External counterpulsation for treatment of chronic stable angina pectoris and chronic heart failure

BlueCross BlueShield Association

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

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Citation

Authors' objectives
The aim of this report is to review the available evidence to determine if external counterpulsation (ECP) therapy improves health outcomes for refractory chronic stable angina pectoris or chronic stable heart failure.

Authors' conclusions
No comparative studies of ECP address the hard outcomes of cardiac death or recurrent cardiac events such as myocardial infarction and revascularization procedures. However, symptom improvement, measured by functional classification scales and quality of life instruments, is perceived as a positive outcome by patients. The other outcomes reported in the studies of ECP are primarily physiologically based (exercise duration, time to ST-segment depression) and are difficult to interpret clinically.

Although the results of the randomized trial of ECP in angina are consistent with observational studies, the trial does not provide convincing evidence of the efficacy ECP treatment. This trial found statistically significant results in 1 of 4 primary outcomes; treatment extended the time to ST-segment depression by 37 seconds. There was no significant difference between treatment groups in the change in exercise duration from baseline to the post-treatment period (p<0.31). In addition, there were no statistically significant differences between groups with respect to angina counts (p<0.09) or nitroglycerin usage (p>0.1). The single-arm case series and multicenter registry studies provide interesting starting points for research questions that need to be addressed with comparative trials.

The evidence supporting the role of ECP as an effective treatment for heart failure is lacking in both quantity and quality. A single, unpublished controlled trial was mostly inconclusive. It found statistically improved, but modest, changes in exercise duration, and improved functional classification, but not in quality of life or peak oxygen uptake. Registry studies for heart failure use angina outcomes and contribute little to the body of evidence. The single-arm study indicates that patients respond with some improvements, but the lack of a comparison arm precludes inference about the true effects of therapy. Treatment durability has yet to be addressed with long-term studies.

Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether external counterpulsation for the indications of refractory angina or heart failure meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

Vasomedical's EECP device received U.S. Food and Drug Administration (FDA) marketing clearance via 510(k) in 1995 for treatment of patients with stable or unstable angina pectoris, acute myocardial infarction, and cardiogenic shock. In 2002, the EECP Therapy System Model TS3 with Pulse Oximetry was cleared for marketing (with heart failure added to the indications for use) as substantially equivalent to the predicate devices, Cardiomedics, Inc. has
FDA 510(k) clearance to market the CardiAssist Counterpulsation System and the CardiAssist ECP System for the same indications as the Vasomedical EECP systems. The technology meets criterion 1.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The available evidence is not sufficient to permit conclusions of the effect of ECP therapy on health outcomes. Both controlled trials had methodologic flaws. The case series and observational studies for both indications, while suggestive of a treatment benefit from ECP, have shortcomings as well.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives.

The available evidence does not permit conclusions regarding the effect of ECP therapy on health outcomes or compared with alternatives.

5. The improvement must be attainable outside the investigational settings.

It has not yet been demonstrated whether ECP therapy improves health outcomes in the investigational setting. Therefore, it cannot be demonstrated whether improvement is attainable outside the investigational settings.

For the above reasons, ECP therapy for treatment of refractory angina pectoris and heart failure does not meet the TEC criteria.

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