Original Article

A midterm follow-up study of the application of a confluent aortic valve neocuspidization technique with pericardium in children

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Background: The treatment of aortic valve diseases in children remains a great challenge. We aim to report outcomes and midterm follow-up data of our confluent neocuspidization technique with pericardium for aortic valve replacement (AVR) in children.

Methods: A retrospective analysis was performed on all 20 children who underwent the confluent neocuspidization technique with pericardium at Children's Hospital of Fudan University from March 2017 to May 2022. Outcome measures included echocardiographic measurements, surgical intervention, and mortality.

Results: A total of 20 patients (17 males *vs.* 3 females), with a median age of 7.5 years [min–max, 0.3–12 years; interquartile range (IQR), 4.4–9.7 years], a median body weight of 24.0 kg (min–max, 6.0–52.3 kg; IQR, 15.6–31.0 kg), and median aortic valve annulus size before surgery of 19.0 mm (min–max, 11.0–25.0 mm; IQR, 17.1–21.5 mm), underwent the neocuspidization technique with pericardium (17 autologous pericardia and 3 bovine patch). With 50% of bicuspid aortic valve and 50% of tricuspid, they were respectively diagnosed as aortic stenosis (AS) (7/20, 35%), aortic regurgitation (AR) (8/20, 40%) and mixed AS and AR (AS & AR) (5/20, 25%). The median postoperative follow-up time was 19 months (min–max, 5–61 months; IQR, 16.3–35 months). The peak pressure gradient across the aortic valve decreased from 81.0±37.0 mmHg in AS group and AS & AR group before surgery to 25.9±15.8 mmHg within 24 hours after surgery ($P<0.001$) and was mostly around 25 mmHg during follow-up. All patients presented mild or less than mild regurgitation within 24 hours after surgery. There were no hospital mortalities. Three patients needed reintervention during follow-up. There was one late death related to mitral valve stenosis.

Conclusions: Though the confluent neocuspidization technique with pericardium provided immediate relief of significant AS or regurgitation, the midterm outcome was suboptimal. More research is needed to find the optimal material for AVR.

Keywords: Aortic valve replacement (AVR); neocuspidization technique; pericardium; the Ozaki technique; children

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Introduction

Surgical treatment of aortic valve diseases in children remains a great challenge considering the high reoperation rate. Aortic valve repair is first considered to treat aortic valve diseases with an improved understanding of aortic valve anatomy and mechanisms causing aortic valve dysfunction in recent years (1). However, for complex aortic valve disease which routine aortic valve repair usually fails to deal with (2), aortic valve replacement (AVR) is supposed to be unavoidable. AVR still has many limitations in children such as rapid deterioration (3,4) in bioprosthetic valves, high risk of anticoagulation-related complications (5,6) in mechanical valves as well as size mismatch in young patients with small annuluses (7). The Ross procedure is a good option for young children but it is not widely applied in developing countries due to relatively high mortality, lack of valved conduit, and risk of impacting both semilunar valves (8,9). Partial heart transplantation contributes a new approach to solve the problem, allowing annular growth, but the risks from immunosuppression remain concern (10). Therefore, with better hemodynamic performance and lack of immunogenicity, AVR with pericardium has the potential to be another choice for AVR.

AVR with the pericardium, especially the Ozaki technique, has been increasingly utilized in adults with aortic valve diseases, obtaining good outcomes in the midterm follow-up (11), but utilization of AVR with pericardium in children is rarely reported (12). As templates of the Ozaki technique are not available to us, since 2017, we have developed a confluent neocuspidization technique with pericardium to replace aortic valves in 20 children. The study aims to introduce our procedures of confluent neocuspidization technique and report outcomes of these patients with a follow-up period of up to 61 months postoperatively. We present this article in accordance with the STROBE reporting checklist (available at https://tp.amegroups.com/article/view/10.21037/tp-23-289/rc).

Highlight box

Key findings

- The confluent aortic valve neocuspidization technique has good post-operative hemodynamic performance, but the midterm follow-up results are suboptimal.

What is known and what is new?

- Surgical treatment of aortic valve diseases in children remains a great challenge considering the high reoperation rate. Aortic valve replacement with the pericardium, especially the Ozaki technique, has been increasingly utilized in adults with aortic valve diseases, but the report about children is rare.
- We developed a confluent neocuspidization technique with the pericardium to replace aortic valves in 20 children. Though the technique provided immediate relief of significant aortic stenosis or regurgitation, the midterm follow-up results were suboptimal.

What is the implication, and what should change now?

- For those children who are not available to the Ross procedure, our technique might provide a palliative chance to delay the transplantation of mechanical valves.

Methods

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of the Children's Hospital of Fudan University [No. 2017(258)] and informed consent was obtained from participants' legal guardians. The study was registered at ClinicalTrials.gov (NCT04152967).

Subjects and data collection

We retrospectively reviewed the clinical data as well as postoperative follow-up results of patients who received the confluent neocuspidization technique from March 2017 to May 2022 in our institution. Death or reintervention of any reason was defined as the endpoint of the observation.

Baseline information and perioperative information of patients were collected from medical records in our institution retrospectively. Echocardiographic evaluation was performed immediately after surgery (within 24 hours) and at 1 month, 3 months, 6 months, 12 months, and every year after surgery during the postoperative clinic visits.

Leaflet design

Assuming the measured diameter of annulus of the aortic valve is D, here we designed our leaflet using these equations derived from series of computational fluid dynamics (CFD) experiments and clinical studies of valved conduit (13-15) (*Figure 1*).

F: length of free margin; $F=1.1*\pi D/3\approx 1.15D$

H: leaflet height; $H=0.8D$

h1: commissural height; $h1=0.2D$

h2: annular margin line radius; $h2=F/2\approx 0.6D$

h3: height of free margin; $h3=0.15D$

Surgical procedures

After successful anesthesia of the patient, routine midline sternotomy was applied. Then the thymus was exposed and then excised if necessary. A large piece of pericardium with an adequate area was harvested, and treated with 0.6% glutaraldehyde solution with a buffer for 10 minutes

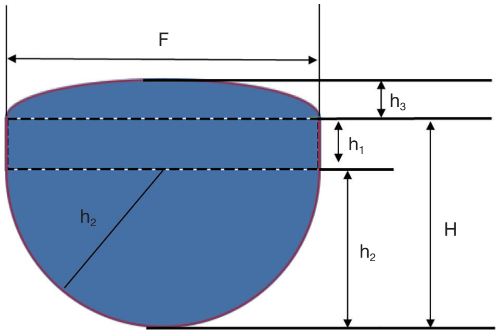

Figure 1 Leaflet design. F: length of free margin; F=1.1*πD/3≈1.15D; H: leaflet height; H=0.8D; h1: commissural height; h1=0.2D; h2: annular margin line radius; h2=F/2≈0.6D; h3: height of free margin; h3=0.15D.

followed by three times of rinsing with normal saline solution as preparation for use (*Figure 2A*) (16). The pericardium was fixed without tension. The space between the aorta and pulmonary artery was dissected. A double purse-string suture was placed on the distal ascending aorta, and a single purse-string suture on the superior vena cava and inferior vena cava respectively. Extracorporeal circulation was then initiated after cannulation on the aorta, superior vena cava, and inferior vena cava. The vent of the left heart was carried out through the right upper pulmonary vein. Cardioplegia of HTK (Histidine Tryptophan Ketoglutarate solution from German CUSTODIOL, produced by Dr. Franz Köhler Chemie Gmbh) or of del Nido formula (from Pedro Del Nido, University of Pittsburgh) was administered through the aortic root. In patients with severe aortic insufficiency, cardioplegia was given directly through the coronary ostia after the ascending aorta is incised.

An incision was made on the aorta above the level of the sinotubular junction. Stay stitches were placed for exposure. After careful exploration, the unrepairable native aortic valve was then excised. The size of the annulus was measured (*Figure 2B*) (16). Then a self-designed template with a corresponding size to the annulus was selected to draw the shape of new valve cusps on the treated pericardium together with some important marking points, the midpoint of a suturing margin and the free margin (*Figure 2C*) (16). Subsequently, three confluent equal-size "U"-shape leaflets with two wing-like structures on both commissural margins were trimmed from the treated pericardium (*Figure 2D*) (16). After marking the suture spots on the aortic wall with a self-designed tool (*Figure 2E*) (16), we curved the shaped pericardium (*Figure 2F*) (16), created three neo-commissures with stitches from inside to outside of the aortic wall (*Figure 2G*) (16), and sutured the annular margin of the shaped pericardium as a new aortic valve by using continuous running suture from the midpoint towards both sides (*Figure 2H*) (16). When we finished the suturing of new aortic valve, we would check its competency. An additional stitch was needed for commissuroplasty in case of incompetency (*Figure 2I*) (16). We preferred to start from the left coronary cusp, then the right coronary cusp and noncoronary cusp. When we created the left-non coronary commissure, which is the closing commissure of the valve, one wing-like structure was placed to overlap the other. All commissures were supported by external pledgets. 5-0 prolene stitch was used in most of the patients, 6-0 prolene stitch in patients with small aortic roots. We put the smooth surface of the pericardium towards the ventricle and the rough surface of the pericardium towards the aortic wall.

Peri-operative management

Cefazolin (50 mg/kg, q12h) was administered intravenously before surgery and continued for 3 days after surgery. After surgery, the patients were transferred to cardiac intense care unit (CICU) where vital signs and echocardiogram (ECG) were continuously monitored. Routine treatments including cardiotonic, diuretics and mechanical ventilation were given. Six hours after the surgery heparin was given (5–15 u/kg/h) intravenously for 2–3 days, which was followed by warfarin to keep the international normalized ratio (INR) between 1.5 to 2.5 during the subsequent 6 months. Oral aspirin was prescribed for at least 2 years postoperatively.

Statistical analysis

Data were presented as median [min–max; interquartile range (IQR) 25th–75th] or mean (SD) for continuous variables, and numbers (%) for categorical variables. All data were analyzed and graphed with the software GraphPad Prism 9. The difference analysis was performed on the software SPSS Statistics. Paired-sample T-test was used to compare the difference between the peak pressure gradient before surgery and within 24 hours after surgery, and the difference between the diameter of the annulus before surgery and the last visit. Paired-sample Wilcoxon rank sum test was used to compare the difference between regurgitation before and after surgery. Relationships between continuous variables were assessed using the

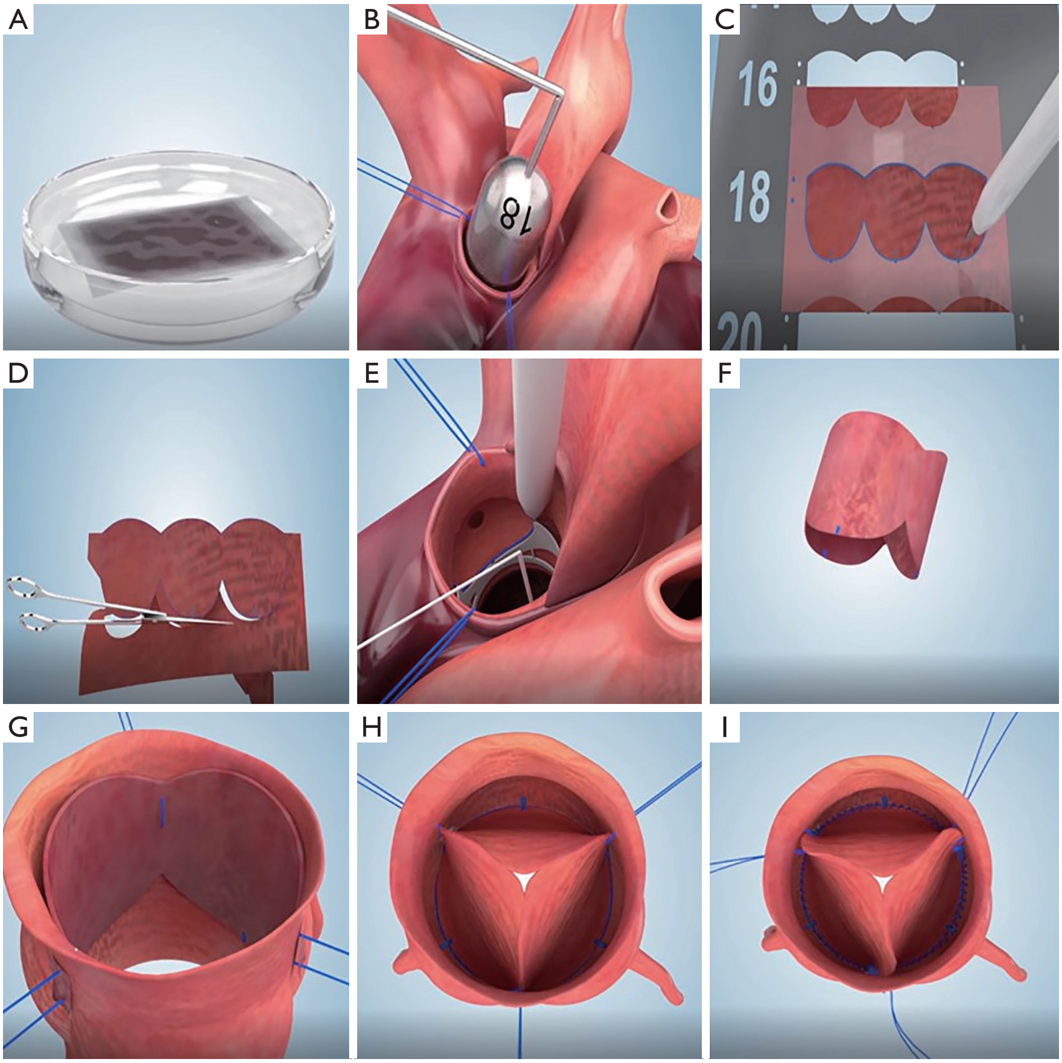

Figure 2 Procedures of our technique. Reprinted/adapted with permission from ref (16). The Society of Thoracic Surgeons. (A) Autologous pericardium treated with glutaraldehyde (10 min). (B) Detect the size of the aortic root. (C) Draw the shape with the self-designed template. (D) Tailor the neo-aortic valve with treated pericardium. (E) Position the suture sites on the aortic wall with a self-designed template. (F) Circle the shaped pericardium. (G) Create three neocommissures with stiches from inside to outside of the aortic wall. (H) Suture from the lowest to both sides to create the neo-aortic valve. (I) Commissuroplasty was performed when needed.

Pearson correlation test. The level of statistical significance was set at $P<0.05$.

Results

Demographic results

As shown in *Table 1*, there were 17 males and 3 females. Their median age was 7.5 years (min–max, 0.3–12.0 years; IQR, 4.4–9.7 years) and the median body weight was 24.0 kg (min–max 6.0–52.3 kg; IQR, 15.6–31.0 kg) at the surgery. The median size of aortic valve annulus was 19.0 mm (min–max, 11.0–25.0 mm; IQR, 17.1–21.5 mm) before surgery. Indications for surgery were aortic stenosis (AS) (7/20, 35%), aortic regurgitation (AR) (8/20, 40%), and mixed AS and AR (AS & AR) (5/20, 25%). Ten patients (50%) were diagnosed with bicuspid aortic valve and another ten (50%) were diagnosed with tricuspid aortic valve. Eight children had previous surgery including repair of coarctation of aorta (3/20, 15%), aortic valve repair (4/20,

Table 1 Baseline patient characteristics (n=20)

Variable	Value
Male	17 (85%)
Median age (year)	7.5 [4.4–9.7]
Median weight (kg)	24 [15.6–31]
Median aortic valve annulus size (mm)	19 [17.1–21.5]
Pericardium	
Autologous	17 (85%)
Bovine	3 (15%)
Surgery indication	
AS	7 (35%)
AR	8 (40%)
Mixed AS and AR (AS & AR)	5 (25%)
Median peak Doppler gradient across the aortic valve (mmHg)	
AS	92 [87–107]
Mixed AS and AR (AS & AR)	48 [35.0–73.8]
Grade of AR	
Severe	10 (77%)
Moderate	3 (23%)
Morphology of the aortic valve	
Tricuspid	10 (50%)
Bicuspid	10 (50%)
Prior surgery	
Yes	8 (40%)
CoA repair	3 (15%)
Aortic valve repair	4 (20%)
CoA repair and aortic valve repair	1 (5%)
Concomitant diseases	
Endocarditis	1 (5%)
Mitral stenosis	1 (5%)
Mitral insufficiency	1 (5%)
Tricuspid regurgitation	1 (5%)
Coronary artery fistula	1 (5%)

Data are expressed as median [IQR] or case (percentage). AS, aortic valve stenosis; AR, aortic valve regurgitation; CoA, coarctation of the aorta; IQR, interquartile range.

20%), and repair of both coarctation of the aorta and aortic valve (1/20, 5%). Five patients had concomitant diseases including endocarditis (1/20, 5%), mitral stenosis (1/20, 5%), mitral insufficiency (1/20, 5%), tricuspid regurgitation (1/20, 5%) and coronary artery fistula (1/20, 5%).

Perioperative results

All patients received the confluent neocuspidization technique under cardiopulmonary bypass. Seventeen patients had a neo-aortic valve with autologous pericardium and 3 patients with bovine pericardium. The median aortic cross-clamping time was 99 minutes (min–max, 78–212 minutes; IQR, 90–111.3 minutes). There was no hospital mortality. The median postoperative mechanical ventilation time was 1 day (min–max, 1–11 days; IQR, 1–2.7 days) and the median ICU stay time was 3 days (min–max, 1–15 days; IQR, 2–4.7 days). Echocardiography was performed within 24 hours after surgery. Results demonstrated that leaflets of the neo-aortic valve coaptated tightly and the coaptation zone was large enough to block blood flow from regurgitation in diastolic phase. Leaflets opened completely and no stiffness was observed in the systolic phase (*Figure 3*). The peak pressure gradient across the aortic valve by echocardiography was 81.0±37.0 mmHg in AS group and AS & AR group before surgery, and decreased to 25.9±15.8 mmHg immediately after surgery (P<0.001) (*Figure 4A*). Degree of regurgitation decreased significantly after surgery in AR group and AS & AR group (P=0.001) (*Figure 4B*).

A significant inverse correlation between AV peak pressure gradient (PPG) within 24 hours after surgery and the z-score of the preoperative size of the aortic annulus (P=0.008, R^2=0.49) was demonstrated (*Figure 5*). The five patients with a relatively lower Z-score of annulus presented relatively high pressure gradient (>25 mmHg) after surgery.

Follow up results of AS and AR

The median follow-up time was 19 months (min–max, 5–61 months; IQR, 16.3–35 months). PPG of patients was mostly around 25 mmHg during follow-up (*Figure 6*). Most patients remained mild or lower than mild AR (*Figure 7*). Additionally, there were three more cases presenting moderate or moderate to severe regurgitation but needing no reintervention. The median left ventricle ejection fraction maintained normal during the follow-up. The median diameter of the annulus of the last follow-up was 18.6±3.6 mm, which increased by 1.6 mm (95% CI:

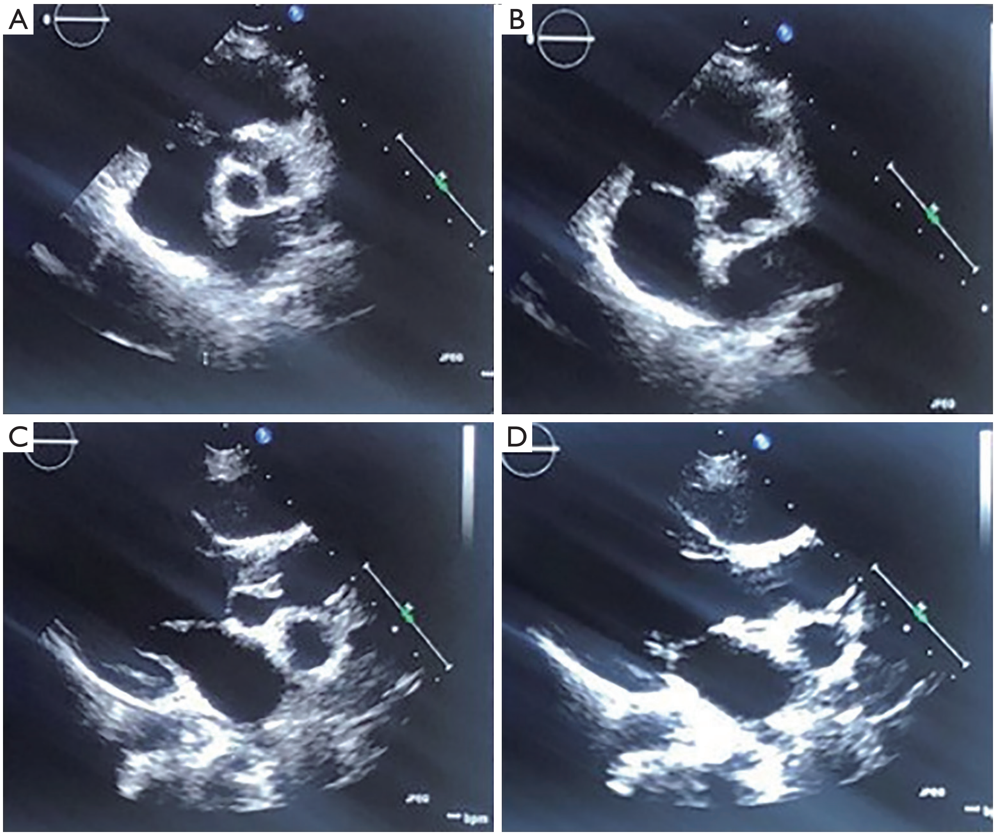

Figure 3 Echocardiography of neo-aortic valve after surgery. (A and C) display adequate leaflet coaptation in the diastolic phase from PLAX and PSAX respectively. (B and D) display the opening of the neo-aortic valve from PLAX and PLAX respectively. Echocardiography demonstrated that in diastolic phase leaflets of neo-aortic valve coaptated tightly and coaptation zoom is large enough to block blood flow from regurgitation. In systolic phase, leaflets open completely and no stiffness is observed. PLAX, parasternal long-axis view; PSAX, parasternal short-axis view.

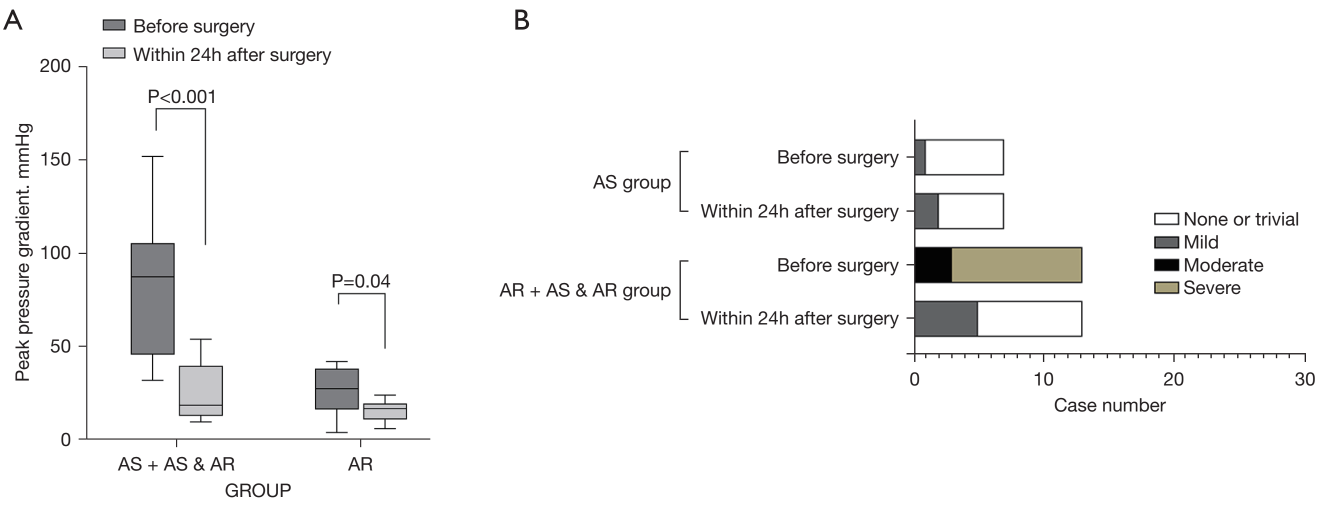

Figure 4 Perioperative results of peak pressure gradient (A) and regurgitation grade (B). AS, aortic valve stenosis; AR, aortic valve regurgitation; AS & AR, mixed aortic stenosis and aortic regurgitation.

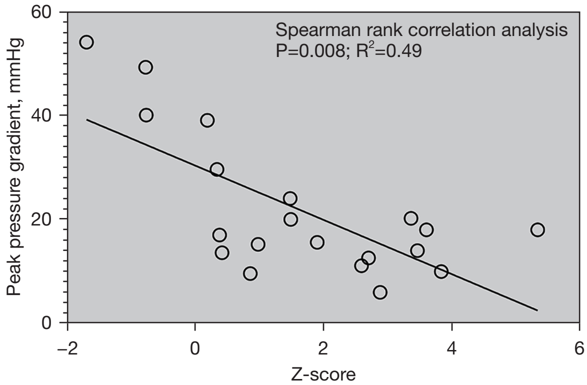

Figure 5 A significant inverse correlation between aortic valve peak pressure gradient within 24 hours after surgery and z-score of preoperative size of aortic annulus (P=0.008, R^2=0.49).

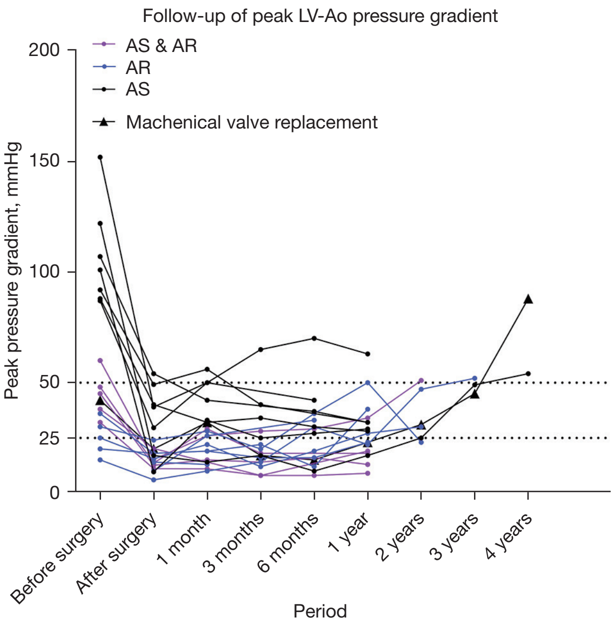

Figure 6 Trajectory of every patient's peak pressure gradient during follow-up. AS, aortic valve stenosis; AR, aortic valve regurgitation; AS & AR, mixed aortic stenosis and aortic regurgitation.

0.39–2.8) comparing the annulus before surgery (P=0.008).

Follow up result of reintervention and mortality

There was one late death related to mitral valve stenosis. No aortic valve-related death was observed. Three patients needed reintervention during follow-up. One patient

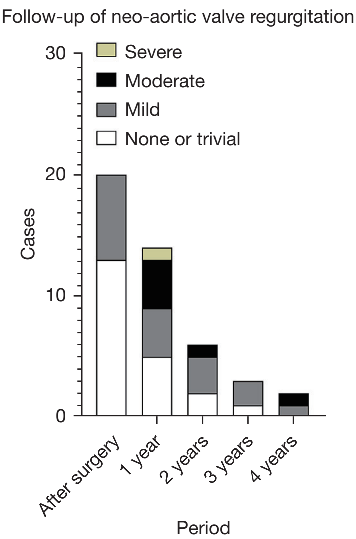

Figure 7 Follow up of neo-aortic valve regurgitation after surgery.

presented severe neo-aortic valve regurgitation at the 1-year follow-up, and echocardiography showed that there was leakage at the bottom of the left coronary sinus due to the loosened stitches. The patient then underwent reoperation to patch and repair the left coronary cusp. The second patient presented moderate to severe AR with severe AS at the 4-year follow-up needing mechanical AVR. The third patient received the Ozaki technique, pulmonary valve replacement, and tricuspid valvuloplasty due to aortic valve stenosis, pulmonary valve stenosis and severe tricuspid valve insufficiency.

Outcomes of the infant

There was only one infant included in the study. The patient underwent with AS and AR, bicuspid AV, and MR. He was performed the neocuspidization technique and mitral valve repair. Immediately after the surgery, the peak pressure gradient decreased from 60 to 15 mmHg, and the degree of regurgitation decreased from moderate to mild. After 36 months follow-up, the neo-aortic valve presented a peak pressure gradient of 51 mmHg and mild to moderate regurgitation. The annular size increased from 9 to 11 mm.

Discussion

We performed this confluent equal-size neocuspidization technique with pericardium for AVR on 20 children. This

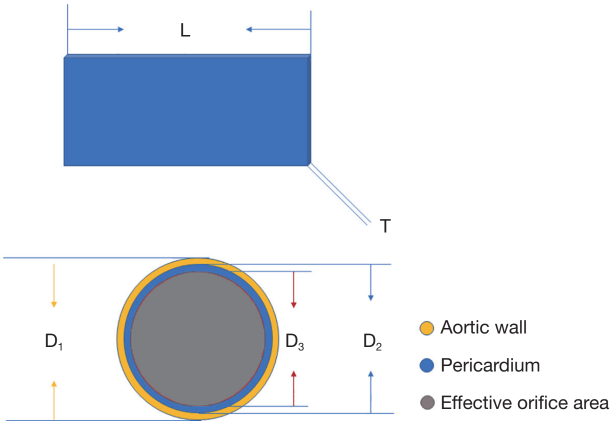

Figure 8 Area portion of aortic root with structures including aortic wall, pericardium and EOA. L, length of pericardium; T, thickness of pericardium; D1, diameter of outer aortic wall; D2, diameter of inner aortic wall; D3, diameter of EOA; SAO, area of the aortic lumen; ST, area of thickness of pericardium; EOA, effective orifice area; eEOA, efficiency of EOA. Deduce of eEOA: eEOA = EOA/SAO = (SAO − ST)/SAO =1 − ST/SAO = 1 −LT/π(D2/2)2 = 1 − πD2T/π (D2/2)2 = 1 − 4T/D2.

study revealed promising results including improvement of hemodynamic performance and acceptable re-intervention rate. The aortic annulus was able to grow significantly with increasing age.

Due to its feasibility, AVR with pericardium has been increasingly applied to aortic valve diseases and has achieved good results in the midterm follow-up (17-20). Ozaki *et al.* performed their technique of AVR (AVneo technique) on 850 adult patients and reported an overall reoperation-free survival of 96.2% at 53 months after surgery (17). Koechlin *et al.* reported a mortality rate of 9% and a reoperation rate of 3% at 645 days after surgery (21). Reuthebuch *et al.* also reported a good result of a 3-month follow-up in 28 patients (22). However, this technique in children is rarely reported. The recent reports in children had limited cases and short follow-up time. Baird *et al.* reported 57 cases with a mean follow-up time of 11.6 months (23). Polito *et al.* reported 22 cases with median follow-up time of 11.3 months (24). Our outcome in 20 children with a longer median follow-up time of 19 months increased knowledge of durability of this technique.

We observed several patients remaining relatively high PPG during the follow-up, most of whom had small annulus size before surgery. Our research revealed a significant inverse correlation between residual peak pressure gradient within 24 hours after surgery and the z-score of the preoperative size of the aortic annulus (P=0.008) (*Figure 5B*). The efficiency of effective orifice area (EOA) theory might explain it well. As shown in *Figure 8*, the efficiency of EOA is positively related to the diameter of the annulus. Polito *et al.* also reported an inverse linear correlation between AV peak gradient at follow-up and preoperative aortic annular size (24,25). Baird *et al.* and Polito *et al.* both agreed to perform annulus enlargement on patients whose annular Z scores <2 or annulus diameter <15 mm, resulting in relatively low PPG (23-25). Marathe *et al.* reported a modified Ozaki procedure to enlarge the annulus in children with annulus diameter smaller than 21 mm (median 17; range, 9.2–20.9 mm) (26). At mean follow-up of 11.9 months, 80% of patients had less than moderate AS and all patients had the annulus Z-score greater than 0. Thus, annulus enlargement should be taken into consideration in patients with small annulus before surgery.

We found that our technique had good results of anti-regurgitation, which may be thanks to leaflet design with higher coaptation points. Baird *et al.* observed a decreased leaflet coaptation height at late follow-up, possibly resulting from the grown annulus, which might be one of the reasons for late aggressive regurgitation (27). Our results also revealed that the diameter of the annulus was able to grow. For this reason, our leaflet is designed to have a longer coaptation length for better anti-regurgitation at the beginning, which surprisingly turns out to compensate for physiologic growth of the valve annulus, similar to the Ozaki technique (28). Gasparyan also reported a leaflet design with a pyramid-shape free margin to raise up coaptation point (29). We can reasonably believe that the design of a little higher coaptation point is very important for long-term anti-regurgitation in the pediatric population.

In our practice, we trimmed the leaflets in equal-size. Our design was based on our successful previous studies about valved conduit for ROVT reconstruction and optimization of the design of leaflets by CFD (13,14,30). Theoretically, different-size leaflets are more possible to present eccentric flow, which increases the stress and strain of leaflets, making leaflets more susceptible to deterioration. Ozaki and associates changed from different-size leaflet to equal-size leaflets since 2012 as they found equal-size leaflets had better movement by postoperative echocardiography (17). Baird *et al.* preferred equal-size leaflets in children due to advantages including less possibility of obstructing coronary flow by placing the coronary ostium in the middle of the sinus, and allowance for more uniform leaflet coaptation (27). Thus we recommended equal-size leaflets to perform the Ozaki technique.

Additionally, the design of confluent leaflets makes commissuroplasty easier. We have a concern that when three single leaflets are sutured to the aortic wall respectively, they may not be at the same level, resulting in decreased coaptation area. Confluent cusps can rid us of this problem, especially for unexperienced doctors. In addition, confluent cusps can decrease the number of stitches at commissure. Gasparyan also reported that his confluent leaflets made the surgery more reproducible (29). Therefore, we believe that the learning curve of our technique was easier. However, the design of confluent leaflets raises a concern that the difference between the left-non coronary commissure and the other two commissures may impair hemodynamic performance. Although we have no direct evidence about the influence of the difference, the Echo results immediately after the surgery indicated satisfactory hemodynamic performance. A routine cardiovascular magnetic resonance examination might be needed to evaluate cardiodynamics of the neo aortic valve in our futural research.

As to how to decide parameters such as free-margin length and leaflet height of a single leaflet, we gained our equations mainly from the clinical experience of valved conduit for ROVT reconstruction and *in vitro* experiments. In our equations, the free-margin length is equal to 1.15D, which is quite close to an equation (L=1.1D, D=diameter of STJ) from Hammer *et al.*, who completed an excellent deduce based on valve geometry (31). However, the semicircle leaflet designed by Dr. Peter was used in adults, which lacked concerns about the growth potential of the annulus in children. Dr. Ozaki did not present their equations in their articles, but he also designed a higher coaptation point for anti-regurgitation, which turned out to compensate for a grown annulus.

Indeed, there has not been a perfect material for neo-AVR up to now. In our cohort, we used both autologous and bovine pericardium to replace the aortic valve. It is believed that autologous pericardium may have better durability due to its lack of immunogenicity. Duran *et al.* and colleagues reported a higher freedom from reoperation in patients with glutaraldehyde-treated autologous pericardia (76.2%) compared to those with bovine ones (69.6%) (32). Some anti-calcification treated pericardia such as Photofix pericardium and CardioCel bovine pericardium are not better than autologous pericardium, which was reported by Baird *et al.* and Jiang *et al.* (27,33). Thus, from our perspective, the autologous pericardium is preferred, while other anti-calcification treated pericardia are considered when the autologous pericardium is unavailable.

Although the result of our new neocuspidization technique with pericardium for pediatric aortic valve diseases is acceptable, it may be not convincing enough due to limited cases and follow-up time. Further investigation in a larger group with longer follow-up is needed.

Conclusions

Though the confluent neocuspidization technique with pericardium provided immediate relief of significant AS or regurgitation, the midterm outcome was suboptimal. More research is needed to find the optimal material for AVR.

Acknowledgments

Our abstract has been accepted for presentation at 101st Annual Meeting of AATS-Seattle, WA/Virtual Event, March 24th, 2021.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tp.amegroups.com/article/view/10.21037/tp-23-289/rc

Data Sharing Statement: Available at https://tp.amegroups.com/article/view/10.21037/tp-23-289/dss

Peer Review File: Available at https://tp.amegroups.com/article/view/10.21037/tp-23-289/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tp.amegroups.com/article/view/10.21037/tp-23-289/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of the Children's Hospital of Fudan University [No. 2017(258)] and informed consent was obtained from participants' legal guardians.

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