IMMEDIATE AND SHORT TERM OUTCOME IN SINGLE-STAGED VERSUS MULTI-STAGED PCI WITH COMPLETE CORONARY REVASCULARIZATION IN MULTIVESSEL NSTEMI PATIENTS

By

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ABSTRACT

Background: Acute coronary syndrome (ACS) can be divided into subgroups of ST-segment elevation myocardial infarction (STEMI), non ST-segment elevation myocardial infarction (NSTEMI), and unstable angina. ACS carries significant morbidity and mortality and the prompt diagnosis, and appropriate treatment is essential.

Objective: To compare the immediate and short-term outcome of two different complete coronary revascularization strategies in patients with NSTEMI and multivessel coronary artery disease.

Patients and Methods: 100 Patients with multivessel CAD and NSTE-ACS that underwent percutaneous coronary intervention were included, during the period from December 2017 to December 2019. They were divided into two equal groups according to revascularization strategy; Group I: had been subjected to complete coronary revascularization during the index procedure (1S- PCI group), and Group II: had been subjected to multistage PCI complete coronary revascularization during the index hospitalization (MS- PCI group). In order to characterize a coronary lesion as culprit on angiography, at least two morphological features suggestive of acute plaque rupture should be present: intraluminal filling defects consistent with thrombus, plaque ulceration, plaque irregularity, dissection or impaired flow. All patients had at least 2 vessels with 50% stenosis, and the angiographic severity of CAD was assessed using the Syntax Angiographic Score.

Results: The occurrence of the primary endpoint was significantly higher in group II (MS-PCI) where there are six cases of cardiac deaths reported. The same results were recorded regarding occurrence of malignant arrhythmias. On the other hand, there were 6 cases of reported CI-AKI with transient rise of serum creatinine managed conservatively without need of renal replacement therapy (2 cases in group I and 4 in group II). Finally, there were 12% of patients had minor bleeding (4% in group I versus 20% in group II with significant statistical difference).

Conclusion: In NSTEMI patients with multivessel disease, total revascularization during the index procedure was superior to multi-staged PCI complete coronary revascularization during the index hospitalization in terms of MACCE.

Keywords: Multivessel Coronary Artery Disease, Non-ST-elevation acute coronary syndrome, Percutaneous coronary intervention.

INTRODUCTION

Non-ST-segment elevation myocardial infarction (NSTEMI) is the most frequent manifestation of ACS, and mortality and morbidity remain high and equivalent to those of patients with ST- segment elevation myocardial infarction (STEMI) during long-term follow-up *(Gilutz et al., 2019).*

There is an ongoing debate about the role of coronary revascularization in the setting of non–ST-segment elevation myocardial infarction (NSTEMI). American and European guidelines currently agree that an early invasive strategy is recommended in patients with at least 1 high-risk criterion *(Roffi et al., 2016).*

Multivessel coronary artery disease represents 50% of patients with NSTEMI undergoing coronary angiography *(Hassanin et al., 2015).* American College of Cardiology /American Heart Association and European Society of Cardiology guidelines are unclear as to which coronary revascularization strategy to suggest in multivessel NSTEMI patients *(Roffi et al., 2016).*

Despite the discrepancy between the results of the observation studies with the majority supportive of complete revascularization compared to the minority that showed no additional effect for full revascularization *(Lee et al., 2011 and Onuma et al., 2013).* There are no RCT that has compared the complete vs. incomplete, neither simultaneous vs. staged revascularization, in patients with NSTEMI.

Two meta-analyses showed that, in patients with NSTEMI and multivessel disease, complete coronary revascularization PCI reduced MACE more than in single-vessel PPCI *(Jang et al., 2015).*

The aim of the present study was to compare the immediate and short-term outcome of two different complete coronary revascularization strategies in patients with NSTEMI and multivessel coronary artery disease.

PATIENTS AND METHODS

This prospective study included 100 consecutive patients presented with NSTEMI and multivessel coronary artery disease undergoing early invasive coronary revascularization strategy (PCI within 24 h of hospital admission) and admitted to the coronary care unit (CCU) of the National heart institute during the period from December 2017 to December 2019.

The study population was divided into two equal groups based on the strategy of management; **Group I:** had been subjected to complete coronary revascularization during the index procedure (1S- PCI group), and **Group II:** had been subjected to multistage PCI complete coronary revascularization during the index hospitalization (MS- PCI group).

All patients with NSTEMI included had multivessel coronary artery diseases. Clinically, relevant multivessel disease is defined as presence of significant obstructive disease in more than one epicardial vessel ($\geq$70% in one major epicardial vessel, and at least $\geq$50% in another major epicardial vessel) *(Khera et al., 2016).*

Exclusion criteria: Cardiogenic shock, chronic total occlusion, previous coronary artery bypass graft surgery, SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score >32, candidate for bypass surgery, severe valvular heart disease, end stage liver disease, and renal failure.

Baseline characteristics, angiographic data, medication use, and other data included GRACE 2.0 risk, CRUSADE bleeding risk score, CHA2DS2VASc score, and echocardiography were prospectively obtained and recorded.

Coronary angiography and the PCI procedure including pre-procedural preparation, PCI procedure details, materials used, intra-procedure complications, and post-PCI management were documented. Baseline SYNTAX score was calculated. The primary endpoint of the study was the incidence of MACCE, which was defined as a composite of cardiac death, any cause death, re-infarction, re-hospitalization for unstable angina, the need for repeat coronary revascularization, and stroke while in hospital and at a minimum of 3 months follow up.

The protocol was accepted by the institutional ethical boards and was performed in accordance with Al-Azhar University ethical committee. All patients provided written informed consents.

Statistical methods:

Data management and statistical analysis was done using SPSS vs.20. Numerical data was summarized as means and standard deviations. Categorical data was summarized as frequencies and percentages. Comparison between two groups for numerical variables were done using Mann Whitney U test. Categorical variables were compared using Chi-square test. When comparing two different readings of the same variable for the same group at different times e.g. (before & after), the paired sample t-test was used. P value less than 0.05 was considered significant.

RESULTS

All groups were well matched with respect to the demographic and clinical characteristics; the baseline characteristics of all groups are presented in **Table 1**. In general, the 2 groups were similar regarding risk factors for CAD and medical history **except for CHA2DS2-VASc score which was significantly lower in group I**.

Table (1): Baseline demographic data, risk factors and Risk score assessment in population study

Parameter	All patients N=100	Group I 1s-PCI N=50	Group II MS-PCI N= 50	P value*
Age (years) mean ±SD	63 ±11	63 ±9	63 ±13	>0.05
Males n (%)	31 (31%)	14 (28%)	17 (34%)	>0.05
Risk factors and comorbidities:				
Current smoking n (%)	32 (32%)	15 (30%)	17 (34%)	>0.05
Diabetic n (%)	75 (75%)	39 (78%)	36 (72%)	>0.05
Hypertensive n (%)	72 (72%)	37 (74%)	35 (70%)	>0.05
Dyslipidemic n (%)	26 (26%)	16 (32%)	10 (20%)	>0.05
Family history n (%)	21 (21%)	11 (22%)	10 (20%)	>0.05
Prior CAD n (%)	8 (8%)	3 (6%)	5 (10%)	>0.05
Risk score assessment:				
GRACE ACS Risk score	174.44 ±11.63	174.78 ±10.86	174.10 ±12.45	>0.05
CRUSADE Score	24.62 ±6.85	24.58 ±6.05	24.86 ±7.59	>0.05
CHA_2DS_2-VASc Score	**3.25 ±1.11**	**3.18 ±0.74**	**3.32 ±1.39**	**< 0.001**

* $p < 0.05$ statistically significant

Diagnostic angiographic data and calculated SYNTAX score for study population were summarized in **Table 2**.

Generally, there were no statistically significant differences between study groups regarding these data.

Table (2): Coronary angiography characteristics and SYNTAX score in study groups

Parameter		All patients N=100	Group I 1s-PCI N=50		Group II MS-PCI N= 50		P value*
		No	No	%	No	%	
Extent of CAD	2-vessel disease	66	30	60	36	72	>0.05
	3-vessel disease	34	20	40	14	28	
Culprit artery	LAD	52	34	68	18	36	
	LCX	26	6	12	20	40	
	RCA	22	10	20	12	24	
Type of artery affected	LAD	88	46	92	42	84	>0.05
	LCX	70	32	64	38	76	>0.05
	RCA	76	42	84	34	68	>0.05
TIMI flow in culprit artery (pre)	0	41	22	44	19	38	
	I	20	2	4	18	36	
	II	30	26	52	4	8	
	III	9	0	0	9	18	
SYNTAX score		21.54 ±14.1	21.3 ±14.2		21.7 ±13.9		>0.05

* $p < 0.05$ statistically significant

PCI procedural data were summarized in **Table 3**. There were no statistically significant differences between study groups regarding PCI related complications.

Table (3): PCI procedural data

Parameter	Patients	All patients N=100	Group I 1s-PCI N=50	Group II MS-PCI N= 50	P value*
Symptom to admission time (hrs) (mean ± SD)		7.38 ±4.14	7.10 ±4.23	7.66 ±4.08	>0.05
Total procedure time (min) (mean ± SD)		50.60 ±14.14	49.3 ±13.13	50.80 ±14.22	>0.05
Contrast amount (ml) (mean ± SD)		238.08 ±54.0	236.58 ±60.39	239.58 ±47.33	>0.05
No. of stents n (%)	2	53 (53%)	23 (46%)	30 (60%)	>0.05
	3	37 (37%)	23 (46%)	14 (28%)	
	4	10 (10%)	4 (8%)	6 (12%)	
TIMI flow in culprit artery (post PCI) n (%)	0	0	0	0	>0.05
	I	1 (1%)	0	1 (2%)	
	II	5 (5%)	3 (6%)	2 (4%)	
	III	94 (94%)	47 (94%)	47 (94%)	
PCI related complications	Abrupt occlusion	1 (1%)	0	1 (2%)	>0.05
	Dissection	2 (2%)	1 (2%)	1 (2%)	
	Perforation	0	0	0	

* $p < 0.05$ statistically significant

The mean time of hospital admission was 4.31 ±1.71 days in all patients (4.20 ±1.51 days in group I versus 4.42 ±1.89 days in group II, P = 0.681). Regarding MACEs, only six cases of cardiac deaths reported in group II with significant statistical difference, p = 0.011. The same results recorded regarding occurrence of malignant arrhythmias. On the other hand, there were 6 cases of reported CI-AKI with transient rise of serum creatinine managed conservatively without need of renal replacement therapy (2 cases in group I and 4 in group II, p= 0.40). Finally, there were 12% of patients had minor bleeding (4% in group I versus 20% in group II with significant statistical difference, p =0.014). No reported cases of major bleeding (Table 4).

At 90 days, post PCI the mean EF% in all patients was 51.91 ±10.5 (52.90 ±10.40 in group I versus 50.82 ±11.03 in group II, p=0.255). Analysis of these findings and comparing it with previous echocardiographic assessment during hospital admission revealed no statistically significant difference between both groups with p value = 0.074 **(Table 4 and 5)**.

Finally, no reported complications during out of hospital follow up apart from recurrent anginal pain recorded in 11 cases (5 in group I and 6 in group II, p 0.612) **(Table 4)**.

Table (4): In hospital follow up and Three months out of hospital follow up

Parameter	Patients	All patients N=100	Group I 1s-PCI N=50	Group II MS-PCI N= 50	P value*

In hospital stay (days) mean ± SD	4.31 ±1.71	4.20 ±1.51	4.42 ±1.89	>0.05
In hospital complications n (%)	30 (30%)	14 (28%)	19 (38%)	>0.05
Cardiac deaths n (%)	**6 (6%)**	**0**	**6 (12%)**	0.011
Re-infarction n (%)	0	0	0	
Cardiogenic shock n (%)	1 (1%)	0	1 (2%)	>0.05
Malignant arrhythmia n (%)	**6 (6%)**	**0**	**6 (12%)**	0.011
Stroke n (%)	0	0	0	
CI-AKI n (%)	6 (6%)	2 (4%)	4 (8%)	>0.05
Major bleeding n (%)	0	0	0	
Minor bleeding n (%)	**12 (12%)**	**2 (4%)**	**10 (20%)**	**0.014**
Non cardiac deaths n (%)	0	0	0	
Three months out of hospital follow up:				
Follow up EF%, mean ±SD	51.91 ±10.5	52.90 ±10.40	50.82 ±11.03	>0.05
Follow up eGFR, mean ±SD	188.57 ±85.73	179.91 ±8118	196.51 ±87.06	>0.05
Out of hospital complications, n (%)	11 (11.45%)	5 (10%)	6 (13%)	>0.05
Cardiac death, n (%)	0	0	0	
Non-cardiac death, n (%)	0	0	0	
Reinfarction, n (%)	0	0	0	
Recurrent angina, n (%)	11 (11.11%)	5 (10%)	6 (13%)	>0.05
Revascularization	0	0	0	

* $p < 0.05$ statistically significant

Finally, no reported complications during out of hospital follow up apart from recurrent anginal pain recorded in 11 cases (5 in group I and 6 in group II, p 0.612) **(Table 4)**.

Table (5): Comparison of LV Ejection fraction after 3 months of follow up

	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		Sig. (2-tailed)
				Lower	Upper	
EF% initial - EF% FU	-1.81%	9.78%	1.00%	-3.803%	0.182%	>0.05

* Paired sample t-test was used ($p < 0.05$ statistically significant).

DISCUSSION

In this non-randomized prospective comparative study, we compared the immediate and short-term outcome of two different complete coronary revascularization strategies in patients with NSTEMI and multivessel coronary artery disease: 1-stage percutaneous coronary intervention (1S-PCI) during the index procedure versus multistage percutaneous coronary intervention (MS-PCI) complete coronary revascularization during the index hospitalization.

In our study, the mean age of patients was 63 years which was not very different from that in other studies published in the literature in the developed countries. An exception was in the SMILE trial, where

the mean age was 72.5 years. This indicates an earlier occurrence of coronary artery disease in our country due to higher prevalence of some CAD risk factors like diabetes and hypertension, reaffirming the urgent need for strict control of these risk factors.

In our study, there was no statistically significant difference between both studied groups as regards age, sex, current smoking, diabetes, hypertension, dyslipidemia, family history of CAD, and prior MI.

These results came in agreement with the SMILE trial done by *Sardella and his Co-workers (2016)* on multivessel NSTEMI patients randomly assigned in a 1:1 manner to 1S-PCI or MS-PCI. They were also concordant with *Yu et al. (2016)* who analyzed data of NSTE-ACS patients aged ≥ 60 years with multivessel percutaneous coronary intervention (PCI). They were also concordant with *Correia et al. (2018)* diagnosed patients with NSTE-ACS and multivessel CAD who underwent percutaneous coronary intervention (PCI).

On the other hand, comparing risk profile between study groups revealed statistically significant difference by *Shishehbor and Bhatt (2010)* who conclude difference in current smoking condition and family history of coronary artery disease between both groups. This finding was discordant with our results. It may be attributed to different population and lack of randomization.

Our results, regarding risk stratification using GRACE ACS risk score 2.0 which estimates admission-6 months mortality for patients with acute coronary syndrome, and CRUSADE Score for Post-

MI bleeding risk, revealed no statistically significant difference between study groups. These findings were concordant with Sardella et al. (2016) and Correia et al. (2018), while discordant with Sadaka et al. (2018) which revealed significant difference between study groups regarding GRACE ACS Risk score 2.0, and CRUSADE Score. On the other hand, we found a statistically significant difference between study groups regarding CHA2DS2-VASc Score.

Regarding echocardiographic data, we did not find significant difference between study groups. This was concordant with *Sardella et al. (2016)*, *Yu et al. (2016)* and *Sadaka et al. (2018)*.

On analysis of angiographic data, we found no significant statistical difference between studies groups regarding culprit vessel, Syntax score, or number of vessels affected. These findings were concordant with *Sardella et al. (2016)*, *Yu et al. (2016)*, and *Correia et al. (2018)*. On the other hand, they were discordant with *Sadaka et al. (2018)* which observed significantly higher mean syntax score in culprit only revascularization than in total revascularization in same setting. In total revascularization in different settings, the mean syntax score has no statistical significance with the other 2 groups.

Regarding PCI procedural data, we found no statistically significant difference regarding total procedural time, contrast amount, number of stents used, TIMI flow in culprit artery pre and post procedure, and PCI related complications. These findings were concordant with *Sardella et al. (2016)*.

In our study, analysis of in-hospital follow up and MACEs, only six cases of

cardiac death reported in group II with significant statistical difference. The same results regarding occurrence of malignant arrhythmias. These results could be related to longer time of ischemia in the MS-PCI. A longer time of myocardial ischemia in MS-PCI group could be also due to a possible erroneous identification of the culprit lesion during coronary angiography or to the presence of multiple culprit lesions and, consequently to incomplete ischemia resolution. This result concordant with *Sardella et al. (2016)* and *Sadaka et al. (2018).*

On the contrary, *Yu et al. (2016)* concluded that staged PCI is associated with the reduced short- and long-term ischemic risks between study groups. This may be attributed to specific population of study where his trial is confined to elderly patients with NSTEACS. The reasons may be multifactorial and partially explained as follows. Any PCI procedure is challenging to the elderly. Compared to the young, elderly patients have higher prevalence of complex coronary lesions, extensive coronary atherosclerosis, comorbidities and physiological impairment. So, "One-time" PCI treatment for the elderly presenting with NSTE-ACS may increase risks for procedural complications, longer procedural time and stent thrombosis in a heightened thrombotic and inflammatory state. On the other hand, PCI on the culprit lesion only and staged non-culprit PCI at a later date with the optimal medical treatment provides stabilization of the elderly patients and allows heart team to reassess the clinical and angiographic state.

In our study 12 percent of patients had minor bleeding (4% in group I versus 20 % in group II) with significant statistical difference. A higher rate of minor bleeding was observed in MS-PCI, probably due to a higher rate of access site switching in the second procedure. These findings were contradictory to *Sadaka et al. (2018)* who observed no significant difference between groups regarding minor bleeding. This may be attributed to different risk of bleeding in population study.

On the other hand, in hospital follow up of other complications (e.g. CI-AKI, major bleeding, stroke, cardiogenic shock) revealed no significant difference between study groups in our observation. These finding concordant with *Yu et al. (2016)* and *Sadaka et al. (2018).*

Finally, there were no complications during out of hospital follow up for three months apart from recurrent anginal pain without statistically significant difference. These findings discordant to *Sardella et al. (2016)* who observed significant higher cardiac deaths and target vessel revascularization in multistage-PCI group after one-year follow up, and *Yu et al. (2016)* who observed significant higher cardiac deaths in single stage PCI group. This conflict may be attributed to relative long time of follow up in these trials in comparison to our study follow up period.

CONCLUSION

In NSTEMI patients with multivessel disease, total revascularization during the index procedure is superior to multi-staged PCI complete coronary revascularization during the index hospitalization in terms of MACCE.

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المتابعة الأولية وقصيرة المدى للمرضى الذين يعانون من إحتشاء عضلة القلب غير المصاحب بإرتفاع المقطع إس تي مع الإصابات المتعددة بالشرايين التاجية وتم التدخل بالقسطرة وتركيب الدعامات لإعادة التروية على مرحلة واحدة أوعلى مراحل متعددة

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خلفيــة البحــث: تعتبــر تضــيقات الشــرايـن التاجيــة الناتجــة عـن تصــلب الشــرايـن مـن أكثـر الأمــراض شـيوعاً. ولقـد أصــبح جليـاً أن النتــائـج المتوقعــة فـي عــلاج هـذه التضـيقات سـواء عـن طريــق جراحــة القلـب المفتـوح أو توسـيع الشـرايـن بإسـتخدام القسـطرة التداخليـة قـد يكـون متكـافئ النتـائـج لحـد كبيـر هـذا ممـا دفـع الكثيـر لعمـل مزيـد مـن الأبحـاث فـي المرضـي المتعـددي تضيـق الشـرايـن لدراسـة الآثـار المترتبـة فـي حالـة توسـيع الشـرايـن التاجيـة المتضـيقة المسـببة والغيـر مسـببة لاحتشـاء عضلـة القلـب.

الهـدف مـن البحـث: عمـل دراسـة مقارنــة مـن حيـث المضـاعفات القريبـة والمتوسـطة المـدى، وتكـرار شـكوي المرضـى ونسـبة النجـاح والأمـان بـين توسـيع الشـريان التـاجي المتضـيق فقـط (والمتسـبب فـي احتشـاء عضلـة القلـب) يتبعـه توسـيع بـاقي الشـرايـن فـي مـرة أخـرى خـلال إقامـة المـريض بالمستشـفى مقارنـة بتوسـيع كـل الشـرايـن المتضـيقة فـي المرضـي ذوى تضيـق شـريانيـن تـاجيـين فـأكثر فـي مـرة واحـدة مـع متابعـة المرضـي خلال ثلاثة أشهر.

المرضـي وطـرق البحـث: تضـمنت هـذه الدراسـة المسـتقبلية 100 مـريض متتـالي تـم تقديمهـم مـع احتشـاء عضلـة القلـب ومـرض الشـريان التـاجي متعـدد السـفن الخاضـعين لاسـتراتيجية التوعيـه التاجيـة الغازيـة المبكـرة وتـم قبـولهم فـي وحـدة العنايـة التاجيـة فـي المعهد القومي للقلب خلال الفترة من ديسمبر 2017 إلى ديسمبر 2019.

وقــد تــم تقســيم المرضــي إلــي مجمــوعتين متســاويتين: **مجموعـــة (1):** تــم توسـيع الشـريان التـاجي المسـبب لإحتشـاء عضـلة القلـب فقـط فـي جلسـة أولـى متبوعـا بتوسـيع بـاقي الشـرايين المتضـيقة فـي جلسـة أخـرى قبـل مغـادرة المستشـفى، **ومجموعة (2):** تم توسيع كل الشرايين المتضيقة دون استثناء في جلسة واحدة.

وقـد أخضـع جميـع المرضـى لبحـث التـاريخ المرضـي والكشـف السـريري (الإكلينيكـي)، وتخطـيط القلـب الكهربـائي، وموجـات فـوق الصـوتية علـي القلـب عبـر الصـدر، وقسـطرة تشخيصـية علـي الشـرايين التاجيـة (علـي أن يكـون هنـاك تضـيق شريانيين تاجيين فأكثر).

نتـائج البحـث: لــم يكــن هنـاك اختلافــاً ذا قيمـة إحصـائية بـين مجمـوعتي البحـث مـن ناحيـة التـاريخ المرضـي وعوامـل الخطـورة والفحـص السـريري، كمـا لــم يكـن هنـاك فـارق إحصـائي بـين النتـائج فيمـا يتعلـق بالموجـات الصـوتية والنتـائج الأوليـة للقسـطرة التشخيصـية. أمـا مـن ناحيـة مقارنـة النتـائج النهائيـة بـين المجمـوعتين فيمـا يخـص المضـاعفات الحصـلة ونسـبة الوفيـات وبـاقي المضـاعفات المتعلقـة بالقسـطرة التشخيصـية فقـد أظهـرت الحـالات التـي تـم عمـل توسـيع لكامـل التضـيقات الشـريانية خلال جلسة واحدة معدل وفيات ومضاعفات أقل من مثيلاتها بالمجموعة الأخرى.

الاسـتنتاج: التوسـيع للتضـيقات المتعـددة للشـريان التـاجي مـن حيـث إتمامهـا فـي جلسـة أو أكثـر يميـل إلـى جانـب التوسـيع فـي جلسـة واحـدة، إلا أنـه لا يمكـن إغفـال جوانـب مهمـة مـن الحالـة العامـة للمـريض والوضـع الإكلينيكـي، وهـو فـي نهايـة المطـاف قـرار مقوماته آراء فردية للفريق الطبى المعالج ووليدة الموقف الطبي للمريض.