Interim Results of the CINCH-FMR Post-Market Registry: Percutaneous Repair in Functional Mitral Regurgitation (FMR) With the Carillon Mitral Contour System®

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Background

- Prospective trials of the Carillon Mitral Contour System® (CMCS: Cardiac Dimensions, Kirkland, WA) have shown effective hemodynamic and clinical improvement in patients with heart failure and functional mitral regurgitation (FMR) including beneficial left ventricular and left atrial remodeling.
- The CINCH-FMR Registry is a multi-center, real-world study of patients treated with the Carillon device as standard of care.

Methods

- The CINCH-FMR Registry is intended to enroll up to 150 patients treated with the Carillon device in accordance with the device labeling and instructions for use in up to 40 centers in Germany.
- Patients were enrolled following informed consent with the first patient included in June 2017. Retrospective enrollment was allowed
- An interim analysis of 101 patients with up to 5 years of follow-up was performed.

Evaluated Parameters

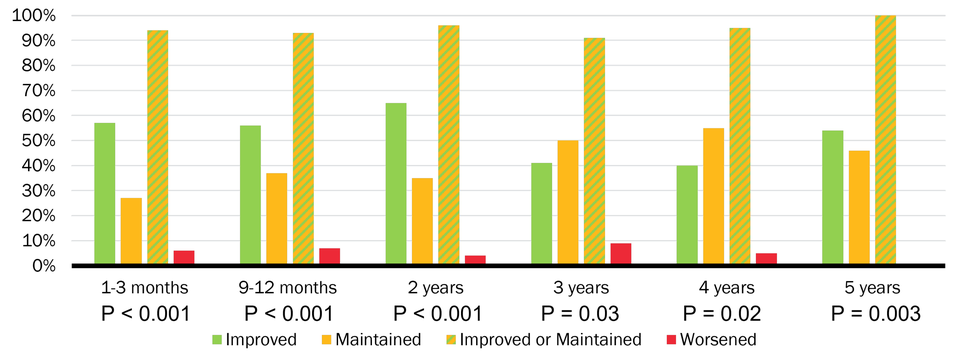
- Primary outcomes out to 5 years follow-up include mortality, device related safety events, change in NYHA classification and heart failure hospitalization
- Echocardiographic assessments were also made –site reported

Patient Demographics

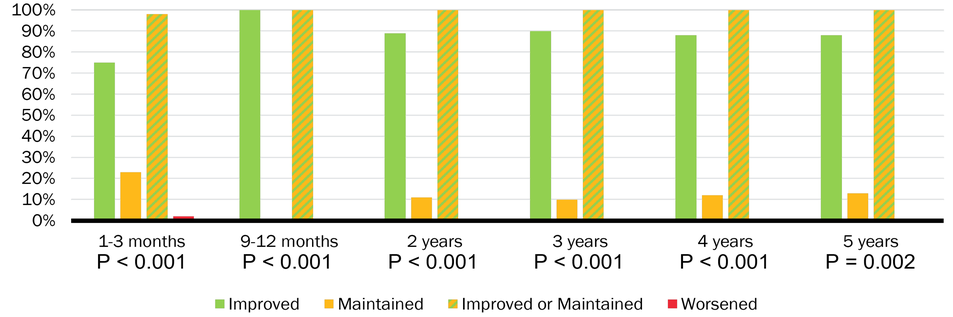
N	101
Age	75+ 9
Gender (%)	
Female	43 (42.6%)
Male	58 (57.4%)
HTN	88 (87%)
Afib	70 (69%)
Coronary artery disease	54 (53%)
Ischemic etiology	46 (46%)
Hx Myocardial Infarction	25 (25%)
ICD present	20 (20%)

LVEF %	43±15
NYHA Class n (%)	
I	2 (2 %)
II	14 (16%)
III	62(69%)
IV	12 (13 %)
MR grade n (%)	
1+	1 (1%)
2+	12 (15%)
3+	53 (68%)
4+	12 (15%)

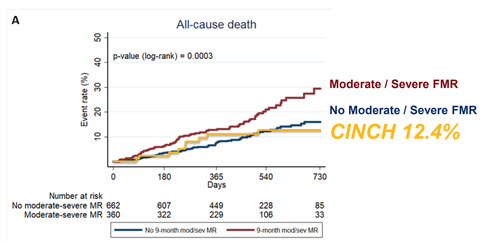
Change in NYHA class compared to baseline



Change in MR compared to baseline



Recent Published Medically Managed CHF Patients



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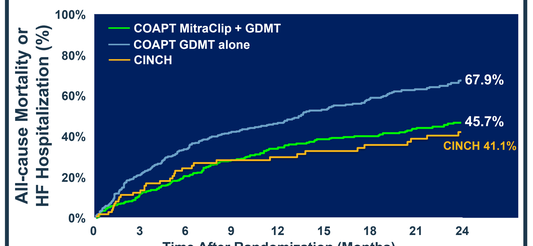
Death or HF Hospitalization



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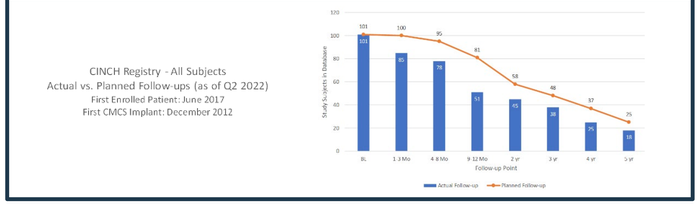
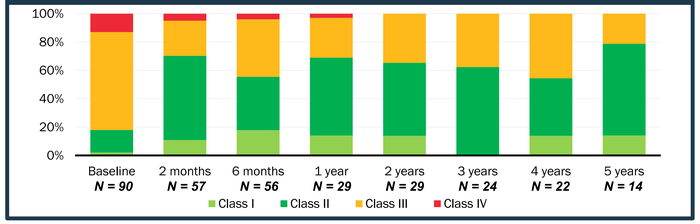
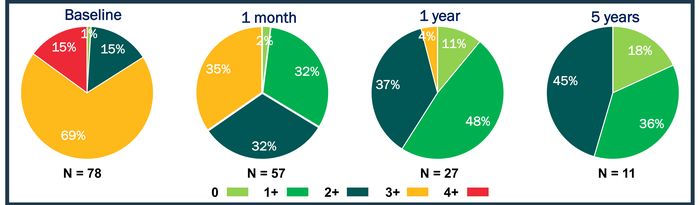
Follow-up – Actual vs Planned



Change in NYHA Class Over Time



Change in MR Over Time



Limitations

- Observations study with site-reported data
- Follow-up not available for all patients

Conclusions

In this real-world registry of patients undergoing Carillon implantation for congestive heart failure and secondary mitral regurgitation, there were

- Sustained decrease in mitral regurgitation compared to baseline
- Improvements and/or stablity in NYHA classification that persisted
- Findings consistent with those seen in controlled, prospective trials, including the blinded, sham-controlled REDUCE FMR randomized trial

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