NICE National Institute for Health and Care Excellence

NICE guidance

Aortic valve reconstruction with processed bovine pericardium

HealthTech guidance
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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 IPG604.

1 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. Find out what only in research means on the NICE interventional procedures guidance page.

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

2.1 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

2.2 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 needed 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.

2.3 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

2.4 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 4 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. 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, and infection and bleeding.

3.4 Commentary from 1 patient who had experience of this procedure was received, which was discussed by the committee.

Committee comments

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

3.6 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.

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

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 604 has been migrated to HealthTech guidance 461. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.