Valve-sparing operation for balloon-induced aortic regurgitation in congenital aortic stenosis

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Objective: Aortic regurgitation after balloon dilation of congenital aortic stenosis may be treated with valve repair as an alternative to replacement.

Methods: Charts and echocardiograms of all patients undergoing aortic valve operations after balloon dilation of congenital aortic stenosis at our institution between January 1988 and December 1999 were reviewed.

Results: Twenty-one patients underwent valvuloplasty for predominant aortic regurgitation 9 months to 15 years (mean, 6.1 years) after balloon dilation. The mean $\pm$ SD age at the time of the operation was 11 ± 7 years. Aortic regurgitation was caused by a combination of commissural avulsion (10), cusp dehiscence with retraction (9), cusp tear (5), central incompetence (2), perforated cusp (1), or cusp adhesion to the aortic wall (1). Repair techniques included commissural reconstruction with a pericardial patch (8), pericardial patch cusp augmentation (6), primary suture repair (6), raphe release and debridement (4), commissurotomy (4), commissural resuspension with sutures (3), and cusp release (1). There were no deaths. At a mean follow-up of 30.1 months (range, 9 months–8 years), all patients were asymptomatic, and the grade of aortic regurgitation had been significantly reduced ($P < .001$). Left ventricular end-diastolic dimension z scores and proximal regurgitant jet/aortic annulus diameter ratios were significantly reduced ($P < .001$) and remained so over time. Freedom from reoperation for late failure was 100%, and overall freedom from reintervention was 80% at 3 years.

Conclusion: Aortic valve repair for balloon-induced aortic regurgitation is reproducible and durable at medium-term follow-up.

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Significant aortic regurgitation (AR) is a recognized complication after balloon dilation of congenital aortic valvular stenosis (cAVS).¹⁻⁵ It has an incidence of 13.2% immediately after balloon dilation, which increases to 38.2% during follow-up in our experience.⁵ Given the current use of balloon dilation as the primary approach to cAVS at many centers, including our own, some of these patients now have significant AR. Mechanical valve replacement is complicated by the need for systemic anticoagulation and lack of annular growth. The pulmonary autograft procedure is an alternative to a mechanical prosthesis with potential for annular growth, but disproportionate dilation of the neo-aortic root, autograft regurgitation, and the need for pulmonary homograft changes remain concerns.⁶⁻¹¹ The number of patients reported who have undergone a valve-sparing procedure for balloon-induced AR is small.¹²⁻¹⁵ We describe our

operative approach and efficacy of repair at follow-up in patients with congenital cAVS who have undergone a valve-sparing repair for AR induced by balloon dilation at our institution.

Patients and Methods

Methods

All patients who underwent balloon dilation for cAVS between January 1988 and December 1999 were identified through the cardiology catheterization laboratory database. All data procurement was carried out after institutional approval according to guidelines established by the committee on clinical investigation. All charts were retrospectively reviewed up to the last entry, and echocardiograms were read by independent reviewers.

Patients

During the 11-year study period, 335 balloon dilations were performed on 281 patients for cAVS, 59 (21%) of whom eventually required aortic valve operations for residual stenosis, AR, or both (Table 1). A valve-sparing procedure was performed in 21 patients in whom the predominant lesion was AR. These patients form the basis of this report. The mean $\pm$ SD age at the time of balloon dilation was 5.1 ± 3.2 years; 4 patients had 2 dilations, and 1 patient underwent 3 such procedures. Postdilation AR, as determined by using angiography, was considered mild in 2 patients, mild to moderate in 11 patients, moderate in 3 patients, and severe in 5 patients. Five other patients underwent valvuloplasties but were excluded from the study group because 4 had predominant aortic stenosis (AS) after unsuccessful balloon dilation, and 1 underwent an associated modified Konno procedure. The remaining 33 patients underwent a Ross procedure with or without the Konno procedure (15), aortic valve replacement (9; homograft: 4; prosthesis: 5), surgical valvotomy (5), or Norwood palliation (4; Table 1). Four patients had a subaortic membrane, and 3 patients underwent aortic coarctation repair.

Echocardiography

Preoperative echocardiograms were compared with the most recent follow-up studies available. All patients had immediate intraoperative assessment of the repair by means of transesophageal echocardiography (TEE). Grading of AR both preoperatively and at follow-up was performed by an independent echocardiographer unaware of individual patient information on a scale of 0 to 4 (0 = none; 1 = trace; 2 = mild; 3 = moderate; 4 = severe). In addition to a qualitative assessment of the AR, measurement of the proximal regurgitant jet diameter was performed from the parasternal long-axis view and expressed as a percentage of the aortic valve anulus diameter. Quantitative left ventricular dimensions (indexed for body surface area) were determined from the preoperative echocardiogram and were compared, when available, with those on the most recent follow-up echocardiogram. Increased AR at follow-up was defined as an increase by at least 1 grade compared with postbypass TEE or predischARGE echocardiogram and any increase in left ventricular end-diastolic dimension (LVEDD) z score. Mild, moderate, and severe AS were defined as a maximum instantaneous gradient of less than 30, 30 to 60, and greater than 60 mm Hg, respectively.

TABLE 1. Aortic valve operations after balloon dilation of congenital AS between 1988 and 1999 at Boston Children's Hospital

Procedure	No.
Ross $\pm$ Konno	15
Aortic valve replacement	9
Valvotomy	5
Norwood stage I procedure	4
Aortic valve repair	26*

*Five patients were eliminated from the final study group (n = 21): 4 patients had aortic valve repair for predominant AS after unsuccessful balloon dilation, and 1 patient had an associated modified Konno (aortoventriculoseptal plasty) procedure.

Surgical Technique

The operation was performed on cardiopulmonary bypass with moderate systemic hypothermia for all patients. A pericardial patch was harvested and fixed in 0.6% glutaraldehyde for 20 to 30 minutes. The fixation time was chosen to improve the handling and increase the strength of the pericardial patch. A left ventricular vent was placed through the right superior pulmonary vein. An aortotomy was made transversely and extended toward the noncoronary sinus of Valsalva. Cold cardioplegia was infused selectively into both coronary ostia. A decision to perform valve reconstruction was at the surgeon's discretion and was a judgment made on the basis of preoperative echocardiography, intraoperative TEE, and direct inspection of the valve. Anatomic elements necessary for valve repair include a sufficient annular diameter to not require left ventricular outflow tract enlargement, mobile cusps or cusps that can be made mobile by resection or shaving of excess fibrous tissue, and an ability to achieve coaptation without inducing stenosis. A variety of valvuloplasty techniques were used.¹²⁻¹⁶ The valve was studied by using fine forceps to approximate the length, depth, and mobility of the cusps. The diameter of the central opening of the valve, as well as the location and mobility of the commissures and raphae, were also noted.

Primary Repair

Excess fibrous tissue, which has a tendency to build up around raphae (rudimentary fused commissures), was aggressively removed (so-called shaving), giving the cusp more mobility. Fused commissures with adequate suspension to the aortic wall were opened with a scalpel. Simple tears involving otherwise competent cusps were repaired primarily, usually with a 5-0 polypropylene (Prolene; Ethicon, Inc, Somerville, NJ) running suture. If the native cusps were deemed adequate, tears involving the anterior commissure (right coronary commissure [RCC]-noncoronary cusp commissure [NCC]) in bicuspid valves were repaired by resuspending the commissure with sutures passed through the aortic wall. Otherwise, the commissure was resected and reconstructed. Prolapsed but otherwise competent and pliable cusps were shortened by resuspension of the cusps to the commissures with pledget-supported sutures. In cases of central cusp incompetence with dilation of the sinuses of Valsalva, a sinus of Valsalva reduction plasty was performed to reduce commissural splaying. This was done by resecting a wedge of noncoronary sinus, followed by primary closure of the aortotomy (Figure 1).

Figure 1. Central incompetence caused by dilation of the sinuses of Valsalva is managed by resection of a wedge of one or more sinuses (top) followed by primary closure (bottom).

Treated Autologous Pericardial Patch Repair

Perforated cusps were repaired with a pericardial patch sutured into the perforation. Deficient cusps, usually resulting from a long-standing balloon-induced tear with retraction of the free cusp edge (Figure 2), were augmented by suturing a half moon-shaped autologous pericardial patch to the free edge of the retracted cusp (Figure 3). The patch was deliberately tailored so that it overlapped the opposite free cusp edge by a few millimeters. However, if the opposite cusp was too far or deficient as well, the patch was not extended; rather, the opposite cusp edges were supplemented with strips of fixed pericardium. By keeping the free edge of the patch slightly longer and redundant, most patches were further anchored to at least one commissure (usually anteriorly), resuspending it. If the native cusp was very stiff or calcified, the cusp was partially or completely resected and reconstructed with a pericardial patch. Generally, however, as much as possible of the native valve was left intact. If the 2 cusps were deficient at a commissure, 2 pericardial patches were used to augment the deficient cusps and reconstruct the commissure.

Statistical Analysis

Continuous data were tested for normality by using the Kolmogorov-Smirnov goodness-of-fit statistic, and all variables were found to follow a normal distribution except qualitative AR and AS grade assessment. Therefore age, follow-up time, LVEDD z scores, proximal AR jet/aortic anulus diameter ratios, and maximum instantaneous gradients were expressed as means $\pm$ SD, with changes evaluated by paired t tests. Qualitative AR and AS grade assessments were presented in terms of medians and ranges with preoperative and follow-up values compared by the Wilcoxon signed-rank test. Actuarial freedom from aortic valve reintervention and freedom from AR rates were estimated by the Kaplan-Meier product-limit method, with 70% confidence intervals (CIs)

calculated by the Greenwood formula. The Cox proportional hazards regression model was used to identify variables independently associated with aortic valve reintervention or AR. Covariates tested in the multivariate stepwise model included age, sex, type of repair (primary vs patch), maximum instantaneous gradient, AR and AS grade, LVEDD z score, and proximal regurgitant jet/aortic anulus diameter ratio. Data were analyzed by means of the SAS software package (version 6.12; SAS Institute, Cary, NC).

Results

Preoperative Data

The mean age at the time of the operation was 11 ± 7 years (range, 9 months–15 years). The mean time between the last balloon dilation and the operation was 6.1 ± 4.5 years. Five patients had decreased exercise tolerance. Severe AR was present in 14 patients, and moderate AR was present in 7 patients (median grade = severe). The mean maximum instantaneous gradient was 43 ± 26 mm Hg. Significant left ventricular dilation was present in 11 patients (LVEDD z score >3).

Intraoperative Data

Description of aortic valves. The valve was bicuspid in 19 patients, tricuspid in 1 patient, and unicuspid in 1 patient. Fusion of the left coronary commissure–RCC was predominant in 15 (71%) patients. Fusion of the RCC–NCC was present in 4 patients, and fusion of both the left coronary commissure–RCC and RCC–NCC was present in 1 patient. Predominant factors contributing to AR were a combination of anterior commissural avulsion in 10 patients, cusp dehiscence with retraction (presumably caused by long-standing balloon-induced tear) in 9 patients, simple cusp tear in 5 patients (anterior in 4 patients and posterior in 1 patient), central incompetence in 2 patients (from calcified cusps in 1 patient and from sinus of Valsalva dilation in 1 patient), a perforated cusp in 1 patient, and free cuspal edge adhesion to aortic wall in 1 patient. The RCC was the most frequently involved cusp (20/21 patients).

Aortic valve reconstruction. The various techniques used are summarized in Table 2. No patients required immediate conversion to aortic valve replacement after failed valvuloplasty. Cardiopulmonary bypass was reinstituted in 2 patients after the initial valvuloplasty. In 1 patient this was because of severe pericardial cusp patch prolapse with resulting AR managed by adding a second pericardial patch to the opposing cusp, thereby improving coaptation with resultant trace AR. In the other patient there was evident AS after valve debridement and primary repair of a tear for which anterior and posterior commissurotomies were carried out, with reduction of the peak systolic ejection gradient from 55 to 35 mm Hg.

Clinical follow-up. There were no early or late deaths. The mean hospital stay was 5 ± 2 days. The mean follow-up was

Figure 2. Typical AR induced by balloon dilation. There is a tear anteriorly in the region of the right coronary cusp. There is retraction of cusp tissue, prolapse of the rest of the cusp, and thickening of the free edges at the site of the tear. The valve is viewed from above (top) and below (bottom).

31 ± 27 months. A pericardial effusion necessitating percutaneous drainage occurred in 1 patient. In another patient severe recurrent AR occurred before discharge after pericardial patch reconstruction with anterior commissural reconstruction of a partially resected cusp. At reoperation, a patch suture line had dehiscence and was repaired, with marked reduction in the AR. One patient underwent a repeat balloon dilation for recurrent AS 3.5 years after her valvuloplasty. Freedom from reoperation (aortic valve replacement or rerepair) for late failure was 100%, and freedom from overall aortic valve reintervention was estimated to be 80% at 3 years (70% CI, 68%-92%; Figure 4). No variables, including type of repair, were found to be significantly associated with aortic valve reintervention in the Cox multivariate model. All patients were asymptomatic at the last follow-up point.

Echocardiographic follow-up. Intraoperative TEE after repair revealed trace AR in 12 patients, mild AR in 8 patients, and moderate AR in 1 patient. The median pull-back gradient, measured intraoperatively in 8 patients, was 25 mm Hg (range, 10-45 mm Hg). All patients had echocardiographic assessment before discharge, with no significant discrepancies with the intraoperative TEE findings.

At further follow-up, echocardiograms continued to reveal a significant reduction in AR grade (median AR grade = mild, $P < .001$; Figure 5). Mean LVEDD z scores were also significantly reduced (3.44 ± 1.97 preoperatively vs

1.54 ± 2.27 at immediate follow-up, $P = .003$; 3.44 ± 1.97 preoperatively vs 1.00 ± 1.73 at late follow-up, $P < .001$; Figure 6), as were proximal AR jet diameter/aortic anulus diameter ratios (0.53 ± 0.18 preoperatively vs 0.17 ± 0.13 at immediate follow-up, $P < .001$; 0.53 ± 0.18 preoperatively vs 0.28 ± 0.17 at late follow-up, $P < .001$). For both LVEDD z scores and AR jet diameter/aortic anulus diameter ratios, immediate follow-up values were not significantly different from late follow-up values ($P = .84$ and $P = .09$, respectively). The freedom from increased AR (see "Methods" section) was 100% at 2 years and 75% at 3 years (Figure 7). Preoperative Doppler maximum instantaneous gradient and that at last follow-up did not change (43 ± 26 vs 43 ± 21 mm Hg, $P = .95$; Figure 8). None of the variables listed above were significantly associated with increased AR in the Cox model ($P > .5$ for each).

Discussion

Balloon dilation has replaced surgical valvotomy as the primary treatment for cAVS in most centers, often with excellent relief of stenosis.¹⁻⁵ The present report is the largest series reported to date dealing specifically with balloon-induced AR in cAVS. Several series, including some intraoperative human studies,^{17,18} have shown that after successful balloon dilation, new AR is more common than residual AS.^{1,2,3,12} Typically, the balloon-dilated bicuspid aortic

Figure 3. Typical autologous pericardial repair of balloon dilation injury. The patch not only fills the defect but also reconstructs the anterior commissure, thereby resuspending the prolapsed leaflet. Note that the patch is slightly redundant and overlaps the adjacent cusp. Views are from above (*left*) and below (*right*).

TABLE 2. Spectrum of aortic valvuloplasty techniques used in 21 patients with AR after balloon dilation for congenital AS

Surgical technique	Patients (n)
Repair without a pericardial patch	7
Primary suture repair	5
Commissurotomy	3
Commissural resuspension	3
Debridement/raphae release	3
Cusp release from aortic wall	1
Repair with a pericardial patch*	14
Single patch	7
Without commissural reconstruction	3
With commissural reconstruction	3
With suture commissuroplasty	1
Double patch	7
With commissural reconstruction†	5
Without commissural reconstruction	2
Additional procedures	7
Resection subaortic membrane	3
Ascending aortic patch enlargement	3
Reduction plasty ascending aorta	1

*All were bicuspid valves, and all reconstructed commissures were anterior.

†One patient had reduction plasty of the noncoronary sinus of Valsalva.

valve tears near or at the anterior commissure, with the RCC being most frequently involved. In this study, as in others,^{17,18} most patients had an anterior lesion involving the RCC, and AR was the predominant lesion. Although when to surgically intervene in these children is a controversial decision, accepted indications are the presence of symptoms, increasing significant LV dilation with or without dysfunction, or both in the setting of moderate or worse AR.

Aortic Valve Repair Versus Pulmonary Autograft

Growing children would benefit if the balloon-damaged aortic valve could be repaired in a reproducible and durable fashion, rather than being replaced.¹⁵ Prosthetic valves usually require anticoagulation and reoperations and have a small risk of endocarditis. The initial enthusiasm for the pulmonary autograft procedure, currently accepted as the best choice for replacing the aortic valve in children,⁶ has been dampened by clinical,^{7,11,19} as well as experimental,⁸ observations of early dilation of the neo-aortic root, sometimes leading to significant regurgitation.^{9,10} Although freedom from homograft replacements after the Ross procedure has been greater than 85% at 8 years,¹⁰ homografts undergo more rapid degeneration in the very young child.²⁰ Elkins and colleagues¹⁰ showed that intra-aortic pulmonary autograft valve replacements tended to follow a normal diameter increase, whereas root replacements tended to dilate. Because the latter technique is usually used in children, progressive dilation remains a serious concern.

Deciding whether to replace or repair an aortic valve remains a difficult task, largely influenced by preoperative and intraoperative 2-dimensional and 3-dimensional echocardiography,²¹ as well as direct inspection. Another factor that needs to be accounted for when trying to decide whether to replace or repair is the size of the aortic anulus and the degree and mechanism of AS. In the present cohort aortic valve repair did not result in increased AS. The preoperative aortic anulus z scores were in the range of -0.9 to 2.4. On the basis of these data, it is our clinical impression that long-standing AR-induced volume load will promote growth of the often hypoplastic anulus of a congenitally stenotic aortic valve, thus allowing for a subsequent repair with less risk of postoperative AS. A patient with mixed

Figure 4. Kaplan-Meier estimates of freedom from aortic valve reintervention. *Error bars* indicate 70% CIs. Numbers of patients in the follow-up on whom the estimates were based are shown in *parentheses*. No patient required reintervention for late recurrence of AR.

Figure 5. Degree of AR at immediate and long-term follow-up for each individual patient ($P < .001$ for preoperative vs last follow-up degree of AR). *post-op*, Postoperative.

severe AS and AR might benefit more from a pulmonary autograft than a repair, despite an operative mortality of 4% with the root replacement.¹⁰ If the decision that a valve can be repaired could be made with certainty preoperatively, asymptomatic children with moderate AR and no left ventricular dilation could undergo valvuloplasty in a proactive effort to prevent further myocardial damage.²²

We currently use any increase in LVEDD z scores as an indication for operation in asymptomatic children. A recent report on 22 valvuloplasties¹⁴ noted that repair of a regurgitant bicuspid aortic valve was significantly less effective than a pulmonary autograft replacement. This is in contradistinction with the results of this report, in which bicuspid or unicuspid valves were present in 91% of patients. After a mean follow-up of 31 months, only 1 patient has progressed to severe AR, with no change in LVEDD z score. A longer period of follow-up was not

Figure 6. Changes in individual LVEDD z scores (see text for statistics). *preop*, Preoperative; *post-op*, postoperative.

Figure 7. Kaplan-Meier estimates of freedom from increased AR. *Error bars* indicate 70% CIs. Numbers of patients in the follow-up on whom the estimates were based are shown in *parentheses*.

Figure 8. Changes in degree of AS ($P = .95$; see text for definitions).

associated with increased AR. Only 3 patients with increasing AR at follow-up also have increased LVEDD z scores, suggesting that aortic valve repair did reliably prevent or reduce further myocardial dilation in the majority of patients.

Type of Repair

Repair of insufficient bicuspid valves, albeit not balloon-damaged valves, was addressed specifically in 2 recent reports.^{16,23} The described repair techniques are similar to ours but are more designed to deal with redundant prolapsing cusps. Balloon-damaged valves often exhibit a localized tissue defect at the site of the previous tear, making it amenable to reconstruction with pericardial patch extension. One recent report¹² focused exclusively on balloon-damaged valves. Repair techniques included only primary repair and debridement performed an average of 35 months after balloon dilation, whereas the patients in the present study were operated on an average of 69 months after balloon dilation. The free cusp edge of the balloon-torn valve has a tendency to roll onto itself, retracting and becoming fibrotic over time. This would explain why pericardial patch augmentation was used in a much larger scale in our cohort and why AS was not a problem postoperatively. The pericardial patch has to counteract the inherent shallowness of the congenitally stenotic valve by giving it more depth (Spinnaker effect).²¹ We have not seen the complication of development of AS caused by crowding of the ventriculoaortic junction with the augmented cusps described in a recent study,¹⁵ which is perhaps related to our less extensive use of patch augmentation.

Conclusion

This study suggests that aortic valve repair for balloon-induced AR can be recommended. It is reproducible and durable at medium-term follow-up in the majority of patients.

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