

Long-Term Survival following TMVr : Pooled Analysis of Prospective Trials with the Carillon Device

Janusz Lipiecki, MD; David M Kaye, MD; Klaus K Witte, MD; Michael Haude, MD; Samir Kapadia, MD; Horst Sievert, PhD, MD; Steven L Goldberg, MD; Wayne C Levy, MD; Tomasz Siminiak, MD

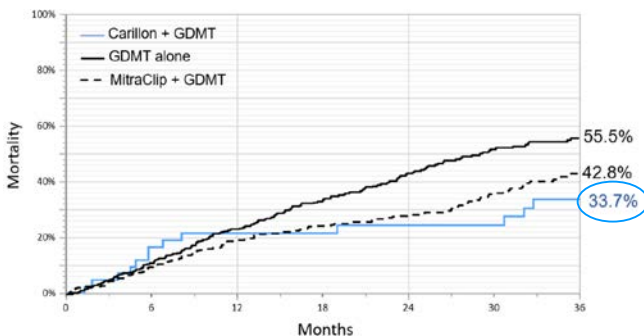
Summary:

A total of 74 patients from the TITAN, TITAN II and REDUCE FMR clinical studies were assessed as part of the analysis. All patients had symptomatic congestive heart failure despite guideline-directed medical therapy, grade 2+ to 4+ FMR, left ventricular enlargement, and reduced ejection fraction. Echocardiographic parameters were available through the 12-month visit and vital status was available through 5 years. The association of patient characteristics and changes in echocardiographic parameters at 6 and 12 months with long-term survival was analyzed using Cox proportional hazards regression.

Results:

Key findings from the analysis include:

- Kaplan-Meier survival rate was 83.6% at 1 year, 73.1% at 2 years, 67.9% at 3 years and 56.2% at 4 and 5 years of follow-up.
- Primary determinants of long-term survival were a decrease in NYHA class, an increase in 6-minute walk test distance, and a decrease in regurgitant volume during the first year of follow-up.
- Three-year mortality rate compared to published outcomes of COAPT and guideline directed medical therapy (GDMT), using matched patient populations, was 33.7% for Carillon, 42.8% for MitraClip in COAPT and 55.5% for GDMT.



Conclusion:

The Carillon Mitral Contour System shows favorable long-term mortality from prospective controlled trials in comparison to GDMT and COAPT results in symptomatic FMR patients.