Psychosocial Aspects of Enhanced External Counterpulsation

EECP (Vasomedical) is a noninvasive treatment that has shown promise in the treatment of ischemic coronary artery disease. Compared to the psychosocial sequelae of coronary bypass surgery and coronary angioplasty, EECP may offer certain psychosocial advantages that would contribute to improved quality of life in angina patients. Overall health perception and overall well being are enhanced greatly in subjects who show objective improvement in ischemia, and also in those without objective evidence of improvement. There are also improvements in depression scores in both subject groups. Given the predictive relationship between depression and mortality from cardiac disease, this may be an important finding to study further.

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Introduction

EECP is a noninvasive outpatient treatment designed to increased coronary flow inth the treatment of angina.[2] This treatment involves wrapping the calves, thighs, and buttocks with pneumatic cuffs. Synchronized pulsatory pressure is applied sequentially from calves to thighs during diastole, returning arterial blood to the heart to increase diastolic pressure in the coronary vessels. Pressure is relieved during systole, reducing afterload and cardiac work, thus decreasing myocardial oxygen requirements. The typical course of treatment is 35 one-hour sessions over a period of 7 weeks. EECP has been shown to improve ischemia in patients who have thallium reperfusion evidence of ischemia. In one study of patients who received EECP, 75% of subjects had resolution of ischemia, demonstrated by improved thallium scintigraphy with normal thallium stress tests except for areas scarred by previous myocardial infarctions. These same subjects showed improved exercise tolerance.[3] Angina pectoris is induced by social and psychological stresses as well as by physical stresses.

Therefore, an important aspect of the use of EECP involves patient acceptability and psychosocial effects of treatment on the angina patient. Several questions can be posed. Is such a time consuming, effort requiring treatment well tolerated

ABBREVIATIONS AND ACRONYMS

BDI	Beck Depression Inventory
CABG	Coronary artery bypass grafting
CAD	Coronary artery disease
EECP	Enhanced external counterpulsation
GHQ	General Health Questionnaire
PAIS-R	Psychosocial Adjustment to Illness Scale (Revised)
PTCA	Percutaneous transluminal coronary angioplasty
SCL 90	Symptom checklist 90
STAI	State Trait Anxiety Inventory

psychologically and socially? Is there improved psychosocial adjustment and if so, would this alone lead to subjective improvements in pain, exercise, and physical well being?

We hypothesize that the attentive nature of the treatment would be well tolerated and might promote adaptation to illness. Mental stress reduction might be physiologically active in reducing myocardial ischemia and psychosocial benefits could have the potential to be both objectively and subjectively effective in reducing symptoms and ischemia. Is EECP better tolerated and accepted in terms of quality of life than treatments such as CABG and PTCA?

There is evidence that mental stress can induce silent myocardial ischemia in patients with CAD.[4,5] Recently, Jiang et al concluded that the presence of mental stress-induced ischemia is associated with significantly higher rates of subsequent fatal and non-fatal cardiac events.[5] This is independent of age of the patient, the baseline left ventricular ejection fraction, and history of previous myocardial infarction.

There is also evidence that depression after a myocardial infarction has a significant impact on 6 month survival.[1] Frasure-Smith et al showed that major depression in patients hospitalized following a myocardial infarction is an independent risk factor for mortality at 6 months. Depression rivals the presence of left ventricular dysfunction and history of previous myocardial infarction as a risk factor.[1]

The ideal treatment for CAD would be well tolerated by the patient. It would create minimal stress and avoid iatrogenic illness while being objectively and subjectively effective in treating CAD, enhancing overall quality of life.

The Psychosocial Impact of Coronary Artery Disease Treatments

Continuing improvement in surgical and anesthetic bypass technology and in postoperative management has reduced morbidity and mortality associated with CABG procedures. This has occurred despite the fact that a greater number of elderly patients are undergoing surgery in recent years. Nevertheless, as Townes et al made clear, the prevalence of major neurologic injury and of lesser neuropsychiatric disturbances that occur post CABG has not diminished.[6,7]

In 1984, Henriksen, a Danish researcher, presented evidence of diffuse brain damage following cardiac operations.[8] In his study, mean cerebral blood flow fell significantly in 24 out of 31 patients after cardiac surgeries. Cerebral blood flow reduction was generally more pronounced in patients who received valve replacements than in CABG patients; however, there was still a significant reduction in those undergoing bypass grafting.

In a recent study, Roach et al in the Multicenter Study of Peri-Operative Ischemia Research Group and investigators at the Ischemia Research and Education Foundation found that there were adverse cerebral outcomes in 129 of out 2108 patients (6.1%) from 24 U.S. institutions.[9] There were 2 types of adverse neurologic outcomes: Type 1 is represented by focal injury, stupor, or coma at discharge; and Type 2 by deterioration in intellectual function, memory deficit, or seizures. A total of 3.1% had Type 1 neurologic outcomes: 8 died of cerebral injury, 55 had nonfatal strokes, 2 had transient ischemic attacks, while 1 experienced stupor. Three percent had Type 2 outcomes: 55 patients had deterioration in intellectual function, while 8 experienced seizures.

In the patient population with adverse cerebral outcomes there was a higher in-hospital mortality; 21% of Type 1 outcome patients died while 10% of those with Type 2 outcomes died. Two percent of those without adverse cerebral outcomes also died. Patients with either Type 1 or Type 2 neurologic outcomes had longer hospitalizations than those without adverse neurologic outcomes. They also had a higher rate of discharge to health related facilities for intermediate or long term care. Those with Type 1 outcomes were transferred 47% of the time; while those with Type 2 outcomes were transferred 30% of the time.

Patients who had proximal aortic arteriosclerotic disease, history of neurologic disorder, and older age were more likely to have Type 1 neurologic outcomes after CABG. Patients with systolic hypertension, pulmonary disease, and a history of alcohol abuse were more likely to have Type 2 neurologic outcomes. The authors suggest that adverse cerebral outcomes after CABG are relatively common and serious. There are substantial increases in mortality, length of hospitalization, and use of intermediate and long term health related facilities after discharge. They feel that it is imperative that new diagnostic and therapeutic strategies be developed to mitigate these adverse cerebral outcomes.

One can surmise that in a substantial number of patients (6.1%) who have adverse cerebral outcomes, the quality of life after CABG is diminished for a substantial period of time. But what of quality of life after PTCA? In another recent study, Hlatky et al in the Bypass Angioplasty Revascularization

Investigation studied medical care costs and quality of life after randomization to PTCA or CABG.[10] They studied a total of 934 patients, compiling detailed, yearly quality-of-life data, and quarterly economic data.

During the first 3 years of follow up, Hlatky et al found functional status scores on the Duke Activity Status Index, a measure of the ability to perform activities of daily living, actually showed greater improvement after CABG than in patients who underwent PTCA. They also administered the Rand Mental Health Inventory, a 5 item scale with total scores ranging from 0 to 100 (the higher scores representing better mental health). This scale assesses anxiety, depression, and positive affect. The mean score for patients status-post PTCA was 72.7 while the mean scores for patients status-post CABG was 73.0. The median scores were 76.0 after PTCA and 76.0 after CABG.

The improvement in scores on the Duke Activity Status Index and the Rand Mental Health Inventory varied according to the patient's clinical profile upon entering the study. Congestive heart failure patients improved significantly less in physical functioning. Women improved less than men both in physical and emotional functioning. This study did not examine the subset of adverse cerebral outcomes. One might anticipate that this group would have had less morbidity and dysfunction after PTCA than after CABG.

Patients in the PTCA group returned to work 5 weeks sooner than did patients in the surgery group. The mean cost of PTCA was 35% lower than that of uncomplicated surgery, but after 5 years the total medical expense of PTCA was up to 95% of that of surgery. PTCA only had lower 5 year costs than CABG in patients with two vessel CAD. The authors concluded that in patients with multivessel coronary disease, CABG correlates with a better quality of life for three years than does PTCA when the initally higher morbidity caused by the procedure is eliminated. Thus, both with CABG and PTCA there seem to be important quality of life concerns.

Psychosocial Aspects of Enhanced External Counterpulsation

In 1995 we published a preliminary study on the psychosocial aspects of EECP.[11] We looked at 12 male subjects with a mean age of 60.2 years using the PAIS-R and a questionnaire on pain, exercise, and medication needs as a reflection of quality of life. The PAIS-R is a 46 item self-report measure that evaluates 7 areas of adjustment to illness.[12] The EECP Quality of Life Questionnaire examined changes in living habits and general health.[11] Twelve out of the 15 subjects completed the PAIS-R, and 9 out of the 12 subjects completed the Quality of Life and Pain Questionnaire in addition to the PAIS-R. On the PAIS-R the range of values for both pre and post EECP generally was below the midpoint; thus these patients demonstrated fairly good overall adjustment to their illnesses.

Those who revealed improvement in ischemia post EECP as demonstrated in improved thallium scintigraphy were compared to those who showed no improvement. There were 9 in the former group and 3 in the latter group. Results showed that those who had no ischemic improvement had an average PAIS-R score of 44.3 with a standard deviation of 7.5 on the Psychological Distress Scale while those with ischemic improvement had a score of 52.9 with a standard deviation of 5.2 ($p<0.05$). Therefore, in those patients in whom EECP was successful in reducing ischemia there was a higher psychological distress score than in those in whom EECP did not reduce ischemia. Both groups demonstrated a significant decrease in the number of times subjects complained of chest pain, experienced chest pain severity, reported using nitrates to alleviate pain.

On the post EECP Quality of Life Questionnaire, 100% of the subjects reported an improvement in their ability to work, energy levels, and overall well being. Two out of the 9 respondents showed no evidence of ischemic improvement, yet they reported improvement in quality of life. The PAIS-R results suggest that this group of angina patients was relatively well adjusted to their CAD. In the small group without ischemic improvement, there was a significantly greater reduction in psychological distress.

We tentatively concluded, based on objective improvement in ischemia and exercise tolerance as well as on subjective improvements, that for that group of subjects EECP was primarily an effective physiological treatment for angina apart from any secondary psychological influences. Nevertheless, these latter influences also may be at work in patients receiving EECP.

Three CAD patients showed no improvement in their thallium scans yet demonstrated subjective improvement, which included reduction in psychological distress. In our more recent unpublished study, we have data on 28 men whose mean age is 63.57. Seventeen had post EECP thallium scan evidence of improvement in their ischemia CAD while

11 showed no change.

We evaluated the GHQ, Speilberger's STAI, the BDI, and the SCL 90 pre and post EECP.[13,14,15,16] The GHQ contains a set of questions pertaining to the effects of illness on psychosocial functioning. The STAI asks questions to reveal both state and trait measures of anxiety, curiosity, and anger. The BDI is a self report measure evaluating 21 statement groups related to depressive symptomatology. The SCL 90 is a weighted 90 item instrument measuring distress in response to various psychological and somatic symptoms. There were signficant improvements in the GHQ, State Anxiety, BDI, and in the Depression Subscale of the SCL 90 among other subscales including the Somatization Subscale, Phobia Subscale, and the General Symptom Index.

We compared those who had ischemic improvement in their ischemia and those who did not have ischemic improvement after EECP. We found that the former group experienced significant improvement in the GHQ as well as improvement in the Depression and Phobia subscales of the SCL 90. However, both groups showed significant improvement in their BDI ($p<0.0066$ for the improved group and $p<0.0212$ for the unchanged group). Both groups also showed an improvement in the SCL 90 Somatization Subscales ($p<0.0364$ for the improved group and $p< 0.0407$ for the unchanged group). The General Symptom Index was improved for both groups on the SCL 90 ($p< 0.0113$ in the improved group and $p< 0.0304$ for the unchanged group). It is also of interest that in the unchanged group there were signficant improvements in the Spielberger State Trait and Anxiety scores.

In the quality-of-life measurement, 100% of the subjects in the improved group felt that there was an increase in their ability to work; 47.1% stating that is was noticeable and 29.4% saying there was a strong increase in their ability to work. In the improved group, 94.1% felt that their energy had increased; 41.2% of these at a moderate level and 29.4% at a much increased level. One hundred percent of patients felt that their overall health had improved after EECP. In the group that showed a decrease in ischemia on thallium scans, 41.2% felt that their improvement was at a noticeable level and 17.6% perceived a strong improvement. Eighty-eight and two tenths percent of patients in the improved group felt an improvement in well being.

In the group, in whom ischemia had not improved after EECP, 100% felt that ability to work had improved and 90% felt that their energy had increased. Eighty-eight and eight-tenths percent of the patients in the unchanged group perceived that their health had improved; 44.4% of these felt it had improved at a noticeable level, and 11.1% even thought that their health had improved to a strong degree. Ninety percent of the post EECP unchanged group felt that their overall well being had improved; 50% to a noticeable degree and 10% to a strong degree.

The improved group showed significant reduction in frequency and severity of pain post EECP. They also showed a significant reduction in the use of nitroglycerin. Though not as significant as the improvement in the group that showed decreased ischemia post EECP, there was also improvement in the unchanged post EECP group: a reduction in both frequency and severity of pain and use of nitroglycerin. Studies employing EECP are required to tease apart what role the placebo effect might be having in this cardiac population.

Summary

EECP does appear to be a well tolerated treatment modality in terms of psychosocial adjustment. In terms of psychological and social tolerability it is an excellent strategy. Given the fact that depression appears to be a significant risk factor for morbidity and mortality after a cardiac event, it is interesting to focus on improvement of mood observed in patients who undergo EECP for CAD. Although, as a group, these patients pre EECP did not score in the clinically depressed range (BDI >14), it is certainly of interest that patients post EECP showed a significant reduction in scores on the BDI. Both post EECP groups, improved and unchanged, showed this reduction in BDI scores, although the patients in the improved group had a more significant reduction and also showed a reduction in the Depression Subscale on the SCL 90.

Patients in the post EECP unchanged group did, however, have significant reductions in both Spielberger's STAI and they also seemed to have a strong belief that their health had improved. This information might lead one to speculate again that while EECP may be an effective physiological treatment for ischemic heart disease, it may provide secondary benefits because of reduced depression and anxiety. These EECP-induced improvements in mood and stress level may themselves have salutary physiological effects at the level of the coronary arteries.

One might hypothesize that there are neurotransmitter changes, perhaps in levels of acetylcholine and serotonin , leading to improvement in mood and reduction in stress that contribute to improved coronary artery function.[17,18] Alternatively or additionally, there may be a neuroimmunologic

effect occurring since there are now hypotheses involving the macrophage both in CAD and in depression.[19,20] Our team will continue to look into these questions.

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