Michigan STS Sir Magdi Yacoub 2016
Lecture: Future of Cardiovascular and Thoracic Surgery
Achievements, Innovation and Future Directions

Joseph E. Bavaria, M.D.
President: Society of Thoracic Surgeons (STS)
Roberts-Measy Professor and Vice Chief CardioVascular Surgery
Director: Thoracic Aortic Surgery Program
University of Pennsylvania, Philadelphia USA

Boyne Michigan, 2016
Future lies in…

- Reparative valve surgery (especially minimally invasive & robotic approaches)
- Small pumps – VADs/CHF
  - ECMO (Rescue, Bridge, etc)
- Thoracic Aortic (endovascular)
  - GenTAC concepts
- Transcatheter endo-cardiac surgery
  - TAVR … (The big concept)
  - Transcatheter mitral valve replacement
    - Transcatheter pulmonic valve replacement
Minimally invasive approach provides at least equivalent results for surgical correction of mitral regurgitation: A propensity-matched comparison

Andrew B. Goldstone, MD, Pavan Atluri, MD, Wilson Y. Szeto, MD, Alen Trubelja, BS, Jessica L. Howard, BS, John W. MacArthur, Jr, MD, Craig Newcomb, MS, Joseph P. Donnelly, BS, Dale M. Kobrin, BA, Mary A. Sheridan, MPAS, PA-C, Christiana Powers, MSN, CRNP, Robert C. Gorman, MD, Joseph H. Gorman III, MD, Alberto Pochettino, MD, Joseph E. Bavaria, MD, Michael A. Acker, MD, W. Clark Hargrove III, MD, and Y. Joseph Woo, MD

Objective: Minimally invasive approaches to mitral valve surgery are increasingly used, but the surgical approach must not compromise the clinical outcome for improved cosmesis. We examined the outcomes of mitral repair performed through right minithoracotomy or median sternotomy.

Methods: Between January 2002 and October 2011, 1011 isolated mitral valve repairs were performed in the University of Pennsylvania health system (455 sternotomies, 556 right minithoracotomies). To account for key differences in preoperative risk profiles, propensity scores identified 201 well-matched patient pairs with mitral regurgitation of any cause and 153 pairs with myxomatous disease.

Results: In-hospital mortality was similar between propensity-matched groups (0% vs 0% for the degenerative cohort; 0% vs 0.5%, $P = .5$ for the overall cohort; in minimally invasive and sternotomy groups, respectively). Incidence of stroke, infection, myocardial infarction, exploration for postoperative hemorrhage, renal failure, and atrial fibrillation also were comparable. Transfusion was less frequent in the minimally invasive groups (11.8% vs 20.3%, $P = .04$ for the degenerative cohort; 14.0% vs 22.9%, $P = .03$ for the overall cohort), but time to extubation and discharge was similar. A 99% repair rate was achieved in patients with myxomatous disease, and a minimally invasive approach did not significantly increase the likelihood of a failed repair resulting in mitral valve replacement. Patients undergoing minimally invasive mitral repair were more likely to have no residual post-repair mitral regurgitation (97.4% vs 92.1%, $P = .04$ for the degenerative cohort; 95.5% vs 89.6%, $P = .02$ for the overall cohort). In the overall matched cohort, early readmission rates were higher in patients undergoing sternotomies (12.6% vs 4.4%, $P = .01$). Over 9 years of follow-up, there was no significant difference in long-term survival between groups ($P = .8$).

Conclusions: In appropriate patients with isolated mitral valve disease of any cause, a right minithoracotomy approach may be used without compromising clinical outcome. (J Thorac Cardiovasc Surg 2013;145:748-56)
A Population-Based Analysis of Robotic-Assisted Mitral Valve Repair

Subroto Paul, MD, Abby J. Isaacs, MS, Jessica Jalbert, PhD, Nonso C. Osakwe, MD, MPH, Arash Salemi, MD, Leonard N. Girardi, MD, and Art Sedrakyan, MD, PhD

Departments of Health Policy and Research and Cardiothoracic Surgery, New York Presbyterian Hospital–Weill Cornell Medical College, New York, New York

**Background.** Robotic-assisted mitral valve repair is becoming more frequently performed in cardiac surgery. However, little is known about its utilization and safety at a national level.

**Methods.** Patients undergoing mitral valve repair in the United States from 2008 to 2012 were identified in the National Inpatient Sample. Inhospital mortality, complications, length of stay, and cost for patients undergoing robotic-assisted mitral valve repair were compared with patients undergoing nonrobotic procedures.

**Results.** We identified 50,408 isolated mitral valve repair surgeries, of which 3,145 were done with robotic assistance. In a propensity score matched analysis of 631 pairs of patients, we found no difference between patients undergoing robotic-assisted and nonrobotic-assisted mitral valve repair with respect to inhospital mortality, complications, or composite outcomes in unadjusted or multivariable analyses. Robotic-assisted mitral valve repair surgery was associated with a shorter median length of stay (4 versus 6 days, \( p < 0.001 \)), and there was no difference in median total costs between the two procedures.

**Conclusions.** In our analysis of a large national database with its inherent limitations, robotic-assisted mitral valve repair was found to be safe, with an acceptable morbidity and mortality profile.

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Fig 1. Port placement for lateral endoscopic approach using robotics (LEAR) surgery.
## No Difference in Outcomes

### Table 2. Inhospital Outcomes for National Sample and Propensity-Matched Cohort

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Robotic MV Repair n = 3,145</th>
<th>MV Repair n = 47,263</th>
<th>p Value</th>
<th>Robotic MV Repair n = 631</th>
<th>MV Repair n = 631</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unmatched Cohort</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhospital mortality&lt;sup&gt;a&lt;/sup&gt;</td>
<td>40 (1.3)</td>
<td>1,039 (2.2)</td>
<td>0.048</td>
<td>*</td>
<td>*</td>
<td>0.78</td>
</tr>
<tr>
<td>Composite outcome&lt;sup&gt;b&lt;/sup&gt;</td>
<td>141 (4.5)</td>
<td>2,863 (6.1)</td>
<td>0.07</td>
<td>27 (4.3)</td>
<td>20 (3.2)</td>
<td>0.31</td>
</tr>
<tr>
<td>Length of stay, days</td>
<td>4 (3–6)</td>
<td>7 (5–9)</td>
<td>0.004</td>
<td>4 (3–6)</td>
<td>6 (4–8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Morbidity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any complication</td>
<td>1,173 (37.3)</td>
<td>17,552 (37.1)</td>
<td>0.94</td>
<td>236 (37.4)</td>
<td>217 (34.4)</td>
<td>0.26</td>
</tr>
<tr>
<td>Cardiovascular complications</td>
<td>132 (4.2)</td>
<td>2,339 (4.9)</td>
<td>0.36</td>
<td>26 (4.1)</td>
<td>19 (3.0)</td>
<td>0.28</td>
</tr>
<tr>
<td>Stroke</td>
<td>112 (3.6)</td>
<td>1,926 (4.1)</td>
<td>0.51</td>
<td>22 (3.5)</td>
<td>15 (2.4)</td>
<td>0.25</td>
</tr>
<tr>
<td>Pulmonary complications</td>
<td>950 (30.2)</td>
<td>13,440 (28.4)</td>
<td>0.35</td>
<td>193 (30.6)</td>
<td>171 (27.1)</td>
<td>0.16</td>
</tr>
<tr>
<td>Infectious complications</td>
<td>115 (3.7)</td>
<td>2,818 (6.0)</td>
<td>0.004</td>
<td>22 (3.5)</td>
<td>21 (3.3)</td>
<td>0.88</td>
</tr>
<tr>
<td>Iatrogenic complications&lt;sup&gt;c&lt;/sup&gt;</td>
<td>206 (6.5)</td>
<td>2,590 (5.5)</td>
<td>0.30</td>
<td>41 (6.5)</td>
<td>32 (5.1)</td>
<td>0.29</td>
</tr>
<tr>
<td>Discharge status&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine</td>
<td>2,046 (65.1)</td>
<td>21,228 (44.9)</td>
<td></td>
<td>220 (34.9)</td>
<td>251 (39.8)</td>
<td>0.07</td>
</tr>
<tr>
<td>Nonroutine&lt;sup&gt;d&lt;/sup&gt;</td>
<td>1,097 (34.9)</td>
<td>26,013 (55.1)</td>
<td></td>
<td>411 (65.1)</td>
<td>380 (60.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total charges, USD</td>
<td>114,959 (92,036–161,358)</td>
<td>123,313 (85,840–186,758)</td>
<td>0.34</td>
<td>114,846 (92,036–161,358)</td>
<td>113,331 (81,237–166,835)</td>
<td>0.16</td>
</tr>
<tr>
<td>Estimated total costs, USD</td>
<td>33,720 (26,537–45,099)</td>
<td>34,509 (26,238–47,513)</td>
<td>0.44</td>
<td>33,638 (26,473–45,099)</td>
<td>31,756 (25,001–43,127)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

<sup>a</sup> Less than 10.  <sup>b</sup> Less than 1% missing data.  <sup>c</sup> Any complication consists of death or stroke.  <sup>d</sup> Accidental puncture or laceration complicating surgery, bleeding complicating procedure.  <sup>e</sup> Including inhospital death.  <sup>f</sup> Cost is estimated using National Inpatient Sample charge data, cost-to-charge ratio files, and a scaling factor by diagnosis-related group published by Healthcare Cost and Utilization Project in 2009; less than 10% missing cost/charge data.

Values are median (IQR) or n (%).

IQR = interquartile range; MV = mitral valve; USD = US dollars.
HeartMate XVE: Things we can fix

**Table 2. Causes of Death.**

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Medical-Therapy Group</th>
<th>LVAD Group</th>
<th>Total</th>
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<tbody>
<tr>
<td>Left ventricular dysfunction</td>
<td>50</td>
<td>1</td>
<td>51</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Failure of LVAD</td>
<td>0</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Miscellaneous noncardiovascular causes</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Miscellaneous cardiovascular causes</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Cardiac procedure</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Perioperative bleeding</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>54</strong></td>
<td><strong>41</strong></td>
<td><strong>95</strong></td>
</tr>
</tbody>
</table>

*LVAD denotes left ventricular assist device.*
New ERA In VAD Therapy – CF LVAD

The NEW ENGLAND JOURNAL of MEDICINE

Advanced I
Continuous-Flow

Mark S. Slaughter, M.D.,
Stuart D. Russell, M.D.,
Benjamin Sun, M.D., An-Toi
James W. Long,
Waqaq Ghumman, M.D., I
for the

Original Article

No. at Risk
Continuous-flow LVAD 133 95 82 69 62
Pulsatile-flow LVAD 59 32 19 5 2

Continuous-flow LVAD
Pulsatile-flow LVAD

Probability of Survival

P=0.008 by the log-rank test

Months since Randomization
Sixth INTERMACS annual report: A 10,000-patient database

James K. Kirklin, MD, a David C. Naftel, PhD, a Francis D. Pagani, MD, PhD, b Robert L. Kormos, MD, c Lynne W. Stevenson, MD, d Elizabeth D. Blume, MD, e Marissa A. Miller, DVM, MPH, f J. Timothy Baldwin, PhD, f and James B. Young, MD g
Table 1  FDA-approved Devices

<table>
<thead>
<tr>
<th>Type</th>
<th>Device</th>
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</thead>
<tbody>
<tr>
<td>Durable devices</td>
<td>Thoratec HeartMate II</td>
</tr>
<tr>
<td>Continuous flow</td>
<td>HeartWare HVAD</td>
</tr>
<tr>
<td></td>
<td>MicroMed DeBakey Child VAD</td>
</tr>
<tr>
<td>Pulsatile extracorporeal</td>
<td>Thoratec PVAD</td>
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<tr>
<td></td>
<td>Berlin Heart EXCOR</td>
</tr>
<tr>
<td>Pulsatile intracorporeal</td>
<td>HeartMate IP</td>
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<tr>
<td></td>
<td>HeartMate VE</td>
</tr>
<tr>
<td></td>
<td>HeartMate XVE</td>
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<tr>
<td></td>
<td>Thoratec IVAD</td>
</tr>
<tr>
<td></td>
<td>Novacor PC</td>
</tr>
<tr>
<td></td>
<td>Novacor PCq</td>
</tr>
<tr>
<td>Total artificial heart</td>
<td>SynCardia CardioWest</td>
</tr>
<tr>
<td></td>
<td>AbioCor TAH</td>
</tr>
<tr>
<td>Temporary devices</td>
<td>Abiomed AB5000</td>
</tr>
<tr>
<td>Short-term devices</td>
<td>Abiomed BVS 5000</td>
</tr>
<tr>
<td></td>
<td>Thoratec Centrimag</td>
</tr>
<tr>
<td></td>
<td>Biomedicus</td>
</tr>
<tr>
<td></td>
<td>Tandem Heart</td>
</tr>
<tr>
<td></td>
<td>Revolution</td>
</tr>
</tbody>
</table>

Implants: June 2006 – December 2013

Evolution and Patient Enrollment
June 23, 2006 to December 31, 2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Implants</th>
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<tbody>
<tr>
<td>2006</td>
<td>1</td>
</tr>
<tr>
<td>2007</td>
<td>11</td>
</tr>
<tr>
<td>2008</td>
<td>23</td>
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<tr>
<td>2009</td>
<td>30</td>
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<tr>
<td>2010</td>
<td>42</td>
</tr>
<tr>
<td>2011</td>
<td>54</td>
</tr>
<tr>
<td>2012</td>
<td>66</td>
</tr>
<tr>
<td>2013</td>
<td>80</td>
</tr>
</tbody>
</table>

Graph showing the number of implants per year from 2006 to 2013.
Perpetual Miniaturization
CircuLite Surgical System

Pump in subcutaneous pacemaker pocket
Right sided mini-thoracotomy
Extubation in OR possible
Off pump procedure

Not available for sale
CAUTION: Investigational device. Limited by United States law to investigational use.
Possible Biventricular Support

CAUTION — Investigational Device. Limited by United States law to investigational use.
Exclusively for Clinical Investigations.
Reparative valve surgery (especially minimally invasive & robotic approaches)

Small pumps – VADs/CHF
- ECMO (Rescue, Bridge, etc)

Thoracic Aortic (endovascular)
- GenTAC concepts

Transcatheter endo-cardiac surgery
- TAVR … (The big concept)
- Transcatheter mitral valve replacement
  - Transcatheter pulmonic valve replacement
All-Cause Mortality or Stroke (ITT)

All Patients

HR [95% CI] = 1.09 [0.90, 1.31]

p (log rank) = 0.39

Error Bars Represent 95% Confidence Limits

![Graph showing All-Cause Mortality or Stroke (ITT)]
Mortality and Stroke: S3i
At 30 Days (As Treated Patients)

Mortality

- All-Cause
- Cardiovascular

<table>
<thead>
<tr>
<th>S3i</th>
<th>O:E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>0.9</td>
</tr>
</tbody>
</table>

O:E = 0.21 (STS 5.3%)

Stroke

- All Stroke
- Disabling

| S3i | 2.6 | 1.0 |

The Partner II Trial
Very well studied/Data driven/RCT
So the Real Question is

……. Why NOT a New TAVI trial into LOW and NTERMEDIATE RISK patients??
The Future will still include....

Incremental improvements in:

- Improved Perfusion Concepts
  - “improvements” to CPB machine
  - Sensors
- All-Arterial CABG
- EP Surgery (?)
- Pain management
Additionally, Future lies in.....

- Greater transparency
- Quality initiatives
- Public reporting of outcomes

- Of course, some of the main components of present cardiac surgery will remain, but with decreased growth
  - Congenital, CABG, standard valve replacement, complex operations, niche areas
Hospital volume of 12 procedures

Medicare population:
- 1994-99
- > 65 yrs
- 2.5 mill pats
- 30 d mortality
- 11/12 inversely related
- Max diff. 16 vs 4 % pancreatic resection
- Min diff. 1.7 vs 1.5 % carotid TEA

Birkmeyer JD et al:
Hospital volume and surgical mortality in the United States
Surgeon volume of 8 procedures

Medicare population:
- 1998-99
- > 65 yrs
- 474 000 pats
- 30 d mortality

Conclusion:
"Surgeon volume was inversely related to operative mortality for all eight procedures"
National Policy OUS based on Volume-Outcome Relationship: The UK NHS
The Bristol (UK) scandal (1988-95)
Brief communication - Congenital
Effects of ‘Bristol’ on surgical practice in the United Kingdom
Colin J. Hilton*, J.R. Leslie Hamilton, Nicola Vitalea, Rune Haaverstadb
Department of Cardiothoracic Surgery, Cardiothoracic Centre, Freeman Hospital, Newcastle-upon-Tyne, NE7 7DN, UK
Received 5 November 2004; received in revised form 27 January 2005; accepted 16 February 2005

Abstract
In 1995 a child died following an arterial switch operation for complex transposition of the great arteries. There had been general concern regarding the outcomes for the arterial switch procedure in the unit in Bristol. A review, prompted by parents whose children had died, showed that 29 children had died and four others suffered from cerebral damage postoperatively. The General Medical Council (GMC) considered the conduct of three doctors from the unit. This hearing culminated in the suspension and subsequent removal from the Medical Register of the senior Cardiac Surgeon and the Chief Executive of the hospital. The second Cardiac Surgeon was banned from practising in the field of paediatric cardiac surgery for three years (his results in adult cardiac surgical practice were not called into question). Following this the Government set up a public inquiry to investigate the causes behind the deaths. This Inquiry, which took three years, made recommendations that have affected the way all doctors in the UK practice.

-GMC inquiry: 15 millGBP and 600 page report
-198 recommendations: Only 31 related to children; only 7 pediatric
-Aim: Fewer pediatric cardiac units, volume >300 and >3 surgeons
-Effects on ALL cardiac surgical practice:
  -Communication
  -Competence
  -Performance monitoring
  -Release of mortality data (hospital and surgeon)
Additionally, Future lies in…..

Organizational Dynamics

- HVC Concept
  - How and Why it works. When it’s virtual
  - Relationship with Interventional Cardiology
- ?? Reorganization of Medical Care
  - MACRA, etc
- STS perch

- Interesting ….. Job Market is Robust!
  - Why? The “Shulkin” effect.
HVC Background

Is AVR (and the HVC) Important (Financially) to the Health System?

How Important?
Now?
Future?
Valve procedures are highly profitable; generating a healthy average contribution margin and per case gain.
We’re Actually doing quite well over 15 years!

Rate of Change in Real per-Enrollee Spending by PayerData are derived from the National Health Expenditure Accounts. Inflation adjustments use the Gross Domestic Product Price Index reported in the National Income and Product Accounts. The mean growth rate for Medicare spending reported for 2005 through 2010 omits growth from 2005 to 2006 to exclude the effect of the creation of Medicare Part D.
Additionally, Future lies in…..

Organizational Dynamics

- **HVC Concept**
  - How and Why it works. When it’s virtual
  - Relationship with Interventional Cardiology
- **?? Reorganization of Medical Care**
  - MACRA, etc
- **STS perch**

- Interesting ….. Job Market is Robust!
  - Why? The “Shulkin” effect.?
$2.5$ Trillion total, $765$ Billion in Waste (>$50\%$ “Medical”)

Source: The Institute of Medicine: The Healthcare Imperative: Lowering Costs and Improving Outcomes.
A Pause ......
Example Patient

<table>
<thead>
<tr>
<th>Name for Scrolling</th>
<th>CROUTHAMEL.PAUL; 000103917606</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRG</td>
<td>219</td>
</tr>
<tr>
<td>Entity</td>
<td>(All)</td>
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</table>

<table>
<thead>
<tr>
<th>Sum of Corrected Cost Amounts</th>
<th>Column Labels</th>
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<tbody>
<tr>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>000103917606</td>
<td>$1,345</td>
</tr>
<tr>
<td><strong>OR SUPPLIES</strong></td>
<td></td>
</tr>
<tr>
<td>01304336 CATHETER ANGIOPLASTY NON LA VALVE</td>
<td>$32,825</td>
</tr>
<tr>
<td><strong>O.R. YELLOW</strong></td>
<td>$173</td>
</tr>
<tr>
<td>01100346 OR 1ST HALF HR</td>
<td>$369</td>
</tr>
<tr>
<td>01100353 OR ADDTL HALF HR</td>
<td>$1,552</td>
</tr>
<tr>
<td>01100452 OR PROVIDER PER 1/2 HOUR</td>
<td>$138</td>
</tr>
<tr>
<td>01100460 CATH LAB PROVIDER PER 1/2 H</td>
<td>$608</td>
</tr>
<tr>
<td>06550008 ART. (THORAC. AORTA) S/I</td>
<td>$173</td>
</tr>
<tr>
<td><strong>NUR-SILVERSTEIN 10</strong></td>
<td>$802</td>
</tr>
<tr>
<td><strong>NUR-SICU-CT/GS</strong></td>
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<tr>
<td><strong>PHAR - IP CENTRAL ROBOT NARC</strong></td>
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<td><strong>BLOOD BANK</strong></td>
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<tr>
<td><strong>PERFUSION SUPPLIES</strong></td>
<td></td>
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<tr>
<td><strong>PERIOP ANES TECHS HUP</strong></td>
<td>$444</td>
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<tr>
<td><strong>AUTO LAB</strong></td>
<td>$71</td>
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<td><strong>INTRAOPERATIVE MONITORING</strong></td>
<td>$400</td>
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<td><strong>RESPIRATORY THERAPY-HUP</strong></td>
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<td><strong>BONE/CHEST/ER SUPP</strong></td>
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<td><strong>INPATIENT PT-HUP</strong></td>
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<td><strong>ECHO LAB</strong></td>
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<td><strong>PERFUSION HUP</strong></td>
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<td><strong>PHLEBOTOMY</strong></td>
<td>$4</td>
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<td><strong>COAGULATION</strong></td>
<td>$7</td>
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<td><strong>PREP &amp; RECOVERY SC</strong></td>
<td>$16</td>
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<td><strong>EKG LABORATORY</strong></td>
<td>$3</td>
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<tr>
<td><strong>CLINICAL LAB</strong></td>
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<tr>
<td><strong>Grand Total</strong></td>
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</tbody>
</table>
Final Thought ….. You’re the Hospital CFO

- Cohort A (STS > 8; mean 10-11) shows clinical “equivalence” between TAVI and Open AVR. However, at $32,500 per Valve, the CM is reduced by $20-25K PER CASE and throwing profitability to a LOSS, basically showing **massive financial superiority** to open AVR. ….. This is bad enough.

- BUT ….. Intermediate Risk (STS 4-8) TAVI (P2A and SURTAVI), where there is even **LESS** equipoise than Cohort A, ….. Is this Financial irresponsibility??

- Obviously I feel it is more complicated than that but ….
TAVR Experience at PENN

“Just the Facts Ma’am” ...... Detective Joe Friday, Dragnet

“There is no Right or Wrong here, Just Decisions and Consequences

My CFO’s response is: Do what you want but the consequences are this means less RESOURCES for your team
Additionally, Future lies in.....

Organizational Dynamics

- HVC Concept
  - How and Why it works. When it’s virtual
  - Relationship with Interventional Cardiology
- ?? Reorganization of Medical Care
  - MACRA, etc
  - STS perch

- Interesting ..... Job Market is Robust!
  - Why? The “Shulkin” effect.?
However, The Real Future of our Specialty Resides in Innovation

The Future Lies in .....
The “Emerging” and Innovative Approach to Treatment?
CT Surgery has Achieved a lot!

However, The only Constant is Change
Circa 1993: Response of a Newly minted Cardiac Surgeon

301 CABG cases, Sir!

No Innovation here!!
Thoracic Aortic Surgery: Emerging and Innovative Therapy and Future Landscape

1. Innovation occurs at a number of Levels:
   1. Conceptual
      1. New operations based on new and improved Knowledge
   2. Device Related
      1. New operations based on availability of New Therapeutic Devices
   3. Conceptual and Device Related

2. All need a **CULTURE** of Innovation and Early Adoption **(with Audit)**
Thoracic Aortic Surgery: Emerging and Innovative Therapy and Future Landscape

1. Increased Valve Sparing Root Surgery (ALWAYS for AI) David V (and BAV repair techniques) (Conceptual)
2. Ascending Aortic TEVAR for High Risk Type A Dissection +/- Endo-Bentall (Device)
   1. Distal Aortic TEVAR Adjunct in Type A Dissection (Conceptual and Device)
3. Hybrid Arch +/- Endo-Arch (Mixture) …… The march towards “More Proximal” Reconstruction (Conceptual and Device)
4. Chronic Type B Dissecting Aneurysms (Mostly Conceptual also Device)
1. Increased Valve Sparing Root Surgery (ALWAYS for AI) David V (and BAV repair techniques) (Conceptual)

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Obliteration of False Lumen and Creation of “Neo-Media” and Distal Graft Anastomosis: “Aggressive” Hemi-Arch

Felt "neo-intima" placed between adventitia and intima
Aortic Root Reconstruction/Sinus of ValSalva Repair

Type A Dissection with Valve Resuspension and Ascending & Hemi-Arch (+/- Bioglue)

Note:
Efficient Conduct of operation
Acute Type A Dissection: Rational Design of an Operation (*What is Missing?*)

<table>
<thead>
<tr>
<th>Cause of death</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute CHF due to AI</td>
<td>Aortic valve resuspension</td>
</tr>
<tr>
<td>Coronary malperfusion</td>
<td>Aortic root repair</td>
</tr>
<tr>
<td>Cerebral malperfusion</td>
<td>Arch replacement</td>
</tr>
<tr>
<td>Free Ascending rupture</td>
<td>Asc aortic replacement</td>
</tr>
</tbody>
</table>
Acute Type A Dissection: Design of an Operation (What is Missing?)

Cause of death
- Acute CHF due to AI
- Coronary malperfusion
- Cerebral malperfusion
- Free Ascending rupture

Fate of Distal Descending Aorta!
Solution (?): Surgical Innovation

Can We Build a Case for the use of an Antegrade delivered TEVAR in Modifying the Descending Aorta in Type A Dissection?
Technical: Conventional Total Arch with Frozen Elephant Trunk:
Standard Zone 3 Arch FET
Distal LZ: Zone 2 Arch +/- Distal TEVAR Solution

Presently in Early FDA Feasibility trials in US; J. Bavaria, PI

J. Bavaria et al; JTCVS 2016 In Press
1. Increased Valve Sparing Root Surgery (ALWAYS for AI) David V (and BAV repair techniques) (Conceptual)

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“More Proximal” Aortic Arch Surgery ENABLING later TEVAR if anatomy Suitable
Saccular Distal/Mid Arch Aneurysm Repair .. Difficult!!!
Hybrid Arch (Proximal Aortic) Procedure and Concept

"Classic" Debranching

Type I

Type II

Type III

J. Bavaria, et al; JTCVS 2011
Water Hammer Pulse AI Aneurysm: Crazy!!!! Ascending application?
Total EndoVascular Arch Procedure

Courtesy of Cherrie Abraham, MD, Montreal, Canada
Thoracic Aortic Surgery: Emerging and Innovative Therapy and Future Landscape

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New Innovation: When do/can You Repair the Aortic Valve?
Aortic Valve Resuspension

Mechanism of Aortic Regurgitation in Type A Dissection

[Diagrams showing the mechanism of aortic regurgitation in Type A dissection]
Marfan Root (41 yr. old Man) with 9 1st Order Relatives with either Dissection, Death from Rupture, or Replaced Roots!
The Challenge for Thoracic Aortic Surgeons is to Spare RELATIVELY normal aortic valves, even if they are regurgitant, when the fundamental disease process is primarily an Aortic issue.
Goal: Restore (even fix) Geometry and Reduce Stress for long lasting repair

T. Gleason, M.D. Univ Penn
The Innovation is **Conceptual** and Improved Knowledge base

Dimensions of Native Aortic Valve

Natural L/D ratio

---

Can We Spare more Complicated Clinical Aortic Valve Presentations?

And Why is this so Important!
Bicuspid Valve and the Aorta: Effect of New guidelines?

1-2 Million people in USA !!!

Note: TEE annular diameter (32 graft)
Young 32 yr. Woman with Bicuspid Aortic Valve with Mild-Moderate AI, Mild AS (leaflet restriction) and 8.0 cm Ascending Aneurysm

Concept of “Sino-Tubular Definition”
The Pure AI BAV Patient with Dilated/Aneurysmal Proximal aorta

NOTE; Pure AI, No Calcified Leaflets

Fairly large opening, no AS

Still frames to depict anatomy
Can we really Repair something like this??

Bicuspid Valve Type 1? or 2?
Surgical Repair BAV AI Classification: Fundamentally we are discussing Ib and c with II

**Most Common combination**

<table>
<thead>
<tr>
<th>AI Class</th>
<th>Type I</th>
<th>Type II</th>
<th>Type III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal cusp motion with FAA dilatation or cusp perforation</td>
<td>Cusp Prolapse</td>
<td>Cusp Restriction</td>
</tr>
<tr>
<td>la</td>
<td>Ib</td>
<td>lc</td>
<td>Id</td>
</tr>
<tr>
<td>Mechanism</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STJ remodeling</td>
<td>Aortic Valve sparing: Reimplantation or Remodeling with SCA</td>
<td>SCA</td>
<td>Prolapse Repair</td>
</tr>
<tr>
<td>(Primary)</td>
<td>Ascending aortic graft</td>
<td></td>
<td>Plication Triangular resection Free margin Resuspension Patch</td>
</tr>
<tr>
<td>(Secondary)</td>
<td>SCA</td>
<td>STJ Annuloplasty</td>
<td>SCA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SCA</td>
<td>SCA</td>
</tr>
</tbody>
</table>

BAV Ib + II usually associated with 15-25% larger annulus than standard for BSA

Problem in the World Wide Cardiac Surgery Community ....... Are we Ready for “Prime Time” 
........ No!
Einstein: Make everything as simple as possible …… But No Simpler!!
So .................
What kind of Operation are we Talking about?
Bicuspid Aortic valve Repair Concepts (Direct Cusp or Leaflet)

- Even the free margin lengths: Plicate (or cut) the prolapsed cusp
- Annular Reduction (10-15%) and Stabilization with either Re-implantation (or Sub-Annular technique)
- Increase height (decrease length) of Free margin (gore-tex) ....if leaflet belly below annular plane.

**Bottom line: “Any purely insufficient valve with enough leaflet surface area can be repaired”**
Goal: Great Coaptation Zone
Measuring the Amount of excess leaflet to resect for Leaflet Free Margin Equality
Treating the Prolapse
Post-Repair Evaluation: For Margin Equality, Perimeter assessment
Raphe Release, Equalization of Free Margin, and Plication/Resection of Redundant leaflet

Coronary Buttons are cut. 210/150 perimeter and Leaflet surface area ratios.
Preparation of the Root for Subannular Suture Placement and Re-Implanation Procedure
Construction of Stable (smaller) Annulus and Reimplantation of the “New Root” in 3 dimensions

210/150 Neo ValSalva Root (Raphed BAV)

Bavaria, J; et al: EJCTS 2013 (presented at EACTS, Barcelona 2012)
So What’s the data on Bicuspid Reimplantation Valve Sparing with Aneurysm and repaired AI?
Outcomes with BAV Repair + Root Reimplantation:

How do they compare to our institutional tricuspid aortic valve root reimplantation?
Freedom from AI >2+ (%)
100% of BAV VSRR had Leaflet Repair

Outcomes are similar.

- TAV VSRR: 97 ± 2%
- BAV VSRR: 94 ± 2%

Log-Rank P = 0.7

Number at risk
- TAV VSRR: 104
- BAV VSRR: 44

Years since surgery
- TAV VSRR: 67, 50, 39
- BAV VSRR: 28, 12, 9

Data thru 4/2014  Bavaria et al  JTCVS 2015
LV Diastolic dimension change

VSRR achieved excellent left ventricular remodeling in both BAV and TAV patients over follow-up. (STS 2014)
1. Innovation occurs at a number of Levels:
   1. Conceptual
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   2. Device Related
      1. New operations based on availability of New Therapeutic Devices
   3. Conceptual and Device Related

2. All need a CULTURE of Innovation and Early Adoption (with Audit)
Why Audit?
Why Audit?

Because we’re human and can make mistakes
Mike “Choogs” Machuga
Professional bowler
10 years on tour
4 PBA titles
Marfan’s Sinus of ValSalva Aneurysm (7.0 cm.) with Severe (+4) AI

Valve Sparing ?? Too much AI, too much aneurysmal dilation, too much leaflet surface area,
Failed Ross in 30 Year Old Male (Redo Buttons): Concept of COMBINATION Root aneurysm and DECREASED Leaflet (Cusp) Surface Area
1. Increased Valve Sparing Root Surgery (ALWAYS for AI) David V (and BAV repair techniques) .. *(Conceptual)*

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3. Hybrid Arch +/− Endo-Arch (Mixture) ...... The march towards “More Proximal” Reconstruction *(Conceptual and Device)*

4. Chronic Type B Dissecting Aneurysms *(Mostly Conceptual also Device)*
Chronic Dissection: Either Residual Type B after Type A Repair or simple Chronic Type B

10 yrs out

Thick chronic Membrane/Flap
Freedom from a Major Adverse Event Through 30 Days


TEVAR n=191
Chronic Distal Aortic Dissection after previous Type A: TEVAR
Chronic Type B aortic dissection: Again all 4 vessels off true lumen
Operative Candidate?
Must Be a Better Option!!!
Patient / Anatomy Selection

TEVAR vs Medical??

Most cases

Open

TEVAR

TEVAR
EndoVascular TAAA: Especially for Atherosclerotic Aneurysm

Chronic Dissecting TAAA further in the future

Courtesy of T. Mastrucci, CCF
How does a Division of Cardiovascular Surgery (or a Department of Surgery) **CREATE** an environment of Innovation and Early Adoption?

None of the stuff we just talked about can happen in a sclerotic surgical environment!
Benefits of a Robust Clinical Research Program

- **Trials:**
  - New Technology early
  - Attracts the best residents to your program
  - Marketing Budget (New Stuff!)
  - Academic Papers, publications

- **Outcomes:**
  - Academic Papers, publications, presentations
  - Quality improvement
  - Tie in with marketing (own the data ..... Superiority of clinical databases over administrative/billing databases.
NIH Year Payline Percentile

Payline Percentile

- Payline Percentile

- 6% !! Ugh!
Examples
TAVI Deployment

It all started in US with Partner Trial (Penn Nov 2007)
So ...... The Four Key Criteria:
CardiAQ™ Gen2 TA FIH

- Performed by Lars Sondergaard and team at Rigshospitalet in Copenhagen
- 88yr old Female, MR 4+, prior CABG, not a candidate for Surgery or MitraClip
- CardiAQ Gen2 Transcatheter Mitral Valve
- New Trans-Apical Delivery System

Pre-Procedural: MR 4+
Post-Procedural: Trace

Disclosure: J. Bavaria; Holder of Founders Shares equity
Innovation does need some Vision
Disclosures/Conflicts

- **Medtronic**: Co-Primary Investigator Talent Trial; Primary Investigator Valiant Valor II Trial, National CV PI Acute Type B Dissection trial; PI Surtavi Trial
- **W.L. Gore**: Primary Investigator TAG Trial; FDA PMA submission; PI Early Feasibility TBE, PI Dissection trial
- **St Jude Medical**: PI Trifecta FDA PMA trial; Portico Trial
- **Cook Medical**: Co-Primary Investigator TX2 Thoracic Aorta Trial, PI Post market TX2 trial
- **Bolton Relay**: sub-PI TEVAR trial
- **Sorin**: sub PI Perceval trial
- **Jotec**: Consultant; FDA E-Vita submission
- **Vascutek**: Aortic Symposium Director
- **Edwards**: PI, Partner Trial/ FDA PMA; PI Commence FDA Trial; PI Intuity FDA Trial
- **CardiAQ/Edwards**: Founding Team, Equity Holder
Disclosures

- **Medtronic**: Consultant; Co-Primary Investigator Talent Trial; Primary Investigator Valiant Valor II Trial, National CV PI Acute Type B Dissection trial
- **W.L. Gore**: Consultant; Primary Investigator TAG Trial; FDA PMA submission; Primary Investigator High Risk Trial, Dissection trial and Large Diameter 45 trial
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- **Bolton Relay**: sub-PI TEVAR trial
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- **Vascutek**: Aortic Symposium Director
- **Edwards**: PI, Partner Trial/ FDA PMA
- **Etc, etc, etc.**

**This is Not a Bad Thing!!**
Partner TAVI Trial High-Risk Enrollment by Site
NEJM 2010, NEJM 2011, NEJM 2012, etc, etc.....

Washington Hospital Ctr
District of Columbia
P. Corso, A. Pichard
40

University of Miami
Miami, FL
W. O Neill, D. Williams
25

Barnes-Jewish Hospital
St. Louis, MO
R. Damiano, J. Lasala
24

Stanford University
Palo Alto, CA
C. Miller, A. Yeung
23

Northwestern University
Chicago, IL
C. Davidson, P. McCarthy
20

St. Paul's Hospital
Vancouver, BC, Canada
A. Cheung, J. Webb
19

Non-University programs

Cedars-Sinai Medical Ctr
Los Angeles, CA
G. Fontana, R. Makkar
116

Columbia University
New York City, NY
M. Leon, C. Smith
97

Medical City Dallas
Dallas, TX
D. Brown, T. Dewey
95

Emory University
Atlanta, GA
P. Block, R. Guyton
67

University of Pennsylvania
Philadelphia, PA
J. Bavaria, H. Horrmann
52

Cleveland Clinic Found
Cleveland, OH
L. Svensson, M. Tuzcu
47
Epiphany .... (Vision):

Eventually, Every Aortic condition will be treated with TEVAR and Every Valvular Condition with Endo-Cardiac treatment and every Bad heart with a small pump !?!
However:

We will need surgeons who can do BOTH open surgery and TEVAR/TAVI.

..... Lots of complications and the necessity for definitive treatment will remain .... And reconstruction always wins.
“The Treatment is best provided by specialists who are great open surgeons AND great endovascular surgeons”

Juan Parodi, MD; STS 2006
Best Landscape for the Continuing Aortic, Valve and LVAD Treatment Revolution?
Thomas Eakins: Gross Clinic (1878@JEFF) and Agnew Clinic (1888@PENN)

Great Progress in 10 years!

Thank You
Mortality and Post Procedural PVL

TAVR Patients

- Moderate - Severe
- Mild
- None - Trace

p (log rank) = 0.0032

No. at Risk

<table>
<thead>
<tr>
<th>M-S</th>
<th>24</th>
<th>16</th>
<th>13</th>
<th>12</th>
<th>7</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>137</td>
<td>98</td>
<td>84</td>
<td>65</td>
<td>52</td>
<td>11</td>
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<tr>
<td>N-T</td>
<td>158</td>
<td>135</td>
<td>120</td>
<td>105</td>
<td>88</td>
<td>34</td>
</tr>
</tbody>
</table>

Months post Implant Procedure

0 12 24 36 48 60
Baseline Patient Characteristics
S3i Patients

Average STS = 5.3%
(Median 5.2%)

Average Age = 81.9yrs

N = 1076

Female 38%
Male 62%

TF, 89%
TAo, 4%
TA, 7%

4.1% 32.2% 43.7% 20.0%
20 mm 23 mm 26 mm 29 mm
### Example Commercial Patient

<table>
<thead>
<tr>
<th>Column Labels</th>
<th>Row Labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>$242</td>
</tr>
<tr>
<td>OR SUPPLIES</td>
<td>$32,500</td>
</tr>
<tr>
<td>01305192 TAVIAORTIC VALVE</td>
<td>$32,500</td>
</tr>
<tr>
<td>NUR-SILVERSTEIN 10</td>
<td></td>
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<tr>
<td>O.R. YELLOW</td>
<td>$2,093</td>
</tr>
<tr>
<td>01100346 OR 1ST HALF HR</td>
<td>$802</td>
</tr>
<tr>
<td>01100353 OR ADDTL HALF HR</td>
<td>$1,552</td>
</tr>
<tr>
<td>06550008 ART. (THORAC. AORTA) S/I</td>
<td>$173</td>
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<tr>
<td>NUR-SICU-CT/GS</td>
<td>$1,606</td>
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<tr>
<td>PHAR - IP CENTRAL ROBOT NARC</td>
<td>$1,140</td>
</tr>
<tr>
<td>PERIOP ANES TECHS HUP</td>
<td>$444</td>
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<tr>
<td>AUTO LAB</td>
<td>$196</td>
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<tr>
<td>BLOOD BANK</td>
<td>$207</td>
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<tr>
<td>RESPIRATORY THERAPY-HUP</td>
<td>$258</td>
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<tr>
<td>BONE/CHEST/ER SUPP</td>
<td>$167</td>
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<tr>
<td>ECHO LAB</td>
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<tr>
<td>INPATIENT PT-HUP</td>
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<tr>
<td>INPATIENT OT-HUP</td>
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<tr>
<td>PHLEBOTOMY</td>
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<tr>
<td>RAD DIAGNOSTIC CAM</td>
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<tr>
<td>CLINICAL LAB</td>
<td>$0</td>
</tr>
<tr>
<td>Grand Total</td>
<td>$242</td>
</tr>
</tbody>
</table>

OR Supplies, driven by valve 78% of direct cost
Future Considerations and Conclusions

- Repairative Heart Valve surgery, Small Pumps, Aortic Endovascular, and Transcatheter “EndoCardiac” procedures will gain traction and grow along with other niche areas.
- Traditional Cardiac Surgery will remain important and steady as will Congenital.
- Cardiovascular Surgery may get a bit smaller (ABTS 135 vs 95) as a specialty.
- Public Reporting of Outcomes and therefore the clinical STS National Database will become essential (also STS/ACC TVT database).
Present State of Thoracic Aortic Surgery: Achievements

1. Stunning Advances in Aortic Root Surgery
2. Extremely Low Morbidity/Mortality Ascending (Proximal Aortic) Treatment Outcomes
3. Advances in Aortic Arch Results
4. Acute Type A Dissection Series in High Volume Centers between 8-14% Mortality
5. Outstanding Descending Aortic Treatment Results
   1. Open and TEVAR (especially “on-Label”)

Rate of Change in Real per-Enrollee Spending by Payer

Data are derived from the National Health Expenditure Accounts. Inflation adjustments use the Gross Domestic Product Price Index reported in the National Income and Product Accounts. The mean growth rate for Medicare spending reported for 2005 through 2010 omits growth from 2005 to 2006 to exclude the effect of the creation of Medicare Part D.