Radiofrequency Ablation at Low Irrigation Flow Rates Using a Novel 12-Hole Gold Open-Irrigation Catheter

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Background: *High irrigation rates during radiofrequency (RF) ablation may cause fluid overload and limit lesion size. This in vivo animal study assessed the safety and efficacy of RF ablation at low irrigation rates using a novel 12-hole gold catheter.*

Methods: *A total of 103 lesions, created on the thigh of five mongrel dogs, were analyzed. Lesions were created using a 12-hole irrigated gold-tip (Au) and a six-hole irrigated platinum–iridium (PtIr) catheter (both 7F/3.5-mm electrode; BIOTRONIK SE & CO, KG, Berlin, Germany) in parallel and perpendicular orientation. RF current was delivered for 60 seconds at 30 W using 8 mL/min and 15 mL/min irrigation. Electrode temperature, steam pops, lesion dimensions, and coagulum formation were recorded.*

Results: *Electrode temperatures were lower for Au compared to PtIr in parallel (8 mL/min: 38.1 ± 1.7°C vs 48.0 ± 4.8°C, $P < 0.0001$; 15 mL/min: 36.0 ± 1.5°C vs 46.9 ± 5.4°C, $P < 0.0001$) and perpendicular position (15 mL/min: 35.5 ± 1.2°C vs 38.4 ± 2.5°C, $P = 0.003$). The number of steam pops between Au and PtIr was comparable for parallel (8 mL/min: 14% vs 27%, $P = 0.65$; 15 mL/min: 14% vs 43%, $P = 0.21$) and perpendicular orientation (8 mL/min: 25% vs 17%, $P = 1.00$; 15 mL/min: 18% vs 0%, $P = 0.48$). Au created larger volumes than PtIr at 8 mL/min irrigation (861 ± 251 mm^3 vs 504 ± 212 mm^3, $P = 0.004$); however, for 15 mL/min, volumes were comparable (624 ± 269 mm^3 vs 768 ± 466 mm^3, $P = 0.46$). No coagulum formation was observed for any of the catheters on the surface and catheter tip.*

Conclusion: *RF ablation at low flow rate using a novel 12-hole irrigation Au catheter is safe and results in larger lesions than with a PtIr electrode. (PACE 2013; 00:1–9)*

catheter ablation, electrophysiology, lesions, irrigated-tip catheter, gold-tip electrode

Introduction

The introduction of irrigated-tip radiofrequency (RF) catheters increased efficacy of catheter ablation procedures.[1] It has theoretical advantages over nonirrigated-tip catheters and higher success rates have been demonstrated for many arrhythmias.[2–5] Several catheter designs are currently available with either a gold (Au)-tip electrode or a platinum–iridium (PtIr)-tip electrode. The irrigated Au-tip electrode has been well evaluated and allows for improved energy delivery at lower catheter-tip temperatures compared to irrigated PtIr-tip catheters.[6,7]

Saline infusion during RF applications allows more energy delivery resulting in increased lesion volume and less coagulum formation.[8] Although high irrigation rates during RF catheter ablation ensures safety, it can be disadvantageous for patients with impaired left ventricular function. Amounts of 1,500–2,000 mL of saline infusion are not uncommon and due to fluid overload occurrence of heart failure or pulmonary edema during the procedure have been reported.[4,9]

The aim of this study was to evaluate the safety and efficacy of a novel 12-hole Au open-irrigation catheter for RF ablation at low irrigation flow rates. Our primary hypothesis was that a reduction in the irrigation flow rate for the Au-tip catheter as compared to typical flow rates for the standard ablation catheter does not compromise safety concerning thrombotic events and ablation effectiveness.

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Methods

Endpoints of the Study

To test our hypothesis, the primary endpoint to assess this objective was the presence of coagulum on the tissue surface at the lesion location after completion of an RF application. In addition to this primary endpoint, a number of secondary endpoints were addressed, aimed at a comparison of additional safety characteristics and collection of data with respect to the ablation performance of the novel 12-hole Au open-irrigation catheter and the six-hole PtIr ablation catheter. The following secondary endpoints were included: formation of coagulum and/or thrombus on the ablation electrode as a result of RF ablation, occurrence of steam pops, lesion dimensions, temperature of the catheter tip and electrode-tissue interface, delivered RF power during RF ablation, and impedance during RF ablation.

Description of the Model

In this study a canine thigh muscle model has been used. This model was developed and first described by Nakagawa et al.[10] This study has been conducted according to good laboratory practice regulations at a certified laboratory. Five mongrel dogs were anesthetized with sodium pentobarbital (25 mg/kg) and either mechanically ventilated with room air or allowed to breathe spontaneously. General anesthesia was maintained with additional doses of sodium pentobarbital. The arterial pressure was continuously monitored by means of a right carotid artery cannulation. A skin incision was made and the skin edges were raised to create a cradle. The cradle was filled with blood (controlled 37°C, activated clotting time >350 seconds), which is exchanged at a rate of 250 mL/min, to mimic cardiac circulation. The ablation electrode was positioned in perpendicular or parallel orientation with respect to the muscle surface and held at a constant contact force of 10 g by use of a custom-made balance. Temperatures were measured by a fluoroptic temperature probe (Luxtron model STB, LumaSense Technologies, Santa Clara, CA, USA) immediately below the surface and as close as possible to the ablation catheter, as an approximation of the electrode–tissue interface temperature. All the temperatures were logged electronically. In addition, the data from the RF generator, including the programmed and actually delivered RF power, impedance, and electrode temperature, were electronically recorded (Fig. 1).

Ablation Catheters

RF ablations were carried out using the AlCath Flux eXtra Gold catheter (BIOTRONIK SE &CO, KG, Berlin, Germany) as the test item and the AlCath Flux Full Circle Pt/Ir catheter (BIOTRONIK) as the reference item. Both catheters are 7F in diameter and have a 3.5-mm ablation tip electrode. The AlCath Flux eXtra Gold ablation catheter has a gold ablation electrode with a novel configuration of 12 irrigation holes (Fig. 2). The AlCath Flux Full Circle catheter has a platinum-iridium electrode with six irrigation holes.

Ablation Protocol

Lesions were created with the ablation catheter oriented parallel and perpendicular to the muscle surface, an RF power of 30 W, and 8 mL/min and 15 mL/min irrigation flow rates. The ablation catheter was irrigated through the catheter lumen with heparinized (2 U/mL) normal saline at room temperature (20–22°C). Ablation settings (RF power, irrigation flow rate) and conditions (catheter type and electrode orientation) were applied in random order to avoid bias using the randomization function in an Excel® spreadsheet (v2010, Microsoft Corp., Redmond, WA, USA). The randomization was carried out according to the following procedure: randomization of the electrode orientation (perpendicular or parallel), for each orientation the type of catheter was randomized, and for each combination of catheter type and electrode orientation the irrigation flow rate was randomized. For each lesion, RF energy was delivered for 60 seconds or until the first steam pop. The occurrence of steam pops was recorded and after each RF application, the muscle surface and the ablation electrode were visually inspected for the presence of thrombus and coagulum formation. Furthermore, the cradle was emptied and inspected for the presence of coagulum on the surface. The location of each lesion was documented to establish a cross-reference between the applied experimental settings and subsequent lesion processing and determination of lesion dimensions.

Tissue Staining and Conservation

Two hours after completion of the RF ablations at the left and right thigh muscle, 30 mL of 2% triphenyl tetrazolium chloride was administered intravenously as a staining, allowing identification of necrotic tissue and revealing the extent of the lesion (Fig. 3). After sacrificing the dog, the muscles were excised and fixated in formalin. Thigh muscle dimensions were determined before fixation to be able to correct for tissue shrinkage due to fixation. Following fixation, the lesions were sectioned and the lesion dimensions were determined as described by Lewalter et al.[11]

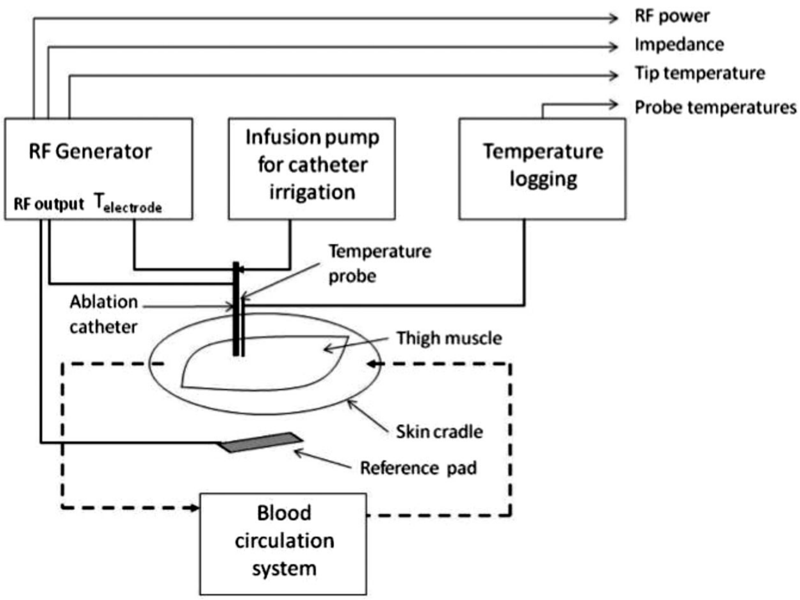

Figure 1. *Schematic representation of the experimental setup. The reference pad is attached to the contra-lateral thigh.*

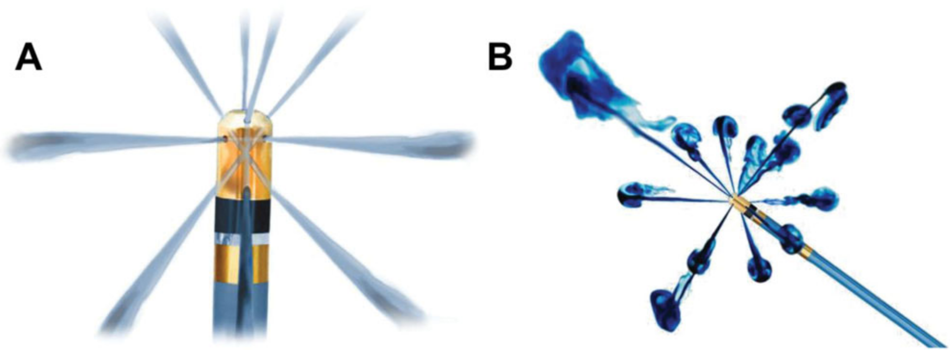

Figure 2. *Image of the novel 12-hole Au open-irrigation catheter displaying the new design (panel A) that allows cooling in all directions of the catheter (panel B).*

Lesion Dimensions

For each created lesion the following dimensions were determined: lesion depth (A), maximum lesion diameter (B), lesion depth at maximum diameter (C), and lesion diameter at surface (D). The lesion volume (V_{lesion}) was calculated using the following formula[12]:

$$V_{lesion} = (1/6) * \pi * (A * B^2 + C * D^2/2).$$

Muscle dimensions before and after fixation by formalin, allowing for correction with respect to tissue shrinkage, were not obtained for all experiments. Therefore, uncorrected results, directly obtained from fixated muscle tissue, were used to calculate mean lesion dimensions. For those experiments in which shrinkage due to fixation could be determined, muscle shrinkage was most frequently less than 5%.

Statistics

Continuous variables were expressed as mean ± standard deviation (SD) and compared with the Student's *t*-test for independent samples. Categorical data were expressed as percentages and compared with the χ^2 test or Fisher's exact test when appropriate. Statistical analysis was performed using SPSS 15.0 (IBM Corp., Armonk, NY, USA). A P value of 0.05 was considered as statistically significant.

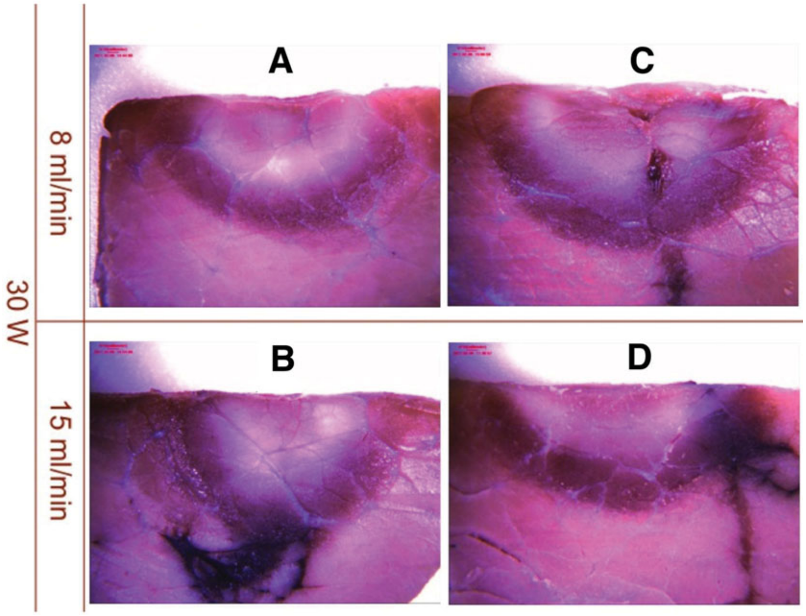

Figure 3. *Macroscopic image of the fixated lesion tissues. Lesions were created using 30 W and either 8 mL/min or 15 mL/min irrigation. Lesions (A) and (B) represent lesions with a parallel catheter position, lesions (C) and (D) were created with perpendicular catheter orientation.*

Results

Lesion Overview

In total 106 lesions were created in five mongrel dog models. Three lesions were excluded from the analysis due to movement of the ablation catheter (n = 1) and inappropriate irrigation (n = 2). Data from the remaining 103 RF applications (51 Au and 52 PtIr electrodes) and resulting lesions were analyzed for the primary and secondary endpoints.

Primary Endpoint Analysis: Incidence of Coagulum on Tissue Surface

No coagulum formation on the tissue surface was observed for any of the 103 RF applications included in the analysis. Due to the absence of any coagulum formation for both catheters, the observed rate of coagulum formation was 0% for the Au-tip catheter as well as for the PtIr-tip catheter.

Secondary Endpoint Analysis: Incidence of Steam Pops

The occurrence of steam pops during RF application is summarized in Table I. As indicated in Table I, no significant difference was observed in the incidence of steam pops between both catheter types. With the electrode in parallel orientation, the Au electrode showed comparable number of steam pops as the PtIr electrode for both 8 mL/min (14% vs 27%, P = 0.65) and 15 mL/min irrigation (14% vs 43%, P = 0.21). Results were identical for lesions created in perpendicular orientation and no difference was found regarding steam pops for 8 mL/min (25% vs 17%, P = 1) and 15 mL/min irrigation flow rates (18% vs 0%, P = 0.48).

Table I.

Incidence of Steam Pops

Orientation	Flow Rate (mL/min)	Catheter	N	Steam Pops	P Value (Au vs PtIr)
Parallel	8	Au	14	2 (14%)	0.65
		PtIr	15	4 (27%)	
	15	Au	14	2 (14%)	0.21
		PtIr	14	6 (43%)	
Perpendicular	8	Au	12	3 (25%)	1
		PtIr	12	2 (17%)	
	15	Au	11	2 (18%)	0.48
		PtIr	11	0 (0%)	

Au = 12-hole gold irrigation catheter; PtIr = six-hole platinum–iridium irrigation catheter.

Delivered RF Power, Impedance, and Dynamic Temperature Profiles

For all ablations the protocol required the target RF power to be programmed to 30 W. The actually delivered RF power as recorded by the

Table II.

Electrode Temperatures during Radiofrequency Applications

Orientation	Flow Rate (mL/min)	Catheter	N	Peak Temperature during Ablation (°C) ± standard deviation (SD)	P Value	Averaged Temperature during Ablation (°C) ± SD	P Value
Parallel	8	Au	14	39.39 ± 1.88	<0.0001	38.07 ± 1.65	<0.0001
		PtIr	15	53.77 ± 8.07		48.02 ± 4.81	
	15	Au	14	37.34 ± 2.51	<0.0001	35.96 ± 1.50	<0.0001
		PtIr	14	50.15 ± 6.49		46.93 ± 5.43	
Perpendicular	8	Au	12	42.11 ± 8.92	0.21	39.89 ± 5.81	0.15
		PtIr	12	46.69 ± 8.41		43.82 ± 6.96	
	15	Au	11	36.68 ± 1.00	0.005	35.55 ± 1.22	0.004
		PtIr	11	40.99 ± 4.32		38.41 ± 2.50	

Au = 12-hole gold irrigation catheter; PtIr = six-hole platinum–iridium irrigation catheter; SD = standard deviation.

RF generator reached the target power within 2 seconds after RF onset and RF power was maintained at this level throughout the entire RF application for all ablations. The mean power output for all lesions during ablation was 29.5 ± 0.05 W. The mean impedance for the Au electrode was 90.1 ± 12.8 Ω and for the PtIr electrode 87.6 ± 10.4 Ω. The impedance drop during ablation was comparable for the Au and PtIr electrodes in both parallel (at 8 mL/min: 11.0 ± 4.2 Ω vs 11.0 ± 4.5 Ω, P = 1; at 15 mL/min: 11.5 ± 3.9 Ω vs 10.1 ± 3.9 Ω, P = 0.331) and perpendicular orientation (at 8 mL/min: 14.7 ± 10.5 Ω vs 12.7 ± 5.0 Ω, P = 0.578; at 15 mL/min: 12.5 ± 3.1 Ω vs 9.9 ± 4.3 Ω, P = 0.115).

Table II presents the mean temperatures during RF application for each combination of electrode orientation, irrigation flow rate, and type of ablation catheter. Except for the perpendicular orientation and an irrigation flow rate of 8 mL/min, the Au-tip ablation catheter was associated with a significantly lower electrode temperature than the PtIr-tip catheter. This observation was done for the peak temperature reached during ablation, as well as for the averaged temperature. Temperatures also tended to be lower for the Au electrode in perpendicular orientation and a flow rate of 8 mL/min, but differences did not reach statistical significance. The tissue-interface temperature for the Au-tip catheter was comparable to the PtIr-tip catheter for parallel (at 8 mL/min: 51.5 ± 21.4°C vs 50.7 ± 19.4°C, P = 0.923; at 15 mL/min: 47.7 ± 14.1°C vs 54.2 ± 16.7°C, P = 0.266) and perpendicular orientations (at 8 mL/min: 55.0 ± 16.2°C vs 54.8 ± 15.8°C, P = 0.974; at 15 mL/min 59.2 ± 27.3°C vs 53.9 ± 21.0°C, P = 0.607) independent of irrigation flow rates. Figure 4 shows the electrode temperature curves for different catheter positions and irrigation flow rates.

Secondary Endpoint Analysis: Coagulum Formation on Electrode

For none of the 103 RF ablations included in the analysis, coagulum was observed on the electrode after RF application. As a result, the rate of coagulum formation is 0% for both the Au catheter and the PtIr catheter.

Secondary Endpoint Analysis: Lesion Dimensions

Mean values for lesion dimensions including only lesions created without steam pop are presented in Table III and Figure 5. The use of a 12-hole Au catheter was associated with greater lesion volumes as compared to PtIr catheters in parallel position at a flow rate of 8 mL/min (861 ± 251 mm^3 vs 504 ± 212 mm^3, P = 0.004). For perpendicular catheter orientations at 8 mL/min irrigation, the Au catheter produced larger lesions; however, this did not meet statistical significance (908 ± 285 mm^3 vs 629 ± 280 mm^3, P = 0.07). At a 15 mL/min flow rate, lesion volumes were comparable for Au and PtIr in both parallel and perpendicular position (624 ± 269 mm^3 vs 768 ± 466 mm^3, P = 0.46; 949 ± 284 mm^3 vs 805 ± 226 mm^3, P = 0.29, respectively).

For lesions created in parallel orientation using the PtIr electrode, the amount of irrigation (8 mL/min or 15 mL/min) did not influence the

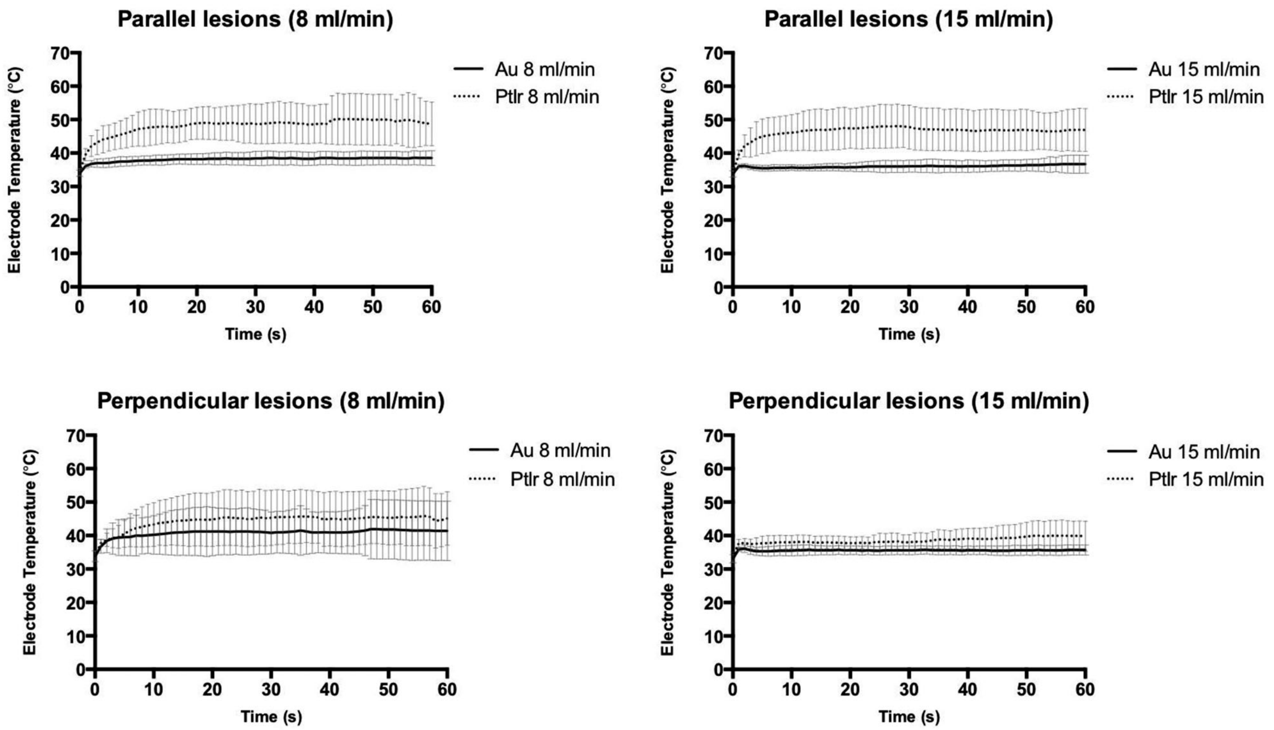

Figure 4. *Integrated mean electrode temperature curves in function of time for Au- and PtIr-tip catheters. Different curves are plotted for catheter orientation (parallel or perpendicular) and amount of saline infusion (8 mL/min or 15 mL/min). The curves are plotted in mean ± standard deviation (SD) values for both catheters.*

Table III.

Mean Lesion Dimensions ± Standard Deviation (SD) (Ablations with Steam Pops Excluded)

Orientation	Flow rate (mL/min)	Catheter	No Histo*	N	Depth (mm)	Max. Diameter (mm)	Volume (mm^3)	P Value (Volume)
Parallel	8	Au	2	10	9.30 ± 1.96	12.75 ± 1.78	861 ± 251	0.004
		PtIr	2	9	7.72 ± 1.48	10.28 ± 1.70	504 ± 212	
	15	Au	4	8	7.63 ± 1.62	11.44 ± 2.67	624 ± 269	0.46
		PtIr	0	8	8.50 ± 2.17	11.88 ± 3.06	768 ± 466	
Perpendicular	8	Au	2	7	8.43 ± 0.93	13.64 ± 1.95	908 ± 285	0.07
		PtIr	1	9	7.61 ± 1.96	11.78 ± 2.69	629 ± 280	
	15	Au	2	7	9.93 ± 1.57	12.93 ± 1.86	949 ± 284	0.29
		PtIr	2	9	8.83 ± 1.37	12.67 ± 1.64	805 ± 226	

*Lesions for which no histology data (lesion dimensions) were available because the lesion was not identifiable in the muscle preparation (after exclusion of steam pop lesions).
Au = 12-hole gold irrigation catheter; PtIr = six-hole platinum–iridium irrigation catheter.

lesion volumes (504 ± 212 mm^3 vs 768 ± 466 mm^3, P = 0.157). The same results were achieved for PtIr electrode in a perpendicular orientation (629 ± 280 mm^3 vs 805 ± 226 mm^3, P = 0.255). For the Au electrode, lesions with 8 mL/min or 15 mL/min irrigation in parallel orientation (861 ± 251 mm^3 vs 624 ± 269 mm^3, P = 0.072) and perpendicular orientation (908 ± 285 mm^3 vs 949 ± 284 mm^3, P = 0.791) had comparable volumes as well.

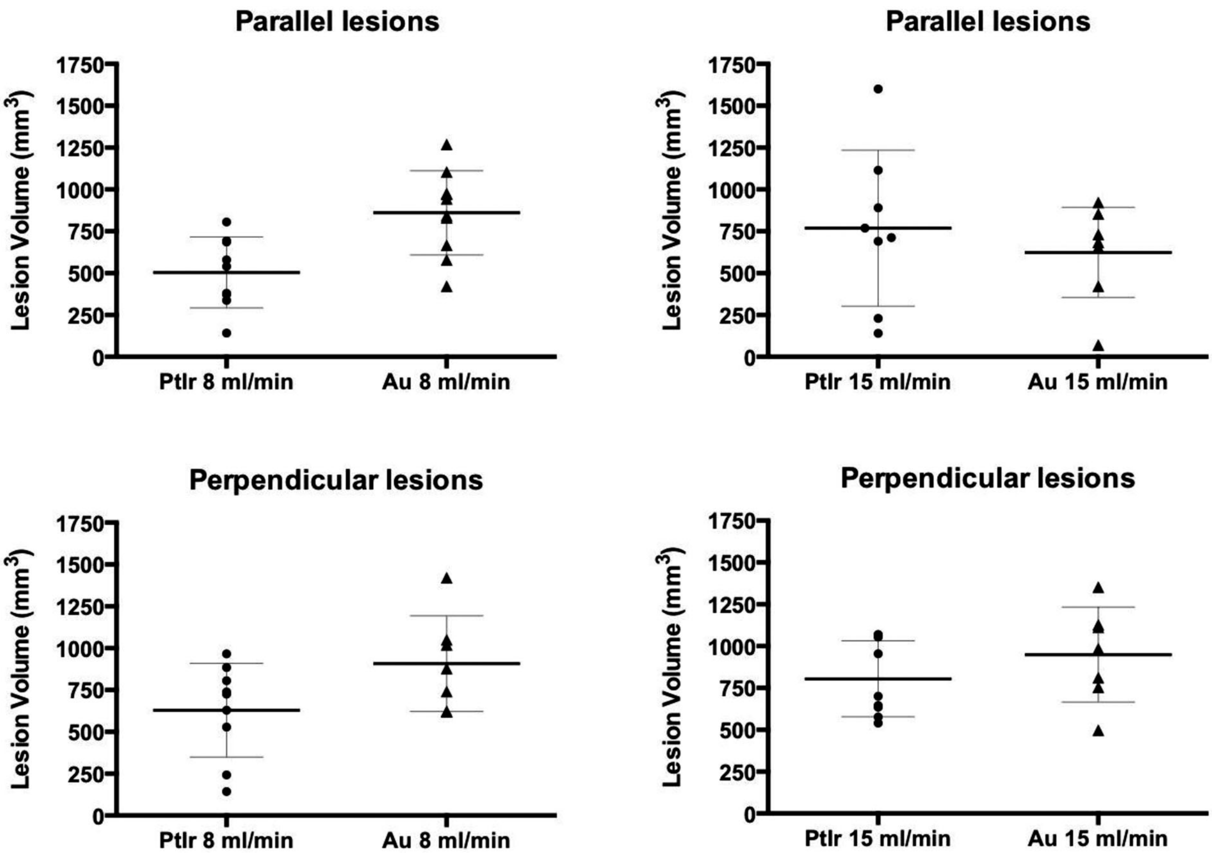

Figure 5. *Lesion volumes for different catheter orientations and amount of saline infusion. Each symbol represents one lesion. Values are plotted in mean ± standard deviation for both catheters.*

Discussion

In this study we assessed the safety and efficacy of a novel 12-hole Au open-irrigation catheter for RF ablation at low irrigation flow rates compared to a six-hole PtIr ablation catheter at standard irrigation flow rates. The primary endpoint was the presence of coagulum on the tissue surface at the lesion location after completion of an RF application. The major finding of this study is that the Au electrode is comparable to the PtIr electrode since no coagulum was observed on the tissue interface after any of the RF application for both catheters. As a result, our data are in support of the hypothesis that using the Au electrode with 12 irrigation holes, RF ablation at low flow rates is safe and results in larger lesions than using a PtIr electrode.

Coagulum Formation

Coagulum formation on the tissue as a result of RF application was studied by Matsudaira et al.,[13] using temperature-controlled RF application in canine thigh muscle model, similar to the model used during this study. Experiments were performed with the electrode oriented perpendicularly to the muscle and application of a 10-g contact force. For a 4-mm nonirrigated ablation electrode, without blood flow in the cradle, and a target electrode temperature of 75°C, coagulum was found in 90% of the RF applications. At an electrode temperature of 65°C and no blood flow, coagulum formation was not observed. The authors suggest that "thrombus" formation is temperature related, possibly due to denaturation of blood proteins. As they also measured the electrode–tissue interface, they conclude that coagulation occurs at interface temperatures well below 100°C. Electrode temperatures measured during the study were generally lower than reported by Matsudaira et al., which may explain the complete absence of coagulum formation in these experiments. Other aspects that may have prevented coagulation include a higher blood circulation in the cradle (250 mL/min vs 150 mL/min) and a possible "washing" effect from the irrigation flow.

Occurrence of Steam Pops

Steam pops occurred in 21 (19.8%) of the 106 ablations performed in these experiments. In 12 occasions, the electrode temperature averaged over the ablation at which a steam pop occurred exceeded the mean electrode temperature for the corresponding setting (electrode type, orientation, and flow rate). Although the averaged electrode temperature during ablation was usually below 50°C, peak values frequently reached temperatures up to 80°C. It cannot be excluded that coagulum formation occurred in these cases, as the destructive process of a steam pop may have destroyed the histological evidence. Furthermore, in this thigh muscle setting the applied force with the ablation catheter is very stable and provides a much better constant wall contact than within the human heart due to heart beating and respiratory movements.

No significant differences were found between the Au and PtIr electrodes with respect to the incidence of steam pops. The mean lesion volume in parallel orientation using 8 mL/min irrigation was significantly larger with the Au electrode compared to the PtIr electrode. In perpendicular orientation at an irrigation flow rate of 8 mL/min, the lesions tended to be larger using the Au electrode as well, but this difference was not statistically significant. However, it appears to be that the differences in the conductive properties of the metal and the novel catheter design are more pronounced using lower irrigation flow rates. Furthermore, the mean electrode temperatures during ablation were consistently lower for the Au catheter. The temperature differences were significant for all settings except for a perpendicular electrode orientation and a flow rate of 8 mL/min.

Limitations

The results of this study demonstrate the feasibility of using a novel 12-hole Au-irrigated tip catheter at reduced irrigation rates. However, these results could be a result of the natural conductive properties of gold instead of the novel catheter design. In order to really elucidate the effect of the novel irrigation system, further comparative studies are required using a six-hole Au-tip catheter.

In this study, ablation was performed using 30 W power for a duration of 60 seconds. The study was designed in a way to acquire sufficient data per ablation setting to draw valid and accurate conclusions. It remains unclear if coagulum formation would occur using 40 W or 50 W during different time periods. Therefore, more data are required to answer the question whether RF ablation at low irrigation flow rates is safe using high-power settings. Furthermore, during this study we aimed to compare a novel 12-hole irrigated-tip catheter with an industry standard catheter. Currently the six-hole-irrigated tip is no longer the industry standard catheter. Therefore, this study cannot be extended to apply to newer PtIr catheter designs.

These data are acquired using an animal model. Although this model mimics the conditions in the human heart as much as possible, the contact force and stability will influence the ablation results. In clinical situations the stiffness of the catheter may result in different ablation results than acquired during this study in an experimental setup. During these experiments, lesions were created with a fixed contact force where catheter stiffness did not influence the results. Therefore, further clinical investigation is needed to reveal the true value of this new 12-hole Au irrigated-tip catheter in everyday practice.

Conclusion

In conclusion, the data obtained during this study demonstrate that the novel 12-hole Au tip ablation catheter allows reduction of the irrigation flow rate compared to the PtIr catheter without compromising safety. Compared to the six-hole PtIr-tip catheter, the Au electrode achieves similar ablation effectiveness at lower electrode temperatures. For patients with an impaired left ventricular function in which fluid overload is a matter of concern this novel Au tip catheter could be valuable.

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