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Are the standard criteria for TAVI too lax or too strict?

Jan Kovac, Julia H Baron, Derek T Chin

Aortic stenosis is the commonest valvular disease in adults in the Western world and, when severe and symptomatic, carries a poor prognosis. Among the elderly, however, up to 50–40% of cases are considered too high risk or inappropriate for conventional open heart surgery and hence remain unattended and untreated. Transcatheter aortic valve implantation (TAVI)—term coined at the joint ESC/EACTS consensus meeting in 2008 as best describing the procedure which involves valve implantation rather than replacement—offers considerable promise in treating these high-risk patients.

TAVI has become a rapidly evolving technique with potential to create a paradigm shift similar to the introduction of percutaneous transluminal coronary angioplasty (PTCA) in the early 1980s. Two devices are currently available and marketed in Europe and around the world: the Edwards Sapien balloon expandable bioprosthesis (Edwards Lifesciences, Irvine, CA, USA) and the Medtronic-CoreValve self-expanding bioprosthesis (Medtronic Inc, Minneapolis, MN, USA).

Following initial data from pivotal safety trials, both devices were CE marked in 2007. The number of prostheses implanted is growing rapidly in Europe, with around 8000 devices implanted by the end of June 2009. Published information from single-centre experiences, safety trials and published registries suggests that the 30-day mortality with this procedure is around 10%, with one year survival around 70% with late mortality almost exclusively related to comorbidity of these patients.

While evidence for the position of these devices in relation to conventional surgery and conservative management is being sought via ongoing (US Partner) or planned (Nordic Trial, UK TAVI Trial, SYNTAXI) randomised trials, this therapy is currently provided to many elderly or severely polymorbid patients around the world as an alternative to surgical aortic valve replacement (AVR), if the risk of surgical AVR is considered too high.

Concern has been expressed about the potential for rapid expansion of the procedures to inappropriate centres without adequate training or expertise, or to inclusion of unsuitable patients. In Europe, a joint position statement (by ESC and EACTS) concerning TAVI has been published. This emphasises the absence of definitive and randomised data and the role of a multidisciplinary “valve team” with extensive experience in diagnosis and treatment of valvular disease. This is echoed in the UK NICE guidance.

Selection criteria for TAVI are clinical and anatomical. Standard or “label” criteria have been developed by the manufacturers, with detailed lists of indications, contraindications and acceptable measurements. During training and proctorship at individual implant centres, these stringent criteria are applied by the companies. This would include central validation of diagnostic findings and measurements in each patient as well as a review of clinical criteria. Adherence to this is a prerequisite for involvement of a centre in the TAVI programme. However, as our experience with TAVI grows, is it still necessary to adhere to these completely?

Clinical risk assessment is complex. There are very few absolute contraindications to surgical AVR (such as porcelain aorta), and there is no current valve specific surgical risk score to apply. EuroSCORE and STS can be used as supportive documentation, but validation of risk and suitability for TAVI should be a by a multidisciplinary team (MDT), who should review each case. The valve team should consist of cardiac surgeons, imaging and interventional cardiologists and a cardiac anaesthetists. Risk can be defined by patient factors present (age being the most common, but not exclusively one) and significant comorbidities, and an assessment of the “potential to improve” post-procedure should also be made. For frailty and general patient assessment, involvement of a physician with an interest in the elderly is desirable. Much of this at present comes down to “clinical judgment”. This in itself makes defining TAVI clinical criteria difficult.

Assessment of anatomical variables is very detailed—the aortic annulus and adjacent structures, the relation and distance to coronary arteries and the cardiac septum size. “Ideal” anatomical criteria are easier to define (and some should be respected absolutely), but deciding which patients fall just outside some of these but can still be successfully treated is harder.

Currently available CE-marked devices cover a range of anatomies for annular sizes between 18–27 mm, with substantial sizing overlap in the middle for both designs (Edwards 18–25 mm, Medtronic CoreValve 20–27 mm). Great attention needs to be paid to precise measurement of annular dimensions (using TTE, TOE, angiography and CT, if necessary), especially at either end of the spectrum or with borderline measurements between the different sizes of the prostheses. The valves are not designed for post dilatation (which theoretically can damage the tissue prosthesis mounted onto metallic frame). Imprecise sizing also brings risk of misplacement, embolisation, aortic regurgitation, aortic rupture/tamponade or need for a second valve in valve as a bailout strategy. While clinical “off-label” usage is ultimately the responsibility of the MDT, recommended annular dimensions should be followed as strictly as possible, especially if longer-term results of suboptimal implant are uncertain.

While these designs are fundamentally different, many patients can be treated successfully with either device. However, they are to some extent complementary, because of the different range of annular sizes and different contraindications in relation to adjacent structures (distance of coronary ostia from the annulus, size of sinotubular junction, sinuses of Valsalva, etc). Furthermore, owing to the size of prostheses there are additional minimal diameter requirements for the size of the femoral artery access (6 mm for current Medtronic CoreValve and 7–8 mm for current Edwards Sapien, respectively). Multislice CT and aortography enable femoral measurement, as well as qualitative assessment of the whole femoro-iliac-aortic path. Alternative access (transapical or transaxillary) may be more appropriate in some patients with excessive calcific tortuosity of the vessel, even if their femoral diameters are sufficient.

In this issue Piazza et al report implants with “off-label” indications and, while implying it is safe at implant and short-term follow-up, longer-term
data will not be available for some time (see page 19). In particular, in “suboptimal” implants, data are required about the significance of aortic regurgitation and in relation to mitral valve performance (there are anecdotal reports of late mitral regurgitation (MR) resulting from low implant position).  

Concomitant MR also needs detailed assessment as it may be independent or secondary to left ventricular dysfunction (which may improve post-TAVI). If independent, it may result in “incomplete re-valving” (a similar to concept of incomplete revascularisation in coronary angioplasty), limiting the clinical effectiveness of the TAVI procedure.

Off-label indications include the appealing (but minimally tested) concept of TAVI for failed bioprosthetic AVR (valve in valve).

As this technology, albeit a proved and undoubtedly very viable concept, is still very new, manufacturers have important role in setting technical/clinical and anatomical specification, and at this stage their specialists play important part in validating patient anatomical criteria in relation to prosthesis specification (label information).

While further evidence is being sought before expanding TAVI further, adherence to anatomical criteria (reflecting current design limitations), should be strict as we have no knowledge of the long-term consequences of even slightly suboptimal anatomical placement or aorto-prosthesis mismatch.

First and foremost, adherence to clinical criteria should involve an emphasis on MDT assessment, taking into account patient risk factors, local results of AVR across the age groups, accessibility of patient vasculature and the patient’s overall survival prospects (and frailty). This is good clinical practice, while evidence is being built via randomised controlled trials and registries.

We can expect the TAVI population to evolve as results from randomised controlled trials become available.

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REFERENCES


