Original Research Article

Cross - sectional study of baseline characteristics, clinical features and biomarkers in patients affected by SARS-CoV-2 in a tertiary care health center in Guntur, Andhra Pradesh

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A B S T R A C T

Background : During the month of December of 2019, a new strain of coronavirus was recognized for the main reason of atypical pneumonia cases in the city of Wuhan in China. This novel virus quickly blowout, causing an epidemic in China in no time, following a global pandemic declared by the World Health Organization in the month of Feb of 2020, nominated this infectious disease as COVID-19.

Aims and objectives of the study: 1. To find out the baseline characteristics of patients suffering from COVID-19 infections. 2. To find out the clinical features among the patients affected. 3. To find out the co-morbid conditions associated with COVID-19 infection

Materials and Methods: The present study is observational cross-sectional study of patients suffering from COVID-19 infected patients affected with corona virus (COVID-19) at Katuri Medical College and Hospital, Guntur, during the period of six months from April 15th 2020 to October 15th 2020.

Total of 567 patients included in the study based on the prevalence of COVID-19 infection in India. Inclusion criteria and exclusion criteria used to study the patients in the study.

Results : Among 567 patients included in the study, majority of the patients are males in the ratio of 71:29. Majority of patients are more than 60 years of age with mean of 61.2 +/-15.9. Smoking history affected majority of the patients. 54.1/24.9/21.0 (%). Among the SARS-CoV-2 infected patients 54.1% of the patients are current smokers, who are severely affected when compared to ex-smokers. Most of the patients manifested signs and symptoms within 2 weeks of incubation period. 51% of the total patients presented with covid-19 is breathlessness with grade 2 and 3 MMRC classification (42%) in majority of the patients and 9% of the patients presented with grade 4 of MMRC classification.42% of the whole patients presented with cough. Majority of the patients presented with fatigue and generalized body pains which constitute around 70.9%. Among the comorbid conditions diabetes mellitus constitute 42.50%, which is the most common comorbid conditions presented. Among the biomarkers and other major investigations, mean D-Dimer is 1100 ng/ml (278-2987) constitute major reliable biomarker for ongoing thrombogenicity of the viral infection following by the serum ferritin with a mean value of 300 ng/ml (278-1198).

Conclusions : Majority of COVID-19 infection patients are male patients of age more than 60 years of age with personal history of smoking. Most of the patients are diabetes followed by systemic hypertension and many people suffered from generalized body pains and fatigue followed by fever and dyspnea with cough. Minority of the patients presented with diarrhea as main chief complaint

1. Introduction

A new strain namely SARS-CoV2 emerged as an epidemic from Wuhan city in china in the month of December 2019. It spread not only in China but also throughout the

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world. WHO declared this new SARS-Co-V2 infection as an epidemic in Feb 2020 and named as COVID-19, which represent year 2019 as the origin of this novel virus. [1]

COVID-19 virus previously nominated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[2] which belong to the same family, later by its different strain and clinical properties it was named as 2019-nCoV.

COVID-19 infection presents from mild disease to life threatening conditions like ARDS (Acute respiratory disease syndrome), myocarditis, coronary artery diseases etc.

Mild COVID-19 manifest with no symptoms or grade 2 or grade 3 MMRC dyspnea scale Diarrhea and fever may present in mild disease within a week of infection Severe COVID -19 manifest with severe dyspnea with more than half of the lung involved Critically life-threatening disease manifest as more than 90 % of lung involvement, with circulatory shock, multiple organ dysfunction syndrome (MODS). Some patients present with sepsis and septic shock finally leading to death of the patient

When compared to 2019-nCoV infection SARS-CoV-2 infection had very less mortality and morbidity. As most of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infected people are with any symptoms, so the case mortality rate is significantly lowest and it has been predicted to be in the range of 0.4 and 0.9 percent.[3]

Lab investigations which lead to poor outcomes are

1. Reduced lymphocyte count
2. Reduced platelet count
3. Elevated AST, ALT levels
4. Increased serum lactate dehydrogenase
5. Increased biomarkers like serum ferritin, D-Dimer and C- reactive protein
6. Other biomarkers include mainly interleukin
7. Increased serum creatine levels

The following cross sectional study will evaluate these biomarkers in COVID-19 infected patients.

Normal incubation period of CORONA-19 virus is within 2 weeks, following contact with an infected person, the following study will evaluate the mean incubation period among patients in Guntur, Andhra Pradesh in India.

2. Aims and objectives of the following study

1. To find out the baseline characteristics of patients suffering from COVID-19 infections
2. To find out the clinical features among the patients affected
3. To find out the co-morbid conditions associated with COVID-19 infection

3. Materials and Methods

The present study included patients affected with corona virus (COVID-19) at Katuri Medical College and Hospital,

Guntur, during the period of 6 months from April 15 2020 to October 15 2020. An ethical committee clearance was obtained.

Informed consent was taken before enrolment. Totally 567 patients enrolled in the study. The criteria for selection of patients were as follows

3.1. Inclusion criteria

Patients diagnosed as COVID -19 infection by the following inclusion criteria

1. Patients are diagnosed as COVID-19 infection by RT-PCR investigation.
2. Patients diagnosed as COVID-19 infection based on CT-SCORING of corona.

Infection based on CO-RADS SCORES.

Patients having CO-RADS score 4 and higher are included in the study, irrespective of the RT-PCR result

3.2. Exclusion criteria

1. Patients with CO-RADS[4] [which means the coronavirus disease 2019 (COVID-19) Reporting and Data System (CO-RADS] score 3 with negative RT-PCT for CORONA infection. CO-RADS SCORE 3 defined as undetermined with unclear diagnosis of COVID-19 infection.
2. hildren with age group of less than 14 years are excluded from the study
3. Re-infected patients already diagnosed and treated and tested RT-PCR negative after treatment completion are excluded from the study

The patients enrolled in the study were subjected to a complete isolation from rest of the family members and admitted to the special wars allotted to the corona patients. Clinical history was obtained from the attenders of patients and patient also. Family members are subjected to CORONA testing with RT-PCR investigation

The risk factor profile of each patient was evaluated mainly

1. Systemic Hypertension defined as a BP recording of >140/90 mmHg
2. Patient's history of heart diseases are evaluated with ECG and echocardiography
3. Smoking history is evaluated based on smoking index and pack years
4. Diabetic patients were diagnosed as per the ADA association guidelines of 2020

3.3. Study design

Observational cross-sectional study of patients suffering from COVID -19 infection.

3.3.1. Statistical Analysis

Statistical analyses done using IBM SPSS Statistics V.24.0. various risk factors like hypertension, Diabetes mellitus, smoking and other variables were reported using descriptive statistics. Age at onset was compared across gender using t-test and value of P<0.05 was considered statistically significant.

3.4. Sample size

In the present cross-sectional study. Sample size calculated using the following formula

$$N= \frac{(za)^2[p*q]}{d^2}$$

(Where the symbol ^ means 'to the power of'; * means 'multiplied by')

Za; the value of z corresponding to this is 1.96 (from the standard normal variate tables

Finally

$$N= \frac{(1.96)^2[p*q]}{d^2}$$

(where the symbol ^ means 'to the power of'; * means 'multiplied by')

p: The prevalence of the condition/ health state.

q: When p is in percentage terms: (100-p)

d (or l): The precision of the estimate.

By using the above formula estimated sample size is 524 patients.

So, the present study of 567 patients was sufficient for the present observational cross- sectional study

4. Results

Table 1: Basic characteristics and clinical manifestations of COVID-19

Age (in %)	61.2 +/-15.9
Gender M: F (in %)	71:29
Smoking history Smoker /ex-smoker (%)/non smoker	54.1/24.9/21.0(%)
Time duration of signs of COVID-19 Before joining health care centre (in days)	6 (5–11)
Dyspnoea	51.9%
Coughwithorwithout sputum	42.1%
Weakness	70.9 %
Fever	69.4%
Diarrhoea	32.5%

5. Discussion

Among the patients suffered from covid-19 infection, most of the patients were males in the ratio of 71:29. Male predominance in present in most of the studies.

Table 2: Associated comorbid conditions

Co-morbid conditions	Percentage (%)
Hypertension	15.30%
Diabetes mellitus	42.50%
Asthma and/or COPD	12.60%
Chronic kidney disease	09.34%
Liver diseases	04.87%
Cardiac diseases	03.10%
Anemia	02.43%
GIT diseases (Acid peptic diseases etc.)	02.10%
No co-morbid conditions	07.76%

Table 3: Biomarkers and other investigations

Investigation	Value	95% CI
WBC (In 10^9/Ls)	8.12 (In 10^9/Ls)	(4.24–10.45)
D-Dimer (in ng/mL)	1100 (in ng/mL)	(612–2987)
Serum Ferritin (in ng/ml)	300 (in ng/ml)	(278–1198)
CRP (in mg/L)	85 (in mg/L)	(36–157)
Platelets (In 10^9/Ls)	298 (In 10^9/Ls)	(187–342)
Serum Creatinine (in mg/dl)	1.2 (in mg/dl)	(0.6–1.6)
ALT (Alanine transaminase) in (iu/L)	39 (iu/L)	(31–65)
AST (Aspartate transaminase) in (iu/L)	41 (iu/L)	(31.8–68.5)
Glucose (in mg/dl)	98 (in mg/dl)	(60-189)
Lymphocytes (In 10^9/Ls)	0.85 (In 10^9/Ls)	(0.56–1.6)

Majority of patients were more than 60 years of age with mean of 61.2 +/-15.9, more morbidity and mortality of the COVID-19 infection increased as age progressed. Older age people with co-morbidities were more effected.

In the present study 61.2 +/-15.9 of patients were above 60 years of age, study similar to this study was done by Cunningham et al.,[5] in China, where 80% of deaths was increased in patients above 65 years of age, with 80 percent of deaths occurring in those aged ≥65 years of age. In divergence, patients aged 14 to 35 years of age reported for only 6 % of COVID-19 patients, where death rate is only 3.1%.[5]

Smoking history affected majority of the patients. 54.1/24.9/21.0 (%). Among the COVID-19 infected patients 54.1% of the patients were current smokers, who were severely affected when compared to ex-smokers.

Ex-smokers which constituted 24.9 % of the overall patients were affected with COVID-19 illness when compared to non-smokers or never smoked people which constitute 21% of the total patients.

Patients manifested with symptoms and signs of COVID-19 infection after an incubation period of 6 days, mean duration of incubation period among several patients was 5-11 days after infected.so most of the patients manifested signs and symptoms within 2 weeks of incubation period.

51% of the total patients presented with covid-19 were breathlessness with grade 2 and 3 MMRC classification

(42%) in majority of the patients and 9% of the patients presented with grade 4 of MMRC classification. 42% of the whole patients presented with cough, among them 35% presented with dry cough where as 7 % of the patients presented with cough along with the expectoration.

Majority of the patients presented with fatigue and generalized body pains which constituted around 70.9%, 69.4 % of the whole patients presented with fever which was the 2nd most symptom.

Diarrhea which constituted 32.5% of the whole complaints.

In a study done by Chen et al.,[6] fever (72%) constitutes major complaint among the patients, where as in our study it constitutes 69.4% of the patients. In a study done by Li,[7] cough (59.5%) was the predominant symptom when compared to 42. % of the patients in the present study.

In a study done by Leung WK[8] gastrointestinal symptoms constituted 17.35% of the affected patients when compared to 32.5 % in our study.

Among the comorbid conditions diabetes mellitus constituted 42.50%, which is the most common comorbid conditions presented. In a study done by Wang et al.,[9] diabetes mellitus constituted only 10.7% which shows difference between the Indian population and Chinese population.

This was followed by systemic hypertension which constituted 15.30 % of the total comorbid conditions. Asthma, COPD and other respiratory conditions contributed 12.6%. Whereas CKD and liver diseases constituted 9.34% and 4.87% respectively.

The following study correlate with the study done by Li Q[7] in china where older patient's age more than 65 years of age with co-morbidities mainly diabetes, systemic hypertension along with chronic kidney disease and liver disorders have higher mortality.

Anemia and other GIT co-morbidities contributed 2.4% and 2.1% respectively.

Among 7.76% of the patients without any comorbid conditions, were affected by the COVID-19 illness.

Among the biomarkers and other major investigations, mean D-Dimer was 1100 ng/ml (278-2987) constituted major reliable biomarker for ongoing thrombogenicity of the viral infection followed by the serum ferritin with a mean value of 300 ng/ml (278-1198).

CRP which was non-specific biomarker also increased to a mean value of 85 mg/l (36-157).

In a study done by Zeng.,[10] there was a substantial increase of serum D-dimer, interleukin-6, C-reactive protein, and white blood cell count levels in patients with COVID-19 infection, with the median value of 150% (WBC) and up to about 22-fold increase in c-reactive protein (CRP) when compared to our study where total WBC count remained with in normal rage and CRP and D-Dimer values increased significantly.

Remaining blood investigations were normal including WBC count and differential counts. Platelets values were normal in majority of the patients where as some minority of the patient's platelet values are slightly increased.

6. Summary

1. Majority of the patients affected by COVID-19 infection were men when compared to women
2. Majority of the patients age were beyond 6o years of age
3. Majority of the patients affected were current smokers followed by the ex-smokers
4. Majority of the patients presented with clinical signs and symptoms within a week of infection
5. Majority of the patients presented by weakness and generalized body pains followed by fever and dyspnea along with cough
6. Diarrhea constituted in minority of patients (32.5%) in the present study
7. Major co-morbid risk factor being diabetes mellitus followed by the systemic hypertension followed of respiratory co-morbidities
8. Chronic kidney diseases, liver diseases, cardiac diseases and GIT co-morbidities contribute minority of cases suffered with COVID-19 illness
9. Very few percentages of people (7,7%) having no co-morbid conditions were affected by the COVID-19 infection
10. Among the biomarkers D-Dimer, serum ferritin were reliable biomarkers increased in the COVID -19 infection.
11. CRP which was nonspecific biomarker also increased in the present infections. Remaining all blood investigations were normal except in minority of patients where platelet count increased.

7. Conclusions

Majority of COVID-19 infection patients were male patients of age more than 60 years of age with personal history of smoking. Most of the patients were diabetes followed by systemic hypertension and many people suffered from generalized body pains and fatigue followed by fever and dyspnea with cough. Minority of the patients presented with diarrhea as main chief complaint

8. Acknowledgement

9. Source of Funding

10. Conflict of Interest

The authors declare that they have no conflict of interest.

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