

# Transcatheter aortic valve implantation for aortic stenosis

## 1 Guidance

- 1.1 The evidence on transcatheter aortic valve implantation for aortic stenosis is limited to small numbers of patients who were considered to be at high risk for conventional cardiac surgery. It shows good short-term efficacy but there is little evidence on long-term outcomes. There is a potential for serious complications; however, the patients on whom this procedure has been used have a poor prognosis without treatment and are at high risk if treated by open heart surgery. Clinicians wishing to use this procedure should do so only with special arrangements for clinical governance, consent and for audit or research.
- 1.2 Clinicians should take the following actions:
- Inform the clinical governance leads in their Trusts.
  - Ensure that patients understand the uncertainty about the procedure's long-term efficacy and its risks, which include death and the potential need for emergency cardiac surgery. They should provide patients with clear, written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from [www.nice.org.uk/IPG266publicinfo](http://www.nice.org.uk/IPG266publicinfo)).
- 1.3 Patient selection should be carried out by a multidisciplinary team including an interventional cardiologist, a cardiac surgeon and a cardiac anaesthetist.
- 1.4 This is a technically challenging procedure that should be performed only by clinicians and teams with special training and experience in interventional cardiology. Units undertaking this procedure should have both cardiac and vascular surgical support for emergency treatment of complications.

- 1.5 The NHS Information Centre for Health and Social Care runs the UK Central Cardiac Audit Database, and clinicians should enter details about all patients undergoing transcatheter aortic valve implantation for aortic stenosis onto this database ([www.ccad.org.uk](http://www.ccad.org.uk)).
- 1.6 Further publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Aortic stenosis (narrowing of the aortic valve) causes impaired outflow of blood from the heart, and is usually progressive. It requires the left ventricle to pump harder to maintain a normal circulation. Over time, left ventricular hypertrophy and heart failure may develop. Symptoms of aortic stenosis typically include exertional chest pain, breathlessness, dizziness and fainting.
- 2.1.2 Management of aortic stenosis depends on the severity of the condition, the presence of comorbidities, the age of the patient and their operative risk. Treatment is only usually needed if aortic stenosis is severe or symptomatic. In these patients, conventional treatment is surgical aortic valve replacement. This involves replacement of the diseased valve with an artificial (biological or mechanical) prosthesis through a median sternotomy approach and using cardiopulmonary bypass. Percutaneous balloon valvuloplasty is usually considered as palliative treatment and may be undertaken in very ill patients who cannot safely undergo surgery.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

- 2.1.3 Transcatheter aortic valve implantation has been undertaken in patients in whom conventional aortic valve replacement would carry a high mortality risk due to advanced age and/or the presence of concomitant illnesses.

## 2.2 Outline of the procedure

- 2.2.1 Transcatheter aortic valve replacement may be carried out under general anaesthesia or under local anaesthesia with sedation. Access to the aortic valve can be achieved transluminally, via the femoral artery or vein (percutaneous or endovascular approach), or surgically, via a minithoracotomy and apical puncture of the left ventricle (transapical or transventricular approach). When the femoral vein is used for a transluminal approach, the interatrial septum is punctured in order to gain access to the left ventricle via the left atrium and mitral valve. When the femoral artery is used, surgical exposure and closure may also be required. The method chosen for catheter access to the aortic valve may be dictated by the presence of peripheral arterial disease, as the transluminal approach may not be feasible in these patients.
- 2.2.2 Whichever approach is used, a balloon catheter is advanced into the left ventricle over a guidewire and positioned within the opening of the aortic valve. The existing aortic valve is dilated in order to make room for the prosthetic valve. Rapid right ventricular pacing may be used to reduce cardiac output through the existing aortic valve and to reduce cardiac movement during implantation. The new valve, mounted on a metal stent, is manipulated into position and is either self-expanding or deployed using balloon inflation. Deployment leads to obliteration of the existing aortic valve.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.

## 2.3 Efficacy

### Transluminal approach

- 2.3.1 In three case series of 86, 50 and 36 patients, a transluminal approach was carried out successfully in 88% (76/86), 86% (43/50) and 75% (27/36) of patients, respectively. Causes of failure were reported as device misplacement in 9% (8/86) and 4% (2/50) of patients and inability to cross the diseased valve in 6% (3/50), 3% (1/36) and 2% (2/86) of patients.
- 2.3.2 Three case series of 50, 13 and 36 patients treated by a transluminal approach reported survival to be 81% (35/43), 45% (5/11) and 41% (11/27) at follow-up of 359 days (median), 305 days (median) and 6 months, respectively. These figures included only those patients in whom the procedure was completed successfully.
- 2.3.3 Four case series of 86, 50, 36 and 13 patients treated by the transluminal approach reported a significant decrease in mean aortic valve gradient from baseline: from 44 to 9 mmHg, 46 to 11 mmHg, 37 to 9 mmHg and 51 to 9 mmHg, respectively, at follow-up periods ranging from discharge to 1 month.
- 2.3.4 Three case series of 50, 36 and 13 patients reported a significant increase in mean aortic valve area from baseline: from 0.6 to 1.7 cm<sup>2</sup> ( $p = 0.0001$ ), 0.6 to 1.9 cm<sup>2</sup> ( $p < 0.0001$ ) and 0.6 to 1.3 cm<sup>2</sup> ( $p < 0.0001$ ), respectively, at follow-up periods ranging from discharge to 1 month.
- 2.3.5 Four case series of 86, 50, 36 and 13 patients reported that mean New York Heart Association (NYHA) functional class improved: from 2.85 at baseline to 1.85 at 30-day follow-up ( $p < 0.001$ ); by at least one class in 50% (25/50) of patients ( $p < 0.0001$ ); to class I in five patients, class II in 14 patients and class III in two patients surviving beyond 33 days (baseline NYHA not reported); and by at least one class in all survivors at 1-month follow-up (9/11;  $p = 0.006$ ), respectively.

### Transapical approach

- 2.3.6 Using the transapical approach, all seven patients in one case series were successfully treated. In two further case series of 59 and 50 patients using the transapical approach (which included duplicate reporting of some patients), conversion to sternotomy was required in 7% (4/59) and 6% (3/50) of patients, respectively. This was due to incorrect valve positioning in all four patients in the first study, and proximal valve dislocation, aortic root dissection and severe calcification of one of the native aortic valve cusps in the second study.
- 2.3.7 The case series of 59 and 50 patients reported mean aortic gradients of 9 mmHg in 40 patients at discharge and 8 mmHg in all survivors at 6-month follow-up, respectively (baseline values not reported).
- 2.3.8 A case series of seven patients reported the mean aortic valve area to be 0.7 cm<sup>2</sup> at baseline (n = 7), 1.8 cm<sup>2</sup> at 1-month follow up (n = 6) and 1.5 cm<sup>2</sup> at 6-month follow-up (n = 4).
- 2.3.9 The case series of seven patients treated by the transapical approach reported that symptoms relating to aortic stenosis had resolved or significantly improved at 1- and 6-month follow-up.

### Transluminal and transapical approach

- 2.3.10 The Specialist Advisers considered key efficacy outcomes to include procedural success, haemodynamic improvement, reduction of symptoms and short- and long-term survival.

## 2.4 Safety

### Transluminal approach

- 2.4.1 Three case series of 86, 50 and 36 patients treated by the transluminal approach reported a 30-day mortality of 12% (10/86; five were intraprocedural), 12% (6/50; one was intraprocedural) and 22% (6/27), respectively. A case series of 13 patients reported in-hospital mortality to be 18% (2/11).

- 2.4.2 A case report on transluminal implantation via the femoral vein described the death of a patient 5 days after the procedure, due to guidewire-induced mitral valve leaflet laceration leading to severe mitral regurgitation and cardiogenic shock.
- 2.4.3 The incidence of stroke within 30 days was reported to be 12% (9/76), 4% (1/27), 9% (1/11) and 2% (1/43) of patients treated by a transluminal approach. The two patients from the latter two studies died within 30 days of the procedure. Additional complications reported within 30 days in these four case series included bradyarrhythmia in 36% (4/11) of patients, major bleeding in 18% (2/11), cardiac tamponade in 10% (9/86), iliac injury requiring vascular repair in 5% (2/43) and access site infection requiring antibiotics in 5% (2/43).

### Transapical approach

- 2.4.4 The reported rates of in-hospital and 30-day mortality in two case series using the transapical approach were 14% (8/59) and 8% (4/50), respectively. A third case series of seven patients reported 30-day mortality to be 14% (1/7).
- 2.4.5 In a case series of seven patients, moderate paravalvular regurgitation was reported in two patients; this decreased after redilation.
- 2.4.6 The case series of 59 patients treated by the transapical approach reported pleural effusion in 31% (18/59) of patients, supraventricular tachyarrhythmia in 31% (18/59), pericardial effusion in 5% (3/59) and stroke in 3% (2/59), and the need for haemofiltration in 14% (8/59), tracheostomy in 14% (8/59), rethoracotomy in 14% (8/59) and cardiopulmonary resuscitation in 7% (4/59).

### Transluminal and transapical approach

- 2.4.7 In addition to outcomes reported in the literature, the Specialist Advisers considered additional theoretical adverse events to include thromboembolic complications; valve embolisation, migration or misplacement; access site complications; the need for conversion to conventional surgery; the need for a permanent pacemaker; early device failure and uncertain durability of the implanted artificial valve.

## 2.5 Other comments

- 2.5.1 The Committee noted that there are a number of devices in use for the approaches to this procedure. They also noted that the devices and techniques used for the procedure are evolving.
- 2.5.2 The Committee noted that patient selection was limited to those at high risk of mortality from conventional valve replacement in the studies considered. More evidence on patient selection may be useful in reviewing the guidance.

## 3 Further information

- 3.1 The Institute has published interventional procedures guidance on balloon valvuloplasty for aortic valve stenosis in adults and children ([www.nice.org.uk/IPG078](http://www.nice.org.uk/IPG078)) and percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction ([www.nice.org.uk/IPG237](http://www.nice.org.uk/IPG237)).

## Information for patients

NICE has produced information on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. See [www.nice.org.uk/IPG266publicinfo](http://www.nice.org.uk/IPG266publicinfo)

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview, available at [www.nice.org.uk/IP685overview](http://www.nice.org.uk/IP685overview)

### Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk)) and quote reference number N1602 for this guidance or N1603 for the 'Understanding NICE guidance'.

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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