

### Sutureless AVR vs TAVI

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Dubai , September 2018



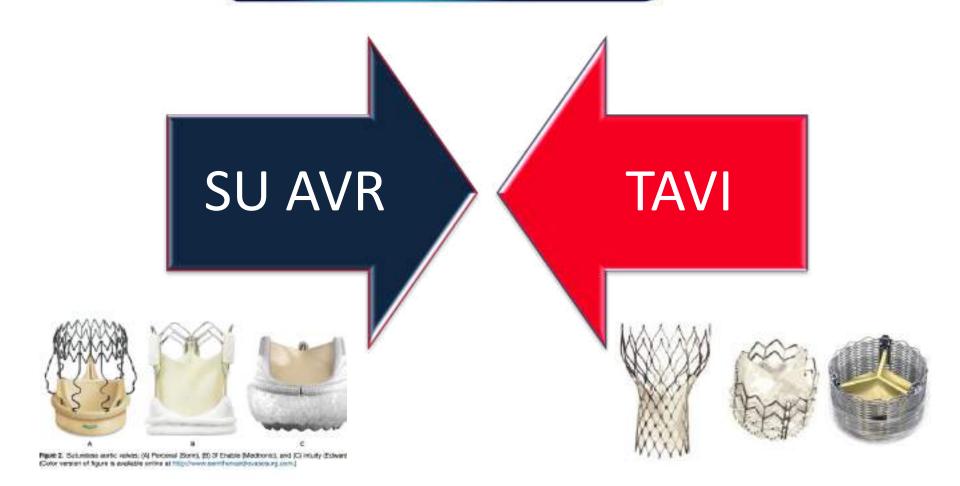
Aortic stenosis (AS) is a deadly disease, with an estimated survival of less than 5 years after symptoms develop.

33% of patients with severe symptomatic AS did not undergo surgery (EuroHeart survey in 2005)

24% of all AS patients are more than 80 years. (STS) database



# SOLUTION



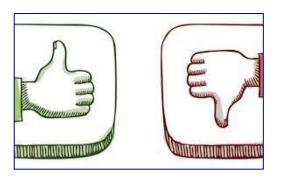


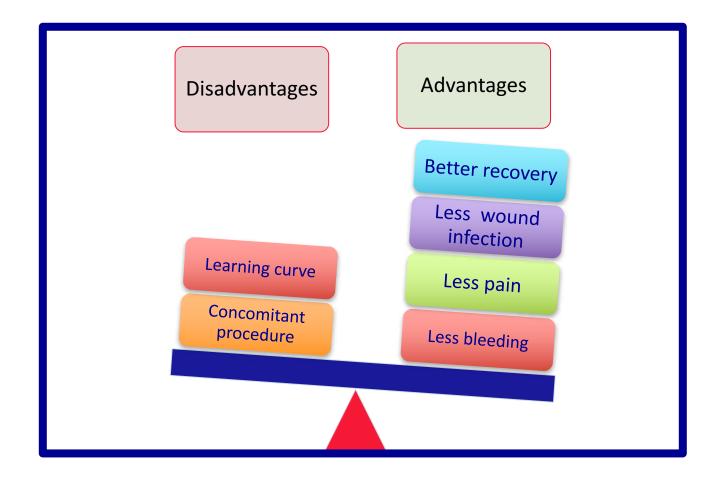
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## **SUAVR**

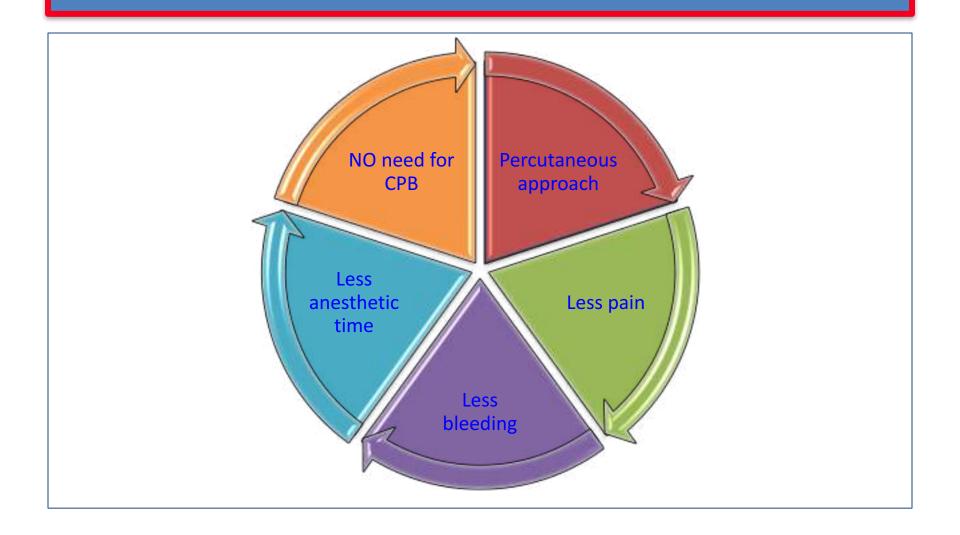
**Reduction of operation time** Simplifies the procedure Replacement vs implantation **Less CPB time and AOX Easier Mini-AVR Good EOA** 



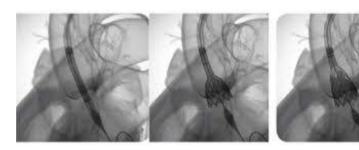




## **TAVI**







calcific native valve is not excised

**AVB & PVL** 

Increased Mortality or Morbidity

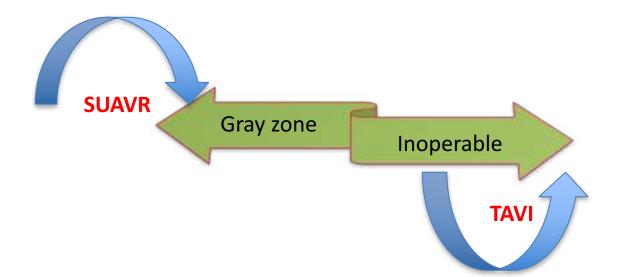
#### Sutureless as alternative to conventional valves for all operable pts Operable Extr. Risk/Inoperable Intermediate High Low (65%)(≈25%) (≈10%) SAVR SAVR OR TAVI TAVI treat. OR TAVI STS: >10% STS: 4-10% STS: <4% STS >15% Log eur: >20% Log eur: 10 -20% Log eur>25% Log eur: <10% **SU AVR**

Sutureless aortic valve replacement as an alternative treatment for patients belonging to the "gray zone" between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis

Augusto D'Onofrio, MD,<sup>a</sup> Antonio Messina, MD,<sup>b</sup> Roberto Lorusso, MD,<sup>c</sup> Ottavio R. Alfieri, MD,<sup>d</sup> Melissa Fusari, MD,<sup>e</sup> Paolo Rubino, MD,<sup>f</sup> Mauro Rinaldi, MD,<sup>g</sup> Roberto Di Bartolomeo, MD,<sup>h</sup> Mattia Glauber, MD,<sup>i</sup> Giovanni Troise, MD,<sup>b</sup> and Gino Gerosa, MD<sup>a</sup>

The Journal of Thoracic and Cardiovascular Surgery · November 2012

No significant differences in hospital mortality, severe postoperative complications, and transprosthetic gradients between groups.



postprocedural paravalvular leak was identified as an independent predictor of late mortality after TAVI (hazard ratio, 3.79).

TABLE 3. Postoperative outcomes after TA-TAVI and SU-AVR

| Variable  | TA-TAVI (n = 38) | SU-AVR (n = 38)  | P Value |
|---|------------------|------------------|---------|
| Hospital mortality, n (%)                           | 2 (5.3)          | 0 (0)            | .49     |
| ARF requiring CVVH, n (%)                           | 1 (2.6)          | 2 (5.3)          | 1.00    |
| AMI, n (%)  | 0 (0)            | 0 (0)            | 1.00    |
| Stroke, n (%)                                       | 0 (0)            | 0 (0)            | 1.00    |
| Bleeding (life-threatening/disabling, major), n (%) | 2 (5.3)          | 1 (2.6)          | 1.00    |
| PPM implantation, n (%)                             | 2 (5.3)          | 2 (5.3)          | 1.00    |
| Mean transaortic gradient, mm Hg                    | $10.25 \pm 5.03$ | $10.95 \pm 3.72$ | .59     |
| AR at discharge (at least mild), n (%)              | 17 (44.7)        | 6 (15.8)         | .001    |
| LVHP at disenarge, % (TK)                           | 00 (55-00)       | 60 (54-65)       | ./5     |
| New-onset atrial fibrillation, n (%)                | 7 (18.4)         | 16 (42.1)        | .04     |
| Orotrachear intubation time, nours (IK)             | 4 (0-5)          | 3.3 (4-8)        | .21     |

TA-TAVI, Transapical aortic valve implantation; SU-AVR, sutureless aortic valve replacement; ARF, acute renal failure; CVVH, continuous venovenous hemofiltration; AMI, acute myocardial infarction; PPM, permanent pacemaker; AR, aortic regurgitation; LVEF, left ventricular ejection fraction; IR, interquartile range.

Paravalvular leakage New onset AFib

# Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

Giuseppe Santarpino, MD, a Steffen Pfeiffer, MD, Jürgen Jessl, MD, Angelo Maria Dell'Aquila, MD, Francesco Pollari, MD, Matthias Pauschinger, MD, and Theodor Fischlein, MD.

The Journal of Thoracic and Cardiovascular Surgery c February 2014

Combining the advantage of standard diseased valve removal with shorter procedural times, minimally invasive sutureless aortic valve replacement may be the first-line treatment for high-risk patients considered in the "gray zone" be ween TAVI and conventional surgery.

| Variable                          | AVK (n = 37)   | (n = 37)       | value |
|-----------------------------------|----------------|----------------|-------|
| In-hospital mortality             | 0              | 3 (8.1%)       | .24   |
| ARF requiring CVVH                | 0              | 2 (5.4%)       | .25   |
| Stroke                            | 2 (5.4%)       | 2 (5.4%)       | >.999 |
| Permanent PM implantation         | 4 (10.8%)      | 1 (2.7%)       | .18   |
| Mean transaortic gradient (mm Hg) | $13.3 \pm 3.9$ | $14.2 \pm 5.8$ | .564  |
| AR at discharge (at least mild)   | 0              | 5 (13.5%)      | .027  |
|                                   |                |                |       |



#### Journal of Cardiology

JOURNAL of CARDIOLOGY

journal homepage: www.elsevier.com/locate/jjcc

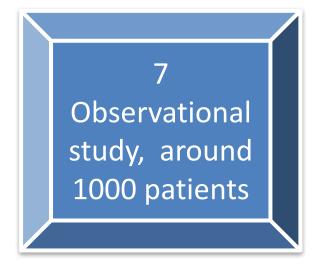
#### Original article

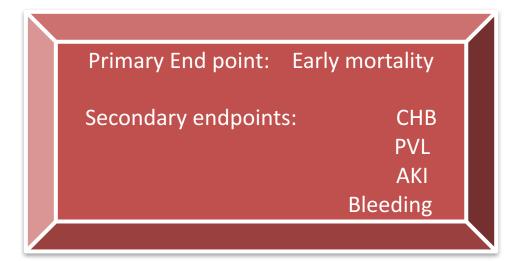
Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation:
A meta-analysis of comparative studies



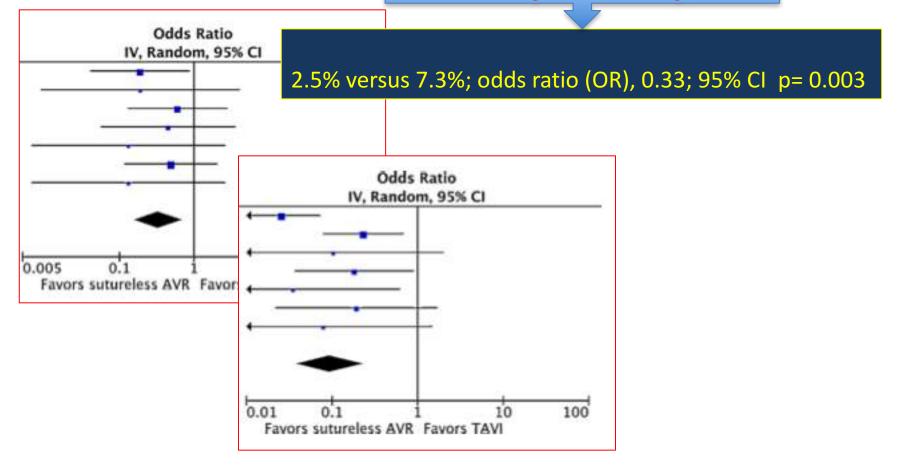
Hisato Takagi (MD, PhD)\*, Takuya Umemoto (MD, PhD) for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Journal of Cardiology 67 (2016) 504–512





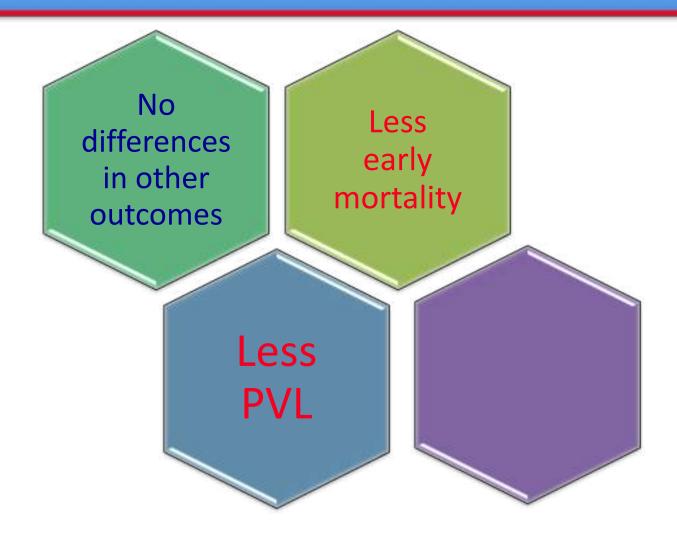
### Early Mortality



3.5% versus 33.2%; OR, 0.09; 95% Cl,p<0.00001



## SUAVR vs TAVI



# Worse survival after transcatheter aortic valve implantation than surgical aortic valve replacement: A meta-analysis of observational studies with a propensity-score analysis\*



Hisato Takagi \*, Takuya Umemoto, for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Department of Cardiovascular Surgery, Shizuoka Medical Center, Shizuoka, Japan

International Journal of Cardiology 220 (2016) 320-327

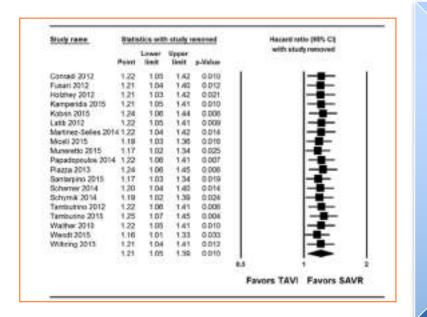
4 RCTs including a total of approximately 1800 patients
19 observational comparative studies, a total of more than 6000 patients,

All cause mortality

#### All cause mortality

19 observational comparative studies, a total of more than 6000 patients,

4 RCTs including a total of approximately 1800 patients



TAVI is likely to be associated with a 21% increase in the hazard

of follow-up all-cause mortality relative to SAVR.

The mean of 3-year survival rates was 71.3% after TAVI and 77.9% after SAVR.

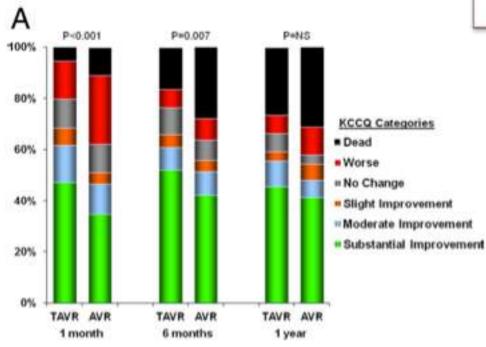
# Health-Related Quality of Life After Transcatheter or Surgical Aortic Valve Replacement in High-Risk Patients With Severe Aortic Stenosis

Results From the PARTNER
(Placement of AoRTic TraNscathetER Valve) Trial (Cohort A)

Matthew R. Reynolds, MD, MSC,\* Elizabeth A. Magnuson, ScD,† Kaijun Wang, PhD,† Vinod H. Thourani, MD,‡ Mathew Williams, MD,§ Alan Zajarias, MD, Charanjit S. Rihal, MD,¶ David L. Brown, MD,# Craig R. Smith, MD,§ Martin B. Leon, MD,§ David J. Cohen, MD, MSC,† on behalf of the PARTNER Trial Investigators

Boston, Massachusetts; Kansas City and St. Louis, Missouri; Atlanta, Georgia; New York, New York;
Rochester, Minnesota; and Dallas, Texas

August 7, 2012:548-58





Correction of severe AS either by TAVR or AVR leads to very great improvement in patient-reported symptoms, functional status, and QOL over the first year of follow-up



The more rapid recovery from TAVR via the TF approach is associated with short-term benefits in health status, which may be important from the patient's perspective.



Tf approach had no evidence of health status benefits either in the short or medium term

#### Direct and adjusted indirect comparisons of perioperative mortality after sutureless or rapid-deployment aortic valve replacement versus transcatheter aortic valve implantation



Hisato Takagi a,\*,1, Tomo Ando b,1, Takuya Umemoto a, for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

International Journal of Cardiology 228 (2017) 327–334

Tavi: Sapien XT,3 Corevalve SL-AVR: Perceval, Intuity, Enable

6 RCT, 30 observational study >15000 patients

Logistic euroSCORE: SL AVR: 12 TAVI 18

## Paravalvular leakage

PVL prevalence was **significantly lower** after SL-AVR than after TAVI

(3.5% versus 33.2%; OR, 0.09; 95% CI, 0.04 to 0.23; p b 0.00001).

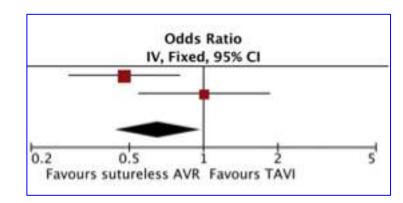
Moderate or severe PVL occurs commonly after TAVI

(11.7%; 95% CI, 9.6% to 14.1%)

Can predict perioperative and follow-up all-cause mortality

## **30 days Mortality**

Significantly lower in SL-AVR than TAVI



No significant difference between C-AVR & TAVI

# Transcatheter aortic valve implantation (TAVI) versus sutureless aortic valve replacement (SUAVR) for aortic stenosis: a systematic review and meta-analysis of matched studies

Nelson Wang<sup>1</sup>, Yi-Chin Tsai<sup>2</sup>, Natasha Niles<sup>2</sup>, Vakhtang Tchantchaleishvili<sup>3</sup>, Marco Di Eusanio<sup>4</sup>, Tristan D. Yan<sup>2</sup>, Kevin Phan<sup>1,2</sup>

J Thorac Dis 2016;8(11):3283-3293

Compared to TAVI, SUAVR had a lower incidence of paravalvular leak

(OR =0.06; 95% CI: 0.03-0.12, P<0.01).

There was no difference in perioperative mortality, however

SUAVR patients had significantly better survival rates at 1 (OR =2.40; 95% CI: 1.40–4.11, P<0.01) and 2 years (OR =4.62; 95% CI: 2.62–8.12, P<0.01).

# Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial

Lars Søndergaard, MD, DMSc; Daniel Andreas Steinbrüchel, MD, DMSc;

(Circ Cardiovasc Interv. 2016;9:e003665. DOI: 10.1161/CIRCINTERVENTIONS.115.

NOTION trial 2

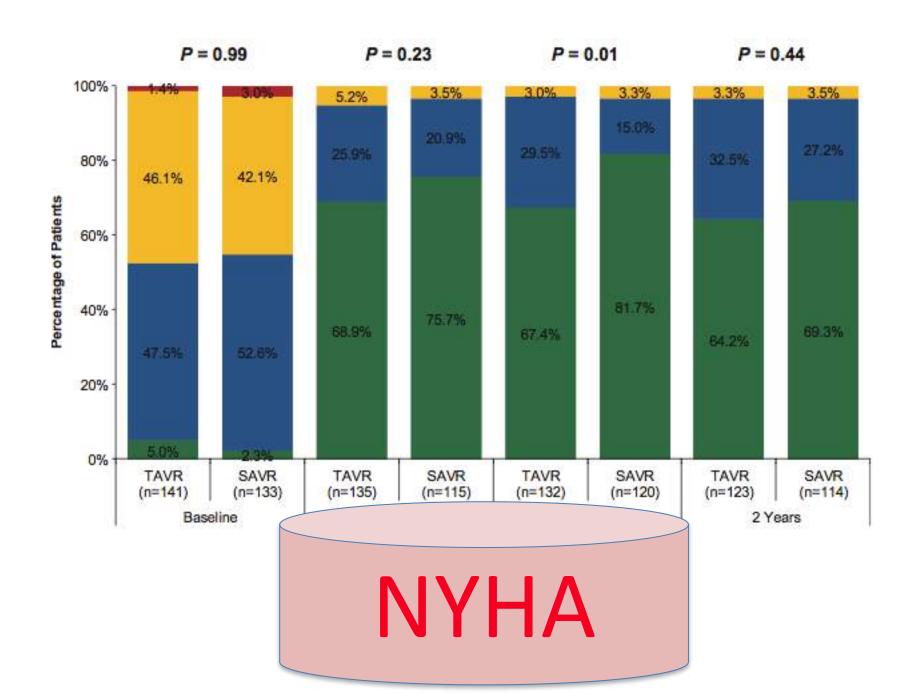
280 patients
Core valve vs
SAVR

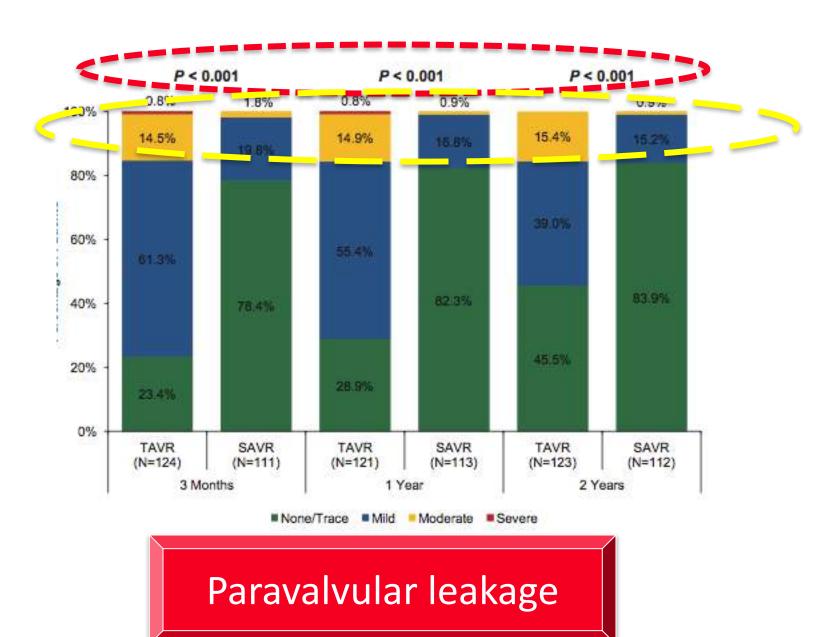
No difference in All cause mortality

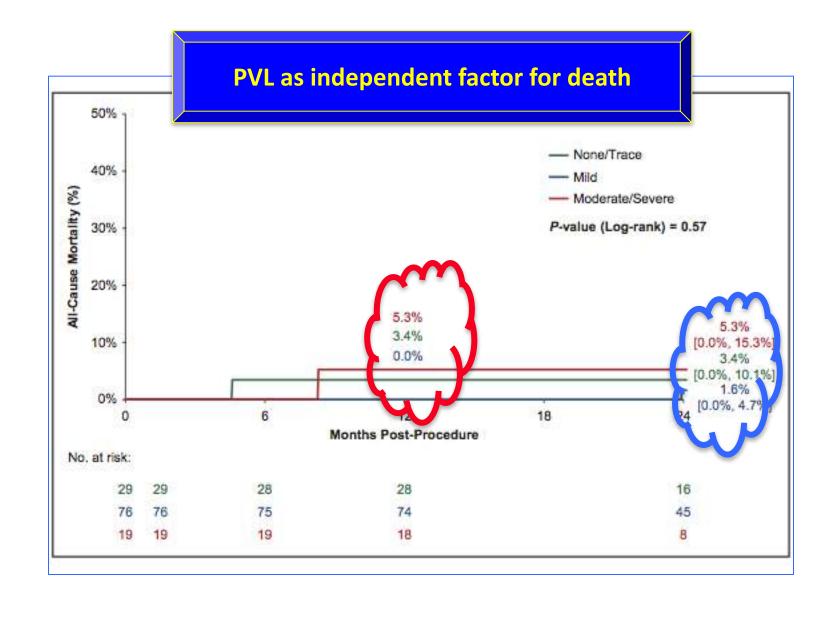
#### Clinical Outcomes at 2 Years in the As-Treated Population

|  | No. of Patients With Events (%)* |           |         |
|--|----------------------------------|-----------|---------|
| Characteristic                             | Transcatheter                    | Surgical  | P Value |
| All-cause death                            | 11 (8.0)                         | 13 (9.8)  | 0.54    |
| Cardiovascular death                       | 9 (6.5)                          | 12 (9.1)  | 0.40    |
| Neurological events                        | 13 (9.7)                         | 10 (7.8)  | 0.67    |
| Stroke                                     | 5 (3.6)                          | 7 (5.4)   | 0.46    |
| Transient ischemic attack                  | 8 (6.0)                          | 4 (3.3)   | 0.30    |
|  |                                  |           | 2.22    |
| New-onset or worsening atrial fibrillation | 32 (22.7)                        | 80 (60.2) | <0.001  |
| Permanent pacemaker implantation           | 55 (41.3)                        | 5 (4.2)   | <0.001  |

PPM A-fib







#### Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

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Lars Søndergaard, MD, DMSc; Daniel Andreas Steinbrüchel, MD, DMSc;
Nikolaj Ihlemann, MD, PhD; Henrik Nissen, MD, PhD; Bo Juel Kjeldsen, MD, PhD;
Petur Petursson, MD, PhD; Anh Thuc Ngo, MD, PhD; Niels Thue Olsen, MD, PhD;
Yanping Chang, MS; Olaf Walter Franzen, MD; Thomas Engstrøm, MD, DMSc;
Peter Clemmensen, MD, DMSc; Peter Skov Olsen, MD, DMSc; Hans Gustav Hørsted Thyregod, MD.

Conclusions—Two-year results from the NOTION trial demonstrate the continuing safety and effectiveness of TAVR in lower-risk patients. Longer-term data are needed to verify the durability of this procedure in this patient population.

Surgeons Predicted ROM) (<4% versus  $\geq$ 4%), there was no statistically significant difference for TAVR and SAVR groups ...... composite outcome for low-risk (14.7%, 95% confidence interval, 8.3–21.2 versus 16.8%; 95% confidence interval, 9.7–23.8; P=0.58) or intermediate-risk patients (21.1% versus 27.1%; P=0.59).

Conclusions—Two-year results from the NOTION trial demonstrate the continuing safety and effectiveness of TAVR in lower-risk patients. Longer-term data are needed to verify the durability of this procedure in this patient population.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01057173.

(Circ Cardiovasc Interv. 2016;9:e003665. DOI: 10.1161/CIRCINTERVENTIONS.115.003665.)



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# Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients Partner 2 trial

2032 intermediate-risk patients with severe aortic stenosis, at 57 centers,

The primary end point was death from any cause or disabling stroke at 2 years.

| Characteristic                                  | TAVR<br>(N = 1011) | Surgery<br>(N = 1021) |
|---|--------------------|-----------------------|
| Age — yr  | 81.5±6.7           | 81.7±6.7              |
| Male sex — no. (%)                              | 548 (54.2)         | 560 (54.8)            |
| Body-mass index†                                | 28.6±6.2           | 28.3±6.2              |
| STS risk score‡                                 | 5.8±2.1            | 5.8±1.9               |
| NYHA class III or IV — no./total no. (%)        | 782/1011 (77.3)    | 776/1020 (76.1)       |
| Coronary artery disease — no. (%)               | 700 (69.2)         | 679 (66.5)            |
| Previous myocardial infarction — no. (%)        | 185 (18.3)         | 179 (17.5)            |
| Previous CABG — no. (%)                         | 239 (23.6)         | 261 (25.6)            |
| Previous PCI — no. (%)                          | 274 (27.1)         | 282 (27.6)            |
| Previous balloon aortic valvuloplasty — no. (%) | 51 (5.0)           | 50 (4.9)              |
| Cerebral vascular disease — no. (%)             | 325 (32.1)         | 317 (31.0)            |
| Peripheral vascular disease — no. (%)           | 282 (27.9)         | 336 (32.9)            |
| Diabetes mellitus — no. (%)                     | 381 (37.7)         | 349 (34.2)            |

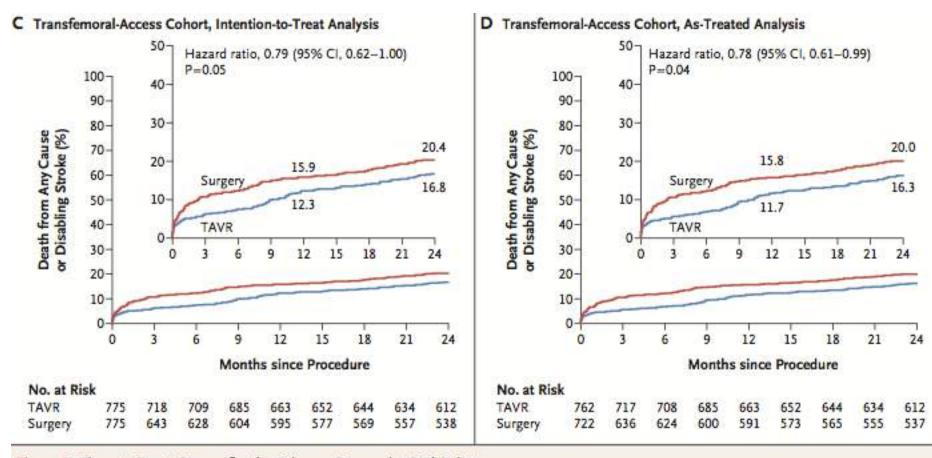
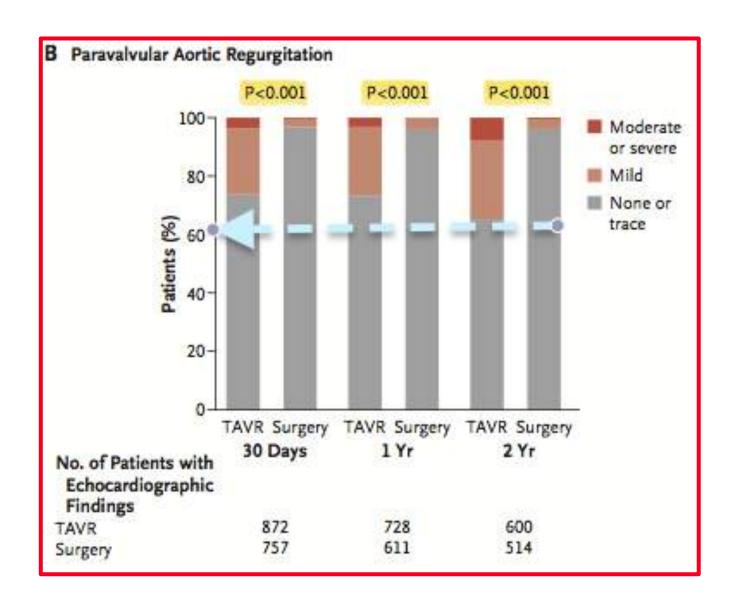
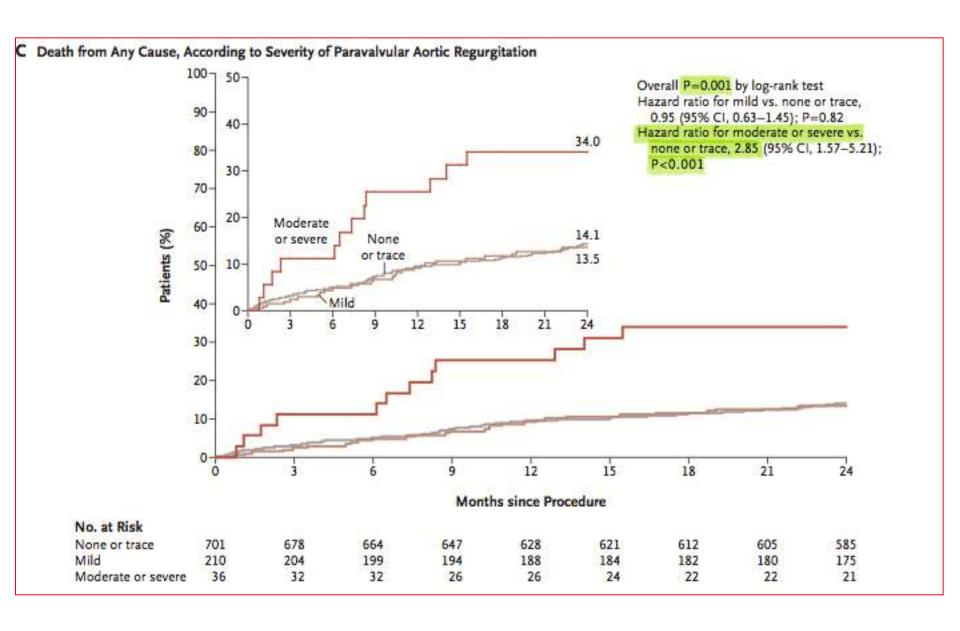


Figure 1. Time-to-Event Curves for the Primary Composite End Point.

The insets show the same data on an enlarged y axis. TAVR denotes transcatheter aortic-valve replacement.





## Coronary revascularization was more commonly performed in the surgery group than TAVR (13.5% vs 3.9%)

The addition of either CABG or PCI to valve-replacement therapies had no deleterious effect on mortality or the rate of stroke.

### Summary of Partner 2 trial

No difference in cardiac death and all cause mortality or CVA

26% redo in SAVR

Vs

24% protected TAVI

Moderate or sever PVL signmeantly increase the mortality

Re-intervention are more common in TAVI

## MACCE no difference

Bleeding complication was higher in SU-AVR

### 773 patients

### No Randomized trial included

<u>TAVI /394 nationts</u> mean agg,  $80.8 \pm 5.5$  years, mean EuroSCORE II 5.6 ± 4.9 %).

# In-hospital mortality

2.6 % after SU-AVR and 5.3 % after TAVI (p = 0.057)

## PPM need

(17.3 vs. 9.8 %, p = 0.003)

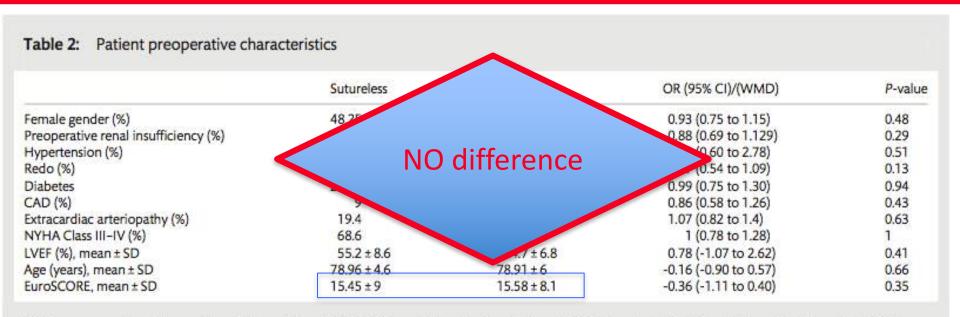
paravalvular regurgitation

moderate—severe (14.1 vs. 0.3 %,

## Sutureless aortic valve replacement versus transcatheter aortic valve implantation: a meta-analysis of comparative matched studies using propensity score matching

Massimo Meco<sup>a,†</sup>, Antonio Miceli<sup>b,c,†</sup>, Andrea Montisci<sup>b,\*,†</sup>, Francesco Donatelli<sup>b,d</sup>, Silvia Cirri<sup>b</sup>,
Matteo Ferrarini<sup>b</sup>, Antonio Lio<sup>b</sup> and Mattia Glauber<sup>b</sup>

Interactive CardioVascular and Thoracic Surgery (2017) 1–8



CAD: coronary artery disease; CI: confidence interval; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; OR: odds ratio; TAVI: transcatheter aortic valve implantation; WMD: weighted mean difference.

Stroke
PVL
PPM need
Vascular complication

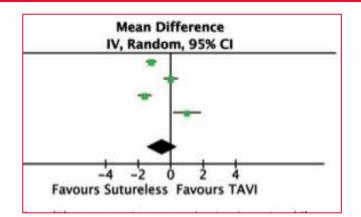
Higher rates in TAVI

Table 3: Postoperative data

| 22                                     | SU-AVR        | TAVI            | P-valu |
|--|---------------|-----------------|--------|
| 30-days mortality (%)                  | 24/741 (3.23) | 44/741 (5.93)   | 0.01   |
| Postoperative stroke (%)               | 12/741 (1.61) | 27/741 (3.64)   | 0.01   |
| Postoperative aortic regurgitation (%) | 21/731 (2.8)  | 133/731 (18.19) | 0.001  |
| Postoperative AKI (%)                  | 35/527 (6.51) | 37/527 (6.89)   | 0.8    |
| Pacemaker implantation (%)             | 69/741 (9.31) | 70/741 (9.44)   | 0.9    |
| Transfused patients (%)                | 88/426 (20.6) | 26/424 (6.1)    | 0.001  |
| Vascular complications (%)             | 0/490 (0)     | 41/490 (8.36)   | 0.001  |

AKI: acute kidney injury.

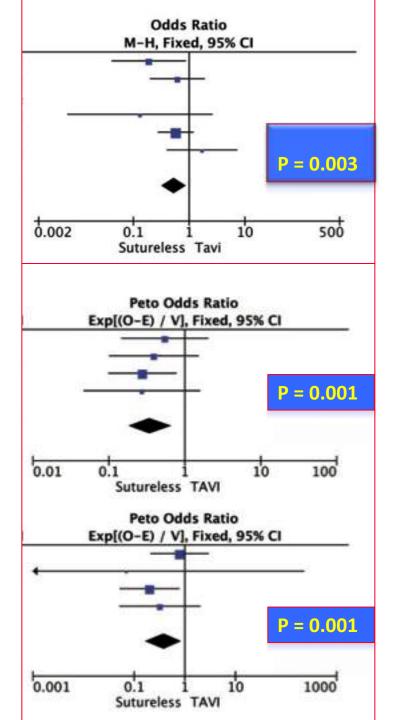
Similar ICU stay



In hospital death

1 yr Survival

2 yr Survival



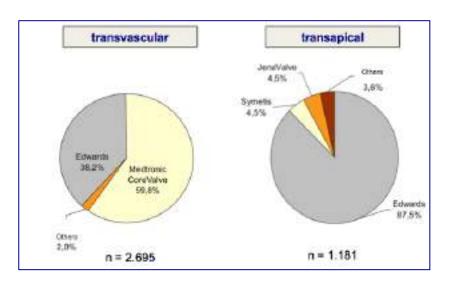
## The German Aortic Valve Registry: 1-year results from 13 680 patients with aortic valve disease

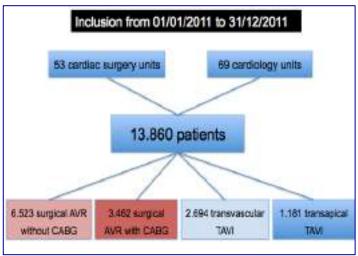
Friedrich W. Mohr", David Holzhey", Helge Möllmann", Andreas Beckmann", Christof Veit",
Hans Reiner Figulla", Jochen Cremer", Karl-Heinz Kuck", Rüdiger Lange", Ralf Zahn", Stefan Sack",
Gerhard Schuler", Thomas Walther", Friedhelm Beyersdorf", Michael Böhm", Gerd Heusch",
Anne-Kathrin Funkat", Thomas Meinertz", Till Neumann", Konstantinos Papoutsis", Steffen Schneider",
Armin Welz" and Christian W. Hamm", for the GARY Executive Board

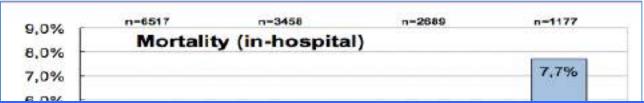
European Journal of Cardio-Thoracic Surgery 46 (2014) 808–816

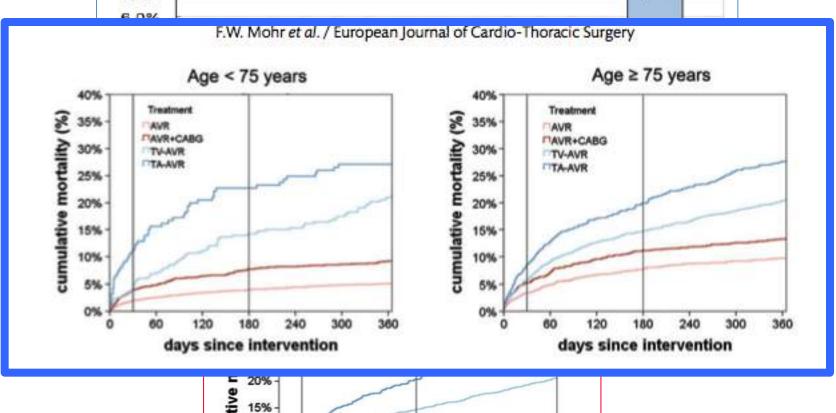


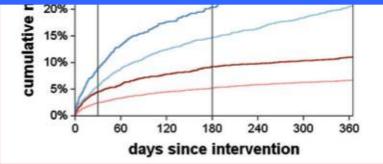
### Deutsches Aortenklappenregister German Aortic Valve RegistrY

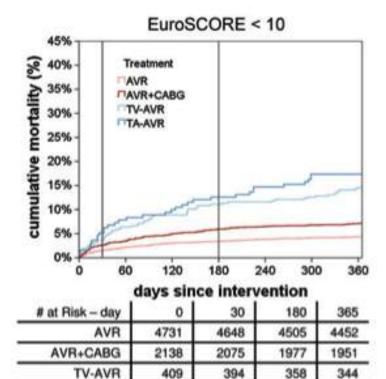




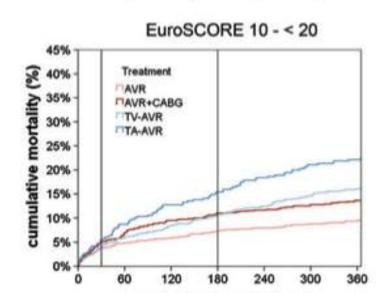




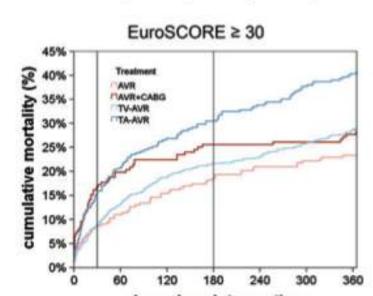




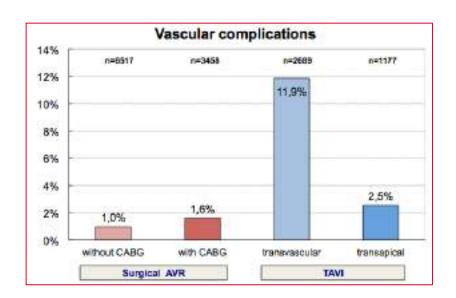
| 45% Tree AV 35% - TAV | atment   | ORE 20 -   |        |     |
|-----------------------|----------|------------|--------|-----|
| 0% 0 60               | 120      | 180 2      | 40 300 | 36  |
| c                     | lays sin | ce interve | ention |     |
| # at Risk day         | 0        | 30         | 180    | 365 |
| AVR                   | 312      | 294        | 270    | 255 |
| AVR+CABG              | 235      | 213        | 188    | 178 |
| TV-AVR                | 514      | 488        | 435    | 402 |

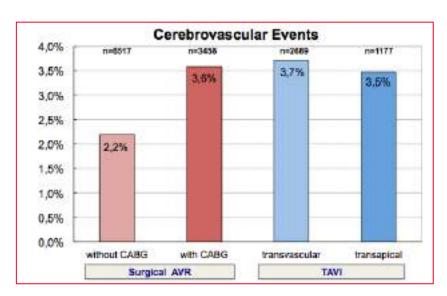


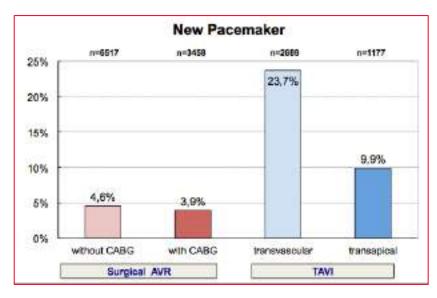
TA-AVR

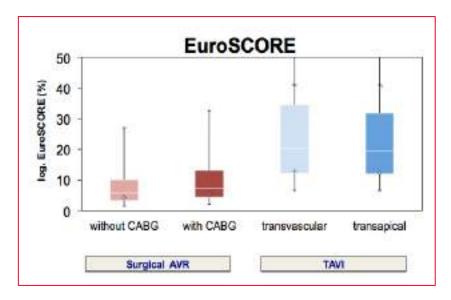


TA-AVR









# GARY confirm in a large 'real-world', all- comer patient population that



Conventional surgery in operable patients yields excellent results in all risk groups.

TAVR is is a good alternative for high-risk patients.

## **TAVI**

# **SUAVR**

Light anesthesia

No need for CPB

Less Invasive

**Concomitant procedures** 

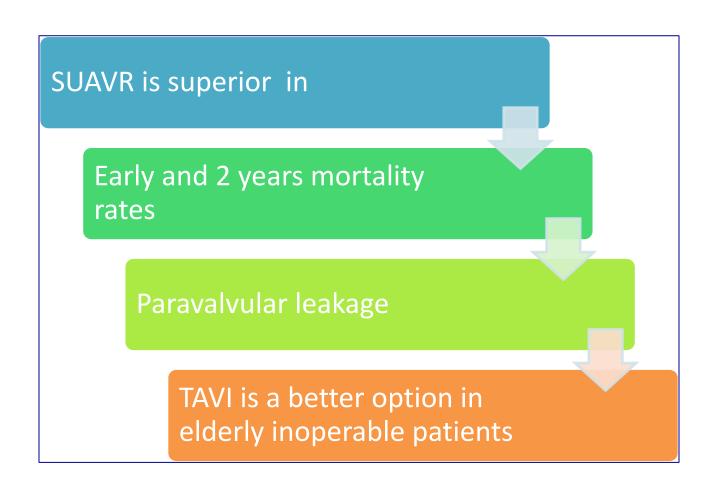
**Less PPM** 

**Less PVL** 

Valve resection



### In summary





# The Major Concern?

**Durability** 

**Long term outcomes** 

The concern with PVL is probably temporary, as TAVI will continue to improve in valve designs

Performance of SUAVR is promising and evolving

Minimally invasive approaches continue to improve the patients outcome

Cardiac Surgeons must be engaged and learn the endovascular surgery

Respect to the current guideline and heart team approach





# Aspects to be considered by heart team for decision between TAVI or SUAVR in high risk patients

|   | Favours<br>TAVI | Favours<br>SAVR |
|---|-----------------|-----------------|
| Clinical characteristics  |                 |                 |
| STS/EuroSCORE II <4% (logistic EuroSCORE I<10%)                     |                 | +               |
| STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)                    | +               |                 |
| Presence of severe comorbidity (not adequately reflected by scores) | +               |                 |
| Age <75 years   |                 | +               |
| Age ≥75 years   | +               |                 |
| Previous cardiac surgery  | +               |                 |

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|   | Favours<br>TAVI | Favours<br>SAVR |
|---|-----------------|-----------------|
| Clinical characteristics (continued)  |                 |                 |
| Frailty   | +               |                 |
| Restricted mobility and conditions that may affect the rehabilitation process after the procedure | +               |                 |
| Suspicion of endocarditis   |                 | +               |
| Anatomical and technical aspects  |                 |                 |
| Favourable access for transfemoral TAVI   | +               |                 |
| Unfavourable access (any) for TAVI  |                 | +               |





|  | Favours<br>TAV I | Favours<br>SAVR |
|--|------------------|-----------------|
| Anatomical and technical aspects (continued)                                   |                  |                 |
| Sequelae of chest radiation  | +                |                 |
| Porcelain aorta  | +                |                 |
| Presence of intact coronary bypass grafts at risk when sternotomy is performed | +                |                 |
| Expected patient-prosthesis mismatch   | +                |                 |
| Severe chest deformation or scoliosis  | +                |                 |
| Short distance between coronary ostia and aortic valve annulus                 |                  | +               |

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|   | Favours<br>TAVI | Favours<br>SAVR |
|---|-----------------|-----------------|
| Anatomical and technical aspects (continued)  |                 |                 |
| 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 |                 | +               |
| Presence of thrombi in aorta or LV  |                 | +               |
| Cardiac conditions in addition to aortic stenosis that requir<br>concomitant intervention         | e consideratio  | n for           |
| Severe CAD requiring revascularization by CABG  |                 | +               |





|   | Favours<br>TAVI | Favours<br>SAVR |
|---|-----------------|-----------------|
| Cardiac conditions in addition to aortic stenosis that require concomitant intervention (continued) | consideratio    | n for           |
| Severe primary mitral valve disease, which could be treated surgically                              |                 | +               |
| Severe tricuspid valve disease  |                 | +               |
| Aneurysm of the ascending aorta   |                 | +               |
| Septal hypertrophy requiring myectomy   |                 | +               |

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### Sutureless aortic valve replacement versus transcatheter aortic valve implantation: a meta-analysis of comparative matched studies using propensity score matching

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Matteo Ferrarini<sup>b</sup>, Antonio Lio<sup>b</sup> and Mattia Glauber<sup>b</sup>

A systematic review and meta-analysis

6 comparative study
731 patients in each group

Table 3: Postoperative data

|  | SU-AVR        | TAVI            | P-value |
|--|---------------|-----------------|---------|
| 30-days mortality (%)                  | 24/741 (3.23) | 44/741 (5.93)   | 0.01    |
| Postoperative stroke (%)               | 12/741 (1.61) | 27/741 (3.64)   | 0.01    |
| Postoperative aortic regurgitation (%) | 21/731 (2.8)  | 133/731 (18.19) | 0.001   |
| Postoperative AKI (%)                  | 35/527 (6.51) | 37/527 (6.89)   | 0.8     |
| Pacemaker implantation (%)             | 69/741 (9.31) | 70/741 (9.44)   | 0.9     |
| Transfused patients (%)                | 88/426 (20.6) | 26/424 (6.1)    | 0.001   |
| Vascular complications (%)             | 0/490 (0)     | 41/490 (8.36)   | 0.001   |

