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INCIDENCE OF BLEEDING COMPLICATIONS IN ACUTE ST-ELEVATION MYOCARDIAL INFARCTION PATIENTS UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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ABSTRACT

Background: This study aims to comprehensively describe the incidence, types, and associated risk factors of bleeding complications in patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PPCI), addressing a critical gap in the literature given the global burden of cardiovascular disease and the inherent bleeding risks of contemporary antithrombotic therapies.

Method: This retrospective cross-sectional study will investigate the incidence and types of bleeding complications, along with associated risk factors, in ST-elevation myocardial infarction (STEMI) patients undergoing primary percutaneous coronary intervention (PPCI) at Adam Malik Hospital Medan, analyzing data from May 2022 to December 2024 through ethical review and statistical analysis using SPSS version 23.

Result: Of 245 STEMI patients undergoing primary PCI, 42.9% experienced bleeding, predominantly minor (BARC 1 and 2, 94.2% combined), with significant associations observed between bleeding and lower hemoglobin, higher leukocyte and creatinine levels, higher TIMI score, Killip class 3 and 4, diabetes, use of maintenance heparin, and increased mortality (84.6% of all deaths occurred in bleeding patients), while hematuria and puncture site hematoma were the most common bleeding sources.

Conclusion: This study found that 42.9% of 245 STEMI patients undergoing primary PCI experienced bleeding complications, predominantly minor (94.2%), with an average age of 55.2 years and a male majority.

Keyword: Bleeding complications, Acute Coronary Syndrome, Primary Percutaneous Coronary Intervention

ABSTRAK

Latar Belakang: *Studi ini bertujuan untuk menjelaskan secara komprehensif insidensi, jenis, dan faktor risiko terkait komplikasi perdarahan pada pasien infark miokard akut dengan elevasi segmen ST (IMA-EST) yang menjalani intervensi koroner perkutan primer (IKPP), guna mengisi kesenjangan krusial dalam literatur mengingat beban global penyakit kardiovaskular dan risiko perdarahan inheren dari terapi antitrombotik kontemporer.*

Metode: *Studi cross-sectional retrospektif ini akan menyelidiki insidensi dan jenis komplikasi perdarahan, beserta faktor risiko terkait, pada pasien IMA-EST yang menjalani IKP primer di RS Adam Malik Medan, dengan menganalisis data dari Mei 2022 hingga Desember 2024 melalui tinjauan etik dan analisis statistik menggunakan SPSS versi 23.*

Hasil: *Dari 245 pasien IMA-EST yang menjalani IKP primer, 42.9% mengalami perdarahan, yang sebagian besar bersifat minor (BARC 1 dan 2, total 94.2%). Asosiasi signifikan teramati antara perdarahan dengan kadar hemoglobin lebih rendah, kadar leukosit dan kreatinin lebih tinggi, skor TIMI lebih tinggi, kelas Killip 3 dan 4, diabetes, penggunaan maintenance heparin, dan peningkatan mortalitas (84.6% dari seluruh kematian terjadi pada pasien yang mengalami perdarahan), dengan hematuria dan hematoma lokasi pungsi sebagai sumber perdarahan paling umum.*

Kesimpulan: *Studi ini menemukan bahwa 42.9% dari 245 pasien IMA-EST yang menjalani IKP primer mengalami komplikasi perdarahan, yang sebagian besar bersifat minor (94.2%), dengan usia rata-rata 55.2 tahun dan mayoritas berjenis kelamin laki-laki.*

Kata Kunci: *Komplikasi perdarahan, Sindrom Koroner Akut, Intervensi Koroner Perkutan Primer.*

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1. Introduction

Patients diagnosed with ST-segment elevation myocardial infarction (STEMI) who undergo primary percutaneous coronary intervention (PPCI) remain vulnerable to a severe complication: bleeding [1]. The occurrence of major bleeding after PPCI ranges between 4% and 10%, significantly increasing the patient's 30-day mortality risk by two to five times. Besides contributing to worse morbidity, bleeding may necessitate discontinuation of the intervention, jeopardizing the management of ischemia and adversely impacting overall patient prognosis [2,3].

Several risk scores have been created based on clinical criteria to help doctors stratify patients' risks in addition to using their clinical judgment. Risk scores are still regarded as useful instruments in clinical decision-making, even though no score is flawless. Over the past few decades, a number of risk prediction models utilized in cardiovascular medicine have been developed since the popular Framingham risk score was published as a prediction model for incident cardiovascular disease. Predictors found in huge datasets are frequently used to create risk models, which are then condensed into risk scores. Each risk factor is given a numerical weight (point), representing the likelihood of a particular result. This makes it simple to compute and analyze the risk scores, and some of them are also used as guidelines to help doctors make decisions in their day-to-day clinical work.

Risk scores can be utilized for risk stratification at several points in the ACS timeframe. When a patient presents with acute chest pain and suspected ACS, risk scores are used to determine who is at low risk of major adverse cardiac events (MACE) and, second, to determine whether to quickly discharge the patient without further invasive testing. Risk scores are used to guide subsequent in-hospital therapy (e.g., timing of coronary angiography) and to evaluate the in-hospital or short-term

risk of mortality and/or hemorrhage at admission. Before being discharged from the hospital, an individual's risk of death, myocardial infarction (MI), or bleeding may be reassessed to establish an outpatient treatment plan. Risk scores are available in the months or years after ACS to assess long-term risk for further cardiovascular events or to compute the ischemic-bleeding trade-off risk for the best antithrombotic treatment. Given these serious consequences, it is crucial to identify patients at risk for bleeding complications [4]. Accurate assessment of bleeding risk is crucial, given the substantial comorbidities and high mortality associated with major bleeding in this population [4]. Although several studies have explored bleeding risk factors in ACS patients broadly, research specifically focusing on the incidence and types of bleeding in STEMI patients undergoing primary PCI (PPCI) remains scarce. This study aims to comprehensively characterize the frequency, risk factors, and types of bleeding events in STEMI patients treated with primary PCI.

2. Method

This observational analytic study used a retrospective cross-sectional design to evaluate routinely recorded data and examine the relationships between patient characteristics, PCI procedures, and bleeding incidence. The study was conducted at Adam Malik Hospital, and data were collected between January 1 and 31, 2025, from medical records dated May 2022 to December 2024.

The target population included all STEMI patients undergoing primary percutaneous coronary intervention (PPCI) without prior fibrinolytic therapy. The accessible population comprised eligible patients admitted during the study period. Consecutive sampling selected patients meeting the inclusion criteria: age >18, STEMI diagnosis, and PPCI treatment. Exclusions were prior fibrinolytics, coronary artery bypass graft (CABG) history, hematologic or hemostatic disorders, and incomplete records. The sample size was calculated using a proportion estimation formula. Based on a 12.35% bleeding rate from previous studies, a 95% confidence level, and 10% precision, a minimum of 42 patients is required. Ethical approval was granted by the Faculty of Medicine, Universitas Sumatera Utara (1486/KEPK/USU/2024), and research permission was granted by the hospital's Research and Development Division (DP.04.03/D.XXVIII/355/2025).

Data collected included age, sex, BMI, Killip class at admission, hemoglobin, leukocyte count, serum creatinine, angiography findings of coronary lesions, temporary pacemaker use, vascular access type (femoral or radial), and antithrombotic therapy (heparin ± GP IIb/IIIa inhibitors or bivalirudin). Bleeding during hospitalization was classified using the Bleeding Academic Research Consortium (BARC) scale.

Statistical analysis was performed with SPSS v23 using descriptive and inferential tests—normality, Chi-Square/Fisher's Exact, and t-test/Mann-Whitney—with significance at $p<0.05$.

3. Results

A total of 302 STEMI patients undergoing PCI (primary, rescue, or early) from May 2022 to December 2024 were considered. After excluding 27 who had prior fibrinolytic therapy (including rescue and early PCI) and 30 with incomplete data, 245 patients remained—140 without bleeding and 105 with bleeding (Figure 1).

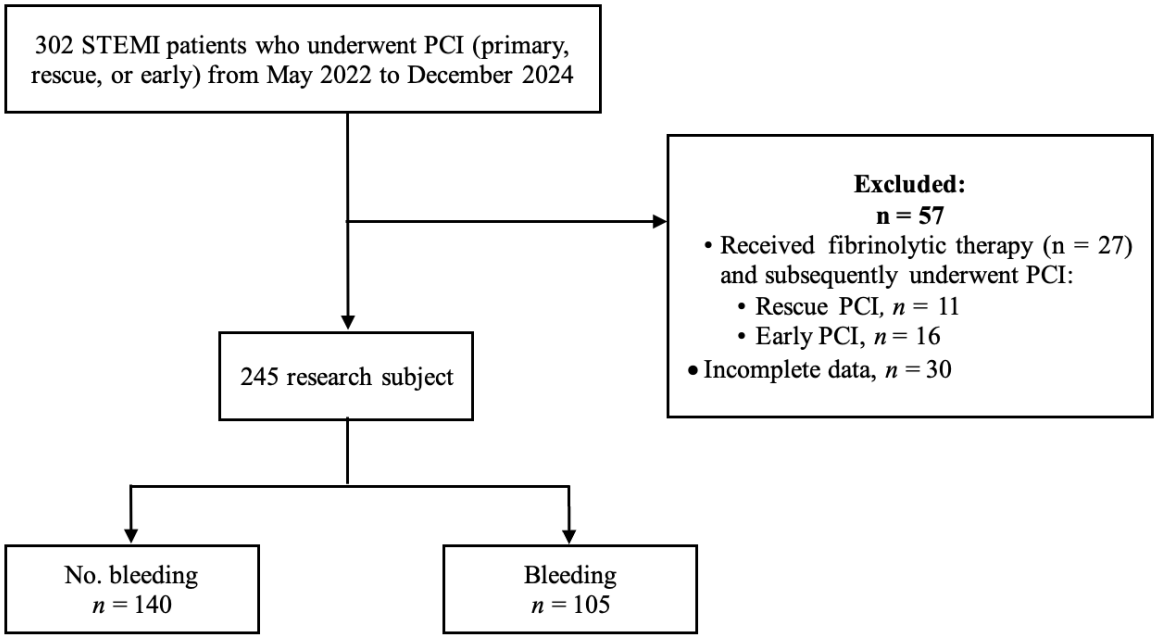

Figure 1. Sampling flow of the study

Table 1 shows bleeding was more common in older patients (57.1 vs. 53.7 years), females (53.5%), those with lower mean hemoglobin (12.6 vs. 13.3 g/dL), higher leukocytes (15,543 vs. 14,032 cells/µL), creatinine (1.6 vs. 1.3 mg/dL), higher TIMI scores (average 3.9), Killip class (98%), diabetes history (55%), and gastritis (51.7%). 52.8% of bleeding patients received heparin, with a mortality rate of 5.3%; most deaths (84.6%) occurred among bleeding patients.

Table 1. Characteristics of the study sample based on the presence or absence of bleeding

Variable	Total Sample (n=245)	No Bleeding (n=140, 57.1%)	Bleeding (n=105, 42.9%)	P value
Baseline Characteristics				
Age (years)	55.2±9.9	53.7±10.1	57.1±9.4	0.009[a]
Sex (%)				
- Male	202 (82.4)	120 (59.4)	82 (40.6)	0.121[c]
- Female	43 (17.6)	20 (46.5)	23 (53.5)	
BMI (kg/m²)	25.8±3.5	25.7±3.7	25.8±3.2	0.371[b]
Diabetes (%)	80 (32.7)	36 (45)	44 (55)	0.007[c]
Hypertension (%)	119 (48.6)	73 (63)	44 (37)	0.071[c]
Dyslipidemia (%)	149 (60.8)	89 (59.7)	60 (40.3)	0.308[c]
Stroke history (%)	14 (5.7)	11 (78.6)	3 (21.4)	0.095[c]
Gastritis history (%)	60 (24.5)	29 (48.3)	31 (51.7)	0.113[c]
Smoking (%)	185 (75.5)	111 (60)	74 (40)	0.113[c]
Initial Examination				
Systolic BP (mmHg)	133.3±28.9	133.2±29	133.6±29	0.007[b]
Heart rate (/minute)	78±20.1	76.1±19.6	80.6±20.6	0.030[b]
Cardiomegaly (%)	129 (52.6)	74 (57.4)	55 (42.6)	0.941[c]
Hemoglobin (g/dL)	13.3±1.8	13.8±1.7	12.6±1.7	0.008[a]
Leukocytes (/µL)	14,032.3±3,825.3	12,899.3±3,237.7	15,542.9±4,035.8	0.000[a]
Creatinine (mg/dL)	1.3±0.6	1±0.3	1.6±0.8	0.004[b]
Random glucose (mg/dL)	181.8±92.5	177.4±87.2	187.8±99.4	0.000[b]

STEMI Type (%)				
- Extensive anterior	38 (15.5)	17 (12.1)	21 (20)	
- Anterolateral	42 (17.1)	28 (20)	14 (13.3)	
- Anteroseptal	54 (22)	38 (27.1)	16 (15.2)	
- Inferior	71 (29)	37 (26.4)	34 (32.4)	
- Inferior + RV infarct	12 (4.9)	4 (2.9)	8 (7.6)	0.037[c]
- Inferolateral	1 (0.4)	1 (0.7)	0	
- Inferoposterior	19 (7.8)	12 (8.6)	7 (6.7)	
- Inferoposterior + RV infarct	6 (2.4)	1 (0.7)	5 (4.8)	
- Inferoposterolateral	1 (0.4)	1 (0.7)	0	
- Posterior	1 (0.4)	1 (0.7)	0	
- STEMI onset (hours)	12.2±10	12.4±9.5	11.9±10.7	0.321[b]
- TIMI Score	3.9±2.1	3.94±2.2	3.9±2	0.002[b]
- Killip class 1 and 2 (%)	193 (78.8)	139 (72)	54 (28)	0.000[c]
- Killip class 3 and 4 (%)	52 (21.2)	1 (2)	51 (98)	
- Cardiac arrest (%)	5 (2)	0 (0)	5 (100)	0.009[c]
Initial Therapy				
- Aspirin loading (%)	245 (100)	140 (57.1)	105 (42.9)	-
- Clopidogrel loading (%)	98 (40)	53 (54.1)	45 (45.9)	0.429[c]
- Ticagrelor loading (%)	147 (60)	87 (59.2)	60 (40.8)	0.429[c]
PPCI Procedure				
- Stent implantation (%)	231 (94.3)	134 (58)	97 (42)	0.266[c]
- Total heparin bolus (IU)	7,037.1±1,508.5	7,100±1,486.1	6,951.9±1,541.5	0.350[b]
- Multivessel disease (%)	156 (63.7)	84 (53.8)	72 (46.2)	0.019[c]
- Femoral access (%)	206 (84.1)	113 (54.9)	93 (45.1)	0.096[c]
- Puncture site change (%)	4 (1.6)	2 (50)	2 (50)	0.771[c]
- Intracoronary Gp2b3a (%)	45 (18.4)	19 (52.2)	26 (57.8)	0.025[c]
- Temporary pacemaker (%)	33 (13.5)	10 (30.3)	23 (69.7)	0.001[c]
During Hospitalization				
- Heparin maintenance (%)	123 (50.2)	58 (47.2)	65 (52.8)	
- UFH (%)	13 (5.3)	2 (1.6)	11 (8.9)	0.002[c]
- Enoxaparin (%)	70 (28.6)	31 (25.2)	39 (31.7)	
- Fondaparinux (%)	40 (16.3)	25 (20.3)	15 (12.2)	
- Length of stay (days)	4.1±2.5	4±2.6	4.1±2.3	0.000[b]
- Mortality (%)	13 (5.3)	2 (15.4)	11 (84.6)	0.002[c]

a: *t independent test*; b: *Mann-Whitney;* c: *chi square*

Bivariate analysis (Table 2) revealed significant bleeding associations with leukocytes >12,000 cells/µL (54.4% vs. 10.8%, p=0.000, OR=9.9), creatinine >1.5 mg/dL (85.9% vs. 13.7%, p=0.000, OR=38.3), Killip class III–IV (98.1% vs. 1.9%, p=0.000, OR=131.3), heart rate >100 bpm (68.6% vs. 31.4%, p=0.001, OR=3.5), blood glucose >200 mg/dL (60.3% vs. 36.2%, p=0.001, OR=2.7), multivessel lesions (46.2% vs. 37.1%, p=0.019, OR=3.2), intracoronary Gp2b3a use (57.8% vs. 39.5%, p=0.025, OR=2.1), heparin maintenance (52.8% vs. 32.8%, p=0.002, OR=2.3), and cardiac arrest (only in bleeding group, p=0.009).

Table 2. Bivariate analysis results

Variable	No Bleeding n (%)	Bleeding n (%)	P value	OR	95% CI
Sex			0.121	1.683	0.868 – 3.262
Male	120 (59.4)	82 (40.6)			
Female	20 (46.5)	23 (53.5)			
Killip Class			0.000	131.278	17.698 – 973.795
I or II	139 (72)	54 (28)			
III or IV	1 (1.9)	14 (98.1)			
Age			0.204	1.437	0.821 – 2.515
< 62 years	105 (59.7)	71 (40.3)			
≥ 62 years	35 (50.7)	34 (49.3)			
Leukocytes			0.000	9.902	4.287 – 22.876
≤ 12,000 cells/µL	58 (89.2)	7 (10.8)			
> 12,000 cells/µL	82 (45.6)	98 (54.4)			
Creatinine			0.000	38.250	18.317 – 79.874
≤ 1.5	126 (86.3)	20 (13.7)			
> 1.5	14 (14.1)	85 (85.9)			
BMI			0.774	0.928	0.558 – 1.544
< 25 kg/m²	64 (55.7)	51 (44.3)			
≥ 25 kg/m²	73 (57.5)	54 (42.5)			
Coronary Lesion			0.019	3.156	1.157 – 8.605
Single	56 (62.9)	33 (37.1)			
Multiple	84 (53.8)	72 (46.2)			
Femoral Access			0.096	1.852	0.889 – 3.855
No	27 (69.2)	12 (30.8)			
Yes	113 (54.9)	93 (45.1)			
History of Stroke			0.095	0.345	0.094 – 1.269
No	129 (55.8)	102 (44.2)			
Yes	11 (78.6)	3 (21.4)			
History of Gastritis			0.113	1.603	0.893 – 2.880
No	111 (60)	74 (40)			
Yes	29 (48.3)	31 (51.7)			
Heart Rate (/min)			0.001	3.475	1.616 – 7.473
≤ 100	129 (61.4)	81 (38.6)			
> 100	11 (31.4)	24 (68.6)			
Cardiomegaly			0.941	0.981	0.591 – 1.628
No	66 (56.9)	50 (43.1)			
Yes	74 (57.4)	55 (42.6)			
Random Blood Glucose			0.001	2.681	1.510 – 4.762
≤ 200 mg/dL	113 (63.8)	64 (36.2)			
> 200 mg/dL	27 (39.7)	41 (60.3)			
Cardiac Arrest			0.009	-	-
No	140 (58.3)	100 (41.7)			
Yes	0 (0)	5 (100)			
Intracoronary Gp2b3a			0.025	2.096	1.088 – 4.039
No	121 (60.5)	79 (39.5)			
Yes	19 (42.2)	26 (57.8)			
Heparin Maintenance			0.002	2.297	1.369 – 3.856
No	82 (67.2)	40 (32.8)			
Yes	58 (47.2)	65 (52.8)			

Among the 105 bleeding patients (Table 3), minor bleeding dominated: BARC 1 (46.6%) and BARC 2 (47.6%), with fewer major bleeding events (BARC 3A 3.8%, 3B 2%). Hematuria was the most common bleeding site (50.4%), followed by puncture site hematoma (21.9%). Upper GI bleeding (6.9%) and epistaxis (0.9%) were less frequent. Some patients showed mixed bleeding sources, primarily hematoma plus hematuria (9.4%). Minor bleeding was the predominant manifestation.

Table 3. Types and sources of bleeding

Type of Bleeding	N	%
Minor Bleeding		
BARC 1	49	46.6%
BARC 2	50	47.6%
Major Bleeding		
BARC 3A	4	3.8%
BARC 3B	2	2%
Source of Bleeding		
Epistaxis	1	0.9%
Puncture site hematoma	23	21.9%
Hematuria	53	50.4%
Upper gastrointestinal bleeding (UGIB)	7	6.9%
Mixed Sources		
Hematoma + Hematuria	10	9.4%
Hematoma + Vaginal Bleeding	1	0.9%
Hematuria + Epistaxis	2	2%
Hematuria + Subconjunctival Bleeding	1	0.9%
UGIB + Hematuria	7	6.7%

4. Discussion

This study investigates the demographic and clinical characteristics of STEMI patients undergoing primary PCI. Patients who previously received fibrinolytic treatment were excluded to avoid bias, as such therapy is linked to higher bleeding risk [5]. The average age of participants was 55.2 ± 9.9 years, and advanced age—supported by studies from Liu, Zhao, Kesti, and Hermanides, among others—was confirmed as a bleeding risk factor. While men constituted the majority of the cohort (82.4%), a larger proportion of women was observed in the bleeding group, consistent with previous reports [6–9].

The analysis of comorbid conditions revealed differences between groups: stroke, hypertension, and dyslipidemia were more prevalent among non-bleeding patients, whereas diabetes, gastritis, and dyslipidemia were common in the bleeding group. Smoking rates were high in both groups. These results align with previous cohort studies identifying diabetes, hypertension, chronic kidney disease, and cerebrovascular and cardiovascular diseases as key comorbid risks in STEMI patients [11,12]. Killip class emerged as a strong predictor of bleeding, with most cases occurring in patients classified as Killip 3 or 4, resonating with findings from Liu and Hermanides [9,10]. Additional independent bleeding-associated factors in this study included leukocyte count, creatinine levels, number of coronary lesions, heart rate, blood glucose, intracoronary use of Gp2b3a inhibitors, and heparin maintenance doses. These findings align with research by Moscucci and Subherwal, which identified age, sex, Killip class, medical history, hemoglobin and creatinine levels, vascular access, and anticoagulant use as important predictors of bleeding in AMI patients [6,13]. Certain variables, such

as sex, age, BMI, history of stroke, and femoral access, did not show a significant correlation with bleeding risk, possibly due to population differences or weaker predictive power. Dual antiplatelet therapy (DAPT) with aspirin and P2Y12 inhibitors remains standard after PCI but increases bleeding risk [7]. Despite the prevalent use of clopidogrel, studies like Mullen et al. show that ticagrelor reduces ischemic events without a significant rise in major bleeding [14]. Procedural factors unique to this population, such as temporary pacemaker insertion and angiography outcomes, were also considered. Although most interventions were via femoral access (84.1%), no significant bleeding increase was noted, potentially reflecting variations in operator technique and experience. Unlike research by Liu, who preferred radial access due to less bleeding, this setting favored femoral access [9]. In post-procedure care, the bleeding group had higher usage of heparin maintenance therapy. Among patients on unfractionated heparin (UFH), most experienced bleeding complications. Evidence from Galli et al. and the ATOLL trial supports that anticoagulants, particularly UFH, elevate bleeding risk, while low-molecular-weight heparin (LMWH) may be safer [15,16]. STEMI patients undergoing PCI face considerable risks of ischemic and hemorrhagic events impacting mortality and morbidity. Bleeding events often lead to DAPT discontinuation, recurrent infarction, impaired hemodynamics, transfusions, and extended hospital stays. The in-hospital mortality rate was 5.3%, predominantly driven by the bleeding subgroup, consistent with Hermanides et al. While bleeding appears to be a primary mortality driver, additional factors such as STEMI severity, comorbidities, and clinical presentation also influence outcomes [10,16].

The study recorded 13 patient deaths (5.3%), with 2 patients (15.4%) from the no-bleeding group and 11 patients (84.6%) from the bleeding group. Even so, mortality in this study was not solely caused by bleeding but was influenced by complex factors such as the type and onset of STEMI upon admission, clinical conditions, comorbidities, and treatment before and after primary PCI, so that patient mortality is the result of the interaction of various risk factors.

Regarding bleeding severity, minor bleeding (BARC 1-2) accounted for most cases, with major bleeding (BARC 3A-3B) seen in 5.8%, a higher rate compared to Murali et al., likely due to greater comorbidity burden and anticoagulation control issues [17]. Overlapping LMWH pre-PCI and UFH during PCI may have intensified anticoagulation because of suboptimal timing and dosing. Therefore, anticoagulant choice must carefully balance ischemic and bleeding risks in STEMI patients undergoing primary PCI. The main sources of bleeding were hematuria (50.4%) due to improper Foley catheter insertion and hematoma at the puncture site (21.9%) triggered by manual compression after femoral procedure without femoral artery closure. Additional factors such as anticoagulant use, quality of post-procedure care, age, and comorbidities also aggravate the incidence of bleeding in patients [18]. Pro-inflammatory states in patients with acute coronary syndrome can trigger pro-hemorrhagic conditions that cause bleeding, especially in the early post-primary PCI phase and in cases of STEMI that show a stronger inflammatory response; this is supported by an independent relationship between white blood cell count and bleeding risk after PCI, while differences in patient management also have the potential to contribute to bleeding tendencies in STEMI despite multivariable adjustments [19][20].

Although this study provides valuable insights regarding the incidence and type of bleeding in STEMI patients undergoing primary PCI, it has several limitations that should be acknowledged. First, as a retrospective study, data collection was dependent on the accuracy and completeness of medical records, which may introduce information bias. Second, the relatively small sample size limits the generalizability of the findings to the broader population, potentially affecting the external validity of the results. Lastly, the lack of long-term follow-up data prevents the assessment of post-discharge

bleeding risks, thereby limiting the study's ability to evaluate the full spectrum of bleeding outcomes over time.

5. Conclusion

In this study with 245 STEMI patients who had primary PCI (82.4% male and an average age of 55.2 ± 9.9 years), it was found that 42.9% had some bleeding complications, with the majority being minor (most were 94.2% while 5.8% were major).

Future research should consider prospective cohort designs to monitor patients over time and collect more detailed data on risk factors. Focus can be placed on the identification and in-depth analysis of the specific risk factors that trigger minor and major bleeding, including a comparison of different antithrombotic and vascular access regimens. In addition, the development or validation of bleeding risk scores tailored to the Indonesian population will be very beneficial for more accurate risk stratification in clinical practice. Finally, the evaluation of the impact of bleeding, both minor and major, on long-term clinical outcomes such as mortality, recurrent major cardiovascular events, and patient quality of life is also an important area for further exploration.

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None

Conflict of interest

The authors declare no conflict of interest.

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