

Evaluation of a Low-Cost Bubble CPAP System Designed for Resource-Limited Settings

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BACKGROUND: Respiratory compromise is a leading contributor to global neonatal death. CPAP is a method of treatment that helps maintain lung volume during expiration, promotes comfortable breathing, and improves oxygenation. Bubble CPAP is an effective alternative to standard CPAP. We sought to determine the reliability and functionality of a low-cost bubble CPAP device designed for low-resource settings. **METHODS:** The low-cost bubble CPAP device was compared to a commercially available bubble CPAP system. The devices were connected to a lung simulator that simulated neonates of 4 different weights with compromised respiratory mechanics (~1, ~3, ~5, and ~10 kg). The devices' abilities to establish and maintain pressure and flow under normal conditions as well as under conditions of leak were compared. Multiple combinations of pressure levels (5, 8, and 10 cm H₂O) and flow levels (3, 6, and 10 L/min) were tested. The endurance of both devices was also tested by running the systems continuously for 8 h and measuring the changes in pressure and flow. **RESULTS:** Both devices performed equivalently during the no-leak and leak trials. While our testing revealed individual differences that were statistically significant and clinically important (>10% difference) within specific CPAP and flow-level settings, no overall comparisons of CPAP or flow were both statistically significant and clinically important. Each device delivered pressures similar to the desired pressures, although the flows delivered by both machines were lower than the set flows in most trials. During the endurance trials, the low-cost device was marginally better at maintaining pressure, while the commercially available device was better at maintaining flow. **CONCLUSIONS:** The low-cost bubble CPAP device evaluated in this study is comparable to a bubble CPAP system used in developed settings. Extensive clinical trials, however, are necessary to confirm its effectiveness. *Key words:* CPAP; bubble CPAP; respiratory distress; low-resource settings; Uganda; neonate. [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

Introduction

Respiratory compromise is a leading contributor to the nearly 3 million neonatal deaths that occur each year.^{1,2} It can result from prematurity, pneumonia, sepsis, and intra-partum-related complications, which are collectively re-

sponsible for > 80% of neonatal deaths globally.^{3,4} An effective means of treating children with respiratory distress has the potential to impact global child mortality. In the developed world, respiratory support is administered via mechanical ventilation or CPAP, which helps maintain lung volume during expiration, promotes comfortable breathing, and improves oxygenation.^{5,6} However, the average stand alone CPAP machine costs more than \$5,000

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USD⁷ and requires highly trained personnel to operate and maintain it, rendering such devices inaccessible to low-resource settings.^{2,8}

Bubble CPAP is an alternative but effective approach to providing CPAP in which pressure is safely maintained by submerging the end of the expiratory tubing in water; the depth of the expiratory tubing dictates the amount of pressure generated. The use of bubble CPAP as well as other approaches to apply CPAP in developed countries has reduced mortality by up to 50%^{2,9} and has reduced morbidity and days in hospital.¹⁰ Studies have shown that the use of bubble CPAP can be equally effective in low-resource settings, but such settings necessitate inexpensive and easily repairable devices.^{5,7,11-13}

A simple, low-cost bubble CPAP device was developed by staff at Massachusetts General Hospital in Boston, Massachusetts. The device, designed for the low-resource settings of Uganda, is composed of only 6 major parts (~25 parts in total), and the expected cost is nearly 50 times less than the average stand alone CPAP device. With appropriate sterilization/disinfection, all aspects of the device can be reused. Because of its expected low cost and relative simplicity, the device has the potential to impact pediatric mortality in Uganda, which has a neonatal mortality rate of 19 per 1,000 live births and an infant mortality rate of 38 per 1,000 live births.¹ However, the device's function has yet to be independently verified. Using simulated models of children with compromised respiratory mechanics, we assessed the accuracy and reliability of the low-cost bubble CPAP device by comparing it to the B&B Bubbler (B&B Medical Technologies, Carlsbad, California), a commercially available bubble CPAP system. We hypothesized that the low-cost bubble CPAP system would function equivalently to the B&B Bubbler without demonstrating clinically important differences.

Methods

This study was funded by and performed in the Department of Respiratory Care, Massachusetts General Hospital (Boston, Massachusetts).

The Device

The low-cost bubble CPAP device consists of relatively few components (see Fig. 1), with a total cost of roughly \$110 USD. The system includes an ambient air compressor, an adjustable flow meter (Dwyer Instruments, Michigan City, Indiana), a pressure regulator (a bubble PEEP valve), inspiratory and expiratory tubing (Finger Lakes Extrusion, Canandaigua, New York), and a water bottle with a RAM cannula (Neotech, Valencia, California); it should be noted that this cannula, though used extensively for CPAP, is not cleared by the Food and Drug Adminis-

QUICK LOOK

Current knowledge

Respiratory compromise is a leading cause of neonatal mortality, and CPAP is an effective treatment. However, standard CPAP setups are expensive and inaccessible to low-resource settings. Bubble CPAP is an alternative approach to CPAP that has been shown to be effective in low-resource settings.

What this paper contributes to our knowledge

In a simulated lung model setting, the low-cost bubble CPAP device provided similar pressures and flows to that of a standard bubble CPAP device. Over a prolonged period of time, flow dropped significantly, but pressure did not.

tration for this purpose. The adjustable flow system provides a continuous flow of room air, and the bubble PEEP valve maintains the pressure delivered to the patient. This bubble CPAP device, in its current design, does not accommodate an external source of oxygen, so blended oxygen delivery is not possible.

The Evaluation

This study was performed in 3 parts. In the first part, we used a lung simulator to test the devices' abilities to establish and maintain pressure and flow under normal conditions as well as under conditions of leak. In the second part, we tested the devices' abilities to deliver flow when attached to a ventilator tester rather than a lung simulator. In the final part, we measured the devices' endurance. For comparison purposes, all trials of this study were conducted using both the low-cost bubble CPAP device and the B&B Bubbler system. When using the B&B Bubbler, a DAC1 dry-air compressor (Siemens, Munich, Germany) was used to generate flow.

Evaluating Pressure and Flow

Using a Lung Simulator Without Leak. Each bubble CPAP device was tested at 3 levels of pressure (5, 8, and 10 cm H₂O), and 3 flows (3, 6, and 10 L/min) were set at each pressure for each of the premature infant weights simulated. Each device was connected to the ASL 5000 breathing simulator (v3.5, IngMar Medical, Pittsburgh, Pennsylvania), which was preprogrammed to simulate preemies of 4 different weights (Table 1). The lung mechanics for each simulated model were determined from previous clinical¹⁴⁻¹⁷ and simulation¹⁸⁻²¹ studies, with specific

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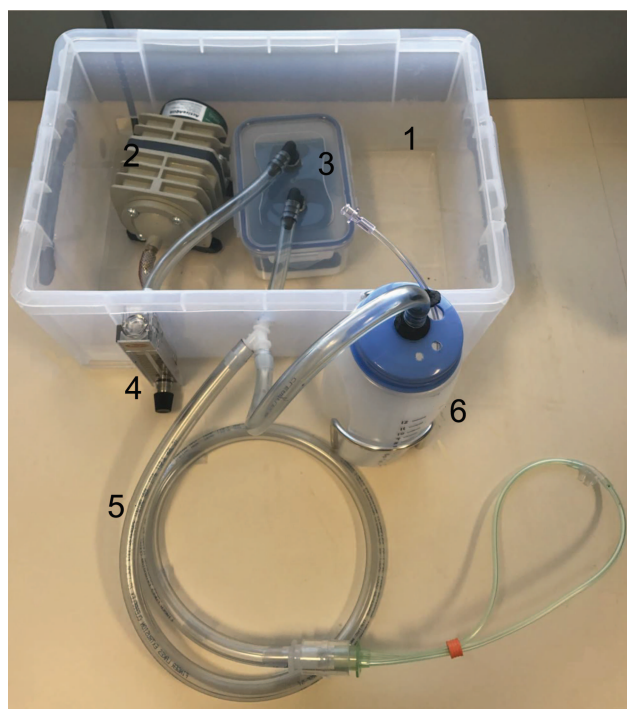


Fig. 1. The low-cost bubble CPAP system. (1) A 10-L, rectangular, plastic housing box. (2) A 45-L/min air pump. (3) A water-filled plastic container used for humidification (a foam space filler was used instead of water in our experiments to minimize potential damage to electronic testing devices). (4) A 10-L/min flow meter. (5) Airway tubing. (6) A water bottle (height > 10 cm) with a RAM cannula attached to the low-cost bubble CPAP device.

references^{15,16,19,20} used for airway occlusion pressure ($P_{0.1}$) and maximum inspiratory pressure. To simulate a trachea, we placed an endotracheal tube between the bubble CPAP circuit and the test lung. Trachea diameter and length were determined from previous clinical studies²²⁻²⁴ (Table 2).

The ASL 5000 was used in this evaluation because of its precision in reproducing a consistent ventilatory pattern during all evaluations. In addition, the 4 neonatal lung models studied could be easily set with the ASL 5000. The ASL 5000 also measures, records, and displays pressures and flow within the simulated respiratory system.

The 9 possible combinations of pressure and flow were run with all 4 simulated pediatric patients (~1, ~3, ~5, and ~10 kg), resulting in a total of 36 trials, each lasting 15 min. Peak inspiratory flow and PEEP were compared between the 2 devices.

Using a Lung Simulator With Leak. To simulate nasal prong leak, we used a stopcock to introduce a 20% leak^{18,25,26} at the distal end of the bubble CPAP delivery system. Peak inspiratory flow and PEEP were compared between the 2 devices. The system pressures, flows, and lung models from the test without leak were used in the test with leak.

Evaluating Flow Using a Ventilator Tester

To test the devices' flow when resistors (stiff lungs) were not present, we attached each device to a PTS 2000 ventilator tester (Mallinckrodt, Dublin, Ireland), which measured both systems' flows. CPAP was set to 5 cm H_2O , and tests were performed at each of the following rates: 2, 4, 6, 8, and 10 L/min for 10 min. The PTS 2000 was used because of its accuracy and precision in the measurement of flow and pressure gradients.

Evaluating Endurance

To evaluate the devices' abilities to maintain pressure and flow over a prolonged period of time, we ran them continuously for 8 h. CPAP was set at 8 cm H_2O , and flow was set to 6 L/min. For the first and the last 10 min, the devices were connected to the ASL 5000 breathing simulator and the PTS 2000 ventilator tester so that pressure and flow data, respectively, could be collected. To avoid any accidental condensation entering the ASL 5000 or the PTS 2000 from the bubble CPAP, the devices were connected to a simpler, non-computerized test lung during the middle 7 h and 40 min to capture condensate. Because some water did evaporate from the PEEP bottles over the 8-h period, we measured the drop in water height so pressure changes could be accounted for.

Finally, a temperature probe was placed on top of the humidifier chamber of the low-cost bubble CPAP device to measure the system's temperature increase. For both the temperature and longevity tests, a total of three 8-h trials were run.

Statistical Analysis

Pressure data were collected using the lung simulator's software (ASL software version 3.5, IngMar Medical) while flow data were collected by both the lung simulator's software and the PTS 2000's software (BreathLab PTS software v2.0, Mallinckrodt). Results are expressed as mean values \pm SD, and means were compared using 2-way t tests. The change in water levels between the 2 systems during the endurance test were compared using a 2-way t test. Statistical analysis was conducted using R Statistical Software (R Foundation for Statistical Computing, Vienna, Austria). A value of $P < .05$ was considered statistically significant. We have reported all results, but we only discuss differences that were both statistically significant ($P < .05$) and clinically important ($> 10\%$ difference).

Differences in performance between the 2 devices were not considered clinically important unless the differences were both significant and $> 10\%$. We used this approach because lung-model studies generate a large number of

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Table 1. Lung Model Settings

Model (Approximate Weight)	P _{0.1} , cm H ₂ O	P _{max} cm H ₂ O	Resistance, cm H ₂ O/L/s	Compliance, mL/cm H ₂ O	Breathing Frequency, Breaths/min	Inspiratory Time, ms
Preemie (~1 kg)	2	4	100	1	60	300
Newborn (~3 kg)	3	6	70	4	50	375
Infant (~5 kg)	4	8	50	6	40	450
Pediatric (~10 kg)	5	10	25	10	30	600

P_{0.1} = airway-occlusion pressure 0.1 s after the start of inspiration against an occluded airway
P_{max} = maximum inspiratory pressure drop

Table 2. Simulated Trachea Settings

Model (Approximate Weight)	Trachea Diameter, mm	Trachea Length, cm
Preemie (~1 kg)	3.0	3.5
Newborn (~3 kg)	3.5	4.0
Infant (~5 kg)	4.0	4.5
Pediatric (~10 kg)	5.0	5.5

data points, and when 2 machines are compared, statistically significant differences may have no clinical relevance. We therefore chose to use a 10% difference to imply clinical importance because this is the tolerance of most settings and measurements on mechanical ventilators. For example, a ventilator set to deliver a tidal volume of 500 mL may generate a breath between 450 and 550 mL, which is considered an acceptable level of accuracy. Thus, we assumed a difference > 10% should raise a concern regarding the performance of devices being compared.

Results

Evaluating Pressure and Flow

Using a Lung Simulator With No Leak. Across all body weights and flows, the B&B Bubbler generated higher PEEP than the low-cost bubble CPAP device at the 5 cm H₂O CPAP level (5.68 ± 0.46 vs 5.24 ± 0.21 cm H₂O, $P < .01$), but the low-cost bubble CPAP device generated higher PEEP than the B&B at CPAP levels 8 and 10 cm H₂O (B&B Bubbler vs low-cost bubble CPAP device: 8.21 ± 0.74 vs 8.26 ± 0.19 cm H₂O, $P = .70$; and 9.65 ± 0.38 vs 10.13 ± 0.22 cm H₂O, $P = 0.008$, respectively). While individual PEEP comparisons were found to be statistically significant and clinically important, the overall PEEP comparisons of the 2 systems were not found to be both statistically significant and clinically important (Fig. 2A).

Across all body weights and CPAP levels, the B&B Bubbler delivered lower flows at each of the 3 flow settings (B&B Bubbler vs low-cost bubble CPAP device:

3.41 ± 1.73 vs 3.75 ± 2.01 L/min, $P = .66$; 4.43 ± 2.53 vs 4.71 ± 2.74 L/min, $P = .79$; and 5.20 ± 3.42 vs 5.48 ± 3.36 L/min, $P = .84$). While individual flow comparisons were found to be statistically significant and clinically important, the overall flow comparisons of the 2 systems were not found to be both statistically significant and clinically important (Fig. 2B).

Using a Lung Simulator With 20% Leak. Across all body weights and flows, the B&B Bubbler generated higher PEEP at the 5 cm H₂O CPAP level (B&B Bubbler vs low-cost bubble CPAP device: 5.19 ± 0.36 vs 5.11 ± 0.26 cm H₂O, $P = .54$), but the B&B Bubbler generated lower PEEP at CPAP levels 8 and 10 cm H₂O (B&B Bubbler vs low-cost bubble CPAP device: 7.50 ± 1.05 vs 8.09 ± 0.36 cm H₂O, $P = .08$; and 8.73 ± 1.79 vs 9.84 ± 0.95 cm H₂O, $P = .07$, respectively). While individual PEEP comparisons were found to be statistically significant and clinically important, the overall PEEP comparisons of the 2 systems were not found to be both statistically significant and clinically important (Fig. 3A).

The B&B bubbler and the low-cost bubble CPAP device delivered average flows of 3.04 ± 2.05 L/min and 3.04 ± 1.85 ($P = .10$) at the 3 L/min flow setting, respectively, but the B&B Bubbler delivered lower flows at the 6 and 10 L/min settings (B&B Bubbler vs low-cost bubble CPAP device: 3.61 ± 1.88 vs 3.81 ± 1.98 L/min, $P = .81$; and 4.55 ± 2.53 vs 4.95 ± 2.7 L/min, $P = .72$, respectively). While individual flow comparisons were found to be statistically significant and clinically important, the overall flow comparisons of the 2 systems were not found to be both statistically significant and clinically important (Fig. 3B).

Evaluating Flow Using a Ventilator Tester

The B&B Bubbler and the low-cost bubble CPAP device generated similar flows when not connected to a lung; no comparisons were both statistically significant and clinically important (Fig. 4).

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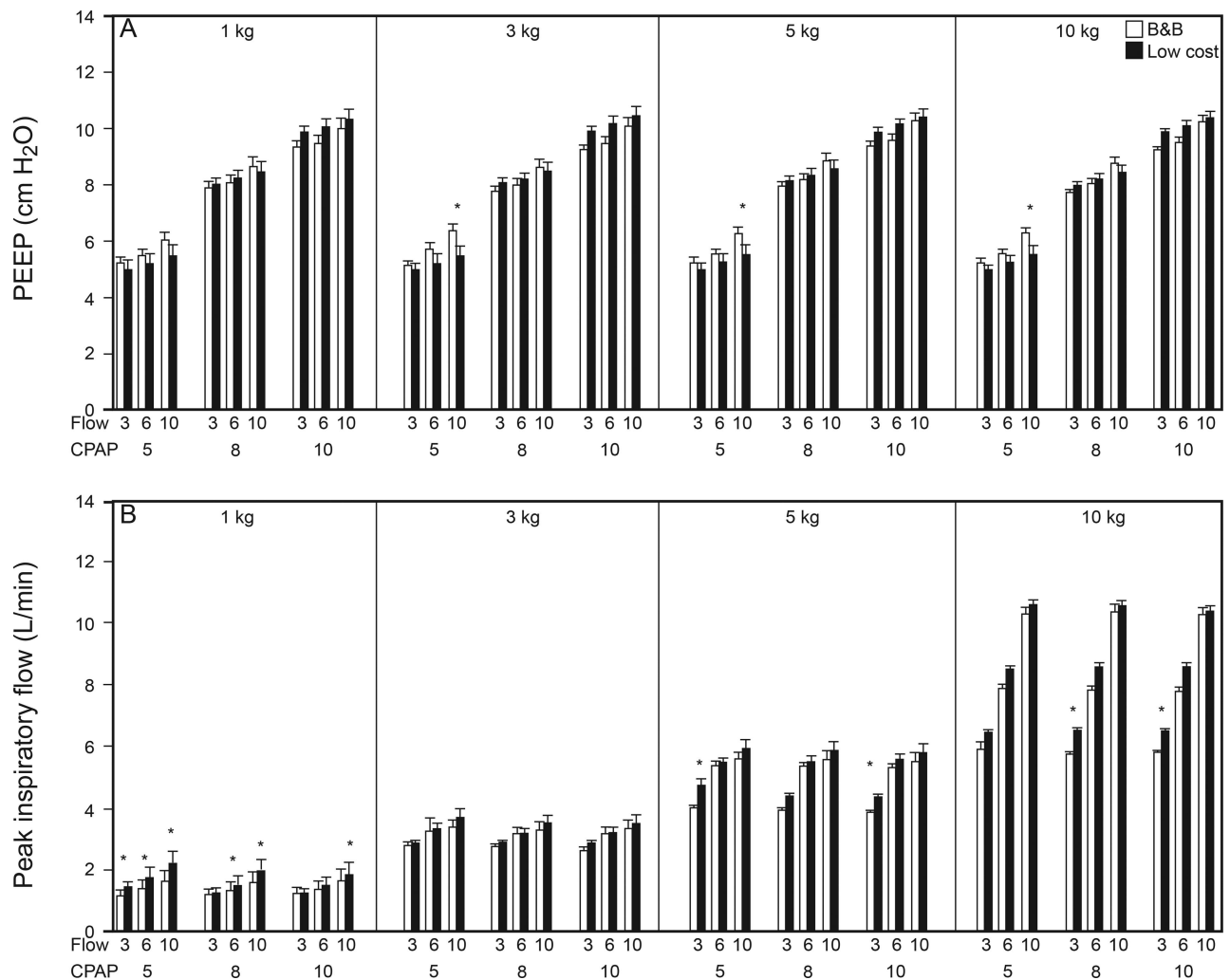


Fig. 2. PEEP and flow comparisons, with no leak. (A) PEEP comparisons. (B) Flow comparisons. *Indicates the comparison was both statistically significant and represented a > 10% difference.

Evaluating Endurance

Over 8 h (set PEEP 8 cm H₂O), the PEEP generated by the B&B Bubbler dropped from an average of 8.27 ± 0.26 cm H₂O to 7.49 ± 0.24 cm H₂O, with an average decrease in water level of 0.5 ± 0.1 cm (Fig. 5A). The PEEP from the low-cost bubble CPAP device dropped from 8.27 ± 0.28 cm H₂O to 7.57 ± 0.25 cm H₂O, with an average decrease in water level of 0.7 ± 0.2 cm. When accounting for the drop in water level, the larger decrease by the B&B was statistically significant ($P < .001$) and clinically important (> 10% difference).

The flow generated by the B&B Bubbler dropped from 6.01 ± 0.03 to 5.83 ± 0.06 L/min, and the flow from the low-cost bubble CPAP device dropped from 6.00 ± 0.06 to 5.51 ± 0.04 L/min (Fig. 5B). The larger decrease exhibited by the low-cost bubble CPAP device was both statistically significant ($P < .001$) and clinically important (> 10% difference).

The low-cost bubble CPAP device's flow pump itself reached a max temperature of $119 \pm 3.0^\circ\text{F}$ ($48.3 \pm 1.7^\circ\text{C}$), but the starting temperature inside the container was $75.0 \pm 1.0^\circ\text{F}$ ($23.9 \pm 0.6^\circ\text{C}$) and rose to $97.0 \pm 1.0^\circ\text{F}$ ($36.1 \pm 0.6^\circ\text{C}$) after 8 h of continuous use.

Discussion

The main findings of this study are that the low-cost bubble CPAP device was capable of delivering pressures and flows equivalent to that of the commercially available B&B Bubbler system, and that the low-cost bubble CPAP device was marginally better at maintaining pressure over a prolonged period of time, but worse at maintaining flow.

Our results demonstrate that, overall, the low-cost bubble CPAP system is able to deliver pressures and flows equivalent to those of bubble CPAP systems used in developed settings. However, there were several individual

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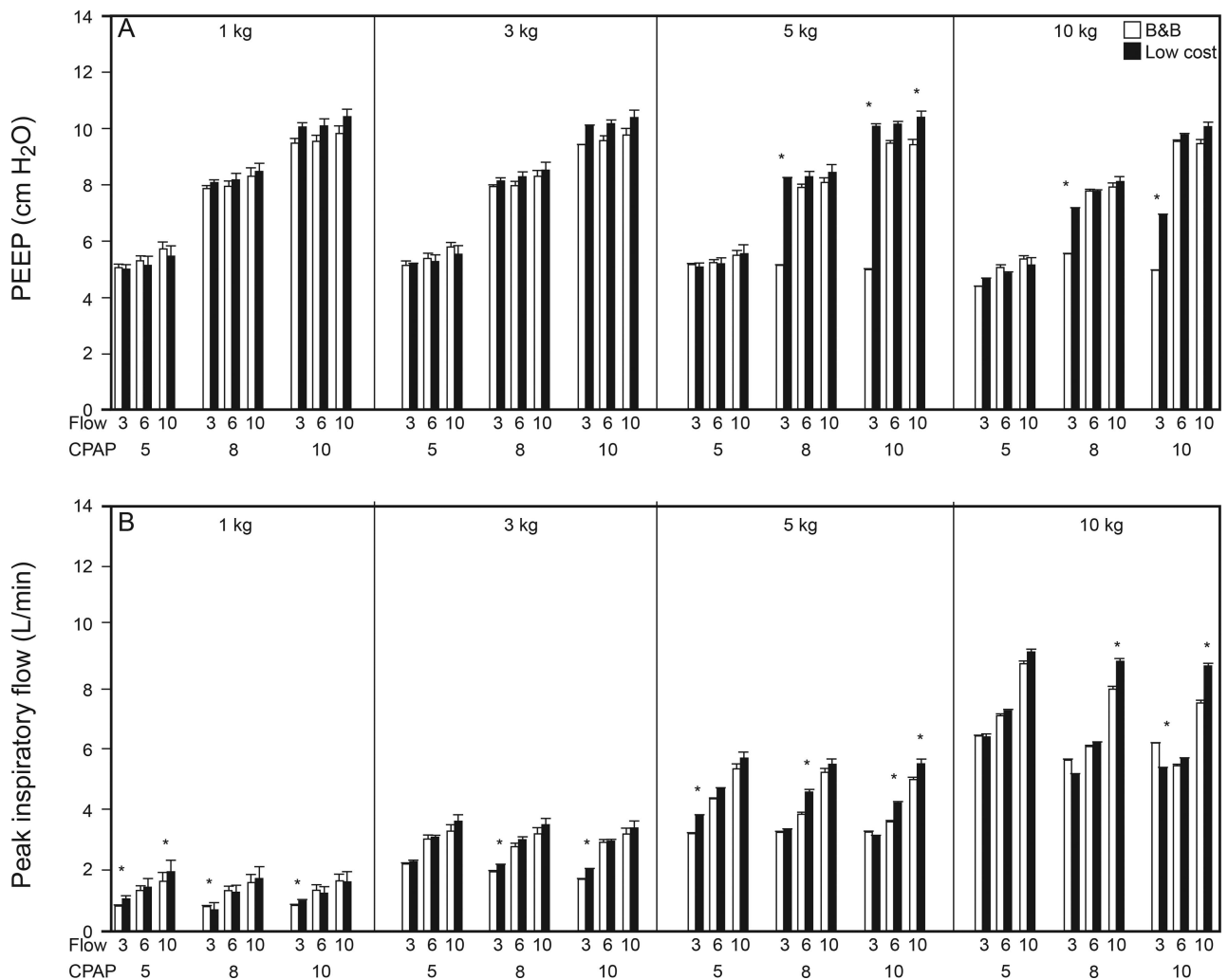


Fig. 3. PEEP and flow comparisons with 20% leak. (A) PEEP comparisons. (B) Flow comparisons. *Indicates the comparison was both statistically significant and represented a > 10% difference.

comparisons that reached statistical significance and represented a > 10% difference. The differences in pressure generated by the 2 devices could be due to the simple method of water-depth measurement on the low-cost bubble CPAP device. The water-depth levels were measured with a ruler, and each line was marked with a pen, which could create slight variability in the actual volume measurement. The differences in both pressure and flow could also be due to the different respiratory circuits used with each system. Kahn et al²⁶ compared delivered versus intended intra-prong, proximal-airway, and distal-airway pressures of a bubble CPAP device and found that delivered pressures at both the intra-prong and proximal-airway overshoot the intended CPAP level, which could be due to the resistance of the exhalation arm of the circuit tubing. During the exhalation phase of the respiratory cycle, the patient exhales into the circuit tubing, which has its own intrinsic resistance, creating

an increase in pressure sustaining the CPAP level. In our study, the B&B Bubbler system's tubing differed from that of the low-cost bubble CPAP device, which could explain the slight differences in pressure and flow at some settings.

Both devices delivered 3.04 L/min of flow at the 3-L/min setting. However, at the 6- and 10-L/min settings, the delivered flows were no higher than 3.81 and 4.95 L/min, respectively. The ability to maintain delivered flow with either of these devices is a concern and may present a clinical issue with larger patients demanding greater flows. The test lung models were designed to simulate compromised respiratory mechanics (low compliances and high resistances), and the delivered flows were much lower than the set flows. When the test lung was not present, both devices were capable of flow output equivalent to the desired flow (Fig. 4), but with highly resistive lungs, the deliverable flow began to plateau.

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The low-cost bubble CPAP device maintained pressure over a prolonged period more effectively than the B&B Bubbler system, but the difference in pressure was < 0.3 cm H₂O, which is likely not substantial in an actual clinical setting. It is important to note, however, that users of either device should be aware of the potential for a decrease in water level in the PEEP bottle over extended periods of time due to rapid bubbling and evaporation. Vigilance and diligent replacement of water are recommended with either unit. The flow dropped significantly more with the low-cost bubble CPAP device, which is likely due to the 45-L/min air pump (Active Aqua Pump, Hydrofarm, Petaluma, California) used in the device. The pump reached a maximum temperature of 119°F (48.3°C); while this temperature was not high enough to evoke safety concerns, the pump may require a more robust cooling system. It is possible that as the motor temperature increases, the pump's efficiency decreases.

While the motor generated heat, the temperature in the container itself remained near body temperature and did not pose a threat because the temperature of the delivered gas cooled as it moved through the circuit to the patient.

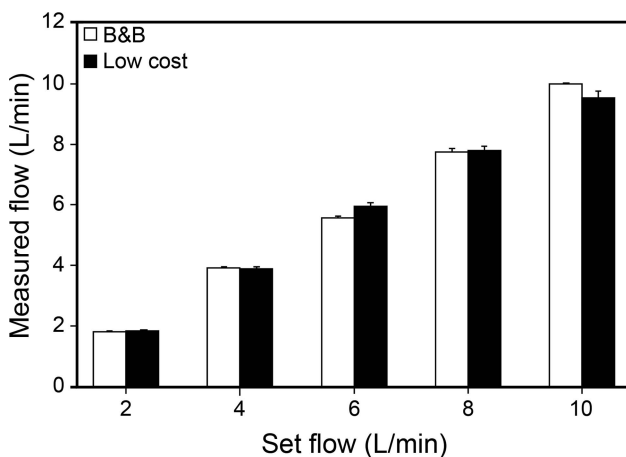


Fig. 4. Flow capability comparison for a B&B device and a low-cost bubble CPAP system when not connected to a test lung.

Flow generation in developed settings can be accomplished with much more complex pumps, which have better cooling mechanics and may not lose as much effectiveness over time. Providers using the low-cost bubble CPAP device in low-resource settings must be aware of the potential for a drop in flow.

The low-cost bubble CPAP device does not have all of the features standard to bubble CPAP devices in developed settings. Most notably, this device does not have a port for an external source of oxygen, so blended delivery is not possible. We recommend oxygen blending be made possible in the next iteration of the device.

The tested low-cost bubble CPAP device is expected to be less expensive than other low-cost bubble CPAP devices designed for low-resource settings. A bubble CPAP device was developed for implementation in Malawi, which included an additional attachment that allowed the blending of oxygen from an oxygen source.⁸ In comparison, however, it did not heat or humidify the air mix delivered to the patient. The low-cost bubble CPAP device in this study humidifies the air via an in-line water chamber, which is heated indirectly by the system itself. An important consideration is whether the end-user will always have access to clean water to be used in the humidification chamber. It is recommended that humidification water sources be changed frequently and the chamber be sanitized according to local standards.

Nahimana et al⁶ assessed provider adherence to standard bubble CPAP protocol in district hospitals in Rwanda and found that providers correctly identified only 59% of infants eligible for bubble CPAP, and only 52% of infants eligible for bubble CPAP received this treatment. Correct identification of a child who may benefit from CPAP, and its subsequent initiation, are potential problems in low-resource settings; as a result, there have been efforts to improve training. Hundalani et al³ developed a simple algorithm for use in low-income settings that helps identify neonates who could benefit from CPAP. They found that

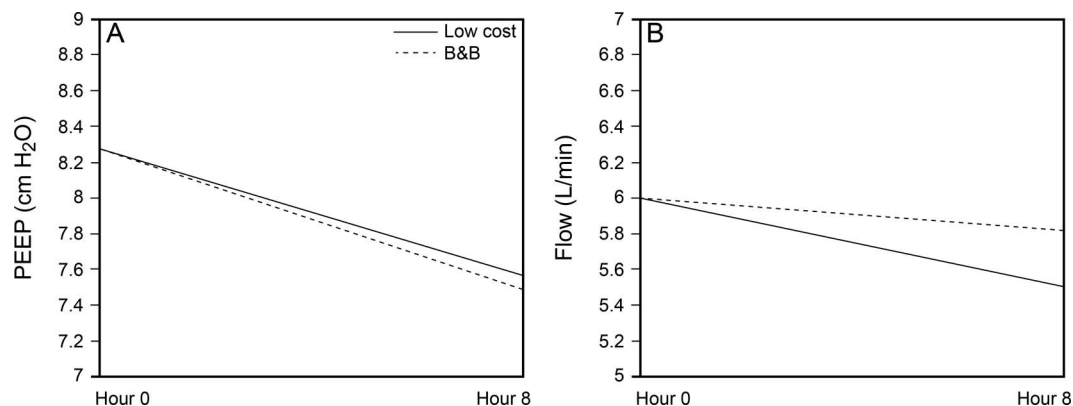


Fig. 5. PEEP (A) and flow changes (B) over 8 h comparing a B&B device and a low-cost bubble CPAP system.

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their algorithm has strong potential to improve the rates of correctly identifying infants in need of CPAP in provincial hospitals. Similarly, McAdams et al²⁷ sought to implement a low-cost bubble CPAP device in a Ugandan neonatal ICU after a short training period in which neonatal ICU staff were taught to employ the Silverman-Andersen respiratory severity score,²⁸ a bedside exam used for assessing the level of respiratory distress in neonates. The group found that neonatal ICU staff easily learned the respiratory severity score and were able to maintain the assessment tool over time. With increased identification of neonates in need of CPAP, devices become all the more necessary and impactful.

Many studies^{5-7,11,12,29} have shown CPAP to be an effective treatment in low-resource settings, but complex CPAP machines are expensive and require a high level of expertise to administer and maintain. Therefore, a simple, inexpensive device is needed. Koyamaibole et al³⁰ described the benefits of bubble CPAP in Fiji but stated, “A challenge for the biomedical industry is to manufacture an inexpensive appropriate technology model for further evaluation in developing countries.” The low-cost device evaluated in this study could be the answer.

There are 2 limitations to this study. First, we did not assess the availability of the resources needed to assemble this device in areas where it would be implemented. Second, this study used a model test lung, not subjects, which raises the question of whether the findings are clinically important. To fully validate the device’s functionality, clinical studies should be conducted.

Conclusions

The low-cost bubble CPAP device evaluated in this study is comparable to a bubble CPAP system used in the developed world. An extensive clinical trial is necessary to validate its effectiveness, but our evaluation suggests that the device has the potential to deliver adequate pressures and flows to treat children with compromised respiratory mechanics, and that this device is inexpensive enough to do so in low-resource settings.

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