A Highly Articulated Robotic System (CardioARM) is Safer than a Rigid System for Intrapericardial Intervention in a Porcine Model

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Abstract— **Minimally invasive surgical access to the heart is facilitated using a subxiphoid approach to the pericardial space. We have successfully utilized this methodology using a rigid video-guided device to deliver a variety of epicardial interventions, but this approach is associated with significant hemodynamic compromise and occasionally fatal arrhythmia. A subxiphoid approach to the pericardial space was carried out in two groups (N=5 each) of large porcine subjects. In group A the CardioARM was used to navigate to 6 intrapercardial anatomical targets via 7 routes. In group B (N=5) the SubX approach and navigation to the same 6 targets was performed with the rigid shaft FlexView device. Generally, hemodynamic parameters were only minimally decreased compared to baseline in Group A, while we observed significant compromise in Group B, for targets located deep inside the pericardial space. Moreover, significant arrythmias were noted in group B only, resulting in the death of one individual. No such arrythmias were present in the CardioARM group. We conclude that the CardioARM highly articulated robotic system provides superior results to the rigid SVP approach both with respect to hemodynamics and arrythmogenicity which may well translate into superior patient safety in future, human applications.**

I. INTRODUCTION

ACCESS to the heart through a small surgical incision sparing the bony structures of the chest wall is an important technique in modern cardiac surgery. The principle motivation for development minimally invasive cardiac surgery (MICS) techniques has been to improve post-surgical recovery times and reduce the complications of surgery inherent in an open approach, such as pain, infection and wound dihiscience. The subxiphoid approach, utilizing a small abdominal incision is one such technique that shows much promise as it avoids thoracotomy entirely, and could spare a human patient general endotracheal anesthesia and lung deflation.[1] We have previously demonstrated the feasibility of interventions in the pericardial space, including left atrial appendage exclusion, pacing lead implantation and epicardial mapping; utilizing this route with both traditional rigid surgical implements and a highly articulated robotic device, the CardioARM.[2-6]

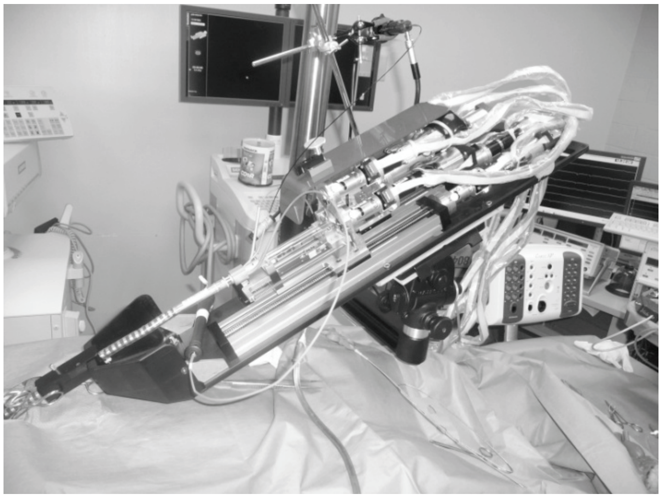

Fig. 1. The CardioARM highly-articulated snake-like robot, mounted a pole in the operating room, in position for the subxiphoid approach

In our previous work, we observed a negative impact on several hemodynamic parameters of our porcine subjects using the rigid subxiphoid videopericardoscopy (SVP). Potentially life-threatneing arryrthmias were also observed. These phenomenona were most pronounced during interventions at remote targets within the pericardium, requiring significant levering action on the heart or pericardium and were largely absent during and anterior approach to the left atrial appendage. We concluded that mechanical compression of the heart and its vessels with the rigid shaft of the videopericardioscopy device was responsible for the observed disturbances in hemodynamic parameters compared to baseline.[3]

We hypothesized these life-threatening intraoperative difficulties might be overcome by using a flexible, highly articulated device. Our recent development of a highly articulated snake-like robot device designed for epicardial intervention presented itself as a potential solution.[3,7] The objective of this study is to compare the effect on the intraoperative hemodynamics of porcine subjects during navigation to six intrapericardial targets via a single

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subxiphoid port, utilizing either a rigid (VPS) technique or a highly articulated robotic system (CardioARM).

I. METHODS

A. Experimental Setup

The study comprised two groups (Group A: CardioARM; Group B: rigid SVP) each consisting of five large healthy Yorkshire swine (either sex, median weight, 45 kg).. All subjects were sacrificed at the end of the experiment. The study protocol was approved by the Institutional Animal Care and Use Committee of the University of Pittsburgh.

All animals were anesthetized with intramuscular injections of 20 mg/kg ketamine and 2 mg/kg xylazine, and 1% to 5% isoflurane was delivered using a face mask. The animal was placed in the supine position and endotracheally intubated. For both the CardioARM (Group A) and rigid SVP (Group B) subjects, a 15-mm subxiphoid incision was made, and the underlying tissue was dissected to the pericardial level. A small pericardiotomy (5 mm) was created under direct visualization. The respective devices were then introduced into the pericardial space.

Heart rate and rhythm were monitored with electrocardiography. The right carotid artery and jugular vein were exposed through an incision on the right side of the neck, and the right carotid artery was cannulated with a 6-Fr catheter to monitor the arterial BP. The jugular vein was cannulated with a 7-Fr Swan-Ganz catheter to monitor the CVP, pulmonary artery pressure, and SvO2. Baseline hemodynamics (systolic, diastolic and mean arterial pressure; systolic, diastolic and mean pulmonary artery pressure; central venous pressure; mixed venous oxygen saturation) were recorded and compared after each target was visually acquired.

B. CardioARM Device and Image Guidance Method

The CardioARM device and the computed tomography (CT) image guidance technique has been described in detail elsewhere.[2,6] Briefly, the CardioARM consists of a 12 mm by 30 cm snake-like body comprised of 50 links connected by spherical joints with two degrees of freedom. Four cables marionette the motion of the robot to follow a curve in a three-dimensional space allowing it to maneuver in the pericardial space. The current device has a minimum radius of curvature of 4.5 cm and three working channels with ports sufficiently sized for passage of 7 Fr. (approx. 2.5 mm OD) surgical tools and catheters. The user commands motion via joystick.

Navigation was accomplished using CT image guidance indexed to nine metal fiducial landmarks emplaced in skin of the animal's ventral thorax at the time of imaging. The working head of the robot is tracked with respect to these fiducials using a three–axis magnetic tracking coil delivered to the head of the robot via a working channel and an external electromagnetic tracking system (Aurora, NDI). 3-D CTA images were obtained using an Helical CT scanner (64-Slice LightSpeed VCT; GE Health-care, Milwaukee, WI). CT scanning (120kV, 800mA, pitch of 0.16:1, 350ms/rotation gantry speed) with a thickness of 0.6mm was performed after intravenous injection of an iopamidol contrast agent. Images were reconstructed and real-time guidance was supplied utilizing dedicated software (Blue Belt Technologies, Pittsburgh, PA). Navigational targets were previously identified on the CTA image and were identical to those described for the rigid technique (below).

C. Rigid SVP Device and Technique

An SVP device (FLEXView System; MAQUET Cardiovascular, San Jose, CA) consisting of a 7-mm extended length endoscope with two proximal entry service ports was inserted into the pericardial cavity via a subxiphoid approach. The surgeon manipulated the SVP device under video guidance to six anatomic targets: right atrial appendage (RAA), superior vena cava (SVC), ascending aorta (AO), left atrial appendage (LAA), transverse sinus (TrvS), and atrio-ventricular groove (AVG). Additionally, the left atrial appendage can be targeted via the anterior approach (LAA-A) or posterior approach (LAA-P). In the anterior approach, the SVP device runs along the surface of the anterior left ventricle from the subxyphoid incision toward the left atrial appendage, and in the posterior approach, the SVP device runs over the surface of the posterolateral left ventricle from the subxiphoid incision toward the left atrial appendage. When the device reached a target, it was drawn out to the subxiphoid incision.

D. Data Analysis

The quantitative results were expressed as the mean percent change from each subjects baseline of a given parameter ± the standard error of the mean (SEM) and analyzed using a software package for statistical analysis (Stata/IC software, version 10.0; Stata Corp., College Station, TX). These percentage changes were compared between groups A and B for each location/route and for each of eight hemodynamic parameters. Wilcoxon's signed-rank test was used to determine the significance of the difference. P values of less than 0.05 were considered statistically significant. Arrythmogenicity was reported qualitatively in a binary manner as either the presence or absence of operator-identifiable arrhythmia on EKG.

II. RESULTS

Both devices were able to successfully navigate through the epicardial space of the beating heart to all 6 anatomical targets via 7 distinct routes. All 5 animals in group A (CardioARM) survived to conclusion of the experiment. One of five (20%) animals in group B (rigid SVP) suffered a fatal ventricular arrhythmia during exposure of the atrio-ventricular groove. Episodes of arrhythmia were noted during the rigid approach via all 7 routes except for the

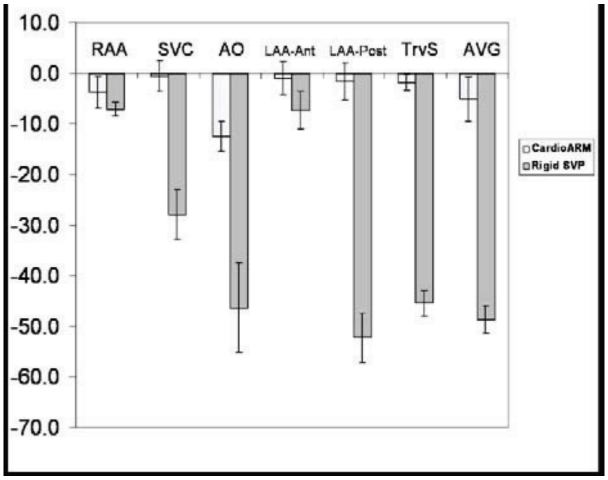

Fig. 2. Percentage change in SvO_2 compared to baseline is greater for rigid SVP (dark grey bars) than CardioARM (speckled bars) at 6 intrapericardial targets (LAA access via two routes). Error bars represent SEM.

anterior approach to the LAA. No arrythmias were observed using the CardioARM. No gross damage was observed to the heart or other mediastinal structures utilizing either approach. We believe the most likely explanation for the fatal episode of ventricular fibrillation (VF) encountered with rigid navigation to the AV groove to be kinking of the left anterior descending coronary artery and/or compression of the left ventricular outflow tract.

The quantitative hemodynamic data parallels the qualitative arrythmogenicity data; in that the rigid approach produces far greater disturbances in cardiac function than the CardioARM. A total of eight hemodynamic parameters were measured for the purpose of physiological studies which will be presented elsewhere. The most clinically relevant parameter we measured is the oxygen saturation of the central venous blood (SvO_2), which is a proxy for cardiac output, as this parameter falls as tissue perfusion decreases. Significantly greater drops in SvO_2 were noted in the rigid SVP group compared to CardioARM during surgical manipulations at five of seven the studied routes: SVC, AO, LAA-Post, TrvS, AVG ($p<0.01$; Fig. 2).

We observed similar changes in central venous pressure (CVP). (Fig 3.) In the case of CVP, the parameter is an inverse proxy for cardiac function, such that the value rises as blood backs up into the venous reservoir with pump failure. The effect on CVP only rises to statistical significance for two locations: the TrvS and AVG. This may reflect the insensitivity of the parameter itself or compensatory physiologic changes outside the scope of our measurement. SvO_2 is the best correlated parameter to observed arrythmias and may have the greatest value as the benchmark for evaluation of future devices and approaches.

III. CONCLUSION

We demonstrated the ability of the CardioARM, a highly articulated robotic system, to navigate through the pericardial space to potential interventional targets on the epicardium, using image guidance alone. Our data demonstrate the clear superiority of CardioARM over a conventional rigid device, in terms of hemodynamic stability of the subject during the procedure. These findings suggest that such highly articulated systems may achieve similar improvements over rigid techniques with regard to patient safety during intrapericardial procedures in human patients.

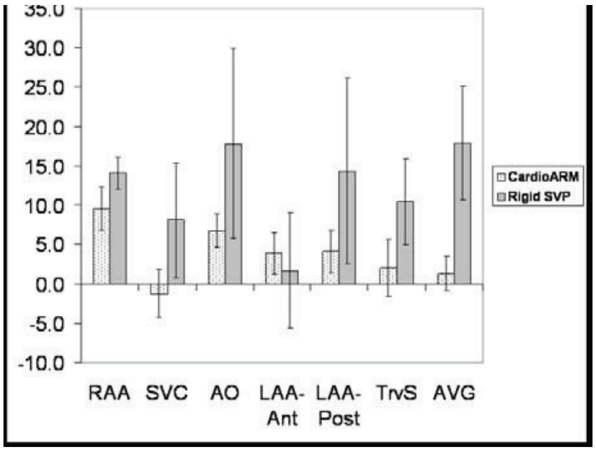

Fig. 3. Percentage change in CVP compared to baseline is greater for rigid SVP (dark grey bars) than CardioARM (speckled bars) at 6 intrapericardial targets (LAA access via two routes). Error bars represent SEM.

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