Feasibility study of a low-cost bubble CPAP system in a neonatal medium care unit in Belgium

Sophie Vanbinst [a,b], Emmi Van Damme [b], Anke Raaijmakers [b,c]

[a] University of Antwerp, Antwerp University Hospital, Department of Paediatrics, Edegem, Belgium
[b] ZNA Jan Palfijn, Department of Paediatrics, Antwerp, Belgium
[c] University of Leuven, Department of Development and Regeneration, Leuven, Belgium

anke.raaijmakers@zna.be

Keywords

Respiratory distress syndrome ; RDS ; respiratory support ; premature birth ; CPAP.

Abstract

Objectives: We aimed to evaluate the implementation and use of a high quality innovative bubble continuous positive airway pressure (bCPAP) System into a neonatal unit in Belgium.

Methods: A prospective observational study of neonates who met criteria for non-invasive respiratory support was conducted. All medical and nursing staff completed an on-line Thinkific course, followed by a live demonstration and practice of device application. Clinical indicator and device settings were recorded for every neonate. Staff surveys were administered after the training, after treatment of a neonate with a Vayu bCPAP System, and eight months after device introduction.

Results: Seven neonates were treated with Vayu bCPAP Systems. Their mean birth weight was 3170g with a median duration of treatment with bCPAP of 19 hours (IQR 2h–6d). Four term neonates had transient tachypnea of the newborn (TTN, n=4). One preterm and one term baby suffered from respiratory distress syndrome (RDS, n=2) and one baby had meconium aspiration syndrome (MAS, n=1). Six of the seven neonates improved their respiratory status and were weaned off the bCPAP System. One neonate needed more extensive ventilatory support and was transferred to a higher level neonatal intensive care unit (NICU). Staff surveys demonstrated that the devices were easy to use and satisfaction rates were high.

Conclusion: It was feasible to use Vayu bCPAP Systems to provide neonates with non-invasive respiratory support in our neonatal unit. Since implementation of this device there is less hesitancy among the medical staff to start babies on CPAP.

Introduction

Complications of prematurity including respiratory distress syndrome (RDS) are among the leading causes of morbidity and mortality during the neonatal period globally (1). To improve outcomes of infants with respiratory distress, WHO recommends use of continuous positive airway pressure (CPAP) as it has been shown effective in reducing morbidity and mortality among premature neonates (2). Early initiation of CPAP on neonates with RDS is associated with a reduced risk of respiratory failure requiring mechanical ventilation (3, 4).

RDS is the leading cause of death in preterm neonates and affects about one percent of newborns worldwide (5). Several advances have been made in the treatment of RDS including use of antenatal steroids, surfactant replacement therapy and CPAP. CPAP is a non-invasive respiratory support system that provides a continuous level of positive pressure to the airways, thereby distending the lungs, preventing alveolar collapse and improving ventilation.

Bubble CPAP (bCPAP) is a relatively low-cost method of assisting ventilation in neonates with respiratory distress. It has been shown an effective method at delivering nasal CPAP to preterm infants with RDS as well as in cases of meconium aspiration, pneumoniae, and apnea of prematurity, among other acute respiratory conditions (4). Most conventional CPAP systems require compressed air and advanced bioengineering support to ensure that the devices accurately deliver the required pressures, flow rates, and fractions of inspired oxygen (FiO2). Specialized training of nurses in CPAP is also necessary.

Over the past few years, Vayu Global Health Innovations has developed a ground-breaking bubble CPAP device (Vayu bCPAP System) that provides inspired concentrations of oxygen, flow rates, and pressures comparable to gold standard CPAP devices, yet does not require compressed air, electricity or highly skilled bioengineering support (6). Prior in vitro studies showed that the bCPAP system provides accurate control of CPAP pressures, oxygen concentration and humidification comparable with commercial CPAP devices. Delivered pressure (4-10 cm H2O) and oxygen concentrations (30-100%) were evaluated within 0.5 cm H2O and 4%, respectively, across all device settings in a breathing lung model (ASL 500 Test Lung). Tidal volume and flow remained consistent across all CPAP and oxygen concentrations settings. The bCPAP System sources humidity both from the humidity present in entrained ambient air and from a passive bubble humidifier. Relative humidity levels were tested by using a 3-dimensional heated lung model and a hygrometer. A relative humidity of > 80% was observed with the bubble humidifier which meets standard levels and is comparable with commercial devices (7). The Vayu bCPAP device was designed to meet the urgent need to make CPAP available, affordable, and easy to use in hospitals worldwide; both in low-income countries where resources are scarce as well as in hospitals in developed countries where the need for CPAP may be infrequent.

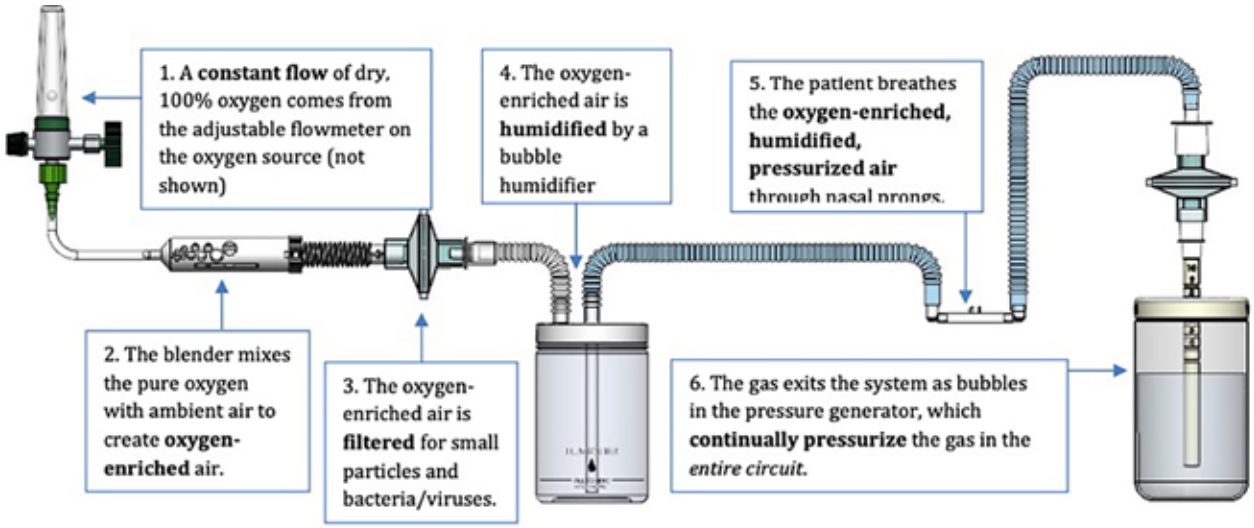
We hypothesized that given its unique properties, the Vayu bCPAP System would be easy to use, increase compliance of hospital staff with CPAP, and protect neonates from deteriorating further. We aimed to assess the feasibility and usability of the Vayu bCPAP System for respiratory support among neonates.

Methods

Setting

This prospective observational study took place in the (medium-care) neonatal unit at ZNA Hospitals Jan Palfijn General Hospital. The delivery suite accommodates approximately 1000 deliveries per year. The neonatal unit consists of 12 medium care beds where non-invasive respiratory support is available for neonates >33 weeks of gestation. In cases of

Figure 1: Description of the system.



prematurity less than 33 weeks' gestation or respiratory failure requiring invasive ventilation, transfer to a higher neonatal intensive care unit (NICU) is initiated. There are three higher level NICU's available within 15 km of our center. Prior to implementation of Vayu bCPAP Systems our unit could not care for more than one neonate on CPAP (Medin, ICC Medical, Germany) at a time.

The Vayu bCPAP System

The Vayu bCPAP System (Figure 1) centers around an innovative air/oxygen blender. The blender is an injected molded piece (polymer) that takes an input of pressurized oxygen and outputs a mixture of ambient air and oxygen (7). The FiO2 of the resulting jet can be adjusted by changing the distance between the nozzle and orifice openings. The FiO2 changes linearly with change in distance. At -25 mm of separation, 30% is achieved. When the nozzle is 25 mm into the orifice opening, the peak FiO2 of 100% is reached. If an FiO2 of 21% is desired the Vayu bCPAP System can be connected to pressurized medical air instead of a continuous oxygen flow. The blender is most efficient in pulling in ambient air at a setting of 40% to maintain bubbling when connected to medical air. The blender can provide 30-100% oxygen. Oxygen was titrated based on saturation monitoring and was set to the lowest possible percentage to maintain saturations > 92%. Furthermore, the mixed gas is filtered for small particles immediately after the blender, with an option to also filter in the exhalation limb. The humidifier filled with sterile water humidifies the oxygen enriched air prior to being delivered to the neonate. The pressure in the system is developed by the neonate's exhalation being delivered into the wand, which is submerged in the pressure generator. The pressure can be adjusted from 4 to 10 cm of water by adjusting the depth of the wand.

Table 1: Characteristics of the included patients.

Characteristics	1	2	3	4	5	6	7
Sex	M	F	M	M	M	M	M
Gestational age	40w+1	41w	40w+1	37w+6	37w+1	37w+4	33w+6
Apgar score (1-5 min)	5-6	8-9	9-9	9-10	9-10	5-6	6-7
Birthweight (g)	3609	4120	3400	3125	2260	3220	2460
Indication	TTN	MAS	TTN	TTN	RDS	TTN	RDS
RSS	5	NA	NA	8	5	8	9
Duration of treatment	5h	5d	2h	25h	7h	19h	6d

* TTN: transient tachypnea of the neonate; MAS: meconium aspirations syndrome; RDS: respiratory distress syndrome; RSS: respiratory severity score, NA: not available.

Table 2: Evaluation of training.

Questions	Participants (n)	Median	Interquartile range
1. How easy or difficult was it to implement the VAYU bCPAP?	26	8	8 – 10
2. How do you compare the ease of use of the VAYU bCPAP systems to other available CPAP devices?	26	9	7 – 10
3. How prepared did you feel using the VAYU bCPAP system after training?	26	9	8 – 10
4. Would you recommend this device to other healthcare providers?	26	9	7 – 10

* Every trainee filled out a questionnaire after the training session.
There were 4 numeric questions who are listed in the table above. The scale of response options went from 0 (very difficult/unprepared/unlikely) to 10 (very easy/prepared/likely).

Intervention

The study was approved by the ethics committee of the hospital network (ZNA hospitals, Antwerp). All nurses and pediatricians were trained through an online course (Thinkific), followed by a one-hour live demonstration and practice session on device application. There were subsequent individual training sessions. An online training course as well as a smart phone Respiratory Severity Score (RSS) calculator were available to all staff (8). Immediately after the initial training a nine-question survey was completed by every participant. There were four numerical questions, one question was yes-or-no and four were open ended. The survey evaluated the quality of training and subjective readiness (Appendix A). The method of cleaning and reprocessing was reviewed in detail with the head of the sterilization department. The breathing tubes, filters and nasal prongs were disposed of after each neonate. Indication for the use of nasal CPAP was determined by the medical staff depending on the degree of respiratory distress and/or apneas associated with TTN (transient tachypnea of the newborn), RDS, MAS (meconium aspiration syndrome), pneumonia,

Appendix A. Questionnaire after training session.

Feasibility/Usability	
How easy or difficult was it to implement the VAYU bCPAP?	Very difficult ---- difficult ---- easy ---- very easy 1 2 3 4 5 6 7 8 9 10
How do you compare the ease of use of the VAYU bCPAP systems to other available bCPAP devices?	More difficult ---- same ease of use ---- Easier 1 2 3 4 5 6 7 8 9 10
Do you believe that the VAYU bCPAP system helps infants? (please circle best answer)	No Unsure Yes
How prepared did you feel using the VAYU bCPAP system after training	Unprepared ---- somewhat prepared ---- Very prepared 1 2 3 4 5 6 7 8 9 10
Describe how the trainings can be improved	
Were there any barriers to the use of VAYU bCPAP systems	
What are the positive attributes of the VAYU bCPAP system (including monitoring, initiating, cleaning…)	
What are the negative attributes of the VAYU bCPAP system(including monitoring, initiating, cleaning…)	
Would you recommend this device to other healthcare providers?	Extremely Unlikely ---- Unsure ---- Extremely Likely 1 2 3 4 5 6 7 8 9 10

sepsis, congenital lung disease or tracheomalacia. In general, an RSS of ≥ 5 was deemed an indication for bCPAP. If the RSS was below 5 but the attending physician found it necessary to place the baby on CPAP, the physician could overrule the score. Exclusion criteria were the same as those for a conventional CPAP system: anatomic anomalies, respiratory failure, pneumothorax, and neurological impairment.

Data and analysis

When a neonate was placed on a Vayu bCPAP device (maximum of two babies at the same time), baseline characteristics including date and time of birth, sex, birth weight, gestational age, respiratory severity score, oxygen saturation, heart rate and respiratory rate were documented. Initial settings of the bCPAP system and any subsequent changes were recorded. During the treatment of a neonate with bCPAP, an evaluation form with three questions were filled out by the nurse taking care of the baby. Eight months after implementation of Vayu bCPAP Systems in our unit an evaluation form directed to those that used Vayu bCPAP Systems was administered. The survey assessed implementation, feasibility, and ease of use.

Results

Between January 1, 2022, and September 30, 2022, seven neonates that showed signs of respiratory distress were placed on Vayu bCPAP Systems (Table 1). Six were male and one female. Three neonates had an RSS of 5, two with 8 and one with 9. The RSS was not recorded in two neonates at the time of CPAP initiation. Six of the seven neonates were term (gestational age beyond 37 weeks) and one was 33 weeks and 6 days. The underlying causes of respiratory distress included transient tachypnea of the newborn (TTN, n=4), RDS (n=2), and meconium aspiration syndrome (MAS, n=1). Three term neonates were treated with Vayu bCPAP Systems for a few hours, one for 19 hours, and another for 25 hours. The neonate with MAS was treated with a Vayu bCPAP System for five days while the premature neonate was treated for six days. Six out of the seven neonates improved with their treatment and were weaned from bCPAP. One of the neonates with RDS was transferred to a higher level NICU because of persistent respiratory distress after seven hours on bCPAP.

Twenty-six health care workers enrolled in the initial training, after which each participant completed the survey. The median of the four numerical questions on this survey was 8 or 9 (Table 2). The yes-or-no question about whether the participant believed the Vayu bCPAP could help infants, was unanimously answered, 'yes'. The ease of installation, ability to provide CPAP without electricity, the compactness, and the possibility to use the Vayu device on transport were seen as favorable attributes. It was also mentioned a few times that bubbling in the pressure generator provided helpful constant feedback on device function, and allowed for rapid discovery of any loss of pressure in the system, such as might arise from tubing disconnections. The nurses described that their understanding of CPAP improved after the training course.

Staff suggestions for device improvements included: add a mechanism to shield the baby from the device noise and include options in length of the breathing tubes. Staff wished to be sure that skin to skin contact with the parents was possible while on bCPAP. Some staff wondered about the need for an orogastric tube instead of a nasogastric tube, which is generally well tolerated by the newborn. Seven staff members responded to the eight month questionnaire. The median score of the two questions about the ease of installation and use of the Vayu device in comparison to a gold standard CPAP device was for both 4 out of 5 (IQR 3–5). The question about the participants' level of support around the implementation of Vayu bCPAP systems in our unit scored a median of 5 out of 5 (IQR 3–5). Generally, the staff felt the Vayu bCPAP System is an asset to our unit.

Discussion

Respiratory distress is common in neonates worldwide and CPAP has been proven to reduce morbidity and mortality. However, until now, commercially available CPAP systems require electricity, compressed air and advanced bioengineering support. In our hospital, we had the opportunity to implement an easy-to-use bCPAP device. Because Vayu bCPAP Systems only need oxygen and sterile water, we hypothesized they could be helpful in our hospital and worldwide, especially where electricity is not reliable. As this system has a lower cost than all other CPAP devices and is less complex, hospitals in developed countries where CPAP is not often used could benefit as well.

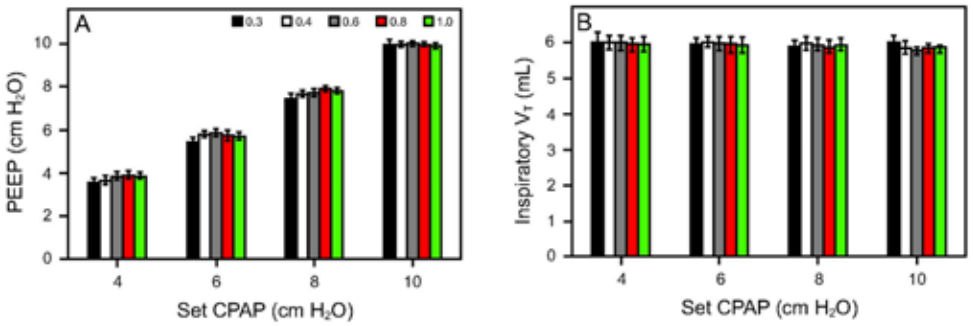
Since we are a neonatal care unit that only admits neonates over 33 weeks of gestation, the number of neonates who need non-invasive respiratory support is relatively small and unpredictable. Even though our observational study had a small study group, our staff agreed on the ease of application and use of this bCPAP device in comparison with our previous conventional CPAP machines. Since there is a need of constant bubbling for the bCPAP to work effectively, it is easy to rapidly identify any connection malfunctions.

The training courses went very smoothly. Since the training course is available online it is convenient to prepare all the nurses and doctors at the same time. Throughout the year of this study the VAYU team was always available for questions and technical support. We recommend retaking the training course at least annually, since the use of CPAP in our hospital is uncommon.

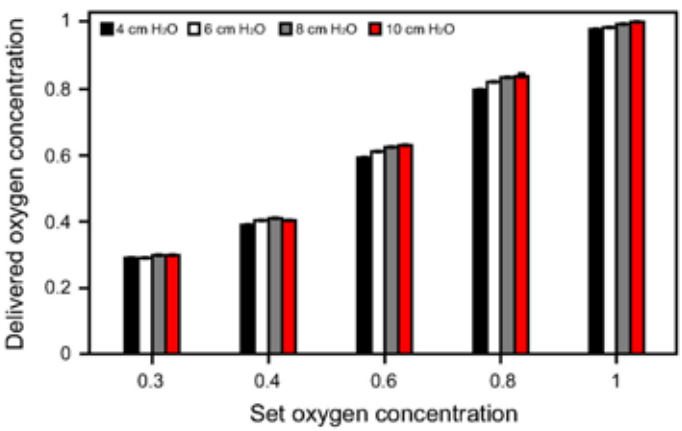
The main disadvantage of the Vayu bCPAP System is the noise produced by the high velocity jet in the blender and the bubbling in the pressure generator. It is known that preterm newborns exposed to elevated ambient noise may be affected adversely (9). We installed our Vayu bCPAP Systems outside of the incubators to protect the neonates from the device's noise. To assess noise and monitor potential improvements, it would be worthwhile to measure dB levels in the neonatal units. Future updates can subsequently focus on further noise reduction.

This study needs to be evaluated within its strengths and limitations. The strengths include the universal training which generated a universal approach to all neonates and the use of a respiratory distress score to indicate the necessity for CPAP. Limitations of the study are the small number of neonates included in the study, however, given the low frequency of CPAP use in units like ours, this was out of our control. We did not compare the former and new CPAP systems as the VAYU bCPAP was FDA approved and implemented as standard care. Further studies could be set up with a parallel control group to compare both devices at the same time to assess the easiness of use and performance. A possible selection bias might have occurred, however, all babies received bCPAP when clinically indicated.

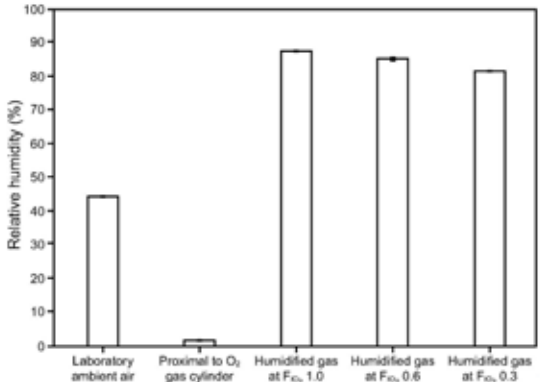
Appendix B. In vitro results on bCPAP device performance (7).



Results for PEEP (A) and tidal volume (B) for all set CPAP levels and oxygen concentration settings. Each bar indicates the mean value of 20 breaths, and the error bars denote SD.



Measured oxygen concentration as a function of a set oxygen concentration to illustrate the deviation from the intended value. Each bar indicates the mean value of 20 breaths and the error bars denote SDs. In each group, the different set CPAPs are denoted by different colors.



The relative humidity at each condition. Each bar indicates the mean of either 1 min of observation or 20 breaths. The error bars denote SDs. The first 2 conditions are reference values to the latter 3 conditions, which are simulated breathing.

Although VAYU Global Health provided the bCPAP devices, they had no influence on the study design and data interpretation. We acknowledge that their support and training might have caused bias in the implementation of the device. However, we decided to treat all babies the same and routine care protocols were adapted.

Additionally, the ratings of the medical staff could be biased as they were collected at the end of the training sessions. The response rate on the eight-month questionnaire was low (7 out of 26 responders); only seven neonates were placed on the Vayu bCPAP, so most staff members responded they could not submit the questionnaire because they didn't attend the installation process.

Altogether our unit agrees on the success and feasibility of implementation of this device. We hope to inform other neonatal units that additional studies and expertise are desired since this system could become an essential and easy-to-use part of their unit.

Conclusions

Implementation of VAYU bCPAP Systems was successful in our neonatal unit. We implemented this device after providing adequate training to our medical staff. The Vayu device is easy-to-use and compact. Noise arising from the blender and the pressure generator could be further optimized. The high quality, portability, low cost, and the lack of reliance on electricity and bioengineering support are considerable benefits for use worldwide. Overall, the staff in our neonatal unit were very satisfied after training and use of the Vayu bCPAP System.

Acknowledgments

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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