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# The Clinical Outcomes of Primary Angioplasty in Hospitalized Patients with ST-Segment Elevation Acute Myocardial Infarction Were Investigated at Imam Reza Hospital from 1399 to 1401

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**ABSTRACT**

**Introduction:** Ischemic heart disease (IHD) is a major global health concern with significant implications for patient mortality and life expectancy. Effective management of IHD heavily relies on vascular reconstruction procedures, including percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG).

**Material and Method:** This study was conducted at Imam Reza Hospital, evaluating 103 patients with myocardial infarction with ST elevation (MI-STE) who underwent PCI. The cohort comprised 84 men and 19 women across varying age ranges. A subset of these patients had a history of CABG, addiction, or a family history of heart disease. The study focused on the types of stents used, with Supraflex and Xience being the most common, primarily in lengths of ≤20 mm and diameters of 2.75 mm. Post-PCI complications were also assessed, including hematoma at the angiography site, rehospitalization, coronary artery revascularization, contrast-induced nephropathy (CIN), no reflow, in-stent restenosis (ISR), coronary artery dissection, and cardiogenic shock.

**Result and Conclusion:** The overall population experienced a low mortality rate of 1.9%. Notably, cardiogenic shock was significantly associated with mortality, posing a 100-fold increased risk. This study underscores the importance of monitoring and managing post-PCI complications to improve patient outcomes and reduce mortality in individuals with IHD. Further research is warranted to explore preventive strategies and optimize treatment approaches for this patient population.

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## Introduction

Ischemic Heart Disease (IHD) significantly impacts modern society, with approximately 15.4 million Americans affected—7.8 million men and 7.6 million with a history of myocardial infarction (MI). The Framingham study indicates that the lifetime risk of developing IHD is 3.6% for men and 1% for women without risk factors. However, this risk escalates to 37.5% for men and 18.3% for women with two or more major risk factors. IHD accounts for 46% of all cardiovascular disease-related deaths, making it the leading cause of mortality among both genders in the U.S. Although there has been a decline in

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coronary artery disease (CAD) mortality rates in recent years, IHD continues to be the foremost cause of death globally (1).

Risk factors for IHD are classified into modifiable and non-modifiable categories. Modifiable factors include obesity, diabetes, high blood pressure, high cholesterol, and smoking, while non-modifiable factors consist of age, gender, race, and family history. A study revealed that 85.6% of myocardial infarction patients had at least one controllable risk factor, whereas 14.4% had none (2).

The WHO projects that IHD mortality will rise from 7.2 million deaths in 2012 to 9.2 million by 2030. Despite advances in diagnosis and treatment, ST-segment elevation myocardial infarction (STEMI) continues to be a significant public health challenge globally. In the U.S., over one million individuals are hospitalized each year for STEMI. While hospitalization rates for myocardial infarction have declined in those over 55, this trend is not seen in younger patients, particularly women (3). AHA estimates indicate that the short-term mortality rate for STEMI is about 5-6% during initial hospitalization and rises to 18-7% within the first year. The greatest risk of ischemic complications occurs within the first 180 days post-MI. The decline in mortality rates among STEMI patients is largely due to reperfusion therapies, including coronary thrombolysis, intravenous thrombolysis, and various percutaneous coronary intervention (PCI) procedures (4). The European Society of Cardiology declared the reduction of non-communicable diseases, especially coronary artery disease, as one of its main goals until 2025 (5). In Iran, coronary artery disease, with a prevalence of 21%, ranks first among chronic diseases (6). The prevalence of coronary artery disease in Iran is higher than in Western countries, with 35,000 to 50,000 heart surgeries performed annually. Approximately 90,000 deaths occur in Iran each year due to this disease (7). Unfortunately, this rate is increasing, with up to 46% of deaths attributed to it. In Iran, coronary artery disease has emerged as the leading cause of death among individuals over 35 years old (8,9).

The management of coronary artery disease involves risk factor control, medication, and vascular reconstruction, including procedures like PCI and coronary artery bypass surgery. While medication is the mainstay for ischemic heart diseases, many patients benefit from PCI. Advances in coronary intervention technology, particularly percutaneous angioplasty and stenting, have emerged as effective alternatives to bypass surgery. The approach to treating STEMI has shifted from drug-based reperfusion to catheter-based techniques, resulting in better short-term and long-term outcomes, along with decreased recurrence and mortality rates (10).

The late 1970s saw the advent of coronary angiography and balloon angioplasty. Initially, balloon angioplasty without stenting led to high rates of restenosis and vessel dissection. The first coronary stent was introduced in 1986, showing improved outcomes in occlusion prevention compared to balloon angioplasty. As a result, coronary stents have become the dominant treatment for coronary artery disease. However, balloon angioplasties still carry a higher risk of in-stent restenosis (ISR) due to neointimal hyperplasia and smooth muscle growth, with previous studies reporting ISR rates of 10% to 20% within six months, potentially leading to myocardial infarction and the need for revascularization (11). Coronary intervention through the skin is the most common method for improving myocardial perfusion. Many specialists believe that angioplasty will replace open-heart surgery in the future (12). A study found that patients viewed angioplasty as a pivotal moment in enhancing their quality of life and resuming normal activities. However, like any invasive procedure, it carries risks. Major complications from coronary angioplasty include recurrent angina, myocardial infarction, restenosis, repeat bypass surgery, and death. The mortality rate post-ST-segment elevation is 5% in stable angina patients but escalates to 30-35% in those experiencing cardiogenic shock (13). The rise in contrast media use for coronary angiography has led to a surge in contrast-induced nephropathy (CIN), a significant cause of acquired kidney dysfunction in hospitals with both short- and long-term

implications. CIN is a frequent complication following emergency PCI for acute myocardial infarction, yet its impact on patients with acute coronary syndrome (ACS) is still not thoroughly investigated (14, 15). Despite all diagnostic and therapeutic advances, STEMI remains a major public health issue in countries. In the United States alone, over one million people are hospitalized annually due to STEMI. Although the rate of hospitalization due to MI in patients over 55 has decreased, this decrease in hospitalization is not observed in younger patients, especially women (16). The significant reduction in mortality in patients with STEMI is mainly attributed to reperfusion therapies, including coronary intracoronary fibrinolysis, intravenous thrombolysis, and the evolution of PCI methods (17). Studies have shown that reperfusion therapy within the first 6 hours after myocardial infarction significantly reduces mortality (18). Therefore, it seems that post-angioplasty complications have a significant impact on patient mortality and life expectancy.

Angioplasty is now a less invasive and more cost-effective alternative to coronary artery bypass surgery, which was the sole treatment for coronary artery disease before 1977 (19). Although metallic stents lower the risk of restenosis compared to balloon angioplasty, 20-30% of patients still experience it, with total occlusion occurring in 10-15% within the first year. Restenosis is particularly common in patients with small vessels, long lesions, and diabetes; however, combining drug therapy with stent placement can help mitigate this issue (20).

Stent thrombosis is a significant risk linked to stent implantation, categorized into three types: acute (within 24 hours), subacute (after 30 days), and late (after one year). The occurrence of stent thrombosis is influenced by clinical factors such as diabetes, kidney failure, heart failure, and acute myocardial infarction, as well as lesion-related factors like length, location, and vessel diameter. Procedural factors, including the technique used, the physician's expertise, and any remaining dissection within the stent, also play a crucial role (21). Predictors of higher mortality risk include older age, diabetes, heart failure, kidney failure, multiple coronary artery involvement, and comorbidities (22). There is clear evidence that early initiation of treatment within the first hour is associated with reduced mortality. Patients undergoing primary angioplasty experience fewer clinical adverse events both within 30 days and 6 months after myocardial infarction compared to those treated with thrombolytic therapy, (18,23).

Studies indicate that patients with conditions like diabetes who undergo primary angioplasty after a myocardial infarction face higher risks of mortality, recurrent MI, and stent thrombosis, though these risks may not be linked to the type of stent used. For instance, those receiving drug-eluting stents (DES) tend to require fewer repeat revascularizations compared to those with bare-metal stents (BMS). Additionally, 40-60% of patients with acute coronary syndrome (ACS-NSTE) show multivessel involvement during angiography, for which the ACC/AHA recommends PCI (24). While multivessel PCI has led to better clinical outcomes and reduced emergency revascularization needs, it also carries heightened risks of periprocedural myocardial infarction, stent thrombosis, bleeding, and contrast-induced nephropathy (25,26). Stroke is a significant complication of revascularization. The risk of stroke within the first 30 days post-PCI is lower than that associated with CABG, and even after five years, patients undergoing PCI have a reduced overall stroke risk. However, between 31 days and five years, there is no notable difference in stroke risk between PCI and CABG (27).

Although various treatment methods have been used in patients with coronary artery lesions, there is still no consensus on a preferred treatment method. Coronary artery angioplasty as an invasive treatment method is preferred by some cardiologists, who consider factors affecting complications in patients based on risk factors to determine the best treatment approach.

The aim of this study was to determine the incidence and clinical outcomes (including stent thrombosis, hospitalization and revascularization rates, cardiogenic shock, restenosis within the stent, hematoma formation, contrast-induced nephropathy,

coronary artery complications, and mortality) of primary angioplasty in patients hospitalized with acute myocardial infarction associated with ST-segment elevation at Imam Reza Hospital in Mashhad from 2020 to 2022.

## Method

The study was conducted at Imam Reza Hospital in Mashhad in the Cardiology Department from 1399 to 1401. The researcher-developed questionnaire was completed based on the entry and exit criteria and the findings obtained from the patients' records after obtaining informed consent. The data included age, gender, LVEF, comorbidities, vascular access (radial or femoral), involved vessel, type of lesion, PCI-related complications (hematoma, access site complications, stent thrombosis, cardiogenic shock, tamponade, coronary dissection, arrhythmia, contrast-induced nephropathy, stroke, and mortality during PCI), stent characteristics (type, length, diameter), reasons for unsuccessful PCI and no reflow, and catheter engagement.

This retrospective cohort study was conducted on patients with STEMI undergoing PPCI at Imam Reza Hospital in Mashhad from 1399 to 1401. The sampling method used in this study was random selection based on patients presenting with ST elevation myocardial infarction (STEMI). All patients who fulfilled the inclusion criteria were part of the study, and data were collected for analysis using SPSS software (version 26). Descriptive statistics were utilized to present the findings, with continuous variables reported as mean ± standard deviation, establishing a significance level of $\alpha=0.05$. The inclusion criteria for this study encompassed individuals over 18 years of age, and there were no exit criteria applied.

The study included all patients with STEMI who underwent PPCI and met the entry criteria from 1399 to 1401. The data of patients were available for a minimum of 24 months. The exit criteria included unwillingness to participate in the study, incomplete patient records, and incomplete follow-up data.

The variables examined in the study included demographic information, LVEF, history of CABG, type of vascular access (radial, ulnar, femoral), balloon angioplasty, number of involved vessels (one, two, or three), type of involved vessels (LAD, LCx, RCA, OM, PDA, SVG), type of stent used (Xience, Firehawk, Biomatrix, etc.), stent length (≥20mm or <20mm), stent diameter (2.25mm, 2.5mm, etc.), and procedural details.

Local anesthesia was used for angiography and stent placement. All patients received antiplatelet therapy and dual antiplatelet therapy post-PCI. Follow-up visits were scheduled at regular intervals after PCI for monitoring and evaluation of any complications. Over a two-year follow-up period, data regarding post-PCI complications, mortality, and cardiogenic shock were systematically collected and analyzed using SPSS software (version 26). This retrospective cohort study included all patients with STEMI who underwent PPCI and met the inclusion criteria between 2020 and 2022, with data compiled for analysis. A significance level of $\alpha=0.05$ was used.

## Result

The study involved a total of 103 patients diagnosed with MI-STEMI who were referred to Imam Reza Hospital for PCI. Among these patients, there were 84 males (81.6%) and 19 females (18.4%). The age distribution included 23 patients (22.3%) aged between 30 to 50 years, 64 patients (62.1%) aged between 51 to 70 years, and 16 patients (15.5%) aged 71 years or older. Additionally, 2 patients (1.9%) had a history of CABG, 33 patients (32%) had a history of addiction, and 9 patients (8.7%) had a family history of heart disease (Table 1).

The findings and characteristics of angioplasty, stent implantation, and balloon dilation performed in the angiographies are collected and presented in the table below (Table 2).

The results and complications of stent implantation and balloon dilation, as assessed clinically and electrocardiographically, along with mortality rates, are presented in Table 3. In total, a mortality rate of 1.9% was observed in the population.

**Table 1.**Demographic information of patients with STE-MI.

| property | | Number | Percent |
|---|---|---|---|
| **Sex** | **Male** | 84 | 81.6 |
| | **Female** | 19 | 18.4 |
| **Age** | **50-30** | 23 | 22.3 |
| | **70-51** | 64 | 62.1 |
| | **71≤** | 16 | 15.5 |
| **BMI** | **24.9-18.6** | 49 | 47.6 |
| | **29.9-25** | 44 | 42.7 |
| | **30≤** | 10 | 9.7 |
| **History** | **No history of illness** | 37 | 35.9 |
| | **Diabetes Mellitus(DM)** | 9 | 8.7 |
| | **Hypertension(HTN)** | 22 | 21.4 |
| | **Dyslipidemia(DLP)** | 3 | 2.9 |
| | **DM+HTN+DLP** | 11 | 10.7 |
| | **HTN+Lung disease** | 4 | 3.9 |
| | **HTN+DLP** | 3 | 2.9 |
| | **DM+HTN** | 11 | 10.7 |
| | **DM+HTN+DLP+Stroke** | 3 | 2.9 |
| **EF** | **40%≤** | 38 | 36.9 |
| | **39-30%** | 42 | 40.8 |
| | **30%≥** | 23 | 22.3 |

**Table 2.**Frequency of angiography findings and stents and coronary access location in patients with STE-MI.

| property | | Number | Percent |
|---|---|---|---|
| **Performing angioplasty with balloon** | | 95 | 92.2 |
| **Access artery** | **Femoral** | 47 | 45.6 |
| | **Radial** | 56 | 54.4 |
| **Number of involved coronary arteries** | **Single Vessel Disease(SVD)** | 38 | 36.9 |
| | **Two Vessel Disease(2VD)** | 37 | 35.9 |
| | **Three Vessel Disease(3VD)** | 28 | 27.2 |
| **Type of involved vein** | **Left Anterior Descending artery(LAD)** | 60 | 58.3 |
| | **Left Circumflex artery(LCX)** | 6 | 5.8 |
| | **Right Coronary Artery(RCA)** | 26 | 25.2 |
| | **Obtuse Marginal artery(OM)** | 7 | 6.8 |
| | **Posterior Descending Artery(PDA)** | 3 | 2.9 |
| | **Saphenous Vein Graft(SVG)** | 1 | 1 |
| **Type of implanted stent** | **Xience** | 31 | 30.1 |
| | **Firehawk** | 13 | 12.6 |
| | **Biomime** | 4 | 3.9 |
| | **CRE8** | 6 | 5.8 |
| | **Angiolitte** | 6 | 5.8 |
| | **Supraflex** | 34 | 33 |
| | **Biomatrixi** | 4 | 3.9 |
| | **Evermime** | 2 | 1.9 |
| | **Onyx** | 3 | 2.9 |
| **Length of stent** | **20mm>** | 40 | 38.8 |
| | **20 mm≤** | 63 | 61.2 |
| **Diameter of stent** | **2.25mm** | 2 | 1.9 |
| | **2.5mm** | 9 | 8.7 |
| | **2.75mm** | 66 | 64.1 |
| | **3.5mm** | 21 | 20.4 |
| | **4mm** | 5 | 4.9 |

**Table 3.**Results and complications of angioplasty in patients with STE-MI.

| Complications/results | | Number | Percent |
|---|---|---|---|
| Rehospitalization | | 6 | 5.8 |
| Revascularization | | 6 | 5.8 |
| Hematoma at the site of angiography | | 7 | 6.8 |
| ST Resolution>50% | | 90 | 87.4 |
| Stent thrombosis | without thrombosis | 100 | 97.1 |
| | Acute thrombosis | 2 | 1.9 |
| | Subacute thrombosis | 1 | 1 |
| In Stent Restenosis | | 3 | 2.9 |
| Multi vessels PCI | | 9 | 8.7 |
| Stroke | | 0 | 0 |
| Coronary perforation | | 0 | 0 |
| No Reflow | | 5 | 4.9 |
| Coronary artery dissection | | 3 | 2.9 |
| Contrast Induced Nephropathy(CIN) | | 6 | 5.8 |
| Cardiogenic shock | | 2 | 1.9 |
| Mortality | | 2 | 1.9 |

The factors influencing mortality after angioplasty were examined using logistic regression analysis, showing that only cardiogenic shock significantly increased the mortality rate by 100-fold (p=0.008). These four variables were able to explain between 11% to 68% of the mortality rate. This model correctly classified 98% of all variables (Table 4).

Due to the non-normal distribution of the data, the Kolmogorov-Smirnov test was used as a non-parametric test for comparing the data.

Based on Table 5, there is no significant clear relationship (p>0.05) between the type of arterial access, stent length, stent diameter, and PCI vessels multi with CIN.

In Table 6, the relationship between a variable called Events Cardiac Adverse Major (MACE), which includes a combination of mortality, stroke, and recurrent heart attack, was evaluated with various variables using the Spearman test.

**Table 4.**Factors affecting mortality after angioplasty in patients with STE-MI.

| variable | Wald | SE | B | Odds ratio (95% CI) | EXP(B) | p-value |
|---|---|---|---|---|---|---|
| Addiction | 0.28 | 1.43 | 0.76 | 2.15(0.13-35.57) | 2.15 | 0.59 |
| History | 0.005 | 0.18 | 0.013 | 1.01(1.45-0.7) | 1.01 | 0.94 |
| Age | 1.6 | 1.28 | 1.63 | 5.12(64-0.41) | 5.12 | 0.2 |
| Cardigenic shock | 7.04 | 1.73 | 4.6 | 100(2997-3.33) | 100 | 0.008 |

**Table 5.**Comparison of various parameters related to stent and CIN in patients with STE-MI.

| Property | | CIN | P-VALUE |
|---|---|---|---|
| Access Artery | Femoral | (6.4%)3 | 0.82 |
| | Radial | (5.4%)3 | |
| Length of stent | 20mm> | (5%)2 | 0.77 |
| | 20 mm≤ | (6.3%)4 | |
| Diameter of stent | 2.25mm | (0)0 | 0.55 |
| | 2.5mm | (11.1%)1 | |
| | 2.75mm | (6.1%)4 | |
| | 3.5mm | (4.8%)1 | |
| | 4mm | (0)0 | |
| Multi vessels PCI | | (0)0 | 1 |
| Hematoma | | (0)0 | 1 |

**Table 6.**Correlation of MACE with various stent variables and angiographic complications.

| Property | The correlation | P-VALUE |
|---|---|---|
| **Access Artery** | -0.062 | 0.53 |
| **Length of stent** | -0.106 | 0.28 |
| **Diameter of stent** | 0.152 | 0.12 |
| **Multi vessels PCI** | -0.09 | 0.33 |
| **Age** | -0.025 | 0.79 |
| **Hematoma** | -0.084 | 0.4 |
| **No Reflow** | 0.25 | 0.01 |
| **Coronary artery dissection** | 0.151 | 0.12 |
| **Contrast Induced Nephropathy(CIN)** | 0.07 | 0.48 |

Only Reflow No showed a significant association with MACE (p=0.01). The relationship between stent diameter and length with angiography complications was compared, and in the entire population with coronary perforation, no relationship was found. Other variables such as Reflow No and coronary dissection did not show any significant relationship with stent diameter and length using the Spearman test (p>0.05). Additionally, the clinical response (Resolution ST >50%) did not have a significant relationship with the type of involved vessel and PCI vessels multi (p>0.05). Other variables examined included the arterial access type and its association with hematoma occurrence, where the type of arterial access had a correlation coefficient of -0.062 and p=0.53, indicating no significant statistical relationship with hematoma occurrence.

## Discussion

In this study, 103 patients with MI-STE undergoing angioplasty were studied, and the results and complications were evaluated. The majority of the population were male with no prior history of disease, aged between 51 and 70, with a BMI of 24.9-18.6 and EF of 39-30%. Angioplasty balloon was performed in 92.2% of patients, with 54.4% through the radial artery. In the angiographies performed, 36.9% involved one coronary artery, 35.9% involved two arteries, and 27.2% involved three coronary arteries, with 58.3% involving LAD, 25.2% RCA, 6.8% OM, 5.8% LCX artery, 2.9% PDA, and 1% SVG showing clear stenosis and being off-cut. In 87.4% of patients, Resolution ST >50% was observed. The most commonly used stents were Supraflex (33%) and Xience (30.1%), with the majority having a stent length ≤20 mm (61.2%). The diameter of the implanted stent in most patients was 2.75 mm.

Complications resulting from MI-STE and coronary angioplasty included hematoma at the angiography site (2.9%), In-Stent restenosis (4.9%), CIN (5.8%), revascularization (5.8%), recurrent ischemia (6.8%), ISR (6.8%), coronary dissection (2.9%), cardiogenic shock (1.9%), equivalent to two individuals, and mortality (1.9%), equivalent to two individuals. The only significant factor contributing to mortality in this study was cardiogenic shock with a 100-fold effect.

In conclusion, this study provides valuable insights into the clinical outcomes of primary angioplasty in patients with ST-segment elevation myocardial infarction (MI-STE) at Imam Reza Hospital. The demographic profile revealed a predominance of middle-aged males with no prior history of cardiovascular disease. The high rate of successful balloon angioplasty and the use of modern stent technologies, such as Supraflex and Xience, contributed to favorable procedural outcomes, including significant ST-segment resolution in the majority of patients.

However, the study also highlights several complications associated with the procedure, including hematoma formation, in-stent restenosis, contrast-induced nephropathy, and recurrent ischemia, albeit at relatively low rates. Notably, cardiogenic shock emerged as a significant predictor of mortality, emphasizing the need for early

recognition and management of this condition to improve patient survival.

Overall, while primary angioplasty demonstrates a promising safety profile and efficacy in managing MI-STE, attention must be given to the associated risks, particularly in patients presenting with cardiogenic shock. Future studies should focus on long-term outcomes and strategies to mitigate complications, thereby enhancing the overall prognosis for this patient population.

## Conclusion

Complications resulting from STEMI and subsequent coronary angioplasty include the following: hematoma at the site of angiography, readmission, revascularization, CIN, no reflow, in-stent restenosis (ISR), coronary artery dissection, and cardiogenic shock. The mortality rate was equivalent to 2 individuals, with cardiogenic shock being the only significant factor influencing mortality in this study, having an effect 100 times greater than other factors.

## Limitations

The main limitation of this study was its observational nature. The lack of randomization prevents the evaluation of the impact of treatments such as IIIa/GPIIb, aspirin thrombosis, IABP, etc., on mortality prevention. Additionally, this study was conducted in a single center within a high-volume tertiary care institution, and the results obtained may not be generalizable to smaller centers with lower volumes. Furthermore, there was no long-term follow-up beyond 2 years in this study, leaving long-term outcomes unknown.

Statistically, despite efforts to control confounding factors, the possibility of residual confounding remains. Moreover, in patients with revascularization, there may be selective biases that were not accounted for in the study population. Ultimately, our results only reflect hospital outcomes and cannot confirm long-term outcomes based on the data.

We were unable to investigate the stages of cardiogenic shock, balloon to Door time for STEMI patients, and revascularization time, which could potentially impact our observed results.

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