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Intra-aortic balloon pump in intensive cardiac care: A registry in Florence

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The *Intra-aortic Balloon Pump* (IABP) is currently the most commonly used mechanical assist device to improve and support hemodynamics in patients with cardiogenic shock; it is widely used also in high-risk patients undergoing percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) [1–9]. However, the impact of IABP on prognosis is so far controversial [5,10].

We assessed the in-hospital mortality and complications in patients treated with IABP consecutively admitted to our Intensive Cardiac Care Unit (ICCU).

From Jan. 1, 2005 to Dec. 31, 2008, 3500 patients were consecutively admitted to our ICCU [11–13]. Among them, 414 (11.8%) underwent IABP during their hospitalization and were prospectively enrolled in our Registry.

Large ischemic risk area (LIRA) was defined as "ejection fraction less than 40% together with proximal occlusion of left descending anterior coronary artery associated or not with critical lesions in other coronary arteries". In these patients IABP was deployed after PCI.

Patients were defined as "high risk" as if one or more of the following criteria were present: ventricular ejection fraction (LVEF) < 40%, killip class 3, persistent malignant ventricular arrhythmias, acute mitral regurgitation and severe coronary artery disease (left main stem or three vessel or vein graft disease).

Major bleeding. Major bleeding was defined according to Replace 2 [14]:

Continuous data (Kolmogorov–Smirnov test) were expressed as mean ± SD, categorical data as frequencies and percentages. All data were analysed by means of Fisher's exact test or Student's t test, when appropriate. Variables resulted significantly different between subgroups were entered as covariates in a backward stepwise logistic regression analysis. A $p < 0.05$ was considered statistical significant (SPSS 13.0 statistical software; SPSS Inc., Chicago, ILL, USA).

The mean age of patients in the study was 68.5 ± 11.4 years; 69.6% were men. Hypertension was detectable in 51.4% (n = 213), dyslipidemia in 32.1% (n = 133) and diabetes mellitus in 22.0% (n = 91). About one fourth of patients (24.4%) showed prior myocardial infarction and prior PCI in the 20.5%.

Table 1 shows indications for IABP in our series. In the majority of patients (67.1%, n = 278) IABP was the only device, while in the remaining (32.9%) it was associated to other devices. The device most frequently associated with IABP was mechanical ventilation (41.7%; invasive: 24.6%; non-invasive 17.1%). The continuous veno-venous renal replacement therapy was used in 13.5% (n = 56) of patients. Unfractioned heparin was used in 97.8% of patients. The majority of patients received dual antiplatelet therapy; acetylsalicylic acid (90.6%) and clopidogrel (83.8%). Therapy with glycoprotein IIb IIIa inhibitors was administered in 59.7% of cases. Inotropic agents (epinephrine, norepinephrine, dopamine and dobutamine) were used in 40.6% of patients, all with refractory cardiogenic shock.

In our series, complications were 13.8% (57/414 patients) (Table 2). Thirty patients (out of 57, 52.7.%) showed severe bleeding, among which half of patients exhibited unknown bleeding site while bleeding at the insertion site occurred in 12 patients. The incidence of IABP-related complications did not differ between males and females (10.6% @versus 13.9% p = 0.398). Patients who developed IABP-related complications showed a higher median duration of the device (48 h; 25–75th percentile 24–72 h versus 36 h; 25–75th percentile 24–48 h; p = 0.007).

In our population, 82 patients died (82/414:19.8%). Among patients who died, IABP was implanted because of: cardiogenic shock in 59 patients (72%), cardiac arrest in 8 patients (9.8%), periprocedural complications of PCI in 5 patients (6.1%), mechanical complication of acute myocardial infarction in 4 patients (4.9%), large ischemic risk area in 3 patients (3.6%), acute pulmonary edema in 2 patients (2.4%) and bridge to CABG in 1 patient (1.2%).

Among the 47 patients who developed IABP-related complications 22 died; two deaths were due to IABP (intestinal ischemia in 1 patients and

Table 1
IABP indications.

Frequencies (%)		
Diagnosis	IABP indication	
STEMI [latency < 12 h] (n = 251 [60.6%])	Large ischemic risk area	86 (34.3)
	Cardiogenic shock	73 (29.1)
	Hypotension	38 (15.1)
	Sudden death/VF	15 (6.0)
	In the caht lab	4 (26.7)
	Outside the cath lab	11 (73.3)
	PCI failure	14 (5.6)
	Acute pulmonary edema	11 (4.4)
	Mechanical complications	10 (4.0)
	Mitral regurgitation	6
	VSD	4
	Peri-procedural complications	2 (0.8)
	Pre-operative support	2 (0.8)
STEMI [latency > 12 h] (n = 38 [9.2%])	Cardiogenic shock	16 (42.1)
	Large ischemic risk area	7 (18.4)
	Mechanical complications	6 (15.8)
	Mitral regurgitation	1
	VSD	5
	Hypotension	5 (13.2)
	Acute pulmonary edema	3 (7.9)
	Others	1
UA/NSTEMI (n = 109 [26.3%])	Severe coronary artery disease in high-risk patients	28 (25.7)
	Hypotension	20 (18.3)
	Cardiogenic shock	16 (14.7)
	Peri-procedural complications	15 (13.8)
	Acute pulmonary edema	12 (11.0)
	Pre-operative support	10 (9.2)
	Sudden death/VF	8 (7.3)
	In the caht lab	4
	Outside the cath lab	4
CHD with CABG indication (n = 9 [2.2%])	Election procedure	3 (33.3)
	Cardiogenic shock	3 (33.3)
	Refractory angina	2 (22.2)
	Peri-procedural complications	1 (11.1)
Pulmonary embolism (n = 5 [1.2%])	Cardiogenic shock	5 (100.0)
Other (n = 2 [0.5%])		

STEMI: ST elevation myocardial infarction; VF: ventricular fibrillation; PCI: percutaneous coronary intervention; UA: unstable angina; NSTEMI: non ST elevation myocardial infarction; VSD: ventricular septal defect; CHD: coronary heart disease.

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Table 2
IABP complications.

Complications (total)		57/414(13.8%)
Strictly related to IABP	Severe bleeding	30 (52.7%)
	Non specific site (acute anemia)	15 (50.0%)
	Bleeding at the insertion site	12 (40.0%)
	Retro-peritoneal hematoma	3 (10.0)
	Limb ischemia	10 (17.5%)
	Sistemic embolization *(renal/mesenteric infarct)*	4 (7.0%)
	Pseudo aneurysm of femoral artery	3 (5.3%)
Not strictly related to IABP	Gastrointestinal and urinary bleeding	10 (17.5%)

severe bleeding associated with retroperitoneal hematoma in 1 patient). In our population overall strictly IABP-related mortality was 0.5% (2/414).

At backward logistic regression analysis the following variables were independent predictors for in-ICCU mortality: killip class (OR 1.86; 95% CI 1.41–2.46; $p<0.001$); age (OR 1.04; 95%CI 1.01–1.08; $p=0.018$); aPTT max (OR 1.007; 95%CI 1.001–1.013; $p=0.015$); eGFR (OR 0.98; 95%CI 0.96–0.99; $p=0.037$) and admission glycemia (OR 2.07; 95%CI 1.39–3.07; $p<0.001$). Hosmer–Lemeshow test: 2.996; $p=0.935$.

At backward logistic regression analysis the following variables resulted as independent predictor for IABP-related complications (when adjusted for age and admission systolic blood pressure, and IABP duration): aPTT max (OR 1.008; 95%CI 1.002–1.013; $p=0.010$); admission glycemia (OR 1.68; 95%CI 1.21–2.34; $p=0.002$); minimum platelet count (OR 0.991; 95%CI 0.985–0.997; $p=0.005$). Hosmer–Lemeshow test: 8.23; $p=0.412$.

The main findings of our Registry are as follows: a) in our clinical practice the most frequent indications for IABP implantation are not included in guidelines; b) the incidence of "strictly IABP-related" mortality and complications are low and c) clinicians should carefully monitor anticoagulation, since aPTT max is an independent predictor for IABP-related complications.

In our institution, the most frequent indication for IABP implantation is represented by large ischemic risk area in STEMI patients treated with primary PCI. So far, this indication is supported mainly by experimental data [15,16]. In a randomized experimental study, Azevedo et al. [16] demonstrated that IABP counterpulsation improves the time course of recovery of LV systolic function after reperfused AMI. Using both tagged and contrast enhanced magnetic resonance imaging, the Authors demonstrated that this beneficial effect is mainly due to an acceleration of the functional recovery of non-infarcted, stunned myocardial regions. A series of 116 subjects at a single center, following successful PCI for anterior AMI and total occlusion received either conventional treatment or an IABP. Those subjects who had IABP after successful PTCA had lower rates of reinfarction (0/48) with respect to patients without IABP 1/42 [17]. In our investigation, though our study design does not allow us to draw any conclusions in regard to benefits (since the lack of randomization), IABP implantation in patients with large ischemic risk area is safe since the incidence of complications in this subgroup is low as well as its mortality.

The most frequent and feared complication is represented by major bleeding and aPTT max resulted an independent predictor for IABP-related complications, thus underlining the importance of a close monitoring of anticoagulation in these patients.

In our series, the incidence of IABP-related complications is higher than that reported in the Benchmark Registry [3], mainly because of the different definitions of severe bleeding and different inclusion criteria for complication. [18–20].

In our daily current practice, indications for IABP implantation are not strictly those reported in guidelines. However IABP can be considered a safe device because of the low incidence of IABP-related complications and mortality.

The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology [21].

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