

Transapical vs. transfemoral aortic valve implantation: Which approach for which patient, from a surgeon's standpoint

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Introduction

Transcatheter aortic valve implantation (TAVI) has gained increasing acceptance for treating patients with severe aortic stenosis (AS), especially in the presence of a higher risk profile. The procedure is performed a number of ways, however, the two main routes of access are the transfemoral (TF) retrograde approach and the transapical (TA) antegrade approach. At the present time TAVI is indicated in the presence of high risk according to current position statements from the European Society Cardiology and European Association Cardiothoracic Surgery (1). TAVI outcomes in intermediate risk patients, presenting with a logistic EuroSCORE lower than 20% or a Society of Thoracic Surgeons (STS) Score between 4% and 8% are currently being evaluated in prospective randomized trials such as the SURTAVI trial (TF CoreValve™ versus conventional surgery) and PARTNER 2 trial (Edwards SAPIEN-XT™ versus conventional surgery). Despite these advancements in endovascular approaches, conventional surgery remains the standard for many patients and is associated with excellent outcomes. For example, in 2011 a German registry reported an overall mortality to be as low as 3% in 11,500 patients undergoing conventional surgery for aortic valve disease (2).

Our common goal is to perform the optimal therapy for an individual patient. This is fundamentally based on a low procedural risk together with immediate functional improvement and good longer term durability. Simplicity and safety will usually lead to good acceptance by the heart team of physicians, mostly cardiologists and cardiac surgeons, to use these approaches. For the individual patient, the overall balance of risks, which cannot be

determined by incision length only but rather should prioritize hard endpoints such as mortality and morbidity such as stroke are extremely important. Thus, an objective pre-procedural informative discussion individualized to each patient's unique risks and potential outcomes is mandatory before choosing between open versus percutaneous options. In this perspective, we highlight the different aspects of choosing the TF versus the TA approach using the best available current literature and propose future prospects for the care of aortic valve disease.

Technical aspects

Since the introduction of TAVI into broad clinical practice, which occurred in parallel with CE's approval of the Corevalve™ and the SAPIEN™ prosthesis in 2008, these procedures have been performed in thousands of patients using standardized techniques. Both access routes—the retrograde TF and the antegrade TA approaches have gained widespread acceptance. Despite many similarities there are, however, distinct differences between the two types of procedures, as shown in *Table 1*.

Overall, when considering the various aspects in *Table 1*, the TA access may offer some potential advantages, despite the current drawback of requiring a minithoracotomy. Larger sheath diameters can be used with the TA access, thus leading to less need for crimping of the valves which may translate into better longevity. Solutions for improving paravalvular leakage may also be implemented into clinical practice through the TA approach (theoretically these solutions require the larger diameters afforded by the TA route). Additionally, clinical trials assessing percutaneous access and closure systems are soon to be underway,

Table 1 A comparison between transfemoral and transapical aortic valve implantation

	Transfemoral (TF)	Transapical (TA)
Access	Femoral artery	Left ventricular apex
Access mode	Retrograde	Antegrade
Incision length [cm]	1-2	~5
Distance to aortic valve [cm]	~70-100	~7-10
Wire insertion	Through the aortic arch, retrograde	Through the aortic arch, antegrade
Wire positioning	Arbitrary, across iliac vessels and aortic arch, irregularities, slack	Coaxial, straight
Valve insertion	Through the aortic arch, retrograde	No touch aorta
Valve orientation	Arbitrary	Commissural (anatomical) alignment possible
Valve implantation	Some mobility during implantation	Little mobility, stepwise and controlled implantation usually feasible
Application system retrieval	Across the aortic arch, relatively long distance	Direct and straight
Access closure	Complication rates as high as 10%	Very low complication rate, ~1%
Perspectives	Smaller systems will become available	Allows access to almost any diameter of the devices – this may lead to potentially better tissue longevity
Future developments	Improved vascular closure systems	Percutaneous access and closure systems

hopefully leading to further improvement and reliance on the TA antegrade technique.

Literature results

Despite the various delivery options for TAVI, current practice seems to favor the TF approach as the first choice in many institutions. Although not the sole reason, the idea that the TF approach is less invasive seems to be the driving force behind this choice. Patients may be happier to hear that the procedure can be performed through a very small incision rather than a minithoracotomy, however, this should not be the deciding factor. Objective consenting should take other procedure related factors into account as well, and as such the TAVI team should prioritize the more hard endpoints when discussing with patients the best option.

Some landmark trials such as the US PARTNER trial were conducted using a TF-first approach, despite a lack of scientific evidence (3,4). Only after the TF approach was ruled out due to patient increased risk from severely atherosclerotic peripheral vessels would the patient be switched to a TA approach. This bias is clearly demonstrated in the SOURCE and the SOURCE-XT registries as patients who received a SAPIEN™ or a SAPIEN-XT™ valve using the TA approach had a significantly higher risk

profile. Although speculative, the higher risk profile of these patients may have contributed to the TA approaches higher procedural mortality rate. Therefore, comparing the TA and TF techniques with the currently available literature must be closely scrutinized and evaluated for inconsistencies before any conclusions can be made.

In addition, some specific risks may not be captured by the currently available scoring systems. As seen in the PARTNER trial where a TF-first strategy was used, the potential differences between the TF and the TA arms could not be documented in terms of different STS scores (3,4). Therefore, the conclusion “TF is less invasive” cannot be substantiated by any evidence from the literature when comparing TF versus TA TAVI. Common practice of showing different survival curves for TF and TA in patients who have completely different risk profiles on one slide should be done with caution or not at all.

There is one national database, the Canadian registry that demonstrates similar outcomes at 2-, 3-, and 4-years following TF and TA TAVI. After combining their multicenter experience results, the overall TA results were as good as the TF approach, despite a significantly higher risk profile in the cohort treated with the TA approach (5). Patient allocation to the different therapeutic options, however, was not randomized.

Data from the Heartcenter in Leipzig provides similar

results. Patients receiving TA approaches usually had higher average risk profiles and better outcomes than those treated via the TA route in the initial four years.

In summary there is no scientific evidence from the current medical literature that demonstrates TF TAVI to be less invasive than TA TAVI. Furthermore, there is reason to believe that in similar patients the TA approach could lead to similar results as TF TAVI implantation. Unfortunately, direct and inclusive data comparing the data in national and international cohorts is not available, and prospective randomized trials evaluating all comers may prove to not be feasible.

Specific risks

Specific risks exist for TAVI that differ substantially from the risks of conventional surgery. TAVI can be performed without using cardiopulmonary bypass and without cardiac arrest, and thus, is minimally invasive. However, calcified native aortic valve cusps remain in situ and may lead to various complications, depending on the individual patients pathology. Paravalvular leaks or annular perforations can occur and further screening mechanisms to avoid these risk should be implemented. The presence of second degree (in the PARTNER trial this was graded “mild”) paravalvular leakage is associated with decreased survival in T-AVI patients, lending further support to instituting screening mechanisms and procedural improvements to prevent leakage (6,7).

Stroke is one of if not the most devastating complication that can occur during TAVI. Many published studies have described the risks of stroke during TAVI, but no direct comparison exists. Reported outcomes in TA TAVI series have shown slightly lower stroke rates than those describing the TF approach. Common direct factors leading to stroke risk during TAVI of any type may be the utilization of balloon valvuloplasty and the process of implanting the valve. However, the access modes of antegrade “no aortic touch” valve implantation versus retrograde passage through the aortic arch also plays a role. No randomized study currently exists. When commenting on the reported neurological outcomes, we further need to keep in mind whether or not the study has been reviewed and revised by a neurologist and whether the patients have undergone either neuroimaging and neurofunctional testing post-procedure. Therefore comparability may be limited for some reports.

Furthermore, 30-day stroke rates after TAVI can be divided into “early” and “delayed” events. Consistent

with our own experience it seems that “early” events (in other words: A patient suffers a stroke clearly during the procedure) are very rare with the antegrade transapical access whereas “delayed” strokes (roughly 50% of all events) seem to affect all patients independent from the chosen access. The phenomenon of these “delayed” strokes is not fully understood. Potentially, new onset atrial fibrillation might be a contributing factor, and it is possible, although speculative at this time, that more aggressive anticoagulation may help prevent delayed neurological adverse events.

Recently an interesting meta-analysis was published encompassing over 10,000 patients comparing three groups of patients: TF Corevalve™, TF Edwards SAPIEN™, and TA Edwards Sapien™ (8). The results of the meta-analysis show that the TF Corevalve™ (n=3226, mean logistic Euroscore of 22%) had a stroke rate of $3.1\pm 2.2\%$, the TF Edwards SAPIEN™ (n=1,733, mean logistic Euroscore of 26%) had a stroke rate of $4.2\pm 2.2\%$, and the TA Edwards Sapien™ prosthesis (n=2,482, mean logistic Euroscore of 29%) had a stroke rate of $2.7\pm 1.4\%$ (8). Despite all potential limitations of any meta-analysis, the presented results therefore are quite clear and demonstrate that individual patients need to be informed about a potentially higher stroke risk whenever retrograde access is planned before TAVI.

The risk of access related morbidity such as vascular injury must also be taken into account for patients undergoing TAVI. The safety of the TA approach was shown in the multicenter PREVAIL TA study on 150 patients, of whom only one patient (0.7%) suffered an access related complications (9).

Perspectives

Looking ahead, more and more technical advances lead to the development of newer devices as we understand the clinical pitfalls of current TAVI instrumentation and procedural approaches. Interestingly, many new devices are initially designed for the “easier” TA access route. This may lead to advancements from the advantages of the TA approach such as decreased tissue valve crimping. In turn, this may result in increased structural integrity and longevity for the implanted device. Additionally, newly designed access and closure systems may allow for safe percutaneous access via a TA incision, combining the advantages of minimally invasive access together with the advantages of an antegrade approach. Improved imaging methodology will further enhance the visibility of the devices and will thus

lead to a further increased safety profile for the procedures. In conclusion, the cardiovascular teams at major referral centers will jointly decide and perform the optimal therapies individualized to each patient's risk stratification. Cross training of cardiologists and surgeons, who are actively and jointly performing all therapies will be the future. This will lead to a new speciality of a structural heart interventionalist to treat high risk patients.

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