L'essentiel de 2021
Valvulopathies

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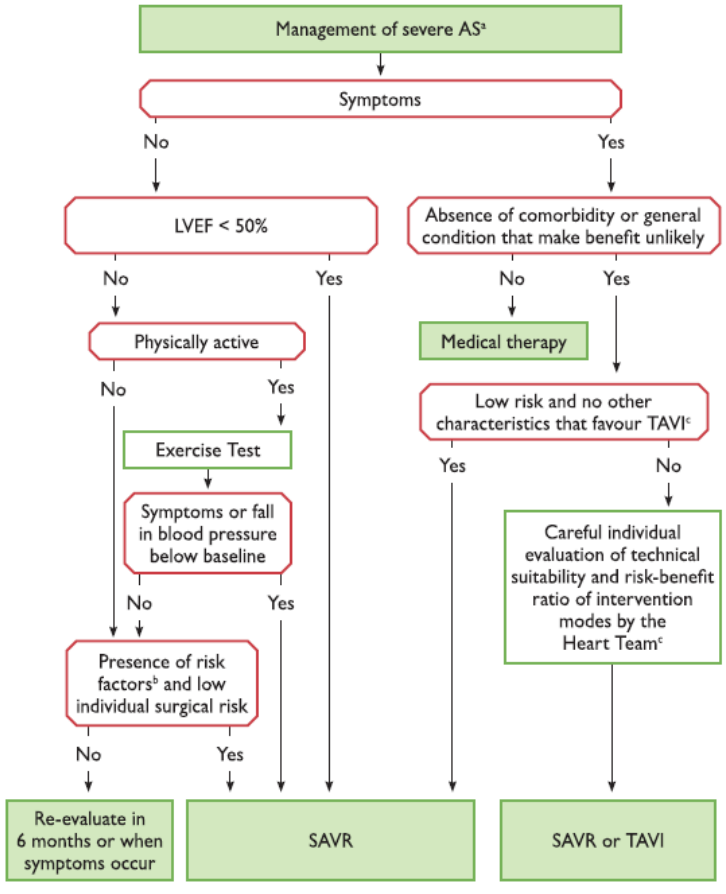
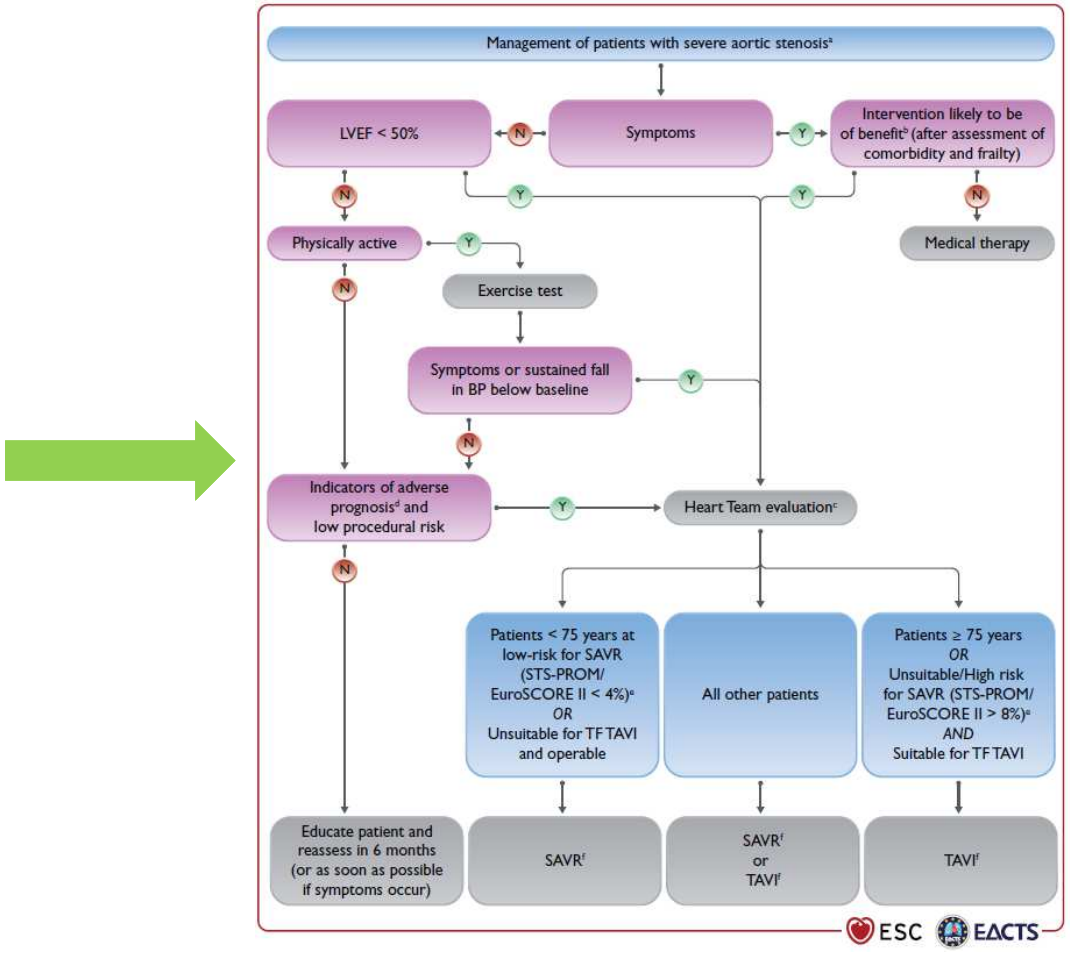
Qui est éligible à un TAVI en 2021





Recommandations ESC 2017 :

- Choix du type de procédure basé sur le niveau de risque STS des patients
- TAVI à partir du risque intermédiaire après décision Heart Team

Recommandations ESC 2021 :

- Heart Team au cœur de la décision
- Choix du type de procédure induit principalement par l'âge des patients
- TAVI, première intention au delà de 75 ans quelque soit le niveau de risque STS

prothèses TAVI vs indications CE

INDICATIONS / TAVI - PLATFORM	EXTREME RISK	HIGH RISK	INTERMEDIATE RISK	LOW RISK	TAV IN SAV	BICUSPID
EVOLUT™ R/PRO						
SAPIEN™ 3						
ACURATE NEO™						
PORTICO™						

INDICATION ✓ CONTRAINDICATION ✗ NO REFERENCE ?

→ 4 PROTHÈSES DISPONIBLE À CE JOUR EN France

Seules deux d'entre elles ont prouvé leur efficacité et ont obtenu les indications CE
pour le Risque intermédiaire, le Low Risk, le TAV-in-SAV et la Bicuspidie (uniquement Evolut™).

Evolut™

vs

SAPIEN 3™

étude solve TAVI

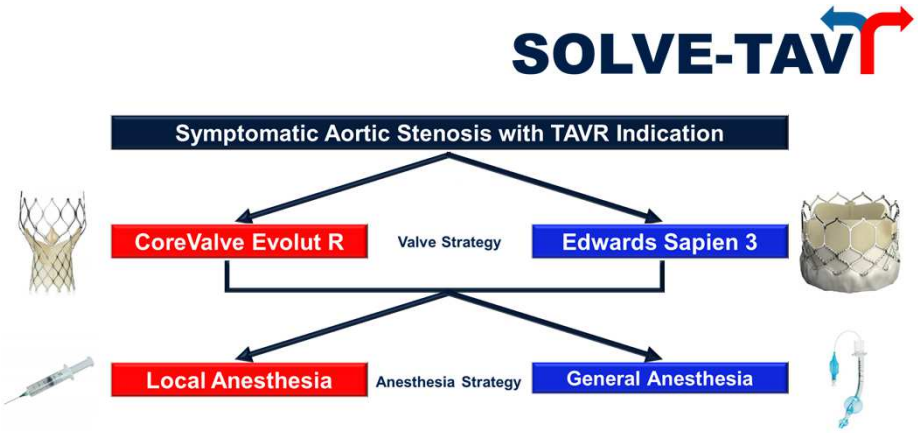
résultats à 1 ans

Evolut™ vs sapien 3

RÉSULTATS SOLVE TAVI À 1 AN

CRITÈRE PRINCIPAL COMPOSITE :
Mortalité toute cause, AVC, fuites paravalvulaire modérée ou sévères et implantation de PM post-TAVI.

POPULATION CIBLE :
Patients à risque chirurgical intermédiaire



DONNÉES ÉQUIVALENTES À 1 AN		
	Evolut R vs Sapien 3	p-value
Composite endpoint*	87 (41.9%) vs 85 (40.4%)	0.76
All-cause mortality	34 (17.6%) vs 33 (17.0%)	0.88
Cardiovascular mortality	1 (0.5%) vs 4 (1.8%)	0.19
Moderate/severe PVL	14 (7.0%) vs 9 (4.5%)	0.35
Permanent pacemaker implantation	54 (24.7%) vs 44 (20.2%)	0.25
Time-related safety (VARC-2)	45 (15.6%) vs 64 (20.8%)	0.10

SUPÉRIORITÉ À 1 AN		
	Evolut R vs Sapien 3	p-value
AVA, cm^2	1.9 vs 1.7	0.063
AVA index, cm^2/m^2	1.0 vs 1.1	0.75
Mean aortic valve gradient, mmHg	6 vs 10	<0.001
Max. aortic valve gradient, mmHg	12 vs 19	<0.001
Stroke	2 (1.0%) vs 14 (6.9%)	0.002

Evolut Low Risk

vs

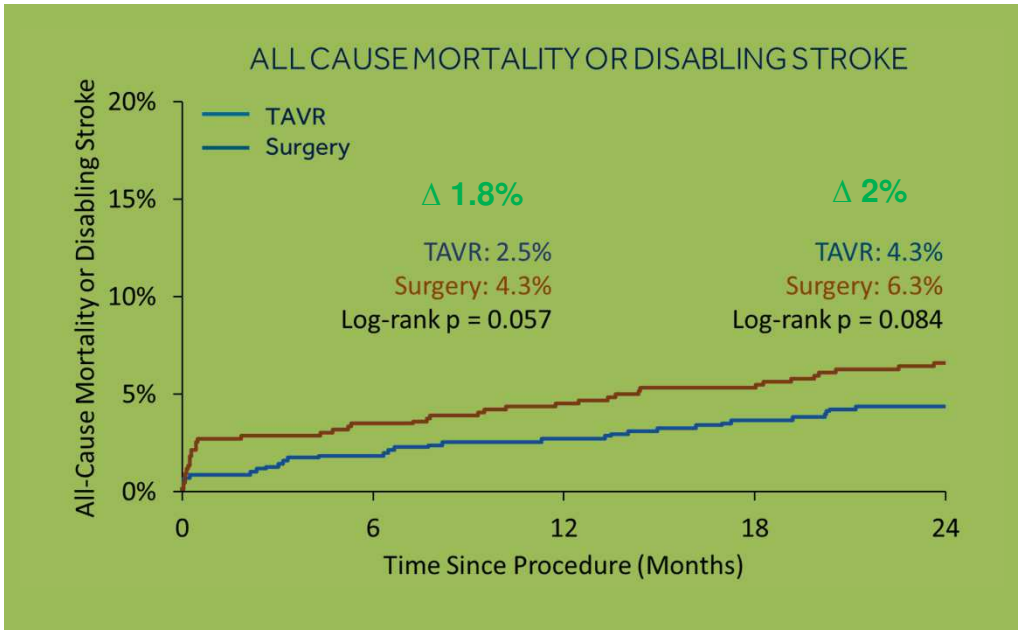
Partner 3

résultats à 2 ans*

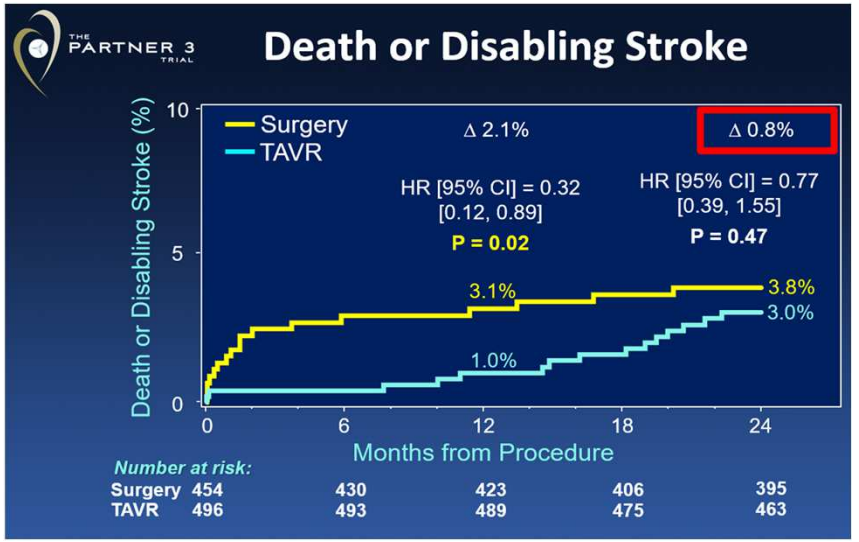
*Evolut Low Risk & Partner 3 sont deux études aux critères d'évaluations différents, elles ne peuvent être directement comparées entre elles.

Evolut low risk vs Partner 3*

RÉSULTATS À 2 ANS



PARTNER 3 – 2Y RESULTS

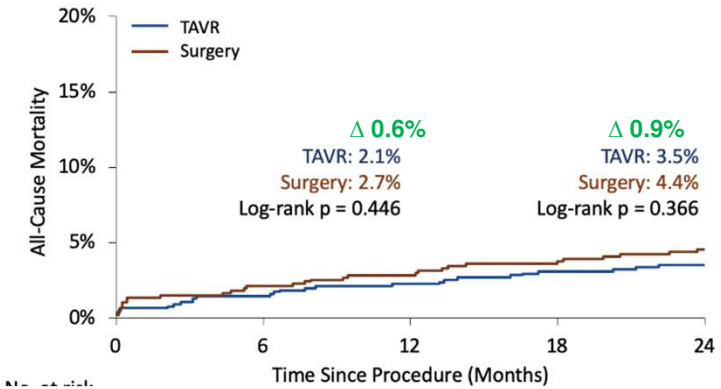


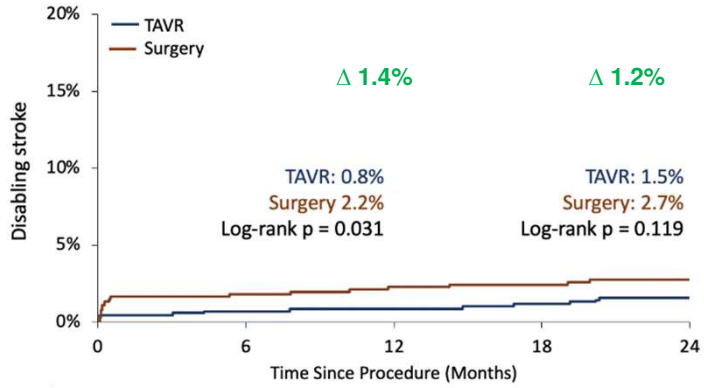
- A 24 mois dans l'étude PARTNER 3, l'écart entre les groupe TAVI ET SAVR se réduit (0.8% à 2 ans vs 2.1% à 1an).
- **Le groupe TAVI semble moins efficace que SAVR entre 1 et 2 ans.**

Evolut Low Risk & Partner 3 sont deux études aux critères d'évaluations différents, elles ne peuvent être directement comparées entre elles.

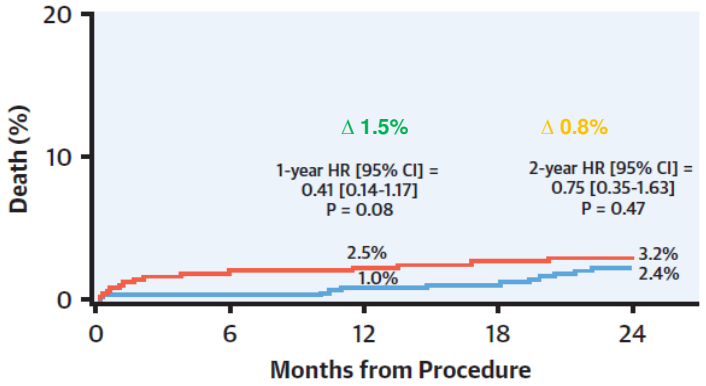
Evolut low risk vs Partner 3*

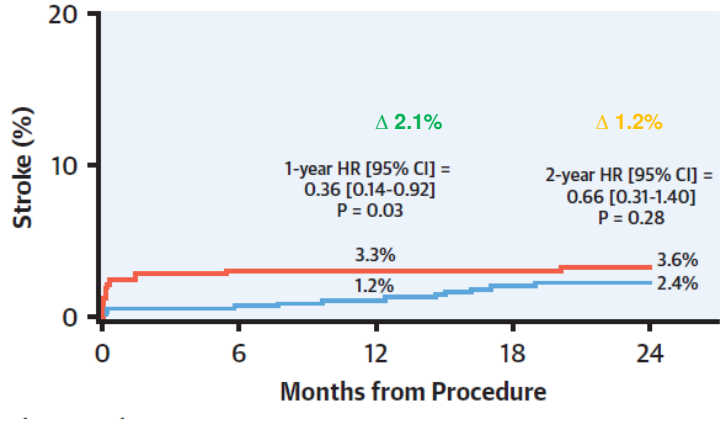
RÉSULTATS À 2 ANS





PARTNER 3 – 2 ans



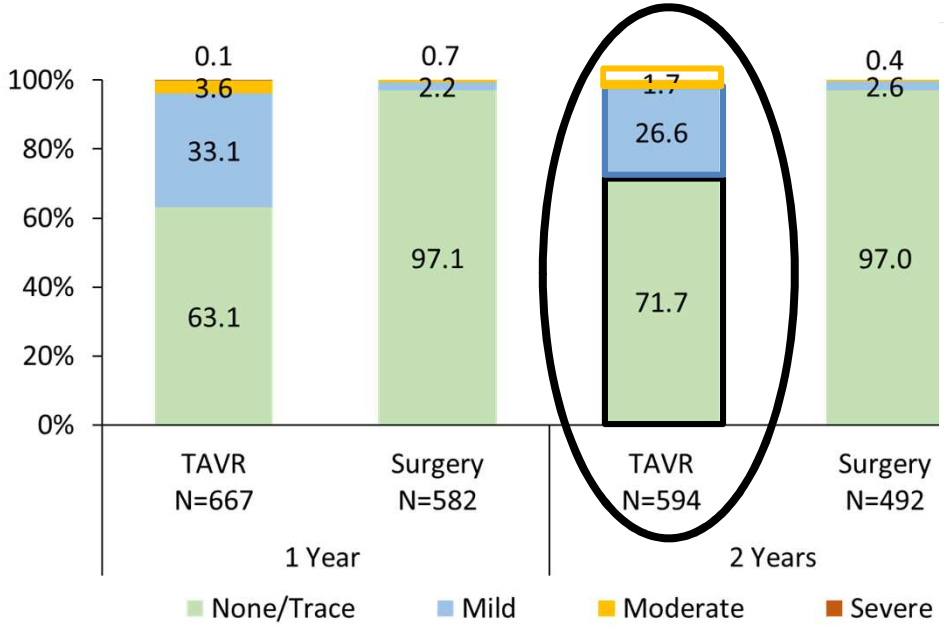


Evolut Low Risk & Partner 3 sont deux études aux critères d'évaluations différents, elles ne peuvent être directement comparées entre elles.

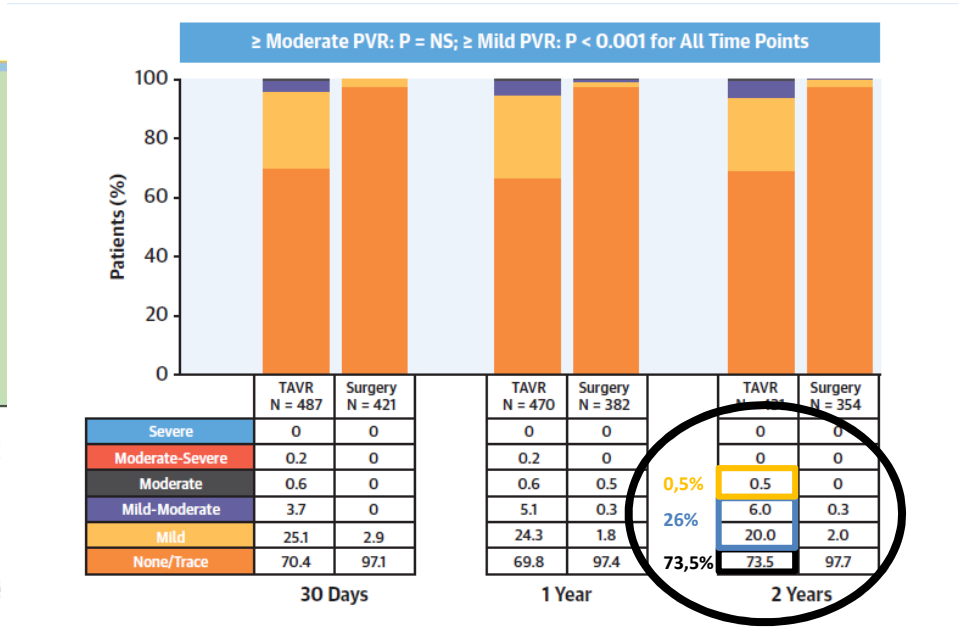
Cet écart = **taux de mortalité en augmentation entre 1 et 2 ans.**

Evolut low risk vs Partner 3*

RÉSULTATS À 2 ANS



PARTNER 3 – 2Y RESULTS



*Evolut Low Risk & Partner 3 sont deux études aux critères d'évaluations différents, elles ne peuvent être directement comparées entre elles.

évaluation de la durabilité

étude Notion

résultats à 8 ans

RÉSULTATS À 8 ANS

étude Notion

<u>OBJECTIF PRINCIPAL</u> :

Comparaison du TAVI vs SAVR dans une population Low Risk *(STS Score : 2.9 vs 3.1)*

<u>CRITÈRE PRIMAIRE</u> :

Composite mortalité toute cause, AVC, infarctus à 1 an *(Critères VARC 2)*

Recrutement : 2009 - 2013

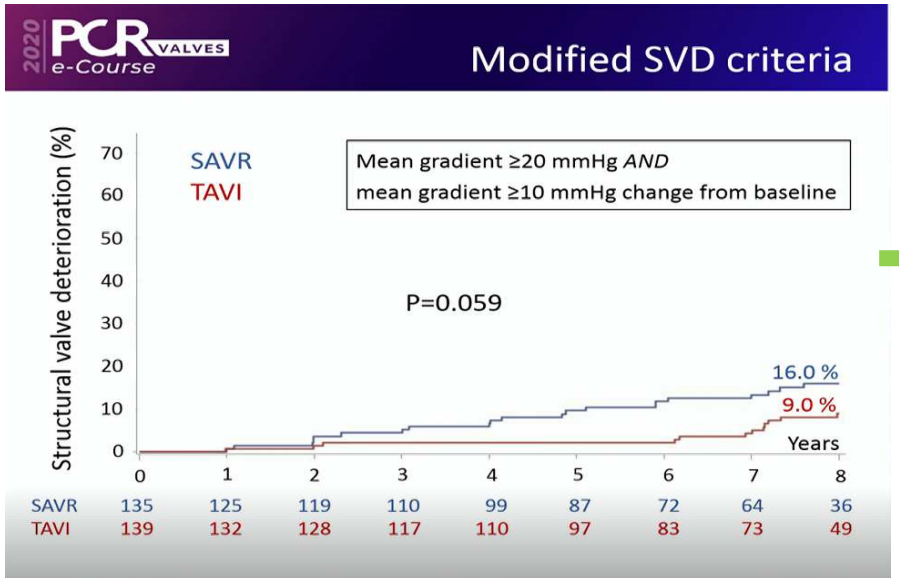
SUIVI A 10 ANS

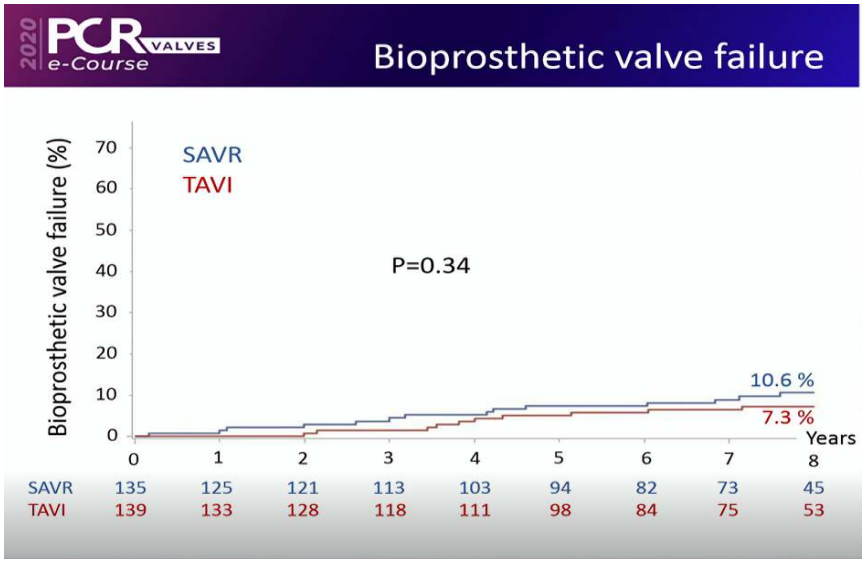
OBJECTIF :
Évaluation durabilité valve TAVI Evolut™

étude Notion

RÉSULTATS À 8 ANS

DURABILITÉ PLATEFORME EVOLUT™





SVD = Structural Valve Deterioration

→ Modifications intrinsèques permanente des feuillets valvulaires conduisant à une dégénérescence et/ou dysfonction hémodynamique

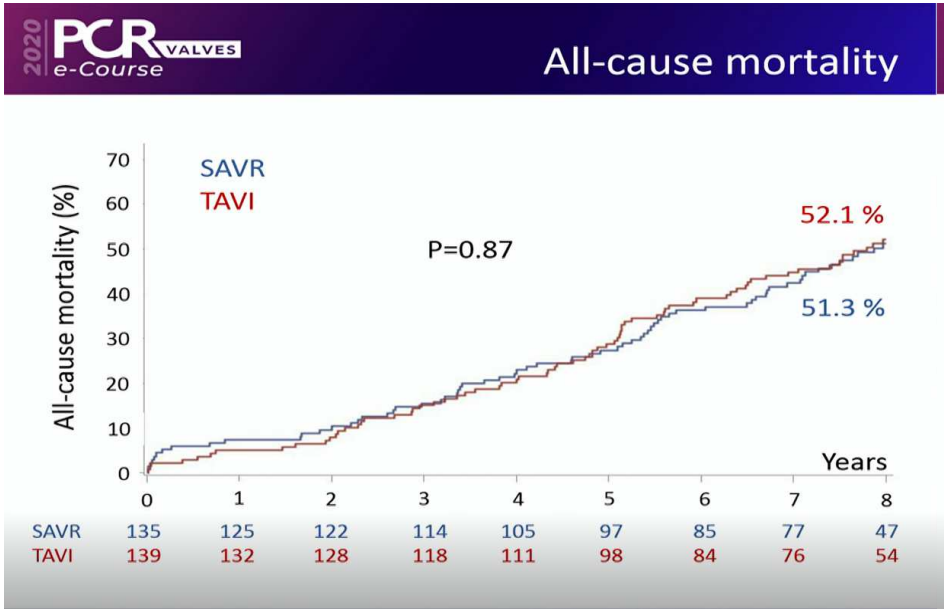
BVF = Bioprosthetic Valve Failure

→ Les BVF intègrent les forment les plus graves de SVD et sont ainsi un critère principal pour évaluer la durabilité des valves TAVI et SAVR.

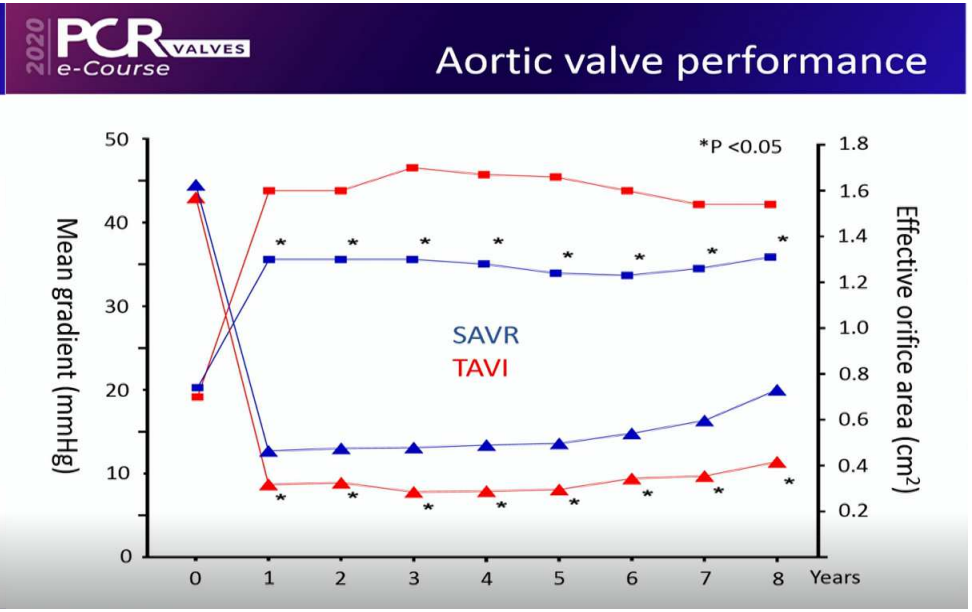
étude Notion

RÉSULTATS À 8 ANS

PAS DE DIFFÉRENCE SAVR VS TAVI
SUR LA MORTALITÉ TOUTES CAUSES
À 8 ANS



SUPÉRIORITÉ HÉMODYNAMIQUE
DU TAVI VS SAVR



TAKE HOME MESSAGE

TAVI:

- Elargissement des indications (ESC)

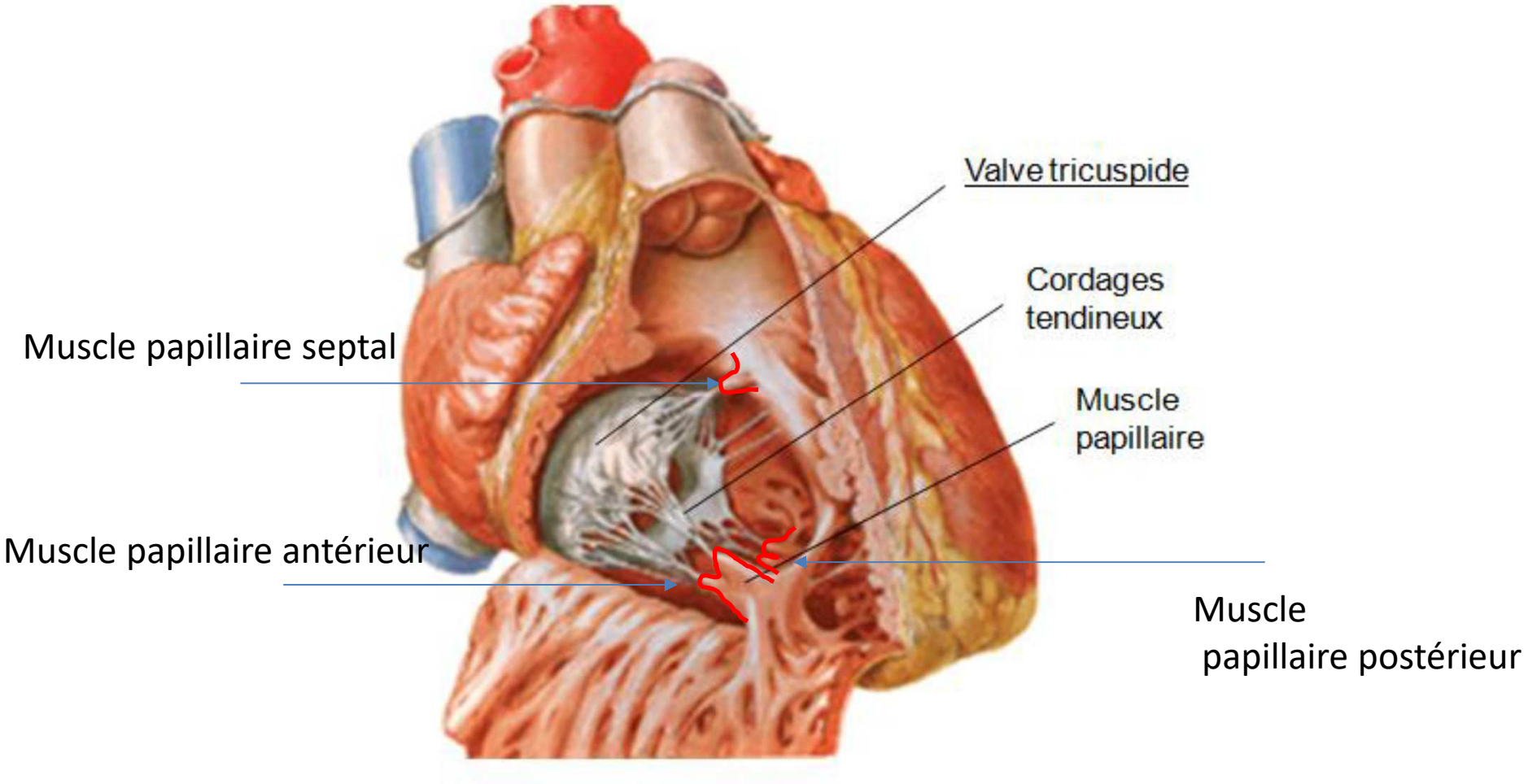
- Indications V-in-V // Bicuspidies // Niveaux de risque

- Optimisation de la procedure

  PM // Accès aux coronaires // PVL

- *Fast procedures*

Anatomie tricuspide

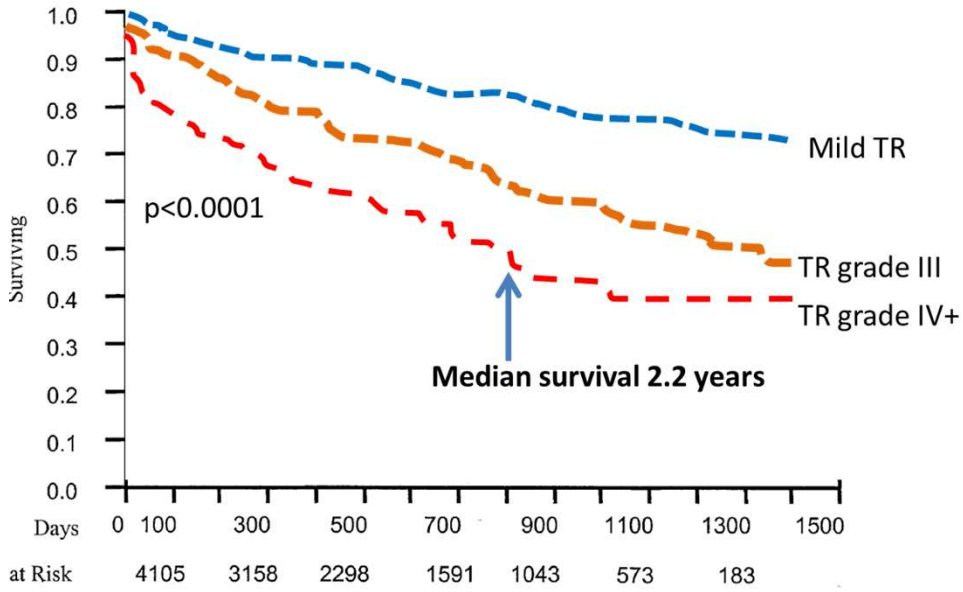


IT fonctionnelles

Table 3. Clinical and Echocardiographic Parameters Associated With Long-Term Survival*

Variable	Chi-Square	p Value
TR		
Mild	0.15	0.70
Moderate	2.65	0.10
Severe	5.79	0.02
Age	65.75	< 0.0001
LVEF	4.28	0.04
IVC		
Dilated	13.95	0.0002
Dilated without collapse	21.15	< 0.0001
RV enlargement		
Mild	0.90	0.34
Moderate and severe	4.05	0.04
RV dysfunction	2.12	0.14

*Using a proportional hazards model.
Abbreviations as in Table 1.



5507 ETT consécutive

601 patients (11.5%) sans IT

3,805 patients (68.8%) avec une IT minime à modérée

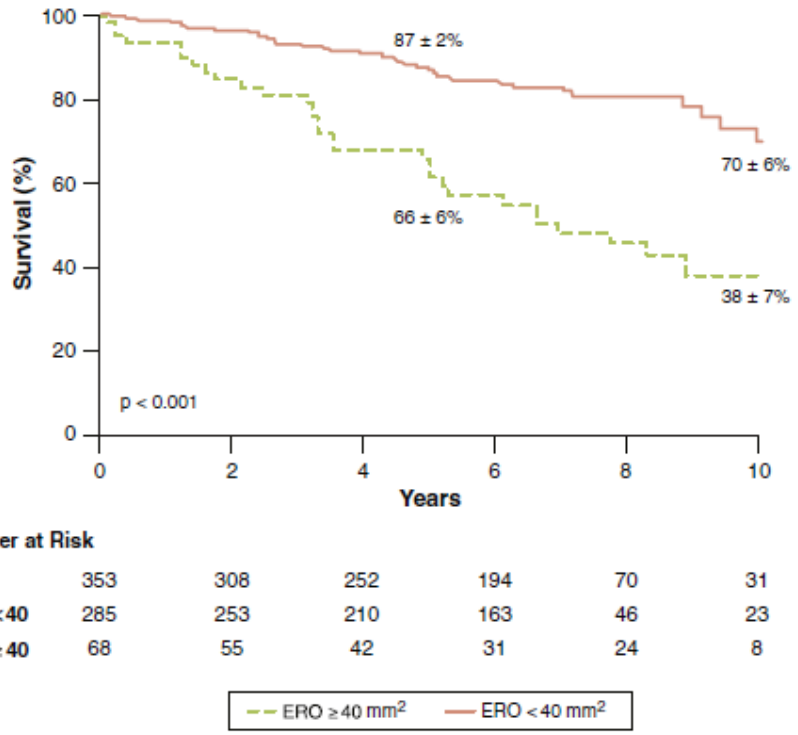
620 (11.8%) patients avec une IT de grade III et 199 (3.8%) de grade IV

La majorité des IT sévères ont une dysfonction VD et une dilatation ventriculaire droite

Jayant Nath, J Am Coll Cardiol 2004

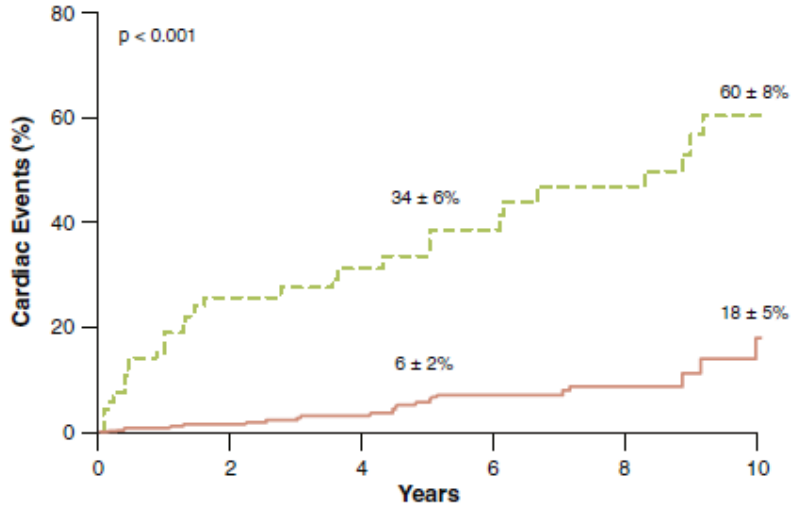
IT isolée

- IT isolée (n=353): Pas d'HTAP, FEVG>50%, pas de sonde de PM, pas d'autre valvulopathie ni d'antécédents de chirurgie



Number at Risk

Total	353	308	252	194	70	31
ERO <40	285	253	210	163	46	23
ERO ≥40	68	55	42	31	24	8



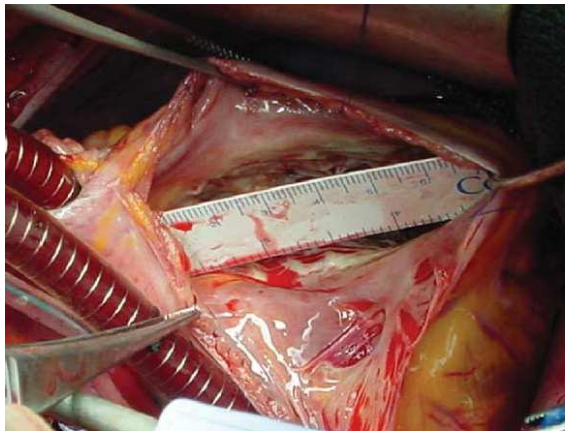
Number at Risk

Total	353	294	242	183	65	29
ERO <40	285	252	209	160	46	23
ERO ≥40	68	42	33	23	19	6

Yan Topilsky, J Am Coll Cardiol Img 2014

TRAITEMENT

Annuloplastie préventive



311 patients referred for mitral repair

<70mm (Groupe 1)
N=163

>70mm (Groupe 2)
N=148

TR ring

Table 3. Tricuspid Regurgitation Grade Measured by Transthoracic Echocardiography

	Before Surgery		After Surgery	
	Group 1 (MVR)	Group 2 (MVR + TVR)	Group 1 (MVR)	Group 2 (MVR + TVR)
Grade 0	54	38	8	102
Grade 1	102	92	33	41
Grade 2	7	16	67	4
Grade 3	0	2	40	1
Grade 4	0	0	15	0
Mean TR grade	0.7 ± 0.5^a	0.9 ± 0.6^a	2.1 ± 1.0^b	0.4 ± 0.6^b

Gilles D. Dreyfus Ann Thorac Surg 2005

Concomitant Tricuspid Repair in Patients with Degenerative Mitral Regurgitation

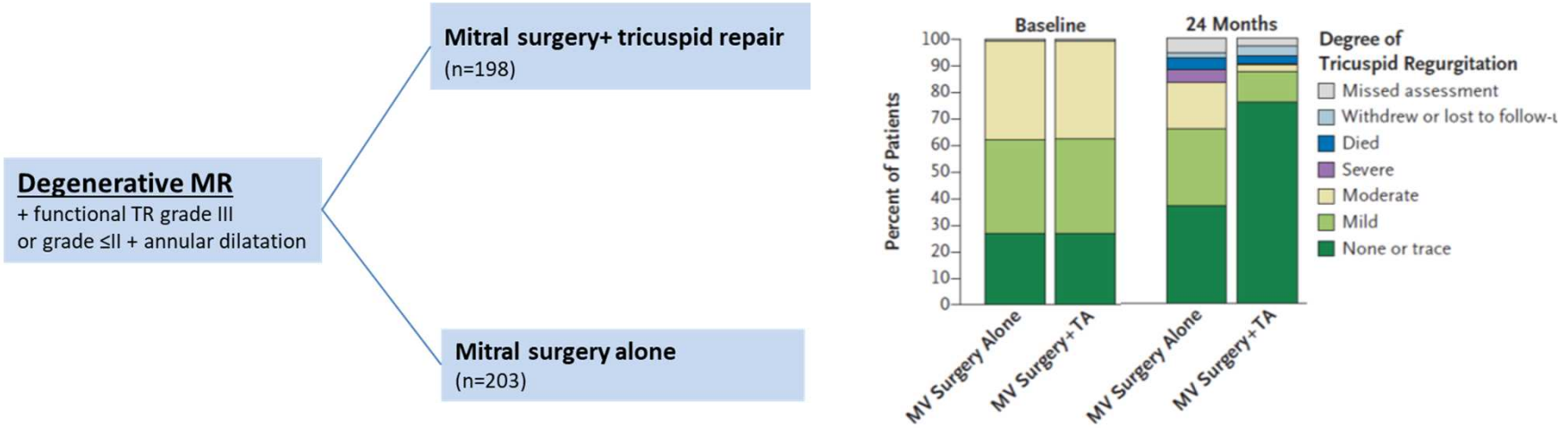
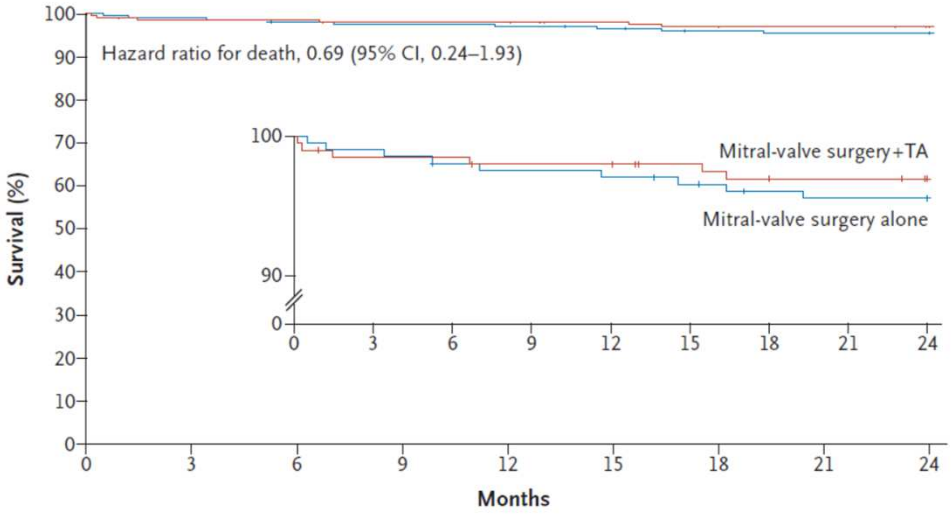


Table 2. Primary End Point.*

Composite End Point	Mitral-Valve Surgery Alone (N=203)	Mitral-Valve Surgery plus TA (N=198)	Relative Risk (95% CI)	P Value
Imputed calculation — % (95% CI)	10.2 (6.0–14.5)	3.9 (1.1–6.7)	0.37 (0.16–0.86)	0.02
Observed calculation — no./total no. (%)	20/188 (10.6)	7/185 (3.8)	0.35 (0.15–0.81)	—
Reoperation for tricuspid regurgitation	0	0	—	—
Progression of tricuspid regurgitation	11/179 (6.1)	1/179 (0.6)	0.09 (0.01–0.69)	—
Death	9/199 (4.5)	6/190 (3.2)	0.69 (0.25–1.88)	—

J.S. Gammie et al. NEJM 2021

Concomitant Tricuspid Repair in Patients with Degenerative Mitral Regurgitation



No. at Risk									
Mitral-valve surgery+TA	198	194	194	192	192	189	187	186	184
Mitral-valve surgery alone	203	201	198	197	196	194	191	190	190

Rate of PM greater in preventive TR repair (14,1% vs. 2,5%)
20 patients treated= 1 severe TR prevented but 2 PM implanted
Longer follow-up requires to evaluate the balance between PM and TR prevention

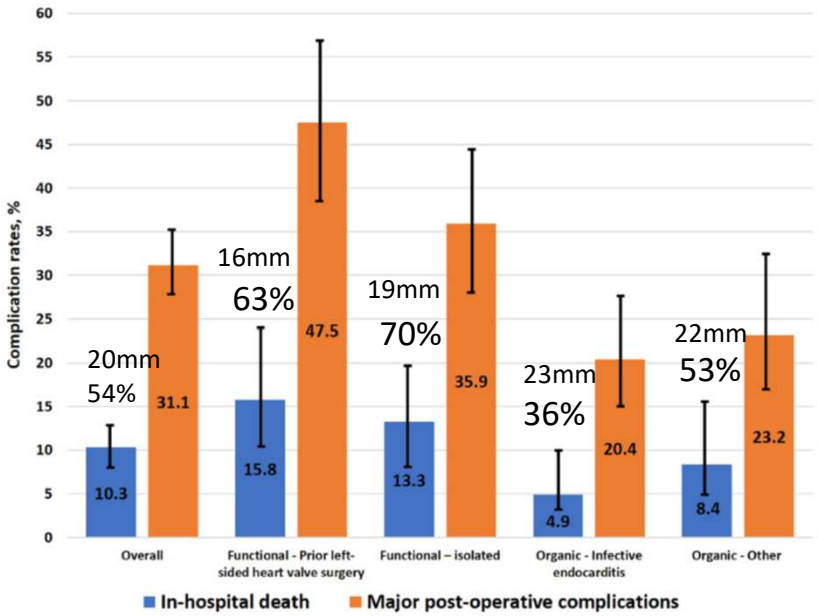
J.S. Gammie et al. NEJM 2021

Recommendations ESC 2021

Recommendations	Class	Level
Recommendations on secondary tricuspid regurgitation		
Surgery is recommended in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.	**I**	**B**
Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥40 mm or >21 mm/m^2 by 2D echocardiography) undergoing left-sided valve surgery.	**IIa**	**B**

IT SÉVERE ISOLÉE

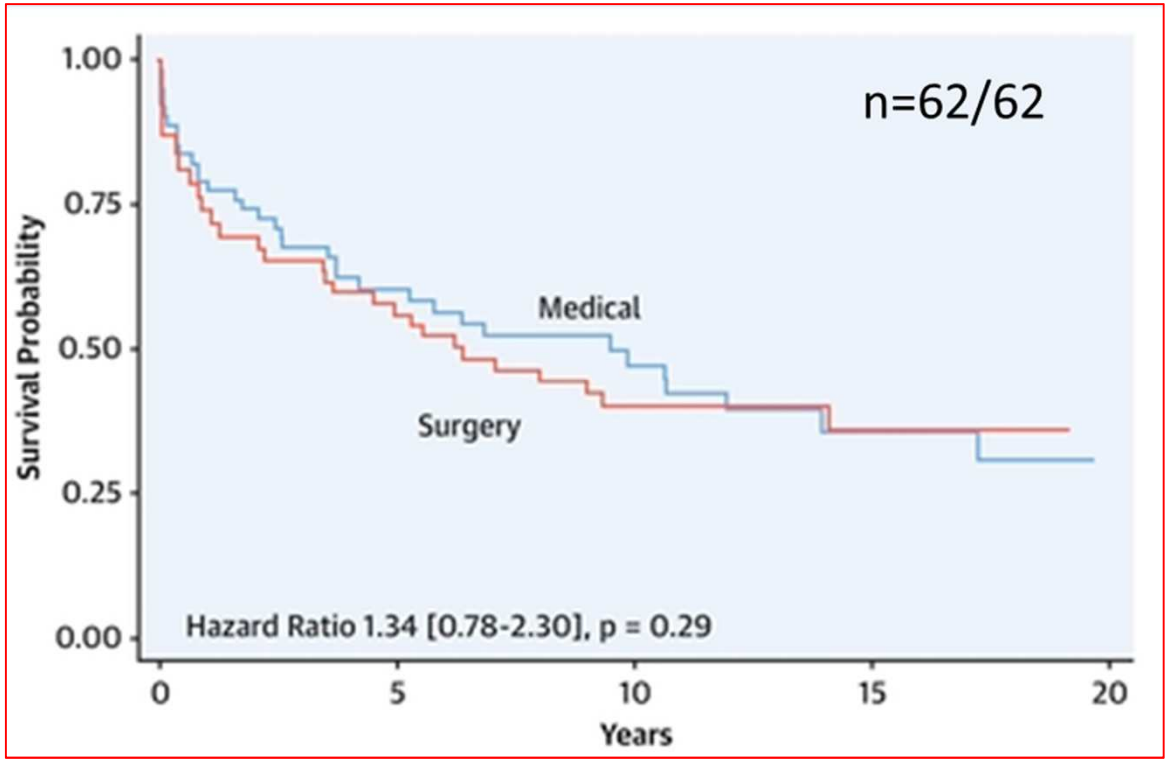
Isolated tricuspid valve surgery: impact of aetiology and clinical presentation on outcomes



- **<u>Chirurgie tricuspide isolée</u>**- 12 centres – (2007-2017) - N=466 (60 ± 16)
- **<u>49% IT fonctionnelle</u>** (22% chirurgie gauche, 27% isolée)
  - Mortalité hospitalière 10% (14% fonctionnelle et 6% organique)
  - Choc cardiogénique 19% (28% fonctionnelle et 10% organique)
- **<u>Facteurs pronostic</u>**
  - NYHA III-IV (OR=2,7)
  - Dysfonction VD subjectif (OR=2,6)
  - Signe d'insuffisance cardiaque droite (OR=2,4)
  - TP (OR=0,98)

Dreyfus J. et a. **European Heart Journal** 2020

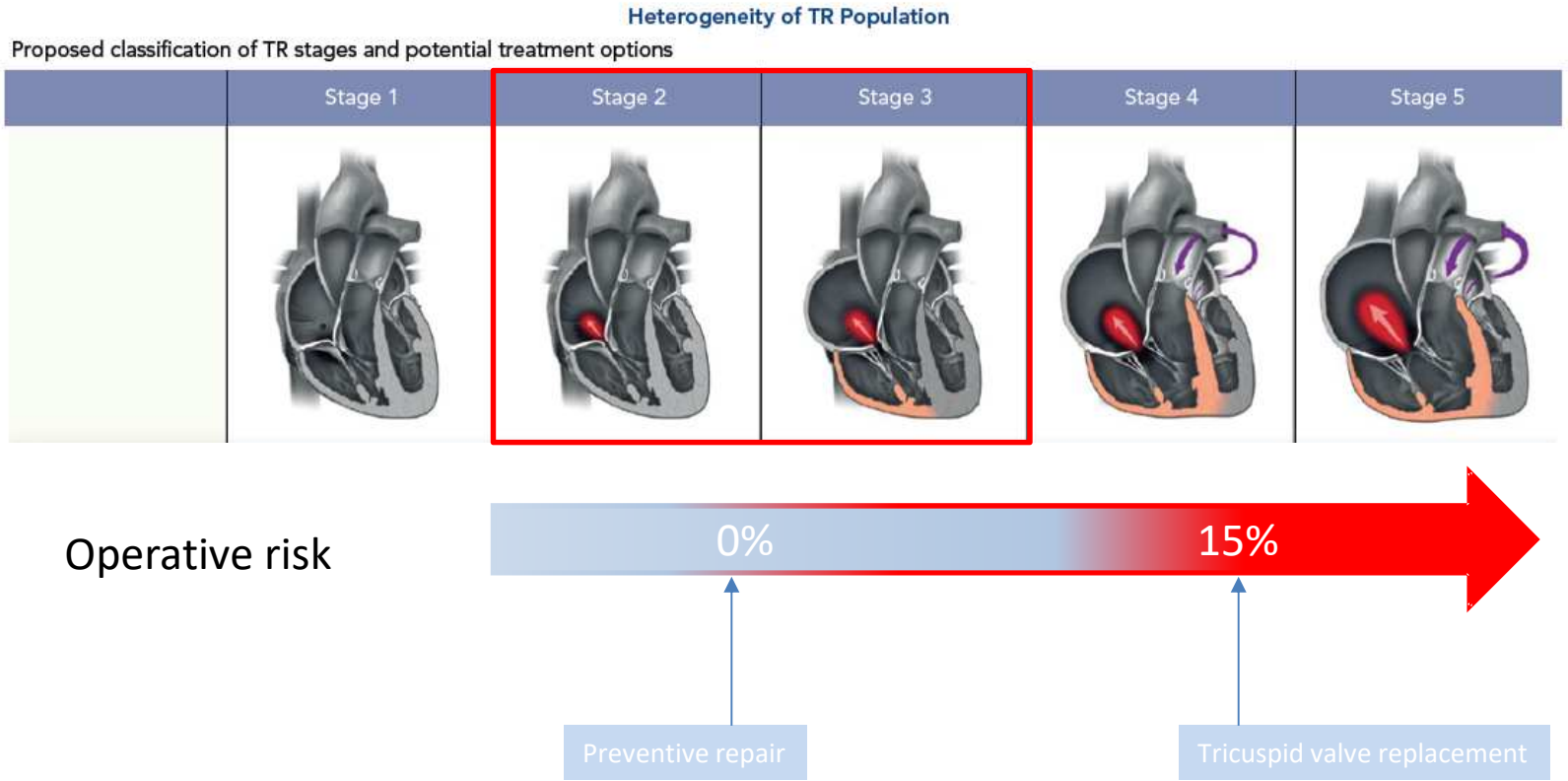
Traitement des IT isolées



Mortalité péri-opératoire=10% - Bénéfice à long terme ?

Axtell et al **J Am Coll Cardiol** 2019

Le risque chirurgical

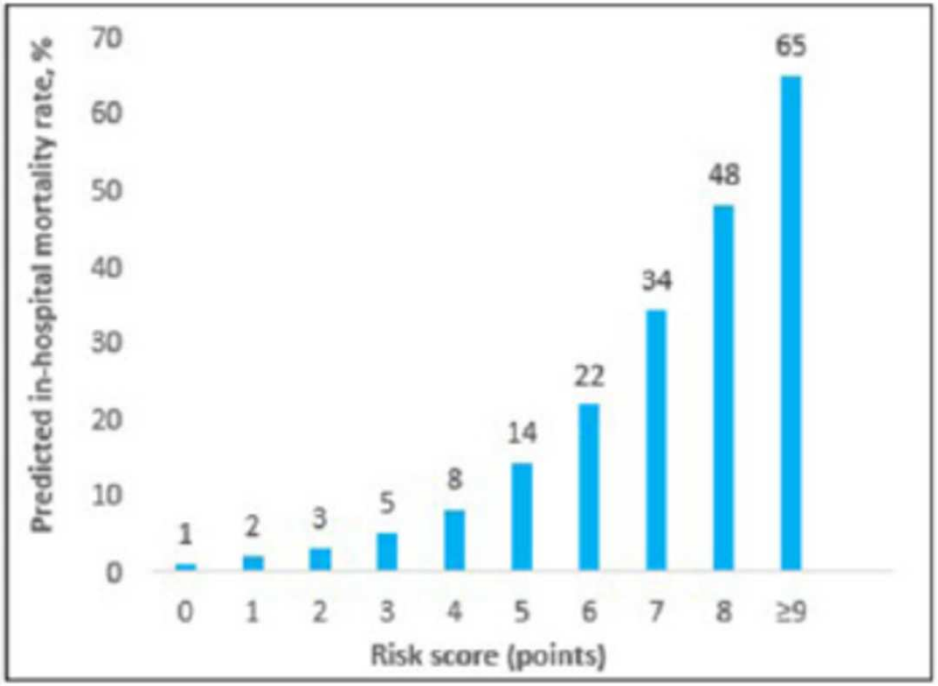


TRI-SCORE: a new risk score for in-hospital mortality prediction after isolated tricuspid valve surgery

Risk factors and scoring system for in-hospital mortality after isolated tricuspid valve surgery

Risk factors (final model from multivariate analysis)	Scoring
Age ≥ 70 years	1
NYHA functional class III-IV	1
Right-sided heart failure signs	2
Daily dose of furosemide ≥ 125mg	2
Glomerular filtration rate < 30 ml/min	2
Elevated total bilirubin	2
Left ventricular ejection fraction < 60%	1
Moderate/severe right ventricular dysfunction	1
Total	12

Predicted in-hospital mortality rate according to the final risk score model

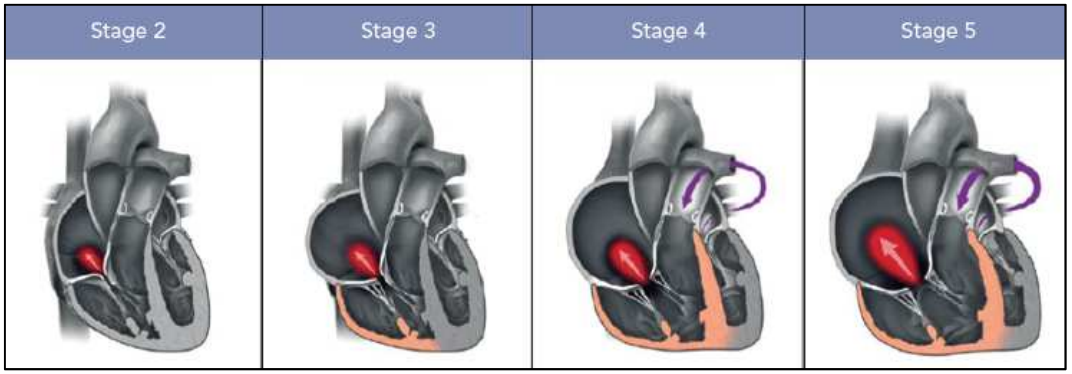


AUC=0,8 for TRI-SCORE vs. 0,63 for Euroscore II

J. Dreyfus et al. Eur Heart J **2021**

Guidelines

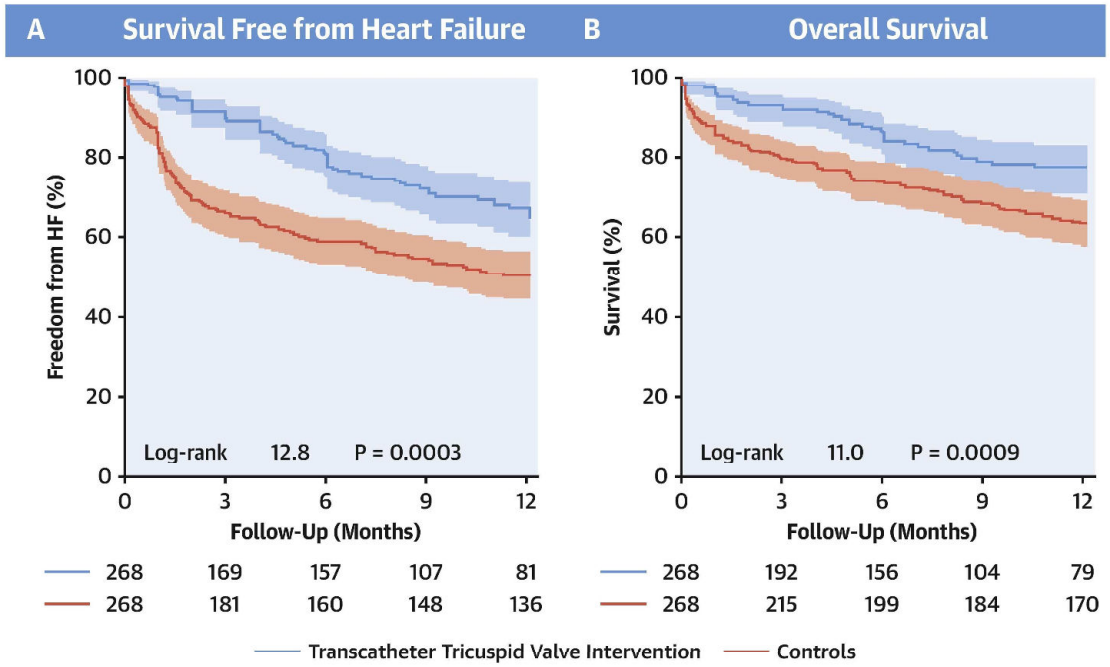
Recommendations	Class	Level
Recommendations on secondary tricuspid regurgitation		
Surgery should be considered in patients with severe secondary tricuspid regurgitation (with or without previous left-sided surgery) who are symptomatic or have RV dilatation, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension.	**IIa**	**B**
Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.	**IIb**	**C**



Faut-il corriger les IT fonctionnelles isolées?

Transcatheter Versus Medical Treatment of Patients With Symptomatic Severe Tricuspid Regurgitation

CENTRAL ILLUSTRATION: Transcatheter Treatment of Severe Tricuspid Regurgitation: Primary and Secondary Endpoints



Taramasso, M. et al. J Am Coll Cardiol. 2019;74(24):2998-3008.

Maurizio Taramasso, J Am Coll Cardiol 2019

CURRENT DEVICES IN THE PIPE

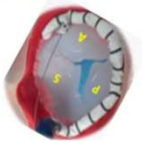
EFS → CE-marked

Annuloplasty

TriCinch

Trialign

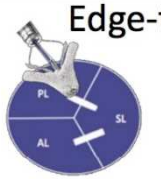
Cardioband



Coaptation

Forma

Edge-to-Edge

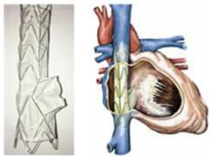


Clip

Pascal

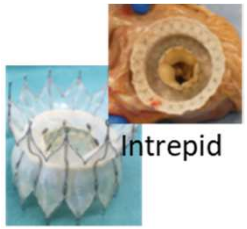
Heterotopic

Tricento



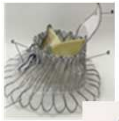
TricValve

Replacement



Intrepid

Tricares



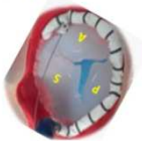
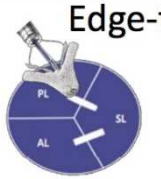
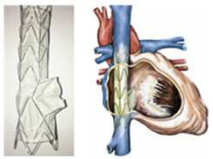
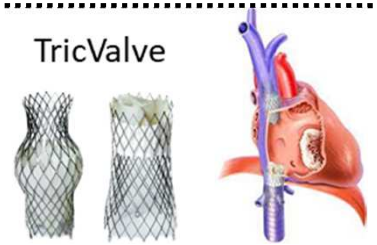
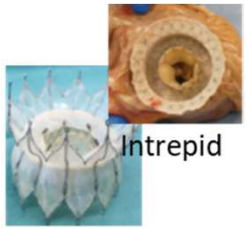
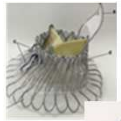
Lux

Navigate

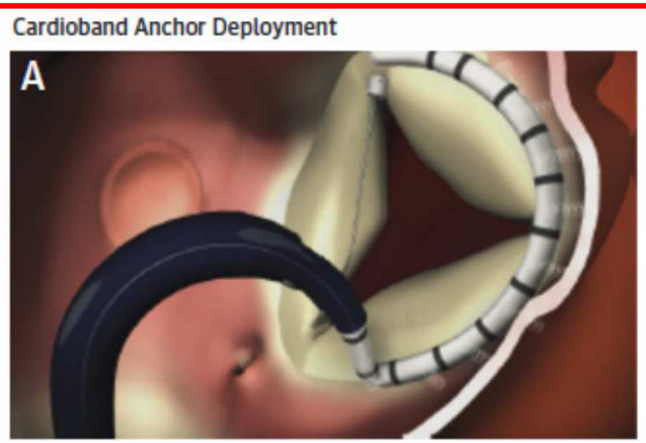
Evoque

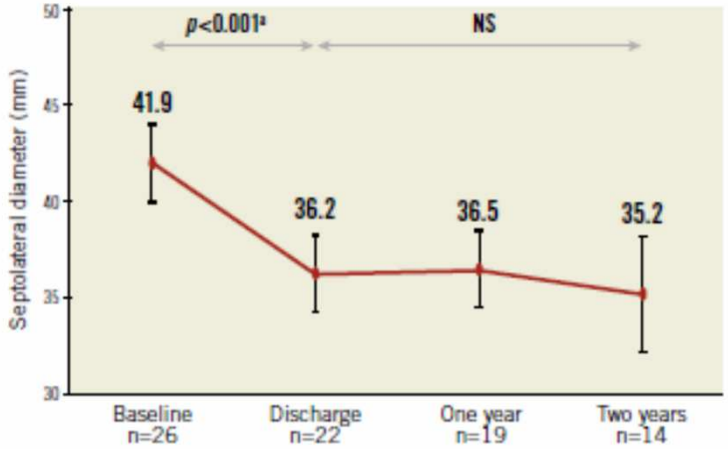
CURRENT DEVICES IN THE PIPE

EFS → CE-marked

Annuloplasty	TriCinch  Trialign  Cardioband 
Coaptation	Forma  Edge-to-Edge  Clip  Pascal
Heterotopic	Tricento  TricValve 
Replacement	 Intrepid Tricares  Lux  Navigate  Evoque

CARDIOBAND





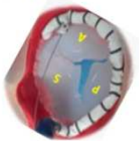
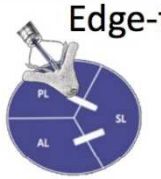
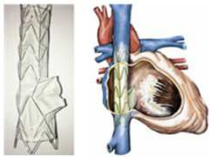
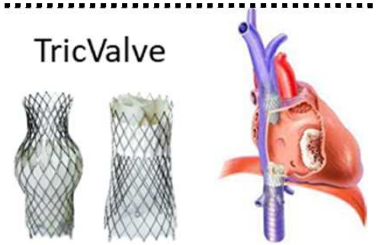
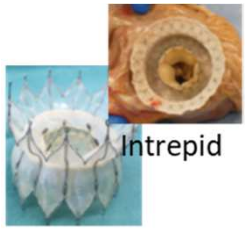
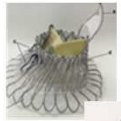
Population: N=30 IT fonctionnelle sévère (EROA=0.79±0.51mm²)
Anatomie: Φ anneau entre 40mm et 50mm, FEVG>30%, PAPS<60mmHg

Résultats: Succès d'implantation 100%, mortalité péri-procédure: 6,7%
Amélioration clinique (82% vs. 17% en classe NYHA II à 2 ans)
Limites
Durée de procédure : **4,2±1,5 heures** (16 vis en moyenne) - ETO+++
Efficacité modérée sur la fuite [**36% grade ≤II,** EROA=0.34±0,23mm² à 2 ans 0.79±0.51mm²]

Georg Nickenig, **Euro-intervention** 2021

CURRENT DEVICES IN THE PIPE

EFS → CE-marked

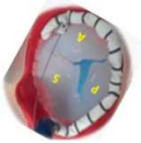
Annuloplasty	TriCinch  ✗ Trialign  ✗ Cardioband  ✓
Coaptation	Forma  Edge-to-Edge  Clip  Pascal
Heterotopic	Tricento  TricValve 
Replacement	 Intrepid Tricares  Lux  Navigate  Evoque

CURRENT DEVICES IN THE PIPE

EFS → CE-marked

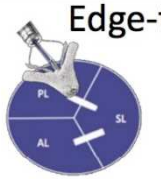
Annuloplasty

TriCinch ✗ Trialign ✗ Cardioband ✓

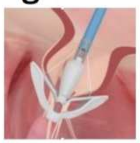


Coaptation

Forma ✗ Edge-to-Edge



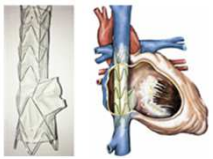
Clip



Pascal

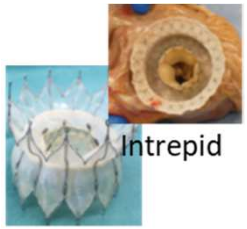
Heterotopic

Tricento



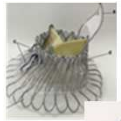
TricValve

Replacement



Tricares

Intrepid

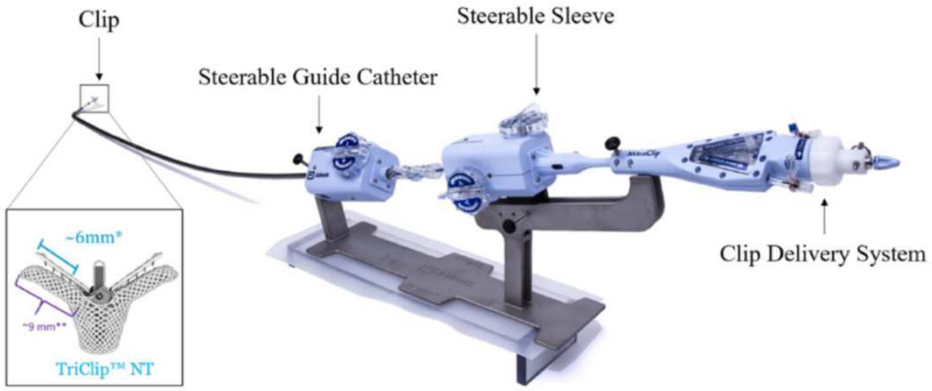


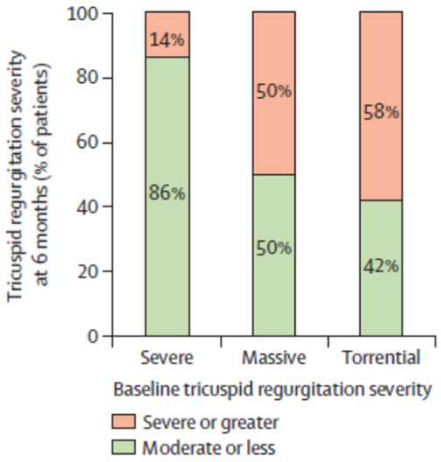
Lux

Navigate

Evoque

Edge-to-edge: MitraClip



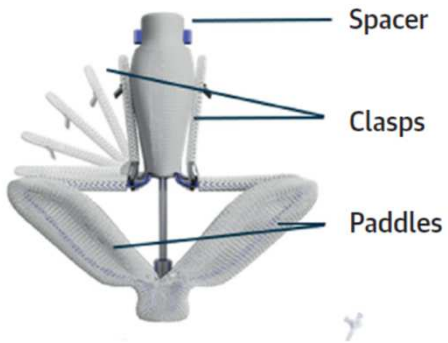


Population: N=85 patients IT fonctionnelle modérée à sévère (EROA=0.65±0.29 mm²)
Anatomie: Défect coaptation <20mm, FEVG>20%, PAPS<60mmHg

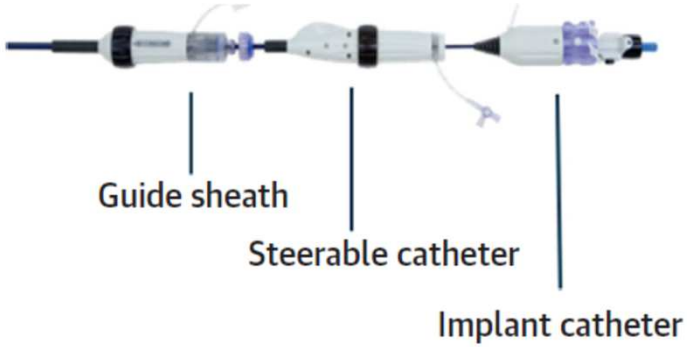
Résultats: 90% Succès implantation – **5% de mortalité à 6 mois** (non liée à la procédure)
Amélioration clinique soutenue (80% vs. 25% en classe NYHA I-II à 1 mois et un an)
Limites
Durée de procédure : 2,6±1 heures (67% 1-2 clips -77% sur la commissure AS)
Qualité imagerie ETO +++
Efficacité modérée sur la fuite [32% grade ≤II, EROA=0.65±0.29cm² to 0.41±0.29cm²]

Nickenig G, **Lancet** 2019 and Lurz P, **J Am Coll Cardiol** 2021

Edge-to-edge: PASCAL



Combinaison de spacer et clips
2 larges clips à mobilité indépendante
Récupérable



Steerable sheath-catheter (22F)
with 3 independent planes

Population: N=34 patients IT fonctionnelle sévère (EROA=0.71±0.33mm²)
Anatomie: gap de coaptation <10mm, longueur de feuillet >8mm FEVG>30%, PAPS<60mmHg
Résultats: 80% Succès implantation – 0% de mortalité péri-procédure
Amélioration clinique (89% vs. 22% en classe NYHA I-II à 1 mois)

Limites
Durée de procédure : **2,8±2,5 heures** (1-2 clips -80% sur les commisures AS)
Qualité imagerie ETO (1/3 exclusion)
Efficacité modérée sur la fuite [Seulement 19% grade ≤II, EROA=0.77±0.32cm² to 0.48±0.24cm²]

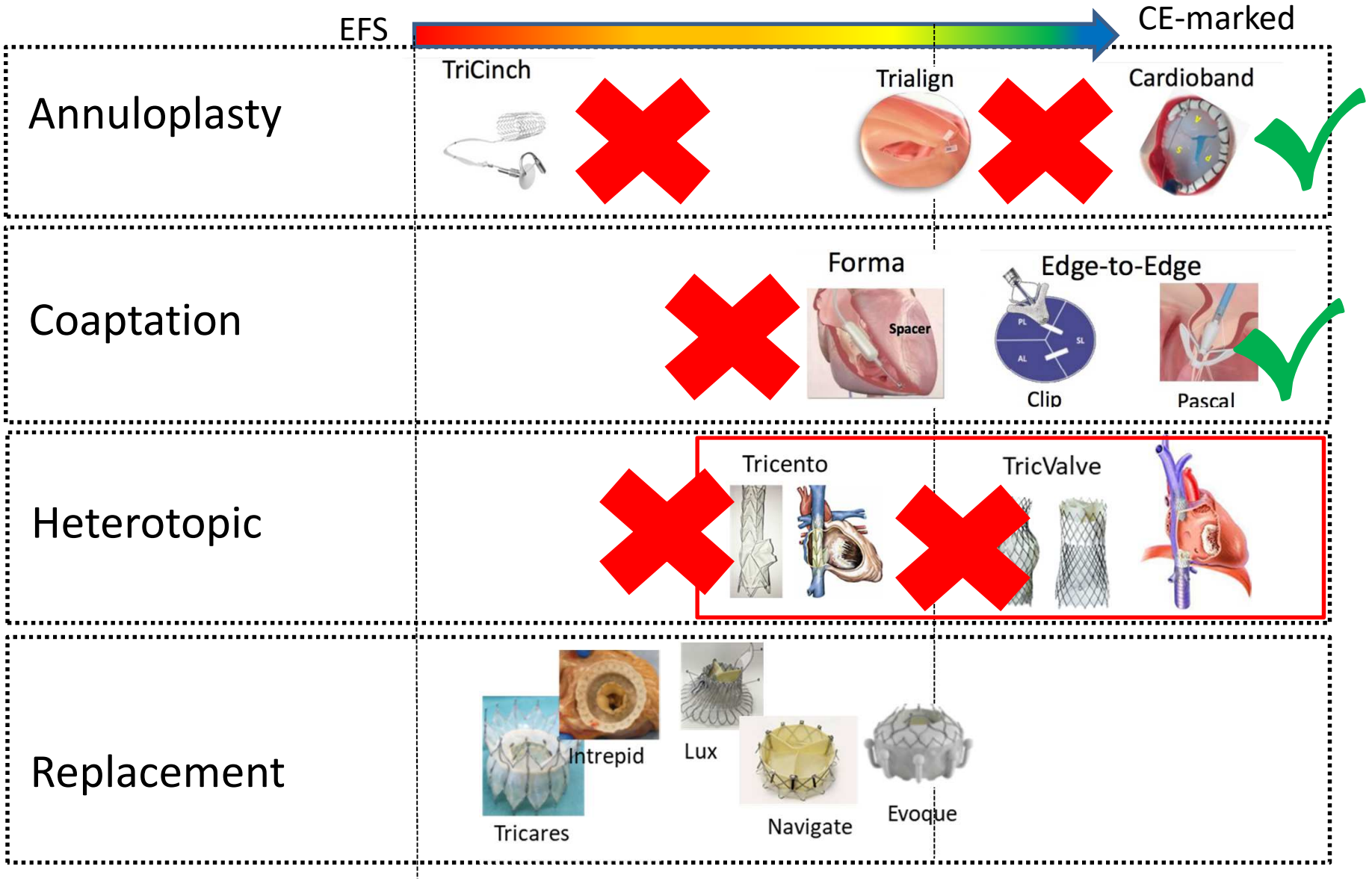
Kodali et al. **J Am Coll Cardiol**. 2021

CURRENT DEVICES IN THE PIPE

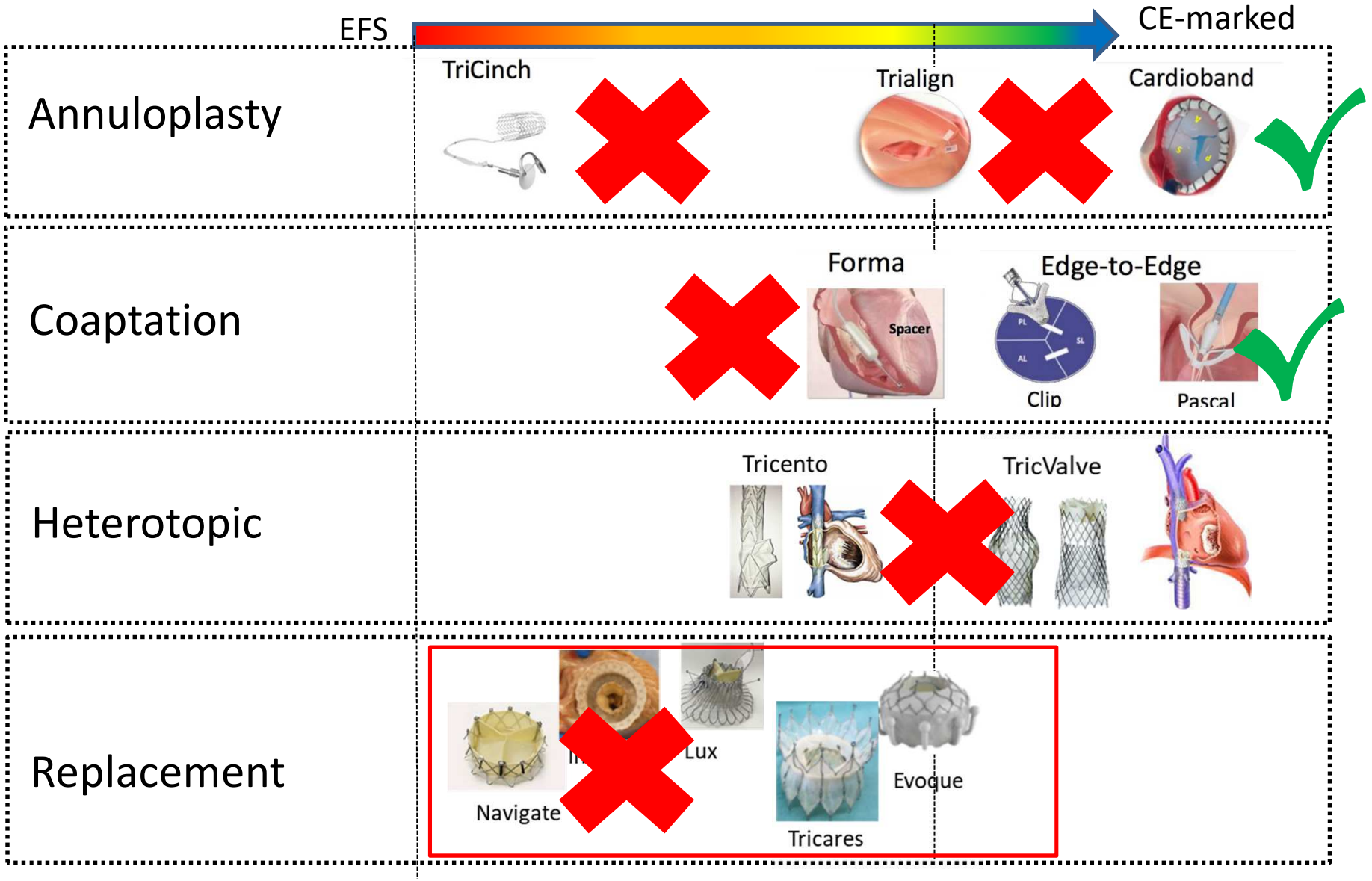
EFS → CE-marked

Annuloplasty	TriCinch ✗ Trialign ✗ Cardioband ✓
Coaptation	✗ Forma (Spacer) Edge-to-Edge (Clip) Pascal ✓
Heterotopic	Tricento TricValve
Replacement	Intrepid Tricares Lux Navigate Evoque

CURRENT DEVICES IN THE PIPE



CURRENT DEVICES IN THE PIPE



EVOQUE (EDWARDS)

A

Deux tailles 44mm (32%) 48 (64%) mm

B

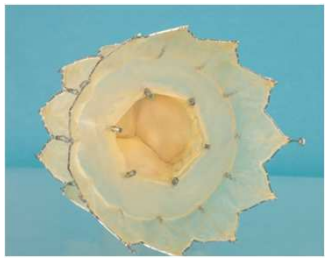
28F – femoral access

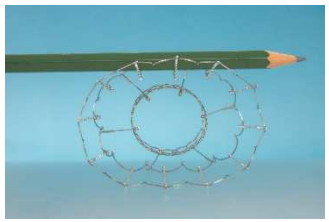
Population: N=25 patients IT fonctionnelle sévère (EROA=0.86±0.21cm²)
Anatomie: Φ anneau<48mm (45±3mm- 3% oversizing), dysfonction VD, PAPS<60mmHg
Résultats: 92% Succès implantation **– 0% de mortalité péri-procédure**
Amélioration clinique (76% vs.4% en classe NYHA I-II à 1 mois)
Efficacité sur la fuite [92% grade ≤I]

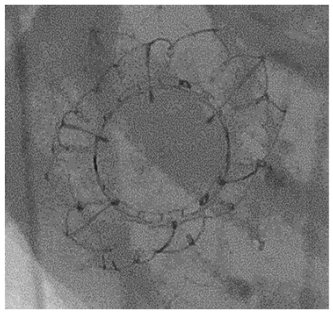
Limites
Durée de procédure : 2,3±2,5 heures
8% de BAV III
Taille des prothèses

Neil P. Fam et al. **J Am Coll Cardiol Intv** 2021

Topaz TTVR Prosthesis







- Designed for transfemoral tricuspid valve replacement
- Self-expanding prothesis – no need to capture leaflets
- Porcine pericardium – three leaflet valve for excellent hemodynamics
- Two stent design
- Conforms to patients' native tricuspid anatomy, outer sent adapts to anatomy while inner valve maintains round and competent to assure perfect leaflet coaptation
- Atraumatic anchors for secure and safe fixation in the leaflets
- Currently for tricuspid annuli up to 45mm

TRiCares Topaz TTVR implant in an animal at 90 days post implant. The outer stent adapts to the elliptic annulus while the inner stent containing the valve is circular

Topaz TTVR - Early Compassionate Use Experience

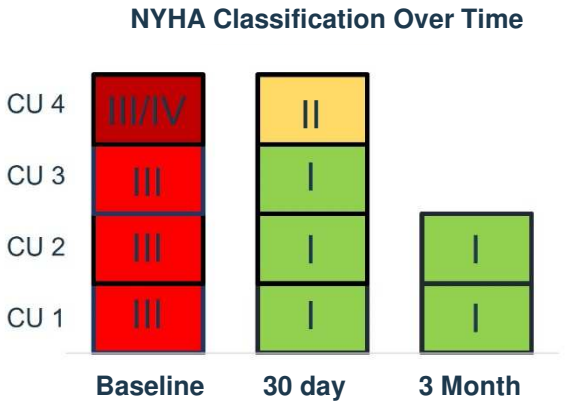
* **Centre Hospitalier Universitaire Henri-Mondor, Créteil, Paris, France**
Emmanuel Teiger, MD
Romain Gallet de Saint Aurin, MD

** **Centre Cardiologique du Nord, Saint-Denis, Paris, France**
Mohamed Nejjari, MD
Julien Dreyfus, MD

Baseline	CU 1* June 7th, 2021	CU 2** June 28th, 2021	CU 3* Oct 4th, 2021	CU4* Oct 4th, 2021
Age, Gender	70, F	86, F	82, F	88, F
NYHA Class	III	III	III	III/IV
Tricuspid Regurgitation (Grade 1-5)	Massive (4)	Torrential (5)	Severe (3)	Torrential (5)
Co-morbidities	Afib, DM, HTN, ASD, chron. Renal Failure,	Afib, HTN, HF, chron. Renal Failure, Pulm. Emphysema,	Afib, chron. Renal Failure, Cancer (Breast 1970&98)	Afib, HF, Pericarditis, chron. Renal Failure, Hypothyroidism
TRI-SCORE[1] estimated in-hospital mortality rate	5 14%	6 22%	5 14%	8 48%

[1] Julien Dreyfus et al. TRI-SCORE: a new risk score for in-hospital mortality prediction after isolated tricuspid valve surgery, Eur Heart J 2021 Sep 29;ehab679. doi: 10.1093/eurheartj/ehab679.

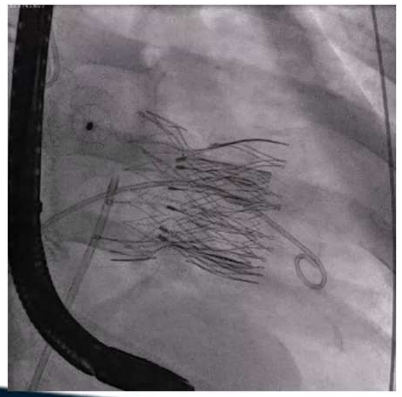
Topaz TTVR - Early Compassionate Use Experience



Procedure Discharge	CU 1	CU 2	CU 3	CU4
Procedure Time*	18 min	12 min	20 min	48 min
NYHA Class Discharge	I	I	I	II
Tricuspid Regurgitation (Grade 1-5)	None (0)	None (0)	None (0)	Mild (1)
Discharged on POD	4	4	15	15

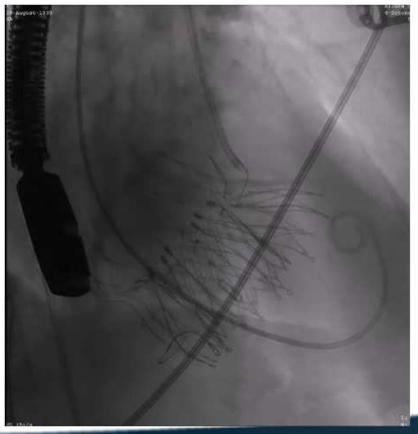
* Definition: Time from Topaz delivery system in, followed by valve deployment to delivery system out

CU 1

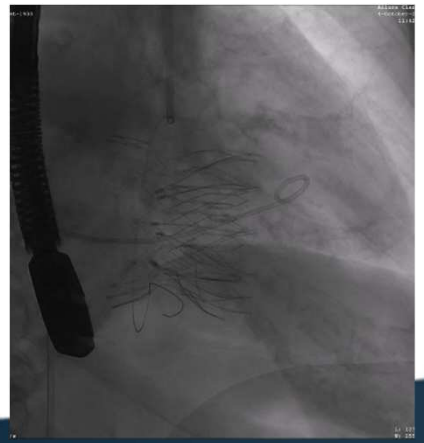


CU 2

CU 3

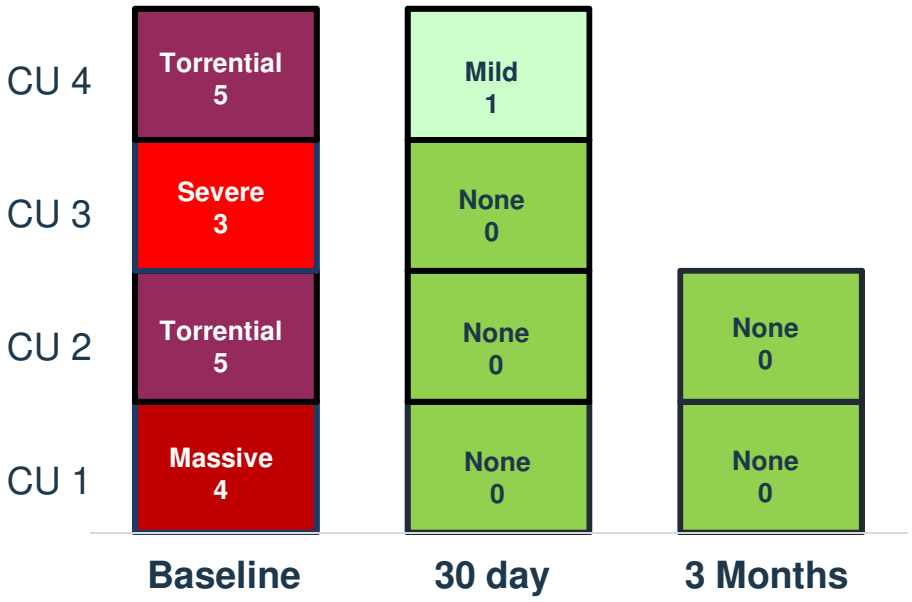


CU 4



Topaz TTVR - Early Compassionate Use Experience

TR Grade Over Time



Adverse Events 30 day	Base N= 4
Mortality	0
Stroke	0
Reintervention*	1
HF hospitalization	0
Dialysis requirement	0
New PPM	0

* Valve implanted as intended, due to two radiation therapy highly pathologic leaflets / very thick and fibrotic, incomplete anchoring, movement of valve at inferior aspect of valve, surgical reintervention, fixation of valve with U pledgeted sutures

Topaz TTVR - Compassionate Use Case 1

Conclusion on First Experience with TRiCares Topaz TTVR

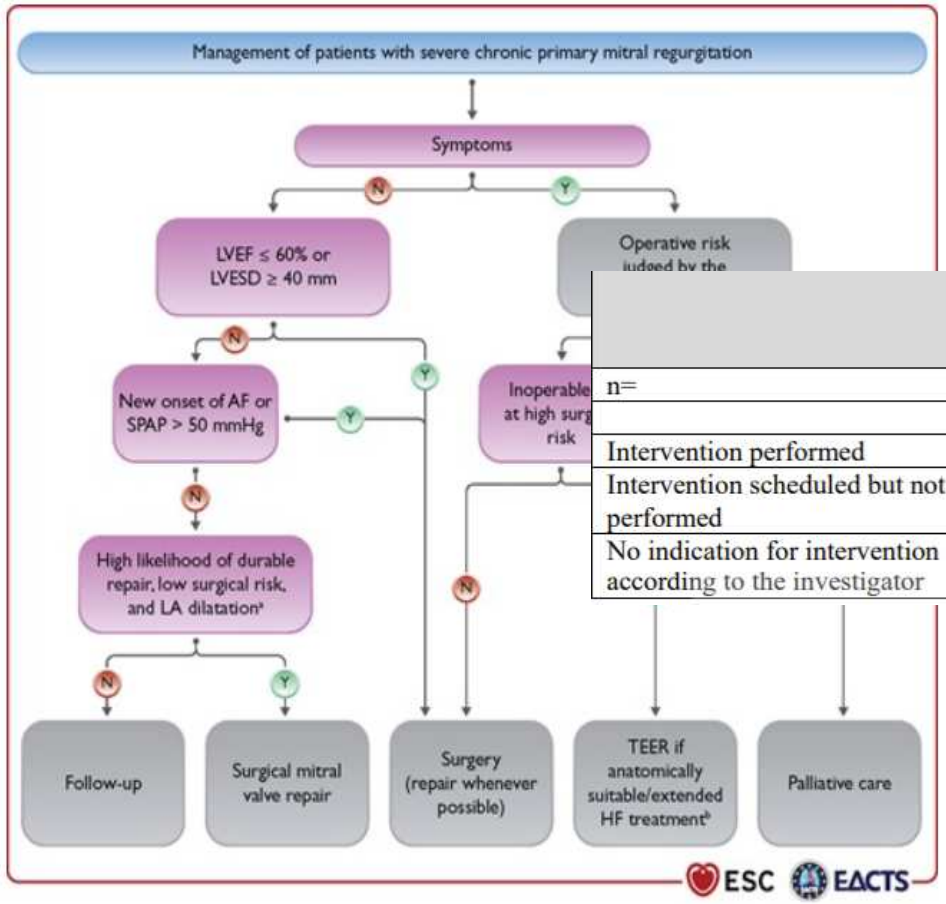
- All four patients improved significantly in NYHA classification at 30-day FUP
- All four patients reduced significantly TR grade by more than three grades
- No in-hospital mortality despite high risks profiles
- No rehospitalization for Heart Failure

Early experience with the Topaz TTVR confirms safe implantation and effective short-term outcome, further data needed.

The **TRICURE F**irst-**I**n-**H**uman Trial is planned for early 2022.

Valves mitrales percutanées : les avancées en 2021

Pourquoi des traitements percutanés?



	Primary mitral reurgitation	Secondary mitral regurgitation
n=	746	368
Intervention performed	277 (37.1)	90 (24.5)
Intervention scheduled but not performed	191 (25.6)	51 (13.8)
No indication for intervention according to the investigator	278 (37.3)	227 (61.7)

Recommendations	Class[b]	Level[c]
Valve surgery/intervention is recommended only in patients with severe SMR who remain symptomatic despite GDMT (including CRT if indicated) and has to be decided by a structured collaborative Heart Team.[247,323,336,337]	I	B
…onary artery or other cardiac		
…tients	I	B
…dged not …t Team on …ristics,[d] PCI …TEER (in …ld be	IIa	C
Patients without concomitant coronary artery or other cardiac disease requiring treatment		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment.[337,338,356,357 e]	IIa	B

Techniques disponibles

- Réparation:
  - Réparation bord à bord
  - Annuloplastie
  - Néocordages
- Remplacement:
  - « valves in »
  - Tendyne
  - Intrepid
  - Autres

Mitraclip: recommandations

IM primitive

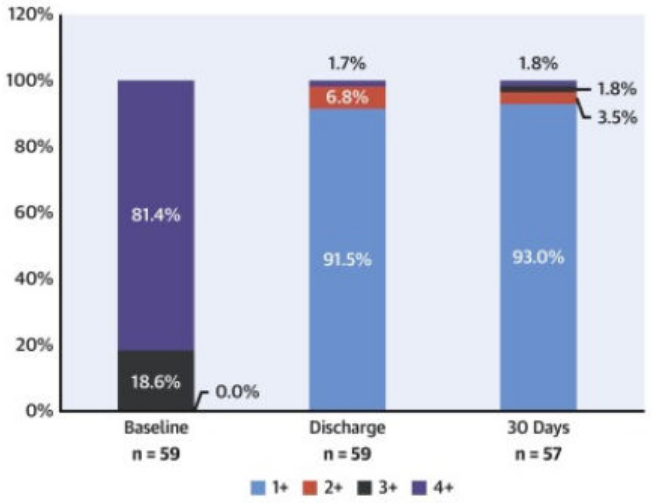
TEER may be considered in symptomatic patients who fulfil the echocardiographic criteria of eligibility, are judged inoperable or at high surgical risk by the Heart Team and for whom the procedure is not considered futile.[299–302]	IIb	B

Remboursement sur les 2 indications depuis fin 2019

IM secondaire

Patients with concomitant coronary artery or other cardiac disease requiring treatment		
Valve surgery is recommended in patients undergoing CABG or other cardiac surgery.[329,330,333]	I	B
In symptomatic patients, who are judged not appropriate for surgery by the Heart Team on the basis of their individual characteristics,[d] PCI (and/or TAVI) possibly followed by TEER (in case of persisting severe SMR) should be considered.	IIa	C
Patients without concomitant coronary artery or other cardiac disease requiring treatment		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment.[337,338,356,357 e]	IIa	B

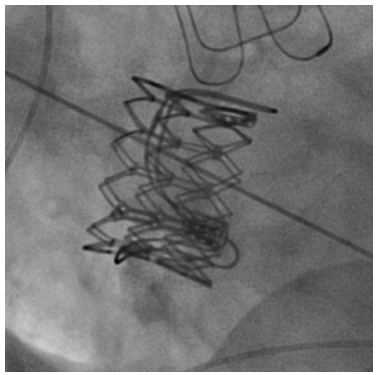
Nouveautés sur le Mitraclip



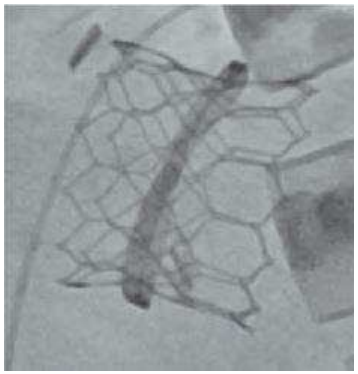
Remplacement: Valves-in

Valve in

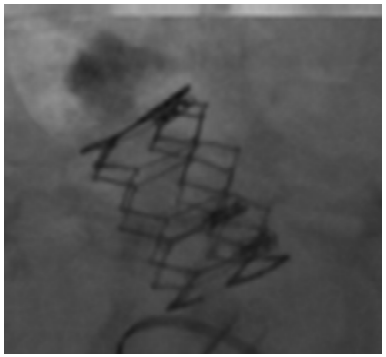
Valve

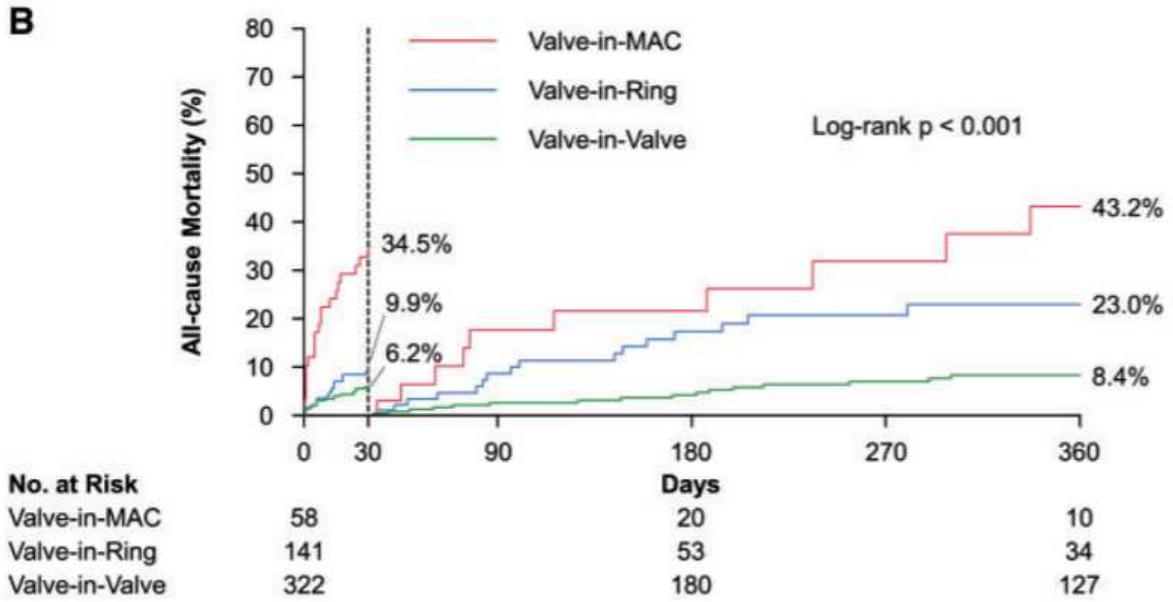


Ring



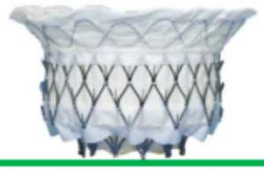
MAC



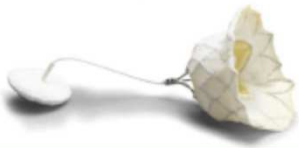

B
All-cause Mortality (%)
80
70
60
50
40
30
20
10
0
Valve-in-MAC
Valve-in-Ring
Valve-in-Valve
Log-rank p < 0.001
34.5%
9.9%
6.2%
43.2%
23.0%
8.4%
0
30
90
180
270
360
Days
No. at Risk
Valve-in-MAC 58 20 10
Valve-in-Ring 141 53 34
Valve-in-Valve 322 180 127

Transapical Systems

Medtronic Intrepid



Abbott Tendyne



Neovasc Tiara

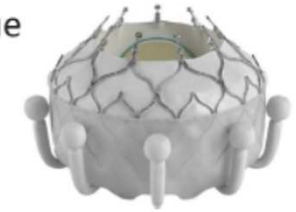
Transseptal Systems

4 C Medical Altavalve

Cardiovalve

Abbott Cephea

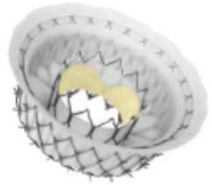
Edwards Evoque



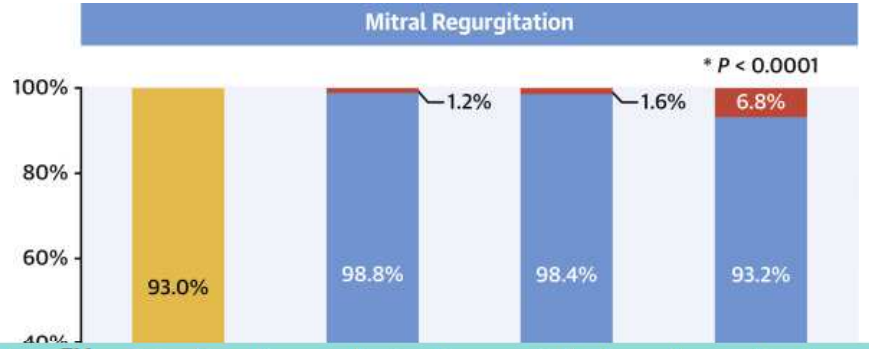
Highlife

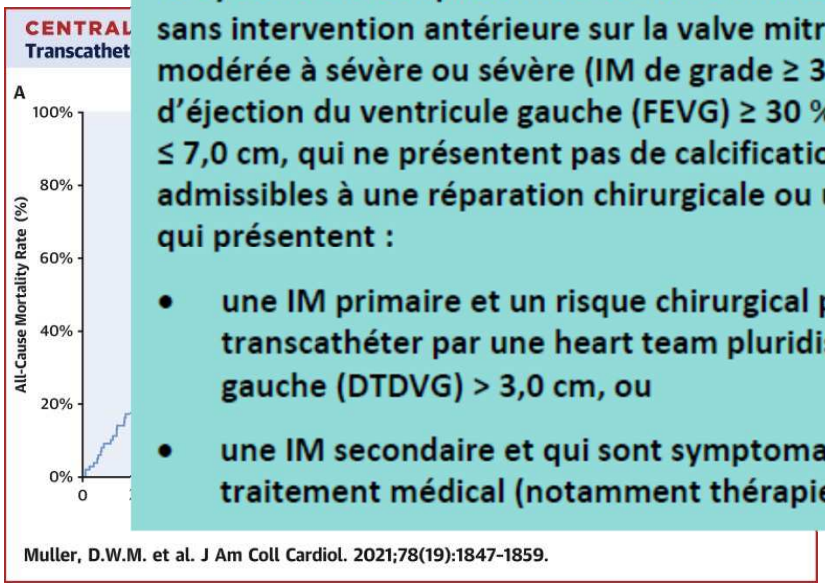
Edwards Sapien M3

Medtronic Intrepid



Résultats à 2 ans

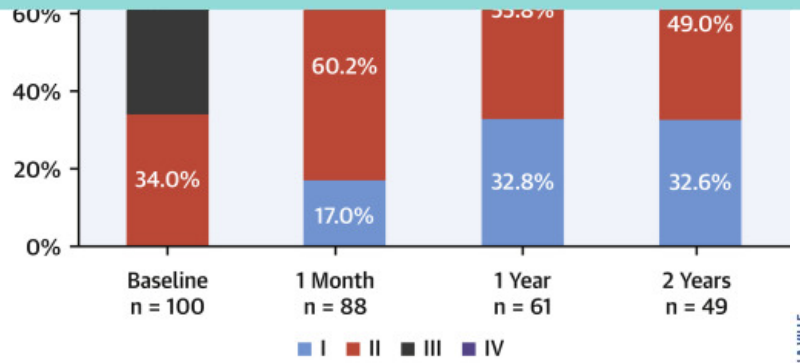




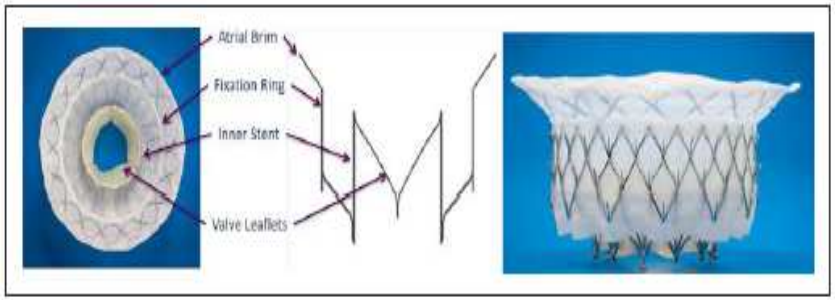
Muller, D.W.M. et al. J Am Coll Cardiol. 2021;78(19):1847-1859.

Le système de remplacement de valve mitrale Tendyne™ est indiqué pour le traitement de la valve mitrale native sans intervention antérieure sur la valve mitrale chez les patients présentant une insuffisance de la valve mitrale modérée à sévère ou sévère (IM de grade ≥ 3+), avec une espérance de vie inférieure à 5 ans, une fraction d'éjection du ventricule gauche (FEVG) ≥ 30 %, une dimension télédiastolique du ventricule gauche (DTDVG) ≤ 7,0 cm, qui ne présentent pas de calcification sévère de l'anneau mitral et qui ne sont pas considérés comme admissibles à une réparation chirurgicale ou un remplacement chirurgical par une heart team pluridisciplinaire, et qui présentent :

- **une IM primaire et un risque chirurgical prohibitif, qui sont considérés comme non admissibles à la réparation transcathéter par une heart team pluridisciplinaire et qui ont une dimension télédiastolique du ventricule gauche (DTDVG) > 3,0 cm, ou**
- **une IM secondaire et qui sont symptomatiques, malgré la prise des doses maximales recommandées de traitement médical (notamment thérapie de resynchronisation cardiaque, si elle est indiquée).**

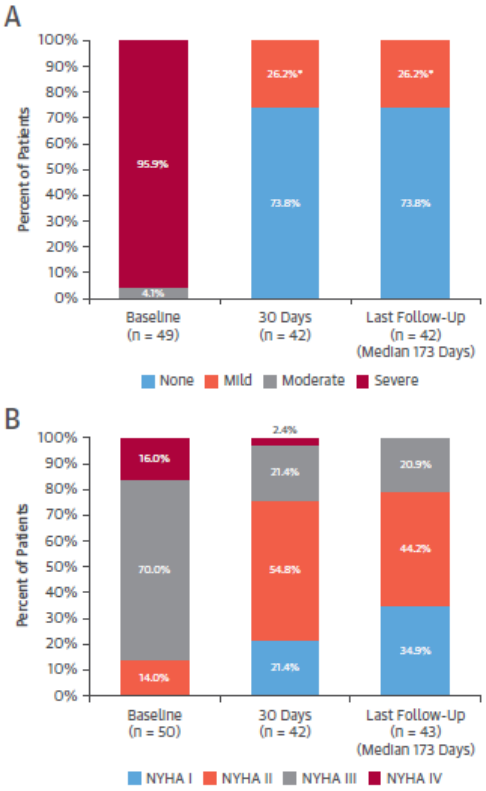


Intrepid



STS predicted risk of mortality for mitral replacement, %	6.4 ± 5.5
EuroSCORE II, %	7.9 ± 6.2

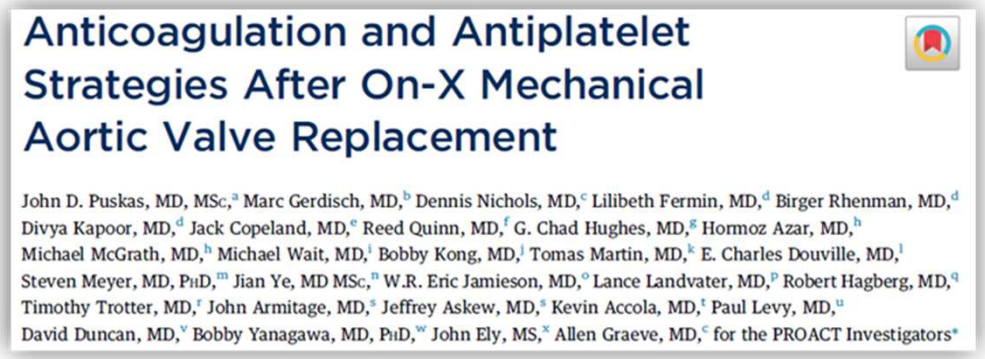
- > 300 patients traités
- Développement d'une voie transfémorale
- TheAPOLLO trial, investigating patients eligible for surgery randomized 1:1 to TMVR versus surgicaltherapy and nonrandomized use in patients ineligible for surgery, is under way. Up to 300 patients with significant MAC are included in the study.



Conclusion

- Mitraclip remboursé dans l'IM primitive et secondaire, plusieurs tailles disponibles, technique la plus mature
- Nouvelles techniques de réparation (anneau, cordages) avec possibilité de combinaison
- Remplacement valvulaire de plus en plus proche, screening des patients, abord transfémoral

PROACT (Reduced INR) High Risk Arm



Anticoagulation and Antiplatelet Strategies After On-X Mechanical Aortic Valve Replacement

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Position	PROACT Study Design	Standard (Control)	Low Dose (Test)	Status
Aortic	Multicenter(n=41), randomized, controlled, non-inferior trial design, 1 or more TE risk factors, home INR monitoring	**Enrollment:** n=190 **First 90 days:** 2.0 – 3.0 INR **Long-term:** 2.0 – 3.0 INR **Aspirin:** 81 mg/day	**Enrollment:** n=185 **First 90 days:** 2.0 – 3.0 INR **Long-term:** 1.5 – 2.0 INR Aspirin: 81 mg/day	**Study completed** (>5 year FU, n=375) - >60% lower bleeding, non-inferior TE rate - Low INR labeling approved by FDA/CE - JACC Publication 2018 - Low INR added to AHA/ACC Guidelines
Mitral	Multicenter(n=41), randomized, controlled, non-inferior trial design, 1 or more TE risk factors, home INR monitoring	**First 90 days:** 2.5 – 3.5 INR **Long-term:** 2.5 – 3.5 INR **Aspirin:** 81 mg/day	**First 90 days:** 2.5 – 3.5 INR **Long-term:** 2.0 – 2.5 INR **Aspirin:** 81 mg/day	**Actively enrolling** (n=310) - ~500 pt-yrs FU - Trending to non-inferiority - ~3 years to FDA approval

1. On-X Prosthetic Heart Valve Instructions for Use
2. Puskas J et al,. J Thorac Cardiovasc Surg. 2014; 147:1202-11.

CARDIOCONNECT
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Votre équipe

PROACT (Reduced INR) High Risk Arm

TABLE 4 Outcomes in the High-Risk Arm

	Standard Warfarin (INR 2.0-3.0) (1,090.0 pt-yrs)		Low-Dose Warfarin (INR 1.5-2.0) (945.2 pt-yrs)		Rate Ratio (Standard/Low-Dose Warfarin)	95% CI	p Value
	n	Rate (%/pt-yr)	n	Rate (%/pt-yr)			
Primary endpoint	102	9.35	52	5.50	0.59	0.42-0.82	0.002
Components of co-primary endpoint							
Major bleeding	43	3.94	15	1.59	0.40	0.22-0.72	0.002
Minor bleeding	38	3.49	12	1.27	0.36	0.19-0.70	0.002
Cerebral bleeding	4	0.37	1	0.11	0.29	0.03-2.58	0.30
Total bleeding	81	7.43	27	2.86	0.38	0.25-0.59	<0.001
Stroke	7	0.64	7	0.74	1.15	0.40-3.29	0.80
TIA	11	1.01	12	1.27	1.26	0.56-2.85	0.60
Any neurological event	18	1.65	19	2.01	1.22	0.64-2.32	0.50
Peripheral TE event	1	0.09	4	0.42	4.61	0.52-41.28	0.20
Valve thrombosis	2	0.18	2	0.21	1.15	0.16-8.19	0.90
Major bleed, TE event or thrombosis	64	5.87	40	4.23	0.72	0.49-1.07	0.10
Sudden death	3	0.28	3	0.32	1.15	0.23-5.72	0.90
Valve-related mortality	4	0.37	2	0.21	0.58	0.11-3.15	0.50
Total mortality	17	1.56	13	1.38	0.88	0.43-1.82	0.70

The primary composite endpoint includes death, any bleeding (major or minor), and any TE and valve thrombosis.
Abbreviations as in Table 2.

Bleeding – 67% Reduction

Stroke – No Difference

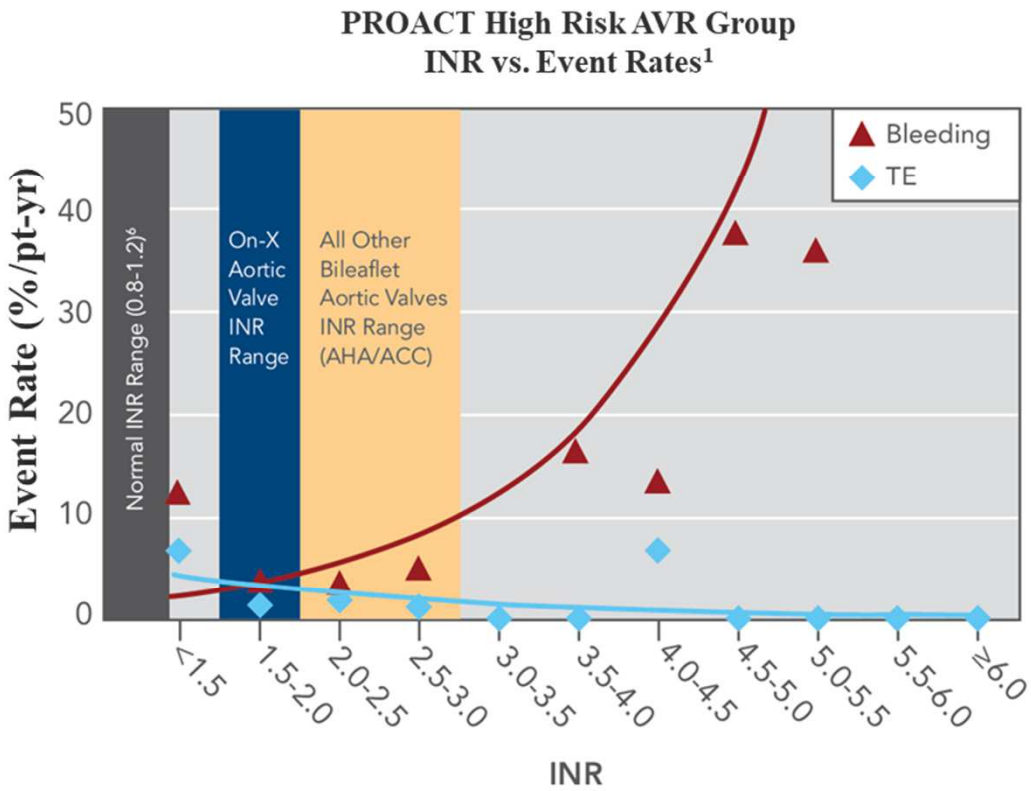
Mortality – 24% Reduction

1. On-X Prosthetic Heart Valve Instructions for Use
2. Puskas J et al,. J Thorac Cardiovasc Surg. 2014; 147:1202-11.

PROACT Results: AVR High Risk Group

Test group had
>60% reduction in total bleeding events

No difference in TE rates
between groups



1. Data on File. 6. Levine M et al., Can Fam Physician. 2012;58:e465-71.

Part 2: 2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease

A mechanical prosthesis should be considered in patients aged <60 years for prostheses in the aortic position and aged <65 years for prostheses in the mitral position [462, 464]. [e]	IIa	B

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian * (ESC Chairperson) (France), Friedhelm Beyersdorf*[1] (EACTS Chairperson) (Germany), Fabien Praz (ESC Task Force Coordinator) (Switzerland), Milan Milojevic[1] (EACTS Task Force Coordinator) (Serbia), Stephan Baldus (Germany), Johann Bauersachs (Germany), Davide Capodanno (Italy), Lenard Conradi[1] (Germany), Michele De Bonis[1] (Italy), Ruggero De Paulis[1] (Italy), Victoria Delgado (Netherlands), Nick Freemantle[1] (United Kingdom), Martine Gilard (France), Kristina H. Haugaa (Norway), Anders Jeppsson[1] (Sweden), Peter Jüni (Canada), Luc Pierard (Belgium), Bernard D. Prendergast (United Kingdom), J. Rafael Sádaba[1] (Spain), Christophe Tribouilloy (France), Wojtek Wojakowski (Poland), ESC/EACTS