NICE National Institute for Health and Care Excellence

NICE guidance

Caval valve implantation for tricuspid regurgitation

HealthTech guidance
Published: 21 August 2024

www.nice.org.uk/guidance/htg726

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 IPG791.

1 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 because of 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 may be 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 8 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 2 registries, 2 non-randomised studies, 1 observational study and 2 case reports. It is presented in the summary of key evidence section in the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved cardiac function (New York Heart 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.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 791 has been migrated to HealthTech guidance 726. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8988-1

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.