**ORIGINAL ARTICLE**

# Hand Sewn Right Ventricle to Pulmonary Artery Conduit using Bovine Pericardium and Polytetrafluoroethylene (PTFE) Leaflets

SALMAN A. SHAH[1], M. ASIM KHAN[2], SAEEDAH ASAF[3], *FAIZ RASOOL[4], TEHMINA KAZMI[5], UZMA KAZMI[6], M. USAID QURESHI[7], NAJAM HYDER[8], JAMAL A. NASIR[9], MASOOD SADIQ[10]*

*[1]Assistant Professor of Pediatric Cardiac Surgery, Children's Hospital and Institute of Child Health Lahore, Pakistan.*
*[2]Department of Pediatric Cardiology. Children's Hospital and Institute of Child Health. Lahore, Pakistan*
*[3]Department of Pediatric Anesthesia. Children's Hospital and Institute of Child Health. Lahore, Pakistan*
*Correspondence to Dr. Salman A. Shah Email: salman1997@yahoo.co, Cell: 0321-4982220*

## ABSTRACT

**Background:** Patients with congenital heart disease (CHD) having hypoplastic or atretic right ventricular outflow tracts (RVOT); such as in transposition of the great arteries with pulmonary stenosis or pulmonary atresia with ventricular septal defect; require right ventricular outflow tract reconstruction, in the form of a right ventricle to pulmonary artery conduit (RV-PA conduit). The most common currently used right ventricle to pulmonary artery conduits (RV-PA) are homografts and bovine jugular vein.
**Aim:** To use handsewn bovine pericardial conduit with polytetrafluoroethylene (PTFE) membrane leaflets.
**Methods:** All patients undergoing RV to PA conduits at Children's Hospital Lahore were included in the study. The conduits used to reconstruct the RVOT were made intra operatively on a back table, using 0.1mm PTFE membrane to construct the valve leaflets and bovine pericardium to make the tube housing the leaflets. The leaflet heights and tube diameter were constructed according to a Z score-based nomogram.
**Results:** From January 2012 to December 2016, 34 patients received 35 hand sewn conduits of sizes 14 to 22mm. Mean age was 7 years (2 months to 18 years), mean weight was 23kg (9.4 to 53). 10 patients had TGA VSD PS, for which Rastelli operation was done. Nine had aortic valve disease for which Ross operation was performed. On 3 to 5 years follow up only one patient (2.9%) had required surgery for re-stenosis at the conduit.
**Conclusion:** On short and intermediate term follow up the handmade bovine pericardial tube with PTFE leaflet valve conduit is a functionally comparable, cost effective and reliable alternative to Homografts and Contegra conduits.
**Keywords:** RV to PA conduit, PTFE valve, bovine pericardium

## INTRODUCTION

Right ventricle to pulmonary artery valve conduits are required to establish continuity between the RV and pulmonary arterial tree. This sort or reconstruction is needed during corrective surgery for many different congenital heart diseases; such as Pulmonary atresia, Truncus Arteriosus, Ross operation, Transposition of great arteries with ventricular septal defect and pulmonary stenosis (TGA VSD PS), and in some forms of Double outlet right ventricle (DORV).

Nearly all conduits used for right ventricular outflow tract (RVOT) reconstruction require replacement because of stenosis or insufficiency, especially in infants and young children. Cryopreserved homografts have been the conduit of choice in the United States for RVOT reconstruction; and younger patient age at time of surgery or small implanted conduit size have been shown to be risk factors for decreased conduit durability[1,2,3]. As patients who have undergone such procedures in younger age outgrow the conduit,they will require further conduit change outs and upsizing. However, limited availability, short shelf life and high cost makes aortic or pulmonary homografts a less attractive option especially in a resource limited country. Another popular conduit is the bovine jugular vein xenograft (Contegra)[2,4], as well as cryopreserved femoral vein conduits[5]. Mechanical or tissue valves housed in a synthetic tube are also options but their cost and their non availability in all sizes are limiting factors, making them available only for older patients who have completed their growth. To overcome the problems of non-availability and cost, some centers are using handmade conduits[6-10].

We have used a 0.1mm thick polytetrafluoroethylene (PTFE) membrane to make three valve leaflets that are measured, cut to appropriate size and shape and then sewn onto a bovine pericardial patch that is then configured into a tube graft.

Received on 03-01-2020
Accepted on 27-05-2020

## MATERIALS AND METHODS

**Data Collection:** The institutional cardiac surgical database was reviewed. Patients who had undergone surgery requiring an RV to PA conduit were selected. A retrospective review of the patient demographics, chart, echo reports and surgical record was done. Cardiac catheterization data and surgical notes were used to record conduit size, cardiopulmonary bypass data, intraoperative findings such as underlying diagnosis, location, and nature of VSD, previous surgeries and other associated abnormalities. The information was entered into a structured database. The results were evaluated using SPSS.

**Surgical Technique:**

**Conduit Construction:** A standard sheet of bovine pericardium measuring 10cm by 15cmis selected.The sheet is cut to a predetermined width, roughly using the mathematical relationship of $Circumference = \pi d$ thereby ensuring the

diameter of the conduit. The length is kept at 10 cm and can be cut as required by the surgeon according to the intraoperative findings. A rectangular shaped piece of 0.1mm thick PTFE membrane of slightly larger width than the bovine pericardium is cut. The relationship between the leaflet height, free edge, commissural height, and overall diameter is fixed according to the nomogram shown below in Table 1.

Table 1: Pulmonary valve construction nomogram:

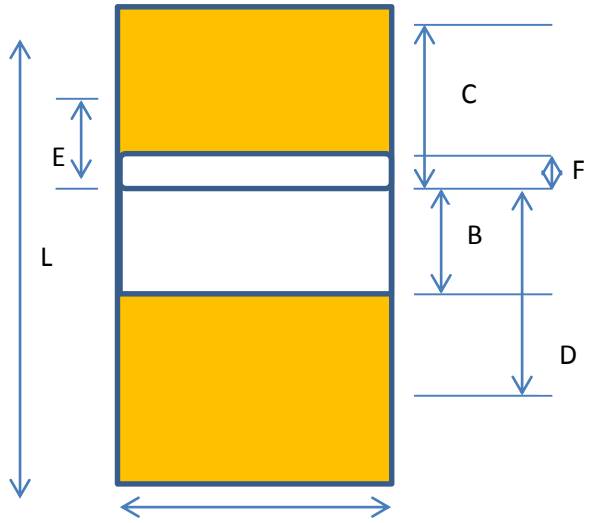
| **PA Size** | 14 | 16 | 18 | 20 | 22 | 24 |
|---|---|---|---|---|---|---|
| L | 100 | | | | | |
| A | 4.8 | 54 | 60 | 66 | 72 | 80 |
| B | 12.5 | 13.5 | 14.5 | 15.5 | 16.5 | 17.5 |
| C | 20 | | | | | |
| D | 20 | | | | | |
| E | 5 | | | | | |
| F | 1 | 1 | 2 | 3 | 3.5 | 4 |

*All measurements are in millimeters (mm)*
*L= Length of conduit*
*A= width of bovine pericardium*
*B= height of the cusp*
*C= distance between the upper end of cusp and distal end of conduit*
*D= length of pericardium under the cusp to be stitched to form tube*
*E= length/height of pericardium above the cusp to be stitched to form tube*
*F= height of Gore-Tex above the commissure. Functions as the free edge of the Gore-Tex leaflets*

The steps in the construction are described below and technical schematics are shown in Figure 1:

1. Mark and cut Bovine Pericardial width (A as per nomogram)
2. Take Gore-Tex membrane (0.1mm thickness) and cut to width B + F as per nomogram. *Keep the membrane a little loose side to side to allow sinus like function.
3. Mark height F and suture at these points.
4. Mark Gore-Tex membrane in thirds and place 6-0 stitches at level of the F stitch--- this point is the upper end of the commissure.
5. Take a second 6-0 stitch 5mm below the F level stitches—this point is the lower end of the commissure.
6. Take a 6-0 double loaded and mark nadir of each cusp.
7. Slit up to 5mm stitch vertically from below and cut lower leaflet corners with rounded edges.
8. Put stitch between the 5mm stitch and F stitch thereby completely closing and completing the commissure.
9. Sew double ended 6-0 up to commissures completely attaching lower end of leaflets to pericardial tube and thereby completing the sinuses.
10. Cut small divots in free edge above the commissure and stitch leaflets to each other.Fold BP tube and sew with 6-0 taking all four layers and completing conduit.

Figure 1.Conduit construction technical diagram:




The actual conduit construction and final product are shown in Figures 2, 3 & 4

Figure 2: Bovine pericardial sheet and 0.1mm PTFE membrane

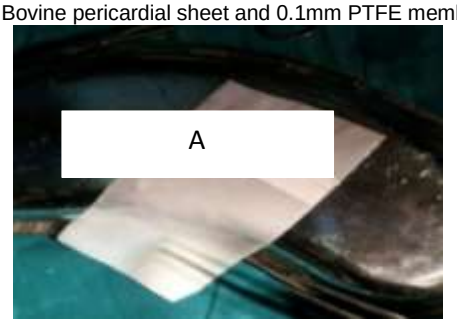



Figure 3: Leaflet construction:

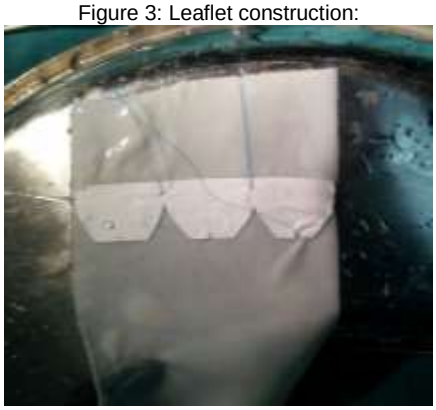
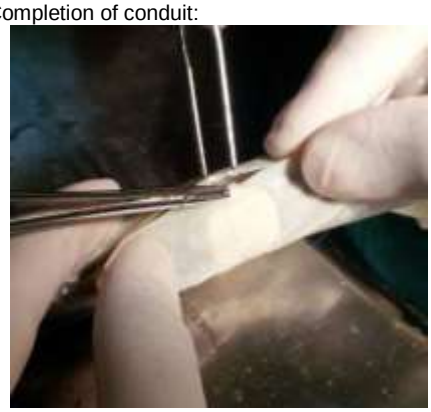


Figure 4:Completion of conduit:



**Conduit Implantation:** All patients underwent a standard first-time or redo median sternotomy.Cardiopulmonary bypass was established with ascending aortic and bicavalcannulations. Ventricular septal defects when presentwere closed first. After making openings in the pulmonary artery and the right ventricle. The distal end of the conduit was trimmed off at approximately 0.5 to 1 cm from the distal margin of the PTFEvalve. The distal anastomosis of the conduit with the pulmonary artery was performed first with a running suture. The proximal end was then trimmed accordingly, and the proximal anastomosis with the right ventricle was performed.

Every patient underwent intra operative epicardial or transesophageal echocardiography. Conduit stenosis was assessed with the help of flow velocity and valvular regurgitation was assessed with color Doppler. Further

echocardiography was performed usually at the first post-operative day, prior to discharge, and then at regularly scheduled follow up with their cardiologists.

All patients were discharged home on antiplatelet treatment in the form of Aspirin (75mg qd) and this was continued for at least the first 6 months after surgery.

## RESULTS

**Patient Characteristics:** From January 2012 to December 2015, we used 35Bovine pericardium with PTFE leaflet hand sewn conduits in 34 patients. There were 21 male and 13 female patients with M:F ratio of 2.6:1. Mean age of the patients was 7 years (range 1 months to 18 years). Mean weight was 23kg (range 4.5kg to 53kg). The most common implanted conduit size was 20mm that was used in 14 patients, 22 mm in 9 patients and size18 mm was used in 8 patients. One patient each had a 16mm and 14mm conduit.

Transposition of great arteries with ventricular septal defect and pulmonary stenosis was the most common diagnosis that was present in 10 patients who required Rastelli operation. Aortic valve disease was second most common pathology in which a Ross operation was performed. Six patients had undergone previous systemic to pulmonary artery palliative shunts.

Four patients had conduit change operation of whom 3 had a Rastelli operation for TGA VSD PS or Truncus arteriosus from some other institute before 2012, while one patient who had undergone a truncus repair at the age of 1 month at which time a size 14 conduit was implanted, requiring a conduit change at the age of 1 year.

There were 2 early mortalities (5.7%). There was no conduit related death. Two patients required immediate postoperative re exploration for bleeding. Intra operative echocardiogram showed no pulmonary regurgitation or stenosis in any of the conduits. At the time of discharge, mean gradient across the conduit was 16 mmHg (6-22). There was no patient who had greater than mild regurgitation in the conduit at the time of discharge. The diagnosis and surgical procedural data are summarized in Table 2.

Table 2: Primary diagnosis and surgical procedures:

| Diagnosis | Operative Procedure | n |
|---|---|---|
| TGA VSD PS | Rastelli operation | 10 |
| Pulmonary atresia VSD | Rastelli operation | 4 |
| Aortic valve disease (AS/ AR) | Ross operation | 9 |
| Truncus arteriosus | Truncus Repair (Rastelli operation) | 2 |
| Conduit stenosis | Conduit change | 4 |
| Tetralogy of Fallot | Rastelli operation | 6 |

**Follow up:** Out of 34 patient, 5 patients were lost to follow up. In 29 patients the follow up period ranged from 4 to 7 years. One patient developed moderate valvular stenosis at one month follow up echocardiogram, that did not progress, and one patient required a conduit change for stenosis (2.9%). Average pressure gradient across the conduit was14.0 mm Hg at 3 years, and 20mm Hg at 5 years and appeared to reach a plateau thereafter. Significant pulmonary regurgitation requiring re intervention did not occur in any of the conduits placed. There were no late mortalities and no reported conduit related endocarditis.

## DISCUSSION

Historically pulmonary or aortic homografts have been the most commonly used conduitsfor RVOT reconstruction to date, they have less than ideal performance in children, especially in neonates and infants[6]. Pakistan is a developing country where third party payers are not the norm and there is no local homograft tissue bank. The prohibitive cost of importing and non- availability of local homografts necessitated the search for alternative measures.

PTFE is a biologically inert, non-immunogenic material and it is relatively inexpensive. The cost of the materials needed for construction of the valved PTFE conduit are one tenth the cost of a similarly sized pulmonary homo-graft conduit. To further decrease the cost and its easy availability and excellent handling, we use bovine pericardium to make the tube.

Results of our study revealed that the Bovine pericardium with 0.1 mm PTFE leaflet hand sewn conduits, when implanted in the pulmonary position were associated with competent valve function with low incidences of conduit stenosis and perioperative complications. Thin 0.1 mm PTFE (Preclude) membrane has been implanted as a valvesince the early 1990s. Brown et al have reportedexcellent long-term results using PTFE as a monocuspvalve within the RVOT in patients undergoing TOF repair with a transannular patch and have significantly reducing early andmidterm pulmonary insufficiency without causing significant stenosis[11].

PTFE membrane has been reported to behave remarkably well in pulmonary position[12,6,13]. PTFE valve specimens on explantation have been reported to have smooth valve surfaceswith pliable leaflets and on microscopic evaluation, nostructural deterioration of the PTFE membrane, cellular infiltration, or calcification has been noted. This compares very favorably to aortic homografts, up to 20% percent of which have been reported to get calcified in 3 years[14]. Zhang et al compared the results of autologous pericardial valve conduits and PTFE valve conduits and concluded that PTFE valve conduit had lower incidence of graft failure[15].In our experience as most of the patients received a near adult size 20 mm conduit the need for conduit explant has been very low.

Some centers have reported constructing and using bileaflet valves, while most of others use trileaflet valves[16,9]. The search for the ideal prosthetic valve or valve conduit remains elusive[17], though the characteristics of an ideal prosthetic conduit have been well known and is one which possesses long-term patency, availability in a range of sizes, good handling characteristics, long-term valve function, growth potential, low cost, low infectious potential, and no need for anticoagulation.

As our study shows on short to medium term follow up the bovine pericardium with PTFE valve fulfills all these qualities except growth potential.

## CONCLUSION

In a low income developing country such as Pakistan, without third party payers where the socioeconomic status makes proven conduits such as Contegra and Homografts prohibitively expensive the self-constructed bovine pericardial conduit with PTFE valve has proven to be a cost effective and reliable alternative. However, more studies with long term follow up are required to determine if these advantages stand the test of time.

## REFERENCES


1. Brown JW, Ruzmetov M, Rodefeld MD, Vijay P, Turrentine MW. Right ventricular outflow tract reconstruction with an allograft conduit in non-ross patients: Risk factors for allograft dysfunction and failure. Ann Thorac Surg [Internet]. 2005 Aug [cited 2020 Jul 30];80(2):655–64. Available from: https://pubmed.ncbi.nlm.nih.gov/16039222/
2. Brown JW, Ruzmetov M, Rodefeld MD, Vijay P, Darragh RK. Valved Bovine Jugular Vein Conduits for Right Ventricular Outflow Tract Reconstruction in Children: An Attractive Alternative to Pulmonary Homograft. Ann Thorac Surg. 2006 Sep;82(3):909–16.
3. Shinkawa T, Tang X, Gossett JM, Mustafa T, Hategekimana F, Watanabe F, et al. Valved Polytetrafluoroethylene Conduits for Right Ventricular Outflow Tract Reconstruction. In: Annals of Thoracic Surgery [Internet]. Elsevier USA; 2015 [cited 2020 Jul 28]. p. 129–37. Available from: https://pubmed.ncbi.nlm.nih.gov/26004923/
4. Ichikawa Y. A new RV-PA conduit with a natural valve made of bovine jugular vein. ASAIO J. 1992;38(3).
5. Schiller O, Sinha P, Zurakowski D, Jonas RA. Reconstruction of right ventricular outflow tract in neonates and infants using valved cryopreserved femoral vein homografts. In: Journal of Thoracic and Cardiovascular Surgery [Internet]. J Thorac Cardiovasc Surg; 2014 [cited 2020 Jul 30]. p. 874–9. Available from: https://pubmed.ncbi.nlm.nih.gov/24342904/
6. Mercer CW, West SC, Sharma MS, Yoshida M, Morell VO. Polytetrafluoroethylene conduits versus homografts for right ventricular outflow tract reconstruction in infants and young children: An institutional experience. J Thorac Cardiovasc Surg [Internet]. 2018 May 1 [cited 2020 Jul 29];155(5):2082-2091.e1. Available from: https://pubmed.ncbi.nlm.nih.gov/29455964/
7. Zhang H, Ye M, Chen G, Jia B. 0.1 mm ePTFE versus autologous pericardium for hand-sewn trileaflet valved conduit: a comparative study. J Artif Organs. 2019 Sep 13;22(3):207–13.
8. Mercer CW, West SC, Sharma MS, Yoshida M, Morell VO. Polytetrafluoroethylene conduits versus homografts for right ventricular outflow tract reconstruction in infants and young children: An institutional experience. J Thorac Cardiovasc Surg [Internet]. 2018 May 1 [cited 2020 Jul 30];155(5):2082-2091.e1. Available from: https://pubmed.ncbi.nlm.nih.gov/29455964/
9. Kasturi S, Prabhu S. Handmade trileaflet valved ePTFE right ventricle to pulmonary artery conduit - How do we do it? Multimed Man Cardiothorac Surg MMCTS [Internet]. 2020 May 26 [cited 2020 Jul 30];2020. Available from: https://pubmed.ncbi.nlm.nih.gov/32459078/
10. Ootaki Y, Williams DA. To create or pull from the shelf? Vol. 155, Journal of Thoracic and Cardiovascular Surgery. Mosby Inc.; 2018. p. 2092–3.
11. Brown JW, Ruzmetov M, Rodefeld MD, Vijay P, Darragh RK. Valved bovine jugular vein conduits for right ventricular outflow tract reconstruction in children: an attractive alternative to pulmonary homograft. Ann Thorac Surg [Internet]. 2006 Sep [cited 2020 Jul 28];82(3):909–16. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16928507
12. Chang TI, Chang CI. An efficient way to make a trileaflet conduit for pulmonary valve replacement. Ann Thorac Surg [Internet]. 2013 Dec [cited 2020 Jul 28];96(6). Available from: https://pubmed.ncbi.nlm.nih.gov/24296231/
13. Ando M, Takahashi Y. Ten-year experience with handmade trileaflet polytetrafluoroethylene valved conduit used for pulmonary reconstruction. J Thorac Cardiovasc Surg [Internet]. 2009 Jan [cited 2020 Jul 28];137(1):124–31. Available from: https://pubmed.ncbi.nlm.nih.gov/19154914/
14. Javadpour H, Veerasingam D, Wood AE. Calcification of homograft valves in the pulmonary circulation - Is it device or donation related? Eur J Cardio-thoracic Surg [Internet]. 2002 [cited 2020 Jul 29];22(1):78–81. Available from: https://pubmed.ncbi.nlm.nih.gov/12103377/
15. Zhang HF, Ye M, Yan XG, Chen G, Tao QL, Jia B. Application of a Simplified Hand-Sewn Trileaflet Valved Conduit in Right Ventricular Outflow Tract Reconstruction as an Alternative for Bovine Jugular Vein Graft: Single-Center Experience. Artif Organs [Internet]. 2018 Jan 1 [cited 2020 Jul 28];42(1):41–8. Available from: https://pubmed.ncbi.nlm.nih.gov/28971487/
16. Ramírez-Marroquín S, Curi-Curi PJ, Calderón-Colmenero J, García-Montes JA, Cervantes-Salazar JL. Common Arterial Trunk Repair by Means of a Handmade Bovine Pericardial-Valved Woven Dacron Conduit. World J Pediatr Congenit Hear Surg [Internet]. 2017 Jan 29 [cited 2020 Jul 30];8(1):69–76. Available from: http://journals.sagepub.com/doi/10.1177/2150135116674439
17. Kaza AK. What is the ideal conduit or technique for reconstruction of the right ventricular outflow tract? Vol. 155, Journal of Thoracic and Cardiovascular Surgery. Mosby Inc.; 2018. p. 2080–1