Use and Effectiveness of Intra-Aortic Balloon Pumps Among Patients Undergoing High Risk Percutaneous Coronary Intervention: Insights from the NCDR®

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Abstract

Background—IABPs are frequently used to provide hemodynamic support during high risk percutaneous coronary intervention (PCI), but clinical evidence to support their use is mixed. We examined hospital variation in IABP use among high risk PCI patients, and determined the association of IABP use on mortality in this population.

Methods and Results—We analyzed data submitted to the CathPCI Registry® between January 2005 and December 2007. High risk PCI was defined as having at least one of the following features: unprotected left main artery as the target vessel, cardiogenic shock, severely depressed left ventricular function, or ST segment elevation myocardial infarction. Hospitals were categorized into quartiles by their proportional use of IABP. We examined differences in in-hospital mortality across hospital quartiles using a hierarchical logistic regression model to adjust for differences in patient and hospital characteristics across hospital quartiles of IABP use. IABPs were used in 18,990 (10.5%) of 181,599 high risk PCIs. Proportional use of IABP varied significantly across hospital quartiles: Q1: 0.0%–6.5%; Q2: 6.6% to 9.2%; Q3: 9.3% to 14.1%; and Q4: 14.2% to 40.0%. In multivariable analysis, after adjustment for differences in patient and hospital characteristics, in-hospital mortality was comparable across quartiles of hospital IABP usage (Q1: Ref; Q2: Odds Ratio (OR) 1.11, 95% CI 0.99–1.24; Q3: OR 1.03, 95% CI 0.92–1.15; Q4: OR 1.06, 95% CI 0.94–1.18).

Conclusion—IABP use varied significantly across hospitals for high risk PCI. However, this variation in IABP use was not associated with differences in in-hospital mortality.

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Keywords

Angioplasty; Atherosclerosis; Heart assist device

Introduction

Among patients undergoing percutaneous coronary intervention (PCI), intra-aortic balloon pumps (IABP) are used in a variety of high risk clinical scenarios ranging from patients with cardiogenic shock to those undergoing PCI of high risk lesions (e.g., unprotected left main coronary artery). However, studies of IABP use in PCI patients have yielded conflicting results. Although a number of studies suggested benefits to IABP use in these populations [1–6], other studies- including randomized trials of routine IABP use in patients undergoing primary PCI-have demonstrated no benefit [7–11], and even harm [12, 13]. Citing the lack of high quality evidence, the 2005 American College of Cardiology/American Heart Association PCI guidelines do not make specific recommendations for IABP use, but suggest it be considered for hemodynamic support in select high risk patients based on the clinical judgment of the operator[14].

At present, there are few data on national patterns of IABP use in high risk PCI in contemporary clinical practice. Furthermore, there remains a need to determine the effectiveness of IABP use in this population. In the absence of definitive evidence to guide the use of IABP in high risk PCI, data from observational studies can provide key insights into current practice and effectiveness of IABP use in patients undergoing high risk PCI. Accordingly, we analyzed data from the National Cardiovascular Data Registry (NCDR®) CathPCI Registry® to examine the use and outcomes associated with IABP among patients undergoing high risk PCI.

Methods

Data Source

The CathPCI Registry has been described previously[15]. In brief, the CathPCI Registry is a national, voluntary cardiac catheterization laboratory registry that catalogs the clinical data and outcomes of both cardiac catheterization and PCI at more than 600 hospitals across the United States. The registry includes a standardized set of data elements and definitions, systematic data entry and transmission procedures, and rigorous data quality assurance standards. The complete definitions of all variables were prospectively defined by a committee of the ACC and are available at the ACC Web site (http://www.acc.org/ncdr/cathlab.htm). Data are collected retrospectively or concurrently and represent consecutive patients treated at each institution and submitted to the CathPCI Registry. All data undergoes extensive quality checks and a random sample of CathPCI sites undergo external auditing to further ensure data quality.

Patient Population

To examine patterns of IABP use and to determine its association with outcomes, we identified a cohort of admissions for patients undergoing high risk PCI at a participating hospital between January 1, 2005 and December 31, 2007 (n=192,716). PCI was considered to be high risk if at least one of the following features was present: unprotected left main artery as the target vessel, cardiogenic shock, severely depressed left ventricular function (<30%), or ST segment elevation myocardial infarction [14]. For patients with more than one PCI during a single hospital admission, we excluded data from the additional PCI (n=9,230). In addition, we excluded PCIs in which it could not be determined whether an IABP was inserted (n=5), PCIs performed on patients with severe aortic insufficiency (n=3360), and

PCIs performed at hospitals that averaged fewer than 10 high risk PCIs per year (n=1170). A total of 181,599 high risk patients who underwent PCI at 681 hospitals were available for analysis.

Outcomes

The primary outcome of the study was in-hospital mortality. Secondary outcomes of interest included vascular complications - bleeding (drop in hemoglobin >3g/dl or hematoma >10cm), access artery occlusion (total obstruction of the vessel requiring surgical repair), pseudoaneurysm, dissection, and embolism.

Data Analysis

Using the cohort defined above, we examined the proportion of high risk PCI patients who received an IABP across NCDR hospitals. We compared demographics, cardiac status, comorbid conditions, and cardiac anatomy between patients who did and did not have an IABP inserted during high risk PCI. A Chi-square test was used for categorical variables, and an F-test from ANOVA was used for continuous variables. In order to identify the factors most strongly associated with IABP placement, we developed a logistic regression model with the receipt of an IABP as the dependent variable. Candidate variables were identified on the basis of clinical sensibility and review of the literature, and selected for inclusion in the final model using stepwise selection (entry P 0.15, retention P 0.05). Multicollinearity was evaluated through examination of Pearson Correlation Coefficients. Variables included in the final model included demographics (age, gender, race, and payor), cardiac status (admitting symptoms, cardiogenic shock, presence of heart failure, New York Heart Association class, left ventricular ejection fraction, and results of non-invasive testing), past medical history (prior MI, history of valve surgery, diabetes, renal dysfunction, renal dialysis, peripheral vascular disease, hypertension, tobacco use, chronic lung disease, dyslipidemia, family history of coronary artery disease, and prior PCI or coronary artery bypass grafting), and procedural characteristics (PCI status, door to balloon time). To assess the extent to which variation in the use of IABP was explained by clustering at the site level (ie by differences across hospitals), we developed a hierarchical logistic regression model using the variables identified previously and calculated a hospital-specific median odds ratio (OR)[16, 17]. The median OR represents that odds that identical patient at randomly chosen hospitals would receive an IABP during high risk PCI.

We then assessed the association of IABP use with outcomes. To accomplish this, we categorized hospitals by their proportional use of IABP in high risk PCI and grouped them into corresponding quartiles. We compared sociodemographics, past medical history, and cardiac status, and past medical history of patients treated at hospitals with high and low proportional IABP use. We also compared hospitals characteristics including profit type, number of beds, teaching status, census region, and annual volume of high risk PCI across hospital quartiles. We performed multivariable hierarchical logistic regression with in-hospital mortality as the dependent variable, after accounting for patient characteristics and hospital-level variables significantly associated IABP use identified in the previous model. In order to examine the relative contribution of each class of variables to the model, we repeated the hierarchical logistic regression models in a sequential fashion by incrementally introducing demographics, cardiac status, past medical history, and hospital characteristics into the models.

We further assessed the association of IABP with outcomes within subgroups of high risk PCI. For each subgroup, we performed multivariable hierarchical logistic regression analysis to determine the independent association of IABP use and mortality. Additional sensitivity analyses were performed excluding patients whose PCI was characterized as salvage, and

again excluding patients with peripheral vascular disease in whom IABP insertion may not have been possible. Finally, adjusted analyses were repeated to assess the independent association of differences in IABP with vascular complications including hematoma, access site occlusion, peripheral embolization, dissection, pseudoaneurym, and arteriovenous fistula. All analyses were performed using SAS 9.1 (Cary, NC). The Yale Human Investigation Committee approved the analysis and determined that informed consent was not applicable to the data collected by the registry.

Results

Among 181,599 high risk PCI performed at 681 hospitals, 21,259 (11.7%) had cardiogenic shock, 144,190 (79.4%) presented with STEMI, 3,592 (2.0%) underwent unprotected left main PCI, and 37,394 (20.6%) had an LVEF <30% (Patients could have more than one high risk characteristic). An IABP was used in 44.4% of cardiogenic shock patients, 10.3% of patients presenting with STEMI, 28.1% of patients undergoing PCI of an unprotected left main artery, and 13.9% of patients with LVEF 30%. The volumes of high risk PCI and the use of IABP varied significantly across participating hospitals. The median number of high risk cases was 202 (Range: 30–1337; Interquartile Range (IQR): 102 to 340), and the median number of IABP cases was 19 (Range: 0 to 223; IQR 9 to 36). Overall, IABPs were used in 10.5% of high risk cases, and IABP use increased modestly over the study period from 10.2% in the first quarter of 2005 to 11.5% in fourth quarter of 2007. There was substantial variation in proportional IABP use across hospitals (Figure 1).

Patients who received an IABP were a higher risk population than patients without an IABP (Table 1). Notably, IABP patients were older, more likely to have had renal insufficiency, present with non-STEMI, NYHA Class IV heart failure, or cardiogenic shock. There were statistically significant but clinically modest differences between the treating hospital characteristics of patients who did and did not receive an IABP. In multivariable analysis, the factors that were strongly associated with IABP use included cardiogenic shock, left ventricular ejection fraction, non-STEMI, heart failure on admission, and admission status. The model had a high c-statistic (0.82), but the high Hosmer-Lemeshow chi-square of 181 (p<0.001) suggests poor model calibration. In the hierarchical model, the median OR for the hospital effect was 1.93, suggesting a 93% greater odds of patients with identical covariates receiving an IABP at one randomly selected hospital compared with another (Table 2). As expected, the magnitude of the median OR is lower than certain clinical variables such as cardiogenic shock and LVEF. However, it does suggest that the hospital effect is exerting a significant influence on the decision of whether or not to use an IABP.

Hospitals were grouped by proportional IABP use into quartiles as follows: Q1 (0.0% to 6.5%), Q2 (6.6% to 9.2%), Q3 (9.3% to 14.1%), and Q4 (14.2% to 40.0%). The characteristics of hospitals with a low proportion of IABP use were comparable to those of hospitals with a high proportion of IABP use (Table 3). However, patient characteristics varied significantly across the hospital quartiles such that patients treated at hospitals in Q4 were older, had lower LVEF, and a higher proportion had renal dysfunction, prior congestive heart failure, diabetes, prior coronary artery bypass grafting, and cardiogenic shock compared with patients treated at hospitals in Q1–Q3 (Table 3). Of note, a lower proportion of patients treated at Q4 hospitals presented with STEMI but a higher proportion underwent salvage PCI compared with Q1–Q3 hospitals. Unadjusted mortality in the study cohort was 4.9% and increased in a near linear fashion across hospital quartiles (Q1 4.2%, Q2 4.8%, Q3 5.1%, Q4 5.6%, p <0.001). The multivariable mortality had high c-statistic (0.89) but similar issues with model calibration (Hosmer-Lemeshow chi-square 86.9, p<0.001). After adjustment for differences in patient and hospital characteristics, in-hospital mortality did not vary across hospital quartiles (Table 4). Sequential introduction of

variables into the model suggested that differences in mortality were to a large degree explained by differences in the cardiac status of patients undergoing high risk PCI. Differences in demographics, past medical history, and hospital characteristics had relatively little impact on the point estimates and associated confidence intervals. Similar findings were observed in subgroup analyses such that there was no subgroup in which a higher proportional use of IABP was associated with improved outcomes. Furthermore, findings were unchanged in the sensitivity analyses excluding patients undergoing salvage PCI and peripheral vascular disease.

Unadjusted complication rates differed significantly across hospital quartiles (Table 5). Crude rates of vascular complications were highest at Q4 hospitals (Unadjusted OR: Q1: reference; Q2: OR 1.01 (0.86–1.19); Q3: OR 1.25 (1.07–1.47); Q4 1.22 (1.04–1.43)). However, after multivariable adjustment, the risk of vascular complications were similar across hospital quartiles (Q1: reference; Q2: OR 0.96 (.81–1.23); Q3: OR 1.16 (0.99–1.36); Q4: OR 1.11 (0.94–1.31).

Discussion

In this cohort of high risk PCI patients, IABP use varied significantly across hospitals. However, the observed variation in IABP use was not associated with differences in either inhospital mortality or complication rates across hospitals. The outcomes of patients treated at hospitals using IABP more selectively were comparable to those of patients treated at hospitals that used IABP more frequently. Our findings provide no evidence to support the greater use of IABP at some hospitals and indicate a pressing need to further define the settings where this intervention provides a net benefit.

Data from the Benchmark Registry suggest that a fifth of all IABP insertions occur in the setting of PCI, and that half of those are performed to provide support and stabilization to patients who are not in cardiogenic shock[18]. In the present analysis, IABPs were used in slightly less than 10% of high risk PCI, and hospital use varied such that there was at least a two-fold difference in IABP use between hospital quartiles that used IABP more and less frequently. Similar variation has been demonstrated in rates of IABP use during coronary artery bypass grafting[19]. These findings highlight the fact that much of IABP use is discretionary. The decision to insert an IABP is likely influenced by physician training, clinical experience, and local practice patterns rather than high quality evidence from clinical studies. To date, however, these favorable properties of IABP have not been convincingly linked to improvements in patient outcome.

The evidence that supports IABP for high risk PCI comes from case series [20–22], and retrospective analyses [2, 4–6, 13]. Although these studies demonstrated feasibility and suggested efficacy of routine IABP use, their findings have not been supported by data from randomized trials. In randomized trials that enrolled patients with AMI undergoing primary PCI, routine IABP use was not associated with differences in procedural success or clinical outcomes [8, 9, 11, 12]. Collectively, these studies do not support the routine use of IABP for patients at high risk of adverse outcomes, but leaves open the question of how aggressive we should be in using this technology.

Several factors have likely contributed to the gap between practice and evidence. First, recruiting patients into randomized trials of IABP has proven difficult. For example, two trials examining the effect of IABP patients with cardiogenic shock failed to meet target enrollment [23]. Second, advances in technology, particularly the routine use of coronary stents, have improved procedural success and significantly reduced risks associated with PCI [24]. As procedural risks have declined, identifying patients who are at sufficiently high

risk of hemodynamic compromise that an IABP would be useful becomes increasingly difficult. Third, in the absence of definitive evidence, physicians and institutions have developed individual thresholds for IABP use. Once practitioners have established a routine use of a new technology, the perceived need to formally evaluate its efficacy may diminish.

Our data cannot be used to define the precise threshold at which an IABP would be beneficial. There are patients, notably those who present with or develop cardiogenic shock refractory to volume expansion, who likely benefit from IABP use, and studies suggest that IABPs have been persistently underused in this situation [1, 25]. Instead, the results of this analysis highlight the variations in IABP use that exist across hospitals, and should prompt interventional cardiologists and PCI capable hospitals to critically examine their practice patterns and, perhaps, consider adopting a more selective approach to IABP use in high risk PCI.

There are several important limitations to this analysis. First, this is a retrospective analysis of registry data. As such, we cannot exclude the possibility that unmeasured factors may confound our results. For example, although the NCDR contains more than 120 fields including the presence of cardiogenic shock, it does not directly capture potentially important variables such as baseline heart rate or blood pressure. Second, we did not perform a formal power calculation to determine whether we had enough power to detect significant differences in mortality across hospitals performing high risk PCI. Nevertheless, with a cohort of more than 180,000 high risk PCI and an overall mortality rate of 4.9%, we believe we could detect clinically meaningful differences across hospitals. Third, the observed variation in hospital use of IABP may not be due to difference in practice patterns, but may instead be a marker for differences between hospitals such as the skill of the interventional cardiologist, the quality of both intra and post-procedural care, or case mix. If so, higher rates of IABP use may mask significant differences in patient outcomes that would otherwise be measurable. Finally, our analysis did not address the timing of IABP use in relation to the performance of PCI, and this may be an important mediator of the benefits of discretionary IABP use.

In conclusion, among hospitals that participate in the NCDR, there was significant variation in the rate of IABP during and after high risk PCI. However, we found no evidence that the outcomes of patients treated at hospitals that used IABP more frequently were better than those of patients treated at hospitals that used IABP less frequently. These findings should prompt a reevaluation of the threshold for IABP in this population.

Acknowledgments

References

1. Chen EW, Canto JG, Parsons LS, Peterson ED, Littrell KA, Every NR, Gibson CM, Hochman JS, Ohman EM, Cheeks M, Barron HV. Relation between hospital intra-aortic balloon counterpulsation volume and mortality in acute myocardial infarction complicated by cardiogenic shock. Circulation. 2003; 108:951–957. [PubMed: 12912817]

2. Brodie BR, Stuckey TD, Hansen C, Muncy D. Intra-aortic balloon counterpulsation before primary percutaneous transluminal coronary angioplasty reduces catheterization laboratory events in high-risk patients with acute myocardial infarction. Am J Cardiol. 1999; 84:18–23. [PubMed: 10404845]

3. Ohman EM, George BS, White CJ, Kern MJ, Gurbel PA, Freedman RJ, Lundergan C, Hartmann JR, Talley JD, Frey MJ. Use of aortic counterpulsation to improve sustained coronary artery patency during acute myocardial infarction. Results of a randomized trial. The Randomized IABP Study Group. Circulation. 1994; 90:792–799. [PubMed: 8044950]

4. Briguori C, Sarais C, Pagnotta P, Airoldi F, Liistro F, Sgura F, Spanos V, Carlino M, Montorfano M, Di Mario C, Colombo A. Elective versus provisional intra-aortic balloon pumping in high-risk percutaneous transluminal coronary angioplasty. Am Heart J. 2003; 145:700–707. [PubMed: 12679768]

5. Briguori C, Airoldi F, Chieffo A, Montorfano M, Carlino M, Sangiorgi GM, Morici N, Michev I, Iakovou I, Biondi-Zoccai G, Colombo A. Elective versus provisional intraaortic balloon pumping in unprotected left main stenting. Am Heart J. 2006; 152:565–572. [PubMed: 16923432]

6. Mishra S, Chu WW, Torguson R, Wolfram R, Deible R, Suddath WO, Pichard AD, Satler LF, Kent KM, Waksman R. Role of prophylactic intra-aortic balloon pump in high-risk patients undergoing percutaneous coronary intervention. Am J Cardiol. 2006; 98:608–612. [PubMed: 16923445]

7. Barron HV, Every NR, Parsons LS, Angeja B, Goldberg RJ, Gore JM, Chou TM. The use of intra-aortic balloon counterpulsation in patients with cardiogenic shock complicating acute myocardial infarction: data from the National Registry of Myocardial Infarction 2. Am Heart J. 2001; 141:933–939. [PubMed: 11376306]

8. Stone GW, Marsalese D, Brodie BR, Griffin JJ, Donohue B, Costantini C, Balestrini C, Wharton T, Esente P, Spain M, Moses J, Nobuyoshi M, Ayres M, Jones D, Mason D, Grines L, O'Neill WW, Grines CL. A prospective, randomized evaluation of prophylactic intraaortic balloon counterpulsation in high risk patients with acute myocardial infarction treated with primary angioplasty. Second Primary Angioplasty in Myocardial Infarction (PAMI-II) Trial Investigators. J Am Coll Cardiol. 1997; 29:1459–1467. [PubMed: 9180105]

9. Redwood, S. [Accessed May 6, 2010.] Balloon-pump Assisted Coronary Intervention Study. Sep 25. 2009 tctmd.comAvailable at: http://www.tctmd.com/show.aspx?id=84124

10. Sjauw KD, Engstrom AE, Vis MM, van der Schaaf RJ, Baan J Jr, Koch KT, de Winter RJ, Piek JJ, Tijssen JG, Henriques JP. A systematic review and meta-analysis of intra-aortic balloon pump therapy in ST-elevation myocardial infarction: should we change the guidelines? Eur Heart J. 2009; 30:459–468. [PubMed: 19168529]

11. Patel MR, Smalling RW, Thiele H, Barnhart HX, Zhou Y, Chandra P, Chew D, Cohen M, French J, Perera D, Ohman EM. Intra-aortic Balloon Counterpulsation and Infarct Size in Patients With Acute Anterior Myocardial Infarction Without Shock. JAMA: The Journal of the American Medical Association. 2011; 306:1329–37. [PubMed: 21878431]

12. van 't Hof AW, Liem AL, de Boer MJ, Hoorntje JC, Suryapranata H, Zijlstra F. A randomized comparison of intra-aortic balloon pumping after primary coronary angioplasty in high risk patients with acute myocardial infarction. Eur Heart J. 1999; 20:659–665. [PubMed: 10208786]

13. O'Murchu B, Foreman RD, Shaw RE, Brown DL, Peterson KL, Buchbinder M. Role of intraaortic balloon pump counterpulsation in high risk coronary rotational atherectomy. J Am Coll Cardiol. 1995; 26:1270–1275. [PubMed: 7594042]

14. Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB 3rd, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO, Antman EM, Adams CD, Anderson JL, Faxon DP, Fuster V, Halperin JL, Hiratzka LF, Hunt SA, Nishimura R, Ornato JP, Page RL, Riegel B. ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention--summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001

Guidelines for Percutaneous Coronary Intervention). Circulation. 2006; 113:156–175. [PubMed: 16391169]

15. Brindis RG, Fitzgerald S, Anderson HV, Shaw RE, Weintraub WS, Williams JF. The American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR): building a national clinical data repository. J Am Coll Cardiol. 2001; 37:2240–2245. [PubMed: 11419906]

16. Larsen K, Merlo J. Appropriate Assessment of Neighborhood Effects on Individual Health: Integrating Random and Fixed Effects in Multilevel Logistic Regression. American Journal of Epidemiology. 2005; 161:81–88. [PubMed: 15615918]

17. Larsen K, Petersen JH, Budtz-Jørgensen E, Endahl L. Interpreting Parameters in the Logistic Regression Model with Random Effects. Biometrics. 2000; 56:909–914. [PubMed: 10985236]

18. Ferguson JJ 3rd, Cohen M, Freedman RJ Jr, Stone GW, Miller MF, Joseph DL, Ohman EM. The current practice of intra-aortic balloon counterpulsation: results from the Benchmark Registry. J Am Coll Cardiol. 2001; 38:1456–1462. [PubMed: 11691523]

19. Ghali WA, Ash AS, Hall RE, Moskowitz MA. Variation in hospital rates of intraaortic balloon pump use in coronary artery bypass operations. Ann Thorac Surg. 1999; 67:441–445. [PubMed: 10197667]

20. Kreidieh I, Davies DW, Lim R, Nathan AW, Dymond DS, Banim SO. High-risk coronary angioplasty with elective intra-aortic balloon pump support. Int J Cardiol. 1992; 35:147–152. [PubMed: 1572734]

21. Kahn JK, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Hartzler GO. Supported "high risk" coronary angioplasty using intraaortic balloon pump counterpulsation. J Am Coll Cardiol. 1990; 15:1151–1155. [PubMed: 2312972]

22. Voudris V, Marco J, Morice MC, Fajadet J, Royer T. "High-risk" percutaneous transluminal coronary angioplasty with preventive intra-aortic balloon counterpulsation. Cathet Cardiovasc Diagn. 1990; 19:160–164. [PubMed: 2317854]

23. Ohman EM, Hochman JS. Aortic counterpulsation in acute myocardial infarction: physiologically important but does the patient benefit? Am Heart J. 2001; 141:889–892. [PubMed: 11376300]

24. Williams DO, Holubkov R, Yeh W, Bourassa MG, Al-Bassam M, Block PC, Coady P, Cohen H, Cowley M, Dorros G, Faxon D, Holmes DR, Jacobs A, Kelsey SF, King SB 3rd, Myler R, Slater J, Stanek V, Vlachos HA, Detre KM. Percutaneous coronary intervention in the current era compared with 1985–1986: the National Heart, Lung, and Blood Institute Registries. Circulation. 2000; 102:2945–2951. [PubMed: 11113044]

25. Menon P, Totaro P, Youhana A, Argano V. Reduced vascular complication after IABP insertion using smaller sized catheter and sheathless technique. Eur J Cardiothorac Surg. 2002; 22:491–492. author reply 492–493. [PubMed: 12204764]
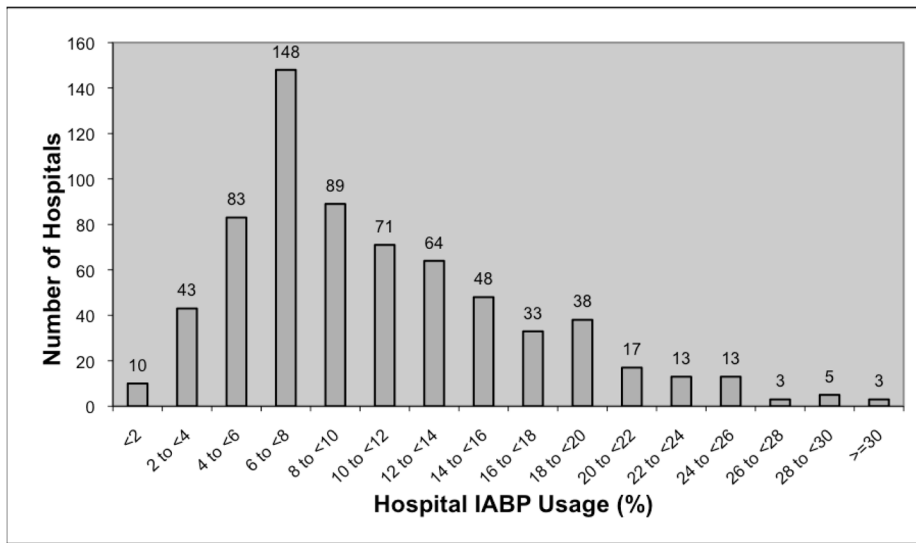
Figure 1.
Hospital IABP Usage

Table 1

Select Baseline Characteristics of High Risk PCI Patients with and without an IABP

		Use of IABP		
	Total (n=181599)	No (n=162609)	Yes (n=18990)	Overall P
Demographics				
Admission Status (%)				<0.001
Outpatient Referral	18549 (10.2)	17628 (10.8)	921 (4.8)	
Emergency Department	96382 (53.0)	85474 (52.6)	10854 (57.2)	
Transfer from Acute Care Facility	62602 (34.5)	55887 (34.4)	6715 (35.4)	
Transfer from Non-Acute Care Facility	2099 (1.2)	1885 (1.2)	214 (1.1)	
Other	2021 (1.1)	1735 (1.1)	286 (1.5)	
Age: Mean (SD)	61.9 (13.1)	61.7 (13.1)	63.7 (13.0)	<0.001
Female (%)	52491 (28.9)	46723 (28.7)	5768 (30.4)	<0.001
Race (%)				<0.001
White	153097 (84.3)	137197 (84.4)	15900 (83.7)	
Black	11643 (6.4)	10600 (6.5)	1043 (5.5)	
Other	16859 (9.3)	14812 (9.1)	2047 (10.8)	
Insurance Payor (%)				<0.001
Government	82549 (45.5)	73119 (45.0)	9430 (49.7)	
Commercial	56831 (31.3)	51469 (31.7)	5362 (28.2)	
HMO	22283 (12.3)	20038 (12.3)	2245 (11.8)	
Other	19936 (11.0)	17983 (11.1)	1953 (10.3)	
Cardiac Status				
Admission Sx Presentation (%)				<0.001
No Angina	6804 (3.7)	6356 (3.9)	448 (2.4)	
Atypical Chest Pain	2225 (1.2)	2124 (1.3)	101 (0.5)	
Stable Angina	4249 (2.3)	4118 (2.5)	131 (0.7)	
ACS: Unstable Angina	11874 (6.5)	11047 (6.8)	827 (4.4)	
ACS: Non-ST Elevation MI	12257 (6.7)	9670 (5.9)	2587 (13.6)	
ACS: ST Elevation MI	144190 (79.4)	129924 (79.5)	14896 (78.4)	
Cardiogenic Shock (%)	21259 (11.7)	11818 (7.3)	9441 (49.7)	<0.001

	Total (n=181599)	No (n=162609)	Yes (n=18990)	Overall P
Use of IABP				
Door to Balloon time (minutes): Mean (SD)	107.6 (246.1)	108.5 (253.6)	101.2 (176.6)	0.002
CHF – Current Status (%)	28794 (15.9)	22774 (14.0)	6020 (31.7)	<0.001
PCI Status				<0.001
Elective	20189 (11.1)	19496 (12.0)	693 (3.6)	
Emergency	120102 (66.1)	105325 (64.8)	6409 (77.8)	
Salvage	2452 (1.4)	1274 (0.8)	1178 (6.2)	
Ejection Fraction: Mean (SD)	41.4 (15.2)	42.2 (15.1)	33.9 (14.2)	<0.001
History and Risk Factors				
Previous MI (>7 Days)	42701 (23.5)	38350 (23.6)	4351 (22.9)	0.039
CHF – Previous History	21127 (11.6)	18669 (11.5)	2458 (12.9)	<0.001
Previous Valvular Surgery	1480 (0.8)	1284 (0.8)	196 (1.0)	<0.001
Diabetes	46577 (25.6)	41050 (25.2)	5527 (29.1)	<0.001
Renal Failure – Previous History	9250 (5.1)	7768 (4.8)	1482 (7.8)	<0.001
Renal Failure – Dialysis	2800 (1.5)	2423 (1.5)	377 (2.0)	<0.001
Peripheral Vascular Disease	16241 (8.9)	14545 (8.9)	1696 (8.9)	0.95
Hypertension	116278 (64.0)	104523 (64.3)	11755 (61.9)	<0.001
Current Use of Tobacco	73587 (40.5)	66786 (41.1)	6801 (35.8)	<0.001
Chronic Lung Disease	27052 (14.9)	23930 (14.7)	3122 (16.4)	<0.001
Dyslipidemia	111215 (61.2)	100773 (61.9)	10482 (55.2)	<0.001
Family History of CAD age <55	41704 (23.0)	37865 (23.3)	3839 (20.2)	<0.001
Previous PCI	39785 (21.9)	36101 (22.2)	3684 (19.4)	<0.001
Previous CABG	18812 (10.4)	17274 (10.6)	1538 (8.1)	<0.001
Hospital Characteristics				
Hospital Location				<0.001
Rural	2289 (1.3)	2085 (1.3)	204 (1.1)	
Suburban	163203 (89.9)	146408 (90.0)	16795 (88.4)	
Urban	16107 (8.9)	14116 (8.7)	1991 (10.5)	
Hospital Profit Type				0.237
Government	24276 (13.4)	21705 (13.3)	2571 (13.5)	
Private/Community	47866 (26.4)	42956 (26.4)	4910 (25.9)	

		Use of IABP		
	Total (n=181599)	No (n=162609)	Yes (n=18990)	Overall P
University	109457 (60.3)	97948 (60.2)	11509 (60.6)	
Patient Beds: Mean (SD)	462 (232)	461 (232)	467 (238)	<0.001

ACS- Acute Coronary Syndrome; CAD- Coronary Artery Bypass Grafting; CABG- Coronary Artery Bypass Grafting; CHF- Congestive

Table 2

Patient and Hospital Characteristics Associated with IABP Use (HGLM)

Description	OR (95% CI)	P
Admission Status		
Emergency Department	Reference	
Outpatient Referral	0.83(0.76–0.91)	<0.001
Transfer from Acute Care Facility	1.03 (0.98–1.07)	0.229
Transfer from Non-Acute Care Facility	0.96 (0.81–1.15)	0.676
Other	1.12 (0.96–1.32)	0.155
Age		
<50	Reference	
50 to <60	1.06 (1.00–1.12)	0.057
60 to <70	1.16 (1.09–1.24)	<0.001
70 to <80	1.17 (1.08–1.25)	<0.001
80	0.98 (0.90–1.06)	0.655
Female	0.87 (0.84–0.91)	<0.001
Race		
White	Reference	
Black	0.83 (0.76–0.90)	<0.001
Other	1.11 (1.03–1.18)	0.003
Payor		
Governmental	Reference	
Commercial	1.02 (0.97–1.08)	0.371
HMO	0.96 (0.90–1.02)	0.216
Other	0.93 (0.87–1.00)	0.039
Without STEMI	0.84 (0.78–0.90)	<0.001
Cardiogenic Shock	12.17 (11.66–12.71)	<0.001
Door to Balloon Time		
<90 minutes	0.98 (0.92–1.04)	0.458
90–120 minutes	0.98 (0.91–1.06)	0.599
>120 minutes	Reference	
Missing	0.91 (0.84–0.98)	0.011
CHF – Current Status	1.74 (1.66–1.83)	<0.001
PCI Status		
Elective	Reference	
Urgent	1.96 (1.77–2.17)	<0.001
Emergency	4.91 (4.43–5.44)	<0.001
Salvage	8.85 (6.67–10.21)	<0.001
NYHA Classification		
Class I	0.75 (0.71–0.80)	<0.001
Class II	0.74 (0.68–0.80)	<0.001
Class III	0.79 (0.75–0.83)	<0.001

Description	OR (95% CI)	P
Class IV	Reference	
Left Ventricular Wall Motion		
Abnormal	Reference	
Not Measured	1.10 (1.00–1.21)	0.053
Normal	0.78 (0.72–0.85)	<0.001
Left Ventricular Ejection Fraction		
>50	Reference	
>40 to 50	1.46 (1.35–1.58)	<0.001
>30 to 40	2.64 (2.45–2.86)	<0.001
>20 to 30	5.15 (4.76–5.58)	<0.001
>10 to 20	7.73 (7.06–8.45)	<0.001
1 to 10	12.53 (10.69–14.69)	<0.001
Not measured	2.80 (2.51–3.13)	<0.001
Stress Test		
Not reported	Reference	
Negative	0.81 (0.72–0.90)	<0.001
Equivocal	0.98 (0.82–1.17)	0.787
Positive	0.76 (0.70–0.84)	<0.001
CHF – Previous History	0.85 (0.80–0.91)	<0.001
Previous Valvular Surgery	1.18 (0.98–1.42)	0.086
Diabetes	1.13 (1.09–1.18)	<0.001
Peripheral Vascular Disease	0.80 (0.74–0.85)	<0.001
Hypertension	0.91 (0.88–0.95)	<0.001
Current Use of Tobacco	0.82 (0.79–0.86)	<0.001
Chronic Lung Disease	0.95 (0.90–1.00)	0.051
Dyslipidemia	0.92 (0.88–0.96)	<0.001
Family History of CAD	1.06 (1.01–1.11)	0.022
Previous PCI	0.91 (0.87–0.95)	<0.001
Previous CABG	0.68 (0.63–0.73)	<0.001
Hospital type		
Government	0.74 (0.42–1.28)	0.280
University	0.84 (0.69–1.03)	0.087
Hospital-specific effects (Median OR)	1.93	

Between Hospital Variation 0.47

Within Hospital Variation 1.02

Table 3

Patients and Hospital Characteristics Stratified by Quartiles of Hospital IABP Usage

Demographics	Total 181599	Hospital IABP Usage				Overall P
		Quartile 1 41941	Quartile 2 49962	Quartile 3 50165	Quartile 4 39531	
Admission Status						<0.001
Outpatient Referral	18549 (10.2)	5945 (14.2)	4183 (8.4)	4727 (9.4)	3694 (9.3)	
Emergency Department	96328 (53.0)	21725 (51.8)	26230 (52.5)	25205 (50.2)	23168 (58.6)	
Transfer from Acute Care Facility	62602 (34.5)	13298 (31.7)	18562 (37.2)	18949 (37.8)	11793 (29.8)	
Transfer from Non-Acute Facility	2099 (1.2)	461 (1.1)	560 (1.1)	662 (1.3)	416 (1.1)	
Other	2021 (1.1)	512 (1.2)	427 (0.9)	622 (1.2)	460 (1.2)	
Age: Mean (SD)	61.9 (13.1)	61.7 (13.1)	61.3 (13.0)	62.3 (13.2)	62.4 (13.1)	<0.001
Female (%)	52491 (28.9)	12244 (29.2)	14189 (28.4)	14563 (29.0)	11495 (29.1)	0.031
Race						<0.001
White (%)	153097 (84.3)	36236 (86.4)	42781 (85.6)	40844 (81.4)	33236 (84.1)	
Black (%)	11643 (6.4)	2551 (6.1)	3238 (6.5)	3478 (6.9)	2376 (6.0)	
Other (%)	16859 (9.3)	3154 (7.5)	3943 (7.9)	5843 (11.6)	3919 (9.9)	
Payor						<0.001
Government (%)	82549 (45.5)	19747 (47.1)	22430 (44.9)	22024 (43.9)	18348 (46.4)	
Commercial (%)	56831 (31.3)	13779 (32.9)	15628 (31.3)	15783 (31.5)	11641 (29.4)	
HMO (%)	22283 (12.3)	3798 (9.1)	5972 (12.0)	7179 (14.3)	5334 (13.5)	
Other (%)	19936 (11.0)	4617 (11.0)	5932 (11.9)	5179 (10.3)	4208 (10.6)	
Cardiac Status						
Admission Symptom Presentation						<0.001
No Angina (%)	6804 (37)	1492 (3.6)	1541 (3.1)	2081 (4.2)	1690 (4.3)	
Atypical Chest Pain (%)	2225 (1.2)	469 (1.1)	526 (1.1)	712 (1.4)	518 (1.3)	
Stable Angina (%)	4249 (2.3)	1057 (2.5)	969 (1.9)	1236 (2.5)	987 (2.5)	
ACS: Unstable Angina (%)	11874 (6.5)	3042 (7.3)	2936 (5.9)	3264 (6.5)	2632 (6.7)	
ACS: Non-ST Elevation MI (%)	12257 (6.7)	2641 (6.3)	3024 (6.1)	3516 (7.0)	3076 (7.8)	
ACS: ST Elevation MI (%)	144190 (79.4)	33240 (79.3)	40966 (82.0)	39356 (78.5)	30628 (77.5)	
Cardiogenic Shock (%)	21259 (11.7)	4122 (9.8)	5479 (11.0)	6204 (12.4)	5454 (13.8)	<0.001
Door to Balloon time: Mean (SD)	107.6 (246.1)	109.1 (256.5)	108.7 (253.4)	104.1 (238.6)	109.1 (235.3)	0.038

Demographics	Total 181599	Quartile 1 41941	Quartile 2 49962	Quartile 3 50165	Quartile 4 39531	Overall P
CHF - Current Status (%)	28794 (15.9)	5897 (14.1)	7600 (15.2)	8595 (17.1)	6702 (17.0)	<0.001
PCI Status						<0.001
Elective	20189 (11.1)	4446 (10.6)	5149 (10.3)	5908 (11.8)	4686 (11.9)	
Urgent	38824 (21.4)	9651 (23.0)	10706 (21.4)	10623 (21.2)	7844 (19.8)	
Emergency	120102 (66.1)	27351 (65.2)	33521 (67.1)	32887 (65.6)	26343 (66.6)	
Salvage	2452 (1.4)	485 (1.2)	582 (1.2)	740 (1.5)	645 (1.6)	
NYHA						<0.001
Class I	40485 (22.3)	10592 (25.3)	10137 (20.3)	11320 (22.6)	8436 (21.3)	
Class II	16279 (9.0)	3879 (9.2)	4384 (8.8)	4136 (8.2)	3880 (9.8)	
Class III	36896 (20.3)	8955 (21.4)	10622 (21.3)	9656 (19.2)	7663 (19.4)	
Class IV	87939 (48.4)	18515 (44.1)	24819 (49.7)	25053 (49.9)	19552 (49.5)	
Ejection Fraction: Mean (SD)	41.4 (15.2)	41.3 (15.1)	42.4 (15.0)	41.2 (15.5)	40.6 (15.2)	<0.001
History and Risk Factors						
Previous MI (>7 Days)	42701 (23.5)	10252 (24.4)	11296 (22.6)	11572 (23.1)	9581 (24.2)	<0.001
CHF - Previous History	21127 (11.6)	4779 (11.4)	5128 (10.3)	6211 (12.4)	5009 (12.7)	<0.001
Previous Valvular Surgery	1480 (0.8)	315 (0.8)	306 (0.6)	438 (0.9)	421(1.1)	<0.001
Diabetes	46577 (25.7)	10538 (25.1)	12492 (25.0)	13057 (26.0)	10490 (26.5)	<0.001
Renal Failure - Previous History	9250 (5.1)	1900 (4.5)	2343 (4.7)	2755 (5.5)	2252 (5.7)	<0.001
Renal Failure - Dialysis	2800 (1.5)	573 (1.4)	670 (1.3)	888 (1.8)	669 (1.7)	<0.001
Peripheral Vascular Disease	16241 (8.9)	3713 (8.9)	4353 (8.7)	4537 (9.0)	3638 (9.2)	0.055
Hypertension	116278 (64.0)	26818 (63.9)	31587 (63.2)	32363 (64.5)	25510 (64.5)	<0.001
Current Use of Tobacco	73587 (40.5)	17648 (42.1)	21387 (42.8)	19178 (38.2)	15374 (38.9)	<0.001
Chronic Lung Disease	27052 (14.9)	6058 (14.4)	7619 (15.2)	7349 (14.6)	6026 (15.2)	<0.001
Dyslipidemia	111215 (61.2)	26555 (63.3)	30103 (60.3)	30584 (61.0)	23973 (60.6)	<0.001
Family History of CAD age <55	41704 (23.0)	9645 (23.0)	11577 (23.2)	11132 (22.2)	9350 (23.7)	<0.001
Previous PCI	39785 (21.9)	9471 (22.6)	10703 (21.4)	11000 (21.9)	8611 (21.8)	<0.001
Previous CABG	18812 (10.4)	4415 (10.5)	4837 (9.7)	5278 (10.5)	4282 (10.8)	<0.001
Hospital Characteristics						
Location						<0.001
Rural	2289 (1.3)	838 (2.0)	315 (0.6)	746(1.5)	390 (1.0)	

Demographics	Total 181599	Hospital IABP Usage				Overall P
		Quartile 1 41941	Quartile 2 49962	Quartile 3 50165	Quartile 4 39531	
Suburban	163203 (89.9)	39304 (93.7)	44854 (89.8)	44679 (89.1)	34366 (86.9)	
Urban	16107 (8.9)	1799 (4.3)	4793 (9.6)	4740 (9.4)	4775 (12.1)	
Profit Type						<0.001
Government	24276 (13.4)	5520 (13.2)	7338 (14.7)	5737 (11.4)	5681 (14.4)	
Private/Community	47866 (26.4)	12057 (28.8)	12196 (24.4)	12705 (25.3)	10908 (27.6)	
University	109457 (60.3)	24364 (58.1)	30428 (60.9)	31723 (63.2)	22942 (58.0)	
Patient Beds: Mean (SD)	461.9 (232.2)	429.8 (231.8)	457.0 (184.0)	485.6 (257.2)	472.0 (249.1)	<0.001

Table 4

Hospital IABP Volume and In-Hospital Mortality[*]

		Hospital IABP Usage			
		Quartile 1	Quartile 2	Quartile 3	Quartile 4
Overall	Unadjusted	Ref	1.17 (1.07–1.28)	1.26 (1.16–1.37)	1.36 (1.25–1.49)
	Adjustment: (1)	Ref	1.18 (1.08–1.28)	1.22 (1.12–1.33)	1.32 (1.21–1.44)
	Adjustment: (2)	Ref	1.10 (0.99–1.23)	1.04 (0.93–1.16)	1.07 (0.95–1.20)
	Adjustment: (3)	Ref	1.10 (0.98–1.23)	1.03 (0.92–1.15)	1.06 (0.94–1.19)
	Adjustment: (4)	Ref	1.11 (0.99–1.24)	1.03 (0.92–1.15)	1.06 (0.94–1.18)
Subgroups:					
STEMI	Adjustment: (4)	Ref	1.09 (0.96–1.23)	1.01 (0.90–1.14)	1.02 (0.90–1.15)
LVEF <30%	Adjustment: (4)	Ref	1.29 (1.09–1.54)	1.19 (1.00–1.42)	1.13 (0.94–1.35)
Unprotected Left Main	Adjustment: (4)	Ref	0.83 (0.53–1.32)	0.92 (0.59–1.42)	0.95 (0.60–1.50)
Cardiogenic Shock	Adjustment: (4)	Ref	1.19 (1.03–1.38)	0.99 (0.86–1.14)	1.06 (0.91–1.22)

[*]Hierarchical Logistic Regression Model

1. Demographics
2. Demographics and Cardiac Status
3. Demographics, Cardiac Status, Medical History, PCI Status
4. Demographics, Cardiac Status, Medical History, PCI Status, and Hospital Characteristics

Table 5

Adverse Outcomes and Complications Stratified by Quartiles of Hospital IABP Usage

| | Total 181599 | Hospital IABP Usage | | | | P |
		Quartile 1 41941	Quartile 2 49962	Quartile 3 50165	Quartile 4 39531	
In-hospital death	8944 (4.9)	1746 (4.2)	2414 (4.8)	2577 (5.1)	2207 (5.6)	<0.001
Vascular Complications (%)						
Bleeding	8637 (4.8)	1789 (4.3)	2110 (4.2)	2732 (5.4)	2006 (5.1)	<0.001
Access Site Occlusion	150 (0.1)	26 (0.1)	31 (0.1)	36 (0.1)	57 (0.1)	<0.001
Peripheral Embolization	234 (0.1)	40 (0.1)	61 (0.1)	63 (0.1)	70 (0.2)	0.012
Dissection	577 (0.3)	85 (0.2)	108 (0.2)	268 (0.5)	116 (0.3)	<0.001
Pseudoaneurysm	816 (0.4)	133 (0.3)	216 (0.4)	238 (0.5)	229 (0.6)	<0.001
Vascular-AV Fistula	128 (0.1)	26 (0.1)	31 (0.1)	36 (0.1)	35 (0.1)	0.428

IABP- Intra-aortic Balloon Pump