

Alternative Access Routes for TAVR

The feasibility, safety, and efficacy of transcatheter aortic valve replacement from the several possible access sites available.

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If left untreated, mortality for symptomatic aortic stenosis exceeds 50% at 2 years.¹ Therefore, aortic stenosis is set to become a major public health problem in the ensuing decades. Aortic valve replacement has been the gold standard intervention for patients with aortic stenosis for more than 40 years.² However, one-third of patients are denied access to surgery, often due to their advanced age.³ Transcatheter aortic valve replacement (TAVR) has recently emerged as an effective therapeutic alternative to conventional aortic valve replacement for high-risk patients with aortic stenosis.

TAVR was initially developed in porcine models,⁴ but it took a decade for this technology to be translated to human subjects.⁵ TAVR is less invasive than open aortic valve replacement and permits replacement of the native diseased valve in the beating heart without the need for sternotomy and cardiopulmonary bypass. Consequently, TAVR may be less influenced by patients' comorbidities and may facilitate faster recovery.

Initially, an antegrade trans-

septal approach was utilized, but this has now been superseded mainly by transapical (TA)⁶ and retrograde percutaneous techniques (transfemoral [TF]).⁷ Both the size and tortuosity of the peripheral vessels and aorta are important because these affect access and help the oper-

ator to decide between the TF or TA approaches. Hence, the peripheral vasculature and aorta must be imaged. Attention is also paid to the atherosclerotic burden in the aortic arch and the orientation of the ascending aorta, which can be achieved with either formal or computed tomographic angiography (CTA). Gadolinium magnetic resonance angiography is an alternative in patients with impaired renal function.

Four transcatheter aortic valve devices have received CE Mark approval for use in Europe: Sapien XT (Edwards Lifesciences, Irvine, CA), CoreValve (Medtronic, Inc., Minneapolis, MN), JenaValve (JenaValve, Munich, Germany), and Acurate (Symetis, Ecublens, Switzerland) (Figure 1). The Sapien XT valve is approved for TA, TF, and transaortic (TAo) approaches.

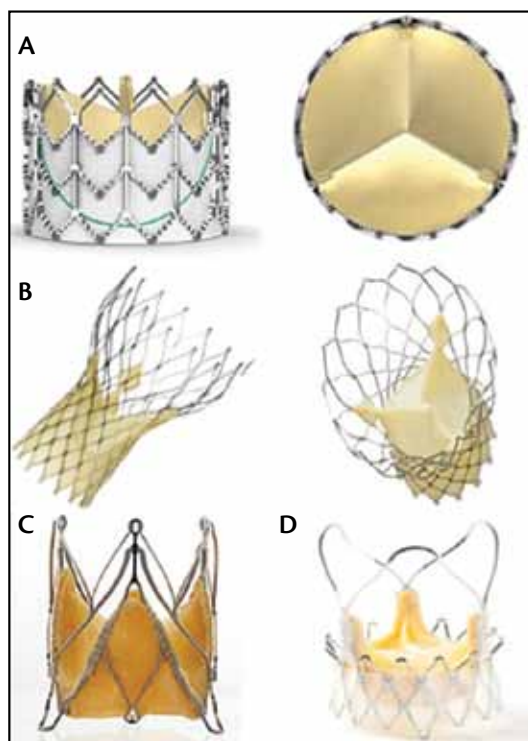


Figure 1. The current transcatheter devices available on the market: the Sapien valve (A), CoreValve (B), JenaValve (C), and Acurate aortic valve implantation system (D).

The CoreValve is approved for TF, transaxillary (TAx), and TAo approaches. JenaValve and Acurate are only approved for TA. In the United States, the Sapien valve is the only FDA-approved and commercially available device to treat surgically inoperable patients. Recently, there has been a rapid expansion in the number of studies investigating TAVR with various approaches in the last 5 years, and these have demonstrated promising results in terms of feasibility, safety, and efficacy. This article discusses the alternative access approaches to TAVR, patient selection, and future directions of this technology.

LIMITATIONS OF STANDARD APPROACHES

Although it is the least invasive, the TF route may not be feasible in every patient and may have an increased risk of stroke. General (absolute and relative) contraindications to the TF approach include severely calcified or tortuous iliac arteries; an iliac artery diameter of < 6 mm to < 9 mm, dependent on the type of device used; previous aortofemoral bypass grafts; severely angulated aorta or atherosclerotic aortic arch; transverse ascending arch (for balloon-expandable devices); and aortic aneurysm with extensive mural thrombus and coarctation of the aorta.

Contraindications for the TA approach are left ventricular thrombus, previous surgical patch of the left ventricle (eg, Dor procedure), calcified pericardium, and the inability to access the left ventricular apex due to anatomical constraints (eg, chest deformity). Furthermore, the reported mortality and morbidity rates for TA are higher, reflecting the patient characteristics and invasive nature of the procedure. This is especially true in patients with severely impaired respiratory function, impaired left ventricular function, and frail, elderly patients. The TA approach is also concerning if, in addition to a forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) ratio $< 70\%$, either the absolute value of FEV1 was < 1 L or FEV1 $< 60\%$.

THE ROLE OF ALTERNATIVE ACCESS

The initial emergence of alternative access routes for TAVR was a result of patient appropriateness (ie, when unsuitable for either the TF or TA approaches). With increasing experience, alternative techniques are now being used more frequently than the TF and/or TA approaches across many centers in Europe.^{8,9}

A multidisciplinary team consisting of interventional cardiologists, cardiothoracic surgeons, cardiac anesthesiologists, and imaging specialists is best suited to make decisions regarding the various approaches to TAVR. The use of different access approaches has increased the number of patients who can be treated successfully.

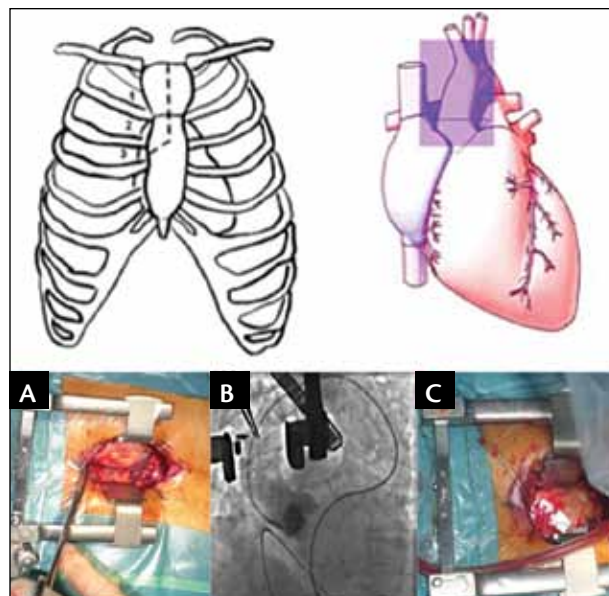


Figure 2. The ministernotomy approach typically carried out through the third or fourth intercostal space. Operative exposure of the ascending aorta through the incision (A). The site for the aortic purse strings is marked on fluoroscopy (B). Double purse strings placed at the site of cannulation (C).

TAo Approach

All cases are performed with the patient under general anesthesia in the hybrid operating room or catheter lab under direct fluoroscopy and/or three-dimensional transesophageal echocardiography. It is possible to approach the aorta either through a ministernotomy or through a mini-right thoracotomy.

In a ministernotomy, a limited skin incision (5 cm) is made starting just below the sternal notch. A partial upper sternotomy (J-shape) is performed through the second or third right intercostal space (Figure 2). The aim is to expose the upper portion of the ascending aorta for cannulation. A ministernotomy is preferred in obese patients, patients with an ascending aorta in the mid-line/to the left or a short ascending aorta, and in patients with poor respiratory reserve because the pleura remains intact, and it has less effect on the respiratory dynamics. This approach can also be used in patients with previous coronary artery bypass grafting and a patent left internal mammary artery (LIMA) graft provided that the LIMA graft is not in the mid-line and the innominate vein and aorta are not in close proximity to the sternum; this can be easily confirmed from the preoperative angiogram and CT scan. Proximal saphenous vein graft anastomoses are usually performed on the proximal two-thirds of the ascending aorta, and hence, they are away from the cannulation site for the procedure, which is in the distal third.

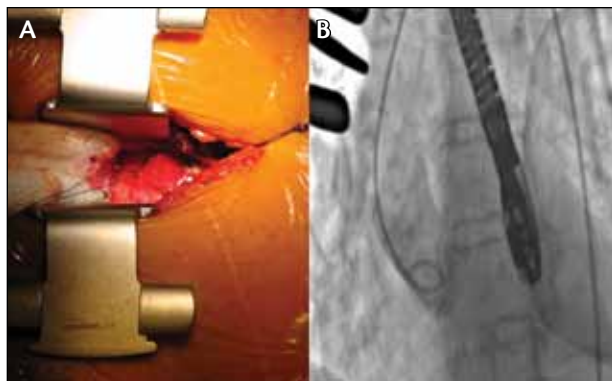


Figure 3. The minithoracotomy approach, usually through the right third intercostal space. Operative exposure of the ascending aorta through the incision is seen (A). A suitable area is marked on fluoroscopy for the aortic purse strings (B).

If the ascending aorta is horizontal and/or shifted to the right side in relation to the sternum, a mini-right thoracotomy approach through the second right intercostal space is preferred (Figure 3); this is used to avoid retraction of the rib cage and/or excision of costal cartilage for exposure. It should also be considered in cases of previous coronary artery bypass grafting in which the LIMA graft is in the mid-line and/or the innominate vein or aorta is stuck to the sternum. The skin incision is usually 5 cm, starting lateral to the sternal margin. The intercostal muscles are divided. The pleura is opened, and the pericardium is incised over the lateral portion of the ascending aorta. The site of the purse-string suture is chosen as through the ministernotomy approach, and the procedure is carried out in a similar manner.

Choosing the correct purse-string/aortic puncture site is of paramount importance. This is achieved with the combination of preoperative CT, on-table aortography, and digital palpation. Noncontrast CT imaging permits evaluation of the suitability of the ascending aorta for cannulation. Even in the so-called porcelain aorta, the portion of the ascending aorta chosen for cannulation is usually free from calcification.¹⁰ On-table aortography identifies the site of the purse strings (Figure 4A), which should (1) be free of calcification, (2) allow the sheath to be directed in a straight line to the aortic valve, and (3) provide enough space between the tip of the sheath and the aortic valve to allow the balloon to fully expand during deployment of the device (depending on the type and size of the device used). This area should be at least 5 cm (3 cm for the balloon and 2 cm for the sheath) above the aortic valve annulus. It is usually on the greater ascending aortic curvature 1 to 2 cm below the origin of the innominate artery (TAo zone) and is confirmed with digital palpation. Two purse-string pledgeted

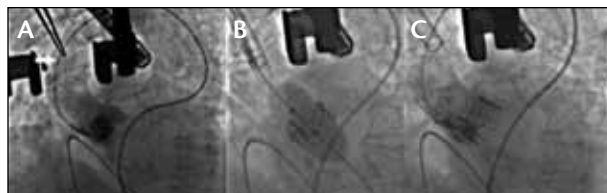


Figure 4. Fluoroscopy demonstrating transaortic TAVR. Aortic cannulation with the Ascendra I delivery system (Edwards Lifesciences) (A). Balloon valvuloplasty with a 3-cm-long, 20-mm crystal balloon (B). Implantation of 23-mm Sapien device (C). Aortography demonstrating good positioning and trivial paravalvular leak (D).

or nonpledgeted sutures are placed with 2-0 or 3-0 prolene. Rapid ventricular pacing is required for balloon-expandable devices but not for self-expandable systems (Figure 4B and C).

Transsubclavian/TAx Approach

The TF or TA approaches are contraindicated in many patients. Additionally, the ascending aorta may be calcified and/or severely atheromatous, in which case, the transsubclavian or TAx approaches should be considered. The setup is similar to that for the TAo approach previously described. However, preoperatively, it must be determined that the size of the arteries (≥ 6 mm) is suitable for cannulation and that they are free of stenoses that are not amenable to angioplasty. The transsubclavian approach is performed preferably via the left subclavian artery. Hence, a patent LIMA graft is a relative contraindication for TAVR from the left side. In these patients, the right subclavian artery can be used; however, it is difficult to achieve the correct angulation of the device during positioning. The presence of a permanent pacemaker in the left pectoral region is not an absolute contraindication.

A 5-cm-long skin incision is made below the left clavicle, starting lateral to the sternal margin. The underlying muscle is retracted or divided. The left subclavian artery is isolated, and slings are placed around it. The application of purse strings and the rest of the principles are as described for the TAo approach. More recently, a percutaneous TAx approach has been reported.¹¹ To avoid major bleeding, and as a target for the puncture, a wire is advanced via the ipsilateral brachial artery followed by a balloon that is placed into the subclavian artery via the femoral artery for temporary vessel blockade before percutaneous vessel closure with vascular closure devices. Puncture of the axillary artery is performed at a distance of 1 to 1.5 cm lateral to the outer border of the first rib. This has been reported to be a feasible and relatively safe option.¹²

Transcarotid Approach

The transcarotid approach should be considered when all other avenues are exhausted and none of the established access sites are suitable. There are few case reports showing the feasibility of this approach, but a concomitant carotid-subclavian bypass, either temporary (shunt) or permanent (Dacron graft), needs to be performed to lower the risk of cerebrovascular ischemia.¹³ The decision to use this method requires a truly dedicated TAVR team approach, establishing a unique access for TAVR patients without regular access options.

FEASIBILITY OF ALTERNATIVE APPROACHES

Alternative approaches to TAVR are feasible with acceptable procedural success rates, without immediate complications, and/or the need to convert to open surgery. The experience in this field is rapidly growing, and early reports of procedural difficulties are likely to have been affected by the operator learning curve. These techniques are becoming more reproducible. Some of the major problems reported with the conventional routes for TAVR have been vascular injury, stroke, and paravalvular leak. The incidence of vascular injury has been shown to occur in up to 18% of TAVR procedures.

The etiology of vascular damage is often attributed to the large-caliber sheaths used with early TAVR devices but is envisaged to be reduced with the inception of low-profile introducers and greater operator experience (SOURCE registry).^{14,15} A similar observation has been made with regard to left ventricular apical injury.¹⁵ Apart from the fact that the aorta is more elastic and forgiving than the ventricular apex, surgeons are familiar with aortic cannulation/decannulation because it is routine in most cardiac operations performed with cardiopulmonary bypass. Given its similarity to existing cardiac procedures, a shorter learning curve is expected for the TAO approach. Stroke and transient ischemic attacks are also sequelae of TAVR deployment (range, 0% to 10%), with a higher frequency associated with TF than TA, and are believed to be the consequence of atheromatous emboli from the arch, ascending aorta, and diseased aortic valve.^{5,6,14-18}

Avoidance of the aortic arch in the TAO approach may be a potential advantage of this approach. We have observed no stroke in our experience with the TAO approach. Paravalvular leak is moderate or severe in up to 15% of patients after TAVI^{13,19-21} and occurs when there is an inadequate seal between the outer surface of the device and the aortic annulus. The incidence is higher if the implant is deployed either too high or low in relation to the plane of the aortic annulus. This may be minimized by selecting the most direct approach, such

as TAO, where there is minimal movement of the device during deployment.

Furthermore, the TAO approach through a partial sternotomy is familiar to surgeons and has been successfully employed in minimally invasive AVR,²² with a reduction in postoperative fraction of inspired oxygen requirement, pain, and lengths of intensive care and hospital stay. We believe that with the design of a dedicated delivery system, the TAO approach may be feasible through a smaller intercostal incision and has the potential to become a near-percutaneous approach. We have shown⁹ that the TAO approach is associated with complication rates that are noninferior to the TA approach, even with more significant respiratory comorbidities and abnormalities of the chest wall. Successful implantation was achieved in all cases, with excellent valve positioning and functioning.

The duration of implantation was 75 ± 15 minutes (mean $\pm$ SD), with a fluoroscopy time of 15 ± 8 minutes (mean $\pm$ SD) and a contrast dose of 120 ± 50 mL (mean $\pm$ SD). We used a 23-mm device in 22 patients, a 26-mm device in 24 patients, and a 29-mm device in four patients. The mean transaortic gradient decreased from 48 ± 14 mm Hg (mean $\pm$ SD) to 10 ± 5 mm Hg (mean $\pm$ SD). The paravalvular regurgitation was < grade 2 in all patients, as assessed by periprocedural transesophageal echocardiography. There were no periprocedural or device-related complications. One of the patients developed a late (> 4 weeks) pericardial effusion after the procedure, requiring percutaneous pericardiocentesis. Another patient developed a pneumothorax due to underlying bullous lung disease requiring chest tube drainage. None of the patients had access-related complications. Recovery was especially satisfactory in patients with severe underlying lung disease. The median length of in-hospital stay among the survivors (11/12) was 8 days (range, 4–14 days); 30-day survival was 92%. One patient died on day 42 due to aspiration and subsequent complications. All other patients made an uneventful recovery and were discharged home.

The transsubclavian technique is also an intriguing approach. The subclavian/axillary artery can be less compliant and more friable, especially in the elderly. It is also prey to similar concerns regarding caliber and calcification as the TF approach. Vascular complications can be difficult to deal with due to the anatomy, including dissection, problematic hemostasis, and the associated increase in blood transfusion.²³ Furthermore, it may not be the best approach for TAVR in the presence of a patent LIMA graft. Because 30% of TAVR patients at our center have previously undergone coronary artery bypass grafting, compromise of a patent LIMA should be kept in mind.

Petronio et al²⁴ recently reported excellent results from the Italian CoreValve series in which 141 consecutive patients undergoing the transsubclavian approach with the CoreValve device were compared to 141 propensity-matched TF patients, except for peripheral vascular disease. The two groups had similar procedural success, major vascular complications, life-threatening bleeding events, and rates of the combined safety endpoint. The transsubclavian group showed lower rates of acute kidney injury/stage 3, minor vascular complications at the 18-F sheath insertion site, and all types of bleeding events related to vascular complications. Survival at 2 years was $74\% \pm 4\%$ in the transsubclavian group compared with $73.7\% \pm 3.9\%$ in the femoral group ($P = .78$). The 2-year freedom from cardiovascular death was $87.2\% \pm 3.1\%$ versus $88.7\% \pm 2.8\%$ in the transsubclavian group versus the TF group, respectively ($P = .84$).

Hence, transsubclavian access should be considered as a valid option not only when the TF approach is impossible but also when it is difficult, albeit feasible. The percutaneous TAx approach has also been reported to be a feasible and relatively safe option.¹¹ Although theoretically possible, there is little experience with the transcarotid approach, with only anecdotal reports and no case series reported. Currently, it should be considered as the last option for TAVR.

FUTURE DIRECTIONS

The evidence base for TAVR is rapidly evolving, and there has been significant growth in the number of new publications during the last 5 years. The evolution of this technology will have important implications for health care policy implementation and may mean greater financial provisions for TAVR in high-risk patients. The technology is likely to improve with smaller delivery sheaths, larger-sized valves, and less-crimped valves. In selected patients, TAVR may be performed by endoscopic methods (P. Etienne, personal communication, July 2012). Long-term outcome data on the comparison between the various TAVR approaches do not exist. In a review by Figulla et al,²⁵ which mainly included retrospective and nonrandomized studies, 1-year survival after use of the TF approach was superior to TA access. However, we do not have similar data for alternative approaches.

Randomized controlled trials are required to determine which method of gaining access to the diseased aortic valve is the most efficacious when undertaking TAVR. Once the feasibility, safety, efficacy, and durability of TAVR approaches have been established, the onus will shift toward health care economic evaluation to identify the most cost-effective means of treating patients with severe aortic stenosis. Despite the fact that the last decade has witnessed the estab-

lishment of the role of TAVR in the management of severe symptomatic aortic stenosis, the long-term benefits of TAVR remain to be seen. ■

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