What have we learned from the U.S. TAVR Registry?

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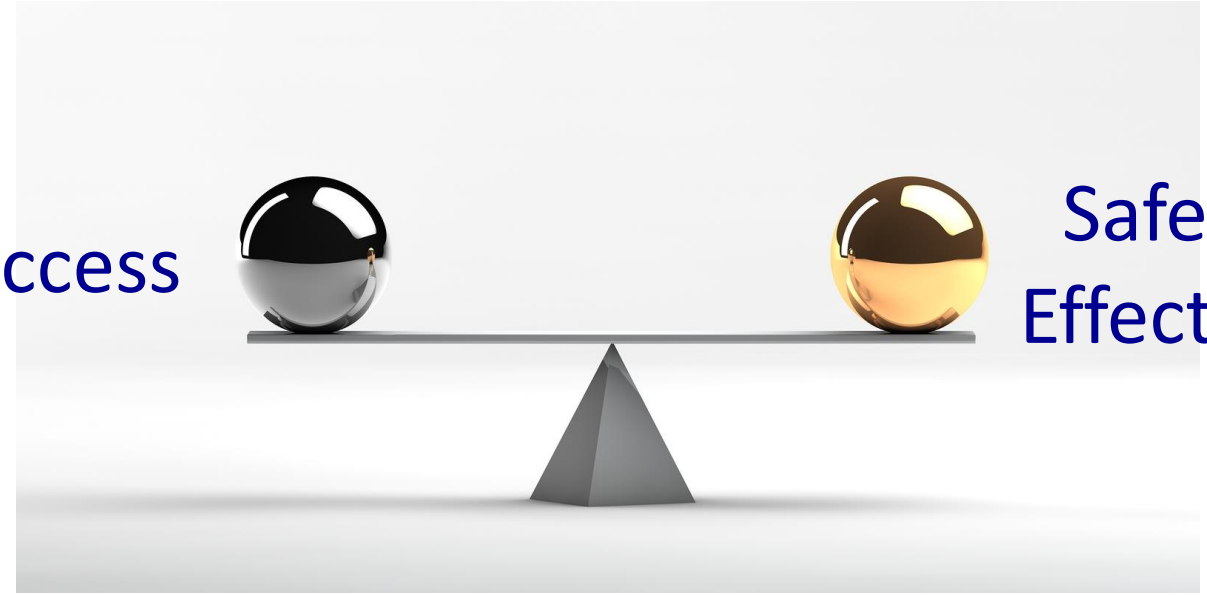
ACC Middle East Conference 2016

Medical device approval and surveillance

Access



Safety and Effectiveness

P T. 2011 Jul; 36(7): 395, 4

PMCID: PMC3171816

Critics Assail F

Slow Review Time

Stephen Barlas

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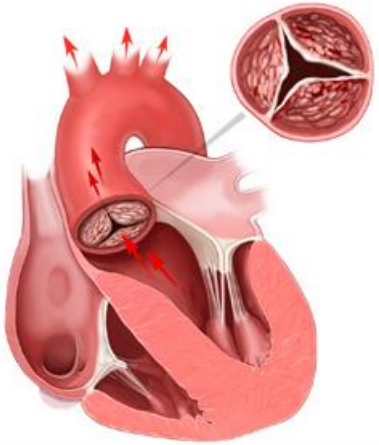
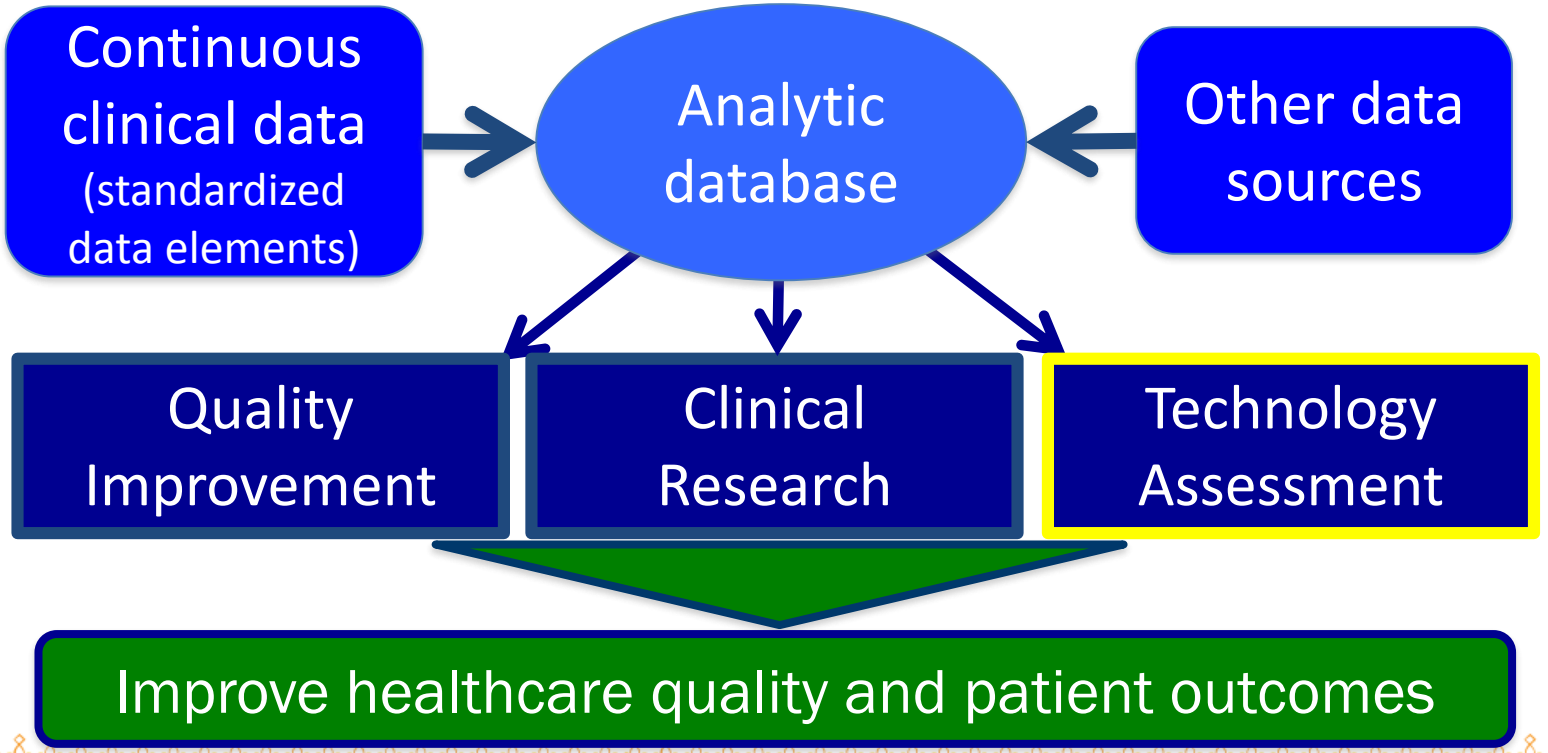


The FDA is attempti … medical devices. Those complaints co… t if the FDA doesn't speed … tals in the U.S. will see patien… fer. The Government A… s criticizing the FDA's approv… atients who might receive a fault…

First U.S. feasibility trial =
4 years after approval in Europe

First FDA approval in US in 2011 =
43rd country to approve

Can clinical registry programs help?



Bhatt D et al. ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise. *J Am Coll Cardiol*. 2015 Nov 17;66(20):2230-45.

Transcatheter Valvular Therapeutics (TVT) Registry

- Developed with U.S. Food and Drug Administration, Medicare (primary payer), and industry
- 470 hospitals
- >75,000 TAVR cases
- Peri-procedure, 30-day, and 1-year outcomes data (including quality of life)

Outcomes similar to clinical trials

Original Investigation

Outcomes Following Transcatheter Aortic Valve Replacement in the United States

Michael J. Mack, MD; J. Matthew Brennan, MD, MPH; Ralph Brindis, MD, MPH; John Carroll, MD; Fred Edwards, MD; Fred Grover, MD; David Shahian, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; John S. Rumsfeld, MD, PhD; Kathleen Hewitt, MSN; Cynthia Shewan, PhD; Joan Michaels, RN; Barb Christensen, RN; Alexander Christian; Sean O'Brien, PhD; David Holmes, MD; for the STS/ACC TVT Registry

Table 5. In-Hospital and 30-Day Mortality in the STS/ACC TVT Registry Compared With Previous Studies

	Mortality, No./Total (%)											
	STS/ACC TVT Registry			PARTNER Trial[5,6]			FRANCE 2[19]	SOURCE[20]		GARY[21]		UK SATIRE[22]
	Inoperable	High-Risk		Inoperable	High-Risk							
	TF	TF	TA	TF	TF	TA		TF	TA	TF	TA	
In-hospital	61/139 (5.4)	146/3833 (3.8)	190/2318 (8.2)	NR	NR	NR	NR	NR	NR	138/2694 (5.1)	62/870 (7.1)	NR
30-Day	30/489 (6.1)	77/1687 (4.6)	112/1147 (9.8)	9/179 (5.0)	9/244 (3.7)	9/104 (8.7)	293/3195 (9.2)	29/463 (6.3)	59/575 (10.3)	NA	NA	91/1181 (7.1)

Abbreviations: NR, data not reported; STS/ACC TVT, Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy; TA, transapical; TF, transfemoral.

Mack MJ et al. *JAMA* 2013;310:2069-2077

Registry data support expanded indications

FDA NEWS RELEASE

For Immediate Release: Sept. 23, 2013
Media Inquiries: Susan Laine, 301-796-5349, susan.laine@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA approval expands access to artificial heart valve for inoperable patients

"To support the labeling change, Edwards Lifesciences Corp. submitted data from the Transcatheter Valve Therapy Registry (TVTR) in the United States"

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369510.htm

Original Investigation

Clinical Outcomes at 1 Year Following Transcatheter Aortic Valve Replacement

CONCLUSIONS AND RELEVANCE Among patients undergoing TAVR in US clinical practice, at 1-year follow-up, overall mortality was 23.7%, the stroke rate was 4.1%, and the rate of the composite outcome of death and stroke was 26.0%. These findings should be helpful in discussions with patients undergoing TAVR.


Home > News/Media > Cardiology Magazine > 2014 > 03 > TVT Registry: One-Year Results Show Real-World TAVR Procedures Consistent With Clinical Trials

TVT Registry: One-Year Results Show Real-World TAVR Procedures Consistent With Clinical Trials

March 31, 2014

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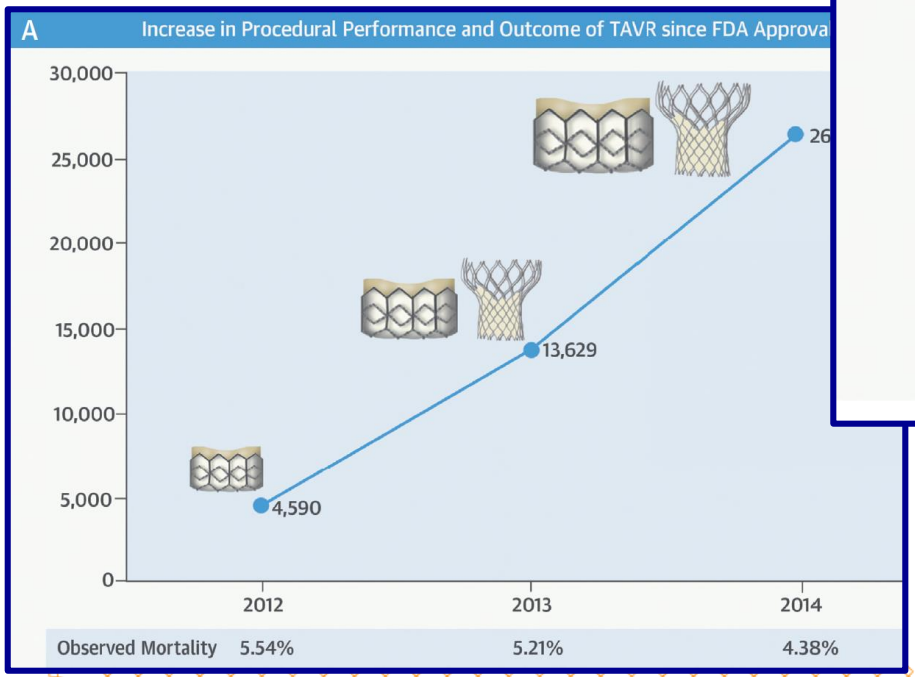
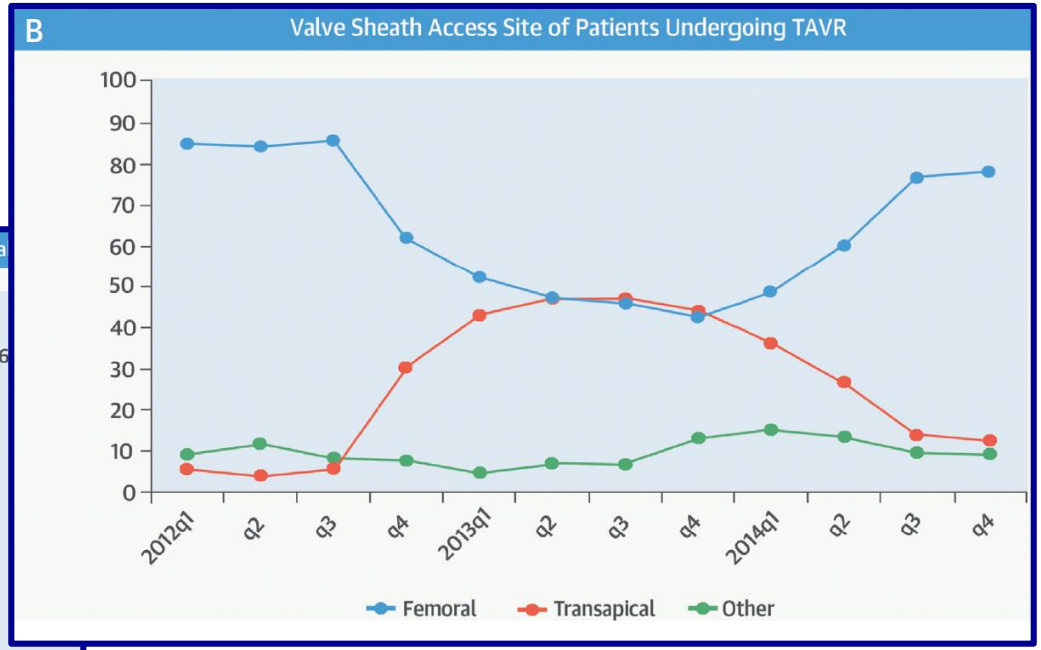
Comments

Recently approved for the treatment of severe, symptomatic aortic stenosis in patients

Annual Outcomes With Transcatheter Valve Therapy

From the STS/ACC TVT Registry





Device complications	
Device complication (any)	2.0
Device migration	0.3
Device embolization, left ventricle	0.3
Device embolization, aorta	0.3
Device recapture or retrieval	0.4
Other device-related event	1.0

Holmes DR Jr. et al. *J Am Coll Cardiol*. 2015. 29;66(25):2813-23

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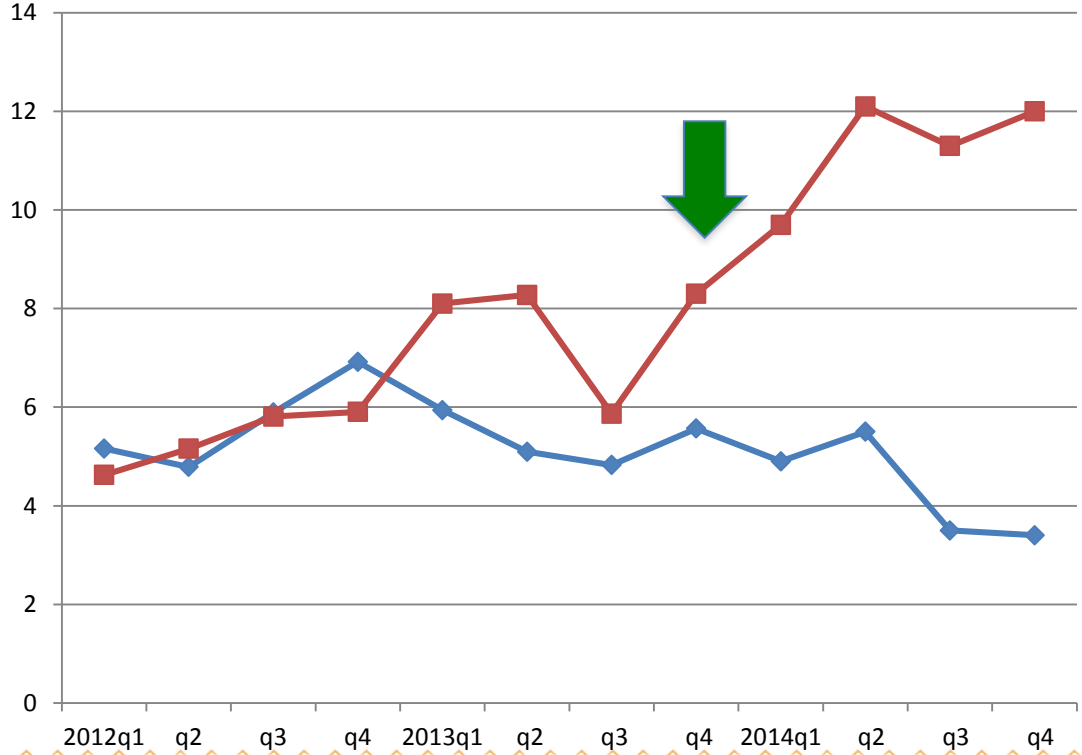
U.S. TAVR Outcomes (in-hospital)

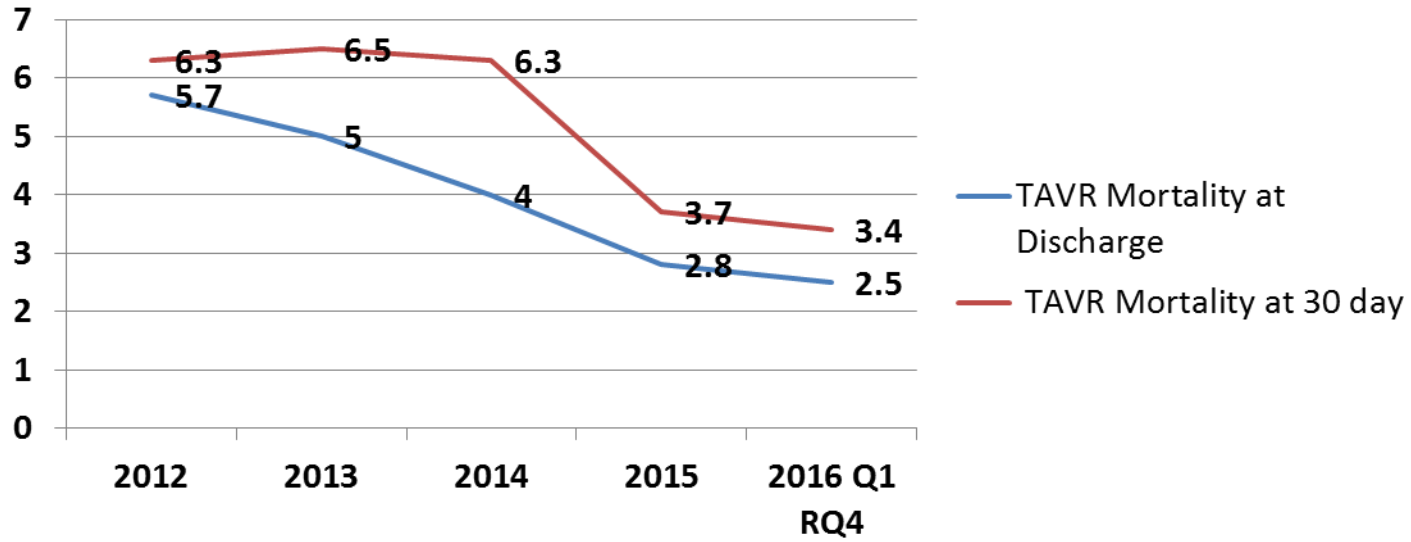


Source: STS/ACC TVT Registry Database
28,658 records from 2012-14

Cardiac arrest

Pacer/ICD

TAVR Mortality at Discharge and 30 Days



SOURCE: STS/ACC TVT REGISTRY DATABASE AS OF JUL 15, 2016

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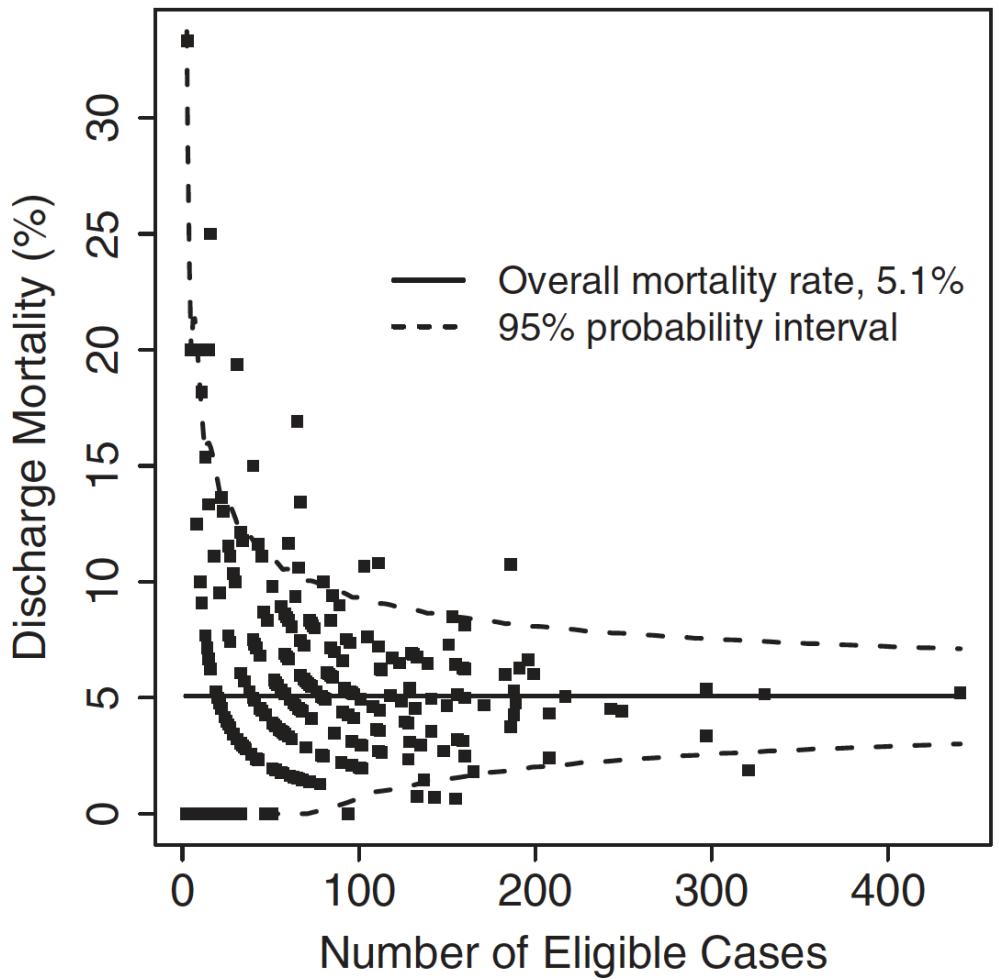


O'Brien SM et al. *Circ Card*
2016;9:560-565

Is treatment effective in subgroups?

Should TAVR be Performed in Nonagenarians? Insights from the STS/ACC TVT Registry

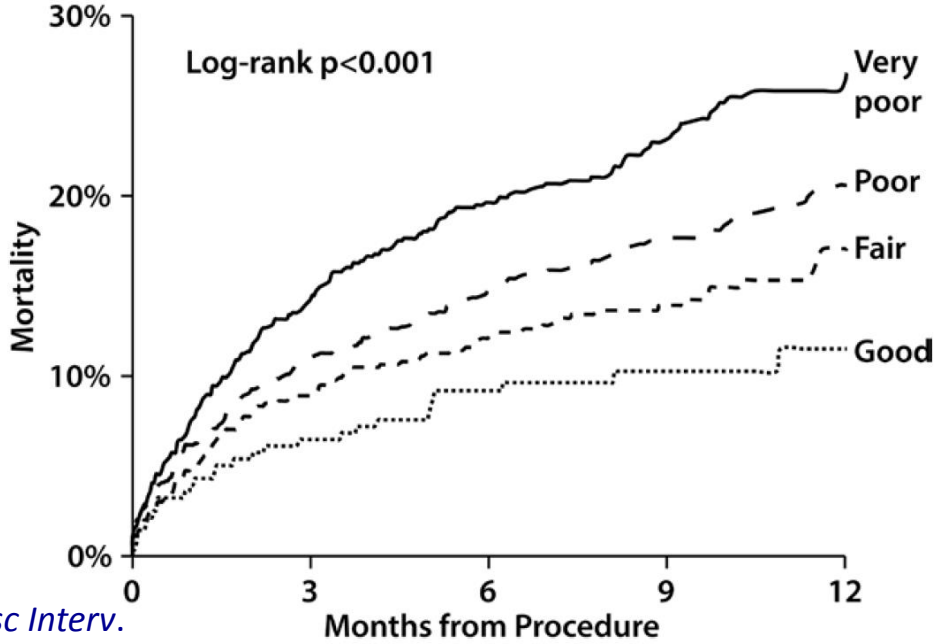
CONCLUSIONS In current U.S. clinical practice, approximately 16% of patients undergoing TAVR are ≥90 years of age. Although 30-day and 1-year mortality rates were statistically higher compared with younger patients undergoing TAVR, the absolute and relative differences were clinically modest. TAVR also improves quality of life to the same degree in nonagenarians as in younger patients. These data support safety and efficacy of TAVR in select very elderly patients.

Arsalan M et al. *J Am Coll Cardiol.* 2016;67:1387-95

Structural Heart Disease

Association of Patient-Reported Health Status With Long-Term Mortality After Transcatheter Aortic Valve Replacement

Report From the STS/ACC TVT Registry



Adjusted HR 2.00; 95% CI 1.58–2.54

Adjusted HR 1.54; 95% CI 1.22–1.95

Arnold SV et al. *Circ Cardiovasc Interv*. 2015 Dec;8(12):e002875.

Health Services and Outcomes Research

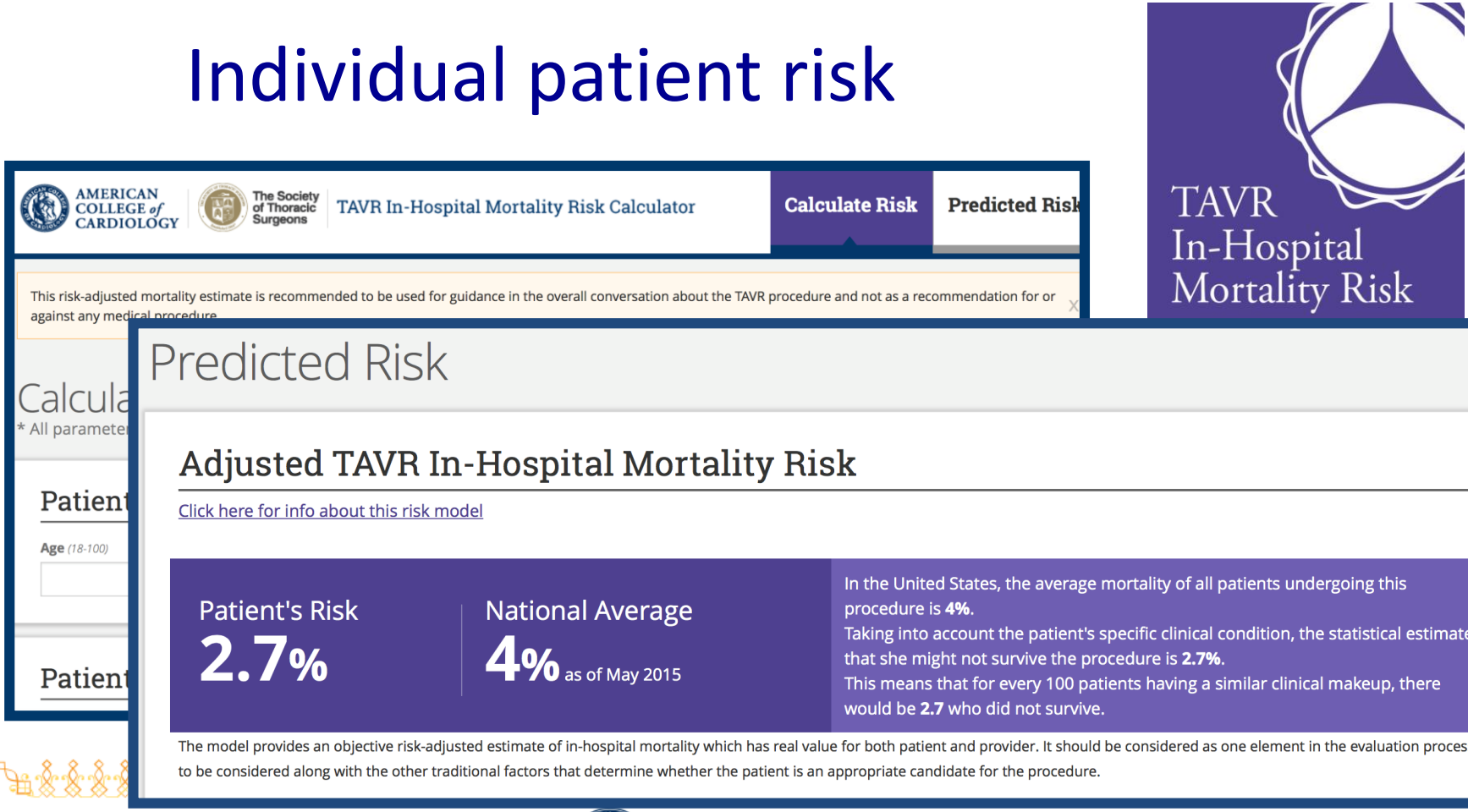
Gait Speed Predicts 30-Day Mortality After Transcatheter Aortic Valve Replacement

Results From the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

- Each 0.2-m/s lower gait speed corresponded to 11% higher 30-day mortality.
- The slowest walkers had 35% higher 30-day mortality than normal walkers, with significantly longer hospital stays and a lower probability of being discharged to home.

Alfredsson J et al. *Circulation*. 2016;133:1351-59

Individual patient risk



http://tools.acc.org/TAVRRisk

What have we learned from the U.S. TAVR Registry?

"Science tells us what we can do;
Guidelines tell us what we should do;
Registries tell us what we're actually doing."

- Lukas Kappenberger, MD

Better health outcomes

Clinical registry programs

Thank you

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