

Transcatheter aortic valve implantation for aortic stenosis

Issued: March 2012

NICE interventional procedure guidance 421

guidance.nice.org.uk/ipg421

NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for 5 years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'



Contents

1 Guidance	3
2 The procedure	5
2.1 Indications and current treatments	5
2.2 Outline of the procedure	5
2.3 Efficacy	6
2.4 Safety	8
2.5 Other comments	10
3 Further information	11
About this guidance	12

1 Guidance

This document replaces previous guidance on transcatheter aortic valve implantation for aortic stenosis (interventional procedure guidance 266).

- 1.1 Evidence on the safety of transcatheter aortic valve implantation (TAVI) for aortic stenosis shows the potential for serious but well-recognised complications.
- 1.2 For patients with aortic stenosis who are considered to be unsuitable for surgical aortic valve replacement (SAVR; see sections 1.6 and [2.1.3](#)) the evidence on the efficacy of TAVI is adequate. For these patients, TAVI may be used with normal arrangements for clinical governance, consent and audit. Details of all patients should be entered into the [UK Central Cardiac Audit Database](#).
- 1.3 For patients with aortic stenosis for whom SAVR is considered suitable but to pose a high risk (see sections 1.5, 1.6 and [2.1.3](#)) the evidence on the efficacy of TAVI is inadequate. For these patients TAVI should only be used with special arrangements for clinical governance, consent and data collection or research. NICE encourages clinicians to enter suitable patients into the [UK TAVI trial](#). In addition, details of all patients should be entered into the [UK Central Cardiac Audit Database](#).
- 1.4 For patients with aortic stenosis for whom SAVR is considered suitable and not to pose a high risk (see sections 1.6 and [2.1.3](#)) the evidence on the efficacy of TAVI is inadequate. For these patients TAVI should only be used in the context of research. NICE encourages clinicians to enter suitable patients into the [UK TAVI trial](#). In addition, details of all patients should be entered into the [UK Central Cardiac Audit Database](#).
- 1.5 Clinicians wishing to undertake TAVI for patients with aortic stenosis for whom SAVR is considered suitable but to pose a high risk (see section 1.3) should take the following actions.
 - Inform the clinical governance leads in their Trusts.

-
- Ensure that patients understand the risk of stroke and death, and the uncertainty about the procedure's efficacy in the long term. Provide them with clear written information. In addition, the use of NICE's information for patients ('[Understanding NICE guidance](#)') is recommended.
- 1.6 Patient selection should be carried out by a multidisciplinary team including interventional cardiologists, cardiac surgeons, a cardiac anaesthetist and an expert in cardiac imaging. The multidisciplinary team should determine the risk level for each patient.
- 1.7 TAVI is a technically challenging procedure that should be performed only by clinicians and teams with special training and experience in complex endovascular cardiac interventions. Units undertaking this procedure should have both cardiac and vascular surgical support for emergency treatment of complications.
- 1.8 NICE encourages further research into TAVI for aortic stenosis. In particular, NICE encourages clinicians to enter all suitable patients into the [UK TAVI trial](#). Information from research trials that will be useful for future guidance includes patient selection criteria and comparisons between TAVI and SAVR in patients who would be suitable for either procedure. Outcomes should include incidence of stroke and other adverse events, symptom relief, quality of life, occurrence of aortic regurgitation, and valve durability in the short and long term.
- 1.9 NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Aortic stenosis causes impaired outflow of blood from the heart and is usually progressive. The increased cardiac workload leads to left ventricular hypertrophy and heart failure. Symptoms of aortic stenosis typically include shortness of breath and chest pain on exertion.
- 2.1.2 SAVR with an artificial (biological or mechanical) prosthesis is the conventional treatment for patients with severe symptomatic aortic stenosis who are well enough for surgery. Optimal medical care has traditionally been the only option for those whose condition is unsuitable for surgery. Aortic balloon valvuloplasty is occasionally used.
- 2.1.3 Patients may be unsuitable for SAVR because of medical comorbidities or because of technical considerations (for example, if the patient has a calcified aorta or scarring from previous cardiac surgery) which mean that the risks of SAVR outweigh the potential benefits. Patients who are suitable for SAVR range from those considered to be high risk (for example, as defined in the PARTNER A trial) to those for whom the benefits of surgery clearly outweigh the risks of surgery.

2.2 Outline of the procedure

- 2.2.1 TAVI aims to provide a less invasive alternative to open cardiac surgery for the treatment of aortic stenosis, avoiding the need for cardiopulmonary bypass.
- 2.2.2 TAVI may be carried out with the patient under general anaesthesia or using local anaesthesia with sedation. Access to the aortic valve may be transluminal, through a large artery (usually the femoral or subclavian artery; percutaneous or endovascular approach), or surgical, via a minithoracotomy with apical puncture of the left ventricle (transapical approach). The choice of access route (transluminal or transapical) depends on various factors; atherosclerotic disease in the arteries may make the transluminal approach impossible.

- 2.2.3 Initially the aortic valve ring is dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and deployed over the existing aortic valve.
- 2.2.4 Different devices are available for this procedure (see section [2.5.4](#)). Some may contain material derived from animal sources.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 Efficacy

- 2.3.1 A European register study of 1038 patients reported short-term procedural success of 94% (956/1019). Procedural success was defined as deployment of the valve, retrieval of the delivery catheter, no conversion to conventional surgery and the patient leaving the intervention room alive. A case series based on the UK TAVI register of 877 procedures (870 patients) reported procedural success in 97% of procedures (absolute figures not reported).
- 2.3.2 A randomised controlled trial (RCT) of 358 patients with severe aortic stenosis who were considered unsuitable for SAVR and who were randomised to treatment either by TAVI (n = 179) or by standard (non-surgical) therapy (n = 179) reported death from cardiovascular causes in 21% and 45% of patients respectively at 1-year follow-up (hazard ratio 0.39, 95% confidence interval 0.27 to 0.56, $p < 0.001$).
- 2.3.3 The case series of 877 procedures (870 patients) from the UK TAVI register reported a 1-year survival rate of 79% and a 2-year survival rate of 74% (Kaplan–Meier analysis; actual numbers of patients not reported). Survival at 1 year and 2 years was significantly better for those who had a transfemoral approach than for those who had a transapical approach (81% [488/599] versus 72% [196/271], $p = 0.002$ and 77% [464/599] versus 65% [177/271], $p < 0.001$ respectively).

- 2.3.4 The RCT of 358 patients reported that, of the patients surviving at 1 year, 75% randomised to treatment by TAVI were asymptomatic or had only mild symptoms (New York Heart Association [NYHA] class I or II) compared with 42% randomised to treatment by standard therapy ($p < 0.001$). NYHA class was not significantly different at baseline in these groups (absolute figures not reported).
- 2.3.5 The register of 1038 patients reported that 76% of patients in whom a transfemoral approach was used and 78% of patients in whom a transapical approach was used were NYHA class III or IV (physical activity limited or symptomatic at rest) at baseline. At 1-year follow-up, 78% of transfemoral patients and 69% of transapical patients were NYHA class I or II (absolute figures not stated).
- 2.3.6 An RCT of 699 patients considered to be well enough for conventional SAVR but at high risk, compared 348 patients randomised to TAVI with 351 patients randomised to SAVR. Patients in the TAVI group could walk further (assessed by 6-minute walk test) than those in the SAVR group at 30-day follow-up ($p = 0.002$; not otherwise described). At 1 year, patients in both groups had improvement in cardiac symptoms and 6-minute walk test distance, but no significant differences between groups were reported.
- 2.3.7 A case series of 99 patients reported significantly improved Short Form (SF)-36 quality of life scores for the summary physical health score from baseline to 3-month follow-up (31.2 to 38.6, $p < 0.01$). There was no significant change in summary mental health score (48.5 to 47.3, $p = 0.50$).
- 2.3.8 The RCT of 699 patients reported similar proportions of patients requiring readmission to hospital within 1 year after being randomised to TAVI or SAVR (18% versus 16%, $p = 0.38$; absolute figures not stated).
- 2.3.9 The Specialist Advisers listed key efficacy outcomes as satisfactory device positioning, haemodynamic improvement, improved survival and quality of life, and fewer readmissions.

2.4 Safety

- 2.4.1 The RCT of 699 patients reported similar mortality rates from cardiovascular causes within 30 days in the TAVI group and the SAVR group (3% [11/348] versus 3% [10/351], $p = 0.9$). The RCT of 358 patients reported death from cardiovascular causes within 30 days in 5% (8/179) of patients in the TAVI group compared with 2% (3/179) of patients in the standard therapy group ($p = 0.22$). Death from any cause occurred in 5% (9/179) and 3% (5/179) respectively ($p = 0.41$). The register of 1038 patients reported a 30-day mortality rate of 9% (88/1038) (including 39 from multi-organ and heart failure and 7 from sepsis).
- 2.4.2 The RCT of 699 patients reported a significantly higher rate of stroke or transient ischaemic attack at 1 year in the TAVI group compared with the SAVR group (8% versus 4%, $p = 0.04$; absolute figures not reported).
- 2.4.3 A systematic review of 2375 patients reported rates of cardiac tamponade ranging from 1% to 10% in the 9 studies that reported this outcome.
- 2.4.4 The register of 1038 patients reported aortic dissection in 2% (9/463) of patients treated via a transfemoral approach and less than 1% (5/575) treated with a transapical approach.
- 2.4.5 The register of 1038 patients reported postoperative aortic regurgitation greater than grade 2+ (not otherwise defined) in 2% (20/1036) of patients (preoperative prevalence not stated). The RCT of 699 patients reported a higher prevalence of moderate or severe paravalvular aortic regurgitation at 30 days in the TAVI group than in the SAVR group (12% versus 1%, $p < 0.001$). A non-randomised comparative study of 175 patients reported paravalvular mild aortic regurgitation in 25% (16/63) of patients, paravalvular moderate aortic regurgitation in 10% (6/63) of patients and severe aortic regurgitation requiring surgical valve insertion in 1 patient in the TAVI group (at median follow-up of 466 days). The case series of 877 procedures (870 patients) from the UK TAVI register reported moderate or severe aortic regurgitation on imaging in 14% of patients (actual number of patients not reported). Length of follow-up ranged from 11 to 46 months. Patients in whom a transfemoral approach was used

had significantly higher rates of moderate or severe aortic regurgitation than patients in whom other approaches were used (16% [91/585] versus 9% [24/264], $p = 0.01$).

- 2.4.6 The register of 1038 patients reported that valve-in-valve surgery was required after TAVI in 2% (22/1036) of patients because of valve incompetence or malpositioning.
- 2.4.7 The RCT of 699 patients reported that similar proportions of patients required a new pacemaker within 1 year in the TAVI group and the SAVR group (6% versus 5%, $p = 0.68$). The case series of 877 procedures (870 patients) from the UK TAVI register reported that a permanent pacemaker was required in 16% (141/867) of patients (follow-up ranged from 11 months to 46 months). A case series of 270 patients reported that 33% (81/243) of patients required a permanent pacemaker within 30 days of the procedure.
- 2.4.8 The RCT of 699 patients reported 2 cases of endocarditis in the TAVI group and 3 cases in the SAVR group at 1 year.
- 2.4.9 The RCT of 699 patients randomised to TAVI or SAVR reported major bleeding in 9% (32/348) and 20% (67/351) of patients within 30 days of the procedure ($p < 0.001$).
- 2.4.10 The RCT of 358 patients comparing TAVI with standard therapy reported major bleeding within 30 days in 17% (30/179) and 4% (7/179) of patients respectively ($p = 0.001$).
- 2.4.11 The RCT of 699 patients reported similar proportions of patients with acute kidney injury requiring renal replacement therapy within 1 year after TAVI and after SAVR (5% versus 7%, $p = 0.56$).
- 2.4.12 The case series of 99 patients reported postoperative renal insufficiency in 15% (15/99) of patients.

-
- 2.4.13 The Specialist Advisers listed anecdotal adverse events as device embolisation and thrombosis. They considered theoretical adverse events to include haemolytic anaemia.

2.5 Other comments

- 2.5.1 The Committee noted that there was very little evidence on patients who were not defined as high risk for SAVR.
- 2.5.2 The Committee recognised the importance of long-term outcomes in patients who are considered suitable for SAVR and was uncertain about whether and in what circumstances using TAVI (rather than SAVR) is justified in these patients.
- 2.5.3 The Committee recognised that many patients with severe aortic stenosis have a poor prognosis as a result of comorbidities. It regarded careful overall assessment of life expectancy as an important consideration when selecting patients for TAVI.
- 2.5.4 The Committee noted that a range of different devices are available for this procedure and there may be differences in clinical outcomes following the use of these different devices, for example, the need for subsequent pacemaker insertion.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('[Understanding NICE guidance](#)'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Changes after publication

May 2012: minor maintenance

Your responsibility

This guidance represents the views of NICE and 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Copyright

© National Institute for Health and Clinical Excellence 2011. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

Contact NICE

National Institute for Health and Clinical Excellence

Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 033 7780