Clinical summary

Quality of life after transcatheter tricuspid valve replacement

THE TRISCEND II PIVOTAL TRIAL

Objectives

The TRISCEND II pivotal trial met its primary endpoint, and results have previously been reported. The objective of the TRISCEND II trial is to compare the health status outcomes of patients with symptomatic ≥ severe tricuspid regurgitation (TR) treated with transcatheter tricuspid valve replacement (TTVR) with the Edwards EVOQUE system plus optimal medical therapy compared to those who received optimal medical therapy alone.

TRISCEND II Trial Design

N=400 randomized (2:1) EVOQUE TTVR vs medical therapy alone

Health Status Assessment

Kansas City Cardiomyopathy Questionnaire (KCCQ) at baseline, 30 days, 6 months, 1 year

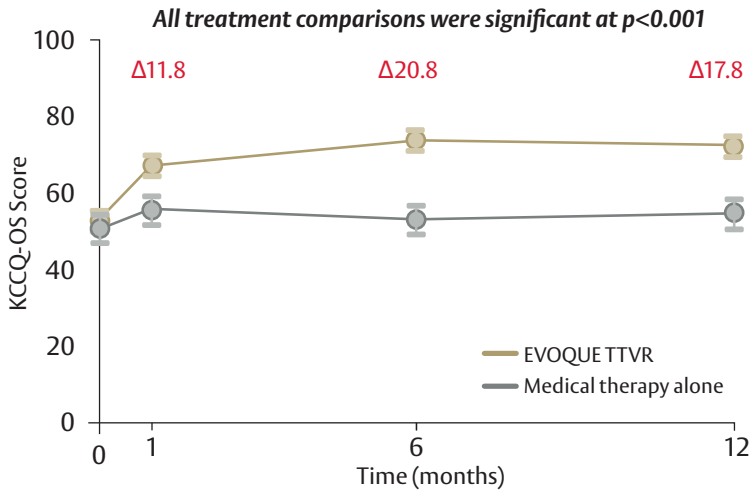
Baseline Characteristics*

Mean Age	Sex
79.2 years	75.5% female
KCCQ-OS	**TR Grade**
52.1 points	56.1% massive/torrential

**mITT (modified intent to treat safety population; n=392)*

Significantly improved KCCQ-OS at 30 days, with further improvements at 6 months that were sustained to 1 year

Figure 1. KCCQ-OS over 1 year



OS = Overall summary

Key Outcomes

- EVOQUE TTVR patients compared to those who received medical therapy alone experienced **significantly greater improvement in KCCQ-OS at 30 days** (Δ11.8 points), with **further improvement through 6 months** (Δ20.8) that was **sustained to 1 year** (Δ17.8).
- **Twice as many patients were "alive and well"** (KCCQ-OS ≥60 and no decline ≥10 points from baseline) **and "alive with large improvement"** (Δ ≥20 points from baseline) at 1 year after EVOQUE TTVR than with medical therapy alone, which was statistically significant.
- Patients with ≥severe TR at baseline experienced significant improvement in KCCQ-OS at 1 year with EVOQUE TTVR compared to medical therapy alone, with the **greatest improvements seen in patients starting with massive and torrential TR** (Δ22.6 and Δ23.3, respectively).
- **Every 10-point increase in KCCQ-OS** from baseline to 30 days was **associated with a significant 19% reduction in the composite death or HF hospitalization** risk at 1 year, regardless of treatment group.

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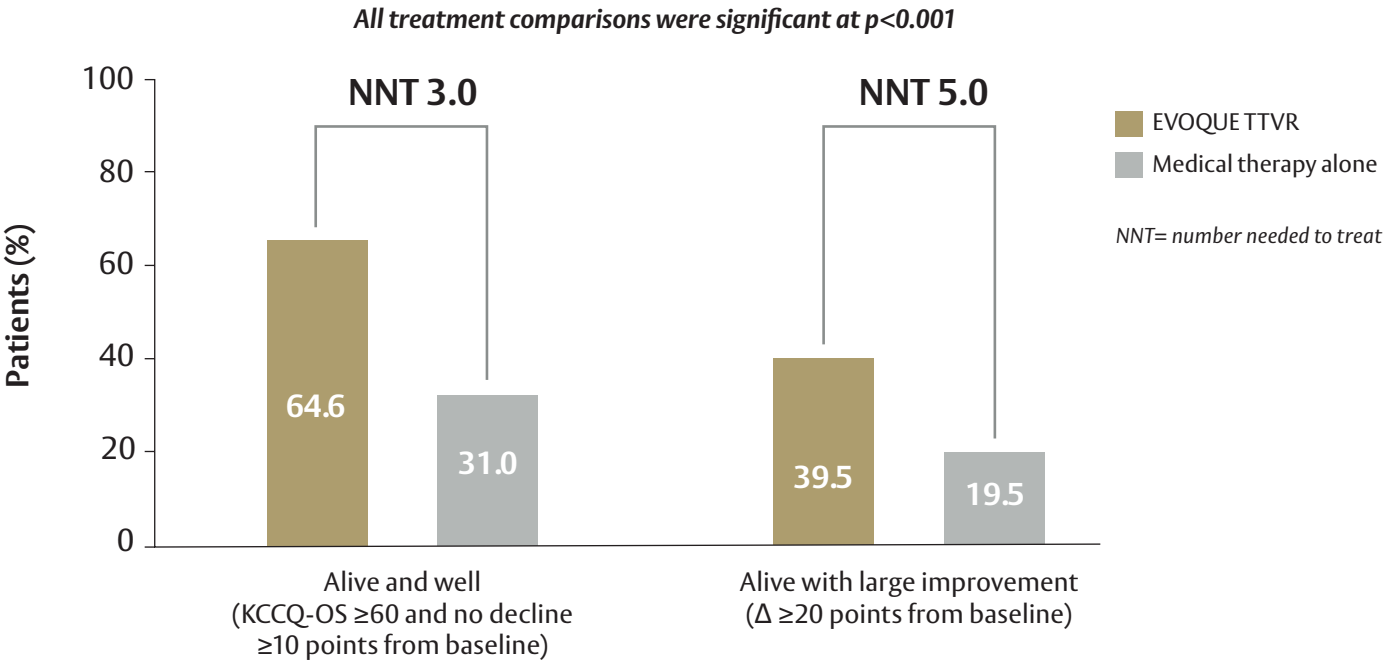
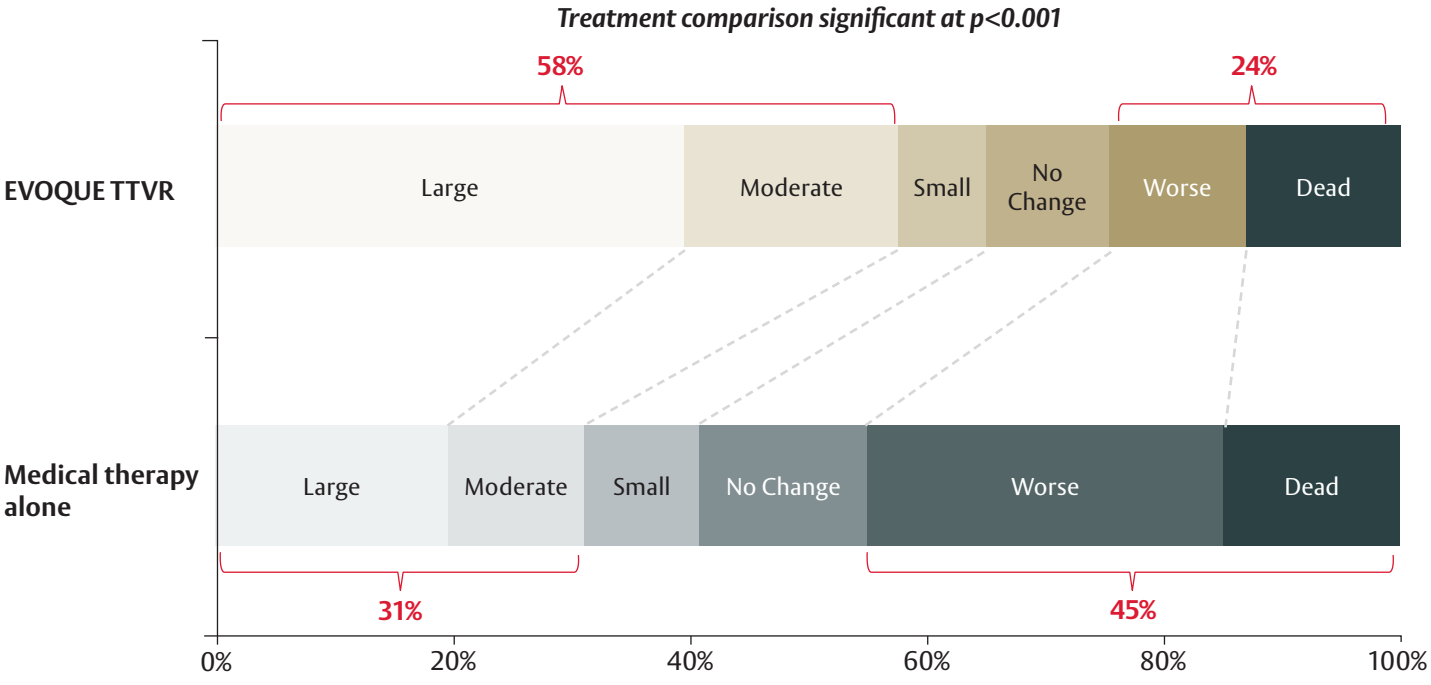
Twice as many patients were "alive and well" and "alive with large improvement" at 1 year after EVOQUE TTVR than with medical therapy alone

Figure 2. Survival and health status at 1 year



A greater proportion of patients experienced large or moderate changes in KCCQ-OS with EVOQUE TTVR; conversely, a greater proportion of patients experienced worse outcomes on medical therapy alone

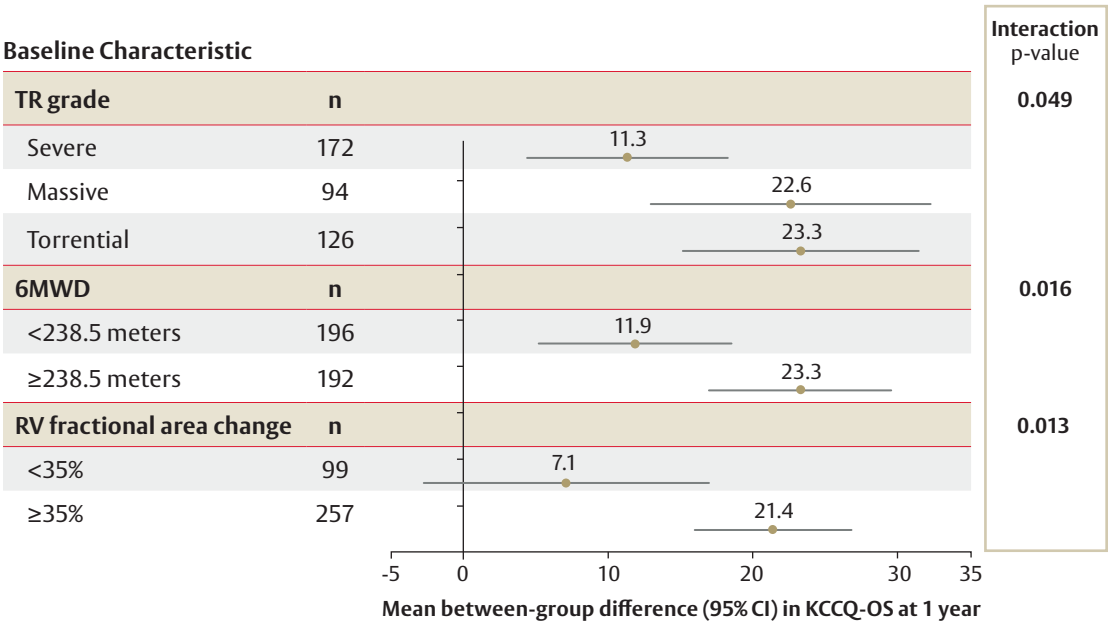
Figure 3. Change in health status by KCCQ-OS at 1 year



Degree of change (in points): large: ≥ 20; moderate: ≥ 10 and < 20; small: ≥ 5 and < 10; no change > -5 and < 5; worse: ≤ -5

Patients with more severe TR, better exercise capacity (6MWD), and preserved right ventricular function (RV FAC) at baseline had significantly greater KCCQ-OS benefit at 1 year after EVOQUE TTVR

Figure 4. KCCQ-OS sub-group analyses by baseline characteristics



Patients with symptomatic ≥ severe TR at baseline experienced significant improvement in KCCQ-OS at 1 year with EVOQUE TTVR vs medical therapy alone, with the greatest improvements seen in patients starting with massive and torrential TR

Every 10-point increase in KCCQ-OS from baseline to 30 days was associated with a significant 19% reduction in the composite death or heart failure hospitalization risk at 1 year, regardless of treatment group

Table 1. Association of KCCQ-OS at 30 days with subsequent risk of death or HF hospitalization through 1 year

	Adjusted Hazard Ratio (95% CI)	p-value	Treatment interaction p-value
Death	0.87 (0.74-1.03)	0.100	0.327
Heart failure hospitalization	0.80 (0.71-0.90)	<0.001	0.419
Death or heart failure hospitalization	0.81 (0.73-0.90)	<0.001	0.945

Hazard ratios are scaled per 10-points on the KCCQ-OS. Adjusted models included age, sex, and chronic obstructive lung disease.

Conclusion

- Patients with symptomatic ≥ severe TR experience substantial impairment in health status.
- Compared with medical therapy alone, treatment of patients with symptomatic ≥ severe TR with EVOQUE TTVR resulted in significant and sustained improvements in patients' symptoms, function, and quality of life.
- Significant health status benefits were evident at 30 days after EVOQUE TTVR, continued to increase through 6 months, and remained durable through 1 year.

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Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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