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The Current Practice of Intra-Aortic Balloon Counterpulsation: Results From the Benchmark Registry

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OBJECTIVES This study presents clinical data from the first large registry of aortic counterpulsation, a computerized database that incorporates prospectively gathered data on indications for intra-aortic balloon counterpulsation (IABP) use, patient demographics, concomitant medication and in-hospital outcomes and complications.

BACKGROUND The intra-aortic balloon pump (IABP) is widely used to provide circulatory support for patients experiencing hemodynamic instability due to myocardial infarction, cardiogenic shock, or in very high risk patients undergoing angioplasty or coronary artery bypass grafting.

METHODS Between June 1996 and August 2000, 203 hospitals worldwide (90% U.S., 10% non-U.S.) collected 16,909 patient case records (68.8% men, 31.2% women; mean age 65.9 ± 11.7 years).

RESULTS The most frequent indications for use of IABP were as follows: to provide hemodynamic support during or after cardiac catheterization (20.6%), cardiogenic shock (18.8%), weaning from cardiopulmonary bypass (16.1%), preoperative use in high risk patients (13.0%) and refractory unstable angina (12.3%). Major IABP complications (major limb ischemia, severe bleeding, balloon leak, death directly due to IABP insertion or failure) occurred in 2.6% of cases; in-hospital mortality was 21.2% (11.6% with the balloon in place). Female gender, high age and peripheral vascular disease were independent predictors of a serious complication.

CONCLUSIONS This registry provides a useful tool for monitoring the evolving practice of IABP. In the modern-day practice of IABP, complication rates are generally low, although in-hospital mortality remains high. There is an increased risk of major complications in women, older patients and patients with peripheral vascular disease. (J Am Coll Cardiol 2001;38:1456–62)

The intra-aortic balloon pump (IABP) is the most widely used of all circulatory assist devices today (1). The IABP was first employed 30 years ago as a treatment of last resort for a mortally ill patient suffering from cardiogenic shock (2,3). Today, this treatment modality is routinely used in a wide range of serious cardiovascular conditions, ranging from hemodynamic stabilization in patients suffering from complications of acute myocardial infarction (AMI) or cardiogenic shock, to very high risk patients undergoing angioplasty or coronary artery bypass grafting (CABG) (4–6).

As potential clinical applications of counterpulsation continue to expand, there is an increasing need to prospectively document the current clinical experience with IABP. No study has extensively documented the indications, clinical outcomes, patient hemodynamics, concomitant medications, complications, risk factors and insertion techniques associated with IABP. Therefore, a comprehensive, prospective, multicenter computerized database program was developed: the Benchmark Counterpulsation Outcomes Registry. The present report summarizes the development and implementation of the registry, and reviews cumulative data compiled from 17,540 IABP records from 16,909 patients between the initiation of data collection in June 1996 and August 2000.

METHODS

The Benchmark Counterpulsation Outcomes Registry was started in June 1996, initially included 22 contributing clinical centers, and presently includes 243 institutions in 18 countries. An independent steering committee (Appendix A) designed and implemented the investigator-initiated registry. Datascope Corp. (Fairfield, New Jersey) provided funding for the database, and the sites included in the registry were institutions that used intra-aortic balloons (IABs) manufactured by Datascope Corp. Patient popula-

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Abbreviations and Acronyms

AMI = acute myocardial infarction
BSA = body surface area
CABG = coronary artery bypass graft
IAB = intra-aortic balloon
IABP = intra-aortic balloon pump
LOS = length of stay
PVD = peripheral vascular disease

tions included all patients in participating institutions who received IABP between June 1996 (or time of institution enrollment) and August 2000. Concomitant medications and procedures were left to the discretion of the treating physician.

Figure 1 outlines data handling within the registry. Participating sites were provided with a computer for entering data on all consecutive IABP cases. Database software (Lotus Notes platform) was custom-written so investigators could easily enter clinical data relating to indications of IABP, details of the balloon insertion, patient hemodynamics, concomitant medications, complications and in-hospital outcomes. Site data were forwarded via modem to a single registry storage location and handled on a central file server. Continuous updates, individual site data and registry information were available on-line at the participating sites. More complex data queries were performed by request at the central storage facility.

Statistics. Descriptive summaries included frequency and percent distributions for the categorical variables, and the sample mean, standard deviation, minimum, median and maximum for the quantitative assessments. Logistic regression methodology was used to study effects of demographic, medical history and preprocedure factors on the occurrence of a major IABP complication. A full model containing all selected factors was first obtained, then a reduced model was generated containing only those factors that individually tested as statistically significant ($p \leq 0.05$) within the model. The reduced model also had to fit as well as the full model as measured by the reduction in the likelihood ratio chi-square statistic. All analyses were performed using SAS, version 8, using the Windows 98 operating system from an IBM-compatible PC.

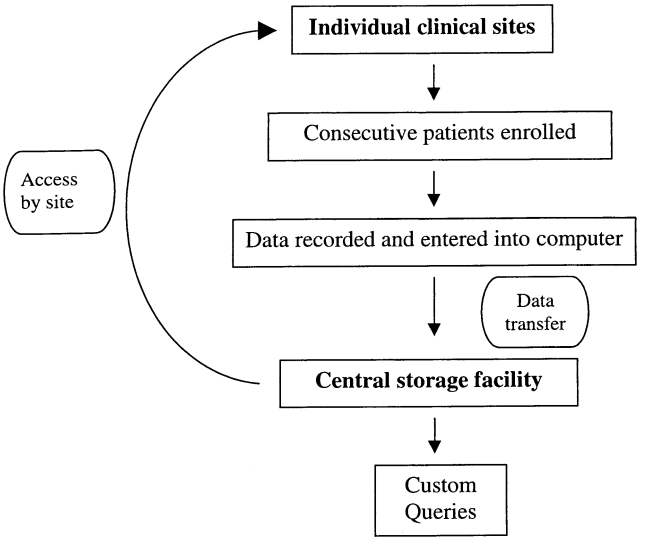

Figure 1. Data handling in the Benchmark Registry. Data from consecutive patients are collected at participating centers, entered into a computer on-site and subsequently transferred to a central storage facility. Individual site and overall registry data are available to the participants, as well as customized queries of the database.

End points. We collected data on four primary end points: ischemia, bleeding, IABP failure and in-hospital mortality. Major limb ischemia was defined as a loss of pulse or sensation, or abnormal limb temperature or pallor, requiring surgical intervention. Minor ischemia was defined as decreased arterial flow as manifested by diminished pulse that resolves with balloon removal, and not resulting in any impairment of body function.

An association with hemodynamic compromise, required blood transfusion or surgical intervention defined severe bleeding. Nonsevere bleeding involved minor hematomas and oozing from puncture site, and did not require blood transfusion or surgical intervention. The IAB failure was defined as poor augmentation, inability to deploy or any IAB leak suggested by blood inside the catheter tubing, gas loss or catheter alarm. All-cause hospital mortality was defined as mortality occurring from any cause during IABP or after IABP. Mortality directly related to IABP was also tabulated. A secondary endpoint was major IAB-related complications, defined as any major limb ischemia, severe bleed, IAB leak or mortality directly attributed to IABP.

Registry validation. In order to maximize the reliability of the registry from which these data were gathered, an external audit (data validation) of the Benchmark Registry was undertaken (StatTrade, Inc., Morrisville, Pennsylvania) that was sponsored by Datascope. Randomly selected database case histories from 21 hospitals with 2,339 patient records were audited and compared to actual local site records. The audit involved 485 (20.7%) records entered in 1999. Seventy items were checked from each record, resulting in an audit of 33,950 entries. Check-box items had at least a 95% accuracy (lower 95% confidence bound), and dates had at least a 90% accuracy. In addition, virtually all IABP cases were being reported by each participating hospital.

RESULTS

Clinical variables and indications. Between June 1996 and September 2000, 16,909 individual IABP patients were enrolled in the database. Of the enrolled patients, 68.8% were male, 31.2% were female and the mean age was 65.9 years (Table 1). From the perspective of clinical history, 25.6% of patients had diabetes, 11.9% had peripheral vascular disease (PVD), 30.6% had experienced a prior myocardial infarction and 14.6% had undergone prior CABG surgery. In 15.4% of patients, the presenting symp-

Table 1. Baseline Demographics

	Total Population (n = 16,909)	Diagnostic Catheterization Only (n = 1,576)	Catheterization and PCI Only (n = 3,882)	Surgery		No Intervention or Revascularization Noted (n = 1,186)
				CABG (n = 9,179)	Non-CABG (n = 1,086)	
Age, yr, mean (SD)	65.9 (11.7)	66.2 (12.2)	65.5 (12.4)	66.5 (10.8)	63.4 (13.5)	64.1 (13.3)
Proportion of women (%)	31.2	31.7	31.9	31.0	37.4	23.4
BSA m^2, mean (SD)	2.0 (0.2)	2.0 (0.3)	2.0 (0.2)	2 (0.2)	1.9 (0.2)	1.9 (0.2)
History of diabetes (%)	25.6	26.1	24.1	27.9	22.2	14.4
PVD (%)	11.9	11.9	9.8	13.5	11.0	7.9
Previous MI (%)	30.6	30.1	28.0	33.8	25.5	19.6
Previous CABG (%)	14.6	14.6	16.9	13.4	20.9	11.2

BSA = body surface area; CABG = coronary artery bypass graft; MI = myocardial infarction; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease.

toms involved the left main coronary artery, while 28.5% had triple-vessel disease. Some of the patients only underwent diagnostic catheterization procedures (9.3%) or percutaneous coronary intervention procedures (23.0%); the majority of procedures were surgical (60.7%; 89.4% of the surgical patients were undergoing CABG). Of the total 16,909 patients, 13,020 (77%) underwent cardiac catheterization and 4,833 (28.6%) underwent percutaneous coronary intervention. Of the 9,179 patients undergoing CABG surgery, 1,672 (18.2%) underwent CABG alone, 6,655 (72.5%) underwent diagnostic catheterization and CABG, and 852 (9.3%) underwent percutaneous coronary intervention and CABG.

The most frequent indication for use of IABP was to provide hemodynamic support during or after cardiac catheterization (20.6% of patients) (Table 2). Other common clinical indications included cardiogenic shock (18.8%), weaning from cardiopulmonary bypass (16.1%), refractory unstable angina (12.3%) and preoperative use in high risk patients (13.0%).

Balloon insertion. Balloon insertions were performed in the catheterization laboratory or procedure room (63.0%), the operating room (24.0%), the intensive care unit (4.0%), the emergency department (0.2%) and other locations (8.8%). Patients received either 40 ml (77.3%), 34 ml (21.5%) or other size balloons (1.2%). Insertion technique involved a sheath in 79.7% of patients, and employed a 9.5F (78.4%) or an 8F catheter (21.6%; 8F devices have been available since June 1, 1997). The insertion was accomplished percutaneously in 95.4% of cases. The approach was right femoral (63.3%), left femoral (35.6%) or an alternate approach (1.1%). The mean duration of IABP in the overall registry cohort was 53 h (median = 41 h, most frequent time = 24 h, range from 5 min to 89 days).

In-hospital balloon-related complications. The incidence of balloon-related complications in the overall registry cohort was low (Table 3). Major complications of balloon counterpulsation were defined as severe bleeding, major limb ischemia, balloon leak or in-hospital mortality related to IABP. A total of 2.6% of all patients experienced at least one major complication.

Limb ischemia (defined as reduced arterial flow as manifested by diminished pulse) occurred in 2.9% of cases, but major limb ischemia (loss of pulse, loss of sensation, abnormal limb temperature or pallor requiring surgical intervention, arterial repair or amputation) was reported in

Table 2. Indications for Use

	Total Population (n = 16,909)	Diagnostic Catheterization Only (n = 1,576)	Catheterization and PCI Only (n = 3,882)	Surgery		No Intervention or Revascularization Noted (n = 1,186)
				CABG (n = 9,179)	Non-CABG (n = 1,086)	
Support and stabilization (%)	20.6	21.4	54.4	9.7	5.0	7.8
Cardiogenic shock (%)	18.8	33.1	23.7	12.3	23.8	29.4
Weaning from cardiopulmonary bypass (%)	16.1	0.4	0.1	24.9	31.4	7.1
Preop: high risk CABG (%)	13.0	4.6	0.2	22.1	6.4	1.9
Refractory unstable angina (%)	12.3	15.3	8.3	15.8	2.2	3.0
Refractory ventricular failure (%)	6.5	9.1	2.5	5.9	15.7	12.7
Mechanical complication due to AMI (%)	5.5	9.8	7.0	4.2	5.2	5.1
Ischemia related to intractable VA (%)	1.7	1.6	1.5	1.9	1.7	1.6
Cardiac support for high risk general surgery patients (%)	0.9	2.1	0.2	0.5	4.3	1.1
Other (%)	0.8	0.7	0.2	0.8	2.5	2.0
Intraoperative pulsatile flow (%)	0.4	0.1	0.1	0.7	0.5	0.2
Missing indication (%)	3.3	1.8	1.9	1.2	1.5	28.1

AMI = acute myocardial infarction; CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; VA = ventricular arrhythmias.

Table 3. Summary of Outcomes/Complications

	Total Population (n = 16,909)	Diagnostic Catheterization Only (n = 1,576)	Catheterization and PCI Only (n = 3,882)	Surgery		No Intervention or Revascularization Noted (n = 1,186)
				CABG (n = 9,179)	Non-CABG (n = 1,086)	
In-hospital mortality (%)	21.2	32.2	18.4	16.8	37.8	34.1
Mortality—balloon in place (%)	11.6	17.6	10.1	9.2	19.8	20.2
IABP-related mortality* (%)	0.05	0.1	0.1	0.0	0.0	0.1
Amputation†	0.1	0.0	0.1	0.1	0.1	0.0
Major limb ischemia‡ (%)	0.9	0.6	0.5	1.2	1.0	0.5
Any limb ischemia (%)	2.9	3.2	1.9	3.5	2.5	1.7
Severe access site bleeding (%)	0.8	0.8	1.2	0.7	0.7	0.3
Any access site bleeding (%)	2.4	2.7	4.4	1.7	1.3	1.4
Balloon leak (%)	1.0	0.9	0.8	1.1	0.5	1.6
Composite outcomes						
Major IABP complication§ (%)	2.8	2.8	2.2	3.0	2.9	2.4
Any IABP complication‖ (%)	7.0	7.6	7.5	7.1	6.0	5.2
Any unsuccessful IABP¶ (%)	2.3	2.5	1.7	2.5	2.4	2.7

*Death as direct consequence of IABP therapy. †All major limb ischemia. ‡Loss of pulse or sensation, abnormal limb temperature or pallor, requiring surgical intervention. §Balloon leak, severe bleeding, major limb ischemia or death as a direct consequence of IABP therapy. ‖Any access site bleeding, any limb ischemia, balloon leak, poor inflation, poor augmentation, insertion difficulty or death as direct result of IABP therapy. ¶Balloon leak, poor inflation, poor augmentation or insertion difficulty.
CABG = coronary artery bypass graft; IABP = intra-aortic balloon pump; PCI = percutaneous coronary intervention.

only 0.9% of patients. Balloon leak occurred in 1.0% of cases. The incidence of severe bleeding (bleeding at the balloon insertion site leading to hemodynamic compromise and requiring a transfusion or surgical intervention) was 0.8%. Of the balloon insertions, 2.6% were unsuccessful due to a balloon leak, poor inflation of a balloon, poor augmentation or difficulties associated with balloon insertion (Table 4). The incidence of in-hospital mortality related to IABP was 0.05%. Not surprisingly, overall in-hospital mortality in this seriously ill population was high (21.2%, 11.6% with the IAB in place). The mean length of stay (LOS) in this cohort was 14 days (median = 10 days, most frequent LOS = 7 days, range from 1 day to 384 days).

Multivariate logistic regression analysis was used to identify significant independent predictors of a major complication of IABP, including death related to IABP, major limb ischemia, severe bleeding or balloon leak. Of the 15 variables screened, only female gender, PVD, small body surface area (BSA) (<1.65 m^2) and higher age (≥ 75 years) significantly increased the risk of a major complication. Table 5 identifies the risk factors in order by odds ratio.

DISCUSSION

The major finding of this study is that the incidence of major balloon-related complications is encouragingly low (2.8%). Advances such as percutaneous insertion and smaller-diameter catheters have considerably reduced the incidence of serious vascular complications (7–23). In addition, the incidence of unsuccessful IABP due to balloon leak, poor inflation, poor augmentation or insertion difficulty was extremely low (2.3%), and to our knowledge, no previous study has examined this issue.

Complications and risk factors. The overall complication rates noted in this real-world observational experience compare favorably with other published observational experiences (Table 6) (24–26). Both major limb ischemia (0.9%) and major bleeding (0.8%) are lower than in the previously reported experiences; this may be due to use of smaller catheters and advances in the use of heparin and glycoprotein inhibitors. Use of the IABP has been shown to reduce recurrent ischemia (24) and improve overall clinical outcomes (4). In the present study, the actual number of deaths attributable to IABP failure or insertion is approximately 5 in 10,000, with a low incidence of other balloon-related complications, suggesting that IABP is a low risk therapeutic option in a high risk patient cohort. In fact, previous studies report low balloon-related mortality, and there seems to be less balloon-related mortality over time (Table 6) (27).

Sheathless insertion techniques have not replaced the

Table 4. Unsuccessful IABP*

	Total Population (n = 389)	Diagnostic Catheterization Only (n = 39)	Catheterization and PCI Only (n = 66)	Surgery		No Intervention or Revascularization Noted (n = 32)
				CABG (n = 229)	Non-CABG (n = 26)	
Balloon leak (%)	52.2	60.6	35.3	52.1	50.1	66.7
Poor inflation (%)	21.7	16.2	35.5	20.0	20.8	18.5
Difficult insertion (%)	13.0	4.0	5.9	16.0	4.2	14.8
Poor augmentation (%)	39.1	40.4	35.3	40.1	41.8	25.9

*Individual patients may have more than one reason for an unsuccessful IABP.
CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention.

Table 5. Risk Factors for Major Complications of IABP*

Risk Factor	Estimated Odds Ratio (Presence/Absence)	95% Confidence Limits	p Value
PVD	1.968	1.557, 2.487	<0.001
Female	1.737	1.414, 2.134	<0.001
BSA <1.65 m^2	1.453	1.095, 1.926	<0.05
Age ≥75 yrs	1.289	1.048, 1.585	<0.05

*The chi-square was highly significant ($p < 0.001$); however, the concordance index was only 61%. The following variables were tested, but were not significant: primary intervention, history of diabetes, previous myocardial infarction, previous coronary artery bypass graft, indications for use (cardiogenic shock, wean from cardiopulmonary bypass), primary/tertiary care institution, catheter size and left vessel main involvement.

BSA = body surface area; IABP = intra-aortic balloon pump; PVD = peripheral vascular disease.

traditional insertion techniques, although this may change in the future. The Benchmark experience to date has only recently (since June 1997) included 8F devices, but usage rates of these smaller catheters are expected to increase as more centers seek to reduce access site injury.

Previous studies have implicated patient size, diabetes and PVD as major IABP risk factors, but have generally been small and retrospective in nature. Multivariate logistic regression (not stepwise) on the present data establish that female gender, PVD, BSA (<1.65 m^2) and age (≥75 years) remain the four prominent, independent predictors of a serious IABP complication. These four high risk groups may become a focus of efforts to improve clinical outcomes and to reduce IABP complications.

Indications. The American College of Cardiology/American Heart Association guideline indications for IABP use include preparation for angiography and revascularization in cardiogenic shock that has not quickly reversed, acute mitral regurgitation or ventricular septal defect, refractory post-MI angina, refractory ventricular arrhythmias with hemodynamic instability, hemodynamic instability, poor left ventricular function or recurrent ischemia (28). However, no study other than this one has examined indications for IABP use. The data from this registry suggest that the most frequent indication for IABP was to provide hemodynamic support in the catheterization laboratory, and the most frequent site of IAB insertion was in the catheterization laboratory. Thus, IABP appears to have been embraced as an adjunctive technique in patients undergoing invasive cardiac procedures. The mean duration of hemodynamic support was 53 h, verifying the use of IABP for short-term hemodynamic support. The IABP was also widely used in patients with cardiogenic shock and in patients undergoing high risk surgical procedures. Interestingly, although CABG is considered a primary indication for IABP use, only 13% of patients received an IABP because they were undergoing a CABG procedure (Table 2). However, of the patients who received an IABP, more than half underwent CABG even if it was not the primary indication.

Registry information. The National Registry of Myocardial Infarction is an ongoing, prospective registry that provides a framework for this registry (29). The ongoing Benchmark Counterpulsation Outcomes Registry provides prospective data on all patients who receive IAB counterpulsation (IABP) support at over 243 hospitals in 18 countries. The database has considerable potential for examining current practice patterns, documenting outcome, and trending use and outcomes over time. For example, the impact of such advances as the recently released 8F balloon catheter system can be rigorously and prospectively evaluated through use of the IABC registry data. In addition, data from this registry will be used as a complement to standards based assessment (Appendix B).

Table 6. IABP Complications and In-Hospital Mortality

Study	n	Dates	Major Bleed	Major Limb Ischemia	Balloon-Associated Mortality	Hospital Mortality
Present study	16,909	1996–2000	0.8%	0.9%	0.05%	21.2%
Makhoul et al. (7)	436	1971–1985	1.1%	8.3%	0.5%	NR
Iverson et al. (13)	395	1973–1986	NR	10.9%	NR	47%
Gottlieb et al. (11)	206	1980–1982	NR	10%	0.5%	33%
Arafa et al. (25)	509	1980–1994	2.0%	7.5%	0.6%	49.1%
Alderman et al. (12)	106	1983–1986	NR	14.2%	0.9%	17.9%
Barnett et al. (8)	580	1983–1990	NR	11.9%	0.5%	44%
Eltchaninoff et al. (17)	231	1985–1990	3.5%	3.9%	0	NR
Busch et al. (26)	472	1985–1995	3.2%	27.5%	0.0%	28.3%
Funk et al. (15)	294*	1986–1987	NR	11.7%	NR	NR
Kvilekval et al. (22)	144	1986–1989	NR	10.4%	NR	17%
Miller et al. (16)	404†	1987–1989	NR	10%	NR	30%
Pi et al. (27)	129	1988–1992	14.7%‡	4.6%	NR	49.6%
Tartar et al. (20)	126	1988–1992	3.2%	12.2%‡	0	23.8%
Gol et al. (21)	493	1988–1993	5.1%	14%	2.6%	53.2%
Patel et al. (9)	691	1993–1995	3.5%	4%	0.4%	NR
Winters et al. (23)	870	1993–1996	6.9%	3.3%	0.2%	NR
Cohen et al. (10)	1119	1993–1997	4.6%	3.3%	0.4%	NR

*9 died acutely. †48 died acutely. ‡Combined major and minor. §30-day mortality.
IABP = intra-aortic balloon pump; NR = not reported.

Study limitations. The limitations of the present study are those inherent in any large-scale retrospective observational registry. This is not a randomized trial; rather, it is a detailed description of ongoing and evolutionary clinical practice. Most of the data were collected prospectively, however, some were collected based on review of patient charts and records. The data have not been 100% validated, but in contrast to other large-scale observational registries, the Benchmark registry has gone to considerable effort to validate the data. Finally, given the large number of participating clinical institutions, there are site-to-site variations in personnel and resources allocated to the registry, individual practice patterns and patient populations.

Retrospective analyses of risk factors should be regarded with caution because there is not necessarily a cause and effect relationship with the risk factors associated with major complications. However, the data strongly suggest the need for greater care and clinical attention in treating patients who are small, female, have PVD or who are at least 75 years of age, in view of their increased risk for experiencing a major complication of IABP.

Summary. In this analysis if 16,909 patients enrolled form June 1996 to August 2000, the incidence of major complications was relatively low (2.8%) as were incidences of unsuccessful IABP (2.3%). In addition, the most frequent indication for use of IABP was for hemodynamic support in the catheterization laboratory, while use of IABP during CABG procedures remained relatively low. Female gender, small BSA, high age and PVD were independent predictors of a serious complication of IABP.

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APPENDIX A: STEERING COMMITTEE

James J. Ferguson III, MD (Chairman)
Texas Heart Institute, Houston, TX
Jan T. Christenson, MA, MD, PhD
Dept. of Cardiovascular and Thoracic Surgery University of Geneva Hospital, Geneva, Switzerland
Marc Cohen, MD
MCP Hahnemann University, Philadelphia, PA
Robert Freedman, Jr, MD
Freedman Memorial Cardiology Associates, Alexandria, LA
Christine Kopistansky, RN, BSN
MCP Hahneman University, Philadelphia, PA
Michael F. Miller, PhD
M.F. Miller Statistical Services, Langhorne, PA
E. Magnus Ohman, MD
University of North Carolina, Chapel Hill, NC
Ramachandra C. Reddy, MD
SUNY Health Science Center at Brooklyn, Brooklyn, NY
Gregg W. Stone, MD
Cardiovascular Research Foundation, New York, NY
Philip M. Urban, MD
The Cardiovascular Surgery Unit, Hospital de la Tour, Meyrin-Geneva, Switzerland

APPENDIX B

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has recently introduced the ORYX[tm] initiative to integrate performance measures into the accreditation process and establish a data-driven continuous survey to complement standards-based assessment. The JCAHO has accepted the Benchmark Counterpulsation Outcomes Registry as having met the initial criteria for inclusion in the ORYX[tm] initiative, which measures clinical performance as a part of the future accreditation process. A total of 8 Benchmark measures of clinical outcome have been accepted by the Joint Commission for accreditation purposes in connection with the ORYX[tm] initiative.

APPENDIX C: PARTICIPATING SITES

Australia (1 Participant)
Alfred Hospital; Prahran, Victoria, Australia

Belgium (5 Participants)
Centre Hospitalier Sart Tilman; Liege, Belgium
Clinique Universitaire; Yvoir, Belgium
Hopital de la Citadelle; Liege, Belgium
Universitair Ziekenhuis Antwerpen; Eilegem, Belgium
Universitair Ziekenhuis; Gent, Belgium

Brazil (1 Participant)
Hospital Sao Mateus S/C Ltda.; Papicua, Forteleza, Brazil

Canada (11 Participants)
Centre Hospitalier de la Vallee de l'Outaouais; Hull, Quebec, Canada
CHUM-Campus Notre Dame; Montreal, Quebec, Canada
Foothills Provincial General; Calgary, Canada
Hopital St-Luc; Montreal, Quebec, Canada
Institut De Cardiologie De Montreal; Montreal, Canada
Kingston General Hospital; Kingston, Ontario, Canada
London Health Service University Campus-Windemer; London ON, Canada
London Health Services Victoria Campus-South St.; London ON, Canada
Royal University Hospital; Saskatoon, Saskatchewan, Canada
Sudbury Regional Hospital; Sudbury, Ontario, Canada
Vancouver Hospital & Health Sciences Center; Vancouver, British Columbia, Canada

Denmark (1 Participant)
Skeijby Universitetshospital; Aarhus, Denmark

France (10 Participants)
Centre Medico-Chirurgical PARLY II; France
CHR Rennes; France
CHU Bon Secours, METZ; METZ Cedex, France
CHU Michallon Grenoble; Grenoble, Cedex, France
CHU Toulouse Hopital Rangueil; Toulouse, France
Hopital de la Timone; Marseille, France
Hopital Louis Pradel; Bron, France
Hopital Pastuer; Nice, France
Hopital Saint Joseph; Marseille, France
Institut Jacques Cartier; Massy, France

Germany (15 Participants)
Berufsgenossenschaftliche Kliniken Bergmannsheil Universitatsklinik; Bochum, Germany
Friedrich-Schiller-Universität Jena-Klinik für Innere Medizin 3-; Jena, Germany
Herzzentrum Frankfurt AG; Franfurt, Germany
Herzzentrum Lahr/Baden; Lahr, Germany
Kaiser Wilhelm-Krankenhaus; Duisburg, Germany
Klinikum der Phillipps-Universität Marburg/Lahn; Marburg, Germany
Klinikum Karlsburg Klinik für Anästhesiologie und Intensivmedizin; Karlsburg, Mecklenburg-Vorpommern, Germany
Klinikum Krefeld; Krefeld, Germany
Kreiskrankenhaus Völklingen; Völklingen, Germany
Medizinische Einrichtungen der RWTH; Aachen, Germany
Städtische Kliniken Dortmund Klinik für Thorax-, Herz- und Gefässchirurgie Prof. Dr. med. M.-J. Polonius; DORTMUND, Germany
Uniklinik Bonn; Bonn, Germany
Universitätsklinik Göttingen; Göttingen, Germany
University-Hospital Luebeck; Luebeck, Germany
University of Gießen; Gießen, Germany

Ireland (1 Participant)
Mater Misecordiae Hospital; Dublin, Ireland

Italy (4 Participants)
Centro Cuore Columbus; Milan, Italy
Ospedale Clinicizzato San Donato; San Donato Milanese, Italy
Ospedale di Mirano; Mirano (Venezia), Italy
Poliambulanza; Brescia, Italy

Netherlands (6 Participants)
Academisch Ziekenhuis Masstricht; Maastricht, Netherlands
Academisch Ziekenhuis Vrije Universiteit; HV Amsterdam, Netherlands
Leids Universtaire Medische Centrum (LUMC); Za Leiden, Netherlands
Medische Centrum Alkmaar; JD ALKMAAR, Netherlands
Medische Spectrum Twente; JX ENSCHEDE, Netherlands
Weezenlanden Hospital; JW Zwolle., Netherlands

New Zealand (1 Participant)
Green Lane Hospital; Epsom Auckland, New Zealand

Poland (1 Participant)
Gornoslaskie Centrum; Poland

Scotland (1 Participant)
Aberdeen Royal Infirmary; Aberdeen, Scotland

South Africa (2 Participants)
Morningside Hospital; Johannesburg, South Africa
Union Hospital; Johannesburg, South Africa

Sweden (1 Participant)
University Hospital; Lund, Sweden

Switzerland (2 Participants)
Inselspital; Bern, Switzerland
La Tour Hospital; Meyrin, Geneva, Switzerland

United Kingdom (14 Participants)
Bristol Royal Infirmary; Bristol, United Kingdom
Cardiothoracic Center Liverpool; Liverpool, United Kingdom
Freeman Hospital; Newcastle Upon Tyne, United Kingdom
Glenfield Hospital; Leicester, United Kingdom
Harefield; Harefield, United Kingdom
Hull Royal Infirmary; Hull, United Kingdom
Morriston; Swansea, United Kingdom
Nottingham City; Nottingham, United Kingdom
Royal Sussex County; Brighton East Sussex, United Kingdom
South Cleveland Hospital; Middlesborough, Cleveland, United Kingdom
The London Chest Hospital; London, United Kingdom
The Royal Brompton Hospital; London, United Kingdom
Walsgrave; Walsgrave, United Kingdom
Wythenshaw Hospital; Wythenshaw, Manchester, United Kingdom

United States (166 Participants)
Alabama (6 Participants)
Baptist Medical Center; Montgomery, AL
Carraway Methodist Med. Center; Birmingham, AL
Jackson Hospital and Clinic; Montgomery, AL
Shelby Medical Center; Alabaster, AL
South Baldwin Hospital; Foley, AL
University of Alabama Hospital; Birmingham, AL

Arkansas (4 Participants)
Baptist Memorial Medical Ctr.; North Little Rock, AR
Northwest Medical Center; Springdale, AR
St. Vincent Infirmary-Med. Ctr.; Little Rock, AR
Univ. Hospital & Amb. Care Ctr.; Little Rock, AR

California (10 Participants)
Downey Community Hospital; Downey, CA
Good Samaritan Hospital; Los Angeles, CA
Grossmont Hospital; La Mesa, CA
Holy Cross Medical Center; Mission Hills, CA
Kaweah Delta District Hospital; Visalia, CA
Long Beach Memorial Med. Ctr.; Long Beach, CA
Providence of St. Joseph's Medical Center; Burbank, CA
Santa Barbara Cottage Hospital; Santa Barbara, CA
Sharp Memorial Hospital; San Diego, CA
St. John's Regional Medical Ctr.; Oxnard, CA

Colorado (2 Participants)
St. Anthony Hospital Central; Denver, CO
St. Mary's Hospital and Med. Ctr.; Grand Junction, CO

Connecticut (2 Participants)
Bridgeport Hospital; Bridgeport, CT
St. Vincent's Medical Center; Bridgeport, CT

Florida (15 Participants)
Broward General Medical Center; Ft. Lauderdale, FL
Charlotte Regional Med. Ctr.; Punta Gorda, FL
Columbia West Florida; Pensacola, FL
Florida Hospital-Orlando; Orlando, FL
Florida Medical Center; Ft. Lauderdale, FL
Largo Medical Center Hospital; Largo, FL
Lucerne Medical Center; Orlando, FL
Munroe Regional Medical Center; Ocala, FL
Naples Community Hospital; Naples, FL
North Ridge Medical Center; Ft. Lauderdale, FL
Sarasota Memorial Hospital; Sarasota, FL
Shands Hosp. at the Univ. of FL; Gainesville, FL
St. Joseph's Hospital; Tampa, FL
Tallahassee Memorial Hospital; Tallahassee, FL
Veterans Affairs Medical Center; Gainesville, FL

Georgia (2 Participants)
Atlanta Medical Center; Atlanta, GA
Medical Center of Central Georgia; Macon, GA

Hawaii (1 Participant)
Kaiser Foundation Hospital; Honolulu, HI

Idaho (1 Participant)
St. Alphonsus Regional Med. Ctr.; Boise, ID

Illinois (14 Participants)
Bromenn Regional Medical Ctr.; Normal, IL
E H S Christ Hospital & Med. Ctr.; Oak Lawn, IL
Gottlieb Memorial Hospital; Melrose Park, IL
Illini Hospital; Silvis, IL
La Grange Memorial Hospital; La Grange, IL
Mercy Ctr. for Health Care Services; Aurora, IL
Methodist Med. Ctr. of Illinois; Peoria, IL
Mt. Sinai Hosp. Med. Center; Chicago, IL
Northwest Community Hospital; Arlington Heights, IL
Proctor Hospital; Peoria, IL
St. Francis Medical Center; Peoria, IL
St. Joseph Medical Center; Joliet, IL
Trinity Medical Center; Rock Island, IL
Westlake Community Hospital; Melrose Park, IL

Indiana (3 Participants)
Bloomington Hospital; Bloomington, IN
Greater Lafayette Health Service, Inc.; Lafayette, IN
Witham Memorial Hospital; Lebanon, IN

Iowa (5 Participants)
Allen Memorial Hospital; Waterloo, IA
Mercy Medical Center; Cedar Rapids, IA
Mercy Medical Center; Dubuque, IA
St. Luke's Methodist Hospital; Cedar Rapids, IA
Univ. of Iowa Hospitals; Iowa City, IA

Kansas (1 Participant)
Hutchinson Community Hospital; Hutchinson, MN

Louisiana (3 Participants)
Ochsner Foundation Hospital; New Orleans, LA
St. Frances Cabrini Hospital; Alexandria, LA
Terrebonne General Medical Ctr.; Houma, LA

Maine (1 Participant)
Maine Medical Center; Portland, ME

Maryland (1 Participant)
Washington Adventist Hospital; Takoma Park, MD

Massachusetts (2 Participants)
New England Medical Center; Boston, MA
St. Elizabeth's Medical Center; Brighton, MA

Michigan (13 Participants)
Bronson Methodist Hospital; Kalamazoo, MI
Genesys Health Park; Grand Blanc, MI
Henry Ford Hospital; Detroit, MI
Ingham Regional; Lansing, MI
Mercy Hospital; Muskegon, MI
Mount Clemens General Hospital; Mt. Clemens, MI
Munson Medical Center; Traverse City, MI
Northern Michigan Hospital; Petoskey, MI
Sparrow Hospital; Lansing, MI
Spectrum Health Downtown; Grand Rapids, MI
St. Joseph Mercy Hospital; Ann Arbor, MI
St. Joseph Mercy Hospital; Pontiac, MI
William Beaumont Hosp. Royal Oak; Royal Oak, MI

Minnesota (4 Participants)
Fairview Southdale Hospital; Minneapolis, MN
Fairview University Hospital; Minneapolis, MN
Hennepin County Med. Center; Minneapolis, MN
North Memorial Medical Center; Robbinsdale, MN

Mississippi (1 Participant)
St. Dominic-Jackson Mem. Hosp.; Jackson, MS

Nebraska (1 Participant)
Nebraska Health Systems-University; Omaha, NE

New Hampshire (2 Participants)
Catholic Medical Center; Manchester, NH
Exeter Hospital; Exeter, NH

New Jersey (7 Participants)
Cooper Hospital/Univ. Med. Ctr.; Camden, NJ
Hackensack Medical Center; Hackensack, NJ
Jersey Shore Medical Center; Neptune, NJ
Newark Beth Israel Med. Center; Newark, NJ
Our Lady of Lourdes Med. Ctr.; Camden, NJ
Passaic General; Passaic, NJ
St. Joseph's Hosp. and Med. Center; Paterson, NJ

New Mexico (1 Participant)
San Juan Regional Medical Ctr.; Farmington, NM

New York (11 Participants)
Albany Medical Center Hospital; Albany, NY
Arnot-Ogden Medical Center; Elmira, NY
Beth Israel Medical Center; New York, NY
Buffalo General Hospital; Buffalo, NY
Long Island Jewish Med. Ctr.; New York, NY
Millard Fillmore Hospital; Buffalo, NY
St. Elizabeth Hospital; Utica, NY
St. Joseph's Hospital Health Ctr.; Syracuse, NY
St. Peter's Hospital; Albany, NY
University Hospital Brooklyn; Brooklyn, NY
Winthrop-University Hospital; Mineola, NY

North Carolina (3 Participants)
Frye Regional Medical Center; Hickory, NC
Moore Regional Hospital; Pinehurst, NC
Wake County Medical Center; Raleigh, NC

Ohio (8 Participants)
Lima Memorial Hospital; Lima, OH
Miami Valley Hospital; Dayton, OH
Northside Medical Center; Youngstown, OH
Ohio State Univ. Hospital; Columbus, OH
St. Rita's Medical Center; Lima, OH
St. Vincent Mercy Medical Center-Cardiac Cath. Lab; Toledo, OH
St. Vincent Mercy Medical Center-Perfusion; Toledo, OH
University Hospital; Cleveland, OH

Oklahoma (4 Participants)
Integris Baptist Med. Ctr.; Oklahoma City, OK
Midwest City Regional Hospital; Midwest City, OK
St. Anthony Hospital; Oklahoma City, OK
St. Francis Hospital; Tulsa, OK

Pennsylvania (9 Participants)
Altoona Hospital; Altoona, PA
Doylestown Hospital; Doylestown, PA
Hahnemann Univ. Hospital; Philadelphia, PA
Hamot Medical Center; Erie, PA
Lancaster General Hospital; Lancaster, PA
Medical College of PA Hospital; Philadelphia, PA
Robert Packer Hospital; Sayre, PA
St. Francis Medical Center; Pittsburgh, PA
UPMC Lee Regional; Johnstown, PA

Rhode Island (1 Participant)
Miriam Hospital; Providence, RI

South Carolina (3 Participants)
Carolinas Hosp. Syst./Florence; Florence, SC
Grand Strand General Hospital; Myrtle Beach, SC
Hilton Head Hospital; Hilton Head, SC

Tennessee (3 Participants)
Erlanger Medical Center; Chattanooga, TN
Univ. of Tenn. Mem. Hospital; Knoxville, TN
Vanderbilt University Medical Center; Nashville, TN

Texas (12 Participants)
Baptist Hospital Southeast Texas; Beaumont, TX
Bayshore Medical Center (PerStat Medical Systems); Clear Lake, TX
Columbia Medical Center West; El Paso, TX
Harris Methodist/H E B North; Bedford, TX
Heart Hospital of Austin; Austin, TX
Houston Northwest Medical Ctr.; Houston, TX
Mc Allen Heart Hospital; Mc Allen, TX
Medical City Dallas Hospital; Dallas, TX
Osteopathic Med. Ctr. of Texas; Ft. Worth, TX
Santa Rosa Northwest Hospital; San Antonio, TX
Seton Medical Center; Austin, TX
St. Luke's Episcopal Hospital; Houston, TX

Virginia (3 Participants)
Henrico Doctors Hospital; Richmond, VA
Sentara Norfolk General Hosp.; Norfolk, VA
Southside Regional Medical Ctr.; Petersburg, VA

Washington (1 Participant)
Providence Yakima Medical Center; Yakima, WA

West Virginia (2 Participants)
Charleston Area Med. Ctr.-Gen. Div.; Charleston, WV
St. Mary's Hospital; Huntington, WV

Wisconsin (3 Participants)
Appleton Medical Center; Appleton, WI
Mercy Hospital of Janesville; Janesville, WI
St. Mary's Medical Center; Racine, WI

Wyoming (1 Participant)
Wyoming Medical Center; Casper, WY