

Transcatheter Aortic Valve Implantation (TAVI)

A position statement of the British Cardiovascular Intervention Society (BCIS) and the Society for Cardiothoracic Surgery (SCTS)

TAVI is a new novel therapy which may be used to as an alternative to standard surgical aortic valve replacement. The procedure is performed on the beating heart without the need for a sternotomy or cardiopulmonary bypass. Currently, 2 devices are CE marked and the procedure may be performed via the transfemoral, subclavian or transapical approaches. A group of members of BCIS and SCTS with experience in the technique and a knowledge of the TAVI literature have agreed the following consensus statements.

- (1) TAVI should currently be reserved for patients who have been considered by a multidisciplinary team (including 2 surgeons and 2 interventional cardiologists) who consider the risk/benefit ratio of open heart surgery and TAVI to favour TAVI. The usual "high risk" patient will have a logistic Euroscore of >20 or an STS score of >10. In ideal circumstances the involvement in the MDT of a general physician with experience in the care of the elderly would be appropriate.
- (2) In general TAVI should be performed for symptomatic severe degenerative aortic stenosis. Under exceptional circumstances and after full discussion within a multidisciplinary team, other forms of aortic valve disease such as a failing aortic bio-prosthesis may be treated.
- (3) TAVI should be performed by a multidisciplinary team (MDT) drawn from a minimum of 2 interventional cardiologists, 2 cardiothoracic surgeons, cardiac anaesthetists and cardiac imaging specialists.
- (4) Patients should be screened into a TAVI programme by this MDT team and not by any individual speciality.
- (5) There should be formal training of the implanting team which should include:
 - Didactic theoretical training.
 - Simulator training if available.
 - A visit to an experienced centre to observe TAVI cases.
 - Support for the initial cases at any site by a proctor.
- (6) Any hospital wishing to set up a TAVI programme should have the following minimum infra-structure available:
 - The ability to set up an MDT (as above).
 - Immediate availability of trans-thoracic and transoesophageal echocardiography.
 - Availability of a dedicated cardiac catheter lab or hybrid theatre.
 - A theatre with "C" arm screening facilities is generally not appropriate for TAVI procedures .
 - CT scanning facilities
 - Immediate availability of perfusion services in case of the need for emergency femoro-femoral bypass.
 - On-site availability of a surgical recovery area and intensive care with staff experienced in looking after patients following surgical aortic valve replacement.
 - Robust arrangements for immediate renal support if necessary.
 - Immediate access to vascular surgeons and interventional radiologists to deal with major peripheral vascular complications.
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At the current time the above requirements will mean that this procedure should only be performed in a unit currently carrying out surgical aortic valve replacement.
- (7) Any unit performing the procedure has to provide procedural, outcome and follow-up data, (in the form of the agreed BCIS/SCTS dataset), to a centrally held DOH database for event tracking.
- (8) It is the view of BCIS and SCTS that the TAVI procedure should be performed by centres who can provide the above infrastructure and that the procedure should be only be done by highly experienced interventional cardiologists and cardiothoracic surgeons. We

believe occasional practice and small volume TAVI units should be actively discouraged. It is difficult to stipulate a minimum number of cases per year for a TAVI programme. Competence is obviously more important than numbers. However a minimum annual number of 24 cases per TAVI unit may be reasonable, but given the learning curve and infrastructure needed we believe somewhere in the order of > 50 cases per year to be optimal.

- (9) Finally we have carefully considered the question of the timing of further studies, in particular a randomised clinical trial. We believe that UK centres need to get beyond their learning curve before entering into a randomised trial. During this run-in phase centres must enter data using the agreed dataset so as to create a prospective cohort study (as described above). We believe that, at the correct time in the development of this technology UK centres should be strongly encouraged to participate in a RCT. Equally we believe a RCT comparing TAVI with conventional AVR should be conducted before widespread dissemination of TAVI into a population who would be considered low/moderate risk for conventional AVR.
- (10) In general we support the position paper produced and published by the European Societies (ESC & EACTS)