

# Meta-analysis protocol: MitraClip system versus surgery for treatment of severe mitral regurgitation

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## Objectives

The purpose of this meta-analysis is to compare the safety, clinical efficacy, and survival outcomes of MitraClip implantation with that for surgical correction of severe MR.

## Methods

### Participants

Patients with severe organic and/or functional MR.

### Interventions

Mitral valve edge-to-edge repair using the MitraClip device and surgical mitral valve repair or replacement.

### Outcome measures

The primary outcome measure of interest include post-procedural MR severity >2 and 30-day mortality. Secondary outcome measures include neurological events, acute procedural success, reoperations for failed MV procedures, NYHA functional class III/IV, and 12-month survival.

### Search strategy

Studies that compare the MitraClip device with surgical intervention for high surgical risk candidates with severe organic and/or functional MR will be included.

Six electronic databases including MEDLINE, EMBASE, PubMed, Cochrane Central Register of Controlled Trials,

Cochrane Database of Systematic Reviews, and Database of Abstracts of Reviews of Effectiveness will be searched for original published studies. The reference lists of all retrieved articles will be reviewed to further identify potentially relevant studies. Experimental or observational studies will be included in the present review. Only studies in English will be included. Case reports, series with less than ten patients, abstracts, editorials, and expert opinions will be excluded.

Two reviewers will independently appraise the studies using a standard form, and extract data on methodology, quality criteria, and outcome measures. All data will be extracted and tabulated from the relevant articles' texts, tables, and figures and checked by an additional reviewer. The quality of studies will be assessed using assessment criteria recommended by the National Health Service Centre for Reviews and Dissemination (University of York, Heslington, United Kingdom).

### Statistical analysis

The odds ratios or weighted mean differences will be used a summary statistic. Random effects models will be used as these account for potential clinical diversity and methodological variation between studies where selection criteria and risk profiles of patients differ.  $I^2$  statistics will be used to estimate the variation across studies due to heterogeneity rather than chance.  $I^2$  values greater than 50% will be considered high and the possible clinical and methodological reasons for this will be explored qualitatively. Statistical significance will be considered at  $P < 0.05$ . All P values will be 2-sided.