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Hemodynamics and its predictors during Impella-protected PCI in high risk patients with reduced ejection fraction☆

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ABSTRACT

Background: Percutaneous ventricular-assistance by Impella (IMP) represents an emerging strategy to manage patients with reduced left-ventricular (LV) ejection-fraction (EF) undergoing percutaneous-coronary-intervention (PCI). The hemodynamic behave during IMP-protected PCI has been scarcely investigated.
Methods: We reviewed the IMP console's function and hemodynamic data (which are continuously recorded during assistance) in a consecutive series of 37 patients who underwent elective IMP-protected PCI in two high-volume centers. All patients had multivessel disease and impaired LVEF. Coronary artery disease burden was graded using the British-Cardiovascular-Intervention-Society jeopardy-score (BCIS-JS) score. IMP motor speed and pressure signals (systolic blood pressure, SBP, and mean blood pressure, MBP) were analyzed. Primary hemodynamic end-points were "critical systolic blood pressure (SBP) drop" (SBP decrease ≥ 20 mm Hg reaching ≤90 mm Hg values) and "critical mean blood pressure (MBP) drop" (MBP decrease reaching ≤60 mm Hg).
Results: Over mean assistance duration of 254 ± 549 min, no IMP motor drop occurred. During PCI, SBP and MBP significantly decreased but all patients had SBP values >78 mm Hg.
Critical SBP and MBP drops occurred in 10.8% of patients. Among all baseline and procedural characteristics, BCIS-JS was the only significant predictor of SBP drop ($p = 0.001$) while BCIS-JS and LV end-diastolic volume significantly predicted MBP drop ($p = 0.001$ for both).
Conclusions: In patients with reduced EF undergoing IMP-protected PCI, a significant pressure decrease occurs during PCI but pressure is systematically maintained at levels warranting vital organ perfusion. Critical pressure drops during PCI occur in some patients with higher jeopardized myocardium and left ventricular diastolic volumes.

1. Introduction

In daily practice, high-risk patients with adverse clinical features, poor left ventricular (LV) function and complex coronary artery disease (CAD) (multivessel disease, left main disease, last remaining vessel) are often recognized to be unsuitable for cardiac surgery and are increasingly referred for percutaneous coronary intervention (PCI). In these patients hemodynamic intolerance may occur, mostly due to procedure-related ischemia. Mechanical cardiac assistance is emerging as a novel strategy able to minimize the risk of hemodynamic instability and life-threatening complications. Among the available devices for cardiac support, percutaneous Impella pump (IMP) has been shown to be a safe and effective device in this complex clinical scenario [1]. Importantly, the criteria to select patients that might benefit from this approach are debated, and data regarding patients' hemodynamic pattern and device function during IMP PCI are scarce.

In the present study, we investigated the IMP pump performance and the occurrence of hemodynamic deterioration during the course IMP-protected PCI, and the hemodynamics in a consecutive series of high-risk patients who underwent IMP-protected PCI using, for the first time, the IMP console's parameters which are automatically and continuously recorded during assistance.

2. Method

2.1. Study population

The databases of two high-volume Italian centers were reviewed from January 2013 to December 2016, and 37 consecutive patients who underwent elective IMP-protected PCI using an Automated Impella Controller (AIC) console equipped with the last-released

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Impella v5.1 software, were retrospectively selected. Patients with pre-PCI cardiogenic shock and acute myocardial infarction within 24 h were excluded. All patients enrolled in this study were considered not suitable for surgical revascularization by formal Heart Team discussion (or, when decision was considered to be not deferred, by cardiac surgeon consultation).

Clinical characteristics, surgical risk score (EuroSCORE I) and procedural data were prospectively collected into the Institutions' databases. Syntax Score before and after the procedure was calculated for all patients. Yet, since a sizable portion of patients had previous percutaneous or surgical revascularization, the overall extent of coronary artery disease was graded according to the British Cardiovascular Intervention Society (BCIS) jeopardy score (JS) algorithm [2]. Revascularization extent was measured using the revascularization index obtained by the formula revascularization index = BCIS-JS_{pre} − BCIS-JS_{post} / BCIS-JS_{pre}, as previously reported [3].

According to the local protocol for IMP work-out, before the procedure, echocardiographic examination was systematically performed and the following parameters were routinely recorded LV ejection fraction (EF), mitral regurgitation, end-systolic and end-diastolic LV volumes. All patients gave written consent to undergo PCI with IMP after detailed explanation of the specific procedure features. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

2.2. Impella-protected PCI

The Impella 2.5 pump or (after its release in Italy) Impella CP pump were used (see Table 3 in Supplementary material for key technical characteristics). The pump positioning was achieved through percutaneous trans-femoral approach. All femoral punctures were angiography-guided. Before Impella sheath placement and pump advancement, angiography (through the radial or contralateral femoral access selected for PCI) was performed to confirm the suitability of the iliac-femoral arterial axis. Accordingly, when severe atherosclerotic burden or tortuosity was found, the contra lateral iliac-femoral axis was checked and the most favorable side was chosen for Impella implantation. The presence of atherosclerotic disease of the iliac-femoral axis with non-significant (<50% diameter) stenosis was not considered an exclusion criterion. However, as a consequence of the screening process performed before the index procedure, none of the patients had bilateral significant iliac-femoral stenosis and no failure to implant the device was recorded. After femoral artery stick, a 6–8 Fr sheath was inserted. Then, "preclosure" technique with suture-based hemostatic devices was usually applied [4]. After dedicated sheath insertion, a 6 Fr diagnostic catheter (Judkins right or pigtail) was advanced into the LV and used to place the Impella's kit 300 cm extra-support guidewire into the LV. Then, the Impella catheter was advanced over the guidewire through the aortic valve into the LV. Impella was then activated after removal of the guidewire and LV assistance maintained throughout the procedure.

PCI was performed by the radial or by contralateral femoral approach using 6–8 Fr guiding catheters. Selection of guidewires, balloons and stents was left to operators' choice. Drug-eluting stent implantation was the main PCI technique and debulking with rotablator was the main adjunctive device used for severely calcific coronary segments.

At procedure end, the pump speed was gradually decreased and patient hemodynamic conditions were evaluated. In case of hemodynamic stability, Impella was removed and hemostasis achieved by tightening the devices' sutures. In the case of mechanical hemostasis failures, manual compression followed by compressive bandage was systematically adopted. Of note, access-artery angiography to confirm hemostasis was usually performed before the patient left the catheterization laboratory.

In all patients, heparin was administered (initial weight-adjusted intravenous bolus then further boluses administered in order to keep the activated clotting time between 250 and 300 s). Unless contraindicated, all patients were treated with double antiplatelet therapy for 12 months. No inotropic drug was administered during the procedures while low doses of nitroglycerin were seldom administered to dilate the coronary vessels when spam was suspected. Blood samples were obtained at 6 and 24 h after the procedure with particular regard to hemoglobin and creatinine (when renal function was not normal). Further laboratory exams were performed only if clinically indicated. Clinical records were carefully evaluated and clinical follow-up was obtained by outpatient visit or by telephone interview (for remaining patients) to ascertain the occurrence of death.

2.3. Assessment of hemodynamics during cardiac assistance

Hemodynamic and device performance data were anonymously extracted from the AIC console for each patient. The AIC prospectively records a series of hemodynamic data during the entire IMP assistance period and tracing examples obtained from two patients are reported in Fig. 3a and b (Supplementary material). In brief, the "placement signal" tracing provides the aortic pressure (mm Hg) as measured by a sensor located at the proximal hub of Impella catheters, motor speed (rotations per minute) provides the Impella pump speed which is the result of the pump activation level as set on the console.

Among the different parameters recorded throughout the procedure, an interventional cardiology fellow (blinded to patient clinical and procedural data) extracted the following data

- Impella assistance time (min)
- systolic blood pressure at procedure start (SBP start) and procedure end (SBP end)
- mean blood pressure at procedure start (MBP start) and procedure end (MBP end)
- lowest systolic blood pressure (SBP low) and lowest mean blood pressure (MBP low) recorded during the procedure.

2.4. Study end-points

The aim of the study was to detect the occurrence hemodynamic deterioration during the course IMP-protected PCI.

The selected primary hemodynamic end-points were the following:

1. "*critical SBP drop*" defined as a SBP decrease ≥20 mm Hg reaching ≤90 mm Hg values [5];
2. "*critical MBP drop*" defined as a decrease reaching a critical value ≤60 mm Hg [6].

Secondary hemodynamic end-points were SBP low, SBP end, MBP low and MBP end.

Primary safety end-point was "device malfunction" defined as motor speed reduction not due to a change in the console speed level set up.

2.5. Statistical analysis

Variables collected and hemodynamic intraprocedural parameters were included in the descriptive tables. In particular, continuous variables are reported as mean ± standard deviation (SD) whereas categorical variables were presented as numbers and percentages.

Student *t*-test or ANOVA were applied to compare different groups of continuous data while categorical variables were evaluated using χ^2 test or Fisher's exact test, as appropriate. To compare pressure trends during the PCI procedure a paired *t*-test was made.

Correlation analysis was performed to determine the association between LVEF and pressure values using Pearson correlation test. A 2-tailed, p-value <0.05 was established as the level of statistical significance. All statistical analyses were performed with SPSS software v22.0 (IBM Corporation, Armonk, New York).

3. Results

3.1. Study population characteristics

A total of 37 consecutive patients treated between January 2013 and December 2016 entered the study. The clinical characteristics of the study population are reported in Table 1. Briefly, the clinical presentation was an acute coronary syndrome in the majority of patients and NYHA functional class was III or IV in 86% of them. All patients had

Table 1
Main clinical baseline characteristics of study population.

Characteristics	N = 37
Age, years ± SD	72 ± 9
Gender, M/F	32/5
Cardiovascular risk factors, n (%)	
Hypertension	28 (76)
Dyslipidemia	26 (70)
Diabetes	22 (59)
Smoke	7 (19)
Family history of CAD	6 (16)
Renal failure	11 (30)
Past cardiac history, n (%)	
Prior MI	14 (38)
Prior PCI	6 (16)
Prior CABG	5 (13)
Clinical presentation, n (%)	
STEMI	5 (13)
NSTEMI	27 (73)
SA	5 (13)
NYHA III–IV	32 (86)
Echocardiographic features	
LVEF, mean ± SD	31 ± 10
LVEDV, mean ± SD	182 ± 67
MR 3+/4+	13 (35%)
EuroSCORE, mean ± SD	10 ± 4
Refused for surgery	37 (100)
Angiographic characteristics	
Multivessel disease, n (%)	37 (100)
Left main disease, n (%)	21 (57)
Syntax Score, mean ± SD	34 ± 12
BCIS-JS, mean ± SD	11 ± 2

CAD = coronary artery disease; MI = myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; STEMI=ST elevation myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; SA = stable angina; NYHA = New York Heart Association; LVEF = left ventricular ejection fraction; LVEDV = left ventricular end-diastolic volume; MR = mitral regurgitation; BCIS-JS = The British Cardiovascular Intervention Society myocardial jeopardy score.

depressed LV function (78% of them with LVEF ≤ 35%). Comorbidities were frequent including diabetes in 59% and renal failure in 30%. Overall, surgical risk was high as measured by a mean EuroSCORE I value of 10 ± 4 (95% of patients having EuroSCORE ≥ 6).

All patients had complex coronary anatomy with three-vessel disease and 57% with left main disease. Mean Syntax Score I was 34 ± 12 and 73% of patients belonged to the highest risk group with a Syntax Score I ≥ 33. The jeopardized myocardium before procedure was wide as testified by BCIS-JS 11 ± 2.

3.2. Procedural characteristics and outcome

The procedural details are reported in Table 2. Nineteen patients underwent left main PCI and more than three-quarters of them were treated on at least two vessels with most lesions including calcifications, bifurcations and diffusely diseased vessels (Table 2). Eight cases required the use of Rotablator because of heavy calcifications. In all patients, at least one drug eluting stent was implanted. Both Syntax score and BCIS-JS significantly decreased after revascularization as compared to baseline values (from 34 ± 12 to 9 ± 8 and from 11 ± 2 to 3 ± 2 respectively, $p < 0.001$ for both). Extensive revascularization was attempted for each patient as demonstrated by mean revascularization index of 0.7.

Impella 2.5 pump was used in 25 patients and CP in 12 patients. No patient died during the procedure and Impella was successfully removed in all cases after a mean assistance time of 254 ± 549 min. Vascular and bleeding complications occurred rarely as reported in Table 2.

At a mean follow-up of 9 months, 3 patients only died (all-cause mortality rate: 8.3%). They showed more comorbidities (mean EuroSCORE = 13) and a greater coronary anatomy complexity (mean Syntax score = 41) as compared to the remaining patients. Two deaths occurred due to progressive heart failure while another patient has unestablished cause of death.

Table 2
Procedural characteristics.

Characteristics	N = 37
Number of treated vessels	
One-vessel PCI	8 (22)
Two-vessel PCI	16 (43)
Three-vessel PCI	13 (35)
PCI in bifurcation	30 (81)
PCI with rotablator	8 (22)
At least one DES implanted	37 (100)
Post-PCI angiographic scores	
Syntax Score	9 ± 8*
BCIS-JS	3 ± 2*
Revascularization index	0.7 ± 0.2
Impella	
2.5 pump	25 (68)
CP pump	12 (32)
Assistance time (min, mean ± SD)	254 ± 549
Hemostasis technique	
Double perclose	25 (68)
Prostar	7 (18)
Manual compression	5 (14)
Need for crossover balloon technique to achieve hemostasis	2 (5)
Access-site or hemorrhagic complications	
Blood transfusions	2 (5)
Distal embolization needing urgent angioplasty	1 (3)
Vascular surgery	0
Hemodynamics	
Pre-PCI SBP, mean ± SD (mm Hg)	144 ± 24
Pre-PCI MBP, mean ± SD (mm Hg)	90 ± 11
Primary hemodynamic end-points, n (%)	
Critical SBP drop	4 (11)
Critical MBP drop	4 (11)
Secondary hemodynamic end-points (mm Hg)	
SBP LOW, mean ± SD	119 ± 21
MBP LOW, mean ± SD	78 ± 14
SBP END, mean ± SD	150 ± 26
SBP END, mean ± SD	98 ± 15
SBP drop (% as compared to baseline), mean ± SD	17 ± 12
MBP drop (% as compared to baseline), mean ± SD	13 ± 12
Critical SBP drop duration (min), mean ± SD	6 ± 9
Critical MBP drop duration (min), mean ± SD	7 ± 9

PCI = percutaneous coronary intervention; DES = drug eluting stent; BCIS-JS = The British Cardiovascular Intervention Society myocardial jeopardy score; SBP = systolic blood pressure; MBP = mean blood pressure.
* $p < 0.001$ as compared with baseline values.

3.3. Pump performance

The review of pump speed and motor current graphics revealed proper function of Impella pump in all the study procedures. The primary safety end-point "device malfunction" was not noticed in any patient. Examples of proper pump function tracings recorded in two different patients are reported in Fig. 3 (Supplementary material).

3.4. Hemodynamics during IMP-protected PCI

All patients showed a baseline SBP start ≥100 mm Hg and a MBP start ≥60 mm Hg: these features clearly reflect the selection of high-risk patients in which "elective" IMP-assisted PCI was attempted and the exclusion of patients with pre-PCI cardiogenic shock.

Fig. 1 shows the SBP and MBP mean values observed in the study population. During PCI, a significant reduction of SBP and MBP and then a return to higher values was noticed. Interestingly, all patients maintained a SBP sufficient to maintain a stable hemodynamic state, so that no patient required a bail-out use of inotropic drugs. The lowest SBP recorded was 78 mm Hg. Moreover, MBP end values were significantly higher than MBP start ($p = 0.002$) thus reflecting a possible acute hemodynamic impact of IMP assisted PCI. Finally, when Impella assistance was dismissed, all patients showed SBP ≥90 mm Hg and MBP ≥70 mm Hg. The lowest SBP levels were not associated with any clinical, angiographic or procedural factors while the lowest MBP levels were associated with BCIS-JS ($p = 0.001$) and tended to be associated with LVEF ($p = 0.06$). End-procedure SBP and end-procedure MBP

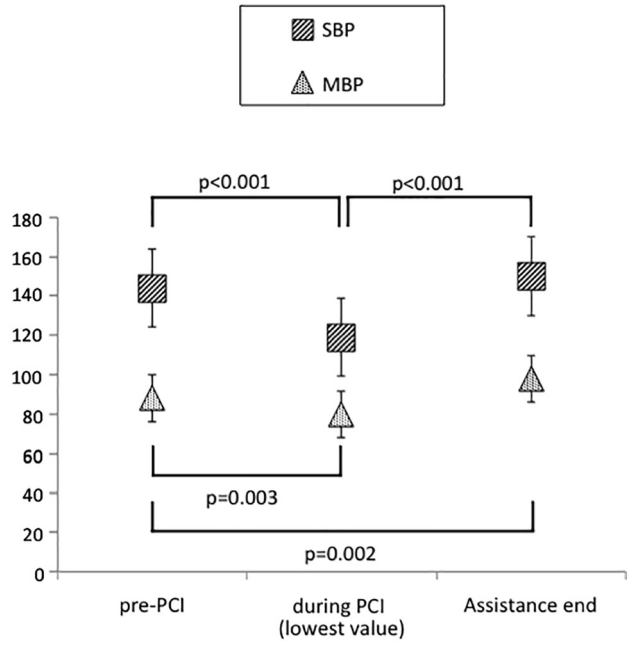

Fig. 1. Systolic blood pressure (box, SBP) and mean blood pressure (triangles, MBP) measured at beginning of procedure, during the procedure (lowest value recorded) and at the end of the procedure. PCI = percutaneous coronary intervention.

were both significantly associated with LVEF ($p = 0.001$ and $p = 0.03$, respectively).

Neither any of the patients needed endotracheal intubation nor any major complication that could affect blood pressure behaviors occurred throughout the entire procedure.

3.5. Pressure drops and their predictors

Critical SBP drop and *critical MBP drop* occurred in 4 (10.8%) and 4 (10.8%) patients, respectively. Three of these patients had both the *critical SBP drop* and *critical MBP drop*. The mean duration of critical SBP drop was 6 ± 9 and 7 ± 9 min (range 2–20 and 3–20 min) for critical SBP drop and critical MBP drop, respectively. One of these patients experienced multiple prolonged critical SBP and MBP drops. She was admitted for acute coronary syndrome and her LVEF was severely impaired (baseline LVEF 25%). Her BCIS-JS was 12 and her Syntax Score was 35. All the three vessels were treated by PCI with a total procedural time of 180′. Fig. 4 and Video 1 (Supplementary material) report the catheterization laboratory caption of a pressure drop in a patient exhibiting transient but complete loss of arterial pressure pulsatility during left main balloon inflation.

Among all the clinical, angiographic and procedural characteristics, BCIS-JS was found to be the only significant predictor of *critical SBP drop* ($p = 0.001$). BCIS-JS ($p < 0.001$) and with LV end-diastolic volume ($p = 0.001$) were independently associated with *critical MBP drop*. Fig. 2 shows the BCIS-JS and intraprocedural MBP relationship highlighting those who experienced critical MBP drop.

4. Discussion

PCI is increasingly adopted worldwide to manage high-risk coronary artery disease patients who are deemed unsuitable for cardiac surgery. When PCI is adopted in patients with both challenging coronary anatomy and poor LV function, the risk of hemodynamic deterioration during the procedure is not negligible so that cardiac assistance may be considered. The role of LV support during high-risk interventions is to reduce LV filling pressures and to increase cardiac output. Theoretically, this may produce two beneficial effects. First, LV unloading contributes limiting the infarct size as demonstrated on canine models [7,8]. Second, the increase of cardiac output avoids hemodynamic collapse, especially during angioplasty balloon inflation-induced myocardial ischemia [9]. Among the different available devices, the percutaneous insertion of the microaxial Impella pumps has a key role since its feasibility in the setting of high risk PCI has been supported by both randomized-controlled trials [10] and large international registries like USpella [11] and Europella [12]. In such context, a further knowledge regarding the hemodynamic behavior and its determinants in patients treated by IMP-protected PCI is interesting since it may help during both the selection and management process. Although previous studies demonstrated good clinical and safety outcomes in IMP-protected PCI, strong heterogeneity characterized treated patients and scarce information regarding the hemodynamic changes and their prediction is available.

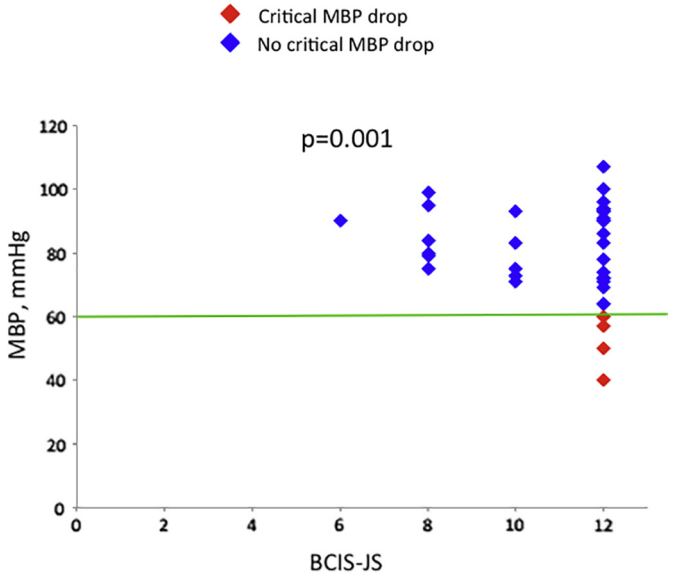

Fig. 2. Relationship between jeopardy score (X axis) and MBP low (Y axis). Red dots represent those patients experiencing critical MBP drop. BCIS-JS = The British Cardiovascular Intervention Society myocardial jeopardy score, MBP = mean blood pressure.

In the present study, conducted in a quite homogeneous high-risk real-world population, we reported for the first time a detailed analysis of key function and hemodynamic parameters continuously recorded by the device's console throughout the IMP-assisted PCI.

As a first important finding, we demonstrated that Impella function was reliable throughout the entire duration of assistance as no motor current drop occurred. This observation reinforces the perception of a perfect suitability for IMP pumps in the high-risk PCI setting where stable patients position and relatively short assistance times are needed.

Moving toward the critical issue of hemodynamics behave during PCI, we have noticed that patients experienced significant pressure decrease during the procedure that, however, never reached critical levels (78 mm Hg being the lowest SBP recorded in the study). This observation supports the concept of systematic adequate cardiac output throughout the ischemic times induced by PCI manipulations. For instance, the prognostic relevance of adequate blood pressures values is underlined by the inclusion of SBP or MBP in the major intensive care units risk scoring systems [13,14].

Interestingly, a subgroup of patients (about 1 out of 10 in the present cohort) exhibited a striking hemodynamic pattern characterized by (*critical*) pressure drop and loss of pulsatile pressure during ischemia induced by coronary manipulations like balloon inflations. Such hemodynamic behave clearly shows a critical dependency of PCI tolerance from IMP assistance in some patients. Since the correct identification of such response may be useful in clinical ground, we conducted a further analysis assessing the predictors of MBP and SBP *critical* drops. In our study population, among all the different baseline characteristics, the occurrence of *critical* pressure drops was significantly associated by coronary anatomy complexity as measured by BCIS-JS and LV end-diastolic volume. The prognostic utility of BCIS-JS for predicting mortality in patients undergoing PCI had been already tested [3]. In this study, it predicted hemodynamic instability confirming its importance during the diagnostic work-up in order to identify those who may benefit most from Impella support. Alongside this, LV volumes were also useful to detect those at risk of hemodynamic instability indicating that not only the LVEF (usually scored in the work-out as the main LV function parameter) but also LV dilation measures may modulate patient tolerance to PCI-related ischemia.

4.1. Study limitations

Our study has some limitations. First, predictors of primary hemodynamic end-points may be affected by the small sample size as only few patients experienced a significant pressure drop. Consequently, neither prognostic factors nor prognostic implications of hemodynamic drops could be found and no cost-effectiveness analysis was made.

Furthermore, although Impella 2.5 and Impella CP pumps may provide different support levels no comparisons could be made due to the low number of patients included in the study.

The number and duration of balloon inflations as well as the number and dosage of vasodilating drugs and fluids could be related to hemodynamic drops. However, these parameters were not recorded and, consequently, not included in the multivariate analysis. For instance, since the

number of variables that could potentially influence BP drop is theoretically huge, the sample size of the present study is too small to be comprehensive and the reported findings have to be considered as exploratory.

5. Conclusions

In conclusion, the present study on IMP-protected PCI reports for the first time a detailed analysis of device's console data automatically and continuously recorded during the procedures. The observed findings show that, in patients with reduced ejection fraction undergoing IMP-protected PCI, a significant pressure decrease occurs during PCI but pressure is systematically maintained at levels warranting vital organ perfusion. *Critical* pressure drops during PCI occur in some patients who are characterized by higher jeopardized myocardium and left ventricular diastolic volumes.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.07.064.

Contributors

Drs Burzotta, Trani and Ribichini organized the Impella program in the two hospitals and conceived the study.

Drs Russo, Piccoli, D'amario, Previ and Paraggio were responsible for the collection and management of the clinical data. Drs Russo and Verdirosi conducted the statistical analyses.

Drs Pesarini, Porto, Leone, Niccoli and Aurigemma performed the procedures and were involved in the decision-making process of the management for complex coronary artery disease patients.

Prof. Crea helped the data interpretation and critically reviewed the manuscript, giving important intellectual advices.

Disclosures

Dr. Burzotta discloses to have been involved in advisory board meetings or having received speaker's fees from Medtronic, St Jude Medical, Abiomed, Biotronic. Dr. Trani discloses to have been involved in advisory board meetings or having received speaker's fees from St Jude Medical, Abiomed, Biotronic. Dr. Aurigemma has been involved in advisory board activities by Biotronic.

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