NICE National Institute for Health and Care Excellence

NICE guidance

# Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation

HealthTech guidance
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www.nice.org.uk/guidance/htg632

# 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 IPG731.

# 1 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 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 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 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 is when blood flows backwards through the tricuspid valve because it does not close properly during systole. 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.

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. There are no specific medicines for treating tricuspid regurgitation itself, but 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 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).

# 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, reduce hospital admissions related to heart failure and improve survival.

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 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 non-randomised comparative studies (1 of which was included in the systematic review), 2 registry reports, 1 single-arm trial (also included in the systematic review), 1 cohort study, 1 case series 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: reduced tricuspid regurgitation, reduced signs and symptoms of right-sided heart failure, improved quality of life, reduced hospital admissions related to heart failure and improved survival.

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

3.4 Patient commentary was sought but none was received.

## Committee comments

3.5 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.

3.6 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.

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

# Update information

**Minor changes since publication**

**January 2026:** Interventional procedures guidance 731 has been migrated to HealthTech guidance 632. The recommendations and accompanying content remain unchanged.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.