AORTIC VALVE DISEASE

RANDOMISED TRIALS

COMPARING

TAVI WITH SAVR

STEPHAN WINDECKER

DEPARTMENT OF CARDIOLOGY
SWISS CARDIOVASCULAR CENTER AND CLINICAL TRIALS UNIT BERN
BERN UNIVERSITY HOSPITAL, SWITZERLAND
RANDOMISED EVIDENCE

TAVI VERSUS SURGERY

INTERMEDIATE RISK PATIENTS

TAVI LIMITATIONS
PCI vs. CABG and TAVI vs. AVR

17 YEARS TO THE FIRST COMPARISON

PCI vs. CABG

1969
First description of CABG (Favolaro)

1977
Coronary angioplasty (Gruntzig)

1989
First description of a transcatheter heart valve (Andersen)

1992
First in man TAVI (Cribier)

1994
Stents introduced

1994 EAST
n=392 CABG/PCI

1995 CABRI
n=1054 CABG/PCI

1996 BARI
n=1829 CABG/PCI (1% BMS)

1998 RITA
n=1011 CABG/PCI

1999
First comparison of PCI vs. CABG

2000
First comparison of TAVI vs. AVR

2002
AWESOME
n=454 CABG/BMS (54%)

2005 ARTS I
n=1205 CABG/BMS (98%)

2005 ERACI II
n=450 CABG/BMS

2007 MASS II
n=611 CABG/BMS (68%)

2008 LE MANS
n=105 CABG/DES (35%)

2008 SOS
n=988 CABG/BMS (97%)

2009 SYNTAX
n=705 CABG/DES

2010
First comparison of PCI vs. CABG and TAVI vs. AVR

TAVI vs. AVR

2010 CARDia
n=510 CABG/BMS

2010 LEIPZIG
n=201 CABG/DES

2011 PreCOMBAT
n=600 CABG/DES

2011 PARTNER A
n=699 TAVI/AVR

9 YEARS TO THE FIRST COMPARISON

2002
First description of a transcatheter heart valve (Andersen)

2010 PARTNER A
n=358 TAVI/MED

2012
First in man TAVI (Cribier)

2012 PARTNER 2
SurTAVI

RECRUITING TAVI/AVR
10 YEARS OF DEVELOPMENT

THE PROCEDURE

2012

PATIENT - ADAPTED

ACCESS SITE SELECTION

ACCORDING TO

INDIVIDUAL ANATOMICAL

CHARACTERISTICS
Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium†


Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document†

PARTNER B

**MEDICAL TREATMENT**

- n = 358 Randomized
  - n = 179
    - 85/85 patients 100% followed at 1 Yr
    - 46/46 patients 100% followed at 2 Yrs
    - 19/19 patients 100% followed at 3 Yrs
  - Cross over 11 pts

**TAVI**

- n = 179
  - 124/124 patients 100% followed at 1 Yr
  - 101/102 patients 99.0% followed at 2 Yrs
  - 80/82 patients 97.6% followed at 3 Yrs
  - Cross over 9 pts
TAVI vs. Medical Treatment

In Inoperable Patients – 3 Year F/U

Leon MB et al. NEJM 2010; Presented at TCT 2012, Miami

**All Cause Death**

HR [95% CI] = 0.53 [0.41, 0.68]  
*p* (log rank) < 0.0001

**Cardiac Death**

HR [95% CI] = 0.41 [0.30, 0.56]  
*p* (log rank) < 0.0001

NNT = 4.0 pts  
NNT = 4.1 pts  
NNT = 3.2 pts  
NNT = 3.0 pts
MORTALITY STRATIFIED BY STS SCORE (ITT)

Leon MB et al. NEJM 2010; Presented at TCT 2012, Miami

**Standard Rx**

**TAVI**

### STS: 0 - 4.9

- Δ = 66.8%
- NNT = 1.5 pts
- 100%

### STS: 5.0 - 14.9

- Δ = 22.3%
- NNT = 4.5 pts
- 77.5%

### STS ≥ 15

- Δ = 20.8%
- NNT = 4.8 pts
- 86.6%

### Numbers at Risk

<table>
<thead>
<tr>
<th></th>
<th>Standard Rx</th>
<th>TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>12</td>
<td>28</td>
</tr>
<tr>
<td>7-12</td>
<td>8</td>
<td>26</td>
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<td>13-18</td>
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<td>31-36</td>
<td>3</td>
<td>19</td>
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<tr>
<td>37-42</td>
<td>0</td>
<td>16</td>
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</table>

**MORTALITY (%)**

- 0%
- 20%
- 40%
- 60%
- 80%
- 100%
INOPERABILITY CONDITIONS BY STS RISK SCORE


<table>
<thead>
<tr>
<th>Frailty</th>
<th>Porcelain Aorta</th>
<th>Radiation</th>
<th>Chest Deformities</th>
<th>Respiratory Disease</th>
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<tr>
<td>13</td>
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<td>6</td>
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<td>28</td>
<td>4</td>
<td></td>
<td></td>
<td>6</td>
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<tr>
<td>24</td>
<td>2</td>
<td></td>
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</tbody>
</table>

%
MANAGEMENT OF SEVERE AORTIC STENOSIS

ESC GUIDELINES ON VALVULAR HEART DISEASE 2012

Severe AS

Symptoms

No

Yes

TAVI should only be undertaken with a multidisciplinary “heart team” including cardiologists and cardiac surgeons and other specialists if necessary.

Class I  Level C

TAVI should only be performed in hospitals with cardiac surgery on-site.

Class I  Level C

TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a “heart team” and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.

Class I  Level B

TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a “heart team” based on the individual risk profile and anatomic suitability.

Class IIa  Level B

Re-evaluate in 6 months

AVR

AVR or TAVI

RANDOMISED EVIDENCE

TAVI VERSUS SURGERY

INTERMEDIATE RISK PATIENTS

TAVI LIMITATIONS
**TAVI vs. Surgery**

**All – Cause Death**


**Intention to Treat Population**

- Hazard ratio, 0.90 (95% CI, 0.71–1.15)
- P=0.41

**As Treated Population**

- Hazard ratio, 0.98 (95% CI, 0.76–1.25)
- P=0.85

![Graph showing death from any cause over months for TAVI and surgery in intention to treat and as treated populations.](image-url)
TAVI vs. Surgery

All – Cause Death


As Treated Patient Population

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>TF TAVI</td>
<td>3.7%</td>
<td>21.3%</td>
</tr>
<tr>
<td>TF SAVR</td>
<td>8.2%</td>
<td>25.2%</td>
</tr>
<tr>
<td>TA TAVI</td>
<td>8.7%</td>
<td>29.1%</td>
</tr>
<tr>
<td>TA SAVR</td>
<td>7.6%</td>
<td>25.3%</td>
</tr>
</tbody>
</table>

P = 0.05 (30 Days TF TAVI vs. TF SAVR)
P = 0.79 (30 Days TF TAVI vs. TA TAVI)
P = 0.33 (12 Months TF TAVI vs. TF SAVR)
P = 0.55 (12 Months TF TAVI vs. TA TAVI)
## TAVI vs. Surgery

### Subgroup Analyses of Treatment Effect


<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Death from Any Cause</th>
<th>Risk Ratio (95% CI)</th>
<th>P Value for Interaction</th>
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<tbody>
<tr>
<td></td>
<td>Transcatheter Replacement</td>
<td>Surgical Replacement</td>
<td></td>
</tr>
<tr>
<td>no./total no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>84/348 (24.1)</td>
<td>89/351 (25.4)</td>
<td>0.95 (0.73−1.23)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>≤85 yr</td>
<td>40/185 (21.6)</td>
<td>43/173 (24.9)</td>
<td>0.87 (0.60−1.27)</td>
</tr>
<tr>
<td>&gt;85 yr</td>
<td>44/163 (27.0)</td>
<td>46/176 (26.1)</td>
<td>1.03 (0.72−1.47)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>57/201 (28.4)</td>
<td>48/198 (24.2)</td>
<td>1.17 (0.84−1.63)</td>
</tr>
<tr>
<td>Female</td>
<td>27/147 (18.4)</td>
<td>41/151 (27.2)</td>
<td>0.68 (0.44−1.04)</td>
</tr>
<tr>
<td>Body-mass index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤26</td>
<td>45/165 (27.3)</td>
<td>51/186 (27.4)</td>
<td>0.99 (0.71−1.40)</td>
</tr>
<tr>
<td>&gt;26</td>
<td>38/181 (21.0)</td>
<td>38/160 (23.8)</td>
<td>0.88 (0.59−1.31)</td>
</tr>
<tr>
<td>STS score</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>≤11</td>
<td>35/176 (19.9)</td>
<td>38/175 (21.7)</td>
<td>0.92 (0.61−1.38)</td>
</tr>
<tr>
<td>&gt;11</td>
<td>48/171 (28.1)</td>
<td>51/174 (29.3)</td>
<td>0.96 (0.69−1.34)</td>
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<tr>
<td>Left ventricular ejection fraction</td>
<td></td>
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<tr>
<td>≤55%</td>
<td>44/168 (26.2)</td>
<td>46/166 (27.7)</td>
<td>0.95 (0.66−1.35)</td>
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<tr>
<td>&gt;55%</td>
<td>38/170 (22.4)</td>
<td>38/172 (22.1)</td>
<td>1.01 (0.68−1.50)</td>
</tr>
</tbody>
</table>
TAVI vs. Surgery

Echocardiographic Findings


Aortic Valve Area

Mean Aortic Gradient

Baseline 30 Day 6 Mo 1 Yr 2 Yr

Baseline 30 Day 6 Mo 1 Yr 2 Yr

TAVI

SAVR

290 224 163 151 110
290 224 163 151 110

301 269 223 210 139
301 269 223 210 139

P=0.32  P=0.01  P=0.08  P=0.005  P=0.16
P=0.54  P=0.53  P=0.79  P=0.22  P=0.87
TAVI vs. Surgery

Effect of TAVI on QoL at 12 Months


Functional Capacity

NYHA Functional Class

6-Minute Walk Test (Median Distance (m))

Baseline 30 Day 6 Month 1 Year

TAVI AVR TAVI AVR TAVI AVR TAVI AVR

NYHA

Dead IV III II I

Baseline 30 Days 6 Months 1 Year
ROLE OF TAVI IN ROUTINE CLINICAL PRACTICE

**All Cause Mortality**

- **Medical Treatment, N=78 (18%)**
- **Surgical AVR: adj. HR = 0.51 (0.30-0.87)**
  - N=107 (24%)

- **TAVI: adj. HR = 0.34 (0.22-0.54)**
  - N=257 (58%)

No. at risk
- Medical: 78
- Surgical: 107
- TAVI: 254

Cumulative incidence:
- **Medical**: 56.4%
- **Surgical**: 20.6%
- **TAVI**: 20.6%

Follow-up, months

N=452
ESC RECOMMENDATIONS FOR THE TREATMENT OF VALVULAR HEART DISEASE

<table>
<thead>
<tr>
<th>Class</th>
<th>Level</th>
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<td>I</td>
<td>C</td>
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<tr>
<td>I</td>
<td>C</td>
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<tr>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>IIa</td>
<td>B</td>
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TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a “heart team” based on the individual risk profile and anatomic suitability.
Randomised Evidence

TAVI versus Surgery

Intermediate Risk Patients

TAVI Limitations
TAVI vs. SAVR
Cerebrovascular Accidents (ITT)

Primary EP: Mortality
Retrospective Assessment of stroke severity
Age = 85 ± 6
EuroScore = 29 ± 16
Atrial fibrillation: 43%
Cerebrovascular dz: 27%

SYNTAX (CABG group)
Stroke = 2.2% @ 1 year
Age = 65 ± 10
EuroScore = 4 ± 3

HR [95% CI] = 1.22 [0.67, 2.23]
p (log rank) = 0.517

Numbers at Risk
<table>
<thead>
<tr>
<th>TAVR</th>
<th>348</th>
<th>287</th>
<th>249</th>
<th>224</th>
<th>162</th>
<th>65</th>
<th>28</th>
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<td>AVR</td>
<td>351</td>
<td>246</td>
<td>230</td>
<td>211</td>
<td>160</td>
<td>62</td>
<td>31</td>
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</tbody>
</table>
TRANSCATHETER AORTIC VALVE IMPLANTATION AND CEREBROVASCULAR EVENTS

STORTECKY S, WINDECKER S CIRCULATION 2012;126:2921-4

Risk

NOAFib

CHRONIC AFIB

ATHEROSCLEROTIC DISEASE BURDEN

TRANSOCATHETER AORTIC VALVE IMPLANTATION

0 1 30 6 12 24 36
DAYS MONTHS TIME

MINIMAL TOUCH TECHNIQUE
EMBOLIC PROTECTION DEVICE
NEW GENERATION VALVE PROSTHESIS

STROKE

INTRA- AND PERIPROCEDURAL ANTITHROMBOTIC THERAPY

PROTECTION

DUAL ANTIPLATELET THERAPY

SINGLE ANTIPLATELET THERAPY

PATIENTS WITH SINUS RHYTHM

PATIENTS WITH AFIB

STRATEGY

(N)OACs
EMBOLIC PROTECTION DEVICES

EMBOLIC DEFLECTOR DEVICES

RADIAL ACCESS

FEMORAL ACCESS

EMBOLIC FILTER DEVICE

RADIAL ACCESS
AORTIC STENOSIS AND ATRIAL FIBRILLATION
IN PATIENTS UNDERGOING TAVI
STORTECKY S ET AL. CIRC CARDIOVASC INTERV FEB 2013; [EPUB AHEAD OF PRINT]

BERN TAVI REGISTRY n=389; AGE 83±6 YEARS; 58% FEMALE GENDER

![Graph showing cumulative incidence of death over days since TAVI]
MECHANISMS OF AORTIC REGURGITATION

Buellesfeld L et al. JACC Cardiovasc Interv 2012;5:578-81
TAVI vs. Medical Treatment
Echocardiographic Outcomes – TAVI Cohort


**Paravalvular AR**
- **30 Days**
  - Severe: 0%
  - Moderate: 0%
  - Mild: 15.3%
  - Trace: 4.5%
  - None: 34.3%
  - Total: 70.3%
- **2 Years**
  - Severe: 0%
  - Moderate: 0%
  - Mild: 20.1%
  - Trace: 31.3%
  - None: 48.6%
  - Total: 100%

**Transvalvular AR**
- **30 Days**
  - Severe: 0.7%
  - Moderate: 27.8%
  - Mild: 38.9%
  - Trace: 32.6%
  - None: 28.4%
  - Total: 100%
- **2 Years**
  - Severe: 0.7%
  - Moderate: 17.9%
  - Mild: 49.3%
  - Trace: 34.3%
  - None: 25.4%
  - Total: 100%

**p-values**
- Paraavalvular AR: p=0.001
- Transvalvular AR: p=0.75
AORTIC REGURGITATION AND IMPACT ON OUTCOMES


**PARAVALVULAR AR**

- None or trace
- Moderate to severe
- Mild

P<0.001 by log-rank test

**DEATH FROM ANY CAUSE (%)**

- None or trace
- Moderate to severe
- Mild

Months after Implantation:

<table>
<thead>
<tr>
<th>Months</th>
<th>None or trace</th>
<th>Mild</th>
<th>Moderate to severe</th>
</tr>
</thead>
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<tr>
<td>0</td>
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<td>36</td>
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</table>

No. at Risk:

- None or trace: 125
- Mild: 162
- Moderate to severe: 34

<table>
<thead>
<tr>
<th>Months</th>
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<th>Mild</th>
<th>Moderate to severe</th>
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<td>108</td>
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<td>31</td>
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</tbody>
</table>

**OVERALL AR**

- None or trace
- Moderate to severe
- Mild

P<0.001 by log-rank test

**DEATH FROM ANY CAUSE (%)**

- None or trace
- Moderate to severe
- Mild

Months after Implantation:

<table>
<thead>
<tr>
<th>Months</th>
<th>None or trace</th>
<th>Mild</th>
<th>Moderate to severe</th>
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No. at Risk:

- None or trace: 125
- Mild: 162
- Moderate to severe: 34

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<td>70</td>
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PARTNER 1 NRCA ONLY

MORTALITY & PARAVALVULAR LEAK

Number At Risk
None or Trace PVL 388 373 339 300 238 127 119 112 76
Mild PVL 400 388 350 303 247 125 114 106 74
Mod or Sev PVL 120 113 97 81 66 37 34 32 23

Time in Days

2-Year Death (%)

Log Rank P= <.001

* Events adjudicated to one year
NEW GENERATION TAVI DEVICES

EFFECT ON PARAVALVULAR AR?

EDWARDS SAPIEN 3

MEDTRONIC ENGAGER

SEALING CUFF
TECHNOLOGY

NATIVE VALVE CLIPPING
MECHANISM
RELATIONSHIP OF THE AORTIC VALVE AND THE CONDUCTION SYSTEM

PIAZZA N ET AL. *Circ Cardiovasc Interv* 2008;1:74-81
PERMANENT PACEMAKER IMPLANTATION

**PARTNER B:** 3.4%
**PARTNER A:** 3.8%
IMPACT OF PERMANENT PACEMAKER IMPLANTATION ON CLINICAL OUTCOMES AFTER TAVI

BUELLESFELD L ET AL. J AM COLL CARDIOL 2012;60:493-501

COREVALVE ADVANCE
PRESENTED BY BAUERNSCHMITT R. AT EUROPCR 2012

prior PPM: HR(95%CI)=1.28(0.65-2.50)
post PPM: HR(95%CI)=1.08(0.63-1.89)
p=0.77

P-value (log rank) 0.799
RANDOMISED EVIDENCE

TAVI VERSUS SURGERY

INTERMEDIATE RISK PATIENTS

TAVI LIMITATIONS
Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

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Munich, Germany

HEART TEAM DECISION
STS - SCORE

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>7.1</td>
<td>6.2</td>
<td>5.8</td>
<td>4.8</td>
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</tbody>
</table>

%
Assessed for eligibility
(n= 3666)
TAVI= 782 (21.3%)
SAVR= 2884 (87.7%)

Unmatched: n= 2856
TAVI= 377
SAVR= 2479

PS matched patients with TAVI
(n= 405)
Lost to follow-up (n=4)

PS matched patients with SAVR
(n= 405)
Lost to follow-up (n=10), Patient declined (n=2)

Not eligible for SURTAVI
(n= 150)
STS <3: n= 99
STS >8: n= 51

PS matched patients with TAVI eligible for SURTAVI (n= 255)
Lost to follow-up (n=3)

PS matched patients with SAVR eligible for SURTAVI (n= 255)
Lost to follow-up (n=8)
Bermuda Triangle

TAVI in Intermediate Risk Patients

Piazza N et al. JACC Cardiovasc Interv. 2013; Ahead of Print

Propensity Score Matched Patient Population

TAVI (n=255) vs. SAVR (n=255)

All – Cause Death @ 30 Days

HR (95% CI): 1.12 (0.58-2.15); p=0.74

All – Cause Death @ 12 Months

HR (95% CI): 0.90 (0.57-1.42); p=0.64

No. At Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVI</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI</td>
<td>255</td>
<td>255</td>
</tr>
<tr>
<td>SAVR</td>
<td>255</td>
<td>255</td>
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</tbody>
</table>

Days after TAVI


Months after TAVI

No. at Risk: 255, 237, 223, 216, 211, 205, 200, 199, 194, 191, 189, 188, 183
**SURTAVI – STUDY DESIGN**

- STS mortality risk ≥4% and ≤10%
- Heart Team Evaluation
  - Confirm Inclusion/Exclusion & Intermediate Risk Classification
- Randomization
  - Stratified by need for revascularization
- Randomized 1:1, non-inferiority study
- Up to 75 worldwide centers
  - Europe
  - Canada
  - United States
- Approx 2,000 total number of trial subjects
- Long-term follow-up through 5 years

N = ~2,000 patients

Medtronic CoreValve® TAVI

SAVR
PARTNER II TRIAL UPDATE

LEON MB, PRESENTED AT TCT 2012

Symptomatic Severe Aortic Stenosis

n=2000 Randomized Patients

Operable (STS ≥4)

ASSESSMENT: Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization

TF TAVR SAPIEN XT VS Surgical AVR

Primary Endpoint: All-Cause Mortality + Major Stroke at Two Years (Non-inferiority)

No

Transapical (TA)

1:1 Randomization

TAVR: TA / TAO VS Surgical AVR

Two Parallel Randomized Trials +5 Nested Registries

Inoperable

ASSESSMENT: Transfemoral Access

Yes >7mm

1:1 Randomization

TF TAVR SAPIEN XT VS TAVR SAPIEN

Primary Endpoint: All-Cause Mortality + Disabling Stroke + Repeat Hospitalization at One Year (Non-inferiority)

Yes 6-7mm

6-7mm Registry

No

Surgical AVR

n=500 Randomized Patients

Enrollment Completed January 2012

Additional Registry: Transcatheter Valve-in-Surgical Valve Registry
NEW GENERATION TAVI DEVICES
Surgeons and cardiologists must work as a team to select appropriate candidates, perform the procedure, and, finally, evaluate the results.”

Vahanian A et al. Eur Heart J. 2008;29:1463-70
10 YEARS TAVI
WHAT DID WE LEARN FROM CLINICAL TRIALS

• TAVI IMPROVES
  ➢ TAVI is superior compared to surgical aortic valve replacement.

• STROKE AFTER
  • Cerebrovascular events are frequent early after TAVI
  • and have a substantial impact on outcomes

• VALVE DURABILITY
  • is maintained beyond 2 years of follow-up
  • Aortic regurgitation impacts on outcomes and needs to be improved

• HEALTH RELATED QUALITY OF LIFE
  • TAVI effectively alleviates symptoms
  • and improves health-related quality of life
10 Years TAVI

What Did We Learn From Clinical Trials

• TAVI Is Safe
  ➢ TAVI is superior compared to medical treatment and non-inferior compared to surgical aortic valve replacement.

• Stroke After TAVI Is an Issue
  • Cerebrovascular events are frequent early after TAVI

• Valve Durability
  • is maintained beyond 2 years of follow-up
  • Aortic regurgitation impacts on outcomes and needs to be improved

• Health Related Quality Of Life
  • TAVI effectively alleviates symptoms
  • and improves health-related quality of life
HEART TEAM APPROACH

PATIENT WITH COMPLEX AORTIC VALVE DISEASE

- General practitioner
- Referring physician
- Geriatrician
- Pneumologist
- Nephrologist
- Interventional cardiologist
- Cardiac surgeon
- Anesthesiologist
- Rehabilitation specialist
- Diabetologist
- Neurologist
RANDOMISED EVIDENCE

10 YEARS OF TAVI

INTERMEDIATE RISK PATIENTS

TAVI Versus Surgery

Cost Effectiveness

TAVI Limitations
Index Admission Costs
Transfemoral

\[ \Delta = ($2,496) \]
\[ P = 0.53 \]

TF-TAVR
- Procedure: $34,863
- Non-Procedure: $31,192
- Total: $71,955

AVR
- Total MD Fees: $5,773
- Non-Procedure: $54,228
- Total: $74,452
Index Admission Costs
Transapical

$\Delta = $11,008
$P = 0.08$

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Non-Procedure</th>
<th>Total MD Fees</th>
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<tbody>
<tr>
<td>TA-TAVR</td>
<td>$39,998</td>
<td>$5,493</td>
</tr>
<tr>
<td>AVR</td>
<td>$15,271</td>
<td>$6,130</td>
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Costs are in dollars.
TAVR vs. AVR: Transfemoral
Cost per QALY gained

\[ \Delta \text{Cost} = - \$2210 \]
\[ \Delta \text{QALYs} = + 0.068 \]

ICER = dominant
% dominant = 59.7

% \(<\$50,000\) per QALY
= 74.7
TAVR vs. AVR: Transapical
Cost per QALY gained

$30,000
$20,000
$10,000
$0
-$10,000
-$20,000
-$30,000

$30,000
$20,000
$10,000
$0
-$10,000
-$20,000
-$30,000

Δ Cost = + 9595
Δ QALYs = - 0.07
ICER = dominated
% dominated = 86.3

% <$50,000 per QALY
= 5.5

Complete Population
Cost-Effectiveness of TAVR vs. AVR
Transfemoral (cost per LY gained)