MitraClip
Who is it for?
How is it guided?

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Echo Hawaii 2020

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Disclosure Statement

No personal COI

Institutional

MedStar Health has Institutional contracts for my work as Director of an Academic Core Lab:

Abbott, Boston Scientific, Edwards, Medtronic, Neovasc, Livanova, GDS, Mitralign.

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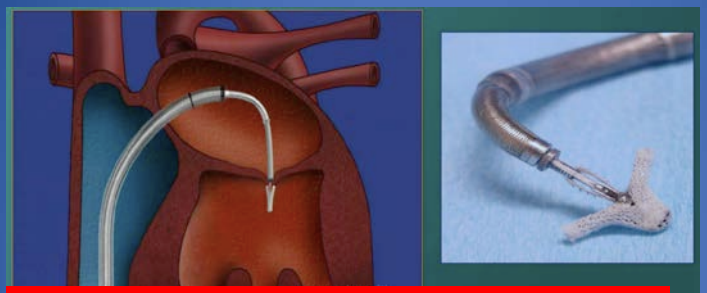
Abbott's MitraClip



FDA approved for inoperable DMR, FMR patients
10/2013 and 4/2019

Evalve clip repair in porcine heart (6 mos post repair)

Circulation 2003, 108:(Supp IV) 493.

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Eligibility Criteria for MitraClip

1) Moderate to Severe or Severe MR

2) Anatomy suitable for MitraClip?

RED LIGHTS:

- **Commisural jets**
- **Multiple, wide jets**
- **Minimal coaptation**
- **Ca++ or cleft at grasping area**
- **Severely degenerated leaflets (RHD, Rx, IE)**
- **MVA < 4 cm2**

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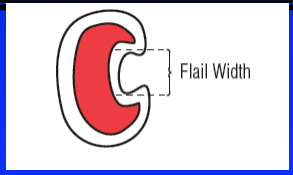
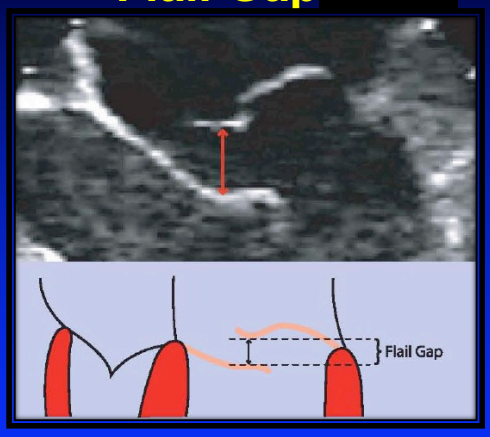
Degenerative MR

Flail Width <15 mm



Flail Gap <10 mm



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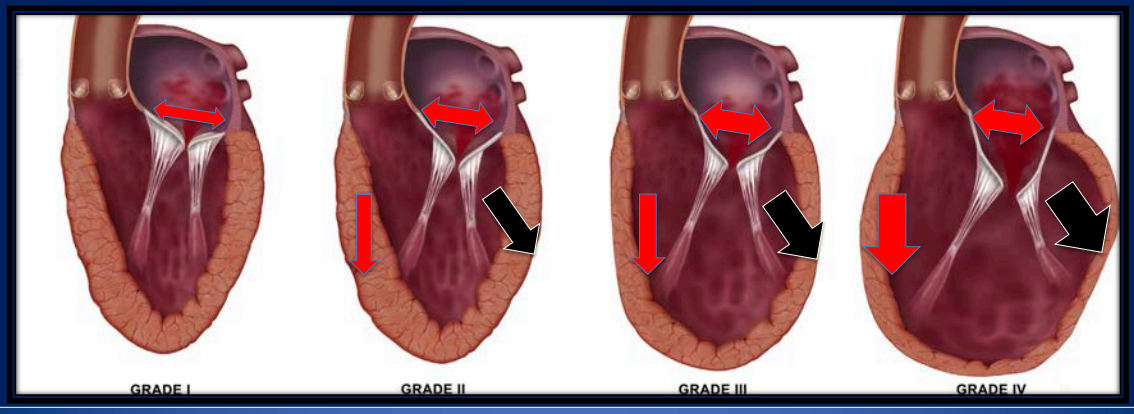
Functional (Secondary) MR

- SMR is a consequence of leaflet tethering and incomplete leaflet coaptation.



Badhwar V et al. J Thorac Cardiovasc Surg 2019 (in press)

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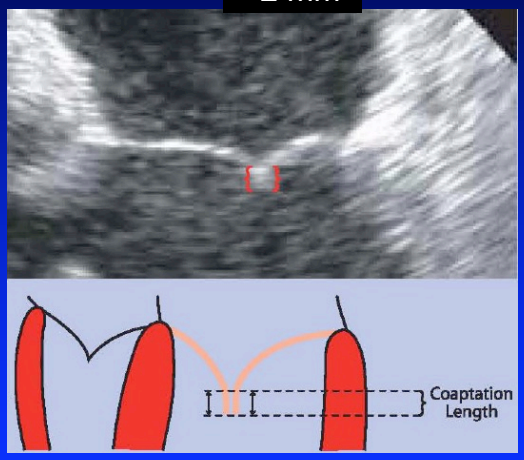
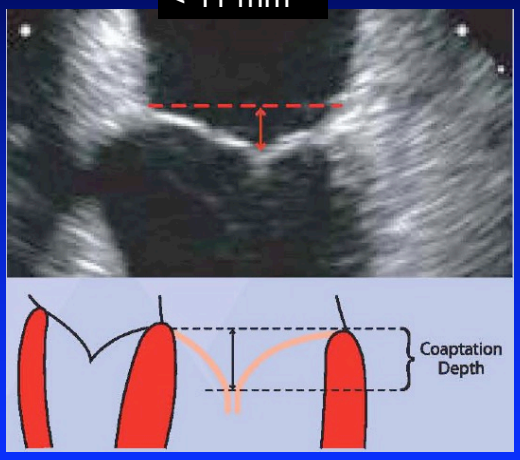
Functional MR

Coaptation Length > 2 mm



Coapt. Depth < 11 mm



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Background (i)

- Secondary or functional mitral regurgitation (SMR) is present in >50% of patients with heart failure (HF), and is severe in ~10-15%.
- Prognosis is poor when SMR is severe.
- Evaluation of SMR is challenging, due to asymmetric leaflet anatomy and regurgitant orifice, eccentric jets and enlarged left cardiac chambers.
- Expert panels have disagreed on how to define the severity of SMR, resulting in conflicting European and American guidelines.

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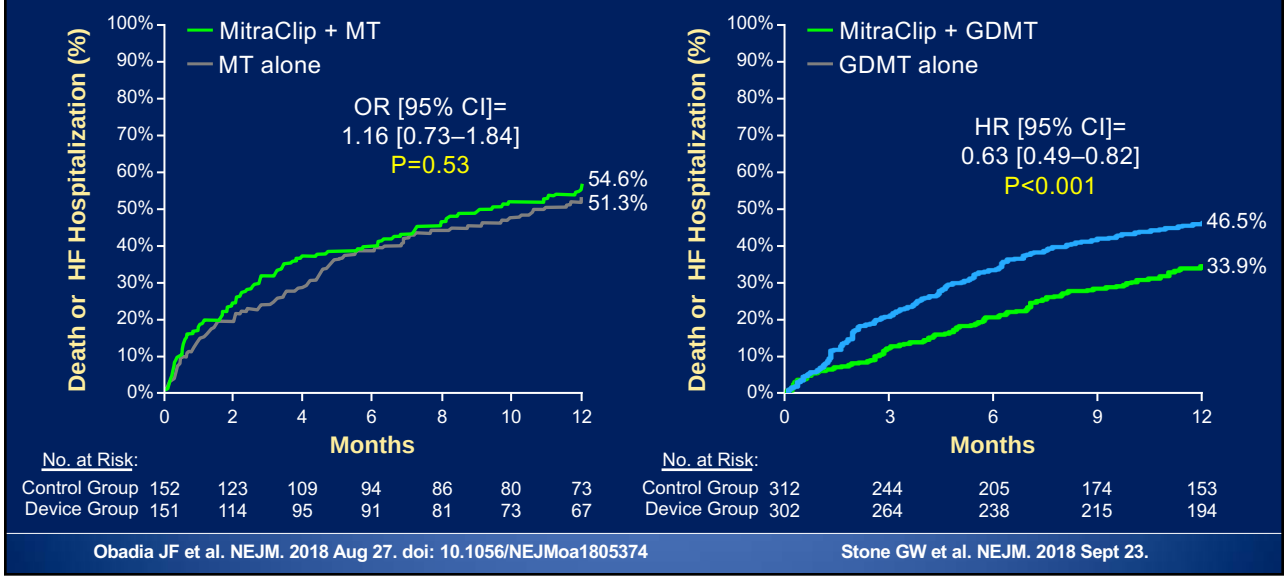
MITRA-FR vs COAPT: 12-Month Death or HF Hosp



Obadia JF et al. NEJM. 2018 Aug 27. doi: 10.1056/NEJMoa1805374

Stone GW et al. NEJM. 2018 Sept 23.

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Why are the COAPT Results so Different from MITRA-FR? Possible Reasons

	MITRA-FR (n=304)	COAPT (n=614)
Severe MR entry criteria	Severe FMR by EU guidelines: EROA >20 mm^2 or RV >30 mL/beat	Severe FMR by US guidelines: MULTIPARAMETRIC EROA >30 mm^2 or PVSFR
EROA (mean ± SD)	31 ± 10 mm^2	41 ± 15 mm^2
LVEDV (mean ± SD)	135 ± 35 mL/m^2	101 ± 34 mL/m^2
GDMT at baseline and FU	Receiving HF meds at baseline – allowed variable adjustment in each group during follow-up per "real-world" practice	CEC confirmed pts were failing maximally-tolerated GDMT at baseline – few major changes during follow-up
Acute results: No clip / ≥3+ MR	9% / 9%	5% / 5%
Procedural complications*	14.6%	8.5%
12-mo MitraClip ≥3+ MR	17%	5%

*MITRA-FR defn: device implant failure, transf or vasc compl req surg, ASD, card shock, cardiac embolism/stroke, tamponade, urg card surg

Courtesy Slide from GW Stone's LBCT, TCT 2018

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SO… How did SMR patients qualify to COAPT?

- MR Severity
- MV Anatomy and other echo characteristics

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Eligibility Criteria for MitraClip

1) Moderate to severe MR

2) Anatomy suitable for MitraClip?

RED LIGHTS:

- **Commisural jets**
- **Multiple, wide jets**
- **Minimal coaptation**
- **Ca++ or cleft at grasping area**
- **Severely degenerated leaflets (RHD, Rx, IE)**
- **MVA < 4 cm2**

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COAPT TRIAL

MR Severity algorithm

Secondary MR, Severity 3+ or 4+
(graded by 1 of 3 criteria)

Tier 1

EROA ≥ 0.3 cm^2

or

PV systolic flow reversal

N=570 (85.7%)

Asch FM et al. JACC 2019 ; 74: 2969

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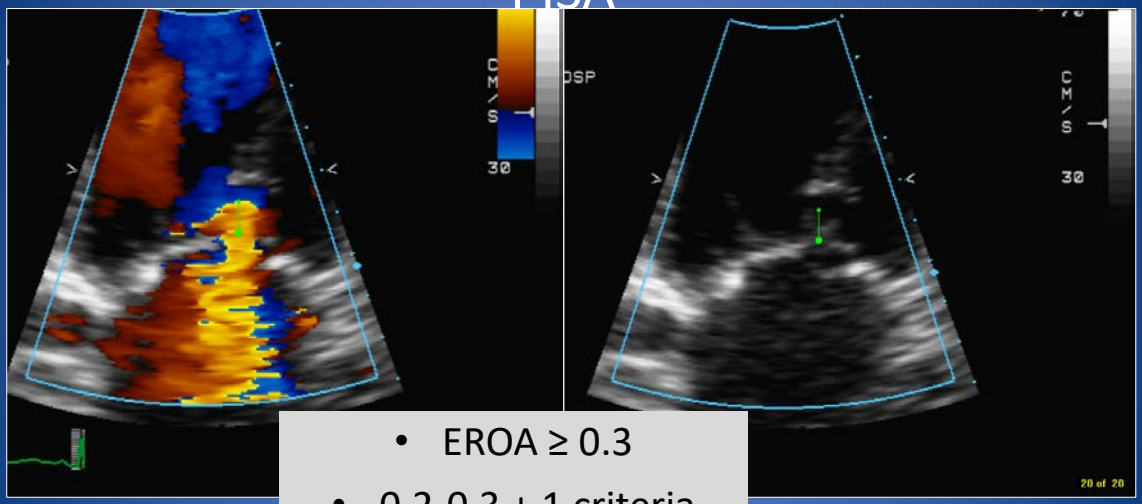
PISA



- EROA ≥ 0.3
- 0.2-0.3 + 1 criteria
- <0.2 + 2 criteria

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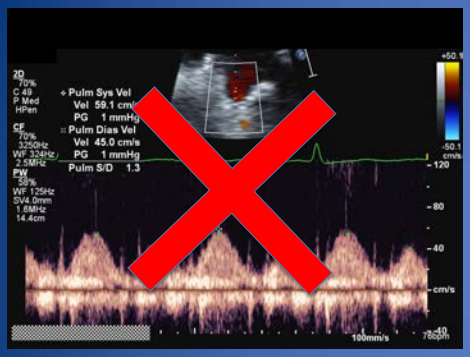
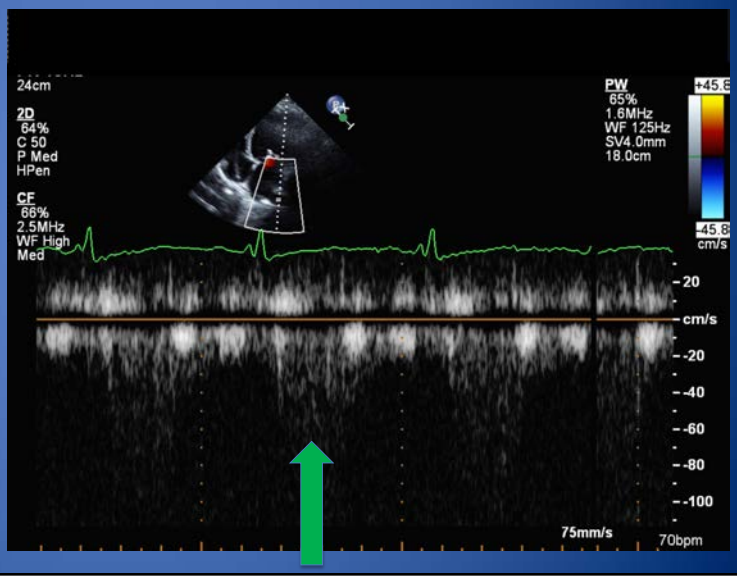
PV flow





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COAPT TRIAL

MR Severity algorithm

Secondary MR, Severity 3+ or 4+
(graded by 1 of 3 criteria)

Tier 1

EROA ≥ 0.3 cm^2

or

PV systolic flow reversal

N=570 (85.7%)

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

N=70 (10.5%)

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

N=25 (3.8%)

Asch FM et al. JACC 2019 ; 74: 2969

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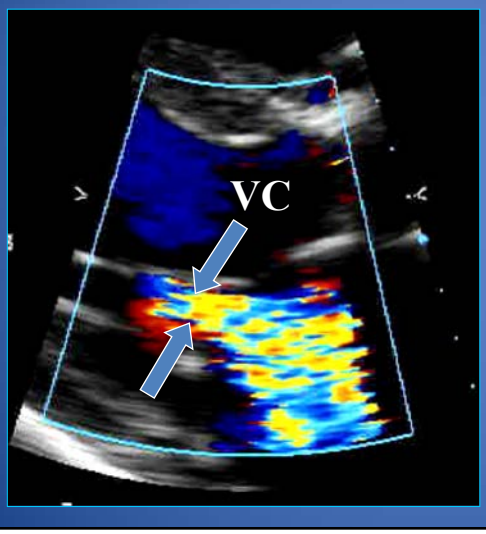
Vena Contracta
Proximal Jet Width



VC width (cm)

Severe > 0.7

COAPT > 0.5

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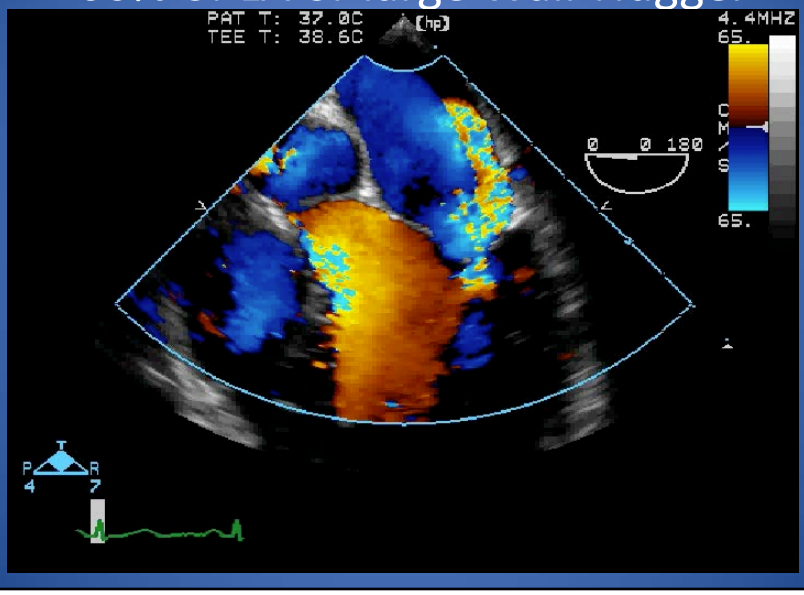
Color Doppler
>60% of LA or large Wall-Hugger



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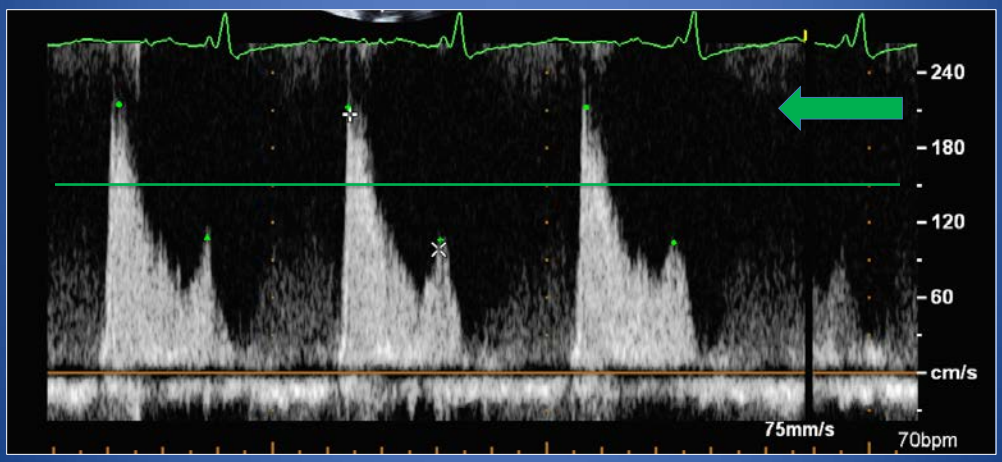
E wave >1.5 m/s



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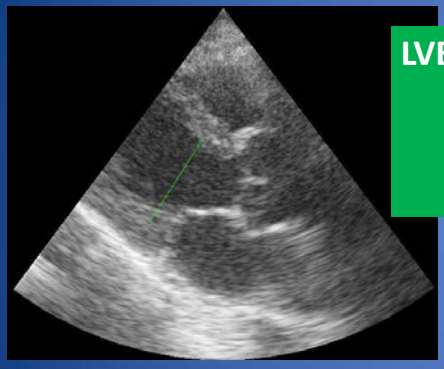
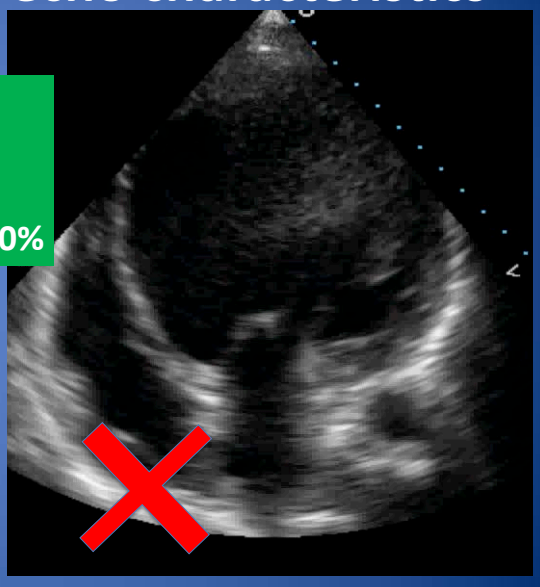
MV Anatomy and other echo characteristics



LVESD < 70mm

LVEF 20-50%



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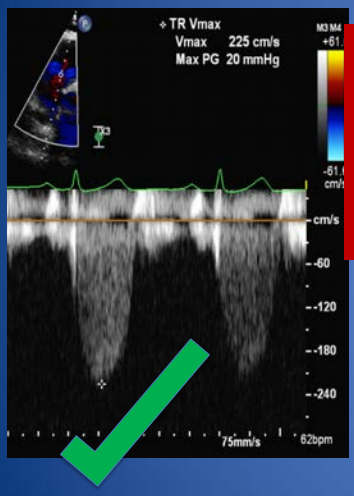
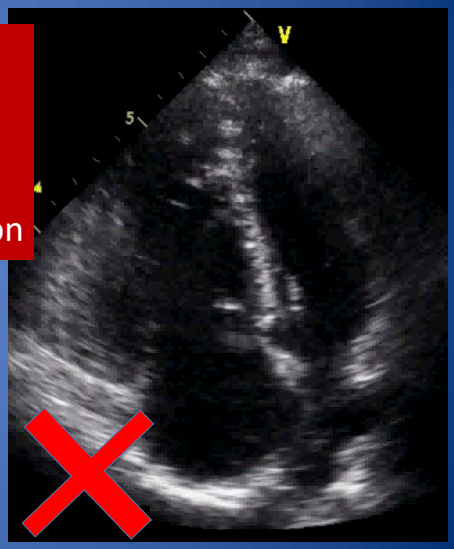
MV Anatomy and other echo characteristics



PASP >70 mmHg

Severe RV dysfunction



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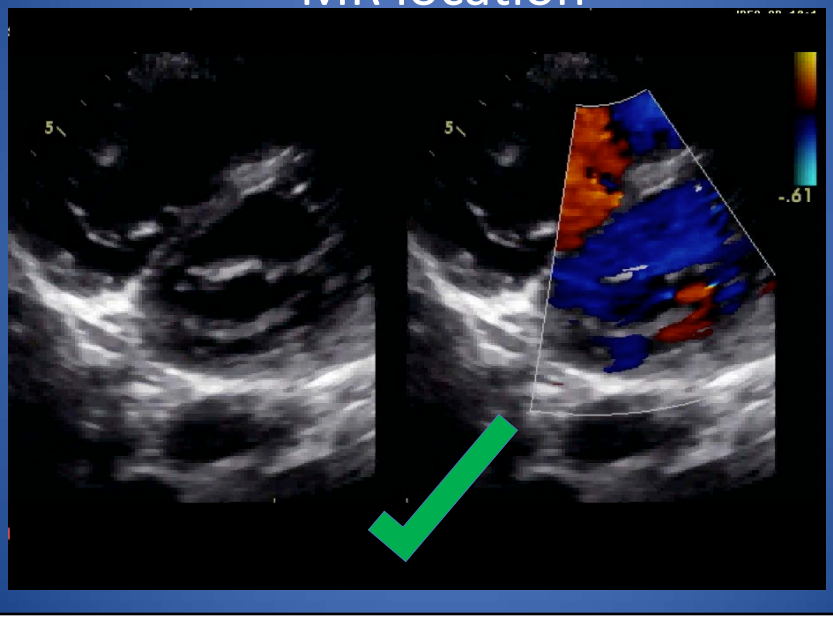
MR location



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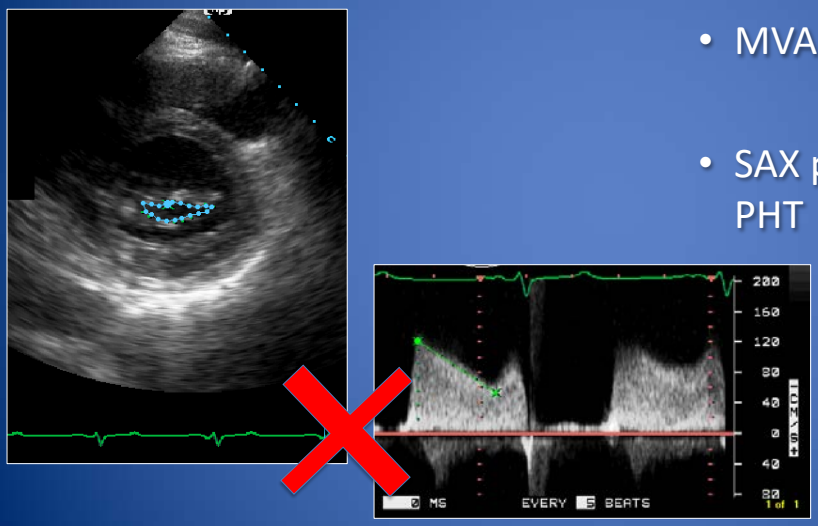
MV area



- MVA must be > 4.0
- SAX planimetry or by PHT

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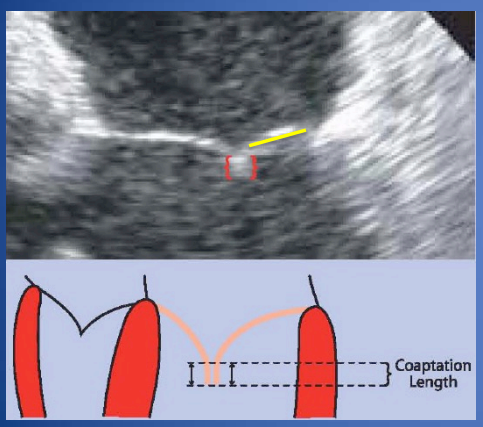
MV Anatomy - Grasping Coaptation and leaflet length



- At site of planned implant
- Long Axis or 4chamber view.

Beware: Ca++ or cleft in grasping area

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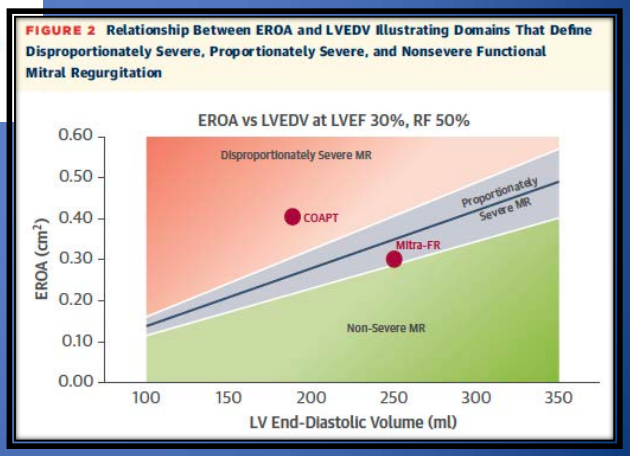
Proportionate vs Disproportionate MR

EDITORIALS AND VIEWPOINTS

Proportionate and Disproportionate Functional Mitral Regurgitation

A New Conceptual Framework That Reconciles the Results of the MITRA-FR and COAPT Trials

Paul A. Grayburn, MD, Anna Sannino, MD, Milton Packer, MD



Grayburn PA, Packer M. JACC Img 2019; 12:353

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Guiding the Procedure
Critical Steps

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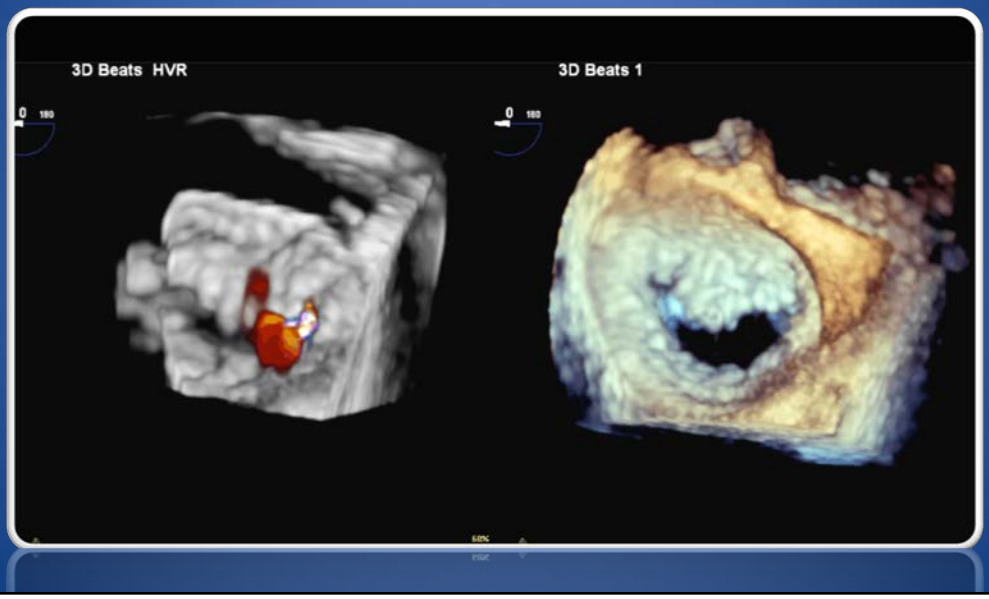
Step 0 - Where to clip? How Many



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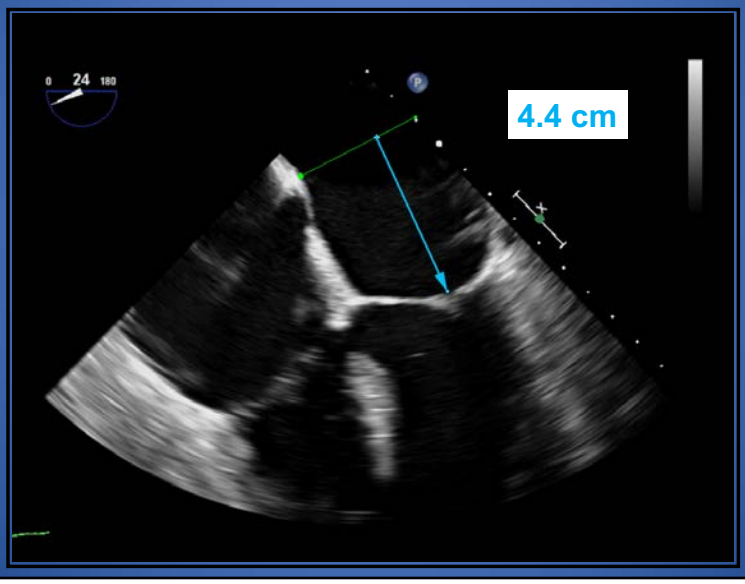
1. Trans-septal puncture
Posterior and high (4-4.5 cm from mitral annulus)



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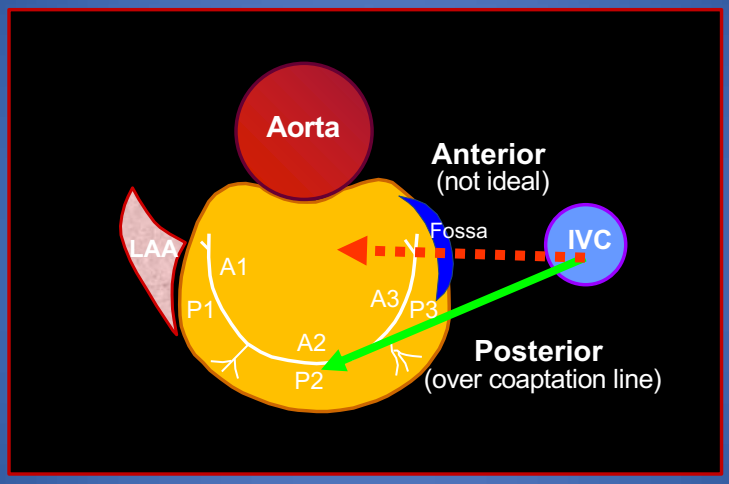
Direction of Transseptal



Preferred for MitraClip → posterior (over the coaptation line)

Courtesy of Dr S Goldstein

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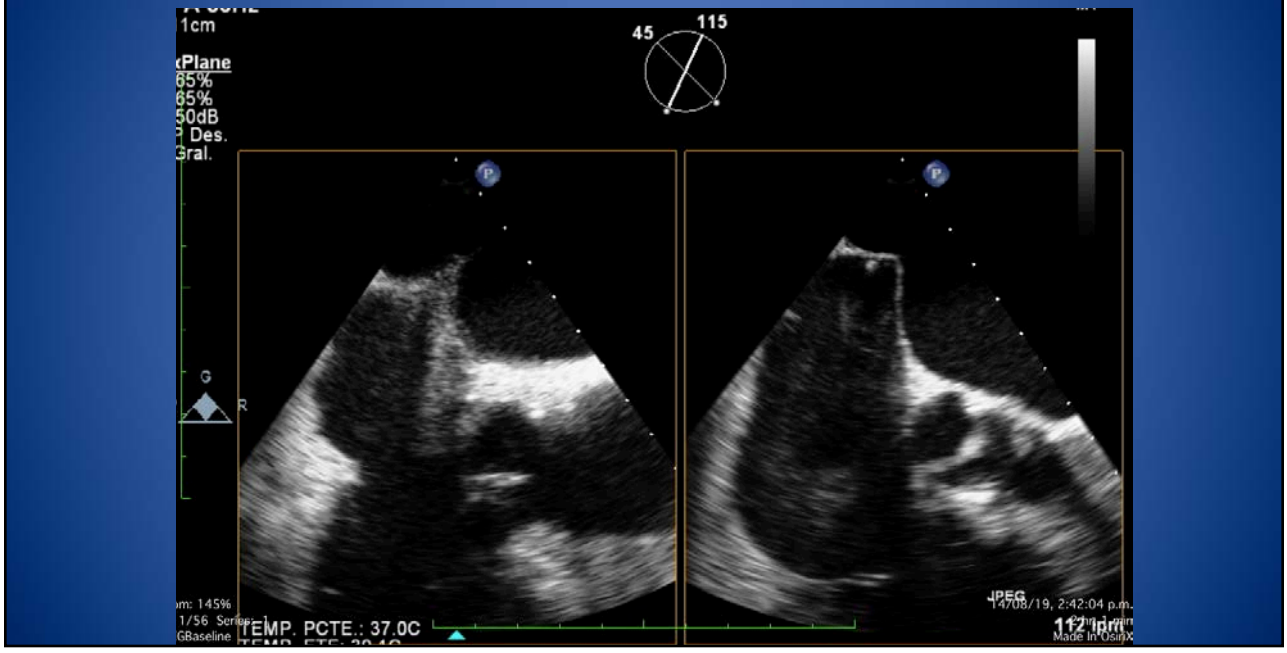

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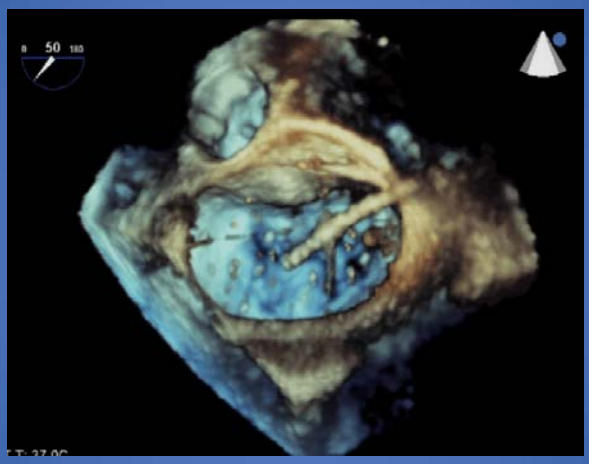

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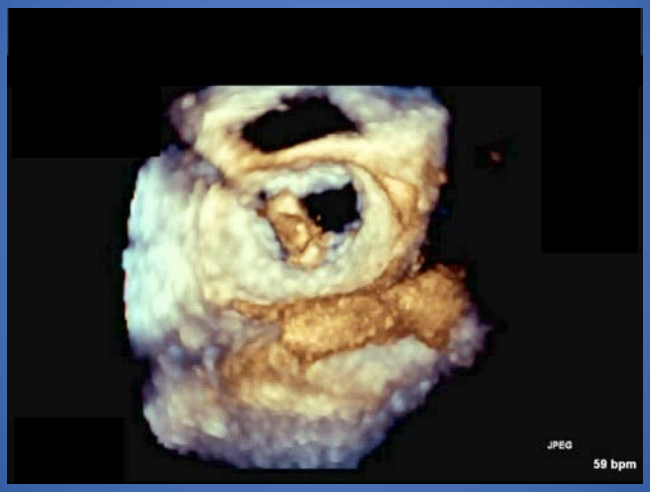
2. Clip positioning and alignment



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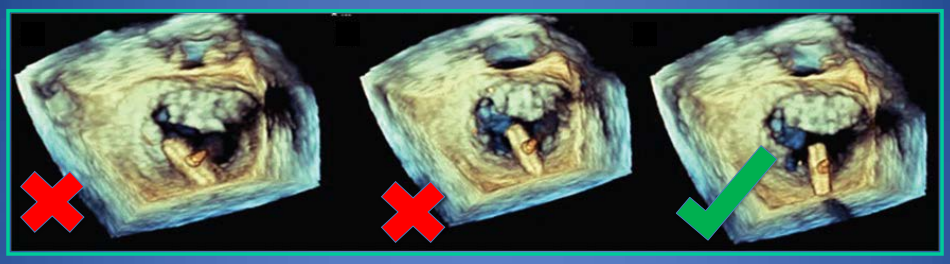
Steering and Positioning the MitraClip above the MV



- Align clip perpendicular to plane of mitral annulus
- Align clip arms perpendicular to coaptation line
- Align clip parallel to antegrade flow
- Move in small iterations
- Center over origin of MR jet

Wunderlich and Siegel Eur Heart J: CV Imaging 2013;;14:935-949

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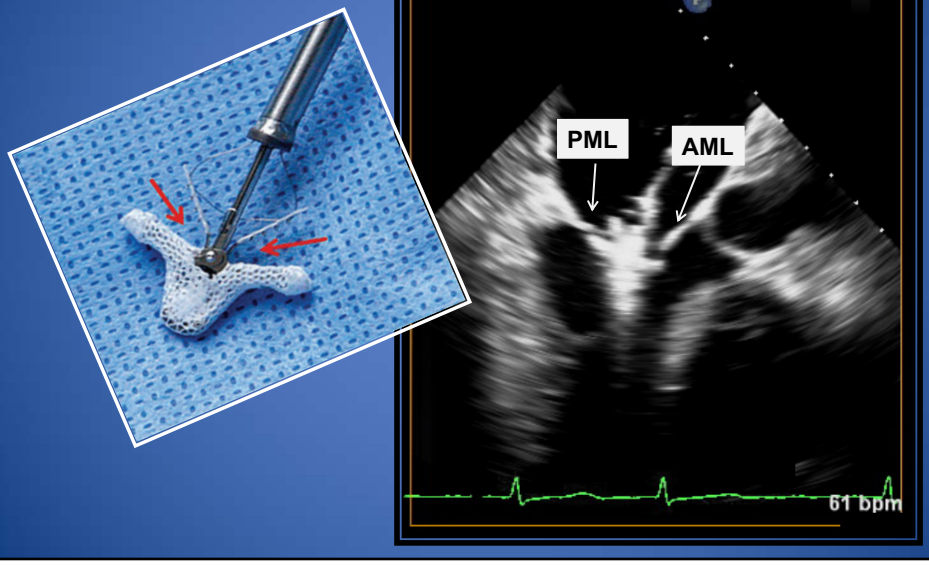
3. Grasping of the Leaflets



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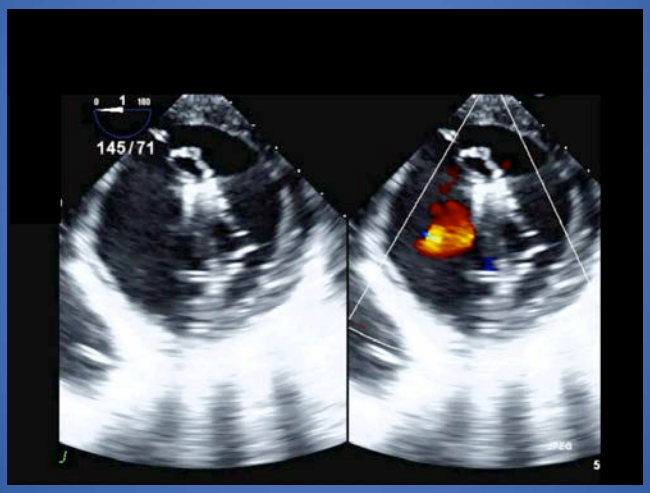
4. Verify residual MR is not >2+



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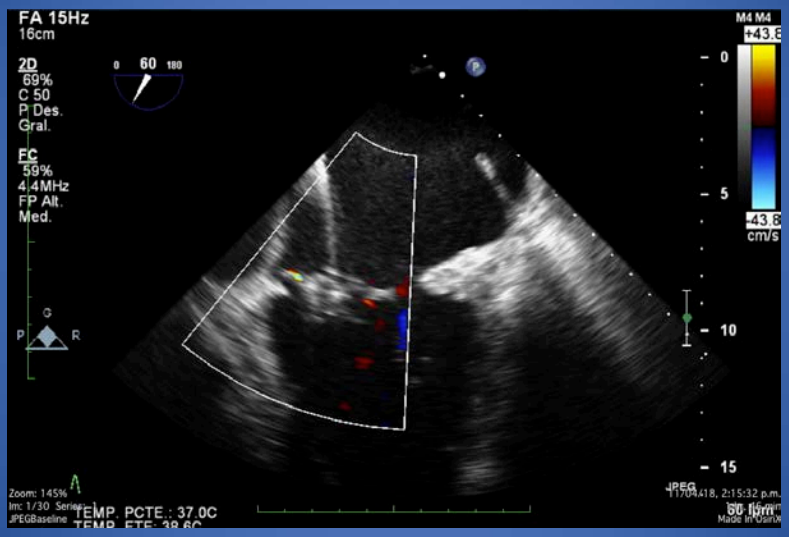

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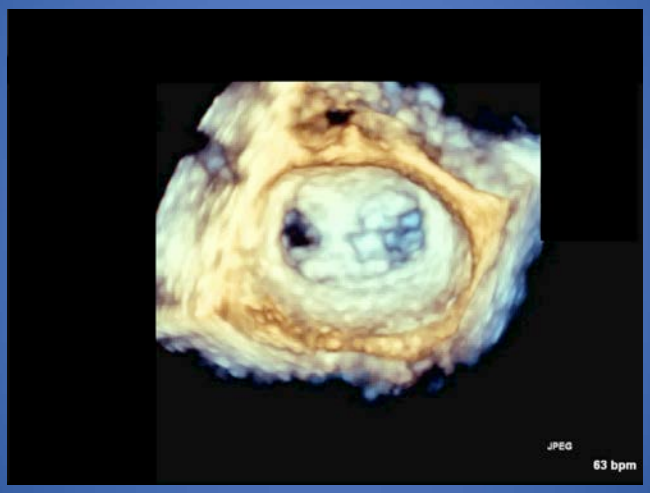

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Conclusions

- Know your patient:
  - MR etiology and Severity
  - Mitral Anatomy
  - LV size and function
- COAPT and MITRA-FR provide important information to help us understand which SMR patients are good and poor candidates for MitraClip.
- To duplicate the COAPT results, specific COAPT screening echo criteria and expert echo analysis should be applied to identify proper candidates for MitraClip.
- Clip implant is Echo- dependant: Guidance requires dynamic collaboration with IC

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Thank You

Cardiovascularcorelab.com

@FedericoAsch

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