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Effect of Chest Physiotherapy with Threshold Valve in Hospitalized Adults with COVID-19 Pneumonia

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Abstract: Background: COVID-19 pneumonia caused by SARS-Cov-2 virus induces alveolar collapse and hypoxia that may become severe. The aim of the study is to analyze the effects of chest physiotherapy using a threshold valve in patients with acute respiratory failure due to COVID-19 pneumonia. Methods; Retrospective observational study, in hospitalized patients from March to May 2020. Breathing exercises were performed with a threshold valve of 10 cmH_2O. Fraction of inspired oxygen, oxygen saturation, heart rate, respiratory rate and dyspnea were collected before and after the first session and at the end of the 5th day of chest physiotherapy treatment. Results: The final sample included 125 patients. Significant differences ($p<0.01$) were found in the pre-post intervention SpO2/FiO2 ratio (250±88.4 vs 275.6±97.5, $p<0.001$), reaching 354.4±110.2 after 5 days of therapy ($p<0.001$ with respect to baseline). Mean baseline respiratory, heart rate and level of dyspnea measure by the Borg scale did not change during the technique performance. In patient maneuvers with FiO2>0.4, the SaO2/FiO2 ratio increase was higher than in patients with milder severity (46.85 ± 77.69, $p<0.01$). Conclusions: Chest physiotherapy with a 10 cmH2O threshold valve is a safe and tolerated intervention with short-term improvement in oxygenation in patients with COVID-19 pneumonia.

Keywords: COVID-19; pneumonia; hospitalized patients; chest physiotherapy; positive expiratory pressure; threshold valve

1. Introduction

The World Health Organization declared on 11 March 2020 a global pandemic of COVID-19 disease caused by the SARS-COV-2 virus [1]. More than 570 million people have been infected by the SARS-2 coronavirus, causing almost 6 million deaths worldwide [2]. In Spain, more than 500,000 people have been hospitalized due to COVID-19, of which 52,215 have been treated in Intensive Care Units (ICU), causing more than 100,000 deaths nationwide [3].

COVID-19 is a disease that can affect multiple organs [4,5], with the lung being the main target organ. The pathophysiological sequence at the pulmonary level includes destruction of the alveolar epithelium, hyaline membrane formation, capillary damage, bleeding, and pulmonary consolidation, which can cause short-term severe acute respiratory failure (ARF), as well as long-term respiratory sequelae [6–8].

Chest physiotherapy (CP) has been applied as a treatment for pneumonia patients for a long time, using different techniques and strategies [9]. One of the techniques used are exercises using positive expiratory pressure (PEEP) devices, which use a threshold resistance to expiratory flow to generate airway pressure higher than atmospheric pressure. The effects of this PEEP in the expiratory phase result in the prevention and resolution of atelectasis, improved ventilation-perfusion ratios, and improved secretion drainage. At the same time, the positive pressure generated by the device increases alveolar pressure, leading to alveolar recruitment [10,11].

The hypothesis of the present study postulates that patients with COVID-19 pneumonia in the early acute phase may benefit from performing the maneuver with the 10 cmH2O PEEP valve, resulting in short-term improvement of oxygenation without significant side effects.

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2. Materials and Methods

The study design was retrospective observational and was conducted at the Hospital Universitario Parc Taulí de Sabadell (HUPTS) (Barcelona) from March 23rd to May 4th, 2020. The study was approved by the hospital's Ethics Committee (reference 2020/571). As the study was carried out during the first wave of the pandemic, participants were only asked for oral informed consent.

The target population included patients in the acute hospital setting for COVID-19 pneumonia with ARF (partial pressure of oxygen less than 60 breathing on room air) under treatment with oxygen therapy (including Venturi mask, reservoir mask or high flow nasal oxygen) and in whom indication for chest physiotherapy by the attending medical practitioner was made. Patients unable to collaborate and requiring non-invasive mechanical ventilation were excluded due to interference with the maneuvers.

The intervention consisted of a daily CP session with a 10 cmH2O PEEP valve (Model 2210000, Intersurgical™, Berkshire, UK) from the day of consultation until hospital discharge. To reduce the spread risk of viral particles, an antibacterial and viral filter (Clear-Guard, Intersurgical™, Berkshire, UK) was added to the device. The protocol consisted of 2 series of 5 exhalations through the device, with short breaks in between, depending on the patient's tolerance. Patients performed the maneuvers while seated in an armchair or in Fowler position in bed. Patients were instructed to perform a deep inspiration at total lung capacity, followed by a tele-inspiratory pause of approximately 3 seconds and a controlled, constant-flow exhalation at the PEEP valve, strong enough to open the valve.

After the first session, patients were given a reminder sheet of the exercises with a QR code, where they could access a video to visualize and remember how to perform the technique (https://youtu.be/4j0WhBmdDOs) (Video S1;breathing exercise). During the session, heart rate (HR) and oxygen saturation (SpO2) were monitored with a pulse oximeter (PulsoxTM-2™, Konica Minolta, Tokyo, Japan) and respiratory rate by counting breaths per minute.

Criteria for stopping the maneuver were: respiratory rate ≥ 35 breaths/min and occurrence of any of the following symptoms: sweating, occurrence of dry cough, dizziness, chest tightness, blurred vision, aerophagia, palpitations or inability to maintain balance.

Data collection: Demographic variables (gender, age), comorbidities, grouped into the Charlson comorbidity index, were recorded at the time of enrolment. The dyspnea level (modified BORG scale [12]) and the SaO2/FiO2 ratio were collected in three phases of the protocol: baseline, post-intervention of the first session and at the end of 5 days of consecutive CP treatment. At the same time, heart rate (heartbeats /min) and respiratory rate (breaths/min) were recorded as safety variables. Concerning severity level, the sample was stratified into patients with severe ARF (FiO2 requirement greater than 0.4 to maintain SpO2 > 94%) or mild-moderate ARF (requirement less than 0.4 to maintain SpO2 > 94%). A 15 % increase in SpO2/FiO2 ratio from baseline was considered a clinically relevant improvement.

Statistical analysis

Quantitative variables were presented as mean and standard deviation or median and interquartile range for non-normally distributed variables. Categorical variables were presented in frequencies and percentages. Comparison for oxygenation (SaO2/FiO2 ratio) and safety parameters (respiratory and heart rate) before and after the intervention was performed using the Student's t-test for paired data. Factors associated with clinically relevant improvement were examined using the Chi-square test. We used the statistical package SPSS version 28 (Chicago, Illinois). The significance level was set at $p<0.05$.

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3. Results

155 interventions were applied to different patients, 30 of them were excluded: 9 requiring non-invasive mechanical ventilation, 14 for not collaboration and 7 for intolerance. 125 patients were included in the study. Table 1 shows the patients' demographic data, comorbidities, hospitalization-related variables, as well as the intubation and mortality rate. The different oxygen therapy devices and the total number of days of treatment are also given. The median FiO2 before starting the intervention was 0.35 (interquartile range 0.28-0.55).

Table 1. Anthropometric characteristics, Descriptive data for the sample (n=125).

Age (years)	66 (29;91)[1]
Female gender	38 (30.6)[2]
Charlson Index	3 (0;12)[1]
FiO_2	0.35 (0.24;0.80)[1]
Oxygen therapy devices	
Nasal prongs	15 (12)[2]
Venturi Mask	75 (60)[2]
Reservoir Mask	29 (23.2)[2]
High-flow nasal oxygen	6 (4.8)[2]
Oxygen therapy days	17 (5;63)[1]
Days until start of physiotherapy	17.5 (3;46)[1]
Physiotherapy treatment days	8 (1;62)[1]
Days of hospitalisation	18 (5;73)[1]
Orotracheal intubation rate	4 (3.2)[2]
Mortality rate	6 (4.8)[2]

Median (interquartile range)[1] and Frequencies (% percentages)[2].

The intervention effect variables are described in Table 2: the pre-post intervention SpO2/FiO2 ratio showed a significant increase after the maneuvers (250±88.4 vs 275.6±97.5, p<0.001), reaching 354.4±110.2 after 5 days of therapy (p<0.001 with respect to baseline). The safety variables, reflected in this table, showed no significant changes in the mean respiratory and heart rate, as well as in the tolerance represented by dyspnea in the post-intervention compared to the pre-intervention.

Table 2. Short-term effects of CR intervention with PEEP valve on the cohort.

	Baseline	**Post-intervention**	***p***	**Pre-intervention 5**	***p***
Heart rate (heartbeats /min)	78.5 ±14	80.8±14	ns		
Respiratory rate (breaths/min)	20.6±6	19.6±6	ns		
SaO_2/FiO_2 ratio	250.1±88.4	275.6±97.5	<0.001	354.4±110.2	<0.001
Borg Scale	0.5±0.7	0.6±0.6	ns		

Means and standard deviations.

Stratified analysis by patient severity determined that 71 patients were included in mild-moderate ARF, while 54 had severe ARF (FiO2 requirement equal to or greater than 0.4). Short-term improvement was superior in patients with severe ARF, with a mean increase in SaO2/FiO2 ratio of

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46.85±77.69 (p=0.008), while in patients with mild-moderate ARF there was no significant improvement (mean difference of 9.19±76.31, p=0.156).

Compared to baseline, 45 patients (36 %) had a 15 % improvement in SaO2/ FiO2 from baseline. Table 3 shows the factors associated with the improvement produced by the intervention. According to these results, the need for FiO2 greater than or equal to 0.4, the lower SaO2/FiO2 ratio and the absence of pre-intervention dyspnea are predictors of favorable response. Finally, the increase in SaO2/FiO2 after the fifth day of CP was also higher in patients with a favorable initial response.

Table 3. Factors associated with a 15% improvement in the SaO_2/FiO_2 ratio respect to baseline-.

	No Improvement (n=80)	**Improvement (n=45)**	*p*
Anthropometric and comorbidity			
Female gender	20 (52)[3]	18 (47)[3]	ns
Age (years)	63.5 ±12.5[2]	66.4± 13.0[2]	ns
Charlson index	2.9± 2.1[2]	3.6 ±2.6[2]	ns
Time-related variables			
Hospital stay (days)	20.1 ±11.8[2]	24.8±15.2[2]	0.05
Days from admission until start of physiotherapy	9.5 ±6.7[2]	11.1 ± 5.9[2]	ns
Clinical and gas exchange variables			
SaO_2/FiO_2 ratio pre-intervention	266.9±86.0[2]	220.7±86.0[2]	0.04
Need for FiO_2 >0.4	29 (36.2)[3]	25 (55)[3]	0.04
Respiratory rate pre (breaths /min)	21.3 ± 6.6[2]	19.4 ±6.4[2]	ns
Heart rate pre (beats/min)	78.0±13.7[2]	77.7± 14.1[2]	ns
Baseline dyspnoea (BORG Scale)	0.7 ±1.5[2]	0.2 ±0.7[2]	0.05
Outcome variables			
Change in SaO_2/FiO_2 ratio (day 5 CR)[1]	86.6 7± 6.1[2]	135.5 ±94.9[2]	0.01
Endotracheal intubation	3(3)[3]	1(2)[3]	ns
Mortality	3(3)[3]	3(6)[3]	ns

[1] SaO_2 FiO_2 after day five of respiratory physiotherapy compared to basal,[2] Median (interquartile range),[3] Frequencies (% percentages).

4. Discussion

The main study findings are that CP with a threshold valve of 10 cmH2O improves short-term oxygenation in patients with COVID-19 pneumonia; this improvement is greater in patients with severe ARF, with lower baseline SaO2/FiO2 ratio values and less dyspnea. It should also be noted that the patient safety parameters, respiratory and heart rates, did not show a statistically significant change at the end of the intervention. The medians were within the published safety range14, demonstrating that it is a safe technique in this kind of patients. The intervention did not produce any significant increase in the modified BORG scale, demonstrating that it was well tolerated in COVID-19 patients with ARF.

The literature on the effect of CP in patients with SARS-CoV infection is scarce, being the articles on this topic mainly focused on expert consensus or clinical practice recommendations13,15. The main novelty in the present study is the feasibility and effectiveness of a bedside intervention during the first period of the COVID-19 pandemic in patients in the acute hospital setting.

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The main indication for PEEP devices as CP adjunctive therapy, as described in the literature, is in obstructive patients with hypersecretion, such as cystic fibrosis and bronchiectasis11 and being the drainage of secretions the main endpoint. In the published clinical practice guidelines for CP in COVID-19 [13,15], CP technique was not recommended in the acute period of COVID-19 pneumonia, being the lack of secretions the main reason. A systematic review of the efficacy and safety of CP in COVID-19 [16] emphasized in the lack of data about the usefulness of CP in this setting and suggesting the interest of the field.

A review article on the clinical application and effects of PEEP devices [10] described the increase in functional residual capacity and tidal volume after its use and defining the prevention and treatment of atelectasis as an indication for such devices. The results of the present study, showing an improvement in oxygenation that could be attributed to alveolar recruitment, agree with the abovementioned publication [10] and reinforced the idea that CF with PEEP valve is feasible in hypoxemic ARF, even in patients needing high FiO2.

Some limitations in the study should be highlighted. First, it is an observational study without a control group of patients who did not undergo CP. The global emergency and the lack of knowledge about the disease in the early phase of the pandemic were serious limitations for carrying out. In addition, medical treatments were not yet standardized, and the patients included in the study did not receive the same therapy, a fact that unequivocally influenced their evolution. Second, the recruitment was restricted by the inclusion criteria, the CP request by the responsible medical practitioner. Furthermore, the study has only been conducted in patients with pneumonia with ARF secondary to COVID-19, so with the available data and given the special pathophysiology of COVID-19, it is not possible to extrapolate the recommendation to other causes of pneumonia or acute respiratory distress syndrome (ARDS). Finally, the relatively small sample size prevents the generalization of its application to other groups of patients (for example, under high flow oxygen therapy)

The patients' stabilization during CP and the improvement in oxygenation confirm that we have found a new non-pharmacological tool for the treatment of acute, non-exudative pneumonia like a COVID-19 pneumonia.

Due to the scarce scientific evidence on this subject and the potential beneficial effects that CP could bring to patients with ARF secondary to this or other causes, we believe it is necessary to continue to carry out more rigorous studies that provide scientific evidence to the usual clinical practice of CP.

In conclusion,

5. Conclusions

CP with a 10 cmH2O PEEP device in patients with COVID-19 pneumonia improved short-term oxygenation, being a safe and well tolerated intervention. Furthermore, patients with lower PaO2/FiO2 ratio and higher FiO2 requirements and lower dyspnea presented greater short-term benefits.

Supplementary Materials: The following supporting information can be visualized at: https://youtu.be/4j0WhBmdDOs, Video S1: breathing exercise.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of NAME OF INSTITUTE (protocol code reference 2020/571, 2020/03 approval).

Informed Consent Statement: Patient consent was waived due to the study was carried out during the first wave of the pandemic; participants were only asked for oral informed consent.

Data Availability Statement: The data presented in this study are available on reasonable request from the corresponding author. The data are not publicly available due to privacy of clinical data.

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Conflicts of Interest: The authors declare no conflict of interest.

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