KEY ADVANTAGES OF NON INVASIVE VENTILATORS (NIV)

1 Introduction

The pandemic caused by SARS-CoV-2 has brought to light several problems related to lung ventilation. These included the adoption of early invasive measures, due to the risk of a repentant worsening of the general condition of hospitalized patients, and the increased probability of spread of the virus through droplets and aerosols. For these reasons, during the emergency situation, intubation with consequent mechanical ventilation was often preferred instead of using an intermediate step, although there was not always an indication for such a drastic measure. However, this approach had consequences: a large number of patients who would have benefited from non-invasive treatment underwent intubation, with an increased risk of ventilator-induced lung damage [1-2-3] and healthcare-acquired pneumonia [4]. In addition, there are numerous problems related to patient extubation, a field in which the use of non-invasive ventilation methods plays an important role.

The new device, **Biorespira**, is a non-invasive ventilator capable of generating high flows. In fact, it allows the operator to combine a ventilation mode with high flow nasal cannulas (HFNC) with a CPAP mode thanks to the setting of various PEEPs, exploiting the advantages of both of these methods. In addition, thanks to the use of a helmet or full face mask, it is possible to create a closed system that prevents the risk of transmission of the virus through aerosols.

2 HFNC

The **Biorespira** HFNC, when associated with a humidifier, allows the creation of an oxygenated, heated and humidified gas administered through nasal cannulas at flows up to 120L / min (the only fan on the market to achieve such high flows). These characteristics allow to maintain the hydration and mobility of secretions, preserving the mucociliary function, and at the same time provide a suitable amount of air even for dyspnoic patients. Thanks to a sufficient quantity of delivered air, the HFNC allows to maintain constant FiO2, avoiding dilutions with the ambient air typical of standard oxygenation techniques (SO). Furthermore, this machinery, with the washing of the nasopharynx, considered anatomical dead space, allows to reduce the patient's expiratory work thus improving ventilatory efficiency. Finally, the expiratory impedance creates a positive expiratory pressure (PEEP) equal to 1cmH2O / 10L / min of flow, favoring the increase in lung volume at the end of expiration.
Numerous studies have shown that HFNC is more tolerated than NIV and SO and provides greater oxygenation than SO [5-6-7]. A significant decrease in the intubation rate in the subgroup of patients with PaO2 / FiO2 <200 has also been demonstrated thanks to the use of HFNC compared to NIV or SO [8]. Thanks to all these characteristics, HFNC is currently to be considered as the first line in patients with COVID-19 pneumonia with mild or moderate hypoxemia according to numerous guidelines, although the topic is still controversial [9].

In the next future **Biorespira** will also be equipped with a monitoring system based on oxygen saturation (SaO2), heart rate (HR), respiratory rate (RR) and the ROX indicator [(SaO 2 / FiO2) / (RR)]. These indicators provide an assessment of the efficacy of the therapy and the patient's condition, allowing early identification of patients who would need intubation, preventing the use of emergency maneuvers. It has in fact been shown that the RR, detected at 2 hours of treatment (RR <29rpm), and the FiO2 <0.59 and ROXI> 5.98, both detected at 8 hours of treatment, are the best predictors of success. of HFNC therapy [10]. A modified version of ROXI, ROXI-HR, which adds heart rate assessment, is also being studied: although validation studies are needed, the ROXI-HR index appears to be a promising tool for identifying failure early. treatment with HFNC for acute hypoxemic respiratory failure or for preventive treatment after a planned extubation [11].

To conclude, HFNC is a very simple and safe method to apply, with excellent compliance by patients. The main risks are related to the administration of an HFNC to unstable or severely hypoxemic patients associated with inadequate monitoring: this can lead to severe hypoxemia and emergency intubation.

3 CPAP

Biorespira allows the operator to set progressively increasing PEEP up to 15 cmH20, so that it can be used as a CPAP. This favors the increase of the residual functional capacity.

Observational studies have shown that NIV and CPAP can stabilize the clinical course of a patient with mild to moderate acute respiratory failure due to COVID-19, provided that the patient does not demonstrate high inspiratory thrust and does not exert excessive inspiratory effort. [1-12].

4 Virus spreading risk

During the pandemic, the European Respiratory Society and the European Society of Intensive Care Medi-cine suggested the use of the helmet as the main interface for the patient, in order to protect healthcare personnel from the dispersion of infected particles, a recommendation also shared from the Italian Society of Pneumology [13-14]. Based on a recent review, it was concluded that CPAP using an oronasal mask and NIV using a helmet with an inflatable neck pillow are the methods of ventilatory support that allow for minimal contamination of the air in the room, and to a lesser extent than any other oxygen delivery system [15].

Despite the use of recommended PPE, a study carried out in 9 hospitals in the Emilia-Romagna region of Italy has shown a contagion rate of 11.4% among healthcare workers in contact with infected patients in a period from 1 March to 10 May [16] . Despite this relevant data, WHO continues to support the use of CPAP or NIV for the management of respiratory failure in COVID-19 patients, provided that personnel wear appropriate PPE [17]. In fact, discouraging the use of non-invasive ventilation methods in the COVID-19 pandemic can increase the need for intubation, leading to greater morbidity and mortality and reduced availability of ventilators, especially in those geographic areas severely affected by the pandemic.

5 Guidelines

Currently, the guidelines of the SITA (Italian Society of anti-Infective Therapy) and SIP (Italian Society of Pneumology) recommend the use of the CPAP helmet (with gentle ventilation and a PEEP not exceeding 10-12 cm of H2O) or HFNC if the patient fails to respond to standard oxygen supplementation and in the absence of urgent indications for endotracheal intubation. Taking into account the risk of rapid deterioration by COVID 19 patients, constant monitoring is necessary in order to perform prompt tracheal intubation and mechanical ventilation in case of deterioration of clinical conditions [18].

Finally, the current recommendations according to the NIH (National Institutes of Health) for patients with COVID-19 are:

• For adults with COVID-19 and acute hypoxemic respiratory failure despite conventional oxygen therapy: use of high-flow nasal cannulae (HFNC) compared to non-invasive positive pressure ventilation (NIPPV) (BI).

• In the absence of an indication for endotracheal intubation: a NIPPV monitor for adults with COVID-19 and acute hypoxemic respiratory failure for which HFNC is not available (BIII).

• For adults with COVID-19 who receive supplemental oxygen: close monitoring for detecting worsening respiratory status and, if necessary, intubation performed by a professional expert in a controlled environment (AII).

6 Conclusions

Patients with COVID-19 frequently develop pulmonary involvement resulting in hypoxemic respiratory failure. Although the approach used during the pandemic is currently valid, it must be taken into account that about 20-25% of patients with COVID-19 can benefit from therapy with HFNC, NIV, CPAP or awake pronation, with possible stabilization of their respiratory status and reduction of the need for intubation. Similarly, some of the patients who, following extubation, manifest respiratory distress or hypoxemia can be stabilized without the need for reintubation with non-invasive techniques [9].

The imperative use of protective measures and equipment is still mandatory in order to protect healthcare workers with negative pressure chambers or HEPA filters together with appropriate PPE in case of using these methods.

7 Bibliography

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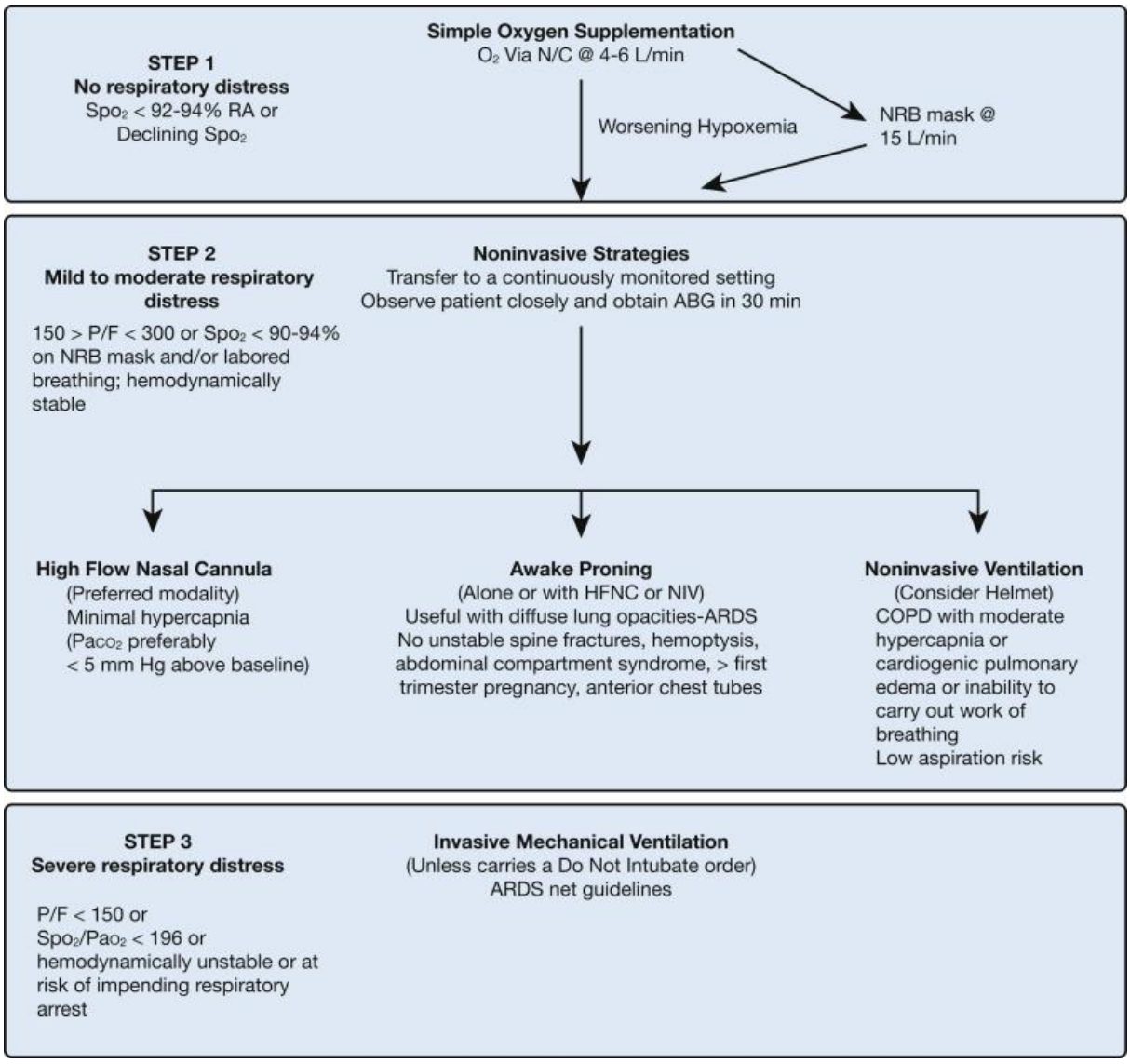

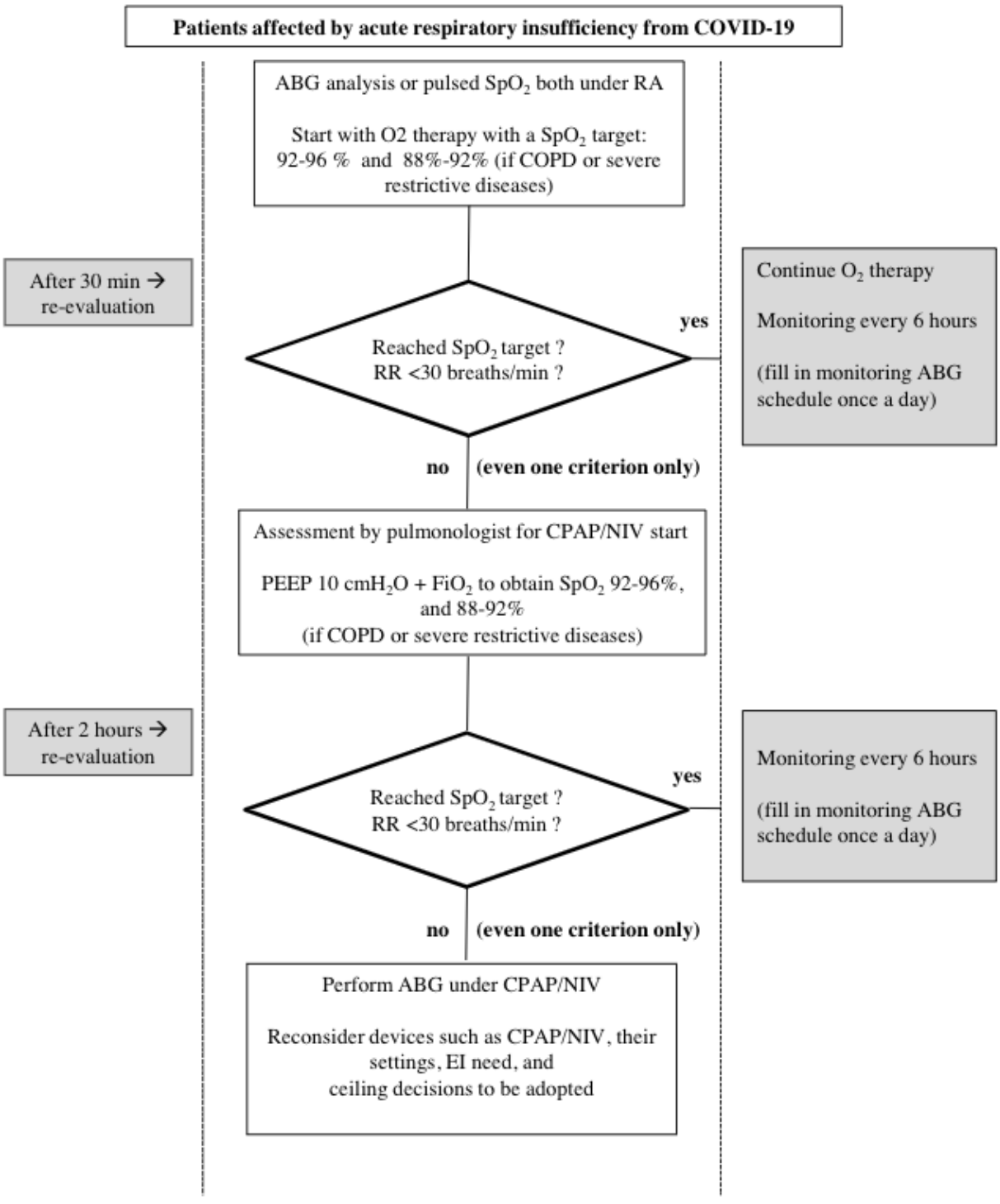
Patients affected by acute respiratory insufficiency from COVID-19
ABG analysis or pulsed SpO2 both under RA
Start with O2 therapy with a SpO2 target: 92-96 % and 88%-92% (if COPD or severe restrictive diseases)
After 30 min → re-evaluation
Reached SpO2 target ? RR <30 breaths/min ?
yes
Continue O2 therapy
Monitoring every 6 hours
(fill in monitoring ABG schedule once a day)
no
(even one criterion only)
Assessment by pulmonologist for CPAP/NIV start
PEEP 10 cmH2O + FiO2 to obtain SpO2 92-96%, and 88-92%
(if COPD or severe restrictive diseases)
After 2 hours → re-evaluation
Reached SpO2 target ? RR <30 breaths/min ?
yes
Monitoring every 6 hours
(fill in monitoring ABG schedule once a day)
no
(even one criterion only)
Perform ABG under CPAP/NIV
Reconsider devices such as CPAP/NIV, their settings, EI need, and ceiling decisions to be adopted