



Valvular Heart Disease

ACCESS EUROPE: A POST MARKET STUDY OF THE MITRACLIP SYSTEM FOR THE TREATMENT OF SIGNIFICANT MITRAL REGURGITATION (MR) IN EUROPE: ANALYSIS OF OUTCOMES AT 6-MONTHS

ACC Oral Contributions

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Background: ACCESS EUROPE (ACCESS-EU) is a prospective, observational, multicenter study to gain information regarding the use of the MitraClip System in Europe with respect to patient selection in a commercial setting, and to provide further evidence of the safety and effectiveness of the MitraClip System. As of April 13, 2011, the ACCESS-EU study had completed enrollment of 567 patients in the MitraClip Device group, 443 of which are accounted for in the 6-Month Analysis Cohort to date. Safety and effectiveness results on a complete 6-Month Analysis Cohort have not been reported.

Methods: Acute procedural safety results at 30 days, survival at 6 months and preliminary survival at 12 months are summarized. Effectiveness results, defined by reduction in MR, and improvement in clinical outcomes, based on changes in NYHA Functional Class, Six Minute Walk Test, and Quality of Life (Minnesota Living With Heart Failure Survey) data, are reported.

Results: Patients enrolled in ACCESS-EU were elderly (mean age 74 ± 10 yrs) with significant baseline co-morbidities (CAD 63%, moderate to severe renal disease 43%). At baseline, 97% of the patients had $\geq 3+$ MR, 77% had functional MR, 85% were in NYHA Functional Class III/IV, and 52% had left ventricular ejection fraction $<40\%$. The average logistic EuroSCORE was $23\% \pm 19$. Preliminary results at 6 months are as follows: Freedom from death was 89%, freedom from MR $>2+$ was 80%, freedom from mitral valve surgery was 97%, the majority of patients (70%) were in NYHA Class I/II, and mean improvement of 66 meters from baseline in six minute walk test distance. Preliminary freedom from death at 12 months was 85%. Significant improvements in Quality of Life were also noted as evidenced by a difference of 12 points between Baseline and 6-Month Quality of Life scores.

Conclusions: Preliminary six month results of the ACCESS-EU study demonstrate important clinical benefits in a real world patient population with significant co-morbidities who are at high surgical risk. Results from the complete 6-Month Cohort of MitraClip Device patients will be presented.