

TAVI hors centre chirurgical évolution réaliste et souhaitable ?

A Tirouvanziam MD FESC
HPLC Nantes / ICPS Massy

- Conflit d'intérêt : Proctor Edwards LifeScience
- Liste d'attente significative ++
- Nécessité déplacement hors secteur pour opérer (éthique, médical, économique)

Pourquoi est ce souhaitable ?

- Extension des indications
- Sécurisation de la procédure
- Perspectives

Etat des lieux en 2017



Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk



| | Favours TAVI | Favours 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 | + | |



Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk *(continued)*

| | Favours TAVI | Favours SAVR |
|--|--------------|--------------|
| <i>Anatomical and technical aspects (continued)</i> | | |
| 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 | | + |

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



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Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk

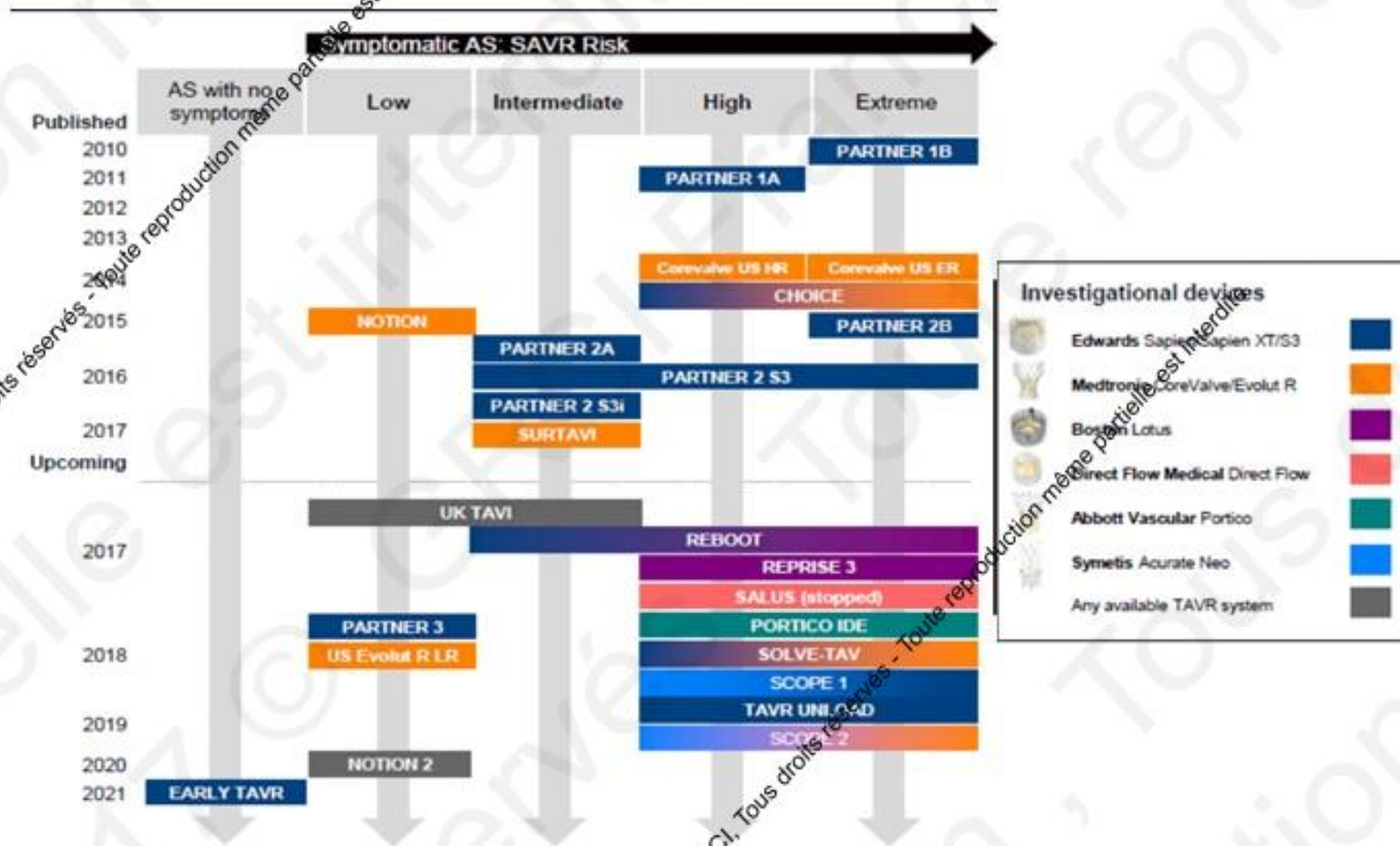
(continued)

| | Favours TAVI | Favours SAVR |
|--|--------------|--------------|
| Anatomical and technical aspects <i>(continued)</i> | | |
| 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 require consideration for concomitant intervention | | |
| Severe CAD requiring revascularization by CABG | | + |

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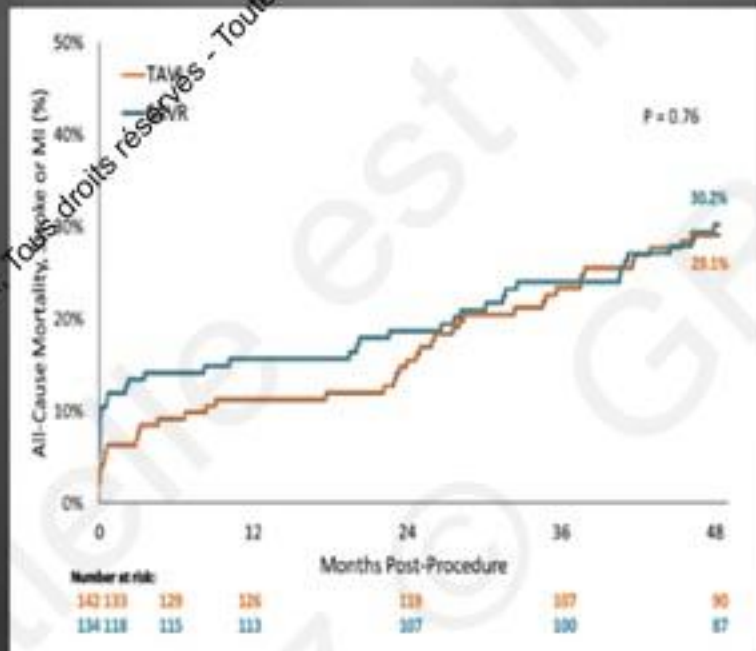
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Indications élargies : 24 RCT

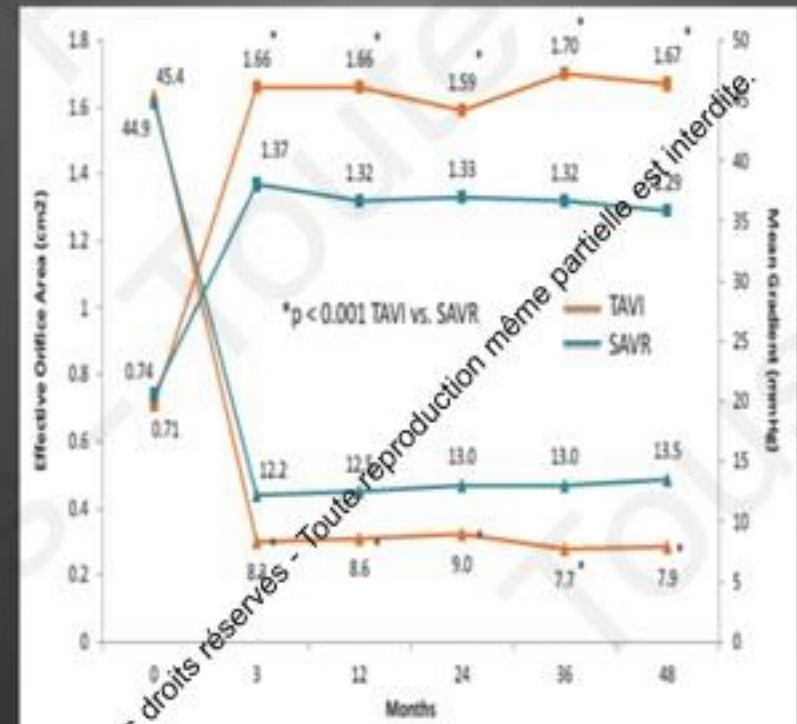


TAVI faible risque

4 Year: Mortality, Stroke, MI

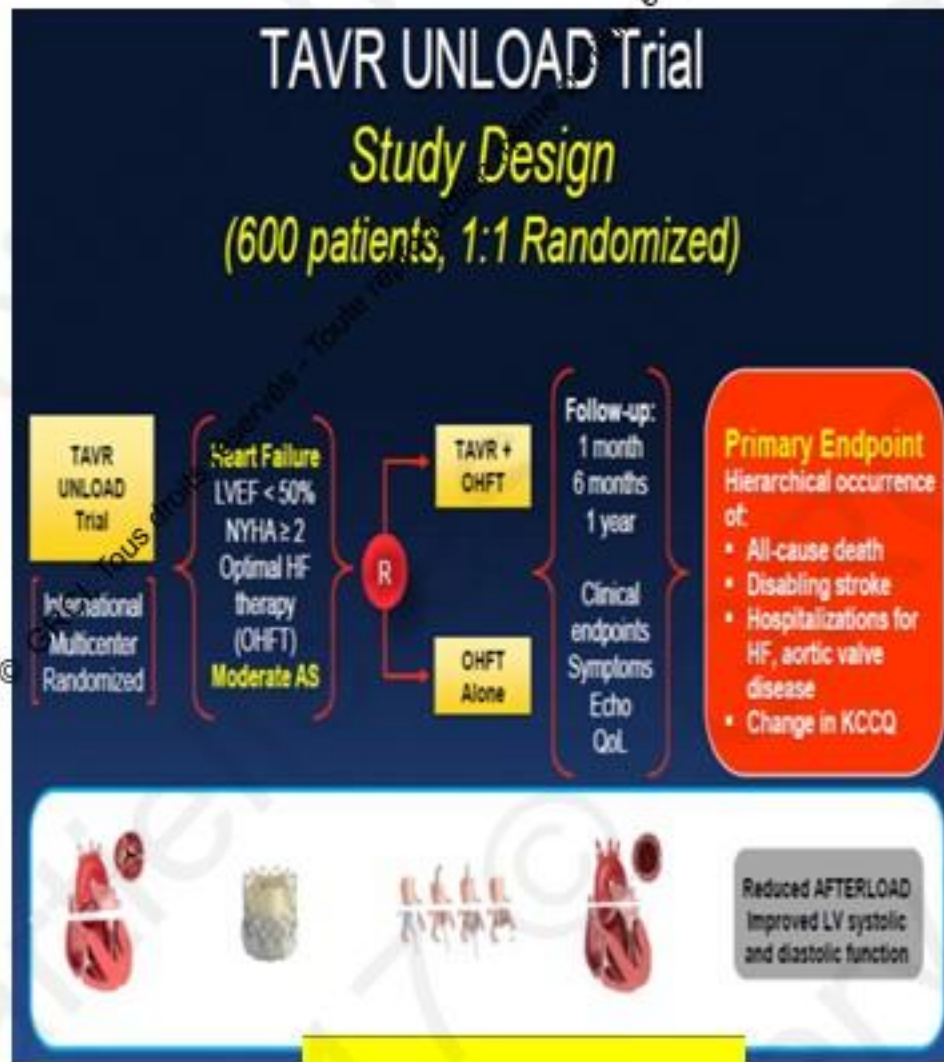


NORDIC Trial: 4 Year valve performance

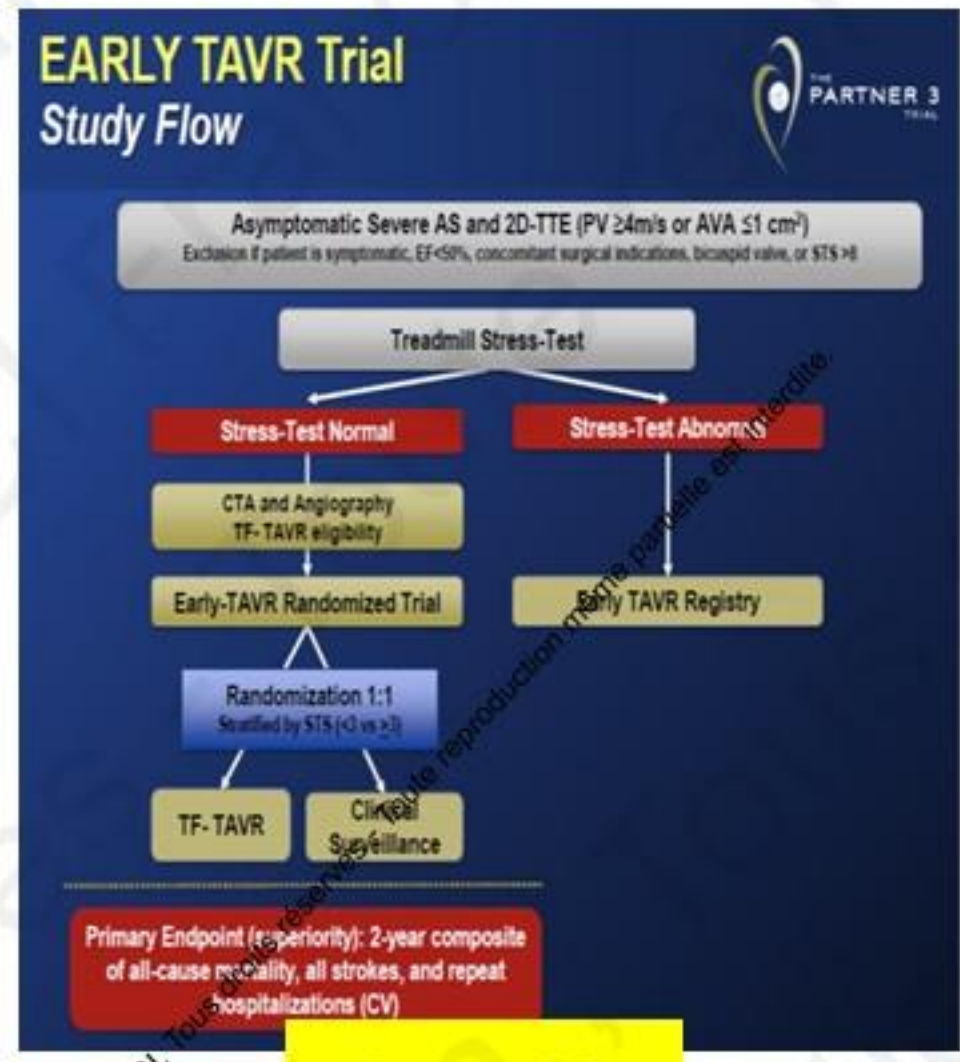


NOTION trial: Lars Sondergaard. EURO PCR 2017

Et au delà du faible risque !



**Moderate AS
Symptoms +**

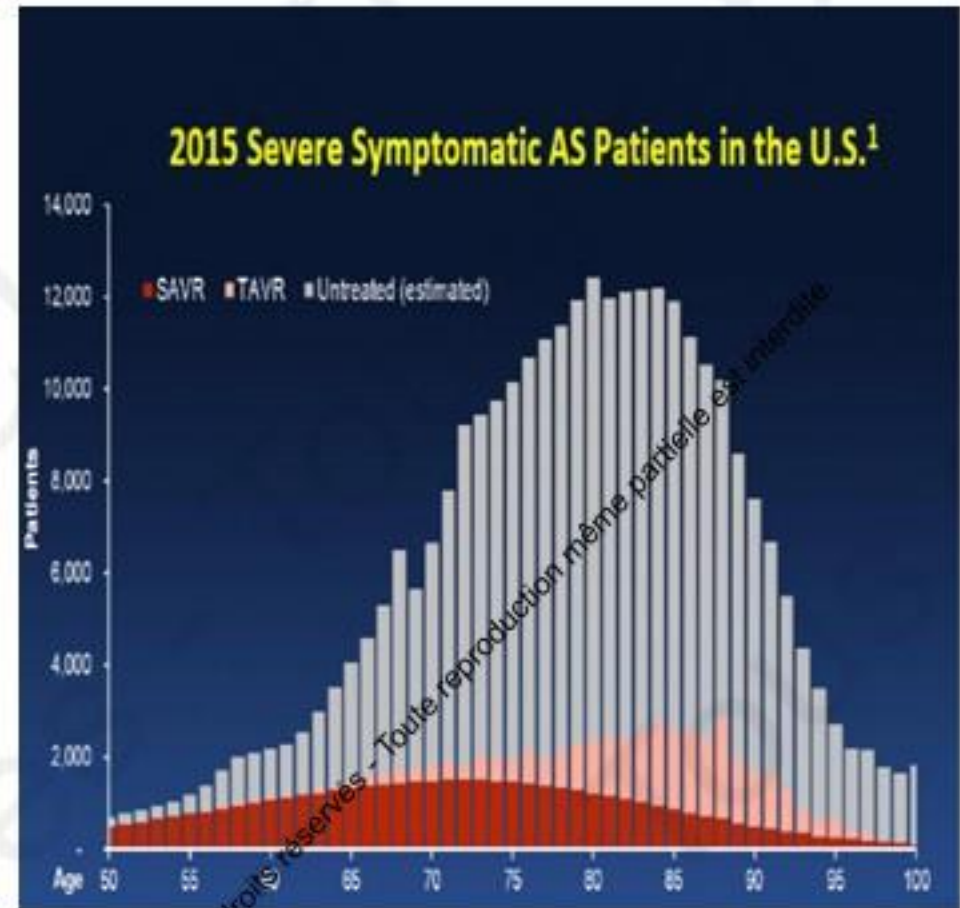
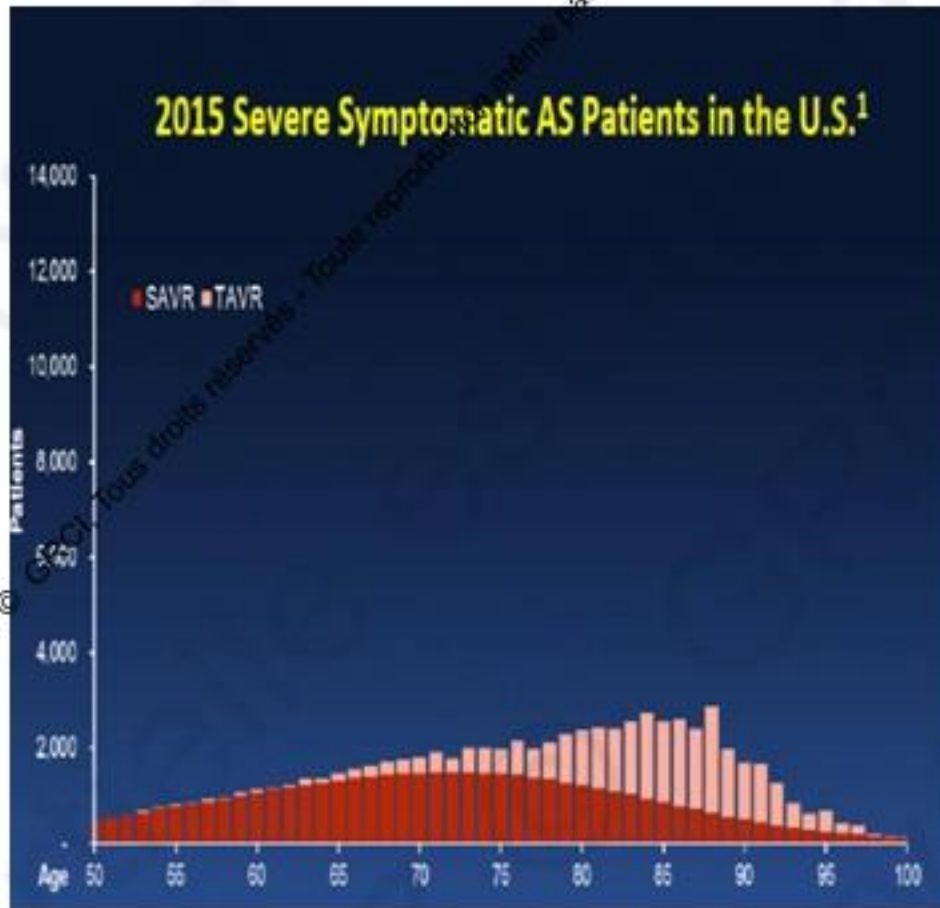


**Severe AS
Symptoms -**

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Perspectives TAVI



(1) Nkomo 2006, Iivainen 1996, Aronow 1991, Bach 2007, Freed 2010, Jung 2007, Pellikka 2005, Brown 2008, Thourani 2015.

TAVI : perspectives WW 2025

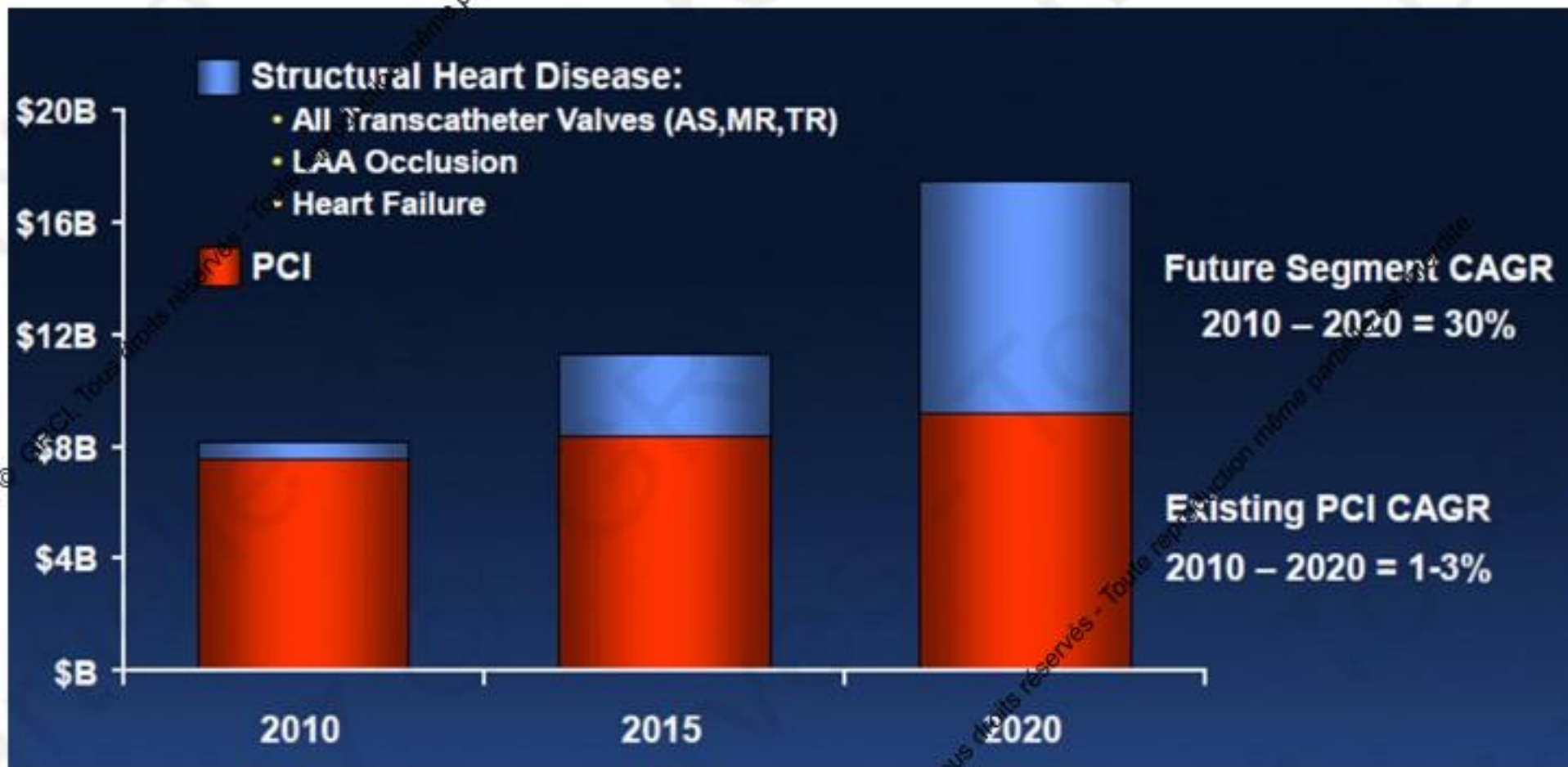
Global TAVR Units



SOURCE: Credit Suisse TAVI Comment - January 8, 2015. An assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 30% EU, 10% Japan, 10% ROW

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TAVI % activité cath lab

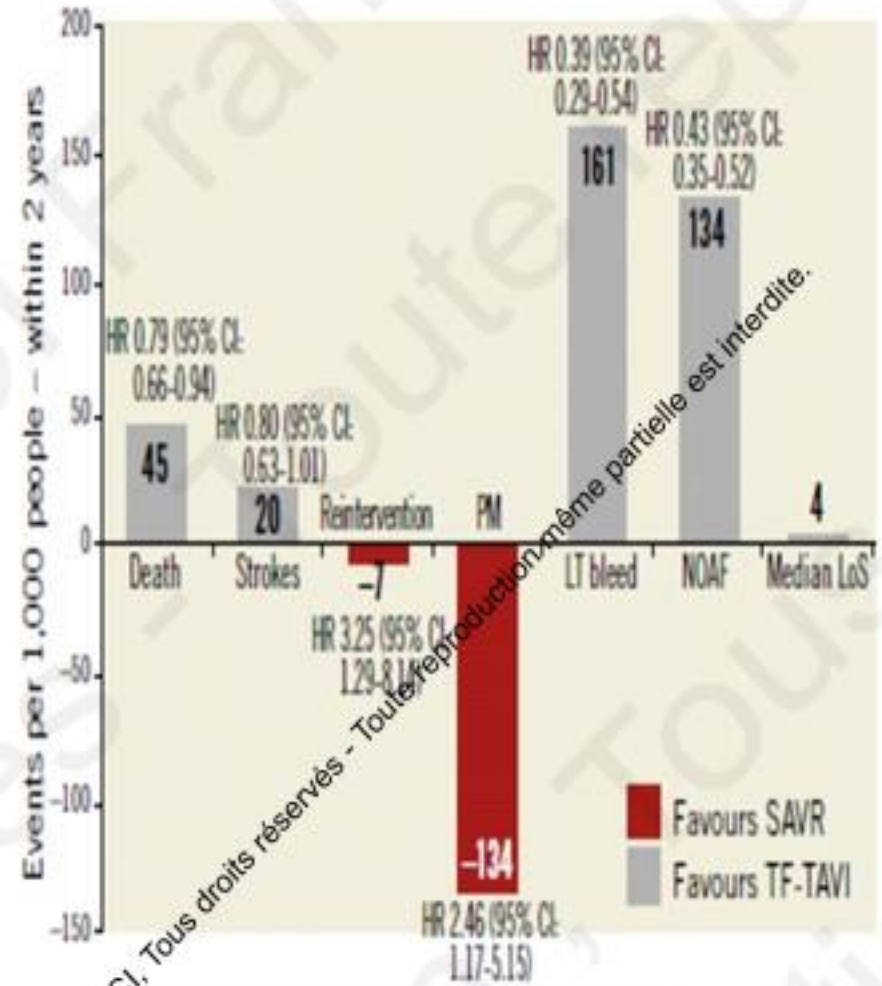
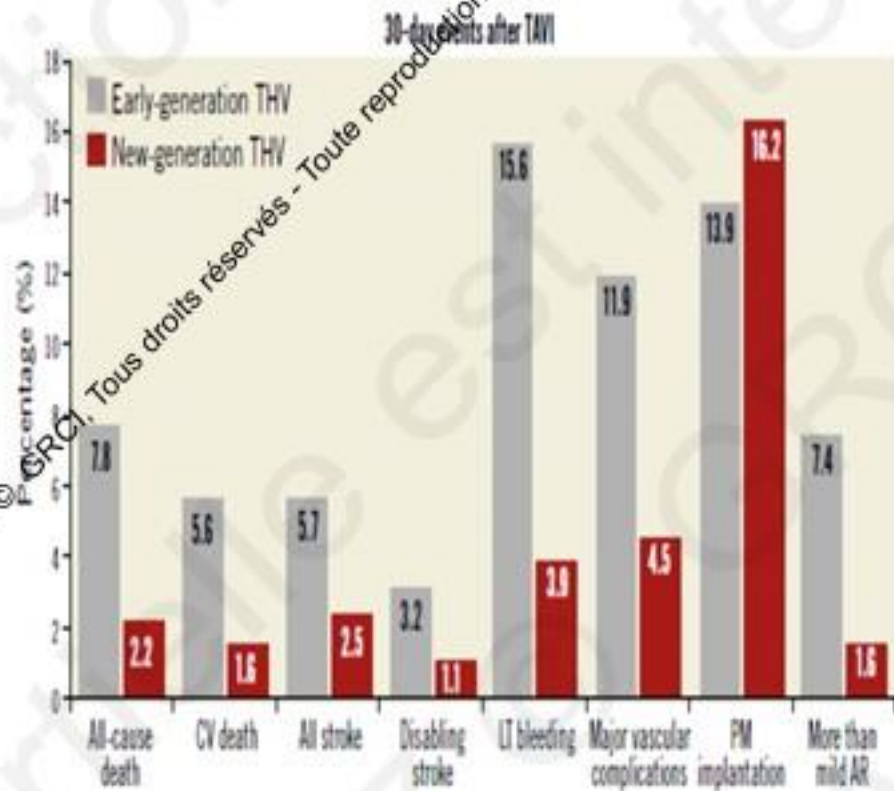


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TAVI sécurité



TAVI sans CEC sur site



European Heart Journal (2016) 37, 2240–2248
doi:10.1093/eurheartj/ehw190

FASTTRACK CLINICAL RESEARCH

TAVI

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*}, Maïke Bestehorn², Michael Haude³, Axel Schmermund¹, Kurt Bestehorn⁴, Thomas Voigtländer¹, Karl-Heinz Kuck⁵, and Rajendra H. Mehta⁶

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

Received 21 March 2016; revised 11 April 2016; accepted 20 April 2016; online published ahead of print 17 May 2016

See page 2249 for the editorial comment on this article (doi:10.1093/eurheartj/ehw228)

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TAVI sans CEC sur site

Table 1 Patient demographics

| | Patients undergoing TF-TAVI in hospitals without CS (n = 1332) | Patients undergoing TF-TAVI in hospitals with CS (n = 16587) | P-value |
|--|---|---|---------|
| Age | 82.1 ± 5.8 (55–97) | 81.1 ± 6.1 (33–100) | <0.001 |
| Age ≤ 75 | 172 (12.9%) | 2529 (15.2%) | 0.022 |
| Female (%) | 722 (54.2%) | 9125 (55.0%) | 0.568 |
| NYct ≤ II | 1204 (90.4%) | 14079 (84.9%) | <0.001 |
| Severe decompensated heart failure (<48 h) | 54 (4.1%) | 518 (3.1%) | 0.062 |
| Pulmonary hypertension | 633 (47.5%) | 7591 (45.8%) | 0.001 |
| Systolic PA pressure >55 mmHg | 257 (19.3%) | 2204 (13.3%) | <0.001 |
| Atrial fibrillation | 392 (29.4%) | 4925 (29.7%) | 0.840 |
| Presence of permanent pacemaker | 177 (13.2%) | 1868 (11.3%) | 0.025 |
| Presence of implanted cardioverter defibrillator | 22 (1.7%) | 282 (1.7%) | 0.896 |
| ASA ≥ 3 | 1242 (93.2%) | 15221 (91.8%) | <0.001 |
| Left ventricular ejection fraction ≤ 30% | 148 (11.1%) | 1687 (10.2%) | 0.183 |
| CAD | 804 (60.4%) | 8995 (54.2%) | <0.001 |
| Left main coronary artery involvement | 67 (5.0%) | 629 (3.9%) | 0.034 |
| Previous myocardial infarction | 183 (13.7%) | 2206 (13.3%) | 0.650 |
| Previous PCI | 457 (34.3%) | 4856 (29.3%) | <0.001 |
| Previous open heart surgery | 238 (17.9%) | 2893 (17.4%) | 0.693 |
| Insulin-dependent diabetes mellitus | 178 (13.4%) | 2355 (14.2%) | 0.400 |
| IVD | 248 (18.6%) | 2504 (15.1%) | 0.012 |
| COPD with medication | 222 (16.7%) | 2104 (12.7%) | 0.001 |
| Previous neurologic event | 186 (14.0%) | 1954 (11.8%) | 0.019 |
| Chronic haemodialysis | 36 (2.7%) | 515 (3.1%) | 0.413 |
| LogEuroSCORE (%) | 23.2 ± 15.8 (3.1–88.8) | 21.0 ± 15.4 (3.1–96.3) | <0.001 |
| LogEuroSCORE < 10% | 213 (16.1%) | 3956 (24.1%) | <0.001 |
| LogEuroSCORE 10–20% | 520 (39.2%) | 5236 (36.9%) | |
| LogEuroSCORE 20–30% | 259 (19.5%) | 2969 (18.2%) | |
| LogEuroSCORE > 30% | 333 (25.1%) | 3407 (20.8%) | |
| GAU-Score 20 (%) | 6.1 ± 5.5 (0.8–57) | 5.5 ± 5.9 (0.6–99.9) | <0.001 |

TAVI sans CEC sur site

Table 5 Case-control analysis: patient characteristics

| | Patients undergoing TF-TAVI in hospitals without CS (n = 555) | Patients undergoing TF-TAVI in hospitals with CS (n = 555) | P-value |
|--|--|---|--------------|
| Age | 83.0 ± 4.4 (66–95) | 83.0 ± 4.4 (66–95) | 1.00 |
| Females (%) | 338 (60.9%) | 338 (60.9%) | 1.00 |
| NYHA ≥III | 479 (86.3%) | 437 (78.7%) | <0.001 |
| Previous myocardial infarction | 34 (6.1%) | 38 (6.8%) | 0.626 |
| Pulmonary hypertension | 234 (42.2%) | 234 (42.2%) | 1.00 |
| Systemic PA pressure >55 mmHg | 80 (14.4%) | 50 (9.0%) | 0.005 |
| Atrial fibrillation | 140 (25.2%) | 132 (23.8%) | 0.577 |
| Presence of permanent pacemaker | 48 (8.6%) | 49 (8.8%) | 0.35 |
| Presence of implanted cardioverter defibrillator | 5 (0.9%) | 5 (0.9%) | 1.00 |
| ASA ≥3 | 490 (88.3%) | 499 (89.9%) | 0.386 |
| Left ventricular ejection fraction ≤30% | 9 (1.6%) | 9 (1.6%) | 1.00 |
| CAD | 261 (47.0%) | 261 (47.0%) | 1.00 |
| Left main coronary artery involvement | 5 (0.9%) | 5 (0.9%) | 1.00 |
| Previous PCI | 136 (24.5%) | 131 (23.6%) | 0.726 |
| Previous open heart surgery | 45 (8.1%) | 45 (8.1%) | 1.00 |
| Insulin-dependent diabetes mellitus | 22 (4.0%) | 21 (3.8%) | 0.877 |
| PVD | 61 (11.0%) | 54 (9.7%) | 0.337 |
| COPD with medication | 86 (15.5%) | 51 (9.2%) | 0.001 |
| Previous neurologic event | 68 (12.3%) | 60 (10.8%) | 0.452 |
| Chronic haemodialysis | 2 (0.4%) | 2 (0.5%) | 0.654/1.00** |
| LogEuroSCORE (%) | 16.4 ± 9.0 (3.5–56.4) | 16.0 ± 9.1 (3.3–56.2) | 0.462 |
| GAV-score 2.0 (%) | 3.7 ± 1.4 (1.3–12.9) | 3.7 ± 1.4 (1.3–12.9) | 1.00 |

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TAVI sans CEC sur site

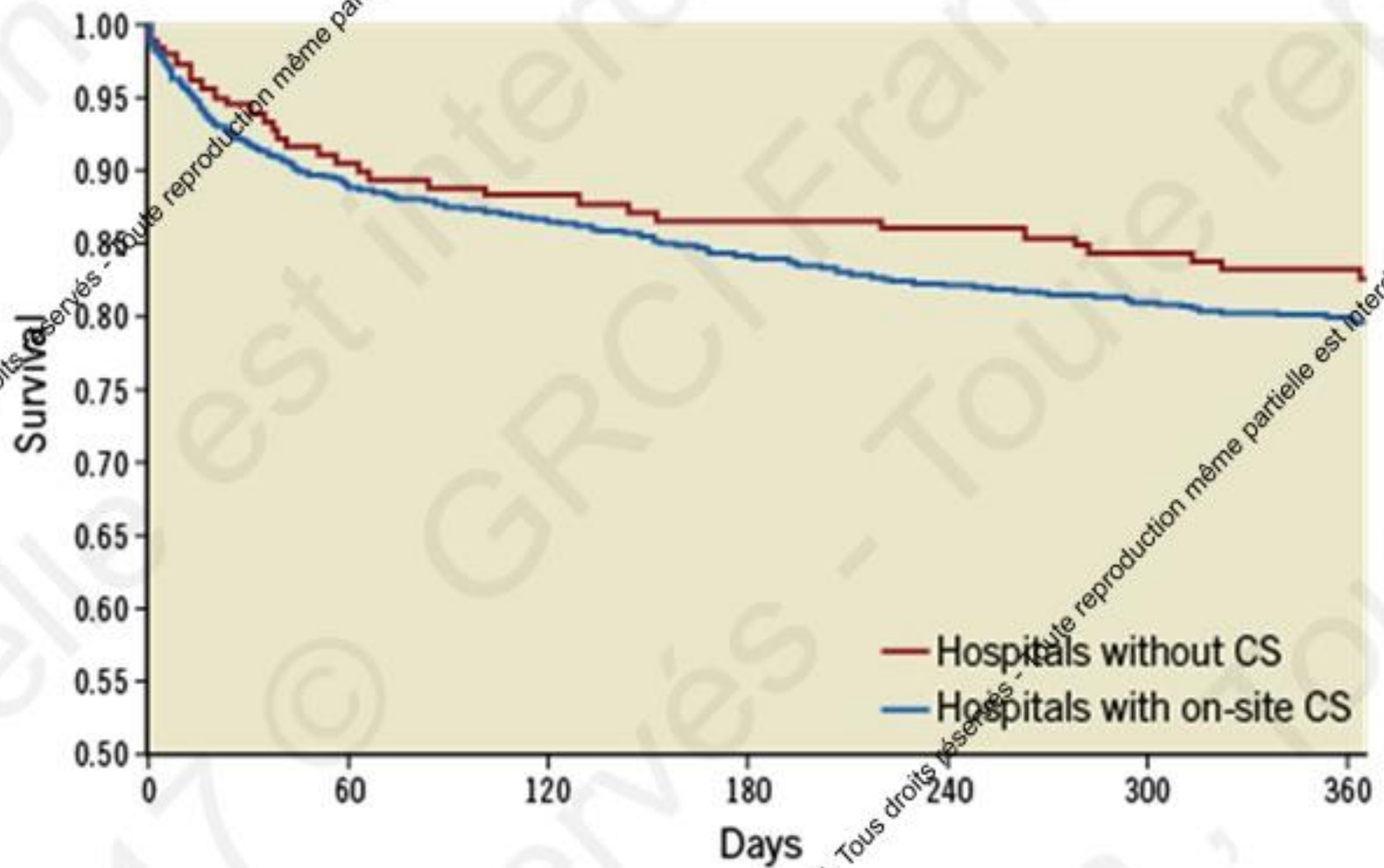
| | Patients undergoing TF-TAVI in hospitals without CS (n = 555) | Patients undergoing TF-TAVI in hospitals with CS (n = 555) | P-value | Odds ratio for categorical var. or stand. mean difference for continuous var. | 95% CI |
|----------------------------------|---|--|---------------|---|--------------|
| Elective procedure | 502 (90.5%) | 497 (89.5%) | 0.617 | 1.1053 | 0.7465–1.637 |
| Procedure time (min) | 108.8 ± 48.1 | 74.2 ± 42.2 | <0.001 | 0.765 | 0.643–0.887 |
| Fluoroscopy time (min) | 19.5 ± 13.4 | 21.5 ± 42.7 | 0.293 | -0.063 | -0.181–0.055 |
| Intraprocedural complications | 51 (9.2%) | 57 (10.3%) | 0.543 | 0.884 | 0.54–1.316 |
| Device malpositioning | 9 (1.6%) | 8 (1.4%) | 0.806 | 1.127 | 0.432–2.943 |
| Device maldeployment | 2 (0.4%) | 2 (0.4%) | 1.00/0.616** | 1.00 | 0.140–7.125 |
| Coronary occlusion | 2 (0.4%) | 4 (0.7%) | 0.387/0.649** | 0.498 | 0.091–2.731 |
| Aortic dissection | 1 (0.2%) | 2 (0.4%) | 0.563 | 0.499 | 0.045–5.520 |
| Annular rupture | 4 (0.7%) | 4 (0.7%) | 1.00/0.723 | 1.00 | 0.249–4.019 |
| Pericardial tamponade | 4 (0.7%) | 7 (1.3%) | 0.363 | 0.568 | 0.165–1.9525 |
| Acute cardiac decompensation | 4 (0.7%) | 2 (0.4%) | 0.413/0.682** | 2.007 | 0.366–11.004 |
| Cerebral embolism | 1 (0.2%) | 1 (0.2%) | 1.00/0.479** | 1.00 | 0.062–16.028 |
| Aortic regurgitation ≥ 2 | 15 (2.7%) | 6 (1.1%) | 0.047 | 2.542 | 0.979–6.600 |
| Rhythm disturbances | 8 (1.4%) | 12 (2.2%) | 0.367 | 0.662 | 0.268–1.632 |
| Vascular injury | 14 (2.5%) | 22 (4.0%) | 0.175 | 0.639 | 0.323–1.262 |
| Conversion to open heart surgery | 2 (0.4%) | 5 (0.9%) | 0.216/0.448** | 0.398 | 0.077–2.059 |



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Table 7 Case-control analysis of postprocedural outcomes

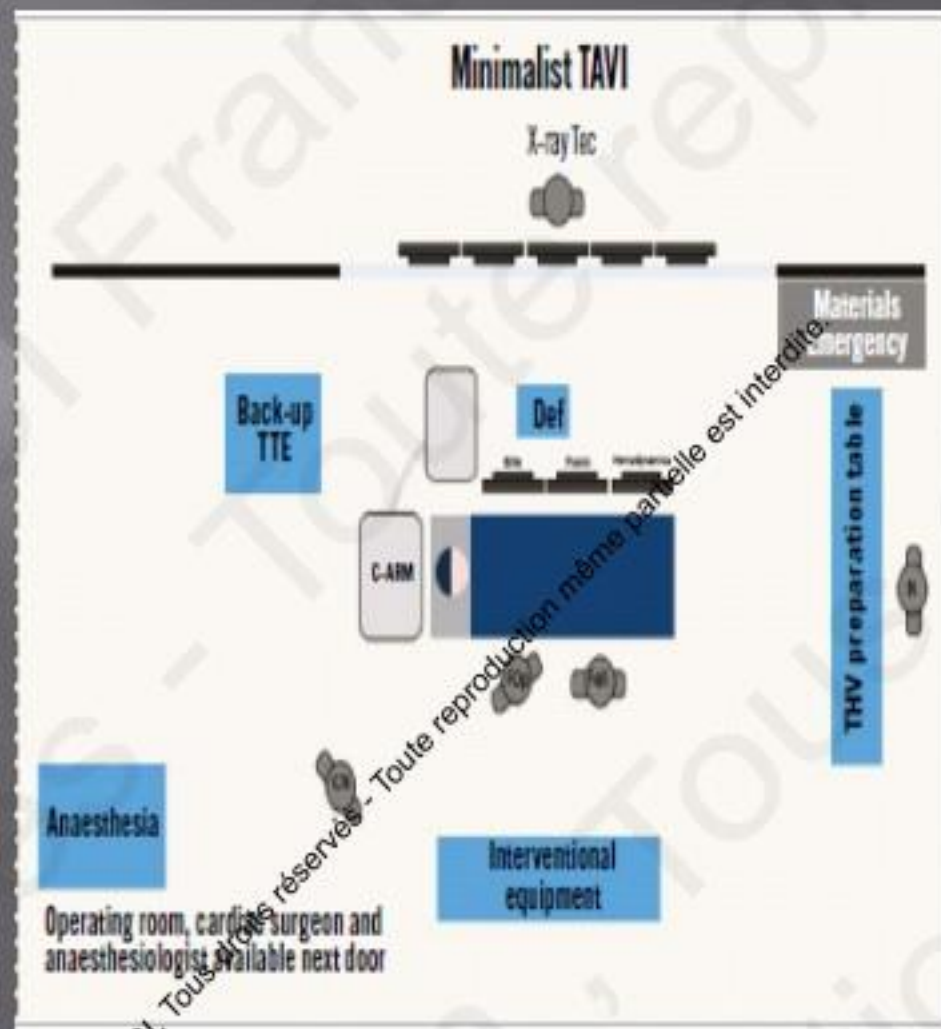
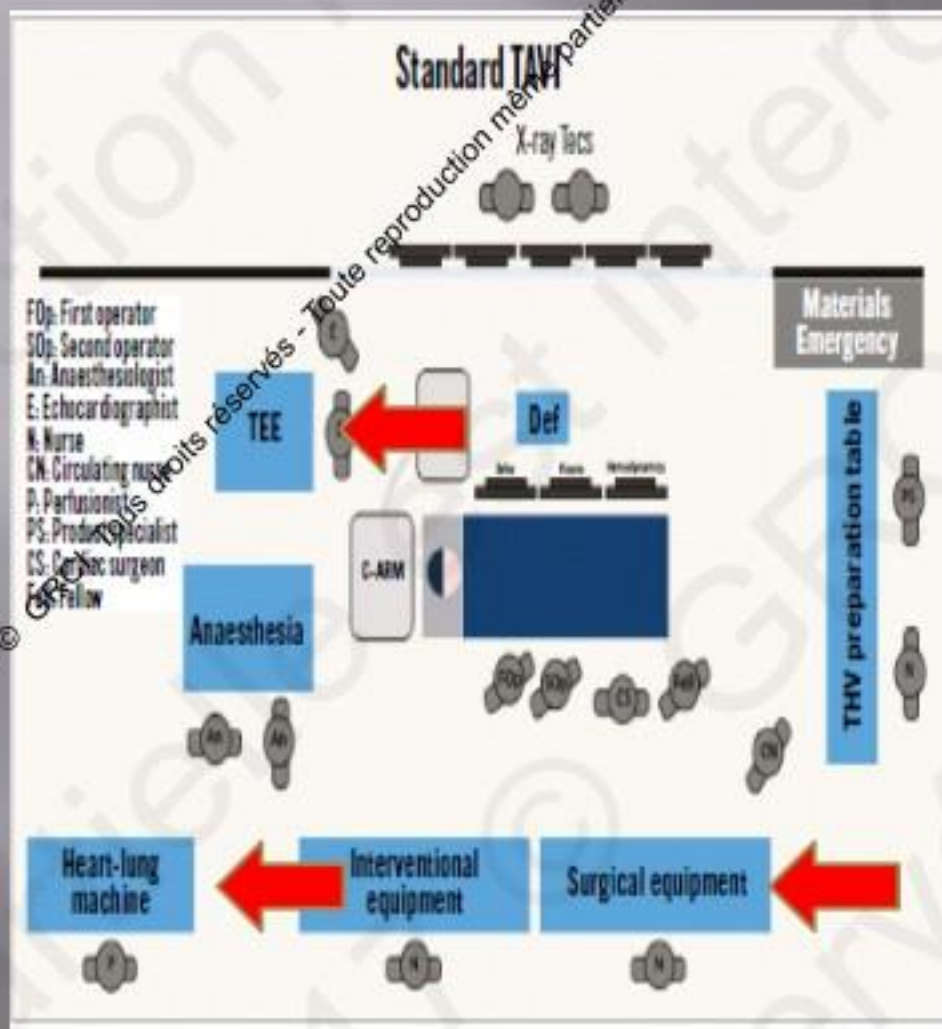
| | Patients undergoing TF-TAVI in hospitals without CS (n = 555) | Patients undergoing TF-TAVI in hospitals with CS (n = 555) | P-value | Odds ratio for categorical var. or stand. mean difference for continuous var. | 95% CI |
|----------------------------------|---|--|-------------|---|--------------|
| In-hospital death | 10 (1.8%) | 16 (2.9%) | 0.234 | 0.618 | 0.278–1.374 |
| Cerebrovascular event | 18 (3.2%) | 18 (3.2%) | 1.00 | 1.00 | 0.515–1.943 |
| Delirium requiring treatment | 18 (3.2%) | 15 (2.7%) | 0.596 | 1.207 | 0.601–2.419 |
| Myocardial infarction | 1 (0.2%) | 1 (0.2%) | 1.00 | 1.00 | 0.062–16.028 |
| Low cardiac output | 6 (1.1%) | 11 (2.0%) | 0.222 | 0.541 | 0.198–1.472 |
| Resuscitation | 10 (1.8%) | 18 (3.2%) | 0.126 | 0.547 | 0.250–1.197 |
| Vascular complications | 39 (7.0%) | 46 (8.3%) | 0.429 | 0.835 | 0.536–1.300 |
| Need for transient dialysis | 3 (0.5%) | 8 (1.4%) | 0.130 | 0.377 | 0.098–1.408 |
| Atrial fibrillation at discharge | 111 (20.0%) | 125 (22.5%) | 0.304 | 0.660 | 0.645–1.147 |
| New pacemaker/ICD implantation | 114 (20.5%) | 105 (18.9%) | 0.497 | 1.108 | 0.824–1.489 |
| Days in hospital after TF-TAVI | 10.4 ± 7.1 (0–93) | 9.8 ± 6.4 (0–56) | 0.139 | 0.088 | –0.029–0.207 |
| Transfer to another hospital | 43 (7.7%) | 86 (15.5%) | <0.001 | 0.458 | 0.311–0.674 |
| Discharge to nursing facility | 5 (0.9%) | 2 (0.4%) | 0.550.448** | 2.514 | 0.486–13.011 |



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Minimalist TAVI



TAVI ambulatoire

Featured Case Reports

CCI 2016

Same Day Discharge after Transcatheter Aortic Valve Replacement: Are We There yet?

Philippe Généreux,^{1,2*} MD, Philippe Demers,¹ MD, and Frédéric Poulin,¹ MD

Early discharge after transcatheter aortic valve replacement (TAVR) has been increasingly reported, and is now becoming routinely performed in experienced TAVR centers. However, to the best of our knowledge, no case has been described where a patient was safely discharged on the same the day of the procedure. This report will present the case of a patient who underwent a successful transfemoral TAVR and was safely discharged home the same day. Specific requirements and criteria are proposed to ensure the safety of this approach. © 2015 Wiley Periodicals, Inc.

Key words: TAVR; TAVI; discharge




Genereux P et al. Catheter Cardiovasc Interv 2016;87:980-2



PCR London Valves Innovators Day 2017. Where will valve intervention be in 2025?

| | |
|-------------|--|
| Engineering | 12 Fr delivery systems will be the standard |
| | Tissue engineered heart valves |
| | Resorbable stent frame |
| | Advanced leaflet technologies such as polymers, printed leaflets customised to the patient |
| | Complications |
| | Pacemaker rates comparable to surgery |
| | No paravalvular leak |

| | |
|----------------|--|
| Implementation | TAVI will account for 90-100% of all aortic valve replacement procedures |
| | Surgery will remain the treatment of choice for some patient groups (infective endocarditis, diffuse complex coronary artery disease, and diseases of the ascending aorta) |
| | Ad hoc TAVI will be a reality |

PCR London Valves Innovators Day 2017. Where will valve intervention be in 2025?

| | |
|----------|--|
| Research | No more randomised trials  |
| | Big data studies with surrogate endpoints |
| | More durability data  |
| | Enhanced TAV-in-TAV data  |
| | New developments in medical therapies for aortic stenosis |

| | |
|-------------|---|
| Geopolitics | Earlier diagnosis |
| | Wider geographical spread  |
| | Cheaper devices  |

Bis repetita



Michael Mack, MD

J Thorac Cardiovasc Surg 2008;136:816-9

The present study suggests that it is feasible to perform coronary angioplasty without surgical standby, provided the physicians are experienced and able to select their patients. A high-volume angioplasty team, backed up by a high-volume cardiac surgery program, remains the ideal setting. However, to demand it for all patients is economically unfeasible and creates unacceptable waiting lists in many areas, significantly hampering the undisputed potential of coronary angioplasty to alleviate myocardial ischemia.

Michael Mack, MD



Thorac Cardiovasc Surg 2008;136:816-9

THE JOURNAL OF
**THORACIC AND
CARDIOVASCULAR SURGERY**



Official Publication of
**American Association
for Thoracic Surgery
Western Thoracic
Surgical Association**

Fool me once, shame on you; fool me twice, shame on me! A perspective on the emerging world of percutaneous heart valve therapy

Michael Mack, MD  

Baylor Healthcare System, Cardiopulmonary Research Science Technology Institute, Dallas, Tex

 PlumX Metrics

Conclusion



- TAVI : + sûre , reproductible , prévisible
- Perspectives très optimistes , valves new génération .
- Validée centres sans CEC (AQUA registry) , mortalité idem
- Expansion généralisée indications irréversible
- TAVI indication première RAO
- Engorgement services , liste attente dangereuse ++
- Nécessité réflexion + discussion accès plus large centres CI
- Déploiement progressif , maîtrisé , contrôlé à tous les centres CEC en France (50/ 60) et au delà (RCT)
- Expérimentés sans CEC , capable de sélectionner patients en Heart Team dédiée .

THE JOURNAL OF
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CARDIOVASCULAR SURGERY**



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Fool me once, shame on you; fool me twice, shame on me! A perspective on the emerging world of percutaneous heart valve therapy

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 PlumX Metrics

L'HISTOIRE SE RÉPÈTE



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