Bubble Continuous Positive Airway Pressure Oxygen Therapy in Children Under Five Years of Age with Respiratory Distress in Pediatric Intensive Care Unit

Lalitha AV[1], Chandrakant G Pujari[2], John Michael Raj[3]

Abstract

Background: Continuous positive airway pressure (CPAP) has been used in children with bronchiolitis for a long time. Currently in the low-resource settings, the method of providing oxygen therapy via bubble CPAP (bCPAP) to children with respiratory distress is not standardized and the existing low-flow oxygen therapy has a high mortality rate.

Objectives: To study the effectiveness and safety of bCPAP as a respiratory support in children with respiratory distress.

Materials and methods: This prospective observational study was conducted in a tertiary care pediatric intensive care unit (PICU) over a period of 3 months. Children with respiratory distress were administered with bCPAP oxygen therapy. Baseline demographic data, such as age, sex, weight, severity of illness was collected. Changes in heart rate, respiratory rate, saturation, respiratory distress score and failure rate after bCPAP therapy were studied.

Results: During the study period, 30 children were recruited. Most common cause of respiratory distress requiring bCPAP was pneumonia (66.7%) followed by pleural effusion (20%) and bronchiolitis (13.3%). The median (IQR) CPAP duration and PICU stay in the study was 48 hours (27–48) and 4 days (4–8), respectively. Heart rate and respiratory rate, respiratory distress score improved significantly after CPAP therapy ($p < 0.05$). CPAP therapy failed in one child and required invasive ventilation. We did not observe any complications due to bCPAP therapy.

Conclusion: The use of bCPAP in the treatment of respiratory distress is safe and effective.

Keywords: Continuous positive airway pressure, Pediatric intensive care unit, Pneumonia, Respiratory distress.

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Highlights

Currently in the low resource settings, oxygen therapy via bubble CPAP (bCPAP) to children with respiratory distress is not standardized. Continuous positive airway pressure (CPAP) delivery through indigenous bCPAP is safe and effective with added advantage of easy titration and quantification of delivered CPAP and FiO_2.

Introduction

In India, pneumonia and other acute lower respiratory infections (ALRI) are the leading contributors to serious illness and death.[1] Pneumonia is currently the leading cause of death among children worldwide, and India has a huge burden of childhood pneumonia than any other country, accounting for 20% of deaths worldwide from the disease.[2]

Hypoxemia is the greatest risk factor for pneumonia-related mortality, and oxygen therapy can significantly decrease pneumonia-related mortality.[3–5] However, despite the provision of oxygen, antibiotics, and supportive care, case-fatality rate of severe pneumonia with hypoxemia remains high in developing countries (8–11%)[6] In conjunction with oxygen therapy, CPAP may play a pivotal role in treating ALRI with respiratory distress. Continuous positive airway pressure has long been studied in children with bronchiolitis, neonates with respiratory distress syndrome, meconium aspiration syndrome, and prematurity-related apnea.[7] The airway pressure is assumed to reduce the

[1,2]Department of Pediatric Critical Care Unit, St. John's Medical College and Hospital, Bengaluru, Karnataka, India

[3]Department of Biostatistics, St. John's Medical College and Hospital, Bengaluru, Karnataka, India

Corresponding Author: Lalitha AV, Department of Pediatric Critical Care Unit, St. John's Medical College and Hospital, Bengaluru, Karnataka, India, Phone: +91 9448461673, e-mail: drlalitha03@gmail.com

inspiratory resistance, improve the work of breathing, and alveolar ventilation.[8]

There are numerous methods for administering CPAP, and bCPAP being one of them. There is limited data from the Indian subcontinent on the usage of bCPAP in children with respiratory distress. In this pilot study, we explored the safety and utility of bCPAP in children with respiratory distress. In addition, we compared the effectiveness of bCPAP therapy to high-flow nasal cannula therapy.
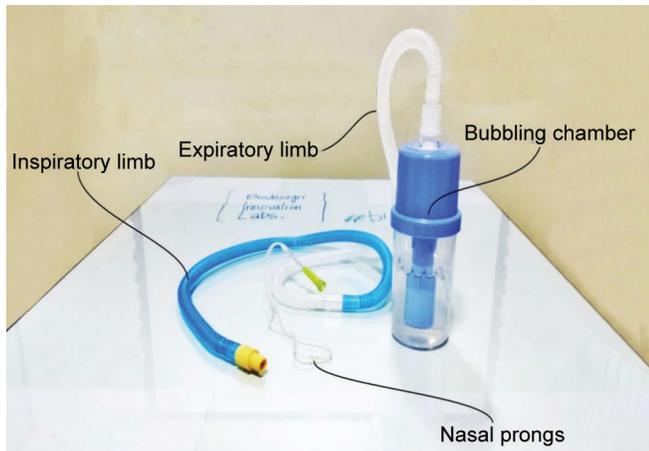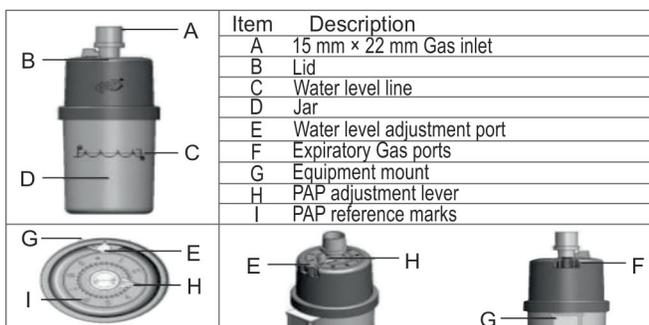
Fig. 1: Design of ResPAP kit

Item	Description
A	15 mm × 22 mm Gas inlet
B	Lid
C	Water level line
D	Jar
E	Water level adjustment port
F	Expiratory Gas ports
G	Equipment mount
H	PAP adjustment lever
I	PAP reference marks

Fig. 2: PAP valve specification

MATERIALS AND METHODS

This was a prospective observational study conducted over 3 months (March 2019 to May 2019), in a 12-bed PICU of an academic and referral hospital. The study was reviewed and approved by the Institutional Ethics Committee (IEC) (142/2019) and clinical trial registry-India (CTRI/2021/08/035409). Written informed consent was obtained from the parents/ guardians.

Children from 6 months of age to 60 months of age, with difficulty in breathing, fast breathing (respiratory rate >50/min in 6–11 months, >40/minute if ages 12–59 months) or with hypoxemia (SpO$_2$ <90%) or respiratory distress despite oxygen therapy were recruited in the study. Severity of respiratory distress was assessed by the following variables – respiratory rate, air entry, retractions, grunt, saturation in room air and level of consciousness. Modified Wood-Downes score was used to grade the severity.[9] Children with congenital heart disease, chronic lung disease or immediate need for invasive respiratory support were excluded.

Device Description

The ResPAP™ Kit consists of an air flow unit (AFU), a pressure generator (PAP valve) and a nasal interface. When assembled, the nasal interface is attached to the patients' nares and one end of the AFU is connected to the air/oxygen supply (Fig. 1). Gas passes through the AFU to the nasal prong and to the patient. The clinician can provide noninvasive positive pressure ventilation, by regulating the gas flow to the circuit and the magnitude of the positive pressure can be controlled by adjusting the regulator in the PAP valve (Fig. 2). The flow rate was initiated at 5 liters/minute

and gradually increased to 8–10 liters/minute to deliver the CPAP effect. The oxygen blender was used to titrate the fraction of inspired oxygen (FiO$_2$) to maintain the SpO$_2$ >94%. The ResPAP circuit was tested for consistency in delivering pressure and it was shown to provide pressure values consistent with the value set at the PAP regulator with an error range of +/–0.3 cm H$_2$O pressure. Details of device design and validation are provided in Annexure 1.

Therapy was continued for at least 24 hours and weaning was considered after sustained improvement in the respiratory distress score (RDS) for at least 6–8 hours. Failure of bCPAP was defined if SpO$_2$ <94% on FiO$_2$ >60% with CPAP >8 cm H$_2$O at any time or severe respiratory distress requiring invasive ventilation. Vital parameters were monitored hourly and bCPAP flow circuit was checked for leakage and underwater bottle for bubbling. In addition, children receiving bCPAP therapy were monitored for complications such as air leaks, pneumothorax, and local redness. Baseline demographic data, such as age, sex, weight, PRISM III scores, and relevant blood tests if any available were collected in predesigned proforma. The following data were collected prospectively after initiating and at 1, 6, 24, 36, and 48 hours of bCPAP: heart rate, respiratory rate, SpO$_2$, and RDS. Blood gas analysis was done before the initiation of bCPAP in all children and repeated 6 hours after the initiation of the therapy. Total duration of bCPAP therapy and complications if any and length of ICU were captured. Patients were followed up till hospital discharge. All patients admitted to the PICU with respiratory distress during the study period received therapies as per our unit protocol.

The data were compared with the cohort of age, sex, and PRISM III score-matched children treated for respiratory distress with high-flow nasal cannula (Fisher & Paykel Healthcare Airvo2) admitted from June to August during the same year.

Statistical Analysis

All parameters that were collected and relevant were summarized by descriptive statistics, such as mean ± SD or median (IQR) for symmetric or nonsymmetric shape of continuous variables, respectively. However, qualitative data were summarized by frequency and percentage. Further parameters of interest were compared between bCPAP and high-flow humidified nasal cannula (HFNC) groups. Mean was compared by independent t-test for symmetric shape of distribution, otherwise Mann–Whitney test was used for the median. A Chi-square test of independence was used to compare the proportions of different levels of categorical parameters between bCPAP and HFNC groups. Linear mixed model analysis was performed to compare the change in the trend of heart rate, respiratory rate, and RDS over 72 hours of ICU stay between bCPAP and HFNC. $p < 0.05$ is considered statistically significant. The statistical software StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC was used to analyze and visualize the data.

RESULTS

A total of 52 children with respiratory infections were admitted to PICU. At the time of admission, bCPAP was administered in 20 children, and a low-flow oxygen device (simple face mask and nasal prongs) was used in 18 cases. 10 children (55%) on low-flow device were shifted to bCPAP for worsening distress. Four children (age >5 years) were treated with high-flow nasal canula, 10 patients were invasively ventilated and low-flow oxygen device (simple face mask and nasal prongs) was continued in 8 cases. The total number of

children requiring bCPAP was 30. The median (IQR) age of study group was 24 months (11–48) with 60% males. The most common cause of respiratory distress requiring bCPAP was pneumonia (66.7%) followed by pleural effusion (20%) and bronchiolitis (13.3%). The median (IQR) CPAP duration in the study was 48 (27–48) hours. One child failed bCPAP therapy after 6 hours requiring ventilation. Blood gas analysis was done before the initiation of bCPAP in all children, 9 of them had PaO_2 less than 80 mm of Hg and the remaining had normal PaO_2 and PCo_2. The most common chest X-ray finding was bilateral alveolar infiltrates (Table 1). The median duration of PICU stay was 4 (4–5) days.

The median (IQR) RDS gradually improved to 3.8 (3.4–4), 3.4 (3–3.6) and 1.8 (1.5–2.1) at 1 hour, 6 hours, and at 48 hours, respectively. Likewise, we observed significant ($p < 0.05$) improvement in the heart rate and respiratory rate at 1 hour, 6 hours, and 48 hours after commencing bCPAP therapy. No complications were observed in the study group.

On further analysis between HFNC and bCPAP group, we noted no significant difference in baseline parameters (Table 2). Although we found that there was a steady decrease in the heart rate and respiratory rate in both the groups over 48 hours, the rate of decline was faster in HFNC group during initial 12 hours (Fig. 3). On the contrary, there was no difference in the improvement in oxygen saturation and RDS between the groups. No significant difference was observed in the median PICU stay between nasal bCPAP and HFNC group [4 days (4–8) vs 4 (3–5)] (Table 2).

DISCUSSION

In our study, we noted that bCPAP was well tolerated and easily administered. Except for one, all were successfully treated.

**Table 1:** Baseline characteristics in bubble CPAP group

	Total (N = 30)
Age in months, median (IQR)	24 (11–48)
Sex	
Female	12 (40%)
Male	18 (60%)
Indications	
Pneumonia	20 (66.7%)
Bronchiolitis	4 (13.3%)
Pleural effusion	6 (20%)
Chest X-ray features	
Consolidation	5
Infiltrates	18
Pleural effusion	8
CPAP duration in hours, median (IQR)	48 (27–48)
CPAP failure	1 (3.33%)
Complications	0
PICU stay in days, median (IQR)	4 (4–5)

CPAP, continuous positive airway pressure; IQR, interquartile range; PICU, pediatric intensive care unit

Table 2: Comparison between bubble CPAP and HFNC group

	Bubble CPAP (n = 30)	HFNC (n = 30)	p-value
Duration of PICU stay median (IQR)	4 (4,5)	4 (3,5)	0.47
Respiratory rate (per min) at admission, Mean (standard deviation)	39 (12)	43 (13)	0.4
Heart rate (per min) at admission, Mean (standard deviation)	124 (23)	128 (22.5)	0.3
Diagnosis			
Pneumonia	20 (66.7%)	22 (73.3%)	0.5
Bronchiolitis	4 (13.3%)	6 (20%)	0.6
Pleural effusion	6 (20%)	2 (6.7%)	0.3
Duration of support in hours, median (IQR)	48 (27–48)	40 (30–48)	0.5
Treatment failure	1 (3.3%)	1 (3.3%)	0.6

CPAP, continuous positive airway pressure; HFNC, high-flow nasal cannula; IQR, interquartile range; PICU, pediatric intensive care unit
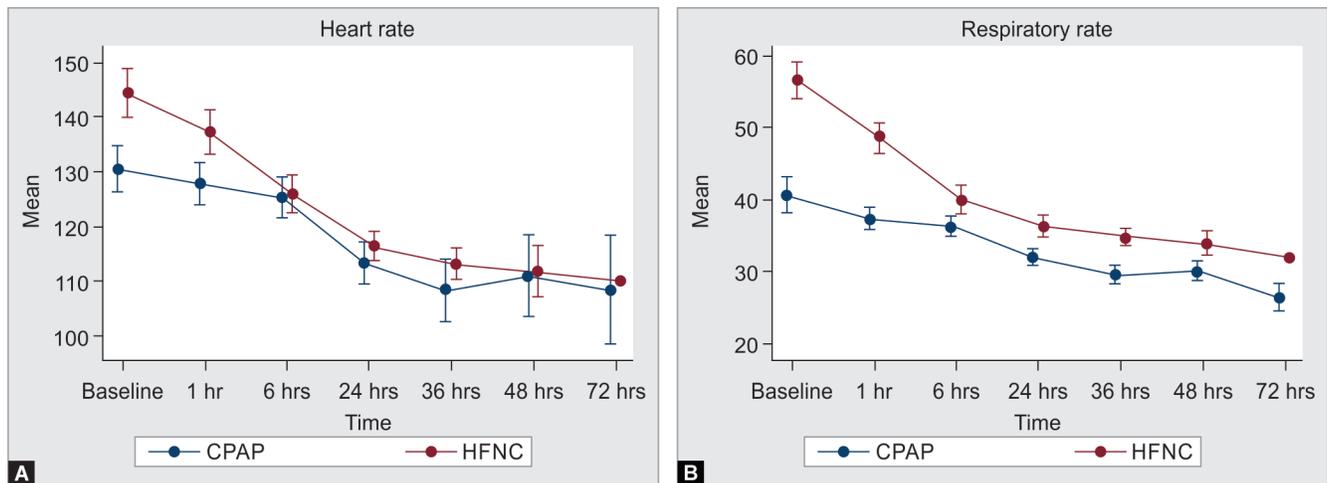
Figs 3A and B: Graph depicting response of heart rate and respiratory rate after initiation of CPAP and HFNC
CPAP, continuous positive airway pressure; HFNC, high-flow nasal cannula

As a mode of respiratory support, bCPAP is widely studied in neonates. Randomized study compared bCPAP with ventilator delivered CPAP in preterm found no difference in the work of breathing and respiratory parameters in both groups.[10] A retrospective study by Lee et al. concluded that the initiation of bCPAP in the delivery room reduced the number of ventilated days.[11] In resource-limited setting, bCPAP is utilized as the first line respiratory support in newborns due to better safety profile, easy to administer and cost.[12–14]

There is insufficient data to contemplate the beneficial effects of bCPAP in children with respiratory distress and it is mostly studied in the treatment of bronchiolitis.[15–18] CPAP delivered via a mechanical ventilator may not be available in most health facilities in developing countries. Anitha et al.[19] used flow inflating device (Mapleson D and F circuits) as an indigenous way of providing CPAP and found successful in 89.7% of the study population. Children with bronchiolitis (98.3%) were successfully managed with CPAP but the amount of CPAP and FiO_2 could not be titrated. In a study by Jayshree et al.[7] CPAP was delivered using a bubbling circuit and the height of the water column was adjusted to titrate the amount of CPAP. In our study, CPAP was delivered using ResPAPTM kit (indigenously prepared by Biodesign Innovation Labs Pvt Ltd) and accurate amount of CPAP was delivered by adjusting the regulator in the PAP valve.

Increased transpulmonary pressure generated by CPAP prevents the collapse of small airways during the expiration[7] and it also abolishes the airway occlusion and improves diaphragmatic tone.[8]

In the present study, improvement in the heart rate, respiratory rate, and RDS was noted after commencing bCPAP. A study from the resource-limited setting by Jayashree et al.[7] used bCPAP in 110 patients. The mean fall in respiratory rate in the bCPAP group at 2 and 6 hours was 6.3 ± 4.7 (4) and 12.1 ± 5.3 (10) ($p = 0.001$), respectively. Prospective observational study by Pulsan et al.[20] on 64 children also observed improvement in RDS and SpO_2 after the initiation of CPAP therapy. We compared the rate of decline in the heart rate and respiratory rate between bCPAP and HFNC group. We found that there was a steady decline in the heart rate and respiratory rate in both the groups over 48 hours although the decline in the heart rate and respiratory rate during the initial 12 hours was favorable in the HFNC group than the bCPAP group. Retrospective study by Metge et al.[18] compared nasal CPAP (nCPAP) to HFNC in infants with acute bronchiolitis and found no difference with respect to respiratory rate and heart rate response. However, a study by Pedersen MB et al.[17] observed that CPAP was superior to HFNC in reducing respiratory rates. On the contrary, results from prospective, randomized, open-label pilot study by Mihir S et al. on 31 children suffering from bronchiolitis showed HFNC was better tolerated than CPAP (delivered via ventilator) in decreasing the heart rate and lower incidence of nasal injury (46.66% vs 75%; $p = 0.21$).[21]

There was no significant difference in median PICU stay between the two groups in the present study. The result is comparable to the previous study.[15] Randomized controlled trial (RCT) by Cesar RG et al.[16] on infants with bronchiolitis showed similar results. There was no difference in the pediatric intensive care unit length of stay between the CPAP and HFNC groups [5 (4–7) days and 5 (4–8) days, $p = 0.46$, respectively].

Our study did not show any difference in failure rate between CPAP and HFNC group. Our results align with the results of the study by Cesar RG et al.[16] where CPAP therapy failed in 10 children (36%) and HFNC failure was seen in 13 patients (37%). An open, RCT by Chisti J et al.[22] from Bangladesh noted no difference in the failure rate between bCPAP and high-flow nasal cannula (6% vs 13%).

Small sample size and non-randomized design are the major limitations of our study. We used India's first indigenous bCPAP for pediatrics and uniqueness of ResPAPTM kit lies in its ease of use and easy to set-up. An accurate amount of CPAP was delivered by adjusting the regulator in the PAP valve. A unique feature of our study was the usage of bCPAP for respiratory distress due to varied etiology such as bronchiolitis, pneumonia and pleural effusion.

CONCLUSION

Our study found bCPAP to be effective in pediatric populations with respiratory distress. It can be used as safer mode of respiratory support, alternative to high-flow nasal cannula in children with respiratory distress. Larger prospective studies (RCTs) using bCPAP are required to confirm our findings.

ORCID

Lalitha AV https://orcid.org/0000-0002-6168-1677
Chandrakant G Pujari https://orcid.org/0000-0002-0485-5802
John Michael Raj https://orcid.org/0000-0002-1526-7432

SUPPLEMENTARY MATERIALS

All the supplementary material are available online on the website of www.ijccm.org

REFERENCES

1. Hasan MM, Saha KK, Yunus RM, Alam K. Prevalence of acute respiratory infections among children in India: Regional inequalities and risk factors. Matern Child Health J 2022;26(7):1594–1602. DOI: 10.1007/s10995-022-03424-3.
2. McAllister DA, Liu L, Shi T, Chu Y, Reed C, Burrows J, et al. Global, regional, and national estimates of pneumonia morbidity and mortality in children younger than 5 years between 2000 and 2015: A systematic analysis. Lancet Glob Health 2019;7:e47–e57. DOI: 10.1016/S2214-109X(18)30408-X.
3. Subhi R, Adamson M, Campbell H, Weber M, Smith K, Duke T, et al. The prevalence of hypoxaemia among ill children in developing countries. Lancet Infect Dis 2009;9:219–227. DOI: 10.1016/S1473-3099(09)70071-4.
4. Duke T, Frank D, Mgone J. Hypoxaemia in children with severe pneumonia in Papua New Guinea. Int J TB Lung Dis 2000;5:511–519. PMID: 11409576.
5. Graham SM, English M, Hazir T, Enarson P, Duke T. Challenges to improving case management of childhood pneumonia at health facilities in resource-limited settings. Bull World Health Organ 2008; 86:349–355. DOI: 10.2471/BLT.07.048512.
6. Ramachandran P, Nedunchelian K, Vengatesan A, Suresh S. Risk factors for mortality in community acquired pneumonia among children aged 1–59 months admitted in a referral hospital. Indian Pediatr 2012;49(11):889–895. DOI: 10.1007/s13312-012-0221-3.
7. Jayashree M, Kiran Babu HB, Singhi S, Nallasamy K. Use of nasal bubble CPAP in children with hypoxemic clinical pneumonia-report from a resource limited set-up. J Trop Pediatr 2016;62(1):69–74. DOI: 10.1093/tropej/fmv063.

8. Smith AG, Eckerle M, Mvalo T, Weir B, Martinson F, Calira A, et al. CPAP IMPACT: A protocol for a randomised trial of bubble continuous positive airway pressure versus standard care for high-risk children with severe pneumonia using adaptive design methods BMJ Open Resp Res 2017;4(1). DOI: 10.1136/bmjresp-2017-000195.

9. Wood DW, Downes JJ, Lecks HI. A clinical scoring system for the diagnosis of respiratory failure. Preliminary report on childhood status asthmaticus. Am J Dis Child 1972;123(3):227–228. DOI: 10.1001/archpedi.1972.02110090097011.

10. Koyamaibole L, Kado J, Qovu JD, Colquhoun S, Duke T. An evaluation of bubble-CPAP in a neonatal unit in a developing country: Effective respiratory support that can be applied by nurses. J Trop Pediatr 2006;52(4):249–253. DOI: 10.1093/tropej/fmi109.

11. Lee KS, Dunn MS, Fenwick M, Shennan AT. A comparison of underwater bubble continuous positive airway pressure with ventilator-derived continuous positive airway pressure in premature neonates ready for extubation. Biol Neonate 1998;73(2):69–75. DOI: 10.1159/000013962.

12. Upadhyay A, Deorari AK. Continuous positive airway pressure – A gentler approach to ventilation. Indian Pediatr 2004;41(5):459–469. PMID: 15181296.

13. Kaur C, Sema A, Beri RS, Puliyel JM. A simple circuit to deliver bubbling CPAP. Indian Pediatr 2008;45(4):312–314. PMID: 18451452.

14. Cambonie G, Milési C, Jaber S, Amsallem F, Barbotte E, Picaud JC, et al. Nasal continuous positive airway pressure decreases respiratory muscles overload in young infants with severe acute viral bronchiolitis. Intensive Care Med 2008;34:1865–1872. DOI: 10.1007/s00134-008-1201-x.

15. Vamvakiti E, Saha A, Linney M. 510 Use of nasal Cpap in infants with bronchiolitis in the South of England: A prospective, multicentre, observational study. Pediatric Research 2010;68(1):261–261. DOI: 10.1203/00006450-201011001-00510.

16. Cesar RG, Bispo BRP, Felix PHCA, Modolo MCC, Souza AAF, Horigoshi NK, et al. High-flow nasal cannula versus continuous positive airway pressure in critical bronchiolitis: A randomized controlled pilot. J Pediatr Intensive Care 2020;9(4):248–255. DOI: 10.1055/s-0040-1709656.

17. Pedersen MB, Vahlkvist S. Comparison of CPAP and HFNC in management of bronchiolitis in infants and young children. Children (Basel) 2017;4(4):28. DOI: 10.3390/children4040028.

18. Metge P, Grimaldi C, Hassid S, Thomachot L, Loundou A, Martin C, et al. Comparison of a high flow humidified nasal cannula to nasal continuous positive airway pressure in children with acute bronchiolitis: Experience in a pediatric intensive care unit. Eur J Pediatr 2014;173:953–958. DOI: 10.1007/s00431-014-2275-9.

19. Anitha GF, Velmurugan L, Sangareddi S, Nedunchelian K, Selvaraj V. Effectiveness of flow inflating device in providing continuous positive airway pressure for critically ill children in limited-resource settings: A prospective observational study. Indian J Crit Care Med 2016;20(8):441–447. DOI: 10.4103/0972-5229.188171.

20. Pulsan F, Sobi K, Duke T. Continuous positive airway pressure in children with severe pneumonia and hypoxaemia in Papua New Guinea: An evaluation of implementation. Acta Paediatr 2019;108(10):1887–1895. DOI: 10.1111/apa.14796.

21. Sarkar M, Sinha R, Roychowdhoury S, Mukhopadhyay S, Ghosh P, Dutta K, et al. Comparative study between noninvasive continuous positive airway pressure and hot humidified high-flow nasal cannulae as a mode of respiratory support in infants with acute bronchiolitis in pediatric intensive care unit of a tertiary care hospital. Indian J Crit Care Med 2018;22(2):85–90. DOI: 10.4103/ijccm.IJCCM_274_17.

22. Chisti MJ, Salam MA, Smith JH, Ahmed T, Pietroni MA, Shahunja KM, et al. Bubble continuous positive airway pressure for children with severe pneumonia and hypoxaemia in Bangladesh: An open, randomised controlled trial. Lancet 2015;386(9998):1057–1065. DOI: 10.1016/S0140-6736(15)60249-5.

Annexure 1

Design History and Validation

Pneumonia affects the alveoli and interferes with the delivery of oxygen from the air sacks into the blood. CPAP (continuous positive airway pressure) is a relatively inexpensive mode of noninvasive ventilation. Bubble CPAP has been used.

Successfully in some referral hospitals in developing countries. The system has three components:

1. **Continuous gas flow into the circuit:** The gas flow rate required to generate CPAP is usually 5–10 L/minute. The system also usually requires an oxygen blender, which connects an oxygen source (cylinder or concentrator) to the continuous airflow to increase FiO_2.
2. **A nasal interface connecting the infant's airway with the circuit:** Short nasal prongs are generally used to deliver nasal CPAP. They must be carefully fitted to minimize leakage of air (otherwise, CPAP will not be achieved) and to reduce nasal trauma.
3. **An expiratory limb with the distal end submerged in water to generate end expiratory pressure:** In bubble CPAP, the positive pressure is maintained by placing the far end of the expiratory tubing in water. The pressure is adjusted by altering the depth of the tube under the surface of the water.

The design intent behind the circuit is: "to create a higher ambient pressure for the patient to inhale and exhale supplemental oxygen" This requires a breathing circuit with a flow generator, PEEP generator and the nasal interface (Annexure Fig. 1). The flow can be derived from the oxygen source and the pressure can be developed by constricting this flow. This constricted flow must be maintained in a chamber, which would be the source of gas at higher pressure relative to atmospheric pressure, in this case the gas is oxygen or air–oxygen mixture. If a nasal interface is attached to this pressure chamber and positioned on the patient's nares tightly, she could breathe at a higher ambient pressure, thus the system would be delivering CPAP. This pressure chamber could be integrated to the circuit itself, essentially making an AFU. A nasal prong could be connected at a convenient length in this AFU. The distal end of the AFU should be connected to a valve that offers resistance to flow. A water column offers the required pressure depending on the depth to which the gas outlet is submerged to.

Validation for the concept was done at various government and private tertiary and secondary care centers in Bengaluru including Bengaluru Medical College and Indira Gandhi Institute for Child Care, and feedback was taken. Peripheral centers were studied prior to this with questionnaires. regarding the concept and the current standards of treatment. This spanned over 20 hospitals and 54 clinicians. Most of the doctors felt the need for the device and approved of its potential use at resource poor settings, and at tertiary centers during emergencies as an alternative for normal nasal oxygen therapy. The feedback for possible design improvements was taken for the next iteration, which was essentially the use of a better and user-friendly bubbling chamber, longer tubing and provision for a passive humidifier.

Specifications of Current ResPAP Design

Inspiratory tube Size: ≈ 1.5 cm diameter X ≈ 75 cm length
Expiratory tube Size: ≈ 1.5 cm diameter X ≈ 75 cm length
Gas Inlet Connector: 360° swivel 15 mm I.D. x 22 mm O.D. connector
Gas Flow Range: 1 to 12 liters per minute
Adjustable Range: 0 to 10 cm H_2O
Accuracy: ±1 cm H_2O to lid set point
Reservoir capacity:
Low Water Line: ≈ 330 mL
Mean Water Line: ≈ 350 mL
High Water Line: ≈ 370 mL
Size: ≈ 9.5 cm diameter X ≈ 25 cm height
Weight: Empty: ≈ 162 grams, at Mean Water Line: ≈ 522 grams
Supplementary Figure 1 provides a detailed depiction of the basic airway circuit, is available for reference on the journal's website.

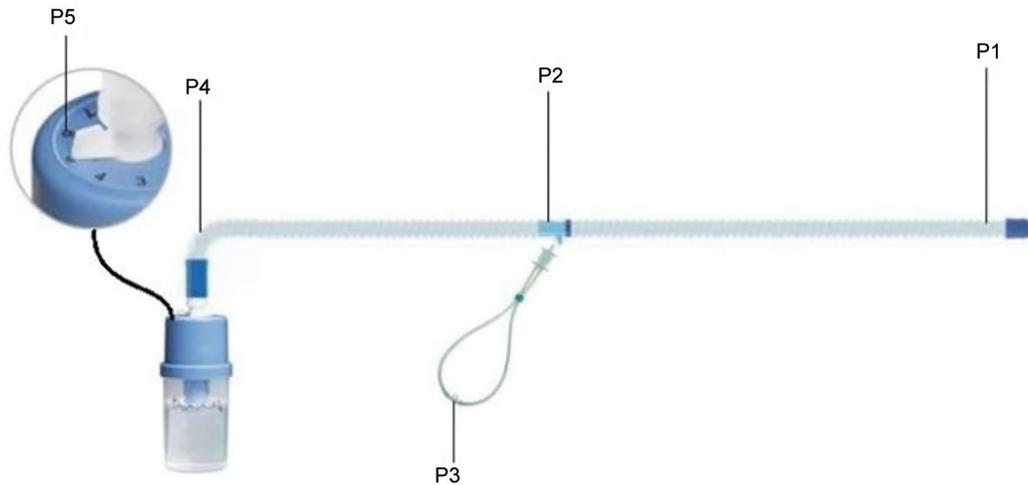## Test for Consistency in Pressure Delivered

A nares template for CPAP prongs served as a sizing template for the simulated nares model (Annexure Fig. 2).

Annexure Fig. 1: Sampling pressure values in the circuit

Annexure Fig. 2: Simulated nares, connects to test lung

P1: Point in the Inspiratory Limb, proximal to the flow generator.	P2: The junction between the nasal interface and the inspiratory limb.	P3: At the nasal prong.	P4: Expiratory limb, proximal to bubbling chamber.	P5: Pressure set at the PAP valve regulator.

P1 min	P1 max	P1 cm	P2 min	P2 max	P2 cmH$_2$O	P3 min	P3 max	P3 cmH$_2$O	P4 min	P4 max	P4 cmH$_2$O	P5 cmH$_2$O
1.7	2.5	2.1	1.8	2.5	2.1	1.7	2.3	2.0	1.9	2.6	2.2	2.0
3.6	4.3	3.9	3.6	4.4	4.0	3.6	4.5	4.0	3.6	4.6	4.1	4.0
5.3	6.3	5.8	5.3	6.1	5.7	5.3	6.2	5.7	5.6	6.3	5.9	6.0
7.2	8.3	7.7	7.3	8.0	7.6	7.3	8.3	7.8	7.7	8.3	8.0	8.0

Annexure Fig. 3: Test results

Medium-sized nares fixtures were constructed and connected to a 1 Liter test lung. Lung compliance and resistance were 0.5 mL/cm H$_2$O and 125 cm H$_2$O/L/s, respectively for the test lung in use. Nasal cannulas were inserted in the model nares assuring that the prong occlusion of the nares did not exceeded 50%. Flow was fixed at 8 L/min of filtered atmospheric air, which was the constant value provided by the flow generator (air compressor) in use. For measuring the differential pressure developed in the circuit during operation, a digital manometer (HTC PM-6102; Range +/-140.6 cm H$_2$O; Resolution 0.1 cmH$_2$O; Accuracy +/-0.3%) was used. Pressure measurement was sampled at 4 unique points in the circuit viz,

P1: Point in the Inspiratory Limb, proximal to the flow generator.
P2: At the junction between the nasal interface and the inspiratory limb.

P3: At the nasal prong.
P4: Expiratory limb, proximal to bubbling chamber.
P5: Pressure set at the PAP valve regulator.

Pressure data were averaged over the minimum and maximum values that occurred during an observation for 1 minute (this fluctuation in pressure values over a minimum and maximum range is attributed to the bubbling action in the bubbling chamber). Mean airway circuit pressure and percent change between the set value at the PAP valve and mean pressure at the nasal model were recorded (Annexure Fig. 3).

In conclusion, the ResPAP airway circuit is shown to provide pressure values consistent with the value set at the PAP regulator with an error range of +/-0.3 cmH$_2$O pressure. It is to be noted that, the effective pressure delivered to the patient is largely dependent

on the right positioning/selection and placement of the nasal cannula, and this test has assessed and understood the consistency of pressure in the circuit with respect to the pressure set at the PAP valve. It was also assessed that there is no significant leakage of gases in the circuit assembly as to create an observable drop, even after prolonged use and handling.