

2023

11<sup>ème</sup>

SÉMINAIRE de CARDIOLOGIE  
INTERVENTIONNELLE de TROYES

01 & 02  
AVRIL



SALLE DU CONSEIL MUNICIPAL  
HOTEL DE VILLE de TROYES

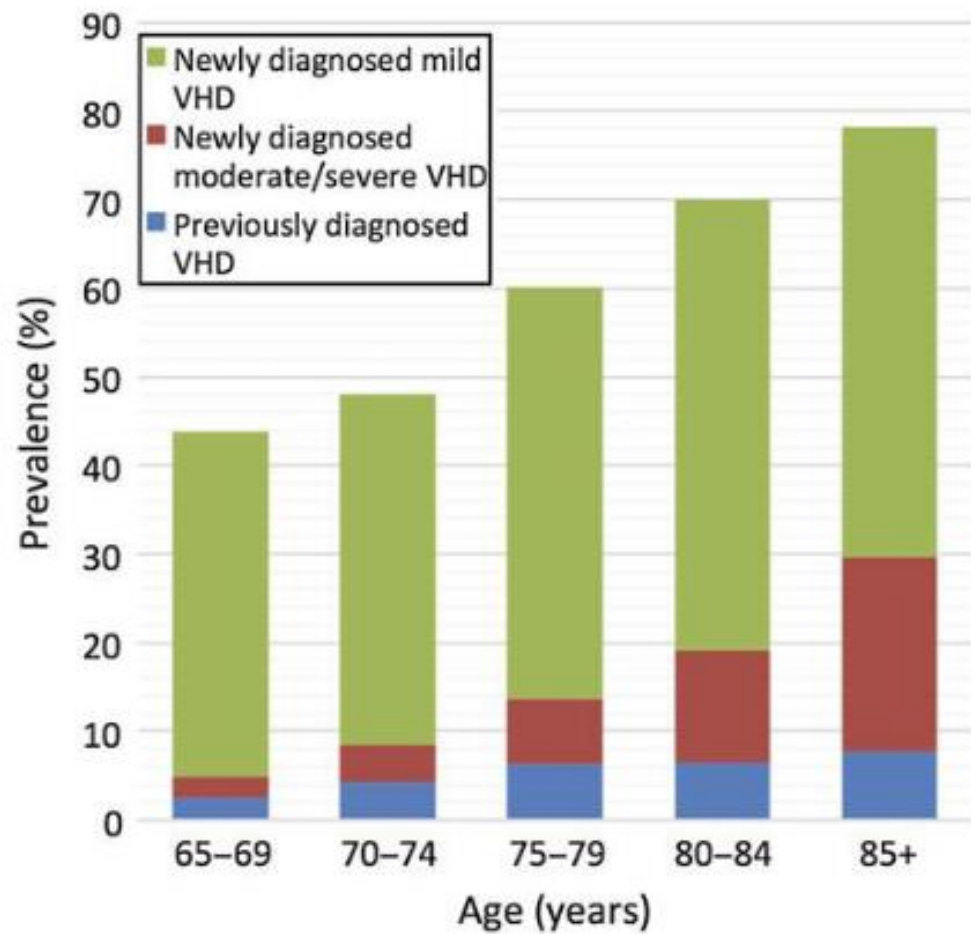


# Interventionnel mitral percutané

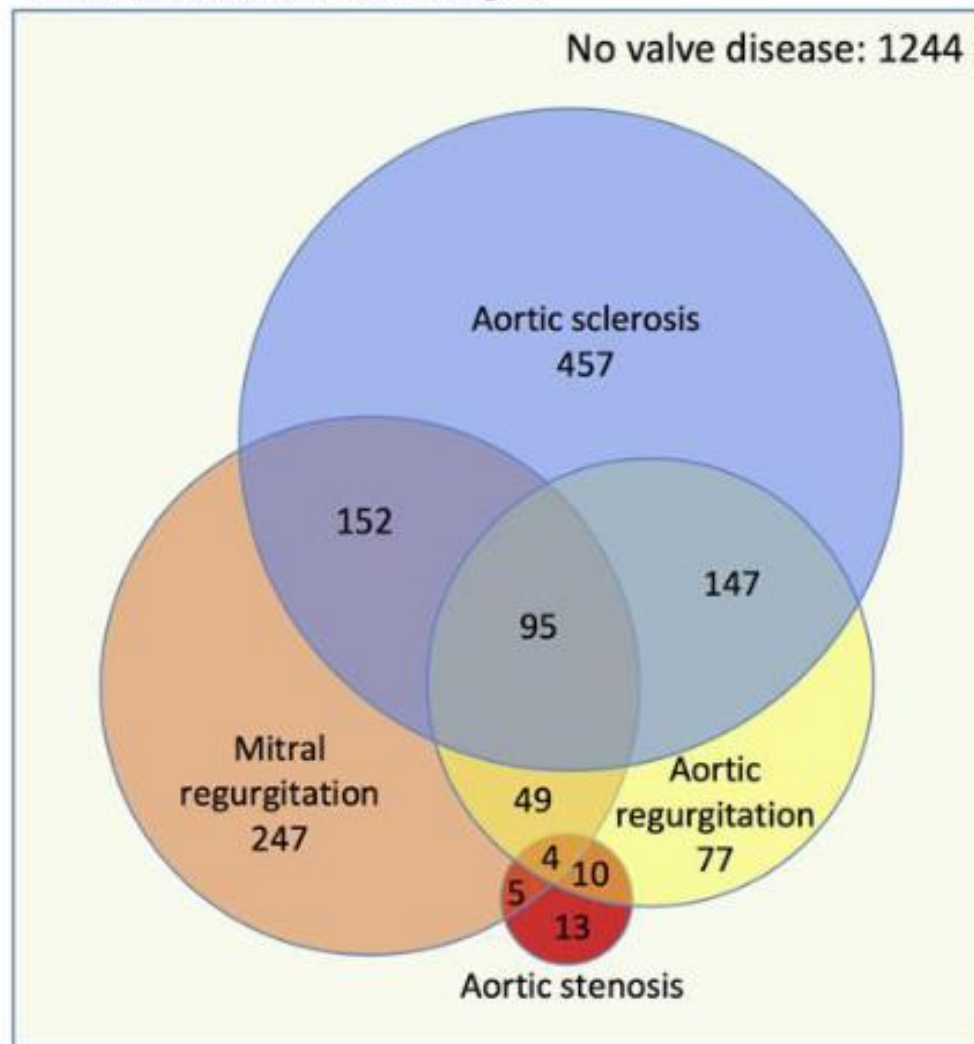
Dr Madjid Boukantar  
CHU Henri Mondor, Créteil  
[Madjid.boukantar@aphp.fr](mailto:Madjid.boukantar@aphp.fr)

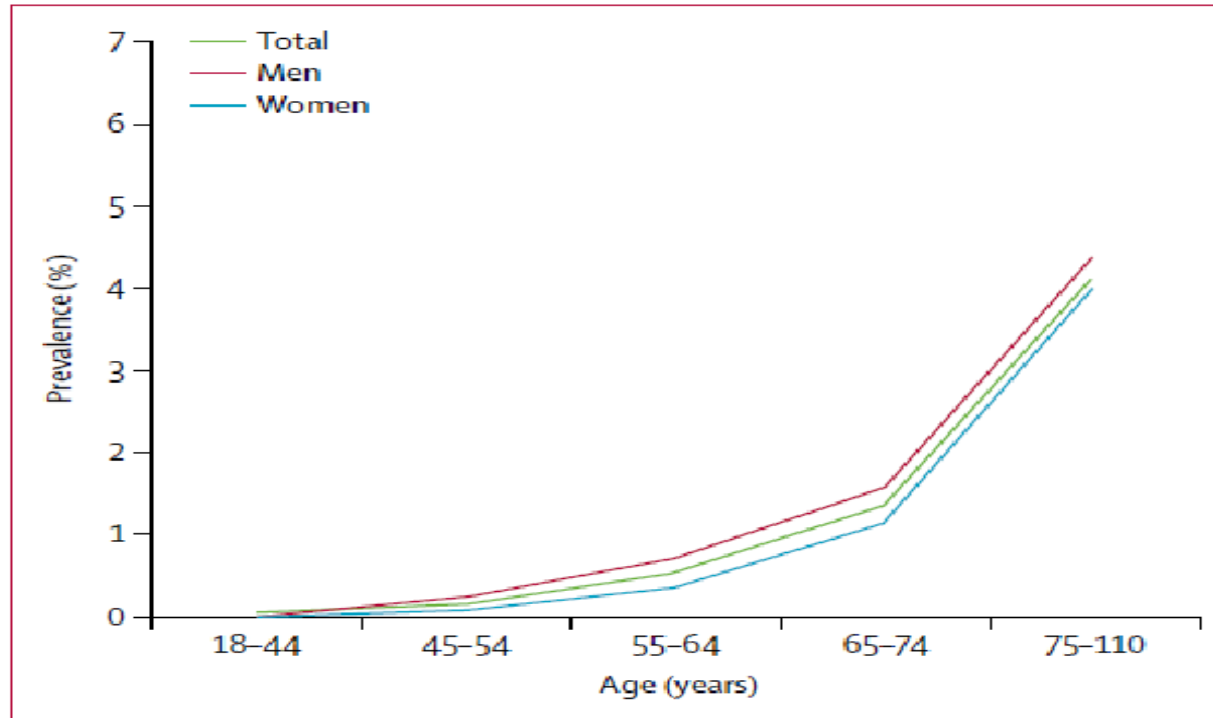
- Aucun conflit d'intérêt à déclarer

Pourquoi des traitements percutanés?



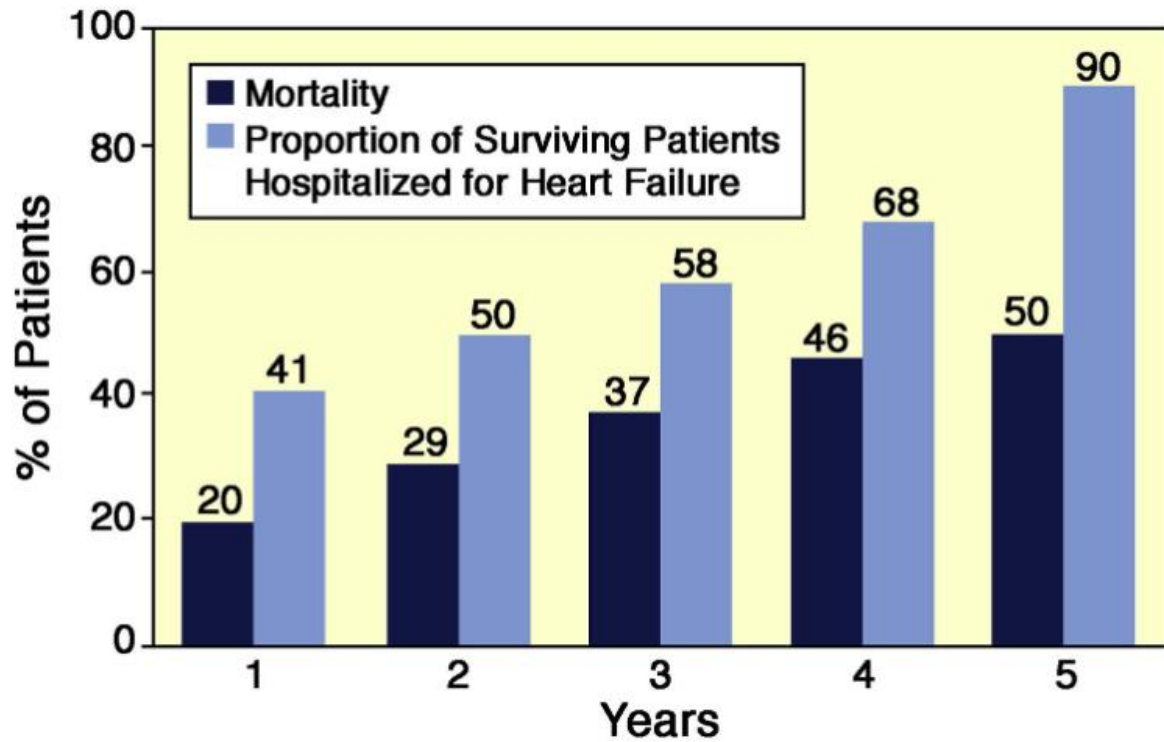
Total cohort: 2500 (rectangle)



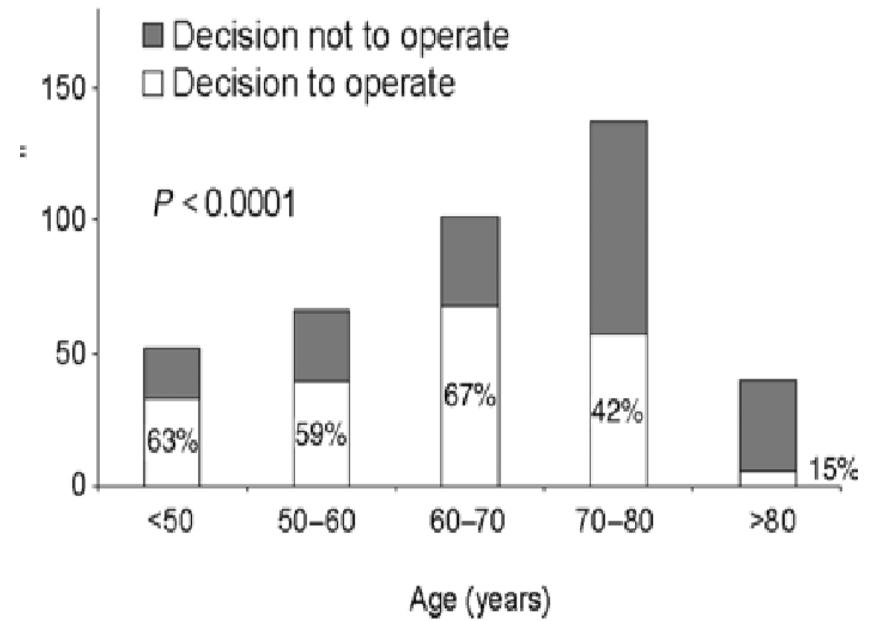


**Figure 1: Prevalence of isolated mitral regurgitation in the community by age**

Dziadzko V, et al. Lancet 2018;391:960-69

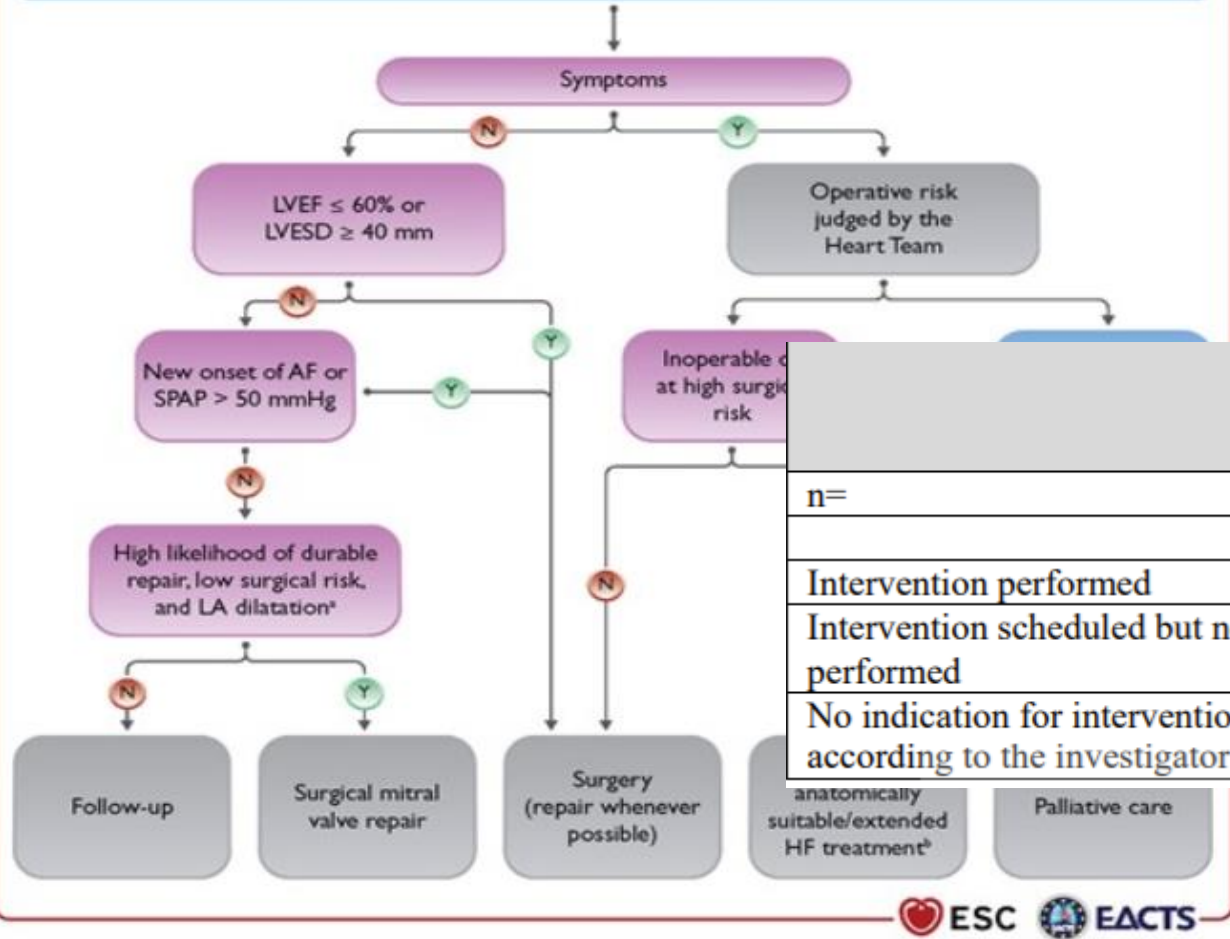


Goel SS, et al. J Am Coll Cardiol.



Mirabel M, et al. Eur Heart J 2007;28:1358-65

Management of patients with severe chronic primary mitral regurgitation



Recommendations	Class <sup>b</sup>	Level <sup>c</sup>
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. <sup>247,323,336,337</sup>	I	B

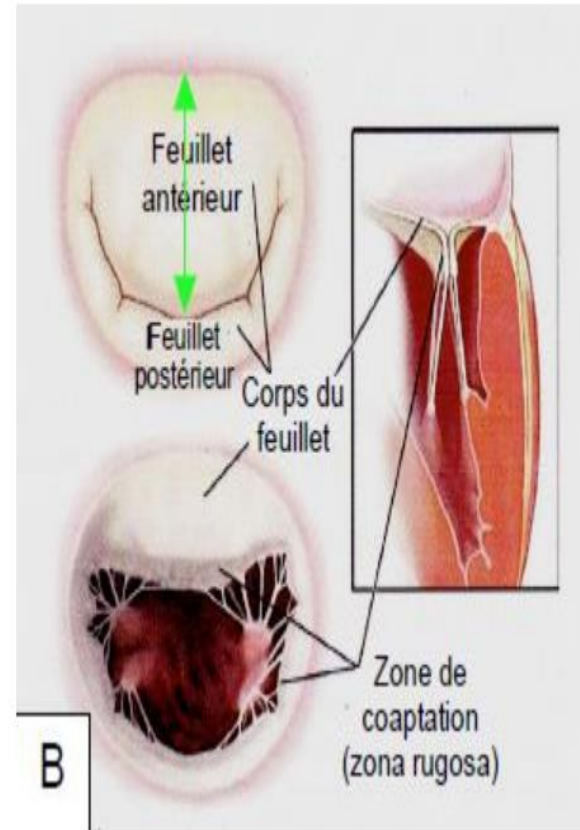
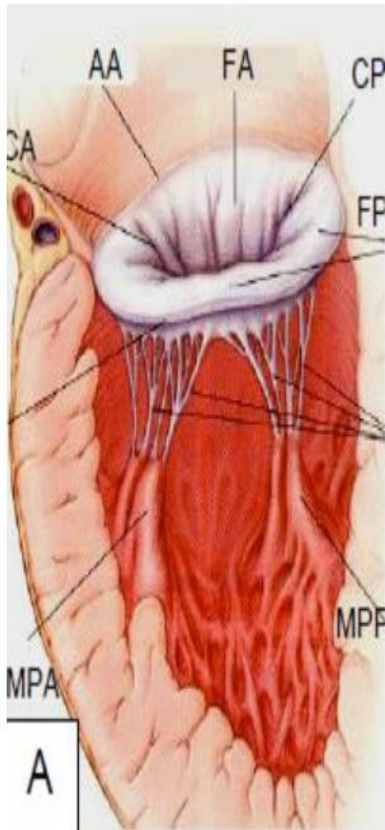
**Patients with concomitant coronary artery or other cardiac disease requiring treatment**

	Primary mitral regurgitation	Secondary mitral regurgitation	
n=	746	368	Patients
Intervention performed	277 (37.1)	90 (24.5)	Judged not eligible for surgery by the Heart Team on the basis of the following characteristics: <sup>d</sup> PCI, CABG, TEER (in addition to surgery should be considered)
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)	

TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment. <sup>337,338,356,357 e</sup>	IIa	B
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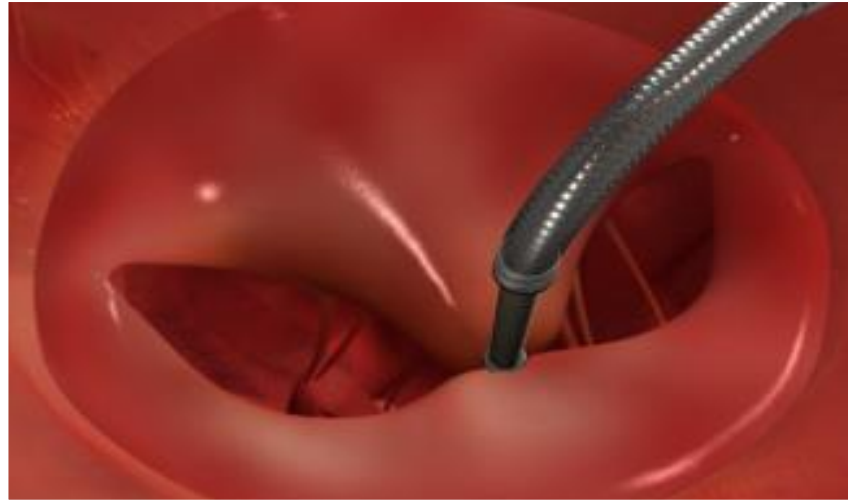
# Techniques disponibles

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





# Réparation bord-à-bord: Mitraclip/Pascal



# Concept

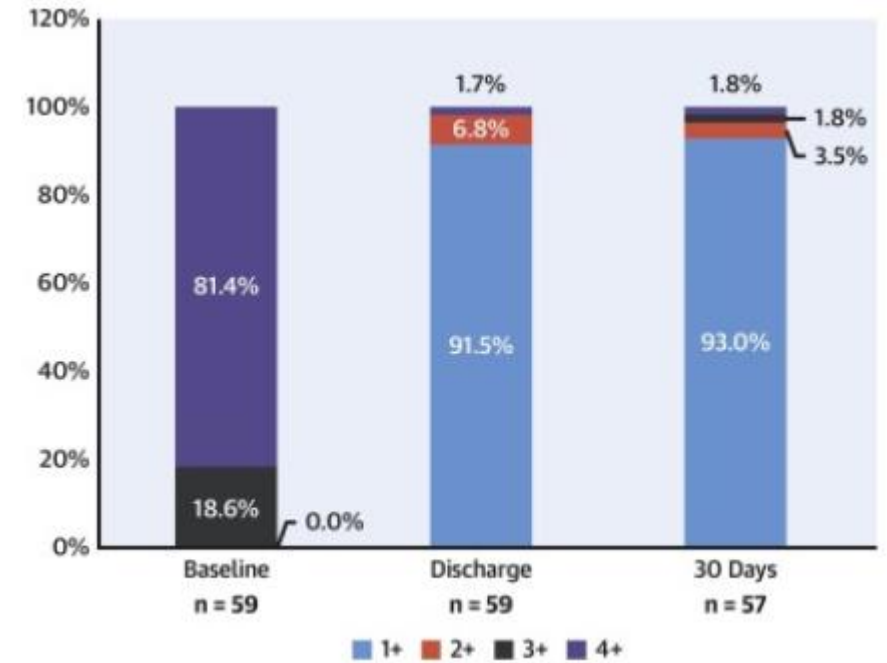
- Technique de réparation de la valve mitrale
- Réparation « bord à bord »:
  - Accrochage ensemble des 2 feuillets de la valve mitrale
  - Inspiré de la chirurgie et de la technique d'Alfieri



# Le matériel

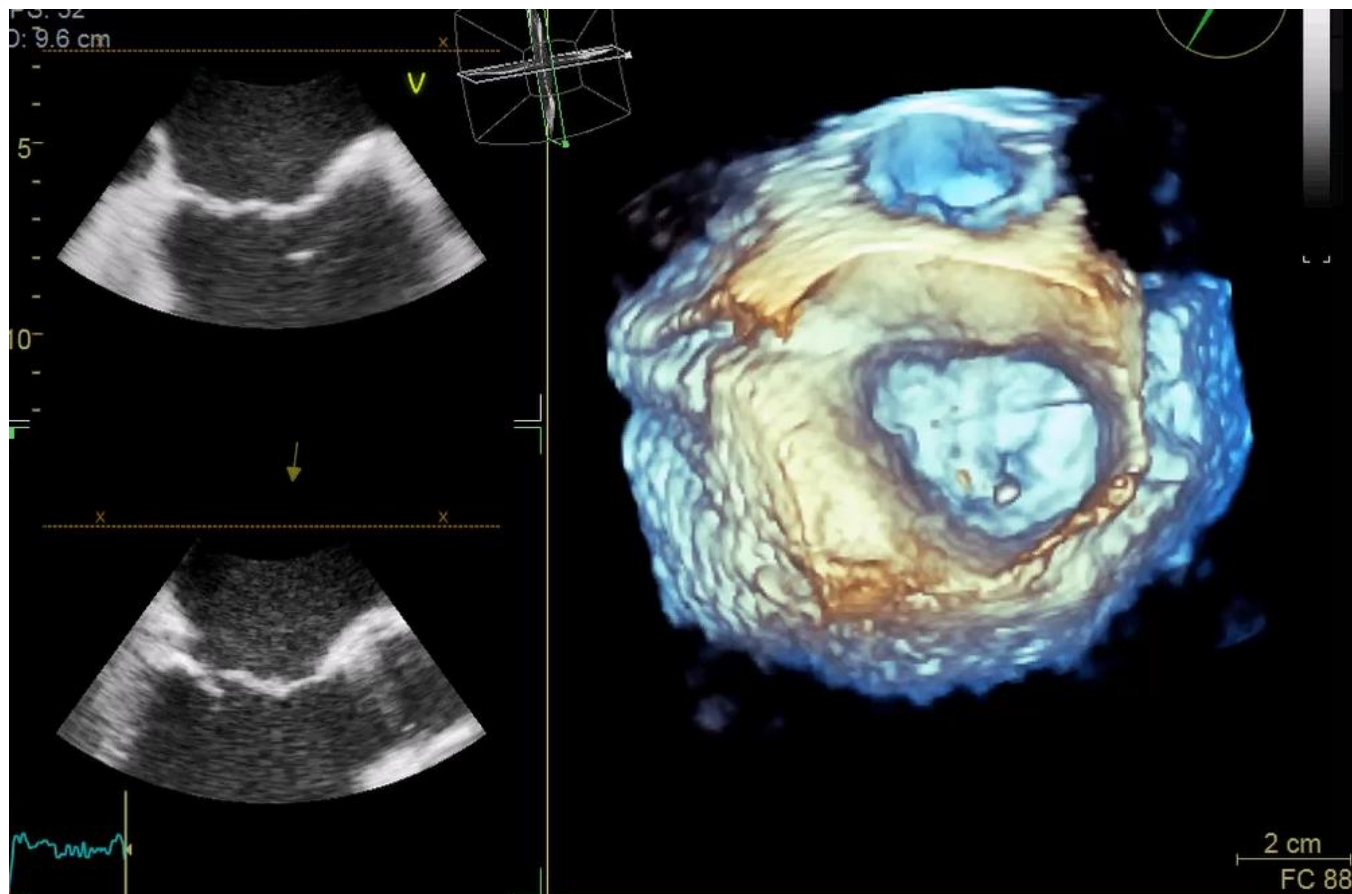


# Mitraclip G4





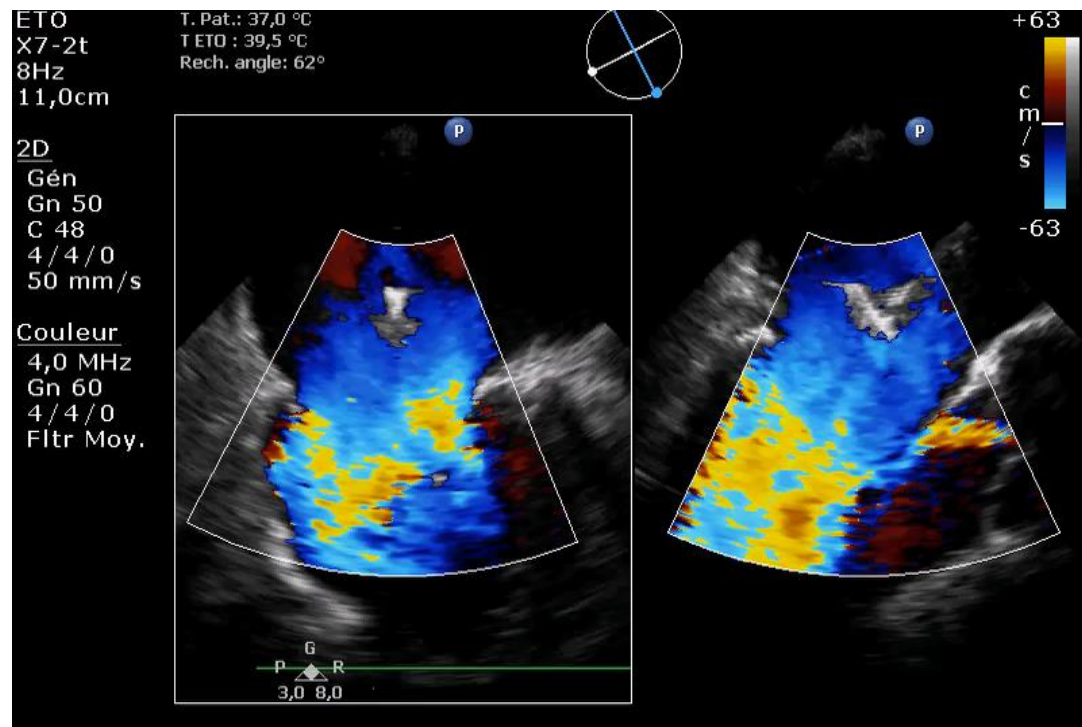
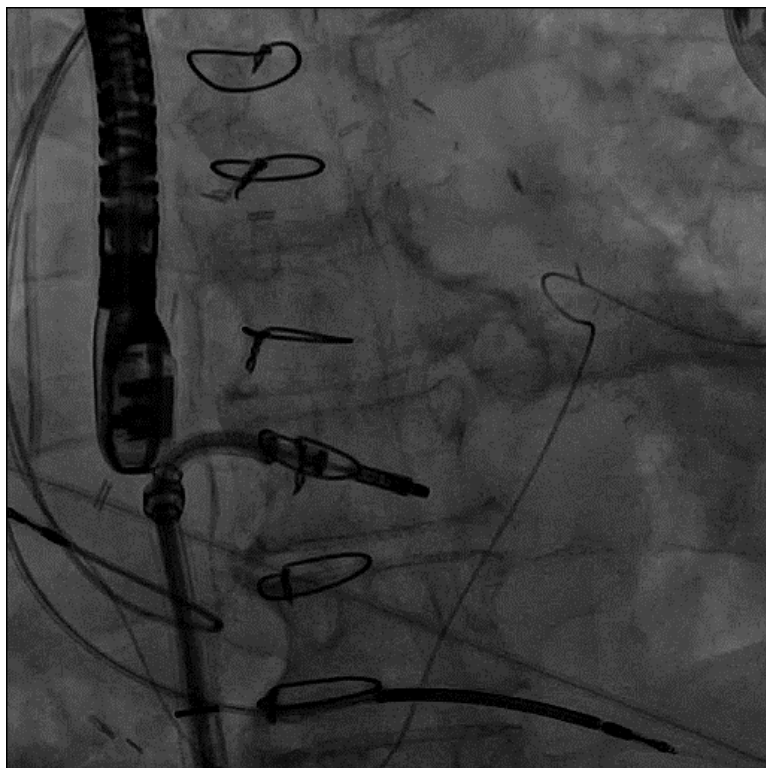
# Insuffisance mitrale dégénérative: ETO



# Procédure en scopie

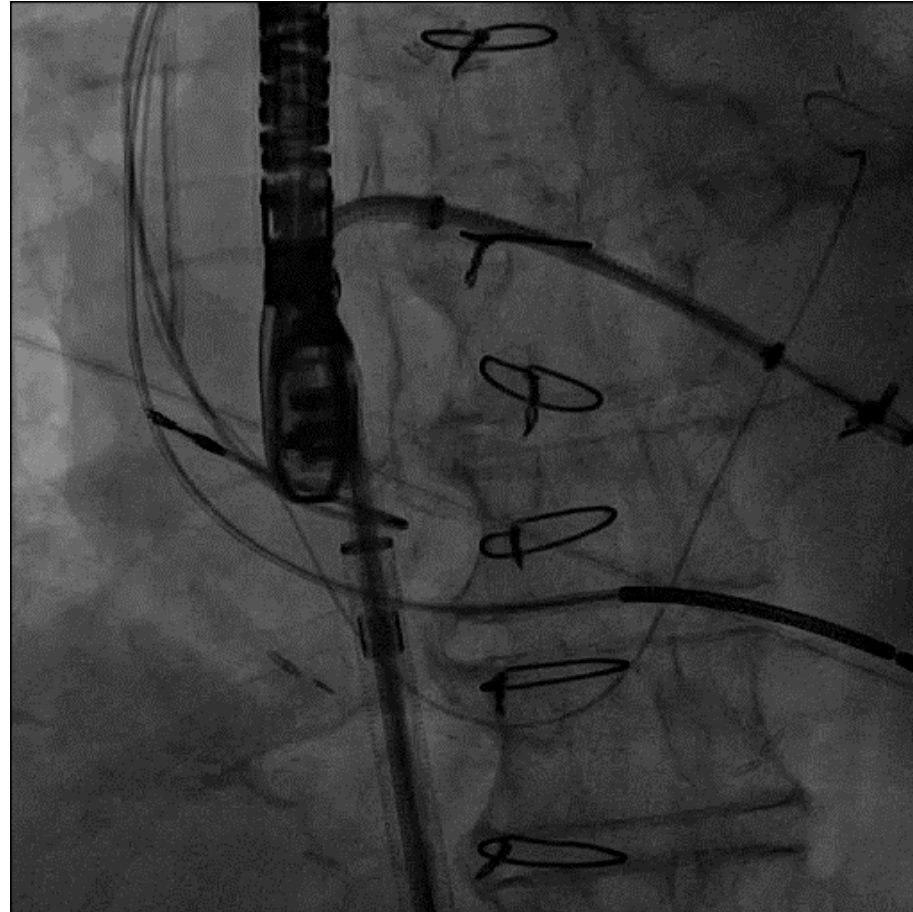


# Procédure : évaluation de la perpendicularité

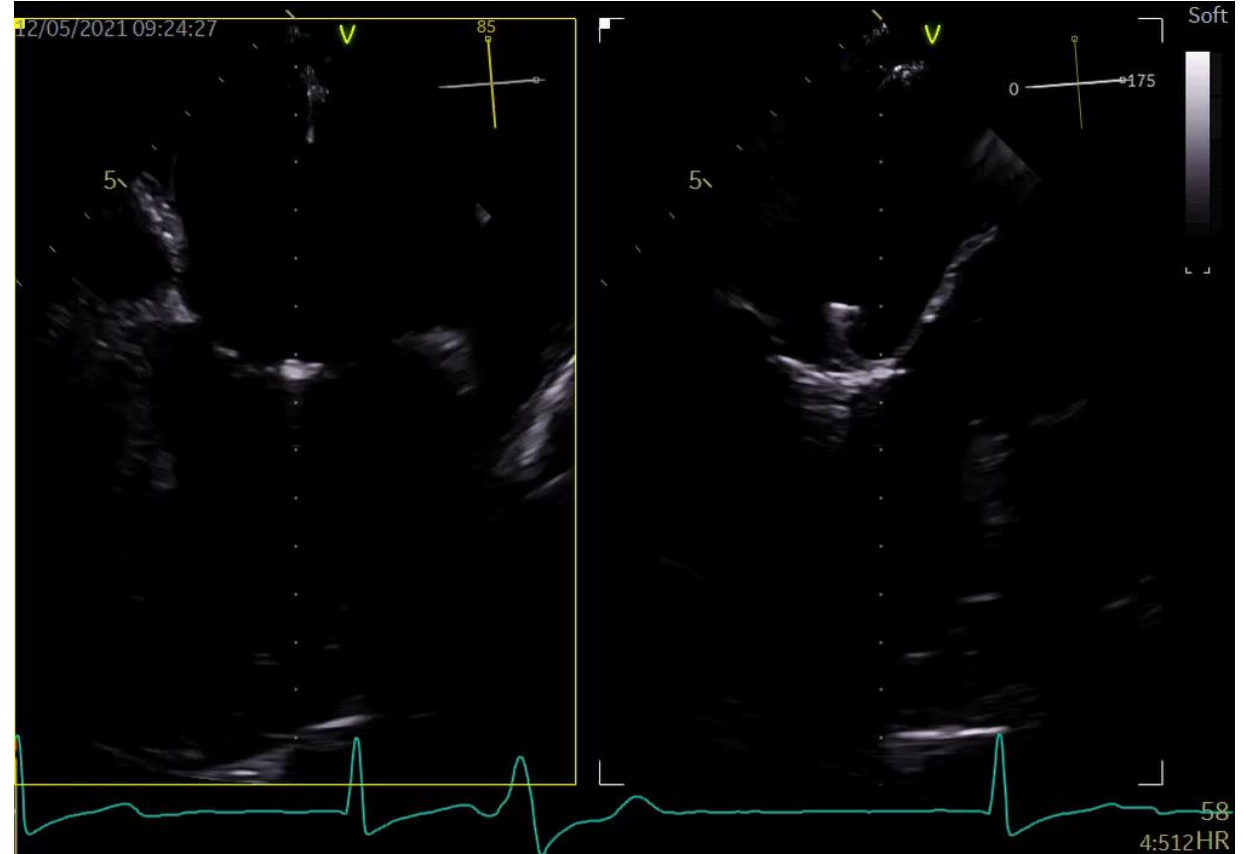
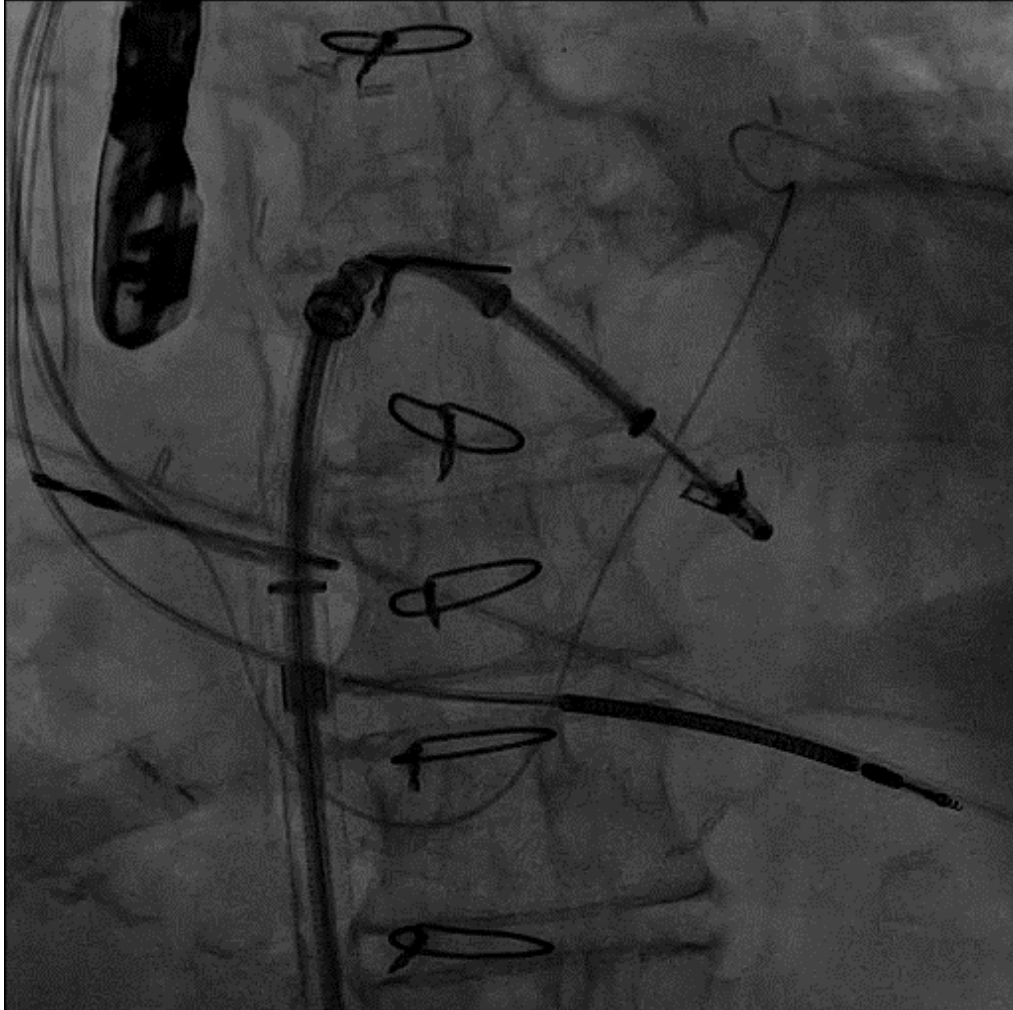




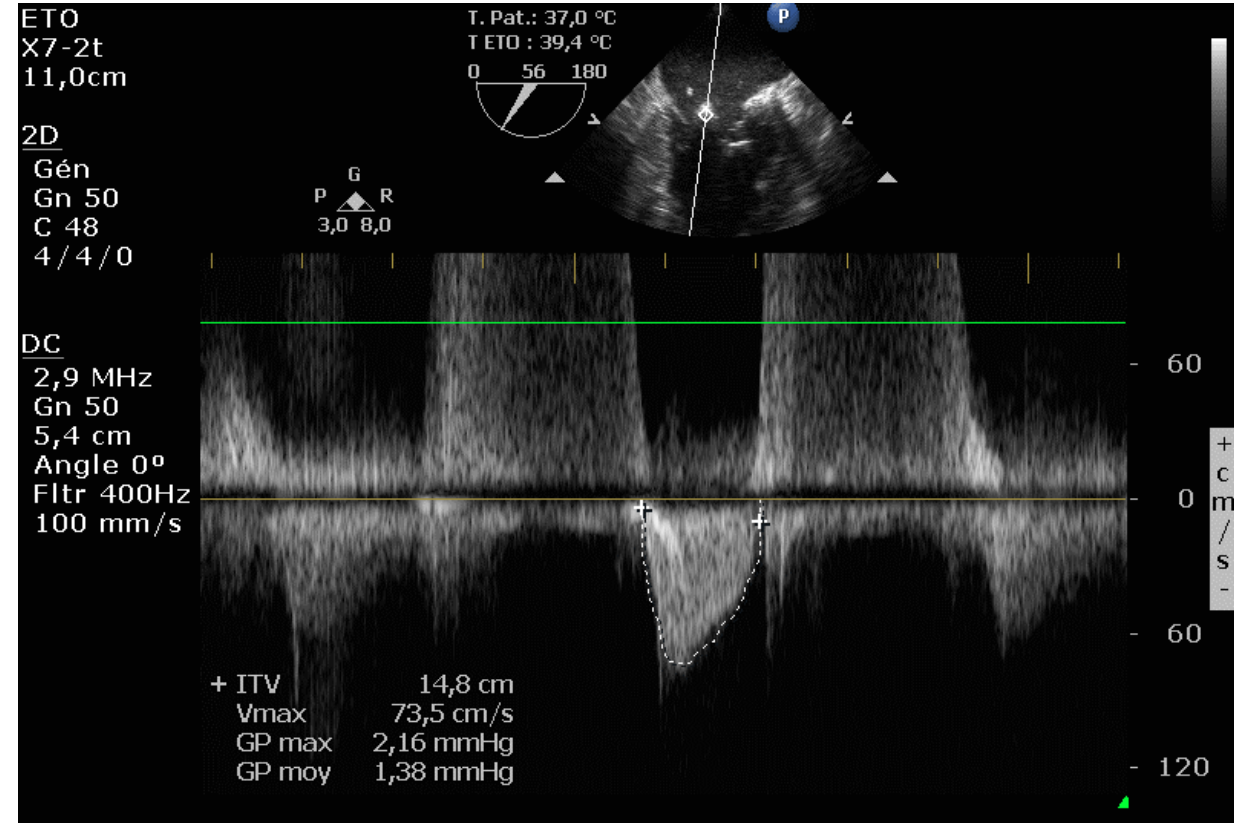
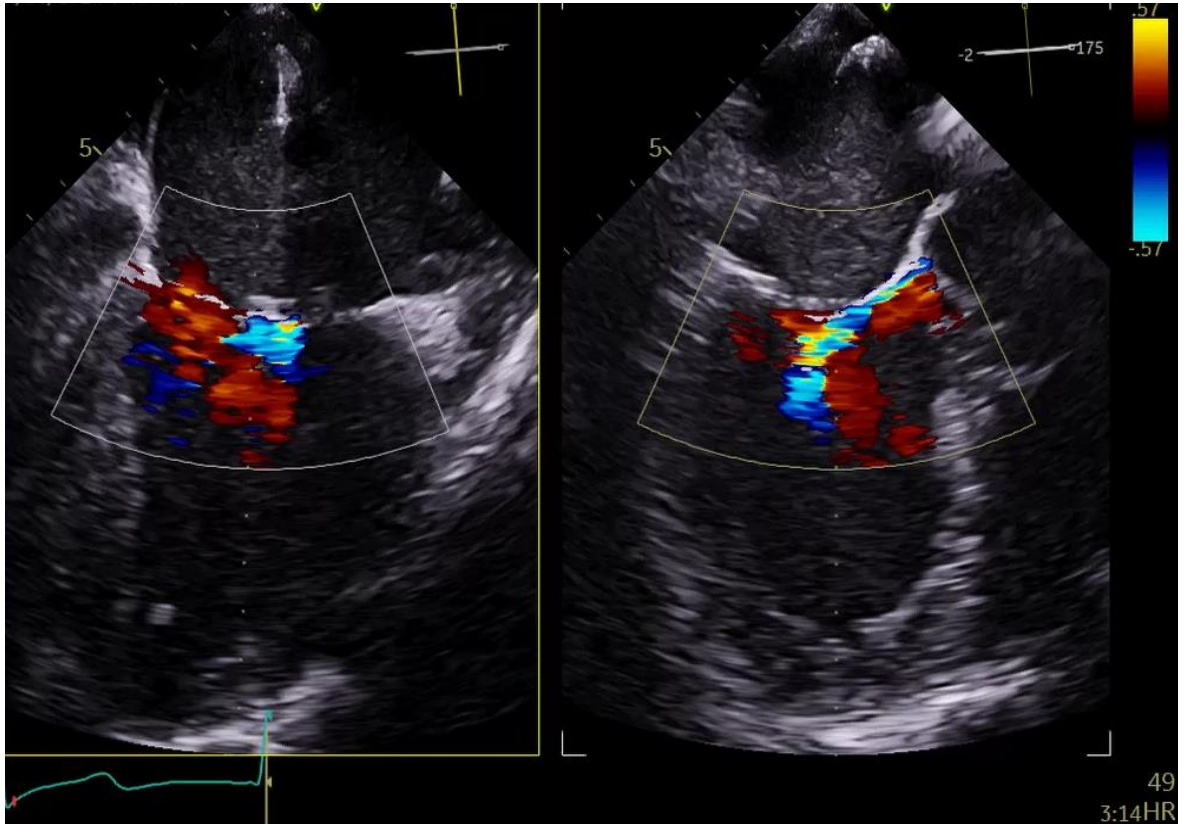
# Franchissement de la valve



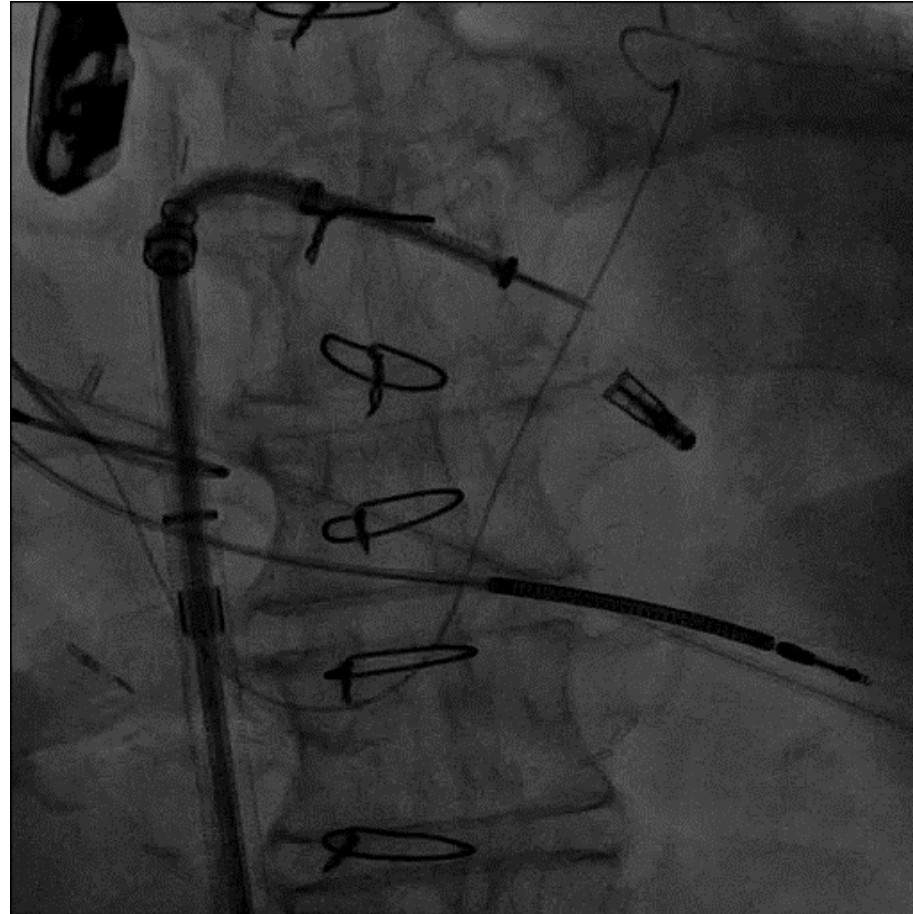
# GRASPING



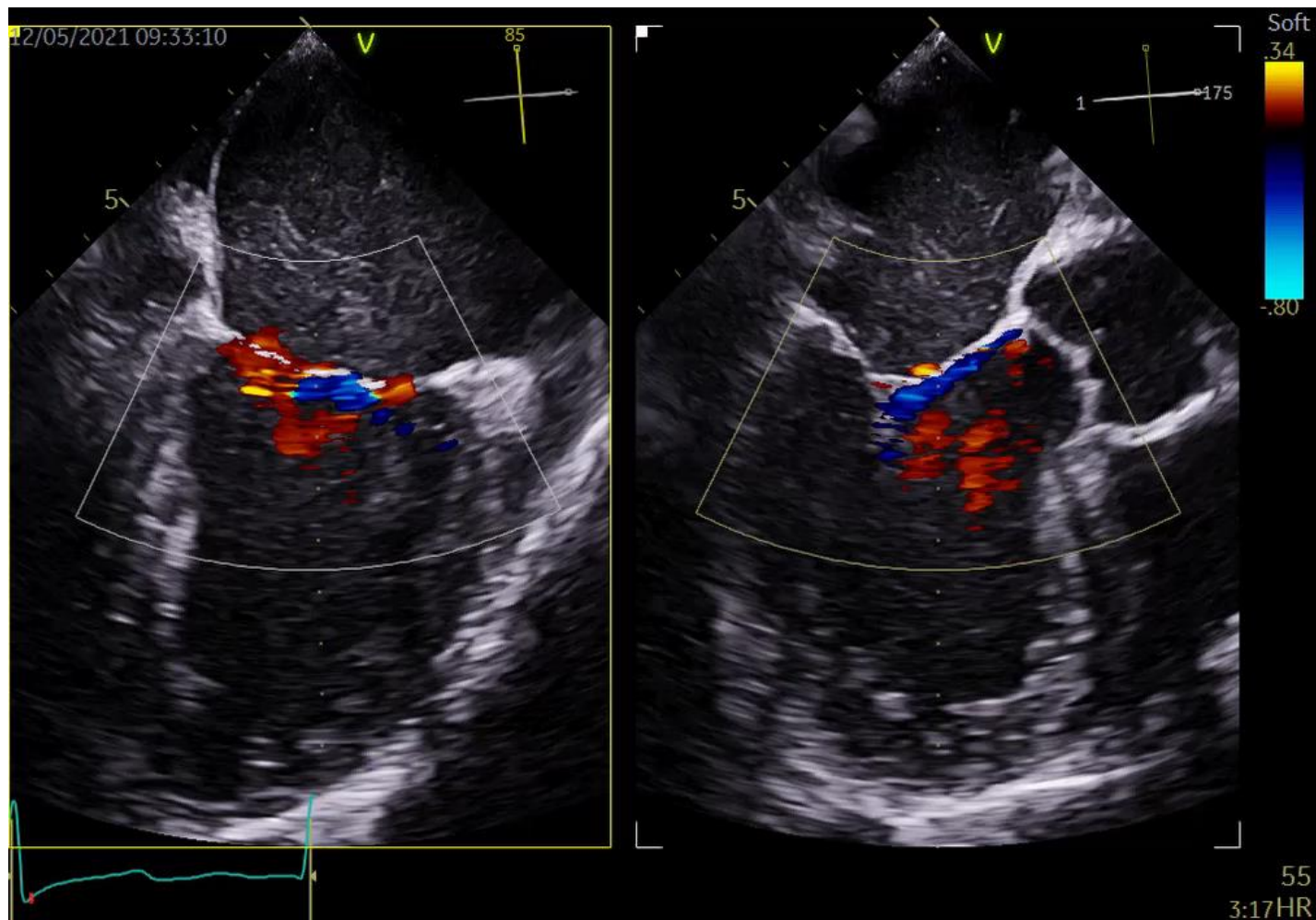
# Contrôle



# Libération du clip

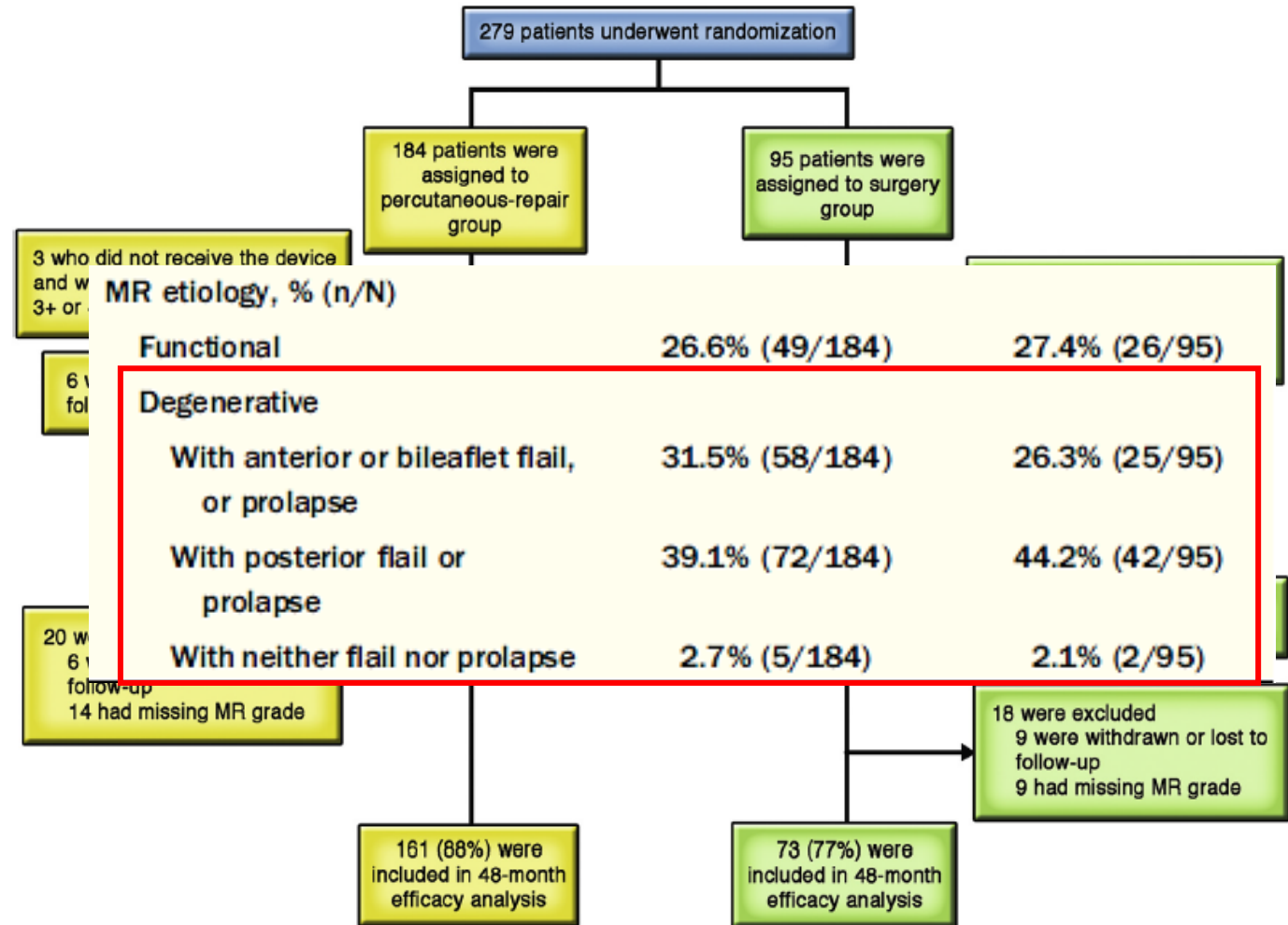


# Résultat



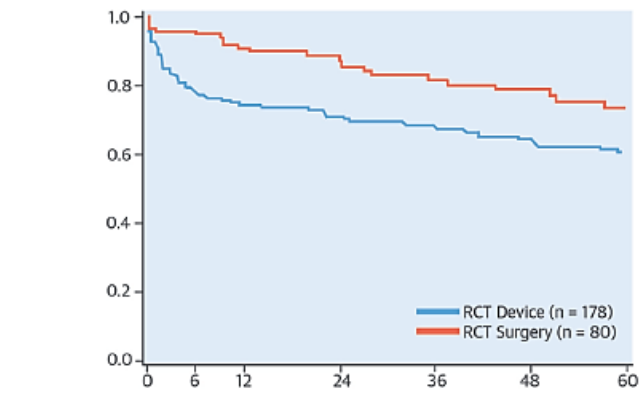
# Etude EVEREST 2

Randomisation 2:1  
Mitraclip vs. Chir  
279 patients



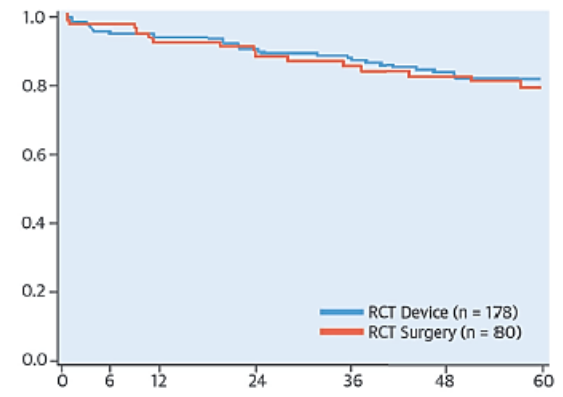
# Résultats Etude EVEREST 2

A. Freedom From Death, MV Surgery or Reoperation



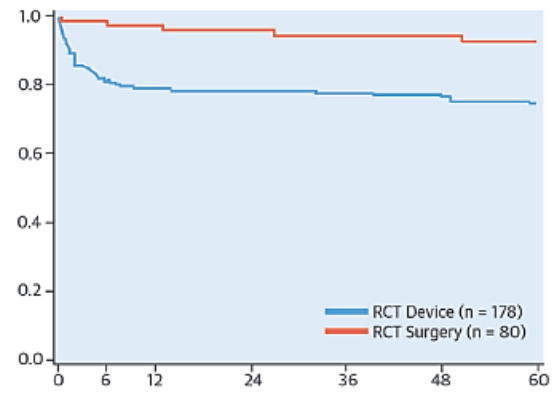
Patients At Risk	Months						
	0	6	12	24	36	48	60
Device Group	178	136	128	117	109	98	45
Control Group	80	75	69	63	54	49	21

B. Freedom From Death



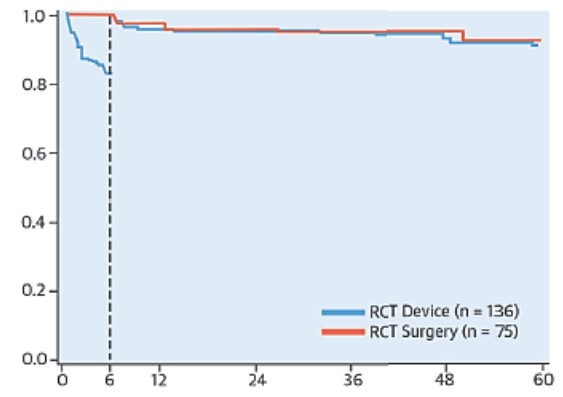
Patients At Risk	Months						
	0	6	12	24	36	48	60
Device Group	178	165	158	143	133	119	58
Control Group	80	76	70	65	57	52	24

C. Freedom From MV Surgery or Reoperation



Patients At Risk	Months						
	0	6	12	24	36	48	60
Device Group	178	136	128	117	109	98	45
Control Group	80	75	69	63	54	49	21

D. Landmark Analysis of Freedom From MV Surgery or Reoperation Beyond 6 Months



Patients At Risk	Months						
	0	6	12	24	36	48	60
Device Group	178	136	128	117	109	98	45
Control Group	80	75	69	63	54	49	21

# IM secondaires: études randomisées

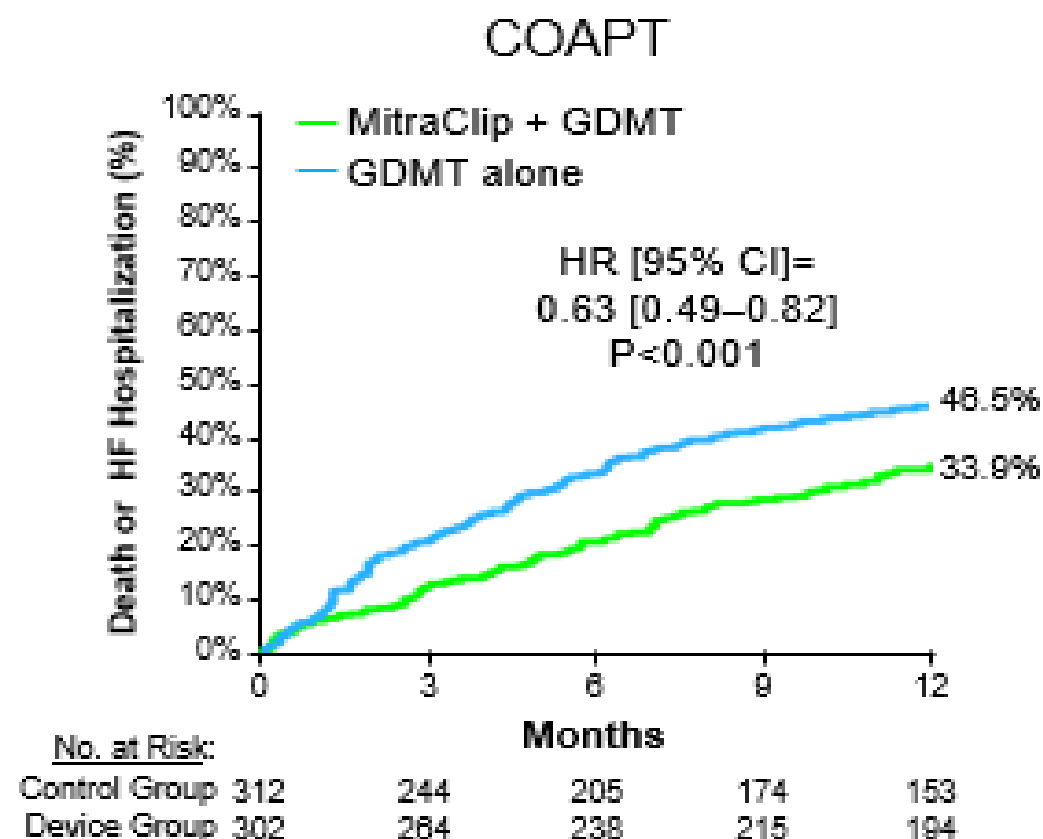
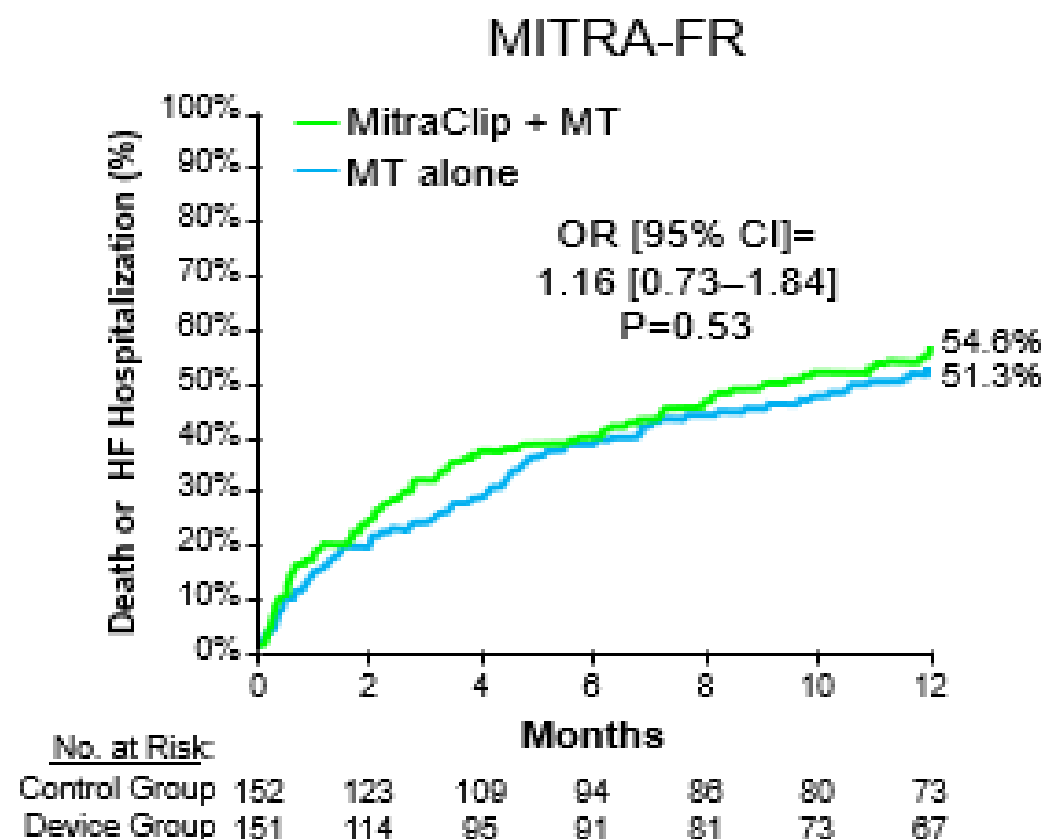
	MITRA-FR	COAPT
Study sponsor	Hospices Civils de Lyon	Evalve (Abbott Vascular)
ClinicalTrials.gov identifier	NCT01920698	NCT01626079
Design	Prospective, randomised	Prospective, randomised
Control arm	Optimal medical therapy	Standard hospital clinical practice
MR aetiology	Secondary	Secondary
Left ventricular ejection fraction (LVEF)	≥15% and ≤40%	≥20% and ≤50%
NYHA class	II to IV	II to IV
Hospitalisation for heart failure within 12 months preceding randomisation?	Yes	Yes
Contraindication to surgery?	Yes (local site Heart Team)	Yes (local site Heart Team)
Primary effectiveness endpoint	All-cause mortality and unplanned hospitalisations for heart failure at 12 months	Recurrent heart failure hospitalisations at 12 months
Estimated enrolment	288 (144×2)	430 (215×2)
Locations	22 centres (France)	67 centres (USA)

SOR>20mm<sup>2</sup>

SOR>30mm<sup>2</sup>



## IM secondaire: COAPT vs. MITRA-FR



Obadia JF et al. NEJM. 2018 Aug 27. doi: 10.1056/NEJMoa1805374

Stone GW et al. NEJM. 2018 Sept 23.

# COAPT vs. MITRA-FR: MR, LV Volumes and Function

	COAPT (n=614)	MITRA-FR (n=304)
EROA, mm <sup>2</sup> (mean ± SD)	41 ± 15	31 ± 10
- <30 mm <sup>2</sup>	14% (80/591)	52% (157/301)
- 30 – 40 mm <sup>2</sup>	46% (270/591)	32% (95/301)
- >40 mm <sup>2</sup>	41% (241/591)	16% (49/301)
LVEF, % (mean ± SD)	31 ± 9	33 ± 7
LVEDV, mL/m <sup>2</sup> (mean ± SD)	101 ± 34	135 ± 35

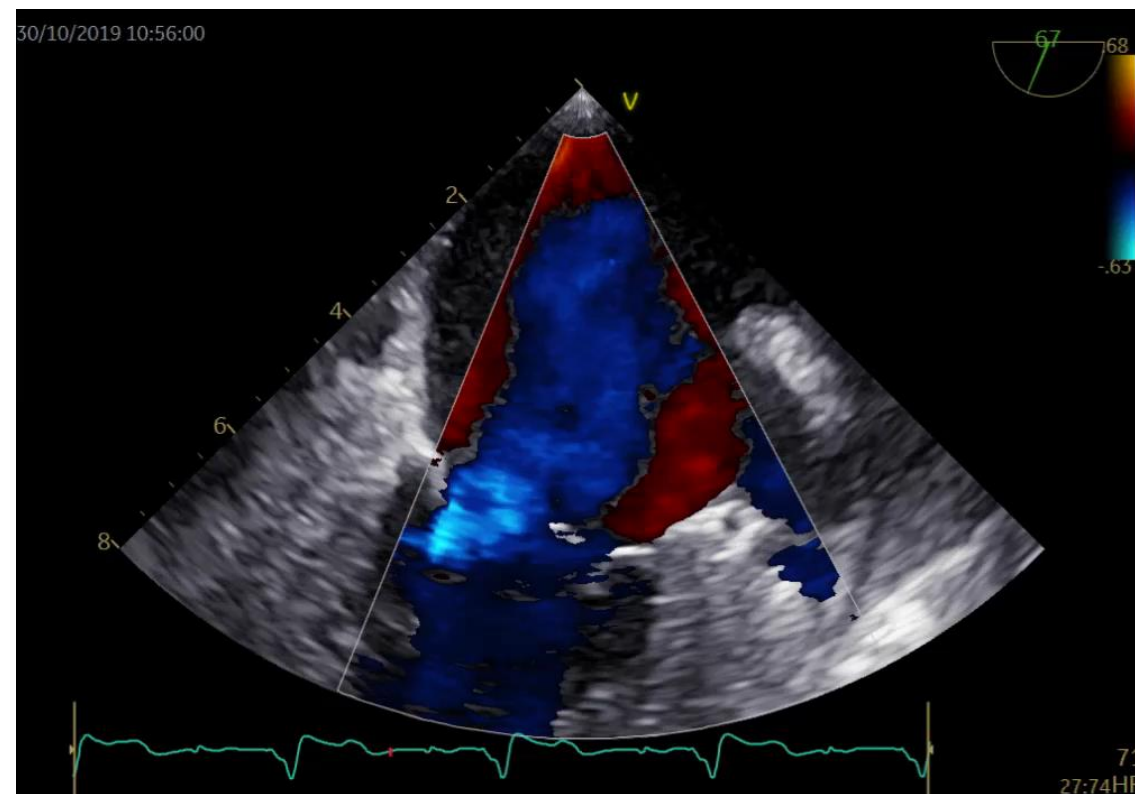
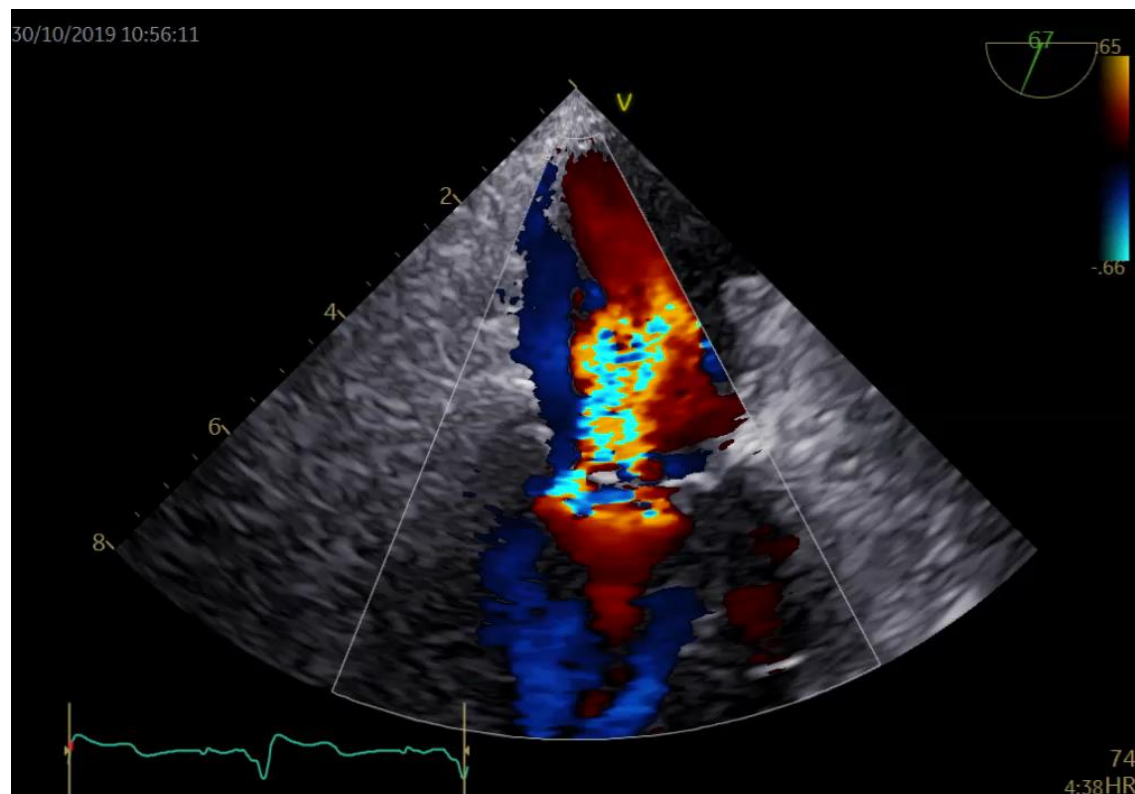
# COAPT vs. MITRA-FR: MitraClip Outcomes

	COAPT (n=302)	MITRA-FR (n=152)
MitraClip attempted	293 (97.0%)	144 (94.7%)
≥1 Clip implanted	287 (95.0%)	138 (90.8%)
Procedural complications	25/293 (8.5%)	21/144 (14.6%)
- Device implant failure	6 (2.0%)	6 (4.2%)
- Transfusion or vasc compl requiring surgery	16 (5.5%)	5 (3.5%)
- ASD	2 (0.7%)	4 (2.8%)
- Cardiogenic shock	1 (0.3%)	4 (2.8%)
- Cardiac embolism/stroke	1 (0.3%)	2 (1.4%)
- Tamponade	1 (0.3%)	2 (1.5%)
- Urgent cardiac surgery	1 (0.3%)	0 (0%)
Acute result: MR ≥3+	5%	9%
12-month result: MR ≥3+	5%	17%

Stone GW et al. NEJM. 2018 Sept 23; Obadia JF et al. NEJM. 2018 Aug 27.

doi: 10.1056/NEJMoa1805374

# IM secondaire



# Mitraclip IM secondaire

<p>Indications retenues :</p>	<p>Patients avec une insuffisance mitrale secondaire de grade 3+/4+ symptomatique malgré une prise en charge médicale optimale et remplissant les critères suivants :</p> <ul style="list-style-type: none"><li>- non éligibles à la chirurgie de réparation ou de remplacement valvulaire,</li><li>- ayant eu une hospitalisation pour insuffisance cardiaque dans les 12 mois précédant l'intervention,</li><li>- ayant une fraction d'éjection ventriculaire gauche comprise entre 20 et 50%,</li><li>- et une surface de l'orifice régurgitant <math>&gt; 0,3 \text{ cm}^2</math> et un volume télédiastolique indexé du ventricule gauche <math>\leq 96 \text{ mL/m}^2</math>.</li></ul> <p>Les patients ayant un ventricule gauche fortement dilaté (défini par un volume télédiastolique indexé du ventricule gauche <math>&gt; 96 \text{ mL/m}^2</math>) et une insuffisance mitrale modérée ou moindre, démontré par un orifice régurgitant de la valve mitrale <math>\leq 0,3 \text{ cm}^2</math>, ne sont pas éligibles à la technique (non indication).</p> <p>Les critères cliniques et échocardiographiques doivent être validés par une équipe multidisciplinaire <i>ad hoc</i>.</p> <p>Les patients ayant une espérance de vie inférieure à 1 an compte tenu de comorbidités extracardiaques ne sont pas éligibles à la technique (non indication).</p>
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# 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.<sup>299–302</sup>

**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.<sup>329,330,333</sup>

**I**

**B**

In symptomatic patients, who are judged not appropriate for surgery by the Heart Team on the basis of their individual characteristics,<sup>d</sup> PCI (and/or TAVI) possibly followed by TEER (in case of persisting severe SMR) should be considered.

**IIa**

**C**

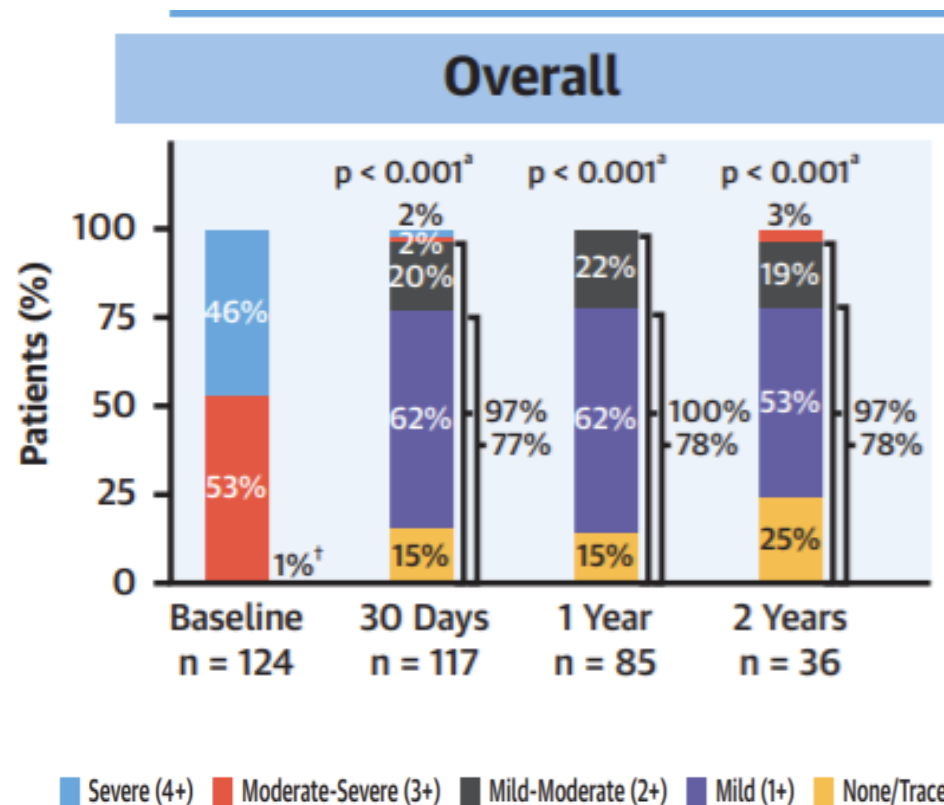
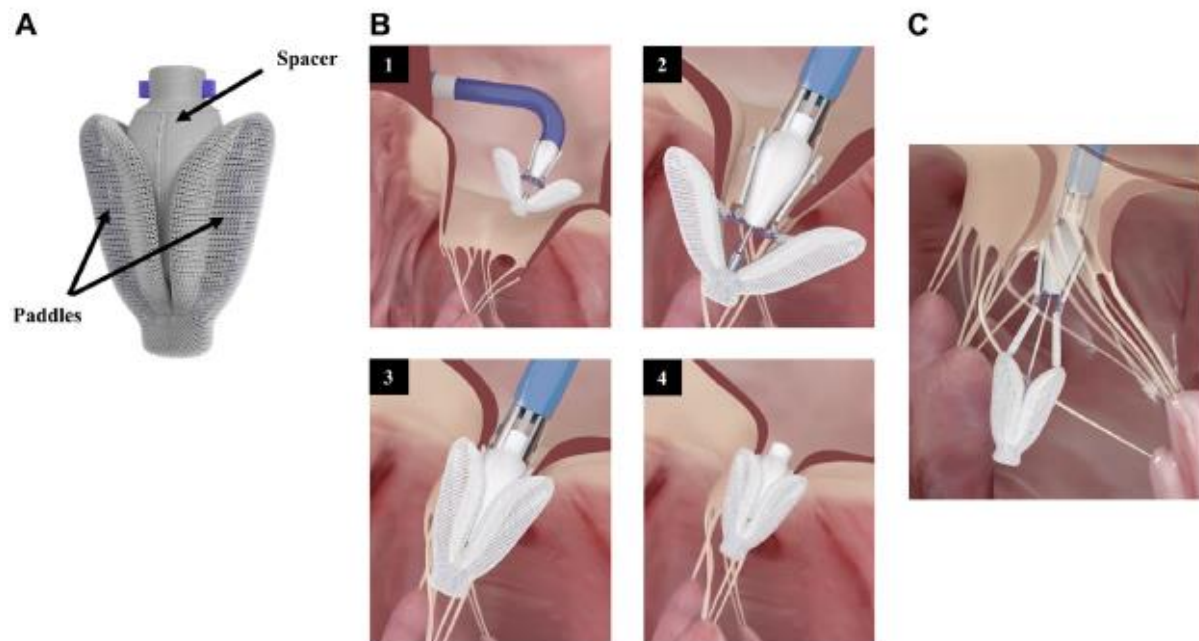
### Patients without concomitant coronary artery or other cardiac disease requiring treatment

TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment.<sup>337,338,356,357 e</sup>

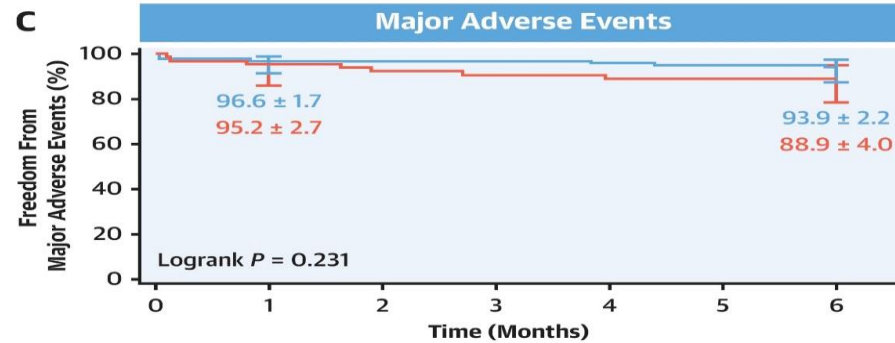
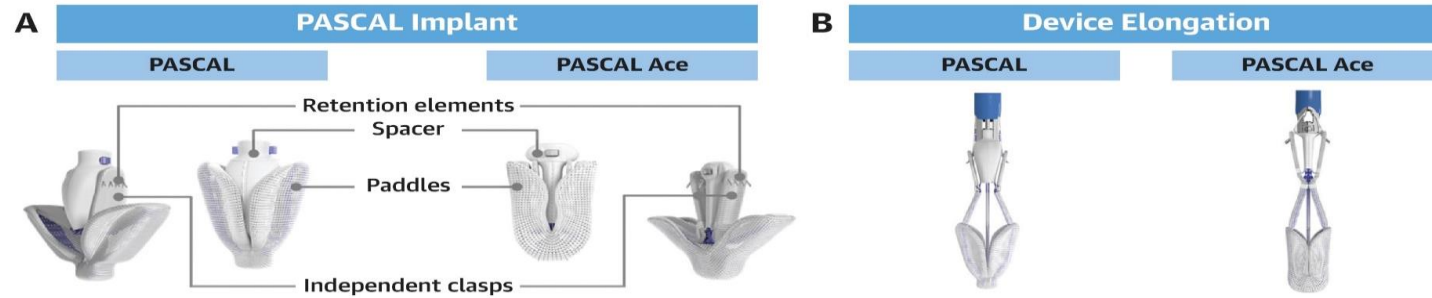
**IIa**

**B**

# Réparation bord-à-bord: Pascal

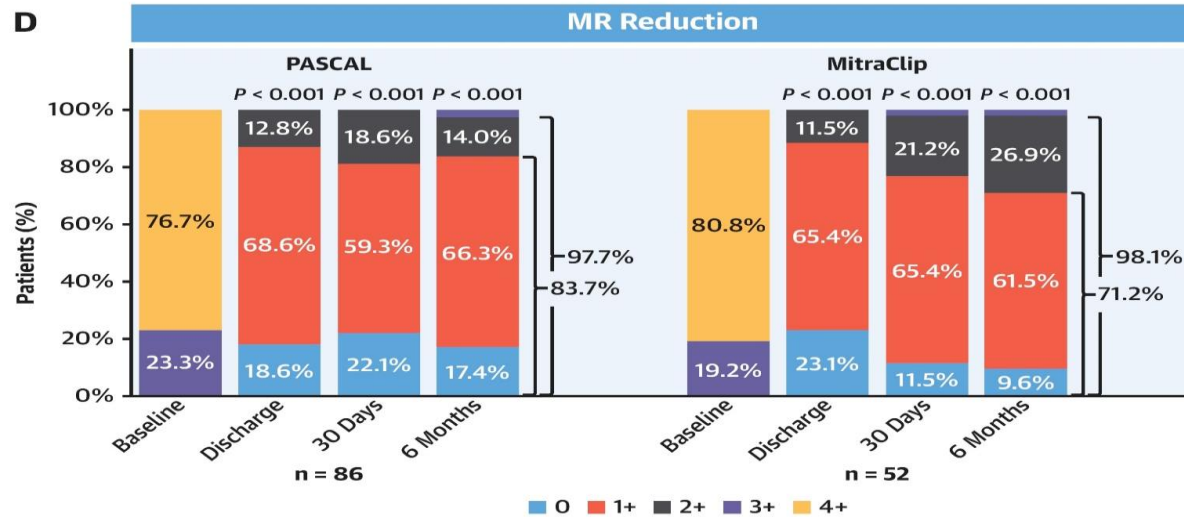


# CENTRAL ILLUSTRATION: The CLASP IID Randomized Trial Key Outcomes at 6 Months



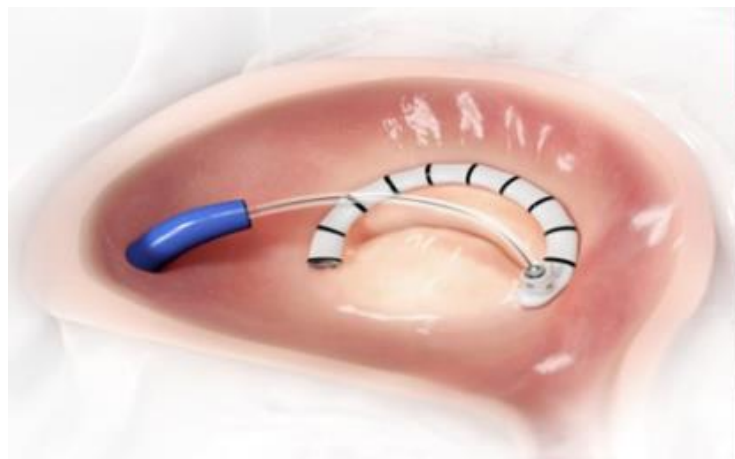
No. at risk:

	0	1	2	3	4	5	6
PASCAL	117	112	112	111	108	107	105
MitraClip	63	60	58	57	56	56	56

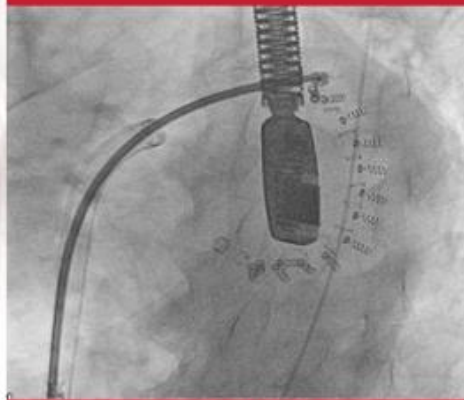




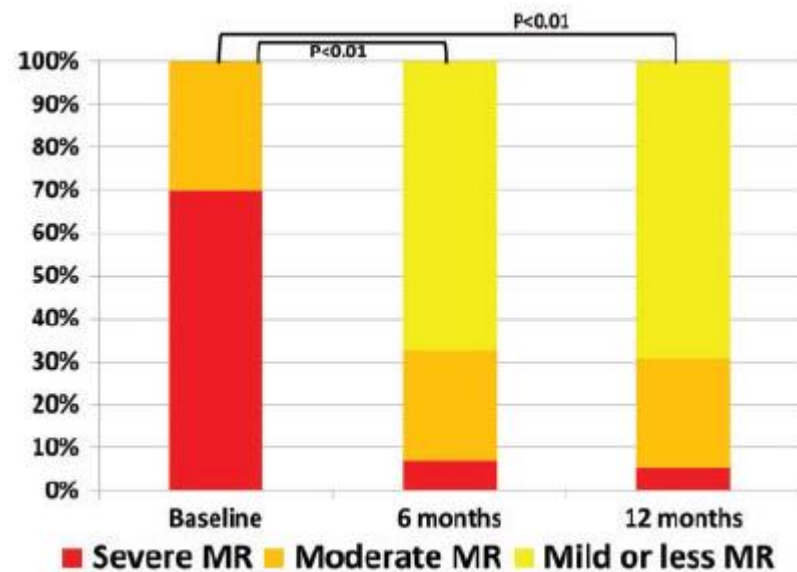
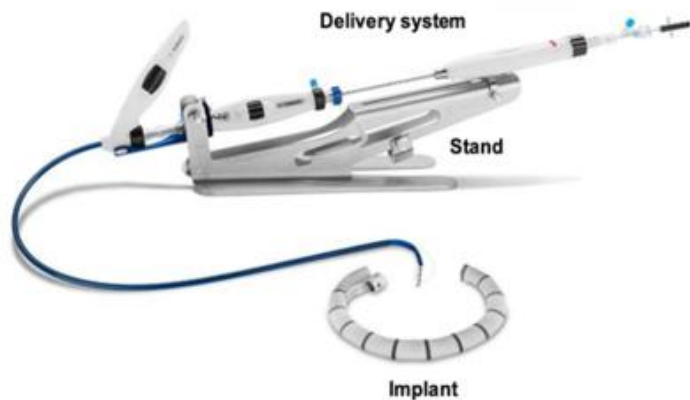
# Annuloplastie: Cardioband



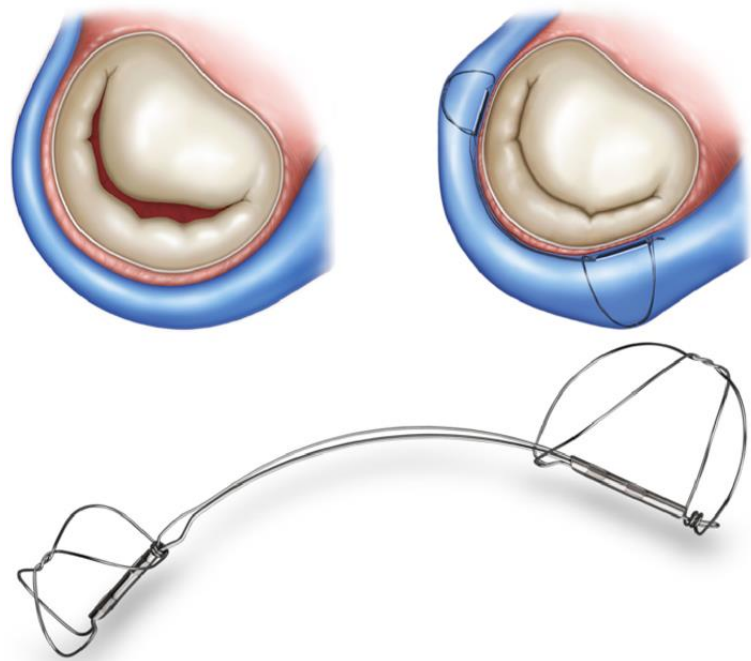
Pre-adjustment



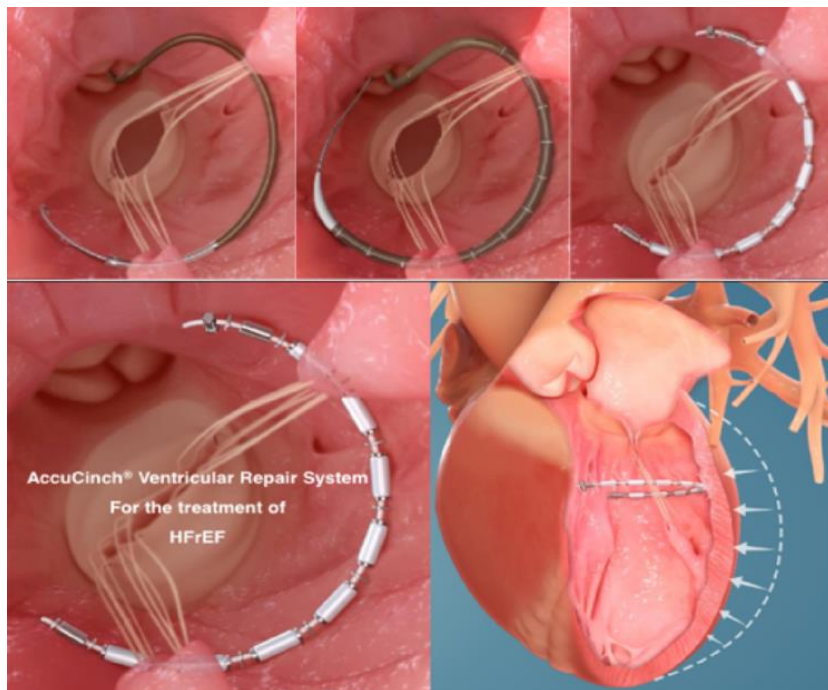
Final adjustment



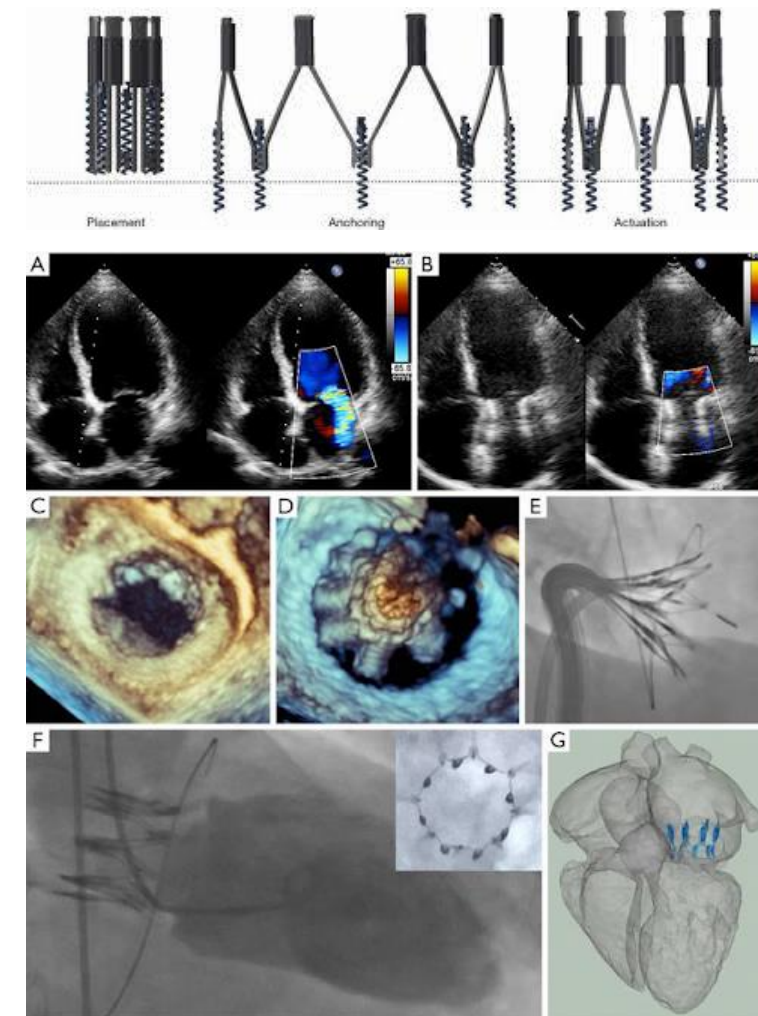
# Annuloplastie: autres



Carillon

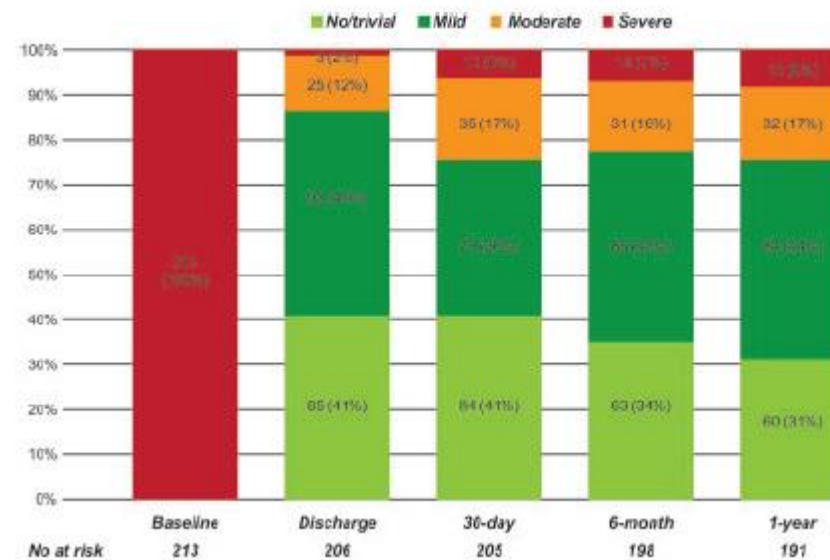
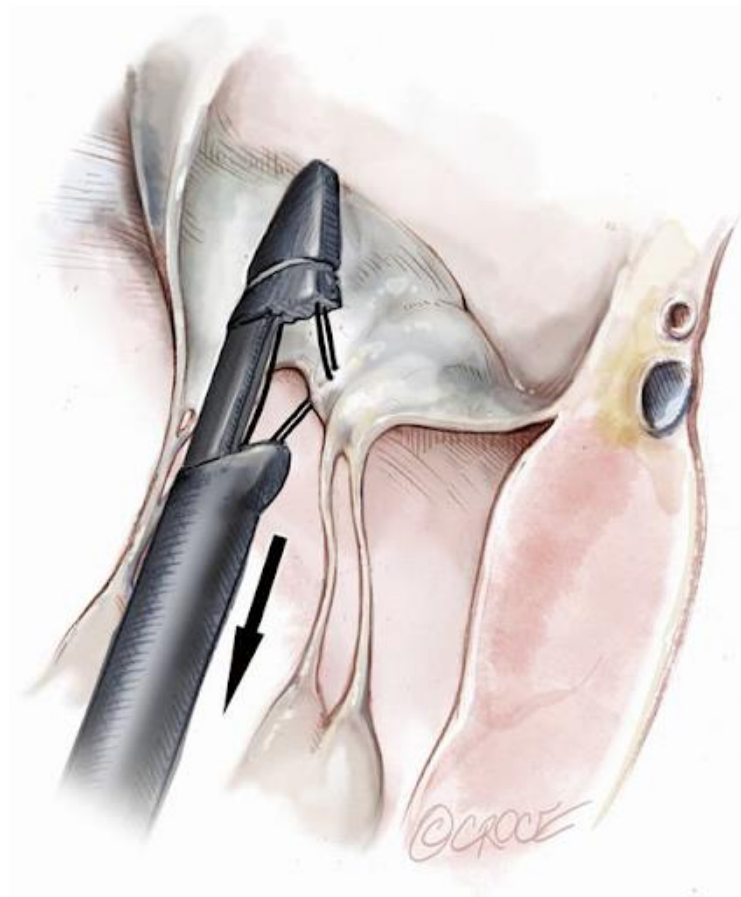


Accucinch



Millipede

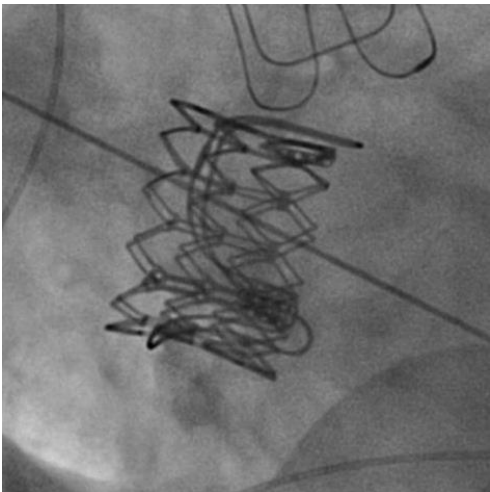
# Néo-cordages par voie trans-apicale



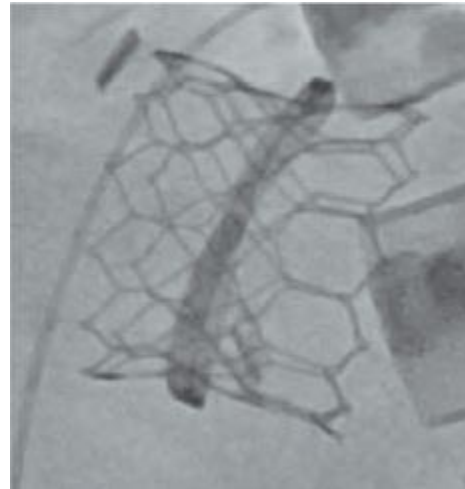
# Remplacement: Valves-in

**Valve in**

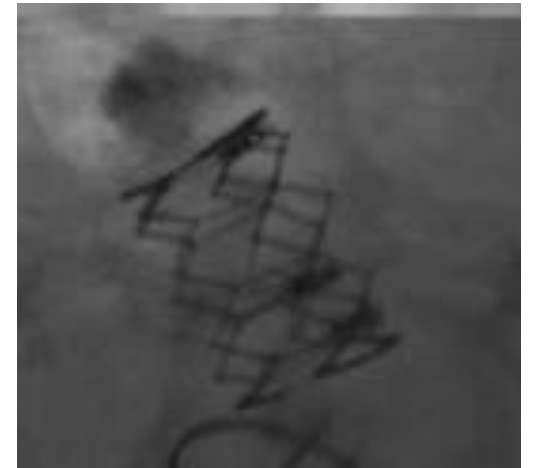
**Valve**



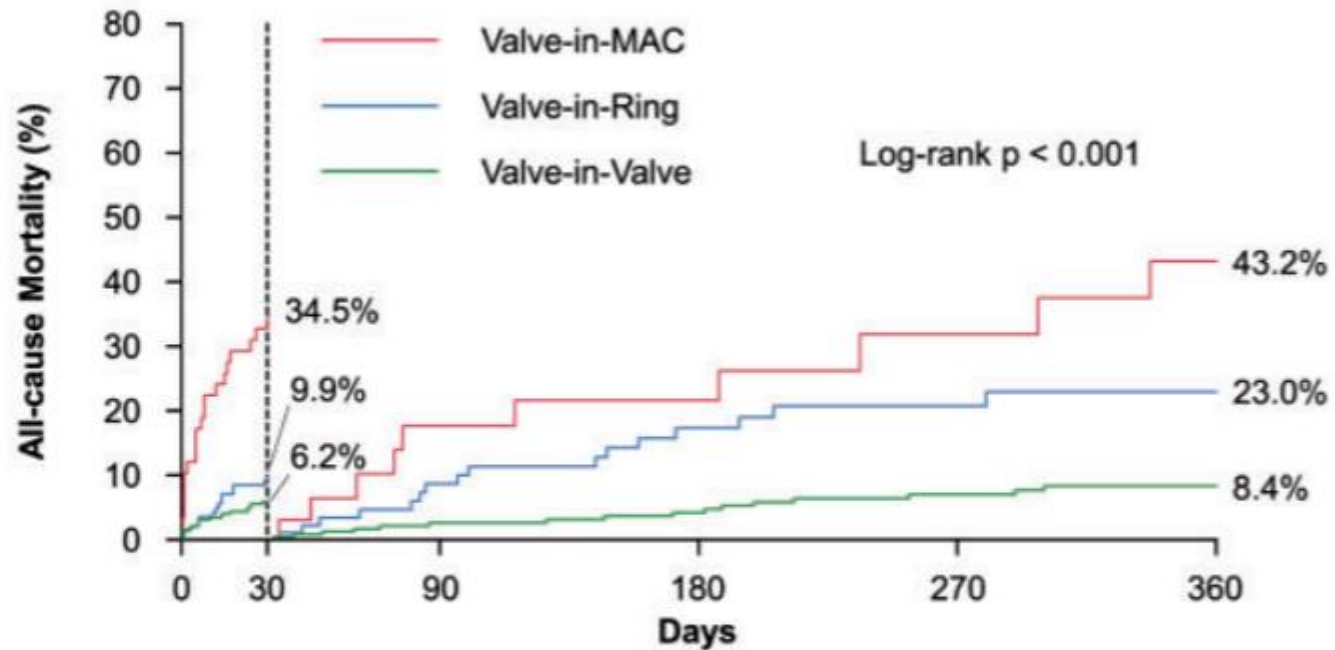
**Ring**



**MAC**



	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P-value
Procedural outcomes					
Conversion to surgery	12 (2.3)	3 (0.9)	4 (2.8)	5 (8.6)	0.004 <sup>d</sup>
Valve embolization	9 (1.7)	3 (0.9)	2 (1.4)	4 (6.9)	0.01 <sup>d</sup>
Left ventricular perforation	4 (0.8)	4 (1.2)	0 (0.0)	0 (0.0)	0.58
Need for second valve implantation	28 (5.4)	8 (2.5)	17 (12.1)	3 (5.2)	<0.001 <sup>c</sup>
LVOT obstruction	37 (7.1)	7 (2.2)	7 (5.0)	23 (39.7)	<0.001 <sup>d,e</sup>
Technical success	454 (87.1)	304 (94.4)	114 (80.9)	36 (62.1)	<0.001 <sup>c,d,e</sup>
Re-intervention	73 (14.0)	35 (10.9)	25 (17.7)	13 (22.4)	0.02 <sup>c,d</sup>
Paravalvular leak closure	18 (3.5)	7 (2.2)	11 (7.8)	0 (0.0)	0.006 <sup>c,e</sup>
Atrial septal defect closure	36 (6.9)	23 (7.1)	7 (5.0)	6 (10.3)	0.38
Alcohol septal ablation	10 (1.9)	2 (0.6)	1 (0.7)	7 (12.1)	<0.001 <sup>d,e</sup>
Mitral valve replacement	10 (1.9)	6 (1.9)	3 (2.1)	1 (1.7)	0.98
Surgery	8 (1.5)	4 (1.2)	3 (2.1)	1 (1.7)	0.77
TMVR	2 (0.4)	2 (0.6)	0 (0.0)	0 (0.0)	>0.99
Device success	402 (77.2)	273 (84.8)	98 (69.5)	31 (53.4)	<0.001 <sup>c,d,e</sup>

**B****No. at Risk**

Valve-in-MAC

58

**Days**

20

10

Valve-in-Ring

141

53

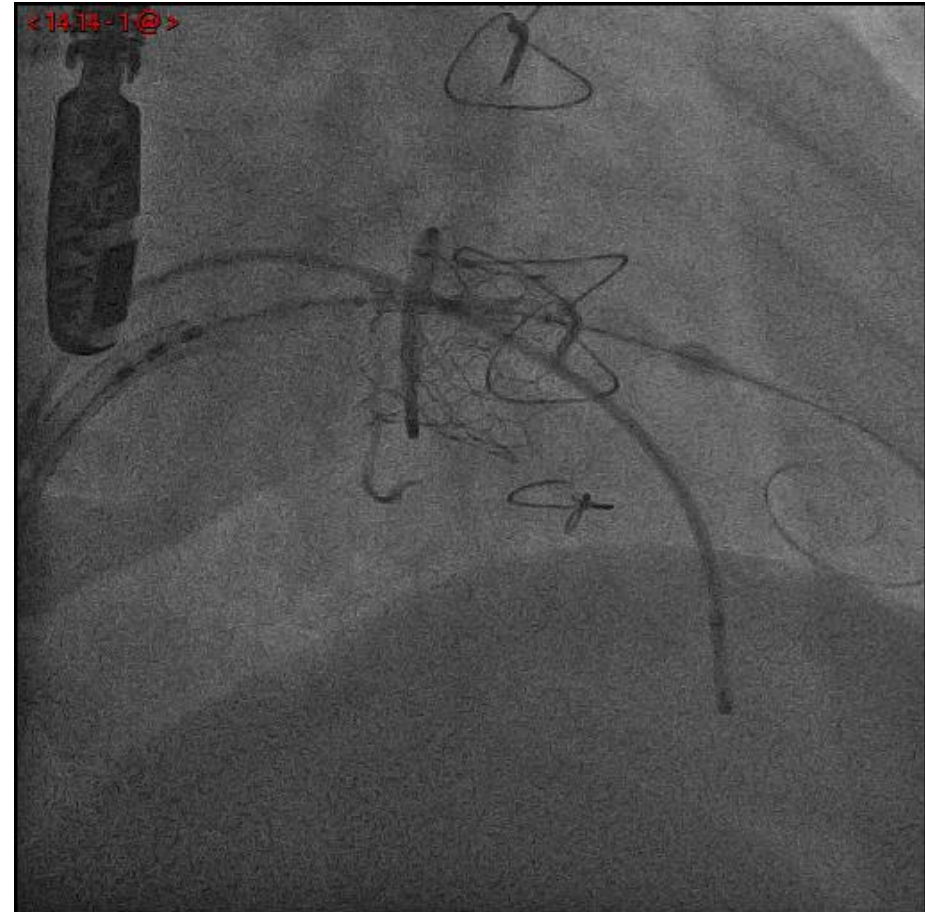
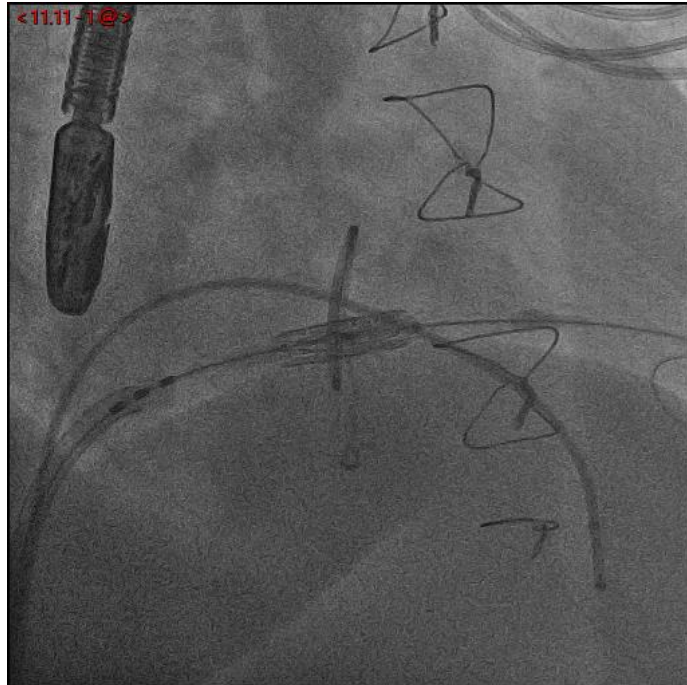
34

Valve-in-Valve

322

180

127



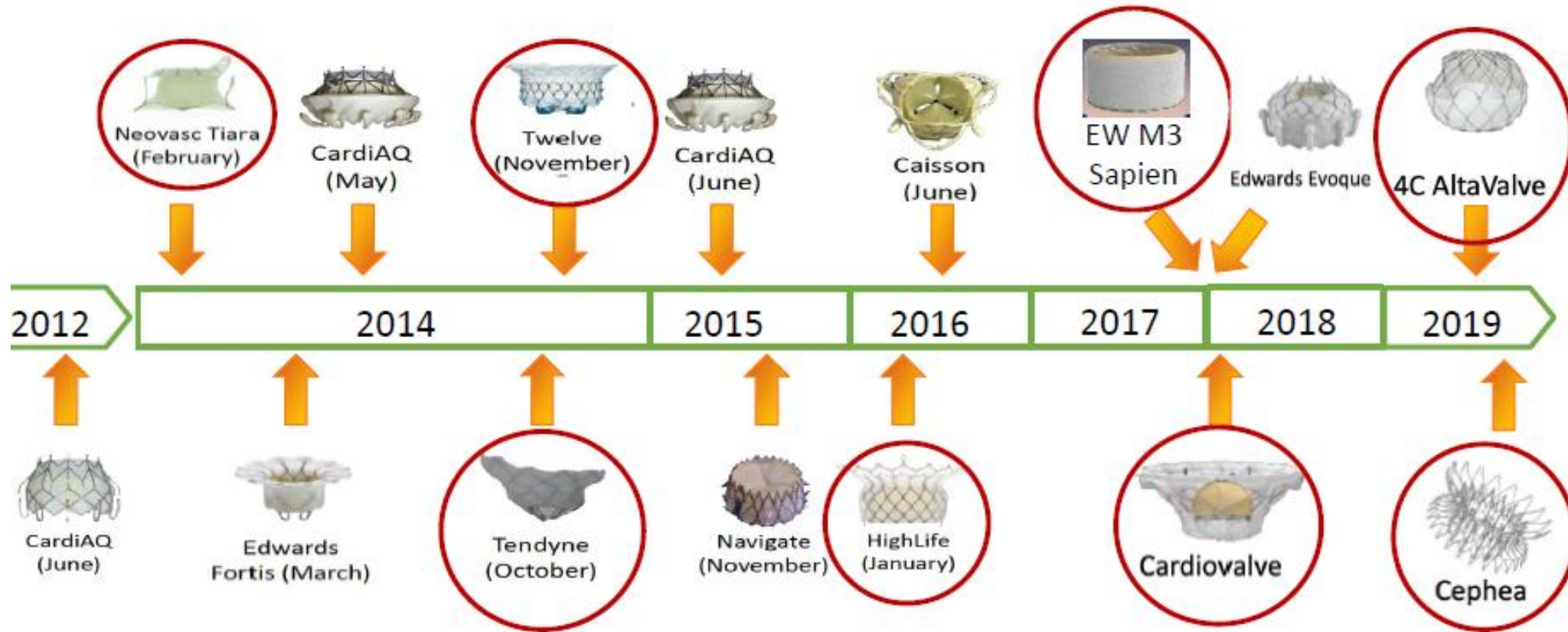
# Les valves mitrales percutanées

## Les challenges:

- Anneau en forme de selle 0cheval
  - Anneau non circulaire (D-shape)
  - Anneau large
  - Obstruction de la chambre de chasse
  - Absence de zone d'ancrage
- 
- Sélection scrupuleuse des patients : imagerie multimodale
  - Equipe multidisciplinaire



# Transcatheter Mitral Valve Implantation First-in-man



## Transapical Systems

Medtronic  
Intrepid



Abbott  
Tendyne



Neovasc  
Tiara



## Transseptal Systems

4 C  
Medical  
Altavalue



Cardiovalve



Abbott  
Cephea



Edwards  
Evoque



Highlife



Edwards  
Sapien M3



Medtronic  
Intrepid



# Tendyne

## Valve

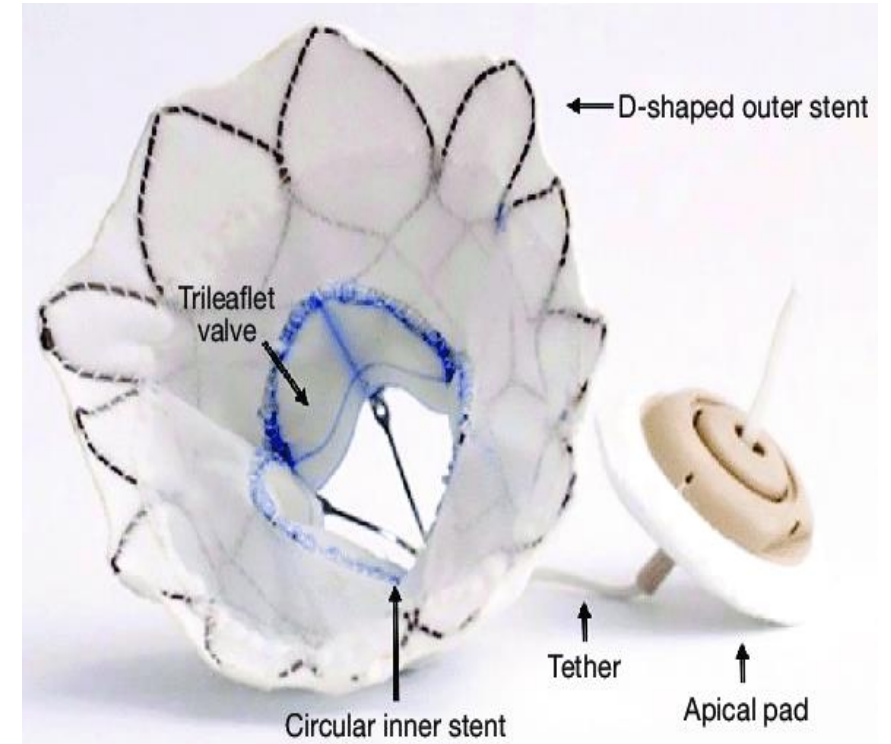
Dual-frame design with ability to customize fit to individual patient anatomies

## Inner frame

Self-expanding, tri-leaflet, bioprosthetic valve

## Outer frame

Contoured design supports a secure seal over native anatomy



- Une valve composée de 3 feuillets péricardiques porcins cousus sur un cadre circulaire auto-expansible en nitinol
- Le cadre extérieur est doté de marqueurs radio-opaques et recouvert d'une collerette en polyéthylène téréphtalate

# **SUMMIT**

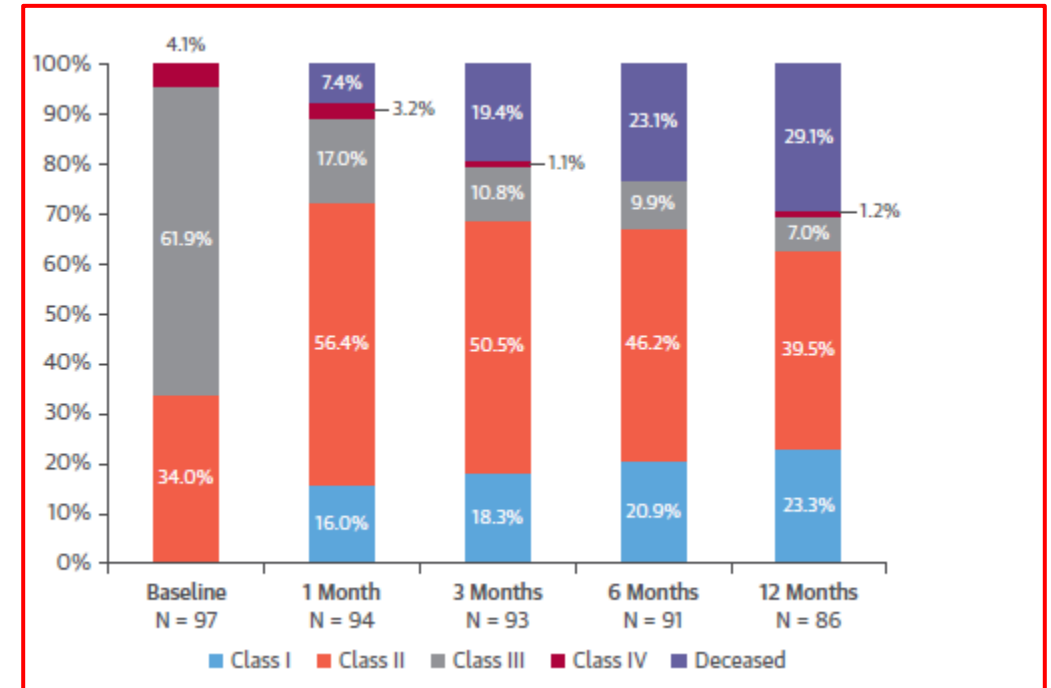
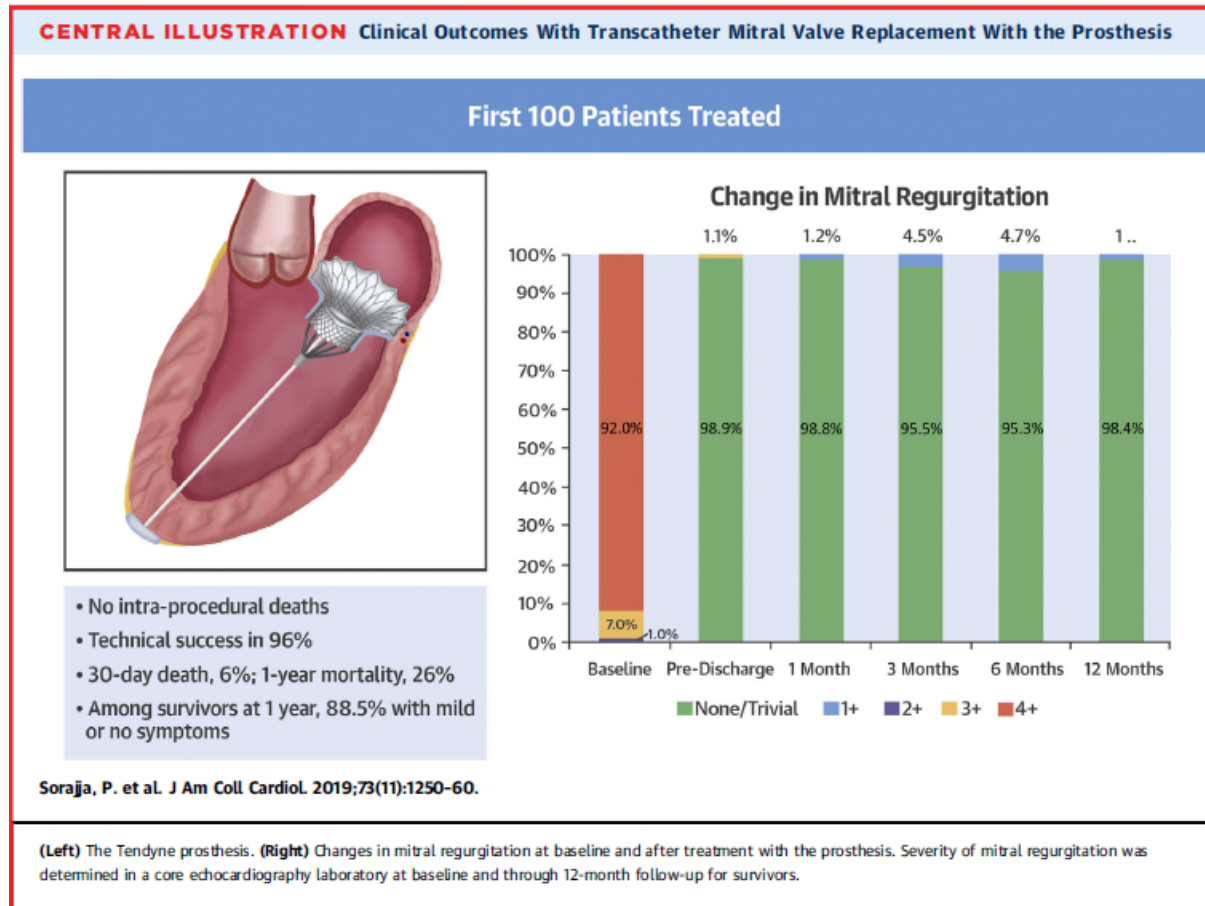
## **TENDYNE TRIAL**

**PROCEDURAL ANIMATION**

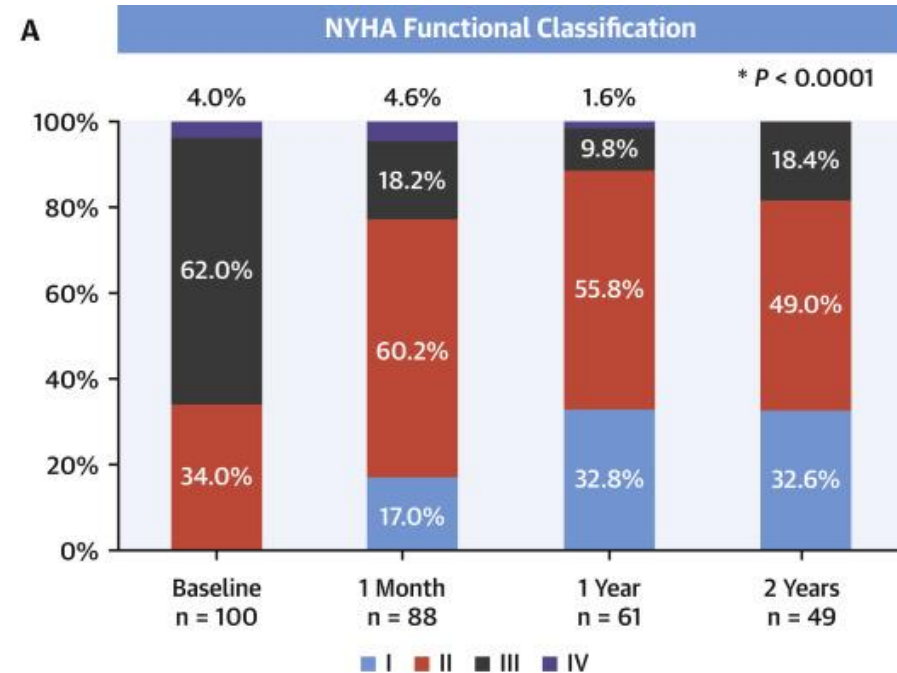
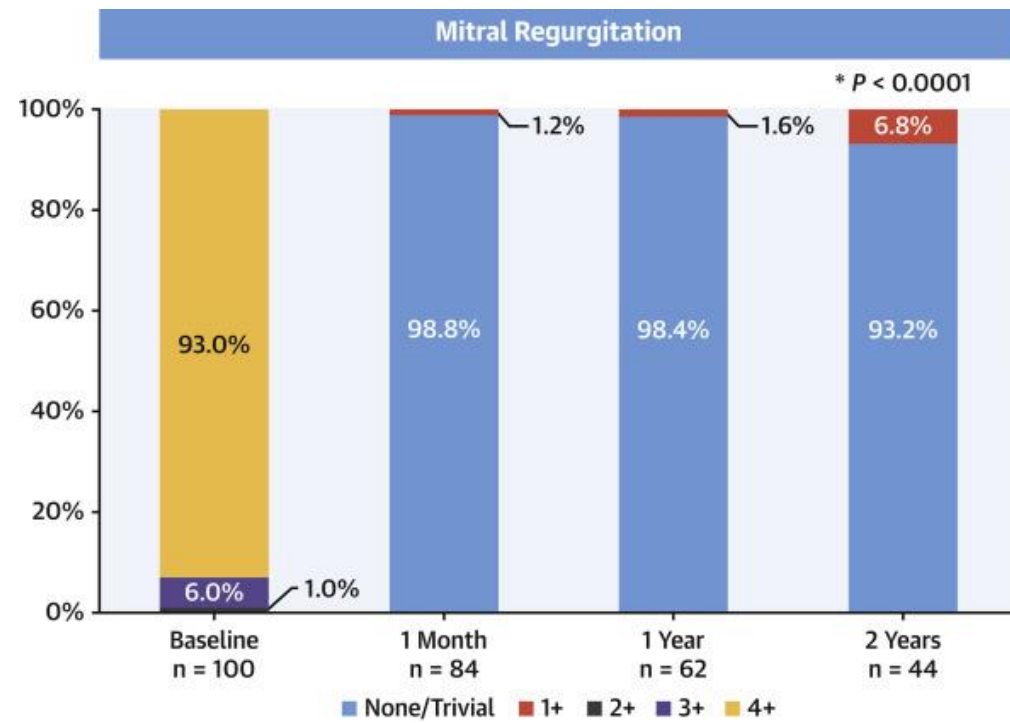
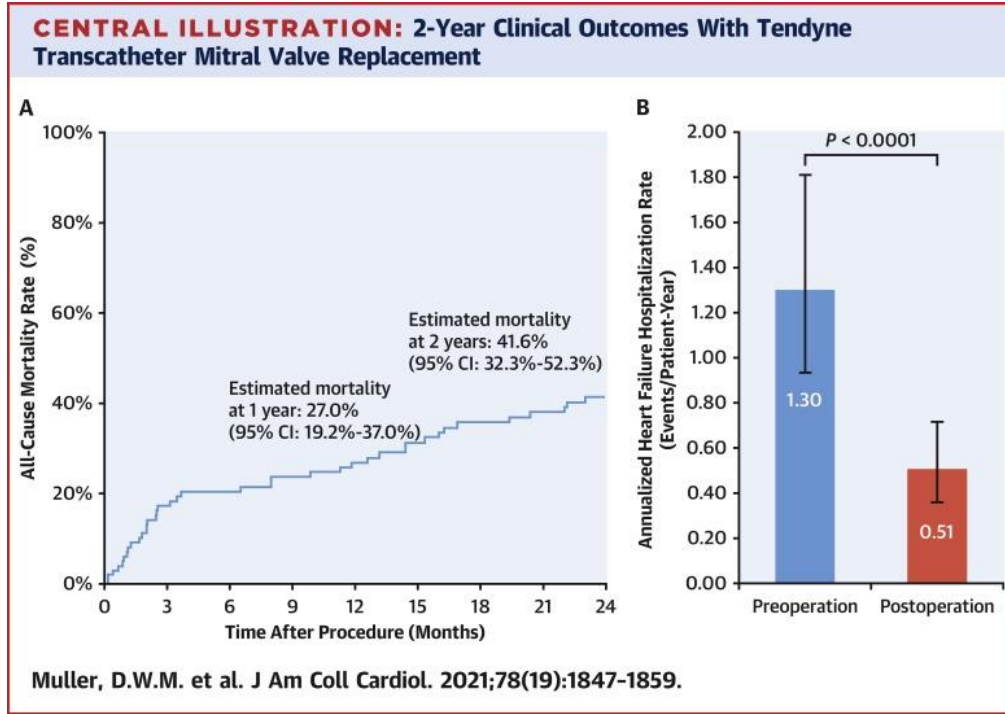
# **TENDYNE™ Transcatheter Mitral Valve Implantation**

**CAUTION:** Investigational device. Limited by Federal (U.S.) law to investigational use only and not available for sale.

# Remplacement: Tendyne



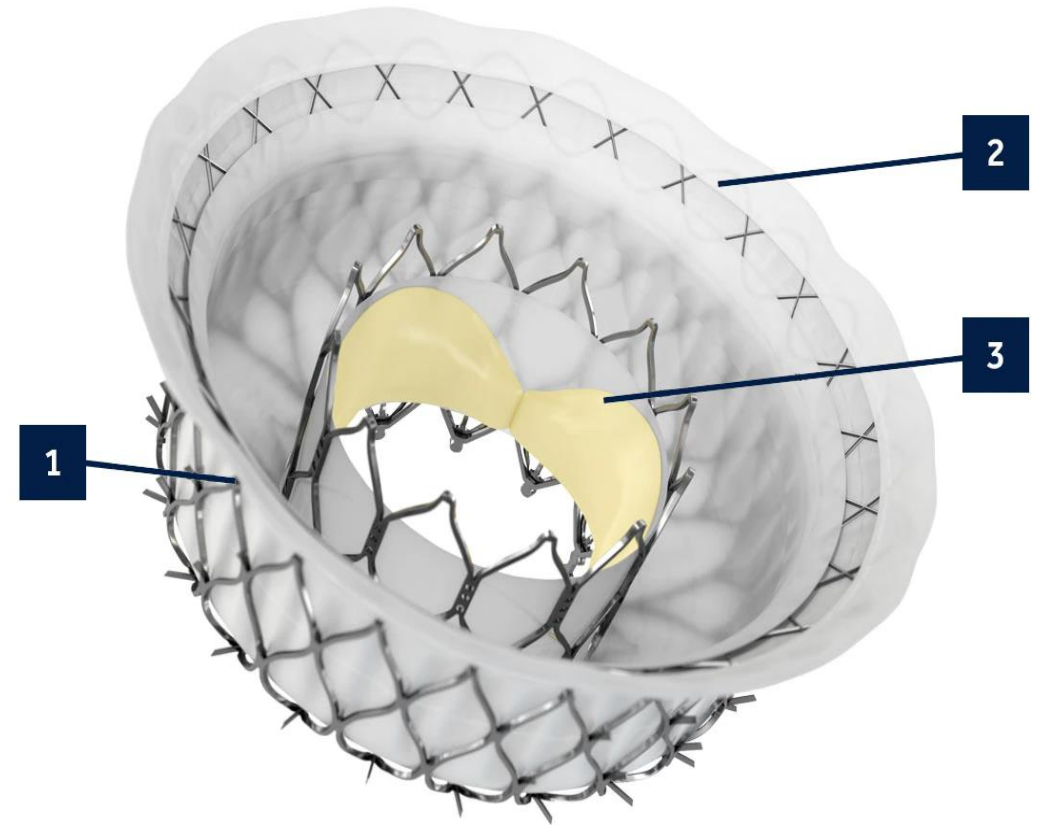
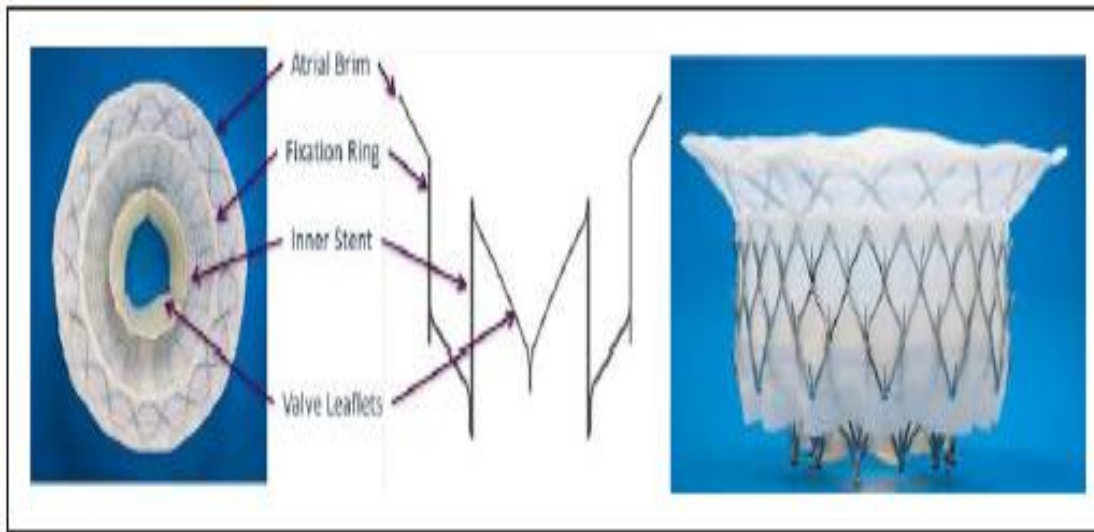
# Résultats à 2 ans



# Durabilité

- 5 patients « compassionnels » implantés en 2015
- 4 vivants en 2021
- Résultat à 6 ans: aucune fuite mitrale, gradient moyen 2 mmHg
- Amélioration de la FEVD et baisse de la PAPS

# Intrepid



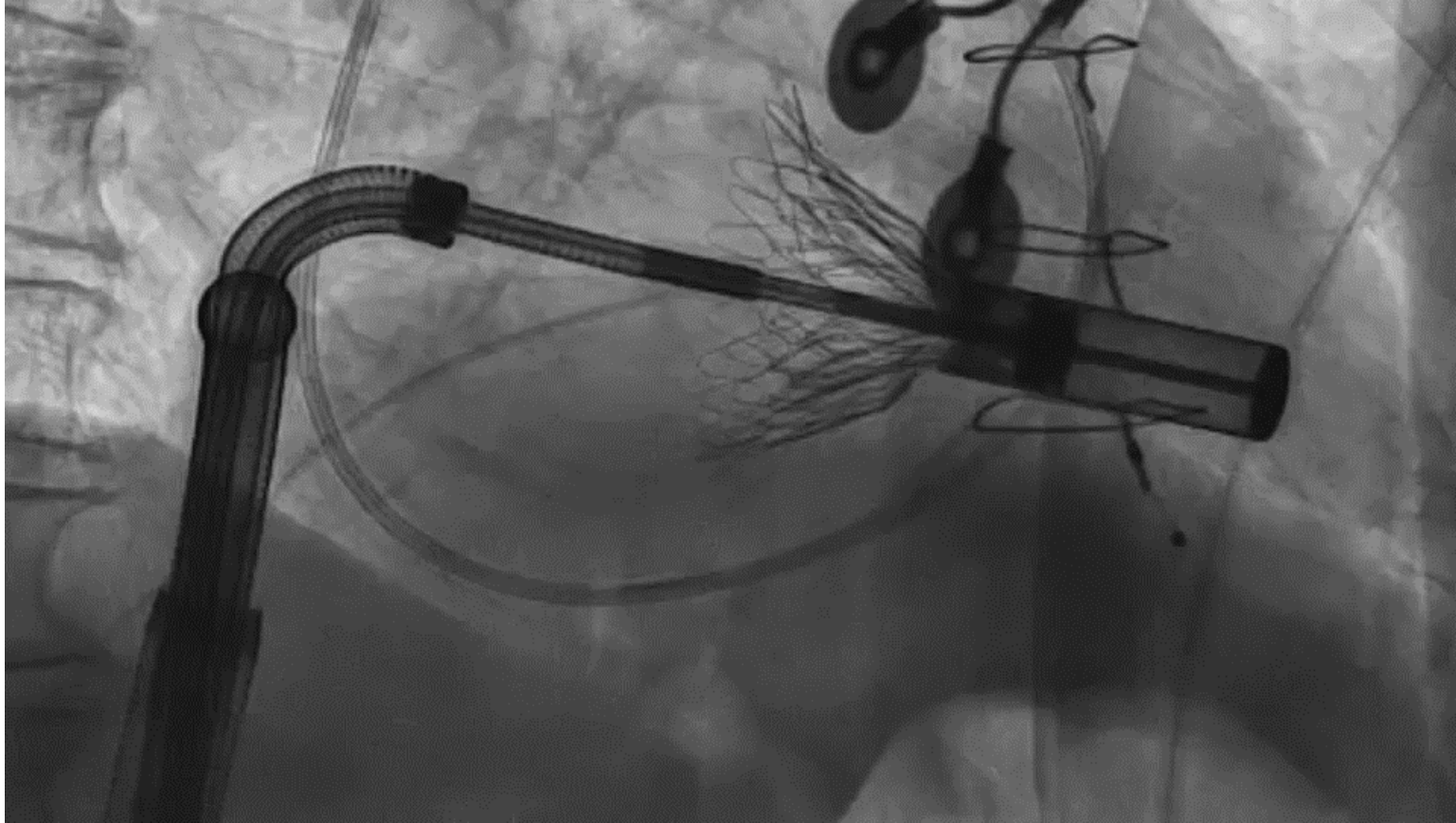
- Développement d'une voie transfémorale
- TheAPOLLO trial, investigating patients eligible for surgery randomized 1:1 to TMVR versus surgical therapy and non randomized use in patients ineligible for surgery, is under way. Up to 300 patients with significant MAC are included in the study.



DEPLOYMENT WITHOUT LEAFLET CAPTURE

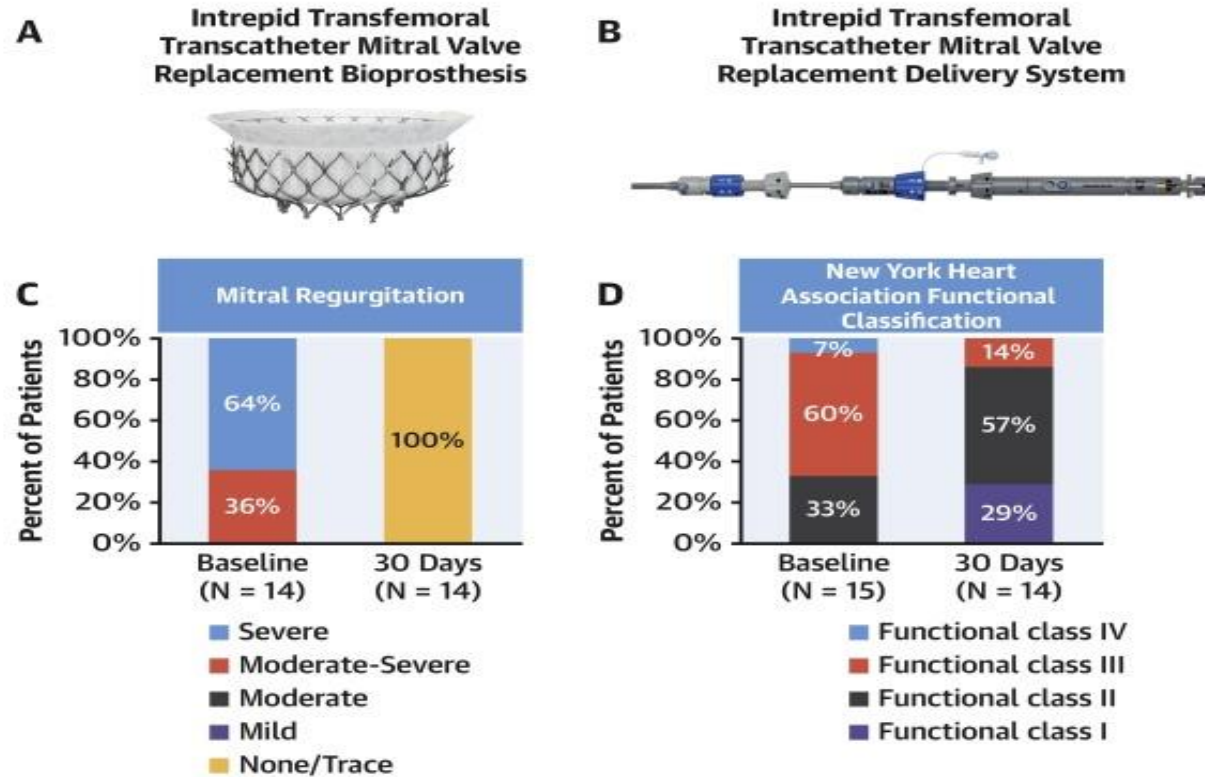


\*ARTICLE: INTERVENTIONAL DEVICE, LIMITED BY FEDERAL LAW AND BY REGULATIONS AND

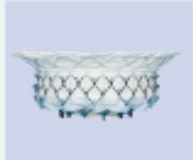






# Intrepid : résultats à 30 jours




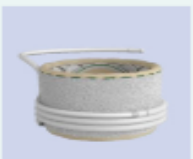
## CENTRAL ILLUSTRATION: 30-Day Outcomes From the Intrepid Transcatheter Mitral Valve Replacement Early Feasibility Study



**30-Day Clinical Outcomes:**  
0% mortality  
0% stroke  
0% reintervention  
0% new pacemaker implantation

	<b>Intrepid</b>	<b>Tendyne</b>	<b>Tiara</b>	<b>AltaValve</b>	<b>Cardiovalve</b>
					
Manufacturer	Medtronic	Abbott Vascular	NeoVasc	4C Medical	Cardiovalve
Frame	Dual-stent self-expanding Nitinol	Dual-stent self-expanding Nitinol	Self-expanding Nitinol	Spherical self-expanding Nitinol	Dual-frame self-expanding Nitinol
Leaflets	Bovine pericardium	Porcine pericardium	Bovine pericardium	Bovine pericardium	Bovine pericardium
Components	1	1	1	1	1
Anchoring	Perimeter oversizing	Apical pad	D-shaped configuration with 3 anchors	Supra-annular valve anchored in left atrium	Mitral valve leaflets/annulus
Delivery	TA	TA	TA	TA/TS	TS
Recapturable	Yes	Yes	No	Partially	Partially
Delivery system size	35-F	34-F	32- and 36-F	32-F	28-F
Ongoing clinical studies	Yes	Yes	Yes	Yes	Yes

**TABLE 1 Continued**

	<b>Cephea</b>	<b>EVOQUE</b>	<b>HighLife</b>	<b>SAPIEN M3</b>
				
Manufacturer	Abbott Vascular	Edwards Lifesciences	HighLife Medical	Edwards Lifesciences
Frame	Dual-stent self-expanding Nitinol	Self-expanding Nitinol	Self-expanding Nitinol	Balloon-expandable cobalt-chromium
Leaflets	NA	Bovine pericardium	Bovine pericardium	Bovine pericardium
Components	1	1	2	2
Anchoring	Mitral annulus: double disk	Mitral valve leaflets/annulus	Subannular ring (valve-in-ring)	Subannular Nitinol dock
Delivery	TS	TS	TS	TS
Recapturable	Yes	No	No	Partially (dock)
Delivery system size	NA	28-F	NA	20-F
Ongoing clinical studies	Yes	Yes	Yes	Yes

**Intrepid**  
(n = 50)

**Tendyne**  
(n = 100)

**Tiara**  
(n = 79)

**AltaValve**  
(n = 1)

**Cardiovalve**  
(n = 5)

**Cephea**  
(n = 1)

**EVOQUE**  
(n = 14)

**HighLife**  
(n = 15)

**SAPIEN M3**  
(n = 35)

# Conclusion

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



*Merçi pour votre attention !*