

# Health Status after Transcatheter Tricuspid-Valve Repair in Patients with Severe Tricuspid Regurgitation:

## Results from the TRILUMINATE Pivotal Trial

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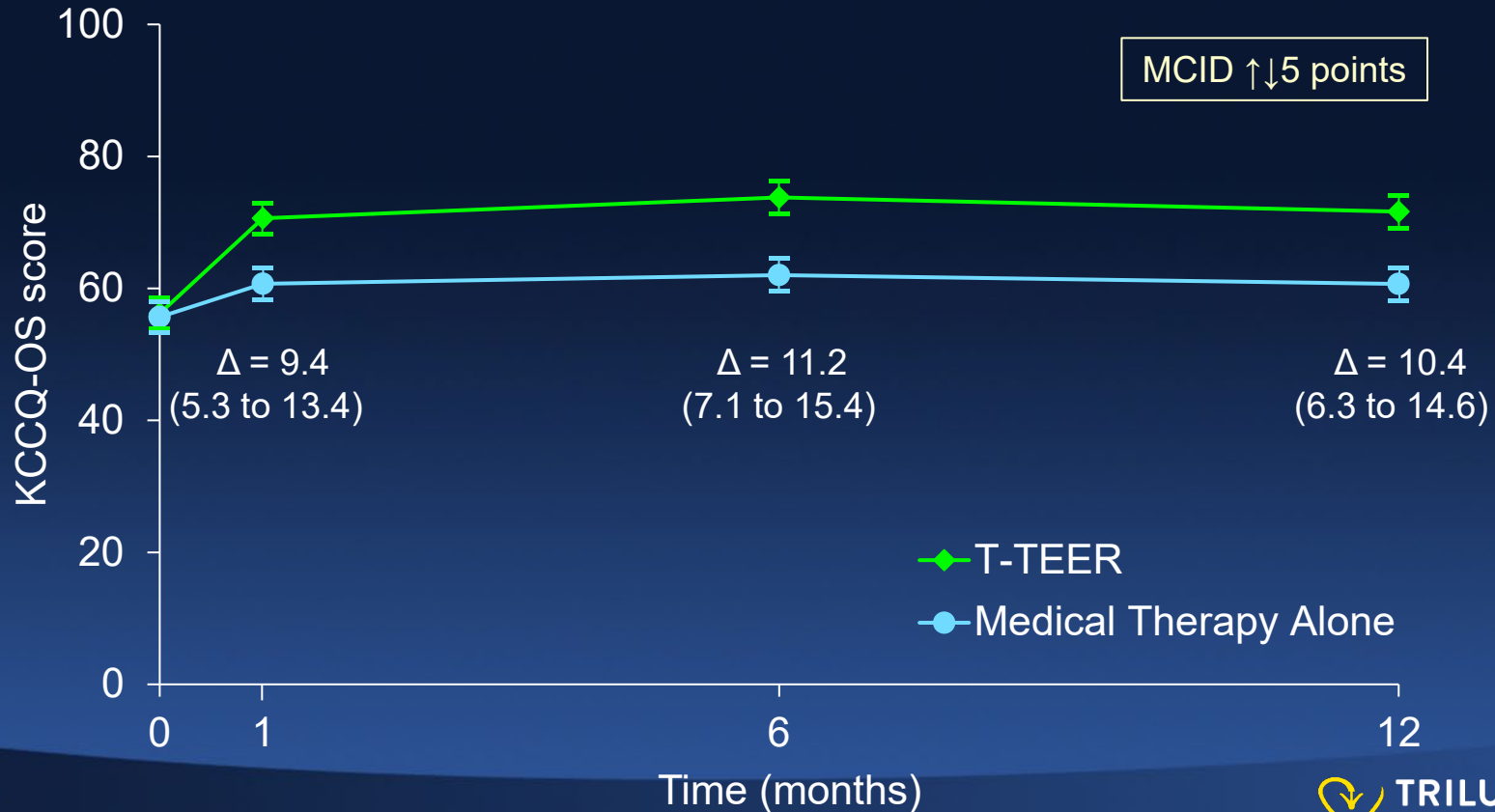
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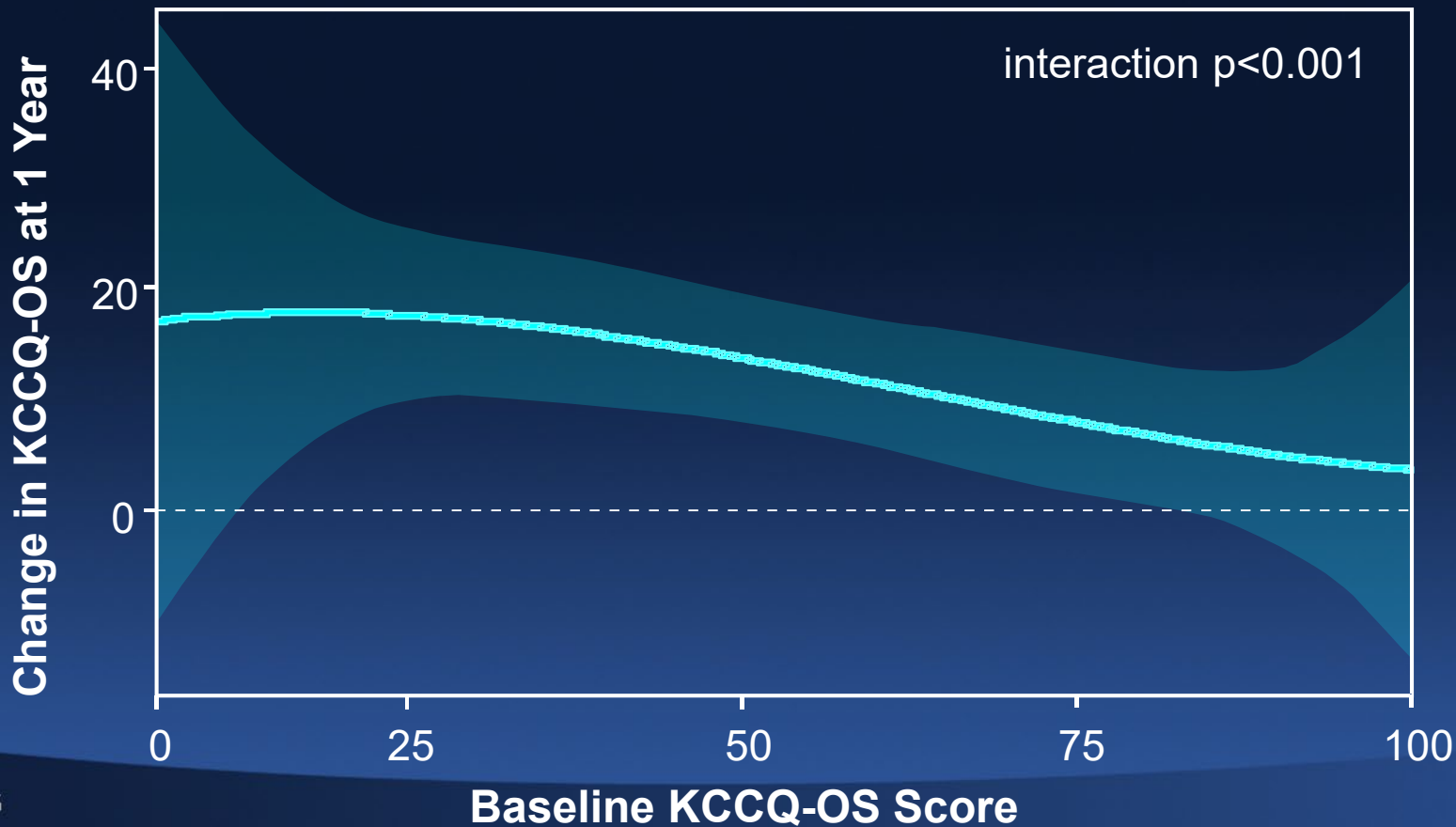
# Background

- The TRILUMINATE Pivotal trial compared T-TEER vs medical therapy alone and found no difference in death or heart failure hospitalizations at 1 year, but there was a significant improvement in patient-reported health status with T-TEER
- We performed an in-depth health status of the health status outcomes in the TRILUMINATE Pivotal trial
  - To describe the timing, magnitude, and consistency of the health status benefits of T-TEER
  - To estimate the biologic correlates of health status after T-TEER and the clinical relevance of the health status benefit

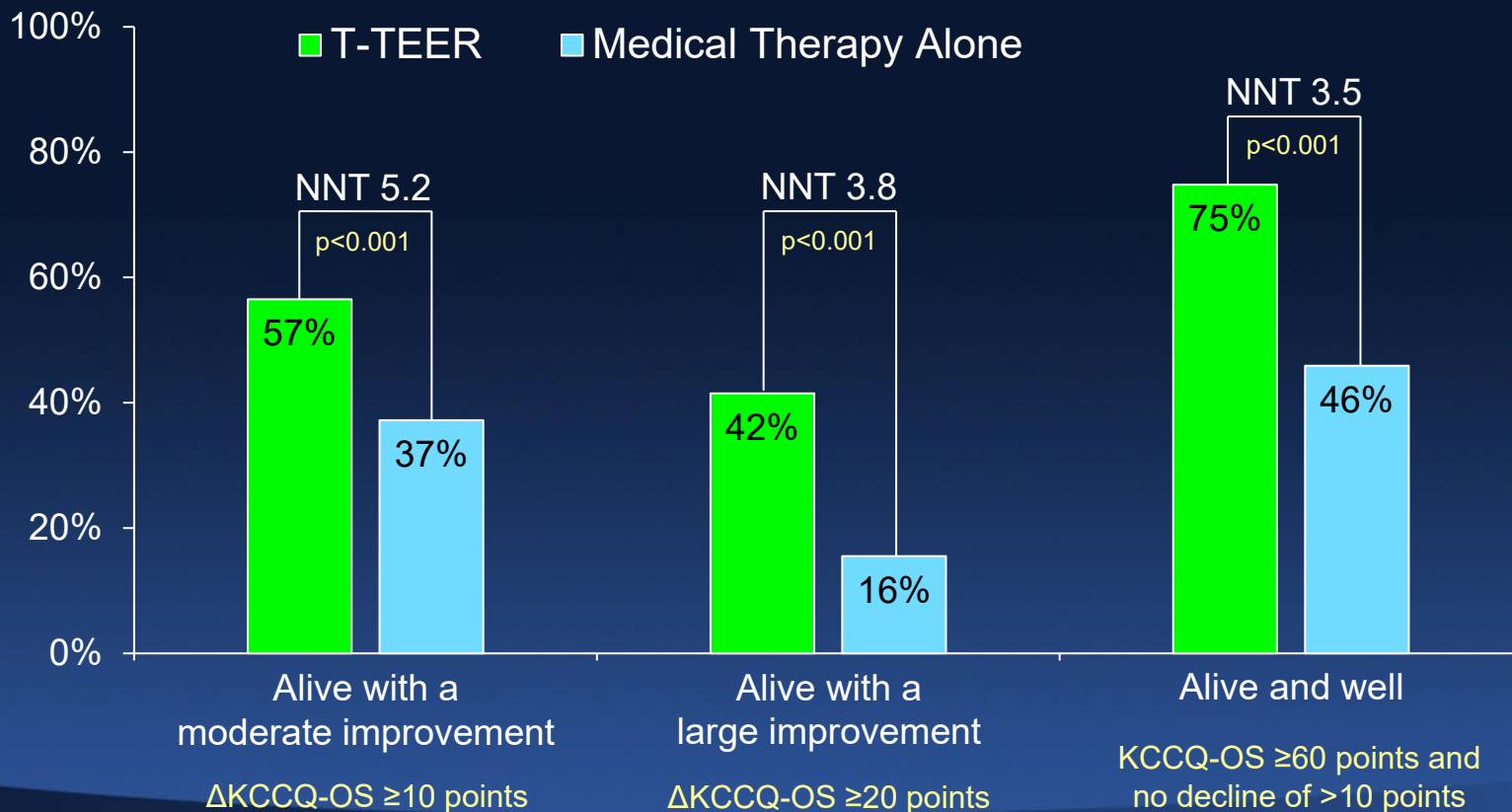
# Key Outcome: KCCQ-OS



# Predicted Benefit of T-TEER According to Baseline KCCQ-OS



# Categorical Outcomes at 1 Year



# Exploratory Analyses Among T-TEER Patients\*

Association of change in KCCQ-OS with change in TR grade (baseline to 1 year)

	Estimate (95% CI)	P-value
Change in KCCQ-OS per 1 grade improvement in TR severity	4.1 (1.8 to 6.5)	0.001

Association of change in KCCQ-OS at 1 month with subsequent events

	Hazard Ratio (95% CI) per 10-point increase in KCCQ-OS	P-value
Death	0.77 (0.64-0.93)	0.007
Heart failure hospitalization	0.70 (0.58-0.84)	<0.001
Death or heart failure hospitalization	0.74 (0.65-0.84)	<0.001

# Summary

- In patients severe TR, T-TEER provided substantial benefits in terms of symptoms, functional status, and quality of life
- The difference in health status between groups was moderately large, fully evident by 1 month, and sustained through 1 year
- Strong treatment interaction with baseline KCCQ-OS; patients with worse health status at baseline were most likely to benefit
- Exploratory analyses suggest that the observed health status improvement is, at least partially, biologically-mediated

# Conclusion

These findings support the use of T-TEER with the TriClip device for improvement in the symptoms, functional limitations, and quality of life in patients with severe TR