NICE guidance

Transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg730

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.

1 Recommendations

1.1 For people with severe and symptomatic tricuspid regurgitation, evidence on the efficacy of transcatheter tricuspid valve annuloplasty 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 annuloplasty 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 annuloplasty for people with severe and symptomatic tricuspid regurgitation should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people (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 everyone 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 everyone 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, is used for 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 annuloplasty is designed to improve the function of the tricuspid valve with less morbidity and mortality than conventional surgical annuloplasty. 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. In one example, an annuloplasty ring or band is delivered through a catheter and implanted around the circumference, or annulus, of the tricuspid valve. A size adjustment tool is used to contract the device, which reduces the tricuspid annular diameter and brings the valve leaflets together. When the appropriate amount of reduction has been achieved, the implant is detached from the delivery system, which is then removed. In other systems, sutures are used to either exclude the posterior leaflet and create a functional bicuspid valve or to reduce the area of the tricuspid annulus. 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 6 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 single-arm trials (1 of which was also included in the systematic review), and 3 case series (2 of which were also included in the systematic review). 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, 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 and damage to adjacent structures, including the right coronary artery.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that, in future, this procedure may be used in combination with or after procedures on the mitral valve.

3.6 The committee noted that the procedure is indicated for people with severe, symptomatic tricuspid regurgitation for whom conventional surgery is too high

risk.

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation