TAVI without STANDBY?
Hans Rickli, St.Gallen

No conflict of Interest to declare
TAVI should only be performed in hospitals with cardiac surgery on-site.
I think it's better to delegate Lars Englberger.
If you want to know the future, look at the past.
On-site cardiac surgery for PCI?

No PCI without on-site surgery.....

«....No cardiac surgery needed: PCI can be done without on-site surgery.....»
CH: First-Stent – PCI without on-site cardiac surgery: 11 years

First TAVI 3/2002
TAVI without on-site cardiac surgery: ?

1997: PCI without on-site cardiac surgery allowed
Percutaneous Coronary Intervention at Centers With and Without On-Site Surgical Backup
An Updated Meta-Analysis of 23 Studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>OR (95% CI)</th>
<th>Events Without On-Site CS</th>
<th>Events With On-Site CS</th>
<th>% Weight</th>
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</thead>
<tbody>
<tr>
<td>Singh et al.</td>
<td>2004</td>
<td>1.00 (0.06, 16.39)</td>
<td>1/57</td>
<td>1/57</td>
<td>0.83</td>
</tr>
<tr>
<td>Wennberg et al.</td>
<td>2004</td>
<td>1.67 (1.48, 1.88)</td>
<td>290/6373</td>
<td>16184/58314</td>
<td>15.15</td>
</tr>
<tr>
<td>Ting et al.</td>
<td>2006</td>
<td>2.01 (0.18, 22.26)</td>
<td>2/285</td>
<td>16184/58314</td>
<td>15.15</td>
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<tr>
<td>Carlsson et al.</td>
<td>2006</td>
<td>1.23 (0.91, 1.66)</td>
<td>13/117</td>
<td>11/117</td>
<td>13.04</td>
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<tr>
<td>Frutkin et al.</td>
<td>2007</td>
<td>1.00 (0.80, 1.24)</td>
<td>121/1192</td>
<td>121/1192</td>
<td>10.78</td>
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<tr>
<td>Pereira et al.</td>
<td>2008</td>
<td>0.75 (0.58, 1.00)</td>
<td>211/1759</td>
<td>211/1759</td>
<td>9.69</td>
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<td>Kutcher et al.</td>
<td>2009</td>
<td>1.22 (0.97, 1.55)</td>
<td>546/1002</td>
<td>372/1002</td>
<td>13.39</td>
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<tr>
<td>Pride et al. (NSTEMI)</td>
<td>2009</td>
<td>1.20 (0.35, 1.53)</td>
<td>12/1237</td>
<td>17/1276</td>
<td>6.93</td>
</tr>
<tr>
<td>Singh et al.</td>
<td>2013</td>
<td>0.50 (0.15, 1.86)</td>
<td>4/1842</td>
<td>8/1842</td>
<td>3.65</td>
</tr>
<tr>
<td>Maddox et al.</td>
<td>2014</td>
<td>2.82 (1.01, 7.82)</td>
<td>14/4549</td>
<td>5/4565</td>
<td>4.63</td>
</tr>
<tr>
<td>DellaValle et al.</td>
<td>1995</td>
<td>0.96 (0.68, 1.34)</td>
<td>132/14149</td>
<td>46/4718</td>
<td>12.42</td>
</tr>
<tr>
<td>Melberg et al.</td>
<td>2006</td>
<td>2.30 (0.52, 10.13)</td>
<td>14/2700</td>
<td>2/884</td>
<td>2.60</td>
</tr>
<tr>
<td>Overall Mixed Effects Model</td>
<td></td>
<td>1.15 (0.94, 1.41)</td>
<td>922/58670</td>
<td>19274/908879</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Clinical outcome of PCI at centers without on-site surgery: no difference!
transcatheter aortic valve implantation (TAVI) and transcatheter mitral valve repair (TMVR) from 2006 to 2015 in Switzerland
Coronary angiographies (CA) and percutaneous coronary interventions (PCI) in all centres during the year 2015 in Switzerland

CH teaching centres
interventional cardiology without on-site surgery
Outcomes of transfemoral transcatheter aortic valve implantation at hospitals with and without on-site cardiac surgery department: insights from the prospective German aortic valve replacement quality assurance registry (AQUA) in 17 919 patients

Holger Eggebrecht\(^1\*\), Maike Bestehorn\(^2\), Michael Haude\(^3\), Axel Schmermund\(^1\), Kurt Bestehorn\(^4\), Thomas Voigtlander\(^1\), Karl-Heinz Kuck\(^5\), and Rajendra H. Mehta\(^6\)

\(^1\)Cardiacangiological Center Bethanien (CCB) and AGAPLESION Bethanien Hospital, Frankfurt, Germany; \(^2\)ProMedCon GmbH, Ebenhausen, Germany; \(^3\)Medical Clinic I, Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany; \(^4\)Technical University of Dresden, Dresden, Germany; \(^5\)Department of Cardiology, Asklepios Hospital St Georg, Hamburg, Germany; and \(^6\)Duke Clinical Research Institute and Duke University Medical Center, Durham, NC, USA

Received 21 March 2016; revised 11 April 2016; accepted 20 April 2016
## Methods

- **Unmatched comparison:**

<table>
<thead>
<tr>
<th></th>
<th>All patients</th>
<th>2013</th>
<th>2014</th>
<th>2013 vs. 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS –</td>
<td>1332</td>
<td>735</td>
<td>597</td>
<td>- 19%</td>
</tr>
<tr>
<td>CS +</td>
<td>16587</td>
<td>6885</td>
<td>9702</td>
<td>+ 41%</td>
</tr>
</tbody>
</table>

Eggebrecht H. et al AQUA. Eur Heart J 2016
Results: Patient characteristics (unmatched)

<table>
<thead>
<tr>
<th></th>
<th>CS- (n=1,332)</th>
<th>CS+ (n=16,587)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>82.1±5.8 (55-97)</td>
<td>81.1±6.1 (33-100)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Females (%)</td>
<td>722 (54.2%)</td>
<td>9125 (55.0%)</td>
<td>0.568</td>
</tr>
<tr>
<td>NYHA ≥ III</td>
<td>1204 (90.4%)</td>
<td>14079 (84.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Systolic PA pressure &gt; 55 mmHg</td>
<td>257 (19.3%)</td>
<td>2204 (13.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>392 (29.4%)</td>
<td>4925 (29.7%)</td>
<td>0.840</td>
</tr>
<tr>
<td>Presence of permanent pacemaker</td>
<td>177 (13.3%)</td>
<td>1868 (11.3%)</td>
<td>0.025</td>
</tr>
<tr>
<td>ASA ≥ 3</td>
<td>1242 (93.2%)</td>
<td>15221 (91.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Left ventricular ejection fraction ≤ 30%</td>
<td>148 (11.1%)</td>
<td>1687 (10.2%)</td>
<td>0.183</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>804 (60.4%)</td>
<td>8995 (54.2%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Unmatched: Without on-site cardiac surgery (CS-): older, more comorbidities, at higher predicted risks of death

LogEuroSCORE ( % )

- LogEuroSCORE < 10%  | 213 (16.1%) | 3945 (24.1%) | <0.001 |
- LogEuroSCORE 10-20% | 520 (39.2%) | 6036 (36.9%) | <0.001 |
- LogEuroSCORE 20-30% | 259 (19.5%) | 2969 (18.2%) |         |
- LogEuroSCORE > 30%  | 333 (25.1%) | 3407 (20.8%) |         |

German Aortic Valve Score 2.0 ( % )

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.1±5.5 (0.8-57)</td>
<td>5.5±5.9 (0.6-99.9)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>


# Results: In-hospital outcomes (unmatched)

<table>
<thead>
<tr>
<th>Event</th>
<th>CS- (n=1,332)</th>
<th>CS+ (n=16,587)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective procedure</td>
<td>1109 (83.3%)</td>
<td>13907 (83.8%)</td>
<td>0.578</td>
</tr>
<tr>
<td><strong>Procedure time (minutes)</strong></td>
<td>110.3 ± 48.2</td>
<td>79.3± 44.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fluoroscopy time (minutes)</td>
<td>18.9 ± 11.7</td>
<td>19.9 ± 33.1</td>
<td>0.273</td>
</tr>
<tr>
<td><strong>Intraprocedural complications</strong></td>
<td>112 (8.4%)</td>
<td>1817 (11.0%)</td>
<td>0.004</td>
</tr>
<tr>
<td>- Device malpositioning</td>
<td>19 (1.4%)</td>
<td>276 (1.7%)</td>
<td>0.512</td>
</tr>
<tr>
<td>- Device embolisation</td>
<td>6 (0.5%)</td>
<td>51 (0.3%)</td>
<td>0.373</td>
</tr>
<tr>
<td>- Coronary occlusion</td>
<td>4 (0.3%)</td>
<td>62 (0.4%)</td>
<td>0.671</td>
</tr>
<tr>
<td>- Aortic dissection</td>
<td>2 (0.2%)</td>
<td>38 (0.2%)</td>
<td>0.555</td>
</tr>
<tr>
<td>- Annular rupture</td>
<td>9 (0.7%)</td>
<td>55 (0.3%)</td>
<td>0.043</td>
</tr>
<tr>
<td>- Pericardial tamponade</td>
<td>6 (0.5%)</td>
<td>171 (1.0%)</td>
<td>0.039</td>
</tr>
<tr>
<td>- Acute cardiac decompensation</td>
<td>7 (0.5%)</td>
<td>118 (0.7%)</td>
<td>0.433</td>
</tr>
<tr>
<td>- Cerebral embolism</td>
<td>2 (0.2%)</td>
<td>30 (0.2%)</td>
<td>0.799</td>
</tr>
<tr>
<td>- Aortic regurgitation ≥ 2</td>
<td>28 (2.1%)</td>
<td>171 (1.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Rhythm disturbances</td>
<td>25 (1.9%)</td>
<td>489 (2.9%)</td>
<td>0.024</td>
</tr>
<tr>
<td>- Vascular injury</td>
<td>33 (2.5%)</td>
<td>739 (4.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Conversion to open heart surgery</td>
<td>4 (0.3%)</td>
<td>115 (0.7%)</td>
<td>0.088</td>
</tr>
</tbody>
</table>
## Results: In-hospital outcomes (unmatched)

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<tbody>
<tr>
<td>In-hospital death</td>
<td>50 (3.8%)</td>
<td>703 (4.2%)</td>
<td>0.396</td>
</tr>
<tr>
<td>In-hospital death for the composite of intraprocedural complications likely to benefit from bail-out surgery</td>
<td>17/46 (37.0%)</td>
<td>220/653 (33.7%)</td>
<td>0.771</td>
</tr>
<tr>
<td>Cerebrovascular event</td>
<td>35 (2.6%)</td>
<td>378 (2.3%)</td>
<td>0.452</td>
</tr>
<tr>
<td>Delirium requiring treatment</td>
<td>47 (3.5%)</td>
<td>635 (3.8%)</td>
<td>0.582</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3 (0.2%)</td>
<td>60 (0.4%)</td>
<td>0.418</td>
</tr>
<tr>
<td>Low cardiac output</td>
<td>33 (2.5%)</td>
<td>431 (2.6%)</td>
<td>0.789</td>
</tr>
<tr>
<td>Resuscitation</td>
<td>39 (2.9%)</td>
<td>493 (3.0%)</td>
<td>0.927</td>
</tr>
<tr>
<td>Vascular complications</td>
<td>134 (10.1%)</td>
<td>1479 (8.9%)</td>
<td>0.161</td>
</tr>
<tr>
<td>Need for transient dialysis</td>
<td>15 (1.1%)</td>
<td>373 (2.2%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Atrial fibrillation at discharge</td>
<td>315 (23.6%)</td>
<td>3811 (23.0%)</td>
<td>0.700</td>
</tr>
<tr>
<td>New pacemaker/ICD implantation</td>
<td>264 (19.8%)</td>
<td>2620 (15.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Days in hospital after TF-TAVI</td>
<td>11.0 ± 7.5 (0-93)</td>
<td>10.4 ± 7.5 (0-162)</td>
<td>0.005</td>
</tr>
<tr>
<td>Transfer to another hospital</td>
<td>142 (10.7%)</td>
<td>2501 (15.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge to rehabilitation unit</td>
<td>186 (14.0%)</td>
<td>3074 (18.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge to nursing facility</td>
<td>12 (0.9%)</td>
<td>77 (0.5%)</td>
<td>0.029</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>50 (3.8%)</td>
<td>703 (4.2%)</td>
<td>0.396</td>
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Eggebrecht H. et al AQUA. Eur Heart J 2016
Methods

- **Unmatched comparison:**

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</tbody>
</table>

- **Matched-pairs analysis:**

- matching according to German Aortic Valve Score 2.0

  *(21 variables: age, female gender, body mass index < 22, BMI > 39, heart failure/NYHA IV, angina at rest/minor exertion, cardiogenic shock < 48 hrs, no pulmonary hypertension, sinus rhythm, ASA class 4, ASA class 5, CAD and left main stenosis, repeat cardiac/aortic surgery, infective endocarditis/septic intervention, diabetes, PVD, renal replacement therapy/crea > 2.3 mg/dl, LVEF<30%, mechanical circulatory support)*

**550 pairs with identical GAV score 2.0 in each group (CS-/CS+)**

Eggebrecht H. et al AQUA. Eur Heart J 2016
### Matched pairs*: Outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>CS- (n=555)</th>
<th>CS+ (n=555)</th>
<th>p</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraprocedural complications</td>
<td></td>
<td></td>
<td>643</td>
<td>0.884</td>
<td>0.594-1.316</td>
</tr>
<tr>
<td>- Device malpositioning</td>
<td>306</td>
<td></td>
<td></td>
<td>1.127</td>
<td>0.432-2.943</td>
</tr>
<tr>
<td>- Device embolisation</td>
<td>00</td>
<td></td>
<td></td>
<td>1.00</td>
<td>0.140-7.125</td>
</tr>
<tr>
<td>- Coronary occlusion</td>
<td>38</td>
<td></td>
<td></td>
<td>0.498</td>
<td>0.091-2.731</td>
</tr>
<tr>
<td>- Aortic dissection</td>
<td>563</td>
<td></td>
<td></td>
<td>0.499</td>
<td>0.045-5.520</td>
</tr>
<tr>
<td>- Annular rupture</td>
<td>00</td>
<td></td>
<td></td>
<td>1.00</td>
<td>0.249-4.019</td>
</tr>
<tr>
<td>- Pericardial tamponade</td>
<td>563</td>
<td></td>
<td></td>
<td>0.568</td>
<td>0.165-1.9525</td>
</tr>
<tr>
<td>- Acute cardiac decompensation</td>
<td>4 (0.7%)</td>
<td>2 (0.4%)</td>
<td>0.413</td>
<td>2.007</td>
<td>0.366-11.004</td>
</tr>
<tr>
<td>- Cerebral embolism</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
<td></td>
<td>1.00</td>
<td>0.062-6.028</td>
</tr>
<tr>
<td>- Aortic regurgitation ≥ 2</td>
<td>3 (0.5%)</td>
<td>2 (0.4%)</td>
<td></td>
<td>2.542</td>
<td>0.979-6.600</td>
</tr>
<tr>
<td>- Rhythm disturbances</td>
<td>3 (0.5%)</td>
<td>2 (0.4%)</td>
<td></td>
<td>1.00</td>
<td>0.268-1.632</td>
</tr>
<tr>
<td>- Vascular injury</td>
<td>14 (2.5%)</td>
<td>22 (4.0%)</td>
<td></td>
<td>0.175</td>
<td>0.323-1.262</td>
</tr>
<tr>
<td>Conversion to open heart surgery</td>
<td>2 (0.4%)</td>
<td>5 (0.9%)</td>
<td></td>
<td>0.255</td>
<td>0.077-2.059</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>10 (1.8%)</td>
<td>16 (2.9%)</td>
<td>0.234</td>
<td>0.618</td>
<td>0.278-1.374</td>
</tr>
<tr>
<td>Cerebrovascular event</td>
<td>18 (3.2%)</td>
<td>18 (3.2%)</td>
<td>1.00</td>
<td>1.00</td>
<td>0.515-1.943</td>
</tr>
<tr>
<td>New pacemaker/ICD implantation</td>
<td>114 (20.5%)</td>
<td>105 (18.9%)</td>
<td>0.497</td>
<td>1.108</td>
<td>0.824-1.489</td>
</tr>
<tr>
<td>Days in hospital after TF-TAVI</td>
<td>10.4 ± 7.1</td>
<td>9.8 ± 6.4</td>
<td>0.139</td>
<td>0.088</td>
<td>-0.029-0.207</td>
</tr>
</tbody>
</table>

*Matched pairs (CS-) vs. (CS+) no difference:
- Intraprocedural complications
- In-hospital death
- New Pacemaker/ICD-Implantation

*identical GAV 2.0 score

Eggebrecht H. et al AQUA. Eur Heart J 2016
# Management of Intraprocedural Complications

<table>
<thead>
<tr>
<th>Intraprocedural complications</th>
<th>CS- (n=555)</th>
<th>CS+ (n=555)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device malpositioning</td>
<td>51 (9.2%)</td>
<td>57 (10.3%)</td>
</tr>
<tr>
<td>Device embolisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary occlusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aortic dissection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pericardial tamponade</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Repositioning / Valve in valve
- Interventional / Case by case

1/500 pts? Why not Cardiac surgery for other Aortic dissection???

On-site heart team and prevention is the best way to treat annular rupture and pericardial tamponade (guide wire selection)

**Annular Rupture During Transcatheter Aortic Valve Replacement**
**Classification, Pathophysiology, Diagnostics, Treatment Approaches, and Prevention**
**J Am Coll Cardiol Intv 2015;8:1–9**

- Experienced team with
  - Neurologist
  - Electrophysiologist
  - Vascular surgeon

Eggebrecth H. et al AQUA. Eur Heart J 2016
Guidelines on the management of valvular heart disease (2016)

**Recommendations**

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

- Close cooperation in the Heart Team is key
- Lack of a CS department on-site should not be regarded as contraindication for TAVI
TAVI without STANDBY?
Thank you!

hans.rickli@kssg.ch