To Assess the Outcome of Primary Percutaneous Coronary Intervention in Patients with Acute ST Elevation Myocardial Infarction

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Authors' contributions

This work was carried out in collaboration among all authors. Author FM designed the study, wrote the protocol and wrote the first draft of manuscript. Author IA managed the statistical analyses of study and reviewed the final manuscript. Authors AA and FN managed the literature searches. All authors read and approved the final manuscript.

Article Information

| *Original Research Article* |

ABSTRACT

Objective: Primary percutaneous coronary intervention (PCI) is the contemporary standard for the management of acute ST-Elevation Myocardial Infarction (STEMI). A few life-threatening complications are associated with primary percutaneous coronary interventions (pPCIs). Therefore, the aim of this study was to assess the outcomes of primary percutaneous coronary interventions in patients with acute ST elevation Myocardial infarction.
Study Design: Descriptive Case Series
Place and Duration: Department of Cardiology, National Institute of Cardiovascular Diseases, Karachi, between March 2019 and September 2019
Methodology: Patients were selected using non-probability, consecutive sampling technique who fulfilled inclusion criteria. A total of 547 patients of both genders with aged 40 to 70 years presented with acute ST-Segment elevation myocardial infarction were included in the study. Frequency and percentages were calculated for gender, hypertension, diabetic mellitus, dyslipidemia, family history of ischemic heart disease, smoking, and outcome variables i.e. acute

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stent thrombosis, stroke, atrial fibrillation and mortality. Chi-square test or fisher exact test was applied for association.

Results: The study results showed that out of 547 patients, 389(71.1%) were males and 158(28.9%) were females Their mean age was 61.4±11.3 years, mean weight was 69.2±8.5 kg, mean height was 1.61±1.30 meters and mean BMI was 25.4±3.5 kg/m^2. Outcome of PCI showed, 6 (1.1%) patients had acute stent thrombosis, 5 (0.9%) had stroke, 14 (2.5%) had atrial fibrillation, in-hospital mortality was documented in 8 (1.5%). An insignificant association was observed between outcomes of PCI and comorbidities (hypertension, Diabetes and Dyslipidemia), age group, gender, body mass index, past history of IHD and smoking.

Conclusion: This study concluded that atrial fibrillation was commonly observed outcome of percutaneous coronary intervention followed by in-hospital mortality and acute stent thrombosis among patients with acute ST segment elevation myocardial infarction. Furthermore, atrial fibrillation was significantly associated with comorbidities (such as diabetes and dyslipidemia).

1. INTRODUCTION

Globally, 17.1 million deaths per year are caused by the Coronary heart disease (CHD) [1]. Therefore, CHD is nowadays the leading distinct contributor to overall death and will persist to dominate mortality trends in the future. It has been documented that most of the deaths in low- and middle socio-economic nations below the age of 70 years are caused by CHD [2]. Myocardial infarction (MI) is one of the leading complication of CHD [3]. MI is more vulnerable in The Asian population [4,5]. It has been predicted that greater risk of (50%) MI is more prevalent in South Asians as compared to white people in the UK [6]. Pakistan is an emergent South Asian country having over 187 million people. Most of the Pakistani population (67.5%) resides in rural areas and tolerates the greatest trouble of heart disease [7]. It has been evidently stated that obesity, smoking, diabetes mellitus (DM), hypertension and hyper-cholesterolemia are leading risk factors for the development of CHD [8]. On the other hand, it has been predicted that incidence of risk factors of MI are higher in Pakistan where above 30% of populace with above 45 years of age [9].

ST elevation myocardial infarction (STEMI) is the most remarkable manifestation of coronary artery disease (CAD) with greater probability of morbidity and mortality [10]. Reperfusion therapy (either pharmacologic or catheter based) is suitable for the patient with constant ST-segment elevation in order to bring back blood flow in blocked coronary artery. Primary PCI is defined as an intervention of the occluded, infracted coronary artery in 12 hours of commencement of symptoms, with no preceding fibrinolytic treatment [11]. Primary PCI is an effectual and favorable approach of revascularization in emergency in patients with acute STEMI. In recent times, it is evidently recommended that excellent outcomes are achieved by revascularization with primary PCI than thrombolysis approach [12]. It is predicted that PCI provides early and more constant reperfusion with a fewer complication than thrombolysis. Additionally, frequency of re-infarction, mortality and stroke are significantly decreased by PCI [13].

Irrespective of all these information, so far primary PCI has not been selected as a first line of treatment in many developing nations like Pakistan particularly in their state-owned hospitals. It is generally for the reason of high procedural expenses, inadequate government resources and insufficient financial support. For that reason, there is not enough data available in Pakistan on primary PCI. Primary PCI is considered as contemporary standard treatment for patients with acute STEMI, if skilled and qualified interventional heart specialists with well-resourced catheterization laboratory along with surgical endorsement are accessible and if the process can be carried out more rapidly in 90 minutes of patient's first remedial contact [14].

Acute ST-segment elevation myocardial infarction is considered as the most striking presentation of coronary artery disease (CAD) with high frequency of morbidity and mortality [10]. Timely primary percutaneous coronary intervention has turn into the most favorable approach for the management of STEMI [11] and provides quick and constant reperfusion with

occurrence of less complication than thrombolysis [15].

As far as the complications associated with primary PCI are concerned, acute stent thrombosis is a infrequent life-threatening complication, with an predicted prevalence of 0.5–2% in elective procedures [16]. The frequency of stent thrombosis is greater in treatment of primary PCI (pPCI) with STEMI patients [17]. Numerous earlier researches have demonstrated that undesirable cardiovascular outcomes and elevated mortality rates are caused by the acute stent thrombosis in patients who have undergone a pPCI [18,19]. On the other hand, Atrial fibrillation is a commonly observed arrhythmia in the situation of acute ST-elevation myocardial infarction and acute coronary syndromes. [20]

2. MATERIALS AND METHODS

Study Design: Descriptive Case Series study.

Study Setting: Department of Cardiology, National Institute of Cardiovascular Diseases, Karachi.

Study Duration: Six months between March 2019 and September 2019.

2.1 Sample Selection

A total of 547 patients of both genders with aged 40 to 70 years presented with acute ST-Segment elevation myocardial Infarction and presented to hospital > 3 hour from beginning of symptoms and underwent primary PCI were included in the study whereas patients with Acute MI who already had treated reperfusion therapy at any other Hospital, presented with Non ST elevation Myocardial Infarction (NSTEMI), renal dysfunction, creatinine values above 2.5 g/dl, past history of cardiac surgery and PCI, heart failure and who did not give permission were excluded from the study.

2.2 Data Collection Procedure

After approval of study from the College of Physicians and Surgeons of Pakistan and ethical permission certificate from supervisor, a written informed permission was taken from all the patients with chest pain and ECG diagnosis of ST Segment elevation Myocardial Infarction. A comprehensive history with particular emphasis on chest pain, duration of pain, comorbidity like diabetes mellitus, hypertension, smoking, family history of IHD and dyslipidemia were recorded. BMI is calculated by the measurement of weight and height. Reperfusion therapy was executed by the specialist having experience of more than 05 years through transfemoral or transradial method. Outcome variables i.e. acute stent thrombosis, stroke, atrial fibrillation and mortality if any happened was documented in duration of hospital stay. Atrial fibrillation and mortality were measured at the end of 4th day post procedure. All the collected details were noted using pre-designed structural questionnaire provided in annexure A.

2.3 Data Analysis

Data was entered and analyzed using SPSS version-21 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp). Mean±SD was calculated for age (years), weight (kg), height (cm) and BMI. Frequency and percentages were calculated for gender, hypertension, dyslipidemia, diabetic mellitus, family history of IHD, smoking, and outcome variables i.e. acute stent thrombosis, atrial fibrillation, stroke and mortality. Chi-square test or fisher exact test was applied for association between outcome variables and comorbidities and effect modifiers. P-value of ≤ 0.05 was considered as criteria of statistical significance.

3. RESULTS

A total of 547 patients were included to determine the outcome of primary percutaneous coronary intervention in patients with acute ST segment elevation myocardial infarction wherein 389(71.1%) were males and 158(28.9%) were females Their mean age was 61.4±11.3 years, mean weight was 69.2±8.5 kg, mean height was 1.61±1.30 meters and mean BMI was 25.4±3.5 kg/m^2, as shown in Table 1.

Outcome of PCI showed that 6 (1.1%) patients had acute stent thrombosis, 5 (0.9%) had stroke, 14 (2.5%) had atrial fibrillation, in-hospital mortality was documented in 8 (1.5%) while no complications was observed for 514 (94.0%) patients, as shown in Table 2.

Table 1. Mean Demographic characteristics of patients. (n=547)

Variable		Mean±SD / n(%)
Gender	Male	389(71.1%)
	Female	58(28.9%)
Age (years)		61.4±11.3
Weight (kg)		69.2±8.5
Height (meters)		1.61±1.30
Body mass index (kg/m^2)		25.4±3.5

Table 2. Frequency for outcomes of primary percutaneous coronary intervention

Outcomes	Frequency	Percentage (%)
Acute Stent Thrombosis	6	1.1
Stroke	5	0.9
Atrial Fibrillation	14	2.5
Mortality	8	1.5
No Complications	514	94.0

Table 3. Frequency of comorbidities and risk factors

Comorbidities and Risk Factors	Yes (%)	No (%)
Hypertension	232 (42.4%)	315 (57.6%)
Diabetes	134 (24.5%)	413(75.5%)
Dyslipidemia	256 (46.8%)	291(53.2%)
Smoking status	199 (36.4%)	348 (63.6%)
History of Ischemic heart disease	153 (28.0%)	394(72.0%)

Table 4. Association of comorbidities with outcome of Primary Percutaneous Intervention

Variables		Acute Stent Thrombosis		p	Stroke		p	Atrial Fibrillation		p	Mortality		p
		Yes	No		Yes	No		Yes	No		Yes	No	
HTN	Yes	2 (0.4%)	230 (42.0%)	0.494	2 (0.4%)	230 (42.0%)	0.641	7 (1.3%)	225 (41.1%)	0.375	3 (0.5%)	229 (41.9%)	0.538
	No	4 (0.7%)	311 (56.9%)		3 (0.5%)	312 (57.0%)		7 (1.3%)	308 (56.3%)		5 (0.9%)	310 (56.7%)	
Diabetes	Yes	2 (0.4%)	132 (24.1%)	0.455	1 (0.2%)	133 (24.3%)	0.643	6 (1.1%)	128 (23.4%)	0.00	4 (0.7%)	130 (23.8%)	0.105
	No	4 (0.7%)	409 (74.8%)		4 (0.7%)	409 (74.8%)		8 (1.5%)	405 (74.0%)		4 (0.7%)	409 (74.8%)	
Dyslipidemia	Yes	3 (0.5%)	253 (46.3%)	0.595	2 (0.4%)	254 (46.4%)	0.560	9 (1.6%)	247 (45.2%)	0.00	5 (0.9%)	251 (45.9%)	0.294
	No	3 (0.5%)	288 (52.7%)		3 (0.5%)	288 (52.7%)		5 (0.9%)	286 (52.3%)		3 (0.5%)	288 (52.7%)	

HTN= Hypertension, p= P-value

Table 5. Association of risk factors with outcome of primary percutaneous intervention

Variables		Acute Stent Thrombosis		p	Stroke		p	Atrial Fibrillation		p	Mortality		p
		Yes	No		Yes	No		Yes	No		Yes	No	
Age Group	40-60	4 (0.7%)	292 (53.4%)	0.423	4 (0.7%)	292 (53.4%)	0.242	9 (1.6%)	287 (52.5%)	0.311	5 (0.9%)	291 (53.2%)	0.456
	>60	2 (0.4%)	249 (45.5%)		1 (0.2%)	250 (45.7%)		5 (0.9%)	246 (45.0%)		3 (0.5%)	248 (45.3%)	
Gender	M	4 (0.7%)	385 (70.4%)	0.556	3 (0.5%)	386 (70.6%)	0.449	8 (1.5%)	381 (69.7%)	0.189	4 (0.7%)	385 (70.4%)	0.173
	F	2 (0.4%)	156 (28.5%)		2 (0.4%)	156 (28.5%)		6 (1.1%)	152 (27.8%)		4 (0.7%)	154 (28.2%)	
BMI	18-24	3 (0.5%)	325 (59.4%)	0.456	4 (0.7%)	1 (0.2%)	0.335	10 (1.8%)	318 (58.1%)	0.375	5 (0.9%)	323 (59.0%)	0.594

BMI= Body Mass Index, p= P-value

Comorbidities of patients revealed that Hypertension was noted in 232 (42.4%) patients while 315 (57.6%) were non-hypertensive. Diabetes mellitus was documented in 134 (24.5%) patients while 413(75.5%) were non-diabetes. Dyslipidemia was observed in 256 (46.8%) patients. Positive family history of IHD was documented in 153(28.0%) patients. Out Of 547 patients, 199 (36.4%) patients were smoker while 348 (63.6%) were non-smoker as shown in Table 3.

The frequencies of diabetes mellitus 2(0.4%), hypertension 2(0.4%), hyperlipidemia 3(0.5%), were lower in the acute stent thrombosis presenting insignificant association between Diabetes, hypertension, Dyslipidemia and acute stent thrombosis (p=0.455, p=0.494 and p=0.595), respectively. Furthermore, frequencies of diabetes mellitus 1(0.2%), hypertension 2(0.4%), hyperlipidemia 2(0.4%), were also observed lower in stroke showing insignificant association between Diabetes, hypertension, Dyslipidemia and stroke (p=0.643, p=0.641 and p=0.560), respectively. As far as Atrial Fibrillation is concerned, frequencies of diabetes mellitus 6(1.1%), hypertension 7(1.3%), hyperlipidemia 9(1.6%), were found lower in Atrial Fibrillation showing significant association between Diabetes and Atrial Fibrillation (p<0.001) and between Dyslipidemia and Atrial Fibrillation (p<0.001). whereas insignificant association found between hypertension and Atrial Fibrillation (p=0.375). Moreover, frequencies of diabetes mellitus 4(0.7%), hypertension 3(0.5%), hyperlipidemia 3(0.5%), were found lower in mortality showing insignificant association between Diabetes, hypertension, Dyslipidemia and mortality (p=0.105, p=0.538 and p=0.294) respectively, as shown in Table 4.

Association of risk factors with outcomes of Primary Percutaneous Intervention showed, 4(0.7%) cases with age 40-60 years and 2(0.4%) cases with age > 60 years reported acute stent thrombosis with an insignificant association (p=0.423). 4(0.7%) cases with age 40-60 years and 1(0.2%) cases with age > 60 years reported stroke with an insignificant association (p=0.423). 9(1.6%) cases with age 40-60 years and 5(0.9%) cases with age > 60 years reported Atrial fibrillation with an insignificant association (p=0.311). Furthermore, there was an insignificant association found between age groups and mortality (p=0.456). As far as gender is concerned, 4 (0.7%) cases in male and 2(0.4%) cases in females reported acute stent thrombosis with an insignificant association between gender and acute stent thrombosis (p=0.556). Moreover, 3 (0.5%) cases in male and 2(0.4%) cases in females reported stroke with an insignificant association between both genders (p=0.449). 8 (1.5%) cases in male and 6(1.1%) cases in females reported Atrial fibrillation with an insignificant association between both the genders (p=0.189). Furthermore, there was an insignificant association found between genders and mortality (p=0.173). Additionally, Moreover, an insignificant association observed between Body mass Index (18-24 kg/m^2) and acute stent thrombosis (p=0.456), stroke (p=0.335), Atrial fibrillation (p=0.375) and mortality (p=0.594), as shown in Table 5.

4. DISCUSSION

Many randomized clinical trials established that primary PCI is more effectual and harmless treatment than fibrinolysis in patients with STEMI [11,21]. According to both AHA and ESC guiding rules, Primary PCI is the first line of treatment in 90 minutes of hospital entrance in patients with STEMI [11,22]. Therefore, this study demonstrated the significance and outcome of primary PCI are now a routine procedure in our settings.

The mortality of STEMI are affected by age, approach of treatment, delayed time to treatment, Killip class, past history of ischemic heart disease, diabetes mellitus, renal impairment, number of occluded vessels and ejection fraction. In one research, in-hospital mortality reported 4.2% [23] after primary PCI that was in accordance with other research wherein in-hospital mortality incidence was reported 4.4%.[24] Our study was consistent with the above reported studies and revealed that out of 547 patients, in-hospital mortality rate was reported 8(1.5%) that was because of life-threatening arrhythmias and sudden cardiac death. The most important reasons for low incidence of in-hospital mortality following primary PCI in our study are timely STEMI diagnosis, prompt application of anti-platelets and anticoagulants, well-resourced catheterization laboratory with skilled interventional cardiologists.

One cross sectional study evaluated the probability and outcomes of primary percutaneous coronary intervention (PCI) as an approach of treatment in acute ST-segment elevation myocardial infarction (STEMI). They

found Out of 50, 30(60%) of the patients were smokers currently, 22 (44%) were diabetic, 25(50%) were hypertensive, and only 1(2%) had cardiogenic shock. The mean time from start of symptom to hospital admission was 5 hours with all-cause mortality was 1%. They had shown effectiveness, probability and safety in carrying out of primary percutaneous coronary intervention with admirable outcomes. [25] As far as the present study is concerned, it was reported that out of 547, 199 (36.4%) were smokers, 134 (24.5%) were diabetic and 232 (42.4%) were hypertensive with the beginning of symptom to hospital admittance was above 3 hours with the all cause mortality rate 8(1.5%). Our study also proved the efficiency, feasibility with fewer complications associated with primary percutaneous coronary intervention.

Similarly, in a study conducted by Ali M, et al, evaluated the association between the involved coronary artery and Hospital mortality rates in patients with primary PCI) following STEMI. They reported the mean age in their study was 67.1±13.4 years wherein 211 (68%) were male. Hospital mortality rate was recorded in 31 patients (10%). [26] The present study was in accordance to some extent with above cited research and found mean age as 61.4±11.3 years, of whom 389(71.1%) were males. Hospital mortality rate was predicted in 8(1.5%) patients.

Concerning Risk factors associated with CHD, one research conducted in Pakistan revealed that risk factors like diabetes, hypertension, and obesity increase the probability of CHD. Their statistics reported that the male MI patients belonged to both urban and rural areas of Punjab in Pakistan were comparatively young (41 - 60 years). [27] that was in accordance with further research indicating that middle-aged males have 2 to 5 folds higher susceptible to MI as compared to females [28]. The present study showed consistency with the above reported studies and indicated that most of the patients having MI were comparatively middle aged (40-60 years) and males were more susceptible to MI than females owing to risk factors associated with CHD such as smoking, hypertension, Diabetes were most frequently observed in males.

Likewise, another research revealed the Dyslipidemia was an additional risk factor and observed in 18.6% cases [29] which was considerably lower than that reported in western countries.[30;31] On the other hand, Indian researches [32,23] have consistently reported a lower prevalence of dyslipidemia. The present study was not supported the above reported studies and proved the higher prevalence of Dyslipidemia 256 (46.8%).

Stent thrombosis is the most life threatening complication of PCI because of greater probability of mortality and morbidity. The frequency of early stent thrombosis is 1.5% as reported in studies and it was also proved that its incidence was higher in patients with STEMI than elective procedures because stent placement in acute STEMI is a risk factor for stent thrombosis [33]. In our study, there were only 6(1.1%) patients of in-hospital stent thrombosis. This was probably because of effectual use of antiplatelets and anticoagulants.

Atrial fibrillation (AF) is the most frequent arrhythmia encountered in clinical settings with effects on longstanding consequences. AF is commonly related with cardiac disorders and comorbidities such as diabetes, hypertension, heart failure, chronic obstructive pulmonary disease and stroke. [34] The present study endorsed the above reported research and revealed that atrial fibrillation was significantly associated with comorbidities such as diabetes and dyslipidemia reflecting the increased probability of atrial fibrillation.

One analysis reported the significantly higher hospital mortality rate due to high percentage of patients with cardiogenic shock [29] as compared to mortality rate 5–9% that was revealed from large registries from western countries [35,36] and from studies of India.[37,23] The present study reported low frequency of in hospital mortality 8(1.1%) because of primary percutaneous intervention timely performed by skilled surgeons.

5. CONCLUSION

This study concluded that atrial fibrillation was commonly observed outcome of percutaneous coronary intervention followed by in-hospital mortality and acute stent thrombosis among patients with acute ST segment elevation myocardial infarction. Furthermore, atrial fibrillation was significantly associated with comorbidities (such as diabetes and dyslipidemia). Additionally, risk factors (such as body mass Index, gender, age) were insignificantly associated with outcomes.

Furthermore, additional studies are needed to support our findings probably with a larger

sample size and with more parameters in multiple study centers in Pakistan.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

All authors declare that 'written informed consent was obtained from the patients.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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ANNEXURE- A

PROFORMA

Title: To Assess the Outcome of Primary Percutaneous Coronary Intervention in Patients with Acute ST Elevation Myocardial Infarction

Name: _____

Age of patient (In years): _____   Weight: (In Kg): _____

Height (In Meters): _____   Body Mass Index (Kg/m^2): _____

GENDER
Male   ☐
Female   ☐
SMOKER
Yes   ☐
No   ☐
COMORBIDITIES

HTN   Yes ☐   No ☐

DM   Yes ☐   No ☐

Dyslipidemia   Yes ☐   No ☐
OBESITY
Yes   ☐
No   ☐

FAMILY HISTORY OF HEART DISEASE
Yes   ☐
No   ☐
OUTCOMES OF PCI

Acute Stent Thrombosis   Yes ☐   No ☐

Stroke   Yes ☐   No ☐

Atrial Fibrillation   Yes ☐   No ☐

Mortality   Yes ☐   No ☐

- **OPERATIONAL DEFINITION:**

Acute St-Segment Elevation Myocardial Infarction (STEMI): Patients with chest pain > 20 minutes consistent with acute MI with new ST elevation at the J point in at least 2 contiguous leads of $\geq$ 2 mm (0.2 mV) in men or $\geq$ 1.5 mm (0.15 mV) in women in leads V2– 13 and/or of $\geq$ 1 mm (0.1 mV) in other contiguous chest leads or the limb leads.

Acute Stent Thrombosis: Defined as sudden onset of typical chest pain indicating acute ischaemia in the distribution of the target vessel, occurring during the 24 hours after the primary PCI, assessed clinically and by angiography showed complete occlusion within the stent segmented artery with evidence of thrombus.

Stroke: It is defined as neurological deficit (focal or global) of cerebrovascular caused that persists beyond 24 hours, confirmed on CT scan brain showing an area of hypodensity (ischemic) or hyperdensity (hemorrhagic) within brain parenchyma was deemed as positive.

Atrial Fibrillation: A patient was considered to have AF if the arrhythmia appeared for at least 60 seconds, at any time during the first 4-days of hospitalization post AMI. It was diagnosed as absence of P waves and presence of QRS complexes in an irregular rhythm with or without the presence of coarse or fine fibrillatory waves.

Mortality: Patient who expired during hospital stay within 04 days.

- **RISK FACTORS OR CONFOUNDING EFFECT MODIFIERS/ EXPLANATORY VARIABLES:**

Hypertension: Patient had systolic blood pressure of $\geq$ 130 mmHg and diastolic blood pressure of $\geq$ 90 mmHg at two occasion 4 hours apart or on antihypertensive medication for at least 6 months.

Diabetes Mellitus: Fasting plasma glucose $\geq$ 6.5 mmol/l (126 mg/dl), or 2 hours post prandial plasma glucose $\geq$ 10 mmol/l (180 mg/dl) or on antidiabetic drugs for more than 6 months.

Smoker: If an individual smoke $\geq$ 10 pack- year either currently smoking for > 1 years or quit smoking since < 6 months.

Dyslipidemia: Presence of any one of the following was labeled as positive.

- High serum LDL-C levels > 100 mg/dl
- Hypertriglyceridemia= serum triglyceride level > 150 mg/dl
- Hypercholesterolemia = cholesterol level > 200mg/di

Family history: Defined as family history of ischemic heart disease in first degree relatives, male less than 55 years of age or female less than 65 years of age.

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