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# Transcatheter aortic valve implantation – should we do it just because we can?

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Transcatheter aortic valve implantation (AVI) has been established in clinical practice proving the feasibility of both the retrograde transfemoral (TF) and the antegrade transapical (TA) approach[1-5]. High risk patients as defined by a logistic EuroScore of ≥ 15% or an STS score of ≥ 10% have so far been included in clinical trials, with an observed mortality that was lower than predicted. Procedure related morbidity includes an imminent risk of stroke, thoracotomy induced respiratory dysfunction, problems with peripheral vascular access caused by the TF approach and the need for permanent pacemaker after dilatation of the calcified aortic valve. Stroke, as the leading complication, is less frequent for the TA (~ 0 to 3%) than for the TF (~ 3 to 9%) approach throughout all reported series, most likely due to limited manipulation in the aortic arch. Even though good results have been obtained with transcatheter AVI in high risk patients, the procedure carries risks at any time. Therefore, the procedure is best performed in a team approach by cardiologists and cardiac surgeons in an environment equipped for both interventional and surgical procedures (in an hybrid operative theatre).

Based on the initial feasibility results, CE approval has been obtained in 2007 for the TF approach using the CoreValve™ and the Edwards SAPIEN™ prosthesis, as well as for the TA approach using the Edwards SAPIEN™ prosthesis. Since that time post market surveillance studies are underway. No randomised studies have been published so far, the USA Partner trial, comparing TF or TA Edwards SAPIEN to conventional surgery, is currently enrolling. In this issue of EuroIntervention three interesting manuscripts regarding transcatheter AVI are being published.

Piazza et al describe the results with 648 CoreValve™ implantations during the first year of post-marked surveillance[6]. This analysis represents important further information on outcomes in a larger series of patients. Results have steadily improved in comparison to those reported in initial feasibility studies. In this multicentre survey of patients with a logistic EuroScore of 23%, an average 30-day mortality of 8% and a stroke risk of approximately 2% are reported. This remarkably good outcome has to be weighed in the light of some limitations of the study: registry data were not complete, follow-up interval is short and not all patients treated during the time period of one year were included. Thus some selection bias may have affected outcome.

Another interesting manuscript in this journal focuses on a new device, the Direct Flow™ prosthesis[7]. The authors have chosen a completely different approach to implanting the device in selected patients in South America to prove the overall feasibility. Transfemoral implantation was followed by immediate conversion to conventional surgical valve replacement. Death in one of these relatively healthy eight patients raises some scepticism about this approach. However, this is an interesting new valve and the manuscript represents the ongoing fast developments in the field of transcatheter AVI. In the meantime, the first permanent TF implantations of the Direct Flow™ prosthesis have been performed successfully. Several other new devices from different companies are currently undergoing preclinical evaluation. The next generation systems will include smaller diameter application devices, the ability to reposition the valve after and during implantation, retrievability and eventually anatomical orientation of the new valve. This may lead to improved outcomes with safer positioning and less risk for paravalvular leakage – to name a few.

The third manuscript is a position paper written by an expert team on behalf of the European Society of Cardiology and the European

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Association of Cardio-Thoracic Surgery[8]. This is an important and timely document giving clear recommendations on the current indication and joint application of the new techniques of transcatheter AVI. Key thoughts included here are to implant these devices in high risk elderly patients and use an objective scoring to assess individual risks. It is well known that the logistic EuroScore overestimates surgical risk, thus the STS Score should be used in addition in all cases. Implantations should be performed by a joint team of cardiologists and cardiac surgeons with state-of-the-art high quality imaging during implantation, if possible, an hybrid operative theatre is recommended.

All three manuscripts underline the technical and clinical progress that has been achieved during the past years in the field of high risk elderly patients suffering from symptomatic aortic stenosis. It is of utmost importance to conduct well controlled prospective clinical trials to further objectively evaluate the exciting emerging techniques for transcatheter AVI. A randomised trial, comparing TF and TA AVI versus conventional aortic valve replacement would be timely to address the open questions with this technology. Conventional cardiac surgery has yielded excellent results in thousands of patients suffering from aortic stenosis, including high risk patients. Age alone is no longer associated with an increased surgical risk. The overall mortality for isolated aortic valve surgery is down below 4% for all comers in several national registries; therefore careful patient selection is important. It will be the task of a "transcatheter valve team" to screen patients, inform them about potential approaches, including conventional surgery, and then offer them the best possible therapeutic option. Important factors that affect outcomes include the overall risk profile (using the STS score together with the EuroScore, rather than the EuroScore alone), specific indications (such as porcelain aorta) and "inoperability" need to be defined and standardized. Specific indications (such as porcelain aorta) and "inoperability" need to be defined and standardised. The rate of patients treated versus those that are rejected (all comer series versus selected series) has to be documented. It is well accepted that patient selection has the largest impact upon results of transcatheter AVI. Incomplete follow-up which is reported for some registries may be related to better results due to under-reporting of potential complications.

In summary transcatheter AVI is an emerging field with a steep increase in implantations and an improvement in clinical outcomes. First generation devices have achieved acceptable clinical outcomes in high risk patients. Next generation devices providing additional features for repositioning and retrievability are on the horizon. Any new development has to match the excellent results with conventional aortic valve surgery. The steadily increasing number of successful implantations, however, is a clear indicator that TF and TA aortic valve implantation are about to reach clinical routine in many centres soon.

Transcatheter AVI – should we do it just because we can? To answer this question, the joint position paper of ESC and EACTS will be of some help. As of now these new procedures should be performed in higher risk patients using a team approach at specialised centres and only after specific training. Without doubt, TF and TA AVI would already be feasible in younger and lower risk patients. Most certainly results would be better in a lower risk group of patients. With the excellent results and the proven long-term outcome with conventional aortic valve surgery, a widening of indication for transcatheter approaches does not seem justifiable. The new techniques would have to match mortality rates well below 3% in younger and lower risk patients. Ethically, a well designed prospectively randomised clinical trial would have to be performed first. Patient request alone – as may happen – has never been, and should not be, an indication for performing a procedure. Long-term outcomes and potential consequences of the new procedures are largely unknown. Therefore proper patient information and consecutive selection for treatment choice of conventional AV surgery (regular risk population) or transcatheter AVI (higher risk cohort) is warranted.

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