Pulmonary valve implantation using self-expanding tissue valve without cardiopulmonary bypass reduces operation time and blood product use

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Objective: The study objective was to review our initial experience with newly developed off-pump pulmonary valve implantation techniques and compare outcomes with the conventional approach.

Methods: Thirteen symptomatic patients with severe pulmonary regurgitation underwent pulmonary valve implantation, 6 without cardiopulmonary bypass (group 1: age, 28 ± 21 years; range, 12-62; body surface area range, 1.38-2.39 m^2) and 7 with cardiopulmonary bypass (group 2: age, 23 ± 13 years; range, 10-46; body surface area range, 1.31-1.89 m^2). Ten patients had previous repair of tetralogy of Fallot, and 3 patients had pulmonary valvotomy/valvuloplasty.

Results: Mean operation times were 166 minutes (range, 110-240) in group 1 and 299 minutes (range, 221-375) in group 2 ($P < .001$). Hemoglobin level after chest closure was 13.4 and 9.8 g/dL in groups 1 and 2, respectively ($P < .001$). Postoperative chest drainage (median) was 78 and 300 mL in groups 1 and 2, respectively ($P = .003$). Blood product requirement was zero and 3 units (median) in groups 1 and 2, respectively ($P < .014$). There was no significant difference in postoperative ventilation time or lengths of intensive care unit and hospital stays between the 2 groups. Mean follow-up was 15 months; all patients are in New York Heart Association I/II. Echocardiography showed that peak velocity across the pulmonary valve was 2.2 and 2.0 in groups 1 and 2, respectively ($P = .46$). No patient had a paravalvular leak or more than mild pulmonary regurgitation.

Conclusions: Off-pump pulmonary valve implantation is a good alternative for pulmonary valve replacement. The procedure reduces operating time, blood loss, and blood product requirement. (J Thorac Cardiovasc Surg 2013;145:1040-5)

CHD

One of the most common late complications after repair of congenital heart defects, such as tetralogy of Fallot, is pulmonary regurgitation (PR). Significant PR results in progressive dilatation and dysfunction of the right ventricle, decrease in exercise tolerance, arrhythmias, heart failure, and increased risk of sudden death. The conventional approach of dealing with this problem is to perform pulmonary valve replacement using cardiopulmonary bypass (CPB). However, this approach is associated not only with long operative time but also side effects related to the use of CPB. Furthermore, because of the natural history of prosthetic valve failure, patients often require multiple repeat open operations for valve replacement over their lifetime, the reoperation becoming increasingly complex on each occasion.

Minimally invasive pulmonary valve implantation is therefore warranted. In recent years, percutaneous pulmonary valve implantation has been developed. However, with the percutaneous technique, a limited size of prosthesis can be inserted, currently up to 26 mm diameter with the Sapien transcatheter heart valve (Edwards Lifesciences LLC, Irvine, Calif) and up to 22 mm with the Melody valve (Medtronic Inc, Minneapolis, Minn).[1,2] Moreover, the technique does not offer the opportunity of treating additional defects that are frequently associated with severe PR, such as pulmonary artery (PA) dilatation, and it cannot be used in a native right ventricular outlet tract (RVOT) because it requires a conduit for adequate fixation.

A newly developed tissue valve mounted on a self-expanding stent, the No-React Injectable BioPulmonic (BioIntegral Surgical Inc, Toronto, Canada) (Figure 1), allows the pulmonary valve to be implanted without using CPB, thereby avoiding its adverse side effects.[3-5] This off-pump pulmonary valve implantation (OPPI) technique requires only minimal mobilization of the heart and great vessels and thus reduces both the operative time and the risks associated with extensive dissection, such as bleeding and injury to the heart, great vessels, and adjacent structures (eg, phrenic nerves). The Injectable BioPulmonic prosthesis currently is available in sizes up to a diameter of 31 mm.

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Abbreviations and Acronyms

CPB = cardiopulmonary bypass
ICU = intensive care unit
MRI = magnetic resonance imaging
OPPI = off-pump pulmonary valve implantation
PA = pulmonary artery
PR = pulmonary regurgitation
RV = right ventricular
RVOT = right ventricular outlet tract

The valve was evolved from a previous Shelhigh injectable pulmonic valve (Shelhigh Inc, Union, NJ) and is now CE marked under the management of BioIntegral Surgical Inc.

We reviewed our initial experience with this valve and compared outcomes with the conventional surgical approach to test the hypothesis that because of its reduced invasiveness, implantation of the No-React Injectable valve is associated with shorter operating time, reduced blood product use, shorter intubation times, and decreased intensive care unit (ICU) and hospital stays.

PATIENTS AND METHODS

This study was approved by the local ethics committee for a new interventional procedure introduced to the Trust. All patients gave their informed consent. This is a retrospective, descriptive study of our initial experience.

Between May 2010 and January 2011, all patients requiring pulmonary valve replacement for significant PR who had a native RV outflow tract (ie, had not undergone previous RV-PA conduit placement) and did not have significant RVOT stenosis were considered for the injectable pulmonary valve. Other anatomic factors did not influence the inclusion of patients into either group. Indications for surgery were an aggregate assessment of multiple factors: clinical symptoms (particularly exercise limitation assessed by formal exercise testing), occurrence of arrhythmias, indexed right ventricular (RV) end-diastolic and end-systolic volumes, RV ejection fraction, and pulmonary regurgitation pressure half-time.

Six patients underwent pulmonary valve implantation without CPB (group 1: age, 28 $\pm$ 21 years; range, 12-62, body surface area range, 1.38-2.39 m^2), and 7 patients underwent pulmonary valve implantation with CPB (group 2: age, 24 $\pm$ 14 years; range, 12-46; body surface area range, 1.31-1.89 m^2). Ten patients had previously undergone repair of tetralogy of Fallot, and 3 patients had previously undergone pulmonary valvotomy. Preoperative patient characteristics are listed in Table 1. Because of the theoretic benefits of avoiding CPB in high-risk cases (particularly patients with significant comorbidities), more of these patients were included in group 1.

In group 1, the self-expanding pulmonary valve was implanted using a transventricular approach via full sternotomy and the valve was fixed with external sutures. In group 2, stented bioprostheses (n = 5) or homografts (n = 2) were implanted using CPB.

The No-React Injectable BioPulmonic valve consists of a porcine pulmonic valve mounted inside a self-expanding Nitinol stent covered by No-React–treated porcine pericardium (NR No-React, BioIntegral Surgical Inc). No-React is a proprietary process for detoxification of glutaraldehyde-treated tissue.

Surgical Procedure

Under general anesthesia, the patient underwent a full median sternotomy. Dissection of adhesions was carried out to expose the anterior surface of the right ventricle and right atrium, main PA and its bifurcation, ascending aorta, and superior and inferior venae cavae. A cell-saver was used routinely in patients undergoing a redo procedure.

In group 1, if the main PA was more than 29 mm in diameter, it was plicated with pledgeted sutures. The PA was then carefully sized using transesophageal and epicardial echocardiography or, if plication had not been necessary, a detailed preoperative magnetic resonance imaging (MRI) scan. A valve 2 mm in diameter larger than the maximum size measured was selected. The selected valve was gently compressed into the introducer, which is similar to a giant syringe, and slid into the provided trocar. Double pledgeted purse-strings were then placed on the anterior surface of the proximal RVOT just proximal to the infundibulum/infundibular patch, avoiding calcified tissue. The location is chosen to lie immediately in line with the PA and far enough away from the annulus of the valve to permit comfortable angulation of the trocar up to the PA.

After heparinization (100 IU per kg of body weight to achieve an active clotting time of 200-300 seconds), a stab incision was made at the site of purse-string sutures. The injector was then slid into the RVOT and advanced to the main PA. With the tip of the injector stabilized and the operator's fingers holding the PA below its bifurcation, the valve was deployed in the main PA immediately distal to the native annulus. The trocar delivery system was then withdrawn and the purse-string sutures controlled. Transesophageal and epicardial echocardiogram was used to assess the valve position throughout the process of deployment. At this stage, manipulation of the valve is still possible by the operator placing his/her finger through the stab incision and passing it through the center of the valve. By catching the distal end of the stent, the valve can be eased more proximally, or if necessary more distally by pressing on the proximal edge of the stent. Care must be taken not to tear the vessel because the stent has small hooks at its proximal and distal margins to aid anchoring. The valve was then secured with external Prolene sutures placed in the proximal and distal rim of the valve.

In group 2, the homograft or xenograft was implanted using CPB with standard aortic and bicaval cannulation and mild hypothermia (35°C). Similar postoperative care was provided to the 2 groups in a routine fashion, and patients were prescribed warfarin or aspirin for 3 months.

The operative time (skin to skin), perioperative blood loss, blood products use (defined as any blood component, eg, packed red cells, platelets, and fresh-frozen plasma), hemoglobin levels, chest drainage, mechanical ventilation time, and ICU and hospital stays were recorded. Follow-up was by clinical assessment and echocardiography in the outpatient clinic.

Statistics

Two-sample Student *t* tests were used to compare the means of the 2 groups. Where variables were not normally distributed, groups were compared using the Mann–Whitney *U* test and medians (ranges) were used for data summary. The Fisher exact test was used to compare proportions. All tests were 2-tailed, and a 5% level of significance was used throughout.

RESULTS

There were no operative deaths. During the period of OPPI valve deployment, there was significant reduction in cardiac output, which was always self-limiting after introducer removal. All patients were hemodynamically stable during the postoperative period. In particular, we have experienced no episodes of coronary artery compromise during or after deployment of the valve.

In group 1, the pulmonary valve sizes implanted were 25 mm in 3 patients, 27 mm in 1 patient, and 29 mm in 2 patients. In group 2, the pulmonary valve sizes were 21 mm in 1 patient, 23 mm in 3 patients, 24 mm in 1 patient, and