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Cost-Effectiveness of Transcatheter Mitral Valve Repair versus Medical Therapy in Patients with Heart Failure and Secondary Mitral Regurgitation: *Results from the COAPT Trial*

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Disclosures

- The COAPT trial (NCT01626079) was sponsored by Abbott and designed collaboratively by the principal investigators and the sponsor
- The cost-effectiveness analysis was conducted independently at Saint Luke's Mid America Heart Institute (Kansas City, Missouri)
- Within the past 12 months, I have had a financial interest, arrangement or affiliation with the organizations listed below:
  - Edwards LifeSciences: Consulting fees
  - Boston Scientific Corp: Research grant support; Advisory board

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Background

- The COAPT trial demonstrated that transcatheter mitral valve repair (TMVr) using the MitraClip device resulted 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 rising cost of health care, it is essential to understand the cost-effectiveness of new therapies, especially when the technology is costly and the target population is large and characterized by significant comorbidities and high rates of healthcare resource utilization

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Objectives

To evaluate the long-term costs and cost-effectiveness of TMVr using the MitraClip device compared with GDMT in patients with heart failure and 3-4+ SMR

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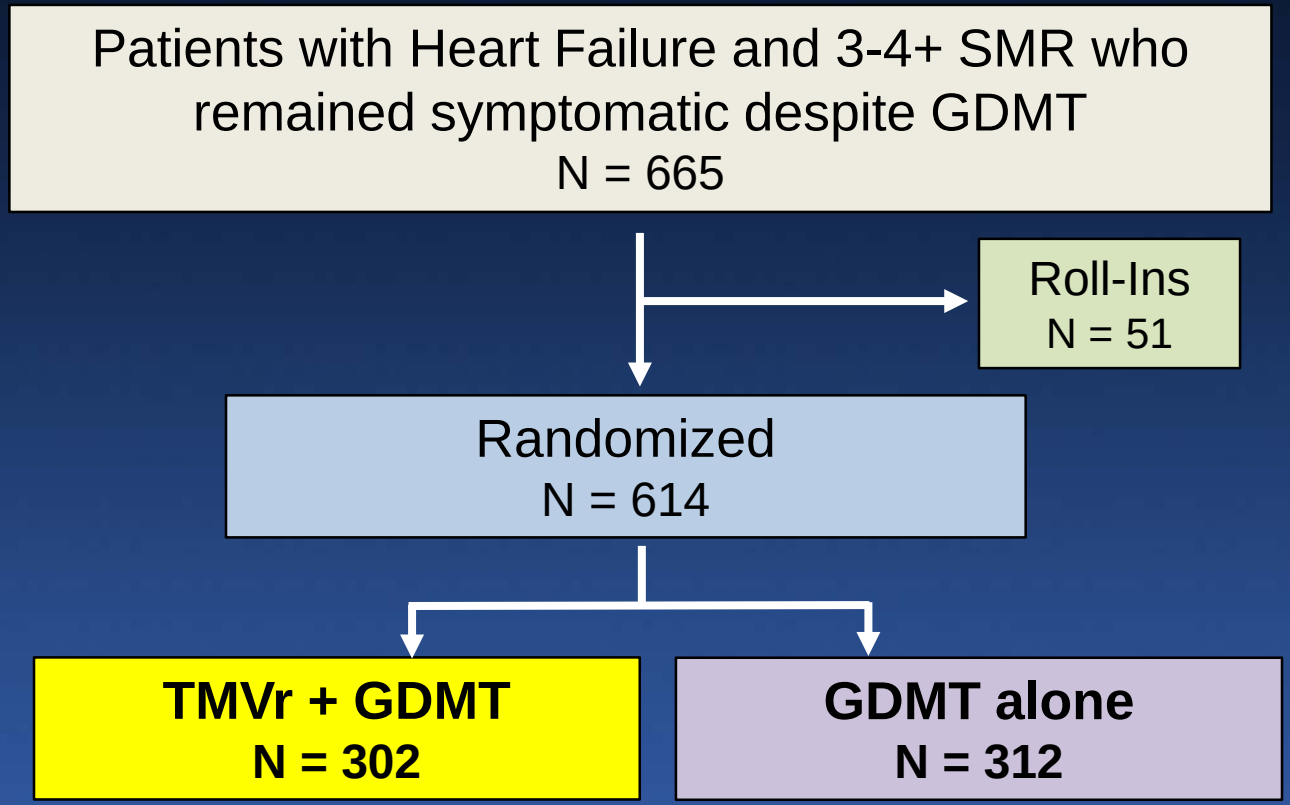
Study Design



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Economic Methods: Overview

- Analytic Perspective
  - U.S. healthcare system (costs in 2018 U.S. dollars)
- Analysis Population
  - 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
  - All future costs and benefits discounted at 3%/year

Methods:
Index Hospitalization Costs

- Index Procedure
  - Assessed using resource-based accounting methods
  - MitraClip Device = $30,000 per procedure
- Non-Procedural Costs
  - Derived from combination of billing data when available and regression modelling when billing data unavailable
- Physician Fees
  - Based on Medicare fee schedule for both procedural and non-procedural care

Methods:
Follow Up Costs

- Re-Hospitalization Costs
  - Based on national average Medicare reimbursement for MS-DRG associated with admission
- Rehabilitation/Skilled Nursing Facility
  - Based on mean cost for services post hospitalization for specific MS-DRG derived from MarketScan data
- Other Follow-Up Costs
  - Emergency room visits
  - Outpatient cardiac medications
  - Cardiac-related office visits

Methods:
Projected Survival, QALYs and Costs

- 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
- Quality-Adjusted Life-Years (QALYs)
  - Utilities (SF-6D) measured at baseline, 1, 6, 12 and 24 months used to calculate in-trial and lifetime QALYs
- Costs
  - Estimated using regression model based on in-trial costs

Statistical Analysis

- In-trial resource use, costs and utilities were estimated at each follow-up time point
- Treatment group means and between-group differences (with 95% CI) for projected life-expectancy, quality-adjusted life-expectancy (QALE) and lifetime costs generated using bootstrap resampling
- Incremental Cost Effectiveness Ratio (ICER) was 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

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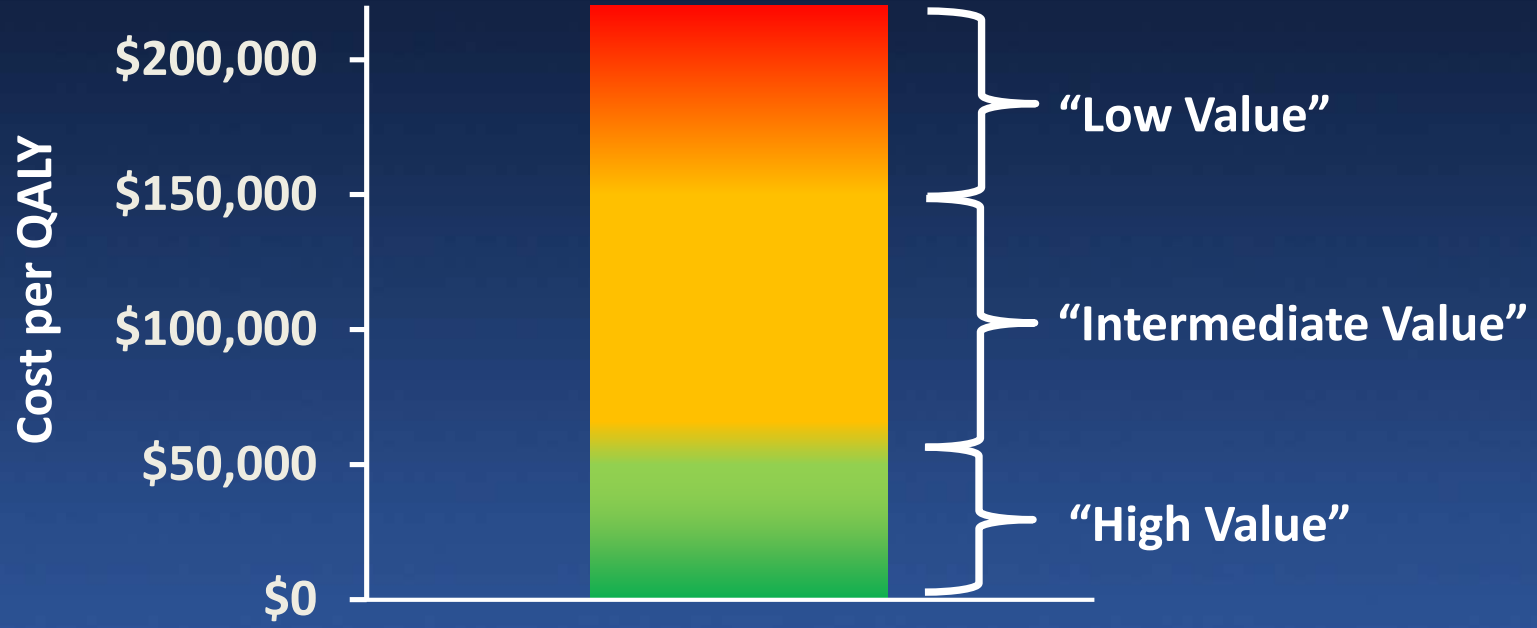
ICER Thresholds for Value



Anderson JL et al. JACC 2014; 63 (21): 2304-22.

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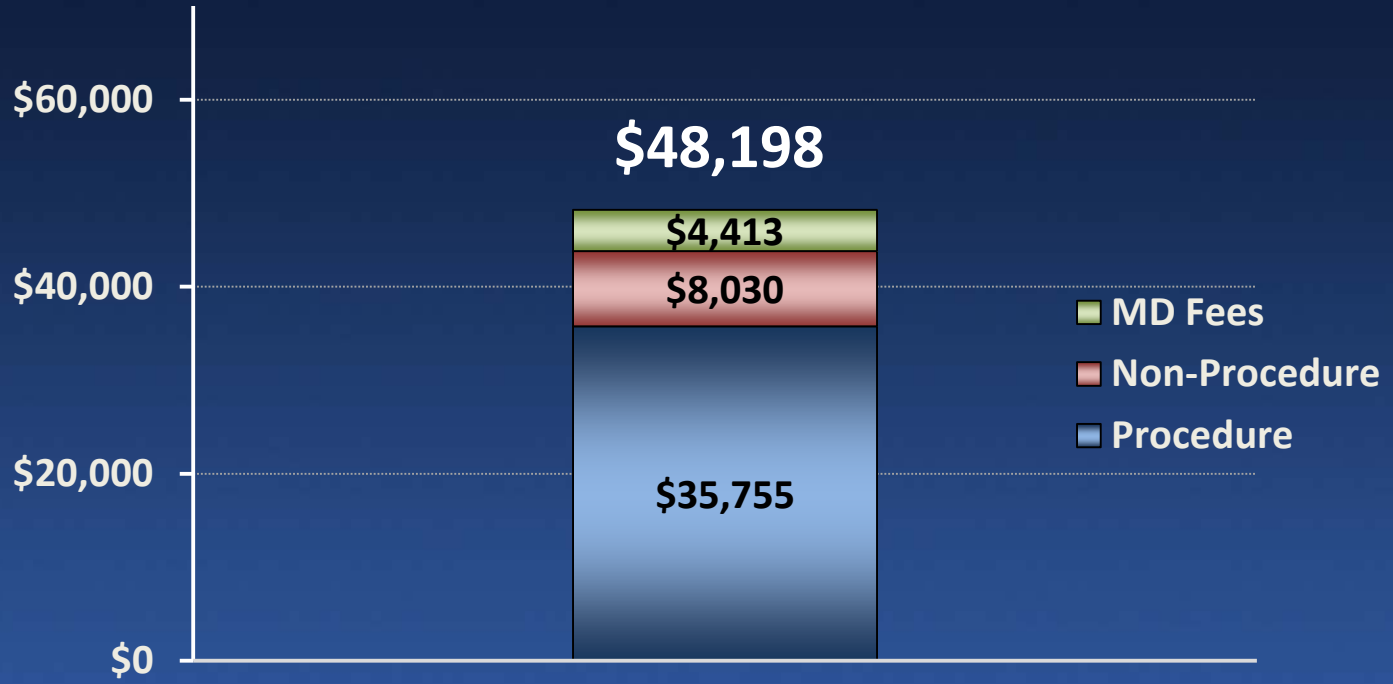
Sensitivity Analyses

- Since duration of benefits associated with TMVr is unknown, three sets of cost-effectiveness analyses performed based on differing assumptions regarding TMVr benefit
  - **"Best Case" Scenario**
    - *Observed in-trial benefits remain constant throughout lifetime*
  - **"Worst Case" Scenario**
    - *No benefit of TMVr after 2 years*
  - **Base Case Scenario**
    - *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

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

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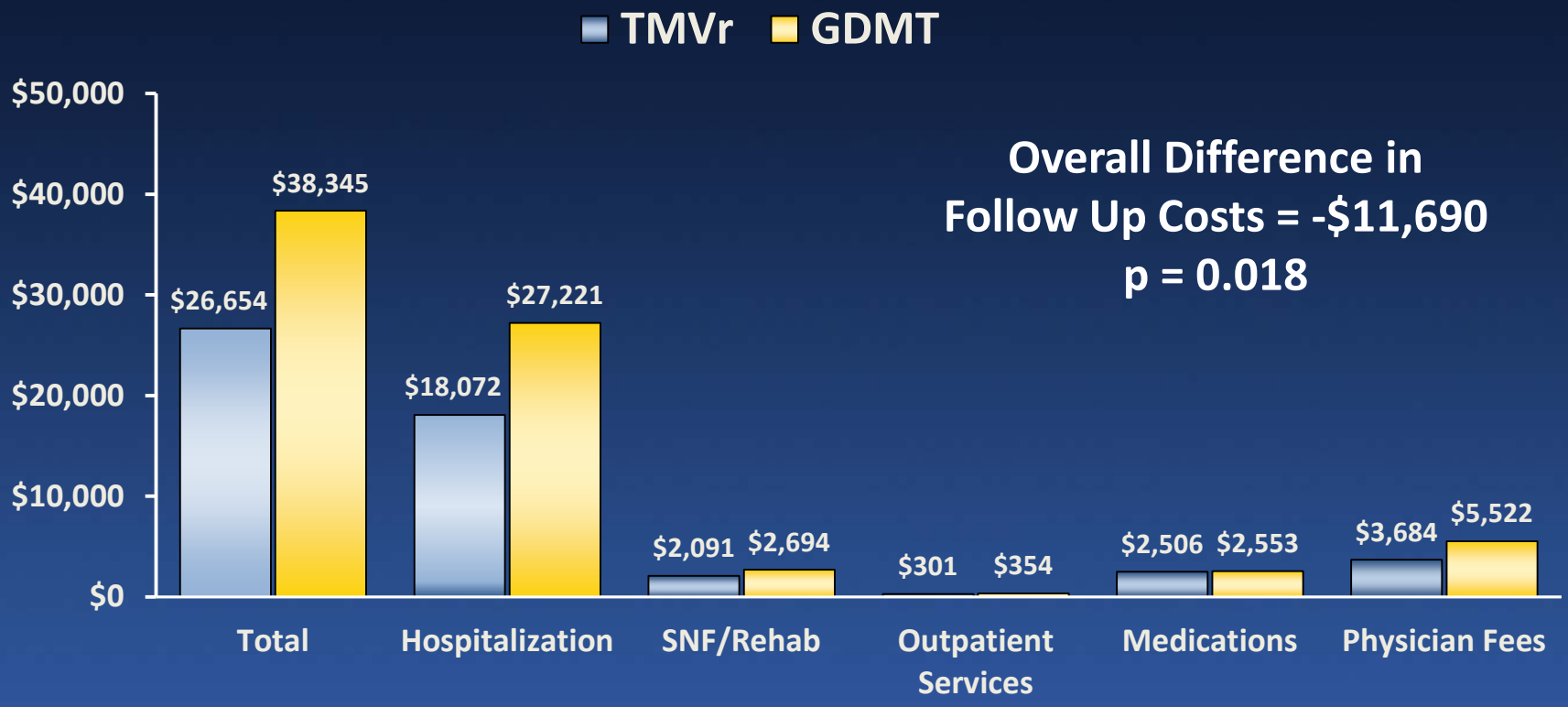
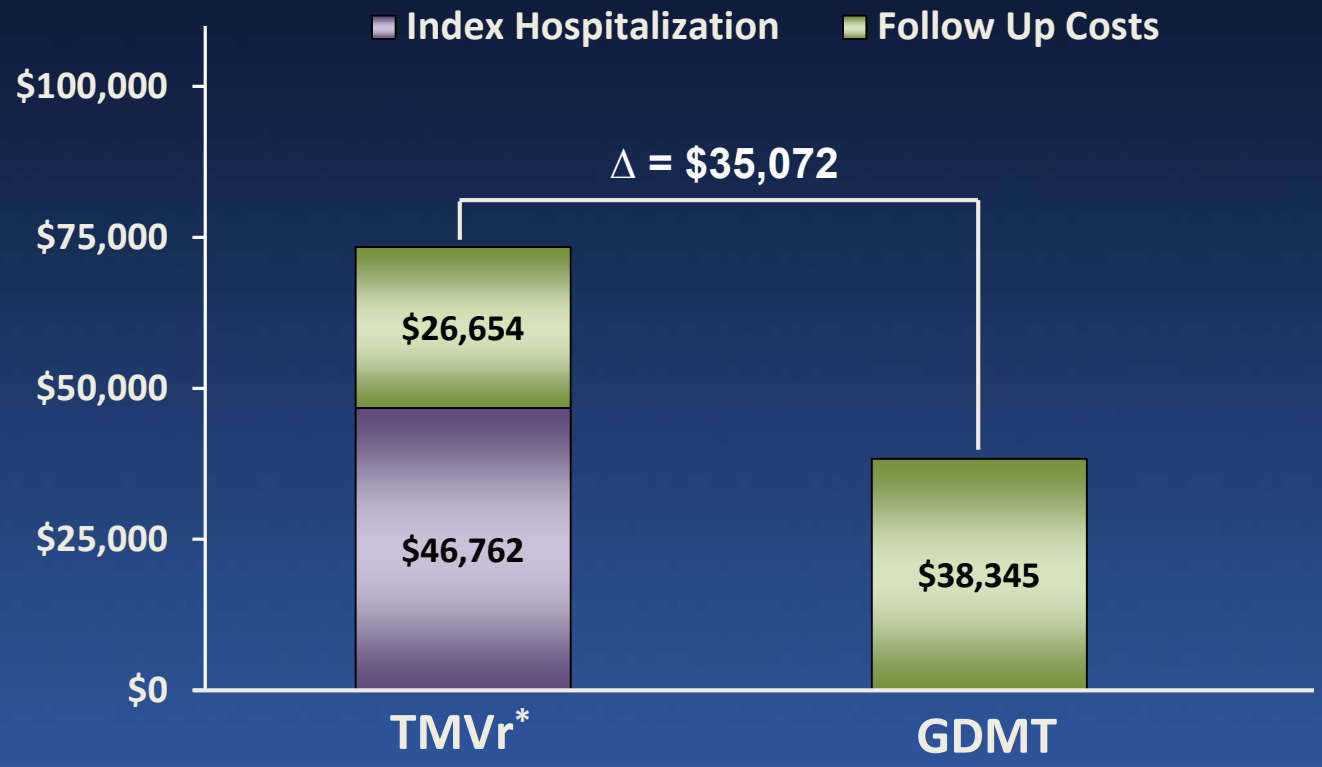
2-Year Follow Up Costs



Overall Difference in Follow Up Costs = -$11,690
p = 0.018

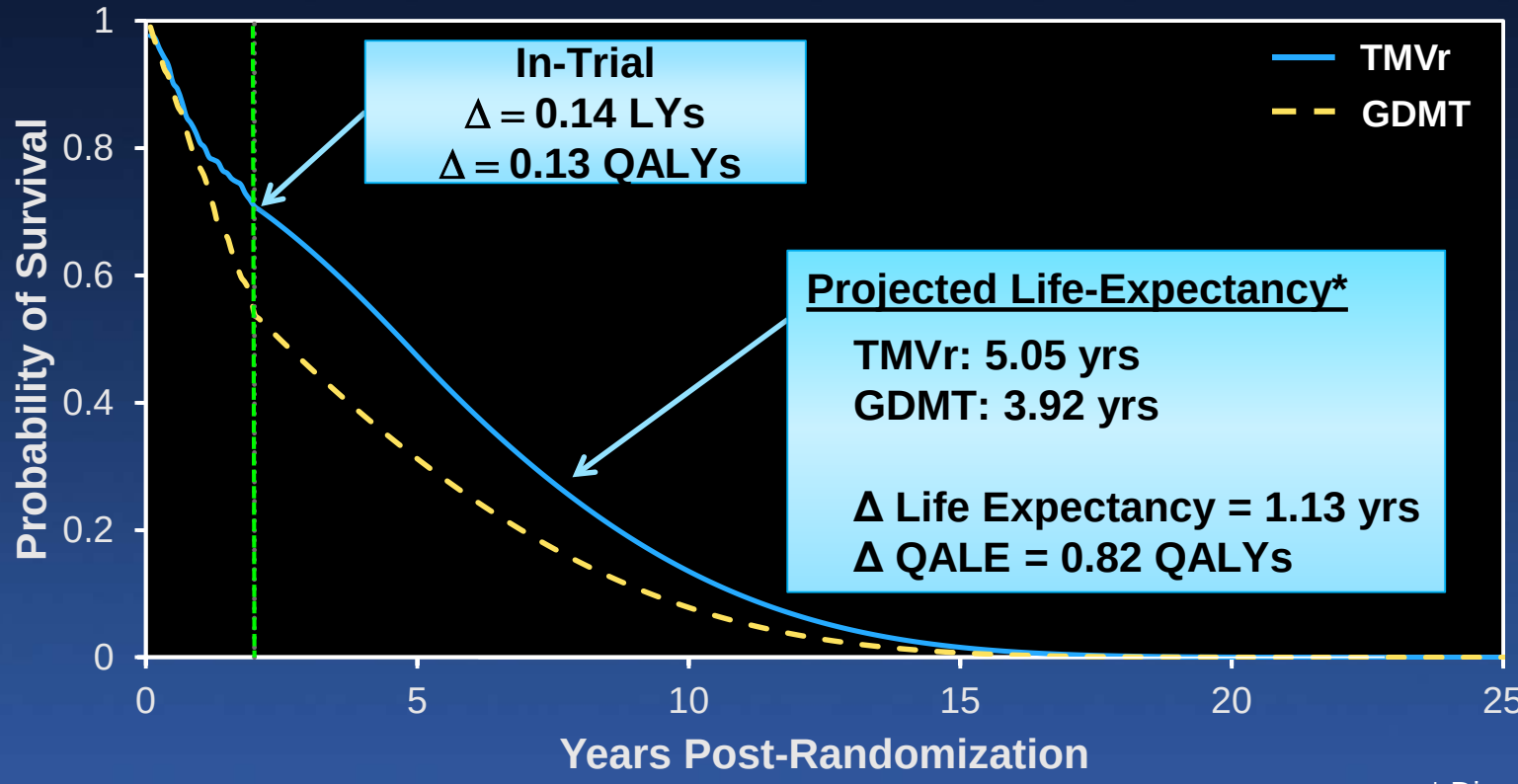
* Adjusted for censoring

Cumulative 2-Year Costs



* Includes all Intention-To-Treat Patients (N = 302)

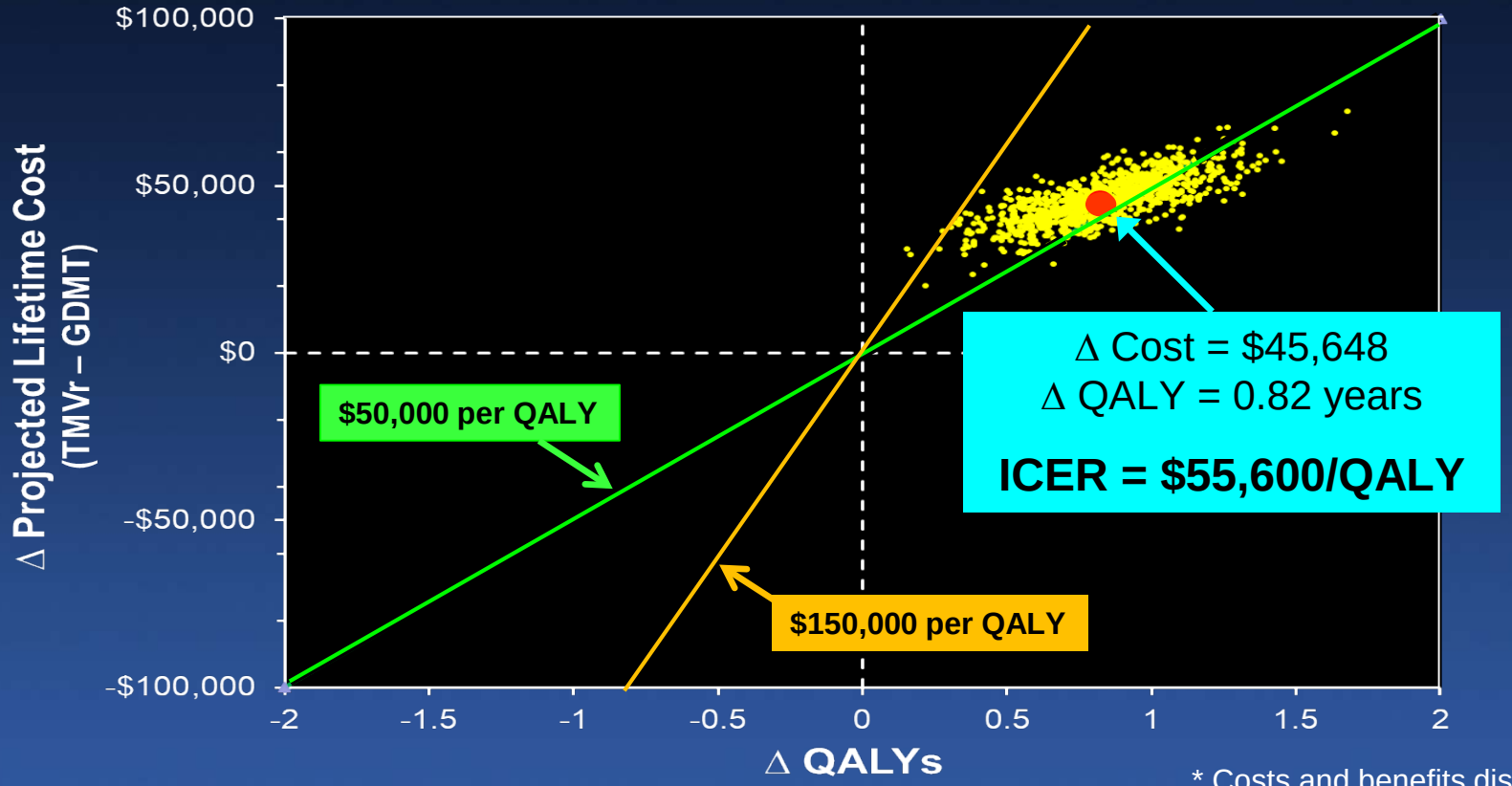
Projected Survival



* Discounted at 3%

TMVR vs. GDMT Cost Effectiveness

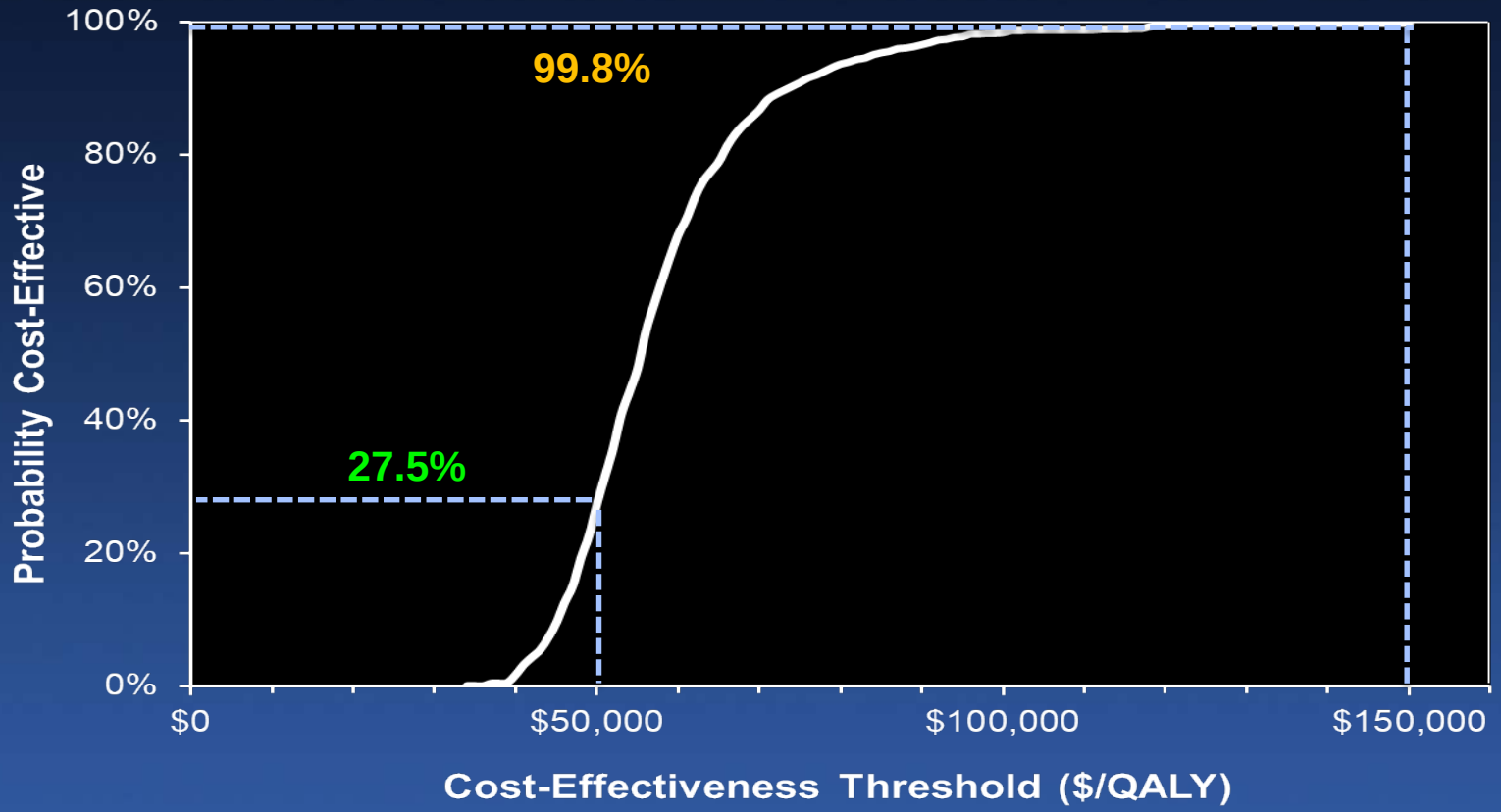
Base Case Analysis



* Costs and benefits discounted at 3%

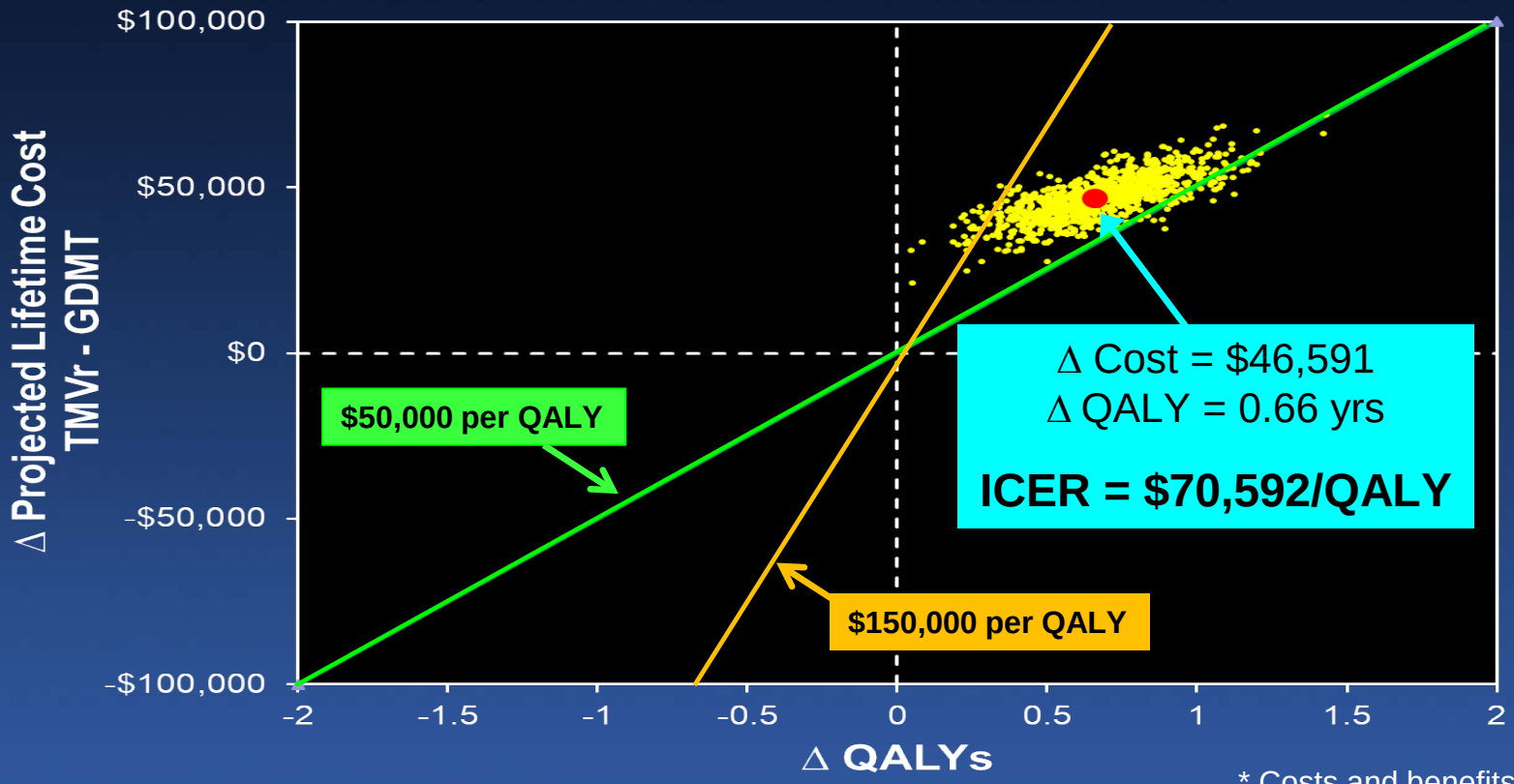
Cost-Effectiveness Acceptability Curve

Base Case Analysis



TMVR vs. GDMT Cost Effectiveness

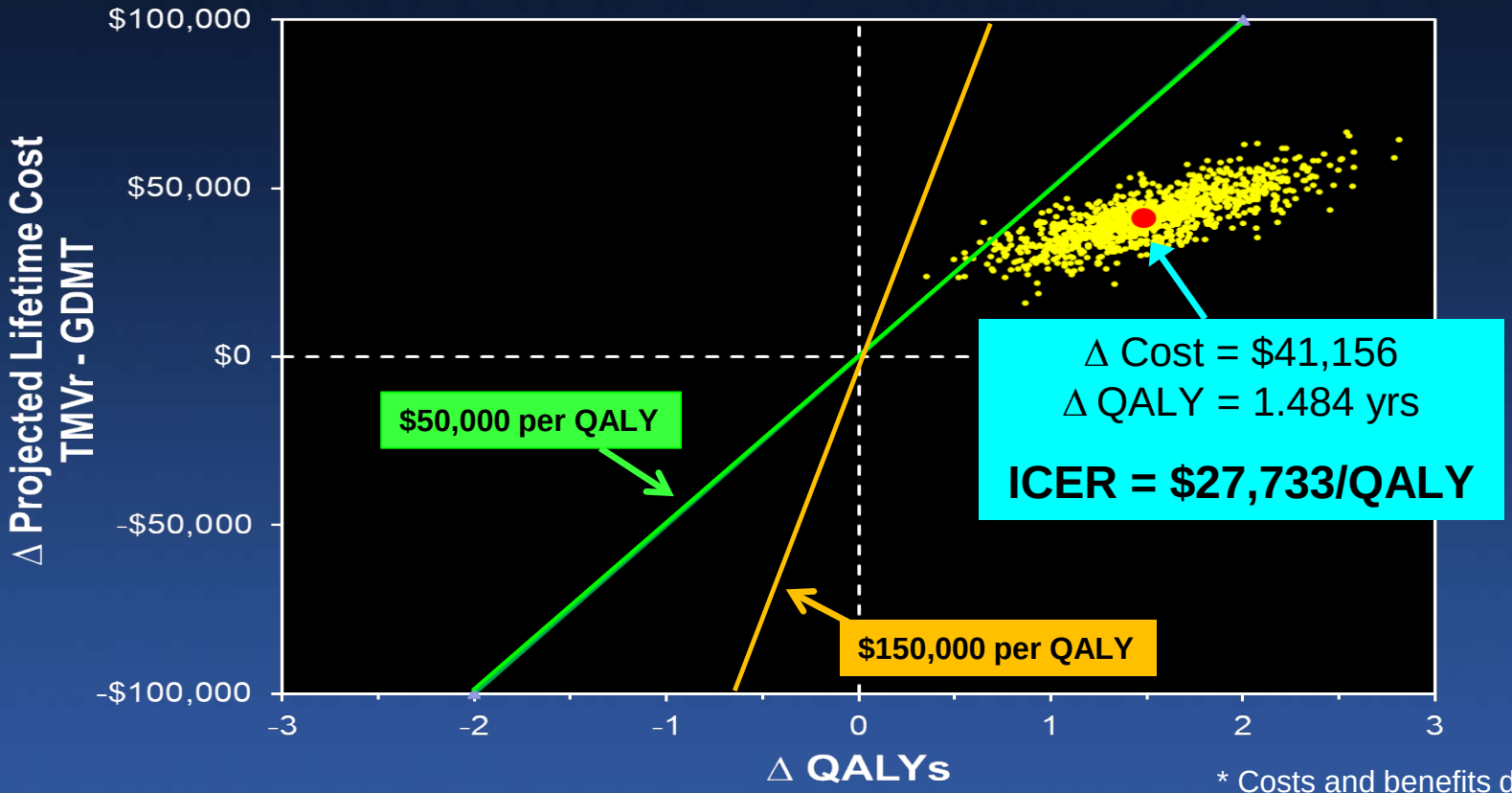
Worst Case Scenario: No Benefit after 2 years



* Costs and benefits discounted at 3%

TMVR vs. GDMT Cost Effectiveness

Best Case Scenario: In-trial benefit continues indefinitely



* Costs and benefits discounted at 3%

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Subgroup Analyses

	ICER ($/QALY)	Probability < $50K/QALY	Probability < $150K/QALY
Age			
< 75 (n = 323)	$39,945	84%	100%
≥ 75 (n = 291)	$91,512	0%	91%
Sex			
Male (n = 393)	$63,003	12%	98%
Female (n = 221)	$42,828	72%	99%
Baseline LVEF			
< 30% (n = 274)	$38,619	90%	100%
≥ 30% (n = 301)	$91,872	3%	72%
Etiology of Cardiomyopathy			
Ischemic (n = 373)	$72,931	7%	90%
Non-Ischemic (n = 241)	$44,614	67%	99%

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Summary

- TMVr reduced 2-year follow-up costs by >$11,000/patient when compared with GDMT alone
- Cumulative 2-year costs remained higher by ~$35,000/patient with TMVr due to the upfront cost of the index hospitalization
- Over a lifetime horizon, TMVr was projected to increase quality-adjusted life expectancy by 0.82 QALYs at an incremental cost of $45,648, yielding a lifetime ICER of $55,600/QALY gained

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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

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Baron SJ, Wang K, Arnold SV, Magnuson E, Whisenant B, Brieke A, Rinald M, Asgar, AW, Lindenfeld J, Abraham WT, Mack MJ, Stone GW, Cohen DJ on behalf of the COAPT Investigators. Cost-effectiveness of transcatheter mitral valve repair versus medical therapy in patients with heart failure and secondary mitral regurgitation: Results from the COAPT trial. *Circulation* 2019. *In Press*.