RESEARCH

COMPARE THE EFFICACY BETWEEN UNDERWATER BUBBLE CPAP AND VENTILATOR DERIVED CPAP AMONG VERY LOW BIRTH WEIGHT BABIES WITH RESPIRATORY DISTRESS REQUIRING CPAP

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Abstract

Background: Respiratory distress is a common cause for admission of neonates to intensive care unit. The objective is to compare the CPAP failure rates between underwater bubble CPAP and ventilator derived CPAP among very low birth weight babies with respiratory distress requiring CPAP. **Materials and Methods:** The present study was conducted at tertiary level neonatal intensive care unit, Department of Paediatrics, S N Medical College Agra, Uttar Pradesh. 96 infants with weight < 1500 gm who had respiratory distress were eligible for the requirement of CPAP therapy. Out of these, 68 infants fulfilled the criteria for study and randomized to either ventilator CPAP or bubble CPAP. **Result:** There was 24(71%) males in ventilator CPAP group and 11(32%) male in bubble CPAP group. Babies in ventilator CPAP group were sicker, 9(26%) had delayed perfusion and 3(9%) babies had hypoglycemia as compared to only 6(18%) babies with delayed perfusion and no babies with hypoglycemia in bubble CPAP group. In ventilator CPAP group 13(38%) babies had RDS as compared to only 7(20%) in bubble CPAP group. Pneumonia were 7(20%) in ventilator CPAP group compared to 10(29%) in bubble CPAP group. The maximum CPAP requirement were significantly more in ventilator CPAP group as compared to bubble CPAP group. There was no significant difference in associated morbidities during hospitalization in both the group of CPAP. **Conclusion:** The CPAP failure rates with bubble CPAP or ventilator CPAP among VLBW babies with mild to moderate respiratory distress is comparable.

INTRODUCTION

Both pulmonary and extra pulmonary causes can present as tachypnea and respiratory distress. While conditions like respiratory distress syndrome (RDS) are seen in premature infants (nearly 80% of infants less than 28 weeks develop RDS) the others like Meconium Aspiration Syndrome (MAS) are considered diseases of term or near term infants. Infections and structural anomalies are seen in both term and preterm infants.

Continuous Positive Airway Pressure (CPAP) is a non-invasive form of respiratory support in which positive pressure is applied to the airways of the spontaneously breathing patient throughout the respiratory cycle. It is an established modality of respiratory support in preterm neonates.3 CPAP could be delivered through continuous flow CPAP or variable flow CPAP. Ventilator CPAP (VCPAP) and bubble CPAP (BCPAP) are two forms of continuous flow CPAP and Infant Flow Driver is example of variable flow CPAP. Studies comparing various types of CPAP are inconclusive and the evidence as to which is the better type of CPAP delivery are scarce.

Ventilator-derived nCPAP and bubble nCPAP are the most common CPAP used in the NICU. There are many studies on bubble CPAP but the studies comparing Ventilator CPAP and bubble CPAP are scarce. Previously, only few randomized studies have compared the ventilator-derived CPAP with bubble CPAP.[1,2,3,4] Given its low cost bubble CPAP has a potentially significant role in resource-poor countries. However the comparative studies to determine the best delivery system for nasal CPAP is lacking. Considering limited availability of data,

we aimed to compare the efficacy between the two methods of CPAP namely ventilator-derived nCPAP and bubble nCPAP in terms of their failure rate in very low birth weight (VLBW) babies with respiratory distress.

MATERIALS AND METHODS

The present study was conducted at tertiary level neonatal intensive care unit, Department of Paediatrics, S N Medical College Agra, Uttar Pradesh. Study Period was from September 2013 to July 2015. Ethical clearance was obtained from the institutional ethical committee for the present study. Informed written consent was taken from parents or guardian of all eligible babies.

Eligible population

1. Any baby with weight < 1500 gm with respiratory distress* was eligible for enrolment into the study.

Respiratory distress was said to be present if Silverman score was >/= 3.

Table 1: Silverman – Anderson score

Criteria/Score	0	1	2
Upper chest retraction	synchrony	Lag in insp.	Sea saw
Lower chest retraction	no retraction	Just visible	Marked
Xiphisternal retraction	no retraction	Just visible	marked
Nasal flaring	None	Minimal	Marked
Exp. Grunting	None	With stethoscope	Audible to unaided ear

Grades of severity according to the total score, 5
1 – 3 - mild respiratory distress
4 –6 - moderate respiratory distress
>6 - severe respiratory distress

Exclusion Criteria

1. Refusal for consent for study.
2. Any baby who had severe respiratory distress, Silverman score =/>7.
3. Any baby requiring ventilation (Apnoeic/ Hemodynamically unstable baby).
4. Any baby who had received mechanical ventilation within last one week and now required CPAP.
5. Any baby with major congenital malformations like Tracheo esophageal fistula (TEF), congenital diaphragmatic hernia (CDH), any upper airways obstruction, and any major cardiovascular/central nervous system/neuro muscular pathology were excluded from the study.
6. Any baby with respiratory distress likely to be due to meconium aspiration. (Baby born with meconium stained liquor and developing respiratory distress within 6 hours was assumed to be having meconium aspiration syndrome as this disease has a different pathophysiology).
7. Baby with pre diagnosed pulmonary air leak.

Sample Size

Assuming failure rate of about 45% in ventilator CPAP group and desiring an absolute reduction of about 30% in failure rate in favour of bubble CPAP we calculated the sample size at 80% power and 5% type-I error to a minimum of 34 in each group. Previous studies 1,2,3 had shown a relative reduction of about 50% in favour of bubble CPAP. With 30% absolute reduction in failure rate we desire a relative reduction of about 70% in favour of bubble CPAP.

Randomization

Random numbers were generated by using the statistical software Statistical Package for Social Sciences (SPSS) version 18. Random numbers allocation sequence and coding for the different group of CPAP was made by the statistician who was completely unaware of clinical details. Also the investigator was blinded to random numbers allocation sequence and coding. Babies eligible for enrollment were randomly allocated to either bubble-CPAP or ventilator-CPAP by using opaque sealed envelopes with labels kept inside and wrapped in aluminum foil. Given the nature of interventions, blinding in the study to the allocation status of baby was not possible.

Equipment used in the Study

Ventilator CPAP and bubble CPAP

Ventilator CPAP

Ventilator derived CPAP was delivered by 4 Schiller GRAPHNET NEO Neonatal Ventilator and 2 Dragger Babylog 8000plus ventilator

Bubble CPAP

Bubble CPAP was delivered by Bubble CPAP machine Fisher & Paykel (model- MR 850 AEU, Auckland, Newzeland).

Data Collection

Information about recording of basic demographic and clinical data including babies' particulars, some antenatal and birth details, clinical examination findings and CPAP details were recorded in the proforma.

Statistical Methods

Data were entered into the MS excel. After the entry, entered data were cross checked for entry error and corrected. All analysis was conducted by using statistical software Statistical Package for Social Sciences (SPSS) version 18. For analysis descriptive statistics and univariate tests (t-test, chi-square test) were used. Probability p-value <0.05 were considered significant.

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RESULTS

96 infants with weight < 1500 gm who had respiratory distress were eligible for the requirement of CPAP therapy. Out of these, 68 infants fulfilled the criteria for study and randomized to either ventilator CPAP or bubble CPAP.

There was 24(71%) male in ventilator CPAP group and 11(32%) male in bubble CPAP group. About half of the babies were admitted within 24 hrs of age, 18(53%) in the ventilator CPAP group and 17(50%) in bubble CPAP group. Babies with gestation >30 weeks were 20(59%) in ventilator CPAP group and 26(76%) in bubble CPAP group. Babies with >/= 1000 gm weight were 25(74%) in ventilator CPAP group and 32(94%) in bubble CPAP group. Babies with birth asphyxia were 9(26%) in bubble CPAP group and 3(9%) in ventilator CPAP group. Mothers of 15(44%) babies in ventilator CPAP group and mothers of 16(47%) babies in bubble CPAP group had received either complete or incomplete dose of antenatal steroid. Babies in ventilator CPAP group were more sick, 9(26%) had delayed perfusion and 3(9%) babies had hypoglycemia as compared to only 6(18%) babies with delayed perfusion and no babies with hypoglycemia in bubble CPAP group. In ventilator CPAP group 13(38%) babies had RDS as compared to only 7(20%) in bubble CPAP group. Pneumonia were 7(20%) in ventilator CPAP group compared to 10(29%) in bubble CPAP group.

Table 2: Baseline characteristics of study population

Characteristics [Frequency,%] / (mean ± SD)		**Ventilator-CPAP (n=34). [Frequency, %]**	**Bubble-CPAP (n=34). [Frequency, %]**
Sex	Male	24 (71)	11 (32)
Admission age	(<24 hrs)	18 (53)	17 (50)
	24hrs-7days	13 (38)	15 (44)
	>7 days	3 (9)	2 (6)
Gestational age	< 30 weeks	14 (41)	8 (23)
	> 30 weeks	20 (59)	26 (76)
Admission wt.	(mean ± SD)	1.214±0.25	1.264±0.161
	<1000 gm	9(26)	2 (6)
	1000-<1500gm	25 (74)	32 (94)
Place of delivery	Home	10 (29)	3 (9)
	Hospital	24 (71)	31 (91)
Mode of delivery	Vaginal	29 (85)	32 (94)
	LSCS	5 (15)	2 (6)
Birth asphyxia	Moderate	3 (9)	9 (26)
Antenatal steroid (incomplete/complete)		15 (44)	16 (47)
Prior surfactant received		0	1 (3)
Vital parameters and blood sugar at admission time	Severe hypothermia	1 (3)	2 (6)
	Moderate hypothermia	14 (41)	10 (29)
	Cold stress	6 (18)	11 (32)
	Saturation <88%	10 (29)	9 (26)
	Delayed perfusion	9 (26)	6 (18)
	Hypoglycemia	3 (9)	0
Silverman score (mean ± SD)		4.647±0.774	4.529±0.507
	RDS	13 (38)	7 (20)
	Pneumonia	7 (20)	10 (29)

The maximum CPAP requirement were significantly more in ventilator CPAP group as compared to bubble CPAP group. The duration of CPAP required were more in ventilator CPAP group as compared to bubble CPAP group but the duration was not statistically significant.

Table 3: Treatment details of study population

Characteristics (mean ± SD)/[Frequency, %]	**Ventilator-CPAP (n=34)**	**Bubble-CPAP (n=34)**	**Chi-value /t-value**	**p-value**
Maximum CPAP (in cm of H2O) (mean ± SD)	5.68±1.00	5.21±0.77	2.219	0.033
CPAP duration (in hours) (mean ± SD)	62.56±45.91	48.74±27.00	1.46	0.07
Maximum FiO2 [Frequency, %] <40% 41-50% >50%	 16 (47) 6 (18) 12 (35)	 23 (68) 6 (18) 5 (15)	 4.138	 0.126
Surfactant	13 (38)	6 (18)	3.578	0.055
Hospital stay (in days)	23.91±14.87	22.21±10.65	0.478	0.32

CPAP = Continuous positive airway pressure; SD = Standard deviation; FiO2 = Fraction of inspired oxygen in percentage.

There was no significant difference in associated morbidities during hospitalization in both the group of CPAP.

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Table 4: Morbidities during Hospital course of study population

Characteristics [Frequency, %]	Ventilator-CPAP (n=34)	Bubble-CPAP (n=34)	Chi-value/t-value	p-value
Culture positive sepsis	5 (15)	5 (15)	0.0	0.0
Shock	14 (41)	13 (38)	0.061	0.80
Meningitis	2 (6)	2 (6)	0.0	0.0
Patent ductus arteriosus	2 (6)	1(3)	0.348	0.555
Acute renal failure	2 (6)	3(9)	0.215	0.64
DIC	3(9)	4(12)	0.159	0.69
Pulmonary hemorrhage	4(12)	1(3)	1.940	0.151
NEC	5 (15)	3 (9)	0.567	0.612
MODS	1(3)	2 (6)	0.348	0.555

DIC = Disseminated intravascular coagulation; NEC = Necrotizing enterocolitis; MODS = Multi organ dysfunction syndrome.

DISCUSSION

In the present randomised trial comparing bubble and ventilator derived CPAP the failure rate with bubble-CPAP was 14.70% while that with ventilator-CPAP was 32.35%. Failure rate in a randomised trial by McEvoy CT et al,[2] was 42% and 48%, while that in another randomised trial by Amit Tagare et al,[4] was found to be 13% and 20% for bubble-CPAP and ventilator CPAP respectively and concluded that failure rate with either of the methods was comparable. Another prospective randomized pilot study by Colaizy TT et al,[3] also found failure rates with both ventilator and bubble CPAP methods was comparable (figures not quoted as only abstract available).

Variations in the failure rates among the few available studies on the subject could relate either to variations in subject population selection or disease severity or co-existence of morbidities or even differences in the way various authors defined CPAP failure in their studies.

A relatively higher failure rate in McEvoy et al,[2] study compared to all other studies including the present study could possibly be related to the fact that babies enrolled in their study were of rather low gestation between 25 to 32 weeks and the maximum level of CPAP pressure they used was only 5 cm of H2O. In contrast our study subjects consisted of VLBW babies and majority (about 68%) of babies in both the groups were more than 30 weeks. Using a higher threshold of CPAP pressure to 7 cm of H2O, for defining failure rate in our study could explain a lower failure rate in our study. In our study population all babies with RDS had received surfactant therapy. However it is not clear from the published abstract as to what was the usage of surfactant in their study.

Amit Tagare et al,[4] enrolled larger preterm babies with a mean birth weight of 1645 gm (1275-2055g) and gestation range between 31-33 weeks compared to VLBW babies with mean weight of 1240 gm in our study. This can be a reason to explain the lower failure rates with both bubble and ventilator CPAP as observed in their study. Most babies (>80%) enrolled in our study were outborn and had associated co-morbidities like sepsis, shock, disseminated intravascular coagulation or multiorgan dysfunction, all of which are likely to adversely affect CPAP outcomes.

Studies on bubble-CPAP among preterm with RDS, by Ammari, et al,[6] Prashanth S Urs et al,[7] and Jagdish Koti et al,[8] reported failure rates to be 24%, 20% and 25% respectively. These rates are higher compared to failure rate of bubble-CPAP in our study (14.70%). This could possibly be due to the fact that study population included in study of Ammari, et al,[6] comprised of babies with weight <1250 gm and 85.5% of babies in their study were < 30 weeks of gestation while in the study of Prashanth S Urs et al,[7] 94% babies were < 34 weeks gestation. However only 23% babies in our study were <30 weeks of gestation and weight of our babies were up to <1500 gm. The higher failure rate in Ammari, et al.6 study could also be because of the difference in definition of CPAP failure, in our study it was defined as infants not maintaining saturation on maximum CPAP pressure of 7 cm of H2O, and FiO2 > 0.6, but they defined it as FiO2 requirement >0.6 for the first 72 hours of life but no PEEP criteria were set in their study. The low PEEP used could be the reason for higher failure rate. Jagdish Koti et al,[8] observed that PDA was predictor of CPAP failure in their study. Prevalence of PDA in their study was 17.8% as compared to only 4.4% in our study population.

In a study on 10 neonates weighing between 750-2000g and gestational age of 28-34 weeks with RDS, Lee et al,[1] concluded that the chest vibrations produced by bubble CPAP may have contributed to gas exchange. In another study of Pillow et al,[9] in which intubated preterm lambs were randomized to bubble CPAP or ventilator CPAP showed that bubble CPAP was associated with a higher pH, PaO2 and oxygen uptake and decreased respiratory quotient and PaCO2 compared with ventilator CPAP. It has been proposed that lower failure rates with bubble CPAP compared to ventilator CPAP, (as seen in the present randomized trial) could be due to additional chest vibrations produced by bubbling which may improve gaseous exchange at alveolar level among babies on bubble CPAP. However there are other authors who do not support this mechanism to explain lower failure rates seen with bubble CPAP. Kahn DJ,[10] shown in a lung model that the pressure oscillations on bubble nasal

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CPAP that are so prominent at the nasal prong level were markedly diminished at the alveolar level, especially once leak was introduced into the system and also in a cross over trial of bubble CPAP and ventilator CPAP Morley et al,[11] reported no differences in oxygenation and arterial CO2.

CONCLUSION

The CPAP failure rates with bubble CPAP or ventilator CPAP among VLBW babies with mild to moderate respiratory distress is comparable.

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