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**Original Research Article**

# Initial approach to a patient presenting with breathlessness in a resource limited centre in the context of the COVID-19 pandemic: standard operating procedure

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## ABSTRACT

**Background:** The community health and training centre at Mugalur village is a primary level healthcare centre. Resident medical officers found an increased number of patients presenting in the winter months with complaints of acute breathlessness as a result of exxcerbations of COPD and asthma. Prior management at the centre included testing for COVID-19 as initial management resulting in delayed treatment of other diseases. To ensure proper management in the context of the COVID-19 pandemic an SOP was designed.
**Methods:** A quality improvement project which is a cross sectional analysis using plan-do-study-act cycles was conducted. Response and effectiveness was later recorded qualitatively from the staff and quantitatively by comparing with baseline data from prior records periodically at the end of each cycle.
**Results:** Out of the 87 patients seen in the PDSA1, the mean age was 56.0 (SD=11.052) years. About 59.3% of patients were male. 27.6% patients belonged to lower socioeconomic status. Understanding was seen by 100% and 78% of doctors and healthcare workers during PDSA1 and by 100% by both groups in PDSA2. 84% followed the SOP in PDSA1 and 93% in PDSA2. Everyone followed SOP in PDSA3. Number of hospital admissions was found to significantly reduce to 25.5% from 30% at baseline and during PDSA1 following implementation of the SOP.
**Conclusions:** A standardized guideline based on local epidemiology of the disease not only eases management for praticising physicians but also results in improved patient outcomes. This novel protocol can be used to manage patients presenting with acute onset breathlessness in similar resource limited centres.

**Keywords:** COVID-19, Rural, SOP, Breathlesness, COPD, Asthma

## INTRODUCTION

The community health and training centre (CHTC) at Mugalur village is a primary level healthcare centre affiliated to St John's medical college & hospital (SJMCH). The centre is located in the area of the Sarjapura primary health centre, Anekal Taluka, Bangalore rural district. Resident medical officers working in CHTC have found that an increased number of patients present in the winter months with complaints of acute breathlessness as a result of exxcerbations of COPD and asthma.

In the time of the COVID-19 pandemic, a practice of triaging was started at the centre from July 2020, wherein all patients with breathlessness were referred for COVID-19 testing as part of initial management. The same protocol was being followed up till December 2020 when this problem was given consideration.

Dyspnoea is defined as a subjective experience of uncomfortable breathing that typically results from cardiopulmonary problems that cause an increased drive to breathe, increased work of breathing, and/or stimulation of specific receptors in the heart, lungs, or vasculature.[1] Severe dyspnoea can lead to acute

ventilatory failure. Ventilatory failure is defined as the inability of the respiratory system to function effectively as a pump normally able to oxygenate arterial blood and eliminate carbon dioxide from the body. This results in arterial hypoxaemia ($PaO_2$<8.0 kPa/60 mmHg) and hypercapnia ($PaCO_2$>6.7 kPa/50 mmHg).[2] Ventilatory failure should be suspected in patients with respiratory distress, visible ventilatory fatigue or cyanosis, or changes in sensorium. Tachypnoea is also a concern; respiratory rates >28 to 30/minute cannot be sustained for very long, particularly in older or weakened patients.[3]

The two most common causes for acute ventilatory failure include exacerbation of COPD and severe acute asthma.[3] COPD is defined as a state characterized by airflow limitation that is not fully reversible, is usually progressive, and is associated with an abnormal inflammatory response of the lungs to inhaled noxious particles or gases.[4] Asthma on the other hand, is a disease characterized by chronic airflow limitation is defined by presence of wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation. Both these diseases are among other diseases which can present with acute breathlessness especially in winter months.[5]

Global prevalence of asthma is about 235 million while COPD is estimated to be around 251 million cases.[6,7] A previous study from our institute have shown respiratory morbidity to be around 37.5% in the elderly population in Mugalur.[8] Following the advent of the pandemic, new protocols were imposed from July 2020 where detection of COVID-19 had been given prominence in the management of breathlessness. Due to continuation of the pre-existing protocol, there was a delay in immediate treatment for patients presenting with excerbations of breathlessness. This problem is particularly marked as the closest COVID-19 testing centre is about 5.5 km from the centre needing vehicular transport which may not be available. Furthermore, testing is conducted primarily in the morning hours, while patients present at this rural centre primarily at night.

Symptoms suggestive of exacerbations of COPD/asthma can be managed at the level of primary care. From the response assessed by focussed group discussions among health care workers (HCWs) and key informant interviews from resident medical officers and interns/trainee doctors, the main themes identified included a therapeutic challenge due to previous restrictions, non-uniformity of treatment, and a perceived poorer patient outcome. All agreed that a uniform guideline would be beneficial to both patients and medical practitioners at the CHTC. With that in mind, a novel standard operating procedure (SOP) based on national and international guidelines was designed and initiated at the centre with the main deciding factor being the local epidemiology of the condition at that particular time i.e. prevalence and distribution of COVID-19 at that particular time. Such an approach has not been seen at a rural centre previously to the best of our knowledge.

### *Objectives*

Objectives of current study were; to ensure proper management of patients presenting with breathlesness in a rural setting by the medical professionals in the context of the COVID-19 pandemic by formulating a document which can be displayed at the centre which provides guidelines for assessment of symptoms, criteria for testing of COVID-19 and management within the scope of the facilities available at a primay health centre.

## METHODS

### *Study design, place and duration*

Current study was a quality improvement project (QIP) which is a cross sectional analysis using plan-do-study-act (PDSA) cycles. The QIP was done in the community health and training centre in rural South India over the course of 4 months. In the first month already existing practices were studied.

### *Inclusion criteria*

Inclusion criterion for current study was all adult consenting patients who presented with dyspnoea according to its operational definition described as a subjective experience of uncomfortable breathing.[1]

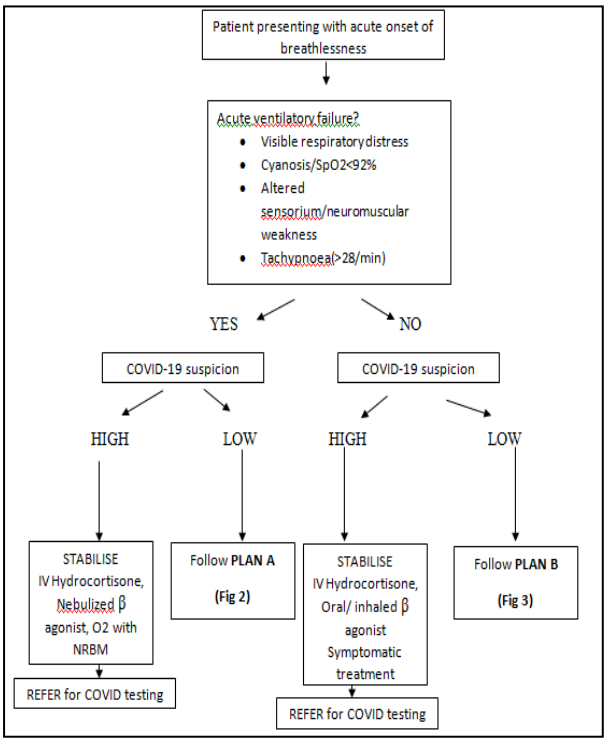
### *Procedure*

A standardised guideline based on national and international guidelines and the St. John's medical college hospital protocols was designed by the QI team led by myself, a trainee doctor. The guideline is illustrated in (Figures 1-3). It was then approved by the faculty member in-charge of the CHTC, and the department of community health, St. John's medical college. Following this, it was implemented as the official policy at the centre. In order to do this effectively we posted it on the notice board of the OPD and electronically shared it with the RMOs and other trainee doctors. Response and effectiveness was later recorded qualitatively from the staff working at the centre and quantitatively by comparing with baseline data collected from prior records mainatained by health care workers at the centre. Relevant data was collected during each PDSA cycle (duration of one month) periodically following implementation of the SOP for reassessment.

### *Statistical analysis*

Data was collected prospectively into a designed structured form. Demographic data and clinical features were analysed by descriptive analysis. Laboratory investigations if performed were assessed. Outcomes including time to recovery, need for hospitalisation, ICU

admission and death were assessed at each cycle. Statistical analysis was performed using SPSS-25.




***High index of suspicion for COVID-19**- h/o fever and/or acute respiratory illness, dysgeusia, anosmia, residence/work/travel in a location with a high risk of transmission or contacts of probable and confirmed cases.[9]

**Low index of suspicion**: absence of repiratory symptoms, no h/o primary exposure or residence in an area with a laboratory confirmed case.[10]

**Figure 1: Initial approach to patient with breathlessness in a resource limited setting in the time of the COVID-19 pandemic.[1,3]**

## RESULTS

Out of the 87 patients seen in the 1st cycle-PDSA1, the mean age of the population was 56.0 (SD=11.052) years. About 59.3% of patients were male. About 24 (27.6%) patients belonged to lower socioeconomic status (BG Prasad scale). Similar demographic statistics were seen in PDSA 2 and PDSA 3, where 70 and 90 patients were seen with breathlessness in each month respectively. Most common symptom in addition to breathlessness was cough seen in 80% of individuals followed by nasal discharge. Fever was seen among 50% in the third cycle.

### *PDSA cycle 1 (30 days)*

During the first cycle we aimed to increase awareness of the problem so that the situation was acknowedged. The QI team assessed the problem by qualitative methods. Focussed group discussions were conducted among health care workers until data saturation was reached. Key informant interviews were conducted using a self-administered questionnaire on epicollect from resident medical officers, interns/trainee doctors and health workers working at the centre.

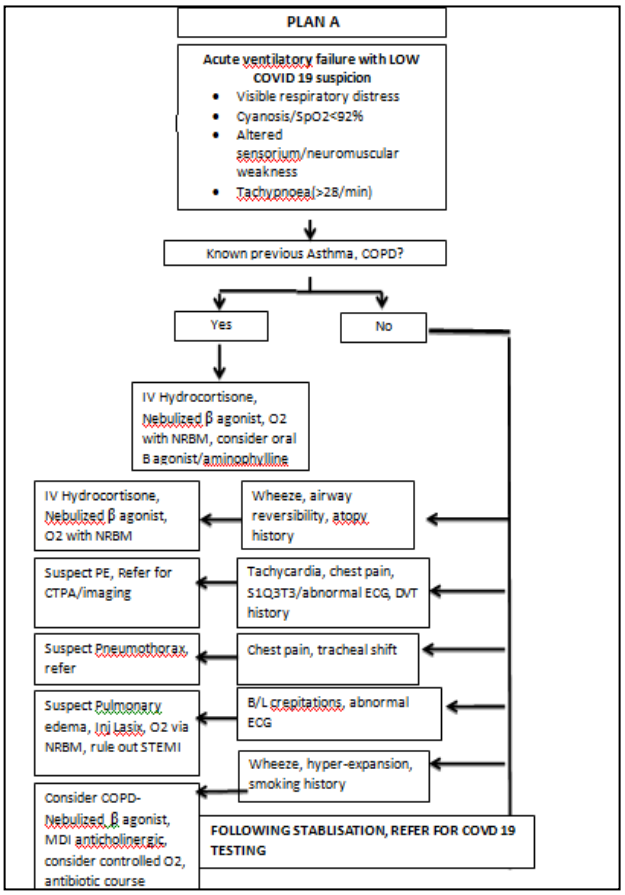



**Figure 2: Flowchart for management of patient with acute ventilatory failure with LOW COVID-19 suspicion.**

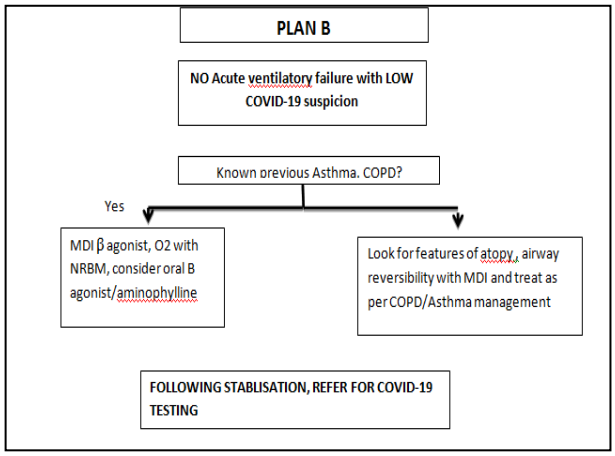



**Figure 3: Flowchart for management of patient with breathlessness with no acute ventilatory failure with low COVID-19 suspicion.**

The main themes identified included a therapeutic challenge due to previous restrictions, non-uniformity of treatment, given the variation in perception of risk of

COVID-19 by each treating doctor and a perceived poorer patient outcome. All agreed that a uniform guideline would be beneficial to both patients and medical practitioners at the CHTC. The new SOP and guidelines was explained and we posted a printed copy on the notice board of the OPD and electronically shared it with the RMOs and other trainee doctors.

During the first cycle the understanding and compliance to the new guidelines were assessed among the doctors as well as health care workers (HCWs) by silent monitoring of inpatient work by the QI team. It was observed that 100% of the doctors and 78% (23 out of 30) of the HCWs understood the guidelines. However, only about 84% (5 out of 6 doctors) and 50% of the HCWs followed these guidelines. Data regarding clinical outcomes was also collected and compared with the data from the other cycles and baseline data. Data is elaborated in (Table 1). Our objective for the next cycle was to assess the reasons for this discrepancy and improve understanding of the guidelines.

**Table 1: Comparison of outcome characteristics following implementation of SOP at the rural centre.**

| Characteristic | Baseline (for 2020) | PDSA1 (N=87) | PDSA2 (N=70) | PDSA3 (N=90) | P value |
|---|---|---|---|---|---|
| **Covid positivity rate, frequency (%)** | (8.7) | 0 | 1 (1.1) | 10 (11.1) | - |
| **Mean time to recovery (days), frequency (%)** | 14.44±13.97 | 13.8+/-2.483 | 13.260 ±5.684 | 9.851±2.483 | 0.8 |
| **Hospital admission, frequency (%)** | (30) | 30 (34.4) | 24 (34.2) | 24 (25.5) | 0.04 |
| **ICU admission, frequency (%)** | (3) | 2 (2.2) | 1 (1.4) | 5 (5.5) | 0.2 |
| **Death** | (1.1) | 0 | 0 | 1 (1.1) | 0.00 |

***PDSA cycle 2 (30 days)***

During the second cycle, the aim was to improve the understanding of the guidelines and to recognize the reasons for those not following the protocol. To improve understanding, the medium of instruction was expanded to Telegu as well as Kannada which were the local languages of the HCWs. To recognize the reasons for not following the protocol, FGDs were conducted among HCWs and interviews among the doctors. Key themes identified for lack of compliance included fear of COVID-19 among all patients with respiratory features, heresay among other villagers and lack of clear history given by the patients.

After further explanation of the protocol in local languages, the understanding of the SOP improved to 93% among HCWs (28 out of 30) with 2 members demonstrating near complete understanding which was later re-explained. The further plan was to conduct frequent sessions to re-enforce understanding of the guidelines at periodic intervals and to supply guideline material in Kannada as well as Telegu. The clinical outcome data of patients was collected from this period as well, elaborated in (Table 1).

***PDSA cycle 3 (30 days)***

During this cycle, the second wave of COVID-19 was rising where positivity rate for COVID-19 increased from 0 positives in PDSA1 to 11.1 % in PDSA3. This gave an opportunity to compare the clinical data in two different epidemiological situations elaborated in (Table 1). When understanding was assessed 100% of both doctors and HCWs had understood the protocol. All doctors and 93% of HCWs followed the protocol. When outcomes were compared across all 3 cycles and baseline, number of hospital admissions was found to reduce to 25.5% from 30% at baseline and during PDSA1 which was statistically significant. All other parameters were not found to be statistically significant. Details are elaborated in (Table 1).

## DISCUSSION

A series of PDSA cycles were tested over 4 months which included three very different epidemiological situations- PDSA1 was in an environment of low prevalence of COVID-19 and PDSA3 was in an environement of high prevalence of COVID-19. The key finding following implementation of the protocol was a statistically signifcantly reduced number of hospital admissions.

Following the COVID-19 pandemic, testing for the same took precedence in any patient presenting with a respiratory illness. While the luxury of waiting for aforementioned test results is feasible in an urban environment, such a delay could prove to be disastrous in a rural set up. This was a problem faced by our medical practioners at the centre, compounded during the winter months when an increased number of cases were seen secondary to excerbations of asthma and COPD. To combat this problem, the SOP was designed and introduced at the centre.

The key difference in clinical approach was to give consideration to the epidemiological situation of the region at the time based on local governement statistics. A high index of suspicion for COVID-19 would be assumed when there was a history of fever accompanying the acute respiratory illness, dysgeusia, anosmia,

residence/work/travel in a location with a high risk of transmission or contacts of probable and confirmed cases.[9] On the other hand, a low index of suspicion would be assumed when there was no history of primary exposure or residence in an area with a laboratory confirmed case.[10] In the absence of such a standardized guide, symptoms were often left to the interpretation of the treating physician or referring HCW and there was an inability to bridge the gap in the quality of healthcare provided. Through successive cycles, we were able to assess the level of understanding and bridge the gap in understanding and implementation.

To assess the effect of the protocol on patients, we looked at clinical outcomes. Laboratory reports were often not in possession of the patients. Number of hospital admission was significantly reduced in PDSA3 when compared to baseline for 2020, PDSA1 and PDSA 2 inspite of a growing positivity rate clearly reiterating that a stadardized approach, keeping in mind the rural dynamics, is greatly beneficial for the patients.

The main strength to our study was the QI-PDSA format which gave the researchers, the ability to have a continous assessment, identify hurdles and discrepancies and correct it in the next cycle. Such an approach for an SOP forgoes the point fix approach of other studies.

### *Limitations*

Limitation of the current study is that the study is a single centre study and its role in a larger population can only be confirmed if tested in other such resource limited centres all over the country.

## CONCLUSION

In conclusion, this novel protocol can be used to manage patients presenting with acute onset breathlessness in a resource limited centre such as the Mugalur CHTC. The need to counsel regarding COVID-19 testing at a later date needs to be borne in mind irrespective of the current epidemiological situation. Such an approach has not been studied or developed in a rural setting in India previously to the best of our knowledge.

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