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Assessment of Type 2 Diabetes Mellitus: Observational Study

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ABSTRACT

Diabetes mellitus (DM) poses a global health challenge with rising prevalence, leading to significant morbidity and mortality. This hospital-based cross-sectional observational study, conducted from December 2018 to May 2020, aimed to assess chronic complications in patients diagnosed with type 2 DM at admission. A total of 101 patients were enrolled after ethical clearance. Pearson's correlation coefficient guided the sample size determination. Demographic data, medical history, and extensive investigations, including HbA1c and serum albumin, were recorded. Statistical analysis employed SPSS 21, with a significance level set at $p < 0.05$. The majority were males (73.27%), aged 56-65 years (33.66%), with a mean diabetes duration of 12.91 years. HbA1c negatively correlated with serum albumin, serum creatinine, and age but positively with fasting and postprandial blood sugar. A significant negative correlation was found between HbA1c and serum albumin ($r = -0.12$, $p < 0.0001$). Albumin levels decreased with increasing HbA1c categories. The study emphasizes the prevalence of chronic complications at DM diagnosis and underscores the importance of early screening. A negative correlation between HbA1c and serum albumin suggests their potential utility as prognostic indicators. Further research is warranted to explore interventions targeting glycemic control and albumin levels in diabetic patients.

Keywords: Diabetes mellitus, HbA1c, Serum albumin, Chronic complications.

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INTRODUCTION

Diabetes mellitus (DM) can affect the people throughout the world, Even though diabetes has been known since a long time, only in the last few decades new discoveries have provided measures to minimize the morbidity and mortality. Diabetic ketoacidosis, which is a major fatal complication of diabetes, its occurrence has decreased due to the discovery of insulin. However, Diabetes is characterized by metabolic abnormalities along with long term microvascular and macrovascular complications. The prevalence of diabetes in developing countries is on the rise. It not only multiplies the risk of coronary artery disease but it also increases the incidence of Cerebrovascular accidents. End stage renal disease and also non traumatic limb amputations [1-3].

Chronic complications of diabetes are often present at the time of diagnosis of Diabetes mellitus. These complications are the major cause of morbidity and mortality. Currently there is limited nation-wide data regarding the prevalence of chronic complications in diabetic patients at the time of diagnosis [4]. By educating the high-risk persons about diabetes related complications, they can be encouraged for seeking medical consultation earlier. Diabetes associated complications can be prevented only up to a certain point. Also, once the complications are set in, treating hyperglycaemia alone itself is not sufficient and even if we treat aggressively, these complications will go on progressing further. This emphasizes on more aggressive screening for both microvascular as well as macrovascular complications at the time of diagnosis [5].

MATERIAL AND METHODOLOGY

The hospital-based cross-sectional observational study was conducted at Krishna Hospital and Medical Research Centre, Karad, over an 18-month period from December 1, 2018, to May 31, 2020. The study, focusing on patients admitted to the ward diagnosed with type 2 diabetes mellitus (DM), obtained ethical clearance from the Institutional Ethics and Protocol Committee, with the assigned protocol number 0253/2018-2019. A total of 101 patients were enrolled in the study.

The sample size calculation was based on Pearson's correlation coefficient from a previous study by S. Tiwari et al, indicating a significant negative correlation between HbA1c and serum albumin (r= -0.284). Using the formula $N = [(Z\alpha+Z\beta)/C]2 + 3$, with $Z\alpha = 1.960$, $Z\beta = 0.842$, and $C = 0.292$, the total sample size required was determined to be 95.

The inclusion criteria comprised males and females aged over 18 years with confirmed type 2 DM. Conversely, exclusion criteria were established, excluding patients with type 1 diabetes mellitus, severe anemia, renal impairment (serum creatinine > 2mg/dl), pregnancy, chronic liver disease (total bilirubin > 3mg/dl), hypertriglyceridemia, and iron or vitamin B12 deficiency.

The method involved recording demographic information, past medical history, personal history, and general examination findings, including weight, height, and BMI, using a standard, pre-validated semi-structured case record proforma. Furthermore, all enrolled patients underwent a series of investigations, including hemoglobin, total leukocyte count, platelet count, urine routine, blood urea, serum creatinine, random blood sugar, fasting blood sugar, postprandial blood sugar, liver function tests, serum albumin, and HbA1c. These investigations were conducted using various methods such as automated 3-part cell analyzers and specific biochemical assays.

The statistical analysis was performed using the statistical package for social science (SPSS) 21(trial version) for windows. The data was recorded in study Performa sheet and was entered into the statistical software for further evaluation. The data was arranged in the form of tables and groups for frequency analysis. Data was expressed as mean values ± standard deviations (SD), percentage for continuous variables. Frequency and proportions were reported for categorical variables. Chi square test was used and The 'P' value of <0.05 was considered statistically significant.

RESULTS

A total 73.27% (74) were males and 26.73% (27) were females in the present study. In the present study male gender was predominant compared to female with a male to female ratio of 1:0.36.

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In the present study the age distribution was assessed. It was observed that majority of the study subjects belonged to the age group of 56 to 65 years (33.66%), followed by 46 to 55 years (25.74%) then 66 to 75 years (18.81%) then more than 76 years (8.91%) The least number of patients were of the age group below 35 years that is 3.96% (4patients). The mean age of the study subjects was 59.78 ± 9.10 years.

The patients were grouped according to the history of duration of Type 2 DM. History of the duration of diabetes mellitus was noted for each patient. 5.94%(6) patients had duration less than 5 years. 32.67% (33) patients had duration between 6 to 10 years. 27.72%33.66% (34) patients had duration of diabetes between 11 to 15 years. 27.72% (28) patients had duration of more than 15 years. 32.67%. The mean duration of Type 2 DM is 12.91 years

In the present study it was observed that the mean HbA1c value was 8.17% with the standard deviation of 1.70. The minimum value observed was 5.2% and the maximum value observed was 13.7%.

Table 1: Assessment - HbA1c

	HbA1c
Mean	8.175
Median	8.000
Mode	8.3
Std. Deviation	1.7053
Variance	2.908
Minimum	5.2
Maximum	13.7

Table 2: Assessment - HbA1c and numerical variables

Parameters	Pearson's correlation coefficient ('*r*')
Serum albumin	-0.12
Duration of Type 2 DM	-0.18
BSL- Fasting	0.02
BSL- PP	0.01
Serum creatinine	-0.09
Age	-0.16

In the present study, the correlation between HbA1c and the other parameters was observed. HbA1c is negatively correlated to serum albumin, serum creatinine and age of the study subject and duration of Type 2 DM. HbA1c is positively correlated to BSL fasting and PP.

The present study aimed at seeing the relation between serum albumin and HbA1c levels in patients of type 2 Diabetes mellitus. The results were analyzed using Pearson's correlation method. A NEGATIVE correlation was observed among both the parameters *('r'* value is -0.12 and P-value is < 0.0001).

Table 3: Assessment - serum albumin and HbA1c

HbA1c		
Albumin	**Pearson Correlation**	**-0.12**
	Sig. (2-tailed)	**<0.0001**
	n	101

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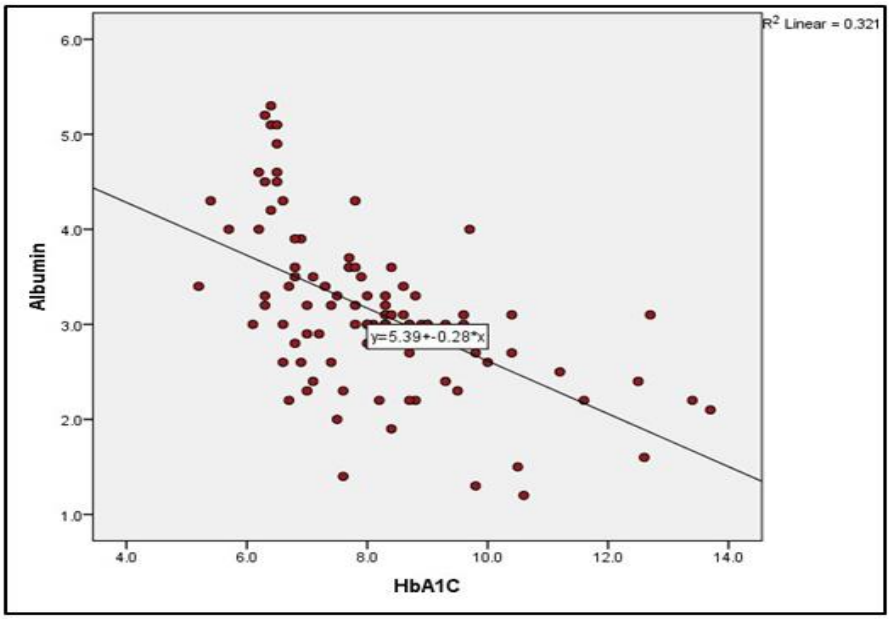
Fig 1 HbA1c levels and mean albumin levels

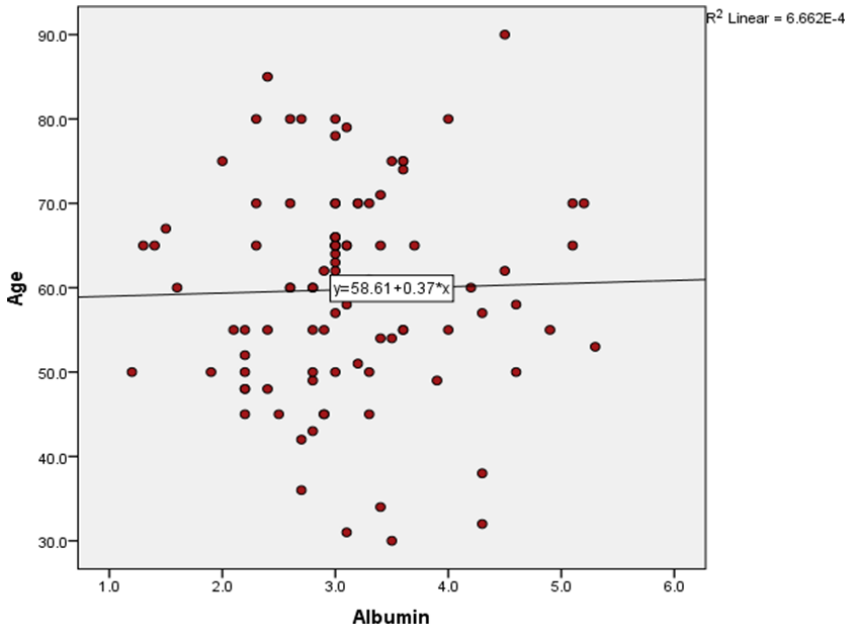


In the present study, the mean albumin levels were compared among HbA1c categories. It was observed that the mean albumin level among less than 7 HbA1c group was 3.89 ± 0.86, group participants with HbA1cbetween 7 to 9 had mean albumin levels of 2.97 ± 0.51, and among the subjects with HbA1c more than 9 had mean albumin levels of 2.48 ± 0.67. It was observed that patients who had higher levels of HbA1c had lower levels of serum albumin, and patients who had HbA1c less than 7%, they had normal or near normal serum albumin levels.

Table 4: Assessment - age and serum albumin

Pearsons's correlation		Albumin
Age	**Pearson Correlation**	0.026
	Sig. (2-tailed)	0.798
	N	101

Figure 2: Correlation between serum albumin and age



A weak negative correlation was observed among both the parameters *('r'* value is 0.026 and P-value is 0.798).

Discussion

In the present study it was observed that majority of the study subjects belonged to the age group of 56-65 years (33.66%), followed by 46-55 years (25.74%), followed by 66 to 75 years (18.81%). The mean age of the study subjects was 59.78 years. The study by Tiwari S et al, observed that the mean age of the subjects was 38.9 ± 13.2 year which is lower than the present study [6]. The study by Sarojini C et al observed that the mean age of subjects was 40.1 ± which is lower than the present study [6]. The study by Santiago Rodriguez et al observed that the mean age of subjects was 50.90 ±10.3 which is lower than the present study [7]. In the present study it was observed that majority of the study subjects were males (73.27%), while 26.73% subjects were females. Male: female ratio observed in the present study was 1:0.36. In the study by Tiwari S et al**,** the majority of the study subjects were males (80%) which is higher than the present study [6]. In the study by Sarojini C et al, majority of study subjects were males (64%) which is similar to the present study. In the study by Santiago Rodriguez et al, majority of the study subjects were males (68%) which is similar to the present study [7].

In the present study the mean duration of diabetes mellitus was 12.91 ± 7.10 years. The study found the most common duration of diabetes to be 11 to 15 years seen in 34 study subjects (33.66%), followed by 6 to 10 years seen in 33 study subjects (32.67%), more than 15 years in 28 study subjects (27.72%) and less than 5 years in 6 study subjects (5.94%). In the study by Shalbha Tiwari et al, majority of the study subjects (32%) had duration of Diabetes mellitus of 5-10 years which is similar to the present study [6]. In the study by Sarojini C et al, majority of study subjects (36%) had duration of Diabetes mellitus of 10-15 years which is similar to the present study [8].

In the study the study subjects were categorized according to their HbA1C levels. It was observed that the mean HbA1c level was 8.175±1.7053. It was observed that 48 (47.5%) study subjects had HbA1c levels between 7 to 9, whereas 31(30.7%) study subjects had the value less than 7, and 22(21.8%) subjects had values more than 9. In the present study the HbA1c levels were compared with age of the subjects. A weak negative correlation among both the parameters (r value is -0.165 and p-value is 0.099). In the study by Sarojini C et al, 60% study subjects had HbA1c more than 7% which is similar to the present study 40% patients had HbA1c less than 7% which is similar to the present study [8]. In the study by Santiago Rodriguez et al, it was observed that 44.6% study subjects had HbA1c less than 7%, 18.6% study subjects had HbA1c between 7 to 9% and 36.8% patients had HbA1c more than 9% which is similar to the present study [8].

In the present study, the mean albumin levels were compared among HbA1c categories. It was observed that the mean albumin level among less than 7 HbA1c group was 3.89 ± 0.86, a group of subjects with HbA1c between 7 to 9 had mean albumin levels of 2.97 ± 0.51, and among the subjects with HbA1c more than 9 had mean albumin levels of 2.48 ± 0.67. In the present study the serum albumin levels were compared with HbA1c levels. The results were analysed using Pearson's corelation method. A NEGATIVE correlation was observed among both the parameters *('r'* value is -0.12 and p-value is < 0.0001). Tiwari S et al**,** also studied the correlation between serum albumin and HbA1c levels, they observed that there was a significant negative correlation between HbA1c and albumin concentration ('*r*' = −0.284; '*P* '< 0.001) which is consistent with the results in the present study [6]. In the study by Santiago Rodriguez et al, the correlation between serum albumin and HbA1c levels was studied. There was a significant negative correlation between HbA1c and serum albumin concentration ('P' <0.001) which is consistent with the results in the present study [9]. In the study conducted by Sarojini C. The study demonstrates that there is a statistically negative correlation between HbA1c and serum albumin levels [8]. Xaio Jing Feng et al observed that HbA1c is inversely associated with serum albumin levels in the patients of Type 2 DM ('P' < 000.1) [10-12].

CONCLUSION

In the present study, population was largely confined to the 5th and 6 th decade with predominance of male gender. Hypertension was the most common comorbidity seen along with type 2 diabetes mellitus. Obesity was the second most common comorbidity. In this study a comparison between serum albumin and glycosylated hemoglobin was done, it was observed that patients who had higher levels of

glycosylated hemoglobin had relatively lower levels of serum albumin and patients who had lower levels of glycosylated hemoglobin had normal or near normal serum albumin levels.

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