

## DISSERTATION DEFENSE: SÔNIA ELVIRA DOS SANTOS MARINHO

**DATE:** JULY 12, 2022

**TIME:** 14:00 pm

**PLACE:** Google Meeting

**TITLE:** EFFECTS OF USING ADAPTED DIVING MASK (OWNER) AND CONVENTIONAL OROFACIAL MASK IN PATIENTS WITH AND WITHOUT COVID-19 DIAGNOSIS WITH NIV INDICATION ON OXYGENATION AND NON-INTUBATION: RANDOMIZED CLINICAL TRIAL

**Key words:** SARS-CoV-2. Non-invasive ventilation. Mechanical ventilation. Continuous positive airway pressure.

**WORDS:** 447

**ABSTRACT:**

Covid-19 causes several systemic manifestations, especially affecting the respiratory system, ranging from mild cold symptoms to severe acute respiratory distress syndrome (ARDS). At the beginning of the pandemic, there was a recommendation for early intubation in order to avoid respiratory deterioration and further lung injury, and non-invasive ventilation (NIV) was seen as an unsafe method for such patients due to the lack of scientific evidence for this and previous research involving viral pneumonias. The objective of this research was to compare the effects of the use of the adapted diving mask (Owner) with the conventional orofacial mask in patients with and without the diagnosis of Covid-19 with NIV indication regarding oxygenation and non-intubation. This is a randomized clinical trial, resulting from a larger study, approved by 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 the Resolution 466/12 of the National Health Council and registered in the Brazilian Clinical Trial Registry (ReBEC) (RBR – 7xmbgsz). Patients admitted to the intensive care units (ICU) of two hospitals, of both sexes, aged between 18 and 90 years and with an indication for NIV due to ARDS, were included in the study. 48 patients were recruited. Patients diagnosed with Covid-19 were considered to be those with a positive reverse transcriptase test (RT-PCR) or serological test. The primary outcomes studied were the  $\text{PaO}_2/\text{FiO}_2$  ratio ( $\text{RPaO}_2/\text{FiO}_2$ ) as a parameter to assess oxygenation and NIV success (non-evolution to intubation/death). The normality and homogeneity of the sample were verified, respectively, through the Kolmogorov-Smirnov and Levene tests. Single-factor ANOVA was used to evaluate the behavior of  $\text{RPaO}_2/\text{FiO}_2$  (before NIV, after 1h, 24h and 48h). The Mauchly sphericity test and the Greenhouse-Geisser correction were performed. For the post hoc analysis, the Sidak test was used ( $P < 0.05$ ). Statistical analysis was performed using SPSS version 20.0. Patients with Covid-19 were allocated in the adapted diving mask group (G1,  $n=12$ ) and in the conventional orofacial mask group (G2,  $n=12$ ) and the patients without Covid-19 were allocated in the adapted diving mask group (G3,  $n=12$ ) and conventional orofacial mask group (G4,  $n=12$ ). There was no sample loss. The adapted and conventional diving masks differed from each other regarding the behavior of  $\text{RPaO}_2/\text{FiO}_2$  in 1h ( $309.66 \pm 11.48$  vs.  $275.708 \pm 11.48$ , respectively) ( $p = 0.042$ ) and in 48h ( $365.81 \pm 16.85$  vs.  $308.787 \pm 18.86$ , respectively) ( $p = 0.021$ ).

The success of NIV (non-intubation) was high in all groups, with 91.7% in G1, G3 and G4 and 83.3% in G2, demonstrating a low failure rate in all groups. It is concluded that NIV was safe and effective in the evaluated patients and there was a better result of the adapted diving mask in improving  $RPaO_2/FiO_2$  and in terms of non-intubation.

**EXAMINATION BOARD:**

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