Ασθενής με σοβαρού βαθμού στένωση αορτικής μετρίου χειρουργικού κινδύνου- TAVR: Δεν χρειάζονται άλλες αποδείξεις

ΒΛΑΣΗΣ ΝΙΝΙΟΣ MD MRCP
ΕΠΕΜΒΑΤΙΚΟΣ ΚΑΡΔΙΟΛΟΓΟΣ
ΚΛΙΝΙΚΗ ΑΓΙΟΣ ΛΟΥΚΑΣ
ΘΕΣΣΑΛΟΝΙΚΗ
Conflict of Interest

Proctor for Mitraclip Abbott
Intermediate risk

- 83 FEMALE
- COAD
- SEVERE AS – NYHA III
  - Mean gradient 35 mmHg, AVA 0.45cm², SVI 21ml/m²
  - Paradoxical low flow low gradient normal EF severe AS
- PA = 50 mm Hg
- NORMAL CORS

- EUROSCORE 14,7%
- EVOLUT R 23mm
STS SCORE
Procedure: AV Replacement

- Risk of Mortality: 4.403%
- Morbidity or Mortality: 20.766%
- Long Length of Stay: 11.364%
- Short Length of Stay: 20.919%
- Permanent Stroke: 1.924%
- Prolonged Ventilation: 14.173%
- DSW Infection: 0.255%
- Renal Failure: 4.148%
- Reoperation: 9.302%
Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode *(continued)*

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in the according table). In addition, the local expertise and outcomes data for the given intervention must be taken into account.</td>
<td></td>
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<tr>
<td>SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II &lt;4% or logistic EuroSCORE I &lt;10% and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.</td>
<td>I</td>
<td>B</td>
</tr>
</tbody>
</table>

2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017; doi:10.1093/eurheartj/ehx391)
## Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode (continued)

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>In patients who are at increased surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥10% or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see according table), with TAVI being favoured in elderly patients suitable for transfemoral access.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>
Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk

<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th>Favours TAVI</th>
<th>Favours SAVR</th>
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</thead>
<tbody>
<tr>
<td>STS/EuroSCORE II &lt;4% (logistic EuroSCORE I&lt;10%)</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Presence of severe comorbidity (not adequately reflected by scores)</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Age &lt;75 years</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Age ≥75 years</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>
Intermediate risk

Pre echo

Pre aogram
Intermediate risk

Post echo

Post Aogram
TAVI Trials

STS score (%)

<table>
<thead>
<tr>
<th>Extreme</th>
<th>High</th>
<th>Intermediate</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARTNER IB</td>
<td>CoreValve ER</td>
<td>PARTNER IA</td>
<td>CoreValve HR</td>
</tr>
<tr>
<td>12</td>
<td>10</td>
<td>8</td>
<td>6</td>
</tr>
</tbody>
</table>
| TAVI Trials – all same age!
TAVI Trials

- Extreme
- High
- Intermediate
- Low

STS score (%)

- PARTNER IB
- CoreValve ER
- PARTNER IA
- CoreValve HR

- PARTNER II
- SURTAVI
- NOTION
Intermediate risk

Primary Endpoint (ITT)
All-Cause Mortality or Disabling Stroke

- Surgery
- TAVR

HR [95% CI] = 0.83 [0.73, 1.05]
p (log rank) = 0.253

All-Cause Mortality or Disabling Stroke

- 24 Months
  - TAVR
  - SAVR
  - 12.6% 14.0%

Number at follow-up:
TAVR: 864
SAVR: 796
Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients


Study Populations
ITT to AT Patient Dropouts

Randomized
n = 2032

TAVR (ITT)
n = 1011

- 0.6% (6) Died before treatment - % (no.)
- 0 Ineligible post-randomization - % (no.)
- 1.1% (11) Withdrawal - % (no.)
- 1.7% (17) Total - % (no.)

Surgery (ITT)
n = 1021

- 0.5% (5) Died before treatment - % (no.)
- 0.4% (4) Ineligible post-randomization - % (no.)
- 6.7% (68) Withdrawal - % (no.)
- 7.5% (77) Total - % (no.)

Procedure Initiated (AT)
n = 994

Procedure Initiated (AT)
n = 944
The PARTNER 2A and S3i Trials
Study Design

Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team

P2 S3i
n = 1078

ASSESSMENT: Optimal Valve Delivery Access

Transfemoral (TF)
- TF TAVR SAPIEN 3

Transapical / Transaortic (TA/TAo)
- TA/TAo TAVR SAPIEN 3

P2A
n = 2032

ASSESSMENT: Transfemoral Access

Yes
- Transfemoral (TF)
  - 1:1 Randomization
  - TF TAVR SAPIEN XT VS Surgical AVR

No
- Transapical / Transaortic (TA/TAo)
  - 1:1 Randomization
  - TA/TAo TAVR SAPIEN 3 VS Surgical AVR

Primary Endpoint: All-Cause Mortality, All Stroke, or Mod/Sev AR at One Year (Non-inferiority Propensity Score Analysis)
Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients


NEJM 2017; 376;14 April 6, 2017

*The modified intention-to-treat (mITT) population includes all subjects with an attempted procedure
Study Timeline

- **2012**: SURTAVI First patient enrolled
- **2015**: CoreValve: 23, 26, 29 mm (US)
  - April 2015: Evolut R (US)
- **2016**: CoreValve: 23, 26, 29 mm (CAN, EU)
  - CoreValve: 31 mm (US, CAN, EU)
  - SURTAVI Enrollment complete
- **2017**: CAS First patient enrolled
  - Evolut R: 23, 26, 29 mm
  - CoreValve: 31 mm
- **2018**: Primary endpoint assessment
  - CAS Enrollment complete
- **2019**: SURTAVI 1-Year follow-up complete
- Oct: SURTAVI RCT 2 Yr Outcomes TCT 2018
2-Year SURTAVI Final Results
ΤΑΒΙ vs ΣΑΒΡ
ΚΡΙΤΗΡΙΑ ΕΠΙΛΟΓΗΣ
ΘΕΝΗΤΟΤΗΤΑ
ΝΟΣΗΡΟΤΗΤΑ
ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ
ΠΟΙΟΤΗΤΑ ΖΩΗΣ
ΑΝΘΕΚΤΙΚΟΤΗΤΑ ΒΑΛΒΙΔΑΣ
ΑΠΟΔΟΧΗ ΑΣΘΕΝΟΥΣ
TF Primary Endpoint (ITT)
All-cause Mortality or Disabling Stroke

HR: 0.79 [95% CI: 0.62, 1.00]
p (log rank) = 0.05

Number at risk:
TF Surgery 775
TF TAVR 775

Months from Procedure

<table>
<thead>
<tr>
<th>Months</th>
<th>TF Surgery</th>
<th>TF TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4.9%</td>
<td>4.9%</td>
</tr>
<tr>
<td>3</td>
<td>7.7%</td>
<td>4.9%</td>
</tr>
<tr>
<td>6</td>
<td>12.3%</td>
<td>7.7%</td>
</tr>
<tr>
<td>9</td>
<td>15.9%</td>
<td>12.3%</td>
</tr>
<tr>
<td>12</td>
<td>20.4%</td>
<td>15.9%</td>
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<tr>
<td>18</td>
<td>20.4%</td>
<td>15.9%</td>
</tr>
<tr>
<td>24</td>
<td>20.4%</td>
<td>15.9%</td>
</tr>
</tbody>
</table>

Number at risk:
TF Surgery 643 628 604 595 577 569 557 538
TF TAVR 634 612
All-Cause Mortality

- TAVR
- SAVR

P-value (log-rank) = 0.91

No. at Risk

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<tr>
<th></th>
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<td></td>
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<td>692</td>
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</table>

30 day surgical mortality 1.6% with STS PROM 4.5% for an O:E of 0.35
All-Cause Mortality or Disabling Stroke
Final Kaplan-Meier Analysis

<table>
<thead>
<tr>
<th>Months Post-Procedure</th>
<th>TAVR</th>
<th>SAVR</th>
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<tbody>
<tr>
<td>0</td>
<td>64</td>
<td>61</td>
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<td>6</td>
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<td>18</td>
<td>663</td>
<td>583</td>
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<tr>
<td>24</td>
<td></td>
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</table>

TAVR 864 840
SAVR 796 761

2-Year KM % 95% CI
TAVR 12.7 10.5, 15.3
SAVR 12.6 10.3, 15.4

P-value (log-rank) = 0.97
ΤΑVI vs SAVR
ΚΡΙΤΗΡΙΑ ΕΠΙΛΟΓΗΣ

ΘΝΗΤΟΤΗΤΑ
ΝΟΣΗΡΟΤΗΤΑ
ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ
ΠΟΙΟΤΗΤΑ ΖΩΗΣ
ΑΝΘΕΚΤΙΚΟΤΗΤΑ ΒΑΛΒΙΔΑΣ
ΑΠΟΔΟΧΗ ΑΣΘΕΝΟΥΣ
ΝΟΣΗΡΟΤΗΤΑ

• ΕΓΚΕΦΑΛΙΚΑ
• ΠΑΡΑΒΑΛΒΙΔΙΚΕΣ ΔΙΑΦΥΓΕΣ
• ΒΗΜΑΤΟΔΟΤΗΣ
• ΝΕΦΡΙΚΗ ΑΝΕΠΑΡΚΕΙΑ
• ΑΝΑΓΚΗ ΓΙΑ ΜΕΤΑΓΓΙΣΗ
• ΑΓΓΕΙΑΚΕΣ ΕΠΙΠΛΟΚΕΣ
PVL: SAVR wins but....

**Total Aortic Regurgitation**

- **None/trace**
  - TAVR: 0.7%
  - SAVR: 0.7%
- **Mild**
  - TAVR: 6.8%
  - SAVR: 6.8%
- **Moderate**
  - TAVR: 3.2%
  - SAVR: 3.2%
- **Severe**
  - TAVR: 34.0%
  - SAVR: 34.0%

*Implanted population, core lab adjudicated*
PARTNER IIA
Severity of PVR at 30 Days and All-cause Mortality at 2 Years (VI)

Overall Log-Rank $p = 0.001$

Moderate/Severe (reference = None/Trace)
$p$ (Log-Rank) < 0.001

Mild (reference = None/Trace)
$p$ (Log-Rank) = 0.82

All-Cause Mortality (%)

Months from Procedure

Number at risk:
- Moderate/Sever 36
- Mild 210
- None/Trace 701

<table>
<thead>
<tr>
<th>Months</th>
<th>Moderate/Sever</th>
<th>Mild</th>
<th>None/Trace</th>
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</thead>
<tbody>
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<td>210</td>
<td>701</td>
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<td>24</td>
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</tr>
</tbody>
</table>

34.0%
14.1%
13.5%
Newer generation TAVIs reduce PVL

Rates of PVL at 30 Days

PARTNER II – Sapien 3

< 4% significant PVL

Evolut PRO System Clinical Trial
ADVANCED SEALING

Low rates of PVL while maintaining low rates of mortality, stroke, and need for new permanent pacemaker

30 Day Outcomes
Mortality 1.7%
Stroke 1.7%
## Clinical Outcomes at 30 Days

<table>
<thead>
<tr>
<th></th>
<th>RCT</th>
<th>TAVR (N=864)</th>
<th>P</th>
<th>CAS</th>
<th>TAVR (N=275)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality or disabling stroke</td>
<td>3.8</td>
<td>2.8</td>
<td>0.26</td>
<td></td>
<td>0.4</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>1.6</td>
<td>2.1</td>
<td>0.50</td>
<td></td>
<td>0.0</td>
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<tr>
<td>Disabling stroke</td>
<td>2.4</td>
<td>1.2</td>
<td>0.06</td>
<td></td>
<td>0.4</td>
</tr>
<tr>
<td>All stroke</td>
<td>5.4</td>
<td>3.3</td>
<td>0.03</td>
<td></td>
<td>1.5</td>
</tr>
<tr>
<td>Life-threatening or major bleeding</td>
<td>9.1</td>
<td>12.0</td>
<td>0.05</td>
<td></td>
<td>6.6</td>
</tr>
<tr>
<td>Transfusion of PRBCs* - n(%)</td>
<td>328 (41.2)</td>
<td>108 (12.5)</td>
<td>&lt;0.01</td>
<td>14 (5.1)</td>
<td></td>
</tr>
<tr>
<td>Acute kidney injury, stage 2-3</td>
<td>4.4</td>
<td>1.6</td>
<td>&lt;0.01</td>
<td></td>
<td>1.8</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>1.1</td>
<td>5.9</td>
<td>&lt;0.01</td>
<td></td>
<td>3.6</td>
</tr>
<tr>
<td>Permanent pacemaker implant</td>
<td>6.5</td>
<td>25.6</td>
<td>&lt;0.01</td>
<td></td>
<td>16.1</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>43.1</td>
<td>12.7</td>
<td>&lt;0.01</td>
<td></td>
<td>12.6</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td></td>
<td></td>
<td>0.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TAVR superior at 30 days for all stroke, transfusion, acute kidney injury and atrial fibrillation
Surgery superior for pacemaker and major vascular injury
ΤΑΒΙ vs ΣΑΒΡ

ΚΡΙΤΗΡΙΑ ΕΠΙΛΟΓΗΣ

ΘΕΝΗΤΟΤΗΤΑ
ΝΟΣΗΡΟΤΗΤΑ
ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ
ΠΟΙΟΤΗΤΑ ΖΩΗΣ
ΑΝΘΕΚΤΙΚΟΤΗΤΑ ΒΑΛΒΙΔΑΣ
ΑΠΟΔΟΧΗ ΑΣΘΕΝΟΥΣ
PPM is less of a problem in TAVI patients
TAVR had significantly better valve performance over SAVR at all follow-up visits (P<0.001)

Hemodynamics: Core-lab Adjudicated

CoreValve SURTAVI Trial
ΚΡΙΤΗΡΙΑ ΕΠΙΛΟΓΗΣ

TAVI vs SAVR

ΘΕΝΗΤΟΤΗΤΑ
ΝΟΣΗΡΟΤΗΤΑ
ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ
ΠΟΙΟΤΗΤΑ ΖΩΗΣ
ΑΝΘΕΚΤΙΚΟΤΗΤΑ ΒΑΛΒΙΔΑΣ
ΑΠΟΔΟΧΗ ΑΣΘΕΝΟΥΣ
Primary Endpoint
KCCQ Overall Summary

TAVR superior at 1 month

Significant interaction (P<0.001) between treatment effect and access site for the primary endpoint and multiple secondary endpoints.

KCCQ Summary Score Over Time

Patients recover quality of life sooner after TAVR than SAVR.

TAVR

SAVR

95% CI for difference

Baseline | 30 Days | 6 Months | 12 Months
---------|---------|----------|---------
TAVR     | 18.4 ± 14.9 | 21.8 ± 22.3 | 20.9 ± 22.2
SAVR     | 5.5 ± 27.5   | 21.3 ± 22.3 | 20.6 ± 22.2

95% CI for difference:

TAVR vs SAVR

(10.0, 15.1)

(-1.9, 2.8)

(-2.2, 2.9)
6 Minute Walk Test Change from Baseline

- 30 Day: TAVR (N=709) = 35.4, SAVR (N=556) = 14.4, p<0.01
- 12 Months: TAVR (N=626) = 37.0, SAVR (N=501) = 17.8, p<0.01

Change is increase or decrease in meters walked in 6 minutes.

NYHA Functional Class

- p=0.42
- p<0.01
- p=0.66

<table>
<thead>
<tr>
<th>% of Patients</th>
<th>TAVR (N=860)</th>
<th>SAVR (N=789)</th>
<th>TAVR (N=822)</th>
<th>SAVR (N=708)</th>
<th>TAVR (N=732)</th>
<th>SAVR (N=636)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100%</td>
<td>5.0%</td>
<td>4.4%</td>
<td>5.0%</td>
<td>3.0%</td>
<td>4.0%</td>
<td>3.0%</td>
</tr>
<tr>
<td>90%</td>
<td>54.7%</td>
<td>53.0%</td>
<td>53.8%</td>
<td>39.7%</td>
<td>37.5%</td>
<td>40.5%</td>
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<tr>
<td>80%</td>
<td>40.3%</td>
<td>41.2%</td>
<td>41.9%</td>
<td>41.4%</td>
<td>41.1%</td>
<td>41.1%</td>
</tr>
<tr>
<td>70%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
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</tr>
<tr>
<td>60%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>50%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>40%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
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<tr>
<td>30%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>20%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>10%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>0%</td>
<td>0.3%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>
KCCQ Summary Score

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>6 Months</th>
<th>1 Year</th>
<th>2 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>18.4 ± 22.8</td>
<td>21.9 ± 22.3</td>
<td>20.6 ± 22.3</td>
<td>18.9 ± 21.2</td>
</tr>
<tr>
<td>SAVR</td>
<td>5.9 ± 27.0</td>
<td>21.3 ± 22.3</td>
<td>20.5 ± 22.2</td>
<td>18.6 ± 22.9</td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.01</td>
<td>0.61</td>
<td>0.88</td>
<td>0.85</td>
</tr>
</tbody>
</table>

Change from Baseline

- TAVR: 18.4 ± 22.8, 21.9 ± 22.3, 20.6 ± 22.3, 18.9 ± 21.2
- SAVR: 5.9 ± 27.0, 21.3 ± 22.3, 20.5 ± 22.2, 18.6 ± 22.9

p < 0.01
6-Minute Walk Test
Change from Baseline

Change is mean increase or decrease in meters walked in 6 minutes
### PARTNER IIA

**Procedural Characteristics (AT)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVR (n = 994)</th>
<th>Surgery (n = 944)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia Time (min)</td>
<td>207</td>
<td>333</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Procedure Time (min)</td>
<td>103</td>
<td>237</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Fluoroscopy Time (min)</td>
<td>20</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Aortic Cross-clamp Time (min)</td>
<td>NA</td>
<td>75</td>
<td>NA</td>
</tr>
<tr>
<td>Total CPB Time (min)</td>
<td>NA</td>
<td>104</td>
<td>NA</td>
</tr>
<tr>
<td>Median ICU Stay (days)</td>
<td>2.0 [2, 4]</td>
<td>4.0 [3, 6]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Median Total Length of Stay (days)</td>
<td>6.0 [4, 9]</td>
<td>9.0 [8, 14]</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
ΤΑΒΙ  vs  ΣΑΥΡ

ΚΡΙΤΗΡΙΑ ΕΠΙΛΟΓΗΣ

- ΘΝΗΤΟΤΗΤΑ
- ΝΟΣΗΡΟΤΗΤΑ
- ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ
- ΠΟΙΟΤΗΤΑ ΖΩΗΣ
- ΑΝΘΕΚΤΙΚΟΤΗΤΑ/ ΔΙΑΡΚΕΙΑ ΒΑΛΒΙΔΑΣ
- ΑΠΟΔΟΧΗ ΑΣΘΕΝΟΥΣ
5-Year outcomes from the NOTION-I trial: TAVR vs. SAVR in lower risk patients

Lars Sondergaard, MD, DMSc
Professor of Cardiology
Rigshospitalet
Copenhagen, Denmark
All-Cause Mortality

P-value (log-rank) = 0.90

No. at risk:

0 1 2 3 4 5

Years Post-Procedure

142 139 135 131 121 114 74

134 129 124 121 113 102 81
Stroke

P-value (log-rank) = 0.67

No. at risk:
- TAVR:
  - 0 years: 142
  - 1 year: 137
  - 2 years: 131
  - 3 years: 126
  - 4 years: 114
  - 5 years: 109
- SAVR:
  - 0 years: 134
  - 1 year: 125
  - 2 years: 119
  - 3 years: 115
  - 4 years: 108
  - 5 years: 96

Percentages:
- TAVR:
  - 0 years: 0%
  - 1 year: 0%
  - 2 years: 0%
  - 3 years: 0%
  - 4 years: 0%
  - 5 years: 10.5%
- SAVR:
  - 0 years: 0%
  - 1 year: 0%
  - 2 years: 0%
  - 3 years: 0%
  - 4 years: 0%
  - 5 years: 8.2%
All-Cause Mortality, Stroke, or MI: STS<4%
Aortic Valve Performance

P < 0.001 TAVR vs. SAVR at all follow-up timepoints

Effective Orifice Area (cm²)

Mean Gradient (mm Hg)

Months Post-Procedural
Structural Valve Deterioration

<table>
<thead>
<tr>
<th>Structural valve deterioration</th>
<th>TAVI</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate haemodynamic SVD</td>
<td>3.6%</td>
<td>23.7%</td>
</tr>
<tr>
<td>Severe haemodynamic SVD</td>
<td>0.7%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

\[ P < 0.001 \]
Bioprosthetic Valve Failure

<table>
<thead>
<tr>
<th>Bioprosthetic valve failure</th>
<th>TAVI</th>
<th>SAVR</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve-related deaths</td>
<td>5.0%</td>
<td>3.7%</td>
<td>0.59</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>2.2%</td>
<td>0.7%</td>
<td>0.62</td>
</tr>
<tr>
<td>Severe haemodynamic SVD</td>
<td>0.7%</td>
<td>3.0%</td>
<td>0.21</td>
</tr>
</tbody>
</table>

**Graphical Representation**

- Bioprosthetic Valve Failure Over Time:
  - TAVI and SAVR are compared over months post-procedure.
  - The graph shows a comparison of failure rates between TAVI and SAVR procedures.
  - The y-axis represents the percentage of bioprosthetic valve failure, and the x-axis represents months post-procedure.
  - The P-values for each category are also indicated on the graph:
    - Valve-related deaths: P = 0.59
    - Re-intervention: P = 0.62
    - Severe haemodynamic SVD: P = 0.21

**Additional Information**

- The graph is part of a presentation titled "THE STRUCTURAL HEART DISEASE SUMMIT 2018: Transcatheter Valve Therapies (TVP) and LAA/PFO Closure" by Cardiovascular Research Research Foundation.
First look at long-term durability of transcatheter heart valves: Assessment of valve function up to 10-years after implantation

Danny Dvir, St. Paul’s Hospital, Vancouver, Canada.

On behalf of coauthors: Helene Elchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Mathew Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone, Sandra Lauck, Sam Lichtenstein, David Wood, Alain Cribier, John Webb
Methods

Pathological examinations

2006: Edwards SAPIEN

2013 (7-years post TAVI):
Non cardiac cause of death.
Minimal atheroma/calcification. Normal leaflet thickness.
Non-degenerated
Freedom from THV degeneration

THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.
Freedom from THV degeneration

Patients WITHOUT chronic renal failure
Freedom from THV degeneration

Patients WITHOUT chronic renal failure

Patients WITH chronic renal failure

p = 0.004
ΤΑΒΙ vs ΣΑΒΡ
ΚΡΙΤΗΡΙΑ ΕΠΙΛΟΓΗΣ

- ΘΝΗΤΟΤΗΤΑ
- ΝΟΣΗΡΟΤΗΤΑ
- ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ
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- ΑΝΘΕΚΤΙΚΟΤΗΤΑ/ ΔΙΑΡΚΕΙΑ ΒΑΛΒΙΔΑΣ
- ΑΠΟΔΟΧΗ ΑΣΘΕΝΟΥΣ

?
SURTAVI Continued Access Study
1-Year Results
All-Cause Mortality or Disabling Stroke
Randomized Controlled Trial and Continued Access

<table>
<thead>
<tr>
<th></th>
<th>1-Year KM %</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>SURTAVI TAVR</td>
<td>7.8</td>
<td>6.2, 9.8</td>
</tr>
<tr>
<td>SURTAVI SAVR</td>
<td>8.5</td>
<td>6.8, 10.8</td>
</tr>
<tr>
<td>Continued Access TAVR</td>
<td>3.8</td>
<td>1.8, 7.9</td>
</tr>
</tbody>
</table>

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>1-Year KM %</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS TAVR</td>
<td>275</td>
<td>273</td>
</tr>
<tr>
<td>SURTAVI TAVR</td>
<td>864</td>
<td>840</td>
</tr>
<tr>
<td>SURTAVI SAVR</td>
<td>796</td>
<td>761</td>
</tr>
</tbody>
</table>
The NOTION 2: Low-risk Trial in Younger Patients

Lars Sondergaard, MD, DMSc
Professor of Cardiology
The Heart Center, Rigshospitalet
Copenhagen, Denmark
PARTNER 3
Low Risk, Symptomatic AS
STS <4
Age >65 years
RCT- TAVR vs SAVR

CoreValve Evolut R
Low Risk Symptomatic AS
STS < 3
No Age Floor

Both fully enrolled

Death
Stroke
Rehospitalization
4D CT Imaging
Substudy -400 patients

Disabling
Stroke
Adaptive
Design
4D CT Imaging Study - 400 Patients
ΣΥΜΠΕΡΑΣΜΑΤΑ

ΕΧΟΥΜΕ ΠΛΕΟΝ ΑΡΚΕΤΑ ΔΕΔΟΜΕΝΑ ΓΙΑ ΝΑ ΠΡΟΚΡΙΝΟΥΜΕ ΤΗΝ TAVI ΣΕ ΑΣΘΕΝΕΙΣ ΜΕΤΡΙΟΥ ΧΕΙΡΟΥΡΓΙΚΟΥ ΚΙΝΔΥΝΟΥ

ΙΣΟΔΥΝΑΜΗ ΘΝΗΤΟΤΗΤΑ (ΥΠΕΡΟΧΗ ΤΗΣ TAVI ΣΕ ΔΙΑΜΗΡΙΑΙΑ ΠΡΟΣΠΕΛΑΣΗ)

ΤΑΧΥΤΕΡΗ ΑΝΑΡΡΩΣΗ, ΚΑΛΥΤΕΡΗ ΠΟΙΟΤΗΤΑ ΖΩΗΣ, ΛΙΓΟΤΕΡΗ ΝΟΣΗΡΟΤΗΤΑ, ΒΕΛΤΙΩΜΕΝΗ ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ

Η ΑΝΑΓΚΗ ΓΙΑ ΒΗΜΑΤΟΔΟΤΗΣΗ, ΚΑΙ ΟΙ ΠΑΡΑΒΑΛΒΙΔΚΗ ΔΙΑΦΥΓΗ (ΜΕΤΡΙΟΥ ΒΑΘΜΟΥ ΚΑΙ ΑΝΩ) ΕÍΝΑΙ ΘΕΜΑΤΑ ΠΟΥ ΧΡΗΣΤΟΥ ΒΕΛΤΙΩΣΗΣ ΚΑΤΙ ΠΟΥ ΗΔΗ ΣΥΜΒΑΙΝΕΙ ΜΕ ΤΟΥΣ ΚΑΙΝΟΥΡΓΙΟΥΣ ΤΥΠΟΥΣ ΤΩΝ TAVI.