TAVR: Review of the Robust Data from Randomized Trials

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Disclosures

• Boehringer Ingelheim Medical Advisory Board
• Edwards Lifesciences Consultant
• Medtronic Research Support
• Novartis Pharmaceuticals Consultant
• St. Jude/Abbott Consultant
Patients at Extreme Surgical Risk

Foundational trials tested new TAVR therapy in patients without the option for a surgical aortic valve replacement.

**US CoreValve Pivotal Trial**

CoreValve, N=489, STS 10.3%

**PARTNER 1B**

SAPIEN, N=179, STS 11.2%

**Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery**

Jeffrey J. Popma, MD,‡ David H. Adams, MD,‡ Michael J. Reardon, MD,‡ Steven J. Yakubov, MD,‡ Neal S. Kleiman, MD,‡ David Heimansohn, MD,‡ James Hermiller, Jr, MD,‡ G. Chad Hughes, MD,‡ J. Kevin Harrison, MD,‡ Joseph Coselli, MD,‡ Jose Diez, MD,‡ Ali Kheiri, MD,‡,‡‡ Theodore Schreiber, MD,‡ Thomas G. Glatston, MD,‡ John Conte, MD,‡‡ Maurice Bachhuber, MD,‡‡ G. Michael Deeb, MD,‡‡ Blase Carabello, MD,‡‡ Patrick W. Serruys, MD, PhD,§ Shurla Chenoweth, MS,§§ Jae K. Oh, MD,†‡ for the CoreValve United States Clinical Investigators

Boston, Massachusetts; New York, New York; Houston, Texas; Columbus, Ohio; Indianapolis, Indiana; Durham, North Carolina; Detroit and Ann Arbor, Michigan; Pittsburgh, Pennsylvania; Baltimore, Maryland; Palo Alto, California; Rotterdam, the Netherlands; and Minneapolis and Rochester, Minnesota

*The New England Journal of Medicine*

OCTOBER 21, 2010

Vol. 363 No. 17

**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., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John C. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, 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. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators
PARTNER showed that by 3 years, TAVR had reduced mortality by approximately 30% compared to standard medical management.

Similar survival results were achieved with CoreValve in the US Pivotal Trial.
Patients at High Surgical Risk

Trials randomizing high risk patients to either TAVR or SAVR soon followed

**US CoreValve Pivotal Trial**

CoreValve, N=390, STS 7.3% vs. SAVR, N=357, STS 7.5%

**PARTNER 1A**

SAPIEN, N=348, STS 11.8% vs. SAVR, N=351, STS 11.7%

Original Article

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators

The NEW ENGLAND JOURNAL of MEDICINE

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., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Sarnir Kapadia, M.D., Vassilis Babaliaros, 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. Alkin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators

E. Grube CRT 2017
PARTNER 1A
5-Year Follow-Up Presented at ACC 2015

- PARTNER showed that ~35% of patients survived to 5 years, regardless of treatment
- This study provided the first confirmation that TAVR is a reasonable alternative to surgery in high risk patients

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**All-Cause Mortality (ITT)**

**All Patients**

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. at Risk</td>
<td>348</td>
<td>351</td>
</tr>
<tr>
<td>0 months</td>
<td>262</td>
<td>236</td>
</tr>
<tr>
<td>12 months</td>
<td>228</td>
<td>210</td>
</tr>
<tr>
<td>24 months post Randomization</td>
<td>191</td>
<td>174</td>
</tr>
<tr>
<td>36 months</td>
<td>154</td>
<td>131</td>
</tr>
<tr>
<td>48 months</td>
<td>61</td>
<td>64</td>
</tr>
</tbody>
</table>

HR [95% CI] = 1.04 [0.86, 1.24]

p (log rank) = 0.76

1Mack, et al., presented at ACC 2015
The CoreValve Pivotal Trial was the first to show a survival advantage with TAVR compared to SAVR, with separation of the all-cause mortality curves maintained to 3 years.

1Deeb, et al., *J Am Coll Cardiol* 2016 Mar 22; doi: 10.1016/j.jacc.2016.03.506
# 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

## Table 8. Summary of Recommendations for AS: Choice of Surgical or Transcatheter Intervention

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical AVR is recommended in patients who meet an indication for AVR (Section 3.4) with low or intermediate surgical risk (Section 2.5 in the full-text guideline)</td>
<td>I</td>
<td>A</td>
<td>(70, 71)</td>
</tr>
<tr>
<td>For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care</td>
<td>I</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival &gt;12 mo</td>
<td>I</td>
<td>B</td>
<td>(72, 73)</td>
</tr>
<tr>
<td>TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.4) and who have high surgical risk (Section 2.5 in the full-text guideline)</td>
<td>IIa</td>
<td>B</td>
<td>(74, 75)</td>
</tr>
<tr>
<td>Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS</td>
<td>IIb</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS</td>
<td>III: No Benefit</td>
<td>B</td>
<td>(72)</td>
</tr>
</tbody>
</table>

AS indicates aortic stenosis; AVR, aortic valve replacement; COR, Class of Recommendation; LOE, Level of Evidence; N/A, not applicable; and TAVR, transcatheter aortic valve replacement.
Randomized trial data comparing TAVR to SAVR in lower-risk patients recently became available.

SAPIEN XT and SAPIEN 3

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

JAMA Cardiology | Brief Report
Outcomes in the Randomized CoreValve US Pivotal High-risk Trial in Patients With a Society of Thoracic Surgeons Risk Score of 7% or Less

The NEW ENGLAND JOURNAL of MEDICINE

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

JAMA Cardiology | Brief Report
Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

E. Grube CRT 2017
The PARTNER 2A Trial showed that TAVR with SAPIEN XT was non-inferior to surgery for the primary endpoint of all-cause mortality or disabling stroke at 2 years.

\[ \text{HR [95% CI]} = 0.89 \, [0.73, 1.09] \]

\[ p \, (\text{log rank}) = 0.253 \]

\(^1\text{Smith, et al., presented at ACC 2016}\)
This study also generated convincing evidence that transfemoral TAVR provides an outcome advantage to intermediate risk patients.

In the as-treated population, TF TAVR significantly reduced all-cause mortality or disabling stroke vs. surgery (p = 0.04).

\(^1\) Smith, et al., presented at ACC 2016
Both TAVR and SAVR significantly improved quality of life, but TAVR facilitated an earlier functional recovery as seen by the 11.4 point difference in KCCQ score at 1 month. This benefit was driven by the transfemoral approach. There was no quality of life benefit relative to SAVR for patients that had a transthoracic approach.

1Cohen, et al., presented at TCT 2016
These data have enabled the recent approval of TAVR for patients at intermediate surgical risk in both Europe and the US.
FDA Approved Valves in the US

Edwards Sapien 3

- Intermediate, high, extreme risk
- Valve in valve

Corevalve Evolut PRO

- Intermediate, high, extreme risk
- Valve in valve
2017 ACC/AHA Updated Guidelines

Updated ACC/AHA Guidelines

Severe AS Symptomatic (stage D)

- Class I
- Class IIa
- Class IIb

Low surgical risk
- Surgical AVR (Class I)

Intermediate surgical risk
- Surgical AVR (Class I)

High surgical risk
- TAVR (Class IIa)
- Surgical AVR or TAVR (Class I)

Prohibitive surgical risk
- TAVR (Class I)

Nishimura, et al. JACC 2017;70:252-89
Surtavi Trial

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


NEJM 2017;376:e1321-31

- TAVR with Corevalve or Corevalve Evolut R vs. SAVR
- All-cause Mortality or Disabling Strokes at 24 months.
- Patients with severe AS at intermediate surgical risk.
- 1 year follow-up of 1660 patients
- 30 day follow-up on 375 continued access patients
All Cause Mortality or Disabling Stroke at 1 Year

P-value (log-rank) = 0.55

TAVR: 7.8%
SAVR: 8.5%

No. at Risk:
SAVR: 796, 723, 678
TAVR: 864, 813, 772
All Cause Mortality at 1 Year

P-value (log-rank) = 0.91

No. at Risk
SAVR    796    723    678
TAVR    864    813    772

Nicolas M. Van Mieghem TCT 2017
Disabling Stroke at 1 Year

P-value (log-rank) = 0.13

No. at Risk
SAVR 796 723 678
TAVR 864 813 772

Nicolas M. Van Mieghem TCT 2017
Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis

1-Year Results From the All-Comers NOTION Randomized Clinical Trial

Hans Gustav Hørsted Thyregod, MD,* Daniel Andreas Steinbrüchel, MD, DMSc,* Nikolaj Ihlemann, MD, PhD,† Henrik Nissen, MD, PhD,‡ Bo Juel Kjeldsen, MD, PhD,§ Petur Petursson, MD,∥ Yanping Chang, MS,¶ Olaf Walter Franzen, MD,† Thomas Engström, MD, DMSc,† Peter Clemmensen, MD, DMSc,† Peter Bo Hansen, MD,# Lars Willy Andersen, MD, DMSc,# Peter Skov Olsen, MD, DMSc,* Lars Søndergaard, MD, DMSc†
Notion Trial

- **DESIGN:** Prospective, randomized, two-arm, multi-center clinical trial of the TAVR vs SAVR

- **OBJECTIVE:** To evaluate safety of TAVR in lower-risk ‘All-Comer’ patients with severe aortic stenosis

- **SETTING:** 2 centers in Denmark, 1 center in Sweden

- **PRIMARY ENDPOINT:** All-cause death, stroke or MI 1 year post procedure
Notion Trial

1576 Patients considered by heart team

1296 Excluded

280 patients enrolled, randomized

ITT TAVR (N = 145)  ITT SAVR (N = 135)

STS = 2.9  STS = 3.1

Implanted TAVR (N = 139)  Implanted SAVR (N = 135)
Notion 1: Primary Endpoint at 1 year

In Hospital or 30 Day Mortality: TAVR 3.2% vs. SAVR 3.8% (p=0.56)
Notion 1: 5 Year All Cause Mortality

Sondergaard et al. EuroPCR 2017
Notion 1: Structural Valve Deterioration

Sondergaard et al. EuroPCR 2017
A literature search was conducted to identify studies reporting procedural and 30-day outcomes for groups of patients treated with new valves in real-world practice.

The rates of paravalvular leak, new pacemaker implantation, stroke, and major vascular complications were tabulated and the weighted average was calculated for each valve type.
45 unique cohorts were identified through the literature search, representing over 15,000 patients treated with new valves in real-world practice.
The rate of all stroke is generally less than 4% with the new valves, a reduction relative to stroke rates achieved with the foundation devices.
In contemporary practice, the overall stroke rate remains around 3.5%.
The rate of new permanent pacemaker implantation is sensitive to device type.
The rates are typically around 15% with Evolut R and SAPIEN 3, and approximately 2x higher with the Lotus valve.

<table>
<thead>
<tr>
<th>Device</th>
<th>Weighted Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lotus (N=1,960)</td>
<td>30.2%</td>
</tr>
<tr>
<td>Evolut R (N=5,232)</td>
<td>18.2%</td>
</tr>
<tr>
<td>SAPIEN 3 (N=6,300)</td>
<td>13.4%</td>
</tr>
<tr>
<td>ACURATE Neo (N=1,273)</td>
<td>8.0%</td>
</tr>
<tr>
<td>Portico (N=389)</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

E Grube CRT 2017
Moderate / Severe Paravalvular Leak
Real-World Evidence

- The Lotus valve virtually eliminates moderate or severe PVL
- Other valves have brought the rates to ~5% or less

E Grube CRT 2017
Major vascular complications have come down under 5% across all valve types.
The preferred access site has been dynamic in the US as the regulatory landscape has changed.

With the introduction of Evolut R and SAPIEN 3, more than 90% of TAVRs are performed through the TF approach.

1Carroll, et al., presented at TCT 2016
Multicenter cohorts of 200 patients or more show only slight differences in transfemoral accessibility according to valve type.
Increased use of the transfemoral approach has facilitated a simpler procedure, shown by the decreased use of general anesthesia in favor of conscious sedation.

Wide variation in anesthesia mode likely reflects geographical differences and individual physician preferences.
TAVR and SAVR Procedures in the TVT and STS ACSD Registry

Source: STS/ACC TVT Registry Database and STS Database as of April 10, 2017

Vinod Thourani, TCT 2017
TAVR: Mean and Median Age

Source: STS/ACC TVT Registry Database as of Jul 17, 2017

STS National Database
NCDR National Cardiovascular Data Registry
Treatment Trends
United States and UK 2012-2015

• Balloon-expandable valves are used in approximately 60% of cases globally.
• Self-expanding valves are used in the remaining 40%.

TVT Registry 2015 (N=24,808)

- Self-Expanding: 66.4%
- Balloon Expandable: 32.6%

WRITTEN Survey 2015 (N=231)

- Self-Expanding: 60.0%
- Balloon Expandable: 40.0%

TAVR: Median LOS (Days)

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
## In Hospital Risk Adjusted Mortality

<table>
<thead>
<tr>
<th>Percentile</th>
<th>10th</th>
<th>25th</th>
<th>50th (Median)</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting timeframe (based on 3 yrs. of data)</td>
<td>Worse</td>
<td>Better</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012-2014</td>
<td>5.5%</td>
<td>5.1%</td>
<td>4.8%</td>
<td>4.5%</td>
<td>4.2%</td>
</tr>
<tr>
<td>2014-2016</td>
<td>3.1%</td>
<td>3.0%</td>
<td>2.8%</td>
<td>2.6%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

Source: STS/ACC TVT Registry Database as of July 17, 2017
% of Elective Valve in Valve TAVR

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
TAVR Procedural Details

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
TAVR Access Site

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
TAVR Major Vascular Complications

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
TAVR Life Threatening Bleed

Source: STS/ACC TVT Registry Database. as of Jul 17, 2017
TAVR: In Hospital Adverse Events

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
TAVR Mortality

Source: STS/ACC TVT Registry Database as of Jul 17, 2017
What does the future hold?
Currently there is significant clinical investment in applying TAVR to younger patients at low surgical risk, both in North America and in Europe.

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Centers</th>
<th>Valves/Routes</th>
<th>Sponsorship</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Low Risk¹</td>
<td>~1200</td>
<td>Up to 80</td>
<td>Evolut R, all routes</td>
<td>Industry-sponsored</td>
<td>10-year</td>
</tr>
<tr>
<td>PARTNER 3²</td>
<td>1228</td>
<td>Up to 64</td>
<td>SAPIEN 3, transfemoral</td>
<td>Industry-sponsored</td>
<td>10-year</td>
</tr>
<tr>
<td>UK TAVI³</td>
<td>808</td>
<td>All UK TAVI centers</td>
<td>All valves, all routes</td>
<td>Publically funded</td>
<td>5-year</td>
</tr>
<tr>
<td>NOTION-2⁴</td>
<td>992</td>
<td>All Nordic countries</td>
<td>All valves, transfemoral</td>
<td>Physician and industry-sponsored</td>
<td>5-year</td>
</tr>
</tbody>
</table>

# Low Surgical Risk Trials

## Overview

<table>
<thead>
<tr>
<th>Primary Endpoint</th>
<th>Medtronic Low Risk</th>
<th>PARTNER 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Endpoint</strong></td>
<td>Death or major stroke at 2 years</td>
<td>Death, all stroke, or re-hospitalization (valve-related or procedure-related and including heart failure) at 1 year</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td>Symptomatic, severe AS and a Heart Team predicted risk of 30-day mortality &lt; 3%</td>
<td>Symptomatic, severe AS and Heart Team assessment of low operative risk and STS &lt; 4%</td>
</tr>
</tbody>
</table>
| **Study Design** | • Multi-center, prospective, randomized  
• 1:1 randomization to either TAVR or SAVR | • Multi-center, prospective, randomized  
• 1:1 randomization to either TAVR or SAVR |
| **Devices** | Investigational TAVR Arm  
• Evolut R  
Control Arm  
• Any commercially available bioprosthesis | Investigational TAVR Arm  
• SAPIEN 3, transfemoral only  
Control Arm  
• Any commercially available bioprosthesis |
## Low Surgical Risk Trials
### Key Exclusion Criteria

<table>
<thead>
<tr>
<th>Medtronic Low Risk</th>
<th>PARTNER 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Bicuspid aortic valve</td>
<td>• Bicuspid aortic valve</td>
</tr>
<tr>
<td>• Multivessel CAD (Syntax &gt;22, unprotected left main)</td>
<td>• Complex CAD requiring revascularization (Syntax &gt;32, unprotected left main)</td>
</tr>
<tr>
<td>• MI within 30 days</td>
<td>• MI within 30 days, stroke/TIA within 90 days</td>
</tr>
<tr>
<td>• Severe MR or TR amenable to surgery</td>
<td>• Severe AR or MR</td>
</tr>
<tr>
<td>• Moderate or severe mitral stenosis</td>
<td>• LVEF &lt;30%</td>
</tr>
<tr>
<td>• Prohibitive LVOT calcification</td>
<td>• Unsuitable iliofemoral vessels for TF</td>
</tr>
<tr>
<td></td>
<td>• Hemodynamic or respiratory instability requiring inotropic support or mechanical ventilation within 30 days</td>
</tr>
<tr>
<td></td>
<td>• CKD - eGFR &lt;30 mL/min</td>
</tr>
<tr>
<td></td>
<td>• Significant frailty (objective measurements)</td>
</tr>
<tr>
<td></td>
<td>• Severe lung disease or home O$_2$</td>
</tr>
</tbody>
</table>
Earlier Intervention
Active Trials

There is interest in using TAVR to intervene earlier in the AS disease process to prevent inevitable myocardial damage and functional decline.

TAVR UNLOAD

TAVR will be compared to medical therapy in patients with moderate AS, symptoms of heart failure, and reduced EF.

TAVR UNLOAD Trial

Study Design

(600 patients, 1:1 Randomized)

Primary Endpoint

Hierarchical occurrence of:
- All-cause death
- Disabling stroke
- Hospitalizations for HF, aortic valve disease
- Change in KCCQ

Follow-up:
- 1 month
- 6 months
- 1 year

Clinical endpoints
- Symptoms
- Echo QoL

TAVR + OHFT

OHFT Alone

E Grube
Early TAVR: Study Flowchart

Asymptomatic, Severe Aortic Stenosis

Screening / Stress Test
Inclusion/exclusion criteria, treadmill stress test

Asymptomatic
Negative stress test OR medical history

1:1 Randomization

Transfemoral TAVR
Clinical Surveillance

Primary Endpoint
2 year composite of all-cause mortality, all stroke, and unplanned cardiovascular hospitalization

Symptomatic
Positive stress test

Registry
Commercial AVR (TAVR or SAVR), Clinical Trial (e.g. PARTNER 3 Trial), etc.

Philippe Genereux, TCT 2017
Inclusion criteria

- Severe symptomatic aortic stenosis, STS score ≤4% & age ≤75 years
- Anticipated usage of bioprosthetic aortic valve
- Bicuspid aortic valves and coronary artery disease allowed

Primary end-point

- Composite rate of all-cause mortality, stroke & MI at 1 year

Design

- RCT, 1:1, TF TAVR vs. SAVR, superior, N=992
- Any bioprosthetic aortic valve allowed

Clinical Trials.gov Identifier NCT02825134
Final Thoughts

- TAVR is now proven in patients at extreme, high and intermediate surgical risk due to robust data.
- There is significant investment in applying this technology to younger patients at low surgical risk.
- Careful study of low risk patients is an absolute requirement because certain TAVR-specific complications remain a concern.
- Survival advantage and quick recovery to improved quality of life achieved with transfemoral TAVR in the intermediate risk trials is highly encouraging.
- It is possible that TAVR will provide an alternative therapy for patients with moderate aortic stenosis and heart failure, and for asymptomatic patients with severe AS. Perhaps earlier intervention will prevent an inevitable decline in cardiac function.
Overall, the future for transcatheter valve therapy is incredibly bright, with an expected 300,000 patients served annually within the next 10 years.