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Original Article

Transcatheter pulmonary valve insertion, expanded use (beyond large conduits from the right ventricle to pulmonary artery), and future directions*

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Abstract Transcatheter pulmonary valve insertion is the most important advance in congenital interventional cardiology since atrial septal defect devices became commonly available 15 years ago. It has changed the way we look at a number of diverse diagnoses and changes how we plan, diagnose, operate, and follow-up patients. It has changed how we counsel families expecting a child that may benefit from it. Expanded use of the Melody® valve, outside its United States Food and Drug Administration approved indications, has helped numerous additional patients. The use of transcatheter pulmonary valve insertion in selected patients following surgical Gore-tex® bileaflet in valve right ventricular outflow tract reconstruction and those with a history of prior small homograft conduits will be discussed.

Keywords: Transcatheter pulmonary valve; Gore-tex® bileaflet valve; melody valve

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Transcatheter pulmonary valve insertion is both a revolutionary and evolutionary procedure as it leads to a shift in the management of a diverse group of congenital heart disease patients. It is revolutionary in that we now have a powerful new tool that at least allows most patients with a right ventricle to pulmonary artery conduit to lengthen the duration of time between surgeries.[1–3] With this change, the accumulated number of total lifetime sternotomies and cardiopulmonary bypass runs should fall significantly. This should almost certainly diminish patient cumulative lifetime morbidity. This applies to patients with diagnoses ranging from pulmonary atresia with ventricular septal defect, following septation and right ventricle to pulmonary artery conduit, to critical aortic stenosis, following the Ross operation to aortic atresia, with ventricular septal defect, following the Yasui operation. Little in the past decade in congenital intervention has influenced as many aspects of care as has transcatheter pulmonary valve insertion. From foetal cardiac counselling for families expecting a baby with pulmonary atresia, to surgical approaches attempting to utilise a larger conduit, to the management of adult congenital patients, the ability to replace the pulmonary valve without a sternotomy alters many aspects of care.

Transcatheter pulmonary valve insertion is evolutionary in that the typical steps for valve delivery build on and derive from prior experience with balloon-expandable stenting.[4,5] This has allowed for the rapid adoption of transcatheter pulmonary valve insertion worldwide. Since Melody® valve (Medtronic, Minneapolis, Minnesota, United States of America) regulatory approval (2006 in the European Union and Canada, 2010 in the United States of America), there have been ~7000 worldwide implants with 165 implanting centres in 27 countries on six continents (unpublished data, Medtronic).

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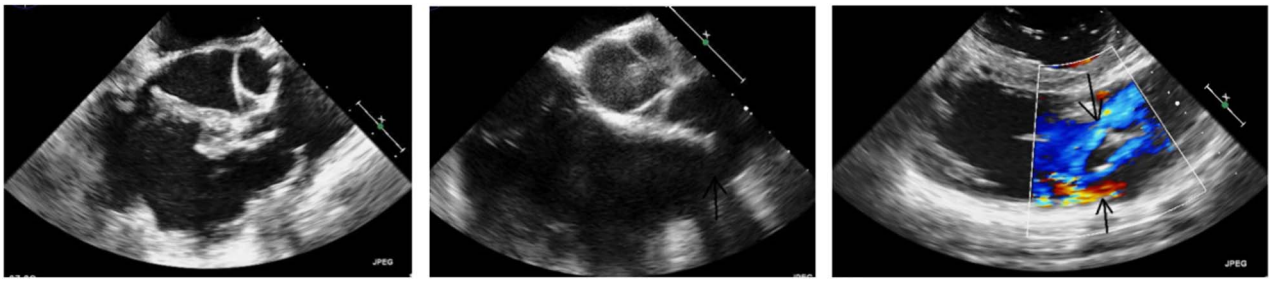

Figure 1.
Transoesophageal echocardiography (TOE) images from three different Gore-tex® bileaflet valve (GTBV) patients. The left panel demonstrates a transcatheter pulmonary valve insertion (TPVI) favourable stuck-open valve leaflet appearance. The middle panel arrow demonstrates complete dehiscence and absence of the anterior pulmonary valve leaflet, not a good TPVI candidate. The right panel arrows demonstrate large paravalvular leaks in both posterior and anterior pulmonary valve leaflets, also not a good TPVI candidate.

As with most new technologies in congenital intervention, the remarkable success of the transcatheter pulmonary valve insertion in right ventricle to pulmonary artery conduit has led to its expanded use in a divergent group of patients with a dysfunctional right ventricular outflow tract. This has included its use in native right ventricular outflow tracts, branch pulmonary arteries, and dysfunctional bioprosthetic valves.[6–9] Delivery of the valve larger than intended (at 24 mm) has also been successful without an appreciable change in valve function.[10] As is typical of any newly available technology, operators have sought to push the equipment forward and expand the patient population that can benefit from its use. Our understanding of both the prevention and treatment of stent fracture and endocarditis have also improved.[11–13]

Finally, the current early experience with the Medtronic native right ventricular outflow tract pulmonary valve opens enormous new doors for patients with congenital heart disease. Although only an engineering feasibility study, it is the logical extension of success thus far with right ventricle to pulmonary artery conduit patients. It is currently estimated that only 15% of patients late following surgical right ventricular outflow tract reconstruction are candidates for current transcatheter pulmonary valve insertion, but with this new development it is highly likely that far more patients will benefit in the future.

In this paper, we intend to discuss and give examples of current transcatheter pulmonary valve insertion beyond approved United States Food and Drug Administration approved uses, and consider future directions.

Methods

Retrospective review of selected patients having undergone transcatheter pulmonary valve insertion in a single centre, extended, or off-label use will be discussed. All use of the Melody® valve was approved by the hospital institutional review board and appropriate consent/assent was obtained for all patients.

Gore-tex® bileaflet valve patients

Our surgical group has had success in the use of hand-sewn Gore-tex® (WL Gore, Flagstaff, Arizona, United States of America) bileaflet valve surgical pulmonary valve replacement without a right ventricle to pulmonary artery conduit. This technique has been used as an alternative to bioprostetic valves, bioprosthetic valved conduit, or homograft right ventricle to pulmonary artery conduits.[14] The advantages of this approach have included excellent initial and medium-term valve function, simplicity of valve construction, lower cost, and lack of biological response to the predominantly inert valve material. It is owing to these advantages that our programme has one of the largest experiences in the world with this type of surgical pulmonary valve replacement. It is also because of this that we have, over the last several years, evaluated many patients late after surgical pulmonary valve replacement with a Gore-tex® bileaflet valve, and found that some of them have been candidates for transcatheter pulmonary valve insertion with the Melody® valve. This has thus far only proven true for patients in whom the Gore-tex® bileaflet valve was made from 0.6 mm thickness Gore-tex®. It appears that late valve dysfunction in this patient group sometimes is because of valve leaflet thickening and calcification. The valve takes a "stuck partially open" appearance on transoesophageal echocardiography and physiologically demonstrates moderate or severe pulmonary stenosis (PS) in combination with moderate or severe pulmonary regurgitation (PR). Among patients with a surgical history of a 0.6mm thickness Gore-Tex bileaflet valve thus far evaluated, marked dehiscence of one or both of the leaflets has been seen in a few (see Fig 1).

We have brought 11 patients for cardiac catheterisation and consideration of late transcatheter

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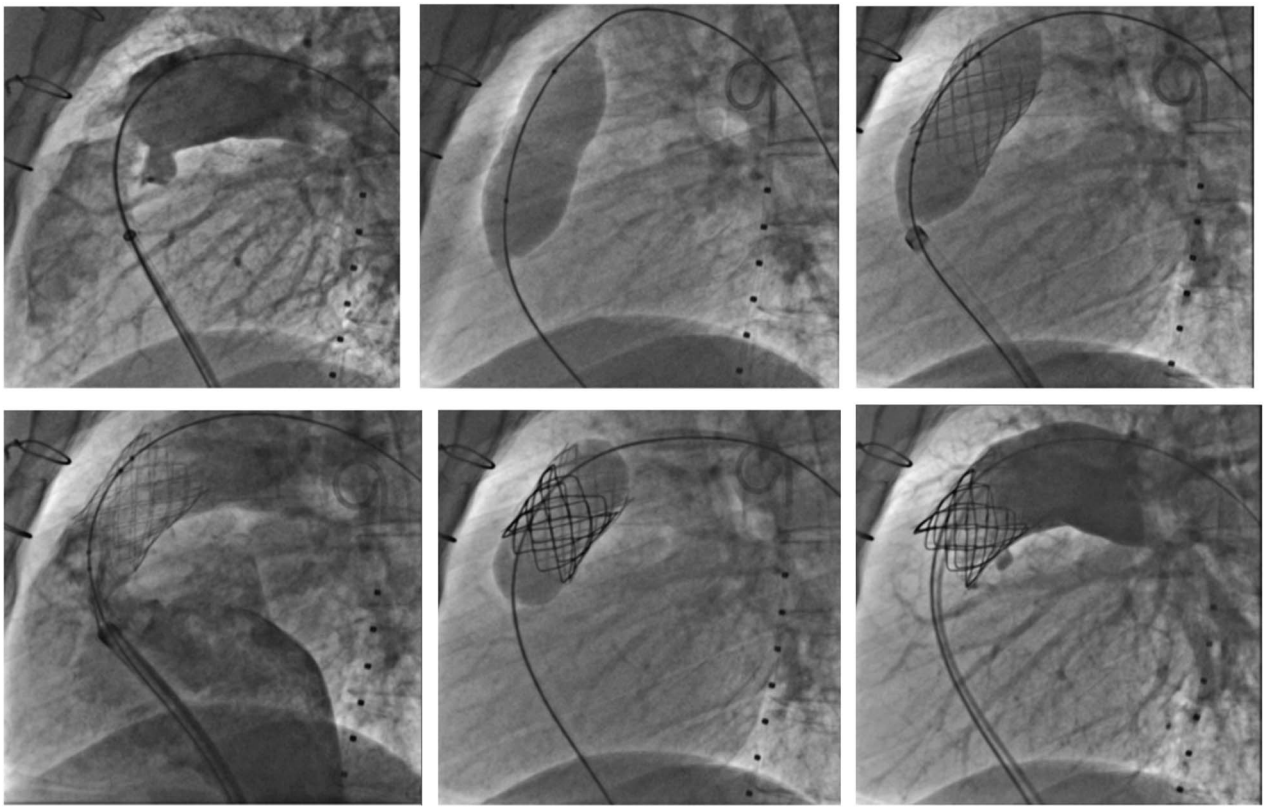

Figure 2.
Top left, Gore-tex® bileaflet valve (GTBV) appearance of valve favourable for transcatheter pulmonary valve insertion (TPVI), thick and minimally mobile leaflets. Top middle, balloon sizing. Top right, pre-stent delivery. Bottom left, pre-stent holding GTBV open. Bottom middle, Melody delivery. Bottom right, competent new valve.

pulmonary valve insertion following Gore-tex® bileaflet valve and 7/11 have been judged to be candidates. Patients' original diagnoses have included tetralogy of Fallot (n = 6), isolated valvar PS (n = 3), post-Ross (n = 1), and common arterial trunk (n = 1). Patient ages have ranged from 12 to 41 years (mean 26.7 years) and 7/11 were male. Indication for transcatheter pulmonary valve insertion were mixed PS/PR (n = 6), PR (n = 3), and PS (n = 2). None of the patients with transcatheter pulmonary valve insertion indication of PR alone were found to be candidates. All procedures were performed under general anaesthesia, and initial valve assessment for transcatheter pulmonary valve insertion candidacy was primarily sorted out with transoesophageal echocardiography. If the appearance of the valve is favourable, the patient undergoes a right and left heart catheterisation and angiography. The Gore-tex® bileaflet valve is balloon-sized and coronary safety is assessed. None of the balloon-sized patients were found to have coronary compression. Pre-stenting of the dysfunctional Gore-tex® bileaflet valve was performed in all patients, followed by Melody® valve delivery on a 22 mm Ensemble® delivery system (see Fig 2). All 7 successfully implanted patients were discharged within 24–48 hours and there were no major adverse events.

For the seven transcatheter pulmonary valve insertion patients, the right ventricular outflow tract gradient dropped from a mean of 36–10.3 mmHg, and the degree of PR dropped from on average moderate to severe to an average of trivial. Fluoroscopy times averaged 29 minutes (range 15.3–39.9 minutes). Follow-up is brief at 16.7 months (range 1–30 months), but none have significant PS and or more than mild PR by transthoracic echocardiography and there have been no stent fractures or episodes of endocarditis.

Small conduits

Occasionally, we have identified patients with a surgical history of a rather small right ventricle to pulmonary artery conduit following infant surgery to have an adequate landing zone to consider transcatheter pulmonary valve insertion. Uniformly and strangely, these patients have usually had minimal or no calcification, despite having a prior surgical homograft right ventricle to pulmonary artery conduit. The use of the Melody® valve in small patients, often with small conduits, such as this has been

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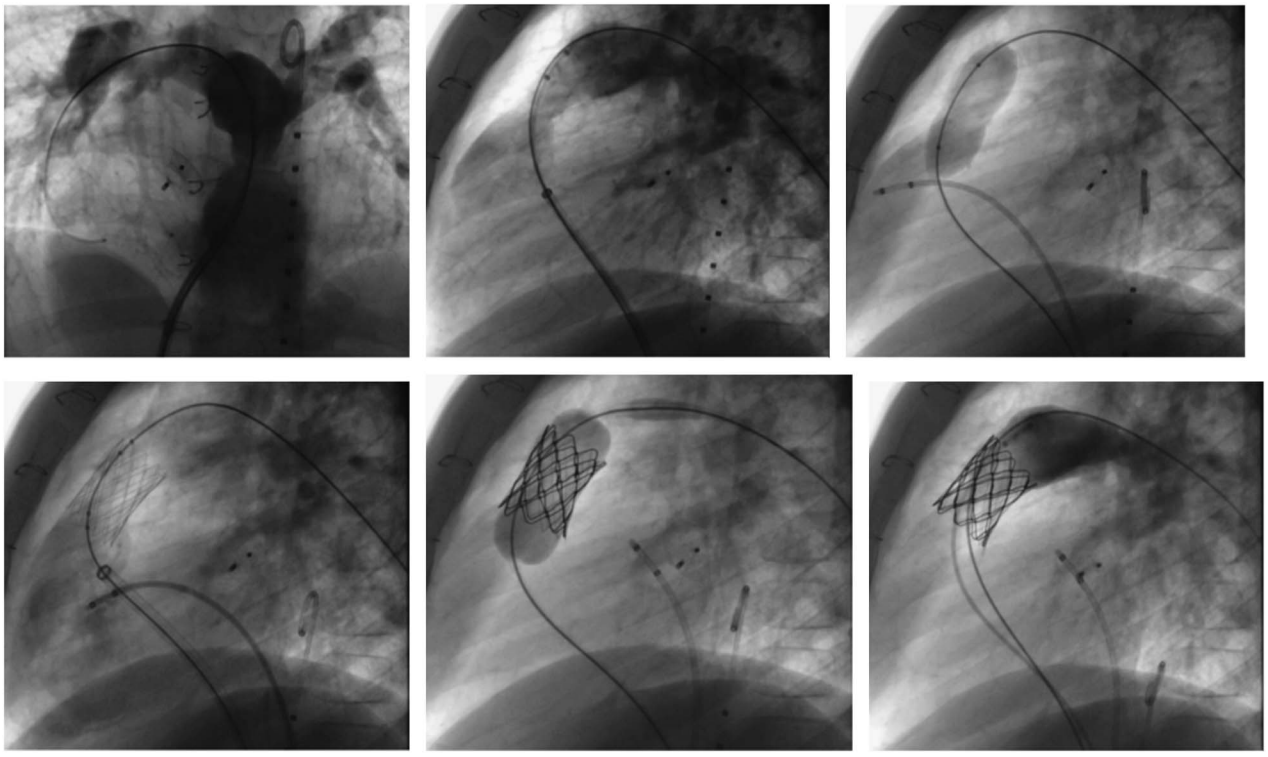

Figure 3.
A 12 mm homograft conduit patient. Top left panel, pre-PA angiogram. Top middle, pre-lateral angiogram. Top right, balloon sizing with 18 mm balloon. Bottom left, post pre-stent. Bottom middle, valve delivery. Bottom right, post-valve.

described in one multicentre study.[15,16] In our centre, we have had three such patients, all unexpectedly found to be candidates for transcatheter pulmonary valve insertion, despite initial conduit diameter of 12 mm in one patient and 15 mm in the other two.

As an example we will present the following case. The patient had an initial diagnosis of pulmonary atresia, ventricular septal defect, confluent but hypoplastic branch pulmonary arteries, and multiple aorto-pulmonary collaterals. At 2 months of age, the patient underwent single-stage unifocalisation of the collaterals to the true pulmonary arteries, patch closure of ventricular septal defect, and placement of a 12 mm pulmonary homograft right ventricle to pulmonary artery conduit. The patient did very well for many years on no medications. He was referred for device closure of an atrial septal defect and branch pulmonary artery angioplasty at 8 years of age that was straightforward and successful. At 11 years of age, he developed mixed moderate PS and PR, right ventricular dilation, and dypsnoea on exertion. At the time, the patient weighed 32.5 kg and had a body surface area of 1.12 m^2. A cardiac magnetic resonance imaging study was conducted that strangely showed the distal and proximal ends of the right ventricle to pulmonary artery conduit to be 16–17 mm in diameter, with a minimal conduit diameter of 11–12 mm, likely at the former valve annulus. It appeared as though the proximal and distal ends of the conduit had actually dilated since the implant as opposed to what is typically seen in homograft right ventricle to pulmonary artery conduit conduits. In chest x-ray, no calcification of the right ventricle to pulmonary artery conduit was observed.

The patient was brought for cardiac catheterisation, angiography, and possible transcatheter pulmonary valve insertion. Angiography findings were consistent with the magnetic resonance imaging (MRI) study. The right ventricle to pulmonary artery conduit was balloon-sized and coronary compression angiograms were performed. The conduit was successfully stented with a 3110 Cordis Palmaz® XL stent (Johnson and Johnson, Miami, Florida, United States of America) delivered on an 18 mm outer balloon diameter × 3 cm long BIB® balloon (Numed, Hopkington, New York, United States of America). A Melody® valve was then delivered on a 20 mm Ensemble® delivery catheter. The new valve functioned well with trivial residual stenosis and no insufficiency immediately post-valve implantation and on discharge echocardiography. Please see Fig 3 for steps of implantation. There were no procedural adverse events. The patient was discharged home the next day.

Although unexpected, transcatheter pulmonary valve insertion should be considered for selected patients with small conduits, particularly those with

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minimal calcification. This is especially true when their conduit size by MRI or angiography could be considered large enough in diameter for expected cardiac output and patient size.

Native right ventricular outflow tract transcatheter pulmonary valve

Although nothing as yet has been published, there is a current ongoing engineering feasibility trial for a new self-expanding stent mounted pericardial tissue valve. This valve is also from Medtronic. Up to 20 patients will eventually be enrolled in this trial. Its delivery system is 25 Fr. This valve is hoped to provide some initial answers for patients who have undergone prior transannular patch right ventricular outflow tract reconstruction. Remember that this patient group makes up the vast majority of patients in need of pulmonary valve replacement. There are currently three sites enrolling patients – Columbus, Boston, and Toronto – and thus far 10 of these valves have been implanted (Cheatham J., personal communication).

Discussion/conclusions

It remains clear and has become more so that transcatheter pulmonary valve insertion has added a major weapon in the armamentarium of congenital interventionalists. It allows for improved pulmonary valve function in a great assortment of clinical scenarios. This includes the patient with a straightforward dysfunctional right ventricle to pulmonary artery conduit, patients with a native right ventricular outflow tract but adequate landing zone, patients with no right ventricular outflow tract landing zone but the proximal branch pulmonary arteries adequately sized to consider valve delivery, and patients with dysfunctional bioprosthetic valves.[1–3,6–9] The Melody valve has functioned well in high-pressure scenarios including in patients with pulmonary hypertension.[17]

Our experience with transcatheter pulmonary valve insertion for patients with a dysfunctional Gore-tex® bileaflet valve will hopefully add to the expanded consideration of this procedure, and hopefully medium- and long-term valve function in this sub-group will prove to be comparable to others. It appears that for selected Gore-tex® bileaflet valve patients, those with intact valve leaflet insertion, transcatheter pulmonary valve insertion offers a good option. Patient selection is key and leaflet assessment by transoesophageal echocardiography appears ideal in sorting out good candidates for an attempt at valve delivery in this cohort.

Although it is always important to review a patient's surgical history in consideration candidacy for transcatheter pulmonary valve insertion, for some patients with small conduits the surgical history may lead one inappropriately not to consider this option. For patients with minimally calcified right ventricle to pulmonary artery conduit, advanced imaging may lead one in an unexpected direction and reconsider transcatheter pulmonary valve insertion. The cause of this is unclear. Could it be that the homograft was missed at harvest? Could the homograft have dilated from elevated pulmonary artery pressure immediately following surgical implantation? The reason for it does obviously does not matter, unless understanding this is a key to surgically placing homograft conduits that "grow".

Taken as a whole, transcatheter pulmonary valve insertion has been a huge leap forward in the care of vast numbers of patients with congenital heart disease. Exciting new developments such as the native right ventricular outflow tract pulmonary valve will only expand what can be less invasively offered to patients with long-term right ventricular outflow tract pulmonary valve dysfunction and all its associated secondary sequelae. It has solidified the cardiologist surgeon relationship necessary to better discuss lifetime strategy in patient care and will likely be shown to diminish long-term patient morbidity.

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Conflicts of Interest

None.

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