Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2024.234154.2873 Volume 30, Issue 1.6, September 2024, Supplement Issue
Manuscript ID:ZUMJ-2312-3066 (R2) DOI:10.21608/ZUMJ.2024.257437.3066.

ORIGINAL ARTICLE

Incidence and Outcome of Post-Discharge Bleeding After Percutaneous Coronary Intervention in Acute Ischemic Patients

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Submit Date: 22-12-2023
Revise Date : 15-01-2024
Accept Date: 17-01-2024

ABSTRACT

Background: Dual antiplatelet treatment (DAPT) duration after percutaneous coronary intervention (PCI) with drug-eluting stents (DES) is still being debated. We aimed to predict and reduce post-discharge bleeding after percutaneous coronary intervention. **Methods:** A prospective cohort study was conducted in Cardiology Department, Zagazig University Hospital from March 2022 to February 2023 and included 337 patients with acute coronary syndrome who underwent successful percutaneous coronary intervention (PCI). All patients who were successfully treated with 1 or more drug-eluting stents (DES) and adequately loaded with acetylsalicylic acid and clopidogrel or ticagrelor were included in the study. Platelets reactivity on aspirin, clopidogrel and ticagrelor were assessed after adequate loading period to ensure full antiplatelets effect. **Results:** Periprocedural bleeding was significantly associated with increase BMI (OR = 1.312, p = 0.0496), and number of lesions (OR = 5.26, p = 0.035). Also, bleeding was significantly associated with streptokinase use before PCI (OR = 128.644, p <0.001) and Unfractionated heparin dose during PCI and (OR = 1.002, p = 0.002). **Conclusion:** We can make prediction and reduction of post-discharge bleeding after percutaneous coronary intervention by control the risk factors, the proper daily use of PPI medications with DAPT and caution of flexion and extension of hip joint at site of vascular access of PCI in first 24 hours after discharge from hospital.

Keywords: Percutaneous coronary intervention, dual antiplatelet therapy, drug-eluting stents, Acute Ischemic Patients.

INTRODUCTION

Percutaneous coronary intervention (PCI) is generally used to open a blocked coronary artery and restore arterial blood flow to heart tissue without having open-heart surgery. In individuals with a constricted or blocked coronary artery, PCI may be the best option for restoring blood flow and preventing angina (chest discomfort), myocardial infarctions (heart attacks), and mortality [1].Today, a PCI procedure typically involves the implantation of stents, including drug-eluting, fully resorbable, and bare-metal stents (also known as naturally disintegrating stents). After PCI, the artery can stay open on its own for the first three months, but after that, it has been demonstrated that the use of stents is crucial. This is the premise for developing bioresorbable stents that naturally dissolve after they are no longer needed [2].

Although there are a lot of dangers associated with PCI, serious procedural problems are rare. The most dangerous possibilities include aortic dissection, myocardial infarction (heart attack), ventricular fibrillation (non-sustained ventricular tachycardia is frequent), and death [3].For those receiving treatment for coronary artery disease with PCI across the whole clinical spectrum, periprocedural bleeding during PCI has been linked to higher short- and long-term morbidity and death. However,

compared to post-discharge ischemic events like myocardial infarction (MI), the significance and importance of nonperiprocedural bleeding episodes to late death are less clear [4].

Several studies classified post-discharge bleeding (PDB) as any of the following: a Thrombolysis in Myocardial Infarction (TIMI) major or minor bleed; a Global Use of Strategies to Open Occluded Arteries (GUSTO) severe or moderate bleed; an Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) significant bleed; or any PDB event requiring medical treatment. The site of bleeding was classified into the following predefined categories: retroperitoneal, genitourinary, central nervous system, gastrointestinal, nonretroperitoneal arterial access point, and other [5]**.**The ideal duration of dual antiplatelet therapy (DAPT) following percutaneous coronary intervention (PCI) using drug-eluting stents (DES) is still being debated. Prolonged DAPT usage is linked to a significant risk of bleeding and may increase mortality, even if it is helpful in reducing unfavorable ischemic events connected to unrelated to stents [6].Therefore, the current study aimed to predict and reduce of post-discharge bleeding after percutaneous coronary intervention.

METHODS

A prospective cohort study was conducted in Cardiology Department, Zagazig University Hospital from March 2022 to February 2023.

Inclusion criteria:All patients presenting with new acute coronary syndrome and submitted to PCI, with age >18 years old and both sexes.

Exclusion criteria: Patients who have any bleeding disorders, patients with cardiac congenital anomalies, patients with chronic hepatic and renal diseases, the occurrence of a major adverse cardiac events during the PCI as (tear or rupture of the heart arteries, bleeding at site of catheter, non-fatal stroke, non-fatal MI and cardiovascular death), patients on anticoagulant or antiplatelets treatment.

Sample size:The study included 337 patients with acute coronary syndrome who underwent successful percutaneous coronary intervention (PCI).The studied patients were divided into two groups according to presence of post-discharge bleeding to post discharge bleeding (PDB) and non-post discharge bleeding groups (non- PDB).

Data Collection and Procedures:

All patients were subjected to complete history taking including personal, complaint, present, past, and family history and full clinical examination either general for all systems or local cardiological examination. All patients in the study underwent successful PCI without any major complications during the procedure. Laboratory investigations included cardiac enzymes, lipid profile, renal function tests, liver function tests, bleeding profile, C reactive protein (CRP), estimated sedimentation rate (ESR), protein C and S and anti-cardiolipin Ab. Echocardiography was done to all patients for measurement of ejection fraction (EF), left atrium (LA), aorta, left ventricular internal dimension in diastole (LVIDD), left ventricular internal dimension in systole (LVISD), interventricular septum in diastole (IVSd), interventricular septum in systole (IVSs), left ventricular posterior wall in diastole (LVPWd) and left ventricular posterior wall in systole (LVPWs). All patients were subjected to coronary angiography and x-rays to assess the blood flows through the arteries. Clinical follow up was scheduled at 30 days, 60 days and 90 days (3 months follow up).

All patients in the study were compared according to occurrence of post discharge bleeding at 3 months. Patients with post discharge bleeding =44 patients with Hb drop +/- 2.5mg and all patients no moderate or severe bleeding but 44 patients were minimal bleeding according to TIMI score (laboratory

dependent) and mild according to GUSTO (clinical dependent) score.

Myocardial Infarction (TIMI) and Global Use of Strategies to Open Occluded Arteries (GUSTO) scores for assessment of bleeding:

Whereas the GUSTO bleeding classification is based in clinical settings, the TIMI bleeding classification is based in laboratories. Four categories are used in the TIMI definition of bleeding: major, mild, minimal, and none. Four categories are also used in the GUSTO bleeding definition: none, moderate, mild, and severe or life-threatening. The PURSUIT researchers classified bleeding occurrences using both classifications. Bleeding problems were classified as significant or life-threatening and moderate by the PARAGON investigators. Any cerebral hemorrhage or bleeding that results in hemodynamic compromise and necessitates intervention was classified as major or life-threatening bleeding. Bleeding that required a transfusion or a drop in hemoglobin of at least 5 g/dl (or a drop in hematocrit of at least 15% in the absence of hemoglobin) was classified as intermediate bleeding.

TIMI and GUSTO scores for assessment of bleeding:

The TIMI bleeding classification is a laboratory-based scale while the GUSTO bleeding classification is a clinically based scale. The TIMI definition of bleeding uses four categories: major, minor, minimal, and none. The GUSTO bleeding definition also uses four categories: severe or life-threatening, moderate, mild, and none. The PURSUIT investigators used both definitions to classify bleeding events. The PARAGON investigators defined bleeding complications as major or life-threatening, and intermediate. Major or life-threatening bleeding was defined as any intracranial hemorrhage or bleeding leading to hemodynamic compromise requiring intervention. Intermediate bleeding was defined as bleeding requiring transfusion or a decrease in hemoglobin 5 g/dl or more (or decrease in hematocrit ≥15% when hemoglobin was unavailable).

Key Elements of the TIMI and GUSTO Bleeding scores:

TIMI Bleeding Classification:	
Major	Intracranial hemorrhage or a ≥5 g/dl decrease in the hemoglobin concentration or a ≥15% absolute decrease in the hematocrit.
Minor	Observed blood loss: ≥3 g/dl decrease in the hemoglobin concentration or ≥10% decrease in the hematocrit
	No observed blood loss: ≥4 g/dl decrease in the hemoglobin concentration or ≥12% decrease in the hematocrit.
Minimal	Any clinically overt sign of hemorrhage (including imaging) that is associated with a <3 g/dl decrease in the hemoglobin concentration or <9% decrease in the hematocrit.
GUSTO Bleeding Classification:	
Severeorlife-threatening	Either intracranial hemorrhage or bleeding that causes hemodynamic compromise and requires intervention.
Moderate	Bleeding that requires blood transfusion but does not result in hemodynamic compromise
Mild	Bleeding that does not meet criteria for either severe or moderate bleeding

GUSTO = Global Strategies for Opening Occluded Coronary Arteries; TIMI = Thrombolysis In Myocardial Infarction.

Ethical and administrative considerations: Every patient provided written informed consent, and the study was authorized by Zagazig University, Faculty of Medicine's Research Ethical Committee (ZU-IRB # 10029-9-11-2022). The study was carried out according to the Ethical code of the World Medical Association (Declaration of Helsinki) for Studies including humans.

Table (1): Effect of demographic characters age, gender and risk factors in Post Discharge bleeding (PBD) group and non- PDB group.

		Bleeding				P-value*
		PDB group (N=44)		No PDB group (N=293)		
		No.	%	No.	%	
Gender	**Male**	38	86.4%	160	54.6%	**<0.001 (HS)**
	Female	6	13.6%	133	45.4%	
Age (years)	**Mean±SD**	65.95± 4.93		65.46± 5.41		0.591 (NS)
Effect of risk factors						
DM	**No**	14	31.8%	238	81.2%	**<0.001 (HS)**
	Yes	30	68.2%	55	18.8%	
HTN	**No**	6	13.6%	120	41.0%	**<0.001 (HS)**
	Yes	38	86.4%	173	59.0%	
Hyperlipidemia	**No**	10	22.7%	167	57.0%	**<0.001 (HS)**
	Yes	34	77.3%	126	43.0%	
Peripheral vascular disease	**No**	16	36.4%	269	91.8%	**<0.001 (HS)**
	Yes	28	63.6%	24	8.2%	
Smoking	**No**	16	36.4%	257	87.7%	**<0.001 (HS)**
	Yes	28	63.6%	36	12.3%	
STEMI or NSTEMI	**NSTEMI**	30	68.2%	283	96.6%	**<0.001 (HS)**
	STEMI	14	31.8%	10	3.4%	

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, * Chi-Square Test, Mann-Whitney U Test, DM=diabetes mellitus, HTN= hypertension, STEMI=st segment elevation myocardial infarction, NSTEMI=non st segment elevation myocardial infarction.

Table (2): Effect of medical treatment in PBD group and non- PDB group.

		Bleeding				P-value
		PDB group (N=44)		No PDB group (N=293)		
		No.	%	No.	%	
Antiplatelets	**Clopidogrel**	18	40.9%	120	41.0%	0.955 (NS)
	Ticagrelor	26	59.1%	173	59.0%	
1st aid anticoagulant	**LMW heparin**	20	45.5%	105	35.8%	0.218 (NS)
	Unfractionated heparin	24	54.5%	188	64.2%	
Streptokinase before PCI		12	27.2%	3	1.0%	**<0.001 (HS)**
Unfractionated heparin dose during PCI		16477.3	±7668.99	7713.3	±2495.1	**<0.001**

P value< 0.05 is significant, P value< 0.01 is highly significant, X2: Chi-Square Test, PCI=percutanous coronary intervention.

Table (3): Operative data in PBD group and non- PDB group**.**

		Bleeding				P-value
		PDB group (N=44)		No PDB group (N=293)		
		No.	%	No.	%	
Vascular access site	**Femoral**	44	100.0%	276	94.2%	0.101 (NS)
	Radial	0	0.0%	17	5.8%	
Number of diseased vessels	**1**	17	38.6%	110	37.5%	**0.038 (S)**
	2	27	61.4%	146	49.8%	
	3	0	0.0%	37	12.6%	
Location of lesion	**Distal RCA**	6	13.6%	90	30.7%	**0.010 (S)**
	Mid LCX	26	59.1%	107	36.5%	
	proximal LAD	12	27.3%	96	32.8%	
Number of diseased vessels	**1**	30	68.2%	61	20.8%	**<0.001 (HS)**
	2	12	27.3%	128	43.7%	
	3	2	4.5%	104	35.5%	
Number of stents		2	±1	2	±1	**0.002**

P value< 0.05 is significant, P value< 0.01 is highly significant, X2: Chi-Square Test,RCA=right coronary artery, LCX=left circumflex artery, LAD= left anterior descending artery.

Table (4): Comparison outcome in PBD group and non- PDB group**.**

		Bleeding				P-value
		PDB group (N=44)		No PDB group (N=293)		
		No.	%	No.	%	
Outcome	**Discharged**	0	0.0%	293	98.6%	**<0.001 (HS)**
	ACS & hospitalization	11	25.0%	0	0.0%	
	Conservative management	33	75.0%	0	0.0%	

P value< 0.05 is significant, P value< 0.01 is highly significant, X2: Chi-Square Test, ACS=acute coronary syndrome.

Table 5: Comparison different parameters in PBD group and non- PDB group.

	Bleeding				P-value
	PDB group (N=44)		No PDB group (N=293)		
	Mean	±SD	Mean	±SD	
Weight/ kg	85.70	±6.07	83.57	±6.12	**0.027**
BMI	29.44	±4.28	27.40	±4.60	**0.001**
Hb.	13.27	±1.06	13.04	±1.19	0.178
WBCs	8.27	±0.97	8.59	±1.21	0.117
Platelets count	232.43	±14.76	231.89	±14.99	0.672
Hb drop	2.54	±0 .06	2.50	±0.08	**0.027**

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, Mann-

Whitney U Test BMI=body mass index, Hb=hemoglobin, Wbcs=white blood cells.

Table 6: Comparison bleeding site in PBD group and non- PDB group.

		Bleeding				P-value
		PDB group (N=44)		No PDB group (N=293)		
		No.	%	No.	%	
Bleeding site	No	0	0%	293	100%	<0.001 (HS)
	GIT bleeding	27	61.4%	0	0.0%	
	Vascular access of PCI bleeding	17	38.6%	0	0.0%	

P value< 0.05 is significant, P value< 0.01 is highly significant, X2: Chi-Square Test, PCI=percutaneous coronary intervention.

Table (7): Multivariate logistic regression analysis for factors predicting bleeding.

Parameters	P-value	Odds ratio (OR)	95%CI	
			Lower limit	Upper limit
Weight/ kg	0.088	1.198	.973	1.475
BMI	**0.0496**	1.312	1.000	1.721
DM	0.161	17.995	.316	1026.138
Hyperlipidemia	0.077	34.978	.680	1799.328
Smoking	0.520	2.493	.154	40.232
STEMI or NSTEMI (1)	0.694	.552	.029	10.622
Streptokinase before PCI	**<0.001**	128.644	71.27	404.256
Unfractionated heparin dose during PCI	**0.002**	1.001	1.001	1.002
Number of lesions	**0.035**	5.260	1.121	24.682
Number of diseased vessels	0.154	9.822	.424	227.572
Number of stents	0.588	1.258	.548	2.891

B: Regression coefficient; S.E.: Standard error, CI: Confidence interval. Variable(s) entered on step 1: Gender, Weight/ kg, BMI, DM, HTN, Hyperlipidemia, Smoking, peripheral vascular disease, STEMI or NSTEMI, streptokinase before PCI, Unfractionated heparin dose during PCI, Number of lesions, number of diseased vessels, Hb drop, Number of stents.BMI=body mass index, DM=diabetes mellitus, PCI=percutaneous coronary intervention, STEMI=st segment elevation myocardial infarction, NSTEMI=non st segment elevation myocardial infarction.

DISCUSSION

Our study showed that the age of studied cases ranged between 56 years to 77 years with mean age was 65.53± 5.35 years. Regarding gender, there were 198 (58.8%) males and 139 (41.2%) females with male to female ratio was 1.42:1.Nugraha *et al*. [7] who found that the female gender was more prevalent and that age was over 70. This difference may be due to different populations.

Our study showed that regarding comorbidities, 85 (25.2%) patients had DM, 211 (62.6%) patients were hypertensive, 160 (47.5%) had hyperlipidemia, and 64 (19%) were smokers. 52 (15.4%) patients had previous history of peripheral vascular disease.Nugraha *et al*. [7] who found that comorbidities, (25.2%) patients had DM, (62.6%) patients were hypertensive, and

(20%) were smokers. (17%) patients had previous history of peripheral vascular disease and our results agree with that.

This study showed that regarding diagnosis, most studied cases (92.9%) patients had non-ST-elevation myocardial infarction (NSTEMI), while 24 (7.1%) patients had ST-elevation myocardial infarction (STEMI).Chen *et al*. [8] who found that 2,381 eligible participants were included in the study out of the 2,520 patients enrolled in the BRIC-ACS study who had a definitive diagnosis of ACS and had undergone PCI with DES: 1,012 patients (42.5%) had unstable angina, of whom 934 patients (39.2%) had STEMI and UA435 patients (18.3%) had NSTEMI and our results agree withthat.

Our study showed that mean weight, and height were 85.42± 6.11 kg, and 1.72± 0.11 m respectively. The mean BMI in studied cases was 29.18 ±4.37 Kg/m^2. Also, the mean hemoglobin level was 13.07± 1.17 g/dl. The mean WBCs and platelets count were 8.55± 1.18 $x10^9$/ L and 231.96± 14.94 $x10^9$/ L respectively.Our results disagreement with Généreux *et al*. [9] who found that individuals with peripheral arterial disease (PAD), congestive heart failure, hypertension, hyperlipidemia, prior MI, and prior coronary revascularization were older, more often female, and had PDB within two years. Hemoglobin and creatinine clearance values were similarly lower at baseline in PDB patients. This may be due to different sample size and the differences in the techniques and normal range of laboratory tests.

Our study showed that post-discharge bleeding was observed in 44 (13.1%) cases. Out of those 44 cases, 27 cases reported GIT bleeding while 17 cases reported vascular access of PCI bleeding. The mean bleeding amount was 52.27± 42.08 ml. The mean bleeding time was 25.95± 6.95 seconds. From History taking of bleeding from patient nearly determined them. The mean hemoglobin drop time was 2.507± 0.08 g/dl.Généreux *et al.* [9] who found that PDB occurred in 535 of 8,577 hospital survivors (6.2%) at a median time of 300 days (interquartile range: 130 to 509 days) post-discharge. The most common cause of PDB (61.7%) was bleeding in the gastrointestinal tract. These results are consistent with the predicted markers of PDB, which included older age, lower baseline hemoglobin, reduced platelet reactivity on clopidogrel, and long-term oral anticoagulant drug use.

Also, our results agreement with Marquis *et al*. [10] who found the death rates did not differ statistically from those of patients who did not have post-discharge bleeding (p 0.095). It was discovered that there were statistical differences in the adjusted HRs between the various time periods since bleeding ($p < 0.001$).

Following PCI, bleeding-related hospitalization following discharge was linked to later death or MI (hazard ratio: 3.09; 95% confidence interval: 2.41–3.96), with the first 60 days following bleeding-related hospitalization carrying the highest risk of death or MI (hazard ratio: 7.16; confidence interval: 3.93–13.05) [11].This study showed that regarding outcome, most cases (86.1%) discharged, 3.3% reported chest pain and acute coronary syndrome that needed hospitalization, and 9.8% were on conservative management. None of died cases was reported in our study. Also, post-discharge bleeding was significantly higher in male cases compared to female cases ($p<0.001$) while no statistically significant difference was observed between the two groups regarding age ($p>0.05$).Généreux *et al*. [9] revealed the age differences were statistically significant. Additionally, our results concur with the very statistically significant difference regarding sex (p value <.05).

We found that post-discharge bleeding was significantly higher in cases used streptokinase before PCI ($p<0.001$). While no statistically significant relation was observed between post-discharge bleeding and use of antiplatelets or 1st aid anticoagulant ($p>0.05$).Our results are in agreement with Sezer *et al.* [12] who found that Two days before PCI, all measures of microvascular function (means ±SD) were significantly better in the streptokinase group than in the control group.

According to our findings, there was a statistically significant correlation between

the number of lesions (p=0.038), the position of the lesion (p=0.01), and the number of vessels (p<0.001) and post-discharge bleeding. However, there is no statistically significant correlation (p>0.05) between the vascular access site and post-discharge bleeding. Post-discharge bleeding and outcome had a statistically significant relationship (p<0.001) in patients with ACS.Généreux *et al*. [9] they discovered that PDB was linked to greater crude rates of death from all causes (13.0% vs. 3.2%; p < 0.0001). PDB was substantially correlated with 2-year mortality after multivariable correction (hazard ratio [HR]: 5.03; p < 0.0001). Our findings support that.

CONCLUSION

We can make prediction and reduction of bleeding upon discharge from percutaneous coronary intervention by control the risk factors, the proper daily use of PPI medications with DAPT and caution of flexion and extension of hip joint at site of vascular access of PCI in first 24 hours after discharge from hospital. More research is needed to fully comprehend how various categories of bleeding severity affect a patient's prognosis with acute ischemic patients that treated with PCI.

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Citation:

Abdelrashied, M., Moustafa, T., Gad, M., Ezzat Abdelhameid, E., Mohamed, M. Incidence and Outcome of Post-Discharge Bleeding After Percutaneous Coronary Intervention in Acute Ischemic Patients. *Zagazig University Medical Journal*, 2024; (2885-2892): -. doi: 10.21608/zumj.2024.257437.3066