NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

The tricuspid valve is a heart valve made up of 3 leaflets (flaps). Tricuspid regurgitation happens when the tricuspid valve does not close properly, and blood flows the wrong way in the heart. This makes the heart work harder and, if severe, can lead to heart failure. In this procedure, a device is inserted into a vein in the groin or the neck (transcatheter) and placed in the heart to support the tissues surrounding the valve (annuloplasty) so that the leaflets are brought towards each other. The aim is to reduce the severity of the leak and make the heart pump more efficiently, improving symptoms and quality of life.

Contents

Abbreviations

Word or phrase	Abbreviation
Confidence interval	CI
Effective regurgitant orifice area	EROA
EuroQol 5-dimensions 5-level health questionnaire	EQ-5D-5L
European System for Cardiac Operative Risk Evaluation	EuroSCORE
Interquartile range	IQR
Mean difference	MD
N-terminal pro-B type natriuretic peptide	NT-pro BNP
New York Heart Association	NYHA
Proximal isovelocity surface area	PISA
Relative risk	RR
Standard deviation	SD

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2021.

Procedure name

- Transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

Professional societies

- The Society for Cardiothoracic Surgery of Great Britain and Ireland
- British Cardiovascular Intervention Society
- Royal College of Physicians

- Royal College of Physicians of Edinburgh
- Royal College of Physicians and Surgeons of Glasgow.

Description of the procedure

Indications and current treatment

Tricuspid regurgitation happens when the tricuspid valve does not close properly during systole and blood flows backwards through the valve. 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. This stretches the annulus that supports the valve leaflets to such an extent that the leaflets do not meet and regurgitation of blood happens. 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.

Treatment may not be needed if there are no or mild symptoms. 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.

People with severe symptoms may have surgery to repair or replace the tricuspid valve. Isolated tricuspid valve surgery is rarely done. It is more commonly done at the same time as surgery to the valves on the left side of the heart (mitral and aortic).

What the procedure involves

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, and reduce hospital admissions related to heart failure.

The procedure is done under general anaesthesia using transoesophageal echocardiography and fluoroscopy guidance. Access to the heart is through the femoral or jugular vein.

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.

Outcome measures

New York Heart Association (NYHA) functional class

The NYHA functional class is used to classify heart failure according to severity of symptoms and limitation of physical activity:

- Class 1 - no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, breathlessness, or palpitations.
- Class 2 - slight limitation of physical activity. Comfortable at rest but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
- Class 3 - marked limitation of physical activity. Comfortable at rest but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
- Class 4 - unable to carry out any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken discomfort is increased.

Kansas City Cardiomyopathy Questionnaire

The Kansas City Cardiomyopathy Questionnaire is a 23-item self-administered questionnaire that measures the patient's perception of their health status, including heart failure symptoms, impact on physical and social function, and how their heart failure impacts their quality of life within a 2-week recall period. Scores are scaled from 0 to 100, where higher scores represent better health status.

Efficacy summary

Technical success

In the single-arm study of 61 people, the device was successfully deployed and the delivery system successfully retrieved as intended in 97% (58/60) of devices. The procedure was abandoned in 1 person because the right coronary artery was perforated by the guidewire before the device was inserted. Procedural success (defined as device success with 30% tricuspid regurgitation reduction in PISA EROA relative to baseline, and without the need for intervention before discharge) was 84% (26/31) and clinical success (procedural success with no major adverse events at 30 days) was 54% (20/37) (Nickenig, 2021).

In the case series of 60 people, technical success (defined as successful delivery, deployment and positioning of device, absence of procedural mortality, and freedom from emergency surgery related to the device) was 97% (58/60) and procedural success (defined as technical success and tricuspid regurgitation reduction of 2 or more grades at discharge) was 45% (27/60) (Körber, 2021).

In the case series of 30 people, device success was 93% (28/30) (Davidson, 2021).

Tricuspid septolateral annular diameter

In the single-arm study of 61 people, the mean tricuspid septolateral annular diameter decreased from 45.5 mm at baseline to 36.1 mm at 30 days follow up ($p<0.001$) (Nickenig, 2021). In the single-arm study of 30 people, it decreased from 41.9 mm at baseline to 36.2 mm at discharge ($p<0.001$), 36.5 mm at 1 year and 35.2 mm at 2 years (Nickenig, 2021b). In the case series of 60 people, septolateral diameter of the tricuspid annulus was reduced by a mean of 10.5 mm after the procedure (Körber, 2021). In the case series of 30 people, the mean end-diastolic tricuspid septolateral annular diameter decreased from 45.2 mm at baseline to 39.5 mm at 30 days follow up ($p<0.001$) (Davidson, 2021).

Tricuspid regurgitation severity

In a single-arm study of 61 people, there was a statistically significant improvement in tricuspid regurgitation severity at discharge and 30 days follow up ($p<0.001$ for both). The proportion of people with no or mild regurgitation increased from 0% at baseline to 26% at discharge and 36% at 30 days. The proportion of people with severe, massive or torrential regurgitation reduced from 94% at baseline to 41% at discharge and 31% at 30 days. At discharge, 78% of people had at least 1 grade reduction and 59% had at least 2 grades reduction in

tricuspid regurgitation. At 30 days follow up, 85% had at least 1 grade reduction and 59% had at least 2 grades reduction (Nickenig, 2021).

In a single-arm study of 30 people, there was a statistically significant improvement in tricuspid regurgitation severity at discharge (n=22), 1 year (n=16) and 2 years (n=11) follow up ($p<0.001$, $p<0.007$ and $p<0.016$ respectively). The proportion of people with mild regurgitation increased from 4% at baseline to 14% at discharge, 13% at 1 year and 36% at 2 years. The proportion of people with severe, massive or torrential regurgitation reduced from 76% at baseline to 45% at discharge, 37% at 1 year and 27% at 2 years (Nickenig, 2021b).

In a case series of 60 people, there was a statistically significant improvement in tricuspid regurgitation severity at discharge and 30 days follow up ($p<0.001$ for both). The proportion of people with severe, massive or torrential regurgitation reduced from 100% at baseline to 39% at discharge and 33% at 30 days (Körber, 2021). In a case series of 30 people, the proportion of people with mild tricuspid regurgitation increased from 0% at baseline to 15% at 30 days follow up. The proportion of people with severe, massive or torrential regurgitation decreased from 100% to 55%. At 30 days, 85% of people had at least 1 grade reduction and 56% of people had at least a 2 grades reduction in tricuspid regurgitation (Davidson, 2021).

NYHA functional class

In the single-arm study of 61 people, the proportion of people with NYHA functional class 1 or 2 increased from 15% at baseline to 74% at 30 days follow up ($p<0.001$) (Nickenig, 2021). In the single-arm study of 30 people, the proportion of people with NYHA functional class 1 or 2 increased from 17% at baseline to 78% at 1-year follow up ($p<0.001$) and 82% at 2 years ($p=0.002$) (Nickenig, 2021b). In the case series of 60 people, the proportion of people with NYHA functional class 1 or 2 increased from 21% at baseline to 81% at 30 days follow up ($p<0.001$) (Körber, 2021). In the case series of 30 people, the proportion of people with NYHA functional class 1 or 2 increased from 32% at baseline to 75% at 30 days follow up ($p<0.001$) (Davidson, 2021).

6-minute walk test

In the single-arm study of 30 people, the mean 6-minute walk test distance increased from 248 metres at baseline to 296 metres at 1-year follow up ($p<0.053$) and 309 metres at 2 years ($p=0.058$) (Nickenig, 2021). In the case series of 30 people, the mean distance was similar at baseline (245.8 metres) and at 30 days (247.0 metres, $p=0.926$) (Davidson, 2021).

Quality of life

In the single-arm study of 61 people, the mean overall Kansas City Cardiomyopathy Questionnaire score improved from 50 at baseline to 69 at 30 days follow up ($p<0.001$). The EQ-5D-5L score improved but the difference was not statistically significant (60 at baseline compared with 44 at 30 days follow up, $p=0.313$) (Nickenig, 2021).

In the single-arm study of 30 people, the mean overall Kansas City Cardiomyopathy Questionnaire score improved from 45 at baseline to 64 at 1 year ($p<0.001$) and 63 at 2 years follow up ($p=0.046$) (Nickenig, 2021b). In the case series of 30 people, the mean Kansas City Cardiomyopathy Questionnaire score improved from 53 at baseline to 69 at 30 days follow up (Davidson, 2021).

Safety summary

Overall

The composite major adverse event rate at 30 days was 20% (12/61) in the single-arm study of 61 people (Nickenig, 2021). A composite end point of death, myocardial infarction, need for urgent cardiothoracic surgery or stroke at 30 days was reported in 7% (4/60) of people in the case series of 60 people (Körber, 2021).

Mortality

One person died from procedure-related renal failure on postoperative day 18 in the single-arm study of 61 people (Nickenig, 2021). Mortality was 17% (5/30) at 1 year and 27% (8/30) at 2 years follow up in the single-arm study of 30 people. Of the 8 deaths, 6 were non-cardiovascular deaths beyond 30 days after the procedure (Nickenig, 2021b). Mortality at 30 days was 3% (2/60) in the case series of 60 people; 1 person died in end of life care 15 days after the procedure and 1 person died 3 weeks after the procedure from COVID-19 (Körber, 2021).

Myocardial infarction

Transient intraprocedural occlusion of the right coronary artery, which resolved spontaneously, was reported in 1 person in the single-arm study of 61 people (Nickenig, 2021). Myocardial infarction was reported in 1 person in the case series of 60 people (Körber, 2021).

Stroke

Stroke was reported in 1 person at 1 year and 2 people at 2 years follow up in the single-arm study of 30 people (Nickenig, 2021b).

Pericardial effusion or cardiac tamponade

Pericardial effusion needing intervention was reported in 1 person in the single-arm study of 61 people (Nickenig, 2021). Cardiac tamponade was reported in 3% (2/60) of people in the case series of 60 people (Körber, 2021) and in 1 person in the case series of 30 people (Davidson, 2021).

Coronary artery injury

Coronary artery injury needing intervention was reported in 7% (4/61) of people in the single-arm study of 61 people (Nickenig, 2021). Right coronary artery perforation was reported in 5% (3/60) of people in the case series of 60 people; 2 had conservative treatment. Right coronary artery stent implantation was reported in 12% (7/60) of people in the same study (Körber, 2021).

Arrhythmia and conduction disorders

Arrhythmia and conduction disorders needing permanent pacing were reported in 1 person in the single-arm study of 61 people (Nickenig, 2021). Conduction system disturbance was reported in 1 person at 1 year and 2 people at 2 years follow up in the single-arm study of 30 people. In the same study, ventricular arrhythmia was reported in 10% (3/30) of people (Nickenig, 2021b). Haemodynamically relevant arrhythmia was reported in 12% (7/60) of people within 30 days of the procedure in the case series of 60 people. A new pacemaker was needed in 3% (2/60) of people (Körber, 2021).

Renal complications

New need for renal replacement therapy was reported in 3% (2/61) of people in the single-arm study of 61 people (Nickenig, 2021).

Renal failure was reported in 1 person in the single-arm study of 30 people (Nickenig, 2021b). Acute renal failure within 30 days of the procedure was reported in 12% (7/60) of people in the case series of 60 people (Körber, 2021).

Access-site and vascular complications

Major access-site and vascular complications were reported in 7% (4/61) of people in the single-arm study of 61 people (Nickenig, 2021). Access-site-related bleeding was reported in 1 person in the case series of 60 people (Körber, 2021).

Severe bleeding was reported in 12% (7/61) of people in the single-arm study of 61 people. All 7 people were on anticoagulation or antiplatelet therapy for pre-existing atrial fibrillation or flutter (Nickenig, 2021). Bleeding complications (extensive, life-threatening, or fatal) were reported in 20% (6/30) of people at 1 year and 23% (7/30) of people at 2 years follow up in the single-arm study of 30 people (Nickenig, 2021b). Major, extensive or life-threatening bleeding was reported in 5% (3/60), 5% (3/60) and 2% (1/60) of people respectively in the case series of 60 people. Blood transfusion was reported in 20% (12/60) of people (Körber, 2021). Severe bleeding was reported in 23% (7/30) of people in the case series of 30 people; 2 were described as life-threatening, 1 was extensive and 4 were major (Davidson, 2021).

Reintervention

Device-related secondary intervention was reported in 1 person at 1 year and 2 people at 2 years follow up in the single-arm study of 30 people (Nickenig, 2021b). Urgent open-heart surgery was needed in 3% (2/60) of people in the case series of 60 people (Körber, 2021).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened).

For this procedure, professional experts listed the following anecdotal adverse events: (partial) detachment of the annuloplasty band, perforation of right atrium or ventricle, worsening of right heart failure, oesophageal injury, ventricular tachycardia, and stroke.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to transcatheter tricuspid valve annuloplasty for tricuspid regurgitation. The following databases were searched, covering the period from their start to 2 September 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with tricuspid regurgitation.
Intervention/test	Transcatheter tricuspid valve annuloplasty
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on about 200 patients who had transcatheter tricuspid valve annuloplasty from 1 systematic review (Montalto, 2020), 2 single-arm trials (Nickenig, 2021; Nickenig, 2021b [also included in the systematic review]) and 3 case series (Körber, 2021; Davidson, 2021; Hahn, 2017 [also included in the systematic review]).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

Study 1 Montalto C (2020)

Study details

Study type	Systematic review and meta-analysis
Country	Not reported for individual studies (3 were described as international)
Recruitment period	Search date: September 2019
Study population and number	n=454 (7 studies); 30 annular reduction, 15 bicuspidalisation by pledget-plication, 47 increased leaflet coaptation surface, 362 edge-to-edge leaflet plasty
Age and sex	Mean 76.7 years; 41% (188/454) male
Patient selection criteria	Studies were eligible if they fulfilled all the following criteria: 1) they included patients with at least moderate tricuspid regurgitation (adjudicated using a semiquantitative method) and treated with transcatheter repair devices; and 2) they reported at least 1 of the primary outcomes of interest at a minimum follow-up point of 30 days. Case reports, letters and studies that did not clearly report the numbers and rates of patients alive at follow-up were excluded from the analysis. Studies in which severe tricuspid regurgitation was treated using transcatheter implantation of prosthetic valves were also excluded.
Technique	Transcatheter tricuspid valve repair. Devices included Cardioband (Edwards Lifesciences, US; n=30), FORMA (Edwards Lifesciences; n=47), MitraClip (Abbott Vascular, US; n=334), PASCAL (Edwards Lifesciences; n=28), and Trialign (Mitralign, US; n=15).
Follow up	range 30 days to 1 year
Conflict of interest/source of funding	None for authors of the review.

Analysis

Follow-up issues: Studies were only included if they had a minimum of 30 days follow up for at least 1 of the primary outcomes of interest.

Study design issues: The review was done in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses and Meta-Analysis of Observational Studies in Epidemiology guidelines. All included studies were interventional, multicentre, single arm, and prospective. The primary endpoints of the analysis were the rate reduction of severe tricuspid regurgitation and NYHA functional class 3 or 4 at longest follow up available. Procedural success definition included at least successful device implantation because of the varying definitions in the studies. Pooled risk ratios and standardised mean differences with 95% CIs were

used as summary statistics for outcomes of interest and were calculated using a random-effects model. Heterogeneity was considered to be low when I^2 was less than 25%, moderate when I^2 was less than 75%, and high when I^2 was more than 75%. No publication bias was identified by visually inspecting funnel plots and by mathematical testing.

Study population issues: Of the 454 patients, only 45 had a procedure that fits the remit of this overview. The remaining patients had a procedure that fits the remit for a separate overview titled 'Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation'.

Patients were at high surgical risk, with a mean EuroSCORE 2 score of 6.8% (95% CI 5.4% to 8.1%). Tricuspid aetiology was mostly functional (90%; 95% CI 82% to 99%), and 90% (95% CI 82% to 100%) of patients were in NYHA functional class 3 or 4.

Studies included the following named trials: TRI-REPAIR, Trivalve, TRILUMINATE and SCOUT.

Key efficacy findings

- Number of patients analysed: 454
- Procedural success: 86% of patients (95% CI 78% to 95%)
- All-cause mortality rate (weighted mean follow up 265 days): 9% (95% CI 5% to 16%)
- The sensitivity analysis revealed that no study significantly changed the relative risk of being in NYHA functional class 3 or 4 at follow-up, as stepwise study omission did not result in a shift of the point estimate out of the 95% CI.
- The random-effect subgroup analysis revealed that at follow-up, the proportion of patients in NYHA functional class 3 or 4 and of patients with tricuspid regurgitation graded severe or worse were reduced regardless of the device used.

Functional and echocardiographic parameters at baseline and after transcatheter tricuspid valve repair

Parameter	Baseline value, incidence or pooled mean (95% CI)	No. of studies	RR or MD	Follow up: RR or MD (95% CI)	p value	I^2 (%)	p for hetero-geneity
Incidence of NYHA class 3 or 4	90% (82% to 99%)	7	RR	0.23 (0.16 to 0.33)	0.004	39	0.13
Mean 6-minute walk distance, metres	245.4 (215.8 to 275.0)	6	MD	64.6 (41.3 to 87.9)	<0.0001	0	0.78
Mean left ventricular ejection fraction, %	57 (52.9 to 61.0)	6	MD	1.2 (-0.5 to 2.8)	0.16	0	0.99
Mean tricuspid annular plane systolic excursion, mm	15.1 (14.3 to 15.9)	6	MD	-0.09 (-1.2 to 0.98)	0.85	64	0.02
Incidence of tricuspid regurgitation severe or greater	95% (87% to 100%)	4	RR	0.38 (0.2 to 0.7)	0.004	90	0.0001
Mean EROA, mm	0.9 (0.7 to 1.0)	6	MD	-3.1 (-4.4 to -1.9)	<0.0001	54	0.06
Mean tricuspid valve annular diameter, mm	44.6 (42.5 to 46.7)	7	MD	-3.0 (-4.7 to -1.4)	0.0004	63	0.01
Mean systolic pulmonary artery pressure, mmHg	41.7 (38.4 to 45.0)	4	MD	-1.6 (-4.9 to 1.7)	0.33	53	0.09

Key safety findings

No safety outcomes were reported.

Study 2 Nickenig G (2021)

Study details

Study type	Single arm (TriBAND study)
Country	13 European centres
Recruitment period	July 2019 to December 2020
Study population and number	n=61 Patients with symptomatic functional tricuspid regurgitation despite diuretic therapy
Age and sex	Mean 78.6 years; 75% (46/61) female
Patient selection criteria	Key inclusion criteria were chronic symptomatic (moderate or worse) functional tricuspid regurgitation confirmed by echocardiographic core laboratory and heart failure symptoms with NYHA functional Class 2 to 4 despite optimal medical therapy including diuretic therapy. Patients were deemed candidates for transcatheter tricuspid repair by the multidisciplinary local Heart Team. Key exclusion criteria were left ventricular ejection fraction less than 25%; pulmonary arterial systolic pressure higher than 70 mmHg by echocardiography or right heart catheterisation; tricuspid PISA EROA at least 2 cm^2; severe right ventricular dysfunction; tricuspid valve anatomy precluding proper device deployment and function; previous tricuspid valve repair or replacement; presence of trans-tricuspid valve pacemaker or defibrillator leads impinging on the tricuspid valve leaflets as evaluated by echocardiography; and renal insufficiency needing dialysis or severe kidney renal disease with an estimated glomerular filtration rate 25 mL/min/1.73 m^2 or lower.
Technique	Device: Cardioband tricuspid valve reconstruction system (Edwards Lifesciences, US). The Cardioband implant was deployed through transfemoral venous access using a delivery system under transoesophageal echocardiography and fluoroscopic guidance. Intraprocedural coronary angiography was done periodically to assess the proximity of the right coronary artery.
Follow up	30 days
Conflict of interest/source of funding	The study was funded by Edwards Lifesciences. 7 authors have received speakers' honoraria or travel/grant support from Edwards Lifesciences. 4 authors have received research funding, educational grants, honoraria for lectures of advisory boards or participated in clinical trials from companies including the Deutsche Forschungsgemeinschaft, the Federal Ministry of Education and Research, the European Union, Abbott, AGA Medical, AstraZeneca, Bayer, Berlin Chemie, BioSensus, Biotronik, Bristol-Myers Squibb, Boehringer Ingelheim, Daiichi Sankyo, Edwards Lifesciences, Medtronic, Novartis, Pfizer, Sanofi, St. Jude Medical, Cardiovalve, Amgen, BMS, Boston Scientific, Cardinal Health, CSL Behring, Johnson & Johnson, Querbet, Polares, Terumo, Sinomed, Abiomed, MedAlliance, V-Wave, Xeltis, Philips Healthcare and Navigate.

Analysis

IP overview: transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

Follow-up issues: 30-day follow up was done in 85% (52/61) of patients. One patient died before the visit, 1 patient exited from the study after an abandoned procedure, and 7 patients had missed or pending visits.

Study design issues: European single-arm, multicentre, prospective post-market clinical follow up study. This study included the first 61 patients to be enrolled. The primary endpoint was reduction in tricuspid regurgitation severity between baseline and discharge. Secondary endpoints included tricuspid regurgitation severity, NYHA functional class, EQ-5D-5L, and overall Kansas City Cardiomyopathy Questionnaire at 30 days follow up. The safety endpoint was a composite of major adverse events, defined as cardiovascular mortality, myocardial infarction, stroke, pericardial effusion needing intervention, coronary artery injury needing percutaneous or surgical intervention, arrhythmia and conduction disorders needing permanent pacing, new need for renal replacement therapy, severe bleeding, nonelective tricuspid valve reintervention (percutaneous or surgical), major access-site and vascular complications, and major cardiac structural complications. Device success was defined as the device deployed and the delivery system successfully retrieved as intended at the time of the patient's exit from the cardiac catheterisation laboratory (per device). Procedural success was defined as device success with 30% tricuspid regurgitation reduction in PISA EROA relative to baseline, and without the need for intervention before discharge (per patient). Clinical success was defined as procedural success with no major adverse events at 30 days (per patient). Analysis was done on the intention-to-treat population.

Study population issues: 85% of patients were in NYHA functional Class 3 to 4. Mean EuroSCORE 2 was 6.8% and Society of Thoracic Surgeons predicted risk of mortality score was 7.1%. All 61 patients had severe or worse functional tricuspid regurgitation based on their site evaluated qualifying echocardiograms; of the 53 patients who were assessed by the echocardiographic core laboratory, 94% had severe or worse tricuspid regurgitation at baseline. Mean NT-pro BNP level was 2,072 pg/mL.

Key efficacy findings

- Number of patients analysed: 61
- In 1 patient, the procedure was abandoned because the right coronary artery was perforated by the guidewire before the device was inserted.
- Device success=96.7% (58/60); 2 patients did not have the device inserted because of partial deployment of anchors leading to inability to contract the implant (n=1) and poor visibility along with right coronary artery proximity and steep atrial wall (n=1).
- Procedural success=83.9% (26/31; EROA unreadable for 30 patients)
- Clinical success=54.1% (20/37)
- Mean fluoroscopy time=67.1 minutes
- Mean length of hospital stay=6.5 days
- Proportion of patients with at least 1 grade reduction in triscuspid regurgitation at discharge=78%
- Proportion of patients with at least 1 grade reduction in triscuspid regurgitation at 30 days=85%
- Proportion of patients with at least 2 grades reduction in triscuspid regurgitation at discharge=59%
- Proportion of patients with at least 2 grades reduction in triscuspid regurgitation at 30 days=59%

Improvements in tricuspid regurgitation severity from baseline to 30 days (proportion of patients)

Severity	Qualifying echocardiogram, n=61	Baseline, n=53	Discharge, n=54	30 days, n=42
None/trace	0	0	6%	5%
Mild	0	0	20%	31%
Moderate	0	6%	33%	33%
Severe	31%	26%	24%	14%
Massive	25%	28%	4%	12%
Torrential	44%	40%	13%	5%
p value	-	-	<0.001	<0.001

Echocardiographic variables at baseline, discharge, and 30 days, mean (SD) or % (n/N)

Variable	Base-line	n	Discharge	n	Change	p value	30 days	n	Change	p value
Tricuspid annular septolateral diameter, mm	45.5 (4.5)	52	36.7 (5.0)	54	-8.7 (3.6)	<0.001	36.1 (5.0)	42	-8.9 (5.1)	<0.001
PISA EROA, cm^2	0.76 (0.48)	41	0.39 (0.35)	36	-0.44 (0.37)	<0.001	0.34 (0.27)	37	-0.45 (0.36)	<0.001
Mean vena contracta, cm	1.5 (0.56)	48	0.89 (0.55)	50	-0.67 (0.44)	<0.001	0.79 (0.52)	37	-0.70 (0.43)	<0.001
Mid-right ventricle end-diastolic diameter, cm	4.0 (0.8)	50	3.7 (0.7)	51	-0.3 (0.6)	0.007	3.6 (0.6)	41	-0.4 (0.7)	0.005
Left ventricular ejection fraction, %	53.3 (7.6)	49	54.5 (7.5)	48	2.0 (4.7)	0.01	54.8 (8.2)	41	1.6 (5.9)	0.123
Right ventricle tricuspid annular plane systolic excursion, cm	1.6 (0.3)	52	1.4 (0.3)	53	-0.2 (0.3)	<0.001	1.5 (0.4)	42	-0.1 (0.3)	0.01
Systolic pulmonary artery pressure, mmHg	33.1 (11.0)	52	41.0 (14.2)	54	7.6 (14.0)	<0.001	38.4 (9.6)	41	3.5 (10.2)	0.045

Improvements in functional and clinical measurements from baseline to 30 days

Outcome	n	Baseline	n	30 days	p value
Proportion of patients with NYHA functional class 1 or 2	61	15%	50	74%	<0.001
Overall Kansas City Cardiomyopathy Questionnaire score, mean (SD)	60	50 (21)	53	69 (23)	<0.001
EQ-5D-5L score, mean (SD)	61	60 (17)	53	44 (19)	0.313

Key safety findings

- All-cause mortality=1.6% (1/61) (the patient died from procedure related renal failure on postoperative day 18)
- Cardiovascular mortality=0% (0/61)
- Myocardial infarction=1.6% (1/61) (transient intraprocedural occlusion of the right coronary artery, resolved spontaneously)
- Stroke=0% (0/61)
- Pericardial effusion needing intervention=1.6% (1/61)
- Coronary artery injury needing intervention=6.6% (4/61)
- Arrhythmia and conduction disorders needing permanent pacing=1.6% (1/61)
- New need for renal replacement therapy=3.3% (2/61)
- Severe bleeding=11.5% (7/61) (all 7 were on anticoagulation or antiplatelet therapy for pre-existing atrial fibrillation or flutter)
- Non-elective tricuspid valve reinterventions=0% (0/61)
- Major access-site and vascular complications=6.6% (4/61)
- Major cardiac structural complications=0% (0/61)
- Composite major adverse event rate=19.7% (12/61)

Study 3 Nickenig G (2021b)

Study details

Study type	Single arm (TRI-REPAIR study)
Country	France, Germany, Italy (8 sites)
Recruitment period	October 2016 to July 2017
Study population and number	n=30 Patients with moderate or greater functional tricuspid regurgitation for whom surgery posed an unacceptable risk
Age and sex	Mean 75.2 years; 73% (22/30) female
Patient selection criteria	Key eligibility criteria included NYHA functional class 2 to 4a, moderate or greater chronic functional tricuspid regurgitation, symptomatic despite stable medical treatment at minimum on a diuretic regimen, tricuspid annular diameter 40 mm or larger, and surgery precluded as a treatment option. Key exclusion criteria included left ventricular ejection fraction less than 30%, systolic pulmonary artery pressure higher than 60 mmHg, echocardiographic evidence of severe right ventricular dysfunction, and recent myocardial infarction or known unstable angina within 30 days before the index procedure.
Technique	Device: Cardioband tricuspid valve reconstruction system (Edwards Lifesciences, US).
Follow up	Mean 604 days
Conflict of interest/source of funding	The study was funded by Edwards Lifesciences. 8 authors have received speakers' honoraria or travel and grant support from Edwards Lifesciences. 4 authors are employees of Edwards Lifesciences. 1 author reported speaker honoraria from Baylis Medical, Edwards Lifesciences and Medtronic, consulting for Abbott Structural, Edwards Lifesciences, Medtronic, Navigate and Philips Healthcare, and being the Chief Scientific Officer for the Echocardiography Core Laboratory at the Cardiovascular Research Foundation for multiple industry-sponsored trials, for which she receives no direct industry compensation.

Analysis

Follow-up issues: Of the 30 patients, 5 died within the first year and 2 died during the second year of follow up. Two patients had a further intervention and 1 withdrew from the study, so 80% (24/30) of patients had a 1-year follow up and 67% (20/30) of patients had a 2-year follow up.

Study design issues: Single-arm, multicentre, prospective study. The primary efficacy endpoint for the study was successful access, deployment, and positioning of the tricuspid implant and reduction of the septolateral annular diameter at the end of the procedure and at discharge. The primary safety endpoint was the rate of major serious adverse events (a composite endpoint of death, myocardial infarction, cardiac tamponade, device-related cardiac surgery, and stroke) and serious adverse device effects at 30 days. These events were adjudicated by an independent clinical events committee. Changes were calculated for paired observations. The authors noted that some site-reported values differed from core laboratory assessments (1 patient had

mild tricuspid regurgitation) and there was missing tricuspid regurgitation quantitation (PISA EROA) because of inadequate imaging.

Study population issues: Most patients (83%) were in NYHA Class 3 to 4. The mean EuroSCORE 2 was 4.1% and the Society of Thoracic Surgeons mortality score was 2.6%. Mean NT-proBNP level was 2,925 ng/L.

Other issues: Data from this trial was also included in the systematic review by Montalto et al. (2020)

Key efficacy findings

- Number of patients analysed: 30
- Technical success=100%
- 2-year survival estimate (Kaplan-Meier)=73%
- Freedom from heart failure hospitalisation at 2 years (Kaplan-Meier)=56%

Improvements in tricuspid regurgitation severity from baseline to 2 years (proportion of patients)

Severity	Baseline, n=25	Discharge, n=22	1 year, n=16	2 years, n=11
Mild	4%	14%	13%	36%
Moderate	20%	41%	50%	36%
Severe	24%	18%	25%	9%
Massive	16%	9%	6%	9%
Torrential	36%	18%	6%	9%
p value	-	<0.001	0.007	0.016

Improvements in functional and clinical measurements from baseline to 2 years

Outcome	n	Baseline	n	1 year	p value	n	2 years	p value
Proportion of patients with NHYA functional class 1 or 2	30	17%	23	78%	<0.001	17	82%	0.002
Proportion of patients without oedema	30	37%	23	70%	0.073	17	88%	0.063
6-minute walk distance in metres, mean (SD)	26	248 (113)	19	296 (130)	<0.053	13	309 (119)	0.058
Overall Kansas City Cardiomyopathy Questionnaire score, mean (SD)	30	45 (23)	23	64 (23)	<0.001	20	63 (26)	0.046

Septolateral annular diameter (mm)

- Baseline=41.9 (n=26)
- Discharge=36.2 (n=22), p<0.001 compared with baseline
- 1 year=36.5 (n=19)
- 2 years=35.2 (n=14)

Echocardiographic variables at baseline, 1 year, and 2 years, mean (SD)

Variable	Base-line	n	1 year	n	Change	p value	2 years	n	Change	p value
Left ventricular ejection fraction, %	57.5 (10.8)	28	59.3 (6.4)	21	2.5 (8.3)	0.206	57.7 (7.0)	16	0.2 (7.6)	0.907
Estimated systolic pulmonary artery pressure, mmHg	35.9 (10.5)	29	38.1 (9.0)	23	1.4 (9.9)	0.513	39.5 (10.9)	15	4.4 (11.2)	0.150
PISA EROA, cm^2	0.78 (0.49)	25	0.37 (0.18)	16	-0.36 (0.40)	0.004	0.34 (0.23)	11	-0.57 (0.47)	0.004
Mean vena contracta, cm	1.23 (0.40)	25	0.85 (0.30)	18	-0.36 (0.41)	0.005	0.79 (0.51)	10	-0.55 (0.40)	0.004
tricuspid valve annulus mid-diastolic septolateral diameter, mm	43.4 (5.0)	30	36.9 (4.0)	21	-6.8 (4.5)	<0.001	34.2 (4.4)	12	-9.8 (4.2)	<0.001
tricuspid valve annulus end-diastolic septolateral diameter, mm	41.9 (4.6)	26	36.5 (4.6)	19	-5.7 (3.2)	<0.001	35.2 (4.6)	14	-6.6 (6.7)	0.006
Right ventricle end-diastolic diameter (mid), cm	3.8 (0.6)	29	3.5 (0.5)	18	-0.1 (0.5)	0.294	3.2 (0.6)	15	-0.4 (0.6)	0.014
Fractional area change, %	35.8 (6.5)	29	35.4 (5.3)	16	-0.4 (5.7)	0.795	37.9 (6.9)	15	2.5 (6.2)	0.142
Right ventricle tricuspid annular plane systolic excursion, cm	1.4 (0.3)	22	1.4 (0.4)	22	-0.1 (0.3)	0.462	1.4 (0.4)	16	0.1 (0.2)	Not significant
Right atrial volume, mL	127 (45)	30	116 (46)	20	-14 (36)	0.103	104 (49)	15	-18 (41)	0.112

Key safety findings

Adverse events

Event	1 year, n (%)	2 years, n (%)
Death	5 (16.7)	8 (26.7)
Stroke	1 (3.3)	2 (6.7)
Myocardial infarction	0	0
Bleeding complications (extensive, life-threatening, or fatal)	6 (20.0)	7 (23.3)
Coronary complications	3 (10.0)	3 (10.0)
Device-related secondary intervention	1 (3.3)	2 (6.7)
Device-related cardiac surgery	0	0
Renal failure	1 (3.3)	1 (3.3)
Conduction system disturbance	1 (3.3)	2 (6.7)
Ventricular arrhythmia	3 (10.0)	3 (10.0)

Of the 8 deaths, there were 6 non-cardiovascular deaths beyond 30 days (progression of chronic lymphatic leukaemia, respiratory failure, worsening of chronic renal failure, multifactorial reasons primarily pulmonary artery embolism, acute renal failure, and metastatic liver cancer).

Study 4 Körber M (2021)

Study details

Study type	Case series
Country	Germany
Recruitment period	October 2018 to February 2020
Study population and number	n=60 Patients with severe secondary tricuspid regurgitation
Age and sex	Median 76 years; 62% (37/60) female
Patient selection criteria	Patients with symptomatic, at least severe tricuspid regurgitation and secondary aetiology were eligible for inclusion. All patients were discussed in an interdisciplinary heart team and deemed inoperable because of high surgical risk. Exclusion criteria included: annular dimensions more than 128 mm device length (cardiac CT), heavily calcified annulus or leaflets, and proximity of right coronary artery less than 6.5 mm in more than 40% of the perimeter. The latter was amended to less than 5 mm in more than 3 segments mid-2019 and was omitted in 2020. Patients who had already participated in the TRI-REPAIR trial were excluded from this study
Technique	Device: Cardioband tricuspid valve reconstruction system (Edwards Lifesciences, US) The largest implant size was used for most patients.
Follow up	Median clinical follow up was 92 days (IQR 43 to 203 days).
Conflict of interest/source of funding	5 of the 11 authors have received research grants and speaker honoraria from Edwards Lifesciences Services, Germany.

Analysis

Follow-up issues: Vital status for the 30 day periprocedural period was available for all 60 patients. During this period, 4 patients died. Information on survival status at 6-month follow up was available for 37 patients (62%).

Study design issues: Retrospective case series of the first 60 patients to have the procedure at 4 high-volume centres. The primary efficacy end point (procedural success) was defined as technical success and tricuspid regurgitation reduction of 2 or more grades at discharge. Tricuspid regurgitation severity was graded using a 5-class grading scheme: mild, moderate, severe, massive, and torrential. Technical success was defined as successful delivery, deployment and positioning of device, absence of procedural mortality, and freedom from emergency surgery related to the device. Device success at follow up was defined as the absence of procedural mortality or stroke, proper placement of device, freedom from unplanned surgery or interventional procedures related to the device, improvement of at least 1 grade in tricuspid regurgitation, absence of device-specific technical failure or complications (specifically damage to tricuspid leaflets, pericardial effusion, and coronary complications), and without significant tricuspid valve stenosis. In the context of device success, only coronary complications with a potentially persistent damage (vessel perforation with active bleeding because of anchor penetration) or needing therapy were considered. The primary safety end point was the overall rate of major adverse events, defined as a composite end point of death, myocardial infarction, need for urgent

cardiothoracic surgery, and stroke through postprocedural day 30. Clinical and functional outcome measures comprised cause specific mortality and change in NYHA functional class.

Study population issues: The median EuroScore 2 was 3.9% (IQR 2.2 to 8.1) and the mean was 6.3%. At baseline, 98% of patients were taking diuretics and 41% were taking an aldosterone antagonist. Most patients (82%) were in NYHA class 3 or 4 and 80% had peripheral oedema. The mean coaptation gap was 6.9 mm. The mean NT-proBNP level at baseline was 2,769 ng/L.

Key efficacy findings

- Number of patients analysed: 60
- Technical success=96.7% (58/60)
- Procedural success=45.0% (27/60)
- Technical success and reduction of tricuspid regurgitation of 1 grade or more=88.3% (53/60)
- Patients who met the primary efficacy end point presented with greater vena contracta diameter at baseline (14.9 compared with 11.3 mm, p=0.004) and more often with torrential tricuspid regurgitation (44.4% compared with 3%, p<0.001) but did not differ in other baseline characteristics.
- The septolateral diameter of the tricuspid annulus was reduced by a mean of 10.5 mm.
- The mean coaptation gap after cinching was 1.4 mm, representing a mean reduction of 5.5 mm.
- Device success at 30 days=73.2% (41/56)

Improvements in tricuspid regurgitation severity (echocardiographic paired analyses at baseline, discharge, and 30 days), proportion of patients, p<0.001

Severity	Baseline, n=59	Discharge, n=59	Baseline, n=43	30 days, n=43
Mild	0	8.5%	0	20.9%
Moderate	0	52.5%	0	46.5%
Severe	47.5%	35.6%	53.5%	30.2%
Massive	30.5%	1.7%	23.3%	0
Torrential	22%	1.7%	23.3%	2.3%

Improvements in NYHA functional class (paired analysis of functional improvement after 30 days), proportion of patients, n=48, p<0.001

NYHA functional class	Baseline	30 days
1	2.1%	22.9%
2	18.8%	58.3%
3	70.8%	18.8%
4	8.3%	0

Key safety findings

30-day events

- Primary safety end point (death, myocardial infarction, need for urgent cardiothoracic surgery, stroke)=6.7% (4/60).
  - 1 patient needed surgical thoracotomy for intramural bleeding.
  - 1 patient needed open heart surgery because of accidental puncture of the right ventricle during pericardiocentesis for pericardial effusion. Pericardial effusion was present before the intervention but progressed afterward with need for intervention 2 days after the procedure.
  - 2 patients died in hospital. One patient with poor left ventricular function at baseline needed persistent vasopressor support after the procedure, which was first attributed to pharyngeal bleeding associated with transoesophageal echocardiography and tracheal tube. Four days after the procedure, the patient developed pulseless electric activity and resuscitation efforts were unsuccessful. The other patient died on postoperative day 10. The patient had a laryngeal injury related to general anaesthesia and transoesophageal echocardiography and had to stay ventilated after the procedure. The patient developed pneumonia and enteritis leading to toxic megacolon and died from septic shock shortly after having abdominal surgery. There was no indication of device malfunction.
- Death=3.3% (2/60)
  - 1 patient died 15 days after the procedure in a palliative setting after being discharged.
  - 1 patient died 3 weeks after the procedure because of a severe acute respiratory syndrome–coronavirus disease 2019 (COVID-19) infection.
- Haemodynamically relevant arrhythmia=11.7% (7/60)
- Need for new pacemaker=3.3% (2/60)
- Acute renal failure=11.7% (7/60)
- Access site-related bleeding=1.7% (1/60)

Bleeding complications

- Overall=11.7% (7/60)
- Major bleeding=5.0% (3/60)
- Extensive bleeding=5.0% (3/60)
- Life-threatening bleeding=1.7% (1/60)
- Fatal bleeding=0
- Blood transfusion=20.0% (12/60)
- Device-related open heart surgery=1.7% (1/60)
- Need for urgent open heart surgery=3.3% (2/60)

Coronary complications (patients may have had more than 1)

- Right coronary artery perforation=5.0% (3/60) (2 were treated conservatively)
- Right coronary artery stent implantation=11.7% (7/60)
- Cardiac tamponade=3.3% (2/60)
- Myocardial infarction=1.7% (1/60)
- Stroke/transient ischaemic attack=0

Study 5 Davidson C (2021)

Study details

Study type	Case series
Country	US
Recruitment period	August 2018 to November 2019
Study population and number	n=30 Patients with severe or greater symptomatic functional tricuspid regurgitation
Age and sex	Mean 77 years; 80% (24/30) female
Patient selection criteria	Patients aged 18 years or over with moderate or greater chronic functional tricuspid regurgitation who were symptomatic despite medical therapy including diuretics were included in the study. The multidisciplinary local heart team determined whether transcatheter tricuspid reconstruction was clinically appropriate for the patient. The criteria for exclusion were tricuspid valve anatomy precluding proper device deployment and function including primary tricuspid valve disease, previous tricuspid valve repair or replacement, presence of transtricuspid pacemaker or defibrillator leads that impinge the tricuspid valve leaflets as evaluated by echocardiography or were implanted within the last 90 days, left ventricular ejection fraction less than 25%, severe right ventricular dysfunction as assessed by the echocardiography core laboratory, kidney dysfunction with estimated glomerular filtration rate 25 ml/min/1.73 m^2 or less or chronic dialysis, and chronic anaemia not corrected by transfusion.
Technique	Device: Cardioband tricuspid valve reconstruction system (Edwards Lifesciences, US) Most patients had the largest available implant size.
Follow-up	30 days
Conflict of interest/source of funding	Study was funded by Edwards Lifesciences. 5 authors have received grant support or consulting fees from Edwards Lifesciences. 1 has served as a speaker and consultant for Edwards Lifesciences and is the Chief Scientific Officer for the Echocardiography Core Laboratory at the Cardiovascular Research Foundation for multiple industry sponsored trials, for which she has received no direct industry compensation. 4 authors are employees of Edwards Lifesciences.

Analysis

Study design issues: Single-arm, multicentre, prospective early feasibility study. The safety endpoint was major adverse events at 30 days defined as a composite of cardiovascular mortality, myocardial infarction, stroke, tamponade, right coronary artery perforation, conduction disorders needing a new permanent pacemaker, new need for renal replacement therapy, severe bleeding, reintervention related to study device, and major access site and vascular complications that needed intervention. Device success was defined as device deployed as intended and the delivery system successfully retrieved as intended at the time of the patient's exit from the cardiac catheterisation laboratory.

Study population issues: At baseline, NYHA functional class was 3 or 4 in 21 (70%) patients. Comorbidities included atrial fibrillation or flutter (97%), pulmonary hypertension (73%), hypertension (62%), prior pacemaker, implantable cardioverter defibrillator or cardiac resynchronisation therapy (23%), prior myocardial infarction (13%), diabetes (30%) and kidney dysfunction (37%). All patients had at least severe tricuspid regurgitation including 73% massive or torrential tricuspid regurgitation with average tricuspid septolateral diameter of 45.2 mm and left ventricular ejection fraction of 58.4%.

Key efficacy findings

- Number of patients analysed: 30
- Device success=93.3% (28/30); 2 patients did not receive the device as intended because of anchor disengagements that happened during contraction with no clinical sequelae.
- Mean length of hospital stay=4.6 days
- The end-diastolic tricuspid septolateral annular diameter statistically significantly decreased from 45.2 mm to 38.8 mm at discharge ($p<0.001$) and was stable at 30 days to 39.5 mm ($p<0.001$) in paired analysis.
- At 30 days, 85% of patients had at least 1 grade reduction and 56% of patients had at least a 2 grade reduction in tricuspid regurgitation.
- Kansas City Cardiomyopathy Questionnaire score results improved from 53 points at baseline to 69 points at 30 days ($p<0.001$).
- The proportion of patients with NYHA functional class 1 or 2 improved from 32% at baseline to 75% at 30 days ($p<0.001$).
- The 6-minute walk distance at baseline was 245.8 metres and remained unchanged at 30 days (247.0 metres; $p=0.926$).

Echocardiographic results, paired analyses, mean (SD)

Variable	Baseline	30 days	n	p value
Left ventricular ejection fraction, %	58.6 (5.8)	58.5 (7.1)	27	0.904
Systolic pulmonary artery pressure, mmHg	37.8 (10.9)	40.3 (12.0)	27	0.259
PISA EROA, cm^2	0.84 (0.39)	0.55 (0.41)	21	<0.001
Mean vena contracta, cm	1.48 (0.48)	0.91 (0.44)	25	<0.001
Right ventricle end-diastolic diameter (mid), cm	4.1 (0.5)	3.7 (0.5)	26	<0.001
Right ventricle end-diastolic diameter (base), cm	5.6 (0.6)	5.2 (0.7)	27	<0.001
Right ventricular fractional area change, %	41.6 (5.2)	38.1 (7.2)	26	0.011
Right atrial volume, mL	134.6 (41.6)	105.7 (42.5)	28	<0.001
Inferior vena cava diameter, cm	2.8 (0.8)	2.4 (0.9)	27	0.002

Improvements in tricuspid regurgitation severity from baseline to 30 days, proportion of patients, p<0.001

Severity	Baseline, n=27	30 days, n=27
Mild	0	15%
Moderate	0	30%
Severe	26%	33%
Massive	19%	11%
Torrential	56%	11%

Key safety findings

Major adverse events at 30 days (adjudicated by Clinical Events Committee)

- Cardiovascular mortality=0
- Myocardial infarction=0
- Stroke=0
- Cardiac tamponade=3.3% (1/30)
- Right coronary artery perforation=0
- Arrhythmia and conduction disorders needing permanent pacing=0
- New need for renal replacement therapy=0
- Severe bleeding=23.2% (7/30)
  - Fatal=0
  - Life-threatening=2
  - Extensive=1
  - Major=4
- Major access site and vascular complications needing intervention=0
- Reintervention on the previously implanted study device=0

Other events

- All-cause mortality=0

Study 6 Hahn R (2017)

Study details

Study type	Case series (SCOUT trial)
Country	US (4 sites)
Recruitment period	November 2015 to June 2016
Study population and number	n=15 Patients with NYHA functional class 2 or higher and at least moderate functional tricuspid regurgitation
Age and sex	Mean 73.6 years; 86.7% (13/15) female
Patient selection criteria	Inclusion criteria: patients with NYHA functional class 2 or higher and greater than or equal to moderate functional tricuspid regurgitation, with no indication of left-sided valve surgery. Exclusion criteria included older than 85 years, pacemaker implantation, systolic pulmonary artery pressure above 60 mm Hg, left ventricle ejection fraction less than 35%; tricuspid annular plane systolic excursion less than 13 mm; or tricuspid EROA greater than 1.2 cm^2.
Technique	Device: Trialign system (Mitralign Inc., US)
Follow-up	30 days
Conflict of interest/source of funding	The first author is a speaker for Edwards Lifesciences, Abbott Vascular, Boston Scientific, and GE Medical; is an unpaid national principal investigator for the SCOUT Trial; and is an uncompensated director of Echo Core for multiple industry-sponsored trials. Seven authors are consultants, proctors or have received research grants or support from companies including Medtronic, Boston Scientific, Edwards Lifesciences, Abbott Vascular, St. Jude Medical, Siemens Healthcare, GE Medical, Dura Biotech and Atricure. One author is a speaker for Medtronic, Edwards Lifesciences, and Abbott Vascular; and holds stock/ownership in BayLabs. One author is an employee of and holds ownership stock in Mitralign. One author holds equity in Thubrikar Aortic Valve and BioTrace.

Analysis

Study design issues: Prospective, single-arm, multicentre, early feasibility study. The primary safety and performance endpoint was technical success at 30 days. Patient quality of life was assessed by using NYHA functional class assessment, 6-minute walk test results, and Minnesota Living with Heart Failure Questionnaire responses.

Study population issues: All patients were symptomatic and in NYHA functional class 2 (33%) or 3 (67%). Most patients had a history of hypertension (80%) or pulmonary hypertension (60%) or had a previous mitral valve intervention (67%) and were in atrial fibrillation (67%). All patients were taking diuretic agents, and most (93%) were also taking a betablocker agent.

Other issues: The device used in this study is no longer available. This study is included in the systematic review by Montalto et al. (2020).

Key efficacy findings

- Number of patients analysed: 15
- All devices were implanted in the correct position, with successful plication.
- Overall technical success at 30 days=80.0% (12/15); in 3 patients, there was echocardiographic evidence of a single pledget detachment from the annulus. The pledgets stayed attached to the remaining pledgeted suture and did not need reintervention or result in adverse events.
- No unplanned or emergency surgery or reintervention related to the device or access procedure within 30 days=93.3% (14/15)

Quality of life outcomes for intention-to-treat patients (n=15)

Outcome	Baseline	30 days	Change	p value
NYHA class 1, n (%)	0 (0)	7 (46.7)	-	0.001
NYHA class 2, n (%)	5 (33.3%)	8 (53.3)	-	
NYHA class 3, n (%)	10 (66.7%)	0 (0)	-	
NYHA class 4, n (%)	0 (0)	0 (0)	-	
Minnesota Living with Heart Failure Questionnaire score, mean (SD)	47.4 (17.6)	20.9 (14.8)	-26.5 (20.4)	<0.001
6-minute walk test (metres), mean (SD)	245.2 (110.1)	298.0 (107.6)	52.9 (72.6)	0.008

In the 3 patients with single-pledget detachment, there were no statistically significant differences between baseline and 30 day values for NYHA functional class**,** Minnesota Living with Heart Failure Questionnaire score and 6MWT**.**

Echocardiographic results in the intention-to-treat group, mean (SD)

Variable	Baseline	30 days	change	n	p value
Left ventricular ejection fraction, %	59.9 (11.5)	59.7 (11.9)	0.4 (7.6)	13	0.853
Right ventricular tricuspid annular plane systolic excursion, cm	1.6 (0.4)	1.6 (0.4)	0 (0.6)	12	0.456
left ventricular outflow tract Doppler stroke volume, ml	67.1 (18.1)	72.8 (23.2)	8.5 (13.4)	13	0.041
Tricuspid regurgitation vena contracta, cm	1.3 (0.3)	1.1 (0.4)	-0.2 (0.4)	14	0.133
Estimated systolic pulmonary artery pressure, mmHg	43.6 (9.3)	40.9 (9.5)	-2.7 (7.0)	15	0.222
PISA EROA, cm^2	0.51 (0.16)	0.41 (0.27)	-0.11 (0.3)	15	0.192
Tricuspid valve annular diameter, cm	4.0 (0.5)	3.9 (0.5)	-0.2 (0.4)	15	0.017

Tethering distance, cm	0.7 (0.2)	0.6 (0.1)	-0.1 (0.2)	15	0.037
2-dimensional tricuspid valve annulus area, cm^2	12.3 (2.8)	11.5 (2.5)	-0.7 (1.4)	15	0.061
Tricuspid regurgitant volume, ml	86.0 (21.3)	78.7 (53.3)	-2.7 (39.5)	13	0.811
Quantitative Doppler tricuspid regurgitation EROA, cm^2	0.93 (0.27)	0.93 (0.74)	0 (0.56)	14	0.530

Change from baseline to 30 days computed using paired data

Echocardiographic results in the as treated group, mean (SD)

Variable	Baseline	30 days	change	n	p value
Left ventricular ejection fraction, %	59.8 (12.7)	59.1 (12.9)	-0.3 (7.3)	11	0.904
Right ventricular tricuspid annular plane systolic excursion, cm	1.7 (0.4)	1.6 (0.2)	-0.1 (0.4)	10	0.308
left ventricular outflow tract Doppler stroke volume, ml	63.6 (17.9)	71.5 (25.7)	11.7 (13.2)	10	0.021
Tricuspid regurgitation vena contracta, cm	1.3 (0.4)	1.0 (0.3)	-0.3 (0.3)	11	0.022
Estimated systolic pulmonary artery pressure, mmHg	44.1 (10.2)	42.0 (9.5)	-2.1 (6.6)	12	0.327
PISA EROA, cm^2	0.51 (0.18)	0.32 (0.18)	-0.2 (0.25)	12	0.02
Tricuspid valve annular diameter, cm	4.0 (0.5)	3.8 (0.6)	-0.2 (0.4)	12	0.038
Tethering distance, cm	0.7 (0.1)	0.6 (0.1)	-0.1 (0.2)	12	0.116
2-dimensional tricuspid valve annulus area, cm^2	12.3 (3.1)	11.3 (2.7)	-1.0 (1.3)	12	0.019
Tricuspid regurgitant volume, ml	79.6 (17.5)	57.1 (29.0)	-18.1 (27.2)	10	0.065
Quantitative Doppler tricuspid regurgitation EROA, cm^2	0.85 (0.22)	0.63 (0.29)	-0.22 (0.29)	11	0.045

Change from baseline to 30 days computed using paired data

Key safety findings

- There were no deaths, strokes, bleeding, tamponade, or valve reintervention.
- In 1 patient, the completion angiogram showed tenting of the distal right coronary artery in the region of the plication with narrowing confirmed by fractional flow reserve of 0.57, which was associated with ST-segment elevations on electrocardiogram. These changes resolved with right coronary stent placement with post-procedure peak troponin concentration of 1.79 mg/l, which decreased to 0.7 mg/l.

Validity and generalisability of the studies

- No randomised controlled trials or non-randomised comparative studies were identified.
- Patients from the US and Europe were included.
- Most studies used the Cardioband device. One study used the Trialign system, which is no longer available.
- The studies included the first patients to have the procedure.
- Most studies only reported 30-day outcomes. The longest mean follow up was 604 days, in a single-arm study of 30 patients (Nickenig, 2021).
- Four studies included patients who had moderate or worse tricuspid regurgitation and 1 included only those who had severe or worse tricuspid regurgitation (Korber, 2021).

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Percutaneous mitral valve leaflet repair for mitral regurgitation. NICE interventional procedures guidance 649 (2019). Available from http://www.nice.org.uk/guidance/IPG649
- Percutaneous mitral valve annuloplasty. NICE interventional procedures guidance 352 (2010). Available from http://www.nice.org.uk/guidance/IPG352

NICE guidelines

- Heart valve disease presenting in adults: investigation and management. NICE guideline 208 (2021). Available from http://www.nice.org.uk/guidance/NG208
- Chronic heart failure in adults: diagnosis and management. NICE guideline 106 (2018). Available from http://www.nice.org.uk/guidance/NG106

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

One professional expert questionnaire for transcatheter tricuspid valve annuloplasty for tricuspid regurgitation was submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 1 company who manufactures a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- This overview includes evidence on transcatheter ring-based or suture-based annuloplasty devices. Evidence on transcatheter leaflet modification devices

has been excluded where possible because it is covered by a separate overview.

- Ongoing trials:
  - Transcatheter Repair of Tricuspid Regurgitation With Edwards Cardioband TR System Post Market Study (TriBAND) (NCT03779490); cohort study; n=150; end date June 2026
  - Berlin Registry of Right Heart Interventions (NCT04570163); registry; n=100; end date Dec 2023
  - International Multisite Transcatheter Tricuspid Valve Therapies Registry (NCT03416166); registry; n=269; end date Nov 2026

References

1. Montalto C, Sticchi A, Crimi G et al. (2020) Functional and echocardiographic improvement after transcatheter repair for tricuspid regurgitation: a systematic review and pooled analysis. JACC Cardiovascular Interventions 13: 2719–29
2. Nickenig G, Friedrichs KP, Baldus S et al. (2021) Thirty-day outcomes of the Cardioband tricuspid system for patients with symptomatic functional tricuspid regurgitation: The TriBAND study. EuroIntervention doi: 10.4244/EIJ-D-21-00300
3. Nickenig G, Weber M, Schuler R et al. (2021b) Tricuspid valve repair with the Cardioband system: two-year outcomes of the multicentre, prospective TRI-REPAIR study. EuroIntervention 16: e1264-e1271
4. Körber MI, Baldus S, Pfister R et al. (2021) Transcatheter treatment of secondary tricuspid regurgitation with direct annuloplasty: results from a multicenter real-world experience. Circulation: Cardiovascular Interventions 009891
5. Davidson CJ, Lim DS, Smith RL et al. (2021) Early feasibility study of Cardioband tricuspid system for functional tricuspid regurgitation: 30-day outcomes. JACC Cardiovascular Interventions 14: 41–50
6. Hahn RT, Meduri CU, Davidson CJ et al. (2017) Early feasibility study of a transcatheter tricuspid valve annuloplasty: SCOUT trial 30-day results. Journal of the American College of Cardiology 69: 1795–806

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	02/09/2021	Issue 9 of 12, September 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	02/09/2021	Issue 9 of 12, September 2021
International HTA database	02/09/2021	-
MEDLINE (Ovid)	02/09/2021	1946 to September 01, 2021
MEDLINE In-Process (Ovid) & MEDLINE ePubs ahead of print (Ovid)	02/09/2021	September 01, 2021
EMBASE (Ovid)	02/09/2021	1974 to 2021 September 01
Embase Conference (Ovid)	02/09/2021	1974 to 2021 September 01

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Literature search strategy

Number	Search term
1	Tricuspid Valve Insufficiency/
2	((Tricuspid or right atrioventricular) adj4 (insufficien* or incompeten* or regurgitat* or disease* or dysfunct* or malfunct* or degenerat* or fail* or leak* or backflow* or back-flow* or flow-back*)).tw.
3	(TR or FTR).tw.
4	or/1-3
5	Cardiac Valve Annuloplasty/
6	(Transcatheter* adj4 tricuspid adj4 valve* adj4 (annuloplast* or repair* or reconstruct* or re-construct* or clos* or device* or interven* or therap* or band* or clip*)).tw.
7	(Percutaneous* adj4 tricuspid adj4 valve* adj4 (annuloplast* or repair* or reconstruct* or re-construct* or clos* or device* or interven* or therap* or band* or clip*)).tw.
8	(direct* adj4 annuloplast*).tw.
9	(Annul* adj4 (repair* or reduc*)).tw.
10	or/5-9
11	4 and 10
12	Cardioband*.tw.
13	11 or 12
14	(Triclip* or MitraClip* or Tricinch* or Trialign* or Gate system* or PASCAL or FORMA).tw.
15	4 and 14
16	11 or 15
17	animals/ not humans/
18	13 not 17

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Reviews that were published before 2020 have not been included.

Additional papers identified

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Arnold M, Haug J, Landendinger M (2021) Tricuspid annuloplasty: transcatheter approaches. Current Cardiology Reports 23: 139	Review	Transcatheter techniques for tricuspid annuloplasty have shown to be safe and the results to be reproducible in the early clinical experience. Surprisingly already minor changes in tricuspid annular dimensions seem to translate into relevant improvement of symptoms and functional status of patients with functional tricuspid regurgitation. This might be because patients with a higher severity of tricuspid regurgitation at a later stage of the disease were selected for the interventional treatment.	Review
Arora L, Krishnan S, Subramani S et al. (2021) Functional tricuspid regurgitation: analysis of percutaneous transcatheter techniques and current outcomes.	Review	Patients currently having transcatheter intervention are typically at high surgical risk and have severe functional tricuspid regurgitation in the absence of severely impaired right ventricular systolic function. Although	Review

Journal of Cardiothoracic and Vascular Anesthesia 35: 921–31		there are limitations to the transcatheter options currently available for patients, the initial data show that these existing devices are relatively safe with good results and functional improvements. Further investigation is needed to optimise indications, patient selection, anatomic eligibility, long-term outcome, and procedural timing for each device category.	
Donatelle M, Ailawadi G (2020) Transcatheter tricuspid valve repair: Bringing the forgotten valve into the spotlight. The Journal of Thoracic and Cardiovascular Surgery 160: 1467–73	Review	It is evident that patients with significant tricuspid regurgitation must be identified earlier and referred to reference centres with expertise in the medical, surgical, as well as transcatheter approaches for treating the tricuspid valve specifically before the onset of torrential tricuspid regurgitation or severe right-sided heart failure symptoms.	Review
Gercek M, Rudolph V, Arnold M et al. (2021) Transient acute right coronary artery deformation during transcatheter interventional tricuspid repair with the Cardioband tricuspid system. EuroIntervention 17: 81–7	Case series n=14	Right coronary artery deformation is relatively frequent after interventional tricuspid annuloplasty but appears to be completely reversible in the absence of flow impairment or vascular damage. Based on early experience watchful waiting is the most appropriate strategy to avoid unnecessary coronary interventions.	Small case series, focusing on the persistence and clinical significance of acute right coronary artery deformation.
Gupta T, Wyler von Ballmoos MC, Goel	Review	Early results with both repair and replacement	Review.

SS (2021) Transcatheter treatment of severe tricuspid regurgitation. Current Opinion in Cardiology 36: 525–37		technologies have shown promising results. Ongoing pivotal studies will shed light on prognostic benefits compared with medical therapy and hopefully provide long-term data. Some important future perspectives in the field include improved preprocedural planning and intraprocedural imaging, standardisation of echocardiographic measures and clinical endpoints for device trials; disease stage and anatomy tailored approach; and defining the optimal timing of treatment.	
Kavsur R, Hupp-Herschel HE, Sugiura A et al. (2021) Prognostic significance of the get with the guidelines-heart failure (GWTG-HF) risk score in patients undergoing trans-catheter tricuspid valve repair (TTVR). Heart Vessels https://doi.org/10.1007/s00380-021-01874-3	Case series n=181 (14% annuloplasty)	The 'get with the guidelines-heart failure' score serves as a risk assessment tool in patients with heart failure and concomitant severe tricuspid regurgitation who have transcatheter tricuspid valve repair to predict 1 year mortality and hospitalisations for heart failure. The inclusion of NT-proBNP led to an improvement of the score's predictive power, emphasising its use in this patient population. Overall, in this present study, the procedure was feasible in most patients and led to a substantial improvement of tricuspid regurgitation and NYHA classes.	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.
Kolte D, Elmariah S (2020) Current state of transcatheter	Review	The short- and mid-term data on the safety and efficacy of various	Review

tricuspid valve repair. Cardiovascular Diagnosis and Therapy 10: 89–97		transcatheter tricuspid valve therapies are encouraging. Procedural and clinical outcomes are expected to improve in the coming years with technological advancement, newer device iterations, and increased experience in this field. Appropriate patient selection, optimal timing of intervention, and evaluation of long-term outcomes and device durability will be key in ongoing and future studies.	
Lauri FM, Fernandez-Golfin C, Zamorano JL et al. (2021) Coronary compression caused by extrinsic adventitial damage: case of an early complication of trans-catheter tricuspid annuloplasty with cardioband device. European Heart Journal doi:10.1093/eurheartj/ehab564	Case report n=1	A large haematoma causing severe extravascular compression was identified during the procedure and a drug eluting stent was implanted. Intravascular imaging elucidated for the first time that one of the mechanisms of coronary occlusion associated to Cardioband annuloplasty procedure is the extrinsic adventitial damage produced by the anchors that leads to flow-limiting extra-adventitial haematoma.	Case report of a bleeding complication.
Miura M, Vicentini L, Taramasso M et al. (2021) Tangled wire in a Dacron band during Cardioband transcatheter tricuspid annuloplasty-How to solve the problem. Catheterization and Cardiovascular	Case report n=1	During the procedure, it was impossible to connect the distal tip of the size adjustment tool and the Dacron band because the cinching wire was tangled around the Dacron band. The issue was resolved without surgical intervention.	Case report of a technical issue.

Interventions 97: e724–26			
Miura M, Alessandrini H, Alkhodair A et al. (2020) Impact of massive or torrential tricuspid regurgitation in patients undergoing transcatheter tricuspid valve intervention. Cardiovascular Interventions 13: 1999–2009	Subanalysis of TriValve registry n=333 Follow up: median 237 days	Baseline massive or torrential tricuspid regurgitation is associated with an increased risk for all-cause mortality and rehospitalisation for heart failure 1 year after transcatheter tricuspid valve intervention. Procedural success is related to better outcomes, even in the presence of baseline massive or torrential tricuspid regurgitation.	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.
Muntane-Carol G, Philippon F, Puri R et al. (2021) Transcatheter tricuspid valve intervention in patients with previous left valve surgery. Canadian Journal of Cardiology 37: 1094–1102	Subanalysis of TriValve registry n=82	In patients with previous left valve surgery, transcatheter tricuspid valve intervention was associated with high rates of procedural success and low early mortality. However, about a third of patients needed rehospitalisation or died at midterm follow-up.	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.
Muntane-Carol G, Philippon F, Puri R et al. (2021) Transcatheter tricuspid valve intervention in patients with right ventricular dysfunction or pulmonary hypertension: insights from the TriValve registry. Circulation: Cardiovascular Interventions 184–92	Subanalysis of TriValve registry n=300	The transcatheter tricuspid valve intervention was associated with high procedural success and a relatively low in-hospital mortality, along with improvements in functional status. However, about 1 out of 5 patients died after a median follow-up of 6 months, with hepatic congestion and renal dysfunction. The lack of procedural success determined an increased risk. These results may improve the clinical evaluation of transcatheter tricuspid valve intervention	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.

		candidates and would suggest a closer follow up in those at increased risk.	
Nagaraja V, Kapadia SR, Miyasaka R et al. (2020) Contemporary review of percutaneous therapy for tricuspid valve regurgitation. Expert Review of Cardiovascular Therapy 18: 209–18	Review	The early data available thus far on percutaneous tricuspid repair and replacement is promising and demonstrates modest reductions in tricuspid regurgitation along with improvement in the quality of life. Different from transcatheter aortic valve intervention, percutaneous tricuspid repair and replacement does not have long-term data. The lack of standardised protocols and definitions for enrolment and outcomes in these early tricuspid trials are a limitation.	Review
Nagaraja V, Mohananey D, Navia J et al. (2020) Functional tricuspid regurgitation: Feasibility of transcatheter interventions. Cleveland Clinic Journal of Medicine 87: 4–14	Review	The published data so far on percutaneous therapies demonstrate promising results in the form of a reasonable reduction in tricuspid regurgitation along with substantial improvement in the quality of life. The transcatheter device technology is currently evolving for the tricuspid valve. Patient selection based on anatomy for the appropriate device technology is imperative. Improved device technology best matched to patient factors is likely to increase the array of options available.	Review
Nickenig G, Weber M, Schueler R et al. (2019) 6-month	Case series (TRI-REPAIR study)	The system performed as intended and appeared to be safe in patients with	A more recent publication from the same

outcomes of tricuspid valve reconstruction for patients with severe tricuspid regurgitation. Journal of the American College of Cardiology 73: 1905–15	n=30 Follow up: 6 months	symptomatic and moderate to severe functional tricuspid regurgitation. Significant reduction of tricuspid regurgitation through decrease of annular dimensions, improvements in heart failure symptoms, quality of life, and exercise capacity were observed. Further studies are warranted to validate these initial promising results.	study is included. This study is included in the systematic review by Montalto et al. (2020).
Rahgozar K, Ho E, Goldberg Y et al. (2021) Transcatheter tricuspid valve repair and replacement: a landscape review of current techniques and devices for the treatment of tricuspid valve regurgitation. Expert Review of Cardiovascular Therapy 19: 399–411	Review	There is currently an unmet clinical need in the treatment of severe tricuspid regurgitation, but this paradigm is slowly shifting and the number of transcatheter tricuspid valve interventions is climbing each year. Promising early results with many of the devices and techniques available have shown the feasibility, safety, and short-term efficacy of transcatheter tricuspid valve repair.	review
Reddy VY, Petru J, Neuzil P et al. (2020) First-in-human percutaneous circumferential annuloplasty for secondary tricuspid regurgitation. JACC: Case Reports 2: 2176–82	Case report n=1 Follow up: 1 year	Description of the first fully percutaneous implantation of a circumferential, semirigid annuloplasty ring to treat massive secondary tricuspid regurgitation. The implanted ring maintained its adjusted diameter out to 1 year after adjustment, with no evidence of ring failure.	Case report.
Santalo-Corcoy M, Asmarats L, Arzamendi D et al. (2020) Catheter-	Review	Preliminary data has shown encouraging results, with significant functional and	Review

based treatment of tricuspid regurgitation: State of the art. Annals of Translational Medicine 8: 964		echocardiographic improvements. Further studies are greatly awaited to provide the necessary background to determine the optimal time and devices to intervene in this less symptomatic population, along with a deeper knowledge of the long-term performance of the variety of technologies currently used in different stages of the disease.	
Tanaka T, Kavsur R, Sugiura A et al. (2021) Prognostic impact of hepatorenal function in patients undergoing transcatheter tricuspid valve repair. Scientific Reports 11: 14420	Case series n=172	The model for end-stage liver disease excluding international normalized ratio score was associated with the risk of 1-year composite outcome, consisting of mortality and heart failure hospitalisation, after the procedure and may help the risk stratification in patients.	The focus of the study was to assess the prognostic significance of hepatorenal dysfunction. Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty.
Taramasso M, Gavazzoni M, Pozzoli A et al. (2020) Outcomes of TTVI in patients with pacemaker or defibrillator leads: data From the TriValve registry. JACC. Cardiovascular Interventions 13: 554–64	Subanalysis of TriValve registry n=470 Follow up: median 7 months	Transcatheter tricuspid valve intervention is feasible in selected patients with cardiac implantable electronic device leads and acute procedural success and short-term clinical outcomes are comparable to those observed in patients without a transtricuspid lead.	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.
Taramasso M, Alessandrini H, Latib A et al. (2019) Outcomes after current transcatheter tricuspid valve intervention: mid-term	TriValve registry n=312 Follow up: median 6.2 months	Transcatheter tricuspid valve intervention is feasible with different technologies, has a reasonable overall procedural success rate, and is associated with low	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty.

results from the international TriValve registry. JACC. Cardiovascular Interventions 12: 155–65		mortality and significant clinical improvement. Mid-term survival is favourable in this high-risk population. Greater coaptation depth is associated with reduced procedural success, which is an independent predictor of mortality.	Most patients had an edge-to-edge repair.
Taramasso M, Benfari G, van der Bijl P et al. (2019) Transcatheter versus medical treatment of patients with symptomatic severe tricuspid regurgitation. Journal of the American College of Cardiology 74: 2998–3008	Non-randomised comparative study (using data from TriValve registry) n=268 matched pairs Follow up: 1 year	In this propensity-matched case-control study, transcatheter tricuspid valve intervention was associated with greater survival and reduced heart failure rehospitalisation compared with medical therapy alone. Randomised trials should be done to confirm these results.	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.
Taramasso M, Hahn RT, Alessandrini H et al. (2017) The international multicenter TriValve registry: which patients are undergoing transcatheter tricuspid repair? JACC. Cardiovascular Interventions 10: 1982–90	TriValve registry n=106 Follow up: 30 days	Patients currently having transcatheter tricuspid valve therapy are mostly high risk, with a functional aetiology and very severe central regurgitation, and do not have severely impaired right ventricular function. Initial results suggest that transcatheter tricuspid valve therapy is feasible with different techniques, but clinical efficacy requires further investigation.	Only a small proportion of the patients had a transcatheter tricuspid valve annuloplasty. Most patients had an edge-to-edge repair.
Wosten M, Baldus S, Pfister R (2020) Case report: Transcatheter valve repair with Cardioband: A new treatment option for secondary tricuspid regurgitation in cardiac transplant patients. European	Case report n=1	Tricuspid regurgitation improved from massive to mild with a mean pressure gradient of 2.9 mmHg. This is the first case report of Cardioband implantation in tricuspid position in a heart transplant patient with the good technical and clinical result, suggesting that this	Case report of the procedure in a patient who had a previous heart transplant.

Heart Journal - Case Reports 4: ytaa451		technique might offer a treatment option to highly selected post-transplant patients with secondary severe tricuspid regurgitation and high surgical risk.	