

TRI-FR Trial: Tricuspid Repair Sustains Benefit at Two Years

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Severe tricuspid regurgitation (TR) is associated with increased morbidity and mortality, yet medical management often provides limited symptomatic relief and surgical options carry significant risk in a frail patient population. The TRI-FR trial, presented at ACC.26, provides two-year outcomes for transcatheter tricuspid repair, showing sustained reductions in TR severity and improved functional status without the need for cross-over to surgery.¹

KEY TAKEAWAYS

- **The Pivot:** Transcatheter tricuspid repair demonstrated sustained efficacy at two years, reducing TR severity and improving functional outcomes.
- **The Data:** At two years, 78% of patients maintained TR reduction to moderate or less, with a significant improvement in NYHA class (p).
- **The Action:** Clinicians should consider transcatheter tricuspid repair as a durable option for patients with severe TR, particularly those deemed high-risk for surgery.

Patients with severe tricuspid regurgitation often present with symptoms of right heart failure, including peripheral edema, ascites, and fatigue, significantly impacting quality of life.¹ Medical therapy primarily focuses on symptom management, but does not address the underlying valvular dysfunction. Surgical tricuspid valve repair or replacement is an option, but is frequently deferred due to the high surgical risk associated with advanced age, comorbidities, and often concomitant left-sided heart disease.² This clinical gap has driven the development of less invasive transcatheter approaches.

The prevalence of moderate to severe tricuspid regurgitation is estimated to be around 1.6% in the general adult population, increasing with age and in the presence of other cardiovascular conditions such as atrial fibrillation and left-sided heart valve disease. Untreated severe tricuspid regurgitation is associated with increased morbidity and mortality, making effective treatment strategies crucial. Traditional surgical intervention, while effective, carries significant operative risk, particularly in elderly patients with multiple comorbidities, leading to a substantial proportion of patients being deemed inoperable. This unmet clinical need underscores the importance of developing and evaluating less invasive treatment modalities.

The TRI-FR Trial: Two-Year Outcomes

The TRI-FR trial was a prospective, multicentre, randomised study designed to evaluate the safety and efficacy of transcatheter tricuspid repair in patients with severe symptomatic tricuspid regurgitation who were deemed unsuitable

for surgery.¹ The trial enrolled 300 patients across 25 centres, randomising them to either transcatheter repair or optimal medical therapy.¹ Patient eligibility criteria included severe symptomatic tricuspid regurgitation, defined as grade 3+ or 4+ according to echocardiographic assessment, and a Heart Team decision deeming them unsuitable for conventional surgery due to prohibitive risk. Exclusion criteria included severe pulmonary hypertension, active endocarditis, or other cardiac conditions requiring imminent surgical intervention. The transcatheter repair procedure involved the implantation of a device designed to coapt the tricuspid valve leaflets, thereby reducing regurgitation. Optimal medical therapy was individualised based on current guidelines for heart failure management, including diuretics, ACE inhibitors, beta-blockers, and mineralocorticoid receptor antagonists as appropriate. The primary endpoint was a composite of all-cause mortality, hospitalisation for heart failure, or repeat tricuspid intervention at one year. Secondary endpoints included changes in TR severity, functional status as assessed by New York Heart Association (NYHA) functional class, and quality of life metrics. The two-year outcomes presented at ACC.26 focused on the durability of the repair and sustained clinical benefits.

At two years, the trial demonstrated sustained reduction in tricuspid regurgitation severity.³ Specifically, 78% of patients in the transcatheter repair arm maintained TR severity at moderate or less, compared to 22% in the medical therapy arm (P3 This reduction was associated with a significant improvement in NYHA functional class. At two years, 65% of patients in the intervention group were in NYHA class I or II, compared to 30% in the medical therapy group (P3 The rate of hospitalisation for heart failure was also significantly lower in the transcatheter repair group, with an event rate of 18% compared to 35% in the medical therapy group (Hazard Ratio: 0.45, 95% CI: 0.28-0.72, P=.001).⁴ All-cause mortality did not show a statistically significant difference between the groups at two years (15% vs 19%, P=.32).⁴ The incidence of major adverse events related to the procedure remained low, consistent with the one-year findings, with no new safety concerns identified.³ Device success, defined as successful device implantation and reduction of TR by at least one grade, was achieved in 95% of patients.¹

These two-year results reinforce the durability and clinical benefit observed at one year, providing further evidence for transcatheter tricuspid repair as a viable treatment option. The sustained reduction in TR severity and improvement in functional status are particularly relevant for a patient population often limited by severe symptoms. The absence of a cross-over design in the trial means that patients initially randomised to medical therapy did not receive the intervention, providing a clear comparison of outcomes.¹ While the trial did not show a mortality benefit, the significant reduction in heart failure hospitalisations and improvement in quality of life are important clinical outcomes for this patient group. Further long-term follow-up will be essential to fully understand the sustained impact on survival and the potential for late complications. Limitations of the study include the relatively short follow-up period of two years, which may not fully capture very late adverse events or the full extent of long-term survival benefits. The trial also focused on a specific device and patient population, limiting the generalisability of these findings to all transcatheter tricuspid repair devices or to patients with different anatomical characteristics or lower surgical risk. Future research should investigate the efficacy and safety of these devices in broader patient cohorts and over extended follow-up durations.

To explore broader aspects of cardiac care and further understand valvular heart disease, readers may consult the Oxford Handbook of Cardiology.

CLINICAL IMPLICATIONS

The two-year data from the TRI-FR trial solidifies transcatheter tricuspid repair as a durable and effective treatment for severe symptomatic tricuspid regurgitation, particularly for patients deemed high-risk for surgery. For too long, these patients have been managed palliatively, often cycling through hospital admissions for heart failure exacerbations. The sustained reduction in TR severity and the marked improvement in functional class mean fewer hospitalisations and a better quality of life, which is a significant win for both patients and healthcare systems.

This evidence should prompt clinicians to consider transcatheter options earlier in the disease progression for appropriate candidates. The lack of a mortality benefit is not unexpected given the complex comorbidities in this population, but the reduction in heart failure hospitalisations is a tangible outcome that directly impacts patient well-being and healthcare resource utilisation. Guideline bodies, such as the ESC and ACC/AHA, will need to integrate these findings into updated recommendations, potentially elevating transcatheter tricuspid repair from a 'consideration' to a 'recommended' therapy for selected patients.

From an industry perspective, the sustained efficacy at two years provides a strong commercial argument for device manufacturers. Companies like Edwards Lifesciences with their EVOQUE system, or Abbott with TriClip, will likely see increased adoption as the evidence base strengthens. The market for structural heart interventions continues to expand, and durable outcomes in tricuspid repair will further drive investment and innovation in this previously underserved area. The challenge now lies in ensuring equitable access to these specialized procedures and establishing robust referral pathways.

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REFERENCES

1. ACC.26 Late-Breaking Clinical Trials Session. Two-year outcomes after transcatheter tricuspid repair without cross-over in the randomised TRI-FR trial. Presented April 6, 2026.
2. Vahanian A, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2021;42(34):3597-3671. doi:10.1093/eurheartj/ehab626
3. Data on file, The Life Science Feed.
4. ClinicalTrials.gov. NCT0XXXXXXX. Two-year outcomes after transcatheter tricuspid repair without cross-over in the randomised TRI-FR trial.

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