NON-INVASIVE RESPIRATORY SUPPORT BY OXYGENATION HELMET IN ACUTE RESPIRATORY FAILURE: A SCOPING REVIEW

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ABSTRACT

Noninvasive ventilation (NIV) has shown promise in the context of acute respiratory failure, as it inhibits the progression of mild to moderate clinical conditions, sometimes sparing the need for invasive ventilation. One of the prominent interfaces, widely used in the scenario of the covid-19 pandemic, was the helmet device – a helmet made of transparent material that surrounds the patient's head like an air reservoir. Despite its wide use, the medical literature is little explored regarding the advantages and clinical indications for the use of this device. For these reasons, the present scoping review aims to elucidate, based on current clinical-scientific evidence, the main concepts, advantages, and challenges involved in NIV, focusing on the *helmet* device. According to the guidelines of the Joanna Briggs Institute, the search was carried out in the MEDLINE/PubMed database. After applying the eligibility criteria, supported by the PRISMA methodology, 33 articles were included and independently summarized and contemplated by peers. In this review, it was verified that NIV, through the *helmet* device, with the possibility of using positive pressure in the airways, is safe and can reduce the need for invasive ventilation, composing an important oxygen therapy option, in addition to being viable for use even outside the intensive care environment. There is still a discussion about which patients would benefit from this device, as well as the appropriate clinical moment to indicate this ventilatory support, demonstrating an important theme to be explored in future clinical trials.

Keywords: Acute respiratory failure. Non-invasive ventilatory support. Non-invasive ventilation. Oxygenation helmet. Helmet.

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INTRODUCTION

Acute respiratory failure (ARF) is one of the frequent medical emergencies, which had a high incidence in the years surrounding the Covid-19 pandemic (Grasselli *et al*., 2023). According to Bellani *et al.,* 2017: which presents discussions about the "*Large Observational Study to understand the Global Impact of Severe Acute Respiratory Failure (LUNG SAFE STUDY)",* pA may present as a more severe inflammatory response condition: acute respiratory distress syndrome (ARDS), defined by the Berlin criteria in the spectrum: mild, moderate and severe.

AfARI is underdiagnosed in Brazil and worldwide, especially when it presents in the mild form, a fact that makes the management of this condition divergent and conflicting in the medical literature (Bellani *et al.,* 2016). However, it is known that, regardless of the etiology of ARF, oxygen therapy is essential to the treatment of patients, who require various levels and modalities of ventilatory support and, currently, the role and efficacy of noninvasive respiratory support in this scenario is much discussed (Liengswangwong *et al.,* 2020).

Noninvasive ventilation (NIV) is a modality of ventilatory support that consists of the use of positive pressure through continuous end-expiratory pressure (CPAP) or two levels of pressure (BiPAP) in the airway, being provided by a non-invasive interface, that is, without a definitive airway – presence of a cuff inflated inside the trachea – including nasal mask, face or oxygenation helmet (Aswanetmanee *et al.,* 2023).

The benefit of using NIV lies in the fact that it avoids the main complications related to invasive mechanical ventilation (MV): barotrauma; aspiration and pneumonia associated with MV; complications related to the endotracheal tube; muscle weakness, among others (Hyzy *et al.,* 2024). The use of NIV has been proven effective in cases of exacerbated chronic obstructive pulmonary disease (COPD); acute edema of the lungs; immediately after high-risk extubation (Liengswangwong *et al*., 2020; Chao; Wang; Liu, 2022).

In the context of NIV, supplemental oxygen can be administered through different modalities and interfaces depending on the clinical presentation. In situations of mild hypoxemia, one option is low-flow oxygen therapy, which can be administered through a nasal cannula or Venturi mask. In cases of more severe respiratory failure, the use of a high-flow nasal cannula (HFNC) or non-invasive positive pressure ventilation can be chosen, which can be offered by face mask or device in the form of a helmet or *helmet* (Al-Dorzi; Kress; Arabi, 2022; Chaudhuri *et al.,* 2023).

Non-invasive helmet ventilation has been widespread in the medical community since the 2000s. Despite this, it was during the Covid-19 pandemic, in which the world had to face one of the largest humanitarian crises due to a shortage of health resources (Aswanetmanee

et al., 2023), that this device stood out as an alternative for the treatment of acute hypoxemic respiratory failure, in and out of intensive care (Grieco *et al.,* 2021; Coppadoro *et al.,* 2021).

The *helmet* device consists of a plastic helmet that seals the individual's entire head, behaving as an air reservoir (Chao; Wang; Liu, 2022). The benefits found are limited to the possibility of prolonged use even at higher levels of positive end-expiratory pressure, which can significantly contribute to the improvement of hypoxemia and the prevention of lung injury (Cesarano *et al.,* 2022).

Given the scenario presented, the present scoping review aims to gather data from the literature with the main concepts of NIV, focusing on the *helmet* device, as well as to identify what would be the advantages and challenges that exist to improve the use of this device in ARI frameworks.

2 THEORETICAL FRAMEWORK

As mentioned, NIV has several possible interfaces: face mask, nasal mask, full face mask, high-flow nasal catheter, and the *helmet* – the objective of analysis of the present study. Current studies have been dedicated to elucidating, in view of the possible clinical indications for the use of NIV, which would be the most appropriate interface for the baseline condition and the exacerbation condition, in addition to which device provides better adherence to treatment and greater tolerance (Khatib *et al*., 2021; Tverring; Åkesson; Nielsen, 2020).

In view of this, although Covid-19 presents a pathophysiology that diverges from the ARF previously studied, given that it presents a loss of pulmonary perfusion regulation, hypoxic vasoconstriction, and a state of hypercoagulability with consequent pulmonary microvascular coagulation, NIV was used on an emergency basis in these cases (Radovanovic *et al.,* 2020).

Among the interfaces used, at the height of hospital overcrowding, the use of the helmet stands out, which was seen as an alternative to face masks and other NIV models, especially if it proves to be safer in terms of the dispersion of viral particles, contributing to the intra-hospital control of the spread of Covid-19 (Amirfarzan *et al.,* 2021; Chao; Wang; Liu, 2022). In addition, it allowed the use of high positive pressures during prolonged treatments, associated with less air leakage and better fit for different facial anatomies, as well as a lower risk of skin lesions and eye irritation (Arabi *et al.,* 2022).

Thus, over the first three epidemic waves, the perception that helmets also contributed to harsh outcomes such as reduced mortality was progressive, a crucial fact for verifying the potential of using them in acute respiratory failure (Piluso *et al.,* 2023). However, despite the benefits already defined by the theory and practice of the use of *helmets* during the pandemic

period, there is still a gap in terms of consistent evidence that identifies the clinical indications and the profile of the patient who would best benefit from this interface (Grieco *et al.*, 2021).

3 METHODOLOGY

Literature review is a methodology that offers a broad and complete view of a topic, and should be conducted with well-defined criteria in order to obtain a solid basis for the advancement of knowledge and facilitate the development of theories (Snyder, 2019). Scoping reviews are a form of literature review that seek to understand what there is of knowledge in an area based on a comprehensive research question, being a method capable of bringing together the main concepts of a theme, demonstrating the dimension, fields explored and potential discussions about that same theme (Arksey; O'malley, 2005). So, such a proposal aims to investigate what is being researched on a certain topic, in addition to verifying the gaps in the literature and, in the future, raising new studies.

To this end, this study was based on the recommendations of the *Joanna Briggs Institute*, using the Population (or Problem), Concept and Context (PCC) method to identify the main data to be considered (Peters *et al.,* 2020). The problem raised was the feasibility of using the *helmet* as a mode of non-invasive ventilation; the Concept encompassed the understanding of the modes of non-invasive ventilation in general, the clinical indications and practical applications; and the Context is the growing number of adult patients in need of ventilatory support, whether or not hospitalized in Intensive Care Units (ICU). Thus, the question that guides the present scoping review is: "What are the advantages and challenges of the use of ventilation helmets among the various modes of noninvasive ventilation available for use in adult patients with acute respiratory failure?"

The protocol of this scoping review was registered in the *Open Science Framework* (OSF) platform in order to better develop and explore the content of this research. The project remains available for consultation through registration under DOI 10.17605/OSF.IO/XT8BP.

3.1 METHODS OF SEARCHING FOR PUBLICATIONS

The *Pubmed database* and descriptors compatible with the theme were used. The following keywords were listed: *"helmet", "non invasive ventilation", "non invasive support", "respiratory failure", "respiratory insufficiency",* and were used with the equivalent descriptors in the *Mesh Terms*, except for the term *helmet*, which was not found as a standardized descriptor, but was manually added to the search strategy.

The terms were concatenated with the Boolean operators 'AND' and 'OR'. The search identified 98 articles in the *Pubmed* database, considering the keywords chosen, the

language used (Portuguese, English, and Spanish), and the restriction on free full texts and the period of publication (2019 - 2024). The search strategy is shown in Chart 1.

Chart 1: Search strategy for articles in the PubMed database in order to answer the search question

Database	PubMed
Search Strategy with Boolean Operators	Search: (helmet) AND ((non invasive ventilation) OR (noninvasive support)) AND ((respiratory failure) OR (respiratory insufficiency)) Filters: Free full text, English, Portuguese, Spanish, Exclude preprints, from 2019 - 2024 Sort by: Most Recent
Expanded Search Strategy with Synonymous Terms	(("head protective devices"[MeSH Terms] OR ("head"[All Fields] AND "protective"[All Fields] AND "devices"[All Fields]) OR "head protective devices"[All Fields] OR "helmet"[All Fields] OR "helmets"[All Fields] OR "helmet s"[All Fields] OR "helmeted"[All Fields]) AND ("noninvasive ventilation"[MeSH Terms] OR ("noninvasive"[All Fields] AND "ventilation"[All Fields]) OR "noninvasive ventilation"[All Fields] OR ("non"[All Fields] AND "invasive"[All Fields] AND "ventilation"[All Fields]) OR "non invasive ventilation"[All Fields] OR (("noninvasive"[All Fields] OR "noninvasively"[All Fields] OR "noninvasiveness"[All Fields]) AND ("support"[All Fields] OR "support s"[All Fields] OR "supported"[All Fields] OR "supporter"[All Fields] OR "supporter s"[All Fields] OR "supporters"[All Fields] OR "supporting"[All Fields] OR "supportive"[All Fields] OR "supportiveness"[All Fields] OR "supports"[All Fields]))) AND ("respiratory insufficiency"[MeSH Terms] OR ("respiratory"[All Fields] AND "insufficiency"[All Fields]) OR "respiratory insufficiency"[All Fields] OR ("respiratory"[All Fields] AND "failure"[All Fields]) OR "respiratory failure"[All Fields] OR ("respiratory insufficiency"[MeSH Terms] OR ("respiratory"[All Fields] AND "insufficiency"[All Fields]) OR "respiratory insufficiency"[All Fields]))) AND ((ffrft[Filter]) AND (excludepreprints[Filter]) AND (english[Filter] OR portuguese[Filter] OR spanish[Filter]) AND (2019:2024[pdat]))

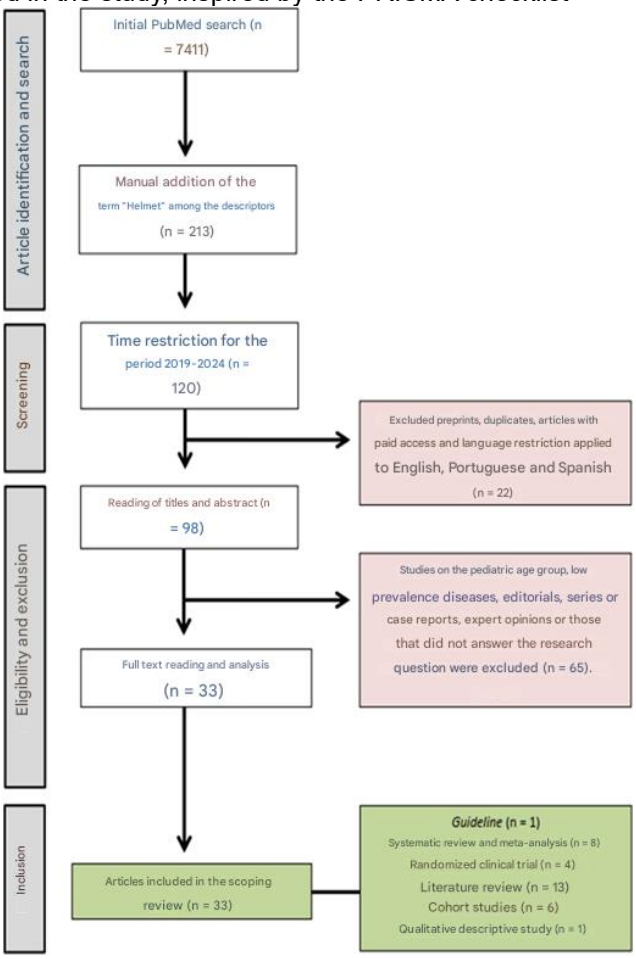
Source: Prepared by the authors

3.2 SELECTION CRITERIA

The selection of studies followed the recommendations of the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) (Galvão *et al.,* 2022). Two reviewers independently extracted the evidence. The disagreements were resolved by consensus or a third reviewer. For the eligibility of *the papers*, we considered reviews, observational studies, or clinical trials with adults undergoing treatment for ARF in or out of the ICU, except for chronic obstructive pulmonary disease or cardiogenic pulmonary edema.

Among the 98 selected articles and after reading the title and abstracts, articles involving pediatric age group or low-prevalence diseases and preclinical studies, case or experience reports, editorials and, in summary, articles that did not answer the research question were excluded. Then, 33 articles were selected for full reading. With the summarization of the main results and conclusions, the same 33 articles were used to construct the scoping review as initially proposed. The article selection flowchart, following the recommendations of PRISMA, is shown in Figure 1.

Figure 1 - Flowchart describing the process of search, identification, screening and exclusion and eligibility criteria of the articles included in the study, inspired by the PRISMA checklist



Source: Prepared by the authors

3.3 DATA EXTRACTION AND SUMMARIZATION PROCEDURES

The selected articles were grouped according to the central objective of the study, in order to bring together similar methodologies and contexts, making the data extraction better ordered during the discussion of the text. Initially, the articles that elucidated the choice of the best NIV interface in the context of ARF were gathered; Next, articles describing the use of *helmets* as the main therapy were evaluated . Subsequently, the review proposed to clarify the practical implications of the use of this device and the available configurations: pressure support ventilation (PSV) and continuous positive airway pressure ventilation (CPAP), also detailing what the literature demonstrates regarding the tolerability and limitations of the use of this device. Finally, based on the most recent evidence, within the context of the Covid-19 pandemic, the benefits raised by the practical use of the interface were discussed.

3.4 ETHICAL IMPLICATIONS OF THE STUDY

The present study is a literature review conducted in public domain databases, so it

does not require approval by an institutional ethics committee. Therefore, the method follows the regulatory standards set forth in Resolution No. 466/2012 of the National Health Council.

4 RESULTS AND DISCUSSIONS.

4.1 CHOICE OF INTERFACE FOR PROVIDING NVI IN THE CONTEXT OF IRpA

ARF is defined by the failure of the respiratory system to effect gas exchange satisfactorily, with insufficient blood oxygenation and, consequently, hypoxemia (reduced concentration of oxygen in arterial blood), which results in a decreased partial pressure of O2 (PaO2) and damage to the gradient of oxygen passage from the blood to the interstitium and tissues. generating hypoxia and compromising the main energy source of cells (Liengswangwong *et al.,* 2020). Therefore, in situations of hypoxemia, whether acute, chronic, or mild or severe, the treatment is to provide oxygen (Bigatello; Persenti, 2019). The selection of the interface that provides oxygen therapy is a clinical decision and is based individually on each patient, the clinical picture presented, comfort and anatomical applicability, with face masks being the most used (Rosà *et al.,* 2023; Menga *et al.,* 2022).

Among the studies evaluated, there are reviews that describe the main concepts involved in NIV oxygen therapy in Afr, and there are those that involved comparing the use of helmets with standard oxygen therapy, which was considered, in most studies, as an O2 flow rate lower than 15L/min via nasal cannula, face mask, or Venturi mask. As mentioned, both face masks and *helmets* can provide non-invasive ventilation by PSV or CPAP, reaching *positive end-expiratory pressure* (PEEP) of 5 to 8 cmH2O or PSV between 7 and 14 cmH20 (Menga *et al.,* 2021a).

Among the physiological factors related to face masks, there is an increase in airway pressure and an increase in arterial oxygenation, and there are even cardiac effects of functional improvement due to a reduction in right ventricular preload and left ventricular afterload, and such benefits result in a decrease in inspiratory effort and respiratory distress. One difficulty encountered is air leaks, given that there is often no adequate adherence of the device to the patient's face and this challenges the maintenance of a satisfactory PEEP (Menga *et al.,* 2021b; Grieco *et al.,* 2021; Rosà *et al.,* 2023).

The main characteristics and specifications regarding the *helmet* are explained in a separate topic, however, by way of initial definition, according to Rosà *et al.* (2023), the *helmet* is a kind of "hood" of different shapes, made of transparent material and manufactured with a "collar" that allows it to be attached to the patient's neck and shoulders, without touching him or her face. The device has a circuit with two tubes, for inhaled and exhaled gas, and needs to be fully expanded to ensure the necessary and effective pressurization that will

reach the patient's airway, which can be achieved through an increased PEEP (10-12 cmH2O) and higher support pressure, which allows the expansion of the interface and the "*washout*" effect, reducing dead space and carbon dioxide (CO2) retention. The *helmet* also allows adequate flow delivery conditions without the need for a humidifier or heater, especially in PSV mode (Grieco *et al.,* 2021; Rosà *et al.,* 2023).

The analysis of the studies allowed us to extract that clinical trials and observational studies comparing face mask NIV and helmet NIV for oxygen therapy in the context of ARF have a low level of evidence. Therefore, the most recent guidelines are still unable to offer definitive recommendations regarding the use of the *helmet* in these conditions, thus presenting conflicting indications.

Among the studies, the systematic review by Chaudhuri et. al. (2022) stands out, which demonstrated that the use of helmets reduced mortality (relative risk 0.56, 95% CI 0.33–0.95; low certainty) and orotracheal intubation index (relative risk 0.35, 95% CI 0.22–0.56; low certainty) when compared to face masks and indicates the possibility of a more cost-effective therapy. Compared with HFNC, helmets may also reduce the progression to intubation (relative risk 0.59, 95% CI 0.39–0.91) (Chaudhuri *et al.,* 2022), however, the quality of the evidence is low and, on both occasions, there was an uncertain effect on reducing mortality between the different devices.

4.2 HELMET AS AN ALTERNATIVE TO STANDARD OXYGEN THERAPY AND AS PRIMARY THERAPY

There are three issues that conflict with the practical use of noninvasive respiratory support: the use of NIV may be associated with failure to recognize severe acute respiratory syndrome early; NIV may be lower than MV to minimize the progression of lung injury and has the potential to cause such injury if excess tidal volume (above 8 ml/kg) is supplied; indicating NIV inappropriately may delay an inevitable OTI and result in negative outcomes, especially in patients with severe ARF (Buell; Patel, 2023).

In view of this, it should be considered that most studies with noninvasive respiratory support have generated data on NIV via face mask, therefore, the conflicts cited are largely not related to *helmet* (Coppadoro *et al.,* 2021). However, with the popularization of the *helmet* during the pandemic crisis, it was noted that the interface has its own characteristics and controversies, also presenting a potential to be an alternative to the more traditional noninvasive respiratory support, as evidenced in the most recent trials and discussed in this review.

From the understanding of the pathophysiology of ARF during spontaneous breathing,

which involves the mechanisms that lead to the condition of "*patient self-inflicted lung injury*" or P-SILI, it is known that ventilation provided via *helmet* has potentiate to reduce this risk of injury. Essentially, such configurations boil down to the possibility of providing high PEEP for an extended period, without interruptions and adverse effects already known from other interfaces (Cesarano *et al.,* 2022).

A high PEEP (10-15 cmH2O) can induce the recruitment of alveoli, preventing their collapse, promotes more homogeneous lung inflation, reducing inspiratory effort, and optimizes the ratio between ventilation and perfusion, resulting in more efficient gas exchange (Hong *et al.,* 2021). This is advantageous over face masks, as the increased PEEP in this device would cause even more significant air leaks, as well as increase patient discomfort during use. Another point to be highlighted is that, during the use of the *helmet*, especially in the PSV mode, it is common to have asynchrony between patient and ventilator, however, this does not generate discomfort, as the patient is able to inhale and exhale in the large reservoir that the interface provides (Cesarano *et al.,* 2022).

4.3 PRACTICAL IMPLICATIONS OF *HELMET* USE: SPECIFIC SETTINGS AND PATIENT TOLERANCE

In more detail, the *helmet* is constructed from a transparent, soft, inextensible synthetic material that wraps around the patient's head without coming into contact with the face and is anchored to the patient's neck or shoulders by means of a collar or straps. It generally has two connectors: one for gas inlet and one for gas outlet, and O2 can be supplied through a Venturi system, a turbine flow generator, or a fan (Coppadoro *et al.,* 2021).

As mentioned earlier, the *helmet* is capable of providing ventilation by two modes: non-invasive positive pressure ventilation (typically pressure support or PSV) and non-invasive continuous positive pressure ventilation or CPAP (Rosà *et al.,* 2023). Both PSV and CPAP are often described together under the generalist designation of noninvasive ventilation, but they have different mechanisms of action and, consequently, an individualized practical approach (Coppadoro *et al.,* 2021).

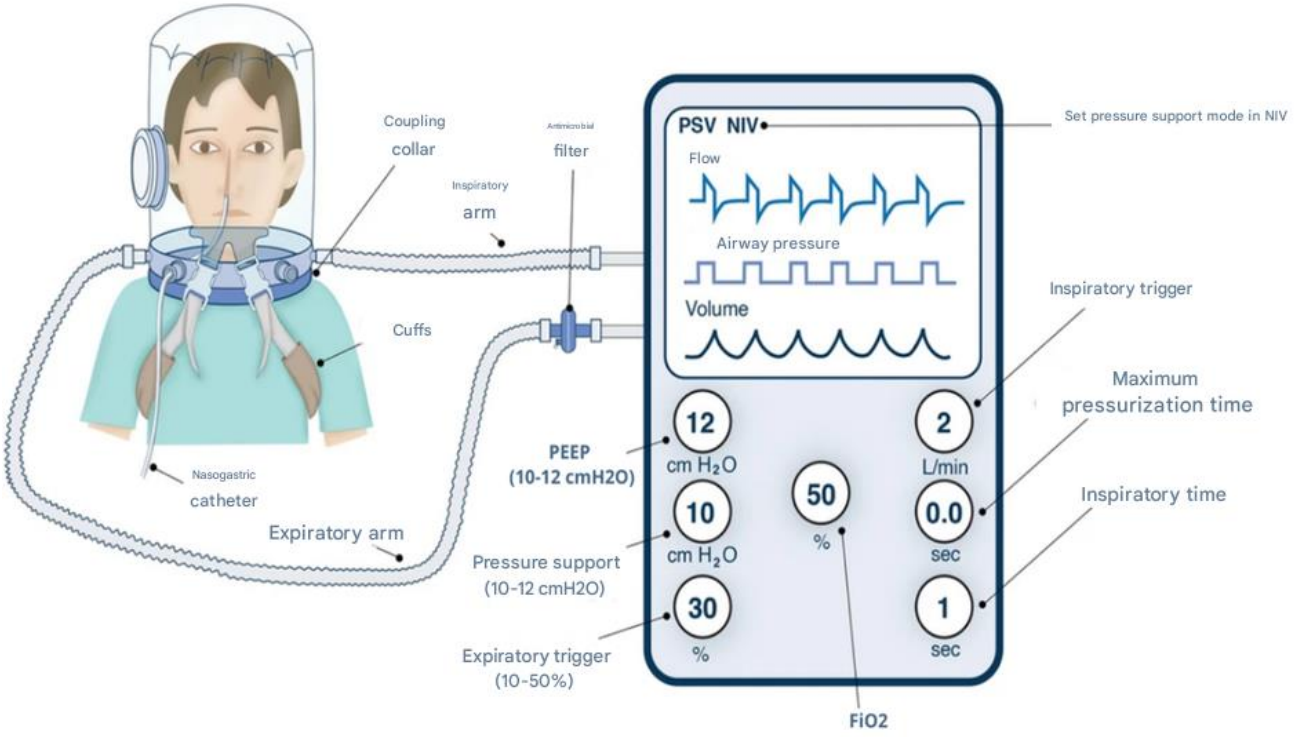
4.3.1 Pressure Support Ventilation (PSV)

The *helmet* is connected to a ventilator using two different connector systems: inspiratory and expiratory route, with a flow rate of about 100 L/min and a support pressure of 8 mmHg, which is increased according to the patient's respiratory rate reduction or the use of accessory muscles (Buell; Patel, 2023). The large dead space to be filled in the *helmet* requires high pressurization, which may result in lower inspiratory pressure in the patient's

airways, which may compromise synchrony with the ventilator.

Thus, specific adjustments that generate a higher PEEP are performed in order to achieve complete helmet expansion, maintain a high level of support pressure, and longer pressurization time (Coppadoro *et al.,* 2021). Therefore, it is preferable to have a circuit with two tubes instead of Y circuits, to adjust the PEEP between 10-15 cmH2O, to maintain a support pressure of about 10-14 cmH2O and to obtain a faster pressurization rate. In addition, in this ventilatory mode and with such settings, humidifiers are not necessary if the flow is maintained around 40 L/min (Cesarano *et al.,* 2022). A representative scheme of this mode of ventilation is depicted in Figure 2.

Figure 2 - Illustration of the *helmet* and circuit diagram configured for PSV



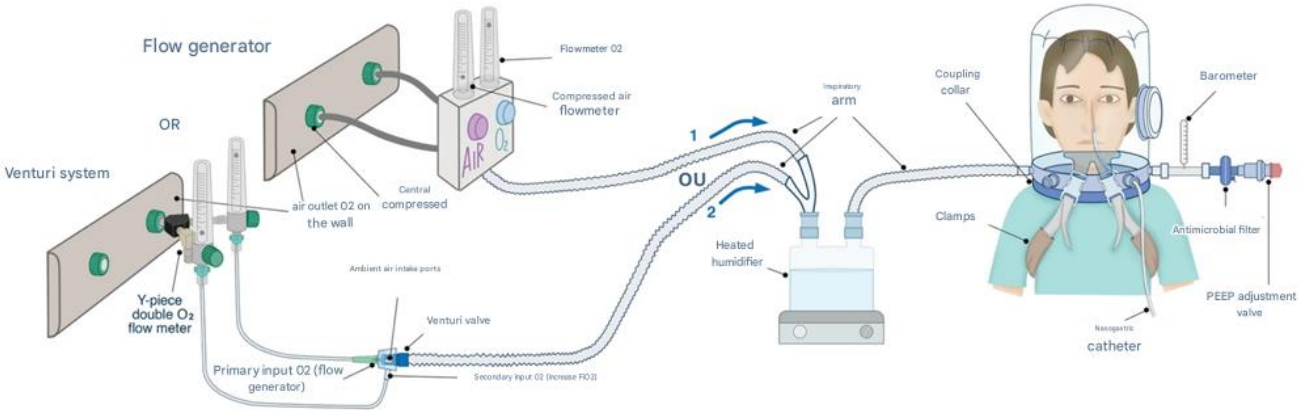
Source: Adapted from Grieco *et al,* 2022b.

4.3.2 Continuous Positive Pressure Ventilation (CPAP)

CPAP is characterized by the continuous flow of oxygen (about 60 L/min) to a variable FiO2 that fills the *helmet* and is dispersed throughout the environment through a valve connected to the expiratory port, which guarantees a PEEP, and can be offered by a ventilator (Cesarano *et al.,* 2022). Adequate flow is essential to expand and fill the helmet, generate positive pressure and avoid CO2 retention as much as possible (Coppadoro *et al.,* 2021), and a flow lower than 40 L/min is associated with significant inspiration of CO2 retained at the interface, so providing 50-60 L/min of flow and a PEEP 10-15 cm H2O represents the safest configuration to provide continuous positive pressure (Cesarano *et al.,* 2022).

Unlike the face mask, the *helmet* system allows for greater compliance for the patient to maintain inspiratory flow without additional effort, if the patient's demand is greater than the flow provided (Coppadoro *et al.,* 2021). In this mode, flow provided by a ventilator is not recommended, as the gas flow corresponds to the patient's minute ventilation and this is insufficient to "wash" CO2 and avoid retention (Buell; Patel, 2023; Coppadoro *et al.,* 2021). A representative scheme of this mode of ventilation is depicted in Figure 3.

Figure 3 - Illustration of the *helmet* and circuit diagram configured for CPAP



Source: Adapted from Grieco *et al,* 2022b.

4.3.3 Patient comfort and tolerability when wearing the *helmet*

As already mentioned, patient comfort is a key point for the success of non-invasive respiratory support. Brugnolli *et al.* (2023) conducted a qualitative study that evaluated the responses of 20 patients regarding feelings during the use of the *helmet*, and all participants described the first hours of use as a great challenge, in which the sensation of suffocation was present, in addition to the noise and pressure felt on the shoulders being points of great discomfort.

Despite this, the perception of these patients revealed that the fact that the helmet allows the maintenance of the diet, the use of glasses, headphones for music, reading books, consulting the cell phone, and communicating with the team and family members contributes to tolerance to the therapy and effectiveness (Brugnolli, *et al.,* 2023; Cammarota *et al.,* 2022). In addition, there are measures that can enhance the patient's comfort during the use of the *helmet*, such as positioning filters and humidifiers, strategically in the inspiratory connector, which attenuate the noise, adjust the humidification of the airflow, avoiding the side effect of xerostomia without excess humidity, which could condense at the interface and reduce visibility to the patient (Cammarota *et al.,* 2022, Coppadoro *et al.,* 2021).

4.4 LIMITATIONS TO BE CONSIDERED REGARDING THE USE OF THE *HELMET*

CO2 rebreathing is an issue to be discussed in the use of the *helmet* and may play a key role in clinical outcomes, since the interface, in principle, has a large "dead space" to be filled by expired CO2 that mixes with the supplied gas (Hong *et al.,* 2021). The concentration of CO2 inside the helmet depends on how much is produced by the patient, how much volume-minute is gene,rated and how much is "washed" by the high flow, and the concentration can reach levels of 18 mmHg when using Y ci,rcuits and that this can be reduced by up to 50% if two independent connectors are used for the inspiratory and expiratory routes. However, for patients with COPD exacerbation, face masks are more effective in reducing dyspnea precisely because of the more significant reduction in CO2 retention, although helmets have equivalent results in terms of better oxygenation and lower OTI index (Coppadoro *et al.,* 2021).

Increasing inspiratory pressure can contribute to removing excess CO2, as previously mentioned, which should be done with caution given the risk of increasing discomfort due to high flow (Hong *et al.,* 2021, Rosà *et al.,* 2023). In any case, continuous monitoring is pertinent, as another limitation of the helmet is that it does not allow an adequate measurement of the tidal volume supplied, since part of the flow supplied is used for expansion of the interface and does not directly enter the patient's airways, so the collection of arterial blood gases and constant pulse oximetry can be tools to ensure that there is an improvement in the oxygenation rate and PO2/FiO2 ratio, as well as the rebreathing of CO2 is as minimal as possible (Buell; Patel, 2023).

4.5 COMPARATIVE STUDIES AND CLINICAL OUTCOMES IN THE CONTEXT OF COVID-19

Based on pre-pandemic data, systematic reviews on clinical conditions other than Covid-19 demonstrated a superiority of *the helmet* among other non-invasive ventilatory modalities with regard to mortality and quality of life after hospitalization (Bellani *et al.,* 2021). Also, as pointed out in the systematic review by Ferreyro *et.al.* (2020), non-invasive helmet ventilation (RR, 0.26 [95% CrI, 0.14-0.46/ absolute risk, -0.32 [95% CrI%, -0.60 to -0.16] had a lower risk of progression to orotracheal intubation (25 studies, with 3,804 patients) when compared to nasal mask and high-flow catheter. In addition, in 21 studies (2,270 patients), the consequent reduction in mortality was observed with the use of helmets to the detriment of other interfaces. However, there are conflicting results as Peng et's review demonstrates. al, (2022), in which there were no differences in the mortality rate when comparing NIV with helmet and HFNC.

It is known that the main factor of severity and cause of ICU admission during Covid-

19 is ARDS, which can present a mortality of 30-40% of patients, even with optimized ventilatory support (Cammarota *et al.,* 2021; Piluso *et al.,* 2023). Noninvasive ventilation technologies were prominent in an attempt to prevent the patient from needing invasive MV (Beliero *et al.,* 2023; Duca *et al.,* 2020), and in the first wave of the pandemic, in the first half of 2020, there was a proportion that for every patient treated in the ICU with invasive mechanical ventilation, another patient was treated in other hospital settings with NIV (Bellani *et al.,* 2021; Coppadoro *et al.,* 2021).

During the pandemic, studies have attempted to assess the optimal management by comparing noninvasive ventilation interfaces. The indication of the *helmet* for Covid-19 was concentrated in patients who had mild to moderate ARDS, with no indication for MV, and the helmet was incorporated into protocols and guidelines of several hospitals around the world and the mode of ventilation most used by this interface was CPAP (Chao; Wang; Liu, 2022; Amirfarzan *et al.,* 2021). Observational studies with the helmet in CPAP mode have shown a positive outcome in more than 60% of patients, avoiding the need for OTI and also reducing mortality (Amirfarzan *et al.,* 2021; Bellani *et al.,* 2021). Accordingly, clinical trials with devices with the same characteristics also had a lower intubation rate and more ventilator-free days than users of high-flow nasal catheters (Chao; Wang; Liu, 2022; Michi *et al.,* 2023).

Divergently, in clinical trials such as the "*HELMET-COVID*" and "HENIVOT TRIAL", no statistical differences were evidenced between the interfaces in relation to mortality and days without ventilatory support (Arabi *et al.,* 2022). However, even so, the "HENIVOT TRIAL" pointed to the superiority of the helmet in relation to the HFNC in terms of the need for orotracheal intubation and mechanical ventilation, in agreement with Grieco et.al. (2021), which also points to an association with improved oxygenation and dyspnea, in addition to an increase in days free of invasive ventilation.

It was then possible to gather sufficient data to predict characteristic parameters of a patient who would best benefit from this technology, and some studies have proposed that the pre-treatment PaCO2 < 35 mmHg and the PaO2/(FiO2 x VAS dyspnea) ratio < 30 (in which VAS is a visual analog scale for the assessment of dyspnea and respiratory distress, varying the score from 0 to 10 as maximum discomfort) are findings that are related to a prognosis of greater benefits (Rosà *et al.,* 2023; Chao; Wang; Liu, 2022; Grieco *et al.,* 2022a).

It is necessary to consider that the factors responsible for the failure of non-invasive ventilation are related to the severity of the patient's own condition, and can be summarized in an intensely reduced PaO2/FiO2 ratio and high scores in *scores* such as SAPS III (Beliero *et al.,* 2023; Bellani *et al.,* 2021). In addition, there was also a concern about the performance of the patient after hospitalization for Covid-19. Rehabilitation after hospitalization of patients

using mechanical ventilation is, in fact, lower when compared to patients who received non-invasive ventilation and is directly related to the duration of ventilator use, but without significant difference between non-invasive interfaces (Arabi *et al.,* 2023; Michi *et al.,* 2023).

In summary, the *helmet* device, in CPAP mode, by reducing the need for invasive ventilation, has proven to be an important oxygen therapy option, since it also has the ability to mitigate the consequences of ICU bed shortages by having viable use even outside the intensive care environment, without major adverse events as demonstrated by Coppadoro et al. (2021) and Amirfarzan et al. (2021). Such findings suggest a potential advantage to be explored, in addition to the safety of helmet use in hypoxemic patients due to Covid-19 (Michi *et al.,* 2023).

4.6 LIMITATIONS OF THIS SCOPING REVIEW

Although recent studies with data from the pandemic period are promising, it is imperative to state that there is an important complexity when analyzing existing clinical studies, since they have some confounding factors. Among them, there is no standardization in relation to patient selection and choice of prototype according to different centers; Also, the tests with the use of the *helmet* depend on the causes inherent to the respiratory failure, as well as the baseline severity of the condition, the patient's cooperation and the team's experience**.** In addition**,** the studies are mostly monocenter, with restricted "n", and in some of the studies with positive results for satisfactory clinical outcomes, there was an association with factors such as: prone position, use of dexmedetomidine for greater patient comfort and adherence, manipulation by a team experienced in ventilatory management, restricted selection of patients in *status* pathological that did not cause a delay in the indication of OTI, previous comorbidities, and corticosteroid use (Piluso *et al.,* 2023; Al-Dorzi; Kress; Arabi*,* 2022).

5 CONCLUSION

Although there have been multiple trials and systematic reviews on noninvasive respiratory support in recent years, with an exponential momentum during the Covid-19 pandemic, it has not yet been possible to define a definitive approach or a protocol regarding the use of *helmets*, since there are divergences in the literature and limitations regarding the analysis of studies. In addition, there is no consensus on the population that would best benefit from the indication of this ventilatory support, what is the ideal time of use, or even standardized blood pressure parameters.

Even so, the *helmet* is widely used in bedside practice and this has been enough to generate clinically relevant data such as the association with a lower risk of progression to OTI and even a lower mortality rate found in some studies. In any case, regardless of the non-invasive ventilatory mode or interface used, the use of adequate flow to avoid CO2 retention, maintaining a satisfactory PEEP and protective ventilation minimizes the risks of P-SILI, in addition to strict monitoring and clinical surveillance are essential to avoid OTI delay in cases where necessary.

Therefore, it is possible to affirm that the *helmet* is a safe alternative as non-invasive respiratory support in patients with ARF according to the clinical context, but given the variability of the cases, the costs of each therapy and irregularity in the distribution of resources among the different hospital units, it is imperative that more multicenter and statistically significant studies be carried out, so that a formal and adequately evidence-based nomination can be established.

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