The efficacy, feasibility and safety of a novel wire-guided ablation catheter for ablation of the right superior pulmonary vein: an experimental study in pigs

Hui Gong1, Fei Peng1, Hexi Zhang1, Lei Liu1, Nu Zhang1, Jianqiang Hu2, Xue Zhao3

1Division of Cardiology, Department of Internal Medicine, Jinshan Hospital, Fudan University, Shanghai, China; 2Division of Cardiology, Department of Internal Medicine, First Affiliated Hospital, Second Military Medical University, Shanghai, China; 3Division of Cardiology, Department of Internal Medicine, Third Affiliated Hospital, Second Military Medical University, Anting Town, Jiading District, Shanghai, China

Received August 28, 2017; Accepted May 24, 2018; Epub September 15, 2018; Published September 30, 2018

Abstract: The efficacy, feasibility of use and safety of a novel wire-guided ablation catheter for atrial fibrillation ablation was evaluated experimentally. Pigs (n = 8) were sedated, intubated and randomized into wire-guided and general saline-irrigated ablation catheter experimental groups (n = 4 per group) successively, in a randomized paired study design. Catheters were inserted into the coronary sinus or right atrial appendage via the femoral vein. Transseptal puncture was guided by X-ray. The left atrium (LA) and right superior pulmonary vein (RSPV) were reconstructed using EnSite Velocity™ mapping. Contact-mapping and contact-ablation were performed in the antrum of the RSPV. Average procedure and exposure times of circumferential RSPV ablation and RSPV-antrum radial-linear ablation were shorter in pigs who received wire-guided catheter ablation compared with those who received saline-irrigated catheter ablation (procedure time: 22.5 ± 3.8 vs. 32.5 ± 5.1 min, and 11.3 ± 1.9 vs. 15.8 ± 2.5 min, respectively; P < 0.001) (exposure time: 7.5 ± 1.1 vs. 11.4 ± 2.2 min, and 3.4 ± 0.5 vs. 6.7 ± 1.3 min, respectively; P < 0.001). During ablation, the catheter fell into the right atrium fewer times, and took less time to re-insert into the LA, in the wire-guided compared with the saline-irrigated catheter group (0.7 ± 0.8 vs. 5.1 ± 1.3 times, and 1.0 ± 0.2 vs. 5.0 ± 0.9 min, respectively; P < 0.001). There were no guidewire-associated thromboses and no scratches, tears or thrombi in the RSPV intima during the experimental period. The findings indicate that the stability, accuracy of positioning and safety of the wire-guided ablation catheter are superior to the general saline-irrigated ablation catheter for ablation of the RSPV.

Keywords: Pulmonary vein, atrial fibrillation, radiofrequency ablation, ablation catheter

Introduction

Circumferential pulmonary vein (PV) ablation is a classical surgical approach for the treatment of atrial fibrillation (AF), but requires complete encirclement of the PV orifice in order to electrically isolate the PVs. The critical factor for achieving PV isolation is that all ablation sites must completely penetrate the atrial muscle layer [1, 2]. Generally, the procedure takes at least 30 minutes for an experienced electrophysiological physician to perform, and can take significantly longer if the practitioner is inexperienced [3]. Furthermore, during the ablation procedure, the direction and distance of travel of the ablation catheter in the left atrium (LA) are poorly controlled, resulting in contact instability and gap formation which can lead to recovery of PV connections and the recurrence of AF after ablation [4, 5].

Effective manipulation of the ablation catheter in the LA is therefore critical to ensuring the success and efficiency of AF ablation. Clinical trials have demonstrated that the major risk factor for the recurrence of AF after PV isolation is the recovery of electrical connections between the PVs and the LA [6]. The recovery of PV connections is dependent on many factors. These include the thickness of the local atrial muscle as well as the positioning and stability of the catheter [7]. The local potential amplitude partially and indirectly reflects the stability and tightness of the contact between the cath-
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Although the use of a pressure sensing catheter provides an effective means of monitoring catheter manipulation and positioning in order to prevent unstable contact, the success of the procedure is still heavily reliant on the experience of the practitioner [4, 9]. Conventional ablation catheters are typically non-wire-guided ablation catheters that are only suitable for the single-target fixed discharge ablation of paroxysmal supraventricular tachycardias. They are not suitable for multi-target mobile discharge ablation of AF.

A novel wire-guided ablation catheter that is based on the principle of compasses for drawing a circle, may have potential in improving both catheter manipulation and the accuracy of catheter positioning and contacting. The aim of this study was to evaluate the efficacy, safety and feasibility of use of a novel wire-guided ablation catheter for ablation of the right superior pulmonary vein (RSPV), in pigs.

**Materials and methods**

**Experimental materials**

The experimental protocol was approved by the Ethics Committees of the Second Military Medical University and Fudan University. The procedures were performed on eight Bama pigs (body weight 50-55 kg), provided by Shanghai Jiaotong University Experimental Animal Center. The novel catheter employed was a wire-guided cold saline-irrigated ablation catheter (Triguy™, HuiTai Medical Devices Co., Ltd, Shenzhen, China) based on an 8Fr cold saline-irrigated ablation catheter (4 mm tip) with an additional guidewire lumen. The proximal opening of the guidewire lumen was in the ablation catheter tail, and the distal opening was in the junction between the adjustable and non-adjustable curve segment, forming an angle of 90° after the bend of the ablation catheter tip. The hydrophilic guidewire (0.038") (Terumo Corporation, Maimai- gi-choFujinomiya, Japan) and guidewire lumen were aligned together (Figure 1A and 1B). The EnSiteNavX three-dimensional electro-anatomical mapping system (St. Jude Medical Inc., Saint Paul, US) and an IB1500T11 radio frequency ablation generator (St. Jude Medical Inc., Saint Paul, US) were used to perform LA and PV model reconstruction and radio frequency current discharge, respectively. An electrophysiological recorder (Segmentation Tool Version 1.0, St. Jude Medical Inc., Saint Paul, US) was used to record 12-lead body surface electrocardiograms (ECGs) and intracardiac ECGs.

**Experimental procedures**

Animals were sedated with ketamine (10 mg/kg, i.m.) and atropine (0.04 mg/kg, i.m.), and retained on the operating table in a supine position for 10 minutes in order to establish intravenous access. Eight pigs underwent endotracheal intubation with an ID7.0 mm catheter, and were mechanically ventilated (A/C model, frequency: 20 beats/min, tidal volume 350-400 ml, respiratory ratio 1:2, oxygen concentration: 60%). General anesthesia was maintained with sevoflurane (1-5%), ketamine (10 mg/kg), and vecuronium (0.04 mg/kg), administered intravenously [10]. The multipolar electrode catheter was inserted into the coronary sinus or the right atrial appendage via the right femoral vein. Transseptal puncture was guided by X-ray at the position of the apex to the xiphost process. After transseptal puncture, an unfractionated heparin bolus (100 IU/kg) was administered, and activated clotting time (ACT) remained at ≥ 300 seconds.

**Figure 1.** Wire-guided ablation catheter applied in mapping of the left atrium of experimental pigs. A. Wire-guided ablation catheter. The guidewire is shown protruding out from the guidewire distal hole lumen (black arrow). B. Wire-guided ablation catheter positioning and mapping of the RSPV. The guidewire was pushed into the distal RSPV. The mapping electrode was placed in the RA appendage.
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Study design

To enable direct comparison of the operating performance of the two catheters, individual animals were randomized into the wire-guided ablation catheter group and the general saline-irrigated ablation catheter group, successively. The experimental protocol included contact/mapping and contact-ablation in the RSPV antrum. Contact-mapping comprised of circumferential PV continuous contact and PV antrum radial-linear contact, and contact-ablation comprised of circumferential RSPV ablation and RSPV antrum radial-linear ablation [11]. The sites of circumferential RSPV contact and ablation were both approximately 0.5 cm outside the RSPV ostium. During experimentation, it was found that the probability of the catheter unintentionally falling into the right atrium (RA), and the success of the catheter re-entering the LA, were significantly different between the two treatment groups. The occurrence of this phenomenon was therefore observed and recorded during the experiments, so that it could be incorporated into the analyses. After completion of the experiment, the LA and PV ablation tissues were excised for gross and histopathological observation.

RSPV angiography

After transseptal puncture, the catheter sheath was aligned with the lower part of the RSPV ostia, and 20 ml of the X-ray contrast agent (Hengrui Medicine Co., Ltd., Jiangsu, China) was injected for RSPV angiography. To determine the RSPV venography, RSPV angiography images were taken in the following projection positions: poster anterior, right anterior, oblique 45°, left anterior oblique 45°, and head position 10°. The RSPV ostia was defined as the maximal inclination between the PV lumen and the LA body in pulmonary venography. The diameter of the ostia in the right anterior oblique 45° position was measured with digital calipers (GE medical, Advantx LCV+, USA).

Contact-mapping

The major differences between the wire-guided and general saline-irrigated ablation catheters are manifested in their controllability and stability in operation. Therefore, the contact-mapping phase was initially designed to enable comparison of the procedure time and exposure time of the two types of catheter at four separate sites of the circumferential RSPV, as well as along the circumferential RSPV, and radial-linear contact-mapping in the RSPV-antrum, for each experimental animal. Standards for contact/mapping under X-ray fluoroscopy were: contacting at each site for at least three seconds, maintaining stability of the ablation catheter and acquiring a clear and stable maximum local potential. Contact-mapping did not involve ablation.

Following atrial septal puncture, the sheath of the catheter entered the LA and PV, and the guidewire was then pushed into the distal RSPV via the guidewire lumen. At that point, the guidewire became a supporting rotating shaft and turned into an axis for the ablation catheter. The ablation catheter was then rotated clockwise or counterclockwise around the guidewire to reach the preset mapping sites. Contact and ablation were achieved by bending or sliding the ablation catheter against the contact-mapping site. The distal catheter rotation was between 0-90°, with the electrode rota-
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Table 1. Basic study parameters

<table>
<thead>
<tr>
<th>Animal</th>
<th>Weight (kg)</th>
<th>Heart rate (beats/min)</th>
<th>Oxygen saturation (%)</th>
<th>Ablation energy (W)</th>
<th>Ablation temperature (°C)</th>
<th>Complications</th>
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<td>30</td>
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PT: pericardial tamponade.

Re-insertion of the ablation catheter into the LA

If, during the experimental procedure, the ablation catheter unintentionally fell into the RA, it had to be re-inserted into the LA before ablation could continue. The number of times the ablation catheter unintentionally fell into the RA and the duration of time it took for it to be re-inserted into the LA from the previous atrial-septal puncture hole, were recorded and compared between the two catheter types (wire-guided and general saline-irrigated).

Pathological observations

As part of the gross pathological inspection, the heart was excised and flushed with saline and the guidewire was installed into the RSPV after the animals had been euthanized. Lesions in the atrial septal puncture, atrial endometrium, RSPV ostium, LA appendage, pulmonary vein outer membrane, and the atrial pericardial surface were examined. The presence of mural thrombus in the distal opening of the guidewire and along the guidewire surface was grossly examined. The RSPV was slit open and carefully observed. For histological evaluation, tissue samples were taken from the RSPV, fixed in 10% buffered formalin, embedded in paraffin, cut into 3 μm thick sections, stained with hematoxylin-eosin (H&E) stain, and analyzed under light microscopy (x200) with an Olympus BX43 microscope.

Statistical analysis

Continuous variables that were normally distributed were presented as means ± standard deviation (SD); non-normally distributed variables were reported as medians and interquartile ranges (IQR). The means of two continuous
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<table>
<thead>
<tr>
<th>Table 2. Contact/mapping of ablation catheter</th>
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<td>Wire-guided ablation catheter (n = 7)</td>
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<tr>
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</tr>
<tr>
<td>Procedure time (min)</td>
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<tr>
<td>Exposure time (min)</td>
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<tr>
<td>Circumferential RSPV continuous contact</td>
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<td>Procedure time (min)</td>
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<tr>
<td>Exposure time (min)</td>
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<tr>
<td>RSPV-antrum radial-linear continuous contact</td>
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<tr>
<td>Procedure time (min)</td>
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<td>Exposure time (min)</td>
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PSPV: right superior pulmonary vein.

 normally distributed variables were compared using the Paired Sample Student’s T-test. Data were analysed by SPSS version 19.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism 6 Software (GraphPad Software Inc., San Diego, CA, USA) was used to construct the schematic diagrams. A P value of < 0.05 was considered statistically significant.

Results

Basic study parameters

Pericardial tamponade occurred in two animals during experimentation, one of which died. Seven animals completed the protocol. The mean diameter of the RSPV, this being the largest point of rotation between the PV and LA, was 14.0 ± 2.1 mm (n = 7), as shown by the RSPV angiography (Table 1).

Contact-mapping

The circumferential RSPV discontinuous contact procedures as well as the circumferential RSPV continuous contact and RSPV-antrum radial-linear continuous contact procedures were each conducted in the same animal successively. The average procedure and exposure times were significantly less in the wire-guided ablation catheter group than in the paired general saline-irrigated ablation catheter group (P < 0.05) (Table 2).

Contact/Ablation

The average procedure times of the circumferential RSPV ablation and the RSPV-antrum radial-linear ablation were significantly shorter in the wire-guided ablation catheter group compared with the general saline-irrigated ablation catheter group (22.5 ± 3.8 min vs. 32.5 ± 5.1 min, and 11.3 ± 1.9 min vs. 15.8 ± 2.5 min, respectively) (P < 0.001) (Figure 3). The average exposure times of these ablation procedures were also significantly shorter in the wire-guided versus the general saline-irrigated ablation catheter groups (7.5 ± 1.1 min vs. 11.4 ± 2.2 min, and 3.4 ± 0.5 min vs. 6.7 ± 1.3 min, respectively) (P < 0.001) (Figure 3). The magnitude of the differences in procedure time and exposure time were, respectively, 30.8%
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and 34.2% for the circumferential RSPV ablation, and 28.5% and 49.3% for the RSPV-antrum radial-linear ablation (Figures 4 and 5).

Re-insertion of the ablation catheter into the LA

During the LA ablation procedure, the ablation catheter unintentionally fell into the RA an average of 0.7 ± 0.8 times in the wire-guided ablation catheter group. This was significantly fewer than that in the general saline-irrigated ablation catheter group (5.1 ± 1.3 times) (P < 0.001) (Figure 6A). The time taken to re-insert the ablation catheter into the LA from the previous atrial septal puncture hole was also significantly less in the wire-guided ablation catheter group compared with the general saline-irrigated ablation catheter group (1.0 ± 0.2 min vs. 5.0 ± 0.9 min) (P < 0.001) (Figure 6B).

Gross pathology observations

From the intimal side of the left superior pulmonary vein (LSPV), the proximal PV with its muscular sleeve appeared red in color, like the LA, while the distal PV without a muscle sleeve appeared white (Figure 7A). The RSPV ostia appeared dark red, with visible swelling and the presence of bulging lesions. Its surface was stained with blood, and part of the area appeared dark brown following circumferential RSPV ablation (Figure 7B). In the longitudinal view of the RSPV, the rough circumferential ablation lesions and associated blood were visible in the RSPV-antrum. The PV intima was smooth and no guidewire related injuries or attached thrombi were visible (Figure 7C).

Histological observations

Tissue transmural injury and coagulation necrosis was visible in the longitudinal sections of the RSPV-antrum radial-linear ablation lesions. The cell structure appeared normal and no obvious endarterectomy detachments were visible (Figure 7D).

Safety outcome

The pericardial tamponade that occurred in two animals during experimentation resulted from transseptal puncture. One of the affected animals died and the other survived through to completion of the experiment after pericardiocentesis. There was no evidence of PV stenosis either during or after surgery. No thromboses were found on the LA appendage, the guidewire lumen distal aperture or the guidewire surface, and no scratches, tears or thromboses in the RSPV intima or esophageal injuries were detected in any of the animals.

Discussion

This study has evaluated the efficacy and feasibility of using of a novel wire-guided ablation catheter for contact-mapping and contact/ablation procedures in the RSPV of experimental pigs. The RSPV of pigs has been used in this study because the anatomy of swine RSPV is the closest to that of human beings [12]. The results have demonstrated that the wire-guided catheter has good controllability and higher stability when compared with a general saline-irrigated ablation catheter, and significantly reduces both the procedure time and the expo-
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sure time. In addition, in the presence of a guidewire, the ablation catheter can more easily be re-inserted into the LA from the previous atrial septal puncture hole in the event that it unintentionally falls into the RA during the ablation procedure. Moreover, no obvious injury to the RSPV was caused by the guidewire.

The effective manipulation of the ablation catheter in the LA, coupled with the accuracy of positioning and stability of the contacts made with the ablation targets, are the most critical factors to ensuring the success and efficacy of AF ablation. For inexperienced electrophysiological physicians, owing to the difficult positioning and contact instability of traditional (saline-irrigated) ablation catheters, their subjective movement can be inconsistent with or even contrary to the actual movement of ablation catheter, both in direction and distance [4]. In recent years, a number of improved AF ablation catheters have been developed, with the sole purpose of improving their controllability and increasing their contact stability.

The introduction of the pressure sensing catheter has significantly increased the long-term success rate of AF ablation. It has reduced the level of distortion in the 3D modelling process that can be caused by the presence of low or high pressure, and thus helps to improve the authenticity and accuracy of three-dimensional mapping. In addition, a pressure sensing catheter has advantages in improving the ablation success rate and in reducing the likelihood of complications arising, by facilitating efficacious and safe contact and ablation, with less dependence on the ‘hand-feel’ of the practitioner [13, 14]. Currently, novel available catheter options include a fixed-curved MARQ catheter [15], PV ablation catheter (PVAC) [10], multi-polar cold saline-irrigated radiofrequency ablation catheter, and a cryo-
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balloon for PV cryoablation [16]. The non-adjustable catheter model increases the stability of catheter contact, but the flexibility of the catheter contact is then lost.

A wire-guided ablation catheter is based on the principle of compasses for drawing a circle, and has a simple structure. When the guide-wire is fixed into the PV, the ablation catheter does not leave PV-antrum, no matter how much the ablation catheter is rotated. As a result, the catheter can achieve more accurate and stable contact with the ablation site(s), regardless of how rapidly or flexibly it is rotated. The wire-guided ablation catheter can be used not only for circumferential PV ablation, but also in LA or RA linear ablation, and apart from the treatment of AF, it is also applicable to right ventricular outflow tract ventricular tachycardia ablation. When the guidewire is inserted into the superior vena cava, the wire-guided ablation catheter can be used in RA ablation, including for the treatment of atrial tachycardia, dual atrioventricular nodal pathways and right heart bypass, and especially for anteroseptal accessory pathway ablation. When the guidewire is inserted into the pulmonary artery, the wire-guided ablation catheter can be used for right ventricular outflow tract ablation, in the treatment of conditions such as right ventricular premature contraction and tachycardia.

The purpose of the contact-mapping conducted in the present study was to enable evaluation of the controllability of the wire-guided ablation catheter in the same animal more comprehensively. In contact-mapping, the ablation catheter was maintained in the target locations for only three seconds with low power discharge, which results in little tissue injury to the atrium and PV, and enables repeated observation. The aim of the circumferential RSPV continuous contact is to stimulate circumferential PV ablation. The ablation catheter is rotated around the guidewire using the principle of compasses and circumferential PV ablation with appropriate pushing or bending of the catheter was completed. Circumferential RSPV discontinuous contact is designed to simulate the process of additional ablation after circumferential PV ablation has been conducted, and to enable assessment of the accuracy of positioning and contacting of the ablation catheter. The RSPV-antrum radial-linear continuous contact aims to stimulate LA linear ablation, with the ablation catheter only just positioned on and making contact along the planned ablation line. The RSPV-antrum radial-linear ablation was then achieved by pushing or bending the catheter. During operation of the wire-guided catheter, there is no need to be concerned about it causing excessive deflection or displacement, for reasons stated above, unless the guidewire causes prolapse of the PV. Therefore, the wire-guided ablation catheter greatly increases the stability of catheter manipulation and shortens the training period for less experienced physicians. The results of the contact-mapping have demonstrated that the controllability of the wire-guided ablation catheter is superior to the general saline-irrigated ablation catheter in achieving circumferential PV continuous contact, discontinuous contact and linear contact. In terms of contact/ablation, the present study has shown experimentally, in pigs, that the wire-guided ablation catheter markedly decreases both the average procedure time and the exposure time of circumferential RSPV ablation and of RSPV-antrum radial-linear ablation, which is consistent with the findings of the contact-mapping part of the study. The advantages of the wire-guided ablation catheter compared with the general saline-irrigated catheter are dependent on the guidewire itself, which plays an important role in aiding the movement of the catheter and in achieving contact with ablation sites. The guidewire and ablation catheter electrode are maintained at a certain angle, so the guidewire cannot establish contact with the ablation electrode and impede its contact during electrical discharge. Thus, the guidewire does not have a negative impact on the efficacy of the ablation, but can actually improve its efficacy because of the increased stability of contact that is achieved. The pathology examinations confirmed that both the wire-guided ablation catheter group and general saline-irrigated ablation catheter group exhibited visible transmural tissue injury as a result of PV tissue ablation, indicating success of the procedure.

The main processes of clinical AF ablation involve the manipulation of the catheter in the LA, and a common event is that the general saline-irrigated ablation catheter falls into the RA, especially in RSPV ablation. If the ablation catheter cannot be re-inserted into the LA after several attempts, it is necessary to repeat transseptal puncture [17]. However, this requires the use of an adequate amount of heparin, which therefore increases the risk of bleeding [18]. In the present study, it was
observed that the wire-guided ablation catheter had superiority over the traditional saline-irrigated catheter in reducing the likelihood of the catheter falling into the RA. In the event that this does occur, the wire-guided catheter can be manipulated very easily (and more quickly) along the axis of the guide-wire though the original atrial septal puncture and into the LA again because the guidewire still remains in the LA. The convenient transportation of the catheter between the RA and the LA is enabled by the use of the wire-guided ablation catheter, and unnecessary manipulations and exposure time can also be reduced.

During catheter manipulation, in the majority of cases the guidewire remains in the PV cavity and keeps constant motion with the PV. Therefore, it was considered important as part of the present study to observe whether its presence in the PV would create friction with and pressure on the PV. In order to prevent this potential damage of the guidewire on the PV intima, it is important that a hydrophilic wire with a soft bending front and a smooth surface should be selected. Furthermore, the distal hole of guidewire lumen should be installed with an anti-leakage locking device to prevent the backflow of blood, but also to prevent the slippage of the guidewire. Moreover, heparin saline could be transfused into the guide-wire lumen side hole to prevent thrombogenesis occurring in the guidewire lumen and the proximal hole. Our anatomical and histological observations revealed no injuries to or thromboses in the PV intima, suggesting that the wire-guided ablation catheter can be used with a high degree of safety.

Study limitations

Apart from its successful application in AF ablation, the wire-guided ablation catheter should, in theory, also be appropriate for use in RA, right ventricular and other arrhythmia ablation. However, the present study did not evaluate these other applications specifically. The procedural endpoint of local ablation was when the local potential disappeared or decreased by more than 90% [2]. However, we did not analyze the histological pathology of all ablation sites in every experimental animal. In the limited sample size, contact/mapping and contact/ablation were performed. Theoretically, the low energy power of the catheter electrode and short time of discharge would be unlikely to cause intimal injury. However, further studies with a larger sample size are required to confirm the findings.

Conclusions

This study has provided experimental evidence that the controllability of the wire-guided ablation catheter is superior to that of the general saline-irrigated ablation catheter for ablation of the RSPV, and that it can be used with a high degree of safety. The direction and distance of travel along the PV can be more reliably controlled with the wire-guided ablation catheter, and it can be more accurately positioned into target ablation sites, improving contact with them.

Acknowledgements

This work was supported by Key Projects in the National Science & Technology Pillar Program during the Twelfth Five-year Plan Period (2014BAI11B04), the National Natural Science Foundation of China (81370442) and the Shanghai Municipal Science and Technology Fund Project (134119b1700). We thank HuTai Medical Devices Co., Ltd, Shenzhen, for providing the wire-guided ablation catheters, and KaEr Kai Medical Devices Co. Ltd, Shanghai, for providing technical guidance and assistance.

Disclosure of conflict of interest

None.

Address correspondence to: Jianqiang Hu, Division of Cardiology, Department of Internal Medicine, First Affiliated Hospital, Second Military Medical University, Shanghai 200433, China. E-mail: hujianqiang@medmail.com.cn; Xue Zhao, Division of Cardiology, Department of Internal Medicine, Third Affiliated Hospital, Second Military Medical University, 700 North Moyu Rd, Anting Town, Jiading District, Shanghai 201805, China. E-mail: xuezhao688@163.com

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