Alternative access for balloon-expandable transcatheter aortic valve replacement: Comparison of the transaortic approach using right anterior thoracotomy to partial J-sternotomy

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Objectives: For transcatheter aortic valve replacement (TAVR), transaortic (TAo) and transapical (TA) approaches are major alternatives in cases unsuitable for the transfemoral approach. Partial J-sternotomy is a widely used access for TAo. However, redo sternotomy or right-sided aorta may preclude this access, and right anterior thoracotomy is potentially beneficial in these cases. This study sought to evaluate the TAo approach using thoracotomy (T-TAo) and compare it to the TAo approach using a sternotomy (S-TAo) and a TA approach.

Methods: In a large single-center series, consecutive TAVR patients were studied. Procedural/clinical outcomes of the T-TAo, S-TAo, and TA groups were compared up to a 30 days follow-up period.

Results: Of 872 TAVR patients, 22 (2.5%) were T-TAo, 29 (3.3%) were S-TAo, and 86 (9.9%) were TA approaches. The TA group showed the shortest intensive care unit stay, with a median 2.0 (interquartile range 1.0-3.0) days: for T-TAo it was 3.0 (2.0-5.3) and for S-TAo, 3.0 (3.5-5.0) ($P < .001$). Although it was not statistically significant, the T-TAo group showed numerically less mortality (1 [4.5%], 5 [17.9%], and 8 [9.4%] in the T-TAo, S-TAo, and TA groups, respectively; $P = .30$), with no difference in other endpoints, including stroke/transient ischemic attack, rehospitalization, and paravalvular leak. Additionally, computed tomographic assessment revealed that T-TAo facilitated a more coaxial approach than S-TAo: $20.4° \pm 8.2°$ versus $30.6° \pm 8.2°$ ($P < .001$).

Conclusions: T-TAo is a feasible approach that can provide greater coaxiality. This option allows tailored and optimal access to the individual patient and facilitates a treatment strategy in nontransfemoral TAVR patients. (J Thorac Cardiovasc Surg 2015;149:789-97)

See related commentary on pages 797-8.

Transcatheter aortic valve replacement (TAVR) has been established as a treatment for patients with symptomatic severe aortic stenosis who are inoperable or high-risk for surgery.[1,2] This emerging technique is maturing and the transfemoral (TF) approach is gaining popularity as the primary access with progressive device iterations. Jilaihawi et al reported that 28% of the patients were suitable for the older system, Edwards Sapien Retroflex TF devices (Edwards Lifesciences, Irvine, Calif), and 78% for the newer system, Edwards XT Novaflex TF device, based on annulus and vasculature size.[3] Conversely, there still remain patients who are unsuitable for a TF approach and alternative approaches are mandated. The transapical (TA) approach was the original method for this purpose, but it is considered relatively invasive because of myocardial injury and the potential for severe vascular complications.[4-8] The transaortic (TAo) approach was popularized by Bapat et al in 2010 and has evolved as another option.[9] Partial J-sternotomy is the widely used access for the TAo approach (TAo approach using sternotomy [S-TAo]),[10,11] but its use is limited in cases with prior cardiac surgery because of redo sternotomy or a horizontal aorta as a result of the right-shifted access point. A TAo approach with right anterior thoracotomy (TAo approach using thoracotomy [T-TAo]) may benefit these cases, but there are no comparative data available currently for this access. This is the first study evaluating the T-TAo procedure in comparison with the TA and S-TAo procedures, the other major alternatives for balloon-expandable TAVR.

METHODS

Patient Population

A large single-center series of patients consecutively undergoing TAVR from November 2007 to January 2014 was reviewed and procedural/clinical outcomes of the T-TAo, S-TAo, and TA TAVR groups were compared. The study was conducted with approval by the institutional review board. All patients agreed with participation in the study and written informed consents were obtained.

All TAVR procedures were performed with the balloon expandable device from Edwards Lifesciences. The prosthetic valves used in this study

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Abbreviations and Acronyms

CT = computed tomography
ICU = intensive care unit
S-TAo = transaortic approach using the sternotomy
STS PROM = The Society of Thoracic Surgeons Predicted Risk of Mortality score
TA = transapical
TAo = transaortic
TAVR = transcatheter aortic valve replacement
TF = transfemoral
T-TAo = transaortic approach using the thoracotomy

were the Edwards SAPIEN, Edwards XT, and S3. The delivery systems were the Retroflex 3, Ascendra, Ascendra 2, and Ascendra + (Edwards Lifesciences). The TF approach was considered as the primary access, and selection of this approach was based on caliber, distribution of calcium, and severity of tortuosity in the iliofemoral vasculature, which was assessed with baseline invasive angiogram and/or a computed tomographic (CT) angiogram. Alternative approaches, TA and TAo TAVR, were considered in patients who were unfavorable for a TF TAVR. The TA approach was first used in July 2008; on the other hand, TAo was started later in January 2013.

The alternative approach was discussed and determined by a multidisciplinary heart team based on a systemic assessment. Relative contraindications to the TA approach include low ejection fraction (<20%) or severe chronic obstructive pulmonary disease (forced expiratory volume in 1 second % predicted: <40%), or both. Relative contraindications to the TAo approach include a porcelain aorta, and that to the S-TAo approach includes redo sternotomy, especially when there is a vessel proximal to the sternum.[11,12] A horizontal aorta also is unfavorable for S-TAo in terms of a right-shifted access point and a potentially noncoaxial approach. Preprocedural assessments of calcification in the ascending aorta and the access-site anatomy were assessed with CT. An S-TAo approach is preferred when the ascending aorta is in the midline or toward the left, whereas the T-TAo is preferred when the ascending aorta is to the right, that is, when 50% of the aorta lies to the right of the sternal border at the level of the second intercostal space.[13]

Procedure

Access preparations. The T-TAo and S-TAo procedures were described previously.[11,13] In brief, for T-TAo, right parasternal thoracotomy is performed through a second intercostal space (Figure 1). A 4-cm skin incision is performed from the right sternal border, and the pleural space is entered. Then, a right internal mammary vessel is either retracted or ligated. Exposure of the ascending aorta was achieved using either soft-tissue retractor alone or with a small rib spreader. The pericardium is incised parallel to the incision and retracted with pericardial stay sutures to expose the ascending aorta. For S-TAo, partial J-sternotomy is performed, usually through a right second intercostal space (Figure 1). A skin incision is performed in the midline extending from the top of the sternum to the level of the second rib. The sternum is divided with an oscillating sternal saw, and then a mini-oscillating saw is used to extend the sternotomy into the second intercostal space. Subsequently, a ministernal retractor is used to open up the sternum, and the pericardium is incised longitudinally to expose an ascending aorta. The site of access is identified under direct visualization, and double purse string sutures are applied on the selected spot.

The TA procedure was also described previously.[11,14,15] First, left lateral thoracotomy through a sixth or fifth intercostal space is performed to expose the left ventricular apex (Figure 1). The incision is determined by fluoroscopy, palpation, echocardiography, and preprocedural CT. The puncture site is prepared with double purse-string sutures placed in a left ventricular apex using strong deep pledgeted 2-0 Prolene stitches (Ethicon, Inc, Somerville, NJ).

Valve implantation. Heparin is given to increase the activated clotting time to 250 to 300 seconds after the exposure of the access site. In the TAo procedure, the ascending aorta is punctured and a 0.035-inch J wire is advanced into an aortic root. A 7F long sheath is then placed and a 5F angled glide catheter is advanced, which is used to cross the aortic valve using a 0.035-inch straight wire. Subsequently, the wire is exchanged for a 0.035 Amplatz extra-stiff wire (AGA Medical Corp, Golden Valley, Minn). In the TA procedure, the apex is punctured and a 0.035-inch J wire is antegradely advanced though the stenotic aortic valve. A 7F long sheath is placed and the wire is exchanged for a 0.035 Amplatz extra-stiff wire advanced into the ascending aorta.

The delivery sheath is then inserted over the Amplatz extra-stiff wire. Next, balloon aortic valvuloplasty is performed under rapid pacing. Following that, a prosthetic valve is crimped on a delivery system, and the valve is advanced gradually across the aortic valve. The pusher is retrieved, and adjustments are performed to place the prosthetic valve in a plane perpendicular to the aortic annulus. The implantation is performed under rapid ventricular pacing at 180 bpm.

Closure of access site. After transesophageal echocardiography to check valve competence and complications, the large-bore sheath is withdrawn under rapid ventricular pacing and the purse string sutures are tied. One pleural chest tube is inserted and the incision is closed after confirmation of stable hemostasis. The sternum is closed using 2 to 3 sternal wires for S-TAo.

Endpoints setting. Outcome data were reviewed up to a 30-day follow-up period. Endpoints were defined based on the Valve Academic Research Consortium–2 definition.[16] The composite endpoints are briefly described below.

Device success was defined as (1) absence of procedural mortality, (2) correct positioning of a single prosthetic heart valve into the proper anatomical location, and (3) intended performance of the prosthetic heart valve (ie, no prosthesis–patient mismatch and mean aortic valve gradient <20 mm Hg or peak velocity <3 m/s, and no moderate or severe prosthetic valve regurgitation).

Endpoints for early safety were defined as (1) all-cause mortality; (2) all stroke (disabling and nondisabling); (3) life-threatening bleeding; (4) acute kidney injury—stage 2 or 3 (including renal replacement therapy); (5) coronary artery obstruction requiring intervention; (6) major vascular complication; and (7) valve-related dysfunction requiring repeat procedure.

Differences of S-TAo and T-TAo by CT assessment. Because the aortic root and the ascending aorta are oriented toward the right shoulder, right anterior thoracotomy may allow a more coaxial approach that can contribute to better delivery and positioning.[12] Depending on the size of the valve, a minimum distance of 5 to 7 cm from the annulus to the access point on the aorta is required for the TAo approach for complete deployment of the device.[12] These factors, which are very important for patient selection for the TAo approach, were retrospectively assessed by CT and compared between the analysis assuming T-TAo access and that assuming S-TAo access.

CT images were analyzed using a dedicated TAVR software package, 3mensio Structural Heart version 6.1 (3mensio Medical Imaging BV, Bilthoven, Netherlands). CT assessment was performed in the TAo cases except in 1 case where CT data were not available. On the workstation, a virtual sheath was generated through the access point on the aorta to the center of the annulus. The access point was defined as the place behind the middle of the sternum for the S-TAo approach and as the point at the right-anterior border of the ascending aorta for the T-TAo approach at