NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Aortic valve reconstruction with processed bovine pericardium

The aortic valve (1 of 4 valves in the heart) sometimes becomes leaky or narrow. This means the blood doesn't get pumped around the body properly, which can cause palpitations, fatigue, shortness of breath and chest pain. In this procedure, chemically treated cow pericardium (the tissue around the heart) is used to make a new valve to replace the damaged aortic valve in the patient. The aim is to improve the patient's symptoms.

The National Institute for Health and Care Excellence (NICE) is looking at aortic valve reconstruction using processed bovine pericardium. 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, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 November 2017

Target date for publication of guidance: February 2018

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of aortic valve reconstruction with processed bovine pericardium is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research should address patient selection and report long-term outcomes, particularly the durability of the valve.

2 The condition, current treatments and procedure

The condition

Aortic valve disease (stenosis or regurgitation) is usually progressive and causes an increase in cardiac workload, left ventricular hypertrophy and heart failure. Symptoms can include palpitations, fatigue, shortness of breath and chest pain on exertion. Mortality rates are high in symptomatic patients.

Current treatments

2.1 The conventional treatment for a significantly diseased aortic valve is surgical replacement with an artificial (biological or mechanical) prosthesis. Transcatheter aortic valve implantation may also be considered. Bioprosthetic valves do not perform as well as native valves and have limited durability, which may be an issue for younger patients. Lifelong anticoagulation is required in patients with mechanical valves, which increases the risk of haemorrhagic complications and is not optimal in women wishing to become pregnant. In some patients with aortic regurgitation, the aortic valve may be repaired with patches as an alternative to replacement.

2.2 Aortic valve reconstruction with bovine pericardium may be considered in patients who cannot or who refuse to take anticoagulation, patients with an aorta too narrow for a standard prosthetic valve and young patients who wish to avoid long-term anticoagulation.

The procedure

2.3 With the patient under general anaesthesia, the heart is accessed by a sternotomy and cardiopulmonary bypass is established. The heart is stopped with cardioplegic arrest, the aorta is opened and the valve is inspected. The diseased valve cusps are carefully removed and the intercommissural distances are measured. Commercially available bovine pericardium is trimmed to the desired size using a template, and sutured to the annulus to replace the removed cusp(s). The aorta is closed, normal circulation is restored and the chest is closed. The function of the valve is assessed intraoperatively by transoesophageal echocardiography.

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 5 sources, which was discussed by the committee. The evidence included 3 case series (1 of which was reported with 9 and 16 years of follow-up) and 1 case report, and is presented in table 2 of the interventional procedures overview ***[add URL]***. Other relevant literature is in Appendix A of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in aortic valve gradient, health-related quality of life measures and exercise tolerance.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: mortality, bypass time and cross-clamp time, valve durability, embolic events including stroke, infection and bleeding.

Committee comments

3.4 This guidance covers the use of processed bovine pericardium, and does not cover the Ozaki procedure which uses glutaraldehyde-treated autologous pericardium.

3.5 The processed bovine pericardium is used as a scaffold in this procedure and has different properties to the bovine pericardium that is routinely used in cardiac surgery.

3.6 The committee was informed that patients who have this procedure receive aspirin but do not need lifelong anticoagulation.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
September, 2017

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