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Functional Status Improvement After Enhanced External Counterpulsation (EECP) for Treatment of Chronic Angina Pectoris

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Summary

The International EECP Patient Registry (IEPR) collects data from 60 sites on consecutive chronic angina patients treated with EECP. The Duke Activity Status Index (DASI), a 12 item patient completed questionnaire, was used to measure functional capacity in patients before and after a course of EECP treatment. The Canadian Cardiovascular Society Classification (CCSC) of angina was used to monitor changes in angina. The majority of patients had severe angina, had prior invasive revascularization, but were not suitable for bypass surgery or percutaneous intervention. Functional status measured by the DASI questionnaire was poor at baseline, but improved significantly after EECP treatment. Co-morbidities although predictive of low baseline DASI, were not associated with failure to achieve functional improvement.

Introduction

There are an increasing number of patients who suffer chronic angina despite maximal medical therapy, and who are not amenable or who reject more conventional invasive revascularization. For these patients Enhanced External Counterpulsation (EECP) is increasingly being used to reduce angina symptoms. EECP is a non-invasive analogue of the intra-aortic balloon pump designed to increase myocardial perfusion pressure and decrease cardiac workload.

In a randomized trial of EECP vs. sham treatment, Arora et al (1) demonstrated that EECP resulted in a statistically significant post-treat-

ment increase in exercise duration, increase in time to S-T depression and a reduction in the frequency of anginal episodes. These randomized patients also showed an improvement in health related quality of life measures for patients who had undergone active treatment (2). In order to obtain data on outcome and safety of EECp in angina patients in a wide variety of treatment settings, the International EECp Patient Registry (IEPR) was established in 1998 (3). An invitation was extended to all providers of EECp treatment to enroll patients. Data were collected on patient baseline characteristics, procedural parameters, and short and long term angina status and adverse events. The registry closed enrollment in July 2001 with over 5000 patients from 89 sites, and three year follow-up is underway (IEPRI). A second phase of the registry was opened in January 2002 (IEPRII). The second phase added measurement of quality of life to the clinical data already collected. The aim of this report was to examine the effect of EECp on the functional status of patients after treatment with EECp, and to determine predictors of increased functional status.

Methods

524 angina patients from 60 clinical sites participating in IEPR II were examined. Data collected before the start of EECp included demographics, angina symptoms and co-morbidities and medical history. After the standard course of 35 hours of treatment, angina symptoms were again recorded as well as information concerning any adverse events during the course of treatment. Quality of life both pre-EECP and post-EECP was assessed using the Duke Activity Status Index (DASI) a 12-item questionnaire completed by the patient (4). The questionnaire contains items concerning the ability of the patient to perform activities of general life ranging from taking care of self and house, to participating in strenuous sporting activities. Specifically the twelve questions address the domains of personal care; ability to walk, run or climb stairs; perform activities around the house and garden; have sexual relations; and participate in moderately active or strenuous recreational activities. A higher score reflects better functioning. The score has been found to correlate well with peak oxygen uptake during exercise testing, and has been used to monitor functional status in many studies of coronary patients (5).

Results

The mean age of the patients was 68 years; 73% were male and 92% were Caucasian. Coronary disease was long standing with a mean duration since diagnosis of 12 years. Most had some prior revascularization, 73% had undergone bypass surgery, and 68% percutaneous coronary

intervention. However at the time of of EECp treatment only 10% were considered suitable for further invasive revascularization. There was a history of myocardial infarction in 71%. Anginal symptoms were severe with 93% reporting CCSC Class III or IV, with a mean of 11 angina episodes a week. Nitroglycerin was used by 74%. A high proportion of patients had comorbidities; diabetes was reported in 42%, congestive heart failure in 32%, peripheral vascular disease in 23%. Medication use included beta-blockers in 78%, calcium channel blockers in 39%, ace inhibitors in 47%, angiotensin receptor blockers in 12%, nitrates in 79% and antiplatelet in 74%. The mean DASI score for these patients pre-EECP was 12.0 ± 10.5 out a maximum of 58.2. These scores reflect an ability to perform an average of 3.8 (median 3, interquartile range 2 – 5) of the 12 activities. Women had a significantly lower DASI score than men (mean 8.7 vs. 13.2, $p < 0.001$), as did patients with more severe angina (8.7 vs. 20.8, $p < 0.001$). Patients with comorbidities likewise tended to have significantly lower scores; diabetes 10.2, peripheral vascular disease 9.1 and congestive heart failure 9.1. In contrast patient without diabetes or peripheral vascular disease or congestive heart failure had a mean score of 14.3. A regression model showed the following to be significant independent predictors of a low DASI score at baseline; severe angina (Class III/IV), congestive heart disease, peripheral vascular disease, prior bypass surgery (all $p < 0.01$). The standard course of 35 hours of treatment was completed by 84% of patients. Adverse events during treatment were very few. Two patients decided to have bypass surgery and 4 patient percutaneous intervention. Other events included skin problems in 14 (2.7%), and exacerbation of heart failure in 8 (1.5%). One patient died and 5 had myocardial infarction. Ten percent of the patients did not complete treatment because they could not tolerate it, or had problems with transport, reimbursement or other issues. Angina was reduced by at least 1 CCSC class in 84% of the patients who completed treatment.

DASI scores post-EECP had improved with a mean score reported of 18.9 ± 12.2 , and a significant mean increase of 5.9 ± 10.6 . This corresponds to an increase of 1.4 (median 1.0, interquartile range 0 – 3) additional activities. Patients who completed the full course of treatment had an increase of 6.8 ± 10.4 , whilst those who failed to complete treatment only increased their scores by a mean of 1.7 ± 10.5 . Increase in DASI score was independently associated with a low score pre-treatment, a reduction in angina and younger age by regression analysis. The co-morbidities associated with lower DASI scores at baseline did not significantly affect the ability to achieve functional improvement.

Conclusions

EECP has previously been shown to be a safe and effective treatment

for chronic angina for those patients who because of co-morbid conditions are not suitable for invasive procedures, or who reject these procedures. This present study shows that the reduction in angina seen in these patients is accompanied by an improvement in their functional status, their ability to perform normal activities of life. This improvement is seen in a very diverse chronic angina patient population with a wide range of comorbidities and anginal status. The increase in DASI score in these patients is only slightly less than that reported for patients one year after bypass surgery and slightly more than that reported for patients undergoing angioplasty (5). This degree of improvement corresponds the ability of the patients to perform a mean of one additional activity, which although small can be quite meaningful to the patient who improves to the point of being able, for example, to take care of a garden, that was impossible before.

EECP is a well tolerated, safe and effective treatment for refractive angina which can be used in a wide range of patients. The reduction in angina achieved at the end of treatment is accompanied by a significant improvement in functional status.

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