NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

The aortic valve (1 of 4 valves in the heart) sometimes becomes leaky or narrow. This means that blood does not get pumped around the body properly, which can cause palpitations, fatigue, shortness of breath and chest pain. It can eventually lead to heart failure and death. In this procedure, the diseased part of the valve is replaced by some of the person's own (autologous) pericardium (the tissue around the heart), which is treated with a chemical called glutaraldehyde. The aim is to allow the valve to function normally and to reduce symptoms.

NICE is looking at aortic valve reconstruction with glutaraldehyde-treated autologous pericardium.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation 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: 18 April 2023

Target date for publication of guidance: August 2023

1 Draft 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 interventional procedures 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 a lot of 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 it is not clear who would benefit most, or how well it works and how safe it is in different groups of people with aortic valve disease. This is particularly relevant for young people who are expected to live for a few decades with the condition. Mechanical valve alternatives can last for over 25 years. The long-term evidence (here more than 20 years) is important. So this procedure is recommended only in research.

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 and the valve is inspected; the diseased valve cusps are 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 discontinued. 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 interventional procedures 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 the use of glutaraldehyde for the fixation of the pericardium have not yet been determined. A small number of 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 may be better than a mechanical or biological valve for young people.

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

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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