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In-Hospital Mortality Associated With the Use of Intra-Aortic Balloon Counterpulsation

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We analyzed in-hospital mortality for patients treated with intra-aortic balloon counterpulsation from the Benchmark Counterpulsation Outcomes Registry (n = 25,136). In-hospital mortality was higher in patients who received only medical interventions (32.5%) than in those who underwent percutaneous (18.8%) and surgical (19.2%) interventions, and was greatest in the first days after hospital admission for all 3 intervention types. Therefore, diagnostic evaluation and treatment decisions should be made as early as possible, and physicians should be aware of associated risk factors in making choices for patients.

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The aim of this study was to analyze a large multicenter international database of patients treated with intra-aortic balloon counterpulsation (IABP),[1–5] with the goal of identifying the incidence, timing, and predictors of in-hospital mortality associated with IABP for patients treated with percutaneous coronary intervention (PCI) or only by medical intervention.

The Benchmark Counterpulsation Outcomes Registry currently includes 260 sites worldwide (186 in the United States and 74 elsewhere; Table 1) and has prospectively collected 27,132 records from 25,136 patients between January 1997 and February 2002. Any patient at a participating hospital who received IABP was entered into the database. If a patient had >1 IABP procedure, then only the record of the last procedure was used in the analysis. Concomitant medical treatment and procedures were decided upon by the clinicians in charge of the patients and were not influenced by inclusion in the database.

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TABLE 1 Patient Enrollment

Countries	No. of Patients
United States	21,181 (84.7%)
Europe	2,675 (10.6%)
Canada	755 (3.0%)
Australia and New Zealand	318 (1.3%)
South Africa	84 (<0.5%)
Central and South America	20 (<0.5%)

A detailed description of data handling and validation has been previously published.[1,5] An independent steering committee (Appendix) designed and implemented the registry. Database management and statistical analyses were done by an independent agency (Miller Statistical Services, Langhorne, Pennsylvania), and Datascope Corp. (Fairfield, New Jersey) provided funding for the project. For the purpose of this analysis, patients were divided into 3 groups according to the last intervention they underwent during the index hospitalization: (1) surgical intervention, (2) PCI, or (3) medical intervention only.

Descriptive summaries included frequency and percent distributions for the categorical variables, and the sample mean, SD, minimum, median, and maximum for quantitative assessments. Logistic regression methods were used to study the effects of demographics, medical history, preprocedures, and procedure-related factors on the occurrence of in-hospital deaths. Registry data were screened so that only the most recent IABP procedure was analyzed. Because it was rapidly apparent that mortality risk factors differed greatly both qualitatively and quantitatively between the 3 intervention groups (surgical, PCI, and medical), they were individually evaluated rather than considered as a whole. Concordance measures for the regression analyses were used to calculate the probability that a randomly selected patient from the mortality cohort and a randomly selected patient from the survive-to-discharge cohort, would be ordered correctly by their logit scores. Mortality risk as a function of time was estimated by hazard-ratio curves for each of the 3 groups, using both the day of hospital admission and the day of IABP insertion as a starting point.

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TABLE 2 Baseline Clinical and Counterpulsation Procedure Characteristics by Intervention

Variable	Surgery (n = 15,287)	PCI (n = 5,642)	Medical (n = 2,352)	Total (n = 25,136)*
Age (yrs)	65.9 ± 11.3	64.8 ± 12.6	66.2 ± 2.7	65.5 ± 11.9
Women	30.7%	31.5%	32.1%	30.5%
Diabetes mellitus	26.5%	23.1%	26.6%	24.8%
BMI (kg/m^2)	27.8 ± 5.2	27.9 ± 5.6	27.6 ± 5.6	27.8 ± 5.4
Peripheral vascular disease	12.2%	9.0%	11.4%	11.1%
Ejection fraction (%)	39.2 ± 16.1	34.9 ± 14.8	33.3 ± 15.5	37.5 ± 16.0
Prior myocardial infarction	33.1%	27.6%	31.0%	30.5%
Prior coronary bypass	13.7%	15.6%	14.0%	14.0%
Indication				
Cardiogenic shock	13.5%	25.4%	33.6%	19.3%
Wean from cardiopulmonary bypass	25.9%	—	—	16.4%
Support in catherization laboratory	8.1%	52.9%	21.1%	19.3%
Unstable angina pectoris	13.1%	7.9%	13.9%	11.4%
Preoperative support	22.4%	—	—	14.5%
All others	17.0%	13.5%	24.4%	19.2%
IABP duration (d)†	2.4 ± 2.5	1.8 ± 2.1	2.7 ± 2.5	2.3 ± 2.5
8Fr catheter	29.1%	37.2%	36.5%	31.7%
IABP wait ≥5 d	17.2	7.1%	8.8%	14.3%
Length of stay (d)†	16.6 ± 16.6	10.2 ± 10.5	11.3 ± 12.5	14.5 ± 15.5

*Information regarding intervention is missing for 1,869 patients.
†IABP duration truncated at 30 days and length of stay truncated at 150 days.
Values are expressed mean ± SD or percentage.

TABLE 3 In-hospital Mortality, Counterpulsation-attributed Mortality, and Complication Rates by Intervention

	Intervention			
Assessment	Surgical (n = 15,287)	PCI (n = 5,642)	Medical (n = 2,352)	Total Cohort (n = 23,281)
In-hospital mortality	2,942 (19.2%)	1,060 (18.8%)	782 (33.2%)	4,784 (20.5%)
IABP in place	1,601 (10.5%)	585 (10.4%)	426 (18.1%)	2,612 (11.2%)
After weaning from IABP	1,341 (8.7%)	475 (8.4%)	356 (15.1%)	2,172 (9.3%)
IABP-attributed mortality	6 (<0.1%)	3 (<0.1%)	4 (0.2%)	13 (<0.1%)
Complications				
Any IABP complication	1,052 (6.9%)	464 (8.2%)	161 (6.8%)	1,677 (7.2%)
Major IABP complications	454 (3.0%)	145 (2.6%)	60 (2.6%)	659 (2.8%)
Major limb ischemia	166 (1.1%)	23 (0.4%)	12 (0.5%)	201 (0.9%)
Severe access site bleeding	106 (0.7%)	84 (1.5%)	19 (0.8%)	209 (0.9%)
Deep vein thrombosis	9 (<0.1%)	19 (0.3%)	2 (<0.1%)	30 (0.1%)
Other peripheral thrombosis	9 (<0.1%)	3 (<0.1%)	1 (<0.1%)	13 (<0.1%)
IABP leak	202 (1.3%)	41 (0.7%)	31 (1.3%)	274 (1.2%)

Because no follow-up was obtained beyond hospital discharge, analyses were extended through 10 days for the medical and interventional groups and 20 days for the surgical group.

Overall, baseline clinical characteristics were generally similar for the 3 intervention categories. Patients who underwent IABP who only received medical intervention were more likely to be older, women, and to have a lower ejection fraction than patients who underwent surgery or PCI (Table 2). They were also more likely to have cardiogenic shock as their indication for use of IABP. Patients who underwent IABP-related to a surgical intervention were more likely to have peripheral vascular disease and to have previously experienced an acute myocardial infarction. The most frequent indications for IABP use in patients who received surgical intervention were directly associated with surgery—weaning from cardiopulmonary bypass (25.9%), preoperative support, and stabilization (22.4%). Patients who underwent PCI were less likely to have peripheral vascular disease or to have experienced a previous AMI. The most frequent indication for patients treated with PCI interventions was catheterization laboratory support and stabilization (52.9%). Although patients treated with PCI had the shortest duration for IABP placement, patients with medical intervention only had the longest duration. Patients treated with surgical interventions had the longest hospital length of stay.

Overall, in-hospital mortality for all patients was 20.5%, although IABP-attributed mortality was <0.1% (Table 3). Although in-hospital mortality by intervention type was greatest in patients who received medical interventions only (33.2%), it occurred less often in those who underwent PCI (18.8%) and surgery (19.2%). Complication rates were generally

TABLE 4 Predictive Scores for In-hospital Mortality for Patients With Counterpulsation by Intervention Type			
Predictor Variable	Surgery	PCI	Medical
Cardiogenic shock	2.8 (2.5–3.1)	2.7 (2.3–3.1)	2.6 (2.2–3.1)
Previous coronary bypass surgery	1.8 (1.8–1.6)	0.8 (0.6–1.0)	1.0 (0.7–1.3)
IABP ≥5 d after admission	1.6 (1.4–1.7)	1.3 (1.0–1.8)	1.7 (1.2–2.3)
Wean from bypass	1.6 (1.5–1.8)	–	–
Age >75 yrs	1.5 (1.4–1.7)	2.2 (1.8–2.6)	2.0 (1.6–2.6)
Peripheral vascular disease	1.5 (1.3–1.7)	1.4 (1.1–1.8)	1.3 (0.9–1.8)
Non-US institution	1.2 (1.0–1.3)	1.6 (1.3–2.1)	1.9 (1.4–2.6)
Left ventricular ejection Fraction <30%	1.2 (1.0–1.3)	1.5 (1.2–1.9)	1.6 (1.2–2.2)
3-vessel disease	0.7 (0.6–0.8)	1.6 (1.4–1.9)	1.1 (0.9–1.4)
Preoperative IABP	0.5 (0.5–0.6)	–	–
Unstable angina pectoris	0.4 (0.4–0.5)	0.5 (0.3–0.6)	0.5 (0.4–0.6)

Values are expressed as odds ratios (95% confidence intervals).
The model had a concordance of 74.9%, 78.6%, and 74.3%, respectively, for the 3 treatment categories.

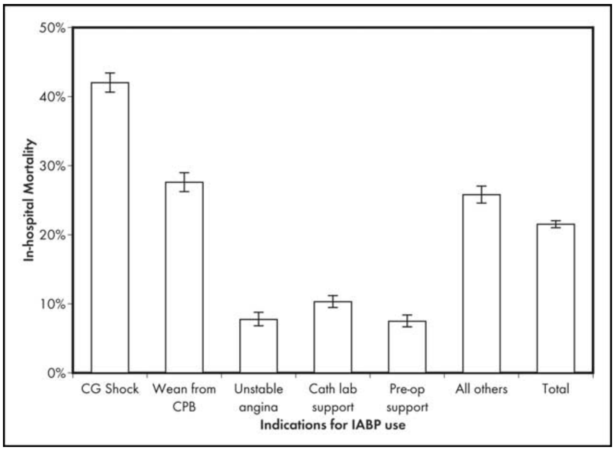

FIGURE 1. In-hospital mortality by indications for IABP use. Cath = catheterization; CG = cardiogenic shock; CPB = cardiopulmonary bypass; lab = laboratory; Pre-op = preoperative.

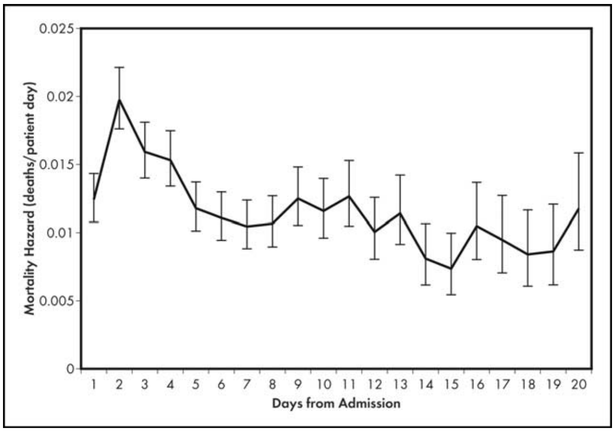

FIGURE 2. Daily in-hospital mortality hazard rates 20 days after admission for surgical interventions (2,942 deaths/15,287 patients). *Error bars*, 95% confidence intervals.

low and did not vary greatly by type of intervention (Table 3).

The odds ratios and predictive scores generated by logistic regression revealed that certain risk factors, including several baseline clinical characteristics as well as IABP timing relative to hospital admission and surgical intervention, were significant predictors of mortality (Table 4). Although some of these predictors were common to all 3 intervention types, for others there were major differences according to the intervention patients received. Cardiogenic shock and IABP insertion ≥5 days after admission had high predictive scores for in-hospital mortality for all 3 intervention types. Previous coronary artery bypass graft surgery had a high predictive score only for patients with surgical interventions, and the presence of 3-vessel disease had a high predictive score only for patients with PCI interventions. Concordance measures were relatively high for each of the intervention types (>74%).

Patients whose indication to treat with IABP was cardiogenic shock had the greatest in-hospital mortality (42.0%). The indications with the lowest in-hospital mortality rates included patients with unstable angina and preoperative support and stabilization (Figure 1). The timing of in-hospital mortality by intervention type for the first 20 days after admission and for the first 20 days after IABP insertion is shown in Figures 2 to 7. Mortality rates for the 3 intervention types were greatest early during hospital stay and decreased throughout its duration.

Although complications associated with IABP use have greatly decreased,[1,6–8] overall in-hospital mortality in this nonhomogeneous patient population remains high. Very few deaths (<0.1%) were attributed to direct or indirect complications of IABP itself, and most deaths were related to the primary disease process.

In-hospital mortality rates were greatest for patients whose indication for use was treatment of cardiogenic shock (42.0%) or weaning from cardiopulmonary bypass after surgery (27.6%). Although high mortality rates are not surprising for these already seriously ill patients, they are considerably lower than the mortality rates frequently seen in patients with cardiogenic shock who are not treated with IABP, which range from 55% to >80%.[9–14] When analyzed according to the type of intervention that patients received, patients who received only medical intervention had the greatest mortality. Although this undoubtedly suggests that IABP may be a more effective mode of therapy when it is associated with mechanical revascularization, the higher mortality rate for medical therapy alone may also in part reflect a selection bias, because some of the sicker patients may have been considered too ill to benefit from revascularization, and others may have died before they could receive surgical or PCI interventions.

The timing of death, revealed by examining daily mortality hazard rates both from admission and from

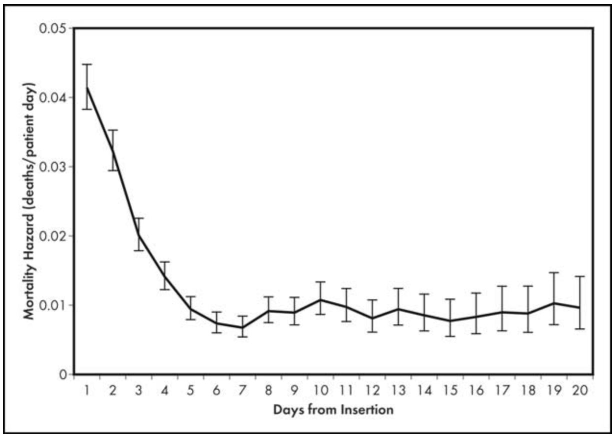

FIGURE 3. Daily in-hospital mortality hazard rates for the first 20 days after IABP insertion for surgical interventions (2,942 deaths/15,287 patients). *Error bars*, 95% confidence intervals.

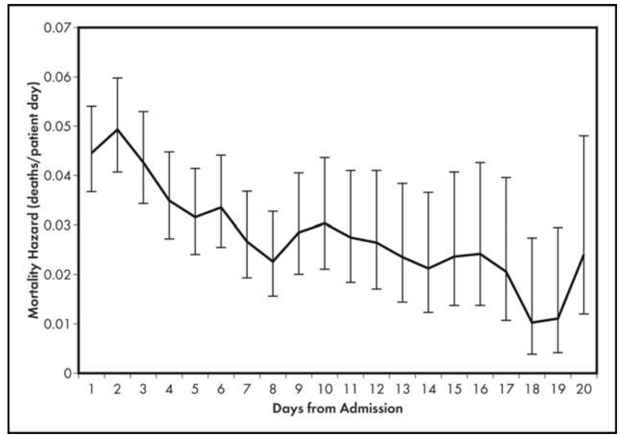

FIGURE 6. Daily in-hospital mortality hazard rates from the first 20 days after admission for medical interventions (782 deaths/2,352 patients). *Error bars*, 95% confidence intervals.

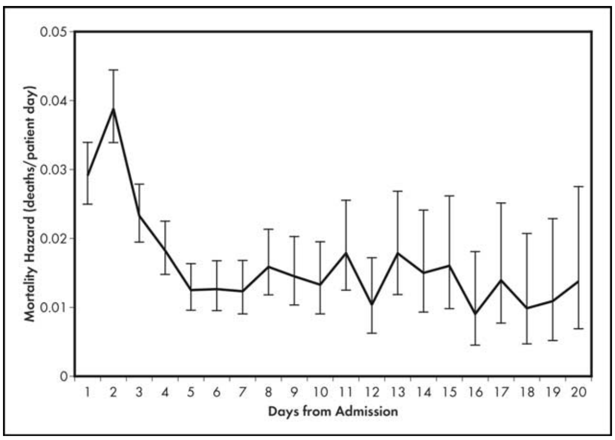

FIGURE 4. Daily in-hospital mortality hazard rates for the first 20 days after admission for PCIs (1,060 deaths/5,642 patients). *Error bars*, 95% confidence intervals.

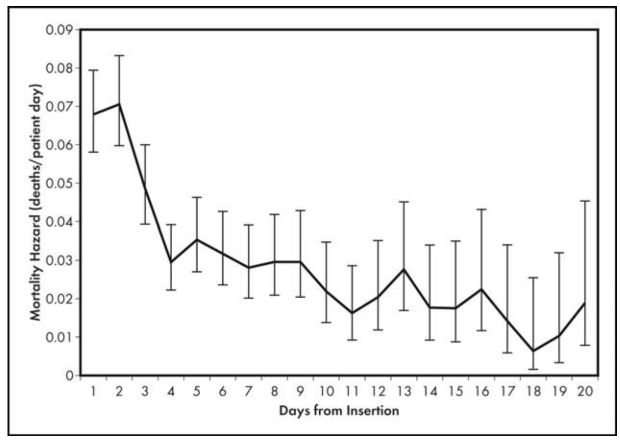

FIGURE 7. Daily in-hospital mortality hazard rates for the first 20 days after IABP insertion for medical interventions (782 deaths/2,352 patients). *Error bars*, 95% confidence intervals.

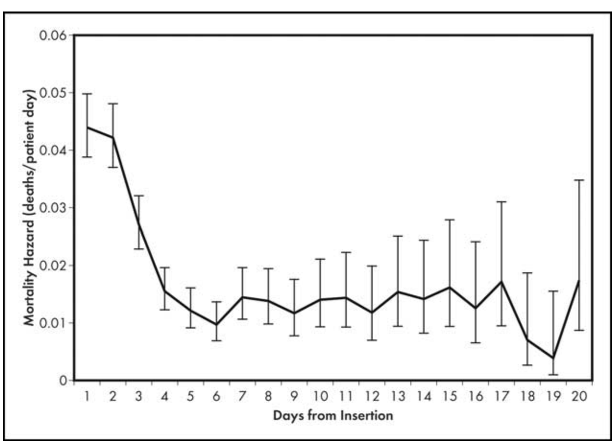

FIGURE 5. Daily in-hospital mortality hazard rates for the first 20 days after IABP insertion for PCIs (1,060 deaths/5,642 patients). *Error bars*, 95% confidence intervals.

IABP insertion, indicates that the major risk of mortality occurred early during the hospital stay for all 3 intervention types. This is a critically important element, because previous studies have shown that patients with cardiogenic shock, which was the major indication for use associated with mortality in the present series, received a significant benefit from emergency revascularization at both 6-month[15,16] and 1-year follow-up.[17] In addition, other studies[18,19] have shown that early preoperative use of IABP therapy appears to be of particular benefit for patients undergoing high-risk coronary bypass surgery and is superior to later selective IABP for patients with poor hemodynamics after cardiopulmonary bypass. The obvious conclusion that can be derived from these data are that very early diagnostic evaluation and decision making need to take place for patients whose cardiovascular status warrants IABP therapy if a significant impact on prognosis is to be attained.

APPENDIX

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