Pulmonary Valve Replacement with Bioprosthetic Valve: Current Technique and Early Results

Kantathut N, MD1, Cherntanomwong P, MD1, Leelayana P, MD1, Samarnkatiwat P, MD1, Khajarern S, MD1

 $^1Division of Thoracic and Cardiovas cular Surgery, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University Bangkok, Thailand \\$

Background: Pulmonary valve replacement has proven benefits in patients with congenital heart disease. Although the choice of replacement valve remains controversial, bioprosthetic valve has an excellent short-term and mid-term durability, no limit in availability and readily to use, and no requirement for anticoagulation.

Objective: The present study aimed to describe our surgical technique for pulmonary valve replacement with bioprosthetic valve and to report early clinical outcomes.

Materials and Methods: All patients from January 2016 to July 2018: 11 patients underwent pulmonary valve replacement with bioprosthetic valve for congenital heart disease and were retrospectively reviewed. Pre-operative and postoperative data were compared.

Results: Mean age was 30.91 ± 12.29 years. Ten (90.91%) patient had prior cardiac surgery. All patients were classified in NYHA class II (90.91%) and III (9.09%). Mean follow-up period was 9.34 ± 4.78 months. Mean ICU stays and hospital stays were 1.63 ± 0.50 and 6.54 ± 4.01 days, respectively. No complications or mortality occurred. All patients' NYHA classifications were improved to class I (100%). Pre-operative LVEF and postoperative % LVEF were similar 59 ± 9.41 vs. 60.36 ± 9.42 (p=0.358). There was no significant difference in pre-operative and postoperative QRS duration 149 ± 27.07 vs. 146.36 ± 28.27 ms, (p=0.616).

Conclusion: Pulmonary valve replacement with bioprosthetic valve with our current surgical technique is simple, safe, reproducible, and has excellent clinical outcomes.

Keywords: Pulmonary valve replacement, Congenital heart disease, Bioprosthetic valve

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Advanced surgical treatment for congenital heart disease has led to an increasing number of patients' surviving through childhood and adolescence. Pulmonary insufficiency and pulmonary stenosis are a common long-term complication of surgical treatment involving reconstruction of the right ventricular outflow tract⁽¹⁾. Pulmonary valve replacement has provided an improvement of right and left ventricular function as well as a reduction in symptoms in previous reports^(2,3). The choice of the replacement valve remains controversial. Pulmonary homograft functions physiologically as an individual heart valve with predictable long-term durability; however, it is limited in availability and sizes⁽⁴⁾. Mechanical valve is more durable but it has higher risk of valve thrombosis as well as bleeding from anticoagulation^(5,6). Bioprosthetic valve is readily available in most cardiac centers, has an

Correspondence to:

Kantathut N

 $Department of Surgery, Ramathibodi \, Hospital, \, Mahidol \, University, \, Bangkok \, 10400, \, Thailand.$

Phone: +66-2-2011315, Fax: +66-2-2011316

E-mail: narongritkan@mahidolac.th

excellent mid-term results, and has no need for anticoagulation⁽⁷⁾. The advantage of bioprosthetic valve is that "valve-in-valve" percutaneous valve replacement can be performed at a later date. This study aimed to describe our current surgical technique for pulmonary valve replacement with bioprosthetic valve in congenital heart disease and to report early clinical outcomes.

Materials and Methods

Patient population and Study design

From January 2016 to July 2018, 11 Patients underwent pulmonary valve replacement with bioprosthetic valve for congenital heart disease; their records were retrospectively reviewed. Patient characteristics included age, gender, body surface area, preoperative comorbidities, prior cardiac surgery, New York Heart Association (NYHA) functional classification, left ventricular ejection fraction (LVEF), QRS duration, diagnosis. The postoperative outcomes included length of stay in the ICU, post-operative hospital stay, postoperative complication (acute kidney injury, respiratory complication, stroke, re-operation for bleeding), and mortality. Postoperative LVEF, QRS duration,

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NYHA classification were compared with pre-operative data. This study was approved by Institutional Review Board (reference number 07-61-55).

Surgical technique for pulmonary valve replacement

The procedure is performed using median sternotomy. Sternal reentry and sufficient dissection of the heart structure can be challenging. Standard central cannulation via the aorta, superior vena cava, and inferior vena cava is preferred. But single venous cannulation can be used if there are no additional cardiac defects requiring surgical repair. Femoral cannulation may be required to establish cardiopulmonary bypass before or during sternal reentry. Usually, we performed pulmonary valve replacement using cardiopulmonary bypass with normothermia or mild hypothermia. Routinely, aortic occlusion with del Nido cardioplegia is used for cardioplegic arrest. The main pulmonary artery or the previous patch is opened longitudinally. The incision is extended superiorly to the pulmonary artery bifurcation and inferiorly across the pulmonary valve annulus into the right ventricular outflow tract (RVOT) as far as necessary to alleviate the infundibular narrowing (Figure 1). The incision can be extended into left or right pulmonary artery if an augmentation of the pulmonary artery is required. Careful visualization of the abnormal coronary artery branches which pass through the RVOT is mandatory. The pulmonary valve leaflet is excised. The valve sizers are used for selection of a replacement valve, typically 21 to 25 mm in diameter. The valve is sewn in place using continuous running 3-0 or 4-0 polypropylene suture, or interrupted 2-0 mattress sutures with felt pledgets, starting from posterior annulus. As the suture line is sewn in each direction, the valve axis should be tilted toward bifurcation of the pulmonary artery cephalad and posteriorly. It is also important not to place the struts against the posterior wall of the annulus to avoid a compression of the left main coronary artery. The main pulmonary artery can be closed primarily if possible or with additional augmentation patch using pericardium, Gore-Tex, or Dacron. The narrowing of the left or right pulmonary artery can be repaired with the same patch, or with separated patch.

Statistical analysis

Continuous data were presented as mean (standard deviation, SD) or median (interquartile range, IQR) and compared by independent sample t-test or the Mann-Whitney U test. Categorical variables were reported as frequency (%) and analyzed by chi-squared or Fisher's exact test. All analyses were performed using STATA version 14 (College Station, TX, USA). Statistical significance was defined as a *p*-value <0.05.

Results

Patient demographics

Mean age was 30.91 ± 12.29 years. Seven (63.64%) patients were male. Mean BSA was 1.57 ± 0.25 m². Ten (90.91%) patient had prior cardiac surgery. All patients were



Figure 1. The pulmonary artery is opened longitudinally. The incision is extended inferiorly into RVOT and superiorly to the pulmonary artery bifurcation. The pulmonary vale cusps are excised. The bioprosthetic valve is implanted at the native pulmonary annulus.

classified in NYHA class II (90.91%) and III (9.09%). No comorbidity recorded. The patient characteristics, diagnosis, and type of operation are summarized in Table 1.

Postoperative outcomes

Mean follow-up period was 9.34 ± 4.78 months. Mean ICU stays and hospital stays were 1.63 ± 0.50 and 6.54 ± 4.01 days, respectively. No complication and mortality occurred. All patients' NYHA classifications were improved to class I (100%). Pre-operative % LVEF and postoperative LVEF were similar 59 ± 9.41 vs. 60.36 ± 9.42 , (p=0.358). There was no significant difference in pre-operative and postoperative QRS duration 149 ± 27.07 vs. 146.36 ± 28.27 milliseconds. Postoperative outcomes are summarized in Table 2.

Discussion

This study demonstrated excellent clinical outcomes of our current surgical technique for pulmonary valve replacement with bioprosthetic valve. No mortality and complications occurred. Postoperative LVEF and QRS duration showed no significant differences compared to

Table 1. Patient characteristics

| Data | n = 11 | Range | 95% CI |
|--|-----------------------|------------|------------------|
| Age (year), mean ± SD | 30.91 <u>+</u> 12.29 | 17,52 | 22.44 to 39.37 |
| Gender, n (%) | | | |
| Male | 7 (63.64) | | |
| Female | 4 (36.36) | | |
| BSA (m^2), mean \pm SD | 1.57 <u>+</u> 0.25 | 1.36, 2.27 | 1.40 to 1.74 |
| Prior cardiac surgery, n (%) | 10 (90.91) | | |
| % LVEF (pre-op), mean ± SD | 59 <u>+</u> 9.41 | 40,72 | 52.67 to 63.32 |
| QRS duration pre-op (ms), mean \pm SD | 149.45 <u>+</u> 27.07 | 101, 177 | 131.26 to 167.64 |
| NYHA classification (pre-op), n (%) | | | |
| I | 0 | | |
| II | 10 (90.91) | | |
| III | 1 (9.09) | | |
| IV | 0 | | |
| Diagnosis, n (%) | | | |
| Previous repair of tetralogy of Fallot | 9 (81.82) | | |
| Ventricular septal defect with severe pulmonary valve stenosis | 1 (9.09) | | |
| Atrial septal defect with severe mitral, tricuspid and pulmonary valve insufficiency | 1 (9.09) | | |

Table 2. Postoperative outcomes

| Data | n = 11 | Range | 95% CI |
|--|--------------------|-------------|------------------|
| Death, n (%) | 0 | | |
| ICU stay (day), mean ± SD | 1.63 ± 0.50 | 1, 2 | 1.29 to 1.97 |
| Hospital stay(day), mean \pm SD | 6.54 <u>+</u> 4.01 | 4, 15 | 3.85 to 9.23 |
| % LVEF (post-op), mean ± SD | 60.36±9.42 | 41, 73 | 54.03 to 66.69 |
| NYHA classification (post-op), n (%) | | | |
| I | 11 (100) | | |
| II | 0 | | |
| III | 0 | | |
| IV | 0 | | |
| QRS duration post-op (ms), mean \pm SD | 146.36+28.71 | 83.181 | 127.07 to 165.65 |
| Follow-up time(month), mean ± SD | 9.34 <u>+</u> 4.78 | 1.50, 16.88 | 6.12 to 12.55 |

Table 3. Comparison postoperative outcomes

| Change (pre-op vs. post-op) | n = 11 | <i>p</i> -value | |
|-----------------------------|------------|-----------------|--|
| LVEF (%), mean ± SD | -1.36±4.69 | 0.358 | |
| QRS (ms), mean ± SD | 3.09±19.85 | 0.616 | |
| NYHA classification, n (%) | Pre-op | Post-op | |
| I | 0 | 11 (100) | |
| II | 10 (90.91) | 0 | |
| III | 1 (9.09) | 0 | |
| IV | 0 | 0 | |

pre-operative data; all patients' symptoms improved.

Pulmonary valve replacement has a low mortality^(2,7-9). It provided an improvement in symptoms and exercise capacity reported by previous studies^(2,3,9). Similarly, the present study exhibited excellent early clinical

outcomes and reduced symptoms. While the choice of replacement valve for pulmonary valve replacement remains controversial, the bioprosthetic valve has a good short-term and mid-term durability⁽⁴⁾. The advantage of bioprosthetic valve is no limit in availability, no need for anticoagulation.

Pulmonary homograft has predictable long-term durability and physiologically functionable as a normal pulmonary valve but it has limits in availability and sizes. Surgical implantation of pulmonary homograft may be challenging. Mechanical valve can be implanted with this current surgical technique but it has higher risk of valve thrombosis as well as related complications from anticoagulation^(5,6).

QRS prolongation is a predictor of sustained ventricular tachycardia and sudden cardiac death in patients with previous repair of tetralogy of Fallot. Although, pulmonary valve replacement leads to an improvement in symptoms and hemodynamic data, QRS duration after pulmonary valve replacement was not reduced significantly⁽⁹⁾. This finding also reported in our study. Babu-Narayan et al reported a late cardiac death from arrhythmia despite successful pulmonary valve replacement⁽⁹⁾. This hemodynamic change in pulmonary valve replacement does not reduce the risk of sudden cardiac death. In patients with QRS prolongation or patients with extensive fibrosis, additional anti-arrhythmic intervention or automated implantable cardioverter defibrillator may be required.

This current surgical technique has numerous of advantages. The replacement valve can be implanted with the largest matched size. The narrowing of the RVOT can be resected or augmented easily. Proximal left or right pulmonary artery stenosis can also be repaired with extension of the superior incision into each pulmonary artery.

Although this technique is simple and reproducible, there are some limitations that should be avoid or performed with special cautions. Abnormal coronary artery branches that pass across RVOT are the most important limitation. This abnormal coronary artery branches can be detected preoperatively by computed tomography or magnetic resonance imaging. Special attentions should be given while we are extending the RVOT incision inferiorly to avoid the injury to the abnormal coronary artery branches.

Limitation

The present study has several limitations. Retrospective design, descriptive basis, lack of cohort comparison are important limitations. Although our early results were promising, long-term follow-up of these patients is needed. The choice of replacement valve for pulmonary valve replacement cannot be concluded because most of pulmonary valve replacement studies are retrospective. Thus, large prospective control study is required.

Conclusion

Pulmonary valve replacement with bioprosthetic valve with our current surgical technique is simple, safe, reproducible, and has excellent clinical outcomes.

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What is already known on this topic?

The choice of the replacement valve for pulmonary valve replacement remains controversial. Pulmonary homograft functions physiologically as an individual heart valve with predictable long-term durability; however, it is limited in availability and sizes. Mechanical valve is more durable but it has higher risk of valve thrombosis as well as bleeding from anticoagulation. Bioprosthetic valve is readily available in most cardiac centers and has excellent mid-term results, and has no need for anticoagulation.

What this study adds?

Pulmonary valve replacement with bioprosthetic valve using our current surgical technique is simple, safe, reproducible, and has excellent clinical outcomes.

Potential conflicts of interest

The authors declare no conflict of interest.

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