Research Article

Effect of the modified snorkel mask as noninvasive ventilatory support in patients with acute hypoxemic respiratory failure due to COVID-19

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Abstract

Background

The shortage of mechanical ventilators during the COVID-19 pandemic led doctors to use alternative noninvasive ventilation systems, including a modified snorkel mask. Data on the use of the modified snorkel mask is limited.

Purpose

The study aims to describe the effect and clinical characteristics of patients with COVID-19 treated with a snorkel mask and to investigate the factors associated with the failure to use noninvasive ventilation with a snorkel mask.

Methods

In this retrospective observational study, adult patients with COVID-19 who were treated with a snorkel mask at Daniel Alcides Carrion Hospital of Huancayo-Perú were selected.

Results

Of the 390 patients included, 158 (20.5%) received noninvasive ventilation with a snorkel, 84 (53.2%) patients were discharged alive without intubation, and the mortality rate was 22%. In the control group that received standard treatment, 129 patients (55.6%) failed (i.e., deceased or admitted to a mechanical ventilator). The mortality rate was 33.2%. ROX index < 4.8, consolidation-type tomographic pattern, and the presence of complications, such as bacterial pneumonia or thromboembolism, were independently associated with a higher risk of noninvasive ventilation failure with snorkels.

Conclusions

Using the snorkel system resulted in an absolute mortality reduction of 11%, and recovery increased by 15% compared to the standard treatment system. Therefore, this device can be used as an acceptable alternative in the absence of mechanical ventilators.

INTRODUCTION

The severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) infection ranges from asymptomatic to pneumonia with acute respiratory distress syndrome (ARDS).[1] The severity of the clinical presentation depends on host susceptibility, age, comorbidities, infectious strain, and viral load. Infection results in the production of high levels of inflammatory cytokines such as IFN-γ, IL-IL-6 and chemokines such as CXCL9.[2]

The primary need of patients infected with COVID-19 who come to healthcare facilities will vary depending on the case severity. In moderate to severe cases, they may require oxygen or ventilatory support. However, there can be limits to the availability of mechanical ventilation resources; therefore, efforts have been focused on finding alternatives, mainly in low-income countries.[3] Patients requiring hospitalization are characterized by moderate to severe hypoxemia with high oxygen requirements. Due to the high mortality in patients who did not receive mechanical ventilation due to resource limitations,[4] noninvasive ventilation (NIV) has been utilized as an alternative respiratory support strategy in managing patients with respiratory failure.[5]

Different types of noninvasive devices are used to treat ARDS related to COVID-19. These include high-flow nasal cannula,[6] the helmet,[7] the Wayrachi nasal continuous pos-

itive airway pressure device (NCPAP),[8] and the modified snorkel mask.[9,10] These devices are used in patients with ARDS who failed to improve with conventional oxygen therapy methods such as the venturi system or the reservoir mask and could not be admitted to the Intensive Care Unit (ICU) due to bed availability.[11]

The snorkel mask was initially modified by Ferrone in Italy for NCPAP delivery.[12] In our hospital, a second modification was made to the mask, adding positive end-expiratory pressure (PEEP) pressure valves, decreasing the length of the corrugated tubing to reduce dead spaces, and adding a double oxygen intake system through a venturi device and another reservoir system.[13] Throughout the COVID-19 pandemic at the Daniel Alcides Carrion Hospital, Huancayo-Perú, the modified snorkel mask has been the most widely used device for NIV support, even though other systems were available. In this hospital, there was an entire intermediate care unit for the use of NIV devices with the snorkel mask.[14,15]

This study aimed to analyze the effect of using a snorkel mask as a NIV system in patients with ARDS admitted with COVID-19.

METHODS

ETHICAL APPROVAL

The study protocol was approved by the Medical Research Ethics Committee of Daniel Alcides Carrion Hospital, Huancayo, Perú (approval No. 16-2021-CEI-HDAC). The study team is committed to protecting patient privacy and complying with the Helsinki Declaration.

POPULATION

Eligible patients for this study were those diagnosed with COVID-19 via SARS-CoV-2 reverse transcriptase polymerase chain reaction or rapid antigen testing. The inclusion criteria were: (1) age > 18 years; and (2) bilateral lung injury or moderate/severe disease. The diagnosis of moderate disease included those with respiratory symptoms and bilateral lung lesions confirmed on chest imaging. Severe disease included those with at least one of the following two conditions: (1) $SpO_2 \leqslant 90\ \%$ while breathing ambient air, or (2) $PaO_2/FiO_2 \leqslant 200$ mmHg.[16] Exclusion criteria included: (1) patients with impaired consciousness, (2) patients with pneumothorax, (3) patients using accessory muscles, (4) patients transferred to another health facility, (5) patients who died within 24 hours of hospitalization to minimize time bias,[14] and (6) patients who were admitted to a mechanical ventilator within the first 48 hours of admission (Figure 1).

The ROX index was used to predict the success of oxygen therapy through the snorkel mask, which combines oxygenation (SpO_2/FiO_2) and the work of breathing (FR)= [SpO2/FiO2]/FR). The index was also used to assess the risk of failure of the snorkel system (i.e., admission to mechanical ventilation or death). Cases included patients receiving oxygen by snorkel mask plus standard therapy, and controls receiving oxygen by Venturi mask or variable FiO2 reservoir bag plus standard therapy.

STUDY DESIGN

We analyzed the data of 1,638 patients hospitalized for COVID-19 from February 1 to December 30, 2021 (the date of admission of the last enrolled patient) at the Daniel Alcides Carrion Hospital in Huancayo, Perú. The data set includes comprehensive clinical information on diagnoses, treatments, oxygen requirements, complications, ICU admissions, imaging, laboratory results, discharge, or death.

In this retrospective case-control study, the outcome of interest was the frequency of improvement of enrolled patients, defined as discharge with recovery. Snorkel failure was defined as the initiation of mechanical ventilation or death. Secondary endpoints were the rate of recovery from hypoxia, ROX index, and length of hospital stay. Hypoxia was defined as oxygen saturation below 90% when inhaling ambient air, according to the values at altitude (3200 meters above sea level). The worsening of hypoxia is defined as an increased requirement of oxygen concentration to maintain normal oxygen saturation resulting in the utilization of mechanical ventilation or death.[17]

The decision to intubate a patient was left to the treating physician's discretion. However, it was generally based on the following criteria: failure to maintain SpO2 > 88% despite receiving the maximum allowed FIO2, persistence or worsening of respiratory failure (PaO2/FiO2<100 mmHg, respiratory rate > 35/min) with associated respiratory distress, development of conditions requiring endotracheal intubation to protect the airway (e.g., coma or seizure disorder), severe metabolic acidosis, or to manage copious bronchial secretions. The patients also received complementary therapies according to the COVID-19 management guide and as indicated by the treating physician. This therapy commonly included systemic glucocorticoids, paracetamol, pronation, cough suppressants, and the infrequent use of convalescent plasma.

The authors extracted data in a structured format, including clinical data before applying the snorkel mask, during the procedure, and 4 hours afterward. The ROX index was recorded before, 4 hours after applying the snorkel mask, and at the patient's discharge. Laboratory data were collected in the same way.

ABOUT THE NONINVASIVE VENTILATION SYSTEM WITH MODIFIED SNORKEL

The snorkel system consisted of a snorkel diving mask that presents a complete separation between the inspiratory and expiratory circuits. An internal silicone pocket covers the mouth and nose where fresh oxygen enters through non-return valves. The exit of exhaled CO2 is through four valves. One is located on each side of the nose. The other two are channelled into the internal side tubes through a pair of non-return valves connected to a piece of polycarbonate known as the Charlotte valve. This valve contains a triple mouth, the first connected to the mask, the second to the exhaled air outlet, which was connected at the end to an ad-
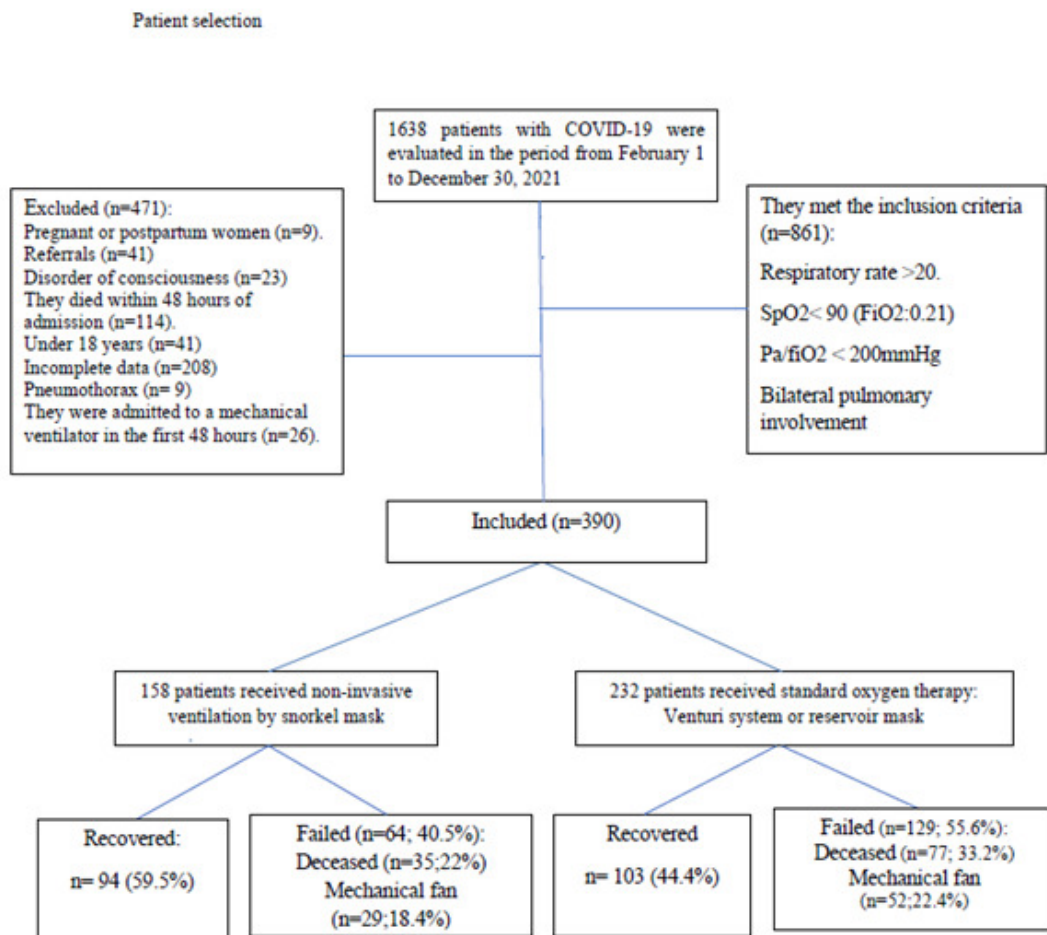
Patient selection

Figure 1. Patient Selection Criteria Flowchart.

justable cylindrical valve of PEEP and then to a ventilatory filter to prevent air contamination with viral particles. The third was the air intake channel, which was connected to a humidifying filter and later to a double independent oxygen intake flow consisting of a venturi system and another to the reservoir mask, each with an independent oxygen point, and each one was independently connected to 15 litres of oxygen per minute, which was to be reduced according to the patient's response (Figure 2).

Installing the snorkel device consisted of placing the patient supine, hermetically fixing the mask on the patient's face to avoid air leaks, setting the valve with PEEP at zero, and administering 15 litres of oxygen. Once oxygen saturation improved, the patient was placed in a prone position. After ten minutes, the alveolar recruitment maneuvers were started, consisting of the progressive increase in PEEP in the following order: zero to 2.5 cm H2O, then 5 cm H2O and finally to 10 cm H2O, each change after ten minutes. The patient remained in this position for at least four hours, followed by a 2-hour rest period with a reservoir mask (15 litres/min). After that, weaning from snorkelling was done according to clinical improvement.

Figure 2. Noninvasive Ventilation System with Modified Snorkel.

STATISTICAL ANALYSIS

All statistical analyses were performed using the statistical program STATA v.14.0. The Chi-square test or Fisher's exact test was used to compare the control and snorkel groups. The continuous variables were presented with mean, interquartile range and standard deviation. A comparison of these was then performed with the Mann-Whitney U test. All statistical tests were bilateral, considering $p<0.05$ as statistically significant. Cox regression modelling was used to determine the probability of failure of snorkel treatment. Hazard ratio (HR) values derived from structural models were adjusted for age and gender.

SAMPLE

Due to limited knowledge of the snorkel mask efficacy, we assumed a resolution rate for the snorkel group of 30% and a resolution rate of 13% for the control group based on a first pilot study of 30 patients for each cluster. We estimated that 144 participants were required for the snorkel group. The sample size increased by about 10% due to incomplete data. Therefore, the trial was designed to include 158 snorkel mask wearers. Enrollment was carried out in a non-randomized consecutive manner until the sample size was reached. The patients who did not use the snorkel mask and met the inclusion criteria were considered part of the control group.

RESULTS

Out of 390 patients who entered the study, 158 used the snorkel mask, and 232 received standard-of-care treatment according to the management guidelines of the institution. The population's average age was 54, and 70% of all patients were male. Of the comorbidities identified, diffuse interstitial lung disease was identified in 32% of participants. Chronic diseases such as diabetes mellitus and arterial hypertension were found in 24% and 11% of the patients. No significant differences were found in the baseline characteristics of both groups (Table 1).

The total average body mass index was 28.5 kg/m^2. The mean length of illness at the time of hospital admission was nine days. The average respiratory rate was 25 per minute; oxygen saturation on admission averaged 78.7%, and the mean ratio of arterial oxygen pressure to the fraction of inspired oxygen (PaO2/FiO2) was 138. The average lung involvement of patients with COVID-19 evaluated by tomography was 57%. Ground glass opacities were present in 56.6% of patients, and diffuse consolidation was evident in 38%.

With snorkel mask treatment, 57% of all patients improved. In the group that received standard therapy, it was 44.4% (P=0.046). Patients who required a mechanical ventilator comprised 20.7% of the total population, 22.4% in the group that received standard treatment and 18.4% in the group that received snorkel masks P<0.001). The mean number of days of snorkel masking was six (Table 1).

The total number of deaths was 28.6% of the study population. The percentage of deaths in the group that received the snorkel mask was 22%, and in the standard therapy group was 33% (P=0.023). The rate of recovery was 59.5% in patients in the snorkel mask group and 44.4% in the group that received standard treatment (P=0.046).

The most frequent complications during hospitalization were nosocomial pneumonia (17.8%) and pulmonary thromboembolism (4.26%). Overall hospital stay was 12.9 days on average, 17.2 days in the snorkel group, and 10.6 days in the standard therapy group.

Comparing the respiratory parameters in the patients who received the snorkel mask, the average values were separated before using the device, 4 hours after the use, and at hospital discharge. The average PaO2/Fio2 remained similar before and 4 hours after using the NIV snorkel, while at discharge, these values were 240 on average. The pre-snorkel ROX index was 4.57, and 4 hours later, it was 4.99, while at discharge, the average of this index was 19.45 (Table 2).

Factors associated with snorkel device failures were: (1) consolidation-type tomographic pattern compared to the other patterns (HR 1.56; 95% CI 1.02-2.35: P=0.036), (2) presenting some complication such as nosocomial pneumonia or thromboembolism (HR 1.22; 95% CI 1.05-2.35: P=0.008) and (3) a pre-snorkel ROX index < 4.8 (HR 1.2024; 95%CI 1.024-2.41: P=0.037) were associated with failure to use NIV-snorkel (Table 3).

The comparison of the risk curves showed the lowest probability of dying or requiring a mechanical ventilator in the group of patients who used the noninvasive system with snorkel (log-rank test P-<0.001) (Figure 3). No clinical improvement to the use of the snorkel mask occurred in 74/158 (46.8%) patients, and in the group that did not use the snorkel mask, 129/232 (55.6%) patients failed.

DISCUSSION

In this study, 390 patients were hospitalized for respiratory failure related to COVID-19 infection. A significant number were successfully managed with the modified snorkel mask and did not require mechanical ventilation, reducing overall mortality by 11% (P=0.023). These data suggest that snorkel mask use during COVID-19 has the potential to decrease the need for invasive mechanical ventilation. We also observed an increase in hospital stay by seven days in the group that received NIV with the snorkel, compared to the group that received standard treatment.

A study comparing the snorkel mask with other systems demonstrated better ventilator-patient interaction in terms of shorter pressurization time and shorter expiratory time delay, better interface performance underscored by lower trigger pressure drop (ΔPtrigger), and higher pressure-time product, which can be explained by the reduced internal volumes of the snorkel mask.[12] Likewise, it showed stability in maintaining the PEEP level at 10 cm H2O. Based on this result, the hospital use protocol aimed to maintain PEEP at 10 cm H2O to meet the alveolar recruitment objective. The other parameters compared in terms of maximum inspira-

Table 1. General characteristics of the 390 patients and comparison between the patients who received noninvasive ventilation with the modified snorkel system and those who received standard oxygenation.

Basal parameters	Total (n=390)	Snorkel (n=158) 40.4%	Control (n=232) 59.6%	Value P*
Age: average years	54 ±13.6	52.8±12.02	53.59±13.18	0.114
Gender: Male: n (%)	270 (70%)	108 (68.8%)	165(70.8%)	0.375
Index: body mass, Kg/m^2	28.5±5.4	28.07±6.7	28.8±4.6	0.337
Sick time: average days	9.86±3.8	9.4±3.38	10.54±4.2	0.362
Comorbidity				
Interstitial lung disease	32(10.9%)	17(11.8%)	15(10.1%)	0.843
Diabetes	73 (24.9%)	31(21.5%)	42(28.2%)	0.271
Arterial hypertension	33(11.3%)	15(10.4%	18(12.1%)	0.483
Chronic kidney disease	12(3.1%)	4(2.5%)	8(3.4%)	0.172
Asthma	7(1.8%)	4(2.5%)	3(1.3%)	0.931
Heart disease	5 (1.3%)	2(1.3%)	3(1.3%)	0.408
Respiratory rate	25.6±4.5	26.6±6.5	25±3.8	0.174
Heart rate	95.9±16.3	96.7±10.9	96.5±16.4	0.1536
SPO$_2$	78.7±10.1	77.59±9.82	80.4±10.2	0.631
Fraction Pa/FIO$_2$	138.6±3.82	141.26±5.4	135.46±67.4	0.51
Percentage of lung involvement on admission	57.6±18.14	59.48±20.9	56.52±16.4	0.2287
Tomographic pattern				
Frosted glass	137(56.6%)	112(71.3%)	25(29.4%)	0.000
Diffuse consolidation	93(38.4%)	42(26.7%)	51(60%)	0.000
Fibrotic	12(4.9%)	3(1.9%)	9(10.6%)	0.057
Basal leukocytes	10.66±5.35	10.61±5.6	10.72±5.02	0.848
Neutrophils	9.32±5.31	9.18±5.5	9.48±4.97	0.606
Lymphocytes	2.61±2.43	3.87±2.82	2.96±1.04	0.368
Lactic dehydrogenase	627.216±379.08	638.31±467.75	621.63±327.12	0.753
Dimer D	3555.61±714.03	3861.61±979.02	2884.72±589.34	0.175
C-reactive protein	123.09±108.03	115.13±112.9	131.56±101.47	0.291
Glucose	152.2±74.88	157.31±71.37	149.51±76.73	0.449
Urea	33.82±15.5	35.67±5.11	33.72±5.91	0.808
Creatinine	0.901±0.72	0.76±0.15	0.91±0.74	0.657
Ferritin	661.82±545.17	648±459.04	670.23±596.88	0.809
Procalcitonin	24.94±13.1	23.3±13.52	25.97±13.59	0.756
Final condition: Deceased	112 (28.7%)	35(22.15%)	77(33.18%)	0.023
Use of mechanical ventilation	81(20.7%)	29(18.4%)	52(22.41%)	0.000
Hospital stay	12.98±9.8	17.19±11.4	10.57±7.96	0.000
Recovery	226 (57.8%)	94(59.49%)	103(44.4%)	0.046
Use of oxygen at discharge	127 (32.5%)	27 (17.1%)	5(2.2%)	0.248
Complications				
Nosocomial pneumonia	46(17.8%)	7(9.6%)	39(21.1%)	0.061
Pulmonary embolism	11(4.26)	2(2.7%)	9(4.8%)	0.052

Note: *SD = standard deviation. *Fisher's exact test was used to calculate the p-value in the case of categorical variables and the Student t test for numerical variables. † The data is in the mean ± DE.

IMC, body mass index; PCR, C-reactive protein; SPO2, Oxygen saturation; PaO2, Partial pressure of oxygen.

tory deflection (ΔPawi) and peak inspiratory (ΔPawe) did not show significant differences.[9,12] Another study incor-porated an enteral feeding route into the snorkel mask to avoid interruption of respiratory care with good results, un-

Table 2. Comparison of the baseline respiratory clinical parameters at 4 hours and at hospital discharge of the patients who received respiratory therapy by snorkel.

Parameters*	Pre-Snorkel	4 hours after snorkel	Recovered
O2 saturation	88.15 ± 7.46	94.23±3.38	90.01±1.61
PaO2/ FiO2	118.3±54.03	117.54±52.57	240.20±47.71
Breathing frequency	24.63±3.65	24.02±3.25	21.55±2.05
ROX Index	4.57±0.76	4.99±0.705	19.45±2.03

*Mean ± Standard deviation. ROX Index: [SPO_2/FIO_2]/Respiratory rate

Table 3. Risk factors in the multivariate model for failure to use snorkel.

Factor	HR*	IC95%	Value P
Diffuse pulmonary consolidation ***	1.56	1.02-2.35	0.036
Complications**	1.22	1.05-1.42	0.008
ROX Index< 4.8	1.51	1.024-2.41	0.037

95%CI = 95% confidence interval

*Adjusted for age and sex. **Nosocomial pneumonia or thromboembolism. ***Compared to the other patterns. ROX Index: [SPO_2/FIO_2]/Respiratory rate
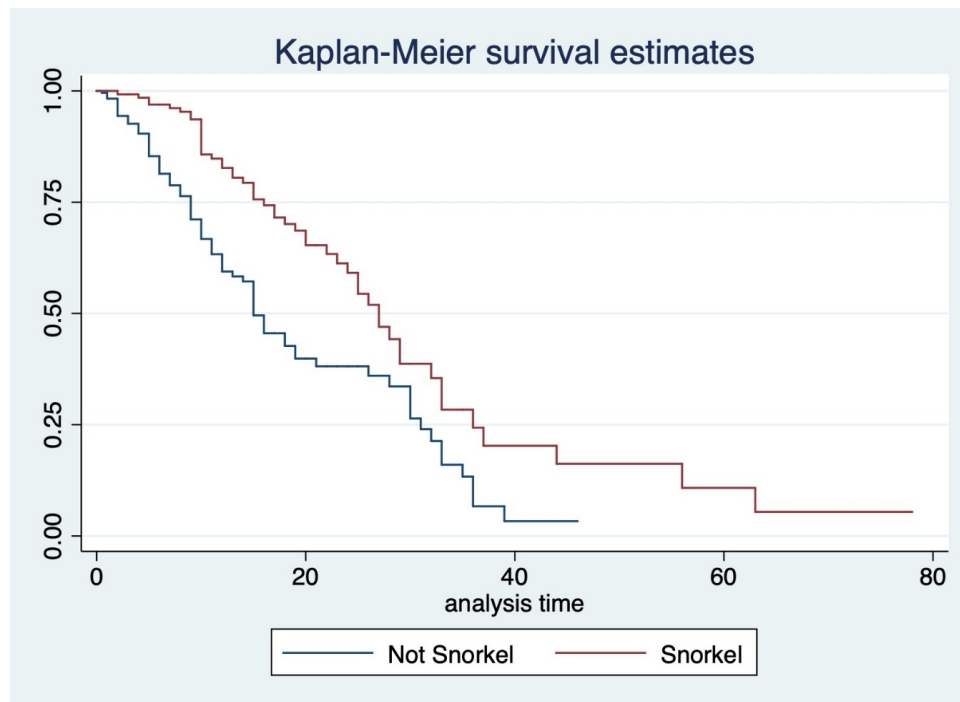
Figure 3. Failure curves (deaths or admission to a mechanical ventilator) of patients with coronavirus disease (COVID-19) stratified according to the use of noninvasive ventilation with a snorkel mask, P< 0.001.

like our study, where the patient had to remove the snorkel mask to receive food.[18]

Avoiding the mechanical ventilator may allow a reduction in complications commonly associated with endotracheal intubation, such as pneumonia, ventilator-associated lung injury, or secondary infections. In addition, avoiding intubation by using a snorkel can help conserve ventilators in the event of a shortage. However, despite these advantages, there is concern that the poor selection of patients with pathologies that affect the ventilatory mechanism (e.g., neurological disorders, respiratory muscle fatigue) could lead to NIV failure. Its functionality depends on the respiratory strength of the affected person.[19]

It has been suggested that given the prolonged duration of COVID-19 illness, adequate use of NIV may have a low failure rate and may delay endotracheal intubation.[20] This study provides evidence that snorkel mask use in patients with COVID-19-related respiratory failure is associated with favourable clinical outcomes. In addition, a decrease in hospital mortality and utilization of a mechanical ventilator was demonstrated. Despite these findings, we accept that the decision on the timing of intubation is specific to

each patient. Poor selection of patients for mask use is also likely to lead to unfavourable clinical outcomes; however, early evaluation within four hours of initiating snorkel use may indicate failure and prompt an immediate search for a mechanical ventilator.

The results suggest that the ROX index will help select the patients who are likely to be successful with this NIV device and avoid initiating mechanical ventilation. This index has also been used as a predictive indicator in other noninvasive systems, such as the use of high-flow cannula.[21,22] This index was also used to predict success after four hours of use, so it is important to monitor this parameter early to identify the success of the snorkel mask.

Our results indicate that in respiratory failure related to COVID-19, the snorkel device can be used before endotracheal intubation. The variation in the ROX index can be evaluated four hours later to assess the need for mechanical ventilation, similar to the use of other non-respiratory devices.[23] In the multivariate analysis, a ROX index <4.8 was significantly associated with failure to use the snorkel device.

The disadvantage of using the snorkel mask is the high oxygen consumption, which can cause drops in hospital oxygen pressure. Likewise, this device requires the doctor to remain next to the patient, mainly during the first hour of use, to progressively increase the PEEP values until reaching 10 cm H2O in the supine position. This avoids air leaks that favour a drop in inspiratory pressures and the appearance of asynchrony. In the post-COVID pandemic era, where a high number of mechanical ventilators are available, the use of a snorkel mask may be a therapeutic alternative for patients with moderate or severe atypical pneumonia with high oxygen requirements before opting for the use of the mechanical ventilator and through its use try to reduce the complications generated by invasive ventilation.[24] It seems to be a better alternative than the other NIV systems.[25]

This study has some limitations. First, this was a retrospective observational study. Although attempts were made to correct for covariates, all confounding factors, such as any additional treatments, may not have been accounted for. Second, our study may not have been able to detect differences in clinical and laboratory outcomes between groups. However, given the results, the snorkel device is highly suitable for application in clinical care, given its ability to reduce the need for mechanical ventilation. Prospective trials are required to explore these advantages further.

CONCLUSIONS

The modified snorkel mask can be used as an acceptable alternative to other forms of NIV and as an early-use alternative before considering the utilization of a mechanical ventilator. The use of a snorkel mask reduced mortality in patients with ARDS due to COVID-19.

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