NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Caval valve implantation for tricuspid regurgitation

The tricuspid valve sits between the upper and lower chambers on the right side of the heart. Tricuspid regurgitation happens when the tricuspid valve does not close properly and blood flows the wrong way through it (regurgitation). The blood can also flow back (reflux) into the 2 main veins (caval veins) that bring blood back from the body to the heart. This makes the heart work harder and, if severe, can lead to heart failure. In this procedure, valves made from animal or human tissue (bioprosthetic) are put (implanted) into one or both caval veins through a vein in the groin. This is done without disturbing the tricuspid valve. The aim is to reduce caval reflux and tricuspid regurgitation, improving symptoms of heart failure and quality of life for people who cannot have open heart surgery.

NICE is looking at caval valve implantation for tricuspid regurgitation.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 23 April 2024

Target date for publication of guidance: August 2024

1 Draft recommendations

1.1 More research is needed on caval valve implantation for tricuspid regurgitation in adults.

1.2 This procedure should only be done as part of a formal research study, with NHS research ethics committee approval.

More research

1.3 More research, in the form of suitably powered randomised controlled trials and supported by safety data from a registry, is needed on:

- patient selection
- type of procedure
- changes in cardiac function
- quality of life
- short- and long-term outcomes
- safety outcomes.

Why the committee made these recommendations

There is very limited short- and long-term evidence on the efficacy and safety of this procedure. Also, the evidence comes from studies that used different techniques to do the procedure, and varied in the number and type of implants used. It is also unclear who would benefit from this procedure. So, it should only be used in research.

2 The condition, current treatments and procedure

The condition

2.1 The tricuspid valve sits between the right atrium and right ventricle of the heart. Tricuspid regurgitation occurs because the tricuspid

valve does not close properly during systole. It can result in blood refluxing back into the right atrium (leading to haemodynamically significant tricuspid regurgitation) and the 2 main caval veins (the superior vena cava and inferior vena cava). This makes the heart work harder and, if severe, can lead to heart failure. Tricuspid regurgitation can mainly be due to a problem with the valve anatomy itself. But it is more commonly secondary to an underlying cardiac problem that causes tricuspid annular dilatation or leaflet tethering. The valve leaflets and chords are normal but, because of annulus dilatation, the valve leaflets fail to close properly and regurgitation of blood occurs.

2.2 People with mild tricuspid regurgitation do not usually have symptoms. If the regurgitation is severe, there may be fatigue and weakness, active pulsing in the neck veins, an enlarged liver, ascites, peripheral oedema and renal impairment. Pulmonary hypertension may develop.

Current treatments

2.3 Treatment may not be needed if there are no or mild symptoms. There are no specific medicines for treating tricuspid regurgitation itself, but symptoms of heart failure are managed with medicines such as diuretics and angiotensin-converting enzyme inhibitors. Medicines to reduce pulmonary artery pressure, pulmonary vascular resistance or both, may be used when there is severe functional tricuspid regurgitation and severe pulmonary hypertension.

2.4 People with severe symptoms may have surgery to repair or replace the tricuspid valve. Isolated tricuspid valve surgery is rarely done because it is associated with high morbidity and mortality. More commonly, it is done at the same time as surgery to the valves on the left side of the heart (mitral and aortic). Transcatheter tricuspid valve interventions (tricuspid valve repair and

replacement) are an alternative for managing tricuspid regurgitation.

The procedure

2.5 Caval valve implantation is indicated for haemodynamically significant tricuspid regurgitation and caval reflux in people who have advanced disease (with severe leaflet tethering and a large coaptation gap) and are at extreme risk from surgery. The aim is to reduce caval reflux and stop venous congestion, so improving symptoms of heart failure and quality of life for people who cannot have open heart surgery.

2.6 The procedure is done under local or general anaesthesia, and with fluoroscopy guidance. Transoesophageal echocardiography may be used to monitor the position and function of the deployed bioprostheses. Depending on the anatomical suitability, caval valve implantation can be single or bicaval. The bioprostheses can be dedicated self-expandable valves or balloon expandable prostheses used for transcatheter aortic valve replacement. They are implanted percutaneously through a delivery system using transfemoral access. The valves are implanted in the inferior vena cava, superior vena cava or both, at the level of the atriocaval junction. This is done without disturbing the native tricuspid valve in a cranial-caudal direction.

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 7 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 2 registries, 2 non-randomised studies, 1 observational study and 1 case report. It is

presented in the summary of key evidence section in the interventional procedures overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved cardiac function (New York Health Association functional class) and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, cardiac adverse events, stroke, bleeding, reoperation, worsening heart failure and end organ failure, and infection.

3.4 One commentary from a patient who had this procedure was discussed by the committee.

Committee comments

3.5 The committee noted that a variety of different techniques are used for doing this procedure and the technology is evolving.

3.6 The committee was informed that people need anticoagulation after the procedure.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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ISBN: