



Valvular Heart Disease

EVEREST II REALISM - A CONTINUED ACCESS STUDY TO EVALUATE THE SAFETY AND EFFECTIVENESS OF THE MITRACLIP DEVICE: ANALYSIS OF RESULTS THROUGH 1 YEAR

Poster Contributions
Poster Hall B1
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Background: EVEREST II REALISM is a prospective, multi-center, continued access study to collect data on “real world” use of MitraClip in both high risk (HR) and non-high risk (NHR) patients. Preliminary 1-year outcomes are presented.

Methods: HR was defined as STS score $\geq 12\%$ or pre-specified risk factors. As of December 2013, 628 HR and 271 NHR patients were enrolled. Echocardiograms were evaluated by an independent core lab. Clinical outcomes at 1 year included change in left ventricular (LV) volume, NYHA Functional Class and quality of life.

Results: Mean ages of HR and NHR patients were 77 and 74 years respectively. Baseline co-morbidities prevalent in both groups included CAD, atrial fibrillation and diabetes. Baseline LVEF was $47 \pm 14\%$ in HR and $56 \pm 11\%$ in NHR. Mortality at 30 days was 4.2% in HR and 1.5% in NHR. Despite advanced age and burden of co-morbidities, 89% of all patients achieved MR reduction to $\leq 2+$ post-procedure and 90% were discharged home. At 1 year, patients showed improvements from baseline in clinical and functional measures.

Conclusion: In EVEREST II REALISM, patients treated with MitraClip are elderly and have significant co-morbidities. In this population, the MitraClip procedure is a safe option that provides meaningful clinical and functional improvements at 1 year. Analysis of the final 1-year results will be presented.

Study funded by Abbott Vascular.

Baseline characteristics and outcomes* in EVEREST II REALISM		
	EVEREST II REALISM (n=899)	
	High Risk Arm (n=628)	Non-High Risk Arm (n=271)
Age	77 \pm 11 years	74 \pm 11 years
Coronary Artery Disease	78%	49%
Atrial Fibrillation	71%	56%
Diabetes	37%	19%
Prior CABG Surgery	54%	17%
Functional MR	70%	32%
LV Ejection Fraction	47 \pm 14 %	56 \pm 11 %
Mortality at 1 year	23.0%	10.0%
Freedom from MR > 2+ at 1 year in surviving patients	83%	83%
Change in LVEDV (1 Year minus Baseline)	-8 \pm 35 ml	-13 \pm 24 ml
Change in SF-36 PCS at 1 year (1 Year minus Baseline)	+5.0 \pm 9.9 points	+6.2 \pm 9.4 points
NYHA Functional Class III/IV: Baseline \square 1 year	81% \rightarrow 15%	51% \rightarrow 9%

*Echo data pending final core lab review; adverse event data pending final CEC adjudication.
Continuous variables expressed as mean +/- SD. Changes from baseline to 1 year reported in survivors with paired data.