NICE National Institute for Health and Care Excellence

NICE guidance

Transcatheter tricuspid valve implantation for symptomatic severe tricuspid regurgitation

HealthTech guidance

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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

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.

1.3 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 the procedure's safety and efficacy, 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.

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 into the National Institute for Cardiovascular Outcomes Research transcatheter mitral and tricuspid valve registry. 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, where all available treatment options can be offered.

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

There is not enough evidence to know if this procedure is safe and effective 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.

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 into the National Institute for Cardiovascular Outcomes Research transcatheter mitral and tricuspid valve registry. Regularly review the data on outcomes and safety.

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What evidence generation and research is needed

Evidence generation and research is needed on:

- patient selection, including aetiology of the tricuspid regurgitation
- device and technique used for the procedure
- longer-term safety outcomes including bleeding, paravalvular leak and the need for pacemaker implantation
- longer-term efficacy outcomes including quality of life, heart failure related hospital admissions, and survival.

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, the benefits outweigh the risks because there are no other options, so transcatheter tricuspid valve implantation can be used as a treatment option 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. The devices also differ by access route.

3 Committee discussion

The interventional procedures advisory committee considered evidence on transcatheter tricuspid valve implantation for symptomatic severe tricuspid regurgitation from several sources. This included evidence submitted by 1 company, a review of efficacy and safety evidence, and responses from stakeholders. Full details are available in the project documents for this guidance.

NICE did a rapid review of the literature on the efficacy and safety of this procedure. The evidence included 1 randomised controlled trial (reported in 2 publications), a post-hoc analysis of the randomised controlled trial, 2 systematic reviews, 2 prospective single-arm studies, 1 retrospective cohort study, 2 registry studies, 1 post-hoc analysis of 2 prospective trials, 3 non-randomised comparative studies, 2 case reports and a review of the US Food and Drug Administration Manufacturer and User Facility Device Experience database. 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.

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 or pulmonary hypertension 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.

Current practice

3.2 Treatment options for symptomatic severe tricuspid regurgitation include medicines, such as loop diuretics. 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 and increased risk of mortality. Medicines do 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 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.

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

- mortality

- bleeding
- paravalvular leak
- need for permanent pacemaker implantation.

3.6 Patient commentary was sought but none was received.

Committee comments

3.7 People need anticoagulation after the procedure and regimens for this are being developed.

3.8 Some 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.

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

3.10 The implanted valves considered in the current evidence are made from animal tissue.

3.11 There are different types of device and different access routes used for implantation, which may affect safety and efficacy outcomes.

3.12 Evidence suggests the procedure may have a greater benefit in people with more severe tricuspid regurgitation but there may also be a higher proportion of adverse outcomes.

3.13 The committee acknowledged that there are different aetiologies of tricuspid regurgitation.

Equality considerations

3.14 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.

3.15 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.

Chairs

Rick Body
Chair, interventional procedures advisory committee

Tom Clutton-Brock
Former 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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