Transcatheter aortic valve implantation for aortic stenosis

HealthTech guidance

Published: 26 July 2017

www.nice.org.uk/guidance/htg446

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG586.

1 Recommendations

1.1 Current evidence on the safety and efficacy of transcatheter aortic valve implantation (TAVI) for aortic stenosis is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Details of all patients should be entered into the UK TAVI registry managed by the National Institute for Cardiovascular Outcomes Research. Contact bartshealth.nicor-generalenquiries@nhs.net for details. Adverse events should be reported to the Medicines and Healthcare products Regulatory Agency.

1.3 Patient selection should be carried out by an experienced multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging and, when appropriate, a cardiac anaesthetist and a specialist in elderly medicine. The multidisciplinary team should determine the risk level for each patient and the TAVI device most suitable for them.

1.4 During the consent process patients should be told about all treatment options and their advantages and disadvantages.

1.5 TAVI is a technically challenging procedure that should only be done in specialised centres and only by clinicians and teams with special training and experience in complex endovascular interventions. Units doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

2 Indications and current treatments

2.1   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. Mortality rates are high in symptomatic patients.

2.2   Surgical aortic valve replacement (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 as bridging or palliative treatment. Transcatheter aortic valve implantation (TAVI) is another less invasive alternative treatment.

2.3   Patients for whom SAVR is suitable range from those considered to be high risk (for example, as defined in the PARTNER 1A trial) to those for whom the benefits of surgery clearly outweigh the risks of surgery. SAVR may not be suitable for patients because of medical comorbidities or 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.

3 The procedure

3.1   Transcatheter aortic valve implantation (TAVI) aims to provide a less invasive alternative to open cardiac surgery for treating aortic stenosis, avoiding the need for sternotomy and cardiopulmonary bypass.

3.2   TAVI may be done with the patient under general anaesthesia or using local anaesthesia with or without sedation. Access to the aortic valve is most commonly transluminal, through a large artery (usually the femoral or subclavian artery; percutaneous or endovascular approach), or occasionally surgical, by a minithoracotomy with apical puncture of the left ventricle (transapical approach). The choice of access route (transluminal or transapical) depends on various patient-related factors including atherosclerotic disease in the arteries, which would make the transluminal approach impossible.

3.3   Initially the aortic valve ring may be dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and inserted inside the existing aortic valve.

3.4   Different devices are available for this procedure and contain material derived from animal sources.

4 Efficacy

This section describes efficacy 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 interventional procedure overview.

Evidence is based only on studies that reported outcomes by the risk level of the patients.

Survival beyond 30 days

4.1   A randomised controlled trial (RCT) of 358 patients (PARTNER 1B) for whom surgical aortic valve replacement (SAVR) was unsuitable compared transcatheter aortic valve implantation (TAVI; n=179) with medical management (n=179). Patients who had TAVI had significantly lower all-cause mortality and cardiovascular mortality compared with medical management at a follow-up of 1, 2 and 5 years (31% compared with 51% at 1 year, 43% compared with 68% at 2 years and 72% compared with 94% at 5 years for all-cause mortality and 21% compared with 45% at 1 year, 31% compared with 62% at 2 years and 58% compared with 86% at 5 years for cardiovascular mortality).

4.2   In an RCT of 795 patients for whom SAVR was suitable but high risk (the CoreValve trial), a Kaplan–Meier cumulative probability analysis for all-cause mortality at 3-year follow-up was 33% for TAVI compared with 39% for SAVR (p=0.068). In another RCT of 699 patients for whom SAVR was suitable but high risk (the PARTNER 1A trial), a Kaplan–Meier probability analysis for all-cause mortality at up to 5 years of follow-up was 68% for TAVI compared with 62% for SAVR (p=0.76). When data were pooled for both RCTs (based on an intention-to-treat [ITT] analysis), the hazard ratios did not show statistically significant differences between TAVI and SAVR for hazard of death (pooled estimates were risk ratio [RR] 0.89; 95% confidence interval [CI] 0.73 to 1.09, p=0.26 at 1 year and RR 0.95; 95% CI 0.79 to 1.13, p=0.55 at 2 years). There were no significant differences for cardiovascular mortality at 1 year (RR 1.05; 95% CI 0.79 to 1.39, p=0.73) and 2 years (RR 0.92; 95% CI 0.67 to 1.28, p=0.79).

4.3   In an RCT of 2,032 patients for whom SAVR was suitable but intermediate risk

(the PARTNER 2A trial) there were no significant differences between TAVI and SAVR at 1- and 2-year follow-up for all-cause mortality and cardiovascular mortality (all-cause mortality: 12% compared with 13%, p=0.69, at 1 year and 17% compared with 18%, p=0.45, at 2 years; cardiovascular mortality: 7% compared with 8%, p=0.4, at 1 year and 10% compared with 11%, p=0.38, at 2 years). In an RCT of 276 patients for whom SAVR was suitable but low to intermediate risk (the NOTION study) there were no significant differences between TAVI and SAVR at 1- and 2-year follow-up for all-cause mortality and cardiovascular mortality (all-cause mortality: 5% compared with 8%, p=0.38, at 1 year and 8% compared with 10%, p=0.54, at 2 years; cardiovascular mortality: 4% compared with 8%, p=0.25, at 1 year and 7% compared with 9%, p=0.40, at 2 years). A systematic review including 2 RCTs and 6 observational studies of 16,638 patients for whom SAVR was suitable and not high risk (comprising 6,875 patients in an analysis) showed a non-significant difference in all-cause mortality for TAVI compared with SAVR (odds ratio [OR] 0.67; 95% CI 0.42 to 1.07, p=0.08, at 30 days; OR 0.91; 95% CI 0.67 to 1.23 at 1 year; OR 1.06; 95% CI 0.59 to 1.91 at long-term follow-up [more than 1 year]). In a systematic review of patients at low and intermediate risk from surgery including 4 RCTs (n=3,179 patients, including the CoreValve trial), in which patients had a mean Society of Thoracic Surgeons' (STS) risk score of 7%, TAVI was associated with a lower hazard of death at 2 years than SAVR when done by the transfemoral but not by the transapical route (transfemoral route: hazard ratio [HR] 0.79; 95% CI 0.66 to 0.94, [risk difference −3.0, 95% CI −0.8 to −4.9]; transapical route: HR 1.34; 95% CI 0.91 to 1.97).

Symptomatic improvement

4.4   The RCT of 358 patients (PARTNER 1B) for whom SAVR was unsuitable compared TAVI (n=179) with medical management (n=179). More patients were asymptomatic or had mild symptoms (New York Heart Association [NYHA] class I or II) in the TAVI group than those in the medical management group (at 2 years: 83% [79/95] compared with 42% [17/40], p<0.0001; at 3 years: 70% [49/70] compared with 50% [7/14], p=0.245; and at 5 years: 86% [42/49] compared with 60% [3/5], p=0.531; NYHA class was not significantly different at baseline among these groups).

4.5   In the RCT of 795 patients for whom SAVR was suitable but high risk (the

CoreValve trial), a greater proportion of patients were in NYHA class I or II in the TAVI group than in the SAVR group at 1 month (83% compared with 73%, p<0.001) and at 6 months (84% compared with 79%, p=0.04). At 12 months, there were no statistically significant differences between the TAVI and SAVR groups (79% compared with 72%, p=0.10). In the other RCT of 699 patients for whom SAVR was suitable but high risk (PARTNER 1A), the proportion of patients in NYHA class I or II was the same (64%) for TAVI and SAVR at 12 months.

4.6 In the RCT of 2,032 patients for whom SAVR was suitable but intermediate risk (PARTNER 2A) there were no significant differences between TAVI and SAVR in the proportion of patients in NYHA class I or II at 1- and 2-year follow-up. In the RCT of 276 patients for whom SAVR was suitable but low to intermediate risk (NOTION) there were no significant differences between TAVI and SAVR in NYHA class at 3-month and 2-year follow-up. The systematic review (4 studies; n=2,146) of patients for whom SAVR was suitable but low to intermediate risk found that TAVI was associated with an increased risk of heart failure symptoms (NYHA class II or more: OR 1.29; 95% CI 1.08 to 1.55) at 2-year follow-up compared with SAVR.

Haemodynamic improvement

4.7 The RCT of 358 patients (PARTNER 1B) for whom SAVR was unsuitable compared TAVI (n=179) with medical management (n=179). There was a significantly higher mean aortic valve area in the TAVI group than in the medical management group at 1-year follow-up (1.6 cm^2 [standard deviation; SD 0.5] compared with 0.7 cm^2 [SD 0.3], significance level not given). Mean pressure gradient improved from 44.7 mmHg (SD 15.4) at baseline to 13.2 mmHg (SD 11.2) for TAVI and changed from 43.2 mmHg (SD 15.4) to 44.3 mmHg (SD 16.1) at 1 year for medical management (p values not reported). Left ventricular ejection fraction (LVEF) improved from 53.9% (SD 13.1) at baseline to 57.2% (SD 10.6) for TAVI and from 51.2% (SD 14.3) to 56.9% (SD 10.3) at 1 year for medical management.

4.8 In the RCT of 699 patients for whom SAVR was suitable but high risk (PARTNER 1A, TAVI [n=348] compared with SAVR [n=351]), there was a significantly higher mean aortic valve area in the TAVI group than in the SAVR group at 30-day, 6-month and 1-year follow-up respectively (1.7 cm^2 [SD 0.5]

compared with 1.5 cm^2 [SD 0.4], p=0.001, at 30 days; 1.7 cm^2 [SD 0.5] compared with 1.5 cm^2 [SD 0.5], p=0.01, at 6 months; and 1.6 cm^2 [SD 0.5] compared with 1.4 cm^2 [SD 0.5], p=0.002, at 1 year). Mean pressure gradients improved but were not statistically significant (9.9 mmHg [SD 4.8] compared with 10.8 mmHg [SD 5.0], p=0.04, at 30 days; 10.2 mmHg [SD 4.3] compared with 10.8 mmHg [SD 4.8], p=0.16, at 6 months; and 10.2 mmHg [SD 4.3] compared with 11.5 mmHg [SD 5.4], p=0.008, at 1 year). LVEFs improved but not statistically significantly (55.5 [SD 11.4] compared with 56.0 [SD 11.4], p=0.63, at 30 days; 56.2 [SD 10.8] compared with 56.8 [SD 9.9], p=0.56, at 6 months; and 56.6 [SD 10.5] compared with 57.1 [SD 10.3], p=0.64, at 1 year). Baseline values were not significantly different for all the outcomes. In the other RCT of 795 patients for whom SAVR was suitable but high risk (CoreValve trial, TAVI [n=394] compared with SAVR [n=401]), there was a significantly higher mean aortic valve area in the TAVI group compared with the SAVR group (1.70 cm^2 [SD 0.49] compared with 1.55 cm^2 [SD 0.51], p<0.001, at 1 year; and 1.79 cm^2 [SD 0.48] compared with 1.53 cm^2 [SD 0.52], p<0.0001, at 3 years). Mean pressure gradients also improved significantly (8.90 mmHg [SD 3.73] compared with 12.17 mmHg [SD 7.10], p<0.0001, at 1 year; and 7.62 mmHg [SD 3.57] compared with 11.40 mmHg [SD 6.8], p<0.0001, at 3 years). Baseline values were not significantly different for all the outcomes.

4.9　　In the RCT of 2,032 patients for whom SAVR was suitable but intermediate risk (PARTNER 2A) the mean aortic valve area was significantly higher in the TAVI group than in the SAVR group at 30 days (1.7 cm^2 [SD 0.5] compared with 1.5 cm^2 [SD 0.4], p<0.001), and this persisted at 1 year (1.6 cm^2 [SD 0.4] compared with 1.4 cm^2 [SD 0.4], p<0.001) and at 2 years (1.5 cm^2 [SD 0.4] compared with 1.4 cm^2 [SD 0.4], p<0.001). Mean pressure gradients also improved significantly (9.7 mmHg [SD 3.5] compared with 10.9 mmHg [SD 4.3], p<0.001) at 30 days and this persisted at 1 year (10.7 mmHg [SD 4.5] compared with 11.5 mmHg [SD 4.4], p=0.001) and 2 years (10.8 mmHg [SD 4.6] compared with 11.7 mmHg [SD 4.8], p<0.001). LVEF was higher for the TAVI group than for the SAVR group (56.9% [SD 10.2] compared with 55.0% [SD 11.0], p=0.04) at 30 days but this was reversed at 1 year (55.9% [SD 11.2] compared with 57.2% [SD 9.9], p=0.04) and at 2 years (54.9% [SD 11.2] compared with 57.2% [SD 9.7], p=0.005). In the RCT of 276 patients for whom SAVR was suitable but low to intermediate risk (NOTION) there were significantly greater improvements in mean valve area in the TAVI group than in the SAVR group (1.7 cm^2 compared with 1.3 cm^2, p<0.001, at 3 months; 1.7 cm^2 compared with 1.3 cm^2, p<0.001, at 1 year; 1.6 cm^2 compared

with 1.3 cm^2, p<0.001, at 2 years). There were no significant differences from baseline for mean pressure gradient.

Quality of life

4.10   In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) there were significant improvements in self-reported quality of life in patients in the TAVI group compared with those in the medical management group (Kansas City Cardiomyopathy Questionnaire [KCCQ] quality-of-life summary score for heart failure: mean difference [MD] 14.8; 95% CI 8.6 to 21.0, p<0.001, at 1 month and greater benefits at 6 months [MD 24.2; 95% CI 17.4 to 31.0, p<0.001] and at 12 months [MD 30.5; 95% CI 22.3 to 38.7, p<0.001]). At 12 months, the TAVI group also had higher SF-12 physical and mental health scores (MD 5.7 and 6.4 respectively, p<0.001).

4.11   In both the PARTNER 1A and CoreValve trials (patients for whom SAVR was suitable but high risk), patients having TAVI using the transfemoral route reported a greater improvement in quality of life (measured using EQ-5D, where 0 equals dead and 1 perfect health-related quality of life) than those having SAVR (PARTNER 1A: average change of 0.08 [SD 0.25] compared with 0.02 [SD 0.25] at 1 month, 0.1 [SD 0.3] compared with 0.09 [SD 0.27] at 6 months and 0.09 [SD 0.23] compared with 0.08 [SD 0.08] at 1 year; CoreValve study: average change of 0.055 [SD 0.23] compared with −0.073 [SD 0.26] at 1 month; 0.053 [SD 0.22] compared with 0.04 [SD 0.17] at 6 months and 0.043 [SD 0.2] compared with 0.0003 [SD 0.02] at 1 year). When data from these 2 trials were pooled for the transfemoral route, the overall estimates for EQ-5D showed statistically significant differences between the TAVI and SAVR groups at 1 month in favour of TAVI (RR 0.09; 95% CI 0.03 to 0.16; p=0.006). However, the differences were not significant at 6 months (RR 0.01; 95% CI −0.02 to 0.05, p=0.47) and at 1 year (RR 0.03; 95% CI 0.00 to 0.06, p=0.09). When data were pooled for transapical TAVI compared with SAVR (from PARTNER 1A) and non-transfemoral TAVI compared with SAVR (from the CoreValve trial), the overall estimates for EQ-5D showed no statistically significant differences between the TAVI and SAVR groups (RR −0.03; 95% CI −0.09 to 0.04, p=0.44 at 1 month, RR −0.02; 95% CI −0.10 to 0.07, p=0.66 at 6 months and RR −0.02; 95% CI −0.09 to 0.05, p=0.58 at 1 year). There was a greater improvement in SF-12 scores (both physical and mental) in the TAVI group

than in the SAVR group at 1-month follow-up (MD for physical summary scores 2.0; 95% CI 0.1 to 3.9, p=0.4 in PARTNER 1A and MD 4.9; 95% CI 3.1 to 6.7, p<0.001 in the CoreValve trial; MD for mental summary scores 5.4; 95% CI 3.1 to 7.7, p<0.001 in PARTNER 1A and 6.1; 95% CI 3.8 to 8.5, p<0.001 in the CoreValve trial). There were no statistically significant differences between TAVI using either the transfemoral or non-transfemoral route and SAVR at 12 months for both physical and mental scores. Statistically significant differences in favour of TAVI were reported for KCCQ quality-of-life summary score at 1-month follow-up in both PARTNER 1A (MD 9.8; 95% CI 4.0 to 15.6, p=0.001) and in the CoreValve study (19.0; 95% CI 13.7 to 24.3, p<0.001) but did not persist at 6- and 12-month follow-up. There were no statistically significant differences in KCCQ quality-of-life scores using either the transapical route in PARTNER 1A or the non-transfemoral routes in the CoreValve study.

4.12   In the systematic review of patients for whom SAVR was suitable but low to intermediate risk (n=2,146, including data from 795 patients in 1 study [CoreValve study] with a follow-up of 2 years), there was a non-significant difference in KCCQ quality-of-life summary score (22.2 for TAVI compared with 18.7 for SAVR, MD 3.5; 95% CI 1.9 to 8.9).

Repeat hospitalisation

4.13   The RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B) compared TAVI (n=179) with medical management (n=179). TAVI had a statistically significantly lower hazard ratio for repeat hospitalisation because of aortic stenosis (including complications because of TAVI) than medical management at 2 year- (HR 0.41; 95% CI 0.30 to 0.58, p<0.001), 3 year- (p<0.0001) and 5-year follow-up (p<0.001).

4.14   In the RCT of 699 patients for whom SAVR was suitable but high risk (PARTNER 1A, TAVI compared with SAVR) there was a non-significant difference in re-hospitalisation rates (59 [19%] compared with 45 [16%], p=0.38, at 1 year; 74 [25%] compared with 60 [22%], p=0.41, at 2 years; and 108 [42%] compared with 81 [34%], p=0.17, at 5 years). In the RCT of 795 patients (CoreValve trial; TAVI, n=394 compared with SAVR, n=401) for whom SAVR was suitable but high risk, there was no significant difference in re-hospitalisation rates (95 [27%] for

TAVI compared with 64 [21.9%] for SAVR, p=0.087) at 3 years. In the RCT of 2,032 patients for whom SAVR was suitable but intermediate risk (PARTNER 2A) there were no significant differences in re-hospitalisation rates between TAVI and SAVR.

4.15   The specialist advisers listed key efficacy outcomes as procedural success, satisfactory device positioning, shorter length of hospital stay, haemodynamic improvement, improvement in left ventricular function, improved quality of life, improved exercise capacity, symptom relief, prolonged survival, reduced mortality and morbidity and reduced re-hospitalisation.

5 Safety

This section describes 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 interventional procedure overview.

Evidence is based only on studies that reported outcomes by the risk level of the patients.

All-cause mortality and cardiovascular mortality within 30 days

5.1   A randomised controlled trial (RCT) of 358 patients for whom surgical aortic valve replacement (SAVR) was unsuitable (PARTNER 1B) compared transcatheter aortic valve implantation (TAVI; n=179) with medical management (n=179). There were no statistically significant differences in all-cause mortality (5% [9/179] compared with 3% [5/179], p=0.41) and cardiovascular mortality (5% [8/179] compared with 2% [3/179], p=0.22) between TAVI and medical management at 30-day follow-up.

5.2   In an RCT of 699 patients for whom SAVR was suitable but high risk (PARTNER 1A; TAVI, n=348 compared with SAVR, n=351) there were no statistically significant differences in all-cause mortality (3% [12/348] compared with 7% [22/351], p=0.07) and cardiovascular mortality (3% [11/348] compared with 13% [10/251], p=0.90) between the TAVI group and SAVR group at 30-day follow-up. In another RCT of 795 patients (the US CoreValve trial; TAVI, n=394 compared with SAVR, n=401) there were also no statistically significant differences in all-cause mortality (3% [13/390] compared with 5% [16/357], p=0.43) and cardiovascular mortality (3% [12/390] compared with 5% [16/357], p=0.32) between the TAVI group and SAVR group at 30-day follow-up. When data were pooled for both studies, the risk ratio (less than 1 favours TAVI) for all-cause mortality was 0.64 (95% confidence interval [CI] 0.38 to 1.39, p=0.06) and for cardiovascular mortality was 0.90 (95% CI 0.52 to 1.56, p=0.70).

5.3   In an RCT of 2,032 patients for whom SAVR was suitable but intermediate or low risk (TAVI, n=1,011 compared with SAVR, n=1,021) there was a non-significant lower all-cause mortality (3% compared with 4%, p=0.24) and cardiovascular

mortality (2% compared with 3%, p=0.72) for TAVI using the femoral route compared with SAVR at 30-day follow-up. For the transthoracic route all-cause mortality (6% compared with 4%, p=0.21) and cardiovascular mortality (5% compared with 3%, p=0.47) were not significantly different. In another RCT of 280 low- and intermediate-risk patients (TAVI, n=145 compared with SAVR, n=135), all-cause mortality (2% [3/142] compared with 3% [5/134], p=0.43) and cardiovascular mortality (2% [3/142] compared with 4% [5/134], p=0.43) were not significantly different. A systematic review of 3,179 patients (with risk scores of 8% or less in 4 RCTs) also reported a non-significant lower all-cause mortality for TAVI compared with SAVR (OR 0.67; 95% CI 0.42 to 1.07).

Cerebral complications

5.4 In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) the hazard ratio for stroke or transient ischaemic attack (TIA) was significantly higher in the TAVI group (hazard ratio [HR] 2.81; 95% CI 1.26 to 6.26, p=0.004) at 3-year follow-up, whereas at 5-year follow-up there were no significant differences between the TAVI and medical management groups (HR 1.39; 95% CI 0.62 to 3.11, p=0.555).

5.5 In 2 RCTs (PARTNER 1A [n=699] and the CoreValve trial [n=795]) in patients for whom SAVR was suitable but high risk, the incidence of stroke and TIA was reported. Both pooled and individual risk ratios from PARTNER 1A and the CoreValve trial showed no statistically significant differences in the incidence of all stroke in patients for whom SAVR was suitable but high risk at 30 days (risk ratio [RR] 1.26; 95% CI 0.56 to 2.86, p=0.57), 1 year (RR 1.21; 95% CI 0.49 to 2.98, p=0.68), 2 years (RR 1.11; 95% CI 0.51 to 2.41, p=0.78), 3 years (CoreValve, ITT RR 1.14; 95% CI 0.53 to 2.46, p=0.75) and 5 years (PARTNER 1A, ITT RR 1.13; 95% CI 0.68 to 1.87, p=0.65). Both pooled and individual risk ratios for TIA from PARTNER 1A and the CoreValve trial also showed no statistically significant differences at 30 days (RR 3.04; 95% CI 0.62 to 15.01, p=0.17), 1 year (RR 1.46; 95% 0.63 to 3.41, p=0.38), 2 years (RR 1.92; 95% CI 0.90 to 4.11, p=0.09), 3 years (CoreValve, ITT RR 1.53; 95% CI 0.55 to 4.25, p=0.42) and 5 years (PARTNER 1A, ITT RR 1.77; 95% CI 0.75 to 4.15, p=0.19).

5.6 In the RCT of 2,032 patients for whom SAVR was suitable but intermediate risk

(PARTNER 2A, TAVI compared with SAVR) there were no significant differences between groups in all strokes at 30 days (55 [6%] compared with 61 [6%], p=0.57), 1 year (78 [8%] compared with 79 [8%], p=0.88) and at 2 years (91 [10%] compared with 85 [9%], p=0.67). An RCT of 276 patients for whom SAVR was suitable but low to intermediate risk (the NOTION study, TAVI compared with SAVR) reported incidence of stroke and TIA at 30 days (4 [3%] compared with 4 [3%], p=0.94), 1 year (7 [5%] compared with 8 [6%], p=0.68) and at 2 years (13 [10%] compared with 10 [8%], p=0.67). The systematic review of 3,179 patients (based on data from 2,576 patients in 3 studies) reported a non-significant reduction in stroke rates (RR 0.80; 95% CI 0.63 to 1.01) for transfemoral TAVI compared with SAVR at 2-year follow-up. Comparing transapical TAVI with SAVR (based on data from 552 patients in 2 studies), the risk ratio was 1.67 (95% CI 0.97 to 2.87) at 2-year follow-up.

Aortic regurgitation

5.7   In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) there were similar rates of moderate or severe aortic regurgitation in both groups at 30-day and 1-year follow-up (15% compared with 17%).

5.8   In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial) the incidence of aortic regurgitation (paravalvular and transvalvular) in patients for whom SAVR was suitable but high risk was reported. Pooled data (RR 4.02; 95% CI 1.99 to 8.11, p=0.0001) at 1 year and individual study data favoured SAVR over TAVI at all follow-up points up to 3 years (PARTNER 1A: at 30 days RR 16.29; 95% CI 3.98 to 66.6, p=0.0001; at 6 months RR 30.26; 95% CI 4.16 to 220.01, p=0.0008; at 2 years p=0.008; CoreValve trial: at 3 years p=0.04).

5.9   In the RCT of 276 patients for whom SAVR was suitable but low to intermediate risk (NOTION, TAVI compared with SAVR) significant differences in moderate to severe aortic regurgitation at 3 months (15% compared with 22%, p<0.001) and at 1 year (16% compared with 1%, p=0.001) were reported. In the systematic review of 3,179 patients (based on data from 3 trials) moderate or severe aortic regurgitation occurred more often after TAVI than after SAVR at 2-year follow-up (RR 12.22; 95% CI 5.17 to 28.88).

Aortic valve re-intervention

5.10　　In the systematic review of 3,179 patients for whom SAVR was suitable but low to intermediate risk (based on data from 3,058 patients in 4 studies) the risk of aortic valve re-intervention was significantly higher after TAVI than after SAVR (RR 3.25; 95% CI 1.29 to 8.14).

Prosthesis-patient mismatch

5.11　　In the RCT of 699 patients (PARTNER 1A) for whom SAVR was suitable but high risk, the overall incidence and severity of prosthesis-patient mismatch was significantly better in the TAVI group than in the SAVR group (assessed at first postoperative echocardiogram: 46% [severe 20%] compared with 60% [severe 28%]; p<0.001 and 42% compared with 57%, p<0.001, at 30 days).

Myocardial infarction

5.12　　In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, comparing TAVI with medical management) there were no significant differences in the occurrence of myocardial infarction (MI) at 2-year (p=0.69) and 3-year (p=0.59) follow-up.

5.13　　In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) the incidence of MI for patients for whom SAVR was suitable but high risk was reported. Pooled data (at 30 days RR 0.72; 95% CI 0.17 to 2.94, p=0.64; at 1 year RR 1.18; 95% CI 0.42 to 3.29, p=0.76; at 2 years RR 0.51; 95% CI 0.06 to 4.05, p=0.52) and individual study data (3-year CoreValve ITT, RR 1.45; 95% CI 0.45 to 2.94, p=0.52 or 5-year PARTNER 1A ITT, RR 0.46; 95% CI 0.16 to 1.31, p=0.14) showed no statistically significant differences between the treatment groups.

5.14　　In 2 RCTs (PARTNER 2A and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients for whom SAVR was suitable but intermediate risk there were no significant differences in incidence of MI between TAVI and SAVR. The systematic

review of 3,179 patients for whom SAVR was suitable but intermediate to low risk (based on data from 3,128 patients in 4 studies) found no difference between the treatment groups for MI (RR 0.87; 95% CI 0.59 to 1.29) at 2-year follow-up.

Endocarditis

5.15 In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, comparing TAVI with medical management) there were no significant differences between the groups in endocarditis at 2-year (3% compared with 1%, p=0.32) and 3-year (2% compared with 1%, p=0.32) follow-up.

5.16 In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) in patients for whom SAVR was suitable but high risk, there were no significant differences between groups in endocarditis (PARTNER 1A: 0% compared with less than 1%, p=0.32, at 1 month; 2 [less than 1%] compared with 3 [1%], p=0.63, at 1 year; 4 [2%] compared with 3 [1%], p=0.61, at 2 years; and 5 [2%] compared with 6 [3%], p=0.65, at 5 years; CoreValve study: 3 [1%] compared with 5 [2%], p=0.346, at 3 years).

5.17 In 2 RCTs (PARTNER 2A study and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients, for whom SAVR was suitable but intermediate risk, there were no significant differences in endocarditis between TAVI and SAVR (RCT of 276 patients: 1 [1%] compared with 0, p=0.33, at 30 days; 4 [3%] compared with 2 [2%], p=0.47, at 1 year; RCT of 2,032 patients: transfemoral route 6 [1%] compared with 6 [1%], p=0.92, at 1 year; 10 [2%] compared with 6 [1%], p=0.33, at 2 years; transthoracic route 1 compared with 0, p=0.32).

Atrial fibrillation

5.18 In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) there were no significant differences in the incidence of new atrial fibrillation between the treatment groups (at 30 days less than 1% compared with 1%, p=1.00; at 1 year less than 1% compared with 2%, p=0.62).

5.19   In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) in patients for whom SAVR was suitable but high risk, there were significant differences in the incidence of atrial fibrillation (PARTNER 1A: 12% compared with 17%, p=0.07, at 1 year; CoreValve study: 12% [45] compared with 31% [108], p<0.001, at 30 days; 16% [60] compared with 33% [115], p<0.001, at 1 year).

5.20   In 2 RCTs (PARTNER 2A and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients, for whom SAVR was suitable but intermediate risk, there were significant differences in the incidence of new atrial fibrillation between the treatment groups. In the RCT of 2,032 patients, for transfemoral TAVI compared with SAVR the incidence was 38 (5%) compared with 204 (27%), p<0.001, at 30 days; 45 (6%) compared with 210 (28%), p<0.001, at 1 year and 55 (7%) compared with 211 (28%) p<0.001, at 2 years. In the same RCT, for transthoracic TAVI compared with SAVR the incidence was 53 (23%) compared with 61 (26%), p=0.50, at 30 days; 55 (24%) compared with 62 (26%), p=0.60, at 1 year; and 55 (24%) compared with 62 [26%], p=0.60, at 2 years. In the RCT of 276 patients the incidence was: 24 [17%] compared with 77 [58%], p<0.001, at 30 days; 51 [38%] compared with 79 [60%] p<0.001, at 1 year; 32 [23%] compared with 80 [60%], p<0.001, at 2 years). The systematic review of 3,179 patients (based on data from 3,058 patients in 3 studies) found that the risk ratio for new onset atrial fibrillation at 2-year follow-up was 0.43 (0.35 to 0.52) for TAVI compared with SAVR.

Need for permanent pacemaker

5.21   In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) the proportion of patients with permanent pacemaker implantation (PPI) was lower in the TAVI group at 2 years (6% compared with 9%, p=0.47) and 3 years (8% compared with 9%, p=0.75) but these differences were not significant.

5.22   In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) in patients for whom SAVR was suitable but high risk, the need for PPI was reported. Pooled data tended to favour the SAVR group. However the differences were not statistically significant at 30 days (RR 1.94; 95% CI 0.70 to 5.34, p=0.20), at 1 year (RR 1.75; 95% CI 0.94 to 3.25, p=0.08) and at 2 years (RR

1.77; 95% CI 0.95 to 3.30, p=0.07). At 3-year follow-up (CoreValve trial: TAVI, n=394, SAVR, n=401) there were significantly fewer PPI in the SAVR group than in the TAVI group (14.5% compared with 28%, p<0.001). At 5 years (PARTNER 1A) there were no statistically significant differences between the treatment groups (9.7% compared with 9.1%, p=0.64).

5.23   In 2 RCTs (PARTNER 2A and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients, for whom SAVR was suitable but intermediate risk, the need for PPI was reported. In the RCT of 2,032 patients there were no significant differences between the groups (9% compared with 7%, p=0.17, at 30 days; 10% compared with 9%, p=0.43, at 1 year; 12% compared with 10%, p=0.29, at 2 years). But in the RCT of 276 patients the need for PPI was higher in the TAVI group than in the SAVR group (46 [34%] compared with 2 [2%], p<0.001, at 30 days; 51 [38%] compared with 3 [2%], p<0.001, at 1 year; and 55 [41%] compared with 5 [4%], p<0.001, at 2 years). The systematic review of 3,179 patients (based on data from 3,128 patients in 4 studies) reported an increased risk of PPI (RR 2.46; 95% CI 1.17 to 5.15) for TAVI compared with SAVR.

Acute kidney injury and renal failure

5.24   In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) there were no significant differences in the occurrence of acute kidney injury (AKI) between the treatment groups at 2-year (3% compared with 8%, p=0.15) and 3-year follow-up (3% compared with 11%, p=0.08).

5.25   In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) in patients for whom SAVR was suitable but high risk, the occurrence of AKI was reported. Pooled data (at 30 days RR 0.51; 95% CI 0.27 to 0.98, p=0.04) and data from the CoreValve study at 3 years (RR 0.45; 95% CI 0.29 to 0.72, p=0.0007) significantly favoured the TAVI group, whereas there were no statistically significant differences in the pooled estimates at 1 year and 2 years (RR 0.76; 95% CI 0.23 to 2.59, p=0.67, at 1 year; RR 0.64; 95% CI 0.31 to 1.34, p=0.24, at 2 years) and from PARTNER 1A at 5 years (RR 1.01; 95% CI 0.58 to 1.74).

5.26   In 2 RCTs (PARTNER 2A and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients, for whom SAVR was suitable but intermediate risk, the occurrence of AKI was reported. The RCT of 2,032 patients reported a lower incidence of AKI in the TAVI group than in the SAVR group at 30 days (13 [1.3%] compared with 31 [3%], p=0.0006). Incidence rates were similar for transthoracic TAVI and SAVR (4% compared with 3%). The incidence rates were significantly lower for transfemoral TAVI than for SAVR (2.2% compared with 5%, p=0.002, at 1 year; 3% compared with 7%, p<0.001, at 2 years) and higher for transthoracic TAVI (7% compared with 4.4%, p=0.18, at 1 year, 8% compared with 6%, p=0.23, at 2 years). The RCT of 276 patients reported a higher occurrence of AKI in the SAVR group than in the TAVI group (9 [7%]) compared with 1 [0.7%], p=0.01) at 30 days. The systematic review of 3,179 patients (based on data from 2,576 patients in 3 studies) reported that the risk ratio of AKI at 2-year follow-up was 0.38 (95% CI 0.27 to 0.54) for transfemoral TAVI and 1.54 (95% CI 0.77 to 3.07) for transapical TAVI compared with SAVR.

Vascular complications

5.27   In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management) the hazard ratio for major vascular complications at 3-year follow-up was statistically significantly higher with TAVI (17%) than with medical management (3%, HR 8.27; 95% CI 2.92 to 23.44, p<0.0001).

5.28   In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) in patients for whom SAVR was suitable but high risk, there were no statistically significant differences between the treatment groups in the incidence of major vascular complications in either pooled data at 30-day (RR 3.04; 95% CI 0.63 to 3.41, p=0.17), 1-year (RR 1.46; 95% CI 0.63 to 3.41, p=0.38) or 2-year follow-up (RR 1.92; 95% CI 0.90 to 4.11, p=0.09), or in the individual studies at 3-year (CoreValve study, p=0.42) or 5-year follow-up (PARTNER 1A, p=0.19).

5.29   In 2 RCTs (PARTNER 2A and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients, for whom SAVR was suitable but intermediate risk, major vascular complications were reported. In the RCT of 2,032 patients there was a higher incidence of major complications in the TAVI group than in the SAVR group (7.9%

compared with 5%, p=0.008 at 30 days; 8% compared with 5.3%, p=0.007 at 1 year and 9% compared with 6%, p=0.006 at 2 years). The incidence rate was lower for transthoracic TAVI than for SAVR. The RCT of 276 patients reported more major vascular complications in the TAVI group than in the SAVR group at 30 days (6% compared with 2%, p=0.10).

Major bleeding

5.30   In the RCT of 358 patients for whom SAVR was unsuitable (PARTNER 1B, TAVI compared with medical management), the risk of major bleeding was statistically significantly higher for TAVI than for medical management (29% compared with 20%, p=0.04) at 2 years, but not statistically significant different (32% compared with 33%, p=0.92) at 3-year follow-up.

5.31   In 2 RCTs (PARTNER 1A [n=699] and the CoreValve [n=795] trial, comparing TAVI with SAVR) in patients for whom SAVR was suitable but high risk, there were no statistically significant differences between the treatment groups in the risk of major bleeding in either pooled data at 30 day (RR 0.67; 95% CI 0.36 to 1.25, p=0.21), 1-year (RR 0.73; 95% CI 0.48 to 1.12, p=0.02) and 2-year follow-up (RR 0.78; 95% CI 0.54 to1.13, p=0.19) or in the individual (CoreValve) study at 3-year follow-up (RR 0.92; 95% CI 0.75 to 1.12, p=0.38). However, major bleeding was significantly lower in the TAVI group than in the SAVR group in the individual (PARTNER 1A) study at 5-year follow-up (RR 0.73; 95% CI 0.57 to 0.95, p=0.02).

5.32   In 2 RCTs (PARTNER 2A and NOTION, comparing TAVI with SAVR) with 2,032 and 276 patients, for whom SAVR was suitable but intermediate risk, the risk of major bleeding was reported. In the RCT of 2,032 patients there was significantly lower life-threatening or disabling bleeding in patients who had TAVI than in those who had SAVR at 30-day (10% [105/1,011] compared with 43% [442/1,021], p<0.001), 1-year (15% [151] compared with 46% [460], p<0.001) and 2-year follow-up (17% [169] compared with 47% [471], p<0.001). The rates were also significantly lower in patients who had transthoracic TAVI than in those who had SAVR (23% compared with 50%, p<0.001, at 30-day, 29% compared with 52%, p<0.001, at 1-year and 30% compared with 54%, p<0.001, at 2-year follow-up). The RCT of 276 patients reported significantly lower bleeding in the TAVI group than in the SAVR group at 30 days (11% [16] compared with 21% [28], p=0.03). The

systematic review of 3,179 patients (data from 2,576 patients in 3 studies) reported that transfemoral TAVI was associated with a significant reduction in major bleeding compared with SAVR (RR 0.39; 95% CI 0.29 to 0.54). Transapical TAVI (based on data from 552 patients in 2 studies) also had a reduced risk of bleeding, RR 0.53; 95% CI 0.42 to 0.67.

Rare safety events

5.33   A number of observational studies reported rare safety events with TAVI for severe aortic stenosis including: acute MI, acute myocardial injury from damage to apical epicardial collateral circulation, acute occlusion of right coronary artery, acute severe occlusion of the left main coronary artery, aortic arch rupture, aortic dissection, aortic perforation, aortic rupture (abdominal), aorto-right ventricular defect (lethal), apical left ventricular thrombus, apical tear, balloon rupture, catheter-induced ventricular septum defect, circumflex artery occlusion, cutaneo-pericardial fistula, delayed ventricular apical bleed, distal coronary embolisation, early valve degeneration, elliptic distortion of the aortic prosthesis, false left ventricular apical aneurysm, guide wire thrombus formation, iatrogenic chordal rupture, iliac artery rupture, intercostal artery pseudoaneurysm, interventricular septum rupture, late prosthesis migration and rotation, left ventricular pseudoaneurysm, major bleeding from the apex, mitral valve destruction by wire entrapment, multivessel coronary artery spasm, papillary muscle rupture, perforation of the medial circumflex branch of the common femoral artery, pseudoaneurysm at the left ventricular apical access site, pseudoaneurysm of the apex, ruptured pseudoaneurysm of a renal artery, Takotsubo syndrome and valve embolisation.

5.34   In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: valve migration, embolisation, thrombosis, valve or annular trauma during TAVI implants leading to late 'fistulous' connections to adjacent cardiac structures. They considered that the following were theoretical adverse events: haemolytic anaemia, infective endocarditis, structural valve failure, reduced leaflet movement and longer-term problems with

device durability needing re-intervention by either SAVR or 'valve-in-valve' TAVI.

6 Committee comments

6.1   The risk of needing a permanent pacemaker and other complications after the procedure depends on the technique and the type of valve used.

6.2   There is a move towards using sedation rather than general anaesthesia for this procedure.

6.3   The longer-term evidence on transcatheter aortic valve implantation (TAVI) is from earlier generation TAVI devices and the technology is evolving. Longer-term evidence is needed and this should be taken into account by the multidisciplinary team.

6.4   TAVI offers a potential treatment for patients with aortic stenosis for whom surgical aortic valve replacement would not be suitable.

7 Further information

7.1   Patient commentary was sought but none was received.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 586 has been migrated to HealthTech guidance 446. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8628-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.