JACC: CARDIOVASCULAR INTERVENTIONS VOL. 5, NO. 3, 2012

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. DOI: 10.1016/j.jcin.2011.12.012


# Incidence of Overall Bleeding in Patients Treated With Intra-Aortic Balloon Pump During Percutaneous Coronary Intervention

## 12-Year Milan Experience

Giedrius Davidavicius, MD,*† Cosmo Godino, MD,*‡ Joanne Shannon, MD,*‡ Kensuke Takagi, MD,*‡ Letizia Bertoldi,* Marco Mussardo, MD,* Alaide Chieffo, MD,* Francesco Arioli, MD,* Alfonso Ielasi, MD,* Mateo Montorfano, MD,* Azeem Latib, MD,*‡ Antonio Colombo, MD*‡

*Milan, Italy; and Vilnius, Lithuania*

**Objectives** This study aims to report a "real-world" experience of in hospital complications and clinical outcome of a large cohort of consecutive patients who underwent percutaneous coronary intervention (PCI) with intra-aortic balloon pump counterpulsation (IABP) support, from a tertiary care center over a 12-year period.

**Background** The incidence of vascular complications in patients treated with PCI and IABP is expected to be higher due to simultaneous puncture of femoral arteries, larger IABP sheath size, and longer duration of IABP therapy.

**Methods** A total of 360 consecutive patients (mean age of 65.9 ± 11.2 years; 80.6% male) who required an IABP support during percutaneous PCI were classified into 3 groups: Urgent: 133 patients (36.9%) admitted with acute coronary syndrome in whom IABP therapy was started before urgent PCI; Emergent: 56 patients (15.6%) in whom emergent IABP insertion was required to manage hypotension during PCI; and Elective: 171 patients (47.5%) with stable angina pectoris in whom IABP was inserted before elective PCI. Overall bleeding was defined according to the newest the Bleeding Academic Research Consortium (BARC) definition criteria.

**Results** BARC bleeding occurred in 68 patients (19%), with the highest incidence noted in the Urgent group (31.1%), in comparison with the Emergent (26.8%) and Elective (7%) groups, $p < 0.0001$. Bleeding related to the IABP access site was 7.5%, which accounted for 82% of any access site–related bleeding. It was significantly higher in the Urgent group (12.8%) compared with the Elective (4.1%) and Emergent (5.4%) groups. At multivariate analysis, IABP treatment duration and renal impairment were the only independent predictors of BARC bleeding.

**Conclusions** Bleeding related to the IABP access site was significantly higher in the Urgent group and accounted for more than two-thirds of overall access site–related bleeding. IABP treatment duration and renal impairment were independent predictors of overall bleeding. (J Am Coll Cardiol Intv 2012;5:350–7) © 2012 by the American College of Cardiology Foundation

From the *Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy; the †Vilnius University, Hospital "Santariskiu Klinikos" Vilnius, Lithuania; and the ‡Interventional Cardiology Unit, EMO-GVM Centro Cuore, Columbus Hospital, Milan, Italy. The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received June 27, 2011; revised manuscript received November 30, 2011, accepted December 8, 2011.

Since the introduction of the intra-aortic balloon pump (IABP) in 1968 (1) to provide hemodynamic stability for the critically ill patient, a large volume of data has been published. In current practice, IABP support is most often required in the following clinical scenarios: 1) to provide hemodynamic support in patients admitted with cardiogenic shock (2); 2) in case of unexpected hypotension during complex percutaneous coronary intervention (PCI); and 3) electively to prevent hemodynamic deterioration during complex and high-risk PCI.

However, despite recent advances in revascularization therapy, medical therapy, and mechanical support with an IABP, in-hospital mortality rates remain high in patients with cardiogenic shock (3). The incremental increase in bleeding complications was reported to be about 3.9% in patients with acute coronary syndrome, 6.7% if glycoprotein (GP) IIb/IIIa inhibitors were used, and 18.2% when IABP was inserted (4). The incidence of vascular complications in patients treated with PCI and IABP is expected to be higher due to simultaneous puncture of femoral arteries, larger IABP sheath size, and longer duration of IABP therapy (5,6). In addition, IABP therapy during and after PCI requires the concomitant administration of antithrombin and antiplatelet agents, which increases the risk of bleeding in an already high-risk patient population. Recently, it has been reported that prophylactic usage of an IABP before high-risk PCI confers no advantage, and should be reserved only for cases associated with acute hemodynamic deterioration (7). We aim to report a "real-world" experience of in-hospital complications and clinical outcomes of a large cohort of consecutive patients who underwent PCI with IABP, from a tertiary care center over a 12-year period.

## Methods

**Study population.** A retrospective analysis of the consecutive patients' case files of those requiring IABP support during PCI in the last 12 years in the Interventional Cardiology Unit of San Raffaele hospital in Milan was performed. Patients were classified into 3 groups according to the indication for IABP insertion: Urgent group: IABP treatment was started before urgent PCI in patients admitted with acute coronary syndrome; Emergent group: IABP inserted during PCI to manage hemodynamic acute deterioration; Elective group: IABP inserted before elective high-risk PCI in patients with stable angina pectoris (e.g., left main or multivessel disease PCI in patients with low ejection fraction, PCI in a single remaining vessel, and so on). IABP insertion was performed in the catheterization laboratory by an experienced interventional cardiologist. In each case, an 8-F IABP catheter (Datascope Corporation, Fairfield, New Jersey) was placed percutaneously from a femoral artery. When IABP was placed after PCI through the same access site, patients were excluded from the final analysis. Balloon counterpulsation was either initiated before or during PCI. The duration of IABP treatment after PCI was dependent on hemodynamic stability, and removal was at the discretion of the physician.

All patients received anticoagulation therapy during the PCI procedure, and subsequent therapy was determined by the clinical status and physician discretion. Most patients (98.3%) received dual antiplatelet therapy (aspirin 325 mg/day and either the thienopyridine ticlopidine 250 mg twice a day, or clopidogrel 300- or 600-mg loading dose followed by 75 mg/day as maintenance therapy).

**Study endpoints.** The study endpoints were the incidence of in-hospital complications, such as: 1) bleeding and limb ischemia; 2) death from any cause; and 3) a combined endpoint of complications 1 and 2.

**Definitions.** Death from any cause was defined as any in-hospital death during treatment with, or after, removal of the IABP. Cardiogenic shock was defined as a systolic blood pressure lower than 90 mm Hg secondary to cardiac dysfunction with the clinical signs of hypoperfusion (oliguria, cold extremities, altered mental status). Acute coronary syndrome was defined as unstable angina pectoris or acute myocardial infarction (ST-segment elevation myocardial infarction or non–ST-segment elevation myocardial infarction as defined by an elevation in serum creatine kinase of >3 times the upper limit of the normal laboratory value).

**Abbreviations and Acronyms**

BARC = Bleeding Academic Research Consortium
CI = confidence interval
EF = ejection fraction
GP = glycoprotein
IABP = intra-aortic balloon pump
IQR = interquartile range
OR = odds ratio
PCI = percutaneous coronary intervention

Overall bleeding was defined according to the newest Bleeding Academic Research Consortium (BARC) definition criteria (8). Bleeding was then classified as access site or nonaccess site bleeding. Bleeding at the access site was defined by the presence of hemorrhage at the femoral artery puncture site either for IABP or for PCI; nonaccess site bleeding was defined as the presence of a lesion in the gastrointestinal, genitourinary tract (e.g., stomach ulcer, melena, macrohematuria), or where the cause could not be identified. Limb ischemia was defined as thrombosis associated with IABP treatment, requiring removal of the IABP and surgical intervention. The combined endpoint included a composite of death, bleeding, and limb ischemia. All events were recorded from baseline (the day of IABP insertion) until discharge from the hospital.

**Statistical analysis.** Continuous results are reported as mean ± SD or as the median and interquartile range (IQR) (range from 25th to the 75th percentile) where appropriate. Categorical data are presented as counts and percentages. The Kolmogorov-Smirnov test was applied to test whether the