# Systematic review protocol: robotically-assisted minimally invasive mitral valve surgery

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# **Objectives**

The primary objective of this systematic review is to assess the safety and efficacy of robotic-assisted MIMVS. The secondary objective is to perform a meta-analysis comparing robotic-assisted MIMVS with conventional mitral valve surgery based on randomized and/or non-randomized studies.

#### **Methods**

#### **Participants**

Adult patients undergoing mitral valve surgery.

# Interventions

Robotic-assisted, minimally invasive surgery, including repair of the valve or replacement with a prosthesis. Currently this refers to studies that used the AESOP 3000, Da Vinci or Zeus surgical robotic systems.

# Outcome measures

The primary outcome measure is safety, including mortality and morbidity (intraoperative outcomes: operative duration, cross-clamp time, conversion rates; perioperative outcomes: myocardial infarction, atrial fibrillation, neurological adverse events, bleeding, transfusion, re-exploration, septic complications, pain, hospital stay, and discharge disposition). Secondary outcome measures include echocardiographic findings, intermediate- and long-term results, quality of life assessments, and cost analysis.

### Search strategy

Studies that report clinical outcomes of robotic-assisted MIMVS will be selected for both qualitative assessment and quantitative data synthesis. Studies comparing robotic-assisted MIMVS to conventional MVS via sternotomy, or to video-assisted thoroscopic techniques will be selected for meta-analysis.

Electronic searches of six databases were performed, including Pubmed, MEDLINE, EMBASE, the Cochrane Database of Systematic Reviews, the Cochrane Database of Abstracts of Reviews of Effects, and the Cochrane Central Register of Controlled Trials. Manual searches of reference lists will be used to identify any studies not found in the initial search. Only studies in English will be included. All abstract and letter articles will be excluded.

An in/out form will be used by two independent reviewers to assess studies for inclusion or exclusion using predetermined inclusion criteria. A PRISMA flow-diagram will summarize inclusion/exclusion of studies. The level of evidence for each study will be reported to assess the quality of the evidence.

# Statistical analysis

The relative risk (RR) will be used as a summary statistic. Both fixed and random effect models will be tested; should there be variations between studies, then a random effect model will be used as the calculated ratios will have a more conservative value.  $\chi^2$  tests will be used to study heterogeneity between trials. If there is a substantial heterogeneity, the possible clinical and methodological reasons for this will be explored qualitatively.