Réparation mitrale percutanée : quoi de neuf ?

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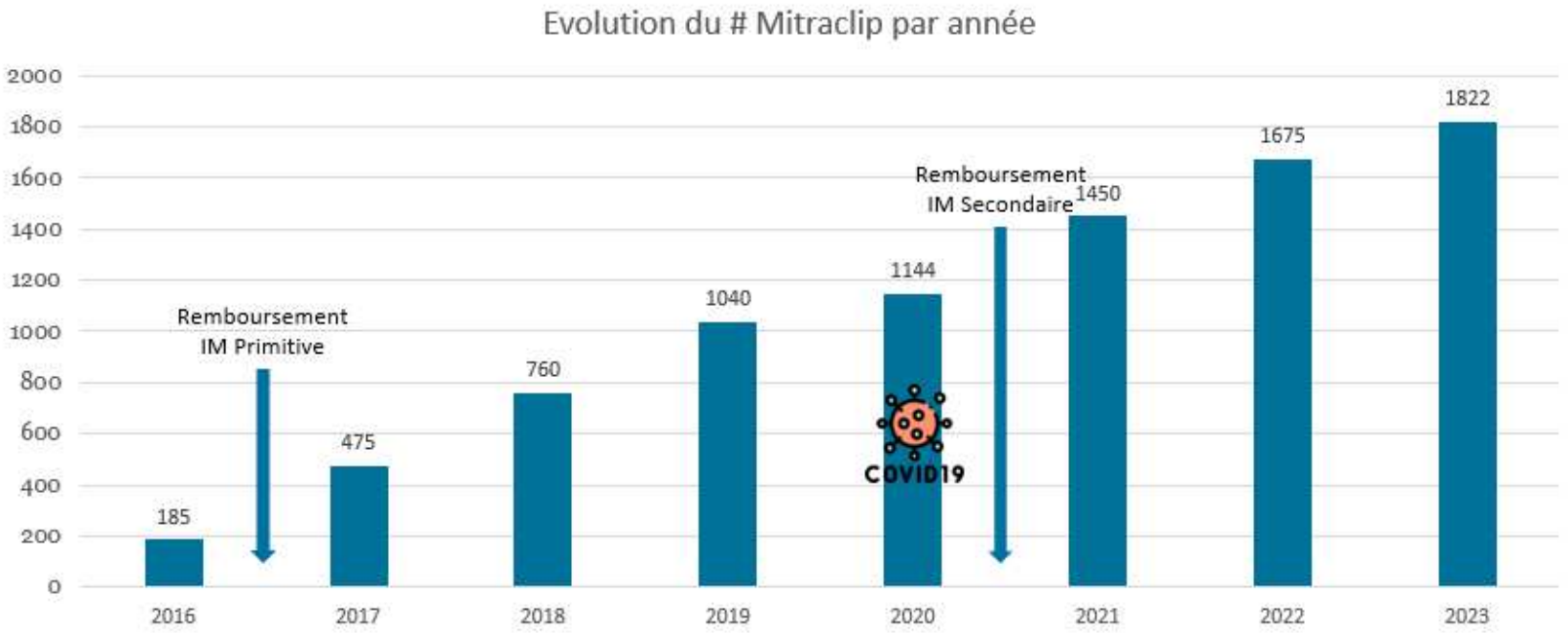
Conflicts of interest

☑ I have the following potential conflicts of interest to report:

Proctoring and speakers fees from Abbott Medical, Edwards Lifesciences

An increasing activity



55 centers

The current indications

HAS
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COMMISSION NATIONALE D'EVALUATION DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE

AVIS DE LA CNEDiMTS
24 mars 2015

CONCLUSIONS

MITRACLIP, clip de réparation mitrale bord à bord

Demandeur : ABBOTT France SAS (France)

Fabricant : Evalve Inc (Etats-Unis)

Les modèles et références retenus sont ceux proposés par le demandeur (cf. page 4)

Indications retenues :	Patients avec insuffisance mitrale sévère, d'origine dégénérative, symptomatique malgré une prise en charge médicale optimale, non éligibles à la chirurgie de réparation ou de remplacement valvulaire et répondant aux critères échocardiographiques d'éligibilité. Tous ces critères et en particulier la contre-indication chirurgicale doivent être validés par une équipe multidisciplinaire *ad hoc*. Les patients ayant une espérance de vie inférieure à un an compte tenu de comorbidités extracardiaques ne sont pas éligibles à la technique (non indication).

HAS
HAUTE AUTORITÉ DE SANTÉ

COMMISSION NATIONALE D'EVALUATION DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE

AVIS DE LA CNEDiMTS
15 novembre 2019

CONCLUSIONS

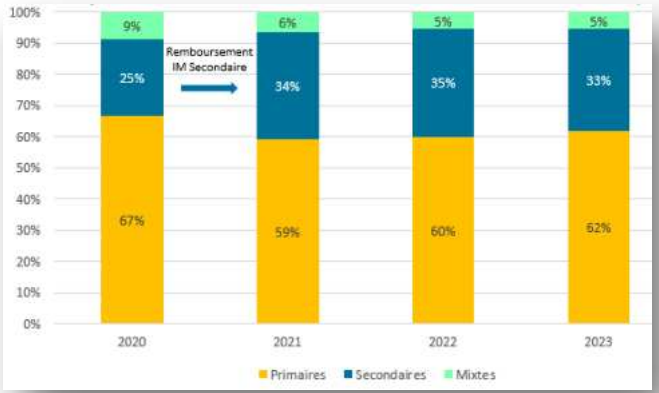
MITRACLIP NTR, clip de réparation mitrale bord à bord

Demandeur : ABBOTT MEDICAL France SAS (France)

Fabricant : ABBOTT Laboratories (Etats-Unis)

Les modèles et références proposés par le demandeur (cf. page 4)

Indications retenues :	Patients avec une insuffisance mitrale secondaire de grade 3+/4+ symptomatique malgré une prise en charge médicale optimale et remplissant les critères suivants : - non éligibles à la chirurgie de réparation ou de remplacement valvulaire, - ayant eu une hospitalisation pour insuffisance cardiaque dans les 12 mois précédant l'intervention, - ayant une fraction d'éjection ventriculaire gauche comprise entre 20 et 50%, - et une surface de l'orifice régurgitant > 0,3 cm² et un volume télédiastolique indexé du ventricule gauche ≤ 96 mL/m². Les patients ayant un ventricule gauche fortement dilaté (défini par un volume télédiastolique indexé du ventricule gauche > 96 mL/m²) et une insuffisance mitrale modérée ou moindre, démontré par un orifice régurgitant de la valve mitrale ≤ 0,3 cm², ne sont pas éligibles à la technique (non indication). Les critères cliniques et échocardiographiques doivent être validés par une équipe multidisciplinaire *ad hoc*. 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).




20 ans
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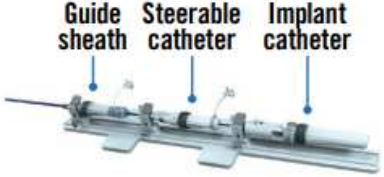
ANNIVERSAIRE

The latest iterations of the devices …

	MitraClip (4th-generation)	PASCAL Precision (2nd-generation)
Delivery catheter		
Available implants	 NT NTW XT XTW	 P10 ACE
Device material	Rigid arms of cobalt-chromium alloy	Flexible arms of nitinol
Central spacer	No	Yes
Optional independent grasping	Yes	Yes
Closure mechanism	Active (locking element)	Passive (nitinol shape memory)
Number of working catheters	2	3
Orientation of hooks/friction elements	Longitudinal	Horizontal
Continuous LA pressure	Yes	Yes
Overall system stability	High	Improved with PASCAL Precision

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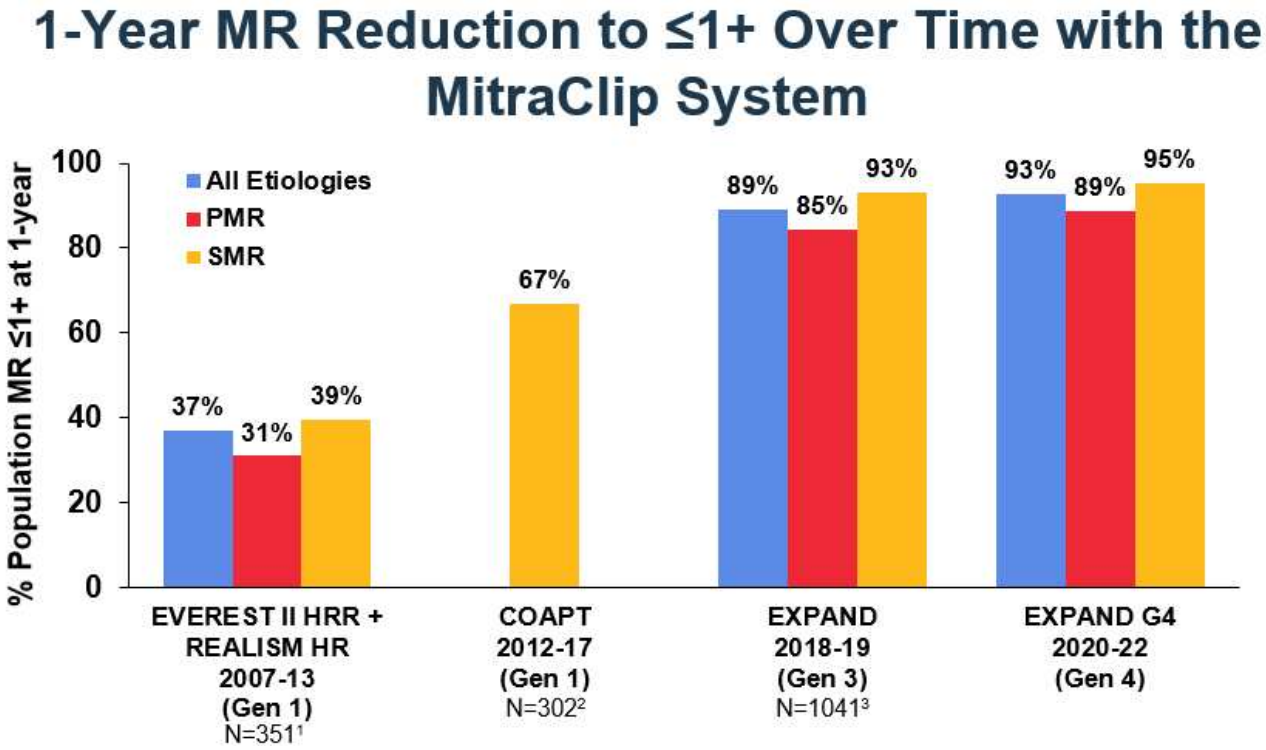
… improve the MR correction



[1]Glower DD, et al. J Am Coll Cardiol. 2014 Jul 15;64(2):172–81.
[2]Stone GW, et al. N Engl J Med. 2018 Dec 13;379(24):2307–18.
[3]Kar S, et al. JACC: Cardiovascular Interventions. 2023 Mar 13;16(5):589–602.

The latest clinical data

TABLE 1 EXPAND G4 Study Population: Baseline Characteristics (N = 1,164)

Age, y	77.5 ± 9.1
Male	55.9 (650)
STS replacement score	7.6 ± 6.2
STS repair score	5.9 ± 6.2

Real-World Outcomes of Fourth-Generation Mitral Transcatheter Repair

30-Day Results From EXPAND G4

Ralph Stephan von Bardeleben, MD,[a] Jason H. Rogers, MD,[b] Paul Mahoney, MD,[c] Matthew J. Price, MD,[d] Paolo Denti, MD,[e] Francesco Maisano, MD,[f] Michael Rinaldi, MD,[g] William A. Bolleñon, MD,[h] Federico De Marco, MD,[i] Bassem Chehab, MD,[j] Mathew R. Williams, MD,[k] Federico M. Asch, MD,[l] Evelio Rodriguez, MD[m]

FIGURE 5 Change in MR From Baseline to 30-Day Follow-Up

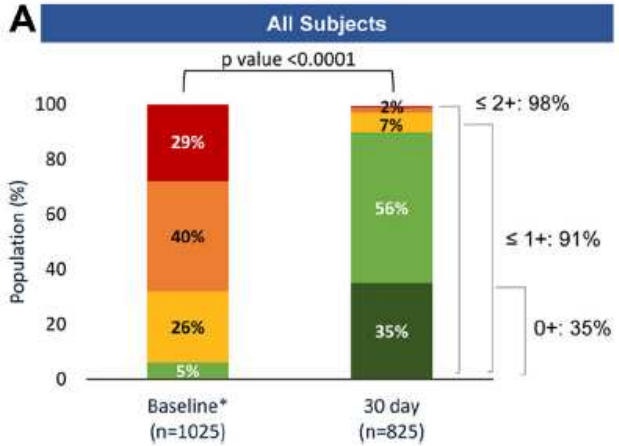


TABLE 4 30-Day Adverse Events in EXPAND G4 (n = 1,158)

Composite MAE	2.7 (31)
All-cause death	1.3 (15)
MI	0.2 (2)
Stroke	0.5 (6)
Nonelective CV surgery for device-related complications	0.9 (10)
Leaflet adverse events SLDA[a]	1.1 (12)

Procedural Outcomes

	PASCAL (N=199)	MitraClip (N=95)	p value
	Mean ± SD, Median [Q1, Q3], %		
Successful implant rate[a]	98.5%	98.9%	1.000
Procedure time, min[b]	88.0 [67.0, 125.0]	81.0 [60.0, 110.0]	0.014
Device time, min[c]	60.0 [39.0, 96.0]	43.5 [28.0, 69.0]	<0.001
Mean no. of devices implanted[d]	1.4 ± 0.56	1.6 ± 0.67	0.022
Total length of stay for the index procedure, days	1.0 [1.0, 2.0]	1.0 [1.0, 2.0]	0.700

21.1% PASCAL Precision System

69.5% MitraClip G4 system

CRF TCT

Continuous variables: Mean ± SD (n) or Median [Q1,Q3] (n), p values based on Kruskal-Wallis test; Categorical variables: n/Total N (%), p values based on Fisher's exact test. [a] Successful implant: patients with study device implanted, deployed as intended and delivery system retrieved successfully. [b] Procedure time: from procedure start (femoral vein puncture/skin incision) to femoral vein access closure. [c] Device time: from PASCAL implant system or MitraClip delivery system insertion into left atrium to guide sheath or steerable guide removal. [d] In patients who received a device. Device type is reported for patients with devices implanted and for whom device type was available; one patient randomized to the PASCAL group received a MitraClip implant and is included in the MitraClip group. One patient was treated with a combination of MitraClip G4 and G3 implants.

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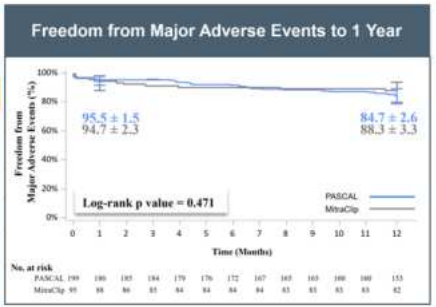
NEW RESEARCH PAPER

One-Year Outcomes From the CLASP IID Randomized Trial for Degenerative Mitral Regurgitation

CEC-adjudicated Major Adverse Events

MAE rates at 30 days and 1 year

	PASCAL N=199	MitraClip N=95
	Patients n (%)	
Composite MAE rate[a] at 30 days	9 (4.6%)	5 (5.4%)
Cardiovascular mortality	1 (0.5%)	2 (2.2%)
Stroke	1 (0.5%)	1 (1.1%)
Myocardial Infarction	0 (0.0%)	1 (1.1%)
Need for new renal replacement therapy	0 (0.0%)	0 (0.0%)
Severe bleeding[b]	7 (3.6%)	2 (2.2%)
Non-elective mitral valve re-intervention (percutaneous or surgical)	3 (1.5%)	1 (1.1%)

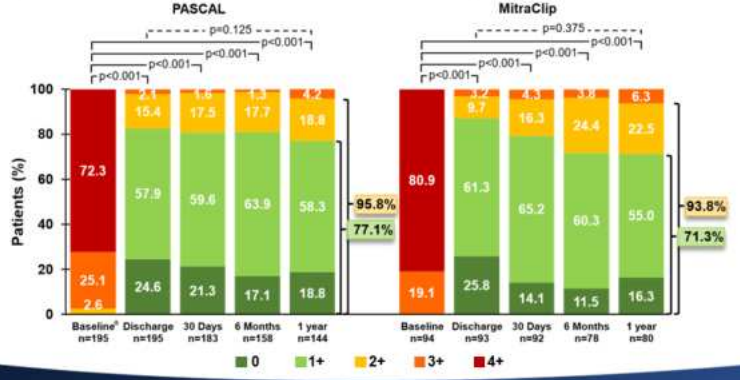


CRF TCT

Categorical variables: Patients n (%). Denominator includes patients who had an MAE or did not have an MAE but were followed for at least 30 days. 5 patient(s) did not have an MAE and were not followed for at least 30 days. [a] Patients may experience more than one event. [b] Major, extensive, life-threatening, or fatal bleeding defined by the Mitral Valve Academic Research Consortium criteria. Graph shows Kaplan-Meier analysis time to first event (KM estimate ± SE) and error bars represent 95% CI. CEC, Clinical events committee; MAE, Major adverse event.

MR Reduction by Core Lab[1]

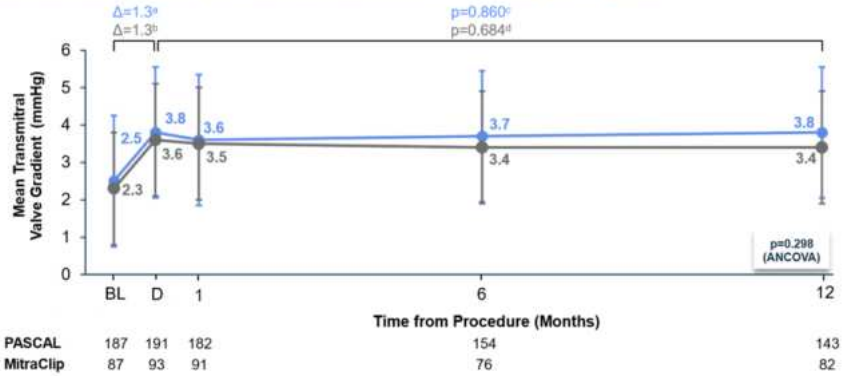
Significant and sustained MR reduction at 1 year



MR severity assessed by TTE. *TEE was used for baseline qualification of 5 patients. Graph shows unpaired analysis; p values relative to baseline were calculated from Wilcoxon signed rank test and p value between discharge and 1 year was calculated for MR ≤2+ by exact McNemar's test. PASCAL: n=140; MR ≤2+ at Discharge 89.3%, 1 year: 95.7%%. MitraClip: n=80; MR ≤2+ at discharge 97.5%, 1 year: 93.8%. †Echocardiographic Core Lab: Atlantic Health System Morristown Medical Center, Morristown, NJ, USA. TTE, Transthoracic echocardiography; TEE, Transesophageal echocardiography.

Transmitral Gradients by Core Lab[1]

Gradients stable and sustained below 5 mmHg at 1 year



Graph shows mean ± SD. Δ represents paired change mean [95% CI]: [a] 1.3 [1.1, 1.5], n=179; [b] 1.3 [0.9, 1.6], n=86; [c] -0.02 [-0.27, 0.23], n=139; [d] -0.07 [-0.39, 0.25], n=82. Intragroup p values were calculated using Student's t-test. Intergroup p value for change from baseline to 1 year was calculated using analysis of covariance (ANCOVA) model adjusted by baseline values and planned treatment as covariates. †Echocardiographic core laboratory: Atlantic Health System Morristown Medical Center, Morristown, NJ. BL, baseline and D, discharge (within 7 days post-procedure).

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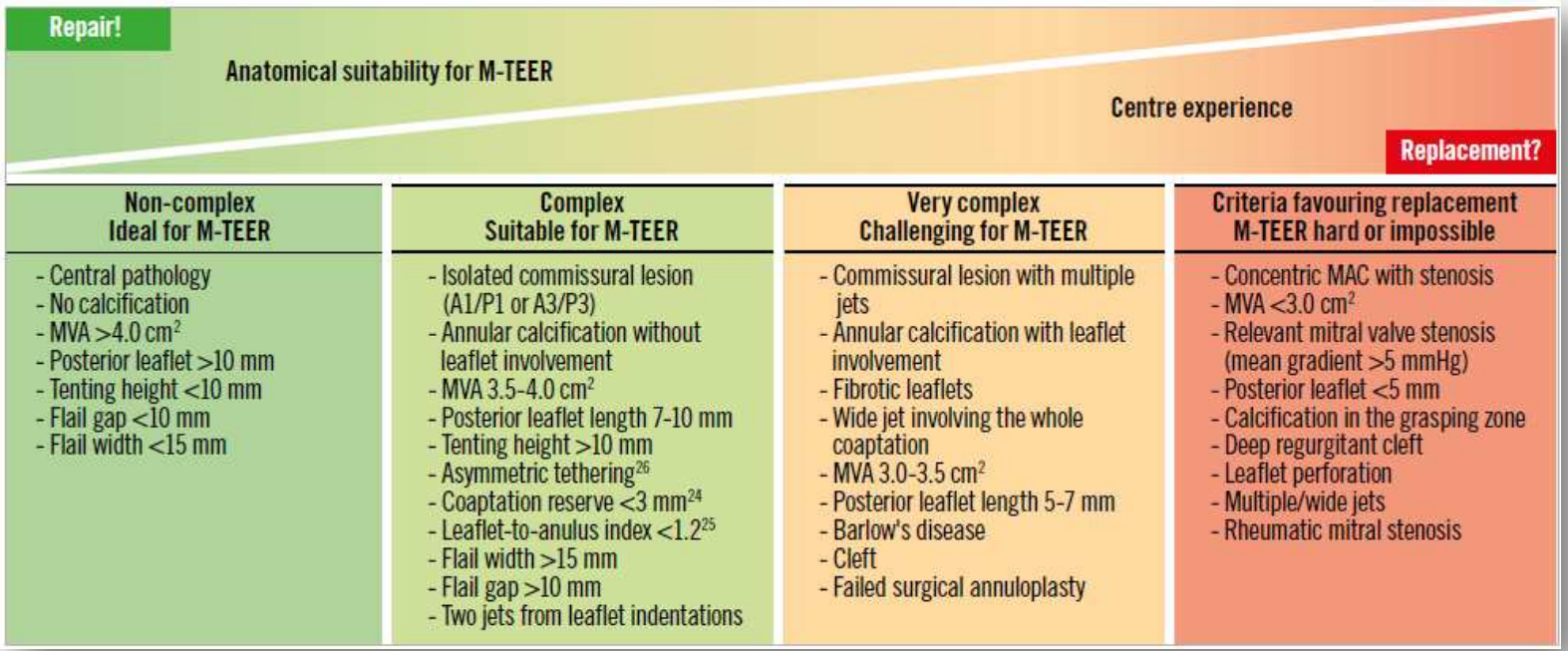
NEW RESEARCH PAPER

One-Year Outcomes From the CLASP IID Randomized Trial for Degenerative Mitral Regurgitation

A more accurate analysis of patient complexity …



Non-complex Ideal for M-TEER	Complex Suitable for M-TEER	Very complex Challenging for M-TEER	Criteria favouring replacement M-TEER hard or impossible
- Central pathology - No calcification - MVA >4.0 cm^2 - Posterior leaflet >10 mm - Tenting height <10 mm - Flail gap <10 mm - Flail width <15 mm	- Isolated commissural lesion (A1/P1 or A3/P3) - Annular calcification without leaflet involvement - MVA 3.5-4.0 cm^2 - Posterior leaflet length 7-10 mm - Tenting height >10 mm - Asymmetric tethering[26] - Coaptation reserve <3 mm[24] - Leaflet-to-anulus index <1.2[25] - Flail width >15 mm - Flail gap >10 mm - Two jets from leaflet indentations	- Commissural lesion with multiple jets - Annular calcification with leaflet involvement - Fibrotic leaflets - Wide jet involving the whole coaptation - MVA 3.0-3.5 cm^2 - Posterior leaflet length 5-7 mm - Barlow's disease - Cleft - Failed surgical annuloplasty	- Concentric MAC with stenosis - MVA <3.0 cm^2 - Relevant mitral valve stenosis (mean gradient >5 mmHg) - Posterior leaflet <5 mm - Calcification in the grasping zone - Deep regurgitant cleft - Leaflet perforation - Multiple/wide jets - Rheumatic mitral stenosis

… for a tailored management

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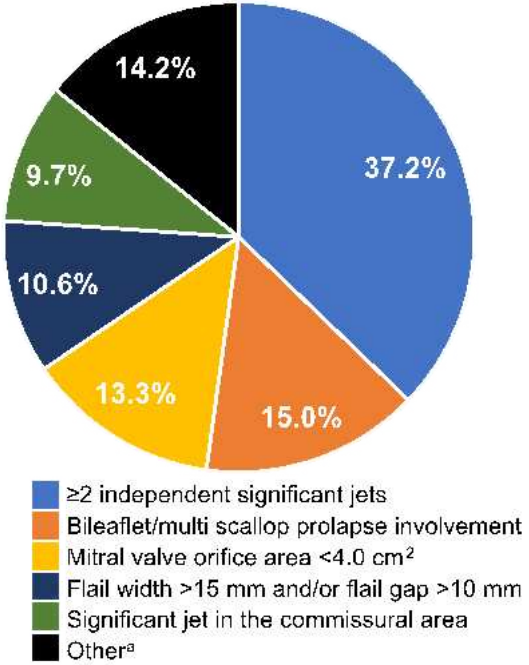
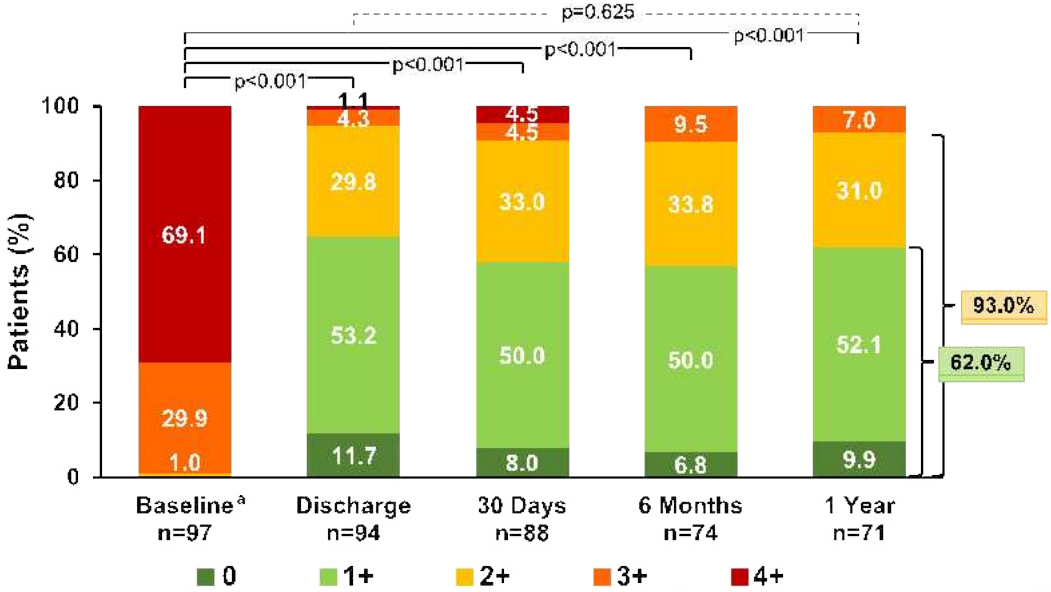
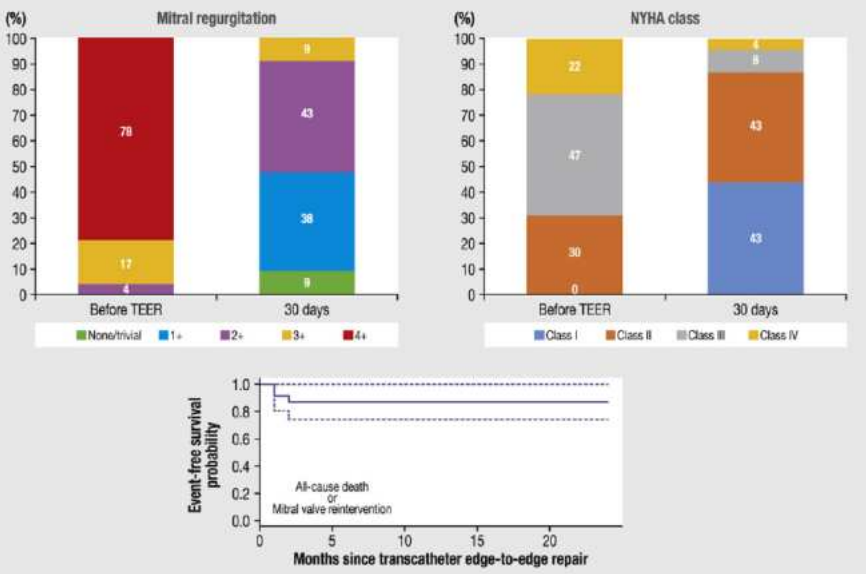
Baseline anatomical complexity distribution



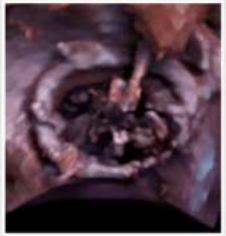
15.3% patients met two complexity criteria



Complexes cases : MR post surgical MV repair



The "clip-in-ring" registry
23 TEER following surgical valve repair with ring implantation in 11 French centers



Technical success	23 (100%)
Median length of stay (days)	4 [3-15]
Significant MR reduction (at discharge)	20 (87%)
At 30 days	
- Device success	19 (82%)
- Procedural success	19 (82%)
- Need for unplanned surgery	2 (9%)
- MVARC adverse event	1 (4%)
- Residual MR 3+/4+*	2 (9%) / 0 (0%)
- Transvalvular gradient* :	
• < 5 mmHg	15 (71%)
• ≤ 5-7 mmHg	6 (28%)
• > 7 mmHg	0 (0%)


Archives of Cardiovascular Disease 115 (2022) 521–528
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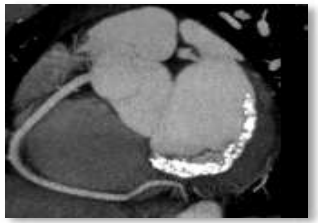
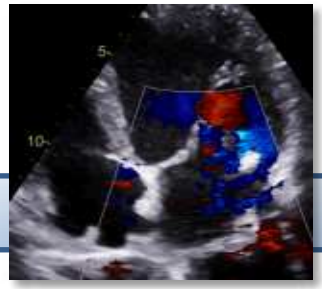
Clinical Research

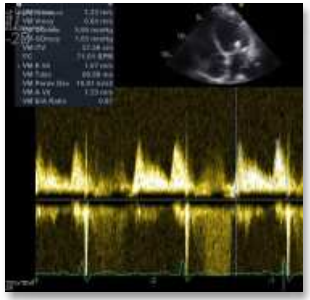
Transcatheter edge-to-edge repair following surgical valve repair with ring implantation: Results from the multicentre "Clip-in-Ring" registry☆

Guillaume Leurent[a,*,1], Vincent Auffret[a], Daniel Grinberg[b], Robin Le Ruz[c], Christophe Saint Etienne[d], Romain Pierrard[e], Didier Champagnac[f], Thomas Benard[g], Guillaume Lecoq[h], Marc Antoine Arnould[i], Guillaume Bonnet[j], Thibault Lhermusier[k], Amedeo Anselmi[l], Hervé Corbineau[l], Erwan Donal[a], for the "Clip-in-Ring" registry investigators

Complexes cases : MR < MAC







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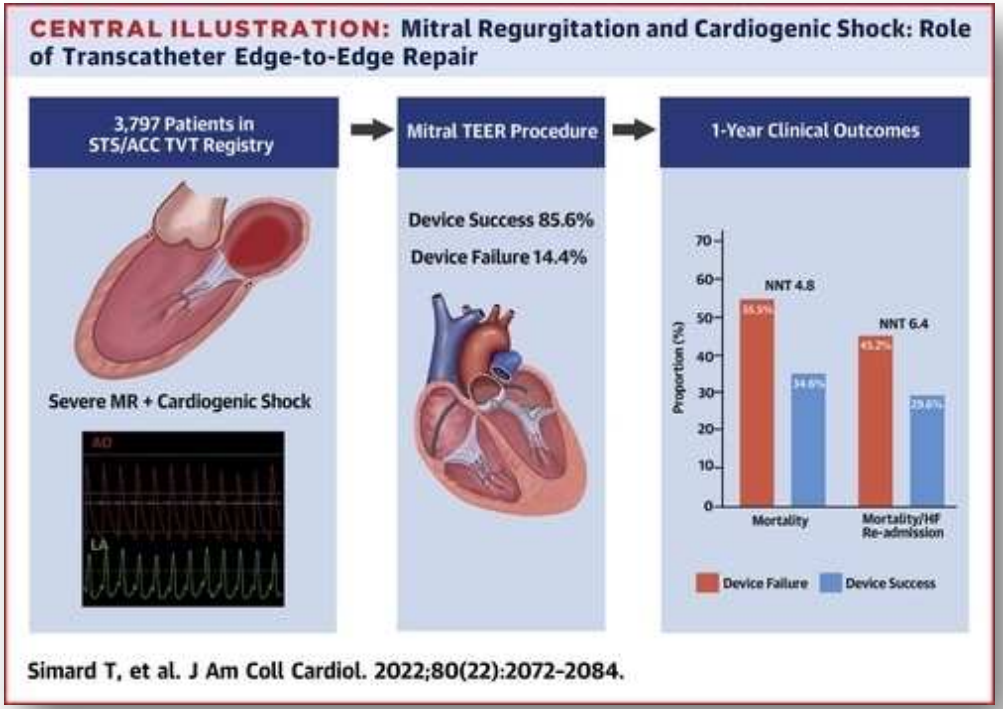
Complexes cases : cardiogenic shock < MR



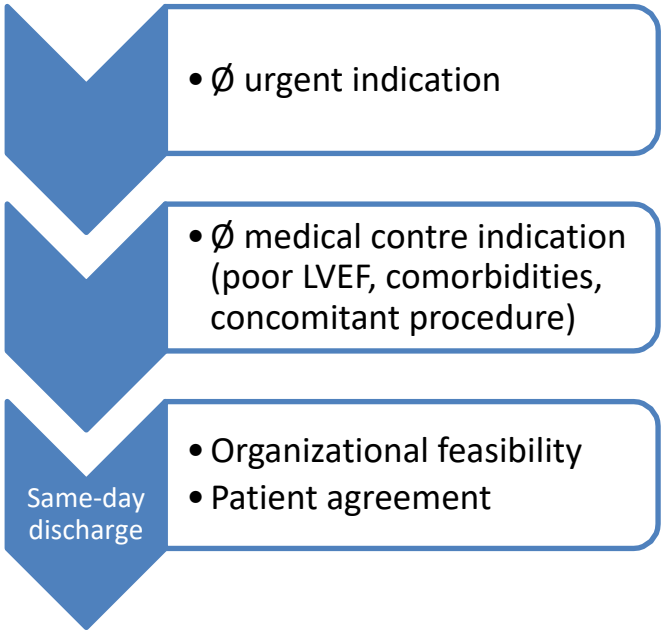
Disponibilité en urgence de la technique ?

CHU Rennes : 75 M-TEER
16 urgent / emergency

An urgent need for a care path optimisation

- Bed shortage
- Fragile population
- Logistical constraints
- Increasing delays

- Trained team
- Care path coordination
- Admission D-0
- Same-day discharge



~ 1 patient /6

To be submitted

Conclusion

- ✓ A safe and efficient technology
- ✓ Place of the Heart team ++

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