Hand Sewn Bovine Pericardial Conduit with Tri-leaflet Valve in Right Ventricular Outflow Tract: Review of 41 patients.

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Abstract

Introduction: The currently available options for restoring right ventricle (RV) to pulmonary artery (PA) continuity are far from satisfactory. In absence of an ideal conduit, hand sewn bovine pericardial conduit with Polytetrafluroethylene (PTFE) tri-leaflet valve (BPCTV) may serve as a satisfactory alternative particularly in low and middle income countries (LMIC). Material and Methods: The hospital records of all patients who received BPCTV in RV to PA position from January 2014 to June 2019 were retrospectively analysed. A total of 41 patients were further classified into two groups; pulmonary hypertension group (PH) and non-pulmonary hypertension group (NPH). The primary endpoints of the study were mortality, and freedom from re-operation for conduit failure. The secondary end point was to study the impact of pulmonary hypertension on the conduit function and durability. Results: The Mean age and weight of patients at time of conduit implantation was 56.8 months (range 2-196 months) and 12.3 kg (range 3-44 kg) respectively. The mean size of conduit was 18 mm (range 12-24 mm). The mean duration of follow up was 30 months (range 8-72 months). The freedom from re-intervention was 86% at 30 months (range 8-72 months). The cost of BPCTV was less than one-sixth of the commercially available bovine jugular vein conduit. Conclusion: The hand sewn BPCTV is a cost effective alternative to commercially available conduits with acceptable outcomes. However, more research with a larger sample size and a longer follow-up is required.

Introduction

Restoration of right ventricle (RV) to pulmonary artery (PA) continuity is an essential component of surgical procedures performed for many congenital heart defects. In addition to the primary procedure, the patient will undergo multiple re-operations for revision of the RV to PA conduit. The cumulative cost of therapy may become substantial in the first decade of patient's life and is comparable to that of patients with single ventricle physiology. (1,2) The considerable resource utilisation for this group of patients can be prohibitive in low and middle income countries (LMICs).

An ideal RV to PA conduit should be easily available, durable, offer resistance to infection, prevent thrombosis and able to grow with the child. Although an ideal conduit does not exist, several options are available. As stated previously, commercially available conduits are expensive and can exponentially increase the cost of surgery in low and middle income countries. Homograft valve banks are resource intensive to maintain and as a result most paediatric cardiac programs in LMICs do not have access to homografts. These factors have renewed the interest in hand sewn conduits. Recent evidence has shown that the hand sewn conduits implanted in RV to PA position have an acceptable clinical outcome which compares favourably with the commercially available conduits. (3) We present a single centre experience with forty one patients who underwent for RV-PA conduit implantation using bovine pericardial conduit with tri-leaflet valve (BPCTV).

Material and Methods

The single centre retrospective study included all 41 patients who received a BPCTV in the RV to PA position between January 2014 to June 2019. Medical records were analysed for the demographic data, surgical procedure, cardiopulmonary bypass parameters, ventilation duration, ionotrope score, hospital stay and follow-up evaluation. These patients were separated into two groups depending on the presence (PH group) or absence (NPH group) of pulmonary hypertension. (Tabel 1& 2) The primary endpoints were mortality and freedom from re-intervention for conduit failure. The criteria for conduit failure were defined as more than moderate regurgitation and/or peak gradient of more than 60 mmHg.

Surgical Technique

The conduit was constructed prior to skin incision with a bovine pericardial sheet (St. Jude Medical, St.Paul, MN) for the tube and 0.1mm thick e-PTFE (Gore-Tex; W. L. Gore & Assoc., Newark, DE) for the tri-leaflet valve. The size of BPCTV conduit was +2 Z score of the pulmonary valve for the body surface area. Three contiguous cusps are fashioned from a sheet of 0.1mm e-PTFE membrane and sutured to the smooth side of bovine pericardial sheet. The bovine pericardial sheet is rolled over a required sizer and its free edges are sutured to create a valved conduit. (Figure 1,2) The formula used for constructing conduits of size 12 to 24 is given in table 3. The surgery was performed through median sternotomy on Cardiopulmonary bypass with moderate hypothermia. The choice of Cardioplegia was antegrade delivery of DelNido's solution at 4 degree C. The distal end of the conduit was sutured to the pulmonary artery confluence on beating heart in presence of pulmonary atresia and type 1 Truncus arteriosus. In all other cases, both ends of the conduit were sutured under cardioplegic arrest.

Statistical Methods:

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student t-test (two tailed, independent) was used to find the significance between groups (Inter group analysis) on metric parameters.

Results

The Mean age, weight and conduit size were 56.8 months (range 2-196 months), 12.3 kg (range 3-44 Kg) and 18.4 mm (range 12-24 mm) respectively. The male to female ratio was 25:16. The age and weight of children in PH group was significantly lower than those in NPH group. There were two early death. A child with truncus arteriosus in PH group died due to intractable pulmonary hypertensive crisis. Another child with Tetralogy of Fallot and anomalous coronary artery crossing the RVOT in NPH group died due to right ventricular dysfunction and sepsis. The conduit was functioning well in all discharged patients. Five patients (12.2%) had mild regurgitation, eight patients (19.5%) had trivial regurgitation and 28 patients (68%) had no regurgitation at discharge.

There was one late unrelated death due to pneumonitis and three patients were lost to follow-up. The remaining thirty-five patients were evaluated at a mean follow-up duration of 30 months (range 8-72 months). Four of these patients were followed up telephonically. They were said to be asymptomatic, but could not be evaluated in the hospital due to socio-economic constraints. Of the thirty-one patients who underwent echocardiogram twenty-nine patients had nil to mild regurgitation and only two patients had moderate regurgitation. The mean gradient at last follow up was 30.7 mmHg (range 6-120 mmHg), Five of the patients had RVOT gradients of more than 60 mmHg. One patient had gradient in the immediate postoperative period due to technical failure and the conduit was revised prior to discharge. The remaining four patients developed gradients at a mean follow-up of 60 months. Two of these have under gone conduit revision and the other two are awaiting re-operation. There was no significant difference between the degree of regurgitation in the pulmonary hypertensive and non-hypertensive group at last follow up (Tabel 4)

Discussion

The quest for an ideal conduit to establish RV to PA continuity began in 1964, when Rastelli et al implanted the first valveless pericardial tube in a patient with pulmonary atresia. (4) It was soon realised that

competent RVOT has its advantages and Ross et al implanted the first valved conduit in an eight year old boy with VSD pulmonary atresia. (5) This was closely followed by Rastelli et al when two children with transposition of great arteries, VSD and pulmonary stenosis underwent the eponymous Rastelli's operation. (6) Irradiated cryopreserved aortic homografts were implanted in all three patients. However, the techniques of cryopreservation were crude resulting in rapid degeneration of the homografts. These were replaced by gluteraldehyde preserved porcine aortic valves mounted in Dacron tube grafts. The midterm outcomes of porcine xenografts are acceptable but the failure rate at 10 years as demonstrated by Belli et al was high. (7) The freedom from re-operation following a Hancock conduit was 98%, 81% and 32% at 1, 5 and 10 years respectively. (7) By the mid-1980s, the techniques of cryopreservation process had improved and once again Homografts became the conduit of choice. Though, homografts had several advantages over Dacron mounted xenografts, ease of handling being one of them, limited availability in smaller sizes led to the emergence of another xenograft in the form of bovine Jugular vein (Contegra, Medtronic Inc). (8,9) The bovine Jugular vein has a trileaflet valve and it delivered outcomes comparable to homografts with an added advantage of availability in smaller sizes. (10) A multi-centre European study by Breymann et al involving 165 Contegra implants found that the results were comparable to homografts. (11). Another study by Sandica et al involving 444 consecutive implantation concluded that the bovine jugular veins in RVOT in patients below 25 years had superior outcomes when compared with cryopreserved homografts. (10)

The commercially available options to choose from are pulmonary or aortic homograft, porcine valve in Dacron tube, Porcine valve in bovine pericardial tube and bovine jugular vein. Though, commercially marketed conduits are easily available, high cost precludes its wider use in countries with limited financial resources. The surgeons are often compelled to use conduits prepared in the operating room from e-PTFE, Dacron and autologous or bovine pericardium. (12,13) The early and midterm outcomes of these hand sewn counts have been satisfactory and comparable with the commercially available options. (14,15)

The majority of the published series with hand sewn conduits have used PTFE tube graft for the conduit. Our series is perhaps the first where bovine pericardial sheet is used to construct the conduit. The bovine pericardium is easy to handle and is haemostatic. One of the drawbacks of the bovine pericardial conduit is that it calcifies and forms dense adhesions with the surrounding structures which can complicate the re-operations. The cost of hand sewn BPCTV is $300 which is one-sixth of the cost of commercially available Contegra bovine jugular vein conduit. This cost advantage makes BPCTV an attractive alternative in low resource environments. The early and midterm results of BPCTV in our series were acceptable with freedom from re-intervention of 86% at 30 months.

Limitations

The larger sample size and a longer follow-up period is required.

Conclusion

This is the first study where hand sewn bovine pericardial conduits have been used to restore RV to PA continuity. The BPCTV functioned well at early and midterm follow-up. The presence of pulmonary hypertension had no impact on the durability of the conduit in early and midterm follow up. The use of the BPCTV in resource limited locations can be a reasonable bridge. However, more research with a larger sample size and a longer follow-up is required.

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Institutional Ethics Committee has approved the study.

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Legend

Tabel 1 : Diagnosis

ACA: Anomalous coronary artery, APVS: Absent pulmonary valve syndrome, DOLV: Double outlet left ventricle, DORV: Double outlet right ventricle, LTGA: l-posed transposition of great arteries, NPH: No pulmonary hypertension, PH: Pulmonary hypertension, PA: Pulmonary atresia, PS: Pulmonary stenosis, TA: Truncus arteriosus, TGA: Transposition go great arteries, TOF: Tetralogy of fallot, VSD: Ventricular septal defect

Tabel 2 : Patient variables

ACC: Aortic cross clamp, CPB: Cardiopulmonary bypass, ICU: Intensive care unit

Tabel 3 : Conduit construction guideline

A: Width of pericardial sheet, B: Height of the cusp without the free edge,C: Free edge of the cusp, D: Commisure height, E: Width of the e-PTFE membrane (A+3), F: Conduit length distal to valve, G: Length of pericardial sheet (F and G are variable and are fashioned as per requirement during implantation)

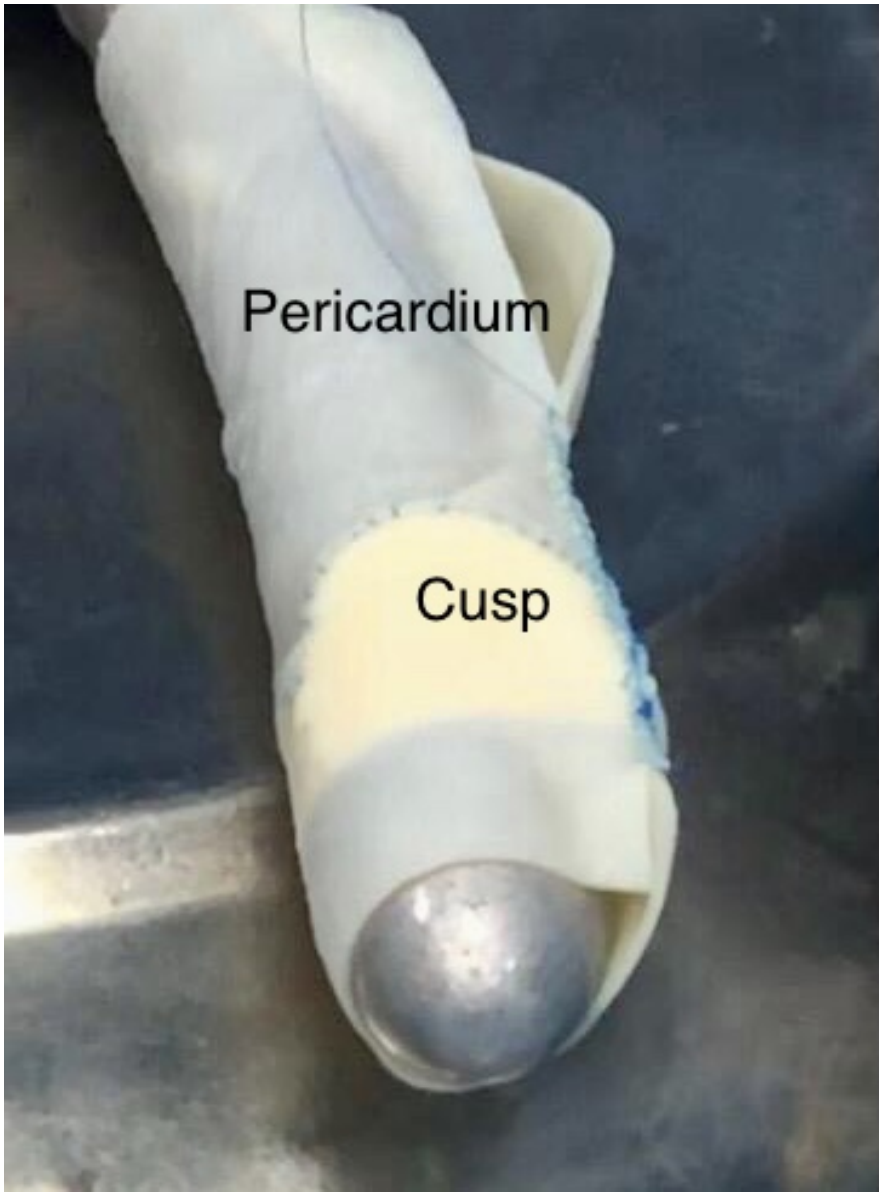
Tabel 4: Conduit regurgitation at discharge and follow-up

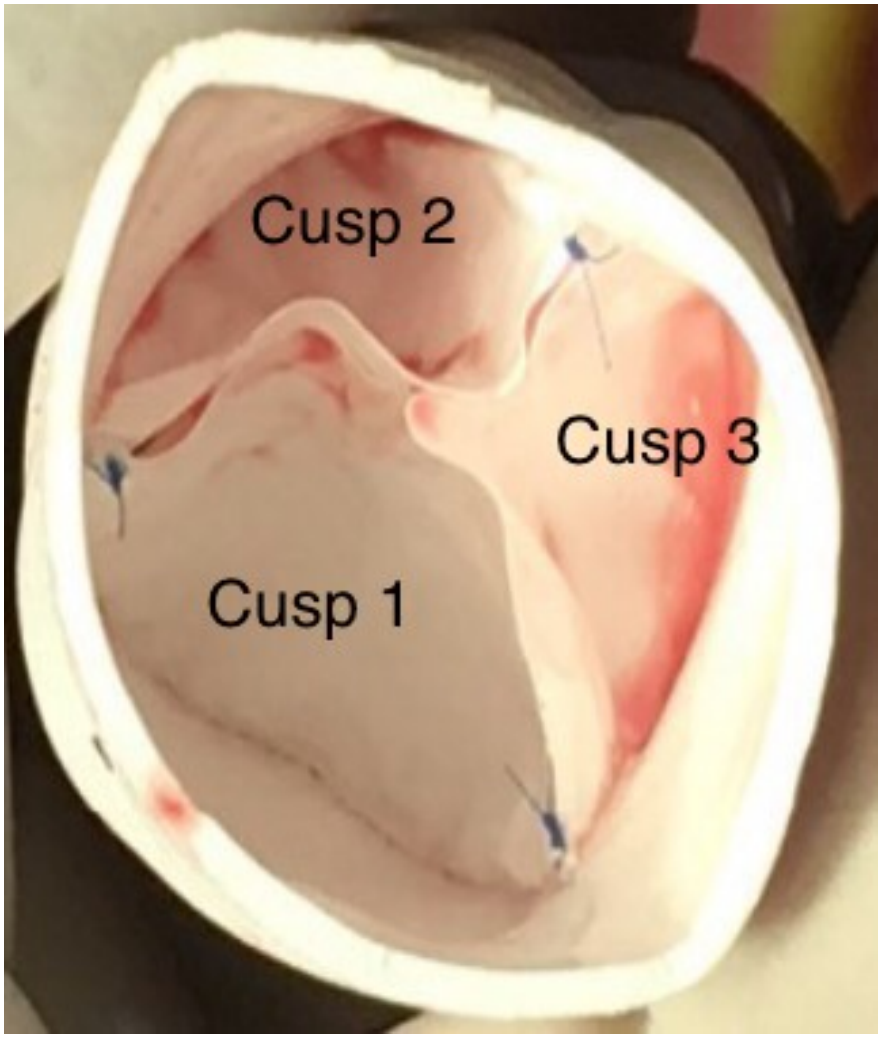
PH: Pulmonary hypertension , NPH: No Pulmonary Hypertension

P value Non significant, Fisher Exact Test

Figure 1 : Construction of bovine pericardial PTFE tri-leaflet valved conduit

Figure 2 : End-On view of the PTFE tri-leaflet valve





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