How to Move Toward the Least Invasive Transfemoral Transcatheter Aortic Valve Implantation Procedure?

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In this issue of Circulation: Cardiovascular Interventions, 2 articles are published that merit our attention because they stimulate our thinking about how to improve the execution of transcatheter aortic valve implantation (TAVI).1,2 Every treatment should be evaluated from a patient’s perspective, namely, it should deliver or increase health (ie, efficacy) without doing harm (ie, safety). One may also argue that every treatment—whatever its nature—should be as comfortable to a patient as possible without compromising the 2 basic principles (safety and efficacy). From a health economic perspective, treatment should be cost effective. These 2 articles, which focus on the methods of anesthesia and of femoral arterial access in patients undergoing TAVI, indicate that less invasive strategies studied may indeed fulfill all of the above premises.

Oguri et al3 evaluated the temporal change away from general anesthesia (GA) and toward local anesthesia (LA) during transfemoral TAVI and the clinical implications of this transition. For that purpose, they used the data set of the French Aortic National CoreValve and Edwards (FRANCE 2) Registry that included 2326 patients who underwent transfemoral TAVI via GA (n=1377) or LA (n=949) with the Medtronic CoreValve System (n=839) or the Edwards Sapien valve (n=1487) between January 2010 and October 2011.

Accepting the inherent limitations of a nationwide registry, as acknowledged by authors—one only mortality was independently adjudicated, all other events were self-reported—in addition to imbalances in baseline characteristics of the GA and LA populations, as well as time bias and, therefore, the effect of experience (GA was used mainly in the early phase and was gradually replaced by LA), no difference in procedural success on hard (ie, mortality) or soft end points according to the Valve Academic Research Consortium (VARC) was found, except for a higher frequency of mild aortic regurgitation (AR) in patients who underwent LA (19 versus 15%). The question, of course, is whether this difference can be attributed to the technique of anesthesia and the less frequent use of transesophageal echocardiography (TOE) during LA (17 versus 76%) or whether it is simply a chance finding. Notably, AR was similar between LA and GA groups in a propensity-matched analysis, which included TOE use as a criterion in the matching algorithm. In this respect, it is a pity that the TOE was used for the selection of the propensity-matched patients, as the similar use of TOE in propensity-matched LA and GA pairs did not elucidate whether this was a determining factor in the incidence of significant AR. It would be interesting to know whether the severity of AR in patients treated under LA differed according to the use of TOE, controlling for other risk factors.

The authors did not reveal any other potential benefits of LA such as earlier ambulation or an eventual reduction in hospital stay or infectious complications, thereby reducing costs. Also, criteria based on which type of anesthesia was selected should be elucidated. Nonetheless, the FRANCE-2 data set may offer a first attempt by assessing which patient benefits most from which anesthesiologic technique (responder—nonresponder).

Perhaps more importantly, the staggering 4-fold increase in the use of LA, from 14% to 59% in nearly 1 year, indicates the extent to which less invasive TAVI strategies are embraced by the medical community, preceding clinical evidence. This is not only because of the fact that transfemoral TAVI is the dominant access strategy (74%)—LA is also possible during subclavian access—but also most likely by the push of society that is asking for less invasive and more patient-friendly treatment of valvular disease, which will hopefully translate into shorter hospital stay. This pressure will likely be boosted further by the gradual application of TAVI in progressively less sick patients, which is a natural evolution of innovative treatment modalities in a society in which patient awareness, preference, and involvement in treatment decisions are playing an increasing role.3-5

As mentioned, one should not compromise on safety and efficacy. Although new-generation valves—repositionable ones in particular—may address the issue of AR, the authors rightfully stress that TOE should not be eliminated from TAVI because it may be needed to evaluate and facilitate treatment of unexplained hemodynamic changes during TAVI. LA during transfemoral TAVI as a default strategy is acceptable provided conversion to GA is possible, which highlights that TAVI is and will remain a multidisciplinary procedure, from patient planning to execution and follow-up.

In a related study, Kadakia et al6 report a single-center observational assessment of open surgical (OS) versus fully percutaneous (PC) access in a series of 331 patients who underwent transfemoral TAVI between 2007 and 2013 in the framework of the PARTNER trials. OS was predominantly performed in the early study period in 120 patients, whereas PC was...
mainly performed later in 211 patients. Again acknowledging the limitations of this study, in particular, lack of random allocation to OS or PC and, therefore, differences in known and unknown baseline characteristics (higher prevalence of antecedent cardio and peripheral vascular disease in patients undergoing OS), differences in operator experience due to the evolution from predominant OS to PC, the use of an early-generation Sapien device, and a highly selected patient population, the main findings of this study were a shorter hospital stay with PC in both the overall population of 331 patients and 112 propensity-matched pairs, without a difference in vascular complications. Notably, the authors also found no difference in major or life-threatening bleeding between OS (4%) and PC (4%) treated patients. This was also true for the use of blood products (26% and 24%, respectively).

The findings of this study are important. They confirm the European experience, in which PC was initiated in 2006.6,7 PC may, therefore, be recommended as a default strategy in patients selected for transfemoral TAVI because it is the least invasive approach associated with greater patient comfort and potentially lower costs as a result of the shorter hospital stay. Yet, the findings of the study reported by Kadakia et al3 should be interpreted in the context of the fact that all patients were meticulously screened by multidisciplinary heart teams during which the access strategy was determined on the basis of detailed anatomic information of the femoral arteries. Also, there was a strict protocol of anticoagulation during TAVI and correction by protamine at the moment of vascular closure in addition to the use of a peripheral angioplasty balloon to assist hemostasis and control angiography to check hemostasis. Also, similar to the European experience, the patients in this series were treated by an experienced group of operators who took part in the Placement of Aortic Transcatheter Valves (PARTNER) study and may, therefore, not be generalizable to other settings.

Both of these studies highlight the essential role of multidisciplinary planning and execution of TAVI as well as its execution in the appropriate environment so that safety and efficacy are ensured when moving toward the least invasive TAVI approach. This holds not only for the current TAVI population, which generally consists of patients who are older, more frail, and have multiple comorbid conditions, but should continue to be the case when TAVI is adopted in lower risk patients and when smaller, less traumatic delivery systems become the norm.

One does not need to be a visionary to see the direction in which treatment of cardiovascular disease will evolve. The key words are minimally invasive, and it is clear that catheter-based treatment of aortic valve disease has all assets in its basket. This is the result of a combination of demand from society (the least invasive treatment performed to high standards of safety and efficacy, with the lowest costs) and the ongoing efforts of biomedical engineers, those with the courage to invest in innovation, and the patients and doctors who undertake experimental treatments in appropriate organizations and carefully monitor outcomes in accordance with clinical scientific standards. The 2 herein discussed articles contribute to this evolutionary process.

Disclosures
Dr de Jaegere is a proctor for Medtronic, Boston Scientific, and St Jude.

References

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