Transcatheter Aortic Valve Implantation: Finding Its Path

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See article by Chandrasekhar et al., pages 1427–1438 of this issue.

The world of cardiology was forever changed when Alain Cribier performed the first transcatheter aortic valve implantation (TAVI) in 2002; this was undoubtedly a landmark achievement as it launched the field of structural cardiology outside of the congenital realm.1 Severe aortic stenosis deemed unsuitable for surgical aortic valve replacement was once one of the “final frontiers” in cardiology, and now a minimally invasive therapy was available for its treatment in the form of percutaneous valve replacement. Doctor Cribier’s first case was actually riskier than what most operators face nowadays. His patient, the first to ever undergo this procedure, had presented with acute heart failure and was nearing cardiogenic shock because of severe aortic stenosis. Yet the patient was awake during the procedure, which was performed transfemorally with no transesophageal echocardiography guidance. This success without general anaesthesia or echocardiographic guidance was remarkable in itself, considering that general anaesthesia and transesophageal echocardiography are now among the gold standards for emerging techniques having the desire to perform TAVI.2

TAVI is growing rapidly, with as many as 65 countries having TAVI programs at the moment and approximately 1000 centres performing this procedure in North America and Europe, which is nearly a fourth of all centres with cardiac catheterization facilities in these areas. The choice between transfemoral and non-transfemoral (or “alternative”) access remains one of the most important decisions to be made on a case-by-case basis. A judicious choice is quite literally the remains one of the most important decisions to be made on a case-by-case basis. A judicious choice is quite literally the path to a successful procedure, as most procedure-related complications are still due to the access site, and are linked to long-term mortality.3 Transfemoral access is considered the default approach, and other non-transfemoral accesses will only be considered when transfemoral access is deemed to be hazardous.

In this issue of the Canadian Journal of Cardiology, Chandrasekhar et al.4 have systematically reviewed the 28 contemporary studies that compared transfemoral (mostly transapical) access for TAVI. The authors showed that transfemoral access was associated with a significant reduction in the 30-day and 1-year mortality. Transfemoral access was also associated with a greater incidence of vascular complications, but the rates of bleeding and strokes were similar in both groups.

First, it must be said that performing a meta-analysis on a TAVI population is a challenge and the clinical significance of the ensuing information is difficult to put in context. Several biases may have been overlooked, such as the varying experience and comfort-level among operators across different centres and the varying case mix between the populations ascertained from one study to another. In the early days of TAVI, the concept of risk/frailty scores (like the Society of Thoracic Surgeons [STS] score and the EuroScore) was infrequently used. In the present meta-analysis, one can observe that these 2 scoring systems were not always available, and when they were available, they sometimes predicted mortality rates that did not correlate with each other. Consequently, some of the cohorts may have had lower mortalities simply because their patients were in fact relatively “lower” in the spectrum of “high-risk” participants. It is of paramount importance to note that predictive scores, while not flawless, are crucial nowadays to compare different cohorts. In another recent meta-analysis on the topic, the adjustment of event rates for the EuroScore yielded a similar mortality for transfemoral and transapical accesses at 1 year, even if the mortality was lower with transfemoral at 30 days.5 Although we can assume that the less invasive approach would reduce mortality early on, it also seems appropriate to assume that the valve’s structure and durability are the main factors accounting for adverse events in the long run.6

As mentioned by the authors, there are no randomized data comparing transfemoral vs non-transfemoral access. Realistically, it would have been difficult for one such study to achieve both statistical and clinical significance, as most of the non-transfemoral approaches have been historically used as a first option in patients with significant peripheral arterial disease that made the more traditional femoral access contraindicated. These patients typically have a higher rate of comorbidities that would unfavourably influence the outcomes, even in the presence of risk score-based adjustments. This is one of the factors that may be suboptimally addressed by the current iterations of the STS score and the EuroScore.
It is foreseeable that better risk assessment scores may emerge in the near future that will help offer superior correlations with adverse events, and several groups are currently working on this issue. Nevertheless, it is crucial for the community to produce randomized data to offer a more thorough answer to the question of access site preference.

Another detail worth mentioning is that the majority of studies gathered in this meta-analysis were performed using the Edwards Sapien valve (Edwards Lifescience, Irvine, CA) and only a few were performed with the Medtronic Corevalve (Medtronic, Minneapolis, MN). This fact is quite important to consider because during the years covered by the meta-analysis, the Edwards Sapien valve required a bigger introducer sheath than the Medtronic Corevalve and was therefore more limiting to access site options. Putting this problem in the contemporary context of 2015, there has been a dramatic miniaturization of femoral introducer sheaths since the 5 years covered by this meta-analysis. For the Edwards valve, the sheath size range has varied from 22-24 F (7.3-8.0 mm) during the span of this meta-analysis to 14-16 F (4.7-5.3 mm), whereas for the Medtronic Corevalve, sheath sizes have varied from 25 F (8.3 mm) initially to 18 F (6 mm) during the period covered in this meta-analysis. The Corevalve platform has been downsized even further to 14 F (4.7 mm). This trend will definitely continue, further tending to lower the risks associated with the transfemoral approach.

When it comes to non-transfemoral access, transapical and direct aortic are currently the most popular choices worldwide, accounting respectively for 20% and 5% of all implants in Europe and respectively 29% and 4% of implants in the United States, whereas the trans-subclavian and the trans-axillary approaches barely account for 1%. The rest of course are mainly transfemoral. Recent data suggest that the mortality rate is equivalent between transapical and transaortic access. Initially, the transapical approach was met with great concern as substudies of the Placement of Aortic Transcatheter Valves (PARTNER) trial had shown a significant increase in mortality. Mortality has since improved with the transapical approach, likely because of greater operator experience and better patient selection. To this day there is still a higher risk associated with the transapical approach in frail patients or those with severe chronic obstructive pulmonary disease or low left ventricular ejection fraction. As for trans-aortic access, it tends to be avoided in patients with severe calcification of the aortic arch and in patient with significant anemia, as it is associated with a greater need for transfusions. As pointed out by the authors, the trans-subclavian and transaxillary approaches indeed appear to have a safety profile similar to transfemoral access, which is understandable as they are all transvascular and typically bound by similar limiting factors.

In 2015, most experienced centres use non-transfemoral routes for TAVIs every week. One might wonder whether the term “alternative access” may already belong to another era. It is now indeed crucial for most programs to offer several access options to their patients to discern which is optimally tailored to the unique anatomy of each individual with severe aortic stenosis. Some institutions have even shown renewed interest in the transcarotid approach. Others have designed a transcaval approach, in which the inferior vena cava is first cannulated before puncturing and crossing into the descending aorta, which can be useful in patients with aortic disease. In any case, the importance of using noninvasive imaging such as computed tomography angiography to guide in the selection of an access site before the procedure is greater than ever.

One last aspect that is mandatory to consider is the cost-effectiveness of each approach. Several aspects must be considered. The multiple vascular closure devices used in the transfemoral approach certainly increase the cost of the procedure. On the other hand, there is incremental financial burden associated with the longer hospital stay usually required with a more invasive access route. Indeed, there is a current trend of increasing early and even same-day discharges from the hospital following a transfemoral TAVI procedure, associated with a notably shorter length of stay, contrary to the observations in the current meta-analysis. The trend to rapid discharge after transfemoral TAVI will undoubtedly prove to be more significant in the next decade.

When contemplating TAVI, the future is coming faster and faster and the trend will likely be to include moderate-risk patients, if not even lower-risk. The recently presented results of the SAPIEN 3 trial show encouraging results in an intermediate-risk cohort, with a mortality of 1.0% at 30 days, which is quite remarkable considering that the surgical mortality predicted using the STS score was at least 5.2%. There is a great chance that the currently ongoing larger trials such as the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) (using the Medtronic Corevalve) and PARTNERS 2A (using the Edwards Sapien valve) will also show that TAVI is at least equivalent if not superior to surgical replacement in the medium-risk population. Additionally, the Nordic Aortic Valve Intervention trial, also presented recently, even included low-risk patients (STS scores less than 4) and showed no statistically significant difference in 1-year mortality between the TAVI group and the surgical group. Projecting the impact of these findings into the coming years, TAVI is likely to become the primary option for participants with severe aortic stenosis with less advanced age and fewer comorbidities, which may in turn result in a dilution in the use of alternative accesses because a higher ratio of patients will be a candidate for the less invasive and more traditional transfemoral approach. It is possible that the discussion of the ideal access site presented here will only apply to a small fraction of patients in 5 to 10 years.

The present meta-analysis shows that patients treated with the transfemoral approach had less mortality at 30 days and at 1 year than patients undergoing TAVI with alternate approaches. It would be tempting to conclude at this point that the femoral approach should therefore be used on every possible candidate. Although these results may have been true for the period of 2007-2013 covered in this study, and certainly reinforce the current trend to consider transfemoral access as the default technique unless contraindicated, we may very well reach more nuanced conclusions over the next few years. The access site certainly influences mortality, and the main contributing factor is still the considerable size of the introducer sheaths. Although these sheaths are getting smaller and smaller for transfemoral access, this will also be the case for non-transfemoral approaches over the coming years. Some groups are working on a percutaneous closure device for minimally invasive transapical access, potentially permitting a
puncture-like opening rather than an incision, which might decrease adverse outcomes significantly. Many experts think that the direct aortic approach is already considerably less invasive in 2015, with the currently available smaller delivery sheaths. Furthermore, most operators agree that control of valve positioning and deployment is easier with non-transfemoral access, because there is simply less distance and tortuosity between the operator’s hands and the treatment site. This advantage, if not outweighed by the fear of access-related complications, could shift the balance of the debate towards non-transfemoral approaches. Perhaps a randomized control study will in fact very soon be justifiable and will be needed to reevaluate which access site should be used as the primary choice.

The journey has started and must continue. Thirteen years after Alain Cribier’s first case, we have clearly seen many variations of the original approach to TAVI, and we are on the brink of seeing this technique increase dramatically in volume. TAVI has truly transformed cardiology in its own rights and has also led to a cross-pollenization of skills between interventional cardiology and cardiac surgery. The “Heart Team” collaboration is crucial and starts in TAVI with every clinician sharing his or her expertise in choosing the best access site, individualized to each patient. In the end, the future of TAVI remains to be defined and there are numerous issues other than just the choice of an anatomical approach. Some of these issues are of an ethical and philosophical nature, whereas some are related to cost-effectiveness. Therefore, just as one always tries to find the best possible route of access to perform this procedure, TAVI itself will have to keep on finding the right “path.”

Disclosures
The authors have no conflicts of interest to disclose.

References