Quality of Life after TAVR What do we know? Why should you care?

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QOL after TAVR- Why Should We Care?

Inoperable Patients

- PARTNER B demonstrated substantial and sustained survival benefit compared with standard care
- However, given the advanced age and multiple comorbidities present in the inoperable patients, improved QOL may be an even more important goal of therapy
- In the absence of improved QOL, it is questionable whether many inoperable patients would want to live longer

QOL after TAVR- Why Should We Care?

Intermediate and High-Risk Surgical Candidates

- No significant survival benefit of TAVR compared with AVR in most studies and some complications may even be increased
 - Vascular complications, paravalvular Al
- Therefore, evidence of improved QOL in either the short or long-term is critical to demonstrating the value of TAVR

TAVR: QOL Insights

Quality of life improves substantially after TAVR, even among inoperable patients

Primary Endpoint: KCCQ Overall Summary



Reynolds MR, et al. Circulation 2011;124:1964-72

PART

KCCQ: Interpretation



Change in KCCQ-Overall Summary Score

Am Heart J 2005; 150:707-15



KCCQ-Summary: Substantial Improvement *

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* Improvement \geq <u>20 points</u> vs. baseline among patients with available QOL data

Generic QOL and Utilities



EQ-5D Utilities



SF-12 Mental



5 point difference comparable to 10-year age difference

Reynolds MR, et al. Circulation 2011;124:1964-72

MCID = minimum clinically important difference

PARTNER

TAVR: QOL Insights

Quality of life benefits of TAVR are durable among surviving patients

CoreValve Extreme Risk: 3 Year QOL KCCQ Overall Summary

KCCQ Overall Summary Score



* Iliofemoral Access

Baron SJ, et al. AHJ 2017 (in press)

TAVR: Key QOL Insights

Although QOL improves substantially after TAVR, on an individual level there is still considerable heterogeneity of benefit

KCCQ-Summary: Significant Improvement *





* Improvement \geq <u>10 points</u> vs. baseline among patients with available QOL data

TAVR: Key QOL Insights

"Less invasive" procedures don't always result in better quality of life

PARTNER A KCCQ Overall Summary





Growth curve analysis; adjusted for baseline MCID = minimum clinically important difference

Reynolds MR, et al. J Am Coll Cardiol 2012

KCCQ Overall Summary TF Subgroup





P-values are for mean treatment effect of TAVR vs. AVR

Reynolds MR, et al. J Am Coll Cardiol 2012

KCCQ Overall Summary TA Subgroup





P-values are for mean treatment effect of TAVR vs. AVR

Reynolds MR, et al. J Am Coll Cardiol 2012 (in press)

CoreValve US Clinical Trials

CoreValve High Risk Benefit of TAVR over SAVR by Access Site



* Non-IF = TAo or Subclavian

Arnold SV, et al. J Am Coll Cardiol Intv 2015;8:1207-17

Differential QOL Outcomes with Femoral vs. Alternative Access: *Potential Mechanisms*

- Non-IF patients are different-- the best TAVR candidates were selected for a TF approach
- Inexperienced operators/Learning curve
 - Improved results seen for other outcomes in continued access TA cohort → ? QOL impact
- Less invasive isn't necessarily less painful
 - Thoracic surgery experience suggests that median sternotomy is generally less painful than other forms of thoractomy

PARTNER A

TF vs. TA: Indirect Comparison KCCQ Summary Scale



Differential QOL Outcomes with Femoral vs. Alternative Access: *Potential Mechanisms*

- Non-IF patients are different-- the best TAVR candidates were selected for a TF approach
- Inexperienced operators/Learning curve
 - Seems unlikely since similar results were observed in PARTNER 2A as well
- Less invasive isn't necessarily less painful
 - Thoracic surgery experience suggests that median sternotomy is generally less painful than other forms of thoractomy

Differential QOL Outcomes with Femoral vs. Alternative Access: *Potential Mechanisms*

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TAVR QOL



- For extreme risk/inoperable patients with severe AS, TAVR provides substantial and sustained QOL benefits compared with medical thrapy alone
- For both high risk and intermediate risk patients, transfemoral (but not transthoraic) TAVR provides an early QOL benefit compared with SAVR and similar late QOL
- Further studies are necessary to...
 - Understand the long-term (5-10 year) durability of QOL benefit of TAVR vs. SAVR
 - Identify patients who will not benefit from TAVR