Original Article

Assessment of Untreated Fresh Autologous Pericardium as Material for Construction of Heart Valve: Result at 5 Years

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Abstract

Introduction: Tetralogy of Fallot requiring transannular repair of the right ventricular outflow tract (RVOT) are exposed to free pulmonary insufficiency and hence inevitable right ventricular dysfunction. This study analyzes the function and structure of untreated autologous pericardium monocusp used to create a competent pulmonary valve. **Materials and Methods:** This is a retrospective analysis of 52 cases operated between December 2006 and December 2012. Untreated autologous pericardium was used for creating a competent pulmonary valve following a transannular patch. They are followed for functional and structural assessment of the pulmonary valve by echocardiography. Positron emission tomography (PET) with 18 fluorodeoxyglucose was performed in two cases for profiling the pulmonary valve. **Results:** Median age was 10.5 years (1–38). The follow-up was complete for 42 (80.76%) patients for 3 years and 25 (48.07%) patients for 5 years. The RVOT gradient was 42 mmHg (16–96) in the year of surgery, which reduced to 26 mmHg (10–58) and pulmonary insufficiency that was present in 8.3% of patients in 1st year was witnessed in 22.7% in the 5th year of follow-up. The monocusp patch was successful in creating a competent valve while maintaining its structure at 3 years; however, it became distorted and retracted at 5 years of follow-up. There was no calcification in any of the patients. PET-computed tomography confirmed the uptake of glucose by monocusp at 1 year of follow-up. **Conclusion:** The untreated autologous pericardium functioned well when it was used to create a competent pulmonary valve at short term and midterm. Although it changed in its structure; there was no calcification at 5 years of follow-up.

Keywords: *Autologous pericardial valve, monocusp valve, right ventricular outflow tract reconstruction*

Introduction

Transannular patch (TAP) is required in patients with tetralogy of Fallot (TOF), when the pulmonary annulus is inadequate for total correction. TAP is associated with appearance of free pulmonary regurgitation (PR) and subsequent right ventricular dysfunction, which may be asymptomatic.[1] There are constant efforts to reduce the PR and delay the right ventricular dysfunction in these cases by either retaining the native pulmonary valve or the use of monocusp valve.[2,3] There are more valves and material being used to create a competent pulmonary valve in cases requiring TAP. None are successful.[4] Although there are numerous commercial valves available for heart valve replacement surgery, the ideal valve is yet awaited. Although mechanical valves are not preferred in pulmonary position, they are also fraught with inherent problems of thromboembolic episodes and bleeding related to anticoagulation, even in modern era.[5] While bioprosthetic valve avoids this problem to a large extent, their structural damage over a period of follow-up equals its benefit accrued over years of freedom from thromboembolic episodes and bleeding related to anticoagulation.[6] Moreover, the bioprosthetic valve is created from tissue of xenogeneic origin; hence, it degrades with calcification and stenosis.[7] The early and long-term result at pulmonary position is dismal.[8] This problem largely arises from the choice of available material for construction of bioprosthetic valve. Most popular materials for the purpose of constructing a bioprosthetic heart valve are either bovine pericardium or porcine valve tissue, both being xenogeneic in nature are amenable to damage in due course.[9] Thus, graft-host reaction is the reason for early deterioration of the valve. Bovine jugular vein, a purely biological conduits with valve, was tried at pulmonary position

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with no different result.[10] Homograft has been used as a viable option in the right ventricular tract reconstruction in children, but its result at 5 and 10 years are fraught with high incidence of reintervention.[11] Hence, there is a need of material for valve construction that may surpass all these concerns. In this study, we analyze the use of untreated fresh autologous pericardium to reconstruct the pulmonary valve in patients of TOF requiring TAP. This study focuses on the suitability of pericardium used in this manner for construction of cardiac valve.

Materials and Methods

This is a retrospective analysis of 52 patients with TOF, TAP with monocusp valve using fresh pericardium operated between December 2006 and December 2012. Requirement of TAP was planned according to Kirklin nomograms. Untreated and fresh autologous pericardium was used for creating a competent pulmonary valve in all the cases requiring either enlargement of pulmonary annulus. The monocusp method, in which the anterior leaflet of the new valve, was created using a patch hanging from the inner surface of TAP at the level of annulus. The details of the surgical procedure are given in the earlier publication. This leaflet with the help of posteriorly placed native leaflets creates a competent pulmonary valve at the position of new enlarged annulus.[12]

All the patients are followed for functional and structural assessment of the newly created pulmonary valve. Echocardiography was utilized for this assessment. Positron emission tomography (PET) using 18 fluorodeoxyglucose (18 FDG) scan is performed in two cases to study the feasibility of assessing the demonstration of autologous pericardial tissue.

Echocardiography

Echocardiography was performed on a Philips HD machine using a 3.2-MHz transducer (Philips Medical Systems, Andover, MA, USA). A single operator to eliminate the bias in recording values performed the procedure. A routine evaluation of the left ventricular dimensions and function were recorded. The newly created pulmonary valve was evaluated for function and anatomy. The function was assessed by measuring gradient across the valve in transthoracic short axis view.[13] Continuous wave Doppler in the same view assessed the PR. The severity of PR was assessed by ratio of its PR-signal duration during diastole. PR signal was considered as mild PR if it was >0.77 and considered severe if it was <0.77.[14] The regurgitation was graded from 1 to 3 (1 was considered as no regurgitation and 3 as severe regurgitation).

18 Fluoro deoxyglucose positron emission tomography scan protocol

The patients were kept fasting overnight. They were injected with 18 FDG contrast 45 min before the plan for PET-computed tomography (CT) scan on the same day. The PET CT scan was performed on GE machine. The CT scan was performed at heart rate of <70/min with 0.9mm slice thickness. The iodine-based contrast was injected with trigger in the right ventricle. The area of interest was right ventricle, right ventricle outflow tract, pulmonary valve, and main pulmonary artery. The standard uptake value was calculated from the anterior leaflet profiled in end systole. The PET CT investigation is performed after 1 completed year of follow-up.

The echocardiographic follow-up was complete for 42 patients for 3 years and 25 patients for 5 years. The median follow-up period is 7 years.

The data are expressed in median and range. All the statistical figures are created using software. All analysis was performed with SPSS 10 version for Windows (SPSS, Inc., Chicago, IL, USA).

Results

The median age of the patients was 10.5 years (1–38), 10 were female and 42 were male. The echocardiographic follow-up was complete for 42 patients for 3 years and 25 patients for 5 years. The right ventricular outflow tract (RVOT) gradient was 42 mmHg (16–96) in the year of surgery, which reduced to 26 mmHg (10–58) [Figure 1]. However, PR was present in 8.3% of patients in 1st year, increased to 22.7% in the 5th year of follow-up [Figure 2]. The patients who completed 5 years of follow-up were evaluated to observe any increase in their RVOT gradient in following years. This is expected when there is deformation and retraction of the monocusp. The increase in RVOT gradient at 5 years by 25% of its value at 2 years was considered significant. This was recorded in 6 out of 25 patients (24%) [Figure 3]. Change in the appearance of the monocusp patch at 5 years is evident in Figure 4. The monocusp of untreated autologous pericardium at 1 year of follow-up was showing un uptake of glucose in PET scan [Figure 5]. None of the patients demonstrated calcification of the pericardial monocusop at follow-up.

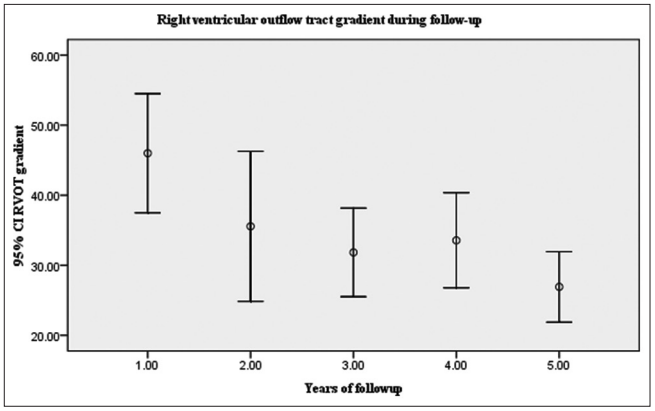

Figure 1: The assessment of gradient across RVOT expressed in mmHg with mean and 95% confidence interval during years of follow-up. RVOT: Right ventricular outflow tract

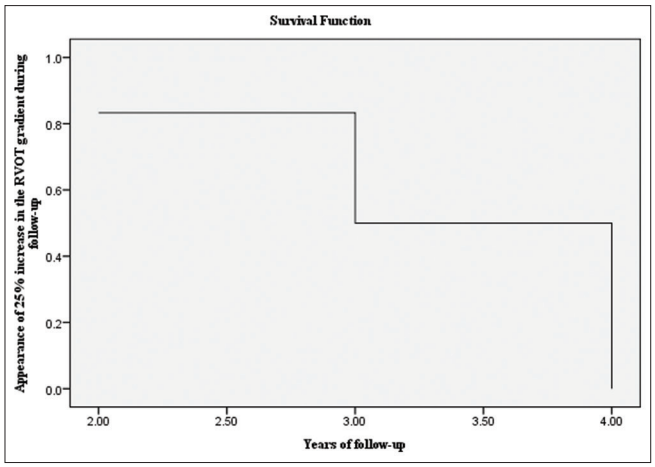

Figure 2: Survival analysis on the appearance of an increase of 25% of RVOT gradient from the value achieved after 1 year of follow-up. Six of 25 patients followed up to 5 years revealed this phenomenon. RVOT: Right ventricular outflow tract

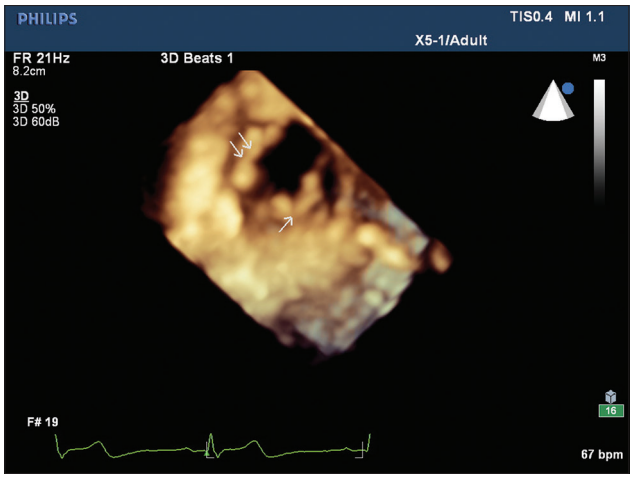

Figure 4: Pulmonary valve of the same patient at 5-year follow-up. Double arrow is indicating native pulmonary valve leaflet. Single arrow indicates distorted and retracted autologous pericardial monocusp valve

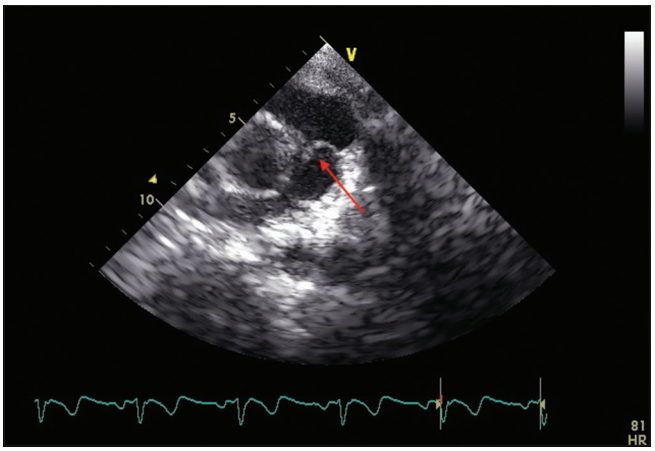

Figure 3: Pulmonary valve in short axis view. Arrow indicating the monocusp valve at 3-year follow-up

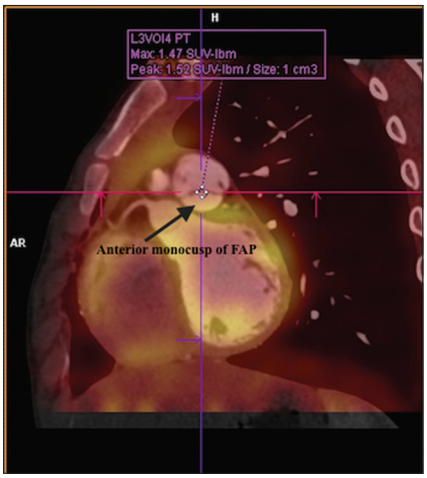

Figure 5: Positron emission tomography scan showing uptake of 18 fluorodeoxyglucose denoted by standard uptake value at the opposition edge of the autologous pericardial monocusp valve (indicated by arrow)

Discussion

Autologous pericardium is the most easily available tissue to be utilized for reconstruction in cardiac ailments.[15] Hence, it is one of the most early tissues to be used for right ventricular tract reconstruction.[16] Untreated fresh autologous pericardium fell out of favor as it was reported to retract and disappear even at very early follow-up.[17] However, few recent studies have shown it to work well in the long term when used for mitral valve reconstruction.[18] It was also observed that; they remain calcification free. The pericardium used to reconstruct the valve at pulmonary position in this study, revealed thickening and retraction at 5 years. There was no evidence of retraction at 3 years. The motion of the pericardial monocusp reduced with retraction and distortion of the monocusp. PR increased due to retraction of the pericardium used as monocusp. Since there is no calcification and restriction in the motion of monocusp, no gradients is produced. PR increased during follow-up but was present in significant proportion in only one 5th of patients. This observation has been validated in our previous study.[19] The severity of PR is also affected by the right ventricular function. Right ventricle starts showing dilation and gradual loss of its function as early as 4 years in follow-up.[20] Hence, there arises a need to address this factor at the index operation.[21] PR in monocusp method may also be affected by the fact that a competent semilunar valve will require an annulus adequate sinus and sinotubular junction apart from freely mobile and supple leaflets.[22] Since the monocusp method used in this study does not address all these aspect, a perfectly competent valve could not be achieved in all cases. Although monocusp was created on calculations, yet the design heavily relied on handcrafting; hence, it may have contributed to insufficiency.[12]

There was no calcification of monocusp witnessed during follow-up. This fact highlights the capability of untreated autologous pericardium to resist structural degeneration.[23] This observation makes autologous

pericardium more suitable than xenogeneic tissue used for construction commercially available biological valves.[9] The process of structural degeneration and calcification is enhanced in younger population therefore autologous pericardium may be suitable in them.[24] The structural deterioration of the commercially available valve is due to immune process of rejection of foreign protein material by host-graft rejection model.[25] The autologous tissue obviates this problem. Usually, the autologous pericardium is treated by glutaraldehyde to make it stiffer and easy to handle. In the process, the living cells are rendered dead. Although they are not shown to retract, they often fail by calcification.[26] It has been observed that the untreated pericardium possesses the ability to stretch in its two axes.[27] This property may work as a shock absorber while valves open and closes. In this study, none of the monocusps calcified. The PET scan showed uptake of glucose by the pericardial monocusp. This proves the ability of monocusp pericardium to assimilate glucose, a property of living tissue. This may be the reason the monocusp valve did not calcify and maintained supple nature.[28] Studies have shown uptake of glucose on PET scan by native valve tissues. This study is in unison with recent studies showing long-term effective use of untreated autologous pericardium in valve reconstruction.[15] The study has shown that the autologous untreated pericardium possesses most of the quality to be the best material for construction of the cardiac valves for the right heart chambers. It fails on the count of retraction and distortion in long follow-up. The other untested factor is its strength to work in systemic circulation. Although a study has shown autologous untreated pericardium to be similar in strength to glutaraldehyde-treated pericardium.[23] There has been very successful use of glutaraldehyde pericardium in reconstruction of aortic valves in humans.[29] Further studies may work in this direction for optimizing the function of untreated fresh pericardium for replacement of right-sided valves.

Conclusion

Untreated autologous pericardium is a viable option for pulmonary valve reconstruction in short term at pulmonary position. During a longer follow-up, it starts to retract and is distorted. Although it maintains motion and does not calcify. Further research is required to find out the reason and mechanism of retraction for this tissue.

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Conflicts of interest

There are no conflicts of interest.

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