TAVR Has Matured: *We only Need One operator*

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Disclosures:

- I have nothing to disclose.
Success of TAVR

The PARTNER 3 TRIAL

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery
Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., D. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makk, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Pedersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients
Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., D. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makk, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Bablaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators
Procedural Complications That Could Lead Immediate Surgical Intervention

- Annular Rupture
- Coronary Obstruction
- Cardiac perforation
- Major Vascular Bleeding
- Valve Embolization
30 Day Composite Major Outcomes Related to Site Annual Volume
2016-2017 Complete One-Year Data from STS-ACC TVT Registry

Frequency of Major Complications %

Site Annual TAVR Volume

- Major Vascular Complications
- Major Bleeding
- Mortality

P<0.001
SAPIEN Valve Evolution

Valve Technology

- SAPIEN
- SAPIEN XT
- SAPIEN 3

Sheath Compatibility

- SAPIEN: 22-24F
- SAPIEN XT: 16-20F
- SAPIEN 3: 14-16F

Available Valve Sizes

- SAPIEN: 23 mm, 26 mm
- SAPIEN XT: 23 mm, 26 mm, 29 mm
- SAPIEN 3: 20 mm, 23 mm, 26 mm, 29 mm

FDA Approval of Valve:

- PARTNER 1: 2011
- PARTNER 2: 2014
- PARTNER 3: 2015
Current Status of reimbursement for TAVR

CMS National Coverage Determination for TAVR (5/1/2012)

B. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following:

1. The heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient’s quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:
   - What is the incidence of stroke?
   - What is the rate of all cause mortality?
   - What is the incidence of transient ischemic attacks (TIAs)?
   - What is the incidence of major vascular events?
   - What is the incidence of acute kidney injury?
   - What is the incidence of repeat aortic valve procedures?

3. The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:
Definition of Co-Surgeon

CMS definition - “Under some circumstances, the individual skills of two or more surgeons are required to perform surgery on the same patient during the same operative session. This may be required because of the complex nature of the procedure(s) and/or the patient’s condition. In these cases, the additional physicians are not acting as assistants-at-surgery.”
Two Surgeons. The individual skills of two or more surgeons are required to perform surgery on the same patient during the same operative session. Each Surgeon bills for the procedure with a modifier 62. Each surgeon will collect 62.5% of the RVUs assigned to the CPT code
# Physician Billing for TAVR

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>2018 National Avg. Physician Payment (Final JAN-DEC)</th>
<th>Each Physician Payment (Modifier-62)*</th>
<th>2018 Facility RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
<td>$1,421</td>
<td>$888</td>
<td>39.46</td>
</tr>
<tr>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
<td>$1,551</td>
<td>$969</td>
<td>43.08</td>
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<tr>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
<td>$1,608</td>
<td>$1,005</td>
<td>44.68</td>
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<tr>
<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
<td>$1,694</td>
<td>$1,059</td>
<td>47.06</td>
</tr>
<tr>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; trans-aortic approach (e.g., median sternotomy, mediastinotomy)</td>
<td>$1,863</td>
<td>$1,164</td>
<td>51.76</td>
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<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)</td>
<td>$2,015</td>
<td>$1,259</td>
<td>55.98</td>
</tr>
</tbody>
</table>

Relative Value Unit (RVU) = 45$

Anticipate 10% reduction with CMS revaluation
TAVR Procedure: Procedural team

- Cardiac Surgeon
- Anesthesiologist
- Structural Fellow
- Cardiology Proceduralist
- Interventional Cardiology fellow
Cardiac Surgeon During TAVR Procedures

- Participation Inconsistent and variable
- Catheter and wire skills inconsistent and variable
- Interest in the procedure variable
- Unavailability leads to cancelled procedures, inefficient use of hospital resources, Patient unhappiness and dissatisfaction and diminished team morale
NCD for TMVR

The National Coverage Determination (NCD) for TMVR specifically states, “TMVR must be performed by an interventional cardiologist or a cardiothoracic surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.” (Source: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273.)
Proposal for the Future of TAVR

- Eliminate the Mandatory requirement that a surgeon and cardiologist do all TAVR procedures together (62 modifier)
- Change to an optional 62 modifier stating that two operators MAY participate in TAVR procedure together
  - Surgeon and cardiologist
  - Two surgeons
  - Two cardiologists
  - Single operator (surgeon or cardiologist)

- Multidisciplinary Heart team will determine need for surgeon
  - Straight forward transfemoral case does not require surgeon
  - Cases with Red Flags should be scheduled with surgical participation
  - Alternate access, highly calcified valve, low lying coronary, should be scheduled with surgical participation
Conclusions

- TAVR procedures have advanced over the past 7 years since commercialization began
- No longer a nascent technology
- Large experience with the procedure
- Later generation equipment has been streamlined
- Complications are much fewer
- Need for intra-procedural surgical intervention is rare
- Skillsets, interest and participation from surgeons variable
- New technology allows for single operator TAVR procedures
- The mandatory requirement for co-participation of a cardiologist and surgeon for TAVR is outdated
- Reimbursement for TAVR is expected to decrease
- Should move towards optional 62 modifier that allows for optional co-participation of surgeon and cardiologist on select complex TAVR cases