

ACCESS-EUROPE Phase 1- Discussion

No Disclosures

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ACCESS-EUROPE Phase 1

- Adds important confirmatory data to existing studies:
 - In expert hands MitraClip implant is feasible at acceptable procedural risk in co-morbid patients
 - Severity of MR is improved to a meaningful extent in the majority (about 80%)
 - Accompanied in many, but not all, by symptomatic and functional improvement

Broader Context

- Real world practice:
 - Majority of procedures performed in co-morbid patients with functional MR, not the EVEREST II randomised population
 - Considerable heterogeneity in activity between centres
 - TRAMI registry n=486, 15 centres, median enrolment 12 (range 1-217)
 - Variable involvement of a heart team including a surgeon in decision making, 35% in TRAMI

ESC Heart Failure Guidelines 2012

- ‘In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge to edge repair may be considered in order to improve symptoms’

Outstanding Questions

- Patient selection
 - 25-35% derive little or no symptomatic benefit
 - ? Valve anatomy
 - ? Accurate quantification of MR
 - ? Irreversible myocardial damage – no reverse remodelling
- ?Pragmatic Randomised Trial
 - Optimised medical therapy, +/- Mitraclip
 - Heart Team driven