

Sutureless aortic valve replacement for aortic stenosis

Issued: July 2013

NICE interventional procedure guidance 456

guidance.nice.org.uk/ipg456



NICE 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'. More information on accreditation can be viewed at www.nice.org.uk/accreditation



1 Recommendations

There is evidence of limited quality supporting the efficacy of sutureless aortic valve replacement for aortic stenosis in the short term. The evidence on safety raises no major concerns in the short term apart from the risk of paravalvular leak. There is concern about the risks of paravalvular and central leaks in the longer term. Most of the evidence on sutureless aortic valve replacement for aortic stenosis is from patients who would be at high risk from standard surgical aortic valve replacement and there is negligible comparative evidence versus standard surgery.

- 1.1 For patients with aortic stenosis for whom surgical aortic valve replacement is considered suitable but for whom it would pose a high risk, sutureless aortic valve replacement for aortic stenosis should only be used with special arrangements for clinical governance, consent and data collection or research. Clinicians wishing to undertake sutureless aortic valve replacement for these patients should take the following actions:
 - Inform the clinical governance leads in their trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and other treatment options, and provide them with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
- 1.2 For patients with aortic stenosis for whom surgical aortic valve replacement is considered suitable and for whom it would not pose a high risk, sutureless aortic valve replacement for aortic stenosis should only be used in the context of research.
- 1.3 Patient selection should be done by a multidisciplinary team which includes cardiologists and cardiac surgeons.
- 1.4 Specific training is important for this procedure and surgeons should perform their initial procedures with an experienced mentor.
- 1.5 Clinicians should enter details about all patients undergoing sutureless aortic valve replacement for aortic stenosis onto the [UK Central Cardiac Audit Database](#).

- 1.6 NICE encourages further research into sutureless aortic valve replacement for aortic stenosis. Studies should document patient selection, aortic cross-clamp times, cardiopulmonary bypass times, perioperative morbidity and specifically the incidence of paravalvular (and central) leaks in the short and long term. Research comparing outcomes of the procedure against those of standard surgical aortic valve replacement would be useful.

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, arrhythmias, and may lead to life-threatening heart failure. Symptoms of aortic stenosis typically include shortness of breath and chest pain on exertion.
- 2.2 Conventional treatment for severe symptomatic aortic stenosis is surgical aortic valve replacement. Medical comorbidities, or technical considerations such as a calcified aorta or scarring from previous cardiac surgery, can make surgical aortic valve replacement unsuitable for some patients. Continued medical care may be the only option for some patients whose condition is unsuitable for surgery. Transcatheter aortic valve implantation (TAVI) for aortic stenosis is an alternative for patients in whom surgery is contraindicated or for whom the risks of surgery are high, but it does not allow for the removal of the stenosed native valve or concomitant coronary artery bypass grafting procedures.

3 The procedure

- 3.1 Sutureless aortic valve replacement for aortic stenosis is an alternative to both conventional surgical aortic valve replacement and transcatheter aortic valve implantation (TAVI). The potential benefits of the procedure are that the diseased valve is removed, combined pathologies of the aortic valve and the coronary arteries can be treated, and the procedure may be quicker because the valve does not need to be sewn in, reducing cardiopulmonary and aortic cross-clamp times.

- 3.2 With the patient under general anaesthesia, access to the heart is usually made through a full- or mini-sternotomy. Once cardiopulmonary bypass and cardioplegia are established, the diseased aortic valve is removed through an incision in the aorta. Bulky calcifications around the native aortic annulus are removed to achieve a smooth round annulus for valve implantation. The valve prosthesis, loaded onto a delivery device, is inserted into the native annulus with the help of 1 or more stitches, which are removed after release of the valve. Balloon dilatation of the new valve may be used to maximise the area of contact between the prosthesis and the aortic annulus. The position and function of the valve are assessed intraoperatively by transoesophageal echocardiography.
- 3.3 Different devices are available for this procedure, all of which 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 [overview](#).

- 4.1 A case series of 140 patients reported freedom from valve-related mortality of 96.5% at 1-year follow-up.
- 4.2 A case series of 30 patients reported that New York Heart Association (NYHA) status improved from class III in 93% patients or class IV in 7% patients (physical activity limited or symptomatic at rest) before the procedure to class I in 57% patients and class II in 39% patients (no limitation or slight limitation of physical activity) at 12-month follow-up (n=23 at follow-up; absolute numbers not reported).
- 4.3 In a propensity-matched study of 76 patients, the mean transaortic gradient decreased from 48 mmHg before the procedure to 11 mmHg before discharge in 38 patients who had isolated sutureless aortic valve replacement and from 51 mmHg before the procedure to 10 mmHg before discharge in 38 patients

who had transapical transcatheter aortic valve implantation (TAVI). The between-group difference was not statistically significant.

- 4.4 A case series of 208 patients reported that the mean peak transvalvular gradient decreased from 76 mmHg before the procedure to 19 mmHg at 1–4 years after valve implantation (significance level not reported).
- 4.5 The case series of 208 patients reported that the mean effective orifice area increased from 0.7 cm² before the procedure to 1.5 cm² at 1–4 years after implantation (level of significance not reported).
- 4.6 The case series of 208 patients reported mean aortic cross-clamping time of 30 minutes in patients undergoing isolated sutureless aortic valve replacement (n=160) and mean 44 minutes in those undergoing procedure with concomitant coronary artery bypass graft (n=48).
- 4.7 A case series of 83 patients reported a mean cardiopulmonary bypass time of 66 minutes in patients having isolated sutureless aortic valve replacement (n=57) and 83 minutes (n=26) in patients having the procedure with concomitant procedures.
- 4.8 The specialist advisers listed the following important efficacy outcomes: shortened operation times, shortened cross-clamp time, technical success of deploying the device, survival at 30 days and 1 year, left ventricular mass regression over time, freedom from long-term structural valve degeneration, and freedom from long-term valve-related thromboembolism.

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 [overview](#).

- 5.1 Death within 30 days was reported in 4% (5/140) of patients in the case series of 140 patients. Two of the deaths (because of multi-organ failure and bi-ventricular heart failure) were classified as valve related.

-
- 5.2 Acute bacterial endocarditis was reported in 1 patient in a case series of 32 patients, at 6 months. The patient developed moderate to severe valvular and paravalvular regurgitation, and was treated by reoperation.
- 5.3 Stroke was reported during hospital stay in 2 patients with a history of cerebral accidents in the case series of 83 patients (treated by anticoagulants).
- 5.4 Malpositioning of the valve in a supra-annular position (related to implantation technique) was reported in 1 patient (resulting in a grade 3/4+ periprosthetic leak immediately after implantation) in the case series of 83 patients. The prosthesis was removed and a stented prosthesis implanted.
- 5.5 Dislocation of the valve was reported 3 months after the procedure in a case report (the patient presented with congestive heart failure associated with haemolytic anaemia). The intact prosthetic valve was re-implanted.
- 5.6 Paravalvular leak during implantation was reported in 9 patients in the case series of 208 patients (7 treated by repeat procedure and 2 with stented bioprosthesis; all had normal recovery; no further details on follow-up was available).
- 5.7 Atrioventricular block needing pacemaker insertion was reported in 8% (16/208) of patients in the case series of 208 patients (timing unclear).
- 5.8 Acute renal failure (needing continuous venovenous haemofiltration) was reported in 5% (2/38) of patients treated by sutureless aortic valve replacement and in 3% (1/38) of patients treated by transapical transcatheter aortic valve implantation (TAVI) in the propensity-matched study of 76 patients (timing unclear; difference was not statistically significant).
- 5.9 The specialist advisers reported an anecdotal adverse event as valve embolisation. The specialist advisers listed the following theoretical adverse events: structural valve deterioration over time, late stroke, and bleeding.

6 Further information

6.1 For related NICE guidance see the [NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). 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](#).

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 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.

Copyright

© National Institute for Health and Care Excellence 2013. 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 Care Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 003 7780

ISBN 978-1-4731-0228-6