Clinical spectrum and outcome of patients visiting coronavirus screening centre in North India and clinical predictors for COVID-19

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ABSTRACT

Aim: The aim of this study is to elucidate the demographics, symptoms and outcome of sick persons visiting coronavirus (COVID) screening OPD of a tertiary institute in North India. **Study Design**: The present descriptive, prospective study was done on 1030 patients and information about presenting symptoms, demographics (age, sex, nationality, residence), contact and travel history, comorbidities etc., were recorded. On the basis of criteria given by Indian Council of Medical Research, patients were divided into suspected (SARS-CoV-2) and non-suspected group. Of the suspected patients, with RT-PCR test positive were classified as confirmed COVID-19 case and negative RT-PCR symptomatic individual were defined as negative COVID-19 case. **Results:** Out of the total patients, 65.6% were male and 34.4% were females. The mean age was 37.04 years. Fever 49.3%, cough 57.1% and sore throat 43.5% were the main symptoms. Comorbidities were seen in 8.5% patients with hypertension (3.5%) and diabetes mellitus (3.4%). Forty patients were positive. Highly significant correlation ($P < 0.01$) was found between COVID-19 positive status and in patients without any symptoms, between COVID-19 and cough and sore throat, between COVID-19 and comorbidity (diabetes mellitus), between COVID-19 and high-risk exposures (resident of hot spot and history of contact with confirmed case). Our study also found COVID-19 positive status, shortness of breath and tachycardia as independent predictors of mortality ($P < 0.05$). **Conclusions**: Most of the patients were young adults and males were mainly affected. Main presentation was cough followed by fever. Infectivity was higher in patients who had underlying comorbid diseases, especially diabetes and chronic kidney disease. Critical patients with decreased oxygen saturation, tachypnoea and tachycardia had strong predictability for COVID-19 positivity. COVID-19 positive status, shortness of breath and tachycardia are important predictors of mortality.

Keywords: COVID-19, clinical predictors, cough, critical condition, tachycardia, tachypnoea

Introduction

Coronavirus (COVID)-19 designated as SARS CoV-2 (severe acute respiratory syndrome coronavirus-2)(1) is a newly emerged beta-coronavirus, which was found on cluster of pneumonia cases of unknown aetiology at Wuhan (in China) in December 2019.[1] The spectrum of its clinical presentation may vary from completely asymptomatic infection to severe life-threatening acute respiratory failure with multi-organ dysfunction determined by various patient-related factors and comorbidities.[1,2] Many studies and meta-analysis from china have shown that the most common symptom of this infection is fever (88.5%), followed by non-productive cough (68.6%), myalgia (35.8%), productive cough (28.2%) and dyspnoea (21.6%).[3] Recently, in April 2020,

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centre for disease control and prevention has included four symptoms to the existing list of clinical spectrum of COVID-19. They are anosmia, ageusia, sore throat and runny nose, which has increased the positive predictive value of COVID-19 infection.[4] Patients remain contagious from 2 days prior to the onset and 8 days after the onset of symptoms.[1,5] In contrast to other respiratory viral infections, COVID-19 is found to have increased prevalence and severity in adults than children, possibly due to cross-reactive non-neutralising antibody-mediated enhancement from other human coronaviruses as well as the differential expression of Angiotensin Converting Enzyme Receptor-2, an entry receptor for SARS-COV-2.[6,7] Because of high transmission efficiency and more prevalence of asymptomatic subclinical infections, COVID-19 was declared a pandemic on March 11, 2020.[6,8] COVID-19 has infected 43.2 million people and caused 1.16 million deaths globally and in India, it has infected 7.91 million people and resulted in 119,000 deaths as on 26 October 2020.[9] Racial disparities and socio-economic factors like food insecurity, unemployment and poor housing conditions are known to badly affect the transmission of the infection and has got serious implications on developing, thickly populated and resource-limited countries like India.[10] The geographical and racial variations of infection prevalence necessitate baseline demographic and clinical profile studies for policy making and future plan of action.

In an attempt to provide pertinent information on demographics, clinical spectrum and final outcome of patients with influenza like illness, to find the correlation between clinical presentation and COVID-19 and to find the clinical predictors for mortality in patients reporting to coronavirus screening centre of a tertiary institute in North India, which will help the primary care physicians as reference guide, present study was undertaken.

Material and Methods

The present descriptive, prospective study was done on patients visiting coronavirus screening OPD at PGIMER, Chandigarh, from March 2020 to June 2020 with approval of institutional ethics committee vide reference no. INT/IEC/2020/SPL-693 dated 03/06/2020. All patients visiting the screening OPD were analysed. Information of all these patients inclusive of demographic profile (age, sex, nationality, residence), history of being hotspot resident, visit to hotspot, contact history (direct or indirect), travel history (international/national) and healthcare workers, clinical features and presence of risk factors were recorded.

On the basis of criteria given by Indian Council of Medical Research (ICMR),[11] patients were divided into suspected (SARS-CoV-2) and non-suspected group [Figure 1]. Out of suspected patients, only those patients whose RT-PCR test were positive were classified as confirmed COVID-19 case and negative RT-PCR symptomatic individuals were defined as negative COVID-19 case.

All other patients who didn't fit into these categories were classified as non-suspected. Non-suspected patients were reviewed after 3 days either telephonically or physically as per the convenience of the patient and were enquired about worsening or onset of new symptoms. In addition, general condition of the patients was also assessed and grouped into normal or critical. Patients with the following features like tachycardia, hypoxia, temperature >100°F and tachypnoea were classified as critical. All these patients were followed up till the final outcome.

Statistical analysis

Our data were of categorical variables so it was reported as counts and percentages. Group comparisons (expired/survived) were made with the Chi-square test or Fisher's exact test. Age was represented as mean ± SD, median and interquartile range. A P value < 0.05 was considered significant. All the statistical tests were two-sided and were performed at a significance level of $\alpha = 0.05$. Analyses were conducted using IBM SPSS Statistics (version 22.0). To find independent predictor for mortality, logistic regression analysis was carried out. The factors which came out to be significant in bivariate analysis by Chi-square test/Fisher's exact test were put to Bivariate Logistic Regression Analysis. After controlling the factors which came out to be non-significant in Bivariate Logistic Regression Analysis, Multinomial Logistic Regression Analysis was carried and Adjusted Odds Ratios were calculated.

Results

A serial data of 1030 patients with influenza-like illness (11) were collected, evaluated, interpreted and correlated with each other. Demographics and clinical presentations for these patients are shown in Table 1.

Out of the total sample of 1030 patients, 676 (65.6%) were male and 354 (34.4%) were females. On the basis of age, only about 47 patients (4.6%) were under 20 years, 651 patients (63.2%) were in the age group of 20–40 years, 246 (23.9%) were in the age range of 41–60 and 86 patients (8.3%) were >60 years of age [Figure 2]. The mean age of the sample was 37.04 years.

According to Ministry of Health and Family Welfare, Hotspot (red zones) can be defined as districts/cities reporting large number of cases/high growth rate.[12] In our study, 109 (10.6%) were residents of hotspot and 44 patients (4.3%) had a history of visit to the hotspot. Around 286 patients (27.8%) were close contacts with positive patients. Out of the analysed patients, 204 (19.8%) were healthcare workers with flu-like symptoms [Figure 3].

On the basis of clinical presentation, out of the total 1030 analysed patients, 291 (28.3%) were asymptomatic and majority of the patients 738 (71.7%) were symptomatic [Figure 4]. Among the various symptoms, fever was present in 508 (49.3%), 588 (57.1%) had cough, 448 (43.5%) had sore throat, 127 patients (12.3%) had runny nose and 171 (16.6%) had shortness of breath as shown [Figure 3]. Both anosmia and ageusia were reported in three patients (0.3%) each [Figure 5].
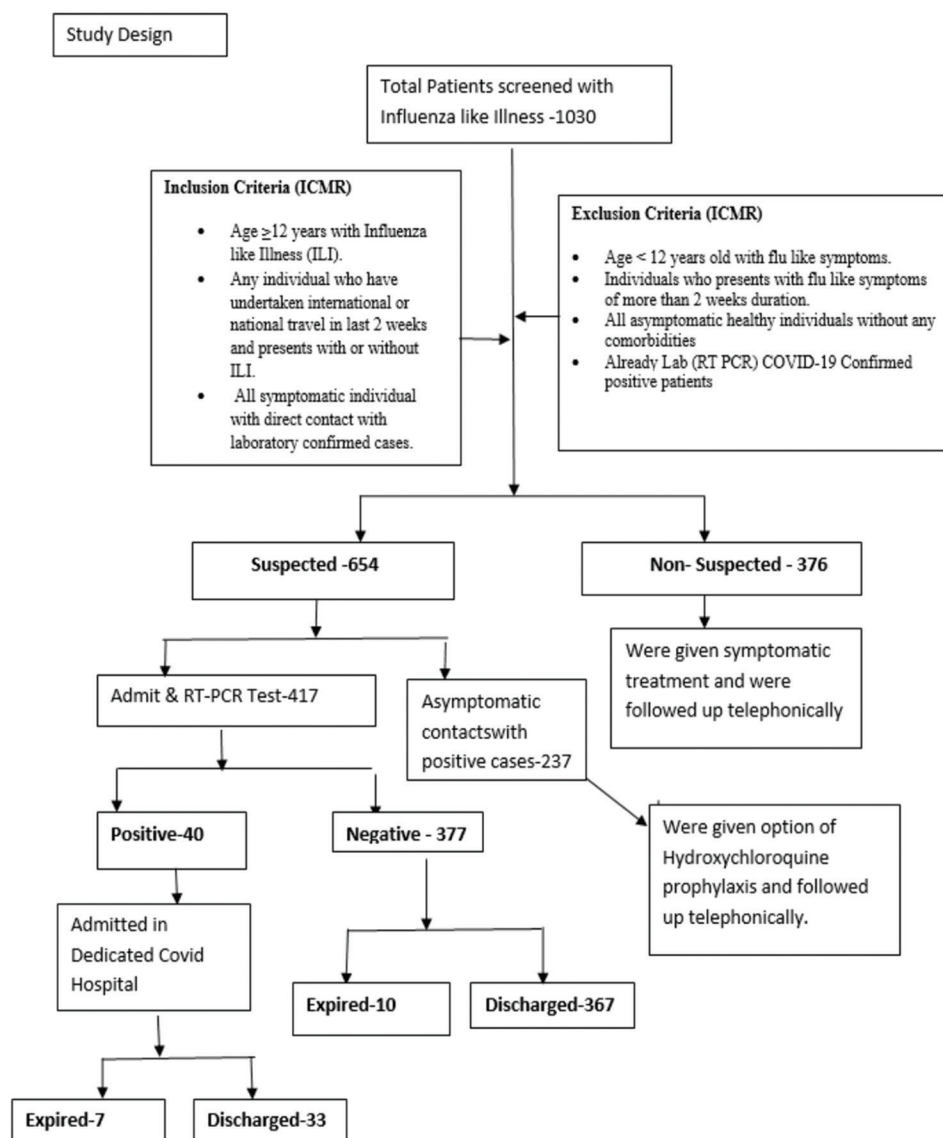
Study Design

Total Patients screened with Influenza like Illness -1030

Inclusion Criteria (ICMR)

- Age ≥12 years with Influenza like Illness (ILI).
- Any individual who have undertaken international or national travel in last 2 weeks and presents with or without ILI.
- All symptomatic individual with direct contact with laboratory confirmed cases.

Exclusion Criteria (ICMR)

- Age < 12 years old with flu like symptoms.
- Individuals who presents with flu like symptoms of more than 2 weeks duration.
- All asymptomatic healthy individuals without any comorbidities
- Already Lab (RT PCR) COVID-19 Confirmed positive patients

Suspected -654

Non- Suspected - 376

Admit & RT-PCR Test-417

Asymptomatic contactswith positive cases-237

Were given symptomatic treatment and were followed up telephonically

Positive-40

Negative - 377

Were given option of Hydroxychloroquine prophylaxis and followed up telephonically.

Admitted in Dedicated Covid Hospital

Expired-10

Discharged-367

Expired-7

Discharged-33

Figure 1: Flow chart depicting the study design and patient distribution
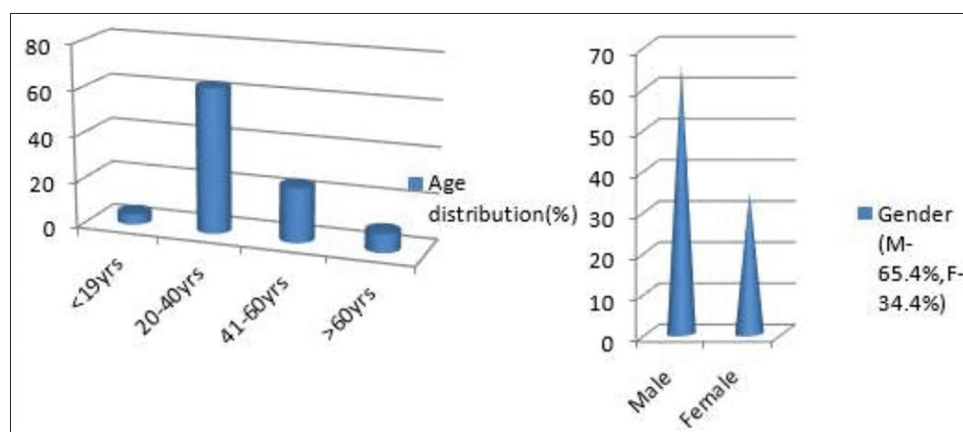

Figure 2: Bar diagram showing age and gender distribution

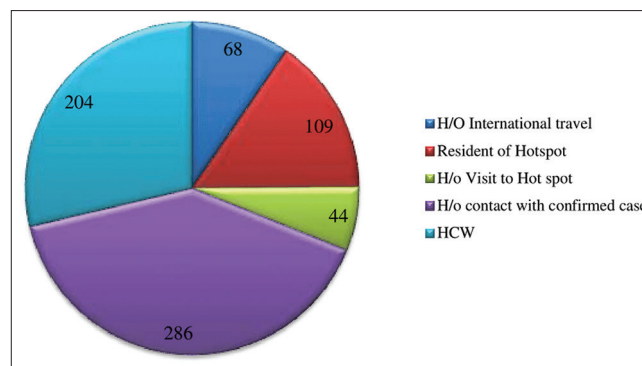Presence of comorbidities was seen in 88 patients (8.5%). The most prevalent comorbidity was hypertension in 36 patients (3.5%) and diabetes mellitus in 35 patients (3.4%), followed by chronic kidney disease (CKD) seen in

Table 1: Baseline characteristics of patients screened in the flu screening centre		
	Number	Total percentage
Total number of patients	1030	
Demographics		
Age		
<20 years	47	4.6
20-40	651	63.2
41-60	246	23.9
>60	86	8.3
Sex		
Male	676	65.6
Female	354	34.4
History of risk of exposure		
Resident of hotspot	109	10.6
History of visit to hotspot	44	4.3
History of contact with confirmed case	286	27.8
History of international travel	68	6.6
Healthcare worker	204	19.8
History of BCG vaccination	1016	98.6
Clinical presentations		
Asymptomatic	291	28.3
Symptomatic	738	71.7
History of fever	508	49.3
Cough	588	57.1
Sore throat	448	43.5
Runny nose	127	12.3
Shortness of breath	171	16.6
Diarrhoea	20	1.9
Myalgia	24	2.3
Anosmia	3	0.3
Ageusia	3	0.3
Comorbidities	88	8.5
Diabetes mellitus	35	3.4
Hypertension	36	3.5
COPD	5	0.5
CKD	29	2.8
CLD	4	0.4
CAD	18	1.7
HIV	4	0.4
Malignancies	7	0.7
General condition (normal)	1005	97.6
General condition (critical)	25	2.4
Tachycardia	130	12.6
Low oxygen saturation	136	13.2
Temp. >100°F	478	46.4
Tachypnoea	151	14.7
COVID-19 suspected	654	63.5

Figure 3: Patient distribution based on high-risk factors

130 patients (12.6%), hypoxia in 136 (13.2%), 478 patients (46.4%) had body temperature >100°F and tachypnoea was recorded in 151 patients (14.7%) [Figure 8].

On the basis of history and ICMR strategy for testing version 3, 4 and 5,[11] 654 patients (63.5%) were classified as COVID-19 suspected and 376 (36.5%) as non-COVID-19 suspected. Among these suspected patients, 417 were admitted and rest 237 patients were asymptomatic contacts of positive cases. Out of 417 patients, 40 came out to be positive. Out of 40 COVID-19 positive patients, 7 expired and 33 patients were discharged in stable condition after 10–14 days of isolation as per Ministry of Health and Family Welfare management guidelines.[13] Out of remaining 377 COVID-19 negative, 10 patients expired. So out of 417 patients, 17 patients expired. The case fatality rate of the sample studied was 5.5% in comparison to national average of 2.8% [Figure 1].[14]

Highly significant correlation ($P < 0.01$) was found between COVID-19 positive status and patient without symptoms, between COVID-19 and symptoms (cough and sore throat), between COVID-19 and comorbidity (diabetes mellitus). A significant correlation was found between COVID-19 and high-risk exposures (resident of hot spot and history of contact with confirmed case). Positive correlation ($P < 0.01$) was also found between COVID-19 and patient in critical condition (tachycardia, tachypnoea, low oxygen saturation) [Table 2].

Moreover, pertinent observation in this study was that COVID-19 positive status, shortness of breath and tachycardia significantly affect mortality of patient with odd's ratio 84.53 with significant P value ($P < 0.05$) [Table 3].

Discussion

The entire world is under the shadow of unprecedented atmosphere and situation, which has arisen due to COVID-19 pandemic outbreak. The disease has spread its tentacles all over the world, which is fighting a war against it. The population of the infected persons is on steep rise. To inhibit transmission of COVID-19, three major challenges have to be fought for and these are, testing of suspected patients, contact tracing and to

29 patients (2.8%) and coronary artery disease (CAD) present in 18 patients (1.7%) [Figure 6].

Based on four parameters, tachypnoea, tachycardia, low oxygen saturation and high temperature patients' general condition were classified as normal or critical. The general condition of 1005 patients (97.6%) was normal and remaining 25 (2.4%) was critical [Figure 7]. Tachycardia was recorded in

Table 2: Correlation between all the parameters and COVID-19

Clinical presentation	COVID-19 negative	COVID-19 positive	*P*
Asymptomatic	269 (93.1%)	20 (6.9%)	0.002**
Fever	494 (97.2%)	14 (2.8%)	0.063
Running nose	127 (100%)	0	0.015
Shortness of breath	160 (93.6%)	11 (6.4%)	0.060
Cough	574 (97.6%)	14 (2.4%)	0.004**
Sore throat	442 (98.7%)	6 (1.3%)	<0.001**
Resident of hot spot	94 (86.2%)	25 (2.7%)	<0.001**
History of visit to hotspot area	43 (997.7%)	1 (2.3%)	0.570
History of international travel	67 (98.5%)	1 (1.5%)	0.285
Healthcare worker	196 (96.1%)	8 (3.9%)	0.980
History of contact with confirmed case	260 (91.5%)	24 (8.5%)	<0.001**
Comorbidity	79 (89.8%)	9 (10.2%)	0.001**
Hypertension	33 (91.7%)	3 (8.3%)	0.161
Diabetes mellitus	30 (85.7%)	5 (14.3%)	0.001**
Chronic liver disease	4 (100%)	0	0.687
CAD	18 (100%)	0	0.389
Chronic kidney disease	25 (86.2%)	4 (13.8%)	0.005**
Oxygen saturation	125 (91.9%)	11 (8.1%)	0.007**
Temperature	463 (96.9%)	15 (3.1%)	0.244
Tachypnoea	140 (92.7%)	11 (7.3%)	0.020*
Critical condition	19 (76%)	6 (24%)	<0.001**
Tachycardia	117 (90.0%)	13 (10.0%)	<0.001**
COVID-19 suspect	615 (94%)	39 (6.0%)	<0.001**

P<0.05; *significant. *P*<0.01; **highly significant

Table 3: Multivariate logistic regression analysis of mortality risk factors for patients with COVID-19

Patient's parameters	*P*	Odd's ratio	95% Confidence interval for odd's ratio
COVID-19 positive	0.001**	11.475	2.63-50.064
Tachycardia	0.020*	6.715	1.34-33.524
Shortness of breath	0.013*	17.52	1.83-167.74

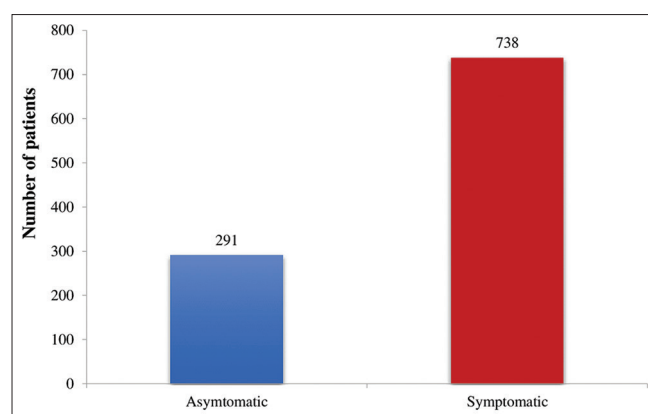*P*<0.05; *significant. *P*<0.01; **highly significant

Figure 4: Symptomatic status of patients reporting to flu screening centre

This is pertinent to mention here that the present study was started in March 2020, when only few cases were reported in India and it is during this period, that outbreaks of other seasonal flus were also commonly seen. So the main objective of the study was to differentiate the clinical presentation of patients with flu-like illness from COVID-19. This was to apprise the primary care physicians about the symptomatology and clinical predictors of this new viral illness, so that they can decrease the panic among general population experiencing flu-like symptoms and also to limit the burden of unnecessary testing.

Around 1030 patients who attended screening OPD from March 2020 to June 2020 were included. In our study, males were found to be affected mainly in concordance with study by Saluja *et al.*, in which male (64.5%) predominance was seen.[15] Increased incidence in males could be because in India generally males move to different parts of country to earn their livelihood that increases the chances of acquiring the infection.

It was observed that patients of all age groups presented with symptoms; 63.2% of the patients were in the 20–40-year age group with mean age of 37.04 years, followed by 40–60 years (23.9%). And elderly population (>60 years) constituted 8.1% of total. This is in concordance with study from De Chang *et al.* in which mean age was 34 years and remaining 86 patients (8.3%) fell in the category of above 60 years.[16] It was observed that most of the patients screened in OPD were young adults with a mean age of 37.04 years and male gender was affected more as compared to females, with an average sex ratio being 0.52.
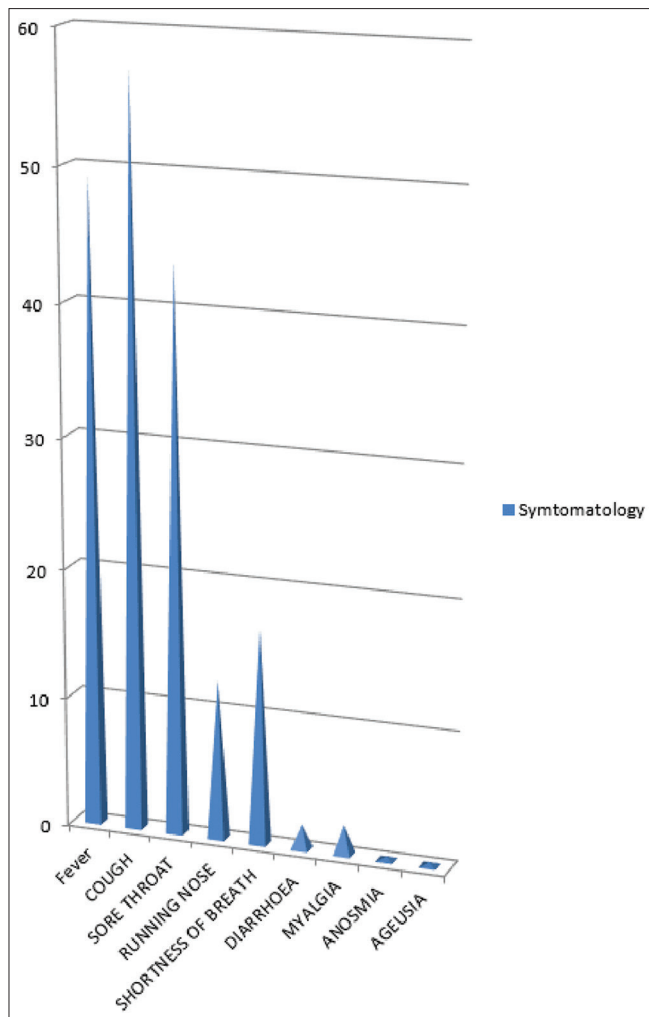
treat the patients (Triple T). This policy is being strictly followed at our institute. Although efforts are being made by the scientists all over the world to find out the vaccine to protect the people from being infected of such disease, till date it has not attained the success.

Figure 5: Various clinical manifestations in patients

Figure 6: Prevalence of different comorbidities in patients
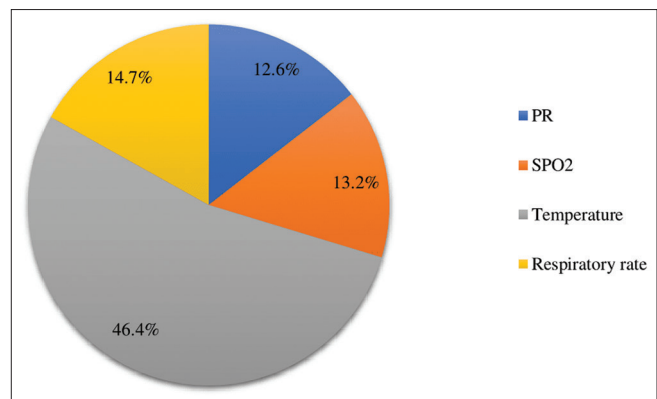
Figure 8: Defining parameters in critical patients with influenza-like illness
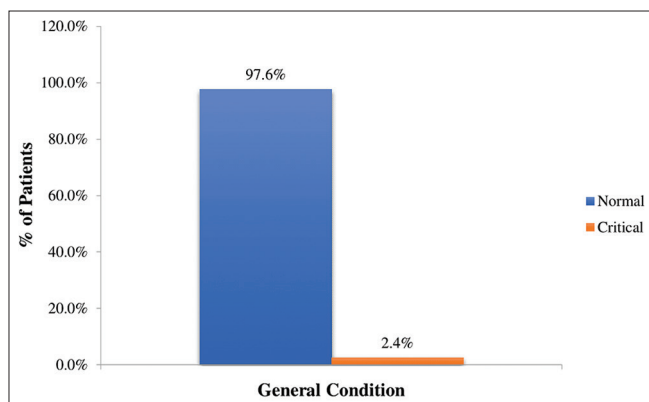

Figure 7: General condition of patients reporting to flu screening centre

Clustering occurred between 20 and 60-year-old patients, which is in contrast to study in China showed clustering of cases between 30 and 80 years of age (1). The mean age (37.04 years) of affected patients was significantly low in suspected COVID-19 patient population in comparison to other countries in which older population was affected more.[17] This could be due to demographic distribution of
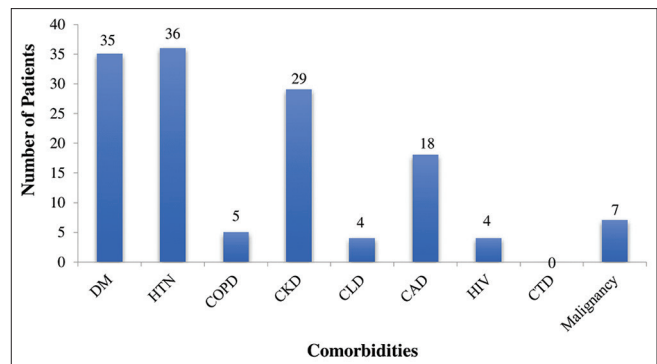
flu-like symptoms, which is seen more in younger population in India.

Out of total 1030 patients, 654 were segregated as suspected cases for COVID-19 on the basis of ICMR guidelines[11] based on multiple factors like resident of hot spot, history of visit to hot spot areas, history of international travel in last 2 weeks, history of contact with confirmed cases and healthcare workers. In concordance with study by Jha *et al.* in which 14.7% of HCW presented with flu-like symptoms, in our study 19.8% were healthcare workers.[18]

Most of the patients, who were symptomatic, presented on second day of illness with cough and fever being the most common presenting features, followed by sore throat, runny nose and shortness of breath, whereas fewer patients presented with non-respiratory symptoms. Non-productive cough (57.1%) was the most common presenting symptom in our study population in contrast to existing literature which will be helpful in understanding onset of disease in Indian perspective for our healthcare workers.[19] Babcock *et al.* on ILI and WHO update on COVID-19 showed most common symptom of ILI is fever (66% and 78.4%, respectively).[1,19] However, this is in accordance with various studies.[20,21] This could be due to the fact that our sample consisted mainly of ILI with small percentage of COVID-19, so clinical presentation of ILI may differ with respect to COVID-19. Symptomatic presentation in COVID-19 was also dependent on

age profile of patients with most of symptomatic patients (about 40.40%) falling in the age range above 50 years of age while none of patients below 20 years of age were symptomatic.[22]

Presence of comorbidities was seen in 88 patients (8.5%) in comparison to study by Guan *et al.* in which comorbidities were seen in 25.1% of cases.[23] The most prevalent comorbidities were hypertension (3.5%) and diabetes mellitus (3.5%), followed by CKD (2.8%) and CAD (1.7%). Other comorbidities were seen in less than 1% of patients.[24] It was observed, in the present study, that comorbidities have a substantial impact on clinical spectrum and course in COVID-19 positive patients, which has been validated by meta- analysis and systemic review done by Yang *et al.*[25] The general condition of 1005 patients (97.6%) was normal and remaining 25 (2.4%) were critical in concordance with the study done by Richardson *et al.* in which tachypnoea was seen in 17.3% cases.[26]

Out of 654, 417 patients were admitted for testing, 40 came out to be positive and 17 patients expired [Figure 1]. The test positivity rate came out to be approximately 10% as compared with national average of 6.73%.[14] Reason behind this could be testing done in our patients was quite limited and strict ICMR guidelines were followed and overall in Chandigarh the test positivity rate was much higher which reflected from the number of total tests done that was also quite less (per lakh population) because of less spread of infection in this area evident from total number of cases in this region.

Significant correlation was found between COVID-19 positive status and asymptomatic status, symptoms like cough and sore throat and comorbidity mainly diabetes mellitus. A significant correlation was found between COVID-19 and high-risk exposures (resident of hot spot and history of contact with confirmed case). Positive correlation was found between COVID-19 and patient in critical condition (tachycardia, tachypnoea, low oxygen saturation).

Our study found COVID-19 positive status, shortness of breath and tachycardia as independent predictors of mortality. The findings of this study would be beneficial for the primary care physicians to diagnose COVID-19 suspected patients by considering tachycardia, tachypnoea and low oxygen saturation as important early clinical warning signs.

Various studies have shown the importance of lab parameters like IL 6, Ferritin, CRP, LDH, Lymphopenia and other CT scan findings as predictive markers for severity of COVID-19 [27,28], but these will require more time, manpower and also put additional burden on patients. However, the clinical findings of our study would be of great value in countries with resource limited infrastructure.[27,28] These will require more time, manpower and also put additional financial burden on patients. However, the clinical findings of our study would be of a great value in countries with resource-limited infrastructure.

Key points

- Majority of patients visiting coronavirus screening OPD were in the age group 20–40 years with male gender mainly affected.
- Most of the patients (nearly three-fourth) were symptomatic at the time of presentation with cough, fever and sore throat as prominent symptoms.
- Risk of exposure and developing COVID-19 were more in residents of hot spot, history of contact with confirmed case and healthcare workers.
- Infectivity was higher in patients who had underlying comorbid diseases, especially diabetes and CKD.
- Clinical presentation in screening OPD in critical condition with decreased oxygen saturation, tachypnoea and tachycardia had strong predictability for COVID-19 positivity.
- COVID-19 positive status, shortness of breath and tachycardia are independent predictors of mortality.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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