NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation

The tricuspid valve is a heart valve made up of 3 leaflets (flaps). Tricuspid regurgitation happens when the valve does not close properly, and blood flows the wrong way in the heart. This makes the heart work harder and, if severe, can lead to heart failure. In this procedure, a device is inserted into a vein in the groin or neck (transcatheter) and placed on the valve in the heart to bring the valve leaflets together. The aim is to reduce the severity of the leak, and enable the heart to pump more efficiently, improving symptoms and quality of life.

NICE is looking at transcatheter tricuspid valve leaflet repair for tricuspid regurgitation.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 17 March 2022

Target date for publication of guidance: July 2022

1 Draft recommendations

1.1 For people with severe and symptomatic tricuspid regurgitation, evidence on the efficacy of transcatheter tricuspid valve leaflet repair is limited in quantity and quality. Evidence on its safety shows there are serious but well-recognised complications. Therefore, for these people, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 For people with mild or moderate tricuspid regurgitation, evidence on the safety and efficacy of transcatheter tricuspid valve leaflet repair is inadequate in quantity and quality. Therefore, for these people, 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.

1.3 Clinicians wanting to do transcatheter tricuspid valve leaflet repair for people with severe and symptomatic tricuspid regurgitation should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).

- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.4 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.5 The procedure should only be done in specialised centres with experience of the interventional management of tricuspid regurgitation. There should be immediate onsite access to cardiac and vascular surgery.

1.6 Further research should include details of patient selection, including the type and severity of tricuspid regurgitation.

2 The condition, current treatments and procedure

The condition

2.1 Tricuspid regurgitation occurs when the tricuspid valve does not close properly during systole, and blood can be pumped backwards through the valve. It can be caused by a problem with the valve itself (primary), but it is more commonly secondary to an underlying cardiac problem that has caused the heart to become dilated. This has the effect of stretching the annulus that supports the valve leaflets to such an extent that the leaflets do not meet and regurgitation of blood occurs.

2.2 People with mild tricuspid regurgitation do not usually have any symptoms. If the regurgitation is severe people may have fatigue and weakness, active pulsing in the neck veins, liver enlargement,

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. Symptoms of heart failure are managed with diuretics and other medicines. Medication to reduce pulmonary artery pressure or pulmonary vascular resistance, or both, are 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. More commonly, it is done at the same time as surgery to the valves on the left side of the heart (mitral and aortic).

The procedure

2.5 Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation is designed to improve the function of the tricuspid valve with less morbidity and mortality than conventional surgical valve repair. It has been proposed as an option for people in whom conventional open surgery poses a high risk. The procedure aims to reduce regurgitation, increase quality of life and reduce hospital admissions related to heart failure.

2.6 The procedure is done under general anaesthesia using transoesophageal echocardiography and fluoroscopy guidance. Access to the heart is through the femoral or jugular vein.

2.7 Different systems have been used and details of the technique vary. A delivery system is used to introduce a device into the heart that can grip the leaflets of the tricuspid valve and bring them closer together. The device is then released from the delivery system.

Adequate reduction of tricuspid regurgitation is assessed using 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 9 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 non-randomised comparative studies, 2 registry reports, 1 single-arm trial, 1 case series and 1 case report. 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: reduced tricuspid regurgitation, reduced signs and symptoms of right-sided heart failure, and improved quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, damage to adjacent structures and device embolisation.

Committee comments

3.4 The committee was informed that this procedure:

- may not be suitable for people with severe tricuspid annular dilatation when the leaflets of the tricuspid valve cannot be brought together
- can be used for people with pacing leads.

3.5 The committee noted that:

- there is more than 1 device available for the procedure
- the procedure is indicated for people with severe, symptomatic tricuspid regurgitation when conventional surgery poses too high a risk.

3.6 The committee encourages the establishment of a registry for this procedure, or its inclusion into an existing registry.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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