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Original Research Article

AGE AND HBA1C IN PREDICTING MAJOR ADVERSE OUTCOME IN INDIAN HOSPITALISED PATIENTS WITH COVID-19 INFECTION: A PROGNOSTIC CLUE

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ABSTRACT

Background: In Following rapid spread of COVID-19, WHO on March 11, 2020, declared COVID-19 a global pandemic. Many earlier studies outside India have shown more aggressive course of COVID-19 pneumonia in diabetic patients. **Material and methods:** A observational study was carried out at Mahatma Gandhi Medical College and Hospital, Jaipur. Data from electronic medical records of seven thirty-one patient admitted from 15 October 2020 to 30 November 2020 were reviewed and analysed. **Results:** Patients with diabetes had significantly high risk of suffering from major adverse events (composite of Oxygen requirement, mechanical ventilation, and death) compared to those without diabetes. No significant difference in mortality rates was observed between two groups in our cohort. No significant difference in mortality rates was observed between two groups in our cohort. ROC analysis has shown that Hba1c > 5.77 % at the time of admission and age > 50 years have sensitivity of 89 % sensitivity of major adverse events in Covid 19 pneumonia. **Conclusion:** Indian diabetic patients with or without pre-existing comorbidity had more severe illness from COVID-19 than those without diabetes during hospital admission. Covid 19 pneumonia patient with HBA1c ≥5. 77 % and age ≥ 50 years have higher risk of suffering from adverse events.

Keywords: Diabetes, Age, HbA1C, COVID-19, Major adverse outcome

INTRODUCTION

The novel coronavirus SARS-nCov2 pandemic initiated in Wuhan, China and has now engulfed all parts of the world. As of 31st December 2020, there have been more than 18 million documented infections and more than 1.8 million deaths from COVID 19. **(1)** SARS- CoV-2 is a positive- stranded RNA virus that is enclosed by a protein- decorated lipid bilayer. SARS- CoV-2 has 82% homology with human SARS- CoV, which led to severe acute respiratory syndrome (SARS) outbreak in the past. **(2)** In humans, the main entry receptor for SARS-CoV-2 is angiotensin- converting enzyme 2 (ACE2), which is highly expressed in lung alveolar cells, cardiac myocytes, vascular endothelium and various other cell types. **(3,4)** Main route of SARS- CoV-2 transmission in humans is through virus- bearing respiratory droplets.**(5)** Generally, patients with COVID-19 develop symptoms at 5–6 days after

infection. SARS- CoV-2 infection induces mild symptoms in the initial stage for about 2 weeks but has the potential to develop into severe illness, including a systemic inflammatory response syndrome, acute respiratory distress syndrome (ARDS), multi- organ involvement and shock.**(6)**

The morbidity and mortality of the disease has been observed to be higher in patients with comorbid conditions, particularly diabetes, hypertension, obesity, coronary artery disease, malignancy etc. **(7)** India has approximately 77 million people affected with diabetes, second to china in term of number of diabetic people. One in six people suffering from diabetes in the world resides in India.

India has been the second most affected country in terms of number of documented cases of COVID 19 pneumonia. Much younger demographic has been proposed as one of the reasons for a comparatively lower mortality in India. However, this advantage can get negated by a high prevalence of diabetes mellitus in the Indian population. This interplay of age and high prevalence of diabetes may affect the course of COVID 19 pneumonia in Indian patients. Our study aims to assess the impact of diabetes mellitus on the outcomes in hospitalised Indian patients with COVID 19 as well to see the to see the feasibility of using age and HBA1C for predicting the severity of the disease.

MATERIALS AND METHODS

This was a single-centre observational study of 731 with COVID-19 pneumonia patients, admitted during the month of October and November 2020 to Mahatma Gandhi Medical College & Hospital, Jaipur, one of the major hospitals designated to provide medical care for COVID-19 patients in Rajasthan.

Due approval was taken from Institutional Ethical Committee before undertaking the present study.

All patients admitted to the hospital with COVID-19 pneumonia confirmed by positive RT PCR test were included in the present study with following inclusion and exclusion criteria:

Inclusion criteria: Age 18 years and above

Exclusion criteria: Age less than 18 years, Patients having incomplete details in their electronic medical record.

Review of electronic record available in the Medical Record Department, Mahatma Gandhi Hospital, was done for patients admitted from 15 th October 2020 to 31st November 2020. All the details including demographic characteristics and clinical data was collected. Patients were classified diabetic and nondiabetic as per presence or absence of past history of diabetes or HBA1c $\geq$ 6.5 %. The major adverse outcome considered in the present was need for oxygen therapy, ventilatory requirement (both non-invasive and invasive) and death.

Data was entered in Microsoft Office Excel Worksheet. Chi square test was applied for qualitative data while t-test was applied for quantitative data.

RESULTS

In the present study, 767 patients were admitted at Mahatma Gandhi hospital with COVID 19 illness. Since the data of 36 patients was incomplete, they were excluded from the study and a total 731 patients were enrolled in the study. Out of 731 patients, 331 patients had pre-existing and/or recently diagnosed diabetes mellitus. Table 1 shows the demographic details of the patients in the present study. Median age of the study population was 60 years, with 63 years median age in patients with diabetes mellitus while 57 years in non-diabetic patients. Males were more than twice the number of females. Nearly half of all patients (49.8%) had other pre-existing comorbidities such as hypertension, coronary artery disease, chronic obstructive pulmonary disease, bronchial asthma, malignancy and cerebrovascular disease. The prevalence of other pre-existing comorbidities was significantly higher in diabetic patients (67 %) as compared with non-diabetics (36 %). Median duration of stay in the hospital was 7 days. In the present study, 48.64% of the diabetic patients with Covid 19 pneumonia had major adverse endpoints while only 25% of non-diabetic patients had major adverse endpoint (Odds ratio: 1.75). This difference was statistically highly significant (p value < 0.001). (Table 2) (Fig 1)

Table -1. Demographic details of the study population

	All patients	Patients with Diabetes Mellitus	Non-diabetic patients
n	731	331(45%)	400 (55%)
Median age (years)	60	63	57
M: F	2.6:1	2.3:1	2.88:1
HbA1c (mean in %)	7.1%	7.9%	5.75%
Other comorbidities*	364 (49.8%)	221 (66.8%)	143 (35.75%)
Duration of hospital stay (median days)	7 days	8 days	6 days

*-Hypertension, Coronary artery disease, Chronic obstructive pulmonary disease, Bronchial asthma, Malignancy, Cerebrovascular disease

Table 2: Distribution of diabetic and Non-diabetic mellitus COVID-19 patients according to Major adverse events (Primary end point)

Major adverse events	Diabetic N (%)	Non-diabetic N (%)	Chi square (df)	Odds Ratio	p value
Present	161 (48.64)	140 (35)	13.356 (1)	1.75 95% (CI= 1.30-2.36)	0.00
Absent	170 (51.35)	260 (65)			
Total	331 (100)	400 (100)			

Figure 1: Bar diagram showing Distribution of diabetic and Non-diabetic mellitus COVID-19 patients according to major adverse respiratory events

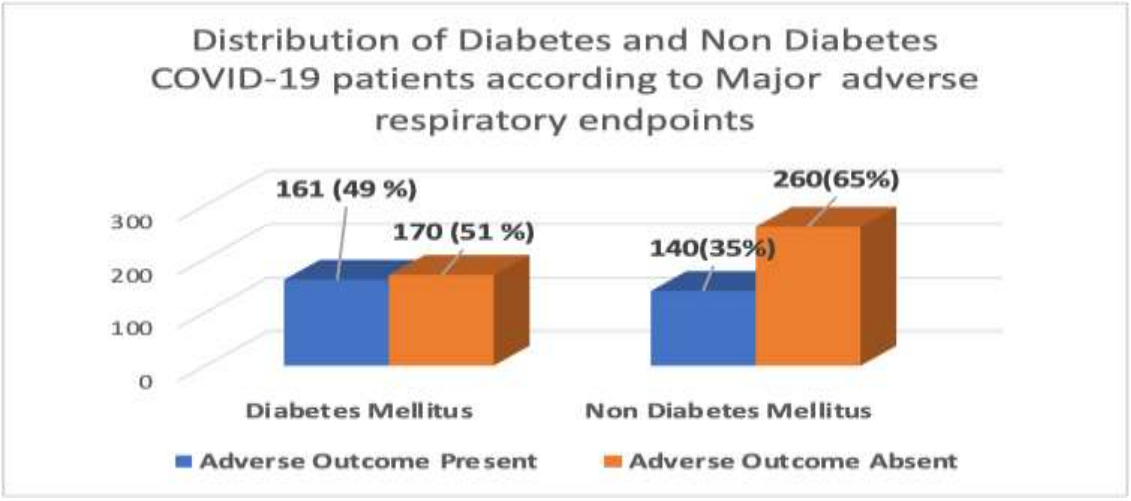


Table 3: Distribution of Diabetic and Non-diabetic mellitus COVID-19 patients according to Oxygen requirement, ventilator requirement and their living status (Secondary Endpoint)

Variables		Diabetic N (%)	Non-diabetic N (%)	Odds ratio	Chi square (df)	p value
Oxygen Requirement	Yes	113 (39.92)	98 (27.37)	**1.76** (1.26-2.45	10.721 (1)	**0.001**
	No	170 (60.07)	260 (72.62)			
Total		283 (100)	358 (100)			
Ventilatory Support	Yes	14 (4.71)	10 (2.71)	1.77 (0.77-4.04)	1.353 (1)	0.245
	No	283 (95.28)	358 (97.28)			
Total		297 (100)	368 (100)			
Death	Yes	34 (10.27)	32 (8)	1.31 (0.79-2.18)	0.878 (1)	0.349

Table 4: Mean HbA1C score of COVID-19 patients according to Oxygen requirement, ventilator requirement and their living status

Variables		Number of patients	HbA1C Score		p value
			Mean	Standard Deviation	
Oxygen Requirement	Yes	145	7.46	1.76	0.001
	No	227	6.85	1.75	
Ventilator Requirement	Yes	27	8.05	1.69	0.004
	No	345	7.015	1.76	
Death	Yes	21	7.69	1.56	0.110
	No	351	7.05	1.79	

Figure 2: Box and whiskers plot of HbA1C levels of patients having oxygen requirement

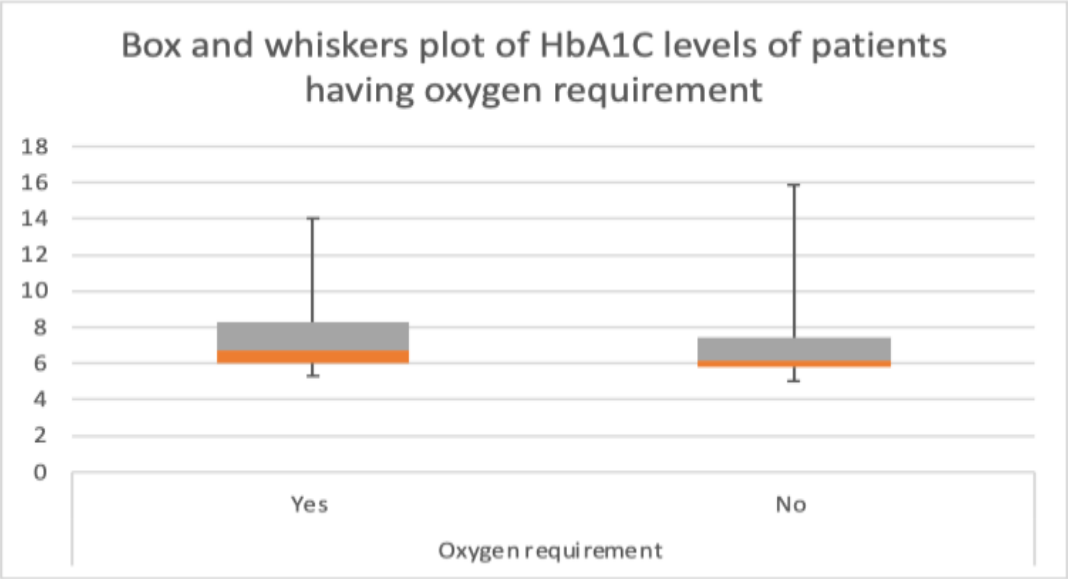
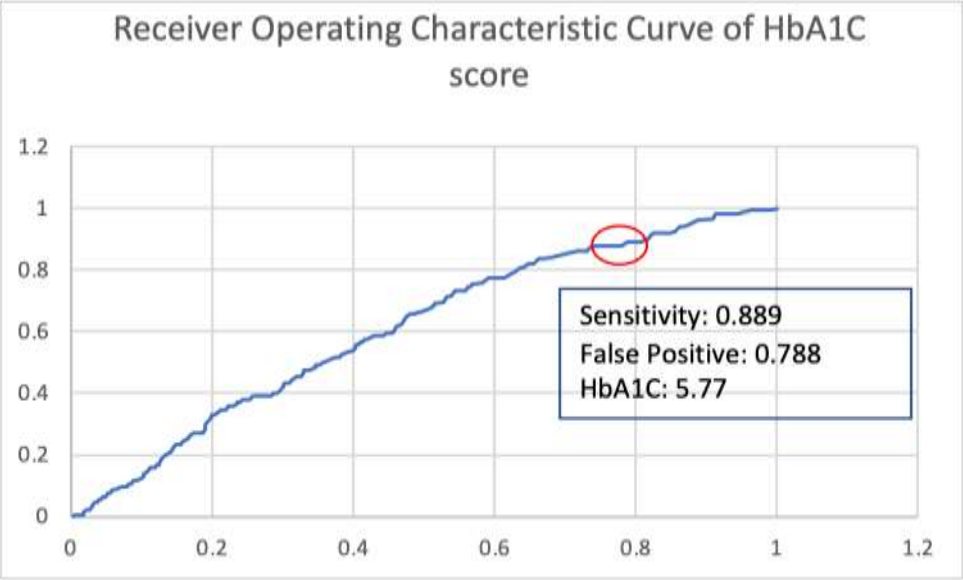


Figure 3: Receiver Operating Characteristic Curve of HbA1C score



Significantly higher number of COVID-19 patients with diabetes (39.92%) required oxygen therapy in comparison to non-diabetic patients (27.37%). On applying chi square test, this difference was found to be statistically significant. 4.71% diabetic patients required ventilator support in comparison 2.71% non-diabetic patients but this difference was not statistically significant. Mortality was seen in 10.27% diabetic patients in comparison to 8% non-diabetic patients but this difference was also not found to be statistically significant. (Table 3)

Table 4 shows the mean HbA1C score of COVID-19 patients according to Oxygen requirement, ventilator requirement and their living status. The mean HbA1C score of patients with oxygen requirement was 7.46 % while those without oxygen requirement was 6.85 %. (Fig 2) On applying t test, the difference was statistically significant (p value < 0.05). The mean HbA1C score of patients with

ventilator requirement was 8.05 while those without ventilator requirement was 7.015. On applying t test, the difference was statistically significant (p value < 0.05).

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Table 5: Mean Age of COVID-19 patients according to Oxygen requirement, ventilator requirement and their living status

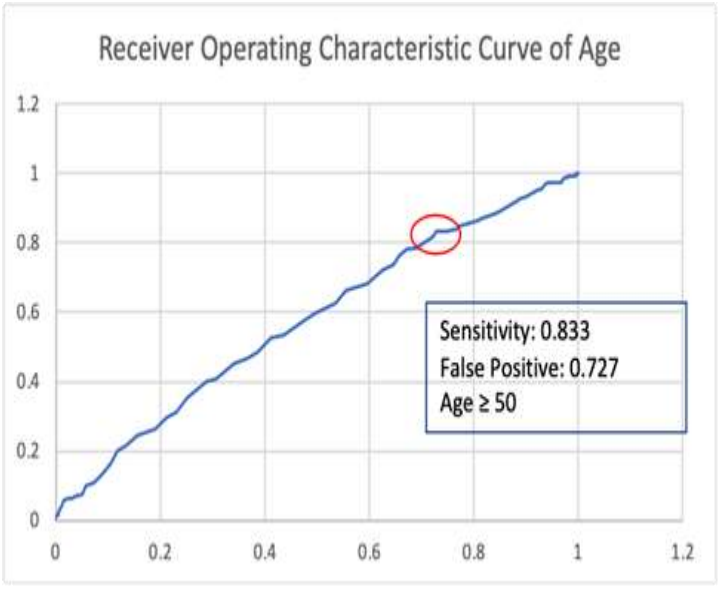
Variables		AGE (Years)			
		Number of patients	Mean	Standard Deviation	p value
Oxygen Requirement	Yes	301	61.6	14.29	0.000
	No	430	57.09	14.43	
Ventilator Requirement	Yes	82	63.56	14.71	0.001
	No	649	58.12	14.36	
Death	Yes	66	64.56	14.59	0.000
	No	665	58.15	14.37	

In the present study, on Receiver Operating characteristic (ROC) analysis, the cut off value of HbA1C was < 5.77 % with sensitivity of 89 %. Those patients with HbA1C < 5.77 have lesser chance of suffering from major adverse outcome in comparison to those with HbA1C > 5.77.(Fig 3)

Table 5 shows the mean Age of COVID-19 patients according to oxygen requirement, ventilator requirement and mortality. The mean HbA1C score of patients with oxygen requirement was 61 years while those without oxygen requirement was 57 years. On applying t test, the difference was statistically significant (p value < 0.05). The mean age of patients with ventilator requirement was 63 years while those without ventilator requirement 58 years. On applying t test, the difference was statistically significant (p value < 0.05). The mean age of patients died due to Covid 19 was 66 years while mean age of those who survived was 58 years.

In the present study, on Receiver Operating characteristic (ROC) analysis the cut off value of age was < 50 years with sensitivity of 88.9%. Those patients with age of <50 years have lesser chance of adverse outcome. (Fig 4)

Figure 4: Receiver Operating Characteristic Curve of Age



In the present study, 41.17% diabetic patients without pre-existing comorbidity had major adverse outcome compared to 29.43% non-diabetics without pre-existing comorbidities. On applying chi square test, the difference was found to be statistically significant. (p value < 0.05) (Table 6)

Table 6: Distribution of Diabetic and Non-diabetic COVID-19 patients without pre-existing comorbidity according to major adverse outcome

		Diabetic without comorbidity N (%) (n=102)	Non-Diabetic without Co-Morbidity N (%)	p value
Major adverse events	**Yes**	42 (41)	78 (29)	**0.035**
	No	60 (59)	187 (71)	
Total		102 (100)	265 (100)	

DISCUSSION

The COVID 19 pandemic has been the greatest threat to public health in nearly a century. The risk has been much more acute for the elderly and particularly those with pre-existing comorbidities. **(8)** India has the dubious distinction of being the diabetes capital of the world. At the same time, diabetic patients in India are much younger than those in the west. We observed a high proportion of diabetic patients in our study population as compared to previous studies. **(9-12)** This might be due to recruitment bias as only hospitalised patients were included in our study. Patients with comorbidities like diabetes even with milder illness were more likely to get admission. The diabetic patients in our study population had a higher median age than non-diabetics but was still lower than previously reported studies. **(13)** The mean HbA1c values in the diabetic group was 7.9% while that of non-diabetic patients was 5.75 % only. Sixty five percent patients with diabetes mellitus had co-morbidities while 35 % non-diabetic patients had co-morbidities. The average duration of stay in the hospital for diabetic patients was 8 days while non diabetic patients was 6 days only. The recovery from COVID-19 infection was slower in diabetic patients than non-diabetic patients.

We observed that patients of COVID 19 with diabetes were more likely to suffer from major adverse events during hospital course. This is consistent with literature previously reported **(9,14-17)** where diabetic patients have been observed to have higher risk for morbidity mortality with COVID19. A meta-analysis done by Ashish Kumar, Anil Arora et al concluded that diabetes in patients with COVID-19 is associated with two-fold increase in mortality as well as severity of COVID-19 in comparison to non-diabetics. **(11)** A similar study done by Emma Barron et al in England also concluded that type 1 and type 2 diabetes were both independently associated with a significant increased odd of in-hospital death with COVID-19. **(9)**

We observed significant increase in requirement of oxygen therapy in diabetic cohort compared to non-diabetic cohort in our study. COVID 19 patients with diabetes had higher requirement of ventilatory support, however it was not significant. We also observed lesser difference in mortality rate in our study between diabetic and non-diabetic cohort. This could be due over all lower age of diabetic patients in our study than what is reported from the western world. **(13)** Overall mortality in our cohort was also lower compared to other earlier published studies. **(14,15,18,19)**

ROC analysis showed that Covid 19 patients with HbA1c $\geq$ 5.77% and age $\geq$50 years are more likely to suffer from major adverse events compared to those who had HBA1c <5.77% and age <50 years. In our study, isolated diabetics (without any pre-existing comorbidity) Covid 19 patients had more significantly severe disease course than non-diabetics (without any pre-existing comorbidity) patients with (Odds ratio for composite major adverse events: 1.65, P value <0.05). This suggests detrimental impact of diabetes on Covid 19 pneumonia disease progression independent of coexistent comorbidities.

The reasons why patients with diabetes are at a higher risk of severe and fatal COVID19 are manifold. First of all, patients tend to be older and

have associated comorbidities like hypertension, cardiovascular disease or kidney disease, all of whom are factors associated with poor outcomes in COVID 19. Hyperglycaemia contributes to a systemic inflammatory state which can worsen the cytokine storm associated with severe COVID 19 infection. Lastly, COVID 19 related lung damage has been found to be partly due microvascular thrombosis, a condition which is precipitated and exacerbated in patients with diabetes. **(12)**

Limitations of the study: It was a retrospective study involving only hospitalised patients leading to a recruitment bias.11 It is likely that higher proportion of diabetics with mild disease got admitted to the hospital as compared to those without comorbidities. The study was conducted for a period of 2 months only. The patients were given the best care and treatment as per the discretion of the treating physicians, but that was not uniform as the understanding of the disease and treatment modalities are still evolving. The diabetic patients were older than non-diabetics patients in our cohort. This could have contributed to worse outcomes in diabetics subgroup. Therefore, further well controlled studies with larger sample size are needed in future to establish an independent role of diabetes in COVID-19 as well as impact of glycaemic control.

CONCLUSION:

We conclude that Indian Covid-19 diabetes patients with or without pre-existing comorbidities have higher risk of suffering from adverse events than non-diabetics during hospitalisation. People with Hba1c $\geq$ 5.77 % and age $\geq$ 50 years are more vulnerable for adverse outcomes for Covid-19 pneumonia. This observation makes them more appropriate candidate of upcoming vaccination drive to maximise the impact of limited resources in fight against one of the worst pandemics faced by the country in recent time.

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