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Original Article

Profile and prognosis of patients hospitalized for COVID-19 virus infection with and without diabetes – An observational study from South India

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ABSTRACT

Background and aims: We studied the profile and outcome of patients hospitalized for coronavirus disease-19 (COVID-19) infection with and without type 2 diabetes (T2DM).
Methods: In this observational study, clinical details of patients with COVID-19, identified by Reverse Transcription – Polymerase Chain Reaction admitted to 4 hospitals in Chennai, Tamil Nadu, India were collected from May to November 2020. A total of 845 (n = 423 with diabetes, n = 422 without diabetes) were selected for the analysis. Clinical details, biochemical and radiological investigations, diabetes treatment, intensive care, mortality and other adverse outcomes were recorded.
Patients with clinical history of T2DM, glycosylated haemoglobin (HbA1c) of ≥6.5% (48 mmol/mol) and/or random blood glucose ≥200 mg/dl (11.1 mmol/l) were included. Statistical analyses were done using chi-square or 't' test and multiple logistic regression analysis.
Results: At admission, patients with T2DM were older ($p < 0.0001$), had higher co-morbidities such as coronary artery disease ($p = 0.02$), hypertension ($p < 0.0001$), hypothyroidism ($p = 0.03$) and renal disorders ($p = 0.01$) than non-diabetes persons. Requirement for intensive care was higher among them. Acute renal injury or failure, pneumonia and myocardial infarction developed in higher percentage of T2DM. Mortality was significantly higher in T2DM (10.2% vs 5.9%, $p = 0.02$). However, in the multiple logistic regression analysis, only age ($p < 0.0001$) and renal disorders ($p = 0.002$) were significantly associated with mortality.
Conclusion: Our study showed that mortality was associated with higher age and renal disorders but did not show an association with diabetes, among patients hospitalized for COVID-19 infection.

1. Introduction

The recent epidemic of coronavirus disease-19 (COVID-19) which has affected the socio-economic scenario throughout the world has impacted India badly. As on December 25, 2020, the total number of COVID-19 cases in India was 10,123,778 and the number of deaths had been 146,756 [1]. A number of studies had reported diabetes to be a major co-morbidity associated with mortality in COVID-19 infection [2–8].

India has a large population with type 2 diabetes (T2DM) [9]. Diabetes and COVID-19 have a two-way interaction [3]. Persons with diabetes have an increased risk of COVID-19 which is likely to increase development of diabetes in susceptible individuals. The viral

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infection may also aggravate glycaemic levels in diabetes patients. Studies from many countries including India have suggested that patients with diabetes have higher mortality rate among COVID-19 patients [2,4–6,10–12]. Although multiple pathophysiological explanations can be given for the association between the two disorders it is felt that the evidences are not conclusive, since many of the publications lack sufficient quality and epidemiological rigor [13,14].

There are only limited prospective studies from South Asia showing the impact of diabetes on the outcomes of COVID-19 infection among hospitalized patients. Our study analysed the outcomes among COVID-19 patients with and without diabetes admitted in different hospitals in a city in Southern India. The total number of cases with COVID-19 infection in the state of Tamilnadu, in India was 694,030 with a death toll of 10,471 by the December 25, 2020 [1].

2. Subjects, material and METHODS

2.1. Study design and participants

This was an observational study conducted in 4 hospitals in the city of Chennai, Tamil Nadu that admitted patients with COVID-19 from May to November 2020. For every diabetes patient, a non-diabetes patient was recruited as the control. We selected a total of 845 COVID -19 cases (non diabetes n = 422, diabetes n = 423) for the analysis.

2.2. Clinical assessment

Presence of COVID-19 infection was diagnosed by the Reverse Transcription – Polymerase Chain Reaction (RT-PCR) test. The necessary clinical investigations including blood pressure, physical, biochemical and radiological procedures were done as per the standard protocol of the hospitals. Clinical details including mode of treatment at admission and during the hospital stay were recorded by the attending physician in a case report form. The duration of stay in the hospital, requirement for intensive care unit (ICU) admission and intubation procedures were recorded.

2.3. Anthropometry and biochemical assessment

Height and weight were measured and body mass index (BMI, kg/m^2) was calculated in ambulatory patients. Blood pressure and other vital signs were measured by standard procedures. Blood glucose at admission was estimated. Patients with a known history of T2DM with records of medical treatment, HbA1c of ≥6.5% (48 mmol/mol) and/or random blood glucose ≥200 mg/dl (11.1 mmol/l) were included in the diabetes group. New onset diabetes with high blood glucose levels but with HbA1c of <6.5% (48 mmol/mol) were excluded. For each selected T2DM patient with COVID-19 infection a non-diabetes case with the infection was selected. Blood glucose was estimated by the glucose-oxidase method and glycosylated haemoglobin (HbA1c) by high performance liquid chromatography in the respective hospitals.

Presence of co-morbid conditions, acute complications developed during hospitalization and number of deaths were recorded. Details of management during the admission period were noted for all patients. The data for analysis was compiled and computerized by a trained research assistant of the coordinating center, India Diabetes Research Foundation, Chennai.

The study was approved by the ethics committee of India Diabetes Research Foundation and Dr.A.Ramachandran's Diabetes Hospitals, Chennai. The study was registered on www.ClinicalTrials.govIdentifier:NCT04634214 and on Clinical Trial Registry of India CTRI/2020/12/029454.

2.4. Statistical analyses

Data are presented as mean ± SD for continuous variables with a normal distribution and as frequency (%) for categorical variables. Independent samples 't' test and χ^2 test were used for intergroup comparisons of continuous variables and categorical variables respectively.

Pearson's correlation analysis was used to identify variables associated with mortality. Multiple logistic regression analysis (enter method) was used to identify variables associated with mortality. Variables that showed correlation with death were included in these analyses in addition to diabetes. Independent risk variables included in the model were; age, gender (reference: female), hypertension (HTN) (reference - no history of hypertension) or renal disorders (reference – no history of renal disorders) and Coronary Artery Disease (CAD) (reference - no history of CAD). In the analysis using mortality as the dependant variable, diabetes was included as an independent variable (reference – diabetes vs. non-diabetes). All analyses were done using SPSS version 21.0. A value of $p < 0.05$ was considered as statistically significant.

3. Results

Table 1 shows the comparison of general characteristics of COVID- 19 patients with and without diabetes. Gender distribution was similar in both groups. The mean age of the patients with diabetes was higher.

Higher percentage of diabetes patients required intensive care. The requirement for intubation was low and similar in both groups. In both groups, HTN and renal disorders were the most common co-morbidities, which were significantly higher among persons with T2DM.

The median duration of hospital stay was similar in both groups (6 days for non-diabetes, 7 days for diabetes patients), the minimum and maximum number were 4 and 10 respectively. ICU admission was required by 14% and 19% of the non-diabetes and diabetes patients respectively. The median days of ICU admission was also similar; 7 and 6 respectively and the duration varied between 3 and 10 days for both groups. Intubation was required in 1% in both groups.

Among the patients with diabetes, at admission, 42% were being treated only with oral hypoglycaemic agents (OHA) (33.8% only with metformin). During the hospital stay, the proportion requiring treatment only with OHA reduced to 25.5%, 18.7% required only insulin and 55.8% required both OHA and insulin. Among the non-diabetes and diabetes patients, 65.1% and 62.4% respectively, required treatment with steroids during hospitalization.

Table 2 shows the adverse events developed during the hospital stay in the two groups. Development of acute complications other than stroke and liver failure was significantly higher among T2DM patients. Number of cases with acute respiratory distress syndrome and pneumonia were high among both groups; their occurrence was higher in T2DM. Although, the number of cases of acute renal injury and kidney failure were generally lower, their occurrence was more in patients with T2DM. Mortality was also significantly higher among diabetes patients (p = 0.02). The major causes of death in both groups were cardiac arrest, respiratory failure and sepsis. Among the non-diabetes patients, there was one death due to stroke. Among patients with diabetes, 14 patients died of various other causes such as pneumonia, liver failure, encephalopathy, hypoxia, myocardial infarction and renal disorders. The multiple logistic regression analysis showed mortality was significantly associated with higher age, and presence of renal disorders (Table 3).

Table 1
General characteristics of COVID- 19 patients - description of non diabetes and diabetes patients.

Variables	Non-Diabetes (n = 422)	Diabetes (n = 423)	P Value
	Value	Value	
Gender, n (%)			
Male	268 (63.5)	285 (67.4)	0.23
Age (years)	51 ± 17	60 ± 13	**< 0.0001**
Hospital Management, n (%)			
Intensive Care Unit	59 (14.0)	80 (18.9)	0.05
Intubated	5 (1.2)	6 (1.4)	0.80
Co-morbidities (at admission), n (%)			
Coronary artery disease	45 (10.7)	68 (16.1)	**0.02**
Hypertension	105 (24.9)	247 (58.4)	**< 0.0001**
Dyslipidemia	62 (14.7)	80 (18.9)	0.10
Cerebrovascular disease	1 (0.2)	1 (0.2)	1.00
Hypothyroidism	31 (7.3)	49 (11.6)	**0.03**
Complications (at admission), n (%)			
Renal disorders	28 (6.6)	50 (11.8)	**0.01**
Retinopathy	–	5 (1.2)	–
Foot Ulcer	–	2 (0.5)	–
Amputation	1 (0.2)	3 (0.7)	0.28
Peripheral vascular disease	2 (0.5)	–	–

Data are presented as mean ± SD for continuous variables with normal distribution and frequency (%) for categorical variables. Independent samples *t*-test and chi-squared test were used to test between group differences for continuous variables and categorical variables.

Table 2
Complications developed among the patients during the hospital stay.

Acute Complications, n (%)	Non-Diabetes (n = 422)	Diabetes (n = 423)	P Value
	n (%)	n (%)	
Diabetic Ketoacidosis	–	12 (2.8)	–
Acute Renal Injury/Failure	9 (2.1)	29 (6.9)	**<0.001**
Acute Respiratory Distress Syndrome	49 (11.6)	63 (14.9)	0.16
Pneumonia	155 (36.7)	196 (46.3)	**<0.01**
Myocardial Infarction	2 (0.5)	12 (2.8)	**<0.01**
Stroke	1 (0.2)	4 (1.0)	0.13
Liver Failure	3 (0.7)	1 (0.2)	0.28
Mortality	25 (5.9)	43 (10.2)	**0.02**

Data are presented as frequency (%) for categorical variables. Chi-squared test were used to test between group differences for categorical variables.

Table 3
Variables associated with death among hospitalized patients – results of the multiple logistic regression analysis.

Dependent variable – Death			
Independent Variable	β coefficient (SE)	Odds Ratio (95% CI)	P value
Age (yrs)	0.069 (0.011)	1.071 (1.049–1.094)	**<0.0001**
Gender (Male)	0.405 (0.311)	1.500 (0.816–2.756)	0.19
Diabetes (Yes)	0.169 (0.283)	1.184 (0.679–2.063)	0.55
CAD (Yes)	0.405 (0.316)	1.499 (0.807–2.784)	0.20
Renal disorders (Yes)	1.029 (0.332)	2.799 (1.460–5.366)	**0.002**

Dependent Variable: Death (No/Yes).
Independent variables used in the equation were age (continuous), gender (reference: female), diabetes (reference: no history of diabetes), coronary artery disease (reference: no history of CAD) and renal disorders (reference: no history of renal disorders) are categorical.

BMI (kg/m^2) could be calculated among 234 non-diabetes and 242 diabetes patients, the respective values were 25.9 ± 4.9 and 26.9 ± 4.6 (p = 0.03). The percentage of persons with overweight (23–24.9 kg/m^2), were 23.2% and 18.9% among the non-diabetes and diabetes patients respectively (p < 0.03). The respective figures for obesity (≥25 kg/m^2) were 50.4% and 68.2% (p < 0.001).

Random Blood Glucose (mg/dl) could be measured in 298 and 354 among the non-diabetes and diabetes patients respectively (145 ± 59 mg/dl and 238 ± 101 mg/dl respectively, p < 0.0001). HbA1c (%) values were measured only in a smaller group of non-diabetes 5.8 ± 0.4 (n = 128) than among diabetes patients (8.3 ± 1.9), (n = 280). Since the values were not available for the total group, values for the above parameters were not included in Table 1 and were not used in the regression equation.

4. Discussion

In this comparative study of hospitalized patients with COVID -19 infection, we observed higher rate of mortality among patients with diabetes in the univariate analysis. However, the multivariate analysis showed higher age and presence of renal disorders were significantly associated with higher rate of death. In other words, old age was a stronger predictor than diabetes for the adverse outcomes.

Studies from different countries reported that diabetes was the commonest co-morbidity among patients with COVID-19 [2,4–6,10,11,15–18]. However, it is not clear whether diabetes increases the risk of contracting COVID-19 infection as these studies only suggest that patients with severe infection are more likely to

have diabetes [13]. Patients with diabetes are generally at a higher risk of infections and probably also for COVID-19 infection [19]. Boyce et al. [20] in a review showed that patients with diabetes had a higher risk of serious form of COVID-19. A large multicentric retrospective study by Zhou et al. [10] in China showed more severe form of COVID-19 infection with acute co-morbid outcomes among patients with diabetes when compared with the non-diabetes group. In concurrence with our observation, another study from China noted that in univariate analysis, odds of hospital mortality were higher among COVID-19 patients with diabetes but it was not significant in the multivariate analysis [21]. Several studies have shown that patients with severe COVID-19 infection had mostly poor glycaemic control and higher rates of adverse outcomes including mortality. This indirectly suggested an association between poor glycaemic control and the adverse events. Similar observations were reported in other earlier studies also [6–8,10,12,24].

In our study, at admission, the prevalence of HTN, CAD and renal disorders were significantly higher among patients with diabetes and they were also older compared to the non-diabetes patients. We noted a strong association of renal disorders with mortality in addition to older age. The associated comorbodities and uncontrolled hyperglycaemia in diabetes could have contributed to higher mortality. However, the presence of renal disorders in older patients could have been a major cause for the increased rate of mortality as shown in the univariate analysis. It is well known that renal disorders are often associated with hypertension. Some of the studies have reported strong association of older age and HTN with severe COVID-19 infection and mortality [18,20,22].

A recent observational study, using data from more than 360,000 participants from the UK BioBank, with a median age of 68 years and comprising of nearly 95% of white population, demonstrated a higher risk of COVID-19 infection in individuals with diabetes and hypertension and CKD and hypertension [23].

Many reviews have pointed out the lack of clear cut evidences to show that increased mortality was associated with the presence of diabetes among COVID-19 patients [2,13,14]. The mortality rate in our patients was much lower than reported from the United States and Europe [24]. Although, mortality was higher in the diabetes group, the association was not seen in the multiple logistic regression analysis. Moreover, there was no difference in the use of steroid therapy between those with and without diabetes.

Earlier publications on COVID-19 infection and diabetes were based on retrospective data collection from hospital medical records. As mentioned by Selvin et al. [13], there was anxiety and urgent need for information on the new virus infection in the early days of the pandemic. There was no clear cut evidence from these studies that patients with diabetes had higher risk of COVID-19 infection [2,13]. The higher prevalence of diabetes among hospitalized COVID-19 patients could be related to the severity of the infection and presence of multiple vascular complications requiring intensive hospitalized care.

A recent publication from India compared the phenotype and biochemical characteristics of new onset diabetes before and during the COVID-19 pandemic. Patient samples were collected from two tertiary care hospitals from Chennai and Delhi (n = 555). Interestingly, it was observed that no significant difference existed in the glycaemic parameters and fasting C-peptide levels among the two different groups of patients. It was concluded that persons with newly diagnosed diabetes during the COVID-19 pandemic did not significantly differ from those diagnosed prior to the infection in symptomatology, phenotype and C-peptide levels. However, they had more severe glycaemia requiring insulin therapy. Direct severe pancreatic damage due to COVID-19 infection was not seen except in two patients who had transient lowering of C-peptide values [25].

We made a comparative analysis on the impact of diabetes on hospitalized patients with COVID-19. It had the limitation of including only patients who required hospitalization. In other words, these were patients with severe infection. Therefore we could not assess the characteristics and treatment outcomes in milder forms of the infection who did not require hospitalization. Since the study was done during the peak of the pandemic, most of the patients had required emergency admissions. In some of them, details of investigations including BMI and HbA1c could not be measured. The impact of glycemic control and different drug therapies during the hospitalization on the outcome could not be analysed. Since the analysis of specific therapies for treatment of COVID-19 was not within the scope of the analysis, we did not include these details. We did not include type 1 and/or new onset type 2 diabetes patients. Therefore the data represents the profile and outcome of patients with fairly severe COVID-19 infection with or without the presence of T2DM.

In conclusion, our study showed that among the hospitalized T2DM patients with COVID-19 infection, higher mortality was mostly present among older patients with complications such as HTN or renal disorders. They were likely to have had more severe form of the infection and hyperglycaemia resulting in adverse outcomes. Diabetes patients with multiple co-morbid conditions were more likely to have severe form of the infection resulting in higher adverse outcomes.

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Duality of interest

No potential conflicts of interest relevant to this article were reported.

Author contributions

Arun R., A.N., A.R., C.S., R.V., K.S., and P.S. contributed to the study design, developing the protocol, supervising study progress, drafting the manuscript and revising it with critical input. SC, TP, STV and ASK contributed to data collection. K.S. helped in statistical analyses. All authors have read and approved the final draft of the manuscript. Prof. A.R. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of data analysis.

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Declaration of competing interest

On behalf of all authors I, Professor Ambady Ramachandran declare that there is no conflict on interest for the authors in the preparation of the manuscript.

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Abbreviation

BMI: Body Mass Index
CAD: Coronary Artery Disease
COVID-19: Coronavirus disease –19
CI: Confidence Interval
HbA1c: Glycosylated haemoglobin
HTN: Hypertension
ICU: Intensive care unit
OHA: Oral hypoglycaemic agents
OR: Odds Ratio
RT-PCR: Reverse transcription - Polymerase Chain Reaction
T2DM: Type 2 diabetes