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An Innovative Balloon-Type Surgical Device for Atrial Fibrillation

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ABSTRACT

Background. The maze procedure and its modifications are the surgical treatment for atrial fibrillation. In an attempt to achieve a less invasive operation, we developed a balloon-type device for electric pulmonary vein isolation and evaluated its effectiveness macroscopically and microscopically.

Methods. We created a left heart system model from 20 pigs. Based on a mold, a balloon was made with silicone resin. When this balloon was inflated, all pulmonary vein orifices were pressed and ablated by probes using radiofrequency and cryotherm as energy sources. Macroscopic and microscopic evaluations were performed.

Results. Complete circular ablation by radiofrequency was confirmed in 2 of 3 veins. The transmural denaturation was pathologically confirmed in all areas ablated at 80° for 2 minutes. The complete circular ablation line and the transmural denaturation were macroscopically and microscopically confirmed after cryoablation at –100° degrees for 2 minutes using liquid nitrogen.

Conclusions. This study proved that the balloon is effective in simplifying pulmonary vein isolation and has potential to become an instrument that contributes to less invasive operations in the near future.

INTRODUCTION

Based on multiple wavelet theory, which is employed in the surgical treatment of atrial fibrillation (AF), Cox et al reported the use of the maze operation for paroxysmal AF in 1991 [Cox 1991]. Haissaguerre et al found that premature atrial contraction took place by ectopic electrical excitement in the pulmonary vein, and reported catheter AF in 1998 [Haissaguerre 1998]. Improvements have been made and the Cox-maze III procedure, or its adaptations, are now performed [Cox 1995]. Although the curative rate for AF by the standard maze operation is high, there have been ongoing efforts to address the shortcomings and simplify this complicated and time-consuming procedure [Jais 2002].

In an attempt to simplify the maze operation and to shorten its operation time, we have developed a balloon-type device that allows simple and easy electric pulmonary vein isolation for mitral valve disease during open heart surgery, and we evaluated the clinical efficacy.

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MATERIALS AND METHODS

Creation of the Balloon

Epoxy resin (Wave, Tokyo, Japan) was poured into the heart chambers of heart-and-lung specimens of 20 pigs (average weight, 70 kg), and molds of a left heart system consisting of pulmonary veins, the left atrium, and the left ventricle were created (Figure 1). When the variation of the molds was checked, there was little difference in the formation of the branches of the pulmonary veins. As the inferior pulmonary veins form into a common trunk in pigs, 3 pulmonary vein orifices occur. A mold was randomly selected from the 20 molds. The balloon was modeled to fit the left atrium, the left ventricle, and the pulmonary vein orifices, and was made of silicone resin KE1300-T (Shin-Etsu Chemicals, Tokyo, Japan) by the dipping method (Figure 2). A tube made from silicone resin was set in the incision on the right side of the left atrium for infusing air or liquid into the balloon at the time of ablation to inflate the balloon and press the probe to the surface of the endocardium.

Ablation Procedure

Eight hearts of sacrificed pigs with an average weight of 70 kg were used for these studies. These hearts were bought from a slaughterhouse. We used radiofrequency (RF) and cryotherm (cryo) energy sources for ablation. RF was applied using a Cobra probe (Boston Scientific EP Technologies, San Jose, CA, USA). We ablated the left atrium of 2 hearts with RF at 80° degrees for 2 minutes, and 2 hearts were ablated at 70° degrees for 2 minutes with our balloon-type device (Figure 3). The ablation line was a circumferential line around each orifice of the 3 pulmonary veins.

Two types of cryoprobes were created. One was the flexible probe made by combining a silicone tube, a copper tube with

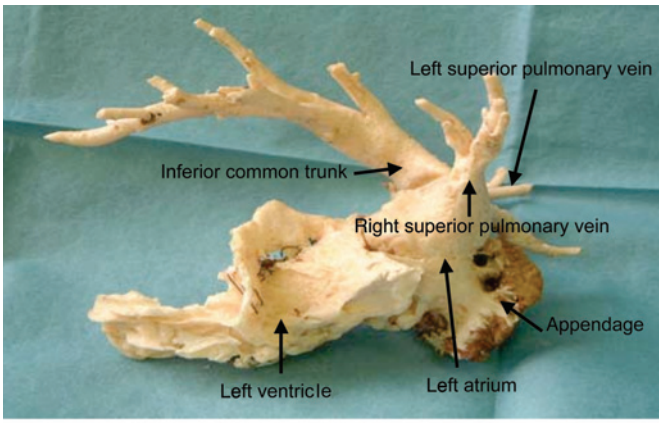

Figure 1. The mold of the left heart system consisting of the left atrium, pulmonary veins, and left ventricle made of epoxy resin.

an outer diameter of 3 mm, and a copper wire with a 0.3 mm diameter (Figure 4). This inexpensive probe had high thermal conductivity. The flexible probe was connected to the end of a PCG12R device for cryosurgery (Spembly Medical, Andover, UK) instead of to the tip and was cooled to –20°. The other probe was inflexible; and was made from a single 3-mm copper tube (Figure 5). The length of the inflexible probe was determined by the 20 molds of the left heart system.

The ablation line was the outer circumferential line around the 3 pulmonary veins at cryoablation. The left atrium was ablated within 6 hours after the pig was sacrificed, without necrotic change. Two hearts were cryoablated with the flexible probe at –20° for 5 minutes using high-pressure carbon dioxide, and another 2 hearts were ablated by the inflexible probe at –100° for 2 minutes using liquid nitrogen.

In addition, we performed epicardial ablation on a beating heart using RF and liquid nitrogen on the left atrium of a pig (body weight, 30 kg) without our device to estimate by Azan dyeing whether or not the ablation lesion was transmural. The pigs ablated with RF at 80° for 2 minutes and with cryoablation at –100° for 2 minutes were sacrificed after 3 weeks with KCL injection under general anesthesia.

Macroscopic and Microscopic Evaluation

Ablation lesions were examined macroscopically and microscopically. Sections were excised in a plane perpendicular to the short axis of the lesions. For the pathological study, specimens were taken from 4 parts randomly selected by the ablation lines of the myocardium and those treated by RF and cryo were stained with hematoxylin and eosin dyeing. In addition, the myocardium ablated from the epicardium by RF and cryo with the same thermal condition were stained with Azan dyeing.

RESULTS

Balloon Construction

The balloon was suitably fit to each pulmonary vein and left heart in all 8 pigs and we confirmed that the balloon effectively executed pressure. Insertion and inflation were smooth and took only about 1 minute. There was no damage to the balloon due to temperature change of the probes.

Macroscopic Observation

Among the 12 veins that were ablated with RF, a circumferential linear ablation was confirmed on the left atrium by 1-time ablation, except for the right upper pulmonary veins. At the right upper pulmonary vein, a circumferential linear ablation line was confirmed on the left atrium by ablating twice. With cryoablation, a circumferential linear ablation was confirmed at the outer circumferential line surrounding

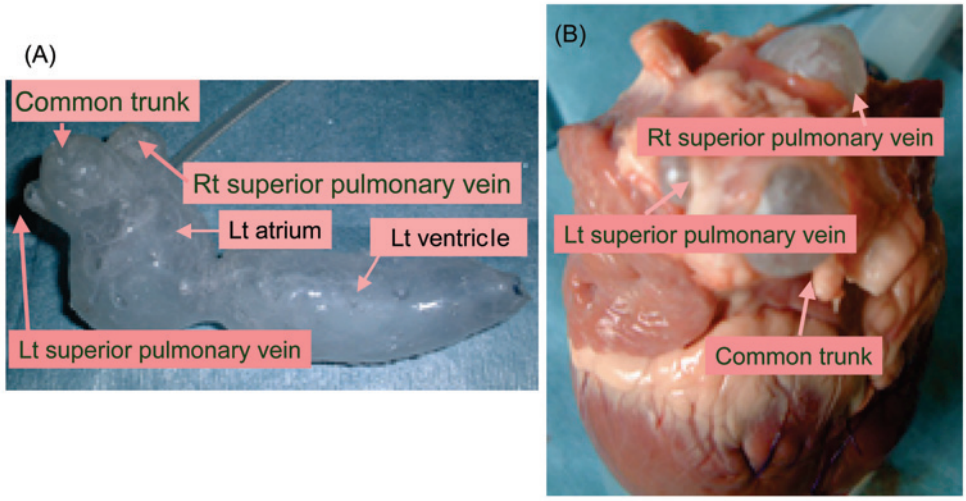

Figure 2. A, The new balloon device made of silicone resin by the dipping method. This balloon consists of 5 components, and the components fit to the left ventricle, left atrium, right superior pulmonary vein, left pulmonary vein, and common trunk. B, The balloon inserted into the pig heart through the right side of the left ventricle.

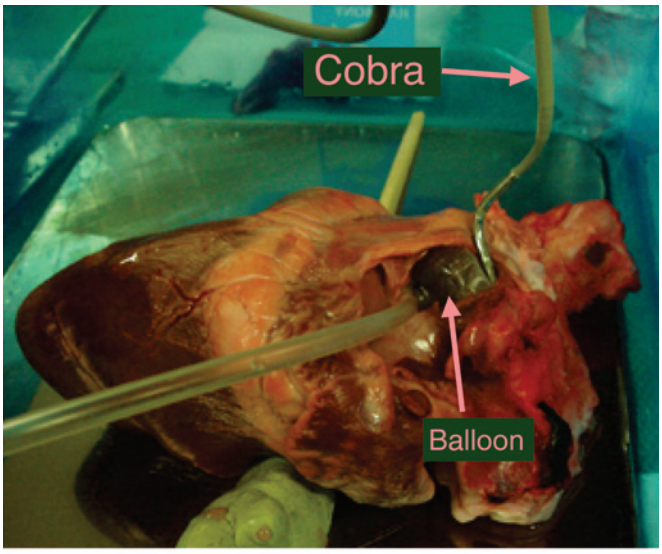

Figure 3. Ablating the left atrium by applying radiofrequency with the balloon.

the 3 veins by 1-time ablation, but was not as clearly recognizable as the RF ablation.

Microscopic Examination

In the specimens from the orifices ablated by RF, the effect of ablation was characterized by the denaturated cells changing to flat against the atrium due to heat. Transmural denaturation of the left atrium was achieved at 80° for 2 minutes, but not at 70° for 2 minutes with RF. Using cryoablation, the effect of ablation was identified by the extent of the expansion of the space between muscular fibers in the left atrium. It was thought that this change was created when the frozen tissue melted. Transmural denaturation of the left atrium was recognized at –100° for 2 minutes, but not at –20° for 5 minutes with cryo. In the chronic model, RF and cryoablated linear lesions turned to blue by Azan dyeing and they showed transmural ablation changes in blue (Figures 6 and 7).

COMMENTS

Purpose

The maze procedure is the treatment for atrial fibrillation with the lowest rate of recurrence and has good treatment results [Cox 2000]. However, due to its complexity and invasiveness, efforts are being made to simplify the maze procedure and make it less invasive. There are 2 ways of simplifying this procedure. One is using ablation instead of incision. The other is omitting the incision line. Although the recurrence rate for modified maze procedures is slightly higher than for the maze procedure, there has been a certain degree of success. We sought to make a new operative device that can achieve the same quality result as the maze procedure.

There are some ablation devices that can be used instead of an incision. They include RF, cryo, microwave, ultrasound, laser, and other such devices [Klein 1979; Shepherd 1982; Guiraudon 1987; Ott 1987; Wonnell 1992; Haissaguerre 1996; Gaita 1998; Spitzer 1999; Chen 1999; Keane 1999; Roithinger 1999; Natale 2000; Tanaka 2001; Sie 2001; Gillinov 2002; Maessen 2002; Mazzitelli 2002; Prasad 2002; Vigilance 2003]. We set out to make a new device using RF or cryo, which are the most popular ablation devices among these sources. The main disadvantage of the standard ablation device currently used is that it takes a long time to make a linear ablation. We made a new cryoprobe for linear ablation to shorten the ablation time and we made a balloon-type device that fits the left atrium and all pulmonary vein orifices to adhere the probe to the endocardium. Using this balloon makes it more certain that the endocardium will be ablated.

Energy

The most common mode of RF, 70° for 2 minutes, and a higher mode of 80° for 2 minutes were applied. At 80° for 2 minutes, transmural ablation lesions were recognized in all collected specimens. At 70° for 2 minutes, nontransmural ablation lesions were recognized in most of the collected specimens. These results suggest that when using RF, a suitable ablation mode is 80° for 2 minutes.

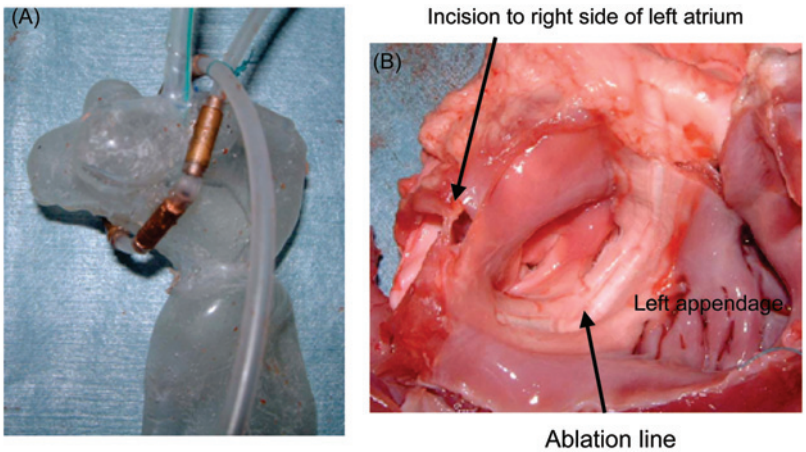

Figure 4. Flexible tube with balloon. Ablated line by flexible tube with balloon. Linear ablation is recognized around the orifices of the pulmonary veins.

Figure 5. Inflexible tube with balloon. Liquid nitrogen goes through the tube.

We developed new probes for cryoablation, 1 flexible and 1 inflexible, that can ablate linear lesions. The flexible probe is ideal for fitting the probe to the endocardium for linear ablation lesions. We used high-pressure carbon dioxide and liquid nitrogen for cryoablation. When liquid nitrogen was poured into the flexible probe, liquid nitrogen leaked. We therefore used the flexible probe only with high-pressure carbon dioxide. High-pressure carbon dioxide is used for cryoablation in general [Shepherd 1982; Guiraudon 1987; Ott 1987]. The probe temperature reached only –20° using high-pressure carbon dioxide. We defined the ablation time as 5 minutes, slightly longer than usual. For more effective cryoablation we used liquid nitrogen with the inflexible probe made of a copper tube. The ablation line at cryo was the outer circumferential line around the 3 pulmonary vein orifices, so making the probe was not difficult. Our results showed that ablation using liquid nitrogen was more suitable and effective than ablation using high-pressure carbon dioxide.

Balloon

The standard balloon-type device that is used now is made for the catheter maze procedure, so it is inserted one by one into the pulmonary vein orifices [Natale 2000; Tanaka 2001]. Our new balloon-type device was made for use with diseases requiring open heart surgery. Our device is different from the balloon-type device currently used because the new balloon device can be attached to several pulmonary vein orifices at the same time and can make simultaneous linear ablation lesions of multiple veins. We used this balloon on 6 pig hearts. It did not take much

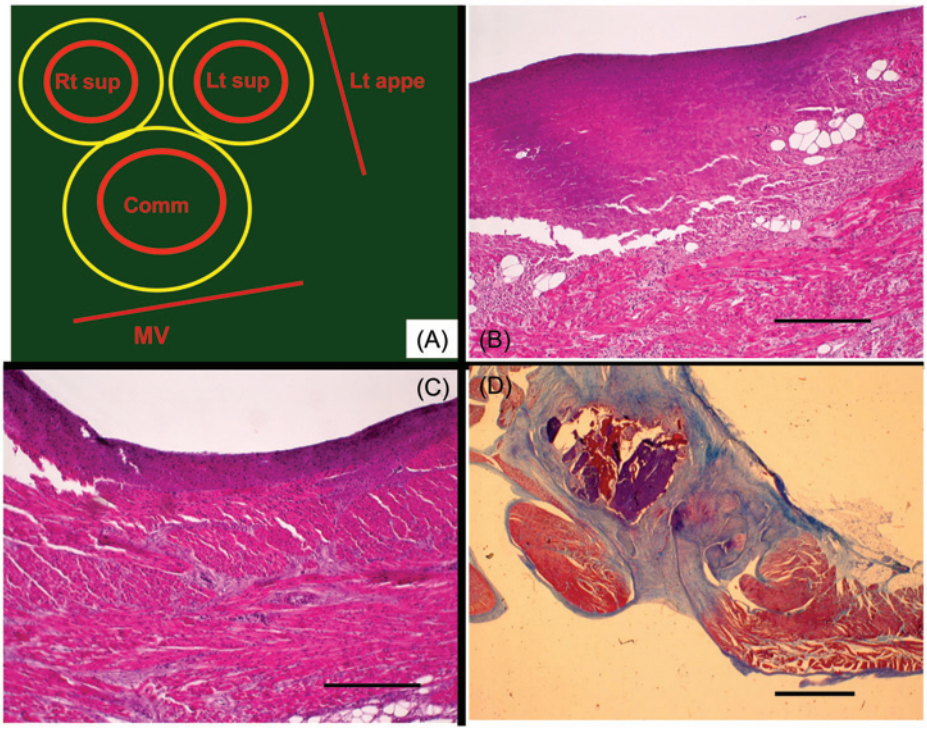

Figure 6. A, Ablation line at radiofrequency. Ablation line was a circumferential line of each orifice of the 3 pulmonary veins. B, Histologic hematoxylin and eosin stained sections taken from the ablation lesion by radiofrequency at 70° for 2 minutes. Transmural change was not recognized (original magnification ×20). The scale bar shows 300 μm. C, Histologic hematoxylin and eosin stained sections taken from ablation lesion by radiofrequency at 80° for 2 minutes. Transmural change was recognized (original magnification ×20). The scale bar shows 500 μm. D, Tissues ablated by radiofrequency, linear lesion turned to blue by Azan dyeing. Transmural change was recognized (original magnification ×20). The scale bar shows 2000 μm. Rt sup indicates the right superior pulmonary vein; Lt sup, left superior pulmonary vein, Lt appe, left appendage; MV, mitral valve.

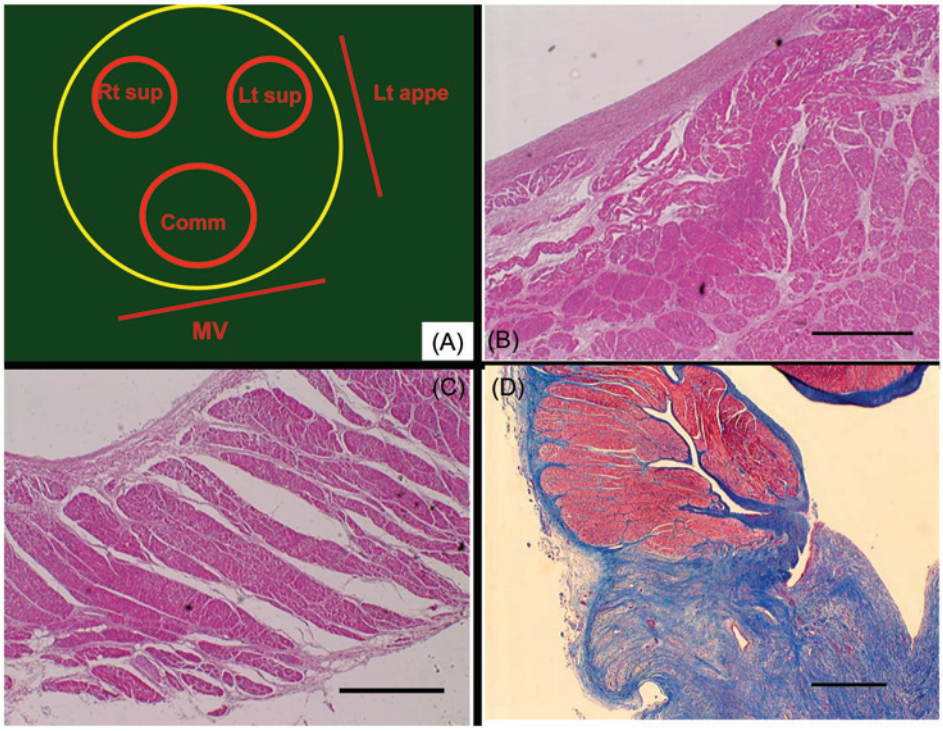

Figure 7. A, Ablation line at cryo. Ablation line was the outer circumferential line surrounding the 3 pulmonary veins. B, Histologic hematoxylin and eosin stained sections taken from the ablation lesion by cryotherm at −20° for 5 minutes. Transmural change was not recognized (original magnification ×8). The scale bar shows 500 µm. C, Histologic hematoxylin and eosin stained sections taken from the ablation lesion by cryotherm at −100° for 2 minutes. Transmural change was recognized (original magnification ×8). The scale bar shows 500 µm. D, Histologic Azan stained sections taken from the ablation lesion by cryotherm at −100° for 2 minutes. Cryoablated linear lesion turned to blue by Azan dyeing. Transmural change was recognized (original magnification ×2.5). The scale bar shows 300 µm. Rt sup indicates the right superior pulmonary vein; Lt sup, left superior pulmonary vein; Lt appe, left appendage; MV, mitral valve.

time to set the new balloon into the pig heart, and it could be easily fit to every pulmonary vein orifice and to the left atrium. Furthermore, this new balloon made of silicone resin was not damaged by heat or cryo, so it made linear ablation more effective. The shortcoming of this device is that it can be used only during cardiopulmonary bypass or open heart surgery. If it were a catheter device it would be less invasive, but this is only an operative device.

Consideration of Literature

The success rate of the traditional maze procedure is reported to be 60% to 90% [Gillinov 2002; Jais 2002]. Most recently, Cox reported that the long-term success rate of maze procedure is 99%, an extremely high result [Cox 2000]. Although the nonrecurrence rate for the modified maze procedure is 60% to 80%, lower than the maze procedure, it has obtained certain fixed results [Isuminoto 2000; Gillinov 2002; Jais 2002].

Complications and shortcomings of the maze procedure are postoperative bleeding, sick sinus syndrome, atrial tachycardia, stored humor due to deceasing secretion of atrial natriuretic peptide after the removal of an appendage, and decrease of atrial contractions. To address these complications, operations such as the left maze and radial maze procedure have been modified and the use of cryo and RF has increased [Haissaguerre 1998; Izuminoto 2000].

A comparison of the 2 widely used ablation devices, RF and cryo, indicates that RF is more often used and is highly safe. In addition, it is advantageous because the ablation lesion can be identified macroscopically. But it has some disadvantages in that it causes thrombus formation due to damage to the endocardium and causes damage near the organ around the ablation lesion [Khairy 2003]. Cryoablation is also highly safe. Its advantage is that it does not cause damage to the endocardium and maintains the structure of atrial tissue. But ablation using cryo takes time, and identification of ablation lesions is difficult [Gillinov 2002]. This study indicated that when attempting to make a more complex ablation line it would be easier with a device using cryo rather than RF. If a flexible probe for cryoablation is made, one that is suitable for the new balloon introduced in this study, it is highly possible that we could create a more complex linear ablation line.

Study Limitations

In this study, we did not evaluate the efficiency of thermal injury to tissue around the heart, thermal conduction with blood perfusion tissue, or the electrophysiological effect of ablation with the animal model of atrial fibrillation. But the pathological study was sufficient enough to evaluate the effect of ablation using both energies.

CONCLUSION

The left heart system balloon with an attached probe is ideal as an ablation device. It is thought that the balloon-type device we developed is effective in shortening the time required for electric pulmonary vein isolation and might become a surgical instrument used for less invasive operations in the near future.

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