Health Status after Transcatheter Mitral-Valve Repair in Patients with Heart Failure and Secondary MR: Results from the COAPT Trial

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On behalf of the COAPT Investigators

Disclosures

Grant Support/Drugs

- Daiichi-Sankyo

Grant Support/Devices

- Edwards Lifesciences
- Medtronic
- CSI
- V-Wave Medical

- Abbott Vascular
- Boston Scientific
- Corvia
- Svelte

Consulting/Advisory Boards

- Medtronic
- Janssen Pharmaceuticals

- Edwards Lifesciences
- Heartflow

DJC: 8/19

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Background

- The 2 major goals in treating heart failure are to prolong survival and to improve health status (i.e., pt's symptoms, functional limitations, and quality of life)
- Recently, the COAPT trial demonstrated that treatment of pts with heart failure and secondary (functional) MR with transcatheter mitral valve repair (TMVr) using the MitraClip resulted in improved survival and fewer heart failure hospitalizations
- To fully define the benefits of TMVr, it is important to understand its impact on health status as well

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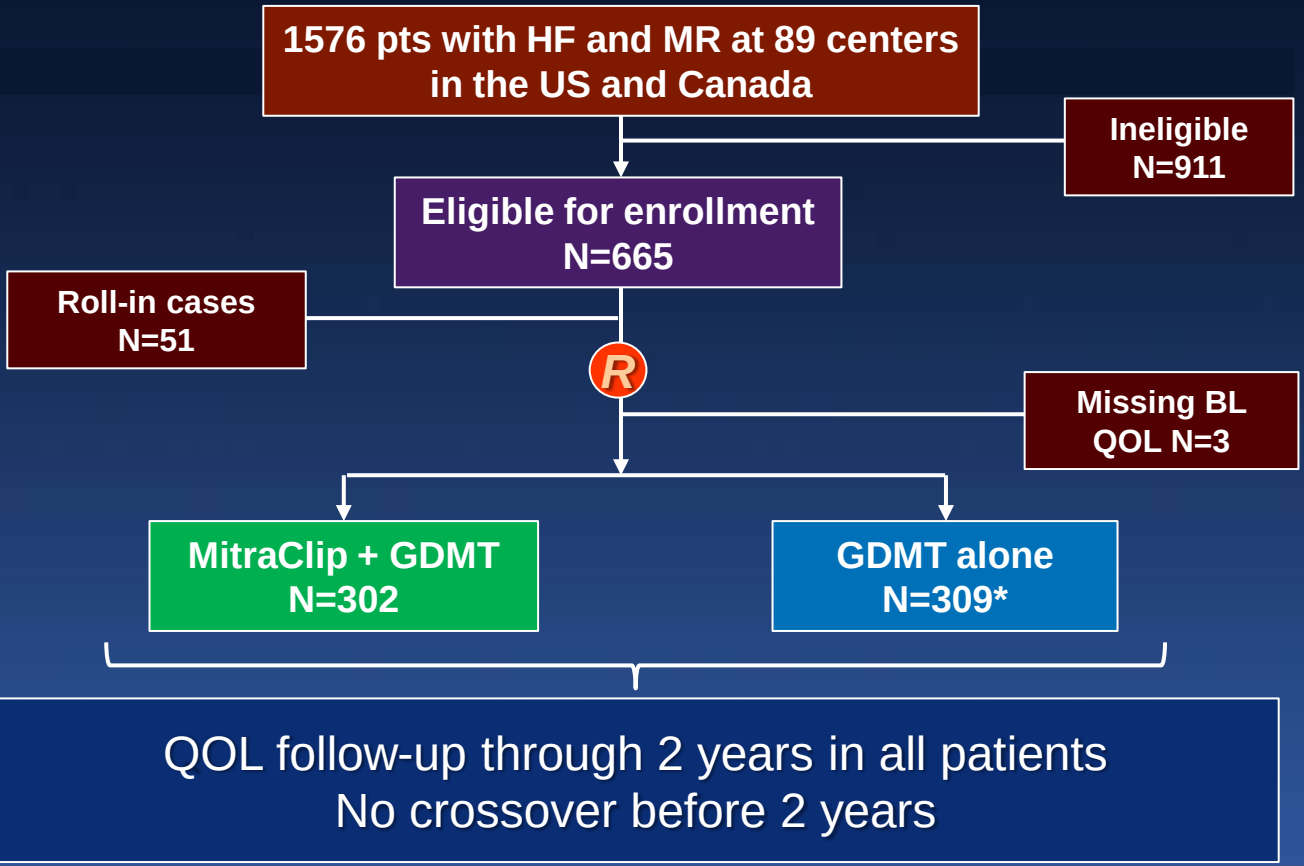
Objectives

1. To compare the early and late health status outcomes of TMVr versus standard care
2. To examine whether the health status benefit of TMVr differs according to patient factors
3. To explore the impact of differences in mortality on the health status benefits of TMVr

QOL Study Design



Study Measures

- Patient-reported health status assessed at baseline and 1, 6, 12, and 24 months
  - Kansas City Cardiomyopathy Questionnaire
    - Scores 0-100; higher=better; MCID=5 points
  - SF-36 Physical and Mental Summary Scores
    - Higher=better; population mean 50 SD 10; MCID=2.5 points

- Primary outcome: KCCQ-overall summary score (KCCQ-OS) over 24 months

Baseline Health Status

	TMVr (n=302)	Standard Care (n=309)
KCCQ		
Overall Summary	53.2 ± 22.8	51.6 ± 23.3
Physical Limitations	58.3 ± 24.5	55.7 ± 26.0
Symptoms	60.3 ± 24.9	58.9 ± 24.7
Quality of Life	45.2 ± 25.6	44.7 ± 25.8
Social Limitation	49.5 ± 29.2	46.8 ± 30.4
SF-36		
Physical Summary	33.0 ± 9.0	32.6 ± 10.0
Mental Summary	46.7 ± 12.7	45.4 ± 13.0

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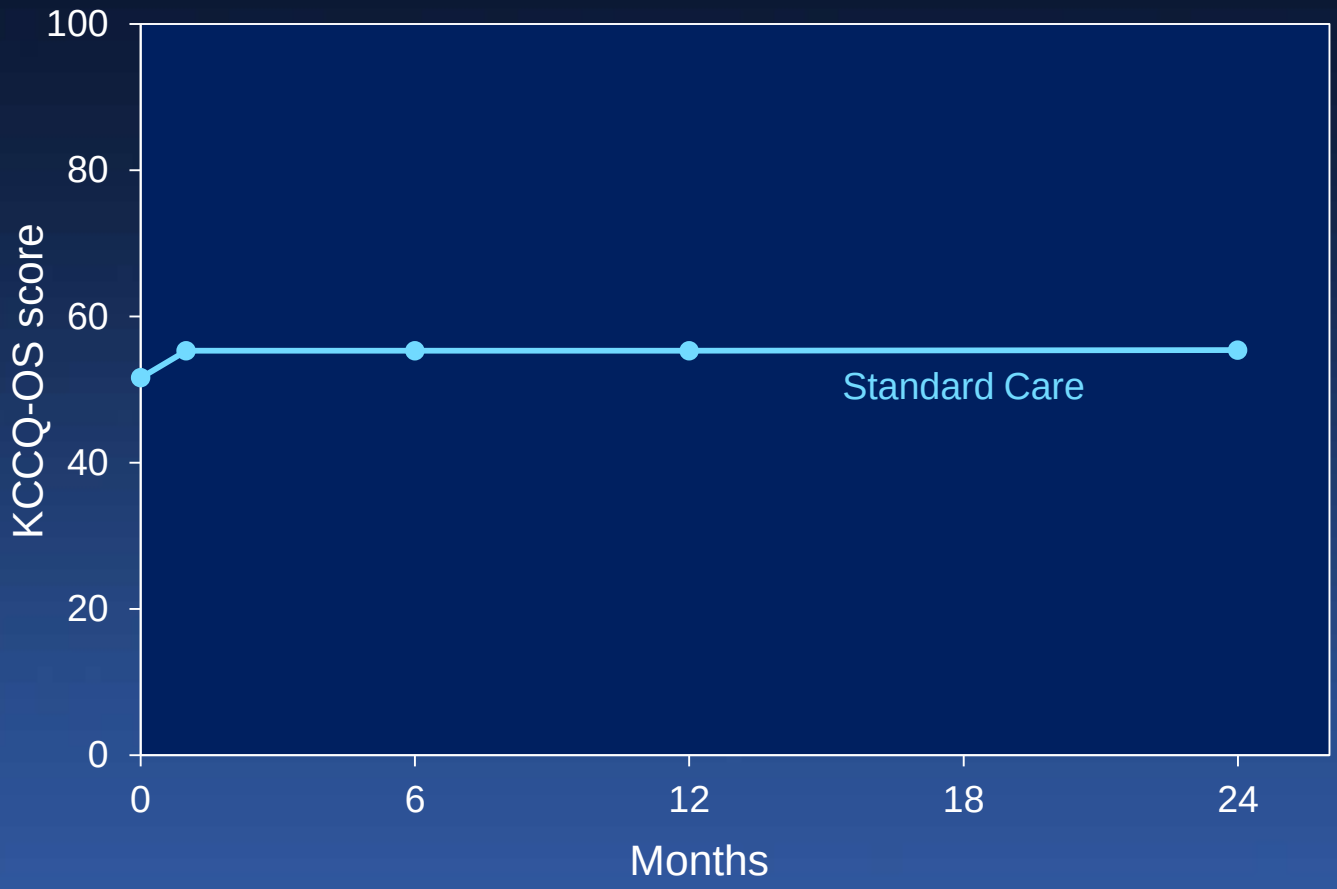
Primary Outcome: KCCQ-OS



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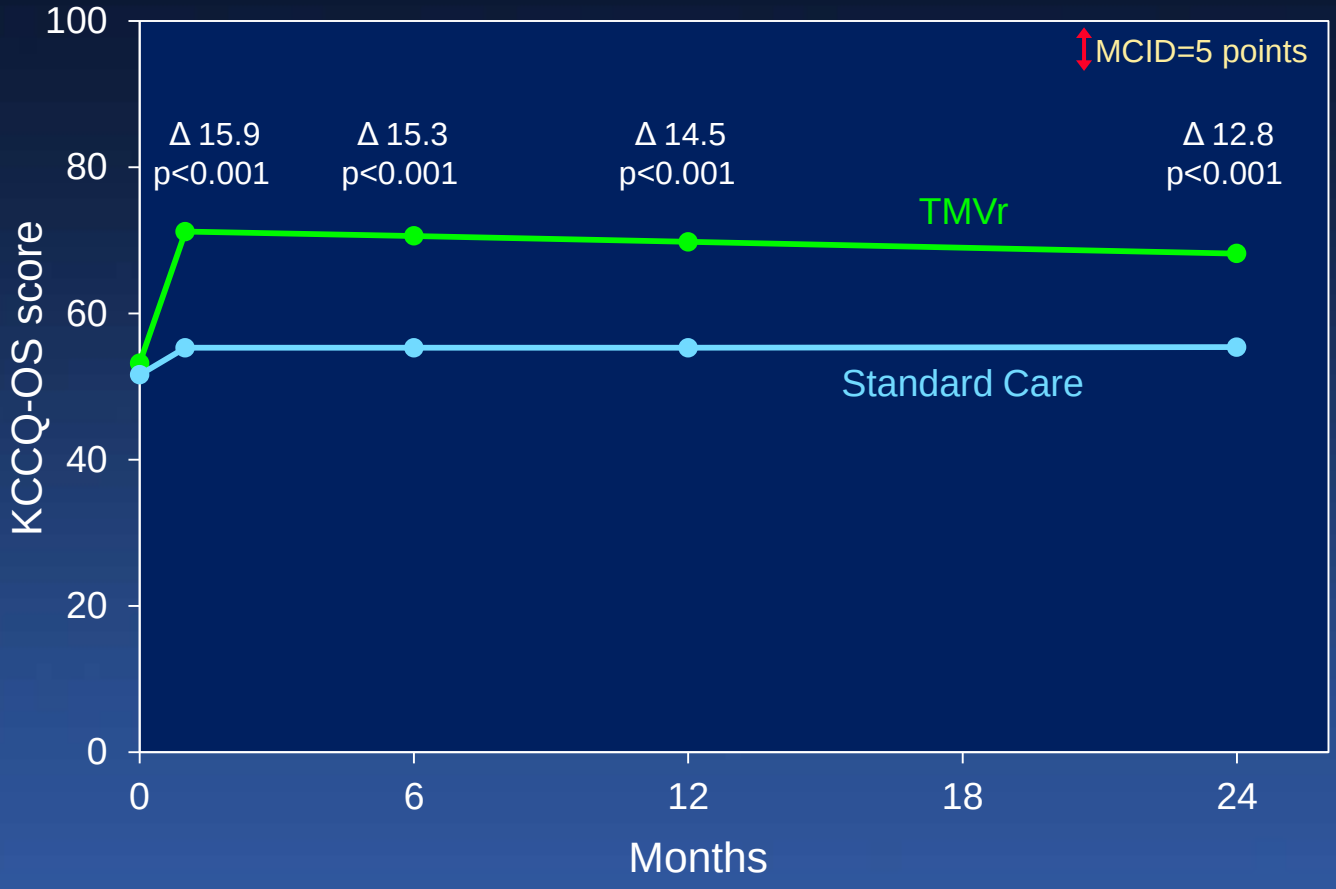
Primary Outcome: KCCQ-OS



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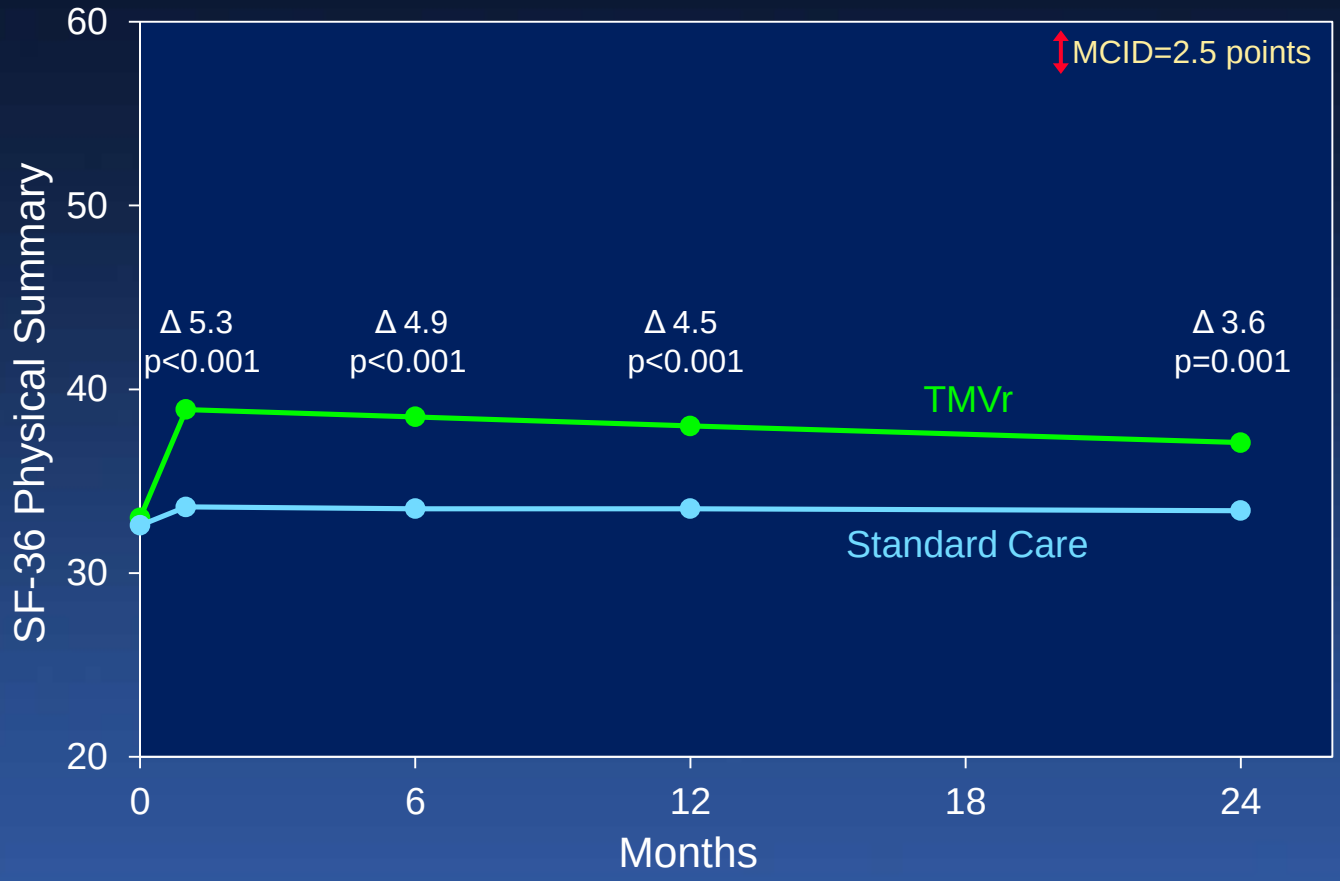
SF-36 Physical Summary



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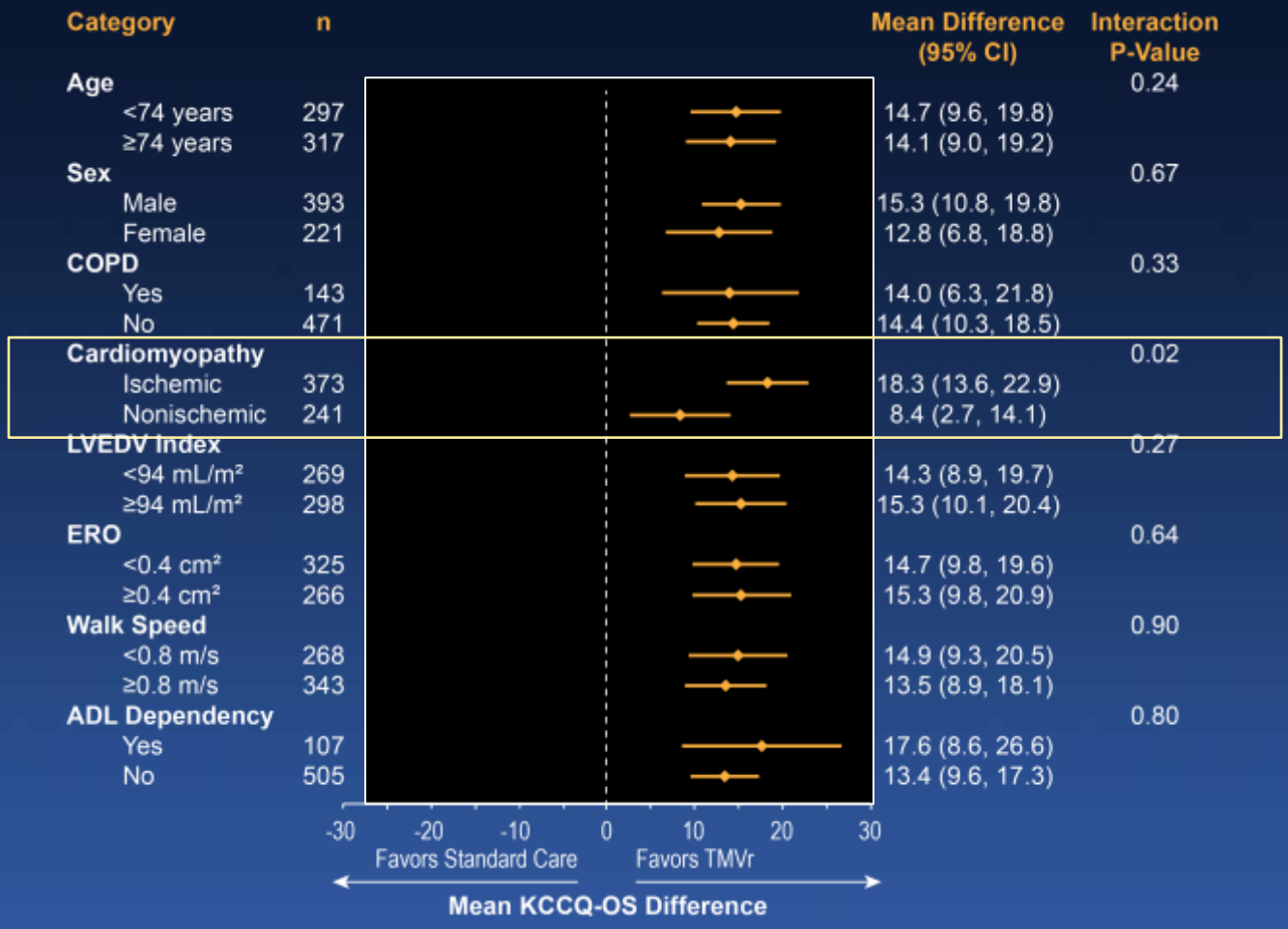
SF-36 Mental Summary

Subgroup Analyses



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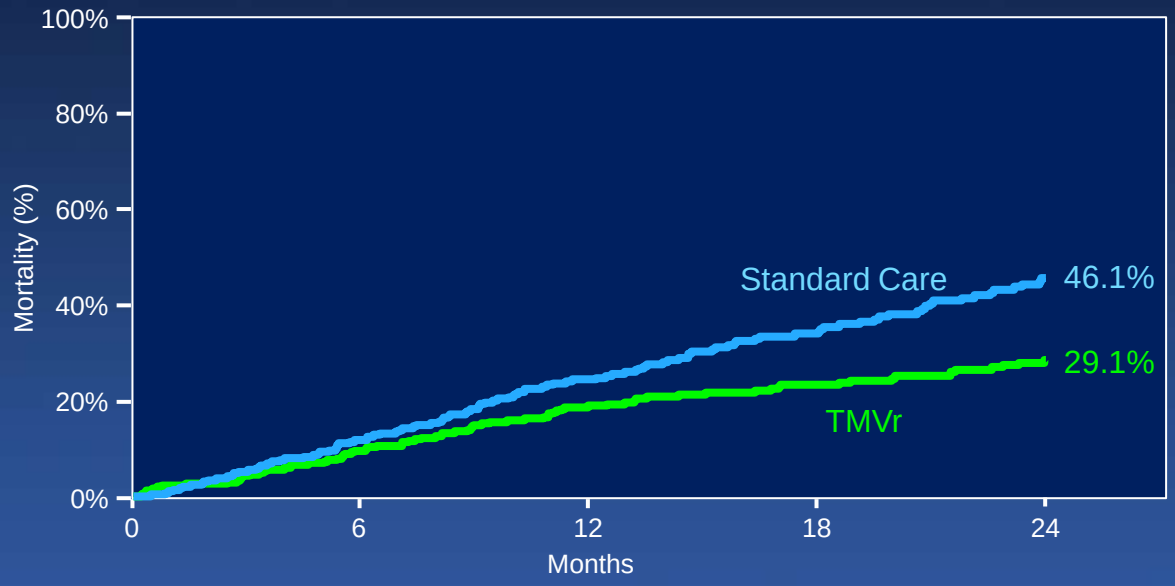
Challenges in Health Status Assessment

Impact of Differential Mortality

Health status can only be assessed in survivors, but those with worse health status are more likely to die



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Challenges in Health Status Assessment

Impact of Differential Mortality

- Strategies to address this challenge:
  - Categorical analyses that integrate survival and health status
  - Jointly modeling health status and mortality, which allows us to understand the expected health status benefit of TMVr assuming the patient survives

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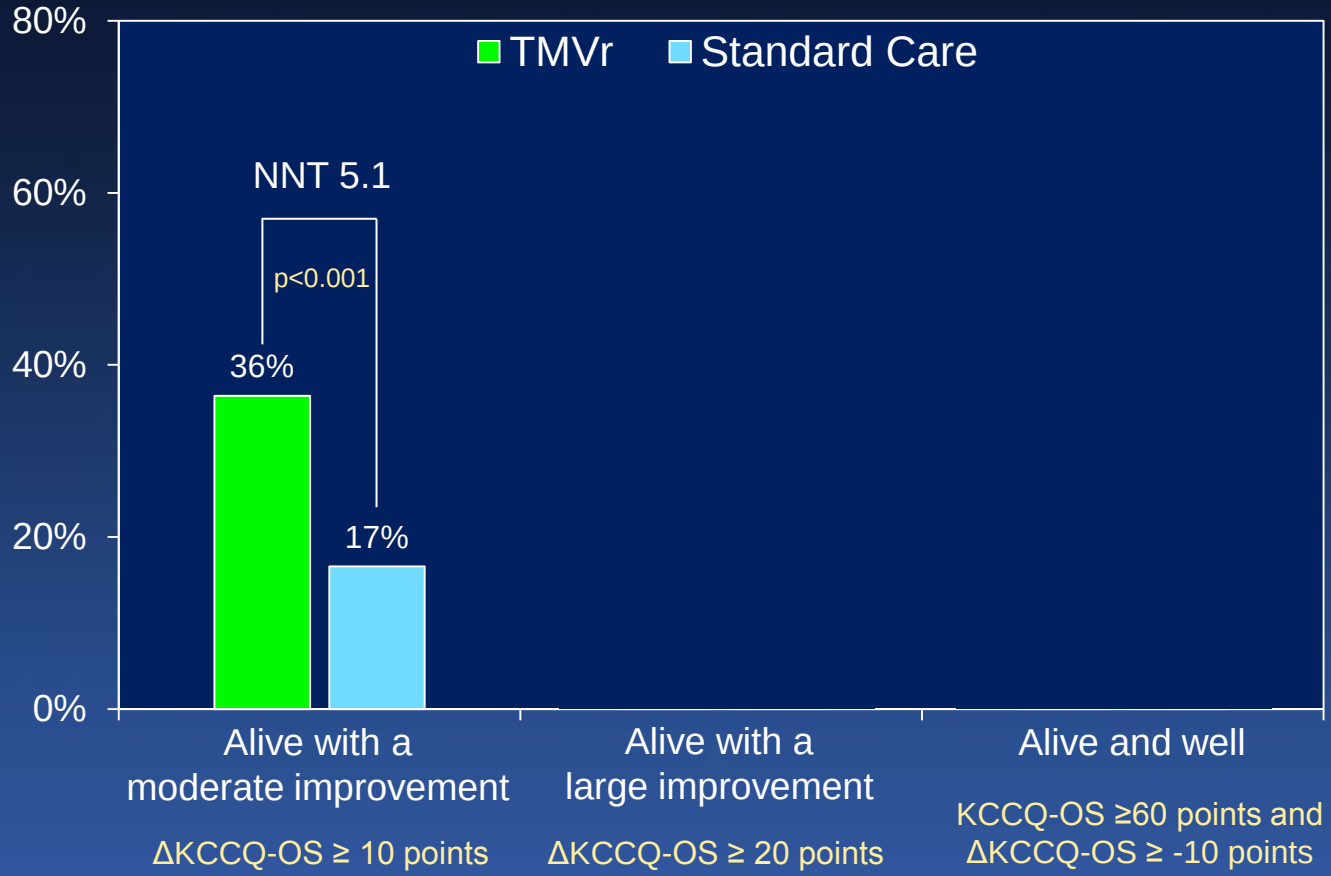
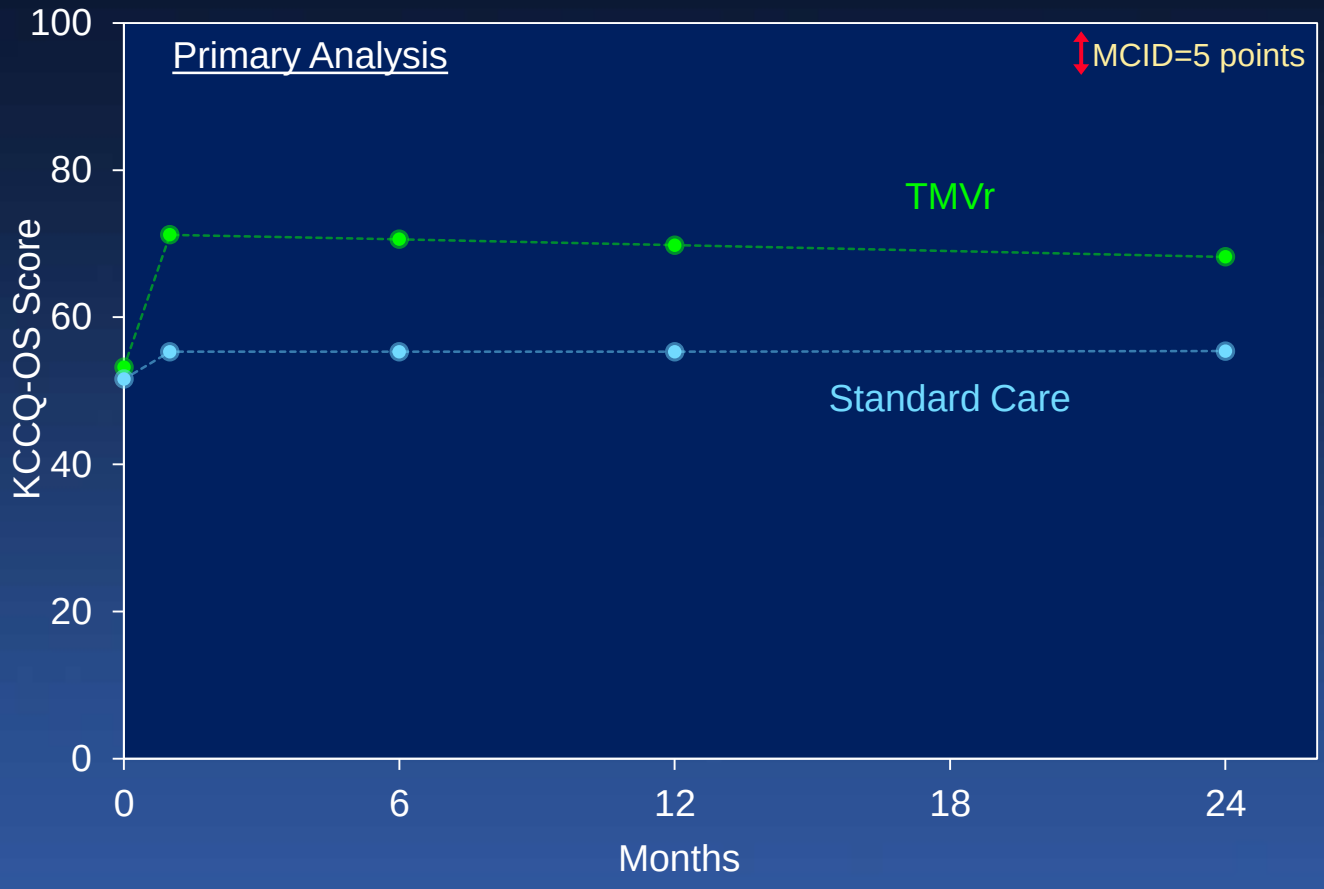
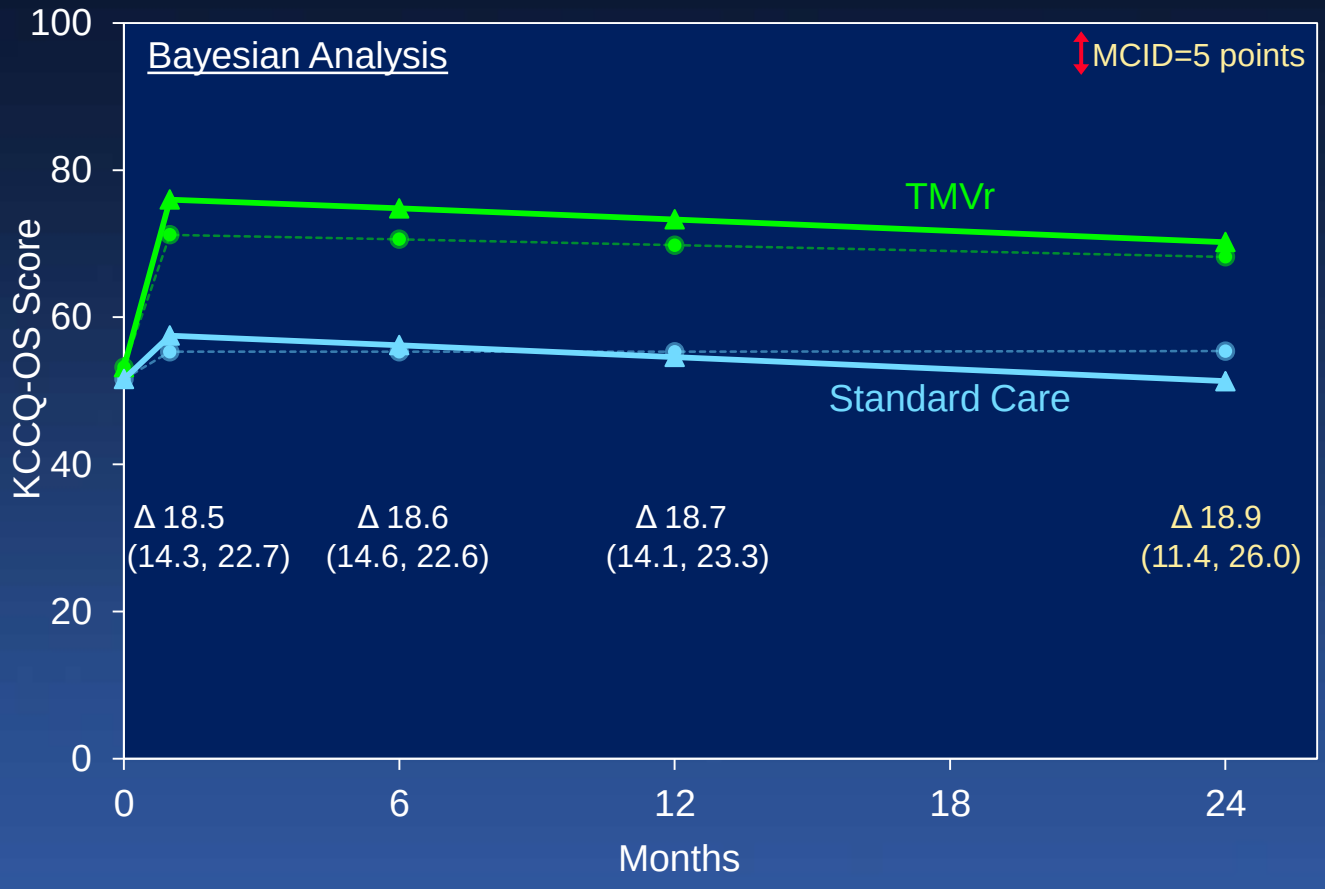
Categorical Outcomes at 24 Months



Joint Model Results: KCCQ-OS



Joint Model Results: KCCQ-OS



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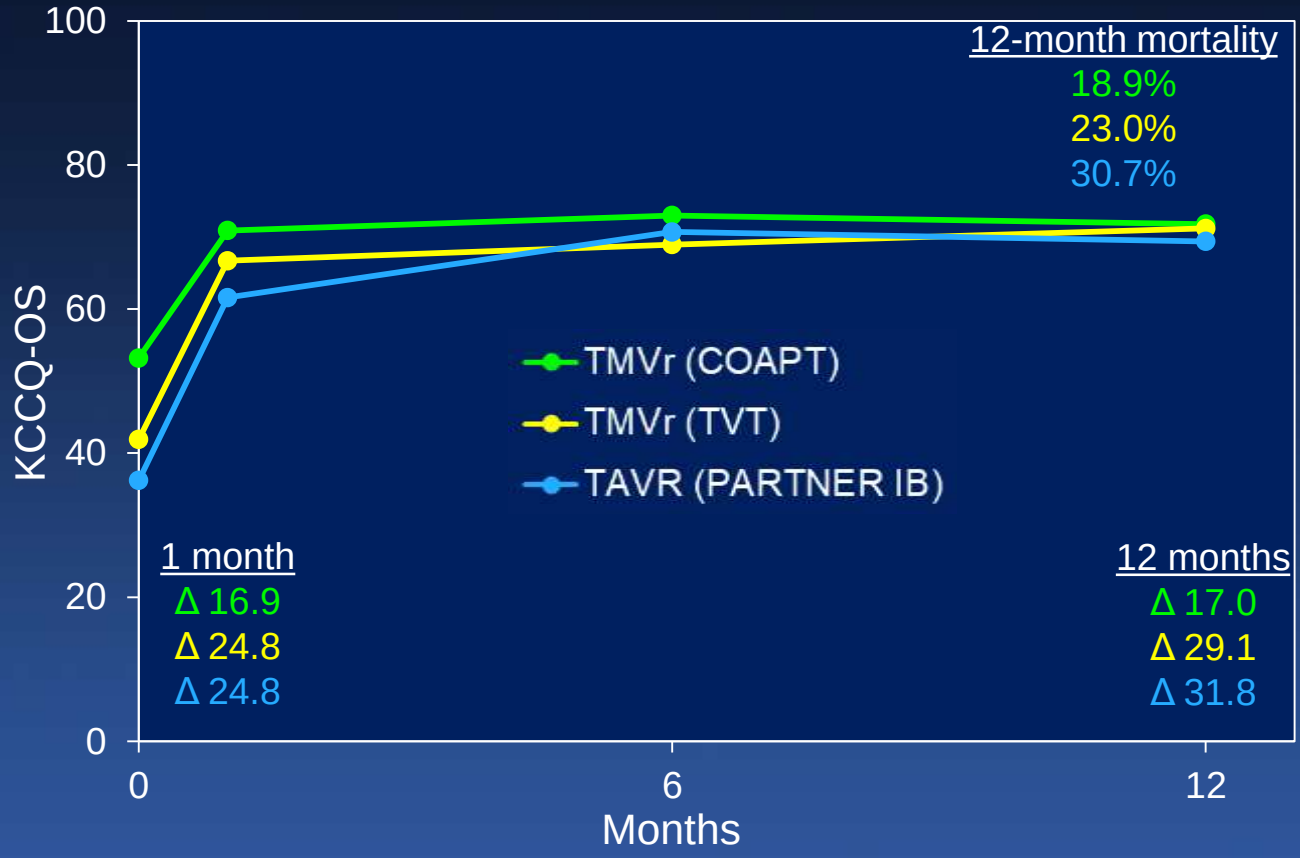
Health Status in COAPT in Perspective



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Summary

- In patients with heart failure and 3+ or 4+ secondary MR, TMVr with MitraClip 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 generally sustained through 24 months
- The health status benefit of TMVr was also consistent across most key subgroups

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Conclusion

Considering the previously reported benefits of TMVr on survival and heart failure hospitalization, these health status results further support the use of MitraClip for patients with heart failure and 3-4+ secondary MR who remain symptomatic despite maximally-tolerated GDMT