NICE guidance

Sutureless aortic valve replacement for aortic stenosis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg624

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.

This guidance replaces IPG456.

1 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. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

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 (SUAVR) for aortic stenosis is an alternative to 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, or right anterior thoracotomy. 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. The valve prosthesis with self-expanding or balloon expanding frame, loaded into a special delivery device, is deployed into the native annulus. Once in position the valve is released. The exact deployment method varies between the different devices available for this procedure and

with some devices; one or more temporary guiding or securing sutures may be used. Balloon dilatation of the new valve may be used to maximise the area of contact between the prosthesis and the aortic annulus. Once the valve is deployed, the delivery system is removed and the aortotomy is closed. All of the devices used in this procedure contain material derived from animal sources.

2.5 This procedure is sometimes described as sutureless aortic valve replacement and sometimes as rapid deployment aortic valve replacement.

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. 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.

Committee comments

3.5 The committee noted that evidence presented on comparisons with TAVI was related to historical data and the technologies have advanced.

3.6 The committee was informed that one device currently on the market for this procedure uses temporary guide sutures to assist with device positioning.

3.7 The committee was informed that the risk of heart block leading to pacemaker implantation may be higher with sutureless aortic valve replacement compared with conventional aortic valve replacement, but the incidence may be falling as experience with the procedure increases.

3.8 The committee was informed that manufacturers deliver a specific training programme for surgeons using this procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.