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Original Research Article

Differences in Clinical Characteristics, Management and In-Hospital Outcomes among Diabetic versus Non Diabetic Patients with Acute Coronary Syndrome

Navdeep Singh Sidhu[1], Sumandeep Kaur[2], Sunil Kumar Kondethimmanahally Rangaiah[3], Dwarikaprasad Ramesh[4]

[1]Assistant Professor, Department of Cardiology, GGS Medical College and Hospital, Faridkot, Punjab, India.
[2]MSc, PhD. University College of Nursing, Baba Farid University of Health Sciences, Faridkot, Punjab, India.
[3]Associate Professor, Department of Cardiology, Sri Jayadeva Institute of Cardiovascular Sciences & Research, Bangalore, India.
[4]Professor and Head of Department, Vydehi Institute of Medical Sciences and Research Centre, Bangalore, India.

Corresponding Author: Navdeep Singh Sidhu

ABSTRACT

Introduction: Diabetes mellitus is one of the strongest risk factors for coronary artery disease (CAD). Many Western studies have shown worse outcomes in diabetic acute coronary syndrome (ACS) patients as compared to non diabetics. This study was conducted to explore the clinical characteristics, management strategies and in-hospital outcomes in ACS patients with or without diabetes.
Materials and methods: We enrolled consecutive adult ACS patients admitted during a period of 12 months (February 2015 to January 2016)
Results: In 621 ACS patients, prevalence of diabetes was 37.2%. Mean age of diabetics was higher than non diabetics (58.26 vs 54.76 years, p=0.000) and females constituted higher proportion in diabetic group (31.6% vs 19.7%, p=0.000). Diabetic patients had higher prevalence of hypertension (64.5% vs 23.8%, p=0.000) and more frequent past history of ischemic heart disease (26% vs 16.9%, p=0.007). Diabetics had higher prevalence of triple vessel disease (27.1% vs 14.6%, p=0.000) and left main disease (6.1% vs 2.5%, p=0.042). Use of evidence based pharmacotherapy was similar in two groups except for the lesser use of beta blockers in diabetics (74.5% vs 84.6%, p=0.001). Although revascularization rates with percutaneous coronary intervention and bypass surgery were similar in two groups, diabetic patients had higher in-hospital major adverse cardiovascular events (29.4% vs 13.1%, p=0.000) and higher in-hospital mortality (5.2% vs 2.1%, p=0.029).
Conclusion: Patients with diabetes were older, more likely to be females and had higher comorbidities like hypertension and past IHD. Diabetic patients had higher prevalence of complex CAD including TVD and left main disease and had higher in-hospital MACE including mortality.

Keywords: acute coronary syndrome, coronary artery disease, ischemic heart disease, diabetes mellitus, percutaneous coronary intervention, bypass surgery, major adverse cardiovascular events, mortality, triple vessel disease, left main disease

INTRODUCTION

Diabetes Mellitus (DM) and coronary artery disease (CAD) are two of the most common non communicable diseases and are the leading causes of mortality and morbidity in many parts of

world, including India. [1] Compared with non-diabetics, diabetics are more likely to have CAD, to have complex and multivessel disease when it occurs, and to have episodes of silent ischemia. As a result of these and many other factors, diabetics with CAD have worse prognosis and higher long-term mortality as compared to nondiabetics with CAD. [2]

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. [1] Furthermore, DM and CAD tend to develop at an earlier age in Indians and associated complications are more frequent as compared to Caucasians. [3-6] In contemporary literature, there are only a few studies from India relating to acute coronary syndromes (ACS) in diabetic adult population. [7,8] This study was conducted to explore the clinical characteristics, management strategies and in-hospital outcomes in ACS patients with or without diabetes being admitted to a tertiary care teaching institution.

MATERIALS AND METHODS

This study was a prospective observational study conducted at ESIC (Employees State Insurance Corporation) Hospital unit of our tertiary care teaching institute (Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bengaluru, India). ESIC hospitals provide exclusive cash-less treatment to persons and their families insured under the scheme. ESIC act of Government of India is applicable to establishments(mostly non-seasonal factories) who employ 10 or more individuals with upper age limit of each individual being Rs 21000/month(305 USD/month). [9] The study protocol was approved by the institutional ethical committee and written informed consent was obtained from each patient during the study period. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

Patient population consisted of consecutive ACS patients aged ≥ 18 years who were admitted during the study period of 12 months (from February 2015 to January 2016). The diagnosis of ACS was made by the presence of typical symptoms like retrosternal chest pain or uneasiness, along with electrocardiographic (ECG) changes and elevated cardiac biomarkers. Patients were classified as having ST elevation myocardial infarction (STEMI)or Non-ST elevation acute coronary syndrome (NSTE-ACS) according to American College of Cardiology/American Heart Association (ACC/AHA) definitions. [10,11]

A case report form was prepared for each patient upon hospital admission and was completed throughout the patient's hospital stay. Variables included in this form were: patient's age and gender, time from onset of symptoms to presentation in the hospital, significant past medical history, baseline clinical characteristics, provisional diagnosis at admission and final diagnosis at discharge, ECG and echocardiographic findings, various laboratory investigations, use of evidence based pharmacological therapy and cardiac interventions and in-hospital outcomes including mortality. To ensure uniformity of the collected data, following standard definitions were used-

Hypertension: self-reported diagnosis of hypertension and/or on anti-hypertensive medications, systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥ 90 mmHg;

Diabetes Mellitus(DM): self-reported diagnosis of diabetes mellitus and/or on antidiabetic medications, fasting glucose levels >126 mg/dL, or glycated hemoglobin levels >6.5%; Dyslipidemia: self-reported diagnosis of dyslipidemia and/or on treatment for dyslipidemia, high density lipoprotein cholesterol (HDL) level <40 mg/dl (men) or <50 mg/dl (women), and triglyceride level>150 mg/dl, serum total cholesterol >200 mg/dl or low density lipoprotein cholesterol (LDL) level >130 mg/dl;

Past history of ischemic heart disease (IHD): prior typical angina, history of prior ACS, prior Percutaneous coronary intervention(PCI) or Coronary artery bypass grafting(CABG).

Smoking: Patients were considered as smokers if they reported smoking/tobacco consumption within the past one year of study enrollment.

Patients with co-existent valvular heart disease, pericardial pathology, cardiomyopathy or congenital heart disease were excluded from the study.

Coronary angiography (CAG) was performed using standard technique within 48 hours of hospital admission, unless contraindicated. Coronary angiograms were analysed by two expert invasive cardiologists. Significant coronary artery disease (CAD) was defined as the presence of >50% diameter stenosis in one or more vessels or in a major branch and patients were accordingly classified as having single vessel disease(SVD), double vessel disease(DVD) or triple vessel disease(TVD). [12] PCI and CABG were performed in eligible candidates as per institutional protocol.In hospital major adverse cardiovascular events(MACE) recorded in our study included in-hospital mortality, heart failure, cardiogenic shock, cardiac arrest, reinfarction, stroke and major bleeding.

Heart failure was defined by the presence of shortness of breath on exertion and/or at rest, orthopnea and/or paroxysmal nocturnal dyspnea, along with clinical signs of pulmonary and/or peripheral edema requiring diuretic therapy.

Cardiogenic shock was defined as persistent hypotension (systolic blood pressure of less than 90 mmHg) unresponsive to fluid administration and requirement for intravenous inotropic therapy or insertion of intra-aortic balloon pump (IABP).

Myocardial reinfarction was defined by new cardiac troponin elevation and new onset chest pain/discomfort or ECG changes consistent with ischemia or both.

Cardiac arrest was defined as the occurrence of sustained ventricular tachycardia or ventricular fibrillation (VT/VF) or asystole.

Stroke was defined by the occurrence of new focal neurological deficit of vascular origin lasting for more than 24 h and confirmed by computed tomogram (CT) or magnetic resonance(MR) imaging.

Major bleeding was defined as the occurrence of overt clinical bleeding associated with a drop in hemoglobin by more than 5 g/dL or bleeding causing hemodynamic instability or necessitating blood transfusion.

Statistical methods

Data were summarized as mean ± Standard Deviation (SD) if they were normally distributed; else they were summarized as the median (first and third quartiles). Differences between diabetic and non-diabetic groups were assessed using Chi square or Fisher's exact tests for categorical variables, student's t tests for continuous and normally distributed variables, and the Mann-Whitney U test for skewed variables. All analyses were considered significant at $p < 0.05$. The analysis was performed using SPSS software, version 23(SPSS Inc. Chicago).

RESULTS

Baseline characteristics

Out of total 651 eligible patients with ACS enrolled during the study period, 30 were excluded from the analysis due to incomplete data. Out of 621 patients, 471(75.8%) were males and 150(24.2%) were females. Overall mean age was 56.06± 11.29 years (range 21-97 years). Majority of the patients had STEMI (62%) whereas NSTE-ACS was seen less commonly (38%). Diabetes mellitus was seen in 231 patients (37.2%).

On comparison between diabetic and non diabetic groups (table 1), it was found than mean age of presentation was significantly higher in diabetics (58.26 vs 54.76 years, p=0.000). Women constituted

31.6 % of ACS cases in diabetics, as compared to 19.7% in non diabetic group (p=0.000). NSTE-ACS cases constituted higher proportion of ACS cases in diabetic group (44.6% vs 34.1%, p=0.009). Hypertension was seen in 64.5% of diabetic patients with ACS as compared to 23.8% of non diabetic ACS patients (p=0.000). Past history of IHD was also seen more commonly in diabetics as compared to non diabetics (26% vs 16.9%, p=0.007). Dyslipidemia was seen in 30.7% of diabetic patients and in 36.9% of non diabetics. However, this difference was not statistically significant (p=0.138). Smoking was seen in 23.8% of diabetics as compared to 24.1% of non diabetics and the difference was not statistically significant (p=0.934). Median time from symptom onset to hospital presentation was not significantly different between the two groups (290 minutes in diabetics vs 281 minutes in non diabetics, p=0.487).

Table 1: Comparison of baseline characteristics, risk factors and time to hospital presentation between diabetic and non diabetic patients with acute coronary syndrome (ACS).

Variable	Diabetics(n=231)	Non diabetics(n=390)	p value
Mean age,SD years	58.26,10.45	54.76,11.58	0.000
Men	158(68.4%)	313(80.3%)	0.000
Women	73(31.6%)	77(19.7%)	0.000
STEMI	128(55.4%)	257(65.9%)	0.009
NSTEACS	103(44.6%)	133(34.1%)	0.009
Risk factors			
I) Hypertension	149(64.5%)	93(23.8%)	0.000
II) Dyslipidemia	71(30.7%)	144(36.9%)	0.138
III) Smoking	55(23.8%)	94(24.1%)	0.934
IV) Past IHD	60(26%)	66(16.9%)	0.007
Time to hospital presentation(mins), median(Q1,Q3)	290(222,402)	281(214,394)	0.487

SD: standard deviation, Q1 Q3: first and third quartiles, STEMI: ST elevation myocardial infarction, NSTE-ACS: Non-ST elevation acute coronary syndrome, IHD: ischemic heart disease

Angiographic profile (table 2)

Overall 503(81%) of ACS patients underwent selective coronary angiography within 48 hours of admission with no significant difference in angiography rate between diabetic and non diabetic groups (78.4% vs 82.6%, p=0.196). Normal epicardial coronaries/insignificant CAD was seen in 86(17.1%) of the patients who underwent coronary angiography, with diabetic patients less likely to have normal coronaries/insignificant disease as compared to non diabetics (12.2% vs 19.9%, p=0.027). Overall, SVD was the most common pattern (seen in 43.3%), with LAD being the most commonly involved vessel (62.8%) followed by RCA (40.2%). As compared to non diabetics, diabetic patients had higher incidence of TVD (14.6% vs 27.1% respectively, p=0.000); left main (LM) disease (2.5% vs 6.1% respectively, 0.042); and a lower incidence of SVD (49.4% vs 32.6% respectively, p=0.000).

Table 2: Comparison of angiographic profiles of diabetic and non diabetic patients with acute coronary syndrome(ACS)

Variable	Diabetics(n=231)	Non diabetics(n=390)	p value
CAG performed	181(78.4%)	322(82.6%)	0.196
Normal coronaries/insignificant CAD	22(12.2%)	64(19.9%)	0.027
SVD	59(32.6%)	159(49.4%)	0.000
DVD	41(22.7%)	62(19.3%)	0.364
TVD	49(27.1%)	47(14.6%)	0.000
LM involvement	11(6.1%)	8(2.5%)	0.042
LAD disease	106(58.6%)	216(67.1%)	0.056
LCX disease	67(37%)	94(29.2%)	0.071
RCA disease	74(40.9%)	128(39.8%)	0.803

CAG: coronary angiography, SVD: single vessel disease, DVD: double vessel disease, TVD: triple vessel disease, LM: left main, LAD: left anterior descending artery, LCX: left circumflex disease, RCA: right coronary artery

In-hospital management (table 3)

Use of dual anti platelet therapy (DAPT) and statins was high in our study

(>96%), without any significant difference between diabetic and non diabetic patients. Use of beta adrenergic blockers were less commonly used in diabetics as compared to non diabetic patients (74.5% vs 84.6%, p=0.001). There was no significant difference in the use of Angiotensin converting enzyme inhibitors (ACEIs) or Angiotensin receptor blockers (ARBs), nitrates and heparin between diabetic and non diabetic groups. The use of invasive revascularization treatment in the form of PCI or CABG was similar in both the groups.

Table 3: Comparison of in-hospital use of evidence based pharmacotherapy and invasive interventions in diabetic and non diabetic patients with acute coronary syndrome (ACS).

Variable	Diabetics(n=231)	Non diabetics(n=390)	p value
Aspirin	225(97.4%)	384(98.5%)	0.354
Clopidogrel	223(96.5%)	382(97.9%)	0.283
Statin	227(98.3%)	383(98.2%)	0.954
ACE-I/ARB	167(72.3%)	284(72.8%)	0.887
Beta-blockers	172(74.5%)	330(84.6%)	0.001
Nitrates	144(62.3%)	264(67.7%)	0.174
Heparin(UFH/LMWH)	208(90%)	362(92.8%)	0.223
PCI	142(61.5%)	215(55.1%)	0.122
CABG	17(7.4%)	23(5.9%)	0.473

ACE-I/ARB: Angiotensin converting enzyme inhibitors or Angiotensin receptor blockers, UFH: unfractionated heparin, LMWH: low molecular weight heparin, PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting

In-hospital outcomes (table 4)

Composite MACE was significantly higher in diabetic patients as compared to non diabetics (29.4% vs 13.1%, p=0.000). This was driven by higher rates of heart failure, cardiogenic shock, re-infarction and in-hospital mortality in diabetic group. There was no significant difference between the groups in terms of occurrence of cardiac arrest, major bleeding and stroke.

Table 4: Comparison of In-hospital outcomes in diabetic and non diabetic patients with acute coronary syndrome(ACS)

Variable	Diabetics (n=231)	Non diabetics (n=390)	p value
Heart failure	26(11.3%)	24(6.2%)	0.023
Shock	9(3.9%)	5(1.3%)	0.033
Cardiac arrest	8(3.5%)	8(2.1%)	0.284
Reinfarction	6(2.6%)	2(0.5%)	0.033
Major bleeding	4(1.7%)	2(0.5%)	0.141
Stroke	3(1.3%)	2(0.5%)	0.269
Death	12(5.2%)	8(2.1%)	0.029
Composite MACE	68(29.4%)	51(13.1%)	0.000

MACE: major adverse cardiovascular events

DISCUSSION

Diabetes mellitus is a major public health problem worldwide and is one of the strongest risk factors for cardiovascular disease. Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of mortality and morbidity among diabetics, especially in patients with type 2 diabetes mellitus in whom it typically occurs earlier by one or two decades, has greater severity and is associated with more diffuse disease distribution than in non diabetics. [2,13] Cardiovascular disease is responsible for about two-thirds of deaths in diabetic patients: out of which nearly 40% are from IHD, 10% from stroke and 15% from other cardiac diseases, mainly heart failure. [2] The incidence of ASCVD, including CAD, stroke and peripheral arterial disease, is two to four times higher in diabetics than in general population. Diabetes not only causes an increased risk of myocardial infarction (MI), but is also associated with an increased mortality during an acute event. Diabetic patients with ACS have a greater risk of complications like heart failure, cardiogenic shock; and have greater reinfarction rates as compared to non diabetic patients. [14] Furthermore, when diabetic patients develop clinical CAD, they have a poorer prognosis than the CAD patients without diabetes. Cardiovascular mortality in diabetics without a history of prior myocardial infarction (MI) is similar to that seen in non diabetic patients with previous MI. [15]

Baseline characteristics

The prevalence of DM among ACS patients in our study was 37.2%. This is higher than seen in CREATE registry

(30.4%) [16] but is comparable to recent Indian ACS registries like Detection and Management of Coronary Heart Disease (DEMAT) registry (39.6%) [17] and Kerala ACS registry (37.6%). [18] It is also comparable to recent studies from developed world like National Cardiovascular Data Registry (35%) [19] and study by Awad et al(38%). [20]
Diabetic patients in our study were older, more likely to be female, more likely to have past history of IHD, had higher prevalence of hypertension and had higher proportion of NSTE-ACS cases as compared to non diabetic patients. These results are similar to many of the previously published studies. [21-25]

Angiographic profile

In our study, the rate of invasive management with CAG was similar between diabetic and non diabetic patients. However, diabetic patients had lower prevalence of normal coronaries/ insignificant CAD and of SVD; had higher prevalence of complex CAD including TVD and left main(LM) involvement. Our results are similar to that seen in many studies from India [26,27] 26,27 and from the western world. [28-31] In a study of ACS population by Sharma et al [26] DVD was seen in 21.08% of diabetic patients, as compared to 16.65% of non diabetics. TVD was seen in 9.70% of diabetic patients as compared to 7.06% of non diabetic patients. In another study on ACS population by Hegde et al, [27] TVD/multivessel disease was seen in 44% of diabetic patients but in only 16% of non diabetic patients. Similar to results in our study, this study had higher prevalence of LM disease in diabetic patients as compared to non diabetics (7.5% and 1% respectively).

In-hospital treatment practices

The use of evidence based pharmacotherapy in ACS patients was high in our study with no significant differences between diabetic and non diabetic groups except for lesser use of beta blockers in diabetic patients. Many previous studies have reported lower use of beta blockers in diabetic ACS patients as compared to non diabetic ACS patients. [8,21,32-34] This may be related to physician reluctance in prescribing beta blockers to diabetic patients, possibly related to popular misconceptions of higher adverse effects including the possibility of masking hypoglycemic symptoms and increasing the impaired glucose tolerance. [32]

The use of PCI and CABG was similar among diabetic and non diabetic patients in our study. Similar rates of PCI between diabetic and non diabetic patients in our study are in concordance with a recent study by Tisminetzky et al, [25] but differ from earlier studies which showed lower utilization of PCI in diabetic patients. [35,36] This probably reflects the changing cardiovascular practices with improved PCI techniques and potent medical therapies enabling more and more complex cases to be treated with PCI.

Although in our study, the rate of TVD and LM involvement was higher in diabetic patients, the rates of CABG were similar in both the groups. These results differ from many of the previous studies which have reported higher rates of CABG among diabetic patients. [8,19,20] The most likely explanation in many diabetic patients was the technical non-feasibility of CABG owing to higher prevalence of small diffusely diseased vessels.

In-hospital outcomes

In our study, diabetic patients had higher composite MACE as compared to non diabetic patients. This was driven by higher rates of heart failure, cardiogenic shock, re-infarction and in-hospital mortality in diabetics. These results are similar to many of the previously reported studies. [19-23,25] There are many factors which contribute to adverse outcomes in diabetic ACS patients. Diabetic patients often have higher prevalence of comorbidities like hypertension and renal failure, which lead to worse outcomes.

Insulin resistance and diabetes is a proinflammatory and prothrombotic state characterised by endothelial dysfunction, increased oxidative stress, up regulation of pro-inflammatory cytokines and acute phase reactants, and increased platelet aggregation and adhesion. [2,37] Diabetic patients often have diffuse or distal CAD, which renders the coronary anatomy to be less suitable for revascularization.

Some limitations of our study need to be acknowledged. Ours is a single centre study of low socio-economic status population from urban India. Hence results of our study cannot be generalized. Our sample size was relatively small; hence our study may not be adequately powered to detect meaningful difference between groups in terms of infrequent events like MACE. This was an in-hospital study and there were no follow-up data collected. Nevertheless, our study has the largest sample size of Indian studies which have directly compared the presentation and management of diabetic and non diabetic ACS patients and to the best of our knowledge, is the first contemporary Indian study which has compared in-hospital outcomes including mortality among these groups.

CONCLUSION

In our study of ACS population from Urban India, nearly one-third of the patients were found to be diabetic. Patients with diabetes were older, more likely to be females and had higher comorbidities like hypertension and past history of IHD. Diabetic patients had higher prevalence of complex CAD including TVD and left main disease. Use of evidence based pharmacotherapy was similar in two groups except for the lesser use of beta blockers in diabetic patents. Although revascularization rates with PCI and CABG were similar in the two groups, diabetic patients had higher in-hospital MACE including mortality.

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