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Original Article

Safety and effectiveness of bubble continuous positive airway pressure in preterm neonates with respiratory distress

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ARTICLE INFO

Article history:

Received 2 July 2013

Accepted 9 August 2013

Available online 26 September 2014

Keywords:

Bubble

Continuous Positive Airway

Pressure

Preterm

Respiratory distress

ABSTRACT

Background: Studies on Bubble Continuous Positive Airway Pressure (B-CPAP) as respiratory support for neonates are few. The aim of our study was to determine the efficacy and safety of B-CPAP in preterm neonates requiring respiratory support.

Methods: A prospective observation study was done on 50 preterm babies requiring respiratory support for mild to moderate respiratory distress. Support was given with short, nasal cannulae. Surfactant was administered when indicated. Monitoring was done clinically, with pulse oximeter, radiologically and with blood gases. Staff members were also asked their views. Follow-up was done for 3 months.

Results: The mean gestational age was 32.46 (+3.23) weeks and mean birth weight 1454.4 (+487.42) g. Respiratory Distress Syndrome was the commonest indication (30/50). The mean maximum pressure was 6.04 cm H₂O and mean maximum FiO₂ was 72.16%. Mean maximum paO₂, paCO₂ and mean minimum paCO₂ were 92.93 mm Hg (+16.97), 52.36 mm Hg (+ 7.78) and 36.46 mm Hg (+ 4.95) respectively. Early initiation resulted in lesser duration of support. Failure rate was 30%. Apnoea, >1 dose surfactant and late initiation had a statistically higher incidence of failure. Main complications were skin abrasions (30%), feed intolerance (26%) and gastric distension (26%). Survival rate was 94%. 68% of staff felt that it was as easy to use and 88% felt it was more reliable than standard CPAP.

Conclusions: Bubble Continuous Positive Airway Pressure is safe, efficacious and easy to use in preterm neonates with mild to moderate respiratory distress.

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<http://dx.doi.org/10.1016/j.mjafi.2013.08.003>

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Introduction

Gregory et al. first pioneered the use of Bubble Continuous Positive Airway Pressure (B-CPAP) in Neonatology with their landmark paper in the 70s.¹ Bubble CPAP differs from conventional CPAP in that in B-CPAP the expiratory limb is placed under water and oscillatory vibrations are transmitted into the chest resulting in waveforms similar to those produced by high-frequency ventilation.² This modality of respiratory support was relegated to the background with invasive forms of ventilatory support becoming popular in the 80s and 90s. In 1987, Avery et al. first reported large site differences in the risk-adjusted incidence of Broncho-Pulmonary Dysplasia (BPD) in a group of 12 academic neonatal intensive care units (NICUs) with Columbia being the lowest. The Columbia approach of using B-CPAP in the delivery room was used as a possible strategy to reduce the incidence of BPD.³ Since then this has gradually become the primary mode of management of respiratory distress in even the tiniest babies. Despite the lengthy period of time over which B-CPAP has been used, surprisingly little is still known about the importance or relevance of the bubble component of this mode of ventilation and its safety. This study was planned to look at its effectiveness of B-CPAP in reducing mortality and need for invasive ventilation and its safety as a form of respiratory support in preterm babies.

Materials and methods

A prospective, observational study with B-CPAP was carried out in the NICU of a tertiary care hospital on 50 preterm babies with respiratory distress to determine:

1. The need for invasive ventilation and mortality (primary outcomes)
2. Complications during use and perception of 'ease of use' by nursing staff (secondary outcomes)

Inclusion criteria were preterm (<37 weeks gestation age) babies with:

- a. Mild to moderate respiratory distress (Downe's Score 3–6 and FiO_2 requirement of <0.6).
- b. Recurrent episodes of apnoea of prematurity (>2 in 12 h not requiring resuscitation).

Exclusion criteria were babies with Persistent Pulmonary Hypertension of Newborn (PPHN), encephalopathy, air leaks, pulmonary haemorrhage, major congenital anomalies and meconium aspiration on presentation.

Informed consent was taken from parents. Details of birth history, risk factors in the pregnancy, type of delivery and need for resuscitation were recorded. Study babies were put on B-CPAP as the initial form of respiratory support with short, nasal Hudson's cannulae on a stand-alone machine B-CPAP machine (Breathline, Mumbai). All babies were nursed under radiant warmers on servo-controlled skin mode in the 30-degree head-up, supine position and stabilised with nesting

pillows. Orogastric tubes were inserted and connected to open syringes (without piston) for venting. Strict asepsis was observed. B-CPAP was started with 5 cm H_2O and FiO_2 adjusted to maintain pulse oximeter saturation between 88%–94% in babies <1.5 Kg and 92%–94% in bigger preterms. Babies with a diagnosis of RDS were given surfactant if indicated (Downe's score 4–6 or requirement of $\text{FiO}_2 > 0.4$ CPAP). This was done by INSURE (Intubate, SURfactant Extubate) technique and babies were then put back on CPAP. Any baby with clinically significant patent ductus (cardiac murmur, bounding pulses) with or without echo confirmation was given 3 oral doses of oral Ibuprofen if renal parameters and platelet counts were normal.

Monitoring was done clinically, with pulse oximetry, X-rays and ABGs for requirement of change in settings, complications, failure and outcome. Time of starting CPAP total duration of therapy and time taken to wean were noted.

All babies who had stable vitals on B-CPAP for >12 h were started on Expressed Breast Milk feeds through orogastric tube. Weaning off B-CPAP was done when the respiratory distress decreased to Downe's score <3 and ABGs were normal. Trials off B-CPAP (cycling) were done before finally discontinuing.

Failure of B-CPAP was defined as one or more of the following:

- a. Requirement of pressure >8 cm H_2O
- b. FiO_2 requirement >0.6
- c. $\text{paO}_2 < 50$ mmHg on maximum acceptable settings
- d. $\text{paCO}_2 > 60$ mm Hg and pH < 7.25 on maximum acceptable settings
- e. Air leak on B-CPAP
- f. Recurrent apnoea on B-CPAP despite caffeine citrate or aminophylline.

A structured, non-validated questionnaire was issued to 25 staff members (resident doctors and nurses) having had training of at least 1 week and work experience in the NICU for at least 1 month to assess their views in 3 areas of B-CPAP: ease of use, reliability and nursing management.

Follow-up

All study babies were followed up for at least 3 months and screened for neuro-developmental delay, hearing impairment and Retinopathy of Prematurity (ROP).

Data was analyzed as mean (SD). Chi square test, Fischer's t test and multivariate analysis were used where applicable. Analysis was done on SPSS (ver 11.2).

Results

The mean gestational age of the study population was 32.46 weeks and birthweight was 1454 g. 96% of the population were Very Low Birth Weight (VLBW) babies weighing less than 1500 g.

The most common disease for starting B-CPAP was RDS ($n = 32$) followed by pneumonia ($n = 8$), TTNB ($n = 6$) and Apnoea ($n = 4$). During the study period a total of 44 babies

suffered from RDS of which 32/44 (72.7%) were put on B-CPAP as initial mode of ventilatory support. The remaining were severe cases which did not fulfil the inclusion criteria for B-CPAP.

The mean duration of CPAP and time to wean were significantly lower when B-CPAP was started on Day 1 of life compared with when it was started later (Table 1).

The mean maximum pressure on B-CPAP was 6.04 (0.71) cm of H₂O and mean maximum FiO₂ was 72.16 (7.78)%. ABG values (done in 39 patients) were well within acceptable limits during therapy (Fig. 1). ABG could not be done in 11 patients due to various reasons (machine failure, non-availability of sample).

The commonest complications on B-CPAP were skin abrasions (15/50), gastric distension (13/45) and feed intolerance (13/45). Skin abrasions were seen mainly under the nose and on the cheeks. No baby had severe columella injury or septal necrosis. Other complications included lung over-distension (2), superficial columella injuries (6), pneumothorax (2) and secondary infection (2). Overall failure of B-CPAP occurred in 15/50 cases or 30%. All babies who failed B-CPAP were put on mechanical ventilation. Failures in RDS group were 9/32 or 28.1%. Failure rate in the pneumonia group was 3/8 or 37.5% and in the apnoea group it was 4/4 (100%). None of the 6 babies put on B-CPAP for TTNB failed this mode of ventilator support. There were 3 babies less than 1 Kg in the study. Of these 2 failed B-CPAP. Babies with apnoea of prematurity, those with RDS requiring >1 dose of surfactant and those put on B-CPAP after 5 h of life showed a statistically higher incidence of (Table 2).

Overall survival rate of the study population was 94%. All babies with RDS survived. On follow-up intact survival (without any neurological or neuro-sensory deficits) was seen in 92%.

Most of the staff dealing with the babies felt that it was easier and more reliable to use B-CPAP than standard CPAP. As regards need for nursing care most felt there was no difference as compared to standard CPAP (Table 3).

Discussion

There is a paucity of data regarding differences in gas exchange and effectiveness between conventional and B-CPAP systems.⁴ Use of B-CPAP systems is also associated with safety concerns, as these devices do not have any pressure alarms to

Maximum parameters on CPAP and ABG values

Fig. 1 – Mean maximum parameters on B-CPAP and ABG values.

alert the clinician when the actual delivered pressures are higher than those intended.⁵

Lipsten et al. compared the work of breathing with B-CPAP with variable flow CPAP. There was an improvement observed in breathing asynchrony and resistive work of breathing with the former in preterm infants with mild respiratory distress.⁶

Gupta et al. did a randomized controlled trial to compare B-CPAP with variable flow CPAP on 140 preterm infants of 24–29 weeks' gestational age and 600–1500 g. The authors concluded that there was no difference in the success of extubation between the two.⁷

Nowadzky et al. studied the use of B-CPAP in VLBW babies with RDS. The investigators compared their data (March 2005 to October 2007) with historical data (January 2003 to February 2005). This included incidence of mechanical ventilation, length of ventilation, incidence of pneumothorax, and incidence of bronchopulmonary dysplasia. During the study time-frame there was a statistically significant reduction in the use and duration of mechanical ventilation.⁸

Respiratory Distress Syndrome remains the most common indication for use of CPAP in neonates the world over.⁹ This was also the case in our study. Verder et al. published the first randomized controlled trial of surfactant instillation during nCPAP showing that in infants with moderate-to-severe RDS

Table 1 – Time of starting B-CPAP and duration and time to wean.

	Age of starting CPAP in hrs (SD)	Duration of CPAP in hrs (SD)	Time required for weaning in hrs (SD)
CPAP started within 24 h (n = 35)	5 (2.42)	44.93 (24.56)	4.21 (1.56)
CPAP started after 24 h (n = 15)	59.71 (27.24)	85.57 (54.16)	22.35 (2.35)
p-value		<0.05	<0.05

Table 2 – Factors contributing to CPAP Failure.

Factors	No	Failure	Significance (Chi square)
1. Reason for initiating B-CPAP			
Apnoea of prematurity	4	4	$p < 0.05$
Other reasons	36	11	
2. Time of initiating B-CPAP			
Before 5 h of life	26	3	$p < 0.05$
After 5 h of life	24	12	
3. Use of surfactant			
>1 dose	3	3	$p < 0.05$
1 dose	23	6	

Table 3 – Views of medical and nursing staff on use of BCAP vs Conventional CPAP (n=25).

Opinion on questionnaire	B-CPAP No (%)	Conv CPAP No (%)	p-value on Chi square test
Easier to use	17 (68%)	8 (32%)	<0.05
More reliable	22 (88%)	3 (12%)	<0.05
Lesser nursing care	13 (52%)	12 (48%)	NS

the need for subsequent mechanical ventilation could be reduced by half after a single dose of surfactant. The effect was even more pronounced if the surfactant treatment was given early in the course of the disease.¹⁰ In our study >81% of babies diagnosed with RDS were given exogenous surfactant of which 23/26 (88.4%) required only one dose of surfactant. Of these, 6/23 (26%) failed CPAP. All 3 babies who required more than 1 dose on surfactant on CPAP had to be put on mechanical ventilation (Table 2). This suggests that B-CPAP may not be effective in severe RDS.

Indian studies on CPAP have shown a failure rate of 25–50%. In a study comparing IPPV and CPAP in about 150 preterm babies between 32 and 34 weeks CPAP did not provide adequate respiratory support in 22 newborns (26%). Of these, 17 received IPPV, five of whom died.¹¹

In a study at Columbia early B-CPAP was successful in 76% of infants ≤ 1250 g and 50% of infants ≤ 750 g with RDS. In analyses adjusted for postmenstrual age (PMA) and small for gestational age (SGA), CPAP failure was associated with need for positive pressure ventilation at delivery, alveolar-arterial oxygen tension gradient >180 mmHg on the first ABG and severe RDS on the initial chest radiograph (adjusted odds ratio [95% CI] = 2.37 [1.02, 5.52], 2.91 [1.30, 6.55] and 6.42 [2.75, 15.0], respectively). The positive predictive value of these variables ranged from 43% to 55%.¹²

In our study 15 cases failed CPAP of which 9 were RDS cases. Overall failure rate seen in our study was 30% and in RDS it was 28.1% which was similar to other studies (29). All babies with RDS put on B-CPAP in our study survived. Our study showed that during B-CPAP there was a good normalization of ABGs. This is consistent with other studies (9).

In a landmark study (COIN Study) Morley et al. looked at early CPAP for tiny babies between 25 and 28 weeks of gestation. They found that early nasal CPAP significantly reduced the need for intubation but did not significantly reduce the rate of death or bronchopulmonary dysplasia, as compared with mechanical ventilation. Even though the CPAP group had more incidences of pneumothorax, fewer infants received oxygen at 28 days, and they had fewer days of ventilation.¹³ In our study we had only 3 babies <1 Kg. Of these, 2 survived without CLD.

Complications during B-CPAP have not been found to be severe. The most common complication was skin abrasions. In a study from a tertiary care NICU in a developing country it was found that complications were minimal with B-CPAP.¹⁴ In another study 15 of 17 neonates showed slight nasal septum irritation after 1 day of B-CPAP. Redness of the nasal septum was mostly seen and dark discoloration was only observed in 2 neonates. Quality of nursing care was found to be the main factor involved.¹⁵ In our study 15 babies showed skin abrasions and 6 showed superficial columella injury. No baby had severe columella injury. All staff members in our unit were

trained for at least 1 week before being given direct responsibility to handle babies on B-CPAP. We did not study the quality or effectiveness of training due to rapid changes in staff.

We fed most of our babies on B-CPAP (45/50). However, 13 babies had feed intolerance with increased gastric aspirates. This could have been due to either overdistension or increased gastro-esophageal reflux as shown by other studies.¹⁶ The overall survival rate was 94% and intact survival was 92% which was comparable to other studies.^{11,12}

In our study the resident doctors and nurses looking after babies on B-CPAP were found to be positively inclined toward this modality of respiratory support in preterm neonates. Staff perceptions regarding B-CPAP have been studied by other authors as well. Koyamaibole et al. found that nurses could safely start and maintain B-CPAP on their own after minimal training.¹⁴ This was found to be cost effective as well. Our study found that 68% of staff felt that B-CPAP was easier to use and 88% found it more reliable because of visualization of bubbles than standard CPAP. However, B-CPAP did not decrease the need for nursing care.

In conclusion, use of B-CPAP in preterm babies is safe and results in decreased requirement of ventilation if started early in cases of respiratory distress syndrome and pneumonia.

Conflicts of interest

All authors have none to declare.

Acknowledgement

This paper is based on Armed Forces Medical Research Committee Project No. 3884/2009 granted by the office of the Directorate General Armed Forces Medical Services and Defence Research Development Organisation, Government of India.

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