Low Cost Bubble CPAP Machine with Pressure Monitoring and Controlling System

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Research Article

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Abstract

Background

Africa contributed to one-third of the world’s neonatal mortality burden. In the Sub-Saharan region, preterm birth complications are the leading, in which a neonate is a higher risk of developing respiratory distress syndrome that will require extra oxygen and help with breathing. When compared to other respiratory supportive methods for treating infants in respiratory distress, bubble continuous positive air pressure (CPAP) is a safe, and effective system that is appealing to many resource-limited neonatal units in low and middle income countries. However, despite of its benefit, the accumulation of condensate in the patient’s circuit’s exhalation limb during a bubble CPAP can significantly increase pressure delivered to the serious physical consequences that can potentially lead to respiratory failure. Currently, existing technology in developing nations is expensive, and they will not control the accumulation of condensate in the exhalation limb. This quietly increases the mortality rate of neonates. Therefore, the objective of this project was to design, and develop a bubble CPAP device that able to monitor and control pressure delivered to the infant.

Methods

In this project, a low-cost bubble CPAP machine with a pressure monitoring and controlling system has been developed. When the neonate expires, the pressure sensor inserted into the expiratory tube reads the instant positive end expiratory pressure (PEEP) and sends it to the microcontroller. The microcontroller decides whether to turn the relay (controls the electric power to the 2 - solenoid valve) to switch the way of expiration between the two expiratory tubes connected to the valves of two outlets. This depends on the pressure reading and the cutoff pressure value manually inserted by the physician.

Results

The prototype was built and subjected to various tests and iterations to determine the device's effectiveness. The developed prototype was tested for accuracy, safety, cost, ease of use, and durability. The prototype was accurate in 10 iterations that had been made to monitor and control the pressure. It was safe and provided accurate pressure for the neonate, and it was built for less than 193 USD.

Conclusion

The proposed design allows physicians, especially those in low resource settings, to easily monitor and control the accumulation of condensate in the exhalation limb of the CPAP machine accurately and safely. This helps to reduce the neonate mortality rate that may occur due to respiratory distress syndrome.
Background

Due to various diseases that neonates face, the period from birth to the first 28 days is the most hazardous period of life [1, 2]. Globally, in 2017 alone, an estimated 6.3 million children died and nearly half (47%) of the under-five deaths occurred in the first month of life. Africa contributed to one-third of the world’s neonatal mortality burden [3, 4]. In the Sub-Saharan region, about 75% of deaths occur during the first week of life, and almost half occur within the first 24 hours [3, 5]. Preterm birth, birth asphyxia, and infections are the major causes of deaths [6]. Among the mortality reasons, preterm birth complications, which contribute to more than one-third of the global neonatal mortality burden, are the leading cause for which a neonate has a higher risk of developing respiratory distress syndrome (RDS) [7–9].

Respiratory distress (RDS) is a cause of death for preterm newborns immediately following birth [7, 10–12]. It causes babies to need extra oxygen and help with breathing [3, 13]. RDS is often seen during the transition from fetal to neonatal life. The successful transition from fetal to neonatal life requires a series of rapid physiologic changes in the cardiorespiratory systems. These changes result in a redirection of gas exchange from the placenta to the lungs and require the replacement of alveolar fluid with air and the onset of regular breathing [14]. Respiratory support is needed to treat RDS that begins immediately after birth to support immature lungs and to establish physiologic stability [15]. These supportive methods are divided into invasive (mechanical ventilation, endotracheal intubation) [12] and non-invasive (various CPAP devices, non-invasive mandatory ventilation, non-invasive pressure ventilation) [15].

In low-income countries, invasive mechanical ventilation is often not available for children at risk of death from respiratory failure [16]. However, continuous positive airway pressure (CPAP), which is one of the non-invasive methods, and also recommended by the World Health Organization (WHO) [12, 17], can improve survival in premature neonates with respiratory distress syndrome, especially for tertiary centers [9, 16, 18]. In developing nations, early use of CPAP along with early rescue surfactant (InSurE) is the best approach to managing the respiratory distress syndrome in preterm and extremely preterm infants [14]. A delivery room with CPAP is feasible and minimizes the use of surfactants and mechanical ventilation by almost 50% [15].

But in higher income countries, in addition to using CPAP, advanced use of technology such as antenatal corticosteroids, exogenous surfactant therapy and mechanical ventilation have been used, and have significantly improved the survival of neonates with RDS [19]. Despite the fact that no study was large, and both were conducted in academic medical centers, research results [20, 21] confirm that CPAP could improve survival beyond the neonatal period in children with primary pulmonary disease. However, the conventional CPAP devices and mechanical ventilation are expensive options, and mechanical ventilation requires high-level expertise and trained personnel, which is not currently affordable in many resource-limited countries [8, 10]. For instance, even if there are several conventional CPAP devices available, they cost up to US $6,000 to US $10,000 [22, 23], while a low-cost bubble nasal continuous positive airway pressure (bNCPAP) system may cost as low as US $350 to US $2000 [8, 24]. This means, comparatively, BNCAP may cost approximately 15% of the cost of the cheapest mechanical ventilator [23].
Although the existing CPAP machine helps prevent the collapse of alveoli in the lungs and increasing survival rates with the CPAP machine, some babies still develop Bronchi pulmonary dysplasia (BPD), which is a serious lung condition that affects newborns that need oxygen therapy [22, 23, 25]. In addition to this, however, the main engineering design gap with the existing CPAP machine was that the condensate in the exhalation limb of the patient circuit during bubble CPAP can significantly increase the pressure delivered to the neonate. The back and forth movement of this condensate fluid causes oscillations in airway pressure that are much greater than the oscillations created by gas bubbling out of the exhalation tube into the water bath [26], and allows delivered pressures to reach pressures significantly higher than those intended. This can result in serious physical consequences such as air leaks, over distention, and gastric distention. Moreover, the accumulation of condensate in the expiratory limb of the bubble CPAP circuit increases the delivered pressure to the infant, which will cause additional resistive loading of the respiratory system, causing serious physiological complications (such as increased PaCO2, reduction in venous return, and compromised cardiac output) and potentially leading to respiratory failure by imposing large airway pressure oscillations that are out of phase with the neonate's intrinsic respiratory efforts [25, 26]. Since neonates are very sensitive, disconnecting the expiratory tube for cleaning will leave them at a higher risk. In addition to this engineering gap, there is still a lack of knowledge regarding factors influencing the implementation of the already existing CPAP machine in relatively limited settings [5]. Due to this, developing countries need to address these preventable deaths by scaling up efforts to implement innovative and yet effective low-tech interventions to achieve the Sustainable Development Goals. The objective of this project was, therefore, to develop a bubble CPAP machine that has features to control the delivered continuous positive air pressure to keep it in a safe range at minimum cost. The developed BCPAP machine delivers safe therapy and monitors the continuous positive air pressure to protect the infants from the excessive pressure caused by the condensate accumulation in the expiratory limb of the circuit.

**Methods**

Different prototype iterations have been conducted to modify the design. The proposed final solution is a low cost bubble CPAP machine that monitors and controls the excess pressure caused by condensate accumulations in expiratory tube by using pressure sensor and two way solenoid valve, that help for alternating breathing. The system includes core components such as the Arduino Mega microcontroller, which controls and processes the entire system based on the uploaded script, a pressure sensor that continuously reads the airway pressure (for this project, the XFPM-050KPGP1 pressure sensor is incorporated to read the pressure inside the expiratory tube), and a solenoid valve that opens alternately depending on the pressure inside the expiratory tube. In addition to this, a plastic water jar or reservoir that is needed for immersing the expiratory limb of the breathing circuit at the required depth to set the positive end expiratory pressure (PEEP), a flow meter that measures gas flowing through the tube, and a pressure gauge used to control the pressure of a fluid or gas to a desired value can be an integral components of the device. Furthermore, the keypad is used by the physician to enter the required amount of pressure value.
Figure 1 below shows the functional and general block diagram of the proposed design. The neonate is given blended and regulated oxygen. While the neonate expires, the pressure sensor inserted into the expiratory tube reads the instant PEEP and sends it to the microcontroller. The microcontroller makes the decision by switching the relay, which controls the electric power, to the 2-way solenoid valve to alternate the way of expiration between the two expiratory tubes, which are connected to the valve of two outlets, and the other side is immersed in the bubbler alternatively, depending on the pressure reading and the cutoff pressure value uploaded to it.

Therefore, Fig. 1 above depicts that, first, the flow of oxygen from the source and compressed atmospheric air produced by the compressor is regulated and mixed up together. Then, this air enters the humidifier and is delivered to the neonate through an inspiratory tube which is connected to one side of the Y-tube. On the other side of the Y-tube, a 2-way solenoid valve is connected through the inlet and the two expiratory tubes are connected at either end of the outlet. Then immerse both tubes in the water containing the jar with the required PEEP, which is controlled by the depth of the immersion.

On the other hand, Fig. 2 below depicts the flow diagram of the proposed design. From Fig. 2, when the operation starts, the pressure sensor, which is placed before the solenoid valve on the expiratory side of the Y-tube, reads the pressure inside the tube and displays the value on the LCD. When the condensate is accumulated inside the expiratory tube and the pressure exceeds the safe range, the microcontroller will switch the pathway of air to the alternate expiratory tube. Moreover, when the pressure is high beyond the needed range and if the solenoid does not switch to the other expiratory tube to decrease the pressure, the alarm will be automatically triggered to remind the care givers. This works in the same way if the pressure is lower than the input value.

Results

Final Design

Different prototype iterations were conducted to come up with the final design. The final design was completed with the goal of obtaining a safe and reasonably priced BCPAP device with a pressure control system. Figure 3 shows parts of the final design. The design includes a delivering mechanism of continuous positive air (from oxygen source and compressed air) system, pressure monitoring (pressure sensor, LCD, alarm) system and pressure controlling (pressure sensor, Arduino mega, two way solenoid valve) system. In addition to this, the flowmeter, expiratory tube, relay, and water jar were components used in the final developed prototype. During the demonstration, the artificial lungs were used to represent infants. The system draws 5V from an external battery (here from a laptop computer, just for demonstration purposes) to power the Arduino microcontroller. Figure 4a-b shows the final design of the AutoCAD and the prototype, which is a low-cost bubble CPAP machine with a pressure monitoring, and controlling system, respectively.
Several tests and iterations were conducted in order to verify the proposed design criteria and specifications. Accuracy, safety, cost effectiveness, ease of use (ease of work load), durability, mechanism to control the pressure delivery, ability to mix oxygen into the flow stream, and adjustable flow rate ability were the parameters tested. Table 1 shows the summary of different tests conducted with their results.

**Table 1**
Tests conducted

| No. | Design Criteria to be tested | Method | Iteration | Design specification | Result |
|-----|------------------------------|--------|-----------|----------------------|--------|
| 1   | Accuracy                     | • Observing tube fixation  
      |                               | • Set the PcmH2o value in the normal range | 10     | • Remaining at the needed depth at all times.  
      |                               |                                                 |         | • It makes alarm whenever it is out of the set range.  |
| 2   | Safety                       | • Observing tube change by solenoid valve. | For 10 hours per a day, for 3 days | Highly increasing pressure determines the changing path. | Safe   |
| 3   | Cost effectiveness           | • Total components cost | - | <193USD | Cost effective |
| 4   | Ease of work load            | • Observing whether the system extend the time to clean the condensate in expiratory and alarm | For 10 hours, for 3 days | It cleans the condensate in the expiratory and alarms whenever there is uncontrolled pressure | Effective |
| 5   | Easy to use                  | Procedure of operation | 1 hour training for nurses and physicians | | |
| 6   | Durability                   | Data sheet for each components used. | 7 + years | | Durable |

**Accuracy Test**

The accuracy test was done by fixing the expiratory tube at a known depth (in cm) inside the water jar and observing it for 24 hours if it would slip in and it can be concluded that once the tube is fixed with the knob, it has not slept. Rather, it has remained at the fixation point. When condensate accumulates inside the expiratory tube and the pressure rises above the safe level, the microcontroller switches the air pathway to the alternate expiratory tube. Moreover, when the pressure was high beyond what was needed and if the solenoid did not switch to the other expiratory tube to decrease the pressure, the alarm
switched on to remind the responsible personnel. The team, along with clinical collaborators, tried this step for ten different iterations in order to ensure the system's accuracy.

**Safety Test**

The safety test was done mainly by observing the changes in pressure inside the expiratory limb and the designed system's response to it. When the pressure sensor reads the current pressure with time, the value is displayed on the LCD. When the value exceeds the maximum value of the entered range, the solenoid valve starts operating by switching to another level. The team was able to observe when the solenoid valve changed between the two alternative options of expiratory tube in order to keep the neonate safe from the excess pressure caused by condensate accumulation. In addition to this, the electric shock absorbance of the system was checked.

**Low cost**

The overall cost of the prototype has been calculated by considering the cost of each component. Accordingly, the total cost of the device is 193 USD or 8000 ETB.

**Ease of work load**

The accumulated condensate in the expiratory tube must be removed constantly. As a result, the system increases the time required to clean the condensate in the expiratory and notifies the nurses whenever there is uncontrolled pressure.

**Durability Test**

Because of the various types of components used, the determination of the device's life span may differ between devices. The life span of a component is known through data sheet assessment and, according to that, the team was able to guess the device's lifetime. Therefore, the estimated life time for the total integrated device for this device is approximately 7 years. Generally, Table 1 depicts the test conducted along with the results obtained.

**Discussion**

Respiratory distress (RDS) is a common problem for preterm newborns immediately following birth [7, 10, 11]. Bubble continuous positive air pressure (CPAP) is a safe and effective system for treating patients with RDS [8, 10, 21]. It is a recommended therapy for neonates who are in desperate need of breathing support. The oscillation created by the bubbles helps the neonates to develop their alveoli surfactant. However, the accumulation of condensate in the exhalation limb of the breathing circuit during bubble CPAP can significantly increase the pressure delivered to the neonate. This results in serious physical consequences that can potentially lead to respiratory failure. Despite its drawbacks when compared to our developed devices, many scholars have worked hard to solve this problem. For instance, the Rice 360° Institute for Global Health (Houston, Texas, USA) developed the Pumani system for low-income countries [27] with a system that includes a driver unit with a built-in bubble bottle for pressure control and a single
inspiratory tube connected to Hudson prongs. The bubble bottle is connected to the inspiratory limb, which works as a pressure release valve upstream of the patient. However, the flow diverted to the bubble bottle will not reach the patient and the bubbling does not represent the flow that the patient receives. The system was later redesigned and presented by Brown et al in 2013 with a capped expiratory limb and the bubble bottle moved to the inspiratory limb [8]. With this design and a situation with no leakage at the interface or through the mouth, there would be total rebreathing with an accumulation of carbon dioxide and subsequent respiratory failure. The Pumani system has since been revised with a bleed port added to the expiratory limb (previously capped) with sufficient flow through the bleed port [27]. However, with this design and a situation with no leakage at the interface or through the mouth, there would be total rebreathing with an accumulation of carbon dioxide and subsequent respiratory failure. On the other hand, B & B Medical’s bubbler [28] is designed to deliver between 0 and 10cm H2O CPAP for infants weighing less than 10kg. It has a dual-chamber wall for monitoring fluid levels. It does not have to be disconnected in order to see the water level. Disrupting the therapy is unnecessary. The drainable air overflow chamber doesn’t allow the water to rise above the prescribed level. This limits the fluid level to being within an optimal range. A fill port is provided for adding fluid without disengaging the circuit and rotating the CPAP dial with a setting lock reduces the risk of inadvertent setting changes. However, the B & B bubbler is a fixed pressure manifold that only opens if the pressure is more than 12.5cm of H2O and this will make it difficult for health care personnel to give the treatment if the neonate requires a pressure above 12.5cm of H2O and if the pressure required by the neonate for treatment is far below 12.5cm of H2O. This makes the gadget specific to the pressure and limited to use. In addition to this, the B & B Bubbler is very expensive, making it unaffordable for middle and low-income countries.

However, our design, called a low-cost Bubble CPAP Machine with Pressure Monitoring as well as a control system, has effectively solved problems related to excess pressure resulting from condensate accumulation in the expiration limb. Any design is preferable if it is precise and simple to use. In this sense, the developed design is simple to use and user-friendly. Vividly, the developed prototype has the following traits: (1) Adjustable flow rates, (2) Ability to mix oxygen into the flow stream; (3) Mechanism to control the pressure delivered to the patient; (4) Low cost; (5) Safe; (6) Durable; (7) Easy to use and repair, and (8) Accurate operation. In our country, there is a limited number of health personnel in NICU to the number of under BCPAP who follow up. The designed bubble CPAP extends the time required to clean the condensate in the expiratory tube and the alarm system calls nurses to check the neonate if there is uncontrolled pressure.

The prototype costs only 192USD, which makes it easily affordable in a low-resource setting. The accuracy of the system has been conducted under the supervision of a physician from the Jimma Medical Center. The prototype is very accurate. When the condensate is accumulated inside the expiratory tube and the pressure exceeds the safe range, the microcontroller will switch the pathway of air to the alternate expiratory tube. As a result, the system is completely confidential. The developed prototype provides a high level of safety. It is free from electric shock, contamination and any type of hazardous radiation exposure.
Conclusion

In order to solve the problem related to respiratory distress in infants, bubble continuous positive air pressure (CPAP) plays a crucial role. The accumulation of condensate in the exhalation limb of the breathing circuit during bubble CPAP, on the other hand, significantly increases pressure delivery to neonates, harming them quietly. In order to solve this, our design, the Low Cost Bubble CPAP Machine with Pressure Monitoring and Controlling System, has the function of both monitoring and controlling this accumulation of condensate and taking action whenever necessary. Cost effectiveness is a very important consideration in resource-poor regions of the world and has to be considered before any intervention is scaled globally. Therefore, our develop device is relatively cost effective than the already existing one. Moreover, the prototype was built and underwent different testing and iteration mechanisms, and it is confidential in monitoring and controlling the accumulation of condensate and the life of the neonate. The proposed method will have a significant impact in low-resource settings where expertise is scarce.

Abbreviations

BCPAP - Bubble Continuous Positive Airway Pressure

BPD - Bronchi Pulmonary Dysplasia

CPAP - Continuous Positive Airway Pressure

PEEP - Positive End Expiratory Pressure

RDS - Respiratory Distress Syndrome

Declarations

Ethics approval and consent to participate

This research project work was complies with Ethiopian National Ethics Review Guideline which was prepared by FDRE Minister of Science, and Technology on September 2014, Fifth edition.

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests
The authors declare that they have no competing interests.

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**Authors’ contributions**

All authors contributed equally to the study. All the authors read and approved the final manuscript.

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28. Pressure Relief Manifold [http://bandb-medical.com/pressure-reliefmanifold/]

**Figures**

![Diagram of a ventilator system](http://bandb-medical.com/pressure-reliefmanifold/)

**Figure 1**
Functional and General Block diagram of the system

![Diagram](image)

**Figure 2**

Flow diagram of proposed solution
Figure 3

Components of the low cost bubble CPAP machine with pressure controlling system.
Figure 4

A) Final AutoCAD design, B) Final Developed Prototype