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Procedural and long-term outcomes of stent post dilatation during primary percutaneous coronary interventions

Sherif W Ayad*, Amr M Zaki, Mohamed A Sadaka and Ahmed M El Amrawy

Department of Cardiology, Faculty of Medicine, Alexandria University, Egypt

Abstract

Background: The role of stent post dilatation (SPD) during primary percutaneous intervention (PPCI) is controversial. Currently there are no clear guidelines or consensus regarding when to perform SPD and it is left to the operator decision. The aim of this study was to evaluate the procedural and long terms outcomes of SPD during PPCI.

Results: We collected retrospectively data of 614 STEMI patients who presented to Alexandria Main University hospital and International Cardiac Center (ICC) hospital, Alexandria, Egypt from January 2018 to December 2018. All patients underwent PPCI. We excluded patients with cardiogenic shock, prior CABG, severe LM disease. Patients were divided into two groups according to SPD procedure. Group 1: who had SPD included 424 patients (69.1%). Group 2: no SPD included 190 patients (30.9%). Both groups were well matched with regard to demographic data and lesion characteristics. Procedural outcomes and clinical outcomes at one year were collected. SPD patients had significantly higher incidence of no reflow during the procedure (33.7% in group 1 *vs.* 21.6% in group 2, P=0.026), but the final TIMI flow was similar between two groups. Also, there was no significant difference between two groups regarding other procedural outcomes as dissection, perforation, or cardiac death. After one year follow up SPD patients had significantly higher incidence of reinfarction (5.6% of group 1 *vs.* 1.5% in group 2, P=0.03) and significantly more target vessel revascularization (TVR) (16.7% in group 1 *vs.* 4.7% in group 2 P<0.001). There was no significant difference between the two groups regarding the incidence cerebrovascular stroke (CVS), heart failure or cardiac death.

Conclusion: Our study shows that SPD during PPCI is associated with an increased risk of procedural no reflow and increased risk of reinfarction as well as need for TVR after 1 year follow up. Finally, SPD did not improve clinical outcomes after 1 year follow up. Nonetheless, large-scale randomized trials are required to establish the role of SPD during PPCI.

Abbreviations: ACS: Acute Coronary Syndrome; CABG: Coronary Artery Bypass Grafting; GRACE: Global Registry of Acute Coronary Events; LCx: Left Circumflex Artery; STEMI: ST Segment Elevation Myocardial Infarction; PCI: Percutaneous Coronary Intervention; PPCI: Primary Percutaneous Coronary Intervention; TIMI: Thrombolysis In Myocardial Infarction; MACCE: Major Adverse Cardiac and Cerebrovascular Events; CVS: Cerebrovascular Stroke; RCA: Right Coronary Artery; LAD: Left Anterior Descending Artery; CAD: Coronary Artery Disease; IVUS: Intravascular Ultrasound; SPD: Stent Post Dilatation; LM: Left Main; MVD: Mutivessel Disease; SVD: Single Vessel Disease; TVR: Target Vessel Revascularization; ISR: In-Stent Restenosis.

Background

Primary percutaneous coronary intervention (PPCI) is the best management for patients presenting with st-segment elevation myocardial infarction (STEMI) according to the latest guidelines [1].

The incidence of stent thrombosis is significantly higher after PPCI than after elective PCI [2]. Previous studies have shown that the most common causes of either acute or late stent thrombosis and restenosis after PPCI are malapposition and stent under expansion [3,4].

The separation of stent struts from the vessel wall seen by intravascular ultrasound (IVUS) is used to define malapposition and this interferes with the endothelialisation of the stent leading to restenosis and stent thrombosis [5,6].

Stent post-dilatation (SPD) using high pressure noncompliant balloons is used to optimize stent deployment, minimize the risk of malapposition and subsequently improve outcomes after elective PCI however this was not the same in the setting of STEMI [7-9]. SPD during PPCI increases distal embolization and leads to increase risk of no reflow [10] resulting in higher in-hospital and long term major adverse cardiac and cerebrovascular events (MACCE) [11,12].

In this study we aimed to evaluate the procedural and long-term outcomes of SPD during PPCI.

Methods

Study design

This was a retrospective observational study conducted on 614 STEMI patients who presented to Alexandria Main University hospital and International Cardiac Center (ICC), Alexandria, Egypt from first of January 2018 till end of December 2018.The Inclusion criteria were established diagnosis STEMI and candidates for PPCI [1]. While the

Correspondence to: Sherif Wagdy Ayad, Department of Cardiology, Faculty of Medicine, Alexandria University, Egypt, E-mail: sherifwagdyayad@yahoo.com

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Exclusion criteria were previous CABG, cardiogenic shock, previous PCI of same culprit vessel and severe Left main (LM) disease. Patients were divided into two groups

Group 1: Included 424 STEMI patients with SPD performed during PPCI.

Group 2: Included 190 STEMI patients with no SPD performed during PPCI.

Data collection

Regarding demographic data, we registered age, gender, comorbidities (hypertension, diabetes, dyslipidemia, family history of coronary artery disease, prior ACS or PCI), and smoking.

Among in-hospital treatments, we registered PCI procedure details including culprit artery, number of diseased vessels, the use of thrombus aspiration catheter, the use of antithrombotic therapy (acetyl salicylic acid, clopidogrel, ticagrelor, heparin, enoxaparin and glycoprotein IIb/IIIa inhibitors), balloon predilatation, stents (number, length and diameter), size of balloon used in SPD and Thrombolysis in Myocardial Infarction (TIMI) flow at the end of the procedure [12]. Baseline and at hospital discharge GRACE risk score was calculated [13].

Endpoint measurements

The procedural outcomes were the TIMI flow in the culprit artery at the end of the procedure and the incidence of complications (No reflow, perforation, dissection, bleeding) and cardiac death while the long-term outcomes were MACCE which was defined as a composite of death, re-infarction, need for revascularization, heart failure and cerebrovascular stroke after a minimum of one year follow up.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS version 20.0. Armonk, NY: IBM Corp) [14]. We described qualitative data using number and percent and we described quantitative data using range (minimum and maximum), mean, standard deviation and median. The used tests were Chi-square test for categorical variables to compare between different groups, Fisher's Exact or Monte Carlo correction for chi-square when more than 20% of the cells have expected count less than 5, Mann Whitney test for abnormally distributed quantitative variables, to compare between two studied groups. Values below 0.05are considered significant for all tests.

Results

Patients characteristics

Both groups were well matched with respect to the demographic data and clinical characteristics with no significant difference between the two groups. The baseline characteristics of both groups are presented in Table 1.

Grace risk score

Patients in group 1 had higher grace risk score at admission than patients in group 2. This was statistically significant (P=0.017). The grace risk score of both groups is presented in Table 2.

Procedural characteristics of the studied population

Regarding the angiographic data, the incidence of multivessel disease was significantly higher in patients of group 2 compared to patients in group 1 (23.2% *vs.* 11.8% P=0.011). There was no statistically significant difference among both groups regarding the culprit artery. In group 1, 84 patients (19.8%) patients received GP IIb/IIIa inhibitors while in group 2, 40 (21.1%) patients did. This was not statistically significant P=0.802. The use of thrombus aspiration catheter was significantly higher in patients of group 2 compared to patients in group 1 (33.7% *vs.* 21.7% P=0.026). Pre-stenting balloon dilatation was significantly higher in patients of group 1 (56.6% in group 1, 10.5% in group 2, P< 0.001). All patients in both groups had drug eluting stents (DES). Patients in group 1 had significantly bigger diameter and longer length of stent used than patients in group 2 (P=0.001 and 0.004 respectively). There was no significant difference among both groups regarding the number of stents used throughout the PPCI. All data of the procedural characteristics of the studied population are summarized in Table 3.

Procedural outcome

Group 1 patients showed higher incidence of No reflow than group 2 patients (33.7% *vs.* 21.6%) this was statistically significant (p=0.026), but there was no statistically significant difference among patients of both groups regarding the TIMI flow in the culprit artery at the end of the procedure. Severe bleeding, perforation and dissection did not occur in any of the patients of both groups. Cardiac death while in hospital occurred in 6 patients of group 1(1.4%) and 4 patients in group 2 (2.1%). This was not statistically significant p=0.69. The data of procedural outcomes are summarized in Table 4.

Table 1. Baseline characteristics of the studied populations. χ^2: Chi square test; p: p value for comparing between the two studied groups; *: Statistically significant at $p \leq 0.05$

	Total (n = 614)	Group 1 (n = 424)	Group 2 (n = 190)	χ^2	P
Sex					
Male	528 (86%)	358 (84.4%)	170 (89.5%)	0.115	0.735
Female	86 (14%)	66 (15.6%)	20 (10.5%)		
Age (years)					
Min. – Max.	26.0 – 85.0	26.0 – 85.0	27.0 – 82.0		
Mean ± SD.	56.80 ± 11.43	57.33 ± 11.59	55.60 ± 11.02	0.279	0.541
Median	57.0	58.0	56.0		
F.H. for CAD	150 (24.4%)	90 (21.2%)	60 (31.6%)	3.808	0.051
Dyslipidemia	146 (23.8%)	104 (24.5%)	42 (22.1%)	0.213	0.645
HTN	296 (48.2%)	210 (49.5%)	86 (45.3%)	0.478	0.489
DM	298 (48.5%)	218 (51.4%)	80 (42.1%)	2.276	0.131
Smoking	268 (43.6%)	170 (40.1%)	98 (51.6%)	3.518	0.061

Long term outcomes (at least 1year follow up)

The incidence of re-infarction and the need for target vessel revascularization (TVR) were significantly higher in patients of group 1 compared to patients in group 2. Re-infarction occurred in 24 patients (5.6%) of group 1and 3 patients in group 2 (1.5%) p=0.03 while the need for TVR occurred in 71 patients (16.7%) in group 1and 9 patients (4.7%) in group 2 p<0.001. There was no significant difference between the two groups regarding the incidence cerebrovascular stroke (CVS), heart failure or cardiac death. The data of 1 year follow up outcomes are summarized in Table 5.

Discussion

Proper stent deployment has been documented to predict better short- and long-term outcomes after PCI [15]. SPD during PCI provides full stent expansion and thus prevents malapposition which is the main factor responsible for stent thrombosis and restenosis in the DES era [16-20].

Table 2. Grace risk score at admission of the studied population. χ^2: Chi square test; p: p value for comparing between the two studied groups; *: Statistically significant at $p \leq 0.05$

GRACE score	Total (n = 614)	Group 1 (n = 424)	Group 2 (n = 190)	χ^2	P
<140	262 (42.7%)	200 (47.2%)	62 (32.6%)	5.668*	0.017*
>140	352 (57.3%)	224 (52.8%)	128 (67.4%)		

Table 3. Procedural characteristics of the studied population. χ^2: value for Chi square; MC: Monte Carlo test; p: p value for comparing between the two studied groups; *: Statistically significant at $p \leq 0.05$

	Total (n = 614)	Group 2 (n = 424)	Group 1 (n = 190)	χ^2	P
MVD	94 (15.3%)	50 (11.8 %)	44 (23.2%)	6.536*	0.011*
SVD	520 (84.7%)	374(88.2%)	146 (76.8%)	0.109	0.741
Culprit vessel					
LAD	342 (55.7%)	252 (59.4%)	90 (47.4%)	5.905	MCp= 0.089
RCA	194 (31.6%)	126 (29.7%)	68 (35.8%)		
LCX	78 (12.7%)	46 (10.8%)	32 (16.9%)		
Thrombus aspiration	156 (25.4%)	92 (21.7%)	64 (33.7%)	4.973*	0.026*
GP IIb/IIIa	124 (20.2%)	84 (19.8%)	40 (21.1%)	0.063	0.802
Pre stent dilation	250 (40.1%)	240 (56.6 %)	10 (10.5%)	23.315*	<0.001*
Stent diameter					
≤2.75 mm	126 (14.7%)	106 (17.6%)	20 (7.8%)	10.65	0.001*
>2.75mm	732 (85.3%)	496 (82.4%)	236 (92.2%)		
Stent length					
≤20mm	150 (17.5%)	124 (20.6%)	26 (10.2%)	8.28	0.004*
>20mm	708 (82.5%)	478 (79.4%)	230(89.8%)		
Number of stents					
1	404 (65.8%)	272 (64.2%)	132 (69.5%)	χ^2= 3.005	MCp= 0.595
2	180 (29.3%)	130 (30.7%)	50 (26.3%)		
3	24 (3.9%)	18 (4.2%)	6 (3.2%)		
4	6 (1.0%)	4 (0.9%)	2 (1%)		

Table 4. Procedural outcomes of the studied population. χ^2: value for Chi square; MC: Monte Carlo test; p: p value for comparing between the two studied groups; *: Statistically significant at $p \leq 0.05$

	Total (n = 614)	Group 1 (n = 424)	Group 2 (n = 190)	χ^2	P
TIMI flow 0	6 (1.0%)	4 (0.9%)	2 (1%)	3.005	MCP=0.595
I	24 (3.9%)	18 (4.2%)	6 (3.2%)		
II	180 (29.3%)	130 (30.7%)	50 (26.3%)		
III	404 (65.8%)	272 (64.2%)	132 (69.5%)		
No reflow	156 (25.4%)	143 (33.7%)	41 (21.6%)	4.973	0.026*
Cardiac death	8 (1.3%)	6 (1.4%)	4 (2.1%)	2.987	0.69
Perforation	0	0	0		
Dissection	0	0	0		
Severe bleeding	0	0	0		

Table 5. One year follow up outcomes of the studied population. χ^2: value for Chi square; FEP: Fisher's Exact significance; p: p value for comparing between the two studied groups; *: Statistically significant at $p \leq 0.05$

	Total (n = 614)	Group 1 (n = 424)	Group 2 (n = 190)	χ^2	P
Reinfarction	27 (4.4%)	24 (5.6%)	3 (1.5%)	10.705*	0.03*
Stroke	26 (4.2%)	18 (4.2%)	8(4.2%)	0.000	FEp=0.999
Heart failure	38 (12.4%)	34 (8.1%)	18 (9.7%)	2.987	0.69
TVR	26 (8.5%)	71 (16.7%)	9 (4.7%)	12.442*	<0.001*
Cardiac death	8(1.3%)	6(1.5%)	2(1%)	2.865	0.65

Currently there are no clear guidelines or consensus regarding when to perform SPD and it is left to the operator decision. Although the appealing benefits of SPD in reducing the risk of in-stent restenosis and stent thrombosis, it has been correlated with serious adverse events as edge dissection and perforation [21,22]. Also, previous trials showed that SPD increases the risk of distal embolization and subsequently the risk of no reflow phenomena after PPCI [23,24].

The rationale beyond this study was that previous trials showed contradictory results about the benefits of SPD during PCI and that previous studies excluded patients presenting with STEMI.

So, we aimed in this study to evaluate the procedural and long terms outcomes of SPD during PPCI.

In our study the incidence of no reflow was significantly higher in the SPD group compared to the non SPD group (33.7% *vs.* 21.6%, p=0.026). Although transient impairment of TIMI flow occurred after SPD but there was no significant difference among the two groups regarding the final TIMI flow due to the use of intracoronary vasodilators. Gao P. et al. also reported higher incidence of no reflow after SPD during PPCI and they speculated that the probable mechanisms of this phenomenon were stent overexpansion, fissure or dissection [25]. Also, previous study conducted by the TIMI group showed that stent overexpansion is associated with higher risk of mortality [26]. On the other hand, Karamasis G. et al. showed that SPD during PPCI did not increase the incidence of no reflow [27].

The main findings in our study were that patients in group1had significantly higher incidence of re-infarction (5.6% *vs.* 1.5%, p=0.03) of and need for TVR (16.7% *vs.* 4.7%, p <0.001) with no significant difference among both groups regarding cardiac death, heart failure or stroke after one year follow up.

These results are consistent with most studies addressing the impact of SPD during PPCI. They concluded that apart from higher incidence of TVR and ISR, there were no significant differences between the two groups of patients in terms of clinical outcomes [25,28-30].

The current study was limited in several ways. Firstly, the current study was a non-randomized trial and the decision to perform SPD was left to the operator preference. Secondly, follow up coronary angiography was not planned to all patients, only a small proportion of patients who had a new event or severe symptoms were referred to coronary angiography and finally, the relatively small sample size. Further randomized studies including bigger sample size and longer follow up duration are needed.

Conclusion

Our study shows that SPD during PPCI is associated with an increased risk of procedural no reflow and increased risk of reinfarction as well as need for TVR after 1 year follow up. Finally, SPD did not improve clinical outcomes after 1 year follow up.

Declarations

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable (no individual personal data are included in the study).

Availability of data and materials: All data analyzed during this research are included in this published article.

Competing interests: All authors declare that they have no competing interests.

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Authors' contributions: SWA, AMZ, and MAS searched the literature, collected the data, performed the statistical analyses, and wrote the manuscript; SWA, AME, and MAS contributed to conception, design, data interpretation, and supervision of the study. All authors read and approved the final manuscript.

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