NICE National Institute for Health and Care Excellence

NICE guidance

Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium for aortic valve disease

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 IPG769.

1 Recommendations

1.1 Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium for aortic valve disease should be used only in research. Find out what only in research means on the NICE guidance page.

1.2 Further research could include the analysis of registry data or similar observational data to investigate patient selection and long-term outcomes, particularly the durability of the valve. Randomised controlled trials would also be useful to address uncertainties.

Why the committee made these recommendations

There is some short-term and medium-term evidence for this procedure. The evidence suggests that it works well, with survival rates of around 90% after 10 years and only a small proportion of people needing another operation within 5 years. But there is a lack of long-term evidence (here more than 20 years), which is important because mechanical valve alternatives can last for over 25 years. This is particularly relevant for young people who are expected to live for a few decades with the condition. It is also not clear how well the procedure works or how safe it is in different groups of people with aortic valve disease. So, more research is needed.

2 The condition, current treatments and procedure

The condition

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

Current treatments

2.2 Conventional treatment for a significantly diseased aortic valve is surgical replacement with an artificial (biological or mechanical) prosthesis, or transcatheter aortic valve implantation (TAVI) with a biological prosthesis. Bioprosthetic and mechanical valves do not perform as well as valves made from the person's own tissue. Their durability is also limited (although mechanical valves last longer than bioprosthetic valves), which may be an issue for younger people. People with mechanical valves need lifelong anticoagulation. This increases the risk of haemorrhagic complications, particularly for older people, and anyone with significant comorbidities or who wants to become pregnant. Aortic regurgitation can be treated by repairing the aortic valve with patches instead of replacing it.

2.3 Aortic valve reconstruction using glutaraldehyde-treated autologous pericardium is suitable for:

- people who cannot or do not want to take anticoagulation
- people with an aorta too narrow for a standard prosthetic valve
- young people who want to avoid long-term anticoagulation.

The procedure

2.4 Under general anaesthesia, the heart is accessed using a full or partial sternotomy, and the person is established on cardiopulmonary bypass. The heart is stopped with cardioplegic arrest. A section of the pericardium is removed and excess adipose tissue removed. The section of pericardium is treated with glutaraldehyde and rinsed with saline to avoid drying. The aorta is opened, the valve is inspected and the diseased valve cusps carefully removed. The intercommissural distances are measured using Ozaki sizers, and the treated pericardium is trimmed to the desired size and stitched to the aortic annulus to replace the removed valve leaflet(s). When aligned, the leaflets are stitched to the wall of the aorta to create a functional valve. The aorta is closed, the heart is de-aired and cardiopulmonary bypass is stopped. The 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 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 1 meta-analysis, 1 case series and meta-analytic comparison study, 1 systematic review, 2 case series, 1 non-randomised comparative study and 2 case reports. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: restoration in heart valve function, improved survival, longevity of the valve and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: operative mortality, bypass time and cross clamp time, infections including endocarditis and embolic events including stroke.

3.4 The committee discussed 13 commentaries from people who have had this procedure.

Committee comments

3.5 This procedure has evolved over time. The optimum concentration and time for glutaraldehyde use for fixation of the pericardium have not yet been determined. A few operations have been done without using glutaraldehyde fixation.

3.6 This is a complex procedure and should only be done by cardiac surgeons with special training and experience in this procedure.

3.7 The committee was told that glutaraldehyde-treated autologous pericardium provides another alternative to mechanical or biological valves for young people.

3.8 The committee recommended that details of everyone having the procedure should be entered into a registry.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 769 has been migrated to HealthTech guidance 689. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.