

A Comparative Clinical study of Patients of Heart Failure in Type 2 Diabetes Mellitus Versus Heart Failure in Non-Diabetic PatientsLaly Divakaran Chandrika¹, Saneer Kottarathil², Sundeep KB³, Roopak Mohan⁴^{1,2,3,4}Assistant Professor, Department of General Medicine, Kannur Medical College, Kannur, Kerala

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Conflict of interest: Nil

Abstract:

Background: Continuous clinical trials have confirmed the association between Diabetes Mellitus (DM) with Heart failure (HF), independent of hypertension, atherosclerosis, coronary artery disease and valvular heart disease. But not universally recognized by physicians though the combination of both the conditions together may lead to morbidity and mortality. Early recognition and suitable management of HF in Diabetics could improve the outcome. But the etiology of heart failure in diabetic patients is still not completely understood. It has multifactorial determinants such as several cellular, molecular and metabolic factors. In addition there are no definite guidelines for grading the HF, early diagnosis, and therapy in DM patients with HF. This study focuses on the clinical presentation, probable pathophysiology, diagnosis, and prevention of HF in DM patients.

Aim of the Study: To study the clinical manifestations of Heart Failure in diabetes type 2 patients and compare them with Heart failure in non DM patients in terms of diagnosis, and management.

Materials: This case control study was carried out in 138 patients, who were divided into two groups. Group A Patients (69) with HF with Diabetes Mellitus and Group B (69): Patients of HF without DM. Necessary data to assess the HF and DM was collected. Standard statistical analytics were used to correlate the findings and study statistical significance. The Investigations undertaken were Demographic details, ECG, 2D ECHO and coronary angiography between diabetic and non-diabetic HF patients.

Results: 138 patients were divided into Group "A" (69 patients) with HF and Diabetes Mellitus type 2 and Group B with only HF. 41 (59.42%) males and 28 (40.57%) females with a male to female ratio of 1.46:1 in Group A and in Group "B" (69 patients) with NON-Diabetes Mellitus, the males were 51 (73.91%) males and 18 (26.08%) females with a male to female ratio of 2.83:1. The overall male to female ratio among the 138 patients was 2:1. The incidence of HF at class intervals of 10 years starting at 25 years to 74 years in group A was: 06, 14, 17, 20 and 12. Corresponding incidence in group B for the same age intervals was 1, 05, 11, 25 and 27. The chi square statistic was 15.44 and the p value was 0.0038.

Conclusions: Diabetes Mellitus is a risk factor for Heart Failure patients and menace of cardiac related mortality and morbidity. Severity of hyperglycemia was correlating with the severity of HF and was statistically significant (p value-0.05). 2D Echo results were helpful in the diagnosis of severity of HF and found to be more profound with patients of HF with DM; with p value less than 0.05. LVEF was less than 40% in patients of HF with DM when compared to HF patients without DM. CAG reports like Triple vessel disease (TVD), SVD and BVD were statistically significant with p value less than 0.05. Percentage of coronary artery block was 96 to 100% in patients with HF and DM. Mortality rate was higher in HF patients with DM than without DM.

Keywords: Heart failure, Diabetes Mellitus, Prognosis, Mortality, Morbidity and CAD.

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Introduction

Way back in 1974, the Framingham from their studies cautioned that there would be two- to five-fold increased risk of heart failure among the patients with diabetes. [1] Later it was noted by other authors also that the mortality rate and duration of hospitalization would be higher among the Heart failure patients suffering from Diabetes. [2, 3 and 4] Heart failure was noted as a "frequent, forgotten, and often fatal complication of diabetes" by many physicians. [5] The pathophysiology of Heart failure with

Diabetes is complex and multifactorial and cannot be classified simply as either microvascular or macrovascular. [6] To complicate this further glycaemic control alone cannot reduce the risk of heart failure. [7] But such glycaemic control may further adversely affect cardiac function in susceptible individuals. [8, 9] The adverse effect of landing into heart failure in patients seems to be due to associated with improved glucose control. It was explained partially by the choice of treatment as reported in a

recent meta-analysis. [10] How the anti-diabetic medications are directly or indirectly contributing to the development of Heart failure or precipitating to Heart failure is still debated and the correct choice of anti-diabetic medicines also still remains as an enigma to the physicians. [11 to 16]

A large network of meta-analysis conducted by Zhuang XD, He X, Yang DY, Guo Y et al [17] in 2018 to find the right choice of anti-diabetic drugs including dipeptidyl peptidase 4 (DDP-4) inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, and sodium-glucose co-transporter 2 (SGLT-2) inhibitors, were superior in terms of major adverse cardiovascular events (MACE) and all-cause mortality, compared with more traditional classes of drugs. Heart failure (HF) is the most common complication noted in patients with diabetes mellitus. (DM), [18] Both HF and DM share common pathogenetic factors and the former develops in the patients without typical risk factors like hypertension and coronary artery disease. [19] Furthermore, certain studies suggested that the increased risk of HF could be due to specific therapies, such as insulin [20], sulfonylurea (SU), gliptins or glitazones. [21].

However, the effects of drugs should be assessed with extreme caution, since diabetic patients often receive multiple therapies simultaneously or over time. The present scenario of DM in India is that there are 3.5 crore population suffering from the disease and the number may rise up to 5.72 crores by 2025. [22] The present study aims to study the clinical manifestations of Heart Failure in diabetes type 2 patients and compare them with Heart failure in non DM patients in terms of diagnosis, and management.

Materials

This was a case control prospective study with the study population of 138 patients attending the department of General Medicine and Cardiology with Heart Failure. The subjects were divided in to two groups. Group A consisted of 69 patients with Diabetes Mellitus- type 2 diseases and Group B consisted of 69 subjects with Heart Failure but without Diabetes Mellitus. An institution ethics committee approved the study and committee approved consent form and proforma were used.

Type of Study: A case control prospective study.

Institution of study: Kannur Medical College and Hospital, Kannur, Kerala.

Year of Study: January 2021 to December 2023.

Inclusion Criteria: Patients aged between 25 and 75 years were included. Patients of both genders were included. Patients with Diabetes Type 2 were included for the Group A. Patients without Diabetes Mellitus were included for the Group B. Patients presenting with the complaints of dyspnea with

activity or when lying down, fatigue and weakness, swelling in the legs, ankles and feet, rapid or irregular heartbeat, reduced capacity to exercise, wheezing, cough not responding to regular treatment and with white or pink mucus with spots of blood, swelling of the belly area, recent and rapid weight gain, nausea and lack of appetite, difficulty concentrating or decreased alertness, chest pain if heart failure is caused by a heart attack were included. Patients without Diabetes Mellitus but with any or all of the symptoms mentioned above were included for Group B. Patients detected for first time as having DM and/ or meeting the criteria for DM by American diabetic association (ADA) were included. For control group patients with HF but not meeting the criteria of ADA were included.

Exclusion Criteria: Patients with very severe HF and uncontrolled DM were excluded. Patients with risk factors of Hypertension, Chronic Kidney Disease were excluded. Patients with immune compromised diseases were excluded. Patients on Steroids for any other disease were excluded. Patients of extremes of age and those not willing to participate in study were excluded.

All the patients were thoroughly elicited of their present and past history in terms of CVS and endocrine systems. Non-cardiac risk factors such as smoking, thyroid deficiency, malnutrition, obesity, lack of exercise, family history and dietary habits were elicited. A thorough clinical examination was done. Laboratory investigations with main focus on CVS examination, endocrine assays, Blood pressure, ECG, CBC, RFT, electrolytes, HbA1C levels were done. CVS investigations included: ECG, 2D ECHO, MRI scans were done in patients based on the requirement for diagnosis and plan of treatment. Microalbuminuria was defined as excretion of 30-300 mg of albumin per 24 hours (or 20-200 mcg/min or 30-300 mcg/mg creatinine) on 2 of 3 urine collections. CMR (Cardiac MRI) was undertaken to calculate the Global wall thickness (GT) to determine HF based on the measures with the highest prognostic associations. Coronary Angiogram wherever necessary was undertaken and its findings were noted down in MS office Excel.

Statistical Analysis: All statistical data were analyzed using SPSS version 19.0 and AMOS version 19.0 statistical packages. The demographic characteristics of the sample were reported as means, and standard deviations for continuous variables, and frequencies and percentages for categorical variables. Correlation and significance was calculated using student T test. Chi Square test and regression analysis were applied for analysis and important correlations and conclusions were drawn.

Results

Among the 138 patients included in the study, Group "A" (69 patients) consisted of Diabetes Mellitus

type 2 patients, there were 41 (59.42%) males and 28 (40.57%) females with a male to female ratio of 1.46:1. Group "B" (69 patients) consisted of NON-Diabetes Mellitus; there were 51 (73.91%) males and 18 (26.08%) females with a male to female ratio of 2.83:1. The overall male to female ratio among the 138 patients, it was 2:1. The chi square test applied to the incidence of HF among the two groups was found to be significant with p value at 0.020 with chi square statistic at 5.34. (p significant at <0.05)

The incidence of HF at class intervals of 10 years starting at 25 years to 74 years in group A was: 06, 14, 17, 20 and 12. Corresponding incidence in group B for the same age intervals was 1, 05, 11, 25 and 27. The chi square statistic was 15.44 and the p value was 0.0038. (Table 1) The result was significant at p <0.05. Other demographic factors like BMI, Social status and Educational status were tabulated in the table 1 and were found to be not significant statistically with p value more than 0.05.

Table 1: Showing the Demographic data of two groups in the study (n-138; Group A-69 & Group-B-69)

Observations	Group A- Number- percentage	Group B- Number- percentage	P value
Age in Years			
25 to 34	06- 08.69	01- 01.44	0.0038
35 to 44	14-20.28	09- 13.04	
45 to 54	17- 24.63	11- 15.94	
55 to 64	20-28.98	25- 36.23	
65 to 74	12- 17.39	27- 39.13	
Mean age in Yrs	51.25±3.25	54.20±4.10	Overall Mean Age: 52.31±1.55
Gender			
Male	41- 59.42	51- 73.91	0.020
Female	28- 40.57	18- 26.08	
Male to female ratio	1.46:1	2.83:1	
BMI			0.141
19 to 22	04- 05.79	06- 08.69	
23 26	16- 23.18	18- 26.08	
27 to 30	30- 43.47	21- 30.43	
31 to 34	19- 27.53	13- 18.84	
Economic Status			0.211
Low	21- 30.43	23- 33.33	
Middle	22- 31.88	25- 36.23	
High	26- 37.68	21- 30.43	
Education			0.301
Inter	29- 42.02	26- 37.68	
Graduate	25- 36.23	23- 33.33	
Post graduate	15- 21.73	20- 28.98	

The incidence of the risk factors such as smoking, Thyroid deficiency, Malnutrition, obesity, lack of physical exercise, family history, and alcohol consumption were noted and tabulated in the Table 2 and it was found to be not statistically significant as all the populations are drawn from the same societal living conditions. (Table 2)

However, Dyslipidemia was more common in the group A patients than in Group B patients. (p value <0.05)

The mean values of total cholesterol, serum triglycerides, and serum LDL were found to be higher side when compared to non-diabetic group patients. (Table 2)

Table 2: Showing the incidence of non- cardiac risk factors in the subjects of two groups (n- 138; Group A-69 & Group-B-69)

Risk Factors	Group A	Group B	P value
Smoking			
Yes	24- 34.78	22- 31.88	0.163
No	45- 65.21	47- 68.11	
Thyroid deficiency			
Yes	11- 15.94	13- 18.84	0.112
No	58- 84.05	56-81.15	
Malnutrition			
Yes	14- 20.28	10- 14.49	0.230
No	55- 79.71	59-85.50	

Obesity			0.001
Yes	19- 27.53	54- 78.26	
No	50- 72.46	14- 20.28	
Lack of exercise			0.721
Yes	44- 63.76	41- 59.42	
No	25- 36.23	28- 40.57	
Family history			0.112
Yes	21- 30.43	25- 36.23	
No	48- 69.56	44- 63.76	
Dyslipidemia			0.004
Present	58- 84.05	32- 46.37	
Absent	11- 15.94	37- 53.62	0.211
Alcohol			
Yes	15- 21.73	18- 26.08	
No	54- 75.26	51- 73.91	

Clinical signs such as Blood pressure was noted in both the groups and found that there was prevalence of high range blood pressure in the subjects of Group "A" compared to Group B patients; and also significant statistically (p value < 0.05). Microalbuminuria was observed in 42 (60.86%) patients of Group A and 20 of the Group B patients which was statistically significant with p value less than 0.05. In Group A diabetic group HbA1C 7.1-8.5 was observed in 54 (78.26%) patients and 24 (34.78%) of Group B non-diabetic patients. Similarly the HnA1c values 4.5 to 7.0 was observed in 15 (21.73%) of Group A patients and 45 (65.21%) of the Group B patients), (Table 3). Correlation of severity of hyperglycemia with severity of HF was statistically significant (p value-0.05). There was similarity in ECG changes in patients belonging to both Diabetes Mellitus type 2 and non-diabetes patients; all the ECG findings were correlating in the subjects of both groups. (p value <0.05) 2D Echo showed RWMA in 28 (40.57%) patients of Group A, when compared to 57 (82.60%) patients of Group B which was statistically significant with p value less than

0.05. LVEF was less than 40% in 26 (37.68%) patients of Group A and 49 (71.01%) of the Group B patients which was statistically significant with p value less than 0.05. Diastolic Dysfunction was present in 51 (73.91%) of the group A patients and 32 (46.37%) patients of the Group B which was significant statistically with p value less than 0.05. (Table 3) CAG reports showed Triple vessel disease (TVD) in 32 (46.37%) patients of the Group A and 11 (15.94%) of the Group B patients which was statistically significant with p value less than 0.05. Percentage of coronary artery block was 96 to 100% in 58 (84.05%) patients of Group A and 34 (49.27%) patients of the Group B which was statistically significant with p value less than 0.05. (Table 3) The GT measured on CMR was more than 5.2 in 10 (14.49%) female patients of Group A; 28 (40.57%) male patients of Group A. Similarly the GT measured on CMR was more than 5.2 in 06 (08.69%) female patients of Group B; 14 (20.28%) male patients of Group B. This was statistically significant with p value less than 0.05. (Table 3)

Table 3: Showing the clinical signs and laboratory findings in the subjects (n- 138; Group A-69 & Group-B-69)

Investigations	Group A	Group B	P value
Blood Pressure			
Above 140/90 mmHg	43- 62.31	26- 37.68	0.012
Below 140/90 mmHg	26- 37.68	43- 37.68	
Microalbuminuria (30 to 300mcg/mg creatinine)			
Yes	42- 60.86	20- 28.98	0.001
No	27- 39.13	49- 71.01	
HbA1C			
4.5 to 7.0	15- 21.73	45- 65.21	0.001
7.1 to 8.5	54- 78.26	24-34.78	
ECG			
ST segment depression	54- 78.26	57- 82.60	
Ischemic ECG changes (T wave inversion, ST segment depression, Abnormal Q wave) Both	11- 15.94	15- 21.73	0.001
	28- 40.57	31- 44.92	
2D Echo			
RWMA			

Present	28- 40.57	51- 73.91	0.001
Absent	41- 59.42	18- 26.08	
LVEF			0.001
➤ 40%	43- 62.31	36- 52.17	
< 40%	26- 37.68	33- 47.82	
Diastolic Dysfunction			
Present	51- 73.91	32- 45.37	0.001
Absent	18- 26.08	37- 53.62	
CAG			0.001
SVD	16- 23.18	37- 53.62	
DVD	21- 30.43	21- 30.43	
TVD	32- 46.37	11- 15.94	
Percentage of Coronary Block			0.001
75 to 95%	11- 15.94	35- 50.72	
96 to 99	29- 42.02	22- 31.88	
100%	29- 42.02	12- 17.39	
Global Wall Thickness (GT) on CMR			0.001
➤ 5.2 in females	10- 14.49	06- 08.69	
➤ > 7.3 in males	28- 40.57	14- 20.28	

In Group A diabetes Mellitus type 2 patients the duration of the disease and the CAG findings were correlated and found that 33 (47.82%) patients were having DM for 11 to 15 years, 24 (34.78%) patients for 06 to 10 years and 12 (17.39%) patients for 0 to 05 years. The CAG findings showed TVD in 32 (46.37%) patients, DVD in 21 (30.43%) patients and SVD in 11 (15.94%) patients. The degree of coronary arteries block was 96 to 100% in 58 (84.05%) patients of Group A and 34 (49.27%) patients of the Group B which was statistically significant with p value

less than 0.05. (Table 4) Glycemic control in patients with Diabetes Mellitus type 2 was correlated with the small vessel disease and coronary artery block was studied and found that TVD in 32 (46.37%) patients, DVD in 21 (30.43%) patients and SVD in 11 (15.94%) patients. The degree of coronary arteries block was 96 to 100% in 58 (84.05%) patients of Group A and 34 (49.27%) patients of the Group B which was statistically significant with p value less than 0.05. (Table 4)

Table 4: Showing the correlation between duration of DM and Laboratory reports and CAG findings (n-138; Group A-69 & Group-B-69)

Duration of DM		Number	Percentage	P value		
Newly detected				--		
0 to 05 Yrs		12- 17.39				
06 to 10 Yrs		24- 34.78				
11 to 15 Yrs		33- 47.82		0.001		
CAG findings						
Small vessel disease		05- 07.24				
SVD		11- 15.94				
DVD		21- 30.43		0.001		
TVD		32- 46.37				
Degree of block in coronaries						
75 to 95%		11- 15.94		0.001		
96 to 99		29- 42.02				
100%		29- 42.02				
Glycemic control versus lesion on CAG	Total	Small vessel disease	SVD	DVD	TVD	P value
7.1 to 8.5	14- 20.48	02- 02.89	04- 05.79	03- 04.34	05- 07.24	0.001
8.6 to 11.0	36- 52.17	06- 08.69	08- 11.59	10- 14.49	12- 17.39	
> 11.0	19- 27.53	05- 07.24	03- 04.34	04- 05.79	07- 10.14	

The final outcome among the patients of this study was compared with the improvement or deterioration of findings in patients of the two groups. It was observed that medical management was alone required in 38 (55.07%) group B patients and 10

(14.49%) patients of Group A. CABG was required in 27 (39.13%) of the group A patients and 21 of the group B patients. PTCA was sufficient in 22 (31.88%) patients of the Group A and 10 (14.49%) patients of the Group B. (Table 5)

Table 5: Showing the comparison of treatment outcome in both groups of subjects (n-138; Group A-69 & Group-B-69)

Final outcome after treatment	Group A	Group B	P value
Medical management	10- 14.49	38- 55.07	0.001
CABG	27- 39.13	21- 30.43	
PTCA	22- 31.88	10- 14.49	
Mortality	10- 14.49	03- 04.34	0.001

Discussion:

Clinical trials conducted at various places in the world have definitely shown an association between Diabetes Mellitus type 2 and Heart Failure independent of hypertension, atherosclerosis, coronary artery disease and valvular heart disease. But this fact is not recognized by all over the world. HF developing in the DM patients significantly contributes to the morbidity and mortality. Hence prevention is possible to bring the awareness of HF among the DM patient and initiate early diagnosis and treatment to avoid mortality. The etiology of HF in DM patients is still to be elucidated thoroughly. It is proved to be multifactorial involving cellular, molecular and metabolic factors. In addition there are no definite guidelines for such patients to be treated. The present study was conducted to study the clinical manifestations of Heart Failure in diabetes type 2 patients and compare them with Heart failure in non DM patients in terms of diagnosis, and management. In this study the 138 patients were divided into Group "A" (69 patients) diagnosed with HF and Diabetes Mellitus type 2 patients and Group B with only HF. Among them 41 (59.42%) males and 28 (40.57%) females with a male to female ratio of 1.46:1 in Group A and in Group "B" (69 patients) with NON-Diabetes Mellitus, the males were 51 (73.91%) males and 18 (26.08%) females with a male to female ratio of 2.83:1. The overall male to female ratio among the 138 patients was 2:1. The chi square test applied to the incidence of HF among the two groups was found to be significant with p value at 0.020 with chi square statistic at 5.34. (p significant at <0.05) The incidence of HF at class intervals of 10 years starting at 25 years to 74 years in group A was: 06, 14, 17, 20 and 12.

Corresponding incidence in group B for the same age intervals was 1, 05, 11, 25 and 27. The chi square statistic was 15.44 and the p value was 0.0038. (Table 1) The result was significant at p <0.05. Other demographic factors like BMI, Social status and Educational status were tabulated in the table 1 and were found to be not significant statistically with p value more than 0.05. The prevalence rate of HF with DM in the previous studies in the institute was 22.54% and without DM was 18.16%. In similar studies by SOLVD Investigators, Yusuf S, Pitt B, Davis CE [24], Zannad F, McMurray JJ [25] and Sarma S, Mentz RJ [26] they found prevalence of HF was nearly 25% in general and in hospitalized patients it was 40%. The authors Greenberg BH,

Abraham WT et al [27] also found that there was increased incidence of death; prolonged hospitalization among the HF patients with DM. presence of DM in HF patients is associated with an increased risk of death, hospitalization, and prolonged hospital stay. The European Heart Failure Association from their long term registry of 9,428 patients with HF; with DM (constituting 36.5% of the total) or without DM (63.5% of the total) attending the outpatient department showed one year all cause deaths 21.8% versus 06.57%. (28) In this study Glycemic control in patients with Diabetes Mellitus type 2 was correlated with the small vessel disease and coronary artery block was studied and found that TVD in 32 (46.37%) patients, DVD in 21 (30.43%) patients and SVD in 11 (15.94%) patients. The degree of coronary arteries block was 96 to 100% in 58 (84.05%) patients of Group A and 34 (49.27%) patients of the Group B which was statistically significant with p value less than 0.05. (Table 4) Similarly Dauriz M, Targher G, Laroche C et al [28] found that there was a significant and independent association between higher values of glycosylated hemoglobin (HbA1c) levels and the risk of 1-year survival outcomes in patients with DM and HF. In a study by Van de Wal et al. [29] who evaluated 94 stable chronic heart failure patients with mean age of 69 ± 12 years; Ischaemia was underlying cause of heart failure in 61 patients showed Microalbuminuria in 32% of patients, which is significantly higher than in the general population. But no association was found with either renal or neurohormonal parameters. The Authors from this study suggested that the endothelial dysfunction and vascular permeability could be the cause for Microalbuminuria. [28] Kawel N, et al [30] studied on the correlation between GT and the Mortality of HF patients associated with DM; they concluded that Global wall thickness (GT) can be calculated from LV mass and end-diastolic volume. [27] GT was reported as the most prognostic measure in patients with normal findings of volume, mass and ejection fraction and no scar. In this study GT was significantly higher among the Group A patients when compared to Group B patients even among the female patients. (Table 3) The CAG findings showed TVD in 32 (46.37%) patients, DVD in 21 (30.43%) patients and SVD in 11 (15.94%) patients. The degree of coronary arteries block was 96 to 100% in 58 (84.05%) patients of Group A and 34 (49.27%) patients of the Group B which was statistically significant with p value less than 0.05. (Table 4) Lindvall B, Brorsson B et al [31] in 1999 published that

Diabetic patients more often had depressed myocardial function (EF<35%); 12% and 8%, respectively (p<0.01), and more extensive coronary artery disease (left main/3-VD; 48% vs. 37%, p<0.001). The mortality during the subsequent 21 months was 7.9% among diabetic patients and 3.6% among non-diabetic patients (p<0.001). In this study the mortality was Mortality was 10 (14.49%) patients of Group A and 03 (04.34%) patients of Group B. (Table 5) But a large size meta-analysis of 381,725 patients including both acute and chronic HF over a median period of follow-up of 3 years by Hussein MF [32], it was stated that DM was associated with a higher risk of all-cause death (HR, 1.28; 95% CI, 1.21 to 1.35), CV death (HR, 1.34; 95% CI, 1.20 to 1.49), and hospitalization (HR, 1.35; 95% CI, 1.20 to 1.50), [29]; however the acute over chronic DM associated with HF, mortality and hospitalization was greater in the later than in the former group.

Conclusions:

Diabetes Mellitus is a risk factor for Heart Failure patients and menace of cardiac related mortality and morbidity. Severity of hyperglycemia was correlating with the severity of HF and was statistically significant (p value-0.05). 2D Echo results were helpful in the diagnosis of severity of HF and found to be more profound with patients of HF with DM; with p value less than 0.05. LVEF was less than 40% in patients of HF with DM when compared to HF patients without DM. CAG reports like Triple vessel disease (TVD), SVD and BVD were statistically significant with p value less than 0.05. Percentage of coronary artery block was 96 to 100% in patients with HF and DM. Mortality rate was higher in HF patients with DM than without DM.

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