Cardioscopy-guided surgery: Intracardiac mitral and tricuspid valve repair under direct visualization in the beating heart

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Objective: Cardioscopy is a novel imaging method that allows closed-chest, real-time fiberoptic imaging of intracardiac structures. This study tested the feasibility and safety of cardioscopy as a platform for mitral and tricuspid valve surgery in the beating heart.

Methods: Through a median sternotomy, cardiopulmonary bypass was established in 10 calves. Lactated Ringer's solution was administered through the pulmonary artery to eliminate residual blood volumes in the lung vasculature and was drained through a left ventricular cannula. A fiberoptic cardioscope within its translucent outer sheath was inserted through the left ventricle. Irrigating solution was continuously administered through the cardioscope sheath for clearer visualization. An endoscopic clip was used for edge-to-edge repair of the mitral and tricuspid valves. After mitral valve clipping, the cardioscope was inserted into the right ventricle. The solution was administered from the right atrium and continuously drained from the pulmonary artery. After tricuspid valve repair, the animal was weaned from cardiopulmonary bypass.

Results: Successful double-valve repair was carried out in all 10 cases. All calves were weaned from cardiopulmonary bypass with dobutamine only. Hematocrit values were maintained during the procedure (pre 29.0% $\pm$ 3.1% vs post 28.5% $\pm$ 3.6%, $P = .70$).

Conclusions: This study showed the technical feasibility of beating heart valve surgery using direct cardioscopic visualization. Cardioscopy represents a promising platform for future interventions and surgery under direct visualization in the beating heart. (J Thorac Cardiovasc Surg 2011;142:199-202)

Although endoscopes have been used in a variety of minimally invasive surgical approaches, an endoscopic system for real-time visualization of moving intracardiac structures has been limited by the amount of blood in the beating heart, which obscures the site targeted for surgery or intervention.^{1,2} Even a small amount of blood can prevent surgeons from obtaining a sufficiently clear image from the cardioscope. Meanwhile, several attempts have been made to view the naturally moving valves in vivo. Imaging through blood using infrared light has been performed in animal experiments and applied to some human cases.³ Investigators demonstrated the feasibility of this approach but also showed the remaining technical

challenges of limited field of visualization. We previously reported results on using the cardioscopy system to visualize intracardiac structures within a non-arrested heart on cardiopulmonary bypass (CPB) and a secondary perfusion circuit, using lactated Ringer's solution.⁴ Major improvements have been made to this system, and we hypothesized that our current protocol would enable surgeons to perform intracardiac beating heart surgery more easily, precisely, and safely. The purpose of this study was to assess the feasibility and safety of intracardiac surgery using this novel approach in an open-chest beating heart bovine model.

MATERIAL AND METHODS

Animal Preparation

Ten healthy male Holstein calves (body weight, 103.0 $\pm$ 6.1 kg; Mike-sell Farms, Frazeeburg, Ohio) were used for this study. This study was approved by Cleveland Clinic's Institutional Animal Care and Use Committee, and all animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" (Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, National Academy Press, Washington, DC, 1996).

Surgical Procedure and Imaging

The animals were anesthetized with ketamine (10 mg/kg, intramuscularly) followed by isoflurane inhalation via mask. After endotracheal intubation, ventilation was maintained through an endotracheal tube attached to a respirator. Anesthesia was maintained with isoflurane (0.5%–2.5%). The animal was placed on the surgical table in a supine position. The electrocardiogram was monitored during the procedure. The heart was accessed through a median sternotomy. Lidocaine (2 mg/kg/h, intravenous) was continuously given to prevent ventricular arrhythmia. An arterial pressure line

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Abbreviations and Acronyms

CPB	= cardiopulmonary bypass
LA	= left atrium
LV	= left ventricle
PA	= pulmonary artery
RV	= right ventricle

was inserted into the left internal thoracic artery, and the pressure was measured during the procedure. The pericardium was opened widely. The superior and inferior venae cavae and the main pulmonary artery (PA) were exposed and isolated. A 24F arterial cannula was inserted into the ascending aorta through purse-string sutures, and short and long versions of an L-shaped 28F venous cannula were inserted, respectively, into the superior vena cava and the right atrium-inferior vena cava toward the inferior vena cava. A 20F cannula was inserted into the PA to perfuse the lactated Ringer's solution. A fluid-filled line was inserted into the left atrium (LA) to monitor LA pressure. After full heparinization (300 U/kg), CPB was initiated and systemic flow was maintained at 5.0 L/min. A 24F soft venous perfusion cannula was also inserted into the LA. A gastroscope (Olympus GIF-130, 9.8 mm, 103 cm; Olympus, Center Valley, Pa) was used as a cardioscope. The cardioscope, enclosed in a translucent outer sheath, was inserted into the left ventricle (LV) through the anterior middle-apex LV wall directly. The outer sheath was specially designed and made of polyurethane (Figure 1). A communicating space between the distal end of the cardioscope and the sheath allowed the infused solution to clear the area in front of the lens of the cardioscope effectively. A 32F soft venous cannula was inserted into the LV apex to drain the solution (Figure 2).

First, the main PA was clamped at the proximal site of the inserted cannula, and 1.0 L of the normothermic lactated Ringer's solution was administered for 1 minute at the rate of 1.0 L/min to the distal PA to flush out any remaining blood in pulmonary vasculature using a separate pump. The ascending aorta was not clamped, and the irrigated fluid was drained mainly from the LV cannula. Hemodilution was avoided by using CAPIOX Hemoconcentrators (reference 62648; TERUMO, Elkton, Md) continuously throughout the experiment. Then, the solution was administered through the LA before left-side visualization (2.0 L/min, 1 minute). LA pressure was kept at less than 10 mm Hg to avoid heart distention. During visualization of the LV, the solution was continuously infused through the outer sheath at a rate of 2.0 L/min. Both the mid portion of the anterior and posterior leaflets of the mitral valve were approximated with an endoscopic clip (Olympus, HX-201UR-135L, <http://www.olympuskeymed.com/index.cfm>) introduced through the cardioscope, in a fashion similar to interventional edge-to-edge repair.⁵ An endoscopic clip was proceeded to the leaflets and opened. In most of the cases, the leaflets were caught by

FIGURE 1. Cardioscope and the outer sheath. The holding fixture (A) with several holes is applied to place the scope at the center of the sheath. Clear lactated Ringer's solution is infused from the side hole of the outer sheath (B) to clear the area in front of the lens of the cardioscope through the holes of the fixture. White arrows show the direction of the flow of clear solution. The proximal part of the outer sheath is snared to infuse the solution only toward the heart.

both ends of the clips at the systolic phase, and then the leaflet captures were performed by just closing the clips. After de-airing of the LV, the LV and LA cannulae along with the cardioscope were removed and the PA was declamped. The calves were weaned from CPB supported with a low dose of dobutamine, and hemodynamics after weaning from CPB were confirmed to be stable for 10 minutes.

CPB was resumed for the repair of the tricuspid valve. A 24F soft venous cannula was inserted into the right atrial appendage to perfuse the solution (Figure 3). The coronary sinus was occluded epicardially. Both venae cavae were occluded for total bypass. The cardioscope within its sheath was inserted into the right ventricle (RV) through the anterior middle RV wall. The PA was clamped distally from the PA cannula, which enabled the complete isolation of the right heart. The solution was administered continuously through the outer sheath (2.0 L/min). The edges of the anterior and septal leaflets were approximated with the clip introduced through the cardioscope. After weaning the animal from CPB with dobutamine, stable hemodynamics were confirmed for 10 minutes. All video images were recorded digitally at the time of the experiment (Sony DCR-TRV480; Sony Corp, Tokyo, Japan). Hematocrit values were measured hourly throughout the procedure.

Autopsy Evaluation

After the completion of the procedure, the animals were killed by intravenous administration of potassium chloride (240 mEq) under deep anesthesia with 5% isoflurane. The clips were accessed from the right atrium, RV, and LV with the heart still in the chest. After excision of the heart, the clip on the mitral valve was evaluated from the LA. The intracardiac structures were evaluated macroscopically.

FIGURE 2. Schema of the actual surgical approach to the mitral valve. CPB is established between the venae cavae and aorta. The cardioscope, enclosed in its sheath, is inserted from the LV anterior middle-apex. The cannulae by which the solution is infused are inserted into the PA and LA. The drainage cannula for a solution is inserted into the LV. The main PA is clamped to reduce the amount of blood returning to the left heart. Ao, Aorta; PA, pulmonary artery; LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle; SVC, superior vena cava; IVC, inferior vena cava; CPB, cardiopulmonary bypass.

FIGURE 3. Schema of the surgical approach to the tricuspid valve. CPB is established between the venae cavae and aorta. The cardioscope, enclosed in its sheath, is inserted from the RV. The cannula by which the solution is infused is inserted into the right atrium. The cannula inserted into the PA for the mitral valve procedure is used to drain the solution. The main PA is clamped to avoid dilution of the blood when it reenters the systemic circulation. Ao, Aorta; PA, pulmonary artery; LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle; SVC, superior vena cava; IVC, inferior vena cava; CPB, cardiopulmonary bypass.

Data Analysis

Data are expressed as mean $\pm$ standard deviation. A paired *t* test was used to analyze data obtained before and after the procedures.

RESULTS

All procedures were successfully performed (Figure 4). After insertion of the cardioscope, the clipping of each valve was completed in approximately 20 minutes in almost all cases. All the clips were correctly placed at the center of

the valves (Figure 5). There was no sign of heart infarction or injury to the intracardiac structures. All valves were weaned from CPB with dobutamine ($3.4 \pm 2.1 \mu\text{g}/\text{min}/\text{kg}$) only. Hematocrit values were maintained during the procedure (pre $29.0\% \pm 3.1\%$ vs post $28.5\% \pm 3.6\%$, $P = .70$).

Comments

This is the first study to demonstrate that cardioscopy-guided beating heart mitral and tricuspid valve surgery can be performed concomitantly and successfully in the animal model. The use of the extracorporeal circuit and cardioscopic instruments was demonstrated to be safe with no adverse effects on cardiac function in repeated experiments.

We published a report describing beating heart cardioscopy as a platform for real-time, intracardiac imaging.⁴ Refinements of this novel platform for intracardiac imaging have allowed us to expand its use to interventions on mitral and tricuspid valves. The hemoconcentrator was used continuously during the procedure, which compensated for hemodilutional effects and resulted in stable hematocrit values throughout the procedures. In the mitral valve procedure, the return of blood to the LV, with subsequent obscuring of the visual field, was avoided by placement of the clamp to the proximal PA. Maintaining systemic flow at 5.0 L/min allowed adequate organ perfusion and hemodynamic stability. The site of insertion of the cardioscope into the LV was moved slightly anterior to the LV apex, which allowed improved visualization of the mitral valve.

The advantage of this image-guided procedure is that it allows the surgeon to perform an operation on naturally moving valves in the beating heart in real time. This technique offers significant potential advantages in comparison with conventional surgery and contemporary percutaneous valve interventions. Preservation of the normal heart movement should allow more precise valve intervention

FIGURE 4. Cardioscopic images of the mitral valve and the clip during the procedure. Left, Endoscopic clip is inserted toward the mitral valve through the hole of the cardioscope. Right, Clipping of the valve is completed.

FIGURE 5. A, Images of the clip on the mitral valve at autopsy (left, LA view; right, LV view). B, Images of the clip on the tricuspid valve at autopsy (left, right atrial view; right, RV view).

while avoiding the risk of myocardial stunning or injury that may occur with conventional valve surgery in the arrested heart.⁶ Furthermore, superior visualization of intracardiac structures could allow a more precise positioning of percutaneous valves, thereby avoiding the potential complications of valve dislodgement and coronary obstruction.⁷ The use of CPB technology secures a stable hemodynamic environment that allows repeated interventions on cardiac valves without the risk of sudden hemodynamic compromise.

Study Limitations

There are several limitations to this study. The study was conducted on healthy calves with normal cardiac function and structurally intact cardiac valves. The coronary sinus was occluded epicardially for RV visualization to prevent venous blood flow into the right atrium, which would have increased the invasiveness of the procedure. In patients, one may need to use a balloon to reduce the amount of blood returning from the coronary sinus.

Further refinements of this platform toward a minimally invasive approach will include the use of peripheral cannulation and performance of intracardiac interventions in the closed chest. These refinements would lead to the ultimate goal of creating a versatile platform for intracardiac interventions under the direct visualization in the closed chest setting.

CONCLUSIONS

This study showed the technical feasibility of performing beating heart valve surgery using direct cardioscopic visualization. Cardioscopy represents a promising platform for future interventions and surgery under direct visualization in the beating heart.

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