Transcatheter aortic valve implantation (TAVI) is now a clinical reality with the commercial approval of two devices in Europe and the enrollment in the United States (US) pivotal trial of one of the devices currently nearing completion. The experience in Leipzig as well as in many other centres highlights the emerging role of transcatheter valve therapy for the management of critical aortic stenosis in high-risk patients. There are two approaches by which most of the devices are currently placed: a transfemoral (TF) approach in which the valve is placed retrograde through the femoral artery, and a transapical (TA) route in which the valve is placed through the apex of the left ventricle in an antegrade fashion, accessed through a small left thoracotomy incision. There have now been over 6000 transcatheter valves implanted worldwide with an estimated 75% of them placed by the TF approach.

Walther and colleagues from Leipzig have pioneered the TA approach for TAVI, and in doing so have set the standard for this procedure in terms of defining the technique, optimal patient selection, perioperative management and fastidious, complete reporting of results [1]. In this issue of the journal, Walther et al. focus on a particularly high-risk group of patients in need of aortic valve replacement, those who have undergone previous cardiac surgery including coronary artery bypass grafting (CABG), mitral valve and aortic valve surgery [2]. They report excellent results in treating this high-risk group of patients by TAVI. These results were achieved in part due to three important factors. First, the procedures were performed by an experienced team of surgeons, cardiologists and anaesthesiologists working in a collaborative relationship. They were able to perform the procedures in an optimal workplace, a hybrid operating room, and they had unfettered patient selection for a single-procedure approach, allowing perhaps the only opportunity to truly evaluate the TA approach. Each of these aspects is noteworthy and deserving of further comment.

Transcatheter valve procedures combine aspects of traditional surgical operations performed under general anaesthesia with imaging guidance more germane to cardiac catheterisation laboratories. Programmes which have achieved the highest degrees of success along with the best results with TAVI are those in which a collaborative working environment is fostered, nurtured and promoted. Optimal patient outcomes are achieved in a programme such as Leipzig, which is focussed on specialty convergence and collaboration.

All transcatheter procedures in this study were performed in a hybrid operating room with catheterisation laboratory imaging quality in a traditional operating room setting, which optimises both procedure success and patient safety. It is well accepted that imaging with both fluoroscopic and echocardiographic guidance is key to procedure success and that optimal radiograph imaging is not provided by portable imaging systems. Optimal patient safety is assured by the performance of these procedures in an operating room setting that provides the capacity for immediate support with cardiopulmonary bypass as well as conversion to open-aortic-valve replacement or vascular access injury repair, should the circumstances dictate. Although the majority of transcatheter procedures using TA or TF approach can be completed without cardiopulmonary bypass support or conversion; should emergent circumstances arise, a traditional operating room rather than a cardiac catheterisation laboratory provides the optimal setting to successfully manage these complications.

The third aspect of this reported experience is the exclusive use of the TA approach. This bears on the comparative role of TA vs TF approaches for TAVI in high-risk patients. There have been concerns raised that outcomes with TA aortic valve implantation may be inferior to those achieved by a TF approach. It should be noted that the overwhelming majority of centres performing TAVI in Europe, Canada and the US have developed programmes around a 'TF first' approach. With this access philosophy, patients who present for transcatheter valve therapy are preferentially treated by a TF route if there is adequate vascular access available. The TA approach is then used only in those patients who are turned down for the TF approach due to severe peripheral vascular disease or small iliofemoral vessels. Indeed, trial design in the Partner Trial, the US pivotal trial of the Edwards Lifescience Sapien THV valve precludes TA placement if adequate vascular access allows a TF delivery of the device. In a 'TF first' approach programme, patients with significant aorto-iliac occlusive disease, peripheral vascular disease, cerebrovascular disease and previous CABG are
The Leipzig experience is unique in that they have employed a 'TA first' approach, which is possible in almost all patients presenting for TAVI, independent of the access issues that preclude the TF approach. The exceptions that preclude the TA approach are few, perhaps only very severe chronic obstructive pulmonary disease (COPD) and chest-wall deformity. The results from Leipzig showing excellent outcomes with TA in the 'all comer' patient population are comparable to outcomes in 'TF first' selected patient population. Unfortunately, the TF first approach adopted in most centres causes selection bias, which mitigates 'for TF' and 'against TA' results, making balanced comparisons of the two techniques impossible.

As this field of study progresses, it is likely that clinical circumstances will dictate that each approach will have merit in specific patient subgroups while a large group of patients will be defined in which both approaches are equally effective. One possible way of clarifying this issue is an 'all comer' trial design similar to the Syntax trial comparing percutaneous coronary intervention with coronary artery bypass grafting in patients with left main and/or three-vessel coronary artery disease [3]. In a trial of this design, all patients who present for TAVI are screened for both approaches. If there is agreement that it is likely that the procedure could be successfully performed by either approach, the patient is then randomised to receive a TA or TF valve. If there is agreement by the investigators that one approach is precluded, for example, TA in patients with severe COPD, TF in severe aorto-iliac occlusive disease, then the patient is placed in a 'nested' registry of each approach. With this trial design, the patient population best treated by each approach could be better defined and a meaningful comparison between the two procedures could be obtained without selection bias. This same trial design could also be employed in future trials comparing TAVI with conventional surgical aortic valve replacement as has been first suggested by Serruys (personal communication).

The Leipzig experience has clearly developed a model for success. They have reported excellent results for the TA procedure overall as well as in a particularly high-risk group of patients as reported here. It remains to be seen whether this experience can be successfully translated to other programmes. A collaborative working relationship between structural interventional cardiologists and cardiac surgeons is critical to continue moving forward. Now that clinical feasibility and some degree of patient safety and clinical efficacy have been demonstrated, it is time to initiate the necessary randomised trials in other clinical scenarios.

References


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