# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# HealthTech draft guidance

# Transcatheter tricuspid valve implantation for symptomatic severe tricuspid regurgitation

The tricuspid valve controls blood flow between the upper and lower right-sided chambers of the heart. If the tricuspid valve does not close properly, blood flows backwards through the valve (regurgitation) when the heart contracts. So, the heart must work harder to pump blood around the body. This can lead to heart failure, which can cause shortness of breath, swollen abdomen and ankles, liver problems and tiredness. Some people have no symptoms. Other people have one or more symptoms (symptomatic) that cannot be controlled by medicines. In this procedure, an artificial valve is put inside the existing faulty valve. This is done through a tube (transcatheter) inserted into a large blood vessel (vein) in the leg or neck. The aim is to reduce symptoms and improve quality of life.

## Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and efficacious these procedures are. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on transcatheter tricuspid valve implantation for tricuspid regurgitation in the NHS. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

**This document has been prepared for consultation with the stakeholders.** It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of efficacy reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

**Note that this document is not NICE's final guidance on transcatheter tricuspid valve implantation for symptomatic severe tricuspid regurgitation. The recommendations in section 1 may change after consultation.**

More details are available in NICE's interventional procedures programme manual.

**Key dates:**

Closing date for comments: 28 October 2025

Second committee meeting: 11 December 2025

# 1 Recommendations

## When open-heart surgery is high risk, and transcatheter valve repair is unsuitable

1.1 Transcatheter tricuspid valve implantation can be used in the NHS during the evidence generation period as an option to treat symptomatic severe tricuspid regurgitation when open surgical tricuspid valve repair or replacement is high risk, and transcatheter tricuspid valve repair is unsuitable. There must be enhanced informed consent and auditing of outcomes.

## When open-heart surgery is not high risk, or transcatheter valve repair is suitable

1.2 More research is needed on transcatheter tricuspid valve implantation to treat symptomatic severe tricuspid regurgitation before it can be used in the NHS when open surgical tricuspid valve repair or replacement is not high risk, or transcatheter tricuspid valve repair is suitable.

1.1 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

**What this means in practice**

**When open-heart surgery is high risk, and transcatheter valve repair is unsuitable**

There are uncertainties around the safety and efficacy of this procedure. It can be used if needed while more evidence is generated.

After this, this guidance will be reviewed and the recommendations may change.

Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with tricuspid regurgitation before a joint decision is made.

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

**Enhanced informed consent**

Because there are uncertainties about whether this procedure is safe and efficacious, there must be an emphasis on informed consent. Healthcare professionals must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's advice on shared decision making and NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

**When open-heart surgery is not high risk, or transcatheter valve repair is suitable**

There is not enough evidence on the safety and efficacy of this procedure when surgery or transcatheter tricuspid valve repair is a suitable treatment option. Transcatheter tricuspid valve implantation for symptomatic severe

tricuspid regurgitation should only be done as part of formal research in these groups.

**For everyone having the procedure**

**Auditing of outcomes**

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure National Institute for Cardiovascular Outcomes Research (NICOR) Transcatheter Mitral and Tricuspid Valve pregistry. Regularly review the data on outcomes and safety.

**Who should be involved with the procedure**

Patient selection should be done by a multidisciplinary team. This procedure should only be done in centres specialised in medical and interventional management of tricuspid regurgitation.

## What evidence generation and research is needed

Healthcare professionals must collect data specifically around the safety and efficacy of this procedure. More research is needed on:

- patient selection
- safety outcomes including bleeding, paravalvular leak and the need for pacemaker implantation
- longer-term outcomes.

## Why the committee made these recommendations

There is some high-quality evidence showing the procedure reduces tricuspid regurgitation and improves quality of life in the short term, compared with medicines. But there is a risk of bleeding during and after the procedure and some people need a permanent pacemaker implanted after the procedure.

There is a lack of longer-term data, which is needed because the durability of the valve replacement is unknown. For some people, open surgical tricuspid valve repair or replacement is too high risk and transcatheter techniques to repair the valve are unsuitable. For these people, transcatheter tricuspid valve implantation can be used while more evidence is generated on longer-term outcomes.

For some people open surgical tricuspid valve repair or replacement, or transcatheter tricuspid valve repair, are suitable options. For these people, it is unclear whether the benefits of this procedure outweigh the risks. So, more research is needed in these groups.

# 2 Information about the procedure

2.1 Transcatheter tricuspid valve implantation is designed to replace the native tricuspid valve in people with symptomatic severe tricuspid valve regurgitation, without the need for open-heart surgery. The procedure is usually done under local or general anaesthesia. An artificial valve is implanted into the existing tricuspid valve. Transfemoral or internal jugular venous access can be used, or the delivery system can be inserted into the right atrium with access through a right anterior lateral thoracotomy in the intercostal space. The valve is positioned within the native tricuspid valve under real-time transoesophageal echocardiography visualisation and fluoroscopy.

2.2 Different transcatheter tricuspid valve implantation systems are available. They differ in terms of valve design, size, stent frame, anchoring mechanism and delivery systems.

# 3 Committee discussion

## The condition

3.1 Tricuspid regurgitation is when blood flows backwards through the tricuspid valve because it does not close properly during systole (when the heart contracts). It can be caused by a problem with the valve itself, but more commonly is a result of an underlying cardiac problem that has caused the heart to become dilated. This stretches the annulus that supports the valve leaflets so they do not meet and regurgitation of blood happens. Mild tricuspid regurgitation does not usually cause symptoms. Severe regurgitation may cause fatigue, weakness, active pulsing in the neck veins, liver enlargement, ascites, peripheral oedema and renal impairment. Medicines may not effectively control the symptoms. Pulmonary hypertension may develop.

## Current practice

3.2 Treatment options for symptomatic severe tricuspid regurgitation include medicines to reduce pulmonary artery pressure or pulmonary vascular resistance. Open-heart surgery to repair or replace the tricuspid valve may also be an option. But surgery on the tricuspid valve only is rarely done because it is associated with high morbidity and mortality. It is more commonly done at the same time as surgery on the valves in the left side of the heart (mitral and aortic). There are also transcatheter techniques for repairing the tricuspid valve, including leaflet repair and annuloplasty.

## Unmet need

3.3 Symptomatic severe tricuspid regurgitation can be debilitating and lead to poor quality of life. Medication does not address the underlying cause and open-heart surgery is often prohibitively high risk. Transcatheter tricuspid valve repair techniques may not be

suitable for some people. Transcatheter tricuspid valve implantation may provide a treatment option for people with severe tricuspid regurgitation who have symptoms despite optimal medical therapy, when open-heart surgery or other transcatheter techniques are unsuitable.

## The evidence

3.4 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 12 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (reported in 2 publications), 1 systematic review and meta-analysis, 2 prospective single-arm studies, 1 retrospective cohort study, 1 registry study, 3 non-randomised comparative studies 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.

3.5 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
- improved quality of life, reduced hospital admissions related to heart failure
- improved survival.

3.6 The professional experts and the committee considered the key safety outcomes to be:

- mortality
- bleeding
- paravalvular leak

- need for permanent pacemaker implantation.

3.7 Patient commentary was sought but none was received.

### Committee comments

3.8 Most people need anticoagulation after the procedure and regimens for this are being developed.

3.9 People who do not already have a pacemaker may need one after this procedure. Pacemaker implantation may be more complex because of the need to avoid having leads going through the implanted valve. It may be necessary to use a leadless pacemaker.

3.10 When the tricuspid valve has been made competent after severe regurgitation, there is a small risk of making heart failure worse if the right heart's function was substantially impaired before the procedure.

3.11 The implanted valves may be made from animal tissue. .

### Equality considerations

3.12 Tricuspid regurgitation has a higher prevalence and faster progression in women than men. Women often present with more severe tricuspid regurgitation, when open-heart surgery is often unsuitable. So this procedure could particularly benefit women, helping to address inequality of care.

3.13 Some people may not want to have a valve containing animal tissue because of their religious or cultural beliefs.

## 4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

## Chair

**Tom Clutton-Brock**

Chair, interventional procedures advisory committee

## NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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