Early experiences and in-hospital results with a novel off-pump apico-aortic conduit†

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Abstract

OBJECTIVES: To offer surgical treatment in patients with aortic valve stenosis and contraindications for aortic valve replacement (e.g. ostial encroachment and previous mitral valve replacement). The aim of this study was to prove the feasibility and efficacy of this novel innovative off-pump apico-aortic conduit technique.

METHODS: The bipartite conduit consists of an 18-mm prosthetic tube graft containing a stentless porcine aortic valve as well as a flexible semi-rigid and curved ventricular connector. Via left anterior lateral thoracotomy, the valved conduit is sutured to the descending aorta. The left ventricular connector is implanted with a gun-like applicator into the apex without cardiopulmonary bypass and with minimal blood loss.

RESULTS: Between March and December 2011, 7 patients (5 females/2 males) with a mean age of 82 (79–89 years) were operated on. The mean logistic EuroSCORE I was 36.4 ± 23.7 (median 36.7%). The mean ejection fraction was 37 (25–56%). Three patients had previous mechanical mitral valve replacement, 1 had a porcelain aorta and 3 had unfavourable distances between the aortic annulus and ostia (ostial encroachment). Implantation was uneventful in all patients, with need for limited cardiopulmonary bypass in only 1 patient. Postoperative mean transaortic gradient was 14 (11–25 mmHg). Approximately 70% of stroke volume was bypassed as measured in postoperative magnetic resonance. One patient died in hospital due to respiratory failure. New York Heart Association class in the other patients diminished from 3.6 to 1.6. No rhythmic disturbances or heart block were encountered.

CONCLUSIONS: With this novel conduit, we observed excellent haemodynamic results. We feel that this additional surgical approach to aortic stenosis in elderly, high-risk patients can augment conventional on-pump and interventional treatments of aortic stenosis.

Keywords: Aortic valve stenosis • Replacement • Aortic valve bypass

INTRODUCTION

Aortic stenosis remains the most frequent degenerative valve disease in the elderly. People aged ≥80 belong to the largest-growing segment of the European population, which is expected to increase from 4.7% in 2010 to 12.1% in 2060 [1]. Surgical aortic valve replacement (AVR) performed via a median sternotomy and with cardiopulmonary bypass (CPB) is still the gold standard for severe symptomatic aortic stenosis. AVR improves symptoms and prolongs survival in all age groups [2]. However, a substantial proportion of patients remains surgically untreated due to their clinical profile, resulting in possibly unfavourable clinical outcomes [3]. With the advent of transcatheter aortic valves (TAVI) in clinical practise since 2002, these limitations appeared to have been overcome [4]. However, data that were published in the Partner Trial in 2011 suggest that 1-year survivals in AVR and TAVI are similar, with diverse risks according to procedural peculiarities [5]. Besides these results, TAVI is an expensive and technically demanding procedure requiring the need for hybrid operation room. Furthermore, it is at least a controversial technique in treating bicuspid aortic valve disease, in cases with a porcelain aorta, as well as in patients with ostial encroachment [6].

Aortic valve bypass (AVB) is considered to be an additional surgical strategy to treat severe aortic stenosis. It was first implanted in man in the early 1960’s by Templeton, but not published [7]. Since then, this device has been applied worldwide in an estimated 1500 patients with >250 cases recorded in the literature. However, due to the lack of appropriate delivery instrumentation and the need for CPB, the surgical adoption of this technique has been low. With the development of a novel, gun-like device that allows coring of the left ventricular apex and

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insertion of the conduit on a beating heart, the routine need for CPB is supposed to be overcome.

The aim of this study is to report our early experience and preliminary results with 7 patients who were treated with AVB between March and December 2011 on beating hearts at our institution.

MATERIALS AND METHODS

This is a retrospective, single Swiss institutional study on 7 high-risk patients who were operated on between March and December 2011. Data were prospectively collected. The study was approved by the institutional ethics committee board. Patient consent was not required due to the retrospective character of the review. All operations were performed on beating hearts. The selection of patients was based on our institutional algorithm, considering risk stratification for conventional AVR, TAVI (transapical or transfemoral) and AVB. In the presented cohort, the decision for AVB was based on apparent porcelain aorta, ostial encroachment and previous mechanical mitral valve replacement.

Patient characteristics are depicted in Table 1. In brief, 5 of 7 patients were female with a mean age of 82 (79–89 years). The mean standard EuroSCORE I was 12 [7–17], mean left ventricular ejection fraction was 37 (25–65%) and mean preoperative trans-aortic gradient was 38 (22–52 mmHg).

Preoperative evaluation

Preoperative work-up was extensive: (i) transoesophageal (TEE) or transthoracic (TTE) echocardiography, (ii) coronary angiography, (iii) computed tomography (CT) angiogram of the chest, abdomen and pelvis without contrast dye, (iv) Doppler sonography of the supra-aortic vessels and (v) pulmonary function testing to determine tolerance for single-lung ventilation. If coronaries showed any severe and clinically apparent stenosis, they were treated by percutaneous transluminal coronary angioplasty and/or stenting prior to AVB. Aortic insufficiency, as well as mitral regurgitation grade ≥3+, was regarded as an exclusion criterion for AVB. Patients with circular calcifications of the descending aorta at the level above the diaphragm were also considered inoperable because of the impossibility of partial clamping. Left ventricular ejection fraction ≥20% was accepted. Patients with concomitant disease with ≤1 year of life expectancy were excluded.

Anaesthesia management

All AVB procedures were performed under general anaesthesia. All patients were treated to attempt early extubation. They were intubated orally with a double-lumen tube (Mallinkrodt™, Covidien, Dublin, Ireland). At the end of the operation, the double-lumen tube was changed to a single-lumen tube before transferring the patient to the intensive care unit. Haemodynamic monitoring consisted of a 12-lead electrocardiogram, pulse oximetry, two invasive arterial blood pressure measurements (right radial and right femoral artery), central venous pressure line (right jugular vein) and BIS monitoring (Bispectral Index System, Covidien, Mansfield, MA, USA) to control the depth of anaesthesia. All patients were equipped with external defibrillator pads (Quick-Combo REDI-PAK™, PhysioControl Medtronic, MN, USA). Presurgical TEE evaluation was performed after induction of anaesthesia in the operating room. The aim of this additional evaluation was to identify any myocardial or valvular abnormalities to delineate the ‘baseline’ before surgical repair. Via TTE, the apex was detected and marked on the skin before incision. A cell-saver was used for blood conservation. To avoid passive hypothermia, an external convective warming system with an underbody blanket (Bair hugger™, Arizant Healthcare, Eden Prairie, MN, USA) and an intravenous fluid heater system (Hotline™, Smiths Medical, Dublin, OH, USA) were used to preserve a core temperature of 36°C. During the procedure, the mean arterial pressure was maintained >65 mmHg. Intraoperative hypotension (mean arterial pressure <65 mmHg) was treated with intravenous crystalloid and/or colloid infusion and boluses of inotropic agents. Heparin (100 IU/kg) was given to achieve an activated clotting time >250 s. Postoperatively, it was reversed in a 1:1 ratio.

For postoperative analgesia, local infiltration of the intercostal space was performed using 40 ml of bupivacaine (2 mg/ml). Further, postoperative analgesia consisted of a bolus of morphine (5–10 mg) as required to achieve a pain score between 2 and 4 on an analogue pain scale from 0 to 10 [8].

Operative technique

The main constituent of the procedure is a bipartite prosthesis with a valve conduit integrating a 23-mm porcine valve and an 18-mm angled LVC as well as the applicator tool (Correx, Inc., Waltham, MA, USA; Fig. 1). The recommended retail price is €14 900. While coring the apex, this gun-like device inserts the LVC into the heart with minimal blood loss. An integrated inflatable balloon protects intraventricular structures from damage

<table>
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<th>Table 1: Preoperative patient characteristics</th>
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<td>Patient characteristics</td>
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<td>All patients (n = 7)</td>
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<td>New York Heart Association class (mean ± SD)</td>
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<td>Previous CABG/PTCA</td>
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<td>Ostial encroachment</td>
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<td>Previous mitral valve replacement (mechanical)</td>
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<td>Porcelain aorta</td>
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<td>EuroSCORE I (standard)</td>
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<td>Atrial fibrillation</td>
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CABG: coronary artery bypass grafting; SD: standard deviation; PTCA: percutaneous transluminal coronary angioplasty.
from the coring knife and assists in capturing the cut tissue plug inside the coring knife.

The patient was positioned in the right lateral decubitus position with hips externally rotated to allow access to the left femoral vessels. The left forearm was extended and fixed laterally overhead. To open the intercostal spaces, the table was arranged in a 'break table' position. CPB was primed and on standby. The left femoral vein was punctured and a Seldinger wire inserted. In the beginning, the venous return cannula was placed in the right atrium, controlled by TEE. An 8-mm Dacron graft was sutured end-to-side to the valved conduit, distal to the valve for potential arterial access. A limited left anterior-lateral thoracotomy was made in the fifth to sixth intercostal space large enough to accommodate a partial occlusion clamp on the aorta. A portion of the rib adjacent to the apex was resected to minimize postoperative pain and to provide a clearance for the LVC. Under single ventilation, the inferior pulmonary ligament was divided and the lung packed off. The length of the valved conduit was trimmed according to the anatomical situation. After heparinization, the aorta was partially clamped and the valved conduit attached to the descending aorta with felt pledgeted 3/0 Prolene interrupted mattress sutures. Subsequently, the pericardium was anteriorly opened to the left phrenic nerve. Lidocaine (100 mg) was given at that time to avoid arrhythmias during manipulation of the apex. A circular insertion site was marked with a pen using the LVC as a template. The coring site was 1.5–2 cm lateral to the true apex to prevent damage to the septum or obstruction of blood flow to the left descending coronary artery (Fig. 2).

Eight 2/0 felt pledgeted Prolene single mattress sutures were placed outside the marked coring site to prevent cutting the threads during coring. The angled LVC was loaded on the gun-like applicator and the device orientated. Sutures were passed through the LVC sewing ring and the applicator introduced into the left ventricle while rotating the applicator handle. After inflating the balloon, the retractor pulled the inflated balloon towards the circular coring knife, and then captured the cored muscle specimen. Haemostasis was maintained at all times. Sutures through the LVC sewing ring were tied, and the balloon was partially deflated. The applicator was then withdrawn from the installed LVC. During withdrawal, the LVC was cross-clamped to maintain haemostasis. Subsequently, the LVC and the valved conduit were joined. The male–female connection was secured with multiple stay sutures and two wraps of umbilical tape. Finally, the LVC was de-aired, and the LVC clamp removed to complete the bypass conduit installation and to relieve the aortic stenosis. The entire AVB procedure was monitored by TEE using the midesophageal four chambers, two chambers and descending aorta short- and long-axis view to assess left ventricular function and the mitral and aortic valves [8].

Postoperative management

All patients were treated with 100 mg of aspirin a day. Patients were extubated after improvement in lung function and inconspicuous chest X-ray. A liberal pain management with patient-controlled anaesthesia was accomplished to have them mobilized the day after surgery. Routine predischarge echocardiography (7 of 7), magnetic resonance imaging (MRI) (4 of 7) and CT (2 of 7) scan were performed.

RESULTS

A total of 7 patients were operated on in our institution between March 2011 and December 2011 and a left ventricular to the descending thoracic aorta AVB implanted. Preoperative characteristics are depicted in Table 1. Most patients were octogenarians in their early 80s and female. The mean logistic EuroSCORE I was 36.4 ± 23.7 (median 36.7%). The rationale for implanting an AVB was previous mechanical mitral valve replacement in 3 (42.9%) patients, ostial encroachment with the risk of coronary occlusion in 3 (42.9%) and severely calcified 'porcelain' ascending aorta in 1 (14.3%). None of the patients was suffering from chronic obstructive pulmonary disease, however, 1 patient was exposed during the working life to asbestos resulting in severe asbestosis.

Intraoperative characteristics are depicted in Table 2. The mean operative time was 185 ± 39 (median 180 min) with a
consistent decrease from 245 min towards 145 min with experience. The median preoperative left ventricular ejection fraction was moderately reduced at 40% and median preoperative pressure mean gradient was as high as 42 mmHg. The mean preoperative aortic valve area was 0.93 ± 0.14 cm². The degree of aortic regurgitation was none to mild in 5 (71.4%) patients and moderate in 2 (28.6%). Although AVB can be performed without CPB, all valved conduits were equipped for safety reasons with an 8-mm side-arm to possibly initiate CPB in a haemodynamically unstable situation. Furthermore, the left femoral vein was punctured in all cases with a guide wire inserted into the right atrium. However, venous cannulation was only accomplished in the first 5 of the 7 cases. One patient had to be connected to CPB due to a tear of the left apex in close proximity to the LVC. After 38 min of extracorporeal circulation and repairing of the tear, the patient could be easily and safely weaned from bypass. In no patient was mechanical support necessary postoperatively. Due to the use of a cell-saver, only 1 patient required foreign blood with 2 units of red blood cells transfused. In all patients, the anterior sixth rib was partially resected to have a kink-free exposure of the conduit. Pain regimen consisted of intramuscular and subcutaneous injection of 40 ml of bupivacaine.

Postoperative complications were depicted in Table 3. Postoperative complications were rare but severe: 1 patient with necrotizing cholecystitis had to undergo cholecystectomy, and 1 patient had to be reintubated because of pneumonia. This patient was additionally suffering from asbestosis, resulting in prolonged ventilation. Unfortunately, he died on postoperative day 16 of septic shock.

One patient suffered from postoperative atrial fibrillation, but no further arrhythmias were detected. Of note, no high-graded heart block requiring continuous monitoring or even pacemaker implantation occurred. Despite delirium in 2 patients, no neurological complications such as stroke or seizure were diagnosed. Renal function was not deteriorated and hypervolemia was treated with Furosemid alone. Heart enzymes ([creatininkinase (CK) and creatininkinase muscle brain subtype CK(MB), Troponin I and myoglobin] were elevated with a short-term peak and subsequent steep decline (Table 3). We consider this to be due to the coring of the apex and the suturing of the LVC to the left ventricular apex and not due to ischaemia, since the left ventricular ejection fraction remained equal with 40.6 ± 16.2% preoperatively and 43.3 ± 11.4% postoperatively. PredischARGE echocardiography revealed a significant decrease in mean pressure gradient over the native aortic valve from 38.7 ± 9.8 to 12.3 ± 1.15 mmHg, respectively. Four patients had a predischarge MRI scan showing that 70.7 ± 13.9% of ejected blood volume passed through the valved conduit. Two patients had a predischarge CT scan to determine the intrathoracic course of the conduit (Fig. 3).

Patients were discharged from the hospital after a mean of 16 ± 5.2 days to commence rehabilitation in a rehabilitation centre.

**DISCUSSION**

To our knowledge, we are the first in Europe to have this novel aortic-valved bypass technology used in clinical practise. Though the concept of AVB was developed in 1955 and has since been applied worldwide in more than 1500 cases with about 250 cases published in the literature, AVB showed only low surgical adoption due to the lack of delivery instrumentation and the need for CPB [7, 9]. This is even more surprising, since long-term clinical data support the benefit of positioning a valved conduit between the apex of the left ventricle and the descending aorta [10, 11]. Thus, the presented technique of AVB therapy is an improved version of the historically proven apico-aortic conduit procedure. The main component of the Corex AVB (Corex, Inc., Waltham, MA, USA) is the applicator that facilitates the implantation of the conduit into the apex. Without the need for going on-pump, it simultaneously cores the heart wall, safely captures the tissue plug, provides haemostasis and supports insertion of the angled LVC. The LVC consists of an 18-mm standard graft material (Vascutec Terumo, Renfrewshire, Scotland) and is...
attached via a male–female connector to the straight valved conduit that includes a third generation bioprosthetic valve used clinically in conventional AVR for more than a decade [12].

So far, we have implanted this novel AVB in 7 patients for different reasons based on our algorithm for aortic valve surgery. After reviewing patient charts and current examinations, we assigned patients in a stepwise and sequential approach to either conventional AVR, TAVI or AVB. Preoperative data in this cohort such as mean age of 81.6 years, mean standard EuroSCORE I of 12, previous CABG, pulmonary hypertension, peripheral vascular disease and impaired left ventricular ejection fraction suggested the avoidance of the conventional surgical approach. In this study, the logistic EuroSCORE was applied to assess perioperative risk, resulting in a potential overestimation of the predicted mortality. Based on the publications by Osswald et al. and Kalavrouziotis et al., the predicted and the observed 30-day mortalities for patients undergoing conventional AVR were significantly different (Osswald et al. 8.3 vs 14.8% and Kalavrouziotis et al. 38.7 vs 11.4%) [13, 14]. Despite knowing the limitations in accurately predicting mortality, we used the widely accepted EuroSCORE due to the lack of a valid substitute.

Based on the position statement of the European Association of Cardio-Thoracic Surgery (EACTS), the European Society of Cardiology (ESC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI), we would have rather favoured a transcatheter valve implantation [15]. However, during the work-up for TAVI, three major impediments occurred:

(i) Three patients had ostial encroachment with <8 mm distance between annulus and coronary ostia. Occlusion of the coronaries in patients with <12 mm distance between annulus and ostia in the CT scan is a rare but potentially lethal complication with TAVI. Thus, a safety margin of minimum 9–11 mm of distance should be considered for a safe transcatheter approach [16, 17].

(ii) Three patients had previous mechanical mitral valve replacement. During percutaneous aortic valvuloplasty, malfunction of the prosthesis with obstruction of one leaflet occurred. It was expected that TAVI would cause similar difficulties due to interference with the mitral valve prosthesis [18].

(iii) One patient had a porcelain aorta with protruding plaques. An occurrence of stroke complicates from up to 10% of TAVI procedures. Protruding plaques in the ascending aorta predispose not only to non-descript cerebral lesions, but also severe clinical neurological deficits [19, 20].

With this in mind, we considered AVB to be a non-touch technique of this hostile aortic valve anatomy, and to be the safest and most reliable approach in these patients. Furthermore, the ascending aorta non-touch concept of the AVB avoids risk of procedure-related heart block with subsequent pacemaker implantation [21, 22]. There is also no risk of paravalvular leakage or as well as no risk for patient-prosthesis mismatch [23].

Due to the conceptual avoidance of CPB, risk of embolization during cannulation or cross clamping of the aorta is avoided. Patients with pre-existing kidney malfunction may also benefit [24]. However, in 1 patient, we had to commence CPB because of a fragile apex. Nevertheless, due to the 8-mm side-arm attached to the conduit for CPB arterial inflow, potential plaque embolization of arterial cannulation could be avoided.

In a recent publication, Thourani et al. [25] showed their retrospective review of 21 high-risk patients undergoing off-pump AVB. The insertion procedure of the apical connector was divided into several subsequent steps of placing an intraventricular Foley catheter, coring the apex under rapid pacing with a 16-mm Hancock Trocar Blade Coring device (Medtronic, Inc), removing the apical plug together with the Foley catheter and placing/suturing the apical connector. The authors showed good periprocedural results with an in-hospital mortality of 14.3%, emphasizing the benefit of avoiding CPB. However, the need for rapid pacing as well as the fragmentation of the most delicate step (connecting the LVC to the apex) may impose a certain risk in inexperienced hands. With the use of the Correx AVB device, the implantation of the LVC can be accomplished in a single process with minimal blood loss and haemodynamic stability [1].

With this series of 7 high-risk patients who were amenable neither for conventional AVR nor for TAVI, we could demonstrate the feasibility of a new off-pump AVB technique. Overall morbidity and mortality were reasonable given the lack of alternative therapeutic options. Further studies are needed to prove the long-term results of this innovative approach to relieving left ventricular outflow tract obstructions in patients with critical aortic stenosis.

Conflict of interest: Reuthebuch is a proctor for Correx Inc. All other authors have no conflict of interest.
REFERENCES


