Alternative access options for transcatheter aortic valve replacement in patients with no conventional access and chest pathology

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Objective: Aortic stenosis is the most common valvular pathology in the elderly. Transcatheter aortic valve replacement has emerged as a safe and feasible alternative for high-risk patients. However, a significant number of patients are still not transcatheter aortic valve replacement candidates because of poor peripheral access and chest pathology. We report the use of alternative access options for such patients.

Methods: Seven patients who had poor peripheral access and chest pathology had transcatheter aortic valve replacement using alternative access techniques. Five patients had the valve delivered by direct cannulation of the aorta via a mini-sternotomy, and 1 patient had the valve delivered via a mini–right thoracotomy. In 1 patient, the right subclavian artery was cannulated. Intraprocedural and 30-day outcome data were analyzed.

Results: The mean age of patients was 85.00 ± 9.59 years, with a Society of Thoracic Surgeons score of 16.81% ± 6.87% and logistic European System for Cardiac Operative Risk Evaluation of 21.59% ± 8.46%. Procedural success was 100%. Procedural and 30-day mortality were zero. There were no access-related complications or neurologic events. Two patients had worsening renal function that did not require dialysis. All patients were discharged with a median hospital stay of 7 days. In our experience of 138 transapical or alternative access patients, 7 died (5%) and for 257 transfemoral patients, 1 died (0.4%).

Conclusions: Despite the high surgical risk of the study population, these techniques had excellent outcome with no mortality and acceptable morbidity. With the use of currently available technologies, these approaches are promising and offer alternative options in patients with no access and prohibitive chest pathology or pulmonary function. (J Thorac Cardiovasc Surg 2014;147:644-51)

Aortic stenosis is the most common valvular pathology in the elderly, with an estimated prevalence of 4.5% in adults aged 75 years or more.[1] The outcome of medically managed symptomatic aortic stenosis is dismal, with approximately 50% of the patients not surviving beyond the first year.[2] Surgical aortic valve replacement (SAVR) is the gold standard in the treatment of symptomatic aortic stenosis and has been proven to have both symptomatic and survival benefits.[3] However, because of the typical elderly patient with many comorbidities, a large number of patients with aortic stenosis are not referred for surgery because they are considered inoperable or are at very high risk.

Since the first successful clinical implantation by Cribier and colleagues[4] in 2002, transcatheter aortic valve replacement (TAVR) has emerged as a therapeutic option for the inoperable and high-risk patient. Currently, the 2 routes by which the valve is delivered are the retrograde transfemoral or antegrade transapical approach. However, there remain a considerable number of patients who are not candidates for either approach because of poor vascular access, poor pulmonary function, or chest pathology.

This report describes our initial clinical experience in 7 patients using a retrograde approach of TAVR by direct cannulation of the ascending aorta or the subclavian artery in patients who had poor peripheral vascular access, respiratory function, and chest pathology.

MATERIALS AND METHODS

Patient Selection

Patients who are considered inoperable or very high risk for SAVR are currently only considered for TAVR at the Cleveland Clinic. A multidisciplinary team consisting of cardiac surgeons and cardiologists assess and discuss each patient and decide on the optimal approach for each patient given the patient demographics and risk factors.

Those selected for a percutaneous approach are then assessed for the retrograde transfemoral or antegrade transapical approach via a left thoracotomy. However, patients in this report were not suitable for either approach for reasons that will be described.

Patient Risk Level Stratification

In addition to clinical assessment of patients, comorbidities, and risk factors, risk scores were used. Both the Society of Thoracic Surgery score and the European System for Cardiac Operative Risk Evaluation were

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Abbreviations and Acronyms

AV = aortic valve
BAV = balloon aortic valvuloplasty
CPB = cardiopulmonary bypass
FEV1 = forced expiratory volume in 1 second
ICU = intensive care unit
SAVR = surgical aortic valve replacement
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography

calculated. The score values were used as an adjunct to clinical decisions, and the numbers were not taken as absolute.

Preoperative Workup

All patients underwent preoperative transthoracic echocardiography and transesophageal echocardiography (TEE). They also underwent diagnostic coronary angiogram. Workup also included pulmonary function test with diffusion capacity.

For assessment of the central aorta and peripheral arteries, patients had computed tomography angiography that included the ascending, arch, thoracoabdominal aorta, iliac, and femoral arteries. Assessment of tortuosity of the aorta and degree of stenosis, calcification, and aneurysm was performed. Measurements of different sections of the peripheral and central aorta were performed to assess whether the valve delivery sheath could be safely accommodated.

Procedure

All procedures were performed under general anesthesia in a hybrid-operating suite. The team consisted of cardiac surgeons, interventional cardiologists, and cardiac anesthesiologists. Cardiac perfusionists with a primed cardiopulmonary bypass (CPB) machine were on standby in all cases. Both fluoroscopy and TEE were used as imaging modalities during the procedure. TEE was used to measure the aortic annulus to size the valve to be deployed and to give a dynamic view of the procedure.

Five patients had access to the ascending aorta via an upper J incision hemisternotomy, 1 via a mini–right anterior thoracotomy and 1 through the left subclavian artery. In the patients with an upper hemisternotomy, an 8-cm skin incision was performed in the midline starting just above the manubriosternal angle. Preoperatively, by using computed tomography scans, the decision was made whether to cut into the right third or fourth intercostal space depending on the position of the aortic annulus.

A regular sternal saw was used to split the sternum at midline starting at the sternal notch. The sternal cut is deviated to the desired right intercostal space forming a J-incision. A mini-sternal retractor was used to spread the split sternum. The pericardium was opened and retracted with stay sutures to the chest wall allowing good exposure of the aorta. In 1 patient (patient 4), the approach was via a mini–right anterior thoracotomy. A 4-cm incision was made over the right second intercostal space just lateral to the sternum. The third rib was transected at the medial end to allow better exposure of the space. A mini–rib spreader was used to open the intercostal space. The pericardium was opened, and the edges were tucked to the chest wall. In patient 7, the access was via the left subclavian artery. A 5-cm long incision was made just across the mid-clavicular line approximately 2 cm below the clavicle. The subclavian artery was exposed, and a 10-mm Dacron graft was anastomosed to a longitudinal arteriotomy. An Edwards (Edwards Lifesciences Inc, Irvine, Calif) delivery sheath was secured to the Dacron graft and acted as a control valve.

In our initial experience and in anticipation of any emergency situation requiring the heart-lung machine, we have obtained generous exposure to easily access the aortic valve (AV). A unilateral cut-down of the femoral artery and vein also was performed. Transvenous pacer wires were introduced and passed via the femoral vein into the right atrium. The patient received 100 U/Kg of unfractionated heparin, and the activated clotting time was maintained at more than 300 seconds until the end of the procedure. Heparin was reversed 1:1 with protamine at the end of the case before closing the chest.

An area denude of any evidence of calcification was selected in the ascending aorta. Care was taken to select the appropriate angle and distance from the aortic annulus to allow manipulation of the valve sheath. The best location is the upper one third of the ascending aorta because this gives adequate length and better curving angle. A double purse string was applied to the left lateral portion of the upper one third of the ascending aorta. Access into the aorta was gained with an 18-G needle and a starter wire. The needle was exchanged for a short 5F sheath, and the starter wire was exchanged with a 0.035-inch straight soft-tip hydrophilic glide wire. Under fluoroscopy, the AV was crossed with a glide wire and 5F catheter. Simultaneous pressure recordings of the left ventricle and aorta were obtained. The wire was exchanged with an extra stiff wire with a soft curved tip. The 5F sheath was then exchanged with the Edwards delivery sheath. A 20-mm balloon dilation catheter was passed over the wire and positioned across the stenotic AV. Under rapid ventricular pacing and ventilator arrest, AV balloon angioplasty was performed. These steps were the same in the subclavian approach.

All patients received SAPIEN (Edwards Lifesciences Inc) percutaneous AVs. The valves used in these cases were loaded in a retrograde fashion as those used in the transfemoral approach. By using a combination of fluoroscopy and TEE guidance, the valve was positioned at the desired level across the AV. Under rapid ventricular pacing and ventilator arrest, the AV was deployed. Our approach has been for a slow deployment of the valve to allow adjustment of the position in case the valve moves while being deployed.

The valve sheath was then removed and replaced with a pigtail. We performed a root aortogram to assess for valvular and paravalvular regurgitation. TEE was used to confirm position, measure gradients, and assess for valvular and paravalvular regurgitation. After deployment, balloon dilation of the valve was sometimes performed if there was evidence of significant paravalvular leak.

A single chest tube was inserted in a para-aortic fashion, and the sternum was closed in the usual manner in cases with sternotomy and mini-thoracotomy. If hemodynamic and respiratory status allowed, extubation was attempted on all patients in the operating room after the procedure.

Statistical Evaluation

Continuous variables were reported as mean ± standard deviation or median with interquartile range given the small sample size. Categoric variables are described as percentages. Paired *t* test was used to compare continuous variables.

RESULTS

Demographic Characteristics

Table 1 summarizes the preoperative baseline characteristics of the patients. The study population had a mean age of 85.00 ± 9.59 years. None of the patients were on dialysis, and the mean creatinine was 1.41 ± 0.55 mg/dL. All patients were hypertensive and had peripheral vascular disease, but none of them were diabetic and receiving insulin.