Novel technique of aortic valvuloplasty

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Received 21 September 2005; received in revised form 27 December 2005; accepted 6 January 2006

Abstract

Objective: The present study was aimed to assess the results of newly developed aortic valve repair technique. Methods: Between 1997 and 2004, 69 aortic valvuloplasties were performed with a new technique addressing the three main components of the aortic root; leaflets (L), sinotubular junction (STJ), and aortic annulus (A). For leaflet correction, additional leaflets were implanted and for STJ and annular reduction, an internal synthetic ring and strip along the fibrous annulus were implanted, respectively. The patients were divided into two groups: 30 patients with isolated aortic regurgitation (group IAR) were treated by correction of STJ + L (n = 21) and STJ + A + L (n = 9), and 39 aortic regurgitation patients with annuloaortic ectasia or ascending aortic aneurysm (group AAR) were treated with STJ correction only (n = 16), STJ + A (n = 6), STJ + L (n = 9), and STJ + A + L (n = 8). Results: The mean age was 43.4 and 49.5 years for groups IAR and AAR, respectively. There was neither operative nor follow-up death in either group. Suture breakage caused one reoperation in group IAR. Mean follow-up was 13.8 and 20.3 months in groups IAR and AAR, respectively. The preoperative aortic regurgitation grade was 3.67 in group IAR and 2.67 in group AAR. The last follow-up aortic regurgitation grade was 1.1 in group IAR and 1.05 in group AAR. No patient, except for the reoperated patient had AR greater than grade 2. The postoperative pressure gradient was 19.3 mmHg in group IAR and 8.4 mmHg in group AAR. Conclusions: The results showed this technique to be safe and effective. Thus far broad application of this repair technique has been demonstrated to be highly feasible.

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Keywords: Aortic valve; Aortic root; Aortic regurgitation; Marfan’s syndrome

1. Introduction

Reconstructive surgery of the aortic valve (AV) has a lengthy history which is comparable to that of mitral valve repair largely composed of leaflet repair for isolated aortic regurgitation (AR) and AV sparing for AR with ascending aortic aneurysm or annuloaortic ectasia. AV leaflet extension with pericardium for isolated AR has been sporadically performed since the late 1980s [1,2]. In the early 1990s, reimplantation of the AV and remodeling of aortic root were introduced in the repair of aortic root aneurysm [3,4]. However, these methods still have problems which remain unresolved.

We recently developed a new AV repair technique, which is believed to have better durability and broader applicability. In this study, we assessed the clinical effects and efficacy of the new aortic valvuloplasty through the review of 69 AR patients operated with this technique over a follow-up period lasting up to 7.5 years.

2. Materials and methods

This study was approved by the institutional ethics committee on human research in Asan Medical Center, Seoul, Korea. Informed consents were obtained from both patients and family members prior to the operation. Left ventricular (LV) ejection fraction less than 30% or immobile leaflets with disrupted hinge points were considered relative contraindications.

2.1. Patients

Sixty-nine AR patients undergoing this procedure from December 1997 to December 2004 were included. Based on
the primary pathology, the patients were grouped into those with leaflet lesions (group IAR, 30 patients) and those with aortic root wall lesions (group AAR, 39 patients) such as ascending aortic aneurysm (22 patients) or annuloaortic ectasia (17 patients). Those with AR associated with aortic dissection were excluded. There were 19 males and 11 females in group IAR (mean age 43.4±14.0 years) and 26 males and 13 females in group AAR (mean age 49.5±17.3 years). Cardiovascular multi-detector row computed tomography (MDCT), magnetic resonance imaging, and echocardiography were performed preoperatively.

The preoperative clinical features from each group are as presented in Table 1. In group AAR, chromosome analyses was positive for Marfan’s syndrome in 13 out of 17 annuloaortic ectasia patients. All patients (30/30) in group IAR and 44% of patients (17/39) in group AAR had leaflet lesions. The main leaflet pathology included leaflet thickening (16 cases) and leaflet prolapse (6 cases) in group IAR, and leaflet thickening (5 cases) and leaflet prolapse (5 cases) in group AAR. Preoperative AR grade on echocardiography was 3.67±0.6 in group IAR and 2.67±1.5 in group AAR (the degree of AR grade which ranged from 1 to 4 was based on the regurgitant jet height).

2.2. Operation method

Cardiopulmonary bypass was performed via median sternotomy with ascending aortic cannulation in group AAR with the exception of three patients who were cannulated through the right axillary artery, while venous lines in the superior and the inferior vena cavae. Antegrade and retrograde blood cardioplegic infusion was the main myocardial protective strategy for both groups. The AR repair technique basically consisted of three components: annulus reduction, STJ reduction (or restriction in some patients in group IAR), and leaflet correction. Even though the nomenclature regarding the aortic root base remains controversial as there is no discrete circular structure which could be considered as a ring or annulus [5], we referred to the imaginary circle at the outflow of the aortic root base as the ‘annulus’ in this report. For AV approach, aortotomy was made about 5—7 mm above the right coronary artery orifice. There were some differences in the method of aortotomy between the two groups. The aortotomy was partial in group IAR, and complete in most cases in group AAR. The space for annulus and STJ reduction was made by careful dissection around the aortic root up to 2—3 mm above the annulus.

Before initiating the repair, the optimal annular and STJ diameter were determined intraoperatively. The length of the muscular portion of the aortic annulus (from commissure between right and non-coronary cusp reaching up to middle of left coronary cusp in counterclockwise direction) (Fig. 1A) was measured with a specially designed annulus seizer[10].

![Fig. 1. Schematic illustrations showing annulus reduction. (A) The annulus reduction at the fibrous portion. (B) The annulus was reduced with specially designed strips along the luminal and adventitial aspect of the fibrous portion of the left ventricular outflow tract.](image-url)
(ScienCity Co., Seoul, Korea), and used as a reference diameter of annulus. Because the fibrous portion was often enlarged, it was not used as a reference. Determination of the STJ diameter was the next step. In group AAR patients having normal leaflet, a Frater stitch [6] was placed on each leaflet after which the STJ diameter conducive to optimal AV coaptation was determined using the STJ seizer ScienCity Co.). The optimal STJ diameter determination in patients with leaflet deformity in either group was based on findings showing a value of 1.0—1.2 in the annular diameter to STJ diameter ratio. The age and body surface area were used as correction variables in determining the optimal annular and STJ diameters.

Of the three basic repair components, annulus reduction was done first. It was performed in 9 (30%) group IAR and 14 (36%) group AAR patients by placing a non-expansible inner and outer annulus strip ScienCity Co.) confined to the fibrous portion of aortic annulus with five interrupted mattress sutures (Fig. 1B), only when the annulus was deemed significantly enlarged.

Next, the STJ reduction was performed in all of the patients. For patients in group IAR having a relatively healthy aortic wall, the STJ inner ring ScienCity Co.) was placed only on the inner surface of aortic wall at the STJ level and fixed to it with multiple mattress sutures which were reinforcement with felt pledges on the aortic adventitial aspect (Fig. 2A). The STJ reduction procedure was done for purposes of protecting the pericardium of the corrected leaflet by limiting the STJ movement rather than to prevent STJ dilatation, which was not even dilated in most of the patients in group IAR. For patients in group AAR with aortic wall disease, the STJ inner and outer rings ScienCity Co.) were placed at the STJ level on both the luminal and outer adventitial aortic wall surface (Fig. 2B). Thirteen patients with severe annuloaortic ectasia or bicuspid AV having high coronary artery take-off, had to have either the STJ outer strip ScienCity Co.) below the coronary arteries, after separation of the coronary arteries from aortic wall (infra-coronary STJ strip implantation in three patients) or STJ outer ring after resection of the coronary ostium and reattachment as buttons in 10 patients (both coronary artery transfer in four cases and right coronary transfer in six cases).

Leaflet correction was the last step. It was done in 30 (100%) patients in group IAR and 17 (44%) patients in group
AAR. Creation of additional leaflets (29 cases) with bovine pericardium [Supple Peri-Guard® (Synovis®, USA)] was the mainstay of the procedure, however, leaflet extension (17 cases), and creation of additional autologous pericardial leaflets (12 cases) was also employed, at the beginning. The development of a leaflet template® (ScienCity Co.) facilitated additional leaflet creation. Pericardium was tailored with a matching sized template with STJ inner ring, and it was attached onto the native aortic valve with 9–11 interrupted sutures for each leaflet (Fig. 3A). New commissure formation was done by suturing the adjacent pericardium, which was used for additional leaflet creation, to each commissure. For repair of bicuspoid aortic valves, they were transformed to tricuspid by splitting the fused leaflets and implanting additional leaflets (Fig. 3B). Quadricuspid valves were also changed to tricuspid by creating a large common additional leaflet instead of leaving two small native leaflets.

Procedures performed in group IAR were as follows: combination of STJ reduction and leaflet correction (21 patients) and all three procedures (9 patients). In group AAR they were as follows: STJ reduction only (16 patients), STJ reduction and annulus reduction (6 patients), STJ reduction and leaflet correction (9 patients), and all three procedures (8 patients). The strip for annulus reduction, ring for STJ reduction, and template for additional leaflet creation were manufactured by ScienCity Corporation and approved by the Korean FDA. For repair of ascending aortic aneurysm less than 6 cm without evidence of intimal pathology, aortic wrapping was the preferred technique (22 cases), whereas artificial graft replacement was performed in aneurysms larger than 6 cm or in those with intimal pathology (16 cases). In two group AAR patients, the dilated portion of the aortic root and ascending aorta were truncated and reattached to the proximal stump after reducing its diameter (Table 2). Additional concomitant procedures such as coronary artery bypass graft (four cases), mitral valve repair (five cases), mitral valve replacement (four cases), tricuspid valve repair (two cases), ventricular septal defect closure (one case), atrial septal defect closure (one case), and Nuss procedure (one case) were performed.

2.3. Follow-up

All the patients were anticoagulated with Warfarin for 3 months. All events were recorded according to the set of definitions established by the ad hoc committee on valve surgery by Edmunds et al. [7]. MDCT was performed to evaluate the changes of aortic root (annulus, sinus, STJ, and tube) before discharge and, thereafter, annually. Echocardiography was conducted on 7–10 days, 3–6 months, 1 year postoperatively, and annually thereafter. Mean follow-up period was 13.8 ± 4.7 months (range 3–30 months) for group IAR and 20.3 ± 15 months (range 1–91 months) for group AAR.

2.4. Statistical analysis

Description as mean ± standard deviation for technological statistics quantity, t-test for comparison between groups, and Kaplan–Meier method for 2-year actuarial survival rate and 2-year freedom from reoperation rate were used by statistical software, SPSS 10.0. Statistical significance was accepted when p-value was less than 0.05.

3. Results

3.1. Echocardiographic findings during follow-up period

Grade of AR, ejection fraction, LV end systolic diameter, LV end diastolic diameter, LV end systolic volume, LV end diastolic volume, and LV mass were measured by echocardiography. Fifty-three patients (IAR 28 and AAR 25) with follow-up longer than 12 months were included as the latest follow-up data. In group IAR, grade of AR was improved from mean preoperative grade of 3.67 ± 0.6 to 1.10 ± 0.8 immediate postoperatively, and remained stable at 1.10 ± 0.8 on latest follow-up. In group AAR, the grade was 2.67 ± 1.5 preoperatively, 0.97 ± 0.7 immediate postoperatively, and 1.05 ± 0.7 on the latest follow-up. In group IAR, three patients who had poor contractility with ejection fraction less than 30% showed grade 3 AR immediate postoperatively and two of them showed improved AR during follow-up. Another patient who had a preoperative ejection fraction of 27% and LV mass of 835 g also showed persistent AR grade 3. Although he showed significant improvement in postoperative ejection fraction (41%) with decrease in LV mass (470 g) and a symptomatic relief, he had to undergo mechanical AV replacement on the 18th postoperative month due to remnant AR. A fracture in the Prolene used for leaflet
Immediate postoperative period in 24 patients of group AAR, who had severe preoperative AR and with these findings remaining stable on follow-up longer than 1 year. Comparing immediate postoperative data and those of latest follow-up, there was no significant change of diameter (Table 4).

### 3.3. Mortality and morbidity rate

There was no operation-related death in either group. Among the 69 patients, 2 group AAR patients underwent postoperative bleeding control and 1 group IAR patient received AV replacement. The 2-year actuarial survival rate for both groups was 100%. Two-year freedom from reoperation rate related to the aortic valve was 100% in group AAR and 96% in group IAR (Fig. 4).

### 4. Discussion

Considering the anatomical structure and function of aortic root, pathologic changes in aortic leaflet and aortic root wall are two major primary causes of the development of AR. Leaflet deformity is the most common and important primary cause of AR. Duran et al. [1] and Haydar et al. [2] had attempted to repair the AR with leaflet deformity by leaflet extension. The main cause of early failure and frequent AR recurrence after leaflet extension with pericardium seemed to be related to phenomenal change of diameter of STJ during cardiac cycle. Although the native aortic leaflet has physiologic elasticity which can keep expanding and shrinking to accommodate the dimensional changes of the aortic root wall during the cardiac cycle, the pericardium used for leaflet extension cannot adjust to such movements of the STJ. Therefore, unless the STJ movement is simultaneously restricted with leaflet extension procedure, good long-term results could not be ensured. The aortic root wall dilatation beyond the power of recoil is another important cause of AR occurring without changes in the leaflet. Actually, the aortic root wall is comprised of the STJ, sinuses, and the annulus. The STJ is known to be the most elastic portion of aortic root wall capable of variations in its diameter throughout the cardiac cycle by as much as 63% [8]. Regarding annulaoaortic ectasia with Marfan’s syndrome, the initiating lesion of AR

### Table 3

Comparison of preoperative and last follow-up echocardiographic data of patients with severe AR in IAR and AAR groups

<table>
<thead>
<tr>
<th>Variables*</th>
<th>IAR</th>
<th>AAR</th>
<th>p-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>28</td>
<td>27</td>
<td>—</td>
</tr>
<tr>
<td>Preop. LVEDD</td>
<td>47.1 ± 9.9</td>
<td>42.8 ± 8.3</td>
<td>0.148</td>
</tr>
<tr>
<td>F/U LVEDD</td>
<td>36.4 ± 7.1</td>
<td>35.6 ± 8.8</td>
<td>0.560</td>
</tr>
<tr>
<td>Preop. LVESD</td>
<td>68.4 ± 9.1</td>
<td>63.2 ± 8.3</td>
<td>0.080</td>
</tr>
<tr>
<td>F/U LVESD</td>
<td>52.2 ± 6.2</td>
<td>51.7 ± 7.6</td>
<td>0.777</td>
</tr>
<tr>
<td>Preop. LVESV</td>
<td>113 ± 71</td>
<td>78.8 ± 36</td>
<td>0.052</td>
</tr>
<tr>
<td>F/U LVESV</td>
<td>99.8 ± 36</td>
<td>65.0 ± 37</td>
<td>0.855</td>
</tr>
<tr>
<td>Preop. LVEVD</td>
<td>233 ± 103</td>
<td>177 ± 71</td>
<td>0.055</td>
</tr>
<tr>
<td>F/U LVEVD</td>
<td>127 ± 55</td>
<td>134 ± 60</td>
<td>0.836</td>
</tr>
<tr>
<td>Preop. LV mass</td>
<td>429 ± 133</td>
<td>332 ± 130</td>
<td>0.050</td>
</tr>
<tr>
<td>F/U LV mass</td>
<td>263 ± 91</td>
<td>261 ± 109</td>
<td>0.739</td>
</tr>
</tbody>
</table>

Preop., preoperative; F/U, follow-up; AR, aortic regurgitation; LVEDD, left ventricular end systolic diameter; LVESD, left ventricular end diastolic diameter; LVESV, left ventricular end systolic volume; LVEDV, left ventricular end diastolic volume; LV, left ventricle.

* Data are expressed as mean ± standard deviation.
† Statistical significance was tested between IAR and AAR group.
progression is at the STJ area at the commissural level. Failure of recoil of the STJ causes severe irreversible dilation of the commissural area, and leads to progressive enlargement of the contiguous aortic root structure, taking the form of a tulip bulb, with eventual progression of AR. As Grande-Allen et al. [9] described, AR is unavoidable if dilation progresses to more than 30–50% of the original diameter.

David et al. [3,10,11] and Yacoub et al. [4,12] basically described two kinds of valve sparing operations in aortic root aneurysm with normal looking aortic valves: reimplantation of the aortic valve and remodeling of the aortic root. However, these operations have several potential problems, such as loss of sinus function, restriction of aortic annulus during systolic expansion as in the reimplantation technique, progressive expansion of the annulus in some cases and narrow clinical indications. Besides, the secondary changes from the vicious interaction between the deformed leaflet and the abnormal aortic root wall can be induced in chronic cases, thus simultaneous management of these two lesions is necessary. Procedures mentioned above could not yield the best outcome because they managed these lesions separately.

However, the new technique was designed to address the two main components of aortic root pathology, the leaflet and aortic root wall, simultaneously. The leaflets were repaired by additional leaflet creation or leaflet extension using bovine pericardium. Aortic root wall correction consisted of annulus reduction and STJ reduction. Various procedure combinations were performed to correct the AR depending on the aortic valve pathology. We would like to emphasize that this technique could be applied to patients over a broad spectrum of AR, even to patients with contraindications to conventional AV sparing or simple leaflet extension techniques. The most distinct advantage of this technique was the maximal structural and functional preservation of the aortic root with minimal insertion of foreign body materials.

Since December 1997, this technique was selectively performed for AR until December 2002, after having confirmed the reproducibility of its efficacy and effects from follow-up in the first 10 cases. Since then we adopted this technique as a routine procedure for AR as a result of which we performed only two cases of AV replacement among 59 consecutive patients undergoing corrective surgery for AR. One patient was reluctant with new technique and the other was excluded because of very poor LV function. During follow-up, progression of AR due to deformity of the pericardium used for leaflet correction, progressive dilation of sinus or annulus, and development of thrombosis, arrhythmia, and aortic stenosis were monitored closely. There was no significant progression of AR during follow-up not only in thickened valve, but also in rheumatic valve disease or bicuspid AV. Restriction of STJ motion was thought to have some protective effect on the newly implanted leaflets. Thirteen Marfan patients with severe AR who received this technique were currently free of relapse. Compared to the immediate postoperative parameters, increments of the diameter of each part of the aortic root up to 10% were observed at 1 year after surgery, but remained stable thereafter. The decrease in wall tension and increased thickening of the aortic wall secondary to annular and STJ reduction were believed to be the two main factors that may have yielded a protective effect against progressive aortic root dilation. We did not experience any thrombosis or arrhythmia. Development of increased pressure gradient across the AV may have been from incomplete resolution of stenotic components such as thickened leaflets or by the insertion of a relatively small STJ ring for body weight. Based on our experience, an STJ inner ring larger than 26 mm and securing the free leaflet mobility are recommended. Consequently, there was no significant clinical contraindication for this new technique for correction of the diseased aortic valve.

Although short-term and mid-term results were excellent, the most critical limitation of this study is the lack of clinical long-term follow-up warranting a longer period of follow-up. However, the results do suggest that this novel aortic valvuloplasty procedure can be effective and reliable with low risk of reoperation, morbidity, and mortality for the management of various kinds of AR.

5. Conclusions

The advantages of novel technique of aortic valvuloplasty can be summarized as follows: wide range of indications in AR, preservation of aortic root function, avoidance of prolonged anticoagulation, easy operative procedure, and low incidence of AR recurrence. Although long-term follow-up is necessary, the results showed this technique to be safe and effective. Thus far broad application of this repair technique has been demonstrated to be highly feasible.

References

Appendix A. Conference discussion

*Dr T. Treasure (London, UK)*: When the coronary arteries take off very high, it makes us think of a Marfan type aortic pathology. I didn’t see clearly whether you had distinguished between that form of aortic regurgitation and others.

*Dr Song*: It’s a kind of AAR group, not IAR group. We divided into two groups. The AAR group has some disease that was in the aortic root.

*Dr Treasure*: So you didn’t exclude the Marfans.

*Dr Song*: We did.

*Dr Treasure*: You did exclude them?

*Dr Song*: No, we did operation for Marfan’s syndrome with annuloectasia.

*Dr Treasure*: So there are other cases with high coronaries who are not Marfans?

*Dr Song*: Yes. Aortic bicuspid valve with high take off coronary artery is not uncommon. For the high coronary arteries, we just dissected between the coronary artery and the aortic wall. So we separated the coronary artery from the aortic wall, and below the coronary arteries we placed the outer ring at the sinotubular junction.

*Dr L. Von Segesser (Lausanne, Switzerland)*: Would you use your technique for a bicuspid aortic valve?

*Dr Song*: Sure. We converted it to the three-cuspid aortic valve by separating the fusion line, and with the creation of additional leaflets and STJ reduction procedure, we could repair the bicuspid aortic valve, we had three cases in our experience.

*Dr Von Segesser*: And you are happy with the results?

*Dr Song*: Of course. We have not had any aortic regurgitation remain.