A Novel One-Shot Circular Stapler Closure for Atrial Septal Defect in a Beating-Heart Porcine Model

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Purpose. **In surgical atrial septal defect (ASD) closure, there are no techniques or devices that can close the ASD accurately in a short time under a beating heart. We have developed a simple and automatic ASD closure technique using a circular stapler. This study assessed the feasibility and efficacy of a new circular stapler closure for ASD.**

Description. **Under a continuous beating heart, hand-sewn patch plasty ASD closure was performed in 6 pigs (group A) and circular stapler ASD closure was performed in 6 pigs (group B). The time to close the ASD and the effectiveness of the closure were compared.**

Evaluation. **Closure was significantly faster in group B (10.5 ± 1.0 seconds) than in group A (664 ± 10 seconds; $p < 0.05$). There was no leakage at the closure site, and sufficient tolerance was confirmed.**

Conclusions. **A circular stapler can be used to treat ASD faster than hand-sewn patch plasty, with sufficient pressure tolerance in a beating heart porcine model.**

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For a secundum atrial septal defect (ASD), transcatheter ASD closure has gained widespread acceptance during the past few years. Approximately 80% of secundum ASDs are reported to be suitable for transcatheter closure [1]. The success rate of transcatheter closure is reported to be 95% to 98% [2–4]. However, the indications for transcatheter approaches are limited to small secundum ASDs [2, 5]. The presence of a large ASD or an insufficient rim (<5 mm) to anchor the closure device decreases the success rate of the procedure and leads to severe complications [5]. The limited long-term follow-up of transcatheter closure and the lack of randomized studies comparing transcatheter and surgical closures make it imprudent to conclude that transcatheter closures are comparable or even preferable to the surgical approach, regardless of patient selection.

Therefore, surgical closure is still an important and necessary method in the treatment of ASD. Surgical closure of ASDs has excellent success rates and long-term outcomes [2]; however, there have not been any remarkable changes in surgical techniques, which involve direct closure or patch plasty by manual suture.

We have developed a simple and automatic ASD closure technique using a circular stapler. This novel technique is different from all closure devices developed so far for surgical or transcatheter closure. This circular stapler closure (CSC) is designed to close the ASD as a completely alternative technique to the hand-sewn patch closure, which is a time-consuming procedure and requires direct vision. Compared with the transcatheter ASD closure device, the CSC staples the closure site to the atrial wall. This leads to the avoidance of the embolism of the device, which is the most severe complication of the transcatheter closure. The aim of this study was to assess the simplicity and feasibility of the ASD closure by comparing hand-sewn patch closure and CSC in a beating heart porcine model.

Technique

Circular Stapler Closure

The Proximate Intraluminal Stapler (Ethicon Endo-Surgery, Cincinnati, OH) was used for CSC. This mechanical circular stapler consists of a rigid applicator shaft and a staple cartridge with a circular knife blade (Fig 1) and is designed to transect, resect, and anastomose automatically. The outside diameter of the circular stapler is 29 mm, the knife diameter is 20.4 mm, and the circular stapler holds 24 titanium staples arranged in 2 circular lines.

The circular stapler was prepared for automatic ASD device closure. For closure preparation, the anvil head was wrapped with bovine pericardium (Edwards

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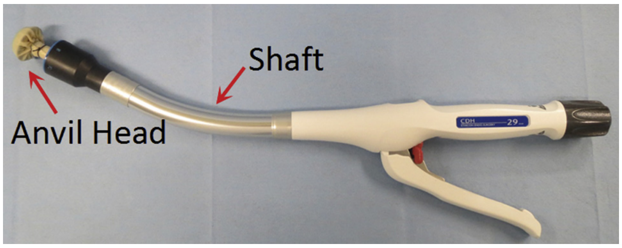

Fig 1. General view of the mechanical circular staple.

Lifescience, LLC, Irvine, CA) and tied with a purse-sting suture (Fig 1). The anvil head was attached to the shaft in the closing procedure. The process of CSC for the ASD had only three steps. First, the anvil head was passed through to the left atrium side via the ASD, and the shaft was kept on the right atrial side (Fig 2A). Second, stapling by the atrial wall and the bovine pericardium was performed, and the circular knife blade cut the inner tissue of the stapler line simultaneously (Fig. 2B). Finally, the anvil head was removed from the stapling site, and the procedure was completed (Fig. 2C).

Surgical Protocols

To evaluate the circular stapler for ASD closure, 12 healthy adult pigs (female, approximately 50–60 kg) were used in the experiment. Treatment of pigs was based on the Guide for the Care and Use of Laboratory Animals, prepared by the National Academy of Sciences and published by the National Institutes of Health (revised 1996) and the Guideline for the Care and Use of Laboratory Animals in Takaramachi Campus of Kanazawa University. The protocols in this study were approved by the animal experimentation committee of Kanazawa University.

Pigs were placed supine, and a median sternotomy was performed to access the heart. After the median sternotomy, the left-to-right shunt ratio (Q_p/Q_s) was measured before the ASD was created (pre-ASD state). Q_p/Q_s was calculated according to the formula: Q_p/Q_s = (SatArt – SatMv)/(SatArt – SatPA). With SatArt indicating arterial oxygen saturation, SatMV indicating mixed venous saturation, SatPA indicating pulmonary artery oxygen saturation, and SatPV indicating pulmonary venous oxygen saturation. SatMV was calculated according the formula: SatMV = (SatSVC + SatIVC)/2. SatSVC and SatIVC were the oxygen saturation in the SVC and the IVC, respectively.

Cardiopulmonary bypass (CPB) was established, and a 15-mm circular ASD was created through the fossa ovalis under direct vision. After the ASD was created, the atriotomy was closed and the pigs were weaned from CPB. Hemodynamic status was confirmed to be stable for 30 minutes for the assessment of the left-to-right shunt by epicardial transapical echocardiography, and the Q_p/Q_s was measured (ASD state).

CPB was resumed for the closure of the ASD. In group A, the ASD was closed by hand-sewn patch plasty in 6 pigs, and in group B, the ASD was closed using the circular stapler in 6 pigs. After the atriotomy was closed, the pigs were weaned from CPB. Left-to-right shunt and the Q_p/Q_s were measured (ASD closure state) with the same method used before the closure.

Postoperative Pressure Study

After the procedure was completed, the pigs were euthanized under deep anesthesia. The heart was excised, and a pressure study was used to assess the

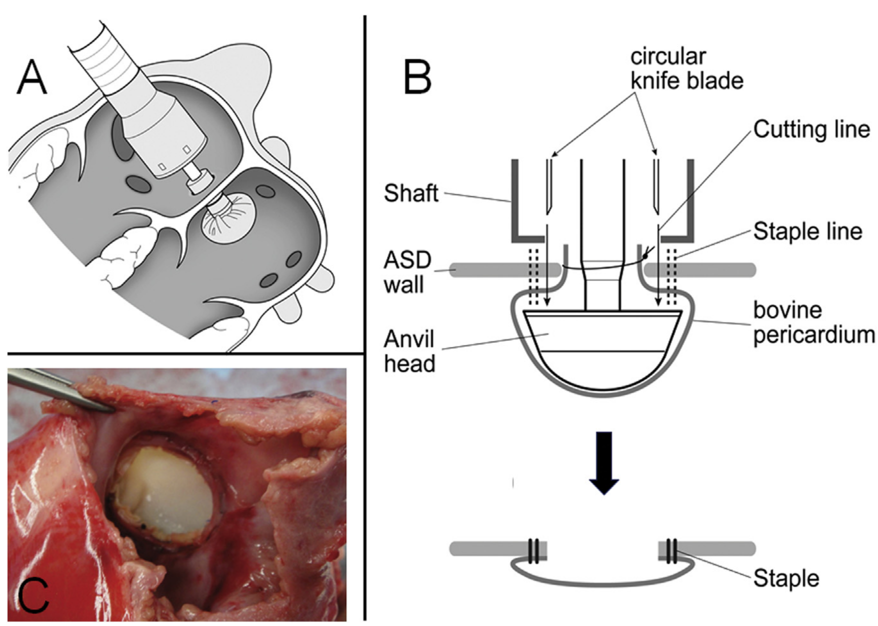

Fig 2. (A) General view of circular stapler closure. (B) Schematic of atrial septal defect (ASD) closure by the circular stapler. (C) Image of the anastomotic site from the right atrium.