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Audu LI
Otuneye AT
Mairami AB
Mukhtar MY

Improvised bubble continuous positive airway pressure (BCPAP) device at the National Hospital Abuja gives immediate improvement in respiratory rate and oxygenation in neonates with respiratory distress

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Audu LI (✉)
Otuneye AT, Mairami AB
Mukhtar MY
Department of Paediatrics,
National Hospital Abuja, Nigeria.
Email: drauduli@yahoo.com

Abstract: *Background:* Prematurity accounts for 25% of Neonatal mortality in Nigeria and Respiratory Distress Syndrome is responsible for half of these deaths. Introducing continuous positive airway pressure for the treatment of RDS in Nigeria where health care financing is predominantly out-of-pocket is quite challenging. It was hypothesized that applying the principle of under-water-seal pressure generation could convert a simple oxygen delivery system into an effective Bubble CPAP device.

Objectives: To provide evidence in support of the immediate clinical effectiveness of the NH-BCPAP device.

Design/Methods: At the neonatal unit of the National Hospital Abuja, we assembled a circuit of tubing connecting a gas source (oxygen concentrator or cylinder) through an interface (nasal prongs) to the baby and this was further connected through an expiratory tube to an under-water-seal bottle to generate CPAP. The device is activated by turning on the oxygen source. The device was applied to preterm babies with RDS as well as some term babies with respiratory distress admitted into the neonatal intensive care units. Respiratory rate, SPO2 and other signs of respiratory distress were monitored before and at 1 hour, 6 hours and 12 hours after the application.

Results: Forty eight newborn babies with respiratory distress were treated with the device out of whom twenty three (48%) were very low birth weight with respiratory distress syndrome. The mean respiratory rate dropped from 64.5 (19.2)/min before commencement of CPAP to 59.5(11.6)/min, 56.6 (10.5), and 56.6(10.7) at 1, 6 and 12 hours respectively, $p<0.05$. The corresponding values for SPO2 were 84.5(14) before and 95.9 (5.3), 95.9(6.5) and 96.9(6.4) at 1, 6 and 12 hours respectively, $p<0.05$. The respiratory changes were however less marked among very low birth weight babies.

Conclusion: The simplified customized device produces clinical responses similar to those reported for the conventional CPAP devices.

Introduction

Prematurity accounts for 25% of neonatal mortality in Nigeria[1] and respiratory distress syndrome (RDS) is responsible for half of these deaths[2]. Effective management of respiratory distress syndrome is therefore a critical factor in their survival. Some form of respiratory support is required with or without surfactant replacement. Mechanical ventilation which was used as the main thrust of respiratory intervention over the years to salvage these babies is fraught with several complications including chronic lung disease of prematurity[3]. Continuous Positive Airway Pressure (CPAP) is increasingly used in the management of preterm babies with RDS, with a concomitant decrease in the use of mechanical ventilation in tertiary and non- tertiary health institutions[4]. Respiratory assistance with continuous positive airway pressure (CPAP) is often sufficient to tide a preterm infant through RDS. Introducing CPAP in a low-resource setting is quite challenging and this has limited its use to a few centers in Nigeria. CPAP use may be associated with nasal septum erosion,

interference with enteral intake ("CPAP belly") and rarely, pneumothorax. Careful selection of appropriate size nasal prongs, passage of orogastric tube for intermittent gastric decompression and careful attention to pressure delivered will minimize these challenges.

Adaptation of Bubble –CPAP: Driven by the desire to provide effective and yet affordable treatment for RDS we resorted to the use of locally sourced materials and applied the principle of 'under-water seal' pressure generation in BCPAP and arrived at a modification of the existing bubble CPAP device which is effective, easy to use and remarkably affordable. This has been previously described[5].

Fig 1: NHA B-CPAP system

Physiologically, CPAP causes airway splinting, alveolar expansion and stabilization, improved alveolar ventilation and enhanced oxygenation [6]. The clinical consequences of these are; disappearance of grunting sounds a drop in the respiratory rate and an improvement in SPO_2.

The objective of this communication is to provide evidence in support of the immediate clinical effectiveness of the NHA-BCPAP device. The findings would provide justification for a planned comparative evaluation of this device with other conventional commercial CPAP devices. It was hypothesized that application of the NHA bubble CPAP device to a baby with respiratory distress would result in an immediate functional improvement in the respiratory status.

Subjects and methods

This was a prospective observational study in which babies admitted into the newborn unit of the National Hospital Abuja with respiratory distress were eligible if they had no congenital abnormalities (bilateral choanal atresia, congenital diaphragmatic hernia and cleft lip/ palate). These babies would otherwise have received supplemental intranasal oxygen in addition to other management relevant to their primary pathologic diagnosis. There are no facilities for mechanical ventilation and only a limited number of variable-flow nasal CPAP devices are available in the unit. Babies were recruited into the study following parental informed consent and Hospital ethics committee approval.

A circuit of tubing attached to a gas source (oxygen cylinder or concentrator) was connected through an interface (nasal prongs) to the baby and this was further connected through an expiratory limb of the tube to an under-water-seal bottle to generate bubble CPAP[5]. The oxygen flow meter is connected to a humidifier containing warm distilled water and this ensures the delivery of warm humidified air to the baby. The high flow rate (6-8L/Min) prevents re-breathing and carbon dioxide accumulation while also ensuring adequate bubbling and under-water pressure generation.

Forty eight babies admitted into the newborn unit with respiratory distress (intercostal, subcostal or sternal recessions, grunting and nasal flaring) over a period of 6 months were treated with this device. They were clinically assessed on admission and at 1, 6 and 12hours after commencement of CPAP. Respiratory rates, cyanosis, grunting and SPO_2 were documented. Also noted and documented were baby's gestational age (*using mothers' EDD and Ballard's score within 24 hours of birth)*, birth weight and diagnosis. The mean (SD) value of RR and SPO_2 before CPAP was commenced was compared with the corresponding mean (SD) values at 1,6 and 12 hours after commencement of CPAP and subjected to statistical analysis *(Student t-test)* to determine the significance of observed differences. Babies who did not improve on CPAP or died while still on CPAP were classified as CPAP failures. The overall mortality rates as well as the case specific mortality rates were also noted.

Results

Table 1: General characteristics

(n=45)	
Sex	17(37.8%)
Male	28 (62.2%)
Female	
Place of delivery (n=48)	
Inborn	23 (47.9%)
Out born	25(52.1%)
Birth weight category (n=48)	
ELBW	5(10.4%)
VLBW	18(37.5)
LBW	12(25%)
NBW	13(27.1)
Clinical diagnosis	
Respiratory Distress Syndrome	30(62.5%)
Congenital pneumonia	11(22.9%)
Cyanotic Congenital heart disease	3(6.2%)
Transient Tachypnoea of the Newborn	2(4.2%)
Recurrent Apnea	1(2.1%)
Hypoxic Ischaemic encephalopathy	1(2.1%)

Indicators of clinical effectiveness (tables 2-5)

The respiratory rate dropped from a mean (SD) value of 64.1 (18.3)/min to 59.5 (11.7)/min within 1 hour of commencing CPAP and this downward trend was maintained, achieving a level of statistical significance at 6 and 12 hours post commencement. The changes observed in the SPO_2 levels also followed the same pattern albeit more rapidly and this was synchronous with improvement in the level of cyanosis and the disappearance of grunting sound. Further stratification of the babies into different Birth Weight categories as shown

in tables shows that respiratory rate changes are only significant for the LBW and NBW babies, whereas the changes in SPO2 are uniformly significant across birth weight categories .

Two extremely low birth weight babies and two with suspected cyanotic congenital heart disease had SPO2 persistently below 82% throughout the period of observation. In six babies (4 VLBW, 2 ELBW), CPAP was reapplied after weaning, as a result of worsening respiratory distress. The P values were determined by comparing the mean (SD) values at 1 hr, 6 hrs and 12 hrs independently with the mean (SD) at 0 hr.

Table 2: Indicators of clinical effectiveness

Variable	CPAP	Duration		
	0 hr	1hr	6hrs	12hrs
Mean (SD)RR/min	64.1 (18.3)	59.5 (11.7)	56.6 (10.4)	56.6 (10.7)
P value		0.145	0.015	0.016
Mean (SD) SPO_2	84.5 (14.0)	95.9 (5.3)	95.9 (6.5)	96.9 (6.4)
P value		0.0001	0.0001	0.0001

Table 3: Respiratory rates (per minute) before and after commencement of B CPAP in relation to birth weight category NS=not significant

Birth weight category	0 hour	1 hour	6 hour	12 hour
ELBW	50.4(9.3)	51.2(19.8) NS	51.6(7.7)NS	50.8(12.1)NS
VLBW	61.5(11.4)	64.1(8.6) NS	58.6(9.2)NS	57.6(8.5)NS
LBW	61.0(12.6)	58.5(9.1) NS	54.2(11.2) P=.057	52.2(9.7) P=.083
NBW	75.6(24.4)	58.4(14.7) P=.009	57.2(12.3) P=.004	61.0(12.4) P=.009

Table 4: Changes in SPO_2 (%) in relation gestational age category

Birth Weight Category	0 hour	1 hour	(P)	6 hour	(P)	12 hour	(P)
ELBW	82.6(12.6)	97.0(3.0)	0.06	97.2(2.0)	0.04	97.8(1.8)	0.480
VLBW	87.7(15.0)	97.3(2.2)	0.01	98.3(1.6)	0.01	97.8(9.7)	0.01
LBW	80.0(16.3)	94.7(6.5)	0.01	94.6(8.3)	0.01	91.8(13.2)	0.04
NBW	83.0(15.0)	94.2(7.7)	0.04	92.6(9.3)	0.07	95.5(4.2)	0.030

Table 5: Variable/sign number of babies with sign

	Before CPAP	1hr after CPAP	6hrs after CPAP	12hrs after
Grunting	8 (79.2%)	26(54.2%)	10(20.8%)	6(12.5%)
Cyanosis	48 (100%)	22(45.8%)	15(31.3%)	10(20.8%)

Ten babies died giving an overall mortality rate of 20.8%. Two of the five mortalities in the RDS group were ELBW, two had sepsis and 1 had recurrent apnoea. Two term normal birth weight babies with suspected Cyanotic congenital heart disease died before specific Echocardiographic diagnosis could be made. Mortality rate was 17.4% among inborn babies and 24% among out born babies. Gestational Age related mortality rates were: ELBW (60%), VLBW (33%), LBW (44%) and NBW (30%).

Table 6 shows the case specific mortality rates with 100% mortality for recurrent apnoea and severe hypoxic encephalopathy.

Table 6: Case specific mortality rate

Diagnosis	Mortality Rate
Respiratory Distress Syndrome	5(16.7%)
Congenital pneumonia	1(9.1%)
Cyanotic Congenital heart disease	2 (66.7%)
Transient Tachypnoea of the Newborn	0(0%)
Recurrent Apnea	1(100%)
Hypoxic Ischaemic Encephalopathy	1(100%)

Discussion

Low-cost and simplified forms of the CPAP delivery systems have been described [7,8]. The uniqueness of our customized device lies in its simplicity and cost effectiveness. Some other modified BCPAP devices reportedly use corrugated tubes, Hudson's nasal prongs[9] or shortened endotracheal tubes[7] which need to be sourced separately, with additional cost burden.

Respiratory Distress Syndrome in very premature neonates is an important indication for nasal CPAP[10,11,12]. However, CPAP has also been successfully used in infants with other respiratory conditions, for instance, Jocelyn Brown et al[13] in Malawi, demonstrated the effectiveness of CPAP in the management of congenital pneumonia and as well as in an infant with Bronchiolitis. In our study, we recruited neonates with respiratory distress syndrome (30) as well as those with respiratory distress from other causes (18) including pneumonia and congenital heart disease.

We set out to demonstrate that our novel device produces physiologic responses similar to those previously observed and documented with different forms of CPAP. Ongoing observations and monitoring of the clinical condition (respiratory rate, heart rate, grunting and cyanosis) and oxygen saturation of patients provide the best assessment of the effectiveness of CPAP[14]. Clinical evidence of an effective CPAP includes a declining respiratory rate and heart rate, as well as increasing oxygenation[15]. In our study, the changes we observed; reduction in respiratory rate, increased SPO_2, and disappearance of cyanosis as well as grunting, therefore point to the promising clinical effectiveness of the customized B-CPAP device. Patrick Wilson et al[16] in Ghana had demonstrated a significant drop in respiratory rate among young children aged three months to two years with Pneumonia treated with CPAP early in the course of their illness. The outcome in these babies from their study was significantly better than those in whom there was a delay (1 hour) in commencing CPAP. The usefulness of pulse oximetry as a monitoring tool for babies on CPAP was noted by Malik et al[17] who reported a rapid rise in SPO_2 to >85% and this was sustained among survivors. This pattern of response is similar to the findings in our study.

The improvement in SPO_2 values (oxygenation) was quite rapid and this preceded the significant reduction in respiratory rate. This is similar to the findings of Wagstaff et al[18] who reported an immediate improvement in oxygenation when they changed from open-mask to a closed CPAP system in a lung model simulating acute respiratory failure. The difference in respiratory changes in the birth weight categories may be a reflection of gestational age dependent respiratory rate variability.

Majority of the babies who did not respond to CPAP were either extreme LBW or had cyanotic congenital heart disease. These would have required mechanical ventilation and intensive haemodynamic assessment and support respectively. Similarly, babies with recurrent apnoea and severe hypoxic ischaemic encephalopathy responded poorly to CPAP (as shown in table 4) presumably because they were unable to centrally maintain adequate respiratory drive needed to benefit from CPAP application. Documented causes of CPAP failure include extreme low birth weight, recurrent apnoea, neonatal sepsis/pneumonia[9,18,19] intracranial haemorrhage and non administration of antenatal steroid[20] In the absence of facilities for arterial blood gases, as is the case in several hospitals in Nigeria, clinical assessment and bedside pulse oximetry are recommended for monitoring babies on CPAP.

The limitation to this study is that our device does not provide blended oxygen, making it difficult to regulate the FiO_2. However, intermittent passage of air through the mouth and nostrils into the nasopharyngeal space cannot be completely ruled out, thus allowing for some air-oxygen blending in the nasopharynx. Furthermore, most oxygen concentrators deliver 80-85% O_2. These tend to provide some window of safety against oxygen toxicity. The mean values of SPO_2 over the period of observation was < 97%, therefore the risk of hyperoxaemia and the resultant effect on the retina especially in the ELBW/VLBW babies was expectedly minimized. Although the level of oxygen saturation associated with severe retinopathy of prematurity is not clearly defined, a Meta analysis by Minghua et al[21] on the association between severe ROP in preterms and SPO2 levels showed that SPO2 values between 70%-96% in the early postnatal weeks was associated with reduced risk of severe ROP. Long term ophthalmologic follow up of these babies is however required for early detection of gestational age dependent, oxygen induced retinopathy.

Conclusion

The NHA-BCPAP device produces immediate clinical responses similar to those reported for the conventional CPAP devices. It is therefore a viable alternative to the more expensive commercial CPAP devices and is therefore recommended for use in tertiary and secondary health centers in low-resource setting. Extended observations will however be needed to establish its long term benefits.

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