Enhanced external counterpulsation for stable angina or heart failure: a systematic review and economic evaluation


CRD summary
The authors concluded that the results from single RCTs did not provide firm evidence of the clinical effectiveness of enhanced external counterpulsation in the treatment of refractory stable angina or in heart failure. The authors’ conclusion reflected the evidence presented and is likely to be reliable.

Authors’ objectives
To evaluate the effectiveness of enhanced external counterpulsation (EECP - non-invasive technique used to improve cardiac perfusion) for the treatment of stable angina and heart failure.

Searching
MEDLINE, EMBASE, CINAHL, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), DARE, Inside Conferences, the National Research Register, ClinicalTrials.gov, Current Controlled Trials Meta Register, the US Food and Drug Administration website, and the website of Vasomedical (the main enhanced external counterpulsation manufacturer) were searched for published and unpublished material from 1980 with no language restrictions. Vasomedical manufacturers were also contacted for relevant information.

Study selection
Eligible for inclusion in the review were studies that compared the use of enhanced external counterpulsation (EECP) with usual care (drugs, cardiac rehabilitation, revascularisation) or placebo in patients with chronic stable angina or heart failure. Eligible studies were required use the prescribed dose of EECP of 35 hours treatment over a continuous period without significant breaks. Eligible study designs were randomised controlled trials (RCTs), non-randomised controlled trials, cohort studies with a contemporaneous control group, and case control studies. Studies reported as meeting abstracts were excluded from the review.

Outcomes of interest included: mortality due to coronary heart disease, all-cause mortality, hospitalisation, change in angina severity classification (Canadian Cardiovascular Society classification), change in heart failure severity classification (New York Heart Association classification), diuretic dose, exercise duration on treadmill, time to one minute ST segment depression, peak oxygen consumption, and health related quality of life and adverse events.

Comparators in the included studies were: sham EECP, usual care and percutaneous coronary intervention.

Two reviewers independently performed the study selection, with any disagreements resolved by consensus.

Assessment of study quality
Study quality was assessed using the following criteria: method of randomisation; allocation concealment; how participants were allocated in non-randomised studies; similarity at baseline; blinding of outcome assessment; and the use of intention to treat analysis.

Two reviewers independently assessed study quality with any disagreements resolved by consensus or the involvement of third reviewer if necessary.

Data extraction
Data were extracted on patient characteristics (age, sex, baseline disease severity, comorbidities), details of intervention and comparator, adherence, length of follow up and study quality.

Data were extracted by one reviewer and checked by a second. Any disagreements were resolved by discussion, and if necessary the opinion of a third reviewer.
Methods of synthesis
Results were presented in a narrative synthesis.

Results of the review
Enhanced external counterpulsation (EECP) for angina: One RCT (n=139 participants) of relative good quality, and three poor quality non-randomised controlled trials evaluated EECP for angina. The RCT showed a statistically significant improvement in exercise induced ischaemia as measured by time to greater than or equal to 1mm ST segment depression in participants who received EECP compared with those who received sham EECP (mean difference 41 seconds, 95% CI 9.10 to 73.90). There was no statistically significant difference between the EECP and control groups in change of exercise duration from baseline to end of treatment, self reported angina episodes per day, or daily nitroglycerin use. There were more withdrawals due to adverse events in the EECP group compared to the control group. Also, a greater proportion of patients in the EECP group experienced adverse events (RR 2.13, 95% CI 1.35 to 3.38).

EECP for heart failure: One multi-centre RCT (n=187 participants) evaluated EECP compared with usual care (pharmacotherapy only) for heart failure. At six months post-treatment, a statistically significant greater proportion of participants in the EECP showed an improvement in the New York Heart Association classification severity scale compared with the control group (RR 2.25, 95% CI 1.25 to 4.06); but there was no statistically significant difference in improvement in peak volume of oxygen uptake, or withdrawals due to adverse events. In the EECP group, the mean number of participants with at least a 60 second increase in exercise duration and the mean exercise duration were greater than in the control group.

Cost information
If quality of life benefits of enhanced external counterpulsation (EECP) were assumed to be maintained for no more than one year after treatment, EECP did not appear to be cost effective, as defined by the National Institute for Health and Clinical Excellence's cost effective threshold range (2004).

If quality of life benefits were maintained over a life time, EECP was cost effective. The base case analysis, based on pooled expert beliefs about the durability of quality of benefits, suggested that EECP was cost-effective (incremental cost effectiveness ratio of £18,643), but the probability that it was more cost-effective than no treatment was around 0.4, indicating high uncertainty of this estimate.

Authors’ conclusions
The results from single RCTs did not provide firm evidence of the clinical effectiveness of enhanced external counterpulsation in refractory stable angina or in heart failure.

CRD commentary
The review addressed a clear research question and was supported by detailed inclusion criteria. The search was adequate and had no language restrictions, which reduced the possibility of language bias. The review processes were performed in a manner that minimised reviewer error and bias.

Study quality was assessed, which meant the reliability of the data included in the review could be determined. Given the variation in study design and patient characteristics, it was appropriate that a narrative synthesis was used.

The authors’ conclusion reflected the evidence presented and is likely to be reliable.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that high quality studies are required to investigate the benefits of enhanced external counterpulsation (EECP) and whether these outweigh the common adverse effects. Long-term trials are required that
assess quality of life in chronic stable angina and heart failure. The design of any future trials should take into account existing angina guidelines. Additional research is also required to investigate: the generalisability of findings to UK practice; impact of EECP on mortality and on major adverse cardiovascular events; difference between quality of life associated with EECP and other comparative treatments; duration of beneficial effects; efficacy in different subgroup populations; and, in particular, symptomatic relief in patients with truly refractory severe angina and the effectiveness of different EECP treatment regimens.

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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.