ºC at 2 mm from the esophageal lumen, which could cause thermal injury to the inner layers of the esophagus. However, we also think that these results might be partially influenced by the type of ablation electrode used, and especially by the location of the temperature sensor inside the electrode. In our study, the temperature sensor consisted of a small thermistor exposed to the surface of the electrode tip, and thermally insulated from the surrounding metallic electrode by a plastic sleeve [20]. It is known that when this type of electrode is used, the thermistor must be in firm contact with the tissue to obtain accurate temperature readings [21]. In our case, smaller angles (between 0º and 45º) meant that the thermistor not only was out of contact with the agar, but was also exposed to the circulating coolant flow (flow direction was perpendicular to the catheter axis). This made the thermistor register readings considerably lower than the maximum temperature reached in the agar, and the generator therefore had to deliver much higher power (see Table 1). This higher applied mean power produced higher temperatures than in the case of the 90º angle, in which the thermistor was firmly in contact with the agar and partially protected from the convective cooling effect.

Increasing the electrode-agar pressure caused a slight drop in the measured temperatures (not significant at T_b). This could have been at least partially caused by the significant drop in the applied mean power (25.3 W versus 9.5 W). This phenomenon has been previously observed [22], and is due to lighter pressure of the electrode on the tissue causing greater convective heat loss to the circulating coolant. However, we are of the opinion that increasing the electrode-agar pressure could have two opposite effects on the temperature reached at depth. On one hand, the resultant loss of cooling effectiveness on the electrode induces lower applied power, and hence lower temperatures at depth. But, on the other hand, when the electrode tip penetrates into the tissue, the location of the hottest point (located ≈1-2 mm from the tip) inside the agar is shifted, and hence gives higher temperatures at depth.

It is also interesting to assess the relationship between applied mean power and the rise of temperature on the balloon for the different parameters considered in this study. The value of T_b could correspond with the intraluminal esophageal temperature measured in a clinical set-up, even though our study included a cooled balloon. We consider that our experimental results could partially explain the lack of correlation previously found between of the rise in esophageal temperature (i.e. T_b) and applied power [18]. In particular, we observed one case in which a significant increase in power was accompanied by a significant increase in T_b (increase of flow rate), two cases in which a significant variation in power did not involve any significant change in T_b (either in angle or pressure), and finally another case in which neither power nor T_b significantly varied (total distance). Similar conclusions can be reached by considering the relationship between power and $T_{2\text{-mm}}$. Our results therefore suggest that applied power is not a good predictor either of esophageal temperature or of the temperature measured 2 mm away, and so could not be used as a control parameter for intraesophageal cooling. These results would probably be different if a constant-power mode was employed. Even though the constant-temperature mode is widely employed in clinical practice, some authors have proposed its use in critical situations when atrium and esophagus are very close, with 30 W as the power limit [23;24]. Experience seems to demonstrate that this is a safety mode, although we do not know if it is still safe under adverse conditions such as short electrode-esophagus distance, or high cooling rates around the electrode. It will probably be necessary to conduct studies to compare both modes under adverse clinical conditions.

Table 2 shows the difference between $T_{2\text{-mm}}$ and T_b when $T_{2\text{-mm}}$ reaches 50ºC. The results indicate that for any given case, this difference is between 10 and 15ºC, which is a fairly limited range. Consequently, the results suggest that to prevent thermal lesion in the deeper layers of the esophagus (i.e. at 2 mm from the lumen), the ablation should be terminated when temperature measured on the balloon surface reaches a threshold value between 35 and 40ºC (the initial temperature on the balloon surface after 2 minutes pre-cooling and before ablation is ≈33ºC [14], which would imply an increase of just 2ºC). Obviously, this conclusion is only valid for the cases considered in this study and a combination of adverse circumstances (e.g. high flow, short distance, acute angle) would probably imply lower threshold values.

This study has important limitations. The first is associated with the use of an agar model and its inherent tissue characteristics. It is known that the composition of the tissue between the atrium and esophagus is very heterogeneous. The second involves the importance of taking into account the possibility of serious histopathology, such as very enlarged atria. Thirdly, the parameters were varied independently, i.e. we did not consider a highly adverse situation involving a combination of short distance, high flow rate, an acute angle and high pressure. Fourthly, we only considered a dry electrode in the study, and hence no conclusions can be obtained about the behavior of irrigated electrodes (also employed in RF ablation). However, we think that their use might be comparable to a condition of higher flow rate, as observed in our study. In this respect, the use of irrigated electrodes could increase the risk to the esophagus, but this hypothesis would have to be validated in future studies. Finally, it is also necessary to remember the fact that performing the procedure with multi-segmented electrodes may not produce only one focal lesion, as modeled in this study, but also numerous other lesions throughout the esophageal wall.

Conclusions

The results show that the parameters studied (total distance, flow rate, angle between electrode and agar surface, and contact pressure) have in general little influence on the temperature recorded on the cooled balloon (T_b). This suggests that the use of a cooled balloon provides effective thermal protection of the esophageal lumen, with the possible exception of a variation of the flow rate, which could make the temperature rise to over 50ºC, even when using a cooled balloon. On the other hand, the temperature 2 mm away from the esophageal lumen ($T_{2\text{-mm}}$) was significantly affected by all the factors considered. The influence of contact pressure minor. In fact, under certain circumstances, such as short esophagus-electrode distance, when the electrode was placed at an acute angle to the tissue, or high flow rates, the temperature reached values that could risk the integrity of the inner layers of the esophagus (e.g. muscular). Finally, they also suggest that when an intraesophageal balloon is employed, applied power is not a good predictor either of esophageal temperature or of the temperature measured 2 mm away.

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Table 1. Mean power delivered for 2 minutes of RF ablation for different values of anatomical factors (total distance between catheter and balloon surface –TD–, and flow rate –F–) and procedural factors (angle between catheter and agar –Φ–, and pressure catheter-agar –P–). C.I.: Confidence interval.

Anatomical and procedural factors		Applied mean power (W)	
		Mean	95% C.I.
Φ	0º	38.0	1.0
	45º	33.0	1.8
	90º	30.2	2.0
TD	6.5 mm (D = 2 mm)	27.6	2.1
	4.5 mm (D = 0 mm)	28.3	2.0
F	0.5 L/min	25.8	2.7
	1.0 L/min	31.8	2.6
	1.5 L/min	38.0	2.5
P	0 g	25.3	1.8
	20 g	9.5	1.7

Table 2. Difference (ΔT) between temperature measured at 2 mm from the surface of the cooling probe ($T_{2\text{-mm}}$) and on the cooling balloon (T_b) at the time when $T_{2\text{-mm}}$ reaches 50ºC ($t_{50ºC}$). Data shown for different values of anatomical factors (total distance between catheter and balloon surface –TD–, and flow rate –F–) and procedural factors (angle between catheter and agar –Φ–, and pressure catheter-agar –P–). Data were obtained from time-course of temperatures from ablation. Data represent mean ± 95% confidence interval. * Extrapolated data due to $t_{50ºC}$ being > 120 s.

Anatomical and procedural factors		ΔT (ºC)	$t_{50ºC}$ (s)
Φ	0º	15.0 ± 1.4	38 ± 9
	45º	13.5 ± 3.2	48 ± 8
	90º	10.4 ± 0.6	90 ± 15
TD	6.5 mm (D = 2 mm)	10.0 ± 1.0	77 ± 25
	4.5 mm (D = 0 mm)	13.2 ± 1.1	39 ± 11
F	0.5 L/min	11.0 ± 0.5 *	600 ± 120 *
	1.0 L/min	9.5 ± 1.2 *	130 ± 27 *
	1.5 L/min	12.2 ± 0.8	51 ± 10
P	0 g	10.5 ± 1.2	90 ± 19
	20 g	11.0 ± 1.1 *	180 ± 30 *

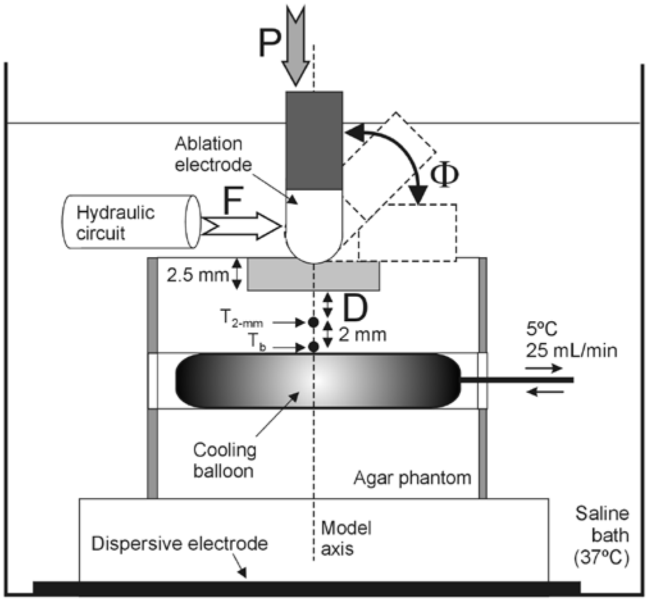

Figure 1 Schematic side view (not to scale) of experimental set-up. The agar phantom (50 mm external diameter) included a cavity (10 mm diameter) to contain the cooling balloon, and temperature sensors on the balloon (T_b) and at a distance of 2 mm ($T_{2\text{-mm}}$). The phantom also included a compartment, 20×20×2.5 mm, placed at top center in the phantom, in which agar fragments of equal dimensions (gray rectangle) were replaced after each ablation (since the agar zone closest to the RF electrode often melted during ablation). The phantom was submerged in a saline bath maintained at 37ºC. A hydraulic circuit simulating blood flow inside the heart was used. We also assessed the effect of varying the following parameters: weight of catheter on the agar (P), flow rate (F) of the hydraulic circuit modeling blood flow, distance between electrode tip and esophageal lumen (by changing distance D), and angle between catheter axis and agar surface (Φ).

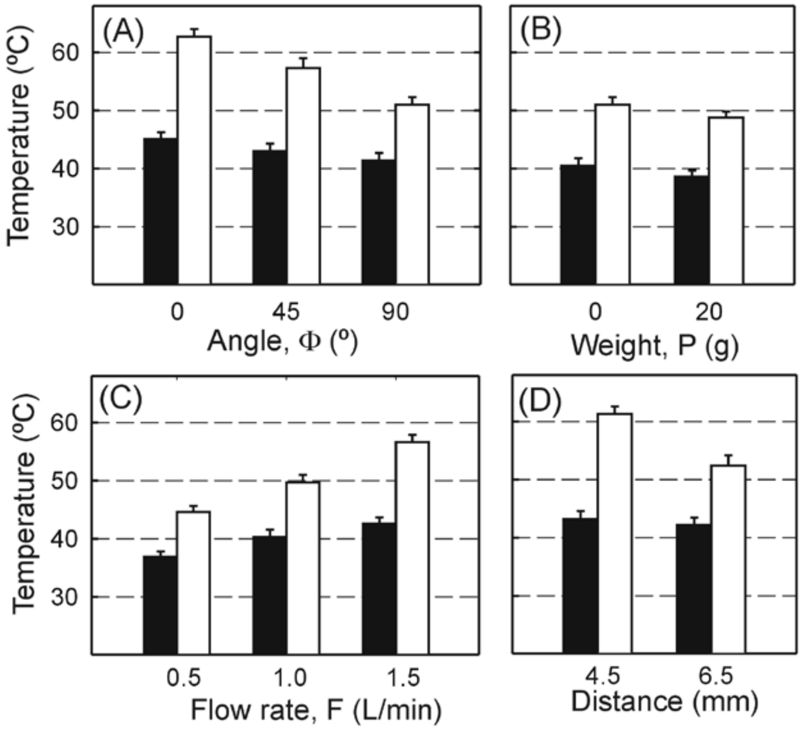

Figure 2 Final temperature measured at 2 mm from the surface of the cooling probe ($T_{2\text{-mm}}$, white bars) and on the cooling balloon (T_b, black bars) for the different cases considered. Ten ablations of 120 s and 55ºC target temperature were conducted for each group. The control parameters were: distance of 6.5 mm between electrode tip and balloon surface (D = 2 mm in Fig. 1), catheter perpendicular to the surface of phantom (Φ = 90º), no extra weight applied to the ablation catheter (P = 0 g), and flow rate F = 1 L/min. Bars represent mean of final temperature and error bars 95% confidence intervals.