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Effect of Priority and Delay of Prone Positioning and Chest Physiotherapy on Respiratory Outcomes in Patients with COVID-19: A Randomized Clinical Trial

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ABSTRACT

Background: COVID-19, caused by the SARS-CoV-2 virus, is a novel coronavirus that has led to a global pandemic. Physiotherapy is among the beneficial treatments for this disease. This study investigated the impact of the priority and delay of prone positioning and chest physiotherapy (CPT) on patients with COVID-19.

Methods: A randomized clinical trial was conducted involving 26 COVID-19 patients who were randomly assigned to two groups: one group prioritizing prone positioning over chest physiotherapy (comprising seven men and six women, with an average age of 67.46±5.91) and the other group prioritizing CPT over prone positioning (comprising eight men and five women, with an average age of 68.38±5.85). Respiratory outcomes, including SpO2, PaO2, FiO2, FEV1, and FVC, were measured using pulse oximetry, arterial blood gas analysis (ABG), and spirometry). FEV1/FVC and SpO2/FiO2 ratios were evaluated both before and after the intervention

Results: The demographic characteristics of the patients and the baseline respiratory outcomes between the two groups did not exhibit significant differences ($P>0.05$). A significant difference was observed in respiratory outcomes within each group before and after the intervention ($P<0.05$). However, after the intervention, there were no significant differences between the two groups in terms of respiratory outcomes ($P>0.05$)

Conclusion: Both prioritizing prone positioning over CPT and prioritizing CPT over prone positioning appeared to improve each respiratory outcome. Nevertheless, it was not observed that prioritizing or delaying prone positioning and CPT improved respiratory outcomes in patients with COVID-19.

Introduction

COVID-19, known as SARS-CoV-2, is a member of the β-coronavirus family and is primarily transmitted through respiratory droplets and human contact [1-4]. This infectious disease typically presents as a mild febrile illness, with symptoms such as fever, dry cough, myalgia, pneumonia, and severe dyspnea appearing a few days after infection [4, 5]. Acute Respiratory Distress Syndrome (ARDS) is a serious and predictable complication of COVID-19 that manifests 8 to 12 days after infection and requires early diagnosis and comprehensive management [5, 6]. It is often associated with severe oxygen deficiency, pulmonary edema, decreased lung compliance, and increased work of breathing [7]. ARDS affects approximately 20% of COVID-19 patients and can lead to mortality rates ranging from 20% to 50% in these individuals [8].

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Regarding radiological findings, COVID-19 can be divided into four phases, including the initial phase, characterized by moderate clinical symptoms, during which lung damage is limited to one or more areas in the pleura and bronchi; the progressive phase, in which lung damage rapidly worsens, leading to acute clinical symptoms; the acute phase, which is characterized by the maximum extent of lung damage; and the disintegration phase, which indicates the development of fibrosis [9].

Based on the severity of symptoms, patients require different types of interventions. Patients with severe symptoms may progress to respiratory failure, necessitating invasive ventilation. Approximately 14% of COVID-19 patients require hospitalization, and 5% need intensive care unit (ICU) intervention [10-13]. However, for those with mild to moderate symptoms, non-invasive interventions such as prone positioning [8], chest physiotherapy (CPT) [4], and other airway clearance techniques [14] may be employed [15].

Prone positioning has been shown to reduce mortality in severe Acute Respiratory Distress Syndrome (ARDS) patients requiring mechanical ventilation. Several studies have suggested that prone positioning can reduce arrhythmias, improve oxygenation, decrease pulmonary shunting, and maintain hemodynamic stability. Zarantonelli et al. [16] and Corsetti et al. [17] reported enhanced oxygenation and increased SpO2 levels after placing patients in the prone position. Consequently, prone positioning is recommended as a standard care approach for patients with severe ARDS, whether or not they have COVID-19 [2, 18-21].

By enhancing ventilation, chest physiotherapy may slow disease progression and reduce the need for mechanical ventilation in patients with Acute Respiratory Distress Syndrome (ARDS) [22]. It has found applications in treating diseases like SARS, COPD, and, more recently, COVID-19 [23]. Chest physiotherapy can lead to decreased hospitalization reduced mechanical ventilation duration, and help prevent ventilation-associated pneumonia in COVID-19 patients requiring mechanical ventilation [24, 25]. Additionally, it can play a role in preventing recurrent respiratory failure after patient discharge [9]. Studies conducted by Thomas et al. [13] and Viticca et al. [14] applied airway clearance techniques in COVID-19 patients and found that these techniques could improve oxygenation and the PaO2/FiO2 ratio [26]. Although the effects of each of these treatment methods have been investigated individually and in combination, no study has compared their effectiveness or determined their superiority concerning respiratory indices.

Taking into account the various beneficial effects associated with each of these methods, as well as the supporting findings from studies that highlight their role in improving respiratory outcomes in various pulmonary conditions, including COVID-19 [27-30], it raises the question of whether the order in which these methods are prioritized can impact the enhancement of respiratory indices. The underlying assumption of this study was that prioritizing chest physiotherapy, which aids in airway clearance, may amplify the effects of prone positioning in facilitating better ventilation in COVID-19 patients, and conversely, prioritizing the prone positioning may enhance the benefits of chest physiotherapy. In light of the need for more in-depth investigations and developing a therapeutic protocol to optimize effectiveness, this study was designed to explore the impact of prioritizing or delaying the use of prone positioning and chest physiotherapy on respiratory outcomes in COVID-19 patients.

Methods

Trial Design

The authors conducted a parallel-arm randomized clinical trial following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [27]. This trial was conducted at Imam Khomeini Hospital in Tehran, Iran, from January 2022 to July 2022. The trial was registered with an IRCT20210505051181N2 registration number in the Iranian Registry of Clinical Trials (IRCT). Ethical approval for the study (IR.IUMS.REC.1400.646) was obtained from the Iran University of Medical Sciences, and informed consent was obtained from all participating patients.

Participants

Eligible participants for this study were adults aged 35 to 75 years who were diagnosed with COVID-19 confirmed through a positive polymerase chain reaction (PCR) test, chest computed tomography (CT) scans, and exhibited signs of the progressive or acute phase of the disease. These individuals were either breathing room air spontaneously or receiving less than 6 L/min of supplemental oxygen via a nasal cannula, and they were receiving daily remdesivir treatment for five days, with the initial dose being 200 mg as a single dose followed by 100 mg daily [28]. Exclusion criteria included the need for mechanical ventilation, the inability to assume a prone position, immediate requirement for endotracheal intubation, a history of neurological disease, chest or abdominal surgery within the last four months, blood coagulation disorders, a history of deep venous thrombosis (DVT), pulmonary embolism, or active bleeding in the chest, or a rib fracture [29, 30]. The study participants were patients admitted to the COVID-19 section of Imam Khomeini Hospital.

Randomization

The authors employed random allocation software to generate a random sequence for the randomization process. The study followed a single-blind design, with the patients unaware of their treatment group assignments.

Trail Protocol (Intervention)

The patients were randomly assigned to one of two groups: Group A, where the priority was given to prone positioning over chest physiotherapy (CPT), and Group B, where the priority was given to CPT over prone positioning. In the prone positioning, patients were placed facedown on the bed for 3 hours a day for six sessions. Chest physiotherapy techniques, including percussion, vibration, diaphragmatic, and segmental breathing, were

performed daily for 30 minutes in 6 sessions. For Group A, the patient started with 3 hours of prone positioning, followed by 30 minutes of CPT, and the first 30 minutes in Group B involved CPT, followed by 3 hours in the prone position. The intervention was conducted over six consecutive days. The physiotherapist had the authority to withdraw a patient from the trial at any time during the study if they deemed the intervention unsafe.

Data Collection

Data related to age, gender, height, weight, BMI, SpO2, PaO2, PaO2/FiO2 ratio, FEV1, FVC, and FEV1/FVC ratio were collected during enrollment. The physiotherapist recorded these assessments during the first and last sessions.

Outcome Measures

SpO2 was measured using a pulse oximeter (Contec Finger Tip Pulse Oximeter). PaO2 and FiO2 levels were determined from arterial blood gas (ABG) analysis and a monometer. FEV1 and FVC measurements were conducted using spirometry (Kala mod, KSP-1000 PC-SPIRO). FEV1/FVC and SpO2/FiO2 ratios were calculated based on these measurements. The validity and reliability of these tests in various pulmonary diseases, including COVID-19, have been established in prior studies [31-33].

Sample Size Calculation

The sample size calculation was based on data from a pilot study involving nine subjects. The variables used for sample size calculation included the following: pilot study baseline SpO2 in PP+CPT (88.51±1.01), pilot study final SpO2 in PP+CPT (93.37±1.59), pilot study baseline SpO2 in CPT+PP (89.44±1.87), and pilot study final SpO2 in CPT+PP (95.12±1.18). With a power of 0.8, a confidence level of 0.95, and accounting for a 10% potential dropout rate, 26 participants were enrolled in the study.

Statistical Analysis

The data obtained from the study were analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 26. Descriptive statistics were calculated, including mean and standard deviation (SD). The normality of the data was assessed with the Shapiro-Wilk test. Parametric tests were used for data with a normal distribution, while non-parametric tests were applied to data with non-normal distribution. An independent t-test was employed to compare the two groups' demographic characteristics and conduct a between-group comparison of the respiratory outcomes at baseline. Within-group comparisons of variables were performed using paired t-tests. Furthermore, an independent t-test was used for the between-group comparison of the changes in each respiratory outcome after the intervention. The statistical analysis was conducted at a 95% confidence level, and a P-value less than 0.05 was considered statistically significant.

Results

A total of 26 participants with Covid-19 who met the inclusion criteria were eligible for the study. The CONSORT flow diagram in Figure 1 illustrates the patient enrollment process. The Shapiro-Wilk test indicated normal distribution for participant characteristics, and for dependent variables, normal distribution (P>0.05) was observed for all respiratory outcomes in group A, except for the FEV1/FVC ratio before the intervention (P<0.05).

Table 1: Baseline characteristics

Variable	Groups	Standard deviation±mean	P value
Age	Priority of prone position over chest physiotherapy	67.46±5.91	0.693
	Priority of chest physiotherapy over prone position	68.38±5.85	
Weight (Kg)	Priority of prone position over chest physiotherapy	76.23±11.81	0.698
	Priority of chest physiotherapy over prone position	78.00±11.16	
Height (cm)	Priority of prone position over chest physiotherapy	164.77±13.39	0.781
	Priority of chest physiotherapy over prone position	166.23±13.15	
BMI (Kg/m^2)	Priority of prone position over chest physiotherapy	28.04±1.66	0.828
	Priority of chest physiotherapy over prone position	28.21±2.26	

Independent-samples t-test and Mann Whitney U test

Table 2: respiratory outcomes between-groups at baseline

Variable	Central Tendency	Groups	Values	P value
SpO_2 (%)	Median (IQR)	Group A[1]	89.00 (88.00-90.00)	0.979
		Group B[2]	89.00 (88.00-90.50)	
PaO_2 (mmHg)	Median (IQR)	Group A	56.00 (54.00-58.00)	0.979
		Group B	56.00 (54.00-59.00)	
PaO_2/FiO_2 (mmHg)	Median (IQR)	Group A	266.67 (257.14-276.19)	0.979
		Group B	266.66 (257.14-280.95)	
FEV1 (L)	Median (IQR)	Group A	72.58 (71.72 -77.34)	0.158
		Group B	72.84 (69.19-74.78)	
FVC (L)	Mean±Standard Deviation	Group A	0.65±1.98	0.828
		Group B	0.67±2.04	
FEV1/FVC (%)	Mean±Standard Deviation	Group A	0.93±2.69	1.00
		Group B	0.93±2.69	

Independent-samples t-test and Mann Whitney U test. [1]Group of Priority of prone position over chest physiotherapy. [2]Group of Priority of chest physiotherapy over prone position

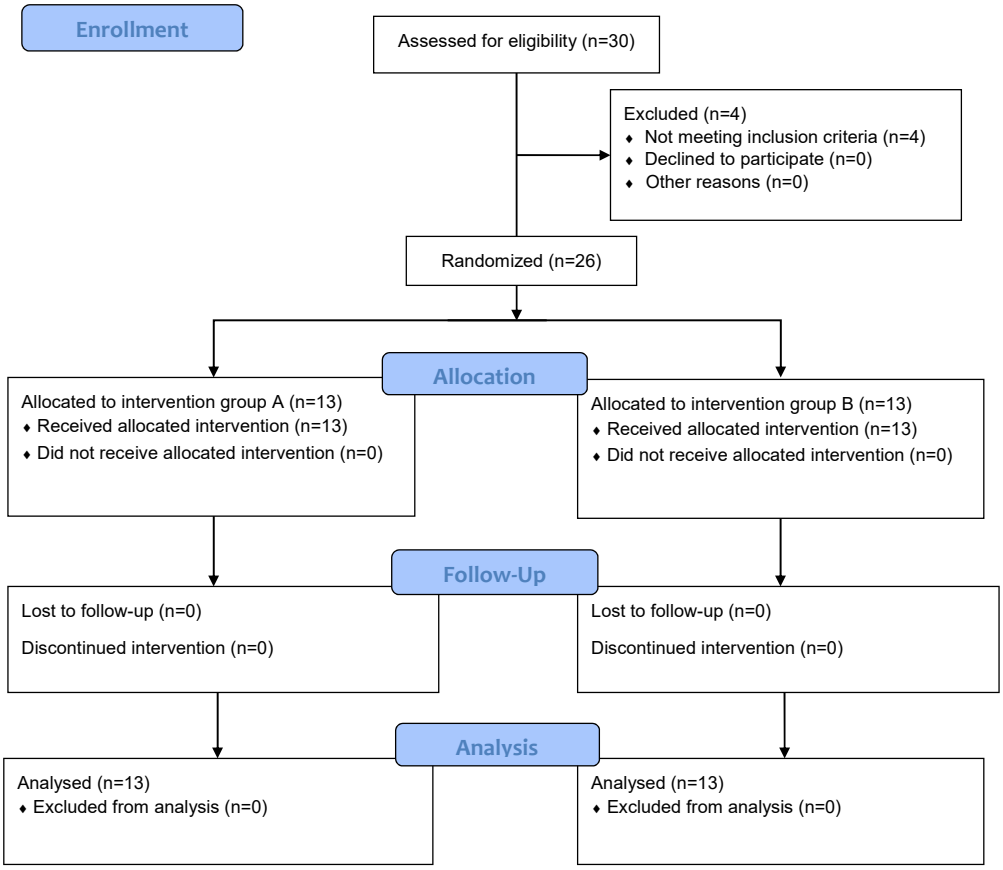

Figure 1: CONSORT flow diagram

In group B, the distribution of SpO2, PaO2, PaO2/FiO2 ratio before the intervention, and FEV1/FVC ratio after the intervention was non-normal (P<0.05). Independent t-tests revealed no significant differences in baseline characteristics between the two groups (P>0.05), as presented in Table 1. Respiratory outcomes did not significantly differ between groups at baseline (P>0.05) (Table 2). In each group, all variables showed significant improvement from baseline to discharge (P<0.05) (Table 3). No significant differences were found in respiratory outcomes between the two groups after the intervention (P>0.05) (Table 4). Therefore, the priority or delay of prone positioning over chest physiotherapy did not improve respiratory outcomes.

Discussion

The primary objective of this study was to explore the impact of prioritizing or delaying prone positioning and chest physiotherapy (CPT) on respiratory outcomes in COVID-19 patients. The key findings of this investigation can be summarized as follows: Prioritizing prone positioning over CPT led to a significant improvement in respiratory outcomes (P<0.05); Prioritizing CPT over prone positioning also resulted in a significant enhancement of respiratory outcomes (P<0.05); After the intervention, there was no significant difference in the improvement of respiratory outcomes between the two groups based on the priority or delay of prone positioning and CPT.

COVID-19 patients often present with moderate to severe respiratory symptoms and have an increased risk of hypoxemic respiratory failure upon admission to the intensive care unit [3, 4]. Consequently, various ventilatory strategies, such as prone positioning and early chest physiotherapy, may be necessary [3, 13, 17].

Table 3: Respiratory outcomes before and after intervention in each group

Groups	Variable	Central Tendency	Before Intervention	After Intervention	P value
Priority of prone position over chest physiotherapy	SpO_2 (%)	Mean±Standard Deviation	89.15±1.40	94.46±1.66	0.000
	PaO_2 (mmHg)	Mean±Standard Deviation	56.46±3.17	79.07±12.86	0.000
	PaO_2/FiO_2 (mmHg)	Mean±Standard Deviation	268.86±15.13	376.56±61.27	0.000
	FEV1 (L)	Mean±Standard Deviation	1.98±0.65	2.44±0.90	0.000
	FVC (L)	Mean±Standard Deviation	2.69±0.93	3.06±1.11	0.000
	FEV1/FVC (%)	Median±(IQR)	72.58 (71.25-77.34)	79.89 (79.25-80.55)	0.001
Priority of chest physiotherapy over prone position	SpO_2 (%)	Median±(IQR)	89.00 (88.00-90.50)	93.00 (92.00-94.50)	0.001
	PaO_2 (mmHg)	Median±(IQR)	56.00 (54.00-59.00)	68.00 (64.00-76.50)	0.001
	PaO_2/FiO_2 (mmHg)	Median±(IQR)	266.66 (257.14-280.95)	323.81(304.76-364.29)	0.001
	FEV1 (L)	Mean±Standard Deviation	0.67±2.04	0.83±2.53	0.000
	FVC (L)	Mean±Standard Deviation	0.97±2.85	1.04±3.19	0.000
	FEV1/FVC (%)	Median±(IQR)	72.84 (69.19-74.78)	79.47 (78.68-80.51)	0.001

Paired T-test and Wilcoxon test

Table 4: Respiratory outcomes between two groups after intervention

Variable	Central Tendency	Groups	Values	P value
SpO_2 (%)	Mean±Standard Deviation	Group A[1]	94.46±1.66	0.066
		Group B[2]	93.23±1.59	
PaO_2 (mmHg)	Mean±Standard Deviation	Group A	79.07±12.86	0.058
		Group B	70.46±8.83	
PaO_2/FiO_2 (mmHg)	Mean±Standard Deviation	Group A	376.56±61.27	0.058
		Group B	335.53±42.04	
FEV1 (L)	Mean±Standard Deviation	Group A	2.44±0.09	0.814
		Group B	2.53±0.83	
FVC (L)	Mean±Standard Deviation	Group A	3.06±1.11	0.761
		Group B	3.19±1.04	
FEV1/FVC (%)	Median (IQR)	Group A	79.89 (79.25–80.56)	0.418
		Group B	79.47 (78.68–80.51)	

Paired T-test and Wilcoxon test; [1]Group of Priority of prone position over chest physiotherapy. [2]Group of Priority of chest physiotherapy over prone position.

Early rehabilitation interventions can play a vital role in mitigating or preventing the adverse effects of prolonged bed rest, enhancing physical function, improving respiratory outcomes, and reducing the length of hospital stays, potentially eliminating the need for mechanical ventilation [34].

Prone positioning is a well-established technique for enhancing oxygenation in severe ARDS [17, 20]. Guerin et al. reported that prone positioning could lower mortality rates [20], emphasizing the importance of using pronation cycles for sustained oxygenation improvements [17]. In the current study, significant improvements in respiratory outcomes were observed after applying the prone positioning technique, with increases of 5.31% in SpO2, 22.66 mmHg in PaO2, 107.69 mmHg in PaO2/FiO2 ratio, 0.48 L in FEV1, 0.37 L in FVC, and 7.31 L in the FEV1/FVC ratio. Although there have been few studies on the effects of prone positioning in COVID-19 patients, all have consistently confirmed its positive impact [8, 13, 16, 17, 35]. For instance, a study involving a 74-year-old woman with covid-19 and non-invasive ventilation demonstrated a significant improvement in SpO2 upon transitioning to the prone position, with the PaO2/FiO2 ratio increasing from 87 mmHg to 203 mmHg in the second hour [16]. Additional research conducted by Carsetti et al. [17] and Moghadam et al. [35] on covid-19 patients under mechanical ventilation showed that prone positioning for 16 and 9 hours daily led to improved oxygenation. This improvement in respiratory outcomes with prone positioning can be attributed to enhanced arterial gas exchange, reduced overexpansion in non-affected lung areas, and improved oxygen delivery, as dorsal regions of the lung are engaged during this procedure [36]. Therefore, it is plausible to explain the observed improvements in respiratory outcomes in the current study by prioritizing prone positioning over chest physiotherapy.

Chest physiotherapy (CPT) for COVID-19 patients encompasses various techniques, including the active cycle of breathing, forced expiratory techniques, percussion, vibration, positive expiratory pressure (PEP), high-frequency oscillatory devices, autogenic drainage (AD), secretion clearance, mobilization, and exercise prescription [9, 13]. CPT has several goals, such as alleviating dyspnea, reducing anxiety and depression in the short term, and enhancing long-term physical function and quality of life [15, 37]. In our study, significant improvements in respiratory outcomes were observed following CPT, with increases of 6% in SpO2, 24 mmHg in PaO2, 57.15 mmHg in the PaO2/FiO2 ratio, 0.49 L in FEV1, 0.034 L in FVC, and 6.63 L in the FEV1/FVC ratio. While there have been fewer studies examining the effects of CPT on COVID-19, they have consistently reported positive effects across different stages of the disease [3, 9, 12, 13, 24, 26]. The study findings align with the conclusions of Lazzeri et al. [26], who found that CPT could benefit mechanically ventilated COVID-19 patients. In a case report by Wong et al. [22], CPT significantly improved arterial oxygenation in a patient experiencing acute respiratory failure.

Based on studies and a critical review of the safety and efficacy of CPT in patients with COVID-19, this could explain the results of this study. A critical review by Auwal Abdullahi [5] concluded that "CPT may improve respiratory function and quality of life in patients with COVID-19, especially after discharge". Additionally, there is a lack of evidence of its usefulness during the acute phase because of the risk of spreading aerosol generated by CPT. However, CPT is an individualized treatment for patients' presentations [5].

The combined effect of prone positioning and CPT has been explored in several studies [38-40], revealing improvements in PaO2/FiO2 ratio and SpO2. The current study and previous research suggest the potential benefits of employing both interventions simultaneously, in addition to the benefits of each intervention alone, to enhance respiratory outcomes. However, based on the current study results, the priority or delay of these interventions did not appear to influence the improvement in respiratory outcomes. Our initial hypothesis postulated that prioritizing chest physiotherapy with its airway-clearing effects might enhance the benefits of prone positioning for better ventilation and vice versa. However, the outcomes of the current research did not support this hypothesis.

It's worth noting that this study was conducted during the Omicron strain epidemic. A significant portion of the upper lung lobes were affected during this period. Considering that prone positioning primarily affects the middle and lower lobes, it's possible that the effect

of prone positioning was somewhat overshadowed and didn't reach the expected level of impact.

Several limitations need to be acknowledged in this study. One significant limitation is the lack of an adequate patient follow-up period, an area for potential improvement in future randomized clinical trials. Another limitation arises from the concurrent use of drug therapy among patients, making it challenging to determine the net effect of the intervention. However, the authors attempted to mitigate this limitation by ensuring the homogenization of drug treatments among participants. Lastly, it's important to note that this study was conducted at a single center, which could impact the generalizability of the findings.

Conclusion

The findings from this study indicate that the priority of prone positioning over CPT and the priority of CPT over prone positioning can lead to improvements in various respiratory outcomes. However, prioritizing either intervention did not result in significantly different outcomes for COVID-19 patients. In other words, both groups showed similar levels of improvement in respiratory variables among COVID-19 patients. Therefore, the order or timing of applying prone positioning and CPT did not appear to substantially impact the rate of recovery in these patients.

Conflict of Interest: None declared.

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