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Early View

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Research Letter

Easy-to-build and affordable CPAP device for adult patients in low-income countries

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To the Editor:

Continuous positive airway pressure (CPAP) is the treatment of choice for several sleep breathing disorders (SDB), of which sleep apnea is an obvious example. Although precise epidemiological data are scarce, SDB are prevalent in low-income countries (LICs) (1-2). Moreover, given that the risk of SDB is associated with the patient's BMI, and that the worldwide obesity pandemic involves not only developed countries but also LICs (2,3), it is expected that the incidence of sleep apnea will continuously increase in LICs, and the need for CPAP devices will accordingly rise. Moreover, the demand for CPAP devices in LICs is also anticipated to increase in light of the few operationally equipped intensive care units in these countries (4). Indeed, cheap CPAP devices, although with less versatile applications than mechanical ventilators, provide rescue and treatment options that can reduce mortality and intubation rates in some patients (5). Unfortunately, these options in LICs are seldom implemented since neither patients nor hospitals are able to afford commercial CPAP devices. It is also noteworthy that CPAP devices specifically designed and commercialized in LICs (6), which achieve cost reductions by avoiding optional device features (7), do not offer a realistic therapeutic alternative.

A potentially viable solution that provides affordable health care products for patients in LICs is to promote and strengthen local health-industry value chains to improve industrial development (8). To this effect, cooperation efforts from developed countries must move their focus from philanthropic provision of Western-made products to empowering LIC teams in designing and manufacturing performant devices locally. Whereas this approach would obviously not work in case of medical devices requiring highly complex technology, it is feasible for medical devices based on simple technical principles, such as CPAP (9). The open-source

hardware approach (10) -which consists on making the design publicly available for free use, modification and redistribution- is aimed at reducing medical device access gaps, particularly in LICs (11). Collaborative design thinking and co-creation initiatives (12) reuniting expert teams from developed and developing countries is an efficient way to implement this approach, for instance to provide bubble-CPAP devices for treating acute respiratory failure in preterm birth and pneumonia in infants (13). In this context, we herein describe our experience of technology transfer collaboration between teams from Europe, USA and Africa in developing an easy-to-build and affordable CPAP device for adults with SBD, an application requiring a technical solution completely different from bubble-CPAP (13).

Consistent with our general approach, we built a CPAP device using off-the-shelf low-cost components bought by *e*-commerce. Nasal pressure is generated by a small (90 g) high-pressure (75 cmH_2O) blower (with corresponding driver) specifically commercialized (CE mark) for CPAP devices (WM7040, Ning Bo Feng Hua Wei Cheng Motor Factory, Zhejiang, China). Pressure is measured by a temperature-compensated transducer (XGZP6847005KPG, 0-50 cmH_2O; CFSensor, Wuhu, Anhui, China) and the blower is controlled by a simple custom-made proportional-integral feedback circuit. An arduino-controlled LCD-display (16x2 characters) shows both the targeted and measured pressures. The minimum generated CPAP is set at 4 cmH_2O to prevent rebreathing, and maximum nasal pressure is prescribed to a safe value of 20 cmH_2O (by limiting the nominal 24-VDC blower power supply to 12-VDC). The retail cost of all the components including the power (nominal 220-VAC/12-VDC, 60W) source and materials for the electronic board and circuit is ≈60 €, a figure that would be reduced in case of wholesale purchase. All the technical information and detailed circuit schematics required to build this CPAP device (which is readily achievable by any electronics technician or first-year engineering

student) are available for release under free terms following the open-source hardware approach (http://www.ub.edu/biofisica/dwn/CPAP%20device%20Technical%20description.pdf).

The performance of this novel CPAP device was evaluated in the bench by connecting it to a piston-pump patient simulator (14) through conventional tubing, including a 5 mm-diameter orifice at the nasal mask to create an intended air leak orifice to avoid rebreathing (minimum washout flow of 20 l/min at 4 cmH_2O). The dynamic stability of the nasal pressure provided by the device for different CPAP settings (4, 8, 12 and 16 cmH_2O) was measured for several simulated patient's breathing flows (tidal volume: 0.5 l; 10, 15 and 20 breath/min) with and without including a simulated unintended air leak (up to 35 l/min at CPAP=16 cmH_2O) at the mask level to simulate poor fitting to patient's face and/or mouth air leak (15). For the sake of comparison, the same bench test conditions were also applied to a high-performance commercially available CPAP device (AirSense 10, Resmed). Figure 1 shows the excellent performance of the designed CPAP device even under the most strenuous conditions: CPAP=16 cmH_2O, respiratory rate set at 20 breath/min, and superimposed air leak of 35 l/min (14, 16). Indeed, pressure fluctuations (peak-to peak along the breathing cycle) measured with an external transducer at the nasal mask level were very small (0.5 cmH_2O) in absence of unintended leaks. Moreover, nasal pressure actually generated by our CPAP device was virtually insensitive to application of a 35 l/min unintended air leak: mean pressure moved from 16.1 to 15.9 cmH_2O and pressure oscillations minimally increased to 0.8 cmH_2O. In fact, the nasal pressure generated by our low-cost prototype was slightly more stable that the one provided by the conventional device which exhibited higher breathing-induced pressure fluctuations and was less stable in response to the 35 l/min unintended leak (Figure 1).

Using the in-house built CPAP device described here in LICs should comply with the existing local regulations on medical devices taking into account that it has not undergone the high-cost medical device regulatory approval (e.g. FDA, CE) required for clinical use in Western countries. However, i~~t~~t should be mentioned that the approach described herein is not aimed at replacing commercially available CPAP devices, which of course should be used whenever possible. ~~since these devices have undergone stringent licensing and approval processes.~~ In reality, our proposal for in-house building of CPAP devices like the one proposed here would be totally unnecessary in the ideal circumstances that the huge economic disparities between developed countries -where most medical device industry is based- and LICs disappeared, or at least were considerably reduced, thereby reducing the onerous and inaccessible pricing that currently precludes their purchase in LICs. However, it would also be unreasonable to passively await and leave patients untreated until the world macro-economy changes for the better. Remarkably, approaches as the current device presented here should provide not only result in readily available CPAP devices, but should also empower clinical, technical and educational teams to implement local industrial projects contributing to economic development (8,11).

In conclusion, under the umbrella of an open-source perspective we designed and tested a high-performance CPAP device for in-house assembly in LIC centers which is low-cost, easy to build, and, most importantly simple to service technically on site. The described procedure should allow the provision of CPAP treatment to LIC patients who otherwise would not have access to this lifesaving therapy.

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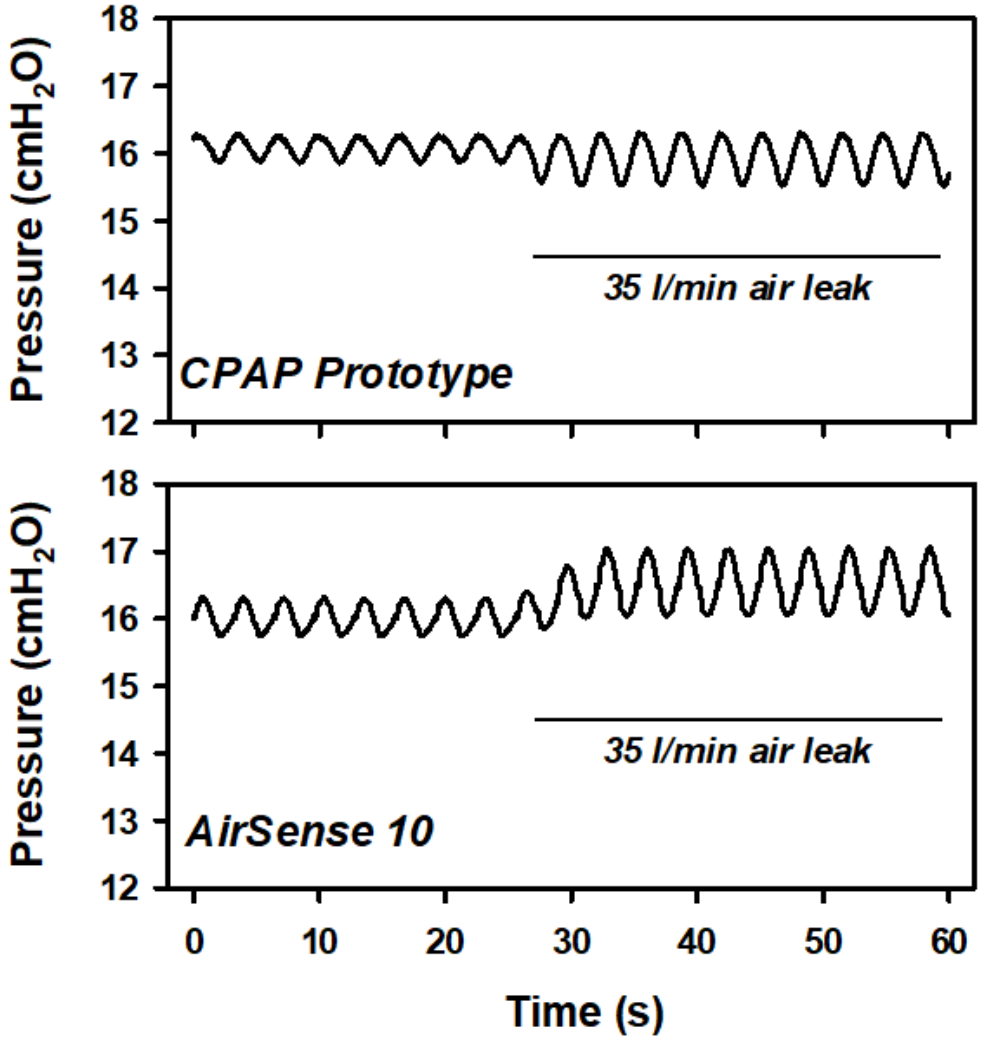
FIGURE LEGEND

Figure 1. Pressure measured at nasal mask of a simulated patient breathing with at a tidal volume of 0.5 l at 20 breath/min, and targeted CPAP=16 cmH_2O. When indicated, a 35 l/min unintended air leak was imposed at the mask level to simulate poor fitting to patient's face and/or mouth air leak. TOP: Designed device. Mean pressure and peak-to peak pressure fluctuations were 16.1 cmH_2O and 0.5 cmH_2O with no unintended leak and 15.9 cmH_2O and 0.8 cmH_2O with unintended leak, respectively. BOTTOM: Commercially available device (AirSense10, ResMed). Mean pressure and peak-to peak pressure fluctuations were 16.0 cmH_2O and 0.6 cmH_2O with no unintended leak and 16.5 cmH_2O and 1.0 cmH_2O with unintended leak, respectively.


Pressure (cmH2O)
18
17
16
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12
35 l/min air leak
CPAP Prototype
Pressure (cmH2O)
18
17
16
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14
13
12
35 l/min air leak
AirSense 10
0
10
20
30
40
50
60
Time (s)