



Lecture Notes

American College of Cardiology 60th Annual Scientific Session & i2 Summit

EVEREST II Randomized Clinical Trial: Two Year Outcomes

Sponsor: Abbott Vascular

Clinical Trial #: NCT00209274

Background

Mitral valve (MV) repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

Summary

The Endovascular Valve Edge-to-Edge Repair trial (EVEREST) showed that percutaneous MV repair is safe and durable with measurable clinical benefits and is a therapeutic option for select patients with significant mitral regurgitation (MR).

Study Design

- Randomized in a 2:1 ratio
- Multicenter
- 279 patients with moderately severe or severe (grade 3+ or 4+) MR
- Either percutaneous repair or conventional surgery for repair or replacement of the MV

Primary Composite Endpoint

- Efficacy defined as freedom from death, from surgery for MV dysfunction, and from grade 3+ or 4+ MR at 12 months

Primary Safety Endpoint

- A composite of major adverse events within 30 days

Results

- At 12 months, the rates of the primary end point for efficacy were 55% in the percutaneous-repair group and 73% in the conventional surgery group ($p=0.007$)
- The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for MV dysfunction, 20% versus 2%, ($p<0.001$); and grade 3+ or 4+ MR, 21% versus 20%



Lecture Notes

American College of Cardiology 60th Annual Scientific Session & i2 Summit

- Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ($p < 0.001$)*
- At 12 months, both groups had improved left ventricular size, NYHA functional class, and quality-of-life measures, as compared with baseline

* p value calculated to test for increased superiority of percutaneous repair compared with surgery by a prespecified safety margin of -2%.

Conclusions

Percutaneous repair was less effective at reducing MR than conventional surgery, but the procedure was associated with superior safety and similar improvements in clinical outcomes.

Further Reading

Feldman T et al. *N Engl J Med* 2011.