

Cost-Effectiveness of TMVr for Patients with Heart Failure and Secondary Mitral Regurgitation Results from the COAPT Trial

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Disclosures

Grant Support/Drugs

MyoKardia/BMS

Grant Support/Devices

- Edwards Lifesciences
- Medtronic
- Corvia
- I-Rhythm

- Abbott Vascular
- Boston Scientific
- Phillips
- Zoll/Therox

Consulting/Advisory Boards

- Medtronic
- Boston Scientific
- Corvia

- Edwards Lifesciences
- Abbott Vascular
- Impulse Dynamics



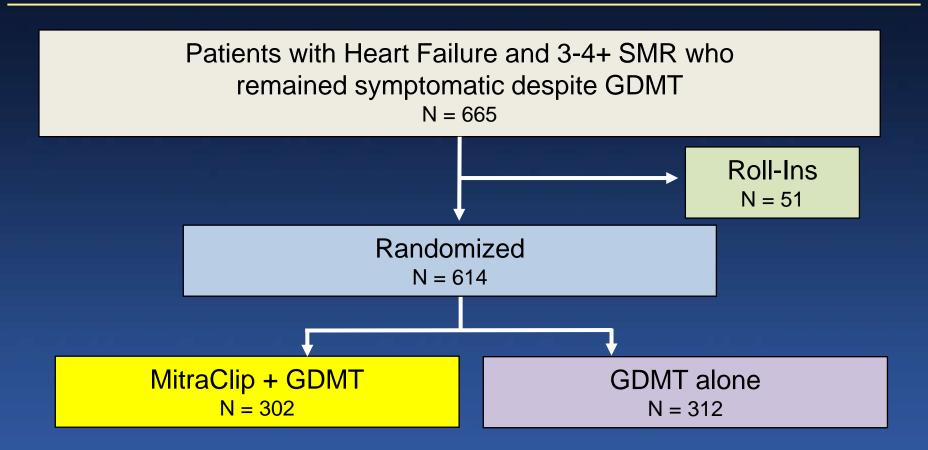
Background

 Recently, the COAPT trial demonstrated that transcatheter mitral valve repair (TMVr) using the MitraClip 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 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)

Analysis Population

Intention-To-Treat Population

General Approach

In-trial economic analysis based on observed data (through 2 years)
 followed by patient-level lifetime projections of survival, quality-adjusted life expectancy, and costs



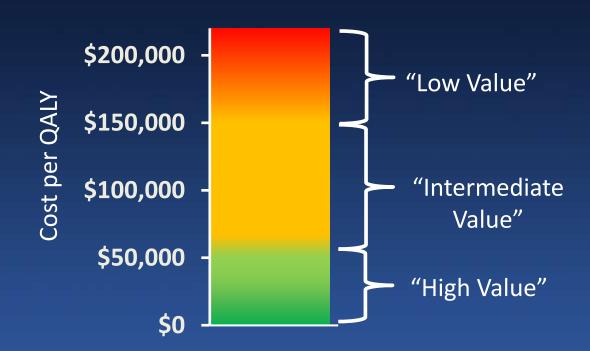
Methods: Scenario Analyses

- 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



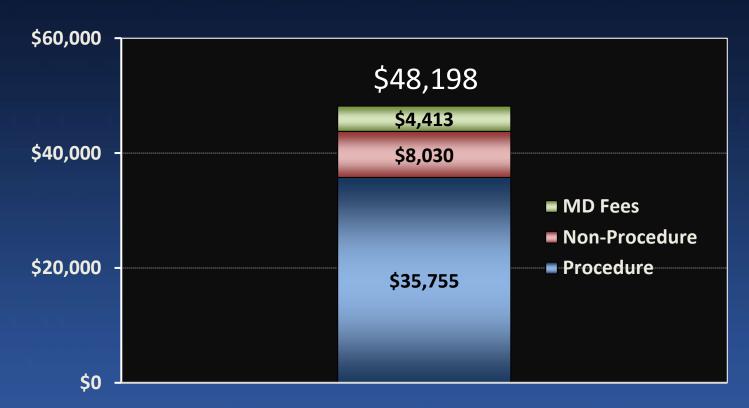
Incremental Cost-Effectiveness

- 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





Index TMVr Hospitalization Cost



^{*} Patients who underwent attempted MitraClip procedure (N = 293)

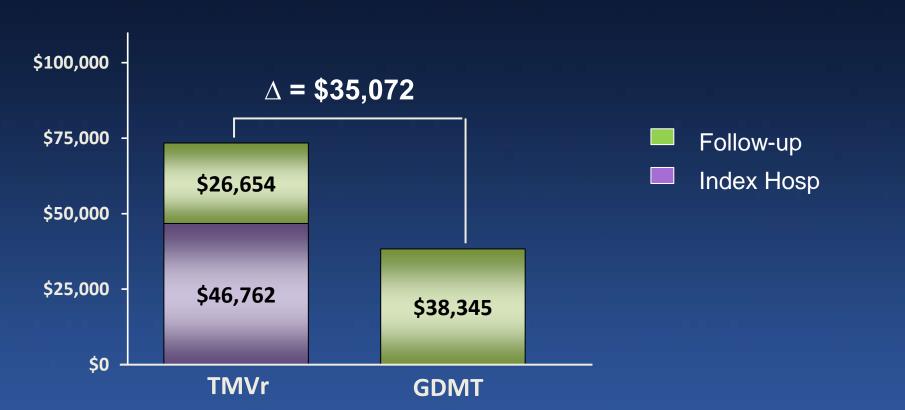
Follow-Up Resource Utilization

Count p	er 100	patients
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	TMVr	GDMT	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
Follow-up Costs	\$26,654	\$38,345	0.018 Adjusted for censor



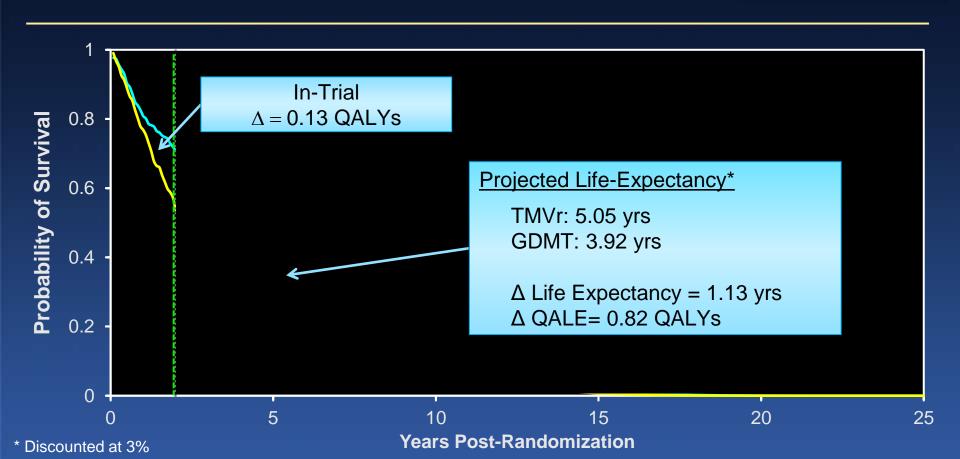
Cumulative 2-Year Costs



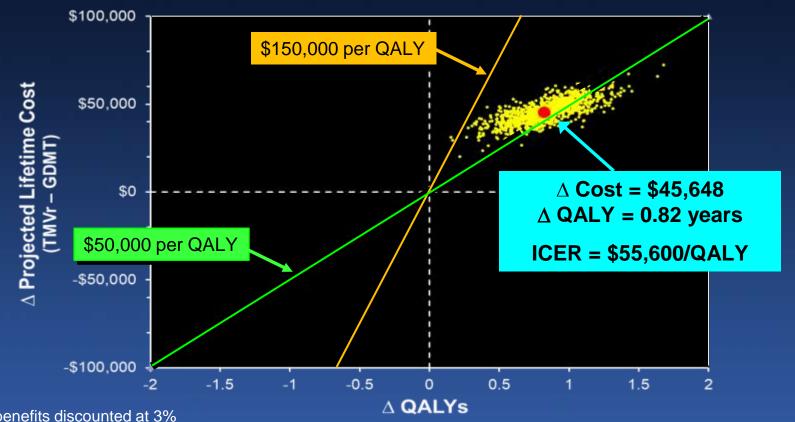
^{*} Includes all Intention-To-Treat Patients



Projected Survival (Base Case)

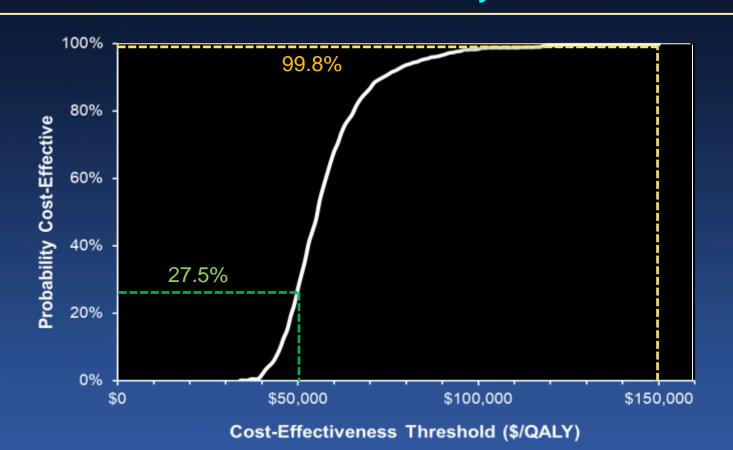


TMVR vs. GDMT Cost Effectiveness Base Case Analysis



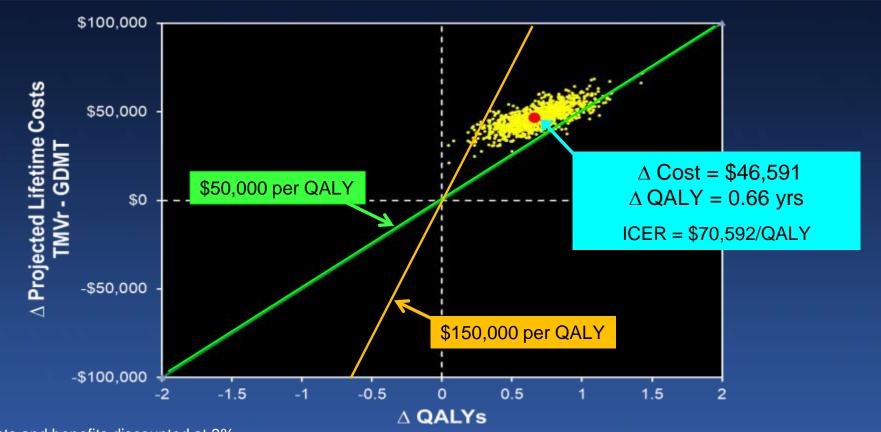
^{*} Costs and benefits discounted at 3%

Cost-Effectiveness Acceptability Curve Base Case Analysis



TMVR vs. GDMT Cost Effectiveness

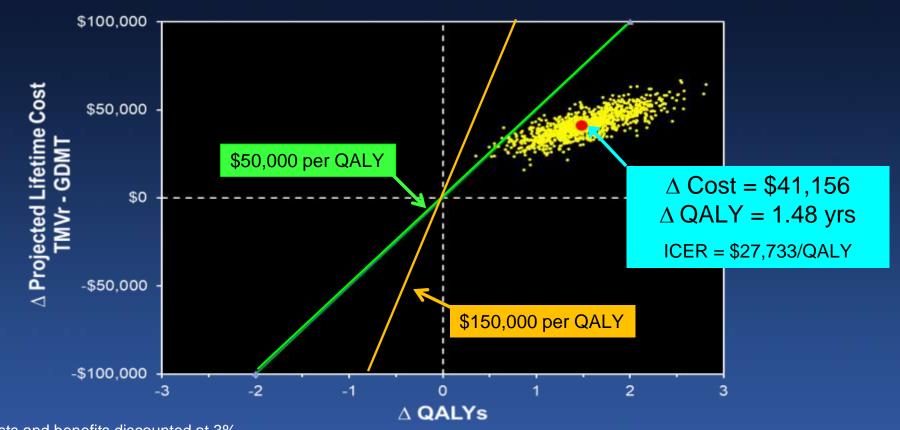
Worst Case Scenario: No benefit after 2 years



^{*} 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%



Subgroup Analyses

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



Summary/Conclusions

- For symptomatic heart-failure patients with 3-4+ SMR (similar to those enrolled in COAPT), TMVr increases quality-adjusted life expectancy compared with GDMT at an incremental cost per QALY gained consistent with <u>intermediate-to-high economic</u> <u>value</u> 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