Incidence of nosocomial pneumonia and clinical outcomes of patients requiring non-invasive ventilation: A systematic review and meta-analysis

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Background. Non-invasive ventilation (NIV) is used for an increasing range of clinical conditions at various levels of care, including intensive care units (ICUs), and has been shown to carry a lower risk of nosocomial pneumonia (NP) compared with invasive mechanical ventilation (IMV).

Objectives. To assess the incidence of NP and clinical outcomes (intubation rates and mortality) in patients receiving NIV as initial support.

Methods. A systematic search of PubMed, Embase and Scopus for relevant research articles published in English was conducted up to 6 February 2025. Eligible studies included adult patients who received NIV for any respiratory condition and reported the incidence of NP. NP was defined as any new-onset pneumonia occurring at any point during the clinical course and ≥48 hours after initiating NIV. Furthermore, a subset of patients in whom NP was attributed solely to NIV support was defined as NIV-associated pneumonia (NIVAP). Two reviewers independently conducted database searches, data extraction and risk-of-bias assessment. A subgroup analysis was performed based on the indication for NIV, country and study design to identify heterogeneity.

Results. We incorporated 30 studies, including 36 049 patients receiving NIV. Of these, 29 studies reported the incidence of NP, while only 22 reported the incidence of NIVAP. Overall, the incidence of NP was 6% (95% confidence interval (CI) 4 - 8; I^2=89.4%), and the pooled incidence of NIVAP was 3% (95% CI 2 - 4; I^2=32.9%). The rate of intubation was 28% (95% CI 22 - 35; I^2=89.3%), and overall mortality was 18% (95% CI 15 - 23; I^2=99.0%) among patients receiving NIV.

Conclusion. NP, including NIVAP, remains a significant complication in patients receiving NIV. Our findings underscore the need for standardised diagnostic criteria for NP in patients receiving NIV.

Keywords: non-invasive ventilation, nosocomial pneumonia, ARDS, invasive ventilation

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Contribution of study

This systematic review and meta-analysis provide robust pooled estimates of nosocomial pneumonia (NP) (6%; 95% CI: 4–8) and NIV-associated pneumonia (NIVAP) (3%; 95% CI: 2–4) among patients receiving non-invasive ventilation (NIV), addressing an important gap in the literature. It shows that the risk of pneumonia persists despite avoidance of intubation, challenging the prevailing assumption that NIV substantially mitigates infection risk. It also reveals significant variability in NP incidence across study designs, geographic regions, and patient subgroups—particularly a higher risk in patients with acute respiratory distress syndrome (ARDS)—highlighting the importance of context-specific risk assessment.

Importantly, it underscores the lack of standardised definitions and diagnostic criteria for NP and NIVAP, which likely contributes to under-recognition and heterogeneity in reported outcomes. Collectively, these findings emphasise the need for improved surveillance, uniform diagnostic frameworks, and targeted preventive strategies for pneumonia in patients receiving NIV, extending beyond the traditional focus on invasive mechanical ventilation.

Non-invasive ventilation (NIV) is used for an increasing range of clinical conditions, such as community-acquired pneumonia and adult respiratory distress syndrome (ARDS), in addition to its well-established indications in chronic obstructive pulmonary disease (COPD), immunocompromised

patients, post-operative atelectasis and weaning from invasive mechanical ventilation (IMV). This may be because NIV is associated with reduced mortality and morbidity compared with IMV.[1-3]

Nosocomial pneumonia (NP) occurs predominantly in patients requiring endotracheal intubation and IMV; therefore, NP will be used as a synonym for ventilator-associated pneumonia (VAP).[4] NIV has been shown to carry a reduced risk of NP by avoiding intubation and its associated impairment of coughing and mucociliary clearance, aspiration of colonised or infected upper airway secretions, and by providing additional benefits such as avoiding sedation and improving oral intake and communication, as shown in various studies.[1,5-6] Therefore, the use of NIV has increased in intensive care units (ICUs) worldwide, with progressive implementation in emergency rooms, hospital wards, postoperative units and even during out-of-hospital transport over the last decade.[6]

All critically ill patients are at risk of NP, including those receiving NIV. When respiratory infections are directly associated with NIV, they are defined as NIV–associated pneumonia (NIVAP). An analysis of the German nosocomial infection surveillance system database, encompassing 400 ICUs, revealed that patients receiving NIV were three times more likely to develop NP than those receiving no ventilation.[7] Although NP does occur in patients receiving NIV, albeit less frequently than in those receiving IMV, its recognition is equally important as that of VAP.[5,7-10] However, the Centers for Disease Control and Prevention (CDC) have not yet defined NP in their list of device-associated events or pneumonia.

NIVAP has emerged as a significant contributor to late NIV failure, which occurs in approximately 8% - 23% of patients, as reported in previous studies.[8,10,11] Prompt intubation and initiation of IMV for improved airway clearance may be preferable to escalation to more aggressive NIV, which may delay appropriate airway management.[8]

This meta-analysis aimed to assess the overall incidence of NP among patients receiving NIV during the clinical course, as well as their clinical outcomes in terms of rate of intubation and overall mortality.

Methods

This systematic review and meta-analysis was conducted to estimate the cumulative incidence of NP in patients receiving NIV, including any kind of non-invasive positive pressure ventilation, such as continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP). A subset of patients who developed NP after receiving ongoing NIV support for ≥48 hours, or those who changed to IMV for <48 hours due to clinical indication, was considered as having NIVAP (Fig. 1). If studies reported no NP incidences, the NIVAP rate was also assumed to be zero in these studies. The secondary objective of this meta-analysis was to explore its associated outcomes (rate of endotracheal intubation and overall mortality).

The study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and the Meta-analysis of Observational Studies in Epidemiology (MOOSE) criteria (Supplementary files 1 - 2).[12,13] The study protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (ID CRD42025645267).

Search techniques and selection criteria

We searched PubMed, Embase and Scopus for relevant research articles published in English up to 6 February 2025. We also manually searched the reference lists of the identified articles for additional relevant studies. The following medical subject headings (MeSH)/descriptors and key search terms were used: 'non-invasive ventilation', 'NIV', 'NPPV', 'NIPPV', 'continuous positive airway pressure', 'CPAP', 'bilevel positive airway pressure', 'BiPAP', 'healthcare-associated pneumonia', 'nosocomial pneumonia' and 'hospital-acquired pneumonia' (Supplementary file 3).

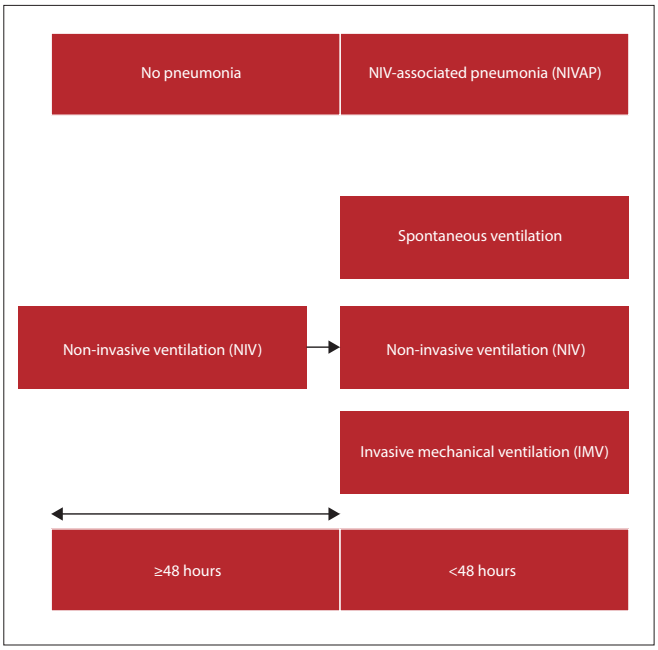

Fig. 1. Diagnostic algorithm of NIVAP

All studies were independently selected and screened by two investigators, and any discrepancies were resolved by consensus. If the investigators failed to reach consensus, a third investigator reviewed the data and resolved the conflict. All selected studies were imported into Rayyan (Qatar Computing Research Institute, Qatar) and duplicates were removed. The selected articles then underwent independent full-text screening by two investigators. Additional studies were identified by screening the cross-references of included studies and by searching Google Scholar. Any disagreement regarding final inclusion was resolved by consensus with a third investigator.

Study selection

Studies were included if they met the following inclusion criteria: adult patients (≥18 years) who received NIV for any respiratory condition (e.g. COPD exacerbation, acute respiratory failure, ARDS). Studies, case reports, reviews, editorials, letters and conference abstracts published in non-English languages were excluded. Studies were also excluded if they did not provide incidence rates of NP, used NIV as a weaning strategy from IMV, used NIV for preoxygenation before endotracheal intubation, used NIV after weaning from endotracheal intubation or used high-flow oxygen therapy.

Data extraction

Extracted data included the first author's name, country where the study was conducted, publication year, proportion of male patients, patient age, respiratory rate (RR), $PaCo_2$, PaO_2, PaO_2/FiO_2, primary diagnoses, mode of NIV, number of total patients, number of patients with NP and number of patients with NIVAP. The number of patients requiring endotracheal intubation or IMV, as well as mortality data, were also collected.

The aim was to report the incidence of NP in patients receiving NIV. We also reported the incidence of NIVAP. NIVAP was diagnosed when a new infiltrate on a chest radiograph was associated with two out of the following four criteria: temperature ≥38.5°C or <36°C, white blood cell

count >12 000/mm³ or <4 000/mm³, purulent sputum or worsening of pulmonary gas exchange. In addition, either a positive tracheal aspirate (if intubated and the sample was collected immediately after intubation), broncho-alveolar lavage (BAL) fluid or sputum collected ≥48 hours after initiation of NIV was required, or the sole administration of new antibiotics in the absence of another site of infection (Fig. 1). Thresholds for positive culture were $\geq 10^3$ CFU/mL for protected specimen brush (PSB), $\geq 10^4$ CFU/mL for BAL or $>10^5$ CFU/mL for sputum.

Risk of bias

Two researchers independently evaluated methodological bias using the Joanna Briggs Institute (JBI) Critical Appraisal Tool for observational studies and the Cochrane Risk of Bias 1 (RoB-1) tool for randomised controlled trials (RCTs).[14,15] A third reviewer resolved any discrepancies.

This appraisal tool consisted of nine items with response options of 'Yes', 'No' and 'Unclear' when a conclusive determination could not be made based on the available data. Each compliant item was assigned a score of one, whereas non-compliant or unclear responses were assigned zero points. Methodological quality was rated based on the total score, with scores ranging from 0 to 3 indicating low quality, 4 to 6 indicating moderate quality and 7 to 9 indicating high quality in the risk-of-bias analysis.

Statistical analysis

A meta-analysis was conducted to determine the pooled incidence of NP and NIVAP among patients receiving NIV using a random-effects model with 95% confidence intervals (CIs). Only studies that reported the incidence of NP were included in the analysis.

The Cochrane Q statistic and I^2 test were used to assess heterogeneity. Sensitivity analyses and subgroup analyses were performed to explore potential sources of heterogeneity, and publication bias was assessed using funnel plots.

All statistical analyses were performed using the statistical programming language R, version 4.2.3 (R Foundation for Statistical Computing, Austria). The pooled incidence of NP, NIVAP and outcomes (intubation rate and mortality) was calculated using the metaprop command.

Results

An initial database search retrieved 628 articles. After removing duplicates and conducting title screening, 47 studies were selected for full-text screening. Following full-text review, 16 studies met the inclusion criteria and 31 were excluded (Supplementary file 4). An additional 14 studies were identified through cross-reference screening and by searching Google Scholar. In total, 30 studies were included in the systematic review (Fig. 2).

These selected studies included 36 049 eligible patients receiving NIV, whose baseline clinical characteristics are presented in Supplementary Table 1.[8-11,16-38] Among these studies, 29 reported the incidence of NP, while 22 reported the incidence of NIVAP.[3,5,6,8-11,16-32,34-38] One study did not report the exact percentage or number of NP and was therefore excluded from the analysis.[33]

Among the 29 studies included in the meta-analysis, 8 were RCTs and 21 were non-randomised controlled studies (NRCSs). Regarding outcomes, 25 studies reported intubation events and 29 reported mortality (Table 1). All included NRCSs/observational studies were rated as being of moderate (8 studies) to high quality (17 studies) (Supplementary file 5).

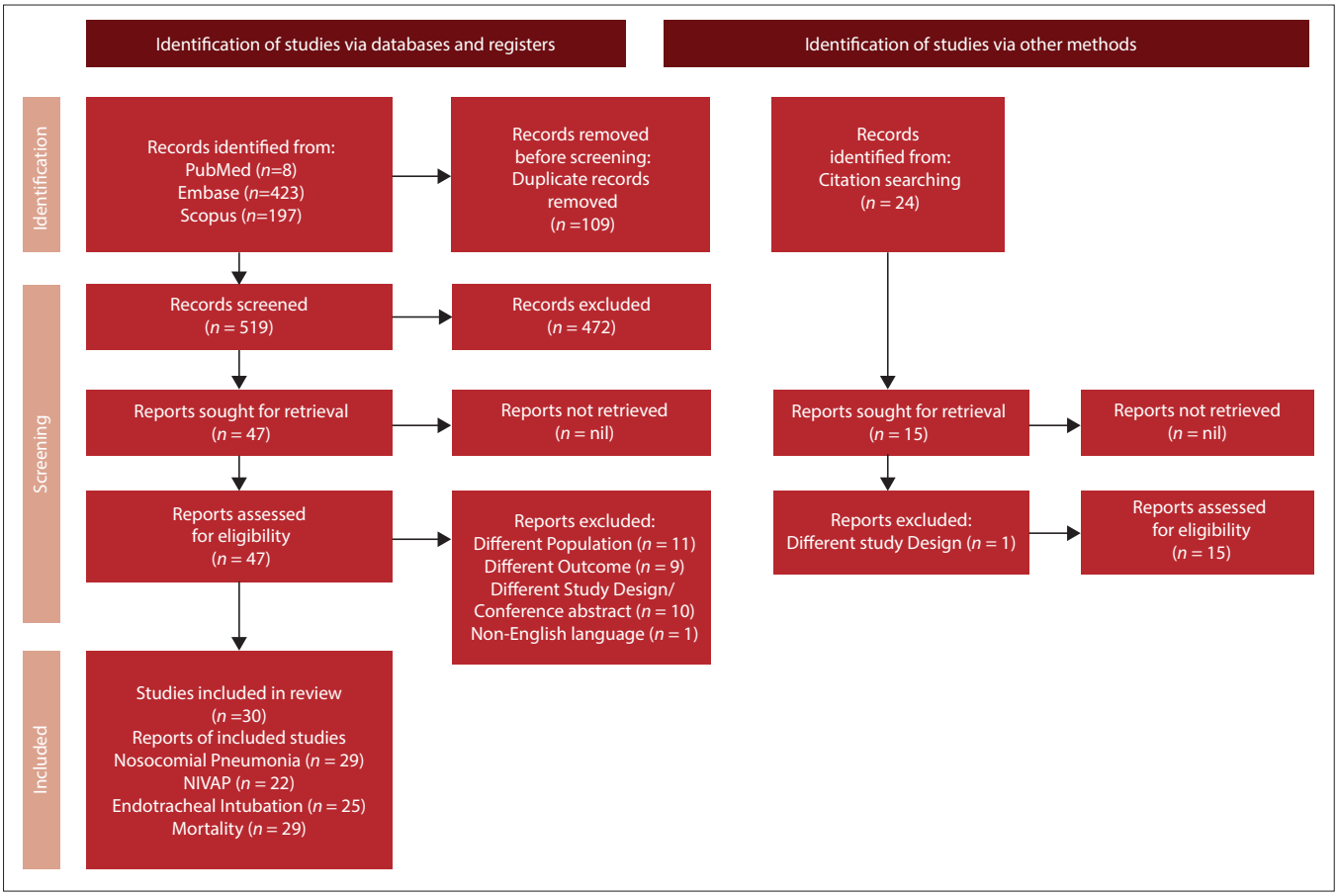

Fig. 2. Schematic presentation of the PRISMA flow diagram.

By contrast, all included RCTs were rated as having 'some concern', primarily owing to insufficient reporting of the randomisation process and limited assessment of selection, blinding and detection biases (Supplementary file 6). Funnel plots assessing publication bias are depicted in Supplementary files 7 - 10.

The pooled meta-analysis, using data from 29 studies, observed an overall incidence of NP of 6% (95% CI 4 - 8; I^2=89.4%) (Fig. 3). Subgroup analysis based on study design revealed that the pooled incidence of NP in RCTs (8%; 95% CI 5 - 11; I^2=0%) was higher than that in NRCSs (5%; 95% CI 4 - 8; I^2=91.5%). Subgroup analyses of NRCSs were performed to explore potential variations in the incidence of NP based on study year, country, study quality, retrospective v. prospective design and diagnosis (Supplementary files 11 - 15). These analyses demonstrated a higher incidence of NP in patients with ARDS receiving NIV, as well as variation in

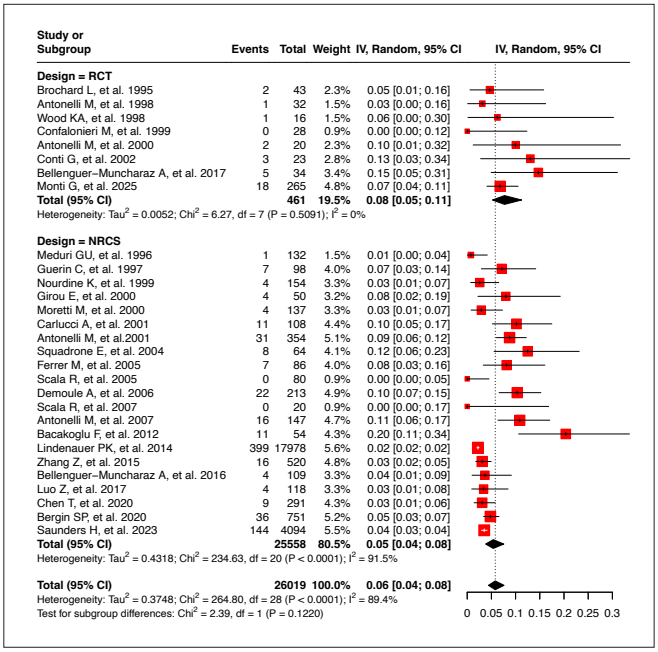

Fig. 3. Forest plot, meta-analytical estimation of nosocomial pneumonia in patients on non-invasive ventilation.

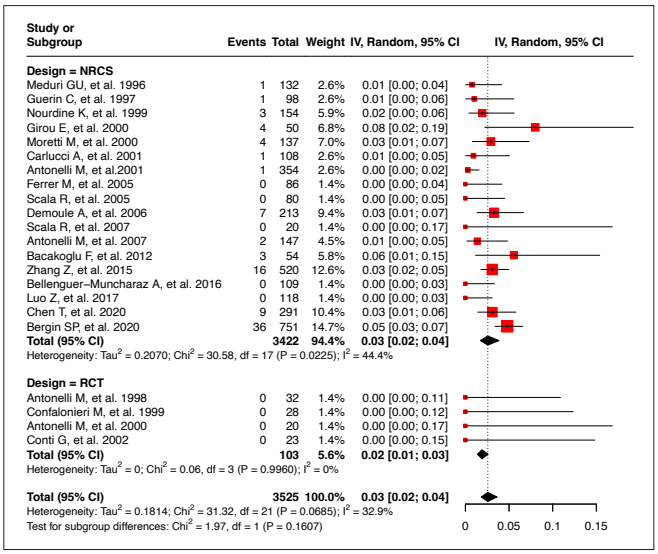

Fig. 4. Forest plot, meta-analytical estimation of NIVAP in patients on non-invasive ventilation.

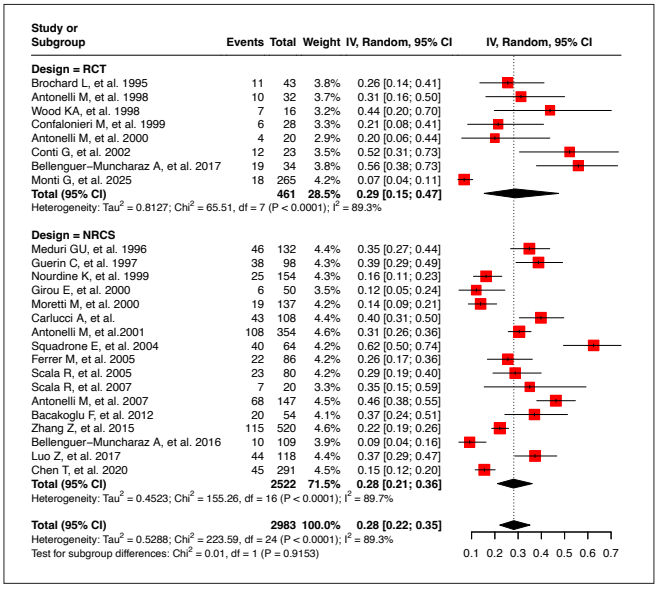

Fig. 5. Forest plot, meta-analytical estimation of endotracheal intubation in patients on non-invasive ventilation.

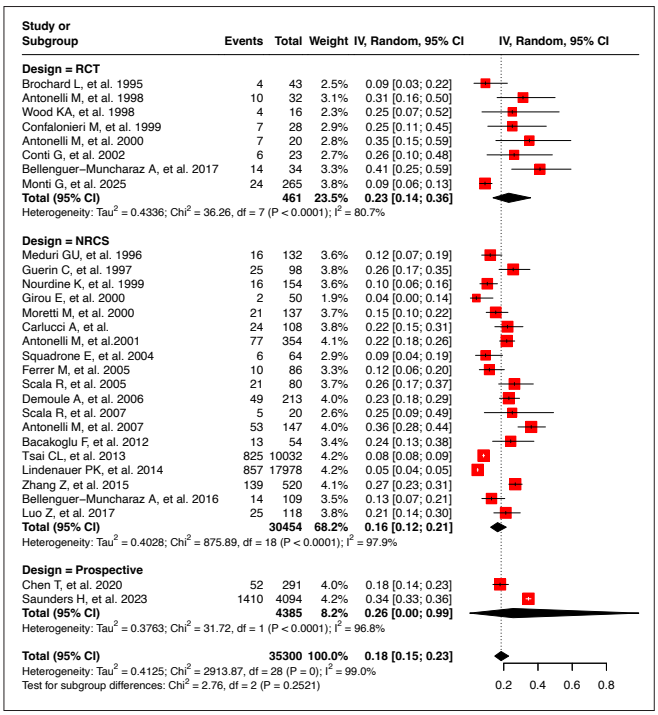

Fig. 6. Forest plot, meta-analytical estimation of mortality in patients on non-invasive ventilation.

NP incidence across different regions and study year. Furthermore, sensitivity analyses were performed by systematically excluding each study from the meta-analysis. These analyses confirmed the reliability and consistency of our findings; however, exclusion of the study by Lindenauer *et al.*[34] reduced heterogeneity to some extent.

Regarding NIVAP, the pooled incidence using data from 22 studies was 3% (95% CI 2 - 4; I^2=32.9%). Subgroup analysis based on study design showed a higher incidence of NIVAP (3%; 95% CI 2 - 4; I^2=44.4%) in NRCSs than in RCTs (2%; 95% CI 1 - 3; I^2=0%). The meta-analysis demonstrated significant heterogeneity (Fig. 4). Further analyses explored potential variation in the incidence of NIVAP based on study year, country, study quality, retrospective v. prospective

design and diagnosis. Sensitivity analyses confirmed the consistency of these findings (Supplementary files 16 - 20).

Meta-analyses using 25 and 29 studies for the outcomes of intubation and mortality, respectively, showed an intubation rate of 28% (95% CI 22 - 35; I^2=89.3%) and mortality of 18% (95% CI 15 - 23; I^2=99.0%) among patients receiving NIV (Figures 5 - 6). To address heterogeneity, subgroup analyses were conducted based on study year, country, study quality, retrospective v. prospective design and diagnosis, as well as sensitivity analyses. Exclusion of individual studies did not substantially affect heterogeneity within subgroups or overall (Supplementary files 21 - 30).

Discussion

Several pathophysiological mechanisms may explain the development of NIVAP. Gastric and oesophageal distension from positive pressure can lead to vomiting and subsequent aspiration, including silent aspiration, which may not be prevented by rapid removal of the NIV mask.[17] Although nasogastric tubes are often employed as a prophylactic measure, they can bypass natural barriers and may increase the risk of infection.[17] Furthermore, hypercapnia, often seen in patients presenting with exacerbations of COPD or hypoventilation, may result in impaired sensorium, further predisposing patients to aspiration.[38]

Recent evidence suggests that airway colonisation before intubation is associated with an increased risk of NP, challenging the notion that intubation is the primary risk factor.[27] Prior antibiotic use before hospitalisation may also increase the risk of colonisation with potentially pathogenic, hospital-acquired microorganisms.[27] This colonisation, coupled with aspiration of infected secretions, may contribute to NIVAP and subsequent NIV failure.

Hypoxaemic respiratory failure, such as ARDS, can lead to an elevated respiratory drive and increased tidal volumes.[38] In the context of NIV, where accurate monitoring of plateau or peak pressures is limited owing to the absence of a closed system, patients may receive tidal volumes exceeding 10 mL/kg body weight. This exceeds the protective range of 6 - 8 mL/kg and may result in self-induced lung injury, predisposing the lung to secondary infection, similar to ventilator-induced lung injury.

In our meta-analysis, the pooled incidence of NP and NIVAP was 6% (95% CI 4 - 8; I^2=89.4%) and 3% (95% CI 2 - 4; I^2=32.9%), respectively. However, the true incidence of NIVAP is likely underreported owing to diagnostic challenges. Unlike IMV, in which bronchoscopy and protected sampling are more feasible, patients receiving NIV are often not subjected to invasive diagnostic procedures, which may lead to underdiagnosis.[9] Moreover, pneumonia that develops in patients initially managed with NIV but later intubated may be incorrectly attributed solely to IMV, further complicating interpretation of incidence data.[39]

The considerable heterogeneity observed in our analysis is likely multifactorial. Contributing factors include variations in study design (retrospective v. prospective v. RCTs), differences in diagnostic criteria for NP or NIVAP (e.g. clinical criteria alone v. microbiological confirmation), country-specific practices, primary indications for NIV and varied clinical settings (ICU v. ward) (Supplementary files 11 - 20). Additional influences include experience administering NIV at different centres, the availability of trained personnel and monitoring protocols, the duration and intensity of NIV use, the choice of NIV interface and humidification practices. Notably, prolonged duration of NIV has been associated with an increased risk of pneumonia.

Our analysis also found that 28% (95% CI 22 - 35; I^2=89.3%) of patients receiving NIV eventually required intubation, while 18% (95% CI 15 - 23; I^2=99.0%) died. These high heterogeneity values may be partly attributable to variations in clinical decision-making, patient preferences such as refusal of intubation, clinician preferences, country-specific protocols regarding end-of-life care and variability in clinical settings, indications, study designs and experience administering NIV (Supplementary files 21 - 30).

When administering NIV in patients with respiratory failure, preventive strategies to reduce the risk of NIVAP should be considered. These include selective oropharyngeal decontamination using topical antiseptics (similar to selective digestive decontamination in IMV), which may reduce bacterial colonisation. Additional interventions include maintaining head-of-bed elevation (30° - 45°), strict hand hygiene, heated humidification for patients with thick secretions and regular sterilisation or disposal of NIV masks and circuits.[27,39] Establishing standardised protocols for the early identification and prevention of NIVAP could improve patient outcomes and reduce rates of NIV failure.

Study strengths and limitations

This study has several limitations. First, there is considerable heterogeneity among the included studies, and the findings may not represent all countries, as articles were retrieved from only a limited number of countries despite searching multiple databases. In addition, only articles published in English were included.

Moreover, factors such as variability in diagnostic definitions, lack of microbiological confirmation in many studies, type of respiratory failure (hypoxaemic v. hypercapnic), varied NIV interfaces (helmet v. face mask), different clinical settings (ICU v. ward) and differences in humidification practices may have influenced the assessment of NP or NIVAP.

Due to insufficient data, some subgroup analyses were not possible. This is a limitation, as one of the strengths of our systematic review lies in the subgroup analyses conducted according to diagnosis, country and study design, which provide insight into the incidence of NP and NIVAP across various respiratory conditions.

A strength of this study is that we analysed the incidence of both NP and NIVAP, demonstrating that the actual incidence of NIVAP likely lies within the overall incidence of NP.

Conclusion

The findings of this systematic review and meta-analysis demonstrate that NP remains a significant complication in patients receiving NIV. The overall incidence of NIVAP appears to be lower than that of NP; however, underdiagnosis and inconsistent reporting due to lack of standardised diagnostic criteria likely obscure the true burden.

Our findings underscore the need for standardised diagnostic criteria to facilitate early recognition, implement preventive measures and improve clinical vigilance in identifying and managing NP, including NIVAP, in patients receiving NIV. Future research should focus on individual patient data meta-analyses or large prospective studies with standardised definitions to identify independent predictors of NIVAP.

Data availability: The datasets analysed during the study are available from the corresponding author on reasonable request.

Declaration. None.

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Author contributions. All studies were independently selected by SS and SKM. If the investigators failed to reach consensus, MG reviewed the data and resolved the conflict. Selected articles underwent independent full-text screening by SS and RG. All authors reviewed and edited the original draft. Conceptualisation: SS and MG. Methodology: SS. Formal analysis: SS, MV, SKM, RG, RKG and BPS. Writing: SS and MV. Supervision: MG, RG and BPS. Software: MV. Validation: MV and RKG. Visualisation: SKM. Investigation: JS.

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