Interventional procedure overview of caval valve implantation for tricuspid regurgitation

Contents

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Table 1 Abbreviations

Abbreviation	Definition
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
CAVI	Caval valve implantation
Gamma-GT	Gamma-glutamyl transferase
GFR	Glomerular filtration rate
IQR	Interquartile range
IVC	Inferior vena cava
KCCQ	Kansas City Cardiomyopathy Questionnaire
MLHFQ	Minnesota Living with Heart Failure Questionnaire
6MWD	Six-minute walk distance
NYHA	New York Heart Association
OMT	Optimised medical therapy
RCT	Randomised controlled trial
RV	Right ventricular
SD	Standard deviation
STS score	The Society of Thoracic Surgeons' risk score
SVC	Superior vena cava
TAVR	Transcatheter aortic valve replacement
TR	Tricuspid regurgitation

Indications and current treatment

The tricuspid valve sits between the right atrium and right ventricle of the heart. TR occurs because the tricuspid valve does not close properly during systole. It can result in blood refluxing back into the right atrium (leading to haemodynamically significant TR) and the 2 main caval veins (the SVC and IVC). This makes the heart work harder and, if severe, can lead to heart failure. TR can occur because of a problem with the valve anatomy itself. But it is more commonly secondary to an underlying cardiac problem that causes tricuspid annular dilatation or leaflet tethering. The valve leaflets and chords may be normal but, because of the annulus dilatation, the valve leaflets fail to close properly and regurgitation of blood occurs.

People with mild TR do not usually have symptoms. If the regurgitation is severe, there may be fatigue and weakness, active pulsing in the neck veins, an enlarged liver, ascites, peripheral oedema and renal impairment. Pulmonary hypertension may develop.

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Treatment may not be needed if there are no or mild symptoms. There are no specific medicines for treating TR itself, but symptoms of heart failure are managed with medicines such as diuretics and angiotensin-converting enzyme inhibitors. Medicines to reduce pulmonary artery pressure, pulmonary vascular resistance or both, may be used when there is severe functional TR and severe pulmonary hypertension.

People with severe symptoms may have surgery to repair or replace the tricuspid valve. Isolated tricuspid valve surgery is rarely done because it is associated with high morbidity and mortality. More commonly, it is done at the same time as surgery to the valves on the left side of the heart (mitral and aortic). Transcatheter tricuspid valve interventions (tricuspid valve repair and replacement) are an alternative for managing TR.

Unmet need

TR is more common in older people and research suggests that there may be significant TR in about 4% of people 75 years or over. Many people with significant TR cannot tolerate open heart surgery because of their age or other comorbidities. This means that many people with the condition have limited treatment options. CAVI is less invasive and may be an option when surgery is contraindicated, and other transcatheter tricuspid valve interventions are not suitable. It also has the potential to reduce symptoms and improve quality of life with fewer side effects.

What the procedure involves

CAVI is indicated for haemodynamically significant TR and caval reflux in people who have advanced disease (with severe leaflet tethering and a large coaptation gap) and are at extreme risk from surgery. The aim is to reduce caval reflux and stop venous congestion, so improving symptoms of heart failure and quality of life for people who cannot have open heart surgery.

The procedure is done under local or general anaesthesia, and with fluoroscopy guidance. Transoesophageal echocardiography may be used to monitor the position and function of the deployed bioprostheses. Depending on the anatomical suitability, CAVI can be single or bicaval. The bioprostheses can be dedicated self-expandable valves or balloon-expandable prostheses used for TAVR. They are implanted percutaneously through a delivery system using transfemoral access. The valves are implanted in the IVC, SVC or both, at the

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level of the atriocaval junction. This is done without disturbing the native tricuspid valve in a cranial-caudal direction.

Outcome measures

The main outcomes include NYHA functional class, health and quality of life status using KCCQ, 6MWD, and maximal oxygen uptake. The measures used are detailed in the following paragraphs.

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 done, discomfort is increased.

KCCQ

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

Maximal oxygen uptake (VO_{2max})

The product of peak cardiac output and maximal arteriovenous oxygen difference is referred to as maximal oxygen uptake. This is the amount of oxygen used by a subject when exercising as hard as possible. The primary endpoint was determined by quantifying maximal oxygen uptake by treadmill spiro-ergometry.

Evidence summary

Population and studies description

This overview is based on 163 patients from 1 RCT, 2 registries, 2 non-randomised studies, 1 observational study, and 2 case reports. Of these,

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198 patients, 139 patients had the CAVI procedure and the remaining 24 patients had OMT. 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 8 studies as the key evidence in table 2 and table 3, and lists 29 other relevant studies in table 5.

The countries where the procedures were carried out include Germany, Canada, Spain, Austria, Switzerland, Lithuania, and the United States. The population is comprised of patients 18 years and over with severe TR. The study designs include RCTs, registries, and non-randomised studies. The follow-up periods ranged from 6 months to 12 months. Table 2 presents study details.

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Figure 1 Flow chart of study selection

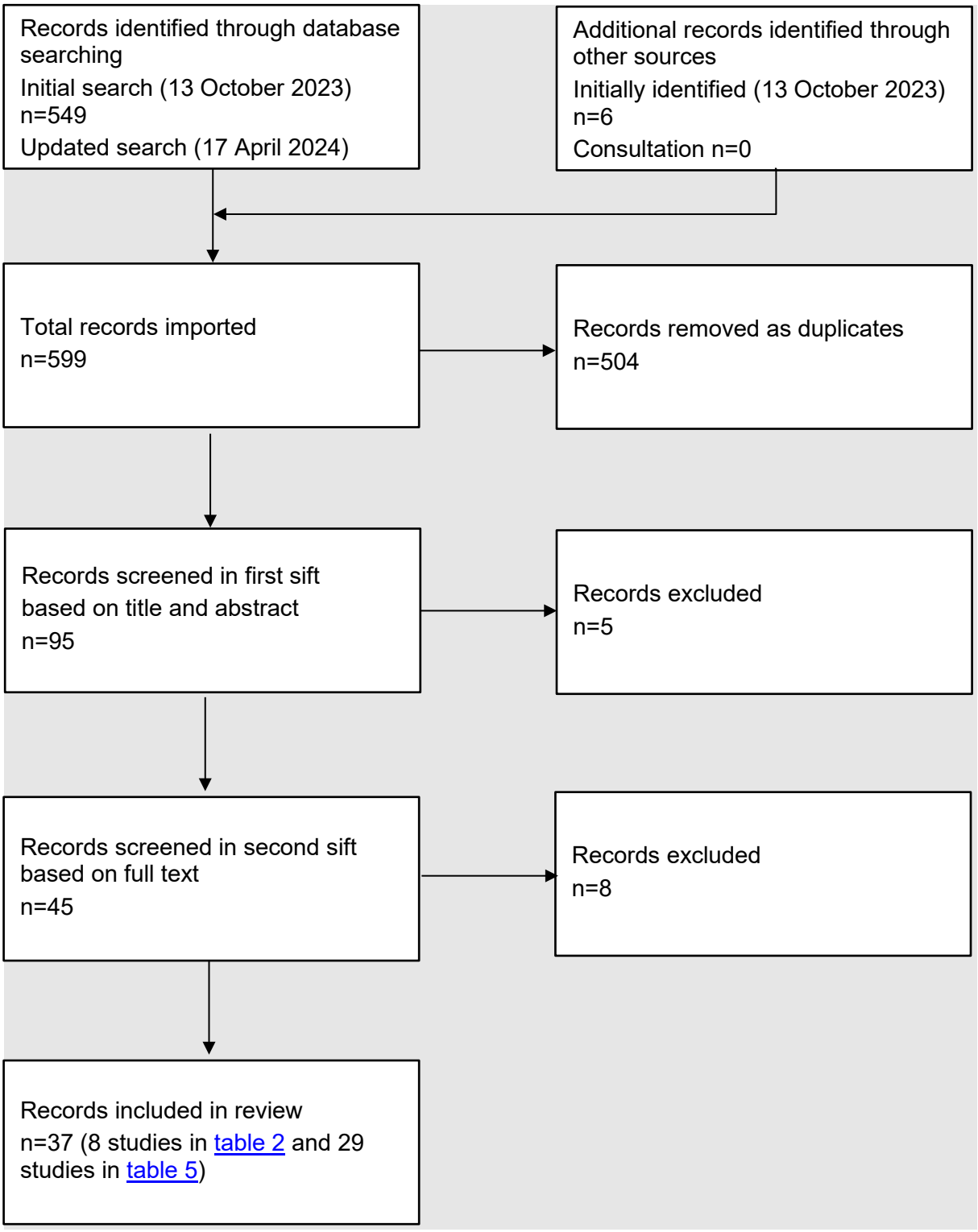

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Table 2 Study details

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up	Comments
1	Dreger H, 2022 Germany	N=28 patients with advanced heart failure CAVI group n=14 (2:12) OMT group n=14 (7:7)	CAVI mean age (IQR): 77 (72.2-79.5) OMT mean age (IQR): 77 (68.2-82.0) years	RCT TRICAVAL trial NCT02387697	NYHA Class ≥2 despite OMT, age ≥50 years, and high surgical risk (logistic EuroSCORE I ≥15% or other contraindications for conventional valve surgery according to the local heart team)	CAVI versus OMT Implantation of a balloon-expandable transcatheter valve (Edwards Sapien XT valve) into the IVC	12 months	The study was stopped early because of major complications related to valve dislocation and stent migration
2	Hewing B, 2021 Germany	N=18 patients with advanced heart failure CAVI group n=8 at completed 3-month follow up)	CAVI mean age (IQR): 79 (68.3-82.6) years	Non-randomised study Subgroup analysis of RCT TRICAVAL trial NCT02387697	Severe secondary TR, NYHA class ≥2, optimal medical treatment and high surgical risk	CAVI versus medical therapy Implantation of a balloon-expandable transcatheter valve (Edwards	12 months	The study evaluated the effects of CAVI on clinical signs of congestion, renal and hepatic function. After

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up	Comments
		(2:6)OMT group n=10 at completed 3-month follow up) (5:5)	OMT mean age [IQR]: 78 (73.3-83.9) years			Sapien XT Valve) into the IVC		major complications, the study was stopped prematurely, resulting in a small study sample size for the present subanalysis.
3	Lauten A, 2018 Germany and Canada (multicentre)	N=25 patients and 31 caval valves implanted (12:13)	Mean age: 73.9 years mean STS score of 14.0±12.7	Multicentre observational study	Patients presenting with symptomatic severe TR despite OMT and considered unsuitable for surgery	Ballon-expandable (Sapien XT) or self-expanding valves (TricValve) (CAVI) Single valve implantation (76%, 19/25) Bicaval valve implantation (24%, 6/25)	12 months	-

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up	Comments
						Balloon-expandable valves (Sapien XT or Sapien 3: 78.3%,17/31) Self-expandable valves (TricValve: 21.7%, 7/31; Directflow valve: 4%, 1/31)		
4	Blasco-Turrion 2024 Spain, Austria, Lithuania	N= 44 patients (8:36)	Mean age ±SD: 76.2±7.5 years	Non-randomised study (TRICUS and TRICUS EURO)	Patients with severe symptomatic severe TR (grade ≥3 in a 5-grade classification) with high surgical risk	CAVI with TricValve	1 year	Combined cohort results of TRICUS EURO study and TRICUS study
5	Wild MG, 2022 Switzerland	N=21 high-risk patients (7:14)	Mean age: 76 years	Multicentre registry	Patients with symptomatic severe TR and advanced right heart failure, ineligible for surgery or other	CAVI with TRICENTO implant that consists of a stent graft that extends	12 months	-

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Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up	Comments
					transcatheter treatment systems	from the IVC to the SVC		
6	O'Neill BP, 2020 United States	N=24 patients had 23 valves implanted (9:15)	Median age: 79.5 years (range, 49-91 years)	Multicentre registry	Patients with symptomatic TR and poor candidates for surgical tricuspid valve intervention as per local heart team discretion	CAVI with implant in IVC only using a single valve (Sapien 3 valve)	350 days	-
7	Wilbring M, 2020 Germany	N=2 patients (2:0)	Ages 74 and 83 years	Case report	Patients with symptomatic severe TR	CAVI with Tricento transcatheter heart valve system	3 months	The radial force of the stent graft seemed to decrease and so it is not sufficient after 3 months to keep the stent completely open during systole
8	Chen 2024, Switzerland	N=1 patient (1:0)	49 years	Case report	Patient with severe TR	CAVI with TricValve	Not reported	-

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Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Dreger H, 2022	**Clinical outcomes** **NYHA functional class (12-month follow up)** NYHA class, ±SD: −0.6±0.5* (CAVI group, p=0.401) and −0.3±0.9 (OMT group, p=0.401) (p=0.025 versus baseline) Improved by 2 classes: 0 (CAVI group) and 0 (OMT group) Improved by 1 class: 5 (63%, CAVI group) and 5 (46%, OMT group) Unchanged: 3 (38%, CAVI group) and 5 (46%, OMT group) Worsened by 1 class: 0 (CAVI group) and 0 (OMT group) Worsened by 2 classes: 0 (CAVI group) and 1 (9%, OMT group) **Exercise capacity** (measured by quantifying maximal oxygen uptake by treadmill spiroergometry at 3 months) primary outcome. VO_{2max}, ml·kg^{-1}·min^{-1}±SD: −1.0±1.6 (CAVI group, p=0.494) and −0.1±1.8 (OMT group, p=0.299) **SMWD** (mean±SD): 18.9±47.0 (CAVI group, p=0.494) and −2.8±71.3 (OMT group, p=0.299)	**Periprocedural complications after CAVI** (resulting in open heart surgery): n=4 2 stent migration leading to cardiac tamponades 2 valve dislocations **Mortality** In-hospital mortality: CAVI group 21% (3/14) 12-month follow up: CAVI group 57% (n=8, including 4 after conversion to surgery) versus OMT group 29% (n=4, from right heart failure, sepsis or haemorrhage) p=0.159 Right heart failure: CAVI group n=4 versus OMT group n=3 Sepsis: CAVI group n=3 versus OMT group n=1 Haemorrhage: CAVI group n=1 versus OMT group 0 Heart failure hospitalisations: CAVI group n=4 versus OMT group n=4 (p=1.00)

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First author, date	Efficacy outcomes	Safety outcomes
	Quality of life (assessed by the MLHFQ) MLHFQ, ±SD: CAVI group −19.9±13.1 versus OMT group −7.6±16.3 (p=0.098) and p=0.004 versus baseline **Dyspnoea** (Likert scale±SD) CAVI group 1.5±1.1 versus OMT group −0.2±1.3 (p=0.008)	
Hewing, 2021	**Clinical signs of venous congestion** **Bodyweight, kg±SD** Baseline: CAVI group 74.6±12.1 versus OMT group 68.4±12.8 12 months: CAVI group 72.6±16.3 versus OMT group 70.7±13.0. **Abdominal circumference, cm±SD** Baseline: CAVI group 97.3±10.8 versus OMT group 97.3±10.3 12 months: CAVI group 96.2±13.2 versus OMT group 98.0±11.6 **Total lower leg circumference, cm (IQR)** Baseline: CAVI group 73.5 (61.3–76.3) versus OMT group 60.5 (54.8–66.6) 12 months: CAVI group 61.5 (48.5–76.5) versus OMT group 56.5 (49.0–66.8) **Renal and hepatic parameters** **Serum creatinine, mg/dl±SD**	**Major complications** Valve dislocations: n=2 (CAVI group) Stent migrations: n=2 (CAVI group) All occurred within 7 to 48 hours after implantation and needed open heart surgery to treat these major complications

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First author, date	Efficacy outcomes	Safety outcomes
	Baseline: CAVI group 1.6±0.6 versus OMT group 1.4±0.4 3 months: CAVI group 1.5±0.5 versus OMT group 1.7±0.7 **GFR (creatinine), ml/min (IQR)** Baseline: CAVI group 36.5 (24.5–62.8) versus OMT group 46.5 (30.0–56.0) 3 months: CAVI group 35.5 (28.0–60.8) versus OMT group 36.5 (23.5–58.8) **Urea, mg/dl (IQR)** Baseline: CAVI group 81.5 (40.8–144.8) versus OMT group 73.5 (47.8–150.8) 3 months: CAVI group 35.5 (28.0–60.8) versus OMT group 63.5 (46.8–124.8) **ALT, U/l (IQR)** Baseline: CAVI group 29.0 (15.0–31.3) versus OMT group 17.0 (13.8–34.3) 12 months: CAVI group 16.5 (11.5–22.8) versus OMT group 20.5 (17.0–27.8) **AST, U/l±SD** Baseline: CAVI group 30.0±6.6 versus OMT group 29.5±9.6 12 months: CAVI group 27.7±7.7 versus OMT group 31.7±8.0 **Gamma-GT, U/l (IQR)** Baseline: CAVI group 64.0 (51.0–116.0) versus OMT group 226.0 (86.0–872.0) (n=5)	

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First author, date	Efficacy outcomes	Safety outcomes
	12 months: CAVI group 65.0 (55.3–105.5) versus OMT group 166.0 (64.5–248.0) (n=5) **Bilirubin, mg/l (IQR)** Baseline: CAVI group 0.7 (0.4–0.9) versus OMT group 0.8 (0.7–1.0) 12 months: CAVI group 0.5 (0.4–0.7) versus OMT group 0.8 (0.6–1.3)	
Lauten A, 2018	Procedural success rate: n=23/25 (92%) **NYHA Functional Class (n)** class 4: 63.2 (12, baseline) and 10.5 (2, post-CAVI) Class 3: 36.8 (7, baseline) and 36.8 (7, post-CAVI) Class 2: 0 and 42.2 (8, post-CAVI) Class 1: 0 and 10.5 (2, post-CAVI) p<0.0001 NYHA improvement: 50% improving to NYHA class 1 or 2 <u>Right atrial pressure</u> Baseline: Mean 21.2±6.0 mm Hg and v-wave 29.5±7.1 mm Hg Post-CAVI: Mean 17.0±3.9 mm Hg (p=0.02) and v-wave 35.5±13.1 mm Hg (p=0.07). <u>IVC pressure</u>	IVC prosthesis migration from the stent into the right atrium: n=1 Early and late valve migration needing surgical intervention occurred: n=1 Conversion to open heart surgery after migration of an SVC prosthesis: n=1 Device embolisation: 8% (2/25) Bleeding complications other than access site: 12% (3/25) In-hospital mortality: 24% (6/25) Thirty-day mortality: 12% (3/25)

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First author, date	Efficacy outcomes	Safety outcomes
	Baseline: Mean 21.7±4.3 mm Hg and v-wave 31.4±6.4 mm Hg Post-CAVI: Mean 17.6±3.3 mm Hg (p=0.01) and v-wave 21.1±4.5 mm Hg (p<0.0001)	
Blasco-Turrion, 2024	**Median KCCQ-12 Score (Q1-Q3)** Baseline: 36.5 (26.0-54.7), n=44 30 days: 57.5 (40.4-79.7), n=38, p<0.001 compared with baseline 3 months: 57.8 (41.7-75.0), n=39, p<0.001 compared with baseline 6 months: 60.9 (41.7- 74.0), n=38, p<0.001 compared with baseline 1 year: 65.6 (42.7-80.2), n=39, p=0.001 compared with baseline **NYHA Functional Class (%)** Baseline: Class 3 =86.5%, Class 4 =13.5% 30 days: Class 1 =8.1%, Class 2 =35.1%, Class 3 =56.8%, p<0.001 compared with baseline 3 months: Class 1 =10.3%, Class 2 =38.5%, Class 3 =51.3%, p<0.001 compared with baseline 6 months: Class 1 =13.5%, Class 2 =51.4%, Class 3 =35.1%, p<0.001 compared with baseline 1 year: Class 1 =10.8%, Class 2 =51.4%, Class 3 =35.1%, Class 4 =2.7%, p<0.001 compared with baseline **Median 6MWT (Q1-Q3)** Baseline: 253.4 (160.0-302.5), n=44	**Major adverse events:** All-cause death: n=3 at 6 months, n=0 at 1 year, 6.8% at overall 1-year Myocardial infarction: n= 0 at 6 months, n= 0 at 1 year, 0% at overall 1-year Tricuspid valve surgery: n= 1 at 6 months, n= 0 at 1 year, 2.3% at overall 1-year Cardiac tamponade: n= 0 at 6 months, n= 0 at 1 year, 0% at overall 1-year Major bleeding: n= 7 at 6 months, n= 2 at 1 year, 20.4% at overall 1-year Stroke: n= 3 at 6 months, n= 1 at 1 year, 9% at overall 1-year **Serious adverse events:** Heart failure rehospitalisation: n= 9 at 6 months, n= 4 at 1 year, 29.5% at overall 1-year Right heart thrombi: n= 4 at 6 months, n= 2 at 1 year, 13.6% at overall 1-year Paravalvular leak: n= 3 at 6 months, n= 0 at 1 year, 6.8% at overall 1-year

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First author, date	Efficacy outcomes	Safety outcomes
	30 days: 235.5 (168.0-324.0), n=30, p=0.902 compared with baseline 3 months: 267.0 (160.0-309.0), n=29, p=0.657 compared with baseline 6 months: 275.0 (200.0-319.0), n=34, p=0.290 compared with baseline 1 year: 284.0 (197.5-341.0), n=32, p=0.246 compared with baseline	
Wild MG, 2022	Procedural success rate 100% **NYHA functional class** **Baseline** NYHA class 1: 0%, class 2: 4.8%, class 3: 85.7%; class 4: 9.5% **Follow up (median 61 days)** NYHA class 1: 30%, class 2: 35%, class 3: 30%, class 4: 5% (p<0.001)	Vascular complications, needing blood transfusion: 19% (n=4) Postprocedural acute kidney injury (stage 1 in 2, stage 2 and stage 3 in 1 case each): n=4 Temporary dialysis in a patient with previous impaired renal function: n=1 Systemic inflammatory syndrome of unclear origin with hypotension: n=1
O'Neill BP, 2020	**NYHA functional class** Baseline NYHA class 3 or 4: 95.9% 1 year follow up: Improvement in NYHA class: 78% Improvement in at least 1 NYHA class: 72.7% Worsened NYHA class: 9.1%	Procedural mortality rate: 0% In-hospital mortality rate: 20.8% 30-day mortality rate: 25% Overall mortality rate: 58% (14/24) at median follow up of 332 days (range, 2-1161 days) Vascular complication rate: 4.2% Acute renal failure rate: 20.8%
Wilbring M, 2020	None reported	Recurrent episodes of right heart failure: n=2 Systolic collapse: n=2
Chen, 2024	None reported	Pacemaker lead dislocation during valve implantation: n=1

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Procedure technique

All studies detailed their procedure technique with variations in the intervention implanted. One approach was CAVI with the balloon-expandable Edwards Sapien XT Valve (TRICAVAL) in patients with advanced heart failure (Dreger 2022). Another study used single and bicaval implantations with balloon-expandable (Sapien XT or Sapien 3) and self-expandable (TricValve) valves (Lauten 2018). One study used the TRICENTO system (transcatheter bicaval valved stent graft; Wild 2022). This device is no longer being manufactured. The TRICUS EURO and the TRICUS study used the TricValve transcatheter bicaval valves system (Blasco-Turrion 2024).

Efficacy

NYHA functional class

In an RCT of 28 patients with severe TR and comparing CAVI with OMT, compared with baseline, CAVI improved NYHA class after 3 months. But there was no statistically significant difference in NYHA class between the CAVI and OMT groups (−0.3±0.9 compared with −0.6±0.5, p=0.401; Dreger 2022).

In an observational study of 25 patients who had CAVI (31 implanted valves), 13 out of 18 patients had NYHA improvement (p<0.0001). In patients discharged from hospital, CAVI was associated with a symptomatic improvement in 50% of patients who improved to NYHA class 1 or 2 (Lauten 2018).

In a multicentre registry of 21 patients who had CAVI with the TRICENTO system, 65% of patients were in NYHA class 1 or 2 at 12-month follow up compared with no patients in NYHA class 1 and 5% in class 2 at baseline (p<0.001; Wild 2022).

In a multicentre registry of 24 patients who had CAVI with an IVC implant using a single valve, 73% of patients had improvement in at least 1 NYHA class from baseline and 9% were considered worse at follow up compared with baseline (O'Neill 2020).

In the prospective non-randomised study of 44 patients who had CAVI with the TricValve system, there was a statistically significant improvement in NYHA functional class because 62% of patients were in functional class 1 or 2 at 1-year follow up compared with 0% at baseline (p<0.001; Blasco-Turrion 2024).

Quality of life

In the RCT of 28 patients, compared with baseline, quality of life (assessed using MLHFQ) improved after 3 months in the CAVI group but not statistically

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significantly so (MLHFQ: −19.9±13.1 compared with −7.6±16.3, p=0.098; Dreger 2022).

In the prospective non-randomised study of 44 patients, there was an increase in at least 15 points in the KCCQ-12 score in 56% of the patients (p<0.001; Blasco-Turrion 2024).

6MWD

In the RCT of 28 patients, there was no statistically significant difference in the 6MWD (a secondary endpoint) between the CAVI and OMT groups (−2.8±71.3 compared with 18.9±47.0, p=0.494; Dreger 2022).

In the prospective non-randomised study of 44 patients, there was improvement in the 6MWT. The score improved from 229±91 m at baseline compared with 270±111 m at 1-year follow up (p=0.285; Blasco-Turrion 2024).

Maximal oxygen uptake

In the RCT of 28 patients, maximal oxygen uptake did not change statistically significantly in either group after 3 months. Also, there was no difference between the OMT and CAVI groups (−0.1±1.8 $ml \cdot kg^{-1}$ min^{-1} compared with −1.0±1.6 $ml \cdot kg^{-1}$ min^{-1}, p=0.4995; Dreger 2022).

Dyspnoea

In the RCT of 28 patients, compared with baseline, dyspnoea statistically significantly improved after 3 months in the CAVI group (1.5±1.1 compared with −0.2±1.3, p=0.008; Dreger 2022).

Clinical signs of venous congestion

In an RCT of 18 patients comparing CAVI (n=8) with OMT (n=10) in patients with severe TR, after 12 months, the 6 patients in the CAVI group who completed 12 months of follow up showed a sustained trend to lower body weight as well as reduced abdominal and leg circumference. But, overall, no statistically significant intra- or intergroup differences in clinical signs of congestion were detected (Hewing 2021).

Renal and hepatic parameters

In a subgroup analysis of the RCT of 18 patients, there was no statistically significant change in levels of laboratory parameters, including serum creatinine, cystatin C, urea, serum protein, serum albumin and calculated GFR (based on creatinine and cystatin C) between baseline and 3-month follow up within each group. Also, there was no statistically significant difference in these parameters

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between the groups at 3-month follow up. In the CAVI group, liver function as measured by ALT, AST, gamma-GT and bilirubin remained stable after 3 and 12 months compared with baseline. Also, there was no statistically significant difference in these parameters between the groups at 3- and 12-month follow up (Hewing 2021).

Safety

Complications

Mortality

In the RCT of 28 patients, there was no statistically significant difference in mortality rate between the groups at 12-month follow up (CAVI 57%, n=8 [including 4 after conversion to surgery] compared with OMT 29%, n=4 [from right heart failure, sepsis or haemorrhage], p=0.159; Dreger 2022).

In the prospective non-randomised study of 44 patients, there was all-cause death in 3 patients, and the overall 1-year percentage was 7% (p=0.285; Blasco-Turrion 2024).

In the observational study of 25 patients,30-day mortality was 12% (3/25). The patients died from progressive multiorgan failure and septic complications (Lauten 2018).

In the multicentre registry of 24 patients, the in-hospital mortality rate (defined as death in the hospital after the procedure) was 21% and the 30-day mortality rate was 25%. Overall mortality occurred in 58% (14/24) patients during a median follow up of 332 days (range, 2-1161 days; O'Neill 2020).

Other major complications

In the RCT of 28 patients, there were 2 major complications in the CAVI group within 7 to 48 hours after implantation. These included 2 valve dislocations and 2 stent migrations leading to cardiac tamponades. All patients needed open heart surgery for removal of dislocated valves and migrated stents (Dreger 2020, Hewing 2021). There were 4 heart failure hospitalisations in each of the groups (p=1.00). Sepsis (n=3) and haemorrhage (n=1) were also reported in the CAVI group (Dreger 2020).

In the prospective non-randomised study of 44 patients, 3 patients had stroke at 6 months and 1 patient had stroke at 1 year. The overall 1-year percentage was 9%. At 6 months, 7 patients had major bleeding and 2 patients had major bleeding at 1 year. The overall 1-year percentage was 20%. Nine patients were rehospitalised for heart failure at 6 months and 4 patients at 1 year. The overall 1-year percentage was 30%. Four patients had right heart thrombi at 6 months

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and 2 patients at 1 year. The overall 1-year percentage was 14%. Three patients had paravalvular leak at 6 months. The overall 1-year percentage was 7% (Blasco-Turrion 2024).

In the multicentre registry of 21 patients, vascular complications and postprocedural acute kidney injury occurred in 4 times for each complication (Wild 2022).

In a case report of 2 patients using the TRICENTO transcatheter heart valve system, within the first 3 months, both patients developed recurrent signs of right heart failure despite sufficient function of the ectopic tricuspid valve system. Also, MRI scans of the heart revealed a nearly complete systolic compression of the stent graft at the level of the right atrium in both patients (Wilbring 2020).

In a case report of 1 patient having CAVI with TricValve, during the valve implantation, pacemaker leads were dislocated into the right brachiocephalic vein, resulting in worsening venous obstruction. But it was successfully resolved during the procedure (Chen 2024).

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 suggested a theoretical adverse event of rhythm disturbance and conversion to open surgery (sternotomy and tricuspid valve repair).

Seven professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

- One small RCT compared CAVI with optimal medical therapy.
- Follow up in studies ranged from 6 months to 12 months.
- Studies included patients with symptomatic severe TR that was ineligible for surgery.

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- Studies on CAVI varied in terms of the approach (unicaval and bicaval), number of implants and the type of implant (self-expandable or balloon-expandable) being used.
- CAVI with balloon-expandable valves (Edwards Sapien XT or Sapien 3) has been done under compassionate clinical use.
- The company producing a dedicated CAVI device currently in clinical use (TRICENTO) are no longer manufacturing this device.
- A CE mark study (NCT04289870) is underway for another device (TRILLIUM device).
- The title of this topic has been amended as 'caval valve implantation for tricuspid regurgitation' to cover both unicaval and bicaval valve implantations.

Related NICE guidance

Interventional procedures

- NICE interventional procedures guidance on Transcatheter tricuspid valve annuloplasty for tricuspid regurgitation IPG730 (Recommendation: special arrangements) Published date: July 2022.
- NICE interventional procedures guidance on Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation IPG731 (Recommendation: special arrangements) Published date: July 2022.

NICE guidelines

- NICE guideline on Heart valve disease presenting in adults: investigation and management [NG208] Published date: November 2021
- NICE guideline on Chronic heart failure in adults: diagnosis and management. [NG106] Published date: September 2018

Professional societies

- Society of Cardiothoracic Surgery of Great Britain and Ireland

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- 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 2 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 team and any relevant points have been taken into consideration when preparing this overview.

References

1. Blasco-Turrión S, Briedis K, Estévez-Loureiro R, Sánchez-Recalde A et al. (2023) Bicaval TricValve implantation in patients with severe symptomatic tricuspid regurgitation. JACC: Cardiovascular Interventions 17(1): 60–72
2. Che M, Moschovitis A, Taramasso M (2024). Pacemaker lead dislocation during TriValve procedure with an extremely small superior vena cava. International Journal of Cardiovascular Imaging 40(5): 1149–51
3. Dreger H, Mattig I, Hewing B et al. (2020) Treatment of severe tricuspid regurgitation in patients with advanced heart failure with caval vein implantation of the Edwards Sapien XT VALve (TRICAVAL): a randomised controlled trial. EuroIntervention 15: 1506–13
4. Hewing B, Mattig I, Knebel F et al. (2021) Renal and hepatic function of patients with severe tricuspid regurgitation undergoing inferior caval valve implantation. Sci Rep 8; 11(1): 21800
5. Lauten A, Figulla HR, Unbehaun A et al. (2018) Interventional treatment of severe tricuspid regurgitation: early clinical experience in a multicenter, observational, first-in-man study. Circ Cardiovasc Interv 11: e006061
6. Wild MG, Lubos E, Cruz-Gonzalez I et al. (2022) Early clinical experience with the TRICENTO bicaval valved stent for treatment of symptomatic severe tricuspid regurgitation: a multicenter registry. Circ Cardiovasc Interv 15: e011302
7. O'Neill B, Negrotto S, Yu D et al. (2020) Cava valve implantation for tricuspid regurgitation: insights from the United States caval valve registry. J Invasive Cardiol 32:470–5

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8. Wilbring M, Tomala J, Ulbrich S et al. (2020) Recurrence of right heart failure after heterotopic tricuspid intervention: a conceptual misunderstanding? JACC Cardiovasc Interv 13: e95–6

Methods

NICE identified studies and reviews relevant to CAVI for TR from the medical literature. The following databases were searched between the date they started to 17.04.2024: MEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The 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 that were not available in the published literature.
- Patients with CAVI.
- Intervention or test: TR.
- 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 the section on other relevant studies.

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

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Table 4 literature search strategy

Databases	Date searched	Version/files
MEDLINE ALL (Ovid)	17/04/2024	1946 to April 15, 2024
EMBASE (Ovid)	17/04/2024	1974 to 2024 April 16,
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	17/04/2024	Issue 4 or 12, April 2024
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	17/04/2024	Issue 3 of 12, March 2024
International HTA database (INAHTA)	17/04/2024	-

MEDLINE ALL search strategy

Tricuspid Valve Insufficiency/
((Tricuspid or right atrioventricul*) adj4 (reflux or insufficien* or incompeten* or regurgitat* or disease* or dysfunct* or malfunct* or degenerat* or fail* or leak* or backflow* or back-flow* or flow-back* or defect*)).tw.
(TR or FTR).tw.
(Caval adj4 (reflux* or insufficien* or incompeten* or regurgitat* or disease* or dysfunct* or malfunct* or degenerat* or fail* or leak* or backflow* or back-flow or defect*)).tw.
Right* side* heart* failur*.tw.
(Function* adj tricusp* adj regurgitat*).tw.
or/1-6
(Transcathet* adj4 tricuspid adj4 valve* adj4 (implant* or Intervent* or device* or intervene* or therap* or solut*)).tw.
((Heart* or Cardiac* or Caval* or Bivalve*) adj4 valve* adj4 Implant*).tw.
(CAVI or CAVR).tw.
transcathet* tricuspid valve intervent*.tw.
TTVIs.tw.
((Bicaval or tricaval) adj4 implant*).tw.
(((Percutan* adj4 tricuspid) or Bicuspid*) adj4 valve* adj4 (device* or interven* or therap* or implant* or solution*)).tw.
or/8-14
7 and 15
Tricvalve.tw.
TriCentro.tw.
17 or 18
16 or 19
Animals/ not Humans/
20 not 21
limit 22 to english language
limit 23 to ed=20231001-20240430

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Other relevant studies

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

Table 5 additional studies identified

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Aalaei-Andabili SH, Bavry AA, Choi C et al. (2020) Percutaneous inferior vena cava valve implantation may improve tricuspid valve regurgitation and cardiac output: lessons learned. Innovations 15: 577–80	Case series N=6 patients who could not have surgery with severe TR who failed medical treatment had percutaneous CAVI with 9-mm SAPIEN 3 valve	The procedure was successfully performed in all 6 patients (100%). No procedural complication was detected. At 30 days, TR improved from severe to trace in 1 patient, to mild-moderate in 3 patients, and 2 patients remained with severe TR. Among patients with improved TR, left ventricular ejection fraction increased from 47.5%±18.5% to 55%±20.4% (p=0.014). No patient had readmission at 30 days. Four patients needed rehospitalisation within 6 months.	Large studies with longer follow up included in evidence summary
Abdul-Jawad Altisent O, and Estévez-Loureiro R (2022) Heterotopic transcatheter tricuspid valve implantation. a promising technology for patients with high-risk TR.	Review	Heterotopic CAVI is a promising technology for patients with high-risk TR and limited treatment options. There are several devices under study, the TricValve gained widespread adoption. The TRICUS EURO study showed a positive effect in clinical outcomes and quality of life.	Review

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CARDIAC INTERVENTIONS TODAY 16 (5): 56–66			
Abdul-Jawad Altisent O, Benetis R, Rumbinaite E et al. (2021) Caval valve implantation (CAVI): an emerging therapy for treating severe tricuspid regurgitation. J Clin Med 10: 4601	Review on CAVI technique	In this review, the current evidence and ongoing uncertainties of CAVI, focusing on the novel CAVI-specific devices was discussed.	Review
Abdul-Jawad Altisent O, Codina P, Puri R et al. (2022) Transcatheter bi-caval valve implantation (CAVI) significantly improves cardiac output: mechanistic insights following CardioMEMS® and TricValve® implantation. Clin Res Cardiol 111: 966–8			No abstract provided
Aparisi Á, Amat-Santos IJ, Serrador A et al. (2020) Current clinical outcomes of tricuspid regurgitation and initial experience with	Case report N=2 patients had CAVI with Tricento and with TricValve	Assessment of potential prognostic benefit by bicavally implanted heterotopic prosthesis needs longer-term studies, but initial experience suggests safe and effective procedural and short-term outcomes.	Large studies with longer follow up included in evidence summary

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the TricValve system in Spain. Rev Esp Cardiol 73: 853–4			
Asmarats L, Puri R, Latib A et al. (2018) Transcatheter tricuspid valve interventions: landscape, challenges, and future directions. Journal of the American College of Cardiology 71, 25: 2935–56	Review	The aim of this review is to provide an updated overview and a clinical perspective on novel transcatheter tricuspid valve therapies, highlighting potential challenges and future directions.	Review
Chandran K, Long A, Bishop J, Berman P et al. (2023) First in-man experience with TricValve transcatheter bicaval valve system in left ventricular assist device Heartmate II patient for high-risk tricuspid regurgitation. Circ Heart Fail 16(6): e010027	Case report An 80-year-old patient with severe TR and HeartMate had TricValve bicaval valve implantation	Patient reported a significant improvement in her symptoms to NYHA class 1 to 2. She has felt an improvement in her quality of life with rare lower extremity oedema.	Large studies with longer follow up included in evidence summary
Datta R, Bharadwaj P, Keshavamurthy G et al. (2023) Caval valve implantation: First of its kind in a rare environment. Medical Journal	Case report N=1 76-year-old lady with severe TR and recurrent right heart failure had CAVI with TricValve in SVC and IVC	Significant haemodynamic and clinical improvement has been noted in this patient at 3-month follow up.	Large studies with longer follow up included in evidence summary

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Armed Forces India. Online 8 February			
Di Mauro M, Guarracini S, Mazzocchetti L et al. (2024) Transcatheter bicaval valve system for the treatment of severe isolated tricuspid regurgitation. Features from a single-Centre experience. Int J Cardiol. 1;402:131864.	Case series n=13 patients with severe isolated TR had TricValve implantation.	This procedure appears to be safe and effective in carefully selected patients. Given the extreme simplicity of the procedure, the TricValve will increasingly represent one of the most viable treatment options for this patient group in the future.	Large studies with longer follow up included in evidence summary.
Dona C, Goliasch G, Schneider M et al. (2020) Transcatheter TricValve implantation for the treatment of severe tricuspid regurgitation. European Heart Journal - Cardiovascular Imaging online E92	Case report 78-year-old patient with heart failure and TR had transcatheter TricValve implantation	The valves were successfully deployed. The patient was discharged 3 days after the procedure. At 3 months, her symptoms and exercise capacity had significantly improved. On transthoracic echocardiogram, TR had decreased from torrential to mild-to-moderate.	Large studies with longer follow up included in evidence summary
Estévez-Loureiro R, Sánchez-Recalde A, Amat-Santos IJ et al. (2022) 6-Month Outcomes of the TricValve System in Patients With Tricuspid Regurgitation: The TRICUS	Non-randomised study (TRICUS EURO study)	Statistically significant improvement in NYHA functional class and quality of life at 6-month follow up compared with baseline. Seven patients had transient shoulder pain during the procedure and 3 had it at 30 days.	Population of this study overlaps with 1 study in evidence summary. Result with longer follow up was included in evidence summary

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EURO Study. JACC Cardiovascular Interventions Volume 15, Issue 13, Pages 1366-1377			
Figulla HR, Kiss K, Lauten A (2016) Transcatheter interventions for tricuspid regurgitation - heterotopic technology: TricValve. EuroIntervention 18;12(Y): Y116–8	Review of concept	CAVI with the TricValve is a relatively simple procedure. However, valve design must cover a great range of caval vein anatomy. The haemodynamic concept is convincing and allows the RV to recover. Clinical experience is presently restricted to compassionate cases.	Review
Galasso M, Cartella I, Soriano F et al. (2023) Bi-caval valve implantation to palliate symptoms in a case of massive tricuspid regurgitation. Cardiovasc Revasc Med53S: S139–S143	Case report N=69-year-old man with significant TR and advanced heart failure without surgical options had heterotopic CAVI with TricValve	At 3-months follow up, the patient was alive and an improvement in functional status and heart failure symptoms (NYHA class 2) noted. Renal and liver function did not worsen while a significant reduction of loop diuretic dosage was possible.	Large studies with longer follow up included in evidence summary
Cruz-González I, González-Ferreiro R, Amat-Santos IJ et al. (2021) TRICENTO transcatheter heart valve for severe tricuspid regurgitation. Initial experience and mid-term follow-	Case series N=6 patients with congestive heart failure had TRICENTO valve implantation for severe functional TR	Device was successfully deployed in all without any major complications. During follow up (11±4.4 months), all patients showed NYHA functional class improvement (class 1 to 2). No patients died. One patient was admitted with acute decompensation of heart failure (41 days after the procedure).	Large studies with longer follow up included in evidence summary

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up. Rev Esp Cardiol 74: 351–4			
Grazina A, Ferreira A, Ramos R et al. (2023) Heterotopic caval valve-in-valve procedure for prosthetic migration: two case reports. European Heart Journal - Case Reports, 7 (8), 1–7	Case report N=2 patients with severe TR and high surgical risk who had CAVI, and device migration to the right atrium (1 IVC and 1 SVC device) had treatment with a caval valve-in-valve procedure.	Both cases reported good technical and clinical results.	Caval valve-in-valve-study
Jin QW, Mohd Ghazi AB, Kolanthaivelu J et al. (2022) Novel treatment of atrial functional tricuspid regurgitation using transcatheter bicaval valve implantation (TricValve). Asia Intervention 6;8(2): 138–42	Case report N=67-year-old woman with underlying atrial fibrillation and severe TR had CAVI with TricValve	The procedure was uneventful and the patient was discharged. At 3-month follow up, there was marked improvement clinically and biochemically.	Large studies with longer follow up included in evidence summary
Kultursay B, Bingol G, Guven B et al. (2022) TricValve pop-out: management of transcatheter caval valve migration. Anatol J Cardiol 26: 414–8	Case report	At the time of deployment, the IVC valve migrated into the right atrium. There was no hemodynamical worsening after migration of the valve. Deployment of another IVC valve protruding into the right atrium and overlapping the popped-out valve was done. After successful deployment of the second IVC valve, no paravalvular leak or caval backflow was seen.	Large studies with longer follow up included in evidence summary

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		Significant improvement in functional capacity was seen at 3-months follow up.	
Lauten A, Ferrari M, Hekmat K et al. (2011) Heterotopic transcatheter tricuspid valve implantation: first-in man application of a novel approach to tricuspid regurgitation. Eur Heart J 32: 1207–13	Case report N=1 patient with severe functional TR after multiple preceding open heart procedures, a self-expanding valve was implanted into the IVC at the cavoatrial junction to reduce regurgitant backflow	Excellent valve function was seen after deployment resulted in a marked reduction of caval pressure and an abolition of backflow to the IVC.	Large studies with longer follow up included in evidence summary
Lauten A, Hamadanchi A, Doenst T et al. (2014) Caval valve implantation for treatment of tricuspid regurgitation: post-mortem evaluation after mid-term follow-up. Eur Heart J 35: 1651	Case report N=1 patient with severe functional TR after multiple preceding open heart procedures, a self-expanding valve was implanted into the IVC at the cavoatrial junction to reduce regurgitant backflow	Successfully deployed and a marked reduction of caval pressure and an abolition of backflow to the IVC was noted. The patient was discharged home and had an improvement of physical capacity and symptoms of right heart failure within the 3-month follow-up period.	Large studies with longer follow up included in evidence summary
Lauten A, Dreger H, Laule M et al. (2022) Caval valve implantation. Intervent Cardiol Clin 11: 95–102	Review on current evidence for CAVI and potential role for treatment of TR	CAVI was applied successfully for compassionate treatment in human patients. Haemodynamic improvement has been consistently seen; the clinical benefit of the procedure still needs further evaluation. It remains to be determined which patients benefit most from this approach and which outcome measures are most suitable.	Review

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Laule M, Stangl V, Sanad W et al. (2013) Percutaneous transfemoral management of severe secondary tricuspid regurgitation with Edwards Sapien XT bioprosthesis: first-in-man experience. J Am Coll Cardiol 61: 1929–31	Case series N=3 patients with severe functional TR had treatment with IVC caval implantation (balloon-expandable valves Edwards Sapien XT valve)	-	Large studies with longer follow up included in evidence summary
O'Neill BP, Wheatley G, Bashir R et al. (2016) Study design and rationale of the heterotopic implantation of the Edwards Sapien XT transcatheter valve in the inferior vena cava for the treatment of severe tricuspid regurgitation (HOVER) Trial. Catheterization and Cardiovascular Interventions 88: 287–93	Prospective non-randomised study. Heterotopic implantation of the Sapien XT valve in the IVC for the treatment of severe TR in patients who are at high risk or cannot have surgery	A total of 30 patients will be enrolled. The primary objective of the study will be to show procedural success at 30-days and patient success at 1-year.	Study design and rationale
Pieri M, Dormio S, Morosato M et al. (2024) Shaping the anesthetic approach to TricValve implantation:	Case series n=8 patients having CAVI with the Tricvalve system.	Study showed the potential of TricValve implantation in effectively managing severe TR with no procedure-related complications and a 100% survival rate. A collaborative, interdisciplinary approach	Large studies with longer follow up included in evidence summary.

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insights from a case series. J Cardiothorac Vasc Anesth. 38(4):911-917.		and targeted anaesthesia management proved crucial for this success. Postoperative shoulder pain emerged as a frequent complication, the pathogenesis of which is still not clear, and successfully was managed using targeted analgesic therapy.	
Plant A, Stewart F, Hooks D. (2024) Implantable cardioverter-defibrillator lead failure and revision following transcutaneous bicaval valve (TricValve®) implantation. J Cardiovasc Electrophysiol. 35(5):1050-1054	Case report n=1 patient had a transcatheter heterotopic bicaval valve implantation with a TricValve® system for TR.	Lead failure after TricValve® implantation, a dedicated self-expanding system for bicaval valve implantation was reported. Lead revision procedure was successful in this setting.	Large studies with longer follow up included in evidence summary.
Romaguera R, Roura G, Ruiz-Majoral A et al. (2021) First bicaval valve implantation in a heart transplant patient to treat severe symptomatic tricuspid regurgitation. Circulation: Heart Failure 14,1278–9	Case report N=1 patient (67-year-old) with severe TR and RV dysfunction had a bicaval valve (TricValve) implantation	At 6-months follow up, functional status improved to NYHA class 2, and the diuretic treatment was tapered without heart failure recurrence. Similar RV dysfunction and absence of systolic reverse flow to cava veins noted.	Large studies with longer follow up included in evidence summary
Rudziński PN, Kalińczuk Ł, Pęczkowska M et al. (2024) Peri-procedural	Case report n=1 patient with carcinoid induced torrential TR had a transcatheter	Procedure was successful. Periprocedural IVUS assessment during bicaval valve implantation correlates with	Large studies with longer follow up included in

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intravascular ultrasound monitoring during bi-caval valve implantation in the treatment of carcinoid-induced tricuspid regurgitation. Eur Heart J Cardiovasc Imaging. 29;25(2):e98.	heterotopic bicaval valve implantation with a TricValve® system.	postprocedural CTA measurements. Also, the online perspective offered by IVUS might be helpful in assessing the functional performance of newly implanted valves.	evidence summary.
Sharkey A, Munoz Acuna R, Belani K et al. (2020) Heterotopic caval valve implantation for the management of severe tricuspid regurgitation: a case series. Eur Heart J Case Rep; 5: ytaa428	Case report N=2 patients with severe TR with symptoms of heart failure refractory to medical therapy had heterotopic CAVI with Edwards SAPIEN 3 valve	Valve was implanted in the IVC/right atrium junction. In both patients, there was improvement in the postoperative haemodynamics as measured by invasive and non-invasive methods. Successful discharge was achieved in both patients with improvement in their symptoms.	Large studies with longer follow up included in evidence summary
Sharma NK, Chouhan NS, Bansal M et al. (2021) Heterotopic caval valve implantation in severe tricuspid regurgitation. Ann Card Anaesth 2021 Jul-Sep;24(3):365–8	Case report N=1 patient with previous mitral valve surgery with chronic severe TR who had CAVI with self-expandable TricValve in SVC	The procedure was successful. The procedure resulted in significant haemodynamic and symptomatic improvement at 3-month follow up.	Large studies with longer follow up included in evidence summary
Toggweiler S, De Boeck B, Brinkert M et al. (2018) First-in-man	Case report N=1 patient with severe TR and holosystolic hepatic vein backflow had	After successful implantation, caval vein regurgitant volume was reduced leading to symptomatic and clinical	Large studies with longer follow up included in

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implantation of the Tricento transcatheter heart valve for the treatment of severe tricuspid regurgitation. EuroIntervention 2018; 14: 758–61	Tricento transcatheter heart valve implantation via the transvenous transfemoral access	improvement at 3-month follow up.	evidence summary

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