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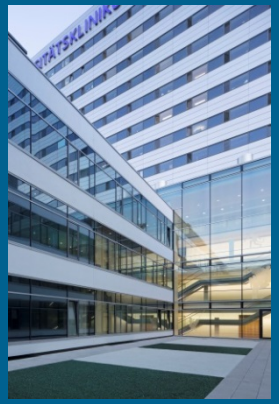
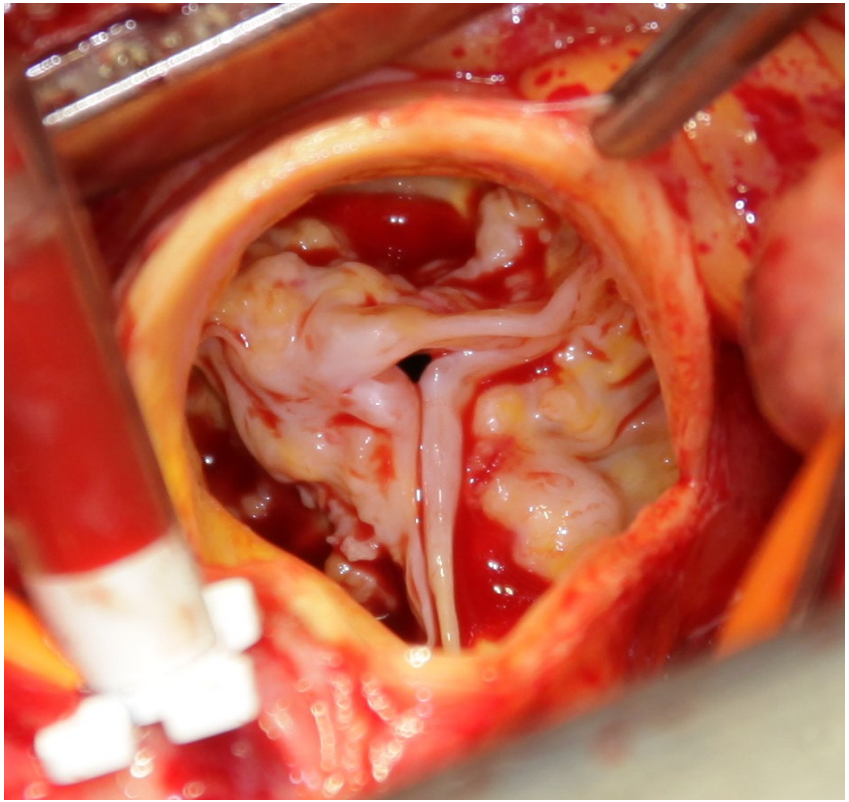
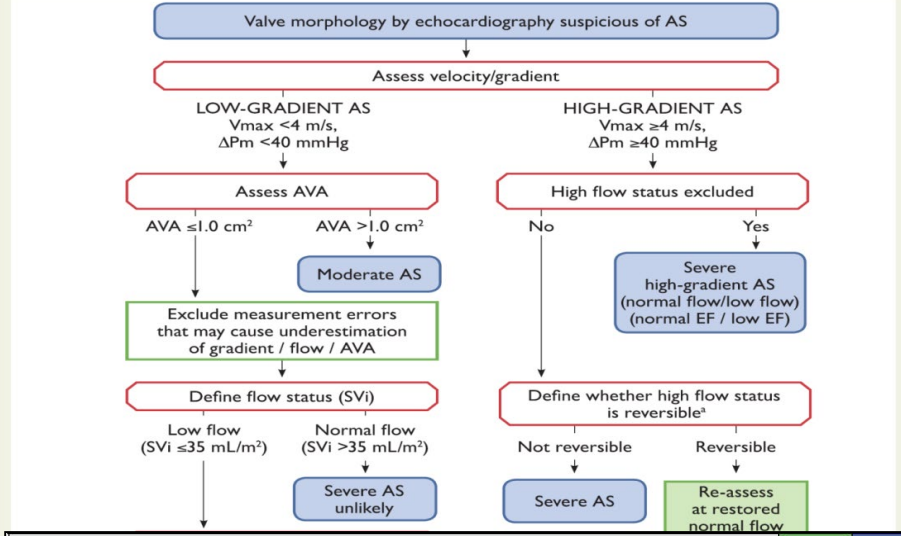
# TAVI in ascending aorta / aortic root dilatation



Prof. Dr. Thomas Walther

# AorticStenosis - Guidelines






| | | |
|---|---|---|
| SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II <4% or logistic EuroSCORE I <10% and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation). | I | B |
| 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. | I | B |

# TAVI and aortic aneurysm

- ?
- Few data published.

PubMed | TAVI and ascending aortic aneurysm

Transcatheter **Aortic** Valve Implantation in a Nonagenarian with **Aortic Aneurysm**: Futility or Utility?

Fennelly E, Lee M, Da Costa M, Sultan S, Sharif F, Mylotte D.

Case Rep Cardiol. 2018 Feb 1;2018:5434953. doi: 10.1155/2018/5434953. eCollection 2018.

PMID: 29487750 **Free PMC Article**

Similar articles

**Items: 12**

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# Transcatheter aortic valve implantation in patients with ascending aortic dilatation: safety of the procedure and mid-term follow-up†

Bartosz Rylski[a,b,*], V
Nimesh D. D

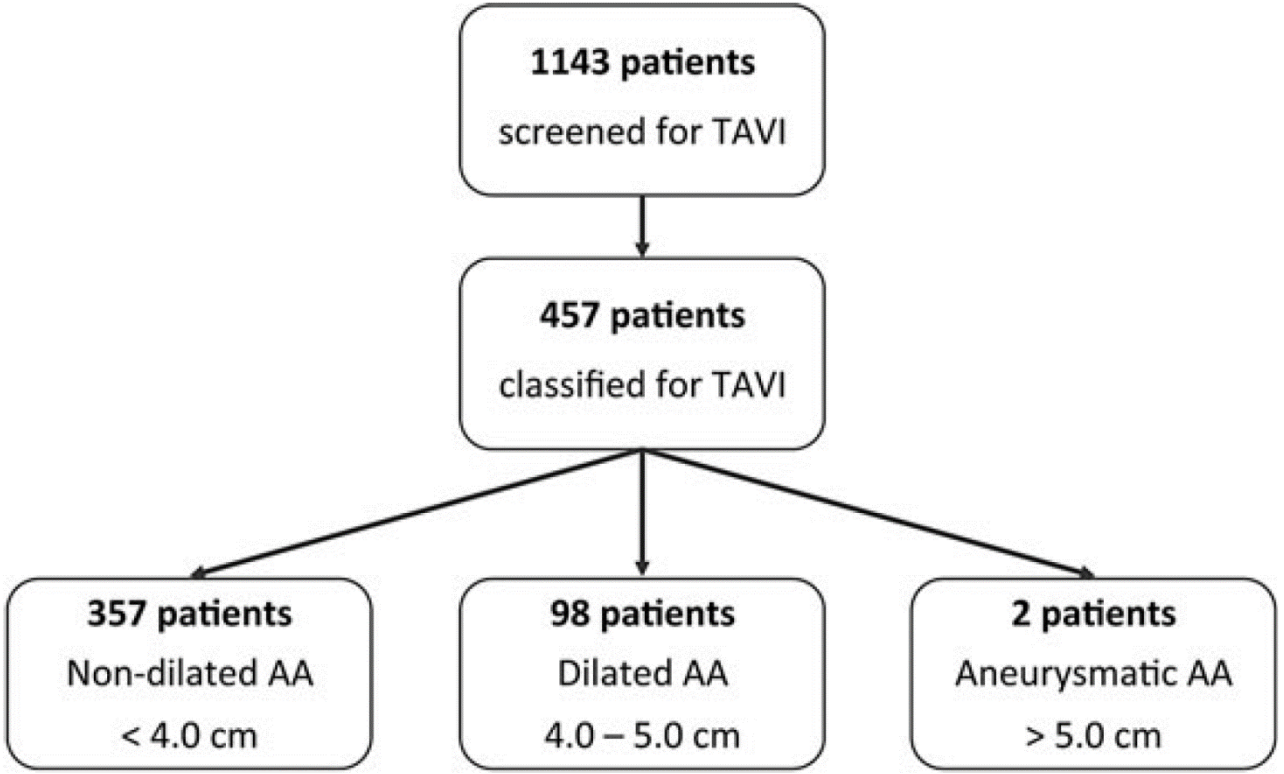
## Abstract

**OBJECTIVES**: Transcatheter aorti
This investigation evaluates the sa

**METHODS**: From November 200
patients met the inclusion criteri
tant ascending aortic dilatation (
up (652.2 patient-years) was 100

**RESULTS**: There was no iatrogeni
with mildly dilatated ascending a
(87%) and 201 of 242 (83%, $P = 0$
mild and moderate dilatation, res
5.0 cm survived the procedure ar

**CONCLUSIONS**: Ascending aorti
adverse aortic events is low. The




*EJCTS 2014;46:228-33*

# TAVI and aortic aneurysm

- ?
- Few data published.

PubMed | TAVI and ascending aortic aneurysm

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PMID: 29487750 **Free PMC Article**

Similar articles

**Items: 12**

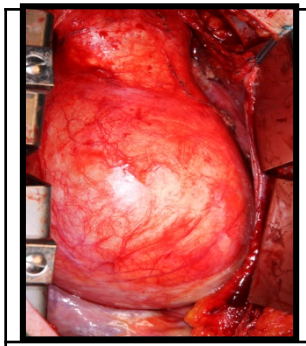
- Fixation ?

# Fixation of TAVI prostheses

| |  |  |  |  |  |  |
|---|---|---|---|---|---|---|
| **Annular fixation** | + | + | + | + | + | (+) |
| **Ascending aortic fixation** | - | + | - | + | - | - |
| **Leaflet fixation** | - | - | - | - | - | + |

# Fixation of TAVI prostheses

## in aortic aneurysm …

|  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|
| **Annular fixation** | + | + | + | + | + | (+) |
| ~~**Ascending aortic fixation**~~ | - | ~~+~~ | - | ~~+~~ | - | - |
| **Leaflet fixation** | - | - | - | - | - | + |

# TAVI - different conditions

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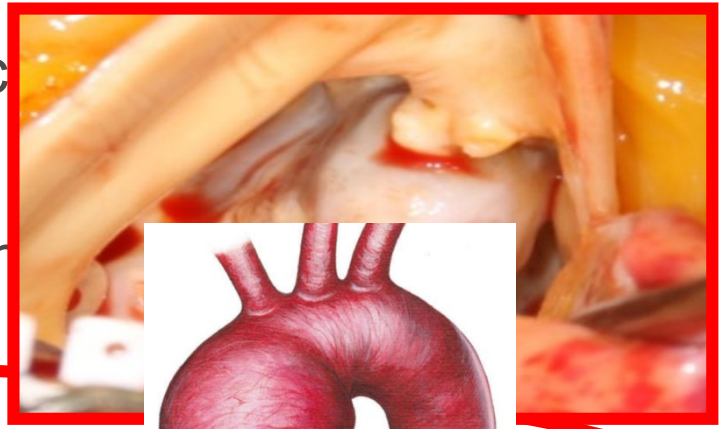
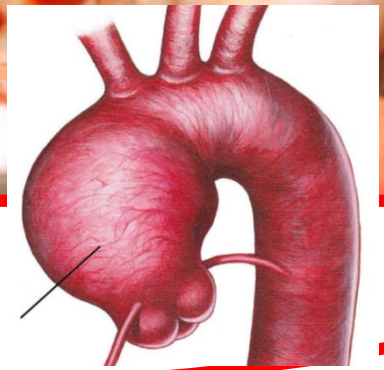
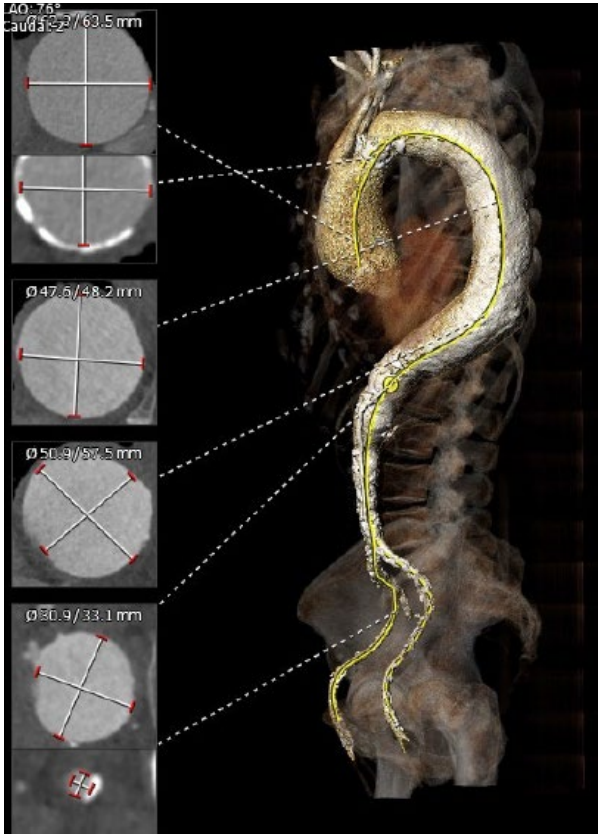
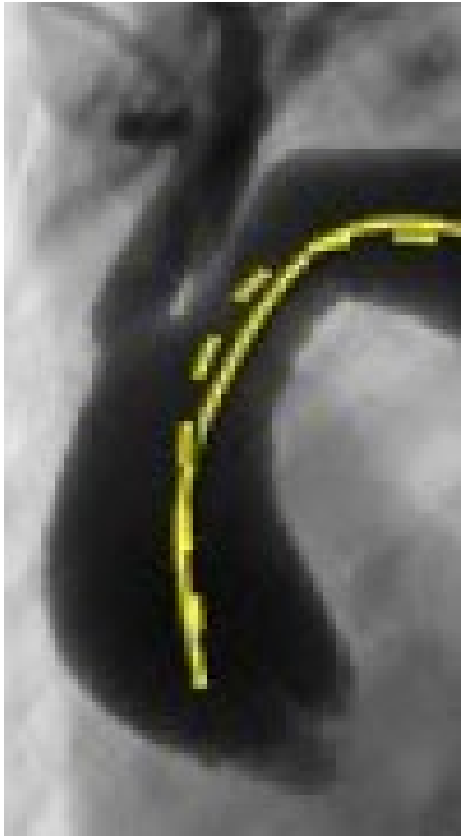
- **straight - forward**
  moderate calcifications, symmetric
- **Variable / intermediate**
  excentric calcifications, short coron
  issues
- **Hostile:** **Aortic stenosis + aortic aneurysm**

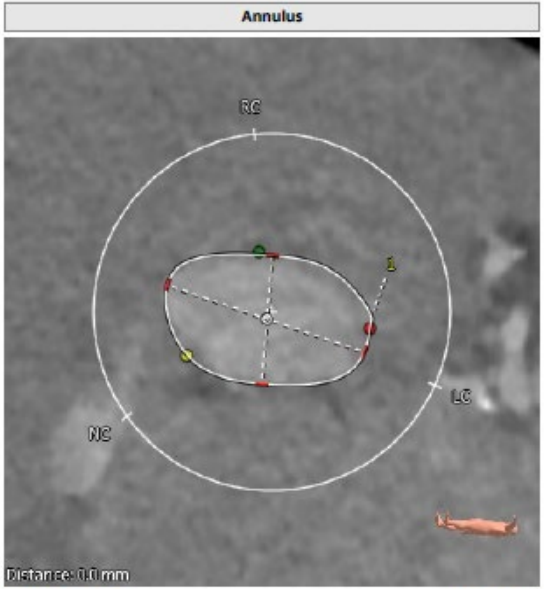




# Pt. example





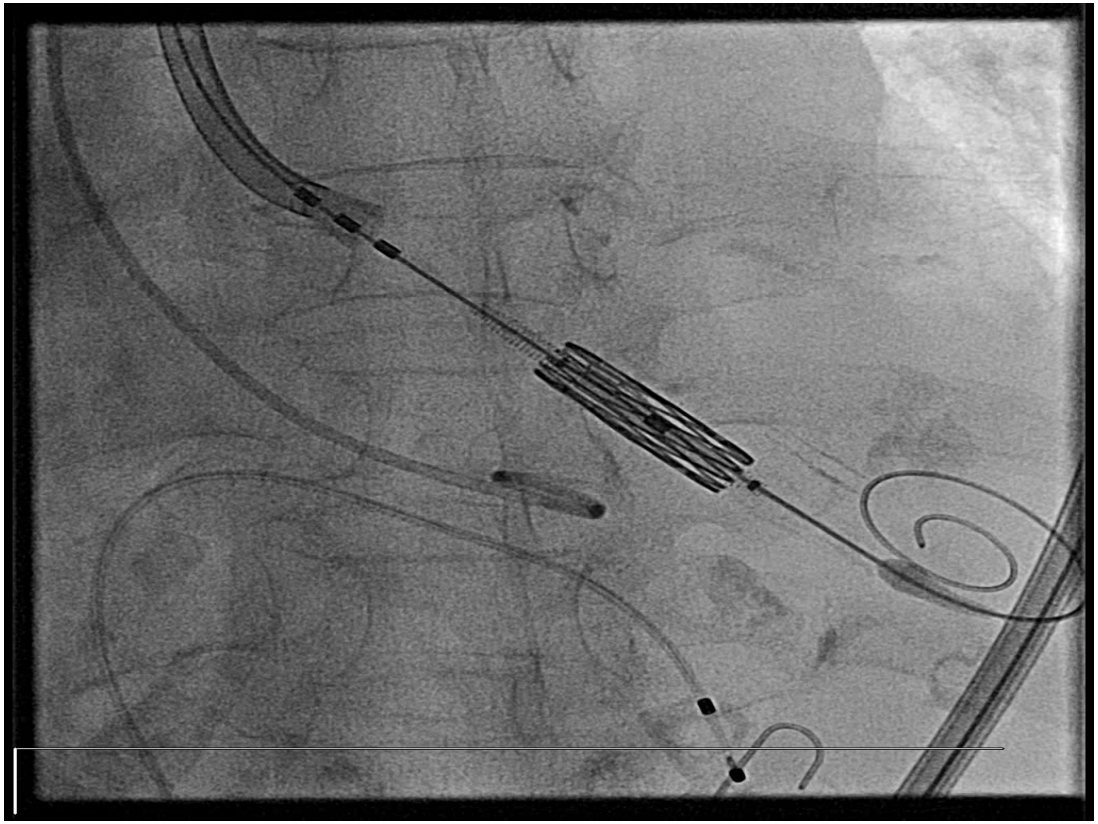

| ID | Type | Label | Value |
|---|---|---|---|
| 1 | Polygon | Min. Ø | 18.0 mm |
| | | Max. Ø | 29.1 mm |
| | | Avg. Ø | 23.6 mm |
| | | Area derived Ø | 23.4 mm |
| | | Perimeter derived Ø | 24.5 mm |
| | | Area | 430.1 mm² |
| | | Perimeter | 76.9 mm |

*courtesy J Kempfert, Berlin*

**=> 24.5mm annulus, TF S3 26mm**

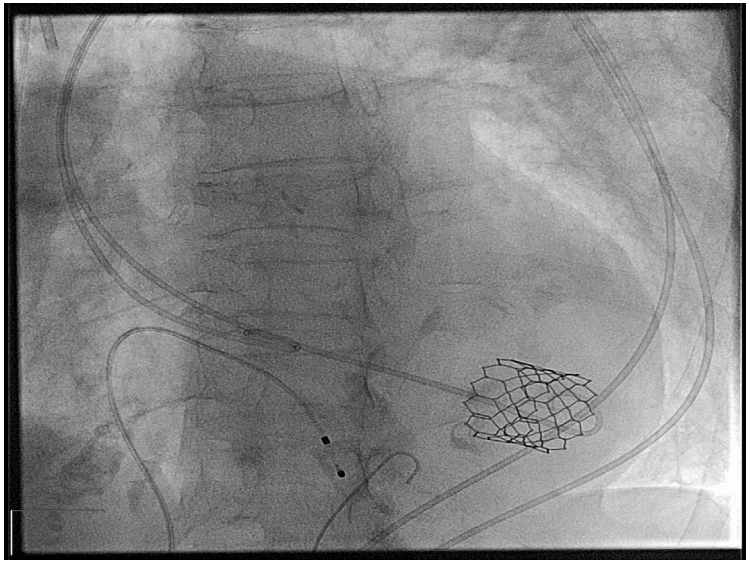
# Pt. example

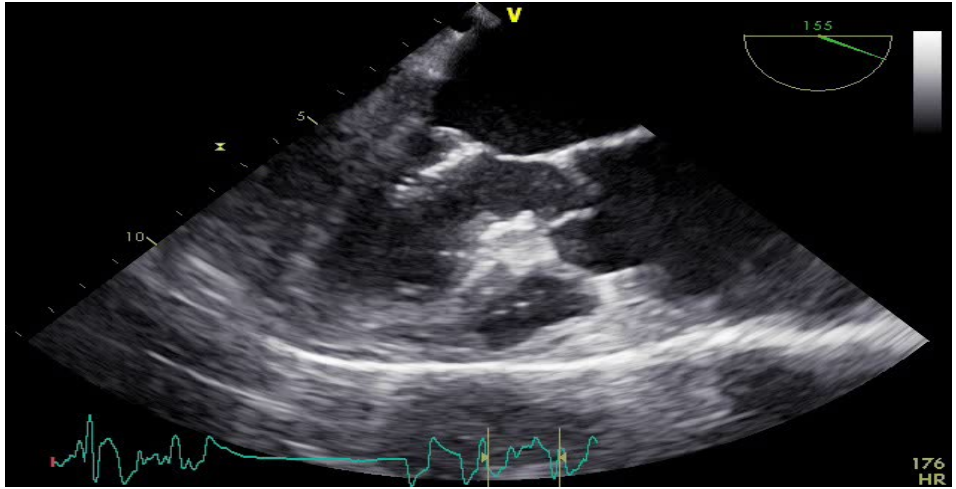
- Little calcification, severe AR
- significant aortic aneurysm > 6cm
- STS 8.8, age 88y, severe dyspnea
- Strong pt. request for TAVI



*courtesy J Kempfert, Berlin*

# Pt. example






- => conversion to conventional surgery, good outcome

*courtesy J Kempfert, Berlin*

# Valvular Heart Dis GL

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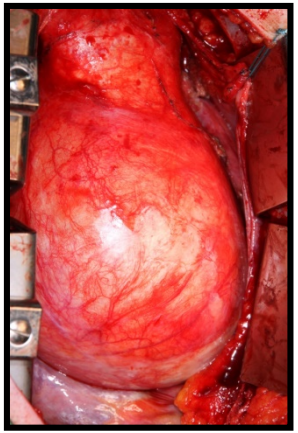
**Table 7** Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk (see Table of Recommendations in section 5.2.)



| Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention | | |
|---|---|---|
| Aneurysm of the ascending aorta | | + |
| | Favours TAVI | Favours SAVR |

*Eur Heart J. 2017;38:2739-2791*
*Eur J Cardiothorac Surg. 2017;52:616-664*

# Valvular Heart Dis GL

| Anatomical and technical aspects | Favours TAVI | Favours SAVR |
|---|---|---|
| Short distance between coronary ostia and aortic valve annulus | | + |
| Size of aortic valve annulus out of range for TAVI | | + |
| Aortic root morphology unfavourable for TAVI | | + |
| Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI | | + |

# Valvular Heart Dis GL

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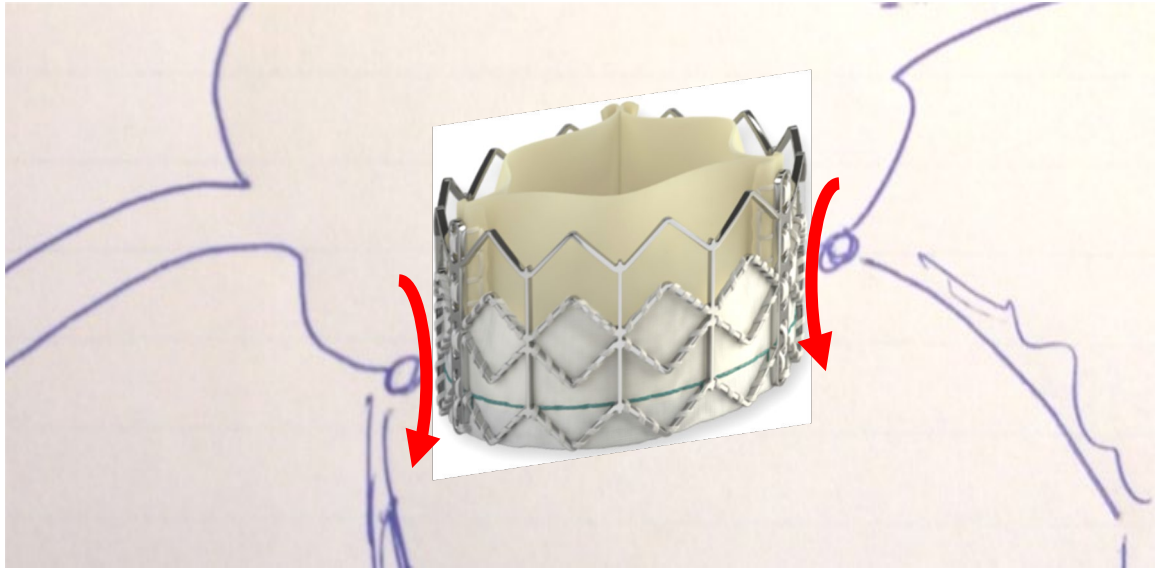
**Table 7** Aspects to be co
for the decision between SA
increased surgical risk (see
in section 5.2.)

| | Favours TAVI | Favours SAVR |
|---|---|---|
| **Clinical characteristics** | | |
| STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a] | | + |
| STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a] | + | |
| Presence of severe comorbidity (not adequately reflected by scores) | + | |
| Age <75 years | | + |
| Age ≥75 years | + | |
| Previous cardiac surgery | + | |
| Frailty[b] | + | |
| Restricted mobility and conditions that may affect the rehabilitation process after the procedure | + | |
| Suspicion of endocarditis | | + |

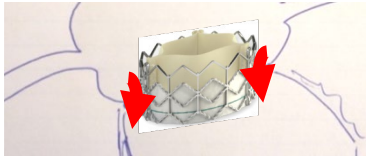
*Eur Heart J. 2017;38:2739-2791*
*Eur J Cardiothorac Surg. 2017;52:616-664*

# TAVI and aortic aneurysm

- Pts present usually with larger annulus
- => risk of paravalvular leak
- Irregular valve configuration



# AS and aortic aneurysm

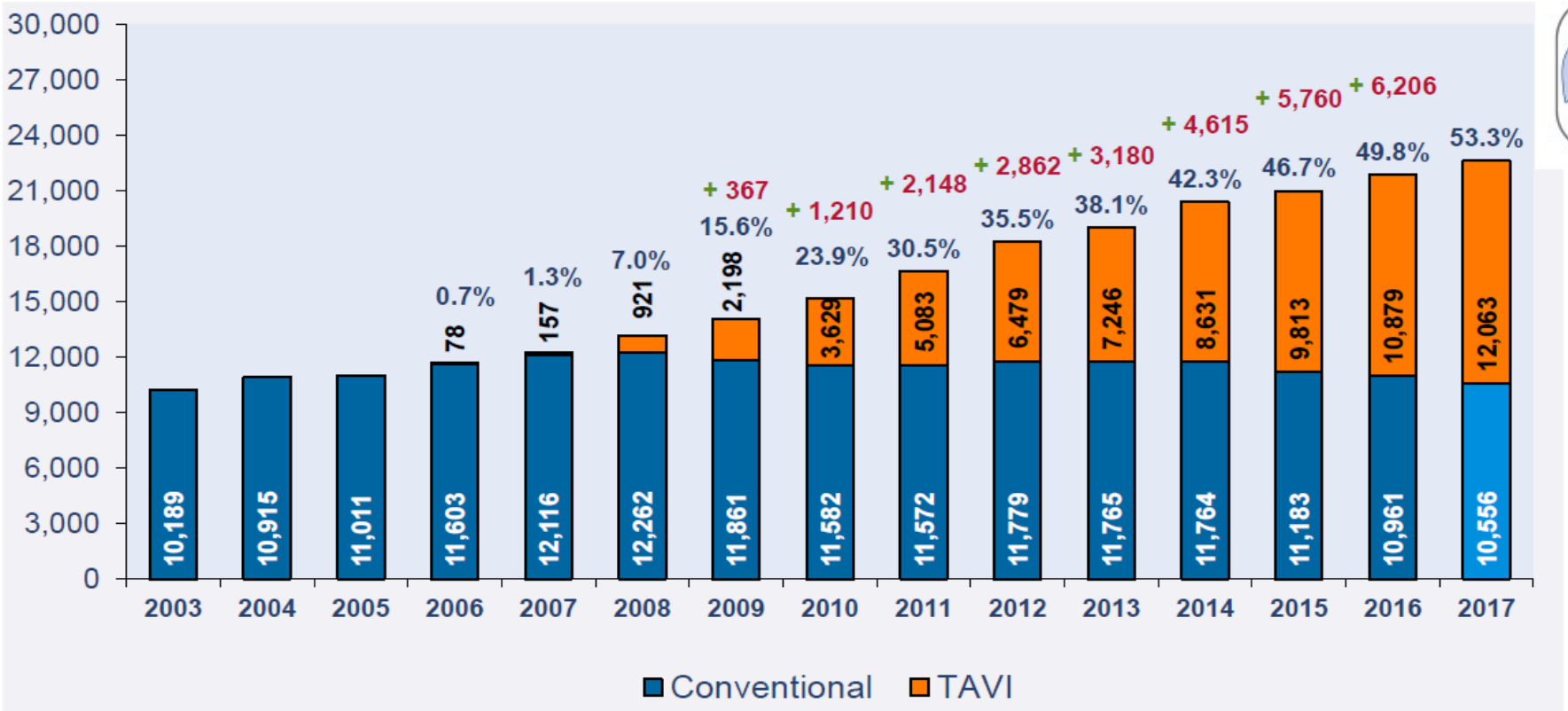


- Sizing charts

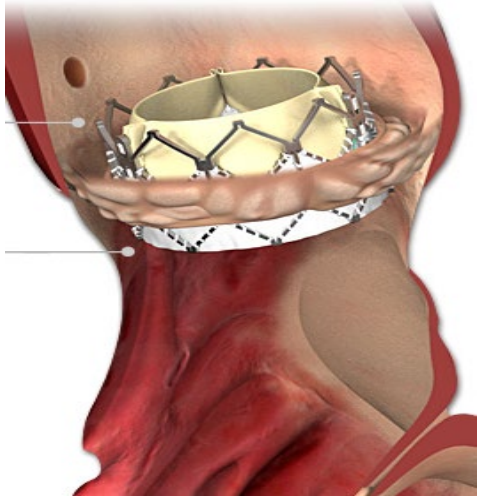
| Annulus size | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 |
|---|---|---|---|---|---|---|---|---|---|---|
| Sapien 3 | 23 | 23 | 23 | 23/26 | 26 | 26 | 26 / 29 | 29 | 29 | 29 |
| Corevalve Evolut R | 23/26 | 26 | 26 | 26/29 | 29 | 29 | 29 | | | |
| Acurate neo | S | S | S | S/M | M | M/L | L | L | | |
| Portico | 23 | 23/25 | 25 | 25/27 | 27 | 27/29 | 29 | 29 | | |
| Lotus | 23 | 23 | 23 | 23/25 | 25 | 25/27 | 27 | 27 | | |

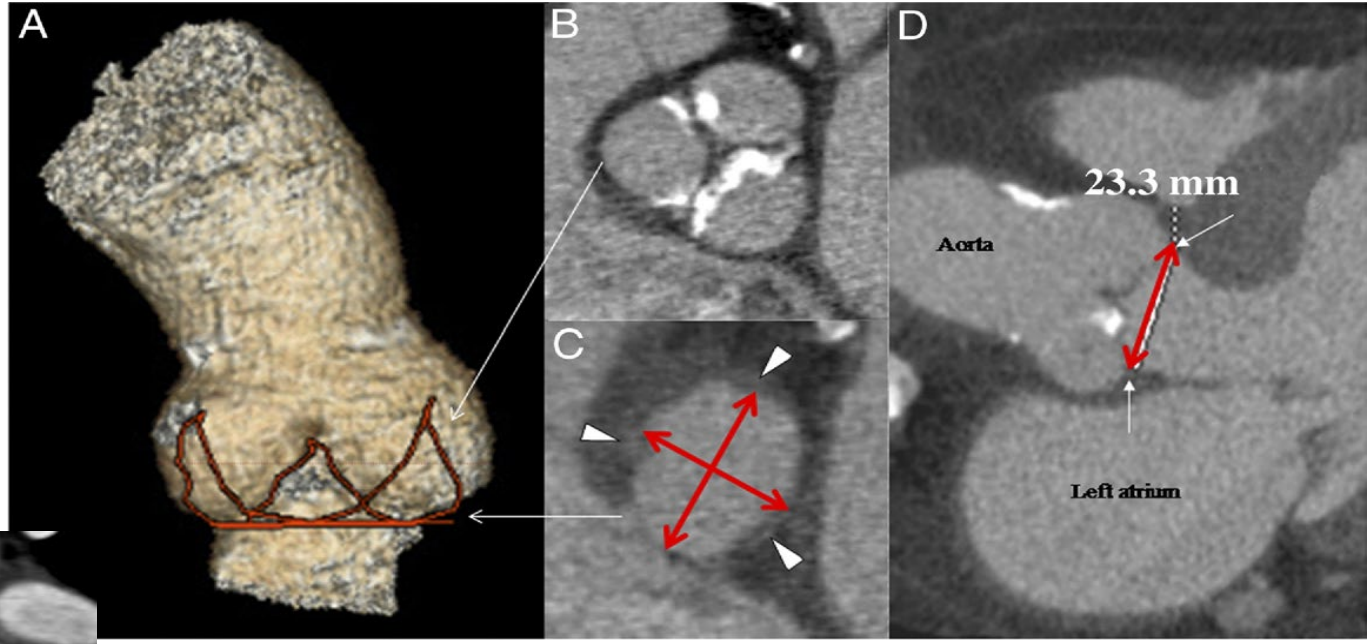
- => larger devices required …

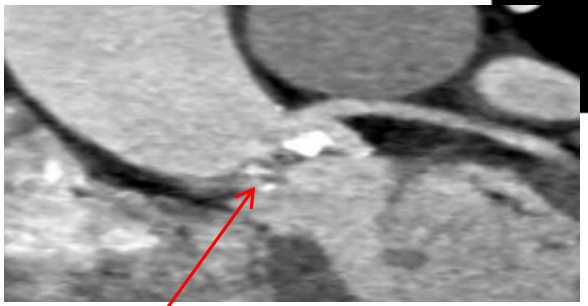
# Isolated sAVR / TAVI in Germany



# TAVI imaging - assessment





# Valve selection criteria (a)

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| Clinical condition | Potential valves | |
|---|---|---|
| Symetric calcification | Any valve | |
| Heavy calcification | Any, balloon expandable or self expandable, consider radial force | Avoid too much oversizing / dilatation |
| Excentric calcification | Any, balloon expandable or self expandable | Careful positioning |
| Bicuspid valve | Sapien, eventually Lotus | |
| LVOT calcium | Self expandable > balloon expandable | |

# Valve selection criteria (b)

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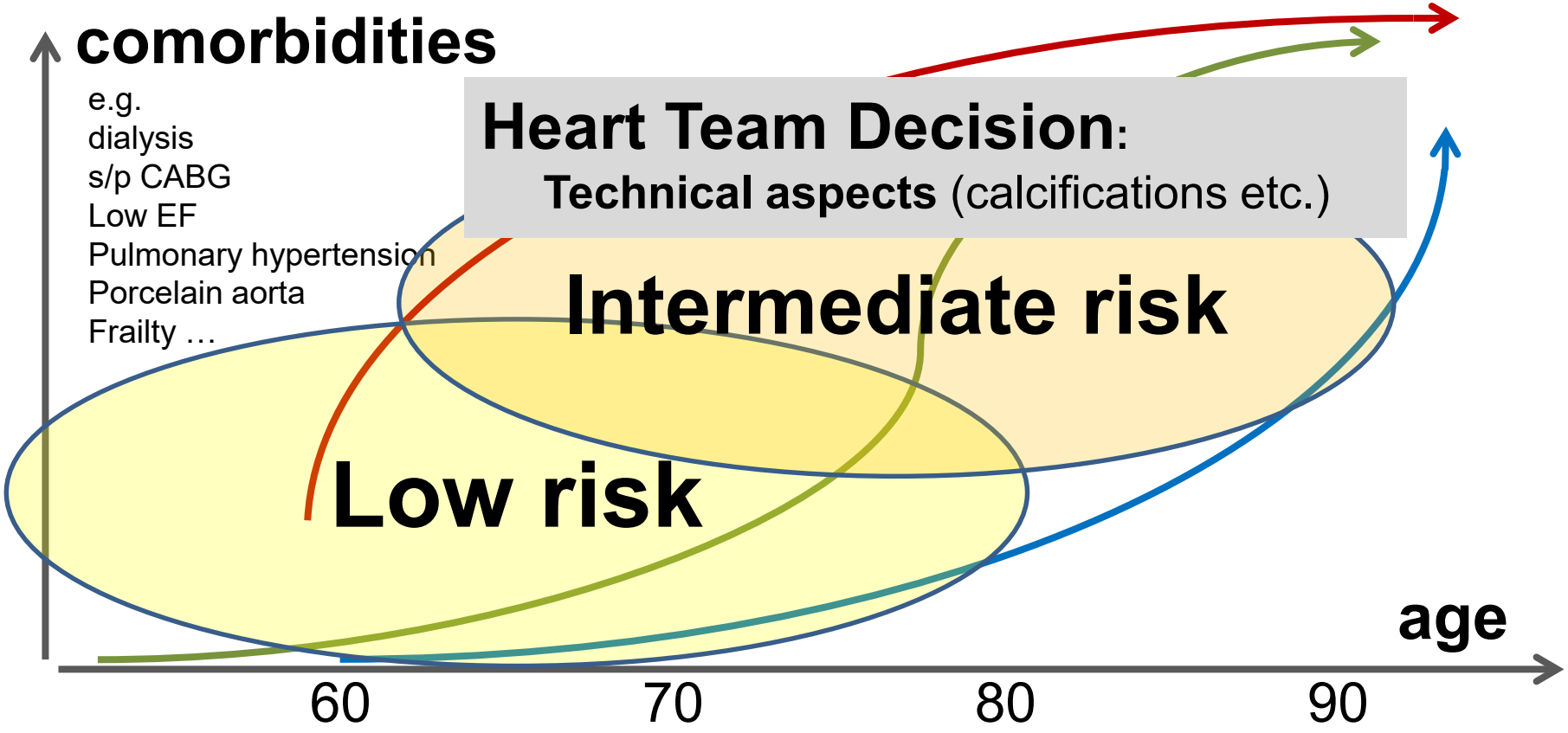
| Clinical condition | Potential valves | |
|---|---|---|
| Short coronary distance | repositionable valve (self expandable) vs. balloon expandable | Guidewire ? |
| Narrow aortic sinuses | repositionable valve (self expandable) vs. balloon expandable | |
| Narrow sinotubular junction | Subcoronary valve (Sapien, Lotus) | |
| Mitral prosthesis in place | Repositionable valve | |

# Valve selection criteria (c)

- **Application system diameter**
- Arch tortuosity / calcification vs. application system flexibility
- **Aortic aneurysm**
- Access vessels
- Access: TF, TA, alternative …

# Patient risk profiles



# Valvular Heart Dis GL

UNIVERSITÄTS KLINIKUM FRANKFURT
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| | Favours TAVI | Favours SAVR |
|---|---|---|
| **Clinical characteristics** | | |
| STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a] | | + |
| STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a] | + | |
| Presence of severe comorbidity (not adequately reflected by scores) | + | |
| Age <75 years | | + |
| Aneurysm of the ascending aorta | | + |
| Short distance between coronary ostia and aortic valve annulus | | + |
| Size of aortic valve annulus out of range for TAVI | | + |
| Aortic root morphology unfavourable for TAVI | | + |

*Eur Heart J. 2017;38:2739-2791*
*Eur J Cardiothorac Surg. 2017;52:616-664*

# Randomized trials TAVI vs. sAVR

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Special Report

**Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis**
First Human Case Description

The NEW ENGLAND JOURNAL of MEDICINE

JUNE 9, 2011

**Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients**

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Scott Lim, M.D., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stewart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

**Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis**

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

**Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients**

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

**Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery**

**5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial**

*Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators*

2002 2007 2010 2011 2012 2013 2014 2015 2016

**Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis**

*Vinod H Thourani, Susheel Kodali, Raj R Makkar, Howard C Herrmann, Mathew Williams, Vasilis Babaliaros, Richard Smalling, Scott Lim, S Chris Malaisrie, Samir Kapadia, Wilson Y Szeto, Kevin L Greason, Dean Kereiakes, Gorav Ailawadi, Brian K Whisenant, Chandan Devireddy, Jonathon Leipsic, Rebecca T Hahn, Philippe Pibarot, Neil J Weissman, Wael A Jaber, David J Cohen, Rakesh Suri, E Murat Tuzcu, Lars G Svensson, John G Webb, Jeffrey W Moses, Michael J Mack, D Craig Miller, Craig R Smith, Maria C Alu, Rupa Parvataneni, Ralph B D'Agostino Jr, Martin B Leon*

**… High risk and Intermediate risk**

# Trials in perspective

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What patients are included ?

- Intermediate risk: PARTNER II, SURTAVI
  **Age ~ 80yrs., STS score 4-5%**

- Low risk (by STS score) :
  PARTNER III (1yr data ACC 2019),
  COREVALVE low risk, NOTION, UK all comers,
  DEDICATE (STS >1 / 2%), etc.

- **Patient age ? Comorbidities ?**

# Ongoing clinical trials in low risk pts.

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| Name | Unique Identifier | Population | Study Design | Primary End Point | THV in TAVR Arm | Sample Size |
|---|---|---|---|---|---|---|
| LRT[23] | NCT02628899 | No age restriction<br>STS ≤3% | Feasibility study<br>Prospective TAVR arm with historical SAVR controls | All-cause mortality at 30 d | Transfemoral SAPIEN 3 or Evolut R/PRO | 200 TAVR in main arm<br>Up to 100 TAVR in bicuspid arm |
| PARTNER 3[24] | NCT02675114 | Age ≥65 y<br>STS <4% | Noninferiority<br>Randomized TAVR vs SAVR | All-cause mortality, all stroke, and rehospitalization at 1 y | Transfemoral SAPIEN 3 | 614 TAVR<br>614 SAVR |
| Medtronic TAVR in low risk patients[25] | NCT02701283 | No age restriction<br>STS <3% | Noninferiority<br>Randomized TAVR vs SAVR | All-cause mortality or disabling stroke at 2 y | Transfemoral or subclavian Evolut R | 625 TAVR<br>625 SAVR |
| NOTION 2[26] | NCT02825134 | Age 18 to 75 y<br>STS <4% | Noninferiority<br>Randomized TAVR vs SAVR | Composite rate of all-cause mortality, myocardial infarction and stroke at 1 y | Transfemoral<br>Any CE-approved THV | 496 TAVR<br>496 SAVR |

*Rogers T et al.: J Am Heart Assoc.* 2018;7:e007147. DOI: 10.1161/JAHA.117.007147.

# Trials in perspective

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## The PARTNER 2A Trial
Clinical Implications

THE PARTNER II TRIAL

- *The results from PARTNER 2A support the use of TAVR as an alternative to surgery in intermediate risk patients, similar to those included in this trial.*

GARY

Deutsches Aortenklappenregister

# Patients at low surgical risk undergoing isolated interventional or surgical aortic valve implantation: in-hospital data and one-year results from the German Aortic Valve Registry (GARY).

Raffi Bekeredjian[1], Ümniye Balaban, Sabine Bleiziffer, Timm Bauer, Stephan Ensminger, Christian Frerker, Andreas Beckmann, Helge Möllmann, Hugo A. Katus, Thomas Walther

[1] University Hospital Heidelberg and Robert-Bosch Hospital Stuttgart

*European Heart Journal 2018, accepted*

GARY

# Patient selection

Deutsches Aortenklappenregister

## All Patients 2014-2015

| | |
|---|---|
| SAVR: | 28133 |
| TA TAVI: | 2944 |
| TV TAVI: | 14490 |

45567

Exclusion:

- Patients SAVR+CABG
- Patient with TAVI + PCI
- Patients with STS ≥ 4%
- Patients with endocartitis
- Patients with missing relevant data
- Double entries

| | |
|---|---|
| SAVR: | 14487 |
| TA TAVI: | 949 |
| TV TAVI: | 5113 |

20549

*European Heart Journal 2018, accepted*

GARY

# Patients

| | All (n=20549) | SAVR (n=14487) | TAVI (n=6062) | p value |
|---|---|---|---|---|
| Age (years) | **70.84 ± 10.88** | 67.48 ± 10.79 | 78.87 ± 5.63 | <0.0001 |
| Gender | | | | 0.0001 |
| Male | **12919 (62.9 %)** | 9230 (63.7 %) | 3689 (60.9 %) | |
| Female | **7630 (37.1 %)** | 5257 (36.3 %) | 2373 (39.1 %) | |
| BMI (kg/m²) | **28.07 ± 4.67** | 28.20 ± 4.79 | 27.75 ± 4.35 | <0.0001 |
| Creatinine | **0.98 ± 0.27** | 0.96 ± 0.26 | 1.02 ± 0.29 | <0.0001 |
| Previous MI | **1296 (6.3 %)** | 634 (4.4 %) | 662 (10.9 %) | <0.0001 |
| Previous PCI | **2760 (13.4 %)** | 1112 (7.7 %) | 1648 (27.2 %) | <0.0001 |
| Permanent Pacer | **974 (4.8 %)** | 471 (3.3 %) | 503 (8.4 %) | <0.0001 |
| Permanent ICD | **181 (0.9 %)** | 98 (0.7 %) | 83 (1.5 %) | <0.0001 |
| Atrial Fibrillation | **2951 (14.4 %)** | 1810 (12.5 %) | 1141 (18.8 %) | <0.0001 |
| Mitral Regurgitation ≥2° | **2791 (13.6 %)** | 1638 (11.3 %) | 1153 (19.0 %) | <0.0001 |
| Previous Cardiac Surgery | **1627 (7.9 %)** | 842 (5.8 %) | 785 (13.0 %) | <0.0001 |
| EF (%) | **56.31 ± 11.50** | 57.04 ± 11.38 | 54.59 ± 11.60 | <0.0001 |
| Hypertension | **16717 (82.2 %)** | 11511 (80.2 %) | 5206 (86.9 %) | <0.0001 |
| Pmean (mmHg) | **45.10 ± 17.61** | 45.59 ± 18.45 | 44.06 ± 15.65 | <0.0001 |
| Neuro Dysfunction | **1778 (8.7 %)** | 961 (6.6 %) | 817 (13.5 %) | <0.0001 |
| COPD | **1661 (8.1 %)** | 1130 (7.8 %) | 531 (8.8 %) | 0.0005 |
| Pulmonary Hypertension | **1182 (5.8 %)** | 535 (3.7 %) | 647 (10.7 %) | <0.0001 |
| Diabetes | **4114 (20.0 %)** | 2818 (19.5 %) | 1296 (21.4 %) | 0.0017 |
| Euro-Score | **7.98 ± 6.77** | 5.94 ± 4.70 | 12.88 ± 8.30 | <0.0001 |
| STS-Score | **2.11 ± 0.95** | 1.79 ± 0.85 | 2.86 ± 0.72 | <0.0001 |

Deutsches Aortenklappenregister

*European Heart Journal 2018, accepted*

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# **Results** - Unadjusted Data

Deutsches Aortenklappenregister

Survival Rate for Patients 2014-2015 SAVR vs. TAVI – **without** Propensity Score Adjustment (survival rates and 95% confidence intervals)

| | In-hospital survival (%) | 30-days survival (%) | 12-months survival (%) |
|---|---|---|---|
| **TAVI** | 98.48 % (98.14 %, 98.76 %) | 98.09 % (97.72 %, 98.41 %) | 90.01 % (89.22 %, 90.74 %) |
| **SAVR** | 98.49 % (98.28 % ,98.68 %) | 98.31 % (98.08 %, 98.50 %) | 95.17 % (94.80 %, 95.51 %) |

*European Heart Journal 2018, accepted*

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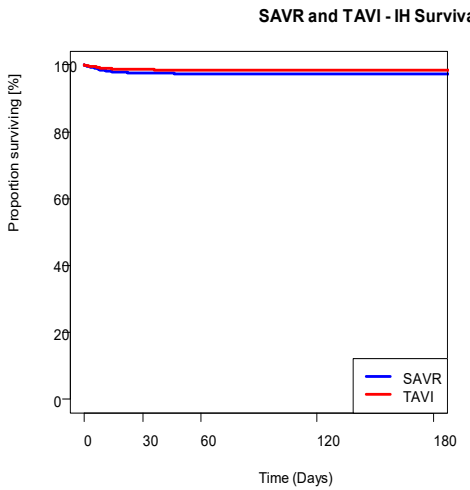
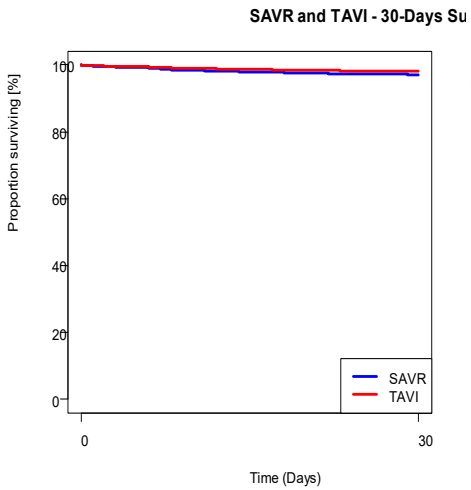
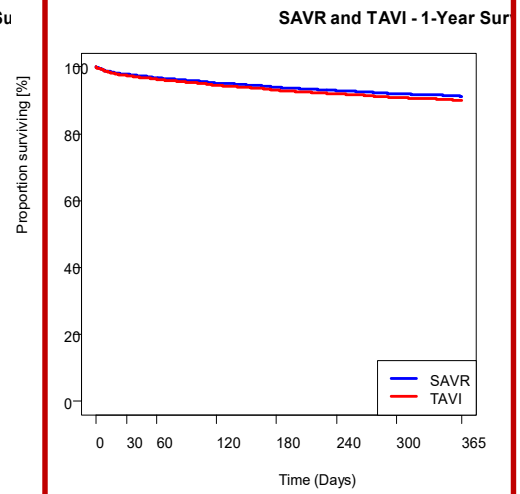
# Results - with Propensity Score adjustment

Deutsches Aortenklappenregister




| | In-hospital survival (%) | 30-day survival (%) | 12-months survival (%) |
|---|---|---|---|
| **TAVI ( 6,062)** | 98.5 | 98.1 | **90.0** |
| **sAVR (14,487)** | 97.3 | 97.1 | **91.2** |
| **p-value** | 0.003 | 0.014 | **0.158** |

*European Heart Journal 2018, accepted*

# TAVI results have significantly improved due to:

- Patient screening and selection (exclude aortic aneurysm)
- Experience and skills of the Heart Teams
- Technical developments: TAVI valves and application systems

# TAVI and aortic aneurysm

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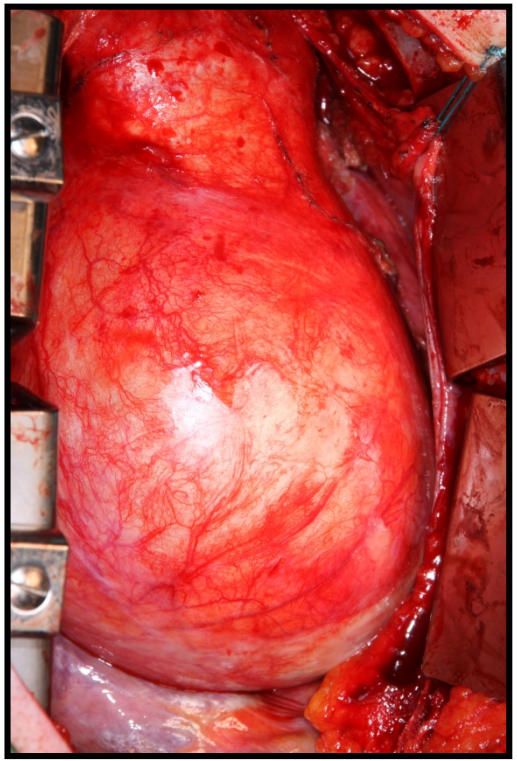
- **TAVI is routine in elderly patients,** high, intermediate and low risk
- **The majority of TAVI pts does not present with aortic aneurysm**
- **Aortic aneurysm will usually be treated in younger pts.** (Heart Team recommendations)



# Ascending aortic endografts

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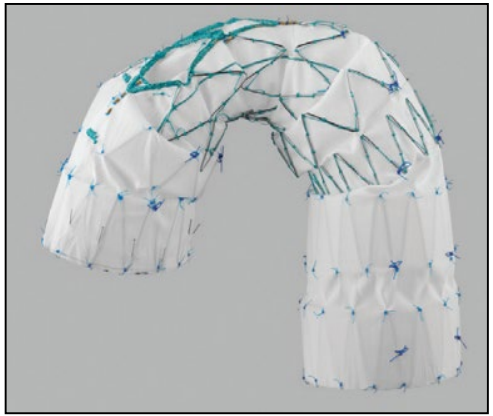
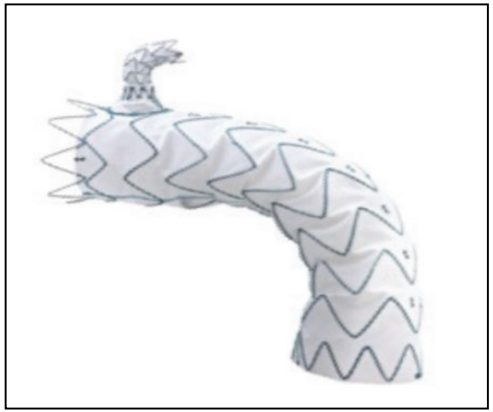
- Hybrid supracoronary endografts
- Branched endografts
- High Risk pts.
- Factors to consider:
  - risk of stroke
  - retrograde dissection
  - kinking
  - unclear sealing zone
  - proper alignment required
  - etc.

*vascularnews Feb 2017*

# Branched aortic arch stent grafts

- Zenith
- TAG
- Valiant Mona LSA
- Nexus
- Ascending thoracic device





*Long KN et al.: Endovascular today, Nov 2016, 15:66-70*

# Endovascular aortic repair: Challenges:

- Anatomy / shape of ascending aorta / arch
- Angulation of great vessels
- Blood flow dynamics and shear forces
- Heart beat variability, respiratory cycle variability
- Coronary artery anatomy and position, aortic valve

# Future developments …

- Branched ascending aorta / aortic arch stent graft with consecutive TAVI
- Transcatheter Bentall prostheses ? Custom made ?
- High risk / inoperable pts. …

# Endovascular aortic repair + TAVI

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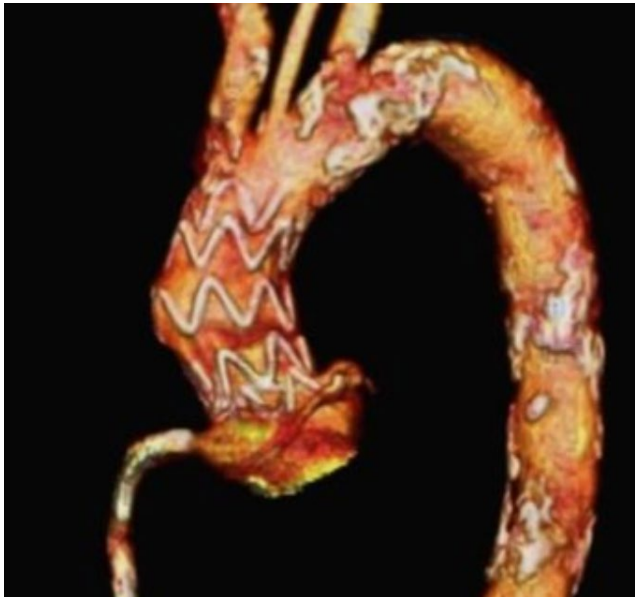
- Imaging, sizing, selection
- **Custom made solutions for individual patients**
- **Complex trials …**
- **…**



# Conclusion

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- TAVI Selection, Experience, Technical developments lead to excellent outcomes
- TAVI experience in pts with aortic aneurysm is very limited
- **specific hybrid prostheses / procedures will be developed, individual therapeutic decisions required**

# Thank you!

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