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ORIGINAL ARTICLE

Complications and Associated Risk Factors of Percutaneous Coronary Intervention: A Comparative Study Between Primary and Elective Patients

Ghulam Hussain Soomro,[1] Fatima Iqbal Hussain,[2] Mahnoor Ali,[2] Uraza Noor,[2] Zainab Aslam Saeed Memon,[2] Nasir Yaqoob[2]

1. Department of Cardiology, Dr. Ziauddin Hospital Clifton Karachi, Pakistan.
2. Department of Medicine, Dr. Ziauddin Hospital Clifton Karachi, Pakistan.

Correspondence to: Dr. Fatima Iqbal Hussain, Email: fatimahussain_94@hotmail.com, ORCiD: 0000-0002-9688-1193

ABSTRACT

Objective: To compare the complications and associated risk factors between primary and elective percutaneous coronary intervention (PCI) among patients attending emergency department of a tertiary care hospital, Karachi, Pakistan.

Methods: This retrospective cross-sectional study was conducted at Dr. Ziauddin University Hospital, Clifton campus, Karachi, from April 2019 to March 2021. All patients who underwent elective or primary PCI over the age of 18 years were included. The complications such as hypotension, coronary dissection, no-reflow, coronary perforation, arrhythmias, cardiac tamponade, stent thrombosis, and in-hospital death were observed. These complications were followed up till one month after the PCI.

Results: Of total 155 patients, the mean age was 60.77 ± 11.15 years. There were 104 (67.1%) males and 51 (32.9%) females. Primary PCI was performed among 103 (66.5%) patients and elective PCI in 52 (33.5%) patients. Complications of PCI was observed in 94 (60.6%) patients. The most common complication presented was no-reflow 31 (32.9%). However, 14 (14.8%) patients presented with hypotension and 10 (10.5%) with hypotension along with no-reflow. Complications were found to be significantly higher in primary PCI 76 (73.8%) as compared to elective PCI 18 (34.6%) (p-value <0.001). Furthermore, mortality rate among primary PCI was found significantly higher as compared to elective PCI i.e., 13 (92.9%) vs. 1 (7.1%) (p-value 0.036).

Conclusion: No-reflow, hypotension and hypotension along with no-reflow are a frequent complication of PCI especially when the patients undergo primary PCI as compared to elective intervention.

Keywords: Angiography, Angioplasty, Myocardial infarction, Percutaneous Coronary Intervention.

INTRODUCTION

Myocardial infarction is one of the leading causes of death worldwide and its treatment is possible via percutaneous coronary intervention (PCI) and fibrinolytic drugs.[1] Coronary angiography is the gold standard test available to identify and localize the stenosis in arteries.[2] PCI refers to the strategy of taking a patient who presents with ST segment elevation myocardial infarction (STEMI) directly to the catheterization laboratory to undergo mechanical revascularization using balloon angioplasty, coronary stents, or aspiration thrombectomy. Elective PCI refers to revascularization of coronary vessels done in patients with stable coronary artery disease.[3]

With advancements in technology and availability of better medical equipment, the practice of primary PCI has increased by more than 60% over the past two decades. In USA, an estimated 600,000 PCIs are performed annually.[4] The invasive nature of the procedure and pre-existing risk factors such as advanced age, renal insufficiency and diabetes mellitus are associated with procedure-related complications which include cardiac and non-cardiac complications.[5,6] The underlying co-morbidities which include coronary artery disease, congestive heart failure with systolic dysfunction, stroke, and bleeding diathesis can make participants vulnerable to complications.[2] Several risk factors have been identified which increase the risk of major adverse cardiac effects (MACE) like higher levels

of lipoprotein, diabetes, and decreased ventricular ejection fraction.[7]

PCI is a frequently occurring procedure in the field of cardiology and complications related to the procedure are significant, but limited studies are available on the comparison of complications between primary and elective PCI. This study will provide evidence-based results on the frequency of complications, associated risk factors and detailed comparison between primary and elective PCI which would be the basis to take precautions while performing this procedure and label high-risk patients beforehand. The objectives of this study are to determine the frequency of complications and to compare its occurrence between primary and elective PCI.

METHODS

This retrospective cross-sectional study was conducted at Dr. Ziauddin Hospital, Clifton campus, which is a 150 bedded tertiary care teaching hospital located in Karachi. Medical records were retrieved for two years period from April 2019 to March 2021. The approval from the ethical review committee (ERC) of the hospital was taken with reference code 3680421GHCAR. Informed signed consent was taken from the patient and confidentiality was maintained throughout the study.

A total number of 155 patients were included in the study. Sample selection was done by non-probability consecutive sampling. The inclusion criterion for primary PCI was all patients over the age of 18 years who presented to the emergency department with chest pain or shortness of breath or diaphoresis and had ST segment elevation on electrocardiogram of 1mm in the precordial leads or 2mm in the limb leads. While elective PCI patients were also 18 years and above and were presented at emergency department or clinic with raised troponin levels, ST segment changes in the electrocardiogram or persistent chest pain and dyspnea not responsive to optimized medical therapy. The exclusion criteria for both primary and elective PCI were patients with hospitalization of more than seven days before the intervention, patients having sepsis or any active malignancy and those who were lost to follow-up. The standard antithrombotic treatment during primary PCI was aspirin and parenteral anticoagulation with intravenous 0.5 mg/kg Enoxaparin. The standard antithrombotic treatment during elective PCI was aspirin and parenteral anticoagulation with intravenous 0.5 mg/kg Enoxaparin. Patients in both groups without $P2Y_{12}$ inhibitor at admission were treated once the coronary anatomy was known and the percutaneous revascularization indication confirmed; the $P2Y_{12}$ inhibitor was chosen by the interventional cardiologist. Stable patients already on Aspirin, Clopidogrel, Ticagrelor or Prasugrel (because of a prior acute coronary syndrome) were also included. Data including the coronary angiography and PCI reports and complications during the course of hospitalization were collected retrospectively from the hospital electronic medical record system while the data of the adverse events one month post-procedure was collected from the clinic records when the patients followed-up with their cardiologist.

The primary endpoint was defined as a composite of hypotension (requiring treatment), coronary dissection, no-reflow, coronary perforation, arrhythmias (requiring treatment), cardiac tamponade, stent thrombosis and in-hospital death, evaluated from hospitalization up till one month after the PCI.

Data entry and analysis were done using a Statistical Package for Social Sciences (SPSS) version 20.0. Mean ± SD were computed for quantitative variables like, age (years), while frequency and percentages were computed for categorical variables like, gender, procedure of PCI, risk factors of PCI, complications and mortality. Inferential statistics were explored using Chi-square/Fisher exact test for comparison of complications and procedure of PCI with general and clinical characteristics. The p-value of ≤ 0.05 was considered statistically significant.

RESULTS

Of total 155 PCI patients, the mean age was 60.77 ± 11.15 years. There were 104 (67.1%) males and 51 (32.9%) females. Primary PCI was performed among 103 (66.5%) patients and elective PCI in 52 (33.5%) patients. The highest risk factor found in patients of PCI was hypertension i.e., 107 (69.0%) followed by diabetes mellitus 83 (53.5%) and smoking 64 (41.3%). The overall mortality rate of PCI patients was 14 (9.0%).

Procedure of PCI showed that primary procedure was found significantly higher in multi-vessel disease 51 (75.0%) as compared to single vessel disease 52 (59.8%) (p-value 0.046). Similarly, primary procedure was found significantly higher in smokers 49 (76.6%) as compared to non-smokers 54 (59.3%) (p-value 0.025). Primary procedure was found significantly higher in patients with hypotension 37 (84.1%) as compared to patients with no hypotension 66 (59.5%) (p-value 0.003). Similarly, primary procedure was found significantly

Table 2: Combination of complications present in PCI patients (n=94)	
Complications	**n (%)**
Hypotension + No-reflow + Arrhythmias	7 (7.3)
Hypotension + No-reflow	10 (10.5)
Hypotension	14 (14.8)
Hypotension + Dissection	3 (3.2)
Hypotension + Arrhythmias	7 (7.4)
Hypotension + Dissection + No-reflow	2 (2.1)
Hypotension + Perforation	1 (1.2)
Dissection	5 (5.3)
No-reflow + Arrhythmias	3 (3.2)
No-reflow	31 (32.9)
No-reflow + Thrombosis	1 (1.2)
Hypotension + Arrhythmias + Tamponade	1 (1.2)
Arrhythmias	7 (7.3)
Arrhythmias + Tamponade	1 (1.2)
Arrhythmias + Thrombosis	1 (1.2)

Table 3: Association of complications of PCI with general and clinical characteristics (n=155)

	Total	Complications		p-value
		Yes (n=94)	No (n=61)	
Age				
≤60 years	73	42 (57.5)	31 (42.5)	0.454^
>60 years	82	52 (63.4)	30 (36.6)	
Gender				
Males	104	68 (65.4)	36 (34.6)	0.085^
Females	51	26 (51.0)	25 (49.0)	
Procedure				
Primary PCI	103	76 (73.8)	27 (26.2)	<0.001^*
Elective PCI	52	18 (34.6)	34 (65.4)	
Severity				
Single vessel	87	43 (49.4)	44 (50.6)	<0.002^*
Multi-vessels	68	51 (75.0)	17 (25.0)	
Risk Factors				
Diabetes				
Yes	83	54 (65.1)	29 (34.9)	0.227^
No	72	40 (55.6)	32 (44.4)	
Hypertension				
Yes	107	64 (59.8)	43 (40.2)	0.752^
No	48	30 (62.5)	18 (37.5)	
Smoker				
Yes	64	49 (76.6)	15 (23.4)	<0.001^*
No	91	45 (49.5)	46 (50.5)	

- Complications included: Hypotension, Dissection, No reflow, Perforation, Arrhythmias, Tamponade, Thrombosis
^Chi-square test applied, *p-value ≤ 0.05 considered significant

higher in patients who had no-reflow 45 (81.8%) as compared to patients who did not have no-reflow 58 (58.0%) (p-value 0.003). (Table 1)

The overall Complications of PCI was observed in 94 (60.6%) patients. Of these 94 patients, the most common complications presented in PCI patients was

Table 1: Association of procedure of PCI with general and clinical characteristics (n=155)

	Total	PCI		p-value
		Primary (n=103)	Elective (n=52)	
Age				
≤60 years	73	53 (72.0)	20 (92.2)	0.126^
>60 years	82	50 (61.0)	32 (39.0)	
Gender				
Males	104	73 (70.2)	31 (29.8)	0.159^
Females	51	30 (58.8)	21 (41.2)	
Severity				
Single vessel	87	52 (59.8)	35 (40.2)	0.046^*
Multi-vessels	68	51 (75.0)	17 (25.0)	
Risk Factors				
Diabetes				
Yes	83	54 (65.1)	29 (34.9)	0.735^
No	72	49 (68.1)	23 (31.9)	
Hypertension				
Yes	107	72 (67.3)	35 (32.7)	0.741^
No	48	31 (64.6)	17 (35.4)	
Smoker				
Yes	64	49 (76.6)	15 (23.4)	0.025^*
No	91	54 (59.3)	37 (40.7)	
Mortality				
Yes	14	13 (92.9)	1 (7.1)	0.036~*
No	141	90 (63.8)	51 (36.2)	
Complications				
Hypotension				
Yes	44	37 (84.1)	7 (15.9)	0.003^*
No	111	66 (59.5)	45 (40.5)	
Dissection				
Yes	10	8 (80.0)	2 (20.0)	0.497~
No	145	95 (65.5)	50 (34.5)	
No reflow				
Yes	55	45 (81.8)	10 (18.2)	0.003^*
No	100	58 (58.0)	42 (42.0)	
Arrhythmias				
Yes	27	21 (77.8)	6 (22.2)	0.170^
No	128	82 (64.1)	46 (35.9)	

- Other complications like perforation was observed in 1 patient, tamponade in 2 patients and thrombosis in 2 patients. All these patients had primary PCI procedure.
^Chi-square/~Fisher exact test applied, *p-value ≤ 0.05 considered significant

no-reflow 31 (32.9%). However, 14 (14.8%) patients presented with hypotension and 10 (10.5%) with hypotension along with no-reflow. (Table 2) Comparison of complications of PCI with general and clinical characteristics showed that complications were found significantly higher in primary PCI 76 (73.8%) as compared to elective PCI 18 (34.6%) (p-value <0.001). Moreover, a significantly higher association of complications of PCI was found with procedure of PCI (p-value <0.001), severity of complications (p-value 0.002), and smoking (p-value <0.001). However, mortality among patients who underwent primary procedure was found significantly higher 13 (92.9%) as compared to the patients who underwent elective procedure 1 (7.1%) (p-value 0.036). (Table 3). Mortality was found significantly higher in patients who had

complications 14 (14.9%) as compared to patients who had no complications 0.0 (0.0%) (p-value 0.002).

DISCUSSION

This study primarily focused on the rate of complications encountered in PCI and then enumerated the frequency of each complication followed by comparison of these complications in primary vs. elective procedure. No-reflow was found to be the most common complication of this invasive procedure, encountered in almost one-third of the cohort. This was followed by hypotension and arrhythmias. It is also interesting to note that about one-fifth of patients had a spectrum of complications where the procedure was complication by a combination of no-reflow, hypotension and arrhythmias. Fortunately, stent thrombosis and cardiac tamponade were encountered in a very small population as its occurrence was found to be directly related to mortality. Furthermore, it demands attention that rate of complications was high in smokers and in those undergoing primary intervention secondary to STEMI.

STEMI - united by persistent ischemic chest pain over 20 minutes, ST-segment elevation on electrocardiogram and the increase of myocardial necrosis biomarkers, is still a rather prevalent cause of mortality and morbidity in clinical practice.[8] PCI has evolved as the mainstay of STEMI management since its first introduction four decades ago, and with the development of new technology, patients' prognosis has been primarily improved.[9] The reperfusion therapy using primary PCI in STEMI is known to give a better result than fibrinolytic therapy.[10] In the early days of PCI, there was a mortality rate of 1– 2.5%, and 1.9-5.8% of patients would proceed to emergency coronary artery bypass graft surgery (CABG).[11] Over the intervening years, as practice has improved, both the mortality rate and patients proceeding to emergency CABG is now <0.4%.[12] PCI is therefore now much safer and the indications for PCI extend to both patients with chronic stable angina as well as patients with myocardial infarction and acute coronary syndrome.[13] However, coronary artery stenting comes with its own set of complications that may lead to failure of the procedure, need for emergency CABG or even on-table death.

In our study, it is quite evident that patients who underwent primary PCI had higher rate of complications and mortality as compared to those who underwent elective intervention. In fact, complications like coronary perforation, cardiac tamponade and in-stent thrombosis unanimously occurred in those who underwent primary intervention. This is comparable with the study conducted by Mallet *et al*. on 2,913 patients who underwent percutaneous transluminal coronary angioplasty in the city of Rio de Janeiro. The study concluded that mortality was high in patients who underwent primary and rescue PCI compared to elective cases and the mortality was higher in patients aged 50 years or more. Renal insufficiency and peri procedure acute coronary syndrome were commonly occurring complications in participants. However, the incidence of coronary dissection was higher in our study group as compared to Mallet *et al.*[14]

Our study findings reported that the commonly occurring complications in elective PCI were no-reflow, hypotension and arrhythmias and the overall mortality in this group was very low. These complications were quite similar to the study of Ferreira *et al*. in Brazil which stated the in-hospital complication rates after elective PCI. In their study, it was found that 3.6% of the patients developed hypotension, 1.6% had arrhythmias, 0.5% died during hospitalization and 3.2% had coronary complications (dissection, perforation or occlusion).[3]

Coronary perforation is a rare but serious complication of PCI which has been shown to have an incidence of about 0.4%.[15] There are two major types of coronary perforations: large vessel perforation and distal vessel perforation, with collateral vessel perforation being another type specific to chronic total occlusion (CTO) interventions. Most coronary perforations are large vessel perforations, but both large and distal vessel perforations are associated with adverse clinical outcomes, highlighting the importance of prevention and early diagnosis and treatment.[16] It is fortunately a rare event, encountered more during intervention rather than diagnostic procedures. The incidence of coronary perforation during stenting in our study was very low. Left main stem (LMS) coronary artery stenosis is associated with significant morbidity and mortality and has traditionally been treated by CABG.[17] The rate of perforations complicating unprotected left main stem coronary artery interventions has been reported to be in the region of 1.2% from single-center experience.[18] Coronary stent delivery can prove challenging in patients with complex anatomy and remains a cause of procedural failure during percutaneous coronary intervention. The incidence of dissection in our study has been higher as compared to other similar studies, out of which 80% of the events occurred during primary PCI whereas elective PCI accounted for only 20% of the coronary dissections. Coronary dissection attributed to GuideLiner catheter occurred in 3.3% and became less frequent over the study period likely as a result of

operator learning curve and improvement in catheter design.[19] Gomez-Morena et al. in 2006 found in their study that 0.04% of cases had catheter induced ascending aorta dissection. The incidence of coronary artery dissection was as high as 30% with balloon angioplasty.[20]

Compared to Zeitouni *et al*., our study had a ten times higher incidence of stent thrombosis with all events happening in patients who underwent primary PCI, whereas in their study on 3,416 patients who underwent elective PCI, the incidence of stent thrombosis was less than one percent.[21] This contrast in the incidences can also be attributed to the difference in the indication of coronary intervention.

The incidence of arrhythmias has significantly declined recently due to the use of iso-osmolar, non-ionic contrast material. Arrhythmias occurred in nearly one-fifth of patients in our study whereas the incidence of cardiac tamponade was less than one percent. This is quite high as compared to the PAMI trial where ventricular tachycardia occurred in only 4.3% of the patients with ST- elevation MI during cardiac catheterization.[22] These arrhythmias usually do not require immediate treatment unless they produce ischemia or hemodynamic instability.

It is important to note that more than half of the patients reached primary endpoint in our study. The increased incidence of complications during or after the procedure can be attributed to the disease process itself. However, it is important to consider external factors which play a major role in delay of door-to-balloon time. These factors can include late arrival to hospital after the onset of symptoms, delay in providing consent for the procedure, delay in financial clearance and hospital related administrative issues, difficult vascular access or delay in crossing the lesion. It is important that such gaps in delivery of service are identified and taken care of in order to decrease the incidence of complications that have an adverse effect on the outcome. Strategies to improve service on the part of healthcare provider could include prioritization of ECG recording for every patient who presents to the emergency department with cardiac symptoms, early interpretation of ECG, ensuring availability of PCI team members on campus and expediting the documentation and laboratory workup needed before the procedure.

PCI for complex lesions is still technically demanding and is associated with less favorable procedural parameters such as lower success rate, longer procedural time, higher contrast volume and unexpected complications. Because the conventional angiographic analysis is limited by the inability to visualize the plaque information and the occluded segment, cardiac computed tomography has evolved as an adjunct to invasive angiography to better characterize coronary lesions to improve success rates of PCI.[23] There are several strengths to this study. First, this study is the first one in our region to determine the rate of complications in primary vs. elective PCI and also establishes an association of the former with the rate of mortality. Second, the patients who underwent PCI were followed for one month after the procedure as the first 30-days are critical after PCI for the development of major adverse cardiac events.

We acknowledge several limitations to this study. First, this is a retrospective study with inherent biases. While prolonged chest pain, electrocardiogram changes and catheterization films could have been under-reported / over-reported, all angiographic films were reviewed in a core lab with blinded adjudication to identify all the intra-procedure complications. Second, a minority of patients were excluded because they were lost to follow-up after the procedure and their data in medical record was missing. Third, factors that delayed service delivery, increased door-to-balloon time and accounted for complications were not studied in detail in this research. Lastly, patients were followed for complications for 30 days after the procedure but different causes of re-hospitalization after a PCI procedure, which is relevant in daily clinical practice, were not taken into account.

CONCLUSION

PCI has become the mainstay of treatment for blocked coronary arteries. With this study, we were able to shed light on some of the most common complications encountered during and after this procedure and how they can affect the overall outcome and mortality. We demonstrated that no-reflow, hypotension and arrhythmias are a frequent complication of PCI, especially when the patients undergo primary PCI as compared to elective intervention. Furthermore, the incidence of these complications is higher in patients with multiple co-morbidities, the most significant being the history of tobacco smoking. The long-term sequelae of these complications are greatly concerning and anticipating them in advance will help us to meticulously adhere to guideline-based practices to minimize the risk of such adverse events. Further studies are needed to elucidate the most effective preventive measures.

ETHICAL APPROVAL: The study was approved by

Ethical Review Committee of Ziauddin Univesity Clifton Karachi (Ref. Code: 3680421GHCAR).

AUTHORS' CONTRIBUTION: GSM: Study design and data analysis. FIH: Data collection analysis and write up. MA: Data analysis. UN: Literature search and write up. ZASM: Data collection. NY: Study design and proofreading. All authors have approved the final article.

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