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A low-cost oxygen-air mixer device extends accessibility of safer neonatal respiratory support in a resource-poor setting

Abstract

Background information: High cost of commercial-grade bubble continuous positive airway pressure (CPAP) machine has led to its limited availability for respiratory support of neonates in resource poor facilities. Most Nigeria facilities resorted to an improvised setup which supplies oxygen at 100% concentration exposing neonates to hyperoxia with possible ROP. PoliteO$_2$ blend® is a cheaper device that mixes supplied oxygen with atmospheric air, delivering variable fractions of inspired oxygen (FiO$_2$) to neonates via tracheal tube or nasal prongs extended into a disposable PEEP water bottle as used in the improvised setup. The system microfilters and humidifies the blended gas unlike conventional improvised application. This study evaluated the PoliteO$_2$blend as a standalone device as well as an upgraded version of improvised-CPAP.

Methods: Four units of the politeO$_2$blend were installed at the University Teaching Hospital Abakaliki for trialling and were operated by four designated staff after prior training on the modes of application of the device. Forty-five neonates, birthweight ≥1500g were treated following parental consents. The systems were operated as improved improvised-CPAP in 16 neonates of which 18.8% (3/16) were delivered preterm. All patients initially experienced respiratory distress with 75% (12/16) having pre-treatment respiratory rate >60c/m and SPO$_2$ as low as 43% in some. The neonatal impact analyses of continuing usage of the devices at the hospital was evaluated based on the fraction of the total number of needy neonates at the centre who necessarily got treated using the device.

Results: The target SPO$_2$ of 90-95% was achieved in all neonates using FiO$_2$ that ranged from 0.21 to 0.6. Duration of improvised setup with PoliteO$_2$blend before successful discharge ranged from 5hrs to 7days.

Conclusion: Our target SPO$_2$ was rapidly achieved at a safer FiO$_2$ in most neonates that received respiratory support. Improvised-CPAP application via PoliteO$_2$blend may reduce the incidence of oxygen toxicity owing to conventional use of improvised setup. PoliteO$_2$blend is recommended as safer alternative for facilities lacking sufficient funds.

Keywords: Oxygen blender, improvised CPAP, neonatal support, RDS, SPO$_2$

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Background

The first quarter of neonatal life in Nigeria has remained the most dreaded period of high mortality for children under the age of 5 years (U5) and has remained the main reason for Nigeria's failure to achieve any significant progress towards the millennium development goal target (no.4) of year 2015.[1,2] The first 48 hours of this period is most challenging for all very, and extremely-preterm, extremely-low birthweight, and all perinatally asphyxiated neonates and those who passed through protracted labour before being born.[3] These neonates are so distressed in the first few hours that the job of breathing is a herculean task if not assisted.

Introduction

A lot of measures have been suggested in the literature for low-cost[4] or nearly no-cost[5] assisted breathing technologies. However, these technologies have been argued to be fraught with some LMIC issues of concern, such as, high maintenance and consumables costs of brands like the Dolphin model (MTTS Asia, Vietnam),[4,6] and safety and functionality deficiencies of the Nigerian improvised bubble CPAP (i-bCPAP) setup.[5,7] Such concerns led to the development and trialling of some other ultra-low-cost and operational-friendly models such as the politeheartCPAP machine which was initially noted with the potential of bridging these undesirable gaps for Nigerian neonatal centres.[4,8] It was noted that the politeheartCPAP machine, for example, ticked all boxes including being priced at <$2,000, which was <16% of the cost of Fisher-&-Paykle model in Nigeria at the time.[4,8]

Observably across Nigeria's special care baby units (SCBU), the introduction of the politeheartCPAP machine was a welcome development. However, the low-cost machine has not shown to have fully solved the problem as many SCBUs still lack the funds to acquire and simultaneously deploy up to six units of the politeheartCPAP to reach many patients in need. The worse-off patients are those who weigh less than 1500 g, who rarely survive if treated with the i-bCPAP procedure, which is the most popular in Nigeria because it is easy to set up at almost no-cost. Hence, the need to boost availability of safe, efficient, and deployable cheaper intervention alternatives led to the present research. The project searched to develop a low-power-driven oxygen-air mixer 'extension' device that could interface to improve the efficiency of the i-bCPAP setup as was earlier desired by the Nigerian Society of Neonatal Medicine (NISONM) in 2017.[6] Published demographic reports suggested that <35% of needy Nigerian neonates were able to access the referral centres, where the few branded bubble-CPAP machines might be available, howbeit, in insufficient quantity to attend to all needy neonates.[9]

This suggests that >65% of needy Nigerian neonates were locked up in the rural centres and some urban cities, left with no mechanised intervention technology for their respiratory aid to survival.[10] Therefore, it would be impactful for a new respiratory system, which could, in addition to ultra-low-cost for affordability, incorporate lightweight, ease of operation, and versatility of usage mode.

Materials and method

The cost factor was kept as a constraint of focus to produce a design that could be purchased with less than 25% of the cost of the politeheartCPAP, hence, projecting an estimated market price of the equivalent of <$450 for this product. The new concept adopted similar design elements and assemblies as the politeheartCPAP, but with altered performance parameters as required.[8] Therefore, the compact design incorporates an inbuilt air compressor (F) for self-supply of atmospheric air via a controlled volume flow regulator (H) (Figure 1). The design provided an input port (B) for oxygen from an oxygen-cylinder or oxygen-concentrator which channels the flow through a volume flow regulator (D). The oxygen-air mixer chamber allows the proper mixing of the differential volumes of each component before delivering the product gas to the patient volume flow control (J). The inspiratory gas goes through the particle filter-column (K), and humidification (M) before reaching the exit (delivery) port (N).

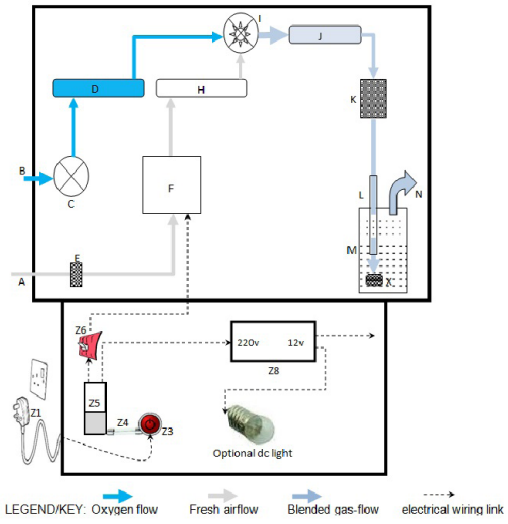

Figure 1 Interface of system assemblies in processing of respiratory gas.

A - Fresh atmospheric air inlet, B - Oxygen supply inlet, C - Oxygen port & pressure safety device, D - Oxygen volume flowmeter/regulator, E - Air pre-process filtration unit serving the compressor, F - Air compressor, H - Air volume flowmeter/regulator, I - Air-Oxygen mixer chamber, J - Blended-gas volume flowmeter/regulator, K - Gas post-process filtration chamber, L - Humidifier gas-inlet straw, M - Humidifier Assembly, X - Humidifier gas diffuser, Z1 – Power inlet assembly, Z3 - Power switching module, Z4 - Fuses/electrical safety pack, Z5 – Power distribution card, Z6 - Compressor control switch, Z8 - Power transformation/rectification chamber.

All assemblies were manufactured using readily available low-cost generic components sourced via the internet and Nigerian local markets. All the external interfaces for the oxygen input and inspiratory gas delivery were manufactured to fit the most common (unbranded) and readily available neonatal nasal cannula found in Nigerian local markets as shown in Figure 2. The air compressor assembly is powered by a single electromagnetic induction pump and capable of delivering up to 6.5 LPM air flowrate into the mixing chamber, where the appropriate 'fraction of inspired oxygen (FiO_2)' is achieved for the specific need of the patient. A desired FiO_2 is selected by discrete adjustments of atmospheric airflow (air regulator knob) and oxygen flow (O_2 regulator knob), guided with a supplied 'oxygen-air-FiO_2' relationship chart. The prototype of the completed design was produced and tested in the laboratory with adjustments to characterize its stability under constant running period of over seven days at an ideal highest combined inspiratory gas flowrate of 10 LPM (Figure 3).

Figure 2 The commonest neonatal nasal cannula in Nigeria local markets.

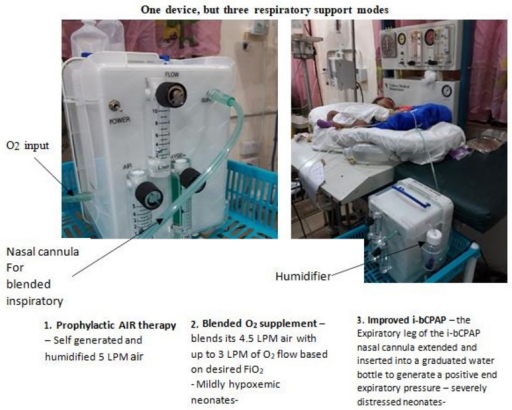

Figure 3 The new device at AEFTH Abakaliki – explaining its 3 modes of operations.

The clinical trialling was initiated following the extended ethics clearance obtained from the Health Research Ethics Committee of the Niger State Ministry of Health, Nigeria (reference STA.495/Vol/132). The trialling lasted for six months at the special care baby unit (SCBU) of the Alex-Ekwueme Federal Teaching Hospital (AEFTH) Abakaliki and was used to rigorously assess the effectiveness and efficiency of its three modes of operation as described in Figure 3. The results so-generated and analysed were presented and favourably reviewed at the 51st scientific conference of the Paediatrics Association of Nigeria in Kano city in January 2020.[11]

Beyond the Kano Nigeria conference, the four units of the new device were formally integrated into the neonatal respiratory intervention techniques at the Teaching Hospital Abakaliki, where the devices have remained in use till the time of writing this manuscript. The usage impact assessment of the new device at the Abakaliki hospital was quantified based on the fraction of all needy neonates at the centre that the device was used to support, and the fraction of the cases that were successfully treated.

Three modes of operation: The device was engineered to be used as a versatile machine to serve multiple classes of neonatal respiratory need in a remote resource-limited setting, described as follows:

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1) Neonates normally arrive very weak after a prolonged labour during delivery. In this situation, the system could be operated on 'prophylactic air only' mode to generate and supply up to 5 LPM air flow to the just-delivered neonate immediately after resuscitation; hence assisting the infant by minimising the required energy for breathing. We hypothesised that such intervention would accelerate the recovering time and hence the discharge of such neonates.

2) The device could be used to deliver a safe supplemental oxygen support in cases of mild neonatal hypoxemic conditions. The SCBU centres in Nigeria would usually use nasal prongs to deliver pure oxygen (~100% FiO_2) directly from the oxygen-cylinder or oxygen-concentrator to the infant, which has been widely believed to lead to another disabling condition known as 'Retinopathy of Prematurity (ROP)'. Therefore, a safe supplemental oxygen delivery requires the intermediary mode of the new device to, first receive the pure oxygen, and then blend this with pre-filtered atmospheric air to achieve a desired gas-FiO_2 before delivering to the neonate (Figure 4b).

3) The third application mode would become necessary if the infant presents with severe respiratory distress when there is no deployable neonatal ventilator to hand. This is usually the situation when Nigerian practitioners would scramble for the so-called i-bCPAP, which is easily assembled with a neonatal nasal cannula, water in graduated transparent bottle, and vertically inserted straw.[5,7] The improved i-bCPAP mode of application of the present new device allows the i-bCPAP oxygen from the cylinder to route through the new device for the required FiO_2 air-oxygen blending, bacterial filtering, and pre-humidification of inspiratory gas. Hence, the rest of the i-bCPAP setup remains the same, except that the nasal cannula takes delivery of inspiratory gas from the politeO$_2$blend device (Figure 4c).

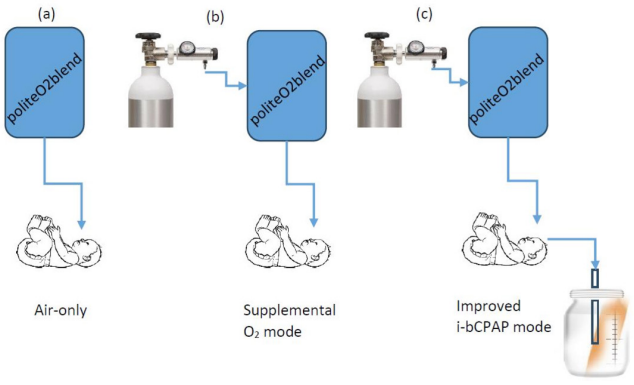

Figure 4 PoliteO$_2$blend modes of application (a) air-only mode (b) supplemental O_2 mode (c) improved i-bCPAP mode.

Results

The prototyping, testing, and re-testing processes yielded the satisfactory final model which maintained its thermal and functional stability, and low-noise level all through the set 168 hours of non-stop operation. At an approximate production cost of $360 per device, four units of the final model were produced and installed. All four machines were deployed and successfully completed the set six months of clinical trialling at the Alex-Ekwueme Federal Teaching Hospital Abakaliki without any reported failures. Forty-five neonates were successfully managed with the device between the two neonatal units of the hospital, and all three modes of the device were appropriately deployed at various time. All the 45 treated needy neonates during the trialling period were of birthweight ≥1500 g. The systems were deployed on prophylactic or oxygen-supplement mission in most of the cases. However, the devices were operated as improved i-bCPAP in 16 neonates of which 18.8% (3/16) were delivered preterm. All improved i-bCPAP cases were noted to have initially experienced respiratory distress with 75% (12/16) having pre-treatment respiratory rate >60c/m and saturation (SPO_2) as low as 43% in some of the cases.

The new device successfully delivered gas mixtures of FiO_2 that ranged from 0.21 to 0.6. between all treated cases. The patient's oxygen saturation target of 90-95% was achieved in all the distressed neonates before successful discharge, which ranged from 25hrs to 7days of treatment.

Out of the 230 needy neonates who accessed oxygen therapy between September 2019 and April 2020, 71 received the therapy via the new politeoxygen-blend, hence, representing 31% of the respiratory support burden. All the modes of application of the device were reasonably engaged, having 30% of cases treated on prophylactic air mode, 46% on supplemental oxygen mode, and 24% as improved i-bCPAP application.

Discussion

Nigerian neonates have for too long been unable to access suitably safe or mechanized models of a non-invasive respiratory machine, essentially owing to high market costs of neonatal ventilators. A few recent models that achieved a drastic reduction of the cost of branded bubble-CPAP machines in Nigeria by over 75%, down to <$2000, were well received and celebrated. However, later observations and interviews across Nigerian centres revealed that the celebrated low-cost was still far too high for most neonatal centres to privately acquire adequate number of the machines for their high demand periods. Nigeria has high incidence of deadly perinatal asphyxia and neonatal respiratory distress, hence, there should be no stopping in this burden-inspired research to discover measures of lowering the cost of accessibility of tailored, safe, portable, and efficient technologies to grant every neonate a fair chance of survival.

In the present research, we have achieved a product that could enable resource-poor centres to acquire a desired fleet of a mechanised respiratory support machine. The new device, politeoxygen-blend, has been demonstrated in this presentation and shown to be capable of three modes of operation as could be relevant to a typical poor neonatal setting in Nigeria. As an add-on device for the so-called improvised bCPAP, it has eliminated the fear of retinopathy of prematurity, which is often associated with this popular intervention technique. A qualitative report of four years of usage of the device from the neonatal centre of the Federal Teaching Hospital Abakaliki claimed that the device's 'prophylactic air mode' of application has relatively improved the recovery time of the supported neonates as compared to prior recovery time for neonates who underwent prolonged-labour. On overall impact of the new device at the Abakaliki hospital, the politeoxgen-blend has allowed access to safe mechanised respiratory support for many needy neonates based on a representative 31% of the burden that the system was used to resolve. This relative share of respiratory intervention burden using the politeoxygen-blend over the last four years at the Abakaliki neonatal centre is remarkable as has been demonstrated in the chart in Figure 5. It is expected that the scaled-up usage of this portable and affordable device across Nigeria and other LMICs would motivate a self-help initiative in acquiring the device by many neonatal centres at resource-constrained locations, hence extending the reach of safer support to more neonates.

Therefore, many neonates who would otherwise die could possibly be saved from the various respiratory conditions.

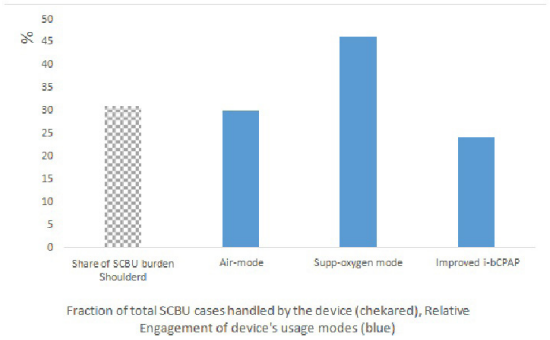

Figure 5 The measure of impact of the new device at Alex-Ekwueme Federal Teaching Hospital, Abakaliki.

Conclusion

The politeO$_2$blend device has demonstrated a significant usefulness during trialling and the subsequent four years of continuous usage at the AFTH Abakaliki, bearing a representative 31% of all workloads. It retained its stability throughout whilst drastically lowering the cost of safe CPAP application to <$400 from almost $2,000 cost of regular politeheartCPAP brand.[8] This safe and ultra-low-cost device offers great opportunity for resource-poor settings to acquire a piece of technology that could help save lives at their various locations

Limitations

This trialling and the subsequent community impact study could have benefitted more with a multicentre assessment, involving up to three independent tertiary hospitals. However, this was hampered by a lack of sufficient funds to manufacture more than four units of the device to make this possible. The period of covid 19 pandemic was a setback that limited the flow of our data collection between 2020–2021.

Author contributions

(1) H. O. Amadi researched the need, conceptualised, designed, and funded the developed device. He also conceptualised and designed the characterization and impact study protocol. He drafted the initial manuscript and led the manuscript polishing and readiness.

(2) C. D. Obu anchored all trialling data capture, supervision of doctors and nursing staff who assisted to monitor the neonates on the devices. She also contributed to the analyses and interpretation of data, and manuscript polishing and readiness.

(3) E. Onwe-Ogah negotiated the study at the centre. He participated in data collection supervision, manuscript polishing, and readiness.

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Conflicts of interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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