Cooled intraesophageal balloon to prevent thermal injury during endocardial surgical radiofrequency ablation of the left atrium: a finite element study

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Short title: Cooled intraesophageal balloon for safe RF atrial ablation

Abstract

Recent clinical studies on intraoperative monopolar radiofrequency ablation of atrial fibrillation have reported some cases of injury to the esophagus. The aim of this study was to perform computer simulations using three-dimensional finite-element models in order to investigate the feasibility of a cooled intraesophageal balloon appropriately placed to prevent injury. The models included atrial tissue and a fragment of esophagus and lung linked by connective tissue. The lesion depth in the esophagus was assessed using a 50 ºC isotherm and expressed as % of thickness of the esophageal wall. The results show that: 1) chilling of the esophagus by means of a cooled balloon placed in the lumen minimizes the lesion in the esophageal wall compared to cases in which no balloon is used (collapsed esophagus) and with a non-cooled balloon; 2) the temperature of the cooling fluid has a more significant effect on the minimization of the lesion than the rate of cooling (thermal transfer coefficient for forced convection); and 3) pre-cooling periods previous to RF ablation do not represent a significant improvement. Finally, the results also suggest that the use of a cooled balloon could affect the transmurality of the atrial lesion, especially in cases where the atrium is of considerable thickness.

1. Introduction

Recent studies on intraoperative monopolar radiofrequency ablation (IRFA) of atrial fibrillation (AF) have reported some cases of thermal injury to the esophagus (Doll *et al* 2003, Gillinov *et al* 2001, Hornero *et al* 2004, Sonmez *et al* 2003). This complication has often resulted in an atrioesophageal fistula, and although the incidence is only 1% (Gillinov *et al* 2001), has even provoked the death of the patient in several cases. In order to minimize this risk, new technologies are now being proposed, such as bipolar electrodes (Gaynor *et al* 2004) and the use of other energy sources (cryoablation, ultrasound, microwave) (Misaki *et al* 2004). Several factors have been proposed as a possible cause of esophageal thermal injury (Lemola *et al* 2004), but have not been experimentally studied. Recently, a modeling study has assessed the effect of different factors on the temperature distribution in the esophagus during IRFA of the left atrium (Berjano and Hornero, 2005). The results showed that the electrical power directly applied to the esophagus is insignificant and hence the esophageal injury is exclusively due to thermal conduction from the atrium. In fact, the esophageal lesion is mainly influenced by the thickness of connective tissue between atrium and esophagus. Bearing this key result in mind, we propose a new system for minimizing the esophageal lesion during IRFA. This consists of a balloon with internal cooling which is situated in the esophagus lumen next to the atrial lesion. In this paper, as the first step in the development of this new device, we performed computer simulations using theoretical models in order to investigate its feasibility.

2. Methods

2.1. Geometric description of the theoretical models

During IRFA for AF suppression, electrical current ($\approx$500 kHz) flows between an active electrode applied by the surgeon to the atrial tissue and a large dispersive electrode located on the patient's back. In our model, we considered a 7F, 12.5 mm active electrode of stainless steel similar to those currently used in cardiac surgery. In order to assess the feasibility of the cooled balloon, we constructed two theoretical models. Figure 1 shows a MRI cross-section with the physical situation considered in this modeling study (left atrium, esophagus and lung). Figure 2 shows the proposed theoretical models. The first model represents an ablation procedure with no balloon (Fig. 2a) with a collapsed esophagus (3 mm wall thickness, 0.1 mm lumen filled of bolus or refluxate material, and a major side of 30 mm). In contrast, the second model (Fig. 2b) represents an ablation procedure with an inflatable balloon placed in the esophagus lumen. In this case, the distended esophagus also has a wall thickness of 3 mm, an outer diameter of 11.7 mm and an inner diameter of 8.7 mm. The balloon was modeled as a layer of thickness zero and infinite electrical resistance. We considered two characteristics of the balloon directly related to the cooling mechanisms: the temperature of the cooling fluid (T_f), and the thermal rate of cooling (forced heat convection). This second parameter was taken into account using a thermal transfer coefficient ($h_{BALLOON}$).

Both models represent an active electrode (stainless steel) with a section of plastic probe (polyurethane), a fragment of the atrial tissue of thickness A, esophagus, deflated lung and connective tissue between organs. A third of the surface of the probe is inserted

into the atrial tissue. The region under study has two symmetry planes, hence only one quadrant of the whole model was considered for computational analysis.

Table 1 shows the values of the physical characteristics used in the model (Chato, 1985, Gabriel *et al* 1996, Diller *et al* 2000, Al-Zaben and Chandrasekar 2005, Berjano and Hornero 2004). We considered a change in the electrical conductivity of biological tissues with temperature of +1.6 % ℃$^{-1}$ (Bhattacharya and Mahajan 2003). We also considered a change in the thermal conductivity of the tissues with temperature of +0.0014 K^{-1} (Diller *et al* 2000).

In this study, and as a result of previous modeling work (Berjano and Hornero 2005), we considered the theoretical worst anatomical case in order to study the effect of the cooled balloon on the esophageal lesion. This case is characterized by: minimum value of atrial thickness, A=1.3 mm (Ho *et al* 1999, Lemola *et al* 2004); minimum connective tissue thickness, C=2 mm (equivalent to the distance between the atrial wall and esophagus); and non-fat layer joined to the atrial epicardium. Secondly, in order to assess whether the use of a cooled balloon could have a negative affect on the success of a transmural lesion in the atrial tissue, we considered a case with unfavorable anatomical conditions characterized by a thick atrium of value A=3.1 mm.

2.2. Numerical method and boundary conditions

The temperature distributions in the tissues were obtained by solving Laplace's equation and the Bio-heat equation which govern thermal phenomena during radiofrequency (RF) heating of biological tissues. The ANSYS program (ANSYS Inc., Canonsburg, PA, USA) was used for all the simulations. The temperature for the surfaces away from the active

electrode was initially assumed to be 32 ºC, modeling the moderate hypothermia experienced during an endocardial ablation in cardiac surgery. Likewise, an initial temperature of 32 ºC was considered in all the tissues. A value of 21 ºC was used for the ambient temperature. The effect of free heat convection in the atrium-ambient and electrode-ambient interfaces were taken into account using a thermal transfer coefficient of value 20 W m^{-2} K^{-1}. We modeled a constant–temperature ablation protocol such as those found in conventional cardiac ablation systems. The value of the electrical voltage on the active electrode was modulated during the heating in order to maintain the edge of the electrode at a temperature value equal to the target temperature $\pm$ 1.5 ºC (sampled each 2 s) (Jain and Wolf 1999). This edge zone corresponds to the typical location of the temperature sensor. In all the simulations, the target temperature was reached in the first 20 s. The electrical voltage on the dispersive electrode was fixed at zero volts. We applied zero electric flux at all the other outer boundaries of the model. To study the efficacy of the cooled balloon in minimizing the esophageal lesion, we conducted computer simulations programming a target temperature of 80 ºC and an ablation duration of 120 s. Subsequently, to assess the effect of the cooled balloon on the transmurality of the atrial lesion, we considered a target temperature of 60 ºC and a ablation duration of 60 s. The typical values used in cardiac surgery are around 80 ºC and 120 s (Chiappini *et al* 2003, Sonmez *et al* 2003, Hornero *et al* 2004, Benussi *et al* 2002).

The outer dimensions (X, Y and Z in Fig. 2) were calculated by means of a sensitivity analysis in order to avoid boundary effects. A convergence test was performed to obtain the adequate spatial and temporal resolution. The value of the maximum temperature

achieved in the tissue was used as a control parameter in all the analyses (more details can be found in Berjano and Hornero 2004).

2.3. Characterization of thermal injury

Since myocardial injury occurs when the temperature reaches approximately 50 ºC (Nath *et al* 1993), previous theoretical models for radiofrequency ablation have assessed the lesion geometry using the 50 ºC isotherm. Nevertheless, it is known that tissue damage is a function of both temperature and time. For this reason, the damage model has recently been implemented using the Arrhenius equation (Chang and Nguyen 2004). However, Haemmerich *et al* (2003) have reported that the use of the isotherm to determine the dimensions of lesions produces errors for treatment times below 30 s in radiofrequency cardiac ablation. In our study, since the heating times were always above 30 s, we considered the 50 ºC isotherm as the lesion marker in all the computer simulations. The esophageal thermal injury was assessed by reporting the lesion depth in the esophageal wall. This value was expressed as % of thickness of the esophageal wall, i.e., a value of 100 % corresponds to the lesion reaching the esophageal lumen. On the other hand, the atrial lesion was reported using the minimum value of the lesion depth along the trajectory of the electrode (see Fig. 3), since we were only interested in continuous lesions.

3. Results

3.1. Construction of the theoretical model

Sensitivity analyses were conducted and optimum outer dimensions gave X = Y = 30 mm,

and Z = 60 mm. The convergence test provided a grid size of 0.3 mm in the finest zone (atrial tissue–active electrode interface), a step time of 0.5 s during the first 60 s and a step time of 1 s for the remaining time. The finite element models had nearly 14500 nodes and used over 75000 tetrahedral elements.

3.2. Effect of the balloon on the esophageal lesion

Figure 4 shows the temperature distributions after 120 s for the worst anatomical case, with a target temperature of 80 ºC, under two different sets of conditions: collapsed esophagus without balloon (Fig. 4a) and distended esophagus with balloon (T_f = 32 ºC; $h_{BALLOON}$ = 2000 W m^{-2} K^{-1}) placed in the lumen (Fig. 4b). The results indicate that the use of a cooled balloon significantly reduces the esophageal lesion. To be more precise, the lesion depth in the esophagus decreased from 100 % for the non-balloon case to 52 % for the cooled-balloon case. This decrease, which is due to the cooling on the internal surface of the esophagus, is also visible in the flatness of the isotherms in the connective tissue (Fig. 4b). Moreover, under these conditions, it can be observed that the lesion geometry in the atrial tissue does not vary substantially when a cooled balloon is employed.

3.3. Effect of the balloon on the transmurality of the atrial lesion

We used the theoretical models to assess the effect of the insertion of a cooled balloon on the transmurality of the atrial lesion. In this part of the study we considered a cooled balloon with T_f = 15 ºC and $h_{BALLOON}$ = 8000 W m^{-2} K^{-1}. We compared two cases with different ablation conditions.

- Case A: the most unfavorable conditions for achieving a transmural lesion in the atrial tissue, i.e. thick atrium A = 3.1 mm, target temperature of 60 °C, and a short ablation of 60 s duration. When these conditions were simulated in a model with no balloon (collapsed esophagus), the transmurality of the atrial lesion was reached at 60 s. However, in the case of the cooled balloon, the minimum lesion depth in the atrium (AL in Fig. 3) was only 50 % at 60 s.

- Case B: the most favorable conditions for achieving a transmural lesion, which are simultaneously the most favorable conditions for damaging the esophagus, i.e. thin atrium A=1.3 mm, target temperature of 80 °C, and duration of 120 s. In this case, ~~the~~ transmurality was reached at $\approx$ 9 s with and without a cooled balloon.

3.4. Effect of the balloon characteristics

We considered the two balloon characteristics directly related to the cooling mechanisms: the temperature of the cooling fluid (T_f), and the thermal rate of cooling (quantified by means of the value of $h_{BALLOON}$). Then, we studied simultaneously the effect of the two parameters on the esophageal lesion. Computer simulations were conducted with the worst anatomical case and the following ablation parameters: target temperature of 80 °C, and duration of 120 s. We considered three values for the temperature of the cooling fluid: 32, 25 and 15 °C; and four values for $h_{BALLOON}$: 20 (non-cooled balloon), 2000, 4000 and 8000 W m^{-2} K^{-1}. Figure 5 shows the lesion depth in the esophagus at 120 s for these values. The results show firstly that in the case of the non-cooled balloon, the esophageal lesion is similar to the case with no balloon, and moreover, the value of T_f has no perceptible

influence. Secondly, in the cases of the cooled balloon ($h_{BALLOON} \geq 2000$ W m^{-2} K^{-1}) the value of T_f has a very significant effect on the capacity for minimizing the esophageal lesion, in fact the lesion depth was reduced from ≈ 50 % to ≈ 25 % when T_f was decreased from 32 ºC to 15 ºC. Conversely, the effect of increasing $h_{BALLOON}$ from 2000 to 8000 W m^{-2} K^{-1} was almost negligible (the lesion depth was reduced by less than 5 %).

3.5. Effect of the pre-cooling period

In order to improve the capacity of the cooled balloon for minimizing the esophageal lesion, we conducted computer simulations with pre-cooling periods of 30, 180 and 360 s. In this part of the study we also considered the worst anatomical case and a balloon with T_f = 15 ºC and $h_{BALLOON}$ = 8000 W m^{-2} K^{-1}. Table 2 shows the characteristics of the lesions created in the esophagus after 120 s of ablation using different pre-cooling periods. Figure 6 shows the temperature distributions in the tissues at different times for an ablation of 120 s using a pre-cooling period of 360 s. Throughout a pre-cooling period of 6 minutes and just before RF ablation, the temperature of atrial tissue (assessed at the location of the temperature sensor) fell from 32 ºC to 20.8 ºC. However, this fact had no significant influence either on the depth of the esophageal lesion after ablation or on the time necessary to achieve a transmural lesion in the atrial tissue. The same effect was observed for pre-cooling periods of lesser duration.

4. Discussion

4.1. Viability of the cooled balloon

The objective of this theoretical study was to assess the viability of a new device for preventing thermal injury to the esophagus during intraoperative radiofrequency ablation of the left atrium. Our computer results suggest that this type of device could be an appropriate option to achieve this objective. The results indicate that the temperature of the cooling fluid has more effect on the minimization of the esophageal lesion than its rate of cooling. The computer results also suggest that in the presence of an atrium of considerable thickness, and when a short duration and a low target temperature are programmed, the use of a cooled balloon could reduce the possibilities of achieving a transmural lesion in the atrium.

Regarding the use of pre-cooling periods, the results suggest that they do not represent a notable improvement. This was probably due to the use of a constant-temperature protocol, which compensates the pre-cooling of the atrial tissue by delivering greater RF energy in order to reach the pre-selected target temperature in the first 20 s of ablation. Consequently, we consider that the pre-cooling of the esophagus neither offers a significant benefit nor has a significant influence on the atrial lesion.

4.2. Limitations of the theoretical model

The proposed cooled balloon model corresponds to a first approximation, e.g. we did not take into account the real thickness of its outer membrane. Also, we considered the ideal mechanism for removing heat from the internal surface of the esophagus. In this respect, if a balloon were to be used under actual conditions the situation could be different. In spite

of these limitations, this modeling study allowed us to obtain a first assessment of the possibilities of the proposed device. On the other hand, our results are based on a model under hypothermic conditions (32 ℃). The results would probably be different under normothermic conditions (36 ℃) or with circulating blood around the electrode (percutaneous catheter ablation).

This modeling study has not considered the possibility of a decrease in the distance between esophagus and atrial wall by the introduction of the balloon as there is no existing case report confirming this phenomenon. In fact, we think it more plausible to consider that the atrial lumen becomes convex and maintains the thickness of the connective tissue between esophagus and atrium. However, this would be a suitable subject for a future experimental and clinic model.

The accurate characterization of the esophageal lesion is a very difficult task in a modeling study. Firstly, no data on the esophagus are available to implement a tissue damage model using the Arrhenius equation (Chang and Nguyen 2004), especially taking into account the dissimilar layers of the esophagus (mucusa, submucusa, muscularis externa and adventitia). In the second place, there are no data on the electrical and thermal characteristics of these layers of the esophagus. We think that only an experimental study focused on histological aspects could correctly quantify this lesion. For this reason, in this modeling study, the 50 ℃ isotherm line was used as a marker for assessing the efficacy of the cooled balloon, and consequently, a decrease in the depth of this isotherm was considered favorable.

4.3. Technological impact

To date, some devices based on catheters or probes have been proposed for transferring heat in body cavities (Vasu 1999, Mori 2003). Vasu (1999) proposed a probe for prevention and treatment of hypothermia during a surgical procedure. The probe is directly introduced into the esophagus, adjacent to the aorta and the posterior heart wall. It has two lumens for supplying and returning a heat exchange media (preferably a liquid kept at a pre-selected temperature ranged from 37 ºC to 41 ºC). Mori (2003) also proposed a catheter for cooling/warming several organs (included the esophagus), in order to treat disease or injury. Likewise, Dobak and Lasheras (2001) proposed an inflatable catheter for selectively heating and cooling different organs. Since this system is based on changing the temperature of the blood supply to an organ, it is not appropriate for cooling the zone of the esophagus close to the left atrium. Other devices based on a catheter with a balloon have also been proposed for heating or cooling a selected portion of the body (Lasheras 2004) such as colon or stomach. However, since they are colon-inserted, they are not appropriate for use in the esophagus. Finally, Dzeng *et al* (2004) have proposed a catheter to cooling the ischemic heart, which is inserted into the esophagus and a cooled fluid is circulated within the catheter, cooling the esophagus, and by thermal conduction, the heart. In conclusion, to the best of our knowledge, there at present exist no medical devices that prevent esophageal injury during radiofrequency cardiac ablation. We believe that this modeling study is the first step in the development of this essential medical device. Future work should be focused on the technical construction of the prototype in the light of the computer results obtained. Moreover, in the application of this device to radiofrequency catheter ablation (Pappone *et al* 2004) care should be taken to minimize both the discomfort

to the patient in the insertion technique, and the possible painful effect due to esophageal cooling.

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Table 1. Characteristics of the materials used in the theoretical models.

Material	σ (S m^{-1})	ρ (kg m^{-3})	c (J kg^{-1}K^{-1})	k (W m^{-1} K^{-1})	Reference
Atrial tissue	0.61	1200	3200	0.70	Berjano and Hornero 2004
Electrode (Stainless steel)	7.4×10^6	8×10^3	480	15	Berjano and Hornero 2004
Esophagus	0.52 [1]	**1000**	**3700**	**0.4**	[1]Al-Zaben and Chandrasekar 2005
Polyurethane	10^{-5}	70	1045	0.026	Berjano and Hornero 2004
Lung (deflated)	0.25 [2]	**600**	1280 [3]	0.35 [4]	[2] Gabriel et al 1996 [3] Chato 1985 [4] Diller et al 2000
Bolus or refluxate material	1.55 [1]	**1000**	**4000**	0.45 [4]	[1]Al-Zaben and Chandrasekar 2005 [4] Diller et al 2000
Connective tissue	0.09 [1]	**1000**	**3200**	**0.4**	[1] Al-Zaben and Chandrasekar 2005

σ: electrical conductivity; ρ: mass density; c: specific heat; and k: thermal conductivity.

Tissue and fluid characteristics were measured or assessed at 32 ℃.

Values in bold were estimated for this study due to lack of experimental data or previous references.

Table 2. Characteristics of the lesions created in the esophagus after 120 s of RF ablation using different pre-cooling periods.

Pre-cooling period (s)	T_{SENSOR} (°C)	$t_{TRANSMURALITY}$ (s)	Lesion depth (%)
0	32	9	25.8
30	30.8	10	24.6
180	24.2	11.5	25.2
360	20.8	12	24.4

T_{SENSOR}: Temperature at the electrode sensor (see Fig. 2) after pre-cooling period and just previous to RF ablation; $t_{TRANSMURALITY}$: time of ablation up to achieving complete transmural lesion in atrial wall (s); the lesion depth is expressed as percentage of the thickness of esophageal wall.
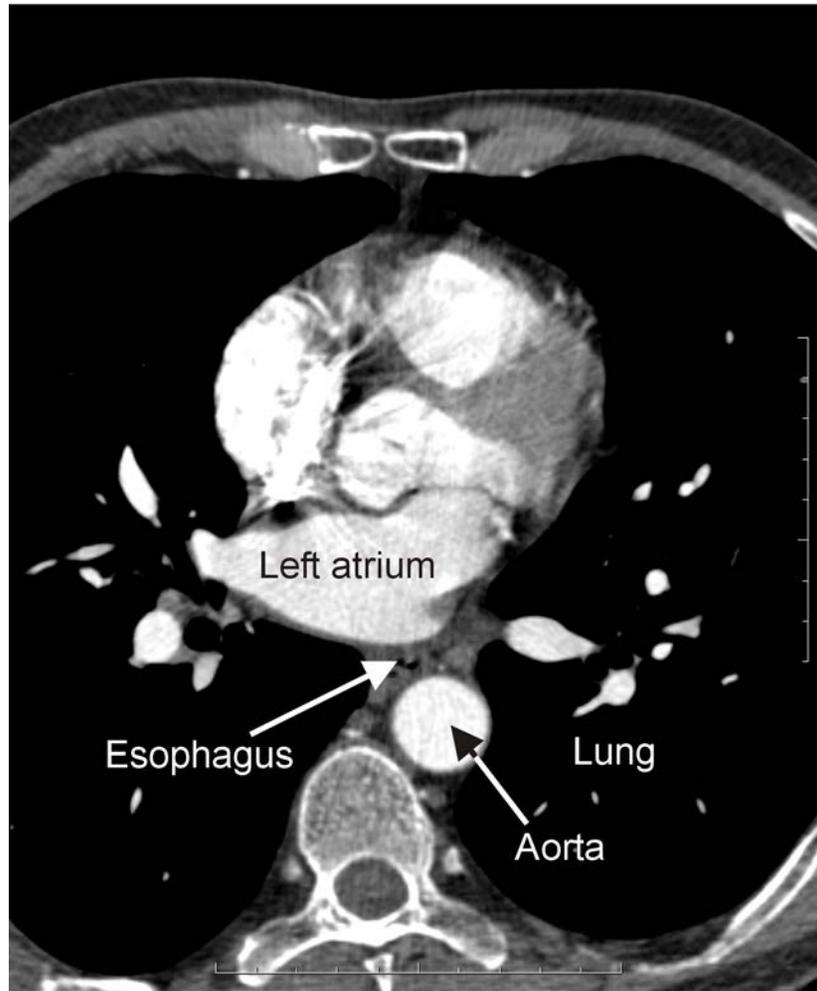
Figure 1   MRI cross-section showing the physical situation of the tissues included in the modeling study (left atrium, esophagus and lung). Scale is in cm.
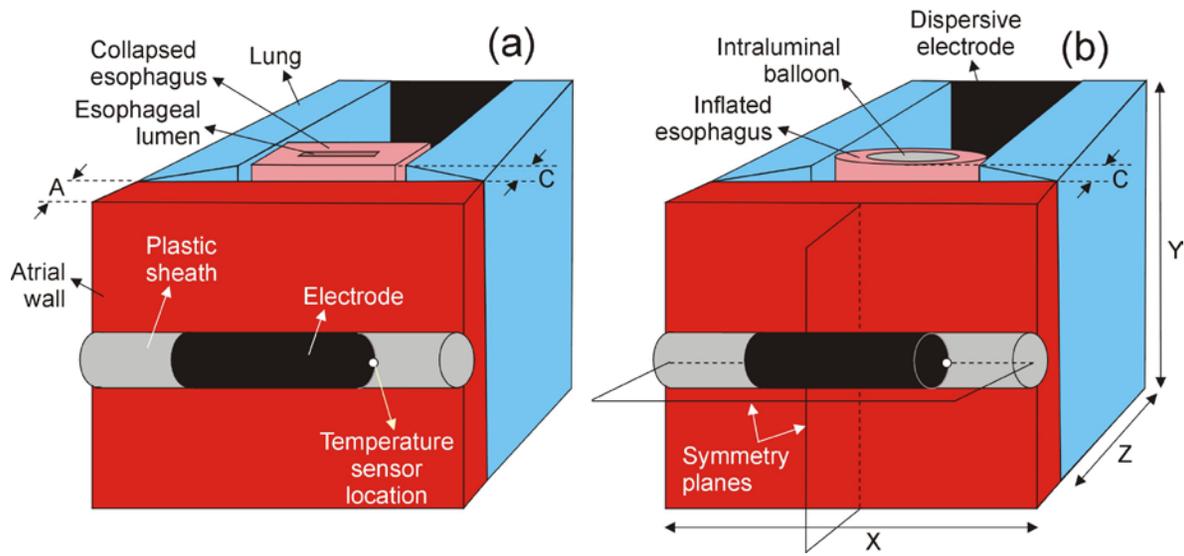
Figure 2 Theoretical models proposed (not to scale). (a) Model of collapsed esophagus without balloon. (b) Model with balloon in the esophageal lumen. Nomenclature: A, Atrial wall thickness; C, connective tissue thickness; X, Y and Z, outer dimensions calculated by means of a sensitivity analysis. The connective tissue (not shown) is joined to the organs (lung, esophagus, and atrium).
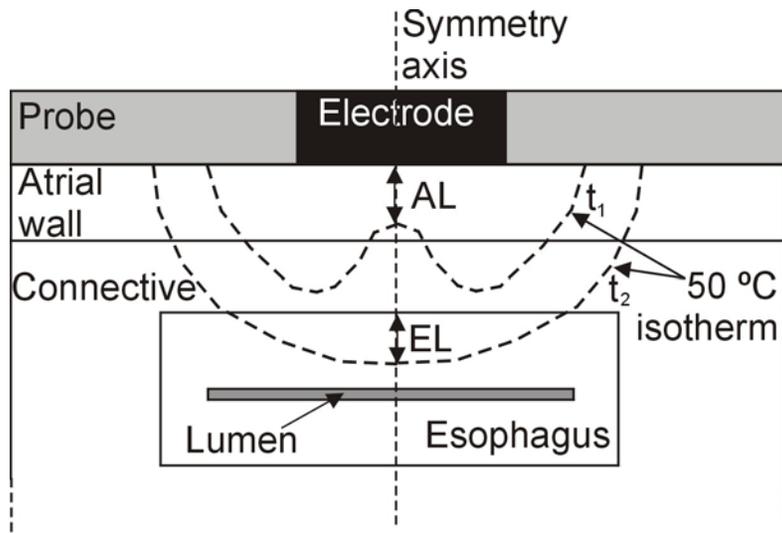
Figure 3   Schematic view of the lesion shape created during the first 10–20 s (t_1) and later (t_2) ($t > 50$ s). The lesions were characterized using the depth of the 50 °C isotherm by a different method in each tissue: minimum depth in atrial wall (AL); and maximum depth in esophageal wall (EL). (Not to scale)
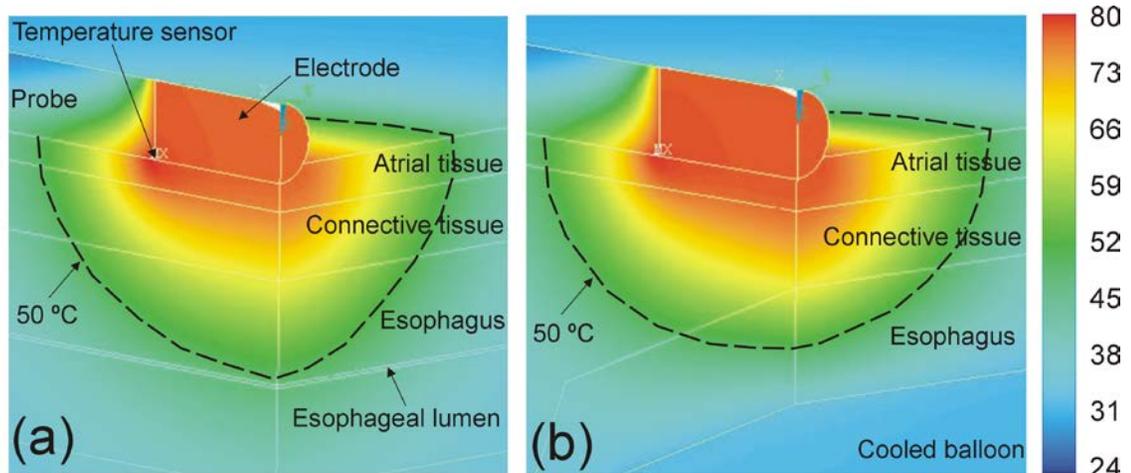
Figure 4   Temperature distributions after 120 s of radiofrequency ablation for the worst anatomical case under two different sets of conditions: (a) collapsed esophagus without balloon and (b) cooled balloon with $h_{BALLOON}$ = 2000 W m^{-2} K^{-1} and a temperature of cooling fluid of 32 ℃. The worst anatomical case is characterized by minimum connective tissue thickness (2 mm), thin atrium (1.3 mm), target temperature of 80 ℃, and without epicardial fat layer. The lesion dimension is stated using the 50 ℃ isothermal line (dotted line). Temperature scale is in ℃.
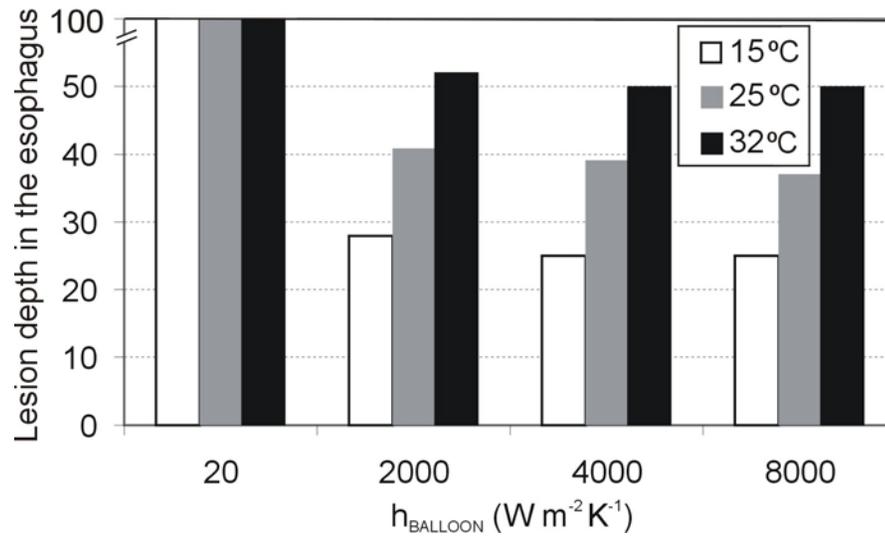
Figure 5   Effect of the characteristics of the cooled balloon on the lesion depth in the esophagus (expressed as % of thickness of the esophageal wall). $h_{BALLOON}$ is the thermal transfer coefficient for forced convection on the internal esophagus surface; and T_f is temperature of the cooling fluid inside the balloon.
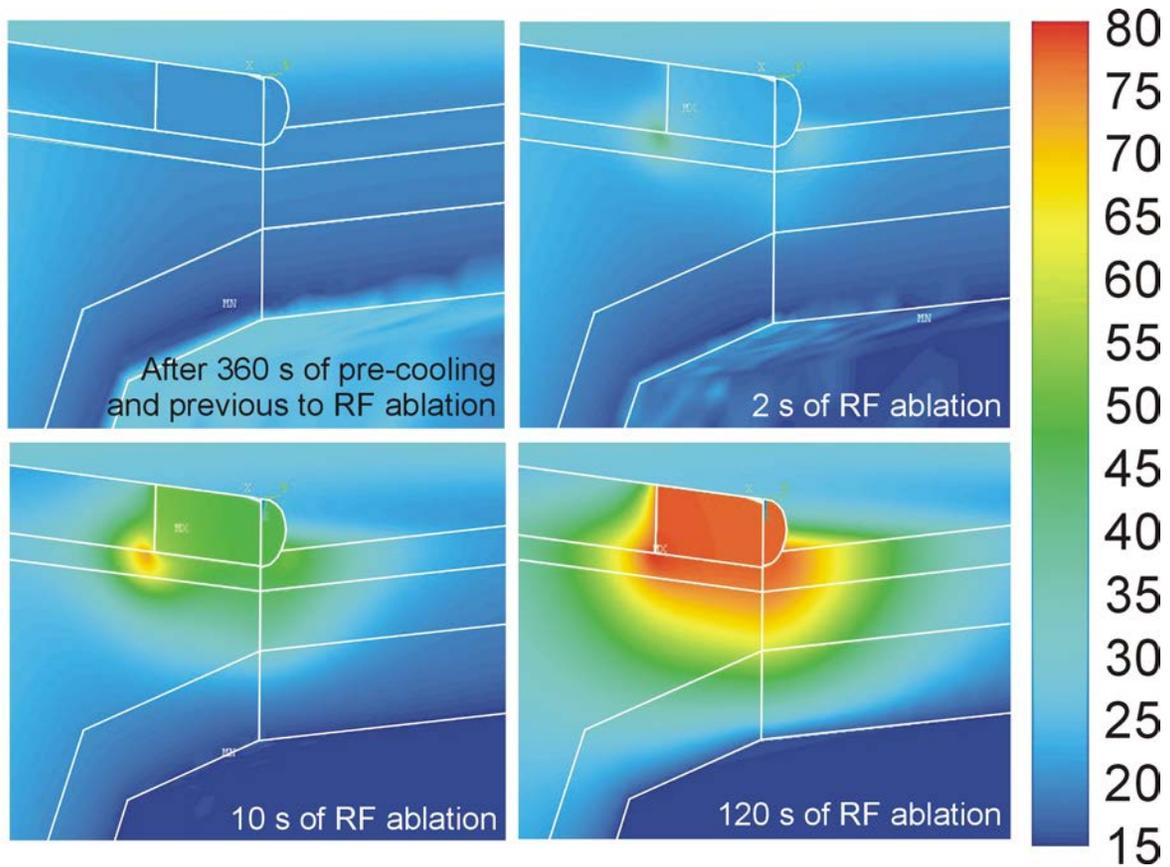
Figure 6   Temperature distributions at different times during a radiofrequency ablation of 120 s just after a pre-cooling period of 360 s ($h_{BALLOON}$ = 8000 W m^{-2} K^{-1}, T_f = 15 ºC). The worst anatomical case was considered, which is characterized by minimum connective tissue thickness (2 mm), thin atrium (1.3 mm), target temperature of 80 ºC, and without a layer of epicardial fat. Temperature scale is in ºC.