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Background. Interest in percutaneous therapy of heart valve disease has focused attention on the high-risk patient with aortic stenosis. Aortic valve bypass (apicoaortic conduit) surgery is the construction of a vascular graft containing a bioprosthetic valve from the apex of the left ventricle to the descending thoracic aorta. We have undertaken a programmatic effort to perform aortic valve bypass surgery as an alternative to conventional aortic valve replacement in selected high-risk patients, and now report our recent experience.

Methods. Between April 2003 and May 2005, 14 patients with aortic stenosis underwent aortic valve bypass surgery at two institutions. All patients selected for aortic valve bypass surgery were deemed to be at very high risk for conventional aortic valve replacement. These patients represented 14 (5.8%) of all 243 patients undergoing isolated aortic valve surgery during the same time period. Mean Society of Thoracic Surgeons predicted risk for operative mortality (11%) was between the 90th and 95th percentile.

Results. Twelve of 14 patients had previous cardiac surgery with patent bypass grafts. Average age was 78 years. Mean aortic valve area was 0.68 cm². All operations were performed through a left thoracotomy on the beating heart (cross-clamp time, 0 minutes). Cardiopulmonary bypass was used for 6 patients (median cardiopulmonary bypass time, 15 minutes). There were 2 perioperative deaths. Median postoperative length of stay was 9 days. Two noncardiac late deaths occurred. Nine of 10 surviving patients are functional class I and are living independently. Early postoperative echocardiography confirms excellent aortic valve bypass function with preservation of ventricular ejection performance.

Conclusions. Treatment of high-risk aortic stenosis patients with aortic valve bypass surgery is promising. Avoidance of sternotomy and cardiopulmonary bypass supports broader application to moderate-risk patients with aortic stenosis and as a control arm for studies of novel interventional therapies.

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Surgical replacement of the stenotic aortic valve is one of the most successful innovations in cardiovascular medicine and has afforded symptomatic relief and prolongation of life for millions of patients worldwide. Since it was first performed in 1961, the fundamentals of conventional aortic valve replacement have remained unchanged [1]. With modern prostheses, myocardial protection, and advanced perioperative care, the in-hospital mortality for isolated aortic valve replacement has fallen below 4% [2]. However, mortality associated with conventional aortic valve replacement is substantially higher in specific patient populations, including the elderly, women, patients requiring reoperation, and patients on hemodialysis [3]. One-year mortality after aortic valve replacement is approximately twice the in-hospital mortality rate [4]. Morbidity after aortic valve replacement is substantial, and the operation continues to require a median sternotomy, cardiopulmonary bypass, aortic cross-clamping, and cardioplegic arrest. There is evidence that a substantial number of elderly patients with symptomatic aortic stenosis are never considered for surgery [5]. Faced with this challenging population of patients with symptomatic aortic stenosis, we have chosen to perform aortic valve bypass surgery for selected very high risk patients with aortic stenosis as an alternative to conventional aortic valve replacement. We now report our recent clinical experience.

Material and Methods

We performed a retrospective chart review. Estimated risk-adjusted operative mortality was calculated using The Society of Thoracic Surgeons (STS) risk calculator (available at: http://66.89.112.110/STSWebRiskCalc/). The STS risk-adjustment model for predicting operative mortality includes 19 preoperative variables and has been previously described [3].

Patients and Indications for Surgery

All patients selected for aortic valve bypass surgery were deemed to be at very high risk for conventional aortic valve replacement. An independent assessment of suitability for aortic valve bypass surgery was performed by at least two attending surgeons (J.S.G., B.P.G.) at the University of Maryland Medical Center and by the operating surgeon (J.W.B.) at Indiana University School of Medicine. Informed consent was obtained after consultation with the patient and family. This review was approved by the institutional review boards of the University of Maryland Medical Center and Indiana University School of Medicine.

Preoperative Evaluation

All patients underwent a standardized preoperative workup that included transesophageal echocardiography, cardiac catheterization, and multislice computed tomography. Patients with significant operable coronary disease, more than moderate aortic or mitral insufficiency, or severe calcification or mural disease of the descending thoracic aorta at the site of planned anastomosis were excluded.

Operative Technique

Patients were placed in the left lateral decubitus position. After double-lumen intubation, heparin (5,000 units) was administered intravenously, and a femoral vein accessed with a heparin-bonded Biomedicus cannula (Medtronic Inc, Minneapolis, MN). The aortic valve bypass conduit was constructed on the back table. In one configuration, a size 18 apical connector (Medtronic, Irvine, CA) was preclotted with thrombin and cryoprecipitate. It was anastomosed to a size 21 stentless porcine valve (Freestyle; Medtronic), which was in turn anastomosed to a size 20 Hemashield (Boston Scientific, Natick, MA) graft with a single 8-mm side branch, which was later used for arterial inflow from the heart-lung machine. The porcine coronary ostia were oversewn with pledgeted sutures. In the other configuration (previously described and illustrated [6]), the conduit consisted of a 20-mm diameter model 10 or 150 Medtronic valved conduit with a stentless porcine aortic valve inserted in its center. The conduit was in turn connected to an 18-mm diameter Medtronic apical connector. No preclotting of the graft was performed.

An anterolateral thoracotomy was performed over the apex of the heart. One author (J.S.G.) inserted a videoscope posteriorly through an exploratory incision to identify the location of the ventricular apex and guide placement of the thoracotomy incision. The inferior pulmonary ligament was mobilized, and the descending thoracic aorta exposed. The overall length of the conduit from the left ventricular apex to the anastomotic site on the descending aorta was determined, and the conduit cut to length. The distal anastomosis was constructed between the conduit and the aorta using running 4-0 monofilament suture or interrupted 2-0 polyester
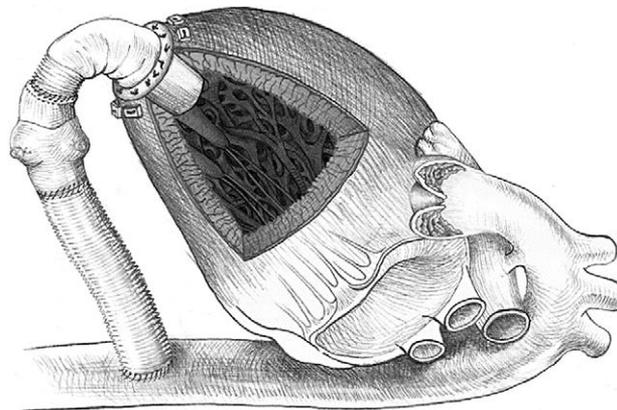

Fig 1. An aortic valve bypass.

pledgeted sutures and a specially designed partial occluding clamp. The apex was exposed, and between 8 and 12 2-0 pledgeted monofilament sutures placed in a circumferential fashion about the location of the proposed ventriculotomy. During insertion of the apical connector, the heart was transiently paced at 200 beats per minute to minimize blood loss [7]. A stab wound was made in the apex, and a Foley catheter inserted and inflated with saline to a diameter that is 3 mm larger than the diameter of the circular coring knife (cork borer). The coring knife was used to create a clean apical hole, and the apical connector inserted and tied down. After deairing the graft with a 20G needle in the angled portion of the connector, blood flow was established from the apex to the descending thoracic aorta (Fig 1).

Postoperative Management

All patients received aspirin (325 mg) after surgery. No patient was given warfarin. All patients underwent routine predismissal echocardiography.

Follow-Up

Follow-up was performed by telephone interview or clinical examination, or both. Mean follow-up was 12 months (range, 2 to 39). All operative survivors underwent early transthoracic echocardiographic examination to evaluate left ventricular ejection performance and residual gradient across the native aortic valve.

Results

Patients

Between June 2002 and May 2005, 14 patients with symptomatic aortic stenosis underwent aortic valve bypass surgery at two institutions. These patients represented 14 (5.8%) of all 243 patients undergoing isolated aortic valve surgery during the same time period. Mean age was 78 years (range, 62 to 87). All patients were New York Heart Association class III or IV before surgery. Peak and mean aortic valve gradients were 67 $\pm$ 11 mm Hg (range, 41 to 82 mm Hg) and 43 $\pm$ 7 mm Hg (range, 24 to 50 mm Hg), respectively. Mean pre-
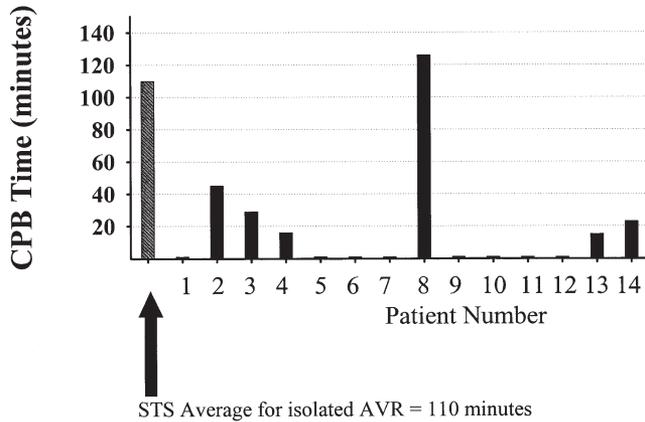
Fig 2. Cardiopulmonary bypass (CPB) times for aortic valve bypass operations. (STS = The Society of Thoracic Surgeons; AVR = aortic valve replacement.)

operative ejection fraction was 52% ± 11% (range, 30% to 65%). Calculated aortic valve areas averaged 0.68 ± 0.13 cm² (range, 0.5 to 0.9 cm²). Risk factors included prior coronary artery bypass surgery (CABG) with patent grafts in 12 of 14 patients (86%). Median serum creatinine was 1.7 mg/dL (mean, 1.5 ± 0.5 mg/dL; range, 0.8 to 2.2 mg/dL). Four patients (29%) had advanced lung disease requiring home oxygen. Eight patients (57%) had significant cerebrovascular disease (at least 75% carotid stenosis, or prior carotid endarterectomy). Diabetes mellitus was present in 8 patients (66%) and hypertension in 10 (71%). Seven patients had been turned down for conventional aortic valve replacement by another cardiac surgeon. Mean STS-predicted risk for operative mortality (11%) was between the 90th and 95th percentile.

Perioperative Results

Cardiopulmonary bypass was used in 6 of 14 patients (Fig 2). Cross-clamp time was 0 minutes for all patients. No patient suffered a stroke, and no patient had permanent renal failure requiring hemodialysis. There was 1 perioperative death in a patient with advanced pulmonary fibrosis who could not be oxygenated in the operating room. Autopsy confirmed an intact and functional aortic valve bypass and severe parenchymal interstitial fibrosis.

One additional patient with a history of pulmonary embolism was discharged on postoperative day 5 and readmitted with multiple pulmonary emboli 2 weeks later. Warfarin therapy was instituted as an outpatient. The patient presented 1 week later in cardiac arrest with an international normalized ratio (INR) of 11 and a massive lateral chest wall hematoma. The conduit was found to be intact at the time of unsuccessful resuscitative thoracotomy. Overall hospital mortality was 14% (2 of 14). Reoperations were performed for bleeding (1 early, 1 late) in 2 patients. Two patients required reoperation for repair of left-ventricular apical pseudoaneurysms: 1 presented with hemodynamic instability and

tamponade 15 days after surgery, and the other was found to have an asymptomatic apical pseudoaneurysm on follow-up computed tomography and was electively returned to the operating room on postoperative day 8. In both cases, defects were closed with several pledgeted sutures. One of these patients was found to have a small (1 × 1 × 2 cm) recurrent apical pseudoaneurysm 4 months postoperatively. That was successfully thrombosed with percutaneously injected coils and thrombin (Fig 3).

Median intensive care unit length of stay was 3.8 days (range, 0 to 48). Median total ventilator time was 16 hours (range, 0.25 to 856). Eight of 12 survivors were intubated less than 24 hours. Median hospital length of stay was 9 days (range, 5 to 54). There were 2 late noncardiac deaths (1 at 2 months from unknown causes, 1 at 3 months from respiratory insufficiency). Nine of 12 surviving patients are in functional class I or II while 1 (3 years postoperative) is in functional class III. Postoperative echocardiography performed within 2 weeks of operation demonstrated a mean ejection fraction of 54% ± 13% (range, 30% to 65%) and an average mean gradient across the native aortic valve of 8.8 ± 3.3 mm Hg (6.6 to 16.6 mm Hg).

Comment

This study demonstrates that aortic valve bypass surgery is an acceptable alternative to conventional aortic valve replacement for the high-risk aortic stenosis patient. We found acceptable morbidity and mortality using this approach for a highly selected group of "no option" patients with multiple comorbidities. Aortic valve bypass surgery afforded excellent relief of left ventricular out-

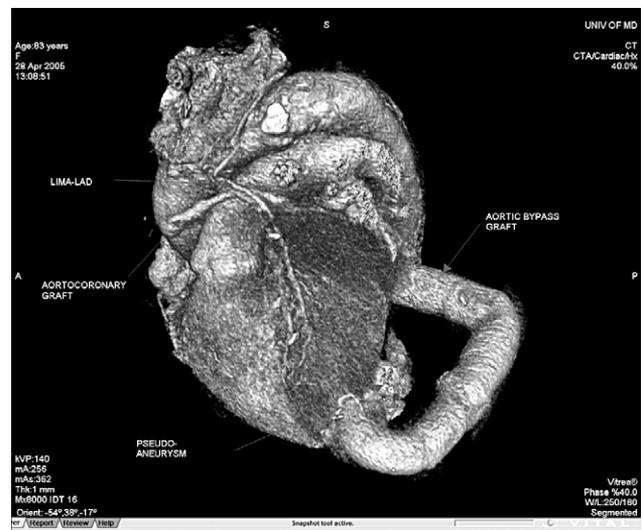

Fig 3. Multislice computed tomography reconstruction demonstrating apical pseudoaneurysm after aortic valve bypass operation. The patient underwent successful percutaneous coil embolization of the pseudoaneurysm 4 months after surgery, and continues to do well clinically 7 months after surgery. (LIMA-LAD = left internal mammary artery [to] left anterior descending coronary artery [bypass].)

Table 1. Clinical Experience With the Aortic Valve Bypass (Apicoaortic Conduit)

Author	Year	No. of Patients	No. of Adults	Operative Mortality	Follow-Up
Brown[a]	1984	23	4	5/23 (22%)	44 mos: 13 alive, class I, no reoperation 4 alive, class I, reoperation 1 late death (infection)
Cooley[b]	2000	7	7	2/7 (29%)	? time 5/7 "well"
Sweeney[c]	1986	38	18	4/38 (10%)	?
Renzulli[d]	2000	4	4	1/4 (25%)	15 years
Vassiliades[e]	2000	3	3	0/3	4 months
Crestanello[f]	2004	13	13	3/13 (24%)	2.1 years: 4 late deaths
Freeman	2005	1	1	0/1	24 years
Current Series	2005	14	14	2/14 (14%)	12 months
Totals		103	64	17/103 (17%)	

[a] Eighteen of 23 done without CPB; 18 of 23 were reoperations; 2 deaths in children with complex congenital problems; 2 deaths in patients in cardiogenic shock; 1 technical problem (80-year-old patient with friable ventricle: bleeding contributed to death); used 20 to 22 mm conduits for adults [6]. [b] Both deaths in high-risk patients; left ventricle connector size range 14 to 20 mm [10]. [c] 8 late deaths; 4 shunt-related (3 disruption of conduit from LV, 1 infection); 26 long-term survivors all asymptomatic, none on anticoagulation, none with thromboembolism; in subgroup of patients 65 and older, 6 of 7 were alive and well an average of 5 years postoperatively [11]. [d] One death due to postoperative sepsis. Patient 2, 19 years out without symptoms, has had two babies; 3 patient had conduit thrombosis due to heavily calcified tissue valve 6 years out, underwent successful reoperation (valve replacement in conduit) and died at 13 years (suicide). Patient 4 required similar valve replacement 3 years postoperatively, now 15 years out and doing well [12]. [e] All cases done off-pump [13]. [f] No thromboembolic complications related to the conduit were observed among hospital survivors.

flow obstruction with preservation of ventricular ejection performance. Early postoperative echocardiographic analysis demonstrated low gradients across the native stenotic valve. All aortic valve bypass operations were accomplished without aortic cross-clamping and with minimal use of cardiopulmonary bypass. We believe that these technical factors contributed to the absence of perioperative neurological complications in a group of patients at very high risk for stroke. Operative survivors are enjoying good functional status at midterm follow-up.

Aortic valve bypass surgery is not a new operation. The concept of an apicoaortic valved conduit to bypass valvular aortic stenosis was conceived by Carrel in 1910 [8], performed experimentally by Sarnoff and colleagues [9] in 1955, and performed clinically by Templeton [6] in 1962. The technique did not gain popularity because of problems with hemolysis and emboli related to the conduit components and because of the success of direct aortic valve resection and replacement. In the early 1970s, a woven Dacron graft containing a porcine valve was introduced for right heart reconstruction. Brown and colleagues [6] used this valved conduit experimentally in the apicoaortic position and found that it functioned well to bypass the obstructed left ventricular outflow tract. Late animal data from Brown's group and early clinical experience by Brown and several other groups stimulated occasional clinical application of the apicoaortic conduit [6]. The published experience with the aortic valve bypass is summarized in Table 1.

Unoperated symptomatic aortic stenosis carries a dismal prognosis [14]. Recent data suggest that there is a large number of patients with critical aortic stenosis who are never referred to surgery [15]. To extend the benefits of surgical relief of aortic stenosis to this higher-risk population, we have undertaken a programmatic effort to perform aortic valve bypass surgery in selected high-risk patients. The current series contains patients who are elderly with multiple comorbidities. We were able to validate our clinical impression of risk using a validated risk prediction algorithm, and found that the mean predicted mortality risk was between the 90th and 95th percentile. The large percentage of patients in our experience requiring reoperation with patent coronary artery bypass grafts (12 of 14, 86%) exemplifies the challenges of conventional aortic valve replacement in this group. Published reports of aortic valve replacement after previous coronary bypass surgery report mortality rates between 6% and 16%, with stroke rates between 6% and 11% [16–18].

There are several advantages of aortic valve bypass surgery compared with conventional aortic valve replacement. Cross-clamping of the ascending aorta is never required. Cardiopulmonary bypass is used infrequently, and when necessary, for a brief period of time. As we have gained experience with the technical aspects of aortic valve bypass surgery, cardiopulmonary bypass has been used less frequently (see Fig 2). The median duration of cardiopulmonary bypass in this series (15 minutes) is far less than that associated with conventional isolated aortic valve replacement (110 minutes) [2].

Conventional aortic valve replacement is associated with a significant risk of thromboembolism that is amortized over the life of the patient. Both mechanical and bioprosthetic aortic valves are associated with a risk of thromboembolism that is estimated to be between 0.5% and 2.0% per year [19]. A recent report of more than 3,000 patients having left heart valve operations and a cumulative follow-up of more than 20,000 patient-years demonstrated linearized embolic stroke rates of 1.3% ± 0.2% for aortic bioprostheses and 1.4% ± 0.2% for aortic mechanical replacement valves [20].

By 15 years after operation, approximately 20% of patients having aortic valve replacement had suffered a stroke. We believe that the basic configuration of the aortic valve bypass may be brain protective. Blood flow to the brain is through the native valve, while the conduit supplies the remainder of systemic blood flow. Thrombi that form on the prosthetic valve likely cannot reach the brain. The thromboembolic burden downstream from the valved conduit may be less than seen from a conventional prosthesis in the native position, because the sewing cuffs (and pledgets) are not exposed to the blood path. Careful scrutiny of the literature (Table 1) demonstrates a complete absence of late strokes among hospital survivors of aortic valve bypass surgery. We have continued to use aspirin alone after aortic valve bypass surgery, and have enjoyed complete freedom from perioperative and late stroke.

Paravalvular leak is present in as many as 6% of patients early after conventional aortic valve surgery [21]. Severe paravalular leak requiring reoperation occurs in 1.0% to 3.5% of patients after conventional aortic valve replacement [22], and is the second most common reason for reoperation after structural valve deterioration of a bioprosthetic valve. Paravalvular leak cannot occur after aortic valve bypass surgery.

Conduction system injury is a recognized complication of conventional aortic valve replacement that does not occur after aortic valve bypass surgery. The incidence of permanent pacemaker insertion after conventional aortic valve replacement is between 3% and 6% [23]. No patient in the current series required a new pacemaker during hospitalization.

Patient-prosthesis mismatch has been estimated to occur in as many as 50% of patients after conventional aortic valve replacement [24]. Patient-prosthesis mismatch has been associated with increased perioperative mortality, decreased postoperative exercise tolerance, and failure of left ventricular mass regression. The aortic valve bypass has two critical advantages over conventional aortic valve replacement in the sizing domain. Patient-prosthesis mismatch is completely avoided with the aortic valve bypass because the surgeon is not limited in the size valve and conduit that can be implanted. In our initial series, we have chosen a nominal size 21 stentless aortic valve coupled to a 20-mm conduit. Stentless valves are associated with a very low incidence of patient-prosthesis mismatch because they have a high performance index (ratio of internal orifice area to external orifice area). We believe that this size is more than adequate for all adult patients undergoing aortic valve bypass for aortic stenosis. The final left ventricular outflow area after aortic valve bypass is the sum of the area of the native stenotic valve (usually 0.5 to 1.0 cm^2) and the area of the valve in the conduit. In comparison, the total effective orifice area after a conventional aortic valve replacement is limited to the internal orifice area of the prosthetic valve.

We observed excellent hemodynamic results after aortic valve bypass surgery in all patients. Left ventricular ejection performance was unchanged after operation. Measured gradients across the native valve were low (mean gradient, 8.8 ± 3.3 mm Hg) and similar to results after conventional aortic valve replacement [25–27], suggesting excellent relief of left ventricular outflow obstruction. Measured gradients across the native valve are equivalent to gradients across the aortic valve bypass. Aortic valve bypass surgery affords durable relief of left ventricular outflow tract obstruction. Freeman and associates [28] recently reported a 24-year survivor of aortic valve bypass surgery, and we (J.W.B.) have a patient who is 25 years out from operation with a normally functioning conduit.

As our experience performing aortic valve bypass surgery has grown, we have learned the importance of certain technical aspects of the operation. The ventricular apex can be a friable structure, particularly in the elderly. The majority of the strength of the apex is within the epicardium. Sutures that are placed to the appropriate depth and that are tied in a manner that creates a hemostatic seal without tearing the epicardium are key to the construction of a hemostatic and reliable anastomosis. Our series is notable for 2 patients who required early reoperation for apical pseudoaneurysms. Control of bleeding from the friable apex and the development of pseudoaneurysms remain a significant concern and perhaps can be mitigated with improved technology—now under development—for inserting and securing the apical connector. We have routinely performed follow-up predismissal multislice computed tomography and have not seen evidence of additional apical anastomotic complications.

This study demonstrates that aortic valve bypass surgery is a promising alternative to conventional aortic valve replacement for the high-risk patient with aortic stenosis. Avoidance of sternotomy and cardiopulmonary bypass supports broader application to moderate-risk patients with aortic stenosis and as a control arm for studies of percutaneous interventional therapies.

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INVITED COMMENTARY

Back to the future? Although highly successful, aortic valve replacement still has a host of problems that need to be managed. These problems include the following: ascending aortic calcification that can embolize or complicate aortic cross clamping or aortotomy closure; a small aortic annulus that may require patch enlargement (a more complex operation with higher risks), or the possibility for patient prosthesis mismatch; possible peri-valvular leak depending on the quality of the aortic annulus and the experience of the cardiac surgeon; heart block; fibrosis and calcification from radiation heart disease; and various problems in patients with patent coronary bypass grafts such as managing proximals attached near the aortotomy, avoiding a left internal mammary artery graft that may be in the midline, and obtaining adequate myocardial protection. Oftentimes primary aortic valve replacement is a low-risk operation. However, elderly patients with comorbidities that lead to high operative risk stimulated the development of percutaneous aortic valve replacement. Just as the advent of stenting pushed surgeons to consider more creative ways to perform coronary artery bypass, the advent of percutaneous valve techniques has stimulated surgeons to

consider alternative approaches to conventional aortic valve replacement. The advantages of the aortic valve bypass as described in this article are to avoid the problems of conventional aortic valve replacement in high-risk patients. A strong advantage over percutaneous aortic valve approaches is the ability to use a known commercially available prosthetic valve with a strong track record for durability. Ideal candidates for this type of approach could include patients with ascending aortic calcification, patients who require complex reoperations, and patients with a small annulus. With new strategies and new technologies this can become a very attractive alternative for a significant percentage of patients undergoing isolated aortic valve replacement (i.e., 5.8% in Gammie and colleagues' [1] experience). However, current state of the art is to modify existing conduits and valves adapted to fit this very different situation. The potential problems with the aortic valve bypass approach include pseudoaneurysm as described in their article, bleeding due to lack of control of the left ventricular (LV) apex, difficulty with the aortic anastomosis in the descending aorta due to extensive calcification of the descending aorta, kinking of the conduit because it is either too long or

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