Enhanced External Counterpulsation (EECP): Enough evidence to support this and the next wave?

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New approaches are emerging for treatment of the increasing number of patients with chronic angina and congestive heart failure (CHF) that is refractory to pharmacologic and interventional therapeutic approaches. Enhanced External Counterpulsation (EECP) is a recently approved device for use in patients with disabling, chronic angina as well as heart failure. The device comprises inflatable cuffs that encompass the calf, thigh and upper thigh and squeeze sequentially from low to high during diastole and then rapidly and simultaneously deflate at the onset of systole. This mechanism is gated off of the electrocardiogram. The arterial hemodynamics generated by the device simulate those of the intra-aortic balloon pump (IABP) with the generation of a retrograde arterial wave pulse. Unlike an IABP, a retrograde venous pulse is generated, as well, which increases venous return. The retrograde arterial wave pulse is the source of the augmented coronary flow while the venous return helps to improve cardiac output and decreases oxygen consumption.[1] The usual course of treatment is 35 one-hour sessions. Patients with angina eligible for Medicare reimbursement for EECP are those who are on medication and deemed not to be good candidates for revascularization. Treatment for heart failure in the absence of refractory angina is currently not reimbursed by Medicare.

To date there have been well over 100 articles published, including a recent large review series looking at the effectiveness of EECP in patients with angina, and cardiogenic shock.[2] Evidence regarding efficacy in patients with CHF is just beginning to emerge. Most of these articles are single center studies of a small cohort of patients or, like the article by Linnemeier et al[3] in this issue of the Journal, an analysis of the EECP registry. The International EECP Patient Registry (IEPR) was started in 1998 and fashioned on the basis of the NHLBI angioplasty registry, in order to study the outcome of patients undergoing EECP.[4] The enrollment of the first phase of this long-term study was closed in July of 2001 with nearly 5200 patients. Although the EECP article in this issue focuses on the efficacy of this treatment in patients with diabetes, the nondiabetic population mirrors other analyses with regard to findings on the beneficial effects of EECP on angina class (about 70% improve at lease 1 class), frequency of angina episodes (average reduction of 60%), and long-term efficacy (80% maintenance of effect at 1 year).[3]

There has been only 1 randomized, placebo controlled trial to study the effect and safety of EECP on patients with chronic angina.[5] There were 139 patients enrolled. Seventy-one patients in the active treatment group had full pressure applied to the cuffs, which was on the order of approximately 250 to 300 mm Hg, whereas the 66 patients in the placebo group had $<$25 mm Hg applied. Both groups had improvement in exercise duration, with the active group exercising for a longer, although not statistically significant, time. The active group did show a statistically significant improvement in time to ST-segment depression, which was 1 primary end point. On demand nitroglycerin use and quality of life in a substudy measured by the SF-36 were also much improved in the active group. These effects (on the order of 20% to 50% improvement) were less impressive than have been found for patients in the registry.

So to date, the data consist of 1 randomized trial with 137 evaluable patients (only 23% of whom where class III or worse angina), numerous nonrandomized observational small studies, and various analyses of the $>$5000 patients entered into the EECP registry. Is this enough to support treatment of the current Medicare population eligible for reimbursement—those individuals with Class III or IV angina that, in the opinion of a cardiologist or cardiac surgeon, is not amenable to revascularization? Given the limited scope of this population and a lack of other proven noninvasive adjunctive therapies, the answer is yes; especially given the improvements in quality of life and angina score that consistently are positive across these analyses.

Because quality indicators have driven decisions to approve EECP, the worth of the procedure is difficult to quantify but the financial cost is not insignificant. Medicare reimbursement is currently around $180 dollars a session, or $6300 per 35-session treatment course. This cost is approximately equivalent to 5 years of medical therapy with 4 evidence-based treat-

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ments (a β-blocker, angiotensin-converting enzyme inhibitor, statin and aspirin). The burden on Medicare is small given the small number of patients with this class of ischemia.

This burden could become much larger if the industry's new target population of CHF patients is approved for reimbursement. There are nearly 3 million individuals aged >65 years with CHF, which amounts to a potential cost of nearly $19 billion if the reimbursement amount were similar and all were to qualify for treatment. This number dwarfs the estimates of cost for placing the proven life-saving therapy of defibrillators in those who meet the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II criteria.[6] Given the difficult decisions regarding resource allocation already being made concerning defibrillators and coated stents, decisions about future reimbursement for implementation of EECP in CHF should be held to a higher standard than was the decision for reimbursement for implementation for the therapy of angina.

In conclusion, for individuals with refractory ischemia who have not responded to maximal medical and revascularization therapy, EECP is a reasonable alternative therapy. There is evidence from both prospective registries and randomized trials that supports its benefit. Investigations into widening the scope of patients who are reimbursed for this therapy is warranted on the basis of existing data, but future approval should be held to the same standards as other current devices with regard to documented benefit in randomized trials of sufficient power to evaluate hard clinical end points.

References

1. Watson JT, Platt M, Rogers D, et al. Similarities in coronary flow between external counterpulsation and intra-aortic balloon pumping. Am J Physiol 1976;230:1616–21.
2. Conti R. Enhanced external counterpulsation (EECP): current experience and future directions. Clin Cardiol 2002;25(Suppl):II1–28.
3. Linnemeier G, Rutter MK, Barsness G, et al. Enhanced external counterpulsation for the relief of angina in patients with diabetes: safety, efficacy and 1-year clinical outcomes. Am Heart J 2003; 146:453–8.
4. IEPR Department of Epidemiology, Graduate School of Public Health. University of Pittsburgh. Data on file.
5. Arora RR, Chou TM, Diwakar J, et al. Multicenter study of enhanced counterpulsation (MUST-EECP): effect of EECP on exercise-induced myocardial ischemia and anginal episodes. J Am Coll Cardiol 1999;33:1833–40.
6. Prystowsky EN, Nisam S. Prophylactic implantable cardioverter defibrillator trials: MUSTT, MADIT, and beyond. Multicenter Unsustained Tachycardia Trial. Multicenter Automatic Defibrillator Implantation Trial. Am J Cardiol 2000;86:1214–5.