



TRISCEND II

CLINICAL TRIAL SUMMARY



Presenters

Edwards Lifesciences

Objectives

To evaluate the safety and effectiveness of the EVOQUE System with optimal medical therapy (OMT) compared to OMT alone in the treatment of patients with at least severe tricuspid regurgitation.

Source: <https://clinicaltrials.gov/study/NCT04482062>



TRIAL DESIGN

Prospective, international, multi-center, randomized controlled pivotal clinical trial

SAMPLE SIZE

267 patients were assigned to the valve-replacement group and 133 to the control group

INCLUSION CRITERIA

- Symptomatic tricuspid regurgitation (TR) despite medical therapy
- TR graded as severe or greater
- Appropriate for transcatheter tricuspid valve replacement per the local heart team



- In the study of 400 patients with severe symptomatic tricuspid regurgitation, participants were randomized 2:1 to receive transcatheter tricuspid-valve replacement with medical therapy or medical therapy alone.
- The primary outcome was a composite of all-cause death, right ventricular assist device implantation, heart transplantation, postindex tricuspid-valve intervention, heart failure hospitalization, and improvements in KCCQ-OS score (≥ 10 points), NYHA functional class (≥ 1), or 6-minute walk distance (≥ 30 m).



RESULTS

At 1 year, the win ratio favoring valve replacement was 2.02. In comparisons of patient pairs, those in the valve-replacement group had more wins than the control group with respect to death from any cause (14.8% vs. 12.5%), postindex tricuspid-valve intervention (3.2% vs. 0.6%), and improvement in the KCCQ-OS score (23.1% vs. 6.0%), NYHA class (10.2% vs. 0.8%), and 6-minute walk distance (1.1% vs. 0.9%).

The valve-replacement group had fewer wins than the control group with respect to the annualized rate of hospitalization for heart failure (9.7% vs. 10.0%).

Severe bleeding occurred in 15.4% of the valve-replacement group and in 5.3% of the control group ($P=0.003$); new permanent pacemakers were implanted in 17.4% and 2.3%, respectively ($P<0.001$).



CONCLUSION

For patients with severe tricuspid regurgitation, transcatheter tricuspid-valve replacement was superior to medical therapy alone for the primary composite outcome, driven primarily by improvements in symptoms and quality of life