Work in progress report - Experimental

Beating-heart mitral valve suture annuloplasty under real-time three-dimensional echocardiography guidance: an ex vivo study

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Abstract

We are developing an alternative mitral valve suture annuloplasty technique on the beating-heart under real-time three-dimensional echocardiography (RT3DE) guidance. The purpose of this initial study was to evaluate a feasibility of this technique using commercially available suturing devices (Sutur Tek Endo 360-degree™, Sutur Tek Inc, North Chelmsford, MA, USA). Isolated porcine hearts (n=10) were mounted in a water-filled tank and attached to an ex vivo pulse simulation device, where varying left ventricle pressures with associated valve motion were generated by pulsatile flow through an apical cannula. The suturing device was inserted through the left atrium. Intra-annular (De Vega type) suture annuloplasty was performed under RT3DE guidance. The procedure was successfully performed in all cases. The diameter of the annulus was effectively reduced (85.5 ± 4.2% of original antero-posterior dimension, 86.7 ± 6.1% of original transverse dimension). The number of tissue bites was 7.4 ± 0.8. The maximum distance between the annulus and sutures placed was 1.1 mm. The total procedure time was 9.4 ± 2.4 min. There was no collateral tissue injury in any of the cases. This ex vivo study demonstrates the feasibility of beating-heart mitral valve suture annuloplasty under RT3DE guidance.

Keywords: Beating-heart surgery; Mitral annuloplasty; Three-dimensional echocardiography; Off-pump

1. Introduction

There is a rapidly growing interest in achieving mitral valve repairs using minimally-invasive surgical or catheter-based techniques to decrease the risk of valve repair but, to date, most devices and techniques have not been as effective as desired [1]. While some of these approaches have focused on valve leaflet repair of prolapse, many techniques aim at mitral annulus size reduction and/or shape modification, mostly using the coronary sinus as the location for the device. We have been developing an alternative surgical annuloplasty technique designed to reduce the annulus size by placing a continuous suture around the left atrioventricular groove. Two-dimensional imaging was used for echo window positioning. Live 3D and 3D zoom imaging modes were used for visualization of the heart and the surgical instrument and real-time procedure guidance.

2. Materials and methods

2.1. Ex vivo experimental setup

Isolated porcine hearts (n=10) were mounted in a custom made water-filled tank perfusion system. The ascending aorta was closed. Through an apically placed cannula, mitral valve leaflet motion was obtained using an ex vivo pulse simulation device with varying left ventricle pressures to generate pulsatile flow (Fig. 1). The heart rate was kept constant at 60 cycles/min throughout the experiment.

2.2. Echocardiography system

RT3DE was performed by using a matrix array probe X7-2 (2–7 MHz) on an iE33 system (Philips Healthcare, Andover, Mass). The probe was used as a direct epicardiac probe touching around the left atrioventricular groove. Two-dimensional imaging was used for echo window positioning. Live 3D and 3D zoom imaging modes were used for visualization of the heart and the surgical instrument and real-time procedure guidance.

2.3. Surgical devices

A commercially available suturing device, Sutur Tek Endo 360-degree™ and 2-0 Sutur Tek 360-degree suture™ (Sutur Tek Inc, North Chelmsford, MA, USA) were used for the procedure. This device has been used for suturing in video-assisted thoracoscopic procedures, but has not been used for intracardiac suturing in the beating-heart.

This device enables simple, intuitive suture placement – consistent, uniformly high-quality intracorporeal stitches and true intracorporeal knot-tying by squeeze of a handle. To minimize artifacts from the metallic device in the ultrasound imaging field, the suturing device was covered...
with a matte finished plastic sheet (Fig. 2, Video 1). We have previously described the use of this type of covering over metallic instruments to limit reverberations from the ultrasound signal and generation of potentially confusing artifacts in the ultrasound image [2–5].

2.4. Procedure

The operator was blinded to the target during the procedure and operated solely under RT3DE guidance. Additional guidance was obtained by palpation of the epicardial surface of the heart at the level of the atrio-ventricular junction near the mitral annulus in order to confirm the contact of the device with the tissue and to stabilize the heart during suturing (Fig. 1). With the left atrial appendage removed, the suturing device was introduced into the left atrium. Intra-annular sutures were placed from the anterior trigone to the posterior trigone (De Vega type annuloplasty) under RT3DE guidance. A pledget was attached to the end of the 2-0 suture to anchor one end to the trigone. After the sutures had been placed around the posterior portion of the annulus, another pledget was passed through the 2-0 suture and then tension was applied to the suture to achieve the desired annulus reduction. Finally, the suture with pledget was fixed with a surgical clip and the suture cut.

The effectiveness of this procedure was assessed by the ability to reduce the annulus diameter, number of stitches, precision of stitch placement, and total time required for procedure. Our goal was a reduction in antero-posterior and lateral annulus dimension to 85% of its original size.

2.5. Statistical analysis

All data are presented as the mean ± standard deviation (S.D.). Comparisons between the preoperative and the postoperative diameter of the mitral annulus were performed by using the paired t-test. All statistics were computed by using the JMP analysis program, version 7.0.2 (SAS Institute Inc, Cary, NC, USA).

3. Results

Mitral valve suture annuloplasty under RT3DE guidance was successfully performed in all cases. The results of each
Table 1
Procedure characteristics

<table>
<thead>
<tr>
<th>Isolated Heart no.</th>
<th>Mitral annulus antero-posterior diameter (cm)</th>
<th>Mitral annulus transverse diameter (cm)</th>
<th>No. of stitches</th>
<th>Distance between the annulus and stitches (mm)</th>
<th>Time (min)</th>
<th>Tissue injury</th>
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<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>% of original size</td>
<td>Pre</td>
<td>Post</td>
<td>% of original size</td>
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<tr>
<td>Mean</td>
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<td>18.6</td>
<td>85.4</td>
<td>32.8</td>
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<td>S.D.</td>
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</table>

\*P<0.01. S.D., standard deviation.

procedure are summarized in Table 1, and representative echocardiographic images of procedure are shown in Fig. 3 and Video 2. RT3DE provided high-quality images with sufficient spatial and temporal resolution to permit instrument navigation and control up to the point of contact with the mitral annulus. The diameter of the annulus was effectively reduced postoperatively (85.5±4.2% of original antero-posterior size, 86.7±6.1% of original transverse size) (Table 1). The number of stitches placed per annuloplasty procedure was 7.4±0.8. The maximum distance between the annulus and stitches placed was 1.1 mm, and the total procedure time was 9.4±2.4 min. The hearts were inspected after the procedure was completed and there was no detectable injury to nearby structures including valve leaflets, coronary vessels, or atrial tissue.

4. Discussion

Our group has previously demonstrated that epicardial RT3DE provides adequate anatomic detail for surgical task performance in an ex vivo model [2] and ASD and VSD closure in an in vivo beating-heart animal model [3, 4]. The main purpose of our group’s study is avoidance of cardiopulmonary bypass in a cardiac surgery. RT3DE provided high-quality images with sufficient spatial and temporal resolution to permit safe instrument navigation in an ex vivo pulsatile heart system. Hisagi et al. reported successful image-guided surgical repair of ventricular septal rupture using self-expanding device [6]. The authors used the Philips iE33 system for RT3DE guidance with a direct epicardiac probe. Rallidis et al. reported excellent images of a real-time three-dimensional transesophageal echocardiography (TEE) in a clinical case [7]. In an in vivo situation, a TEE might be useful to observe a wide view of intracardiac anatomy and, in addition, a direct epicardiac echo should be used to observe detailed procedures including device position, suture bite interval, mitral valve motion, mitral valve hinge point, in other words, the annulus itself, and pledget position.

In our study, we found that digital palpation with the opposite hand of that holding the suturing device was a very useful maneuver to confirm tissue contact by the suturing device, and provide detailed information regarding precise positioning of the device with respect to the previous suture and the mitral valve annulus. This haptic feedback is a viable approach if performed clinically because it is similar to an off-pump coronary artery bypass...
grafting (OPCAB). OPCAB is usually performed with commercially available stabilizers which suck the epicardium around a target coronary artery and an apex directly.

We are also developing alternative techniques using image-based tracking of the surgical instrument, contact sensors on the instrument tip [8], and robotic control of the surgical instrument to eliminate the need for digital palpation [9, 10].

In recent years, there has been a resurgence of the mitral valve suture annuloplasty, modified De Vega type, and favorable mid-term results have been reported by a number of authors [11, 12]. In this study, we chose this type of suture annuloplasty because of its simple, reproducible, and reasonable technique with acceptable mid-term results in not only adult cases but also children.

On the other hand, a new concept in the annuloplasty technology has been introduced recently. Bioring® (Kalanagos’ ring, Lonay, Switzerland) is a polydioxanone biodegradable ring for mitral and/or tricuspid valve annuloplasty [13]. This ring includes a re-absorbable polymeric ‘C’ curved segment of a poly-1,4-dioxanone polymer, prolonged by a 2/0 monofilament polyvinylidene fluoride suture – in continuity over the entire biodegradable ring – with a swaged stainless steel needle in each end. Clinical experience with this absorbable ring has demonstrated its effectiveness in children and adults. If a Sutur Tek suturing device’s needle combines a Bioring, it might be possible to insert the ring in the mitral anulus using our annuloplasty technique on the beating-heart under RT3DE guidance.

4.1. Limitations

Although this method represents a minimally-invasive approach, partial sternotomy or left thoracotomy would be required to perform the procedure, thus the main potential advantage currently is avoidance of cardiopulmonary bypass. However, with the recent availability of the real-time 3D transesophageal echocardiographic imaging and robotic controlled instruments, the size of the incision can be further minimized. Also, for this initial feasibility study, we used normal porcine hearts with no mitral regurgitation, and no mitral annulus dilatation. We, therefore, had to set up a somewhat artificial goal for the degree of annulus reduction. Further studies in vivo are currently in progress.

In summary, this ex vivo study demonstrated the feasibility of beating-heart mitral valve suture annuloplasty under RT3DE guidance. This approach demonstrates an alternative to current techniques of minimally-invasive valve annuloplasty including surgical procedures and catheter-based techniques.

References