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Abstract

Background: We set out to evaluate mitral valve repair with the loop technique under dynamic conditions, using a U-Clip to anchor the loop unit to a papillary muscle.

Methods: Mitral valve prolapse was artificially developed by resecting 4 chordae tendineae of a resected porcine heart. The loop unit was anchored to the papillary muscle using U-Clips. Each chordal loop was fixed on the prolapsed leaflet. A roller pump perfused the left ventricle. The left ventricular pressure was maintained at 250 mm Hg. Morphological assessment of the loop reconstruction was performed using an endoscope.

Results: 10 independent chordal reconstructions were performed. In all cases, the loop unit remained anchored against pressures exceeding 250 mm Hg. Upon increasing the water filling volume, rupture of a chorda tendinea occurred in 7 cases, rupture of the papillary muscle occurred in 2 cases, and left ventricle rupture occurred in 1 case. In all rupture cases, the loop unit remained anchored to the papillary muscle.

Conclusion: This dynamic evaluation of the loop technique using U-Clips to anchor the loop unit to a papillary muscle showed that the loop technique using U-Clips is a safe method.

Keywords

Chordae tendineae, Mitral valve prolapse, Surgical instruments, Suture techniques

Introduction

Chordal replacement with expanded polytetrafluoroethylene (ePTFE) CV-5 sutures (WL Gore & Associates, Inc., Flagstaff, AZ, USA) is an established technique that provides good long-term results.^{1,2} On the other hand, ePTFE sutures have the disadvantage of slipping easily at ligation. Mohr and von Oppell³ reported a loop technique in which a loop unit (4 pre-measured loops and a small pledget) is fixed on the prolapsed leaflet.⁴ The loop technique makes it easier for the surgeon to repair the mitral valve.⁵ Since we introduced the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) in 2005, it has been used for minimally invasive mitral valvuloplasty.⁶ Although mitral valvuloplasty using the da Vinci system has been facilitated by the loop technique, it is difficult to anchor the loop unit to the papillary muscle because of the narrow and deep working space. The nitinol U-Clip (Medtronic, Inc., Minneapolis, MN, USA) was designed to facilitate coronary anastomosis by reducing the complexity and difficulty of the

anastomotic process.⁷ The U-Clip immediately snaps back to its preferred closed-loop configuration and fixes tissues by pressing a release mechanism. In this experiment, we evaluated the loop technique under dynamic conditions using the U-Clip to anchor the loop unit to a papillary muscle. Dynamic evaluation of the grasping power of the U-Clip has not been previously reported.

Material and methods

In the loop technique, the normal part of the chordal length is measured. One loop of CV-5 is made to this premeasured length by tying a knot over a small

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pledget. Both ePTFE suture needles are passed back through the pledget twice and ligated, so that the knot does not add further length to the loop when anchored to the papillary muscle.³ Four loops are made on one loop unit. In the U-Clip experiment, the loop unit was anchored to the papillary muscle by single-armed S105 U-clips.

For the traction test, a specimen of papillary muscle was removed from the heart of an edible swine. The loop unit was anchored to the papillary muscle over a second pledget like a sandwich, using two U-Clips. This material was mechanically pulled on both sides, and the value of the tractive force was measured when it became disconnected (Figure 1).

The force on the whole mitral valve (F_0) was calculated as: $F_0 = S \times P \times 1.33 \times 10^{-2}$ ($\text{kg} \cdot \text{m} \cdot \text{s}^{-2}$), where S = mitral valve area (cm^2), P = left ventricular pressure in mm Hg ($1 \text{ mm Hg} = 1.33 \times 10^{-2} \text{ kg} \cdot \text{m} \cdot \text{s}^{-2} \cdot \text{cm}^{-2}$).

Focusing on the number of reconstructed artificial loops, the force on the loop unit anchored to the papillary muscle in the left ventricle (F_1) was calculated as: $F_1 = F_0 \times n'/n$ ($\text{kg} \cdot \text{m} \cdot \text{s}^{-2}$), where n' = the number of loop reconstructions, and n = the total number of chordae tendineae.

Focusing on the area of the leaflet supported by loops, the force on the loop unit anchored to the papillary muscle in the left ventricle (F_2) was calculated as: $F_2 = F_0 \times S'/S = F_0 \times R$ ($\text{kg} \cdot \text{m} \cdot \text{s}^{-2}$), where S' = the area of the leaflet supported by loops, and R = the ratio of the leaflets supported by loops in the mitral valve.

For the pressure test, the left ventricle and aorta were selected from the heart of an edible swine without injury to the mitral valve. A water tube was

retrogradely inserted into the left ventricle through the aorta. A roller pump perfused the left ventricle with pulsatile flow. When the left ventricle was filled with water, mitral regurgitation occurred because of dilatation of the left ventricle and the mitral annulus. The left ventricle was wrapped up manually to prevent mitral regurgitation. The left ventricular pressure was measured by a needle through the apex. The left ventricle was perfused for 1 h, maintaining its pressure from 200 to 250 mm Hg.

In the chordal reconstruction model, mitral valve prolapse was artificially developed by resecting 4 chordae tendineae. The normal chordal length was measured, and the loop unit was made. The loop unit was anchored to the papillary muscle over a second pledget like a sandwich, using two U-Clips. Each chordal loop was fixed on the prolapsed leaflet using CV-5 sutures (Figure 2A). Morphological assessment of the loop reconstruction was performed using an endoscope with a diameter of 5 mm through the apex (Figure 2B).

Results

In the traction test, 10 specimens were evaluated. The tractive force that caused the U-Clips to detach from the papillary muscle was $8.55 \pm 1.87 \text{ kg} \cdot \text{m} \cdot \text{s}^{-2}$ (mean $\pm$ standard deviation). Ten chordal reconstruction models were assessed. In all cases, the loop unit remained anchored to the papillary muscle by U-Clips against 250 mm Hg for an hour. On increasing the amount of water filling the left ventricle, rupture of a chorda tendinea occurred in 7 cases, rupture of a papillary muscle not anchored by U-Clips occurred

Figure 1. Traction test. Left: the loop unit is anchored to a specimen of papillary muscle over a second pledget by U-Clips. Right: the machine pulls the material on both sides and measures tractive force.

in 2 cases, and rupture of the left ventricle occurred in 1 case (Figure 3). The loop unit remained anchored to the papillary muscle in all rupture cases. Figure 4 shows the endoscopic findings in the left ventricle. As the left ventricle filled with water, the mitral valve closed and the chordal loops were strained. The U-Clips were absolutely stationary. If the chordal loop was slack, mitral regurgitation occurred. The slack loop was refixed at the preferred position of the prolapsed leaflet, thus repairing the mitral regurgitation.

Figure 2. Chordal reconstruction model. (A) The loop unit is anchored to the papillary muscle using two U-Clips. Artificial loops are fixed onto the prolapsed leaflet with CV-5 sutures and (B) The water tube is retrogradely inserted through the aorta. The needle for measuring left ventricular pressure and the endoscope are passed through the apex.

Discussion

We evaluated the loop technique under dynamical conditions, using U-Clips to anchor the loop unit to a papillary muscle. Dynamic evaluation of the grasping power of the U-Clip has not been previously reported. The loop unit remained anchored to the papillary muscle even when rupture of a papillary muscle or the left ventricle occurred, demonstrating that the loop technique using U-Clips is a safe method.

Using a calculation formula that assumed the mitral valve area was 6 cm^2 , left ventricular pressure was 250 mm Hg, the number of loop reconstruction was 4, and the total number of chordae tendineae was approximately 25, the force on the mitral valve (F_0) and the force on the loop unit (F_1) were 19.95 and

Figure 4. Endoscopic findings in the left ventricle of the chordal reconstruction model. The U-Clips anchored the chordal unit to the papillary muscle (white arrow). One of the 4 loops was slack (white arrowhead), inducing mitral regurgitation. After the slack loop was refixed to the preferred position, the loop was strained.

Figure 3. Images of the left ventricle after the pressure test. The loop unit remained anchored to the papillary muscle. Left: rupture of the left ventricular wall (white arrow). Right: rupture of the papillary muscle (white arrowhead).

3.19 kg·m·s⁻², respectively.⁸ According to our traction test, the mean value of the tractive force when the U-Clips came off the papillary muscle was 8.55 kg·m·s⁻². From the above-mentioned data, the grasping power of the U-Clips anchoring the loop unit to the papillary muscle was more than sufficient. Furthermore, if the ratio of the leaflet supported by loops in the mitral valve is 0.43, the force on the loop unit (F_2) reaches 8.55 kg·m·s⁻². This denotes that the loop unit using U-Clips can support A1 + P1 or A1 + A2 leaflets, for example.

Mohr and von Oppell³ developed the loop technique to overcome the drawback of the slipperiness of ePTFE sutures. The loop technique has proven to be more time efficient and makes chordal reconstruction easier to perform than previous techniques used.⁹ However, the loop unit was anchored to the papillary muscle using ePTFE sutures. It is necessary to tie 8 knots of slippery ePTFE sutures in one spot. This requires skill and time because of the deep and narrow working space of chordal reconstruction. We introduced the da Vinci system in 2005, and since then, it has been used for internal thoracic artery harvesting, mitral valvuloplasty, atrial septal defect closure, and resection of cardiac tumors.^{6,10,11} Although mitral valvuloplasty using the da Vinci system has been facilitated by the loop technique, it is often difficult to anchor the loop unit to the papillary muscle because of a small incision and port access. There is always a potential risk of cutting off the papillary muscle by overtightening.

The U-Clip was designed to facilitate coronary anastomosis by reducing the complexity and difficulty of the anastomotic process.⁷ It consists of a self-closing clip, fabricated from nitinol, a shape memory alloy, attached to a conventional curved suture needle via a flexible member. Pressure applied to the release mechanism immediately releases the clip, allowing it to return to its preferred closed-loop configuration. The elastic property of the nitinol wire is used to allow precise positioning of the device and produce strong and atraumatic tissue approximation. In this experiment, the use of U-Clips to anchor the loop unit to papillary muscle, and its grasping power, were evaluated dynamically. Tying knots in the left ventricle during chordal reconstruction is required to anchor the loop unit to the papillary muscle and fix it on the prolapsed leaflet. Smith and colleagues⁹ reported their experience of using a single-armed V60 U-Clip to fix a loop on the prolapsed leaflet. Our results provide additional support for the possibility of a “no tying knots” loop technique.

In this study, the motion of the artificial loops in the left ventricle after loop reconstruction was evaluated using an endoscope with a diameter of 5 mm through the apex. Although assessment of the mitral valve motion after edge-to-edge repair has been reported,^{12,13}

morphologic assessment of loop reconstruction has been not been reported. Our endoscopic findings provided visual proof that the artificial loops functioned as native chordae tendineae and prevented mitral valve prolapse. Furthermore, endoscopic findings revealed that mitral regurgitation, which occurred due to the slackness of an artificial loop, was repaired by refixing the slack loop to the preferred position on the prolapsed leaflet. There was almost no wall motion of the left ventricle, although pulsatile flow was used in this experiment. Additional tests for durability under beating heart conditions are necessary. Furthermore, long-term results must be examined. However, according to our findings, U-Clips are not released against pressures exceeding 250 mm Hg. We concluded that the loop technique safely uses U-Clips to enable fixation of the loop unit, without tying knots.

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Conflicts of interest statement

None declared.

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