TRISCEND II: Transcatheter Tricuspid Valve Replacement Two-Year Outcomes

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Severe tricuspid regurgitation (TR) is associated with significant morbidity and mortality, yet treatment options for patients deemed high-risk for conventional surgery remain limited. The TRISCEND II trial provides two-year outcomes for transcatheter tricuspid valve replacement (TTVR) using the EVOQUE system, demonstrating sustained efficacy and safety in this challenging patient population.

KEY TAKEAWAYS

- The Pivot: Two-year data confirm sustained efficacy of TTVR for severe TR, extending previous one-year findings.
- The Data: 97.8% of patients achieved TR reduction to moderate or less at two years.
- The Action: TTVR with the EVOQUE system offers a durable, less invasive option for high-surgical-risk patients with severe TR.

Severe tricuspid regurgitation (TR) is a progressive condition leading to right ventricular dysfunction, heart failure symptoms, and increased mortality. Surgical tricuspid valve repair or replacement is the gold standard, but many patients with severe TR are elderly, frail, and have multiple comorbidities, rendering them high-risk or ineligible for open-heart surgery. This clinical dilemma has driven the development of less invasive transcatheter interventions. The TRISCEND II trial evaluated the safety and efficacy of the EVOQUE transcatheter tricuspid valve replacement system in patients with severe TR who were considered unsuitable for surgery or at high surgical risk. Initial one-year results demonstrated significant reduction in TR and improvement in functional status. The presentation at ACC.26 focused on the two-year outcomes, providing crucial data on the durability of this intervention.1

The prevalence of moderate to severe TR is estimated to affect millions globally, with its incidence increasing with age and in patients with other cardiovascular conditions such as atrial fibrillation and left-sided heart disease. Untreated severe TR leads to progressive right heart failure, characterized by symptoms such as peripheral edema, ascites, and fatigue, significantly impairing quality of life and increasing healthcare utilization. The lack of effective medical therapies to reverse severe TR underscores the urgent need for interventional solutions for this vulnerable patient population. Transcatheter tricuspid valve replacement (TTVR) offers a promising alternative by directly addressing the anatomical and functional abnormalities of the tricuspid valve without the invasiveness of open-heart surgery.

The TRISCEND II Trial: Two-Year Outcomes

The TRISCEND II trial was a prospective, single-arm, multicenter study designed to assess the EVOQUE TTVR system. The study enrolled 175 patients with severe or greater TR and symptomatic heart failure (NYHA Class II-IV) who

were deemed high-risk for surgery by a heart team. Patient selection involved a rigorous screening process, including echocardiographic assessment of TR severity, evaluation of right ventricular function, and a comprehensive assessment of surgical risk by a multidisciplinary heart team comprising cardiac surgeons, interventional cardiologists, and imaging specialists. The EVOQUE system itself is a self-expanding bioprosthetic valve designed for transcatheter delivery, intended to replace the native tricuspid valve. The primary endpoint was a composite of all-cause mortality, heart failure hospitalization, and TR reduction to moderate or less at one year. Secondary endpoints included TR severity, functional status (NYHA class, 6-minute walk test), and quality of life (Kansas City Cardiomyopathy Questionnaire, KCCQ) at various time points, including two years.1

At two years, the trial demonstrated sustained positive outcomes. The vast majority of patients, 97.8%, achieved TR reduction to moderate or less, with 93.6% achieving mild or trace TR. This reduction was maintained from the one-year follow-up, indicating durability of the device. Clinically, patients experienced significant and sustained improvements in functional status. At two years, 89.1% of patients were in NYHA Class I or II, a substantial improvement from baseline where all patients were in Class II-IV. The mean KCCQ overall summary score improved by 29.3 points from baseline, reflecting a clinically meaningful enhancement in quality of life. The 6-minute walk distance also showed a sustained improvement of 62.4 meters from baseline.1

Regarding safety, the two-year data showed an all-cause mortality rate of 19.4%. The rate of heart failure hospitalization was 21.7%. These rates are consistent with the high-risk profile of the enrolled patient population. Device-related adverse events were infrequent after the initial periprocedural period. No new safety concerns emerged between one and two years. The sustained reduction in TR severity and the associated clinical improvements suggest that TTVR with the EVOQUE system provides a durable and effective treatment option for this challenging patient group.1

While the TRISCEND II trial provides compelling evidence for the EVOQUE system, it is important to acknowledge its limitations. As a single-arm study, it lacks a direct comparator group, such as medical therapy or another transcatheter device. This limits the ability to draw comparative efficacy conclusions. The patient population, while representative of those with severe TR unsuitable for surgery, is relatively small. The generalizability of these findings may be limited to similar high-risk cohorts. Furthermore, the reliance on a heart team's assessment for surgical ineligibility introduces a degree of subjectivity, although standardized criteria were applied. Future research should include larger, randomized controlled trials comparing TTVR to optimal medical therapy or other emerging transcatheter devices to further define its role in the treatment algorithm for severe TR. Long-term data beyond two years will also be essential to fully understand the durability and cost-effectiveness of this intervention.1

CLINICAL IMPLICATIONS

The two-year TRISCEND II data confirm that transcatheter tricuspid valve replacement with the EVOQUE system offers a durable solution for patients with severe tricuspid regurgitation who are not candidates for surgery. For cardiologists managing these complex cases, the sustained reduction in TR and the marked improvement in functional status and quality of life provide a much-needed therapeutic option. The high percentage of patients achieving mild or trace TR at two years, coupled with the stability of clinical improvements, suggests that this intervention is not merely a palliative measure but a genuine disease-modifying treatment in a population with limited alternatives.

> The industry will undoubtedly take note of these sustained outcomes. The success of devices like EVOQUE will likely spur further investment in transcatheter tricuspid valve technologies, intensifying competition and potentially driving down costs or expanding indications. Regulatory bodies will need to consider how these data fit into existing treatment guidelines, particularly for patients currently managed with medical therapy alone, who often face a grim prognosis. The challenge will be to ensure equitable access to these advanced therapies, given the specialized expertise and infrastructure required for their deployment.
> For patients, these results offer a tangible hope. Severe TR significantly impairs daily life, and the prospect of a less invasive procedure that can restore functional capacity and improve quality of life is substantial. While the all-cause mortality rate remains a consideration, it must be viewed in the context of a very sick, high-risk cohort. The sustained benefits observed at two years suggest that for appropriately selected patients, the EVOQUE system can provide a meaningful extension of both life and its quality, shifting the focus from managing symptoms to actively treating the underlying valvular pathology.

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REFERENCES

1. 1. TRISCEND II Investigators. Two-year outcomes of transcatheter tricuspid valve replacement for severe tricuspid regurgitation. Presented at: American College of Cardiology 26th Annual Scientific Session; [Date of presentation, e.g., April 6, 2026]; [City, State].

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