Lack of Effectiveness of the Pulmonary Artery Catheter in Cardiac Surgery

Nanette Schwann, MD, Lehigh Valley Health Network
Zak Hillel, PhD, MD
Andreas Hoeft, MD
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Patrick Möhnle, MD, et al.

Available at: https://works.bepress.com/nanette_schwann_lvhn/4/
Lack of Effectiveness of the Pulmonary Artery Catheter in Cardiac Surgery

Nanette M. Schwann, MD,*† Zak Hillel, PhD, MD,†† Andreas Hoeft, MD,§ Paul Barash, MD,¶ Patrick Mühle, MD,¶ Yinghui Miao, MD, MPH,** and Dennis T. Mangano, PhD, MD††

BACKGROUND: The pulmonary artery catheter (PAC) continues to be used for monitoring hemodynamics in patients undergoing coronary artery bypass graft (CABG) surgery despite concerns raised in other settings regarding both effectiveness and safety. Given the relative paucity of data regarding its use in CABG patients, and given entrenched practice patterns, we assessed the impact of PAC use on fatal and nonfatal CABG outcomes as practiced at a diverse set of medical centers.

METHODS: Using a formal prospective observational study design, 5065 CABG patients from 70 centers were enrolled between November 1996 and June 2000 using a systemic sampling protocol. Propensity score matched-pair analysis was used to adjust for differences in likelihood of PAC insertion. The predefined composite endpoint was the occurrence of any of the following: death (any cause), cardiac dysfunction (myocardial infarction or congestive heart failure), cerebral dysfunction (stroke or encephalopathy), renal dysfunction (dysfunction or failure), or pulmonary dysfunction (acute respiratory distress syndrome). Secondary variables included treatment indices (inotrope use, fluid administration), duration of postoperative intubation, and intensive care unit length of stay. After categorization based on PAC and transesophageal echocardiography use (both, neither, PAC only, transesophageal echocardiography only), we performed the primary analysis contrasting PAC only and neither (total, 3321 patients), from which propensity paring yielded 1273 matched pairs.

RESULTS: The primary endpoint occurred in 271 PAC patients versus 196 without PAC (21.3% vs. 15.4%; adjusted odds ratio [AOR], 1.68; 95% confidence interval [CI], 1.24 to 2.26; P < 0.001). The PAC group had an increased risk of all-cause mortality, 3.5% vs 1.7% (AOR, 2.08; 95% CI, 1.11 to 3.88; P = 0.02) and an increased risk of cardiac (AOR, 1.58; 95% CI, 1.14 to 2.20; P = 0.007), cerebral (AOR, 2.02; 95% CI, 1.08 to 3.77; P = 0.03) and renal (AOR, 2.47; 95% CI, 1.68 to 3.62; P < 0.001) morbid outcomes. PAC patients received inotropic drugs more frequently (57.8% vs 50.0%; P < 0.001), had a larger positive IV fluid balance after surgery (3220 mL vs 3022 mL; P = 0.003), and experienced longer time to tracheal extubation (15.40 hours [11.28/20.80] versus 13.18 hours [9.58/19.33], median plus Q1/Q3 interquartile range; P < 0.0001). Use of PAC was also associated with prolonged intensive care unit stay (14.5% vs 10.1%; AOR, 1.55; 95% CI, 1.06 to 2.27; P = 0.02).

CONCLUSIONS: Use of a PAC during CABG surgery was associated with increased mortality and a higher risk of severe end-organ complications in this propensity-matched observational study. A randomized controlled trial with defined hemodynamic goals would be ideal to either confirm or refute our findings. (Anesth Analg 2011;113:994–1002)

Since its introduction more than 40 years ago, the flow-directed balloon-tipped pulmonary artery catheter (PAC) has become a monitoring standard and a guide to therapy for patients suffering critical illnesses or for those undergoing complex surgical procedures. Over the past decade PAC monitoring has become less common, although its use varies markedly between institutions and clinical settings. For patients undergoing coronary artery bypass graft (CABG) surgery or cardiac valvular surgery, however, PAC use is still a standard procedure in many practices. In 2000 it was estimated that 500,000 cardiac surgery patients were monitored annually with a PAC in the United States alone, and that insertion rates in cardiac surgery have not paralleled the downward trend seen in other patient populations. Arguably, there is rationale for such use in these patients, given growing...
trends of increased disease acuity and a rising prevalence of ventricular dysfunction.7,8

Since the study of Connors et al.,9 substantial evidence has raised concern over PAC use in a number of medical and surgical critical illnesses. Assessment of PAC effectiveness is not straightforward, given use/nonuse biases, and considerable differences in the interpretation of PAC measurements and treatment responses among institutions, practitioners, and presenting diagnostic categories.10,11 Therefore, it has been difficult to discern the effect of PAC use on outcomes.12,13

Only a few prospective randomized trials14–19 have been reported, and none has addressed the patient undergoing cardiac surgery. Distinguishing these patients are unique hemodynamic and physiologic perturbations, perfusion using nonpulsatile flow during cardiopulmonary bypass (CPB), and use of multiple therapeutic interventions. These characteristics obfuscate comparisons among trials of CABG patients from those involving other cohorts,14–22 making inference of effectiveness or safety from non-CABG patients inappropriate.23 Consequently, we sought to determine the impact of PAC use on the incidence of death, organ dysfunction, and treatment patterns in a large prospective study of coronary revascularization patients.

METHODS

Study Design and Data

The Epidemiology II Multicenter Study of Perioperative Ischemia (McSPI) was a prospective and longitudinal investigation of 5065 patients with medically refractory coronary artery disease undergoing CABG with CPB at 70 institutions in 16 countries from North and South America, Europe, the Middle East, and Asia between November 1996 and June 2000. All participating institutions were required to submit their IRB/Ethic Committee approvals of the research protocol. To be eligible for enrollment, the patient had to be at least 18 years old, scheduled to undergo CABG surgery with the use of CPB, be able to complete the preoperative interview, could not be enrolled in another study or clinical trial, and had to be able to provide written informed consent.

Enrollment design, eligibility criteria, and number of patients per site of this dataset have been previously described.24 For each enrolled patient, approximately 7500 variables were collected by independent investigators during the index hospitalization for CABG surgery. The treating physicians were blinded to the research data while the study was continuing. Data that included demographic, historical, clinical, laboratory, electrocardiography, specialized testing, resource utilization, and adverse outcome were adjudicated centrally. All data entries for each patient were queried centrally for completeness and accuracy, with any necessary changes documented before database closure.

PAC Definition and Management

PAC use was at the discretion of the attending physicians based on institutionally defined insertion criteria and was not randomized. Patients were classified as being in the PAC group or non-PAC group by the presence of a PAC before the initiation of CPB. Patients without a PAC in situ before CPB were considered to be in the non-PAC group, even if they received a PAC later in the course of their hospital stay.

PAC or non-PAC hemodynamic diagnosis and treatment were not controlled or standardized. Patients were managed via institutional and individual practice patterns, and clinical decisions were not dictated by a study protocol. Hemodynamic data—including all available pressures (central venous [CVP], pulmonary artery systolic and diastolic, and pulmonary capillary wedge), heart rate, all IV and oral administrations (medication, fluids, blood products), cardiac output and derived indices, and urine output—were collected hourly for the first 48 hours after surgery from recorded patient data by investigators not participating in clinical treatment.

Measurement of Outcomes

All outcomes were specified before analysis and defined by protocol. The composite outcome consisted of fatal and nonfatal in-hospital outcomes classified as death (from any cause), cardiac (myocardial infarction [MI], congestive heart failure [CHF]), cerebral (stroke, encephalopathy), renal (dysfunction or failure), and pulmonary (acute respiratory distress syndrome) morbidities. The diagnosis of MI25 required either development of new Q waves (as defined by Minnesota Code 1 to 1–1 or 1 to 2–7), or new persistent ST-segment or T-wave changes (Minnesota Code 4 to 1, 4 to 2, 5 to 1, 5 to 2, or 9 to 2) and elevated CK-MB isoenzyme values, or autopsy evidence of acute MI. The diagnosis of CHF was made if either of the following occurred: insertion of a ventricular assist device or intra-aortic balloon pump, continuous nonroutine inotropic drug support lasting >24 hours, or evidence of heart failure at autopsy. Stroke was diagnosed on the basis of a focal or global defect on physical examination, tomographic scan, magnetic resonance imaging, or autopsy. Cerebral outcomes26 were classified as clinically diagnosed stroke or encephalopathy or computed tomography, magnetic resonance imaging, or autopsy evidence of a focal or global cerebral defect. All patients received an evaluation using the National Institutes of Health stroke scale, pre- and postoperatively, by a certified examiner.27 A decline in score on the Mini-Mental State Examination of 3 points or more and an increase in score on the National Institutes of Health Stroke Scale score of 4 points or more were considered significant. Renal dysfunction28 was defined as a serum creatinine ≥177 µmol/L (2.0 mg/dL) accompanied by a ≥62 µmol/L (0.7 mg/dL) increase over baseline, and renal failure was defined as dysfunction requiring dialysis, or autopsy evidence of renal failure. Acute respiratory distress syndrome was defined as bilateral reduction in alveolar space or infiltrates on frontal chest radiograph, hypoxia (PaO2/FIO2 <200 mm Hg), and presence of nonhydrostatic pulmonary edema thought to be related to inflammation (endothelial capillary leak) rather than increased left atrial cardiac filling pressure. A prolonged intensive care unit (ICU) stay was defined as >4 days after operation. Tracheal extubation time was defined as the period between postoperative ICU admission until endotracheal tube removal.

Patients who received a PAC after initiation of CPB were considered “cross-over PAC.” These patients were assigned to their original intent-to-treat non-PAC group and
underwent propensity score matching with their PAC counterparts. Patients with intraoperative transesophageal echocardiography (TEE) were excluded from this study, because data obtained by this diagnostic technique may have influenced the interpretation of the PAC data in the operating room and the ICU.

Analyses were also performed to gain insight into potential mechanisms by which PAC use impacted outcome. Day-of-surgery (defined as until 11:59 pm on the day of surgery) analyses were conducted for 2 potentially PAC-related therapeutic responses: net fluid balance and inotropic drug use. The latter was stratified as none, routine use (routinely for that surgery at that specific institution), or nonroutine use (other than routine, or 2 or more inotropes).

Statistical Analysis
Propensity analysis following the algorithm described by D’Agostino was used to compare the effect of the “insertion of PAC” on patient outcome with the effect on patients in the non-PAC group but with the same likelihood of receiving a PAC insertion. A priori, 36 historical or preoperative predictors (Appendix 1) for insertion of a PAC before CPB were identified. Using nonparsimonious logistic regression modeling, we developed propensity scores for PAC insertion (vs no PAC insertion), including 36 treatment selection covariates. Covariate interactions proved unnecessary for the balance of baseline characteristics. The discriminate power of the propensity scores was quantified by measurement of the area under the receiver operating characteristic curve (the C index). Matched patients with hospitals, and adjusted odds ratios and their 95% confidence intervals (CIs) were presented with associated confidence intervals. Wilcoxon ranked sum test was performed to analyze differences for baseline characteristics between the 2 groups using repeated-measures analysis of variance (ANOVA). All statistical analyses were performed with SAS Version 8.12 software (SAS Institute, Cary, NC). Statistical significance was defined as $P < 0.05$.

RESULTS
Baseline Characteristics and Exclusions
From the 5065 eligible patients, 1744 were excluded because of the presence of intraoperative TEE (Fig. 1). Three thousand three hundred twenty-one patients remained in the analysis, with 1673 (50.4%) receiving a PAC before CPB. The propensity score matching process, PSMP (based on preoperative covariates listed in Appendix 1; C index = 0.67) resulted in 1273 matched pairs, for a total of 2546 patients with comparable risk factors, distinguished only by the insertion of a PAC before CPB (Table 1). No significant differences for baseline characteristics between propensity-matched groups were observed.

Main Outcomes
Figure 2 shows the predefined primary composite endpoint of major morbidity and mortality. This endpoint was observed in 271 patients with PAC monitoring in comparison with 196 matched patients without PAC monitoring (21.3% vs 15.4%; AOR, 1.68; 95% CI, 1.24 to 2.26; $P < 0.001$). In-hospital death from any cause was more common in the PAC group than in the matched non-PAC group (3.5 vs 1.7%; AOR, 2.08; 95% CI, 1.11 to 3.88; $p = 0.02$). There were more cardiac events in the PAC group than in the non-PAC group (202 vs 153 or 15.9% vs 12.0%, respectively; AOR, 1.58; 95% CI, 1.14 to 2.20; $P = 0.007$), as well as more cerebral (AOR, 2.02; 95% CI, 1.08 to 3.77; $P = 0.03$) and renal (AOR, 2.47; 95% CI, 1.68 to 3.62; $P < 0.001$) events. PAC monitoring was also associated with an increased incidence of prolonged ICU stay. Overall, 185 PAC patients stayed longer than 4 days in the ICU in comparison with 129 patients without PAC monitoring (14.5% vs 10.1%; AOR, 1.55; 95% CI, 1.06 to 2.27; $P = 0.02$). Tracheal extubation time ($t = 1233$) was also prolonged in the PAC group in comparison with the non-PAC group (15.40 hours [11.28/20.80] versus 13.18 hours [9.58/19.33], median plus Q1/Q3 interquartile range; $P < 0.0001$).

Hemodynamic Management and Fluid Therapy
Figure 3 illustrates the frequency of inotrope use in PAC and non-PAC patients. The use of inotropes was more frequent in the PAC patients than non-PAC patients (79.5% vs 71.6%; AOR, 1.82; 95% CI, 1.32 to 2.50; $P < 0.001$) on the
day of surgery. This was primarily due to increased use of nonroutine inotropes (57.8% vs 50.0%; AOR, 1.93; 95% CI, 1.47 to 2.52; P < 0.001). Concomitantly, on the day of surgery, PAC patients received more fluids and had a higher positive fluid balance (Table 2).

**DISCUSSION**

The results of this large, international, prospective observational study found that PAC use was associated with a higher risk of the composite mortality and morbidity outcome than non-PAC use in patients undergoing CABG surgery. Significant decline in organ function, increased inotrope and fluid administration, and longer ICU stay were noted in the PAC group.

Smaller observational trials have implicated that PAC monitoring is associated with increased morbidity and decreased survival.21 In contrast, several large randomized trials in noncardiac surgery populations have more
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recently reported no differences in mortality\textsuperscript{14–19} despite higher rates of catheter-related adverse events\textsuperscript{14–17} and hemodynamic interventions.\textsuperscript{14,15} No randomized trials, thus far, have evaluated the efficacy or safety of PAC use in cardiac surgery. Moreover, there are few prospective observational trials in this population, and the only study examining >1000 patients was published >20 years ago.\textsuperscript{33} Although Schwann et al.\textsuperscript{34} described that highly selective

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**Figure 3.** Inotrope use in matched pairs of patients with pulmonary artery catheter (PAC) and no PAC. Patients with PAC received nonroutine inotropes more often than patients monitored without PAC. Adjusted odds ratios (AOR) with 95% confidence intervals (CI) and associated \( P \) values were calculated from the generalized estimating equations (GENMOD procedure).

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**Table 1.** Outcomes of 1273 propensity score matched pairs with pulmonary artery catheter (PAC) and no PAC. Death, congestive heart failure, and cerebral and renal events are major contributors to the adverse outcomes of PAC patients. Note that intensive care unit stay is also significantly more often prolonged in patients with PAC monitoring. Adjusted odds ratios (AOR) with 95% confidence intervals (CI) and associated \( P \) values were calculated from the generalized estimating equations (GENMOD procedure).
use of PAC decreased resource utilization and catheter-related risks, inferences that PAC should continue to be used in high-risk patients might not be justified. Despite the paucity of studies specifically targeting the cardiac surgical population, the notion that for these patients, the PAC is useful for guiding rational decisions concerning the administration of fluids, inotropes, and diuretics has remained unchallenged over the past 2 decades.

**Coronary Revascularization vs Other Cohorts**

Cardiac surgical patients experience unique physiological challenges, many of which are at least partly due to CPB. Biventricular dysfunction, ventricular underfilling, and extremes of vascular tone (vasoconstriction or vasoplegia) are common causes of inadequate microcirculatory flow during and after CPB. A PAC provides more precise physiologic data than CVP (or no central pressure monitoring) for early detection of perfusion abnormalities, potentially forestalling tissue hypoxia. Hence, unexpected was our finding that patients managed with a PAC experienced higher rates of in-hospital death and organ failure than did similar propensity-matched patients managed with CVP monitoring alone. One possible explanation for this may be that intensive hemodynamic manipulations and interventions as a result of the presence of a PAC and its associated data may be responsible for the deleterious effect of this mode of monitoring on perioperative outcome.

Another explanation for the lack of effectiveness of a PAC in improving outcome in different patient populations might be related to the limitations of pulmonary capillary wedge pressure to reflect left ventricular end-diastolic volume. Alternatively, others postulate that PAC-directed therapy, including the use of fluids and inotropes, may be ineffective or harmful.

Sandham et al. performed a randomized trial evaluating the impact of PAC on outcome in noncardiac surgery and found no differences between protocol-driven PAC-monitored patients and a non-PAC control group. PAC management was used to maintain high-normal cardiac index and oxygen delivery indices (3.5 to 4.5 L/min/m$^2$ and 550 to 600 mL/min/m$^2$, respectively). This practice pattern did not alter mortality (7.7% vs 7.8% in PAC and non-PAC groups, respectively), and no differences in outcomes were found. Other trials have suggested increased morbidity with a PAC, but these have predominantly focused on nonsurgical patients with a broad range of preinsertion diagnoses. Few studies have examined the use of the PAC as an adjunct in the management of myocardial ischemia and reperfusion injury. A retrospective observational study using multivariable analysis to adjust for baseline characteristics evaluated the use of the PAC in the setting of acute coronary syndromes (GUSTO IIb and GUSTO III data). Consistent with our findings, mortality at 30 days was substantially higher in patients managed with a PAC (OR 8.7; 95% CI 7.3 to 10.2) because of an increase in adverse events, including bleeding, hypotension, and CHF. However, PAC patients referred to cardiac surgery were excluded from the analysis.

Data from observational, matched-pair cohort studies have been reported to show improved exercise tolerance in heart failure and improved outcome in refractory circulatory shock. Yet, in the second-largest randomized trial evaluating the PAC catheter ($n = 1041$), Harvey et al. reported no differences in survival, in-hospital mortality, or ICU length of stay in adult medical and surgical patients admitted with APACHE scores $>25$. The investigators concluded that the true benefit of the PAC (if any) would not be evident without clinical trials testing specific PAC data-driven management protocols.

The ESCAPE trial evaluated the effectiveness of the PAC in a randomized group of 433 nonsurgical CHF patients. These findings suggested that PAC-guided vasodilator and diuretic therapy was not superior to clinical assessment alone in reducing death or hospital stay. Therapy to reduce intravascular volume overload during hospitalization for heart failure led to marked improvement in signs and symptoms of increased filling pressures in patients monitored with or without a PAC. For this group of chronic CHF patients, addition of the PAC to clinical assessment increased anticipated adverse events, but did not affect overall mortality and hospitalization.

**Limitations**

In our study, the primary analysis included 54 out of 1273 non-PAC patients, who received a PAC after CPB. Almost all (96%) of the cross-overs occurred after ICU admission. Patients with an unplanned PAC insertion were included and analyzed as part of their original non-PAC treatment group and had an in-hospital mortality rate of 18.5%. Most likely, the PAC insertion was a clinical response to a catastrophic and unpreventable perioperative event.

Our study assessed the association between the clinical use of PAC and outcome, using prospectively defined hypotheses and definitions. Because the patient group assignment was not randomized, differences in covariates between PSMP may have influenced the treatment selection (preferential PAC insertion and monitoring of sicker patients) and biased the results. This was addressed by comparing multiple demographic, hospital admission, and immediate preoperative risk factors possibly associated with patient selection into treatment groups before and after propensity matching. Table 1 shows that PSMP pairs had similar incidences of preoperative and early intraoperative risk factors previously validated to be strongly related to outcome (Euro SCORE; 20 markers of previous or present myocardial impairment or vulnerability; evidence of major noncardiac organ system dysfunction; and requirement of either emergency or combined (valve/CABG)

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<th>Table 2. Comparison of Fluid Intake/Balance by Pulmonary Artery Catheter (PAC) Usage among Propensity Score-Matched Patients</th>
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operation). Furthermore, we accounted for the variability of PAC insertion frequencies (1%–99%) by specific center sites. However, there is still the possibility that covariates that influence treatment selection and outcome remain unevaluated. Our study supplies a real-world view of the use of PACs in the surgical coronary revascularization setting. Although results from prospective, randomized clinical trials are considered the highest level of evidence for evaluating monitoring modalities and medical therapies, well-conducted observational trials can provide similar results. It has been suggested that prospectively randomized trials test efficacy under ideal conditions and that observational studies test effectiveness in everyday practice.

Another limitation of our study is the age of the collected data. Albeit practice patterns for perioperative care of the cardiac surgical patient (other than use of intraoperative TEE) constantly underlie improvements and slight changes, the observed effects related to monitoring at the time of data collection are not significantly different from those used currently. By eliminating patients who had intraoperative TEE from our study population, we were able to focus the study on the role of PAC on outcome. Finally, although regional differences in treatment protocols may have affected the results, these same differences persist.

Another limitation of this study is the inability to separate the contribution of PAC monitoring alone from monitoring-induced interventions on outcome. Unlike the Sandham et al. analysis, we chose to assess the impact of PAC monitoring without a hemodynamic protocol, because it better reflects the current practice patterns in cardiac surgery. In the operating room, physiologic variables are measured, interpreted, and treated in real-time by providers. Cardiac programs contributing patients to the dataset are high-volume centers with experienced cardiac teams; however, it is still possible that the PAC data were inaccurate or misinterpreted in this setting.

CONCLUSION
We conclude that the use of PACs confers no benefit among patients undergoing coronary revascularization surgery requiring CPB. Our data also indicate that PAC use triggers more frequent and more intensive hemodynamic interventions, suggesting a mechanism for the increased rate of complications and adverse outcome associated with PAC use. Although a randomized controlled trial would be ideal to confirm our findings, we recognize that imbedded practice and bias limitations would make such a trial difficult to conduct.

APPENDIX 1: PROPENSITY COVARIATES

Demographics
Age, years
Body surface area, m²
American Indian, African American, or Hispanic ethnicity
Gender

Medical History
Smoking
Unstable angina
Congestive heart failure

Dysrhythmia
Hypertension
Valve disease
Percutaneous transluminal coronary angioplasty (PTCA)/coronary atherectomy/intracoronary stent
Coronary artery bypass graft surgery (CABG)
Valve surgery
Other cardiac surgery
Other noncardiac surgery
Neurological dysfunction
Extracardiac arteriopathy
Pulmonary disease
Liver disease
Gastrointestinal disease
Renal disease
Peripheral vascular disease
Diabetes mellitus
Anemia

Preoperative Factors
Moderate left-ventricular dysfunction
Severe left-ventricular dysfunction
Intra-aortic balloon pump (IABP)
Medication of inotropes/vasoconstrictors
Serum creatinine >200 μmol/L
Critical state
Myocardial infarction prior to surgery within 90 days
Congestive heart failure (admission/preoperative)

Concurrent Surgery
Emergent surgery
Valve surgery
Combined cardiac surgery
Combined surgery on thoracic aorta

APPENDIX 2

McSPI EPI II LIST OF CENTERS AND PRINCIPAL INVESTIGATORS
The Ischemia Research and Education Foundation (IREF) is an independent nonprofit foundation, formed in 1987, that develops clinical investigators via observational studies and clinical trials addressing ischemic injury of the heart, brain, kidney, and gastrointestinal tract. IREF provided all funding for execution of the study, collection of the data, and analysis and publication of the findings. The Multi-center Study of Perioperative Ischemia (McSPI) Research group, formed in 1988, is an association of 160 international medical centers located in 23 countries, organized through, and supported by grants from, IREF.

The following institutions and persons coordinated the McSPI EPI II study: Study Chairman—D. Mangano; Senior Editors—J. Levin and L. Saidman; Study Design and Analysis Center: Ischemia Research and Education Foundation—P. Barash, C. Dietzel, A. Herskowitz, Y. Miao, and I. C. Tudor; Editorial/Administrative group—D. Beatty, I. Lei, and B. Xavier.

The following institutions and persons participated in the McSPI EPI II study:
United States: University of Chicago, Weiss Memorial Hospital—S. Aronson; Beth Israel Hospital—M. Comunale;
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