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Type of Article: Prospective Observational

Manuscript Title: Effect of Respiratory Exerciser on Pulmonary Functions of COVID-19 patients; A Prospective Observational Study

Running Head: Respiratory Exerciser on COVID-19

Document Date: 08.02.2021

NCT Number: 04826731

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Introduction

SARS-CoV-2 is a novel coronavirus that is responsible for the current pandemic. Its clinical presentation varies from asymptomatic infection to severe respiratory failure requiring intensive care stay. In earlier studies, loss of respiratory function had been observed in survivors of other coronaviruses. The degree of respiratory function loss and if any intervention may reduce or prevent it remains an issue to be clarified.

The study aimed to investigate the effects of pulmonary rehabilitation via a supporting device on COVID-19 patients during a follow-up period of one month. The primary method of investigation of pulmonary functions was comparing peak expiratory flow (PEF) at the time of diagnosis and after treatment.

The study hypothesized that patients who had successfully used a respiratory exerciser or a similar aid device would have better PEF results at the end of the first-month evaluation.

Methods

The study was performed in Faculty of Health Sciences Dışkapı Yıldırım Beyazıt Training and Research Hospital Pulmonary Medicine Department. The local ethics committee approved the study with decision number 10/4 and the decision date of 08.02.2021. As a prospective study, the first patient admission began on March 29th, and The study completion date was accepted as of June 30th, which was the last date for patient admission. All follow-up evaluation was performed one month after hospital discharge.

Patients were selected among those who had applied to emergency service and evaluated by a pulmonary medicine resident or specialist. The general population of the study was made from the patients whose hospital admission to the COVID-19 ward was required after pulmonary medicine evaluation requested by an emergency medicine specialist. Inclusion criteria were being over 18 years old, approval given both written and orally for participation, COVID-19 positivity proven by reverse transcription-polymerase chain reaction (RT-PCR) testing, and deemed suitable for pulmonary function testing by a pulmonary medicine specialist. Exclusion criteria were planned mostly for optimal function testing, which included any pathological findings that impede pulmonary function testing such as chest deformity, an additional persistent pulmonary pathology that would prevent hospital discharge even after COVID-19 treatment, known severe pulmonary function loss (characterized by a FEV1 of %30 or less or being unable to participate in respiratory function testing), persistent COVID-19 findings which may affect respiratory functions (characterized by being bedridden or extended stay requirement due to desaturation not responding to nasal oxygen therapy) and former COVID-19 history.

Due to ethical considerations and the assumption that respiratory physiotherapy performed by the respiratory exerciser would be beneficial, all patients accepted into the study were offered enlistment to the treatment group. Those willing to participate in the study but refused device usage were accepted as the control group. Patients in the treatment group were asked to use the respiratory exerciser at least four times per day, with each session not lasting longer than 10 minutes and with at least an hour in between sessions.

Regardless of suitability for the study, all patients undergo a respiratory function test evaluation at the end of the first month, as per routine hospital approach to COVID-19 patients requiring hospital admission. The follow-up results of those who had participated were recorded from this evaluation. Additional follow-up was performed as a part of routine COVID-19 follow-up, such as an RFT at three months; however, these results were not a part of this study and thus were not accessed or recorded.

PEF, as both percentile and absolute value change, was accepted as the study's primary outcome. Mortality was considered as the secondary outcome parameter. The presence of known respiratory diseases was accepted as the main confounding parameter, and thus, as defined earlier, patients with known respiratory limitations had to be removed from the study. Other comorbidities were evaluated by Charlson Comorbidity Index (CCI). Forced Expiratory Volume (FEV) and Forced Vital Capacity (FVC) percentages were used to confirm the respiratory stability before COVID-19 diagnosis, values of both being over 80% was deemed normal. Demographic data was also included due to being required to calculate respiratory function thresholds.

Patients' data were retrieved from the hospital record system and from the respiratory function testing center. Demographic data, treatment modalities, and evaluation dates were also evaluated from electrical patient files from the hospital record system. Initial PEF results were taken from the patients' personal peak flow meter devices, and the final results were recorded from both hospital spirometer results and personal devices. Retesting was performed when a difference above 10% was observed between two different methods. If a difference was to be observed again, the result from the patient's device was accepted as the end result.

Selection bias was the main expected bias, and it was expected to be lessened by offering participation to all patients admitted to the COVID-19 ward. However, due to the study design, patients whose status was considered stable for outpatient treatment were excluded, which was expected to affect the results in favor of the treatment group. Additional treatment requirements were also considered another source of bias, as patients admitted to the COVID-19 ward often received more intensive treatment than outpatient regimens. However, the treatment regimen given to those admitted to the ward, which the study population consisted of, was assumed to be the same. Similarly, a combination of comorbidities was also considered another bias that might hinder a patient's ability to participate in respiratory testing, regardless of former capacity; thus, Charlson Comorbidity Index (CCI) was used to investigate comorbidities and ensure that comorbidities are present that patients remain within an acceptable range.

A total of 50 patients were assumed to be recruited into the study, with an even distribution between control and treatment groups. Excluding respiratory function test results, no further quantitative variable grouping was performed.

Descriptive analyses were utilized for data presentation. Nonparametric testing was utilized due to non-standard distribution and reduced sample size. Mann-Whitney U test was used to evaluate the distribution patterns between groups. Spearman's rho was utilized for correlation analysis. No subgroup analyses were planned for the study. If a patient had a missing PEF value for any reason, the patient would be removed from the study regardless of other values. As the second value of PEF would be recorded at the follow-up, any loss to follow-up would also be a reason for exclusion. IBM SPSS Statistics 25th Edition was used as the statistical program.