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Original article

Safety and Efficacy of Direct Stenting versus Balloon Pre-Dilatation in Patients with Chronic Coronary Syndrome

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Abstract

Background: Direct stenting (DS) or balloon pre dilatation according to scenarios of cases as in thrombotic lesions where operators usually attempt DS to avoid distal embolization and no-reflow, unless balloon pre-dilation is needed due to inadequate visualization of the distal vessels to deployment the stent In non-calcified , non-complex lesions the operator usually choose direct stent strategy but in lesions with high degree complexity and /or severe calcification usually needed balloon pre-dilatation before stent deployment. **Methods:** This randomized clinical trial study was conducted on 80 patients in the Cardiovascular Medicine Department of Matria Teaching Hospital (MTH) and Cardiovascular Department, Faculty of Medicine, Benha University. All studied cases were subjected to the following: Detailed history taking, including [Personal history, risk factors, family history, Clinical examination, Laboratory investigations included complete blood count (CBC), Creatinine, urea, and international normalized ratio (INR), Investigations included (12-lead electrocardiogram (ECG), echocardiography Complete comprehensive transthoracic echocardiographic examinations **Results**: At 3-months follow-up, Hb concentration was significantly lower in group 1 compared to group 2 (P=0.028), with no significant difference between both groups regarding serum creatinine level. Regarding the outcome at 3-months follow-up, recurrent symptoms were observed in 10 (25%) patients in group 1 and 7 (17.5%) patients in group 2, myocardial infarction occurred only in 1 (2.5%) patient in group 2, arrhythmia occurred in 2 (5%) patients in group 1 and 3 (7.5%) patients in group 2 and heart failure occurred in 7 (17.5%) patients in group 1 and 9 (22.5%) patients in group 2. No cases of death were observed in any of the studied groups. **Conclusion:** Direct stenting was associated with significantly shorter procedural times and a lower volume of contrast compared to the balloon pre-dilatation strategy. There was also a tendency toward lower hemoglobin Hb levels with direct stenting at 3-month follow-up; the clinical relevance of this finding remains unknown,

taking into account that there was no significant outcome difference between both strategies.

Keywords: Safety; Direct Stenting; Balloon Pre Dilatation; Chronic Coronary Syndrome.

Introduction

Percutaneous coronary intervention (PCI) is a common cardiac procedure and there have been significant advances in the technologies over past decades that have improved the safety of these procedures. The achievement of complete revascularization, appropriate technique for stent insertion and intracoronary imaging during these procedures also can have a significant impact on the clinical outcomes in symptomatized patient. Moreover, patients with coronary artery disease should be treated with appropriate medical therapy after the PCI [1].

Direct stenting reduces microcirculatory dysfunction compared with stenting that follows pre-dilation (CS). The index of microcirculatory resistance is a sensitive invasive marker of coronary micro-vascular resistance [2].

Direct Stenting associated with decreased distal embolization and improved reperfusion in patients with ST-segment elevation myocardial infarction [3].

Direct stenting or balloon pre dilatation according to scenarios of cases as in thrombotic lesions where operators usually attempt DS to avoid distal embolization and no-reflow, unless balloon pre-dilation is needed due to inadequate visualization of the distal vessels to deployment the stent In non-calcified , non-complex lesions the operator usually choose direct stent strategy but in lesions with high degree complexity and /or severe calcification usually needed balloon pre-dilatation before stent deployment [4]. The Direct stent implantation without balloon pre-dilatation in selected lesions may decrease the procedure time, radiation exposure time and cost [5].

The Balloon dilatation before stent implantation to facilitate passage and deployment of the stent but after Stent technology has changed tremendously resulting in stents with improved properties, which may allow stent placement without prior balloon dilatation [6].The selection coronary lesions without significant calcification the direct stenting may reduce costs, injury to the vessel wall and decreased utilization of contrast but, in general, does not significantly reduce procedure times [7].

Direct stenting strategy did not improve myocardial and pericardial reperfusion indexes, not recommended in all patients with acute myocardial infarction and associated with a higher incidence of in-stent restenosis but the balloon pre dilatation before stenting should be recommended in acute myocardial infarction [8].Direct stenting without balloon pre-dilatation decrease risk of extended dissections, decrease fluoroscopy exposure [9].

Coronary stenting is the primary therapeutic option for many coronary lesions, the direct stenting decrease duration of ischemia and reduce the risk of ischemic complications during balloon inflation by implanting the stent without previous dilatation of the lesion [10].

Chronic coronary syndrome is a pathological process characterized by atherosclerotic plaque accumulation in the coronary arteries. This process can be modified by lifestyle adjustments, pharmacological therapies and invasive interventions designed to achieve disease stabilization or regression. The disease can have long, stable periods, stable anatomical atherosclerotic and/or functional alternations of vessels and /or microcirculation according to recent guidelines [11].

This study aims to assess the safety and the efficacy of direct coronary stenting versus stenting with balloon pre-dilatation in patient with chronic coronary syndrome.

Patients and methods

This prospective randomized clinical trial study was conducted on 80 patients in the Cardiovascular Medicine Department of Matria Teaching Hospital (MTH) and Cardiovascular Department, Faculty of Medicine, Benha University in the duration from 2023 to 2024

An informed written consent was obtained from the patients. Every patient received an explanation of the purpose of the study and had a secret code number. The study was done after being approved by the Research Ethics Committee, Faculty of Medicine, Benha University (Approval code: MS 4-6-2023).

Inclusion criteria were patients with chronic coronary syndrome, age >18, and both sexes.

Exclusion criteria were patients above 75 years, patients with type (C) lesions [diffuse (>2 cm length) , chronic total occlusion >3 months old, excessive tortuosity of proximal segment, inability to protect major side branches, extremely angulated segments, >90°, and degenerated vein grafts with friable lesions], Patients with left main lesions, patients with very tortuous vessels, patients with acute coronary syndrome, patients with CKD (creatinine clearance less than 30 ml/min), and patients' refusal.

Randomization: The participants were randomized into two equal groups using a computer-generated list of random numbers sealed in an opaque envelope and were randomly allocated into two groups on a scale of 1:1. Patients are randomized into two groups: Group 1 (n=40): including patients with direct stenting in elective PCI. Group 2 (n=40): included patients with stenting with balloon pre-dilatation in elective PCI.

All studied cases were subjected to the following: Detailed history taking, including **[**Personal history: name, age, sex, occupation, residence, special habits of medical importance and marital status, Risk factors: hypertension (HTN), (DM), dyslipidemia, Previous IHD, Smoking, family history, Clinical examination, with particular emphasis on the pulse and blood pressure of the patients, as well as auscultation of the back to elicit the presence of any clinically detectable pulmonary diabetes mellitus venous congestion, auscultation of the heart for the presence of third heart sounds or audible murmurs and vital signs included (Heart rate: sinus tachycardia, heart rate more than 100 bpm and observed by patient says that he senses of his heart beats that he has not sense before that, Systolic blood pressure, diastolic blood pressure, oxygen saturation, and temperature). Laboratory investigations included complete blood count CBC (HB,

TLC, and Platelet), Creatinine, urea, and international normalized ratio (INR).

Investigations included (12-lead electrocardiogram (ECG), echocardiography Complete comprehensive transthoracic echocardiographic examinations were performed using a Philips EPIQ 7C machine with the S5-1 probe with simultaneous ECG signal. Subjects were examined in the left lateral decubitus position. Images obtained included 2D, color, pulsed-wave and continuous-wave Doppler. All echocardiographic examinations were obtained and recorded for offline analysis. It is used to assess rhythm, ischemic changes, arrhythmia, and ejection fraction (%), RWMA and chamber enlargement. The ejection fraction was measured according to the Simpson's method [12].

All patients underwent coronary angiography and PCI finding, Coronary angiography remains the standard for the diagnosis and treatment of coronary artery disease within the cardiac catheterization lab, many lesions required more investigation to determine their overall significant in causing symptoms and direct measurement coronary flow (Unlu and Fahed, 2023). All patients received 300 mg of clopidogrel and then 75 mg/d in addition to 150 mg/d of aspirin. The rest, however, were treated using regularly applied techniques. Patients in group I received a direct stent, while the predisposition of the balloon with a 2×15 mm mercury balloon was mandatory before stent placement in group II.

All patients were treated with a single eluting drug or bare metal stents. A subsequent dilatation was performed with the same stent balloon to optimize the angiographic deployment, especially in case of any insufficient deployment. During the procedure, boluses of intravenous heparin were administered. The PCI vessel was identified as LAD, LCX or RCA. The use of intravenous lIb / IlIa glycoprotein inhibitors was at the discretion of the operator and was observed if it was administered. The posterior dilation, the fluoroscopy time, the procedure time, the amount of contrast used, the success of the procedure, the involvement of the lateral branch, the slow flow was recorded in the proforma. To assess the safety and efficacy (composite of total procedural time, contrast volume, or TIMI-flow grade **[13]**).

Follow up: After 3 months, death, recurrent symptoms, reinfarction, arrhythmia, and HF were evaluated.

Co-primary endpoint included safety (composite of intra-procedural complications as dissection, No-reflow, side-branch compromise, or perforation), and efficacy (composite of total procedural time, contrast volume, or TIMI-flow grade).

Sample size

The sample size was calculated using G*power software version 3.1.9.2 based on a previous study done by Shahzad et al., who reported an effect size of fluoroscopy time of 0.8 between the studied groups. The total sample size was 80 patients (40 per group). Alpha and power were adjusted at 0.05 and 0.95, respectively [14].

Statistical analysis

Statistical analysis was done by SPSS v28 (IBM Inc., Armonk, NY, USA).

Quantitative variables were presented as mean and standard deviation (SD) and compared between the two groups utilizing unpaired Student's t- test. Qualitative variables were presented as frequency and percentage (%) and were analyzed utilizing the Chi-square test or Fisher's exact test when appropriate. A two tailed P value < 0.05 was considered statistically significant.

Results

In this study, 119 patients were assessed for eligibility, 27 patients did not meet the criteria and 12 patients refused to participate in the study. The remaining 80 patients were randomly allocated into two groups (40 patients in each). All allocated patients were followed-up and analyzed statistically. **Figure 1**

Regarding the demographic data (age and sex) there was an insignificant difference between both groups. There was an insignificant difference between both groups regarding the risk factors including smoking, family history, diabetes mellitus, hypertension, and past history of IHD. Regarding clinical examination of vital signs revealed that HR, SBP, DBP, RR and pSo2 were insignificantly different between both groups. **Table 1**

Regarding the laboratory investigation there was an insignificant difference between both groups including Hb, platelets, TLC, serum creatinine, urea and INR. Electrocardiography findings (sinus rhythm, ischemic changes, and arrhythmia) were insignificantly different between both groups. The Echocardiography findings revealed that EF, RWMA and chamber enlargement were insignificantly different between both groups. **Table 2**

The total procedural time and contrast volume were significantly lower in group 1 compared to group 2 (P<0.001). There was an insignificant difference between both groups regarding the grade and mean TIMI-flow. Regarding the intra-procedural complications, no-reflow occurred only in 1 (2.5%) patient in group 2 and side branch compromise occurred in 11 (27.5%) patients in group 1 and 8 (20%) patients in group 2. Dissection and perforation were not observed in any of the studied groups. There was an insignificant difference between both groups regarding the incidence of no-reflow and side branch compromise. **Table 3**

At 3-months follow-up, Hb concentration was significantly lower in group 1 compared to group 2 (P=0.028), with no significant difference between both groups regarding serum creatinine level. Regarding the outcome at 3-months follow-up, recurrent symptoms were observed in 10 (25%) patients in group 1 and 7 (17.5%) patients in group 2, myocardial infarction occurred only in 1 (2.5%) patient in group 2, arrhythmia occurred in 2 (5%) patients in group 1 and 3 (7.5%) patients in group 2 and heart failure occurred in 7 (17.5%) patients in group 1 and 9 (22.5%) patients in group 2. No cases of death were observed in any of the studied groups.

There was an insignificant difference between both groups regarding the outcome at 3 months' follow-up including recurrent symptoms, myocardial infarction, arrhythmia, and heart failure. **Table 4**

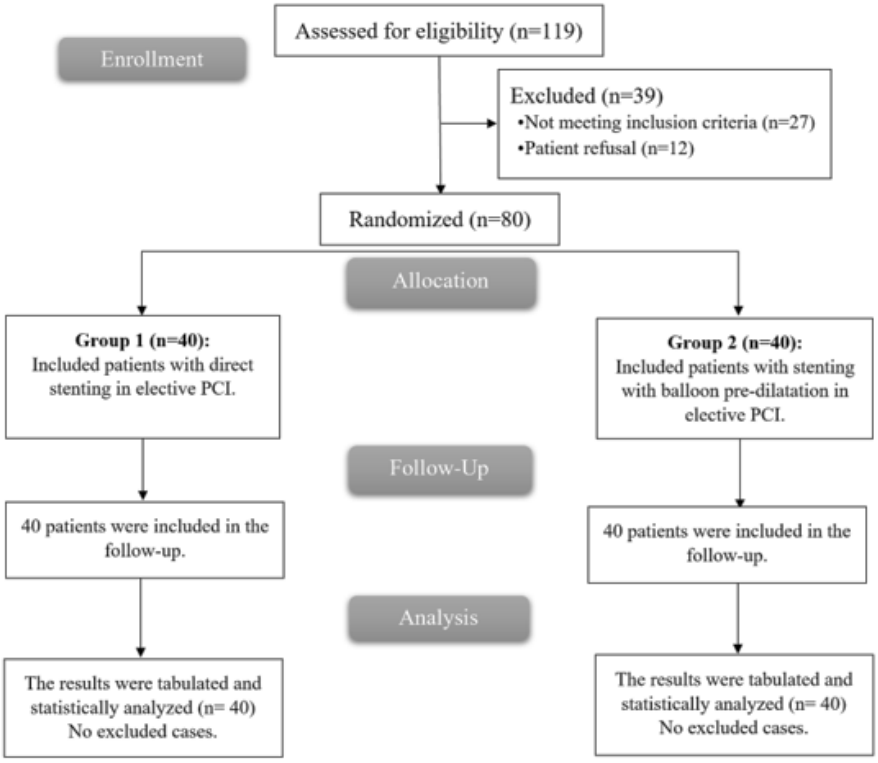

Figure 2: CONSORT flowchart of the enrolled patients

Table 1: Demographics, risk factors and clinical examination of vital signs of the studied groups

		Group 1 (n=40)	Group 2 (n=40)	P value
Age (years)		56.1 ± 9.26	55.3 ± 10.77	0.731
Sex	**Male**	25 (62.5%)	26 (65%)	0.816
	Female	15 (37.5%)	14 (35%)	
		Risk factors		
Smoking		21 (52.5%)	24 (60%)	0.499
Family history		2 (5%)	2 (5%)	1.00
Diabetes mellitus (DM)		18 (45%)	25 (62.5%)	0.116
Hypertension (HTN)		19 (47.5%)	23 (57.5%)	0.370
Past history of IHD		23 (57.5%)	17 (42.5%)	0.180
		Clinical examination of vital signs		
HR (beats/min)		74.6 ± 4.72	75.7 ± 5.71	0.362
SBP (mmHg)		123.3 ± 10.23	126.5 ± 10.99	0.175
DBP (mmHg)		78.8 ± 6.48	80.3 ± 6.98	0.322
RR (breaths/min)		20.4 ± 1.58	20.3 ± 1.57	0.724
pSo2 (%)		97.15 ± 1.33	96.88 ± 1.40	0.371

Data presented as mean ± SD. IHD: ischemic heart disease, HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, RR: respiratory rate, pSo2: partial O2 saturation.

Table 2: Laboratory investigations, electrocardiography and echocardiography of the studied groups

	Group 1 (n=40)	Group 2 (n=40)	P value
Hb (g/dL)	12.1 ± 1.46	12.8 ± 1.69	0.052
Platelets (*10^9/L)	291.9 ± 75.86	267.8 ± 86.75	0.188
TLC (*10^9/L)	7.8 ± 2.89	8.1 ± 2.82	0.705
Serum creatinine (mg/dL)	1.08 ± 0.19	0.99 ± 0.2	0.058
Urea (mg/dL)	36.7 ± 8.19	36.5 ± 10.33	0.924
INR	1.13 ± 0.2	1.06 ± 0.09	0.064
Electrocardiography			
Sinus rhythm	40 (100%)	40 (100%)	---
Ischemic changes	39 (97.5%)	39 (97.5%)	1.0
Arrhythmia	0 (0%)	2 (5%)	0.494
Echocardiography			
EF (%)	53.38 ± 7.31	54.65 ± 8.13	0.463
RWMA	34 (85%)	33 (82.5%)	0.762
Chamber enlargement			
Left ventricle	3 (7.5%)	2 (5%)	1.0

Data presented as mean ± SD, Hb: hemoglobin, TLC: total leukocyte count, INR: international normalized ratio, EF: ejection fraction, RWMA: regional wall motion abnormality.

Table 3: Angiography and procedural and Intra-procedural complications of the studied groups

		Group 1 (n=40)	Group 2 (n=40)	P value
Total procedural time (min)		27.0 ± 4.36	38.0 ± 7.23	**<0.001***
Contrast volume (ml)		482.8 ± 90.78	885 ± 112.77	**<0.001***
TIMI-flow grade	**TIMI II**	2 (5%)	1 (2.5%)	1.00
	TIMI III	38 (95%)	39 (97.5%)	
Intra-procedural complications				
Dissection		0 (0%)	0 (0%)	---
No-reflow		0 (0%)	1 (2.5%)	1.00
Side branch compromise		11 (27.5%)	8 (20%)	0.431
Perforation		0 (0%)	0 (0%)	---

Data presented as NO (%) or mean ± SD

Table 4: Laboratory findings at 3-months follow-up and Outcome at 3-months follow-up of the studied groups

	Group 1 (n=40)	Group 2 (n=40)	P value
Hb (g/dL)	11.49 ± 0.99	12.0 ± 1.05	**0.028***
Serum creatinine (mg/dL)	1.17 ± 0.12	1.17 ± 0.14	0.864
Outcome at 3-months follow-up			
Death	0 (0%)	0 (0%)	---
Recurrent symptoms	10 (25%)	7 (17.5%)	0.412
Myocardial infarction	0 (0%)	1 (2.5%)	1.00
Arrhythmia	2 (5%)	3 (7.5%)	1.00
Heart failure	7 (17.5%)	9 (22.5%)	0.576

Data presented as mean ± SD, Hb: hemoglobin, *: statistically significant as p value <0.05.

Discussion

Stents are now used in up to 95% of all PCI procedures. Increases in stent and balloon applicative procedures have allowed the development of direct stent strategy DS (stent delivery without prior dilation) instead of conventional stenting (CS), which is the implantation of a stent after balloon pre-dilation [15].

Several studies have shown that this technique is feasible and safe in selected cases, resulting in reduced procedure costs, duration, and exposure to radiation. However, in randomized trials, the DS technique showed results similar to the standard CS for long-term clinical outcome [14]. This technique is advantageous by saving the time of fluoroscopy and procedure, the amount of contrast agents and using fewer balloons. A possible disadvantage of this approach is limited visualization due to the decrease in distal contrast leakage through the unilateral lesions that can hinder the stent positioning and the appropriate choice of its dimensions. Other drawbacks may be the incomplete deployment of the stent, the loss and displacement of the stent in the un-dilated lesion, and the impossibility of crossing the lesion [16].

Previous study found that there was only significant difference between genders in both groups ($p<0.005$) but there was no significant difference regarding mean age, diabetic mellitus, hypertension, smoking, dyslipidemia, and family history of ischemic heart disease between two groups [14].

In the present study, it was found that HR, SBP, DBP, RR and pSo2 Hb, platelets, TLC, serum creatinine, urea, INR, sinus rhythm, ischemic changes, and arrhythmia, EF, RWMA and chamber enlargement were insignificantly different between both groups.

In the present study, it was found that there was total procedural time and contrast volume were significantly lower in group 1 compared to group 2 ($P<0.001$). There was an insignificant difference between both groups regarding the grade and mean TIMI-flow. Regarding the intra-procedural complications, no-reflow occurred only in 1 (2.5%) patient in group 2 and side branch compromise occurred in 11 (27.5%) patients in group 1 and 8 (20%) patients in group 2. Dissection and perforation were not observed in any of the studied groups.

A study by **Kumar et al,** [14] highlighted that there was no significant difference in treatment of vessels and different types of stents. Fluoroscopic time was significantly lower in group I as compared to group II (6.7 ± 3.8 vs 4.1 ± 2.5; p-value<0.005. **Martinez-Elbal et al,** [17] revealed that there was no difference in the distribution of treated vessels, type of lesion (ACC/AHA classification) or vessel tortuosity between the two groups. There was no significant difference in vessel reference diameter, minimal lumen

diameter, percentage of diameter stenosis and acute gain, and there was no difference in the distribution of treated vessels, type of lesion (ACC/AHA classification) or vessel tortuosity between the two groups. There was no significant difference in vessel reference diameter, minimal lumen diameter, percentage of diameter stenosis and acute gain **[17]**.

The revealed that there was reduced fluoroscopy and procedural time, number of guiding catheters and contrast quantity used in DS group. Direct stent implantation resulted in a significantly reduced overall procedural times (15.2 (12.3) minutes in direct *v* 18.7 (10.8) minutes in optional stenting, p = 0.043) and fluoroscopy times (2.3 (3.1) minutes in direct *v* 3.5 (2.8) minutes in optional stenting, p = 0.0069). The amount of contrast medium used was also reduced in the direct stenting group (61 (21) ml in direct *v* 73 (32) ml in optional stenting, p = 0.0034), as was the number of angioplasty catheters used (1.1 (1.1) in direct *v* 1.7 (1.1) in optional stenting, p = 0.003) [18]. (Sub) acute vessel occlusion complicating coronary intervention occurred more often in the conventional angioplasty group (3 *v* 0 in the direct stenting group, p = 0.13). The incidence of post procedural and overall myocardial infarction also differed between the groups, but these differences were not significant. No patient underwent acute coronary bypass surgery. One patient in the optimal angioplasty group underwent elective bypass surgery for failed angioplasty. No patient died during follow up. Five patients in the direct stenting group were reallocated to the conventional angioplasty group [18].

In study by **Stys et al,** [19] and colleagues with 128 patients revealed the success rate was 99% with direct stent technique without major procedural complications. Six-month follow-up also showed statistically insignificant main the main general adverse cardiovascular events concluding better long-term outcome comprising low complication and better success rate.

A previous study stated that showed that regarding angiographic measurements there were no differences in terms of stent diameter, stent length, maximal stent inflation pressure, and stent inflation time between both strategies. Most lesions required only 1 stent (p< 0.62). Case duration and radiation exposure in group A (42.1 18.7 and 10.3 7.7 minutes, respectively) were significantly lower compared with group B (51.5 23.8 and 12.5 6.4 minutes, respectively; p< 0.004 for case duration and p > 0.002 for fluoroscopic time). There was a significant difference in favor of direct stenting in the amount of contrast dye used (p< 0.0001). One hundred seventy-one patients were treated in group A by direct stenting. Initial deployment was successful in 162 patients (95%. In 9 cases of direct attempted stenting, the stent failed to pass through the stenosis and was successfully retrieved in the guiding catheter. These lesions were successfully stented following predilation (crossover rate 5%). Only 1 patient of

group A (0.6%) developed a distal dissection requiring the deployment of a second stent. In group B, a dissection occurred in 7 patients (4.9%) following predilation treated successfully with stent implantation in all cases. No flow occurred in 2 cases of each group [20].

In the present study, it was found that at 3-months follow-up, Hb concentration was significantly lower in group 1 compared to group 2 (P=0.028), with no significant difference between both groups regarding serum creatinine level, recurrent symptoms, myocardial infarction, arrhythmia, and heart failure.

In a study by **Martinez-Elbal et al,** [17] comparing these techniques concluded that in selected coronary cases, the DS is as safe and composite outcome as midterm clinical outcome where in the first month after hospital discharge, five patients (all in the pre-dilated group) underwent repeat cardiac catheterization because of chest pain. None of them showed restenosis or new coronary lesions. The 6-month mortality rate was 0·5% (one patient) in the direct stenting group and 1% (two patients) in the pre-dilated group (P=ns). One patient (pre-dilated group) died due to an acute myocardial infarction. In the other two patients' death was due to non-cardiac causes. Four patients developed an acute myocardial infarction, one in the direct stenting group and three in the pre-dilated group (P=ns). Fifty-one patients underwent coronary revascularization, two with CABG and 49 with PTCA (26 patients [12·4%] in the direct stenting group, and 24 patients [11·6%] in the pre-dilated group; P=ns). There was no significant difference in the total number of major adverse coronary events between the two groups.

This study has some limitations including small sample size, single center study, and short follow- up duration.

Recommendations included provide larger sample size with multicenter cooperation to validate our results, provide a longer follow-up period (e.g. 6 months), and further research is recommended to generalize our results and well mentioned our results.

Conclusion

The present study demonstrated that direct stenting was associated with significantly shorter procedural times and a lower volume of contrast compared to the balloon pre-dilatation strategy. There was also a tendency toward lower Hb levels with direct stenting at 3-month follow-up; the clinical relevance of this finding remains unknown, considering that there was no significant outcome difference between both strategies.

List of abbreviations:

CBC	Complete blood count
DBP	Diastolic blood pressure
DM	Diabetes mellitus
DS	Direct stenting
ECG	12-lead electrocardiogram
EF	Ejection fraction
Hb	Hemoglobin
HR	Heart rate
HTN	Hypertension
IHD	Ischemic heart disease
INR	International normalized ratio
INR	International normalized

PCI	Percutaneous coronary intervention
RR	Respiratory rate
RWMA	Regional wall motion abnormality
SBP	Systolic blood pressure
STEMI	ST-segment elevation myocardial infarction
TLC	Total leukocyte count

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