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Aortic valve replacement with single strip autologous pericardium


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Conflict of Interest: The authors declare that they have no conflict of interest.

Abstract:
Background: Aortic valve replacement with mechanical valves is the standard treatment for aortic valve disease in Indonesia. Its usage is associated with high cost, risk of endocarditis and thromboembolic event, and lifetime consumption of anticoagulants. We perform a novel replacement technique of the aortic valve using an autologous pericardium and evaluate short-term outcomes.

Methods: From April 2017 to April 2020, 16 patients underwent aortic valve replacement with a single-strip autologous pericardium. Outcomes of left ventricle reverse remodeling (LVRR), six minutes walking test (6MWT), and soluble suppression of tumorigenicity-2 (sST-2) were measured at 6 months post-operation.

Results: A total of 16 surgeries were performed using aortic valve replacement with single strip pericardium without conversion to mechanical valve replacement. The patients included 8 males and 8 females, and the mean age was 49.63 ± 12.54 years old. The most common diagnosis was mixed aortic valve stenosis and regurgitation (9 cases). The mean aortic cross-clamp time was 139.88 ± 23.21 min and cardiopulmonary bypass time was 174.37 ± 33.53 min. At 6 months post operation, there was an increase of 6MWT (p = 0.006) and a decrease of sST-2 level (p = 0.098). Echocardiographic showed 2 patients had LVRR. Survival and freedom from reoperation are 100% at one-year follow-up.

Conclusion: Aortic valve replacement with single strip pericardium is a good alternative to aortic valve replacement with a mechanical valve. Short-term evaluation at 6 months post-operation showed improvement in clinical status and echocardiographic parameters compared to baseline

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**Introduction**

Aortic valve replacement with a mechanical valve is the standard treatment for aortic valve disease in Indonesia. However, there are some limitations regarding the use of mechanical valves including high cost, increased risk of endocarditis and thromboembolic event, and lifetime consumption of anticoagulants. Aortic valve replacement using autologous pericardium is developed as an alternative to overcome these problems. The aortic valve neo-cuspidization (AVNeo) by Ozaki et al. is widely accepted worldwide. The Ozaki technique is challenging to perform as surgeons have to measure the inter-commissure distances for each leaflet before trimming and molding the pericardium, significantly increasing the aortic cross-clamp duration. We developed a novel and easier aortic valve replacement technique with single strip pericardium.

**Methods**

This study had received ethical clearance from the Ethics Committee of the Faculty of Medicine, University of Indonesia with protocol number 16-12-576. We performed aortic valve replacement with single strip pericardium on 16 patients from April 2017 to April 2020. We reviewed these 16 cases and evaluated short-term results of left ventricle reverse remodeling (LVRR) incidence, 6 minutes walking test (6MWT) distance, and soluble suppression of tumorigenicity-2 (sST-2) level.

The criteria for
LVRR was increased of ejection fraction (EF) more than 10% with decreased of left ventricular end diastolic diameter (LVEDD) more than 10%. The 6MWT is used to assess patient’s clinical function and sST-2 level is used to assess myocardial stress. Several studies showed that both 6MWT and sST-2 test have prognostic value following aortic valve replacement.

The patient is under general anaesthesia and underwent median sternotomy. The anterior pericardium with the size of 5 cm x 13 cm was harvested. The harvested pericardium was preserved by soaking it in 0.6% glutaraldehyde for 10 minutes and then rinsed using NaCl 0.9% three times each for 5 minutes. The cardiopulmonary bypass machine was established. We then perform a partial aortotomy to expose and remove all diseased aortic valves (Figure 1A). Annulus diameter and the commissure height and inter-commissures length are measured using the St. Jude aortic valve sizer (Figure 1A). In case of aortic root dilatation, we use the sinotubular junction diameter instead of the annulus as we believe the coaptation edge of the neo aortic leaflets are also determined by the sinotubular junction diameter. The threshold of the sinotubular junction diameter is less than 1.5 times of the expected normal diameter. Measurement results are converted as follows, annulus or sinotubular junction diameter to single strip pericardium length, commissures height to single strip pericardium width, and inter-commissures length as suturing mark on the single strip pericardium (Figure 1B). We use a self-developed marker to imprint the single strip pericardium. This marker imprint around 8 mm more in single strip pericardium length and 4 mm more in width than the measured annulus to account for shortening after suture placement.

The pericardium is cut according to the measurement (Figure 1B) and sutured at three commissures on the aortic valve annulus, first at the LCC-RCC commissure. The suture
is placed exactly at the upper border of the annulus to avoid the membranous septum (Figure 1C). The single strip pericardium is then sutured continuously along the aortic valve annulus. Then both edges of the single strip pericardium were also sutured, forming a pericardial tube toward the left ventricle (Figure 1C). The pericardial tube is pulled outward from the ventricle toward the aorta, and then each commissure is sutured toward the sinotubular junction (Figure 1D), forming the new aortic valve with three leaflets (Figure 1D). We evaluate the function of the new developed aortic valve for any regurgitation. Transoesophageal echocardiography is used to evaluate valve function and de-airing adequacy. If there is moderate aortic regurgitation then the neo aortic valve is repaired until no to mild aortic regurgitation is achieved. Then aorta is sutured, and the heart is de-aired. The patient is then removed from the cardiopulmonary bypass machine, and cannulations are removed. Drainage tubes are put in place, and the chest wall is closed layer by layer.

Results

There were 8 males and 8 females. Their mean age was 49.6 ± 12.5 years old. Three patients had aortic stenosis (AS), 4 patients had aortic regurgitation (AR), and 9 patients had mixed aortic stenosis and regurgitation. Infective endocarditis (IE) was observed in 2 patients. Concomitant procedures included 5 coronary artery bypass graft (CABG) operations and 1 left atrial appendage plication. In addition of aortic valve replacement, 12 patients underwent either mitral valve repair or tricuspid valve repair. There were no case of bicuspid aortic valve (BAV). The BAV can’t be replaced with this technique due to its elliptical annulus shape.
Preoperative echocardiography revealed the mean peak pressure gradient (PG) through the aortic valve was $25.7 \pm 16.8$ mmHg. The mean aortic root diameter was $25.8 \pm 3.2$ mm. The baseline of left ventricular end diastolic diameter (LVEDD), left ventricular end systolic diameter (LVESD), and ejection fraction were $49.1 \pm 10.8$ mm, $34 \pm 11.8$ mm, and $61.4 \pm 13.4$ % respectively. Preoperative 6MWT was $309 \pm 126.6$ m and sST-2 level was $18.3 \pm 15.6$ pg/ml.

There were no patients converted to prosthetic valve replacement. The mean aortic cross clamp time was $139.9 \pm 23.2$ min and cardiopulmonary bypass time was $174.4 \pm 33.5$ min. In patient with isolated aortic valve replacement, the aortic cross clamp time was 102 min and the cardiopulmonary bypass time was 123 min. There was no in-hospital death with cardiac or non-cardiac causes. There was also no-embolic event recorded in all patients. The newly created aortic valves had a mean coaptation height at $5.27$ (SD $1.01$) mm and effective height at $11.83$ (SD $0.82$) mm.

At 6 months follow-up, the mean PG through the aortic valve decreased significantly to $11.7 \pm 6.5$ mmHg ($p = 0.007$). The 6 months LVEDD, LVESD, and EF respectively changed to $48.2 \pm 4.5$ mm ($p = 0.673$), $31.5 \pm 4.2$ mm ($p = 0.605$), and $59.5 \pm 6.3$ % ($p = 0.179$). The rate of LVRR at 6 months was 12.5%. Four patients had moderate aortic regurgitation, six patients had mild aortic regurgitation, and six patients had no aortic regurgitation. Six minutes walking test distance significantly increased to $431.9 \pm 93.4$ m ($p = 0.006$) while sST-2 level decreased $11.5 \pm 7$ pg/ml ($p = 0.063$). At one year follow up, survival and freedom from reoperation were 100%.

Discussion
The single strip autologous pericardium technique is performed by creating three symmetric aortic valve leaflets without the need to measure the size of each leaflet, making this technique easy to perform. For isolated aortic valve repair, the single strip pericardium technique had similar or shorter aortic cross clamp time and cardiopulmonary bypass time compared to previous studies by Ozaki et al. who reported a mean aortic cross clamp time of 110.1 ± 26 minutes with mean CPB time of 149 ± 29.9 minutes and Duran et al., who reported a mean aortic cross-clamp time of 110.1 ± 26 minutes with a mean CPB time of 149 ± 29.9 minutes. Based on a study by Ino et al., the length of the duration of the aortic cross-clamp time is an independent predictor of postoperative morbidity and mortality after aortic valve replacement in aortic stenosis. The mortality risk is increased along with an increment in aortic cross-clamp time. The cut off duration is >150 minutes (OR: 2.68; 95%, CI 1.66 – 4.32; p < 0.001). Meanwhile study from Chalmers et al. showed that CPB time was significantly associated with mediastinal blood loss (p < 0.001), duration of ICU stays (p = 0.01) and postoperative length of stays (p < 0.001) and in-hospital mortality (OR 1.02, 95% CI 1.01 - 1.04, P = 0.01).

The newly created aortic valves had a mean coaptation height at 5.27 (SD 1.01) mm and effective height at 11.83 (SD 0.82) mm. Aortic valve replacement is considered a success if coaptation height >4 mm and effective height >10 mm. Coaptation height <4 mm increased the risk of recurrent aortic valve regurgitation by 40% and >70% if it’s lower than the aortic annulus.

At 6 months post operation we found significant decrease of mean PG through the aortic valve and significant increase of 6MWT distance. The results of this study are in line with the results of the study by Straiton et al. which assessed the functional
capacity and quality of life of patients after transcatheter aortic valve replacement. The study showed an increase in 6MWT distance of 41.48 meters (95% CI 9.69–73.28, p = 0.01) after transcatheter aortic valve replacement. Currently, no other study compares functional capacity before and after aortic valve replacement with autologous pericardium.

The level of sST-2 level also decreased at 6 months post operation with LVRR incidence of 25%. Lupón et al.\textsuperscript{10} reported that sST-2 levels was an independent predictor of reverse remodeling and clinical variables. LVRR is mostly observed at 1-2 years post operation, there is a high chance that the incidence of LVRR will increased with longer follow-up period.

One of known predictor factors for long term aortic valve repair failure is aortoventricular dilatation. Schäfers et al.\textsuperscript{11} reported that suture annuloplasty with Ethibond and polytetrafluoroethylene Gore-Tex significantly improved patient’s outcomes compared to those without annuloplasty, especially in bicuspid valve cases. Continuous suture of the single strip pericardium to the aortic annulus automatically create a suture annuloplasty that can prevent aortoventricular dilatation. Annuloplasty created with single strip pericardium technique is expected to prevent aortoventricular dilatation and increased valve durability.

We reported a new aortic valve replacement technique using single strip autologous pericardium with good hemodynamic and clinical outcomes. It is a feasible alternative to aortic valve replacement especially in limited resources country like Indonesia.

**Contributor’s Statement**

Conception and design of the work: ID, JR, IP, IA, SS, S, IKL, MS, AAJ, WM
Data collection: ID, WM, IT, SM

Analysis and interpretation of the data: ID, IA, SS, S, IKL, MS, AAJ, WM, IT, SM

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References


Figures
A. Excision of leaflets and determining annulus diameter

B. Marking and cutting of the single strip pericardium

C. Suturing the single strip pericardium to the annulus

D. Suturing along the sinotubular junction at the 3 commissures
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