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Fresh Pericardial Valved Conduit for Reconstruction of Right Ventricular Outflow Tract in Tetralogy of Fallot with Pulmonary Stenosis or Pulmonary Atresia—Early Results

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Abstract

Objective: To study early results of hand made fresh (autologous/homologous) pericardial valved conduit in achieving right ventricle to pulmonary artery continuity. Method: Between November 2014 and September 2015, 19 cases, with diagnosis of Tetralogy of Fallot with Pulmonary stenosis (PS) or Pulmonary atresia (PA) underwent intracardiac repair and Right Ventricular Outflow Tract (RVOT) reconstruction with hand made fresh [autologous (n = 2)/homologous (n = 17)] pericardial valved conduit. Mean age of the patients at time of surgery was 6.37 years (range 3 months to 18 years), mean weight was 18.52 kilograms (range 6 kg to 40 kg) and mean size of the conduit was 20.7 mm (range 16 mm to 24 mm). Results: All patients had a smooth post-operative course, with mean ICU (Intensive Care Unit) stay of 3.6 days (range 3 days to 6 days) and mean post-operative hospital stay 8.5 days (range 7 days to 16 days). Intra-operative and Post-operative echocardiography revealed moderate Pulmonary regurgitation (PR) in one patient, mild PR in 5 patients and no or trace PR in 13 patients. No patient has developed conduit stenosis or calcification till now. Conclusion: Autologous or homologous pericardial valved conduit provides good early results and is especially suitable for developing world because of zero cost. Long term usefulness of such option remains to be confirmed in terms of dilation, calcification and freedom from intervention.

Keywords

RV-PA (Right Ventricle-Pulmonary Artery) Continuity, Tetralogy of Fallot, Pericardial Valved Conduit

1. Introduction

Creating right (venous) ventricle to pulmonary artery continuity is essential in repair of many complex congenital heart diseases. A valved conduit always performs better than a non-valved conduit and helps in preserving the right ventricular function. An ideal valved conduit still remains the Holy Grail in cardiac surgery. It should comply with the following requisites: (1) some potential for its diameter to increase with time, (2) low likelihood of shrinkage or development of intimal peel or thrombus, (3) long-lasting valve function, (4) ready availability, and (5) low cost [1].

Rastelli and colleagues [2] reported the use of a nonvalved pericardial conduit in the right ventricular outflow tract (RVOT) of a patient with tetralogy of Fallot (ToF) and pulmonary atresia with ventricular septal defect (VSD) and Ross and Somerville [3] reported the use of a homograft. The first patient with a non-valved pericardial conduit, who has been followed up for more than 30 years, has not had to undergo reoperation [1]. After the wide experience with the use of unpreserved pericardium in the reconstruction of the right ventricular outflow tract in ToF, Schlichter Andrés J. *et al*. produced excellent results [1]. We created and modified later a tricuspid valved conduit instead of Schlichter's bicuspid conduit by studying the normal pulmonary and aortic valve cusp diameters and cusp shapes [4] [5] [6].

2. Patients and Method

2.1. Patient Selection

All patients of Tetralogy of Fallot with Pulmonary Stenosis (PS) or Pulmonary Atresia (PA), who required Right Ventricle (RV)-Pulmonary Artery continuity using valved conduit for any reason, were included in the study. The patients were diagnosed by echocardiography and catheterization studies by the Cardiologists. These investigations are approved by the institutional ethical committee.

2.2. Patient Population

Between November 2014 to July 2015, 19 handmade pericardial valved conduits were placed to achieve venous ventricle to pulmonary artery continuity. This study is a prospective research study. Two patients received autograft (*i.e.* pericardium harvested from themselves only) while rest of the patients received homograft from blood group matched donors undergoing operations in adjacent operation theatre. Autograft were harvested from the patients in whom adequate pericardium could be obtained to make a 22 or 24 mm sized conduit, in rest of the patients the homografts were applied. Appropriate informed consent was taken from the both donor and the recipients before the procedure. Mean age of the patients at time of conduit implant was 6.37 years (range 3 months to 18 years), mean weight was 18.52 kilograms (range 6 kg to 40 kg) and mean size of the conduit was 20.7 mm (range 16 mm to 24 mm). Indications of conduit placement were mainly Pulmonary atresia (n = 3), Coronary crossing RVOT (n = 7), Borderline branch pulmonary arteries (n = 7) and severe RV dysfunction (n = 2). Various conduit sizes between 16 mm to 24 mm in diameter were used so as to place the conduit without kinking or sub-sternal compression. One patient had Dandy-Walker Syndrome in whom total correction was done following a ventriculo-peritoneal shunt. Table 1 shows characteristic of patients and implanted conduit size.

2.3. Follow-Up

Patients were followed up regularly at Outpatient clinic. CT angiography was performed in initial few (n = 4) patients to rule out any structural abnormality, constriction or kinking. Later we abandoned the practice of CT angiography in rest of the patients. All patients underwent echocardiography at 6 weeks post-operatively. Echocardiography was performed in all the patients to look for diameters and conduit function. Diameters were taken at two different sites and mean value was considered as the recorded diameter. Pressure gradients were

Table 1. Patients characteristics.

Age/Sex	Weight (kg)	Indication for Conduit	Conduit Size	Post operative PR
3 months/Male	6	Pulmonary Atresia	16	No
8 months/Male	8.5	Coronary Crossing RVOT	16	No
2 years/Female	14	Pulmonary Atresia	18	Mild
4 years/Male	15.5	Borderline pulmonary arteries	18	No
6 years/Male	18.5	Borderline pulmonary arteries	20	Mild
5 years/Male	16	Pulmonary Atresia	20	Trace
4.5 years/Female	14	Coronary Crossing RVOT	18	No
7 years/Female	24	Borderline pulmonary arteries	24	Mild
2.5 years/Male	12.5	Coronary Crossing RVOT	18	No
3 years/Female	13	Coronary Crossing RVOT	18	Moderate
4 years/Female	15	Borderline pulmonary arteries	20	No
8 years/Female	22	Borderline pulmonary arteries	24	Mild
7 years/Male	16	Coronary Crossing RVOT	20	Trace
9 years/Female	20	Coronary Crossing RVOT	24	No
8 years/Male	18	Borderline pulmonary arteries	24	Trace
6 years/Male	14	Borderline pulmonary arteries	24	No
12 years/Male	27	Coronary Crossing RVOT	24	Mild
14 years/Female	38	Severe RV Dysfunction*	24	Trace
18 years/Female	40	Severe RV Dysfunction*	24	No
Mean 6.4 years	Mean 18.52 kg	*= Auto graft	Mean 20.7	

taken at valvular level and distal anastomotic site. Continuous wave Doppler and vena contracta were used during post operative echocardiographic studies by the Cardiologists to classify post operative Pulmonary Regurgitation (PR).

2.4. Statistics

Since the volume of the study is low and follow-up period is small, we did not perform detailed statistical analysis for the study. We intend to increase the number of cases and follow the patients for longer period to produce Kaplan-Meir Survival and freedom from reintervention charts.

2.5. Surgical Technique

Pericardium is removed from the right to the left phrenic nerves (leaving a 1-cm width being intact) and placed on a wet drape (saline solution). The serous layer of the pericardium will be the inner surface, and the fibrous pericardium will be the external aspect of the conduit. The harvested pericardium is then trimmed into two different geometric forms: a large rectangle (the future conduit tube) and a strip (the future valve cusps). The sizes of these pericardial forms are related to the diameter of the conduit as shown in **Table 2** and **Figure 1**.

We take approximately 10 cm length of the rectangle, which is more than enough for the length required to cover the RV-PA distance. The rectangle is cut with an appropriate width for the size (Dimension A in **Figure 1**). A strip of pericardium having length 2 or 3 mm more than Dimension A (to create expected cusp redundancy) and having width equal to sum of Dimension B and D is cut from the main piece of harvested pericardium. The strip is placed on the rectangle and anchoring sutures of annulus taken Points X1, X4, Y1 and Y4 with Prolene 7-0 suture. Rest of the annular stitches (X2, X3, Y2 and Y3) are taken in the same way ensuring equal distribution of redundancy to each of the cusp and ensuring the underlying rectangle to be sutured firmly with the strip. Thickness of the annulus remains constant (C = 5 mm) for all conduit size. The upper parabolic redundant part (height shown as D) of the cusp varies with the size; greater the diameter, more the redundancy we added. Apical stitches (points Z1, Z2 and Z3) are taken. The strip is now cut in cusp shaped fashion. Upper curvature (upper parabolic part as described previously) is created, edges along the length of rectangle sutured to create a tubular conduit. Mean conduit making time was 59.89 minutes, and conduits were made by a separate surgeon or senior resident on side trolley to cut short the operating time.

Table 2. Conduit dimensions.

PA Size	14	16	18	20	22	24
L				100		
A	48	54	60	66	72	80
B	12.5	13.5	14.5	15.5	16.5	17.5
C				5		
D	1	1	2	3	3.5	4

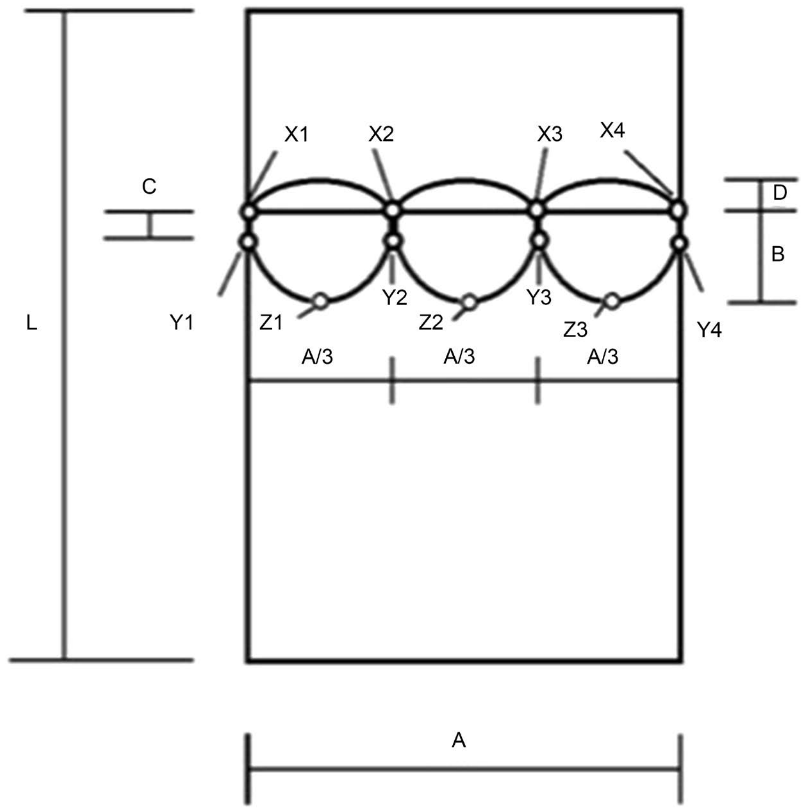

Figure 1. Conduit making.

Figure 2 shows the hand-made pericardial valved conduit prepared in a same fashion using Gortex 0.1 mm thick membrane for cusp creation. In initial 2 cases, we used Gortex membrane to create cusps. Later we started making the cusps from pericardium to cut the cost and make to conduit more affordable for poor patients (**Figure 3**). **Figure 4** shows intra-operative pictures of conduit and **Figure 5** shows final appearance of implanted conduit.

3. Results

Mean Cardio pulmonary Bypass (CPB) time was 102 minutes and mean aortic cross clamp time was 45 minutes. All conduits were placed off-cross clamp. 18 patients were extubated on post-operative day one. Mean ICU stay was 3.68 days and mean hospital stay after surgery was 8.5 days. There was no immediate or late mortality.

No patient was lost to follow-up, all patients have undergone 6 months of follow-up and 11 patients have undergone 1 year of follow-up. Mean follow-up for the patients is 9.94 months. No patient has undergone re-operation or re-intervention.

4. Conduit Function

Echo done in immediate post-operative period revealed moderate pulmonary regurgitation (PR) in one patient, mild PR in 5 patients and no or trace PR in 13 patients with good coaptation of leaflets. CT angiography in 4 patients done at 6

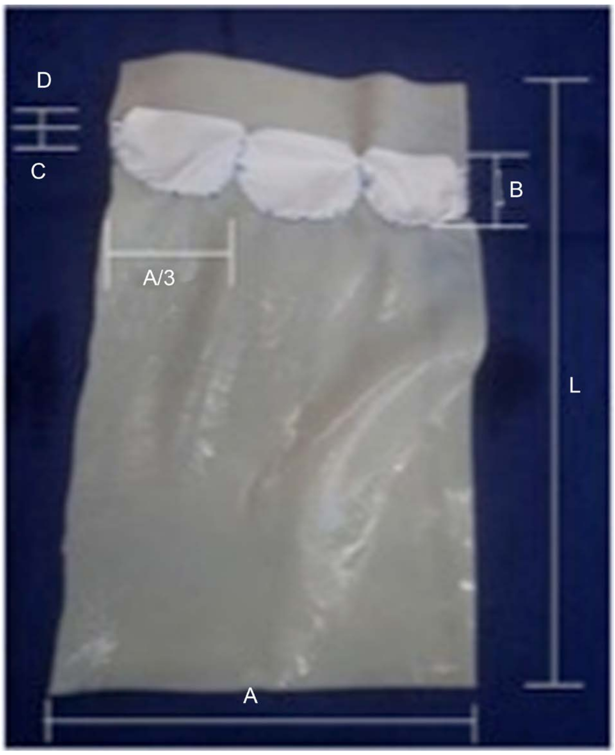

Figure 2. Conduit made from Gortex membrane.

Figure 3. Conduit made from pericardium.

weeks showed good lie of the conduit without external compression or kinking. Pre-operative severe Right Ventricle (RV) dysfunction was turned into moderate

Figure 4. Intra-operative picture of conduit implantation.

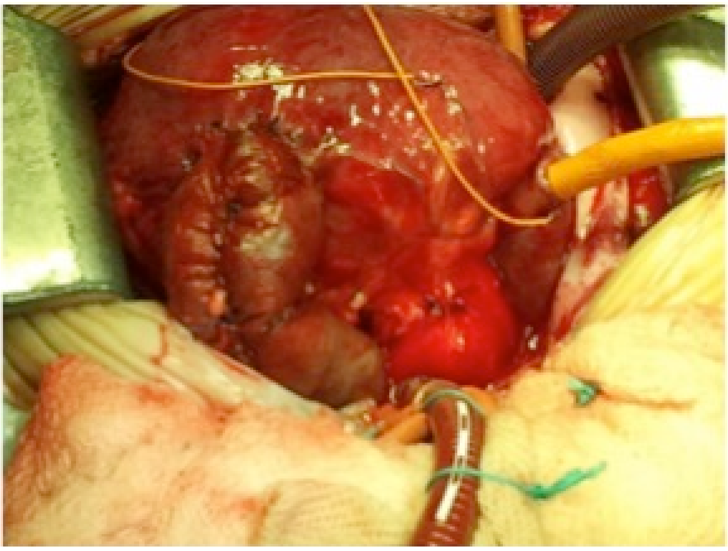

Figure 5. Final appearance of implanted conduit.

RV dysfunction in both the two patients despite moderate PR in one patient. Mean diameter of Conduit at the time of implantation was 20.7 mm, and we recorded no significance enlargement or decrease in the diameter at 6 weeks in all the patients and in 11 patients at 1 year.

Echocardiography suggested no (n = 9) or trace (n = 4) PR in 13 cases, mild PR in 5 cases and moderate PR in one case at 6 weeks of follow-up.

5. Discussion

The online search for Autologous Pericardial Valved Conduits (APVC) showed very few studies [1] [7].

While the RV-PA continuity remains a major concern in congenital heart surgery, cost of the homograft, availability of homograft bank and increasing number of neonatal surgeries favor development of the alternative ways for the same in developing countries like India. Cryopreserved homografts have replaced heterografts as the conduit of choice in the past 2 decades. Good short-term results have been obtained with homografts [8] [9], but the long-term results are disappointing [10] [11] [12], showing a high incidence of reoperations because of obstruction caused by shrinkage, calcification, or outgrowth of the conduit [10] [11] [12] [13]. Comparing to these results, autologous unpreserved pericardium has been shown to be a durable tissue that is pliable and easy to handle and suture [1]. The conduit we have prepared from unpreserved pericardium can be used in TGA (Transposition of Great Arteries) (either dextro-TGA or Levo-TGA), VSD and LVOTO (left ventricular outflow tract obstruction), broadening its application. Regarding usage of these conduits in Truncus arteriosus, Schlichter *et al.* described that they implanted smallest size of the conduit for repair of this disease, and at the time of re-operation it required only patch augmentation of distal anastomotic site [1].

These conduits offer several advantages, including availability, low cost, easy construction, absence of antigenicity, no need for sterilization and no need for cryopreservation. Regarding costs, all it requires only 4 Prolene 7-0 sutures to construct the conduit, making it several times cheaper than the available homografts.

The sizes we have selected were far large than Kirklin's minimum acceptable valve ring diameter full size, taking the leverage of conduit outgrowth.

The construction of this valved conduit requires a learning curve and practice. Initially we made many conduits from the harvested pericardium and tested them for leak from the suture lines and valvular regurgitation. We found that it requires meticulous stitching without excessive tension on both of the pericardial pieces, still creating a water-proof sealing.

Though we were inspired by the work of Schlichter *et al.* [14] in understanding the dimensions of the conduit valve, our conduit is different from their conduit by several ways.

1) They made bicuspid conduits whereas ours is tricuspid, 2) They used a trapezoid shaped strip to create valvular cusp, we use rectangular strip, 3) They didn't take the upper parabolic curvature into consideration as we did. We adopted our design from the cusp design described by Fan R. *et al.* [4], Billar *et al.* [5] and sinus drawings by Schäfers Hans-Joachim *et al.* [15].

Schlichter *et al.* showed a considerable number of patients developing cusp adherence with the luminal wall [1]. This is probably because of lack of the sinus of Valsalva in hand made conduit. The anatomy of sinus of Valsalva is very important in generating closing pressure and closing currents in the supravalvar area. Lack of sinus may result in non-coaptation of the leaflets despite of structural integrity and pliability. We tried to offset this phenomenon by creating a lager redundant upper curvature (Height D) helping the cusp to create a space for the vortices of the blood to enter the supra-cuspal space corresponding to sinus.

The short period of competence of the APVC valve is a relative disadvantage. Pulmonary competence in the immediate postoperative period is associated with better outcome [16] and pulmonary regurgitation is mostly well tolerated in the late outcome if not associated with other residual defects such as VSD, distal stenosis or pulmonary hypertension, and tricuspid regurgitation.

Our aim is to collect a long term data describing conduit function over the years, changes in conduit diameter, re-operation rate and histo-pathology at the time of explant.

6. Conclusion

Autologous or Homologous pericardial valved conduit provides good early results. They are especially suitable for developing countries like India because of zero cost. Long term usefulness of such option remains to be confirmed in terms of dilation, calcification and freedom from intervention. More studies are needed in this field. Construction of this conduit requires a learning curve which may hinder its usefulness. But with practice it can be an important tool in the hand of a congenital cardiac surgeon with virtually no cost.

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