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# Does the use of a diving mask adapted for non-invasive ventilation in hypoxemic acute respiratory failure in individuals with and without COVID-19 increase the ratio of arterial oxygen partial pressure to fractional inspired oxygen? A randomized clinical trial

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## Abstract

Non-invasive ventilation (NIV) can be used in acute hypoxemic respiratory failure (AHRF); however, verifying the best interface for its use needs to be evaluated in the COVID-19 pandemic scenario. The objective of this study was to evaluate the behavior of the ratio of arterial oxygen partial pressure to fractional inspired oxygen ($PaO_2/FiO_2$ ratio) in patients with AHRF with and without COVID-19 undergoing NIV with the conventional orofacial mask and the adapted diving mask. This is a randomized clinical trial in which patients were allocated into four groups: i) group 1: COVID-19 + adapted mask (n=12); ii) group 2: COVID-19 + conventional orofacial mask (n=12); iii) group 3: non-COVID-19 + adapted mask (n=2); iv) group 4: non-COVID-19 + conventional orofacial mask (n=12). The $PaO_2/FiO_2$ ratio was obtained 1, 24, and 48 hours after starting NIV, and the success of NIV was evaluated. This study followed the norms of the Consolidated Standards of Reporting Trials statement and was registered in the Brazilian Registry of Clinical Trials under registration RBR-7xmbgsz. Both the adapted diving mask and the conventional orofacial mask increased the $PaO_2/FiO_2$ ratio. The interfaces differed in terms of the $PaO_2/FiO_2$ ratio in the first hour [309.66 (11.48) and 275.71 (11.48), respectively] (p=0.042) and 48 hours [365.81 (16.85) and 308.79 (18.86), respectively] (p=0.021). NIV success was 91.7% in groups 1, 2, and 3, and 83.3% in group 4. No adverse effects related to interfaces or NIV were observed. NIV through the conventional orofacial mask interfaces and the adapted diving mask was effective in improving the $PaO_2/FiO_2$ ratio; however, the adapted mask presented a better $PaO_2/FiO_2$ ratio during use. There was no significant difference between interfaces regarding NIV failure.

## Introduction

Acute hypoxemic respiratory failure (AHRF) is one of the main causes of hospitalization for adult patients in intensive care units (ICU), with a high evolution rate to orotracheal intubation (OTI) [1]. However, invasive mechanical ventilation is associated with the occurrence of serious adverse events, and the use of non-invasive methods in treating AHRF and OTI prevention is associated with a decrease in mortality [2].

Non-invasive ventilation (NIV) is used to reduce hypoxemia, the work of breathing, and the need for supplemental oxygen therapy [3]. As a result of the COVID-19 pandemic, NIV has been used in patients with moderate to severe AHRF and can be applied inside and outside the ICU using adapted interfaces [4-6].

The need for hemodynamic and respiratory support with positive end-expiratory pressure (PEEP) to improve oxygenation has become necessary for severe cases in which the patient develops AHRF. Implementing NIV becomes vital until pharmacological treatment becomes effective, and the need to evaluate other NIV systems and interfaces (such as the use of an adapted diving mask) arose due to massive hospitalizations caused by respiratory distress and the need for OTI during the COVID-19 pandemic [7,8].

Conventional orofacial masks for NIV using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) have been widely used, while the safety and efficacy of new NIV interfaces that promote stable oxygenation levels, avoid OTI, and reduce aerosolization have been tested [9-13].

The ratio between the partial pressure of oxygen ($PaO_2$) and the fraction of inspired oxygen ($FiO_2$) ($PaO_2/FiO_2$) has primarily been investigated as a marker of disease severity [14], oxygenation status, and length of hospital stay [15]. In the context of COVID-19, Colaneri *et al*. [16] found a univariate correlation between the $PaO_2/FiO_2$ ratio and disease severity. A study by Zinellu *et al*. suggested that a single $PaO_2/FiO_2$ measurement in the first 24 hours of admission can independently predict the length of hospital stay in patients with COVID-19 [17].

Investigating the effects of NIV on AHRF caused by COVID-19 or by another diagnosis is necessary since its application can minimize respiratory failure when properly indicated and constitutes a fact that justifies developing studies such as this one. Thus, the present study aimed to evaluate the behavior of the $PaO_2/FiO_2$ ratio in patients with AHRF with and without a diagnosis of COVID-19 and submitted to NIV with different interfaces (conventional orofacial mask and adapted diving mask). This study is based on the hypothesis that the use of NIV through an adapted interface is not inferior when compared to NIV using a conventional mask and may improve the $PaO_2/FiO_2$ ratio of these patients.

## Materials and Methods

This is a randomized and controlled clinical trial developed in the ICU of two hospitals in the state public network of Pernambuco (Regional Hospital of Agreste, Caruaru and Otávio de Freitas Hospital, Recife, Brazil) in the period from September 2020 to July 2021. The study was developed after approval from the Research Ethics Committee and the National Research Ethics Committee (CAAE: 30783720.7.0000.5343, opinion no. 4.305.813), respecting all the norms of Resolution 466/12 of the National Health Council. Patients or their guardians consented to their participation in the study by signing the Informed Consent Form. This study followed the norms of the Consolidated Standards of Reporting Trials (CONSORT) statement [18]. The study was registered in the Brazilian Registry of Clinical Trials, under registration number RBR-7xmbgsz. There was no source of funding for this study.

Patients admitted to the ICUs of the participating hospitals, with or without the diagnosis of COVID-19, of both genders, aged between 18 and 90 years, with a $PaO_2/FiO_2$ ratio <200 and clinical indications for the use of NIV, were included in the study. Patients with claustrophobia, facial anomalies, facial trauma or burns, severe hematemesis, massive hemoptysis, hemodynamic instability (systolic blood pressure <90 mmHg or using vasopressors or inotropes), ongoing angina/acute myocardial infarction or arrhythmia with hemodynamic impact, or those who showed poor adaptation signs to the interface, were unable to protect the airways, refused to use NIV, in a coma (Glasgow coma scale <8), in the postoperative period of esophageal or of the upper respiratory tract in the last two weeks, in post cardiorespiratory arrest, or those who refused to participate in the study were excluded.

The sample was selected consecutively, and the patients were randomized into blocks through the *randomization.com* program by a researcher not involved in the study, placed in opaque and numbered envelopes, and then handed over to the researchers responsible for patient care. The patients were allocated into four groups: i) group 1: COVID-19 + adapted diving mask; ii) group 2: COVID-19 + conventional orofacial mask; iii) group 3: non-COVID-19 + adapted diving mask; iv) group 4: non-COVID-19 + conventional orofacial mask. The adapted diving mask can be seen in Figure 1 [19].

The technology used in the adapted diving mask was developed by the *Mergulhadores do Bem* group, which was responsible for the manufacturing and 3-dimensional printing of the mask parts [20]. These masks were initially used as personal protective equipment for health professionals, but over time they were adapted for NIV, aiming to reduce the demand for invasive ventilatory support equipment [13]. The group of researchers disseminated this technology in Brazil, first by performing equipment safety tests such as the bench test and then supplying it to a research group at the University of Santa Cruz do Sul [20], from which this study was derived.

The sample size was initially calculated in a pilot study with 20 participants, divided into the adapted diving mask group (n=10) and the conventional mask group (n=10). Based on the mean(standard deviation) of the $PaO_2/FiO_2$ ratio being 371.74 (81.07) in the first group and 248.27 (45.64) in the second group, a total of 12 individuals was estimated with an effect size of 1.88. Given the occurrence of the COVID-19 pandemic and the availability of patients with and without a diagnosis of COVID-19, the researchers decided to increase the sample and create four groups with and without a diagnosis of COVID-19 for each of the two types of masks.

The adapted diving mask has its own fasteners made of fabric, and its contact area with the face is made of silicone to improve patient comfort. Adjustments were made to guarantee greater uniformity in the contact areas of the mask with the skin, avoiding greater pressure on bony prominences.

The primary outcomes evaluated were the $PaO_2/FiO_2$ ratio obtained 1, 24, and 48 hours after initiating NIV, and NIV failure for clinical purposes was defined as the evolution to OTI within 48 hours of starting NIV, secondary to the occurrence of lack of adaptation to the interface, hemodynamic instability, depression of the cognitive state, psychomotor agitation, lack of airway defense, and severe bronchospasm [21]. Furthermore, the present study considers NIV success as a non-evolution to OTI.

An anamnesis was initially performed containing clinical data (symptoms, comorbidities, characterization of smoking), anthropometric and sociodemographic data, in addition to the perception of dyspnea (Borg scale), and arterial blood gas analysis ($PaO_2$, partial

pressure of carbon dioxide, pH, and arterial oxygen saturation) for sample characterization purposes.

The predicted body mass (Kg) was estimated considering the height and gender variables using the formula described by Schultz *et al*. [22] and Seiberlich *et al*. [23] for men [50+0.91×(height-152.4)] and for women [45.5+0.91+(heigh-152.4)]. Height (m) was calculated using a 1.5-m inelastic anthropometric tape with a 1-cm interval, as proposed by Mitchell and Lipschitz [24]. The body mass index was subsequently calculated through the ratio between body mass and height squared [25]. The perception of effort was assessed using the Borg scale, adapted from the scale used to measure dyspnea [26]. Numerical indices ranging from 0 (no effort) to 10 (exhaustive effort) were considered for the interpretation [27].

Arterial blood gas analysis was obtained at the patient's admission to the unit, and the $PaO_2/FiO_2$ ratio was then calculated before starting NIV. This variable was calculated at baseline (before NIV) and again at 1, 24, and 48 hours after NIV.

Two interfaces were used to perform NIV: the conventional orofacial mask and the adapted orofacial mask (adapted diving mask). The adapted diving mask (Owner) was developed to produce greater comfort for the patient and safety for health professionals, being composed of 3D-printed parts [10]. The conventional orofacial mask is a silicone interface that allows nasal or oral breathing but makes communication difficult, is widely used for NIV, and causes higher leakage rates [28].

NIV was instituted using a dual-limb mechanical ventilator available at the health facility (preferably the SERVO-S, Maquet Critical Care, São Paulo, Brazil). A viral and bacteriological filter with 99.9% filtration was used to avoid the spread of particles.

NIV was instituted for one hour in CPAP or BiPAP mode. Inspiratory pressure and expiratory pressure ranged between 10 and 16 $cmH_2O$ and 5 and 10 $cmH_2O$, respectively. CPAP was adjusted between 5 and 10 $cmH_2O$. Both modalities (CPAP or BiPAP) were associated with a minimum $FiO_2$ (between 35 and 60%) to measure $SpO_2$ between 93% and 96%, $FiO_2 \leq 50\%$, and respiratory rate <24 bpm after the first hour of NIV.

Hemodynamic instability (heart rate <60 or >120 bpm, systolic blood pressure <90 mmHg, mean arterial pressure <65 mmHg), bronchoaspiration, aerophagia, and lowered consciousness (due to hypoventilation) were considered adverse effects regarding NIV. Skin lesions and irritation, claustrophobia, leaks, dryness in the oral and nasal regions, and excessive mask pressure on the face were considered adverse effects of NIV masks.

The following interruption criteria were considered: clinical worsening, hemodynamic instability, depression of cognitive status, psychomotor agitation, lack of airway defense, poor adaptation to the interface, and the presence of severe bronchospasm or sustained desaturation.

## Statistical analysis

The Kolmogorov-Smirnov and Levene tests were used to verify the distribution of normality and homogeneity of the variances of the study variables (before, after 1, 24, and 48 hours after NIV), respectively. A relative and absolute description of the patients who received NIV was performed, with non-evolution to OTI being considered a "success", while NIV failure, which proceeded to OTI during the follow-up period in the study (up to 48 hours), was considered "unsuccessful".

One-way analysis of variance was used to verify the initial differences between patients, and the analysis of repeated measures




**Figure 1.** Adapted diving mask. A) Side view of adapted diving mask (Owner type); B) front view of adapted diving mask (Owner type). Reproduced from: https://www.owntec.com.br/mergulhadores/

with two factors was used to evaluate the oxygenation behavior ($PaO_2/FiO_2$ ratio) throughout the study (before, at 1, 24, and 48 hours), considering the presence of COVID-19 (yes or no) and the type of mask used (adapted or conventional diving mask), and checking all possible interactions. Then, the Mauchly sphericity test was performed, followed by the Greenhouse-Geisser correction. Sidak's test was used for post hoc analysis ($p<0.05$). The variation (d) of the $PaO_2/FiO_2$ ratio was evaluated for each mask, and the difference between the last mask and the previous one at the initial, 1, 24, and 48-hour NIV times was expressed as the mean and confidence interval. The paired Student's *t*-test was used to compare these changes. The statistical analysis was performed using SPSS version 20.0. The method was developed according to the project of Paiva *et al.* [20].

## Results

A total of 48 patients with AHRF and NIV indications participated in the study. The CONSORT flow diagram is represented in Figure 2.

The sample characteristics are described in Table 1. There was no record of losses in the sample, nor was there any report of adverse effects. After the analysis of variance between the groups (COVID-19 and non-COVID-19), the masks (adapted and conventional diving mask), and $PaO_2/FiO_2$ (before, 1, 24, and 48 hours) variables, no interaction was observed between the $PaO_2/FiO_2$ ratio and the group ($p=0.221$), or the $PaO_2/FiO_2$ ratio, group, and mask ($p=0.114$), with an interaction between the $PaO_2/FiO_2$ ratio and mask [$F$ (1.830; 80.533)=9.951, $p=0.005$], and the $PaO_2/FiO_2$ ratio and the evaluation moments (1 and 48 hours after) [$F$ (1.830; 80.533)=188.320, $p<0.001$].

The moments (before, 1, 24, and 48 hours) of the $PaO_2/FiO_2$ ratio differed from each other ($p<0.001$). An interaction was also observed between the moments of obtaining the $PaO_2/FiO_2$ ratio and the type of interface (adapted diving mask and conventional orofacial) ($p=0.006$); however, no difference was observed between them ($p=0.079$) within the moments in which the $PaO_2/FiO_2$ ratio was obtained when the mask was considered in the analysis.

Regarding the type of mask and the moments in which the $PaO_2/FiO_2$ ratio was obtained, as considered in the analysis model, it was observed that patients who used the adapted diving mask showed improvement in the $PaO_2/FiO_2$ ratio at 1 hour ($p<0.001$), 24 hours ($p<0.001$), and 48 hours ($p<0.001$) in relation to the time before NIV was instituted. No difference was observed between the moment of 1 hour in relation to the moment of 24 hours ($p=0.773$) in obtaining the $PaO_2/FiO_2$ ratio.

An increase in the $PaO_2/FiO_2$ ratio was observed in relation to the conventional mask at 1 hour ($p<0.001$), 24 hours ($p<0.001$), and 48 hours ($p<0.001$) after NIV. However, no differences were observed between the 1-hour and 48-hour moments ($p=0.051$), or between the 24-hour and 48-hour moments ($p=0.824$) in obtaining the $PaO_2/FiO_2$ ratio for patients who used this face mask.

The adapted and conventional orofacial diving masks differed from each other regarding the behavior of the $PaO_2/FiO_2$ ratio at 1 hour [309.65(11.47)×275.70(11.47); $p=0.042$] and at 48 hours [365.81(16.86)×308.78(16.86); $p=0.021$]. The adapted diving mask presented a better oxygenation level in relation to the conventional orofacial mask at these times. Table 2 expresses the behavior of the $PaO_2/FiO_2$ ratio before, at 1, 24, and 48 hours after the use of NIV, comparing the two interfaces used.

Regarding the ventilatory modes, 79.2% of the sample used CPAP and 20.8% used BiPAP. On average, group 1 (COVID-19 + adapted diving mask) had a mean PEEP of 8.3 (2.18) $cmH_2O$ and $FiO_2$ of 47.91% (7.21). The mean PEEP in group 2 (COVID-19 + conventional orofacial mask) was 8.41 (1.67) $cmH_2O$ and $FiO_2$ 47.08% (7.21); group 3 (non-COVID-19 + adapted diving mask) had a mean PEEP of 8.58 (1.62) $cmH_2O$ and $FiO_2$ 49.58% (7.52); and group 4 (non-COVID-19 + conventional orofacial mask) had a mean PEEP of 9 (1.27) $cmH_2O$ and $FiO_2$ 45% (6.03).

It can be observed that the outcome of NIV clinical success among those who used an adapted diving mask was 91.7% for both group 1 (n=11) and group 3 (n=11). Moreover, success for the conventional orofacial mask was 91.7% (n=11) for group 2 and 83.3%

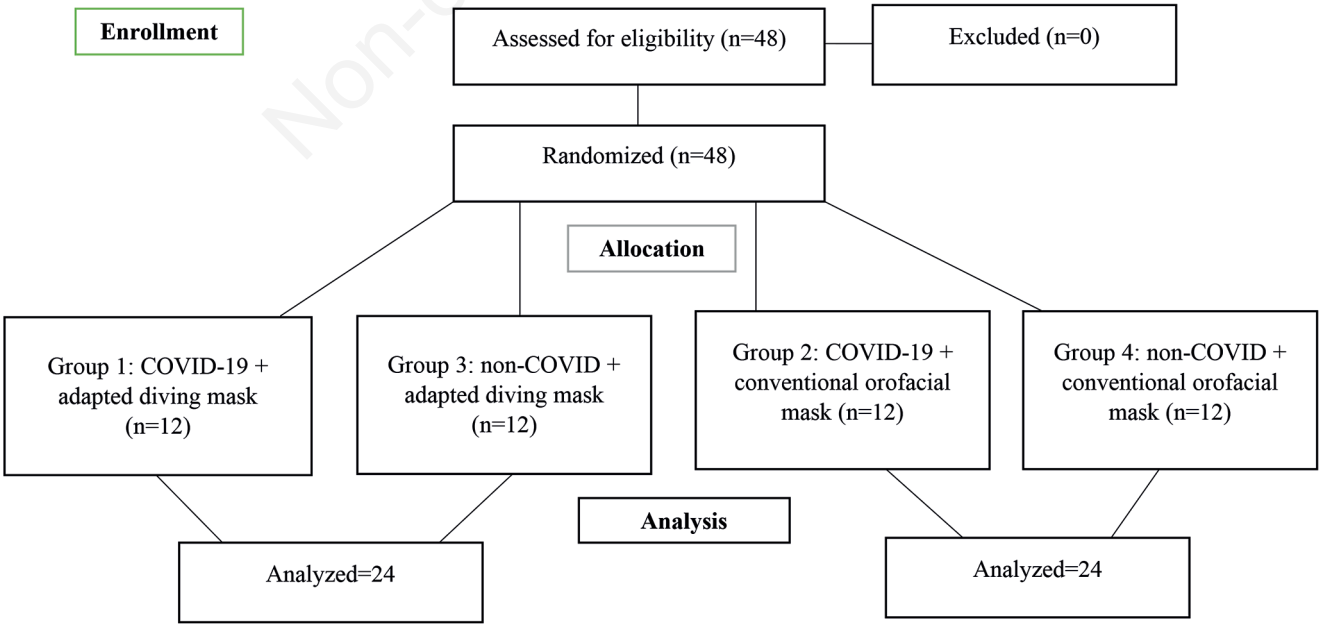


**Figure 2.** Flowchart of the study.

(n=10) for group 4. The failure outcome was 8.3% (OTI) for the adapted diving mask groups (groups 1 and 3), while it was 16.7% (death, 2 patients) for group 2 and 8.3% (OTI) for group 4 who used the conventional mask, respectively.

## Discussion

The present study was the first randomized clinical trial on the use of a mask adapted for NIV in the context of the COVID-19 pandemic and demonstrated that NIV increased the $PaO_2/FiO_2$ ratio in the first hour using a conventional mask and an adapted diving mask. However, patients who used the adapted diving mask obtained greater oxygenation over the evaluation time (48 hours) than the conventional orofacial mask.

Although the adapted diving mask was initially used as personal protective equipment for health professionals [10,29,30], studies have been developed using it in patients with COVID-19 [13,31], in which it was able to reverse AHRF and improve the $PaO_2/FiO_2$ ratio.

The use of the adapted diving mask and the conventional orofacial mask for NIV in critically ill patients with and without the diagnosis of COVID-19 developed in the present study proved to be effective in improving the $PaO_2/FiO_2$ ratio; however, the former showed better rates of this ratio up to 48 hours during which these patients were monitored. These results provide evidence that NIV can reverse AHRF in these patients.

The clinical relevance of this study regards the use of an adapted orofacial mask that did not present adverse effects during its use and enabled NIV success when compared to the conventional orofacial mask. Considering the scenario caused by the pandemic, clinical improvement and non-progression of patients to invasive mechanical ventilation using this ventilation strategy with both masks proved to be safe and efficient in these patients, especially considering the performance of the adapted mask.

Adapted interfaces have been used in cases of AHRF to reduce the risks of OTI and mortality [2,13], similar to what was performed in this study. One type of relatively common interface is the Helmet. The study by Chaudhuri *et al*. [32] used the Helmet in hypoxemic patients to reduce mortality and the OTI rate compared to the use of conventional orofacial masks and high-flow nasal catheters, in which they found a similar finding to our study, namely, that the group that used the conventional orofacial mask presented a higher OTI rate than those who used the Helmet, but its effect on mortality is uncertain. However, the evidence of this study is low due to its methodological limitations, making it necessary to develop better-quality randomized controlled trials.

Although studies with diving masks adapted for NIV are still scarce, Wagner *et al*. reported their use in a clinical case of a patient



**Table 1.** Initial characteristics of patients before non-invasive ventilation (one-way analysis of variance, p<0.05).

| Variables | Group 1 (n=12) | Group 2 (n=12) | Group 3 (n=12) | Group 4 (n=12) |
|---|---|---|---|---|
| Gender (M) n% | 7 (58.3) | 7 (58.3) | 7 (58.3) | 7 (58.3) |
| Age (years) mean (SD) | 63.75 (20.77) | 52.17 (14.90) | 68.00 (14.00) | 56.42 (22.18) |
| Height (meters) mean (SD) | 1.70 (0.10) | 1.69 (0.07) | 1.72 (0.10) | 1.70 (0.09) |
| Pred weight (Kg) mean (SD) | 64.75 (11.00) | 64.70 (9.47) | 66.48 (11.14) | 63.59 (9.93) |
| BMI ($Kg/m^2$) mean (SD) | 25.90 (4.70) | 24.32 (5.00) | 24.41 (3.53) | 25.56 (4.23) |
| Comorbidities n (%) | | | | |
| SAH | 7 (58.5) | 2 (16.7) | 9 (75.0) | 9 (75.0) |
| DM | 4 (33.3) | 3 (25.0) | 3 (25.0) | 3 (25.0) |
| Obesity | 1 (8.3) | 2 (16.7) | 3 (25.0) | 4 (33.3) |
| Dyslipidemia | 4 (33.3) | 0 (0.0) | 4 (33.3) | 3 (25.0) |
| Ischemic heart disease | 1 (8.3) | 0 (0.0) | 3 (25.0) | 4 (33.3) |
| CHF | 3 (25.0) | 1 (8.3) | 5 (41.7) | 4 (33.3) |
| Pulmonary heart disease | 1 (8.3) | 0 (0.0) | 1 (8.3) | 4 (33.3) |
| Cancer | 1 (8.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| $PaO_2$ (mmHg) mean (SD) | 61.66 (6.70) | 65.05 (5.80) | 62.46 (5.75) | 62.97 (5.75) |
| $PaCO_2$ (mmHg) mean (SD) | 29.45 (6.09) | 29.36 (4.78) | 30.31 (7.22) | 32.68 (6.87) |
| pH mean (SD) | 7.41 (0.06) | 7.43 (0.06) | 7.43 (0.06) | 7.40 (0.06) |
| $SaO_2$ mean (SD) | 90.81 (2.11) | 91.58 (1.87) | 91.20 (1.98) | 90.55 (2.31) |
| Borg median (IQR) | 8.00 (6.00-8.00) | 7.50 (5.00-10.00) | 7.50 (5.00-10.00) | 6.0 (5.00-10.00) |

M, male; SD, standard deviation; BMI, body mass index; SAH, systemic arterial hypertension; DM, diabetes mellitus; CHF, congestive heart failure; $PaO_2$, partial pressure of oxygen; $PaCO_2$, partial pressure of carbon dioxide; pH, hydrogen potential; $SaO_2$, arterial oxygen saturation; IQR, interquartile range.

**Table 2.** Average of changes (δ) with regards to the ratio of arterial oxygen partial pressure to fractional inspired oxygen between the masks.

| Time | Conventional mask (CI 95%) | δ (%)* | p value | Adapted diving mask (CI 95%) | δ (%) | p value |
|---|---|---|---|---|---|---|
| Before | 170.48 (157.72-183.25) | | | 163.78 (151.02-176.55) | | |
| 1 hour | 275.70 (252.60-298.81) | 105.22 (52.03) | <0.001 | 309.65 (286.55-332.76) | 145.87 (45.94) | <0.001 |
| 24 hours | 297.93 (273.31-322.54) | 22.22 (38.29) | <0.001 | 317.57 (292.95-342.19) | 7.91 (21.71) | 0.87 |
| 48 hours | 308.78 (274.84- 342.73) | 10.85 (42.09) | 0.21 | 365.81 (331.87-399.76) | 48.24 (49.18) | <0.001 |

CI 95%, confidence interval; Paired Student's *t*-test, p<0.05; *δ compared to the previous evaluation time point.

with severe COVID-19 and AHRF [31]. In this case, NIV was associated with the prone position, and an increase in the $PaO_2/FiO_2$ ratio and clinical success were observed. The adapted diving mask was also used in another case study developed by Bibiano-Guillen *et al*. with patients with COVID-19 and experiencing AHRF [13]. According to these authors, an increase in peripheral oxygen saturation was observed in the first hour of its application, and no serious adverse events were found in the patients. Our study was the first to develop a controlled clinical trial with this same population of patients to verify the efficiency of this mask in clinical practice in relation to the conventional mask, and the results are favorable to its use in clinical practice.

Regarding the clinical success of NIV, our results point to AHRF resolution within the first 48 hours, with stabilization in most patients and for both interfaces used. NIV success criteria [33,34] do not necessarily represent success, especially when other factors may be contributing to the clinical deterioration and were not analyzed during the study, since the presence of associated comorbidities and pro-inflammatory cytokine storm leads to the clinical worsening of respiratory failure [35].

Burton-Papp *et al*. [36], Ashish *et al*. [37], and Sartini *et al*. [38] evaluated the NIV success rates in patients with COVID-19 in AHRF (82.5%, 93.2%, and 96%, respectively) with similar findings to those of this study; however, they only used a conventional orofacial mask. Contrary to the above findings, some observational studies have observed NIV success rates of 48.1% [39], and 58% [40], and higher OTI rates in these patients. Burns *et al*. found success in 50% of patients who used NIV [41]; however, they were able to verify that failure was associated with age over 80 years and the presence of comorbidities. The main factors associated with variability in success rates are related to the type of study (observational) and the methods of applying NIV without standardization or randomization for these patients.

The evaluation period used in the study comprised controlling ARF signs and symptoms; however, adaptation to the ventilatory interface may have contributed to improving and maintaining the $PaO_2/FiO_2$ ratio. Among the factors associated with adaptation to the interface, the comfort provided by the adapted diving mask may be responsible for the tendency to gain oxygenation over time in these patients.

The COVID-19 pandemic has provided and still provides an investigation of resources that can provide relief and reversal of severe AHRF cases; the use of NIV can prove effective in these situations, provided that the indication is accurate, that there is care about environmental contamination, and that it is taken by professionals. According to our results, the application of NIV using conventional and adapted orofacial masks provided clinical and $PaO_2/FiO_2$ ratio improvements, with success rates considered satisfactory. The adapted mask provided higher oxygenation levels throughout the follow-up period for these patients when compared to the conventional mask.

The choice of the ventilatory interface may be associated with the success of NIV. Interfaces that provide less air leakage, greater comfort, and better communication between the patient and the physiotherapist, as is the case with the adapted diving mask, may present better acceptance and favor its use. However, choosing the "ideal" interface is hampered by availability in the health service, high production costs, and high demand [42].

## Limitations

As this is an experimental study with a diving mask adapted for use in NIV, the studies published to date were limited to the description of cases [13,31], thus making it difficult to compare our findings with studies of better methodological quality. However, even in this difficult scenario, it was possible to develop an accurate and judicious protocol when evidence was still scarce and the vast majority of studies were observational. Given the urgency and severity of patients with AHRF and the need to save lives, this study was concerned with establishing evaluation and follow-up criteria to add to the knowledge that already existed and, until now, was incipient. The monitoring period of the $PaO_2/FiO_2$ ratio needs to be expanded in these patients in future studies.

## Conclusions

The use of NIV as a therapeutic method in patients with AHRF and with or without COVID-19 improved the $PaO_2/FiO_2$ ratio. Both NIV interfaces used (conventional orofacial and adapted diving masks) proved to be effective, although it was observed that the adapted mask showed better performance in maintaining the $PaO_2/FiO_2$ ratio up to 48 hours after starting its application. There was no significant difference between interfaces regarding NIV failure.

## References

1. Scala R, Heunks L. Highlights in acute respiratory failure. Eur Respir Rev 2018;27:180008.
2. Ferreyro BL, Angriman F, Munshi L, et al. Association of noninvasive oxygenation strategies with all-cause mortality in adults with acute hypoxemic respiratory failure: a Systematic Review and Meta-analysis. JAMA 2020;324:57-67.
3. Xu XP, Zhang XC, Hu SL, et al. Noninvasive ventilation in acute hypoxemic nonhypercapnic respiratory failure: a systematic review and meta-analysis. Crit Care Med 2017;45:e727-33.
4. Guan WJ, Zheng YN, Yu H, et al. Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med 2020;382: 1708-20.
5. Winck JC, Scala R. Non-invasive respiratory support paths in hospitalized patients with COVID-19: proposal of an algorithm. Pulmonology 2021;27:305-12.
6. Wang P, Liu L, Iketani S, et al. Increased resistance of SARS-CoV-2 variants B.1.351 and B.1.1.7 to antibody neutralization. Res Sq 2021;rs.3.rs:155394.
7. Vergano M, Bertolini G, Giannini A, et al. Clinical ethics recommendations for the allocation of intensive care treatments in exceptional, resource-limited circumstances: the Italian perspective during the COVID-19 epidemic. Crit Care 2020;24:165.
8. Spina S, Marrazzo F, Migliari M, et al. The response of Milan's emergency medical system to the COVID-19 outbreak in Italy. Lancet 2020:e49-50.
9. Gómez CC, Rodríguez P, Torné ML, et al. Clinical consensus recommendations regarding non-invasive respiratory support in the adult patient with acute respiratory failure secondary to SARS-CoV-2 infection. Rev Esp Anestesiol Reanim 2020;67: 261-70.
10. Germonpre P, Rompaey DV, Balestra C. Evaluation of protection level, respiratory safety, and practical aspects of commercially available snorkel masks as personal protection devices against aerosolized contaminants and SARS-CoV2. Int J Environ Res Public Health 2020;17:4347.
11. Lazzeri M, Lanza A, Bellini R, et al. Respiratory physiotherapy in patients with COVID-19 infection in acute setting: a position

paper of the Italian Association of respiratory physiotherapists (ARIR). Monaldi Arch Chest Dis 2020;90:1285.
12. Ñamendys-Silva SA. Respiratory support for patients with COVID-19 infection. Lancet Respir Med 2020;8:e18.
13. Bibiano-Guillen C, Arias-Arcos B, Collado-Escudero C. Adapted diving mask (ADM) device as respiratory support with oxygen output during COVID-19 pandemic. Am J Emerg Med 2021;39:42-7.
14. Charron C, Repesse X, Bouferrache K, et al. PaCO2 and alveolar dead space are more relevant than PaO2/FiO2 ratio in monitoring the respiratory response to prone position in ARDS patients: a physiological study. Crit Care 2011;15:R175.
15. Feiner JR, Weiskopf RB. Evaluating pulmonary function: an assessment of PaO2/FIO2. Crit Care Med 2017;45:e40-8.
16. Colaneri M, Sacchi P, Zuccaro V, et al. Clinical characteristics of coronavirus disease (COVID-19) early findings from a teaching hospital in Pavia, North Italy, 21 to 28 February 2020. Euro Surveill 2020;25:2000460.
17. Zinellu A, De Vito A, Scano V, et al. The PaO2/FiO2 ratio on admission is independently associated with prolonged hospitalization in COVID-19 patients. J Infect Dev Ctries 2021;31: 353-59.
18. Dainesi SM, Aligieri P. Como as recomendações CONSORT podem assegurar a qualidade dos relatos de estudos clínicos?. Rev Assoc Med Bras 2005;5:6. [Article in Portuguese].
19. Mergulhadores do Bem. Apresentação. Available from: https://www.owntec.com.br/mergulhadores/.
20. Paiva DN, Wagner LE, Marinho SES, et al. Effectiveness of an adapted diving mask (Owner mask) for non-invasive ventilation in the COVID-19 pandemic scenario: study protocol for a randomized clinical trial. Trials 2022;23:218.
21. Associação de Medicina Intensiva Brasileira (AMIB), Sociedade Brasileira de Pneumologia e Tisiologia (SBPT). Diretrizes Brasileira de Ventilação Mecânica, 2013. Available from: https://cdn.publisher.gn1.link/jornaldepneumologia.com.br/pdf/Cap_Suple_91_01.pdf. Accessed on: 20/04/2023. [Material in Portuguese].
22. Schultz MJ, Haitsma JJ, Slutsky AS, Gajic O. What tidal volumes should be used in patients without acute lung injury?. Anesthesiology 2007;106:1226-31.
23. Seiberlich E, Santana JÁ, Chaves RA, Seiberlich RC. Ventilação mecânica protetora, por que utilizar?. Rev Bras Anestesiol 2011;61:659-67. [Article in Portuguese].
24. Mitchell CO, Lipschitz DA. Arm length measurement as an alternative to height in nutritional assessment of the elderly. JPEN J Parenter Enteral Nut 1982;6:226-9.
25. Araújo MLD, Andrade MLSS, Prado LVS et al. Precisão do IMC em diagnosticar o excesso de gordura corporal avaliada pela bioimpedância elétrica em universitários. Nutr Clín Diet Hosp 2018;38:154-60. [Article in Portuguese].
26. Borg G. Physiological bases of perceived exertion. Med Sci Sports Exerc 1982;14:377-81.
27. Cabral LL, Lopes PB, Wolf R, et al. A systematic review of cross-cultural adaptation and validation of Borg´s rating of perceived exertion scale. J Phys Educ 2017;28:e2853.
28. Holanda MA, Reis RC, Winkeler GFP, et al. Influence of total face, facial and nasal masks on short-term adverse effects during noninvasive ventilation. J Bras Pneumol 2009;35:164-73. [Article in Portuguese].
29. Coia, JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. J Hosp Infect 2013;85:170-82.
30. Kroo L, Kothari A, Hannebelle M, et al. Pneumask modified full-face snorkel masks as reusable personal protective equipment for hospital personnel. BMJ 2020;4:e20078907.
31. Wagner LE, Basegio KG, Dornelles CFD, et al. Diving mask adapted for non-invasive ventilation and prone position in a patient with severe covid-19: case report. Rev Epidemiol Control Infect 2020;10:15402.
32. Chaudhuri D, Jinah R, Burns KEA, et al. Helmet non-invasive ventilation compared to facemask non-invasive ventilation and high flow nasal cannula in acute respiratory failure: a systematic review and meta-analysis. Eur Resp J 2022;59:2101269.
33. Wang, K,Wei Z, Li J, et al. The experience of high-flow nasal cannula in hospitalized patients with 2019 novel coronavirus-infected pneumonia in two hospitals of Chongqing, China. Ann Intensive Care 2020;10:37.
34. Associação de Medicina Intensiva Brasileira (AMIB). Orientações sobre o manuseio do paciente com pneumonia e insuficiência respiratória devido a infecção pelo coronavírus (SARS-CoV-2) - Versão n.05/2020*. Available from: https://portaldeboaspraticas.iff.fiocruz.br/wp-content/uploads/2020/06/vm_ai_vjs_v5_abr_2020_final.pdf. Accessed on: 20/04/2023. [Material in Portuguese].
35. Anka AU, Tahir MI, Abubakar SD, et al. Coronavirus disease 2019 (COVID-19): an overview of the immunopathology, serological diagnosis and management. Scand J Immunol 2021; 93:e12998.
36. Burton-Papp HC, Jackson AIR, Beecham R, et al. Conscious prone positioning during non-invasive ventilation in COVID-19 patients: experience from a single centre. F1000Res 2020;9:859.
37. Ashish A, Unsworth A, Martindale J. CPAP management of COVID-19 respiratory failure: a first quantitative analysis from an inpatient service evaluation. BMJ Open Resp Res 2020; 7:e000692.
38. Sartini C, Tresoldi M, Scarpellini P, et al. Respiratory parameters in patients with COVID-19 after using noinvasive ventilation in the prone position outside the intensive care unit. JAMA 2020;323:2338-40.
39. Menzela F, Barbieri C, Fornatana M, et al. Effectiveness of non-invasive ventilation in COVID 19 related-acute respiratory distress syndrome. Clin Respir J 2021;15:779-87.
40. Nightingale R, Nwosu N, Kutubudin F, et al. Is continuous positive airway pressure (CPAP) a new standard of care for type 1 respiratory failure in COVID-19 patients? A retrospective observational study of a dedicated COVID-19 CPAP service. BMJ Open Resp Res 2020;7:e000639.
41. Burns GP, Lane ND, Tedd HM, et al. Improved survival following ward-based non-invasive pressure support for severe hypoxia in a cohort of frail patients with COVID-19: retrospective analysis from a UK teaching hospital. BMJ Open Resp Res 2020;7:e000621.
42. Pierucci P, Portacci A, Carpagno GE, et al. The right interface for the right patient in noninvasive ventilation: a systematic review. Exp Rev Respir Med 2022;16:931-44.