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## **FREQUENCY OF GASTROINTESTINAL BLEEDING IN PATIENTS UNDERGOING PERCUTANEOUS INTERVENTION FOR ACUTE MYOCARDIAL INFARCTION**

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## ABSTRACT

**Background:** Coronary artery disease (CAD) is one of the leading causes of morbidity and mortality in the world. Established way of treating patients according to ACC/AHA guidelines is with combination of dual anti platelets (Aspirin and clopidogrel) and anticoagulants. Cardiac benefit of this treatment modality is proven; however, their benefits are matched by a parallel increase in the gastrointestinal (GI) complications including bleeding with a frequency of 7.1%, which has been observed to be a poor prognostic marker, and is one of the most frequent non cardiac complication after PCI.

**Objectives:** To determine the frequency and risk factors of gastrointestinal bleeding in patients undergoing primary percutaneous coronary intervention for acute myocardial infarction.

**Study Design :** Observational, prospective cohort study.

**Duration and place of study.** Department of Department of Cardiology, MTI Mardan Medical Complex Mardan, KP – Pakistan from jan 2023 to july 2023

**Materials and Methods:** The study was initiated after taking approval from hospital ethical committee and an informed written consent was taken from each patient. A sample size of 207 was calculated using the WHO software with confidence interval of 95%, with population prevalence of 71.1% and margin of error as 3.5%. The sampling was done via non-probability consecutive sampling. Basic demographic information including name, age and gender were recorded on a pre-designed performa and time duration of 1.2 hours post symptoms were taken for consideration. After getting consents the patient underwent PPCI followed by observation for gastrointestinal bleeding. After observing the patients who develop GI bleeding up to 72 hours post procedure, its frequency was calculated among the total cases included in the study.

**Results:** Among the Patients selected for this study, 132 were males and 75 were females, with a mean age of  $54.1 \pm 12.2$  years. Out of these patients, those having an inferior wall MI were 120 (58%), anterior wall MI were 30 (14.5%), Lateral wall MI were 29 (14%) and Posterior wall MI were 28 (13.5%). GI bleeding after PCI was found in 16 (7.7%) of people. Stratification for age, gender and ACS status was also carried out, showing an incidence of gastrointestinal bleeding in 16 (7.7%) with equal distribution among different age groups, whereas predominantly involving male gender and patients with acute inferior wall MI.

**Conclusion:** In contrast to other studies our study found higher instances of bleeding in STEMI patients, particularly the male population. The chances of major bleeding can therefore be minimized with advancement in procedural methods and pharmaceutical tactics.

**Keywords:** Primary percutaneous coronary intervention; acute myocardial infarction; gastrointestinal bleeding.

## INTRODUCTION

Coronary artery disease (CAD) is one of the leading causes of morbidity and mortality in the world. Although the mortality rate has decreased in the past few years due to better management, yet an approximately 7.2 million people die every year indicating around 12% of all deaths worldwide.<sup>1</sup> According to World Health Organization (WHO) in 2014, mortality due to CAD in

Pakistan reached 111,367 accounting for 9.87% of the all-cause mortality. 2 Primary percutaneous coronary intervention (PPCI) is the treatment modality of choice for acute STEMI, if performed timely, ideally within 90-120 minutes of first contact with medical care provider. However, age, delayed treatment, treatment modality, prior MI history, diabetes mellitus, chronic kidney disease and degree of disease in coronary arteries are some of the most powerful predictors of adverse outcomes, leading one among them are gastrointestinal bleeding. Female gender has also emerged as an independent predictor of early mortality and bleeding complications. 3,4 Established way of treating patients according to ACC/AHA guidelines is with combination of dual anti platelets (Aspirin and clopidogrel) and anticoagulants which is practiced widely in patients with STEMI and NSTEMI. They receive a full dose of aspirin and anticoagulation with unfractionated or low molecular weight heparin for at least 48 hours. Cardiac benefit of this treatment modality is proven; however, their benefits are matched by a parallel increase in the gastrointestinal (GI) complications including bleeding with a frequency of 7.1%, which has been observed to be a poor prognostic marker 5, and is one of the most frequent non cardiac complication after PCI comparable with that of ischemic events. 6 Particularly, it is a common cause of non-access site-related bleeding after PCI 7 and is linked with an in-hospital mortality of  $\leq 10\%$ . 8 The aim of this study is to determine the frequency, predictors, and demographics of GIB in patients undergoing PCI. It also quantifies the burden of GI bleeding in STEMI patients who are offered primary PCI especially in correlation with the pharmacologic therapy provided during PPCI, its effectiveness and safety in both genders and the potential importance of gender as a predictor of outcome. This study will also help in the local setups, to have better patient selection for the procedure; take the needful steps after procedure like active monitoring for any upper and lower GI bleed signs and symptoms and its prompt management and optimizing an antiplatelets plan. These steps will also help to minimize the sufferings of the patients.

## MATERIAL AND METHODS

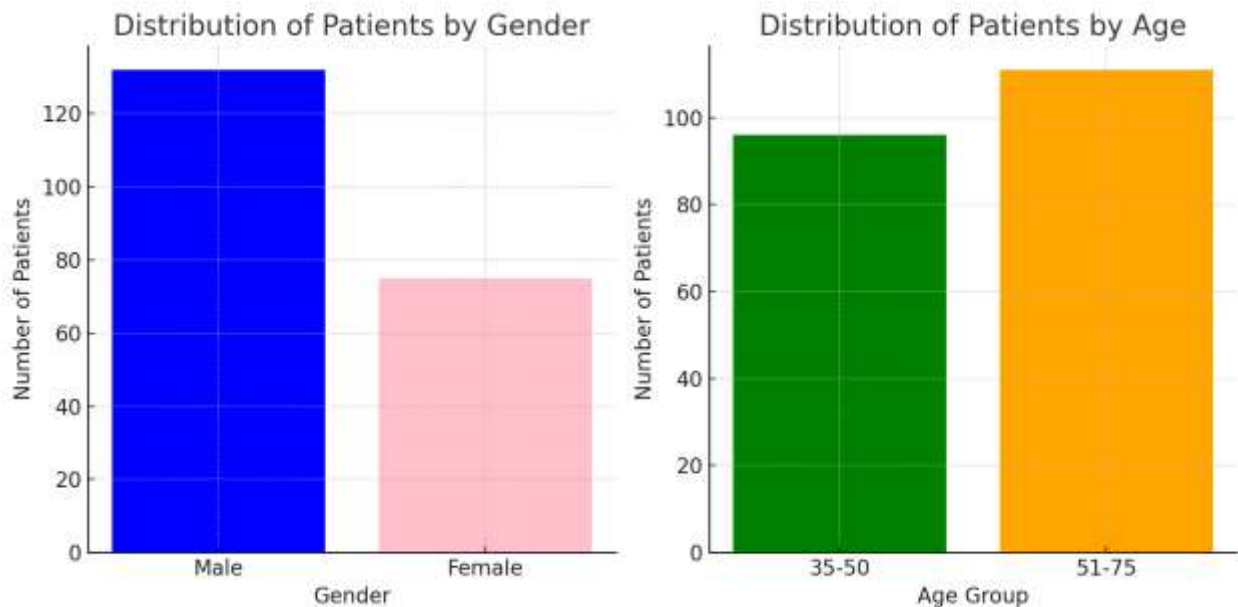
The study was initiated after taking approval from hospital ethical committee and an informed written consent was taken from each patient. A sample size of 207 was calculated using the WHO software with confidence interval of 95%, with population prevalence of 71.1% and margin of error as 3.5%. The **sampling was done via** non-probability consecutive sampling during which inclusion criteria was followed in which patients having an acute myocardial infarction (ST elevation greater than 1mm in at least two leads or new bundle branch block on ECG), patients who underwent primary PCI after STEMI, both gender having an age range of 35-75 years and those receiving a GpIIb/IIIa receptor antagonist were recruited. Strict exclusion criteria was followed to control confounding by excluding patients who have underwent thrombolysis, diagnosed as case of GI malignancy, patients with thrombocytopenia and hereditary or acquired clotting factors disorders

Basic demographic information including name, age and gender were recorded on a pre-designed performa and time duration of 1.2 hours post symptoms were taken for consideration. After getting consents the patient underwent PPCI followed by observation for gastrointestinal bleeding. After observing the patients who develop GI bleeding up to 72 hours post procedure, its frequency was calculated among the total cases included in the study. Data was recorded on a performa.

**Data analysis procedure:** Data was analyzed using SPSS 20.0. Quantitative variables like age were described as mean $\pm$ standard deviation. Categorical variables like gender and number of patients with GI bleed were described as frequencies and percentages. GI bleed was stratified by effect modifiers like age, gender and acute coronary syndrome status to see effect modification. Post stratification, Chi-Square test was applied in which P value  $\leq 0.05$  was considered significant.

## RESULTS

Among the Patients selected for this study, 132 were males and 75 were females (table#1), with a mean age of  $54.1 \pm 12.2$  years (table#2). Out of these patients, those having an inferior wall MI were 120 (58%) anterior wall MI were 30 (14.5%), Lateral wall MI were 29 (14%) and Posterior wall MI were 28 (13.5%). GI bleeding after PCI was found in 16 (7.7%) of people (table#3). Stratification for age, gender and ACS status was also carried out, showing an incidence of gastrointestinal bleeding in 16 (7.7%) (Table#4) with equal distribution among different age groups (table#5), whereas predominantly involving male gender and patients with acute inferior wall MI (Table#6,7).



**Table-1: Distribution of patients by gender**

Gender	Number	Percentage
Male	132	63.8
Female	75	36.2
<b>Total</b>	<b>207</b>	<b>100.0</b>

**Table-2: Distribution of patients by age**

Age (Year)	Number	Percentage
35-50	96	46.4
51-75	111	53.6
Total	207	1000
<b>Mean±SD</b>	<b>54.1±12.2</b>	

**Table -3: Acute coronary syndrome status**

Status	Number	Percentage
Anterior wall MI	30	14.5
Posterior wall MI	28	13.5
Inferior wall MI	120	58.0
Lateral wall MI	29	14.0
Total	207	100.0

**Table-4: Gastrointestinal (GI) bleeding**

GI bleeding	Number	Percentage
Yes	16	07.7
No	191	92.3
<b>Total</b>	<b>207</b>	<b>100.0</b>

**Table-5: Stratification for age about GI bleeding**

Age	Gastrointestinal bleeding		Total	Chi square/ p value
	Yes	No		
35-50	8	88	96	$\chi^2=0.092$ P=0.762
51-75	8	103	111	
<b>Total</b>	<b>75</b>	<b>15</b>	<b>240</b>	

**Table-6: Stratification for gender about GI bleeding**

Gender	Gastrointestinal bleeding		Total	Chi square/ p value
	Yes	No		
Male	13	119	132	$\chi^2=2.294$ P=0.130
Female	03	72	75	
<b>Total</b>	<b>16</b>	<b>191</b>	<b>207</b>	

**Table-7: Stratification for acute coronary syndrome status about GI bleeding**

ACS status	Gastrointestinal bleeding		Total	Chi square/ p value
	Yes	No		
Anterior wall MI	1	29	30	$\chi^2=1.252$ P=0.740
Posterior wall MI	3	25	28	
Inferior wall MI	10	110	120	
Lateral wall MI	2	27	29	
<b>Total</b>	<b>16</b>	<b>191</b>	<b>207</b>	

## DISCUSSION

The advent of potent antiplatelet and antithrombotic medications has led to a substantial improvement of ischemic outcomes among patients with coronary artery disease undergoing percutaneous coronary interventions (PCIs). However, bleeding has become an important concern because it represents the most frequent noncardiac complication after PCI with an adverse prognostic impact comparable with that of ischemic events. In particular, gastrointestinal bleeding (GIB) is a common source of non access site-related bleeding after PCI and has been associated with an in-hospital mortality of  $\leq 10\%$ . The risk factors and clinical sequelae of gastrointestinal bleeding (GIB) in the current era of drug-eluting stents, prolonged dual antiplatelet therapy, and potent P2Y<sub>12</sub> inhibitors are not well established.<sup>3</sup>

In a study done by Wajih et al, thirty-one patients (6.2%) developed bleeding complications after coronary intervention; major bleed in four cases (0.8%) and minor bleed in 27 cases (5.6%). The frequency of bleeding complications was 8.5% among females and 5.7% among males.<sup>9</sup>

We determined the frequency of gastrointestinal bleeding in patients with STEMI undergoing primary coronary intervention. Although previous studies identified patient- and medication-related factors predisposing to GIB after PCI, several issues were raised. First, earlier reports focused on populations with characteristics, which per se portend an increased bleeding risk, including severe heart failure or patients with acute coronary syndromes (ACSs) receiving intensive antithrombotic regimens. Second, previous studies were restricted to GIB occurring during the in-hospital period. Although prolonged (12 months) duration of dual antiplatelet therapy (DAPT) is the current standard of care after PCI with drug-eluting stents (DES), the time course, predictors, and prognostic implications of GIB occurring late after PCI have not been systematically assessed. Third, although prasugrel and ticagrelor have been associated with an increased risk of GIB in the setting of randomized trials, the safety profile of these novel P2Y<sub>12</sub> inhibitors in unselected patients is not well established. Finally, considering the differential

correlates and prognostic significance of bleeding in the upper versus lower gastrointestinal tract in general populations, the relative frequency and clinical impact of upper versus lower GIB after PCI remain largely unknown. In current study, gastrointestinal bleeding (GIB) occurred in 7.7% of patients with STEMI undergoing primary coronary intervention. Our findings are in agreement with a study carried out by Aziz (2014), they demonstrated GIB in 7.1% of patients. While some previous studies have shown that 0.7 to 3.0% of patients with acute coronary syndrome had GI bleeding. Patients in our study appeared to have a higher incidence of GI bleeding.<sup>5</sup>

### CONCLUSION

Despite their rarity, serious bleeding issues during PCI are a significant factor in patient hospitalization and death. In conclusion, as compared to other studies our study found higher instances of bleeding in STEMI patients, particularly the male population. The chances of major bleeding can therefore be minimized with advancement in procedural methods and pharmaceutical tactics.

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**Conflict of Interest:** There is no conflict of interest.

**Funding Disclosure:** Nil

### Authors Contribution

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