Evolving and Expanding Indications for TAVR

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Penn Aortic Valve Repair Symposium
Philadelphia 2015
## Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Grant/Research Support</td>
<td>• Edwards Lifesciences, Medtronic, Vascutek, Sorin</td>
</tr>
<tr>
<td>• Consulting Fees/Honoraria</td>
<td>• Microinterventional Device</td>
</tr>
</tbody>
</table>
A BREAKDOWN OF OUR 1,000 TAVR CASES

Nov. 2007 – Jan. 2015

PARTNER Trial
(N=475)

PARTNER 1 (n=185)
- 115 TF
- 70 TA

PARTNER 2

P2A (n=39)
- 25 TF
- 1 TAO
- 13 TA

P2B (n=140)
- 112 TF
- 4 TAO
- 24 TA

Sapien 3

Commercial TAVR Cases
(N=518)
- 368 TF
- 150 Alternative Access
- 337 Sapien (65.1%)
- 95 Sapien XT (18.3%)
- 86 Corevalve (16.6%)

SURTAVI (N=7)
- 6 TF
- 1 Alternative Access

High Risk
(n=45)
- 32 TF
- 3 TAO
- 10 TA

Intermediate Risk
(n=66)
- 60 TF
- 1 TAO
- 5 TA
U Penn
AVR / TAVR Continues to Grow

2007 - 2013

VOLUME

2007 2008 2009 2010 2011 2012 2013

Open AVR  TAVR
Patient Selection
TAVR vs AVR

Operable AS patients

High Risk

Too Sick

Inoperable

Low-Intermediate Risk

II A

A

B

C

90%

10%

%?
Nishimura, RA et al.
2014 AHA/ACC Valvular Heart Disease Guideline

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Developed in Collaboration With the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

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*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply; see Appendix 1 for recusal information.
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The Heart Team

Class I

Patients with severe VHD should be evaluated by a multidisciplinary heart valve team when intervention is considered.

(Level of Evidence: C)
Prohibitive Risk

Class I

TAVR is recommended in patients who meet an indication for AVR who have a prohibitive risk for surgical AVR and a predicted post-TAVR survival greater than 12 months

(Level of Evidence: B)
High Risk

Class IIa

TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR and who have high surgical risk for surgical AVR

(Level of Evidence: B)
5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial


Kapadia, TCT 2014
All-Cause Mortality (ITT)

Crossover Patients Censored at Crossover

<table>
<thead>
<tr>
<th></th>
<th>Standard Rx (n = 179)</th>
<th>TAVR (n = 179)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30.7%</td>
<td>50.8%</td>
<td></td>
</tr>
<tr>
<td>43.0%</td>
<td>53.9%</td>
<td></td>
</tr>
<tr>
<td>68.0%</td>
<td>80.9%</td>
<td></td>
</tr>
<tr>
<td>80.9%</td>
<td>87.5%</td>
<td></td>
</tr>
<tr>
<td>87.5%</td>
<td>93.6%</td>
<td></td>
</tr>
</tbody>
</table>

HR [95% CI] = 0.50 [0.39, 0.65]

p (log rank) < 0.0001

* In an age and gender matched US population without comorbidities, the mortality at 5 years is 40.5%.
5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

All-Cause Mortality (ITT)

All Patients

HR [95% CI] = 1.04 [0.86, 1.24]
p (log rank) = 0.76

No. at Risk

<table>
<thead>
<tr>
<th>Group</th>
<th>0</th>
<th>12</th>
<th>24</th>
<th>36</th>
<th>48</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>348</td>
<td>262</td>
<td>228</td>
<td>191</td>
<td>154</td>
<td>61</td>
</tr>
<tr>
<td>SAVR</td>
<td>351</td>
<td>236</td>
<td>210</td>
<td>174</td>
<td>131</td>
<td>64</td>
</tr>
</tbody>
</table>

Error Bars Represent 95% Confidence Limits
CoreValve® US Pivotal Trial
High Risk Study 2-Year Results
Results Presented at ACC 2015

Reardon, ACC 2015
Expanding the Indications
Practice Gaps

- Intermediate risk
- Significant MR / TR
- Valve in Valve
- Renal failure / Dialysis
- Bicuspid aortic valve
- Aortic Insufficiency
Low / Intermediate Risk

Class I

Surgical AVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk

(Level of Evidence: A)
Intermediate Risk

• PARTNER II
  – Enrollment completed

• SURTAVI
  – Enrollment ongoing
Clinical and Echocardiographic Outcomes at 30 Days with the SAPIEN 3 TAVR System in Inoperable, High-Risk and Intermediate-Risk AS Patients

Susheel Kodali, MD
on behalf of The PARTNER Trial Investigators

ACC 2015  |  San Diego  |  March 15, 2015
Evolution of the Edwards Balloon-Expandable Transcatheter Valves

- **Cribier-Edwards** (2002)
- **SAPIEN** (2006)
- **SAPIEN XT** (2009)
- **SAPIEN 3** (2013)

*Sheath compatibility for a 23 mm valve*
The PARTNER II S3 Trial
Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT by Heart Valve Team

n = 1076 Patients

Intermediate Risk Operable (PII S3i)

ASSESSMENT: Optimal Valve Delivery Access

Transfemoral (TF)

TF TAVR SAPIEN 3

Transapical / Transaortic (TA/TAo)

TAA TAVR SAPIEN 3

n = 583 Patients

High Risk Operable / Inoperable (PII S3HR)

ASSESSMENT: Optimal Valve Delivery Access

Transfemoral (TF)

TF TAVR SAPIEN 3

Transapical / Transaortic (TA/TAo)

TAA TAVR SAPIEN 3

2 Single Arm Non-Randomized Historical-Controlled Studies

PII A SAVR

PI A SAPIEN

The PARTNER II S3 Trial Study Design
Mortality and Stroke: S3HR
At 30 Days (As Treated Patients)

Mortality

- All-Cause
- Cardiovascular

O:E = 0.26
(STS 8.6%)

Stroke

- All Stroke
- Disabling

S3HR

O:E = 0.26
(STS 8.6%)
Mortality and Stroke: S3i
At 30 Days (As Treated Patients)

Mortality
- All-Cause
- Cardiovascular

O:E = 0.21
(STS 5.3%)

Stroke
- All Stroke
- Disabling
Paravalvular Leak: S3HR & S3i
(Valve Implant Patients)

- None/Trace: 55.0%
- Mild: 41.3%
- Moderate: 3.7%
- Severe: 0.1%

No. of Echos: 1504

30 Days
Bicuspid Aortic Valve
Bicuspid Aortic Valve
Transcatheter Aortic Valve Replacement in Bicuspid Aortic Valve Disease

Darren Mylotte, MB, MD,† Thierry Lefèvre, MD,‡ Lars Søndergaard, MD,‖ Yusuke Watanabe, MD,¶ Thomas Modine, MD,‖ Danny Dvir, MD,¶ Johan Bosmans, MD,# Didier Tchétche, MD,** Ran Kornowski, MD,†† Jan-Malte Sinning, MD,†† Pascal Thériault-Lauzier, PhD,† Crochan J. O’Sullivan, MB, MD,‡§ Marco Barbanti, MD,§§ Nicolas Debruy, MD,‖ Jean Buitheu, MD,‖ Pablo Codner, MD,‖ Magdalena Dorfmeister, MD,¶¶ Giuseppe Martucci, MD,‖ Georg Nickenig, MD,‖ Peter Wennaweser, MD,¶§ Corrado Tamburino, MD,¶¶ Eberhard Grube, MD,‖ John G. Webb, MD,¶ Stephan Windecker, MD,¶§ Ruediger Lange, MD, PhD,¶¶ Nicolò Piazza, MD, PhD,¶¶

### TABLE 2 Bicuspid Aortic Valve Type

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>All Patients (n = 120)</th>
<th>Sapien (n = 40)</th>
<th>CoreValve (n = 80)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 0</td>
<td>32 (26.7)</td>
<td>8 (20.0)</td>
<td>24 (30.0)</td>
<td>0.28</td>
</tr>
<tr>
<td>Type 1</td>
<td>82 (68.3)</td>
<td>31 (77.5)</td>
<td>51 (63.8)</td>
<td>0.15</td>
</tr>
<tr>
<td>LR</td>
<td>60 (50.0)</td>
<td>26 (65.0)</td>
<td>34 (42.5)</td>
<td></td>
</tr>
<tr>
<td>RN</td>
<td>15 (12.5)</td>
<td>2 (5.0)</td>
<td>13 (16.3)</td>
<td></td>
</tr>
<tr>
<td>LN</td>
<td>7 (5.8)</td>
<td>3 (7.5)</td>
<td>4 (5.0)</td>
<td></td>
</tr>
<tr>
<td>Type 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LR/RN</td>
<td>6 (5.0)</td>
<td>1 (2.5)</td>
<td>5 (6.2)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

Values are n (%). Classification of bicuspid aortic valve morphology according to Sievers et al. (19).

LN = left - non; LR = left - right; RN = right - non.
TABLE 3  Procedural Information and Outcomes

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients (n = 139)</th>
<th>Sapien (n = 48)</th>
<th>CoreValve (n = 91)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAV size, mm</td>
<td>27.8 ± 2.2</td>
<td>26.3 ± 2.2</td>
<td>28.5 ± 1.8</td>
<td>0.0002</td>
</tr>
<tr>
<td>23 mm</td>
<td>10 (7.2)</td>
<td>10 (20.8)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>26 mm</td>
<td>50 (36.0)</td>
<td>23 (47.9)</td>
<td>27 (29.7)</td>
<td>0.04</td>
</tr>
<tr>
<td>29 mm</td>
<td>59 (42.4)</td>
<td>15 (31.3)</td>
<td>44 (48.4)</td>
<td>0.07</td>
</tr>
<tr>
<td>31 mm</td>
<td>20 (14.4)</td>
<td>-</td>
<td>20 (22.0)</td>
<td>-</td>
</tr>
<tr>
<td>MSCT cover index, %</td>
<td>13.2 ± 9.1</td>
<td>8.9 ± 5.7</td>
<td>16.3 ± 9.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>MSCT-based TAV sizing</td>
<td>88 (63.3)</td>
<td>37 (77.1)</td>
<td>51 (56.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>Vascular access</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoral</td>
<td>109 (78.5)</td>
<td>30 (62.5)</td>
<td>79 (86.8)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Postimplantation echocardiography

<table>
<thead>
<tr>
<th></th>
<th>All Patients (n = 139)</th>
<th>Sapien (n = 48)</th>
<th>CoreValve (n = 91)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic regurgitation, grade (1–4)*</td>
<td>1.1 ± 0.9</td>
<td>1.0 ± 0.9</td>
<td>1.1 ± 0.9</td>
<td>0.53</td>
</tr>
<tr>
<td>≥ Grade 2</td>
<td>38 (28.4)</td>
<td>9 (19.6)</td>
<td>29 (32.2)</td>
<td>0.11</td>
</tr>
<tr>
<td>≥ Grade 3</td>
<td>8 (6.0)</td>
<td>3 (6.5)</td>
<td>5 (5.5)</td>
<td>0.99</td>
</tr>
<tr>
<td>Aortic valve gradient, mm Hg*</td>
<td>11.4 ± 9.9</td>
<td>11.7 ± 8.7</td>
<td>11.3 ± 10.4</td>
<td>0.82</td>
</tr>
<tr>
<td>Aortic valve area, cm²*</td>
<td>1.7 ± 0.5</td>
<td>1.6 ± 0.4</td>
<td>1.7 ± 0.5</td>
<td>0.23</td>
</tr>
<tr>
<td>Contrast media, ml</td>
<td>174 ± 88</td>
<td>176 ± 118</td>
<td>172 ± 81.5</td>
<td>0.17</td>
</tr>
<tr>
<td>Fluoroscopy duration, min</td>
<td>20 (14–28)</td>
<td>14 (9–25)</td>
<td>20 (15–29)</td>
<td>0.004</td>
</tr>
</tbody>
</table>

Postimplantation echocardiography

<table>
<thead>
<tr>
<th></th>
<th>All Patients (n = 139)</th>
<th>Sapien (n = 48)</th>
<th>CoreValve (n = 91)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion to SAVR</td>
<td>3 (2.2)</td>
<td>2 (4.2)</td>
<td>1 (1.1)</td>
<td>0.30</td>
</tr>
<tr>
<td>Aortic regurgitation, grade (1–4)*</td>
<td>1.1 ± 0.9</td>
<td>1.0 ± 0.9</td>
<td>1.1 ± 0.9</td>
<td>0.53</td>
</tr>
<tr>
<td>≥ Grade 2</td>
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<td>29 (32.2)</td>
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<td>11.3 ± 10.4</td>
<td>0.82</td>
</tr>
<tr>
<td>Aortic valve area, cm²*</td>
<td>1.7 ± 0.5</td>
<td>1.6 ± 0.4</td>
<td>1.7 ± 0.5</td>
<td>0.23</td>
</tr>
<tr>
<td>Contrast media, ml</td>
<td>174 ± 88</td>
<td>176 ± 118</td>
<td>172 ± 81.5</td>
<td>0.17</td>
</tr>
<tr>
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<td>14 (9–25)</td>
<td>20 (15–29)</td>
<td>0.004</td>
</tr>
</tbody>
</table>
# Bicuspid AV and TAVR

Table 4
Long-term results

<table>
<thead>
<tr>
<th></th>
<th>BAV (n = 23)</th>
<th>No-BAV (n = 70)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up (months)</td>
<td>11.4 ± 1.3</td>
<td>11.6 ± 1.5</td>
<td>1.00</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>5 (18%)</td>
<td>14 (17%)</td>
<td>1.00</td>
</tr>
<tr>
<td>All-cause mortality in patients</td>
<td>2 (11%)</td>
<td>10 (15%)</td>
<td>0.72</td>
</tr>
<tr>
<td>with PVLR &lt;2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality in patients</td>
<td>3 (33%)</td>
<td>4 (21%)</td>
<td>0.36</td>
</tr>
<tr>
<td>with PVLR ≥2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New York Heart Association</td>
<td>1.6 ± 0.6</td>
<td>1.8 ± 0.6</td>
<td>0.23</td>
</tr>
<tr>
<td>class at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>53.5 ± 18.1</td>
<td>51.1 ± 12.7</td>
<td>0.53</td>
</tr>
<tr>
<td>Aortic prosthetic valve area (cm²)</td>
<td>1.6 ± 0.4</td>
<td>1.7 ± 0.3</td>
<td>0.73</td>
</tr>
<tr>
<td>Mean gradient (mm Hg)</td>
<td>10.3 ± 5.4</td>
<td>9.8 ± 2.8</td>
<td>0.64</td>
</tr>
<tr>
<td>Aortic regurgitation ≥2</td>
<td>6 (22%)</td>
<td>17 (22%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Mitral regurgitation ≥2</td>
<td>5 (19%)</td>
<td>25 (32%)</td>
<td>0.32</td>
</tr>
</tbody>
</table>

Kochman et al, JACC, 2014
Aortic Insufficiency
History of Homograft
Initial German Experience With Transapical Implantation of a Second-Generation Transcatheter Heart Valve for the Treatment of Aortic Regurgitation

Moritz Seiffert, MD,* Ralf Bader, MD,† Utz Kappert, MD,‡ Ardawan Rastan, MD,§ Stephan Krapf, MD,|| Sabine Bleiziffer, MD,¶ Steffen Hofmann, MD,§ Martin Arnold, MD,** Klaus Kallenbach, MD,†† Lenard Conrad, MD,* Friederike Schlingloff, MD,† Manuel Wilbring, MD,‡ Ulrich Schäfer, MD,† Patrick Diemert, MD,* Hendrik Treede, MD*

FIGURE 2 Jena Valve THV Prosthesis
**ESCVS article - Experimental**

**Transcatheter aortic valves inadequately relieve stenosis in small degenerated bioprostheses**

Ali N. Azadani, Nicolas Jaussaud, Peter B. Matthews, Liang Ge, Timothy A.M. Chuter, Elaine E. Tseng*

Department of Surgery, University of California at San Francisco Medical Center (UCSF) and San Francisco Veterans Affairs Medical Center (SFVAMC), San Francisco, CA, USA

Received 12 October 2009; received in revised form 12 March 2010; accepted 25 March 2010

---

### Table 1

Transvalvular mean pressure gradient (mmHg) before and after TAVI compared with normal bioprosthesis

<table>
<thead>
<tr>
<th>Degenerated bioprosthesis</th>
<th>Valve-in-valve</th>
<th>Normal bioprosthesis</th>
<th>Cohen’s $d$</th>
<th>Effect-size correlation $r_s$</th>
<th>Percentile standing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± S.D.</td>
<td>Mean ± S.D.</td>
<td>Mean ± S.D.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 mm</td>
<td>57.1 ± 4.3</td>
<td>46.5 ± 9.3</td>
<td>16.2 ± 2.2</td>
<td>4.5</td>
<td>&gt; 98</td>
</tr>
<tr>
<td>21 mm</td>
<td>52.3 ± 7.0</td>
<td>19.5 ± 5.0*</td>
<td>12.4 ± 2.0</td>
<td>1.9</td>
<td>97</td>
</tr>
<tr>
<td>23 mm</td>
<td>50.9 ± 4.7</td>
<td>9.1 ± 4.1*</td>
<td>5.5 ± 0.8</td>
<td>1.2</td>
<td>88</td>
</tr>
</tbody>
</table>

*P < 0.001 between degenerated bioprostheses and valve-in-valve.

*P < 0.02 between valve-in-valve and normal bioprosthesis.

Cohen’s $d$, the effect-size correlation $r_s$, and percentile standing reflect valve-in-valve vs. normal bioprosthesis.

TAVI, transcatheter aortic valve implantation; S.D., standard deviation.

---

### Table 2

Effective orifice area (cm²) before and after TAVI compared with normal bioprosthesis

<table>
<thead>
<tr>
<th>Degenerated bioprosthesis</th>
<th>Valve-in-valve</th>
<th>Normal bioprosthesis</th>
<th>Cohen’s $d$</th>
<th>Effect-size correlation $r_s$</th>
<th>Percentile standing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± S.D.</td>
<td>Mean ± S.D.</td>
<td>Mean ± S.D.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 mm</td>
<td>0.75 ± 0.17</td>
<td>0.76 ± 0.09</td>
<td>1.28 ± 0.10</td>
<td>5.5</td>
<td>&gt; 98</td>
</tr>
<tr>
<td>21 mm</td>
<td>0.72 ± 0.04</td>
<td>1.17 ± 0.14*</td>
<td>1.49 ± 0.13</td>
<td>2.4</td>
<td>98</td>
</tr>
<tr>
<td>23 mm</td>
<td>0.65 ± 0.06</td>
<td>1.81 ± 0.48*</td>
<td>2.20 ± 0.15</td>
<td>1.1</td>
<td>86</td>
</tr>
</tbody>
</table>

*P < 0.003 between degenerated bioprosthesis and valve-in-valve.

*P < 0.003 between valve-in-valve and normal bioprosthesis.

Cohen’s $d$, the effect-size correlation $r_s$, and percentile standing reflect valve-in-valve vs. normal bioprosthesis.

TAVI, transcatheter aortic valve implantation; S.D., standard deviation.
Analysis of post procedural gradients

Rate of Post-procedural mean gradients ≥ 40mmHg (%)

Edwards SAPIEN
Post procedural mean aortic-valve gradients (mmHg)

CoreValve
Post procedural mean aortic-valve gradients (mmHg)

Surgical valve internal diameter (mm)
Impact of MR: TAVR vs AVR

Barbanti et al, Circulation 2013
TAVR vs AVR/MVR

Fig 5. Long-term landmark survivor analysis of patients with significant mitral regurgitation, comparing aortic valve replacement/mitral valve replacement (AVR/MVR [blue line]) versus transcatheter aortic valve replacement (TAVR [red line]).

Fig 7. Landmark survival analysis for 50 matched pairs using comorbidity model. (Blue line = aortic valve replacement/mitral valve replacement [AVR/MVR]; red line = transcatheter aortic valve replacement [TAVR].)

McCarthy et al; Annals of Thorac Surg, 2014
TAVR: Dialysis vs Non Dialysis
Medicare Study: 5000 patients

McCarthy et al, STS 2015
TAVR vs AVR in Dialysis
Propensity Matched 194 pts

McCarthy et al, STS 2015
-1 to 1 Landing Zone Concept

Endobentall

Endo Arch

Synergy

TAVR/TEVAR
The Heart Team

Penn Physicians:
- Cardiovascular Surgeons
- Interventional Cardiologists
- Echocardiologists
- CT anesthesiologists
- Outside Referring Physicians

Hybrid OR Staff
- ICU Nurses
- Research Coordinators
- Sponsoring Company
- Patient Families

Team Work
Members

Wilson Szeto, MD (Co-Chair)  Susheel Kodali, MD
Kevin Greason, MD (Co-Chair)  Marty Leon, MD
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                      Hersh Maniar, MD
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Ted Feldman, MD  Michael Reardon, MD
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Howard Herrmann, MD  Vinod Thourani, MD
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Neil Kleiman, M  Mat Williams, MD