2022 PCR london valves

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

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EAPCI
European Society of Cardiology

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Potential conflicts of interest

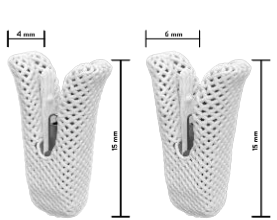
☒ I have the following potential conflicts of interest to report:

Receipt of grants / research support: Abbott, Medtronic, Edwards Lifesciences, Biotronik, Boston Scientific Corporation, NVT, Terumo; receives Consulting fees, Honoraria from Abbott, Medtronic, Edwards Lifesciences, Swissvortex, Perifect, Xeltis, Transseptal solutions, Cardiovalve, Magenta; has Royalty Income/IP Rights Edwards Lifesciences and is Shareholder, Cardiogard, Magenta, SwissVortex, Transseptalsolutions, 4Tech, Perifect

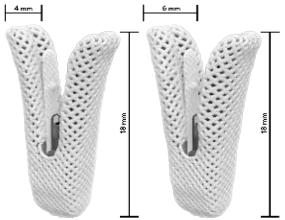
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Background

- 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.*

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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)

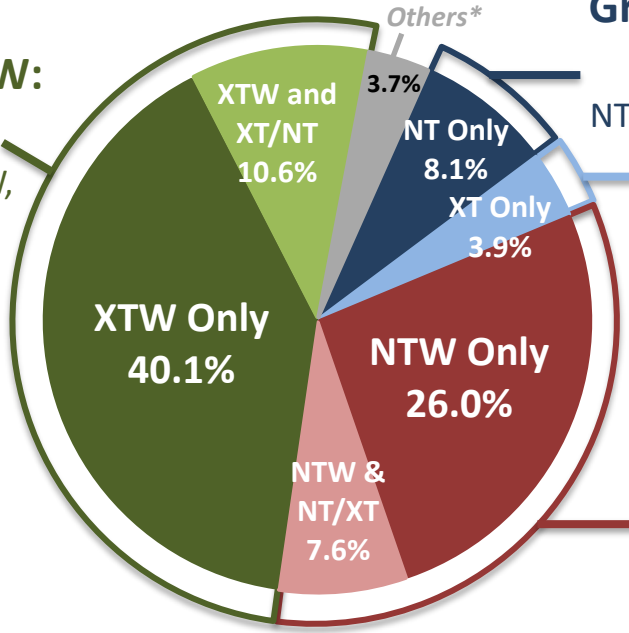
Objectives:

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.

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Methods: Analysis of Clip Usage

EXPAND G4 Clip Usage (N = 1146)



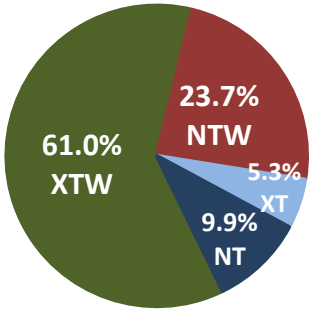
Group XTW: 50.7%
1st clip XTW, no NTW

Group NT: 8.1%
NT Clips Only

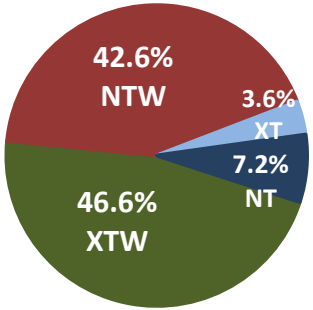
Group XT: 3.9%
XT Clips Only

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.

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

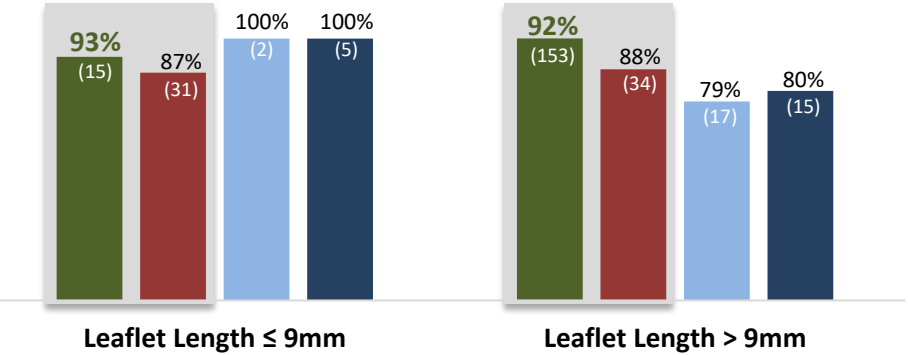
*** Primary MR includes PMR only (n=405) and Mixed patients (n=8)*

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%

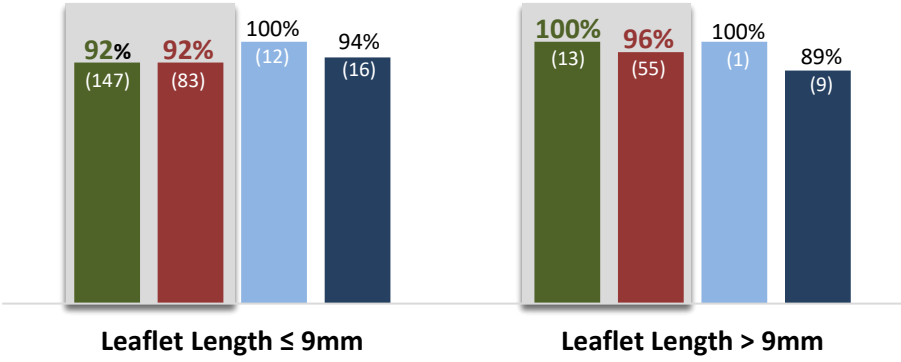
30-Day MR ≤ 1+



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.

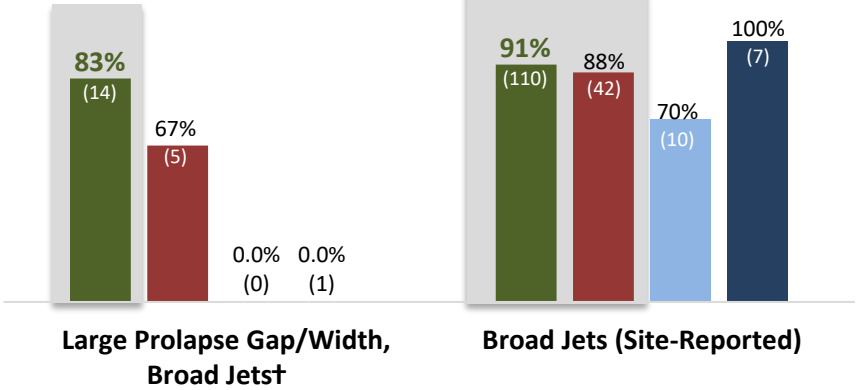
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Anatomical Considerations – *Broad Jets*

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%

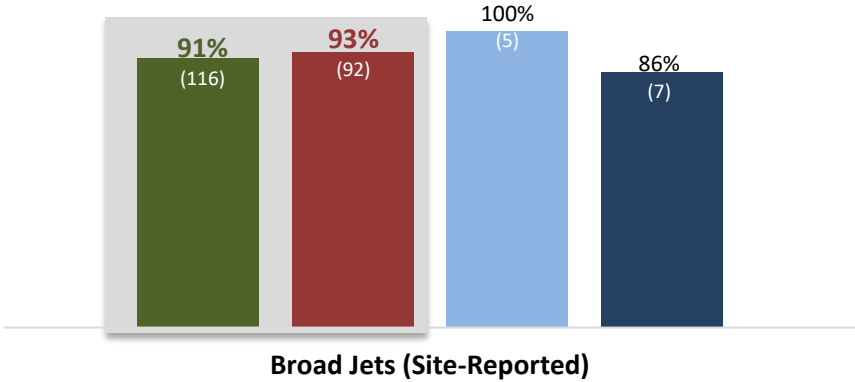
30-Day MR ≤ 1+



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.

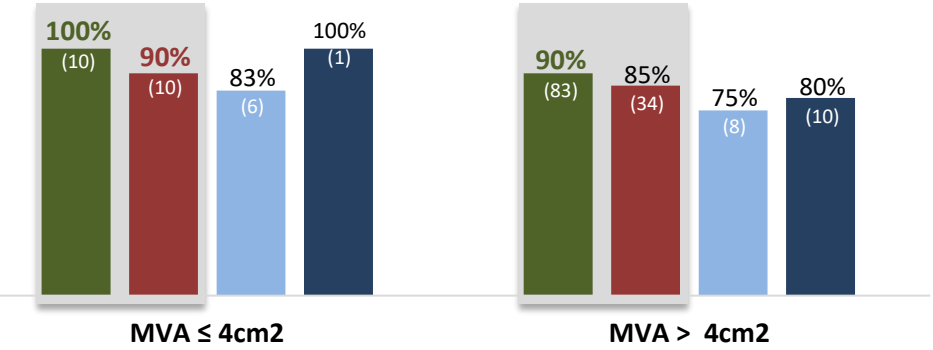
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Anatomical Considerations – *Mitral Valve Area*

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%

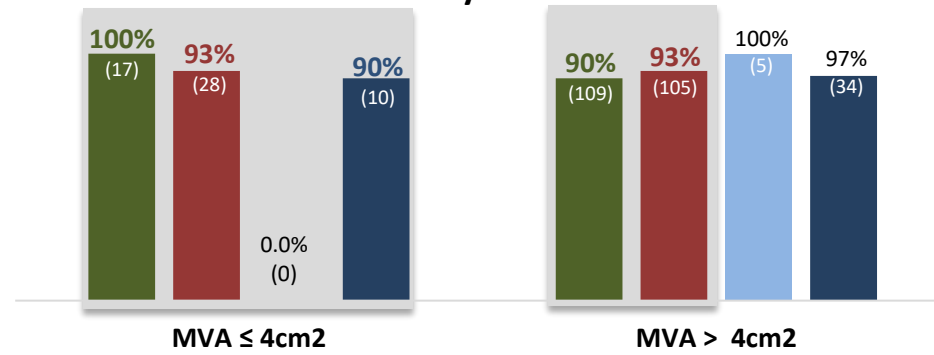
30-Day MR ≤ 1+:



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+:



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

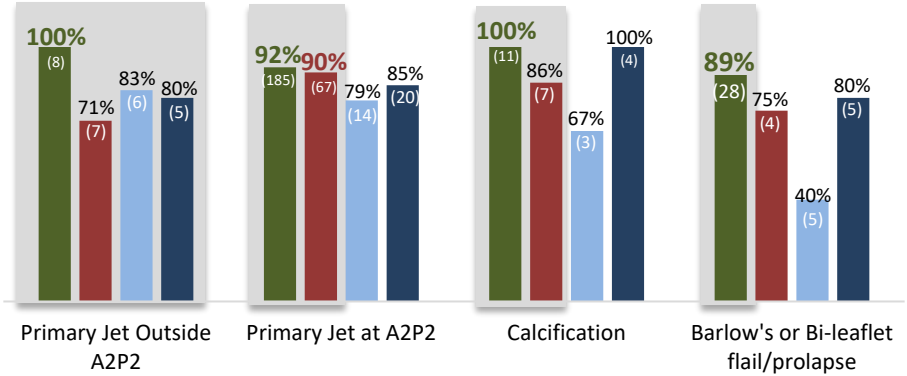
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Additional Anatomical Considerations

Primary MR

Baseline Echo Characteristics		Group XTW	Group NTW	Group XT	Group NT
Primary Jet Outside A2P2	Yes (N=32)	31.3%	28.1%	18.8%	21.9%
	No (N=380)	63.4%	23.4%	4.2%	8.9%
Mitral Annular or Leaflet Calcification (N=34)		44.1%	26.5%	8.8%	20.6%
Barlow's or Bi-leaflet flail/ prolapse (N=53)		64.2%	13.2%	9.4%	13.2%

30-Day MR ≤ 1+

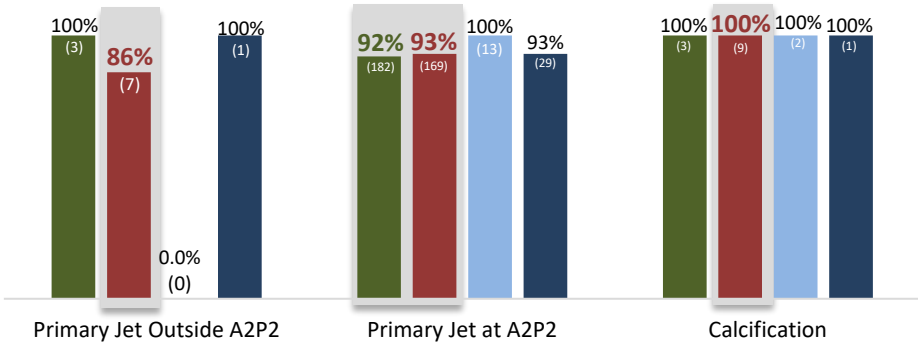


In PMR, XTW was the clip of choice in subjects with central jets and valve complexities.

Secondary MR

Baseline Echo Characteristics		Group XTW	Group NTW	Group XT	Group NT
Primary Jet Outside A2P2	Yes (N=14)	28.6%	64.3%	0.0%	7.1%
	No (N=539)	46.9%	42.1%	3.7%	7.2%
Mitral Annular or Leaflet Calcification (N=21)		23.8%	57.1%	9.5%	9.5%

30-Day MR ≤ 1+

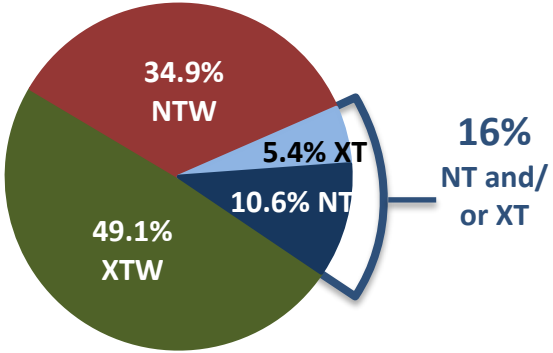


In SMR, NTW was preferred for valve complexities and central jets were treated with wide clips.

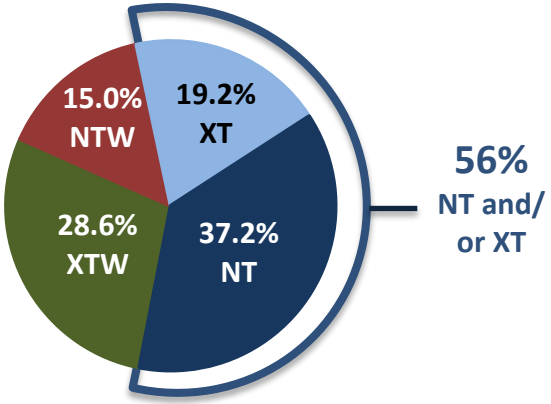
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NT/XT Clip Use: "The Clip of Choice as 2nd or 3rd Clip"

Single-Clip Cases (N=745)

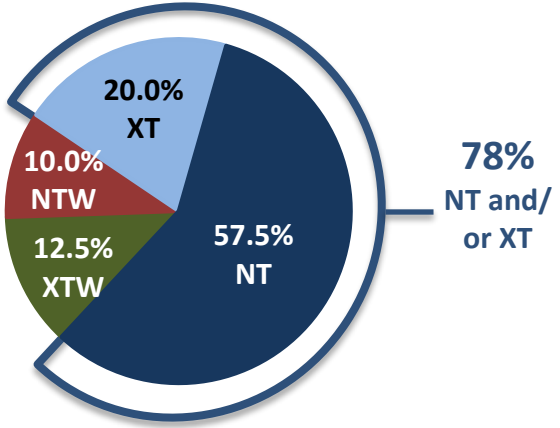


2nd Clip Use in 2-Clip Cases (N=360)



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.

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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.

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Recommendations for Clip Selection

Based on Real World Observations from EXPAND G4

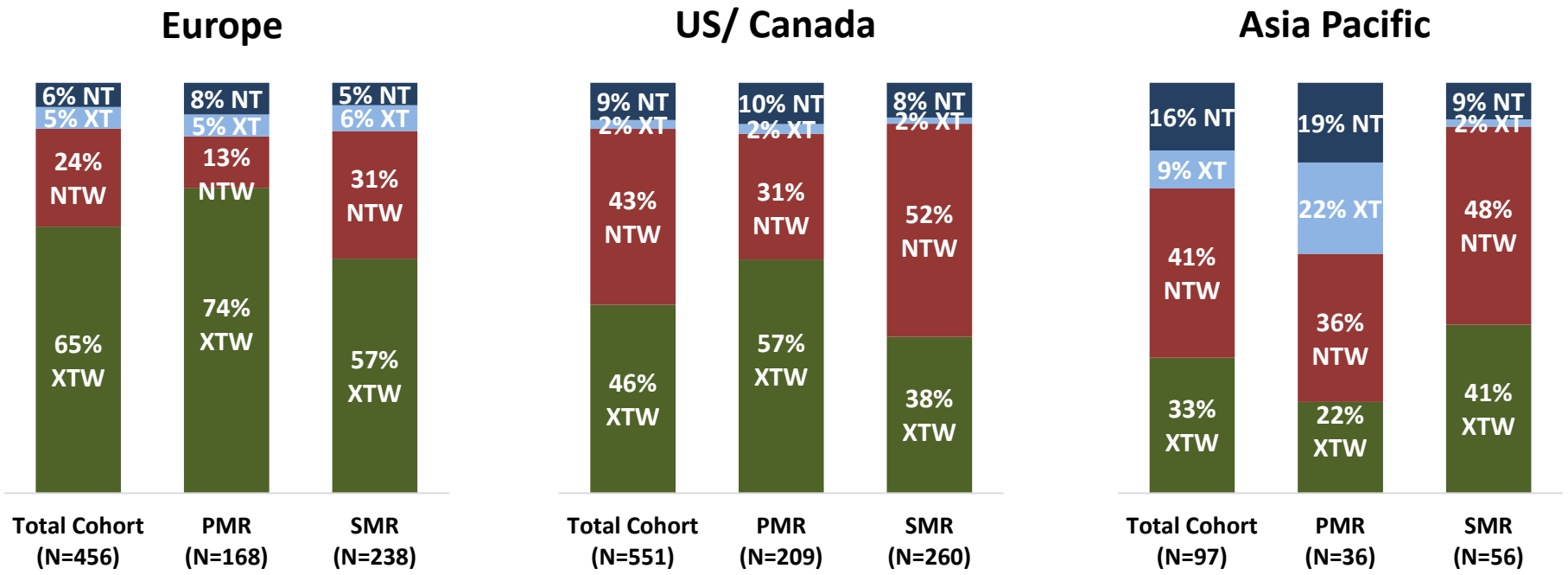
Anatomical Considerations		Favors NTW	Favors NT	Favors XTW	Favors XT
1. Leaflet Insertion	Length ≤ 9mm	✓	✓		
	Length > 9mm			✓	✓
2. Large Prolapse Width/Wide Jet	Prolapse Width (≥15mm)	✓		✓ (PMR)	
3. MVA	Small Valve (≤4cm^2)	+	✓	+	+
	Large Valve (>4cm^2)	✓		✓	✓
4. Primary Jet Location	**A2P2**	+		+	
	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+

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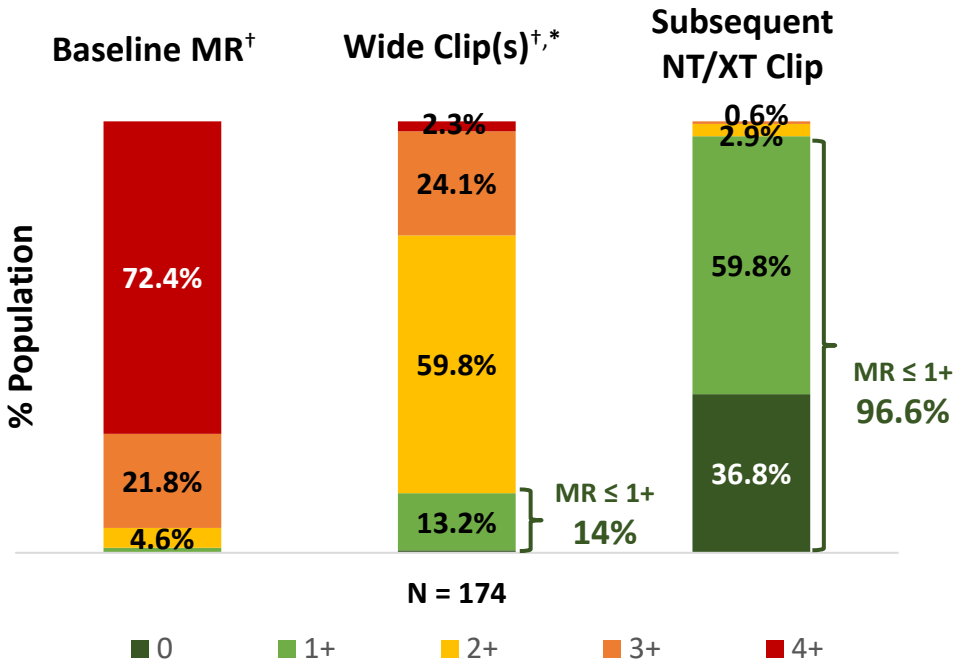
Clip Usage in Different Regions



In Europe, XTW was the clip of choice; in US and Canada, XTW and NTW were used more evenly; in APAC, NTW was used more often regardless of MR etiology.

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NT/XT Optimizes MR Reduction in Multi-Clip Cases



Reasons for subsequent NT, XT reported: small MVA, small jet width, high gradient, or shorter leaflet lengths.

† Site-reported baseline/ intra-procedural MR
*In 2 clip cases, wide clip was used 1st with a subsequent NT/ XT. In 3 clip cases, wide clip was used 1st and 2nd with a subsequent NT/XT

While NTW/XTW was used as the first clip to target the MR lesion, the subsequent NT/XT clips ensured maximum and safe MR reduction.

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MITRACLIP™ CLIP DELIVERY SYSTEM

Indications for Use

- The MitraClip™ G4 System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.
- The MitraClip™ G4 System, when used with maximally tolerated guideline-directed medical therapy (GDMT), is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR ≥ Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.

Contraindications

The MitraClip G4 System is contraindicated in patients with the following conditions: Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regime; Patients with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity; Active endocarditis of the mitral valve; Rheumatic mitral valve disease; Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

Potential Complications and Adverse Events

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip G4 procedure: Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials (nickel / titanium, cobalt, chromium, polyester), and drug reactions to anticoagulation, or antiplatelet drugs, Vascular access complications which may require transfusion or vessel repair including: wound dehiscence, catheter site reactions, Bleeding (including ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, vascular occlusion, Emboli (air thrombotic material, implant, device component); Peripheral Nerve Injury; Lymphatic complications; Pericardial complications which may require additional intervention, including: Pericardial effuse on, Cardiac tamponade, Pericarditis; Cardiac complications which may require additional interventions or emergency cardiac surgery, including: Cardiac perforation, Atrial septal defect; Mitral valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single Leaflet Device Attachment (SLDA), Thrombosis, Dislodgement of previously implanted devices, Tissue damage, Mitral valve stenosis, Persistent or residual mitral regurgitation, Endocarditis; Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, and unstable / stable angina); Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post procedure pulmonary embolism); Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction / failure / atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Blood cell disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Hypotension / hypertension; Infection including: Urinary Tract Infection (UTI), Pneumonia, Septicemia; Nausea / vomiting; Chest pain; Dyspnea; Edema; Fever or hyperthermia; Pain; Death; Fluoroscopy, Transesophageal echocardiogram (TEE) and Transthoracic echocardiogram (TTE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation; Esophageal perforation, Gastrointestinal bleeding

Source: PCR LV November 2022

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