

# AORTIC VALVE/INTERVENTIONAL VALVES RESEARCH OPPORTUNITIES AND GAPS

**CARDIOTHORACIC SURGERY EXPLORING  
COLLABORATIVE CLINICAL RESEARCH  
OPPORTUNITIES SYMPOSIUM AND WORKSHOP  
*BETHESDA, MD APRIL 26 AND 27, 2011***

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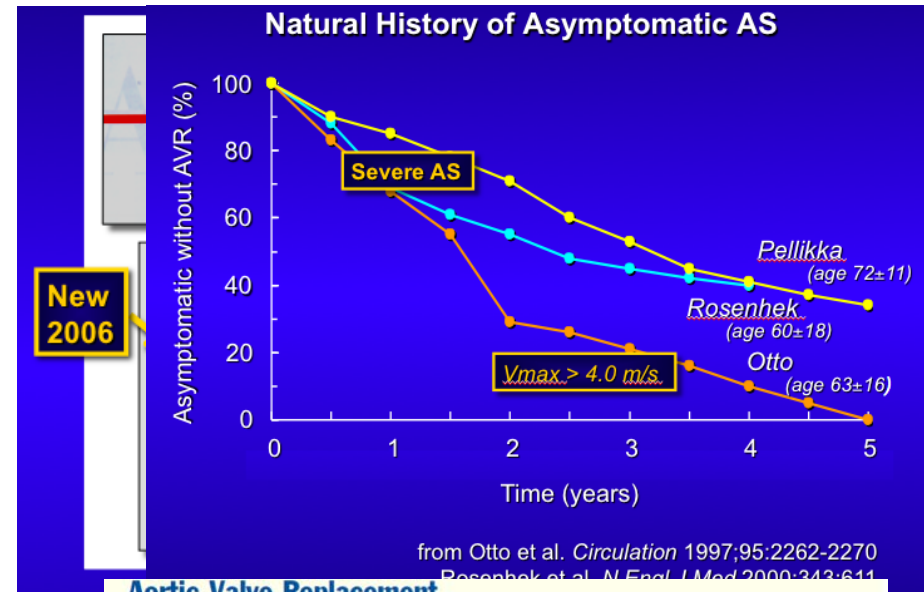
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# Aortic Valve/Interventional Valves Research Opportunities and Gaps

- Aortic Stenosis
  - Asymptomatic
    - AVR vs. Observation
  - Low Gradient
    - AVR vs. Medical Management
- AVR
  - Mechanical vs. Bioprostheses in Young (50-65 years) Patients
- TAVR
  - Neurologic Outcomes
  - Long-term Effects of Paravalvular Leak
- Aortic Stenosis
  - ***National Valve Registry***

# Management of Aortic Stenosis

- Asymptomatic AS
  - RCT AVR vs. Observation Until Symptoms
  - Pros:** Gap    **Cons:** None



## Low Gradient AS

- Low Gradient/Low EF
- Low Gradient Normal EF
- RCT AVR vs. Medical Therapy
- Pros:** Gap    **Cons:** None

### Aortic Valve Replacement for Low-Flow/Low-Gradient Aortic Stenosis

Operative Risk Stratification and Long-Term Outcome: A European Multicenter Study

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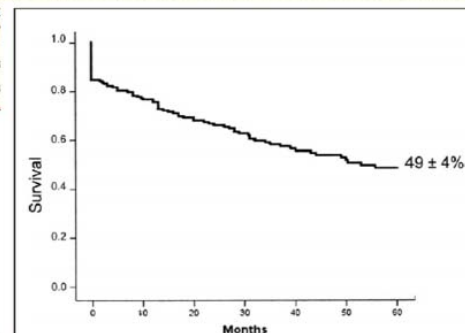


Figure 1 5-Year Overall Survival Curve in the Total Population

## 4

# Aortic Valve Replacement

- Valve Choice in Younger Patients
  - RCT in Patients 50-65 Years
  - Mechanical vs. Biosprosthesis
  - Pros:** Gap **Cons:** Enrollment, >10 years

## Prosthetic Valve Type for Patients Undergoing Aortic Valve Replacement: A Decision Analysis

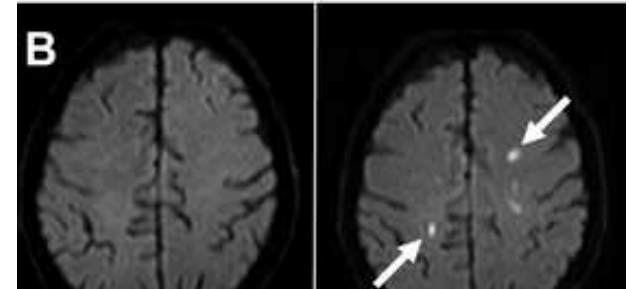
Nancy J. O. Birkmeyer, PhD, John D. Birkmeyer, MD, Anna N. A. Tosteson, ScD, Gary L. Grunkemeier, PhD, Charles A. S. Marrin, MB, BS, and Gerald T. O'Connor, DSc

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	<b>Mortality, Reoperation and Bleeding Rates at 12 years</b>							
	<b>Patient Age at Valve Implant (Years)</b>							
	<b>50</b>		<b>60</b>		<b>70</b>		<b>80</b>	
	<i>tissue</i>	<i>mech</i>	<i>tissue</i>	<i>mech</i>	<i>tissue</i>	<i>mech</i>	<i>tissue</i>	<i>mech</i>
<b>Mortality (%)</b>	<b>28</b>	<b>27</b>	41	42	61	63	90	91
<b>Reoperation (%)</b>	<b>32</b>	<b>6</b>	21	6	12	4	3	1
<b>Major Bleeding Episode (%)</b>	<b>4</b>	<b>16</b>	5	21	6	24	5	22
<b>Mortality, Reoperation, or Major Bleeding Episode (%)</b>	<b>57</b>	<b>43</b>	59	58	71	75	92	94

# Transcatheter Aortic Valve Implantation (TAVI)

- Neurologic Outcomes in TAVI vs. AVR
  - Clinical Assessment
  - DW MRI
  - Neurocognitive testing
  - **Pros:** nonrandomized, major gap
  - **Cons:** trial design



**DW-MRI**

Valve

New lesions

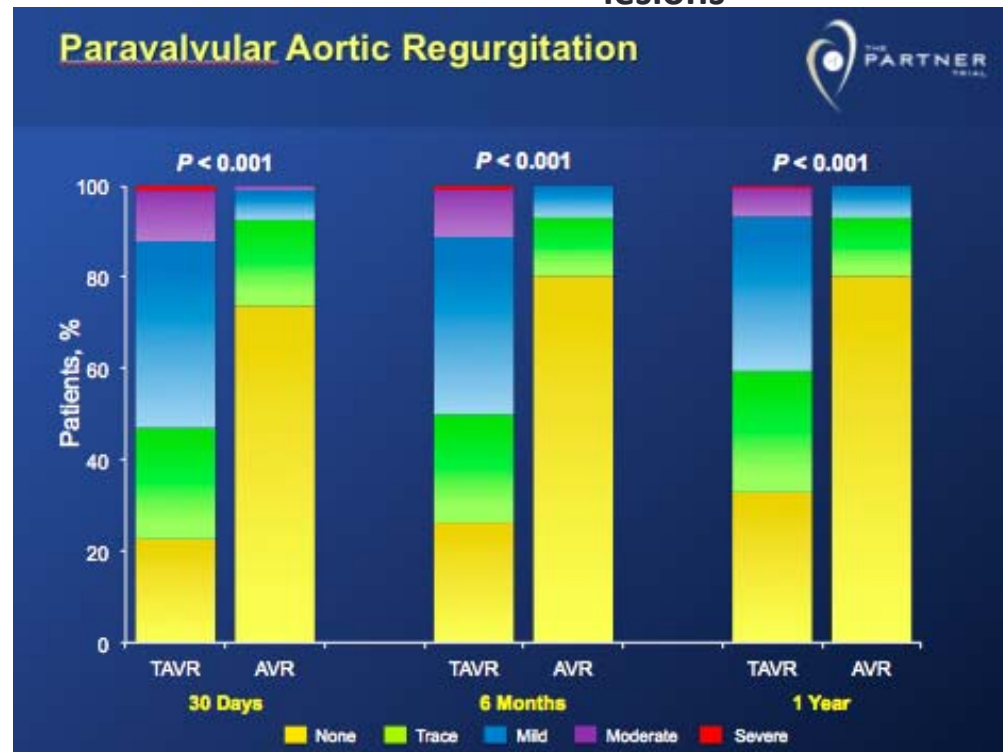
Strokes

## Paravalvular Leak

Occurs in 70% of TAVI  
 No short term detriment  
 Energy Loss Across Valve  
 Effect on Clinical Outcomes, LV Function

**Pros:** Topical, Gap

**Cons:** May be answered by industry trial sponsors



# National Registry of Aortic Stenosis

- Proposal: Create A “National Registry” For Aortic Valve Disease
- Mechanism: Link 2 clinical outcomes databases and 2 administrative databases

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## ACC INTERVENTIONAL SCIENTIFIC COUNCIL: NEWS AND VIEWS

### ASCERT: The American College of Cardiology Foundation–The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies

Lloyd W. Klein, MD,\* Fred H. Edwards, MD,† Elizabeth R. DeLong, PhD,‡  
Laura Ritzenthaler, PA, MBA,§ George D. Dangas, MD,|| William S. Weintraub, MD¶

- STS-NCD
- ACC NCDR
- Social Security Death Master File (SSMDF)
- CMS Med PAR Claims Database
- Precedents
  - National registries in England, Germany
  - ASCERT Trial of CABG and PCI (STS/ACC/SSMDF/Med Par)-NIH funded-proof of concept
  - STS-SSMDF linkage feasibility for cardiac surgery
  - INTERMACS Registry for LVAD's
  - PROSPECT Grant already written

## Potential

- Risk-adjusted outcomes

**PROS**- critical need, perfect timing

ACC and STS supported

Support received from FDA- device submission and post approval surveillance

Prototype for all cardiovascular disease

Prototype for linking to other national registries (global database)

**CONS**- cost, magnitude of scale

**Response to RFA-HS-10-005  
ARRA-AHRQ Recovery Act 2009  
Limited Competition PROSPECT**