

The MitraClip Asia-Pacific Registry (MARS): Update

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National Heart
Centre Singapore
SingHealth

MARS Registry



- Asia-Pacific MitraClip Registry
- Retrospective registry
- Feb 2011- 2014



MARS Registry

- 8 centers
- 5 countries (Singapore, Malaysia, Australia, Indonesia, China)
- Clinical, imaging and follow-up data obtained by respective sites

Current Sites

- Australia
 - Sir Charles Gairdner Hospital, Perth
 - St Vincent's Hospital, Sydney
 - Prince Charles Hospital, Brisbane
- Malaysia
 - Institut Jantung Negara
- Singapore
 - National Heart Centre Singapore
 - National University Heart Centre
- Indonesia
 - Medistra Hospital, Jakarta
- China
 - Second Affiliated Hospital, Zhejiang

Patient Selection

- MR $\geq 3+$
- Underwent MitraClip procedure
- Multidisciplinary team approach and guidelines

Efficacy Outcomes

- 1^o outcome: MR \leq 2+ at 30 days.
- 2^o outcomes
 - Acute procedural success
 - NYHA Class
 - Echo parameters
 - QoL scores

Safety Outcomes

- 30-day mortality
- Stroke, MI, Bleeding requiring >1 unit of blood transfusion, septicaemia, non-elective cardiac surgery, renal failure, ventilation for >48 hours and new-onset AF

Echo Parameters

- MR severity
- LVEDD
- LVESD
- LV volumes
- LA diameters and volumes
- Right heart parameters

Common Data Collection Forms

MARS Clinical Data Form 25 Mar 2013

Hospital: _____ Patient ID: _____

MitraClip Data Collection Form

Date Of Birth: / /

(dd / mm / yyyy)

Gender: Male Female

Race: Chinese Malay Indian Eurasian

Others : _____

Date Of Admission: / /

(dd / mm / yyyy)

Date Of Admission: / /

(dd / mm / yyyy)

Weight: Kg

Height: cm

Past Medical History

Diabetes Mellitus: Yes No UKN

If yes, Diet control Medical Therapy Insulin Requiring

Smoker: Smoker Non-smoker Ex-smoker- since: _____

Hypertension: Yes No UKN

Congestive Heart Failure: Yes No UKN

If yes, no of admissions in last 1 year: _____

Peripheral Vascular Disease: Yes No UKN

Dialysis: Yes No UKN

Chronic Pulmonary Disease: Yes No UKN

Hyperlipidemia: Yes No UKN

Atrial Fibrillation: Yes No UKN

Chronic Lung disease: Yes No UKN

History Of Valve Operation: Yes No If yes, please specify: _____

Prior CVA: Yes No UKN

Prior CAD: Yes No UKN

Prior PCI : Yes No UKN

Prior CABG: Yes No UKN

Prior MI: Yes No UKN

MARS Clinical Data Form 25 Mar 2013

Hospital: _____ Patient ID: _____

Clinical Presentation

Baseline NYHA Class: I II III IV

Initial SBP: / mmHg

Logistic EuroSCORE: _____ %

EuroSCORE II: _____ %

STS score: _____

Baseline MLHF: _____

Baseline AqoL-6D: _____

Baseline EQ-5D: _____

Baseline 6 min walk test: _____ m

Laboratory Tests

Creatinine: Done Not Done mg/dl

Hemoglobin: Done Not Done g/dl

BNP: Done Not Done pg/ml

Pre-procedure

Date Of Procedure: / /

(dd / mm / yyyy)

Pre-procedure location: Outpatient Floor ICA/HD ICU

Venous access closure method: Manual pressure PerClose Cut-down stitch

Procedure start time (start of transseptal access): : (24 hour clock)

Time septum crossed (end of transseptal access): : (24 hour clock)

Clip procedure start time (time of Guide Catheter placement): : (24 hour clock)

Clip Procedure end time: (Guide removal from femoral vein) : (24 hour clock)

Total Fluoroscopy Duration: (minutes)

Blood products required: _____ Type and number of units in ml: _____

Common Data Collection Forms

MARS Echo Form 25 Mar 2013

Hospital: _____

Patient ID: _____

Baseline TTE

Date: _____

MV and LV Parameters	Other Parameters
Mitral Regurgitation Severity (1+,2+,3+,4+)	Aortic Valve Area (cm ²)
Vena Contracta width (cm)	Aortic Valve mean gradient (mmHg)
MR Volume (ml)	Aortic Regurgitation (1+,2+,3+,4+)
MR fraction	Tricuspid Regurgitation (1+,2+,3+,4+)
MR orifice area (cm ²)	PASP (mmHg)
Mitral valve MPG (mmHg)	TR Peak Velocity (m/s)
Mitral valve orifice area (cm ²)	TAPSE (cm)
Mitral Annular Calcifications (Nil, Mild, Moderate, Severe)	RA Major (cm)
Mitral Annulus Diameter (cm)	RA Minor (cm)
LVEF (%)	RV End Diastolic Diameter (cm) (at base)
LV End Diastolic Diameter (cm)	RV End Diastolic Diameter (cm) (at mid)
LV End Systolic Diameter (cm)	RV End Diastolic length (cm)
LV End Diastolic Volume (indexed) (ml/m ²)	Tricuspid annulus diameter (cm)
LV End Systolic Volume (indexed) (ml/m ²)	Degenerative TR (yes/no)
LA Major (cm)	Functional TR (yes/no)
LA Minor (cm)	
LA volume (indexed) (ml/m ²)	

MARS Echo Form 25 Mar 2013

Hospital: _____

Patient ID: _____

Baseline TEE

Date: _____

Parameters	Functional MR
Mitral Regurgitation Severity (1+,2+,3+,4+)	MV coaptation depth (cm)
Vena Contracta width (cm)	MV coaptation length (cm)
MR Volume (ml)	
MR fraction	
MR orifice area (cm ²)	Degenerative MR
Mitral valve MPG (mmHg)	Prolapse (Nil, Ant, Post, Bileaflet)
Mitral valve orifice area (cm ²)	Barlow's present (yes/no)
Thrombus Mass (yes/no)	Flail (Nil, Ant, Post, Bileaflet)
	Flail Gap (cm)
	Flail Width (cm)

Type of MR: Functional (Ischemic) Functional (Non Ischemic) Degenerative
(tick more than one if more apply)

Immediate Post Procedure TEE

Date: _____

Parameters
Mitral Regurgitation Severity (1+,2+,3+,4+)
Mitral valve MPG (mmHg)

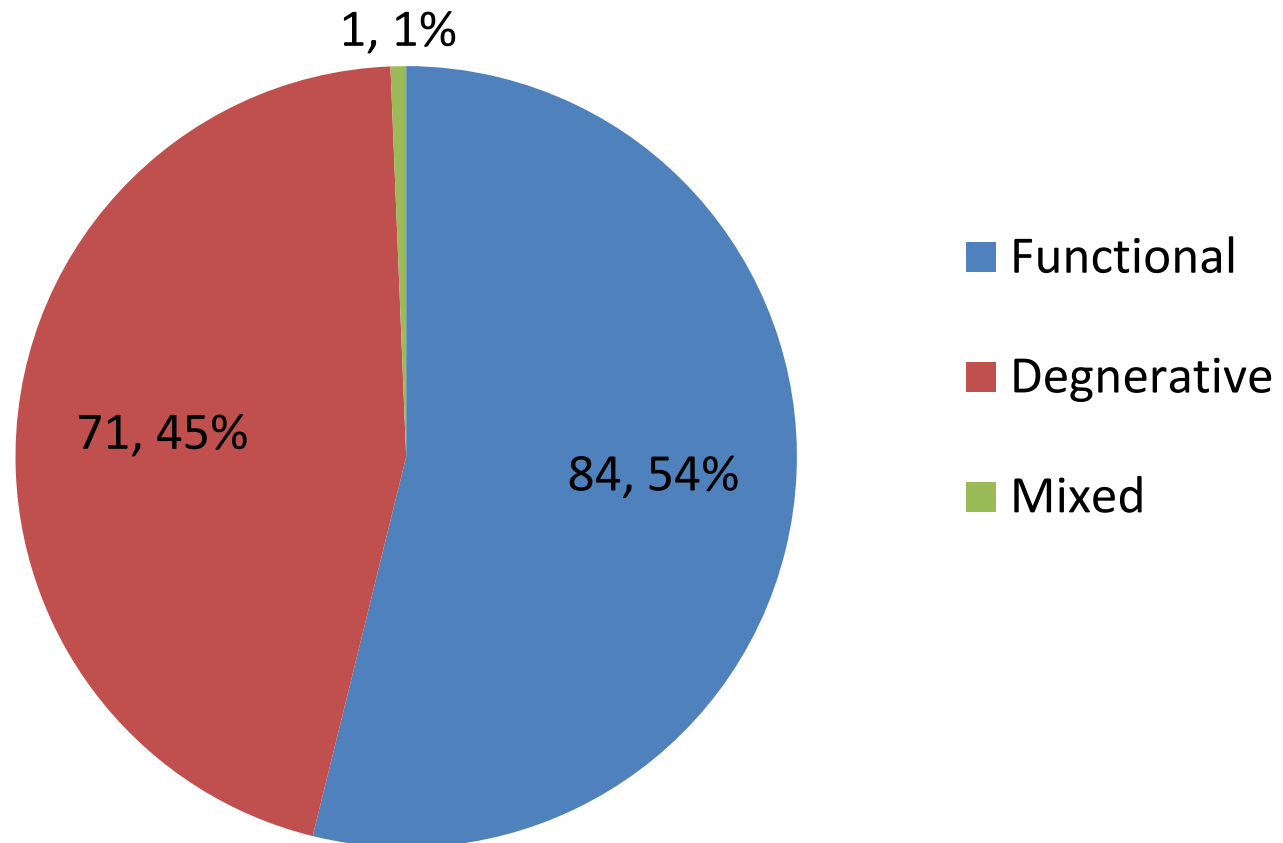
Study Population

- 159 patients recruited
 - 156 with MitraClip deployed
 - 3 excluded (1 Chiari network, 1 inability to grasp leaflet, 1 fractured actuator knob)
- Singapore (2 centres, n=69), Australia (3 centres, n=49), Malaysia (n=23), Indonesia (n=9), China (n=6)

Baseline Characteristics

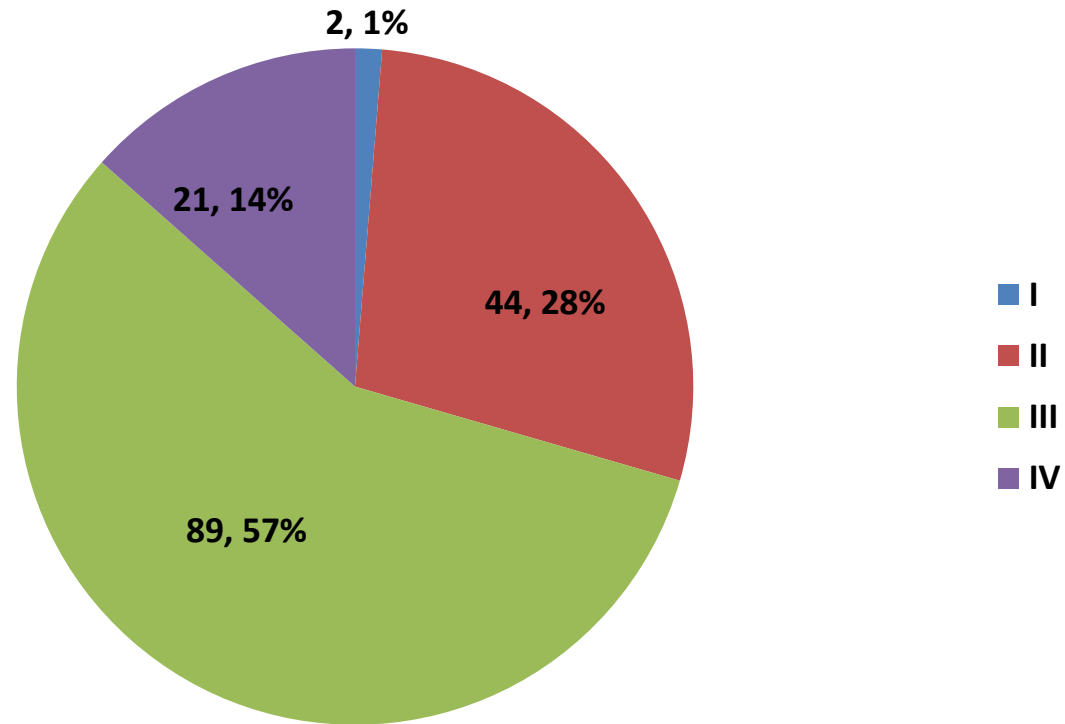
	Patients (n=156)
Age, yr (SD)	71 (12)
Male	103 (66%)
BMI (SD)	24.7 (4.7)
DM	46 (30%)
Hypertension	98 (63%)
Hyperlipidemia	87 (56%)
COPD	18 (12%)
Prev CVA	19 (12%)
IHD	96 (62%)

Type of MR



Functional Status

NYHA Class



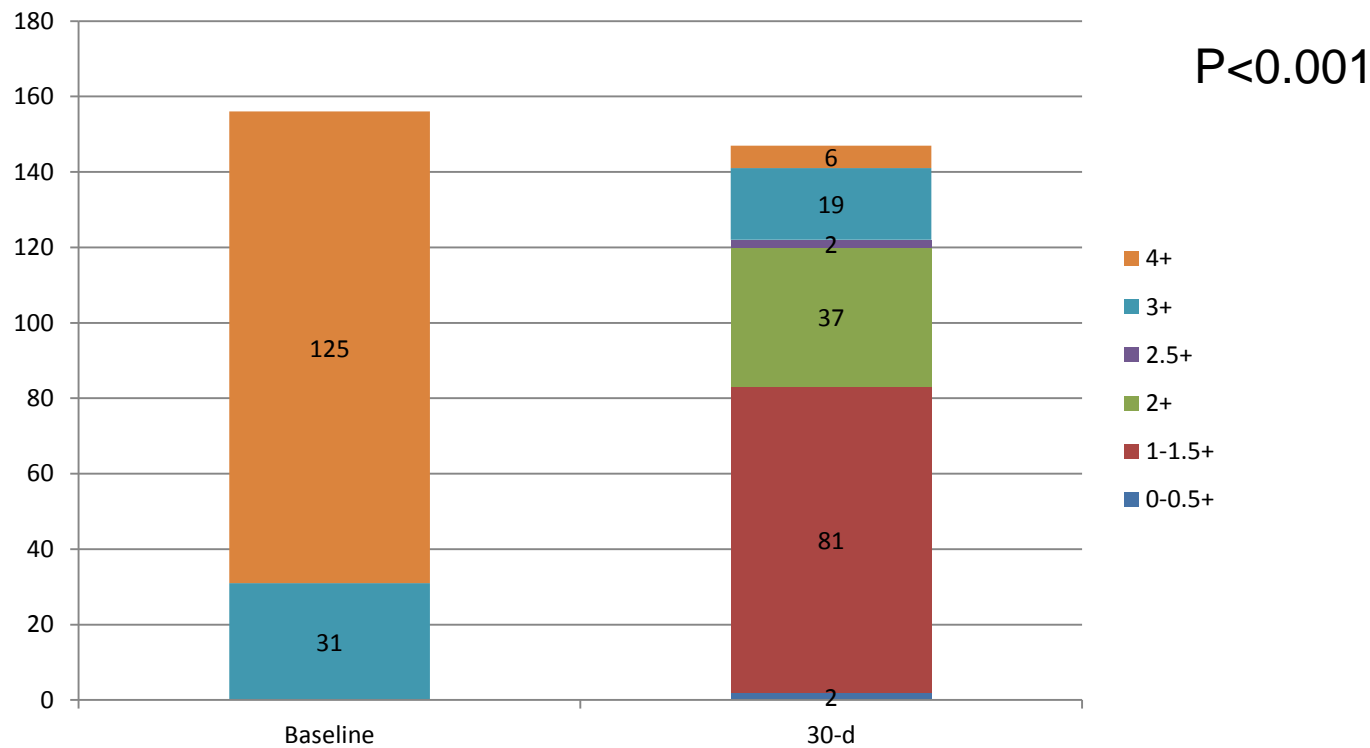
- 6MWT (n=94)
 - 303 ± 147 m

Procedural Results

- Acute procedural success
 - 93.6% (146/156)
 - 6 SLA, 1 torn chord, 1 difficulty grasping leaflet, 1 MR 3+
- 49.3% (n=77) one clip
- 46.2% (n=72) two clips
- 4.5% (n=7) three clips
- Procedural Time: 130 ± 98 min
- Hospital stay: 6.5 ± 8.4 days

Primary Efficacy Outcome

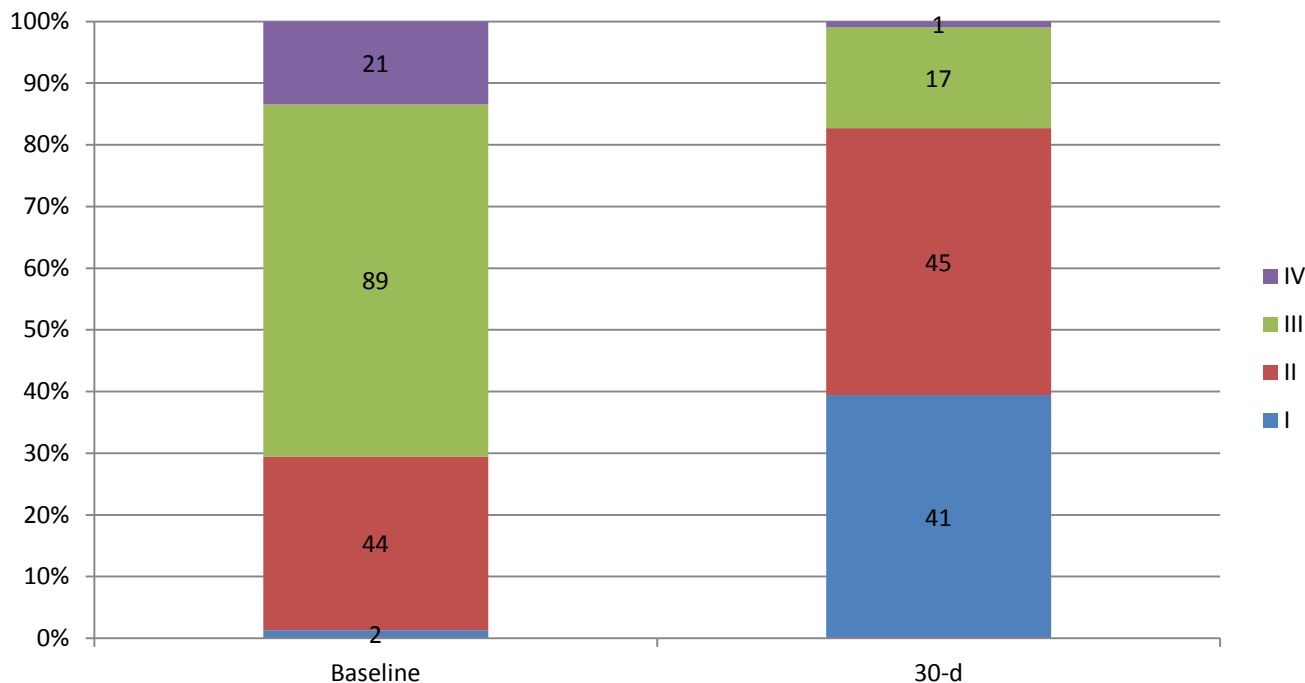
- 30-d MR $\leq 2+$
 - 76.9 % (120/156)



Echocardiographic parameters

	Baseline	30-d	n	p value
LVEDD (SD)	6.0 (1.0)	5.7 (1.1)	139	<0.001
LVESD(SD)	4.5 (1.2)	4.3 (1.3)	134	<0.001
LVEF (SD)	47 (16)	46 (17)	134	0.048
PASP (SD)	45 (20)	41 (16)	136	0.011

30-d NYHA Class



- 82.7% NYHA I-II at 30days vs 29.5% at baseline
($p < 0.001$)

Primary Safety Outcomes

- 30-d mortality rate
 - 5.8% (n=9)

- 30-d MACE rate
 - 12.8% (n=20)
 - 1 MV surgery, 5 blood transfusion, 2 sepsis, 1 prolonged intubation, 2 heart failure admissions

Conclusion

- Early experience
- Learning curve
- MitraClip is a safe and efficacious therapy in MR patients in the Asia-Pacific

MARS: Site PIs

- Australia
 - Eric Yamen, Sir Charles Gairdner, Perth
 - David Muller, St Vincent's Hospital, Sydney
 - Darren Walters, Prince Charles Hospital, Brisbane
- Malaysia
 - Nasir Muda, Institut Jantung Negara
- Singapore
 - KK Yeo, National Heart Centre Singapore
 - Edgar Tay, National University Heart Centre
- Indonesia
 - Teguh Santoso, Medistra Hospital, Jakarta
- China
 - Xianbao Liu, Second Affiliated Hospital, Zhejiang

Publications: EuroInterventions

Percutaneous mitral valve repair with the MitraClip: early results from the MitraClip Asia-Pacific Registry (MARS)

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Future plans

- Rotating 1st authorship
- Establishment of echocardiography Core-lab
- Addition of further sites: Australia, New Zealand, Indonesia, Malaysia, China, Brunei, Korea, Japan, Hong Kong, India
- Bodes well for regional collaboration