

New implantable therapeutic device for the control of an atrial fibrillation attack using the Peltier element

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Abstract— For the development of the new therapeutic device for the atrial fibrillation, implantable cooling device using Peltier element was developed in this study. An implantable cooling device had been consisted from Peltier element with transcutaneous energy transmission system (TETS). 1st coil can be contacted from outside of the body, when the patients will feel palpitation. Electrical current will be induced to the implanted 2nd coil. Peltier element will able to cool the surface of the atrium. For the confirmation of the effect of the cooling device, trial manufacture model was developed. Animal experiments using six healthy adult goats after animal ethical committee allowance was carried out. Fourth intercostals space had been opened after anesthesia inhalation, and various sensors had been inserted. AF was induced by the electrical current with battery. As the results, AF had been recovered to the normal sinus rhythm after cooling in all six goats. So, this cooling system for the control of AF showed evident effect in these experiments. Smaller size cooling device has been under development aiming at totally implantable type. Catheter type cooling device for the insertion by the use of fiber-scope type is now under planning for the clinical application. This new type device may be able to become good news for the patients with uncontrollable AF

I. INTRODUCTION

In some previous papers, atrial fibrillation (AF) has been reported to be difficult to control in some cases with conventional therapy like medication or the ablation. Stroke has been occurred due to the thrombus formation in atrium by AF in some cases. Quality of life in patients with stroke has been limited in almost cases, unfortunately (1-3).

For the treatment of AF, the Maze operation, or catheter ablation have been used in the hospital for the severe patients resistant to medical therapy. However re-attack of AF has been observed in many cases after the invasive treatments.

New therapeutic strategy has been invented in our laboratory. After the development, animal experiments using new therapy have been carrying out. Satisfactory results have been obtained in this study.

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Activity of the human cell is reduced by cooling. So, methodology of cooling has been used in the hospital as the cardiopulmonary bypass for the cardiovascular surgery. By the use of this methodology, totally implantable epilepsy control device had been developed in our laboratory (3-9). By the use of this epilepsy control machine, Seizure attack had been stopped.

AF may also be able to be controlled by the cooling methodology.

Fig.1 showed the mock up model for the basic concept of an implantable AF control machine using the Peltier element with Transcutaneous energy transmission system (TETS). When the patients feel palpitation, attach the 1st coil from outside of the body. Electrical current will be induced by the magnetic force, and the Peltier elements will cool the surface of the atrium. By this cooling device, AF will be able to be controlled.

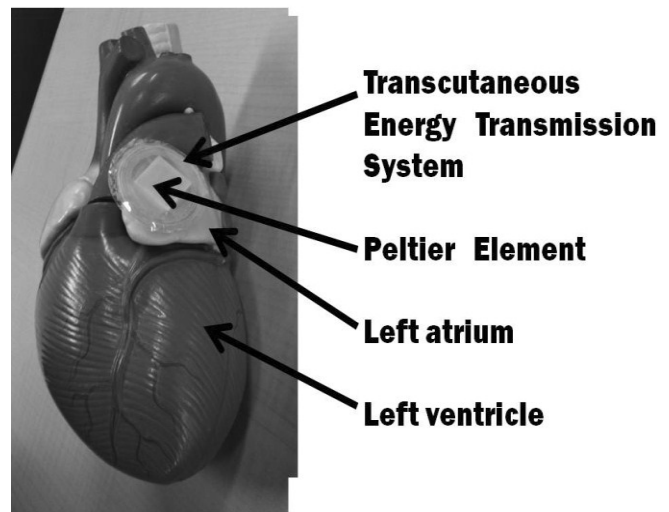


Fig.1 Mock-up model for the implantable Atrial Fibrillation (AF) control device on the model of heart

II. TRIAL MODEL THE CONFIRMATION OF THE EFFECT OF COOLING

Firstly, the effect of cooling for AF should be evaluated. In this study, the Peltier element device was used to cool the surface of the atrium. Another surface would be heated on this system. For the control of the heating in the other side of Peltier element, water flow cooling circuit had been designed.

Design concept of the Peltier cooling device was shown in fig.2. In this system, heat had been transferred from one side to another side. One side contacting to the atrium has been cooled, though other side has been heated. In the test piece for animal experiments, heated side has covered with copper heat sink, and has been cooled by the water cooling system with radiator fin

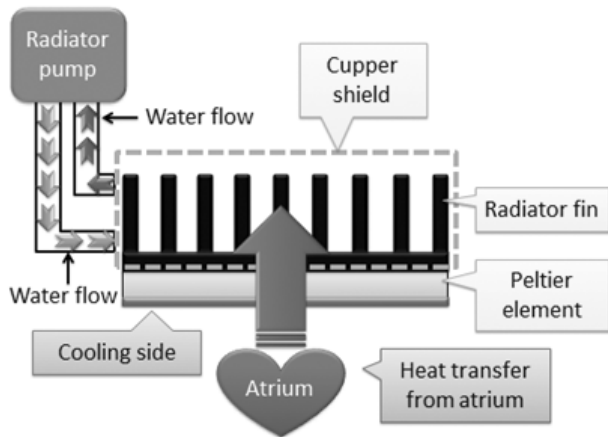


Fig. 2 Prototype 1st model of the basic concept of the implantable AF control device

Two types of system had been developed. There were the large surface type and the small surface type. Large one had the 40mm square to cover all atrial surface, and small one had 15 mm square to cool the small area of the focus of AF. They will be able to be selected by the anatomical condition and pathophysiological condition.

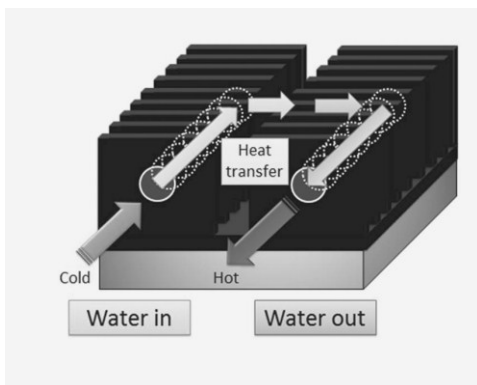


Fig.3 Water flow system for the Peltier cooling device

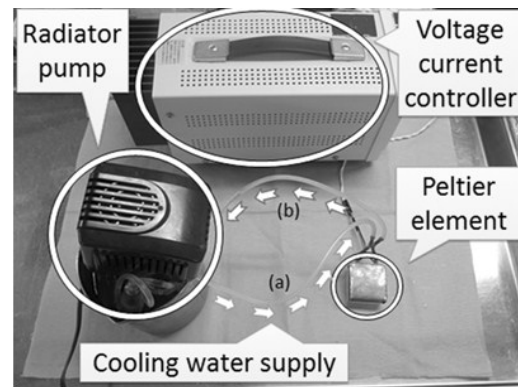


Fig.4 A photograph of the Peltier cooling device

III. MATERIAL AND METHOD

For the quantitative evaluation of the cooling effect of peltier device, thermo-camera (AVIO, TVS200, Tokyo, Japan) had been used in this experimental series.

Electrical current was controlled by the voltage current controller, and water cooling system was perfused with Radiator pump as we shown in fig.2. Water cool system with radiator fin enabled the cooling of another side as we shown in fig.3.

As we show the results in fig.5, the bench test cooling characteristics recorded from the surface attached to the heating water was satisfactory. Total evaluation time was 3.0 min. Each measurement had been performed in every ten seconds.

After the confirmation of the basic characteristics of the device for cooling under development, the animal experimental series were carried out after ethical committee allowance for animal experiments in the Tohoku University Graduate School of Medicine.

After the anesthesia introduction with the inhalation of Halothane, the experimental goats had been moved from cage to the surgical bed. Tracheal tube intubation was carried out and the fourth intercostals space was opened for the approach to the chest cavity. Hemodynamic recording was carried out by the various sensors inserted into heart cavity. Electrocardiography (ECG), high atrium ECG, pressure time series data of the cardiac ventricle were recorded for the evaluation.

IV. RESULTS

Time series data of the temperature changes on the surface of the Peltier attached to the heated water in the bench test had been evaluated, and shown in fig.5. With higher electrical current voltage, higher cooling effect had been evident. Effect of cooling had been kept by the water perfusion system.

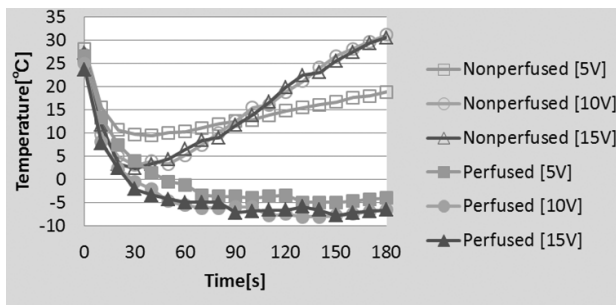


Fig.5 Temperature change of the surface of the Peltier cooling device with water perfusion

As the results of the developments, Cooling effect was shown to be evident in every condition. Cooling was realized by the use of Peltier element. Cooling device to control AF was embodied, and cooling effect of surface was shown in this data. Water perfusion effect for rapid cooling was evident. Keeping effect of cooling were observed in the water perfusion system.

Consistent cooling should be considered, when we would like to realize the consistent cooling of atrium. Selection of the device must be considered on the patho-physiological condition of the AF in every patient. For the patients, who need short time cool, simple Peltier device might be needed. For the patients, who need long time cool, the Peltier with water cool device might be desirable.

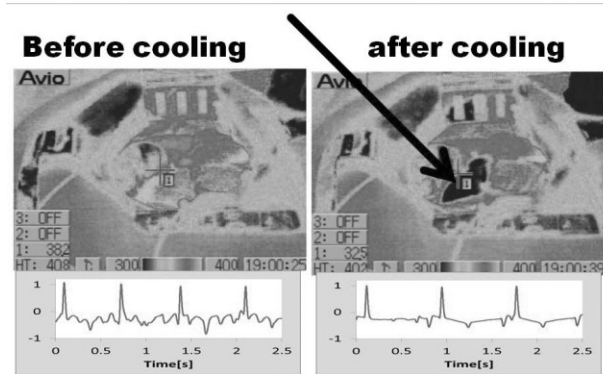


Fig.6 Thermography of the heart during animal experiments using a healthy adult goat with AF induced by the electrical current, and recovered to the normal sinus rhythm

Satisfactory cooling effect was observed in these experimental series, so, we had performed the animal experiments using healthy adult goats after the ethical committee allowance of the animal experiments in Tohoku University Graduate School of Medicine.

Animal experiments were performed with six healthy adult goats. Anesthesia was induced with the halothane inhalation and left chest cavity was opened in the forth

intercostals space. AF was induced by the electrical current with battery.

After the induction of AF, Peltier element had been contacted to the surface of the left atrium. After the attachment, ECG had been returned to the normal sinus rhythm as we shown in fig.6 with thermo camera.

Left atrium was significantly cooled after the contact of peltier cooling device as we shown in fig.6.

Before cooling, f wave was observed in ECG, though f wave was diminished after cooling.

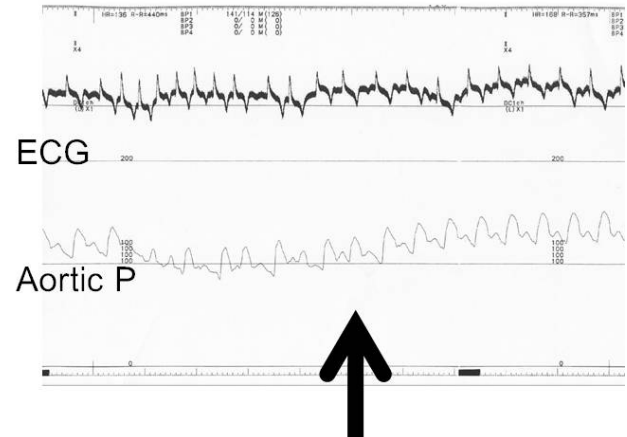


Fig.7 ECG and aortic pressure during Peltier treatment

In six experimental cases of the goats, all goats returned to the sinus rhythm by this Peltier device. The results suggested the usefulness of the cooling device to control AF.

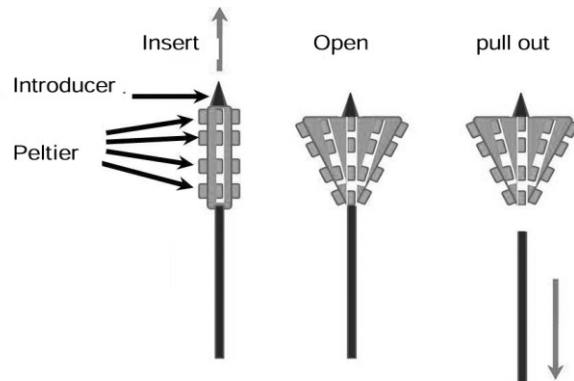


Fig.8 Basic concept of the Peltier insertion system

As we shown in fig.7, heart rate rhythm was randomized by AF induction with electrical current. This randomized rhythm indicated the AF rhythm. Blood pressure levels had been fallen by AF. By the contact of Peltier(arrow), the Blood pressure returned to the normal level, and ECG rhythm returned to normal sinus rhythm.

In the next stage, discussion must be considered concerning the cooling time, because almost AF rhythm returned to the normal sinus rhythm within relatively short time.

As the results, satisfactory hemodynamic parameters recovery had been observed in these experimental series.

V. DISCUSSION

In six experimental cases of the goats, all goats returned from Af rhythm to the normal sinus rhythm by the Peltier cooling device. So, the effect of this new therapeutic method to treat AF had been evident in animal experiments.

Cooling time must be discussed depending on pathological condition to treat the AF patients. Optimal cooling time must be proposed after the electro physiological study data of each patients. In the experimental data, AF of almost goats returned to the normal sinus in relatively short time. So, it might be enough by short time cooling without water circuit.

The mechanism of this therapeutic effect is now under discussion. The reduced activity by cooling may be origin. Vagal activity and autonomic function may be important. We will continue our study to evaluate the mechanism.

Open heart surgery is not so desirable when we consider the QOL of patients. So, new insertion system for the Peltier cooling device is now under development. This insertion system was inserted directly into the pericardial space as we shown in fig.8, so invasion will become too small.

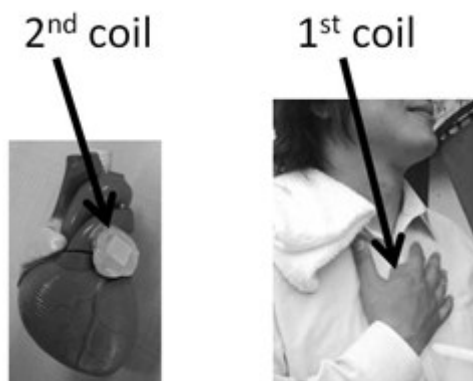


Fig. 9 Patients will be able to attach the 1st coil, when they will feel arrhythmia

In conclusion, AF can be returned to normal sinus rhythm by our system. If our system will be embodied, patients will be able to stop the palpitation by themselves. Patients will easily contact the portable 1st coil from outside of the body. Electrical current will be able to be induced by magnetic force. The focus of AF attack will be cooled. Palpitation will be terminated.

Peltier cooling system may be the good news for the patients with AF in near future.

A conclusion section is not required. Although a

conclusion may review the main points of the paper, do not replicate the abstract as the conclusion. A conclusion might elaborate on the importance of the work or suggest applications and extensions.

Acknowledgment

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References

- [1] M. Nair et al “Results of radiofrequency ablation of permanent atrial fibrillation of >2 years duration and left atrial size >5 cm using 2-mm irrigated tip ablation catheter and targeting areas of complex fractionated atrial electrograms” *Am J Cardiol.* 2009 Sep 1;104(5):pp683-8.
- [2] I. Peshko et al. “Fiber photo-catheters for laser treatment of atrial fibrillation.” *Opt Lasers Eng.* 2007 Apr 1;45(4):pp495-502.
- [3] *Jpn.Pt.Appl* 2006-141993. Cooling device.
- [4] T. Yambe, et al, “Chaos analysis of electro encephalography and control of seizure attack of epilepsy patients” *Biomed Pharmacother.* 2005 Oct; 59:pp236-8.
- [5] T. Yambe, et al, “Can personality traits predict pathological responses to audiovisual stimulation?” *Biomed Pharmacother.* 2003 Oct;57 Suppl 1:pp83s-86s.
- [6] WO2004/112868. artificial myocardium
- [7] *Jpn.Pt.Appl* 2007-82898. Transcutaneous energy transmission system
- [8] 01121110.5. China, Pt. Artificial Sphincter
- [9] *Jpn.Pt.Appl.*2006-281664 Control acupuncture
- [10] H. Sato, et al. “Efficacy of bundle ablation for cavotricuspid isthmus-dependent atrial flutter: combination of the maximum voltage-guided ablation technique and high-density electro-anatomical mapping.” *J Interv Card Electrophysiol.* 2010 Jun;28(1):pp39-44.