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Comparative study of clinical outcomes of primary percutaneous interventions in acute myocardial infarction in diabetic versus non-diabetic patients in relation to age and gender of patients in Chennai, India

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Abstract

Cardiovascular complications are more common among diabetic patients and are usually associated with a significantly greater risk of morbidity and mortality than in non-diabetic subjects. Identification of the underlying causes is the foremost importance in the diagnosis and treatment of the cardiovascular diseases.

The present study was designed and undertaken with the aim to assess the age, gender, family history, smoking status, body mass index and co-morbidities related differences in acute coronary syndrome (ACS) among the diabetic and non-diabetic patients who presented in a hospital setup in Chennai, Tamil Nadu, India. The various inclusion and exclusion factors affecting the disease were scrupulously followed during the entire course of study. Results of the present study revealed that most of the non-diabetic patients (n=16, 32%) and diabetic patients (n=24, 43.64%) were clustered in the 51-60 years age group. The mean age distribution was 54.36 years in the non-diabetic patients and 57.05 years in the diabetic patients. Males constituted 90% (n=45) of the non-diabetic study group and 87.27% (n=48) of the diabetic study group. The mean BMI was significantly less in the non-diabetic group compared to the diabetic group by a mean difference of 2.21 (8% less). The incidence of obesity was 3 times more in the diabetics compared to the non-diabetics. Most of the non-diabetic patients had hypertension as the main comorbidity (n=15, 30%) followed by hypercholesterolemia (n=3, 5.45%). Most diabetic patients had hypertension as the main comorbidity (n=24, 43.64%) followed by hypercholesterolemia (n=8, 16%). Non-smokers consisted of 98% (n=49) of the non-diabetic study group and 98.18% (n=54) of the diabetic study group. Patients with positive family history of CVD constituted 4% (n=2) of the non-diabetic study group and 7.27% (n=4) of the diabetic study group.

The findings of the present study concluded with a positive correlation of requirement of primary percutaneous interventions among the patients presented with myocardial infarction and age, gender, smoking status, comorbidities and obesity. This is a single-centre study with a small sample size, and this is a major study limitation. Moreover, we evaluated patients at a tertiary care hospital, and more than 90% patients underwent some coronary intervention, and the findings may not reflect the general situation in India. Further study with broader perspective and wider inclusive factors is warranted involving the patients at primary and secondary diagnostic as well as therapeutic centres.

Keywords: NIL.

INTRODUCTION

In general, there are many sex-related differences with regard to coronary heart disease (CHD). First, compared to men, older and smaller women are more prone to hypertension, diabetes mellitus, hypercholesterolemia, peripheral vascular disease, and unstable angina and have more severe angina (Canadian Cardiovascular Society Class III–IV). Furthermore, although left ventricular systolic dysfunction is less frequent in women, they more often have congestive heart failure [1].Women with CHD also receive less intensive treatment than men as their more increased home environment obligations make them neglect health-care needs[2] Hence, despite a lower incidence of myocardial infarction and its later presentation in women than in men, the former are associated with higher mortality and morbidity rates[3]. Although men experience coronary events four times more than women, women are more likely to die after the first episode of an acute myocardial infarction (AMI) [2]. Women are generally characterized by higher short-term mortality than men partly due to their higher age, higher comorbidity, and less aggressive treatment. Moreover, gender differences with regard to post-AMI mortality risk are even more apparent in young women compared with similarly aged men [4].

Cardiovascular complications are more common among diabetic patients and are usually associated with a significantly greater risk of morbidity and mortality than in non-diabetic subjects [5]. Presence of diabetes worsens prognosis in acute coronary syndrome (ACS). The relative risk of myocardial infarction (MI) is 50% greater in diabetic men and by 150% greater in diabetic women compared to age-matched non-diabetic subjects [6]. Sudden cardiac death is 50% more frequent in diabetic men and 300% more frequent in diabetic women compared to age-matched non-diabetic controls[7].

The higher mortality in AMI patients with versus without diabetes may, in part, be due to more extensive coronary atherosclerosis and concomitant comorbid conditions, reduced cardiac reserve, and excessive delay from symptom onset to presentation [8, 9, 10]. Treatment of diabetes with sulfonylurea oral hypoglycemic drugs may further diminish the ability of the myocardium to tolerate ischemia [11]. Diabetes has also been associated with abnormal coronary endothelial function, diminished coronary flow reserve, and impaired ischemic preconditioning all of which may result in abnormal myocardial perfusion [12,13.14].

Diabetes also influences outcomes following ACS, and therefore, secondary prevention in diabetic individuals is equally critical. Consequently, the diabetic patient needs special management and monitoring, with a view to the prevention, control, and treatment of the various manifestations of coronary artery disease [15].

India has the dubious distinction of being known as the "diabetic capital" of the world and is home to estimated 75 million diabetics with a prevalence of 8.7% among the adult population [16]. Furthermore, DM and CAD tend to develop at an earlier age in Indians and associated complications are more frequent as compared to Caucasians [17, 18, 19, 20]. In contemporary literature, there are only a few studies from India relating to acute coronary syndromes (ACS) in diabetic adult population [21, 22, 23].

Hence the present study was designed and conducted to assess the age, gender, family history, smoking status, body mass index and co-morbidities related differences in acute coronary syndrome (ACS) among the diabetic and non-diabetic patients who presented in a hospital setup in Chennai, Tamil Nadu, India.

Materials and Methods

This prospective observational study was conducted from April 2016 to May 2017 and included 105 consecutive patients who presented to the Emergency Room of the hospital within 12 hours of onset of symptoms, with features of Acute ST Elevation Myocardial Infarction and who underwent primary PCI.

Inclusion Criteria:

All patients undergoing Primary PCI with DES for acute myocardial infarction with the following features:

1) Presenting with the onset of symptoms within 12 hours.
2) ECG showing ≥ 1-mm ST-segment elevation in at least 2 anatomically contiguous limb leads, ≥ 1-mm ST-segment elevation in a precordial lead V4 through V6,

   ≥ 2-mm ST-segment elevation in V1 through V3 or a new left bundle branch block.

Exclusion Criteria:

1) PCI with BMS

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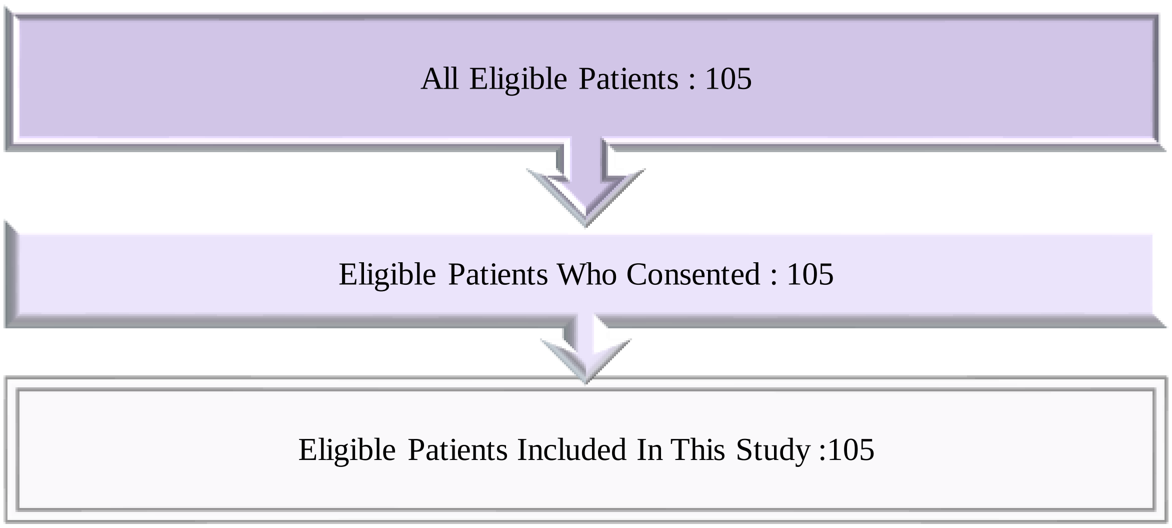
2) Prior PCI / CABG
3) Patients with CKD stage III or more

Sampling Method:

Judgement sampling method was adopted.

Observations

The overall design of the study is depicted in the flowchart given in (Figure 1).



Among the 105 patients, 55 were diabetics and the remaining 50 were non-diabetics. The parameters studied were age, gender, BMI, comorbidities, smoking status and family history of CVD.

Data Analysis:

Descriptive statistics were done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test. Categorical variables were analysed with the Fisher's Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 16 and Microsoft Excel 2007.

Results

From April 2016 to May 2017, 105 consecutive patients who were eligible for this study underwent primary PCI. Among the 105 patients, 50 were non-diabetics and the remaining 55 were diabetics.

Age wise distribution of the patients in Non-Diabetic and Diabetic groups are presented in Table 1 and Figure 1.

Table 1. Age wise distribution of the patients in Non -Diabetic and Diabetic groups

Age Distribution (Groups)	Non-Diabetic	Diabetic	Non-Diabetic (%)	Diabetic (%)
≤ 30 years	1	0	2.00	0.00
31-40 years	8	2	16.00	3.64
41-50 years	11	11	22.00	20.00
51-60 years	16	24	32.00	43.64
61-70 years	9	15	18.00	27.27
> 70 years	5	3	10.00	5.45
Total	50	55	100.00	100.00

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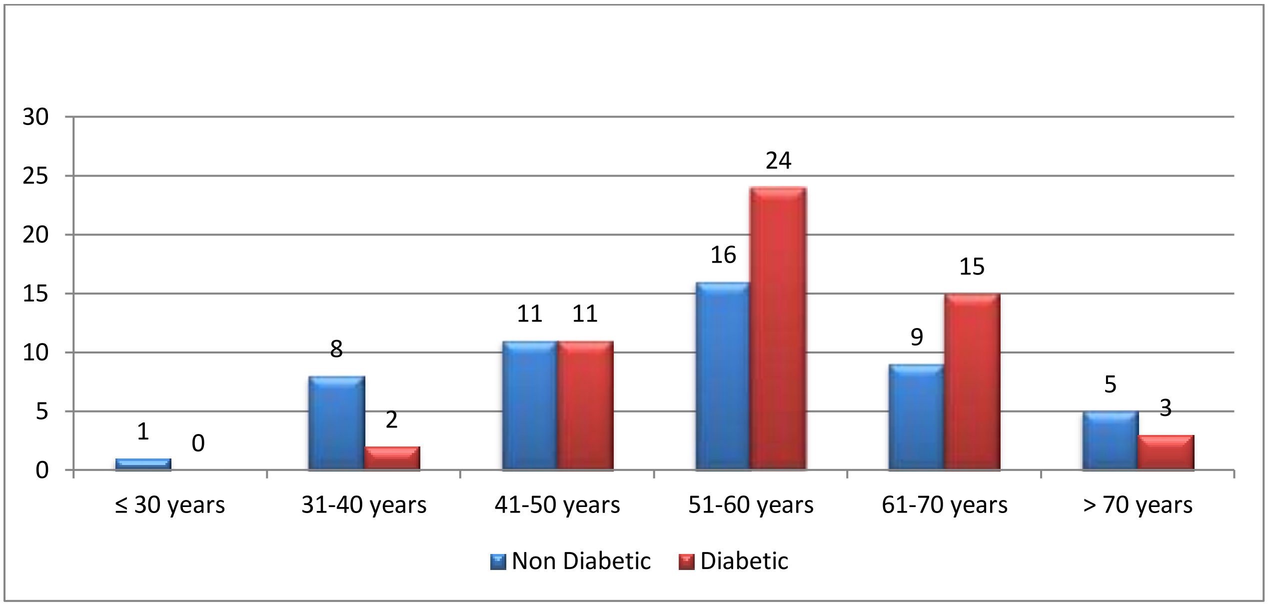
Age Distribution	Non-Diabetic	Diabetic
Mean	54.36	57.05
SD	13.03	8.44
p-value **Unpaired t Test**		0.2074

Figure: 1. Age wise distribution of the patients in Non-Diabetic and Diabetic groups



Most of the non-diabetic patients (n=16, 32%) and diabetic patients (n=24, 43.64%) were clustered in the 51-60 years age group. The mean age distribution was 54.36 years in the non-diabetic patients and 57.05 years in the diabetic patients. There was no statistically significant difference in relation to age distribution between the study groups with a p-value of >0.05 as per the unpaired t test.

The gender status of the patients in Non-Diabetic and Diabetic groups is represented in Table 2 and Figure 2.

Table 2. Gender wise distribution of the patients in Non-Diabetic and Diabetic groups

Gender Status	Non-Diabetic	Diabetic	Non-Diabetic (%)	Diabetic (%)
Male	45	48	90.00	87.27
Female	5	7	10.00	12.73
Total	50	55	100.00	100.00
p-value **Fisher's Exact Test**			0.9843	

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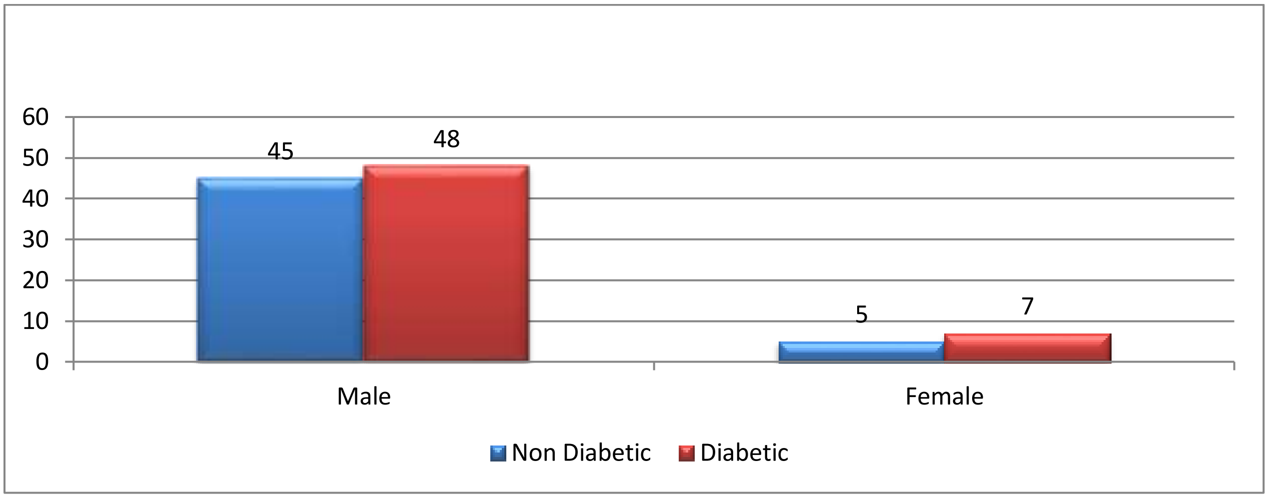
Figure: 2. Gender Status



Males constituted 90% (n=45) of the non-diabetic study group and 87.27% (n=48) of the diabetic study group. There was no statistically significant difference in relation to gender status between the study groups with a p-value of >0.05 as per the Fisher's Exact Test.

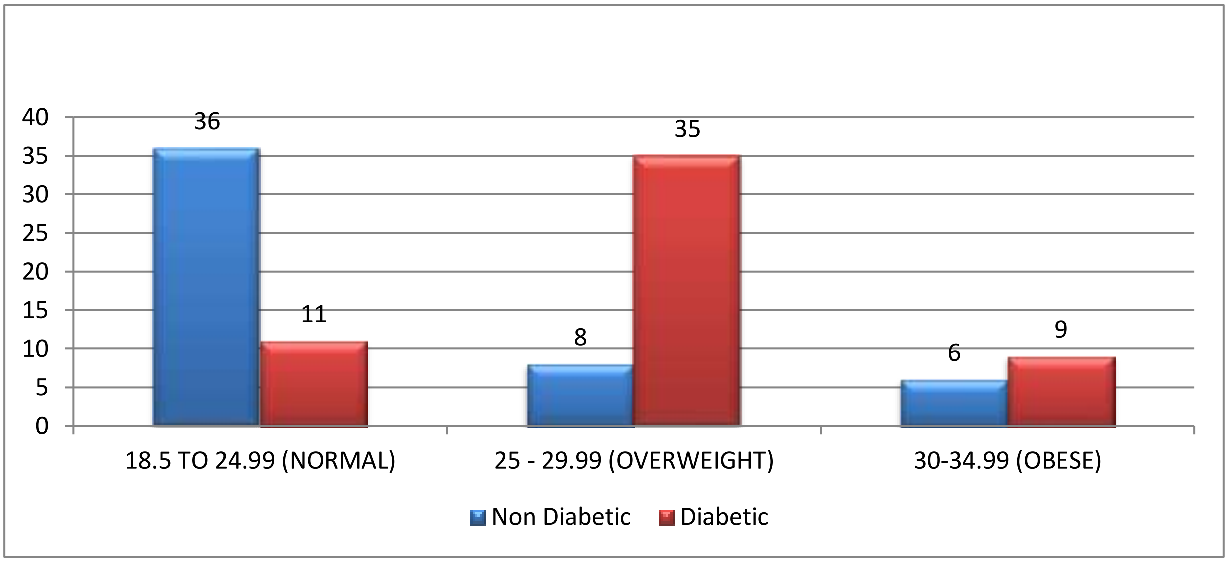
Data on Body Mass Index (BMI) of the patients in Non-Diabetic and Diabetic groups is represented in Table 2 and Figure 2.

Table 3. Body Mass Index (BMI) distribution of the patients in Non-Diabetic and Diabetic groups

BMI Distribution (Groups)	Non-Diabetic	Diabetic	Non-Diabetic (%)	Diabetic (%)
18.5 TO 24.99 (NORMAL)	36	11	72.00	20.00
25 - 29.99 (OVERWEIGHT)	8	35	16.00	63.64
30-34.99 (Obese)	6	9	12.00	16.36
Total	50	55	100.00	100.00

BMI Distribution	Non-Diabetic	Diabetic
Mean	24.38	26.59
SD	2.61	2.00
p-value **Unpaired t Test**		<0.0001

Figure: 3. Body Mass Index (BMI)



The mean BMI was significantly less in the non-diabetic group compared to the diabetic group by a mean difference of 2.21 (8% less). The incidence of obesity was 3 times more in the diabetics compared to the non-diabetics. This difference is significant with a p-value of <0.0001as per the unpaired t-test.

There was a statistically significant difference in relation to BMI distribution between the non-diabetic group (mean=24.38, SD=2.61) and the diabetic group (mean=26.59, SD=2.00) with a p -value of <0.05 as per the unpaired t test.

Table 4. Comorbidities among the patients in Non-Diabetic and Diabetic groups

Comorbidities	Non-Diabetic (n=50)	Diabetic (n=55)	Non-Diabetic (%)	Diabetic (%)	p-value Fisher's Exact Test
Hypertension	15	24	30.00	43.64	0.1628
Hypercholesterolemia	8	3	16.00	5.45	0.1115
COPD / BA	4	1	8.00	1.82	0.1891
GID	1	0	2.00	0.00	0.4762
Hypothyroidism	1	2	2.00	3.64	>0.9999
H/O CVA	0	0	0.00	0.00	NA
CKA	0	0	0.00	0.00	NA

Most of the non-diabetic patients had hypertension as the main comorbidity (n=15, 30%) followed by hypercholesterolemia (n=3, 5.45%). Most diabetic patients had hypertension as the main comorbidity (n=24, 43.64%) followed by hypercholesterolemia (n=8, 16%).

There was no statistically significant difference in relation to comorbidity status between the study groups with a p-value of >0.05 as per the Fisher's Exact Test.

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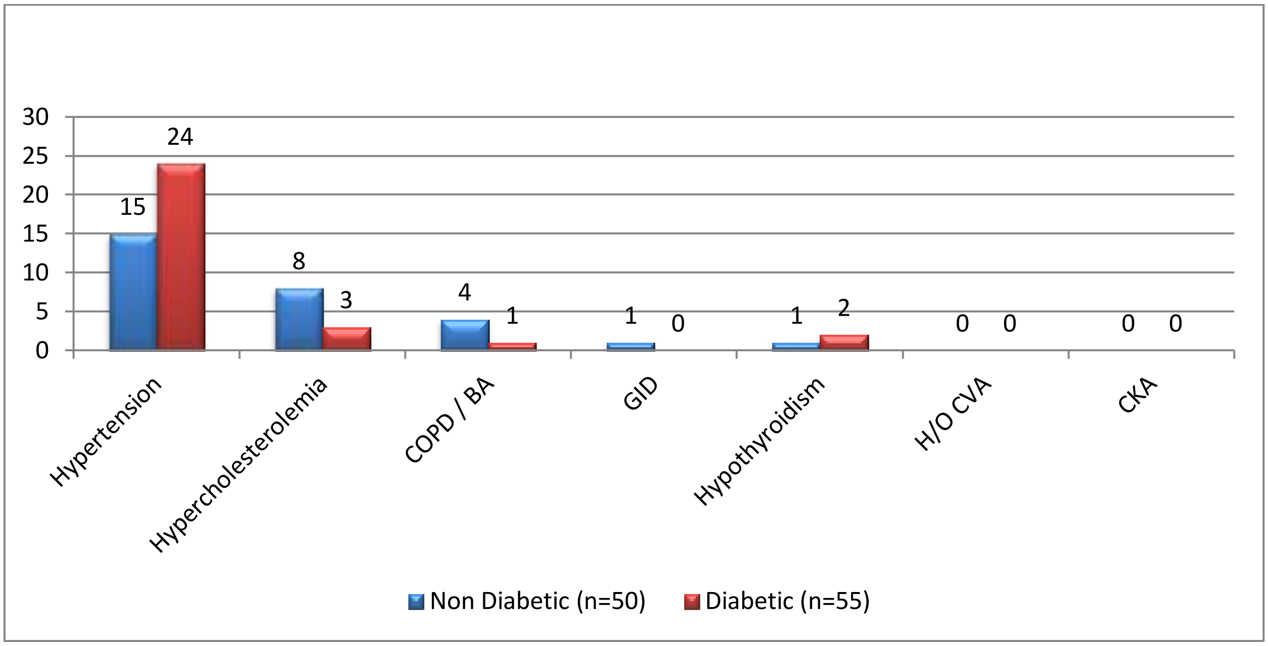
Figure: 4. Comorbidities among the patients in Non-Diabetic and Diabetic groups



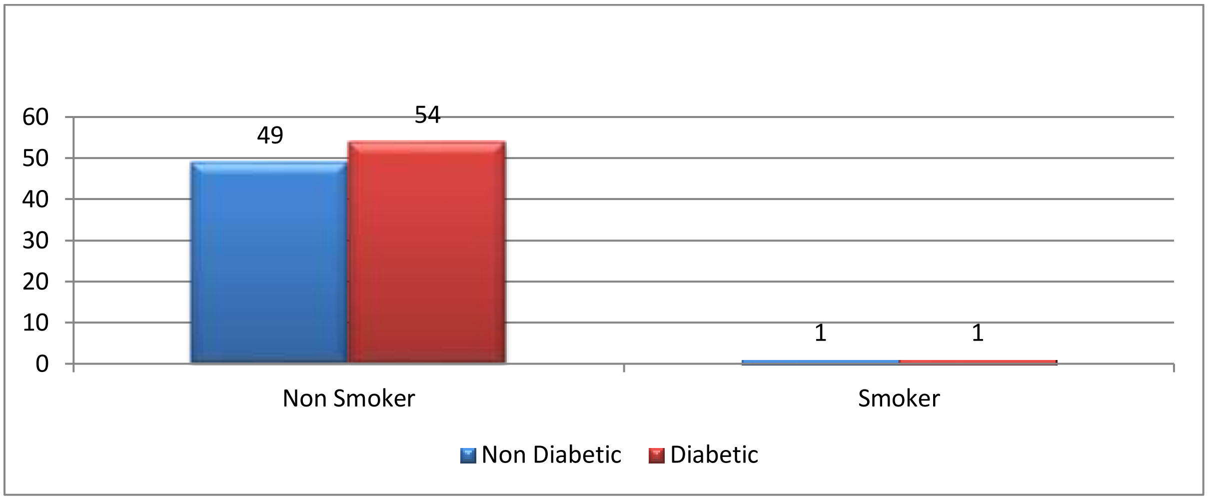
Data on Smoking Status among the patients in Non-Diabetic and Diabetic groups is presented in Table 5 and Figure 5.

Table 5. . Smoking Status among the patients in Non Diabetic and Diabetic groups

Smoking Status	Non-Diabetic	Diabetic	Non-Diabetic (%)	Diabetic (%)
Non-Smoker	49	54	98.00	98.18
Smoker	1	1	2.00	1.82
Total	50	55	100.00	100.00
p-value Fisher's Exact Test			>0.9999	

Non-smokers consisted of 98% (n=49) of the non-diabetic study group and 98.18% (n=54) of the diabetic study group. There was no statistically significant difference in relation to smoking status between the study groups with a p-value of >0.05 as per the Fisher's Exact Test.

Figure: 5. Smoking Status among the patients in Non-Diabetic and Diabetic groups

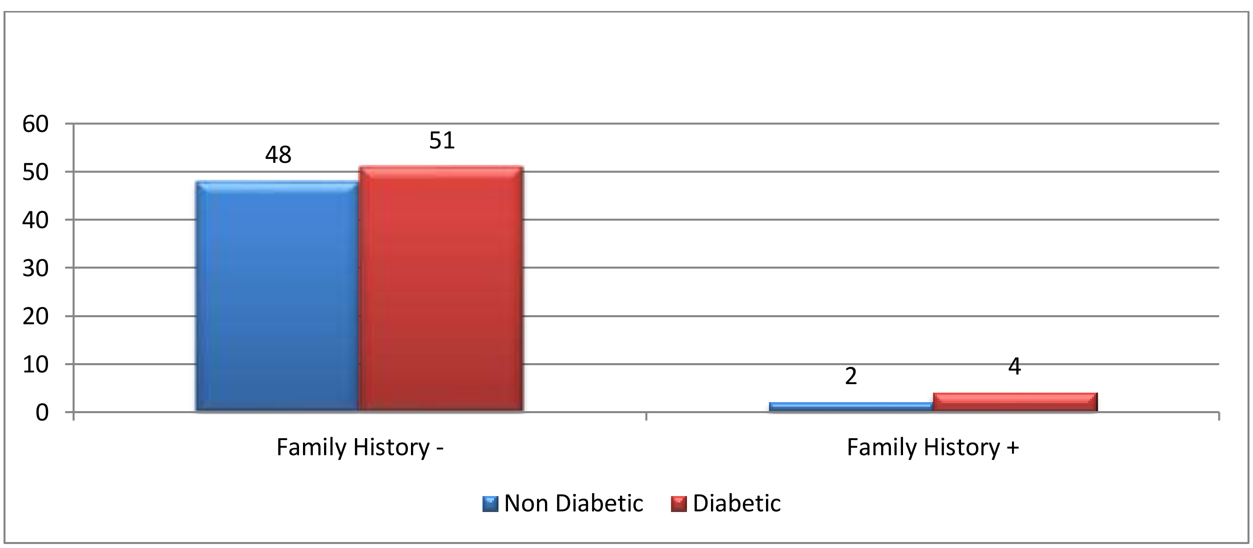


Data on Family H/O CVD among the patients in Non-Diabetic and Diabetic groups is presented in Table 6 and Figure 6.

Table 6. Family H/O CVD among the patients in Non-Diabetic and Diabetic groups

Family H/O CVD	Non-Diabetic	Diabetic	Non-Diabetic (%)	Diabetic (%)
Family History -	48	51	96.00	92.73
Family History +	2	4	4.00	7.27
Total	50	55	100.00	100.00
p-value Fisher's Exact Test			0.6805	

Figure: 6. Family H/O CVD among the patients in Non-Diabetic and Diabetic groups



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Patients with positive family history of CVD constituted 4% (n=2) of the non-diabetic study group and 7.27% (n=4) of the diabetic study group. There was no statistically significant difference in relation to family history of CVD status between the study groups with a p-value of >0.05 as per Fisher's Exact Test.

Discussion

Diabetics exhibit multiple concomitant metabolic abnormalities, including hypertension, obesity, and hyperlipidaemia[24, 25]. Diabetes by itself can be risk equivalent to a prior cardiac event. Presence of additional risk factors in a diabetic patient will certainly augment the peril. Nevertheless, obesity is considered an independent risk factor for macrovascular disease across sexes [26]**.** Research evaluating the association of BMI with risk of death among patients with diabetes has shown inconsistent results with many studies showing a U-shaped association between BMI and all-cause mortality [25]. Even though in our study more females had a higher BMI, central obesity was not measured which has more relevance to metabolic syndrome. In observational studies, people with both diabetes and hypertension have approximately twice the risk of cardiovascular disease as non-diabetic people with hypertension [26]. It is observed that diabetic women tend to have a higher likelihood of associated hypertension than do their male counterparts which again is a significant risk factor for CAD [27].

In the present study, 105 consecutive patients, who underwent primary PCI for acute MI at The Madras Medical Mission Hospital, Chennai, India were recruited into the study as per inclusion and exclusion criteria over a period of one year, after obtaining ethical and scientific committee approval. Among the 105 patients, 55 were diabetics and the remaining 50 were non-diabetics. All patients had undergone primary PCI at the cardiologist's discretion after the procedure was discussed with the patients and their respective relatives. All the 105 patients were followed up for six months without any drop-out at three pre-specified stages, namely, at discharge, at one-month, and 6 month follow-ups.

The total number of patients included in this study is comparable to majority of previous single-centre and multi-centre studies (Table 7). In our study, unequal distribution of 55 in the diabetic group and 50 in the non-diabetic group was due to non-randomization. Silva *et al.*[28] compared the angiographic and clinical outcome of 76 non-diabetic patients and 28 diabetics consecutively treated with primary stenting for acute MI.

Table 7. Number of patients in various studies conducted at various geographical locations

Study	Region	Years of Enrollment	Number of centres	Total	DM	NON DM
Our study	India	2016-2017	1	105	55	50
Silva *et al.*[28]	USA	1999	1	104	28	76
Zia *et al.*[29]	Canada	2014	1	52	16	36
Ojeda-Peña*et al.*[30]	Mexico	2016	1	60	30	30
Timmer *et al* [31]	Netherlands	2005	1	386	64	322

Earlier study conducted by Zia *et al.*[29], fifty-two patients (16 diabetics and 36 non-diabetics) were enrolled after primary percutaneous coronary intervention and underwent cardiac MRI to assess

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myocardial edema. Ojeda-Peña *et al.*[30] conducted a cross-sectional study in 60 patients with acute myocardial infarction with ST-segment elevation (30 diabetic and 30 non-diabetic) to assess epicardial fat thickening. Similarly another study was conducted by Timmer *et al.*[31] on 386 patients to assess myocardial blush grade, out of which 64 (17%) had DM. The mean age in the diabetic group was 57.05 years and 54.36 in the non-diabetic group in our study. Majority were in age group of 51- 60 years of age.

In a study conducted by Silva *et al.* [28], non-diabetic patients had slightly a mean age of 61 +/- 14 years and diabetic patients had a mean age of 65 +/- 12 years. This study had patients more in their sixties. In a study conducted by Aguilar *et al.*[32], previously known diabetics had a mean age of 66.5 ±10.4 years, the newly detected diabetics had a mean age of 63.9 ± 11.8 years and the non-diabetics had a mean age of 64.4 ±12.2 years.

Our study had relatively younger population and the onset of atherosclerosis as well as other risk factors start early in life. In our study, male patients predominated in both groups and constituted 90% of the non-diabetic study group and 87.27% of the diabetics. Females contributed to 10% of the non-diabetic group and 12.73 % of the diabetic group. The earlier study conducted by Aguilar *et al.*[32] reported a higher percentage of female population in comparison to findings of our study. Our study suggests that the incidence of MI occurs more in male patients, especially in the diabetic population.

The mean BMI was significantly less in the non-diabetic group as compared to the diabetic group by a mean difference of 2.21 (8%). Our study concluded that the incidence of obesity was 3 times more among the diabetics in comparison to the non-diabetic individuals. This is in accordance with earlier studies [31,32]. The earlier study conducted by Aguilar *et al.* (2004) [32] reported the BMI of 29.40 ± 5.4 in the previously diagnosed diabetics, BMI of 28.70 ±5.2 in the newly diagnosed diabetes, and BMI of 27.3 ± 4.6 in the non-diabetics. Most of the non-diabetic patients had hypertension as the main comorbidity (n=15, 30%) followed by hypercholesterolemia (n=3, 5.45%). Most of the diabetic patients also had hypertension as the main comorbidity (n=24, 43.64%) followed by hypercholesterolemia (n=8, 16%).The observations of our study are in agreement with Aguilar *et al.* [32], who had reported hypertension as the most common comorbidity followed by dyslipidemia among the study population.

In the present study, incidence of airway disease was less in both groups and accounted for 8% in the non-diabetics and 1.82% in the diabetics. Our study excluded patients with a prior history of revascularization in the form of PCI or CABG. No patient in either group had a history of stroke in the past. Gastro intestinal disease was seen in 2% of the non-diabetics in the form of acid peptic disease and needed single antiplatelet therapy. No patient in the diabetic group presented with gastro intestinal disease. Patients with chronic kidney disease beyond stage III were excluded from the present study.

Our study had very few patients with smoking habits. The study revealed 98% of non-diabetics and 98.18% of diabetics were non-smokers. This is in contrast to the earlier studies [32, 33], wherein the incidence of smoking was reported to be much higher. Increased awareness of smoking and primordial prevention could be reasons for lower incidence of smoking in our study. Also this suggests that risk factors other than smoking could be the contributing factors towards atherosclerosis and coronary artery disease. Family history of coronary artery disease was also lower in our study, with 4 % of the non-diabetics and 7.27 % of the diabetics having a strong family history of CHD.

Conclusion

Our study shows positive correlation of requirement of primary percutaneous interventions among the patients presented with myocardial infarction and age, gender, smoking status, comorbidities and obesity. This is a single-centre study with a small sample size, and this is a major study limitation. Moreover, we evaluated patients at a tertiary care hospital, and more than 90% patients underwent some coronary intervention, and the findings may not reflect the general situation in India. Larger and multi-centric studies are required to identify patterns of ACS in diabetes, management strategies, outcomes, and secondary prevention therapies. Long-term studies to assess adherence to therapies and lifestyle measures as well as long-term outcomes are also required. Other limitations of the study include lack of assessment of prehospital phase of ACS, details of symptoms, and in-hospital management. Our study is also underpowered to identify the importance of clinical

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outcomes. Further study with broader perspective and wider inclusive factors is warranted involving the patients at primary and secondary diagnostic as well as therapeutic centres.

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Conflicts of interest: There are no conflicts of interest.

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