




BMJ Open Nasal mask versus conventional oxygen supply for endoscopy under intravenous sedation: protocol for a systematic review and meta-analysis

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To cite: Ji W, Deng Y, Zheng M, *et al.* Nasal mask versus conventional oxygen supply for endoscopy under intravenous sedation: protocol for a systematic review and meta-analysis. *BMJ Open* 2024;**14**:e092868. doi:10.1136/bmjopen-2024-092868

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2024-092868>).

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Received 25 August 2024
Accepted 15 November 2024



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ABSTRACT

Introduction Hypoxaemia is a frequent complication associated with endoscopy conducted under intravenous sedation, highlighting the need for effective and practical interventions. This systematic review aims to evaluate the effectiveness of nasal mask oxygenation in reducing the incidence of hypoxaemia during endoscopy under intravenous sedation compared with the conventional oxygen supply.

Methods and analysis This study strictly adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol guidelines. PubMed, Embase, Cochrane Library, Web of Science and China National Knowledge Infrastructure databases will be electronically searched from their inception to May 2024 to identify randomised controlled trials comparing a nasal mask with conventional oxygen supply for endoscopy under intravenous sedation. The study selection, data extraction and quality assessment processes will be conducted independently by two reviewers. The risk of bias in the included studies will be assessed using the Cochrane Risk of Bias Tool for Randomized Trials, and the strength of evidence will be assessed using the Grading of Recommendations Assessment, Development, and Evaluation guidelines. The meta-analysis will be performed using STATA V.16.0, with effect sizes calculated using the standardised mean difference and 95% CI. Heterogeneity will be assessed using Cochran's Q statistics, and inconsistency will be measured using I^2 statistics. Potential sources of bias will also be evaluated.

Ethics and dissemination The data used for this systematic review will be exclusively extracted from published studies. Additional ethical approval and informed consent are not required. This systematic review will be published in a peer-reviewed journal and will be presented at conferences and congresses.

PROSPERO registration number CRD42024545231

INTRODUCTION

In recent years, there has been a significant paradigm shift in endoscopic diagnostics and therapeutics, driven by a steadfast commitment to enhancing patient comfort and minimising the discomfort associated with procedures. An essential component of this

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will comprehensively evaluate the effectiveness of a nasal mask in reducing the incidence of hypoxaemia during endoscopic procedures under intravenous sedation by comparing with conventional oxygen delivery.
- ⇒ Analysis of various sources of heterogeneity and assessment of the risk of bias in the included studies will be crucial for determining the effectiveness of a nasal mask in endoscopic procedures.
- ⇒ One limitation of this study is the lack of standardisation in the design of the nasal mask used across different endoscopic procedures, which will introduce an unintended bias and limit the generalisability of the findings.
- ⇒ The emphasis of this research is narrowed to the realm of intravenous sedation, potentially ignoring the possibilities in other anaesthesia techniques and the effects of different drugs in this mode.

progress has been the integration of sophisticated anaesthesia techniques, particularly intravenous sedation, which has emerged as the preferred option because of its ease of administration and superior outcomes.^{1 2}

The convergence of cutting-edge endoscopic methodologies and state-of-the-art monitoring technologies has strengthened the role of intravenous sedation as a cornerstone in modern endoscopic practice.^{3 4} This therapeutic approach facilitates the unimpeded performance of minimally invasive interventions and fosters swift recovery, thereby augmenting patient contentment and enhancing the operational efficiency of endoscopic facilities. However, intravenous sedation is associated with risks and potential adverse events.⁵ The spectrum of common complications encompasses hypotension, respiratory depression, nausea, vomiting, allergic reactions and aspiration. Hypoxaemia, characterised by diminished oxygen

saturation levels, is a pivotal concern, and its aetiology is multifactorial.^{5 6}

Oxygen is typically administered through conventional oxygen therapy during endoscopic procedures, with the most commonly employed devices being a low-flow nasal cannula and a simple face mask.⁷ Several techniques have been developed to reduce the risk of hypoxaemia during endoscopic procedures.⁸ High-flow nasal cannula (HFNC) therapy effectively reduces hypoxaemia by providing up to 60 L/min of high-flow oxygen.^{7 9 10} In contrast, conventional oxygen therapy provides a maximum flow rate of only 15 L/min and a limited oxygen concentration of 30%–50%.^{10 11} In addition, the use of nasopharyngeal catheterisation may reduce the incidence of hypoxaemia during sedation.^{12 13} However, these methods often require specialised auxiliary oxygen delivery devices or systems and may lead to adverse events, such as nasopharyngeal bleeding.^{9 13} Therefore, it is crucial to develop an effective approach that both prevents hypoxaemia and minimises side effects during endoscopy performed under intravenous sedation.

A noteworthy study published in 2022 reported that subjects receiving oxygen from a nasal mask exhibited significantly higher oxygen saturation levels during intravenous sedation for gastroscopy, suggesting a potential benefit in reducing the risk of hypoxaemia.¹⁴ However, a subsequent study found that oxygen delivery via a nasal mask, compared with a face mask, did not result in any significant improvement in oxygenation or respiratory parameters in the obese patient cohort.¹⁵ Consequently, the overall impact of a nasal mask on the efficacy and safety of endoscopic procedures remains uncertain. An upcoming meta-analysis and systematic review will synthesise existing data to evaluate the practical role of a nasal mask in reducing the risk of hypoxaemia during endoscopic procedures, thereby providing clear guidance for clinical practice.

METHODS

This systematic review protocol is guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) 2015 statement.¹⁶ The study was prospectively registered with the PROSPERO review database for the benefit of peer review, reducing duplication efforts and increasing the transparency of the research.¹⁷ The registration number for this review protocol in PROSPERO is CRD42024545231.

Eligibility criteria

Types of studies

All included studies will be designed as randomised controlled trials (RCTs). The inclusion of methodologically rigorous studies ensures a high standard of evidence, facilitating the objective synthesis of clinical trial data. This approach is instrumental in assessing the effectiveness of a nasal mask in mitigating the risk of hypoxaemia in patients undergoing endoscopic procedures.

The following criteria will be applied to exclude studies that did not meet the methodological and demographic specifications required for the meta-analysis:

- ▶ Studies involving paediatric populations to ensure homogeneity in patient characteristics.
- ▶ Trials that focus on non-endoscopic procedures or those conducted under emergency conditions may introduce variables that are not relevant to the broader context of elective endoscopic surgeries.
- ▶ Research employing methodologies other than RCTs will be excluded, given the need for robust study designs that minimise bias and confounding factors.
- ▶ Studies lacking relevant clinical outcome measures are essential for a comprehensive evaluation of the impact of interventions.
- ▶ Non-empirical studies such as reviews, qualitative research, animal experiments and laboratory studies do not provide the clinical data required for this analysis.

Special Considerations

For studies featuring multiple intervention arms, including those comparing a nasal mask with conventional oxygen delivery methods, only the arms directly relevant to this meta-analysis will be included. This approach can ensure that the synthesised data remained specific to the comparative evaluation of a nasal mask versus conventional oxygen delivery in the context of endoscopic procedures.

Types of patients

Patients scheduled to undergo endoscopic procedures under intravenous sedation will be included. Eligibility is contingent upon age, with participants being at least 18 years old, and the American Society of Anesthesiologists (ASA) physical status classification ranging from I to III.

Types of interventions

The intervention needs to involve the use of a nasal mask for oxygen administration. Conventional methods of oxygen delivery, such as nasal cannula and standard face mask, will be used in the control group.

Types of outcome measures

Primary outcomes

The primary outcome of interest is hypoxaemia, defined as oxygen saturation using pulse oximetry (SpO_2) $\leq 90\%$.¹⁸

Secondary outcomes

The secondary outcome variables include a range of parameters, such as the incidence of subclinical respiratory depression (defined as $90\% \leq \text{SpO}_2 < 95\%$ for > 5 s);¹⁹ the incidence of severe hypoxaemia (defined as $\text{SpO}_2 \leq 75\%$ at any time or $\text{SpO}_2 < 90\%$ for ≥ 60 s);^{14 19} the duration of hypoxaemia and minimum SpO_2 ; the incidence of other adverse events, including cough, hiccups, nasal symptoms, nausea and vomiting, reflux, aspiration and laryngospasm; procedural characteristics, including total dose of analgesic or sedative drugs, duration of the

Table 1 Search strategy used in the PubMed database

Number search terms	
#1	"Endoscopy"(MeSH Terms)
#2	"Endosonography"(MeSH Terms)
#3	"Endoscopes"(MeSH Terms)
#4	(endoscopy) OR (endoscopic procedure) OR (fibroscopy) OR (fibroscope) OR (gastroscope) OR (gastroscopy) OR (coloscope) OR (coloscopy) OR (colonoscopy) OR (colonoscope) OR (endoscopic retrograde cholangiopancreatography) OR (ERCP) OR (esophagogastroduodenoscopy) OR (EGD) OR (bronchoscope) OR (bronchoscopy) OR (angioscopy) OR (arthroscopy) OR (cystoscopy) OR (hysteroscopy) OR (colposcopy)
#5	#1 OR #2 OR #3 OR #4
#6	"Positive-Pressure Respiration"(MeSH Terms)
#7	(nasal mask) OR (nCPAP) OR ("Nasal Continuous Positive Airway Pressure")
#8	#6 OR #7
#9	"Anesthesia, Intravenous"(MeSH Terms)
#10	"Conscious sedation"(MeSH Terms)
#11	"Deep sedation"(MeSH Terms)
#12	("monitored anesthesia care") OR (sedation) OR ("procedural sedation and analgesia") OR (PSA) OR ("MAC anesthesia")
#13	#9 OR #10 OR #11 OR #12
#14	"Randomized Controlled Trial"(MeSH Terms)
#15	("randomized controlled trial") OR ("controlled clinical trial") OR (randomized) OR (randomly) OR (RCT)
#16	#5 AND #8 AND #13 AND #15

EDG, esophagogastroduodenoscopy; ERCP, endoscopic retrograde cholangiopancreatography; MAC, monitored anaesthesia care; MeSH, Medical Subject Heading; nCPAP, nasal continuous positive airway pressure; PSA, procedural sedation and analgesia; RCT, randomised controlled trial.

procedure and recovery time and postoperative satisfaction scores as assessed by anaesthesiologist, endoscopist and patients.

Methodology for study identification

Electronic database inquiry

An extensive search across five reputable electronic databases, PubMed, Embase, Cochrane Library, Web of Science and China National Knowledge Infrastructure, will be conducted without imposing language constraints, with the aim of identifying RCTs published from their inception to May 2024. The search will employ a set of keywords, including 'nasal mask', 'intravenous sedation' and 'endoscopy.' For each database, the search strategy has been meticulously crafted by integrating Medical Subject Heading terms with free-text queries. This dual approach is designed to enhance the specificity and relevance of the search results, ensuring a high degree of precision and focus. This methodology aims to conduct a comprehensive and targeted search, thereby improving the overall quality and integrity of the findings. In addition, a manual search of reference lists will be performed to identify potentially pertinent articles that may not have been captured electronically.

The PubMed search strategy is detailed in [table 1](#) and includes all relevant search terms. This strategy serves as a template for conducting searches in other databases, with necessary adaptations to account for the specific search

functionalities and indexing terms of each database. The search will be inclusive, with no restrictions on language or publication status, ensuring a broad and inclusive scope for the literature review.

Complementary resource exploration

In addition to electronic database searches, a thorough investigation will be conducted across various resources, including PROSPERO, the International Clinical Trials Registry Platform, ClinicalTrials.gov, dissertation databases and grey literature repositories. This comprehensive approach aims to identify systematic reviews and clinical trials pertinent to nasal mask applications in medical settings. To augment our search, manual searches will also be performed in journals and conference proceedings known to publish research in this domain.

Data collection and analysis

Selection of studies

The study selection process will be conducted by two independent reviewers, YD and MZ. They will initially screen the search outputs based on the titles and abstracts. On retrieval of the full texts, these reviewers will engage in a detailed evaluation to determine the relevance of each article to the study's objectives. Disagreements will be resolved through a collegial discussion between the reviewers, with the option of consulting a third-party adjudicator, WTJ, to ensure fair and unbiased resolution. The

systematic methodology of study selection is succinctly outlined and graphically depicted in a PRISMA flow diagram. In addition, we need to make sure that the included article has been published and that the data are publicly available.

Data extraction

Prior to the extraction process, a standardised protocol for data collection needs to be meticulously formulated according to the study's inclusion criteria. Two independent reviewers, XTZ and JHL, will be responsible for collating relevant data. The data collected will include patient baseline characteristics, such as age, sex, body mass index and ASA physical status classification. Additionally, operative variables, such as the duration of the procedure and recovery time, along with details on the use of analgesic or sedative drugs, including type and dosage, will be recorded. Any supplementary outcomes relevant to the study objectives will also be included in the data extraction. In cases where the requisite data for conducting a meta-analysis of continuous variables are not available, the corresponding author will be contacted to request the raw data. If no response is received, the methodology for data estimation proposed by Hozo *et al* will be used. This approach involves the calculation of mean and SD estimates using the median and IQR when raw data are not accessible.¹¹ In instances where consensus on data extraction is not achieved through discussion between the two primary reviewers, final arbitration will be made by a third reviewer (WTJ).

Assessment of study quality

In our systematic evaluation, we will use the Cochrane Risk of Bias Tool for Randomised Trials 2.0 to assess the risk of bias in the included studies.²⁰ This meticulous process will involve a comprehensive examination of various potential sources of bias, including selection, performance, attrition and reporting. The assessment will be conducted by two independent reviewers, XTZ and JHL, who will meticulously evaluate each aspect of the Cochrane risk of bias tool and assign ratings of 'low', 'high' or 'unclear' to each element. In the event of any disagreement between the reviewers, differences will be resolved through collaborative deliberation with expert colleagues, BL and LLB.

Furthermore, to assess the quality of evidence derived from these RCTs, we will employ the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. This framework will facilitate the categorisation of the strength of evidence into 'high', 'moderate', 'low' or 'very low' tiers, depending on the consistency and certainty of the findings from the studies.²¹ By using the GRADE approach, we aim to offer a transparent and evidence-based synthesis of the existing literature, thereby ensuring the reliability and applicability of our conclusions.

Statistical analyses and data synthesis

STATA V.16.0 (StataCorp LLC, College Station, TX, USA) software package will be used for data synthesis.

Specifically, the pooled effects of binary outcomes will be analysed using the risk ratio metric, derived by applying the Mantel-Haenszel method. The results are reported with 95% CI for added precision. In addition, the pooled effects of continuous outcomes will be evaluated using the mean difference metric and 95% CI. This approach facilitates a comprehensive understanding of effect sizes. Statistical significance is determined by a p value of less than 0.05.

Assessment of heterogeneity

To ensure a comprehensive and unbiased assessment, we will use the I^2 statistic to quantify statistical heterogeneity. Specifically, I^2 values of 50% or lower will be classified as low heterogeneity, whereas I^2 values greater than 50% will be considered to indicate high heterogeneity. In addition to the statistical analysis, two experienced reviewers, YD and MZ, will independently evaluate the clinical heterogeneity of the studies. This rigorous evaluation will be further reinforced by the insights of our consulting group, which includes WTJ and XTZ. In cases where substantial clinical or statistical heterogeneity is detected, we will opt for a random-effects model to account for variability among studies. In contrast, if the observed heterogeneity is minimal, a fixed-effects model will be employed to pool the data in a more conservative manner. By adhering to these procedures, we aim to provide a precise and nuanced understanding of this research topic.

Assessment of publication bias

Funnel plot analysis will be used to detect publication bias when a minimum of 10 RCTs are available for quantitative scrutiny. In instances where the number of included studies falls below this threshold, Egger's test will be employed as an alternative.²² Egger's test p value of 0.05 or higher indicates no significant publication bias or the presence of small-study effects. However, it is important to note that funnel plot asymmetry should not be interpreted solely as evidence of reporting bias. Instead, we will consider alternative explanations, such as methodological flaws in the studies or genuine heterogeneity among research findings. This multidimensional approach may ensure a thorough assessment of potential biases.

Subgroup and sensitivity analyses

Upon detection of heterogeneity within a study, a detailed subgroup analysis will be conducted to identify and elucidate the sources of this variability. The criteria for this analysis will include the type of endoscopic procedure, ranging from digestive endoscopy to tracheoscopy, as well as demographic factors, such as patient age and other risk factors. Additionally, the complexity of the nasal mask design should also be considered, with the analysis exploring both the type of nasal mask and the selected ventilation mode. Understanding and addressing heterogeneity are crucial for maintaining the integrity and reliability of the trial results. This approach is essential for

thoroughly examining each variable and enhancing the robustness and generalisability of the research findings.²³

Sensitivity analysis will be performed to evaluate the stability of the overall effect estimates and to determine whether any individual study substantially contributes to the observed heterogeneity. This will be achieved by iteratively excluding each study from the meta-analysis. If low-quality studies are identified and subsequently excluded, a second meta-analysis will be conducted. A comparative analysis and discussion of the results and effect sizes of the two meta-analyses will be performed.²⁴

Trial sequential analysis

To control for type I and type II errors, trial sequential analysis (TSA) will be performed using TSA software (V.0.9.5.10 Beta, The Copenhagen Trial Unit, Denmark). The TSA results will establish whether the evidence in our meta-analysis is reliable and conclusive by providing the boundaries for the required sample size.²⁵

Patients and public involvement

This study is designed as a systematic review and does not require the direct involvement of patients or the general public in primary research activities. Nonetheless, the dissemination of our findings through academic channels is expected to have broader societal implications. The publication of our research in the scientific literature may facilitate the sharing of new insights, potentially influencing the clinical practices among anaesthesiologists and serving as a valuable resource for informing health policy decisions.

Ethics and dissemination

This systematic review will be conducted using published data, thereby precluding the need for ethical approval or informed consent from the patients. The outcomes of the review are intended to be submitted to a peer-reviewed journal, ensuring that the findings undergo rigorous academic scrutiny. Furthermore, the results will be presented at conferences to engage the professional community and stimulate discussion. In addition, the findings will be strategically shared through appropriate social media platforms to extend their reach to a wider audience. This multifaceted approach to dissemination aims to maximise the impact of the research and ensure that the insights derived from the review are accessible to all relevant stakeholders, thereby contributing to collective knowledge and practice within the field.

DISCUSSION

This meticulously designed meta-analysis aims to elucidate the effectiveness of a nasal mask in mitigating hypoxaemia during intricate endoscopic procedures. By conducting a systematic review and critical evaluation of existing research, this study attempts to construct a robust evidence base to inform clinical decision-making and

enhance surgical protocols. The ultimate goal is to ensure that clinical insights are grounded in empirical evidence.

The stringent inclusion and exclusion criteria of the protocol, combined with the application of standardised instruments for assessing the risk of bias, are pivotal for safeguarding the methodological rigour and validity of the studies under review. Thorough data extraction pertaining to procedural details, patient demographics and outcome metrics enables a detailed examination of potential confounding factors and moderators that may influence the observed effects. Notably, the design of the nasal mask varies across different endoscopic procedures, which could pose a challenge to the synthesis of findings. However, the underlying principle of the nasal mask, to create an enclosed, oxygen-enriched environment around the nasal cavity, remains consistent and cannot be replicated with a nasal cannula or nasal pillow.²⁶ This theoretical advantage of the effectiveness of oxygen delivery warrants empirical validation through real-world evidence and rigorous testing.

Although both nasal and face masks are crucial for providing enriched oxygen, a nasal mask can allow the mouth to remain uncovered. Clinical evidence suggests that nasal CPAP (continuous positive airway pressure) can maintain upper airway patency and may offer more effective ventilation than full-mask CPAP.²⁷ It appears that the mode of positive pressure ventilation may have a more pronounced impact than the hyperoxic environment created by the nasal mask. Therefore, a subgroup analysis focusing on various ventilation modes is critical to understanding the influence of hyperoxic environments facilitated by a nasal mask.

Despite the methodological rigour of this protocol, it is essential to recognise potential limitations. One such limitation is the study's focus on intravenous sedation, which may inadvertently overlook the utility of a nasal mask in other anaesthetic techniques. Moreover, the primary outcome of this study will be hypoxaemia, defined as pulse oxygen saturation <90%, and studies reporting a drop in saturation as a percentage of the baseline will not be considered. This may lead us to miss some research findings. In addition, this study does not consider HFNC therapy, which is believed to be effective in reducing hypoxaemia in patients undergoing endoscopy.^{7 28 29} The study aims to compare a nasal mask with conventional oxygen delivery methods, such as a face mask and nasal cannula, limiting our ability to assess the comparative benefits of a nasal mask vs HFNC in the context of endoscopic procedures. However, we believe that HFNC is not a conventional oxygen supply and that, if included, new biases will be introduced owing to its established effectiveness.

In conclusion, this meta-analysis protocol offers a comprehensive framework for assessing the impact of a nasal mask on hypoxaemia during endoscopic interventions. The forthcoming findings are expected to provide evidence for a nasal mask as a new approach to deliver oxygen during intravenous anaesthesia and lead

to revisions in patient management strategies, ultimately improving patient safety and surgical outcomes.

Acknowledgements We thank the primary authors and sponsors who have provided access to their trial's database.

Contributors BL and LLB designed this study. BL and WTJ are the principal investigators. WTJ, YD, and MZ are the main implementers. XTZ, JL, and JHL provided the statistical and epidemiological support. WTJ wrote the article with support from BL and LLB. LLB is the guarantor of this study. All authors revised and approved the final version of the manuscript.

Funding This work is supported by the Shanghai Science and Technology Committee Rising-Star Program (19QA1408500).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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