Current indications for the intra-aortic balloon pump The CP-GARO registry

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Title : Current indications of intra-aortic balloon pump: The CP-GARO registry

French title : Indications actuelles de la contre-pulsion par ballonnet intra-aortique : le registre CP-GARO

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Key words: Intra-aortic balloon pump, registry, cardiogenic shock, circulatory assistance

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Relationship with industry: This registry was supported by an unrestrictive grant from Maquet SA.

Vincent Auffret received fellowship support from the Fédération Française de Cardiologie and research grants from Abbott, Edwards Lifescience, Medtronic, Biosensors, Terumo and Boston Scientific. Other authors have no conflict of interest to report.

Word count : 4405.

This original manuscript has never been previously published or submitted to another journal.

Résumé

Contexte : L'utilisation de la contre-pulsion par ballonnet intra-aortique fait partie de la routine clinique depuis les années 70. Suite à la publication d'études randomisées de grande envergure, les recommandations ont dégradé sa place, notamment dans la gestion du choc cardiogénique.

Objectifs : Ce registre a pour objectif de décrire l'utilisation contemporaine de la contre-pulsion par ballonnet intra-aortique, à la lumière de ces dernières données.

Méthode : Ce registre prospectif, multicentrique, a inclus 172 patients implantés d'une contre-pulsion par ballonnet intra-aortique en 2015 dans 19 centres français. Une analyse des caractéristiques des patients, des étiologies menant à l'implantation et des complications liées à la maladie ou à la contre-pulsion par ballonnet intra-aortique a été menée. Les mortalités hospitalière et à un an ont été étudiées.

Résultats : 172 patients (âge moyen de 65.5 ± 12 ans ; 118 hommes [68.6%]) ont été inclus. Les causes d'implantation de la contre-pulsion par ballonnet intra-aortique furent hémodynamique pour 107 patients (62.2%), l'attente de revascularisation pour 34 patients (19.8%), et 4 autres indications « rares » pour 36 patients (20.9%). Les mortalités intra-hospitalière et à un an furent respectivement de 40.7% et 45.8%. 15 patients (8.7%) ont présenté des complications hémorragiques ou ischémiques, dont 7 (4.1%) en rapport avec la contre-pulsion par ballonnet intra-aortique.

Conclusion : Malgré les recommandations concernant l'utilisation de la contre-pulsion par ballonnet intra-aortique dans le choc cardiogénique ischémique sans complication mécanique, cette étiologie reste la principale cause d'implantation dans l'ère contemporaine.

Abstract

Background: Intra-aortic balloon pump is routinely used since the 1970s. Recently, large randomized trials failed to show a meaningful benefit of intra-aortic balloon pump therapy, and international recommendations downgraded its place, particularly in cardiogenic shock.

Aims: The aim of this registry was to describe the contemporary use of intra-aortic balloon pump, in light of these new data.

Methods: This prospective and multicenter registry included 172 patients implanted of intra-aortic balloon pump over 2015 in 19 French cardiac centers. Baseline characteristics, etiologies leading to intra-aortic balloon pump use, intra-aortic balloon pump and disease related complications were assessed. In-hospital and one-year mortalities were studied.

Results: 172 patients were included (mean age: 65.5 years ± 12, 118 men (68.6%)). The causes of intra-aortic balloon pump implantation were hemodynamic, representing 107 patients (62.2%), followed by 34 bridges to revascularization (19.8%), and 4 other “rare” etiologies accounting for 36 patients (20.9%). In-hospital and one-year mortality were 40.7% and 45.8% respectively. 15 patients (8.7%) experienced ischemic or hemorrhagic complications, which were directly related to intra-aortic balloon pump in 7 patients (4.1%).

Conclusion: Despite current international guidelines regarding the place of intra-aortic balloon pump in ischemic cardiogenic shock without mechanical complications, this etiology remains the leading cause of its utilization in the contemporary era.

Abbreviations

ACS: Acute Coronary Syndrome

CP-GARO: Registre des Contre-Pulsions par ballonnet intra-aortique du Groupe des Angioplasticiens de la Région Ouest

CRISP-AMI: Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction

ECMO: Extra-Corporeal Membrane Oxygenation

IABP: Intra-Aortic Balloon Pump

IABP-Shock II: Intraaortic Balloon Pump in Cardiogenic Shock II

Background

Intra-aortic balloon pump (IABP) is the most widely used mechanical circulatory support device, since decades, due to its inexpensiveness, ease of use, low complication rate, and rapidity of insertion in acute settings [1-3]. However, its benefit is still a subject of debate [4] and a considerable gap exists between current guidelines and clinical practice. Retrospective non-randomized studies and animal experiments showed benefits of IABP therapy, especially on hemodynamic data [5-8]. In the thrombolysis era, studies spurred by insights from GUSTO-I (Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries) [9], demonstrated trends toward lower 30-days mortality with IABP. Recently, large randomized trials, in percutaneous coronary intervention (PCI) settings, failed to show a meaningful benefit of IABP therapy in cardiogenic shock, and therefore routine use of IABP has been downgraded in the recent European guidelines [10], to a class III recommendation, although it had been alleged their low representativeness of real life.

We conducted an observational analysis to explore the use of IABP (indications, tolerance and efficacy) with a 1 year follow-up, in the contemporary era.

Methods

This French multicenter, prospective, observational, registry was dedicated to investigate the contemporary use of IABP and its tolerance and efficacy according to its indication.

The CP-GARO Registry

The CP-GARO registry (Registre des Contre-Pulsion par ballonnet intra-aortique du Groupe des Angioplasticiens de la Région Ouest) collected demographic, clinical, biological, echocardiographic, procedural data and complications on all patients who underwent IABP implantation in the GARO's centers (n=19), from 01/01 to 12/31/2015, with a 1-year follow-up. Postoperative IABP implantations and extra-corporeal membrane oxygenation (ECMO)-unloading indications were excluded in order to analyze an homogeneous population. Although reported, implantation failures were excluded from the analysis. Data about the index hospitalization were prospectively collected by the treating physician. The left ventricular ejection fraction (LVEF) was determined by echocardiography using biplane Simpson's method or by left ventriculography. LVEF timing assessment depended on the

patient's status, and could have been perform before or after IABP implantation. The 1-year follow-up interviews were conducted by telephone by research nurses using a dedicated questionnaire. In case of any events, the hospitalization reports and all medical examination results were recovered. All data were centralized in a dedicated database. Patients for whom follow-up data were lacking were considered lost to follow-up.

Study Population and design

We conducted an observational registry of consecutive patients treated with IABP over 2015, in 19 cardiac centers (7 university hospitals, 8 general hospitals and 4 private hospitals), basically based in the north-west part of France. Patients and procedural details were recorded at the time of the implantation.

Risk factors, medical history and long-term patient's therapy were assessed. Hemodynamic and clinical status at implantation, biology and echocardiography, technical data on IABP implantation and angiographic data were collected at implantation. In-hospital endpoints and safety data, and clinical status were collected. One-year all-cause mortality, functional status (New York Heart Association (NYHA) class), and non-fatal cardiac events were analyzed. Last, patients who received IABP for an hemodynamic indication were compared according to survival at hospital discharge.

Definitions and clinical outcomes

Cardiogenic shock was defined as a sustained (>30 minutes) episode of systolic blood pressure <90 mm Hg secondary to a decreased cardiac output, and/or the requirement for inotropic or mechanical support to maintain blood pressure and adequate systemic perfusion, with pulmonary congestion or increased left ventricular pressures and organ malperfusion signs [11]. Definitions of ST-elevation myocardial infarction [STEMI] and Non-STEMI were consensual [12] and patients were treated according to guidelines in effect at this time [10]. "Bridge to revascularization" was defined as IABP implantation in the objective of urgent need of surgical revascularization, in patients with severe coronary disease. "High-risk PCI" was defined according to BCIS-1 (balloon pump-assisted coronary intervention study) criteria, as impaired left ventricular function with ejection fraction less than 30% (quantified by echocardiography or LV angiography) and a large area of myocardium at risk defined as unprotected left main stem target lesion, or a Jeopardy Score greater or equal to 8, or target vessel providing collateral supply to an occluded second vessel which supplies more than 40% of myocardium [13]. "Mechanical complications" comprised acute mitral regurgitation and cardiac wall rupture (free wall or interventricular septum) secondary to MI. "PCI

complications" were adjudicated by the treating cardiologist and included dissections, vessel occlusion, intracoronary thrombosis, and coronary perforation. Chronic renal insufficiency was defined as a glomerular filtration rate < 60mL/min/1.73m² with the use of Cockcroft-Gault formula. Acute renal failure was defined as an increase of serum creatinine > 26 µmol/L during hospitalization. Low urine output was defined as urine flow < 30mL/hour. "Medical therapy" described patients' usual treatment, before inclusion. Coronary anatomy referred to significant stenoses defined by coronary angiography as a diameter reduction ≥50% compared with the reference diameter. Culprit lesion was defined at the discretion of the treating cardiologist as the lesion involved in the MI.

Etiologies leading to IABP implantation were divided as follows: "Hemodynamic indications" regrouping cardiogenic shocks with or without mechanical complication, "Prophylactic indications" corresponding to high-risk PCI, with decision to implant IABP before coronary procedure, "Coronary perfusion related-indications" corresponding to non-shocked acute myocardial infarction (AMI), PCI complications and TIMI (Thrombolysis in myocardial infarction flow score) flow <3 post-PCI and "Bridge to revascularization indications".

The primary endpoint was defined as in-hospital mortality. Secondary endpoints were defined as total strokes, coronary ischemia by re-infarction or stent thrombosis, ventricular tachycardia of fibrillation, tamponade and acute renal failure.

Safety endpoints were defined as 1-year mortality, all clinically significant hemorrhages, IABP-related ischemic complication, and related-IABP hematoma needing surgery or blood transfusion.

Non-fatal 1-year cardiovascular events included: angina, acute MI, performance of coronary angiography or percutaneous coronary intervention, cardiac transplantation, cardiac surgery, stroke, defibrillator or pacemaker implantation. One-year functional status was assessed using the NYHA classification.

Ethics

The trial design received ethical approval from the National Commission for Data Protection and Liberties and Advisory Committee for Data Processing in Health Research (Decision DR-2015-340). All patients or their legally authorized representatives provided written informed consent prior to inclusion. The university hospital of Rennes coordinated the registry and carried out the data management and analyses.

Statistical analysis

Quantitative variables were expressed as mean and standard deviation (SD), or median and interquartile range (IQR), as appropriate. Qualitative variables were expressed as absolute

frequencies and percentages. Qualitative data were compared using Chi-square or Fisher exact tests as appropriate. Continuous data were compared using independent samples t-tests or Mann-Whitney tests depending on their distribution. Continuous variables were compared according to IABP annual volume using the Kruskal-Wallis test. Survival was calculated by the Kaplan-Meier method. A two-sided *p*-value of 0.05 was considered statistically significant for all tests. Statistical analysis was performed with the use of Statistical Package for Social Sciences, version 22.0 (SPSS, IBM, Chicago, IL).

Results

Baseline population

A total of 172 consecutive patients (mean age: 65.5 ± 12.0 years; 118 men [68.6%]) who underwent IABP implantation were included in the present analysis. Flowchart is described in Figure 1 and the relevant clinical features of the study population are described in Table 1.

The main causes of hospital admission were acute myocardial infarction without shock, (ST-elevation myocardial infarction (STEMI) and Non ST-elevation myocardial infarction (NSTEMI)), in one half of patients (n=89;51.7%), followed by cardiogenic shock (n=39;22.7%) and sudden cardiac death (n=28;16.3%). Twelve patients (7.0%) were admitted for scheduled hospitalization.

Patients' clinical status at implantation is detailed in Table 2. Most patients had a precarious hemodynamic presentation with low blood pressure. Sinus rhythm was found in 136 patients (87.2%). Mean serum creatinine was 115.7±61µmol/L, with large heterogeneity between groups. Left ventricular ejection fraction was severely impaired (33.7±15%).

The "hemodynamic indication" group (n=107, 62.2%) was composed of 15 mechanical complications and 92 cardiogenic shock without mechanical complications. The "prophylactic indication" group encompassed 18 high-risk PCI patients (10.5%) whereas the "coronary perfusion related-indications" group (n=11, 6.4%) included 5 non-shocked AMI, 4 PCI complications and 2 TIMI flow <3 post-PCI. The "bridge to revascularization" group was composed of 34 patients (19.8%). The etiology leading to IABP use was missing in 2 patients (1.2%).

Procedural characteristics

Coronary angiogram

Procedural data are summarized in appendix 1. Almost all patients underwent coronary angiography (98.8%). Two-third of patients presented with anterior myocardial infarction.

Radial access was used in the majority of patients (53.5%), especially in stable patients within the “Coronary perfusion-related indication” and “prophylactic indication” groups (20/28; 71.4%). Coronary lesions were severe, with frequent left anterior descending artery (LAD) involvement (76.2%) and a third of patients harboring left main stem (LMS) stenosis. In the “bridge to revascularization” group, patients were more likely to exhibit multivessel disease including LMS stenosis (20/33; 60.6%). PCI was performed in 108 patients (66.7%). Complete revascularization was achieved in 55.2% of patients. Drug-eluting stents were used in most patients (65.7%).

IABP implantation

Balloon size was chosen according to the patient’s template. All IABP were implanted by femoral approach. IABP-related anticoagulation was led by unfractionated heparin in 122/136 patients (89.7%) and low molecular weight heparin 8/136 (5.9%). Moreover, 3 patients (2.2%) did not receive any anticoagulant, but in these cases, IABP was removed within hours of insertion. Two implantation failures were recorded and excluded from the analysis. Last, mainly 7-French catheters were used for 83/167 patients (49.7%). No catheters larger than 9 French were used. Delays between hospital admission and IABP implantation were highly variable. Patients admitted for cardiogenic shock were implanted at 50.06 hours ± 162, patients with mechanical complication were implanted at 25.98 hours ± 44 and patients with scheduled hospitalization and secondly diagnosed with high risk PCI or bridge to revascularization were implanted within the first day, at 11.52 hours ± 21.

Evolution

IABP duration of use ranged from 0 (immediate post-procedural removal) to 210 hours with a median of 40.8 [interquartile range: 22.5-78.2] hours. The median hospitalization stay was 12.0 [6.0-20.5] days.

Endpoints

Primary and secondary endpoints

In-hospital overall mortality was 70/172 (40.7%). In the “bridge to revascularization”, “coronary perfusion related-indication” and “prophylactic indication” groups, mortality rates were 14.7% (5/34), 18.2% (2/11), and 22.2% (4/18) respectively. For hemodynamic indications, the mortality rate reached 53.3% (57/107). Most deaths were of cardiac causes (83.6%).

One-year overall mortality was 76/166 (45.8%). Among the 90 survivors at hospital discharge with complete follow-up data, 6 patients (6.2%) died during follow-up, one half from cardiac reasons (1 sudden cardiac death, 2 low cardiac output), one patient (1.1%) from unknown cause, and 2 (2.2%) from non-cardiac causes (1 cancer, 1 stroke). Survival curves are presented in Figure 2.

In-hospital strokes occurred in 6 patients (3.5%), being equally distributed between ischemic and hemorrhagic causes. Five cases (83.3%) arose in the “hemodynamic-indication” group.

Three patients (1.7%) experienced ventricular fibrillation or tachycardia. Tamponade was diagnosed in 3 patients (1.7%), including 2 in the immediate post-PCI setting, and 1 post-coronary artery bypass graft (CABG).

In-hospital coronary ischemia was noticed in 2.9% of patients (n=5), including 2 stent thrombosis (1.2%) and 3 re-infarction (1.7%) unrelated to stent thrombosis. All these events occurred in the “hemodynamic indication” group.

Primary and secondary endpoints are detailed in Table 3.

Safety endpoints

During the in-hospital period, we did not record any hematoma needing surgery or blood transfusion at IABP’s insertion site.

Nine patients (5.2%) suffered from hemorrhages: 3 (1.7%) were intracerebral including 1 after biventricular assistance device implantation. Two (1.1%) were linked to IABP, 2 (1.1%) were of abdominal origin, and in one case the hemorrhagic site was unknown. One (0.6%) fatal heparin-induced thrombopenia occurred. A total of 17 patients (10.5%) required blood transfusions including 15 cases after cardiac surgery, which were not included in the “safety endpoints”.

Five patients had IABP-related ischemic complications (2.8%): 1 (0.6%) aortic thrombosis after IABP insertion, 1 (0.6%) lower limb ischemia requiring mid-metatarsal amputation and 3 (1.7%) lethal mesenteric ischemias.

Therefore, a total of 7 patients had direct IABP-related complications (3.9%). IABP-related mortality was 2.3%.

One-year Non-fatal cardiovascular events

At 1-year follow-up, 63 survivors (70.0%) had complete data regarding NYHA functional status among whom 95.3% were NYHA class I or II. During follow-up, patients experienced 11 (12.2%) non-fatal cardiovascular events. Three patients had (3.3%) clinical anginas. One patient (1.1%) underwent coronary angiography with subsequent PCI. Three patients (3.3%) received defibrillator implantation including 2 (2.2%) cardiac resynchronization therapy implantation. Two patients (2.2%) suffered a stroke. Heart transplant and MitraClip® device implantation were successfully performed in 1 patient (1.1%) each.

Predictive features of mortality in the hemodynamic group

We conducted a complementary analysis to better understand the main factors linked to survival in cardiogenic shock. The complete comparison is available in Appendix 2. We found that age (66.8±11 versus 61.9±12 r, p=0.036), serum creatinine at IABP implantation (139.2±93 versus 103.1±43, p=0.039), and radial access for the coronary angiography (72.2 versus 51.2%, p=0.03) were significantly associated with in-hospital death in univariate analysis.

Discussion

The CP-GARO registry describes contemporary etiologies and outcomes of 172 IABP implantation in 19 French centers in 2015. The main results of the present study are as follows: 1) hemodynamic indications remained the main indication of IABP treatment (n=107; 62.2%), but many others indications justified IABP implantation, 2) Overall in-hospital mortality was 40.7%, with really few events after index hospitalization, and excellent 1-year functional status, and 3) this registry confirmed the safety of IABP use in the contemporary era.

Implantations etiologies

In the present registry, cardiogenic shock remained the leading cause of IABP implantation (62.2%). Sandhu et al. demonstrated, in a recent observational study of US patients with cardiogenic shock, an overall IABP implantation rate of 42.5% from 2009 to 2013 [14]. However, a 0.3%/quarter decline was observed after 2012 conceivably owing to the

publication of the IABP-Shock II (Intraaortic Balloon Pump in Cardiogenic Shock II) trial. It should also be highlighted that the use of other percutaneous mechanical circulatory supports (O-MCS) considerably expanded over the same period, which may play a significant role in this trend. For instance, Impella® (Abiomed, Danvers) use increased from 500 in 2008 to 3000 in 2011 in the United States [15].

IABP in cardiogenic shock has been challenged by the recent publication of the IABP-Shock II study [15], and since 2014, routine use of IABP is not recommended in cardiogenic shock without mechanical complication in European guidelines [10]. Thiele and al. prospectively demonstrated, including 600 patients randomly assigned to primary PCI and IABP vs. primary PCI alone, that 30-day mortality did not differ significantly with the use of IABP (39.7% vs. 41.3%, RR=0.96, 95% CI: 0.79-1.17; p=0.69). Nevertheless, one can wonder if the IABP-Shock II population still represents a real life cardiogenic shock population. Indeed, nearly half of this population experiencing resuscitation before IABP implantation probably resulted in a poor neurological prognosis in many of these patients, independently of their cardiac disease. Furthermore, almost all included patients were receiving catecholamine at implantation. Overall these data testify for the highly “selected” and severe profile of the IABP-SHOCK II population questioning the potential benefit of IABP among these patients? Current European or US guidelines do not precise the optimum timing to implant IABP, leaving the issue unresolved.

Moreover, a recent meta-analysis [16], analyzed the impact on mortality of IABP in cardiogenic shock without mechanical complication and confirmed the result of IABP-Shock II regarding in-hospital mortality (HR=0.87;95% CI: 0.65-1.18; p=0.36). Despite these negative results, we believe that IABP may still be beneficial in subgroups of patients such as younger patients with a first myocardial infarction as suggested in a sub-analysis of IABP-Shock II [17], or patients with ongoing ischemia after PCI as suggested by a small CRISP-AMI [Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction] [18]) sub study. Finally, literature showed that there is trends toward an increasing use of O-MCS in cardiogenic shocks, but without any evidence on survival, such as IABP [19].

In the particular group of cardiogenic shocks with mechanical complications, there is no randomized trial about the efficacy of IABP. Moreover, in all studies regarding IABP, mechanical complication was an exclusion criteria. Only a post-hoc analysis of the SHOCK study [20] found hemodynamic improvement 30 minutes after IABP insertion in 55 patients with cardiogenic shock with mechanical complication, with a rise in mean blood pressure from 81mmHg to 102mmHg (p<0.001). Despite this lack of proof, IABP remains consistently used, and guidelines recommends IABP use in this case with a class IIa, level C [10].

However, Rob and al. [21] recently suggested that early ECMO in patients with ventricular septal rupture and refractory cardiogenic shock might prevent irreversible multiorgan failure by improved end-organ perfusion, yet with frequent bleeding complications.

Bridge to revascularization was the second most frequent etiology for IABP insertion in the present study. A recent meta-analysis [22], has shown a significant reduction of in-hospital mortality among high-risk patients associated with the use of IABP pre-CABG in a pooled analysis of 8 randomized control trials conducted between 1997 and 2011 (OR=0.20; 95%CI: 0.09-0.44,p<0.0001, I^2=0%). However, this result could not be demonstrated in the analysis of observational studies, which led authors to conclude that given the issues with previous trials and the lack of consensus on “high-risk” criteria further validation in a dedicated multicenter randomized trial remained mandatory. Despite this somewhat conflicting data, the use of IABP in bridge to revascularization was common in routine practice in the present registry, demonstrating favorable clinical outcomes with a 1-year mortality rate of 16.7%.

There are stronger evidence of the efficacy of IABP in high-risk PCI, based on a prospective randomized trial, including 300 high-risk PCI patients with severe left ventricular dysfunction and extensive coronary disease [13]. Although the systematic elective use of IABP failed to reduce in-hospital major adverse cardiovascular events [23], it showed a favorable association with survival at a median follow-up of 51 months compared with a strategy of PCI without planned IABP support (HR=0.66; 95% CI: 0.44-0.98, p=0.039). Moreover, a recent meta-analysis [24], analyzed 10 prospective studies, and confirmed a benefit of IABP in high-risk PCI, showing a significant reduction of long-term all-cause mortality (OR=0.55; 95% CI: 0.38-0.80, p=0.002).

Safety

Seven IABP-related complications (4.1%) were recorded, including 5 ischemic and 2 hemorrhagic complications. This result is consistent with a study by Ternus et al., conducted from 2009 to 2015, [25], which highlighted 3.7% of complications among 778 patients. Moreover, in IABP-Shock II, the safety endpoints encompassed 13 ischemic complications (4.3%) and 10 severe bleeding (3.3%), confirming a low complication rate associated with the contemporary use of IABP.

Anticoagulation during IABP support is a matter of debate reflected in the lack of current guidelines on this specific subject. In the present registry, almost all patients (89.7%) received unfractionated heparin whereas only 3 were not anticoagulated due to rapid

removal of IABP. A provocative literature review by Pucher and al [26], summarizing data of 4 studies including 502 patients, showed that heparinization for IABP did not result in a significant reduction in limb ischemia, and incidence of bleeding was significantly increased in the heparinized patients. Reacting to this review, Okonta and al [27] highlighted the notion that the use of thinner catheters and/or a sheathless technique resulted in a marked decrease in lower limb ischemia rates (from 20.7% with 12 French catheters to 8.4% with 9.5 French catheters). In our registry, all catheters were mainly 7 French (all of them ≤ 9 French). This is an interesting element which may explain the single lower limb ischemia we recorded. Therefore, one can wonder whether anticoagulation is really mandatory for IABP if there is no other anticoagulation indication.

Limitations

We acknowledge some limitations. The CP-GARO registry is by nature a nonrandomized study, but reports real-life IABP activity and patient management. Despite meticulous screening, it is possible that a few IABP insertions could not be recorded in the participating centers, but we carefully gathered data to avoid missing data. Etiologies leading to IABP were adjudicated by the treating physician, which could lead to some misdiagnosis. We did not record the patient progression through units, nor their inter-hospital transfers. Finally, we did not record all cardiogenic shocks during the inclusion period, so we could not study the IABP/total cardiogenic shocks ratio. However, this gathering was almost impossible, because of the various pathways of care of this pathology.

Conclusion

Despite the IABP-Shock II trial results and the guidelines recommendations, cardiogenic shock without mechanical complication remains the most frequent etiology leading to IABP implantation in France in 2015.

Funding statement

This work was supported, with unrestricted grant, by Maquet® medical systems (Wayne, NJ, USA).

Participating centers

CHU Rennes, CHU Brest, CHU Nantes, Clinique Saint-Gatien Tours, CHU Tours, Polyclinique des Fleurs Ollioules, CH Chartres, CHU Angers, CHU Caen, CH Bretagne-Atlantique Vannes, CH Saint-Brieuc, CH Saint-Nazaire, Clinique Saint-Joseph Angers, CHU Rouen, CH Cornouaille Quimper, Clinique Saint-Hilaire Caen, CH Le Mans, CH Saint-Malo, CH Bretagne Sud Lorient.

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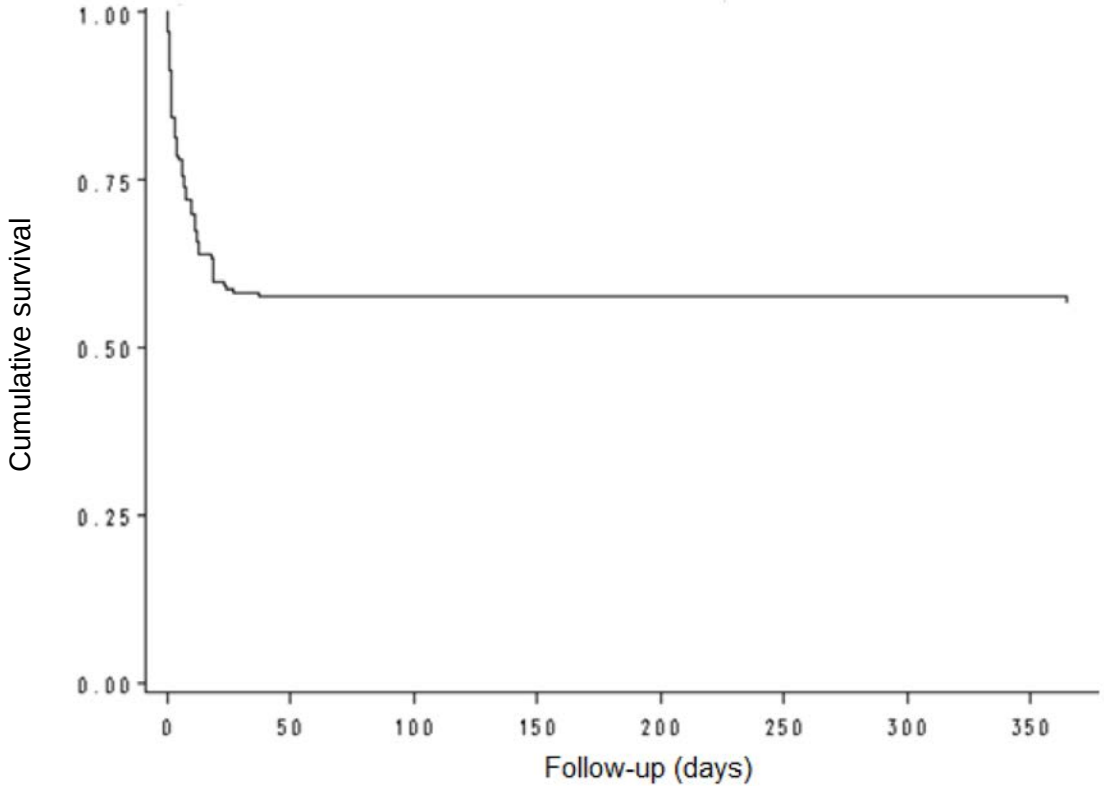
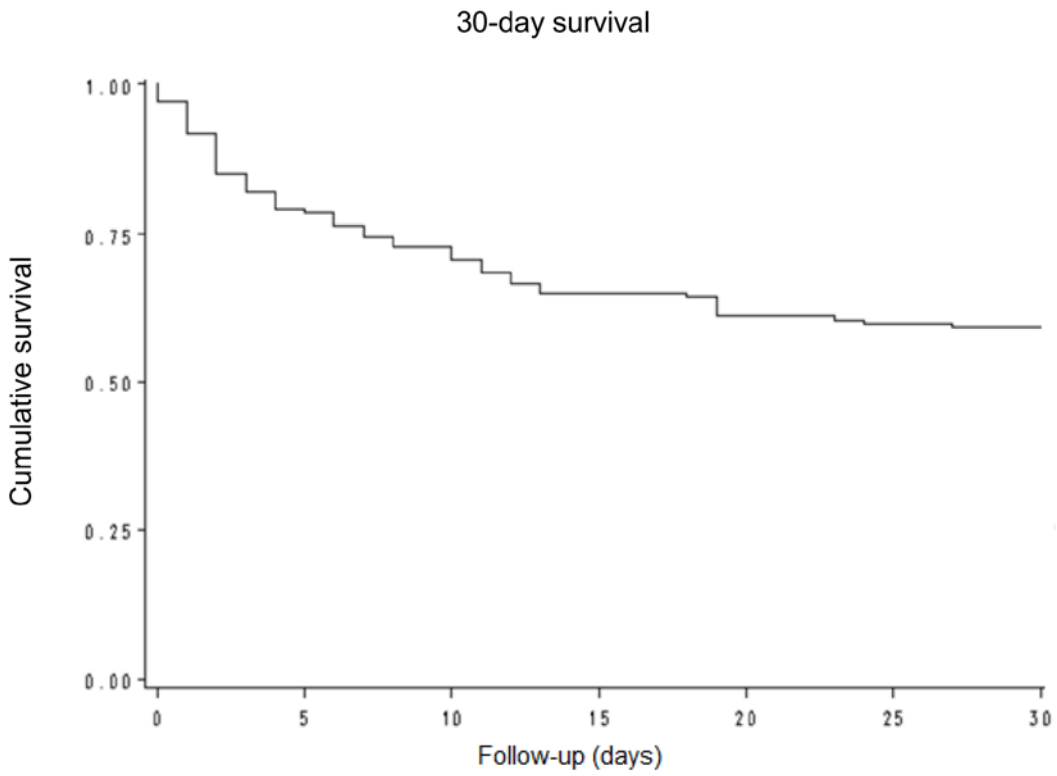
Survival during 1-year follow-up



No. at risk	172	91	91	91	91	91	91	90 (at day 365)

Losts to follow-up have been excluded from survival analysis



No. at risk	172	128	121	113	109	107	106

Clinical features	Total (n=172)	Hemodynamic indication (n=107)	Bridge to revascularization (n=34)	Coronary perfusion-related indication (n=11)	Prophylactic indication (n=18)
Mean Age	65.5 ± 11.6	64.6 ± 12.0	67.4 ± 10.8	65.7 ± 9.9	70.2 ± 11.3
Men	118 (68.6)	68 (63.6)	27 (79.4)	11 (100)	10 (55.6)
Cardiovascular risk factors					
Hypertension	98 (57.0)	52 (48.6)	24 (70.6)	6 (54.5)	14 (77.8)
Dyslipidemia	42 (24.4)	20 (18.7)	9 (26.5)	7 (63.6)	6 (33.3)
Smoker	51 (29.7)	33 (30.8)	11 (32.4)	3 (27.3)	3 (16.7)
Diabetes mellitus	36 (20.9)	20 (18.7)	13 (38.2)	1 (9.1)	4 (22.2)
Heredity	31 (18.0)	14 (13.1)	9 (26.5)	4 (36.4)	3 (16.7)
Mean BMI (min-max)	26.9 (17.7-45) ± 4.9	26.8 (17.7-41.8) ± 4.6	27.3 (19-41.2) ± 5.4	26.6 (20.3-36.2) ± 4.2	25.6 (19.7-33.3) ± 4.3
Obeses (BMI>30kg/m²)	34 (19.8)	20 (18.7)	7 (20.6)	1 (9.1)	4 (22.2)
Medical History					
Myocardial infarction	27 (15.7)	15 (14.0)	5 (14.7)	2 (18.2)	4 (22.2)
PCI	31 (18.0)	14 (13.1)	9 (26.5)	3 (27.3)	4 (22.2)
CABG	5 (2.9)	3 (2.8)	0 (0.0)	0 (0.0)	2 (11.1)
Peripheral vascular disease	14 (8.1)	5 (4.7)	5 (14.7)	1 (9.1)	2 (11.1)
Chronic kidney disease	7 (4.1)	4 (3.7)	1 (2.9)	1 (9.1)	0 (0.0)
Medical therapy *					
Low-dose Aspirin	60 (34.9)	25 (23.3)	19 (55.9)	6 (54.5)	9 (50.0)
P2Y12 receptor inhibitors	26 (15.1)	11 (10.3)	7 (20.6)	2 (18.2)	5 (27.8)
Anticoagulant	11 (6.4)	7 (6.5)	0 (0.0)	0 (0.0)	3 (16.7)
Betablockers	56 (32.6)	29 (27.1)	16 (47.1)	3 (27.3)	7 (38.9)

BMI : Body Mass Index (kg/m²) / CABG : Coronary artery bypass graft / PCI : Percutaneous coronary intervention

** Usual patients' medical therapy before inclusion*

Patients' clinical status at implantation	Total (n=172)	Hemodynamic indication (n=107)	Bridge to revascularization (n=34)	Coronary perfusion-related indication (n=11)	Prophylactic indication (n=18)
Heart rate - beats/min	87.2 ± 27.1	91.8 ± 29.9	79.5 ± 17.2	73.1 ± 27.0	78.5 ± 18.2
Rhythm					
Sinus	136/156 (87.2)	81/95 (85.3)	30/33 (90.9)	9/9 (100)	14/17 (82.4)
Atrial fibrillation/Flutter	13/156 (8.3)	7/95 (7.4)	3/33 (9.1)	0/9 (0.0)	3/17 (17.6)
Other	7/156 (4.5)	7/95 (7.4)	0/33 (0.0)	0/9 (0.0)	0/17 (0.0)
Blood pressure - mmHg					
Systolic	96 ± 26.9	88.4 ± 26.7	113.5 ± 18.0	90.8 ± 29.0	108.7 ± 22
Diastolic	57.5 ± 14.8	57.7 ± 15.6	65 ± 9.1	51.5 ± 15.4	61.3 ± 6.0
Mean	70 ± 16.6	65.1 ± 14.0	84.5 ± 18.3	65.2 ± 25.6	76.6 ± 7.4
Serum Creatinine (µmol/L)	115.7 ± 60.6	127.1 ± 68.5	88.7 ± 31.2	121.4 ± 50.3	107.4 ± 57.0
LVEF (%)	33.7 ± 15.4	31.9 ± 14.9	40.7 ± 15.5	36.2 ± 18.3	30.5 ± 15.0
Catecholamine infusion	83/157 (52.9)	79/97 (75.3)	2/31 (6.5)	5/11 (45.5)	3/18 (16.7)

LVEF : Left Ventricular Ejection Fraction (in %)

Endpoints	Total (n=172)	Hemodynamic indication (n=107)	Bridge to revascularization (n=34)	Coronary perfusion related-indication (n=11)	Prophylactic indication (n=18)
Primary endpoints					
In-hospital Mortality	70/172 (40.7)	57/107 (53.3)	5/34 (14.7)	2/11 (18.2)	4/18 (22.2)
Cardiac mortality	51/61 (83.6)	41/50 (82.0)	4/5 (80.0)	*Missing*	4/4 (100)
Secondary endpoints					
1-year mortality	76/166 (45.8)	61/107 (57.0)	6/30 (20.0)	2/10 (20.0)	5/17 (29.4)
In-hospital stroke	6/172 (3.5)	5/107 (4.7)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
Ischemic	3/172 (1.7)	3/107 (2.8)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
Hemorrhagic	3/172 (1.7)	2/107 (1.9)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
In-hospital coronary ischemia	5/172 (2.9)	5/107 (4.7)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
By re-infarction	3/172 (1.7)	3/107 (2.8)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
By stent thrombosis	2/172 (1.2)	2/107 (1.9)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
VT/VF	3/172 (1.7)	3/107 (2.8)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
Tamponade	3/172 (1.7)	1/107 (0.9)	1/34 (2.9)	0/11 (0.0)	1/18 (5.6)
Acute renal failure	64/144 (44.4)	47/86 (54.7)	8/29 (27.6)	2/11 (18.2)	7/18 (38.9)
Safety endpoints					
Hematomas needing surgery or blood transfusion	0/172 (0.0)	0/107 (0.0)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
Hemorrhages	9/172 (5.2)	8/107 (7.5)	0/34 (0.0)	0/11 (0.0)	0/18 (0.0)
IABP-related ischemic complications	5/172 (2.9)	3/107 (2.8)	2/34 (5.9)	0/11 (0.0)	0/18 (0.0)
Median IABP duration (hours)	41.0 ± 52	46.2 ± 52	50 ± 50	33.6 ± 44	21 ± 50

IABP : Intra-aortic balloon pump / VT/VF : Ventricular Tachycardia / Ventricular Fibrillation

Coronary angiography Data	Total (n=172)	Hemodynamic indication (n=107)	Bridge to revascularization (n=34)	Coronary perfusion-related indication (n=11)	Prophylactic indication (n=18)
Pre-procedural thrombolysis	6/86 (7.0)	5/71 (7.0)	0/4 (0.0)	1/6 (16.7)	0/3 (0.0)
Angiography performed	167/169 (98.8)	103/104 (99.0)	33/34 (97.1)	11/11 (100)	18/18 (100)
Radial Access	83/155 (53.5)	35/95 (36.8)	26/30 (8.7)	8/11 (72.7)	12/17 (70.6)
Anterior wall myocardial infarction	92/135 (68.1)	57/88 (64.8)	14/22 (63.6)	9/10 (90.0)	10/13 (76.9)
Coronary anatomy					
LMS	56/160 (35.0)	23/97 (23.7)	20/33 (60.6)	3/11 (27.3)	9/17 (52.9)
LAD	122/160 (76.2)	72/97 (74.2)	26/33 (78.8)	9/11 (81.8)	13/17 (76.5)
LCx	80/160 (50.0)	36/97 (37.1)	27/33 (81.8)	5/11 (45.5)	10/17 (58.8)
RCA	90/160 (56.2)	49/97 (50.5)	23/33 (69.7)	4/11 (36.4)	12/17 (70.6)
Graft	6/158 (3.8)	3/97 (3.1)	0/31 (0.0)	0/11 (0.0)	2/17 (11.8)
Multivessel Disease	104/161 (64.6)	49/97 (50.5)	31/33 (93.9)	7/11 (63.6)	15/18 (83.3)
Culprit Lesions					
LMS	41/142 (28.9)	19/89 (21.3)	11/26 (42.3)	3/10 (30.0)	7/15 (46.7)
LAD	68/142 (47.9)	43/89 (48.3)	9/26 (34.6)	7/10 (70.0)	7/15 (46.7)
LCx	15/142 (10.6)	5/89 (5.6)	8/26 (30.8)	1/10 (10.0)	0/15 (0.0)
RCA	19/142 (13.4)	15/89 (16.8)	1/26 (3.8)	1/10 (10.0)	0/15 (0.0)
Graft	1/142 (0.7)	1/89 (1.1)	0/26 (0.0)	0/10 (0.0)	0/15 (0.0)
Not found	15/142 (10.6)	10/89 (11.2)	3/26 (11.5)	0/10 (0.0)	1/15 (6.7)
PCI					
Performed :	108/162 (66.7)	75/102 (73.5)	4/30 (13.3)	9/10 (90.0)	18/18 (100)
LMS	34/108 (31.5)	19/75 (25.3)	2/4 (50.0)	3/10 (30.0)	9/18 (50.0)
LAD	67/108 (62.0)	49/75 (65.3)	0/4 (0.0)	6/10 (60.0)	10/18 (55.6)
LCx	17/108 (15.7)	14/75 (18.7)	1/4 (25.0)	0/10 (0.0)	1/18 (5.6)
RCA	23/108 (21.3)	15/75 (20.0)	1/4 (25.0)	1/10 (10.0)	4/18 (22.2)
Graft	1/108 (0.9)	0/75 (0.0)	0/4 (0.0)	0/10 (0.0)	0/18 (0.0)
Complete revascularization	53/96 (55.2)	40/75 (53.3)	0/4 (0.0)	4/10 (40.0)	7/17 (41.2)
Type of stent					
Implantation failure	3/108 (2.8)	1/76 (1.3)	1/4 (25.0)	1/9 (11.1)	0/18 (0.0)
BMS	29/108 (26.9)	24/76 (31.6)	1/4 (25.0)	1/9 (11.1)	1/18 (5.6)
DES	71/108 (65.7)	45/76 (59.2)	3/4 (75.0)	6/9 (66.7)	16/18 (88.9)
Balloon alone	10/108 (9.3)	6/76 (7.9)	1/4 (25.0)	1/9 (11.1)	0/18 (0.0)
Mean (min-max) no. of stents	1.53 (0-6)	1.6 (0-6)	0.13 (0-1)	1.2 (0-4)	1.8 (1-2)
Thromboaspiration	53/115 (46.1)	46/81 (56.8)	0/4 (0.0)	4/10 (40.0)	1/18 (5.6)
*Procedural anticoagulation**					
UFH	94/153 (61.4)	61/97 (62.9)	7/25 (28.0)	6/11 (54.5)	18/18 (100)
LMWH	21/153 (13.7)	19/97 (19.6)	1/25 (4.0)	0/11 (0.0)	0/18 (0.0)
Bivalirudin	7/153 (4.6)	3/97 (3.1)	1/25 (4.0)	3/11 (27.3)	0/18 (0.0)
No AC	31/153 (20.3)	13/97 (13.4)	16/25 (64.0)	1/11 (9.1)	0/18 (0.0)
Use of AntiGpIIb/IIIa	23/153 (15.0)	18/97 (18.6)	0/25 (0.0)	1/11 (9.1)	2/18 (11.1)

AC : Anticoagulant / BMS : Bare-Metal Stent / DES : Drug-Eluting Stent / LAD : Left Anterior Descending / LCx : Left Circumflex / LMS : Left Main Stem / LMWH : Low Molecular Weight Heparin / PCI : Percutaneous Coronary Intervention / RCA : Right coronary artery / UFH : Unfractionned Heparin.

** : More than one anticoagulant could have been used during procedure.*

Table – Comparison of patients of the hemodynamic indication group according to survival at discharge from the index hospitalization			
Variables	**Survivors (n=50)**	**Dead (n=57)**	**p-value**
Baseline characteristics			
Age, years	61.9 ± 12.2	66.8 ± 11.4	0.036
Male sex	34/50 (68.0)	36/57 (63.2)	0.60
Hypertension	20/45 (44.4)	33/52 (63.5)	0.06
Dyslipidemia	11/31 (35.5)	11/34 (32.4)	0.79
Current smoker	15/46 (32.6)	19/51 (37.3)	0.63
Diabetes Mellitus	6/46 (13.0)	14/52 (26.9)	0.09
Heredity	8/44 (18.2)	7/46 (15.2)	0.71
Prior MI	7/48 (14.6)	9/54 (16.7)	0.77
Prior PCI	6/48 (12.5)	9/53 (17.0)	0.53
Prior CABG	2/48 (4.2)	1/54 (1.9)	0.49
Peripheral vascular disease	2/44 (4.5)	3/53 (5.7)	1.00
Chronic Kidney Disease	0/44 (0.0)	4/50 (8.0)	0.12
Treatments before hospitalization			
Aspirin	14/46 (30.4)	12/53 (22.6)	0.38
P2Y12 receptor inhibitor	8/47 (17.0)	3/53 (5.7)	0.07
Oral anticoagulants	1/47 (2.1)	6/53 (11.3)	0.12
Beta-blockers	12/47 (25.5)	17/52 (32.7)	0.43
Clinical status at implantation			
Heart rate, b.p.m	96.7 ± 28.4	87.4 ± 30.2	0.13
Rhythm			0.53
Sinus	39/44 (88.6)	43/52 (82.7)	
Atrial fibrillation/flutter	1/44 (2.3)	6/52 (11.5)	
Other	4/44 (9.2)	3/52 (5.7)	
Blood pressure, mmHg			
Systolic	87.1 ± 24.0	88.3 ± 29.9	0.84
Diastolic	55.7 ± 13.8	53.2 ± 17.6	0.48
Mean	64.9 ± 11.9	64.0 ± 16.7	0.82
Serum Creatinine, µmol/l	103.1 ± 43.1	139.2 ± 93.2	0.039
LVEF, %	33.9 ± 14.7	29.8 ± 15.2	0.22
Procedural Characteristics			
Thrombolysis	3/28 (10.7)	3/45 (6.7)	0.67
Angiography performed	48/49 (98.0)	57/57 (100.0)	0.46
Anterior MI	22/40 (55.0)	37/50 (74.0)	0.06
Radial access	22/43 (51.2)	39/54 (72.2)	0.03
Significant lesion			
Left Main	10/44 (22.7)	14/54 (25.9)	0.71
Left anterior descending artery	33/44 (75.0)	41/55 (74.5)	0.96
Left Circumflex	19/44 (43.2)	17/54 (31.5)	0.23
Right coronary artery	26/44 (59.1)	23/54 (42.6)	0.10
Graft	2/43 (4.7)	1/55 (1.8)	0.42
Culprit lesion			0.84
Left Main	7/36 (19.4)	13/47 (27.7)	
Left anterior descending artery	18/36 (50.0)	23/47 (48.9)	
Left Circumflex	2/36 (5.6)	2/47 (4.3)	
Right coronary artery	7/36 (19.4)	8/47 (17.0)	
Graft	1/36 (2.8)	0/47 (0.0)	
PCI performed	33/48 (68.8)	44/56 (78.6)	0.26
Left Main	7/33 (21.2)	13/46 (28.3)	
Left anterior descending artery	18/34 (52.9)	25/46 (54.3)	
Left Circumflex	1/34 (2.9)	2/46 (4.3)	
Right coronary artery	7/34 (20.6)	6/46 (13.0)	
Stent type			0.55
BMS	9/34 (26.5)	15/44 (34.1)	
DES	22/34 (64.7)	25/44 (56.8)	
Balloon alone	2/34 (5.9)	4/44 (9.1)	

Number of stents	1.12 ± 0.93	1.48 ± 1.34	0.12
Thromboaspiration	21/36 (58.3)	27/47 (57.4)	0.94
Complete revascularization	16/31 (51.6)	26/46 (56.5)	0.67
Procedural anticoagulation			0.39
Unfractionated heparin	24/45 (53.3)	38/54 (70.4)	
Low-molecular weight heparin	10/45 (22.2)	9/54 (16.7)	
Bivalirudin	2/45 (4.4)	2/54 (3.7)	
No anticoagulant	8/45 (17.8)	5/54 (9.3)	