



## The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at $\geq 5$ TIMI score in public sector hospital

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### Abstract

**1.1 Background:** The Thrombolysis in Myocardial Infarction, TIMI risk score for STEMI is a simple arithmetic score that proved to be useful in patients treated with primary PCI. To

**2.Introduction:**

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Cardiovascular disease (CVD) is among the most deadly disease-causing mortality rate to increase and almost one-third of the population have been suffering from it.[1] Substantial advance in the treatment of acute myocardial infarction (AMI) is the intervention in order to provide basic care towards STEMI patients while involving myocardial research with the help of randomized control trials RCTs. [2,3]

The report structures towards designing strategies in which patients will be analyzed in order to investigate proper intervention in order to create proper strategies for mitigating the mortality rate regarding STEMI. [4] Despite its challenges, it will be defined toward randomized control trial RCTs which will be reported 6-9% in which 30-35 days whereas the report also covers thrombolytic therapy within 6 hours. [5,6]

Often, the report also discussed alternative options and certain therapies which will provide improvement an agent treatment plan to mitigate the risk associated with the disease. It is recommended to provide special attention to additional factors which can increase the risk and associated mortality rate. The report will also investigate the early invasive which will be therapeutic and increase the survival chance related to the disease. For Acute Coronary Syndromes (ACS) the related intervention will also be explained and analyzed. [7]

Whereas those patients who receive therapies in order to deal with STEMI will be examined and analyzed. The risks in terms of long-term and short-term impacts can also be seen. [8-10]

After analyzing the STEMI intervention, it can be seen that there are a lot of early interventions designed to overcome the mortality rate and various therapies have been successful in implementing positive outcomes. Hospitals staff and nurse management is a crucial factor to combat against disease with the help of clinical and expert resources. [11]

A study by Reddy et al stated the fact that the success rate of angioplasty is much more and has positive outcomes with fewer chances of reoccurrence of ischemic. [12] Study by Ranjan et al provided insight into the development in the field of STEMI and its prevention. The option of angioplasty reveals a success rate of 98% along with transradial which is in demand in the field. [13] Another study conducted by Ellen C et all focuses on PCI which restoring angiographically among the normal flow, [14,15] whereas fibrinolytic therapy does so in only 50 to 60% of such patients. [14]

The procedural success was 97%.[16] Patients classified as high risk (TIMI  $\geq$  5) had a higher incidence of adverse events than the low-risk group: mortality 14.8% vs.2.1%, (p=0.0001); heart failure 15.3% vs.4.1%, (p=0.0001); development of cardiogenic shock 10.9% vs.1.5%, (p=0.0001); ventricular arrhythmias 14.8% vs. 5.9%.[17]

While analyzing TIMI the risk score for STEMI would be simple arithmetic in order to provide a further description of mortality. In this era of technology, some evident interventions in the field of STEMI range

from pharmacologic to devise therapy. These recent development aids in improving the lifestyle of STEMI patients. [18]

The TIMI risk score for STEMI preferred to be used for presenting STEMI while placing it with the bedside of patients. [19] For each patient, the Score calculated in such a way as to justify the (range, 0–14).[20] CKD is considered to be an independent risk factor for coronary artery disease (CAD). [21]

The South Asian countries of India, Pakistan, Bangladesh, Sri Lanka, and Nepal make about a quarter of the world's population and this region has the highest rate of cardiovascular diseases compared with any other region globally and is, therefore, the leading cause of death in the Indo-Pak subcontinent. [22] the impact of CVD and PCI tends to more on people living a life of low and middle-income class whereas it is very common among developing countries where there are health-related risks like obesity and tobacco usage<sup>16</sup> and also these are the leading cause of death for both men and women all over the world. [23,24]

However, knowledge of the adverse events is primarily derived from developed countries thus knowledge of the importance of the adverse events in the local population groups should be considered because of the different body habitus, environment and dietary habits, moreover, the TIMI risk score is the easiest, bedside and accessible way for risk stratification of patients after acute MI going for Primary PCI. Patients with a TIMI score >5 are more prone to develop complications. As there is limited local data available, therefore my study will provide the correct magnitude of complications in our local population and it will also identify more common adverse events among these complications in our local population and it will be helpful for the healthcare provider to evaluate and identify the high-risk patients and minimize and prevent the complications during and after the procedure. In case of complication, prompt action will be taken, and manage them accordingly, which will further help in decreasing morbidity and mortality. Thus to determine the frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST-segment elevation myocardial infarction at  $\geq 5$  TIMI score in public sector hospitals makes strong rationale to conduct this research in a large number of patients.

### **3. Literature Review**

#### **3.1 ST ELEVATION MYOCARDIAL INFARCTION**

ST-segment elevation myocardial infarction (STEMI) accounts for approximately 30–45% in total whereas accounting for 1.5 million for acute coronary syndromes annually hospitalization.[25] The main reason of STEMI is due to sudden-onset plaque rupture and occlusion of the coronary artery. [26] hence, it is among the most dangerous yet life-threatening acute coronary syndrome and requires immediate intervention. In this era of technology, some evident interventions in the field of STEMI range from

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pharmacologic to devise therapy. These recent development aids in improving the lifestyle of STEMI patients. [27,28]

Recent studies show that the mortality rate in STEMI especially in the USA has been lower in-between the years 1997 to 2006. People interventions and efforts of certain experts' results in defining a path through which treatment can be possible. The patient survival rate has been improved with the help of new advanced interventions. Apart from male 90% as TIMI 3 flow, infarct-related vessel compared with only approximately 50% with thrombolytic therapy, therefore improvising the prevention meanwhile saving from recurrent ischemia through the treatment of severe stenosis after the successful surgery of thrombolysis. [29]

It is mandatory to perform primary PCI by an interventional cardiologist to treat the disease with a full high volume. According to the National Registry of Myocardial Infarction (NRFMI), the PCI primary procedures per month basis leads to reduce the mortality rate among hospitals versus the lower volume. [30]

A subsequent NRFMI-2 and NRFMI-3 registry ensures and implies the importance of PCI primary to be more effective as compared to thrombolytic therapy as patient survival rate has been increased. [31]

After analyzing the survival rate following primary PCI, experts suggest that this mode of intervention must be there to provide full authentication to patient.[32] as per the completion of this requirement, it is evident that primary PCI has been lowered by 25%, reinfarction by 64%, intracranial hemorrhage by 95%, and stroke by 53% versus thrombolytic therapy. [32]

### **3.2 DOOR-TO-BALLOON TIME**

For the purpose of STEMI and to improvise survival chances, Primary angioplasty is required offering salvaging ischemic myocardium. [33 after the analysis of 20 summary data points obtained from RCTs beetworm PCI and thrombolytic with the help of meta-regression analysis. The result shows the evidence of D2B time of >90 minutes is capable of discarding mortality rate and benefit of primary PCI versus thrombolytic therapy. It also proceeds that B2B time recommended D2B time <90 minutes. [34]

It is evident that certain ways have been defined to improvise the D2B time. With the advanced digital system, hospitals must be capable of reducing the timeframe to increase the survival rate of the patient. Experts suggest utilizing emergency medicine physicians to activate the catheterization laboratory which indicates to lessen the total of eight minutes. Another reduction of 14 minutes means that a single call must be made to the central page operator for the activation of catheterization. The activation of catheterization during the transportation of the patient to the hospital will also save another of 15 minutes timeframe. The expectation from catheterization laboratory staff timeframe must be within 20

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minutes after they receive page mean reduction of 19 minutes versus 30 minutes, While if the hospital has in staff interventional cardiologist present then it will save 15 minutes. Whereas having an emergency department and catheterization laboratory with the help of real-time data utilization will save other 9 minutes. [35]

It is very important to overcome the time spent on different evaluations in order to treat the patient effectively. The entire hospital paradigm must not be designed to sit and wait for consequences. It is required to manage time properly so that the patient survival rate can be increased. As to lower the D2B timeframe, another key factor is the commitment placed by HR and admin staff to ensure proper support for its implication. Whereas the other staff must comprehend close collaboration with the catheterization laboratory personnel involving nurses, coronary care unit staff, and emergency unit staff to communicate and act on a rapid basis. These factors help to complete the implementation of D2B services properly. The evident reduced time in D2B management has been witnessed among hospitals from 2005 where primary PCI took 96 minutes to complete. But as of now, it reduced to 60 minutes in the year 2010 and the majority (91.4%) with D2B time <90 minutes in 2010 versus 44.2% in 2005. [36]

As per the research surveys, patients with STEMI approaching hospitals without PCI capability require longer time for D2B like 120 minutes can end up providing great results as compared to that thrombolytic therapy at non-PCI facilities. Patients undergoing interhospital to nearby PCI centers might take longer hours as compared to those who do not have PCI before. [37-42]

Whereas, the situation in remote areas is much worsening as compared to rural areas. The populations living in remote areas have less access towards all the facilities regarding health care and other departments as compared to people living in downtowns and cities, the primary reason to construct a building fewer resources and to improvise the health care system. People dealing with STEMI might not be able to survive as because of the unavailability of PCI primary. Primary PCI is not available to certain remote areas, therefore, causing an increment in mortality rate. The percentage of availability of PCI in remote areas is -25%.[43] whereas in USA 91% of the population needs to drive for one hour to reach PCI center. [44] it is suggested to increase the approach towards PCI centers will lead to improving the survival rate otherwise it will be difficult for people to reach them in proper time. The intervention is suggested to treat STEMI patients properly. [40,45,46]

The bypass model is one evident approach that can be helpful to treat STEMI patients. Under this model, pre-hospital ECG diagnosis of STEMI can be done under the supervision of experts and a crew of ambulances in order to transport the patient to the most nearby PCI center. The ambulance crew under the supervision of the physician inside the ambulance must be prepared for any emergency call. [45] The Boston EMS Bypass STEMI Triage Plan and Treatment Registry can be said an example meanwhile certain other protocols are also happening inside the country. The successful primary PCI centers

approach and STEMI model can only be successful with the contribution of hospital, nurses, staff, and PCI center availability.

Although it is important to see the other consequence of this ambulance aid, as ECG generated in an ambulance can show false positive results which cannot reduce the contact balloon time. [45]

The transfer model is ought to be the second approach under which established protocols help to transfer the patient to PCI centers using an integrated hospital system where non-PCI are triaged. [40]

Minneapolis Heart Institute's regional system has been taken as the prototype for this transfer type model using a standardized PCI approach for the primary treatment for STEMI patients. According to this transfer model, 20 hospitals under the 210-mile radius will be involved. According to the statistical information provided by the hospital mortality rate, it is suggested that medical first D2B time still follow 60 to 210 mile taking 120 minutes. [40]

Whereas third intervention for STEMI would be allowing primary PCI without onsite surgery, [46] as per the fact revealed by C-PORT (the Atlantic Cardiovascular Patient Outcomes Research Team) trial. [47] The study revealed many shocking facts stating that regardless of being less privileged with the help of training, Primary PCI without the need of onsite can be achieved with the help of training programs and can lower death rate as well. It can also shorter the stay period in hospitals and can empty the slot for further patients to be achieved with or stroke up to 6 months versus thrombolytic therapy. This will improve present hospital conditions to increase the intervention and improvement chances among patients. Whereas patients coming for coronary artery bypass surgery without any emergency situations can be acquired for PCI-related complications. It is very important to ensure that all the resources must be available as in stents or other interventions to work on pace. Whereas the current primary PCI is minor to emergencies. [48]

In order to keep on safe loop, these on-site cardiac surgeries must stay communicated with the tertiary center in order to transfer the emergency patients to prevent any sort of complication which cannot be handled with the help of pharmacological therapies. Meanwhile, it is suggested that the measures which are not acceptable D2B time, and in case of non-availability of PCI centers, or any experts physician like a cardiologist. The initial surgery is required to treat the patient properly and to ensure the survival rate. It is advisable to have an initial surgery team in order to provide early intervention and to save the patient from further complications. [48]

The recent research in order to identify the terminology behind clopidogrel, an oral antiplatelet drug, it is advisable that it can treat thrombolytic therapy in order to reduce the complications related to the infarct-related artery. [49,50] it is vital to identify some proper interventions to decrease the impact of it. [50]

### 3.3 OPTIONS FOLLOWING SUCCESSFUL THROMBOLYSIS

This section of the report aims to identify the successful thrombolysis in case of unavailability of primary PCI. There are certain administration in order to define strategies to career successful thrombosis with the help of therapies as the latter alone if not treated can cause the re-occlusion do you do the residues stenosis. This can happen to most of the patients having STEMI. [29]

The real task is to identify the need to treat these patients conservatively in order to undergo revascularization in case of recurrent ischemia. This can be detected during the stress test done in the pre-surgery stage in order to see the capability of patients to deal with there after-effects of PCI. In case of successful reserves, it is advisable to transfer the patient to a PCI-capable hospital or a center in order to perform coronary angiography to treat the patient and in case of anatomy approved it. [51-54]

Many randomized control trials have been done in order to observe the dilemma regarding this theory. Certain analyses have suggested routine PCI or early PCI following the thrombolytic therapy is helpful in reducing the endpoint of disease. It also aids in providing improvement and lowering the mortality rate after disease diagnosis. Where is certain side effects related to their disease and its adverse events like stroke or excessive bleeding can also be controlled with the help of PCI and thrombolytic therapy? [51-54]Therefore, it is advisable to treat the patient properly with the help of thrombolytic therapy and corona re angiogram which must be done after the submission of the patient within 2 to 24 hours. [55,56]

The process of routine angioplasty and stenting for the purpose of enhancement of Enhance Reperfusion in Acute Myocardial Infarction reveal the fact that PCI done in six hours after patient submission also following thrombolysis therapy have evidence result of improvement be finding a composite solution to STEMI, Whereas it also improved endpoint of death, recurring of disease, or to control the congestive heart failure for living cardiogenic shock. Certain other side effects of the disease can also be prevented. Therefore it is advisable to focus on the primary PCI along with thrombolytic therapy within six hours after the patient arrived to increase the survival rate and life expectancy. [57]

### 3.4 RESCUE PCI

This part of the literature review goes where's thrombosis therapy and it's a successful resource which is mostly seen in 50 to 60 percent of patients,[29] the concept of this therapy relating to rescue PCI help to lower the infarct of dysfunction of ventricular. After the randomized controlled trials of PCI, certain benefits have been mapped out which reduced the mortality rate to 35% whereas the reinfarction rate is also reduced to 36% S compared to the conservative method. [58]

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Rapid Early Action for Coronary Treatment (REACT) trial study suggested patients approaching PCI as an instant intervention have evident improved results whereas reducing their mortality rate. It is advisable once diagnosis patient must be reached to nearest PCI Center for better prevention and diagnosis. Certain side effects like stroke, brain injury, heart failure, all excessive bleeding can also be prevented within six months with the help of repeated thrombolysis therapy. [59]

Talking about the other option regarding thrombolytic would be creating a bridge in between pharma and PCI in order to create a better intervention which will follow pharmacological regimen where half or full dose with or without glycoprotein IIb/IIIa inhibitor will be used under the approach towards thrombolytic. [60]

### **3.5 SAFETY AND EFFICACY OF A NEW TREATMENT STRATEGY FOR ACUTE MYOCARDIAL INFARCTION**

Talking about PCI efficiency, as the mortality in the PCI group increased, it results in shutting the trial prematurely [61] and the FINESSE (Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events) trial on the basis of abciximab plus half-dose reteplase or abciximab evaluated as PCI versus Primary PCI. Meanwhile, LIPSIA-STEMI (Leipzig Immediate Prehospital Facilitated Angioplasty in ST-Segment Myocardial Infarction) trial [62] among STEMI patients <3 hours mainly in primary PCI implies that there is no such difference in results. Therefore, facilitated PCI should no longer be considered in STEMI patients. [62]

### **3.6 RECANALIZATION OF OCCLUDED ARTERY BEYOND THE 12-HOUR WINDOW**

In this section, recanalization has been discussed where patients coming to get myocardial salvage are less likely to get it done if they reach the place within 12 hours since the symptoms have discovered. The treatment-related to myocardial comes as dilemma related to recanalization of infarct related artery. Whereas certain research indicates that one-third of patients suffering STEMI are unlikely to receive reperfusion therapy because of the late presentation. [63,64 ]

The idea is to research and find out the solution in order to cater to the need of proper recanalization. As a result, the patient might not receive proper care and intervention in order to reduce the mortality rate. Meanwhile, the option for myocardial salvage is also very less whereas it also involves complications and risks, including the provision of collateral in order to mitigate risk in the future. [65-71]

Whereas defining the dilemma related to the optimal therapy in which patients presented as a sample to perform OAT Occluded Artery Trial in order to conduct RCT of 2166 patients having inclusion of

infarct-related artery 3 to 28 days after attracting myocardial infarction and left ventricular ejection fraction <50% or proximal vessel occlusion to routine PCI and stenting with the help of optimal therapy which can be beneficial to resolve the issues. [71]

Cumulative primary events rates of the 4-year program ensure that similarities are present in between the two groups. Whereas the research provide evidence or cardiac benefit. [72]

One should idealize the thought that OAT study as in NYHA class III or IV heart failure and shock must be controlled in order to increase survival chance. Whereas patients suffering from these problems might have the recommendation to perform angioplasty and stent thrombosis.<sup>73</sup> Thus, if the STEMI patients present >12 hours. Seems to be stables after surgery it is recommended not to perform further interventions. [73]

### **3.7. PHARMACOLOGY ADVANCES**

#### **3.7.1. Antiplatelet Therapy**

There is a significant role played by plat alerts for the initiation and the traveling of thrombus during STEMI after the plague has ruptured. It is anticipated that antiplatelet therapy is very useful to reduce complications after STEMI. [74] Clopidogrel is very useful when used with aspirin for STEMI patients which are only suffering from thrombolytic therapy and PCI that comes after it. [75] Although it is also suggested that Clopidogrel is not considered to be an optimal oral ADP-receptor inhibitor because of it inter-individual variability. [76] It is because of this reason that gnu inhibitors are being used for STEMI patients, called prasugrel [77], and ticagrelor. [78]

In TRITON-TIMI (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel- Thrombolysis in Myocardial Infarction) 54, there has been improved results in ischemic complications with the use of prasugrel which is far better than clopidogrel [79] in patients suffering from acute coronary syndromes and were previously treated with stent implantation. [77] There was an added benefit of prasugrel but there was an increased risk of bleeding in those patients. It was also noted that some patients had bad results when treated with prasugrel rather than clopidogrel. [77]

The patients who previously had ischemic strokes were better off without prasugrel therapy. Moreover, people having a body weight of fewer than 60 kilograms and more than the age of 75 could also not show good results with prasugrel therapy. [77] So, many patients were not pre-loaded with prasugrel during their treatment after coronary angiography. Ticagrelor also proved to be beneficial for the patients suffering from ischemic complications which also included cardiac mortality when compared with clopidogrel in PLATO (Platelet Inhibition and Patient Outcomes). [78]

The patients who were treated conservatively without revascularization showed similar results with the patients treated otherwise in the PLATO study. It was because mechanical or pharmacologic therapy was received by only 1/3rd of STEMI Patients. [63]

It is very assuring to know that ticagrelor is working and improving the survival chances of such patients. It can be added that there were no patients who showed the worst outcomes when compared with clopidogrel if they were being treated by less than 100 mg dosage of concomitant aspirin. Coughing and asymptomatic bradycardia were the only side effects that were frequenting in these patients. When compared with clopidogrel, there was less bleeding risk involved with ticagrelor. When the comparison is being made with clopidogrel, it is evident that the new antiplatelet agents are more effective and the patients suffering from STEMI are more likely to benefit from these new agents whose treatment is followed by primary PCI. [78]

### 3.7.2. Anticoagulant

While looking at the patients with stable angina and low-risk acute coronary syndrome, bivalirudin has been showing exceptional results providing effective anticoagulation when angioplasty is being done and the risk of bleeding is very low [80, 81] When compared with any other therapy, the patients undergoing primary PCI with stenting were more likely to benefit from bivalirudin when the HORIZONS-AMI (Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction). [82] It was evident from the trial that it was a clinical success since there were fewer bleeding complications and the cardiac mortality was also reduced significantly in those patients going through bivalirudin therapy. The initial procedure suggested that these benefits are going to be maintained up to three years. [83]

When compared with heparin plus glycoprotein IIb/IIIa inhibitor therapy, there was a significant increase in the acute stent thrombosis rate in the bivalirudin group. But censored can be considered as a clinical success, bivalirudin should be preferred as an anticoagulant therapy treatment for patients that are undergoing primary PCI. [83]

### 3.7.3. GP IIB/IIIa Inhibitors

Glycoprotein IIb/IIIa inhibitor therapy is very successful in STEMI patients if they are not pretreated with antiplatelet oral agents. One of the most recent studies has shown the results of intracoronary bolus administration of these agents and they are proven to be more successful when measured by infarct size. This is especially successful in patients running a high risk. [85-87]

For better post-PCI microvascular perfusion, the potential mechanisms may include higher local platelet glycoprotein IIb/IIIa receptor tenancy. [88] The results have not been regular when it comes to running

bigger trials. [89,90] There is a chance of improved survival for Pre-PCI TIMI Grade 3 flow of infarct-related artery, and it can be regarded as a positive predictor. [91]

TITAN (Time to Integrilin therapy in Acute Myocardial Infarction)- TIM34 was a success because that resulted in improved infarct vessel patency. [ 92] This study can be rendered as underpowered because it was unable to evaluate the clinical benefit of the early eptifibatide therapy which can be considered for STEMI Patients as this can increase the reperfusion. There was an unexpected finding in which it can be seen that there was an increased acute stent thrombosis rate in the bivalirudin group as compared with Glycoprotein group. [93]

There is a chance that the treatment done by glycoprotein IIb/IIIa inhibitor for a long period of time can be harmful to the patient. There is a chance of increase bleeding complications, and this can be reduced if the patient is treated with concomitant potent oral therapy. [ 94]

There has been seen a reduced residual ST-segment deviation because of administration of high-dose of bolus tirofiban before the patient is brought to the hospital [95]. And compared with placebo the cardiac events were also less [96].

### **3.8. DRUG-ELUTING STENTS COMPARED WITH BARE-METAL STENTS**

Bare-metal stents are becoming more of a choice for treatment during primary PCI because it reduces the target vessel revascularization. [97,98] There is another reason for the selection of Bare-metal stents because Drug-eluting stents are becoming a safety hazard because of thrombosis risk [99]. But then there were other studies that suggested that the use of Drug-eluting stents can be more beneficial by reducing the target vessel revascularization [100-102]. Although there was no difference when it comes to the mortality, reinfarction or any thrombosis risk, still there is a high risk of late reinfarction in patients treated with Drug-eluting stents [102].

It can be said that the chances of late stent thrombosis that is not associated with higher mortality can be because of the results shown by late stent thrombosis [103]. Without running the risk of stent thrombosis, if only the selective use of drug-eluting stents can be permitted. It is difficult to analyze the use of second-generation Drug-eluting Stents compared with first-generation stents because of late stent thrombosis [104].

There was, however, a random trial conducted to see the effects of both the generations of Drug-eluting stents and the results were found out on STEMI Patients where the adverse cardiac events were reduced [105]. Although the results were promising but there is still a long way to cover before any progress can be made in this regard.

It is likely that the STEMI patients are going to suffer during primary PCI, so it is very important for them to have distal protection and thrombectomy devices attached. But it is only a hypothesis, and it is not being backed by any evidence [106]. When both mechanical thrombectomy and simple thrombectomy is being compared, there are no added benefit of mechanical thrombectomy [106]. While the use of manual thrombus aspiration has shown significant results and has improved survival [107,108].

### **3.9. LV ASSIST DEVICES**

It is highly recommended in the patients undergoing reperfusion therapy to go through intra-aortic balloon counterpulsation (IABP). There are other percutaneous ventricular assistant devices that are being studied and it has come to the observation that it can improve hemodynamics when they come in comparison with IABP. [112,113] These devices are particularly helpful if IABP does not suffice [113].

It is still a difficult task to analyze whether the treatment of STEMI patients without the cardiogenic shock is going to be any help for them using IABP Therapy. Thus, CRISP AMI (Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction) high-risk anterior STEMI patients were randomized to primary PCI or prophylactic IABP before primary PCI and continued for at least 12 hours, with infarct size assessed by cardiac magnetic resonance imaging few days after PCI [114].

Patients who had had a previous MI or CABG were not eligible. In addition, if the primary PCI alone group had prolonged hypotension or cardiogenic shock, uncontrolled arrhythmias, or acute mitral regurgitation or ventricular septal defect, bail-out IABP was authorized. There was no significant difference in infarct size between the two groups in the trial, and there were no significant differences in infarct size between the two groups in the trial. It is not to be regularly used for the patients [114].

### **3.10. ACCESS SITE**

Bleeding complications were once common, especially at the vascular access site, due to the intensive anticoagulation and antiplatelet therapy utilized during STEMI treatment<sup>81</sup>. As a result, an alternative access site for primary PCI, such as the radial artery, may give a safer approach with less bleeding and, as a result, fewer ischemic complications, as substantial bleeding has been linked to an increased risk of ischemic complications [113-115]. [116]RIVAL (radial versus femoral access for coronary intervention) was the first large, multicentre, randomized trial comparing the potential benefit of radial access, mainly STEMI patients, despite many observational studies suggesting this possibility [117].

Although there was no significant difference in overall survival rates between the radial and femoral access groups, there was a significant benefit in patients with STEMI who underwent primary PCI, with

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a lower composite endpoint of death, recurrent myocardial infarction, or stroke, as well as death. The radial group also had a lower incidence of major vascular problems. Meta-analysis of all randomized studies comparing trans-radial versus transfemoral methods in STEMI patients found that the trans-radial group had a much lower rate of death, severe adverse cardiac events, and access site problems [118,119].

Because part of the bleeding problems is due to non access sites, there was only a trend toward a reduction in severe bleeding [117]. As a result, when it comes to the increased-volume radial centers, primary PCI through radial artery access may minimize access-site vascular problems as well as overall ischemic consequences when compared to transfemoral access.

### **3.11. THERAPEUTIC HYPOTHERMIA**

Many STEMI patients arrive with heart attacks outside the hospital [120], and when these patients are successfully tried and brought back to life by the ambulance staff, they are then transported to hospitals, there are concerns regarding persistent hypoxic/anoxic brain damage even after giving reperfusion treatment with the use of primary PCI. Mild therapeutic hypothermia from 32 to 34 degrees Celsius has been found to promote neurologic recovery in such cases, which can lead to hypothermia in worldwide guidelines on post-resuscitation treatment [123].

It is seemingly safe, but the induced hyperthermia is not efficient and is a relatively weak treatment. [124,125] So, there is a demand to run a random trial to make sure that its efficacy is tested [126]. It is still unsure whether moderate hypothermia in conjunction with primary PCI appears to be a moderate option in this regard if the emergency department and ICU staff adhere to strict guidelines. [127]

### **3.12. CELL THERAPY**

Several studies in this particular field have looked at the possibility of making the use of bone marrow cells to ensure that the left ventricular function in STEMI patients, is enough to save all of the myocardium in danger and this can result in better treatments in the future. Positive results have shown that treatments, such as REPAIR-AMI (Reinfusion of Enriched Progenitor Cells and Infarct Remodelling in Acute Myocardial Infarction), are statistically proven to be more significant in making sure that the improvement is being administered in intracoronary bone marrow treatment which can be prolonged to 3-7 days in MI. [129]

Aside from the time of intracoronary treatment after the person has gone through myocardial infarction, the administrative route can be rendered as significant in improving the functionality of the left

ventricular. 130,131 In future research, more information will be made available on the potential efficacy of bone marrow cell delivery in STEMI patients. [132]

### **3.13 MULTIVESSEL PCI VERSUS INFARCT-RELATED ARTERY PCI**

One of the most difficult aspects of primary PCI is treating serious lesions in non-infarct-related arteries during STEMI. STEMI patients are thought to have had multivessel coronary artery disease in 50% of cases. [133-136] Multi-vessel coronary artery disease patients have a worse prognosis than single-vessel coronary artery disease patients. [137]

Despite the lack of a large randomized trial comparing the advantages and disadvantages of infarct-related vessel PCI versus multivessel PCI in these patients, the most recent guidelines state that PCI of non-infarct-related vessels during STEMI in hemodynamically stable patients is contraindicated with a level III recommendation. [138]

Simultaneous multivessel PCI during primary PCI is associated with higher mortality and stent thrombosis risk in these patients, according to recent retrospective studies [136,139] and a meta-analysis. [140] One small but well-designed prospective randomized trial comparing different strategies in these patients (culprit vessel angioplasty alone with no further revascularization, staged revascularization at a later date, or simultaneous treatment of both infarct-related and non-infarct-related vessels) found that culprit vessel angioplasty alone was associated with significantly higher in-hospital mortality. [141]

The clinical outcomes of the other two groups, on the other hand, were similar after 2.5 years. According to a large New York State PCI Registry analysis, multi-vessel PCI during the index hospitalization resulted in higher in-hospital mortality compared to culprit-vessel PCI, but patients who underwent staged multi-vessel PCI within 60 days of the primary PCI of the infarct-related vessel had a significantly lower 12-month mortality compared to culprit-vessel PCI only.

Until further definitive randomized studies are available, it appears that treating the infarct-related vascular entirely at the index procedure and staging the nonculprit severe lesions within 60 days of the first PCI is the best option. Furthermore, when compared to angiography alone, the use of fractional flow reserve during staged procedures could better identify functionally significant coronary artery lesions [143] and improve outcomes, including significant reductions in mortality and myocardial infarction [144] in multivessel coronary artery disease patients.

### **3.14 NOVEL STENTS**

New stents with a decreased risk of stent thrombosis may be advantageous in STEMI patients since drug-eluting stents have a higher risk of late stent thrombosis than bare-metal stents. These innovations

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can range from truly biodegradable [145,146] to a biodegradable polymer coating of the metallic scaffold [147] to stents coated with antibodies against circulating endothelial progenitor cells to increase early endothelialization and reduce stent thrombosis. [148,149] These stents are currently being developed for elective procedures, but if their safety and efficacy can be proven, they could be extremely beneficial to STEMI patients.

### **3.15 NEED FOR PUBLIC EDUCATION AND FASTER TRANSFER FOR PRIMARY PCI**

It is commonly accepted that the sooner revascularization is performed after the onset of symptoms, the better the chances of myocardial salvage and a favorable long-term outcome. [150,151]

Although the time from symptom onset to the balloon is critical for infarct size reduction, the period from symptom onset to the balloon is far more important. Recent primary PCI trials indicated that infarct size measured by technetium-99 m sestamibi single-photon-emission computed tomography imaging was least when total symptom onset to balloon time was less than 2 hours and increased with longer time to reperfusion. As a result, it's vital that the general public is educated on the signs and symptoms of STEMI and that medical care is sought as soon as possible. [152]

According to one poll, public awareness of heart attack symptoms was low and did not increase between 2001 and 2007,[153] highlighting the need for greater public education programs. Women have also been found to have a higher risk of misinterpreting symptoms and experiencing atypical symptoms. [154,155] Because many STEMI patients still present to hospitals without on-site primary PCI, and because transfer for primary PCI is still preferred if the overall door-to-balloon time is kept within the recommended time, the “door-in to door-out” (DIDO) time is critical in preserving myocardium in these patients. According to a recent study, the acceptable DIDO is only acquired in a small fraction of the population (10%) across the country. [156]

As a result, innovative DIDO time-improvement technologies are required. Finally, new randomized, elective PCI studies with complicated architecture, such as left main coronary artery disease [157,158, may provide the foundation for a more aggressive PCI strategy during STEMI for complex lesions not treated with primary PCI. [159]

### **3.16 ADVERSE EFFECTS WITH PCI**

Primary PCI presents its own set of problems and challenges that must be addressed as part of the treatment strategy.

Bleeding, hematomas, pseudoaneurysms, and arteriovenous fistulas are among vascular issues that can occur at the access site. Transfusions are required in about two-thirds of patients as a result of these events, which occur in 2 to 3% of individuals. [3,47,160] Around 7% of people who have the operation endure significant bleeding (including bleeding at the access site)[29]. Because of lower heparin doses and smaller catheters being used now than in the past, as well as increased experience among interventional cardiologists and auxiliary personnel, the rate of bleeding has decreased. Compared to fibrinolytic therapy, primary PCI has a reduced risk of cerebral hemorrhage (0.05 percent vs. 1 percent, P0.001). [29] PCI patients can develop severe nephropathy in as little as 2% of cases (induced, at least in part, by radiographic contrast material). 14 People with cardiogenic shock 10 or underlying renal insufficiency [161], as well as those who are older, are more likely to get it. [162] Anaphylactic reactions to radiographic contrast material occur in a very tiny percentage of patients. [163]

4.3 percent of people who get their first PCI develop ventricular tachycardia or fibrillation. Despite spending more time in the hospital than patients without ventricular tachyarrhythmias, their long-term prognosis is similar. Up to 3% of patients receiving elective balloon angioplasty [165] have abrupt closure of the infarct-related artery (during or within hours after treatment); it may occur significantly more commonly in those undergoing primary balloon angioplasty. The rate of abrupt closure of the infarct-related artery is reduced to roughly 1% after stenting, lowering the need for immediate bypass surgery [16]6 and, in some scientists' opinion, obviating the need for on-site surgical competence. [167,168] Stenting is the preferred first operation if the coronary architecture is acceptable. As previously stated, stents reduce the risk of restenosis, which has been shown to be even more significant when drug-eluting stents are utilized. [169-171] In most stenting trials, stent thrombosis occurred in less than 1.5 percent of patients who received either a bare-metal or a drug-eluting stent within the first year. [171-174]

Only a small percentage of people who have primary PCI have major cardiovascular problems. In the above-mentioned data of 4366 procedures, the rates of emergency heart surgery and in-hospital death were 4.3 percent and 2.5 percent, respectively. [14] Patients whose perfusion has not been restored are considerably more likely to experience such events. At centers where primary PCIs are performed, there is a direct correlation between procedural volume and results. Patients who receive an elective PCI at a facility that performs 200 or more such operations per year have a lower probability of needing emergency bypass surgery and dying than those who receive care at a facility that does fewer than 200 PCIs per year. [175]

### **3.17 AREAS OF UNCERTAINTY**

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It is evident that PCI primary is beneficial yet has a successful outcome, but it has attached uncertainties that can trigger additional problems. There are some issues that have not evident solutions. It can be seen in certain aspects like brinolytic agent or platelet glycoprotein IIb/IIIa inhibitor administration referred to as facilitated interventions which rely on concepts under which PCI can be prompted with pharmacology therapies along with complete restoration of flow in the infarct-related artery than PCI alone.

But after analyzing this concept with trails, it was found that patients with myocardial infarction with ST-segment elevation who gone through PCI might suffer from patent infarct-related artery as compared who do not receives PCI . [60]

The process of routine angioplasty and stenting for the purpose of enhancement of Enhance Reperfusion in Acute Myocardial Infarction reveal the fact that PCI done in six hours after patient submission also following thrombolysis therapy have evidence result of improvement be finding a composite solution to STEMI, Whereas it also improved endpoint of death, recurring of disease, or to control the congestive heart failure for living cardiogenic shock. At present, it is unknown whether facilitated PCI with the use of only platelet glycoprotein IIb/IIIa inhibitors is superior to primary PCI alone. [14]

Whereas it is the clinical characteristics through which medical experts decide and make choices whether to use the fibrinolytic therapies or approaching Primary PCI.175 Rapid Early Action for Coronary Treatment (REACT) trial study suggested patients approaching PCI as an instant intervention have evident improved result whereas reducing their mortality rate. It is advisable once diagnosis patient must be reached to nearest PCI Center for better prevention and diagnosis. Certain side effects like stroke, brain injury, heart failure, all excessive bleeding can also be prevented within six months with the help of repeated thrombolysis. [44]

Moreover, patients treated with Primary PCI and have acute STEMI likely to have further multivessel coronary artery disease. This increases the chance for further infections and problems rather than coming to the recovery side, care is an important factor while physicians must stay accountable for making decisions in order to increase survival chances. [14]

In clinical practices, interventions must be performed under all the consequences to mitigate the associated risk. The idea is to keep the growth steady and optimized to ensure its success. A patient who receives primary PIC tends to be on the safer side and have more favorable results [176-178]The risk score developed in the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) study, indicates the successful results due to primary PCI. Myocardial Infarction (TIMI) risk score for STEMI is a simple assessment based on clinical data at the time of patient arrival at the hospital. [20]

The Thrombolysis In Myocardial Infarction (TIMI) risk score for STEMI.<sup>20</sup> The process of routine angioplasty and stenting for the purpose of enhancement of Enhance Reperfusion in Acute Myocardial Infarction reveals the fact that PCI is done six hours after patient submission also following thrombolysis therapy have evidence result of improvement be finding a composite solution to STEMI. Whereas it also improved the endpoint of death, recurring of disease, or to control the congestive heart failure for living cardiogenic shock. Certain other side effects of the disease can also be prevented. [11 ]

In the TIMI risk score, it was evident that accountability of variables was 97% in terms of its predictivity capacity. Whereas TIMI score did not count females samples, however, 3% of the predictive capacity for 30-day mortality (OR 1.2; 95% CI: 1 to 1.2). [18]

## **4. Original Study**

### **4.1 OBJECTIVE:**

With the help of frequency, the objective is to determine the primary percutaneous coronary intervention (PCI) in those having STEMI myocardial infarction at  $\geq 5$  TIMI scores in public sector hospitals.

### **4.2 OPERATION DEFINITION:**

#### **Primary Percutaneous Coronary Intervention (PCI):**

Primary PCI consisted of urgent balloon angioplasty (with or without stenting) to reach an infarct-related artery during an acute myocardial infarction with ST-segment elevation.

#### **Acute ST-Segment Elevation Myocardial Infarction:**

It was stated that the patient approach having severe chest pain leading to substernal crush having the patient in time tend to observe the duration which was 20 minutes along with squeeze type sensation while the pain travel through the left arm. The following are the main points referred from ECG:

1. New ST elevation at the J point in at least 2 contiguous leads of  $\geq 2$  mm (0.2 mV) in men or 1.5 mm (0.15 mV) in women in leads V2–V3.
2. New ST elevation of  $\geq 1$  mm (0.1 mV) in contiguous chest leads
3. New ST elevation of  $\geq 1$  mm (0.1 mV) in contiguous limb leads.”

**Acute Left Bundle Branch Block:**

The diagnostic criterion for left bundle branch block included the presence of any 2 Within 12 hours of the onset of symptoms as described in acute ST-segment elevation myocardial infarction

1. QRS duration of > 120ms.
2. Broad monophasic R wave in leads 1.
3. Absence of Q waves in leads V5 and V5.

**ADVERSE EVENTS:**

**Death (14.8%)<sup>20</sup>:** Patient died during hospital stay within one month including one on table death.

**Heart failure (15.3%)<sup>23</sup>:** Heart failure was diagnosed on clinical examination and confirmed through chest x-ray in patients with acute ST-segment elevation myocardial infarction.

Clinical findings include crepitus and **S3** heart sound ('gallop' sound) on auscultation of the chest.

The signs of heart failure on chest x-ray included:

- Pulmonary edema – it refers as bats wings which can appear but it may vary and often taken as lung mark increment
- Pleural effusions - blunting of the costo-phrenic angles.
- Increased vascular markings.
- Kerley-B lines (horizontal lines in lower zones of lung below 5th anterior ribs).
- Increased heart size (> 50% of the cardiothoracic ratio)

**Cardiogenic Shock (10.9%)<sup>20</sup>:** Cardiogenic shock was defined as the presence of any two was labeled as cardiogenic shock positive otherwise negative

1. Systolic blood pressure [SBP] of < 90 mmHg for at least 30 minutes
2. Diminished urine output (<30ml/hr.).
3. Cold extremities on touch.

**Ventricular Arrhythmias (14.8%)**<sup>20</sup>: it involves ventricular tachycardia. Ventricular tachycardia can be referred to as consecutive QRS at a rate of exceeding 100 beats/min.

TIMI risk score  $\geq 5$  considered as moderate and high risk.

High-Risk Features	Points
Age $\geq 75$ yrs	3
Age 64 to 75 yrs	2
Diabetes, Hypertension or Angina	1
Systolic Blood Pressure $< 100$ mmHg	3
Heart Rate $> 100$ /min	2
Killip Class II-IV	2
Weight Less Than 65 Kg	1
Anterior wall MI or Left BBB	1
Time to Therapy $> 4$ hrs	1
Total score calculated as arithmetic sum of individual points (Maximum=14)	

**TIMI risk groups:**

	Score
Low risk	0 to 4
Moderate risk	5 to 8
High risk	9 to 14

**Diabetes:** Known diabetic patients on insulin or taking oral hypoglycemic medications for equal or greater than 3 years.

**Hypertension:** known hypertensive patients on antihypertensive medications for equal or greater than 3 years.

**Smoker:** A smoker was defined as a person who smokes at least 03 cigarettes a day for more than 1 year.

**Socio Economic Status Of Parents:**

Low income group having  $< 10000$  Rs/month,

Middle income group 10000 to 20000 Rs/month,

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Upper income group >20000 Rs/month.

#### 4.4 MATERIAL & METHODS

**Settings:** This study was conducted at the National Institute of Cardiovascular Disease, Karachi, Pakistan

**Duration:** Six months from 28th October 2016 to 29th April 2017

**Sample size:** By using the sample size calculator “Open Epi”. The calculated sample size was 150 patients of STEMI at TIMI score  $\geq 5$  on the basis of the least percentage of Cardiogenic shock 10.9 %.(20) margin of error 5%, at 95% Confidence level.

**Sample technique:** Non-probability consecutive sampling was used for the study.

**Study Design:** Case Series

#### 4.5 SAMPLE SELECTION:

##### Inclusion Criteria:

- Patient with  $\geq 5$  TIMI score as per operational definition.
- Both Gender
- Age limit 35-80 years.
- The onset of typical chest pain and associated symptoms in last 12 hours persists at least more than 20 minutes.
- ECG changes consistent with the diagnosis of acute STEMI.
- Patient with HTN as per operational definition.
- Patient with Diabetes mellitus as per operational definition.
- Smoker as per operational definition.
- Patient without the previous administration of fibrinolytic therapy
- Patient without the previous administration platelet glycoprotein IIb/IIIa inhibitors.

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**Exclusion Criteria:**

- Patient with low TIMI (<5) risk group as per operational definition.
- Previous history of myocardial infarction.
- Previous history of thrombolytic therapy.
- Previous history of coronary angioplasty
- Previous histories of coronary artery bypass grafting.
- Prinzmetal angina (previous history of cardiac chest pain less than 20 mins at rest that occurs in cycles).
- History of cardiogenic shock at admission.

**4.6 DATA COLLECTION PROCEDURE:**

This reporting approach the College of Physicians and Surgeons of Pakistan in order to get approval. After the consent has been approved all the patient suffering from STEMI in N.I.C.V.D has been asked their consent to utilize their personal data for the report in written format. Each patient's personal information regarding age, gender, name, and biography has been gathered. The report has included those patients who agreed on the inclusion criterion whereas that patient who was in exclusive criterion was not included. After selecting the patient as samples, all of them got shifted in order to start the process of the arterial sheath in the Angiography department. It was done with the help of the femoral route. The procedure was completed by an expert interventional cardiologist having least 05 years of working experience.

An interventional cardiologist performs the femoral in which occlusion area was identified with the help of angiography for ballooned/stented. The certain consequences involve TIMI risk score points which were recorded for each patient.

According to the scores each patient gets, it is then segregated into three sections (0–4 low-risk, 5–8 moderate-risk, 9–14 high risk). The entire research methodology was completed under great experts whereas research enters Performa to keep the accuracy of results.

**4.7 DATA ANALYSIS PROCEDURE.**

Data were entered and analyzed through SPSS 22.

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Mean and standard deviation was used for quantitative variables i.e. age, height, weight, BMI while frequency and percentage were used for qualitative variables i.e. gender, smoking status, anemia, DM, HTN, Socioeconomic status, TIMI score (moderate/ high), Outcome(i.e. adverse events). Effect modifier age, gender, anemia, smoking status, HTN, DM, BMI, TIMI score (moderate/ high) & Socioeconomic status were controlled through stratification to see the effect of these on outcomes and post-stratification chi-square test was applied by taking P-value  $\leq 0.05$  as significant.

## **Results**

A total of 150 patients of either gender with ages 35 to 80 years was approached and examined in terms of inclusion criterion. They were approached to study the percutaneous coronary intervention (PCI) in patients with acute ST-segment elevation myocardial infarction at  $\geq 5$  TIMI scores. SSPS version 21 was used to study and calculate stratification mainly descriptive type.

For stratification, a Chi-square test was applied to observe the effect of modifiers on the outcome. P-value  $\leq 0.05$  was considered as significant. Out of 150 study subjects, 28 were female and 122 were male. Table 1 shows the detailed version of frequency distribution.

The overall mean age of study subjects was  $58.41 \pm 13.51$  years. Table 2 provided evidence of detail descriptive statistical analysis. Whereas age has been classified under two classes. Graph 1 shows the presentation of frequency and percentage of patients. Table 3 shows a detail description of age segregation.

Talking about height and weight of mean as a whole was  $1.56 \pm 0.06$  meters and  $73.20 \pm 11.57$  kg. table 4 and 5 shows the descriptive statistics in terms of height and weight.

The overall mean BMI was  $29.71 \pm 3.67$  kg/m<sup>2</sup>. Table 6 was able to interpret the detailed descriptive statistics. The BMI was further stratified into two groups. BMI  $\leq 30$  considered non-obese. Whereas graph 2 demonstrates the frequency and percentage of people involved in the testing. The frequency and percentage of patients among these groups are presented in Graph-2. Table-7 demonstrates detailed descriptive BMI stratified.

$7.24 \pm 2.42$  was the mean of overalls study subject precisely for TIMI score. Table 8 shows a detailed analysis of the TIMI score. The TIMI was further stratified into two groups. Graph 3 represents the percentage of patients in certain groups. Table 9 demonstrates the overall descriptive TIMI score.

Out of 150 study subjects, 24.7% were smokers as presented in Table-10. In total, 42.7% were hypertensive, 16.7% were diabetic and 8% were anemic. The detailed frequency distribution is presented from Table-11 to Table-13 respectively.

Most of the study (57.3%) subjects were from middle-class society. The detailed frequency distributions of socio-economic status are presented in Table-14.

In our study, adverse events i.e. death was observed in 14.7% of cases, heart failure in 18.7% cases, cardiogenic shock in 12% cases, and ventricular arrhythmias were observed in 16% cases. The detailed frequency distributions of adverse events are presented in Table-15.

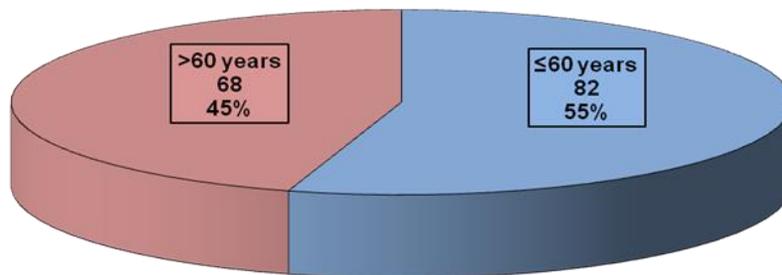
Stratification with respect to gender, age, BMI, TIMI score, smoking status, hypertension, diabetes mellitus, anemia and socio-economic status was done to observe the effect of these modifiers on adverse events (i.e. death, heart failure, Cardiogenic shock and ventricular arrhythmias). P-value  $\leq 0.05$  was considered as significant.

The results showed that there was a significant association of Death with age ( $P=0.001$ ) and BMI ( $P=0.012$ ). Heart failure was found significant with Socioeconomic status ( $P=0.040$ ) and hypertension ( $p=0.001$ ). Cardiogenic Shock was found significant with Gender ( $p=0.025$ ). While gender ( $p=0.010$ ) and socioeconomic status ( $p=0.049$ ) was also found significant with ventricular arrhythmias. The detailed results of associations are presented from Table-16 to Table-23.

**GRAPH - 1**

**PERCENTAGE OF PATIENTS**

**ACCORDING TO AGE GROUPS (n=150)**

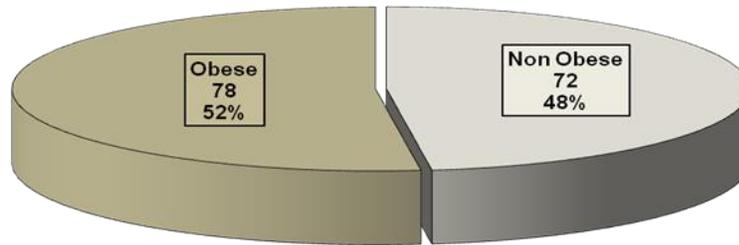


**GRAPH - 2**

**PERCENTAGE OF PATIENTS**

**ACCORDING TO BMI GROUPS (n=150)**

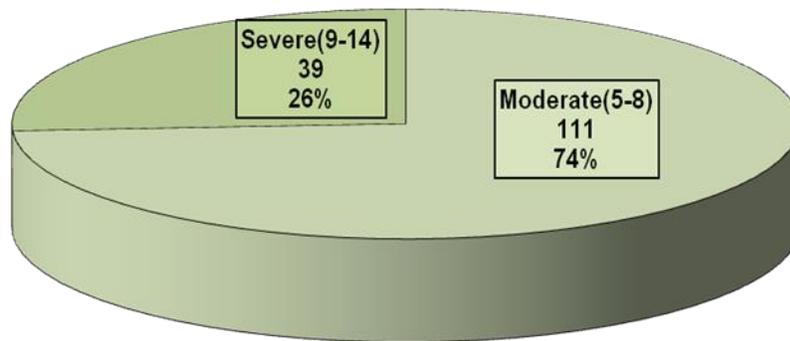
Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at  $\geq 5$  TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2



**GRAPH – 3**

**PERCENTAGE OF PATIENTS**

**ACCORDING TO TIMI RISK GROUPS (n=150)**



**TABLE – 1**

**FREQUENCY DISTRIBUTION OF GENDER (n=150)**

	<b>Frequency</b>	<b>%</b>
<b>Male</b>	122	81.3%
<b>Female</b>	28	18.7%
<b>TOTAL</b>	<b>150</b>	

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**TABLE – 2****DESCRIPTIVE STATISTICS OF AGE (years) (n=150)**

<b>Mean ±SD</b>	58.41±13.51
<b>95%CI</b>	56.23 To 60.59
<b>Median (IQR)</b>	58.50 (24)
<b>Range</b>	45
<b>Minimum</b>	35
<b>Maximum</b>	80

**TABLE – 3****DESCRIPTIVE STATISTICS OF AGE - ACCORDING TO GROUPS (n=150)**

	<b>≤60 years</b> (n=82)	<b>&gt;60 years</b> (n=68)
<b>Mean±SD</b>	47.62±7.29	71.42±5.21
<b>95%CI</b>	46.01-49.22	70.16-72.668
<b>Median (IQR)</b>	48.00 (12)	71.00 (9)
<b>Range</b>	25	19
<b>Minimum</b>	35	61
<b>Maximum</b>	60	80

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**TABLE – 4****DESCRIPTIVE STATISTICS OF HEIGHT (m) (n=150)**

<b>Mean ±SD</b>	1.56±0.06
<b>95%CI</b>	1.55 To 1.57
<b>Median (IQR)</b>	1.57 (0.11)
<b>Range</b>	0.23
<b>Minimum</b>	1.45
<b>Maximum</b>	1.68

**TABLE – 5****DESCRIPTIVE STATISTICS OF WEIGHT (kg) (n=150)**

<b>Mean ±SD</b>	73.20±11.57
<b>95%CI</b>	71.33 To 75.06
<b>Median (IQR)</b>	70.00 (20)
<b>Range</b>	43
<b>Minimum</b>	50
<b>Maximum</b>	93

TABLE – 6

DESCRIPTIVE STATISTICS OF BMI (kg/m<sup>2</sup>) (n=150)

<b>Mean ±SD</b>	29.71±3.67
<b>95%CI</b>	29.12 To 30.31
<b>Median (IQR)</b>	30.25 (5.28)
<b>Range</b>	19.90
<b>Minimum</b>	20.10
<b>Maximum</b>	40.0

TABLE – 7

DESCRIPTIVE STATISTICS OF BMI ACCORDING TO BMI GROUPS (n=150)

	<b>Non Obese &lt;30</b> (n=72)	<b>Obese ≥30</b> (n=78)
<b>Mean±SD</b>	26.56±2.40	32.62±1.69
<b>95%CI</b>	26.00-27.13	32.24-33.01
<b>Median (IQR)</b>	27.10 (3.68)	32.60 (2.05)
<b>Range</b>	9.70	9.90
<b>Minimum</b>	20.10	30.10
<b>Maximum</b>	29.80	40.00

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at ≥ 5 TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2

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TABLE - 8

## DESCRIPTIVE STATISTICS OF TIMI SCORE (n=150)

<b>Mean ±SD</b>	7.24±2.42
<b>95%CI</b>	6.84 To 7.63
<b>Median (IQR)</b>	6.00 (4)
<b>Range</b>	9
<b>Minimum</b>	5
<b>Maximum</b>	14

TABLE - 9

## DESCRIPTIVE STATISTICS OF TIMI SCORE ACCORDING TO GROUPS (n=150)

	<b>Moderate (5-8) (n=111)</b>	<b>Severe (9-14) (n=39)</b>
<b>Mean±SD</b>	5.97±0.93	10.84±1.59
<b>95%CI</b>	5.79-6.14	10.32-11.36
<b>Median (IQR)</b>	6.00 (2)	10.00 (2)
<b>Range</b>	3	5
<b>Minimum</b>	5	9
<b>Maximum</b>	8	14

TABLE - 10

## FREQUENCY DISTRIBUTION OF SMOKERS (n=150)

	<b>Frequency (n)</b>	<b>%</b>
<b>Yes</b>	37	24.7
<b>No</b>	113	75.3
<b>TOTAL</b>	<b>150</b>	

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**TABLE - 11**

**FREQUENCY DISTRIBUTION OF HYPERTENSION (HTN) (n=150)**

	<b>Frequency (n)</b>	<b>%</b>
<b>Yes</b>	64	42.7
<b>No</b>	86	57.3
<b>TOTAL</b>	<b>150</b>	

**TABLE - 12**

**FREQUENCY DISTRIBUTION OF DIABETES MELLITUS (DM) (n=150)**

	<b>Frequency (n)</b>	<b>%</b>
<b>Yes</b>	25	16.7
<b>No</b>	125	83.3
<b>TOTAL</b>	<b>150</b>	

**TABLE - 13**

**FREQUENCY DISTRIBUTION OF ANEMIA (n=150)**

	<b>Frequency (n)</b>	<b>%</b>
<b>Yes</b>	12	8
<b>No</b>	138	92
<b>TOTAL</b>	<b>150</b>	

TABLE – 14

## FREQUENCY DISTRIBUTION OF SOCIO-ECONOMIC STATUS (n=150)

	Frequency (n)	%
<b>Lower</b>	38	25.3
<b>Middle</b>	86	57.3
<b>Upper</b>	26	17.3
<b>TOTAL</b>	<b>150</b>	

TABLE – 15

## FREQUENCY DISTRIBUTION OF ADVERSE EVENTS (n=150)

		Frequency (n)	%
<b>Death</b>	<b>Yes</b>	22	14.7
	<b>No</b>	128	85.3
<b>Heart Failure</b>	<b>Yes</b>	28	18.7
	<b>No</b>	122	81.3
<b>Cardiogenic shock</b>	<b>Yes</b>	18	12
	<b>No</b>	132	88
<b>Ventricular arrhythmias</b>	<b>Yes</b>	24	16
	<b>No</b>	126	84

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at  $\geq 5$  TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2

**TABLE – 16****FREQUENCY AND ASSOCIATION OF DEATH ACCORDING TO SOCIO-DEMOGRAPHIC FACTORS**

(n=150)

		Death		TOTAL	P-Value
		Yes	No		
<b>Gender</b>	<b>Male</b> (n=122)	19	103	<b>122</b>	0.767**
	<b>Female</b> (n=28)	3	25	<b>28</b>	
<b>Age</b>	<b>≤60 years</b> (n=82)	5	77	<b>82</b>	0.001*
	<b>&gt;60 years</b> (n=68)	17	51	<b>68</b>	
<b>Socio-Economic Status</b>	<b>Lower</b> (n=38)	5	34	<b>38</b>	0.534**
	<b>Middle</b> (n=86)	16	71	<b>86</b>	
	<b>Upper</b> (n=26)	3	23	<b>26</b>	

Chi Square Test was applied.

P-value≤0.05 considered as significant.

\* Significant at 0.05. \*\* Not significant at 0.05.

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at ≥ 5 TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2

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TABLE - 17

## FREQUENCY AND ASSOCIATION OF DEATH- ACCORDING TO CLINICAL FACTORS (n=150)

		Death		TOTAL	P-Value
		Yes	No		
<b>BMI Group</b>	<b>Non Obese</b> (n=72)	16	56	<b>72</b>	0.012*
	<b>Obese</b> (n=78)	6	72	<b>78</b>	
<b>TIMI Score Group</b>	<b>Moderate</b> (n=111)	15	96	<b>111</b>	0.501**
	<b>Severe</b> (n=39)	7	32	<b>39</b>	
<b>Smoker</b>	<b>Yes</b> (n=37)	5	32	<b>37</b>	0.819**
	<b>No</b> (n=113)	17	96	<b>113</b>	
<b>Hypertension</b>	<b>Yes</b> (n=64)	8	56	<b>64</b>	0.518**
	<b>No</b> (n=86)	14	72	<b>86</b>	
<b>Diabetes Mellitus</b>	<b>Yes</b> (n=25)	6	19	<b>25</b>	0.210**
	<b>No</b> (n=125)	16	109	<b>125</b>	
<b>Anemia</b>	<b>Yes</b> (n=12)	3	9	<b>12</b>	0.386**
	<b>No</b> (n=138)	19	119	<b>138</b>	

Chi Square Test was applied.

P-value $\leq$ 0.05 considered as significant. \* Significant at 0.05. \*\* Not significant at 0.05.

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at  $\geq$  5 TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2

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TABLE - 18

**FREQUENCY AND ASSOCIATION OF HEART FAILURE- ACCORDING TO SOCIO-DEMOGRAPHIC FACTORS (n=150)**

		Heart Failure		TOTAL	P-Value
		Yes	No		
<b>Gender</b>	<b>Male</b> (n=122)	26	96	<b>122</b>	0.083**
	<b>Female</b> (n=28)	2	26	<b>28</b>	
<b>Age</b>	<b>≤60 years</b> (n=82)	12	70	<b>82</b>	0.164**
	<b>&gt;60 years</b> (n=68)	16	52	<b>68</b>	
<b>Socio-Economic Status</b>	<b>Lower</b> (n=38)	8	30	<b>38</b>	0.040*
	<b>Middle</b> (n=86)	11	75	<b>86</b>	
	<b>Upper</b> (n=26)	9	17	<b>26</b>	

Chi Square Test was applied.

P-value≤0.05 considered as significant.

\* Significant at 0.05.

\*\* Not significant at 0.05.

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at ≥ 5 TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2

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TABLE - 19

## FREQUENCY AND ASSOCIATION OF HEART FAILURE- ACCORDING TO CLINICAL FACTORS

(n=150)

		Heart Failure		TOTAL	P-Value
		Yes	No		
<b>BMI Group</b>	<b>Non Obese</b> (n=72)	13	59	<b>72</b>	0.854**
	<b>Obese</b> (n=78)	15	63	<b>78</b>	
<b>TIMI Score Group</b>	<b>Moderate</b> (n=111)	21	90	<b>111</b>	0.894**
	<b>Severe</b> (n=39)	7	32	<b>39</b>	
<b>Smoker</b>	<b>Yes</b> (n=37)	7	30	<b>37</b>	0.964**
	<b>No</b> (n=113)	21	92	<b>113</b>	
<b>Hypertension</b>	<b>Yes</b> (n=64)	20	44	<b>64</b>	0.001*
	<b>No</b> (n=86)	8	78	<b>86</b>	
<b>Diabetes Mellitus</b>	<b>Yes</b> (n=25)	6	19	<b>25</b>	0.573**
	<b>No</b> (n=125)	22	103	<b>125</b>	
<b>Anemia</b>	<b>Yes</b> (n=12)	3	9	<b>12</b>	0.698**
	<b>No</b> (n=138)	25	113	<b>138</b>	

Chi Square Test was applied.

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P-value≤0.05 considered as significant.

\* Significant at 0.05.

\*\* Not significant at 0.05.

**TABLE – 20**

**FREQUENCY AND ASSOCIATION OF CARDIOGENIC SHOCK - ACCORDING TO SOCIO-DEMOGRAPHIC FACTORS (n=150)**

		Cardiogenic shock		TOTAL	P-Value
		Yes	No		
<b>Gender</b>	<b>Male</b> (n=)	18	104	<b>122</b>	0.025*
	<b>Female</b> (n=)	0	28	<b>28</b>	
<b>Age</b>	<b>≤60 years</b> (n=)	9	73	<b>82</b>	0.672**
	<b>&gt;60 years</b> (n=)	9	59	<b>68</b>	
<b>Socio-Economic Status</b>	<b>Lower</b> (n=38)	4	34	<b>38</b>	0.830**
	<b>Middle</b> (n=86)	10	76	<b>86</b>	
	<b>Upper</b> (n=26)	4	22	<b>26</b>	

Chi Square Test was applied.

P-value≤0.05 considered as significant.

\* Significant at 0.05.

\*\* Not significant at 0.05.

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad "The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at ≥ 5 TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients" MAR Cardiology 3.2

TABLE - 21

## FREQUENCY AND ASSOCIATION OF CARIOGENIC SHOCK- ACCORDING TO CLINICAL FACTORS

(n=150)

		Cardiogenic shock		TOTAL	P-Value
		Yes	No		
<b>BMI Group</b>	<b>Non Obese</b> (n=72)	6	66	<b>72</b>	0.184**
	<b>Obese</b> (n=78)	12	66	<b>78</b>	
<b>TIMI Score Group</b>	<b>Moderate</b> (n=111)	15	96	<b>111</b>	0.405**
	<b>Severe</b> (n=39)	3	36	<b>39</b>	
<b>Smoker</b>	<b>Yes</b> (n=37)	4	33	<b>37</b>	1.000**
	<b>No</b> (n=113)	14	99	<b>113</b>	
<b>Hypertension</b>	<b>Yes</b> (n=64)	9	55	<b>64</b>	0.502**
	<b>No</b> (n=86)	9	77	<b>86</b>	
<b>Diabetes Mellitus</b>	<b>Yes</b> (n=25)	3	22	<b>25</b>	1.000**
	<b>No</b> (n=125)	15	110	<b>125</b>	
<b>Anemia</b>	<b>Yes</b> (n=12)	2	10	<b>12</b>	0.639**
	<b>No</b> (n=138)	16	122	<b>138</b>	

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Chi Square Test was applied.

P-value≤0.05 considered as significant.

\* Significant at 0.05.

\*\* Not significant at 0.05.

**TABLE – 22**

**FREQUENCY AND ASSOCIATION OF VENTRICULAR ARRHYTHMIAS ACCORDING TO SOCIO-DEMOGRAPHIC FACTORS (n=150)**

		Ventricular Arrhythmias		TOTAL	P-Value
		Yes	No		
<b>Gender</b>	<b>Male</b> (n=122)	24	98	<b>122</b>	0.010*
	<b>Female</b> (n=28)	0	28	<b>28</b>	
<b>Age</b>	<b>≤60 years</b> (n=82)	10	72	<b>82</b>	0.163**
	<b>&gt;60 years</b> (n=68)	14	54	<b>68</b>	
<b>Socio-Economic Status</b>	<b>Lower</b> (n=)	2	36	<b>38</b>	0.049*
	<b>Middle</b> (n=)	19	67	<b>86</b>	
	<b>Upper</b> (n=)	3	23	<b>26</b>	

Chi Square Test was applied.

P-value≤0.05 considered as significant.

\* Significant at 0.05. \*\* Not significant at 0.05.

Citation: Ahmed S, Ali N, Hussain T, Ahmed T, Kumar J, Shahzad “The frequency of adverse events of primary percutaneous coronary intervention (PCI) in patients with acute ST segment elevation myocardial infarction at ≥ 5 TIMI score in public sector hospital makes strong rationale to conduct this research in a large number of patients” MAR Cardiology 3.2

TABLE - 23

**FREQUENCY AND ASSOCIATION OF VENTRICULAR ARRHYTHMIAS ACCORDING TO CLINICAL FACTORS (n=150)**

		Ventricular Arrhythmias		TOTAL	P-Value
		Yes	No		
<b>BMI Group</b>	<b>Non Obese</b> (n=72)	13	59	<b>72</b>	0.509**
	<b>Obese</b> (n=78)	11	67	<b>78</b>	
<b>TIMI Score Group</b>	<b>Moderate</b> (n=111)	16	95	<b>111</b>	0.372**
	<b>Severe</b> (n=39)	8	31	<b>39</b>	
<b>Smoker</b>	<b>Yes</b> (n=37)	7	30	<b>37</b>	0.577**
	<b>No</b> (n=113)	17	96	<b>113</b>	
<b>Hypertension</b>	<b>Yes</b> (n=64)	11	53	<b>64</b>	0.732**
	<b>No</b> (n=86)	13	73	<b>86</b>	
<b>Diabetes Mellitus</b>	<b>Yes</b> (n=25)	4	21	<b>25</b>	1.000**
	<b>No</b> (n=125)	20	105	<b>125</b>	
<b>Anemia</b>	<b>Yes</b> (n=12)	3	9	<b>12</b>	0.409**
	<b>No</b> (n=138)	21	117	<b>138</b>	

Chi Square Test was applied.

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P-value $\leq$ 0.05 considered as significant.

\* Significant at 0.05.

\*\* Not significant at 0.05.

## Discussion

After providing a complete research report covering the population of STEMI, it was revealed that the population of STEMI is completely different and varied from person to person. This is an important issue as there will be adverse effects and different interventions must be designed to cater to each patient accordingly. In order to evaluate the prognosis, it is important to make correct stratification as to provide complete intervention without making any risk. It is exit stated that ideal risk or as to predict prognosis must be we did as it can be different. [17,20,179,180]

Moreover, the clinical stratification gathered from the data obtained from samples present in the hospital can determine the TIMI score for STEMI. It is also situated that the data obtained with the help of treatment to patients can wait and there is a chance of thrombolytic therapies which can also be done after analyzing the data with the help of randomized control trials. According to the results, it was evident that most of the patients are at risk. [20]

The patient was analyzed before and after the treatment in order to calculate the validated at the unselected patient population in the National Registry of Myocardial Infarction in order to observe the mortality and survival rate. [11]

In a study, patients who underwent primary PCI, 32% were stratified as high risk (TIMI risk score  $\geq$ 5) before the procedure.17 Thune et al. in the DANish trial in Acute Myocardial Infarction-2 (DANAMI-2) stratified patients by TIMI risk score; 25% of patients were high risk (TIMI  $\geq$ 5).

After following up the trial for three years it was revealed that primary PCI versus thrombolytic therapy can be more beneficial who reduced the mortality rate and provide better intervention for those patients who are at higher risk. Lev et al. Also reported the fact that people with high risk along with the TIMI score, must provide primary PCI in order to increase their survival rate. [181]

The report also revealed that the idea of TIMI risk score has been closely associated with increased frequency of mortality in hospitals, it is common among those who would see primary PCI without any cardiogenic shock. The report revealed that it is comparable with the CADILLAC risk score in the same group of patients (TIMI c-statistics = 0.80 and CADILLAC c-statistics = 0.83). [17]

There have been many interventions and close therapies which can prevent the mortality rate among STEMI patients, in order to reduce the death rates it is very important to predict the post-procedure

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complications as it has strong effects on the patient after the surgery. [17] In the meta-analysis of Keeley et al. revealed that the cause of death and opposite effects of PCI like stroke and excessive bleeding are less likely to happen for those who have strong stamina and gone through thrombosis.[29] Kent et al. also revealed the fact that primary PCA is very beneficial for high-risk patients. [182]

Negasso et al. reported a decision-tree structure prognostic which involves the primary care an intervention plan after the PCI in order to predict the complications and consequences. There are certain complications like heart failure, age factor, diabetes, heart stroke, and excessive bleeding. Hospitals must be prepared enough to deal with such kinds of consequences as per the prediction. Where is the purpose of TIMI risk score is to provide future predictions about deaths but one must not rely on them solely. (TIMI risk  $\geq 5$ ), who not only have a mortality rate eight times higher than the low-risk group (TIMI risk  $< 4$ ), but also have an increased frequency of in-hospital adverse events such as heart failure ( $p=0.0001$ ), development of cardiogenic shock ( $p=0.0001$ ), ventricular arrhythmias ( $p=0.001$ ), and no-reflow phenomenon ( $p=0.01$ ), it may happen due to the less intervention plan by the hospital in order to treat the patient of STEMI. It is important to cater to the patient As for the need according to the high risk and low risk. [17, 183]

The study reveals that patients having diabetes how to receive PCI care, Killip class  $> 2$ , previous stroke, and the duration of ischemia. [184,185] An overall frequency of 16.4%, with significantly higher prevalence in the high-risk group than in the low-risk group was reported in a study. [171,86]

### **Study Limitations**

Two factors that service the limitation to complete the study were the single-center experience and nonrandomized study design which serve as a barrier to complete the overall research. Whereas a small sample size was selected in an urban area. There is a possibility that the data might be generalizable to the large sample.

### **Conclusion**

The report is concluded with the fact that the TIMI score explores the reality of PCI under which patients with a high risk of mortality can be the biggest factor to increase mortality rate. These patients are also liable for certain other complications like heart failure, heart stroke, and excessive bleeding. In order to provide the best approach towards risk stratification, it is suggested to utilize the TIMI score as it ought to be reliable. Time delays are other crucial factors to provide proper intervention to STEMI patients.

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