Systematic review of off-pump coronary artery bypass surgery with the aid of the Octopus Tissue Stabilizer: update and re-appraisal 2001

Authors' objectives
To identify any literature published subsequent to the ratification of the ASERNIP-S report (see Other Publications of Related Interest no.1) on the safety and efficacy of off-pump coronary artery bypass surgery with the aid of tissue stabilisers, which may constitute a change in the evidence-base, and consequently, the ASERNIP-S classifications derived from that evidence-base.

Searching
The authors searched MEDLINE (January 1966 to 08 February, 2001), Current Contents (week 1, 1993 to week 6, 2001), EMBASE (week 1, 1974 to week 5, 2001) and the Cochrane Library (January 1966 to Issue 1, 2001). The search terms were listed in the paper. For CPB-CABG, the search strategy was restricted to review articles published since 1997. Only English language articles were included in the review. The bibliographies of all publications included in the review were examined for relevant references that may have been missed in the database search.

Study selection
Study designs of evaluations included in the review
The study designs included in the review were randomised-controlled trials (RCTs), non-randomised comparative studies, case series and case reports.

Specific interventions included in the review
The inclusion criteria specified the use of the Octopus Tissue Stabilizer in conjunction with off-pump coronary artery bypass graft surgery (OPCAB) via full median sternotomy (Octopus OPCAB) compared to coronary artery bypass graft with cardiopulmonary bypass (CPB-CABG). Studies of any other surgical approach, such as thoracotomy, were excluded. Papers that pooled data from different surgical approaches and/or mechanical stabilizers were excluded unless data for the full median sternotomy approach and/or Octopus Tissue Stabilizer could be separated.

Participants included in the review
The authors did not state any global inclusion or exclusion criteria for patients in the review. For Octopus OPCAB, only studies on non-pregnant adults undergoing treatment for single- or multiple- vessel coronary artery disease were included.

Outcomes assessed in the review
The outcomes reported were classified as safety and efficacy. The peri-operative safety outcomes were: myocardial infarction, intra-aortic balloon pump required, cerebrovascular accident, mean cross-clamp time, mean coronary artery occlusion time, mean duration of bypass, average blood loss, transfusion, atrial fibrillation, mean duration of ischaemia, inotropic support required, and low cardiac output requiring treatment.

The post-operative safety outcomes were: mortality, new onset atrial fibrillation, myocardial infarction, cerebrovascular accident, renal insufficiency or failure, sternal infection, re-intervention for bleeding, transfusion, atrial arrhythmias, low cardiac output syndrome, intra-aortic balloon pump required, inotropic support required, neurological complication, confusion, and the early use of diuretics.

The peri-operative efficacy outcomes were: mean operative time, mean intensive care unit stay, mean hospital stay, mean duration of ventilation, mean graft time, mean number of grafts per patient, and conversion to CABG.

The post-operative efficacy outcomes were: re-treatment rate (repeat surgery or percutaneous transluminal coronary angioplasty), anastomosis patency, stenosis-free patency, free of anginal symptoms, myocardial ischaemia, and chest pain during exercise.
How were decisions on the relevance of primary studies made?
For most of the studies no information was given on how relevance decisions were made. For two studies, it was not clear to the review authors whether they should have been included in the review or not, so the study authors were contacted. Following such contact, both studies were included in the review.

Assessment of study quality
No formal validity assessment was undertaken. Each study was assigned a level of evidence score based on those described by the National Health and Medical Research Council, according to study design. The authors did not state how many reviewers did this. The authors also discussed aspects of the studies in the text, such as randomisation, blinding and loss to follow-up.

Data extraction
The authors did not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. Data from all of the studies were presented in tabular format. Three categories of data were extracted: patient status, peri-operative outcomes and post-operative outcomes.

Methods of synthesis
How were the studies combined?
The authors stated that a meta-analysis was not performed, because the majority of studies were of poor evidence quality and they varied widely in outcome measures and study design. The results of the studies were described in a narrative review.

How were differences between studies investigated?
Differences between the studies were described in the text.

Results of the review
A total of 21 studies, with a total of 1,784 patients, were included in the review: 2 RCTs (n=46), 10 non-randomised comparative studies (n=1,235) and 9 case series (n=503). For the purposes of the review, the data were considered as one RCT (n=26), 5 non-randomised comparative studies (n=545) and 15 case series (n=1,213), because not all compared the two interventions of interest and in these cases only data from the trial arm of interest were used.

The limited comparative data showed little difference in safety outcomes between Octopus OPCAB and CPB-CABG. The authors stated that the incidence of adverse outcomes following Octopus OPCAB was generally lower than following CPB-CABG.

The serious complications often associated with CPB-CABG, such as renal failure and cerebrovascular accident, were largely absent in the Octopus OPCAB case series studies.

Incidences of peri-operative morbidity were reported in fewer patients in the Octopus OPCAB case series, compared with the large CPB-CABG series.

The limited comparative data available suggested that operative time, duration of ventilation, mean intensive care unit and hospital stay were similar for CPB-CABG and Octopus OPCAB. A comparison of the length of hospital stay between the Octopus OPCAB case series studies and the large CPB-CABG series was equivocal. The lack of information regarding length of follow-up made it difficult to compare post-operative variables, such as reoperation rate and angina-free rates, with the large CPB-CABG series. The comparative data suggested that Octopus OPCAB caused significantly less damage to myocytes than CPB-CABG. The results for each study were given in the review.

Authors' conclusions
The safety and efficacy of Octopus OPCAB cannot be determined at the present time due to an incomplete and poor-
quality evidence-base. The authors noted the difficulty in pooling results from studies that are non-randomised, and discussed some of the difficulties encountered in trying to design good randomised studies.

**CRD commentary**

This was a good review of an area in which there was little good-quality evidence. The authors included all study designs in their review, but assigned designations of levels of evidence to each study according to its design. Furthermore, these designations were amended in the light of the applicability of the comparisons to the review. The methods and reasons for these changes were described and appear justified. Aspects of methodological validity were discussed, but no formal validity assessment was undertaken.

The search strategy included multiple databases. It is unclear why the search strategy was restricted to review articles for CPB-CABG. Only English language articles were included in the review, which might have resulted in the exclusion of smaller or less well publicised studies. However, the authors noted that the foreign language papers, based on their abstract, did not offer any significantly different or more extensive results to those reported in the English language papers.

For Octopus OPCAB, only studies on non-pregnant adults undergoing treatment for single- or multiple-vessel coronary artery disease were included. This exclusion criterion was not applied to studies on CPB-CABG, suggesting that the studies included for the two groups may have differed in their patient group; there were insufficient details of the included studies to determine whether this was the case or not. The authors discussed the effect that the differing underlying disease in patients treated in the two ways would have on the results, but did not explain why they did not consider only patients with single- or multiple-vessel coronary artery disease in the CPB-CABG studies.

The implications of the review are generally suitably conservative in view of the poor quality of the individual studies, although the DARE reviewer does not agree that there is sufficient evidence for the authors to state that the incidence of adverse outcomes following Octopus OPCAB was generally lower than following CPB-CABG. This report has also been published as a journal article (see Other Publications of Related Interest no.2).

**Implications of the review for practice and research**

**Practice:** The authors state that Octopus OPCAB should only be performed on appropriately selected patients by a properly trained cardiac surgeon. Before performing Octopus OPCAB, the surgeon should participate in a formal training workshop that includes surgical theory, animal wet lab experience, and an observational visit to a surgical unit that routinely performs Octopus OPCAB. Cardiac surgeons should obtain institutional support and appropriately inform their patients before commencing Octopus OPCAB. Ideally, angiography with short-term follow-up should be performed on at least the first ten patients. This initial data can then be used by the institution to determine whether to proceed with the Octopus OPCAB programme, continue close surveillance or recommend further surgical training. Minimal access approaches, such as limited thoracotomy, should only be attempted after an acceptable standard in full sternotomy has been achieved.

**Research:** The authors state that more rigorous studies with longer follow-up periods and larger sample sizes must be conducted before a definitive conclusion can be reached regarding the safety and efficacy of Octopus OPCAB in comparison to CPB-CABG.

**Bibliographic details**


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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.