PROPHYLACTIC VALUE OF PREINCISION INTRA-AORTIC BALLOON PUMP: ANALYSIS OF A STATEWIDE EXPERIENCE

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Objective: The objective of this study was to determine whether preincision use of an intra-aortic balloon pump improves survival and shortens postoperative length of stay in hemodynamically stable, high-risk patients undergoing coronary artery bypass grafting.

Methods: A post hoc analysis of the Alabama CABG Cooperative Project database was performed by using propensity scores to model the likelihood of receiving a prophylactic preincision intra-aortic balloon pump. Every patient receiving a prophylactic preincision balloon pump was matched with another patient of similar propensity score who did not receive one. We then compared outcomes for matched pairs.

Results: There were 7581 patients of whom 592 received a prophylactic preincision balloon pump. Patients with preoperative renal insufficiency, heart failure, or left main coronary artery disease, or who had undergone previous bypass grafting were significantly more likely to receive a prophylactic preincision balloon pump. By using propensity scores, we matched 550 patients who received a prophylactic preincision balloon pump with 550 who did not. Survival did not significantly differ by whether a prophylactic preincision balloon pump was used. However, surviving patients who received a preincision balloon pump had a significantly shorter postbypass length of stay (7 ± 7.3 days) than did matched patients not receiving a balloon pump (8 ± 6.2 days; $P < .05$).

Conclusions: No survival advantage was found for use of a prophylactic intra-aortic balloon pump in hemodynamically stable, high-risk patients undergoing bypass grafting, as opposed to placing a balloon pump on an “as needed” basis during or after the operation. However, the patients receiving the balloon pump had improved convalescence as shown by significantly shorter length of stay. (J Thorac Cardiovasc Surg 2000;120:1112-9)

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There are retrospective^{1,2} and prospective^{3,4} single center studies that show decreased morbidity and mortality with the use of preincision intra-aortic balloon pumps (IABPs) in high-risk patients undergoing coronary artery bypass grafting (CABG). However, these studies included many patients with ongoing myocardial infarction and preoperative cardiogenic shock, which are generally accepted *therapeutic* rather than *prophylactic* indications for IABPs.

The Alabama CABG Cooperative Project is a statewide process-oriented project involving all hospitals performing CABG in the state.⁵ As part of the project, numerous demographic, procedural, and outcome variables were gathered. Two of these variables were use of an IABP (yes/no) and time of IABP insertion relative to the CABG procedure (preincision/intraoperative/postoperative).

Table I. Characteristics of patients who were hemodynamically stable, had no impending or very recent myocardial damage, and underwent nonemergent CABG: the Alabama CABG Cooperative Project

	All patients	Preincision IABP	No preincision IABP
N	7581	592	6989
Age (mean y) (SD)	71 (7)	71 (8)	71 (8)
Race (% African American)	9.1	8.4	9.2
Sex (% female)*	34.6	25.3	35.3
Postincision IABP (%)*	4.30	0	4.7
Renal insufficiency (%)	6.3	9.3	6.0
Heart failure (%)*	25.9	65.7	22.5
Diabetes (%)	29.9	31.9	29.8
Comorbidity score (SD)	1.83 (0.92)	1.85 (0.93)	1.83 (0.92)
Left main artery stenosis > 70%*	9.6	15.5	9.1
Had previous CABG surgery (%)*	13.5	36.7	11.5

* $P < .01$ for comparisons of those who received preincision IABP versus those who did not.

The present study analyzes data gathered by the Alabama CABG Cooperative Project to determine the effect of prophylactic preincision IABP use in hemodynamically stable, but high-risk patients undergoing CABG by comparing risk-adjusted patient outcomes. Patients with evidence of very recent or impending myocardial damage or with hemodynamic instability were not included in this analysis. Only the demographic variables and descriptors of patient disease that were available before the operation were used to define risk. The hypothesis tested is that prophylactic preincision IABP placement in hemodynamically stable, high-risk patients undergoing CABG favorably influences in-hospital mortality and post-CABG length of hospital stay (LOS).

Methods

The Alabama CABG Cooperative Project is an extension of a statewide Cooperative Cardiovascular Project that began in 1994.⁵ For the initial phase of the Alabama CABG Cooperative project, a sample of Medicare patients who underwent CABG surgery was selected. This sample consisted of all Medicare patients discharged from participating hospitals between July 1, 1995, and June 30, 1996 (initial round of data abstraction) and between January 1, 1998, and June 30, 1998 (second round of data abstraction). Patients with a diagnosis-related group (DRG) of 106 (coronary artery catheterization and CABG surgery during the same admission) or DRG 107 (only CABG surgery during the admission) were included. Patients with DRG 104 (cardiac valve procedure with catheterization), DRG 105 (cardiac valve procedure without catheterization), and DRG 468 (extensive procedure unrelated to principal diagnosis) were excluded.

Initially we had data on 9235 CABG procedures. After deleting missing data on clinical outcome, sex, and race, records for 8972 hospitalizations were left for analysis. In our analysis, placement of an IABP is considered therapeutic rather than prophylactic for patients with impending or very recent myocardial

damage or for patients with hemodynamic instability. We therefore excluded the following patients: (1) those in shock and/or undergoing mechanical ventilation before the operation (N = 377) and (2) those undergoing emergency CABG, those who had undergone percutaneous transluminal coronary angioplasty (PTCA) within the 6 hours preceding CABG, or those who had a documented myocardial infarction no more than 3 days before the operation (N = 1198). There were 184 patients in the groups 1 and 2 described in the previous sentence. Hence, we were left with 7581 patients for our analyses, of whom 592 received a preincision IABP. Patients undergoing intraoperative or postoperative IABP were included in the group not receiving preincision IABP.

Analyses. After performing descriptive statistics on the CABG Project dataset, we engaged in the following steps.

Step 1. Generation of a propensity score to model the likelihood of prophylactic preincision IABP use, based on patient characteristics available to the surgeon preoperatively, and likely to influence the surgeon's decision to place an IABP.

Step 2. Bivariate analyses of associations between patient characteristics, propensity scores, receipt of preincision IABP, and study outcomes: mortality in-hospital and at 30, 60, 180, 360, and 1000 days, as well as postoperative LOS.

Step 3. Development of multivariable models for each of these outcomes (mortality and LOS) as dependent variable, and with receipt of preincision IABP as the main independent variable, and propensity score as well as other clinical factors as covariates.

Step 4. Matching of each patient receiving preincision IABP with another patient of similar propensity score and similar presentation based on other key variables. Outcomes for these matched pairs were compared.

We therefore tested our hypothesis by using 2 approaches. First, in above steps 2 and 3, we examined the association between receipt of preincision IABP and outcome, before and after adjusting for the a priori likelihood that the patient would receive a preincision IABP, based on his/her likelihood to receive one (propensity score), and on other clinical characteristics. Second, in step 4, we directly compared a set of patients who received a prophylactic preincision IABP with

Table II. Propensity score model: Adjusted odds ratios and 95% confidence intervals (CI) for receiving a prophylactic preincision IABP: the Alabama CABG Cooperative Project

Covariate	Adjusted odds ratio	95% CI
Age, y (≥ 75 vs < 75)	1.20	0.98-1.45
Sex (male vs female)*	1.31	1.07-1.61
Renal insufficiency	1.06	0.76-1.46
Heart failure†	6.63	5.50-8.00
Diabetes	1.02	0.84-1.24
Cormorbidity score (per unit increase)*	0.88	0.80-0.98
Left main artery stenosis $> 70\%$ †	1.47	1.13-1.90
Had previous CABG surgery†	4.24	3.48-5.17

C-statistic for model: 0.791.

* $P < .05$.† $P < .005$.

another who did not, even though for each pair their likelihood of receiving a preincision IABP was similar.

Development of the propensity score model. The propensity score method, described by Rosenbaum and Rubin,^{6,7} allows a direct estimation of the likelihood of receipt of the treatment under study (in our case, preincision IABP) on the basis of the variables deemed important in making the treatment decision. The propensity score can then be used to adjust globally for the characteristics that were deemed influential in the decision to treat or not to treat and becomes a powerful tool for adjusting for treatment selection bias (confounding by indication) in observational studies such as ours. In this study, the propensity score is the probability of IABP insertion predicted by a multiple logistic regression (MLR) model where actual preincision IABP receipt is the dependent variable and the variables mentioned next are the independent variables.

Currently, cardiac surgeons place or do not place a preincision IABP according to their subjective assessment of its potential benefits. We queried 2 cardiac surgeons who reached consensus on which of the variables collected by the Alabama CABG Cooperative Project were influential in the decision to insert a preincision IABP. Those variables chosen include patient age, sex, comorbidity (index adapted from Charlson), history of diabetes mellitus, history of prior CABG, renal insufficiency at presentation (creatinine greater than 2.0 mg/dL or blood urea nitrogen of 35 mg/dL or greater, or on dialysis), congestive heart failure at presentation (ejection fraction of 0.30 or less by imaging procedure, clinical presentation consistent with heart failure, or history of cardiac decompensation within 2 weeks before the operation), or left main coronary artery stenosis of 70% or greater. These were the variables used to develop our propensity score. Other patient characteristics were deemed indications for a preincision IABP, but as treatment rather than prophylaxis. Hence, these variables were used as exclusion criteria and not in the propensity score or elsewhere in our analyses. These variables included the following: hemodynamic insta-

Table III. Characteristics of 550 matched pairs of patients managed with and without preincision IABP: the Alabama CABG Cooperative Project

Variable	IABP (n = 550)	No IABP (n = 550)
Propensity for IABP	0.172	0.172
IABP at any time (%)*	550 (100%)	52 (9.5%)
Model estimate, probability of 1-year survival (using propensity score)	0.896	0.892
Mean age (y) (SD)	71 (7.9)	70 (8.2)
Mean index of comorbidity (SD)	1.84 (0.81)	1.84 (0.81)
Mean postoperative LOS (d) (SD)*	7 (7.3)	8 (6.2)
African American ethnicity (N) (%)	50 (9.1)	60 (10.9)
Female sex (N) (%)	139 (25.3)	139 (25.3)
Renal insufficiency (N) (%)	43 (7.8)	43 (7.8)
Heart failure (N) (%)	354 (64.4)	354 (64.4)
Diabetes (N) (%)	177 (32.2)	177 (32.2)
Left main artery stenosis $> 70\%$ (N) (%)	68 (12.4)	68 (12.4)
Had previous CABG surgery (N) (%)	187 (34)	187 (34)

IABP at any time, IABP used at any time relative to surgery (NB: All "IABP" patients had prophylactic preincision IABP. Some "No IABP" patients had an intraoperative or postoperative IABP); postoperative LOS, post-CABG hospital LOS.

* $P < .05$.

bility (shock as determined by blood pressure after arrival at hospital and before incision), initiation of mechanical ventilation before entering the operating room, PTCA performed at most 6 hours before CABG, and very recent myocardial infarction (at most 3 days before CABG).

We developed our propensity score model in several iterative steps in which we categorized our variables in a way to optimize the fit of the model to the data. Because we were focusing on optimal prediction, we left every initial variable in the final model, regardless of the level of statistical significance of its coefficient. We tested whether the propensity score would adjust completely for all the covariates it incorporates by checking for differences in individual covariates for patients with and without an IABP after stratifying for quintiles of propensity score. Because several variables showed statistically significant differences in some of the quintiles of propensity scores, we also used them as covariates in the subsequent MLR modeling outcomes. In addition, we made similarity of those variables a matching condition when we created matched pairs of patients receiving and not receiving a prophylactic preincision IABP.

Case-matching procedure. Each patient who received a preincision IABP was matched with another patient who did not receive a preincision IABP but with a similar propensity score (the difference in propensity score for members of the same pair had to be < 0.03). We also matched the pairs on those covariates where the analysis by quintile of propensity score had suggested that there were differences between those who did versus those who did not receive a preincision IABP. Thus, we ensured that the members of each matched pair were similar in terms of those characteristics deemed influential in the decision regarding a prophylactic preincision IABP.

Fig 1. Adjusted survival of patients receiving prophylactic preincision IABP compared with all patients who did not receive one.

Table IV. Survival of 550 matched pairs, by whether prophylactic preincision IABP was inserted: the Alabama CABG Cooperative Project

Survival time	IABP		No IABP	
	No.	%	No.	%
In-hospital	520	94.5	522	94.9
30 days	515	93.6	519	94.4
60 days	510	92.7	511	92.9
180 days	498	90.5	498	90.5
365 days	487	88.5	484	88.0
1000 days	459	83.5	439	79.8

Mortality modeling. For each patient, we had vital status as of June 22, 1999, ascertained from Medicare denominator files. Therefore, we were able to determine in-hospital mortality for all patients, as well as 30-, 60-, 180-, 360- and 1000-day mortality for most. In fact, we had length of survival, with censoring at 374 days for all. Therefore, we were able to perform MLR modeling to predict mortality by using for dichotomous outcomes death in-hospital, or death at 30, 60, 180, 360, and 1000 days. We did this by using the propensity score and other clinical characteristics as predictor variables.

We performed Cox proportional hazards analyses with death as the outcome variable and censoring as of June 22, 1999 (hence variable follow-up time for each patient). For all these models, actual receipt of preincision IABP was the main independent variable, whereas propensity score and other clinical variables were covariates. These covariates included the variables for which quintile of propensity score analysis had shown that the propensity score might not fully adjust, as well as variables to adjust for hospital character-

istics, such as bed size (dichotomized at 400 beds). We developed a statistical model that predicted a patient's expected risk for operative mortality according to preoperative clinical factors. Potential clinical risk factors were chosen on the basis of a number of previously published CABG risk models.⁸⁻¹⁰ The details of this risk adjustment model have been published.⁵ For this study, we also built models with the study outcomes as dependent variables, receipt of preincision IABP as main independent variable, and the previously derived risk-adjusted mortality as a covariate. The coefficients for preincision IABP were similar to those obtained when we used propensity scores, so we do not present these other models.

Results

Of all 8972 CABG patients without missing data, 15.3% received an IABP either before or after incision. Of the 7581 study patients who were potential candi-

Table V. Proportional hazards model for 7581 patients: adjusted hazard ratios and 95% confidence intervals (CI) for death over entire follow-up period*

Variable	Adjusted hazard of death ratio	95% CI
Clinical		
Received prophylactic preincision IABP	0.90	0.72-1.13
Heart failure	2.01 [†]	1.55-2.61
Previous CABG	1.63 [†]	1.22-2.19
Renal insufficiency	2.47 [†]	2.09-2.93
Diabetes	1.15 [‡]	1.01-1.31
Comorbidity (1 unit)	1.40 [†]	1.32-1.49
Demographic		
Age older than 75 y	1.67 [†]	1.47-1.89
Hospital		
Bed size > 400	0.81 [†]	0.71-0.91

*Model also adjusted for propensity score, race, sex, and hospital teaching status, but these coefficients were not statistically significant.

[†] $P < .01$.

[‡] $P < .05$.

dates for a prophylactic preincision IABP, 7.8% received one. Men, patients with preoperative renal insufficiency, heart failure, or significant left main stenosis, or those who had previous CABG surgery were significantly more likely to receive prophylactic preincision IABP (Table I).

When we developed our propensity score model, heart failure, comorbidity score, left main stenosis, and previous CABG remained independent predictors of receiving a preincision IABP (Table II). The propensity score model had high discrimination, as measured by a C-statistic of 0.79. The predicted probability of receiving a preincision IABP, using this model, was on average 18.5% for those 592 patients who received one and 6.9% for those 6898 who did not. The mean predicted 1-year survival computed by using propensity scores and other initial presentation variables but no actual receipt of IABP was 89% for those who received a preincision IABP and 92% for those who did not ($P < .005$).

We were able to successfully match 550 pairs of patients. For each pair, one member received a prophylactic preincision IABP and the other did not, but their propensity scores were within 3% of one another (Table III). Mean predicted 1-year survival (computed by using propensity scores and other clinical initial presentation variables but no actual receipt of IABP) was not statistically significantly different depending on whether pair members had received an IABP, confirming that we had patients with similar risk of death in the 2 groups. Unadjusted in-hospital, 30-, 60-, 180-day and 1-year survival for the matched pair members did not differ, at a statistically significant level, by whether a preincision IABP was received (Table IV). However,

an intermediate-term survival benefit from IABP was suggested (Fig 1).

Of note, patients who received a preincision IABP had a significantly shorter post-CABG LOS. This may reflect fewer adverse events during the operation for patients with a prophylactic preincision IABP and a more rapid convalescence. For the matched pairs, and excluding in-hospital deaths, those with prophylactic preincision IABP had a mean post-CABG LOS of 7 days, compared with 8 for those without preincision IABP ($P < .05$). An alternative hypothesis is that survivor bias resulted in a shorter LOS for the IABP group. However, when the analysis was repeated to include the patients who died, the LOS difference remained significant and in favor of preincision IABPs (9 ± 7.8 days versus 11 ± 7.3 days; $P < .005$).

When we compared unadjusted survivals in the entire population, as opposed to just the matched pairs, patients who had received preincision IABPs had consistently lower survivals than those who had not. When we refined these comparisons by multivariable adjustment via Cox proportional hazards modeling on the entire population, whether preincision IABP had been received was no longer significantly associated with survival (Table V). In fact, the hazard ratio for IABP was less than 1 (0.90), which would suggest some beneficial effect for IABP, except that the 0.90 hazard ratio had a 95% confidence interval of 0.72 to 1.13, which overlaps 1. Hence, no inference of a beneficial effect should be made.

Discussion

Patients who received a preincision IABP and are included in this study did not have evidence of very

recent or impending myocardial damage or of hemodynamic instability. Nevertheless, they were identified before CABG as candidates for a prophylactic IABP, reflecting the surgeons' assessment that these patients had a high risk for cardiac death or a postoperative morbid event.

To measure the benefit of prophylactic preincision IABPs, we developed propensity scores for individual patients. By using this propensity score and also adjusting for additional risk factors for post-CABG death, our study failed to convincingly demonstrate a lower adjusted mortality for patients who received a prophylactic preincision IABP, as compared with risk-matched patients who did not receive a preincision IABP. Thus, there did not appear to be any survival advantage in placing an IABP before the operation in these high-risk patients, as opposed to placing an IABP on an "as needed" basis during or after the operation. We did, however, find that prophylactic IABP use was associated with a significantly shorter postoperative LOS, indicating that these patients had an improved convalescence. Furthermore, the trend in survival that is evident at 1 to 3 years after the operation (Fig 1) may become a significant survival benefit for prophylactic IABPs as the duration of follow-up increases.

The avoidance of morbid events by prophylactic use of an IABP, rather than by placing an IABP after acute myocardial ischemia has already occurred, represents an important change in the care of patients undergoing CABG. It is, however, one that should not be taken lightly, because the prediction of morbid events or death in individual patients is still somewhat imprecise. In other words, the benefit of prophylactic IABP use in hemodynamically stable patients is achieved at the cost of placing IABPs in some patients who would have tolerated CABG without IABP support.

Our findings in this study agree with Christenson's observation that a preincision IABP improves the high-risk patient's postoperative course,^{3,4} even though we could not show a survival benefit. Our survival data are also different from the retrospective single center experiences of Dietl and colleagues¹ and Gutfinger and coworkers.² The apparent inconsistencies highlight the difficulty in addressing this complex issue and warrant a closer look at the other studies¹⁻⁴ that demonstrated lower mortality with preincision IABP use.

The prospective randomized trials published by Christenson and colleagues^{3,4} are the most compelling evidence in support of preincision IABP use for high-risk patients. However, 50% to 60% of the patients in each of Christenson's studies had unstable angina or ongoing infarction, which is an important difference

from our study that excluded these patients from the prophylactic IABP group. It is likely that preincision IABP use favorably affects short-term post-CABG mortality when it is placed before the operation as treatment for severe unstable angina or ongoing infarction. This statement is based on published experience with IABP support,^{2,11} the ability of a prophylactic IABP to ameliorate acute intraoperative ischemia (a cause of perioperative myocardial infarction¹²), and the difficulty in promptly diagnosing new or worsening myocardial ischemia during CABG procedures.¹³⁻¹⁵

The retrospective analysis of Dietl and colleagues¹ examined 30-day mortality for patients with a left ventricular ejection fraction of 0.25 or less who had CABG with or without preoperative insertion of an IABP. Despite a significantly higher prevalence of previous CABG, New York Heart Association class III or IV symptoms, emergency surgery, recent myocardial infarction, and left main stenosis in patients who have had IABP support, there was a significantly lower mortality as compared with non-IABP patients. Of note, the patients in Dietl's series who received a preincision IABP had a significantly higher prevalence of urgent or emergency operation, intravenous nitroglycerin use, recent (0-7 days) myocardial infarction, and unstable angina. The issue of patients who are hemodynamically stable and who do not have the more severe types of unstable angina or myocardial infarction was not addressed. It is this group of patients who pose the greatest challenge for decisions regarding prophylactic use of an IABP and who were the subjects in our analysis.

The article from Gutfinger and associates² is another retrospective study of preoperative IABP use in high-risk patients undergoing CABG. High risk in this study was defined by age of 70 years or older, urgent operation for failed PTCA, emergency CABG reoperation, left main stenosis of 70% or more, left ventricular ejection fraction of 0.40 or less, and angina refractory to medical management. The patients who received an IABP were compared with patients who were 70 years or older but did not receive a preoperative IABP. The preoperative IABP patients had a significantly higher prevalence of acute myocardial infarction and congestive heart failure before the operation. This group also had significantly lower left ventricular ejection fractions and higher Parsonnet scores. The absence of a statistically significant difference in mortality between groups was considered to be evidence for a benefit. The outcomes of hemodynamically stable but high-risk patients were not defined.

Synthesis of the information on preincision IABP use¹⁻⁴ indicates that this practice favorably influences

mortality and morbidity in CABG patients with myocardial ischemia or hemodynamic instability before the operation. A benefit for prophylactic preincision IABPs in high-risk patients requiring CABG who have no signs of hemodynamic instability was demonstrated by our study, but the benefit is less than in patients with preoperative hemodynamic instability. As more precise methods for predicting postoperative morbidity and mortality in CABG patients become available, the benefits of prophylactic preincision IABP use in appropriately selected patients are likely to increase.

A recent analysis of the Massachusetts Health Data Consortium database¹⁶ showed wide variations among participating hospitals in risk-adjusted rates for IABP use at any time before, during, or after the CABG operation. This finding indicates that there is not currently a consensus among practicing surgeons regarding the indications for IABPs. Consensus regarding best practices in cardiac surgery has typically been achieved slowly. However, changes in the CABG operation during the past two decades, including an increase in the prevalence of internal thoracic grafting and uniformity in the dosing schedule for aspirin in CABG patients, show that surgeons reach consensus when there are data proving the benefit of a recommended practice.

Large multihospital studies, like the Alabama CABG Cooperative Project⁵ and others,^{17,18} provide a mechanism to evaluate the processes of care involved in cardiac surgery. Information from cooperative regional studies similar to the Alabama Project, accompanied by additional prospective and retrospective research to address specific questions, will allow surgeons to achieve consensus on optimal processes of care and move from consensus to implementation more rapidly than has previously been possible.

Disclaimer

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