Predictors for 90-day-mortality following transcatheter aortic valve implantation

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Disclosure

R Bauernschmitt is proctor to Edwards (Sapien transapical) and Medtronic (CoreValve transvascular).
Severe Symptomatic Aortic Stenosis:
Percent of Cardiology Patients Treated

at least 30-40% of AS patients remain untreated!!

2. Iung B et al. The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243
Catheter valve implantation becomes more and more established

It is unclear which patient population benefits from TAVI

There are no well-defined indications for TAVI

We aimed to identify risk factors for 90 days mortality in a cohort of 300 patients after TAVI
1. Stent with a three leaflet porcine pericardial valve

2. Catheter 18 French
Sapien
Delivery routes

Transarterial

Transapical
Implantations 06/2007 to 05/2010

N=132 transapical
N=33 other
N=9 Implantation not successful

N=256 transfemoral
N=132 transapical
N=33 other
N=9 Implantation not successful

N=249 CoreValve
N=5 CoreValve
N=6 Ascending aorta
N=27 Subclavian
N=7 Edwards Sapien
N=127 Edwards Sapien
N=27 Subclavian
N=7 Edwards Sapien
Survival after TAVI

30 days: 89.2%
90 days: 80.2%
6 months: 77.2%
1 year: 75.4%
# Survival after TAVI

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Valve and access</th>
<th>30day survival (%)</th>
<th>6 months survival (%)</th>
<th>1 year survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VANCOUVER</td>
<td>114</td>
<td>Sapien TF</td>
<td>92.1</td>
<td>87</td>
<td>80</td>
</tr>
<tr>
<td>REVIVE</td>
<td>106</td>
<td>Sapien TF</td>
<td>86.8</td>
<td>78.6</td>
<td>71.4</td>
</tr>
<tr>
<td>SOURCE</td>
<td>293</td>
<td>Sapien TF</td>
<td>93.6</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>CoreValve 18F S+E</td>
<td>124</td>
<td>CoreValve TF</td>
<td>85.5</td>
<td>77</td>
<td>72</td>
</tr>
<tr>
<td>TRAVERCE</td>
<td>168</td>
<td>Sapien TA</td>
<td>85.1</td>
<td>70</td>
<td>65</td>
</tr>
<tr>
<td>SOURCE</td>
<td>309</td>
<td>Sapien TA</td>
<td>88.4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Grube (Circ Cardiovasc Int, 2008)</td>
<td>102</td>
<td>CoreValve TF</td>
<td>89.2</td>
<td>68</td>
<td>68</td>
</tr>
<tr>
<td>Rodés-Cabau (JACC 2010)</td>
<td>345</td>
<td>Sapien TA + TF</td>
<td>89.6</td>
<td>(78%)</td>
<td></td>
</tr>
<tr>
<td>German Heart Center</td>
<td>368</td>
<td>Sapien TA + TF, CV TF and others</td>
<td>89.2</td>
<td>77.2</td>
<td>75.4</td>
</tr>
</tbody>
</table>
Patient selection

N=311 patients „intend to treat“ TAVI between 26.06.2007 and 28.09.2009

N=5 patients excluded from study (no catheter valve was implanted):
• N=2 decompensation after valvuloplasty, exitus in tabula
• N=2 intraannular valve positioning not successfull
• N=1 malplacement (-> surgical AVR)

90 days FU complete in 300/306 (98%) patients → study population n=300 patients
Patient demographics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N=300</strong></td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>n=188 (62.7%)</td>
</tr>
<tr>
<td>Mean age</td>
<td>81±6 years</td>
</tr>
<tr>
<td>Mean aortic valve area</td>
<td>0.64±0.18 cm²</td>
</tr>
<tr>
<td>Mean aortic gradient</td>
<td>49±17 mmHg</td>
</tr>
<tr>
<td>Logistic EuroScore</td>
<td>21±13%</td>
</tr>
</tbody>
</table>
Methods

Logistic regression analysis
To identify factors associated with 90 days mortality after TAVI
Methods

28 factors were tested with univariate analysis:

Female gender
Age (years)
Coronary heart disease
Peripheral vessel disease
Cerebrovascular disease
Pulmonary hypertension >60mmHg
Previous cardiac surgery
Renal insufficiency (GFR < 60ml/min)
Respiratory disease
NYHA class 4
Mitral insufficiency > moderate
Tricuspid insufficiency > moderate
Ejection fraction less than 50%
Additive EuroSCORE
Logistic EuroSCORE (%)
STS score (%)
Preoperative BNP value
Implanted valve type
Implantation route
Post-implant prosthesis dilatation
Procedure length (min)
Prosthesis malplacement
Intraprocedural resuscitation
Implantation of second valve
Amount of contrast agent (ml)
Prosthesis regurgitation ≥ moderate
Fluoroscopy time (min)
Dose-area product (µGycm²)
## Results

<table>
<thead>
<tr>
<th>univariate</th>
<th>90-day survivors (n=241)</th>
<th>Death within 90 days (n=59)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal insufficiency (GFR&lt;60ml/min)</td>
<td>117 (48.5%)</td>
<td>39 (66.1%)</td>
<td>0.016</td>
</tr>
<tr>
<td>NYHA class 4</td>
<td>35 (14.5%)</td>
<td>21 (35.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tricuspid insufficiency &gt; moderate</td>
<td>14 (5.9%)</td>
<td>11 (19.3%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Ejection fraction &lt; 50%</td>
<td>90 (37.3%)</td>
<td>30 (50.8%)</td>
<td>0.058</td>
</tr>
<tr>
<td>STS score (%)</td>
<td>6.1±4.2</td>
<td>8.1±5.2</td>
<td>0.002</td>
</tr>
<tr>
<td>Preoperative BNP value</td>
<td>5838±9195</td>
<td>11383±24212</td>
<td>0.012</td>
</tr>
<tr>
<td>Procedure length (min)</td>
<td>84±32</td>
<td>112±68</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intraprocedural resuscitation</td>
<td>9 (3.7%)</td>
<td>16 (27.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prosthesis regurgitation moderate or higher</td>
<td>12 (5%)</td>
<td>8 (13.6%)</td>
<td>0.018</td>
</tr>
<tr>
<td>Prosthesis malplacement</td>
<td>12 (5%)</td>
<td>7 (11.9%)</td>
<td>0.052</td>
</tr>
</tbody>
</table>
## Results

<table>
<thead>
<tr>
<th>Logistic regression</th>
<th>Univariate p</th>
<th>Multivariate p</th>
<th>OR</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA 4</td>
<td>&lt;0.001</td>
<td>0.006</td>
<td>2.810</td>
<td>1.336-5.912</td>
</tr>
<tr>
<td>TR &gt; moderate</td>
<td>0.001</td>
<td>0.041</td>
<td>2.809</td>
<td>1.044-7.561</td>
</tr>
<tr>
<td>Procedure length</td>
<td>&lt;0.001</td>
<td>0.023</td>
<td>1.008</td>
<td>1.001-1.016</td>
</tr>
<tr>
<td>Intraprocedural resuscitation</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>5.986</td>
<td>2.190-16.365</td>
</tr>
<tr>
<td>AR moderate or higher</td>
<td>0.018</td>
<td>0.043</td>
<td>3.116</td>
<td>1.035-9.381</td>
</tr>
<tr>
<td>Malplacement</td>
<td>0.052</td>
<td>0.024</td>
<td>3.518</td>
<td>1.177-10.517</td>
</tr>
</tbody>
</table>
Results

NYHA 4

Tricuspid regurgitation > moderate

Survival

patients at risk

271   221   81
25    13    8
Results

Need for intraprocedural resuscitation

Prosthesis regurgitation moderate or higher

Prosthesis malplacement
Causes of death within 90 days

- Valve-related
- Non-valve-related
- Sudden, unexplained death

- Cardiac death
- Non-cardiac death

n

- Valve-related
- Non-valve-related
- Sudden, unexplained death

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With a high prevalence of comorbidities it is difficult to identify patients who are at higher risk to die after TAVI.

It is to discuss if NYHA class 4 and a higher grade tricuspid insufficiency should be regarded as contraindications for TAVI.

Intraprocedural complications are not well tolerated by these frail patients and significantly increase the 90 days mortality, even if optimally treated by an interdisciplinary team.

All attempts must be made to prevent any complications (e.g. precise measurements of aortic root anatomy, hemodynamics management).