

To Study the Retrospective Investigations of the Benefits of Prone Positioning with NRBM in Covid 19 Patients

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Abstract

Objective :To detect the improvement in oxygenation (spO₂) with prone position ventilation with nrbm in non intubated patients. To detect the haemodynamic changes and evaluate the side effect with prone position ventilation. **Methods**: Continuous vital signs were monitored. Oxygen therapy was initiated with face mask at 5 L/minute and the flow rate was titrated to reach the target SpO₂ >94%. If the target SpO₂ was not achieved then non-rebreathing mask (NRBM) at 10 to 15 L/minute was considered. Noninvasive ventilation (NIV) was started if respiratory distress worsened or hypoxemia not alleviated by standard oxygen therapy. **Results**: The median maximum prone duration per session was 2 hours. The median P/f ratio significantly improved from supine to prone position from day 1 to day 10. We were able to reduce the intubation rates, avoid the problems related to invasive ventilation. The mean duration of stay was 10 days in HDU. Two out of 15 patients who required intubation were shifted to ICU and subsequently expired. **Conclusion**: Awake prone positioning showed marked improvement in P/f ratio and SpO₂ in COVID-19 patients with improvement in clinical symptoms and minimal complications. We were able to reduce the intubation rates which helped in offloading the resource and manpower burden on healthcare system in pandemic.

Keywords: Non-Rebreathing Mask (NRBM), Noninvasive Ventilation (NIV), Respiratory Distress, Hypoxemia, Oxygen Therapy.

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Introduction

Covid -19 disease is caused by novel coronavirus and was identified as pandemic by WHO on 11 march 2020. Corona virus disease presents with a multitude of clinical manifestation with very high morbidity and mortality. Increased mortality leads to Covid -19 positive patient's needs intensive care unit beds and ventilators. To delay intubation & ICU admission by awake & self prone positioning has been used in non-intubated patients during Covid -19 pandemic.[1,2]

Patients in a supine position have compromised pulmonary function, due to

- Atelectasis of the dorsal alveoli.
- Over-inflation of ventral alveoli due to increased respiratory drive.
- Ventilation-perfusion mismatch.

The proposed mechanisms explaining the improved oxygenation after awake prone are:

- More uniform distribution of tidal volume and end-expiratory lung volume, thus reducing the cyclical opening and closing of alveoli (reduced atelectasis)
- Recruitment of areas in the posterior part of the lung, thus improving compliance, and decreasing the shunt.
- Decreased lung deformation (increased homogeneity) and lungs

are less compressed in prone, thereby increased ventilation.

- Dorsal lung regions have a higher density of blood vessels (which is independent of gravity). Prone improves the ventilation in these nondependent lung fields, thereby improving the ventilation:perfusion (V:Q) matching
- Increased perfusion toward the anterior alveoli; improving the V:Q ratio.
- The chest wall compliance reduces, as the anterior part of the chest is now facing the bed surface, reducing the regional lung stress and potentially decreasing the possibility of patient self-inflicted lung injury (p-SILI). Contraction of muscular diaphragm exerts a more uniform distribution of stress.
- Better secretion drainage.

Prone in ARDS has shown to improve survival, possibly explained by the reduction in ventilator-induced lung injury (VILI), as first theorized by Albert in 1997. Using personalized computer-simulated models of lung ventilation in 31 obese patients (11 healthy, 20 asthmatics), Foy et al demonstrated the benefits of prone by reducing ventilator heterogeneity and improving ventilation. These effects were more pronounced in patients with a body mass index (BMI) >30 kg/m².

Prone position in ARDS has shown to improve survival. Possibly explained by the reduction in ventilator induced lung injury 1st recognized by Albert in 1997 the mechanism explaining the improvement in oxygenation after awake prone position are more uniform distribution of tidal volume and end expiratory tidal lung volume & reduced atelectasis. More uniform distribution of tidal volume and end-expiratory lung volume, thus reducing the cyclical opening and closing of alveoli (reduced atelectasis). We have to do this study to retrospectively investigate the benefits of prone positioning with NRBM in COVID-19 patients.[1-5]

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Materials and Methods

Study area and participants:-Retro prospective observational study will be conducted by all the investigators of Department of Anaesthesiology Government medical college Ratlam.

Inclusion criteria: for Self awake Prone position

- Patients tested positive for SARS COV-2 infection (confirmed by Reactive Reverse Transcription PCR)
- Awake prone position in conscious,oriented,cooperative,alert patients able to adjust own position with minimal assistance.
- Intubated in patients with SPO2 (between 85% to 94%) advised early awake proning.
- Awake prone position in patients on oxygen supplementation via NRBM as per their tolerance & comfort.

Exclusion criteria:- Patients with tachycardia, tachypnoea, severe hypoxemia, respiratory failure.Patients who are uncooperative, altered mental condition, haemodynamic instability, Arrhythmias. Patients will unstable spine, pelvic instability, obese patients, chest trauma ,pregnancy

Study design- Retro prospective observational study

Sample size: Total 80 patients taken as sample size(as in a previous study performed by Thompson et al ,he had taken 88 patients for similar type of observational study in year 2020).This is also similar type of observational study, so we have taken sample size of 80 patients(nearly similar number and rounding off to 80).

Study Period:- From 1st May to 31 May

Data Collection

After institutional ethical committee approval 100 patients of Covid - 19 positive who’s SPO2 was (between 85% to 94%) in triage and after NRBM oxygen delivery device and prone position ventilation. We studied how many patients improved with prone ventilation .

Informed consent

Consent not required

Institutional permission for data collection was taken by DEAN GMC Ratlam.

Approval for the study and a waiver of the consent was obtained from the institutional ethics committee. This case series describes 80 patients with COVID-19 pneumonia requiring oxygen supplementation admitted from 1st May to 31 May 2020 in HDU in our hospital. All patients were diagnosed with COVID-19 disease by RT-PCR (real-time polymerase chain reaction) technique. Patients who were hemodynamically stable, SpO₂ <88% on presentation, and able

to adjust their prone position were included in the study. Those who were hemodynamically unstable, drowsy, or uncooperative were excluded from the study.

Continuous vital signs [SpO₂, non-invasive blood pressure (NIBP), respiratory rate, and temperature] were monitored. Oxygen therapy was initiated with face mask at 5 L/minute and the flow rate was titrated to reach the target SpO₂ >94%. If the target SpO₂ was not achieved then non-rebreathing mask (NRBM) at 10 to 15 L/minute was considered. Noninvasive ventilation (NIV) was started if respiratory distress worsened or hypoxemia not alleviated by standard oxygen therapy. Tracheal intubation and invasive ventilation were considered when the patient deteriorated, i.e., altered sensorium, hypotension, or shock.Awake prone position was explained to every patient and they were encouraged to spend as much time in prone position as they could tolerate. The target time in prone position was 10 to 12 hours per day. Proning was performed 1 hour after meals to avoid gastrointestinal side effects. Specific COVID-19 treatment was given to all patients according to the institutional protocol which included remdesivir, tocilizumab, dexamethasone, and low-molecular weight heparin. Target for discharging from HDU was SpO₂ of >95% and P/f ratio of >200 mm Hg. Patients were shifted to ward when they were weaned off oxygen at least for 24 hours.In a sick patient, proning should be interrupted if there is evidence of increased work of breathing, use of accessory muscles of respiration, failure of improvement in oxygenation with proning/further desaturation,or hemodynamic instability/arrhythmias. An improvement in oxygen saturation on awakeproning should not be an assurance of the improvement in the disease condition. Vigilance should be kept for signs of respiratory distress or increased work of breathing, which are an indication to interrupt awakeproning and the need for invasive ventilation. The decision to intubate and invasively ventilate should be based on clinical assessment of work of breathing and other clinical criteria. Delaying intubation, just due to improvement in oxygenation can lead to catastrophic outcomes.

Observation Chart

Oxyhemoglobin Saturation (SpO₂) 1 Hour After Initiation of the Prone Position in Awake, Nonintubated Patients With COVID-19
 100 90 80 70 SpO₂, % Awake proning . Start 1 h SpO₂ before and 1 h after initiation of the prone position in awake, nonintubated patients with COVID-19 severe hypoxemic respiratory failure

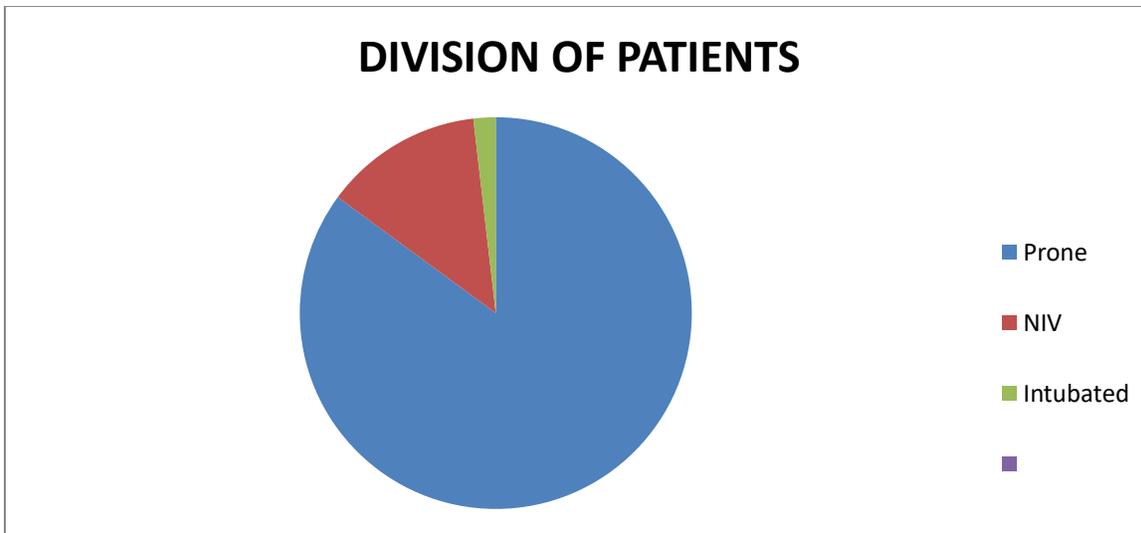


Fig 1 :Showing Division Of Patients In Our Study Group

Table 1: Showing Significant Variations In Vital Parameters In The Group

Vital parameters	Prone	P -value Significance	NIV	P -value Significance	Intubated	P -value Significance
Significant variation in pulse	6	>.05Not significant	5	<.05Significant	3	<.05Significant
Significant variation in Blood pressure	5	>.05Not significant	5	<.05Significant	4	<.05Significant
Significant variation in saturation	5	>.05Not significant	5	<.05Significant	3	<.05Significant
Significant variation in ECG	2	>.05Not significant	3	<.05Significant	3	<.05Significant

Table 2: Showing Various Trends In Our Study Group

	Prone group	P -value Significance	NIV	P -value Significance	Intubated	P -value Significance
No .of patients	65	-	10	-	5	-
Significant improvement in 10 days	60	<.05 Significant	8	<.05 Significant	1	>.05 Not significant
Significant alterations in vital parameters	5	>.05 Not significant	5	<.05 Significant	2	>.05 Not significant
Co morbid conditions	35	<.05 Significant	8	<.05 Significant	5	<.05 Significant
Mortality	0	<.05 Significant	1	<.05 Significant	2	<.05 Significant

Results

Out of 80 patients ,60 were successfully treated with prone ventilation method with NRBM mask.5 patients of prone ventilation group required NIV support and later shifted back on prone ventilation. The median maximum prone duration per session was 2 hours The median P/f ratio significantly improved from supine to prone position from day 1 to day 10. 13 patients couldn't tolerate prone and 2 refused .Out of them ,10 did well on NIV mode and were later shifted to prone positioning , 5 were intubated and 3 out of them died. We were able to reduce the intubation rates, avoid the problems related to invasive ventilation and with use of sedation and neuromuscular blockers. The mean duration of stay was 10 days in HDU.

Statistical Analysis: Data was compiled using MS excel 2007 and analysis was done with the help of Epi-Info 7 software. Frequency and percentage were calculated & statistical test (Chi Square) was applied wherever applicable; $p < 0.05$ was taken as statistically significant.

Discussion

Patients with severe disease often require high oxygenation support. High-flow oxygen therapy and noninvasive positive pressure ventilation have been used. Some patients may develop ARDS and warrant invasive ventilation. Hence, any therapy which can improve oxygenation and reduce lung injury should be used to improve the survival rate. The initial approach for managing such patients was to intubate early to decrease the work of breathing and prevent patient self-inflicted lung injury (P-SILI). Later on, it was found that the complications and mortality were high with this approach. Moreover, during the pandemic time, it led to resources and manpower crisis, especially in developing nations. [1,2]

The role of prone position ventilation is well established in classical ARDS. In prone position, there is homogeneous distribution of the gas which reduces the ventilation-perfusion (V/Q) mismatch. This reduces the intrapulmonary shunt and opens the atelectatic lung areas with adequate sputum drainage, improving oxygenation. Also, the transpulmonary pressure gradient is reduced which decreases barotrauma. Most patients tolerated the prone position well and reported the improvement in symptoms. We are also cognizant that other COVID-19 therapies could have modified the disease course as well. Hence, awake proning with high-flow oxygen therapy proved to be a low risk, easy to perform, easily tolerated, and low cost rescue therapy in COVID-19 patients. [3,4]

Coppo and colleagues conducted a prospective study to evaluate the effects of prone positioning in non-intubated patients with acute respiratory failure due to COVID-19. Fifty-six patients were included to this study, and it was reported that oxygenation significantly

improved from supine to prone positioning partial arterial oxygen pressure/fraction of inspiratory oxygen – $\text{PaO}_2/\text{FiO}_2$ ratio 180.5 ± 76.6 vs 285 ± 112.9 $p < 0.0001$. But only 50% of study patients could maintain this improved oxygenation after resupination, and this improvement was not significant compared with before prone positioning. [4] Dorsal lung regions have a higher density of blood vessels which is independent of gravity. Prone improves the ventilation in these nondependent lung fields, thereby improving the ventilation:perfusion (V:Q) matching. In another experience from Jiangsu province in china, lower mortality was shown in COVID-19 with with early recognition and intervention which included awake PP. Another pilot observational cohort study was carried out in a single emergency department (ED) in New York City which included 50 patients having COVID-19 with hypoxia ($\text{SpO}_2 < 90\%$). Elharrar et al presented a prospective before and after, single-center, French hospital study of 24 patients with acute hypoxemic respiratory failure and infiltrates on computerized tomography (CT) chest. [5-8]

In a Singapore study of 10 COVID-19 pneumonia patients requiring supplemental oxygen inwards underwent 1-hour session each of prone position, five sessions a day, each 3 hours apart. Similar results were seen in Italy, where Coppo and colleagues enrolled 56 confirmed COVID-19- related pneumonia receiving supplemental oxygen or non-invasive CPAP, who were prone for a minimum duration of 3 hours. In a study in Columbia University, all consecutive patients admitted to the step-down unit between April 6 and April 14, 2020 ($n = 88$) with laboratory confirmed COVID-19 with severe hypoxemic respiratory failure [respiratory rate (RR) ≥ 30 breaths/minute or $\text{SpO}_2 \leq 93\%$] receiving supplemental oxygen 6 L/minute via nasal cannula and 15 L/minute via NRBM were included. [9-11]

Singh P et al conducted a retrospective case study to look for benefits of awake proning with oxygen therapy in non-intubated COVID patients. The COVID-19 patients often present with low oxygen saturation requiring supplemental oxygen. However, absence of dyspnea and tachycardia is seen aptly described as "happy hypoxia". In recent time, awake prone position therapy has come up with great benefits. This technique improves oxygenation and decreases the need for invasive ventilation. With the global pandemic putting a strain on many countries' resources, a high-flow oxygen therapy with awake prone position seems to be of low risk, easy to perform, and low cost management strategy in non-intubated patients. Awake prone positioning showed marked improvement in P/f ratio and SpO_2 in COVID-19 patients with improvement in clinical symptoms with reduced rate of intubation. [12]

A systematic review and meta-analysis by Sryma PB et al on awake prone positioning in non-intubated patients for the management of

hypoxemia in COVID-19. Coronavirus disease may lead to hypoxemia, requiring intensive care in many patients. Awake prone positioning (PP) is reported to improve oxygenation and is a relatively safe modality. A meta-analysis was performed to estimate the proportion of patients requiring intubation. The degree of improvement in oxygenation parameters (PaO₂: FiO₂ or PaO₂ or SpO₂) was also calculated. Sixteen studies (seven prospective trials, three before-after studies, six retrospective series) were selected for review. There was a significant improvement in PaO₂: FiO₂ ratio, PaO₂, and SpO₂ during awake PP.[13] Jayakumar D et al compared standard care vs. awake prone position in adult non-intubated patients with acute hypoxaemic respiratory failure secondary to COVID-19 infection in a multi-centre feasibility randomized controlled trial. The feasibility and safety and its impact on outcomes if any was studied on awake prone positioning in non-intubated patients with COVID-19 pneumonia requiring supplemental oxygen. The primary outcome was the proportion of patients adhering to the protocol in each group. Secondary outcomes include failure of therapy leading to escalation of respiratory support, number of hours prone, maximum hours of continuous prone positioning in a day, length of stay in ICU, ICU mortality, total number of patients needing intubation and adverse events. There was no significant difference in any of the secondary outcomes between the two groups and there were no adverse events. Conclusion of the study was that awake proning in non-intubated patients with acute hypoxic respiratory failure is feasible and safe under clinical trial conditions. The results of our feasibility study will potentially help in the design of larger definitive trials to address this key knowledge gap.[14] Sodhi K et al reviewed the literature of awake proning in non-intubated patients and described a safe protocol to practice the same. Prone positioning has been shown to improve oxygenation for decades. However, proning in awake, non-intubated patients gained acceptance in the last few months since the onset of coronavirus (COVID-19) pandemic. To overcome the shortage of ventilators, to decrease the overwhelming burden on intensive care beds in the pandemic era, and also as invasive ventilation was associated with poor outcomes, proning of awake, spontaneously breathing patients gathered momentum. Being an intervention with minimal risk and requiring minimum assistance, it is now a globally accepted therapy to improve oxygenation in acute hypoxemic respiratory failure in COVID-19 patients. [15] A meta-analysis was done by Cardona S et al on intubation rate of patients with hypoxia due to COVID-19 treated with awake proning. Awake proning was associated with an intubation rate of 28% among COVID-19 patients. Their search identified 1043 articles. The intubation rate was 28% (95% CI 20%–38%, $I^2 = 63\%$). The mortality rate among patients who underwent awake PP was 14% (95% CI 7.4%–24.4%). Potential sources of heterogeneity were study design and setting (practice and geographic). The study demonstrated an intubation rate of 28% among hypoxic patients with COVID-19 who underwent awake PP. Awake PP in COVID-19 is feasible and practical, and more rigorous research is needed to confirm this promising intervention.[16]

A case series by Shanbhag V et al on utility of awake prone positioning with low-dose systemic corticosteroids in coronavirus disease acute respiratory distress syndrome patients. Awake prone positioning and systemic corticosteroids are simple interventions, which can prevent the requirement of mechanical ventilation and also lead to reduction in the inflammatory response and disease severity. They reported a case series of six patients who diagnosed with COVID-19 ARDS and were benefitted by awake prone positioning sessions and low-dose systemic corticosteroid therapy.[17] Evidence-based National Consensus: Recommendations for Physiotherapy Management in COVID-19 in Acute Care Indian Setup was done by Jiandani MP et al. Physiotherapists participated as frontline workers to contribute to management of patients in COVID-19 in reducing morbidity of these patients and aiding them to road to recovery. With infrastructure and patient characteristics different

from the West and lack of adequate evidence to existing practices, there was a need to formulate a national consensus. This document offers physiotherapy evidence-based consensus and recommendation to planning physiotherapy workforce, assessment, chest physiotherapy, early mobilization, preparation for discharge planning, and safety for patients and therapist in acute COVID-19 setup of India. The recommendations have been integrated in the algorithm and are intended to use by all physiotherapists and other stakeholders in management of patients with COVID-19 in acute care settings.[18]

COVID-19 pneumonia is a specific disease whose distinctive features are severe hypoxemia often associated with near normal respiratory system compliance. Hence, an unusual phenomenon of “happy hypoxia” or “silent hypoxemia” is seen in many patients. Patients appear to be normally functioning without dyspnea and tachycardia despite being hypoxemic. In recent studies, awake prone positioning was used in emergency department and ward settings to maintain oxygenation of COVID-19 patients. Studies have shown to avoid intubation with early application of prone positioning with high-flow nasal cannula (HFNC) in moderate ARDS patients. In our study, we also found that the median P/f ratio significantly improved from supine to prone position from day 1 to day 10. We were able to reduce the intubation rates, avoid the problems related to invasive ventilation and with use of sedation and neuromuscular blockers. The mean duration of stay was 10 days in HDU.

Conclusion

Awake prone positioning showed marked improvement in P/f ratio and SpO₂ in COVID-19 patients with improvement in clinical symptoms and minimal complications. We were able to reduce the intubation rates which helped in offloading the resource and manpower burden on healthcare system in pandemic.

Limitations

- There was no randomization to a control group.
- Sample size of the study was small.
- High-flow nasal cannula was not available in our set up which is highly recommended.

What This Study Add To Existing Knowledge

Awake self-proning has been shown to improve oxygenation in COVID-19 patients in multiple observational studies. It may not successfully prevent all intubations but is a zero-cost tool to use with minimal complications. Its effects on mortality are yet to be studied in controlled trials. Though it appears promising, careful, and frequent monitoring of patients requiring high oxygen flows is recommended. Also, whether awake proning will help in non-C-ARDS, is yet an unanswered question, but it may be a potential low-cost therapeutic option in an acute hypoxemic respiratory failure of all causes.

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