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Coronavirus Pandemic

Comparative effectiveness of noninvasive ventilation strategies in moderate-to-severe COVID-19: A network meta-analysis of randomized controlled trials

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Abstract
Introduction: Noninvasive respiratory support (NIRS) using helmet devices is an emerging treatment for acute respiratory failure in patients with coronavirus disease 2019 (COVID-19). However, the comparative efficacy of helmet NIRS versus other strategies in this context remains elusive.
Methodology: A network meta-analysis was conducted to compare the efficacy of various NIRS strategies in randomized controlled trials (RCTs) involving COVID-19 patients with acute respiratory failure. Strategies assessed included high-flow nasal oxygen (HFNO), continuous positive airway pressure (CPAP), helmet bilevel positive airway pressure (BiPAP), and standard oxygen therapy (SOT). Relevant RCTs were identified via PubMed, Embase, and Cochrane Central Register of Controlled Trials. Outcomes of interest included intubation rate, mortality rate, length of intensive care unit (ICU) stay, and length of hospital stay.
Results: Five RCTs published between 2021 and 2022 were included. Helmet BiPAP was associated with a significantly lower intubation risk compared with HFNO (relative risk (RR): 0.37, 95% confidence interval (CI): 0.16-0.86) and SOT (RR: 0.24, 95% CI: 0.10-0.62). Additionally, helmet BiPAP was linked to shorter ICU stay compared with SOT (RR: 0.10, 95% CI: 0.02-0.67). However, no significant differences were identified in mortality or hospital stay length between SOT, HFNO, CPAP, and helmet BiPAP groups.
Conclusions: Helmet BiPAP is recommended over HFNO and SOT for moderate-to-severe COVID-19 patients with acute respiratory failure, due to its lower intubation risk and shorter ICU stay. No significant differences were noted in mortality or length of hospital stay among the NIRS strategies.

Key words: COVID-19; noninvasive ventilation; oxygen inhalation therapy; helmet bilevel-positive airway pressure; continuous-positive airway pressure.

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Introduction

The novel coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) infection, is highly transmissible [1]. In severe cases, COVID-19 can lead to acute respiratory distress syndrome (ARDS) [2], which is characterized by hypoxia and dyspnea, and it may progress to acute respiratory failure [3,4]. Patients with acute respiratory failure mainly require critical care, including invasive mechanical ventilation in severe cases [5]. However, invasive mechanical ventilation is associated with a high mortality rate and prolonged ventilation duration [6].

Noninvasive respiratory support (NIRS) comprises various respiratory strategies for managing acute respiratory failure of various etiologies. These strategies include high-flow nasal oxygen (HFNO) and non-invasive ventilation (NIV) [7,8]. According to the mode of ventilation, non-invasive ventilation can be further categorized into continuous-positive airway pressure (CPAP) and bilevel-positive airway pressure (BiPAP) [9]. Both HFNO and NIV have been extensively utilized in the management of COVID-19-induced acute respiratory failure [10,11]. Among NIV techniques, the utilization of a helmet interface has exhibited efficacy in improving outcomes for patients with acute respiratory failure and has been widely adopted in the treatment of COVID-19 [12]. Despite the widespread use of these strategies, there remains a need to compare the efficacy of different NIRS modalities in managing COVID-19-related respiratory failure to optimize clinical decision-making.

Thus, the present meta-analysis of randomized controlled trials (RCTs) was conducted to compare the efficacy of different NIRS strategies in patients with COVID-19.

Methodology

Literature search

On November 29, 2022, a comprehensive search was conducted across the PubMed, Embase, and Cochrane Library databases to identify RCTs investigating NIRS in patients with COVID-19. The key items included ("high flow nasal oxygen" OR "non-invasive ventilation" OR "continuous positive airway pressure" OR "biphasic positive airway pressure" OR "helmet non-invasive ventilation") AND "COVID-19" AND "randomized controlled trials".

Study selection

The inclusion criteria were as follows: RCTs; patients with confirmed COVID-19; interventions involving HFNO, NIV, continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), or helmet NIV; and (4) reported outcomes including mortality rate, intubation rate, length of intensive care unit (ICU) stay, or length of hospital stay. The exclusion criteria were as follows: non-RCT study design; interventions involving mixed or unspecified respiratory strategies; or (3) absence of relevant outcome data. Two reviewers independently assessed the inclusion or exclusion of each study through full-text screening. Discrepancies were resolved through discussion until a consensus was reached.

Data extraction and quality assessment

The mortality rate, intubation rate, length of ICU stays, and length of hospital stay were assessed. Two investigators independently conducted data extraction. Any discrepancies in the selection of RCTs were resolved through discussion until consensus was achieved.

The Cochrane collaboration risk of bias tool was employed to assess study quality, evaluating key domains, such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other potential sources of bias.

Figure 1. Flowchart of study selection.

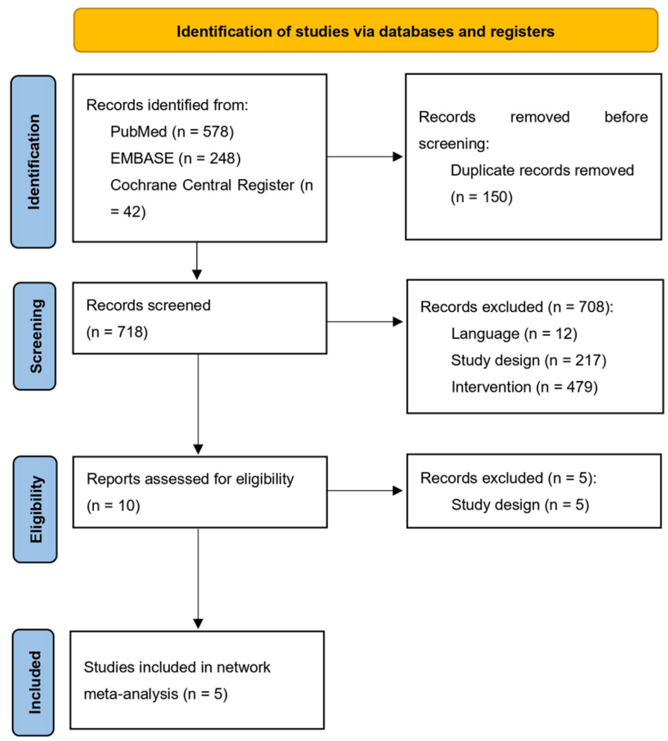
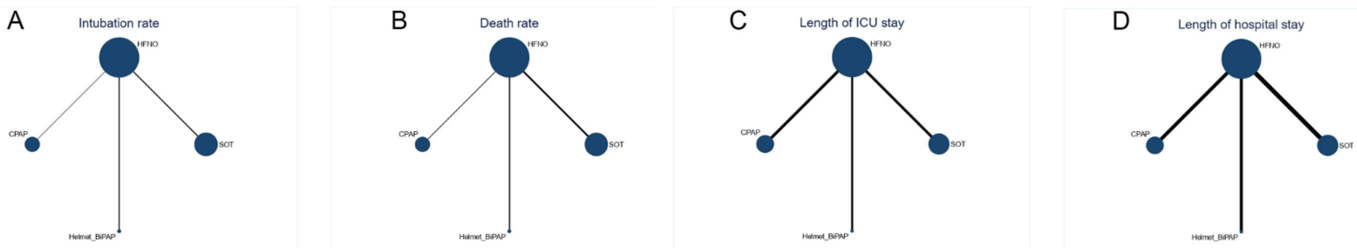


Table 1. The characteristics of the included randomized controlled trials.

Source	Registration number	Intervention	Age (years)	Male/Female ratio	Outcomes
Perkins, 2022 [13]	ISRCTN16912075	CPAP (n = 380) HFNO (n = 418)	56.7 ± 12.5 57.6 ± 13.0	260/120 272/146	Tracheal intubation rate (within 30 days) Mortality rate (within 30 days) Length of ICU stay Length of hospital stay
Grieco, 2021 [12]	NCT04502576	Helmet BiPAP (n = 54) HFNO (n = 55)	66.0 ± 3.8 63.0 ± 3.6	42/12 46/9	Tracheal intubation rate (within 28 days) Mortality rate (within 28 days) Length of ICU stay Length of hospital stay
Ospina-Tascón, 2021 [15]	NCT04609462	HFNO (n = 99) SOT (n = 100)	66.0 ± 4.8 59.0 ± 4.6	71/28 63/37	Tracheal intubation rate (within 28 days) Mortality rate (within 28 days) Length of ICU stay Length of hospital stay
Frat, 2022 [16]	NCT04468126	HFNO (n = 357) SOT (n = 354)	61.0 ± 12.0 61.0 ± 12.0	250/107 247/107	Tracheal intubation rate (within 28 days) Mortality rate (within 28 days) Length of ICU stay Length of hospital stay

CPAP: continuous-positive airway pressure; HFNO: high-flow nasal oxygen; SOT: standard oxygen therapy; BiPAP: bilevel-positive airway pressure.

Figure 2. Network plot of noninvasive respiratory support strategies for patients with COVID-19.



A. Intubation rate. **B.** Mortality rate. **C.** Length of ICU stay. **D.** Length of hospital stay. SOT: standard oxygen therapy; HFNO: high-flow nasal oxygen; CPAP: continuous-positive airway pressure; helmet BiPAP: helmet bilevel-positive airway pressure; ICU: intensive care unit.

Data synthesis and meta-analysis

Network meta-analysis was performed using the random-effects model. Relative risks (RRs) and 95% confidence intervals (CIs) were calculated to evaluate outcomes, including mortality rate, intubation rate, length of ICU stay, and length of hospital stay.

Forest plots illustrating RRs and their 95% CIs for each NIRS strategy were constructed. The network meta-analysis was conducted using STATA 15.0 software (StataCorp., College Station, TX, USA), while risk of bias assessments and summary graphs were generated using Review Manager 5.3 software.

Results

Literature search

In total, 868 relevant studies were retrieved from the databases. After excluding duplicate articles and those that did not meet the eligibility criteria, five RCTs were selected for inclusion. The screening process is illustrated in Figure 1.

Study characteristics

The characteristics of five RCTs [12-16] are presented in Table 1. The included studies were published between 2021 and 2022, involving various NIRS strategies, such as HFNO, CPAP, helmet BiPAP, and standard oxygen therapy (SOT). Figure 2 illustrates a network plot representing the eligible NIRS strategies used in patients with moderate-to-severe COVID-19.

Quality of the included studies

The results of the risk of bias assessment are illustrated in Figure 3. Four studies demonstrated a low risk of bias in random sequence generation [12,13,15,16], while allocation concealment was adequately described in three studies [12,13,15]. Blinding of participants and personnel was reported in two studies [15,16], and outcome assessment was performed in a blinded manner in three studies [12,15,16]. All five included studies exhibited a low risk of bias related to incomplete outcome data and selective reporting [12-16].

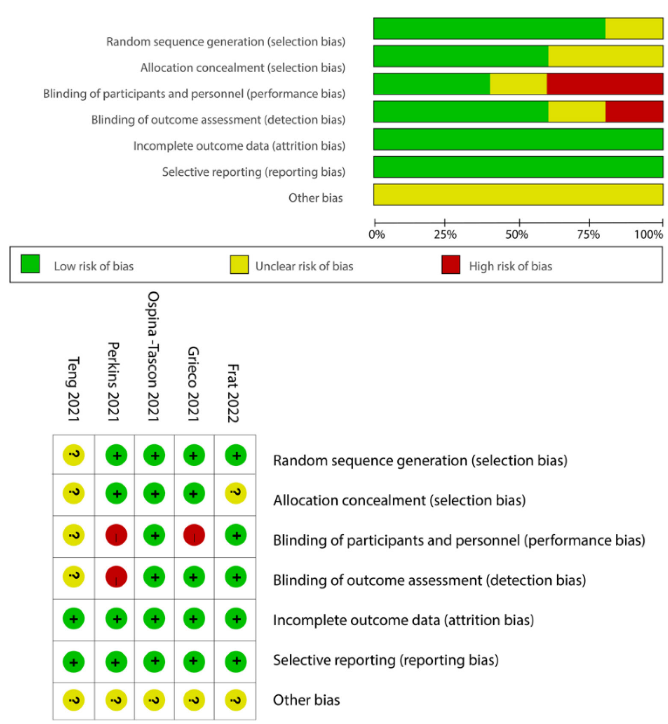
Intubation rate

As illustrated in Figures 4A and 5A, the helmet BiPAP group was associated with a significantly lower risk of intubation than the HFNO group (RR: 0.37, 95% confidence interval (CI): 0.16-0.86) and SOT group (RR: 0.24, 95% CI: 0.10-0.62). Compared with the SOT group, intubation rates in HFNO group (RR: 0.66, 95% CI: 0.44 0.99) and CPAP group (RR: 0.45, 95% CI: 0.25-0.81) were also significantly reduced.

Short-term mortality rate

The difference in short-term mortality rates of patients treated by the NIRS strategies was not

Figure 3. Risk of bias graphs and summary.



A. Risk of bias graph. **B.** Risk of bias summary.

statistically significant (Figures 4B and 5B). However, short-term mortality rate in the helmet BiPAP group was lower than that in the SOT (RR: 0.55, 95% CI: 0.17-1.78), HFNO (RR: 0.78, 95% CI: 0.28-2.18), and CPAP (RR: 0.93, 95% CI: 0.30-2.86) groups. Notably, short-term mortality refers to death occurring within 30 days after the intervention or treatment.

Length of ICU stay

Compared with SOT, the length of ICU stay of patients treated by HFNO (RR: 0.28, 95% CI: 0.15-0.54) and helmet BiPAP (RR: 0.10, 95% CI: 0.02-0.67) was significantly shorter than that of other treatment modalities (Figures 4C and 5C).

Length of hospital stay

The difference in the length of hospital stay of patients treated by different NIRS strategies was not statistically significant (Figures 4D and 5D). However, the length of hospital stay in the helmet BiPAP group was slightly shorter than that in the SOT group (RR: 0.11, 95% CI: 0.00-3.79) and HFNO group (RR: 0.37, 95% CI: 0.01-9.13).

Discussion

The results of this study indicated that helmet BiPAP was associated with a significantly lower risk of intubation compared with HFNO (RR: 0.37, 95% CI: 0.16-0.86), CPAP (RR: 0.45, 95% CI: 0.25-0.81), and SOT (RR: 0.24, 95% CI: 0.10-0.62). The length of ICU stay was significantly shorter in patients treated with HFNO (RR: 0.28, 95% CI: 0.15-0.54) and helmet BiPAP (RR: 0.10, 95% CI: 0.02-0.67) compared with SOT.

Previous meta-analyses have highlighted the efficacy of HFNO in managing COVID-19 patients [17-19]. He *et al.* found remarkable advantages in terms of short-term death rates, length of hospital stay, and oxygen index in the HFNO group compared with the NIV group [18]. Peng *et al.* demonstrated that HFNC was associated with a lower mortality rate compared with non-invasive ventilation. However, subgroup analysis comparing HFNO with CPAP, including helmet-based interfaces, did not demonstrate a significant difference [17]. Notably, these findings were derived from studies that did not exclusively analyze RCTs due to the limited number available at the time.

NIV could be divided into CPAP and BiPAP categories according to the mode of ventilation [20]. CPAP delivers a constant airway pressure throughout the respiratory cycle [21], whereas BiPAP provides

Figure 4. Network meta-analysis (NMA) of the outcomes of interest.

A

SOT	0.66 (95% CI 0.44,0.99) *	0.45 (95% CI 0.25,0.81) *	0.24 (95% CI 0.10,0.62) *
	HFNO	0.68 (95% CI 0.44,1.05)	0.37 (95% CI 0.16,0.86) *
		CPAP	0.54 (95% CI 0.21,1.39)
			Helmet BiPAP

B

SOT	0.70 (95% CI 0.39,1.26)	0.59 (95% CI 0.28,1.23)	0.55 (95% CI 0.17,1.78)
	HFNO	0.84 (95% CI 0.53,1.32)	0.78 (95% CI 0.28,2.18)
		CPAP	0.93 (95% CI 0.30,2.86)
			Helmet BiPAP

C

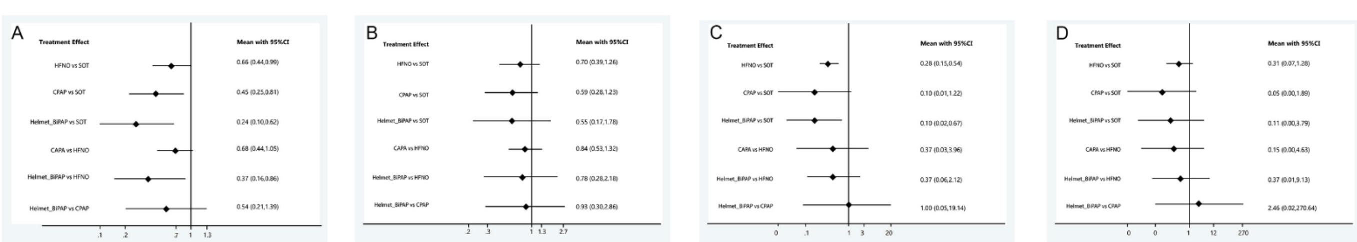
SOT	0.28 (95% CI 0.15,0.54) *	0.10 (95% CI 0.01,1.22)	0.10 (95% CI 0.02,0.67) *
	HFNO	0.37 (95% CI 0.03,3.96)	0.37 (95% CI 0.06,2.12)
		CPAP	1.00 (95% CI 0.05,19.14)
			Helmet BiPAP

D

SOT	0.31 (95% CI 0.07,1.28)	0.05 (95% CI 0.00,1.89)	0.11 (95% CI 0.00,3.79)
	HFNO	0.15 (95% CI 0.00,4.63)	0.37 (95% CI 0.01,9.13)
		CPAP	2.46 (95% CI 0.02,270.64)
			Helmet BiPAP

A. Incubation rate. **B.** Mortality rate. **C.** Length of intensive care unit (ICU) stay. **D.** Length of hospital stay. Relative risks (95% confidence intervals) are presented for comparators (rows) versus reference groups (columns).

Figure 5. Forest plot for noninvasive respiratory support strategies for patients with COVID-19.



A. Intubation rate. **B.** Mortality rate. **C.** Length of ICU stay. **D.** Length of hospital stay. SOT: standard oxygen therapy; HFNO: high-flow nasal oxygen; CPAP: continuous-positive airway pressure; helmet BiPAP: helmet bilevel-positive airway pressure; ICU: intensive care unit.

variable pressures during inspiration and expiration [22]. Both modes have been widely utilized in the management of COVID-19-related acute respiratory failure [17]. It has been reported that NIV with a helmet device could reduce the rates of intubation and mortality in patients with acute respiratory failure [23]. Notably, helmet-based NIV has been associated with reduced intubation and mortality rates, and it can be employed with both BiPAP and CPAP modes in COVID-19 patients with acute respiratory failure [12,24-26]. One RCT specifically evaluated the efficacy of helmet BiPAP compared with a single respiratory strategy [12].

In the present study, data from five RCTs were analyzed to evaluate intubation rates, short-term mortality, length of ICU stay, and length of hospital stay in patients with moderate-to-severe COVID-19. A significant advantage of HFNO over SOT was found in terms of intubation rate, aligning with the results of the study by Xu *et al*. [19]. In addition, helmet BiPAP outperformed HFNO in terms of intubation rate. Although helmet BiPAP provided additional benefits over HFNO in terms of short-term mortality (RR: 0.78, 95% CI: 0.28–2.18), length of ICU stay (RR: 0.37, 95% CI: 0.06–2.12), and length of hospital stay (RR: 0.37, 95% CI: 0.01–9.13), these differences were not statistically significant due to wide 95% CIs.

The strength of the present network meta-analysis is that it revealed the advantage of helmet BiPAP to HFNO in terms of intubation rate. Besides, BiPAP was not inferior to HFNO concerning short-term mortality, length of ICU stay, and length of hospital stay. However, the major limitation of the present study is the involvement of a limited number of RCTs, necessitating further validation through well-designed RCTs. Moreover, helmet CPAP, another recommended NIRS modality for COVID-19 patients [27], was excluded from this network meta-analysis due to the lack of relevant RCTs.

Conclusions

In patients with moderate-to-severe COVID-19, helmet BiPAP demonstrated superior efficacy over HFNO and SOT in reducing intubation rates and was associated with shorter ICU stays compared with SOT. Consequently, helmet BiPAP is recommended as a preferred non-invasive respiratory support strategy for COVID-19 patients with acute respiratory failure in clinical practice.

Authors contributions

Both authors (L. L., Y. G., and H. J. L.) made substantial contributions to the conception and design of the study, as well as to the acquisition, analysis, and interpretation of the data. Authors (C. W., S. Z. H., and M. S.) were involved in drafting the manuscript, and all authors provided final approval of the version to be published. All authors (L. L., Y. G., C. W., S. Z. H., M. S., J. M. L., and H. J. L.) have contributed sufficiently to the study to take public responsibility for appropriate portions of the content. They agree to be accountable for all aspects of the study, ensuring that any questions related to the accuracy or integrity of the content are thoroughly investigated and resolved.

Availability of data and materials

The dataset generated and analyzed during the current study is available from the corresponding author upon reasonable request.

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Conflict of interests

No conflict of interests is declared.

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