Predilation in Primary Percutaneous Coronary Intervention

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Abstract

Background: In primary percutaneous coronary intervention (pPCI), balloon predilation is frequently carried out before stenting but there is a lack of data regarding optimal balloon size and the effect of balloon size on procedural and clinical outcomes. **Aims:** This study compares small balloon predilation (≤50% of proximal vessel diameter) with large balloon predilation (>50% of proximal vessel diameter) in pPCI. **Methods:** This multicentre prospective observational study included consecutive ST elevation MI (STEMI) patients undergoing pPCI at three tertiary centres in Egypt. Demographic, clinical and angiographic data were collected for all the patients. The primary outcome was the presence of no reflow at the conclusion of the procedure and secondary outcomes included procedural complications – no reflow, dissection, abrupt vessel closure, fluoroscopy time and procedural time – and clinical outcomes – in-hospital left ventricular ejection fraction (LVEF), cardiogenic shock, stent thrombosis, ventricular fibrillation, stroke, death, ST-segment resolution >50% 1 hour after PCI and LVEF at discharge. **Results:** A total of 384 pPCI procedures were included. The small balloon group (n=222) and the large balloon group (n=162) were comparable in terms of baseline characteristics. The large balloon group had a significantly higher incidence of no reflow (n=23 [14.2%] versus n=6 [2.7%], p<0.001), procedural complications: n=31 [19.4%] versus n=10 [4.5%], p<0.001) and contrast volume (190.4 ± 40.2 ml versus 177.4 ± 29.4 ml, p=0.0003) compared to the small balloon group. ST-segment resolution >50% after PCI was more frequent in the small balloon group (n=182 [81.98%] versus n=109 [67.28%], p<0.001). **Conclusion:** This study suggests that using a smaller balloon size for predilation in pPCI is associated with improved coronary flow, reduced procedural complications and better ST-segment resolution.

Keywords

Balloon predilation, percutaneous coronary intervention, primary percutaneous coronary intervention

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Ethics: This study was approved by the ethical committee of Misr University for Science and Technology. The study was carried out according to the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Consent: Informed consent was obtained from all participants for participation in the study.

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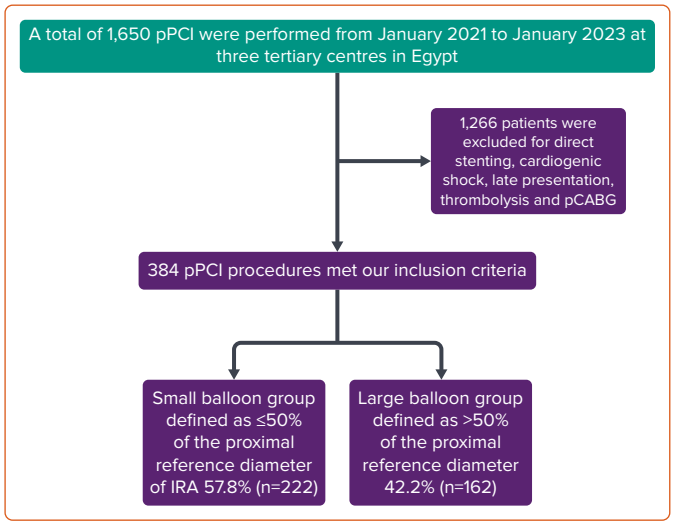
Primary percutaneous coronary intervention (pPCI) is widely acknowledged as the gold standard for the treatment of acute ST elevation MI (STEMI) as recommended by the European Society of Cardiology (ESC) and American College of Cardiology/American Heart Association (ACC/AHA) clinical guidelines.[1,2]

Direct stenting, a technique where stenting is performed without prior balloon predilation has advantages in terms of reduced procedure time, contrast volume and radiation exposure compared to cases where balloon predilation was performed. Furthermore, few prior studies have shown that direct stenting may be associated with improved clinical outcomes, including reduced rates of MI and mortality.[3–5]

However, direct stenting may not be feasible in all cases of pPCI, especially when there is inadequate visualisation of the distal vessel, severely calcified lesions, long diffuse lesions, lesions at a high degree of angulation and lesions with undefined thrombus burden.[6] Some studies have proposed the use of the 'bougie' or 'milking' technique of passing an uninflated balloon through the segment that is occluded by the thrombus to allow visualisation of the downstream artery and assessment of the culprit lesion, resulting in more frequent direct stenting. However, the success rate of this technique was at most 68% in arteries with ≤1 Thrombolysis in MI (TIMI) grade.[7]

In cases when balloon predilation is indicated in pPCI, data about appropriate balloon sizing and its subsequent impact on procedural and clinical outcomes are lacking, and practice varies according to the operator. While some recommend sizing the balloon >50% of the reference vessel diameter, others recommend a small balloon just to restore flow. The optimal predilation balloon size in relation to the

Figure 1: Flow Diagram for Study Participants



IRA = infarct-related artery; pCABG = primary coronary artery bypass graft; pPCI = primary percutaneous coronary intervention.

Table 1: Baseline Demographics and Clinical Characteristics in the Small Balloon Cohort versus the Large Balloon Cohort

Characteristics	Cohort		p-value
	Small Balloon (n=222)	Large Balloon (n=162)	
Age (years)	59.03 ± 7.77	60.10 ± 8.34	0.197*
Ethnicity			0.484†
• White	219 (98.6%)	161 (99.4%)	
• Black	3 (1.4%)	1 (0.6%)	
• Other	0	0	
Women	71 (32.0%)	49 (30.2%)	0.358†
BMI	31.2 ± 3.6	29.6 ± 2.99	**<0.001***
Diabetes	148 (66.7%)	98 (60.5%)	0.106†
Smokers	110 (49.5%)	86 (53.1%)	0.246†
Dyslipidaemia	97 (43.7%)	71 (43.8%)	0.489†
Chronic kidney disease	33 (14.9%)	22 (13.6%)	0.361†
Prior stroke	15 (6.8%)	9 (5.6%)	0.315†
Prior coronary artery disease	51 (23.0%)	32 (19.8%)	0.224†
Prior MI	12 (5.4%)	8 (4.9%)	0.419†
Prior coronary intervention	19 (8.6%)	13 (8.0%)	0.425†
Left ventricular ejection fraction	49.8 ± 9	51 ± 7.5	0.167*
Heart rate (BPM)	82 ± 14	79 ± 19	0.075*
Systolic blood pressure (mmHg)	139 ± 27	142±24	0.261*
Diastolic blood pressure (mmHg)	79 ± 16	81 ± 7	0.137*
Heart failure (Killip class at presentation)			0.19†
I	108 (48.6%)	70 (43.2%)	
II	68 (30.6%)	64 (39.5%)	
III	46 (20.7%)	28 (17.3%)	
IV	0	0	

*Data are presented as n (%) or mean ± SD. *Student's t-test of significance (t). †χ^2 test of significance. Significant p-values are in bold.*

reference diameter of the infarct-related artery (IRA) during pPCI is yet to be established.[6,8]

To address this gap in knowledge, this study aims to examine outcomes with small versus large balloon predilation during pPCI and determine whether either technique would be associated with improved outcomes with pPCI.

Methods

Study Approval

This study was approved by the ethical committee of Misr University for Science and Technology. This research project fully complies with the ethical principles outlined in the Declaration of Helsinki and informed consent was obtained from all human research subjects for participation in the study.

Study Population

The study was a multicentre prospective observational study that included all consecutive patients who presented with STEMI and met criteria for pPCI at three tertiary centres in Egypt from January 2021 to January 2023. Exclusion criteria included age <18 years or >90 years, cardiac arrest or life-threatening arrhythmias, cardiogenic shock, late presentation (>12 hours from onset of symptoms), those who received thrombolysis prior to pPCI, those who underwent direct stenting and/or thrombus aspiration, patients with previous coronary artery bypass graft (CABG), and those who declined or could not provide consent.

Demographic, clinical and angiographic data were collected for all patients. pPCI was carried out according to the 2018 ESC guidelines for management of STEMI. If needed, the diameter of predilation balloon used was left to the operator's discretion. Based on the diameter of balloon used relative to the angiographic proximal reference diameter of the infarct-related artery, the study population was divided into two groups: the small balloon group where the balloon was ≤50% of the proximal reference diameter of IRA, and the large balloon group where the balloon was >50% of the proximal reference diameter. Two independent operators who were blinded to the diameter of balloon used and to the final angiographic result of the procedure, analysed all diagnostic coronary angiograms to determine the proximal reference diameter of the IRA and discrepancies were resolved by consensus.

Outcomes

The primary outcome was presence of no reflow/slow flow at the conclusion of the procedure defined as TIMI flow <3. Secondary outcomes were procedural and clinical outcomes. Procedural outcomes included no reflow, dissection, abrupt vessel closure, fluoroscopy time and procedural time. While secondary in-hospital clinical outcomes included all-cause death, cardiogenic shock, acute stent thrombosis, ventricular arrhythmias, stroke, ST-segment resolution >50% 1 hour after PCI, and left ventricular ejection fraction (LVEF) before discharge.

Statistical Analysis and Sample Size

There were no national studies that evaluated the effectiveness of small versus large balloons in predilation during pPCI that had been published before or were currently in progress, so it was not possible to estimate the minimum anticipated observed effect size (correlation coefficient) so feasibility was used to determine the minimum sample size (number of study participants) that needed to be recruited.

Univariate distributions of all variables are described. Continuous variables are reported as means ± SD, or medians (IQR). Categorical variables are presented as frequencies and percentages. Comparisons between groups were performed using Pearson's χ^2 test for categorical

variables. Continuous variables were compared using Student's t-test; if data were not normally distributed, non-parametric Wilcoxon rank-sum test was used and p<0.05 was considered significant. All data were analysed and calculated using IBM SPSS 25.

Results

From January 2021 to January 2023, a total of 1,650 pPCI were performed at three tertiary centres in Egypt. Of those, 384 pPCI met our inclusion criteria (*Figure 1*). The mean age of the included cohort was 59.5 years, 31% (n=71) were women and 2% were black.

Among the total cohort, 222 patients (57.8%) underwent predilation using small balloons (<50% of proximal vessel diameter) while 162 patients (42.2%) underwent predilation using large balloons (≥50% of proximal vessel diameter). Both groups had similar demographics including age (59.0 ± 7.8 versus 60.1 ± 8.3), women (31.9% versus 30.2%), as well as major comorbidities, except for obesity which was more common in the small balloon group (31.2 ± 3.6 versus 29.6 ± 2.99, p<0.001) compared with the large balloon group (*Table 1*).

Periprocedural characteristics of all patients were recorded including type of access – femoral or radial, time from onset of symptoms, number of obstructed vessels, IRA artery, preinterventional TIMI flow, length of the culprit lesion, vessel diameter, thrombus grade, lesion characteristics, glycoprotein IIb/IIIa inhibitor therapy, balloon diameter and length, administration of intracoronary adenosine, number of stents placed, percentage of patients who received post-dilation, final inflation pressure, contrast volume and number of vessels with interventions (*Table 2*).

Regarding procedural characteristics, the balloon size was significantly smaller in the small balloon group (1.54 ± 4.3 mm versus 2.4 ± 0.7 mm; p<0.0001) versus the large balloon group. Contrast volume was significantly higher (p=0.0003) and glycoprotein IIb/IIIa inhibitor therapy administration was significantly more frequent (p=0.033) in the large balloon group versus the small balloon group. The rest of the periprocedural characteristics were similar in both groups (*Table 2*).

Regarding procedure outcomes, no reflow and slow flow were present more significantly in the large balloon group compared with the small balloon group (16.66% versus 9.46% with p=0.017) and the overall number of procedural complications was higher in the large balloon group compared with the small balloon group (19.4% versus 4.5%; p<0.001) (*Table 3*).

Procedural time and fluoroscopy time in the small balloon group were 34 ± 20 minutes and 7.2 ± 3.5 minutes, respectively, whereas longer durations were observed in the large balloon group 42 ± 18 minutes and 8.8 ± 3.3 minutes, respectively; p<0.001 (*Table 3*).

Secondary Outcomes

In-hospital events were comparable in both groups; however, ST-segment resolution after PCI was significantly more frequent in the small balloon group (p<0.001) (*Table 4*).

Discussion

Timely and successful restoration of blood flow using pPCI is crucial for reducing myocardial infarct size and improving outcomes in patients with STEMI. However, pPCI can be associated with a significant procedural challenge known as the no-reflow phenomenon which is believed to be caused by various underlying factors, including distal embolisation, injury from the restoration of blood flow and the vulnerability of the microcirculation in the coronary arteries.[5-9]

Besides adjunctive pharmacological treatments, such as vasodilators and/or glycoprotein IIb-IIIa inhibitors, efforts to improve PCI have focused on balloon design and technical advancements. Advanced

Table 2: Procedural Characteristics in Small Balloon Versus Large Balloon Cohorts

Characteristics	Cohort		p-value
	Small Balloon (n=222), n (%)	Large Balloon (n=162), n (%)	
Femoral access Radial access	133 (59.9%) 89 (40.1%)	105 (64.8%) 57 (35.2%)	0.328†
Time in minutes from onset of symptoms to reperfusion (first balloon)	202 ± 92	190 ± 104	0.233*
Number of vessels with obstructive disease	2.11 ± 1.31	2.3 ± 1.11	0.135*
IRA artery			
• Left main coronary artery	15 (6.8%)	12 (7.4%)	0.402†
• Left anterior descending/ diagonal artery	90 (40.5%)	68 (42.0%)	0.388†
• Left circumflex artery/ marginal branch	55 (24.8%)	33 (20.4%)	0.155†
• Right coronary artery	62 (27.9%)	49 (30.2%)	0.310†
TIMI flow pre-intervention			0.909†
• 0/1	186 (83.8%)	133 (82.1%)	
• 2	20 (9.0%)	16 (9.9%)	
• 3	16 (7.2%)	13 (8.0%)	
Lesion length (mm)	17.71 ± 9.67	19.1 ± 8.77	0.148*
Coronary artery diameter at the start of the procedure proximal to the culprit lesion (mm)	2.81±1.57	3.07 ± 0.97	0.0631*
Thrombus grade			0.308†
• 0/1	85 (38.3%)	71 (43.8%)	
• 2	40 (18.0%)	21 (13.0%)	
• 3	42 (18.9%)	24 (14.8%)	
• 4	55 (24.8%)	46 (28.4%)	
Lesion characteristics according to American Heart Association lesion classification[6]			**0.29**†
A B1 B2 C	0 40 (18.0%) 122 (55.0%) 60 (27.0%)	0 26 (16.0%) 81 (50.0%) 55 (34.0%)	
Glycoprotein IIb/IIIa inhibitor therapy	105 (47.3%)	92 (56.8%)	**0.033**
Balloon diameter	1.79 ± 0.4	2.4 ± 0.7	**<0.0001***
Balloon length	15.4 ± 4.3	16.5 ± 7.2	0.0628*
Intracoronary adenosine therapy	18 (8.1%)	11 (6.8%)	0.314†
Number of stents placed	1.28 ± 1.44	1.05 ± 1.29	0.107*
Post-dilation	59 (26.6%)	41 (25.3%)	0.389†
Final inflation pressure (kPa)	16.1 ± 5.4	17 ± 5.1	0.099*
Contrast volume (ml)	177.4 ± 29.4	190.4 ± 40.2	**0.0003***
Number of vessels intervened on	1.01 ± 0.31	1.04 ± 0.45	0.439*

*Data are presented as n (%) or mean ± SD. IRA = infarct-related artery; TIMI = Thrombolysis in MI. *Student's t-test of significance (t). †χ^2 test of significance. Significant p-values are in bold.*

Table 3: Procedural Outcomes in Small versus Large Balloons Cohort

Outcomes	RR [95% CI]		p-value
	Small Balloon	Large Balloon	
TIMI flow <3 by the end of the procedure	21 (9.5%)	27 (16.7%)	**0.017**†
Procedural complications	10 (4.5%)	31 (19.1%)	**<0.001**†
No-reflow	6 (2.7%)	23 (14.2%)	**<0.001**†
Abrupt closure	2 (0.9%)	3 (1.9%)	0.208†
Dissection	1 (0.5%)	3 (1.9%)	0.091†
Procedural time (minutes)	34 ± 20	42 ± 18	**<0.001***
Fluoroscopy time (minutes)	7.2 ± 3.5	8.8 ± 3.3	**<0.001***

*TIMI = thrombolysis in MI. *Student's t-test of significance (t). †χ^2 test of significance. Significant p-values are in bold.*

Table 4: Clinical Outcomes in Small versus Large Balloons Cohort before Hospital Discharge

Outcomes	RR [95% CI]		p-value
	Small Balloon	Large Balloon	
LVEF at discharge (%)	48.6 ± 7.7	49.2 ± 8.9	0.48*
Cardiogenic shock	17 (7.7%)	14 (8.6%)	0.363†
Acute stent thrombosis	0 (0%)	1 (0.6%)	0.56†
Ventricular arrhythmias	3 (1.4%)	2 (1.2%)	0.46†
Stroke	1 (0.5%)	0 (0.0%)	0.55†
All-cause death	2 (0.9%)	2 (1.2%)	0.375†
ST-segment resolution‡	182 (82.0%)	109 (67.3%)	**<0.001**†

*LVEF = left ventricular ejection fraction. *Student's t-test of significance (t). †χ^2 test of significance. ‡ST-segment resolution >50% after percutaneous coronary intervention. Significant p-values are in bold.*

balloons with improved trackability, flexibility and deliverability have been developed to enhance lesion preparation and precise positioning within the coronary artery, facilitating optimal stent deployment. Additionally, researchers have worked on optimising predilation protocols, exploring factors such as inflation pressure, duration and deflation techniques.[6-15] By modifying these parameters, clinicians aim to improve lesion preparation, minimise complications and enhance the overall efficacy of the procedure.

However, there remains a lack of sufficient data to evaluate the relationship between predilation balloon size and procedural and clinical outcomes in patients with STEMI treated with pPCI. This study aims to bridge the literature gap with the aim of enhancing procedural success rates, reducing complications and ultimately improving patient outcomes.

Our hypothesis suggests that employing a large-sized balloon during predilation may lead to substantial alterations in coronary haemodynamics, potentially causing distal embolisation and microcirculation dysfunction. These adverse effects have been linked to increased mortality rates. In contrast, using a smaller predilation balloon to visualise the length of the culprit lesion and the diameter of the downstream artery is expected to yield decreased fragmentation and dissemination of the thrombus. As a result, this approach is anticipated to reduce the risk of the no-reflow phenomenon.

However, the use of a large-sized balloon might lead to more significant changes in coronary haemodynamics due to distal embolisation and microcirculation dysfunction, which are associated with increased mortality rates.[16–20]

The primary finding of this study indicates that adopting a smaller balloon (≤50% of the proximal reference diameter of IRA) during predilation may be associated with a more favourable coronary flow compared to the flow achieved using a larger balloon. In this study, the periprocedural characteristics were comparable in both groups. However, it is worth noting that the larger balloon group were associated with a significantly higher contrast volume, procedural time and fluoroscopy time (p 0.0003, p<0.001 and p<0.001 respectively). Within this group, there was also a higher likelihood of glycoprotein IIb/IIIa inhibitor therapy administration. This observation may be attributed to a larger dissemination of thrombus in the coronary circulation. Additionally, this group was more likely to have a TIMI flow <III and showed a higher incidence of no reflow.

While most in-hospital clinical outcomes were similar in both groups, the rate for ST-segment resolution >50% after PCI was significantly higher in the small balloon group compared with the larger balloon group.

Our study has several notable strengths. It is the first of its kind to specifically compare predilation balloon sizes and their impact on procedural and clinical outcomes in patients undergoing primary PCI. This adds significant value to the existing literature. Our study provides preliminary evidence indicating that using predilation balloon sizes less than half the diameter of the infarct-related artery during pPCI may improve procedural and in-hospital clinical outcomes. By carefully selecting balloon sizes, we can potentially reduce complications associated with thrombus fragmentation and the occurrence of the no-reflow phenomenon, thereby improving patient outcomes.[21,22]

However, our study has some limitations; it did not include some variables that can alter our results such as number and duration of balloon inflations. Evidence from studies regarding coronary angioplasty agrees that balloon inflation lasting longer than 60 seconds seems to be linked to better immediate post-inflation outcomes.[13,23] Ischaemic conditioning is linked to better clinical and angiographical outcomes related to better lesion preparation and stenting outcomes.[24] However, the benefits of multiple balloon inflations are related to elective procedures without heavy thrombus burden and may cause worse distal embolisation and endothelial damage in pPCI patients. There are not enough data to provide guidance to practitioners about these different techniques for use in patients with acute MI. More research is needed to determine the ideal length of extended balloon inflation and to compare the different number of inflations. The authors suggest there should be more research on pPCI patients as they often undergo angioplasty.

It is important to acknowledge that our study is an observational one and has certain limitations. As with all observational studies, the potential for confounding variables and bias cannot be entirely ruled out. Therefore, larger, multicentre, randomised controlled trials are needed to further investigate and establish the precise relationship between balloon predilation size and clinical outcomes in STEMI patients treated with pPCI. These trials would provide more robust evidence and help guide clinical practice in optimising predilation balloon sizes for improved patient outcomes. ❑

Clinical Perspective

- Using a smaller balloon size (≤50% of vessel diameter) in primary percutaneous coronary intervention (PCI) is associated with better outcomes, including a lower incidence of 'no reflow'.
- Smaller balloons used for predilation can significantly reduce procedural complications, such as vessel dissection, abrupt closure and overall procedural complications.
- Patients in the small balloon group had a higher rate of ST-segment resolution >50% after PCI indicating better myocardial reperfusion.
- The smaller balloon size also resulted in a lower contrast volume used during the procedure, which may reduce contrast-induced nephropathy risks.
- The reduced risk of complications and improved ST-segment resolution suggest that smaller balloon predilation may lead to better in-hospital clinical outcomes, including preservation of left ventricular ejection fraction post-procedure.
- Recommendation for clinical practice: this study supports the use of smaller balloons for predilation in primary PCI, particularly in patients with ST-elevation MI, to improve procedural safety and myocardial recovery.

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