Supplemental Table S1. Evidence for percutaneous therapies for tricuspid regurgitation

Study ID (PMID)	Study design	Intervention	Comparator	Population	Sample size	Outcome measures	Results	Adverse events
				Vena cava stenting				
Lauten et al. (29445001)	Observational, first-in-man study	Single (inferior vena cava-only) or bicaval valve implantation (inferior vena cava + superior vena cava). Either balloon-expandable valves (Sapien XT/3) or self-expandable valves (TricValve and Directflow)	N/A	Inoperable patients with severe symptomatic TR despite optimal medical treatment under a compassionate clinical use program	25	Procedural success, hemodynamic effect defined as venous pressure reduction, and safety defined as periprocedural adverse events, with clinical follow-up at discharge and up to 12 months. Functional impact was evaluated by NYHA functional class at discharge.	Caval valve implantation for the treatment of severe TR and advanced RV failure is associated with a high procedural success rate and seems safe and feasible. Hemodynamic efficacy was shown with consistent elimination of TR-associated venous backflow and initial clinical improvement.	Early and late valve migration requiring surgical intervention occurred in 1 patient each in single and bicaval valve implantations.
TRICUS EURO (35583363)	Nonblinded, nonrandomised, single-arm, prospective trial	Heterotopic bicaval stenting using the TricValve system	N/A	Severe symptomatic TR despite optimal medical therapy	35	KCCQ QOL score and NYHA functional class improvement at 6-month follow-up	The dedicated bicaval system for treating severe symptomatic TR was associated with a high procedural success rate and significant improvements in both QOL and NYHA functional classification at 6-month follow-up	No device-related mortality at 6 months. The most frequent complication was major bleeding (17.1%).
				TV-specific intervention				
TriValve International Registry (31568868)	Propensity-matched case-control study	TTVI mainly MitraClip	TTVI vs. medical therapy	Propensity score matched patients with ≥ moderate TR	536	1-year mortality or HF rehospitalisation or the composite	TTVI is associated with greater survival and reduced HF rehospitalisation compared with medical therapy alone	None reported.
TriValve International Registry (31395215)	Observational Study	Transcatheter TEER (MitraClip NT and MitraClip XTR)	N/A	Symptomatic TR with high risk for surgery in compassionate and/or off-label use	249	Procedural and 1-year clinical and echocardiographic outcomes	Transcatheter TEER can achieve TR reduction at 1 year, resulting in significant clinical improvement.	No procedural deaths. One patient was converted to open heart surgery because of procedural failure. Two patients with concomitant mitral valve interventions had ischemic strokes. Further adverse events included bleeding, acute kidney injury, and infections.
TRI-REPAIR (33046437)	Single-arm, prospective clinical trial	Cardioband TV reconstruction system	N/A	Symptomatic ≥ moderate functional TR deemed inoperable	30	1- and 2-year outcomes including NYHA functional class, echocardiograph data, 6-minute walk distance and KCCQ QOL score	Annular reduction and TR severity reduction remained significant and sustained at 2 years. Patients experienced improvements in QOL and exercise capacity.	Two patients underwent device-related secondary interventions as a result of worsening TR.
TriBAND (34031021)	Single-arm, prospective post-market clinical follow-up study	Cardioband TV reconstruction system	N/A	Symptomatic ≥ severe functional TR despite diuretic therapy	61	The primary endpoint is reduction in TR severity between baseline and discharge. Secondary endpoints include TR severity, NYHA functional class, EuroQol 5-dimensions 5-level health questionnaire (EQ-5D-5L), and KCCQ QOL score at 30 days post implant. Safety endpoint is MAEs.	Cardioband TV reconstruction system led to favourable outcomes at discharge and 30 days including significant reductions in annular diameter and TR severity, early right heart remodelling and improvements in functional status and QOL.	One patient developed device- and procedure-related pericardial effusion with severe bleeding and died. One patient experienced device- and procedure-related myocardial infarction that resolved spontaneously. Four patients experienced coronary artery injuries requiring intervention. One patient experienced intraprocedural bradycardia. Seven patients developed severe bleeding.

Fam et al. (33582084)	Observational, first-in-man study	EVOQUE TTVR device	N/A	Symptomatic severe TR with right-sided HF deemed inoperable in compassionate use	25	Procedure success, NYHA functional class, TR grade, and major adverse cardiac and cerebrovascular events assessed at 30-day follow-up.	EVOQUE TTVR demonstrated high technical success, acceptable safety, and significant clinical improvement.	No major adverse outcomes acutely and at 30-day follow-up
Webb et al. (35272772)	Observational at 1 year in the expanded first-in-human study	EVOQUE TTVR device	N/A	Symptomatic severe TR with right-sided HF deemed inoperable in compassionate use	27	All-cause mortality, symptom status, TR severity, HF hospitalisation, and major adverse cardiovascular events at 1-year follow-up.	EVOQUE TTVR demonstrated durable efficacy, persistent improvement in symptom status, and low rates of mortality and HF hospitalisations at a 1-year follow-up.	New permanent pacemaker implantation was required in 1 patient. Three patients developed hypoattenuated leaflet thickening. Four major bleeding developed at 1 year (2 procedural and 2 nonprocedural).
TRISCEND (35272771)	Observational, prospective, single-arm, study	EVOQUE TTVR device	N/A	Symptomatic moderate or greater TR despite medical therapy	56	A composite measures including rate of MAE, echocardiographic parameters, and clinical, functional, and QOL were assessed at 30 days.	EVOQUE system demonstrated technical feasibility, acceptable safety, TR reduction, and symptomatic improvement at 30 days.	One cardiovascular death in a patient with a failed procedure, 2 reinterventions after device embolisation, 1 major access site or vascular complication, and 15 severe bleeds at 30 days.
TRILUMINATE (31708188)	Prospective, observational single-arm study	TriClip system, a clip-based edge-to-edge repair technique	N/A	Moderate or greater TR, NYHA functional class II or higher who were adequately treated per applicable standards	85	Reduction in severity of TR on echocardiography at 30 days, composite of MAEs at 6 months.	TriClip system appears to be safe and effective at reducing TR by at least one grade at 30 days. This reduction could translate to significant clinical improvement at 6 months post procedure.	At 6 months, 3 patients experienced a MAE. Single leaflet attachment occurred in 5 patients. No periprocedural deaths, conversions to surgery, device embolisation, myocardial infarctions, or strokes.
CLASP (33509390)	Single-arm, prospective, observational early feasibility study	PASCAL transcatheter valve repair system	N/A	Symptomatic TR despite optimal medical therapy	34	Composite of MAE rate, echocardiographic, clinical, and functional data at baseline, discharge, and the 30-day follow-up	At 30 days, 85% of patients achieved a TR severity reduction of at least 1 grade, with 52% with moderate or less TR; 89% of the patients improved to NYHA functional class I/II, the mean 6-min walk distance improved by 71 m, and the mean KCCQ QOL score improved by 15 points.	Implants were retrieved in 5 patients whose leaflets were unable to be captured with no adverse clinical sequelae. No cardiovascular mortality, stroke, myocardial infarction, renal complication, or reintervention.
TRILUMINATE Pivotal (36876753)	RCT	Percutaneous tricuspid TEER	TEER versus medical therapy	Symptomatic severe TR	350	Death from any cause or TV surgery; hospitalisation for HF; KCCQ QOL score with an improvement defined as an increase of at least 15 points in the KCCQ score at the 1-year follow-up	Tricuspid TEER was safe for patients with severe TR, reduced the severity of TR, and was associated with QOL improvement. The incidence of death or TV surgery and the rate of HF hospitalisation did not appear to differ between the groups.	Rare; 98.3% of TEER patients were free from MAEs at 30 days. Major bleeding occurred in 5.2% of patients who underwent TEER within 1 year.

Abbreviations

HF	heart failure
KCCQ	Kansas City Cardiomyopathy Questionnaire
MAE	major adverse event
NYHA	New York Heart Association
QOL	quality of life
TEER	transcatheter edge-to-edge repair
TR	tricuspid regurgitation
TTVI	transcatheter tricuspid valve interventions
TTVR	transcatheter tricuspid valve replacement
TV	tricuspid valve