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Impact of left-ventricular end-diastolic pressure as a predictor of periprocedural hemodynamic deterioration in patients undergoing Impella supported high-risk percutaneous coronary interventions

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ABSTRACT

Background: An increasing number of high-risk percutaneous coronary interventions (PCI) are performed with mechanical circulatory support (MCS) to minimize the risk of periprocedural hemodynamic compromise. Prior studies have demonstrated that an elevated left-ventricular end-diastolic pressure (LVEDP) is associated with worse outcome after acute myocardial infarction or cardiac surgery. Although LVEDP is frequently measured, little is known about the usefulness for predicting periprocedural hemodynamic deterioration in high-risk PCI. The objective of this study is to assess the impact of preprocedural measured LVEDP in non-shock patients undergoing high-risk PCI with MCS on periprocedural hemodynamic deterioration.

Methods and Results: We reviewed the PCI protocol and the Automated Impella Controller in a consecutive series of 64 patients (mean age 73 years, 80% male), who underwent high-risk PCI with Impella MCS (period 01/2017–12/2018). LVEDP (17 ± 8 mm Hg) was measured in all cases before Impella insertion and start of PCI. Periprocedural hemodynamic deterioration was defined as: systolic blood pressure (SBP) drop (decrease ≥20 mm Hg or ≤90 mm Hg), or transient loss of arterial pressure pulsatility. Hemodynamic deterioration occurred in 33% (n = 21) of all patients but did not lead to a hemodynamic compromise due to the Impella support. Regression analysis of LVEDP for periprocedural hemodynamic deterioration or in-hospital major adverse cardiac and cerebrovascular events (MACCE) showed no significant results.

Conclusion: LVEDP was not associated with periprocedural hemodynamic deterioration or a higher rate of in-hospital MACCE. Our data propose that LVEDP may not be used as a risk stratification variable for MCS usage in non-shock patients undergoing high-risk PCI.

1. Introduction

Percutaneous coronary interventions (PCI) are increasingly performed in patients with severe coronary artery disease (CAD) [1]. These patients are often at high risk because of complexity of the coronary anatomy, the patient's age and comorbidities, and the clinical presentation, including hemodynamic status [2]. These factors may lead to a lower physiologic tolerance for complex revascularization techniques [3]. In light of the shifting patient demographics, the concept of high-risk interventional coronary procedures has developed, in which mechanical circulatory support (MCS) is increasingly utilized during percutaneous revascularization procedures of this higher-risk patient group [4].

Among the available MCS devices, the percutaneous Impella microaxial blood pump has been shown to be a safe and effective device in this complex clinical scenario [5–7]. In this context, different variables are discussed to assist during decision-making. Measurement of the left ventricular end-diastolic pressure (LVEDP)

Abbreviations: CAD, coronary artery disease; HD, hemodynamic deterioration; LVEDP, left ventricular end-diastolic pressure; MACCE, major adverse cardiac and cerebrovascular events; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention; SBP, systolic blood pressure.

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before PCI is often discussed to have important impact on the medical treatment during PCI or the decision to use a mechanical unloading device [8]. This hypothesis is based on that LVEDP during left heart catheter reflects ventricular compliance relating to both acute and chronic conditions that effect ventricular performance [9]. There is an inverse physiologic relationship between coronary perfusion and high LVEDP, as well as an increased myocardial oxygen demand that occurs with higher left ventricular wall tension [10]. Prior studies have demonstrated that an elevated LVEDP was associated with worse outcome after acute myocardial infarction and cardiac surgery [11,12].

Although LVEDP is frequently measured, little is known of the usefulness of this acute measurement for predicting periprocedural hemodynamic deterioration in high-risk PCI using a MCS. We therefore investigated the impact of preprocedural measured LVEDP in patients undergoing high-risk PCI with MCS and aimed to determine its predictive value for periprocedural hemodynamic deterioration.

2. Methods

2.1. Study design and population

We included 64 consecutive patients, who underwent percutaneous coronary interventions with MCS from January 2017 to December 2018 at our tertiary care center. Details about the prospective cohort were previously published [2].The decision was based on a "Heart Team-based" algorithm (NOVA-HRI) that uses the best available evidence for an individualized treatment decision [2]. This algorithm incorporated the anatomical lesion complexity (defined by the SYNTAX I score), comorbidities (oxygen-dependent chronic obstructive pulmonary disease, severe aortic valve stenosis III°, carotid artery disease, chronic kidney disease stage ≥4, severe pulmonary hypertension, peripheral artery disease stage 4, stroke within 30 days prior to PCI, active infection/sepsis and cancer with concurrent cancer therapy), and clinical presentation, including hemodynamic status (left-ventricular ejection fraction), to identify patients at high-risk of coronary interventions.

We here focused on patients with Impella-supported high-risk percutaneous coronary interventions. In non-shock patients the first device was the Impella 2.5, in patients presenting with cardiogenic shock the Impella CP was selected. Patients with cardiogenic shock and those presenting with ongoing cardiopulmonary resuscitation (prior to coronary angiography) were excluded from the study. All patients received Impella (Abiomed, Danvers, MA, USA) for MCS. The study was approved by the institutional ethics committee of the University of Duisburg-Essen (Essen, Germany – 18-8523-BO). All procedures were performed in accordance with relevant guidelines and regulations [8,13,14]. All study participants gave written informed consent.

2.2. Procedural characteristics

After achieving vascular access, LVEDP was determined in the catheterization laboratory using a calibrated fluid filled system. LVEDP was measured at the Z-point, which is identified on the left ventricular pressure trace as the point at which the slope of the ventricular pressure upstroke changes, approximately 50 ms after the ECG Q-wave, and generally co-inciding with the ECG R-wave. After assessment of LVEDP, the Impella device was implanted prior to PCI. The Impella was weaned and removed in all cases in the catherization laboratory. The patients were monitored for at least 24 h after PCI on an intensive care unit. Data on laboratory values, risk factors and clinical diagnoses of patients were obtained from all available hospital records.

2.3. Assessment of hemodynamics

Hemodynamic and device performance data were anonymously extracted from the Automated Impella Controller (AIC) console and reviewed for each patient. The AIC prospectively records a series of hemodynamic data during the entire Impella assistance period. 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.

2.4. Study outcome measures

The primary outcome measure was the incidence of periprocedural hemodynamic deterioration (HD) defined as: systolic blood pressure (SBP) drop (SBP decrease ≥20 mm Hg or SBP ≤90 mm Hg), or transient loss of arterial pressure pulsatility [15–17] ≥30 s. The secondary outcome measures were the incidence of in-hospital major adverse cardiac and cerebrovascular events (MACCE), defined as death, new myocardial infarction – defined as in the current ESC guidelines [18] – or stroke.

2.5. Variable definitions

The indications for revascularization in chronic coronary syndrome (CCS) patients was the persistence of symptoms despite medical treatment and/or proven ischemia (evaluated by means of non-invasive testing or with the use of fractional flow reserve or instant wave-free ratio) [20]. In cases of CCS, complete revascularization, defined as a residual SYNTAX I score ≤8 [18], was aimed for. Patients presenting with ST segment elevation myocardial infarction underwent a culprit lesion only PCI during the index procedure, followed by the deferred complete coronary revascularization of nonculprit lesions if required. Patients with unstable angina and non-ST-segment elevation myocardial infarction were completely revascularized during the HRI procedure.

2.6. Statistical analysis

Data are presented as the mean ± standard deviation if normally distributed, or as medians and interquartile ranges otherwise. Categorical variables are presented as frequencies and percentages. Categorical data were compared between groups using χ^2 test. Continuous variables were compared using Student's *t*-test if normally distributed, or the Mann–Whitney *U* test if not. Logistic regression analysis was used to evaluate the association of preprocedural measured LVEDP with hemodynamic deterioration and MACCE using the following adjustment sets: (1) unadjusted; (2) age-adjusted model. Effect sizes are depicted as odds ratio (OR) and 95% confidence interval (CI). For continuous variables, effect sizes were calculated per standard deviation change. A p-value of <0.05 indicated statistical significance. All analyses were performed using PASW Version 21.0 (IBM SPSS, Chicago, IL, USA).

3. Results

3.1. Baseline and procedural characteristics

Between January 2017 and December 2018, a total of 64 patients underwent high-risk interventional procedures with Impella 2.5 support. Baseline characteristics are given in Table 1.

Table 1
Baseline characteristics.

	All (n = 64)	LVEDP < 15 mm Hg (n = 26)	LVEDP ≥ 15 mm Hg (n = 38)	p-value
Age [yrs], mean ± SD	73 ± 10	71 ± 11	75 ± 10	0.13
Male gender, n (%)	51 (80)	20 (77)	31 (82)	0.66
Body mass index [kg/m^2], mean ± SD	27 ± 5	28 ± 5	27 ± 5	0.72
Logistic EuroSCORE [%], mean ± SD	11 ± 14	7 ± 5	18 ± 15	0.03
SYNTAX I score [%], mean ± SD	34 ± 7	33 ± 8	34 ± 7	0.47
LV-EF [%], mean ± SD	39 ± 10	40 ± 8	39 ± 12	0.84
Prior stroke, n (%)	0	0	0	
Chronic obstructive pulmonary disease, n (%)	10 (16)	4 (15)	6 (16)	0.93
Peripheral artery disease stage, n (%)	18 (28)	6 (23)	12 (32)	0.43
Pulmonary hypertension, n (%)	3 (5)	1 (4)	2 (5)	0.26
Active infection/sepsis, n (%)	6 (9)	2 (8)	4 (11)	0.87
CAD with prior revascularization, n (%)	53 (83)	20 (77)	33 (87)	0.31
Coronary artery bypass grafting, n (%)	5 (8)	1 (4)	4 (11)	0.30
Prior cardiac surgery, n (%)	5 (8)	1 (4)	4 (11)	0.31
Atrial fibrillation, n (%)	9 (14)	3 (12)	6 (16)	0.59
Hypertension, n (%)	53 (83)	21 (81)	32 (84)	0.58
Diabetes mellitus, n (%)	24 (34)	13 (50)	11 (29)	0.08
Baseline creatinine [mg/dl], mean ± SD	1.38 ± 0.9	1.23 ± 0.4	1.49 ± 1.2	0.32

CAD: coronary artery disease; LVEDP: left ventricular end-diastolic pressure; LV-EF: left-ventricular ejection fraction.

The review of pump speed and motor current graphics revealed proper function of Impella pump in all the study procedures. The PCI procedure was successful in all cases, with a high rate of left-main interventions (Table 2). A multi-vessel PCI was performed in 89% of all procedures with a rate of complete revascularization in 86% of all procedures. No Rotablation was performed in our study. The median support time was 61 min. The measured LVEDP was elevated with 17 ± 8 mm Hg. LVEDP was not significantly higher in ACS patients (LVEDP in elective patients 16 ± 5 mm Hg vs. LVEDP in ACS patients 17 ± 10 mm Hg; p = 0.67). The two observed deaths were cardiovascular deaths at day 5 and 10 days after procedure. (Table 3).

3.2. Hemodynamic deterioration

Hemodynamic deterioration occurred in 33% (n = 21) of all patients but did not result in hemodynamic instability (Table 3). The main reason for hemodynamic deterioration was a systolic blood pressure drop often in combination with a loss of pulsatility during MCS. We observed no association between complexity of the PCI or procedure time and hemodynamic deterioration.

LVEDP was lower in patients with HD (14.6 ± 6.5 mm Hg) as compared to patients without HD (17.5 ± 8.8 mm Hg, p = 0.18). Likewise, LVEDP did not significantly differentiate in patients with and without in-hospital MACCE (LVEDP in patients with MACCE 17.3 ± 10.9 mm Hg vs. LVEDP in patients without MACCE 16.5 ± 8. 1 mm Hg; p = 0.87) (Fig. 1). For a more detailed analysis of the subgroups, we used a LVEDP cutoff of 15 mm Hg. Of course, the LVEDP differed between the groups (9 ± 4 mm Hg vs. 22 ± 6 mm Hg; p < 0.001), but only the logistic EuroSCORE was significantly higher in the group with LVEDP ≥15 mm Hg (7 ± 5% vs. 18 ± 15%; p = 0.03). Significant differences in rates of hemodynamic deterioration or MACCE were not observed (Table 3).

3.3. Regression analysis

In regression analysis, no association of LVEDP with hemodynamic deterioration was observed for unadjusted (OR [95% CI]: 0.95 [0.89–1.06], p = 0.18) and age-adjusted model (OR [95% CI]: 0.95 [0.88–1.03], p = 0.19). LVEDP was also not associated with in-hospital MACCE in unadjusted model (OR [95% CI]: 1.01 [0.88–1.16], p = 0.87) and upon age adjustment (OR [95% CI]: 1.03 [0.88–1.19], p = 0.71).

4. Discussion

The findings of our study are as follows: (i) periprocedural pressure decrease occurred in one third of all patients undergoing high-risk PCI but did not result in hemodynamic instability due to Impella support; (ii) high preprocedural LVEDP values were not associated with higher rate of periprocedural hemodynamic deterioration or MACCE.

In daily practice, an increasing number of high-risk PCIs are performed with mechanical circulatory support [5]. In these comorbid patients with severe coronary artery disease hemodynamic intolerance may occur, mostly due to procedure-related ischemia [17].

Table 2
Procedural data.

	All (n = 64)	LVEDP < 15 mm Hg (n = 26)	LVEDP ≥ 15 mm Hg (n = 38)	p-value
Acute coronary syndrome, n (%)	31 (48)	15 (58)	16 (42)	0.23
LVEDP [mm Hg], mean ± SD	17 ± 8	9 ± 4	22 ± 6	<0.001
Impella, n (%)	64 (1 0 0)	26 (1 0 0)	38 (1 0 0)	
Multi-vessel PCI	57 (89)	24 (92)	33 (87)	0.49
Residual SYNTAX I score <8%, n (%)	55 (86)	21 (81)	34 (89)	0.53
PCI left main artery, n (%)	50 (78)	21 (81)	29 (76)	0.68
PCI left anterior descending coronary artery, n (%)	59 (92)	23 (88)	36 (95)	0.37
PCI left circumflex coronary artery, n (%)	47 (73)	19 (73)	28 (74)	0.96
PCI right coronary artery, n (%)	7 (11)	4 (15)	3 (8)	0.35
PCI bypass graft, n (%)	2 (3)	1 (4)	1 (3)	0.79
Last remaining vessel, n (%)	3 (5)	2 (8)	1 (3)	0.36
Contrast agent [ml], mean ± SD	274 ± 105	272 ± 105	277 ± 107	0.86

LVEDP: left ventricular end-diastolic pressure; PCI: percutaneous coronary intervention.

Table 3
In-hospital major adverse cardiac and cerebrovascular events (MACCE) and adverse events.

	All (n = 64)	LVEDP < 15 mm Hg (n = 26)	LVEDP ≥ 15 mm Hg (n = 38)	p-value
Hemodynamic deterioration, n (%)	21 (33)	8 (31)	13 (34)	0.78
SBP drop <90 mm Hg, n (%)	19 (30)	7 (27)	12 (32)	0.53
Loss of pulsatility during MCS, n (%)	12 (19)	6 (23)	6 (16)	0.42
MACCE, n (%)	3 (5)	2 (8)	1 (3)	0.36
Stroke, n (%)	1 (2)	1 (4)	0	0.23
New myocardial infarction, n (%)	1 (2)	0	1 (3)	0.41
Death, n (%)	2 (3)	1 (4)	1 (3)	0.96
Acute kidney injury, n (%)	8 (13)	5 (19)	3 (8)	0.18
Vascular complications, n (%)	2 (3)	0	2 (5)	0.24
Coronary complications, n (%)	3 (5)	1 (4)	2 (5)	0.63

MCS: mechanical circulatory support; SBP: systolic blood pressure.

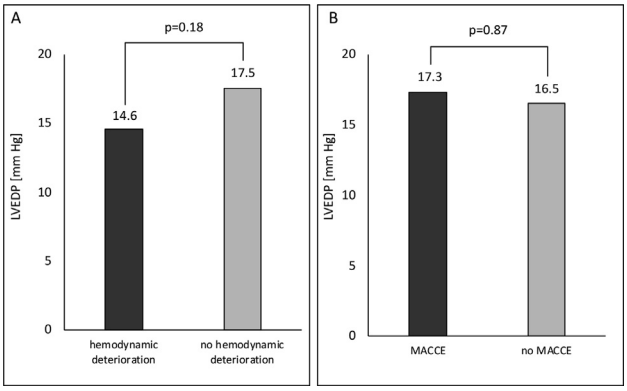

Fig. 1. Relationship between preprocedural left ventricular end-diastolic pressure (LVEDP) and (A) hemodynamic deterioration (B) major adverse cardiac and cerebrovascular events (MACCE).

LVEDP is often used as a decision-making aid but was never investigated in non-shock patients undergoing high risk PCI with MCS. With this study, we aimed to investigate the impact of preprocedural LVEDP on hemodynamics during PCI and short-term adverse events in non-shock patients.

The baseline characteristics of our study patients reflect a high-risk real-world population with high anatomical complexity, characterized by high SYNTAX I scores [19,20]. Moving toward the critical issue of hemodynamics behave during PCI, we noticed that 33% of all patients experienced a pressure decrease during the procedure. This observation supports the concept of systematic adequate cardiac output throughout the ischemic times induced by PCI manipulations. The observed pressure decrease or loss of pulsatility however, never reached critical levels as the used Impella device maintained stable systemic hemodynamics. The prognostic relevance of adequate blood pressures values is underlined by the inclusion of systolic or mean blood pressure in the major intensive care units risk scoring systems [21,22]. A complete revascularization was achieved in patients undergoing high-risk PCI with MCS support. Such complete revascularization with the need for extensive lesion preparation, difficulty to deliver balloons and stents, may increase the exposure of the at-risk myocardium to ischemia, exacerbate ventricular dysfunction, and result in the potential for hemodynamic collapse [10].

Elevated LVEDP, especially in light of compromised cardiac index/power, leaves the patient at risk for an ischemic spiral of hypotension as a result of reduced coronary perfusion, and patients fitting this profile are the most likely to benefit from the use of mechanical circulatory support during high-risk PCI [23]. The preprocedural measured LVEDP in our cohort was elevated (17 ± 8 mm Hg). However, a higher LVEDP was not associated with a higher rate of hemodynamic deterioration or a higher rate of in-hospital MACCE in our analysis.

LVEDP has predominantly a prognostic impact in emergency patients presenting with acute coronary syndrome (ACS). In patients presenting with STEMI LVEDP (cut-off 22 mm Hg) measured during primary PCI was an independent predictor of in-hospital (OR [95% CI]: 1.22 [1.02–1.46]) and longer term (OR [95% CI]: 1.40 [1.23–1.59]) cardiovascular outcomes [24]. In patients presenting with non-ST-segment elevation myocardial infarction LVEDP had a only prognostic impact regarding congestive heart failure readmission after ACS (LVEDP ≥26.5 mm Hg: OR [95% CI]: 6.65 [1.74–25.5]) [11]. On the contrary, LVEDP was not an independent predictor with respect to in-hospital mortality, one-year mortality and one-year ischemic complications. In our cohort 48% of all patients presented with an acute coronary syndrome and LVEDP was not significantly higher in ACS patients. In this special subgroup a higher LVEDP was also not associated with a higher rate of hemodynamic deterioration or a higher rate of in-hospital MACCE.

4.1. Limitations

The present study has several limitations. The analysis is based on a single-center cohort. Overall, our study is limited by number of patients. Therefore, these data should be considered hypothesis-generating. Our observational cross-sectional data can only report associations.

5. Conclusions

High preprocedural LVEDP values were not associated with higher rate of periprocedural hemodynamic deterioration or in-hospital MACCE. These data support the fact that LVEDP may not be used as a risk stratification variable for MCS usage in non-shock patients undergoing high-risk PCI.

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