

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Sutureless aortic valve replacement for aortic stenosis

Aortic stenosis happens when the aortic valve, which lets blood flow out of the heart, becomes narrowed (stenosed). This reduces blood flow from the heart. This puts strain on the heart and can cause an enlarged heart, irregular heartbeat, chest pain and sudden collapse. In this procedure, a cut is made in the chest. The heart is then connected to a heart-lung bypass machine. The narrowed aortic valve is removed and replaced with an artificial valve that holds itself in place.

The National Institute for Health and Care Excellence (NICE) is looking at sutureless aortic valve replacement for aortic stenosis. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 24 May 2018

Target date for publication of guidance: August 2018

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of sutureless aortic valve replacement 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 Patient selection should be done by a multidisciplinary team, including cardiologists and cardiac surgeons.
- 1.3 Specific training is important for this procedure and surgeons should do their initial procedures with an experienced mentor.

- 1.4 Clinicians should enter details about all patients having sutureless aortic valve replacement for aortic stenosis onto the UK [National Institute for Cardiovascular Outcomes Research database](#).

2 The condition, current treatments and procedure

The condition

- 2.1 Aortic stenosis causes impaired blood flow out of 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.

Current treatments

- 2.2 Conventional treatment for patients with severe symptomatic aortic stenosis is surgical aortic valve replacement. Surgical aortic valve replacement may not be suitable for some patients because of medical comorbidities or technical considerations, such as a calcified aorta or scarring from previous cardiac surgery. Continued medical care may be the only option for some patients. Transcatheter aortic valve implantation (TAVI) for aortic stenosis is an alternative for patients for whom surgery is unsuitable, but it does not allow for concomitant coronary artery bypass grafting.

The procedure

- 2.3 Sutureless aortic valve replacement (S-AVR) for aortic stenosis is an alternative to both conventional surgical aortic valve replacement. 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 as they can in conventional surgical aortic valve replacement. Also, the procedure may be quicker because the valve does not need to be sewn in, which reduces cardiopulmonary and aortic cross-clamp times.

- 2.4 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 accessed and removed through a cut in the aorta. Bulky calcifications around the native aortic annulus are removed to achieve a smooth round annulus for valve implantation. One or more stitches may be needed to guide correct positioning of the new valve. The valve prosthesis, loaded into a delivery device, is inserted into the native annulus. The valve is then released and guide stitches are removed. 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.
- 2.5 Different devices are available for this procedure, all of which contain material derived from animal sources.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 6 systematic reviews and meta-analyses and 2 case series and is presented in table 2 of the

[interventional procedures overview](#) [add URL]. There is an overlap of studies included in systematic reviews and some of the studies did not specify the number of patients included. Other relevant literature is in the appendix of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, clinical improvement, haemodynamic outcomes, valve durability and long-term outcomes.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: paravalvular leakage, in-hospital mortality and need for pacemaker implantation.
- 3.4 Seventeen [commentaries from patients](#) who had experience of this procedure were received, which were discussed by the committee.
- 3.5 This guidance is a review of NICE's interventional procedures guidance on [sutureless aortic valve replacement for aortic stenosis](#).

Committee comments

- 3.6 The committee noted that evidence presented on comparisons with TAVI was related to historical data and the technologies have advanced.
- 3.7 The committee was informed that 1 device currently on the market for this procedure uses sutures for guidance during deployment.
- 3.8 The committee was informed that the risk of heart block leading to pacemaker implantation was higher with sutureless aortic valve replacement compared with conventional aortic valve replacement.

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