The First Fifty Consecutive Bentall Operations with a Prefabricated Tissue-Valved Aortic Conduit: A Single-Center Experience

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Background and aim of the study: Composite replacement is the standard treatment for the repair of aortic aneurysm with aortic valve pathology. With improved long-term durability and no requirement for long-term anticoagulation, tissue-valved conduits have become increasingly popular. Herein are reported the results achieved with 50 consecutive ‘Bentall’ operations, using the first commercially available prefabricated stentless tissue-valved conduit (Vascutek BioValsalva).

Methods: Between September 2007 and September 2009, a total of 50 patients (10 females, 40 males; mean age 65 ± 7 years) received a BioValsalva conduit. Concomitant procedures included coronary artery bypass grafting (CABG; n = 15), other valve (n = 5), and aortic arch replacement with circulatory arrest (n = 20; three of these had an additional frozen elephant trunk). Four of the procedures were re-operations. A six-month follow up with echocardiography and clinical examination was completed in 25 patients.

Results: The 30-day mortality was 8% (4/50). Three of these patients underwent concomitant procedures. The cardiopulmonary bypass (CPB) and cross-clamp times were 178 ± 30 min and 106 ± 7 min, respectively. The triple-layered vascular graft proved to be hemostatic, without suture-line bleeding. Both, the initial and follow up echocardiography showed no valvular insufficiency, with a mean gradient of 13 ± 5 mmHg. All patients were in NYHA class I-II.

Conclusion: The BioValsalva prefabricated tissue-valved conduit showed very good early results. The ischemic time required to construct a ‘home-made’ stentless tissue-valved conduit was eliminated, thus reducing the cross-clamp time. The conduit also offered the hemodynamic advantages of a stentless valve.

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Currently, composite replacement with a mechanical-valved conduit, as first described by Bentall and De Bono, represents the standard treatment for the repair of aortic aneurysms with aortic valve pathology (1-3). However, the need for anticoagulation resulting in thromboembolic complications, the increasing age of patients, and the poor long-term durability of biological prostheses has led to a shift towards the use of tissue-valved conduits (4-9).

In the past, the manufacture of tissue-valved conduits has proved to be difficult because of the different storage modalities of the components. Tissue valves are stored in fluid to which glutaraldehyde has been added, whereas a coated Dacron tube must be stored dry in order to maintain its impermeability to blood. Consequently, until recently it was necessary for the surgeon to assemble the tissue-valved conduit on the surgical table following sizing of the aortic annulus, and this led (at least potentially) to an extension of the aortic cross-clamp time and a prolongation of cardiac ischemia. For this reason, very few surgeons assemble a ‘home-made’ stentless tissue-valved conduit intraoperatively. Moreover, these ‘home-made’ conduits have not been tested in vitro, thus increasing the risk of unrecognized prosthetic dysfunction (10).

The Vascutek BioValsalva

The BioValsalva™ (Vaskutek Terumo, UK), the first ready-to-use tissue-valved conduit, was introduced during 2007 (Fig. 1). This vascular graft consists of three layers, with the inner layer being an uncoated version of a Gelweave™ Dacron graft, and the outer...
layer an expanded polytetrafluoroethylene (ePTFE) graft. The two layers are glued together with a central, self-sealing elastomeric membrane that renders the graft impermeable to blood (11-13). In addition, the aortic vascular graft mimics the sinuses of the aortic root in its Valsalva-like shape. Thus, the BioValsalva graft is believed to reduce tension on the coronary buttons, and to improve both coronary flow and valve hemodynamics (14,15). The valvular part of the BioValsalva consists of a stentless tissue porcine valve (Elan™; Kohler, Leeds, UK), which is inserted into the vascular graft and reinforced at the suture-line by porcine pericardium (16). The BioValsalva valve is available in all sizes, from 21 to 27 mm, and its vascular prosthesis is long enough to replace ascending aorta including proximal aortic arch in one piece.

The authors’ experience and early results with this novel tissue-valved conduit valve are reported.

Clinical material and methods

Patients

Between September 2007 and September 2009, a total of 50 patients (10 females, 40 males; mean age 65 ± 7 years; range: 38 to 81 years) with combined pathologies of the aortic valve and ascending aorta were operated on at the authors’ institution, using the BioValsalva conduit. Of these patients, 23 were aged ≥70 years. Six of the patients were emergency cases (four presented with an acute type A aortic dissection, and two with aortic valve endocarditis). The mean preoperative NYHA class of the patients was 2.7 ± 0.7; additional preoperative patient characteristics are listed in Table I.

This prospective study was approved by the institutional review board of the Hannover Medical School, and informed consent to participate was obtained from all patients.

Surgical technique

All procedures were performed via a median sternotomy. Cardiopulmonary bypass (CPB) was used in all patients via a central cannulation of the aorta and right atrium. The pathologic aortic valve and ascending aorta were removed, followed by implantation of the tissue-valved conduit using a modified Bentall technique, with re-implantation of the coronaries as buttons.

The conduit was implanted in the aortic annulus with pledgeted single sutures. The openings for the coronaries in the Triplex vascular graft were made using a sharp blade, and not by electrocautery. The distal anastomosis was completed with a running monofilament suture-line. All available sizes of BioValsalva conduit were inserted, ranging from 21 mm to 27 mm.

In case of replacement of the aortic arch, core cooling was accomplished to 26 ± 2°C rectal temperature, and selective antegrade cerebral perfusion with cold blood (temperature of 15°C) was used. In six cases (12%), the entire aortic arch was replaced (three of these included the proximal segment of the descending aorta by frozen elephant trunk). Additional concomitant surgical procedures included coronary artery bypass grafting (CABG) (n = 15; 30%), hemi-arch replacement (n = 14; 28%), tricuspid valve repair (n = 3; 6%), mitral valve repair (n = 1; 2%), mitral valve replacement (n = 1; 2%), and maze procedure (n = 1; 2%) (Table II).
The operations were performed by six different surgeons in the authors’ department. Anticoagulation (aspirin 100 mg per day) was administered only from the first postoperative day.

Follow up

After discharge, follow up examinations were conducted using transthoracic echocardiography, and clinical examination. Among the first 25 patients, the mean follow up period was 8.0 ± 1.4 months (maximum 16 months).

Statistical analysis

The statistical analyses were carried out using SPSS 15.0 statistical software (SPSS, Chicago, IL, USA). Continuous variables were expressed as mean ± SD, and categorical variables as percentages. Survival analyses were calculated using the Kaplan-Meier actuarial technique.

Results

Operative outcome

The mean CPB and cross-clamp times were 178 ± 30 and 106 ± 7 min, respectively. Deep hypothermic circulatory arrest was used in 20 patients, with a mean circulatory arrest time of 19 ± 4 min. The mean blood transfusion was 3.1 ± 1.4 units in the entire cohort; in isolated Bentall patients the blood transfusion was only 2.1 units. Most patients were weaned from the respirator at an average of 35 ± 4 h. The mean ICU and hospital stays were 2.3 ± 0.7 and 10.3 ± 3.5 days, respectively. Notably, these times were shorter in patients who received an isolated BioValsalva conduit (Table III). There were no intraoperative deaths, but four patients (8%) died within the first 30 postoperative days. The first of these patients was a 78-year-old man with severe aortic valve insufficiency, coronary artery disease and reduced ejection fraction. He received a combined Bentall and CABG, but died from cardiac failure at three days after surgery.

The second patient was suffering from coronary artery disease, mitral and aortic valve insufficiency, and had severe cardiac failure. He received concomitant CABG and mitral valve replacement (MVR) in addition to the Bentall procedure, but died due to low cardiac output syndrome.

The third patient underwent additional aortic arch and MVR with tricuspid valve repair. Extracorporeal membrane oxygenation (ECMO) was applied due to low cardiac output, but the patient died from sepsis on the sixth postoperative day.

The fourth patient, who received an isolated Bentall procedure, died on the 23rd postoperative day due to respiratory insufficiency, followed by multiorgan failure.

One patient developed endocarditis of the bio-conduit during the first postoperative month; however, when the bio-conduit was replaced by an aortic homograft the patient did well.

Re-thoracotomy due to cardiac tamponade or bleeding occurred in seven (14%) patients, six of whom had combination procedures. Two of these patients died perioperatively. No patient suffered renal failure, central or peripheral neurological dysfunction. Five patients (10%) required a permanent pacemaker due to third-degree atrioventricular block, and a tracheotomy was required in two patients (4%) due to respiratory insufficiency.

Follow up

The median follow up was 8.0 ± 1.4 months, with an overall survival of 90%. One 76-year-old patient with chronic obstructive pulmonary disease, who under
went additional CABG and tricuspid valve repair, died during the follow up period due to respiratory insufficiency. All survivors did well and were in NYHA class I-II at the last examination. None of the patients experienced thromboembolic events or other prosthesis-associated complications. On echocardiographic examination, no prosthetic aortic valve insufficiency was observed. The effective orifice area (EOA) and mean transvalvular gradient were 1.6 ± 0.1 cm² and 13 ± 5 mm Hg, respectively (Table IV).

Actuarial survival was 91% and 88% for all patients at one and 12 months, and 94% at both times for those patients undergoing isolated BioValsalva implantation (Fig. 2).

Discussion

In the past, composite replacement with a mechanical-valved conduit has been the standard treatment for the repair of aortic aneurysms with aortic valve pathology (1,3,17,18). However, the absence of anticoagulation, the increasing age of patients and an increased durability of biological valves have resulted in a shift towards the use of tissue-valved conduits. Moreover, an increasing number of patients are accepting the risk of reoperation and deciding in favor of tissue-valved conduits in order to avoid anticoagulation therapy. Compared to mechanical or stented-tissue valves, stentless tissue valves have minimal transvalvular gradients, a larger EOA, and better hemodynamics (19-21). In contrast to synthetic vascular grafts, biological conduits such as homografts or xenografts tend to degenerate and are immunogenic, which makes reoperation not only necessary but also technically demanding (4,22). Until the introduction of the BioValsalva graft, in those patients requiring a tissue-valved conduit, a stented biological valve was sutured to a synthetic vascular prosthesis intraoperatively, thus increasing the cross-clamp time (23). However, due to the potential increase in cross-clamp time, few surgeons are prepared to assemble a stentless biological-valved conduit. Hence, the present prospective study was the first to present the results with a prefabricated, commercially available, tissue-valved conduit - the BioValsalva.

The majority of the patients underwent combined procedures, with correspondingly longer cross-clamp times, although the cross-clamp times for isolated Bentall procedures with the BioValsalva were shorter and comparable to those of other groups (15,24,25).

Although the present mortality rate of 8% was higher than reported elsewhere (11,24,25), when taking into consideration the concomitant procedures performed, it would appear that these patients would profit most from use of the BioValsalva, due to the ease of implantation and the lack of any need to prepare a ‘home-made’ bio-conduit.

The Triplex-layered BioValsalva prosthesis is reported to be superior to conventional prostheses in terms of hemostasis (15) and, indeed, the present authors’ experience has confirmed this observation. No suture-line bleeding was observed, and neither was the rate of reoperation due to bleeding higher than that of other groups performing Bentall operations with the BioValsalva (15,24,25). Nevertheless, these groups had smaller numbers of patients and fewer combination and emergency procedures. All patients requiring rethoracotomy in the present collective were either emergency or combination cases.

During the follow up period, the present patients experienced an improvement in their clinical status, were in a better NYHA class, and had an increased ejection fraction. Moreover, echocardiography confirmed the lack of regurgitation and a low mean gradient of the tissue valve.

The BioValsalva unifies the advantages of the stentless Elan aortic valve prosthesis with the hemodynamic benefits of the Valsalva vascular prosthesis (14,26).
Moreover, as the valve is not sutured to the aortic annulus in the proximal anastomosis, it is believed that in the case of reoperation the valve could be separated easily from the vascular graft and replaced by new aortic valve prosthesis, without the need to explant the whole conduit. Indeed, this procedure has been documented in separate animal experiments, where re-do aortic valve replacement was performed in sheep with previously implanted Vascutek BioValsalva conduits (data presented at the annual meeting of the European Association for Cardiothoracic Surgery meeting, Vienna, 2009). This could make reoperation technically simpler, and render the BioValsalva an alternative conduit, even in young patients.

In conclusion, the tissue-valved conduit BioValsalva has shown good early results, as well as eliminating the ischemic time required to construct the ‘home-made’ tissue-valved conduit and offering the hemodynamic advantages of a stentless valve. Nonetheless, long-term studies must be conducted to compare the outcome of the Bentall procedure with that using a conventional prosthesis.

Disclosures
The authors had full control of the patient selection, operative technique, study design, data analysis and preparation of the manuscript. The authors’ hospital received a grant from Vascutek (Germany) for data collection costs. There was no personal conflict of interest.

References
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