Contemporary Outcomes with MitraClip™ (NTR/XTR) System in Primary Mitral Regurgitation: Results from the Global EXPAND Study

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Disclosure Statement

D. Scott Lim, MD

Personal consulting:

Abbott, Edwards Lifesciences, Pipeline, Venus

Equity:

510Kardiac, Venus

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Background

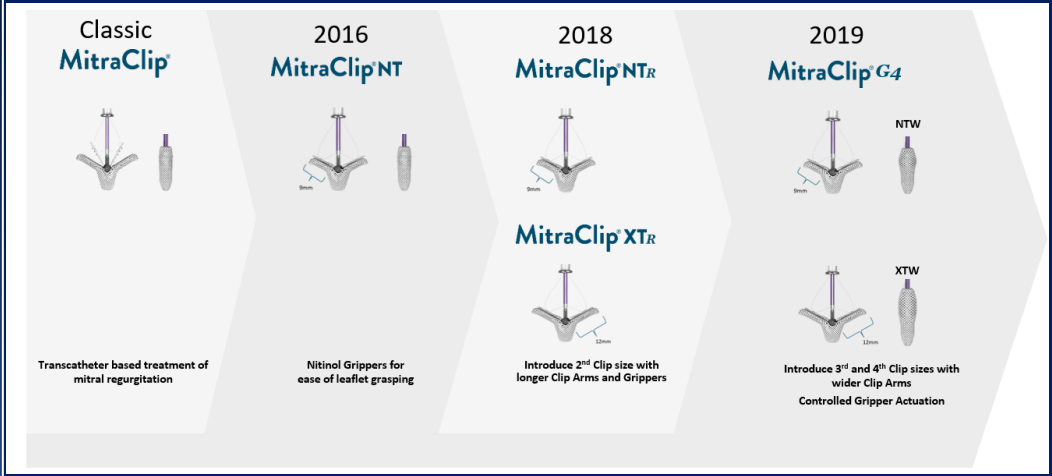
MitraClip™ for the Treatment of Primary MR

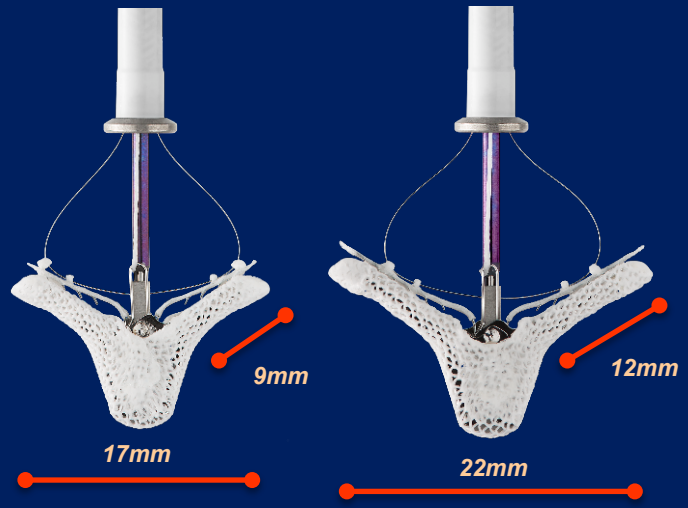
- The MitraClip™ System was FDA approved in 2013 for the treatment of subjects with primary (or degenerative) mitral regurgitation who are at prohibitive risk for mitral valve surgery

- Since the original EVEREST II trials, no new core-lab adjudicated data on subjects with primary MR have been reported

Background

MitraClip™ Evolution - NTR/XTR





NTR

Improved delivery system

XTR

Longer arms, with an improved delivery catheter system

Primary Objective

To Report on:

Real World, Echo Core Lab and Clinical Events Committee Adjudicated Outcomes in Patients with Significant Primary Mitral Regurgitation Treated with the Next Generation MitraClip™ NTR and XTR Systems in the 1000+ Patient Global EXPAND Study

Secondary Objectives

- Evaluate MR reduction outcomes as a function of mitral valve anatomic complexity
- Confirm the safety (including single leaflet device attachments and leaflet injuries) and effectiveness of MR reduction associated with the MitraClip™ NTR and XTR systems

Methods
EXPAND Study Design

- **Design:** Prospective, Multi-center, Single Arm, International, Post-Market, Real World, Observational Study Conducted in United States, Europe, and the Middle East
- **Intended Sample Size:** A minimum of 1000 consecutive consented subjects receiving the MitraClip NTR/XTR at up to 60 sites
- **Follow-up:** Baseline, Discharge, 30 days, 6 months, and 12 months
- **Key Outcome Measures:** MR Severity, Major Adverse Events, Survival, Procedural Measures, Quality of Life Assessed using Kansas City Cardiomyopathy Questionnaire (KCCQ), and functional capacity assessed using New York Heart Association (NYHA) functional class
- **Data Adjudication:** *Clinical Events Committee (CEC)* utilized for adjudication of adverse events; *Echocardiographic Core Laboratory (ECL)* utilized for adjudication of echocardiographic measures; *An Independent Physician Committee* utilized for evaluation of single leaflet device attachment (SLDA) and leaflet damage events

Methods
EXPAND Study Design

INCLUSION CRITERIA

1. Subjects with symptomatic MR (≥3+) as assessed by sites
2. Subjects provided consent for study participation
3. Subjects eligible to receive the MitraClip per the current approved indications for use in their respective geographies

EXCLUSION CRITERIA

1. Subjects participating in another clinical study that may impact the follow-up or results of this study.

ECL MR Severity Assessment Methodology

- **A multiparametric algorithm adapted from the criteria recommended by the American Society of Echocardiography Guidelines employed for MR severity assessments consistent with the previous MitraClip trials (EVEREST II, REALISM).**

MR Severity 3+ or 4+ (graded by 1 of 3 criteria)	
Tier 1	EROA ≥ 0.3 cm^2 or PV systolic flow reversal
Tier 2 EROA 0.2 cm^2 - <0.3 cm^2	With any 1 of the following: • RV ≥ 45 ml/beat • RF ≥ 40% • VC width ≥ 0.5 cm
Tier 3 EROA not measured or <0.2 cm^2	With at least 2 of the following: • RV ≥ 45 ml/beat • RF ≥ 40% • VC width ≥ 0.5 cm • PISA radius > 0.9 cm, but CW of MR jet not done • Large (≥ 6.0 cm) holosystolic jet wrapping around LA • Peak E velocity ≥ 150 cm/s

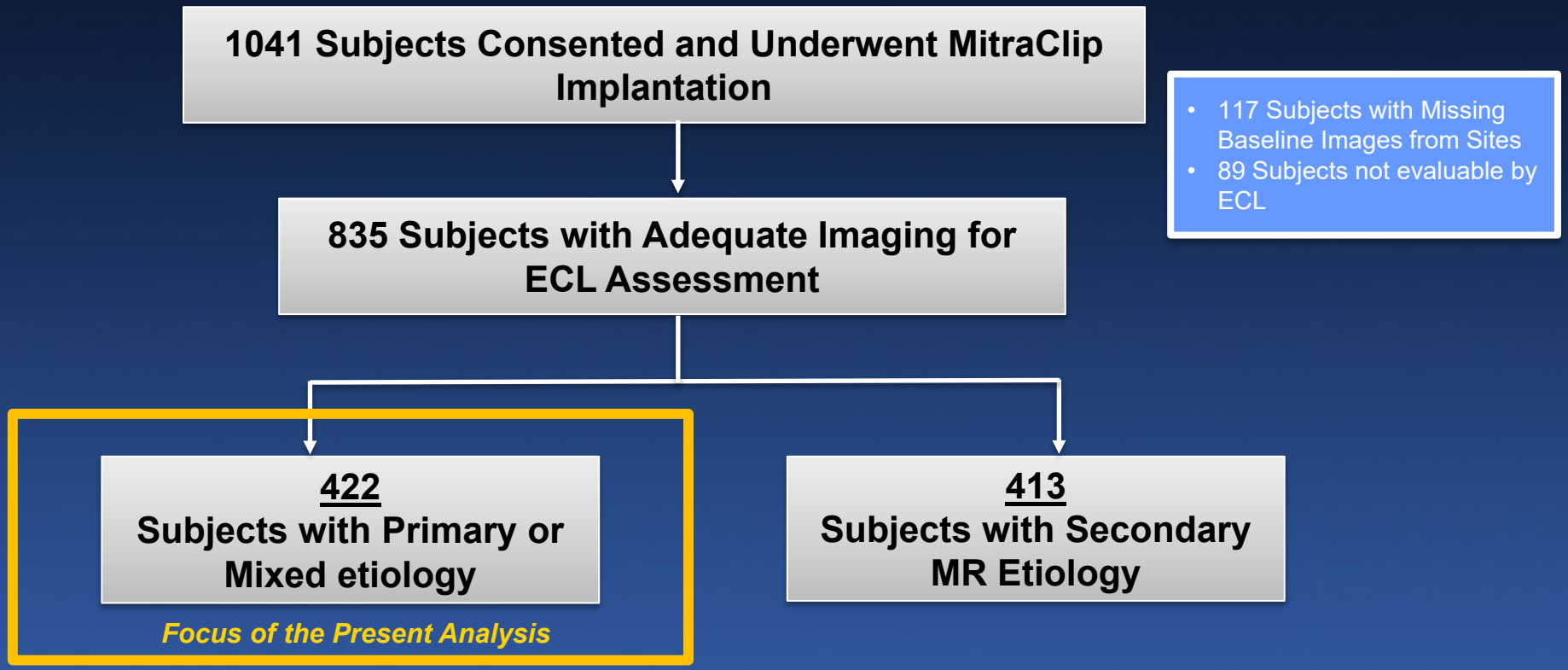
MR Grade	Color Doppler Area Size	PV flow	Vena Contracta
1+, Mild	Central and small, (<4 cm^2 or <10% of the LA area)	Systolic dominant	<0.5 cm
2+, Moderate	Central and moderate (4-6 cm^2 or 10-30% of the LA area)	Diastolic dominant	
3+, Moderate to Severe	Central, large (6-8 cm^2 or 30-40% of the LA area) or eccentric reaching 1 PV.	All diastolic (systolic blunting)	≥0.5 cm
4+, Severe	Eccentric, large (≥8 cm^2 or ≥40% of the LA area), or eccentric reaching the second PV	Systolic flow reversal	

ECL MV Complexity Assessment Criteria

- **Presence of at least one of the functional and anatomic features below at the baseline echocardiogram:**

Primary jet outside of A2P2
Presence of more than one significant jet
Presence of an extremely wide jet
Small Valve
Calcification Landing Zone
Minimal leaflet tissue for attachment
Presence of severely degenerative leaflets or wide flail gaps or widths

Overall Study Subject Population



Echo Core Lab (ECL) Adjudication

- Enrollment period: April 2018 through June 2019
- 2 ECLs utilized to ensure consistency of measurements across sites:

MR Etiology

MR Severity

ECL -1

- Utilized for assessment of MR etiology (Baseline) and MR severity (Baseline and Follow-Up)
- Ensure consistent assessment with prior MitraClip trials (e.g. EVEREST II, REALISM, COAPT etc)

MV Anatomic Characterization

LV Assessment

ECL -2

- Utilized for detailed baseline mitral valve anatomic characterization and LV dimensional measurements over the study follow-up duration

Baseline Characteristics

Demographics and Comorbidities	Value (N=422)
Age (years)	79.5 ± 9.4
Male	52.1% (220/422)
Body Mass Index (kg/m^2)	25.2 ± 4.8
STS Replacement Score* (%)	**7.3 ± 5.6**
STS Repair Score (%)	**5.5 ± 5.4**
Cardiac Arrhythmia	60.5% (254/420)
○ Atrial Fibrillation	92.5% (235/254)
Renal Failure	28.2% (119/422)
Diabetes	19.2% (80/416)
Dyslipidemia	52.5% (219/417)
Hypertension	79.5% (334/420)
Prior Heart Failure Hospitalization within 1 year	43.2% (164/380)
Prior Myocardial Infarction	13.5% (56/415)

** Continuous data presented as mean ± s.d.; Categorical data presented as a proportion of subjects where data was provided (missing data excluded)*

*** STS PROM formula has changed since EVEREST Trials. For reference, STS Replacement Mortality Risk (Mean±SD) for EVEREST II HRR was: 18.2± 8.0 (n=78); for EVEREST II REALISM was 11.1± 7.0 (n=628); and for Prohibitive Risk Primary MR Cohort was 13.2 ± 7.3% (n=127)*

ECL Adjudicated Baseline Echo Parameters for Subjects with Primary MR

ECL Measure	Value
Baseline MR of 3+ or 4+	66.4% (279/420)
Baseline MR of ≤2+*	33.6% (141/420)
Effective Regurgitant Orifice Area (EROA, cm^2)	0.40 ± 0.21 (282)
Mean Mitral Inflow Velocity (cm/sec)	47.0 ± 14.1 (342)
Baseline TR of 3+ or 4+	22.6% (84/372)
Left Ventricular Ejection Fraction (LVEF, %)	62 ± 10 (390)
Left Ventricular End Systolic Volume (LVESV, mL)	47.9 ± 30.4 (390)
Left Ventricular End Diastolic Volume (LVEDV, mL)	121.0 ± 48.6 (390)

***These patients assessed as baseline MR Severity 3+/4+ by the sites.**

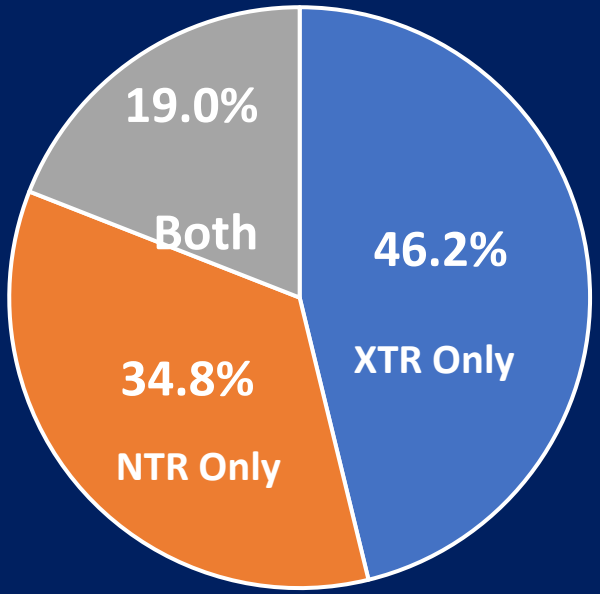
Procedural Outcomes vs. Previous Trials

	PROHIBITIVE RISK PRIMARY MR [1,2] (N=127)	TVT Registry[3] (N=2,952)	EXPAND PRIMARY MR (N=422)
Implant Rate % (n/N) [95% Confidence Interval]	95.3%[1] (121/127)	NA	99.5% (420/422) [98.3%, 99.9%]
Acute Procedural Success (APS)* % (n/N) [95% Confidence Interval]	NA	91.8% (2,709/2,952) Site-Reported	**94.5% (396/419)** [91.9%, 96.5%] (ECL)
Fluoroscopy Time (min) Median [Inter-Quartile Range]	39.0[2] [NA]	NA	18.0 [11.3-27.0]
Procedure Time (min) Median [Inter-Quartile Range]	134[2] [NA]	NA	82.0 [53.0- 120.0]
Length of Stay in Hospital for Index Procedure (days) Median [Inter-Quartile Range]	2.9 ± 3.1 days[1] (mean ± sd)	2.0 [1.0–5.0]	1.0 [1.0-3.0] (US)

APS defined as successful implantation of the MitraClip® device with resulting MR severity of 2+ or less on discharge Echocardiogram (30-day echocardiogram was used if discharge is unavailable or uninterpretable). Subjects who die or undergo mitral valve surgery before discharge are considered to be an APS failure

[1]Lim et al. ACC 2018
[2]MitraClip Summary of Safety and Effectiveness for Prohibitive Risk DMR
[3]Sorajja et al. J Am Coll Cardiol 2017;70:2315–27)

MitraClip Type Used in Subjects w/ Primary MR



- *XTR was used more frequently to treat primary MR compared to NTR ($p < 0.0001$)*

Clip Usage by Baseline MR Severity

Baseline MR Severity	XTR Only (N=194)	NTR only (N=146)	XTR and NTR (N=80)
≤ 2+: Moderate[1]	26.3% (51/194)	**47.6% (69/145)**	25.3% (20/79)
≥ 3+: Severe[1]	**73.7% (143/194)**	52.4% (76/145)	**74.7% (59/79)**

- **The baseline MR severity were statistically different across the 3 device groups**
- ***More XTR Clip usage (XTR-only or XTR and NTR) in subjects with baseline MR ≥3+***

[1]: p < 0.0001 Pearson's Chi-square test

Mitral Gradients (ECL Adjudicated) by MitraClip Size

	XTR Only (N=194)	NTR only (N=146)	XTR and NTR (N=80)	Total (N= 420)
Pre Procedure Mitral Gradient, mmHg	2.51 ± 1.35 (145)	2.31 ± 1.22 (121)	2.71 ± 1.62 (57)	2.48 ± 1.40 (318)
30 day Mitral Gradient, mmHg	3.51 ± 1.69 (156)	3.89 ± 1.89 (121)	3.99 ± 1.82 (66)	3.74 ± 1.79 (337)

- ***Pre-procedure gradient was not different across clip type groups (P =0.17)***
- ***MitraClip XTR was not associated with increased mitral valve gradient post procedure compared to MitraClip NTR.***

30-Day Major Adverse Events*

All-cause Death	**2.4% (N=10)**
Myocardial Infarction	**0.0% (N=0)**
Peri-procedural MI	0.0% (N=0)
Spontaneous MI	0.0% (N=0)
Stroke	**1.2% (N=5)**
Ischemic	1.0% (N=4)
Hemorrhagic	0.2% (N=1)
Non-elective CV surgery for device-related complications	0.9% (N=4)

**CEC Adjudicated*

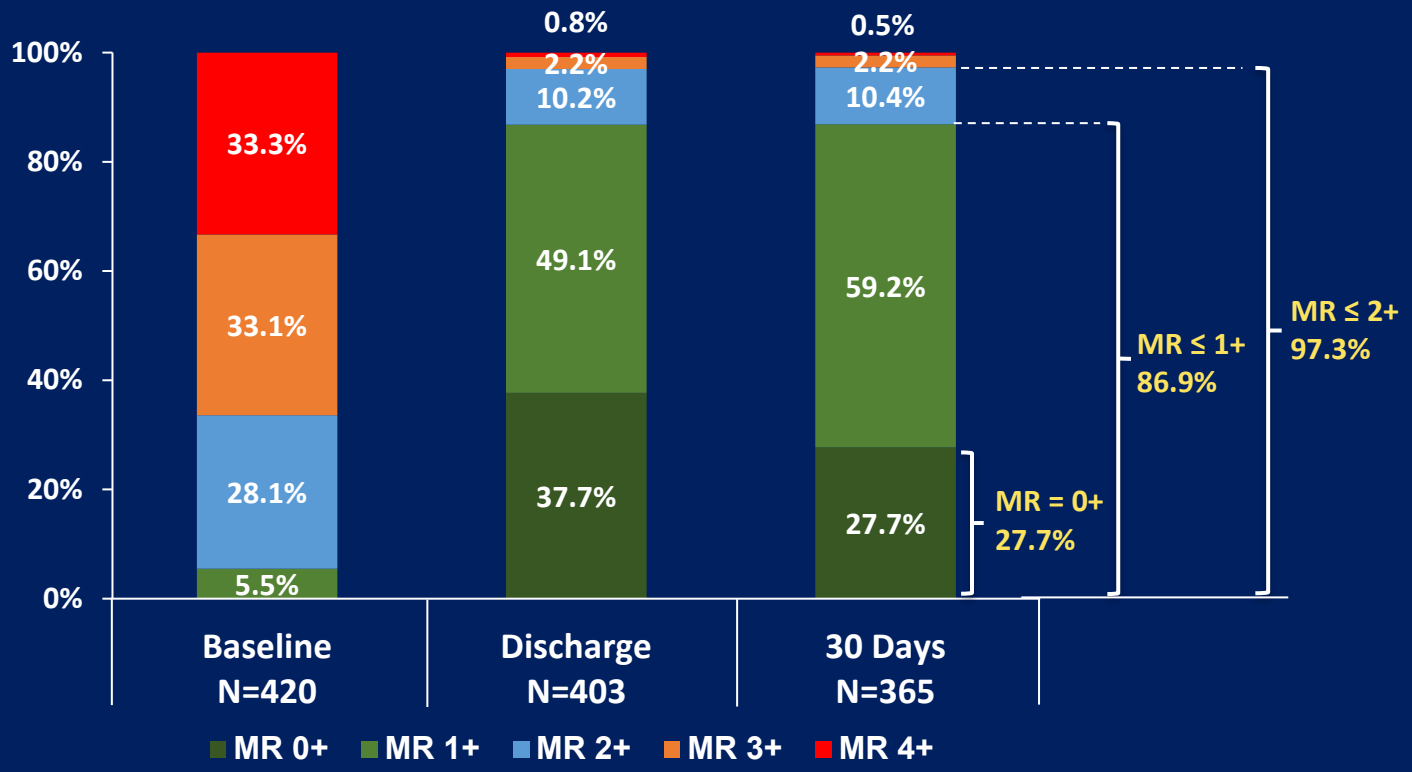
Device Related Leaflet Adverse Events

	Confirmed Events
Single Leaflet Device Attachment (SLDA)	**1.9% (N=8)***
Leaflet injury (leaflet tear or perforation)	**0.2% (N=1)**

- ***An independent multidisciplinary physician committee (including the ECL) reviewed and adjudicated all SLDA and leaflet injury events (including review of procedural and follow-up echoes as well as confirmation from surgery, etc.)***
- ***Overall, 8 subjects were confirmed to have an SLDA and 1 subject experienced a leaflet injury***

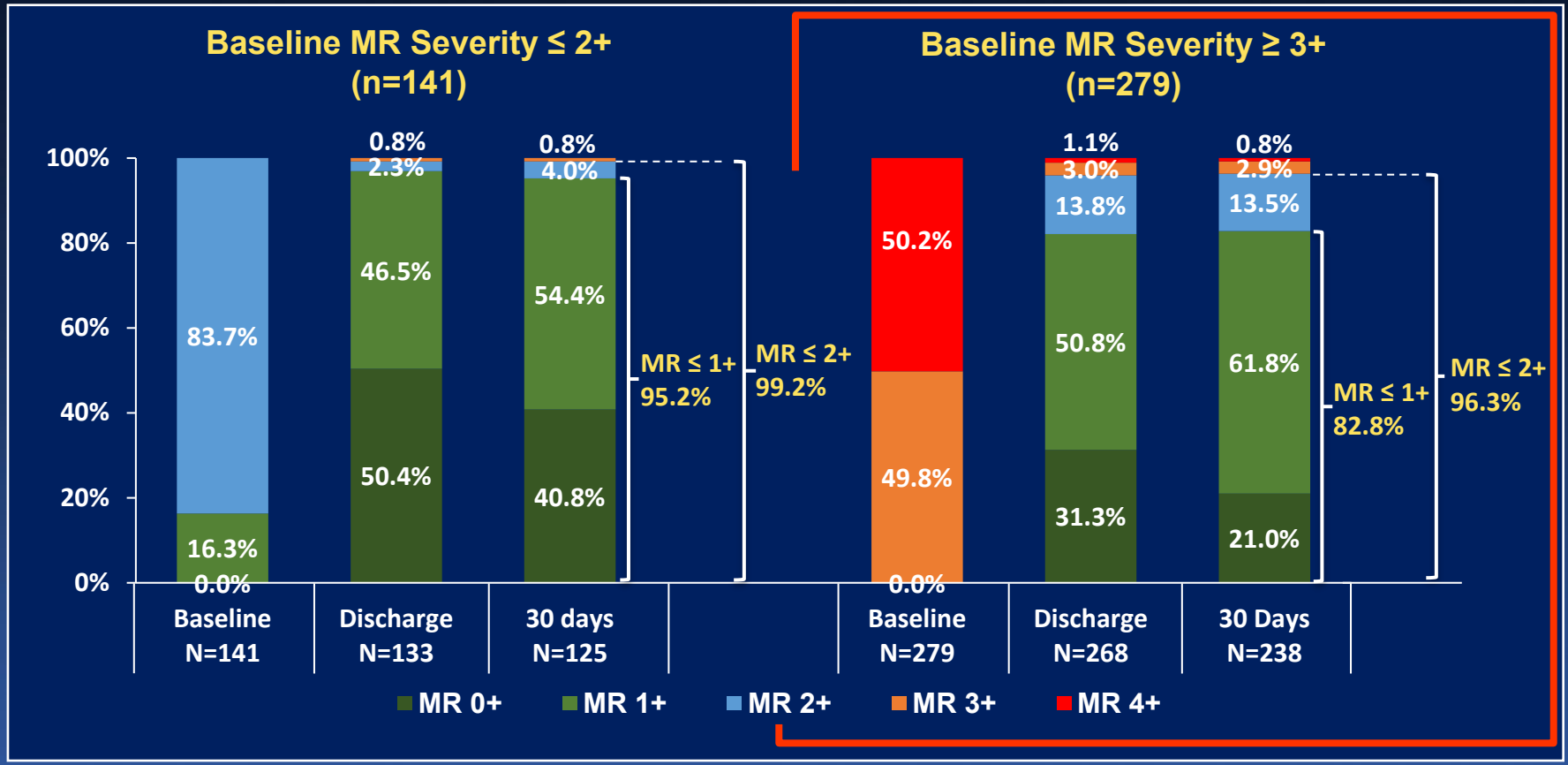
****Adjudication for 3 SLDA events were inconclusive due to missing echo images at the time of the panel review, and not included in the final adjudication results.***

ECL Adjudicated MR Severity

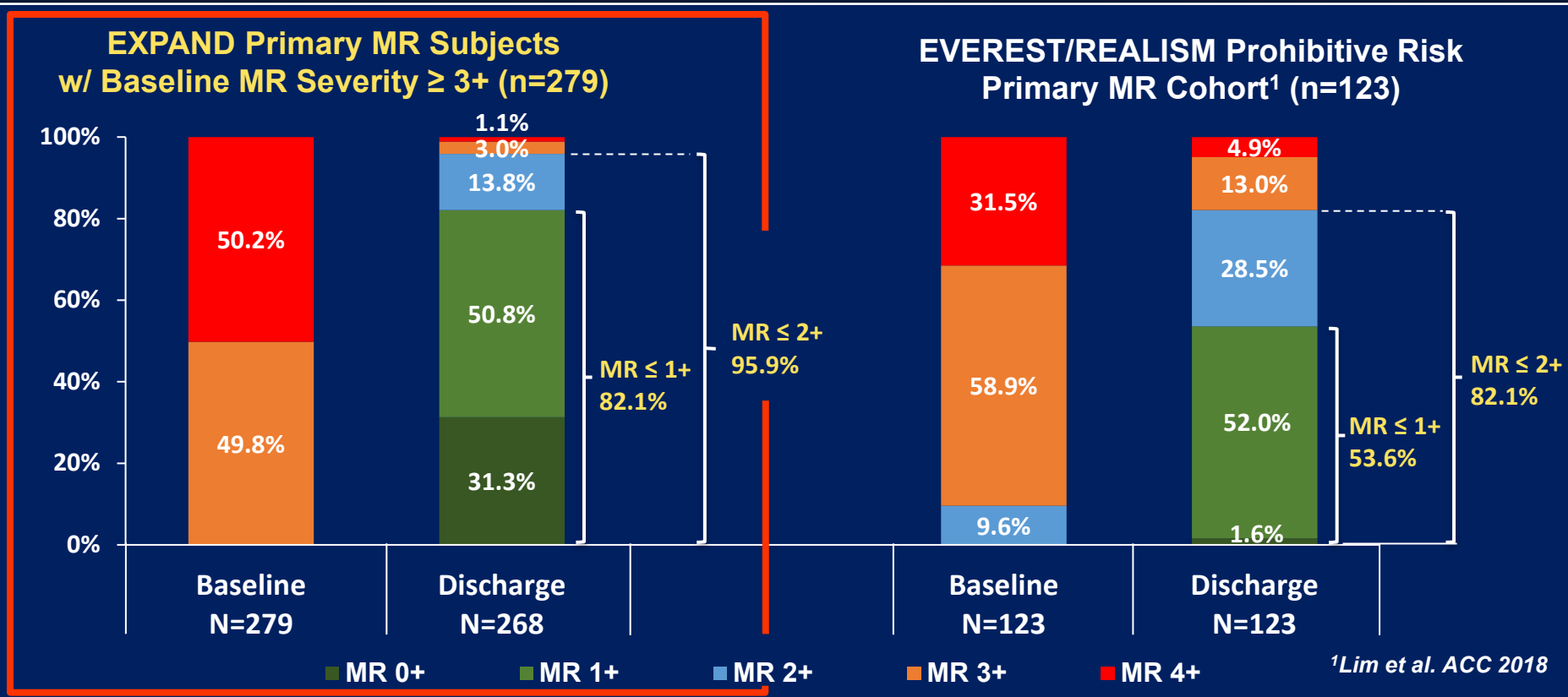


- MR Reduction to None/Trace was achieved in 27.7% of primary MR subjects; MR ≤ 1+ was achieved in 86.9% and MR ≤ 2+ was achieved in 97.3% at 30 days follow up.

ECL Adjudicated MR Severity – by Baseline MR



ECL Adjudicated MR Severity

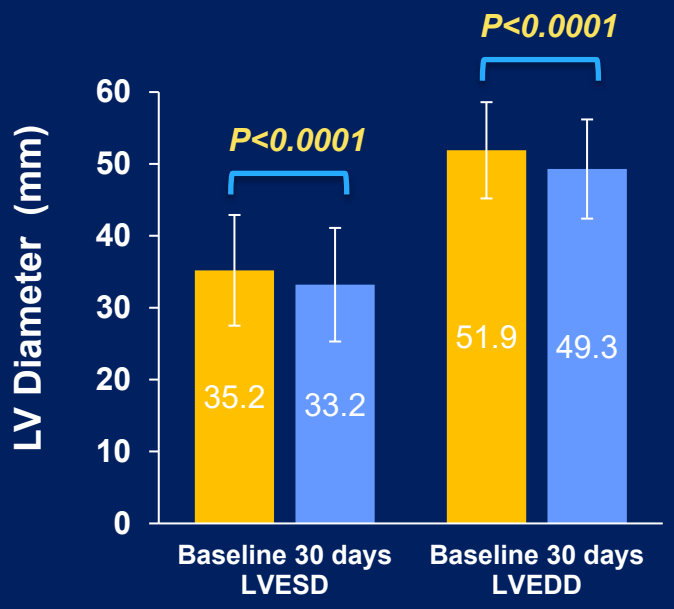


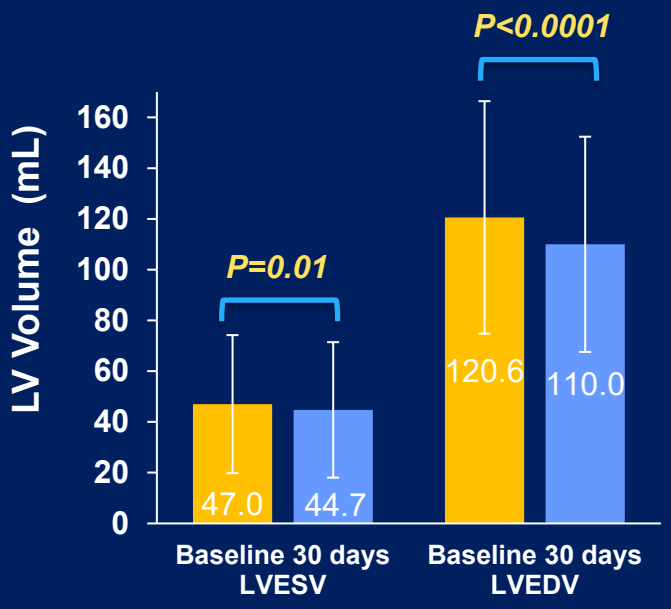
[1]Lim et al. ACC 2018

- ***MR Reduction to ≤ 1+ at 30 days was numerically greater in EXPAND compared to Prohibitive Risk Cohort from prior EVEREST studies (Same ECL and methodology used)***

LV Remodeling

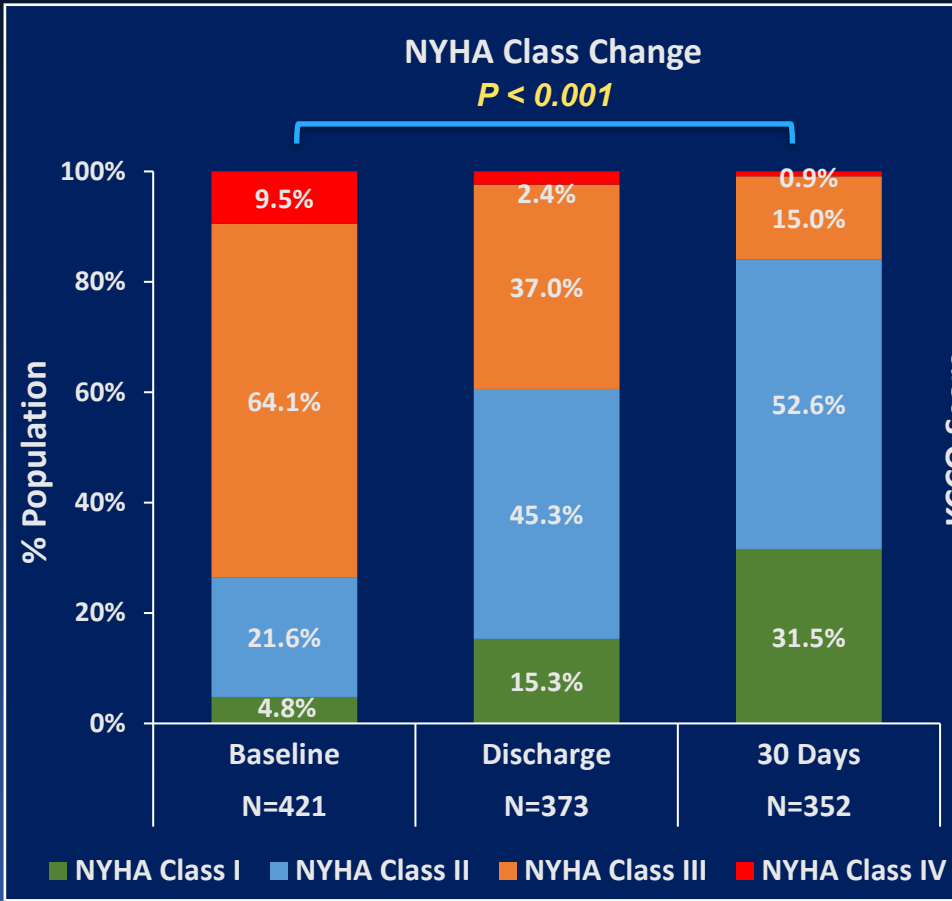
Left Ventricle Dimensions and Volumes at 30 Days vs. Baseline

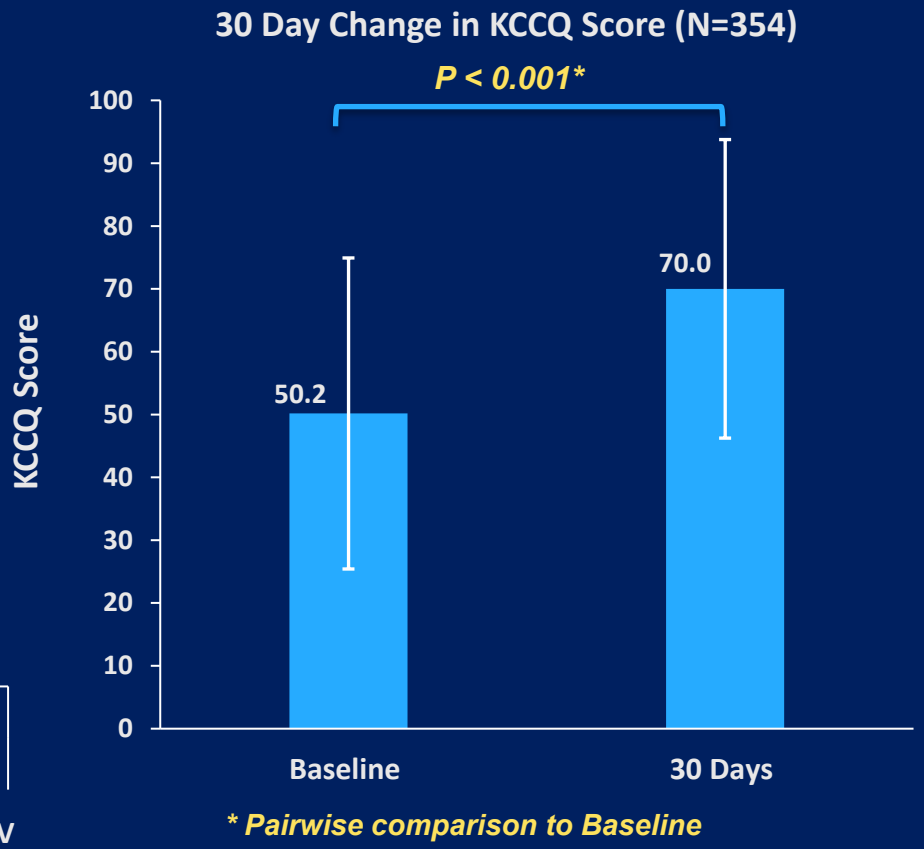




- *Early evidence of reduction in left ventricular dimensions and volumes; Larger, more clinically significant changes may be evident at longer term follow-up*

Quality of Life and Functional Capacity

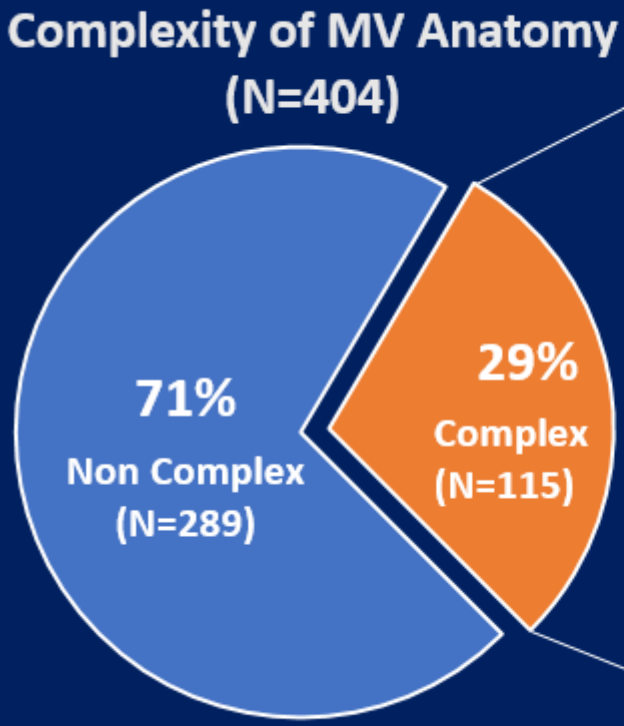




OUTCOMES STRATIFIED BY MITRAL VALVE ANATOMIC COMPLEXITY

ECHO CORE-LAB ASSESSMENT

ECL Adjudicated MV Complexity



MV Complexity Criteria	% of Complex Anatomies (N=115)
Primary jet outside of A2P2	**7.8% (9/115)**
Presence of more than one significant jet	0.9% (1/115)
Presence of an extremely wide jet	**29.6% (34/115)**
Small Valve	3.5% (4/115)
Calcification Landing Zone	**35.7% (41/115)**
Minimal leaflet tissue for attachment	5.2% (6/115)
Presence of severely degenerative leaflets or wide flail gaps or widths	**62.6% (72/115)**

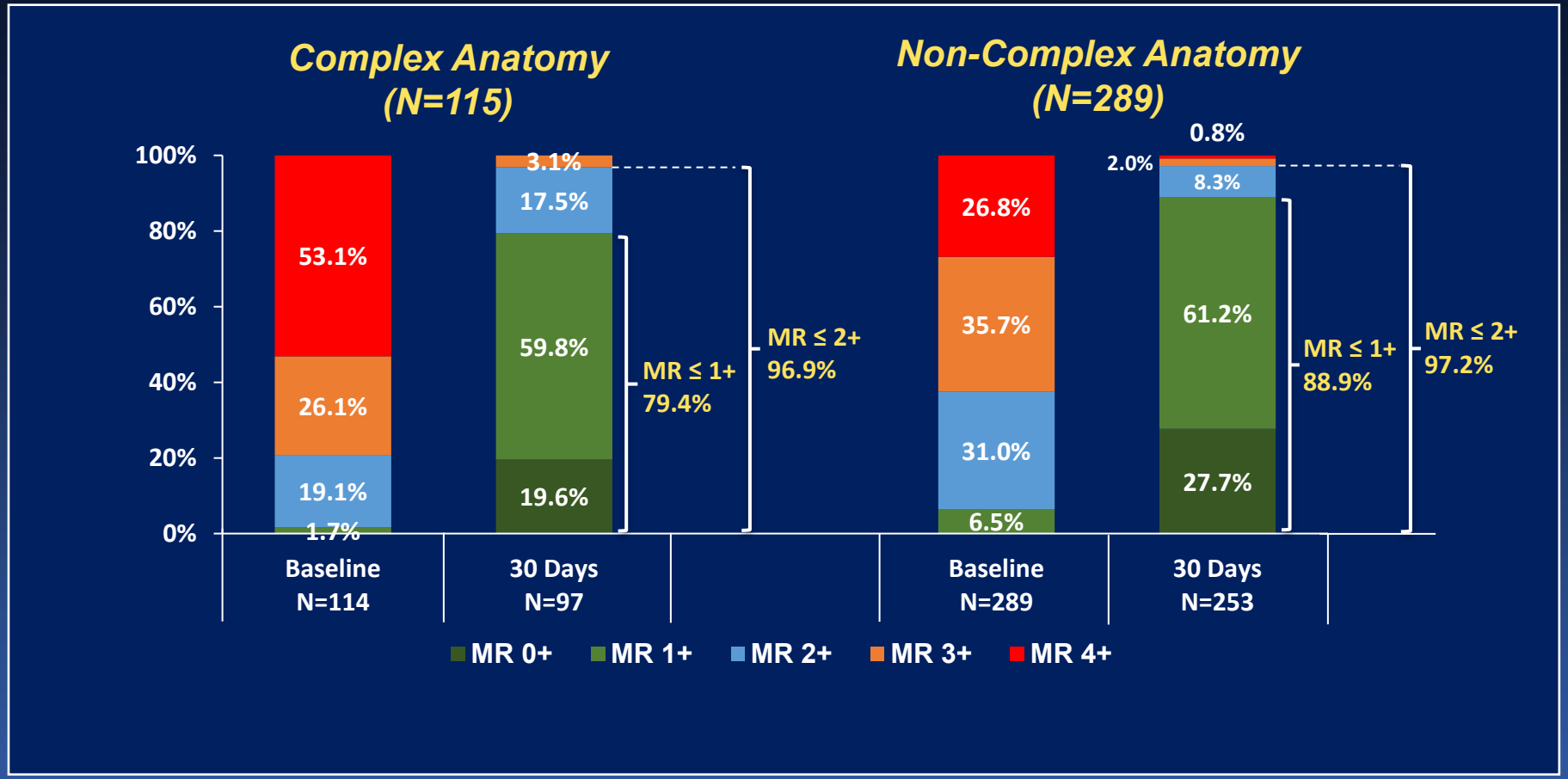
Baseline MR Severity by MV Complexity

Baseline MR Severity	Subjects with Complex Anatomies (N=115)	Subjects with Non-Complex Anatomies (N=289)
2+ or less[1]	20.9% (24/115)	**37.7% (109/289)**
3+ or higher[1]	**79.1% (91/115)**	62.3% (180/289)

- ***Subjects with complex anatomies had greater degrees of MR at baseline compared to subjects with non-complex anatomies***

[1]: p = 0.0011

MR Reduction – Complex vs. Non-Complex



NTR/XTR CLIP USE BASED ON MITRAL VALVE ANATOMIC MEASURES

ECHO CORE-LAB ASSESSMENT

MV Anatomic Complexity

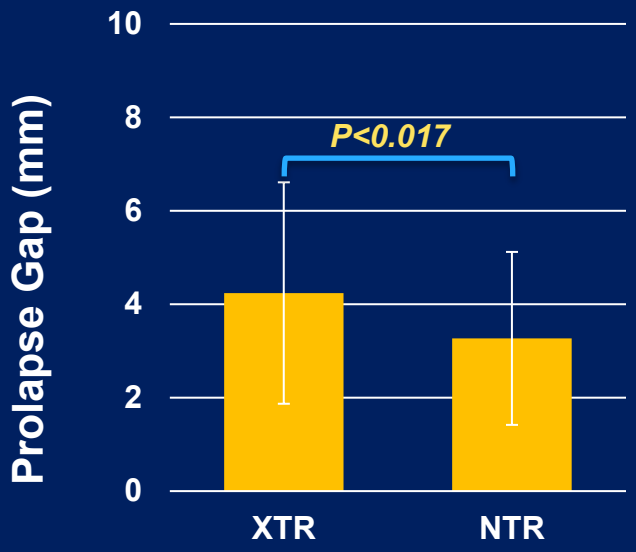
	XTR Only (N=194)	NTR only (N=146)	XTR and NTR (N=80)
Non-Complex (n=289)	71.8% (135/188)	72.8% (99/136)	68.7% (55/80)
Complex (n=115)	28.2% (53/188)	27.2% (37/136)	31.3% (25/80)

- ***Type of clip used was not different across subjects with non-complex vs. complex MV anatomies***

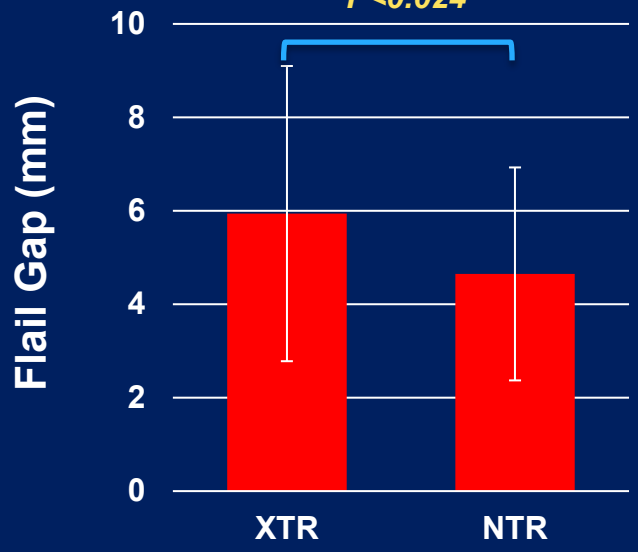
MV Anatomic Characteristics

XTR vs NTR Use

Prolapse Gap

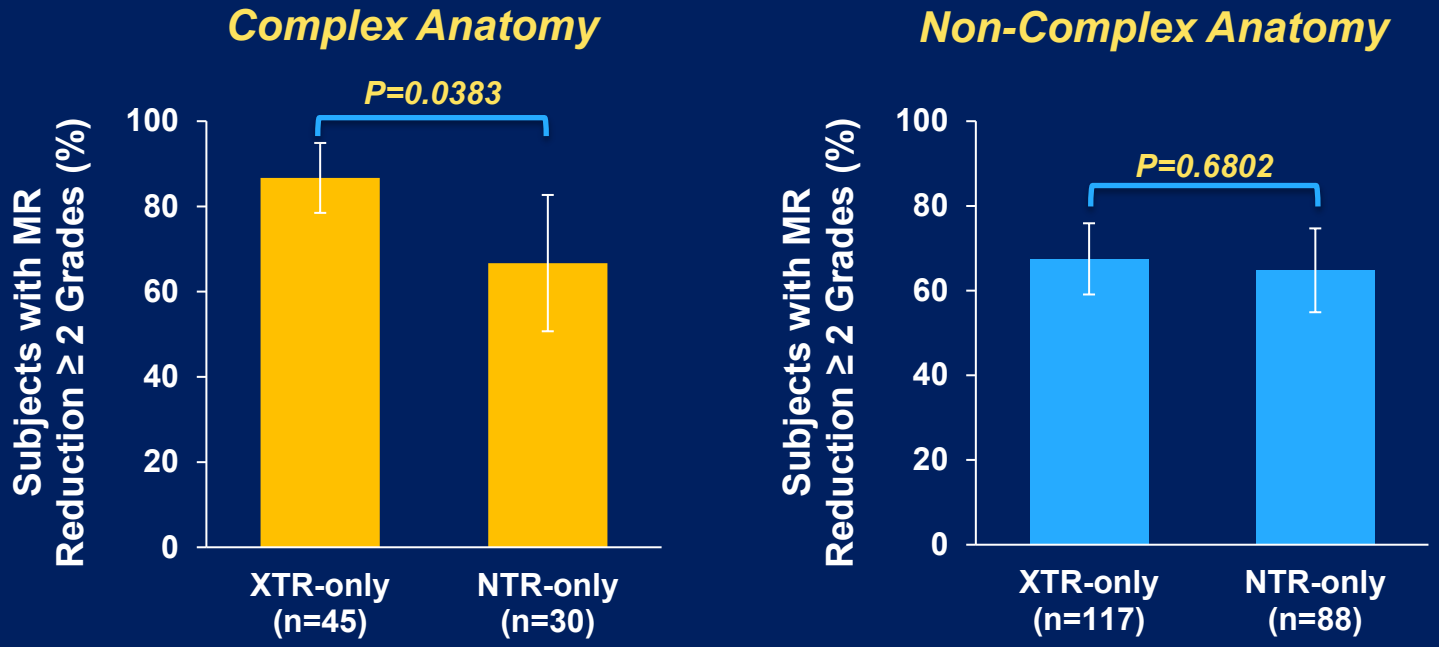


Flail Gap



- *XTR was more often used in subjects with larger prolapse/flail gaps*

30 day MR Reduction of ≥ 2 Grades



- *Greater MR reduction achieved using the XTR clip in Complex Anatomies (p = 0.0383)*

Limitations

- *Real world nature of the study results in variability in the quality of echocardiographic acquisitions and hence certain measurements were not available for all patients*
- *Enrollment was based on site interpretation of MR Severity rather than prospective core lab adjudication*
- *Only acute procedure outcomes presented; Longer term follow-up ongoing*

Conclusions

- This study represents the first contemporary report of ECL and CEC adjudicated 30 day clinical outcomes in patients with primary MR treated with the next generation NTR and XTR MitraClips
- Approximately one-third of patients had a complex mitral valve anatomy that reflects the difference in patients treated in the real world in comparison to past clinical trials.
- Results show that MR ≤ 1+ is being achieved more often with MitraClip™ NTR and XTR than previously observed in EVEREST II trials
- MitraClip™ XTR was associated with greater MR reduction compared to NTR, in more complex anatomies

Summary

- ***The EXPAND study confirms the safety and effectiveness of the next generation MitraClip NTR/XTR system in Primary MR patients in a contemporary, real-world setting***

Thank you

APPENDIX

Baseline Characteristics (ii)

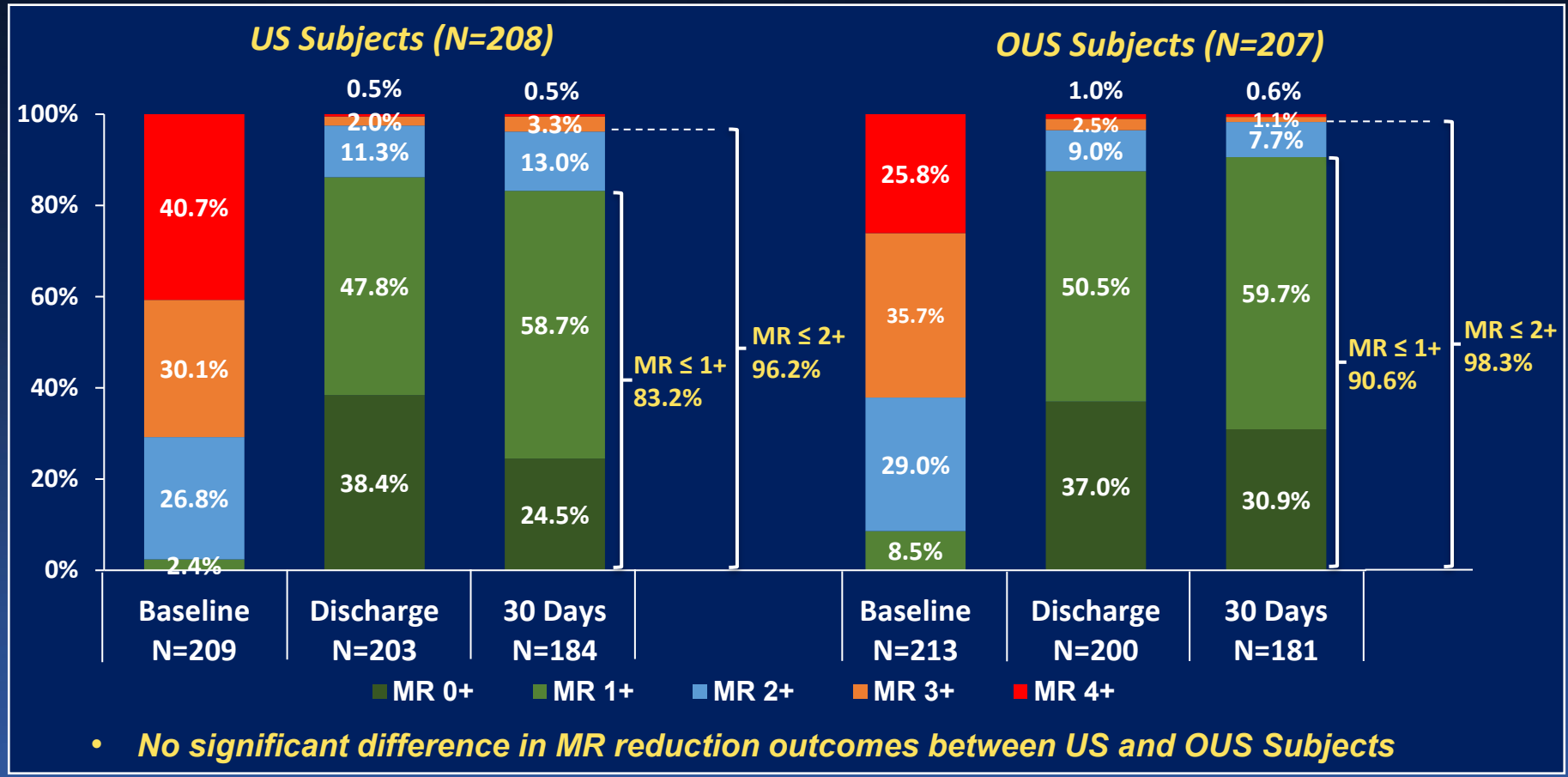
Prior Interventions	Value (N=422)
Permanent Pacemaker	12.1% (51/422)
Cardiac Resynchronization Therapy (CRT or CRT-D)	3.6% (15/422)
Intracardiac Defibrillation (ICD or CRT-D)	5.9% (25/422)
Prior Valve Procedure (Surgery or Transcatheter)	15.4% (65/422)
○ Prior Mitral Valve Procedure (Surgery or Transcatheter)	6.6% (28/422)
• Prior Surgical Mitral Valve Repair or Annuloplasty	3.3% (14/422)
• Prior Transcatheter Mitral Valve Repair**	3.3% (14/422)
○ Prior Aortic Valve Procedure (Surgery or Transcatheter)***	8.8% (37/422)
Prior Coronary Revascularization	30.8% (130/422)
○ Prior CABG	11.4% (48/422)
○ Prior PCI	24.7% (104/422)

** Continuous data presented as mean ± s.d.; Categorical data presented as a proportion of subjects where data was provided (missing data excluded)*

*** One subject with transcatheter repair also underwent a surgical procedure, and counted as one under surgery.*

****One subject had both prior aortic and mitral valve procedures, and counted as one under mitral repair.*

ECL Adjudicated MR Severity – US vs. OUS



- *No significant difference in MR reduction outcomes between US and OUS Subjects*

ECL Adjudicated Baseline Echo Parameters – Mean ± SD, Range

Effective Regurgitant Orifice Area (EROA, cm^2)	Mean ± SD (n) Range (Min, Max)	0.40 ± 0.21 (282) (0.06, 1.52)
Mean Mitral Gradient (mean MVG, mmHg)	Mean ± SD (n) Range (Min, Max)	2.47 ± 1.36 (323) (0.38, 10.89)
Left Ventricular Ejection Fraction (LVEF, %)	Mean ± SD (n) Range (Min, Max)	62 ± 10 (390) (15.44, 81.63)
Left Ventricle End Systolic Diameter (LVESD, mm)	Mean ± SD (n) Range (Min, Max)	35.4 ± 7.7 (401) (20.9, 62.5)
Left Ventricle End Diastolic Diameter LVEDD, mm)	Mean ± SD (n) Range (Min, Max)	52.0 ± 6.6 (403) (35.6, 79.2)
Left Ventricle End Systolic Volume (LVESV, mL)	Mean ± SD (n) Range (Min, Max)	47.9 ± 30.4 (390) (11.89, 278.49)
Left Ventricle End Diastolic Volume (LVEDV, mL)	Mean ± SD (n) Range (Min, Max)	121.0 ± 48.6 (390) (41.25, 376.61)

Length of Stay – US vs. OUS

	US Subjects (N=209)	OUS Subjects (N=213)
Length of Stay in Hospital for Index Procedure (days)		
Mean ± SD (n)	2.7 ± 3.5 (209)	8.0 ± 6.9 (213)
Median [Inter-Quartile Range]	1.0 (1.0, 3.0)	6.0 (4.0, 9.0)

- ***Longer length of stay is reported for OUS subjects compared to US (p<0.0001)***

30 Day MAE* vs. Previous Trials

RISK COHORT DATA ADDED

	Prohibitive Risk Primary MR Cohort[1] (N=127)	EVEREST II HRR[2] (N=78)	EVEREST II REALISM[3] (N=628)	EXPAND Primary MR (N=420)
All-cause Death	6.3% (8)	7.7% (6)	4.1% (26)	**2.4% (10)**
Myocardial Infarction	0.8% (1)	2.6% (2)	0.5% (3)	**0.0% (0)**
Peri-procedural MI	NA	0.0% (0)	0.0% (0)	0.0% (0)
Spontaneous MI	NA	1.3% (1)	0.5% (3)	0.0% (0)
Stroke	2.4% (3)	2.6% (2)	2.1% (13)	**1.2% (5)**
Ischemic	NA	2.6% (2)	NA	1.0% (4)
Hemorrhagic	NA	0.0% (0)	NA	0.2% (1)
Non-elective CV surgery for device-related complications	0.8% (1)	0.0% (0)	1.3% (8)	0.9% (4)

[1]Lim et al. Prohibitive Risk Cohort. ACC 2018,
[2]Whitlow et al. EVEREST II HRS. JACC 2012,
[3]Feldman et al. REALISM HR data. EuroPCR 2015

**CEC Adjudicated*

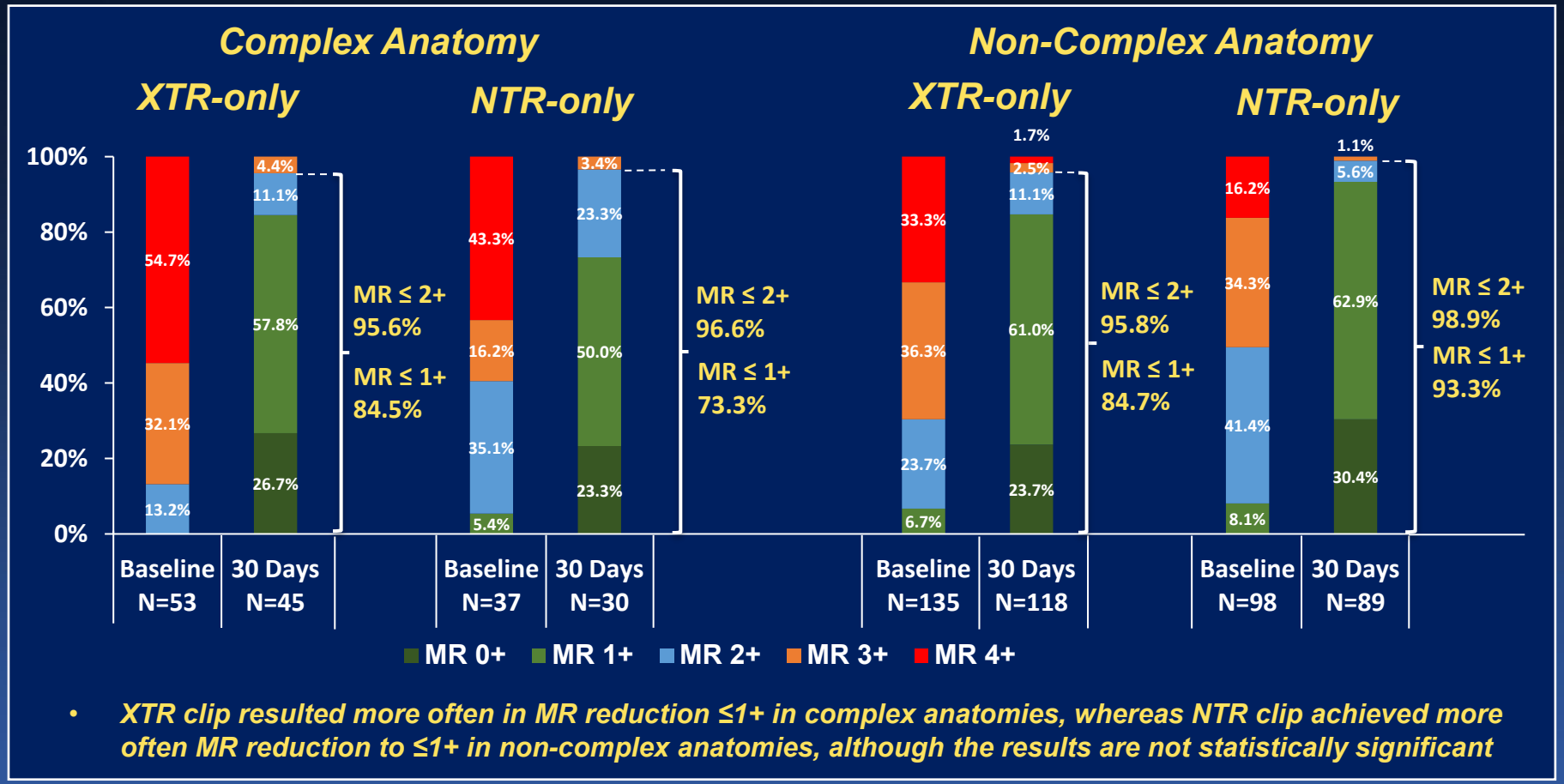
MV Anatomic Complexity / TTE

	XTR Only (N=194)	NTR only (N=146)	XTR and NTR (N=80)	P-value
Primary jet outside of A2P2	4/53 (7.5%)	1/37 (2.7%)	4/25 (16.0%)	0.160[1]
Presence of more than one significant jet	1/53 (1.9%)	0/37 (0.0%)	0/25 (0.0%)	1.000[2]
Presence of a wide jet	16/53 (30.2%)	8/37 (21.6%)	10/25 (40.0%)	0.296[1]
Small Valve	1/53 (1.9%)	2/37 (5.4%)	1/25 (4.0%)	0.683[2]
Calcification Landing Zone	**11/53 (20.8%)**	**20/37 (54.1%)**	**10/25 (40.0%)**	**0.005[1]**
Minimal leaflet tissue for attachment	5/53 (9.4%)	1/37 (2.7%)	0/25 (0.0%)	0.260[2]
Presence of severely degenerative leaflets or wide flail gaps or widths	**39/53 (73.6%)**	**17/37 (45.9%)**	**16/25 (64.0%)**	**0.028[1]**

- **For primary MR subjects with complex MV anatomy:**
  - **Calcification Landing Zone and Presence of severely degenerative leaflets or wide flail gap are statistically different across the three groups of device use**
  - **More subjects with NTR have Calcification Landing Zone**
  - **More subjects with XTR present severely degenerative leaflets or wide flail gaps**

1: Pearson's Chi-square test
2: Fisher's exact test

30 Day MR Severity XTR vs. NTR



- *XTR clip resulted more often in MR reduction ≤1+ in complex anatomies, whereas NTR clip achieved more often MR reduction to ≤1+ in non-complex anatomies, although the results are not statistically significant*

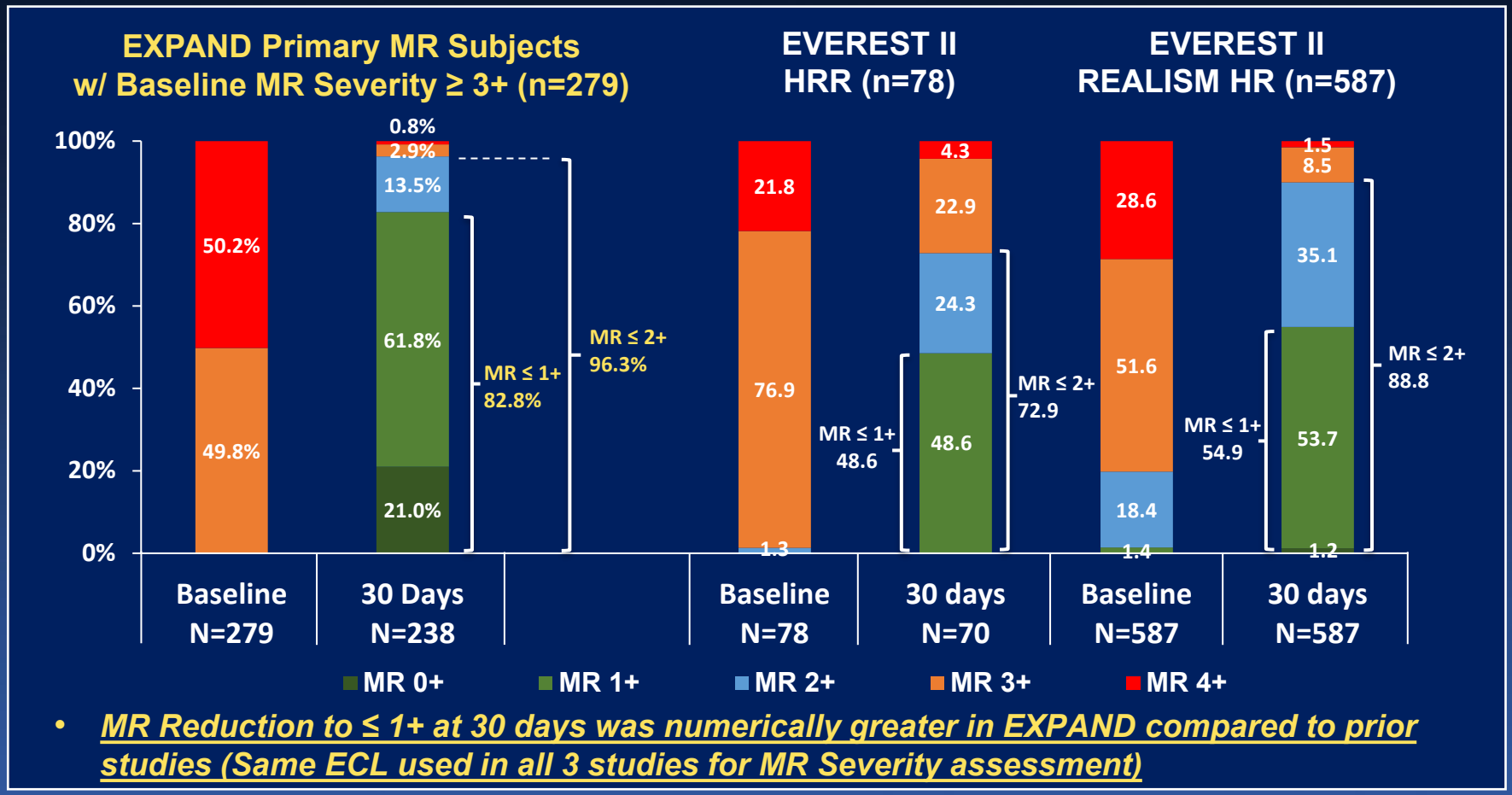
Procedural Outcomes vs. Previous Trials

	EXPAND PRIMARY MR	EVEREST II HRR[1]	EVEREST II REALISM[2]	TVT Registry[3]
Implant Rate % (n/N) [95% Confidence Interval]	99.5% (420/422) [98.3%, 99.9%]	96.2% (75/78)	96.0% (603/628)	NA
Acute Procedural Success (APS)* % (n/N) [95% Confidence Interval]	**94.5% (396/419)** [91.9%, 96.5%] (ECL)	71.8% (56/78) (ECL)	84.8% (518/611) (ECL)	91.8% (2,709/2,952) Site-Reported
Device Time (min) Median [Inter-Quartile Range]	48.0 [33.0-76.0]	NA	94.0 [NA]	NA
Fluoroscopy Time (min) Median [Inter-Quartile Range]	18.0 [11.3-27.0]	NA	33.0 [NA]	NA
Procedure Time (min) Median [Inter-Quartile Range]	82.0 [53.0- 120.0]	NA	126.0 [NA]	NA
Length of Stay in Hospital for Index Procedure (days) Median [Inter-Quartile Range]	1.0 [1.0-3.0] (US)	2.0 [NA]	2.0 [NA]	2.0 [1.0–5.0]

APS defined as successful implantation of the MitraClip® device with resulting MR severity of 2+ or less on discharge Echocardiogram (30-day echocardiogram is used if discharge is unavailable or uninterpretable). Subjects who die or undergo mitral valve surgery before discharge are considered to be an APS failure

[1]Whitlow et al. EVEREST II HRS. JACC 2012
[2]Feldman et al. REALISM HR data. EuroPCR 2015
[2]Sorajja et al. J Am Coll Cardiol 2017;70:2315–27)

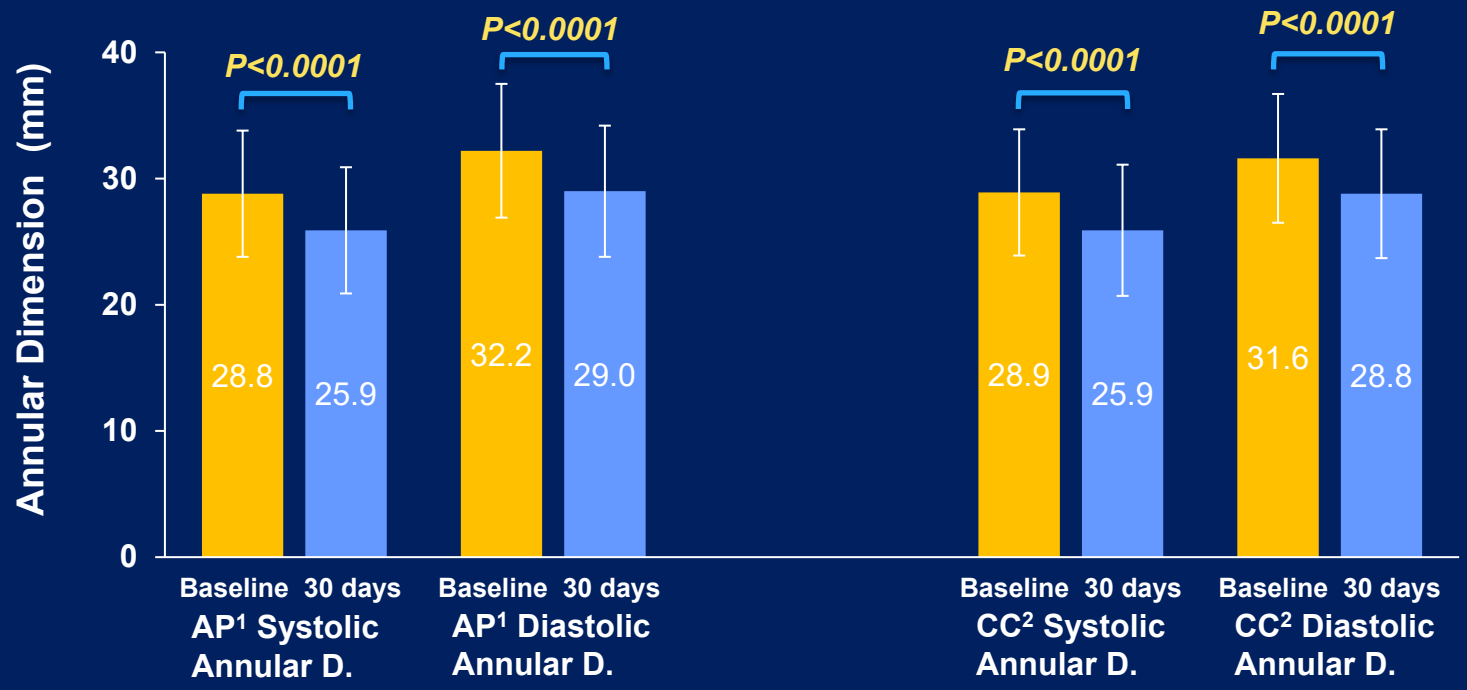
ECL Adjudicated MR Severity



- ***MR Reduction to ≤ 1+ at 30 days was numerically greater in EXPAND compared to prior studies (Same ECL used in all 3 studies for MR Severity assessment)***

Mitral Valve Remodeling of the Annulus

Mitral Valve Annular Dimensions at 30 Days vs. Baseline

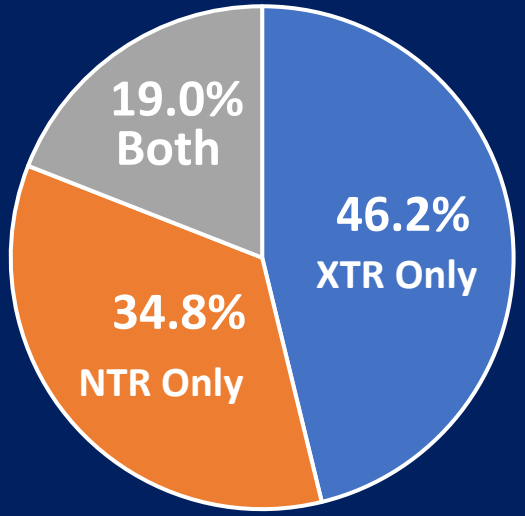


- ***Significant reduction in annular dimensions within 30 days of treatment***

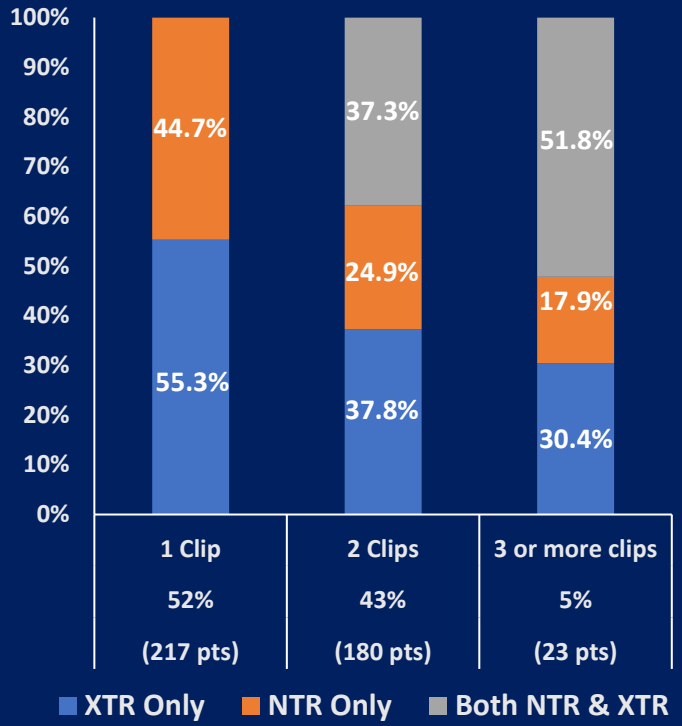
[1]AP: Anterior Posterior
[2]CC: Commissure to Commissure

MitraClip Use in Subjects w/ Primary MR

Clip Size Use in Primary MR



Clip Size Use by # of Clips



- ***XTR was used more frequently to treat primary MR compared to NTR (p < 0.0001)***

Mitral Gradients (ECL Adjudicated) by MitraClip Size

	XTR Only (N=194)	NTR only (N=146)	XTR and NTR (N=80)	Total (N= 420)
Pre Procedure Mitral Gradient, mmHg	2.51 ± 1.35 (145)	2.31 ± 1.22 (121)	2.71 ± 1.62 (57)	2.48 ± 1.40 (318)
Discharge Mitral Gradient, mmHg	3.48 ± 1.92 (173)	3.96 ± 1.81 (124)	4.02 ± 1.68 (73)	3.75 ± 1.87 (363)
30 day Mitral Gradient, mmHg	3.51 ± 1.69 (156)	3.89 ± 1.89 (121)	3.99 ± 1.82 (66)	3.74 ± 1.79 (337)
1 Clip Only	61.9% (120/194)	66.4% (97/146)	0.0% (0/80)	51.7% (217/420)
2 Clips	34.5% (67/194)	30.8% (45/146)	85% (68/80)	42.9% (180/420)
3+ Clips	3.6% (7/194)	2.7% (4/146)	15% (12/80)	5.0% (21/420)

- ***Pre-procedure gradient was not different across clip type groups (P =0.17)***
- ***MitraClip XTR was not associated with increased mitral valve gradient post procedure compared to MitraClip NTR.***