

Prevalence and incidence of pressure injury in adult patients receiving non-invasive ventilation for acute respiratory failure: a systematic review and meta-analysis protocol

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ABSTRACT

Objective: This systematic review aims to assess the prevalence and incidence of pressure injury associated with non-invasive ventilation (NIV) in adult patients treated for acute respiratory failure (ARF).

Introduction: Facial pressure sores are a common complication of NIV, impairing skin integrity, patient comfort, and therapy efficacy. However, the ranges of incidence and prevalence reported in the literature are very wide.

Eligibility criteria: This review will include analytical observational and experimental studies reporting prevalence and/or incidence of pressure sores in adults treated with NIV for hypoxemic or hypercapnic ARF using oronasal, full-face, or hybrid masks. Any study or study arm testing interventions to reduce pressure sores will be excluded. Studies on pediatric patients and adult patients treated with other interfaces (ie, helmets) will also be excluded.

Methods: This systematic review will be conducted in accordance with the JBI and PERSyst methodology for systematic reviews of prevalence and incidence. Searches will be conducted in PubMed, Cochrane Library, Web of Science, Embase, national health-agency surveillance systems, Centers for Disease Control and Prevention data, gray literature, and clinical trial registers to identify unpublished studies. No language limitations will be applied provided an English abstract is available. Two reviewers will independently select studies, and data will be extracted using a customized form. Narrative synthesis will be conducted and, where appropriate, pooled prevalence and incidence proportion will be calculated using the DerSimonian and Laird method. Methodological quality will be assessed using JBI's Critical Appraisal Tool for Prevalence and Incidence Studies.

Review registration: PROSPERO CRD42024604191

Keywords: acute respiratory failure; incidence; non-invasive ventilation; pressure sores; risk factors

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Introduction

Non-invasive ventilation (NIV) has become a cornerstone in the management of acute respiratory failure (ARF), providing effective respiratory support without the need for endotracheal intubation. Despite the controversial outcomes and the lack of conclusive evidence regarding NIV in moderate-to-severe de novo hypoxemia and acute respiratory distress syndrome (ARDS),¹ this approach has proven crucial in conditions such as mild-to-moderate acute hypoxemic respiratory failure and ARDS, as well as chronic obstructive pulmonary disease exacerbations, offering benefits like reduced risk of nosocomial infections² and shorter hospital stays.^{1,3-6} Over the years, technological advancements have expanded NIV applications, making it a preferred first-line therapy in both intensive care unit (ICU) and non-ICU settings, including general hospital wards.⁷⁻⁹ However, despite its clinical advantages, the use of NIV is often accompanied by complications, most notably pressure injuries.¹⁰

Facial pressure sores are among the most common and distressing complications of NIV. Studies have shown that the risk of skin break down and facial pressure injuries increases with prolonged NIV use, especially with oronasal masks that exert significant pressure on the facial structure.^{11,12} These injuries compromise not only the skin integrity but also the patient's tolerance to NIV, often reducing the therapy's effectiveness¹³ and leading to increased discomfort,¹⁰ potential for infection,¹⁴ and extended hospital stays.¹⁵ Reported prevalence rates vary widely, from as low as 3.9% to as high as 100%, reflecting differences in patient demographics, clinical practices, and mask designs.^{9,16} This variability may also be influenced by underreporting in the literature, particularly regarding the types of interfaces used and the duration of NIV treatment. Risk factors such as diabetes, prolonged ventilation duration, edema, and the choice of mask type further exacerbate the likelihood of pressure injuries.^{10,11,17} Innovations like helmet ventilation or improved mask designs may reduce these complications, but their adoption remains inconsistent across health care systems.¹⁸

Pressure ulcers not only affect patient well-being but also impose substantial demands on health care providers who must balance the benefits of NIV in stabilizing respiratory function against the challenges of preventing skin damage. In recent years, awareness

around preventing these injuries has grown, with strategies including rotation of mask types, use of protective dressings, and regular skin assessments being implemented to mitigate risk. This issue has gained even greater relevance during the COVID-19 pandemic, where NIV has been a critical tool for managing mild-to-moderate respiratory distress outside ICU settings.^{9,19,20} Despite this, high variability in the reported prevalence rates and the lack of information regarding the type of interface used and the duration of the NIV treatment highlight the need for comprehensive evaluations that accurately quantify the incidence of pressure injuries in this population. Such data are essential to inform evidence-based protocols that enhance patient comfort, reduce injury occurrence, and support optimal outcomes in NIV therapy. A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and *JB* Evidence Synthesis was conducted and no current or in-progress systematic reviews on the topic were identified.

This systematic review protocol aims to address these knowledge gaps by rigorously assessing the prevalence and incidence proportion of pressure sores associated with NIV in hospitalized adult patients with ARF. By synthesizing existing literature and examining the frequency, risk factors, and preventive measures, this review seeks to provide actionable insights for improving clinical practices surrounding NIV and enhancing patient safety in critical care environments. Understanding the risk factors for developing pressure injuries will further enable the implementation of targeted prevention strategies for individuals at higher risk, which is particularly important in the context of limited health care resources.

Review question

What is the prevalence and incidence of pressure injury in adult patients receiving NIV for ARF?

In particular, what is the prevalence and incidence of pressure sores related to NIV according to the type of ward (ICU/intermediate respiratory care unit [IRCU] vs. non-ICU/IRCU [ie, internal medicine, pneumology ward]), interfaces (ie, oronasal mask, full-face mask, hybrid mask), and respiratory failure (hypoxemic vs. hypercapnic ARF).

Eligibility criteria

Population

Studies including adult patients aged 18 years or older with hypoxemic non-hypercapnic ARF or hypoxemic and hypercapnic ARF needing NIV administered through oronasal, full-face, or hybrid mask via mechanical ventilator will be considered for inclusion. Studies focused on the following factors will be excluded:

- i) pediatric patients
- ii) patients with hypoxemic non-hypercapnic ARF or hypoxemic and hypercapnic ARF but treated with interfaces different from masks (ie, helmets)
- iii) patients needing NIV for ARF secondary to cardiogenic pulmonary edema or obstructive sleep apnea syndrome
- iv) patients treated with prophylactic NIV (ie, the planned preventive use of NIV in patients without established ARF, such as post-extubation or post-operative support, typically delivered in short, intermittent sessions)
- v) patients treated with NIV to facilitate weaning.

We will also exclude patients with brief or minimal NIV exposure (eg, those with pulmonary edema, obstructive sleep apnea syndrome, or receiving prophylactic NIV or NIV for weaning), which will reduce variability in NIV duration, allowing for a more consistent assessment of pressure-injury risk.

Condition

Studies reporting pressure injuries related to NIV initiated for the treatment of ARF will be eligible for inclusion. *Pressure injuries* are defined as localized damage to the skin and/or underlying soft tissues, typically occurring over a bony prominence, although they may also be associated with medical devices.²¹ The injury may present with intact skin or as an open ulcer and can be associated with significant pain. In this review, pressure injuries will be considered medical device-related, as they are primarily caused by mechanical forces exerted on the skin by the NIV interface; consequently, the morphology and distribution of the lesion often reflect the shape of the device. Only pressure injuries clearly attributable to the NIV interface will be included. Pressure injuries that are present prior to the initiation of NIV will be excluded. Given the heterogeneity in reporting across studies, pressure injuries of all stages or grades will be

eligible, regardless of the classification system used. Where reported, pressure injuries may be classified according to established frameworks, such as the National Pressure Ulcer Advisory Panel (NPUAP) staging system.²¹ Studies that do not report data on the prevalence or incidence of NIV-related pressure injuries will be excluded.

Context

Studies considering patients treated with NIV in all acute hospital settings, both in ICU/IRCU and in hospital wards outside the intensive settings, will be included. NIV used in palliative and end-of-life care for patients admitted to the hospital with an acute event will also be considered.

Types of studies

Analytical observational studies reporting data on incidence/prevalence of NIV pressure sores, including prospective and retrospective cohort, and analytical cross-sectional studies, will be considered for inclusion in this review, along with descriptive observational and cross-sectional studies. Control groups from experimental studies reporting prevalence and incidence related to NIV pressure sores will also be considered. Any study or study arm testing interventions aiming at reducing pressure sores will be excluded.

Methods

This systematic review will follow the JBI methodology for systematic reviews of prevalence and incidence and will adhere to the prevalence and incidence review methods developed by the PERSyst group.^{22,23} This protocol has been registered with PROSPERO (CRD42024604191).

Search strategy

A comprehensive and structured search strategy following the JBI 3-step approach will be implemented to identify both published and unpublished studies. First, a limited preliminary search will be conducted in key databases to analyze text words in titles/abstracts and relevant index terms. Second, a full search will be carried out across commercial and non-commercially operated electronic databases, including MEDLINE (Ovid), Embase (Elsevier platform), Cochrane CENTRAL (included in the Cochrane Library), CINAHL (EBSCOhost), and Scopus, from their inception. The strategy will incorporate thesaurus terms (eg, Medical

Subject Headings [MeSH]) and free text, combining keywords through Boolean operators. A full sample of the search terms used for MEDLINE (Ovid) is provided in Appendix I. Sources in all languages will be considered for inclusion, provided that an English abstract is available.

Third, additional searching will be performed to ensure the sources located are comprehensive. This will include screening the reference lists of all included full-text articles and topic-relevant, frequently cited reviews, as well as searching national health-agency surveillance systems that publicly report hospital adverse-event data. These will include the United States Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN); the United Kingdom National Health Service (NHS) Digital and Hospital Episode Statistics (HES); the European Centre for Disease Prevention and Control (ECDC) datasets and EU member states' open-data portals; the Australian Institute of Health and Welfare (AIHW); and accessible public-health surveillance sources in China, such as China CDC Weekly, National Health Commission statistical bulletins, and the China Public Health Data Center, where English-language or machine-translatable content is available. Trial registries, including ClinicalTrials.gov and the International Clinical Trials Registry Platform (ICTRP), will also be searched to identify in-progress or completed but unpublished studies.

All searches will be rerun before final data synthesis to capture any newly published studies. The results of the search will be reported in full in the final systematic review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.²⁴

Study selection

Following the search, all citations retrieved will be imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia)²⁵ and duplicates will be removed. A pilot screening of 20 citations, selected using first sequential records, will be conducted. After the pilot test, 2 reviewers (both clinicians and researchers experienced in systematic reviews) will independently screen the titles and abstracts against the eligibility criteria. Studies deemed potentially relevant will undergo full-text review. Any disagreements during screening will be resolved through discussion or with a third reviewer (clinician and researcher

experienced in systematic reviews). In case of insufficient agreement during the pilot phase, the criteria and extraction form will be refined, and reviewers will undergo an additional calibration exercise until satisfactory consistency is achieved. Reasons for exclusion of full-text studies will be documented in the final review.

Assessment of methodological quality

Two independent reviewers (both clinicians and researchers experienced in systematic reviews) will assess the methodological quality of included studies using the JBI Standardized critical appraisal instrument for studies reporting prevalence and incidence data.^{23,26,27} This tool provides a structured and comprehensive framework to critically appraise the internal and external validity of prevalence studies, focusing on key domains, including sampling strategy, adequacy of sample size, validity of the methods used to identify and measure the condition, and appropriateness of the statistical analysis. The use of this instrument allows for a consistent evaluation of methodological rigor across diverse study designs and settings. Any disagreements will be resolved by consensus or with a third reviewer (a clinician and researcher experienced in systematic reviews).

Specifically, we will use the JBI tool to assess the representativeness of the sample, the precision and accuracy of measurement tools, and the potential for bias in the data collection process. By systematically assessing these elements, the tool enhances transparency in reporting and strengthens the credibility of review findings. The results of the appraisal will be presented in both narrative and tabular formats and will be used to perform a stratified analysis by study quality (low vs high quality based on proportion of JBI criteria met according to the scale used). Given the absence of standardized criteria for defining high-quality studies, several thresholds based on the percentage of criteria from the critical appraisal tool that each study met ($\geq 60\%$, $\geq 70\%$, and $\geq 80\%$) will be applied to classify study quality.

Authors of included studies will be contacted to clarify or obtain missing information, if necessary. Up to 3 contact attempts will be made, with at least 1 week between each attempt. If no response is received, studies will be included provided they meet the eligibility criteria, and missing data will be reported accordingly. The potential impact of missing data will be considered in the risk of bias assessment and, where

appropriate, explored through sensitivity analyses. All studies, regardless of their appraisal outcome, will be included in the data extraction and synthesis phases to ensure comprehensive capture of available evidence.

Data extraction

Data will be extracted by 1 reviewer and checked for accuracy by another (both clinicians and researchers experienced in systematic reviews) using a standardized data extraction tool for prevalence and incidence studies embedded in a standardized electronic spreadsheet. Any discrepancies or uncertainties will be discussed and resolved, and the data extraction tool will be refined, if necessary, to ensure clarity, consistency, and completeness of the extracted information. Extracted data will include study characteristics (eg, authors, study design, publication year, country, sample size, and number of subjects with the event), population characteristics (ie, gender), prevalence, incidence, pressure sore type/site and number, type of masks applied and duration, comorbidities, risk factor associated (ie, Braden score, serum albumin, need for invasive mechanical ventilation during hospitalization and duration, ICU stay, hospital stay, administration of vasopressor, sepsis, hospital outcome), characteristics of the condition (type of ARF, ie, post-extubation ARF or not), and context (hospital ward type). Once the studies are selected, in the event of missing data on the type of interface, ARF treated, and indication to NIV or hospital ward, corresponding authors of the identified eligible published studies will be contacted for additional or missing data (eg, where there are uncertainties related to data or reports are unclear). All data will be included in a single database.

Data synthesis

The primary outcomes of interest are the prevalence and incidence proportion of pressure sores associated with NIV. Meta-analyses will be performed if data from at least 3 independent studies are available. We will use random effects models to account for expected heterogeneity, applying the DerSimonian and Laird method²⁸ to calculate the pooled prevalence and incidence proportion and the corresponding 95% CI. To stabilize variances, prevalence and incidence data will undergo logit transformation; Freeman-Tukey transformation will be applied in sensitivity analyses to verify robustness. Heterogeneity will be assessed using the I^2 index, with thresholds of 50% or more considered substantial. Publication bias will be examined using Doi plots

and an LFK index. The presence of publication bias is indicated by LFK index values greater than 1 or lower than -1. An influence analysis will be conducted to evaluate the contribution of each study to pooled estimates. All analyses will be performed in R using the meta package (R Foundation for Statistical Computing, Vienna, Austria). As this review focuses on prevalence and incidence outcomes, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will not be applied, in accordance with current JBI guidance.

Subgroup and sensitivity analyses

To assess the impact of study design, type of respiratory failure, indication for NIV, interface, and ward on prevalence and incidence of pressure sores, a stratified analysis will be performed. Pooled estimates will be calculated according to study design (observational vs experimental studies), type of respiratory failure (hypoxemic vs hypercapnic subjects), type of interface (oronasal vs other including full face and hybrid), ward (subject hospitalized in ICU/IRCU vs non-ICU/IRCU), indication for NIV (to treat ARF or to treat post-extubation ARF), duration of treatment, and usage of protective skin coverings. The stratified analysis will also be performed considering sex, age (using the median of the average ages reported in the included studies), and study quality, with studies classified as high or low quality to account for differences in demographic characteristics and methodological quality. Random effects pooled estimates will be calculated for each stratum using the Der Simonian and Laird method²⁸ and Cochran Q test will be used to assess between strata differences. Also, in this case, the analyses will be performed if at least 3 estimates are available for each stratum, otherwise the pooled estimate will be calculated only in the stratum in which enough studies are available. Random effects meta-regression models will also be used as a sensitivity analysis to assess differences between strata, considering the same variables used in the stratified analyses: sex, age, study quality, study design, type of respiratory failure, indication for NIV, interface, ward, duration of treatment, and use of protective skin coverings.

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Global priority and equity alignment

This review aligns with Sustainable Development Goal 3 (Good Health and Well-being). It contributes to improving the quality and safety of care for patients with ARF by synthesizing evidence on the prevalence and incidence of pressure injuries associated with NIV. By providing a comprehensive and methodologically rigorous synthesis of the available evidence, this review aims to support the development of evidence-based prevention strategies and clinical protocols across different health care settings, including resource-limited environments, and to promote equitable standards of care.

Author contributions

FM, TE, ER, and RV designed the study. LS designed the analysis. EB, ADM, AC and RV supervised the work. FM, TE, ER, and RV wrote the original manuscript. EB, ADM, LG, CC, CG, PN, GC, and AC made substantial contributions to manuscript revision. All authors read and approved the final manuscript.

Availability of data, code, and other materials

Access to the template data collection forms, data extracted from included studies, data used for all analyses, analytic code, any other materials used in the review will be restricted to the coordinating team, and third parties will only have access to it upon receiving authorization from the principal investigator, who will analyze each research proposal and statistical analysis plan.

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Appendix I: Search strategy

MEDLINE (Ovid)		
Search conducted: November 25, 2025		
Search	Query	Records retrieved
#1	exp Noninvasive Ventilation/	4397
#2	((non-invasive* adj2 ventilat*) or niv or nimv or "non-invasive respiratory support" or "non invasive respiratory support" or "noninvasive respiratory support").ti,ab,kf.	10,678
#3	exp Positive-Pressure Respiration/	30,903
#4	("positive-pressure respiration" or "positive-pressure ventilation" or ppv or "continuous positive airway pressure" or cpap or "intermittent positive-pressure breathing" or ippb or "intermittent positive-pressure ventilation" or ippv or "bilevel positive airway pressure" or bipap or "inspiratory positive airway pressure" or ipap or "expiratory positive airway pressure" or ipap or nrs).ti,ab,kf.	71,067
#5	(((non or "not") adj2 (intubat* or endotrach*)) or "do not intubate" or dni).ti,ab,kf.	3539
#6	((mask* adj2 ventilat*) or (mask* adj2 non-invasive*)).ti,ab,kf.	2781
#7	1 or 2 or 3 or 4 or 5 or 6	101,574
#8	exp Pressure Ulcer/	15,087
#9	((decubitus or pressure or skin*) adj2 (ulcer* or injur* or sore* or damag* or lesion* or breakdown*)).ti,ab,kf.	80,659
#10	(mdrpi or mdr-mmpi).ti,ab,kf.	59
#11	8 or 9 or 10	84,340
#12	7 and 11	453