Discussion: GARY Registry
AHA November 14, 2016

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Disclosure: For my role in the PARTNER Trials I receive reimbursement for travel and customary expenses related to Trial management
GARY: Summary Comments

- Design and exclusions appear appropriate
- The intermediate risk proportion (23%) is about right
- Overall lower risk than PARTNER II, esp SAVR
- Excellent mortality in both arms (O:E 0.7 in both)
- Stroke similar, 19% PPM in TAVR

- Site-dependent effects potentially very confounding
- Can propensity analysis hope to balance such marked baseline differences?
New York State Cardiac Database 2011 through 2014

Volume and Mortality (%) by Type of procedure by Year

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<tbody>
<tr>
<td>Aortic Valve Replacement</td>
<td>2618 (2.18)</td>
<td>2617 (2.03)</td>
<td>2506 (1.76)</td>
<td>7741 (1.99)</td>
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<tr>
<td>TAVR</td>
<td>715 (6.71)</td>
<td>1350 (6.37)</td>
<td>1771 (4.80)</td>
<td>3836 (5.71)</td>
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Unpublished data, courtesy of Ed Hannan
Presented 11-4-16 to NYS Cardiac Advisory Committee
“Real-World/All-Comers” Challenges for TAVR: Durability

Freedom from THV degeneration

AV mean gradient population trends

Courtesy of Dvir et al
EuroPCR, May 2016
Unpublished data

Raw Data
GARY: Looking Ahead

Which better represents the future in intermediate risk: GARY or Sapien 3i?

Will a mortality gap persist in low risk?

Centers of excellence vs real world

Durability remains the big unknown