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Improvement in LV end-diastolic pressure after primary PCI and its impact on patients' recovery

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Key words

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In this study, we evaluated the change in left ventricular end-diastolic pressure (LVEDP) after primary percutaneous coronary intervention (PCI) and its impact on in-hospital outcomes and 30-day and three-month quality of life (SAQ-7), ejection fraction (EF), and major adverse cardiovascular events (MACE). LVEDP ≥19 mmHg was taken as elevated LVEDP. In a sample of 318 patients, 18.9% (n=60) were females and mean age was 55.7 ± 10.52 years. Post-procedure elevated LVEDP was observed in 20.8% (n=66) with a mean reduction of 1.65 ± 4.35 mmHg. LVEDP declined in 39% (n=124) and increased in 10.7% (n=34). In-hospital mortality rate (9.1% *vs.* 2.4%, p=0.011), 30-day MACE (9.1% *vs.* 4.0%), and three-month MACE (21.2% *vs.* 5.6%) were found to be significantly higher among patients with elevated LVEDP, respectively. Elevated LVEDP was found to be associated with a reduced SAQ-7 score (89.84 ± 8.09 *vs.* 92.29 ± 3.03, p<0.001) and reduced (25–40%) EF (55.6% *vs.* 22.6%) at three-month follow-up. LVEDP declined acutely in a significant number of patients after primary PCI. Post-procedure elevated LVEDP was found to be associated with poor quality of life and an increased risk of immediate and short-term MACE.

Introduction

ST-elevation myocardial infarction (STEMI) is an acute ischaemic event associated with an increased risk of clinical complications, poor recovery, and adverse cardiovascular events.[1] Owing to the recent development and advancements in management, outcomes of STEMI patients have improved significantly.[2] Primary percutaneous coronary intervention (PCI) remains the recommended treatment option by both European and American clinical practice guidelines.[3,4]

In addition to improvements in the management strategy, risk stratification of patients with STEMI improved extensively with the introduction of various risk-stratification modalities.[5] Over the years, various biomarkers and clinical characteristics have been evaluated for their prognostic role, including gender, age, patient-related comorbid conditions, arrhythmias, location and size of the infarct, haemodynamic complications (cardiogenic shock), and ischaemic mitral regurgitation.[1] The prognostic role of left ventricular systolic dysfunction (i.e. left ventricular ejection fraction – LVEF) is well established for patients with STEMI.[6] However, the acute event of STEMI causes multiple functional and structural changes at the microcirculation level, which leads to elevated left ventricular end-diastolic pressure (LVEDP). Therefore, left ventricular diastolic dysfunction (i.e. LVEDP) recently gained attention as a prognostic marker for patients with STEMI.[7–10]

LVEDP is an integrative measure of total left ventricular function, and LVEDP change can be utilised as a significant prognostic indicator to guide medical therapy, and assess risk for post-STEMI adverse events. LVEDP is often measured during primary PCI, and a few studies have been conducted assessing the relationship between LVEDP and myocardial salvage.[11] Not many of these studies have been conducted in South Asia, particularly in Pakistan. Therefore, we aimed to assess the improvement in post-procedure LVEDP after PCI and its impact on short-term (three-month) outcomes in terms of quality of life (Seattle Angina Questionnaire [SAQ]-7), ejection fraction (EF), and major adverse cardiovascular events (MACE).

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Materials and method

Study setting

This descriptive observational cohort study was conducted at a tertiary care cardiac centre in Karachi, Pakistan. The study was approved by the ethical review board of the hospital (ERC/121/2021) and consent for participation in the study and follow-up was taken from all the patients. Study duration was between January 2022 and June 2022.

Study population

In this study, we included consecutive patients of a first acute event of STEMI, either gender, age ≥18 years, and undergoing primary PCI. Patients with a prior history of coronary artery disease (CAD) or heart failure (HF), patients in cardiogenic shock at the time of presentation to the emergency department, and patients with any structural abnormality that can potentially lead to an increase in LVEDP were excluded from this study.

According to the study conducted by Cap *et al.*,[12] the mean pre-primary PCI LVEDP was 22.1 ± 4.8 mmHg, and the post-primary PCI LVEDP was 19.4 ± 4.8 mmHg; using these statistics to test the hypothesis of significant post-procedure improvement in LVEDP at 5% level significance and 80% power of the test, the minimum required sample size for the study was calculated to be 27 patients. However, considering the expected three-month MACE rate of 15%, at a 95% confidence level (95%CI) and 4% margin of error, the sample size was calculated to be 307 patients. Hence, a total of 318 patients were recruited for this study.

Management and assessment of outcomes

As per the institutional protocol, all the primary PCI procedures were performed free of cost by the on-call team of interventional cardiologists. The pre- and post-LVEDP (mmHg) was measured for all patients as a measurement of pressure within the left ventricle following the completion of diastolic filling, just prior to systole. The primary end point of the study was the assessment of an improvement in post-procedure LVEDP. The secondary end point was the assessment of quality of life, improvement in EF (%), and MACE three months after the procedure.

Table 1. The comparison of clinical and demographic characteristics for patients with and without elevated left ventricular end-diastolic pressure (LVEDP) after primary percutaneous coronary intervention (PCI)

	Total	Post-procedure LVEDP		p value
		<19 mmHg	≥19 mmHg	
Total, N (%)	318	252 (79.2%)	66 (20.8%)	
Male, n (%)	258 (81.1%)	198 (78.6%)	60 (90.9%)	0.023
Female, n (%)	60 (18.9%)	54 (21.4%)	6 (9.1%)	
Height, mean ± SD cm	166.4 ± 8.42	165.49 ± 8.79	169.88 ± 5.61	<0.001
Weight, mean ± SD kg	69.8 ± 10.26	69.4 ± 10.19	71.3 ± 10.45	0.181
Age, mean ± SD years	55.7 ± 10.52	56.43 ± 10.77	52.94 ± 9.03	0.016
Systolic blood pressure, median (IQR) mmHg	130 (110–145)	130 (110–150)	120 (110–140)	0.018
Diastolic blood pressure, median (IQR) mmHg	80 (70–90)	80 (70–90)	80 (70–82)	0.245
Heart rate, median (IQR) bpm	86 (76–96)	84 (75–92)	88 (78–100)	0.069
Chest pain to ER time, median (IQR) minutes	240 (120–360)	233 (120–360)	240 (180–480)	0.094
ER to cath lab time, median (IQR) minutes	100 (65–130)	100 (65–130)	100 (60–130)	0.724
Killip class, n (%)				
I	252 (79.2%)	214 (84.9%)	38 (57.6%)	<0.001
II	42 (13.2%)	22 (8.7%)	20 (30.3%)	
III	24 (7.5%)	16 (6.3%)	8 (12.1%)	
Comorbid conditions, n (%)				
Hypertension	174 (54.7%)	132 (52.4%)	42 (63.6%)	0.102
Diabetes mellitus	120 (37.7%)	92 (36.5%)	28 (42.4%)	0.377
Smoking	94 (29.6%)	74 (29.4%)	20 (30.3%)	0.882
Family history of IHD	36 (11.3%)	28 (11.1%)	8 (12.1%)	0.818
Chronic kidney disease	6 (1.9%)	6 (2.4%)	0 (0%)	0.206
Type of myocardial infarction, n (%)				
Anterior	166 (52.2%)	122 (48.4%)	44 (66.7%)	0.068
Inferior	108 (34%)	90 (35.7%)	18 (27.3%)	
Inferior, posterior	18 (5.7%)	16 (6.3%)	2 (3%)	
Lateral	16 (5%)	16 (6.3%)	0 (0%)	
Posterior	8 (2.5%)	6 (2.4%)	2 (3%)	
Posterior, lateral	2 (0.6%)	2 (0.8%)	0 (0%)	

Key: CAD = coronary artery disease; ER = emergency room; IHD = ischaemic heart disease; IQR = interquartile range; LVEDP = left ventricular end-diastolic pressure; SD = standard deviation

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All the patients were followed, by telephone or physically, during their hospital stay, 30 days after discharge, and three months after discharge, and MACE, along with EF on transthoracic echocardiography (TTE) and quality of life using the SAQ-7 were assessed.

Measurements and definitions

STEMI was diagnosed based on positive electrocardiogram (ECG) findings at the time of presentation in the emergency department and a history of typical chest pain for at least 20 minutes. The positive ECG changes included ST-elevation in at least two contiguous leads >2 mm in men or >1 mm in women in leads V2 to V3, and/or >1 mm in other contiguous chest leads or limb leads. In-hospital outcomes included emergency coronary artery bypass grafting (CABG), major bleeding (requiring blood transfusion), stent thrombosis, cerebrovascular accident (CVA)/stroke, and death. The 30-day and three-month cumulative MACE included in-hospital all-cause death, post-discharge all-cause death, re-infarction/myocardial infarction, repeat revascularisation, and hospitalisation due to heart failure.

Data analysis procedure

The total SAQ-7 score was computed as an average of seven elements re-scaled to 0 to 100 from a scale of 1–6 for five elements and 1–5 for two elements. The SAQ score was categorised as fair (<50), good (50–75), and excellent (75–100). The EF was categorised as 25–40%, 41–50%, and more than 50%. Although multiple cut-off values for LVEDP have been used in the literature, a cut-off value of LVEDP >18 mmHg (i.e. ≥19 mmHg) has proven to be a significant predictor of MACE following primary PCI;[10] therefore, we categorised patients into two groups with LVEDP ≥19 mmHg as criterion for elevated LVEDP. Clinical characteristics and outcomes were compared between the two groups with the help of appropriate independent sample *t*-test/Mann-Whitney U-test or Chi-square test/Fisher's exact test at a 5% level of significance using IBM SPSS version 21.

Table 2. The comparison of angiographic findings for patients with and without elevated LVEDP after primary PCI

	Total	Post-procedure LVEDP		p value
		<19 mmHg	≥19 mmHg	
Total, N (%)	318	252 (79.2%)	66 (20.8%)	
Pre-procedure LVEF, mean ± SD %	40.25 ± 9.12	41.98 ± 7.76	33.64 ± 10.83	<0.001
Pre-procedure LVEDP, mean ± SD mmHg	17.25 ± 5.97	15.88 ± 5.71	22.45 ± 3.67	<0.001
Fluoroscopy times, mean ± SD minutes	13.85 ± 6.8	13.07 ± 6.04	16.8 ± 8.59	<0.001
Contrast volume, median (IQR) ml	100 (90–120)	100 (90–120)	100 (100–120)	0.208
Export catheter used, n (%)	16 (5%)	10 (4%)	6 (9.1%)	0.090
Pre-procedure TIMI flow grade, n (%)				
0	164 (51.6%)	116 (46%)	48 (72.7%)	0.001
I	26 (8.2%)	22 (8.7%)	4 (6.1%)	
II	72 (22.6%)	62 (24.6%)	10 (15.2%)	
III	56 (17.6%)	52 (20.6%)	4 (6.1%)	
Pre-procedure MBG grade, n (%)				
0	168 (52.8%)	116 (46%)	52 (78.8%)	<0.001
I	28 (8.8%)	22 (8.7%)	6 (9.1%)	
II	82 (25.8%)	76 (30.2%)	6 (9.1%)	
III	40 (12.6%)	38 (15.1%)	2 (3%)	
Number of involved vessels, n (%)				
Single-vessel disease	110 (34.6%)	92 (36.5%)	18 (27.3%)	0.369
Two-vessel disease	106 (33.3%)	82 (32.5%)	24 (36.4%)	
Three-vessel disease	102 (32.1%)	78 (31%)	24 (36.4%)	
Culprit vessel, n (%)				
Left anterior descending artery	168 (52.8%)	124 (49.2%)	44 (66.7%)	0.030
Right coronary artery	98 (30.8%)	86 (34.1%)	12 (18.2%)	
Left circumflex artery	46 (14.5%)	36 (14.3%)	10 (15.2%)	
Diagonal	6 (1.9%)	6 (2.4%)	0 (0%)	
Post-procedure TIMI flow grade, n (%)				
0	4 (1.3%)	4 (1.6%)	0 (0%)	0.038
I	4 (1.3%)	4 (1.6%)	0 (0%)	
II	12 (3.8%)	6 (2.4%)	6 (9.1%)	
III	298 (93.7%)	238 (94.4%)	60 (90.9%)	
Post-procedure MBG grade, n (%)				
0	0 (0%)	0 (0%)	0 (0%)	0.259
I	4 (1.3%)	4 (1.6%)	0 (0%)	
II	26 (8.2%)	18 (7.1%)	8 (12.1%)	
III	288 (90.6%)	230 (91.3%)	58 (87.9%)	
Post-procedure LVEDP, mean ± SD mmHg	15.59 ± 5.15	13.56 ± 3.16	23.33 ± 3.73	<0.001
Change in LVEDP, mean ± SD mmHg	–1.65 ± 4.35	–2.32 ± 4.58	0.88 ± 1.71	<0.001

Key: IQR = interquartile range; LVEDP = left ventricular end-diastolic pressure; LVEF = left ventricular ejection fraction; MBG = myocardial blush grade; SD = standard deviation; TIMI = thrombolysis in myocardial infarction

Results

A total of 318 patients were included in this study; the proportion of female patients was 18.9% (n=60), and the mean age of the study

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sample was 55.7 ± 10.52 years. Elevated post-primary PCI LVEDP was observed in 20.8% (n=66) of the patients. LVEDP declined (by at least 1 mmHg) in 39% (n=124), increased (by at least 1 mmHg) in 10.7% (n=34), and remained the same in the remaining 50.3% (n=160) of the patients. Post-procedure elevated LVEDP was found to be associated with male gender (90.9% *vs.* 78.6%, p=0.023) and Killip class II (30.3% *vs.* 8.7%) or III (12.1% *vs.* 6.3%, p<0.001) (**table 1**).

A mean reduction of 1.65 ± 4.35 mmHg in LVEDP was observed after the procedure compared with the pre-procedure LVEDP. Post-procedure elevated LVEDP was found to be associated with pre-procedure TIMI (Thrombolysis in Myocardial Infarction) flow grade 0 (72.7% *vs.* 46.0%), myocardial blush grade (MBG) 0 (78.8% *vs.* 46.0%), culprit left anterior descending artery (66.7% *vs.* 49.2%), elevated pre-procedure LVEDP (22.45 ± 3.67 *vs.* 15.88 ± 5.71 mmHg), and reduced LVEF (33.64 ± 10.83% *vs.* 41.98 ± 7.76%) (**table 2**).

In-hospital mortality rate (9.1% *vs.* 2.4%, p=0.011), 30-day MACE (9.1% *vs.* 4.0%), and three-month MACE (21.2% *vs.* 5.6%) were found to be significantly higher among patients with elevated LVEDP compared with patients with normal LVEDP level, respectively. Elevated LVEDP was also found to be associated with a reduced LVEF and SAQ-7 score at 30-day and three-month follow-ups (**tables 3 and 4**).

Discussion

The LVEDP measures total left ventricular function; it has been observed to be a significant marker of prognosis after acute myocardial infarction. In this study, we evaluated the change in LVEDP after primary PCI in patients with STEMI, and the association of post-procedure elevated LVEDP with quality of life and short-term major adverse outcomes. In summary, an improvement (decline of at least 1 mmHg) in LVEDP was observed in a significant number of patients after primary PCI. However, post-procedure elevated LVEDP manifestation of clinically adverse characteristics was found to be associated with male gender, Killip class II/III at presentation, total occlusion of the culprit artery with pre-procedure TIMI flow grade 0 and MBG grade 0, mainly culprit

Table 3. The comparison of post-procedure in-hospital, 30-day, and 3-month outcomes for patients with and without elevated LVEDP after primary PCI

	Total	Post-procedure LVEDP		p value
		<19 mmHg	≥19 mmHg	
Total, N (%)	318	252 (79.2%)	66 (20.8%)	
In-hospital outcomes, n (%)				
Successful procedure	312 (98.1%)	250 (99.2%)	62 (93.9%)	0.005
Discharged home	304 (95.6%)	244 (96.8%)	60 (90.9%)	0.037
Emergency CABG	2 (0.6%)	2 (0.8%)	0 (0%)	0.468
Stent thrombosis	0 (0%)	0 (0%)	0 (0%)	–
Major bleeding	0 (0%)	0 (0%)	0 (0%)	–
Stroke/CVA	0 (0%)	0 (0%)	0 (0%)	–
Death	12 (3.8%)	6 (2.4%)	6 (9.1%)	0.011
30-day outcome				
Available, N (%)	236 (74.2%)	188 (74.6%)	48 (72.7%)	0.756
LVEF %, n (%)				
Echo not done	40 (16.9%)	40 (21.3%)	0 (0%)	<0.001
25–40%	108 (45.8%)	72 (38.3%)	36 (75%)	
41–50%	48 (20.3%)	36 (19.1%)	12 (25%)	
>50%	40 (16.9%)	40 (21.3%)	0 (0%)	
SAQ-7 score, mean ± SD	91.16 ± 7.3	91.19 ± 7.55	91.07 ± 6.31	0.923
Fair: SAQ-7 score (≤50), n (%)	0 (0%)	0 (0%)	0 (0%)	0.562
Good: SAQ-7 score (51–75), n (%)	14 (5.9%)	12 (6.4%)	2 (4.2%)	
Excellent: SAQ-7 score (76–100), n (%)	222 (94.1%)	176 (93.6%)	46 (95.8%)	
3-month outcome				
Available, N (%)	204 (64.2%)	168 (66.7%)	36 (54.5%)	0.068
LVEF %, n (%)				
Echo not done	88 (43.1%)	80 (47.6%)	8 (22.2%)	<0.001
25–40%	58 (28.4%)	38 (22.6%)	20 (55.6%)	
41–50%	18 (8.8%)	12 (7.1%)	6 (16.7%)	
>50%	40 (19.6%)	38 (22.6%)	2 (5.6%)	
SAQ-7 score, mean ± SD	91.86 ± 4.44	92.29 ± 3.03	89.84 ± 8.09	<0.001
Fair: SAQ-7 score (≤50), n (%)	0 (0%)	0 (0%)	0 (0%)	0.086
Good: SAQ-7 score (51–75), n (%)	4 (2%)	2 (1.2%)	2 (5.6%)	
Excellent: SAQ-7 score (76–100), n (%)	200 (98%)	166 (98.8%)	34 (94.4%)	

Key: CABG = coronary artery bypass grafting; CVA = cerebral vascular accident; LVEDP = left ventricular end-diastolic pressure; LVEF = left ventricular ejection fraction; SAQ = Seattle Angina Questionnaire; SD = standard deviation

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Table 4. Major adverse cardiovascular events (MACE) at 30 days and 3 months for patients with and without elevated LVEDP after primary PCI

	Total	Post-procedure LVEDP		p value
		<19 mmHg	≥19 mmHg	
Total, N (%)	318	252 (79.2%)	66 (20.8%)	
30-day MACE, n (%)				
Lost to follow-up	70 (22%)	58 (23%)	12 (18.2%)	0.194
No	232 (73%)	184 (73%)	48 (72.7%)	
Yes	16 (5%)	10 (4%)	6 (9.1%)	
In-hospital mortality	12 (75%)	6 (60%)	6 (100%)	–
Post-discharge mortality	0 (0%)	0 (0%)	0 (0%)	
Hospitalisation due to HF	2 (12.5%)	2 (20%)	0 (0%)	
Repeat revascularisation	2 (12.5%)	2 (20%)	0 (0%)	
Re-infarction/MI	0 (0%)	0 (0%)	0 (0%)	
3-month MACE, n (%)				
Lost to follow-up	98 (30.8%)	78 (31%)	20 (30.3%)	<0.001
No	192 (60.4%)	160 (63.5%)	32 (48.5%)	
Yes	28 (8.8%)	14 (5.6%)	14 (21.2%)	
In-hospital mortality	12 (42.9%)	6 (42.9%)	6 (42.9%)	–
Post-discharge mortality	4 (14.3%)	0 (0%)	4 (28.6%)	
Hospitalisation due to HF	6 (21.4%)	4 (28.6%)	2 (14.3%)	
Repeat revascularisation	4 (14.3%)	4 (28.6%)	0 (0%)	
Re-infarction/MI	2 (7.1%)	0 (0%)	2 (14.3%)	

Key: HF = heart failure; LVEDP = left ventricular end-diastolic pressure; MACE = major adverse cardiovascular event; MI = myocardial infarction

left anterior descending artery, elevated pre-procedure LVEDP and reduced LVEF. The post-procedure elevated LVEDP was observed to be associated with an increased risk of in-hospital, as well as 30-day and three-month MACE, including all-cause mortality. It has also been associated with a decreased quality of life after three months of primary PCI.

The findings of an increased incidence of MACE during the short-term follow-up after primary PCI of patients with baseline or post-procedure elevated LVEDP are not new to our study. Multiple studies have reported similar observations.[7–12] However, poor quality of life among MACE-free patients with post-procedure LVEDP is a point of concern in these patients. Multiple studies have taken both LVEDP (diastolic dysfunction) and LVEF (systolic dysfunction) for the prediction of the short- and long-term fate of patients after primary PCI. A study conducted by Ndrepepa *et al.*[13] reported a ratio of LVEF/LVEDP as an independent and significant predictor of long-term (eight-year) mortality after primary PCI. This ratio has also proved a significant prognostic marker for the prediction of MACE during 43 ± 31 months follow-up after STEMI.[8] A LVEDP of >22 mmHg measured during primary PCI is found to be associated with an increased risk of mortality, congestive heart failure, and cardiogenic shock at 90 days after primary PCI.[14] Similar to these findings, Planer *et al.*[6] also reported baseline elevated LVEDP as an independent predictor of adverse outcomes on a short- and long-term basis. The association of elevated LVEDP with reduced myocardial salvage and the extent of the ischaemia can be a possible mechanism behind an increased risk of adverse outcomes in patients with STEMI.[11] Another index, derived as the ratio of systolic blood pressure to LVEDP, is reported to be an independent predictor of in-hospital mortality at the critical cut-off of ≤4.[15] Another combination of criteria of LVEDP >18 mmHg and index of microcirculatory resistance >32 has been found to have added advantage for detecting MACE among patients undergoing primary PCI.[10] Two of the recent studies from our population reported the prognostic role of elevated LVEDP. The first by Kumar *et al.*[1] reported LVEDP ≥20 mmHg as an independent predictor of short-term MACE after primary PCI with an adjusted hazard ratio (HR) of 1.81 (95%CI 1.3 to 2.51). The second study by Ammar *et al.*[16] reported LVEDP of ≥20 mmHg as an essential predictor of contrast-induced acute kidney injury after primary PCI, especially in patients with a LVEF ≤40%.

Similar to our finding regarding clinical co-variates of elevated LVEDP, Zhou *et al.*[17] reported that patients with elevated LVEDP had more frequently descending branches as infarct-related arteries, along with the larger left atrial end-systolic and diastolic diameter, higher levels of myocardial necrosis, regional wall motion abnormality, and small ejection fraction, along with the higher incidence of mortality and heart failure. Another study reported a significant relationship between elevated LVEDP and wire-crossing time among patients undergoing primary PCI.[18] Very limited data are available regarding the effective treatment options for reducing elevated LVEDP. In a study by Khan *et al.*,[9] the administration of furosemide along with glyceryl trinitrate was a safe and effective strategy for reducing LVEDP in STEMI patients. Similar to our findings of the decline of only 1.65 ± 4.35 mmHg, a study conducted by Khan *et al.*[7] too reported a marginal drop in LVEDP from 18 (interquartile range [IQR] 12 to 22 mmHg) pre-procedure to 15 (IQR 10 to 20 mmHg) post-procedure.

Even though this is the first study of its kind in the Pakistani population, some limitations

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have to be acknowledged, which included single-centre coverage, the observational nature of the study, the small sample size, and a high rate of loss to follow-up. Large-scale multi-centre studies are warranted to understand the prognostic role of LVEDP, and its association with the quality of life of patients on a long-term basis.

Conclusion

In conclusion, LVEDP declined acutely in a significant number of patients after primary PCI, but the quantum of decline was mostly marginal. Post-procedure elevated LVEDP was found to be associated with poor quality of life and an increased risk of immediate and short-term MACE. Further studies are required to formulate effective strategies for reducing LVEDP levels to minimise its detrimental effects on short- and long-term outcomes after primary PCI

Key messages

- Left ventricular end-diastolic pressure (LVEDP) declined acutely in a significant number of patients after primary percutaneous coronary intervention (PCI), but the quantum of decline was mainly marginal
- Post-procedure elevated LVEDP was found to be associated with poor quality of life and an increased risk of immediate and short-term major adverse cardiovascular events (MACE)
- Further studies are required to formulate effective strategies for reducing LVEDP levels to minimise its detrimental effects on short- and long-term outcomes after primary PCI

Conflicts of interest

None declared.

Funding

None.

Study approval

This study was approved by the ethical review committee (ERC) of the National Institute of Cardiovascular Diseases (NICVD), Karachi (ERC-121/2021). Verbal informed consent was obtained from all the patients regarding their participation in the study and publication of data, while maintaining confidentiality and anonymity. Due to the observational nature of the study, ERC waived the written consent and verbal consents were approved by the ERC.

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