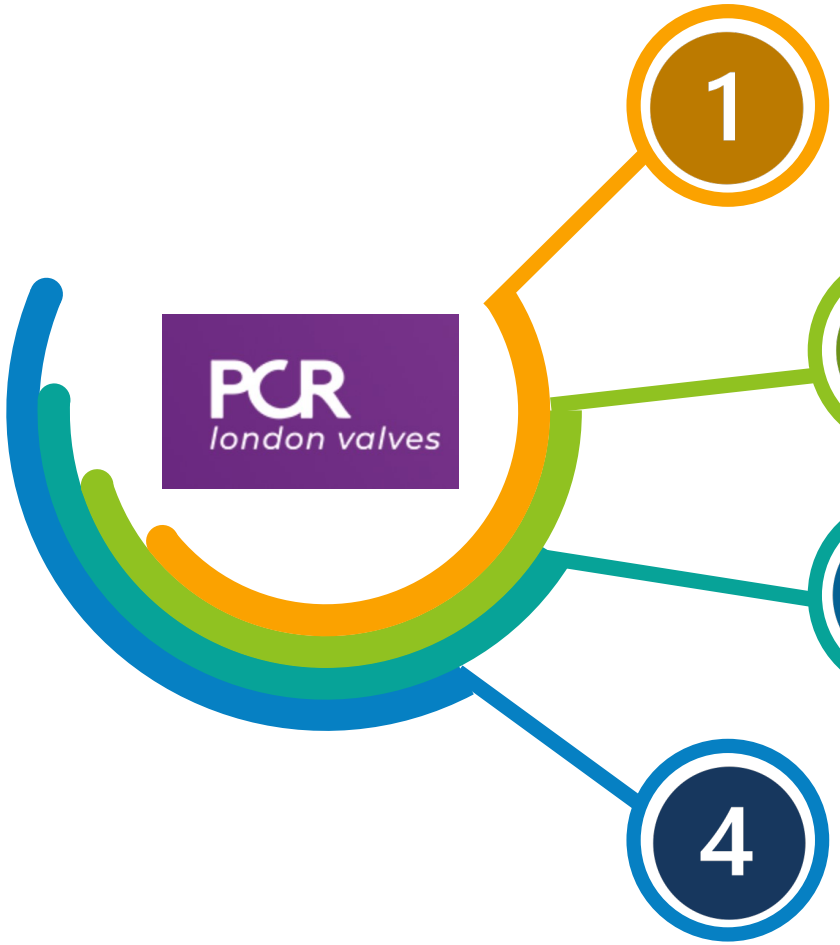
NHỮNG TIẾN BỘ TRONG ĐIỀU TRỊ BỆNH VAN HAI LÁ

TS. Phan Tuấn Đạt

Bộ môn Tim mạch – Trường ĐHYHN

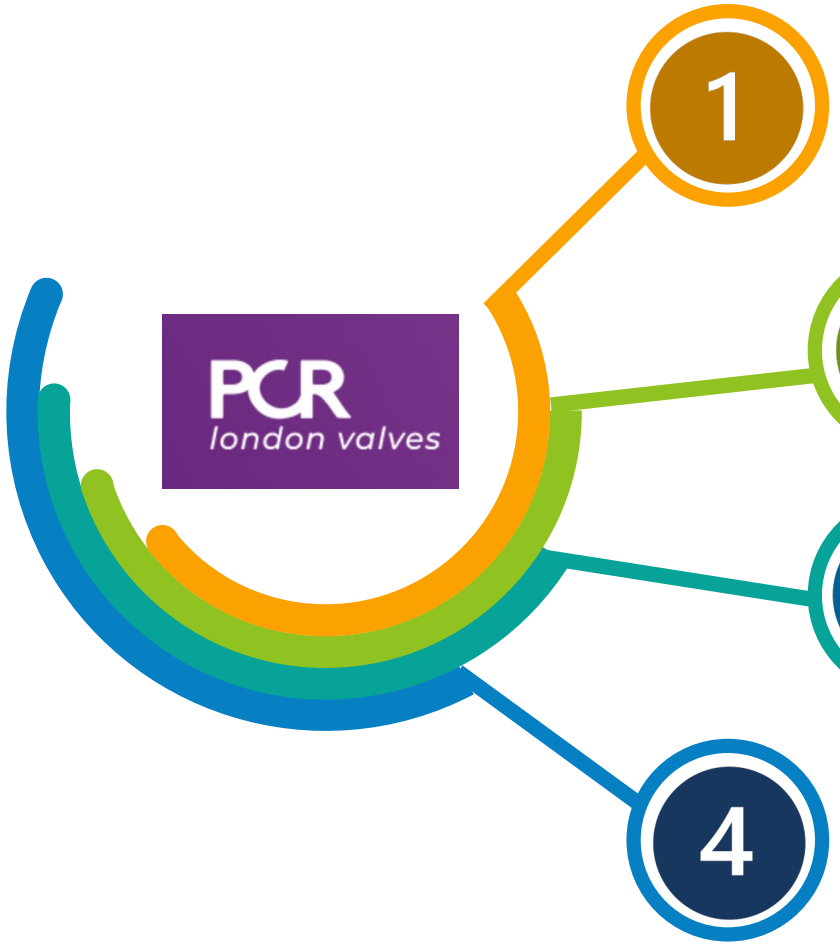
Viện Tim mạch Việt Nam

Nội dung báo cáo



1. Giới thiệu Lịch sử Hội nghị tim mạch can thiệp PCR PCR London Valves 2022
2. Những nghiên cứu cập nhật của dụng cụ Mitraclip
3. Những tiến bộ hứa hẹn trong sửa van hai lá qua đường ống thông
4. Những tiến bộ hứa hẹn trong thay van hai lá qua đường ống thông

Nội dung báo cáo



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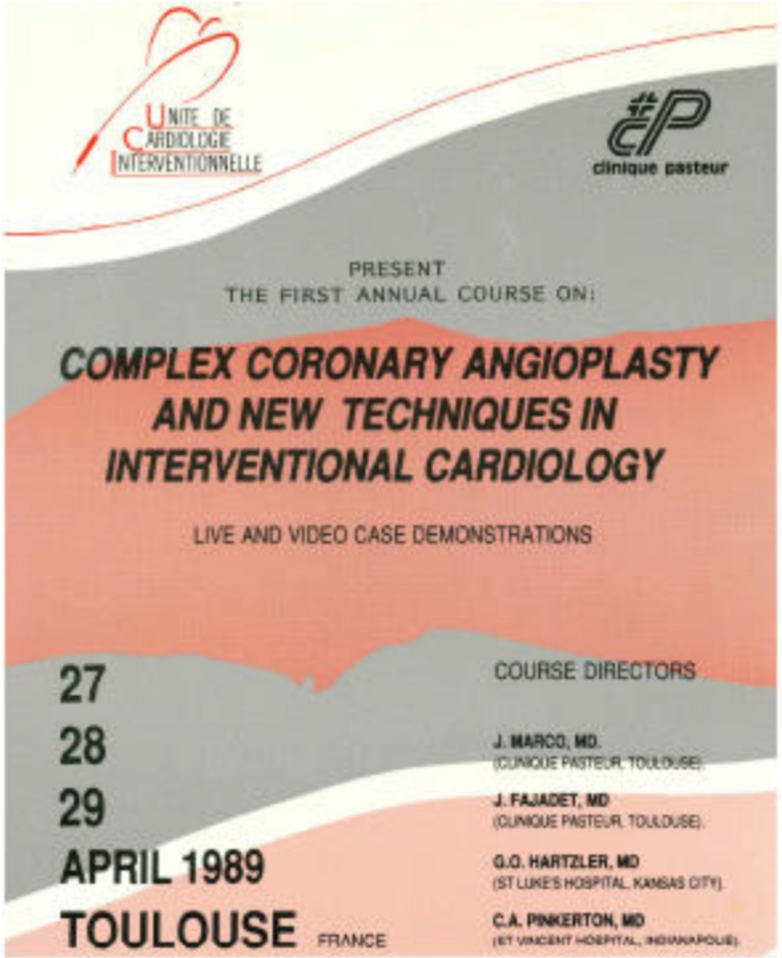
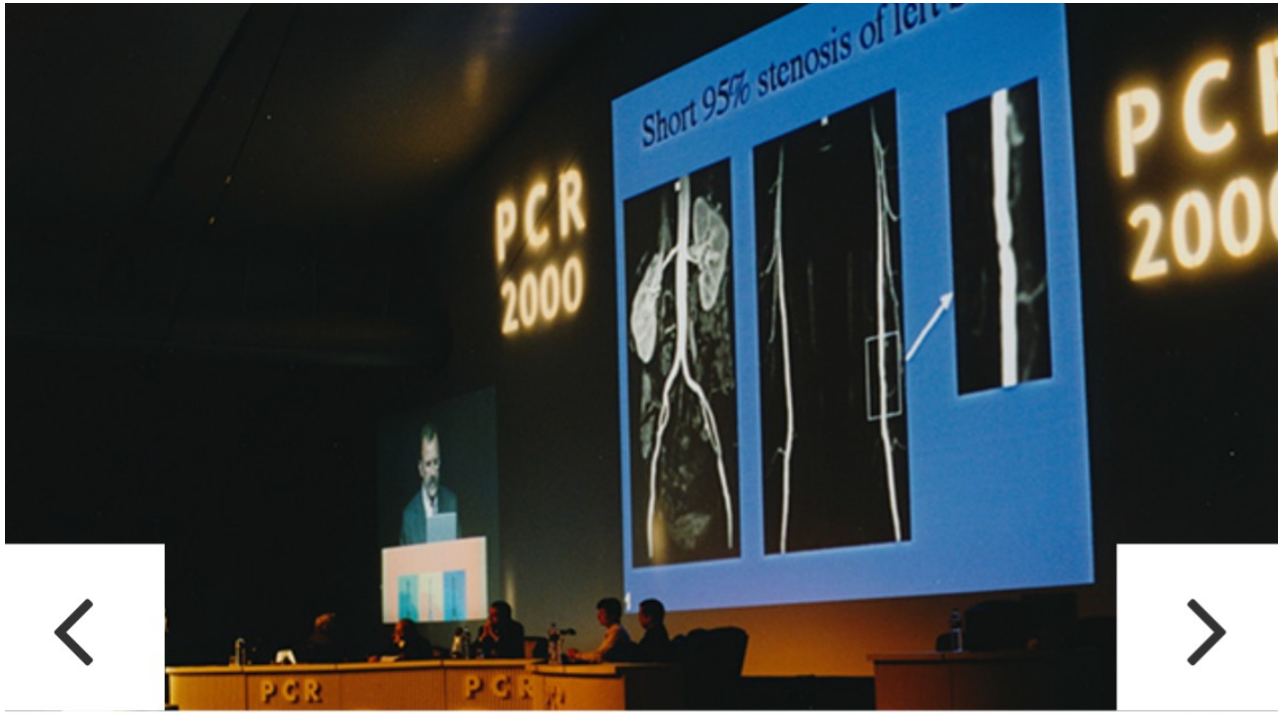
Lịch sử Hội nghị Tim mạch can thiệp PCR



Năm 1989, GS Jean Marco lần đầu tiên tổ chức hội nghị **"Complex Coronary Angioplasty and New Techniques in Interventional Cardiology"** tại Toulouse, Pháp. Đây là hội nghị Tiếng Anh

Lịch sử Hội nghị Tim mạch can thiệp PCR

- **Năm 2000**, hội nghị được chuyển đến tổ chức tại Paris với tên gọi là **"the Paris Course of Revascularisation", viết tắt là PCR**
- Hội nghị sau đó đổi tên thành EuroPCR.
- Năm 2002, trang web PCRonline ra đời.
- Năm 2005, phát hành tạp chí Eurointervention



Hệ thống Hội nghị Tim mạch can thiệp PCR

GENERAL	VALVULAR INTERVENTIONS	OTHER COURSES
EuroPCR	PCR London Valves	PCR Innovators Day
GulfPCR-GIM	PCR-CIT China Chengdu Valves	EAPCI-PCR Fellows Course
AICT-AsiaPCR	PCR Tokyo Valves	PCR Seminars
AfricaPCR	PCR Imaging Valves Madrid	Advanced Course on Transseptal Puncture

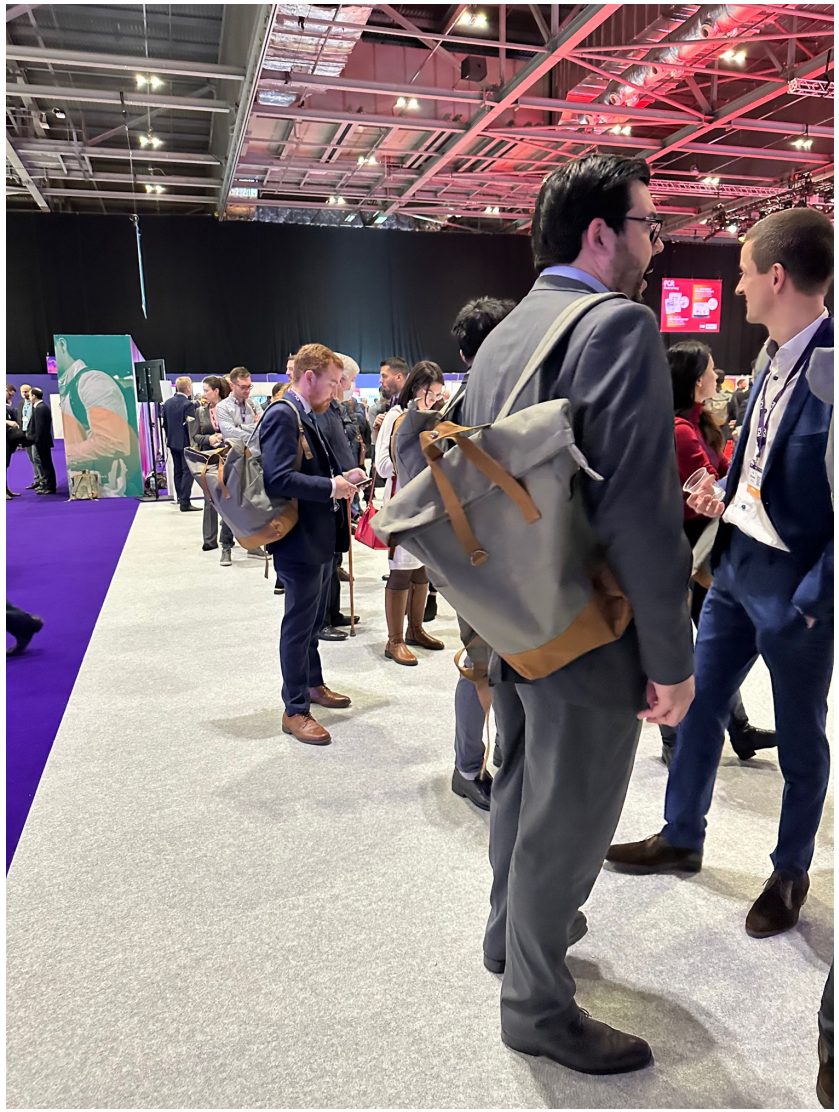
Hội nghị PCR London valves 2022

- Diễn ra trong 3 ngày hội thảo
- 3500 người tham gia
- 286 falcuty
- 230 bài báo cáo
- 3 phòng truyền hình trực tiếp
- 90 phiên đào tạo
- 3 phòng tương tác ca bệnh và phiên posters
- 3 trung tâm tham gia truyền hình trực tiếp tại Thành phố: London, Toulouse và Copenhagen

Hội nghị PCR London valves 2022

Hội nghị PCR London valves 2022

Hội nghị PCR London valves 2022



Hội nghị PCR London valves 2022

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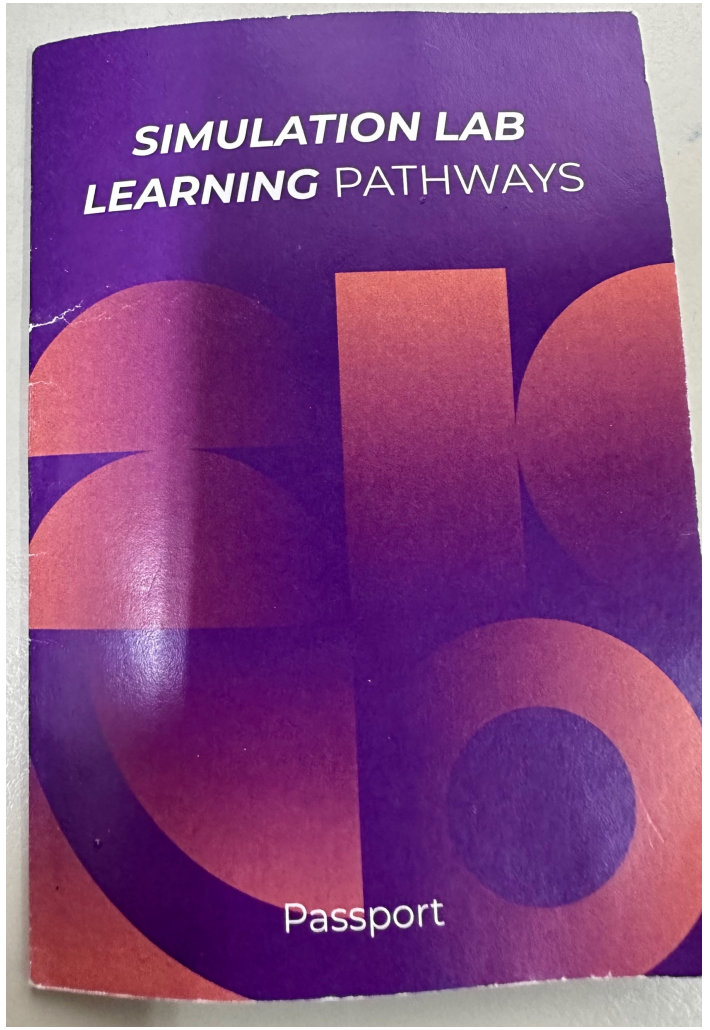
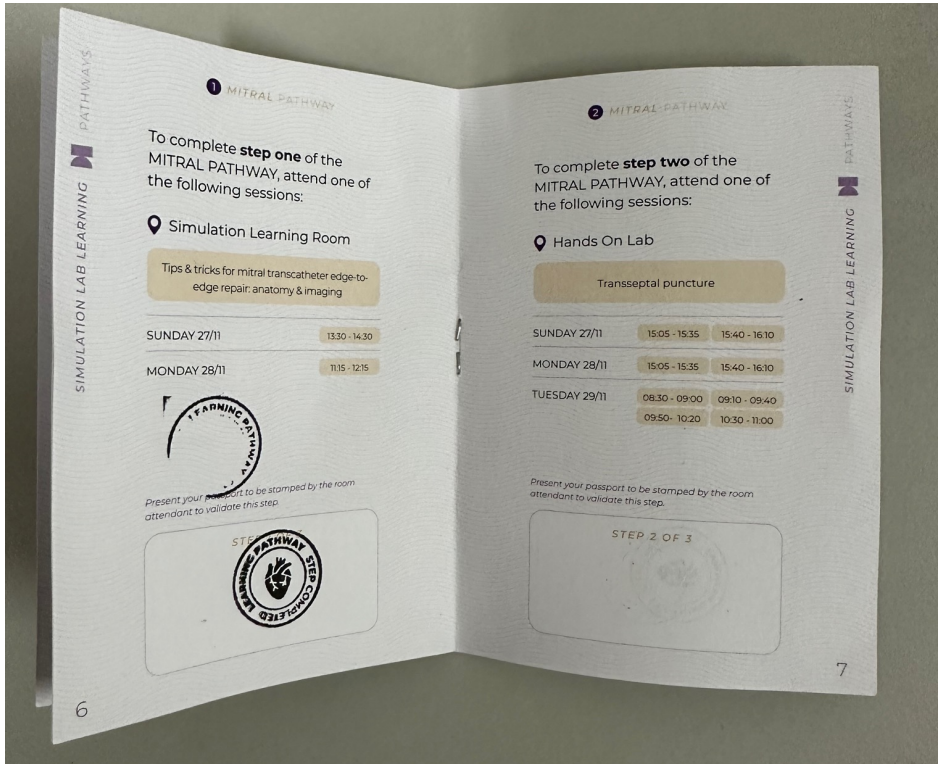
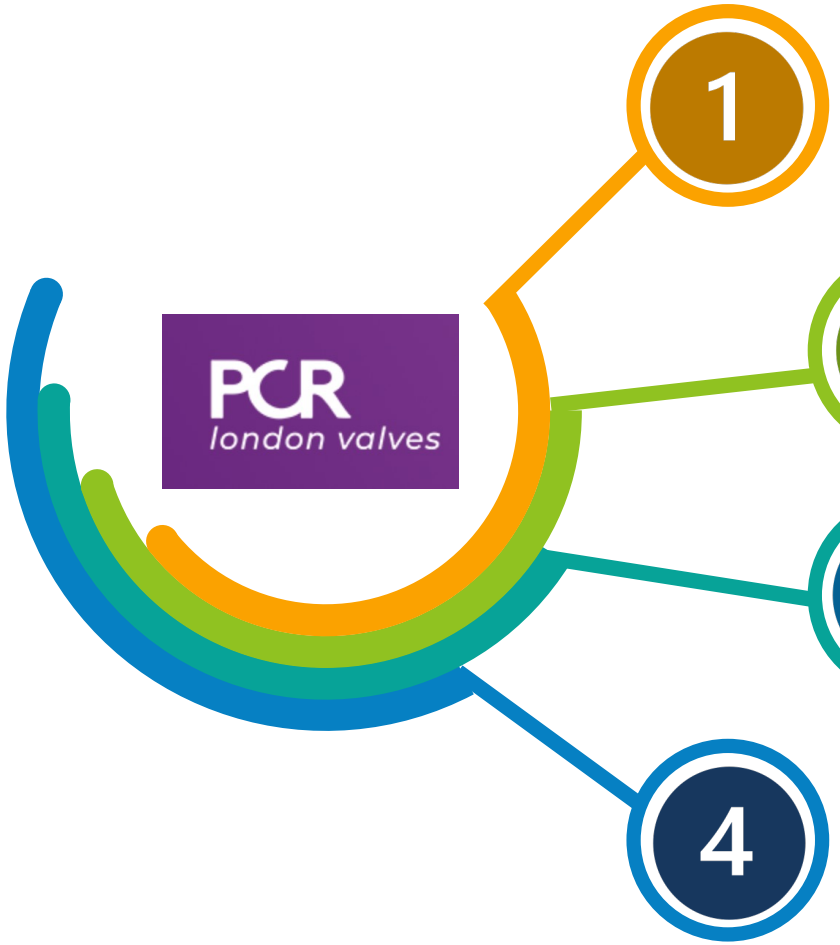




Nội dung báo cáo



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17+ Years of Commitment to Evidence and Innovation

2003 — MITRACLIP FIRST IN HUMAN

EVEREST I
Feasibility Study
55 Patients Enrolled
2003-2006

2005 — EVEREST II
RCT
279 Patients Enrolled
2005-2008

2007 — EVEREST II HIGH RISK STUDY
Single-Arm Study
78 Patients Enrolled
2007-2008

2008 — MITRACLIP CE MARK APPROVAL

2009 — EVEREST II REALISM
Continued Access
965 Patients Enrolled
2009-2014

2009 — ACCESS EUROPE
Single-Arm Study
567 Commercial Patients Enrolled
2009-2012

2013 — MITRACLIP FDA APPROVAL FOR PMR

COAPT™
RCT
614 Patients Enrolled
2013-2017

2013 — MITRACLIP PAS
Prohibitive Risk Primary MR
Commercial Registry
1998 Patients Enrolled
2013-2016

2014 — MITRACLIP AVAILABLE IN CANADA

MITRA-FR*
RCT
304 Patients Enrolled
2014-2017

2015 — MATTERHORN* & RESHAPE-HF2*
RCT
Currently Enrolling
2015-Present

2017 — MITRACLIP AVAILABLE IN JAPAN

COAPT CAS
Continued Access
Enrollment Complete
162 subjects
2017-2019

2018 — COAPT Data Release at TCT

EXPAND STUDY
Observational Study
Core Lab/CEC Adjudication
Enrollment complete
1041 Patients

MITRACLIP JAPAN PMS
Post-Market Surveillance
Enrollment complete
500 Patients

2019 — MITRACLIP FDA APPROVAL For SMR

MITRACLIP PAS
Secondary MR
Commercial Registry
Currently Enrolling
5000 Patients

2020 — EXPAND-G4 STUDY
Observational Study
Core Lab/CEC Adjudication
Currently Enrolling
1000 Patients

REPAIR MR
Multi-Center RCT – IDE Trial
Currently Enrolling
500 Patients

MITRACLIP RUSSIA
Single-Arm Study
Enrollment began and Completed
16 Patients

MITRACLIP CHINA PMS
Post-Market Surveillance
Currently Enrolling
50-100 Patients

MITRACLIP KOREA PMS
Post-Market Surveillance
Currently Enrolling
600 Patients / 4 Years

MITRACLIP INDIA PMS
Post-Market Surveillance
Enrollment Starts
All consenting patients within 2 Yrs of Launch

2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021

Commercial approvals

Clinical Study

*Investigator-sponsored studies

Data on File at Abbott.

† Largest real world study in transcatheter mitral valve repair

Advancing Clinical Evidence

100k+ Patients Treated

59k+ Patients Studied

2500+ Publications

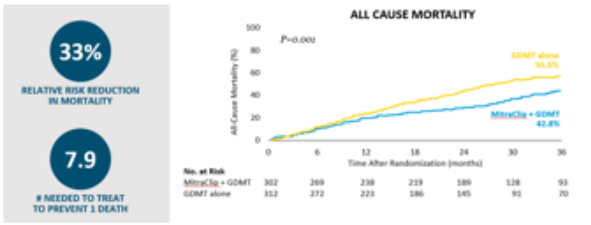
Largest Real World Studies†

MitraClip™ Clinical Performance: The COAPT™ Clinical Trial

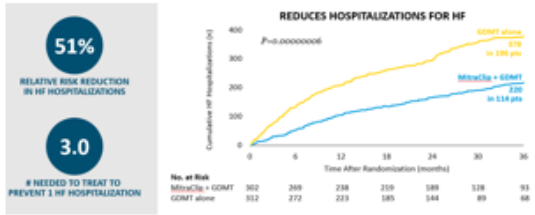
At 3 years, MitraClip continues to save lives.[2]

CLICK TO EDIT MASTER TEXT STYLES

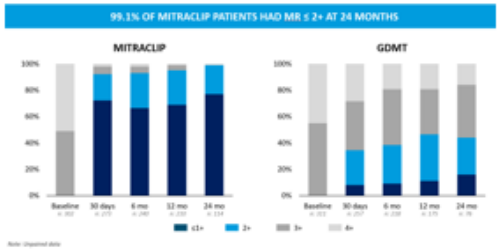
Improves survival[2]



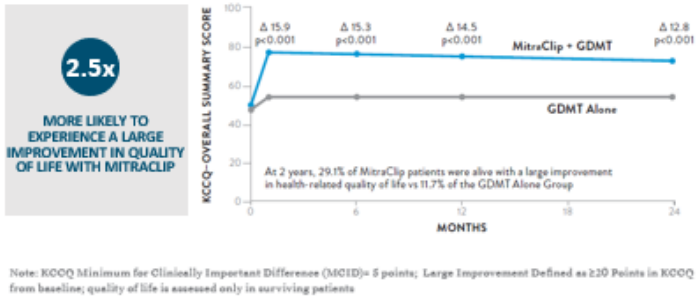
Reduces the rate of HF hospitalizations[2]



Provides sustained reduction of MR[1]



Improves quality of life and functional capacity[3]



Note: KCCQ Minimum for Clinically Important Difference (MCID)= 5 points; Large Improvement Defined as ≥20 Points in KCCQ from baseline; quality of life is assessed only in surviving patients

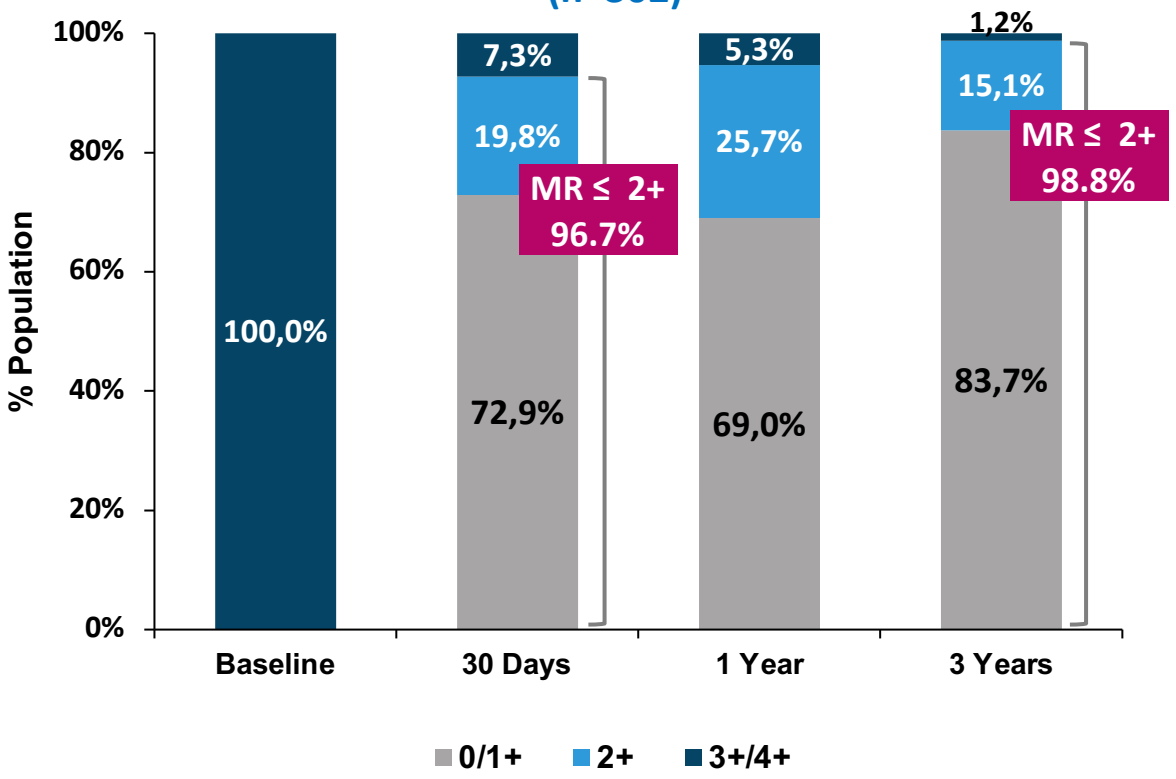
Is safe: **96.6%** freedom from device-related complications at 12 months[1]

*For Heart Failure patients with EF <=50%, with moderate to severe or severe secondary MR.

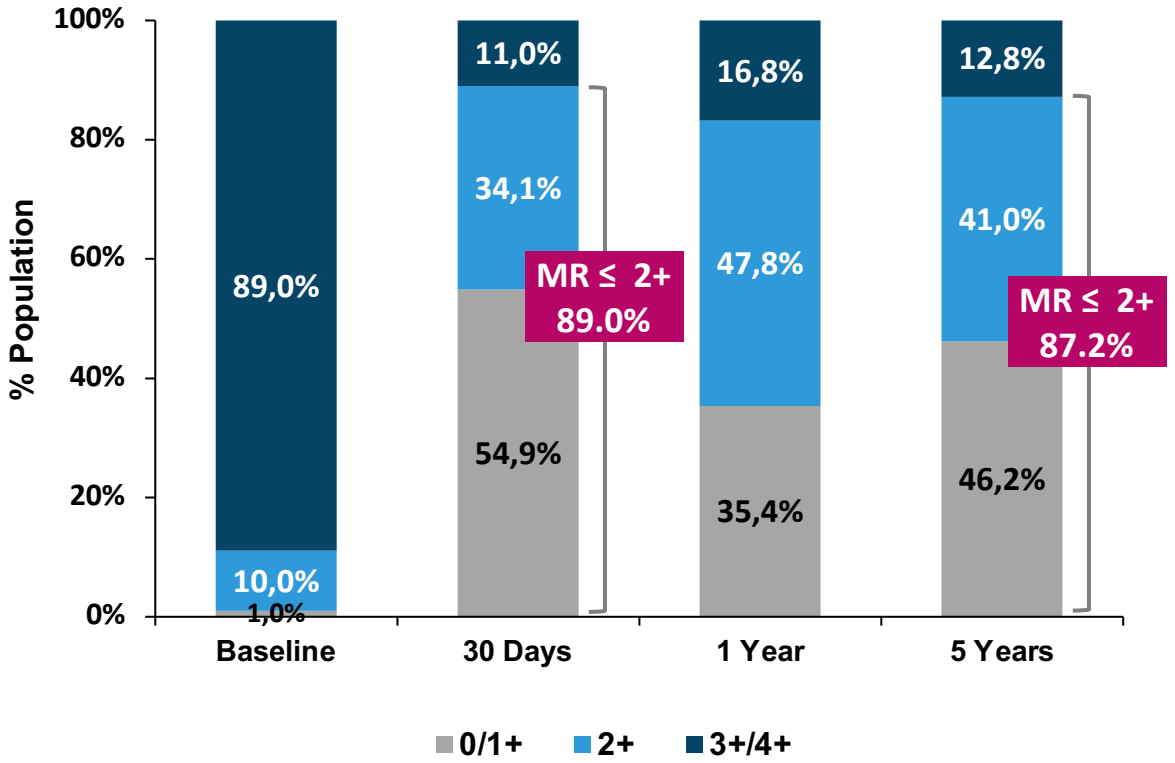
1. Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med*. September 23, 2018. DOI: 10.1056/NEJMoa1806640
2. Mack MJ, et al. COAPT Investigators. 3-Year Outcomes of Transcatheter Mitral Valve Repair in Patients With Heart Failure. J Am Coll Cardiol. 2021 Mar 2;77(8):1029-1040. doi: 10.1016/j.jacc.2020.12.047
3. Arnold SV et al. Health status after transcatheter mitral valve repair in heart failure and secondary mitral regurgitation. JACC Mar 2019, 25951; DOI: 10.1016/j.jacc.2019.02.010

Durable Results with MitraClip in Primary and Secondary MR

COAPT 3 Year Outcomes[1]
(n=302)



EVEREST II REALISM 5 Year Outcomes[2]
(n=264)



NOTE: Data not from head to head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

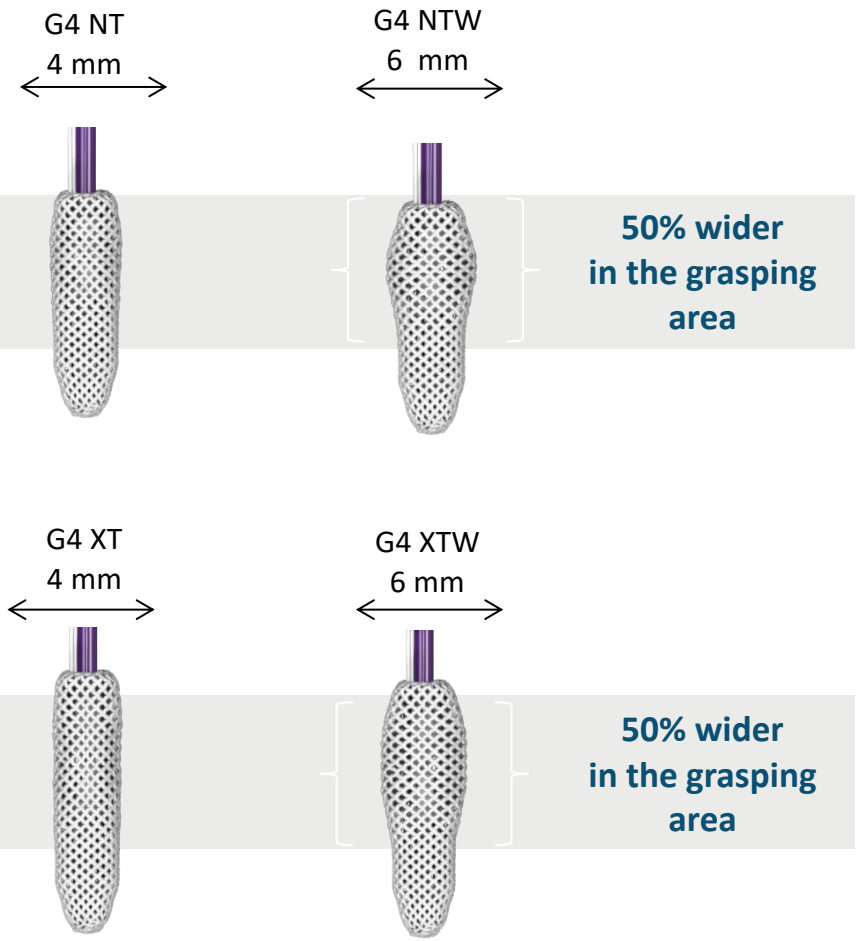
[1]Mack, M.J. et al. J Am Coll Cardiol. 2021;77(8):1029–40.
[2]EVEREST II REALISM Non High Risk (HR) Cohort, Abbott Internal Data

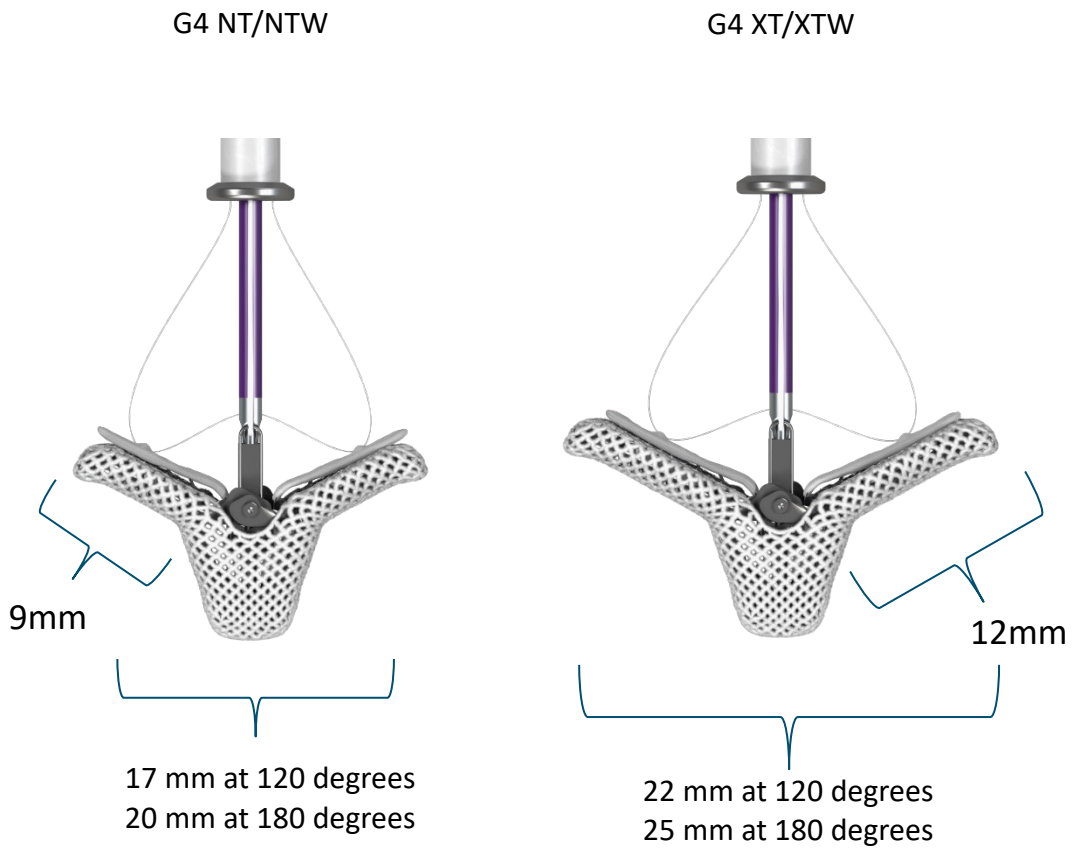
Can the MitraClip Do Better?

- Inadequate leaflet insertion for sufficient MR reduction: **Longer Clip (XT)**
- Inability to grasp both leaflets simultaneously: **Independent Gripper Functionality**
- Need for multiple clips/prolonged procedure duration in the setting of broad jets: **Wide Clip (NTW, XTW)**
- Limited means to assess physiologic results prior to clip release: **Continuous LA pressure monitoring**

MitraClip™ G4: Expanded Clip Size

Tailor your treatment with four clip sizes

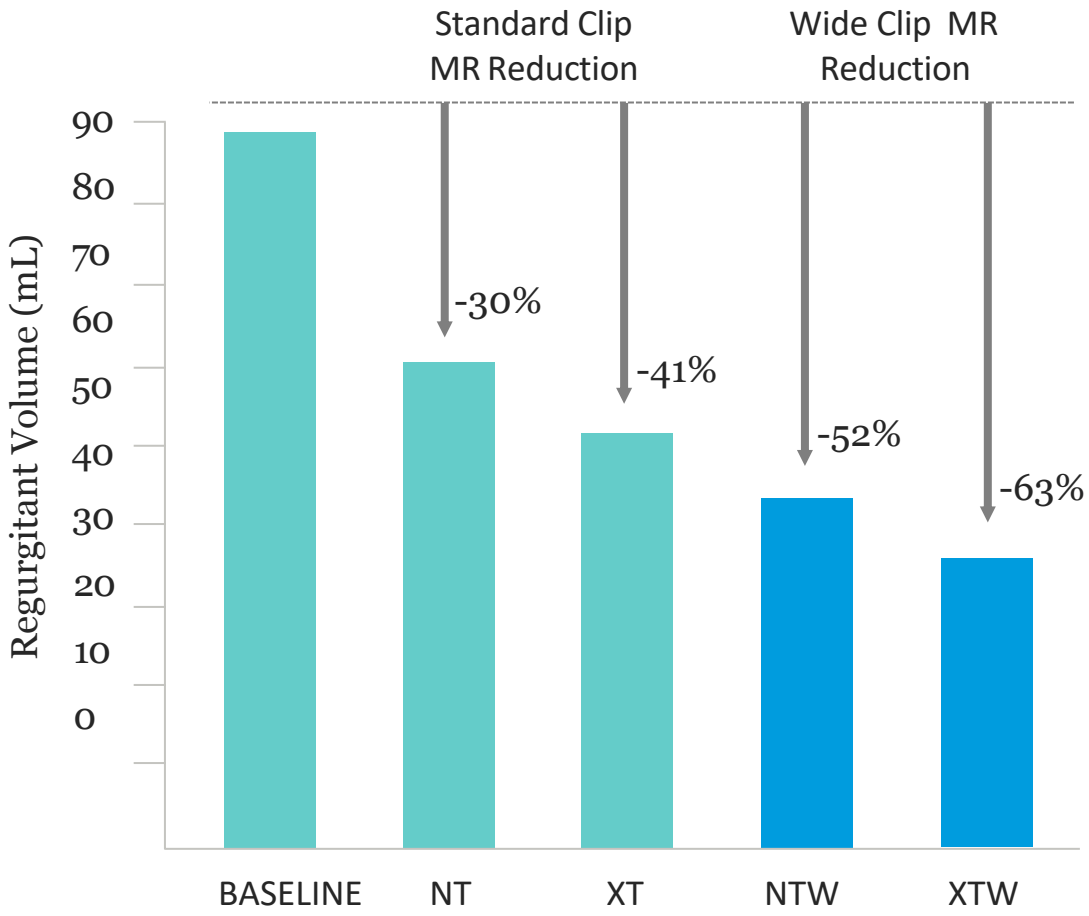


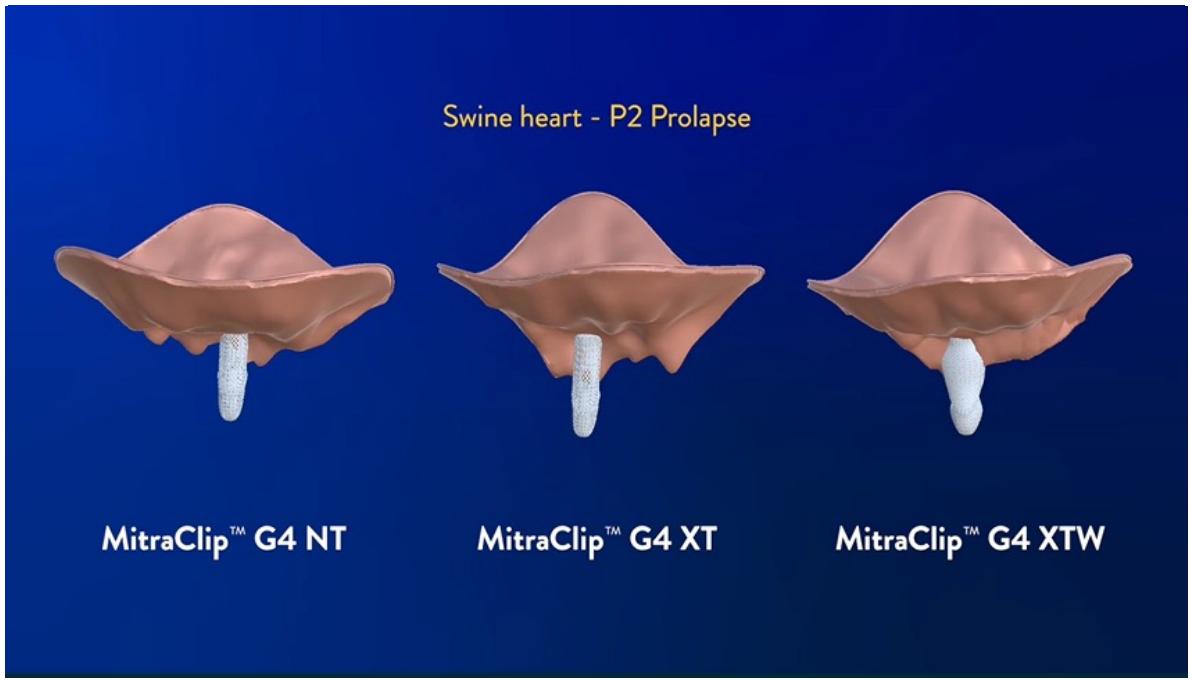


The four Clip sizes of the MitraClip G4 system gives you a choice for each patient's mitral valve anatomy/pathology

Test performed by and data on file at Abbott.

MitraClip™ G4 Designed To Further Reduce MR With 1 Clip





Movie clip showing larger coaptation area:
NTW vs. XT vs. XTW

Test performed by and data on file at Abbott

MitraClip™ G4: Controlled Gripper Actuation to confirm and Optimize Leaflet Grasping

Test performed by and data on file at Abbott. MitraClip G4 IFU.

2022 PCR london valves

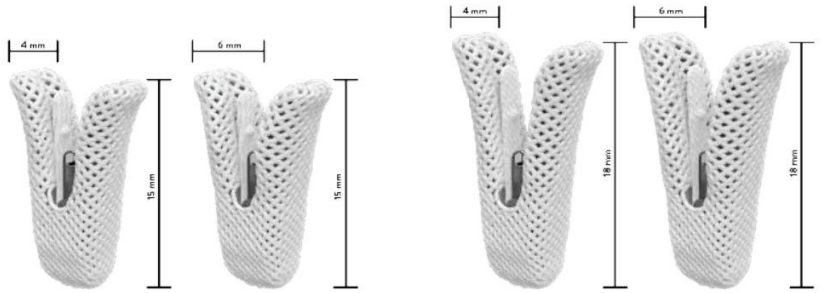
Clip Selection Strategy with 4th Generation MitraClip™: Evidence-Based Recommendations from the Global EXPAND G4 Study

Francesco Maisano, Paolo Denti, Paul Mahoney, Andrew Morse, Federico De Marco, Matthew Price, Federico M. Asch, Janani Aiyer, Evelio Rodriguez, Stephan von Bardeleben

EAPCI
European Society of Cardiology

Background

- The latest generation MitraClip G4 System introduced **two wider Clips: XTW and NTW, in addition to the standard width Clips, NT and XT, to tailor mitral valve repair.**
- The global **EXPAND G4 Study** was initiated to evaluate safety and effectiveness of the MitraClip G4 System, and **showed significant 30-Day MR reduction (91% MR ≤ 1+) and low rate of adverse events in real world settings**[1,2]



STANDARD LENGTH ARM (G4 NT / G4 NTW)

LONG LENGTH ARM (G4 XT / G4 XTW)

- **Consensus-based recommendations for clip usage were provided by an expert physician panel** based on the following anatomical considerations[3,4,*].

	Anatomical Considerations		Favors G4 NTW	Favors G4 NT	Favors G4 XTW	Favors G4 XT
1. Leaflet insertion	Length of mobile leaflet in grasping zone?	Leaflet Length < 9 mm	+	+		
		Leaflet Length ≥ 9 mm			+	+
2. Jet Width	Width of jet?	Broad jet	+		+	
3. MVA	Area of valve?	Smaller Valve		+		
		Larger Valve	+		+	+

[1] Von Bardeleben et al. Contemporary Outcomes of 1000+ Patients Treated with MitraClip™ G4, TCT 2022

[2] Rinaldi et al. Safety and Echo Outcomes with MitraClip™ G4, PCR LV 2022

[3] Rottbauer WD. Contemporary Clinical Outcomes with MitraClip™ (NTR/XTR) System: Core-lab Echo Results from +1000 Patient the Global EXPAND Study. Data presented at PCR 2020.

[4] Maisano F. Clip Selection Strategy and Outcomes with MitraClip™ (NTR/XTR): Evidence-Based Recommendations from the Global EXPAND Study. Data presented at PCR 2020.

** Tests performed by and data on file at Abbott.*

Study Design and Objectives

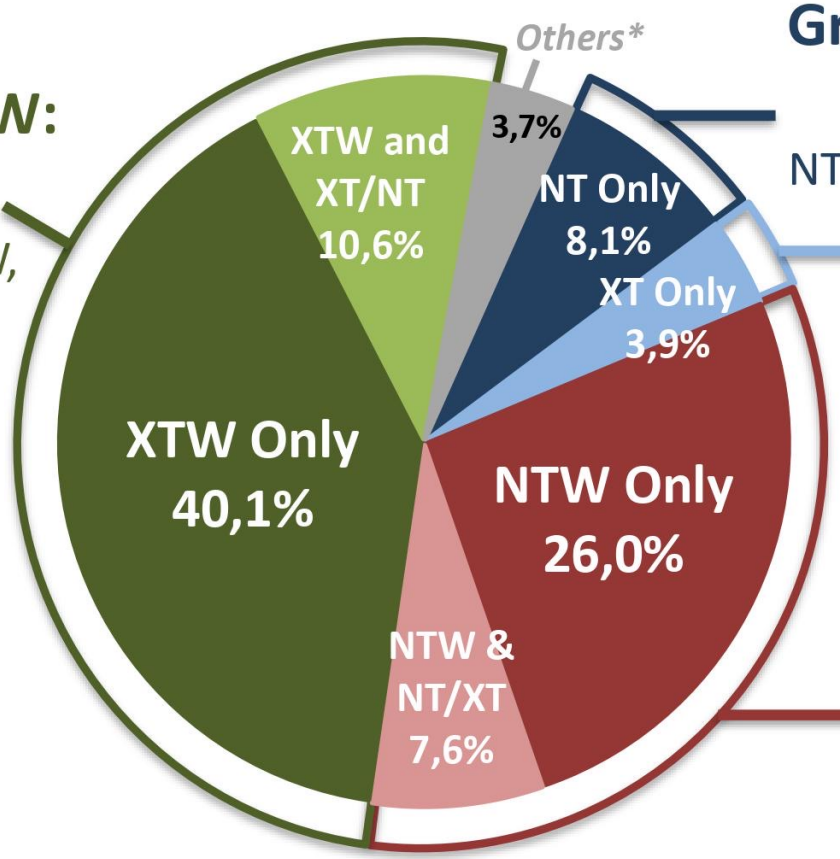
- EXPAND G4 was a global, prospective, real-world study that enrolled 1164 subjects with mitral regurgitation (MR) who received the MitraClip G4 System at 63 centers across USA, Europe, Canada, and Japan.
- All echocardiograms were assessed by an independent echo-core-laboratory (ECL)

Objectives:

1. To characterize baseline mitral valve anatomies associated with the selection of XTW, NTW, XT and NT Clips,
2. To evaluate the current recommendations for the use of MitraClip G4 clips based on observations from the real-world EXPAND G4 Study.

Methods: Analysis of Clip Usage

EXPAND G4 Clip Usage (N = 1146)



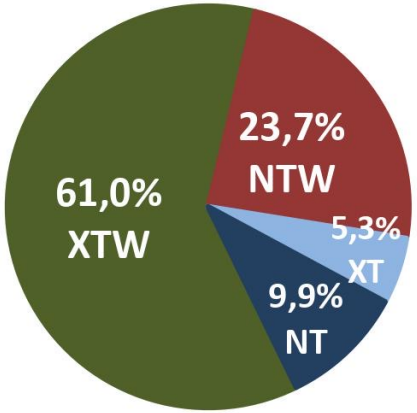
Group XTW: 50.7%
1st clip XTW, no NTW

Group NT: 8.1%
NT Clips Only

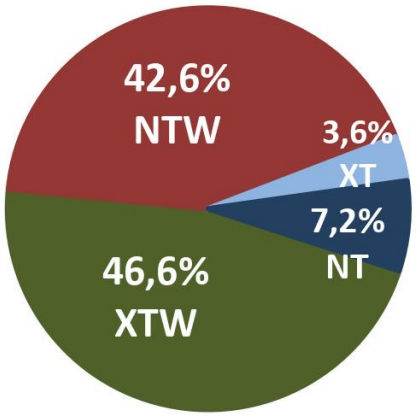
Group XT: 3.9%
XT Clips Only

Group NTW: 33.6%
1st clip NTW, no XTW

Primary MR** (N=413)



Secondary MR (N=554)



Subgroup analysis was performed to assess the association between the clip use, baseline anatomical characteristics and 30-day MR reduction in Primary and Secondary MR.

** Others: XTW + NTW, NT/XT followed by XTW/NTW, NT/XT (N = 42) were excluded from present analysis*

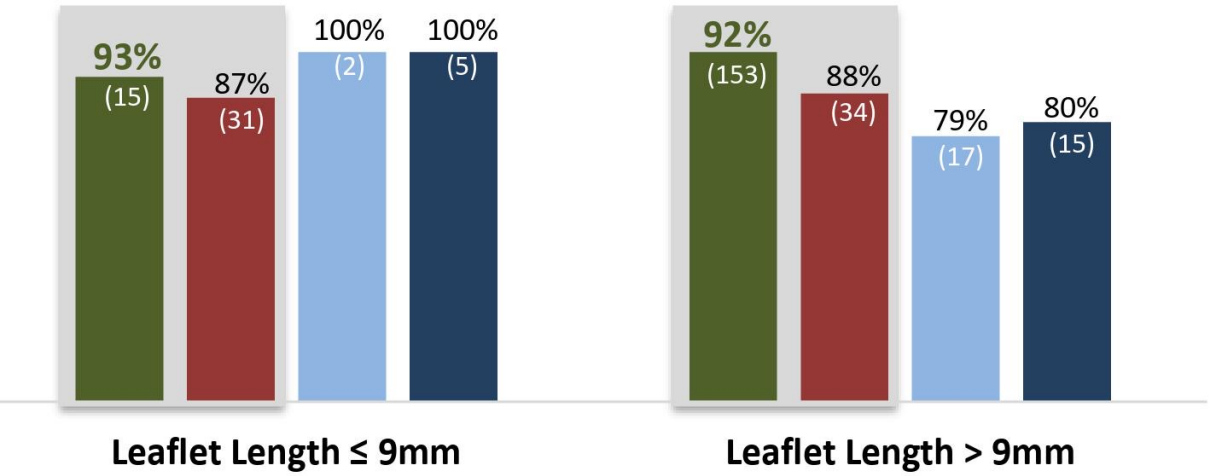
*** Primary MR includes PMR only (n=405) and Mixed patients (n=8)*

Anatomical Considerations – *Leaflet Length*

Primary MR

Baseline Echo Characteristics		Current Guidelines	Group XTW	Group NTW	Group XT	Group NT
Leaflet Length *(Site-Reported)*	≤9mm (N=67)	NTW, NT	23.9%	**58.2%**	3.0%	14.9%
	>9mm (N=293)	XTW, XT	**69.3%**	16.0%	6.5%	8.2%

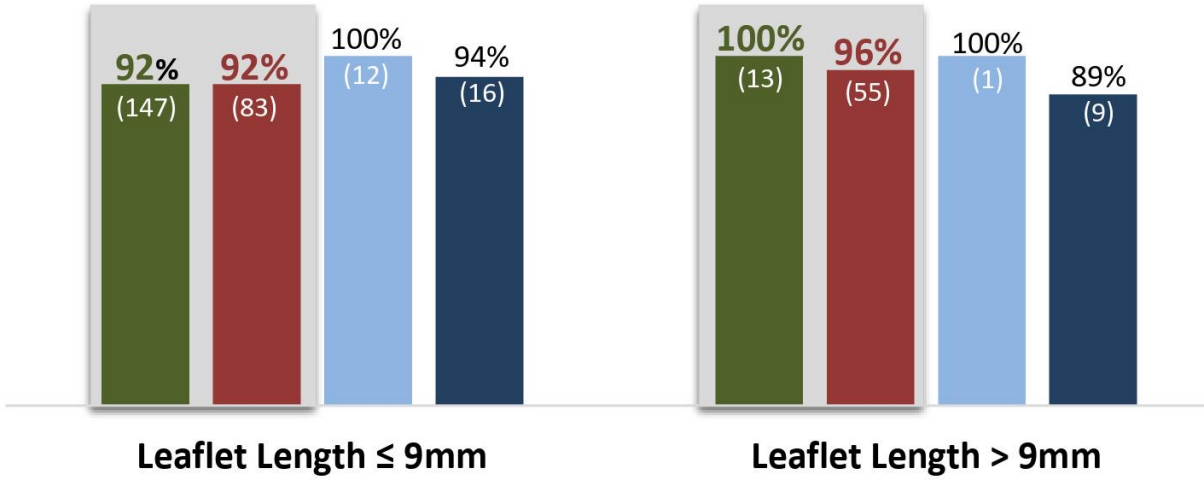
30-Day MR ≤ 1+



Secondary MR

Baseline Echo Characteristics		Current Guidelines	Group XTW	Group NTW	Group XT	Group NT
Leaflet Length *(Site-Reported)*	≤9mm (N=112)	NTW, NT	17.0%	**69.6%**	2.7%	10.7%
	>9mm (N=348)	XTW, XT	**57.8%**	31.6%	4.9%	5.7%

30-Day MR ≤ 1+



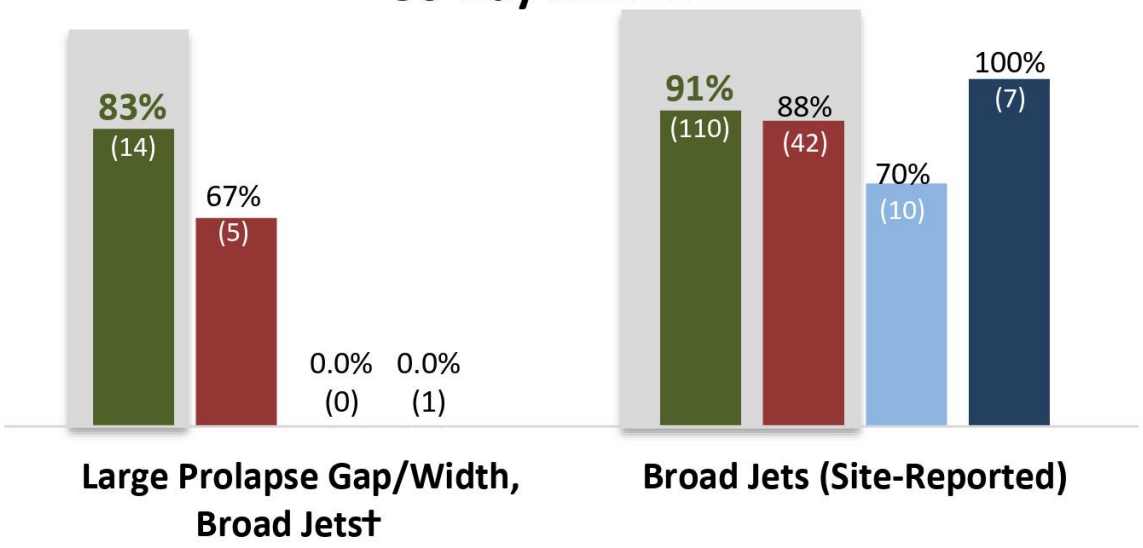
The clip selection recommendations for leaflet length were followed and resulted in maximum 30-day MR reduction in both PMR and SMR.

Anatomical Considerations – *Broad Jets*

Primary MR

Baseline Echo Characteristics	Current Guidelines	Group XTW	Group NTW	Group XT	Group NT
Large Prolapse Width (≥15mm), Broad Jets (N=24)	XTW, NTW	62.5%	29.2%	0.0%	8.3%
Broad Jets *(Site-Reported)* (N=222)	XTW, NTW	64.4%	25.2%	4.5%	5.9%

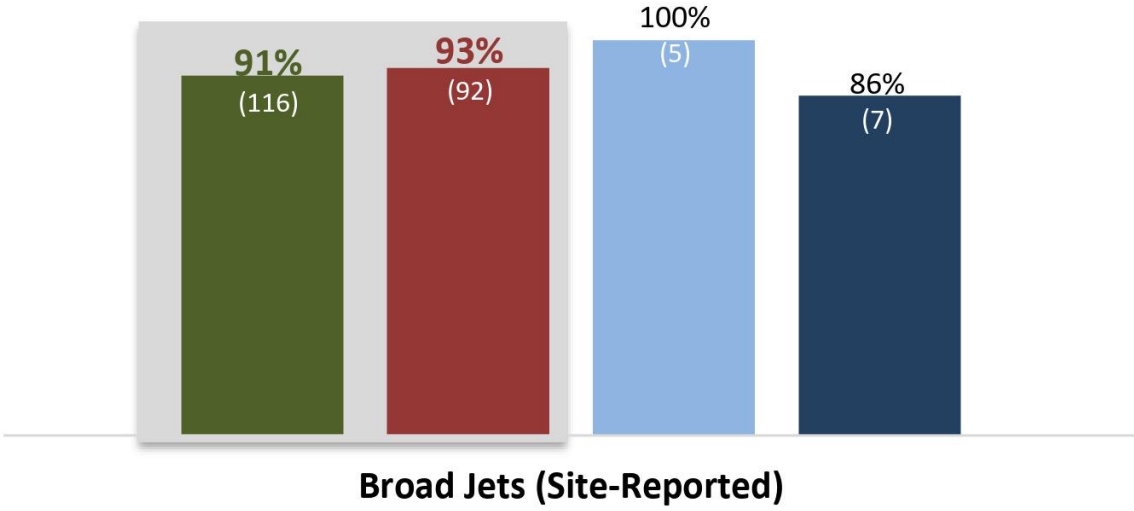
30-Day MR ≤ 1+



Secondary MR

Baseline Echo Characteristics	Current Guidelines	Group XTW	Group NTW	Group XT	Group NT
Broad Jets *(Site-Reported)* (N=297)	XTW, NTW	52.5%	41.4%	2.7%	3.4%

30-Day MR ≤ 1+



The clip selection recommendations for jet width were followed and resulted in maximum 30-day MR reduction in PMR and SMR.

Anatomical Considerations – *Mitral Valve Area*

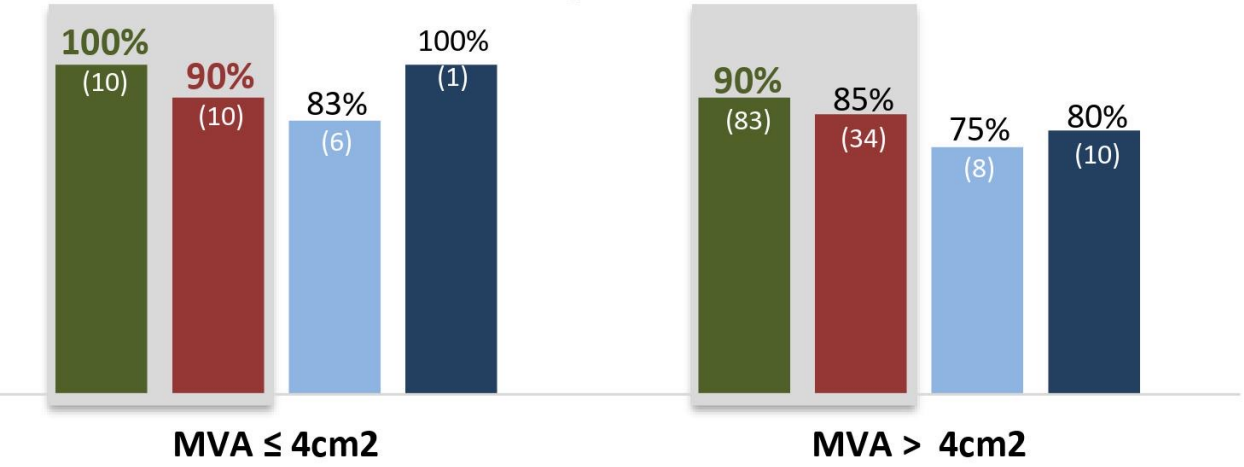
Primary MR

Baseline Echo Characteristics		Current Guidelines	Group XTW	Group NTW	Group XT	Group NT
Mitral Valve Area	≤4cm² (N=32)	NT	**43.8%**	34.4%	18.8%	3.1%
	>4cm² (N=156)	XTW, NTW, XT	**60.3%**	26.3%	5.1%	8.3%

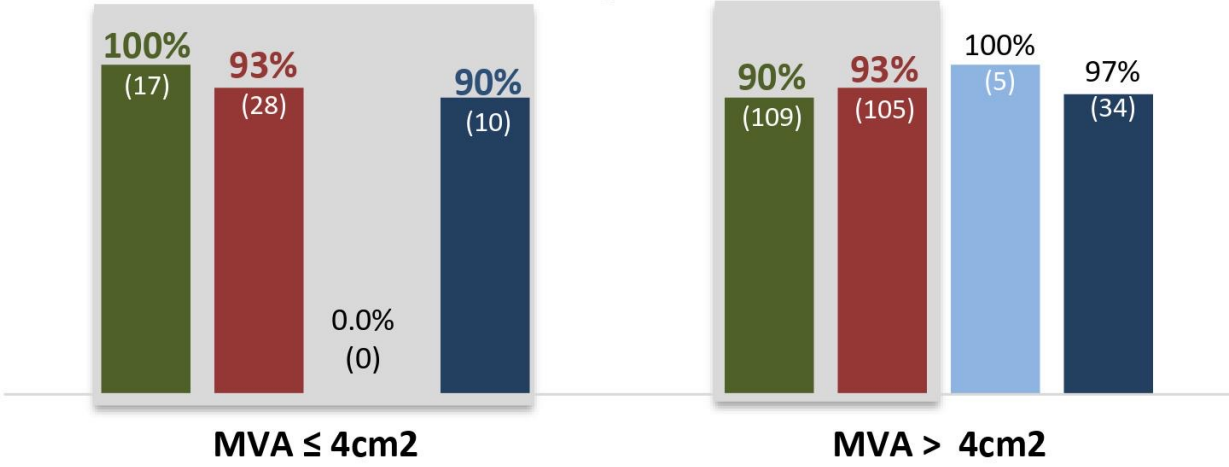
Secondary MR

Baseline Echo Characteristics		Current Guidelines	Group XTW	Group NTW	Group XT	Group NT
Mitral Valve Area	≤4cm² (N=66)	NT	30.3%	**51.5%**	1.5%	16.7%
	>4cm² (N=279)	XTW, NTW, XT	**48.6%**	**45.3%**	2.2%	4.0%

30-Day MR ≤ 1+:



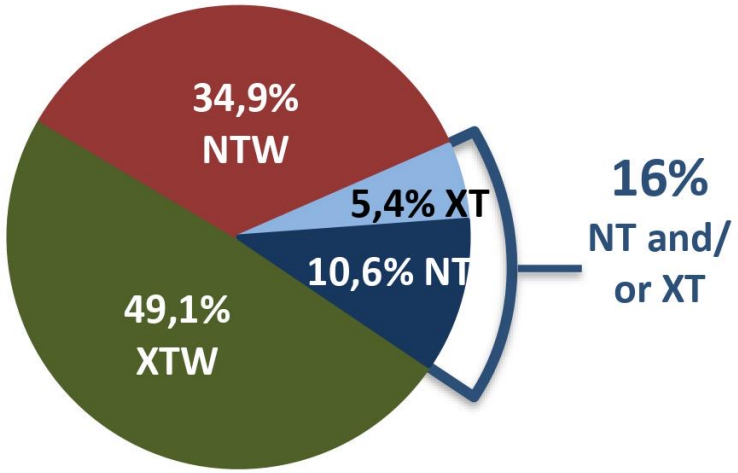
30-Day MR ≤ 1+:



NTW and XTW were used both in larger (>4 cm²) and smaller mitral valves (≤4 cm²) and resulted in maximum 30-day MR reduction.

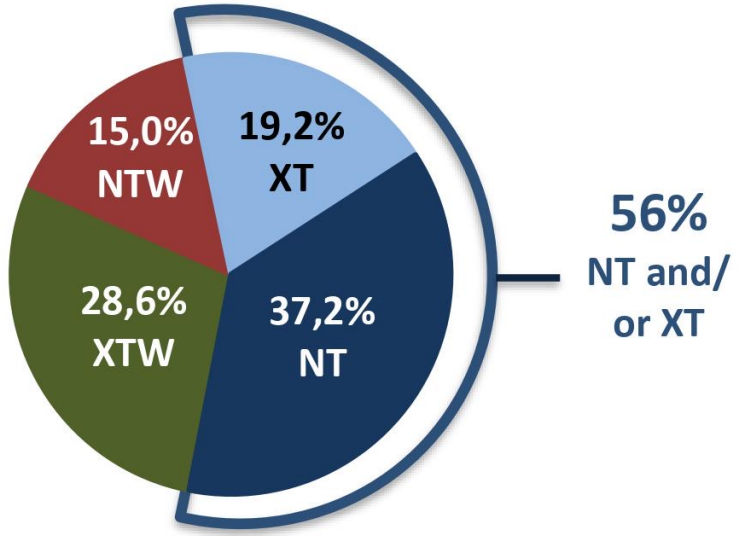
NT/XT Clip Use: "The Clip of Choice as 2nd or 3rd Clip"

Single-Clip Cases (N=745)



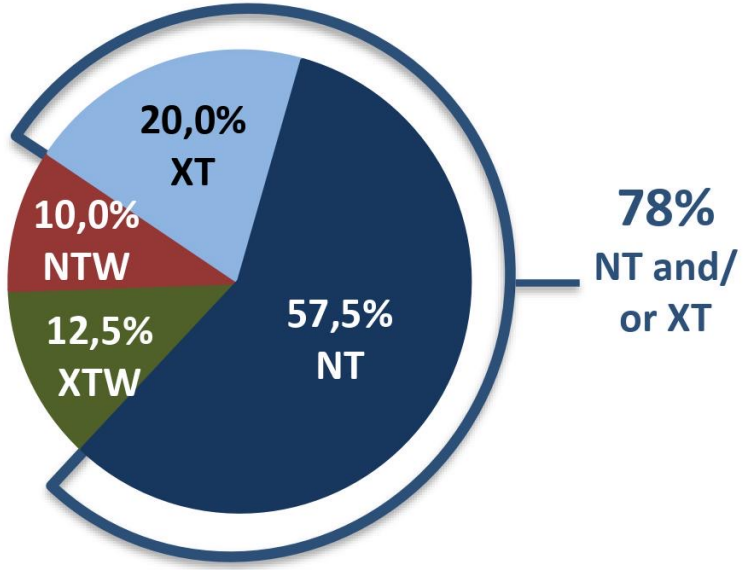
Discharge MR ≤ 1+ with NTW/XTW clips: 93.8%

2nd Clip Use in 2-Clip Cases (N=360)



Discharge MR ≤ 1+ with NT/XT clips: 96.5%

3rd Clip Use in 3-Clip Cases (N=40)



Discharge MR ≤ 1+ with NT/XT clips: 100%

The usage of NT and XT clips increased with the number of clips implanted in the procedure and resulted in excellent MR reduction.

Conclusions

- **Wider clips were preferred as the first clip in 84.3%** of subjects (XTW: 50.7%, NTW: 33.6%)
- **PMR: XTW was used most often and achieved favorable MR reduction**, particularly in patients with longer leaflets, large prolapse or wider jets, calcified leaflets or annulus and Barlow's or bileaflet prolapse.
- **SMR: NTW and XTW clips were used evenly and achieved favorable MR reduction.**
- **NT and XT** were used **more frequently in multiple-clip cases and improved MR reduction.**

Clip selection recommendations for MitraClip G4 based on real-world evidence from EXPAND G4 provide guidance for physicians to individualize TEER to patient anatomy and achieve maximum MR reduction.

Recommendations for Clip Selection

Based on Real World Observations from EXPAND G4

Anatomical Considerations		Favors NTW	Favors NT	Favors XTW	Favors XT
1. Leaflet Insertion	Length ≤ 9mm	✓	✓		
	Length > 9mm			✓	✓
2. Large Prolapse Width/Wide Jet	Prolapse Width (≥15mm)	✓		✓ (PMR)	
3. MVA	Small Valve (≤4cm^2)	+	✓	+	+
	Large Valve (>4cm^2)	✓		✓	✓
4. Primary Jet Location	**A2P2**	+		+	
	Outside A2P2	+ (SMR)	+	+	+
5. Calcification		+ (SMR)	+	+ (PMR)	
6. Barlow's or Bi-leaflet flail/ prolapse				+ (PMR)	

Initial recommendations confirmed by this analysis is marked with ✓

Additional recommendations added + for anatomical considerations that the clip size used often and resulted in the highest 30-Day MR reduction to ≤ 1+

ESC European Society of Cardiology

European Heart Journal (2022) **43**, 641–650
https://doi.org/10.1093/eurheartj/ehab496

CLINICAL RESEARCH
Valvular heart disease

Conservative, surgical, and percutaneous treatment for mitral regurgitation shortly after acute myocardial infarction

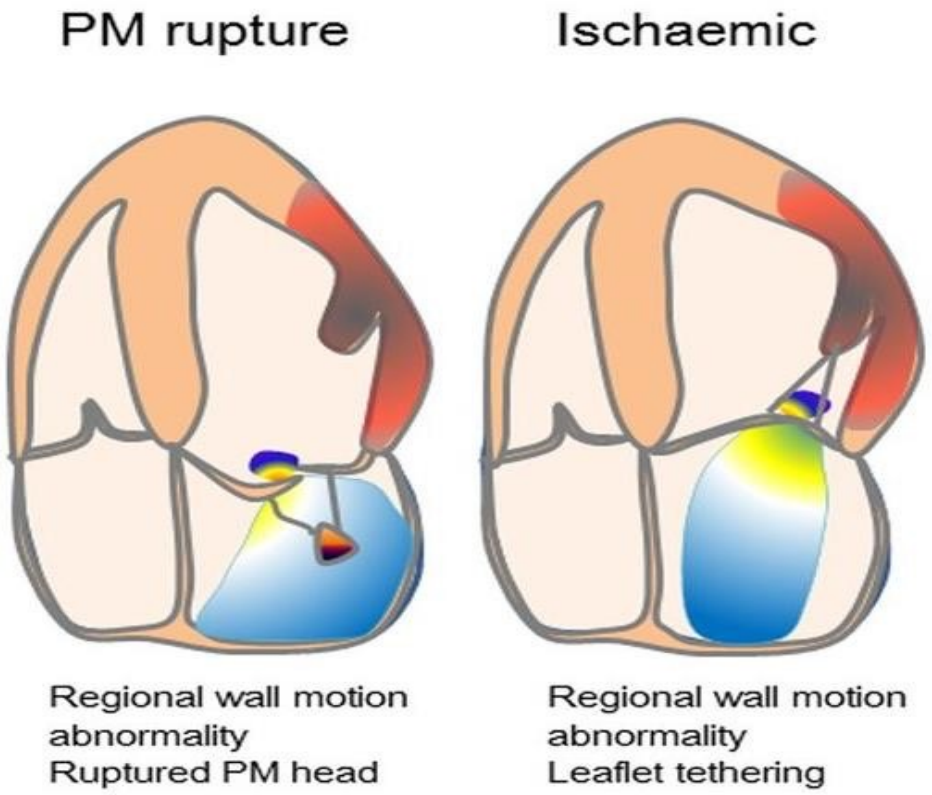
Dan Haberman [1*†], Rodrigo Estévez-Loureiro [2†], Tomas Benito-Gonzalez [3], Paolo Denti [4], Dabit Arzamendi [5], Marianna Adamo [6], Xavier Freixa[7], Luis Nombela-Franco [8], Pedro Villablanca[9], Lian Krivoshei[10], Neil Fam[11], Konstantinos Spargias[12], Andrew Czarnecki [13], Isaac Pascual [14], Fabien Praz [15], Doron Sudarsky [16], Arthur Kerner [17],Vlasis Ninios [18], Marco Gennari[19,20], Ronen Beeri [21], Leor Perl [22], Yishay Wasserstrum [23], Haim Danenberg[21], Lion Poles[1], Jacob George[1], Berenice Caneiro-Queija[2], Salvatore Scianna[20], Igal Moaraf[24], Davide Schiavi [4], Claudia Scardino [25], Noé Corpataux [15], Julio Echarte-Morales[3], Michael Chrissoheris[12], Estefanía Fernández-Peregrina [5], Mattia Di Pasquale [6], Ander Regueiro[7], Carlos Vergara-Uzcategui [8], Andres Iñiguez-Romo[2], Felipe Fernández-Vázquez [3], Danny Dvir[26], Francesco Maisano[4], Maurizio Taramasso [20†], and Mony Shuvy[21,26*†]

Acute mitral regurgitation (MR) in the setting of myocardial infarction (MI)

- **Acute mitral regurgitation (MR) in the setting of myocardial infarction (MI) is the result of**

1) **Papillary muscle rupture (PMR)**
2) **Rapid remodeling of infarcted left ventricle**

Patients often present with pulmonary edema and cardiogenic shock and associated with high mortality rates

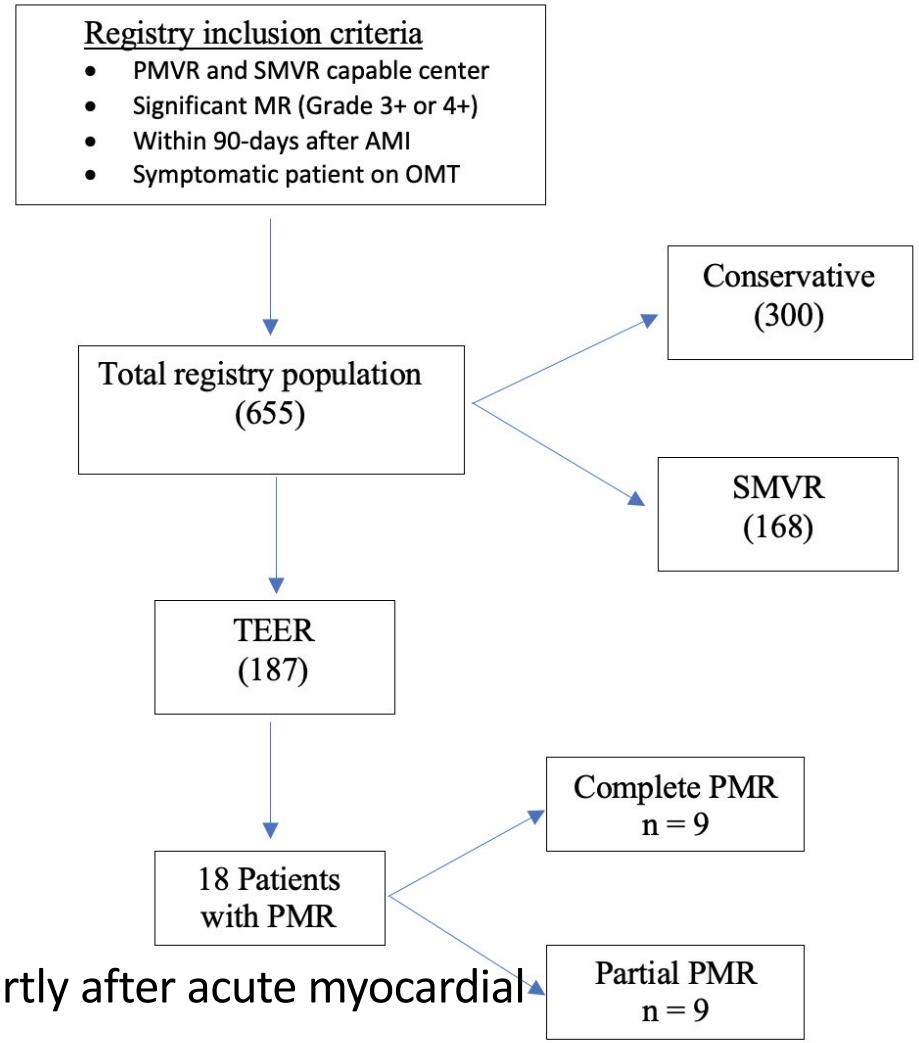


71-677.

Methods

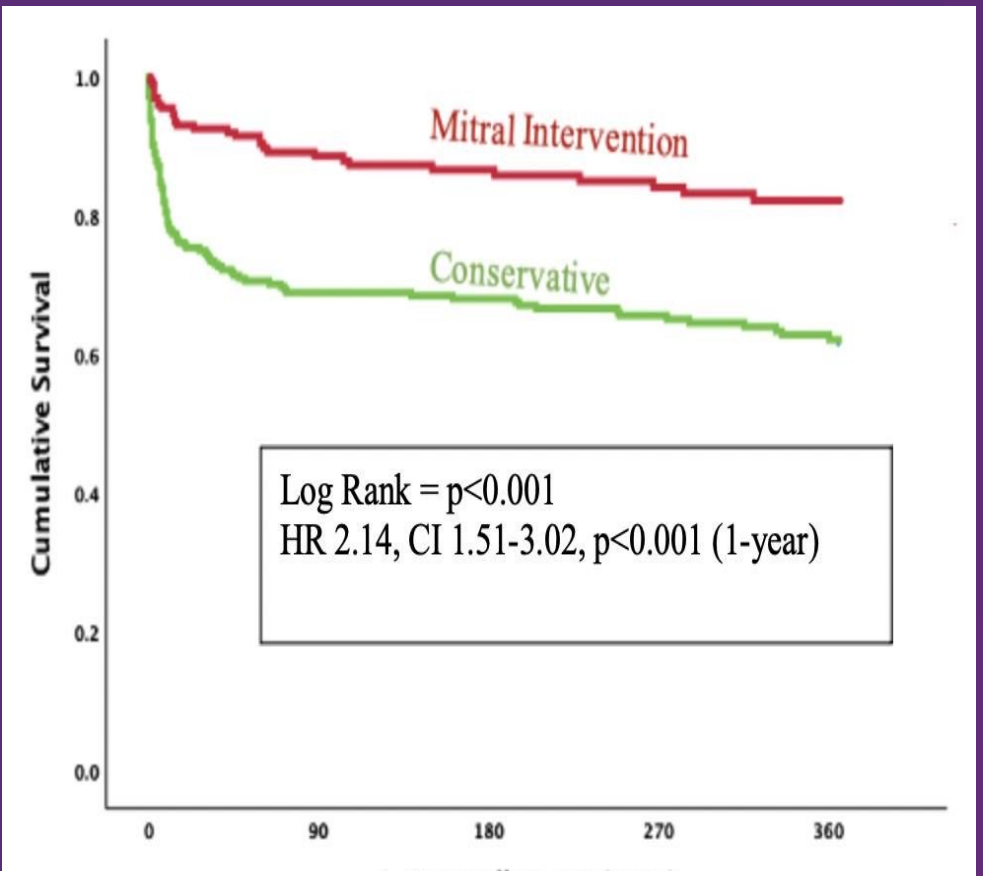
- **Retrospective analysis of patients with significant MR (3^+ or 4^+) and heart failure symptoms (NYHA >3) within 90-days following acute MI**

- **Data obtained from The International Registry of Mitraclip in acute mitral regurgitation following acute Myocardial Infaction (IREMMI), over 25 centers in Europe, North America and the Middle East .**



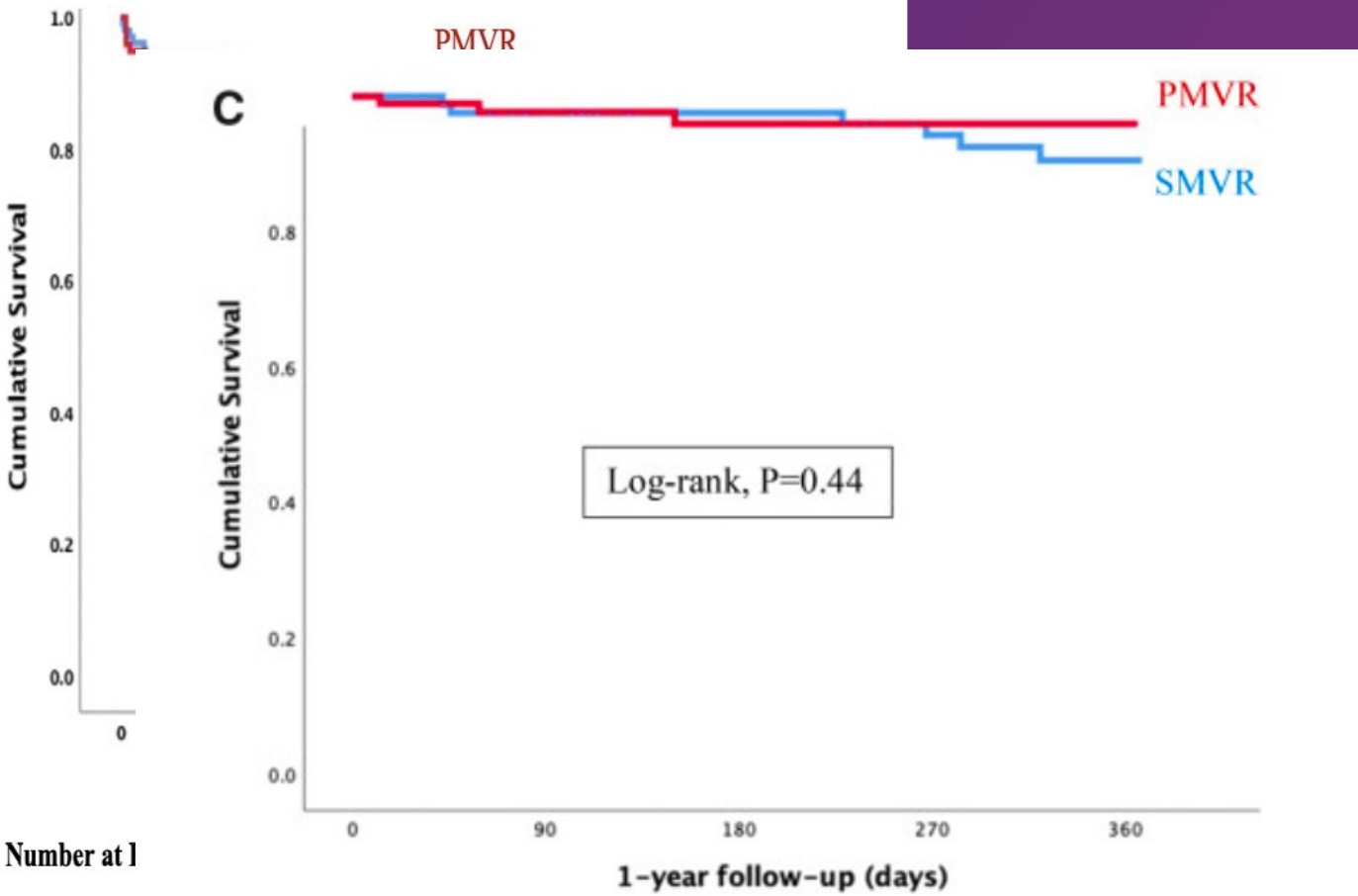
Conservative, surgical, and percutaneous treatment for mitral regurgitation shortly after acute myocardial infarction. Eur Heart J. 2022 Feb 12;43(7):641-650

Conservative vs. Intervention



Conservative	256	161	147	126	90
Intervention	201	184	139	115	64

PMVR vs. SMVR



Number at Risk	0	3-Month	6-Month	9-Month	1-Year
SMVR	86	73	66	54	40
PMVR	92	62	48	38	28

Conservative, surgical, and percutaneous treatment for
infarction. Eur Heart J. 2022 Feb 12;43(7):641-650

Conclusion

Early intervention may mitigate the poor prognosis associated with conservative therapy in patients with post-MI MR. Percutaneous mitral valve repair can serve as an alternative for surgery in reducing MR for high-risk patients

Conservative, surgical, and percutaneous treatment for mitral regurgitation shortly after acute myocardial infarction. Eur Heart J. 2022 Feb 12;43(7):641-650

2022 PCR london valves

Transcatheter edge-to-edge repair for Mitral Regurgitation due to Papillary Muscle Rupture; data from multinational registry

Mony ShuvyMD,

behalf of The International Registry of Mitraclip in acute mitral regurgitation following acute Myocardial Infaction (IREMMI)

EAPCI
European Society of Cardiology

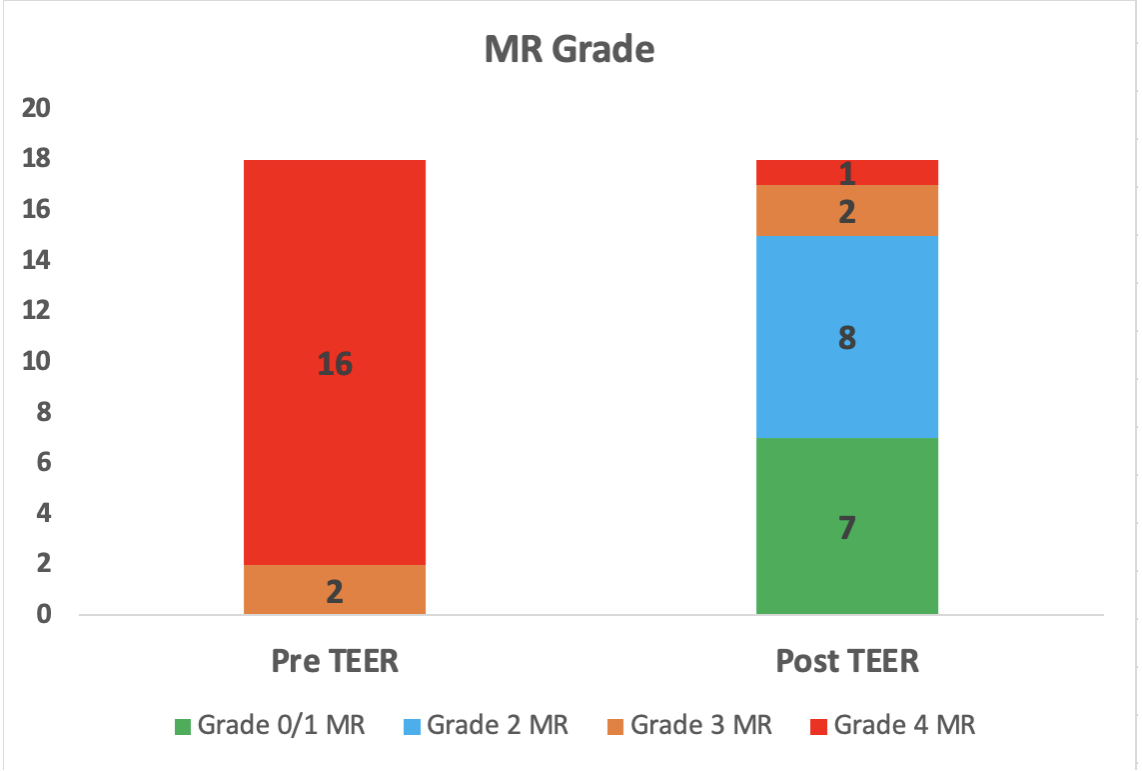
Results

In this study we focused on patients with Primary MR treated with TEER.

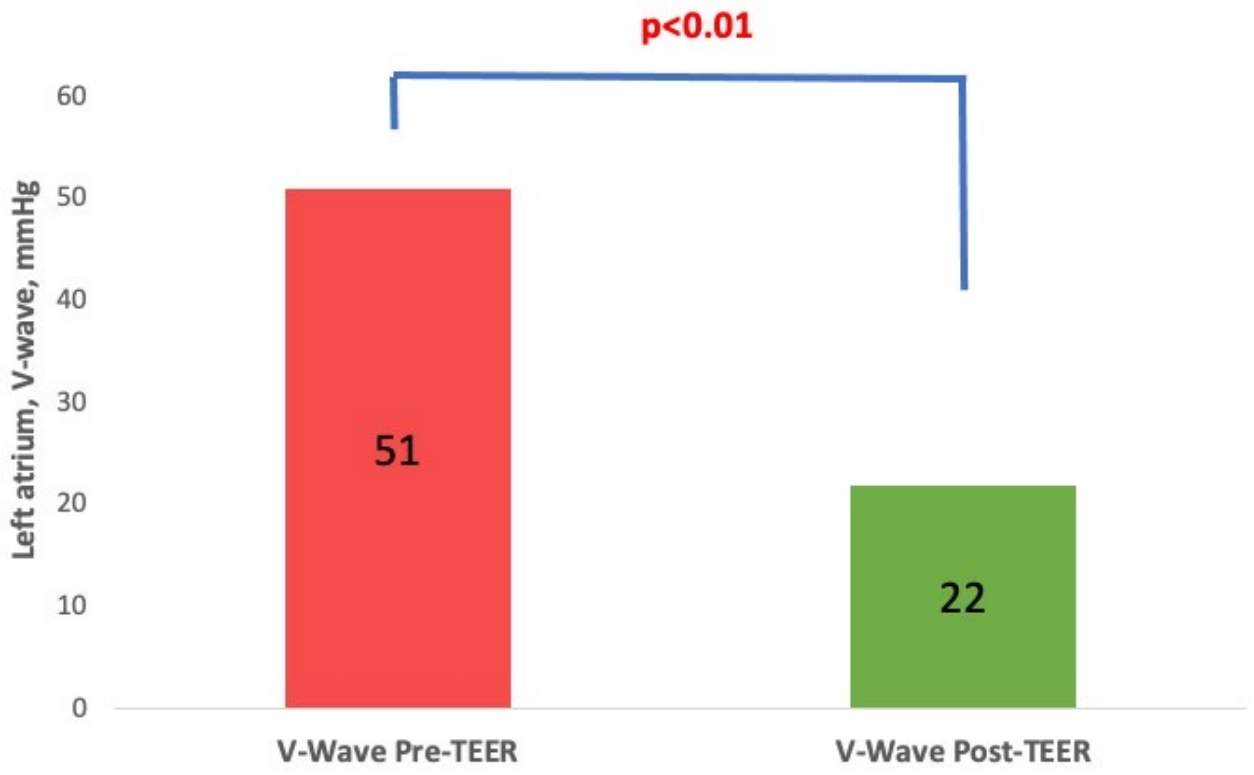
Variable	PMR
N	18
Age, years	67 ± 13
Gender (females), n (%)	9 (50)
Prior MI, n (%)	11 (61)
Multivessel CAD, n (%)	12 (67)
Anterior wall involved, n (%)	4 (22)
Left Ventricle EF, %	49 ± 13
Euroscore 2, % (IQR 1,3)	23 (13 – 31)
Cardiogenic shock, n (%)	16 (94)
Mechanical Ventilation, n (%)	14 (82)
Mechanical circulatory support, n (%)	13 (72)
VA – ECMO, n (%)	3 (18)

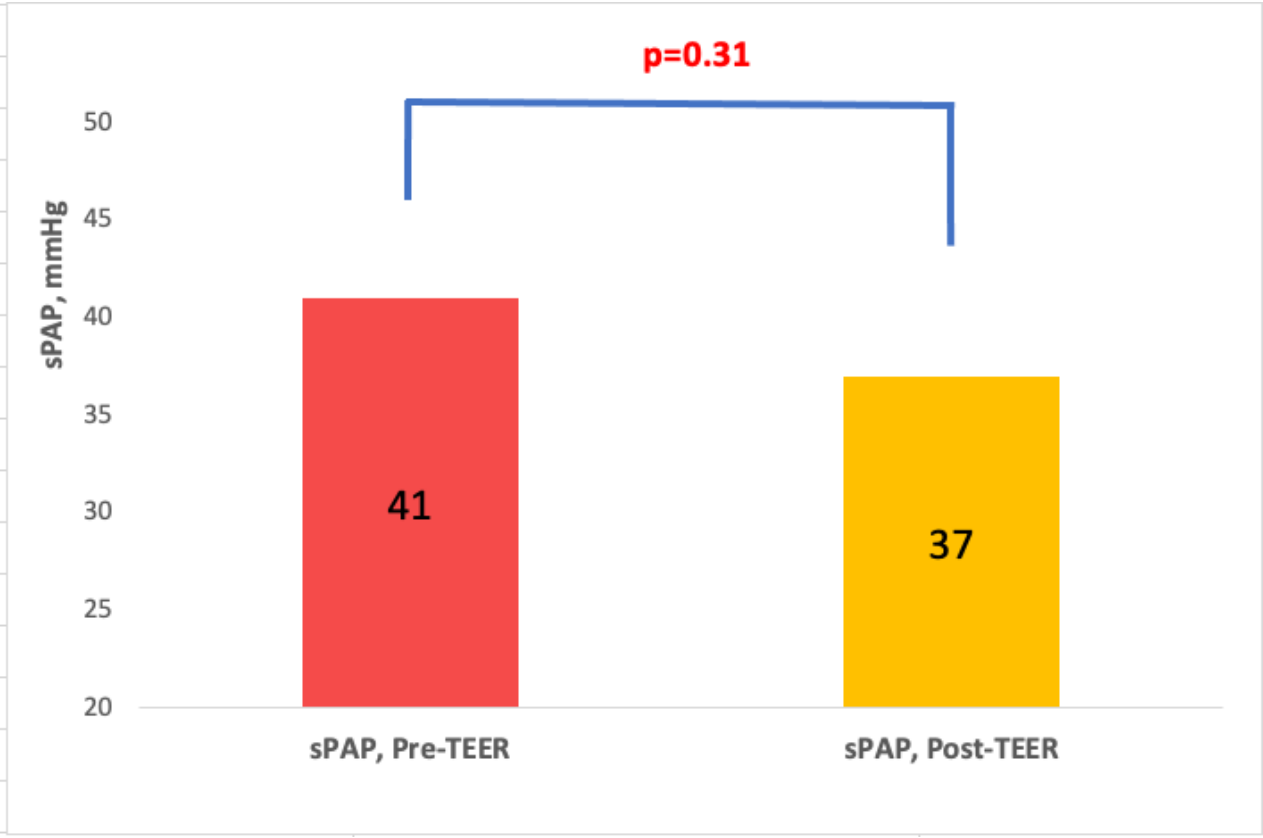
Results

Variable	PMR
N	18
Procedure Time, Min (IQR)	117 (60-150)
MI to Procedure, days (IQR)	6 (4-12)
Procedure Success, n (%)	16 (89)
Major complication, n (%)	2 (11)
Hospital Stay, days (IQR)	18 (12-24)
ICU Stay, Median days (IQR)	8 (6-16)



Results

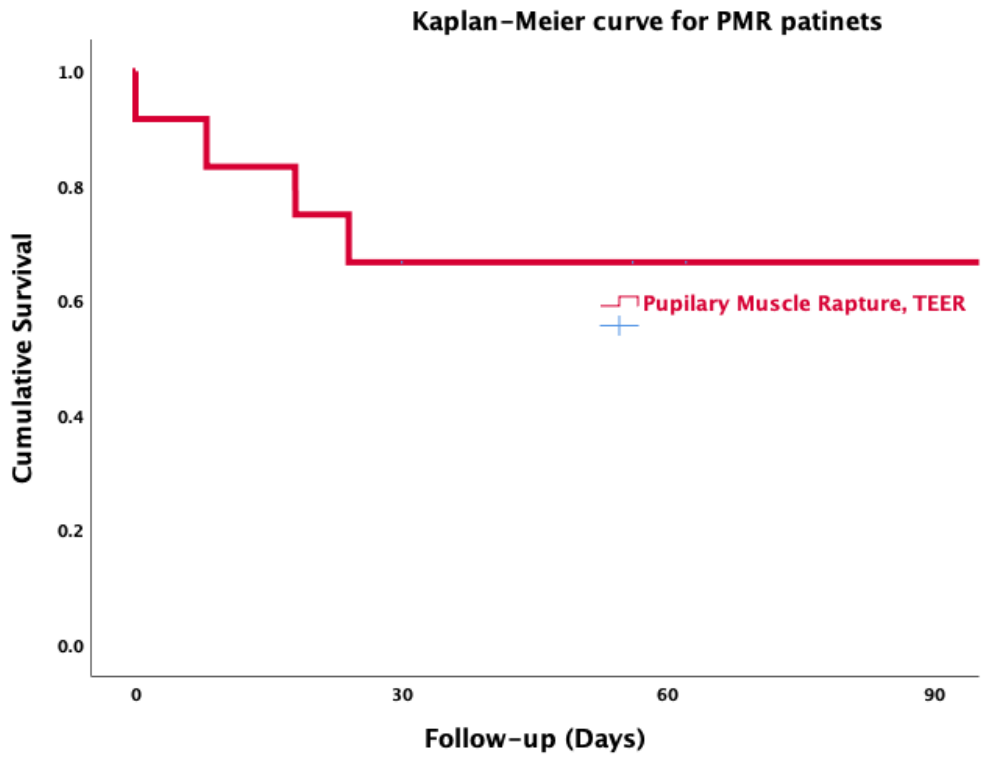

p<0.01
Left atrium, V-wave, mmHg
60
50
40
30
20
10
0
51
22
V-Wave Pre-TEER
V-Wave Post-TEER


p=0.31
sPAP, mmHg
50
45
40
35
30
25
20
41
37
sPAP, Pre-TEER
sPAP, Post-TEER

Results

- Twelve patients (66.7%) survived to hospital discharge

- Ultimately, Five patients underwent mitral valve surgery (of 12 patients survived) at median time of 120 days (IR 39-270) after index event



Conclusions

- Papillary muscle rupture often presents with pulmonary edema and cardiogenic shock. Patient are at very high risk for surgery
- TEER was safe and effective in reducing MR and improving hemodymanic parameters
- TEER should be considered as an alternative or a bridge to emergent mitral valve surgery

2022 PCR london valves

Transcatheter edge-to-edge repair for mitral regurgitation early after acute myocardial infarction: aetiology-based analysis

The International Registry of Mitraclip in acute mitral regurgitation following acute Myocardial Infarction (IREMMI)

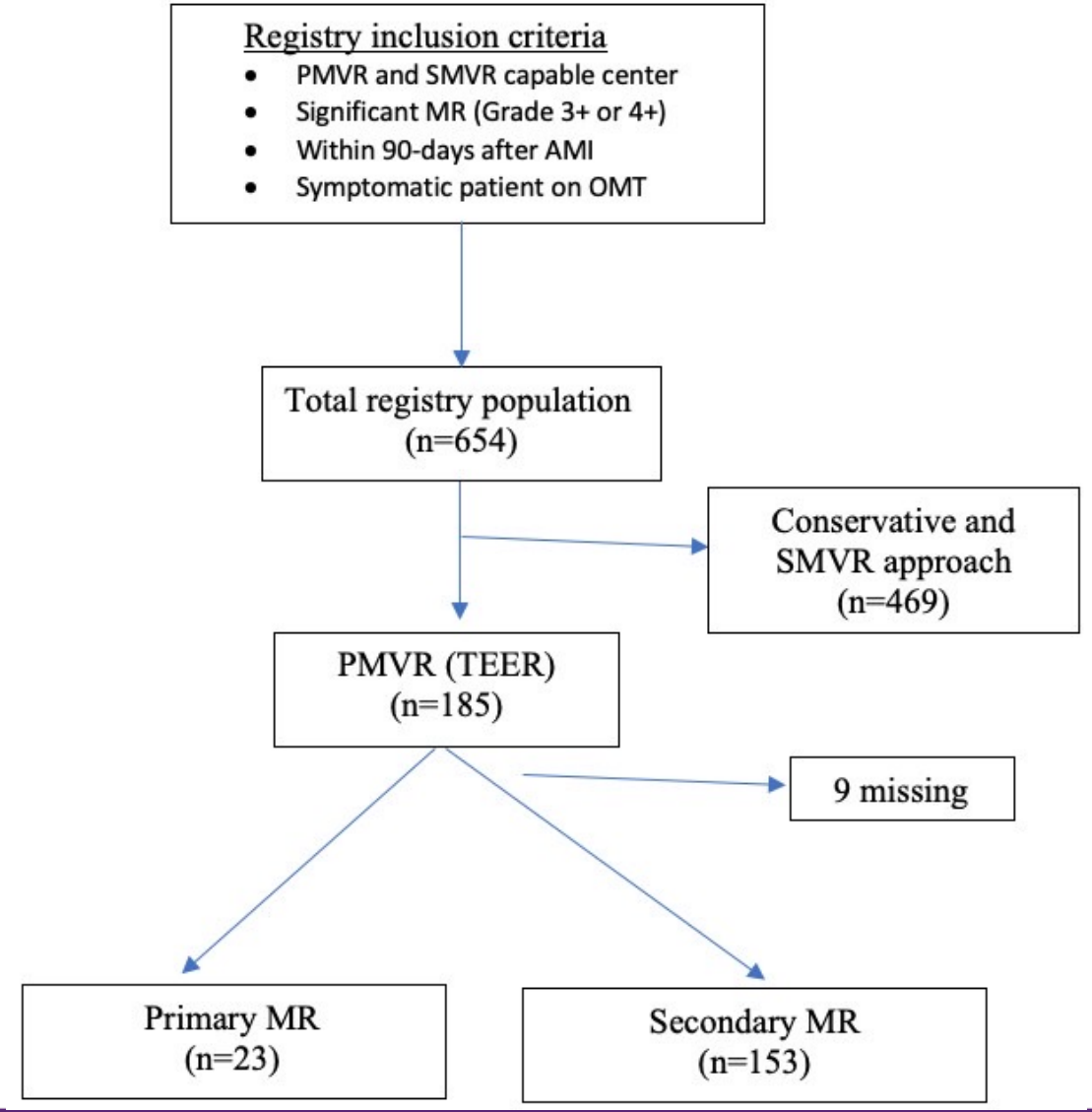
EAPCI
European Society of Cardiology

Methods

- Retrospective analysis of patients with significant primary and secondary MR (3+ or 4+) and heart failure symptoms (NYHA>3) within 90-days following acute MI

- Data obtained from IREMMI, over 25 centers in Europe, North America and the Middle East

- We compared post-MI acute MR patients, based on underling aetiology; primary and secondary



Results - Baseline characteristics

Primary MR
- Higher risk
- More severe presentation

Secondary MR
- Lower LVEF

Variable	Primary MR	Secondary MR	P Value
N	23	153	
Age, years	68 ± 13	71 ± 10	0.32
Gender (females), n (%)	10 (44)	64 (42)	0.88
Euroscore 2, %	27 ± 21	17± 15	**0.01**
Left Ventricle EF, %	45 ± 21	35 ± 10	**<0.01**
Mean Killip class,	3.8 ± 0.5	3.2 ± 0.9	**0.01**
Cardiogenic shock, n (%)	19 (91)	73 (51)	**<0.01**
Mechanical Ventilation, n (%)	18 (86)	60 (41)	**0.12**
Mechanical circulatory support, n (%)	16 (70)	51 (34)	**>0.01**

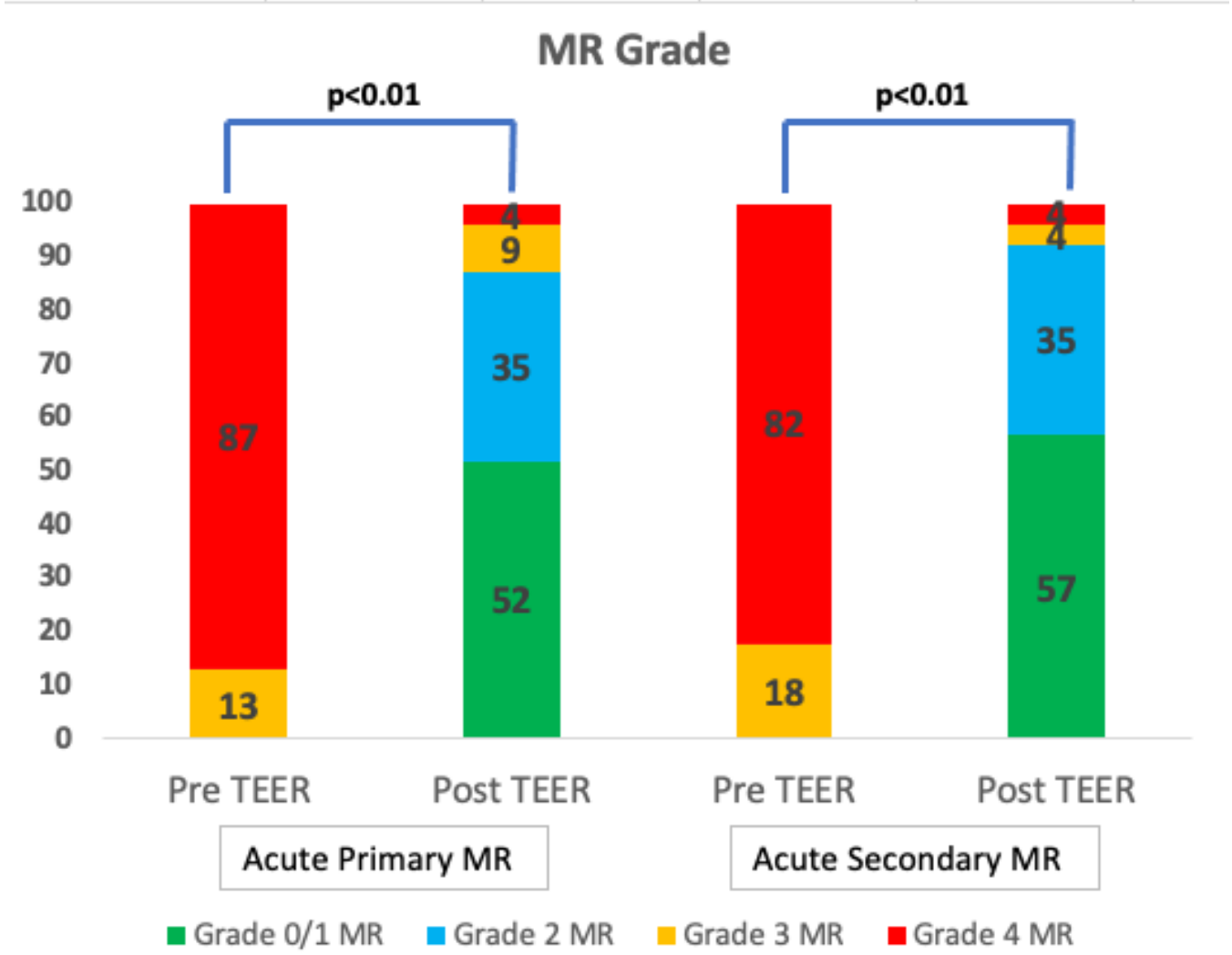
Results – Procedural outcomes

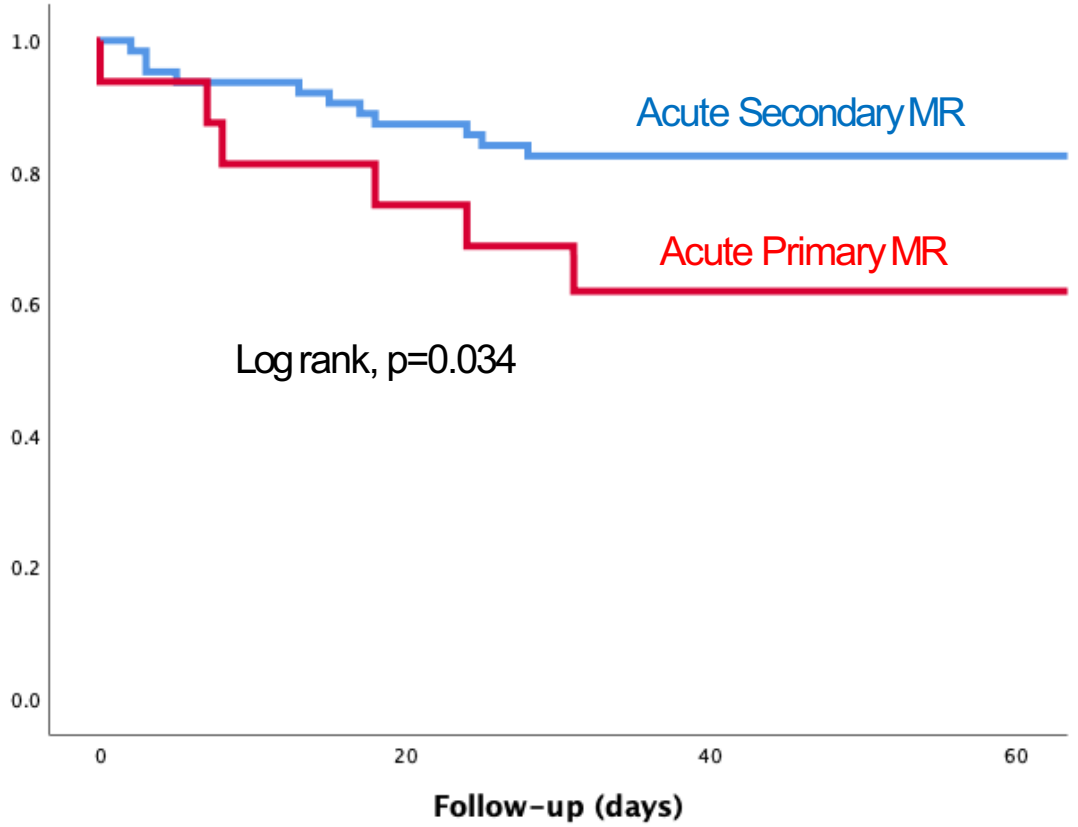
Primary MR

- Shorter MI to procedure time
- Similar procedural success
- Higher in-hospital mortality
- Higher convertion to MVR

Variable	Primary MR	Secondary MR	P Value
N	23	153	
Procedure Time, Min (IQR)	117 (60 – 150)	92 (60 – 128)	0.28
MI to Procedure, days (IQR)	6 (3.5 - 12)	20 (12 - 37)	**<0.01**
Procedure Success, n (%)	20 (87)	140 (92)	0.49
Major complications, n (%)	2 (9)	12 (8)	0.36
Hospital Stay, days (IQR)	18 (12 - 29)	16 (8 - 31)	0.68
ICU Stay, Median days (IQR)	12 (7 - 18)	8 (2-20)	0.17
In-hospital Mortality, n (%)	7 (30)	10 (7)	**<0.01**
Conversion to MVR, n (%)	5 (22)	5 (3)	**<0.01**

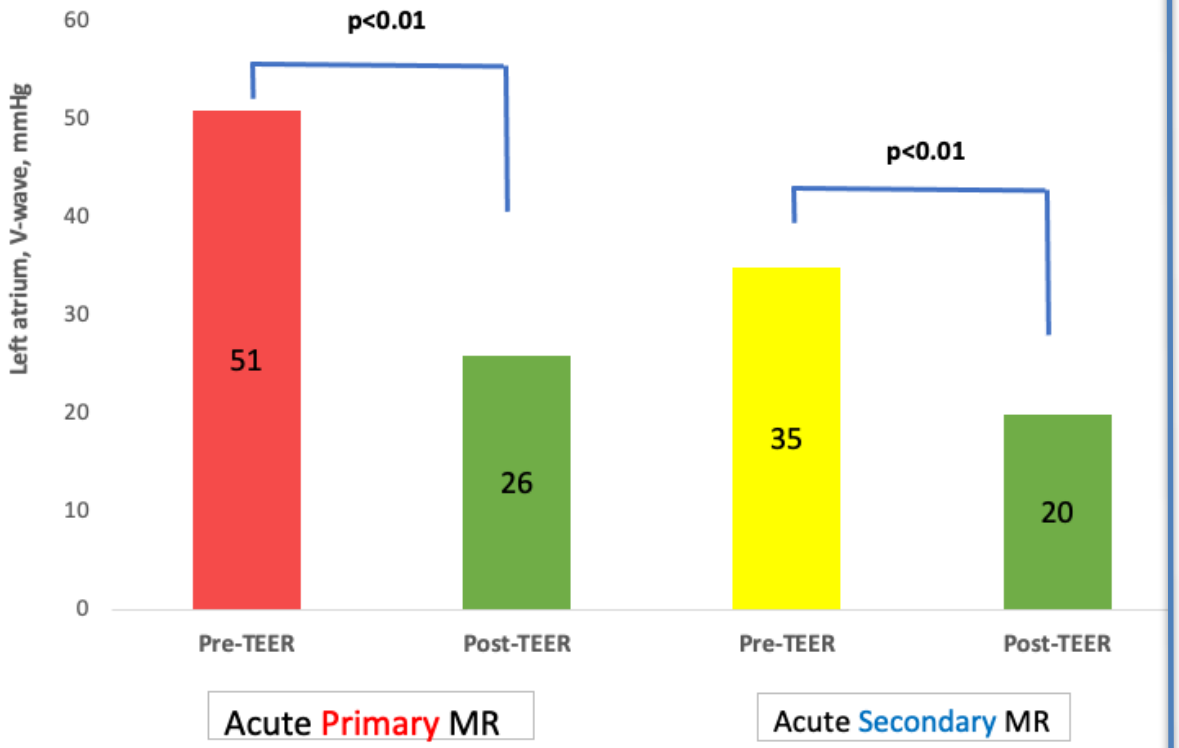
Results – Mortality and MR reduction



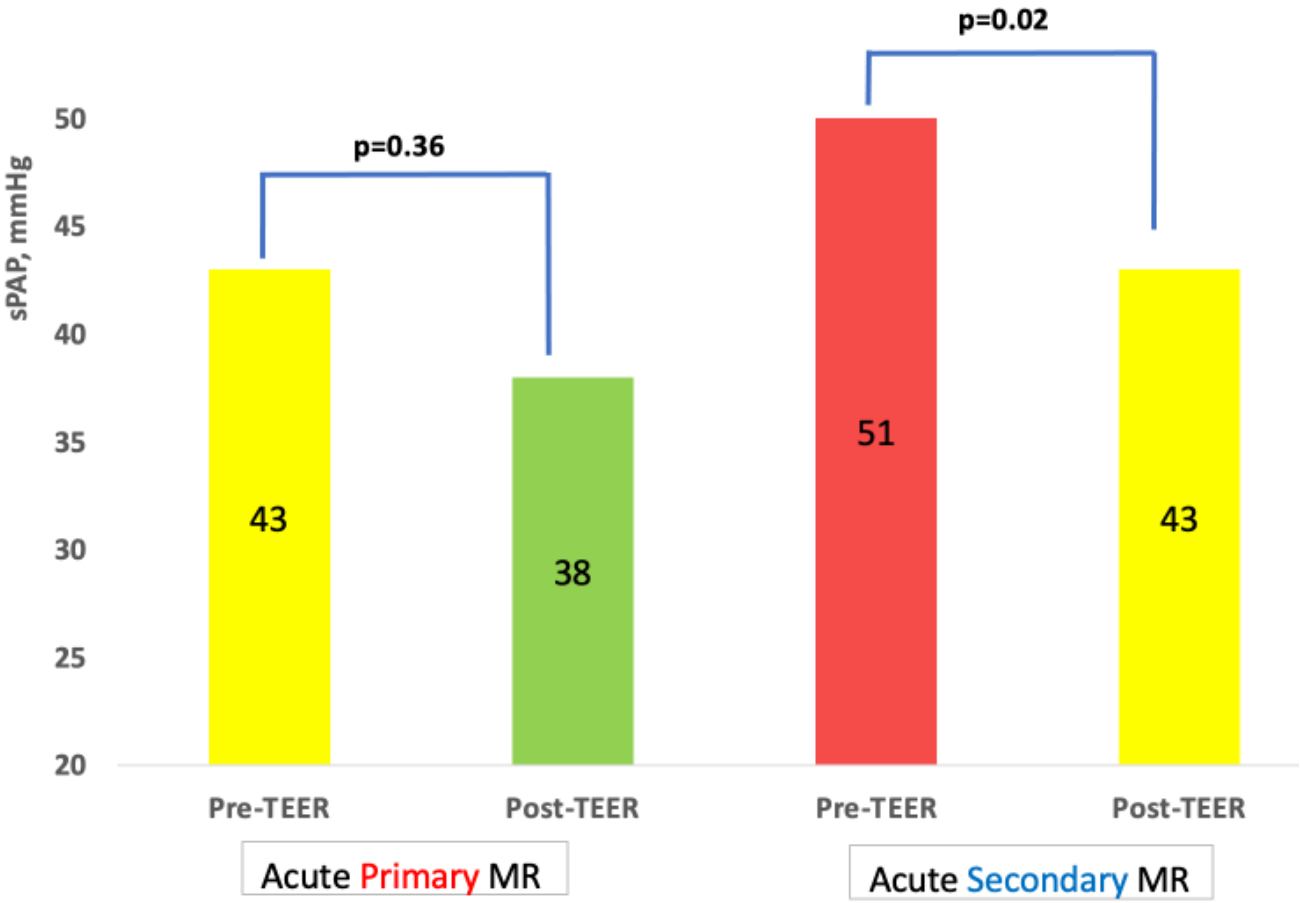


Results - Hemodynamics

V-Wave



sPAP

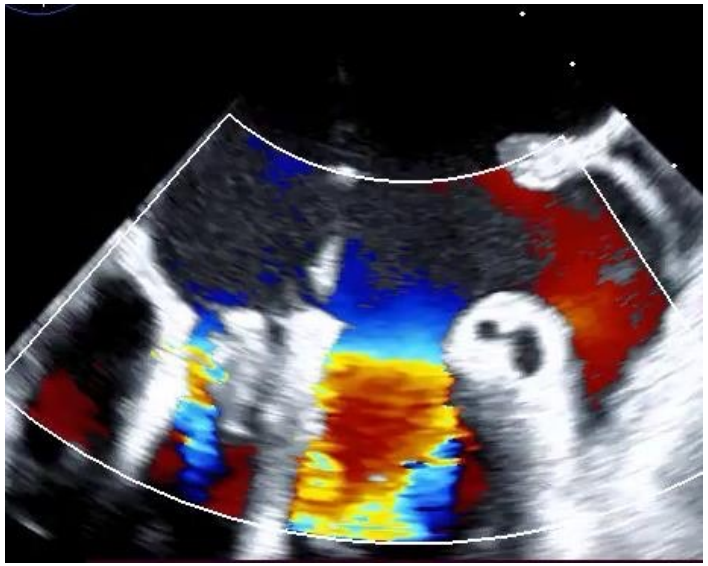


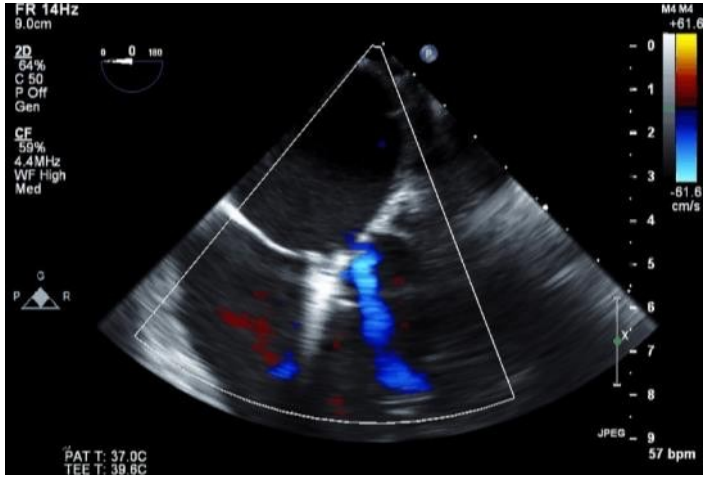
Conclusions

- Post MI significant MR is associated with poor outcomes, TEER is an emerging treatment option in this population

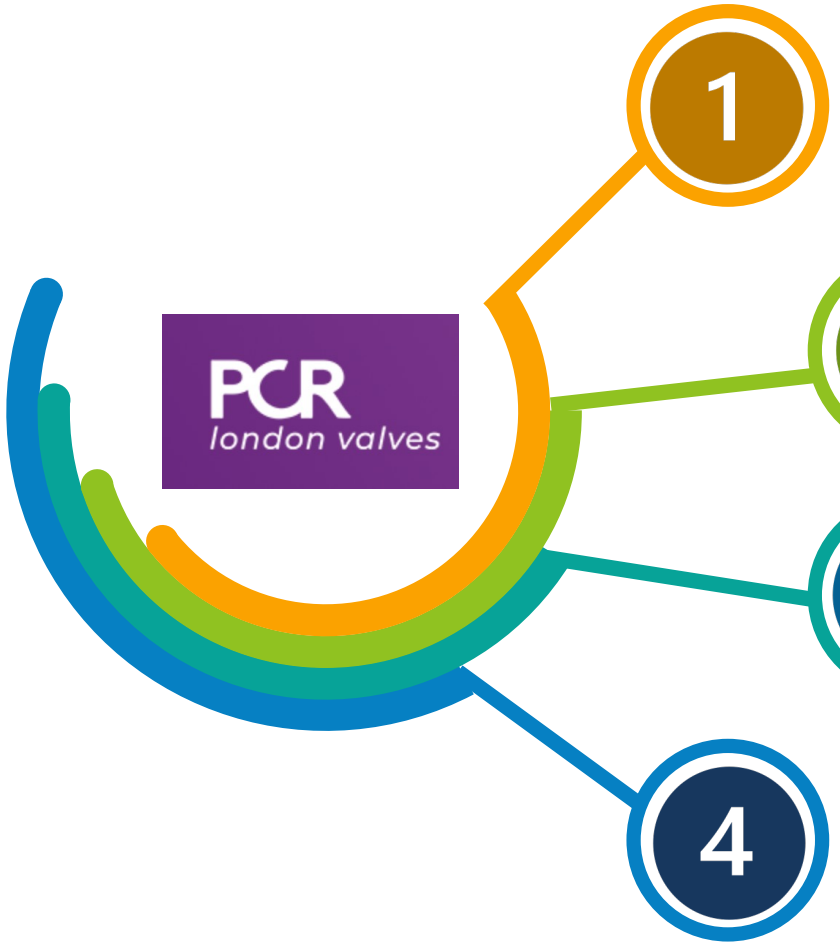
- TEER for primary MR was conducted earlier then secondary MR with comparable procedural success

- TEER in primary MR is associated with higher in- hospital mortality and higher conversion to MVR over secondary MR





Nội dung báo cáo



1. Giới thiệu Lịch sử Hội nghị tim mạch can thiệp PCR PCR London Valves 2022
2. Những nghiên cứu cập nhật của dụng cụ Mitraclip
3. **Những tiến bộ hứa hẹn trong sửa van hai lá qua đường ống thông**
4. Những tiến bộ hứa hẹn trong thay van hai lá qua đường ống thông

CLASP

2022 PCR london valves

Three-year outcomes for transcatheter mitral repair from the CLASP study

Konstantinos Spargias, MD

Hygeia Hospital, Athens, Greece

on behalf of the CLASP study investigators

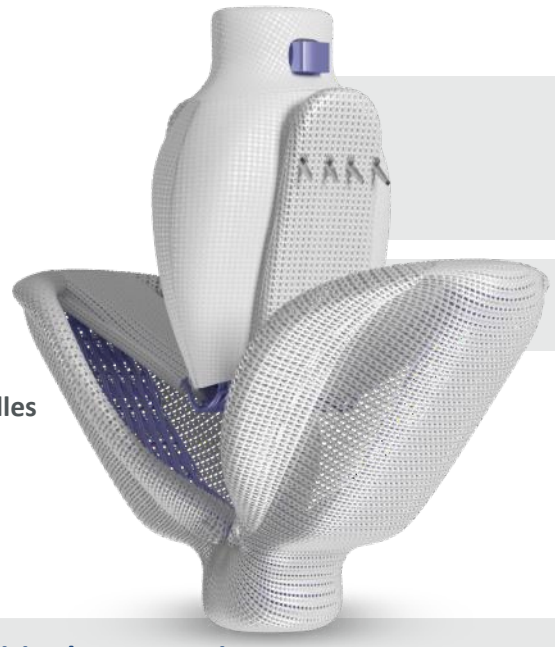
EAPCI
European Society of Cardiology

What did we study?

Edwards PASCAL transcatheter valve repair system

For Mitral and Tricuspid Regurgitation

PASCAL Implant



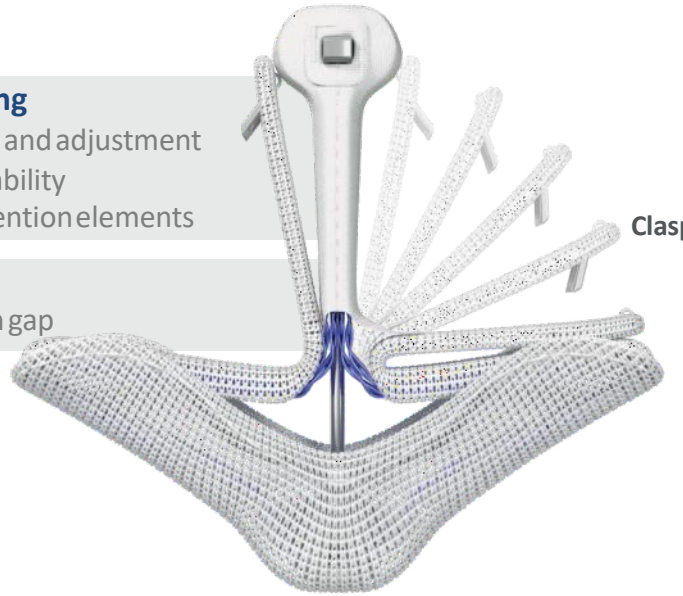
Independent grasping

- Staged leaflet capture and adjustment
- Clasp and reclasp capability with single row of retention elements

Central spacer

- Bridge the coaptation gap

PASCAL Ace Implant



Nitinol construction

Passive closure, acute implant flexing

Elongation

Navigate in dense chordae

Two Implants

PASCAL with a wider spacer and broad contoured paddles and Ace with a narrower profile and spacer provide options for varied clinical needs

How was this study executed?

Edwards PASCAL Transcatheter Mitral Valve Repair System Study

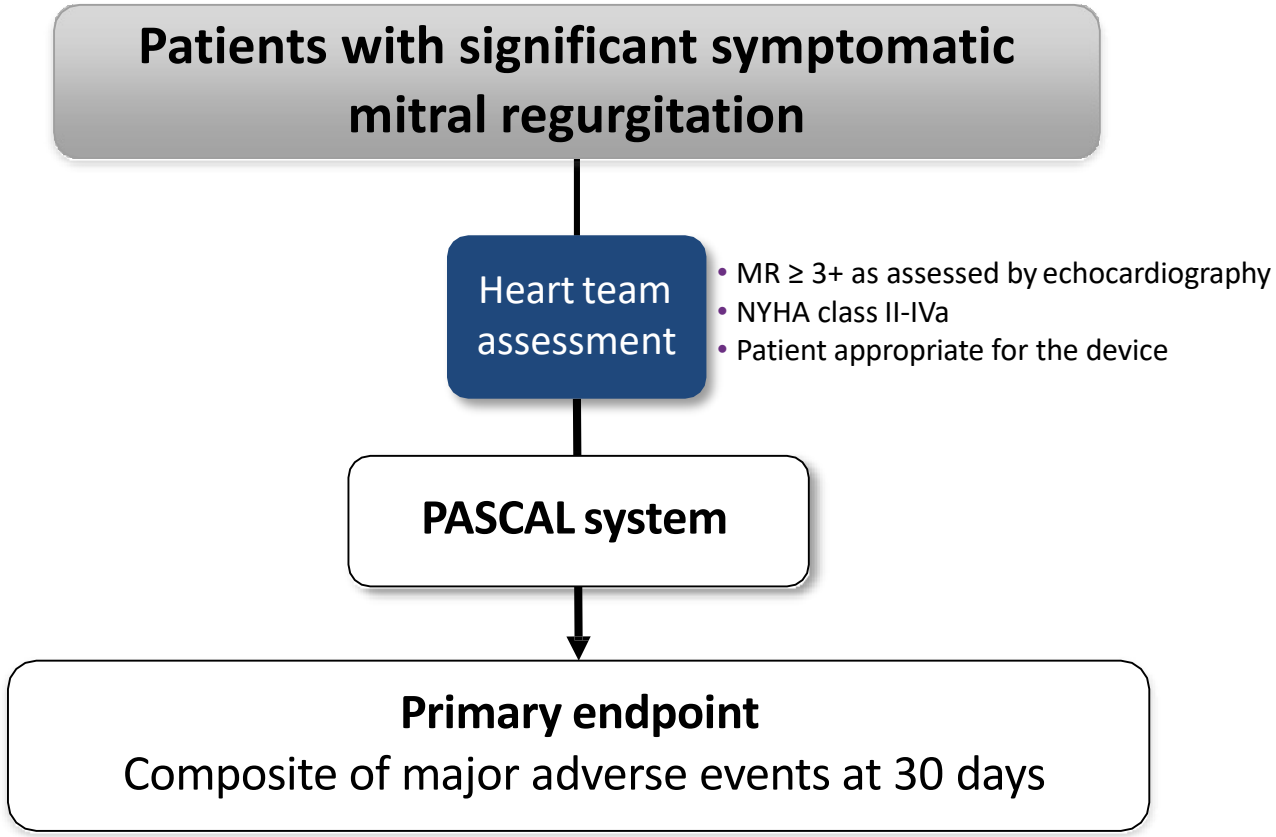
Prospective, multicentre, single-arm study

Purpose:
Assess the safety, performance and clinical outcomes of the PASCAL system

Principal investigators:
Molly Szerlip, MD
Gideon Cohen, MD
Ulrich Schäfer, MD

Trial oversight:
- Central screening committee
- Echocardiographic core laboratory
- Clinical events committee
- Data safety monitoring board

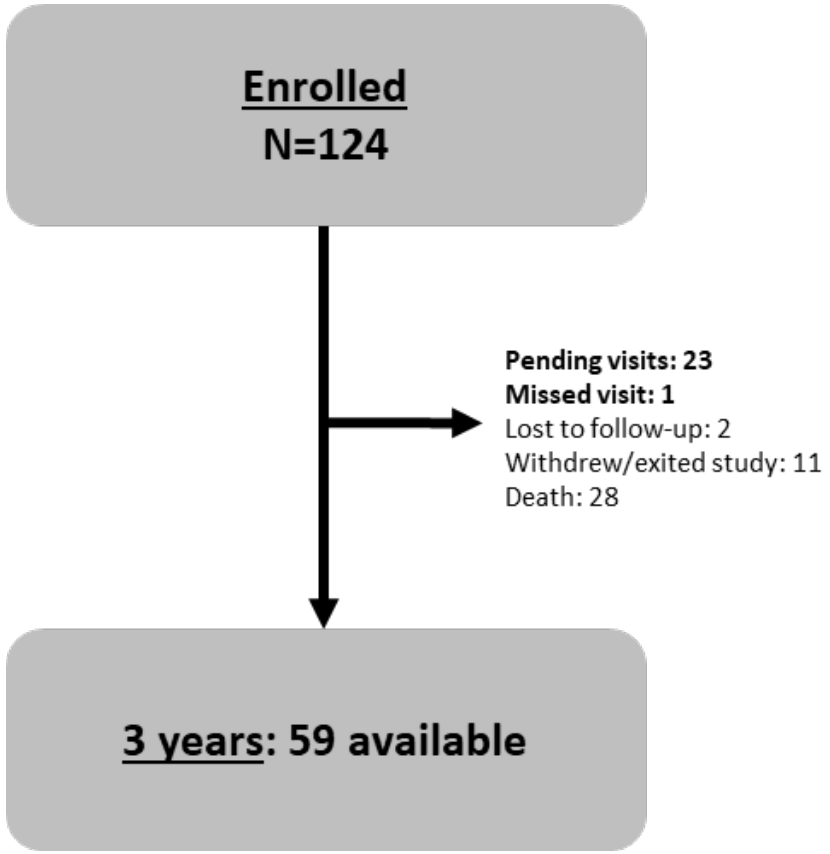
ClinicalTrials.gov: NCT03170349



Follow-up: 30 days, 6 months, 1 year and annually up to 5 years

What are the essential results?

Patient enrolment and baseline characteristics



Baseline characteristics	N=124 % or Mean ± SD
Age, years	75 ± 11
Male	56%
NYHA functional class III or IVa	60%
STS score (MV repair), %	4.6 ± 3.3
EuroSCORE II, %	5.8 ± 5.4
MR aetiology	
Functional	69%
Degenerative	31%
MR severity ≥3+	100%
LV ejection fraction, %	43.8 ± 14.5
PISA EROA, cm^2	0.38 ± 0.15
Regurgitant volume, ml	57 ± 20
Vena contracta width, A-P, mm	6.3 ± 1.4

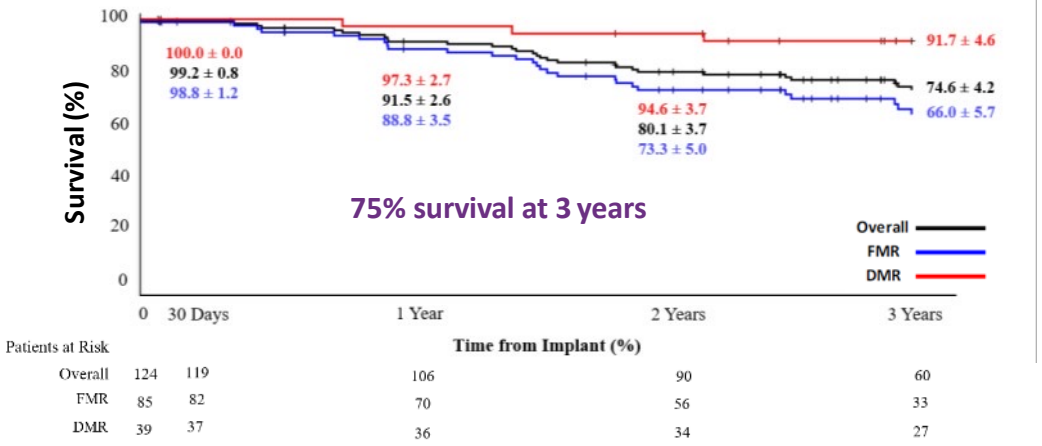
NYHA: New York Heart Association, *STS*: Society of Thoracic Surgeons; *MR*: mitral regurgitation; *LV*: left ventricle.

What are the essential results?

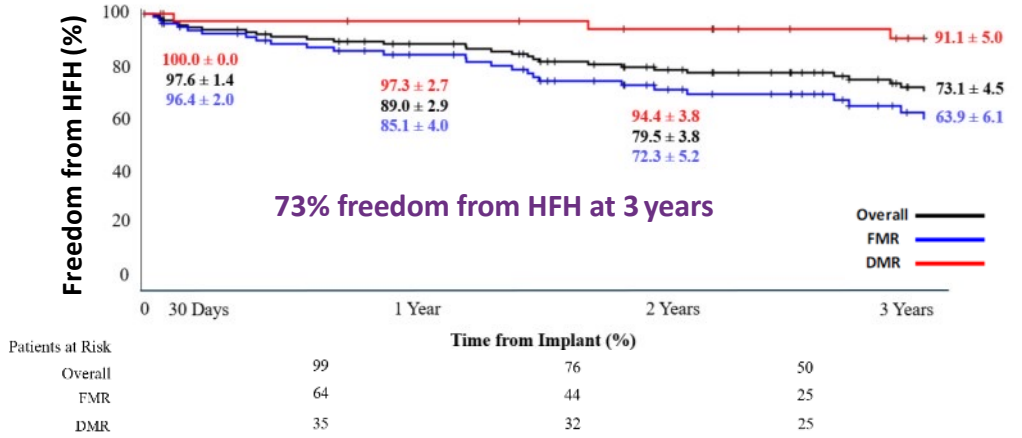
Favourable outcomes to 3 years[1]

Major adverse events	Overall N=124 % (n)	FMR n=85 % (n)	DMR n=39 % (n)
Cardiovascular mortality	14.5% (18)	18.8% (16)	5.1% (2)
Stroke	4.0% (5)	4.7% (4)	2.6% (1)
Myocardial infarction	3.2% (4)	2.4% (2)	5.1% (2)
New need for renal replacement therapy	1.6% (2)	2.4% (2)	0% (0)
Severe bleeding*	10.5% (13)	11.8% (10)	7.7% (3)
Reintervention for study device related complications	4.0% (5)	3.5% (3)	5.1% (2)
Composite MAE rate	**26.6% (33)**	**30.6% (26)**	**17.9% (7)**
Other events			
All-cause mortality	22.6% (28)	29.4% (25)	7.7% (3)
Heart failure rehospitalisation	24.2% (30)	31.8% (27)	7.7% (3)
Single leaflet device attachment (all within 30 days)	3.2% (4)	4.7% (4)	0.0% (0)

KM estimate for survival[2]



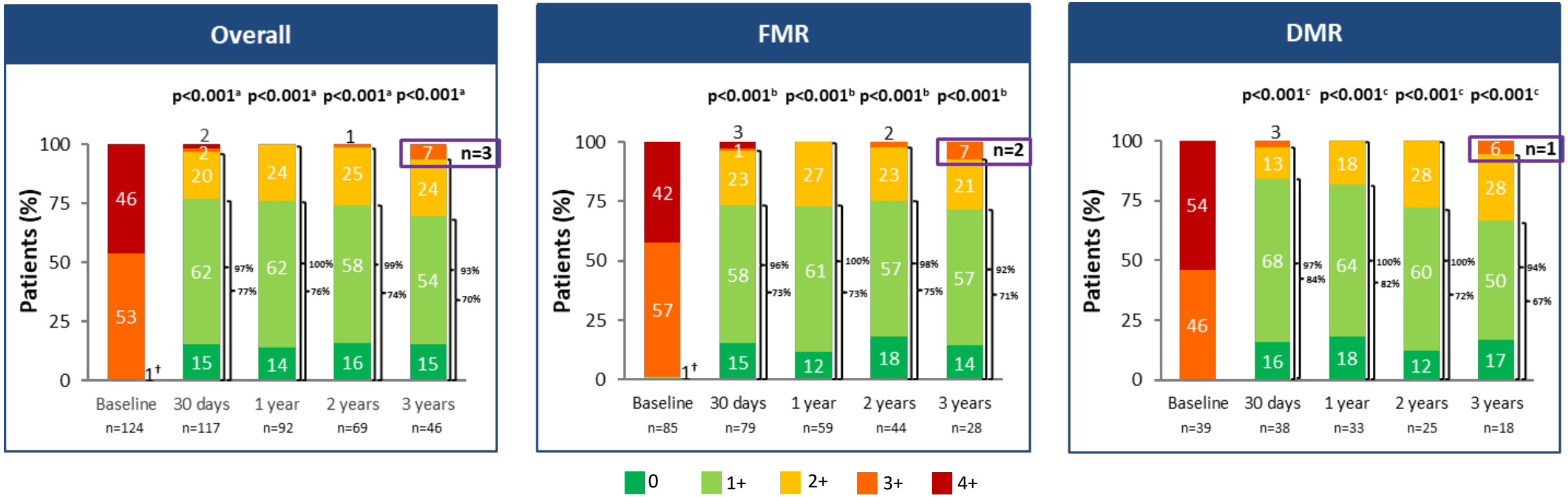
KM estimate for freedom from HF hospitalisation[2]



*Severe bleeding is major, extensive, life-threatening or fatal bleeding, as defined by MVARC. [1]Events are site-reported. [2]Kaplan-Meier analysis time to first event ± SE. *HF*: heart failure, *KM*: Kaplan-Meier, *MAE*: major adverse event.

What are the essential results?

Significant and sustained MR reduction by core lab[1] at 3 years

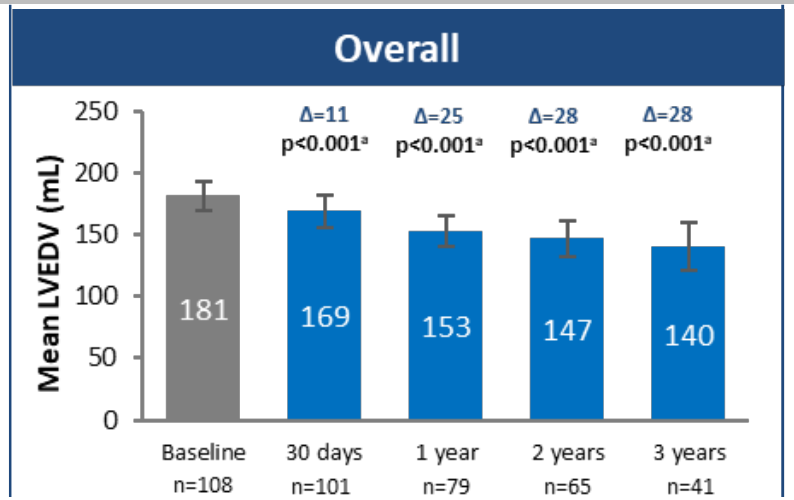


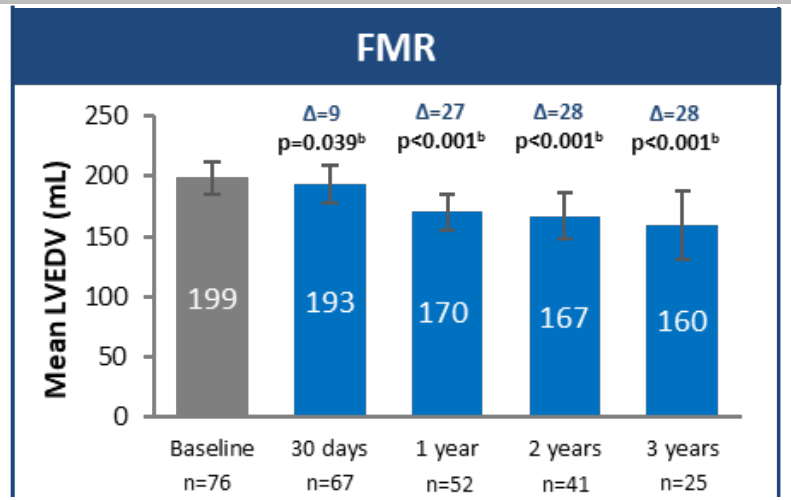
At 3 years, 93% of patients with MR ≤2+ and 70% MR ≤1+

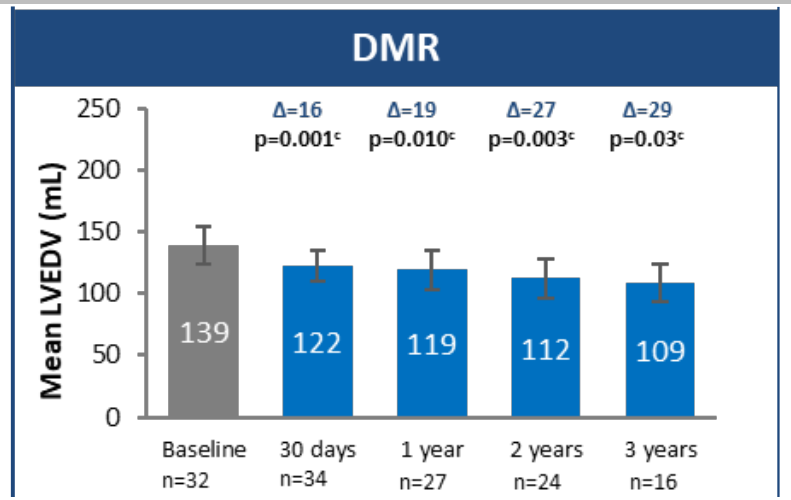
[1]Cardiovascular Core Lab at Morristown Medical Center, Morristown, NJ, USA. Graphs show unpaired analysis. p-value calculated from paired analysis using Wilcoxon signed rank test, [a]baseline vs. 30 days (n=117; MR≤1+=77%; MR≤2+=97%), 1 year (n=92; MR≤1+=76%; MR≤2+=100%), 2 years (n=69; MR≤1+=74%; MR≤2+=99%) and 3 years (n=46; MR≤1+=70%; MR≤2+=93%), [b]baseline vs. 30 days (n=79; MR≤1+=73%; MR≤2+=96%), 1 year (n=59; MR≤1+=73%; MR≤2+=100%), 2 years (n=44; MR≤1+=75%; MR≤2+=98%) and 3 years (n=28; MR≤1+=71%; MR≤2+=93%), [c]baseline vs. 30 days (n=38; MR≤1+=84%; MR≤2+=97%), 1 year (n=33; MR≤1+=82%; MR≤2+=100%), 2 years (n=25; MR≤1+=72%; MR≤2+=100%) and 3 years (n=18; MR≤1+=67%; MR≤2+=94%). †TEE was used for baseline qualification of one patient due to discordance of MR severity between TTE and TEE. *DMR*: degenerative mitral regurgitation, *FMR*: functional mitral regurgitation.

What are the essential results?

Favourable LV reverse remodelling by core lab[1] at 3 years

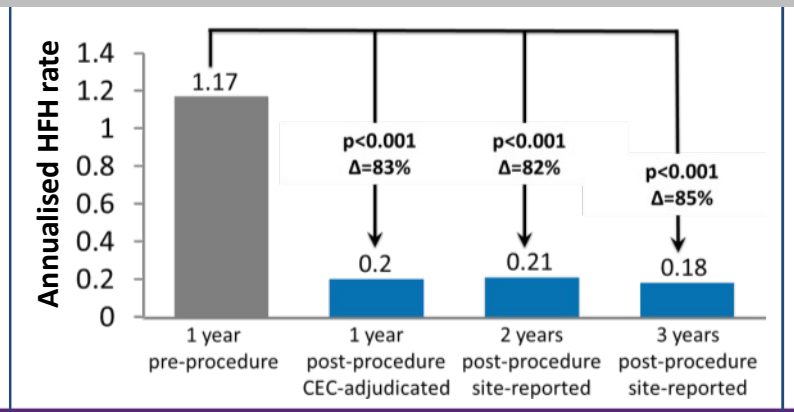


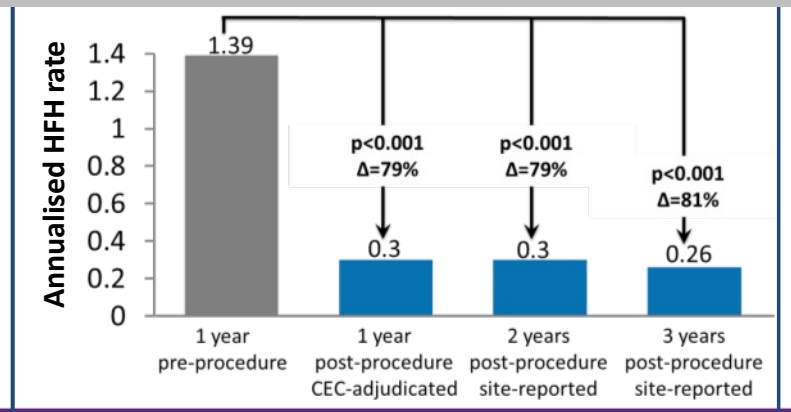


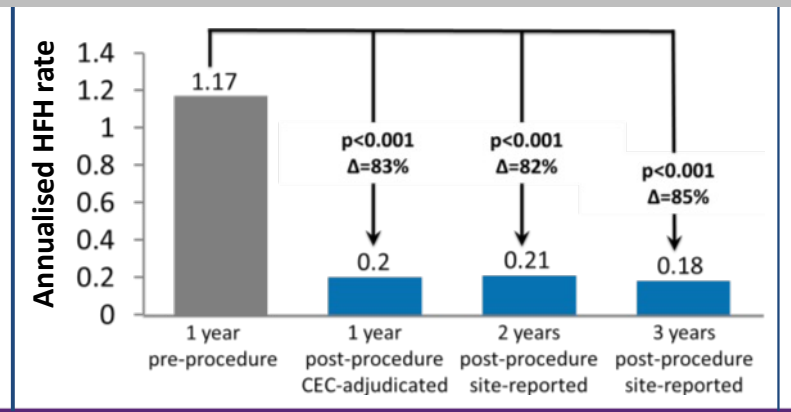


[1]Cardiovascular Core Lab at Morristown Medical Center, Morristown, NJ, USA. Graphs show unpaired analysis. Δ and p-value presented for paired analysis. Error bars represent 95% CI. p-value calculated using Student's T-test, [a]baseline vs. 30 days (n=91; mean baseline LVEDV=184.5; mean 30-day LVEDV=173.7), 1 year (n=73; mean baseline LVEDV=178.0; mean 1-year LVEDV=153.3), 2 years (n=58; mean baseline LVEDV=181.8; mean 2-year LVEDV=154.2) and 3 years (n=35; mean baseline LVEDV=178.6; mean 30-day LVEDV=150.3), [b]baseline vs. 30 days (n=62; mean baseline LVEDV=205.4; mean 30-day LVEDV=196.9), 1 year (n=48; mean baseline LVEDV=197.1; mean 1-year LVEDV=169.7), 2 years (n=38; mean baseline LVEDV=201.3; mean 2-year LVEDV=173.5) and 3 years (n=22; mean baseline LVEDV=199.3; mean 3-year LVEDV=171.5), [c]baseline vs. 30 days (n=29; mean baseline LVEDV=139.9; mean 30-day LVEDV=124.1), 1 year (n=25; mean baseline LVEDV=141.3; mean 1-year LVEDV=122.0), 2 years (n=20; mean baseline LVEDV=144.7; mean 2-year LVEDV=117.7) and 3 years (n=13; mean baseline LVEDV=143.6; mean 3-year LVEDV=114.5). *LVEDV*: left ventricular end diastolic volume.

85% reduction in annualised HF hospitalisation rate sustained at 3 years

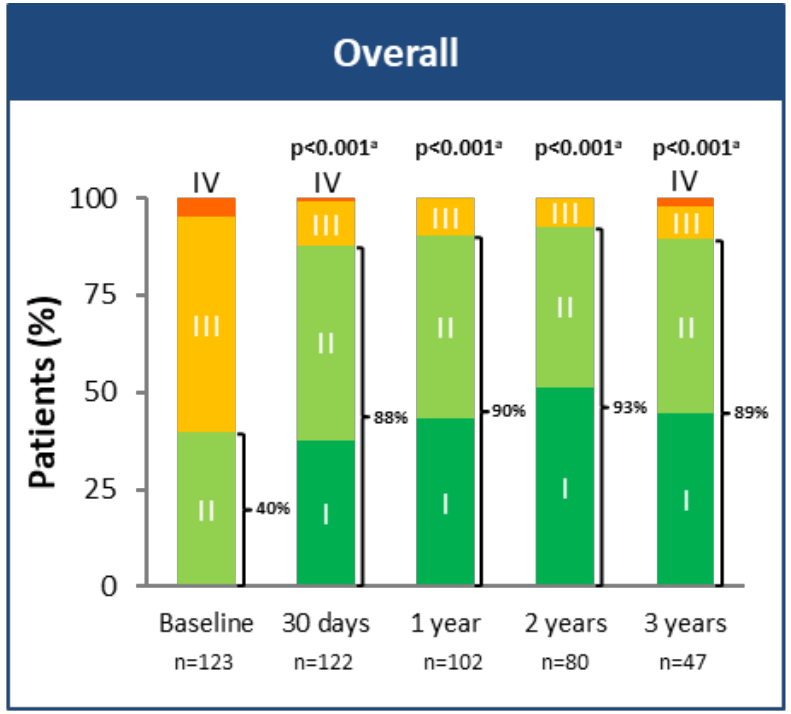


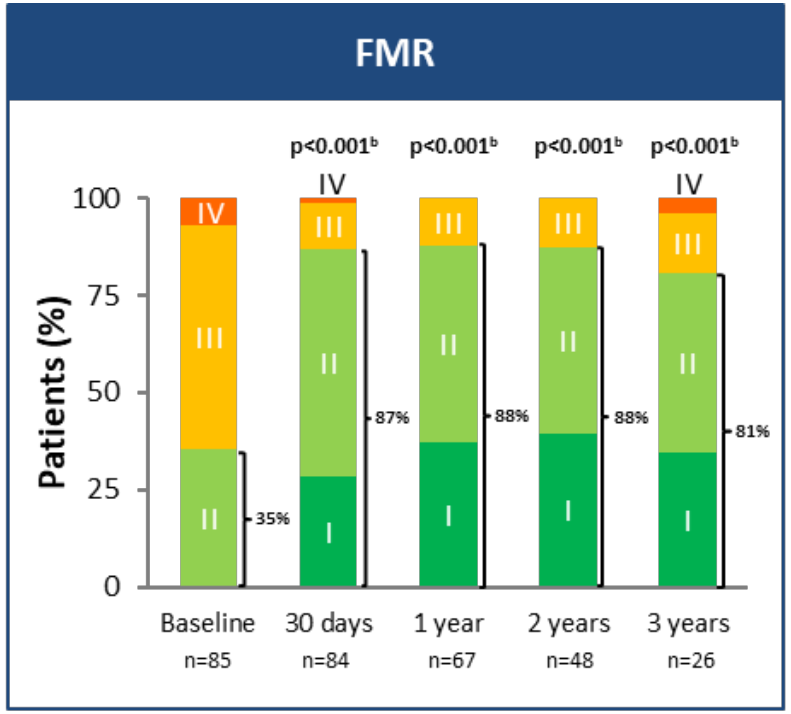


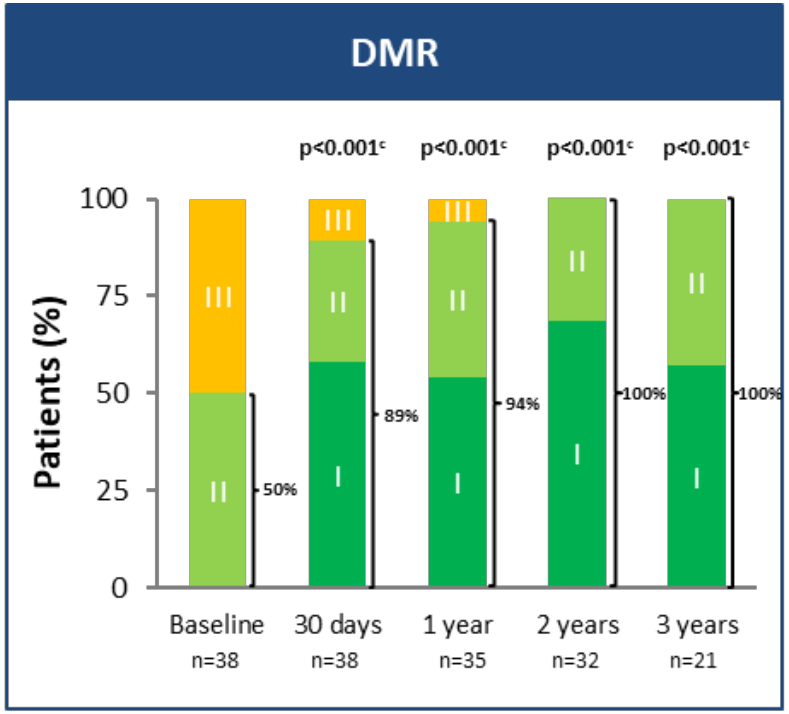


What are the essential results?

Significant and sustained symptomatic improvement at 3 years







At 3 years, 89% of patients in NYHA class I/II

p-value calculated from paired analysis using Wilcoxon signed rank test, [a]baseline vs. 30 days (n=121; NYHA class I/II=88%), 1 year (n=101; NYHA class I/II=90%), 2 years (n=79; NYHA class I/II=92%) and 3 years (n=46; NYHA class I/II=89%), [b]baseline vs. 30 days (n=84; NYHA class I/II=87%), 1 year (n=67; NYHA class I/II=88%), 2 years (n=48; NYHA class I/II=88%) and 3 years (n=26; NYHA class I/II=81%), [c]baseline vs. 30 days (n=37; NYHA class I/II=89%), 1 year (n=34; NYHA class I/II=94%), 2 years (n=31; NYHA class I/II=100%) and 3 years (n=20; NYHA class I/II=100%). *NYHA*: New York Heart Association.

The essentials to remember

Why this study?	• Severe mitral regurgitation (MR) is a prevalent disease and if left untreated is associated with increased risk of morbidity, mortality, and heart failure hospitalisation
What did we study?	• The PASCAL transcatheter valve repair system is a favourable option in the treatment of MR
How was the study executed?	• We report 3-year outcomes from the single-arm, multicentre, prospective CLASP study in patients with symptomatic, clinically significant MR ≥3+

What are the results?	• Outcomes at 3 years:
	  ◦ High survival and low complication rates
	  ◦ Low rates of heart failure hospitalisation
	  ◦ Core lab adjudicated sustained MR reduction with evidence of progressive LV reverse remodelling
	  ◦ Significant and sustained symptomatic improvement
	  ◦ Positive outcomes in both FMR and DMR patients

Why is this important?	• In early experience with the original system and new users, the long-term results from the CLASP study at 3 years demonstrated favourable and durable outcomes with the PASCAL system in patients with clinically significant MR • These results add to the growing body of evidence establishing the PASCAL system as a valuable therapy for patients with significant symptomatic MR • The currently enrolling CLASP IIF and the ongoing CLASP IID randomized trials are underway (NCT03706833)

2022 PCR london valves

One-Year Outcomes of Tendyne TMVR Treating Symptomatic MR: Expanded Study Population

Dr. Alison Duncan
Royal Brompton Hospital, London, UK

EAPCI European Society of Cardiology

KING'S HEALTH PARTNERS

SUMMIT
TENDYNE TRIAL

PROCEDURAL ANIMATION

TENDYNE™ Transcatheter Mitral Valve Implantation

Why this study?

- The Tendyne™ bioprosthetic mitral valve system
  - custom-made, catheter-based technology
  - treatment of severe MR of varying aetiology
  - the only CE-approved TMVR device
  - deployed transapically without the need for CBP or rapid pacing

- Largest previous Tendyne experience (Global Feasibility Study)
  - first 100 high surgical risk patients (STS-PROM score 7.9%) undergoing Tendyne-TMVR
  - 2-year results published
  - all-cause mortality 39.0%
  - 43.6% deaths occurred during first 90 days

- The **Tendyne Expanded Clinical study** * larger cohort (n=191)
- Aim: 1-year results and define predictors of outcome in largest TMVR study group to date

* The Expanded Clinical Study is funded by Abbott (NCT02321514).

How was the study executed?

- Single-arm, prospective, multi-centre investigational study
- Transapical Tendyne-TMVR between November 2014 and June 2020
- 36 investigation sites worldwide

- Patients enrolled in the study had:
  - MR 3+ or 4+
  - NYHA functional class ≥ II
  - Guideline directed medical therapy including CRT if indicated

- All study patients evaluated by the local heart team at baseline
- Study conducted in compliance with Declaration of Helsinki and with individual site ethical institutional review board approval

Patients Characteristics (n=191)

Baseline Patient Characteristics	
Age (year)	74.1 ± 8.0
Age ≥ 80	24.1%
Sex, male	62.8%
STS-PROM for MV replacement (%)	7.7 ± 6.6
EuroSCORE II (%)	6.6 ± 5.3
NYHA Class, III/IV %	70.2%
MR etiology, secondary %	88.5%
Coronary artery disease	68.1%
Prior CABG	38.7%
Renal Insufficiency, GFR < 60 mL/min/1.73m^2	58.1%
Valvular heart disease other than mitral	35.1%
Pulmonary arterial hypertension	51.1%
ICD or pacemaker	40.3%

Results – Serious Adverse Events (n=191)

Serious Adverse Events	0 - 30 Days	31 – 365 Days	0 – 365 Days
Hospital re-admission	18.8%	48.3%	53.4%
Heart failure hospitalization	7.9%	21.8%	25.7%
Bleeding (All)	15.7%	6.3%	20.9%
Life threatening	5.2%	2.3%	7.3%
Fatal	0.5%	1.7%	2.1%
Acute Kidney Injury	11.0%	9.2%	17.3%
Requiring dialysis	6.3%	5.7%	10.5%
Atrial fibrillation	7.9%	1.7%	8.9%
Permanent pacemaker	3.1%	2.9%	5.8%
Myocardial infarction	1.0%	3.4%	3.7%
Disabling stroke	1.6%	1.1%	2.6%
Apical access site complications	0.5%	0.6%	1.0%
Mitral valve stenosis	0.0%	0.0%	0.0%

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Result – Device Specific Adverse Events (n=191)

Serious Adverse Events	0 - 30 Days	31 – 365 Days	0 – 365 Days
Device Specific Adverse Events			
Paravalvular leak	6.3%	3.4%	8.4%
Evidence of device thrombus	1.6%	3.4%	4.7%
Endocarditis	1.6%	2.9%	3.7%
Migration or malposition	1.6%	1.7%	3.1%
Haemolysis	0.5%	1.1%	1.6%
Cardiac perforation	0.0%	0.6%	0.5%
Damage to cardiac tissue and/or structures	0.5%	0.0%	0.5%
Cardiac tamponade	0.5%	0.0%	0.5%
Bioprosthetic valve dysfunction	0.0%	0.0%	0.0%
Embolization	0.0%	0.0%	0.0%
Device fracture	0.0%	0.0%	0.0%
MV reintervention	1.0%	1.7%	2.6%

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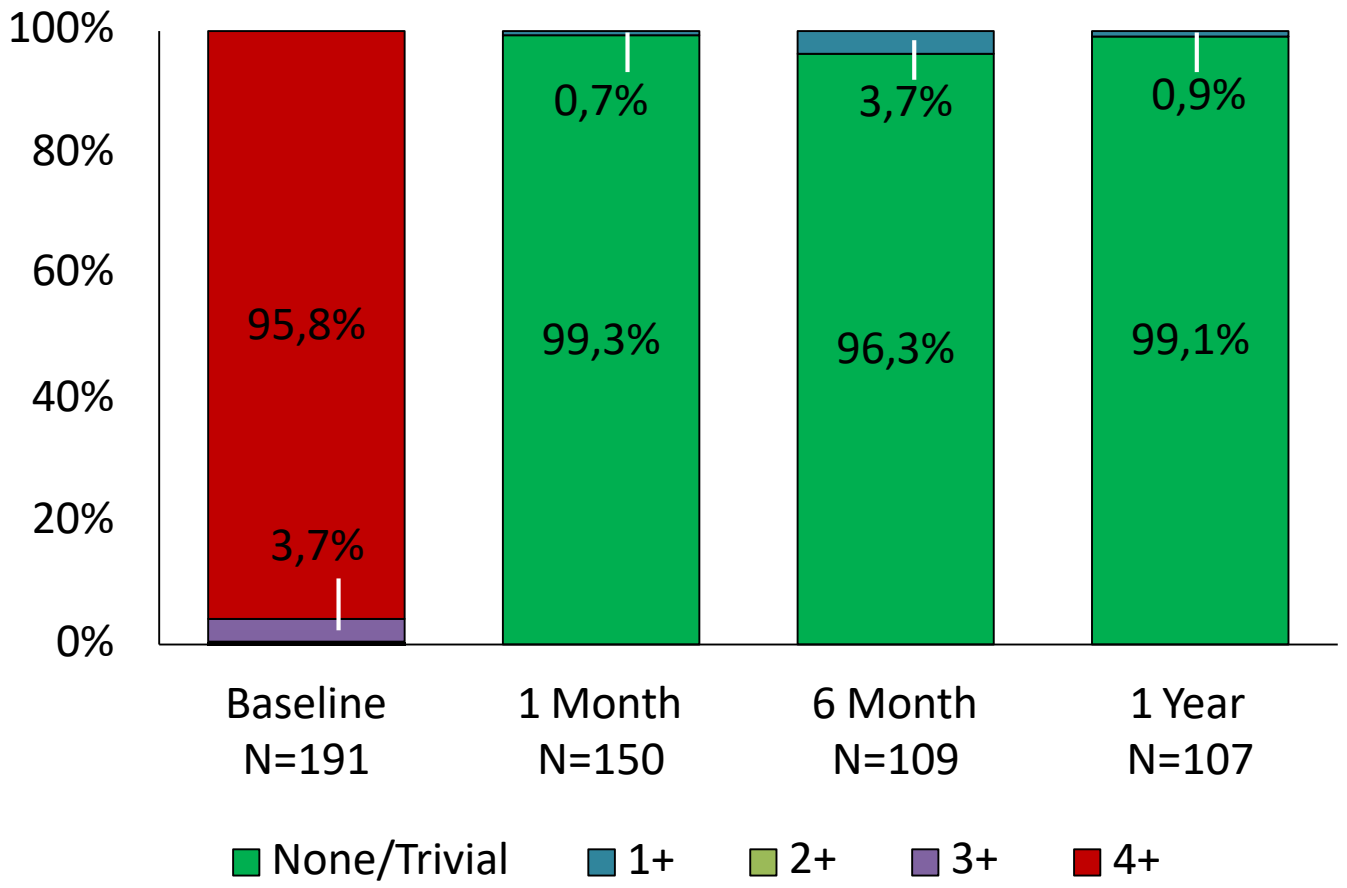
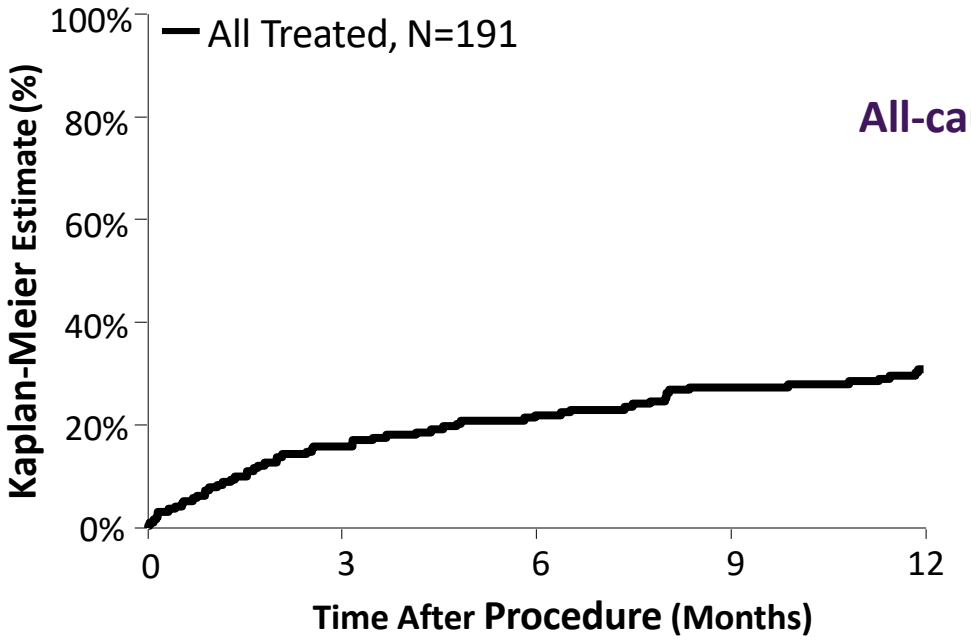
MR Reduction at 1 Year (n=191)



All-Cause Mortality at 1 Year



All-cause mortality: 30.8%

Days	0	30	90	365
Patient At Risk	191	174	155	123
Event Rate% (n)	0.5% (1)	7.9% (15)	16% (30)	30.8% (57)
95% CI	[0.1%, 3.7%]	[4.8%, 12.7%]	[11.4%, 22.0%]	[24.7%, 38.0%]

Procedure/Device-Related Mortality at 1-year

Mortality at 1 year	
Death due to procedure- and /or device related death	15.7 % (n=30)
Cardiac Arrest	20 % (n=6)
Multiple organ failure	20 % (n=6)
Shock	20 % (n=6)
Endocarditis	10 % (n=3)
Worsening heart failure	10 % (n=3)
Respiratory failure	6.7 % (n=3)
Cardiac perforation	3.3 % (n=1)
Device migration or malposition	3.3 % (n=1)
Myocardial infarction	3.3 % (n=1)
Stroke	3.3 % (n=1)

Predictors of 1 Year Mortality

60 factors incl. demographics, medical history, Echo/CT assessments, site experience

Predictors	Hazard Ratio (95% CI)	p value
History of pulmonary hypertension	2.82 [1.52, 5.26]	0.001
Age	1.07 [1.03, 1.12]	0.002
Prior CABG	0.40 [0.20, 0.79]	0.009
Left ventricular end-systolic dimension (cm)	0.64 [0.45, 0.90]	0.011

Why is this study important?

- Tendyne Expanded Clinical study is the largest treated TMVR cohort to date

- Low-rate of device-related adverse events
- Reliable and sustainable MR elimination in >99% patients
- Significant improvement in functional capacity and symptoms

- All-cause 1 year mortality 30.8%
- Procedure- or device-related 1-year mortality 15.7%

- Risk factors associated with increased risk of one-year mortality:
  - Intrinsic clinical features (PHT, advanced age)
  - Small left ventricular size
  - Centre inexperience <u>not</u> predictor of 1-year mortality

2022 PCR london valves

The Mitra-Cut Technique

Sharp mitral valve leaflet dissection before transcatheter mitral valve implantation

Mach M., Kerbel T., Poschner T., Bartunek A., Sauer J., Laufer G., Andreas M.

Department of Cardiac Surgery, Medical University of ViennaAustria

EAPCI
European Society of Cardiology

Clinical Vignette

71 year old lady

Past medical history:

» Uterine cancer prior radio-chemo-therapy (life-expectancy >1 year)

Current medical status:

» **Severe mitral stenosis (mean pressure gradient 11 mmHg)**,

» **Severe mitral regurgitation**

» Severe tricuspid regurgitation (TR IV)

» Secondary pulmonary hypertension (PAP: 46 mmHg)

Comorbidities:

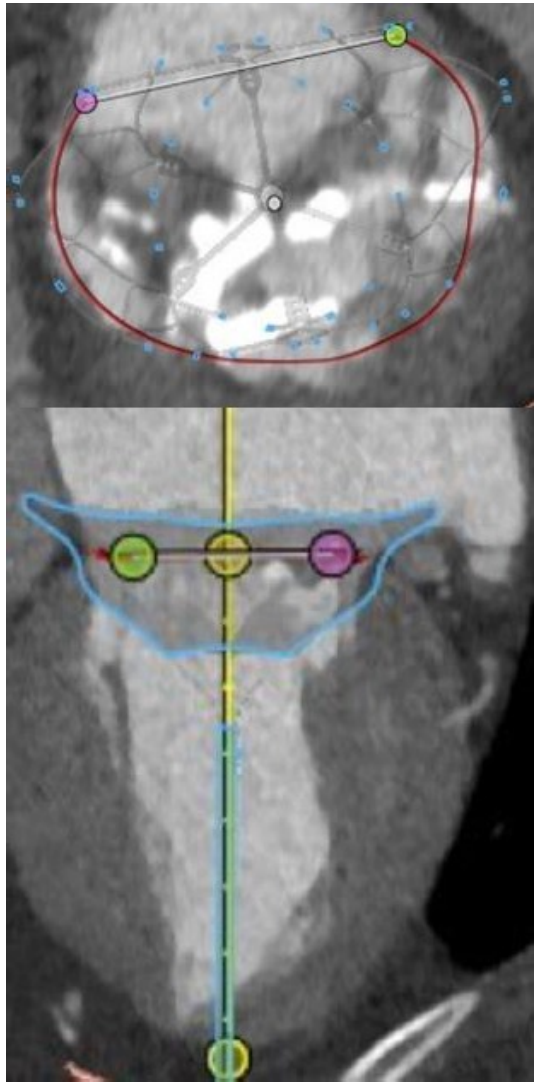
» Arterial hypertension

» NYHA III

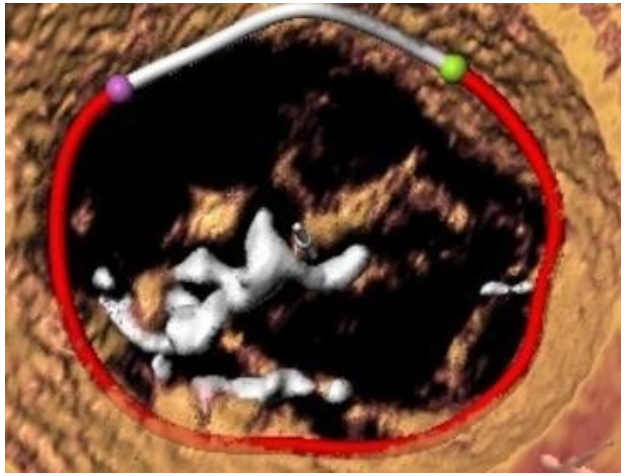
Operative risk:

» EuroSCORE II: 1.79 %, STS score 3.7 %

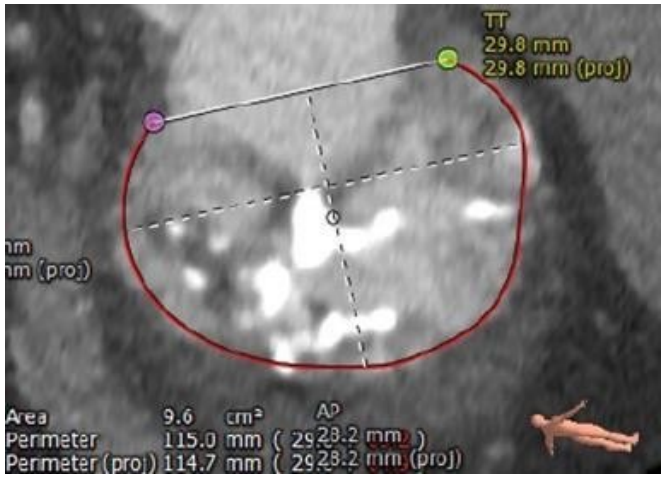
» Very frail



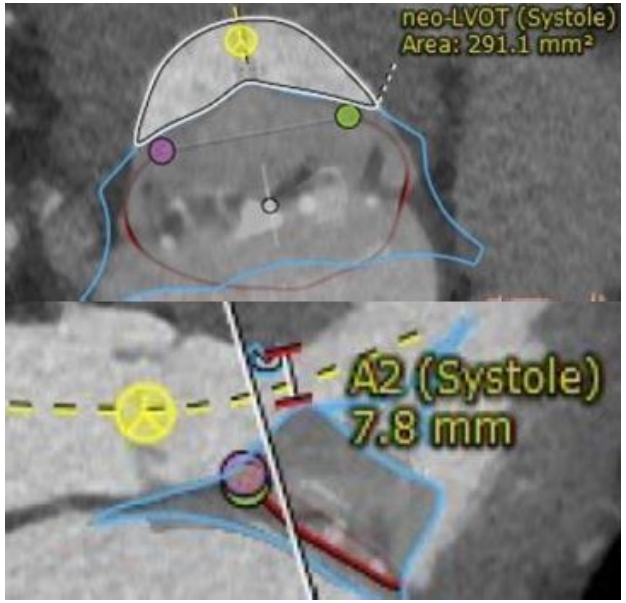
Procedure Planning and Risk Assessment



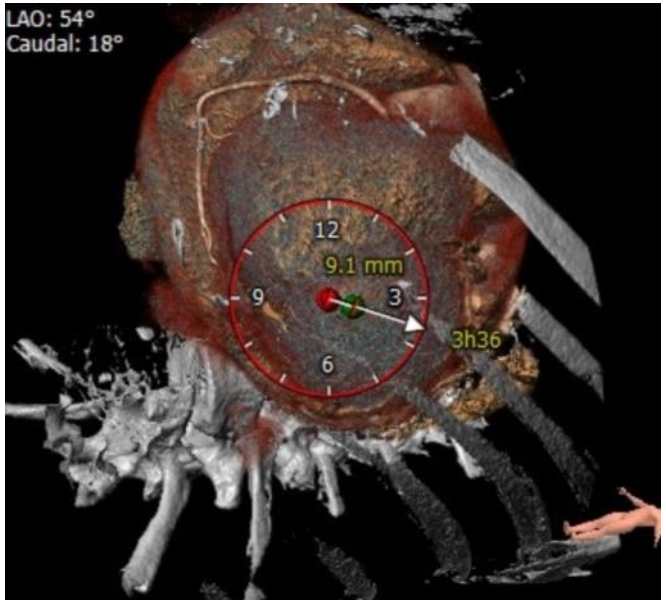
- **High calcific burden**
- Especially in the **anterolateral commissure**



- **Annular dimensions:** suitable for 29mm low-profile valve (Tendyne ™, Abbott Medical, USA)
- **Pre-dilatation:** 26mm non-compliant balloon



- **Low risk** for **left ventricular outflow tract obstruction**
- A2 clearance: 7.8 mm
- Neo-LVOT: 291 mm^2



- **Apical access** (green) **9mm laterally** from true apex (red)
- Good myocardial tissue quality expected

The Procedure

Standard apical access

High calcific burden + pre-dilatation →
transradial cerebral embolic protection device
(Sentinel ™, Claret Medical, USA)

Intraoperative TEE: **Severe fusion anterolateral commissure** between A1/P1 towards A2/P2

Balloon valvuloplasty - 26mm non-compliant balloon
(Bard Peripheral Vascular Inc, Arizona, USA)

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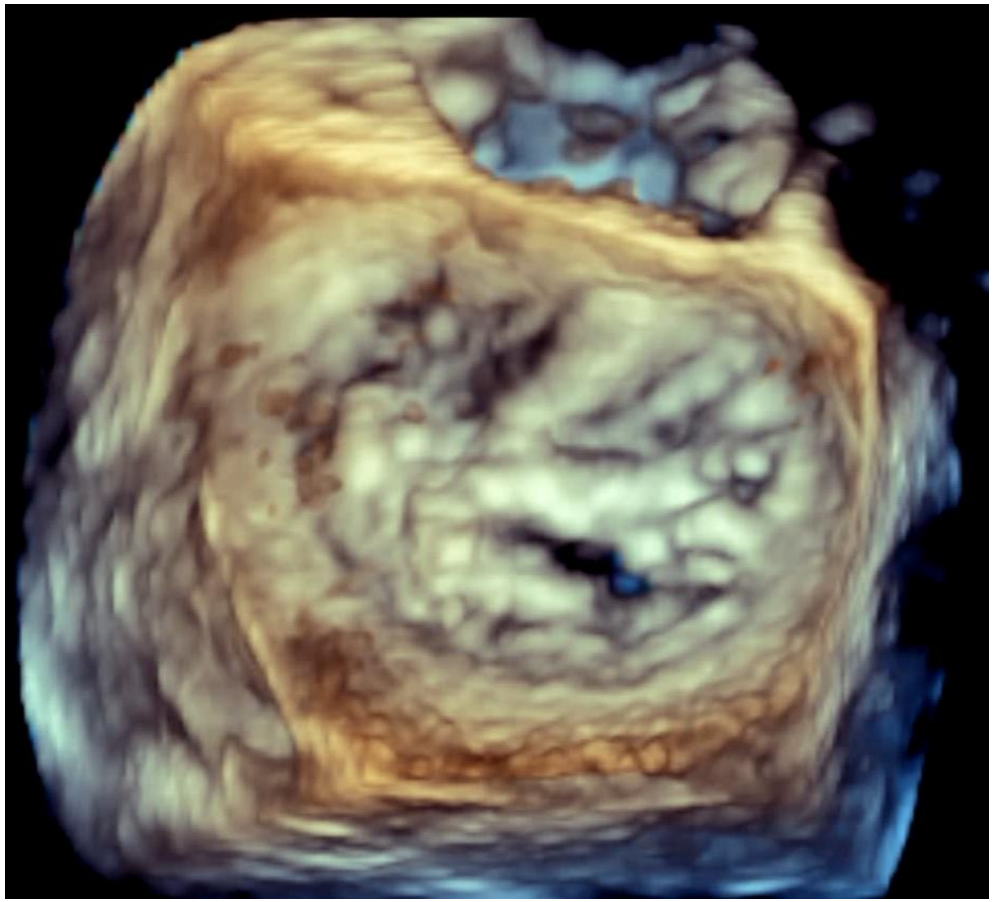
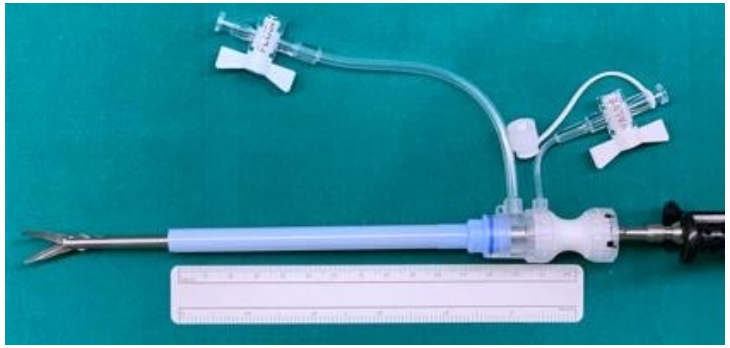


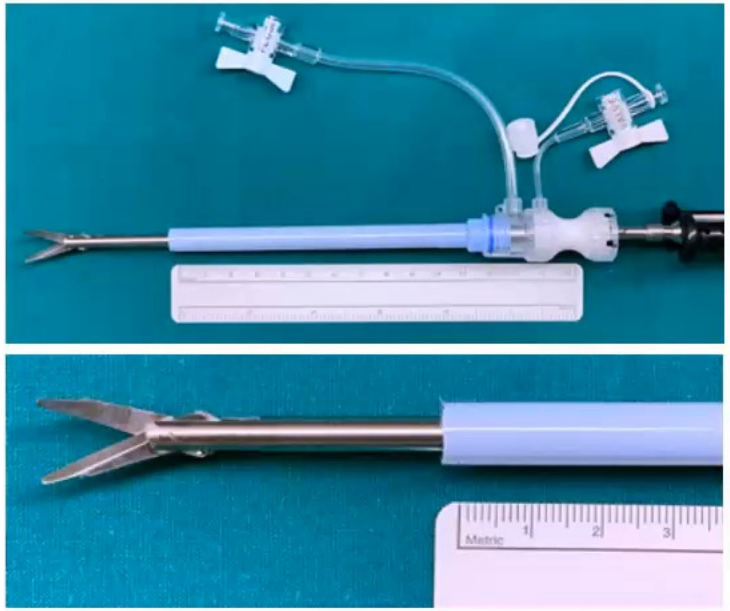
TEE after tripple balloon valvuloplasty

The Mitra-Cut Technique



- Manually **shortened 26 Fr sheath:** ~10 cm
- **Transapical sheat insertion** with standard **endoscopic scissors**

The Mitra-Cut Technique



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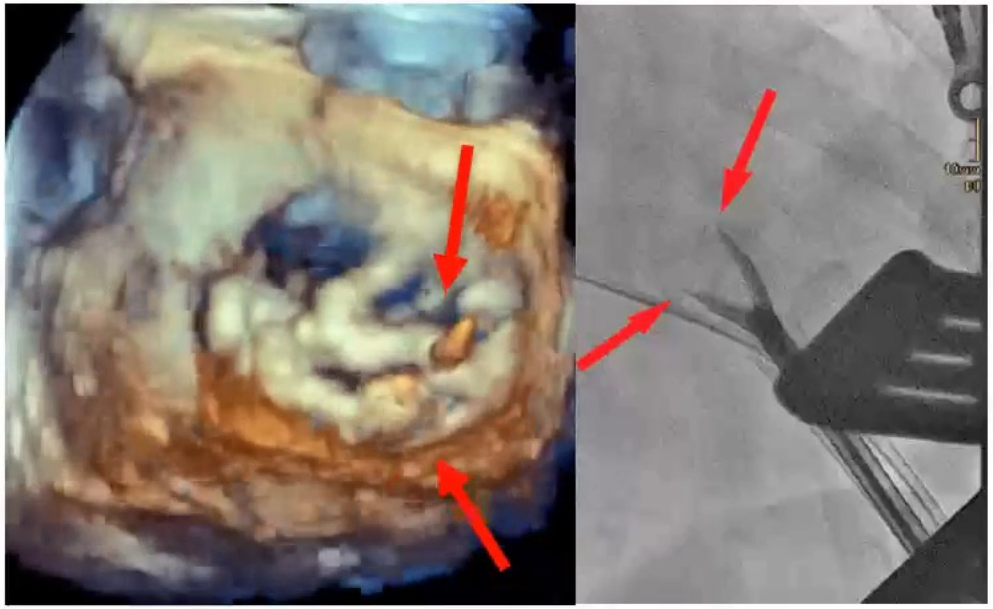
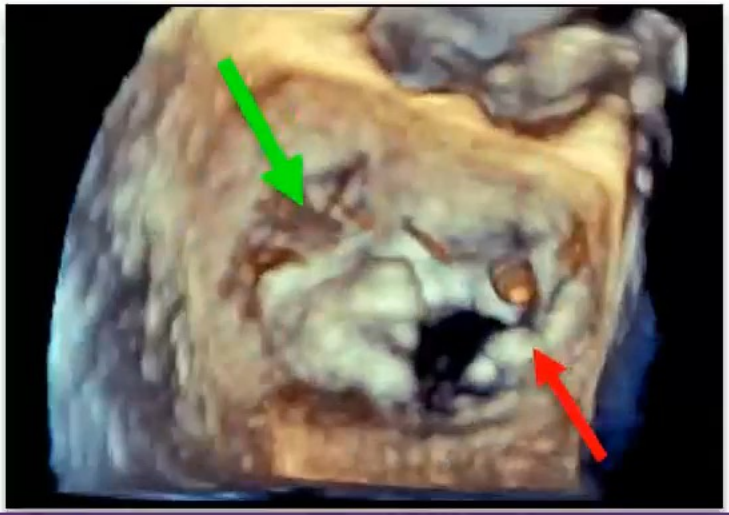
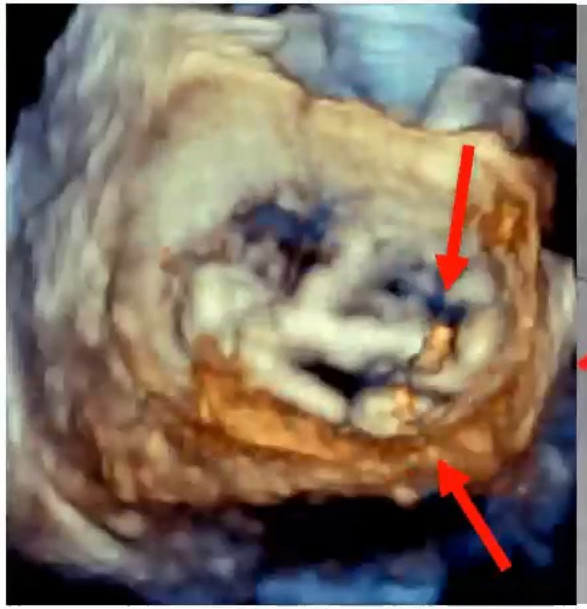


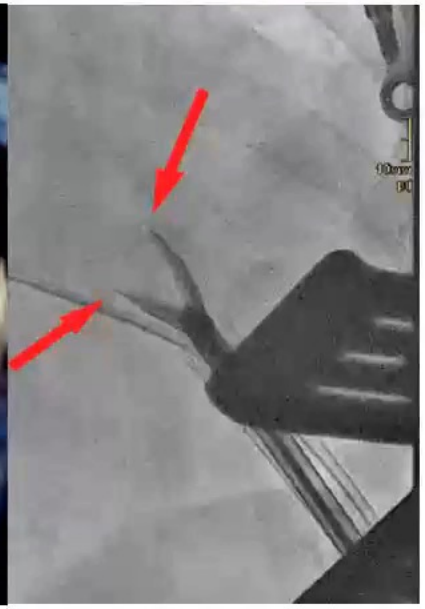
- **3D TEE, fluoro guidance**
- **Alignment** of the **scissor tips (red arrows)**
- Scissor mediated **sharp dissection**

The Mitra-Cut Technique



- Manually **shortened 26 Fr sheath:** ~10 cm
- **Transapical sheat insertion** with standard **endoscopic scissors**
- **Scissor mediated commissurotomy**
- **Scissor tips** (red arrow)
- **Neo-commissure** (green arrow)

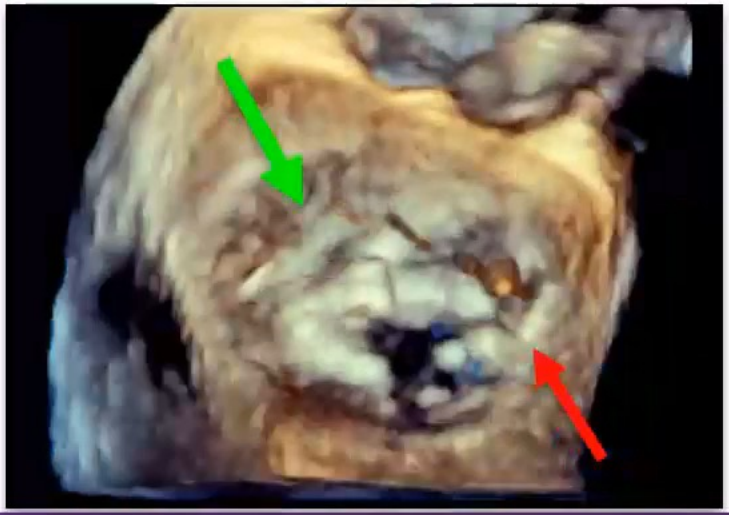




- **3D TEE, fluoro guidance**
- **Alignment** of the **scissor tips (red arrows)**
- Scissor mediated **sharp dissection**

The Mitra-Cut Technique

- Manually **shortened 26 Fr sheath:** ~10 cm
- **Transapical sheat insertion** with standard **endoscopic scissors**



- **Scissor mediated commissurotomy**
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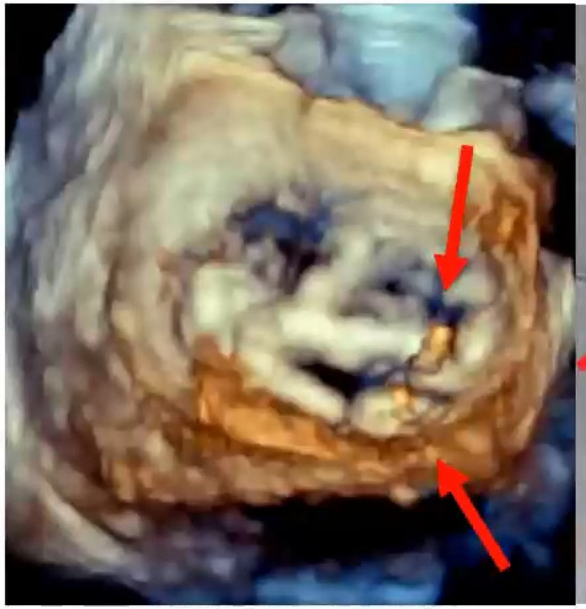
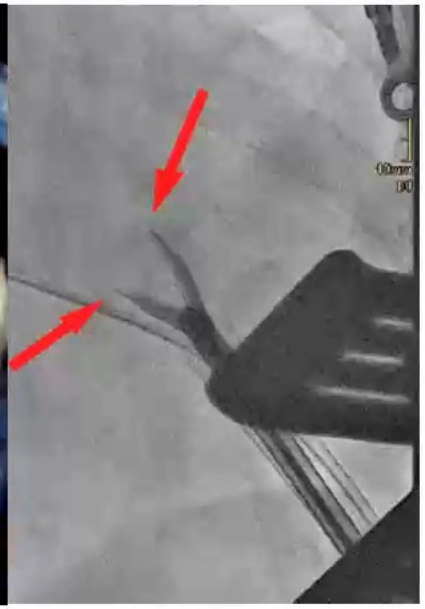
- **Neo-commissure** (green arrow)





- **3D TEE, fluoro guidance**
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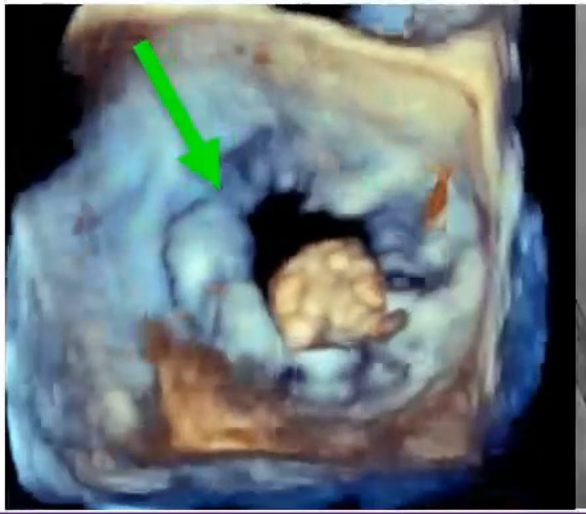
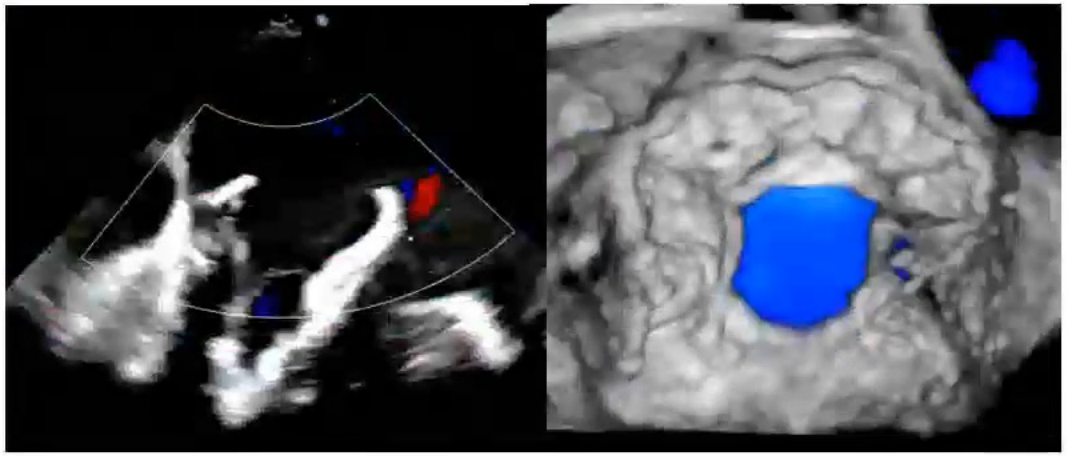


- **Unobstructed ant.-lat. commissure**
- **Unimpeded valve implantation**

Results

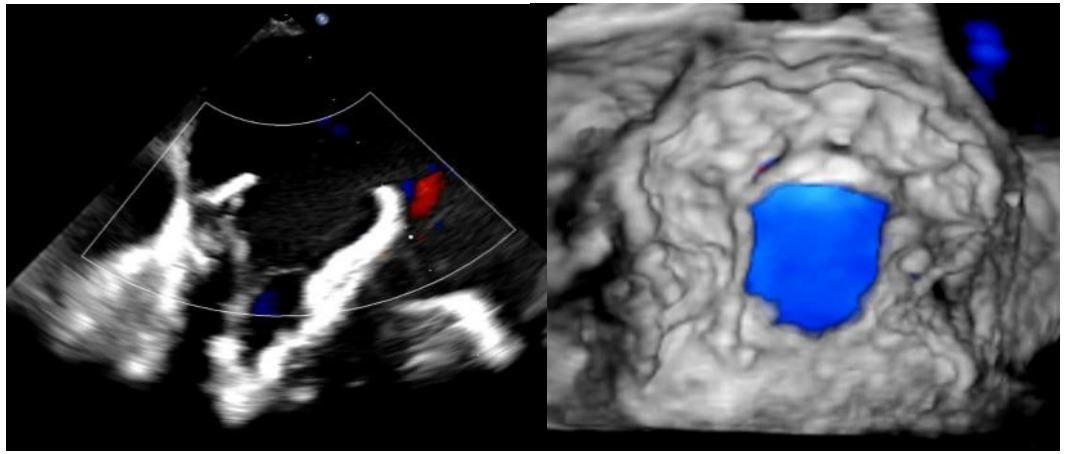
Intra-operative



- **Complete expansion** of the **inner stent frame**
  → **good haemodynamics** (MPG 4 mmHg)
- Trace paravalvular leakage (PVL)

Results

Intra-operative



- **Complete expansion** of the **inner stent frame**
  → **good haemodynamics** (MPG 4 mmHg)
- Trace paravalvular leakage (PVL)

Discharge

- Postop. day 21
- **NYHA II**
- **Minor stroke** – no residual symptoms

2 month follow-up

- **Primary TR III** - transcatheter edge-to-edge repair **(TEER)**
  → **TR I**
- **Mitral valve:** MPG 3 mmHg, no PVL

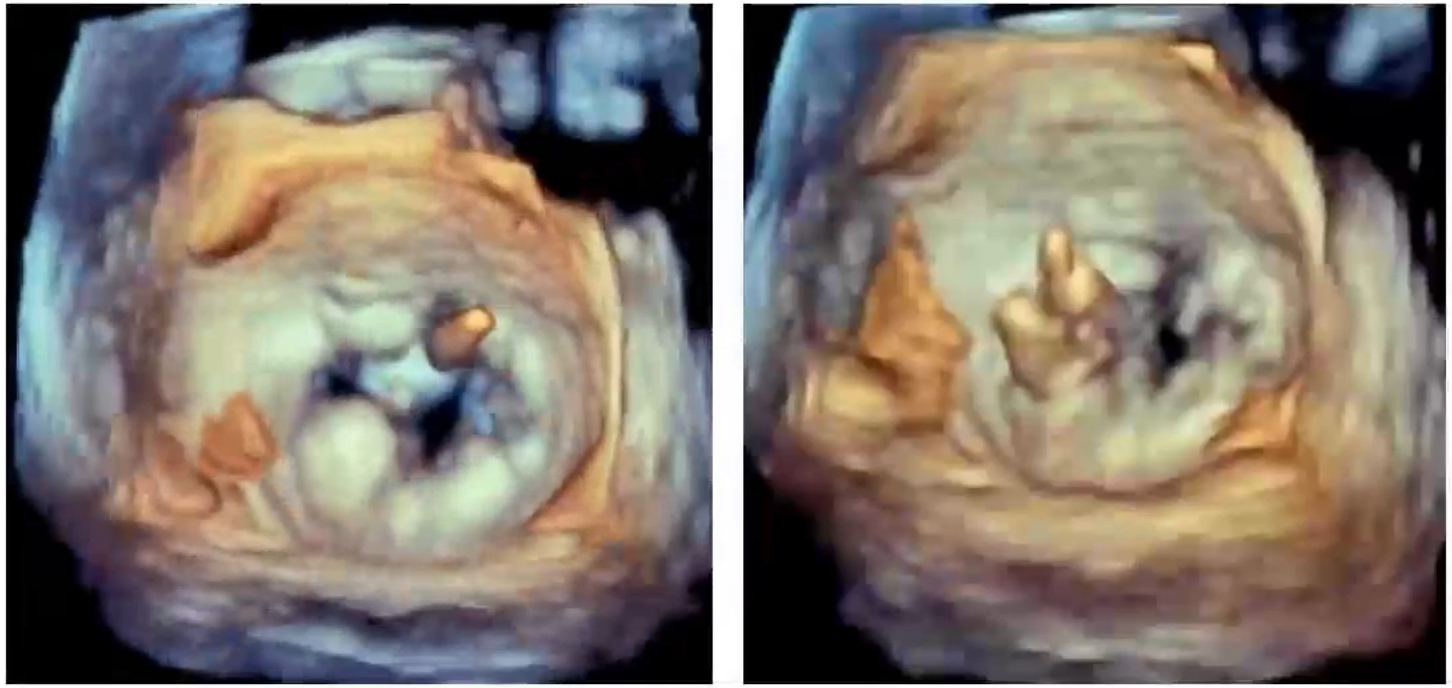
6 month follow-up

- **NYHA I**
- **TR I** after TEER
- **Mitral Valve:** MPG 3 mmHg, no PVL

Conclusion

The Mitra-Cut Technique – Field of Use

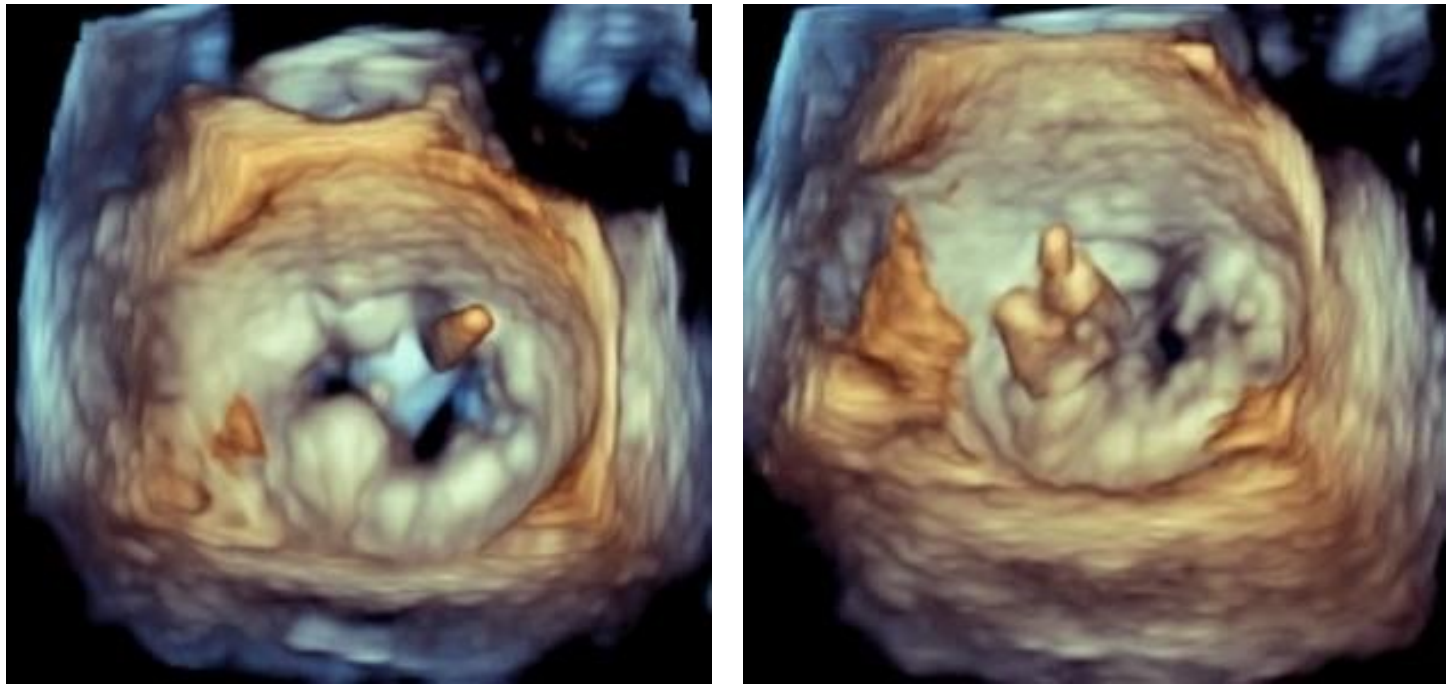
AML dissection in high risk for LVOT- obstruction



Quick and simple alternative to the often time-consuming LAMPOON-technique

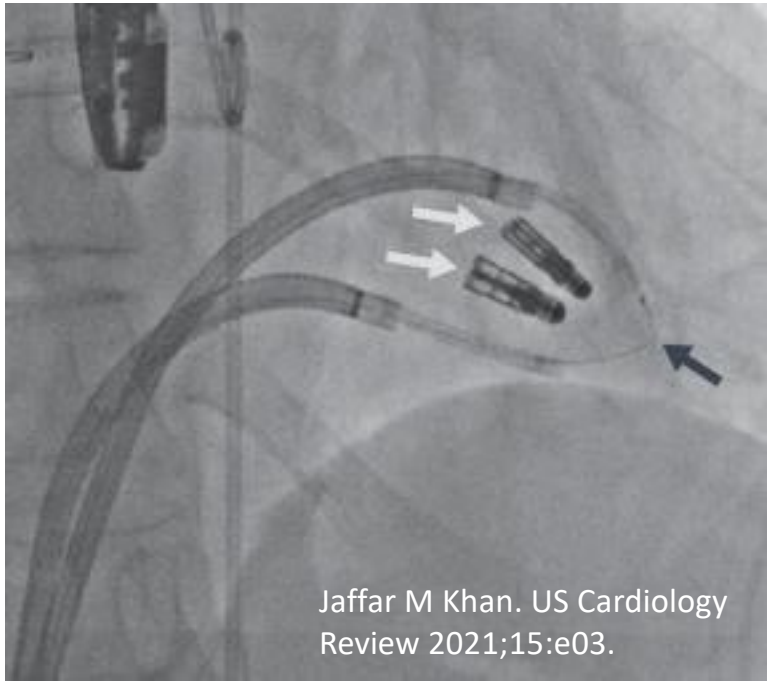
The Mitra-Cut Technique – Field of Use

AML dissection in high risk for LVOT- obstruction



Quick and simple alternative to the often time-consuming LAMPOON-technique

Failed TEER in mitral position



Alternative to the ELASTA Procedure

2022 PCR london valves

MitraClip procedure and other structural heart interventions in augmented reality

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EAPCI
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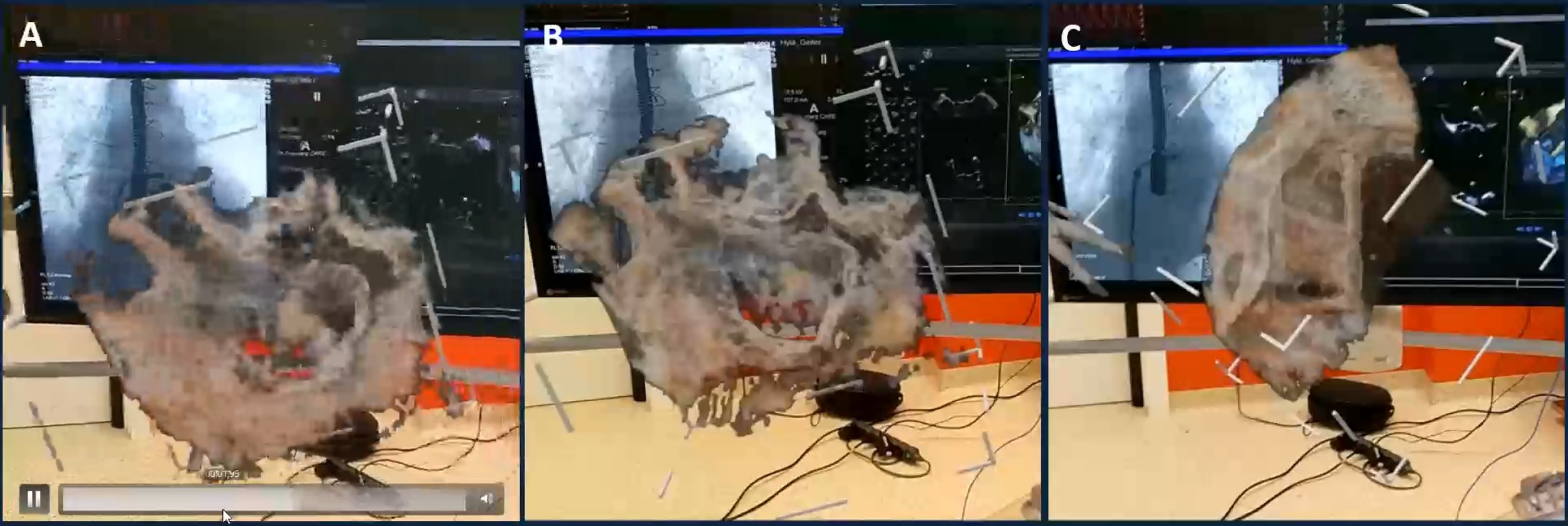
Introduction

- Holography is a new visualization technique which may augment the reality for structural heart interventions
- Holographic images can be created in real time from 3D TEE data by using the CarnaLife Holo system (MedApp) and the HoloLens 2 device (Microsoft)
- The system voice and gesture control enables moving and scaling holographic images

MitraClip procedure in Holography



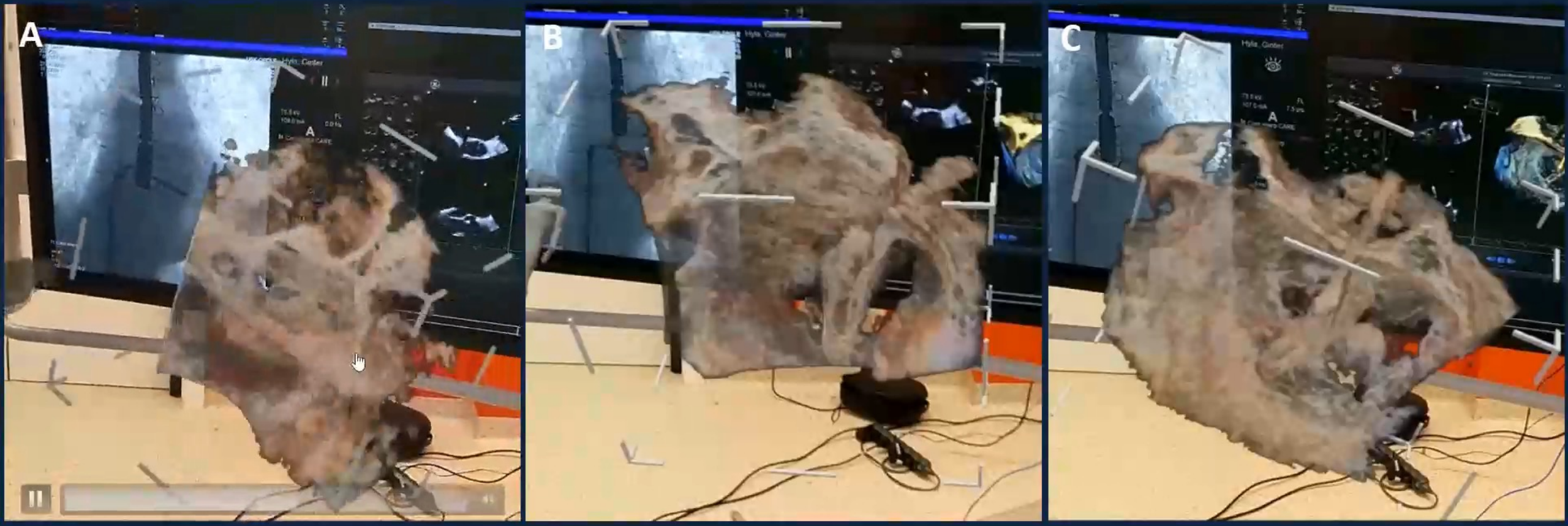
The operator's view through the Hololens:

A. The view of mitral valve from the perspective of the left atrium („mitral smile").

B. The long-axis view on mitral valve.

C. The closed clip in the left atrium.

MitraClip procedure in Holography



The operator's view through the Hololens:

A. The closed clip facing mitral valve.

B. The clip is open.

C. The clip is rotated to the 12 o'clock position.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