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Research Article

Correlation between COVID-19 Disease Severity and its Outcome in Diabetes Mellitus Patients

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A B S T R A C T

Introduction: Diabetes mellitus is a common metabolic disorder that contributes a significant burden on the healthcare system. It is one of the major comorbidities associated with COVID-19 and affects its severity.

Aim: To study the correlation between COVID-19 disease severity and its outcome in diabetes mellitus patients and to correlate HbA1C with COVID-19 disease severity, NEWS, Ct RT-PCR value and clinical outcome in COVID-19 diabetic patients

Settings and Design: This was a prospective cross-sectional observational study conducted in the Department of Medicine, Maulana Azad Medical College.

Method and Material: The study included a total of 60 subjects 30 in the diabetic group and 30 in the non-diabetic group. NEWS was calculated on the day of admission. HbA1C was correlated with disease severity, NEWS, Ct RT-PCR value and clinical outcome of patients. The data gathered were processed by SPSS version 25. The correlation between HbA1C, disease severity, NEWS, and Ct RT-PCR value was determined using Pearson correlation coefficient.

Results: Diabetic patients have more severe COVID-19 disease. NEWS at admission was higher in these patients. Higher HbA1C is associated with severe disease. HbA1C positively correlates with NEWS but negatively correlates with Ct RT-PCR value. Incidences of organ injury and inflammatory markers were higher in diabetic patients. Diabetes was associated with more complications and worse outcomes.

Conclusions: Diabetic patients are more susceptible to the development of severe and worse outcomes in COVID.

Keywords: SARS-CoV-2, News, HbA1C, RT-PCR Cycle Threshold Value

Introduction

SARS-CoV-2, a novel coronavirus was recognised as a causative agent for coronavirus disease (COVID-19) on December 2019 in Wuhan, China.[1] World Health Organization declared COVID-19 a pandemic on 11 March 2020. SARS-CoV-2 belongs to the coronaviruses family that is enveloped, positive sense, single-stranded RNA virus that infects a variety of human and animal hosts. Previously six members of the coronaviruses family were known. SARS-CoV-2 is the recently discovered seventh member of the family that can affect humans. It causes a variety of illness that ranges from respiratory tract infection in humans to gastrointestinal infection, demyelination, and encephalitis in animals.[2] Old age, hypertension, cardiovascular disease, diabetes mellitus, obesity etc are associated with a higher risk of developing severe disease and increased risk of mortality.

Various studies have demonstrated that diabetes mellitus is associated with an increased risk of developing infections such as influenza and pneumonia.[3] Few studies have elaborated on the impact of diabetes mellitus on disease severity and clinical outcome in COVID-19 patients. Comorbidities associated with diabetes such as nephropathy, cardiovascular syndrome, and metabolic syndrome contribute to severe outcomes in COVID-19. Diabetes mellitus and SARS-CoV-2 infection both are associated with hyperinflammatory response and hypercoagulable state which contribute to severe outcomes and rapid deterioration in these patients. The prevalence of diabetes mellitus in COVID-19 patients in various Chinese studies ranges from 5%-20%.[4]

Many studies have shown a higher incidence of severe COVID-19 disease in diabetic patients as compared to non-diabetic patients (13.8%-40.0% vs 3.5%-11.0%).[5] This study is intended to find out the correlation between COVID-19 disease severity and its outcome in diabetes mellitus patients. In this study, HbA1C has been associated with different categories of COVID-19 disease severity, NEWS, COVID-19 Ct RT-PCR value and clinical outcome as there is a paucity of data regarding the same in literature.

Subjects and Methods

It was a cross-sectional descriptive study which enrolled 60 subjects, after the required clearance from the Institutional Ethics Committee. It was conducted in department of medicine, Maulana Azad Medical College from April 2022 to September 2022. Adults between 18-65 years who were COVID-19 positive by reverse transcriptase polymerase chain reaction (RT-PCR) were included as subjects in this study after taking informed consent. The exclusion criteria were patients with obesity (BMI > 30), renal disease, hepatic disease, coronary artery disease, and other acute medical or surgical conditions. Patients with shock, acute respiratory distress, multiorgan dysfunction syndrome and patients admitted in the intensive care unit were also excluded from the study. All the admitted patients were provided treatment and care in line with the standards of care prescribed by the Ministry of Health and Family Welfare, Government of India (MoHFW).[6]

A total of 60 subjects were enrolled and they were divided equally into two groups based on whether they were diabetic or not. In both groups, a detailed history and examination were done regarding the history of duration of diabetes mellitus and severity of COVID-19 disease. The average National Early Warning Score (NEWS) was calculated on the day of admission. Blood investigations including complete blood count (CBC), kidney function test (KFT), liver function test (LFT), PT-INR, D-dimer, HbA1C, fasting and post-prandial blood sugar, C-reactive protein (CRP), interleukin-6 (IL-6), serum ferritin and serum procalcitonin level were done. The RT-PCR sample was sent for SARS-CoV-2 and the cycle threshold (Ct) values of E gene and RdRp gene were obtained.

NEWS was first developed in 2012 as a simple tool for the early detection of in-hospital patient deterioration.[7] It is an easy scoring system wherein a rating is assigned to physiological measurements such as peripheral oxygen saturation, respiratory rate (RR), need for supplemental oxygen, systolic blood pressure (SBP), body temperature, heart rate (HR) and neurological status on the Alert, Verbal, Painful and Unresponsive (AVPU) scale. Since all vital signs are included in a single, continuous variable, it provides a comprehensive picture of the actual status of a patient. It has been validated in hospital wards to detect patients with increased risk of unplanned ICU admission, cardiac arrest, and in-hospital death within 24 h.[8]

Patients were monitored throughout the admission for clinical scoring (NEWS) and to study the outcomes. NEWS from 0-4 was considered as low, 5-6 as medium, and equal to or more than 7 as high. Various outcomes were studied such as time from admission to recovery, death, first oxygen requirement, deterioration of NEWS from low/medium to high category, intensive care unit (ICU) transfer, development of any complication (sepsis, respiratory failure, acute myocardial infarction, acute renal failure, acute liver failure, acidosis, secondary infection, coagulopathy, bleeding etc).

Statistical Analysis

The data obtained were processed by Statistical Package for Social Sciences (SPSS) version 25, tabulated and represented graphically for interpretation. Continuous variables were presented as mean and standard deviation and were compared by Student t test. Categorical variables were

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presented as frequencies or per cent values and were compared by Chi-square test. A p-value of less than 0.05 was considered significant for all tests. Correlation between the HbA1C value and other parameters (NEWS and Ct RT-PCR) of COVID-19 disease were analysed by Pearson correlation coefficient.

Results

The maximum number of patients in the non-diabetic and diabetic groups were in the age groups of 18-30 years and 51-60 years respectively. The mean age of patients in the non-diabetic group was 42.67 years and that in the diabetic group was 51.77 years. Non diabetic group had 73.3% (n = 22) males and 26.7% (n = 8) females whereas diabetic group had 46.7% (n = 14) males and 53.3% (n = 16) females (Table 1). Based on the guidelines of MoHFW, patients were categorised into mild (SpO_2 ≥ 94%), moderate (SpO_2 - 91-93%) and severe categories (SpO_2 < 90%). Control/ non-diabetic group had 60% (n = 18) in mild, 16.7% (n = 5) in moderate, and 23.3% (n = 7) in severe categories. Case/ diabetic group had 33.3% (n = 10) in mild, 13.3% (n = 4) in moderate, and 53.3% (n = 16) in severe categories.

The diabetic group had a significantly higher mean score (NEWS) at admission, of 6.10 (± 3.32) as compared to the non-diabetic group which had a mean score (NEWS) of 3.47 (± 3.28) with a p value of 0.001 (Table 1).

The mean HbA1C level in the non-diabetic group was 5.54% and in the diabetic group, it was 8.93%. Mean TLC, serum creatinine, serum ferritin, serum procalcitonin, IL-6, and CRP were higher in the diabetic group as compared to the non-diabetic group. CRP level was significantly higher in the diabetic group (p value = 0.01). Other parameters except serum glutamic-oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGPT) were higher in the diabetic group though not significant (Table 2). The mean value of HbA1C was 8.7 (± 2.01). It was lower in the mild category as compared to the moderate and severe categories (9.18 ± 2.22 and 9.01 ± 2.23 respectively) in the diabetic group. The non-diabetic group also had lower HbA1C in the mild category (5.32 ± 0.51) as compared to moderate and severe categories (6.0 ± 0.50 and 5.77 ± 0.61 respectively). Though HbA1C was lower in the mild category in both groups, it was significant only in the non-diabetic group (Table 3).

Table 1.Characteristics of Patients in Non-diabetes and Diabetes Group

Parameters	Non diabetes (n = 30)	Diabetes (n = 30)	P Value
Age (years) (mean ± SD)	42 ± 14.12	51.77 ± 8.92	0.01
Male gender	22 (73.3%)	14 (46.7%)	0.03
Female gender	8 (26.7%)	16 (53.3%)	0.03
Age-wise distribution (years)			
18-30	10 (33.3%)	0 (0.0%)	0.0006
31-40	3 (10.0%)	4 (13.3%)	0.69
41-50	7 (23.3%)	7 (23.3%)	1
51-60	7 (23.3%)	14 (46.7%)	0.59
61-65	3 (10.0%)	5 (16.7%)	0.44
Category-wise distribution			
Mild (SpO_2 ≥ 94%)	18 (60.0%)	10 (33.3%)	0.04
Moderate (SpO_2 - 93-91%)	5 (16.7%)	4 (13.3%)	0.7
Severe (SpO_2 < 90%)	7 (23.3%)	16 (53.3%)	0.01
Average NEWS (mean ± SD)	3.47 ± 3.28	6.10 ± 3.32	0.001

Table 2.Laboratory Parameters of Patients in Non-diabetes and Diabetes Group

Parameters	Non-diabetics (n = 30)	Diabetics (n = 30)	P Value
Biochemical profile (mean ± SD) HbA1C %	5.54 ± 0.58	8.93 ± 2.09	0.001
Total leukocyte count (cell/mm^3)	7780.67 ± 4023.25	9272.53± 4425.74	0.17
Creatinine (mg/dl)	0.72 ± 0.21	0.75 ± 0.30	0.95
SGOT (U/L)	72.93 ± 50.37	65.66 ± 42.32	0.56
SGPT (U/L)	75.26 ± 49.96	63.56 ± 51.62	0.22

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Serum ferritin (µ/dl)	414.98 ± 556.7	595.42 ± 641.85	0.08
Serum procalcitonin (ng/dl)	0.056 ± 0.063	0.102 ± 0.107	0.05
C Reactive protein (mg/dl)	46.30 ± 88.08	64.21 ± 79.79	0.01
IL-6 (pg/ml)	14.03 ± 19.73	21.62 ± 26.59	0.33
Ct RT-PCR value (mean ± SD)			
E gene	27.17 ± 4.62	22.73 ± 4.25	0.001
RdRp gene	27.70 ± 4.27	23.01 ± 3.93	0.001

Table 3.Mean HbA1C Levels in various Categories of COVID-19 Disease Severity and NEWS

Groups	Mild (SpO_2 > 94%)	Moderate (SpO_2 - 91-93%)	Severe (SpO_2 < 90%)	P Value
Non-diabetes	5.32 ± 0.51	6.0 ± 0.50	5.77 ± 0.61	0.03
Diabetes	8.7 ± 2.01	9.81 ± 2.22	9.01 ± 2.23	0.94

Table 4.Correlation of HbA1C with different Parameters

Parameters	Diabetes		Non-diabetes	
	R value	P value	R value	P value
Average NEWS	0.35	0.05	0.382	0.037
Ct RT-PCR value (E gene)	-0.10	0.61	-0.262	0.162
Ct RT-PCR value (RdRp gene)	-0.10	0.592	-0.245	0.192

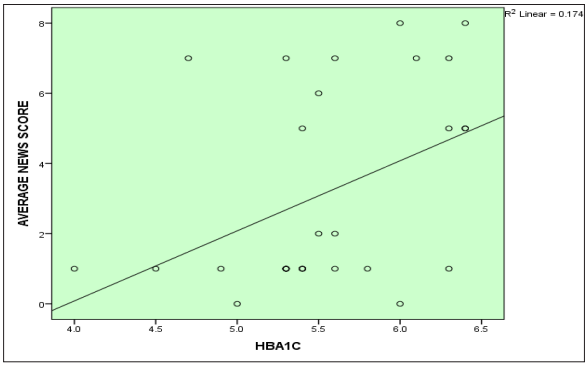

Figure 1.Correlation of HbA1C with NEWS in Diabetic Group

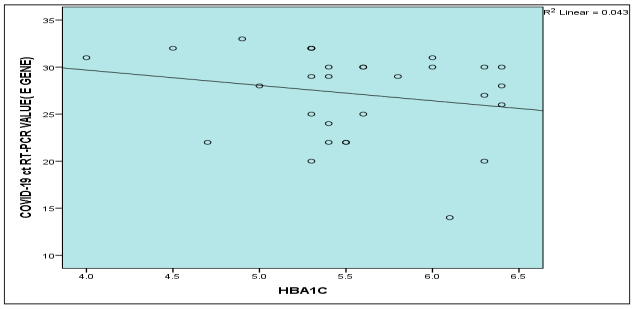

Figure 2.Correlation of HBA1C with COVID-19 Ct RT-PCR Value in Diabetic Group

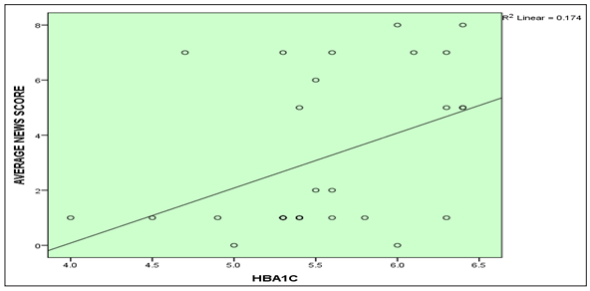

Figure 3.Correlation of HbA1C with NEWS in Non-diabetic Group

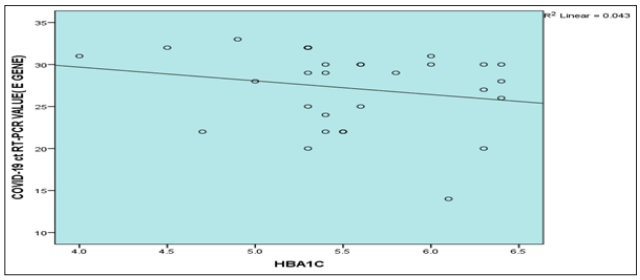

Figure 4.Correlation of HBA1C with COVID-19 Ct RT-PCR Value in Non-diabetic Group

The mean Ct value of RT-PCR for E gene was 27.17 and for RdRp gene, it was 27.70 in the non-diabetic group, whereas, in the diabetic group, it was 22.73 for E gene and 23.01 for RdRp gene. The cycle threshold valve was significantly lower in the diabetic group as compared to the non-diabetic group with a p value of 0.001. The correlation between HbA1C and different parameters is shown in Table 4. In the diabetic group, there was a positive correlation between HbA1C and average NEWS with an r value of 0.35 and a p value of 0.05 (Figure 1). There was a negative correlation between HbA1C and COVID-19 Ct RT-PCR value with an r value of -0.10 for both genes and a p value of 0.61 for E gene and 0.592 for RdRp gene (Figure 2). In the non-diabetic group also, there was a positive correlation between HbA1C and NEWS and a negative correlation between HbA1C and Ct RT-PCR value (Figures 3 and 4).

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In our study, mortality was seen in 3.3% (n = 1) of participants in the non-diabetic group and 6.7% (n = 2) of participants in the diabetic group. Mortality as an outcome was more in the diabetic group but was not significant (p value = 1.0). In our study, ICU requirement was present in 3.3% (n = 1) of participants in the non-diabetic group whereas, it was 20% (n = 6) in the diabetic group. Patients who initially didn't have oxygen requirements at admission but required supplemental oxygen during hospital stay constituted 3.3% (n = 1) of non-diabetic group and 7.7% (n = 2) of diabetic group. Patients who were initially in the mild/ moderate category at the time of admission but progressed to severe category were about 10% (n = 3) in the non-diabetic group and 13.3% (n = 4) in the diabetic group (Table 5). In our study, we compared various types of complications such as secondary infection, respiratory failure, acute kidney injury coagulopathy, and sepsis in both groups. Complications were more in the diabetic group (33%) than in the non-diabetic group (6.6%) and were significant (p value = 0.01). Individual complications in both groups are shown in Table 5.

In this study, we compared the number of days taken for different outcomes in both groups. The mean number of days from admission to recovery was 9.69 days in the non-diabetic group whereas, it was 15.69 days in the diabetic group. The number of days for death outcome was 15 days in one non-diabetic patient and 14.57 days in the diabetic group. The number of days taken for ICU transfer was 10 days in the non-diabetic group and 4.86 days in the diabetic group. The mean number of days taken for deterioration was 3.67 days in the non-diabetic group and 3 days in the diabetic group (Table 6). In our study, higher HbA1C was present in patients who had mortality as the outcome as compared to patients who survived (11.55 ± 0.49 vs 8.74 ± 2.04). Higher HbA1C was also present in those who had complications and oxygen requirements as compared to those who didn't (Table 7).

Table 5.Clinical Outcome of Patients in Non-diabetes and Diabetes Group

Parameters	Non-diabetics (n = 30) n (%)	Diabetics (n = 30) n (%)	P Value
Clinical outcome			
Survival	29 (96.7)	28 (93.3)	1.0
Death	1 (3.3)	2 (6.7)	1.0
Worsening during hospital stay			
Oxygen requirement	1 (3.3)	2 (6.7)	0.45
Mild/ moderate to severe	3 (10.0)	4 (13.3)	0.69
Category ICU transfer	1 (3.3)	6 (20.0)	0.04
Complication			
Absent	28 (93.33)	20 (66)	0.01
Present	2 (6.66)	10 (33)	0.01
Type of complication			
Secondary infection	0 (0)	1 (3.3)	0.32
Respiratory failure	0 (0)	2 (6.7)	0.152
Acute kidney injury	1 (3.3)	2 (6.7)	0.54
Coagulopathy	0 (0)	1 (3.3)	0.32
Sepsis	1 (3.3)	4 (13.3)	0.163

Table 6.Time taken for different Outcomes in both Non-diabetes and Diabetes Groups

Parameters	Non-Diabetics (N=30)	Diabetics (N=30)
Number of Days Required for Different Outcome from Admission (Mean±Sd)		
To Recovery	9.69±6.21	15.29±6.50
To Death	15	14.57±12.02
To Oxygen Requirement to Icu Transfer	4	4
To Development of any Complication	10	4.86±3.18
To Deterioration of News Score from Low/Moderate to High	26	3.92±1.89

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Table 7.Mean HbA1C Levels in Various Types of Outcomes in Diabetes Mellitus Patients

Outcomes	Yes	No
Survived	8.74 ± 2.04	11.55 ± 0.49
Complications	8.63 ± 2.04	9.31 ± 2.17
Oxygen requirement	8.87 ± 2.07	9.75 ± 3.04
Low/ moderate to severe category	8.96 ± 2.11	8.72 ± 2.26

Discussion

Diabetes mellitus is a well-known risk factor for increased risk for various infections such as influenza, pneumonia, H1N1, and MERS-CoV.[9] Through the present study, we tried to find out how diabetes mellitus affects COVID-19 disease severity and clinical outcome of COVID-19 patients. In this study, we also tried to find out HbA1C levels in different categories of COVID-19 disease severity as well as its association with average NEWS and COVID-19 Ct RT-PCR value.

The mean age of enrolled patients in the control/ non-diabetes group was 42.67 years and in the case/ diabetes group was 51.77 years in our study. Our study included a population belonging to 18-65 years of age to reduce the chances of errors owing to the advanced age-related increase in morbidity and mortality. More number of patients of the severe category (53.3%) were seen in the diabetic group as compared to the non-diabetic group (23.3%). This is in consensus with the study done by Wu J et al. and Zhang Y et al. who also demonstrated that more percentage of patients in the diabetic group belonged to the severe category.[10,11]

We also found that at admission, diabetic group had a significantly higher mean average NEWS (6.10 ± 3.32) as compared to the non-diabetic group (3.47 ± 3.28) with a p value of 0.001. A study conducted by Chung SM et al. also found that NEWS was higher in diabetes patients (4.0 ± 4.2) as compared to non-diabetes patients (1.9 ± 2.1) with a p value of 0.015 suggesting that diabetic patients are prone to develop more severe disease.[12] In COVID-19, the underlying pathways linking diabetes and illness severity are likely complicated and complex. Diabetes patients have defective innate and adaptive immunity, a hyperinflammatory response associated with hyperglycaemia, and a restrictive type of lung dysfunction with decreased pulmonary diffusion capacity and impaired gaseous exchange.

Diabetic patients have hyperinflammation and exacerbated cytokine storm syndrome as a result of altered immune responses leading to an increase in inflammatory markers. ACE-2 receptor is expressed in a variety of cells and tissues in the body such as vascular endothelial and smooth muscle cells, glomerular endothelium, podocytes and proximal tubule cells, cholangiocytes and hepatocytes, lung epithelial and alveolar cells, enterocytes and myocardial cells etc.[13] A study by Roca-Ho H et al. showed that patients with diabetes have an increased expression of ACE-2 receptor in these tissues.[14] All these mechanisms lead to an increase in organ injury in diabetic patients infected with COVID-19. In our study, TLC, creatinine and all the inflammatory markers were higher in the diabetic group as compared to the non-diabetic group which is similar to the results of studies by Zhang Y et al and Yan Y et al.[11,15]

Our study showed higher HbA1C levels in the severe category as compared to the mild category, however, it was not significant. A study conducted by Ren H et al. also showed similar findings that patients with severe disease had higher HbA1C values (6.7% vs 6.0%).[16] In our study HbA1C correlated positively with NEWS in both diabetic and non diabetic group indicating severity score increases as HbA1C increases. A study conducted by Mithal A et al. showed that baseline HbA1C correlated significantly with outcome severity scores (r = 0.136, p = 0.013) but in this study, the WHO ordinal scale for clinical improvement was used for accessing COVID-19 disease severity instead of NEWS.[17] A study conducted by Wang Z et al. showed that the HbA1C value was negatively correlated with oxygen saturation of patients with an r value of -0.22 and a p value of 0.01.[18] Hyperglycaemia induced increase in advanced glycation end product lead to increase in reactive oxygen species, reactive nitrogen species, lipid peroxidation and mitochondrial dysfunction has been associated with severe and rapid clinical deterioration in covid-19 diabetic patients.

Ct value has been related to the severity and course of COVID-19 disease. A study by Yu X et al. showed that baseline viral load is directly related to the severity of disease progression in COVID-19 and patients with higher baseline viral loads are more likely to develop a severe disease later.[19] A study conducted by Rajyalakshmi B et al. found an inverse correlation between Ct value and mortality, need for ICU admission, duration of ICU stay, and incidence of shock.[20] Magleby R et al. also showed that a Ct value less than 25 was significantly associated with increased risk for severe disease, hospitalization, and mortality.[21] In our study, the mean cycle threshold value was significantly lower in the diabetic group as compared to the non-diabetic group (p = 0.001). There was a negative correlation between HbA1C and Ct value with an r value of -0.10 for both genes but it was not significant.

As seen in our study, the diabetic group had more mortality (6.7% vs 3.3%) and ICU requirement (20% vs 3.3%) as compared to the non-diabetic group. A study conducted by

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Chung SM et al. also showed almost similar findings that ICU requirement was more in diabetic patients (27.6% vs 6.2%).[12] Yan Y et al. also observed that diabetic patients had higher ICU requirements, more need of mechanical ventilation, and higher mortality.[15] In our study, more number of diabetic patients required oxygen supplementation (6.7% vs 3.3%) and progressed to severe category (13.3% vs 10.0%) during hospitalisation. We compared various types of complications such as secondary infection, respiratory failure, acute kidney injury, coagulopathy, and sepsis in both groups. More complications were present in the diabetic group as compared to the non-diabetic group (33% vs 6.66%). A study conducted by Chung SM et al. also demonstrated similar findings that acute respiratory distress syndrome, septic shock, acute kidney injury, and acute cardiac injury were significantly higher in the diabetic group.[12]

It was seen in the present study that the mean number of days for recovery and death outcome was greater (15.29 vs 9.69) and lower (14.57 vs 15) respectively in the diabetic group. The number of days taken for other outcomes such as ICU transfer, oxygen requirement, development of complications, and deterioration of NEWS was lower in the diabetic group as compared to the non-diabetic group. Zhang Y et al. also found that recovery occurred later in the diabetic group (26.3 days) as compared to the non-diabetic group (23 days) and death occurred earlier in the diabetic group (12.4 days) as compared to the non-diabetic group (16.2 days).[11] We also found that higher HbA1C was associated with more mortality, more development of complications, and oxygen requirement.

Conclusion

Diabetic patients with COVID-19 have an increased risk of more adverse outcomes and higher mortality. Due to the significant prevalence of diabetes mellitus all over the world, these people form a large vulnerable part of the COVID-19 population. People with diabetes are likely to have a worse prognosis as a result of immune dysfunction, restrictive type of lung dysfunction, other complications associated with diabetes, increased risk of secondary infection and susceptibility to COVID-19. Peoples with diabetes are more susceptible to severe disease as compared to non-diabetics. HbA1C correlates positively with NEWS and negatively with Ct RT-PCR value. The sample size taken in our study was small and this reduced the statistical significance of our study, hence it was not possible to estimate the accuracy of the data obtained and corroborate it with the larger population.

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