ORIGINAL RESEARCH PAPER

Paediatrics

KEY WORDS: Pneumonia; HHHFNC; CPAP; Infant; Respiratory Distress; Non-invasive Ventilation.

EFFICACY AND SAFETY OF HEATED HUMIDIFIED HIGH-FLOW NASAL CANNULA VERSUS CONTINUOUS POSITIVE AIRWAY PRESSURE IN INFANTS UNDER 12 MONTHS WITH MODERATE PNEUMONIA-INDUCED RESPIRATORY DISTRESS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Pneumonia remains a leading cause of morbidity and mortality in infants worldwide. Non-invasive ventilation is a key strategy in preventing respiratory failure1,5. Continuous Positive Airway Pressure (CPAP) is widely used but may be associated with discomfort and complications13. Heated Humidified High-Flow Nasal Cannula (HHHFNC) therapy has emerged as a potential alternative4,6,10. **Aim:** To compare treatment success, complication rates, tolerance, and clinical outcomes between HHHFNC and CPAP in infants <12 months with moderate pneumonia-induced respiratory distress. **Methods:** A randomized controlled trial involving 162 infants was conducted from October 2024 to October 2025. Participants were randomized to HHHFNC (n=85) or CPAP (n=77). Primary outcome was treatment success—defined as achieving stable SpO_2 ≥94% and reduction in respiratory distress without escalation to mechanical ventilation. Secondary outcomes included changes in respiratory rate (RR), SpO_2 improvement time, duration of oxygen therapy, sedation requirement, complication rate, patient comfort, and mortality. **Results:** Treatment success was similar between groups (HHHFNC 87.05% vs CPAP 81.81%, p=0.29). However, HHHFNC significantly outperformed CPAP in secondary outcomes—with lower complication rates (9.4% vs 24.6%, p<0.01), markedly reduced sedation requirement (12.9% vs 49.3%, p<0.001), and superior patient comfort. Improvement in RR and SpO_2 was faster with HHHFNC, and duration of respiratory support was shorter. **Conclusion:** While treatment success rates were statistically comparable, HHHFNC demonstrated clinically superior performance with significantly fewer complications, better tolerance, and reduced sedation need. HHHFNC should be considered the preferred first-line non-invasive ventilation strategy for infants with moderate pneumonia-associated respiratory distress.

INTRODUCTION

Pneumonia remains a major cause of hospitalization and mortality in children under five years of age[1,5]. Infants represent a vulnerable group due to immature immunity, smaller airway caliber, and rapid deterioration risk. Early effective non-invasive ventilation (NIV) strategies are essential to avoid escalation to invasive ventilation which carries higher morbidity.

CPAP is a widely used NIV technique that generates positive end-expiratory pressure, reduces atelectasis, and improves gas exchange[2,3]. Despite its efficacy, CPAP may be poorly tolerated due to nasal interface discomfort[13], gastric distension, and leak-related pressure loss, often necessitating sedation.

Heated Humidified High-Flow Nasal Cannula therapy delivers heated, humidified oxygen at high flows, reduces dead-space rebreathing, improves oxygenation, and provides mild distending pressure[4,6,10]. Improved comfort and less interface trauma make it an attractive option.

However, evidence comparing CPAP and HHHFNC in pneumonia cases, especially among Indian pediatric populations, remains limited. This study aims to compare treatment success, safety, and clinical outcomes of HHHFNC versus CPAP in infants <12 months with moderate pneumonia-related respiratory distress.

OBJECTIVES

Primary Objective

To compare treatment success between HHHFNC and CPAP, defined as:

- Maintaining SpO_2 ≥94% for >6 hours
- Reduction in respiratory distress score (RR reduction ≥10 breaths/min, reduced retraction severity)
- No escalation to mechanical ventilation

Secondary Objectives

- Rate and time of improvement in RR and SpO_2
- Duration of respiratory support
- Complications (nasal trauma, abdominal distension, barotrauma)
- Sedation requirement
- Comfort score based on standardized infant comfort scale
- Mortality

Review of Literature

Multiple studies have evaluated high-flow oxygen therapy. Franklin et al. demonstrated improved outcomes when HHHFNC was used as initial support in bronchiolitis[1]. Liu et al. compared HHHFNC to CPAP in pneumonia-induced respiratory distress and found similar treatment success but lower complication rates with HHHFNC[2].

Meta-analysis by Luo et al. reported HHHFNC had fewer adverse events, better tolerance, and comparable effectiveness to CPAP[4]. However, variations in flow settings, age groups, and indications warranted further controlled trials.

In India, most studies focus on bronchiolitis rather than pneumonia. The present trial contributes locally relevant evidence.

Materials and Methods

Study Design and Setting

A prospective randomized controlled study conducted in the Paediatric Department of Hi-Tech Medical College from October 2024 to October 2025.

Sample Size

Sample size of 162 calculated using 80% power, 95% CI, and 10% expected difference in success rate.

Inclusion Criteria

- Age <12 months
- Radiologically confirmed pneumonia
- Moderate respiratory distress (RR >50/min, chest retractions, SpO_2 <92% on room air)

Exclusion Criteria

- Congenital heart disease
- Neuromuscular disorders
- Immediate intubation requirement

Interventions

Parameter	HHHFNC	CPAP
Initial Setting	2 L/kg/min (max 20 L/min)	6–8 cmH_2O
FiO_2 Target	Maintain SpO_2 ≥94%	Maintain SpO_2 ≥94%

Outcome Measures

Primary Outcome:

- Successful non-invasive support without mechanical ventilation.

Secondary Outcomes:

- Change in RR and SpO_2
- Length of oxygen therapy
- Complications (barotrauma, nasal trauma, gastric distension)
- Sedation requirement
- Comfort score
- Mortality

Statistical Analysis

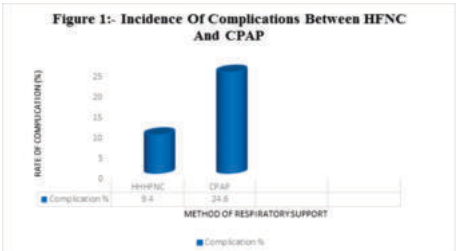
SPSS Version 26 used. Independent t-test applied to continuous variables. Chi-square applied to categorical variables. Kaplan-Meier analysis conducted for oxygen-weaning duration. $p<0.05$ considered significant.

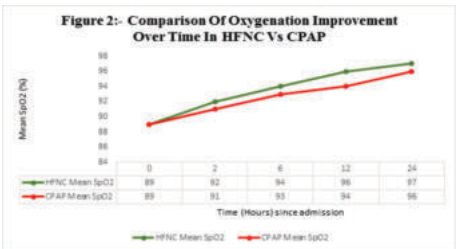
RESULTS

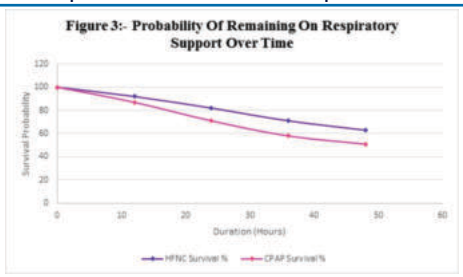
Both groups were statistically comparable at enrollment ($p>0.05$).

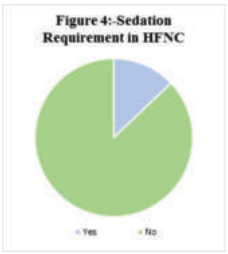
Table 1:- Comparison of Clinical Outcomes -

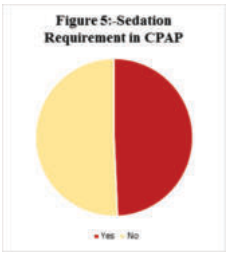
Outcome	HHHFNC (n=85)	CPAP (n=77)	p-value
Treatment success	74 (87.05%)	63 (81.81%)	0.29
Mechanical ventilation	6 (7.05%)	8 (10.38%)	0.43
Sedation required	11 (12.9%)	38 (49.3%)	<0.001*
Complication rate	9.4%	24.6%	<0.01*
Mortality	1 (1.17%)	2 (2.59%)	0.53
Average improvement			
In RR within 6 hours	18±6	11±5	<0.01*
Mean duration of Oxygen support	58 hours	78 hours	<0.05*











DISCUSSION

Although both HHHFNC and CPAP achieved similar treatment success and prevented mechanical ventilation in most infants, secondary outcomes clearly favored HHHFNC. HHHFNC achieved faster normalization of respiratory parameters, reduced duration of respiratory support, and demonstrated significantly fewer complications. The substantially lower sedation requirement indicates superior tolerance and comfort, highlighting a major clinical advantage[7,8,10,12].

CPAP's tight nasal interface increases risk of nasal pressure injury and gastric insufflation[13], explaining higher complication rates and sedation needs. In contrast, HHHFNC allows spontaneous breathing with minimal interface discomfort[10], enabling active feeding and bonding, which may contribute to faster recovery.

Previous randomized and meta-analysis studies similarly reported improved tolerance and fewer complications with HHHFNC (Manley et al.; Liu et al.; Luo et al.)[2,3,4]. Results of the present trial align with these findings and add India-specific pediatric evidence.

Clinical significance: Although statistical non-inferiority relates to success rate alone, the global clinical impact strongly favors HHHFNC due to safety, comfort, and faster recovery—important determinants in infant care.

Ethical Considerations

Ethical approval obtained from the institutional ethics committee. Written informed consent obtained from caregivers.

CONCLUSION

HHHFNC provides comparable treatment efficacy to CPAP in infants with moderate pneumonia while offering distinct clinical superiority in terms of safety, tolerance, reduced sedation requirement, faster physiological stabilization, and shorter support duration. Therefore, HHHFNC can be recommended as the preferred and more patient-friendly first-line non-invasive ventilation modality in pediatric pneumonia management.

Limitations

- Single-center study
- No analysis of specific pathogens or viral loads
- Short follow-up period
- Future multicenter longitudinal studies are recommended.

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