

Standardized subannular repair in type IIIb mitral regurgitation: 1-year results from REFORM- MR Registry



Background / Study Objective



- **Type IIIb MR results** from LV distortion → papillary muscle displacement → leaflet tethering and reduced systolic leaflet motion
- **Isolated annuloplasty in type IIIb MR** is associated with high recurrence rate, while mitral valve replacement (MVR) results in increased perioperative mortality / morbidity
- **Subannular repair by papillary muscle repositioning** + annuloplasty has been developed to improve the stability of MV repair in type IIIb MR
- **REFORM-MR** is a prospective multicentre single-arm registry to evaluate the safety and efficacy of standardized subannular repair



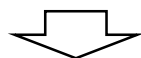
Patients

INCLUSION criteria

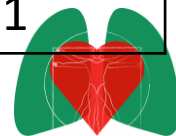
- Secondary MR
- LVEF \leq 50%
- LVEDD \geq 55mm
- Tenting PML/AML $>$ 10mm

EXCLUSION criteria

- Degenerative MR
- Type I MR (isolated ring dilatation)
- Simultaneous aortic valve surgery
- Redo surgery (sp CABG/valvular surgery)



Patients (n)	97	NYHA III-IV	65 (67)
Age (years)	64.8 \pm 9.9	NT pro-BNP (pg/ml)	1913 (1144 – 5518)
Male	66 (68)	CAD	72 (74)
EuroScore II [%]	4.8 \pm 4.5	LVEF [%]	36.4 \pm 10.3
STS Mortality [%]	3.1 \pm 3.3	LVEDD [mm]	60.8 \pm 9.1

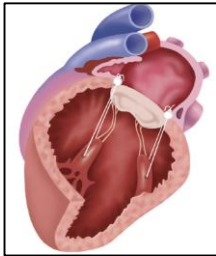


Methods

Single-arm prospective multicenter Registry

97 patients / 6 high-volume heart centres*

Bilateral papillary muscle repositioning



Annuloplasty using
Carpentier-McCarthy-Adams IMR ETlogix®



Primary endpoint: freedom from MR \geq 2 at 2-years

Secondary endpoints: Survival, MACCE, Reinterventions

* *First two cases were proctored by a Core-center*

- **Echo** CoreLab
- **MRI** CoreLab



Results 1 – Perioperative outcome

Intraoperative variables

Mini-thoracotomy access	31 (32)
Urgent surgery	32 (33)
Concomitant surgery	
- CABG	52 (54)
- Ablation	23 (24)
- Tricuspid valve repair	13 (14)
CPB time	158 ± 40
Aortic cross-clamp	97±32
Mean annuloplasty ring	29.6±1.9

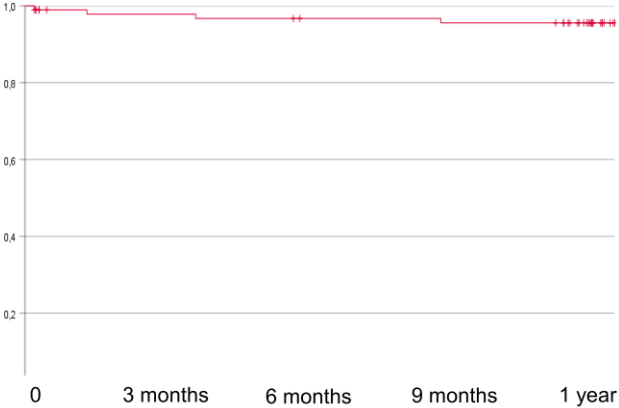
Postoperative variables

LCO syndrome	5 (5)
- <i>ECMO</i>	2 (2)
Stroke	2 (2)
ICU stay (days)	3.1±3.0
Residual MR at discharge*	
- <i>None</i>	43 (49)
- <i>Mild</i>	35 (40)
- <i>Moderate</i>	9 (10)
In-hospital mortality	1 (1.4)

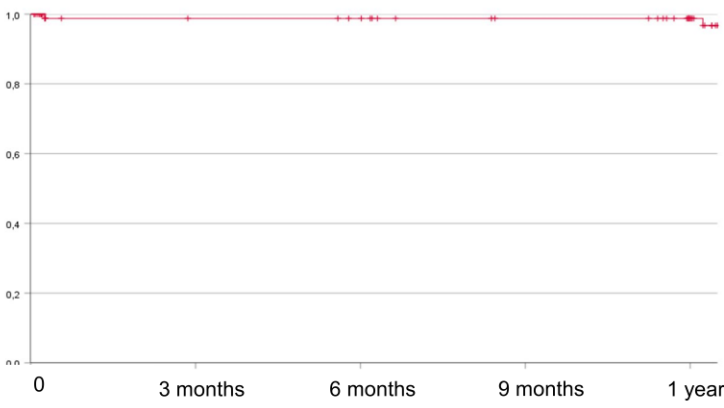


Results 2 – 1-year follow-up

Survival



Freedom of MR > 2



	0	3 months	6 months	9 months	1 year
Patient at risk	97	87	84	83	71
Survival	98.6	97.8	96.7	95.5	95.5
Cum. deaths	1	2	3	4	4

	0	3 months	6 months	9 months	1 year
Patient at risk	97	74	71	65	54
Freedom of MR > 2	98.8	98.8	98.8	98.8	98.8
Cum. events	1	1	1	1	1



Conclusion

- **Standardized subannular repair by papillary muscle repositioning** is safe and reproducible in a multicentre setting (REFORM-MR) and is associated with:
 - acceptable in-hospital results
 - reasonable survival at 1-year
 - low risk of recurrent MR > 2 at 1-year
 - reduced tenting parameters at 1-year
- 2-year follow-up of the study cohort is under way

