

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 $16.81\% \pm 6.87\%$ and logistic European System for Cardiac Operative Risk Evaluation of $21.59\% \pm 8.46\%$. 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 colleagues⁴ 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 devoid 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 \pm standard deviation or median with interquartile range given the small sample size. Categorical 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.

TABLE 1. Clinical characteristics

Clinical characteristics	Patient 1	Patient 2	Patient 3
Age (y)	80	87	90
Sex	M	F	F
Creatinine (mg/dL)	2.28	1.23	0.70
Dialysis	N	N	N
BSA (m ²)	1.89	1.64	1.50
HTN	Y	Y	Y
PVD	Y	Y	Y
DM on insulin	N	N	N
FEV1 (L)	1.97	0.71	0.54
FVC (L)	3.34	0.96	0.56
NYHA	IV	III	IV
CCS	I	I	I
EF (%)	20	54	62
Pulmonary hypertension	Mild	Moderate	Severe
Preoperative echocardiogram			
AVA (cm ²)	0.72	0.66	0.64
Peak AV gradient (mm Hg)	49	96	89
Mean AV gradient (mm Hg)	25	47	46
Valvular insufficiency	1+ AI	1+ AI, 1+ MR, 1+ TR	2+ AI, 3+ MR, 3+ TR
Comorbidities	Atrial fibrillation, PVD	PVD, RLD, HOCOM, scoliosis, atrial fibrillation, Mobitz II, PPM	Atrial fibrillation, gout, breast CA (XRT)
Indications for alternative approach	PVD, unable to pass sheath in iliac artery	Home oxygen, severe lung disease, PVD	Severe calcification and tortuosity of aorta and iliac arteries, severe lung disease, on home oxygen
euroSCORE	25.10	14.59	20.05
STS score	18.17	18.74	17.85

SD, Standard deviation; BSA, body surface area; HTN, hypertension; PVD, peripheral vascular disease; DM, diabetes mellitus; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; NYHA, New York Heart Association; CCS, Canadian Cardiovascular Society; EF, ejection fraction; AVA, aortic valve area; AV, aortic valve; euroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgery; AI, aortic insufficiency; MR, mitral regurgitation; TR, tricuspid regurgitation; HOCOM, hypertrophic obstructive cardiomyopathy; PPM, permanent pacemaker; CA, cancer; XRT, radiotherapy; *sp CABG*, status post-coronary artery bypass grafting; CRF, chronic renal failure; CVA, cerebrovascular accident; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; DLCO, diffusing capacity for carbon monoxide; N/A, not available.

Three patients had forced expiratory volume in 1 second (FEV1) less than 1 L/s, and the mean FEV1 was 1.60 ± 1.00 . The mean forced vital capacity was 2.30 ± 1.42 L (range, 0.56-4.48l).

All patients except one did not have symptoms that were attributed to coronary artery disease. Two of the patients were in New York Heart Association class IV, and 5 patients were in class III. All procedures were done on urgent basis because of the patients' presenting symptoms and history.

Preoperatively, the echocardiography characteristics showed a mean ejection fraction of $45.14\% \pm 17.87\%$. The AV stenosis was critical with an AV area mean of 0.62 ± 0.13 cm². The peak AV gradient was 74.86 ± 23.28 mm Hg, and the mean gradient was 41.43 ± 10.45 mm Hg. Five patients had some mild degree of aortic insufficiency preoperatively, and 1 patient had moderate aortic insufficiency preoperatively. One patient had moderate to severe mitral regurgitation, and 2 patients had moderate to severe tricuspid regurgitation.

All patients had multiple comorbidities as indicated in Table 1. The mean Society of Thoracic Surgery score for the patients was $16.81\% \pm 6.87\%$, and the logistic euro-HEART was $21.59\% \pm 8.46\%$.

Intraoperative Results

Table 2 shows the intraoperative parameters. There was 100% success in valve deployment. The position of the valve, as visualized by intraoperative TEE, was satisfactory in all cases. There was no intraoperative emergency conversion to SAVR. None of the patients required CPB for hemodynamic compromise intraoperatively or intra-aortic balloon pump postoperatively.

Fluoroscopy time was 18.86 ± 7.39 minutes. Mean patient radiation exposure was 960 ± 966 mGy. Both fluoroscopy times and exposure to radiation decreased with successive cases, indicating a learning curve in the process. Patient 6 had a combined percutaneous coronary

TABLE 1. Continued

Patient 4	Patient 5	Patient 6	Patient 7	Mean (SD)/%
66	86	91	95	85.00 ± 9.59
M	F	M	M	
1.26	1.41	1.00	2.00	1.41 ± 0.55
N	N	N	N	0
2.02	1.21	2.05	1.98	1.76 ± 0.32
Y	Y	Y	Y	100
Y	Y	Y	Y	100
N	N	N	N	0
3.40	0.98	2.20	1.70	1.60 ± 1.00
4.48	1.25	2.87	2.64	2.30 ± 1.42
III	III	III	III	
II	I	I	I	
59	46	55	20	45.14 ± 17.87
Mild	Moderate	Severe	Severe	
0.70	0.34	0.60	0.70	0.62 ± 0.13
109	63	51	67	74.86 ± 23.28
58	40	34	40	41.43 ± 10.45
1+ AI, 1+ MR	1+ AI, 1+ MR, 1+ TR	1+ AI, 1+ MR, 3+ TR	2+ MR, 2+ TR	
Hodgkin's lymphoma, chest radiation, PVD, carotid stenosis	CRF, asthma	CVA, residual weakness, atrial fibrillation, CAD	Atrial fibrillation, CRF, COPD, pulmonary fibrosis	
PVD, previous chest radiation, s/p CABG	Small iliac arteries, on home oxygen	Severe PVD, Jehovah's witness	Severe PVD, pulmonary fibrosis, DLCO 40% predicted	
9.92	19.83	25.49	36.13	21.59 ± 8.46
3.73	18.01	N/A	24.34	16.81 ± 6.87

intervention and TAVR procedure, which was the reason for longer fluoroscopy time and higher radiation. The mean

radiation exposure is less than for transfemoral TAVR at the Cleveland Clinic.

TABLE 2. Procedure variables

Parameter	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Mean ± SD/%
Access	Mini-sternotomy 4th space	Mini-sternotomy 4th space	Mini-sternotomy 3rd space	Mini-anterior thoracotomy right 3rd space	Mini-sternotomy 3rd space	Mini-sternotomy 4th space	Left subclavian artery	
Fluoroscopy time (min)	28.1	21.6	11.8	16.4	12.2	28.9	13.0	18.86 ± 7.39
Radiation (mGy)	1708	2823	685.3	672.8	261.8	1874	385	960 ± 966
Good valve positioning	Y	Y	Y	Y	Y	Y	Y	100
Conversion to surgical replacement	N	N	N	N	N	N	N	0
Reexploration for bleeding	N	N	N	N	N	N	N	0
Use of CPB/IABP	N	N	N	N	N	N	N	0

SD, Standard deviation; CPB, cardiopulmonary bypass; IABP, intra-aortic balloon pump.

TABLE 3. Outcomes

Parameter	Patient 1	Patient 2	Patient 3	Patient 4
Mechanical ventilation (d)	0	20	1	1
ICU stay (d)	1	23	2	2
Hospital stay (d)	7	51	9	5
Postoperative echocardiogram				
Peak AV gradient (mm Hg)	21	53	26	15
Mean AV gradient (mm Hg)	12	29	12	7
Valvular insufficiency	2+ AI para post jet	Trivial AI	2+ AI para post	Trivial AI
Stroke/TIA	N	N	N	N
Reexploration for bleeding	N	N	N	N
Postoperative complications	B/L pleural effusion, increased creatinine, no dialysis	Respiratory failure, PTX, trachea, DVT	Second-degree AVB (PPM), left pleural effusion	None
Discharge destination	Skilled nursing facility	Skilled nursing facility	Home with nursing help	Home
30 d	Readmit ×2 for increase swelling for fluid overload	Patient admission >30 d	No issues	No issues

SD, Standard deviation; CI, confidence interval; ICU, intensive care unit; AV, aortic valve; TIA, transient ischemic attack; AI, aortic insufficiency; B/L, bilateral; PTX, pneumothorax; DVT, deep vein thrombosis; AVB, atrioventricular block; PPM, permanent pacemaker; TR, tricuspid regurgitation; RRT, renal replacement therapy.

Postoperative Results and Hospital Course

Table 3 shows the postoperative course. Three patients were extubated in the operating room. Another 3 patients were extubated within hours to intensive care unit (ICU) admission, ranging from 2 to 6 hours. Patient 2, who had extreme restrictive lung disease (FEV1, 0.71; forced vital capacity, 0.96) was initially extubated on postoperative day 2 but then had to be reintubated for respiratory failure. She eventually was weaned from the ventilator 20 days after undergoing a tracheostomy. She was decannulated before discharge.

The median ICU stay was 2 days (interquartile range, -1.89 to 12.75). The median hospital stay was 7 days (interquartile range, -1.08 to 29.65). None of the patients required reexploration for bleeding.

There was zero procedural and 30-day mortality. The incidence of transient ischemic attack and stroke was also zero. Two patients had worsening renal function that did not require dialysis. Two patients also had pleural effusions and required bedside thoracentesis. One patient had heart block and required a transvenous permanent pacemaker. One patient had deep vein thrombosis that required anticoagulation for 3 months.

All patients received a complete echocardiographic evaluation before discharge or within 30 days of the procedure. Postoperative echocardiogram showed a significant decrease of peak AV gradient from 74.86 ± 23.28 to 21.86 ± 14.90 ($P = .003$) and a significant decrease in mean AV gradient from 41.43 ± 10.45 to 11.43 ± 8.46 ($P = .004$). Some of the implanted valves showed evidence of aortic insufficiency. Three patients had 2+ paravalvular leak, and the remaining patients had 1+ or less aortic insufficiency. Those with significant paravalvular leaks found on operative TEE were reballoned immediately. No patient

was returned for reballoning if follow-up echocardiogram showed aortic insufficiency.

Despite the high surgical risk of the study population, 3 of the patients were eventually discharged home. The other 4 patients were discharged to a skilled nursing facility. Two patients were readmitted within 30 days, 1 with fluid overload that responded to diuresis. The other patient with pericarditis was managed successfully with anti-inflammatory agents.

DISCUSSION

Aortic stenosis in the elderly is a common occurrence in the general population, with the prevalence in adults aged 75 years or more estimated at 4.6%.⁵ In modern medicine, few diseases have the symptomatic and survival benefit of SAVR in AS. However, given that degenerative AS is a disease of old age, a good proportion of patients do not undergo SAVR because of high operative morbidity and mortality. The European Heart Survey showed that only 31.8% of patients underwent AV replacement. In another study from southern California, 61% of patients with critical aortic stenosis never underwent SAVR.⁶ Various reasons may be behind deferring surgical intervention, but increased surgical risk from comorbidities is probably one of the leading causes. For instance, coronary artery disease occurs in more than 50% of patients with AS who are aged 70 years or more. This number increases to more than 65% in those aged 80 years or more.⁷ Coronary artery disease has been shown to be an independent predictor of increased mortality in patients undergoing SAVR.^{8,9}

With medical management, patients do poorly, with approximately 50% of symptomatic patients not surviving their first year. In the pre-TAVR era, balloon aortic valvuloplasty (BAV) was used as an attempt to resolve symptoms and affect survival. However, the procedure has a 17%

TABLE 3. Continued

Patient 5	Patient 6	Patient 7	Mean \pm SD/median (95% CI)
0	1	0	1 (–3.55 to 10.12)
6	2	2	2 (–1.89 to 12.75)
16	6	6	7 (–1.08 to 29.65)
9	18	11	21.86 \pm 14.90
3	11	6	11.43 \pm 8.46
No AI	2+ AI, 2+ TR	1+ AI	
N	N	N	
N	N	N	
Acute on chronic renal failure, no RRT	Poor mobility Residual stroke	None	
Skilled nursing facility	Home	Skilled nursing facility	
No issues	Readmitted for left chest pain, pericarditis	No issues	

30-day mortality with no impact on long-term survival because the rate of restenosis is high. The survival benefit of BAV is only seen in those who were bridged to SAVR who have a 78% 1-year survival compared with 44% in patients not undergoing surgery.⁵

Given the poor outcome of BAV alone and with SAVR being a predictor for survival, there was a need for less-invasive aortic intervention for high-risk patients. Since the first successful clinical report by Cribier and colleagues⁴ in 2002, TAVR has progressed rapidly from the transseptal venous approach to transfemoral¹⁰ and transapical^{6,10} approaches. With each new approach, a number of advantages but also limitations appeared.

The initial results of TAVR were promising, both short and mid-term, proving the feasibility of the procedure and clinical benefits. In the 1-year report by the PARTNER trial investigators, TAVR was not inferior to SAVR. The 30-day mortality in those with TAVR was lower than in the surgical group but did not reach statistical significance. However, at 1 year, TAVR had survival similar to that for SAVR.¹¹ These findings were seen again in the 2-year report in which the survival was similar in the 2 groups.¹²

However, although these 2 reports proved the feasibility and noninferiority of TAVR via the transfemoral and the transapical approaches, there were inherent problems with this new technology compared with traditional SAVR. The rate of all neurologic events was higher in the TAVR group than in the SAVR group at 30 days (5.5% vs 2.4%, $P = .04$) and at 1 year (8.3% vs 4.3%, $P = .04$). The rate of major stroke was higher in the TAVR group but did not reach statistical significance.¹¹ At 2 years, the frequency of stroke did not differ significantly between the 2 groups (hazard ratio, 1.22; 95% confidence interval, 0.67-2.23).¹²

The fact that the risk of neurologic events is higher initially in the TAVR group and then normalizes toward that

of the surgical group beyond 30 days indicates that this is probably inherent to the surgical technique used rather than patient-related factors.¹³ In addition to its decrementing effect on the quality of life, stroke greatly increases the hazard of death,¹² with 43% of patients with a neurologic event ultimately expiring compared with 29% of those without.¹³ Thus, it is important that approaches in TAVR improve to reduce the rate of stroke. In the transfemoral approach, the incidence of periprocedural neurologic events is attributed to manipulation of wires and catheters in the arch. Thus, the increased rate of stroke in patients with associated coronary artery disease who generally have an increased incidence of peripheral calcification.¹⁴ In addition, for unclear reasons, it has been observed that assignment to a transapical approach because of not being a candidate for a transfemoral approach is a strong predictor for neurologic events.¹³ Direct cannulation of the ascending aorta avoids manipulation of wires and catheters in the arch. Although our sample size is small, we do not have any documented neurologic events in the first 30 days. The ascending aorta is assessed for disease from the preoperative computed tomography scan, intraoperative direct palpation for calcium-free area, and, if needed, intraoperative peri-aortic ultrasound. The degree of manipulation of the aorta is minimal throughout the procedure. This technique still does not eliminate the risk of stroke from deploying the valve and crushing the severely calcified AV.

Vascular access complication is an important issue in the transfemoral TAVR approach. Even in minimal procedures such as BAV, the rate of access-site complications requiring surgery was 6%.¹² Dewey and colleagues¹⁴ reported lower transfemoral TAVR access-site complications of 2.3% to 4.8%. However, in the PARTNER trial, the incidence of any vascular complication was 17%, of which 11% have been classified as major.^{11,12} In this report, we did not

have any access-site complications. The procedure is done with direct vision of the aorta, and the cannulation site is repaired with a purse-string suture and checked for hemostasis and repaired before closure.

With the subclavian approach, the potential advantage is that the artery tends to be devoid of significant calcification and generally less tortuous compared with the iliac artery. The subclavian artery is a fragile vessel, but repairs of injuries are less invasive than that of iliac artery. The subclavian approach has been described with the Core-Valve (Medtronic Inc, Minneapolis, Minn).¹⁵ The Core-Valve can be delivered only in a retrograde fashion and has a flexible sheath design that allows better manipulation in tortuous vessels. However, the SAPIEN valve can be delivered both antegrade and retrograde.

Bapat and colleagues¹⁶ reported using a transaortic approach for the Sapien valve with good results. In a recent study by Bruschi and colleagues¹⁷ from Milan, the authors describe the use of the CoreValve via direct aortic cannulation via a mini-right thoracotomy approach. The authors had excellent 30-day outcome. Compared with our report, there was no mention of respiratory complications, such as prolonged ventilation and ICU stay. Poor vascular access and respiratory concerns were the main determinants in the selected approach. The transfemoral SAPIEN valve, as mentioned earlier, has inherent design differences compared with the CoreValve that pose different technical issues if delivered directly transaortic or via the subclavian artery.¹⁷

Although the transapical approach avoids peripheral access issues, it also has its own limitations. The left ventricular puncture carries the risk of a major tear and bleeding, especially in this age group, requiring conversion and going on CPB to repair the defect. The TRAVERCE trial reports an incidence of 4.8% of access site complications,¹⁸ with others reporting delayed bleeding and pseudoaneurysm formation.^{19,20} Manipulation of the ventricular muscle carries the risk of hemodynamic instability, requiring the use of CPB during the procedure and intra-aortic balloon pump in up to 8% of patients.^{6,21} There is no direct manipulation of the ventricle with the transaortic and subclavian approaches, and the risk of ventricular injury is low. None of our patients required CPB for hemodynamic instability or repair of access site. In addition, none required an intra-aortic balloon pump postoperatively for hemodynamic instability.

One of the main limitations of the transapical approach is the anterior lateral thoracotomy to access the left ventricular apex. Thoracotomy incisions are known to be painful. The performance of this incision in patients with poor pulmonary function runs the risk of postoperative respiratory failure as a result of anatomic deformity of the chest wall, anatomic collapse of areas of the left lung, and increased pain that interfere with good respiratory efforts in the patient. The mini-sternotomy approach has been shown to

have better ventilator outcomes when compared with the anterolateral thoracotomy.^{22,23} Except for 1 patient who required prolonged ventilation, our median ventilation time was less than 1 day despite the poor respiratory function of some of the patients. These approaches also allow safer access, avoiding encountering the lung and causing prolonged air leak in patients with previous surgeries or radiation therapy to the chest wall.

CONCLUSIONS

The current report has a limited number of patients with a limited follow-up and no direct comparison made with conventional open surgical replacement or other transcatheter approaches. However, these approaches are promising and offer alternative options in patients with no access and prohibitive chest pathology or pulmonary function. They warrant being investigated further with a larger sample size and longer follow-up.

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