TCT-786

Cost Effectiveness of the MitraClip® Compared with Mitral Valve Surgery: 12-month Results from the EVEREST II Randomized Controlled Trial

Matthew Reynolds[1], Benjamin Galper[2], Patricia Apruzzese[1], Joshua Walczak[1], Laura Mauri[3], Ted Feldman[4], Donald Glower[5], David Cohen[6]
[1]Harvard Clinical Research Institute, Boston, MA, [2]Brigham & Women's Hospital, Boston, MA, [3]Harvard Medical School, Boston, Massachusetts, [4]Evanston Northshore Healthcare, Evanston, IL, [5]N/A, Durham, North Carolina, [6]Saint Luke's Mid America Heart Institute, Kansas City, USA

Background: The EVEREST II randomized trial showed that percutaneous repair of the mitral valve with the MitraClip® device (Abbott Vascular, Santa Clara, CA) reduced mitral regurgitation less completely than conventional surgery, but was associated with superior safety and similar clinical outcomes at 12 months. The potential cost-effectiveness (CE) of the MitraClip procedure compared with mitral valve surgery is not presently known.
Methods: We conducted a 12-month U.S. CE analysis comparing the MitraClip procedure with mitral valve surgery based on the EVEREST II trial. Index admission costs were calculated using hospital billing data or estimated using regression models. Costs for follow-up hospitalizations were estimated based on Medicare reimbursement. Resource-based costs were also included for rehabilitative and long-term care services. SF-36 data, collected at baseline, 1 and 12 months, was used to calculate quality-adjusted life years (QALYs). Results were assessed in a primary modified intention to treat (mITT) population excluding randomized but not treated patients.
Results: Results were sensitive to assumptions on the duration of QOL benefit with MitraClip relative to surgery (present at 1 but not 12 months), the price of the MitraClip device, and the analytic population. In our base case the MitraClip strategy slightly increased QALYs through 12 months (0.015) At the study price of $18,000 the clip strategy reduced costs by $2,200/patient, making MitraClip economically dominant. At a clip price of $26,200 (approximate European sales price), overall costs were higher with the clip strategy by $6,192 and the incremental CE ratio was unfavorable (>$400,000 per QALY gained). In a sensitivity analysis limiting to patients with acute procedural success (per protocol population), the QALY gain was larger (0.041), the cost-offsets with the clip greater, and cost-effectiveness more favorable (dominant at a MitraClip price of $18,000, ~$54,000 per QALY gained at $26,200).
Conclusions: The potential cost-effectiveness of MitraClip compared with mitral valve surgery in EVEREST II varied depending primarily on MitraClip price and acute procedural success.

TCT-787

Effectiveness of Transcatheter Mitral Valve Repair in Degenerative Mitral Regurgitation in High Surgical Risk Patients

D. Scott Lim[1], Saibal Kar[2], Patrick Whitlow[3], Michael Argenziano[4], Alfredo Trento[5], Gorav Ailawadi[1], Donald Glower[6], Ted Feldman[7]
[1]University of Virginia Health System, Charlottesville, VA, [2]Cedars-Sinai Medical Center, Los Angeles, USA, [3]Cleveland Clinic, Cleveland, Ohio, [4]Columbia University Medical Center, New York, New York, [5]Cedars-Sinai Medical Center, Los Angeles, California, [6]Duke University Medical Center, Durham, North Carolina, [7]Evanston Northshore Healthcare, Evanston, IL

Background: Mitral valve surgery is generally indicated for patients with severe degenerative mitral regurgitation (DMR). However, surgical correction of MR may not always be possible in high surgical risk patients. The purpose of this analysis is to describe clinical benefit including improvements in left ventricular (LV) size and function observed following treatment with the MitraClip device (Abbott Vascular, Menlo Park, CA) in high surgical risk patients with DMR.
Methods: EVEREST II High Risk Study and REALISM Continued Access Registry patients had significant MR (3+/4+) and were deemed high risk for surgery as determined by a STS predicted surgical mortality ≥12% or surgeon assessment. Clinical measures including NYHA Functional Class, quality of life (QOL) and hospitalizations for CHF as well as echocardiographic measurements analyzed by an independent core lab were evaluated.
Results: 62 high surgical risk DMR patients underwent a MitraClip procedure with a 94% implant rate. Patients were elderly (mean age 83±8 yrs) with significant comorbidities (CHF 100%, CAD 75%, prior cardiac surgery 47%). The mean predicted surgical mortality by STS calculator was 14.8±9.1%. Observed mortality at 30 days and 12 months was 6.5% and 25.8%, respectively. 37 patients had matched echocardiograms between Baseline and 12 months, of which 78% achieved MR severity ≤2+. Clinical benefit was demonstrated at 12 months with significant improvements in LV volumes, NYHA Functional Class, and QOL (Table). Compared to 12 months prior the MitraClip procedure, the annual rate of CHF hospitalizations decreased 77% in the 12 months post-procedure.

Mean±SD (N)	LVEDV (ml)	LVESV (ml)
Baseline	135±40 (51)	51±26 (51)
30 Days†	123±41 (51)	53±27 (51)
Change from Baseline to 30 Days	-12±16	2±13
p-value	<0.0001	0.32
Baseline	137±43 (35)	51±29 (35)
12 Months	118±38 (35)	49±25 (35)
Change from Baseline to 12 Months	-19±20	-2±14
p-value	<0.0001	0.38

LV Ejection Fraction (%)	NYHA Functional Class I/II (%)
63±8 (51)	18 (55)
58±10 (51)	73 (55)
-5±8	55
<0.0001	<0.0001
64±9 (35)	21 (39)
59±10 (35)	85 (39)
-5±7	64
0.0004	<0.0001

Quality of Life PCS Score	Quality of Life MCS Score
31±10 (51)	49±12 (51)
38±10 (51)	50±11 (51)
7±10	1±12
<0.0001	0.59
33±10 (34)	49±13 (34)
39±12 (34)	53±10 (34)
6±9	4±12
0.0005	0.085

†Echocardiographic measures were evaluated at Discharge
PCS = Physical Component Summary, MCS = Mental Component Summary

Conclusions: The MitraClip procedure resulted in significant improvements in MR severity, LV reverse remodeling, and clinical outcomes and is an important therapeutic option for patients with significant degenerative MR who are not suitable candidates for surgery.

TCT-788

The EVEREST II Randomized Controlled Trial (RCT): Three Year Outcomes

Ted Feldman[1], Elyse Foster[2], Mansoor Qureshi[3], Brian Whisenant[4], John Williams[5], Donald Glower[6], Laura Mauri[7]
[1]Evanston Northshore Healthcare, Evanston, IL, [2]University of California, San Francisco, San Francisco, CA, [3]St. Joseph Mercy Hospital, Ypsilanti, MI, [4]Intermountain Heart Institute, Salt Lake City, USA, [5]Oklahoma Heart Hospital, Oklahoma City, OK, [6]Duke University Medical Center, Durham, North Carolina, [7]Harvard Medical School, Boston, Massachusetts

Background: EVEREST II is a prospective multi-center RCT comparing safety and effectiveness of the MitraClip System with mitral valve (MV) surgery in the treatment of severe (3+ or 4+) mitral regurgitation (MR). We report outcomes at 3 years to evaluate durability of clinical endpoints and changes in MR severity and left ventricular (LV) volumes.
Methods: 279 patients, randomized 2:1 to transcatheter MitraClip treatment or surgery were enrolled at 37 sites in North America. Each patient had core lab assessed echocardiograms prior to enrollment. Clinical benefit was assessed at 3 years by measures of LV function, NYHA Functional Class (NYHA-FC) and freedom from mortality and MV surgery or re-operation.
Results: Mean age was 67 years; baseline LV ejection fraction was 60%. Half were in NYHA-FC III/IV and 73% had degenerative MR. Through 3 years, 24 MitraClip and 11 surgery patients withdrew. Of 258 treated patients, Kaplan-Meier (KM) estimate of freedom from mortality at 3 years was 87% in MitraClip and 85% in surgery groups. KM estimate of freedom from surgery was 78% in MitraClip patients and freedom from re-operation was 94% in surgery patients, both unchanged from 1 year. In patients with matched data, MR severity was ≤ 2+ in 84% of MitraClip and 96% of surgery groups. Compared to baseline, LV end-diastolic volumes at 3 years decreased by 29 mL and 44

POSTERS