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Rohit Mody *

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Research Article

Clinical Outcomes of Direct or Direct like Stenting in Patients Undergoing Primary Pci for Stemi

Rohit Mody [1*], Debabrata Dash [2], Bhavya Mody [3], Ankit Agrawal [4], Inderjeet Singh Monga [5], Lakshay Rastogi [6]

[1] Department of Cardiolgoy, Max Super Specialty Hospital, Bathinda, Punjab, India.

[2] Department of cardiology, Aster Hospital, Mankhool, Dubai, Al Quasis, UAE.

[3] Department of Medicine, Kasturba Medical College, Manipal, Karnataka, India.

[4] Department of Cardiology, Cleveland Clinic, 9500 Euclid Avenue Cleveland, Ohio 44195, USA.

[5] Department of Cardiology, Command Hospital Chandimandir, Panchkula, Haryana, India.

[6] Department of Cardiology, MBBS, Kasturba Medical College, Manipal, India.

***Corresponding Author:** Rohit Mody, House no. 438, Model Town Phase 2, Near Model Town Phase 2 Market, Bathinda - 151001, Punjab, India.

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Abstract

Background

Significant Improvement in reperfusion markers is observed by direct stenting (DS) in patients with ST-elevation myocardial infarction (STEMI) undergoing percutaneous coronary intervention. However, clinical outcomes are variable, and information on the number of patients with STEMI who can be treated with DS or direct-like stenting is lacking.

Aim

To determine the feasibility and clinical outcomes of DS or direct-like stenting in patients with acute STEMI

Methods

This single-center and retrospective clinical study analyzed data from 514 patients admitted to the hospital with STEMI from October 2016 to March 2021. Most of these patients were treated with DS or direct-like stenting, and the operator was as direct as possible in performing the procedure. The outcomes were noted at the 2-year follow-up, and the incidence of on-table complications was analyzed.

Results

The total motality was 11.2% and the major adverse cardiac events (MACE) were seen in 13.62% at the 2-year follow-up. The post-procedural thrombolysis in myocardial infarction grade 3 flow was achieved in >86% of patients. A lower risk of edge dissection was observed. Our study revealed that DS reduced radiation exposure time, procedure time, and contrast volume used. Patients with cardiogenic shock have worst outcomes than patients with normal hemodynamics. It is a well-known fact that the cardiogenic shock patients have worst outcomes than normal hemodynamic patients. We analyzed this group of patients separately, so as to see the still better outcomes with DS in this high-risk sub-set of patients.

Conclusions

Study results demonstrated that DS or direct-like stenting is a quite promising method in most patients with STEMI and causes fewer on-table complications. Additionally, it supports the hypothesis that DS may result in better 2-year follow-up results.

Keywords: stemi; drug-eluting stent; death, stroke; myocardial infarction; stent thrombosis

Introduction

The primary percutaneous coronary intervention strategy is the preferred method for restoring blood flow in cases of ST-elevation myocardial infarction (STEMI). However, unanswered questions remain about potential complications such as reperfusion injuries [1], the no-reflow phenomenon, and distal microvascular embolization. Thus, newer strategies are being explored, such as direct stenting (DS), to address these issues [2]. DS is a technique where the stent compresses the loose material of the plaque and thrombus to prevent distal embolization [3]. A recent meta-analysis of five small trials revealed that DS improved reperfusion [4] and reduced the no-reflow phenomenon and in-hospital mortality, but the sample size was too small to draw firm conclusions. Additionally, data about the use of adjunctive medical therapy and drug-eluting stent (DES) are limited [2]. This case series indicates the use of DS or direct-like stenting in timely PCI in reducing no-reflow, improving thrombolysis in myocardial infarction (TIMI) flow, and preventing on-table complications, which could lead to better long-term outcomes.

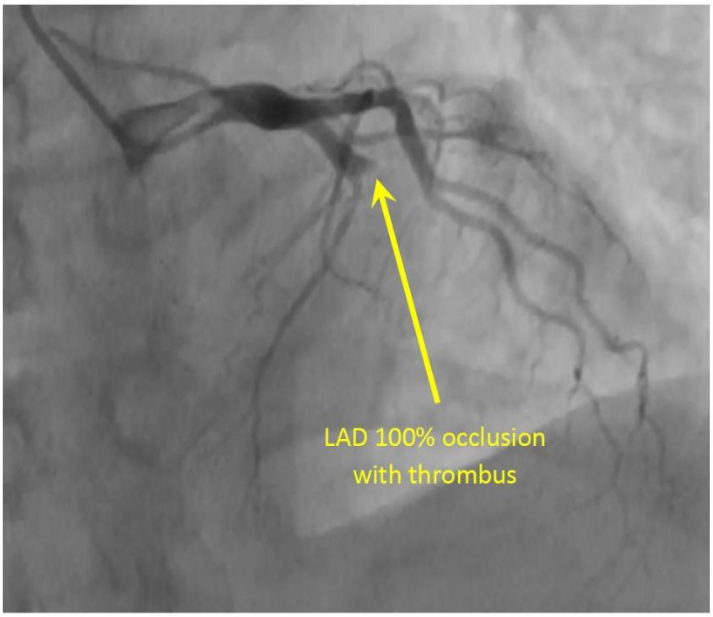
Materials and Methods

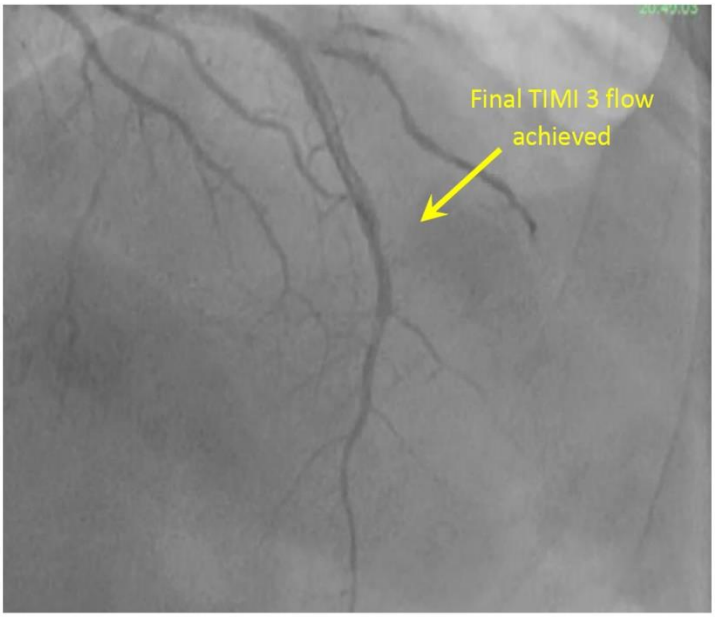
Study design and population

This observational, retrospective, and single-center study enrolled 514 consecutive patients at the Max Super Specialty Hospital in Bathinda, India, who underwent primary percutaneous coronary intervention (PCI) with stenting from October 2016 to March 2021. This study enrolled patients aged over 18 years based on their presentation with consistent symptoms of ongoing ischemia evidenced between 12 and 24 h and within 12 h of the onset of STEMI symptoms. The primary modality of treatment was DS, but direct-like stenting was performed in cases where DS was not feasible. By direct-like stenting, it was the practice to do either thrombosuction or making way with a 1.5 mm small balloon, so that the distal landing zone was visible and then the procedure was completed by stenting across the lesion and the clot. Hence, it was named like direct-like stenting. Measures were taken to ensure that the stenting was as direct as possible. Participants with aspirin and ticagrelor contraindications, other contraindications for performing PCI, pregnancy, heavily calcified or excessive proximal tortuosity, or a lack of relevant patient or procedural data were excluded from the study. The study did not require medical ethics committee approval as the patients were included in the study as part of their normal day-to-day treatment.

Study protocol

During primary PCI, DS was performed in patients who had TIMI flow of ≥1 during initial injection or after wire insertion. Alternative techniques, such as ballooning with a small balloon or thrombosuction, were utilized before DS in cases where DS was not feasible. This type of intervention was labeled as direct-like stenting. The idea was to disturb the clot as minimally as possible and to be as direct as possible in deploying the stent. Some patients required thrombosuction before the distal landing zone was visible. DS was considered to be successfully performed if <30% residual stenosis and coronary TIMI flow grade 3 were achieved during procedure completion. The study includes four clinical cases, which are shown in Figures 1–4.



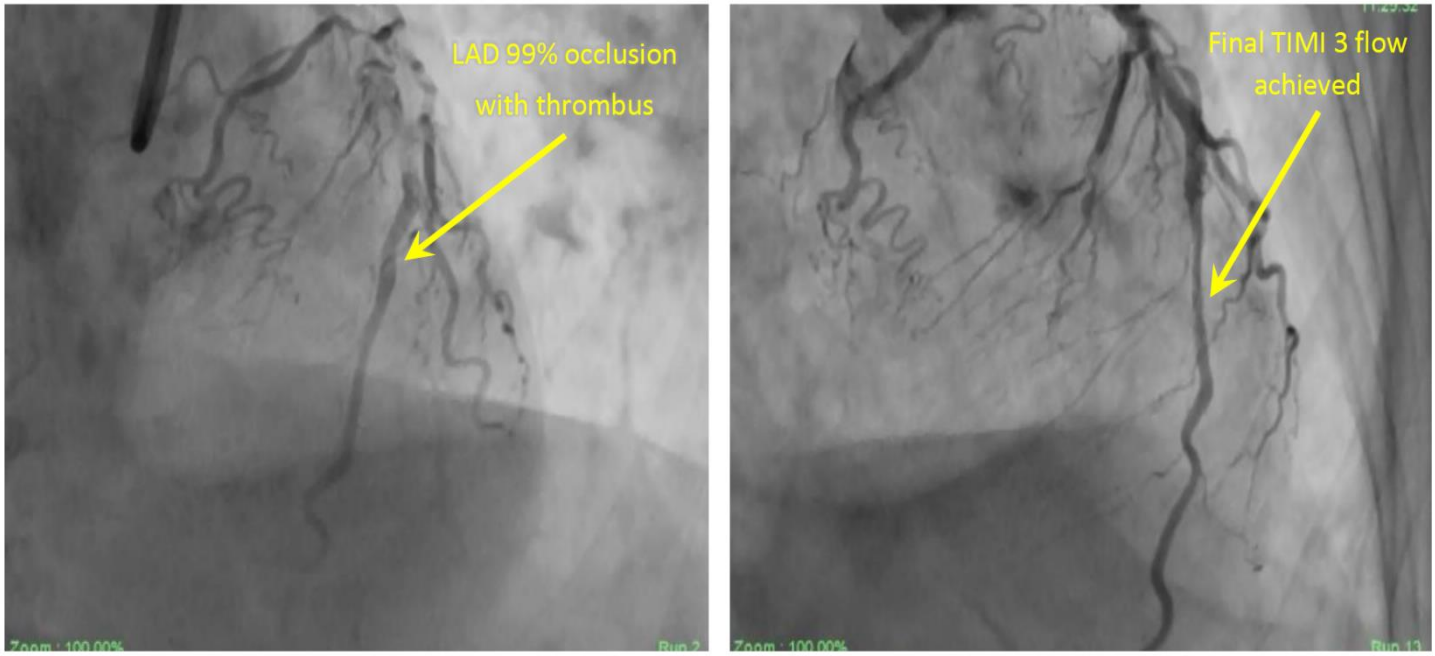


1A: 100% lesion with high grade clot burden in LAD (arrow)

1B: TIMI grade-3 flow demonstrated by post PCI CAG (arrow).

†DS: Direct stenting PCI: Percutaneous Coronary Intervention; CAG: Coronary Angiogram; LAD: Left Anterior Descending artery; TIMI: Thrombolysis in Myocardial Infarction.

Table 1: Case 1 Pre and Post PCI CAG after DS

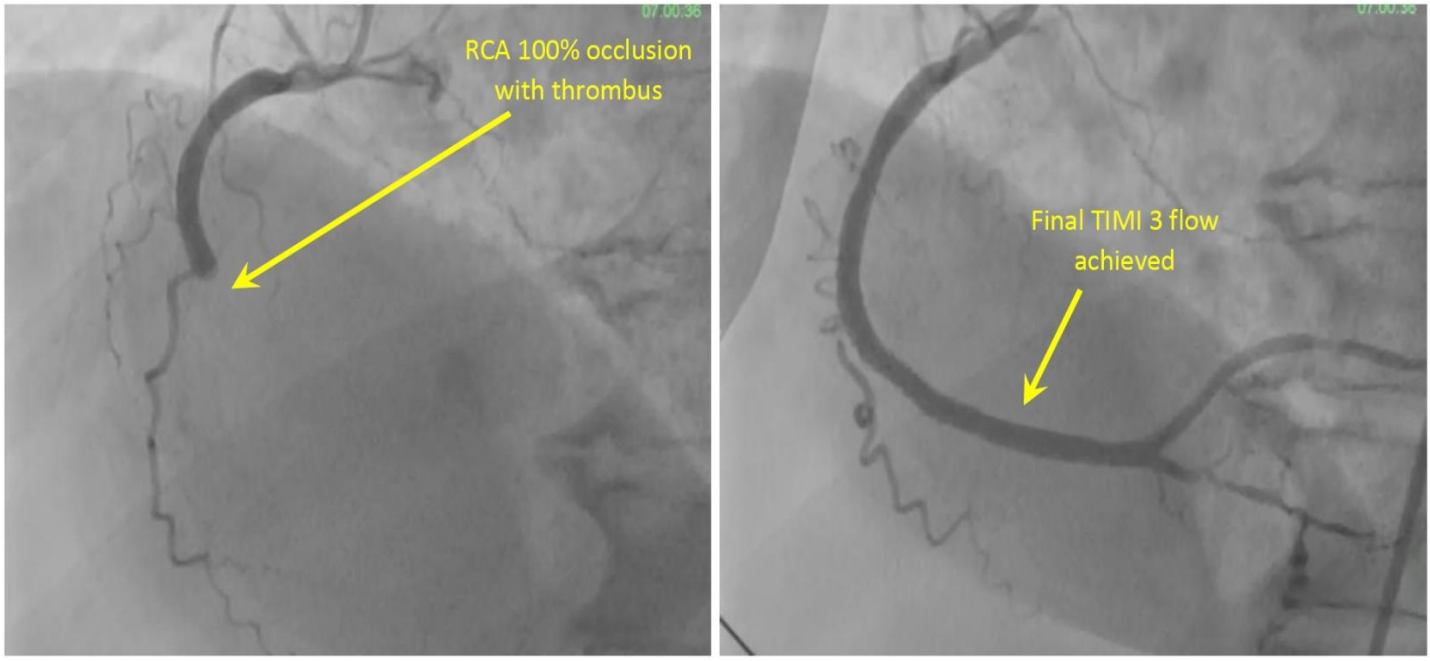


2A: 99% lesion in proximal LAD demonstrated by CAG (arrow)

2B: TIMI grade-3 flow demonstrated by post PCI CAG (arrow).

†DS: Direct Stenting PCI: Percutaneous Coronary Intervention; CAG: Coronary Angiogram; LAD: Left Anterior Descending artery; TIMI: Thrombolysis in Myocardial Infarction.

Figure 2: Case 2 pre and post PCI CAG after DS

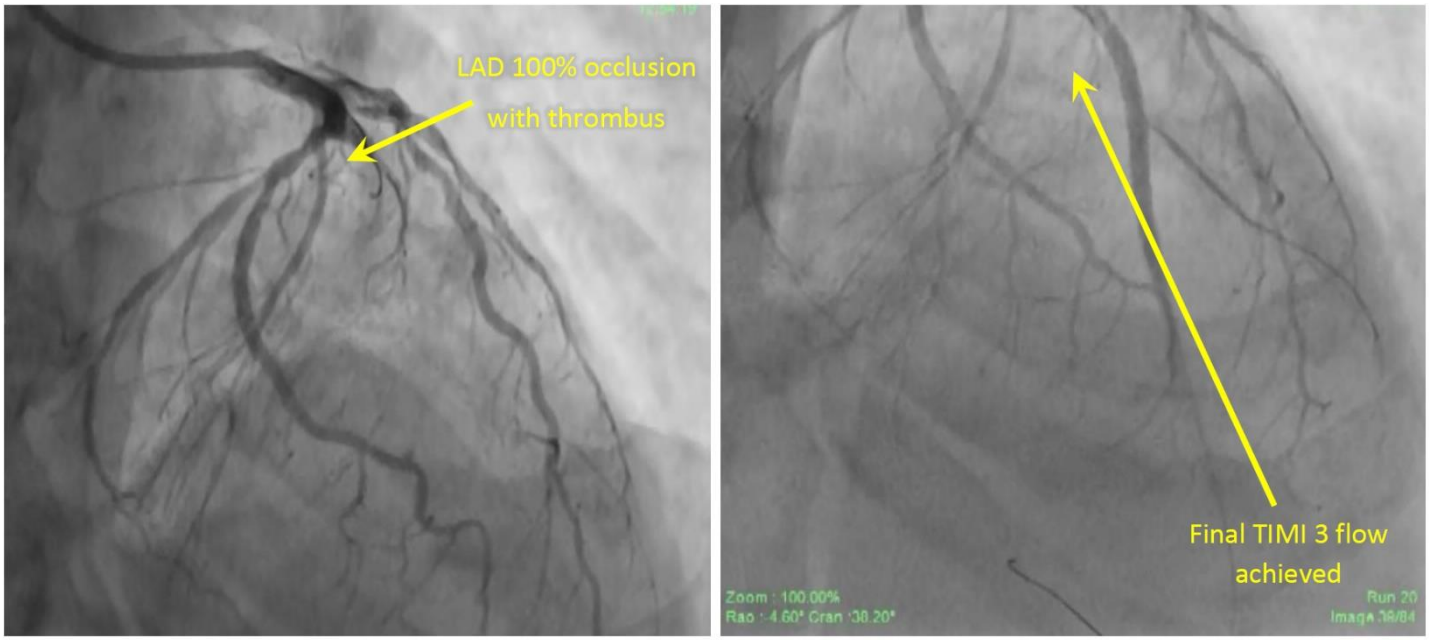


3A: 100% lesion with high grade clot in proximal RCA demonstrated by CAG (arrow)

3B: TIMI grade-3 flow demonstrated by post PCI CAG (arrow).

†DS: Direct Stenting PCI: Percutaneous Coronary Intervention; CAG: Coronary Angiogram; RCA: Right Coronary artery; TIMI: Thrombolysis in Myocardial Infarction.

Figure 3: Case 3 pre and post PCI CAG after DS



4A: 100% lesion in LAD with high grade clot demonstrated by CAG (arrow)

4B: TIMI grade-3 flow demonstrated by Post PCI CAG (arrow).

†PCI: Percutaneous Coronary Intervention; CAG: Coronary Angiogram; LAD: Left Anterior Descending artery; TIMI: Thrombolysis in Myocardial Infarction.

Figure 4: Case 4 Pre and Post PCI CAG

What did we study?

From October 2016 to March 2021, 514 patients with STEMI were treated with DS or direct-like stenting technique by DES implantation. We evaluated patients with stable hemodynamics and cardiogenic shock separately, because of gross difference in outcomes. Practically the stent was deployed by DS (372 patients), thrombosuction with DS (51 patients), thrombosuction and pre-dilatation with a small balloon (25 patients) (direct-like stenting), and pre-dilatation with a small balloon (66 patients) (direct-like stenting). Either the thrombosuction before deploying the stent directly or a pre-dilation with a very small 1.5-mm balloon was performed and the stent was deployed if the distal landing zone was visible, or both in direct-like stenting. After PCI, these patients were assessed angiographically and the outcomes were recorded. Clinical events, such as cardiac death, target vessel revascularization (TVR), and myocardial infarction (MI) were noted in 1-month, 3-month, and 2-year in-hospital follow-ups. Baseline demographics and clinical characteristics of patients are shown in Table 1 and lesion characteristics are shown in Table 2.

Variables	STEMI with stable hemodynamics	STEMI with cardiogenic shock
Total pts (%)	376 (73.1)	138 (26.9)
Age, mean [years]	62.0 ±12	65.1 ±12.5
Smoker, n (%)	190 (50.5)	64 (46.4)
Ejection fraction, mean (%)	47.9 ±9.1	36.1 ±11
Diabetes mellitus, n (%)	151 (40.2)	56 (40.6)
Hypertension, n (%)	173 (46.0)	63 (45.7)
Hyperlipidemia, n (%)	67 (17.8)	31 (22.5)
Prior MI, n (%)	35 (9.3)	28 (20.3)
Prior PCI, n (%)	37 (9.8)	11 (8.0)
Prior CABG, n (%)	6(1.6)	4 (2.9)
Renal insufficiency, n (%)	47 (12.5)	21 (15.2)
Ischemia time, mean [min]	116.2 ±40.8	114.1 ±39.1

† PTS: Patients; STEMI: ST-elevation Myocardial Infarction; MI: Myocardial Infarction; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft

Table 1: Baseline demographics and clinical characteristics

Parameter	STEMI with normal hemodynamics (n = 376)	STEMI with cardiogenic shock (n = 138)
Culprit artery:		
Left anterior descending	112 (29.8)	46 (33.3)
Left circumflex	28 (7.4)	23 (16.7)
Right coronary	210 (55.9)	53 (38.4)
Other	26 (6.9)	16 (11.6)
Procedural complication:	28 (7.4)	20 (14.5)
Edge dissection	11 (2.9)	9 (6.5)
No reflow	17 (4.5)	11 (8.0)
Procedural characteristics:		
Post-dilation	50 (13.3)	16 (11.6)
Aspiration thrombectomy	22 (5.9)	8 (5.8)
Stent length, mean [mm]	18.8 ±6.22	21.92 ±6.62
Stent diameter, mean [mm]	2.71 ±0.21	2.30 ±0.16
Procedure time, mean [min]	46.0 ±12.1	47.1 ±15.5
Fluoroscopy time, mean [min]	9.6 ±4.1	13.0 ±5.6
Contrast volume, mean [ml]	123.2 ±51.1	152.5 ±85.0
Postprocedural TIMI flow III, n (%)	354 (94.1)	124 (89.9)
Lesion location:		
Proximal	117 (31.1)	51 (37.0)
Mid	207 (55.1)	64 (46.4)
Distal	52 (13.8)	23 (16.7)
Additional stent, n (%)	78 (20.7)	30 (21.7)
Multivessel disease, n (%)	50 (13.3)	26 (18.8)
Calcific lesion, n (%)	50 (13.3)	22 (15.9)
Thrombus burden:		
Low thrombus burden	208 (55.3)	51 (37.0)
High thrombus burden	172 (45.7)	87 (63.0)
Glycoprotein IIb/IIIa inhibitors	300 (79.8)	114 (82.6)
Bifurcation stenting	8 (2.1)	2 (1.4)
Thrombectomy	56 (14.90)	20 (14.5)
TIMI flow at baseline		
0	211 (56.1)	76 (55.1)
1	97 (25.8)	34 (24.6)
2	30 (8)	11 (8.0)
3	38 (10.1)	13 (9.4)
Final TIMI flow 3	320 (85.1)	120 (87.0)
No reflow	2 (0.5)	1 (0.7)
Dissection	8 (2.1)	2 (1.4)
Distal embolization	16 (4.3)	7 (5.1)
Average contrast volume used	50±20	40±10
IABP use	Nil	131 (95)

† STEMI: ST-elevation Myocardial Infarction; TIMI: Thrombolysis in Myocardial Infarction

Table 2: Lesion characteristics

Data collection

Retrospective data collection included information on patient demographics, clinical characteristics, and procedure details. The thrombus burden, calcification state, and TIMI flow grade were evaluated by a team of two expert interventional cardiologists after the procedure. A coronary angiography (CAG) laboratory was used to collect data on procedural time, fluoroscopy time, and contrast media volume. Various sources, such as phone calls, registry databases, and electronic medical records were used to collect information on various in-hospital and clinical outcomes, such as in-hospital death, recurrent MIs, target lesion revascularization (TLR), TVR, and definite stent thrombosis (ST). Routine or control angiography was not performed in the absence of any clinical indication during the follow-up time, but it was performed within the 2-year follow-up after the initial PCI coronary angiographies driven by various events.

Study endpoints and definitions

The occurrence of major adverse cardiac events (MACEs) defined as TLR, TVR, MI, or definite ST during the follow-up was considered the primary endpoint of this study. In-hospital patient death and in-hospital TLR were considered as the secondary endpoint. PCI and bypass grafting were considered TVR as they are the procedures targeting the target vessel. TLR was defined as the need for additional PCI or bypass grafting of the treated lesion within the stent or a segment 5 mm proximal or distal to the initial stent margins. MI was defined in this analysis as consistent with the most recent guidelines [5]. The criteria of the Academic Research Consortium [6] were used to determine definite ST. The time from the chest pain onset to the inflation of the first balloon during the primary PCI was defined as the total ischemic time. TIMI thrombus classification system was used to characterize the angiographic thrombus burden, and it was characterized by patients with high thrombus burden (grades 4 and 5) and patients with low thrombus burden (grades 1, 2, and 3) [7]. Additionally, procedural complications, such as no-reflow and edge dissection, were considered in this study.

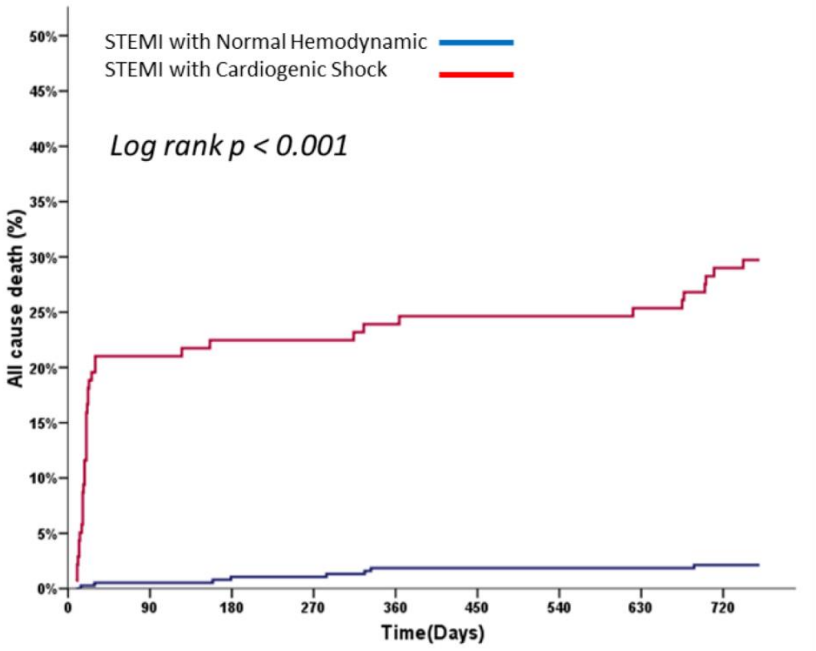
Results

How was the study executed?

- Patients with acute STEMI were studied, and all-comer patients were enrolled, including patients with cardiogenic shock. Intra-aortic balloon pump (IABP) was used to stabilize patients presenting with cardiogenic shock following the discretion of the operator. The IABP use in our patients with cardiogenic shock was 95% (131 patients). Patients with clinical hypotension were simultaneously stabilized with intravenous (IV) inotropic support.
- After confirming the diagnosis using an electrocardiogram (ECG) and echocardiogram (ECHO), urgent angiography was performed in a recommended timely manner. After the coronary artery angiography, most of the PCIs were performed by radial approach. Before PCI, 300 mg of aspirin and 180 mg of ticagrelor were administered. Additionally, heparin by IV bolus at 70 units/kg dose and tirofiban at 25 ug/kg bolus was administered. Tirofiban by IV infusion at 0.15 ug/kg for 12 h was continued if tolerated.
- The procedure was completed by crossing the lesion with a 0.014’ guidewire and the following steps were followed:
  - DS in 372 patients, directly DES was deployed.
  - Pre-dilatation with a 1.5-mm balloon was performed in 66 patients to create a passage for the DES, and then DES was deployed.
  - Thrombosuction with DS in 51 thrombosuction was performed using an aspiration catheter, and then DES was deployed.
  - Thrombosuction was first performed in 25 patients, then pre-dilatation using a 1.5-mm balloon was performed, and then DES was deployed directly.

What are the essential results?

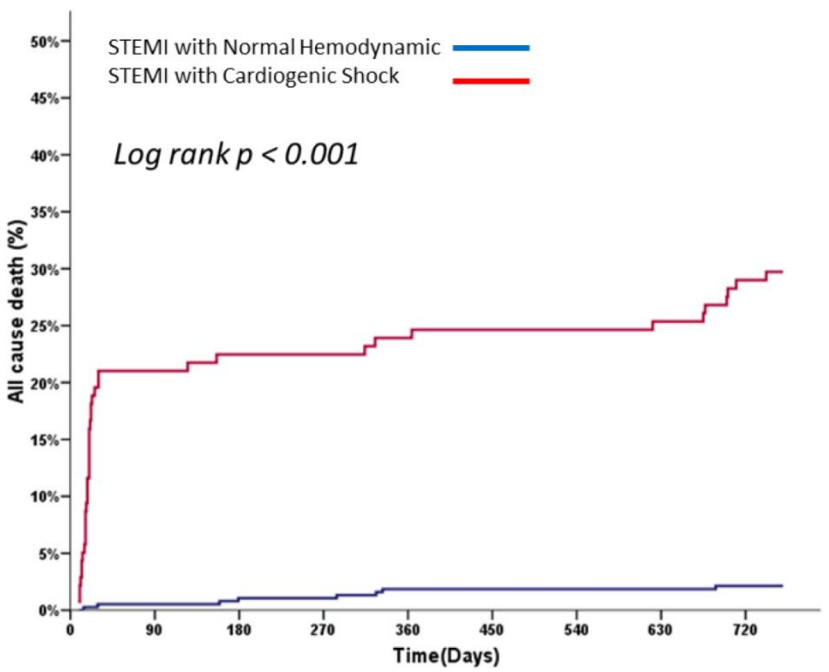
- This study enrolled 376 (73.1%) patients with a mean age of 62.0 ± 12 years for in-hospital patients with normal hemodynamics and 138 (26.9%) patients with a mean age of 65.1 ± 12.5 for in-hospital patients with cardiogenic shock. In terms of other comorbidities, diabetes, hypertension, hyperlipidemia, previous MI, and previous PCI were reported in 151 (40.2%), 173 (46.0%), 67 (17.8%), 35 (9.3%), and 37 (9.8%) in-hospital patients with normal hemodynamics and in 56 (40.6%), 63 (45.7%), 31 (22%), 28 (20.3%), and 11 (8.0%) in-hospital patients with cardiogenic shock. The Baseline and demographic characteristics of the patients are shown in table 1.
- Procedural complications of edge dissection and no-reflow phenomenon occurred in 28 (7.4%) and 20 (14.5%) in-hospital patients with normal hemodynamics and cardiogenic shock, respectively. TIMI flow grades 0–3 were seen in 211 (56.1%), 97 (25.8%), 30 (8%), and 38 (10.1%) in-hospital patients with normal hemodynamics and in 76 (55.1%), 34 (24.6%), 11 (8.0), and 13 (9.4%) in-hospital patients with cardiogenic shock, respectively. Lesion characteristics of patients are shown in table 2. The hemodynamic characterstics of patients with cardiogenic shock are described in table 3.
- Successful treatment of the target lesion was performed in 494 (96%) patients. Minor dissections (type A to C dissections) occurred in five (1%) lesions. No patient had any coronary perforation. The no-reflow was observed in 3% and TIMI 3 flow was achieved in 86% of patients. Myocardial blush grade (MBG) 2 was achieved in 74% of the cases. Any major Cath lab complications occurred in only two patients. Angiographic success was achieved in 96% of 514 treated lesions.
- The secondary endpoint of in-hospital death, MACE, and TVR occurred in 1 (0.26%), 7 (1.86%), and 3 (0.79%) in-hospital patients with normal hemodynamics and in 27 (19.56%), 4 (2.89%), and 2 (1.44%) in-hospital patients with cardiogenic shock, respectively. Death, MACE, and TVR occurred in 8 (2.1%), 28 (7.4%), and 16 (4.3%) patients with normal hemodynamics and in 41 (29.71%), 19 (13.8%), and 7 (5.1%) patients with cardiogenic shock, respectively, at the 2-year follow-up. Clinical outcomes in-hospital, at 1-month, 1-year, and 2-years are shown in table 4. Kaplan-Meier curves regarding MACE and survival are shown in figures 5 and 6.



	Number at risk	0	90	180	270	360	450	540	630	720
Group :	STEMI with Normal Hemodyanmic	376	374	372	372	369	369	369	369	368
Group :	STEMI with Cardiogenic Shock	138	109	107	107	105	104	104	103	98

†MACE: Major Adverse Cardiac Events; STEMI: ST-elevation Myocardial Infarction.

Figure 5: Kaplan Meier curve showing comparison of all cause death at follow-up of 2-years.



	Number at risk	0	90	180	270	360	450	540	630	720
Group :	STEMI with Normal Hemodyanmic	376	374	372	372	369	369	369	369	368
Group :	STEMI with Cardiogenic Shock	138	109	107	107	105	104	104	103	98

†**MACE:** Major Adverse Cardiac Events**; STEMI:** ST-elevation Myocardial Infarction.

Figure 6: Kaplan Meier curve showing comparison of MACE free survival at follow-up of 2-years.

Total number of patients of cardiogenic shock (n = 138)	
SCAI stage of cardiogenic shock	48 patients in stage D & E
Mean Systolic pressure	72 ± 18 mm of Hg
Mean diastolic pressure	52 ± 12 mm of Hg
Mean of mean pressure	58 ± 20 mm of Hg
Mean pulmonary artery pressure	20/10 ± 20/15 mm of Hg
Mean PAPI	<1.4 in more than 18 patients
Mean Cardiac output	3 ± 1.6 L/min
Number of inotropic agents used	>3 in 80% patients
IABP used	95%

- † SCAI: Society of Angiography & Interventions; PAPI: Pulmonary Artery Pulsatility Index; IABP: Intra-aortic Balloon Pump.

Table 3: Details of Hemodynamics in cardiogenic shock patients

Clinical Outcomes in-hospital		
Parameter	STEMI with normal hemodynamics (n = 376)	STEMI with cardiogenic shock (n = 138)
MI	3 (0.79)	2 (1.44)
TLR	2 (0.53)	1 (0.72)
TVR	3 (0.79)	2 (1.44)
ST	1 (0.26)	2 (1.44)
MACE	7 (1.86)	4 (2.89)
All-cause death	1 (0.26)	27 (19.56)
Clinical outcomes at follow-up of 1-month		
Parameter	STEMI with normal hemodynamics (n = 376)	STEMI with cardiogenic shock (n = 138)
MI	4 (1.06)	3 (2.17)
TLR	3 (0.79)	2 (1.44)
TVR	5 (1.32)	3 (2.17)
ST	1 (0.26)	2 (1.44)
MACE	9 (2.39)	6 (4.34)
All-cause death	2 (0.53)	29 (21.01)
Clinical outcomes at follow-up of 1-year		
Parameter	STEMI with normal hemodynamics (n = 376)	STEMI with cardiogenic shock (n = 138)
MI	11 (2.92)	7 (5.07)
TLR	6 (1.59)	4 (2.89)
TVR	10 (2.65)	5 (3.62)
ST	2 (0.53)	3 (2.17)
MACE	19 (5.05)	8 (5.79)
All-cause death	7 (1.86)	34 (24.63)
Clinical outcomes at follow-up of 2-years		
Parameter	STEMI with normal hemodynamics (n = 376)	STEMI with cardiogenic shock (n = 138)
MI	20 (5.3)	10 (7.2)
TLR	8 (2.1)	9 (6.5)
TVR	16 (4.3)	7 (5.1)
ST	2 (0.5)	4 (2.89)
MACE	44 (11.70)	26 (18.8)
All-cause death	8 (2.1)	41 (29.71)

† STEMI: ST-elevation Myocardial Infarction; MI: Myocardial Infarction; TLR: Target Lesion Revascularization; TVR: Target Vessel Revascularization; MACE: Major Adverse Cardiac events

Table 4: Clinical outcomes and follow-up at in-hospital, 1-month, 1-year and 2-years.

Discussion

PCI is the preferred reperfusion strategy in patients with STEMI. Some studies have revealed that DS results in less distal embolization and microvascular obstruction. DS is widely used in practice, but with no currently accepted guidelines [8]. Our present study retrospectively analyzed patients of STEMI who were offered primary angioplasty promptly. We included all the incomer patients who met our inclusion criteria for DS or direct-like stenting. This strategy is feasible in most of the patients. We analyzed patients with cardiogenic shock and normal hemodynamics at presentation separately. Our article emphasizes the use of DS rather than the comparison of these groups.

The TAPAS [9], TASTE [10], and TOTAL [11] studies are three of the largest randomized clinical trials that compare the use of routine manual thrombus aspiration during PCI with PCI alone in patients with STEMI. Researchers from these studies derived the largest observational data from the Thrombectomy Trialists Collaboration (TTC) [12]. This study looked into the use of DS with thrombus aspiration to improve cardiac reperfusion and clinical outcomes by analyzing data from the TTC. The study compared the use of DS to traditional stenting during primary PCI and evaluated the role of aspiration thrombectomy [13]. Only 32% of the 17,329 patients in the study underwent DS. The study revealed that DS was possible in more patients after aspiration thrombectomy, and that aspiration thrombectomy was used to facilitate DS. The contrast was less used in DS, and the fluoroscopy time was shortened ($P < 0.001$ for both comparisons). However, study results demonstrated that clinical outcomes at 30-day and 1-year follow-ups were not improved by the DS method in comparison to the conventional stenting (CS) approach. Notably, the study revealed that many patients who underwent DS also underwent thromboaspiration before stenting. Further, the thrombectomy device used in thrombus aspiration before the DS method may have caused distal embolization due to its dithering effect [14]. Thus, the potential benefits of DS in avoiding distal embolization were not completely realized.

The study revealed lower rates of cardiovascular mortality and cerebrovascular incidents at the 1-month follow-up (1.7% vs. 1.9%). Additionally, a negligible rate of death from any cause, heart attack, or ST was observed, as well as a lower rate at which vessels needed to be re-vascularized after 1 year. Previous research has attributed a higher rate of stent failure to the presence of malapposition and insufficient lesion coverage, but this study reassuringly revealed no higher risk of these consequences than previously thought. Additionally, the study revealed that a lower number of patients undergoing DS had inadequate ST-segment resolution and MBG of 0 and 1 in the TAPAS [9] and TOTAL [11] studies, respectively. These studies utilized thrombectomy devices before DS in a significant number of patients, which suggests that only a fraction of DS potential has been used, although thrombectomy may lead to distal embolization.

Unfortunately, the data from these trials do not yet demonstrate a clear advantage of DS over traditional stenting. Notably, DS decreases distal embolization, even if the capture of embolized material by distal protection devices and the removal of the clot by aspiration thrombectomy should have affected the result positively. However, a noticeable direct impact has been difficult to achieve. Distal thrombus embolization and plaque-induced STEMI have already occurred upon reperfusion initiation via primary PCI. The problem could become even more severe if reperfusion injury sets in. Accordingly, device-based therapies can only affect a single component of reperfusion in STEMI. Mortality and improve outcomes in the modern era were significantly reduced with the help of optimized PCI and the finest available adjunctive medication. Any further improvement is unlikely to be noticeable in clinical practice because of the already low mortality rate in simple STEMI (<2%) [2]. Positive clinical outcomes of DS cannot be ignored. Recently, a study revealed DS as a safe and promising therapeutic strategy in patients with acute reperfused STEMI with significantly lower infarct size in comparison to CS, and DS subsequently reduced the risk of various other complications, such as mortality and heart failure hospitalization [7]. Conversely, some studies revealed no statistically significant difference between DS and CS [15,16,17,18]. Seven studies directly comparing DS and CS methods concluded that DS yielded superior results. However, most of the studies included in this meta-analysis were observational, and the DES employed was from the first generation, which could explain the lack of promising findings [15,16].

The Swedish Coronary Angiography and Angioplasty Registry revealed notably low rates of restenosis and ST. These positive findings in research may be attributed to the use of the most recent generation of DES. We seem to make progress in the fight against restenosis. These results are already encouraging, but larger studies involving individuals with more severe complications, such as cardiogenic shock, are needed to make further progress [19].

A meta-analysis of 12 clinical trials entitled, “Comparing Direct Stenting with CS In Patients with Acute Coronary Syndromes (ACS): A Meta-Analysis of 12 Clinical Trials,” [20] revealed that DS has better short-term outcomes, with fewer cases of the no-reflow phenomenon, and better long-term outcomes, with lower rates of mortality after 1 year.

Researchers of the LIPSIA CONDITIONING trial, which is a pre-defined sub-study, revealed that DS resulted in smaller infarct sizes on magnetic resonance imaging and reduced 6-month death rates when compared to CS [21].

Demonstrating the subtle impact of DS on mortality may be challenging because of the remarkable decrease in primary angioplasty mortality in recent years, which is now <2% in simple MI. Patients at high risk, such as those with STEMI and cardiogenic shock [22], should be considered when evaluating the potential benefits of using DS.

The key takeaway is that distal embolization is minimal when DS or a similar technique is performed even in patients with high-grade thrombus during STEMI. Direct-like stenting can be done by modification with a small balloon and/or after thrombosuction in patients in whom DS is not feasible. The success rate of DS can be increased using a deflated balloon, as supported by the literature [23].

A recent study evaluating very long-term clinical outcomes after DS in patients with STEMI indicates reduced long-term all-cause mortality and no relevant effect of the stenting technique on clinical outcomes in patients with large thrombus burden [24]. Additionally, our study seems to favor the 2-year MACE as compared to previous studies of primary angioplasty in MI as GUSTO-2 [25].

Study Limitations

This is a single-centre retrospective observational study with certain inherent limitations. Certain variables like left ventricular ejection fraction, length and diameter of stent were not analyzed in this study. In conventional stenting strategy, the Left anterior descending infarct-related artery was quite common which can affect the clinical outcomes. Other major limitation associated with the study is that only first-generation DES were implanted in patients. The only thrombus aspiration system used in this study was Rheolytic thrombectomy. It is an observational study and is not a comparison with conventional stenting hence, propensity score based methods cannot be done.

Why is this important?

- DS is possible and often successful in most individuals, and direct-like stenting can be performed in cases where the stent will not cross or the distal landing zone is not visible.
- Less contrast is used with no difficulties at the operating table during direct or direct-like stenting. Most patients achieved increased TIMI-3 flow and decreased distal embolization.

- Direct or direct-like stenting without thrombectomy may be more effective; however, a proper randomized controlled trial is needed to prove this.
- In summary, our study and subsequent discussion suggest that we should be as direct as possible when dealing with patients undergoing primary PCI for STEMI.
- Comparing our non-randomized study to the GUSTO-2 Trial for primary PCI, we revealed that the total MACE was 14%, comprised of 5.7% mortality, 4.0% reinfarction, and 1% stroke. Our outcomes compare favorably with a mortality rate of 2.1%, a reinfarction rate of 5.3%, and a major adverse cardiac event rate of 7.4%.
- Conducting a randomized controlled trial of direct and direct-like stenting as compared to conventional modality for primary PCI will be prudent.

Conclusions

- DS or direct-like stenting is possible in most patients with acute STEMI and even with high-grade thrombus.
- Direct-like stenting is feasible in patients where the stent is unable to cross and the zone distally used for landing is not visible on the angiogram.
- Less contrast is used with minimal complications at the operating table with DS or direct-like stenting.
- The rate of distal embolization significantly decreases and the rate at which TIMI grade 3 flow is achieved increases.
- Our findings and discussion indicate that we should be as direct as possible when dealing with patients undergoing primary PCI for STEMI.
- The results of this non-randomized study were favorable compared to the GUSTO-2 trial for primary PCI, with lower mortality and MACE rates.

Author's Summary

The study suggests direct stenting or direct-like stenting as a feasible option for most patients undergoing primary PCI for STEMI. This method simplifies the procedure, reduces the amount of contrast used, and minimizes complications. TIMI-3 flow is achieved in the majority of patients, and the risk of distal embolization was less. However, a randomized controlled trial is needed to further demonstrate the effectiveness of this strategy compared to traditional methods. This study can serve as a starting point for a hypothesis-making trial to investigate the use of DS and direct-like stenting in primary PCI as compared to conventional modality.

Author Contributions

The lead author of the clinical research is Dr Rohit Mody. Dr Debabrata Dash, Dr Bhavya Mody, Ankit Agrawal, Inderjeet Singh Monga and Lakshay Rastogi had equal and substantial contributions in the formation of this clinical research. They were involved in conceptualization, data curation, formal analysis, resources, software, validation, visualization, writing - original draft, Writing, review & editing.

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Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

Ethical approval was not required since it is an accepted procedure

Consent for Publication

Written consent has been obtained to publish the case report from the guardian. The consent copy is available with the authors and ready to be submitted if required.

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