The Role of TAVI in high-risk and normal-risk Patients

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Disclosure

Speaker name:
Joachim Schofer, MD, PhD

I have the following potential conflicts of interest to report:
X Consulting of Direct Flow Medical
The typical TAVI patient?

- Old...very old...
- Frail...very frail
- Lots of co-morbidities...
  - Prior CABG (poor LV function)
  - Chronic kidney disease
  - Severe COPD
  - Peripheral arterial disease
  - Chronic atrial fibrillation
  - Cancer in remission

But still enjoying life!
Who should not undergo TAVI?

- Patient Goals and Preferences
- Clinical Risk Stratification
- Multidisciplinary Heart Valve Team
- Anticipated Benefit
- Geriatric Risk Stratification
- TAVR Beneficial
- Proceed with TAVR
- Uncertain
  - Clinical Judgment
  - Alternative care plan without TAVR
- TAVR Futile

Severe AS Clinical and Geriatric Comorbidities
What is most influencing health status (symptoms, QoL)?
Severe AS Clinical and Geriatric Comorbidities

Anticipated Benefits

Lindman B et al., JACC CV Interv 2014
PARTNER Trial – Inoperable Cohort B

All-Cause Mortality (ITT)
Crossover Patients Censored at Crossover

- Standard Rx (n = 179)
- TAVR (n = 179)

HR [95% CI] = 0.50 [0.39, 0.65]
p (log rank) < 0.0001

* In an age and gender matched US population without comorbidities, the mortality at 5 years is 40.5%.

Kapadia, TCT 2014
Are “surgical” risk scores the key?

### Definition of Surgical Risk

No universally accepted criteria which clearly separates risk categories

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>Intermediate Risk</th>
<th>High Risk</th>
<th>Extreme Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>VARC-2 (2012)</td>
<td>Estimated 30 day mortality &lt;4%</td>
<td>Estimated 30 day mortality &gt;10%</td>
<td>Est 30 day mortality &gt;15% (very high risk) Est &gt;50% irreversible morbidity or mortality (extreme risk)</td>
</tr>
<tr>
<td>AHA/ACC (2014)</td>
<td>STS &lt;4% - with no additional risk indicators</td>
<td>STS 4-8% - 1 Frailty index - 1 Major Organ System compromised - Possible Procedure impediment</td>
<td>Predicted risk of death or major morbidity &gt;50% at 1 y - ≥3 Major Organ System compromised - Severe Procedure impediment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STS &gt;8% - ≥ 2 Frailty indices - 2 Major Organ System compromised - Possible Procedure specific impediment</td>
<td></td>
</tr>
</tbody>
</table>

1 Kappetein AP et al., *J Am Coll Cardiol* 2012; 60:1438-54
2 Nishimura R et al., *J Thorac Cardiovasc Surg* 2014;148: e1-e132
TAVI in lower risk patients

European Experience
TAVI in lower risk patients
It’s already happened!

A 3-Center Comparison of 1-Year Mortality Outcomes Between Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement on the Basis of Propensity Score Matching Among Intermediate-Risk Surgical Patients

Nicolo Piazza, MD, PhD,† Bindu Kalesan, PhD,‡ Nicolas van Mieghem, MD,§ Stuart Head, MSc,‖ Peter Wenaweser, MD,¶ Thierry P. Carrel, MD,¶ Sabine Bleiziffer, MD,¶ Peter de Jaegere, MD, PhD,§ Brigitte Galli,§ Robert H. Anderson, MD, PhD,¶ Arie-Pieter Kappotein, MD, PhD,¶ Ruediger Lange, MD, PhD,¶ Patrick W. Serruys, MD, PhD,¶ Stephan Windecker, MD,¶ Peter Jüni, MD¶ Munich, Germany; Bern, Switzerland; Rastatt, the Netherlands; Montreal, Canada; and Newcastle–Upon–Tyne, United Kingdom

Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients
A Glimpse Into the Future
Ruediger Lange, MD, PhD, Sabine Bleiziffer, MD, Domenico Mazzitelli, MD, Yacine Elhmiidi, MD, Anke Opitz, MD, Marcus Krane, MD, Marcus-Andre Deutsch, MD, Hendrik Ruge, MD, Gernot Brockmann, MD, Bernhard Voss, MD, Christian Schreiber, MD, Peter Tassani, MD, PhD, Nico Piazza, MD, PhD
Munich, Germany

Clinical outcomes of patients with estimated low or intermediate surgical risk undergoing transcatheter aortic valve implantation
Peter Wenaweser†‡, Stefan Stortecky‡, Sarah Schwander¹, Dik Heg³, Christoph Huber¹, Thomas Pilgrim¹, Steffen Gloecker¹, Crochan J. O’Sullivan¹, Bernhard Meier¹, Peter Jüni², Thierry Carrel¹, and Stephan Windecker¹,²

Transcatheter vs surgical aortic valve replacement in intermediate-surgical-risk patients with aortic stenosis: A propensity score-matched case-control study
Azeem Latib, MB ChB, ‡§, Francesco Maisano, MD, ‡§ Letizia Bertoldi, MD, ‡§ Andrea Giacomini, MD, ‡§ Joanne Shumon, MD, ‡§ Mircale Cioni, MD, ‡§ Alfonso Ielasi, MD, ‡§ Filippo Figini, MD, ‡§ Kazuake Tagaki, MD, ‡§ Annalisa Franco, MD, ‡§ Remo Daniel Covello, MD, ‡§ Antonio Grimaldi, MD, ‡§ Pietro Spagnolo, MD, ‡§ Gill Louise Buchman, MD, ‡§ Mauro Garlino, MD, ‡§ Aidaie Chieffo, MD, ‡§ Matteo Montorfano, MD, ‡§ Ottavio Alfieri, MD, ‡§ and Antonio Colombo, MD, ‡§ Milan, Italy

Structural Heart Disease
Acute and Late Outcomes of Transcatheter Aortic Valve Implantation (TAVI) for the Treatment of Severe Symptomatic Aortic Stenosis in Patients at High- and Low-Surgical Risk

Gerhard Schymik, M.D., ¹ Helge Schröfel, M.D., ² Jan S. Schymik, ³ Rainer Wondraschek, ¹ Tim Süselbeck, M.D., ⁴ Rüdiger Kiefer, ³ Veronika Balattrasar, M.D., ² Armin Luik, M.D., ¹ Herbert Fosval, M.D., ² and Claus Schmitt, M.D. ¹
From the ¹Medical Clinic IV, University Hospital Karlsruhe, Germany; ²Clinic for Cardiac Surgery Karlsruhe, Germany; ³University of Munich, Germany; and ⁴Department of Medicine, University Medical Centre Mainz, Germany

Transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis: Results from an intermediate risk propensity-matched population of the Italian OBSERVANT study
Paola D’Errigo ², Marco Barbanti ²,³, Marco Ranucci ², Francesco Onorati ², Remo Daniel Covello ², Stefano Rosato ², Corrado Tamburino ²,³, Francesco Santini ², Gennaro Santoro ², Fulvia Seccareccia ³, and on behalf of the OBSERVANT Research Group

TAVI Populations in Europe

~50% have logistic EuroSCORE <20%

Retrospective Risk-Stratification

Lower risk patients have favorable outcomes
A 3-Center Comparison of 1-Year Mortality Outcomes Between Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement on the Basis of Propensity Score Matching Among Intermediate-Risk Surgical Patients

Nicolo Piazza, MD, PhD,⁎† Bindu Kalesan, PhD,‡ Nicolas van Mieghem, MD,§ Stuart Head, MSc,|| Peter Wenzeser, MD,¶ Thierry P. Carrel, MD,# Sabine Bleiziffer, MD,⁎† Peter P. de Jaegere, MD, PhD,§ Brigitta Gahl,⁎ Robert H. Anderson, MD, PhD,⁎⁎ Arie-Pieter Kappetein, MD, PhD,|| Ruediger Lange, MD, PhD,⁎† Patrick W. Serruys, MD, PhD,§ Stephan Windecker, MD,¶ Peter Jüni, MD‡
3666 patients enrolled
TAVI – 782
SAVR – 2884

2856 patients excluded based on propensity scores
TAVI 377
SAVR 2479

810 matched patients
TAVI – 405
SAVR - 405

300 patients excluded based on STS score <3% and >8%

510 matched patients (STS scores 3-8%)

TAVI
255 patients analyzed
(Lost to follow-up 3)

SAVR
255 patients analyzed
(Lost to follow-up 8)

Matched TAVI vs. SAVR
STS 3-8%

30-day All-cause mortality: 7%
1-year All-cause mortality: 17%

Similar outcomes between TAVI & SAVR in “matched” intermediate risk . . .

<table>
<thead>
<tr>
<th></th>
<th>Piazza(^1)</th>
<th>OBSERVANT(^2)</th>
<th>Latib(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVI (n=255)</td>
<td>SAVR (n=255)</td>
<td>p</td>
</tr>
<tr>
<td>STS (% mean)</td>
<td>3-8</td>
<td>3-8</td>
<td>na</td>
</tr>
<tr>
<td>Log EuroSCORE (% mean)</td>
<td>17.3</td>
<td>17.6</td>
<td>8.9</td>
</tr>
<tr>
<td>30 Day Mortality (%)</td>
<td>7.8</td>
<td>7.1</td>
<td>0.74</td>
</tr>
</tbody>
</table>

\(^3\) Latib, et al. Am Heart J 2012; 164:910-7
TAVI in lower risk patients

US Experience
## TAVI Populations in the US

Definition of Extreme and High risk is a moving target

<table>
<thead>
<tr>
<th>STS Score</th>
<th>Inoperable / Extreme Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PARTNER B TAVR</strong></td>
<td>11.2%</td>
<td>11.8%</td>
</tr>
<tr>
<td><strong>PARTNER IIB SAPIEN</strong></td>
<td>11.0%</td>
<td>10.9%</td>
</tr>
<tr>
<td><strong>PARTNER IIB SAPIEN XT</strong></td>
<td>10.3%</td>
<td>7.3%</td>
</tr>
<tr>
<td><strong>CoreValve ER Iliofemoral</strong></td>
<td>10.3%</td>
<td>7.0%</td>
</tr>
<tr>
<td><strong>CoreValve ER Continued Access</strong></td>
<td>9.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td><strong>TVT Registry SAPIEN TF</strong></td>
<td><strong>7.0%</strong></td>
<td><strong>5.0%</strong></td>
</tr>
</tbody>
</table>

**May 2007**  **July 2013**
The PARTNER IIA Trial

Study Design

Symptomatic Severe Aortic Stenosis

n = 2000 Randomized Patients

Operable (STS ≥4)

ASSESSMENT by Heart Valve Team

1:1 Randomization

• 2011 patients enrolled in 22 months!
• Mean STS ~6%
• ~75% TF access

Primary Endpoint: All-Cause Mortality + Disabling Stroke at Two Years (Non-inferiority)
SURTAVI: Intermediate Risk

Heart Team Evaluation
- Confirm inclusion/exclusion
- Risk Classification
- Treatment strategy for CAD

Randomization
- Stratified by need for revascularization

N = ~2,500 patients

SURTAVI Study Status
- Active discussions with FDA
- Inclusion change: moderate risk as defined as 3% or greater mortality at 30-days
- Enrollment has accelerated; working with FDA on reasonable timeframes for approval
Conclusions I

• “Lower” risk patients are currently being treated (Europe > US), they may have other reasons not to undergo surgery
• Clinical outcomes in patients with lower surgical risk scores are excellent.
Conclusions II

• Offering TAVR to intermediate surgical risk patients is justified if performed within the confines of a Heart Team

• Although there are good reasons to believe that in “normal” risk patients TAVI compares favorable to surgery, the definite answer will come from the ongoing randomized trials (which, however, are using devices that are no longer used in Europe)
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