Interventional procedure overview of transcatheter tricuspid valve implantation for tricuspid regurgitation

Contents

Table 1 Abbreviations

Abbreviation	Definition
CI	Confidence interval
EuroSCORE	European System for Cardiac Operative Risk Evaluation
IQR	Interquartile range
KCCQ	Kansas City Cardiomyopathy Questionnaire
LVEF	Left ventricular ejection fraction
NYHA	New York Heart Association
OMT	Optimal medical therapy
RV	Right ventricular
SD	Standard deviation
SE	Standard error
STS	Society of Thoracic Surgeons
STVR	Surgical triscuspid valve replacement
TR	Tricuspid regurgitation
TTE	Transthoracic echocardiography
TV	Tricuspid valve
TTVR	Transcatheter tricuspid valve implantation

The procedure, condition, current practice and unmet need

Information about the procedure, condition, current practice and unmet need is available in section 2 and 3 of NICE's interventional procedures consultation document on transcatheter tricuspid valve implantation for tricuspid regurgitation.

Clinical assessment tools

Most studies used a scoring system for assessing the risk of in-hospital mortality after cardiac surgery. The main ones are described below.

EuroSCORE 2

EuroSCORE 2 is a validated and commonly used risk model for assessing the perioperative risk of mortality after major cardiac surgery. It is based on patient

factors, such as age, sex and comorbidities, cardiac specific factors, such as NYHA class, and procedural factors, such as urgency. It is expressed as a percentage on a scale of 0 to 100%, with lower scores indicating a lower risk.

STS score

The STS score is a risk stratification model, composed of up to 30 variables that predict short- and long-term mortality and morbidity after cardiac surgery. In general, an STS predicted risk of surgical mortality of 4 to 8% is considered intermediate risk and 8% or greater is considered high risk.

TRI-SCORE

The TRI-SCORE is a risk score model for predicting in-hospital mortality after isolated tricuspid valve surgery on a native tricuspid valve, based on 8 preoperative parameters divided into 3 categories: clinical (age, NYHA functional class, right heart failure signs and daily dose of diuretics), biological (glomerular filtration rate and total bilirubin) and echocardiographic (left and right ventricular systolic function). The score ranges from 0 to 12, with lower scores indicating a lower risk.

Outcome measures

The main outcomes included procedural success, reduction in TR, functional outcomes, quality of life, echocardiographic outcomes, mortality and complications. Some of the measures used are detailed in the following paragraphs.

TR severity grading

TR severity is typically graded on a 5-grade scale based on echocardiographic parameters:

- Mild (1+)

- Moderate (2+)
- Severe (3+)
- Massive (4+)
- Torrential (5+)

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.

Echocardiographic outcomes

Most studies reported echocardiographic measurements, including linear dimensions and volumes. Other outcomes are described in the following paragraphs.

LVEF is the ratio of blood ejected during systole (stroke volume) to blood in the ventricle at the end of diastole (end-diastolic volume). A normal range is typically between 50 and 70%. Values below 30% are considered a severe reduction.

TAPSE is a measure of RV function that evaluates RV longitudinal systolic performance. TAPSE is measured using TTE and the systolic displacement of the annulus is recorded in millimetres. A lower TAPSE value, typically less than 17 mm, suggests impaired RV function and is often seen in conditions such as pulmonary hypertension and heart failure.

RV fractional area change reflects the percentage change in the RV chamber area between end-diastole and end-systole, providing an estimate of the RV's ability to contract. A normal value is 35% or higher.

Evidence summary

Population and studies description

This interventional procedures overview is based on 1,569 people from 1 randomised controlled trial (Hahn 2025, Arnold 2025), 1 systematic review and meta-analysis (Bugan 2022), 2 prospective single-arm studies (Pan 2025, Kodali 2023), 1 retrospective cohort study (Angellotti 2025), 1 registry study (Stolz 2024), 3 non-randomised comparative studies (Wang 2024, Wang 2025, Huang 2024) and 2 case reports (Chen 2023, Jiang 2024). Of these 1,569 people, 1,242 had the procedure. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents

11 studies (reported in 12 papers) as the key evidence in table 2 and table 3, and lists 28 other relevant studies in appendix B, table 5.

Studies included data from North America, Europe and Asia. Most people had severe or greater TR and were described as high surgical risk. There was a high prevalence of comorbidities, such as atrial fibrillation and hypertension. Most people were in NYHA functional class 3 or 4 at baseline. In all studies except 1 there was a higher proportion of females than males. Excluding the 2 case reports, the mean age of people who had TTVR ranged from 65 to 79 years.

The randomised controlled trial (TRISCEND 2) included 400 people who had severe or greater TR treated by TTVR (using the EVOQUE system) with OMT or by OMT alone (Hahn 2025). The mean EuroSCORE 2 score was 5.4% in the TTVR group and 5.6% in the control group and 70% of people were in NYHA class 3 or 4. The primary outcome was an hierarchical composite of death from any cause, implantation of a right ventricular assist device or heart transplantation, tricuspid-valve reintervention, hospitalisation for heart failure, an improvement of at least 10 points in the score on the KCCQ overall summary, an improvement of at least 1 NYHA functional class, and an improvement of at least 30 metres on the 6-minute walk distance. A win ratio was calculated for the primary outcome by comparing all possible patient pairs, starting with the first event in the hierarchy. The follow-up period was 1 year. Quality of life outcomes from the study were also reported in a separate paper (Arnold 2025).

The systematic review and meta-analysis included 321 people with at least moderate TR from 9 studies, all of which were observational (Bugan 2022). The mean EuroSCORE 2 score was 8.2% and 83% of people were in NYHA class 3 or 4. Evidence was included from 3 different devices: NaviGate, EVOQUE and LuX-Valve, using a transatrial or transjugular approach.

The prospective single-arm study by Pan (2025) included 126 people with severe or greater TR, all of whom were in NYHA class 3 or 4 and the mean STS score was 9.2. TTVR was done through a transatrial approach, using the LuX-Valve system. The primary endpoint was all-cause mortality and hospitalisation for heart failure at 1-year follow-up.

The prospective single-arm multicentre study by Kodali (2023) included 176 people with at least moderate symptomatic TR, despite medical therapy. The mean age was 78 years and there was a high burden of comorbidities. The mean EuroSCORE 2 score was 5.1% and 75% of people were in NYHA class 3 or 4. A transfemoral approach was used for TTVR, with the EVOQUE tricuspid valve replacement system. The follow-up period was 1 year and outcomes included major adverse events, reduction in TR grade, haemodynamic outcomes by echocardiography, and clinical, functional, and quality-of-life parameters.

The retrospective cohort study by Angellotti (2025) was a real-world study of transfemoral TTVR using the EVOQUE system, including 176 people with at least severe TR. The median EuroSCORE 2 was 6.2% and 80% of people were in NYHA functional class 3 or 4. There was a high prevalence of comorbidities and 48% of people had been hospitalised for heart failure in the previous 12 months, despite optimised medical treatment. Efficacy and safety endpoints followed the Tricuspid Valve Academic Research Consortium definitions. The follow-up period was 1 month.

Stolz (2024) reported outcomes from an international retrospective registry study, with a special focus on people who had larger devices implanted (55 mm and above). It included 76 people with symptomatic TR (75% massive or worse), 91% of whom were in NYHA functional class 3 or 4. The median EuroSCORE 2 was 4.5% and there was a high prevalence of cardiovascular comorbidities. Unlike other studies, the proportion of women (47%) was lower than men. A transjugular approach was used for TTVR, with a LuXValve Plus system. The endpoints were

procedural TR reduction, in-hospital death, adverse events, and survival at 30 days and results were stratified by device size.

There were 3 non-randomised comparative studies that used the LuXValve system with a transjugular or transatrial approach, all of which were based in China. They all reported statistically significant differences in baseline characteristics between the TTVR and control groups. Wang (2024) retrospectively compared TTVR with medical therapy alone in 88 people with symptomatic severe or greater TR and high surgical risk. People in the TTVR group had a higher STS score, and higher proportions of NYHA class 3 or 4 and torrential TR than those in the medical therapy group. The primary end points of the study were all-cause mortality and the combined rate of hospitalisations for heart failure and all-cause mortality. Median follow-up was 12 months in the TTVR group and 19 months in the medical therapy group (p=0.36). Wang (2025) retrospectively compared TTVR with totally thoracoscopic beating-heart tricuspid valve replacement or repair in 116 people with symptomatic severe or worse TR who were ineligible for conventional surgery. People in the TTVR group were older than those in the control group, with a higher mean EuroSCORE 2 (11.0% versus 6.7%, p<0.001) and a higher proportion of NYHA class 3 or 4 (100% versus 80%, p=0.009). The primary endpoints included 2-year all-cause mortality and combined all-cause mortality and hospitalisations for heart failure. The median follow-up was 645 days for the TTVR group and 615 days for the control group (p=0.39). Huang (2024) prospectively compared TTVR with isolated STVR in 88 people with severe or worse TR. The mean age and surgical risk scores were higher in the TTVR group than the STVR group and there was a higher proportion of NHYA class 3 or 4 (79% versus 52%, p=0.011). The inclusion criteria for TTVR were that surgical procedures posed high or extremely high risk and TV anatomy was unsuitable for transcatheter edge-to-edge repair. The primary endpoints included all-cause mortality within 30 days and at 1 year, as well as readmissions for heart failure within 1 year.

Two case reports describing adverse events after TTVR have been included. The first describes device delivery failure associated with exfoliated intima wrapping the prosthetic valve (Chen 2023) and the second describes complete heart block and sudden cardiac death after TTVR in a person who had previously had a heart transplant (Jiang 2024).

Table 2 presents study details.

Figure 1 Flow chart of study selection

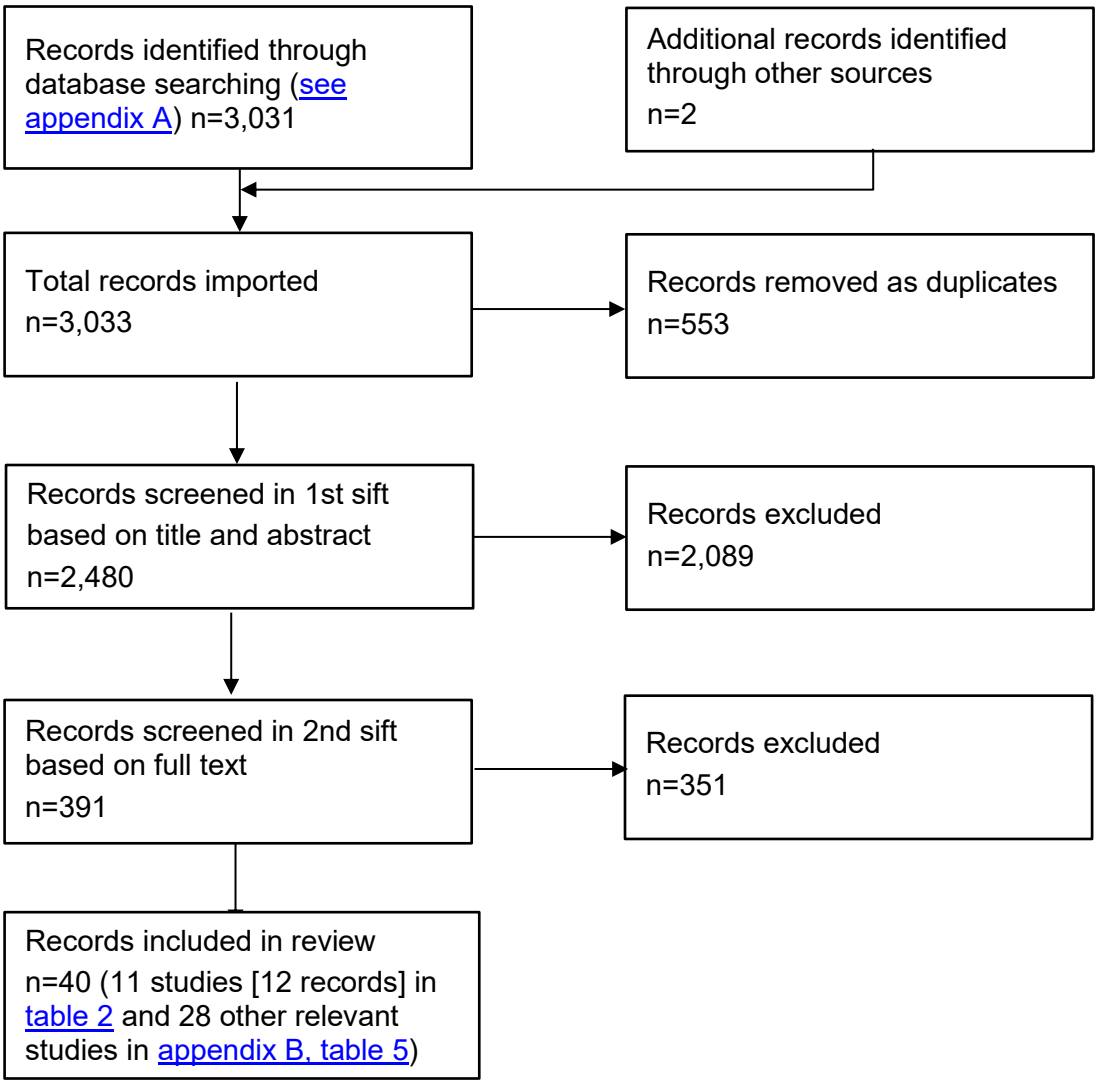

Table 2 Study details

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Hahn R, 2025 US, Germany Arnold S, 2025 reported quality of life outcomes from the same study.	n=400 (267 TTVR) 8 people randomised to TTVR died or withdrew before it was attempted. Mean age=79 years Female sex=74% Self-reported race or ethnic group: • white=73% • black=4% • Asian=6% Mean EuroSCORE 2: • TTVR and OMT=5.4 • OMT alone=5.6 NYHA class 3 or 4=70% TR grade:	Randomised controlled trial (TRISCEND 2) The first 150 people to be randomised were designated as the breakthrough pathway cohort and were evaluated for safety at 30 days and for tricuspid regurgitation, quality of life, and functional outcomes at 6 months. Randomisation period: May	Aged 18 years or older with severe TR. All people had signs or symptoms of TR or had been hospitalised for associated heart failure despite medical therapy. In addition, all were eligible for valve replacement with the EVOQUE system. Exclusion criteria: severely depressed RV systolic function, heart transplantation, anatomy that precluded proper device delivery, estimated glomerular filtration rate of 25 ml per	• TTVR and OMT=267 • OMT alone=133 EVOQUE tricuspid valve-replacement system (Edwards Lifesciences) was used with transfemoral access. Medical treatment included stable oral diuretic medications, unless there was a history of unacceptable side effects. For those who had TTVR, warfarin or another anticoagulant plus	1 year At 1 year, there were 224 people in the TTVR group and 104 people in the control group. The 1-year visit was complete for 215 and 97 people, respectively.

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Severe=43% • Massive=24% • Torrential=32% Comorbidities: • Hypertension=91% • Chronic kidney disease=56% • Stage 2 to 5 renal insufficiency=56% • Pacemaker or cardiovascular implantable electronic device=39% • Valve surgery or intervention=33%	2021 to April 2023 Analyses of the primary and safety outcomes were done in the modified intention-to-treat safety population, which included all those in the TTVR group who had an attempted trial procedure (skin incision).The effectiveness outcomes were analysed in the modified intention- to-treat population, which included those who had guide-sheath insertion.	minute per 1.73 m^2 of body-surface area or less or on long-term renal-replacement therapy, or life expectancy less than 12 months.	aspirin was recommended for at least 6 months after the procedure. 22 people in the control group crossed over to receive valve replacement within the 1-year visit window (320 to 410 days) after completing their 1-year visit.	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
2	Bugan B, 2022 Countries of individual studies not reported	n=321 (9 studies) Mean age=75.8 years Female sex=67% Mean EuroSCORE 2 score=8.2 NYHA class 3 or 4=83% Severe, massive, or torrential TR=95% Comorbidities (mean incidence): • Diabetes mellitus=31% • Hypertension=39% • Coronary artery disease=32% • Renal impairment=52% • Atrial fibrillation=88% • CABG or prior valve surgery=67%	Systematic review and meta-analysis 4 published studies, 2 case series, and 3 conference presentations were included. There were no randomised controlled trials. Search date: November 2021	Studies were considered eligible if they fulfilled all the following criteria: (1) the study population was patients with at least moderate native TR and treated with orthotopic TTVR; (2) the design was a case series study enrolling 4 or more patients; (3) at least 1 of the efficacy outcomes included all-cause mortality. Patients with structural dysfunction of bioprostheses, failed surgical annuloplasty rings, valve-in-valve, valve-in- ring, and heterotopic TTVR were excluded.	Evidence from 3 different devices was included: • NaviGate (n=71); delivered via transatrial or transjugular approach • EVOQUE (n=157); delivered via transatrial approach with a transfemoral system • LuX-Valve (n=93); delivered through a minimally invasive right thoracotomy and transatrial approach.	Weighted mean=122 days

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Permanent pacemaker=31%				
3	Pan X, 2025 China	n=126 Mean age=65.8 years Female sex=79% Mean Society of Thoracic Surgeons score=9.2 NYHA class 3 or 4=100% TR grade: • Severe=51% • Massive=35% • Torrential=14% Comorbidities included atrial fibrillation or flutter (72%), coronary artery disease (6%), chronic kidney disease (21%) and prior left-sided valve	Prospective, multicentre, single-arm trial (TRAVEL) June 2020 to August 2021	Ineligible for conventional surgery, age over 18 years, severe or greater TR, NYHA functional class 2 or higher, 4 failed optimal medical therapies, and suitable right heart anatomy measured by CT. Exclusion criteria: LVEF less than 40%, systolic pulmonary arterial pressure above 60 mmHg, prior tricuspid valve surgery or left-sided valve surgery within the past 6 months, concomitant lesion needing other major cardiac procedures or infective endocarditis, and	LuX-Valve (Jenscare Biotechnology Co Ltd) was positioned using a transatrial approach through the delivery system. General anaesthesia was used.	1 year

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		surgery or interventions (68%).		severe RV dysfunction or clinical futility evaluated by the multidisciplinary heart team.		
4	Kodali S, 2023 US, Canada, France, Switzerland	n=176 Mean age=78.7 years Female sex=71% NYHA class 3 or 4=75.4% Mean EuroSCORE 2=5.1% TR severe or greater=88% Comorbidities included atrial fibrillation (92%), hypertension (84%), pulmonary hypertension (75%), dyslipidaemia or hyperlipidaemia	Prospective single-arm multicentre study TRISCEND (NCT04221490)	Symptomatic, severe TR despite medical therapy. Key exclusion criteria were TV anatomy precluding device placement or function, haemodynamic instability, severe pulmonary hypertension, severe right ventricular dysfunction, refractory heart failure needing advanced intervention, and need for emergent surgery or planned cardiac surgery within the next 12	The EVOQUE TV replacement system was used (Edwards Lifesciences, US). A right femoral vein approach was used in 94% of cases.	1 year

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		(65%), renal insufficiency or failure (59%), and ascites (22%).		months. Additional exclusion criteria were LVEF less than 25% and severe renal insufficiency.		
5	Angellotti D, 2025 5 European countries	n=176 Mean age=77.8 years Female sex=72% NYHA class 3 or 4=80% Median EuroSCORE 2 score=6.2% Median TRI-SCORE=5 TRI-SCORE 6 or above=51% TR grade: • Severe=28% • Massive=36%	Retrospective multicentre cohort study October 2023 to February 2025	The indication for TTVR was determined by the respective local heart team. The study population consisted of an all-comers, real-world cohort of consecutively treated people with severe TR, including those who had the 56 mm valve size, which was not yet commercially available during the study period.	Transfemoral TTVR with the EVOQUE system The most frequently used device size was the 52 mm valve (91 of 176, 51.7%). 16 people had implantation of the 56 mm EVOQUE valve under compassionate-use conditions.	1 month

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Torrential=36% Comorbidities included atrial fibrillation (89%), chronic kidney disease (69%), and diabetes (26%). 37% had cardiac implantable device leads crossing the TV at baseline. 48% of people had been hospitalised for heart failure within the previous 12 months. 8 people had a history of previous TV intervention and 6 had a history of previous TV surgery.				

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
6	Stolz L, 2024 International (Germany, Canada, US, Denmark, France, Hong Kong, Spain)	n=76 Median age=78 years 47% women NYHA functional class 3 or 4=91%. Median TRI-SCORE=6 Median EuroSCORE 2=4.5% Massive or torrential TR=75% High prevalence of cardiovascular comorbidities (atrial fibrillation=91%, arterial hypertension=73%, dyslipidemia=65%, and diabetes mellitus=24%).	Retrospective multicentre registry study January 2022 to February 2024	All consecutive patients who had TTVR using the LuX-Valve Plus device for symptomatic TR during the study period were included. People were treated according to each centre's standard of care practice. No inclusion or exclusion criteria for treatment with this device were defined.	LuX-Valve Plus system (Jenscare Biotechnology Co Ltd). Transjugular access was used for all procedures. A device size 55 mm or larger was implanted in 75.0% of people. Large valves were more commonly implanted in men.	30 days

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
7	Wang Y, 2024 China	n=88 (31 TTVR) Mean age=66 years Female sex=67% Mean Society of Thoracic Surgeons score • TTVR and OMT=11.0 • OMT alone=10.2 p=0.011 Mean TRI-SCORE • TTVR and OMT=6.9 • OMT alone=5.7 p<0.001 NYHA class 3 or 4: • TTVR and OMT=100% • OMT alone=81% p<0.001 TR grade in TTVR and OMT group: • Severe=10%	Retrospective single centre non-randomised comparative study People included in the study were identified through the outpatient electronic medical record system and the inpatient system. May 2020 and 30 April 2023	Age over 50 years, symptomatic severe or greater TR, NYHA functional class 2 or higher, high risk for TV surgery, as indicated by an STS score above 8%. Exclusion criteria: Invasively systolic pulmonary arterial pressure measured by right heart catheterisation more than 60 mmHg (1 mmHg=0.133 kPa), LVEF less than 40%, presence of other significant cardiac diseases needing additional interventional or surgical correction, left-sided valve surgery within the past 6 months or prior TV surgery.	• TTVR, n=31 (using the LuX-Valve system and guideline-directed medical therapy) • Guideline-directed medical therapy alone, n=57 The right atrium approach was used in 15 TTVR procedures and the transjugular approach was used in 16 procedures, determined by preoperative assessment.	Median follow up in months (IQR): • TTVR=12 (9 to 26) • Medical therapy=19 (12 to 25) p=0.36

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Massive=26% • Torrential=64% TR grade in OMT alone group: • Severe=79% • Massive=16% • Torrential=5% p<0.001 There was a statistically significantly higher incidence of chronic obstructive pulmonary disease, chronic kidney disease and severe liver disease in the TTVR group. The incidence of coronary artery disease was statistically significantly higher in the OMT group.				
8	Wang Y, 2025 China	n=116 (38 TTVR) Mean age (years): • TTVR=67.3	Retrospective non-randomised comparative study	People with symptomatic severe TR who were ineligible for	• TTVR, n=38 (using the LuX-Valve system, JensCare	Median follow-up (days)

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Thoracoscopic TV surgery=60.7 p<0.001 Female sex=58% Mean EuroSCORE 2 • TTVR=11.0% • Thoracoscopic TV surgery=6.7% p<0.001 Mean TRI-SCORE • TTVR=5.9 • Thoracoscopic TV surgery=5.2 p=0.003 NYHA class 3 or 4: • TTVR=100% • Thoracoscopic TV surgery=80% p=0.009 TR grade in TTVR group: • Severe=13% • Massive=29% • Torrential=58%	May 2020 to November 2023	conventional surgery. Inclusion criteria: age over 18 years, TR severity severe or greater, NYHA functional class 2 or above, failed guideline-directed medical therapy, Euro-SCORE above 4. Exclusion criteria: LVEF less than 40%, systolic pulmonary arterial pressure above 60 mmHg, prior TV surgery or left-sided valve surgery within the past 6 months, irreversible poor RV function, concomitant significant lesion needed for other major cardiac procedures or infective endocarditis.	Biotechnology, China) • Thoracoscopic TV surgery, n=78 (totally thoracoscopic beating-heart tricuspid valve replacement or repair). All procedures were done under general anaesthesia. In the TTVR group, 20 procedures were done through the transjugular vein approach and 18 through the right atrial approach. In the thoracoscopic surgery group, 30 had replacement procedures, 24	• TTVR=645.0 (IQR 547.5 to 810.0) • Thoracoscopic TV surgery= 615.0 (IQR 450.0 to 720.0) p=0.39

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		TR grade in thoracoscopic TV surgery group: • Severe=26% • Massive=39% • Torrential=36% p=0.07 There was a statistically significantly higher incidence of chronic obstructive pulmonary disease and severe liver disease in the TTVR group.			had repair surgery with annuloplasty, and 24 had other repair procedures.	
9	Huang L, 2024 China	n=88 (29 TTVR) Mean age: • TTVR=67.6 • STVR=52 p<0.001 Female sex=76% Mean TRI-SCORE • TTVR=5.0 • STVR=3.0	Prospective non-randomised comparative study January 2019 to December 2022	Inclusion criteria for the TTVR group: surgical procedures posed high or extremely high risk and TV anatomy was unsuitable for transcatheter edge-to-edge repair. Exclusion criteria: poor left or right ventricular function	• TTVR, n=29 (using the LuX-Valve system (JensCare Biotechnology, China) • STVR, n=59 (using biological or	1 year

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		P<0.001 NYHA class 3 or 4: • TTVR=79% • STVR=52% p=0.011 TR grade in TTVR group: • Severe=38% • Massive=28% • Torrential=34% TR grade in STVR group: • Severe=56% • Massive=25% • Torrential=19% p=0.188 Previous left-sided valvular surgery • TTVR=90% • STVR=68% p=0.026 Atrial fibrillation • TTVR=76%		(LVEF less than 50%), TAPSE less than 10 mm or RV fractional area change less than 20%, severe pulmonary hypertension, untreated severe coronary artery disease. Inclusion criteria for the STVR group: isolated STVR. Exclusion criteria: active infective endocarditis, need for concurrent surgery for coronary artery disease or additional valve repair or replacement procedures, and combined congenital heart disease.	mechanical prostheses) TTVR procedures were done through a minimally invasive thoracotomy and transatrial approach without cardiopulmonary bypass. STVR procedures were done under extracorporeal circulation, using median sternotomy (n=28) or thoracotomy (n=31).	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• STVR=52% p=0.036				
10	Chen F, 2023 China	n=1 84-year-old woman with severe isolated TR	Case report	Not applicable	LuX-Valve Plus system (Jenscare Biotechnology). The procedure was done under general anaesthesia using a transjugular approach.	2 weeks
11	Jiang A, 2024 Canada	n=1 46-year-old woman with symptomatic severe TR after heart transplantation for post-partum cardiomyopathy. She had renal failure and needed ongoing haemodialysis after a failed kidney transplant.	Case report	Not applicable	EVOQUE system, Edwards Lifesciences	6 days

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Hahn, 2025 Arnold, 2025	The hierarchical composite primary outcome was death from any cause, implantation of a right ventricular assist device or heart transplantation, post index tricuspid-valve intervention, hospitalisation for heart failure, an improvement of at least 10 points in the score on the KCCQ overall summary, an improvement of at least 1 NYHA functional class, and an improvement of at least 30 metres on the 6-minute walk distance. A win ratio was calculated for the primary outcome by comparing all possible patient pairs, starting with the first event in the hierarchy. At 1 year, the win ratio favouring TTVR was 2.02 (95% CI 1.56 to 2.62; p<0.001). **Mean all-cause mortality at 1 year (Kaplan-Meier estimates)** • TTVR and OMT=12.6% (SE 2.1) • OMT alone=15.2% (SE 3.3) **Mean all-cause mortality at 1 year, starting at 30 days (Kaplan-Meier estimate)** • TTVR and OMT=9.4% (SE 1.9) • OMT alone=15.2% (SE 3.3) **Mean hospitalisation rates for heart failure at 1 year (Kaplan-Meier estimates)**	**All-cause mortality at 30 days** • TTVR and OMT=3.5% • OMT alone=0% **Deaths from cardiovascular cause at 30 days** • TTVR and OMT=3.1% • OMT alone=0% **Severe bleeding at 30 days** • TTVR and OMT=10.4% • OMT alone=1.5% **Severe bleeding at 1 year** • TTVR and OMT=15.4% • OMT alone=5.3%, p=0.003 **Stroke at 1 year** • TTVR and OMT=1.5% • OMT alone=0%, p=0.30 **Arrhythmia and conduction disorders leading to the permanent placement of a pacemaker at 1 year** • TTVR and OMT=17.8% • OMT alone=2.3%, p<0.001

First author, date	Efficacy outcomes	Safety outcomes
	• TTVR and OMT=20.9% (SE 2.6) • OMT alone=26.1% (SE 4.1) **Mean composite of death from any cause or first hospitalisation for heart failure (Kaplan-Meier estimates)** • TTVR and OMT=28.4% (SE 2.8) • OMT alone=33.3% (SE 4.3) **Mean composite of death from any cause or post index tricuspid-valve intervention** • TTVR and OMT=13.7% (SE 2.2) • OMT alone=20.8% (SE 3.7) **Increase of at least 10 points in the KCCQ overall summary score** • TTVR and OMT=66.4% (mean increase=18.4 points, 95% CI 15.4 to 21.4) • OMT alone=36.5% **Decrease of at least 1 NYHA class** • TTVR and OMT=78.9% • OMT alone=24.0% **Increase of 30 metres or more in 6 minute walk test** • TTVR and OMT=47.6% (mean increase 23.2 metres, 95% CI 9.4 to 37.1) • OMT alone=31.8%	**New pacemaker or cardiac implantable electronic device in those without a pacemaker at baseline** • TTVR and OMT=27.8% • OMT alone=3.8%, p<0.001

First author, date	Efficacy outcomes	Safety outcomes
	Echocardiographic outcomes at 1 year • No residual TR: TTVR and OMT=72.6%, OMT alone=0% • Mild TR: TTVR and OMT=22.6%, OMT alone=2.3% • Moderate TR: TTVR and OMT=3.8%, OMT alone=13.8% • Severe TR: TTVR and OMT=0.9%, OMT alone=41.4% • Massive TR: TTVR and OMT=0%, OMT alone=19.5% • Torrential TR: TTVR and OMT=0%, OMT alone=23.0% **Quality of life outcomes from Arnold (2025)** Both disease-specific and generic health status were markedly impaired at baseline (mean KCCQ Overall Summary Score 52.1 and mean 36-Item Short Form Health Survey physical component summary score 35.2). **Adjusted Effect of TTVR and OMT versus OMT According to Mixed Linear Regression Models – predicted mean at 1 year (95% CI)** **KCCQ Overall Summary Score** • TTVR and OMT=72.4 (69.8 to 75.1)	

First author, date	Efficacy outcomes	Safety outcomes
	• OMT alone=54.7 (50.8 to 58.6), p<0.001 **KCCQ physical limitations** • TTVR and OMT=66.9 (63.9 to 69.8) • OMT alone=56.1 (51.8 to 60.5), p<0.001 **KCCQ total symptoms** • TTVR and OMT=75.5 (72.6 to 78.3) • OMT alone=58.7 (54.5 to 62.9), p<0.001 **KCCQ quality of life** • TTVR and OMT=74.9 (71.8 to 77.9) • OMT alone=51.5 (47.0 to 56.0), p<0.001 **KCCQ social limitations** • TTVR and OMT=71.5 (67.8 to 75.2) • OMT alone=50.0 (44.6 to 55.4), p<0.001 **Medical Outcomes Study SF-36 physical component** • TTVR and OMT=40.4 (39.3 to 41.5) • OMT alone=36.2 (34.6 to 37.8), p<0.001 **Medical Outcomes Study SF-36 mental component** • TTVR and OMT=54.1 (52.8 to 55.3) • OMT alone=48.1 (46.3 to 50.0), p<0.001	

First author, date	Efficacy outcomes	Safety outcomes
	In subgroup analyses, TTVR with OMT improved health status to a greater extent among people with torrential or massive TR versus severe TR (treatment effect 23.3 versus 22.6 versus 11.3; interaction p=0.049). At 1 year, 64.6% of people who had TTVR with OMT were alive and well (KCCQ-OS 60 points or more and no decline of 10 points or more from baseline) compared with 31.0% with OMT alone. The authors noted that the improvement in functional and quality of life metrics after TTVR was clinically relevant.	
Bugan, 2022	**Pooled estimate for procedural success=92% (95% CI 87% to 96%)** **Pooled estimate for technical success** • NaviGate: 90% (95% CI 78 to 95%) • EVOQUE: 95% (95% CI 90 to 97%) • LuX-Valve: 98% (95% CI 91 to 99%) **Incidence of NYHA functional class 3 or 4** • Baseline: 83% (95% CI 73% to 90%) • Follow-up: RR=0.20 (95% CI 0.11 to 0.35, p<0.001, 7 studies, I^2=63%) **Mean 6-minute walk distance (metres)** • Baseline: 217.9 (95% CI 190.1 to 245.8)	The incidence of periprocedural and non-periprocedural stroke was 0%. • **Paravalvular TR=31% (95% CI 15% to 53%)** • **Central TR=15% (95% CI 6% to 34%)** **Prevalence of atrioventricular block by device:** • NaviGate=6% (95% CI 2% to 15%) • EVOQUE=7% (95% CI 3% to 12%) • LuX-Valve=1% (95% CI 0.4% to 8%) **Prevalence of paravalvular leakage by device:** • NaviGate=50% (95% CI 12% to 87%) • EVOQUE=52% (95% CI 33% to 70%)

First author, date	Efficacy outcomes	Safety outcomes
	• Follow-up: mean difference=91.1 (95% CI 37.3 to 144.9, p<0.001, 3 studies, I^2=50%) **Incidence of TR severe or greater** • Baseline: 95% (95% CI 89% to 98%) • Follow-up: RR=0.19 (95% CI 0.10 to 0.36, p<0.001, 9 studies, I^2=66%) **Mean tricuspid annular plane systolic excursion (mm)** • Baseline: 13.8 (95% CI 0.7 to 0.59) • Follow-up: mean difference=-1.42 (95% CI -3.08 to 0.24, p=0.09, 4 studies, I^2=54%) **Mean right ventricle basal diameter (mm)** • Baseline: 5.2 (95% CI 4.9 to 5.5) • Follow-up: mean difference=-0.51 (95% CI -0.83 to -0.20, p=0.002, 3 studies, I^2=14) **Mean RV fractional area change (%)** • Baseline: 37% (95% CI 36% to 38%) • Follow-up: mean difference=-3.18 (95% CI -9.75 to 3.38, p=0.34, 3 studies, I^2=75%) **Mean LVEF (%)** • Baseline: 57% (95% CI 55% to 59%) • Follow-up: mean difference=0.02 (95% CI -3.23 to 3.28, p=0.99, 3 studies, I^2=0%)	• LuX-Valve=9% (95% CI: 4% • to 20%) **In-hospital and 30-day mortality** In hospital and 30-day mortality was similar to predicted rates (RR=1.03, 95% CI 0.41 to 2.59; p=0.95; 5 studies, I^2=19) Other complications described in the studies included major bleeding (including vascular complications and gastrointestinal bleeding), renal complications, conduction disturbances needing a permanent pacemaker, device malpositioning and conversion to open heart surgery.

First author, date	Efficacy outcomes	Safety outcomes
	Pooled mean operation time (minutes)=122.3 (95% CI 82.1 to 162.5) **Pooled mean length of hospital stay (days)=10.7 (95% CI 4.5 to 16.9)** **Mortality beyond 30 days** At last available follow-up after TTVR, 28 people (10%; 95% CI 6% to 17%) had died. Mortality beyond 30 days was not statistically significantly higher than predicted (RR=1.39, 95% CI 0.69 to 2.81, p=0.35, 5 studies, I^2=0%).	
Pan, 2025	**Procedural success=97.6%** **All-cause mortality at 1 year (Kaplan-Meier estimate)=10.3% (13/126)** **Hospitalisation rate for heart failure at 1 year (Kaplan-Meier estimate)=4.0% (5/126)** **NYHA function class 2 or less at 1 year=79.8% (79/99), p<0.001** **TR severity moderate or less at 1 year=95.3% (101/106), p<0.001** **Mean 6-minute walk distance, metres** • Baseline=279.9 • 1 year=383.2, p<0.001, n=79	**Composite major adverse event rate at 30 days=15.1% (19/126)** **Composite major adverse event rate at 1 year=19% (24/126)** **Events at 30 days** • Stroke=0.8% (1/126) • New onset renal failure needing dialysis=3.2% (4/126) • New onset conduction block needing permanent pacemaker=0.8% (1/126) • Endocarditis=0.8% (1/126) • Nonelective tricuspid valve reintervention=4.0% (5/126) • Device related=0.8% (1/126) • Severe bleeding=11.9% (15/126)

First author, date	Efficacy outcomes	Safety outcomes
	Mean RV fractional area change, % (SD) • Baseline=42 (7.6) • 1 year=41.6 (8.5), n=86 • Difference=-0.5 (1.6), p=0.736 **Mean mid RV end-diastolic diameter, mm (SD)** • Baseline=41.8 (3.9) • 1 year=35.6 (3.6), n=89 • Difference=-6.2 (5.1), p<0.001 **Mean right atrial systolic volume, ml (SD)** • Baseline=145.5 (11.7) • 1 year=125.4 (11.4), n=84 • Difference=-19.1 (15.5), p<0.001 **Mean systolic pulmonary artery pressure, mmHg (SD)** • Baseline=39.6 (4.9) • 1 year=31.5 (8.8), n=72 • Difference=-7.3 (11.6), p<0.001 **Mean inferior vena cava diameter, mm (SD)** • Baseline=23.7 (6.3) • 1 year=20.2 (5.5), n=101 • Difference=-3.5 (8.5), p<0.001 **Mean LVEF, % (SD)** • Baseline: 56.7 (4.2)	• Cardiovascular mortality=2.4% (3/126) • Gastrointestinal haemorrhage=4.8% (6/126) • New onset liver failure=1.6% (2/126) • Device thrombosis=0.8% (1/126) **Events at 1 year (cumulative)** • Stroke=2.4% (3/126) • New onset renal failure needing dialysis=4.0% (5/126) • Myocardial infarction=0.8% (1/126) • New onset conduction block needing permanent pacemaker=1.6% (2/126) • Endocarditis=0.8% (1/126) • Nonelective tricuspid valve reintervention=4.8% (6/126) • Device related=3.2% (4/126) • Severe bleeding=14.3% (18/126) • Cardiovascular mortality=4.8% (6/126) • Gastrointestinal haemorrhage=5.6% (7/126) • New onset liver failure=2.4% (3/126) • Device thrombosis=0.8% (1/126) The non-elective reinterventions were 1 surgical conversion for valve embolisation and 4 valve-in-valve implantations for early hypoattenuated leaflet thickening.

First author, date	Efficacy outcomes	Safety outcomes
	• 1 year=57.4 (3.8), n=73 • Difference=0.9 (1.6), p=0.238	

Kodali, 2023	Successful femoral access was achieved in 99.4% of patients.
	
	Device success=94.4% (defined as successful device deployment and delivery system retrieval at exit from the catheterisation laboratory)
	
	Procedural success=93.0% (defined as device success without clinically significant paravalvular leak by TTE at discharge as determined by the core lab)
	
	Clinical success=77.1% (defined as procedural success without major adverse events at 30 days)
	
	All-cause mortality rate at 1 year=9.1%
	
	Rate of hospitalisation for heart failure at 1 year=10.2%
	
	There was a 74.9% relative reduction in the rate of heart failure hospitalisation in the 12 months before versus after the procedure (p<0.001).
	
	In paired analysis from baseline to 1 year, 97.6% of implanted patients had TR that was mild or less, with 69.0% having no or trace TR (p<0.001).
		Composite rate of major adverse events at 30 days=18.6% (32/172)
		• Cardiovascular mortality=1.7% (3/172)
		• Stroke=0.6% (1/172)
		• Renal complications needing unplanned dialysis or renal replacement therapy=1.7% (3/172)
		• Non-elective tricuspid valve reintervention=2.3% (4/172)
		• Major access site and vascular complications=2.3% (4/172)
		• Severe bleeding=16.9% (29/172)
		  ○ Major=8.1% (14/172)
		  ○ Extensive=7.0% (12/172)
		  ○ Life threatening=1.7% (3/172)
		  ○ Fatal=0.6% (1/172)
		
		Composite rate of major adverse events at 1 year=30.2% (45/149)
		• Cardiovascular mortality=9.4% (14/149)
		• Stroke=1.3% (2/149)
		• Renal complications needing unplanned dialysis or renal replacement therapy=3.4% (5/149)
		• Non-elective tricuspid valve reintervention=4.0% (6/149)

First author, date	Efficacy outcomes	Safety outcomes

	Reduction in TR severity grade at 1 year
	• 1 grade or more=100%
	• 2 grades or more=97.6%
	• 4 grades or more=33.3%
	
	NYHA class 1 or 2 at 1 year=93.3%
	
	Quality of life
	The mean KCCQ overall summary score increased from 46.0 points at baseline to 71.7 points at 1 year (p<0.001).
	
	SF-36 mental scores improved by 5.7 points (p<0.001) and physical scores by 7.4 points (p<0.001).
	
	Increase in 6-minute walk distance=56.2 metres, p<0.001
	
	The proportion of patients with absent or grade 1+ oedema (assessed by standard pitting) improved from 63.9% at baseline to 86.6% at 1 year (p<0.001).
	
	Change in RV mid-ventricular end-diastolic diameter from baseline to 1 year=-6.3 mm (SD 9.5), p<0.001
		• Major access site and vascular complications=2.7% (4/149)
		• Severe bleeding=25.5% (38/149)
		  ○ Major=10.7% (16/149)
		  ○ Extensive=10.7% (16/149)
		  ○ Life threatening=4.7% (7/149)
		  ○ Fatal=0.7% (1/149)
		
		New permanent pacemakers (not included in the pre-defined composite major adverse event definition) were implanted in 15 people (13.3% of those without a pre-existing pacemaker), all within 9 days after the procedure.
		
		Paravalvular leak at 1 year
		• None or trace=88.2%
		• Mild=10.6%
		• Moderate=1.2%

First author, date	Efficacy outcomes	Safety outcomes
	Change in inferior vena cava diameter at end-expiration from baseline to 1 year=-7.2 mm (SD 5.9), p<0.001 **RV fraction area change reduced from 38.7% to 30.3% at 1 year, p<0.001** **TAPSE reduced from 15.3 mm to 12.5 mm, p=0.006** **LVEF increased from 54.1% to 55.6%, p=0.197** **Stroke volume (left ventricular outflow tract) increased from 54.8 ml to 65.3 ml, p<0.001** **Increase in cardiac output=0.6 litres/minute (SD 1.2), p<0.001**	
Angellotti, 2025	**Clinical success at 30 days=86.9% (153/176)** (defined as: proper position of the device with adequate performance [TR reduction to moderate or less, TV mean gradient less than 5 mmHg]; and absence of mortality, stroke, unplanned reintervention, life-threatening bleeding, major vascular or cardiac complications, stage 2 or 3 acute kidney injury, myocardial infarction, and major valve thrombosis) **TR reduction to none or mild=98.2% (173/176)**	**Procedural outcomes** • In-hospital mortality=3.4% (6/176); 2 people died of acute RV failure, 2 of advanced heart failure and 2 of sepsis. • Device malposition=0.6% (1/176) • In-hospital reintervention=0.6% (1/176) • Acute right heart failure needing inotropic support=1.1% (2/176) • Periprocedural cardiac decompensation=4.5% (8/176)

First author, date	Efficacy outcomes	Safety outcomes

	NYHA class 1 or 2
	• Baseline=20.2% (28/138)
	• 30 days=79.7% (110/138), p<0.001
	
	Improvement of at least 1 NYHA functional class at 1 month=71%
	
	Massive or torrential TR at baseline was more common among people who improved compared with those with stable or worsening NYHA functional class (75 of 98 [76.5%] versus 20 of 40 [50.0%]; p=0.004).
	
	Peripheral oedema
	• Baseline=67.6% (87/130)
	• 1 month=22.3% (29/130), p<0.001
	
	Mean weight, kg
	• Baseline=70.5
	• 1 month=68.5, p<0.001
	
	Mean TAPSE, mm (n=99)
	• Baseline=17.8
	• 1 month=13.1
	• Mean difference=-4.7 (95% CI -3.6 to -7.2, p<0.001)
	
	RV fractional area change, % (n=78)
		There were no conversions to cardiac surgery.
		
		Safety outcomes at 1-month
		• All-cause mortality=5.1% (9/176)
		• Heart failure hospitalisation=5.1% (9/176)
		• New conduction disturbance=23.9% (42/176)
		• New pacemaker implantation
		  ○ Overall=14.2% (25/176)
		  ○ Pacemaker-naïve people=18.9% (21/111)
		• New arrhythmia=2.8% (5/176)
		• Bleeding=9.7% (17/176)
		• Life threatening bleeding=1.7% (3/176)
		• Vascular complication=4.5% (8/176)
		• Major vascular complication=1.1% (2/176)
		• Acute kidney injury=12.5% (22/176)
		  ○ Stage 2 or higher=5.1% (9/176)
		• Hypoattenuated leaflet thickening=6.3% (11/176)
		  ○ Reduced leaflet motion=1.7% (3/176)
		• Major valve thrombosis=1.7% (3/176)
		• Reintervention=0.6% (1/176)

First author, date	Efficacy outcomes	Safety outcomes
	• Baseline=41.4 • 1 month=30.6 • Mean difference=-9.8 (95% CI -7.6 to -11.4, p<0.001) **Laboratory changes** In paired analysis, renal function improved with estimated glomerular filtration rate increasing from 47.0 ml/min/1.73 m^2 at baseline to 53.7 ml/min/1.73 m^2 at 30 days (paired mean difference +6.7, 95% CI 4.2 to 7.4; p<0.001). Total bilirubin level decreased from 14.2 micromoles/ml at baseline to 11.0 at 1 month (paired mean difference -3.1; 95% CI -1.6 to -3.9; p<0.001). In a multivariate logistic regression analysis including age, sex, pulmonary hypertension, and TR severity, the presence of moderate or severe RV dysfunction at baseline was an independent predictor of clinical failure (OR 3.60; 95% CI 1.39 to 9.32; p=0.008).	
Stolz, 2024	Intraprocedural success=93.4% (71/76) **TR severity after the procedure** • 2+ or less=94.7% (72/76) • 1+ or less=90.8% (69/76) • 0+=65.8% (50/76) **Clinical success at 30 days=91.8% (56/61)**	There were 4 conversions to TV surgery (1 malpositioning of the valve, 1 device embolisation,1 anchor detachment with subsequent pericardial tamponade, and 1 pericardial effusion before device deployment). 1 procedure was aborted because of insufficient extension of the leaflet graspers.

First author, date	Efficacy outcomes	Safety outcomes
	Clinical 1-month follow-up was available for 61 of 67 (91.0%) eligible people **TR severity at 30 days** • 2+ or less=95.1% (58/61) • 1+ or less=86.9% (53/61) • 0+=47.5% (29/61) **NYHA functional class at 30 days** • 1=43.6% (24/61) • 2=41.8% (23/61) • 3=7.3% (4/61) • 4=7.3% (4/61) **Heart failure symptoms at baseline and 30 days** • Oedema=83.3% and 25.0%, p<0.001 (n=60) • Ascites=39.0% and 3.4%, p<0.001 (n=59) • Pleural effusion=32.4% and 8.1%, p=0.013 (n=37) **Echocardiographic data at baseline and 30 days, median** • TAPSE (mm)=18.0 and 15.0, p=0.034 • LVEF (%)=55.0 and 60.0, p=0.138	• Bleeding complications needing transfusion=6.6% (5/76) • New in-hospital conduction disturbances that needed permanent pacemaker implantation=3.9% (3/76) • Acute renal failure needing dialysis=2.6% (2/76) • Reoperation for access site complication=1.3% (1/76) • In-hospital mortality=5.3% (4/76); 2 after emergency surgery, 1 from gastrointestinal bleeding after the procedure, and 1 from right heart failure. **Safety outcomes at 30 days** • Overall 30-day pacemaker rate=5.2% (4/76) in all people and 7.5% (4/53) among those without a pre-existing pacemaker. • Follow-up echocardiography revealed detachment of the septal anchor in 2 people. One had subsequent heterotopic tricuspid valve replacement, and 1 had STVR. • Between discharge and 30 days, there was 1 further bleeding event.

First author, date	Efficacy outcomes	Safety outcomes
	• RV mid-diameter (mm)=42.0 and 39.0, p=0.096 • RV base diameter (mm)=49.0 and 47.0, p=0.031 • Right atrial area (cm^2)=30.2 and 28.0, p=0.006 • Right atrial volume (ml)=120.0 and 96.0, p=0.013 **Outcomes stratified by device size** Symptomatic status and heart failure symptoms were comparable between those who had a valve smaller than 55 mm and those who had a valve 55 mm or larger. There were no statistically significant differences in NYHA functional class improvement, and TR reduction after stratification by device size.	There was no statistically significant difference in prevalence of procedural complications when stratified by valve size. **Residual TR 3+ or 4+=5.3% (4/76)** Residual TR was paravalvular in all cases.

Wang, 2024	Technical and procedural success=100%
	
	Outcomes in TTVR group (n=31 at baseline, 30 at follow up), p values are against baseline
	
	Mean 6-minute walk test distance, metres (SD)
	• Baseline=229.4 (64.6)
	• 30 days=287.1 (41.7), p<0.001
	• 6 months=355.3 (59.1), p<0.001
	
	Mean KCCQ (SD)
	• Baseline=34.9 (7.4)
	• 30 days=48.0 (7.3), p<0.001
	• 6 months=58.3 (5.8), p<0.001
	
	Mean TAPSE, mm (SD)
	• Baseline=14.3 (2.0)
		One person (3.2%) in the TTVR group died during hospitalisation because of a lung infection and related to the procedure via the right atrium approach.
		
		Major adverse events, n (%)
		• Myocardial infarction
		  ○ TTVR=1 (3.2%)
		  ○ Medical therapy=5 (8.8%), p=0.11
		• Stroke or transient ischaemic attack
		  ○ TTVR=0 (0%)
		  ○ Medical therapy=0 (0%)
		• Gastrointestinal haemorrhage
		  ○ TTVR=3 (9.7%)

First author, date	Efficacy outcomes	Safety outcomes
	• 30 days=15.1 (1.7), p=0.08 • 6 months=16.4 (1.8), p<0.001 **Mean RV fractional area change, % (SD)** • Baseline=35.6 (2.1) • 30 days=38.9 (3.7), p<0.001 • 6 months=41.1 (3.8), p<0.001 **Mean RV end-diastolic diameter base, mm (SD)** • Baseline=52.4 (9.1) • 30 days=48.3 (5.4), p=0.039 • 6 months=43.2 (1.9), p<0.001 **Mean RV end-diastolic diameter mid, mm (SD)** • Baseline=44.2 (5.0) • 30 days=40.7 (5.2), p=0.011 • 6 months=37.2 (4.9), p<0.001 **Mean right atrium volume index, ml/m^2 (SD)** • Baseline=75.0 (8.2) • 30 days=62.5 (5.2), p<0.001 • 6 months=55.2 (2.7), p<0.001 **Mean inferior vena cava diameter, mm (SD)** • Baseline=34.5 (1.8) • 30 days=27.9 (2.1), p<0.001 • 6 months=24.5 (1.8), p<0.001	○ Medical therapy=19 (33.3%), p<0.001 • Hepatic sclerosis ○ TTVR=1 (3.2%) ○ Medical therapy=4 (7.0%), p=0.06 • Acute kidney injury ○ TTVR=2 (6.4%) ○ Medical therapy=5 (8.8%), p=0.11 • Renal failure needing dialysis ○ TTVR=3 (9.6%) ○ Medical therapy=15 (26.3%), p=0.001

First author, date	Efficacy outcomes	Safety outcomes
	Hospitalisations for heart failure (incidence per 100 person years of follow-up) • TTVR=9.2 (95% CI 4.2 to 17.5) • Medical therapy alone=27.1 (95% CI 18.8 to 40.7), p<0.001 **2-year survival** • TTVR=75.8% • Medical therapy alone=48.4%, p=0.019 **Freedom from 2-years combined endpoint (all-cause mortality and heart failure hospitalisation)** • TTVR=61.5% • Medical therapy alone=45.9%, p=0.007 **Freedom from cardiovascular death** • TTVR=78.3% • Medical therapy alone=57.1%, p=0.071 The TTVR subgroup with a TRI-SCORE less than 6 had the most favourable outcome, with a statistically significant difference compared to the other 3 subgroups (TTVR group with score 6 or higher, medical therapy group with score below 6 and	

First author, date	Efficacy outcomes	Safety outcomes
	medical therapy group with score 6 or above; all inter-group differences p<0.05).	
Wang, 2025	**Technical success was 100% in both groups.** **Procedural success** • TTVR=97.4% • Thoracoscopic TV surgery=92.3%, p=0.51 **Outcomes at last follow-up** **Mean increase in 6-minute walk test distance, metres (SD)** • TTVR=93.2 (55.9) • Thoracoscopic TV surgery=54.2 (55.9), p=0.001 **Mean increase in KCCQ, (SD)** • TTVR=34.2 (9.9) • Thoracoscopic TV surgery=18.4 (11.2), p<0.001 **NYHA functional class 1 or 2** • TTVR=88.2% (30/34) • Thoracoscopic TV surgery=66.2% (47/71), p<0.001 **TR grade less than severe** • TTVR=100% (34/34) • Thoracoscopic TV surgery=84.5% (60/71), p=0.001	**Complications** **Low cardiac output** • TTVR=0% (0/38) • Thoracoscopic TV surgery=12.8% (10/78), p=0.05 Two of these had replacement operations that resulted in cardiac death during hospitalisation. **Life threatening bleeding** • TTVR=0% (0/38) • Thoracoscopic TV surgery=3.8% (3/78), p=0.55 **New-onset conduction disturbance needing permanent pacemaker** • TTVR=0% (0/38) • Thoracoscopic TV surgery=2.6% (2/78), p=0.81 **Severe pneumonia** • TTVR=2.6% (1/38) (the person died during hospitalisation) • Thoracoscopic TV surgery=2.6% (2/78), p=0.99 **Pericardial effusion** • TTVR=2.6% (1/38)

First author, date	Efficacy outcomes	Safety outcomes
	Signs of right-sided heart failure • TTVR=14.7% (5/34) • Thoracoscopic TV surgery=33.8% (24/71) **Mean increase in TAPSE, mm (SD)** • TTVR=2.4 (1.9) • Thoracoscopic TV surgery=0.11 (1.8), p<0.001 **Mean increase in RV fractional area change, % (SD)** • TTVR=3.1 (4.1) • Thoracoscopic TV surgery=0.6 (2.8), p=0.001 **Mean change in RV end-diastolic diameter base, mm (SD)** • TTVR=-5.5 (10.9) • Thoracoscopic TV surgery=4.4 (5.4), p<0.001 **Mean change in RV end-diastolic diameter mid, mm (SD)** • TTVR=-3.9 (6.0) • Thoracoscopic TV surgery=3.2 (3.8), p<0.001 **Mean change in right atrium volume, ml (SD)** • TTVR=-66.0 (13.0) • Thoracoscopic TV surgery=-26.5 (14.4), p<0.001 **Mean change in inferior vena cava diameter, mm (SD)**	• Thoracoscopic TV surgery=5.1% (4/78), p=0.89 **Acute kidney injury** • TTVR=0% (0/38) • Thoracoscopic TV surgery=5.1% (4/78), p=0.38 **30-day mortality** • TTVR=2.6% (1/38) • Thoracoscopic TV surgery=5.1% (4/78), p=0.89

First author, date	Efficacy outcomes	Safety outcomes
	• TTVR=-8.0 (2.61) • Thoracoscopic TV surgery=-3.0 (2.4), p<0.001 **Mean change in LVEF, % (SD)** • TTVR=-3.8 (4.9) • Thoracoscopic TV surgery=-4.6 (5.7), p=0.47 **Freedom from 2-year all-cause mortality** • TTVR=85.2% • Thoracoscopic TV surgery=70.8%, p=0.13 **Freedom from combined endpoint (all-cause mortality and hospitalisations for heart failure)** • TTVR=75.3% • Thoracoscopic TV surgery=49.8%, p=0.0049 After stratification by TRI-SCORE, TTVR subgroups showed statistically significant difference in combined endpoint, and both also showed significant difference compared to the corresponding thoracoscopic surgery subgroups (all log-rank p<0.05). In multivariate Cox regression analysis, TRI-SCORE 6 or above was independently correlated with all-cause mortality (HR 3.91, 95% CI 1.48 to 10.34; p=0.006) and combined endpoint (HR 4.07, 95% CI 1.92 to 8.61; p<0.001).	
Huang, 2024	**Mortality at 1 year follow-up** • TTVR=10.3% (3/29)	There were no intraoperative deaths in either group.

First author, date	Efficacy outcomes	Safety outcomes
	• STVR=11.9% (7/59), p=0.82 **Hospital readmissions for heart failure at 1 year follow-up** • TTVR=13.8% (4/29) • STVR=10.2% (6/59), p=0.62 **TR severity at 30 days (p=0.003 between groups)** • None/trace: TTVR=67.9%, STVR=94.4% • Mild: TTVR=21.4%, STVR=3.7% • Moderate: TTVR=10.7%, STVR=1.9% **TR severity at 1 year (p=0.351 between groups)** • None/trace: TTVR=80.8%, STVR=90.4% • Mild: TTVR=15.4%, STVR=7.7% • Moderate: TTVR=0%, STVR=1.9% • Severe: TTVR=3.8%, STVR=0% **Mean TAPSE at baseline and 1 year, mm** • TTVR=15.9 and 13.4, p<0.05 • STVR=18.6 and 13.9, p<0.05 p=0.504 between groups at 1 year **Mean RV fractional area change at baseline and 1 year, %** • TTVR=38.6 and 41.3, p=not significant • STVR=43.0 and 43.3, p=not significant p=0.206 between groups at 1 year	**In-hospital mortality** • TTVR=3.4% • STVR=8.5%, p=0.38 **Adverse events at 30 days** • TTVR=13.8% (4/29) • STVR=23.7% (14/59), p=0.533 **Reoperation for bleeding** • TTVR=10.3% (3/29) • STVR=5.1% (3/59), p=0.391 **Bleeding needing transfusion** • TTVR=6.9% (2/29) • STVR=8.5% (5/59), p>0.999 **Need for support device (extracorporeal membrane oxygenation, intra-aortic balloon pump, or others)** • TTVR=6.9% (2/29) • STVR=5.1% (3/59), p>0.999 **Acute kidney failure with dialysis** • TTVR=3.4% (1/29) • STVR=5.1% (3/59), p>0.999 **Permanent pacemaker implantation**

First author, date	Efficacy outcomes	Safety outcomes
	Mean RV end-diastolic area at baseline and 1 year, cm^2 • TTVR=25.5 and 17.5, p<0.05 • STVR=24.8 and 17.7, p<005 p=0.556 between groups at 1 year **Mean RV end-systolic area at baseline and 1 year, cm^2** • TTVR=15.4 and 10.3, p<0.05 • STVR=14.2 and 10.2, p<0.05 p=0.848 between groups at 1 year **Mean right atrium volume at baseline and 1 year, ml** • TTVR=138.0 and 94.0, p<0.05 • STVR=137.1 and 79.3, p<0.05 p=0.162 between groups at 1 year **LVEF at baseline and 1 year (%)** • TTVR=61.3 and 61.6 • STVR=61.2 and 62.1 p=0.688 between groups at 1 year **Mean inferior vena cava diameter at baseline and 1 year, mm** • TTVR=22.7 and 18.4, p<0.05 • STVR=22.0 and 18.3, p<0.05 p=0.864 between groups at 1 year	• TTVR=0% (0/29) • STVR=5.1% (3/59), p=0.548 **Stroke** • TTVR=0% (0/29) • STVR=3.4% (2/59), p>0.999 One person in the STVR group had a deep sternal wound infection. **Post procedural paravalvular TR** • TTVR=34.5% (10/29) • STVR=3.4% (2/59), p<0.001 **Paravalvular TR at 1 year follow-up** • TTVR=19.2% (5/26) • STVR=3.8% (2/52), p=0.038 In the TTVR group, 4 people had moderate paravalvular leaks, and 3 of them died during follow-up. One person died within 30 days from lung infection, and the other 2 died from right heart failure during the follow-up of 30 days to 1 year. The fourth person had STVR because of device migration within 1 year.

First author, date	Efficacy outcomes	Safety outcomes
	Peak TV velocity at 1 year (metres/second) • TTVR=1.3 • STVR=1.5 (bioprosthetic valves only, n=39) p=0.014 between groups **Mean TV gradient at 1 year, mmHg** • TTVR=3.0 • STVR=4.2 (bioprosthetic valves only, n=39) p=0.012 between groups	At 1 year, there was 1 additional stroke and 2 additional permanent pacemaker implantations, all in the STVR group.
Chen, 2023	The procedure was not completed because the valve failed to expand.	**Delivery failure associated with exfoliated intima wrapping the prosthetic valve** During the procedure, the crimped prosthetic valve did not expand when withdrawing the outer sheath as expected. Real-time echocardiography confirmed that the system was not entangled with the TV apparatus. Advancing the outer sheath failed to recapture the unexpanding valve and bail-out, on-pump beating-heart TV surgery was necessary. The prosthetic valve, except for its anchoring tongue and grasper components, was completely wrapped by a membranous structure. It expanded as expected after incising the structure. The valve was taken off, and the delivery system was removed from the transjugular access. Visual analysis suggested the membranous structure was tubular exfoliated intima. A new 50-mm LuX-Valve was sewn to the TV annulus. The final imaging showed a stable

First author, date	Efficacy outcomes	Safety outcomes
		valve position, mild paravalvular regurgitation, and a mean pressure gradient of 1 mmHg.
Jiang, 2024	The procedure was successful with adequate valve placement and function. The woman was discharged on postoperative day 3 with an ambulatory electrocardiogram monitor.	**Complete heart block and subsequent sudden cardiac death after TTVR** 6 days after TTVR, the woman was taken to hospital after a syncopal episode. She was clinically in cardiogenic shock with complete heart block on electrocardiogram. Despite resuscitative efforts, she subsequently died after cardiac arrest. Post-mortem examination showed a normally seated bioprosthetic valve without evidence of perforation, abscess, thrombus or vegetation. However, there was focal necrosis to the area of the atrioventricular node and His bundle. The ambulatory electrocardiogram monitor demonstrated intermittent complete heart block starting the day before presentation.

Procedure technique

The key studies reported outcomes using 4 different systems for TTVR. A small number of cases using other devices are described in table 5. The systems differ in terms of valve design, stent frame, anchoring mechanism, available valve sizes, and delivery systems.

The systematic review included evidence from 3 systems: NaviGate, EVOQUE and LuX-Valve. Of the other 7 studies, 4 used LuX-Valve, 1 used LuX-Valve Plus and 2 used EVOQUE. The systematic review stated that LuX-Valve was delivered through a minimally invasive right thoracotomy and transatrial approach, EVOQUE was delivered through a transfemoral approach, and NaviGate was delivered through a minimally invasive right thoracotomy and transatrial approach or transjugular approach (Bugan 2022). A transfemoral approach was used in the 3 primary studies that used EVOQUE (Hahn 2025, Kodali 2023, Angellotti 2025). In the studies by Pan (2025), Wang (2024) and Wang (2025), the LuX-Valve was delivered through a minimally invasive thoracotomy and transatrial approach or transjugular approach. In the study by Huang (2024), the LuX-Valve was delivered through a minimally invasive thoracotomy and transatrial approach. In the study by Stolz (2024) the LuX-Valve Plus system was used with transjugular access. This device covers valve sizes up to 65 mm, which is larger than other TTVR systems.

Efficacy

Mortality

Eight studies reported mortality or survival beyond 30 days as an outcome. All-cause mortality at 1 year after TTVR ranged from 9% to 13%.

In the systematic review of 9 studies, mortality beyond 30 days was not statistically significantly higher than predicted (RR 1.39, 95% CI 0.69 to 2.81,

p=0.35, I^2=0%; Bugan 2022). In the randomised controlled trial of 400 people, Kaplan-Meier estimates of mean all-cause mortality at 1 year were 13% in the TTVR with OMT group compared to 15% in the OMT alone group (p value not reported, Hahn 2025). In the non-randomised comparative study of 88 people who had TTVR or STVR, mortality at 1 year was 10% (3/29) for TTVR and 12% (7/59) for STVR (p=0.82; Huang 2024). In the non-randomised comparative study of 88 people comparing TTVR and medical therapy, 2-year survival was 76% in the TTVR with OMT group compared to 48% in the OMT alone group (p=0.019; Wang 2024). In the non-randomised comparative study of 116 people, freedom from 2-year all-cause mortality was 85% in the TTVR group compared to 71% in the group who had thoracoscopic TV surgery (p=0.13; Wang 2025).

Hospitalisation for heart failure

Five studies reported heart failure hospitalisation rates as an outcome after TTVR, ranging from 4% to 21% at 1 year.

In the randomised controlled trial of 400 people, Kaplan-Meier estimates of mean hospitalisation rates for heart failure at 1 year were 21% in the TTVR with OMT group compared to 26% in the OMT alone group (p value not reported; Hahn 2025). In the non-randomised comparative study of 88 people comparing TTVR and medical therapy, the incidence of hospitalisations for heart failure per 100 person years of follow-up were 9.2 in the TTVR with OMT group (95% CI 4.2 to 17.5) compared to 27.1 in the OMT alone group (95% CI 18.8 to 40.7, p<0.001; Wang 2024). In the non-randomised comparative study of 88 people who had TTVR or STVR, hospital readmissions for heart failure at 1 year were 14% (4/29) for TTVR and 10% (6/59) for STVR (p=0.62; Huang 2024).

Composite outcomes including mortality and heart failure hospitalisations

In the randomised controlled trial of 400 people, the primary outcome was an hierarchical composite of death from any cause, implantation of a right ventricular

assist device or heart transplantation, post index tricuspid-valve intervention, hospitalisation for heart failure, an improvement of at least 10 points in the score on the KCCQ overall summary, an improvement of at least 1 NYHA functional class, and an improvement of at least 30 metres on the 6-minute walk distance. A win ratio was calculated for the primary outcome by comparing all possible patient pairs, starting with the first event in the hierarchy. At 1 year, the win ratio favouring TTVR was 2.02 (95% CI 1.56 to 2.62; p<0.001).

In the non-randomised comparative study of 88 people comparing TTVR against medical therapy, the freedom from 2-years combined endpoint of all-cause mortality and heart failure hospitalisation was statistically significantly higher in the TTVR with OMT group (62%) compared to OMT alone (46%; p=0.007; Wang 2024). In the non-randomised comparative study of 116 people, freedom from the combined endpoint of all-cause mortality and heart failure hospitalisation was statistically significantly higher in the TTVR group (75%) compared to the group who had thoracoscopic TV surgery (50%; p=0.0049; Wang 2025).

KCCQ

KCCQ scores after TTVR were reported in 4 studies, all of which showed improvements from baseline.

In the randomised controlled trial of 400 people, 66% of those in the TTVR with OMT group had an increase of at least 10 points in the KCCQ overall summary score compared to 36% in the OMT alone group (p value not reported; Hahn 2025). The predicted mean score at 1 year was statistically significantly higher in the TTVR group (72.4, 95% 69.8 to 75.1) compared to the OMT group (54.7, 95% CI 50.8 to 58.6; p<0.001; Arnold 2025). The predicted mean subgroup scores for physical limitations, total symptoms, quality of life and social limitations were all statistically significantly higher in those who had TTVR (p<0.001).

In the prospective single-arm study of 176 people, the mean KCCQ overall summary score increased from 46.0 points at baseline to 71.7 points at 1 year ($p<0.001$; Kodali 2023). In the non-randomised comparative study of 88 people, the mean KCCQ score improved from 34.9 at baseline to 58.3 at 6 months in the TTVR group ($p<0.001$; Wang 2024). In the non-randomised comparative study of 116 people, the mean increase in KCCQ at last follow-up was statistically significantly higher in the TTVR group (34.2) compared to the group who had thoracoscopic TV surgery (18.4; $p<0.001$; Wang 2025).

NYHA functional class

Changes in NYHA functional class after TTVR were reported as an outcome in 7 studies, all of which showed improvements.

In the systematic review of 9 studies, there was a statistically significant reduction in the proportion of people in NYHA functional class 3 or 4 at a weighted mean follow-up of 122 days (RR 0.20, 95% CI 0.11 to 0.35, $p<0.001$, 7 studies, $I^2=63\%$; Bugan 2022). In the randomised controlled trial of 400 people, 79% of those in the TTVR with OMT group had decrease of at least 1 NYHA class compared to 24% in the OMT alone group (p value not reported; Hahn 2025). In the 2 prospective single-arm studies, the proportion of people in NYHA class 1 or 2 at 1 year was 80% and 93% (Pan 2025, Kodali 2023). In the retrospective cohort study of 176 people, the proportion of people in NYHA class 1 or 2 increased from 20% at baseline to 80% at 30 days ($p<0.001$); 71% of people had an improvement of at least 1 NHYA functional class (Angellotti 2025). In the registry study of 76 people, 86% of people were in NYHA functional class 1 or 2 at 30 days follow-up (Stolz 2024). In the non-randomised comparative study of 116 people, the proportion of people in NYHA class 1 or 2 was statistically significantly higher in the TTVR group (88%) compared to the group who had thoracoscopic TV surgery (66%; $p<0.001$; Wang 2025).

6-minute walk test

The 6-minute walk test distance after TTVR was reported as an outcome in 6 studies, all of which showed improvements from baseline.

In the systematic review of 9 studies, the mean increase in distance in the 6-minute walk test was 91.1 metres (95% CI 37.3 to 144.9, p<0.001, 3 studies, I^2=50%) at a weighted mean follow-up of 122 days (Bugan 2022). In the randomised controlled trial of 400 people, 48% of those in the TTVR with OMT group had an increase of at least 30 metres compared to 32% in the OMT alone group (p value not reported; Hahn 2025). In the prospective single-arm study of 126 people, the mean distance increased from 279.9 metres at baseline to 383.2 metres at 1 year (p<0.001; Pan 2025). In the prospective single-arm study of 176 people, the mean increase at 1 year was 56.2 metres (p<0.001; Kodali 2023). In the non-randomised comparative study of 88 people, the mean distance increased from 229.4 metres at baseline to 355.3 metres at 6 months after TTVR (p<0.001; Wang 2024). In the non-randomised comparative study of 116 people, the mean increase in distance was statistically significantly higher in the TTVR group (93.2 metres) compared to those who had thoracoscopic TV surgery (54.2 metres; p<0.001; Wang 2025).

Reduction in TR

Reduction in TR was reported as an outcome in 8 studies.

In the systematic review of 9 studies, there was a statistically significant reduction in the proportion of people with severe or greater TR at a weighted mean follow-up of 122 days (RR 0.19, 95% CI 0.10 to 0.36, p<0.001, 9 studies, I^2=66%; Bugan 2022).

In the randomised controlled trial of 400 people, 73% of those in the TTVR with OMT group had no residual TR at 1 year and none had massive or torrential TR. In the OMT alone group, all people had some TR at 1 year, 20% had massive TR

and 23% had torrential TR (Hahn 2025). In the single-arm study of 126 people, 95% had TR severity moderate or less at 1 year (p<0.001; Pan 2025). In the prospective single-arm study of 176 people, everyone had a reduction of at least 1 grade in TR severity at 1 year, 98% had a reduction of 2 grades or more and 33% had a reduction of 4 grades or more (Kodali 2023). In the retrospective cohort study of 176 people, 98% had a reduction of TR to none or mild at 30 days follow-up (Angellotti 2025). In the registry study of 76 people, 95% had TR severity of 2 or less, 91% had 1 or less and 66% had severity of 0 at 30 days follow-up (Stolz 2024). In the non-randomised comparative study of 116 people, everyone in the TTVR group had TR grade less than severe at last follow-up compared to 84% of those who had thoracoscopic TV surgery (p=0.001; Wang 2025). In the non-randomised comparative study of 88 people who had TTVR or STVR, 81% of those in the TTVR had none or trace TR at 1 year compared to 90% of those who had STVR (Huang 2024).

TAPSE

TAPSE was reported as an outcome in 7 studies, 5 of which reported a statistically significant reduction and 2 reported an increase.

In the systematic review of 9 studies, the mean reduction in TAPSE was 1.4 mm at a weighted mean follow-up of 122 days (95% CI -3.08 to 0.24, p=0.09, 4 studies, I^2=54%; Bugan 2022). In the prospective single-arm study of 176 people, TAPSE reduced from 15.3 mm at baseline to 12.5 mm at 1 year, p=0.006 (Kodali 2023). In the retrospective cohort study of 176 people, mean TAPSE reduced from 17.8 mm at baseline to 13.1 mm at 1 month (p<0.001; Angellotti 2025). In the registry study of 76 people, median TAPSE reduced from 18.0 mm at baseline to 15.0 mm at 30 days follow-up, p=0.034 (Stolz 2024). In the non-randomised comparative study of 88 people, the mean TAPSE increased from 14.3 mm at baseline to 16.4 mm at 6 months after TTVR (p<0.001; Wang 2024). In the non-randomised comparative study of 116 people, the mean

increase in TAPSE was 2.4 mm after TTVR and 0.11 mm after thoracoscopic surgery (p<0.001; Wang 2025). In the non-randomised comparative study of 88 people who had TTVR or STVR, the mean TAPSE reduced from 15.9 mm at baseline to 13.4 mm (p<0.05) in the TTVR group and from 18.6 mm to 13.9 mm (p<0.05) in the STVR group at 1 year (p=0.504 between groups at 1 year; Huang 2024).

RV fractional area change

Mean RV fractional area change was reported as an outcome in 7 studies, with 4 reporting a decrease and 3 reporting an increase from baseline.

In the systematic review of 9 studies, the mean reduction in RV fractional area change was 3.2% at a weighted mean follow-up of 122 days (95% CI -9.75 to 3.38, p=0.34, 3 studies, I^2=75%; Bugan 2022). In the prospective single-arm study of 126 people, there was a reduction of 0.5% (p=0.736; Pan 2025). In the prospective single-arm study of 176 people, the RF fractional area change reduced from 38.7% at baseline to 30.3% at 1 year, p<0.001 (Kodali 2023). In the retrospective cohort of 176 people, the mean RV fractional area reduced from 41.4% at baseline to 30.6% at 1 month (p<0.001; Angellotti 2025). In the non-randomised comparative study of 88 people, the mean RV fractional area change increased from 35.6% at baseline to 41.1% at 6 months after TTVR (p<0.001; Wang 2024). In the non-randomised comparative study of 116 people, the mean increase in RV fractional area change was 3.1% after TTVR and 0.6% after thoracoscopic surgery (p=0.001; Wang 2025). In the non-randomised comparative study of 88 people who had TTVR or STVR, the mean RV fractional area change increased from 38.6% at baseline to 41.3% in the TTVR group and from 43.0% to 43.3% in the STVR group at 1 year, which were not statistically different (p=0.206 between groups at 1 year; Huang 2024).

RV basal diameter

RV basal diameter was reported in 4 studies, all of which showed a decrease after TTVR.

In the systematic review of 9 studies, the mean decrease in RV basal diameter was 0.51 mm at a weighted mean follow-up of 122 days (95% CI -0.83 to -0.20, p=0.002, 3 studies, I^2=14%; Bugan 2022). In the registry study of 76 people, median RV base diameter reduced from 49.0 mm at baseline to 47.0 mm at 30 days follow-up, p=0.031 (Stolz 2024). In the non-randomised comparative study of 88 people, the mean RV end-diastolic diameter base decreased from 52.4 mm at baseline to 43.2 mm at 6 months after TTVR (p<0.001; Wang 2024). In the non-randomised comparative study of 116 people, there was a mean decrease in RV end-diastolic diameter base of 5.5 mm after TTVR and a mean increase of 4.4 mm after thoracoscopic surgery (p<0.001; Wang 2025).

LVEF

LVEF after TTVR was reported in 5 studies, none of which showed a statistically significant difference from baseline.

In the systematic review of 9 studies, the mean difference in LVEF was 0.02% at a weighted mean follow-up of 122 days (95% CI -3.23 to 3.28, p=0.99, 3 studies, I^2=0%; Bugan 2022). In the prospective single-arm study of 126 people, the difference was 0.9% (p=0.238; Pan 2025). In the prospective single-arm study of 176 people, the LVEF increased from 54.1% at baseline to 55.6% at 1 year, p=0.197 (Kodali 2023). In the non-randomised comparative study of 116 people, the mean decrease in LVEF was 3.8% after TTVR and 4.6% after thoracoscopic surgery (p=0.47; Wang 2025). In the non-randomised comparative study of 88 people who had TTVR or STVR, the mean LVEF increased from 61.3% at baseline to 61.6% in the TTVR group and from 61.2% to 62.1% in the STVR

group at 1 year, which were not statistically different (p=0.688 between groups at 1 year; Huang 2024).

Safety

Composite outcomes

The rate of major adverse events in the 2 single arm trials was 15% and 19% at 30 days and 19% and 30% at 1 year (Pan 2025, Kodali 2023). The rate of adverse events at 30 days was 14% (4 out of 29) after TTVR and 24% (14 out of 59) after STVR (p=0.533) in the non-randomised comparative study by Huang (2024).

In-hospital and 30-day mortality

All studies reported in-hospital or 30-day mortality as a safety outcome.

In hospital and 30-day mortality was similar to predicted rates in the systematic review of 9 studies (RR=1.03, 95% CI 0.41 to 2.59, p=0.95, 5 studies, I^2=19; Bugan 2022). At 30 days, all-cause mortality was 3.5% and cardiovascular related mortality was 3% after TTVR and there were no deaths in the OMT alone group in the randomised controlled trial of 400 people (Hahn 2025). 30-day mortality was 3% (1 out of 38) after TTVR and 5% (4 out of 78) after thoracoscopic surgery (p=0.89) in the non-randomised comparative study of 116 people (Wang 2025). Cardiovascular mortality at 30 days was 2% (3 out of 126 and 3 out of 172) in the single-arm trials of 126 and 176 people, respectively (Pan 2025, Kodali 2023). In-hospital mortality was 3% (6 out of 176) and all-cause mortality at 1 month was 5% (9 out of 176) in the retrospective cohort study of 176 people (Angellotti 2025). In-hospital mortality was 5% (4 out of 76) in the registry study of 76 people (Stolz 2024), and 3% after TTVR and 8% after STVR (p=0.38) in the non-randomised comparative study of 88 people (Huang 2024). Wang (2024) reported 1 procedure-related death out of the 31 people who had TTVR.

In the case report by Jiang (2024), a 46-year-old woman with a history of heart transplantation had complete heart block and died 6 days after TTVR. Post-mortem examination showed focal necrosis to the area of the atrioventricular node and His bundle.

Bleeding

Bleeding was reported as a safety outcome in 8 studies, 3 of which reported rates of severe bleeding at 30 days and also at 1 year.

Severe bleeding at 30 days was reported in 10% of people who had TTVR and 2% of those who had OMT alone in the randomised controlled trial of 400 people. There was a statistically significant higher rate of severe bleeding at 1 year in the TTVR group (15% versus 5%, p=0.003; Hahn 2025). At 30 days, severe bleeding was reported in 12% (15 out of 126) of people and gastrointestinal haemorrhage was reported in 5% (6 out of 126) of people in the single arm study of 126 people. At 1 year, the cumulative rates were 14% (18 out of 126) for severe bleeding and 6% (7 out of 126) for gastrointestinal haemorrhage (Pan 2025). Severe bleeding was reported in 17% (29 out of 172) of people at 30 days and 26% (38 out of 149) at 1 year, in the single arm study of 176 people. The most common cause of bleeding after 30 days was gastrointestinal (Kodali 2023). Life threatening bleeding was reported in 2% (3 out of 176) of people in the retrospective cohort study by Angellotti (2025). Bleeding complications needing transfusion were reported in 7% (5 out of 76) of people in the registry study by Stolz (2024). Gastrointestinal haemorrhage was reported in 10% (3 out of 31) of people who had TTVR and 33% (19 out of 57) of people who had OMT only (p<0.001) in the non-randomised comparative study (Wang 2024). There were 3 cases (4%) of life-threatening bleeding after thoracoscopic TV surgery and none after TTVR (p=0.55) in the non-randomised comparative study of 116 people (Wang 2025). The rates of reoperation for bleeding were 10% (3 out of 29) after TTVR and 5% (3 out of 59) after STVR (p=0.391) and rates of bleeding needing

transfusion were 7% (2 out of 29) and 8% (5 out of 59) respectively (p=1.00) in the non-randomised comparative study of 88 people (Huang 2024).

Access site and vascular complications

Major access site and vascular complications at 30 days were reported in 2% (4 out of 172) of people in the single arm study of 176 people (Kodali 2023). Major vascular complications were reported in 1% (2/176) of people in the cohort study of 176 people (Angellotti 2025). Reoperation for access site complications was reported in 1 person in the registry study of 76 people (Stolz 2024).

Stroke

The incidence of stroke was reported in 6 studies, which ranged from 0% to 2% after TTVR.

The rate of stroke at 1 year was 1.5% in the TTVR with OMT group and 0% in the OMT alone group (p=0.30) in the randomised controlled trial of 400 people (Hahn 2025). There were no reports of periprocedural or non-periprocedural stroke in the systematic review of 9 studies (Bugan 2022). There was 1 stroke at 30 days in each of the 2 single arm studies (Pan 2025, Kodali 2023). At 1 year, the rate of stroke was 2% (3 out of 126) and 1% (2 out of 149), respectively. There were no reports of stroke or transient ischaemic attack in the non-randomised comparative study of 88 people (Wang 2024). Stroke was reported in 3% (2 out of 59) of people in the STVR group and 0% (0 out of 29) in the TTVR group in the non-randomised comparative study by Huang (2024).

Permanent pacemaker implantation

The rate of permanent pacemaker implantation was reported in 7 studies.

Arrhythmia and conduction disorders leading to permanent pacemaker implantation at 1 year was reported in 18% of people in the TTVR with OMT group and 2% in the OMT alone group (p<0.001) in the randomised controlled

trial of 400 people. Among those without pacemakers at baseline, a new pacemaker or cardiac implantable electronic device was placed in 28% of people in the TTVR group and in 4% of those in the control group (p<0.001; Hahn 2025). New onset conduction block needed a permanent pacemaker was reported in 1 person at 30 days and an additional person at 1 year in the single arm study of 126 people (Pan 2025). New permanent pacemakers were implanted in 15 people (13% of those without a pre-existing pacemaker), all within 9 days after TTVR in the single arm study of 176 people (Kodali 2023). New conduction disturbance was reported in 24% (42 out of 176) of people and new pacemaker implantation was reported in 14% (25 out of 176) of people in the cohort study of 176 people (Angellotti 2025). For pacemaker-naïve people, the rate of pacemaker implantation was 19% (21 out of 111). New in-hospital conduction disturbances that needed permanent pacemaker implantation were reported in 3 people (4%) in the registry study of 76 people. The overall 30-day pacemaker rate was 5% (4 out of 76) in all people and 8% (4 out of 53) among those without a pre-existing pacemaker (Stolz 2024). There were no reports of new-onset conduction disturbances needing a permanent pacemaker after TTVR but there were 2 (3%) after thoracoscopic surgery and 3 after STVR (5%) in 2 non-randomised comparative studies (Wang 2025, Huang 2024).

Paravalvular leak

Paravalvular leak was reported as an outcome in 4 studies.

The rate of paravalvular TR was 31% (95% CI 15 to 53) in the systematic review of 9 studies (Bugan 2022). Mild paravalvular leak was reported in 11% of people and moderate leak in 1% of people at 1 year in the single arm trial of 176 people (Kodali 2023). Post procedural paravalvular TR was reported in 34% (10 out of 29) of people after TTVR and 3% (2 out of 59) after STVR (p<0.001). At 1 year, the rates were 19% (5 out of 26) and 4% (2 out of 52), respectively (p=0.038) in the non-randomised comparative study by Huang (2024). Four people had

moderate paravalvular leaks, 3 of whom died during follow-up. The fourth person had STVR because of device migration within 1 year. Paravalvular residual TR was reported in 5% (4 out of 76) of people in the registry study by Stolz (2024).

Renal failure

Renal failure needing dialysis was reported in 5 studies.

New onset renal failure needing dialysis was reported in 3% (4 out of 126) of people at 30 days and 4% (5 out of 126) at 1 year in the single arm study of 126 people (Pan 2025). Renal complications needing unplanned dialysis or renal replacement therapy was reported in 2% (3 out of 172) of people at 30 days and 3% (5 out of 149) at 1 year in the single arm study of 176 people (Kodali 2023). Acute renal failure needing dialysis was reported in 3% (2 out of 76) of people in the registry study by Stolz (2024). Renal failure needing dialysis was reported in 10% (3 out of 31) of people who had TTVR and 26% (15 out of 57) of people who had medical therapy only (p=0.001) in the non-randomised comparative study of 88 people. Acute kidney injury was reported in 6% and 9% of people, respectively (p=0.11; Wang 2024). Acute kidney failure with dialysis was reported in 3% (1 out of 29) of people who had TTVR and 5% (3 out of 59) of people who had STVR (p=1.00) in the non-randomised comparative study by Huang (2024).

Liver failure

Liver failure or hepatic sclerosis was reported in 2 studies.

New onset liver failure was reported in 2% (2 out of 126) of people at 30 days and 2% (3 out of 126) at 1 year in the single arm study of 126 people (Pan 2025). Hepatic sclerosis was reported in 1 person (3%) who had TTVR and 4 people (7%) who had medical therapy (p=0.06) in the non-randomised comparative study of 88 people (Wang 2024).

Other

Nonelective tricuspid valve reintervention was reported in 4% and 2% of people at 30 days and 5% and 4% of people at 1 year in the 2 single arm trials (Pan 2025, Kodali 2023). Four conversions to TV surgery were reported in the registry study of 76 people, for malpositioning of the valve, device embolisation, anchor detachment with subsequent pericardial tamponade and pericardial effusion before device deployment (Stolz 2024). Device thrombosis and endocarditis were reported in 1 person each at 30 days in the single arm trial of 126 people (Pan 2025). Severe pneumonia and pericardial effusion were reported in 1 person each after TTVR in the non-randomised comparative study of 88 people (Wang 2025). Device malposition and in-hospital reintervention were reported in 1 person each and major valve thrombosis was reported in 2% of people in the retrospective cohort study of 176 people (Angellotti 2025). In the same study, hypoattenuated leaflet thickening was reported in 6% of people with reduced leaflet motion in 2%.

A case report by Chen (2023) described device delivery failure associated with exfoliated intima wrapping the prosthetic valve. The membranous structure prevented the valve from expanding as expected. Conversion to TV surgery was necessary and a new valve was subsequently sewn to the TV annulus.

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following theoretical adverse events:

- allergic reaction
- aneurysm or pseudoaneurysm
- angina or chest pain
- arteriovenous fistula
- cardiac injury
- cardiogenic shock
- chordal entanglement or rupture
- coronary artery occlusion
- damage to or interference with function of pacemaker or implantable cardioverter defibrillator
- embolisation or thrombus
- oesophageal irritation, perforation or stricture
- injury to the tricuspid apparatus including chordal damage, rupture, papillary muscle damage
- mesenteric ischaemia or bowel infarction
- nerve injury
- neurological symptoms, including dyskinesia, without diagnosis of transient ischaemic attack or stroke
- pannus formation
- paralysis
- peripheral ischaemia
- pleural effusion
- pulmonary oedema
- pulmonary embolism
- retroperitoneal bleed
- right ventricular outflow tract obstruction
- structural deterioration (wear, fracture, calcification, leaflet tear, leaflet thickening, stenosis of implanted device, or new leaflet motion disorder)
- valve leaflet entrapment

- valve malposition or migration
- vascular injury or trauma, including dissection or occlusion.

Six professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure here https://www.nice.org.uk/guidance/indevelopment/gid-ipg10416/documents.

Validity and generalisability

- In the key studies identified, data was reported from North America, Europe and Asia.
- Most studies reported outcomes at 1-year follow-up, although 1 small non-randomised comparative study had a median follow-up of 645 days after TTVR (Wang 2025).
- Most studies included people with severe or greater TR.
- Four studies were retrospective, which increases the risk of bias (Angellotti 2025, Stolz 2024, Wang 2024, Wang 2025).
- There was a large randomised controlled trial comparing TTVR with OMT against OMT alone (Hahn 2025). The primary outcome was a hierarchical composite end point that was analysed using a win ratio. The trial was not powered to detect differences in individual components of the composite primary outcome, including death from any cause and hospitalisation for heart failure.
- The 2:1 randomisation ratio used in Hahn (2025) resulted in a small control group, which was further reduced by disproportionate withdrawals from the control group, missing follow-up data, and crossovers to valve replacement. Of the 133 people randomised to the control group, 16 (12%) withdrew, 13 died and the 1-year data was complete for 97 people (73%). In the TTVR group, there were 10 (4%) withdrawals, 33 deaths and 1-year data was complete for 215 (80%) people.

- A placebo effect may have some influence on improvements in patient-reported symptoms scores and quality of life measures seen after TTVR.
- There was moderate heterogeneity between the studies included in the systematic review by Bugan (2022) and only single-arm studies were identified. The authors noted that definitions of pulmonary arterial pressure differed for the inclusion and exclusion criteria between studies included in the review.
- The studies by Pan (2025) and Wang (2024) were done during the COVID-19 pandemic in China, which may have affected the collection and reliability of the primary endpoint and follow-up data, including all-cause mortality.
- TR has different causes and this may affect the efficacy outcomes of TTVR.
- Most of the studies reflected early experience with the procedure. The registry study reported early compassionate use outcomes in a population with multiple comorbidities and increased surgical risk (Stolz 2024).
- The 3 non-randomised comparative studies had small sample sizes and all reported statistically significant differences in baseline characteristics between the TTVR and control groups (Wang 2024, Wang 2025, Huang 2024). People who had TTVR were generally older with higher surgical risk scores and higher proportions of torrential TR.
- The non-randomised study that compared TTVR against medical therapy excluded patients with worsening left heart function and other significant cardiac diseases during the selection process, which may limit the generalisability of the findings (Wang 2024). Also, the control group included people who were ineligible for TTVR, which may have introduced bias into the results. The medical therapy was described as guideline directed medical therapy, but it was not defined and may not be the same as that used in the UK NHS.
- Different TTVR systems were used in the studies, with different approaches for device implantation.

- The randomised controlled trial by Hahn (2025) and the single-arm study by Kodali (2023) were funded by Edwards Lifesciences, US. Many of the authors who contributed to the registry study of 76 people reported being a consultant for companies, including Edwards Lifesciences, Abbott, Cardiovalve, Medtronic, Boston Scientific, NeoChord and Jenscare (Stolz 2024). The other key studies reported that there were no conflicts of interests.
- Two non-randomised comparative studies had the same first author and were done at the same single centre with overlapping study periods (Wang 2024 and 2025).

Ongoing trials

There are multiple trials with population size less than 50, with study completion dates between 2026 and 2030. These include several different devices. Larger trials are listed below:

TRISCEND II Pivotal Trial; n=1,070; study completion date Dec 2029

Clinical Study of the InQB8 TTVR System; n=50; study completion date Oct 2029

The TRICURE EU Pivotal Study (TRICURE EU); n=80; study completion date Dec 2030

Real World European Investigation of Safety and Clinical Efficacy of the EVOQUE System (TRISCEND III EU); n=500; study completion date Sep 2033

Global Multicenter Registry on Transcatheter TRIcuspid Valve RePLACEment (TRIPLACE); n=200; study completion date Aug 2027

Safety and Performance of the Cardiovalve TR Replacement System (TARGET); n=100; study completion date Dec 2026

A Study to Evaluate the Safety and Performance of LuX-Valve Plus System for Tricuspid Replacement; n=150; study completion date Aug 2030

THE TRAVEL II TRIAL: Transcatheter Right Atrial-ventricular Valve rEplacement With LuX-Valve Via Jugular Vein; n=150; study completion date March 2027

Transcatheter Interventions for Tricuspid Insufficiency in Italy (TRIC-IT); n=200; study completion date Jan 2027

THE TRAVEL TRIAL: Transcatheter Right Atrial-ventricular Valve rEplacement With LuX-Valve (TRAVEL); n=150; study completion date June 2026

2019-06 TRISCEND Study; n=228; study completion date Jan 2029

Related NICE guidance

Interventional procedures

Caval valve implantation for tricuspid regurgitation (2024) NICE interventional procedures guidance 791 (Recommendation: more research is needed)

Transcatheter tricuspid valve annuloplasty for tricuspid regurgitation (2022) NICE interventional procedures guidance 730 (Recommendation: special arrangements for people with severe and symptomatic TR; research for people with mild or moderate TR)

Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation (2022) NICE interventional procedures guidance 731 (Recommendation: special arrangements for people with severe and symptomatic TR; research for people with mild or moderate TR)

NICE guidelines

Heart valve disease presenting in adults: investigation and management (2021) NICE guideline NG208

Professional societies

- Society of 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.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was considered by the interventional procedures technical team and any relevant points have been taken into consideration when preparing this overview.

References

1. Hahn RT, Makkar R, Thourani VH et al. (2025) Transcatheter Valve Replacement in Severe Tricuspid Regurgitation. The New England Journal of Medicine 392: 115–26

   Arnold SV, Hahn RT, Thourani VH et al. (2025) Quality of Life After Transcatheter Tricuspid Valve Replacement: 1-Year Results From TRISCEND II Pivotal Trial. Journal of the American College of Cardiology 85: 206–16

2. Bugan B, Cekirdekci EI, Onar LC et al. (2022) Transcatheter Tricuspid Valve Replacement for Tricuspid Regurgitation: A Systematic Review and Meta-analysis. Anatolian Journal of Cardiology 26: 505–19

3. Pan X, Lu F, Wang Y et al. (2025) Transcatheter Tricuspid Valve Replacement With the Novel System: 1-Year Outcomes From the TRAVEL Study. JACC. Cardiovascular Interventions 18: 1276–85

4. Kodali S, Hahn RT, Makkar R et al. (2023) Transfemoral tricuspid valve replacement and one-year outcomes: the TRISCEND study. European Heart Journal 44: 4862–73

5. Angellotti D, Mattig I, Samim D. et al. (2025) Early Outcomes of Real-World Transcatheter Tricuspid Valve Replacement. JACC. Cardiovascular Interventions https://doi.org/10.1016/j.jcin.2025.06.002

6. Stolz L, Cheung A, Boone R et al. (2024) Transjugular Transcatheter Tricuspid Valve Replacement: Early Compassionate Use Outcomes. JACC. Cardiovascular Interventions 17: 1936–45

7. Wang Y, Liu Y, Meng X et al. (2024) Comparing outcomes of transcatheter tricuspid valve replacement and medical therapy for symptomatic severe

tricuspid regurgitation: a retrospective study. European Journal of Medical Research 29: 407

8. Wang Y, Liu Y, Xuezeng et al. (2025) Transcatheter Tricuspid Valve Replacement Versus Totally Thoracoscopic Beating-Heart Surgery for Tricuspid Regurgitation. Cardiovascular Drugs and Therapy https://doi.org/10.1007/s10557-025-07669-2
9. Huang L, Sun Z, Cai Y et al. (2024) Comparison of clinical and echocardiographic outcomes between mini-thoracotomy transatrial LuX-Valve transcatheter and surgical tricuspid valve replacement. Frontiers in Cardiovascular Medicine 11: 1417757
10. Chen F, Qian H, Zhao Z et al. (2023) Exfoliated Intima Wrapping the Prosthetic Valve During Transcatheter Tricuspid Valve Replacement. JACC. Cardiovascular Interventions 16: 993–6
11. Jiang A, Davey R, Tweedie EJ et al. (2024) Complete heart block and subsequent sudden cardiac death following transcatheter tricuspid valve replacement in a heart transplant patient: a case report. European Heart Journal. Case Reports 8: ytae599

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to transcatheter tricuspid valve replacement for tricuspid regurgitation from the medical literature.

Search strategy design and peer review

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).

A NICE information specialist ran the literature searches on 25/04/2025. See the search strategy history for the full search strategy for each database. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4a, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Limits and restrictions

The search was not limited by date or language.

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.

The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin K, Scherer R, Lefebvre C (1994) Systematic Reviews: Identifying relevant studies for systematic reviews. BMJ 309(6964): 1286.

Main search

Table 4a Main search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	25/04/2025	Wiley	Issue 3 of 12, March 2025	46
Cochrane Database of Systematic Reviews (CDSR)	25/04/2025	Wiley	Issue 3 of 12, March 2025	0
Embase	25/04/2025	Ovid	1974 to 2025 April 24	1394
INAHTA International HTA Database	25/04/2025	https://database.inahta.org/	-	10
MEDLINE ALL	25/04/2025	Ovid	1946 to April 24, 2025	1581

Search strategy history

MEDLINE ALL search strategy

1 Tricuspid Valve Insufficiency/ 7866

2 (tricuspid adj4 (Insufficienc* or Regurgitat* or incompetence* or degenerat* or disease*)).tw. 11143

3 (TR or FTR).tw. 29627

4 or/1-3 41119

5 Tricuspid Valve/ 10443

6 (Replac* or transplant* or implant* or prosthes*).tw. 1604112

7 5 and 6 2940

8 ((Transcatheter or Transapical or transventricular) adj4 (tricuspid or "heart valve") adj4 (Replac* or transplant* or implant* or prosthes*)).tw. 598

9 TTVR.tw. 108

10 7 or 8 or 9 3415

11 4 and 10 1493

12 animals/ not humans/ 5297610

13 11 not 12 1455

14 EVOQUE.tw. 121

15 Intrepid valve.tw. 3

16 LuX-Valve.tw. 28

17 Cardiovalve.tw. 11

18 Trisol.tw. 8

19 MonarQ.tw. 2

20 (NaviGate adj4 valve).tw. 7

21 or/14-20 176

22 13 or 21 1581

Embase search strategy

1 tricuspid valve regurgitation/ 32134

2 (tricuspid adj4 (Insufficienc* or Regurgitat* or incompetence* or degenerat* or disease*)).tw. 19748

3 (TR or FTR).tw. 45698

4 or/1-3 76513

5 tricuspid valve replacement/ 2671

6 ((Transcatheter or Transapical or transventricular) adj4 (tricuspid or "heart valve") adj4 (Replac* or transplant* or implant* or prosthes*)).tw. 889

7 TTVR.tw. 202
8 or/5-7 3378
9 4 and 8 1675
10 Nonhuman/ not Human/ 5678162
11 9 not 10 1654
12 EVOQUE.tw,dv,dm. 215
13 Intrepid valve.tw,dv,dm. 12
14 LuX-Valve.tw,dv,dm. 68
15 Cardiovalve.tw,dv,dm. 68
16 Trisol.tw,dv,dm. 38
17 MonarQ.tw,dv,dm. 3
18 (NaviGate adj4 valve).tw,dv,dm. 14
19 or/12-18 333
20 11 or 19 1855
21 (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. 6243752
22 20 not 21 1394

Cochrane Library (CDSR and CENTRAL) search strategy

#1 MeSH descriptor: [Tricuspid Valve Insufficiency] this term only 144
#2 (tricuspid NEAR/4 (Insufficienc* or Regurgitat* or incompetence* or degenerat* or disease*)) 593
#3 (TR or FTR) 12191
#4 {OR #1-#3} 12636
#5 MeSH descriptor: [Tricuspid Valve] this term only 126
#6 (Replac* or transplant* or implant* or prosthes*) 153619
#7 #5 AND #6 50
#8 ((Transcatheter or Transapical or transventricular) NEAR/4 (tricuspid or "heart valve") NEAR/4 (Replac* or transplant* or implant* or prosthes*)) 58

#9 ttvr 18

#10 {OR #7-#9} 116

#11 #4 and #10 51

#12 EVOQUE 7

#13 Intrepid valve 3

#14 LuX-Valve 0

#15 Cardiovalve 0

#16 Trisol 1

#17 MonarQ 0

#18 (NaviGate NEAR/4 valve) 1

#19 {OR #11-#18} 57

#20 "conference":pt or (clinicaltrials or trialsearch):so 815946

#21 #19 NOT #20 in Cochrane Reviews, Cochrane Protocols 0

#22 #19 NOT #20 in Trials 46

INAHTA HTA Database search strategy

1 (Tricuspid Valve Insufficiency)[mh] 11

2 (tricuspid AND (Insufficienc* or Regurgitat* or incompetence* or degenerat* or disease*)) 13

3 (TR or FTR) 0

4 #3 OR #2 OR #1 13

5 (Tricuspid Valve)[mh] 12

6 (Replac* or transplant* or implant* or prosthes*) 2083

7 #6 AND #5 8

8 ((Transcatheter or Transapical or transventricular) AND (tricuspid or "heart valve") AND (Replac* or transplant* or implant* or prosthes*)) 6

9 TTVR 0

10 #9 OR #8 OR #7 9

11 #10 AND #4 8

12 EVOQUE 1

13 Intrepid valve0
14 LuX-Valve 1
15 Cardiovalve 0
16 Trisol 0
17 MonarQ 0
18 (NaviGate AND valve) 0
19 #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10
10

Inclusion criteria

The following inclusion criteria were applied to the abstracts identified by the literature search.

Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events not available in the published literature.

People with TR.

Intervention or test: TTVR.

Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in Appendix B: Other relevant studies.

Find out more about how NICE selects the evidence for the committee

Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary (tables 2 and 3) are listed in table 5 below.

Case reports were excluded unless they described a safety event that was not described in the main evidence.

Table 5 additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Abushouk A, Layoun H, Harb SC et al. (2024) Real-World Patient Eligibility and Feasibility of Transcatheter Edge-to-Edge Repair or Replacement Interventions for Tricuspid Regurgitation. Journal of cardiac failure 30: 1265–72	Observational study n=128 Follow-up: 1 year	A total of 11% of the population were deemed eligible for investigative therapies, 20% were offered off-label clipping, 20% were offered surgery and 49% had medical treatment. At 1 year, there was a statistically significant reduction in TR severity in the investigative group ($p<0.001$) in comparison with the medical treatment group. However, the results were comparable to off-label clipping ($p=0.60$) and inferior to surgery ($p=0.04$). Current real-world eligibility for emerging transcatheter TR therapies remains limited, underscoring the need for continued innovative efforts to offer	Observational study focusing on the eligibility of people for transcatheter TR treatments.

		device therapies to a broader TR cohort.	
Barreiro-Perez M, Gonzalez-Ferreiro R, Caneiro-Queija B et al. (2023) Transcatheter Tricuspid Valve Replacement: Illustrative Case Reports and Review of State-of-Art. Journal of Clinical Medicine 12(4), 1371	Review and case series (n=3) Cardiovalve (n=2) and LuX-Valve Plus (n=1)	Transcatheter TV interventions are an appealing treatment option for a common disease in a group of people often with comorbidities, high surgical risk, and poor surgical outcomes when not addressed at an early stage. Particularly, TTVR with orthotopic prosthetic valves offers a definitive treatment maintaining the physiological functions of right heart chambers (as opposed to heterotopic prosthesis) and the possibility of treatment of people with contraindications to other percutaneous interventions such as edge-to-edge repair or annuloplasty devices.	The paper describes a small case series and a non-systematic review.
Cannata F, Sticchi A, Russo G et al. (2025) Mitral regurgitation evolution after transcatheter tricuspid valve interventions - A sub-analysis of the TriValve registry. European Heart Journal Cardiovascular Imaging 26: 135	Subanalysis of TriValve registry n=359 (12 TTVR)	Most cases of 'evolving mitral regurgitation' showed an improvement, above all if transcatheter tricuspid valve intervention is successful and if baseline characteristics associated with a ventricular functional mitral regurgitation subtype are present. Moreover, an effective transcatheter tricuspid valve intervention with significant TR reduction may prevent mitral regurgitation worsening	Most people had transcatheter edge-to-edge repair and only a small proportion had TTVR.

		and possibly trigger an improvement.	
Chen Y, Cai C, Qiao F et al. (2022) Preoperative 6-minute walk test predicts prolonged hospitalization after transcatheter tricuspid valve replacement. Medicine 101: e32379	Retrospective cohort study n=41	Preoperative decreased 6MWT distance was an independent risk factor for prolonged hospitalisation in high-risk TR patients after TTVR.	Larger studies are included.
Dershowitz L, Lawlor MK, Hamid N et al. (2024) Right ventricular remodeling and clinical outcomes following transcatheter tricuspid valve intervention. Catheterization and Cardiovascular Interventions 103: 367–75	Single-centre retrospective cohort study n=61 (25 TTVR) Follow-up: 147 days	Greater TR reduction was achieved by TTVR versus transcatheter tricuspid valve repair, which was in turn associated with RV reverse remodelling. RV dimension in follow-up was associated with increased risk of a composite outcome of death, heart failure hospitalisation, or redo tricuspid valve intervention.	Small retrospective study with mixed interventions.
Fam NP, von Bardeleben RS, Hensey M et al. (2021) Transfemoral Transcatheter Tricuspid Valve Replacement With the EVOQUE System: A Multicenter, Observational, First-in-Human Experience. JACC. Cardiovascular interventions 14: 501–11	Observational single arm study n=25 Follow-up: 30 days EVOQUE system (Edwards Lifesciences, US)	There were statistically significant improvements in NYHA functional class, signs of right-sided heart failure, and biochemical indexes of hepatic congestion, with a subset of people needing fewer diuretic agents at 30-day follow-up. As expected, right ventricular function was slightly reduced at follow-up, but this was offset by significant reductions in pre-load and right ventricular volumes with evidence of reverse remodelling by	Larger studies are included.

		echocardiographic and CT assessment. The main complications were valve reintervention (4%), new conduction abnormalities requiring permanent pacemaker implantation (8%), and major bleeding (12%). 36% of people had pacemaker leads, and all had successful TTVR with either no or mild paravalvular TR at the site of the lead, with no change in pacemaker function, including patients who were pacemaker dependent at baseline.	
Hagemeyer D, Merdad A, Sierra LV et al. (2024) Clinical Characteristics and Outcomes of Patients Screened for Transcatheter Tricuspid Valve Replacement: The TriACT Registry. JACC. Cardiovascular interventions 17: 552–60	Multicentre observational study (TriACT registry) n=38 Follow-up: 30 days EVOQUE (Edwards Lifesciences), Cardiovalve (Cardiovalve), Topaz (TRiCares) and VDyne (VDyne)	A total of 149 people with TR were screened but only 38 were eligible for TTVR. There were statistically significant functional improvements (NYHA functional class 1 or 2 from 21% to 68%, p<0.001), with TR 1 or less in 97% at 30-day follow-up (p<0.001 from baseline). Technical success was 91%, with no intraprocedural mortality or conversion to surgery. At 30-day follow-up, mortality was 8%, heart failure hospitalisation 5%, major bleeding 18%, and reintervention 9%.	Larger studies are included.
Hahn RT, George I, Kodali SK et al. (2019) Early Single-Site Experience With Transcatheter	Single centre case series n=5	In this series of people with symptomatic, very severe functional TR, TTVR was feasible with short-term improvement	Larger studies are included.

Tricuspid Valve Replacement. JACC. Cardiovascular Imaging 12: 416–29	Follow-up: 30 days GATE System (NaviGate Cardiac Structures, Inc., US)	in RV remodelling and cardiac output. Comorbidities, particularly right ventricular function, might be important determinants of outcomes.	
Hahn RT, Kodali S, Fam N et al. (2020) Early Multinational Experience of Transcatheter Tricuspid Valve Replacement for Treating Severe Tricuspid Regurgitation. JACC. Cardiovascular Interventions 13: 2482–93	Multicentre case series n=30 Mean follow-up: 127 days GATE System (NaviGate Cardiac Structures, Inc., US)	• Technical success=87% • In-hospital mortality=10% • Mild or less TR at discharge=76% • NYHA functional class 1 or 2 at follow-up=62% Device malpositioning happened in 4 people, with conversion to open heart surgery in 2 (5%). Of those who had the device, 100% had reductions in TR of 1 or more, and 75% had reductions of 2 or more grades. In most people (79%), there was continued improvement in TR grade between discharge and 30 days.	Larger studies are included.
Hausleiter J, Stolz L, Lurz P et al. (2025) Transcatheter Tricuspid Valve Replacement. Journal of the American College of Cardiology; 85: 265–91	Review	Clinical outcomes from initial studies and compassionate use cases highlight the effectiveness of TTVR in reducing TR, inducing reverse right ventricular remodelling, and enhancing patients' quality of life. There are still uncertainties about the effect of TTVR on hard	A systematic review and meta-analysis is included.

		clinical endpoints such as mortality and heart failure hospitalisation. Potential complications and challenges associated with TTVR include new-onset conduction disturbances, bleeding complications, and afterload mismatch. TTVR is currently mainly done when transcatheter edge-to-edge repair is unsuitable, but it may expand to include the situation when expected TR reduction from repair is suboptimal. Future research will address whether there are differences between the available devices.	
Khan MS, Baqi A, Tahir A et al. (2024) National Estimates for the Percentage of All Readmissions With Demographic Features, Morbidity, Overall and Gender-Specific Mortality of Transcutaneous Versus Open Surgical Tricuspid Valve Replacement/Repair. Cardiol Res. 15: 223–32	Retrospective observational study (data from a US Nationwide Readmissions Database) n=10,506 (429 TTVR)	TTVR is an emerging alternative to open TVR in people with TV disease, especially high-risk populations with severe TR to improve the quality of life. Analysis of a large pool of NRD data has shown promising trends towards lower morbidity and mortality and lower overall healthcare cost burden with TTVR compared to open TVR.	Limited data, which includes both transcatheter repair and replacement.
Kodali S, Hahn RT, George I et al. (2022) Transfemoral Tricuspid Valve Replacement in Patients With Tricuspid Regurgitation: TRISCEND Study 30-Day Results. JACC.	Prospective, single-arm, multicentre study (TRISCEND) n=56 Follow-up: 30 days	At 30 days, TR was reduced to mild or less in 98%. The composite major adverse events rate was 27% at 30 days caused by 1 cardiovascular death in a patient with a failed procedure, 2 reinterventions after	A more recent publication of the same study with longer follow-up is included.

Cardiovascular Interventions 15: 471–80	EVOQUE system (Edwards Lifesciences, US)	device embolisation, 1 major access site or vascular complication, and 15 severe bleeds, of which none were life-threatening or fatal. NYHA significantly improved to functional class 1 or 2 (79%; p<0.001), 6-minute walk distance improved 49.8 m (p<0.001), and KCCQ score improved 19 points (p<0.001).	
Lawlor MK, Ng V, Ahmed S et al. (2023) Baseline Characteristics and Clinical Outcomes of a Tricuspid Regurgitation Referral Population. American Journal of Cardiology 196: 22–30	Retrospective observational study n=408 (77 had transcatheter tricuspid valve interventions)	Advanced regurgitation severity and right-sided cardiac remodelling with haemodynamic decompensation portend poor prognosis in TR, and late referral for surgical therapy with advanced disease is associated with high rates of morbidity and mortality. People who had transcatheter tricuspid valve interventions were at greater preoperative risk than were those who had surgery. Further study is warranted to investigate risk stratification and selection for and timing of procedural intervention in people with TR.	It is unclear what the transcatheter interventions were and the aim of the study was to characterise the natural history of the highly selected TR referral population.
Lawlor MK, Hamid N, Kampaktsis P et al. (2022) Incidence and predictors of cardiogenic shock following surgical or transcatheter tricuspid valve intervention.	Retrospective single centre observational study n=122 (28 TTVR)	In people who have TV intervention for TR, surgery versus transcatheter tricuspid valve intervention and elevated central venous pressure are associated with advanced	Only a small proportion of the study population had TTVR.

Catheterization and Cardiovascular Interventions 99: 1668–78		postprocedural cardiogenic shock. Patients developing advanced CS are at increased risk of in-hospital mortality.	
Liu J, Tan T, Huang H et al. (2023) Outcomes of minimally invasive isolated tricuspid valve reoperation after left-side valve surgery: A single-center experience. Frontiers in Cardiovascular Medicine 10: 1033489	Retrospective single-centre cohort study n=21 (5 TTVR) Median follow-up: 16.8 months LuX-Valve	Minimally invasive procedures were successfully done without any perioperative mortality, sternotomy conversion, or reoperation. NYHA class improved from baseline (p=0.004). TR severity was significantly improved during postoperative and follow-up period (both p<0.001). Compared with the endoscopic group, the TTVR group had a higher clinical risk score (8.00 versus 5.00, p=0.001), but a higher success rate in reducing TR to less than grade 1+ (100 versus 44%, p=0.045) at follow-up.	Only a small proportion of the study population had TTVR.
Lu F-L, An Z, Ma Y et al. (2021) Transcatheter tricuspid valve replacement in patients with severe tricuspid regurgitation. Heart 107: 1664–70	Multicentre cohort study n=46 Follow-up: 6 months LuX-Valve	Radial force-independent transcatheter bioprosthetic tricuspid valve replacement in high-risk patients with severe TR is feasible, safe and with low complication rates.	Larger studies are included.
Lu F-L, Ma Y, An Z et al. (2020) First-in-Man Experience of Transcatheter Tricuspid Valve Replacement With LuX-Valve in High-Risk Tricuspid Regurgitation	Prospective case series n=12 LuX-Valve	Transthoracic echocardiography at 30 days showed none-to-mild residual TR was documented in all but 1 patient (91%). Significant symptomatic improvement was observed with improved	Larger studies are included.

Patients. JACC. Cardiovascular Interventions 13: 1614–16		6-minute walk tests (377 versus 277.5 metres, p<0.05) and NYHA functional status (54.5% at NYHA functional class 2; p<0.05).	
Mao Y, Li L, Liu Y et al. (2022) Safety, efficacy, and clinical outcomes of transcatheter tricuspid valve replacement: One-year follow-up. Frontiers in Cardiovascular Medicine 9: 1019813	Single-centre observational study n=15 Follow-up: 1 year LuX-Valve	TR was significantly reduced to 2+ or less. One person died on postoperative day 12 of a pulmonary infection that was considered unrelated to the procedures or the devices. The remaining 14 people reached the primary end point. One person was rehospitalised during 1-year follow-up because of device thrombosis. 79% of people had NYHA functional class 2 at 1 year. Rates of peripheral oedema and ascites decreased from 100% and 47% at baseline to 29% and 14% at 1 year, respectively.	Larger studies are included.
Mao Y, Liu Y, Meng X et al. (2023) Treatment of severe tricuspid regurgitation induced by permanent pacemaker lead: Transcatheter tricuspid valve replacement with the guidance of 3-dimensional printing. Frontiers in Cardiovascular Medicine 10: 1030997	Single-centre observational study n=6 Follow-up: 2 years LuX-Valve	All people showed significant improvement in symptoms at 6 months. TR severity measured by TTE decreased from 100% for severe regurgitation to 100% for no or trace regurgitation. At 2 years, 2 people had NYHA functional class 1, 4 had NYHA functional class 2, and there were no device-related complications. The 6-minute walking test improved from 200 to 342.5 metres. KCCQ	Larger studies are included.

		scores improved from 30.5 to 62.0.	
Miura M, Alessandrini H, Alkhodair A et al. (2020) Impact of Massive or Torrential Tricuspid Regurgitation in Patients Undergoing Transcatheter Tricuspid Valve Intervention. JACC. Cardiovascular Interventions 13: 1999–2009	Multicentre registry data (TriValve) n=333 transcatheter tricuspid valve interventions Median follow-up: 237 days	Baseline massive or torrential TR was associated with an increased risk for 1-year death of any cause or rehospitalisation for heart failure after transcatheter tricuspid valve interventions compared with patients with severe TR. Procedural success was related to better outcomes, even in the presence of baseline massive or torrential TR.	Most procedures were valve repairs rather than replacements.
Ning X, Cao J, Wang W et al. (2023) Impact of transcatheter tricuspid valve replacement for tricuspid regurgitation on hepatic, cardiac, and venous structure. International Journal of Cardiology 372: 33–39	Case series n=22 Follow-up: 6 months LuX-Valve	TR elimination was associated with the reverse remodelling of liver, heart, and veins. LuX-Valve is a promising alternative for severe TR.	Larger studies are included.
Sazzad F, Zhu Y, Leo HL et al. (2023) A Systematic Review of the Design, Method of Implantation and Early Clinical Outcomes of Transcatheter Tricuspid Prostheses. Reviews in Cardiovascular Medicine 24: 231	Systematic review 11 articles	Of the 4 studies that reported NYHA class at follow-up, EVOQUE (79%) (Edwards Lifesciences, US), GATE (72%) (NaviGate Cardiac Structures Inc., US), and TricValve (53%) (P+F Products + Features, Austria) showed that most people were NYHA class 1 or 2 at follow-up, as compared to class 3 or 4 preoperatively. The remaining study, Edwards Sapien XT (Edwards Lifesciences, US) reported that 63% of	Review included studies on caval valve implantation as well as TTVR, and there was no meta-analysis.

		people improved by 1 NYHA class. Most devices are circular and are inserted and secured using radial forces.	
Scotti A, Coisne A, Taramasso M et al. (2023) Sex-related characteristics and short-term outcomes of patients undergoing transcatheter tricuspid valve intervention for tricuspid regurgitation. European Heart Journal 44: 822	Multicentre registry data (TriValve) n=556 (13 TTVR) Follow-up: 1 year	In the TriValve registry, after transcatheter tricuspid valve intervention in high-risk people with significant TR, there were no sex-related differences in terms of survival, heart failure hospitalisation, functional status, and TR reduction up to 1 year. The inverse probability of treatment weighting analysis suggests that transcatheter tricuspid valve intervention may be associated with a substantial and consistent increase in survival in both women and men compared with medical therapy alone. Future studies are needed to assess whether sex-related differences in outcomes may emerge at longer term follow-up.	Only a small proportion of the study population had TTVR.
Sun Z, Li H, Zhang Z et al. (2021) Twelve-month outcomes of the LuX-Valve for transcatheter treatment of severe tricuspid regurgitation. EuroIntervention 17: 818–26	Single centre case series n=6 Follow-up: 12 months LuX-Valve	All people had successful implantations of LuX-Valves through the right atrium with a substantial reduction in the degree of TR. Although 1 person with moderate paravalvular leakage died because of right heart failure during 3-month follow-up, the other 5 had no significant paravalvular leakage, and displayed significant	Larger studies are included.

		improvements in mean transvalvular gradient, right heart sizes, conventional right ventricular function indices, and a reduction in NYHA functional class during 12-month follow-up.	
Taramasso M, Alessandrini H, Latib Azeem et al. (2019) Outcomes After Current Transcatheter Tricuspid Valve Intervention: Mid-Term Results From the International TriValve Registry. JACC. Cardiovascular Interventions 12: 155–65	Multicentre registry data (TriValve) n=312	Procedural success (defined as the device successfully implanted and residual TR 2+ or less) was 73%. 30-day mortality was 4% and was lower among patients with procedural success (2% versus 7%; p=0.04); Actuarial survival at 1.5 years was 83% and was higher among patients who had procedural success.	Only a small proportion of the study population had TTVR.
Wang Y, Zhai M, Mao Yu et al. (2024) Transcatheter tricuspid valve replacement for functional tricuspid regurgitation after left-sided valve surgery: A single-center experience. Catheterization and Cardiovascular Interventions 103: 626–36	Single centre case series n=20 Follow-up: 6 months Lux-Valve	All people moderate or less TR immediately after the procedure. 1 person had a procedure-related major adverse event, leading to in-hospital mortality because of pulmonary infection. At the 6-month follow-up, 90% improved to NYHA functional class 1 to 2 (p<0.001). The overall KCCQ score improved from 35.9 points to 58.9 points, p<0.001.	Larger studies are included.
Webb JG, Chuang AM-Y, Meier D et al. (2022) Transcatheter Tricuspid Valve Replacement With the EVOQUE System: 1-Year Outcomes of a Multicenter, First-in-Human Experience.	Multicentre cohort study n=27 Median follow-up: 379 days	At baseline, all people were at high surgical risk (mean STS score=8.6%) with 89% NYHA functional class 3 or 4. TR was predominantly functional in aetiology (70%). At 1 year, mortality was 7% (2/27),	Larger studies are included.

JACC. Cardiovascular Interventions 15: 481–91	EVOQUE system	70% of patients were NYHA functional class 1 or 2, and 96% and 87% of patients had a TR grade 2+ or less and 1+ or less, respectively. Between 30 days and 1 year, there were 2 heart failure hospitalisations, and 1 person needed a new pacemaker implantation.	
Wei W, Ning Li, Xiaoping N et al. (2022) Haemodynamics of transcatheter tricuspid valve replacement with Lux-Valve. Frontiers in Cardiovascular Medicine 9: 1007888	Prospective case series n=30 Follow-up: 6 months Lux-Valve	The surgical success rate was 100%. The cardiac index and stroke volume increased sharply from 2.42 and 47.8 to 3.04 and 57.2, respectively. The right atrium pressure difference dropped from 9.0 to 5.0. There was no significant change in the pulmonary artery pressure.	Larger studies are included.