

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?



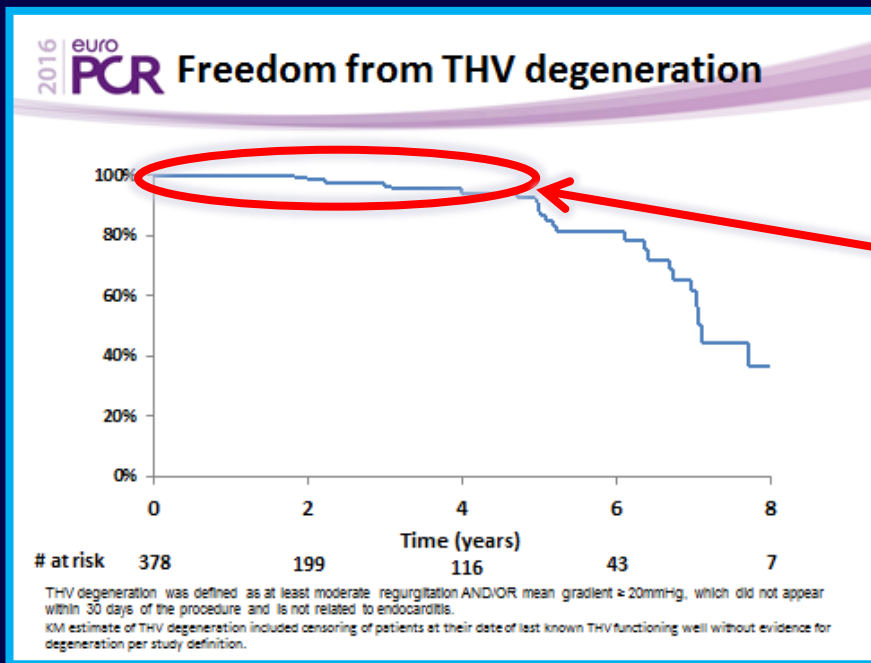
New York State Cardiac Database 2011 through 2014

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

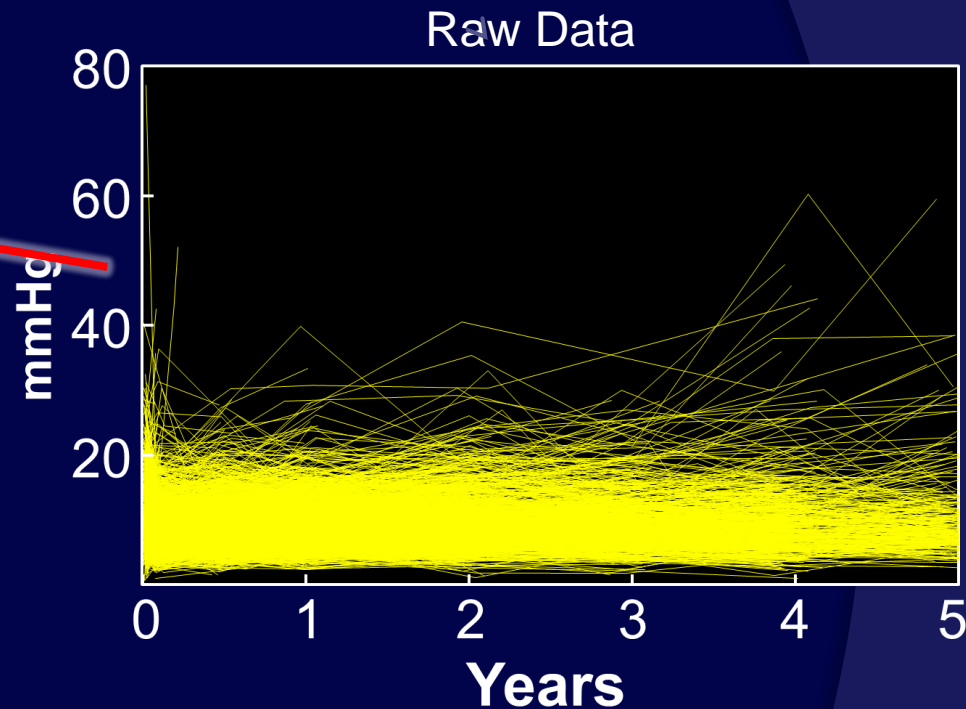
Type of Surgery	12/2011- 11/2012	12/2012- 11/2013	12/2013- 11/2014	12/2011- 11/2014
Aortic Valve Replacement	2618 (2.18)	2617 (2.03)	2506 (1.76)	7741 (1.99)
TAVR	715 (6.71)	1350 (6.37)	1771 (4.80)	3836 (5.71)

Unpublished data, courtesy of Ed Hannan
Presented 11-4-16 to NYS Cardiac Advisory Committee

“Real-World/All-Comers” Challenges for TAVR: Durability



Courtesy of Dvir et al
EuroPCR, May 2016
Unpublished data



AV mean gradient population trends
Douglas et al, TCT November 2016



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

