The Importance of Hybrid OR in the Current Era of Cardiovascular Surgery and How to Influence Management to Build One.

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The Transcatheter Valve Lecture to Give to Hospital CEO, CFO, and Administration (and others who don’t get it!)

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Everyone is building a hybrid OR to perform hybrid procedures.

What is “hybrid”?
What is a Hybrid Procedure?

• A conventional open surgical procedure which is supported by sophisticated imaging

• A interventionalal procedure which is supported by conventional surgery
Why Hybrid OR / Hybrid Procedures?

Combine the benefits of the OR, cath lab, and IR suite to optimize and improve patient care and clinical outcome.

Perform procedures **not possible** previously due to infrastructure and logistical constraints.
First Hybrid OR at Penn (2005): Vascular/TEVAR
Second Hybrid OR at Penn: Cardio-Aortic-TAVI Focus
Making the Case to Hospital: Volume of New CV Cases

Being Prepared for the Future!!

.........Shame ....... Not Guilt!!
Debate “PRO” for Hybrid OR with your Administration

- The Future of a **SIGNIFICANT** part of CardioVascular Surgery Volumes will need Hybrid OR
- There will be an **INCREASING** number of existing CV surgical cases Relocating to Hybrid OR suite
- If you are **NOT** Prepared for the Future, you will **LOSE**!
- Typical Cases done in the Hybrid OR (Examples)
- How Important is CV Surgery and Valve Surgery to the Institution vis-à-vis the **TAVI Revolution**
- Importance of Disaster management and therefore **REDUCED** liability and better outcomes
- Focus **AGAIN** on the Future!
Typical Procedures in CardioVascular Surgery Hybrid Suites at Penn

- TEVAR
- Hybrid Arch TEVAR
- Type A Aortic Dissection
- Hybrid Coronary work
- TAVI Transcatheter Valves (TF, TA, TS, Tao))
- Thoracic Aortograms
- Other (Coarct, PA, Ascending TEVAR, etc)
- Advanced Structural Heart (Complex)

- EP (??)
Example of Types of Procedures done in Hybrid OR with either:

1. CardioVascular Surgery Alone
2. Cardiovascular-Vascular Team
3. Cardiac Surgery-Interventional Cardiology Team
TEVAR: Classic Indication, Now Standard of Care
Acute Type B “High Risk Un-Complicated” with Distal Aortic Remodeling

Perfect Coverage of Subclavian and LZ 2

Tight Zone 2: Need for Excellent Imaging
TEVAR: High Zone 2 LZ on Carotid: Need for Serious Imaging at “Mag 2”
How Access to Left Carotid helps in the “Conduct of Operation”
Very Complex (Multiple Access Venues) Type B Dissection Complicated
Type A Dissection in Hybrid OR

- Future EndoVascular “Adjunct” Procedures and Diagnostic “Finish” Angiogram
Type A (Debakey Type I) Dissection: Pre and Post Proximal Repair with E-Vita (type) Distal Graft

Beijing, China

E-Vita: 90% Thoracic Aortic False Lumen Obliteration

Acute Type A “Stented Elephant Trunk”
Pochettino, Szeto, and Bavaria; AnnThor Surg 2009
Hybrid Arch Procedure and Concept

“Classic” Debranching

Type I

Type II

Type III
Completed (Flouro) 2 Component Repair: Antegrade Delivery: Often have Prox and Distal LZ Diameter Discrepancies
Transcatheter AVR

Transfemoral

Transapical
Multi-Disciplinary Approach
Trans-Catheter Aortic Valve

The PARTNER TAVI Trial
Team Work

Surgeon

Cardiologist
Now (at TAVI = 350): **Junior Faculty** performing TAVI
TAVI Mean Gradient
Post THV: They Work!

Mean Gradient

Baseline, 24 Hr, Discharge, 30 Day, 3 Month, 6 Month, 1 Year

Error bars at ± 1 Standard Deviation

size 23 n
size 26 n

26 mm
23 mm
Background for Administration

Is Aortic Valve Surgery Important (Financially) to the Health System?

How Important?
Contribution Margin of Various Cardiac Treatments

Valve procedures are highly profitable; generating a healthy average contribution margin and per case gain

Key:
1) Bubble Size = Total Contribution
2) Axes Cross at Averages (393, $12,075)

Avg CM = $32K/case
Background for Administration

TAVI: Overwhelming Volume??
Implantations 06/07-06/09

N=262

CoreValve
n=198
- Transfemoral
  N=180
- Transapical
  N=5
- Subclavian artery
  N=9
- Ascending aorta
  N=4

Edwards Sapien
N=64
- Transfemoral
  N=4
- Transapical
  N=60

300 TAVI on August, 28th, 2009
292 patients (42.9%) received a major therapeutic procedure: cardiac surgery or BAV.

This does not include those patients pending who will eventually receive a major therapeutic procedure.
Data Driven Administration: Screen Failure Discharges: Case Types FY108 through FY10

69 of the total 289 discharges had a valve surgery DRG

<table>
<thead>
<tr>
<th>Cardiovascular Surgery Valve</th>
<th>Cases</th>
<th>Days</th>
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<tbody>
<tr>
<td>Cardiovascular Surgery Valve</td>
<td>69</td>
<td>1,020</td>
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<tr>
<td>Cardiac valve without card cath with MCC</td>
<td>40</td>
<td>544</td>
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<tr>
<td>Cardiac valve without card cath with CC</td>
<td>13</td>
<td>173</td>
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<tr>
<td>Cardiac valve with card cath with MCC</td>
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<tr>
<td>Cardiac valve with card cath with CC</td>
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<td>64</td>
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<td>Cardiovascular Surgery non-valve</td>
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<td></td>
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<td>ECMO/Trach</td>
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<td>487</td>
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<tr>
<td>VAD</td>
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<td>30</td>
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<td>Other CV Surgery</td>
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<td>42</td>
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<tr>
<td>Vascular</td>
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<td>46</td>
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<tr>
<td>Medical Cardiology (CHF, etc)</td>
<td>71</td>
<td>419</td>
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<tr>
<td>BAV</td>
<td>34</td>
<td>338</td>
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<tr>
<td>Other PTCA/PCI</td>
<td>12</td>
<td>64</td>
</tr>
<tr>
<td>Interventional - Cardiac Cath</td>
<td>49</td>
<td>300</td>
</tr>
<tr>
<td>Interventional Cardiology – EP procs</td>
<td>9</td>
<td>71</td>
</tr>
<tr>
<td>Non-CV (GI, Urology, ID, etc)</td>
<td>22</td>
<td>119</td>
</tr>
<tr>
<td>Medical Respiratory</td>
<td>8</td>
<td>80</td>
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<tr>
<td><strong>Grand Total</strong></td>
<td><strong>289</strong></td>
<td><strong>3,016</strong></td>
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</table>
Why are mobile C-arms insufficient for hybrid procedures?

Power: 2 - 25 kW
Anode can overheat and shut down
Heat storage capacity ≤ 300,000 HU
Frame rate: 2 – 25 f/s

Power: 80 - 100 kW
Special anode is cooled
Heat storage capacity > 1Mill HU
Frame rate: 30 – 60 f/s
Hybrid OR: Imaging Excellence

Mobile C-arm 15 kW
Guidewires are invisible / difficult to depict (0.2-0.3 mm)
Catheters (1-3 mm) can be detected (as shown)
Exact quantification of stenoses impossible

Fixed C-arm 100 kW
Guidewire is clearly depicted (0.2-0.3 mm)
(Magnified image)
“These requirements typically include a high-frequency generator with outputs of 80 to 100 kW at X-ray pulse rates of 30 pulses per second. (...) To visualize the smallest coronary arteries and complex variations in lumen geometry, focal spots of 0.6 to 0.8 mm are necessary. To acquire multiple angiographic sequences lasting up to 10 to 30s at rates of 30 fps (and higher), the tube must be able to absorb large amounts of energy (…).”

Making the Case to Hospital Administration for Hybrid OR: Serious TAVI Complications Management and therefore Hospital Liability Reduction
For example---------Rational and Discussion with Administration Regarding TAVI

1. Serious Heart Team Input
2. Rational for CardiacEndosuite

e.g. Disaster Management!
Why these procedures should be done in Operating Room EndoCardiovascular Suite “Hybrid OR”? 

- Ileo-Femoral access Complications and Vascular Catastrophes (Type A Dissection)
- Conversion to Open AVR
- CPB back up and CPB Resuscitation
- Tamponade from LV/RV perforation
- CV Anesthesia, TEE, ICE, NCM, Perfusion
- Sterility
- ETC, ETC.....
Vascular Access Complications: Completely Avulsed External Iliac (Iliac on-a-stick)

Vascular rupture by introducer/sheath
TAVI : TF K-M Survival by Procedural Vascular Complications

Log Rank P=0.0004
Coverage of Coronaries, High (Aortic) positioning and Paravalvular AI and Profound Hemodynamic Instability ….. CPB Stabilization
Aortic Rupture/Dissection after Implant

Annular Rupture 94 yr Sapien TA

83 yr old Aortic Rupture CoreValve TF

Courtesy of R. Langer, et al, Munich
Lessons: A Look at a Typical TAVI Series from Europe (the Initial 250 cases):

Transfemoral and Transapical Results: Real World, Large Series

- There are multiple series very similar
Transcatheter Valve

S Bleiziffer, et al; EJCTS, 2009 (Munich, Germany); Presented at EACTS 2008 Update at AATS Boston May 2009 (n=250)

- Complications Needing a CV Surgeon and Best Treated in “Hybrid OR”:
  - Peripheral Vascular and Dissection: 11.7%
    - both major and minor
  - Conversion to open AVR: 0.7% (2% in Partner)
  - Circulatory Collapse requiring CPB Resuscitation: 3%
  - Pericardial Effusion > 1 cm on TEE: 3.6%

- Total = 19%
Background for Administration

Ultimately ..... Being Prepared for The Future
US CMS/FDA “Patient Focused” Analysis of TAVI: “Characteristics of the HEART TEAM to perform TAVI for best patient outcomes

Developed with ACC, STS, SCAI, AATS ….. Four Society Document adopted by CMS

- Cardiac Surgeon Criteria (AVR Volumes, High Risk AVR Experience, Large Bore Sheath, etc)
- Interventionsal Cardiologist Criteria (PCI volumes, Structural Heart Experience, etc)
- Institutional Requirements: Cardiology Cath Lab Program Volumes, Cardiac surgery Program volumes AND
  - Physicians performs procedure in INSTITUTION with excellent Imaging facility (Hybrid Room)
- Program Quality Measures (1 yr and 30 day mortality, Vascular and CVA complication rates, etc)
Eventually, Every Aortic condition will be treated with TEVAR !?!
TEVAR for Aortic Arch Aneurysm with **Fenestrated** Endograft: University of Tokyo
Total EndoVascular Arch Procedure

Courtesy of Cherrie Abraham, MD, Montreal, Canada
The Future of Ascending TEVAR?: Repair of Ascending Aortic Aneurysm Trans-Apically with Stent Graft

Szeto, Bavaria, et al; ATS 2010

The Marriage of TAVI and TEVAR!!!
GORE TAG® Branched Thoracic Endoprosthesis

- Modular Construction
  - Off-the-shelf components
  - Inner lumen for anchoring and sealing branch component
EndoVascular TAAA: Especially for Atherosclerotic Aneurysm

Chronic Dissecting TAAA: Future is Now!
Transcatheter Valves in Development

- Edwards SAPIEN
- CoreValve
- Jena Valve
- Direct Flow
- Sorin Perceval
- Lutter Valve
- ATS/3F Enable
- ATS/3F Entrata
- ABPS PercValve
- Sadra Lotus
- AorTx PAVR
- Heart Leaflet

Heart Leaflet
Background for Administration

Ultimately ….. Being Prepared for The Future

And Since the Mitral valve is Such a big part of this Mtg …..
Transcatheter Mitral Valve Implantation

- CardiAQ Valve Technologies, Inc. (CVT)
  - True trans-vessel percutaneous interventional approach:
    - Transfemoral Vein,
    - Transseptal
    - Antegrade

Initially presented at EACTS 2009 and TCT 2009 (by invitation), Euro PCR 2010 (brief communication), update at EACTS 2010 (by invitation) and TCT 2010 (abstract): (J. Bavaria, A. Quadry, B. Ratz, et al)
Transcatheter MVR (Animals): Trans Venous, Trans-Septal access with Mitral Annular Fixation, No MR, No SAM, Total Chord preservation

Abstract presented at TCT 2010: A. Quadry, et al
Will Transcatheter Therapies Replace Surgery for Mitral Regurgitation?
Will Transcatheter Therapies Replace Surgery for Mitral Regurgitation?

Yes, it’s only a question of time
Administration Alert: Make Sure the Room can be used for “Standard” Cardiac and Vascular Procedures ........ (Concept of Never Empty!)

Tactics: Cardiac, Vascular, Interventional Cardiology “Alignment” with the Hospital, “The Heart Team”
Weekly Penn Aortic Valve and TAVI Conference: **Heart Team** in Action
Besides, They are really Cool! : Artis zeege: Robotic C-Arm

*Future 510k*
Hybrid OR Planning is Key!!!

Thank You
Background for Administration

Ultimately ..... Being Prepared for The Future

And Since this is a Mitral Conclave!!