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A Highly Articulated Robotic Surgical System for Minimally Invasive Surgery

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Purpose. **We developed a novel, highly articulated robotic surgical system (CardioARM) to enable minimally invasive intrapericardial therapeutic delivery through a subxiphoid approach. We performed preliminary proof of concept studies in a porcine preparation by performing epicardial ablation.**

Description. **CardioARM is a robotic surgical system having an articulated design to provide unlimited but controllable flexibility. The CardioARM consists of serially connected, rigid cyclindrical links housing flexible working ports through which catheter-based tools for therapy and imaging can be advanced. The CardioARM is controlled by a computer-driven, user interface, which is operated outside the operative field.**

Evaluation. **In six experimental subjects, the CardioARM was introduced percutaneously through a subxiphoid access. A commercial 5-French radiofrequency ablation catheter was introduced through the working port, which was then used to guide deployment. In all subjects, regional ("linear") left atrial ablation was successfully achieved without complications.**

Conclusions. **Based on these preliminary studies, we believe that the CardioARM promises to enable deployment of a number of epicardium-based therapies. Improvements in imaging techniques will likely facilitate increasingly complex procedures.**

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A variety of "epicardium-based" therapies are under development, including ablation, injection, pacing lead placement, and atrial appendage occlusion. We are particularly interested in subxiphoid access for therapeutic delivery. The subxiphoid approach is a useful method to access the pericardial space for diagnostic and therapeutic interventions, as there are no significant anatomic barriers. We previously reported some accomplishments using a rigid shaft, subxiphoid video-pericardioscopic device through a subxiphoid approach, such as the left atrium appendage ligation, pacing lead implantation, and epicardial mapping [1–3]. However, rigid shaft instruments provide only limited access to the posterior aspect of the heart due to their limited degree-of-freedom.

We have developed a novel, highly articulated, robotic surgical system (CardioARM) that can accommodate considerable anatomical complexity in the mediastinum. In this study, we demonstrated the use of this tool by performing epicardial ablation in a porcine model.

Technology

Device Design

The CardioARM is composed of 50 rigid cylindrical links serially connected by three cables. Two adjacent links can rotate approximately ±10 degrees relative to each other. The current distal apparatus is 10 mm in diameter and 300 mm in length, with 105 degree-of-freedom. A novel feature of this mechanism is that all of the links do not have to be individually controlled; this device is sometimes called a "follow-the-leader" mechanism. When the user specifies inputs for the distal tip of the robot, all the other links follow its location. Hence, the distal apparatus is capable of preserving its previous three-dimensional (3-D) configuration (Fig 1A). The operator uses a 2-degree-of-freedom joystick to control the distal link together with a button to control forward/backward motions. The radius of curvature of the distal apparatus is 35 mm at minimum. The maximum speed of forward and

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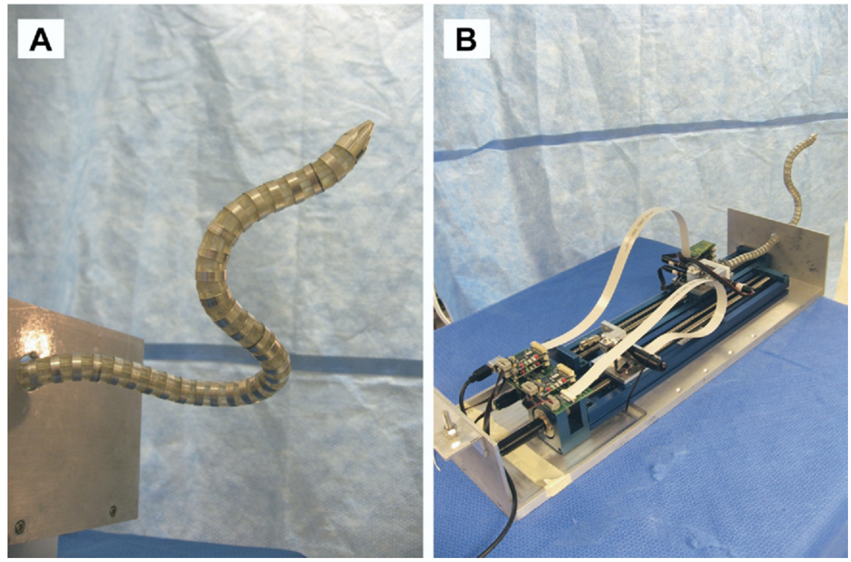

Fig 1. (A) Distal apparatus of the CardioARM consisting of cylindrical links articulated by spherical joints. (B) The feeder instrumentation box contains all mechanics necessary for probe manipulation, which includes motors for controlling the cables and actuators for the driving system.

reverse movement is up to 20 mm/s. All mechanics responsible for maneuverability are mounted in a feeder instrumentation box (500 mm length, 170 mm width, and 100 mm height) (Fig 1B). The custom-designed software translates the master manipulator's input into movement of the CardioARM. In case of emergency the mechanism can be turned limp so that it can be withdrawn safely and quickly. We are able to pass catheter-based tools for therapy and imaging through the CardioARM. Visualization is provided by an onboard optical 15-K bundle fiber scope with an integrated light guide, 65° field of view, 640 × 480 CCD camera (fiber, FIGH-30-850N [Myriad Fiber Imaging Technology, Dudley, MA]; camera: EO-2AN, [Edmund Optics, Barrington, NJ]).

Technique

In Vivo Testing

Healthy large swine (n = 6) were anesthetized and placed in a supine position. A small subxiphoid skin incision (length, 20 mm) and pericardiotomy (diameter, 15 mm) were created under direct visualization. The CardioARM was mounted on a surgical table in a position for easy insertion through the subxiphoid incision. The distal apparatus of CardioARM was introduced into the pericardial space under the surgeon's control while watching a monitor display of the onboard optic fiber view (Figs 2A and 2B). First, navigation trials to acquire several anatomical targets (ie, right atrial appendage, superior vena cava, ascending aorta, left atrial appendage, transverse sinus from the left side, and atrioventricular groove in the posterior wall of the heart) were performed. When one target was acquired, the distal apparatus retracted to the initial position (ie, the subxiphoid incision), then moved to another target. After the navigation trials, left atrial ablation trials were performed. Once the tip of the CardioARM was positioned at the vicinity of a target on the left atrium, a 5-French radiofrequency ablation catheter (Biosense Webster, Diamond Bar, CA) was passed through a working port of the CardioARM, and a linear

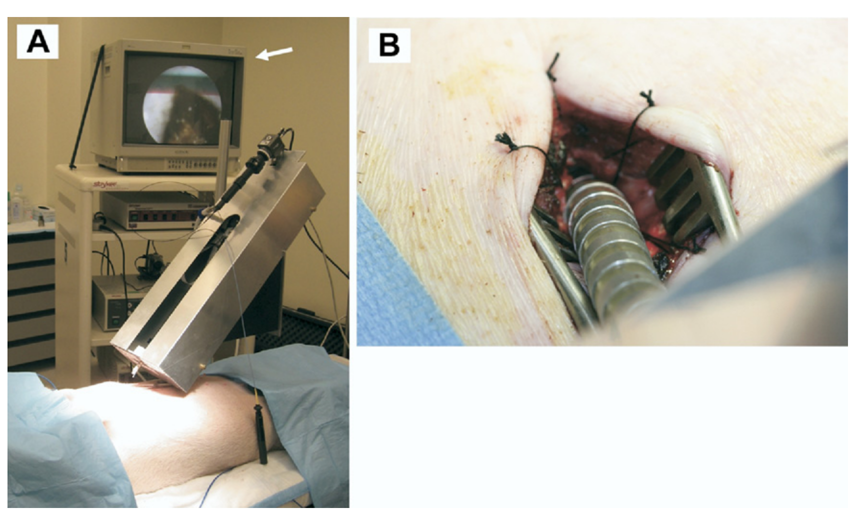

Fig 2. Intraoperative pictures during porcine trials. (A) The CardioARM is mounted on the operating table using a custom mounting frame. The onboard optic fiber view is displayed on the monitor (arrow). (B) A small subxiphoid incision and small pericardiotomy are manually made under direct visualization. The distal apparatus of the CardioARM passes through the pericardiotomy.

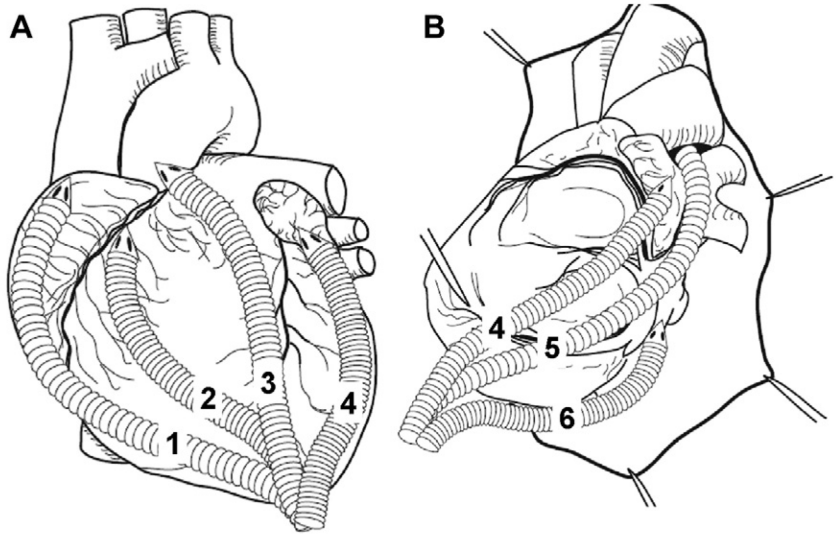

Fig 3. The accomplished courses of the distal apparatus of the CardioARM in the navigation trials. (A) Front view. (B) Left lateral view. (#1 = superior vena cava; #2 = right atrial appendage; #3 = ascending aorta; #4 = left atrial appendage; #5 = transverse sinus; #6 = atrioventricular groove.)

ablation lesion was created on the left atrial epicardium. A radiofrequency energy generator (Stockert 70; Biosense Webster) was set to deliver a power of 30 watts for 30 seconds per lesion. Blood pressure and electrocardiogram were monitored throughout the trials. The animals were euthanized at the end of the trials, and postmortem examination was performed.

The protocol was approved by the Institutional Animal Care and Use Committee of the University of Pittsburgh. All animals received humane care in compliance with the Guide for the Care and Use of Laboratory Animals, published by the National Institutes of Health in 1996.

Clinical Experience

Results

All animals tolerated the procedures well, until their elective euthanasia. In the navigation trials, the distal apparatus of the CardioARM followed a complex three-dimensional path from the subxiphoid incision along the ventricular wall to each target (Fig 3). All navigation targets were acquired without complications (eg, fatal arrhythmia, hypotension, bleeding). The onboard camera provided adequate visualization for navigation (Fig 4A).

In the ablation trials, a linear lesion composed of several consecutive "dot-to-dot" lesions at the base of the left atrial appendage was successfully completed (Figs 4B and 4C). No adverse event was noted during the trials. There was no injury due to the positioning of the robot and the manipulation of the tools to the surrounding mediastinal structures (ie, phrenic nerve, lung, pulmonary artery) on postmortem examinations.

Comment

Catheter-based ablation has recently been a major treatment for arrhythmias [4]. The standard approach for catheter-based ablation is from the endocardial aspect of the heart. The endocardial catheter-based technique, however, suffers from significant potential for complications (eg, cerebrovascular accident, tamponade, pulmonary vein stenosis) [5, 6]. In addition, there is a significant

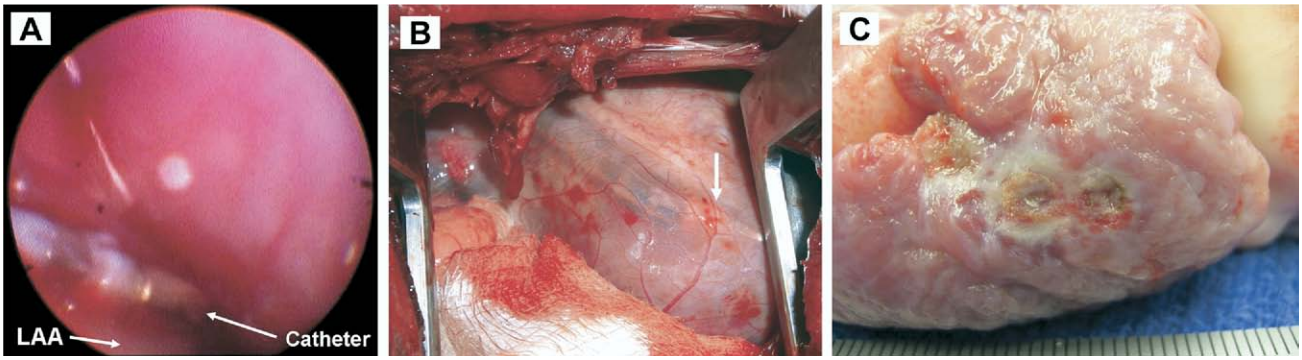

Fig 4. (A) A picture of the onboard view during the epicardial ablation trials. (B) The distal apparatus of the CardoARM is seen through the pericardium (arrow). The tip of the robot is navigated to the left atrial appendage over the lateral wall of the heart. A left thoracotomy was created only for photographing probe movement. (C) A linear "dot-to-dot" lesion at the base of the left atrial appendage of the excised heart. (LAA = left atrial appendage.)

NEW TECHNOLOGY

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number of cases refractory to endocardial ablation, where an arrhythmia circuit is located close to the epicardial surface of the heart [7].

Epicardial ablation has been successfully used for the management of several arrhythmias (eg, ventricular tachycardia, atrial fibrillation) [8], and has proven to be safe and effective treatment [4]. Due to the lack of dedicated minimally invasive technology, however, epicardial ablation is typically performed using such relatively invasive approaches as full sternotomy or thoracotomy, considering the intrinsically simple nature of the procedure. Consequently, epicardial ablation trends to be performed in conjunction with concomitant surgical procedures. Sosa and colleagues [9] reported the minimally invasive catheter-based subxiphoid access to the intrapericardial space for epicaldial ablation using fluoroscopic image guidance [9]. This approach, however, can not provide proper visualization to recognize anatomical landmarks on the surface of the heart, as well as precise navigation.

As commercially available robotic systems aimed at minimally invasive cardiac surgery have gained popularity, surgeons have also realized their significant limitations. The ability to operate in highly confined and dynamic spaces is of particular concern in cardiac surgery and as Krummel has noted, "the back of the heart is a tough place to get to, no matter how you try it" [10]. As a potential solution to such difficulties, Krummel has also suggested the development of "active catheters" [10] for greater accuracy in accessing deeply remote anatomy that has been proposed.

The CardioARM is developed in an effort to provide dedicated intrapericardial therapeutic delivery with single port access (ie, subxiphoid approach). The CardioARM is capable of navigating the entire surface of the heart with visualization, including the posterior of the heart. In addition, the CardioARM can accommodate any commercially available catheter-based tools through the working ports of the robot (up to 8-French for the current CardioARM model). Therefore, it is technically feasible to perform not only epicardial ablation, as in this study, but also epicardial injection, biopsy, mapping, and left atrial appendage ligation.

The most important advantage of the CardioARM is the ability to preserve its previous configuration and shape in three-dimensional space during navigation. This feature is distinctively different from general endoscopic devices, which rely on a static shaft and the ability to only control the tip. The "shape-keeping" ability of the CardioARM is especially important in the pericardial space, where there is concern about interference with the beating heart.

Our future work will focus on improving the maneuverability capability of the device by downsizing the diameter of the distal apparatus and by reducing the radius of curvature of the mechanism. Moreover, haptic feedback will be incorporated to signal interaction between the device and its surrounding tissue to improve operator controllability. The development of a dedicated catheter-based instrument to dissect pericardial reflections will enable the CardioARM to achieve pulmonary vein isolation ("a box lesion set") through a subxiphoid approach.

In conclusion, we have developed a novel robotic surgical system the CardioARM to facilitate minimally invasive intrapericardial therapeutic delivery. In this study, we successfully demonstrated the use of the CardioARM by performing epicardial ablation using a porcine beating heart through a closed-chest subxiphoid approach.

Disclosures and Freedom of Investigation

The project was supported by the National Heart, Lung, And Blood Institute (grant no. R01HL079940 awarded to MAZ). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute or the National Institutes of Health. Two of the authors (HC and MAZ) are co-inventors of the Robotic Surgical System and hold equity in Cardiorobotics Inc (licensee of the technology is Cardiorobotics Inc). The authors had full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

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