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A Novel Highly Articulated Robotic Surgical System For Epicardial Ablation

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Abstract

We have developed a novel, highly articulated robotic surgical system to enable minimally invasive intrapericardial interventions through a subxiphoid approach and have performed preliminary tests of epicardial left atrial ablation in porcine (N = 3) and human cadaver (N = 2) preparations.

In this study, the novel highly articulated robotic surgical system successfully provided safe epicardial ablations to the left atrium in porcine beating heart models via a subxiphoid approach. We have also performed complex guidance of the robot and subsequent ablation in a cadaveric preparation for successful pulmonary vein isolation.

I. Introduction

Percutaneous catheter-based endocardial ablation technique has currently become one of the major treatment strategies for arrhythmia (i.e. atrial fibrillation, ventricular tachycardia) [1]. Despite its accelerated rate of adoption, there is significant potential for serious complications with these catheter-based techniques, including but not limited to cerebrovascular accidents, pulmonary vein stenosis, esophageal perforation, phrenic nerve injury and tamponade [2-5]. On the other hand, epicardial ablation is an established strategy for treatment of arrhythmia—particularly those with an epicardial arrhythmogenic focus refractory to endocardial ablation [6]. Hybrid epicardial and endocardial ablation of the left atrium has also been shown to be feasible and effective in difficult cases of persistent or permanent atrial fibrillation [7].

Several minimally invasive approaches to access the atrial epicardium have been recently reported, including total thoracoscopic ablation [8] and catheter-based subxiphoid access to the intrapericardial space [9]; with these approaches however, placement of several ports, double lumen ventilation, general anesthesia, and significant fluoroscopic exposure are increasingly necessary and contribute to morbidity.

Recognizing that the subxiphoid approach is the most direct way to access the epicardium for diagnostic and therapeutic interventions, we have developed a novel highly-articulated robotic surgical system (RSS) to enable minimally invasive intrapericardial therapeutic deliveries. The previous prototypes of the RSS were tested with in-vivo porcine experiments [10,11]. An on-board fiber optic camera was also used to provide visualization for single port access into the intrapericardial space. In this study, we performed preliminary radiofrequency epicardial ablation trials with the current RSS using a beating porcine heart via a closed-chest subxiphoid approach and in a human cadaveric preparation.

II. Methods

A. Design of the RSS

The fundamental mechanics of the RSS were described previously [10,11]. Briefly, the RSS is composed of 50 rigid cylindrical links strung together by cables. Two adjacent links can rotate approximately ± 10 degree relative to each other. All mechanical apparatuses to maneuver the probe are mounted within a feeder instrumentation box. The custom-designed software translates the master manipulator's input into movement of the RSS.

While the current RSS model inherits the capability of preserving its previous 3-dimensional configuration ("follow-the-leader") and multiple degrees-of-freedom (DOF) from the previous prototypes (i.e. 105 DOF in the present model) (Fig. 1A), the current model has been upgraded in several aspects. Specifically, the distal apparatus of the RSS has been downsized, resulting in a minimum radius of curvature of 35 mm. The maximum speed of forward and reverse movement was improved to 20 mm/s and the response rate of the steering is now quicker and more precise than previous prototypes. Additionally, the construction of the working ports was improved to allow the use of multiple instruments either simultaneously or separately.

Visualization was provided by an on-board optical fiber scope (fiber: FIGH-30-850N, Myriad Fiber Imaging Technology, Dudley, MA, camera: EO-2AN, Edmund Optics, Barrington, NJ).

B. Porcine epicardial ablation trials

Healthy Yorkshire swine (N = 3, body weight 35 to 45 kg) were anesthetized and placed in a supine position. A small subxiphoid incision (20 mm) and pericardiotomy (15 mm) were created. The RSS was mounted on a standard surgical table (Fig. 1B) and positioned for easy insertion through the incisions. The distal apparatus of the RSS was advanced into the pericardial space using a master manipulator under the surgeon's control while watching a video monitor display of the on-board camera view. A 5 Fr radiofrequency ablation tip catheter (Biosense Webster, Diamond Bar, CA) was introduced through a working port of the RSS, and a linear 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 recorded throughout the trials. The animals were euthanized at the end of the trials, and postmortem examination was performed. The excised ablation lesions were examined for transmural with triphenyltetrazolium chloride (TTC) and Gomori trichrome stains.

The study protocol was approved by the Institutional Animal Care and Use Committee (IACUC) 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 (1996).

C. Human cadaver epicardial ablation trials

Two unpreserved human cadavers (one male: height 180cm, one female: height 165cm) were used. One trial was performed under the full sternotomy and the other was under the subxiphoid approach. The setup of the RSS and instrumentation for radiofrequency ablation was the same as that of the porcine trials. We separately performed an intrapericardial navigation trial and a pulmonary veins isolation box lesion trial in the respective cadavers (Fig. 2). The heart was excised at the end of the trials for macroscopic examination.

To observe the behavior of the robot within the pericardial space, a mediastinoscope was also inserted from the right thoracic wall through an additional pericardiotomy, which the surgeon did not use for visualization during the trials.

The study protocol was approved by the University of Pittsburgh's Committee for Oversight of Research Involving the Dead (CORID).

III. Results

A. Porcine trials

The distal apparatus of the RSS followed a complex tridimensional path from the subxiphoid incision along the anterolateral ventricular wall to the junction of the left atrium and the left upper pulmonary vein around the beating heart. A linear lesion composed of several consecutive “dot-to-dot” lesions at the base of the left atrial appendage was completed in the last trial (Fig. 3). All animals tolerated the procedure without incident until elective euthanasia. There were no occurrences of fatal arrhythmia, unstable hemodynamics, or bleeding during the trials. Surrounding mediastinal structures (i.e. pericardium, phrenic nerve, lung, pulmonary artery) were intact upon postmortem examinations. Transmurality of all linear lesions was histologically confirmed by TTC and Gomori trichrome stains.

B. Human cadaver trials

The RSS proved to be a good fit for the human mediastinal anatomy without difficulty—having free access to the entire surface of the heart throughout the navigation trial. A box lesion set was successfully performed using the on-board camera view in the box lesion trial. The distal apparatus of the RSS accessed the transverse sinus from the left side and maneuvered to the pericardial reflection posterior to the superior vena cava. The superior portion of the box lesion set was then ablated with the RSS distal apparatus moving in reverse (Fig. 4A, B, and 5). Subsequently, upon reaching the leftmost border of the transverse sinus, the left and inferior side lesions were made in continuity with the superior lesion by ablating inferiorly and then rightward through the oblique sinus (Fig. 4C, D). Ablation was stopped upon reaching the pericardial reflection between the right lower pulmonary vein and the inferior vena cava. The distal apparatus of the RSS then accessed the right side of the heart via the anterior wall, and completed ablation for the remaining right side lesion. The continuity of the box lesion (i.e. absence of gaps) was confirmed by macroscopic examination of the heart following excision. No perforations from the box lesion ablation were noted. Similarly, no significant injuries to surrounding structures (i.e. lung, esophagus, or uninvolved pericardium/heart) due to the ablation or robot manipulation were noted.

IV. Discussion

Due to a lack of dedicated minimally invasive technology, epicardial ablation therapy is at present typically performed using a relatively invasive approach (i.e. full sternotomy or thoracotomy/thoracoscopy), considering the intrinsically simple nature of these procedures. The subxiphoid approach is a useful method to access the pericardial space, as there are no significant anatomic barriers except in cases of severe pericarditis or previous surgical intervention. This approach allows facilitated access to the pericardial space through a single port while potentially not requiring general endotracheal anesthesia and lung deflation. Our group previously reported that using a prototype rigid shaft subxiphoid videopericardioscopy device with a percutaneous subxiphoid approach, endoscopic ligation of the left atrium appendage and pacing lead implantation was accomplished [12,13]. Rigid shaft instruments, however, provide inadequate access to the posterior recesses of the pericardium due to their limited DOF [14]. Furthermore, rigid-type endoscopic instruments, including the DaVinci robotic surgical system, are unable to navigate complex tridimensional paths like the pericardial space occupied by the beating heart and may cause fatal complications (i.e. injury, arrhythmia, and hypotension).

We have developed a novel highly articulated RSS in an effort to provide dedicated intrapericardial therapeutic deliveries with enhanced minimally invasiveness. The RSS is designed to accomplish a task in the intrapericardial space through single port access (i.e. subxiphoid approach). Furthermore the RSS is capable of reaching the entire surface of the heart, including the posterior heart, which often is challenging to access with even full sternotomy.

The current iteration of the RSS made it possible to draw a linear lesion using a commercially available ablation catheter, compared with a single dot lesion by the previous prototype [10]. The current RSS was also able to provide fine and accurate manipulation required by the surgeon while using visualization from the on-board camera. An upgrade in the working port of the robot, the RSS also allowed simultaneous use of several tools (i.e. ablation catheter and irrigation/suction tool), which greatly contributed to the achievements in this study. The advances in the design of the probe were exemplified in our most recent ablation studies, where a box lesion set was accomplished in a human cadaveric preparation—requiring passage through an anatomically complicated path.

One of the most important advantages of the robot is the ability to preserve its previous configuration and shape in 3-D 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 RSS is especially important in the pericardial space, where there is concern about interference with the beating heart. As expected, there were no associated adverse events in the beating heart porcine trials.

The working port of the RSS allows utilization of commercially available endoscopic devices and catheters, which adds to the versatility of the RSS. As such, we have previously described pericardial biopsy, left atrial appendage ligation, and abdominal cavity access using off-the-shelf devices, in addition to epicardial ablation noted in this study [11]. Given the intrinsic flexibility of the present model of the RSS, future studies will focus on the feasibility of additional epicardial interventions, including epicardial injection, mapping, and pacing lead placement.

Although our present focus is mostly towards intrapericardial interventions for minimally invasive cardiac surgery, the RSS is not exclusive to this field. Accordingly, we also plan to study the RSS in various gastrointestinal and intravascular interventions. Because the length of the RSS distal apparatus can theoretically be extended as long as needed, the possibility exists for future RSSs designed for access to the small intestines—a difficult to reach location with general endoscopic equipment—through natural orifices (i.e. transoral or transrectal) [15]. The precise maneuverability of the RSS may also potentially serve as a technological innovation in intravascular treatments like percutaneous coronary interventions.

The concept of the RSS will make it potentially feasible to perform a procedure under local anesthesia on an outpatient basis, as opposed to other commercially available multi-arm robots requiring double lumen endotracheal intubation and multiple port placements.

While a box lesion set was accomplished in the human cadaver trials, only a linear lesion on the left atrial appendage was able to be completed in the porcine trials. Because the heart and great vessels were in motion and filled with blood in the porcine model, the pericardial space was tighter than that of human cadavers. As a result, the on-board camera failed to provide adequate visualization of the anatomy to allow the user to navigate the probe into the transverse or oblique sinuses. We believe this technical difficulty will be resolved in future prototypes by both downsizing the diameter of the robot and improving the quality of the visualization equipment.

In conclusion, the RSS successfully completed proof-of-concept epicardial ablations in both porcine beating heart and human cadaveric preparations via a subxiphoid approach. In the porcine model, safe left atrial epicardial linear ablations on a beating heart confirmed our hypothesis that the RSS could easily and accurately maneuver within the pericardial space using minimal surgical access. A feasibility study of pulmonary vein isolation with the RSS was also confirmed in a human cadaver preparation. In the future the RSS design and engineering will continue to focus on facilitating both minimally invasive intrapericardial and general surgical therapeutic deliveries.

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Fig. 1.

A: Distal apparatus of the Robotic Surgical System (RSS) consisting of cylindrical links articulated by spherical joints. B: Intraoperative picture during porcine trials. The RSS is mounted on the operating table using a custom mounting frame

Fig. 2.

The anatomy of the pericardium and its reflections along with the great vessels and sinuses after removing the heart. The path for a box lesion set is described by the circular dashed line. (IVC: inferior vena cava, SVC: superior vena cava, Ao: aorta, PA: pulmonary artery, PV: pulmonary vein)

Fig. 3.
A linear lesion at the base of the left atrial appendage.

Fig. 4.

A, B: The course of the distal apparatus of the Robotic Surgical System to make the superior linear lesion of the box lesion set. C, D: The course for the left, inferior and right lesion. (The heart is removed in the figures A and C)

Fig. 5. Mediastinoscopic views in the human cadaver trial. A: Intrapericardial view. The distal apparatus of the Robotic Surgical System (RSS) (arrow 1) advances between the pericardium and the heart surface. B: Transverse sinus view. An ablation catheter touches the left atrial wall (arrow 2). (P: pericardium. LV: left ventricle. T: the tip of the distal apparatus of the RSS. LAA: left atrial appendage)