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The Case for Interventional Cardiology Devices: TAVR as a model

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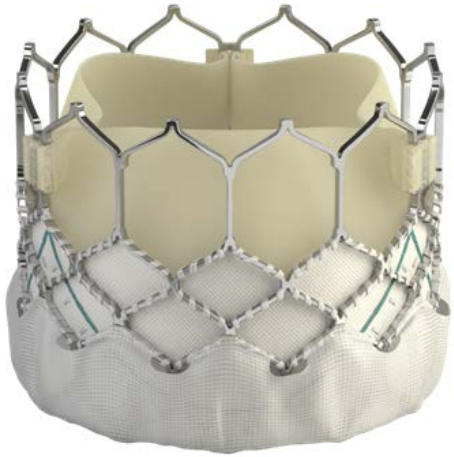
Disclosures

- I have no financial relationships to disclose
- I am an investigator for the PARTNER 2 (Edwards) and SALUS (Direct Flow) trials
- I will be discussing off-label uses, as well as non- FDA approved devices



Evolut R 26mm

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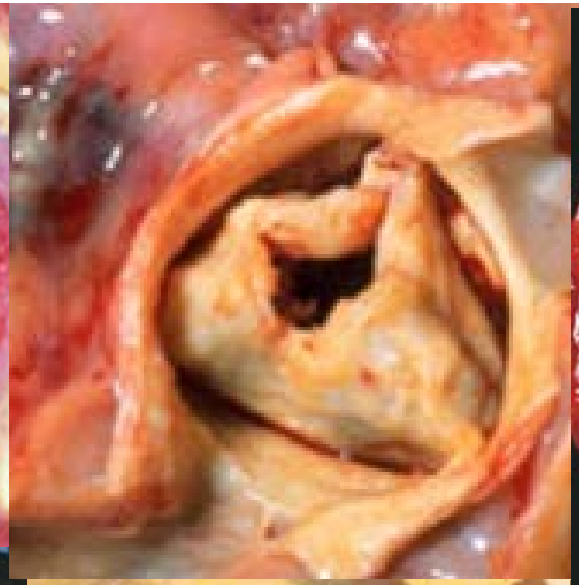
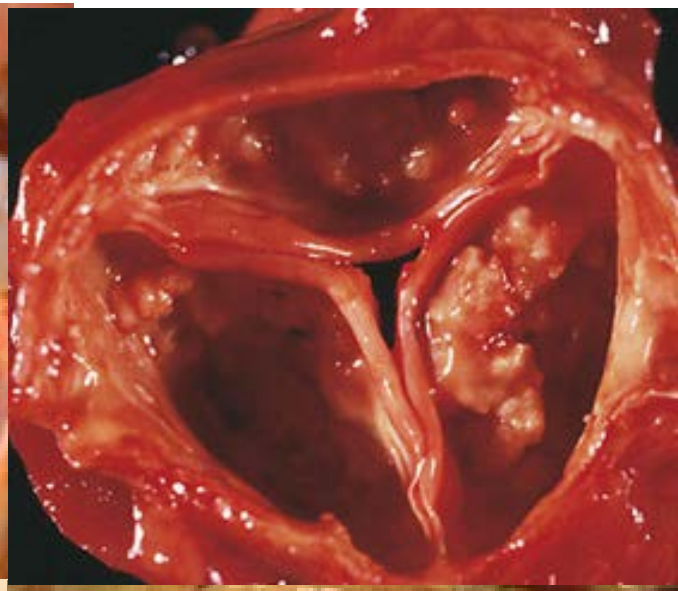
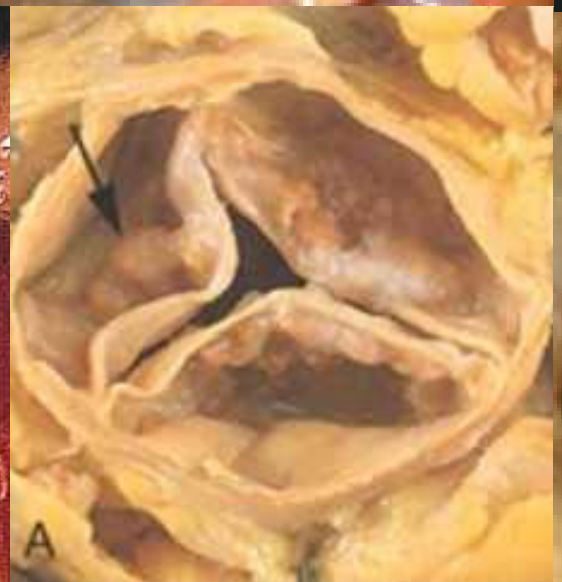
Aortic Stenosis







Aortic Stenosis

- Prevalence of severe, symptomatic AS in pts 75 or older is 3.4%
- Mortality and cost in these patients is high when left untreated

JAm Coll Cardiol. Aortic Stenosis in Elderly. 2013;62:1002-1012

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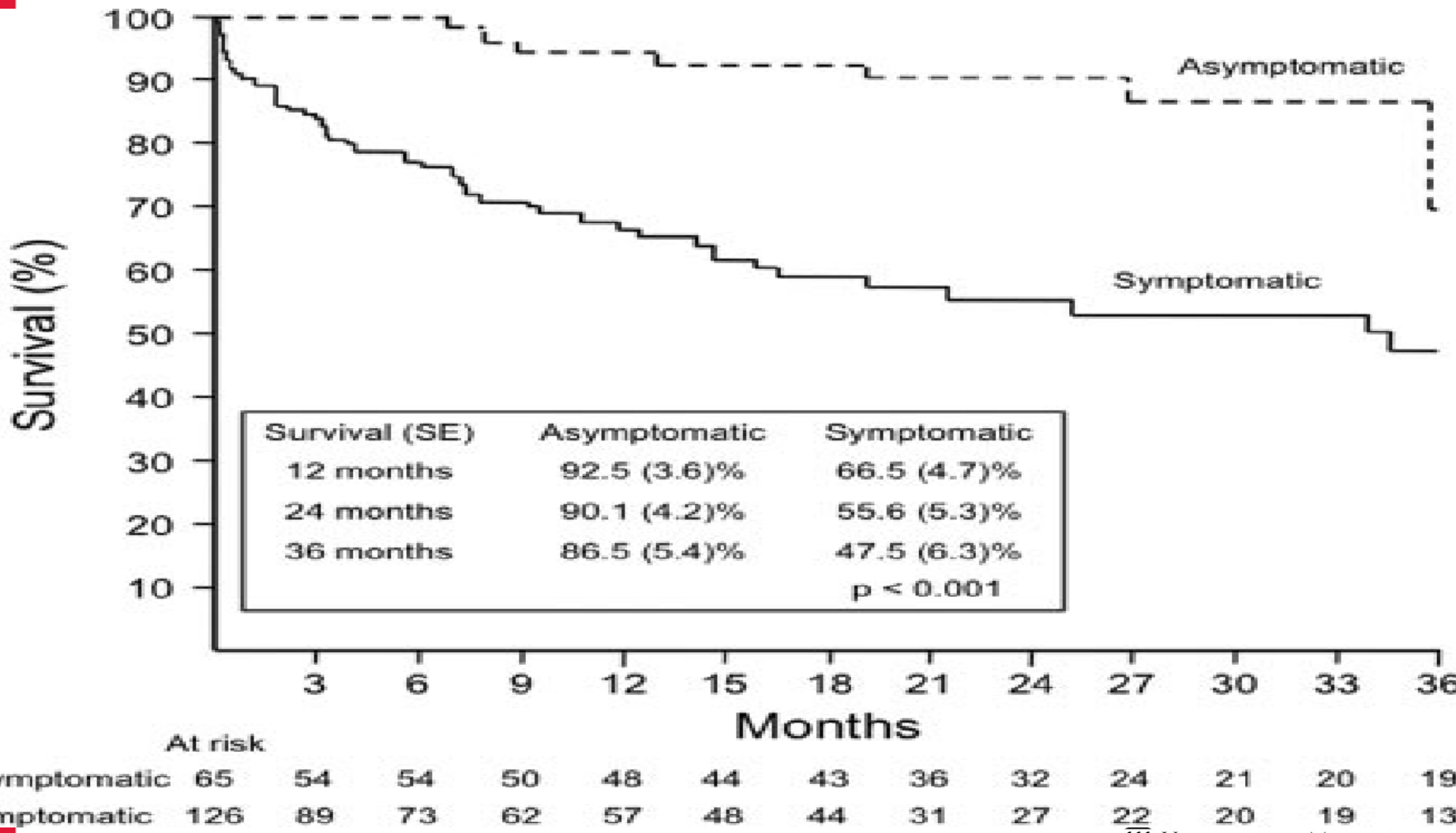
Medically Managed AS=death



Circ Cardiovasc Qual Outcomes. 2009 Nov;2(6):533-9.

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Medically Managed AS=cost

Using 2003 Medicare Administrative Data:

- 5 year survival 12%; mean survival 18 months
- 5 year costs $65000; annual mean cost $29,000

(***Circ Cardiovasc Qual Outcomes. 2012;5:697-704.***)

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Aortic Stenosis

- What are the reasons patients don't undergo AVR:
  - –Advanced age
  - –Worsening ejection fraction
  - –Increasing comorbidities

Circ Cardiovasc Qual Outcomes. 2009 Nov;2(6):533-9.

New Transcatheter Valves

Figure 1. Sadra Medical Lotus™ aortic valve.
Courtesy of Sadra Medical, Inc./Boston Scientific, Natick, Massa

Figure 2. Direct Flow Medical aortic valve.

Figure 3. Symetis Acurate TA™ Aortic Bioprosthesis.

Figure 4. St. Jude Medical Portico™ Transcatheter

Figure 5. Medtronic Engager™ Transcatheter Aortic V

Figure 6. JenaValve aortic valve prosthesis for transapical use
Courtesy of JenaValve™ Technology, Inc., Munich, Germany.

Sinning JM et al. Methodist DeBakey Cardiovascular Journal 2012

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High Mortality Rates at 5 years

Inoperable Pts

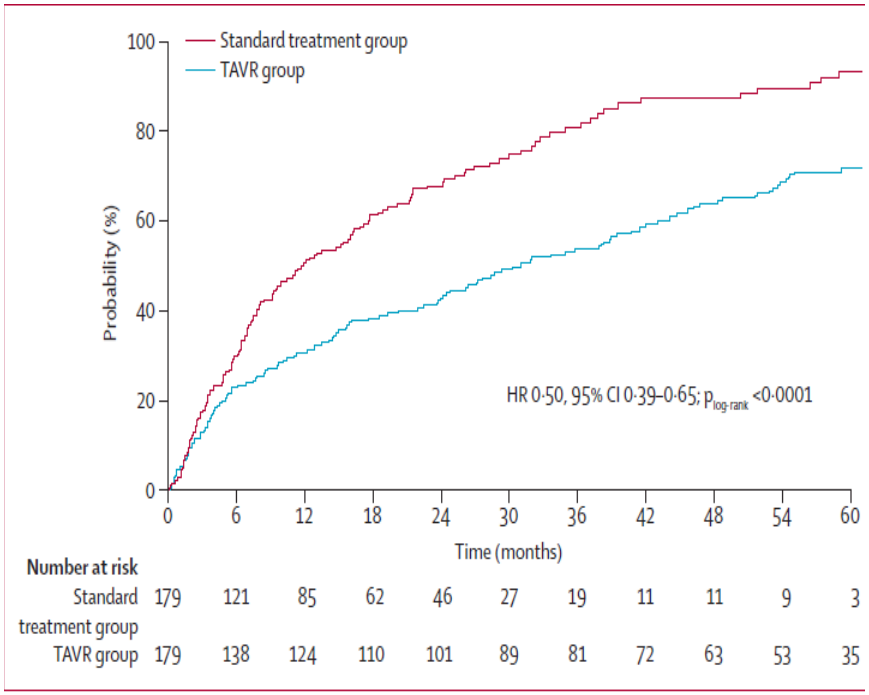
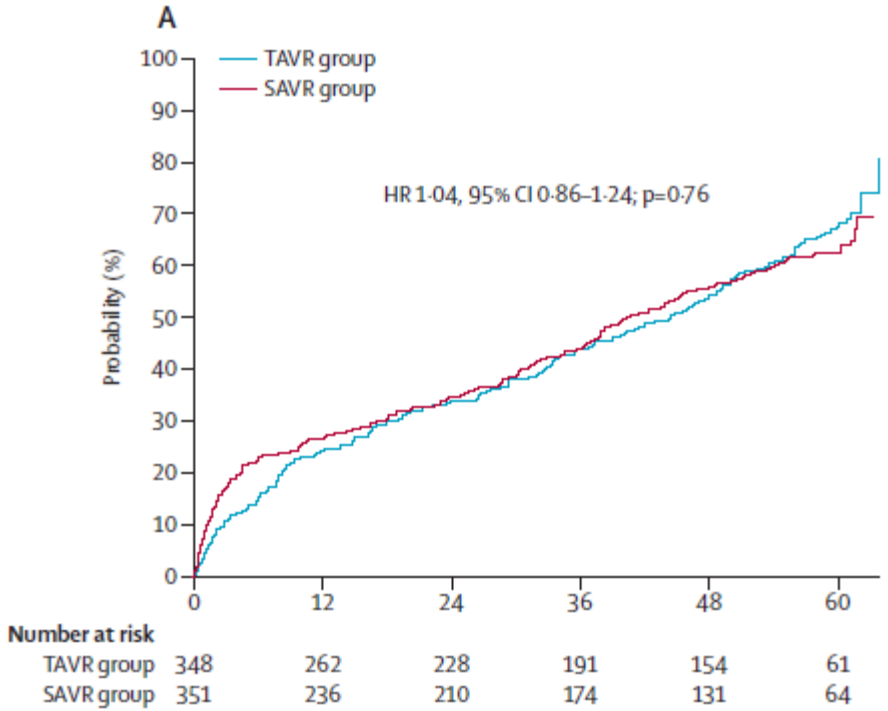


Figure 1: Kaplan-Meier analysis of all-cause mortality for the intention-to-treat population
TAVR=transcatheter aortic valve replacement. HR=hazard ratio.

High risk Pts



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Sapien 3 data, 30 day

Table 1. 30-Day Outcomes by Patient Risk: As-Treated Analysis

	Inoperable/High-Risk Cohort
All-Cause Mortality	2.2%
CV Mortality	1.4%
All Stroke	1.5%
Disabling Stroke	0.9%

Table 1. 30-Day Outcomes by Patient Risk: As-Treated Analysis

	Intermediate-Risk Cohort
All-Cause Mortality	1.1%
CV Mortality	0.9%
All Stroke	2.6%
Disabling Stroke	1.0%

FEATURE | HEART VALVE REPAIR | JANUARY 15, 2016| DAVE FORNELL

FDA OKs TAVR Trial for Low-Risk Patients Using Sapien 3 Device

The trial will be the first to examine transcatheter valve use in low-risk patients, which may change the standard of care

FierceMedical Devices

NEWS TOPICS ANALYSIS FEATU

Topics: Clinical Trials

Medtronic to start TAVR trial for aortic stenosis patients at low risk of surgical mortality

February 22, 2016 | By Stacy Lawrence

Press Release | Thu Jan 21, 2016 11:34am EST

MedStar: First-of-Its-Kind Study Launched Evaluating Use of Less Invasive Procedure in Low Risk Patients With Diseased Heart Valves

* Reuters is not responsible for the content in this press release.

MedStar: First-of-Its-Kind Study Launched Evaluating Use of Less Invasive Procedure in Low Risk Patients With Diseased Heart Valves

EDITOR'S CHOICE

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Questions from the Data Driven Physician

- In high- risk trials, 5- year follow-ups were reasonable due to high event rates. What follow-up is reasonable in a low- risk patient population whose valves should last 10 years without structural deterioration?

Questions from the Data Driven Physician

- Although Edwards has an imaging substudy, do we reasonably understand the issue of valve thrombosis? Will it be acceptable in a younger patient population

Questions from the Data Driven Physician

- In a younger patient population, where a second valve is likely to be necessary, is it reasonable to know what the higher gradients for valve-in-valve mean?

Questions from the Data Driven Physician

- The problem of paravalvular regurgitation, though diminished, has not been eliminated. Is it fair to risk this complication when surgical AVRs have a much lower rate of moderate-severe PVL?

Questions from the Data Driven Physician

Interventional Cardiology has been fortunate to have major advances occur in our lifetime

Maintaining that success requires cooperation between FDA, industry, and professional societies

Possible Role of MDEpiNET

Linkage between TVT registry and survival databases with SSN and Medicare

Longitudinal tracking of valve function via linkage to commercial EHRs

Systematic tracking of long-term cost of TAVR patients vis a vis linkages