Children with Congenital Disease Amenable to Aortic Valve Repairs: Lessons for Management and where do these Techniques Currently Stand?

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Abstract

Aortic Valve Repair (AVRep) appeared to be the first considered in the armamentarium to treat AV disease in children of various ages for the last two decades because of its lifelong durability and reproducibility. Several advantages of AV Rep over techniques of Aortic Valve Replacement (AVR) are identified. Surgical repair strategy should be individualized to the age of the patient depending on aortic root growth potential. New repair techniques developed by innovative surgeons are gradually becoming adopted.

Keywords: Aortic valve; Aortic valve neocuspidization; Aortic valve repair; Children; Reintervention

Introduction

The Aortic Valve (AV) can be commonly affected in children by several disease pathologies, frequently requiring multiple palliative intervention. Surgical repair for congenital Aortic Stenosis (AS) with cardiopulmonary bypass was first described by Lillehei, et al. and colleagues in 1956 and was the only treatment option for three decades [1]. Surgery initially had a high mortality rate, over 50% in the 1980 to 1990s [2]. During the 1980s and 1990s, the development of AVRep in surgery we choose, congenital AS carries the lifelong risk of reintervention.

First, extensive external annular reinforcement in small children would prevent growth. Second and most importantly, the age at presentation is a marker of severity and the pathology in adults is far less severe than in children. Nevertheless, any Aortic Valve (AV) operation in children (repair, Ross or mechanical replacement) is a palliation and reinterventions are frequent. One justification for use of AV repair is the ability to delay AV replacement techniques to an older age. The ultimate goal of these AVRep or reconstruction techniques is to provide the best survival, minimal reintervention risk, and high quality of life. From this point of view, the purpose of this article is to analyze the current surgical strategies and techniques of treating AV disease and unsolved repair related issues in children.

What is the primary procedure of choice in children with aortic valve stenosis?

Treatment of congenital AV stenosis usually requires multiple interventions. The ultimate goal of treatment should result in the adequate relief of obstruction while minimizing significant regurgitation. Both BV and Surgical Aortic Valvulotomy (SAV) have been widely applied, but the primary intervention for congenital AV stenosis in children still remains controversial [6].

In 2015, Prijic, et al. and colleagues reported a study that evaluated the long-term results of BV (n=39, 1.3 months to 17 years old) and SAV (n=23, 1.2 months to 15 years old) from 1987 to 2013. The freedom from reintervention rates were 71% for SAVs and 61% for BV in 10 years, but 42% for SAV and 23% for BV in 20 years [7]. These results reveal that the long-term outcome of SAV is better than that of BV, though the early results might look less different. Not surprisingly, freedom from Aortic Valve Replacement (AVR) for BV (32%) is lower than that for SAV (53%). But no matter what type of surgery we choose, congenital AS carries the lifelong risk of reintervention.

In 2015, Soulages and colleagues analyzed 93 patients (1 day to 18 years, 2.4 years on average) who underwent BV as the primary treatment from 1992 to 2012 [8]. The long-term survival rate was 88.2% in whole cohort. The freedom from reintervention rate was 58% (54% in neonates and 65.6% in infants) with the mean follow-up duration of 11.4 years and the freedom from surgery was 66% (58.5 in neonates and 75.8 in infants). The applied as the primary treatment...
in infants and children. While in 2006, Miyamoto and colleagues reported a freedom from reintervention of 85.1%, 78.0%, and 53.5% at 5, 10, and 15 years respectively in patients who underwent primary SAV due to the critical AS aged less than 3 months between 1983 and 2003 and they concluded that SAV was the most appropriate strategy to treat neonates and young infants with critical AS.

### Table 1: Aortic valve repair in the pediatric population for congenital aortic valve disease

| Authors                          | Journal | Year | Number | Age               | Technique                                         | Material                  | Mortality | Follow-up | Results                                      | Freedom from re-intervention |
|---------------------------------|---------|------|--------|-------------------|--------------------------------------------------|---------------------------|------------|-----------|---------------------------------------------|------------------------------|
| Hasaniya et al. (Loma Linda)    | JTCVS   | 2004 | 21     | Mean 8.1 years    | Nocusat extension                                | -                         | None       | Mean 5.3 years | 11% residual moderate AR postoperatively      | 47% reoperation at mean 28.3 months postoperatively |
| Tweddell et al. (Milwaukee)     | JTCVS   | 2005 | 147    | Mean 6 years      | Simple repair (valvulotomy, commissurotomy + thinning) | -                         | Early: 15 (10.2%), 2 late deaths | Mean 2.9 years | Moderate AR:27%, severe AI 6%, mean AS gradient: 20 mm Hg | 96% at 5 years, 86% at 10 years |
| Oemets et al. (LosAngeles)      | ATS     | 2005 | 31     | Mean 25.5 years   | Multiple suture leaflet extension in all          | GTAP                     | Early: one, no late deaths | Mean 25 months | Moderate AR in 6%, moderate AS in one patient | Patients< 18 years:100% at 2 years |
| Alisoufi (Toronto)              | ATS     | 2006 | 22     | Mean 11.4 years   | Multiple suture leaflet extension in all          | GTAP                     | No early or late deaths | Median 1.7 years | Moderate AR in seven (32%) patients, median postoperative gradient 29 mm Hg, 7 (32%) > 30 mm Hg postoperatively | 80% at 2.5 years |
| Hawkins (Sub-LakeCity)          | JTCVS   | 2006 | 54     | Mean 8.5 years    | Multiple leaflet extension                        | GTAP                     | Early: one (19%), no late deaths | Mean 76 months | Reoperation: 13/54 (23%) at 48 months postrepair, two patients with moderate severe AR | 68% at 5 years, 58% at 10 years |
| McManus et al. (Melbourne)      | JTCVS   | 2007 | 21     | Mean 12.6 years   | Multiple suture leaflet extension in all          | GTAP                     | No early or late deaths | Mean 34.7 months | Early reoperation: two, late reoperation: two, moderate AR: 4 of 21 (25%), severe AS: one | Reoperation >= moderate AR: 75% at 36 months |
| Quader (Cleveland)              | Heart, Lung & Circulation        | 2006 | 56     | Mean 13.4 years   | Multiple, cusp extension in 14%                   | GTAP                     | Early death: one, Late death: two | Median 37 months | Aortic stenosis group, n = 7: 4 (57%) moderate AS, AR group, n = 24: 3 (12.5%) moderate AR, (41%) require reoperation | 99% at 1 year, 80% at 5 years |
| Bacha (Boston)                  | JTCVS   | 2008 | 81     | Median 8.6 years  | Multiple leaflet extension                        | GTAP                     | Three (3.7%) early and late combined | Median 4.5 years | Rerepair: three, valve replacement: 25 (31%), balloon aortic valvuloplasty: 8 (10%), in the remaining patients-moderate AR: 21 (38%) and moderate AS: 14% | 91% at 1 year, 63% at 5 years |
| D’Udekem (Melbourne)            | JTCVS   | 2013 | 142    | Median 9 years    | Leafflet extension, n = 96                       | GTAP                     | Two early (1.4%), one late | Mean 3.4 years | Moderate AR: 23 (19%), severe AR: 1, moderate AS: 12 (10%), coronary ischemia, n = 5 (early death 2, ECMO 1, on-table revision 2 | 80% at 5 years |
| Kandakure, et al. (Liverpool)   | WJPCHS  | 2014 | 39     | Median 5.5 years  | Multiple leaflet extension, neocommissure creation in all | GTAP                     | Early: 3 (7.7%),            | Mean 12.7 months | Moderate AR: 2 (5.1%), Moderate AS: 3 (7.7%) | 95% at 3 years |
| Vergnat et al. (Sankt Augustin) | FACTS  | 2017 | 193    | Median 9 years    | Multiple leaflet extension, replacement and neocommissure creation in all | GTAP                     | Early: 1 (0.5%), 2 late deaths | Mean 5.1 years | Moderate AR: 13 (27%), Moderate AS: 7 (15.7%) | 89%, 79%, 57% at 1, 5 and 7 years postoperatively |
| Fraser et al. (Baltimore)       | JTCVS   | 2019 | 100    | Median 13.6 years | VSRB                                              | -                        | 22% (peri-operative), 7 late deaths (7%) | Mean 4.7 years | Moderate and greater AR: 9 (9%) | 100%, 88.5%, 70.4% at 1, 5 and 10 years postoperatively |

**Abbreviations:** ATS: Annals of Thoracic Surgery; JTCVS: Journal of Thoracic and Cardiovascular Surgery; GTAP: Glutaraldehyde-Treated Autologous Pericardium; AR: Aortic Regurgitation; AS: Aortic Stenosis.

*Recently published series with mean or median follow-up less than ten years.*
Collectively, these data suggest that the outcomes of BV in younger patients were no better, if not worse, than those of SAV [9]. In reference to a recent meta-analysis [10], we can intuitively see that SAV and BV had similar early mortality, but the long-term outcomes (the freedom from reintervention) of SAV were superior overall and in infant alone (P<0.001).

The Ross procedure: the ultimate operation?

AVR with a pulmonary autograft, the Ross procedure, is widely used in children. Given the advantageous features of the autograft conduit for children (absence of anticoagulation, no age limitation, growth potential), Ross procedure became the operation of choice in children. The German Dutch Ross registry shows a 10-year freedom of reoperation in excess of 90%, far superior to any report on AoV repair for Aortic Regurgitation (AR) in children that is consistent with a report comprised a 10-year freedom from reoperation of 95.2% in a series of 31 neonates and infants [11,12]. Nevertheless, there is a growing body of evidence in the paediatric field that dilatation and failure of neo-aorta occur in up to 28% at median follow-up duration of 5.2 years after Ross procedure [13].

In the study from Children’s Hospital of Philadelphia, 97% of the children had a neo-aortic root z-score of >4 at six years and 60% had moderate or greater neo-aortic regurgitation [14].

Techniques preventing this drawback (modified Ross) have developed but can only be applied in a mature child. Performing the AVRep would allow for aortic root growth and the postponement of the Ross procedure to a time when such modified procedure or if possible [15], secondary AVRep can be used. In the Vergnat, et al. report, of the 48 patients who eventually required AVR, the median age at repair was 8.0 years, and replacement could be postponed at a median age of 12.0, which allowed in some patients the use of supportive Ross techniques [16]. As described later, older age may also allow consideration of further techniques for recurrent repair (such as leaflet replacement) that could have not been used in younger patients because of limited durability.

Aortic valve repair techniques: current development and results

With the development of valve repair techniques, AVRep shows several advantages over replacement. On the one hand, repair can be performed in almost all ages and utilizes native tissue, do not require anticoagulation, and has a low risk of endocarditis, calcification or thromboembolism. Furthermore, valve repair stabilizes left ventricular (LV) dimensions, hemodynamics and results in symptomatic improvement, and various strategies can be utilized as the patient grows. Surgical repair of AV can be classified as simple or complex. Simple methods include valvulotomy, valve debridement, commissurotomy, valve suspension, and commissure suspension. Complex AVRep methods include cusp extension, leaflet replacement, and other valve reconstruction. Ideally, AVRep would relieve the hemodynamic burden on the LV, permit growth, provide the tolerance against infectious endocarditis, avoid AVR and the need for anticoagulation. Thus, the implementation of AVRep is extremely broadly favored that allow the largest proportion of patients to have the smallest number of reinterventions over their lifetime. Regarding the Poncelet, et al. data, the latter event contributed to the expansion of the use of AVRep air. The enrollment pattern for AVRep, Ross procedures and AVR over four decades is illustrated in Figure 1. So, Poncelet, et al. reported the freedom rates from AVR at 5, 10 and 15 years of 90, 81, and 74.8%, respectively. compare favourably to other contemporary studies [22]. Indeed, Bacha, et al. [23] reported 5- and 10-year rates of freedom from AVR of 72% and less than 50%, respectively.

Khan, et al. reported a 5-year rate of freedom from AV reintervention of 75% (excluding the truncal repair group) [24]; and d’Udekem, et al. [21] recently reported 90 and 50% freedom from AVR at 5 and 10 years for their entire cohort of repair, which included about 100 paediatric patients older than 1-year-old. The frequency of AVRep is also, as in Brussel experience, favored in contrast to BV and Ross operation (Figure 2). The stability of the repair in our study was satisfactory with 90, 72 and 72% freedom from AV reintervention at 5-, 10- and 15 years, respectively. One of the reasons for this improved longevity might reside in the fact that in Melbourne experience, it was rarely used leaflet extension as a tool to obtain a competent AV.
Only 10 patients (15%) underwent leaflet extension in our 38 years of experience. In comparison, leaflet extension was used in 30% of the patients in the Melbourne experience and in 80% of the Boston experience [21,23]. Indeed, the subgroup of patients in Melbourne without the leaflet extension technique had a much higher freedom from AV reintervention. Also supporting this hypothesis, Wilder, et al. [25] demonstrated a nearly 50% valve-related reoperation rate in their series of older children when they used leaflet extension, with a mean time to re-repair/replacement of 4.4 years. Recently, Vergnat, at al. showed the favorable long-term results as a freedom rate from reoperation at 1, 5 and 7 years of 89% (95% CI, 85-94%), 70% (95% CI, 63-78%) and 57% (95% CI, 47-66%), respectively.

**Aortic root growth and aortic valve geometry-based strategy**

Patient growth has a major impact on repair durability as it varies in various children ages. The growth potential of the AV complex can be considered in 2 directions: vertical (from cusp nadir to Arantius nodula) and horizontal (inter commissural). Regarding to growth of the AV and patients’ ages, the whole repair procedures are subdivided in 2 variations:

- Unrestrictive procedures (commissurotomy shaving or neocommissure creation) maintain growth potentials in both directions
- Restrictive procedures (leaflet replacement and extension) restrain intercommissional growth Basing on Vergnat et al. data, a restrictive procedure in small children (especially under the age of 1 year) leads to a reoperation sooner rather than later. In young patients (<10 years), neocommissure creation is promising; 2 other techniques (commissurotomy shaving or leaflet replacement) are equally effective. In older patients (>10 years), all techniques except leaflet extension offered 80% freedom from reoperation at 8 years of follow-up [32].

Stenosis as the primary indication was present in about 2/3 of the patients. The results show a 80% freedom of reoperation at 8 years of follow-up, entirely consistent with the previous studies cited above. The end point in the study by Vergnat, et al. is freedom from reoperation. While this end point is widely accepted, reoperation is a measure of physician behaviour and is not always a reflection of the physiologic burden on the LV, that is, recurrent stenosis or regurgitation impacting on the success of repair.

Valve morphology may influence on outcomes with tricuspid morphology providing a protective effect against reoperation and, more importantly, against replacement [32]. This effect may be due either to the underlying morphology, to a better geometrical configuration favouring durability or to the maintenance of the further possibility of re-repair (leaflet rereplacement instead of valve replacement).

**Aortic valve repair by using patch material**

As noted above, regurgitation repairs fail in not too distant time, since repairs for this type of disease demand extensive use of additional materials either xenograft patches or fixed autologous pericardium. In addition, suture lines are required to flex repeatedly and repair forces are commonly concentrated into a small region, resulting in structural failure. These materials are subject to rapid degeneration due to fibrosis with retraction and calcification. In primary repairs with a usage of treated autologous pericardium reoperation shows 2 main mechanisms of failure: restrictive motion leading to late reoperation and excessive motion leading to early reoperation. Though experience and reports in the literature have accumulated, the debate on the optimal material is still ongoing, especially given the disparity of data (children and adults mixed), the small number of pediatric patients and the new materials.

**Outcomes of the aortic valve neocuspidization-Ozaki technique in children**

AV reconstruction was first reported by Dr. Duran, et al. His procedure attempted to reproduce tailored valves as much as possible [33]. They used three consecutive bulges of different sizes as templates to
guide the shaping of the pericardium, which was made according to the dimensions of the aortic annulus. The pericardial leaflets were sutured to the AV remnant or to the annulus. Duran shared the experience of 51 patients who underwent Duran procedure with the survival rate of 84.53% at the follow-up of 60 months, and 72.59% of the patients was free from any event after the operation. He concluded that early outcomes encouraged us to reconstruct the AV by using autologous pericardium.

Aortic Valve Neocuspidization (AVNeo) was developed by Ozaki nearly a decade ago [34]. The Ozaki procedure consists of using glutaraldehyde-treated autologous pericardium to replace aortic valve leaflets but improves significantly in measuring the diseased valve and using templates to cut fixed pericardium compared with the Duran procedure. The suture line forces are distributed over a much a larger area, and the new leaflets have a large area of coaptation, further relieving stress on the repair. As no foreign material is required, postoperative anticoagulation is unnecessary, and the AVNeo was thus considered as valve repair rather than replacement [32]. AVNeo has become more widely adopted with the advent of leaflet templates, thereby making the technique more standardized and reproducible. AVNeo achieved excellent result in large series of patients, but pediatric cases accounted a small proportion and further follow-up is needed particularly in the pediatric population. In this setting, The Boston Children’s Hospital experience with AVNeo began in 2014. Regarding a report of their experience, 57 patients with a median age of 12.4 years underwent Ozaki procedure [35]. Twenty-four patients had AR, 6 had AS, and 27 patients had mixed disease. Four patients had truncus arteriosus. Thirty-four patients had prior AV repairs and 5 had replacements. Autologous, Photofix®, and CardioCel® bovine pericardium were used in 20, 35, and 2 patients. Eight patients underwent aortic root enlargements and 20 had non-coronary sinus enlargements. There were no hospital mortalities or early conversions to valve replacement. There were no differences in outcomes based on operative indication. At median follow-up of 8.1 months, 96% and 91% of patients had less than moderate regurgitation and stenosis, respectively [35].

In 2015, Mazzitelli, et al. reported their experience with 3 pediatric AVNeo procedures in patients 5, 11, and 15 years of age. Tissue-engineered bovine pericardium (Cardiocel®) was used to create cusps and there were no reoperations at early follow-up [36].

In addition, a more uniform repair technique amenable to a variety of anatomic situations may simplify our approach and achieve consistent results. One persistent weakness is the use of devitalized pericardium that will predictably degenerate in children. Perhaps non-bioprosthetic material may be considered such as 0.1 mm polytetrafluoroethylene. While it will not grow, it is not subject to degeneration or neointimal in growth and could prove to be more durable.

Congenital aortic valve diseases associated aneurysm of the proximal aorta and aortic sinuses: The supplement for guideline treatment

Aortic root aneurysms are rare in children that are usually associated with connective tissue diseases or conotruncal congenital heart anomalies. The traditional surgical approach for these pathologies has been to replace the aortic root with concomitant AV using a valve-and-graft composite, the so-called Bentall procedure. Despite the yielded low mortality and low morbidity at follow-up, AVR with mechanical valve mandates lifelong anticoagulation or potential need for reoperation because of degeneration of placed bioprosthetic valve. Thus, Valve-Sparing Root Replacement (VSRR) has evolved over the past few decades to improve the quality of life for patients requiring these procedures through the pioneering work surgeons such as David and colleagues [37], David and Feindel, et al. [38], and Sarsam and Yacoub, et al. [39]. VSRRs is an appealing surgical approach in children with aortic root aneurysms because it allows for avoidance of the problems associated with long-term anticoagulation, carries a low risk of thromboembolism or endocarditis, and has shown promising intermediate-term outcomes. Given the absence of predictors of dissection or rupture in paediatric patients presenting with aortic root aneurysms [40], absolute indications for intervention in children remain elusive. Nevertheless, VSRR is undertaken to mollify further dilatation and hamper potentially fatal complication as rupture. Recently, Fraser et al reported an experience that highlighted a freedom from reoperation of 100%, 88.5% and 70.4% at 1, 5 and 10 years, respectively, after the 100 consecutive valve-sparing root replacement in children with a median age of 13.6 years [41]. Their data also attested to the durability of the reimplantation technique that is superior when compared with remodeling technique by stabilizing the aortic root, improving hemostasis. Moreover, of the 84 patients undergoing a reimplantation procedure, 4 (4.8%) underwent late AVR versus 5 (31.3%) of the 16 patients who underwent a remodeling procedure (p=0.001) [41].

Institutional experience and patient selection are known as crucial factors and relate to outcomes after VSRR, particularly in children. Accordingly, the Johns Hopkins Hospital elaborated the well-known guidelines for aortic root replacement that are driven on the basis of the presence of connective tissue disorders and the disease subtype or severity of disease taking into account of multiple risk factors [41] (Table 2). It should be noted that there have been instituted several contraindications for VSRR in children with connective tissue disorders as significant leaflet fenestration and asymmetry, acute aortic dissection in unstable patients, bicuspid aortic valve (BAV) with extensive calcification, severe prolapse, marked fenestrations.

### Table 2: Current guidelines for aortic root replacement at the Johns Hopkins Hospital.

| Diagnosis                              | Indications for VSRR in Children                      |
|----------------------------------------|-------------------------------------------------------|
| Marfan Syndrome                       | Maximum diameter>5.0 cm or increase of>0.5 cm/y      |
|                                       | Diameter of 4.5-5.0 cm if:                           |
|                                       | Family history of rupture                             |
|                                       | Aortic valve regurgitation                           |
|                                       | Need for mitral valve repair and aortic root         |
| LDS                                   | Diameter of 4.0-5.0 cm                               |
| LDS Types I and II                    | Severe craniofacial features                         |
| LDL Type III                          | Increase in diameter of>0.5 cm/y                     |
| LDL Type IV                           | Increase in diameter of>0.5 cm/y                     |
| Bicuspid Aortic Valve                 | Maximal diameter=5.5 cm                              |
| Non-Syndromic Thoracic Aortic Aneurysm| Maximal diameter=5.5 cm                              |

**Abbreviations**: VSRR: Valve-sparing root replacement; LDS: Loeys-Dietz syndrome.
Bicuspid aortic valve associated aortopathy: A complication with high incidence need to pay more consideration

BAV is the most common congenital cardiac malformation and is present in 1% to 2% of the general population [42]. Dilation of the aorta is a frequent complication in patients with BAV and the aorta in this population grows more rapidly compared to the normal population [43]. Although the majority of young patients with BAV have mild dilation, the rare patient can have progressive dilation and is prone to risk for morbidity and premature death [44].

Ruzmetov, et al. demonstrated that the R/N fusion of BAV was strongly associated with ascending aorta dilation [45], whereas patients with R/L subtype were more likely to have aortic root dilation as measured by change in Z-score over time. In addition, patients with R/N fusion presented at a younger age and were more likely to have AS. The latter data is consistent with a report of Fernandes and his colleagues [46]. Revealing the association aortic dilation with BAV, Schaefer and associates proposed an integrated classification system based on both leaflet fusion and aortic root shape [47]. The authors found that patients with R/L leaflet fusion most commonly presented with type “N” (normal shape), whereas those with R/N leaflet fusion were more likely to have a type “A” (ascending dilation) or type “E” (effaced root) root anatomy. The latter finding also was found in in a series of Children’s Hospital of Illinois [45].

Some studies found that moderate or greater AR was associated with higher aortic root and ascending aortic diameter Z-scores in children with BAV [48,49]. Nonetheless, it is unclear whether dilation entails regurgitation, regurgitation begets dilation, or both. Some authors have considered haemodynamic causes that could account for the AR contributing to aortic dilation such as increased wall stress due to increased stroke volume from AR [48]. Other authors have suggested that aortic dilation likely precedes AR with the progression of aortic dilation causing poor coaptation of the aortic valve leaflets that leads to AR [50].

Despite considerable controversy, some believe that the vascular complications of BAV are not secondary to valvular dysfunction and can manifest in young adults without significant AS or regurgitation [51,52]. Nistri and colleagues determined that more than 50% of young patients with normally functioning BAVs have echocardiographic evidence of aortic dilation [51], whereas in a series of Children’s Hospital of Illinois [45], 33% of young patients with BAV have evidence of dilation (z score >3).

Conclusion

Commissurotomy with thinning appeared to be approved as regards AS underlining its durability and real-world applicability. Allowing the patient to grow to an age when more definitive solutions are available, surgical AVRep strategy should be individualized to the age of the patient. AVRep can achieve intermediate and long-term results without affecting LV function that may be a reasonable primary choice in comparison with AVR in children, especially if the alternative is prosthetic valve replacement that requires extensive annular enlargement. Ultimately, AVRep should reduce the use of replacement procedures in the growing child. Future work in this area should be directed to developing more consistent techniques and better materials that will result in more durable repairs. In children, for whom the surgical options including AVRep numerous techniques may be limited, AVNeo can be considered as an alternative method for application. Some studies suggest that BAV morphology may be associated with patterns of aortic dilation and valve dysfunction. Recognition of these differences may eventually be helpful for echocardiographic surveillance and potential medical intervention.

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