


REVIEW

Effectiveness and safety of nasal mask versus binasal prongs for providing continuous positive airway pressure in preterm infants—A systematic review and meta-analysis

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Abstract

Continuous positive airway pressure (CPAP) delivered via binasal prongs has been the cornerstone of respiratory management in preterm infants. Though effective, the use of binasal prongs is associated with nasal trauma, and CPAP failure. To overcome these issues, nasal masks are increasingly used to deliver CPAP in preterm infants. The aim was to conduct a systematic review of randomized controlled trials (RCTs) comparing nasal mask versus binasal prongs to deliver CPAP in preterm infants. Medline, Embase, Cochrane Central Register of Controlled Trials, Cumulative Index of Nursing, and Allied Health Literature, and E-abstracts from the Pediatric Academic Society meetings were searched in May 2017. All RCTs comparing nasal mask versus binasal prongs for delivering CPAP in preterm infants were included. Primary outcome was CPAP failure (need for mechanical ventilation within 72 h of initiating CPAP). Secondary outcomes included duration of CPAP, moderate to severe nasal trauma, any nasal trauma, pneumothorax, severe IVH, bronchopulmonary dysplasia at 36 weeks postmenstrual age, and mortality. Five RCTs with low risk of bias were included. Nasal mask significantly decreased the risk of CPAP failure (4 RCTs [N = 459]; relative risk [RR]: 0.63; 95% confidence interval [CI]: 0.45-0.88; P = .007; I² = 0%, NNT: 9), and the incidence of moderate to severe nasal trauma (3 RCTs [N = 275], RR: 0.41; 95%CI, 0.24-0.72; P = 0.002; I² = 74%, NNT: 6). Other outcomes did not differ significantly between the groups. Compared to binasal prongs, nasal mask may provide a safe and effective alternative by minimizing the risk of CPAP failure in preterm infants needing CPAP support.

KEYWORDS

continuous positive airway pressure, mask, meta-analysis, preterm infant, prongs

1 | INTRODUCTION

Early use of nasal continuous positive airway pressure (NCPAP) has become the standard of care for managing respiratory distress syndrome (RDS) in preterm infants.¹⁻³ The optimal delivery and effectiveness of NCPAP depend primarily on the nasal interface and the pressure generating source. Short binasal prongs are more

effective than single nasal/nasopharyngeal prongs in reducing the rate of re-intubation.⁴ However, binasal prongs are associated with complications such as increased resistance to gas flow, peri-nasal leak, and nasal trauma.^{5,6} Observational studies have reported nasal injury in 62.9-68.1% of preterm infants on non-invasive ventilation with nasal prongs.^{7,8} The high incidence of nasal injuries associated with nasal prongs have led to the emergence of newer generation

anatomically shaped nasal masks, designed using 3D facial scanning. Such masks are thought to provide a good seal, resulting in improved efficacy, and reduced risk of nasal injury.⁹ Yong et al⁹ reported a randomized controlled trial (RCT) comparing the incidence of nasal trauma following NCPAP with either binasal prongs or nasal mask in very low birthweight (VLBW) infants. The incidence of nasal trauma was similar between the study groups but the sites of nasal injury differed with each interface.⁹ Subsequent RCTs comparing the efficacy and adverse effects of nasal mask and binasal prongs in preterm infants have reported varying results.^{10–13} Given the significance of the issue, we aimed to conduct a systematic review of RCTs comparing the effectiveness, and safety of nasal mask versus binasal prongs to deliver NCPAP in preterm infants.

2 | METHODS

Guidelines from the Cochrane Neonatal Review Group,¹⁴ Centre for Reviews and Dissemination (<http://www.york.ac.uk/crd/guidance/>), and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)¹⁵ statement were followed for undertaking and reporting this systematic review and meta-analysis. Ethics approval was not required.

2.1 | Eligibility criteria

2.1.1 | Types of studies

Only RCTs available in English databases were included in the review. Observational studies, narrative reviews, systematic reviews, case reports, letters, editorials, and commentaries were excluded but read to identify potential additional studies.

2.1.2 | Types of participants

Preterm neonates born before <37 weeks' gestation, low birth weight (LBW: <2500 g), or both, and on NCPAP were eligible.

2.1.3 | Intervention and comparison

NCPAP administered via nasal mask versus binasal prongs.

2.1.4 | Outcomes

Primary outcome

CPAP failure defined as the need for intubation and mechanical ventilation within 72 h of initiation of NCPAP.

Secondary outcomes

Duration of CPAP, incidence of any nasal trauma, moderate to severe nasal trauma, bronchopulmonary dysplasia at 36 weeks postmenstrual age, death, pneumothorax, and severe IVH.

2.2 | Search strategy

The databases PubMed (www.ncbi.nlm.nih.gov, 1966–May 2017), Embase (Excerpta Medica dataBASE) via Ovid (<http://ovidsp.tx.ovid.com>, 1980–May 2017), Cochrane Central Register of Controlled Trials (www.thecochranelibrary.com, through May 2017), Cumulative Index of Nursing and Allied Health Literature via Ovid (<http://ovidsp.tx.ovid.com>, 1980–May 2017), and E-abstracts from the Pediatric Academic Society meetings (www.abstracts2view.com/pasall, 2000–May 2017) were searched in May 2017. Abstracts of the proceedings of Perinatal Society of Australia and New Zealand, European Academy of Pediatric Societies, and the British Maternal, and Fetal Medicine Society meetings were searched in Embase. Google Scholar was searched for articles that might not have been cited in the standard medical databases. Gray literature was searched through the national technical information services (<http://www.ntis.gov/>), Open Gray (<http://www.opengrey.eu/>), and Trove (<http://trove.nla.gov.au/>). The reference lists of eligible studies and review articles were searched to identify additional studies. Reviewers BJ and AI conducted the literature search independently. No language restriction was applied. Only published data were used for those studies, where available. We searched PubMed for the following terms: prongs (All Fields) AND (“continuous positive airway pressure”[MeSH Terms] OR (“continuous”[All Fields] AND “positive”[All Fields] AND “airway”[All Fields] AND “pressure”[All Fields]) OR “continuous positive airway pressure”[All Fields]) AND preterm[All Fields]. (“masks”[MeSH Terms] OR “masks”[All Fields] OR “mask”[All Fields] AND (“continuous positive airway pressure”[MeSH Terms] OR (“continuous”[All Fields] AND “positive”[All Fields] AND “airway”[All Fields] AND “pressure”[All Fields]) OR “continuous positive airway pressure”[All Fields]) AND preterm [All Fields]. The other databases were searched for similar terms.

2.3 | Study selection

Abstracts of the citations obtained from the initial broad search were read independently by three reviewers (BJ, AI, and SR) to identify potentially eligible studies. Full text articles of these studies were obtained and assessed for eligibility by three reviewers independently (BJ, SR, and AI) under the predefined eligibility criteria. Differences in opinion were resolved by group discussion among all reviewers to reach consensus. Care was taken to ensure that multiple publications of the same study were identified and excluded to avoid duplication of the data.

2.4 | Data extraction

Reviewers BJ, AI, and SR extracted the data independently using a data collection form designed for this review. Information about the study design and outcomes was verified by all reviewers. Discrepancies during the data extraction process were resolved by discussion and consensus among all reviewers. We contacted authors for additional information and clarifications when details were not available in published manuscripts. Such studies were excluded if there was no response from the authors.

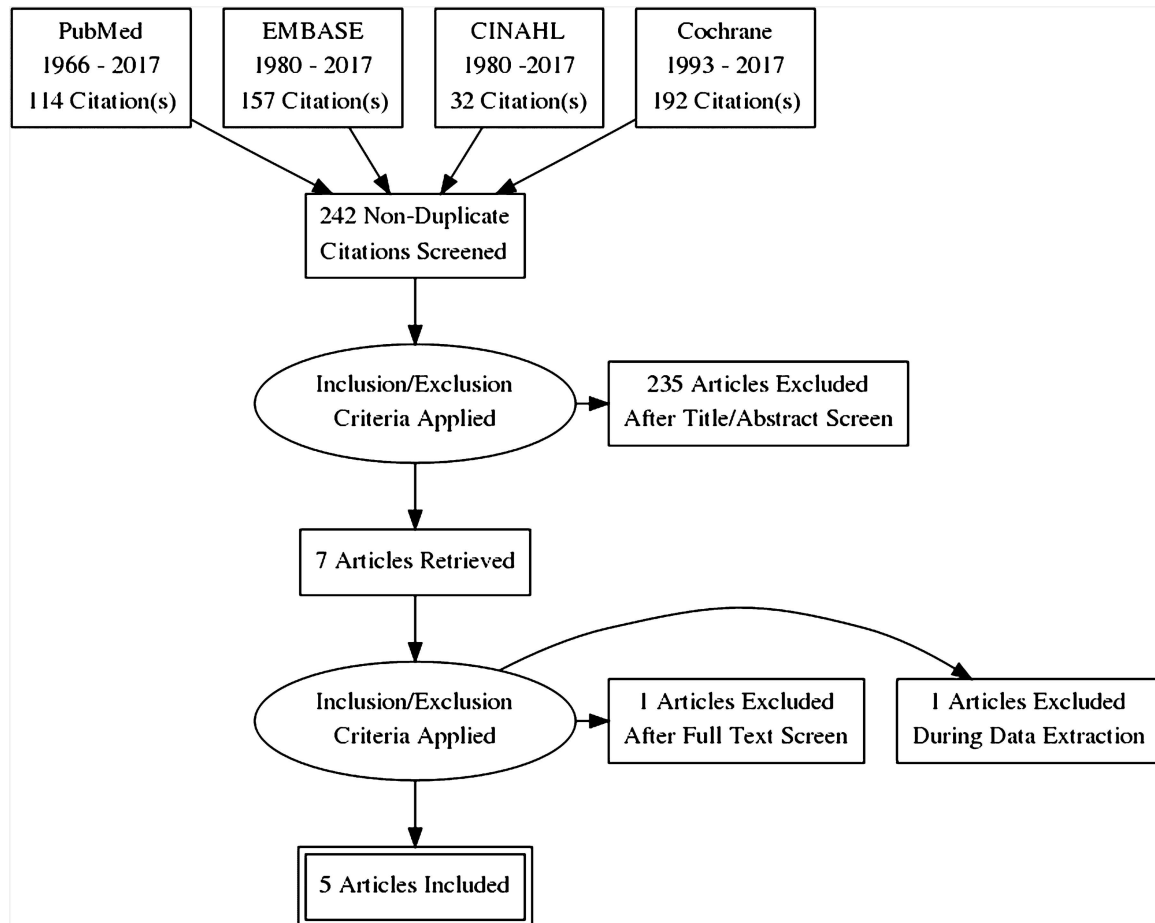


FIGURE 1 Flow diagram of search strategy and study selection

TABLE 1 Characteristics of the included studies

Study ID	Study characteristics
1. Yong et al ⁹	Participants: very low birth weight (<1501 g) infants with respiratory distress. Intervention: NCPAP (IFD) via NP or NM. Sample size: 89 (48 in NP vs 41 in NM group). Primary outcome: any nasal trauma (12/41 (29%) in NM versus 17/48 (35%) in NP group; <i>p</i> : 0.5). Secondary outcomes: CPAP failure: Not assessed. Moderate to severe nasal trauma: 10/41 in NM versus 13/48 in NP group
2. Kieran et al ¹⁰	Participants: infants with gestational age <31 weeks with respiratory distress. Intervention: NCPAP (IFD, IFA, IFS) via NP or NM. Sample size: 120 (62 in NP vs 58 in NM group) Primary outcome: CPAP failure within 72 h (32/62 (52%) in NP versus 16/58 (28%) in NM group; <i>P</i> :0.007) Secondary outcomes: moderate to severe nasal trauma: not assessed
3. Goel et al ¹¹	Participants: infants with gestational age 27-34 weeks with respiratory distress. Intervention: NCPAP (bubble CPAP) via NP or NM. Sample size: 118 (57 in NP vs 61 in NM group) Primary outcome: CPAP failure within 72 h (14/57 (25%) in NP vs 8/61 (13%) in NM group; <i>P</i> : 0.15) Secondary outcomes: moderate to severe nasal trauma: 13/57 (22.8%) in NP versus 4/61 (6.5%) in NM group
4. Say et al ¹²	Participants: infants with gestational age 26-32 weeks with RDS. Intervention: NCPAP (SLE 2000 ventilator) via NP or NM. Sample size: 149 (75 in NP vs 74 in NM group) Primary outcome: BPD (15/75 (20%) in NP versus 11/74 (14.9%) in NM group. Secondary outcomes: CPAP failure within 72 h (13/75 (17.3%) in NP versus 12/74 (16.2%) in NM group; <i>P</i> :0.65) Moderate to severe nasal trauma: not assessed.
5. Chandrasekaran et al ¹³	Participants: Infants with gestational age 26-32 6/7 weeks with respiratory distress. Intervention: NCPAP (Bubble CPAP) via NP or NM Sample size: 72 (35 in NP vs 37 in NM group) Primary outcome: mean FiO ₂ requirement at 6, 12, and 24 h of CPAP initiation. Secondary outcomes: CPAP failure within 72 h (7/35 (20%) in NP versus 5/37 (14%) in NM group; <i>p</i> :0.46) Moderate to severe nasal trauma: 10/35 (31%) in NP versus 0/37 in NM group

NP: nasal prongs, NM: nasal mask

TABLE 2 Assessment of the ROB of included RCTs

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Yong et al ⁹	Low risk	Low risk	High risk	High risk	Low risk	Low risk	Low risk
Kieran et al ¹⁰	Low risk	Low risk	High risk	High risk	Low risk	Low risk	Low risk
Goel et al ¹¹	Low risk	Low risk	High risk	High risk	Low risk	Low risk	Low risk
Say et al ¹²	Unclear risk	Low risk	High risk	High risk	Low risk	Low risk	Low risk
Chandrasekaran et al ¹³	Low risk	Low risk	High risk	Low risk	Low risk	Low risk	Low risk

2.5 | Assessment of risk of bias

We assessed the risk of bias (ROB) by using the Cochrane “Risk of Bias Assessment Tool.”¹⁴ Authors BJ and SR independently assessed the ROB in all domains including random sequence generation, allocation concealment, blinding of intervention, and outcome assessors, completeness of follow-up, selectivity of reporting, and other potential sources of bias. For each domain, the ROB was assessed as low, high, or unclear risk based on the Cochrane Collaboration guidelines.

2.6 | Data synthesis

Meta-analysis was conducted using Review Manager 5.3 (Cochrane Collaboration, Nordic Cochrane Centre, Copenhagen, Denmark). A fixed-effects model (FEM) (Mantel-Haenszel method) was used. However, analysis using random effects model (REM) was also conducted to ensure that the results and conclusions were not influenced by the type of model used for the meta-analysis. Effect size was expressed as relative risk (RR) and 95% confidence intervals (CI). Statistical heterogeneity was assessed with the χ^2 test and I^2 statistic and by visual inspection of the forest plot (overlap of CIs). A $P < 0.1$ on the χ^2 statistic was considered to indicate heterogeneity. I^2 statistic values were interpreted according to the guidelines of Cochrane Handbook as follows: 0-40%, might not be important; 30-60%, may represent moderate heterogeneity; 50-90%, may represent substantial heterogeneity; 75-100%, considerable heterogeneity.¹⁴

2.7 | Summary of findings table

The key information about the quality of evidence, the magnitude of effect of the intervention, and the sum of available data on the main outcome was presented in the summary of findings table according to

the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) guidelines.¹⁶

3 | RESULTS

The literature search retrieved 495 potential relevant citations, of which 488 were excluded, and seven RCTs were considered eligible for inclusion. Finally, 5 RCTs were included in the systematic review, and meta-analysis.⁹⁻¹³ The remaining studies had to be excluded because of lack of information from the published manuscripts. The study by Newnam et al¹⁷ was excluded as it didn't report outcomes relevant to the review. The flow diagram of the study selection process is given in Figure 1.

Out of the five included studies, though CPAP failure was reported in four studies,¹⁰⁻¹³ it was the primary outcome of interest in two studies, whereas BPD, incidence of nasal trauma, and mean FiO2 requirement at 24 h of CPAP initiation were the primary outcomes in Say et al,¹² Yong et al,⁹ and Chandrasekaran et al¹³ respectively. All the included trials evaluated CPAP as primary mode of respiratory support. In addition to primary support, Kieran et al¹⁰ evaluated CPAP as a post extubation mode of respiratory support. Incidence of any nasal trauma was reported in all five studies but moderate to severe nasal trauma was reported in three studies.^{9,11,13} The detailed characteristics of the included studies are given in Table 1.

3.1 | ROB of included studies

Of the five included RCTs, (80%) were judged to have low ROB for the domain of random sequence generation, and all were considered to have low ROB for allocation concealment. Details of the ROB assessment are given in Table 2.

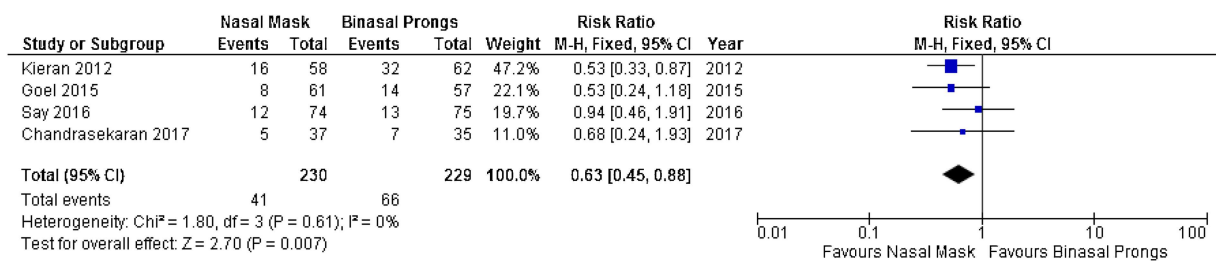


FIGURE 2 Forest plot: CPAP failure: nasal mask versus binasal prongs for CPap in preterm infants

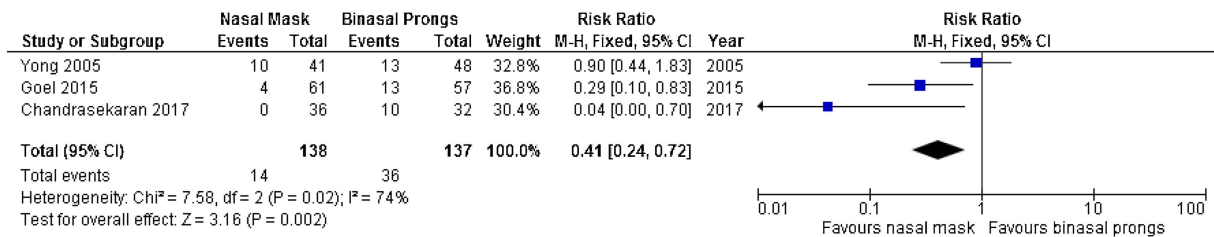


FIGURE 3 Forest plot: moderate to severe nasal trauma: nasal mask versus binasal prongs for CPAP in preterm infants

3.1.1 | Primary outcome

Meta-analysis (FEM) of data from 4 RCTs¹⁰⁻¹³ ($n = 459$) showed that the use of nasal mask significantly decreased the risk of CPAP failure (RR: 0.63; 95%CI: 0.45-0.88; $P = 0.007$; $I^2 = 0\%$, NNT: 9) (Figure 2).

3.1.2 | Secondary outcomes

Meta-analysis (FEM) of data from 3 RCTs^{9,11,13} ($N = 275$) showed that the use of nasal mask significantly reduced the incidence of moderate to severe nasal trauma (RR: 0.41; 95%CI, 0.24-0.72; $P = 0.002$; $I^2 = 74\%$, NNT: 6) (Figure 3). Other secondary outcomes did not differ significantly between the two groups.

3.1.3 | Summary of findings

The overall evidence according to GRADE guidelines was graded as low in view of the small sample size, lack of blinding, inability to assess publication bias due to limited number of studies, and statistical heterogeneity (Table 3).

4 | DISCUSSION

The results of our systematic review of five RCTs ($N = 544$) (Level of evidence [GRADE]: low) suggest that compared with binasal prongs, the application of nasal mask significantly decreases the risk of CPAP failure, and moderate to severe nasal trauma in preterm infants. To our knowledge, this is the first systematic review, and meta-analysis of RCTs evaluating the use of nasal mask versus binasal prongs to deliver NCPAP in preterm infants.

Four out of the five RCTs⁹⁻¹² included in our review had high-risk of bias with regards to blinding of outcome assessment. The risk of bias was otherwise low in other domains in all trials. The trial by

Chandrasekaran et al¹³ assessed nasal trauma using digital photographs taken once a day. A neonatologist, masked to the treatment allocation, graded nasal trauma by viewing serial photographs of the infants' nostrils.¹³ Future trials could incorporate similar techniques to avoid bias in assessing such outcomes.

Newnam et al¹⁷ have reported results of their three arm RCT comparing the frequency and severity of nasal trauma in preterm VLBW neonates allocated to receive NCPAP by either continuous nasal prongs ($n = 21$), continuous nasal mask ($n = 35$), or alternating mask/prongs ($n = 22$). Neonatal skin condition scores (NSCS) were recorded at least every 10-12 h. Skin injury was significantly less (erythema $P < 0.001$, excoriation $P = 0.007$) in the rotation interface group compared to the other two groups.¹⁷ Evaluation of alternating nasal interfaces is a novelty in this trial which might improve the effectiveness of the interface as well as mitigate the frequency of nasal trauma. The limitations include the small and skewed sample size distribution between groups and lack of standardized outcomes.

The site and degree of nasal trauma differs on the type of nasal interface used to deliver CPAP, being more common over the nasal bridge, and junction of the philtrum and nasal septum with nasal mask, while mucosal trauma with prongs commonly occurs at the medial aspect of nasal septum and columella.^{18,19} Mucosal injury with prongs can be associated with staphylococcus sepsis and may have long term functional consequences.^{20,21} Chandrasekaran et al¹³ was the only trial which used separate scoring systems^{22,23} to assess nasal trauma for each interface but these tools need to be standardized and tested across different ethnicities and gestational age to be widely accepted in clinical practice.

The limitations of our systematic review need to be acknowledged. These include the small sample size of included trials, the heterogeneity of the characteristics of participants, and interventions (bubble, variable flow, ventilator-derived CPAP, different brands of

TABLE 3 Summary of findings according to GRADE guidelines¹⁶

Outcome	Absolute Risk		Relative effect, RR (95%CI)	Number of participants	Quality of evidence GRADE	Comment
	Nasal mask	Binasal prongs				
CPAP failure	41/230 (17.82%)	66/229 (28.82%)	0.63; (0.45-0.88); $P = 0.007$	459	Low	See below
Moderate to severe nasal trauma	14/138 (10.14%)	36/137 (26.27%)	0.41; (0.24-0.72); $P = 0.002$	275	Low	See below

The evidence was deemed low in view of the small sample size, lack of blinding of participants, personnel and outcome assessors in majority of the trials, inability to exclude publication bias due to limited number of studies and statistical heterogeneity.

nasal prongs, and masks), and lack of standardized assessment of nasal trauma. Despite the limitations, our results suggest that nasal mask has the potential to reduce the risk of CPAP failure with regards to avoiding the need for intubation and mechanical ventilation and nasal injuries. Based on our review, the current incidence of CPAP failure with the use of binasal prongs appears to be around 30%. To test the hypothesis that the new generation nasal mask CPAP will reduce this incidence to 20%, with an alpha error of 5% and a power of 80%, one would need a total sample size of 626 (ie, 313 per group). Considering the size of the population at risk and the frequency of use of devices for NCPAP, achieving this sample size may not be difficult. Translating the evidence into practice will not be difficult if the results of such a superiority trial confirm our findings.

In summary, the results of our systematic review and meta-analysis of RCTs suggest that in comparison to nasal prongs, nasal mask may provide a safe and effective alternative by minimizing the incidence of CPAP failure and risk of moderate to severe nasal trauma in preterm infants needing CPAP support. Adequately powered RCTs are essential to confirm these findings.

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