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# **Original Research Article**

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Bubble continuous positive airway pressure machine versus indigenous bubble continuous positive airway pressure as a respiratory support in preterm babies with respiratory distress syndrome: a prospective outcome research at a tertiary care centre in Gujarat, India

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## **ABSTRACT**

**Background:** In India, there is high burden of prematurity in newborns due to high birth rate and lack of good antenatal care. The objective of this study was to compare the outcome (efficacy and safety) of Bubble Continuous Positive Airway Pressure (B-CPAP) machine and Indigenous Bubble Continuous Positive Airway Pressure (I-CPAP) as a primary mode of respiratory support in preterm new-borns with respiratory distress syndrome (RDS). It was a prospective observational comparative study conducted at NICU of a tertiary care teaching hospital of western Gujarat, India, from December 2016 to July 2017.

**Methods:** Eighty-one preterm babies <36 weeks of gestation age with respiratory distress (Silverman Anderson scoring >4) within 6 hours of birth were included (out of 182 preterm newborns with respiratory distress syndrome) and put on respiratory support either with B-CPAP machine (n = 48) or with I-CPAP (n = 33). Outcome was compared in the form of CPAP failure, survival and complication rates.

**Results:** There was no significant difference in the demographic profile of patients in both groups except number of neonates between 1.5-2.5 kg birth weight were significantly high in B-CPAP (45.8%) compared to I-CPAP (33.3%) (p = 0.00074). There were no significant differences in CPAP failure rates in B-CPAP (27%) versus I-CPAP (24.2%). The survival rate (72.9% in B-CPAP) versus (75.7% in I-CPAP) in both groups was also similar (CI 95%, p = 0.774). The complications, such as moderate to severe nasal septal damage, occurred significantly more frequent with B-CPAP machine (47.9%) than on I-CPAP (6%) (CI 95%, p = 0.000062).

**Conclusions:** Efficacy of I-CPAP as a primary mode of respiratory support for preterm new-born with respiratory distress was comparable to B-CPAP. The ease with which it can be assembled makes it a suitable alternative to B-CPAP.

Keywords: B-CPAP, CPAP failure, Indigenous continuous positive airway pressure, Respiratory distress syndrome

### INTRODUCTION

In India, there is high burden of prematurity in new-borns due to high birth rate and lack of good antenatal care.

Lack of awareness and suboptimal perinatal practices, result in frequent RDS in premature babies. Incidence and mortality reported due to Respiratory Distress

Syndrome (RDS) is 1.2% and 13.5% respectively among live births each year in India.<sup>2</sup>

Bubble continuous positive airway pressure (B-CPAP) is a well-established mode of respiratory support in preterm new-borns with RDS.<sup>3</sup> It helps by preventing the alveolar collapse and increasing functional residual capacity (FRC) of lungs.<sup>4</sup> B-CPAP is proved to be superior as compared to ventilator derived CPAP in premature infants. Bubble CPAP differs from conventional CPAP in that B-CPAP expiratory limb is placed in underwater seal which causes oscillatory vibration of chest due to gas flow under water, which is transmitted to infant's airway. These vibrations simulate waveforms produced by high frequency ventilation, but B-CPAP machine is costly (approximate cost Rs. 1.5-2 lacs) and is not often available in adequate numbers in many NICUs of our country.<sup>5</sup>

While indigenously assembled B-CPAP (costs around Rs. 500 except the humidifier which is available for Rs. 4500-8000) can prove to be effective and non-invasive way to provide ventilation to patients of RDS in a setup with limited resources.<sup>6,7</sup> It can be used as a delivery room CPAP at peripheral health centres and for transport of new-borns to tertiary care hospital.

Widespread use of this system has the potential for saving lives in small hospitals where there is no facility for mechanical ventilation. To the best of our knowledge and literature search; we could not find any study which compared outcome of Bubble CPAP machine with Indigenous Bubble CPAP. Therefore, the goal of this study was to compare the efficacy and safety (survival and complication rates) of Bubble CPAP machine (B-CPAP) with Indigenous Bubble CPAP (I-CPAP) in preterm neonates with RDS.

### **METHODS**

This prospective observational comparative study was conducted at NICU of a tertiary care teaching hospital of western Gujarat, India, for 8 months, from December 2016-July 2017. The study was approved by Institutional Ethics Committee.

During the study period 182 newborns with RDS were admitted. Of these, 81 preterm babies ≤36 weeks of gestation age with respiratory distress (Silverman Anderson scoring >4) within 6 hours of birth, with chest X-ray suggestive of RDS, were included in the study.<sup>8</sup> New-borns with respiratory distress due to other causes (birth asphyxia, meconium aspiration syndrome, sepsis, major congenital malformation, inborn error of metabolism etc.) were excluded from the study. Written informed consents were obtained from parents. Detailed antenatal and natal history was noted.

We preferred B-CPAP machines as the initial form of respiratory support with short binasal prongs. If B-CPAP

machine was not available then an I-CPAP, assembled from locally available materials in our NICU with due care to prevent air leak under aseptic precautions, was used.

There are two ways of making I-CPAP. One is by the use of Intercostal Drainage (ICD) bag, Endotracheal tube (ET) connector, nasal prongs and needle cap. Another way is by using a 3 ways cannula, an empty 500 ml IV fluid bottle, IV set and nasal prongs. The techniques are described in Box I.

## Methods of preparing I-CPAP

## Technique I

Take one nasal prong and cut one of its patient inlet tubes. Block one end of the tube which has been cut with cap of needle and attach ET tube connector to the other end of tube which has been cut. Another end of ET connector is joined with ICD bag. Oxygen supply comes from humidifier end of nasal prongs. ICD bag needs to be filled with distilled water with 0.25% acetic acid. The level of water in centimetres corresponds to Positive End Expiratory Pressure (PEEP). ICD bag should be placed below the level of the newborn (Figure I).

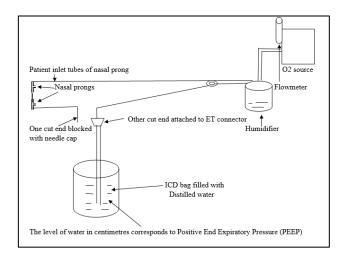


Figure 1: Indigenous CPAP (with use of ICD bag).

## Technique II

First of all, cut the common tube of nasal prongs; attach a three-way to both cut ends of nasal prongs so that one end will go to patient inlet and other to oxygen source via humidifier. Attach 3<sup>rd</sup> channel of 3 ways to IV set with other end of IV set brought into bottle and fill this bottle up to 10 cm level of distilled water with 0.25% acetic acid to generate PEEP.

Pressure is regulated by depth of submerged end of the IV set tube. Bottle should be placed below the level of newborn. An appropriate size of nasogastric feeding tube is placed and kept open to reduce distension of stomach (Figure 2).

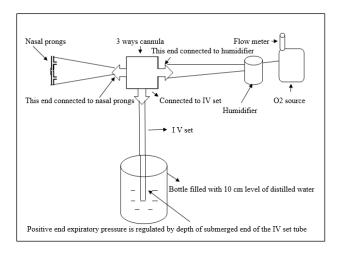


Figure 2: Indigenous CPAP (with use of 3-way cannula).

Initially, PEEP was set at 5 cm of H<sub>2</sub>O with flow rate 4-5 litre/min to produce steady stream of bubbles in water in both B-CPAP and I-CPAP. However, FiO<sub>2</sub> which was initially set at 0.4 (40%) in B-CPAP only is not possible to be set in I-CPAP. Continuous monitoring of vitals, Silverman Anderson scoring and SpO<sub>2</sub> was done. Chest X-ray and Arterial Blood Gas Analysis (ABGA) were done as and when required to monitor and for changing CPAP settings which were adjusted to maintain SpO<sub>2</sub> at 90-95%, PaO<sub>2</sub> at 55-80 mmHg, PaCO<sub>2</sub> at 40-55 mmHg and pH at 7.3-7.4.

Surfactant (Survanta -100 mg/kg or 4 ml/kg) was given by Intubation Surfactant Extubation (INSURE) technique as soon as possible, to those patients who had moderate to severe RDS on chest X-ray or/and required >0.4 FiO<sub>2</sub>. Patients who were not maintaining SpO2 >89% even on maximum parameters (PEEP 8 cm of water and FiO<sub>2</sub> 0.8) or ABGA was showing PaO2 <50 mmHg, PaCO2 >60 mmHg, pH <7.2 or developing recurrent episodes of apnoea (>3 episodes within 24 hours) or had severe metabolic acidosis or developed shock requiring inotropic support after 24 hours of starting CPAP; these patients were shifted to mechanical ventilators and were considered as CPAP failure cases.

Patients were weaned off from CPAP when the ABGA values were normal;  $SpO_2$  was between 90-95% on <4 cm  $H_2O$  PEEP and Silverman Anderson score between 0 and1 (requiring <0.3 FiO<sub>2</sub> in B-CPAP). After weaning, patients were shifted to  $O_2$  hood. Time of weaning from Bubble-CPAP and  $O_2$  hood was noted.

Patient's data such as birth weight, gestational age (new Ballard score), history of antenatal steroid, any significant antenatal history, history of resuscitation, Silverman Anderson score (SAS), shake test result, X-ray chest (CXR), arterial blood gas analysis (ABG), FiO2 and PEEP values of B-CPAP on admission, were recorded.

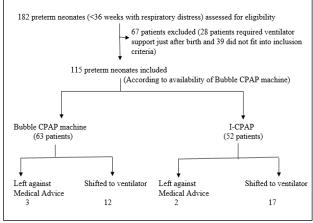
Based on CXR, severity of RDS was graded as mild (mild granularity of lung), moderate (generalized granularity of lung on air bronchogram with preserved cardiac borders) and severe (white out lung with loss of cardiac borders).

Patients were discharged when all complications resolved, and oral feed was accepted. Patients were screened for Retinopathy of Prematurity (ROP), Bronchopulmonary Dysplasia (BPD) and Periventricular Leukomalacia (PVL) (as seen in cranial USG on 7<sup>th</sup> day, at the time of discharge and at 40 weeks of gestational age) during admission and on follow up visits. <sup>10,11</sup>Outcome parameters observed were duration of oxygen therapy in form of CPAP and O<sub>2</sub> hood, duration of hospital stay, CPAP failure, survival rate and complication rate.

The data so collected was tabulated in Microsoft excel and quantitative statistical analysis (Chi square and t-test) was done. A p value <0.05 was considered significant

## **RESULTS**

Out of 182 preterm babies with RDS, 81 babies fulfilled inclusion criterion (Figure 3).



48 patients included in B-CPAP Group 33 patients included in I-CPAP Group

Figure 3: Indicating patients' inclusion and exclusion.

Out of 48 patients in B-CPAP group, 64.5% were males. This group had a mean gestational age of 31.7 weeks and mean birth weight of 1.480 kg. Similarly, out of 33 patients in I-CPAP group, 45.4% were males. The mean gestational age and weight for this group were 30.01 weeks and 1.483 kg respectively (Table 1).

Number of neonates between 1.5-2.5 kg birth weight were significantly high in B-CPAP (45.8%) compared to I-CPAP (33.3%) (p=0.00074). Surfactant was given to 14.5% and 9% patients of B-CPAP and I-CPAP respectively.

As shown in Table 2, there was no significant difference between the two groups with respect to average SAS score on admission, average starting PEEP value, average duration on CPAP and oxygen hood, average duration of hospital stay, survival rate and CPAP failure rate.

Table 1: Demographic profile of patients.

Characteristics		B-CPAP Machine (n=48) No. (%)	I-CPAP (n=33) No. (%)	P-value
Male:Female**		31:17	15:18	0.0877
Gestation age (weeks)	*	31.7 (2.8)	30.01 (2.74)	0.416
	<28 #	9 (18.7%)	3 (9.0%)	0.422
	29 – 32 #	18 (37.5%)	17 (51.5%)	0.50
	33 – 36 #	21 (43.7%)	13 (39.3%)	0.333
Birth weight (kilogram)	*	1.480 (0.346)	1.483 (0.319)	0.055
	<1#	3 (6.2%)	2 (6.0%)	0.068
	1-1.5#	23 (47.9%)	20 (60.6%)	0.083
	1.5-2.5#	22 (45.8%)	11 (33.3%)	0.00074
Inborn/Outborn**		30/18	23/10	0.503
Mode of delivery**	Vaginal / LSCS	40 / 8	27 / 6	0.859
Antenatal steroid dose#	Complete##	3 (6.25%)	5 (15.1%)	0.664
	Incomplete##	4 (8.33%)	1 (3.0%)	
Maternal complications#	Gestational Diabetes Mellitus	2 (4.16%)	0	0.701
	Preeclampsia	1 (2.08%)	2 (6.0%)	
	Multiple pregnancy	1 (2.08%)	0	
Surfactant given#		7 (14.5%)	3 (9.0%)	0.460
Shake test (positive) #		17 (35.4%)	13 (39.3%)	0.715
Chest X-ray (air bronchogram/white out lung) #		8 (16.6%)	5 (15.1%)	0.855

Values in \*mean (SD), # number (%) or \*\*number, ##Betamethasone-complete when 2 doses given >24 hours but <7 days before delivery, incomplete when any dose given <24 hours or >7 days before delivery.

Table 2: Comparison of outcome parameters of two groups.

Parameters		I-CPAP (n=33)	p value
Average Silverman Anderson score on admission*		5.636(1.05)	0.447
Average starting PEEP value* (cm of H2O)		5.121 (0.89)	0.354
Average duration on CPAP*(days)		5.266 (1.74)	0.471
Average duration on O2 hood* (days)		8.48 (2.90)	0.176
Duration of hospital stay (days)*		13.87 (5.35)	0.361
Total	35 (72.9%)	25 (75.7%)	0.774
<28	3 (33.3%)	1 (33.3%)	1.00
29-32	15 (83.3%)	13 (72.2%)	0.422
>32	17 (80.9%)	11 (91.6%)	0.408
Sepsis	11 (22.9%)	4 (12.12%)	0.219
NSD	23 (47.9%)	2 (6.0%)	0.000062
ROP	2 (4.1%)	1 (3.0%)	0.770
BPD	1 (3.0%)	3 (9.0%)	0.152
Pneumothorax	1 (2.0%)	2 (6.0%)	0.351
PVL	2 (4.1%)	1 (3.0%)	0.770
PDA	7 (14.5%)	4 (12.12%)	0.750
CPAP failure#		8 (24.2%)	0.774
	* (cm of H2O) days) l* (days) //s)*  Total <28 29-32 >32 Sepsis NSD ROP BPD Pneumothorax PVL PDA	* (cm of H2O) 5.208 (1.11) days) 5.027(2.86)  1* (days) 8.28 (4.63)  7s)* 13.37 (6.65)  Total 35 (72.9%)  <28 3 (33.3%) 29-32 15 (83.3%)  29-32 17 (80.9%)  Sepsis 11 (22.9%)  NSD 23 (47.9%)  ROP 2 (4.1%)  BPD 1 (3.0%)  Pneumothorax 1 (2.0%)  PVL 2 (4.1%)  PDA 7 (14.5%)  13 (27.0%)	a score on admission*       5.604(1.08)       5.636(1.05)         * (cm of H2O)       5.208 (1.11)       5.121 (0.89)         days)       5.027(2.86)       5.266 (1.74)          * (days)       8.28 (4.63)       8.48 (2.90)          * (days)       8.28 (4.63)       8.48 (2.90)          * (days)       13.37 (6.65)       13.87 (5.35)          * (Total       35 (72.9%)       25 (75.7%)          * (28       3 (33.3%)       1 (33.3%)          * (29-32)       15 (83.3%)       13 (72.2%)          * >32       17 (80.9%)       11 (91.6%)          * Sepsis       11 (22.9%)       4 (12.12%)          * NSD       23 (47.9%)       2 (6.0%)          * ROP       2 (4.1%)       1 (3.0%)          * BPD       1 (3.0%)       3 (9.0%)          * Preumothorax       1 (2.0%)       2 (6.0%)          * PVL       2 (4.1%)       1 (3.0%)          * PDA       7 (14.5%)       4 (12.12%)

Values in \*mean (SD) or # number (%); NSD: Nasal Septal Damage; ROP: Retinopathy of Prematurity; BPD: Broncho-Pulmonary Dysplasia; PVL: Peri Ventricular Leukomalacia; PDA: Patent Ductus Arteriosus

However, the incidence of nasal septal injury was found to be significantly higher in B-CPAP group (p <0.05).

Nasal septal damage was classified as mild (erythema and tenderness), moderate (indentation over nasal

septum/excoriation) and severe (columella necrosis/bleeding). In I-CPAP group two patients developed mild NSD, while in B-CPAP, 23 patients developed moderate to severe NSD. Other complications, such as ROP (4.1% in B-CPAP versus 3% in I-CPAP, p value 0.770), BPD (3% in B-CPAP versus 9% in I-CPAP, p value 0.152), pneumothorax (2% in B-CPAP versus 6% in I-CPAP, p value 0.351), PVL (4.1% in B-CPAP versus 3% in I-CPAP, p value 0.770) and PDA (14.5% in B-CPAP vs 12.12% in I CPAP, p value 0.750) were not significant.

### DISCUSSION

We found similar outcome with the use of both CPAPs {CPAP failure, survival and complication rates (except NSD)} between B-CPAP and I-CPAP groups. Furthermore, CPAP failure rates of the present study were similar to some previous studies. 12-14 Jain et al and Kawaza et al, using indigenously prepared CPAP, has shown survival rates of 66.7% and 64.6% respectively. In our study, the survival rate was 72.9 % in B-CPAP group and 75.7% in I-CPAP group. 6,15 Thus, I-CPAP has similar survival rates as compared to B-CPAP. complications, such as, culture proven sepsis (22.9% in B-CPAP versus 12.12% in I-CPAP) and NSD (47.9% in B-CPAP vs 6% in I-CPAP, p value 0.000062) were comparable to another recent study. 12 Nasal septal damage was significantly less and only mild in nature in I-CPAP group. The only limitation of I-CPAP is that FiO2 can't be measured directly but by continuous SpO2 monitoring of the neonates we can adjust O2 flow rate.

The cost factor is an important determinant in providing quality healthcare in private and government-controlled hospitals. Providing low cost and effective alternatives can increase greater salvage of sick infants in low income resource limited settings and during epidemics. I-CPAP is not difficult to assemble and use. Furthermore, B-CPAP use requires disposable circuits amounting to Rs. 4000-5000, whereas the I-CPAP is totally a disposable unit. Thus, there is an enormous cost saving in use of I-CPAP. It can be used at all levels of health care facilities. This low cost I-CPAP can be assembled by Medical Officer at primary health centre to provide respiratory support to neonates while they are being transferred. It would definitely reduce mortality and morbidity of neonates with respiratory distress. Medical officers who are handling deliveries should be trained for making I-CPAP which will make big difference in survival of neonates. Further research is required to support use of I-CPAP.

## **CONCLUSION**

This head to head comparative study provides evidence to show that I-CPAP is an equally effective, safer and an affordable extremely low-cost alternative to B-CPAP. The ease with which it can be assembled and used by medical officers and nurses in primary, secondary and tertiary health care settings is added advantage of I- CPAP. Its liberal use can result in decrease in infant mortality rate and enormous savings which can be used for providing additional lifesaving facilities.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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