Transcatheter Heart Valve Procedures for Mitral or Tricuspid Valve Disorders

Effective: September 1, 2025

Next Review: June 2026
Last Review: July 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Conventional treatment of heart valve disorders includes surgical repair or replacement, which require open-heart surgery using cardiopulmonary bypass. Transcatheter (percutaneous or catheter-based) valve procedures use a catheter to access the heart and heart valves without the need for open-heart surgery and cardiopulmonary bypass. During the procedure, a compressed artificial heart valve or bioprosthetic valve is implanted.

MEDICAL POLICY CRITERIA

Note: This policy does not address mitral valve transcatheter edge-to-edge repair.

I. Transcatheter mitral valve replacement of a degenerated bioprosthetic valve (valve-in-valve) may be considered **medically necessary** when both of the following criteria are met (A.–B.):

   A. The device is approved by the U.S. Food and Drug Administration; and

   B. Patient has a failed (stenosed, insufficient, and/or combined) previous surgical bioprosthetic valve.

II. Percutaneous transcatheter tricuspid edge-to-edge valve repair (T-TEER) may be considered medically necessary when all of the following criteria are met (A.-C.):

A. The device is approved by the U.S. Food and Drug Administration; and

B. Patient has severe symptomatic tricuspid regurgitation (see Policy Guidelines); and

C. Patient is considered at intermediate or high risk for open surgery (see Policy Guidelines).

III. Transcatheter tricuspid valve replacement may be considered medically necessary when all of the following criteria are met (A.-B.):

A. The device has been approved by the U.S. Food and Drug Administration; and

B. Patient has severe symptomatic tricuspid regurgitation (see Policy Guidelines); and any of the following:

1. Tricuspid valve repair is not feasible due to lack of pliable leaflet tissue; or

2. Documented assessment by a cardiac surgeon and one other heart-care specialist (e.g., interventional cardiologist, cardiologist with training and experience in heart failure management, electrophysiologist, multi-modality imaging specialists, or interventional echocardiographer) has determined tricuspid replacement is appropriate.

IV. Transcatheter mitral valve replacement of a degenerated bioprosthetic valve, transcatheter tricuspid valve repair, and transcatheter tricuspid valve replacement are considered **investigational** when Criterion I., II., or III. is not met.

V. The following transcatheter heart valve procedures are considered **investigational**:

A. Transcatheter mitral valve replacement for native mitral valve disease

B. Transapical mitral valve repair with placement of artificial chordae tendinae

C. Transcatheter mitral valve annuloplasty reconstruction

D. Transcatheter tricuspid valve annulus reconstruction

E. Caval valve implantation

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Severe tricuspid regurgitation (TR) may be defined by echocardiography using the following Grade Scale:

	Trace/mild	Moderate	Severe 3 (Severe)	Severe 4 (Massive)	Severe 5 (Torrential)
Vena contracta (biplane, mm)	<3	3-6.9	7-13	14-20	≥21
PISA radius (mm)	<6	6-9	>9	>9	>9
EROA (mm^2)	<20	20-39	40-59	60-79	≥80
Regurgitant volume (mL)	<15	15-44	40-59	60-74	≥75
3D VCA or quantitative EROA (mm^2)			75-94	95-114	≥115

IVC diameter (cm)	<2	2.1-2.5	>2.5	>2.5	>2.5
Hepatic flow	Systolic dominant	Systolic blunt	Systolic reversal	Systolic reversal	Systolic reversal

Abbreviations: 3D VCA: three-dimensional vena contracta area; EROA: effective regurgitant orifice area; IVC: inferior vena cava; PISA: proximal isovelocity surface area.

The FDA definition of intermediate or high risk for open surgery is:

- High risk: Society of Thoracic Surgeons (STS) predicted operative risk score of 8% or higher or judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.
- Intermediate risk: STS predicted risk of mortality between 3% and 7%.[1]

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- For transcatheter mitral valve replacement: Documentation that confirms the presence of a failing previously placed bioprosthetic mitral valve
- For transcatheter tricuspid valve repair: Documentation that confirms tricuspid regurgitation severity, and surgical risk.
- For transcatheter tricuspid valve replacement: Documentation that confirms tricuspid regurgitation severity, with documentation of inadequate leaflet tissue, or the assessment of a cardiac surgeon and one other heart-care specialist that transcatheter tricuspid valve replacement is appropriate.
- The name of the valve system to be implanted

CROSS REFERENCES

1. Transcatheter Aortic Valve Implantation for Aortic Stenosis, Surgery Policy No. 201

BACKGROUND

HEART VALVE DISORDERS

The American Heart Association (AHA) and American College of Cardiology (ACC) recommend classifying valvular heart disease (VHD) by stages based on symptoms, valve anatomy, the severity of valve dysfunction, and the response of the ventricle and pulmonary circulation.[2] To evaluate patients with valvular heart disease, patient history and physical examination should be correlated with results of non-invasive testing (e.g., electrocardiogram (ECG), chest x-ray, and transthoracic echocardiogram). If there is discordance between physical examination and initial non-invasive testing, further non-invasive testing (e.g., computed tomography, cardiac magnetic resonance imaging, and stress testing) or invasive testing (e.g., transesophageal echocardiography or cardiac catheterization) may be considered to determine treatment.

The AHA/ACC classification of the progression of VHD includes four stages, A to D:

- Stage A (at risk) is defined as patients with risk factors for development of VHD.
- Stage B (progressive) is defined as patients with progressive VHD (mild to moderate severity and asymptomatic).
- Stage C (asymptomatic severe) is defined as:
    - Stage C1: symptomatic patients with severe VHD in whom the left ventricle (LV) or right ventricle (RV) remains compensated
    - Stage C2: asymptomatic patients with severe VHD with decompensation of the LV or RV
- Stage D (symptomatic severe) is defined as patients who have developed symptoms as a result of VHD.

Indications for intervention and periodic monitoring are dependent on 1) the presence or absence of symptoms, 2) the severity of VHD, 3) the response of the LV and/or RV to volume or pressure overload caused by VHD, and 4) the effects on the pulmonary or systemic circulation.

The purpose of valvular intervention is to improve symptoms, prolong survival, and minimize the risk of VHD-related complications, such as irreversible ventricular dysfunction, pulmonary hypertension, stroke, and atrial fibrillation (AF).

Mitral Regurgitation

Mitral regurgitation (MR) is the second most common valvular heart disease, occurring in 7% of people older than age 75 years and accounting for 24% of all patients with valvular heart disease. MR with accompanying valvular incompetence leads to left ventricular (LV) volume overload with secondary ventricular remodeling, myocardial dysfunction, and left heart failure. Clinical signs and symptoms of dyspnea and orthopnea may also be present in patients with valvular dysfunction. MR severity is classified as mild, moderate, or severe disease on the basis of echocardiographic and/or angiographic findings (1+, 2+, and 3+ to 4+ angiographic grade, respectively).

Patients with MR generally fall into 2 categories: primary (also called degenerative) and secondary (also called functional) MR. Primary MR results from a primary structural abnormality in the valve, which causes it to leak. This leak may result from a floppy leaflet (called prolapse) or a ruptured cord that caused the leaflet to detach partially (called flail). Because the primary cause is a structural abnormality, most cases of primary MR are surgically corrected. Secondary MR results from LV dilatation due to ischemic or dilated cardiomyopathy. This causes the mitral valve (MV) leaflets not to coapt or meet in the center. Because the valves are structurally normal in secondary MR, correcting the dilated LV using medical therapy is the primary treatment strategy used in the U.S.

According to the American College of Cardiology, the treatment of choice for mitral regurgitation is transcatheter edge-to-edge repair (TEER), which is not addressed in this policy.[3] Surgical approaches to mitral regurgitation other than TEER have been suggested for people with anatomical barriers to TEER (e.g., coaptation gap $\geq$15mm, flail gap $\geq$10mm) who are not candidates for surgery. [3, 4] Interventions for mitral valve regurgitation addressed in this policy

are transcatheter mitral valve replacement (TMVR), transapical mitral valve repair, and transcatheter mitral valve annuloplasty reconstruction (TMVAR).

Tricuspid Regurgitation

Tricuspid regurgitation (TR) refers to the backward flow of blood through the tricuspid valve due to inadequate closure of the valve during systole and is the most common indication requiring tricuspid valve repair or replacement.[5] TR may be classified as primary, due to intrinsic abnormalities of the valve apparatus, or more commonly secondary (functional), caused by right ventricular remodeling and annular dilation. Common etiologies include pulmonary hypertension, left heart disease, atrial fibrillation, and the presence of cardiac implantable electronic devices. Clinically significant TR is common in older adults, affecting approximately 4% of individuals over age 75 and up to 7% of those over 65, with a higher prevalence in women.[6] TR has been observed to be independently associated with increased mortality, heart failure hospitalizations, and reduced quality of life, even in moderate forms.[7]

Historically, treatment options for TR were limited to diuretics for symptom relief or surgical intervention in conjunction with other valve procedures.[8] According to the current American College of Cardiology and the American Heart Association guidelines (ACC/AHA), the only class one surgical indication for treating TR is in patients undergoing left-sided valve surgery; with all isolated surgeries having a class two level of evidence. Isolated surgical tricuspid repair or replacement has been associated with high perioperative mortality of up to 10% and is infrequently pursued.[9] Many patients are deemed inoperable due to frailty, comorbidities, or advanced disease. Until recently, there were no approved minimally invasive therapies specifically indicated for TR, leaving a large proportion of patients untreated and symptomatic despite maximal medical therapy.

Transcatheter tricuspid valve repair or replacement is an emerging alternative to surgical therapy for patients with severe TR, particularly those at elevated surgical risk. TR may result from a primary structural abnormality of the tricuspid valve or, more commonly, from secondary annular dilation and leaflet tethering due to right ventricular remodeling associated with left-sided heart failure, pulmonary hypertension, or atrial fibrillation. Surgical intervention for isolated TR is often underutilized due to high perioperative risk and limited referral, highlighting a substantial unmet need for less invasive treatment options. Two transcatheter devices, TriClip™ (Abbott) and EVOQUE™ (Edwards Lifesciences), have been developed to address this gap. TriClip, a transcatheter edge-to-edge repair system, is designed to reduce TR by approximating valve leaflets, while the EVOQUE system provides a complete transcatheter valve replacement through a self-expanding prosthesis anchored within the native valve structure. Both devices are intended for patients with severe symptomatic TR who are not suitable candidates for surgery and continue to experience symptoms despite optimized medical therapy.

Another approach to TR is heterotropic caval valve implantation (CAVI). The goal of CAVI is not to reduce TR, but to reduce systemic venous congestion, thereby alleviating the resultant effects on the liver, kidney, and gastrointestinal tract.[10] The concept centers in the heterotopic placement of a valve in the inferior vena cava (IVC) and another in the superior vena cava (SVC), at the cavo-atrial junctions. At the chronic phase, reduction in peripheral congestion decreases the risk of cardiac cirrhosis, also reducing right heart overload promoting a degree of reverse RV remodeling, and possibly even reductions in tricuspid annular dilatation, and

thus the severity of TR in some cases.[11] By alleviating caval regurgitant volume CAVI may also ultimately increase RV stroke volume and improve cardiac output.

REGULATORY STATUS

Multiple manufacturers have transcatheter heart valve devices with FDA approval. FDA-approved transcatheter heart valve devices include but are not limited to the following:

- The SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System received premarket approval from the United States Food and Drug Administration on September 9, 2020.[12] This device is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring. In March 2024, the FDA expanded the indication for the Edwards SAPIEN 3 Systems to include, "patients with a failing surgical bioprosthetic mitral valve who are at intermediate risk for open surgical therapy."[13] In May 2024, the FDA granted 4C Medical Technologies' AltaValve™ System dual Breakthrough Device Designation for the treatment of moderate-to-severe or severe MR, including cases with significant mitral annular calcification (MAC).
    - The Edwards SAPIEN 3 is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, a trileaflet bovine pericardial tissue valve, a polyethylene terephthalate (PET) internal fabric skirt, and a PET external sealing skirt for reduction of paravalvular regurgitation.
    - Product code: NPU

- The EVOQUE Tricuspid Valve Replacement System (Edwards) received premarket approval from the United States Food and Drug Administration on February 1, 2024.[14] This device is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, for whom tricuspid valve replacement is deemed appropriate by a heart team.
    - The EVOQUE system consists of an artificial tricuspid valve (EVOQUE valve) and a delivery catheter. The valve is made of bovine tissue attached to a self-expanding nickel-titanium frame for support.
    - Product code: NPW

- The TriClip G4 System (Abbott Medical) received United States Food and Drug Administration premarket approval on April 1, 2024 for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.[15]
    - The TriClip G4 System is designed to repair the native tricuspid valve without open heart surgery by grasping and bringing together (coapting) the tricuspid valve leaflets to reduce tricuspid regurgitation (TR). The device is composed of the TriClip Steerable Guide Catheter (SGC), the TriClip G4 Delivery System (TDS), and Accessories.
    - Product code: NPS

Several additional devices are referenced in the evidence review below. They include the

PASCAL™ Transcatheter Valve Repair System, a transcatheter edge-to-edge repair device similar to TriClip, and the Cardioband™ Tricuspid Valve Reconstruction system, an annuloplasty device, both by Edwards Lifesciences.

EVIDENCE SUMMARY

TRANSCATHETER MITRAL VALVE REPLACEMENT

Native mitral valve disease

Systematic Reviews

Ahmed (2023) published a systematic review which examined the Tendyne Transcatheter Mitral Valve System for transcatheter mitral valve replacement (TMVR) over the last 10 years.[16] 26 articles were included with a total of 319 patients, including 192 males and 127 females. Mitral annular calcification was reported in 107 patients. Preoperatively, mitral regurgitation grade one was identified in three patients, grade two was identified in five patients, and grades three to four were identified in 307 patients. Postoperatively, mitral regurgitation grade one was identified in 12 patients, grade two was identified in three patients, and grade four was identified in one patient, overall, resulting in a significant mitral regurgitation improvement. Technical success was achieved in 309 patients. Follow-up periods varied from days before discharge to six years and at the end of follow up, 79 patients died, including 52 due to cardiovascular causes. The authors concluded that further research is needed with longer duration follow-up phases and randomized controlled trials.

Del Val (2019) conducted a systematic review of TMVR for the treatment of severe mitral regurgitation in patients with high surgical risk.[17] A total of 16 studies with 308 total patients met inclusion criteria. The etiology of mitral regurgitation was secondary or mixed in 87.1% of patients, and 81.5% of the patients were in New York Heart Association (NYHA) class III or IV. The procedure was conducted via the transapical approach in 81.5% of patients. Devices used included the AltaValve, Caisson TMVR, CardAQ Valve, CardioValve, Fortis, HighLife, Interpid TMVR, MValve, Tiara, Sapien M3, and Tendyne. Technical success was 91.7%, postprocedural mean transmitral gradient was 3.5 mm Hg, and 1.5% of cases presented residual postprocedure moderate to severe mitral regurgitation. Procedural and all-cause 30-day mortality were 4.6% and 13.6%, respectively. Four percent of patients were converted to open heart surgery. Left ventricular outflow obstruction was reported in 0.3% of patients, respectively. All-cause and cardiovascular-related mortality rates were 27.6% and 23.3%, respectively, after a mean follow-up of 10 (range: 3 to 24) months.

Nonrandomized Studies

The retrospective study by Ziegelmueller (2024) compared transcatheter mitral valve implantation/replacement (TMVR) using the Tendyne system with surgical mitral valve replacement (SMVR) in elderly patients at intermediate surgical risk, using a 1:2 matched cohort design at a single German center.[18] A total of 40 patients receiving TMVR between 2020 and 2023 were matched to 80 SMVR patients; the median age in both groups was 78 years, and the median STS-PROM score was 5.2% for TMVR and 4.1% for SMVR. Mitral Valve Academic Research Consortium (MVARC)-defined device success at 30 days was significantly higher in the TMVR group (82.5% vs. 57.5%; p=0.04), and procedural success also trended higher but was not significantly different between groups (75.0% vs. 52.5%; p=0.07). Technical success was identical (97.5% in both), and 30-day mortality rates were

comparable (2.5% vs. 3.8%; p=0.47). Rates of stroke (5.0% vs. 4.9%), major bleeding (17.5% vs. 18.7%), and renal failure requiring dialysis (7.5% vs. 15.2%) were also similar between groups. Length of stay was shorter after TMVR (intensive care unit stay: 1.0 vs. 5.0 days, p=0.001; hospital stay: 9.0 vs. 12.5 days, p=0.004).

Hell (2024) published the retrospective TENDER (Tendyne European Experience) registry that evaluated the Tendyne transcatheter mitral valve replacement (TMVR) system at 31 high-volume heart valve centers (Germany, Austria, Belgium, France, Italy, Spain, Switzerland, and the United Kingdom).[19] The study included 195 patients eligible for one-year follow-up, with a median age of 77 years and a median Society of Thoracic Surgeons Predicted Risk of Mortality of 5.6%. Technical success was achieved in 94.9% of patients. Cardiovascular mortality rates were 6.7% at 30 days and 16.9% at one year, while all-cause mortality rates were 9.3% at 30 days and 28.6% at one year. The rate of heart failure hospitalization significantly decreased from 68.1% in the year prior to the procedure to 25.4% in the one-year post-procedure period. At one-year follow-up, a reduction of mitral regurgitation to mild or less (≤1+) was achieved in 97.9% of patients, and 82.5% of patients were in NYHA functional class I or II, compared to 22.6% at baseline. Within the one-year post-discharge follow-up, major adverse events included disabling stroke (2.4%), myocardial infarction (1.3%), new-onset atrial fibrillation (5.4%), and new conduction disturbances (1.2%). Device-specific events comprised valve thrombosis (3.0%), valve migration (0.6%), and paravalvular leak >1+ inch (5.2%).

Ludwig (2020) reported outcomes of seven patients treated with the Tendyne and four patients treated with the Tiara TMVR systems.[20] Etiologies included primary, secondary, and mixed mitral regurgitation. All patients were symptomatic (NYHA III/IV) and at high surgical risk (logEuroSCORE II 8.1% [4.0, 17.4]). All patients achieved technical success. Following treatment, all patients had no or only trace mitral regurgitation. Overall mortality at three and six months was 10.0% and 22.2%, respectively. This study is limited by small sample size and lack of a comparison group.

Webb (2020) published outcomes of 14 patients treated with the EVOQUE transseptal TMVR system for moderate or greater mitral regurgitation.[21] One patient was converted to surgery and the rest achieved technical success. Adverse events within 30 days included one noncardiovascular mortality (7.1%), two paravalvular leaks (14.3%), and two strokes (14.3%). There were no myocardial infarctions or rehospitalizations. At 30 days, mitral regurgitation was mild or less in all implanted patients, with no mitral regurgitation in 10 patients (83.3%). The NYHA functional class improved to II or lower in in patients (81.8%). This study is limited by small sample size and lack of a comparison group.

Bioprosthetic valve failure

Systematic Reviews

Ismayl (2023) published a systematic review of six observational studies comprising 707 patients with bioprosthetic mitral valve (MV) degeneration to compare outcomes of valve-in-valve transcatheter mitral valve replacement (ViV-TMVR) to redo surgical mitral valve replacement (redo-SMVR).[22] The reviewers employed a random-effects model to calculate odds ratios (OR) with 95% confidence intervals (CI). Median follow-up time was 2.7 years. The studies included in this review were retrospective and observational in nature, and while propensity matching was used to reduce selection bias, patients in the ViV-TMVR group were older and had more co-morbidities than those in the redo-SMVR group. No differences in , mortality rate primary outcomes were identified: in-hospital mortality (OR 0.52, 95% CI 0.22 to

1.23, p=0.14), 30-day mortality (OR 0.65, 95% CI 0.36 to 1.17, p=0.15), one-year mortality (OR 0.97, 95% CI 0.63 to 1.49, p=0.89), and two-year mortality (OR 1.17, 95% CI 0.65 to 2.13, p=0.60). ViV-TMVR was associated with significantly lower risks of stroke, bleeding, acute kidney injury, arrhythmias, and permanent pacemaker implantation, as well as shorter hospital length of stay. The reviewers reported that overall heterogeneity among studies was low and found no evidence of publication bias. The review authors concluded that ViV-TMVR was associated with better outcomes than redo-SMVR in patients with degenerated bioprosthetic mitral valve, including lower complication rates and shorter hospital length of stay, with no significant difference in mortality rates. The studies included in this meta-analysis have multiple limitations. All included studies had an observational design and multiple studies had relatively small sample sizes (range 51 to 215). Patient selection for these therapies is influenced by age, co-morbidities, surgical risk, and operator experience which creates inherent selection bias. All studies had a median follow-up time of one to 4.5 years, and the review authors concluded that additional studies with longer term follow-up are needed to better assess treatment durability, long-term outcomes, and application of ViV-TMVR to patients at lower surgical risk.

Zhou (2022) performed a systematic review and meta-analysis of the same studies included in Ismayl (2023)[22], with an additional three retrospective cohorts.[23] This review found that TMVR was associated with lower in-hospital mortality (OR 0.44; 95% CI: 0.30-0.64; p<0.001) but the differences in 30-day mortality (OR 0.65; 95% CI: 0.36-1.17; P=0.15) and one-year mortality were not significant (OR 0.96; 95% CI: 0.63-1.45; p=0.84). TMVR was also associated with fewer postoperative strokes (OR 0.44; 95% CI 0.29-0.67, p=0.0001), lower risk of renal dysfunction (OR 0.52; 95% CI: 0.37-0.75, p=0.0003), a lower vascular complication rate (OR 0.58; 95% CI 0.43-0.78, p=0.004), fewer pacemaker implantations (OR 0.23; 95% CI: 0.15-0.36, p< 0.00001), and decreased risk of exploration for bleeding (OR 0.24; 95% CI: 0.06-0.96, p=0.04). However, the rate of postoperative paravalvular leak was higher in the TMVR group (OR 22.12, 95% CI: 2.81-174.16, p=0.003). The difference in mitral valve gradient was not significant (p=0.87). Heterogeneity between the studies was low (0%). The study limitations include the possibility of selection bias due to lack of randomization, the retrospective design of the studies and short follow-up times. The authors conclude that there is evidence that TMVR is associated with fewer surgical complications and can reduce in-hospital mortality compared to SMVR but large randomized studies are needed to confirm the review findings.

Non-randomized studies

Simard (2022) published the five-year outcomes of patients with degenerated mitral valve prostheses treated with TMVR or redo surgical mitral valve replacement (SMVR).[24] The cohort included 86 patients (40%) treated with TMVR (75 [87%] valve-in-valve and 11 [13%] valve-in-ring) and 129 patients (60%) who underwent SMVR. The TMVR cohort was older (p<0.0001), more symptomatic (p=0.0003) and had more chronic lung disease (p=0.02), worse renal function (p=0.02), and higher right ventricular systolic pressures (p<0.0001). 30 day mortality was lower with TMVR versus SMVR (2.4% vs. 10.2%, odds ratio [OR] 4.69 [95% CI 1.25 to 30.5], p=0.04) with probability of mortality at one, two, and five years being 14.7% versus 17.5%, 24.5% versus 20.7%, and 49.9% versus 34.0%, respectively. Mode of prosthesis degeneration, baseline hemodynamics, and valve selection did not appreciably impact outcomes. The authors concluded that TMVR for degenerated mitral prostheses is associated with better early survival compared to SMVR despite a greater burden of comorbidities. In contrast, five-year survival rates appear more favorable with SMVR, which may reflect the lower baseline risk of this population.

Zahid (2022) performed a retrospective analysis using the Nationwide Readmission Database on readmission outcomes from TMVR valve-in-valve replacement compared to surgery redo (SMVR) in 3,691 patients with a history of bioprosthetic mitral valve.[25] The researchers used a propensity-matched analysis to determine the adjusted odds ratio. After propensity matching 791 cases were TMVR and 841 were SMVR. The study found that the following were significantly different:

- All-cause in-hospital mortality was higher in the SMVR group (7.3% vs. 2.6%; p<0.01).
- Discharges to sites other than home were higher after SMVR despite the TMVR group having more co-morbidities (77.2% vs 46.1%; p<0.01).
- In-hospital complications: stroke, need for blood transfusion or pacemaker, and pneumonia were all higher with SMVR (each p<0.01).
- In-hospital cardiac arrest higher with SMVR (p=0.02).
- Hospital length of stay was longer with SMVR (15 days vs. 4 days; p<0.01).

Findings that were not significantly different:

- Mortality during episode of readmission at 30 days (p=0.36).
- All-cause readmission (p=0.57).
- Need for blood transfusion, stroke, vascular complication, pacemaker, or pneumonia at 30 days.
- Readmissions (p=0.13) and mortality (p=0.11) during hospitalization at 6 months.

The authors concluded that TMVR was associated with fewer in-hospital deaths and complications which indicate TMVR has superior short-term safety. TMVR is also associated with shorter LOS and higher discharge-to-home rates than SMVR. The similar readmission in-hospital mortality rates, and complications at 30 days and six-months indicate outcomes compared to SMVR. findings indicate that TMVR has similar overall safety and efficacy as SMVR. Limitations include that deaths outside the hospital were not captured in the data.

Section Summary

The evidence regarding transcatheter mitral valve replacement consists of systematic reviews and non-randomized studies. There is not enough research to show that transcatheter mitral valve replacement improves health outcomes for people with mitral regurgitation due to native valve disease. Available studies are limited by small sample sizes and lack of comparisons of transcatheter mitral valve replacement to other treatments.

There is enough evidence that transcatheter mitral valve replacement for failed bioprosthetic valves is associated with improved health outcomes, including fewer procedure-related complications than open surgery (e.g., stroke, bleeding), possibly a lower rate of in-hospital mortality, with no difference in post-procedure outcomes at 30 days and one-year.

TRANSAPICAL MITRAL VALVE REPAIR WITH PLACEMENT OF ARTIFICIAL CHORDAE TENDINAE

Systematic Reviews

Ahmed (2021) published a systematic review of six studies of mitral valve repair using the NeoChord DS1000 device, which is inserted into the beating heart to place artificial chordae tendinae.[26] The studies involved 249 patients who were classified as NYHA functional class I-

IV, but the majority (225) were class II or III, and 243 had severe MR. Intraoperative events included arrhythmia in six patients (2.4%) and significant bleeding in eight patients (3.2%). There were no intraoperative deaths. The most frequent post-operative complications were pleural effusion (34.5%), atrial fibrillation (19.7%), acute kidney injury (5.6%), and would dehiscence (5.6%). The post-operative mortality rate was 1.6%. The review was limited by the retrospective design of the included studies and small sample sizes. The authors state larger study results are expected in 2025 and 2027.

Section summary

There is not enough research to show that transapical mitral valve repair with placement of artificial chordae tendinae improves health outcomes of people with mitral valve regurgitation. Prospective studies that compare transapical mitral valve repair with placement of artificial chordae tendinae to other treatments are needed.

TRANSCATHETER MITRAL VALVE ANNULOPLASTY RECONSTRUCTION (TMVAR)

Randomized Studies

Several indirect annuloplasty devices, including the Carillon Mitral Contour System (Cardiac Dimension) and the Monarc device (Edwards Lifesciences), have been evaluated. Witte (2019) published the REDUCE-functional mitral regurgitation (FMR) study, a double-blind, randomized sham-controlled proof-of-concept study that evaluated the effects of the Carillon mitral annuloplasty device on FMR severity and left ventricular (LV) remodeling in people with FMR despite medical therapy.[27] The primary endpoint was change in mitral regurgitant volume at one year compared to baseline between the treatment group and sham control group. Secondary safety and efficacy endpoints included major adverse events, changes in LV end-systolic and end-diastolic volumes, changes in 6-minute walk distance and NYHA functional class as compared to baseline at 12 months. One hundred and twenty subjects were randomized in a 3:1 treatment to control ratio (87 to treatment and 33 to sham control). Device implantation was not carried out in 14 patients. Two deaths occurred within 30 days in implanted patients, and one was judged to be possibly related to the procedure. At 12-months, there was 10.4 ml/beat difference in mean mitral regurgitant volume between the two groups (95% confidence interval [CI]: 0.1 to 20.7; -7.1ml/beat [95% CI -11.7 to -2.5] vs. 3.3 ml/beat [95% CI: -5.98 to 12.62]; p = 0.049). The treatment group demonstrated a median 22.4% decrease in mitral regurgitant volume (MRV), while the control group had a 1.5% increase in MRV. 12-month improvement in FMR was greater in the treatment arm (50%) than the control arm (20%; p=0.02). There were significant decreases in LV end-diastolic volume (p=0.03) and end-systolic volume (p=0.04) in the treatment arm whereas the control arm had increases in both measures. The treatment arm showed significant improvement in 6-minute walk test (p=0.002) from baseline while the controls did not (p=0.29). The treatment group also showed improvement in their NYHA classification (p=0.002) while the control group did not (p=0.29). There were no significant differences in major adverse events or heart failure hospitalizations. Paired echocardiography data to assess mitral regurgitation severity was available for only 57% of subjects. Other limitations of the study include that it was not powered to show between group differences. The authors note that while the study achieved its primary endpoint, further research is needed.

Khan (2021) published follow-up data from REDUCE-FMR that compared functional outcomes through one year in participants with moderate-to-severe FMR treated with the Carillon mitral annuloplasty device or sham control.[28] Of 83 subjects from the REDUCE-FMR (62 from

treatment arm and 21 from sham control arm). The study found that the treatment arm had higher mean improvement in 6-minute walk distance (24m vs. 9m), Kansas City Cardiomyopathy Questionnaire (KCCQ) score (12 vs. 5), and ≥1 NYHA class change (48% vs. 33%), and freedom from hospitalization or death (60% vs 48%) compared to the control group. The study notes that while the study findings suggest improvement with the Carillon device, they are considered exploratory, not confirmatory because the study is inadequately powered. Further studies are needed to determine actual benefit and long-term outcomes beyond one year.

Section Summary

There is not enough research to show that TMVAR improves health outcomes for people with mitral valve regurgitation. Additional research to determine TMVAR efficacy and long-term outcomes is needed.

PERCUTANEOUS TRANSCATHETER TRICUSPID VALVE REPAIR

Systematic Reviews

Saito (2025) published a systematic review and meta-analysis that compared four treatments for isolated TR: medical therapy alone, transcatheter tricuspid valve (TV) repair (T-TEER and annuloplasty), surgical TV repair, and surgical TV replacement.[29] Twenty-two studies involving 25,831 patients were included. The primary outcome, long-term mortality at one-year or longer follow-up, was reported in 16 studies (18,035 patients). Medical therapy alone was associated with higher long-term mortality than surgical TV repair (HR [95% CI] 1.72 [1.34-2.23]), surgical TV replacement (HR [95% CI] 1.49 [1.13-1.95]), and transcatheter TV repair (HR [95% CI] 1.52 [1.30-1.78]). Surgical TV repair was associated with lower long-term mortality than surgical TV replacement (HR [95% CI] 0.86 [0.79-0.95]), but the difference in long-term mortality between surgical TV repair and transcatheter TV repair was not significant. There were no significant heterogeneities (I^2=0%; p=0.59). Secondary outcomes, assessed for the three procedures, were short-term mortality, length of hospitalization, and periprocedural complications. Transcatheter TV repair had a lower risk for short-term mortality than surgical TV repair (RR [95% CI] 0.40 [0.22-0.72]) and surgical TV replacement (RR [95% CI] 0.35 [0.19-0.66]). Transcatheter TV repair was also associated with shorter hospital stay and lower risk of periprocedural complications. Limitations of the study include the potential for selection bias since only one included study was an RCT. The authors concluded that TR repair is an attractive option for TR treatment but further research is needed to know the best treatment for TR.

Rehan (2023) conducted a systematic review and meta-analysis that assessed TR severity and additional echocardiographic outcomes in patients undergoing transcatheter edge-to-edge repair with the TriClip, MitraClip, and PASCAL devices.[30] The review included one RCT and 14 observational studies of patients with moderate-to-severe TR (grade III to V). Outcomes included echocardiographic and quality of life determining outcomes such as improvement in TR severity grade ≥3, New York Heart Association (NYHA) functional class ≥3, procedural success, 6-minute walking distance (6MWD), and adverse outcomes. Analysis revealed a substantial reduction in TR volume (p<0.00001), TR grading (p<0.00001), tricuspid annular diameter (p<0.00001), proximal isovelocity surface area radius (p<0.00001), effective regurgitant orifice area (p<0.00001), and improvement in NYHA class (p<0.00001) at 30 days from baseline, post procedurally. A significant increase in 6MWD at one year (p=0.001) was also recorded. No significant differences in left ventricular ejection fraction (p=0.87), fractional

area change (p=0.37), or tricuspid annular plane systolic excursion (p=0.76) were observed. The review authors concluded that large scale RCTs comparing the tricuspid transcatheter edge-to-edge repair (T-TEER) devices are needed to strengthen the present findings.

Montalto (2020) published a systematic review and meta-analysis of the feasibility, efficacy, and clinical outcomes of transcatheter repair of TR.[31] Studies were included if enrolled patients had at least moderate TR, determined by a semi-quantitative method, and if at least one of the primary outcomes had a minimum follow-up of 30 days. Case reports, letters, and studies which did not clearly report the numbers and rates of alive patients at follow-up were excluded. Seven studies of 454 patients were included in the pooled analysis. 95% of patients had at least severe TR, and 91% were in NYHA functional class III or IV. Successful implantation occurred in 86% of patients. At the longest follow-up (mean=265 days), 9% of patients had died. Compared to the pre-treatment baseline, a significantly lower proportion of patients had at least severe TR (relative risk, 0.38; 95% confidence interval (CI) 0.20 to 0.70; p=0.004) and were in NYHA functional class III or IV (relative risk, 0.23; 95% CI 0.20 to 0.30; p=0.001). Increases in 6MWD were observed (mean difference +64.6 minutes; p<0.001). Significant reductions in tricuspid valve annular diameter were also reported (mean difference -3 millimeters; p<0.001). Left and right ventricular function were not significantly altered.

Randomized Controlled Trials

Donal (2025) presented the Tri.Fr randomized clinical trial (NCT04646811), an independent, investigator-initiated study conducted across 24 centers in France and Belgium.[32] This randomized (1:1) trial compared T-TEER plus medical therapy to medical therapy alone in 300 patients with severe symptomatic TR. Participants had a mean age of 78 years, and most had either massive (63%) or torrential (28%) TR at baseline. The primary endpoint was a composite outcome at one year, incorporating NYHA class change, patient global assessment (PGA) change (>4 points), and major cardiovascular hospitalization or death, which was assessed by a blinded adjudication committee. The primary endpoint was achieved in 74.1% of the T-TEER group versus 40.6% in the control group (p<0.001). At one year, only 6.8% of T-TEER-treated patients had massive or torrential TR compared to 53.5% of controls (p<0.001). The mean KCCQ score at one year was significantly higher in the T-TEER group (69.9 vs. 55.4; p<.001), and the composite win ratio for secondary endpoints (time of death, time of secondary tricuspid valve surgery, heart failure hospitalization, KCCQ improvement, freedom from major adverse cardiovascular (CV) event, freedom from CV death) tested hierarchically was 2.06 (95% CI, 1.38 to 3.08; p<.001), favoring T-TEER. Procedural success was high (97.3%), and adverse events were infrequent and similar between groups. Limitations of the Tri.Fr trial include its unblinded design, reliance on subjective outcome measures, exclusion of patients with concomitant valve disease, and a relatively short 1-year follow-up.

Sorajja (2023) published an RCT (TRILUMINATE) which evaluated the safety and efficacy of percutaneous (T-TEER) for the treatment of severe tricuspid regurgitation at 65 centers in the United States, Canada, and Europe.[33] 350 patients with symptomatic severe tricuspid regurgitation were randomly assigned in a 1:1 ratio to receive either T-TEER (n=175) or a medical therapy control (n=175). Mean age was 78 years, and 54.9% of patients were women. The primary composite endpoint included death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and an improvement in quality of life as measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ), with an improvement defined as an increase of at least 15 points in the KCCQ score (range, 0 to 100, with higher scores indicating better quality of life) at one-year follow-up. Primary endpoint results favored the T-TEER group

(win ratio, 1.48; 95% confidence interval, 1.06 to 2.13; p=0.02). The incidence of death or tricuspid-valve surgery and the rate of hospitalization for heart failure were similar between the two groups. The KCCQ quality-of-life score changed by a mean (±SD) of 12.3±1.8 points in the T-TEER group, as compared with 0.6±1.8 points in the control group (p<0.001). At 30 days, 87.0% of the patients in the T-TEER group and 4.8% of those in the control group had tricuspid regurgitation of no greater than moderate severity (p<0.001). T-TEER was found to be safe; 98.3% of the patients who underwent the procedure were free from major adverse events at 30 days. This study is limited by lack of long-term outcomes beyond one year.

Tang (2025) reported one-year outcomes from the full TRILUMINATE randomized cohort, expanding enrollment to 572 patients across 68 centers.[34] The study maintained the same design and eligibility criteria as Sorajja (2023) and continued enrollment beyond the primary analysis population as part of the trial's adaptive design. In the full cohort, the primary endpoint again favored the T-TEER group, with a win ratio of 1.84 (p<0.0001). Although no difference was observed in freedom from all-cause mortality or TR surgery (90.6% vs. 89.9%; p=.82) or in hospitalization for heart failure (HFH) (0.17 vs. 0.20 events/patient-year; p=.40), the proportion of patients achieving a ≥15-point improvement in KCCQ score was significantly higher in the T-TEER group (52.3% vs. 23.5%; p<0.0001). Secondary endpoints also favored T-TEER, including TR severity reduction to moderate or less at 30 days (88.9% vs. 5.3%; p<0.0001), mean KCCQ score improvement (13.0 vs. -0.5 points; p<0.0001), and 6-minute walk distance (+1.7 m vs. -27.4 m; p<0.0001). Freedom from major adverse events was 98.9% in the device group, exceeding a pre-specified performance goal of 90%. Despite these favorable outcomes, limitations remained consistent with the earlier report: limited follow-up duration, lack of blinding, and reliance on subjective endpoints. Additionally, post-hoc subgroup comparisons and unadjusted multiplicity in secondary outcomes may influence the interpretation of statistical significance.

Kar (2025) reported the two-year outcomes of the full TRILUMINATE cohort.[35] The prespecified two-year endpoints were recurrent HFH and a modified composite outcome of freedom from all-cause mortality, tricuspid valve surgery, or T-TEER intervention. By the two-year follow-up, only 57 participants remained in the control group receiving guideline-directed medical therapy alone, although most comparisons used an intent-to-treat analysis. This reduction was due to 49% (n=142) of eligible control participants crossing over to T-TEER at one year, 11 deaths occurring prior to two years, 16 participant withdrawals, six individuals undergoing tricuspid valve surgery, and 12 participants missing their two-year follow-up assessment. Individuals who crossed over to T-TEER were more likely to be symptomatic, with a higher proportion in NYHA class III/IV (47% vs 30%), and more frequently exhibited torrential TR (65% vs 42%) compared to those who did not cross over. The trial met its primary two-year endpoint, demonstrating a significant 28% relative risk reduction in recurrent HFH in the T-TEER group compared to control (Hazard Ratio [HR] 0.72; p=0.02), and a significant difference when comparing annualized HFH event rates (0.19 vs. 0.26 events/patient-year; p=0.02). Freedom from the composite endpoint was 77.6% (95% CI: 72.2% to 82.1%) in the T-TEER group versus 29.3% (95% CI: 23.8% vs. 34.9%; p<.0001) in control participants driven by crossover of eligible patients to T-TEER, although both all-cause mortality and valve surgery rates remained similar. At two years, 84% of T-TEER individuals had TR severity reduced to moderate or less, and the mean KCCQ score improved by 15.4 points from baseline. Adverse event rates were low and included: stroke (1.9%), transient ischemic attack (1.7%), tricuspid valve surgery (2.3%), cardiogenic shock (0.4%), and permanent pacemaker implantation (5.5%). In the crossover group, comparable improvements in HFH rates, KCCQ scores, and TR severity were observed, along with similarly low adverse event rates at the one-year follow-

up. Limitations included high crossover in the control arm after one year, which diminished the size of the pure control group and potentially created a selection bias where sicker patients with more uncontrolled TR were likelier to crossover.

Arnold (2023) published results from the TRILUMINATE pivotal trial, a prospective, multicenter, randomized, open-label trial of tricuspid edge-to-edge transcatheter valve repair with the TriClip device in patients with severe symptomatic tricuspid regurgitation.[36] Eligible patients had severe, massive, or torrential tricuspid regurgitation confirmed by an independent echocardiography laboratory, NYHA functional class II to IVa symptoms, pulmonary artery systolic pressure less than 70 mm Hg, and no other cardiovascular conditions in need of interventional or surgical correction (e.g., severe mitral regurgitation). Participants were also on stable guideline-directed medical therapy for heart failure for at least 30 days. Mean participant age was 78± 7 years, and 45% of participants were men. 12% of participants had chronic lung disease. Participants were randomized to receive either tricuspid edge-to-edge transcatheter valve repair (n=169) or medical therapy only (n=163 participants). Health outcomes were assessed at baseline, one month, six months, and 12 months with KCCQ scores. Alive and well was defined as a KCCQ overall summary score greater than or equal to 60 and no decline from baseline greater than 10 points at one year. Compared with medical therapy, tricuspid edge-to-edge transcatheter valve repair significantly improved health status at one month (mean between group difference in KCCQ overall summary score 9.4 points; 95% CI, 5.3 to 13.4 points). A small, additional improvement occurred at one year (mean between-group difference 10.4 points; 95% CI, 6.3 to 14.6 points). Patients who received tricuspid edge-to-edge transcatheter valve repair were more likely to meet the alive and well criteria at one year compared to patients who received medical therapy (74.8% vs. 45.9%; p<0.001). This study is limited by susceptibility of patient-reported outcomes to bias due to lack of blinding, lack of assessment of clinical outcomes of death or heart failure hospitalization, and lack of long-term follow-up beyond one year.

Nonrandomized Studies

Schlotter (2025) published the prospective, multicenter European Tricuspid Regurgitation and Repair registry (EuroTR), which was conducted across 12 centers in Europe from 2016 to 2022.[37] The study enrolled 1,885 patients with symptomatic severe TR, including 1,300 treated with T-TEER using TriClip or PASCAL, and 585 conservatively managed with medication alone. Patients were categorized into early (21%), intermediate (62%), and advanced (17%) TR disease stages based on biventricular function, renal function, and natriuretic peptide levels. The median age was 79 years, and NYHA class III/IV symptoms were present in >85% of the cohort. One-year mortality was 6%, 15%, and 31% for early, intermediate, and advanced stages, respectively. In the intermediate-stage subgroup, one-year mortality was significantly lower with T-TEER compared to conservative management (13% vs. 21%; Hazard Ratio [HR] 0.73, 95% CI: 0.52 to 0.99; p=0.03). No significant mortality difference was observed in early or advanced stages. Procedural success (defined as residual TR ≤ grade 2) was 83% overall in T-TEER-treated individuals and did not differ by disease stage.

The retrospective, observational study by Shimoda (2025) was conducted using a sample of Medicare beneficiaries in the United States.[38] The study analyzed 1,143 patients aged 65 to 99 years with symptomatic tricuspid regurgitation (TR) who underwent either T-TEER (n=409) or isolated surgical tricuspid repair (STVR, n=734) between July 2016 and December 2020. Participants in the T-TEER group and STVR group had similar ages, comorbidities, and frailty scores after propensity matching. The two-year all-cause mortality was comparable between

groups (adjusted hazard ratio 0.84; 95% CI, 0.63 to 1.13; p=.25). T-TEER was associated with significantly lower in-hospital mortality (2.5% vs. 12.5%, p<0.001), permanent pacemaker implantation (0.0% vs. 12.7%, p<0.001), acute kidney injury (11.9% vs. 33.8%, p<0.001), and cardiogenic shock (4.0% vs. 17.1%, p<0.001). The median hospital stay was also shorter in the T-TEER group (2 vs 11 days, p<.001), with more patients discharged home (88.4% vs. 48.4%). However, tricuspid valve reintervention was significantly more frequent in the T-TEER group (HR, 8.03; 95% CI, 2.87 to 22.48; p<.001).

Mohamed (2023) published a retrospective, population-based study using the U.S. National Inpatient Sample (NIS).[39] This study compared inpatient outcomes of transcatheter versus surgical tricuspid valve repair. The study included 37,115 hospitalized patients with tricuspid regurgitation (TR) from 2016 to 2020, of whom 1,830 (4.9%) underwent T-TEER and 35,285 (95.1%) underwent surgical tricuspid valve repair (STVR). Following 1:2 propensity-score matching, 1,520 T-TEER and 2,920 STVR cases were analyzed. After matching, T-TEER patients remained older (mean 76 vs 64 years) and more likely to have co-morbid conditions. T-TEER was associated with significantly lower inpatient mortality (3.0% vs 6.7%; adjusted odds ratio [aOR] 0.43; 95% CI: 0.31 to 0.59; p<0.01), fewer cardiovascular complications (8.2% vs 19.5%; aOR 0.37; 95% CI: 0.30 to 0.45; p<0.01), fewer renal complications (24.0% vs 36.1%; aOR 0.56; 95% CI: 0.45 to 0.64; p<0.01), fewer infectious complications (4.9% vs 10.6%; aOR 0.44; 95% CI: 0.34 to 0.57; p<0.01), reduced need for mechanical circulatory support (2.0% vs. 8.4%; aOR 0.22; 95% CI: 0.15 to 0.32; p<0.01), and a shorter mean hospital stay (7 vs. 15 days; p<.01). No significant differences in major bleeding or cardiac arrest were observed.

Lurz (2024) published one-year outcomes from the bRIGHT study (An Observational Real-World Study Evaluating Severe Tricuspid Regurgitation Patients Treated With the Abbott TriClip™ Device).[40] The bRIGHT study is a postapproval, open-label, single-arm, prospective, observational registry study being conducted at 26 sites in Europe to assess echocardiographic outcomes of tricuspid transcatheter edge-to-edge repair with the TriClip system. Enrolled subjects were elderly (79±7 years) with significant comorbidities; 88% of patients had baseline massive or torrential tricuspid regurgitation, and 80% percent of subjects were in NYHA class III/ IV. Tricuspid regurgitation was reduced to moderate or less in 81% of patients at one-year post-treatment. Significant improvements in NYHA class (21% to 75% I/II, p<0.0001) and KCCQ score (19±26-point improvement, p<0.0001) were observed. One-year mortality was significantly lower in subjects who achieved moderate or lower tricuspid regurgitation at 30 days. However, there was no difference in mortality among subjects that achieved moderate, mild, or trace tricuspid regurgitation at 30 days. In addition to tricuspid regurgitation reduction at 30 days, baseline serum creatinine and baseline right ventricular tricuspid annular plane systolic excursion (RV TAPSE) were independently associated with mortality at one year (odds ratio [OR]: 2.169, 95% CI 1.494 to 3.147, p<0.0001; OR: 0.636, 95% CI 0.415 to 0.974, p=0.0375). Mortality was not associated with baseline TR grade, nor with center volume.

Wild (2024) conducted an observational cohort study of 1059 high-risk patients treated with PASCAL transcatheter tricuspid valve repair in 16 European centers between 2019 and 2023.[41] Echocardiographic assessments at baseline, discharge, and follow-up were centrally analyzed. At baseline 96% of participants had severe or higher graded TR. At baseline 17% of subjects had NYHA functional class I/II; which improved to 66% at one year (p<0.001). Intraprocedural success was 85% and the authors noted improved TR reduction (63% vs. 49%; p<.001), shorter procedure times (p<0.001), and higher clinical success rates (56% vs.

50%; p=0.044) with the newer Precision device compared to the first-generation PASCAL system. The authors concluded that the PASCAL system reduces TR and is associated with significant clinical improvements at one year follow-up.

Lurz (2023) published short-term outcomes from the bRIGHT study.[42] Participant mean age was 79± 7 years, and participants had significant comorbidities. 88% of participants had baseline massive or torrential tricuspid regurgitation, and 80% were in NYHA functional class III or IV. Tricuspid regurgitation was reduced to less than or equal to moderate at 30 days post-implantation in 77% of participants. Associated significant improvements in NYHA functional class (I/II, 20% to 79%; p<0.0001) and KCCQ score (19 ± 23 points improvement; p<0.0001) were also observed at 30 days. 14 subjects (2.5%) experienced a major adverse event by day 30 (e.g., cardiovascular mortality, stroke, new onset renal failure, or non-elective cardiovascular surgery for device-related adverse event). This study is limited by lack of a comparison group and long-term follow-up.

Nickenig (2024) reported a prospective, multicenter TRILUMINATE single-arm study that was conducted across 21 sites in Europe and the United States.[43] The trial enrolled 98 patients with symptomatic moderate or greater TR who were at high surgical risk and deemed suitable for leaflet repair. Participants had a mean age of 77.5 years, and 66% were female. A large proportion of participants were NYHA class III/IV (76%). TR severity was torrential in 33.7%, massive in 28.6%, and severe in 32.7%. The mean EuroSCORE II was 8.3%. At 3 years, 79% of subjects with evaluable echocardiograms (n=61) achieved TR reduction to moderate or less, while 92% demonstrated at least one-grade improvement. This benefit was sustained from one to three years (p=.912). Functional improvements were also maintained: NYHA class III/IV status declined from 76% at baseline to 19% at three years (p<.0001), and mean KCCQ scores showed a sustained improvement of 10 points from baseline (p=.006). The cumulative rate of major adverse events was 25% at 3 years, including cardiovascular mortality in 18.8%, stroke in 4.2%, and renal failure in 8.3%. No device-related surgeries, device embolizations, or cases of endocarditis were reported.

Von Bardeleben (2023) published two-year outcomes from 85 participants in the TRILUMINATE trial, an ongoing international, multicenter, single-arm study evaluating safety and performance of tricuspid transcatheter edge-to-edge repair with the TriClip implant.**[44]** At year two, tricuspid regurgitation was reduced to moderate or less in 60% of subjects, and reduction of at least one grade was achieved in 85.4% of participants. Tricuspid regurgitation reduction was sustained in 75% of patients. Substantial improvements in 6MWD, NYHA functional class, and KCCQ score were sustained from 30 days to two years. The all-cause hospitalization rate decreased from 1.30 events per patient per year to 0.66 events per patient per year two years after the TriClip procedure, a 49% reduction (p<0.0001). This study is limited by lack of a comparison group and small sample size.

Freixa (2022) published a retrospective multicenter study that collected data from all patients undergoing edge-to-edge tricuspid valve repair with the TriClip system in Spain between June 2020 and March 2021 (n=34 patients).[45] The primary endpoint was achievement of a tricuspid regurgitation reduction of at least one grade at discharge. 91% of patients had a history of atrial fibrillation, and one patient had a pacemaker lead. The primary endpoint was met in all patients. At three months, no mortality events occurred. 88% of patients were in New York Heart Association (NYHA) class less than or equal to two, and 80% had residual tricuspid regurgitation less than or equal to two. One patient experienced a partial clip detachment,

which was stabilized with additional clips in the same procedure. This study is limited by small sample size and lack of long-term follow-up beyond three months.

Orban (2020) published an observational study which evaluated the effect of transcatheter edge-to-edge tricuspid valve repair (T-TEER) for severe tricuspid regurgitation (TR) on hospitalization for heart failure (HHF) and HF-related endpoints.[46] Isolated T-TEER was performed in 119 patients. Results were compared with those of 114 patients who underwent combined mitral and tricuspid valve repair. Procedural success with a reduction to moderate or less tricuspid regurgitation and no in-hospital death was achieved in 82% of patients. At a median follow-up of 360 days, a reduction to moderate or less tricuspid regurgitation was achieved in 72% of patients (p<0.001). T-TEER reduced the annual rate of HHF by 22% (1.21 to 0.95 HHF per patient per year; p=0.02). Clinical improvement was also observed for NYHA functional class (patients in class II or lower: 9% to 67%; p<0.001), 6MWD (+39 m; p=0.001), and Minnesota Living with Heart Failure Questionnaire score (-6 points; p=0.02). N-terminal pro-B-type natriuretic peptide level decreased by 783 picograms per milliliter. Procedural success was associated with improved one-year survival (79% vs. 60%; p=0.04) and event-free-survival (death + first HHF: 67% vs. 40%; p=0.001). Transcatheter mitral and tricuspid valve repair-treated patients had comparable outcomes.

Nickenig (2017) published an observational study of safety and feasibility of transcatheter repair of chronic severe tricuspid regurgitation with the MitraClip system.[47] In addition, the effects on clinical symptoms were assessed. Patients with heart failure symptoms and severe tricuspid regurgitation, on optimal medical therapy, were treated with the MitraClip system. Safety was defined as periprocedural adverse events such as death, myocardial infarction, stroke, or cardiac tamponade. Feasibility was defined as successful implantation of one or more MitraClip devices and reduction of tricuspid regurgitation by at least one grade, after 30 days. 64 patients (mean age 76.6±10 years), deemed unsuitable for surgery, underwent MitraClip treatment for chronic, severe tricuspid regurgitation. Severe or massive tricuspid regurgitation was present in 88% of patients, and 22 patients were also treated with the MitraClip system for mitral regurgitation in a combined procedure. The MitraClip device was successfully implanted in the tricuspid valve in 97% of cases. After the procedure, tricuspid regurgitation was reduced by at least one grade in 91% of the patients. In 13% of patients, tricuspid regurgitation remained severe after the procedure. No intraprocedural deaths, cardiac tamponade, emergency surgery, stroke, myocardial infarction, or major vascular complications occurred. Three (5%) in-hospital deaths occurred. NYHA class was significantly improved (p<0.001), and 6MWD increased significantly (165.9±102.5 minutes versus 193.5±115.9 minutes; p=0.007).

Section Summary

There is enough research to show that percutaneous transcatheter tricuspid valve repair improves health outcomes for people with severe tricuspid regurgitation despite the use of medical therapy who are considered at intermediate or high surgical risk. Available evidence includes two randomized controlled trials (TRILUMINATE and Tri.Fr), a prospective single-arm report of the TRILUMINATE study, several database or real-world registry studies, and multiple additional case series.

TRANSCATHETER TRICUSPID VALVE ANNULUS RECONSTRUCTION

Nonrandomized Studies

Zhang (2023) published a compassionate use study of the K-clip transcatheter annular repair system for severe functional TR.[48] 15 patients were enrolled. At 30 days, reductions in tricuspid annular circumference (by 14.30%) and area (by 25.96%) were observed. No major adverse events were reported at 30 days. Clinical evaluation indicated that 86.67% of patients were finally in NYHA functional class I or II (p<0.001), and overall KCCQ score improved from 62.28 ± 18.97 to 77.90 ± 11.70 (p=0.016). This study is limited by small sample size and lack of a comparison group. The authors concluded that while early results are promising, controlled trials with longer term follow-up are necessary to establish the safety and effectiveness of transcatheter valve annulus reconstruction devices.

Gray (2022) published one-year outcomes from a single-arm multi-center study of tricuspid regurgitation treated via annual reduction with the Cardioband Tricuspid Valve Reconstruction System.[49] 37 patients with functional (97.3%) or mixed (2.7%) tricuspid regurgitation were enrolled. One-year follow-up was available for 29 patients. Tricuspid annular diameter significantly decreased (p<0.0001). Echocardiogram demonstrated significant reductions in tricuspid regurgitation severity between 30 days and six months (p=0.0029) and at one year (p<0.0001). NYHA functional class improved at one year (p<0.0001). At one year cardiovascular mortality was 8.1% (n=3) with one death deemed possibly related to the study device. The severe bleed rate was 35.1%. The study was limited by small sample size, and lack of control arm.

Davidson (2021) published 30 day outcomes from an early feasibility study of the Cardioband tricuspid system for the treatment of functional tricuspid regurgitation.[50] 30 patients with severe or greater symptomatic functional tricuspid regurgitation were enrolled who were deemed candidates for transcatheter tricuspid repair with the Cardioband tricuspid system by the local heart team and multidisciplinary screening committee. The mean patient age was 77 years. 80% of patients were women, 97% had atrial fibrillation, 70% were in NYHA functional class III to IV with mean left ventricular ejection fraction of 58%, and 27% had severe, 20% massive, and 53% torrential tricuspid regurgitation. Device success was 93% and all patients were alive at 30 days. Between baseline and 30 days, septolateral tricuspid annular diameter was reduced by 13% (p<0.001), 85% of patients had greater than or equal to one grade tricuspid regurgitation reduction. 44% of patients had moderate or less tricuspid regurgitation, 75% were in NYHA functional class I to II (p<0.001), and overall Kansas City Cardiomyopathy Questionnaire (KCCQ) score improved by 16 points (p<0.001).

Nickenig (2021) reported a prospective single-arm study of 30 patients implanted with the Cardioband tricuspid valve reconstruction system for the treatment of moderate or severe functional tricuspid regurgitation (TRI-REPAIR study).[51] Outcomes were collected prospectively for up to two years, with a mean duration of 604 days. Technical success was 100%. Prior to implantation, 83% of patients were in NYHA Class III to IV, and at two years 82% of patients were in NYHA Class II to II (p=0.02). 6MWD and KCCQ scores improved by 73 minutes (p=0.058) and 14 points (p=0.046), respectively. There were eight deaths within the two-year follow-up. This study is limited by lack of a comparison group and small sample size.

Section summary

There is not enough research to show that transcatheter tricuspid valve annulus reconstruction improves health outcomes for people with tricuspid valve regurgitation. While early results of studies investigating tricuspid valve annulus reconstruction are promising, controlled trials are

necessary to establish the safety and effectiveness of transcatheter valve annulus reconstruction devices.

TRANSCATHETER TRICUSPID VALVE REPLACEMENT (TTVR)

Randomized Studies

Hahn (2025) conducted the TRISCEND II trial, which represents the first pivotal randomized controlled trial evaluating transcatheter TTVR using the EVOQUE system in patients with severe symptomatic TR.[52] Conducted across 45 centers in the United States and Germany between May 2021 and April 2023, the study enrolled 400 patients in a 2:1 ratio to receive either TTVR with the EVOQUE device plus medical therapy (n=267) or medical therapy alone (n=133). Participants had a mean age of 79.2 years, 73% were classified as New York Heart Association (NYHA) functional class III or IV, and 54% had chronic kidney disease. TR was torrential or massive in 53% of patients, and the mean EuroSCORE II was 5.4%. The predominant mechanism of TR was secondary (74.1%), followed by primary and mixed causes.

The primary endpoint was a hierarchical composite outcome evaluated at one year, including all-cause mortality, right ventricular assist device implantation or transplantation, postindex tricuspid intervention, hospitalization for heart failure (HFH), and improvements in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score, NYHA functional class, and 6-minute walk distance (6MWD). A win ratio method was used for analysis, comparing all possible patient pairs between groups. The primary outcome significantly favored the valve replacement group, with a win ratio of 2.02 (95% CI, 1.56 to 2.62; p<0.001). Patients in the EVOQUE group had greater clinical benefit across most individual components, including a higher proportion achieving ≥ 10-point improvement in KCCQ (66.4% vs. 36.5%), NYHA class improvement (78.9% vs. 24.0%), and ≥ 30-meter increase in 6-minute walk distance (47.6% vs. 31.8%). Although the rates of death (12.6% vs. 15.2%) and HFH (20.9% vs. 26.1%) were numerically lower in the valve replacement group, the study was not powered to detect significant differences in these endpoints individually. TR reduction to mild or less was achieved in 95.3% of patients in the EVOQUE arm at one year, compared to only 2.3% in controls. Severe bleeding occurred in 15.4% of valve-treated patients compared to 5.3% in the control group (p=0.003), and 17.4% of treated patients required new unplanned permanent pacemakers, compared to 2.3% of controls (p<0.001). Reintervention of the tricuspid valve occurred in 3.2% of patients in the TTVR group and 0.6% in the medical therapy group; however, specific details regarding the type of reintervention performed were not reported. Limitations of the trial consisted of the presence of crossover in the control group, higher attrition in the control arm, and reliance on hierarchical composite outcomes, which were driven by subjective patient-reported metrics.

Nonrandomized Studies

Kodali (2023) conducted a prospective, single-arm study (TRISCEND) in 176 participants and reported major adverse events, reduction in regurgitation grade and hemodynamic outcomes by echocardiography, and clinical, functional, and quality-of-life parameters.[53] Patients were 71.0% female, mean age 78.7 years, 88.0% with greater than or equal to severe tricuspid regurgitation, and 75.4% New York Heart Association classes III-IV. Tricuspid regurgitation was reduced to less than or equal to mild in 97.6% (p<0.001), with increases in stroke volume (10.5 ± 16.8 mL, p<0.001) and cardiac output (0.6 ± 1.2 L/min, p<0.001). New York Heart Association class I or II was achieved in 93.3% (p<.001), Kansas City Cardiomyopathy

Questionnaire score increased by 25.7 points (p<0.001), and six-minute walk distance increased by 56.2 m (p<0.001). All-cause mortality was 9.1%, and 10.2% of patients were hospitalized for heart failure. Longer-term follow-up is needed to confirm sustained improvements in these outcomes.

Section Summary

There is enough research to show that transcatheter tricuspid valve replacement improves health outcomes for people with severe tricuspid regurgitation despite the use of medical therapy when tricuspid valve repair is not feasible. The available evidence for the use of the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in patients with symptomatic tricuspid regurgitation (TR) includes a single-arm feasibility study (TRISCEND), a pivotal randomized controlled trial (TRISCEND II), and several additional case series.

CAVAL VALVE IMPLANTATION (CAVI)

Nonrandomized studies

Estevez-Loureiro (2022) published six-month outcomes from the Safety and Efficacy of the TricValve® Transcatheter Bicaval Valves System (TRICUS EURO) study, a prospective single-arm study with 35 patients from 12 institutions in Spain and Austria.[54] The study participants had NYHA functional class III or IV TR, symptoms of right heart failure, and were ineligible for open heart surgery. The primary endpoint was NYHA functional class and quality of life (QOL) measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ) at six-months after valve implantation. Secondary endpoints included major adverse events and functional capacity measured with a six-minute walk test. Compared to baseline, there was significant improvement in NYHA functional class at six months with 79.4% of participants in functional class I or II (p=0.0006). KCCQ scores were also significantly improved at six months (p=0.004). There were three deaths at six months, but none were procedural or recorded as cardiovascular. Major bleeding was seen in six participants (17.1%), all of whom were receiving anticoagulation. Two cases of bleeding were due to access-site complications. Seven participants (20%) were readmitted to the hospital for heart failure. The difference in six-minute walk test distance was not significant (p=0.46). The authors concluded that CAVI led to improved functional status and QOL with a low rate of procedural complications, but longer term follow-up is needed.

Blasco-Turrion (2024) published one-year follow-up data from the TRICUS EURO study, with additional information from the TRICUS study, an early feasibility study with nine participants (n=44).[55] At one year, 42 participants (95.5%) had at least one of the following: an increase of $\geq$15 points in KCCQ score, improvement to NYHA functional class I or II, or an increase of $\geq$40 meters in the six-minute walk test. There were three deaths (6.8%) at one year and 29.5% of participants were hospitalized for heart failure. Hepatic vein backflow was alleviated in 63.8% of patients leading to reduced congestive heart symptoms, n-terminal pro-B-type natriuretic peptide levels, and diuretic treatment. The authors concluded that CAVI treatment using TricValve® system is safe and leads to stable functional and QOL improvement.

Section Summary

There is not enough research to show that caval valve implantation improves health outcomes for people with tricuspid regurgitation. CAVI devices are potentially promising alternatives in

the treatment of tricuspid valve regurgitation, however there is a need for additional research on CAVI devices using comparative designs with follow-up assessment.

PRACTICE GUIDELINE SUMMARY

American Heart Association (AHA) and American College of Cardiology (ACC)

In 2020, the American College of Cardiology and American Heart Association released joint clinical practice guidelines for the management of valvular heart disease.[2] The guidelines do not address the procedures in this policy.

SUMMARY

TRANSCATHETER MITRAL VALVE REPAIR

There is enough research to show that transcatheter mitral valve replacement (TMVR) can improve health outcomes for people with previously placed, failed bioprosthetic mitral valves. Compared to surgery, TMVR is associated with fewer procedure-related complications (e.g., stroke, bleeding), possibly a lower rate of in-hospital mortality, with no difference in post-procedure outcomes at 30 days and one-year. Therefore, TMVR may be considered medically necessary for people who meet policy criteria.

There is not enough evidence to show that transcatheter mitral valve replacement (TMVR) improves health outcomes for mitral valve regurgitation due to native mitral valve disease. Therefore, TMVR is considered investigational when policy criteria are not met.

TRANSAPICAL MITRAL VALVE REPAIR WITH PLACEMENT OF ARTIFICIAL CHORDAE TENDINAE

There is not enough research to show that transapical mitral valve repair with placement of artificial chordae tendinae improves health outcomes of people with mitral valve regurgitation. The current evidence is limited by retrospective study designs and small sample sizes. Prospective studies that compare transapical mitral valve repair with placement of artificial chordae tendinae to other treatments are needed. Therefore, transapical mitral valve repair with placement of artificial chordae tendinae is considered investigational for people with mitral valve regurgitation.

TRANSCATHETER MITRAL VALVE ANNULOPLASTY RECONSTRUCTION (TMVAR)

There is not enough research to show that transcatheter mitral valve annuloplasty reconstruction (TMVAR) improves health outcomes for people with mitral valve regurgitation. Therefore, TMVAR is considered investigational for people with mitral valve regurgitation.

PERCUTANEOUS TRANSCATHETER TRICUSPID VALVE REPAIR

There is enough research to show that percutaneous transcatheter tricuspid valve repair improves health outcomes for people with severe tricuspid regurgitation despite medical therapy. Therefore, percutaneous transcatheter tricuspid valve repair is considered medically necessary when policy criteria are met.

There is not enough research to show that percutaneous transcatheter tricuspid valve repair improves health outcomes when criteria are not met. Therefore, percutaneous transcatheter tricuspid valve repair is considered investigational when policy criteria are not met.

TRANSCATHETER TRICUSPID VALVE ANNULUS RECONSTRUCTION

There is not enough research to show that transcatheter tricuspid valve annulus reconstruction improves health outcomes for people with tricuspid valve regurgitation. Therefore, transcatheter tricuspid valve annulus reconstruction is considered investigational.

TRANSCATHETER TRICUSPID VALVE REPLACEMENT

There is enough research to show that transcatheter tricuspid valve replacement improves health outcomes for people with severe tricuspid regurgitation despite medical therapy, and for whom tricuspid valve repair is not feasible. Therefore, transcatheter tricuspid valve replacement is considered medically necessary when policy criteria are met.

There is not enough research to show that transcatheter tricuspid valve replacement improves health outcomes when criteria are not met. Therefore, transcatheter tricuspid valve replacement is considered investigational when policy criteria are not met.

CAVAL VALVE IMPLANTATION

There is not enough research to show that caval valve implantation improves health outcomes for people with tricuspid regurgitation. Therefore, caval valve implantation is considered investigational for people with tricuspid regurgitation.

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CODES

Codes	Number	Description
CPT	0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
	0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)
	0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae
	0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
	0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
	0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis
	0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to the primary procedure)
	0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
	0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
	0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
HCPCS	None	

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