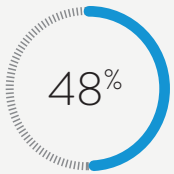


REDUCED HEART FAILURE HOSPITALIZATION RISK AT EXTENDED FOLLOW-UP IN THE TRI.FR TRIAL

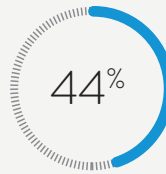
In the Tri.Fr randomized controlled trial (n=300), TriClip transcatheter tricuspid edge-to-edge repair (T-TEER) plus optimal medical therapy (OMT) **significantly reduced** the burden of heart failure (HF) hospitalizations compared with OMT alone during extended follow-up, while preserving randomized treatment assignment with **no crossover before 2 years**.¹



48% RELATIVE REDUCTION IN RECURRENT HF HOSPITALIZATIONS¹

37 HF hospitalizations with T-TEER + OMT vs 64 HF hospitalizations with OMT alone

Rate ratio 0.52; P=0.0073



44% RELATIVE REDUCTION IN FIRST-EVENT COMPOSITE OUTCOME¹

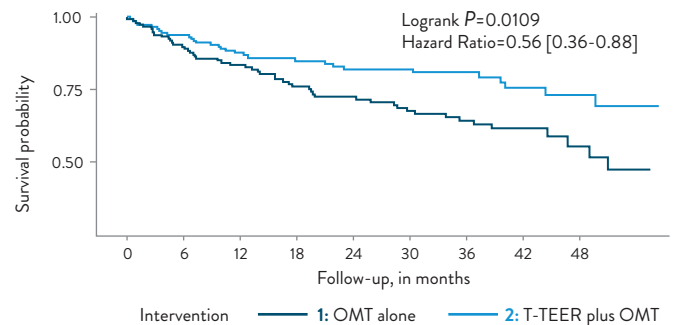
Composite of first HF hospitalization, tricuspid valve surgery, or cardiovascular death

Hazard ratio 0.56; P=0.0109

RECURRENT HF HOSPITALIZATIONS

Model, Endpoint	Total (Event/Censored)	HR/RR (95% CL)	P-value
Recurrent Event Model			
LWYY	349 (72/277)		0.0255
Negative binomial	101 events/697 person years		0.0454
Joint Frailty Model			
S Recurrent Event			0.0199
S Terminal Event			0.0434
R Recurrent Event			0.1689
R Terminal Event			0.0444

TIME-TO-FIRST COMPOSITE EVENT CURVE



	1	2	3	4	5	6	7
1	148	131	111	88	81	69	52
2	152	137	107	86	81	75	57

Across multiple complementary recurrent-event and joint models, T-TEER + OMT consistently reduces heart failure hospitalization burden over 2 years relative to OMT alone.¹

Time to first HF hospitalization, tricuspid valve surgery, or cardiovascular death favored TriClip™ TEER + OMT versus OMT alone.¹

TRI.FR IS THE **SECOND RANDOMIZED CONTROLLED TRIAL TO SHOW SIGNIFICANT REDUCTION IN HF HOSPITALIZATION RISK WITH TRICLIP TEER RELATIVE TO MEDICAL THERAPY.**^{1,2}

TRI.FR TRIAL OVERVIEW³



N=300



24 centers



1:1
randomized



T-TEER + OMT vs
OMT alone



No crossover
before 2 years



Prespecified long-
term follow-up

PATIENT PROFILE



78
years



64%
women



95%
atrial fibrillation



91%
massive/torrential
TR

1. Donal E, et al. Transcatheter edge-to-edge repair for severe isolated tricuspid regurgitation — extended follow-up — the Tri.Fr Randomized Clinical Trial. Presented at ACC 2026, March 29, 2026.
2. Kar S, Makkar RR, Whisenant BK, et al. Two-Year Outcomes of Transcatheter Edge-to-Edge Repair for Severe Tricuspid Regurgitation: The TRILUMINATE Pivotal Randomized Controlled Trial. *Circulation*. 2025;151(23):1630-1638. doi:10.1161/CIRCULATIONAHA.125.074536
3. Donal E, Dreyfus J, Leurent G, et al. Transcatheter Edge-to-Edge Repair for Severe Isolated Tricuspid Regurgitation: The Tri.Fr Randomized Clinical Trial. *JAMA*. 2025;333(2):124-132. doi:10.1001/jama.2024.211

For U.S. audience only.

Rx Only

Important Safety Information

TriClip™ G5 SYSTEM

INDICATIONS

The TriClip™ G5 System is indicated 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 repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.

CONTRAINDICATIONS

The TriClip™ G5 System is contraindicated for use in patients with the following conditions: Intolerance, including allergy or untreatable hypersensitivity, to procedural anticoagulation; Untreatable hypersensitivity to Implant components (nickel-titanium alloy, cobalt-chromium alloy); Active endocarditis or other active infection of the tricuspid valve.

POTENTIAL ADVERSE EVENTS:

The following events have been identified as possible complications of the TriClip™ G5 Procedure. Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials and drug reactions to anticoagulation, or antiplatelet drugs; Additional treatment / surgery from device-related complications; Bleeding; Blood disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, unstable angina, and stable angina); Cardiac perforation; Cardiac tamponade; Chest pain; Death; Dyspnea; Edema; Embolization (device or components of the device); Endocarditis; Fever or hyperthermia; Fluoroscopy and Transesophageal echocardiogram (TEE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation, Esophageal perforation, Gastrointestinal bleeding; Hypotension / hypertension; Infection including: Septicemia; Nausea or vomiting; Pain; Pericardial effusion; Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction or failure or atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Thrombosis; Tricuspid valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single leaflet device attachment (SLDA), Dislodgement of previously implanted devices, Tissue damage, Tricuspid valve stenosis, Worsening, persistent or residual regurgitation; Vascular access complications which may require additional intervention, including: Wound dehiscence, Bleeding of the access site, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation (rupture), vascular occlusion, Embolism (air, thrombus), Peripheral nerve injury; Venous thrombosis (including deep vein thrombosis) and thromboembolism (including pulmonary embolism).

For U.S. audience, see Important Safety Information referenced within. For audiences outside of the U.S., always check the regulatory status of the device in your region.

CAUTION: Product(s) intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use inside the product carton (when available) or at www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file with Abbott.

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