Traitement percutané de la Valve Tricuspide

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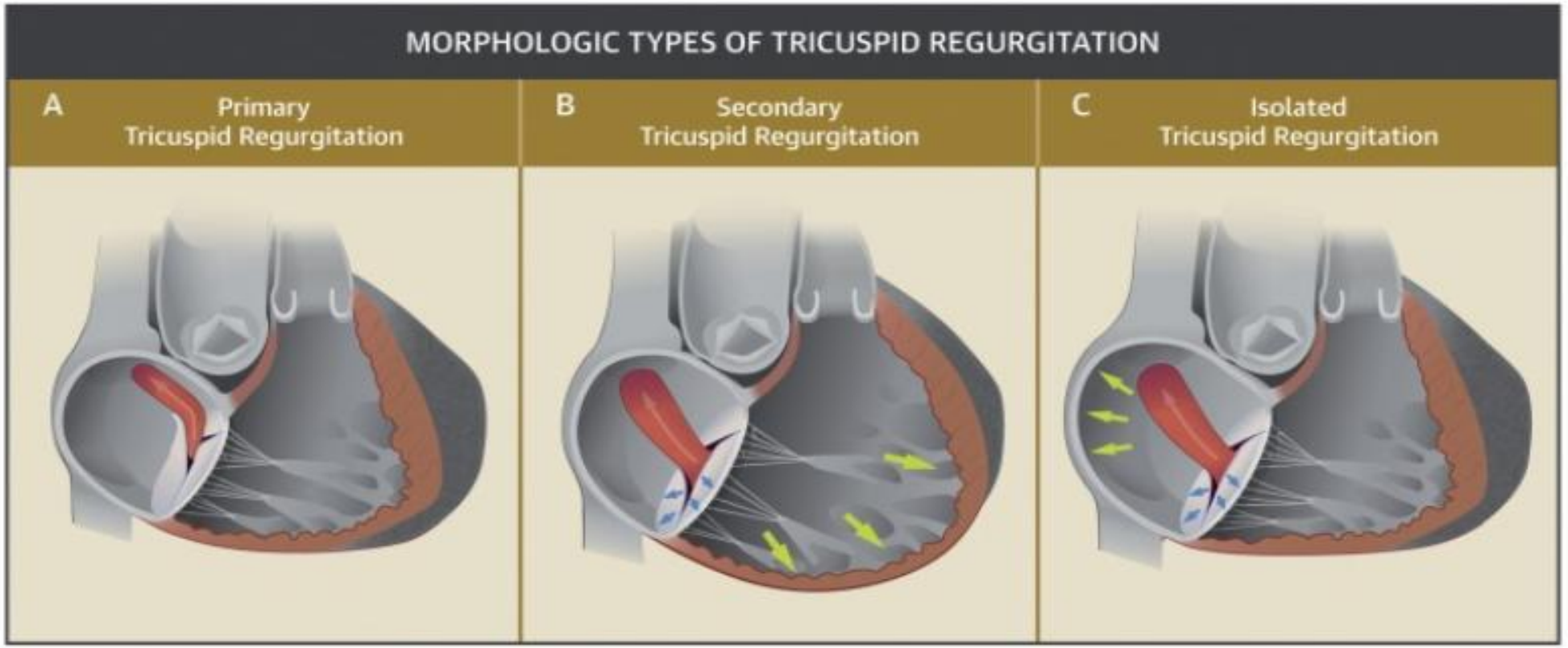
Généralités

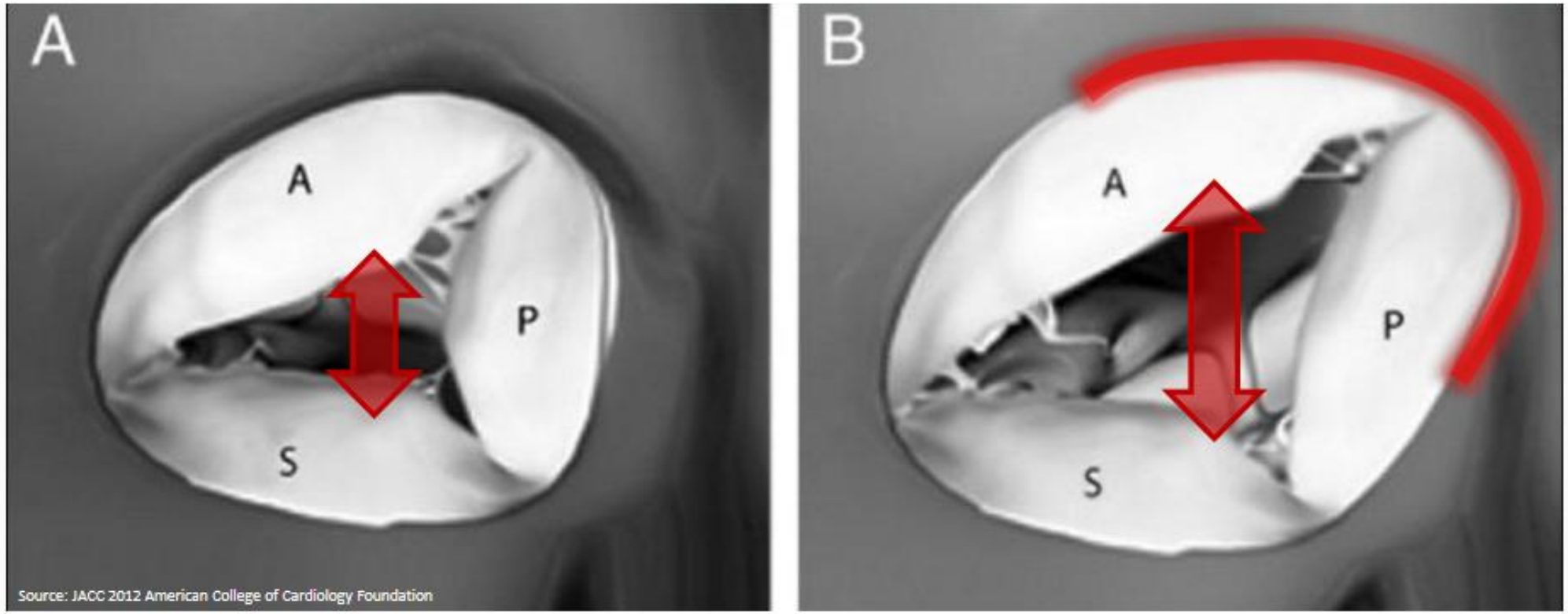


Prihadi, E.A. et al. J Am Coll Cardiol Img. 2019;12(3):491-9.

Mécanisme : dilatation annulaire

ValveTricuspid Normale

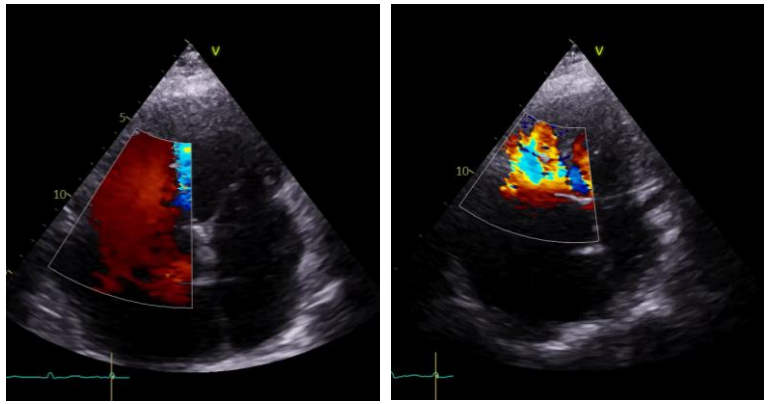
Dilatation Antero-Posterieur de l'Anneau Tricuspide



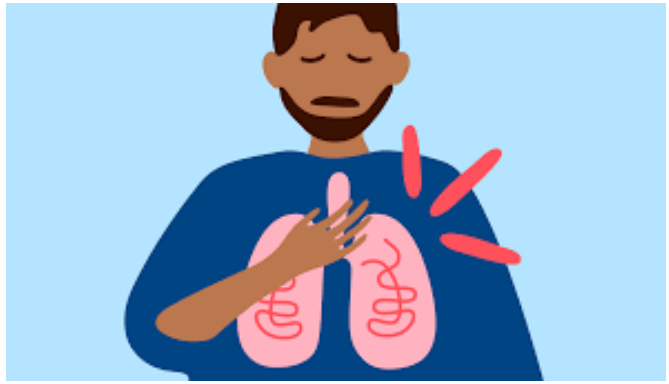
A = Anterior leaflet; P = Posterior leaflet; S = Septal leaflet

Treatment objectives

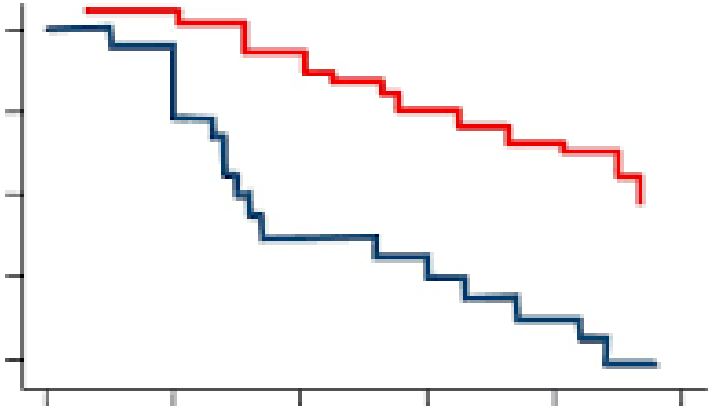
Reduce TR grade



Reduce symptoms



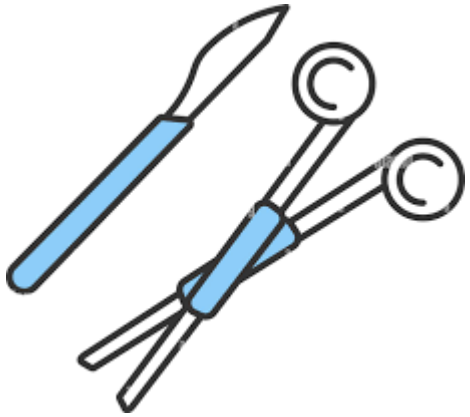
Improve survival



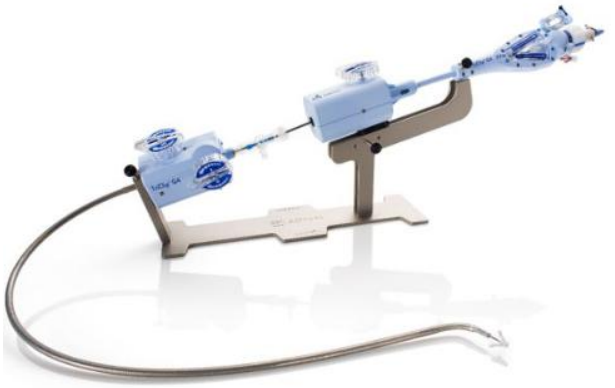
Treatment options

OMT

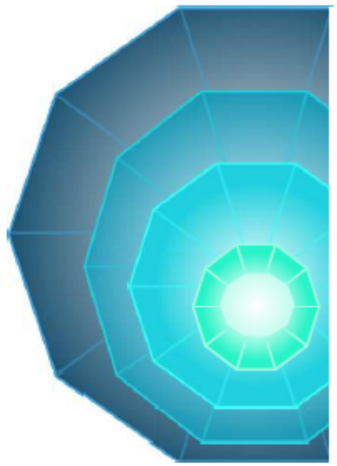
Surgery



TTVR/R



Epidemiologie



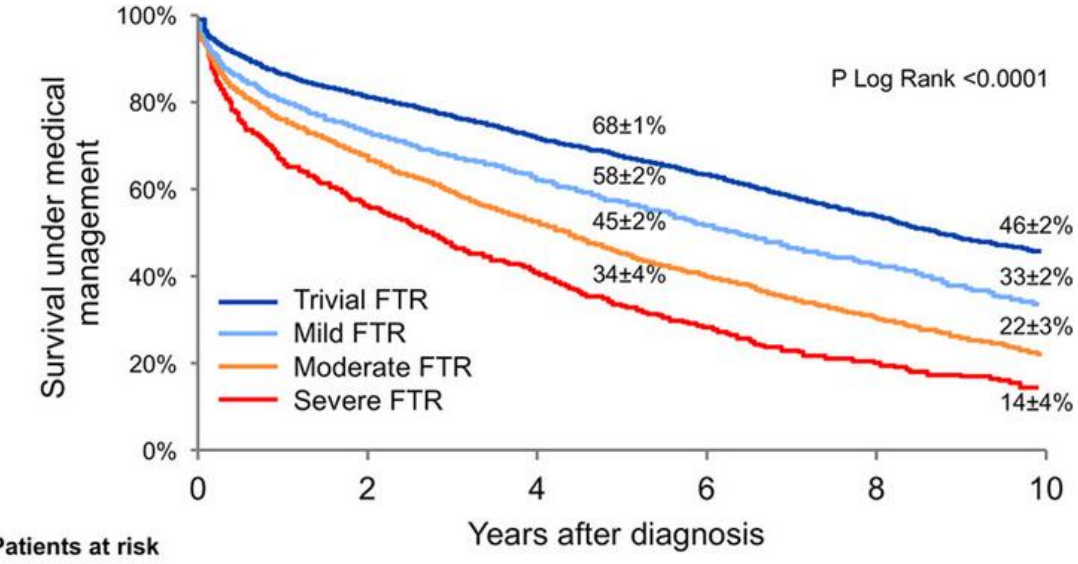
1’600’000 TR Cases (Moderate to Severe*)

250’000 Annual new TR

50’000 Annual MR Surgeries

<8’000 Annual TR Surgeries

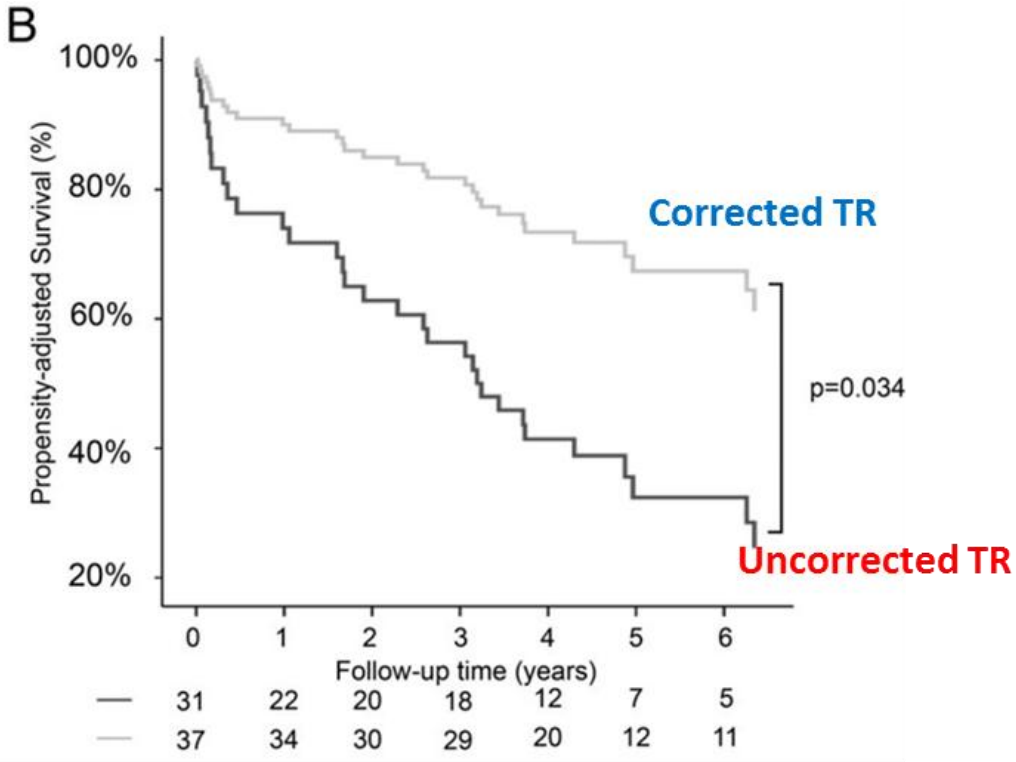
< 0,5%
of TR cases



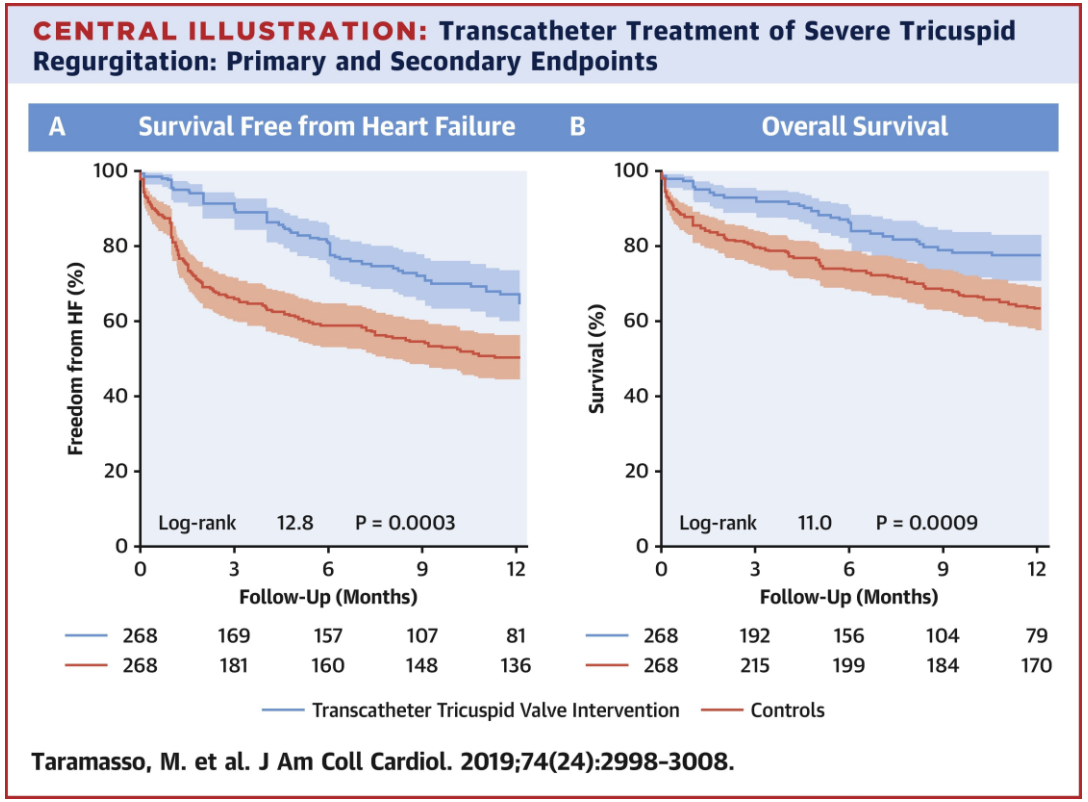
Patients at risk

Trivial FTR	4329	3218	3069	2384	1640	762
Mild FTR	4178	2789	2119	1384	809	359
Moderate FTR	2255	1336	935	555	307	119
Severe FTR	745	352	230	135	65	23

Faut –il corriger les IT?



Rogers Curr Opin Cardiol 2014



Maurizio Taramasso, J Am Coll Cardiol 2019

Is a surgical approach interesting?

Isolated Tricuspid Valve Surgery on Native Valve (N=466)

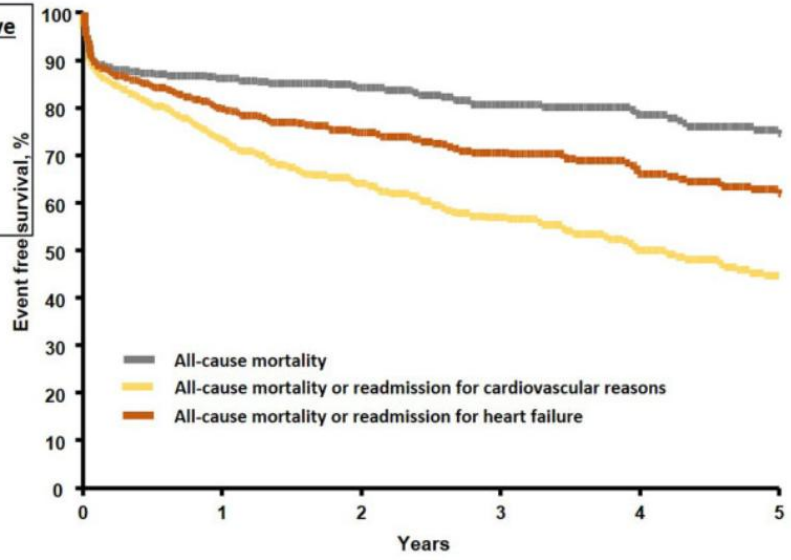
- **Functional tricuspid regurgitation (N=229)**
  - Prior left-sided heart valve surgery (N=101)
  - Isolated (N=128)
- **Organic tricuspid regurgitation (N=237)**
  - Infective endocarditis (N=142)
  - Other (N=95)

Pre-operative presentation

- **Clinical** (NYHA class III/IV, right heart failure signs)
- **Biological** (lower prothrombin time, lower glomerular filtration rate)
- **Echocardiography** (moderate/severe RV dysfunction or dilatation)

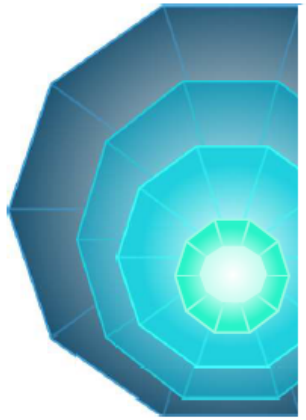
Outcome

- **In-hospital death: 10%**
- **In-hospital major complications: 31%**
- **Overall survival, survival free of cardiovascular readmission and survival free of heart failure readmission at 5 years were 75%, 44% and 62%.**



Isolated tricuspid valve surgery is associated with high mortality and morbidity, both in-hospital and during follow-up, predicted by the severity of the pre-operative clinical, biological and echocardiographic presentation but not by etiology or the mechanism tricuspid regurgitation mechanism

Dreyfus et al. EHJ 2021



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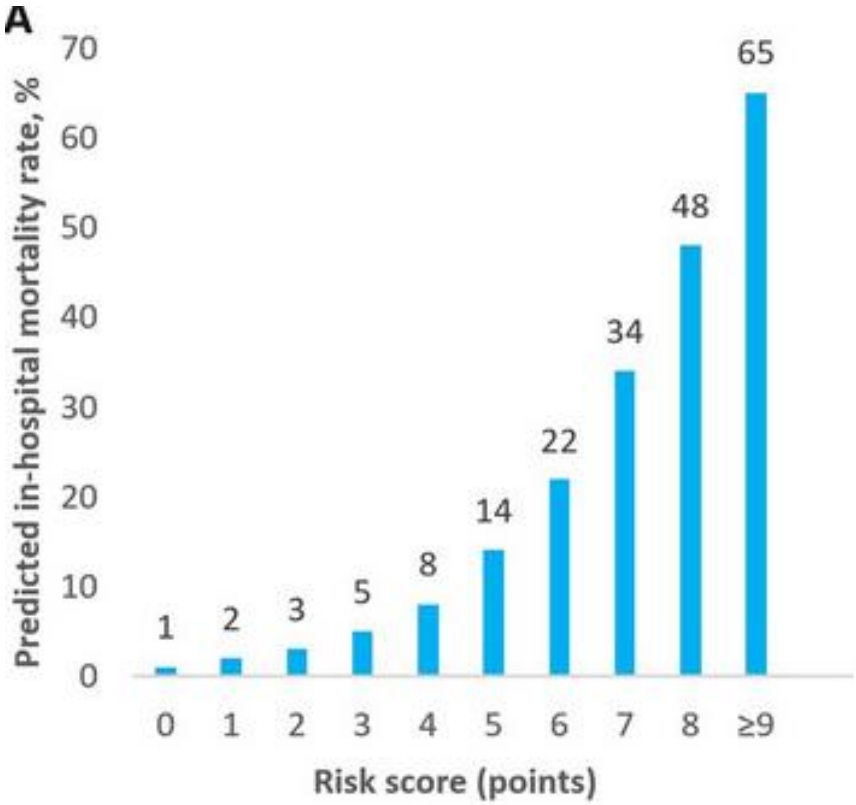
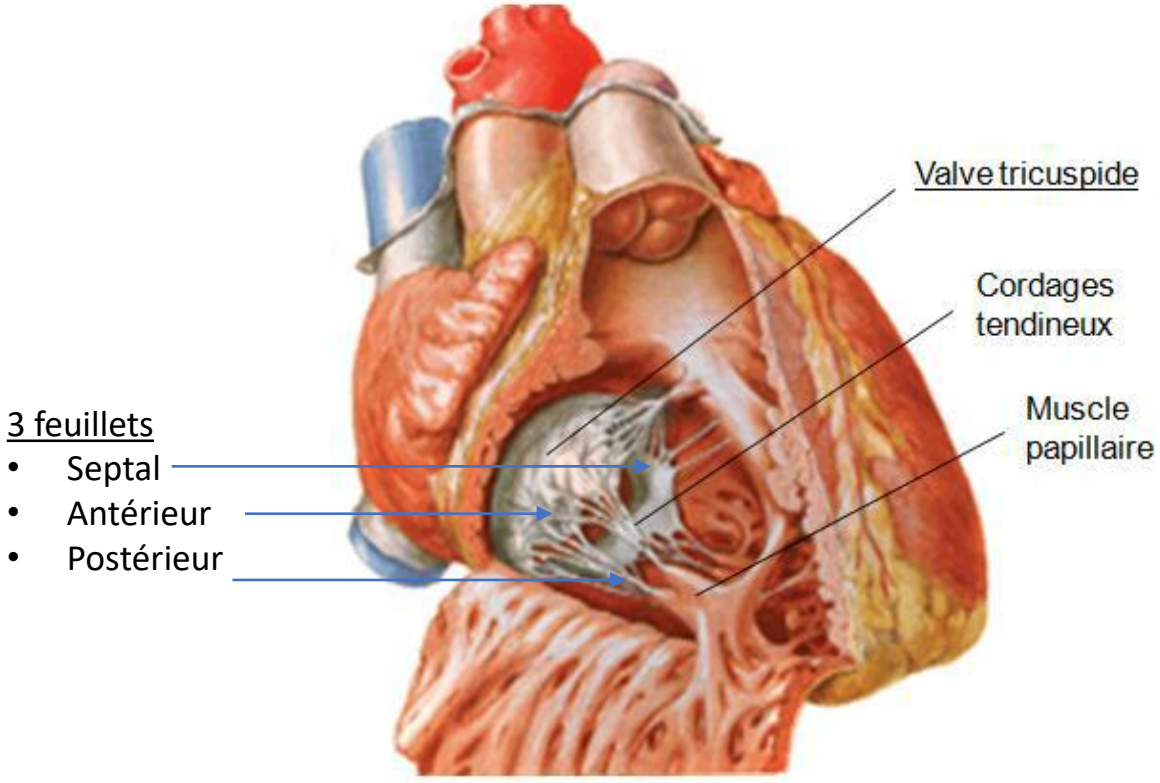
TRI-SCORE

Facteurs de risque et système de score pour la mortalité intrahospitalière après une chirurgie valvulaire tricuspide isolée	
Facteurs de risque (modèle final issu d'une analyse multivariée)	Score
Âge ≥ 70 ans	1
Classe fonctionnelle NYHA III-IV	1
Signes d'insuffisance cardiaque droite	2
Dose quotidienne de furosémide 125 mg	2
Débit de filtration glomérulaire < 30 ml/min	2
Élévation de la bilirubine totale	2
Fraction d'éjection ventriculaire gauche < 60 %	1
Dysfonction ventriculaire droite modérée/sévère	1
Total	12



Dreyfus, J., Audureau, E., Bohbot, Y., Coisne, A., Lavie-Badie, Y., Bouchery, M. et al. TRI-SCORE: a new risk score for in-hospital mortality prediction after isolated tricuspid valve surgery. *Eur Heart J*, 2022, *43*, 654-662.

Réparer ou remplacer?

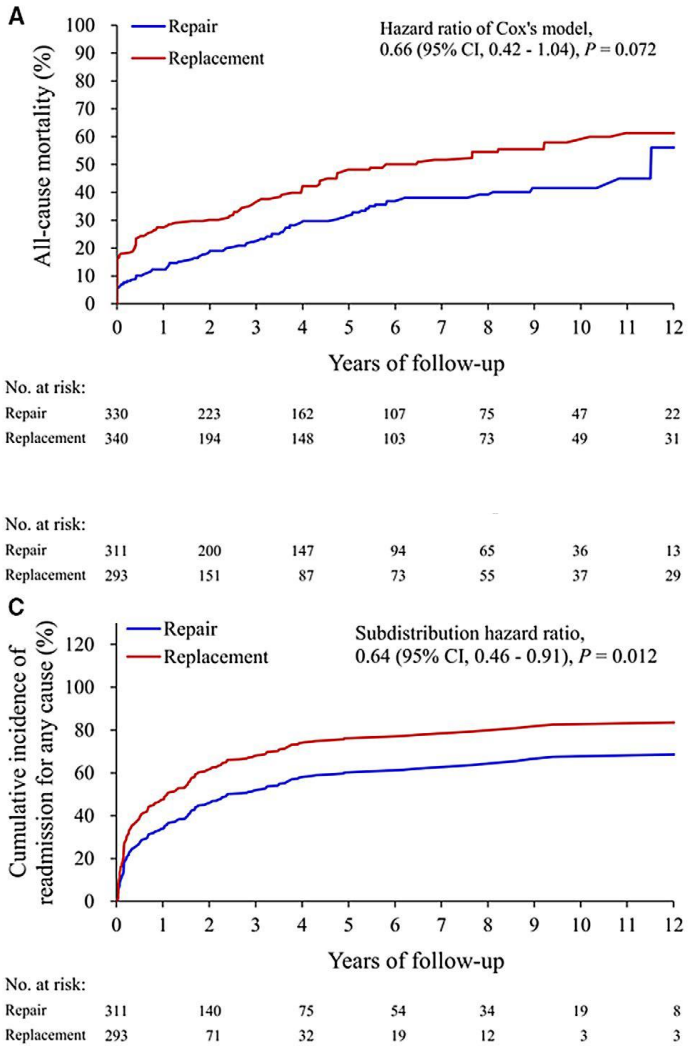


- 3 feuillets
- Nombreux cordages

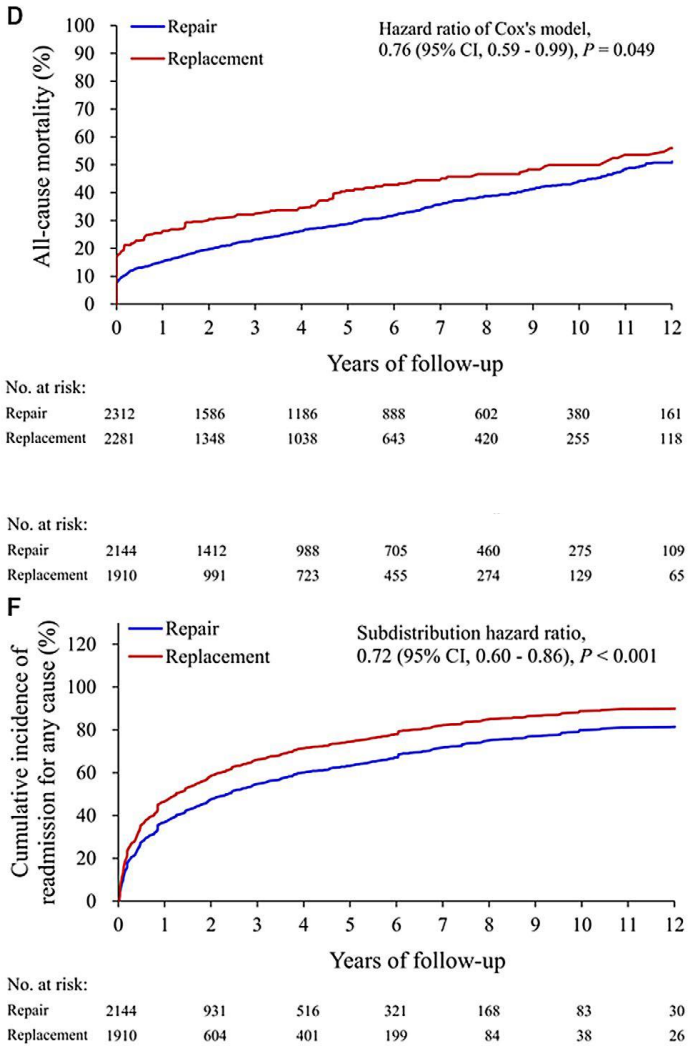
→ complique potentiellement la réparation

Les leçons de la chirurgie

Isolated tricuspide surgery



Concomitant tricuspide surgery



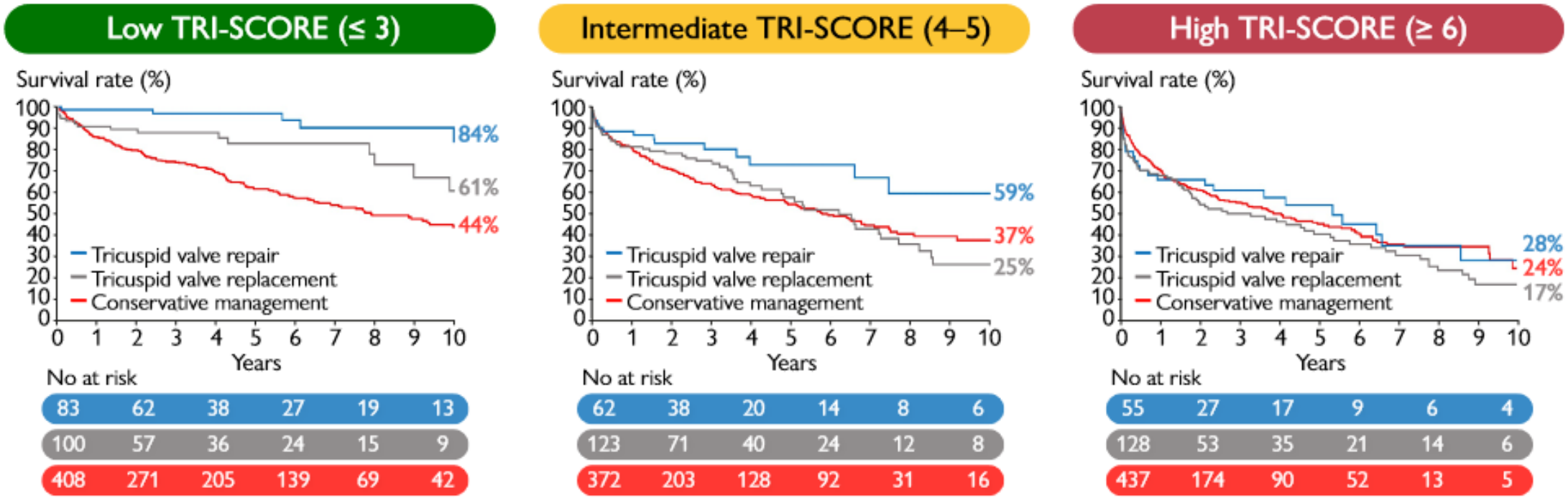
Journal of the American Heart Association **2020**

ORIGINAL RESEARCH

Late Outcomes of Valve Repair Versus Replacement in Isolated and Concomitant Tricuspid Valve Surgery: A Nationwide Cohort Study

Wang-Kin Wong, BDS, MD*; Shao-Wei Chen, MD, PhD*; An-Hsun Chou, MD, PhD; Hsiu-An Lee, MD; Yu-Ting Cheng, MD; Feng-Chun Tsai, MD; Kuang-Tso Lee, MD; Victor Chien-Chia Wu, MD; Chun-Li Wang, MD; Shang-Hung Chang, MD, PhD; Pao-Hsien Chu, MD

Surgical approach: repair or replace?



Should TR be treated?

Recommendations on primary tricuspid regurgitation		
Surgery is recommended in patients with severe primary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery is recommended in symptomatic patients with isolated severe primary tricuspid regurgitation without severe RV dysfunction.	I	C
Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with isolated severe primary tricuspid regurgitation and RV dilatation who are appropriate for surgery.	IIa	C

Recommendations on secondary tricuspid regurgitation		
Surgery is recommended in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.[423–427]	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.[423,425–427]	IIa	B
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.[418,433 e]	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.[f]	IIb	C

INSUFFISANCE TRICUSPIDE

Révision

	Classe	Niveau
2021	IIb	C

⬇

	Classe	Niveau
Révision 2025	IIa	A

Indications d'intervention chez les patients présentant une régurgitation tricuspide sévère sans valvulopathie gauche nécessitant une chirurgie					
Le TEER (ou autre technique) peut être envisagé chez les patients symptomatiques inopérables, dans un centre spécialisé dans les valvulopathies cardiaques (Heart Valve Centre) disposant d'une expertise dans la prise en charge des pathologies de la valve tricuspide.	IIb	C	Le traitement transcathéter de la valve tricuspide devrait être envisagé pour améliorer la qualité de vie et favoriser le remodelage du ventricule droit chez les patients à haut risque, présentant une régurgitation tricuspide sévère symptomatique persistante malgré un traitement médical optimal, en l'absence de dysfonction sévère du ventricule droit ou d'hypertension pulmonaire précapillaire.	IIa	A

Percutaneous options

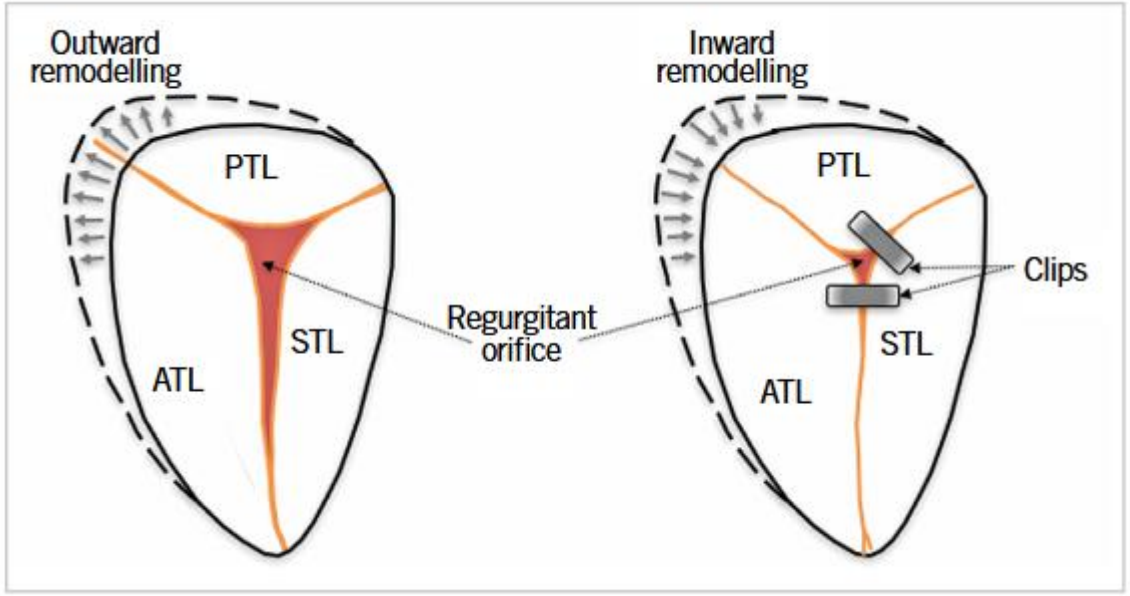
Repair:

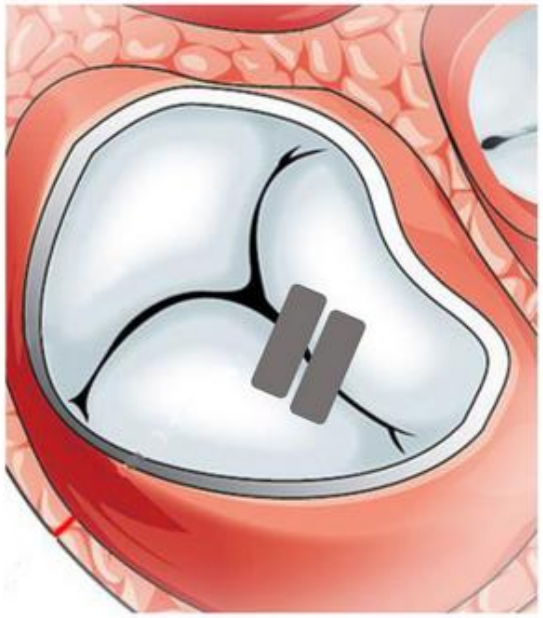
- **<u>TEER</u>**
- Annuloplasty

Replacement:

- Less data
- Good functionnal results

Percutaneous treatment: repair





Percutaneous treatment: repair

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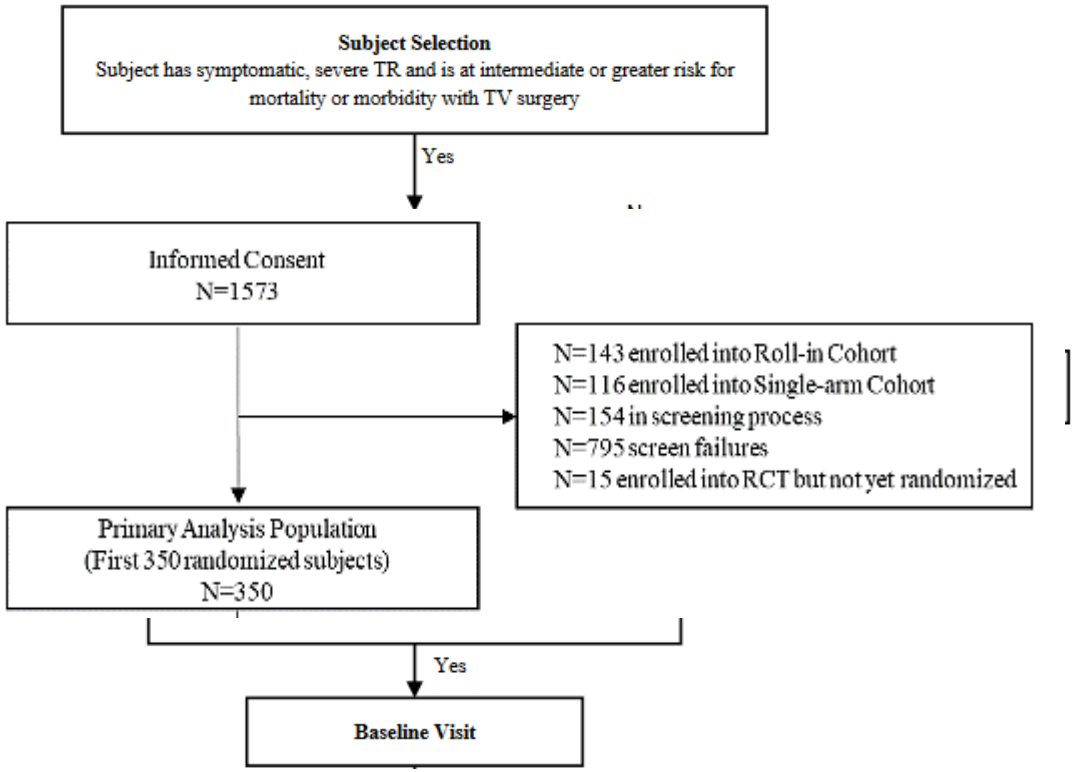

JAMA | Original Investigation

Transcatheter Edge-to-Edge Repair for Severe Isolated Tricuspid Regurgitation
The Tri.Fr Randomized Clinical Trial

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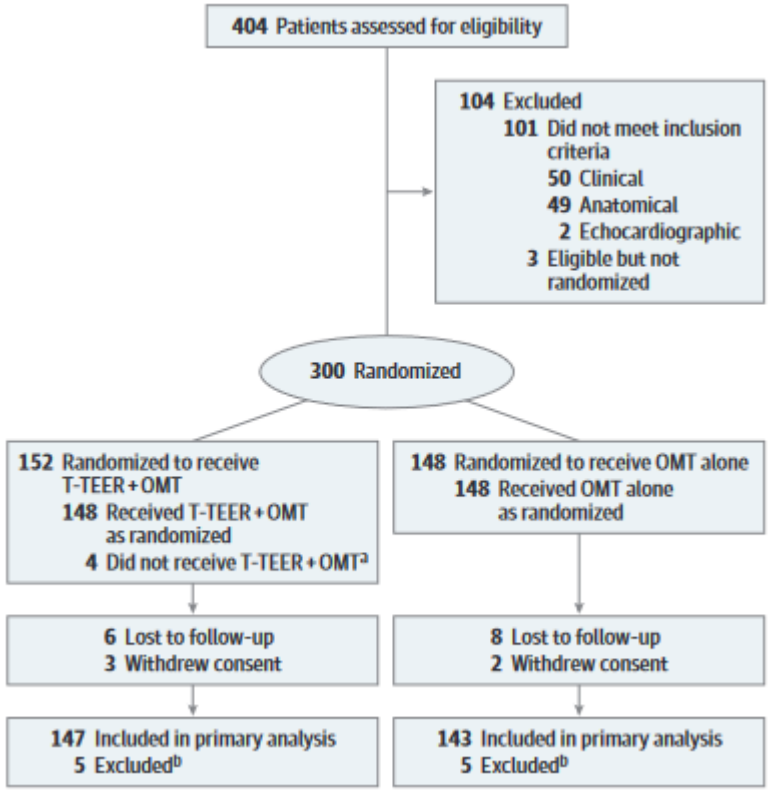

Percutaneous repair: TR reduction and symptoms

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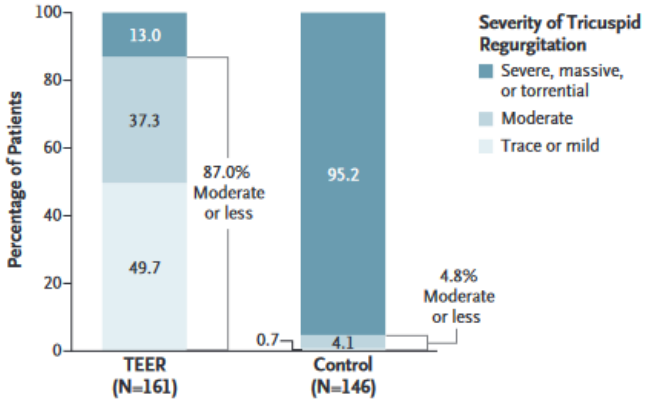

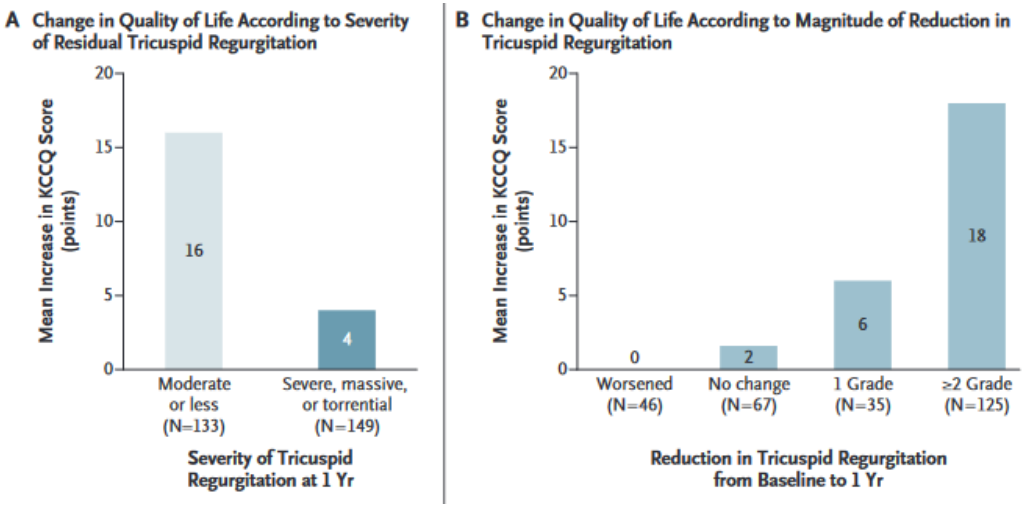

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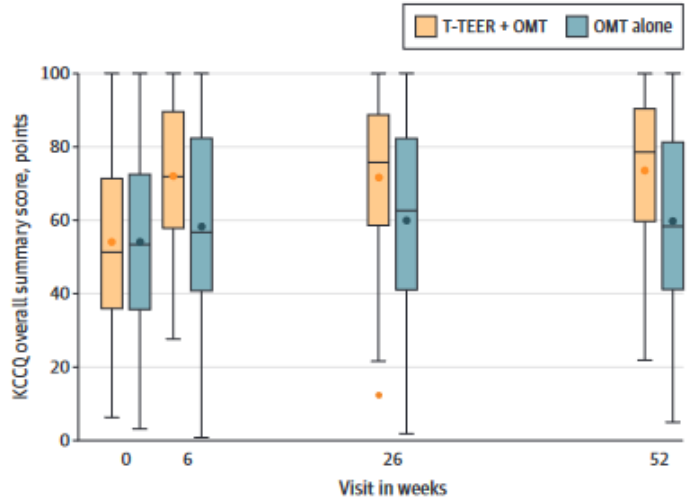
TR grade at 1 y, No. (%)		
<2+	104 (78.3)	14 (11.0)
3+	20 (15.0)	45 (35.4)
4+	5 (3.76)	49 (38.6)
5+	4 (3.01)	19 (15.0)



Percutaneous repair: outcome

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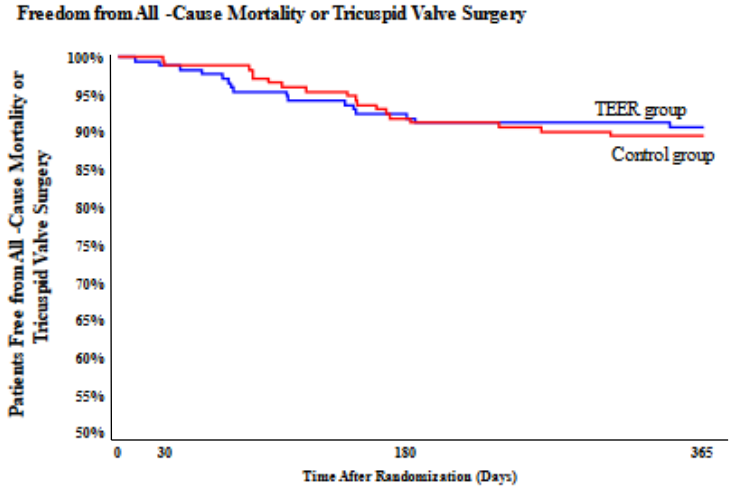

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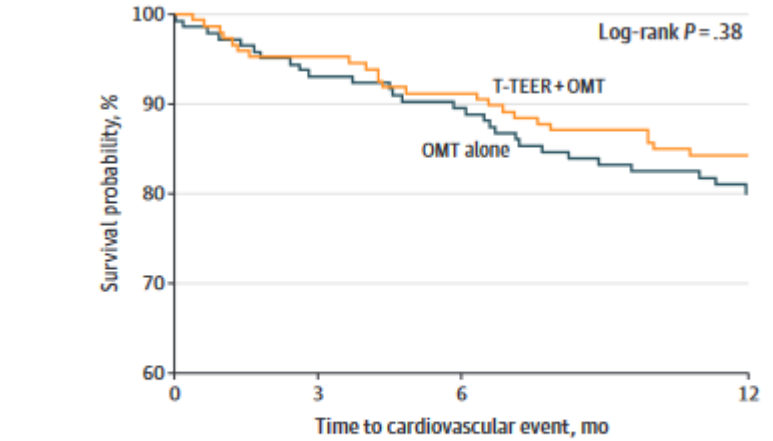
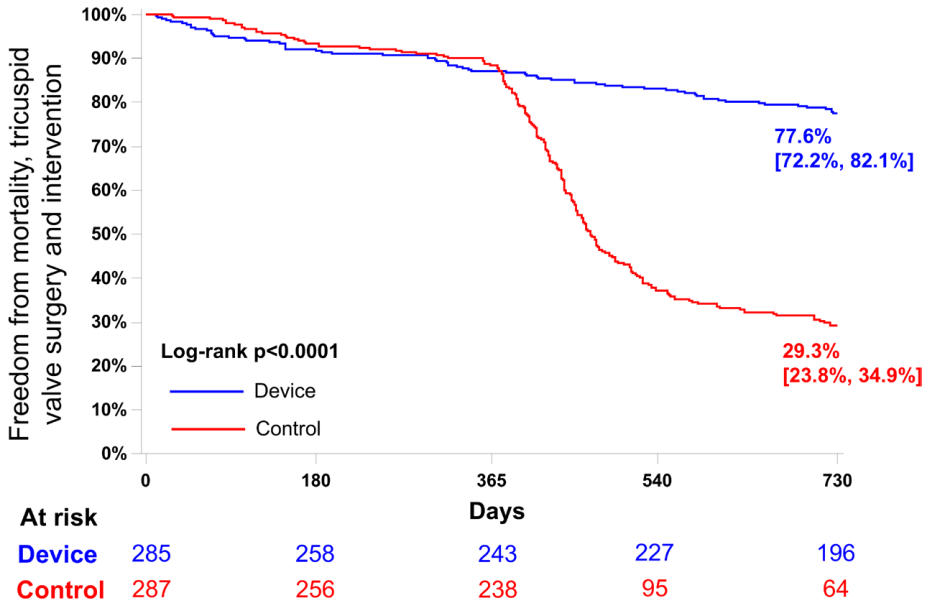
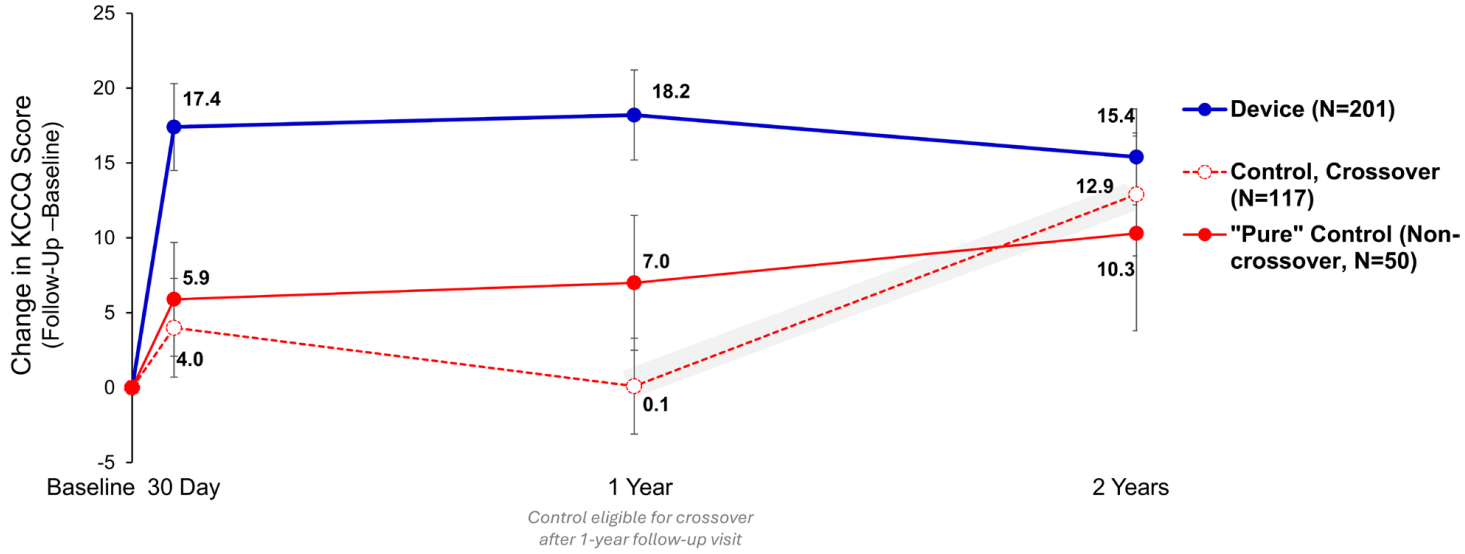


Trilluminate 2 years: outcome and symptoms

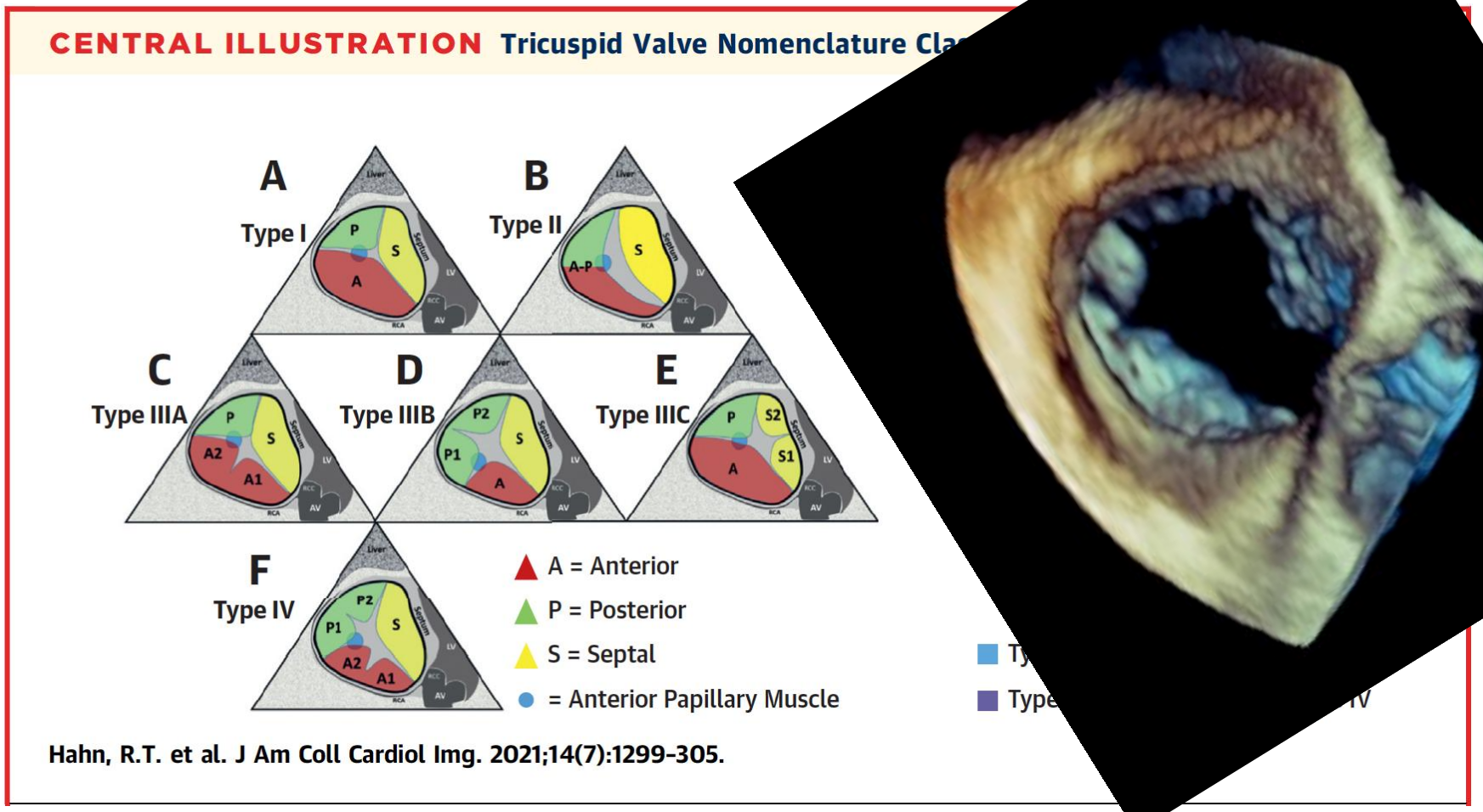


Component	Device N=285	Control N=287	p-value
Composite of mortality/TVS/TVI	**22.4% (62)**	**70.7% (185)**	**<0.0001**
All-cause mortality	17.9% (49)	17.1% (45)	
TVS	2.3% (6)	4.3% (11)	
TVI	3.8% (10)	61.5% (142)	



Kar et al. Circulation. 2025 Jun 10;151(23):1630-1638

T-TEER eligibility? - Anatomy



T-TEER eligibility? – Patients' selection

Table 3. Anatomical criteria for device selection.

Strategy	Favourable anatomy	Feasible anatomy	Unfavourable anatomy
Leaflet approximation	Small septolateral gap ≤7 mm[10] Anteroseptal jet location Confined prolapse or flail Trileaflet morphology	Septolateral coaptation gap >7 but ≤8.5 mm[65] Posteroseptal jet location Non-trileaflet morphology Incidental CIED RV lead (i.e., without leaflet impingement)	Large septolateral coaptation gap >8.5 mm[65] Leaflet thickening/shortening (rheumatic, carcinoid)/perforation Dense chordae with marked leaflet tethering Anteroposterior jet location Poor echocardiographic leaflet visualisation CIED RV lead leaflet impingement Unfavourable device angle of approach

Praz et al. EuroIntervention 2021;17:791-808

T-TEER eligibility?

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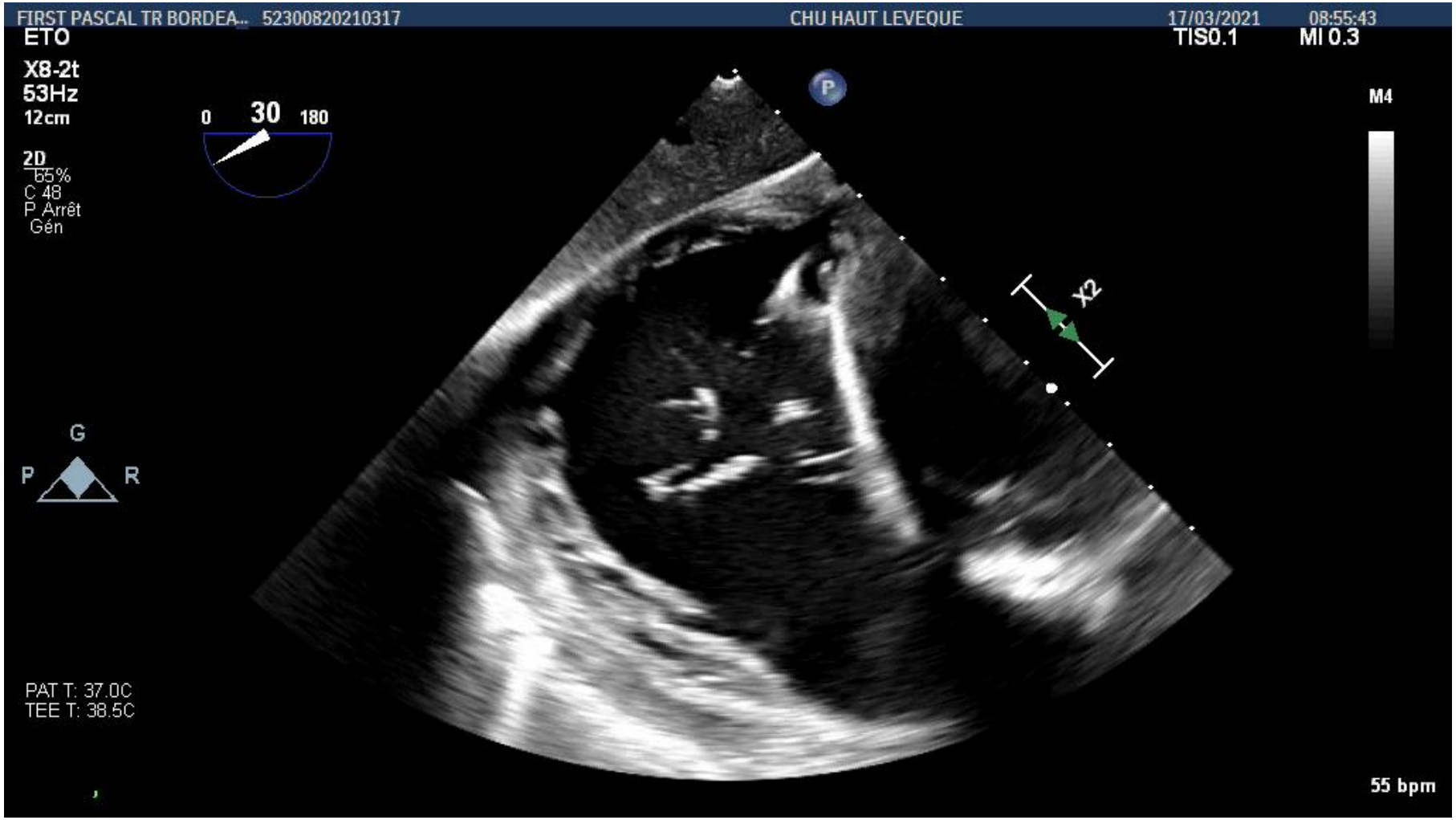
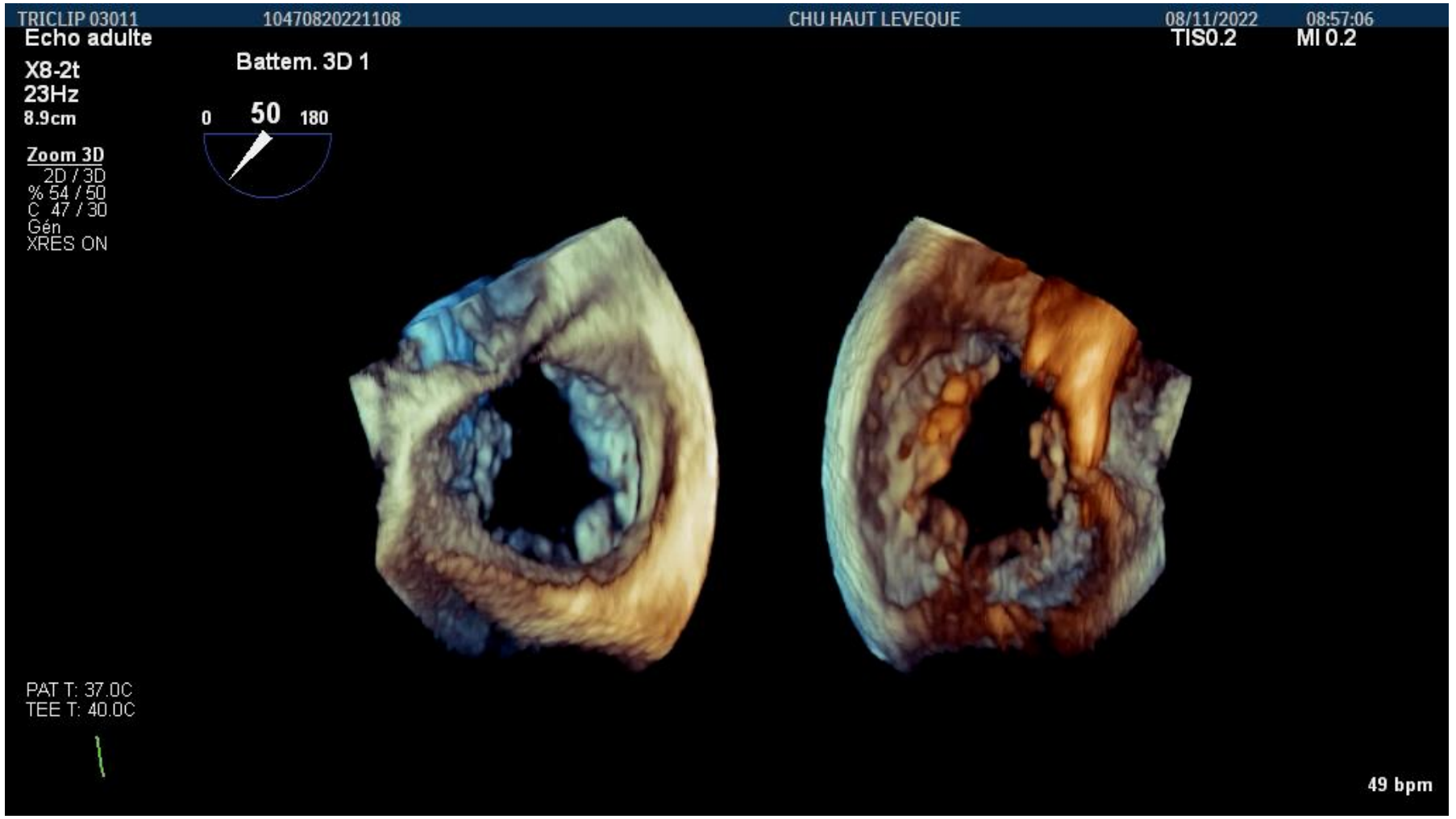
Praz et al. EuroIntervention 2021;17:791-808

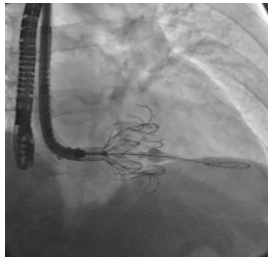
T-TEER eligibility? Good images



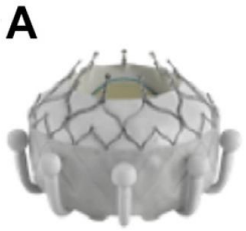
T-TEER eligibility? Good images



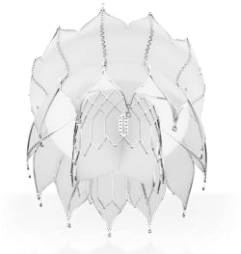
Percutaneous approach:Tricuspid replacement

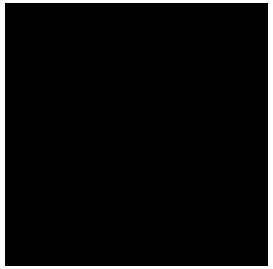


Evoque (Edwards)

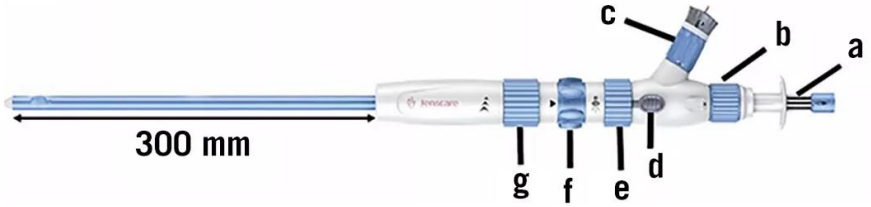


Topaz (Tricares)



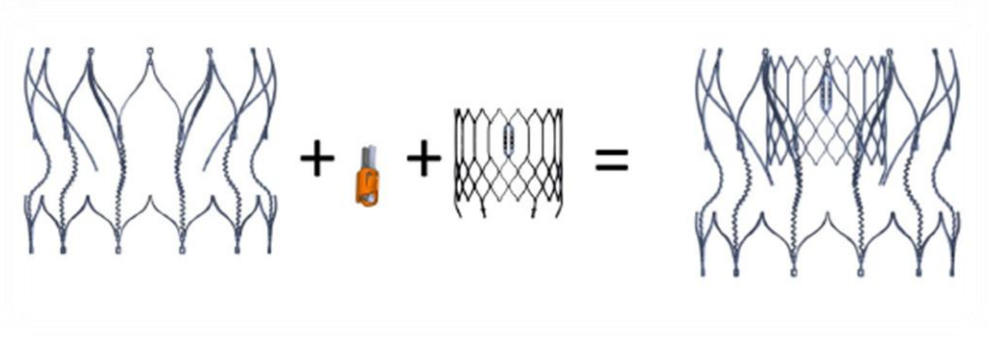


LuxValve (Jenscare)



CardioValve

TOPAZ Valve (TRICARES)



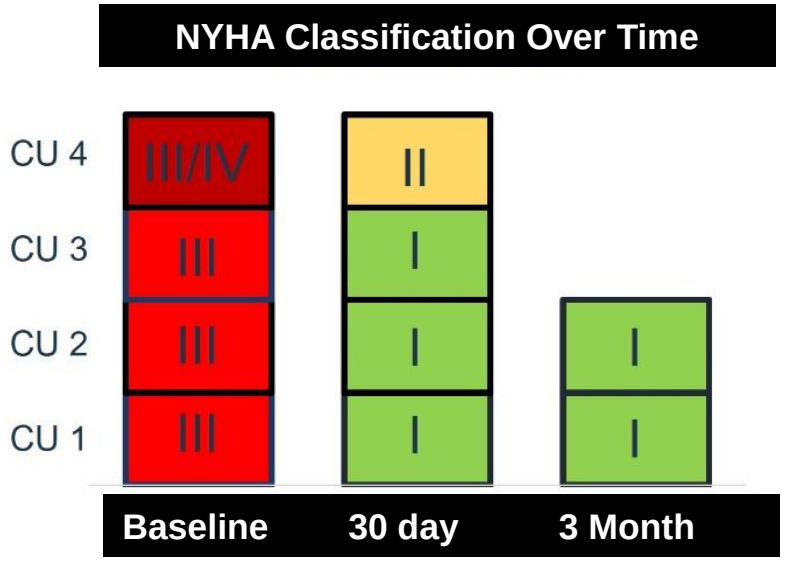
- stent très souples permettant de suivre les variations géométriques du VD
- Dé-corrélation de la fonction ancrage et valvulaire

Teiger E. et al. Eurointervention; November 18, 2022

Topaz valve TriCares

Topaz valve TriCares

Topaz TTVR - Early Compassionate Use Experience



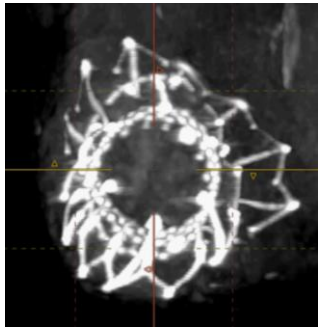
Procedure Discharge	CU 1	CU 2	CU 3	CU4
Procedure Time*	18 min	12 min	20 min	48 min
NYHA Class Discharge	I	I	I	II
Tricuspid Regurgitation (Grade 1-5)	None (0)	None (0)	None (0)	Mild (1)
Discharged on POD	4	4	15	15

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

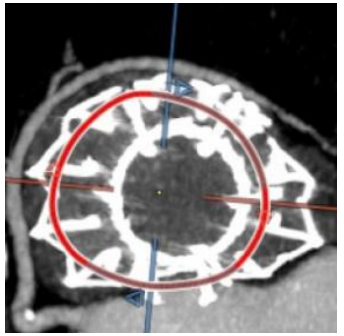
CU 1
post deployment

CU 2
post deployment

CU 1
CT 3 Mon FUP



CU 2
CT 3 Mon FUP



EuroIntervention
2025;21:e1-e9
published online e-edition xxx 2025
DOI: 10.4244/EIJ-D-25-00423

TRICURE: first-in-human study of the Topaz transcatheter tricuspid heart valve system

Emmanuel Teiger[1]*, MD, PhD; Mohammed Nejjari[2], MD; Liesbeth Rosseel[3], MD, PhD; Joëlle Kefer[4], MD; Stefan Verheye[5], MD, PhD; Patrizio Lancellotti[6], MD; Léopold Oliver[7], MD; Jean-François Obadia[8], MD; Federico M. Asch[9], MD; Philipp Blanke[10], MD; Julien Dreyfus[2], MD, PhD

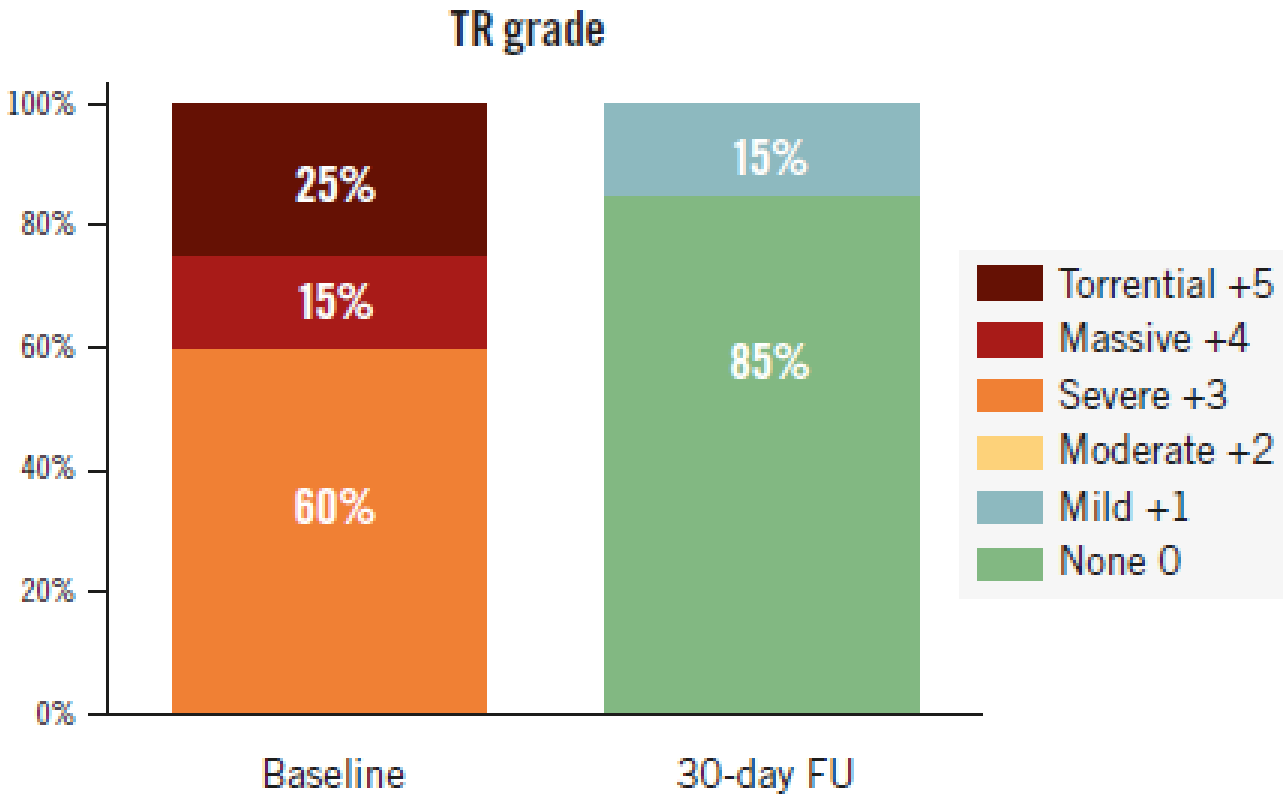
Corresponding author: CHU Henri Mondor, 51 Av du Mal de Lattre de Tassigny, 94010, Créteil, France.

Table 1. Baseline characteristics.

	N=20
Age, years	77.0±6.6 (61-81)
Sex	
Male	2 (10)
Female	18 (90)
NYHA Class	
II	6 (30)
III	13 (65)
IV	1 (5)
EuroSCORE II, %	4.2±2.3 (1.3-10.2)
STS-PROM score, %	9.7±5.4 (4.6-22.1)
TRI-SCORE	4.6±2.5 (2-11)
TRI-SCORE predicted in-hospital mortality, %	17.6±20.1 (3-65)
Concomitant mitral valve disease	10 (50)
Concomitant aortic valve disease	3 (15)
Coronary artery disease	4 (20)
Cardiac rhythm	
Bundle branch block	4 (20)
Atrial flutter/fibrillation	17 (85)
History of previous CIED implantation	0 (0)
Previous stroke	5 (25)
Peripheral vascular disease	3 (15)
Chronic obstructive pulmonary disease	2 (10)
Renal insufficiency*	19 (95)
eGFR, mL/min/1.73 m²	40±19
Pulmonary hypertension	9 (45)
Pulmonary artery systolic pressure, mmHg	39.8±13.1
Cancer	6 (30)
Diabetes	5 (25)
Arterial hypertension	15 (75)
Hyperlipidaemia	13 (65)
Smoker	6 (30)

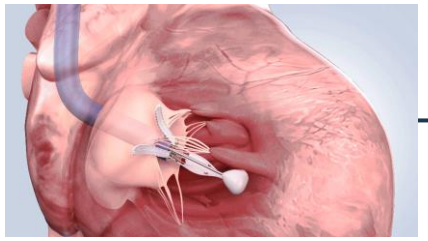
Table 2. Clinical outcomes at 30-day follow-up.

	N=20
Hierarchical composite MAE endpoint*	**7 (35)**
All-cause mortality	3 (15)
Cardiovascular mortality	2 (10)
Non-cardiovascular mortality	1 (5)
Reintervention#	3 (15)
Elective (Topaz remained *in situ*)	2 (10)
Non-elective	1 (5)
Hospitalisation for heart failure	1 (5)
Additional safety endpoints	
Myocardial infarction	0 (0)
Stroke	0 (0)
Renal complications	0 (0)
Vascular bleeding	0 (0)
Device-related pulmonary embolism	0 (0)
Topaz-related pacemaker implantation†	0 (0)
Thrombotic event	0 (0)



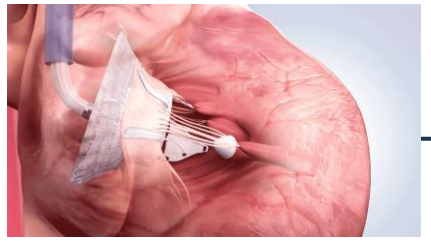
Innovative Design of LuX-Valve Plus TTVR

- Designated as the **"Breakthrough Device" by the FDA**
- Enrolled in the **Total Product Life Cycle Advisory Program ("TAP") by the FDA**
- Enrolled in the **Expert Panel Scientific Advice Pilot Program by the EMA**
- Admitted into the **Innovative Medical Device "Green Path" by the NMPA**



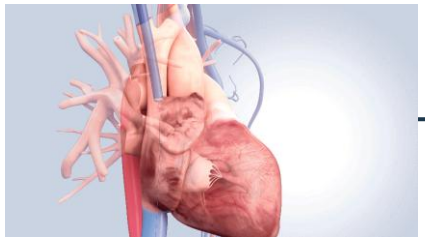
Non-radial Force Anchoring Design

- Interventricular septal anchoring free from radial force, complemented by a multi-dimensional fixation design using dual leaflet-grasping clips
- Facilitates postoperative right heart remodeling
- Reduces the risk of postoperative permanent pacemaker implantation



Innovative Self-adaptive Braided Ring

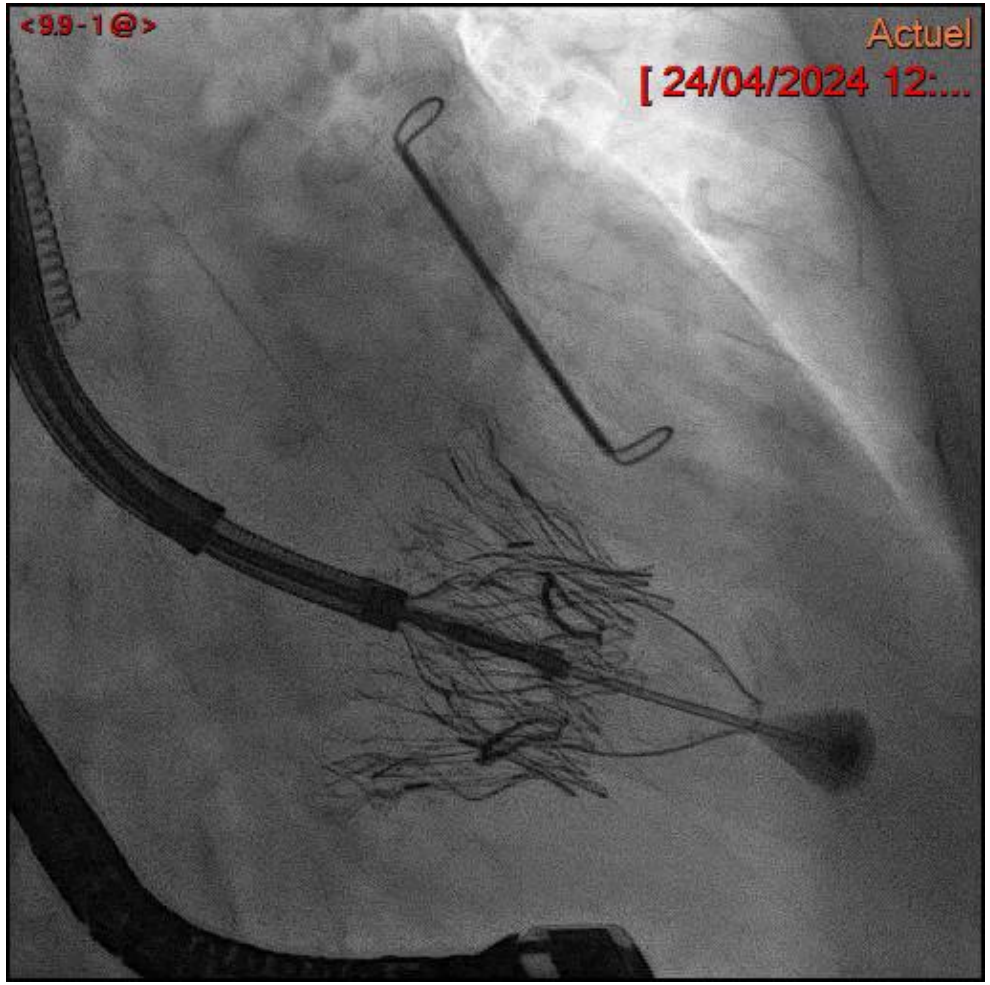
- Effectively reduces annular dilation
- Reduces postoperative PVL risk due to complex anatomical structures
- Braided ring sizes up to 70mm and inner annulus diameter sizes 30mm



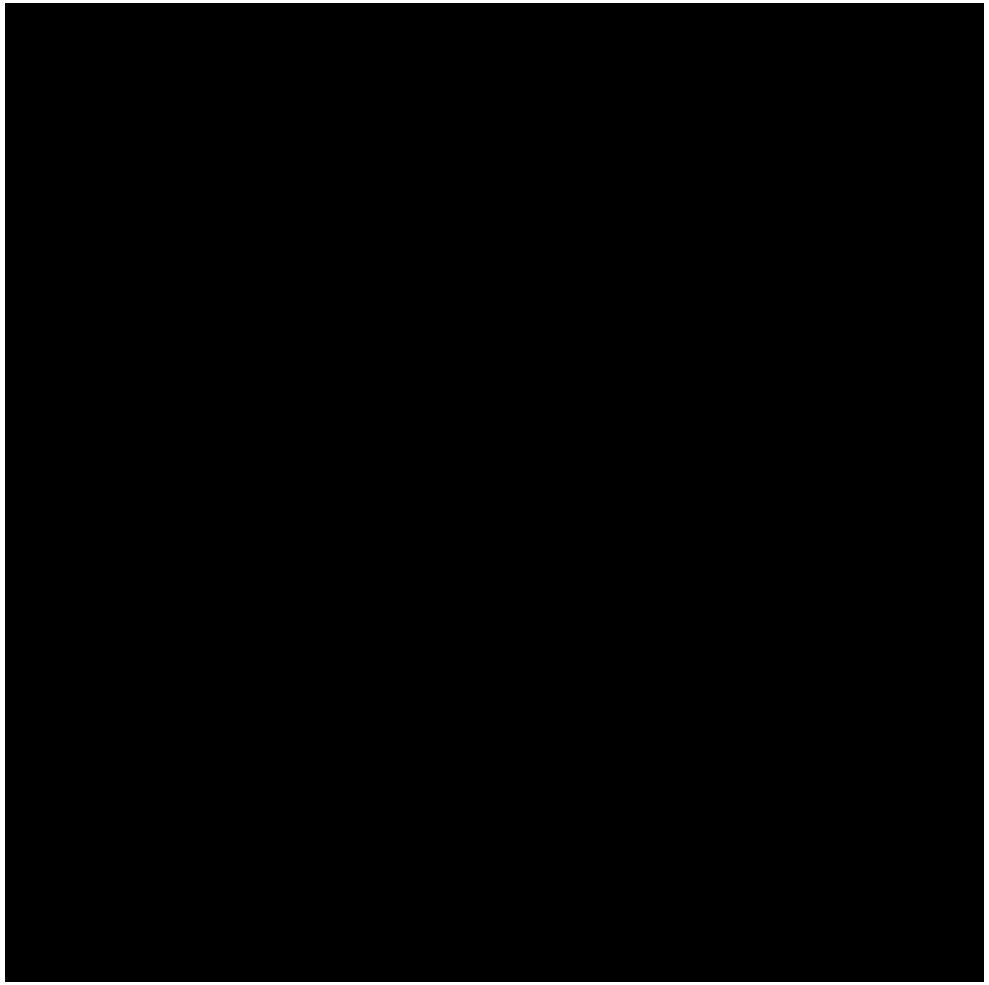
Multi-dimensional Adjustable-Deflectable Delivery System

- Precise valve release positioning during the procedure
- Facilitates good coaxial alignment, reducing the risk of postoperative valve instability and PVL

LuX-Valve : Jenscare

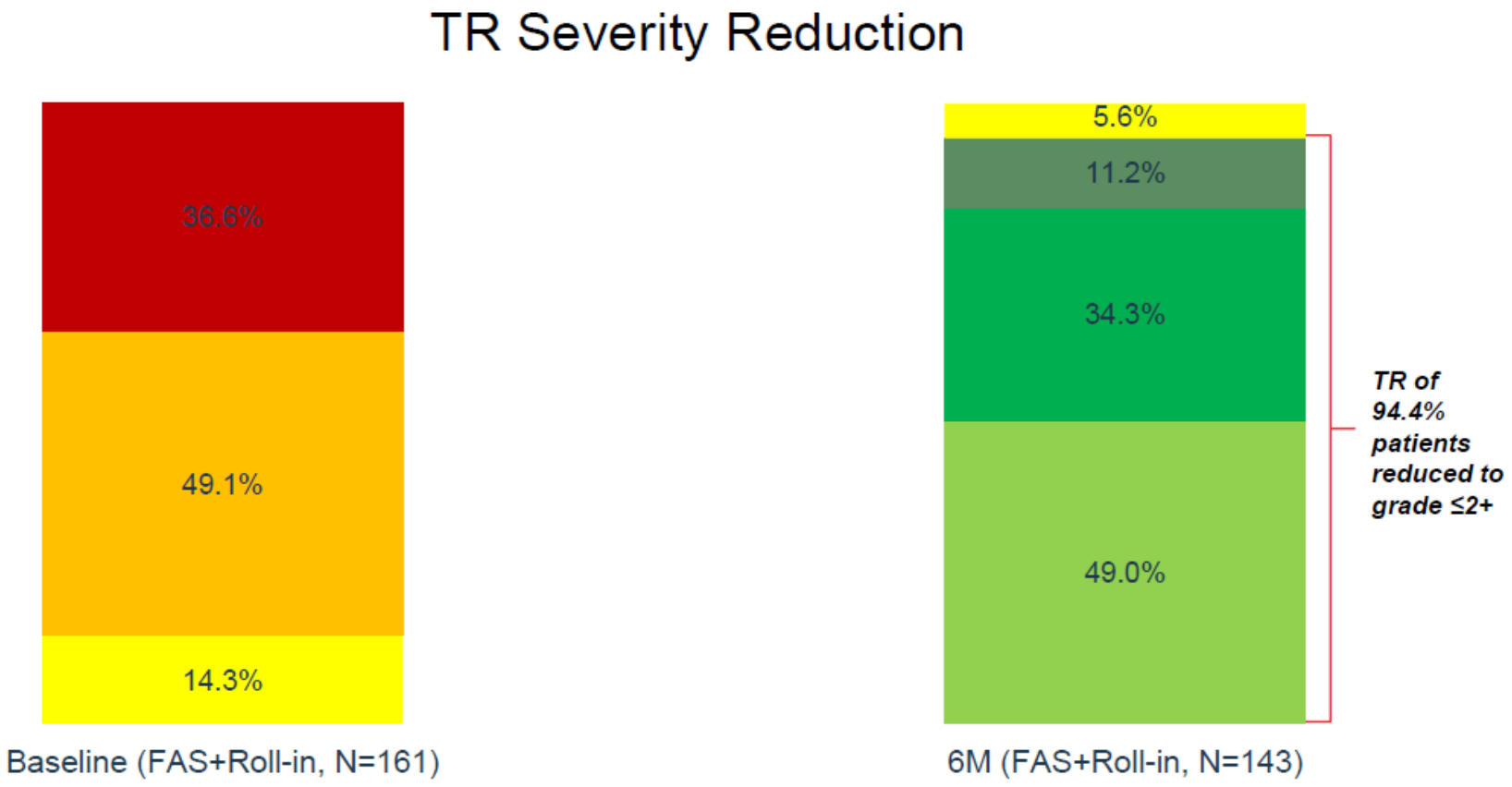


LuX-Valve : Jenscare



LuX-Valve : TRINITY Trial

Clinical Outcomes on Performance at 6-Month

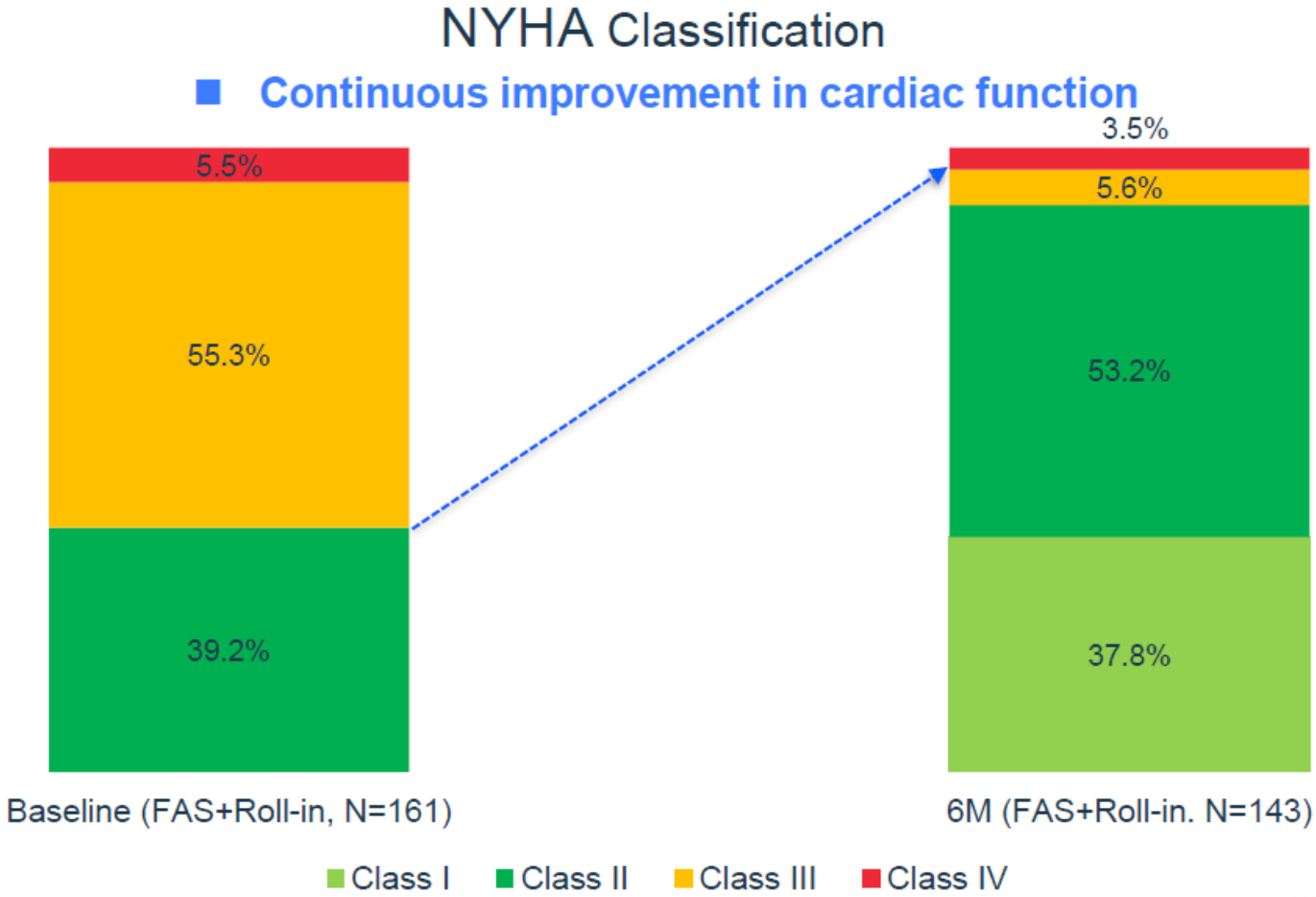


CRF TCT

- *All TTE echo results were assessed and validated by central echo core lab.*
- *The lack of primary performance endpoints of 18 patients were due to: 1) 10 patients: deaths, 2) 4 patients: delivery system failed to pass suprarenal caval vein, 2 of them were dead, 3) 5 patients: TTE echo images not available due to 6M follow-up not performed, 4) 1 patient: valve explanted.*

LuX-Valve : TRINITY Trial

Clinical Outcomes on Functions at 6-Month



LuX-Valve : TRINITY Trial

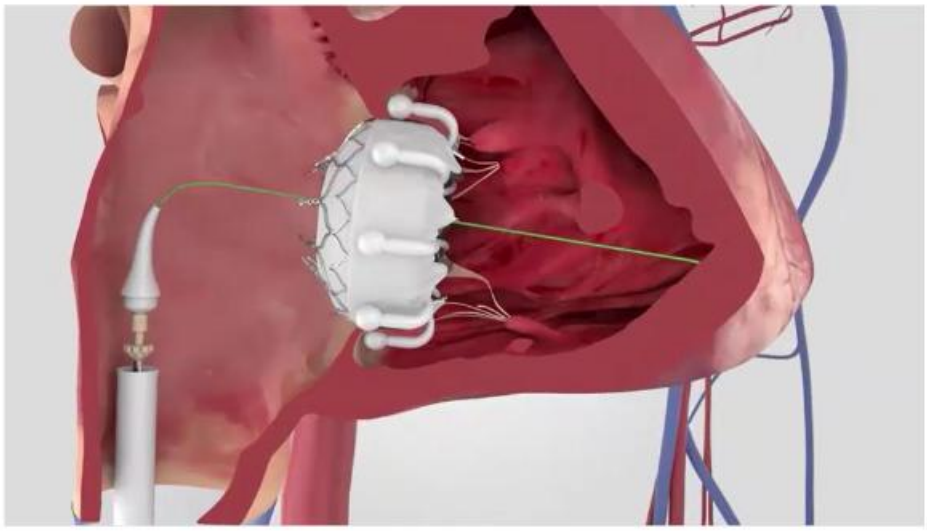
Rate of Composite Adverse Events at 6-Month

■ *CEC-adjudicated Composite Adverse Events*

Composite Events at 6-Month	FAS + Roll-in, N=161
Cardiovascular mortality	6/161 (3.7%)
Myocardial infarction	0
Strokes	1/161 (0.6%)
New onset renal failure	2/161 (1.2%)
Severe bleeding (includes fatal, life-threatening and extensive bleeding as defined by MVARC)	8/161 (5.0%)
Non-selective tricuspid valve surgery / intervention post procedure	4/161 (2.5%)
Major cardiac structural complications	5/161 (3.1%)
Major access site and vascular complications	0
Device-related pulmonary embolism	0
New pacemaker implantation due to AV block New pacemaker implantation due to AV block (Naive)	14/161 (8.7%) 14/118 (11.9%)

- ***The overall CEC-adjudicated composite events rate at 6 month of FAS + Roll-in group is 19.9%.***
  - ***Device success rate is 96.64%, and procedural success rate is 91.95%.***
  - ***Average device time is 41.60±19.62 minutes, with the shortest device time being 11 minutes.***

Valve Evoque



Atraumatic anchors compatible with pre-existing leads and respect the native anatomy

Conforming frame designed to achieve optimal retention force

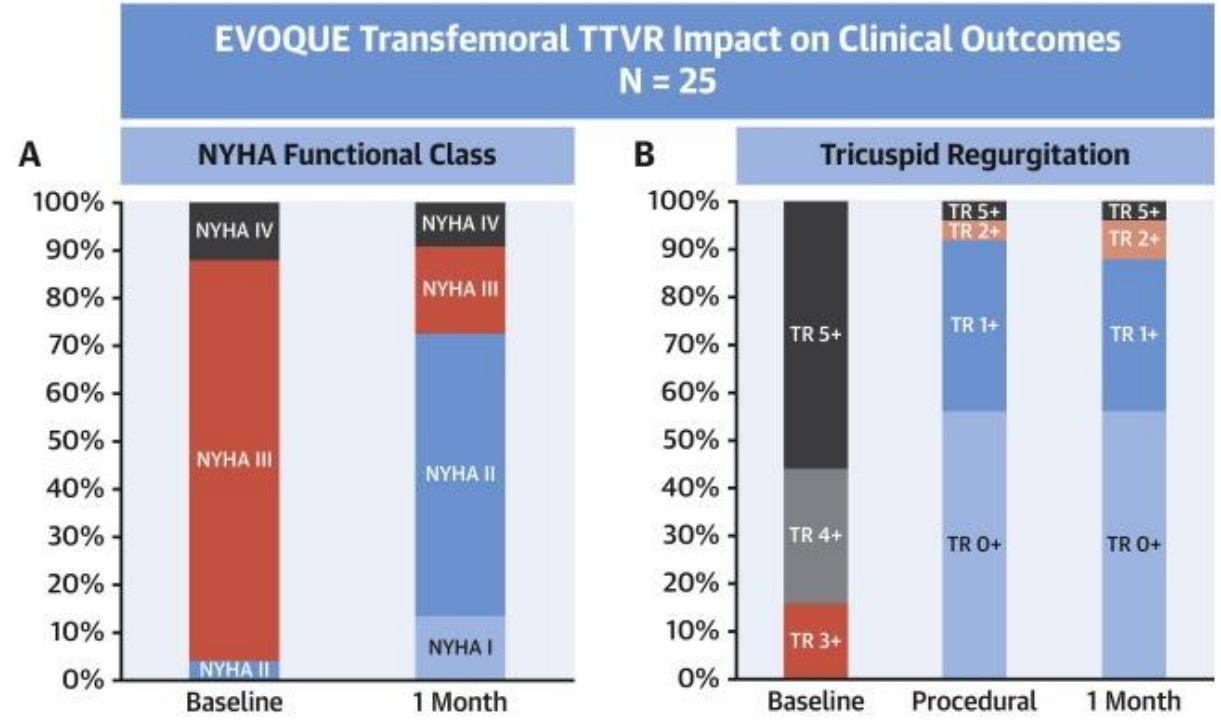
Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (52, 48, 44 mm)

28F transfemoral delivery system compatible with all valve sizes

Evoque (Edwards)

Deux tailles 44mm (32%) 48 (64%) mm 28F – femoral access

CENTRAL ILLUSTRATION: Outcomes After EVOQUE Transfemoral Transcatheter Tricuspid Valve Replacement for Severe Tricuspid Regurgitation

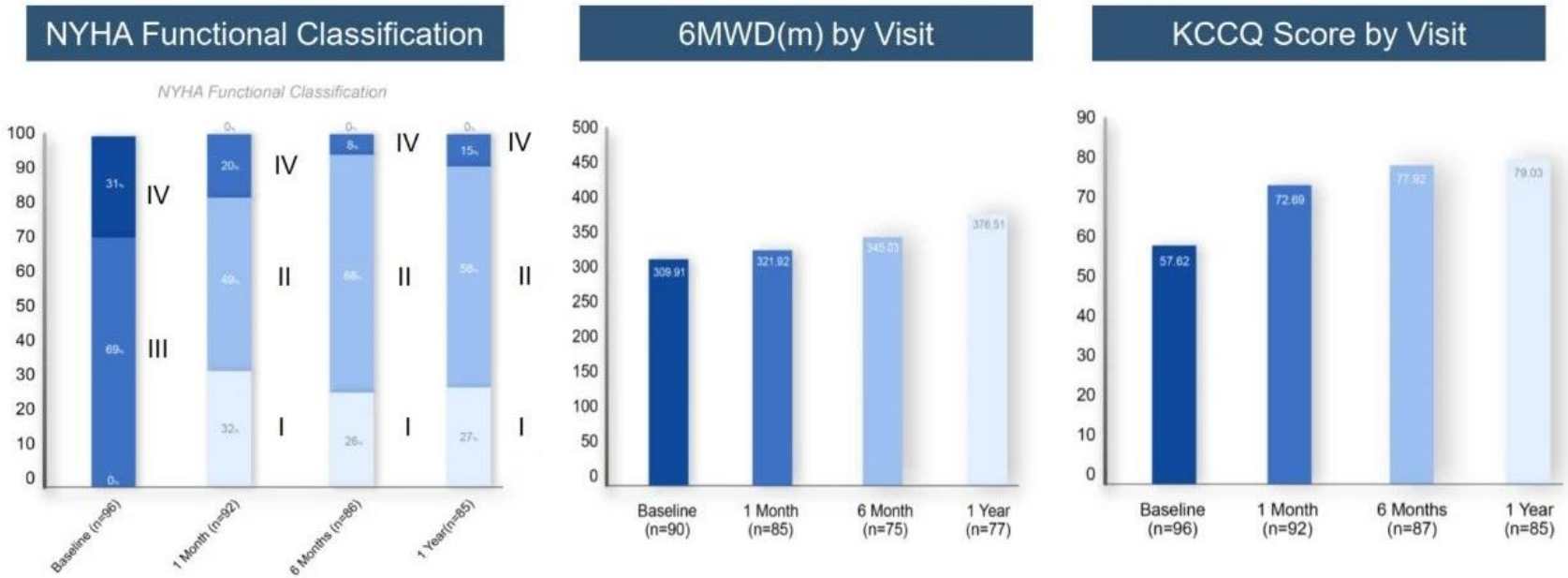


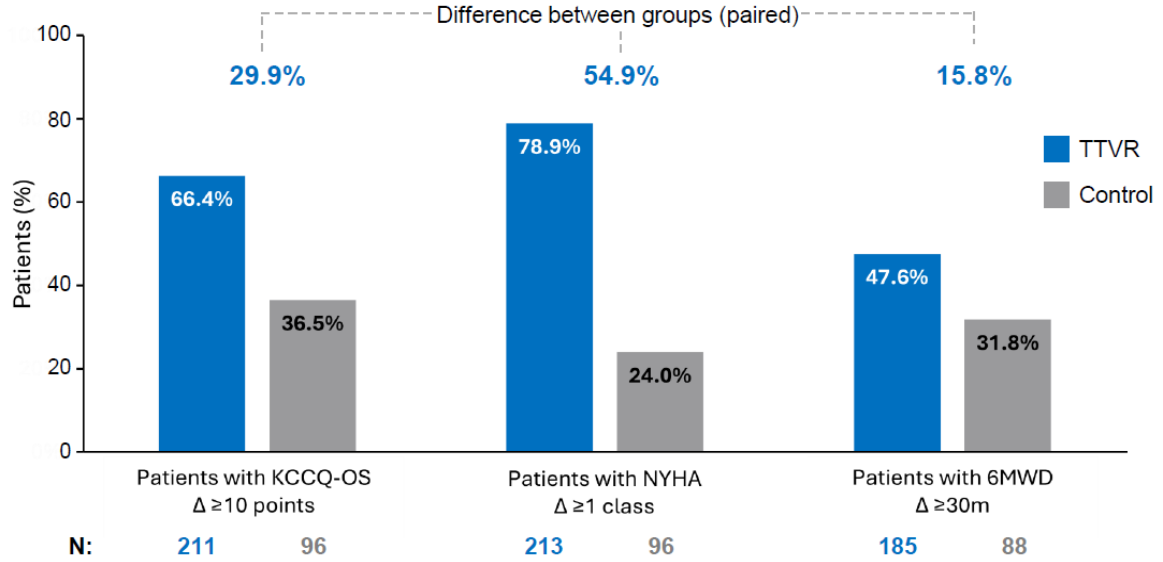
Fam, N.P. et al. J Am Coll Cardiol Intv. 2021;14(5):501-11.

TRISCEND Study : 1 month

TRISCEND II

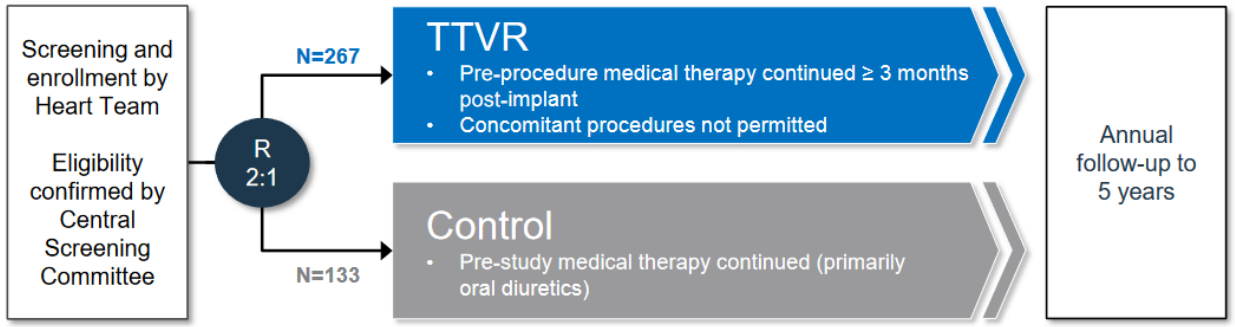
Percutaneous treatment: replacement

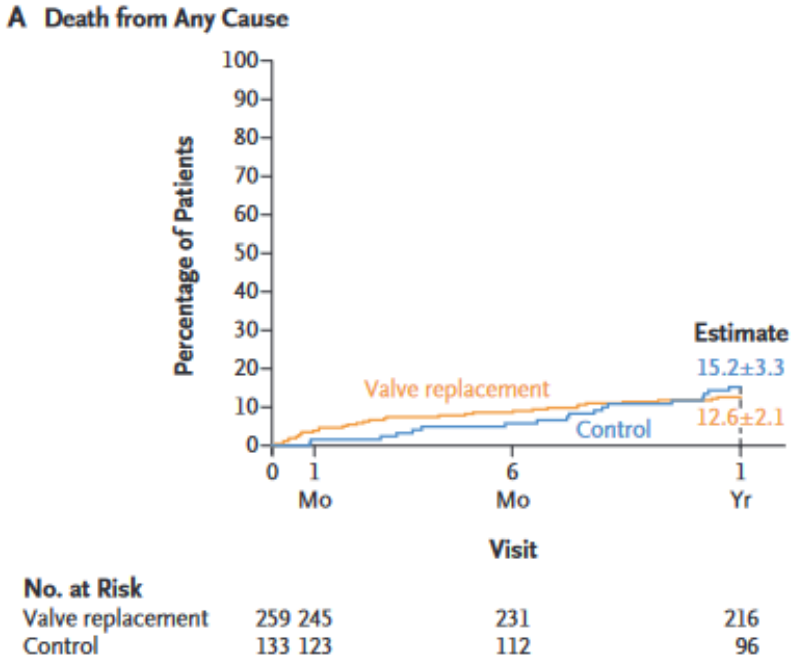


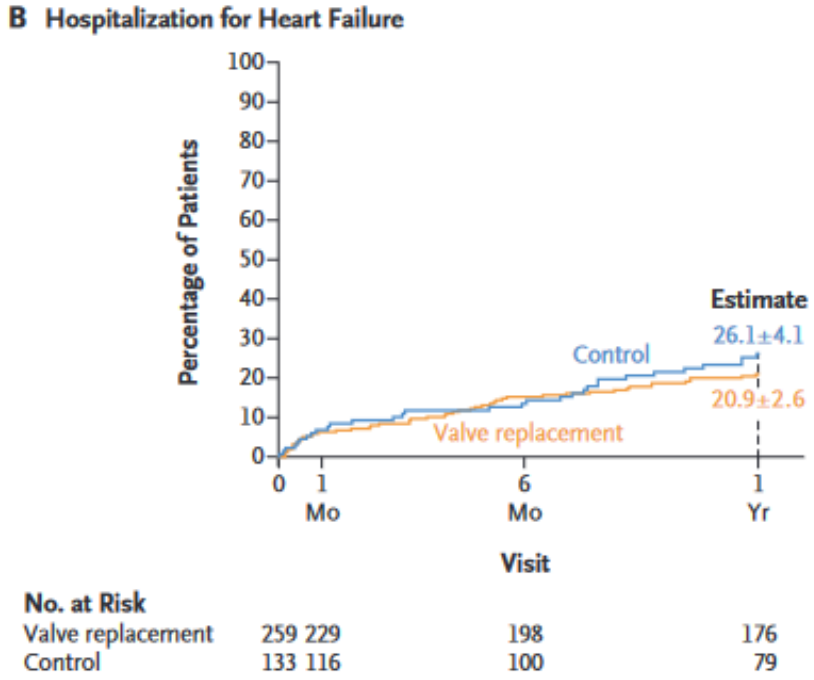


TRISCEND II

Percutaneous treatment: replacement







Percutaneous replacement: challenges

- Devices accessibility
- Patients selection
- Management of procedural complications
- Durability of prosthesis
- Thrombotic risks

Conclusion

- Valves percutanées Tricuspides/Réparation bord à bord
  - Exclusion anatomique: moins fréquente (évolution taille des dispositifs)
  - Durée de procédure: plus courte
  - Dépendance à l'imagerie: plus faible
  - Résultats semble-t-il plus complets en terme de correction de la fuite
  - Impact sur le pronostic dans cette population traitée non encore démontré
- Questions en suspens
  - Durabilité ? Thrombose ?
  - Patients cibles idéaux