Clin. Cardiol. 24, 435–442 (2001)

Clinical Investigations

The International EECP Patient Registry (IEPR): Design, Methods, Baseline Characteristics, and Acute Results

GREGORY BARSNESS, M.D., ARTHUR M. FELDMAN, M.D.,* DAVID R. HOLMES, JR., M.D., RICHARD HOLUBKOV, PH.D.,†
SHERYL F. KELSEY, PH.D.,† ELIZABETH D. KENNARD, PH.D.,† AND THE INTERNATIONAL EECP PATIENT REGISTRY INVESTIGATORS

Mayo Clinic Foundation, Rochester, Minnesota; *Cardiovascular Institute of the UPMC Health System, Pittsburgh, Pennsylvania; †University of Pittsburgh, Pittsburgh, Pennsylvania, USA

Summary

Background: In 1998, the International EECP Patient Registry (IEPR) was organized to document patient characteristics, safety, and efficacy during the treatment period, and long-term outcomes. All centers with EECP facilities were invited to join the voluntary Registry. The Registry population comprises all patients starting EECP therapy for treatment of angina pectoris in participating centers.

Hypothesis: The study was undertaken to determine whether EECP is a safe and effective treatment for patients with angina pectoris regardless of their suitability for revascularization by more conventional techniques.

Methods: After 18 months of operation, 43 clinical centers representing over half of clinical sites using the EECP system contributed cases. The data reported here were collected before the first EECP treatment and upon completion of final treatment. EECP can be used for patients ineligible for either coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI), as well as for those who prefer noninvasive treatment to avoid or delay revascularization. In this report, patients considered to be candidates for revascularization are compared with those not considered suitable.

Results: Of the 978 patients analyzed, 70% had Canadian Cardiovascular Society Classification class III or IV angina before starting treatment, and 62% used nitroglycerin. Most (81%) had been previously revascularized, and 69% were considered unsuited for either PCI or CABG at the time of starting EECP. A full treatment course (usually 35 h) was completed in 86%, of whom 81% reported improvement of at least one angina class immediately after the last treatment.

Conclusion: In a broad patient population, EECP has been shown to be a safe and effective treatment.

Key words: external counterpulsation, angina pectoris, coronary artery disease, registry

Introduction

Enhanced external counterpulsation (EECP) is a noninvasive analogue of the intra-aortic balloon pump designed to increase myocardial perfusion pressure and decrease cardiac workload. Based on small clinical series, the Food and Drug Administration cleared EECP for the treatment of myocardial infarction, cardiogenic shock, and unstable and stable angina in March 1995.[1, 2] Since then, the use of EECP for the treatment of angina pectoris has continued to increase, based on both scientific and anecdotal evidence of efficacy in this population both in the United States and other countries.[3–7] The use of EECP in the treatment of patients with cardiovascular disease has been reviewed by Soran *et al.*[8] and by Soroff *et al.*[9]

In 1995, a randomized trial, the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP) trial was begun.[10] Enrollment was completed in 1997. In all, 139 patients with coronary artery disease and chronic stable angina pectoris were assigned at random to either full-pressure counterpulsation (Active-CP) or low-pressure counterpulsation (Sham-CP). Patients were masked to the treatment received. The Active-CP patient group showed a statistically significant post-treatment increase in exercise duration, increase in time to ST depression, and a reduction in the frequency of anginal episodes. The Sham-CP group demonstrated only an increase in exercise duration. Between-group differences were statistically different for time to ST-segment depression and angina counts.

The results of the MUST-EECP trial confirmed that EECP was a safe and effective treatment for patients with chronic

The International EECP Patient Registry is sponsored by Vasomedical, Inc., Westbury, New York, USA

Address for reprints:

Elizabeth D. Kennard, Ph.D.
Department of Epidemiology
University of Pittsburgh
127 Parran Hall
130 DeSoto St.
Pittsburgh, PA 15261, USA

Received: July 25, 2000
Accepted with revision: September 27, 2000

angina. However, while patients in MUST-EECP had to meet strict criteria in order to be enrolled, they were not screened for anatomic suitability or vascular response to EECP, as doing so would have defeated patient masking. The trial population was also more homogeneous in demographics and disease characteristics than the wider patient community undergoing EECP for the treatment of chronic angina. Thus, a patient registry, the International EECP Patient Registry (IEPR), was initiated in 1997 to document both the safety and efficacy of EECP and the long-term outcome in a heterogeneous consecutive series of patients treated in the wider community. This report presents the methods used in this registry and the results of the first 978 patients enrolled.

Methods

Each clinical center, whether hospital based or a freestanding facility using EECP as a treatment modality, was contacted by the sponsor and invited to join the Registry. The Registry is purely voluntary, and there are no payments to either the clinical centers or patients for participation. This report describes the results obtained from the first 43 centers joining the Registry. Overall responsibility for Registry procedures and policies is governed by a Steering Committee with representatives from the clinical centers, the Coordinating Center at the University of Pittsburgh, and the sponsor (see Appendix II). All clinical centers have been approved by their Institutional Review Boards for participation in the Registry (if required), and patients in the Registry are required to give informed consent.

All Registry patients were treated with EECP® equipment (Vasomedical, Inc., Westbury N.Y., USA) which consists of an air compressor, a control console, a treatment table, and three pairs of pneumatic cuffs. Prior to a treatment session, these cuffs are wrapped around the patient's legs and buttocks. In early diastole, pressure is applied sequentially from the lower legs to the lower and upper thighs to propel both arterial and venous blood toward the heart. The result is an increase of diastolic blood pressure (diastolic augmentation) with retrograde aortic blood flow, as well as an increase in venous return during diastole. At end diastole, air is released simultaneously from all the cuffs to remove the external applied pressure, allowing the compressed vessels to reconform, thereby reducing vascular impedance and decreasing cardiac workload. In general, treatment is applied 1 or 2 h daily, 5 or 6 days a week, for a minimum total of 35 h.

The Registry aims to collect data on as broad a range of patients as possible. The criteria for entry are only that the patient give informed consent and have at least 1 h of EECP treatment. Every center enrolls all consecutive patients entering treatment with no exclusions due to demographics, clinical status, or outcome.

Each patient is noted on a screening log maintained at the clinical centers. The logs are sent monthly via facsimile transmission to the Coordinating Center. The screening log serves as a quality control measure ensuring that the Registry records all patients being treated. Because of the voluntary nature of the Registry, care was taken while formulating the data collection methods to keep data collection simple by limiting the number of forms and data items required. Before the first hour of treatment, a one-page form is completed describing demographics, medical history, disease characteristics, and symptoms. At the last hour of treatment, another single page form is completed describing the length of treatment, the degree of diastolic augmentation achieved (the ratio of diastolic to systolic area as measured by finger plethysmography), untoward clinical events, and symptomatology. A patient is considered to have not completed a full treatment course under the following circumstances: a medical event disrupted EECP treatment, the patient chose to discontinue treatment, or the patient missed five consecutive treatments for any reason. Subsequent to the last treatment, follow-up by telephone contact occurs at 6 months, and 1, 2, and 3 years. The follow-up form records clinical events, hospitalizations, and anginal status. The patient's quality of life is assessed at each contact by means of a three-item questionnaire assessing current quality of life, health status, and satisfaction with quality of life. Each quality-of-life measure is rated by the patient on a five-point scale on which 1 represents the best and 5 the poorest rating. Each data item is defined in detail in a Manual of Operations provided to every center, and every center is trained individually for data collection by means of a telephone conference call between the Coordinating Center and the clinical center coordinators. All forms are faxed to the Coordinating Center at the University of Pittsburgh for data entry and processing.

The primary outcome measure is exertional angina status, as gauged by the Canadian Cardiovascular Society Classification.[11] Other measures include the number of angina episodes and nitroglycerin intake per week as reported by the patient. To afford insight as to whether particular categories of patients might be more or less responsive to EECP, the Registry analyzes important subgroups. For this report we compared those who were judged not suitable for revascularization by more conventional techniques such as coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI), and those who were considered suitable, but chose EECP to delay or avoid revascularization . Chi-square tests and *t*-tests, as appropriate, are used to compare patients who are and are not revascularization candidates. A two-sided p value of < 0.05 was deemed statistically significant.

Results

At the end of the first 18 months of operation, there were 43 centers in the Registry, including four from outside North America, with a total of 1,246 patients enrolled. A listing of centers is shown in Appendix II. Compliance has been excellent, with 98% of all pre-EECP forms and 93% of post-EECP forms having been completed. From January 1, 1998, to April 30, 1999, there were 978 patients entered into the Registry for whom data at baseline (including revascularization status) and at completion of treatment were available. These patients form the basis of this report.

Baseline Characteristics

Enhanced external counterpulsation is a therapy used primarily for treatment of chronic angina pectoris in patients who either are not suitable for more conventional forms of revascularization or have been previously revascularized but have recurrent symptoms. The characteristics of the patient population reflect this, with 671 (68.6%) considered to be not suitable candidates for conventional revascularization at the time of commencing EECP therapy. The remaining 307 patients have been judged suitable for either PCI or CABG, but have chosen EECP to avoid or postpone invasive revascularization. Of those who were candidates, 68% were regarded as suitable for PCI and 85% as suitable for CABG with 17% suitable for either procedure. The baseline characteristics of patients not candidates for revascularization were compared with suitable candidates in Tables I and II. Overall, the patients had a mean age of 66.2 years (range 31–97 years) and were most frequently white (92%) and male (76%). They had long-standing coronary disease with a mean duration since diagnosis of 9.5 years. Multivessel coronary disease was present in 78% of patients. Demographic characteristics were similar for the candidates and the noncandidates.

Over 80% of the patients had previous revascularization with either PCI or CABG, and 7% had had a previous course of treatment with EECP before the Registry was started. Other relevant medical history included a previous myocardial infarction in 68% of patients, congestive heart failure in 28%, and noncardiac vascular disease in 32%. Risk factors for coronary disease occurred with high frequency; family history of coronary artery disease in 74%, diabetes in 40%, hypertension in 68%, hyperlipidemia in 75%, and a history of smoking in 71%. It was not surprising that, compared with the candidates, the patients who were not candidates for revascularization had a more unfavorable disease profile, with significantly higher proportions having previous revascularization, prior myocardial infarction, congestive heart failure, and noncardiac vascular disease. However, the prevalences of traditional CAD risk factors were similar in the two groups.

Angina status and extent of coronary disease are shown in Table II. Over 69% of patients had Canadian Cardiovascular Society Classification (CCSC) class III or IV angina, with a mean of 8.6 episodes of angina per week. Those who were not revascularization candidates had significantly worse angina classification, significantly lower left ventricular ejection fractions, and were significantly more likely to have multivessel disease. Nitroglycerin (sublingual or spray) was used by 62% with a mean frequency of 8.8 times a week. Nitroglycerin usage was much higher in the group who were not candidates (68 vs. 50%, $p < 0.001$).

Quality of life at the beginning of EECP treatment was poor. Only 34% of noncandidates and 52% of revascularization candidates rated their health as good or excellent (1, 2, or 3 on the 5 point scale). This difference was statistically signif-

TABLE I Baseline characteriscs of patients

	Not candidates for revascularization	Candidates for revascularization	All patients
Number of patients	671	307	978
Age (years)	66.2 ± 10.6	66.3 ± 10.3	66.2 ± 10.5
Age > 65 years	58.2	58.7	58.4
Male gender	74.3	78.5	75.6
White race	93.0	89.8	92.0
Medical history			
Duration of CAD (years) [a]	10.3 ± 8.0	7.8 ± 7.7	9.5 ± 8.0
Prior PCI [b]	63.4	56.3	61.2
Prior CABG [a]	67.2	39.7	58.6
Prior PCI or CABG [a]	86.3	69.7	81.1
Previous EECP treatment	7.2	7.5	7.3
Prior MI [a]	70.1	56.9	68.3
Congestive heart failure [a]	32.2	17.7	27.7
Noncardiac vascular disease [a]	31.9	32.6	32.1
Risk factors			
Family history of CAD	73.9	75.3	74.3
Diabetes	40.4	39.0	40.0
Hypertension	68.5	66.9	68.0
Hyperlipidemia	75.8	73.7	75.2
Smoking (present or past)	71.3	71.6	71.4

All data are percentages unless otherwise stated.

[a] $p < 0.001$, [b] $p < 0.01$ testing candidates against noncandidates.

Abbreviations: CAD = coronary artery disease, MI = myocardial infarction, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft, EECP = enhanced external counterpulsation.

TABLE II Disease status at start of EECP treatment

	Not candidates for revascularization	Candidates for revascularization	All patients
Number of patients	671	307	978
Angina characteristics [b]			
CCSC class			
I	3.6	9.8	5.5
II	23.5	27.7	24.8
III	49.9	44.0	48.1
IV	23.0	18.6	21.6
Unstable [c]	3.3	1.0	2.8
LVEF% — mean [a]	44.8 ± 13.6	49.8 ± 12.3	46.4 ± 13.4
LVEF < 35% [b]	19.8	10.5	16.9
Angina episodes/week (mean) [b]	9.4 ± 14.0	6.8 ± 12.2	8.6 ± 13.5
Nitroglycerin use [a]	67.7	49.5	62.0
Vessel disease [a]			
None or single	18.2	30.6	22.0
Double	25.9	29.9	27.1
Triple	55.9	39.5	50.9

Data are percentages unless otherwise noted.
[a] $p < 0.001$, [b] $p < 0.01$, [c] $p < 0.05$ comparing noncandidates with candidates.
Abbreviations: CCSC = Canadian Cardiovascular Society Classification, LVEF = left ventricular ejection fraction. Other abbreviations as in Table I.

icant ($p < 0.001$). Similar differences were seen in the quality of life rating (rated good or excellent by 48% of noncandidates vs. 65% of candidates, $p < 0.001$), and satisfaction with quality of life (rated good or excellent by 45% of noncandidates vs. 58% of candidates, $p < 0.001$).

Post EECP Results

The post EECP results for patients completing treatment are shown in Table III. Similar proportions of both groups completed treatment (84.1% for those not candidates and

TABLE III Post EECP outcome for patients who completed treatment

	Not candidates for revascularization	Candidates for revascularization	All patients
Number of patients	564	261	825
(% of total starting treatment)	84.1	85.0	84.4
Hours of treatment (mean)	37.3 ± 7.0	37.2 ± 7.8	37.3 ± 7.2
Post EECP outcome			
Diastolic augmentation ratios (mean)			
First hour area	0.96 ± 0.58	1.01 ± 0.57	0.98 ± 0.57
Last hour area [a]	1.26 ± 0.74	1.49 ± 0.82	1.33 ± 0.77
Angina status			
No angina	17.2	23.0	19.0
CCSC class [b]			
I	32.8	42.9	36.0
II	35.6	25.3	32.4
III	11.0	7.3	9.8
IV	3.4	1.5	2.8
Angina decreased > = 1 class	79.8	83.5	81.0
Decrease in angina episodes/week (mean) [c]	7.1 ± 12.7	4.7 ± 9.1	6.4 ± 12.6
Nitroglycerin discontinued [c]	58.6	71.1	61.7
Quality of life (patient assessment)			
Health improved	67.9	66.3	67.4
Quality of life improved	63.1	63.6	63.3
Satisfaction improved	67.7	64.4	66.7

Data are percentages unless otherwise indicated.
[a] $p < 0.001$, [b] $p < 0.01$, [c] $p < 0.05$ comparing noncandidates with candidates.
Abbreviations as in Table I.

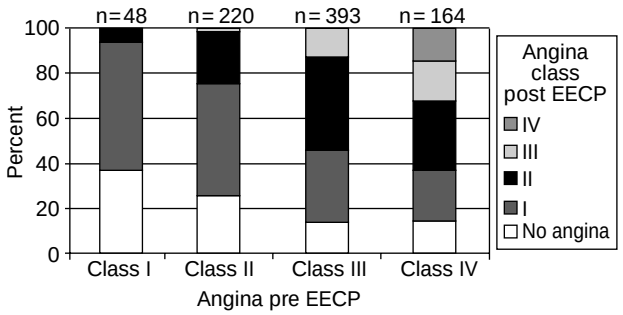

FIG. 1 Distribution of angina class after enhanced external counterpulsation (EECP) treatment for each angina class before treatment (all patients who finished treatment n = 825).

85.0% for those who were candidates). Patients failed to complete treatment for a number of different reasons; a medical event occurred which disrupted EECP treatment, or the patient chose to discontinue treatment (usually due to vacation, or time pressures of work).

For patients completing treatment, there was a significant difference between the two groups in the mean diastolic augmentation area ratio (diastolic/systolic area under the curve) achieved. Patients who were candidates achieved a mean area ratio of 1.5, compared with 1.2 for those not candidates, $p < 0.001$. However, both groups of patients reported much improved anginal functional status post EECP, as evidenced by a decrease in at least one CCSC angina class (83.5% of candidates vs. 79.8% of noncandidates, p = NS), a mean decrease in angina episodes per week (4.7 for candidates vs. 7.1% for noncandidates, $p < 0.05$), and a substantial decrease in use of nitroglycerin (71.1% of candidates using nitroglycerin had discontinued its use by the end of EECP, vs. 58.6% of noncandidates, $p < 0.05$). The change in angina class from pre- to post-EECP treatment is shown in Figure 1 for all patients completing treatment.

Quality of Life Measures Post EECP

After treatment, quality of life was ranked good or excellent by 86% of noncandidates and 92% of candidates, and satisfaction with quality of life was ranked good or excellent by 83% of noncandidates and 90% of candidates. These differences were statistically significant ($p < 0.05$ for all three measures). However, a more sensitive indicator of changes in quality of life is the difference in reported quality of life pre-and post-EECP treatment (as shown in Table III). Here there were no statistically significant differences between the two groups. Overall there was an improvement in health status for 67% of patients, in quality of life for 63%, and in satisfaction with life for 67%.

Adverse Events

The overall adverse event rate was low, with only 11 patients (1.1%) reporting withdrawal from treatment because of a serious cardiac event (death, myocardial infarction, CABG, or PCI). These serious events occurred after a mean treatment time of 19 h, and none occurred within 48 h of a treatment session. Clinical events were cited as the reason for discontinuing treatment in 43.8% of the patients withdrawing. The other withdrawals were reported as being due to the patient's decision. The clinical events reported in these patients are listed in Table IV. There were no statistically significant differences between the two groups of patients. Clinical events included unstable angina (2.4%), congestive heart failure (2.1%), and myocardial infarction (0.4%). Revascularization by conventional means (CABG 0.5% and PCI 0.3%) also occurred even among those patients initially judged to be unsuitable for

TABLE IV Events during EECP treatment

	Not candidates for revascularization		Candidates for revascularization		All patients	
Number of patients	671		307		978	
	N	%	N	%	N	%
Death %	2	0.3	0	0.0	2	0.2
Unstable angina %	16	2.4	7	2.3	23	2.4
Myocardial infarction %	3	0.4	1	0.3	4	0.4
Congestive heart failure %	18	2.7	3	1.0	21	2.1
CABG %	2	0.3	3	1.0	5	0.5
PCI %	3	0.4	0	0.0	3	0.3
Other cardiac %	11	1.6	4	1.3	15	1.5
Skin breakdown %	8	1.2	3	1.0	11	1.1
Musculoskeletal %	14	2.1	7	2.3	21	2.1
Other medical %	39	5.8	14	4.6	53	5.4

Data are percentages.
Events are not exclusive.
Abbreviations as in Table I.

revascularization. Events specific to EECP and that interrupted treatment included problems with skin abrasion (1.1%) and musculoskeletal problems (2.1%). The event rate for other noncardiac medical events was 5.4%.

Discussion

The results presented here represent the largest reported series of consecutive patients treated with EECP for chronic angina pectoris. These patients show a profile of long-standing coronary disease, with chronic angina unrelieved by medical means or conventional revascularization. A small number of patients presented with unstable angina, the majority of whom were not candidates for other revascularization treatment. Concomitant diseases such as congestive heart failure and diabetes were frequent. The majority of the patients were not considered candidates for conventional revascularization at the start of the EECP treatment. Of the patients considered suitable candidates many had already had either surgical or percutaneous revascularization previously. The registry collects data concerning previous revascularizations but not details regarding the outcome of procedures.

Most patients, regardless of whether or not they were considered suitable for conventional revascularization procedures, experienced relief of angina after a complete course of EECP treatment. Patients reported decreases in the number of angina episodes and use of nitroglycerin, as well as less restriction because of angina as measured by the CCSC class. Quality of life was also improved for the majority, along with this increase in angina class. These initial results from the IEPR are consistent with those obtained in previous trials and observational studies, including the findings of the MUST-EECP trial, that EECP treatment is a safe and effective method for reducing chronic angina. The fact that there were few adverse effects of EECP is important.

The results of the quality of life measures also are consistent with those of the MUST-EECP trial[12] and a previous psychosocial study that showed the considerable improvement in well being of patients after treatment with EECP.[13]

In the 32% of Registry patients who were deemed to be candidates for either PCI or CABG, but had instead chosen to be treated with EECP, the majority tolerated EECP well and showed considerable reduction in angina at the end of treatment. Only three of these patients stopped EECP and underwent surgical revascularization before the completion of EECP.

Another important issue is that 15% of the patients starting EECP therapy did not complete the prescribed course of treatment. In many of these cases, interrupting noncardiac medical events caused termination of EECP treatment. Determining which patients are more likely to not complete treatment and whether these patients return to complete EECP after resolution of their medical problems, will be an important goal of the Registry. The EECP therapy, while noninvasive, is time consuming for the patient and requires daily attendance for many weeks. This can be burdensome for some patients, either because they are currently employed and cannot obtain the required leave time, or because they are dependent on others to provide transportation. The question of whether these patients subsequently return for treatment will be addressed. Furthermore, it would be important to know whether shorter intervals of EECP could be as effective in improving anginal status.

Whether the benefits of EECP persist after the end of the course of treatment and if so, for how long, is crucial. A study by Lawson *et al.*[2] demonstrated a 3-year sustained benefit in patients as measured by stress thallium test and anginal status, and patients at 5 years demonstrated morbidity and mortality comparable with those undergoing CABG.[14] Of the patients in the MUST-EECP trial, 70% showed quality of life benefits at 1 year.[12] The Registry will follow all patients for at least 3 years to determine whether these sustained benefits, seen in the prior studies on small numbers of patients, are replicated in everyday clinical use.

Limitations

A primary limitation of this analysis is the lack of a control group to assess the extent of the reported improvement due to other interventions or to the "placebo effect" that may be expected with a population of symptomatic patients enthusiastic about a newly emerging treatment. An observational registry study cannot directly address whether the treatment benefit observed in the MUST-EECP randomized trial extends to the entire EECP population. However, the Registry does document the safety of the approach and suggests a benefit in a wider range of patients than has been validated with randomized trials.

Conclusions

Enhanced external counterpulsation has been shown to be a safe and effective treatment for the reduction of chronic angina in a heterogeneous group of patients, including those for whom more conventional revascularization techniques are an alternative. Adverse events occur infrequently during the course of treatment. Events specifically associated with the treatment itself (musculoskeletal pains and problems with skin abrasion) also had a low rate of occurrence and infrequently were severe enough to cause discontinuation of therapy.

Appendix I

Current IEPR Clinical Sites, Investigators, and Coordinators

Advanced Heart Care, Paris, TX: Jeffrey Gladden, M.D., Gina Pritchard, N.P.; Adventist Outpatient Cardiac Services, Rockville, MD: Dennis Friedman, M.D., Nancy Lauzon, R.N.; Heartgen Midtown, Indianapolis, IN: Stanley Adkins, M.D., Shawna Toombs, R.N.; Ash Heart Center, New York, NY: Patrick Fratellone, M.D., Spencer Liebman, E.M.T.;

Bahamas Heart Institute, Nassau, Bahamas: C. Dean Tseretopoulos, M.D., Jannette Martin-Isaacs, R.N.; BCS Heart, College Station, TX: W. Richard Cashion, M.D., Michael Muehlendorf, L.V.N., Mallisa Karonka, L.V.N.; Beaumont Hospital, Dublin, Ireland: Prof. John Horgan, Deirdre Dodd, R.N.; Brookville Hospital, Brookville, PA: Jivan Patel, M.D., Jeanna Reinard, L.P.N.; Cardiac Disease Specialists PC, Atlanta, GA: Harvey Sacks, M.D., Shelley Holt, R.N., C.C.R.N.; Cardiology and Medicine Associates, Inc., Vero Beach, FL: Nancy Cho, M.D., Joanne Giordano, L.P.N.; Cardiology Associates, Johnson City, NY: Richard Ryder, M.D., Deborah Norris, R.N.; Central Arkansas Cardiology, N. Little Rock, AR: Charles R. Caldwell, M.D., Karen Schales, L.P.N.; Central Cardiovascular Associates, Pittsburgh, PA: Thomas Pinto, M.D., Louanne Tempich, L.P.N., R.C.V.T.; Chandra Cardiovascular Consultants, Dakota Dunes, SD: Yunus Moosa, M.D., Mary Schaumacher, R.N.; Christ Hospital and Medical Center, Oak Lawn, Il: Marc Silver, M.D., Carol Pisano, R.N.; Central Maine Medical Center, Lewiston, ME: Mark Lanzieri, M.D., Emily French, R.N., Carol Domingue, R.N.; Columbia Presbyterian Medical Center, New York, NY: Rohit Arora, M.D., Michael Timoney, E.M.T., Nicole Baron; Consultants in Cardiology, Inc, Erie, PA: James P. MacKrell, M.D., Sylvia Rumberger, R.N.; Desert Cardiology of Tuscon, Tucson AZ: Brenda Peart, M.D., Julie Jenkins, C.C.R.N.; EECP Center of Nevada, Las Vegas, NV: Matthew McMahon, D.O., Linda Olson, C.V.T., Kathleen Sponseller; EECP Center of Northern Virginia, Reston, VA: Kenneth Brooks, M.D., Elizabeth La Rose, R.N.; EECP Center of Northwest Ohio, Toledo, OH: James Roberts, M.D., Jean French; EECP Center of South Florida, Hollywood, FL: Jonathan Jaffe, M.D., Dimitri Pyrros, M.D., Scott Elrod, E.M.T.; EECP of Nassau, Valley Stream, NY: Edward Davison, M.D., Janet Hyland, R.N., Diane Bonagura, R.N.; Falmouth Cardiology, Falmouth, MA: Bruce Levy, M.D., Joanne Madden, R.N., B.S.N.; Fundacion Clinica Shaio, Bogota, Colombia: Daniel Isaza-Restrepo, M.D., Susana Reyes; Heart Care Clinic of Arkansas, Little Rock, AR: Charles Fitzgerald, M.D., Barbara Wall, R.N.; Heart Centers of America, LLC, Portland, OR: Ronald W. Schutz, M.D., Brenda L.P. Hammock, R.N.; HeartGen South, Indianapolis, IN: Stanley Adkins, M.D., Mary Ann Adkins, Pam Ward, R.N.; HeartGen North, Indianapolis, IN: Stanley Adkins, M.D., Theresa Eaton, R.N.; Cardiovascular Research Institute, Inc., Columbus, OH: Bruce Fleischman, M.D., Karen Manzo, R.N.; Howard County General Hospital, Columbia, MD: Harry A. Oken, M.D., Gladys Curley; Integrated Cardiovascular Therapeutics, Woodbury, NY: Ronnie Hershman, M.D., Debra Chalmers, A.N.P.; Kaiser Permanente, Denver, CO: David Flitter, M.D., Debra Clemetson, R.N.; Mayo Clinic, Rochester, MN: Gregory Barsness, M.D., Theresa Schnell, R.N.; Miami Heart Institute, Miami Beach, FL: Kevin Coy, M.D., Paula Reeser, R.N., Dania Tabares, R.C.V.T.; Missouri Heart Center, Columbia, MO: Robert Doroghazi, M.D., Alicia Glenn, R.N., Jeanette Quick, R.N.; Nebraska Heart Institute, Lincoln, NE: Steve Krueger, M.D., Pat VerMaas, R.N., M.S.N.; New York Heart Center, Syracuse, NY: Eugene C. Lozner, M.D., Dean R. Humphreys, R.N., M.S.; New York United Hospital, Port Chester, NY: Joseph Tartaglia, M.D., Debbie Fitzgerald, C.V.T.; North Suburban Cardiology Group, Ltd., Arlington Heights, IL: Edward Pinsel, M.D., Sally Jacobs, R.N.; Ocean View Medical Group, Inc., Santa Monica, CA: Monroe Rosenthal, M.D., Martin Turner; Ochsner Foundation Hospital, New Orleans, LA: Mandeep Mehra, M.D., Bobbett Robichaux, R.N.; Perennia Heart Centers, Atlanta, GA: Matthew Britton, M.D., Pauline Cooke, R.N.; South County Cardiology Associates, Inc., Wakefield, RI: Neil Brandon, M.D., Elizabeth Laffey, R.N.; State University of New York, Stony Brook, NY: William Lawson, M.D., Denise F.O. D'Ambrosia, R.N.; Staten Island Heart, Staten Island, NY: James Lafferty, M.D., Laura Ferrara, R.N.; The Cardio-Pulmonary Continuum, Manhasset, NY: Perry Frankel, M.D., Leah Cervantes, R.N.; The Heart Center, Huntsville, AL: J. Michael Campbell, M.D., Jewell Owens, L.P.N.; The Heart-Lung Center, Hawthorne, NJ: John Strobeck, M.D., Robin Reade, R.N.; The Ohio Heart Health Center, Inc., Cincinnati, OH: Charles Abbottsmith, M.D., Sandy Metze, E.M.T.; University of California at San Diego Medical Center, San Diego, CA: Ori Ben-Yehuda, M.D., Johanna van Dijk, R.N., Lisa Stocks, R.N.; University of California San Francisco, Moffitt Hospital, San Francisco, CA: Tony Chou, M.D., Kim Prouty, R.N., Sue Spence, R.N.; University of Pittsburgh Medical Center-Century Cardiac Care, White Oak, PA: Daniel Jovanovich, M.D., Judi Scheponik, R.N., C.C.R.N.; University of Pittsburgh Medical Center, Pittsburgh, PA: Lawrence Crawford, M.D., William Wade; University of Virginia, Charlottesville, VA: Ian Sarembock, M.D., Ellen Longmoore, C.N.M.T.; Uptown Heart Center, New Orleans, LA: John Cook, M.D., Tracy Lazzaro, E.P., Gina Caronna, R.N.; Whitaker Wellness Institute, Newport Beach, CA: Allan Sosin, M.D., April Johnson, L.V.N.

Appendix II

IEPR Steering Committee

Jonathan R. Jaffe, M.D. (Chair), Cardiovascular Medical Specialists, Hollywood, FL; Sheryl F. Kelsey, Ph.D., Richard Holubkov, Ph.D., Elizabeth D. Kennard, Ph.D., Katherine M. Detre, M.D, Dr.PH., Lawrence Crawford, M.D., Arthur M. Feldman, M.D., Ph.D., University of Pittsburgh, Pittsburgh, PA; William Lawson, M.D., SUNY, Stony Brook, NY; Joseph Tartaglia, M.D., New York United Hospital, Port Chester, NY; Anthony E. Peacock, Gudrun M. Lang, R.N., B.S.N., Vasomedical Inc, Westbury, NY.

Coordinating Center—University of Pittsburgh

Sheryl F. Kelsey, Ph.D., Registry Director, Elizabeth D. Kennard, Ph.D., Registry Coordinator, Richard Holubkov, Ph.D., Statistician, Nichole D. Dwyer, B.A., Data Manager.

Registry Sponsor

Vasomedical, Inc., Westbury, NY.

References

1. Lawson WE, Hui JCK, Soroff HS, Zheng Z, Kayden DS, Sasvary D, Atkins H, Cohn P: Efficacy of enhanced external counterpulsation in the treatment of angina pectoris. *Am J Cardiol* 1992;70: 859–862
2. Lawson WE, Hui JCK, Zhen ZS, Oster Z, Katz JP, Diggs P, Burger L, Cohn C, Soroff H, Cohn P: Three-year sustained benefit from enhanced external counterpulsation in chronic angina pectoris. *Am J Cardiol* 1995;75:840–841
3. Zheng Z, Li T, Kambic H, Chen G, Yu l, Cai S, Zhan C, Chen Y, Wo S, Chen G, Ma H, Chen P, Huang B, Nose Y: Sequential external counterpulsation (SECP) in China. *Trans Am Soc Artif Intern Organs* 1983;29:599–603
4. Werner D, Hui JC, Kropp J, Daniel WG: Pneumatische externe Gegenpulsation—Therapieoption bei Angina pectoris. *Z Cardiol* 1998;87(suppl 2):193–198
5. Karim S, Sani A, Karo-Karo S, Kasim M, Basha A, Gunadhi I, Japaries W, Suwita R: Enhanced external counterpulsation in the treatment and rehabilitation of coronary patients in Indonesia. *Asian Cardiovasc Thor Ann* 1995;3:26–28
6. Tartaglia J, Stenerson J: Case studies. Enhanced external counterpulsation. *CVR & R* 1997;18:26–33
7. Strobeck JE, Baklagian R, Hannen JC: The emerging role of enhanced external counterpulsation in cardiovascular disease management. *CVR & R* 1997;18:20–25
8. Soran O, Crawford LE, Schneider VM, Feldman AM: Enhanced external counterpulsation in the management of patients with cardiovascular disease. *Clin Cardiol* 1998;22:173–178
9. Soroff HS, Hui JCK, Giron F: Historical review of the development of enhanced external counterpulsation technology and its physiological rationale. *CVR & R* 1997;10:34–40
10. Arora RR, Chou TM, Jain D, Fleishman, B, Crawford L, McKiernan T, Nesto R: The Multicenter Study of Enhanced External Counterpulsation (MUST-EECP): Effect of EECP on exercise-induced myocardial ischemia and anginal episodes. *J Am Coll Cardiol* 1999;33:1833–1840
11. Campeau L: Grading of angina pectoris (letter to the editor). *Circulation* 1976;54:522–523
12. Arora RR, Chou TM, Diwakar J, Nesto R, Fleishman B, Crawford L, McKiernan T: Results of the Multicenter Enhanced External Counterpulsation (MUST-EECP) Outcomes Study: Quality of life benefits sustained six months after treatment. *Circulation* 1998;98: I-350
13. Fricchione GL, Jaghab K, Lawson WE, Hui JC, Jandorf L, Zheng Z, Cohn P, Soroff H: Psychosocial effects of enhanced external counterpulsation in the angina patient. *Psychosomatics* 1995;36 (5):494–497
14. Lawson WE, Hui JC, Cohn PF: Long-term prognosis of patients with angina treated with enhanced external counterpulsation: Five-year follow-up study. *Clin Cardiol* 2000;23:254–258