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Original Article

Polytetrafluoroethylene pulmonary valve conduit implantation for chronic pulmonary insufficiency*

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Abstract Pulmonary valve replacement in patients with congenital cardiac disease is now being performed with more liberal indications in light of the data that chronic pulmonary insufficiency is not a benign lesion. The beneficial effects of valve replacement with low operative mortality and morbidity support this approach. Many options exist for a pulmonary valve prosthesis, which underscores the fact that there is no ideal valve available. Our efforts are focussed around a synthetic valve that avoids the bio-degeneration of a bio-prosthesis and avoids the need for life-long coumadin. We developed a bicuspid (bileaflet) polytetrafluoroethylene valve design, which has now gone through three major revisions in > 200 patients over 14 years. We began the experience utilising a polytetrafluoroethylene hand-sewn bicuspid valve in the right ventricular outflow tract, initially using 0.6 mm and more recently 0.1 mm polytetrafluoroethylene. The 0.1 mm thickness material functions well as a leaflet, maintaining a relatively thin and flexible nature. It does not calcify or initiate thromboses at least for the first several years. We identified issues with dehiscence of the leaflet from the right ventricular outflow tract muscle, especially in the larger, potentially expansive right ventricular outflow tracts, and this prompted our latest design change to place the valve within a polytetrafluoroethylene tube. This current version of the polytetrafluoroethylene valve conduit has excellent short-to-intermediate-term function. Further follow-up is necessary to determine late durability and life-long valve-related procedural risk for our patients.

Keywords: Pulmonary insufficiency; pulmonary valve replacement

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THE NEED FOR PULMONARY VALVE REPLACEMENT is increasing for many congenital cardiac patients.[1–26] In the past, chronic pulmonary insufficiency after repair of tetralogy of Fallot was felt to be benign. More recent evidence suggests that pulmonary insufficiency and volume overload physiology cause significant morbidity, producing right ventricular dilatation and dysfunction, exercise intolerance, arrhythmias, and possible sudden death.[1,2,5] We will review the beneficial haemodynamic effects, as well as the indications and technique for insertion of a polytetrafluoroethylene pulmonary valve conduit for pulmonary valve replacement in patients with chronic pulmonary insufficiency.

There are numerous reports that support the role of pulmonary valve replacement in patients with chronic pulmonary insufficiency.[3–5] Pulmonary valve replacement allows for symptomatic improvement and improved right heart function, and possibly improved control of arrhythmias when performed within a reasonable time frame. Unfortunately, recent data also show lack of recovery of right cardiac indices following pulmonary valve replacement in adults with long-standing pulmonary insufficiency and right cardiac dysfunction.[8] Timing of surgical therapy is therefore important in obtaining an optimal surgical result for the patient. In addition, an aggressive programme of preoperative electrophysiologic evaluation, combined with intra-operative cryoablation, has been shown to optimise control of arrhythmias in the appropriate patient.[9]

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Indications for pulmonary valve replacement continue to evolve. These are based on the accumulation of natural history data, as well as the short- and long-term effects of surgical therapy. Current indications for pulmonary valve replacement include patients with moderate-to-severe pulmonary insufficiency and:

- NYHA class II exertional symptoms;
- right ventricular dysfunction and/or dilatation (>150 ml/m^2 by MRI);
- decreased performance on exercise testing;
- ventricular arrhythmias and/or prolonged QRS duration (>160 ms).

Overall, the operative technique for pulmonary valve replacement utilises cardiopulmonary bypass with or without aortic cross-clamping, depending on surgeon preference and the need to repair additional lesions such as septal defects. The majority of these procedures require re-entry sternotomy and can present significant challenges to the surgeon. Appropriate preoperative planning and judicious use of peripheral cannulation are implemented as needed. The operative mortality is in the range of 1–2%.

There are many surgical prosthetic options available for pulmonary valve replacement. The ideal valve does not exist and all choices have limitations. Most patients receive a bio-prosthesis such as a homograft or heterograft, either stented or un-stented.[10–12] All of these valves are non-living and non-repairable, and share a common durability issue. They undergo a bio-degenerative process and ultimately will fail with obstruction and/or insufficiency over time. There are complex interactions among many variables that determine the mode and time to failure of these prosthesis. In addition, homografts seem to generate an immune-mediated response, which may augment their degradation and also produce high panel reactive antibody levels.[13] Current interest is high with regard to viable valve leaflet tissue valves (bio-engineered), but many issues need resolution before these are utilised in everyday practice.[14] Alternatively, a mechanical valve is an option, albeit with limited experience in the pulmonary position. The possibility of thromboembolic events and the need for systemic anticoagulation with coumadin generally make this a less attractive option.[15]

Our interest in an alternative to the aforementioned options stemmed from the inevitable failure of biological valves placed in children and young adults. We sought to utilise a synthetic valve (polytetrafluoroethylene), which avoids the bio-degradation of all biological valves and also avoids the need for life-long coumadin. Preliminary data with polytetrafluoroethylene as a monocusp[16] demonstrated freedom from calcification, thickening, and obstruction as a mode of failure; however, these valves became incompetent in a relatively short period of time. We developed a bicuspid (bileaflet) polytetrafluoroethylene valve design,[17,18,19,20] which has now gone through three major revisions in >200 patients over 14 years. We began the experience utilising a polytetrafluoroethylene hand-sewn bicuspid valve in the right ventricular outflow tract, initially using 0.6 mm and more recently 0.1 mm polytetrafluoroethylene. The 0.1 mm thickness material functions well as a leaflet, maintaining a relatively thin and flexible nature. It does not calcify or initiate thromboses at least for the first several years. We identified issues with dehiscence of the leaflet from the right ventricular outflow tract muscle, especially in the larger, potentially expansive, right ventricular outflow tracts, and this prompted our latest design change to place the valve within a polytetrafluoroethylene tube.

The leaflets within the tube are protected from strong radial forces and seem to function quite well. The construction of the valve is now somewhat easier and reproducible in a uniform diameter tube. Implantation is also simpler as an interposition graft. Our early-to-intermediate experience (4 years' unpublished data) demonstrates excellent valve competence and freedom from obstruction using aspirin therapy alone. Longer-term follow-up will determine durability compared with other available options. In addition, this valve conduit should provide an excellent landing zone for future trans-catheter valve deployment as needed.

In summary, pulmonary valve replacement in the patient with congenital cardiac disease is now being performed with more liberal indications in light of

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the data that chronic pulmonary insufficiency is not a benign lesion. The beneficial effects of valve replacement with low operative mortality and morbidity support this approach. There are many options for a pulmonary valve prosthesis, which underscores the fact that there is no ideal valve available. Our efforts are focussed around a synthetic valve that avoids the biodegeneration of a bio-prosthesis and avoids the need for life-long coumadin. The current version of the polytetrafluoroethylene valve conduit has excellent short-to-intermediate-term function. Further follow-up is necessary to determine late durability and life-long valve-related procedural risk for our patients. Bioengineered viable tissue valves with life-long regenerative capabilities and minimally invasive methods of inserting a normally functioning valve are forthcoming. The ideal valve for pulmonary valve replacement at this time, however, is far from reality.

Acknowledgement

None.

Ethical Standards

The authors assert that all procedures contributing to this study comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. This project is approved by the Institutional Review Board of All Children's Hospital.

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