Cost-Effectiveness of MitraClip for Patients with HF and Severe Secondary MR: *Results from the COAPT Trial*

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Disclosures

Institutional Research Support

- Edwards Lifesciences - Abbott Vascular
- Boston Scientific - Medtronic
- Corvia - CathWorks
- Phillips - Zoll/Therox
- I-Rhythm - JC Medical
- JenaValve

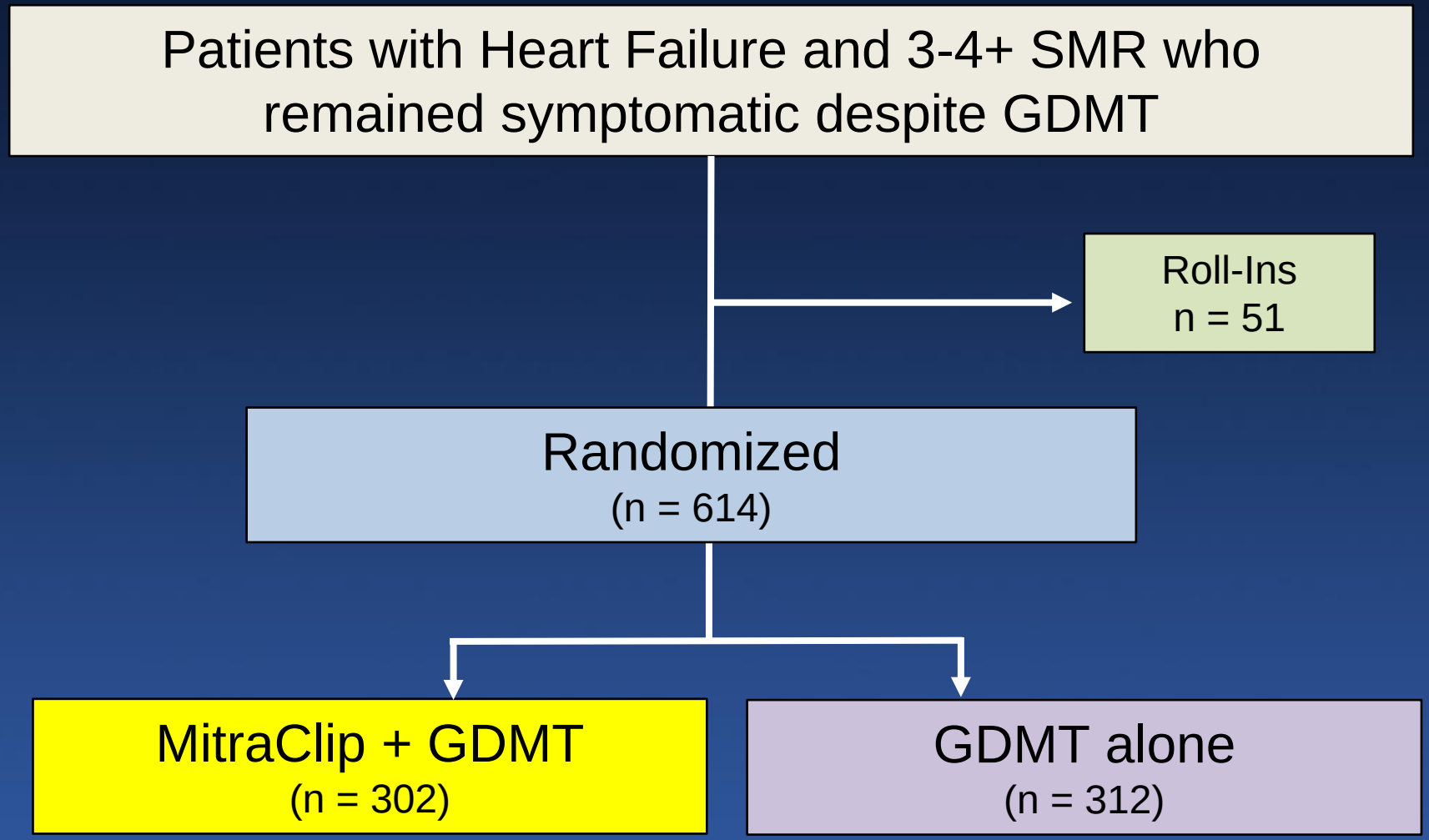
Consulting/Advisory Boards

- Medtronic - Edwards Lifesciences
- Boston Scientific - Abbott Vascular
- HeartBeam

Background

- The COAPT trial has shown that transcatheter mitral valve repair (TMVr) using the MitraClip results in reduced mortality and heart failure hospitalizations when compared with guideline-directed medical therapy (GDMT) in patients with symptomatic heart failure and 3-4+ secondary mitral regurgitation (SMR)
- Given the high cost of the MitraClip ($30,000) and large affected population, it is important to understand the cost-effectiveness of this approach relative to other cardiovascular and HF-specific therapies

Study Design



Economic Methods: Overview

Analytic Perspective

- U.S. healthcare system (costs in 2018 U.S. dollars)
- All analyses based on intention-to-treat population

General Approach

- In-trial economic analysis based on observed data followed by patient-level lifetime projections of survival, quality-adjusted life expectancy, and costs

Costs

- Based on observed resource utilization for the 2-year trial period
- MitraClip cost = $25,000

Methods: Lifetime Projections

Survival

- GDMT: life-expectancy beyond trial period estimated using age and sex-adjusted U.S. life tables calibrated to 2-year trial data
- TMVr: HR derived from landmark analysis of trial data (30 days to 2 years) and applied to calibrated life tables

QALYs

- Utilities (SF-6D) measured at baseline, 1, 6, 12 and 24 months used to calculate in-trial QALYs → regression models used to project beyond trial time-horizon

Costs

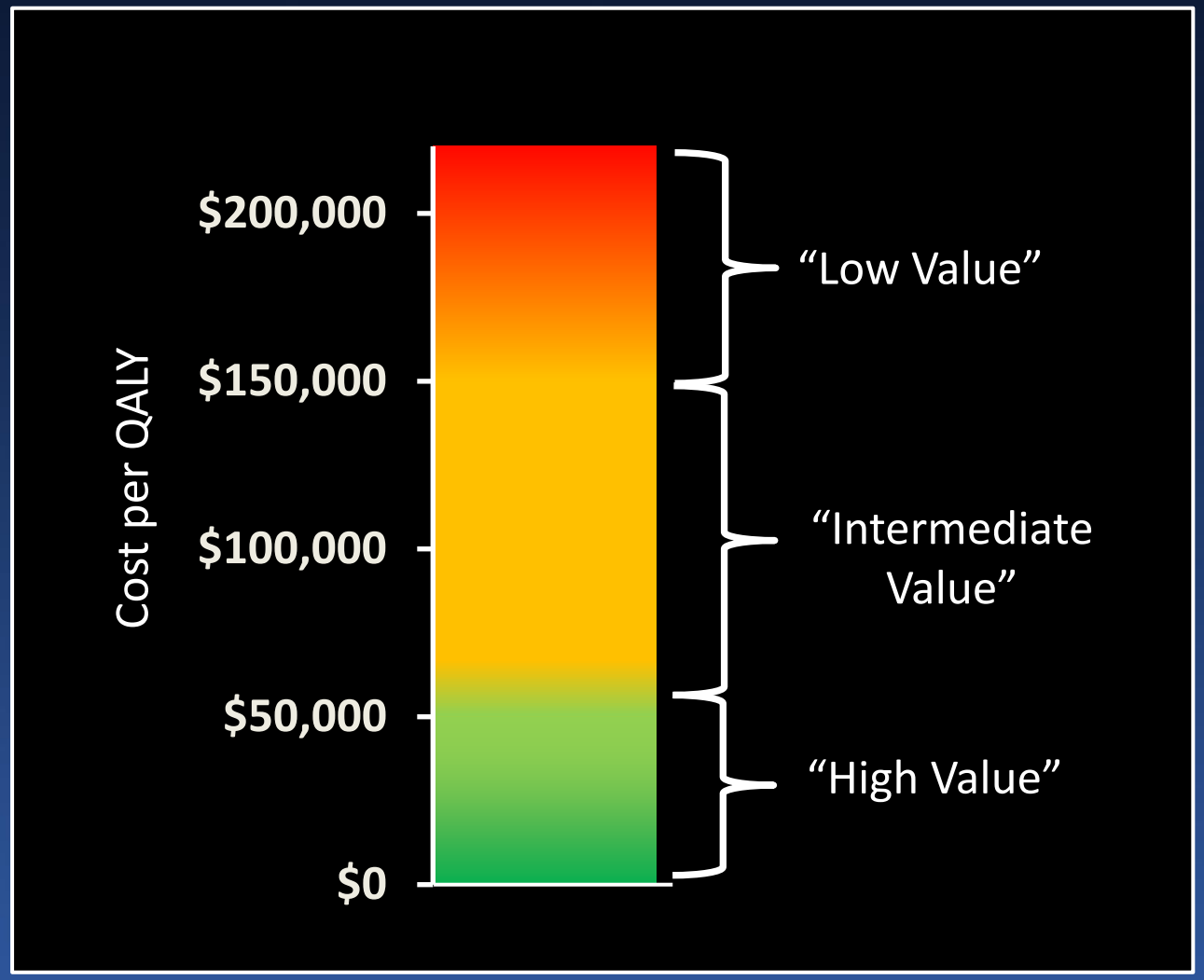
- Estimated using regression model based on in-trial costs

Scenario Analyses

- Since duration of benefits associated with TMVr is unknown, 3 sets of cost-effectiveness analyses performed based on differing assumptions
  - "Best Case" Scenario: Observed in-trial benefits remain constant throughout lifetime
  - "Worst Case" Scenario: No benefit of TMVr after 2 years
  - Base Case: Survival, quality of life and economic benefits of TMVr decrease in linear fashion between years 2-5 of follow up such that no benefit of TMVr is seen beyond year 5

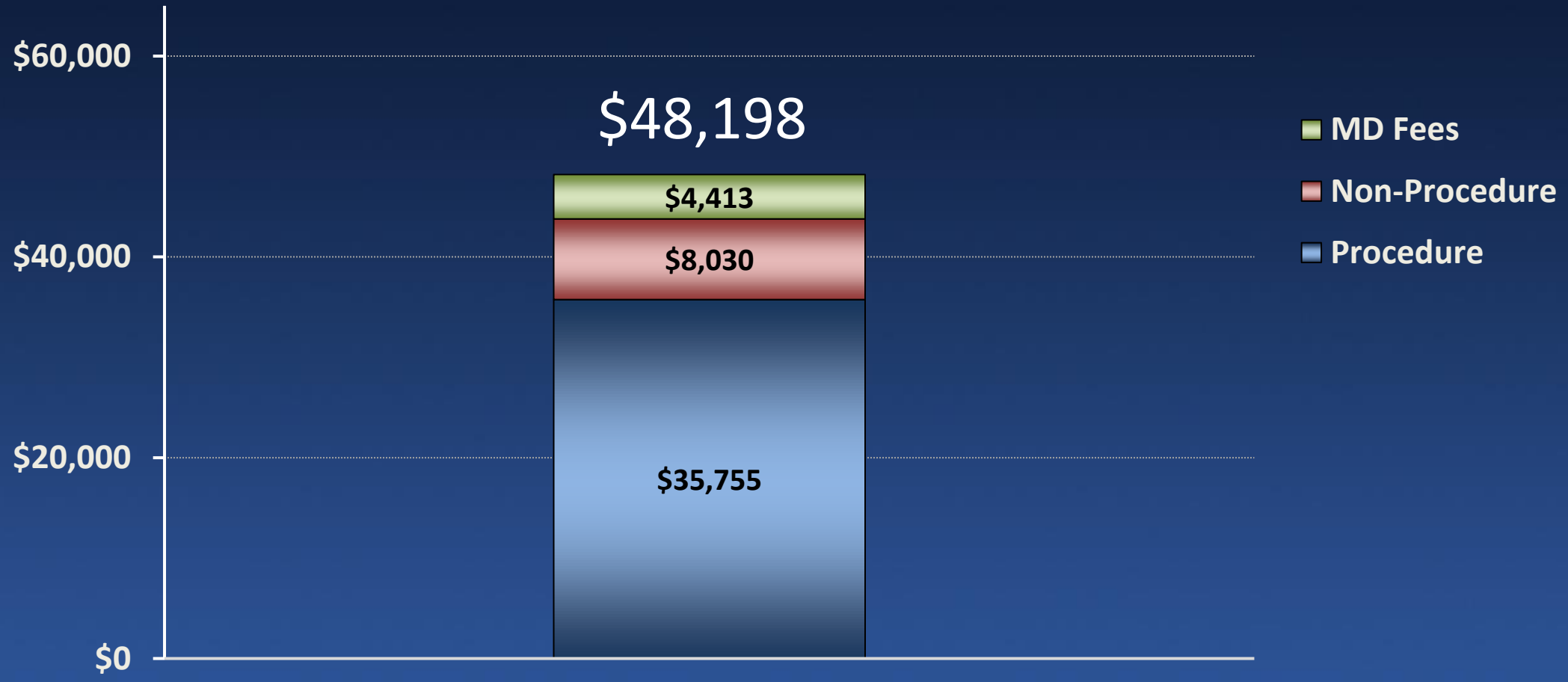
Incremental Cost-Effectiveness

- Incremental Cost Effectiveness Ratio (ICER) calculated by dividing difference in lifetime costs by difference in QALYs
- Uncertainty in joint distribution of lifetime cost and survival for ICER estimated using bootstrap resampling



Anderson JL et al. JACC 2014; 63 :2304-22

Index TMVr Hospitalization Cost



* Includes only patients who underwent attempted MitraClip procedure (N = 293)

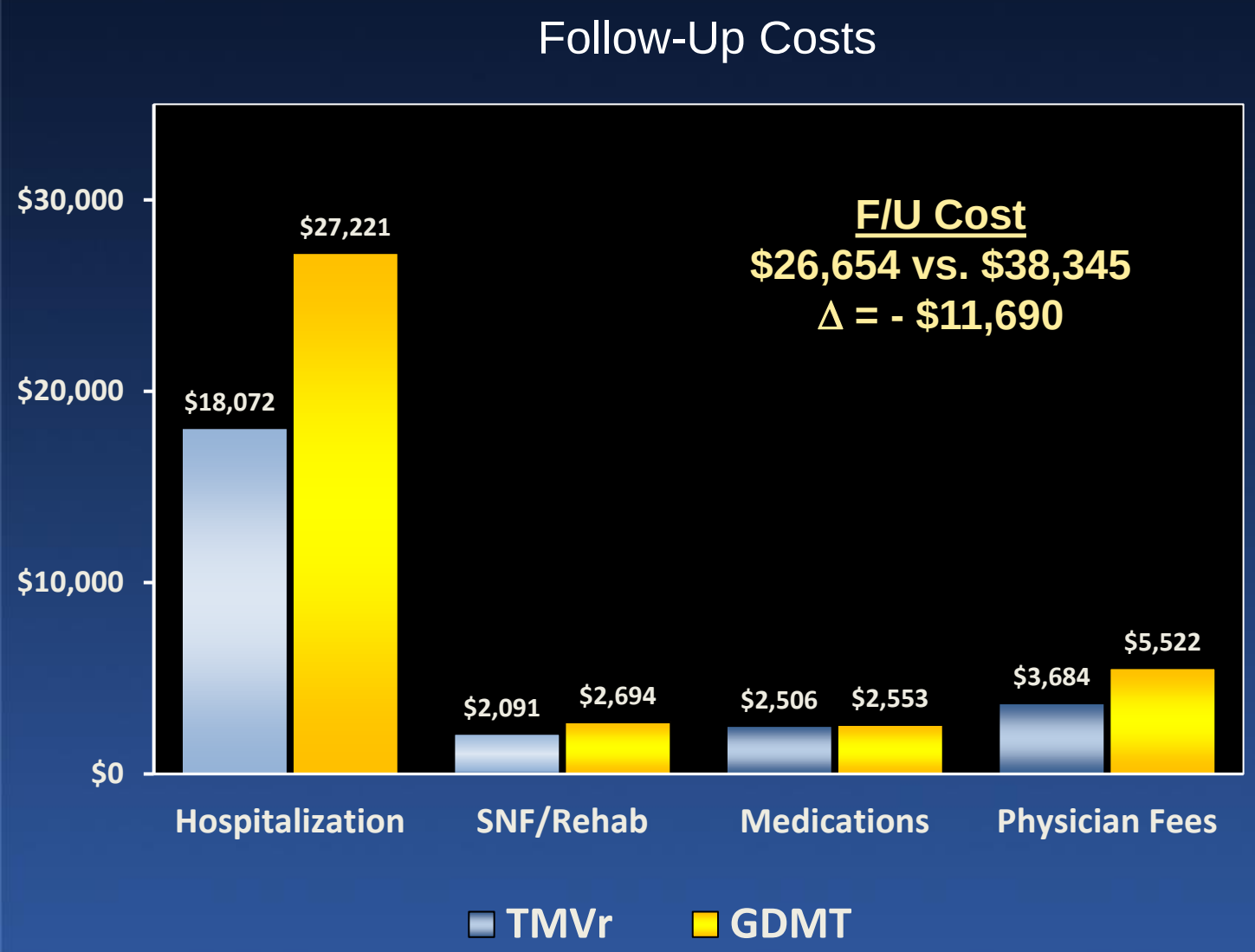
Follow-Up Resource Utilization*

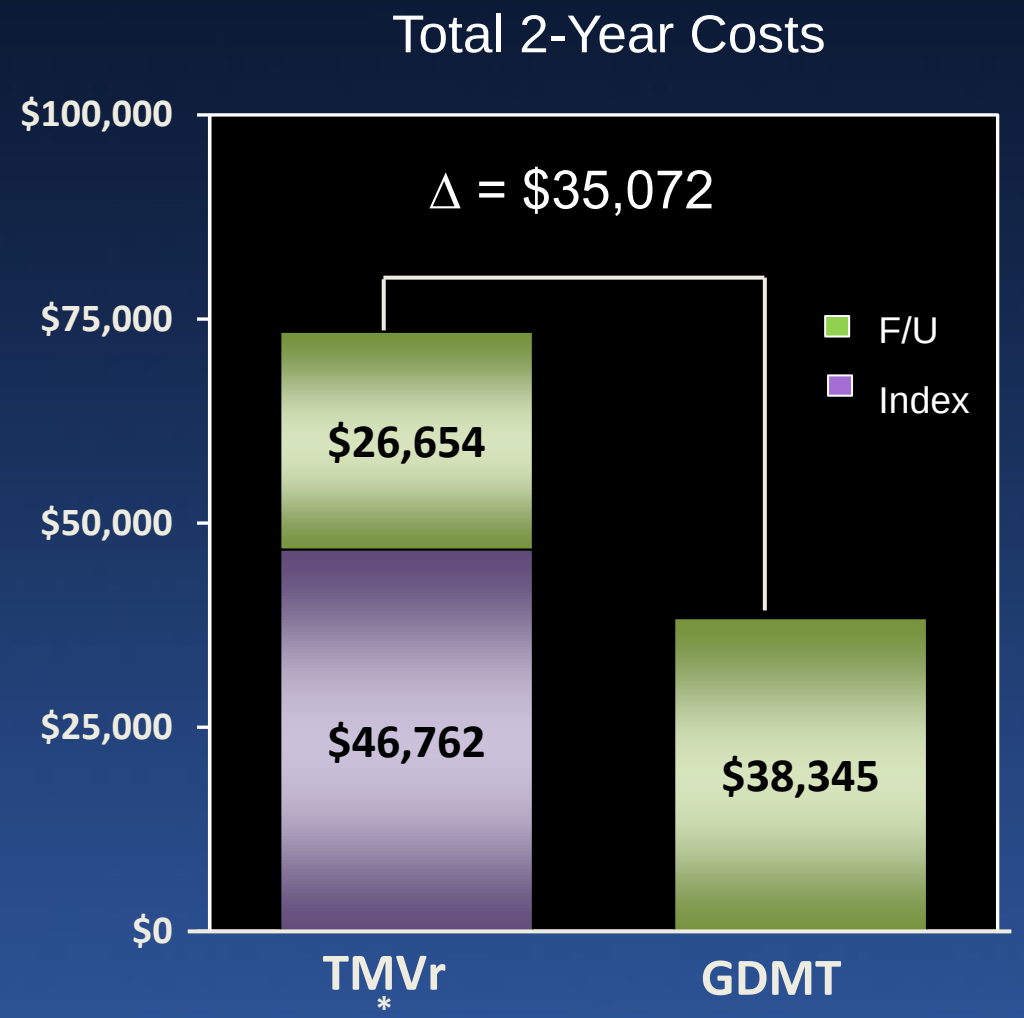
Count per 100 patients

	TMVr N = 302	GDMT N = 312	P-Value
Hospitalizations	169	218	0.004
Heart Failure	56	95	< 0.001
CV but Non-HF	35	35	0.972
Non-Cardiovascular	78	89	0.270
Hospital Days	1060	1383	0.060
SNF/Rehab Days	289	375	0.040
HF-related Office Visit	94	105	0.668

* Adjusted for censoring

Follow-Up Costs



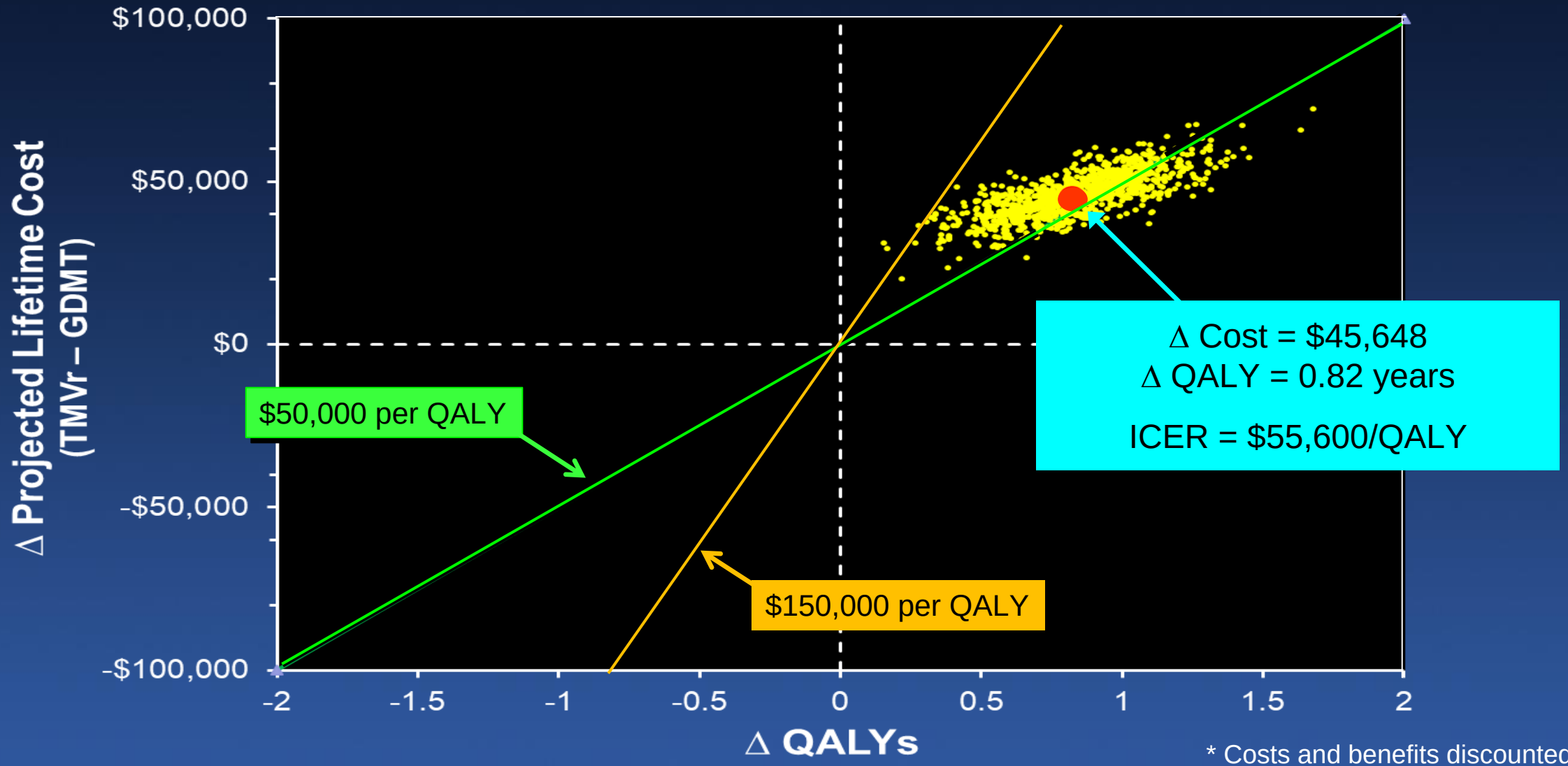


Projected Survival

* Discounted at 3%

TMVr vs. GDMT Cost Effectiveness

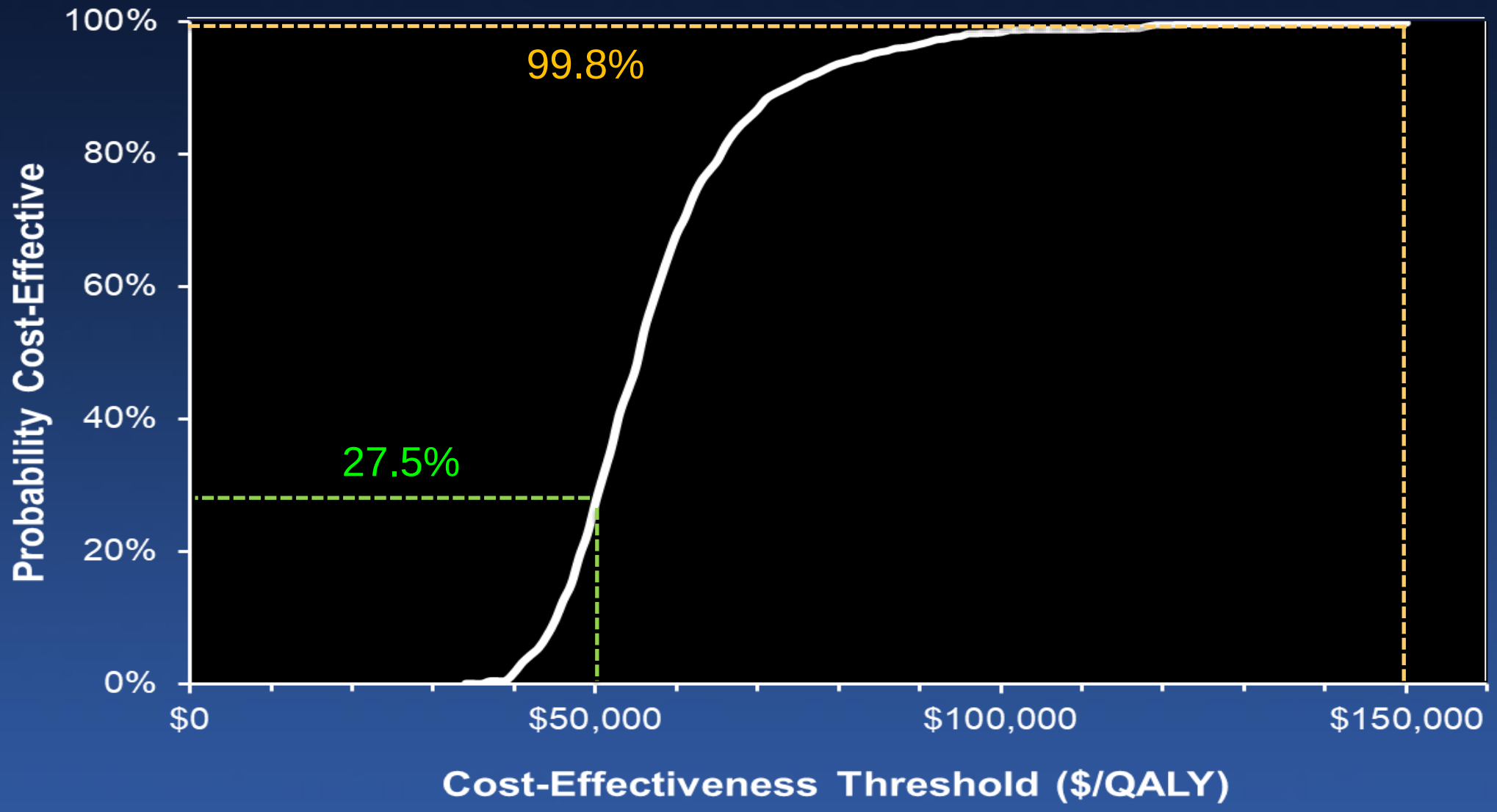
Base Case Analysis



* Costs and benefits discounted at 3%

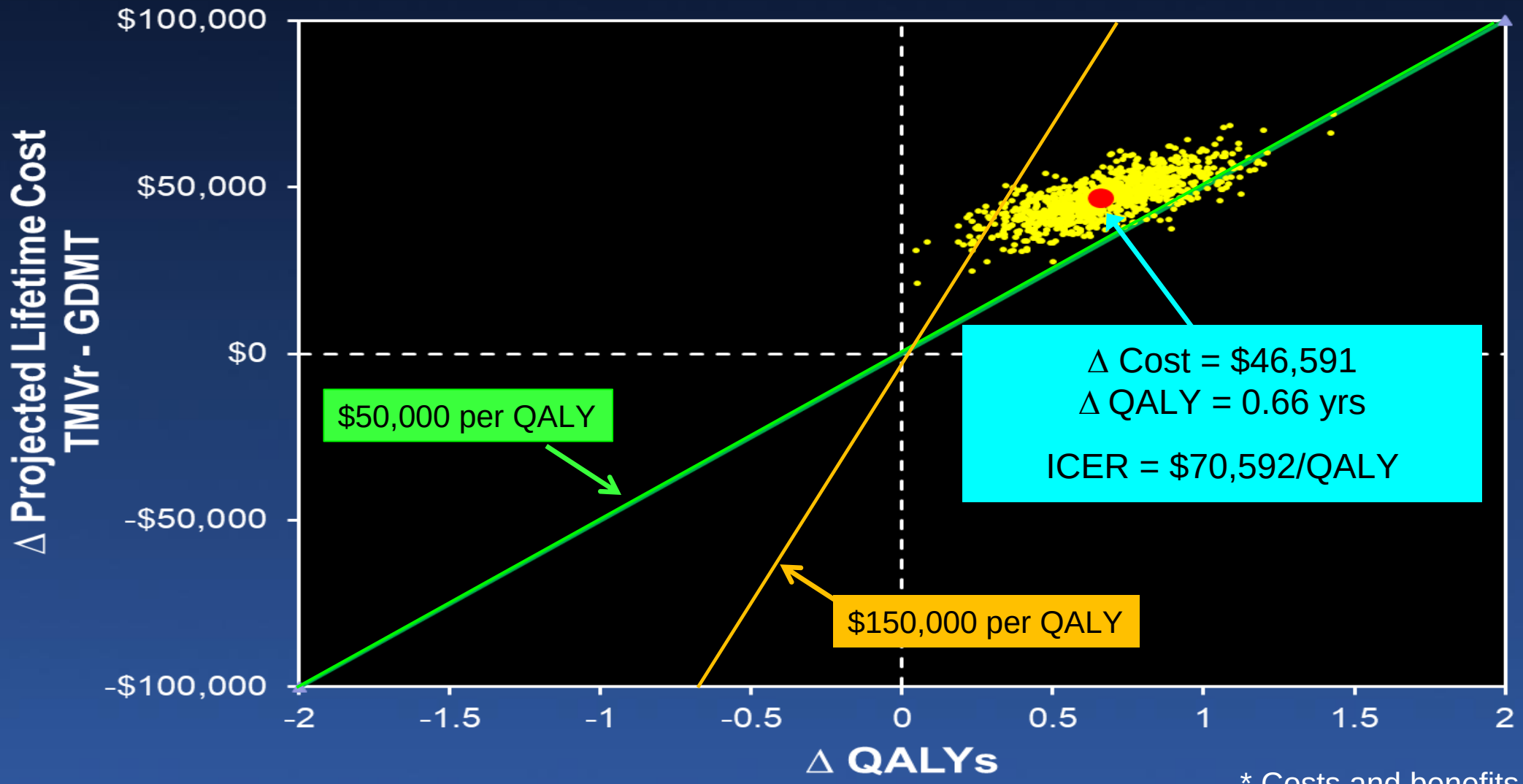
Cost-Effectiveness Acceptability Curve

Base Case Analysis



TMVr vs. GDMT Cost Effectiveness

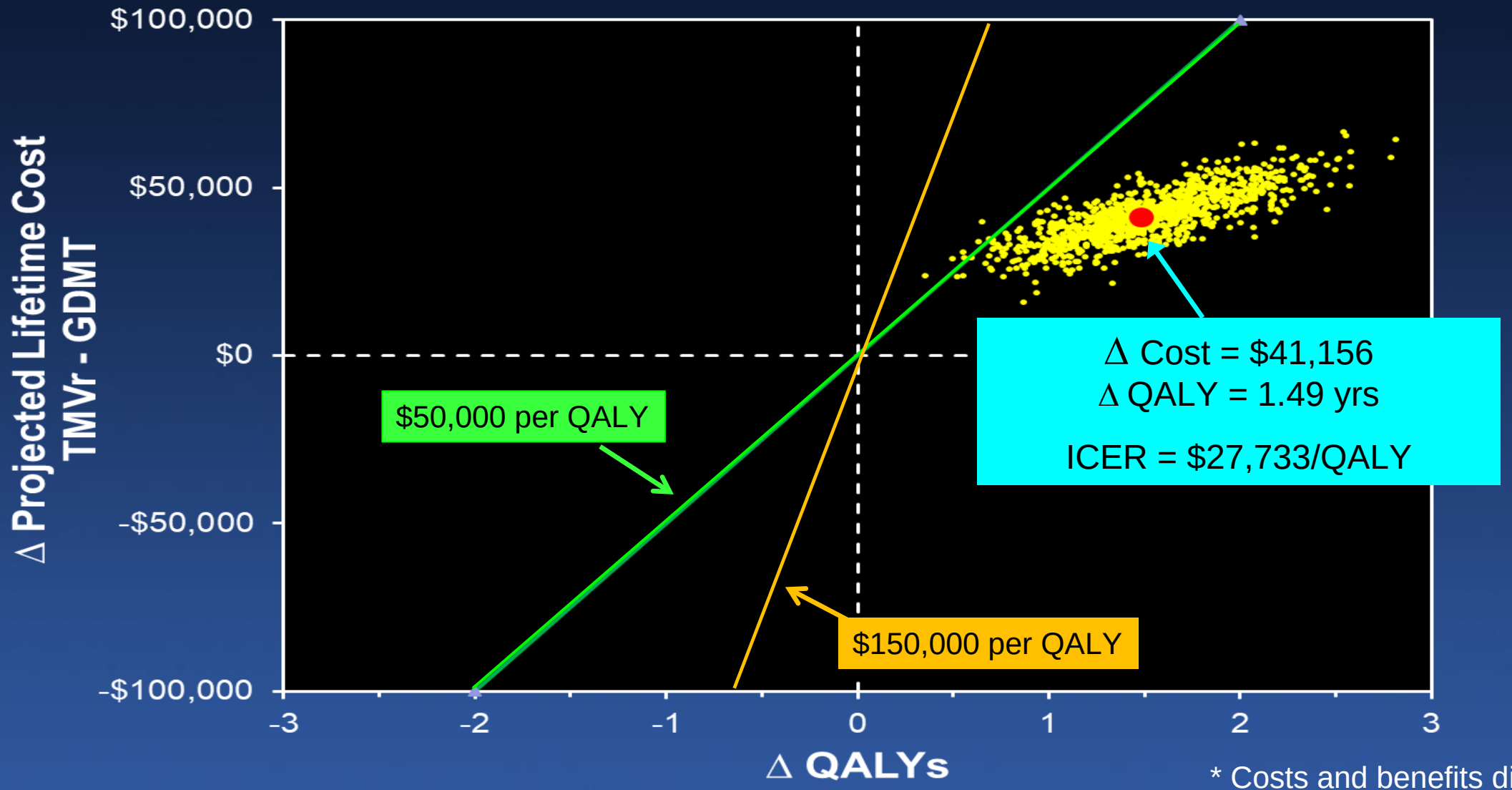
Worst Case Scenario: No Benefit after 2 years



* Costs and benefits discounted at 3%

TMVr vs. GDMT Cost Effectiveness

Best Case Scenario: In-trial benefit continues indefinitely



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Conclusions

- For symptomatic heart-failure patients with 3-4+ SMR, TMVr increases quality-adjusted life-expectancy compared with GDMT at an incremental cost per QALY gained consistent with intermediate-to-high economic value based on currently accepted U.S. thresholds
- Future studies are needed to examine the durability of TMVr benefit in this population and to evaluate the cost-effectiveness of TMVr compared with other available and emerging mitral valve therapies