

Using STS/ACC TVT Registry™ Data for Quality Improvement (QI)

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Learning Objectives

- Sources for data analysis for Transcatheter Aortic Valve Replacement (TAVR) patients
- Examples to display this analysis
- Interventions for Quality Improvement



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Overview

- We all want to improve the results of TAVR for our patients.
- The first step is to understand how we are doing.
 - Are our outcomes comparable to other sites?
 - Are we treating similar patients in terms of their risks and burden of comorbidities?
 - How is our program different from others?
- To answer these questions we must compare our data to others.



Benchmarking

- Benchmark – (verb) something that can be used as a way to judge the quality or level of other, similar things
 - a point of reference from which measurements may be made
 - something that serves as a standard by which others may be measured or judged



TVT Registry Benchmarking

1. Benchmarking will be standard in TVT Registry Site Reports later in 2014
 - Starts with in-hospital metrics and then expand to follow-up outcomes.
2. What other sources of benchmarking can be used now?
 - First publication of data from TVT Registry:
 - Clinical trials using same device in similar patient populations



Original Investigation

Outcomes Following Transcatheter Aortic Valve Replacement in the United States

Michael J Mack, MD, J Matthew Brennan, MD, MPH, Rabih Brindji, 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. Burnett, MD, PhD, Kathleen Hewitt, MSN, Cynthia Shewan, PhD, Joan Michaelis, RN, Barb Christensen, RN, Alexander Christian, Sean O'Brien, PhD, David Holmes, MD, for the STS/ACC TVT Registry

CONCLUSIONS AND RELEVANCE Among patients undergoing TAVR at US centers in the STS/ACC TVT Registry, device implantation success was achieved in 92% of cases, the overall in-hospital mortality rate was 5.5%, and the stroke rate was 2.0%. Although these postmarket US approval findings are comparable with prior published trial data and international experience, long-term follow-up is essential to assess continued efficacy and safety.

JAMA. 2013;310(19):2069-2077.



Where To Start And What Numbers Are Important?

- STS/ACC TVT Registry Extracts
- STS/ACC TVT Registry Beta Reports
- VARC 2 Endpoints¹
- PARTNER I² and PARTNER II³ (research outcomes)
- Published Articles⁴
- State reporting if available
- Health System comparison

Valve Academic Research Consortium (VARC)



STS/ACC TVT Registry Beta Report Simplified

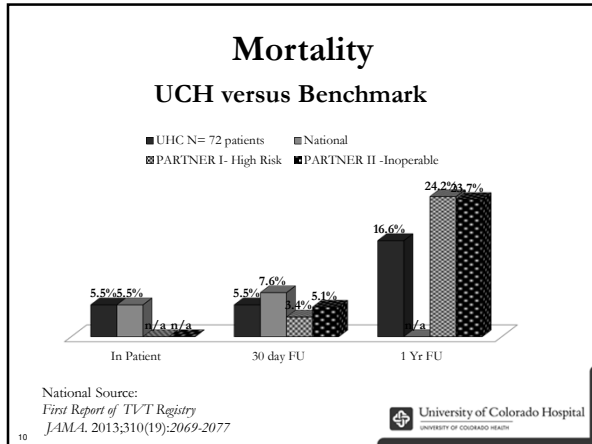
White	97%	
Male	41%	
Average Age	81	
Medicare	97%	
Access	60.0%	Femoral
	37.5%	TransApical
	1.4%	Transaortic
Aborted	8.3%	6
Median ICU LOS	52 hrs	
Median LOS	7 days	
Median pLOS	6 days	
pLOS >6 days	44%	
Actual In House Mortality	5.5% of 72	2-pulmonary, 1-infection, 1-cardiac
Discharge Location	79%	Home
		Other
	3%	Hospital
	4%	Nursing
	13%	Home
		Extended care/TCU/Rehab

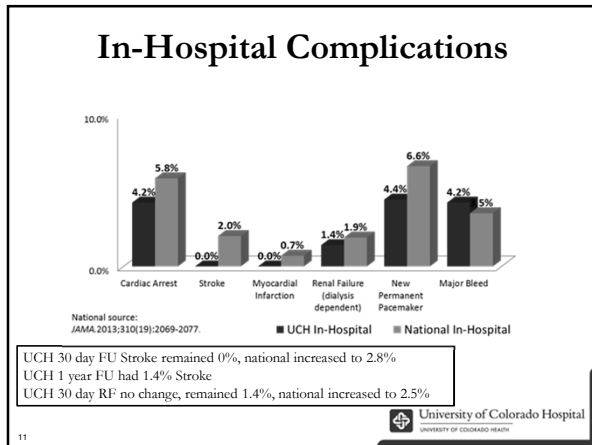


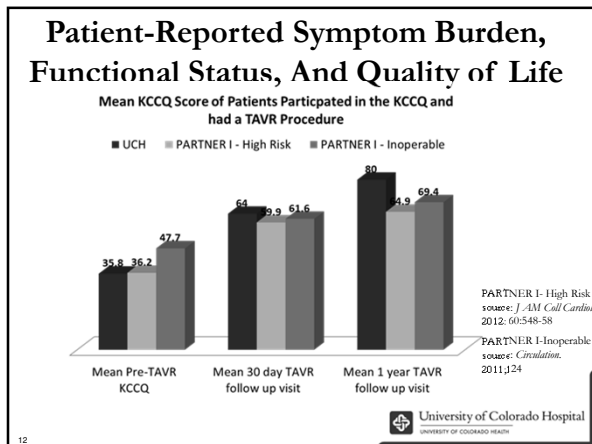
Overview of UCH Experience

- Long-standing structural heart disease program
- TAVR clinical program started with commercial approval of Sapien
 - 72 commercial cases up until December 2013
- TAVR research program
 - PARTNER 2 clinical site, currently enrolling in Sapien 3 protocol in intermediate risk patients
 - 14 investigative cases up until March 2014










Hospitalization Metrics

National source:
JAMA. 2013;310(19):2069-2077

	Inoperable		High Risk	
	TF (n=12)	Alternative (n=8)	TF (n=29)	Alternative (n=23)
	Average ICU Stay (Hours)	64 vs 37	77 vs 55	65 vs 34
Average pLOS (Days)	6 vs 5	9 vs 8	6 (29) 5	9 vs 8

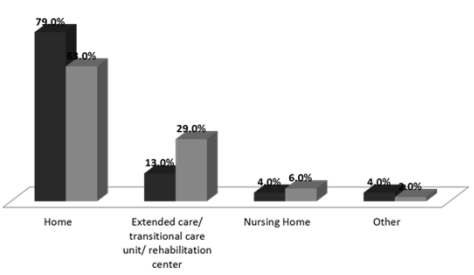
At UCH we are in the process of implementing Transcatheter Aortic Valve Replacement Optimal Clinical Care Pathways through a study.

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Discharge Disposition

■ UHC ■ National



Disposition	UHC (%)	National (%)
Home	79.0%	84.0%
Extended care/transitional care unit/rehabilitation center	13.0%	29.0%
Nursing Home	4.0%	6.0%
Other	4.0%	10.0%


National Source:
JAMA. 2013;310(19):2069-2077

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Next Steps:

- Include TAVR team, at least quarterly with outcomes for feedback and insights
- Internal review of all mortality cases, lessons to learn and patient selection
- Review all outlier patients for trends and insights
- Share outcomes with referring physicians and patients
- Act on the DATA!
 - Implement clinical care pathways to improve post procedure LOS

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References

- ¹A. Pieter Kappetein, Stuart J. Head, Philippe Genereaux, et al., "Updated Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation." *J Am Coll Cardiol*. (2012);60:1438-1454.
- ²Carig R. Smith, MD; Martin B. Leon, MD; Michael J. Mack, MD; et al., "Transcatheter versus Surgical Aortic Valve Replacement in High-Risk Patients." *N ENGL J Med*. (2011);364:2187-98.
- ³Martin B. Leon, MD on behalf of The Partner Trial Investigators, "A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: Partner II, Inoperable Cohort." *ACC 2013*, San Francisco, March 10, 2013.
- ⁴Michael J. Mack, MD; Matthew Brennan, MD, MPH; Ralph Brindis, MD, MPH; John Carroll, MD; Fred Edwards, MD; Fred Grover, MD; David Shahian, MD; 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 Christan; Sean O'Brien, PhD; David Holmes, MD, for the STS/ACC TVT Registry. "Outcomes Following Transcatheter Aortic Valve Replacement in the United States." *JAMA*. (2013);310(19):2069-2077.
- Mathew R. Reynolds, MD, MSE; Elizabeth A. Magnuson, ScD; Yang Lei, MSE; et al., "Health-Related Quality of Life After Transcatheter Aortic Valve Replacement in Inoperable Patients With Severe Aortic Stenosis." *Circulation*. (2011); 124.
- Mathew R. Reynolds, MD, MSE; Elizabeth A. Magnuson, ScD; Kaijun Wang, PhD; et al. "Health-Related Quality of Life After Transcatheter or Surgical Aortic Valve Replacement in High-Risk Patients With Severe Aortic Stenosis." *J Am Coll Cardiol*. (2012);60:548-58.