A new treatment option for pulmonary valvar insufficiency: first experiences with implantation of a self-expanding stented valve without use of cardiopulmonary bypass

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Received 14 June 2006; received in revised form 9 October 2006; accepted 10 October 2006; Available online 17 November 2006

Abstract

Objective: Pulmonary regurgitation is the predominant problem in the long-term follow-up of tetralogy of Fallot (TOF) patients after primary repair. Apart from standard homograft implantation, a percutaneous valve delivery approach has been described recently. A right ventricular outflow tract (RVOT) diameter of greater than 22 mm, however, precludes percutaneous valve delivery. We describe a novel technique with a transventricular implantation of a stented bio-prosthesis without cardiopulmonary bypass that allows for implantation of prostheses with diameters greater than 22 mm.

Methods: All patients (9—27 years of age) had undergone total correction of TOF at a mean age of 4.2 [1.4] years. The RVOT was enlarged at that time with a transannular patch in all but one patient. All patients presented with severe pulmonary regurgitation without any significant RVOT obstruction. Mean MRI pulmonary regurgitation was 53 ± 8%. The mean magnetic resonance imaging (MRI) right ventricular end diastolic volume index (RVEDVI) was 143 ± 23 ml/m², with a mean MRI right ventricular ejection fraction (RVEF) of 46 ± 9%. In another two patients indication for treatment was based on reduced exercise capacity with patients being in NYHA Class III. After repeat sternotomy, a porcine valve mounted inside a self-expandable stent, covered with No-React® treated porcine pericardium (Shelhigh, Model NR-4000MIS), was introduced just beneath the RVOT without use of cardiopulmonary bypass. External sutures were placed at the proximal and distal site of the valve to ensure fixation.

Results: The implantations were uneventful, with the patients hemodynamically stable throughout the procedure. One patient with severely dilated RVOT (up to 31 mm) exhibited paravalvular leakage and the valve was replaced by a homograft after 2 days. At 6—12 month follow-up the remaining five patients exhibited no more than mild pulmonary regurgitation. The mean MRI RVEDVI was 94 ± 18 ml/m², with a mean MRI RVEF of 58 ± 27%.

Conclusions: Cardiopulmonary bypass for repeat RVOT interventions can be avoided in selected patients with this newly available device. In combination with a wide range of prosthesis sizes it offers yet another important treatment option.

Keywords: Heart valves; Bioprosthesis; Congenital heart disease; Tetralogy of Fallot

1. Introduction

The described method of off-pump pulmonary valve replacement was a precursor to the present Shelhigh valve and was initially reported by Amin [1], and was similar to the method used by a group that conducted animal experiments with another self-expandable valved stent off-bypass [2]. To date, however, only two groups worldwide have gained actual clinical experience in humans. Apart from our report on this innovative method of implantation of a pulmonary valve without the use of cardiopulmonary bypass [3], the University Hospital in Bern, Switzerland, reported recently its experience with four patients [4]. Since our first report, we have now treated a total of six patients. This manuscript focuses on the description of the underlying morphology of the individual right ventricular outflow tract (RVOT), implications of pre- and perioperative diagnostics, description of operative maneuvers and potential complications, and first clinical results.
2. Methods

The Ethics Committee of the Technical University Munich (Project number 1342/05) approved implantation of the 'Shelhigh injectable porcine pulmonary valve, No-React\textsuperscript{®} treated, Model NR-4000MIS (Minimally invasive surgery implantation with external fixation)'. The valve consists of a porcine pulmonary valve mounted inside a self-expandable stent, which is covered with No-React\textsuperscript{®} treated porcine pericardium (EC certificate 97 07 0045 CT).

All patients had undergone total correction of tetralogy of Fallot (TOF) including ventricular septal defect (VSD) closure, commissurotomy of the pulmonary valve, and infundibular resection. The RVOT was enlarged with a transannular patch in all but one patient. Three patients had undergone palliative procedures prior to total correction (modified Blalock–Taussig anastomosis, n = 1, commissurotomy of the pulmonary valve, n = 2). Total correction was performed at a mean age of 4.2 ± 4.0 years. The clinic and hemodynamic characteristics of the patients are depicted in Table 1. Inclusion criteria were therefore significant pulmonary regurgitation together with either an enlarged right ventricle or reduced exercise capacity. Patient 1 also suffered from supraventricular tachycardia. Exclusion criteria were any other cardiac defect other than significant pulmonary regurgitation.

All patients underwent magnetic resonance imaging (MRI) prior to surgery. All studies were performed on a standard 1.5 T scanner (Philips Gyroscan ACS NT Intera, software Release 8.0), using a surface coil with five elements. At the beginning of each study steady state free precession scans (field of view, 430 mm, steady-state free procession, repetition time = 2.8 ms, echo time = 1.4 ms, voxel size 2 mm \times 3 mm \times 8 mm) through the heart in all three orthogonal imaging planes were performed for anatomic orientation and exclusion of baffle obstruction. For measurement of ventricular volumes short axis scans covering the entire heart were acquired using a multiphased balanced fast field echo sequence. Scans were retrospectively ECG triggered and performed under breathhold. Slice thickness was 6 mm without slice gap, field of view 350–400 mm, and the matrix 256 × 256 yielding an in plane resolution of 1.4–1.6 mm. Each slice was imaged in 17–32 phases of the cardiac cycle. Out of the short axis cuts right ventricular volumes in end diastole and end systole were calculated. End diastolic and end systolic volumes were indexed to body surface area. Ejection fraction of the right ventricle was calculated by dividing stroke volume in the main pulmonary artery (measured by phase velocity MRI) by end diastolic volume of the right ventricle [5]. For volume calculation, endocardial borders of the right ventricle were outlined manually in each slice on a separate work station using dedicated software (MASS\textsuperscript{®} Medis Inc., Netherlands). For phase velocity MRI a conventional phase sensitive gradient echo sequence was used in a double-oblique plane perpendicular to the ascending aorta at the level of the sinotubular junction. The following acquisition parameters were used: repetition time 25 ms, echo time 6 ms, slice thickness 6 mm, flip angle 30°, receiver bandwidth 31.25 kHz, rectangular field of view 260–330 mm, matrix 256 × 256, number of excitations 2. The highest flow velocity to be encoded was set to 2.5 m/s. Data were reconstructed to provide 25–33 magnitude (anatomic) and phase (velocity-mapped) images per cardiac cycle. Data analysis was performed offline utilizing commercially available software (Massflow\textsuperscript{®}, MEDIS Inc., Netherlands). According to the study protocol, all patients were also scheduled for echocardiography studies, MRI reevaluation, and angiography at 6–12 months after valve implantation.

The operative procedure is described in detail previously [3]. One patient was 10, two 14, one 16, and two 27 years old at time of operation. After repeat sternotomy and dissection, the valve was loaded into an injector gun. Then, the supplied introducer tip was affixed to the end of the trocar. Two purse-string sutures were placed just beneath the transannular outflow patch about 2.5 cm proximal to the pulmonary valvar plane. Intraoperatively, all patients received heparin with the aim of establishing a partial thromboplastin (PTT) time of 40–60 s. After a stab incision at the site of the purse-string sutures, the injector gun was slid into the RVOT. The correct position was confirmed by transesophageal and epicardial echocardiographic assessment. Additional manual palpation at the area of the pulmonary trunk avoided delivery of the valve at the site of the pulmonary artery bifurcation. After ejecting the valve, the injector gun was withdrawn and the purse-string sutures tightened. Externally pledgeted sutures each were placed at the proximal and distal site of the valve to ensure fixation. Cell saving and postoperative shed mediastinal blood retransfusion was performed. Oral anticoagulation, with warfarin, was then commenced aiming to achieve an international normalized ratio (INR) of 2–3 for 3 months.

3. Results

The implantations were uneventful in all patients, with the patients being hemodynamically stable throughout the procedure. Echocardiographic assessment confirmed the adequate position and function of the valve (Fig. 1). Fig. 2 depicts RVOT dimensions of each patient and final position of the injectable valve. In patient 3 with hugely dilated RVOT (up to 31 mm), a homograft was implanted after 2 days due to paravalvular leakage.

In the early postoperative course, a prolonged PPT led to increased blood loss in two patients (900 and 1545 ml). There was no need for allogenic blood transfusion due to cell saving and postoperative shed mediastinal blood retransfusion. Intermittent bradycardia required atrial pacing in another two patients until postoperative day one.
At 6–12 month follow-up, the remaining patients exhibited no more than mild pulmonary regurgitation. The mean MRI RV EDVI was $94 \pm 18 \text{ml/m}^2$, with a mean MRI RV EF of $58 \pm 27\%$.

The changes of the hemodynamic characteristics before implantation of the injectable pulmonary valve and at 6–12 month follow-up are illustrated in Fig. 3.

Fig. 4a and b depict patient 4. Follow-up MRI 10 months after implantation of the pulmonary valve showed a well functioning tricuspid pulmonary valve graft without any relevant regurgitation. Planimetric valve area was 1.6 cm$^2$. Right ventricular volume index decreased to 83 ml/m$^2$. Corresponding to the MRI findings, the patient reported an improvement of physical activity and reduced episodes of headache.

4. Discussion

Recently, Bonhoeffer and co-workers [6,7], who have established a percutaneous approach, tried to overcome the given problem that percutaneous pulmonary valve replacement is limited to patients with a RVOT that does not exceed 22 mm in diameter. Their experimental study reports on off-pump pulmonary valve replacement using a combined approach. A left thoracotomy was first
performed, and then the main pulmonary artery banded. Then percutaneous pulmonary valve replacement followed. In line with these trials on valve implantation into the pulmonary position, first results describe modified valve delivery into the aortic and even mitral position [8—11].

A very largely dilated RVOT cannot, however, usually be treated with other than implantation of a valve or a valved conduit and institution of cardiopulmonary bypass. The newly available Shelhigh valve in combination with a wide range of prosthesis sizes offers another option in treatment of selected patients with severe pulmonary regurgitation.

In our experience, patient selection was based on a combination of data from MRI, echocardiography, and clinical status. Since the study protocol only allowed inclusion of patients with no other pathology than pulmonary valve regurgitation, the aim was to define the dimensions of the RV and the RVOT in detail. Our preliminary clinical experience showed that intraoperative assessment of the RVOT, with both a transesophageal and epicardial echocardiography, proved essential in regard to the choice of the prosthesis size and the desired position of the stented valve. It is important to note, however, that we consider echocardiographic assessment alone, both pre- and intraoperatively, as not sufficient. MRI assessment is today regarded as an essential tool in evaluating ventricular performance, dimensions and valve function. In regard to the assessment of the RVOT, we have experienced a paravalvar leakage in one patient. RVOT dimensions, right ventricular to pulmonary artery junction and sinotubular junction, ranged in this patient from 21 up to 31 mm. We initially thought a valve size 23 mm could fit into the main pulmonary artery. However, even external fixation did not preclude from valve motion with subsequent leakage within the dilated proximal pulmonary artery towards the sinus of valsalva. The stented valve is currently available in sizes 11, 12, 13, 14, 15, 16, 17, 19, 21, 23, 25, 27, 29 and 31 mm. In our mind, ‘oversizing’ of at least 2 mm upon intraoperative echocardiographic assessment should be performed. As depicted in Fig. 2, a conically shaped RVOT may, however, allow for a snug fit of the stented valve once the dimensions are within the mentioned sizes. This is in contrast to the description of the Swiss group, who reshaped a huge RVOT in one case and subsequently injected the valve [4].

In the patients we described, repeat MRI evaluation confirmed right ventricle end distolic volume decrease. These findings support the currently accepted data that pulmonary valve replacement should be undertaken before the right ventricular end-diastolic volume reaches 170 ml/m². Therrien et al. [12] postulate that in patients with RV end diastolic volumes above 170 ml/m², RV volumes do not ‘normalize’ after valve replacement. However, there are contradictory reports on RV function after pulmonary valve replacement, largely due to different timing of the procedure [13,14]. In our group of patients, four presented with an RVEDI of more than 140 ml/m². Again, the indications were partially based on the current opinion that even 150 ml/m² should be seen as a cut-off point, and that MRI overcomes limitations of other diagnostic methods such as angiography [15]. The right ventricle in congenital heart disease, with its complex geometry and unique adaptive mechanisms, remains a challenge for both the cardiologist and the surgeon [16]. The mode of application described and the newly available device in combination with the wide range of prosthesis sizes offers yet another treatment option for patients with a severe pulmonary regurgitation, dilated RVOT, and impaired right ventricular function. Since implantation of the NR-4000MIS still requires repeat sternotomy, there might be room for designing less invasive modes of implantation, such as different securing methods of the stented valve, or even a robotic guided closed chest approach.

Acknowledgment

The authors wish to thank Shelhigh Inc. Union, New Jersey, for providing the valve.
References


