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OxyJet CPAP: an electricity-free low-cost emergency respiratory support device

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Abstract

Background: Respiratory support devices in resource-limited settings should be inexpensive, portable, effective, and easy to use. Non-invasive respiratory support devices can reduce expensive ICU admissions, but these facilities are severely lacking in low-resource settings. Here, we describe the design and validation of a low-cost, portable, electricity-free, and 3D-printed continuous positive airway pressure (CPAP) device named 'OxyJet' that can provide non-invasive respiratory support outside the ICU. The OxyJet is uniquely built using off-the-shelf components and 3D printing technology, making it both inexpensive and easy to produce. OxyJet costs less than 10% of the price of a similar CPAP system. Inspired by the fundamental mechanics of gas ejectors and harnessing the potential energy of a high-pressure oxygen jet, the device can deliver a high flow of oxygenated air up to 65 L/min (approx.), a positive end-expiratory pressure (PEEP) within 5–15 cmH_2O, and a fraction of inspired oxygen (FiO_2) of up to 100%.

Results: The device was bench-tested following UK-MHRA RMCPAP guidelines and tested on healthy volunteers (n = 5) and hypoxemic patients (n = 5). A comparative pilot study involving 23 hypoxemic adult patients conducted in Dhaka, Bangladesh, showed a significant improvement ($p < 0.05$) in the peripheral oxygen saturation (SpO_2) of patients following the administration of OxyJet CPAP. The mean SpO_2 increase was 12.0% (95% CI 10.8–13.2) with OxyJet versus 11.5% (95% CI 9.3–13.8) for standard CPAP ($p = 0.695$). The findings indicate the device's feasibility and short-term physiological effects comparable to those of standard CPAP systems. Further studies are required to confirm its clinical efficacy and broader utility in resource-limited settings.

Conclusion: Our findings suggest that OxyJet CPAP has the potential to serve as an emergency respiratory support device outside the ICU, strengthening health systems in resource-limited settings.

Methods: OxyJet's performance was first assessed through benchtop testing following the UK-MHRA RMCPAP protocol. This was followed by preliminary human testing in healthy volunteers and hypoxemic patients to evaluate safety and usability. A pilot feasibility study involving hypoxemic adult patients in Dhaka, Bangladesh, was then

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conducted to compare the device's physiological effects with those of standard CPAP therapy.

Keywords: Continuous positive airway pressure (CPAP), Chronic obstructive pulmonary disease (COPD), Low- and middle- income countries (LMIC), Noninvasive respiratory support, Oxygen therapy

Background

Respiratory diseases are a leading cause of global mortality and morbidity [1]. Chronic obstructive pulmonary disease (COPD) alone claimed more than three million lives in 2019 [2], while the COVID-19 pandemic pushed respiratory illness-related mortality even higher, causing over six million deaths worldwide [3]. In many cases, respiratory disease patients suffer from hypoxemia and require supplementary oxygen, as is the case for COVID-19. However, regarding respiratory support devices and infrastructure, hospitals in low-income countries face unique challenges compared to high-income countries. These include a shortage of ICU beds [4–7], lack of skilled workforce [4], inadequate supply of oxygen [6–9], scarcity of respiratory support devices [6, 7, 10], and unreliable power supply [11]. The general wards of these resource-limited hospitals cannot provide more than 15 L/min of oxygen [8]. As a result, when a hypoxemic patient's condition deteriorates in the general ward, they often receive inadequate treatment with a standard non-rebreather mask (15 L/min of oxygen) until an ICU bed with advanced treatment facilities becomes available. In the absence of an ICU bed, such patients often expire in the general wards or during transfer to other facilities. According to the World Health Organization (WHO) guidelines, hospitalized patients with severe hypoxemia are initially treated with low-flow oxygen therapy (0–15 L/min). If the patient is not clinically stable on 15 L/min of 100% oxygen, the guideline recommends a trial of high-flow nasal cannula (HFNC) or non-invasive respiratory support, including CPAP and BiPAP (Fig. 1a; Conventional), before escalating to intubation [12, 13]. However, the United Kingdom (UK) National Health Service (NHS) guidelines support the early administering of CPAP therapy [14]. The systematic review in [15] also identified that non-invasive ventilation via a mask was associated with a significantly lower risk of intubation and mortality. The RECOVERY-RS [16] study, involving patients with acute respiratory failure, also found that an initial strategy of CPAP showed a significant reduction in the risk of intubation and mortality compared with standard oxygen therapy. Moreover, multiple studies [17, 18] have reported that CPAP can be delivered effectively outside traditional critical care. Thus, the evidence suggests that CPAP in the general wards can be an effective bridging therapy in resource-limited hospital settings where HFNC devices and ICU beds are scarce.

Traditional CPAP devices are mainly designed to treat obstructive sleep apnea (OSA) and do not have the provision for a high FiO_2 (%). These devices are not always suitable for resource-limited settings, mainly due to high cost, lack of expertise, and requirement for uninterrupted electric power. During the pandemic, the UK Medicines and Healthcare products Regulatory Agency (MHRA) published a guideline outlining the essential features for developing a CPAP system to treat hypoxemic patients [19]. The conventional CPAP systems do not comply with the MHRA requirements; for example, they often lack proper virus filtration, or mechanisms for FiO_2 (%)

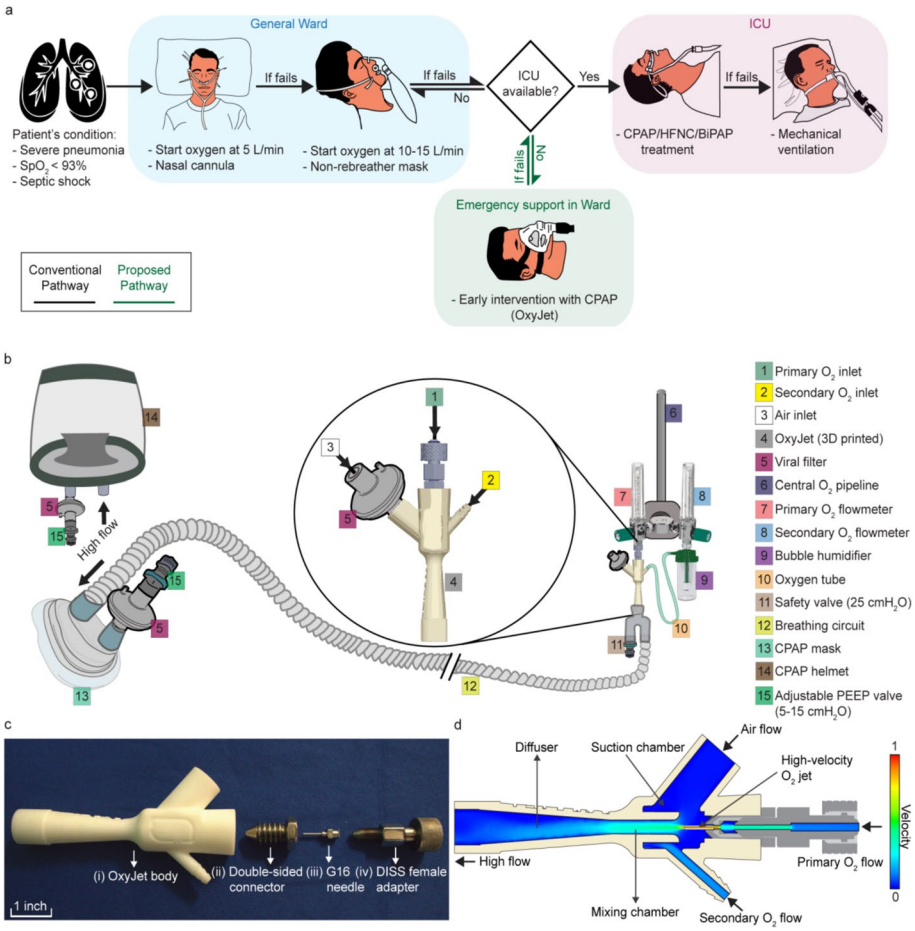


Fig. 1 The OxyJet CPAP as an emergency non-invasive respiratory support device in low-resource setting hospitals. **a.** The treatment pathways for severe pneumonia and/or hypoxemic patients. Black arrows show the conventional treatment pathway starting from low-flow oxygen in the ward to the ventilator in the ICU. The green arrows show an alternate treatment pathway using OxyJet CPAP as an emergency non-invasive respiratory support device while critical care is unavailable. **b.** A schematic diagram of the proposed OxyJet CPAP system showing its parts and components. **c.** Photograph of the exploded view of an OxyJet flow generator. **d.** Normalized computational fluid dynamics (CFD) result for the velocity distribution throughout the fluid domain of the OxyJet flow generator, shown in the cross-sectional profile

control. In contrast, Venturi-based CPAP systems—such as WhisperFlow devices [20] and a more recent UCL-Ventura [21]—were shown to comply with MHRA criteria for Rapidly Manufactured CPAP (RMCPAP) solutions [19]. High-flow Venturi-based CPAP systems have in fact been used extensively in the past, most notably the WhisperFlow devices [20, 22]. Multiple studies have demonstrated that Venturi-driven systems could deliver high flows and effective CPAP in acute hypoxemic respiratory failure [22–24]. However, these devices require high-precision manufacturing infrastructure, skilled technicians, and imported raw materials, which make them expensive and difficult to produce locally. As a result, they remain largely inaccessible in many LMIC settings (Table S1). Thus, low-cost and easily usable CPAP systems can be a lifesaving solution in healthcare systems in low- and middle-income countries (LMICs).

To address this gap in LMICs, we develop a low-cost CPAP system, "OxyJet CPAP," that can deliver a high flow of oxygenated air and positive pressure without requiring electric power. Unlike existing Venturi-driven solutions, our device is 3D-printed, easy to assemble, and compatible with existing medical gas outlets commonly available in low-resource healthcare settings, enabling rapid deployment for hypoxemic patients (Fig. 1b). Our engineering design ensures that the device meets the UK-MHRA emergency CPAP performance standards [19]. Benchtop experiments show that it can deliver a flow of up to 65 L/min (approx.), PEEP within 5–15 cmH_2O and a FiO_2 of up to 100% (Table S2; Video S1; Operation). We conducted a short pilot study in Dhaka, Bangladesh, to assess the feasibility and preliminary effectiveness of the device in the pre-ICU settings. Our analysis shows that the peripheral oxygen saturation (SpO_2) of patients improved significantly (p-value < 0.05) shortly after administering the CPAP device, while the other physiological parameters remained stable (p-value > 0.05). The study also found that the short-term physiological effects in patients treated with OxyJet CPAP were comparable to those of a standard CPAP system. It is worth mentioning that during the COVID-19 pandemic, OxyJet received emergency approval for hospital use by the Directorate General of Drug Administration (DGDA), Dhaka, Bangladesh [25, 26]. This local innovation was also featured in the 2022 publication "Good Practices in South-South and Triangular Cooperation" by the United Nations Office for South-South Cooperation (UNOSSC) [27].

Results

Analysis of total flow and device optimization

OxyJet flow generator harnesses the potential energy of the pressurized oxygen as it flows through a converging needle (nozzle). The needle comes in standard gauges, and altering the gauges (G15–G20) modifies the flow characteristics of the generator. This allows the generator's performance to be tailored for specific applications. To identify the most suitable configuration, we assessed the total flow output of the device across needle gauges at a fixed primary oxygen input (15–16 L/min). The results (Fig. 2a–c; Table S4) demonstrate that total output flow decreases with higher positive end-expiratory pressure (PEEP) or increasing needle diameters. Among all configurations tested, the G16 needle provided a balance between oxygen consumption and total output, appropriate for use in resource-constrained settings.

To minimize variability in clinical environments, we standardized the primary oxygen flow to 15–16 L/min, effectively operating the OxyJet as a fixed-flow generator (Fig. 2b). In this configuration, a standard flowmeter regulates the source pressure (up to 3.5 bar) by constraining the volumetric oxygen flow. The Mach number (M) of the primary oxygen jet through a G16 nozzle was theoretically estimated as 0.651 based on nozzle geometry and flow parameters, confirming subsonic flow conditions. The minimum operating pressure required to sustain this jet was calculated as 1.347 bar, well within the range of typical hospital oxygen outlets and cylinders (3.5 bar) (*see Methods*, Eqs. (1) and (2)). Complementing the analytical model, computational fluid dynamics (CFD) simulations confirmed that the high-velocity oxygen jet creates a low-pressure zone that induces ambient air through the suction chamber (Fig. 1d). At this configuration, the flow generator delivers over 50 L/min of oxygen-enriched air—sufficient for

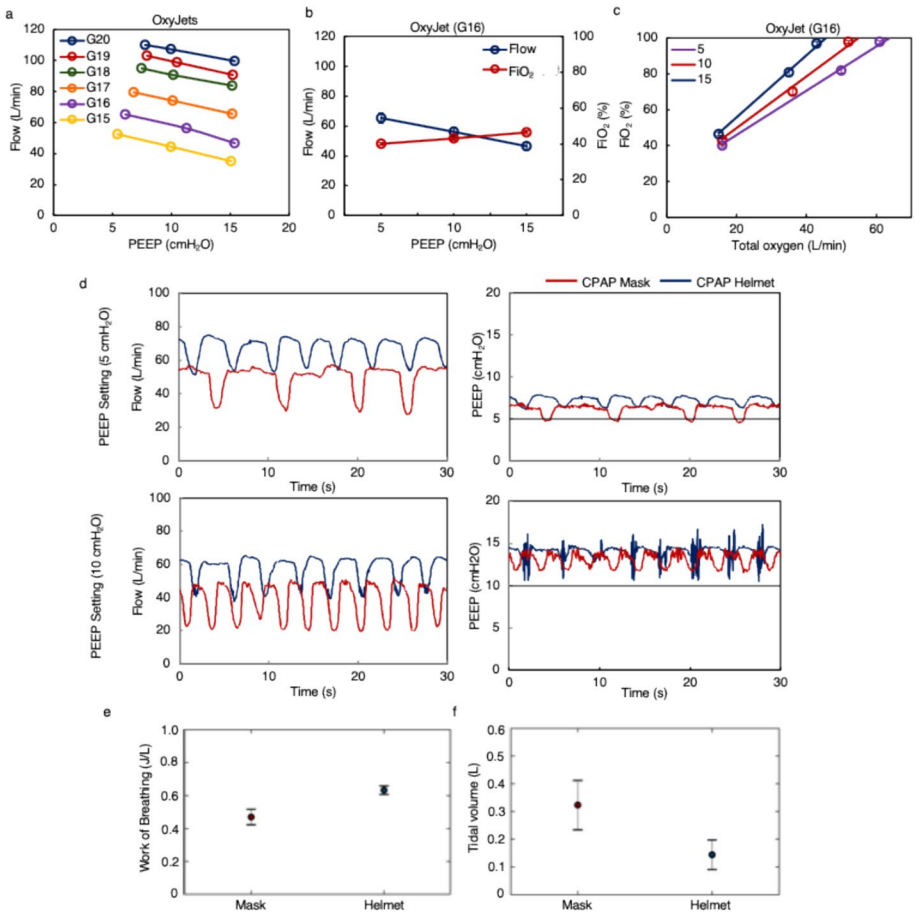


Fig. 2 Device Characterization and Validation on Healthy Volunteers. **a.** The output flow of the OxyJet flow generator as functions of PEEP and needle gauges (G20, G19, G18, G17, G16, and G15), for 15–16 L/min of primary oxygen flow. **b.** Maximum output flow and minimum FiO_2 (no secondary oxygen flow) of the OxyJet flow generator containing a G16 needle versus PEEP for a 15–16 L/min of primary oxygen flow. **c.** FiO_2 of the output flow of the OxyJet flow generator containing a G16 needle versus total oxygen supplied at different PEEP settings (5, 10, and 15 cmH_2O). The primary oxygen flow was set to 15–16 L/min, and additional oxygen was supplied with a secondary flowmeter (secondary oxygen flow). Measurements shown in **b.** and **c.** are taken from multiple OxyJet devices (n = 75). The means (center values) and standard deviations (error bars) are plotted. **d.** The expiratory flow and pressure of a participant with time, measured at two PEEP settings (5 cmH_2O and 10 cmH_2O). Continuous measurements were recorded at the patient interface. The rises and falls in the curves indicate the exhalation and inhalation of the participant, respectively. The red and blue curves indicate that the CPAP was delivered using a CPAP mask and helmet, respectively. The grey lines indicate the set PEEP values. **e.** The work of breathing (J/L) of participants. **f.** The tidal volume (L) of participants

non-invasive respiratory support in hypoxemic patients [19]. Also, by limiting the total flow, the device can deliver higher levels of FiO_2 (%) while consuming less oxygen. This minimizes oxygen wastage, which is extremely important in LMIC settings [6–9].

Characterization results of OxyJet flow generator

Figure 2b shows the measurements of the output flow and the minimum FiO_2 (no secondary oxygen flow) delivered by the OxyJet flow generator at different PEEP settings (Fig. S2, Table S5). The flow generator provides an output flow of 65.3(±3.7) L/min at 15–16 L/min primary oxygen flow and 5 cmH_2O PEEP. However, the output flow decreases by 9.4(±0.5) L/min, and the minimum FiO_2 increases by 3.18(±0.1) %

for every 5 cmH_2O increase in the PEEP value. Figure 2c shows the FiO_2 measurements of the output flow delivered by the OxyJet flow generator versus total oxygen supplied at different PEEP settings (Fig. S2, Table S6). For a given primary oxygen flow (15–16 L/min), needle gauge (G16), and PEEP setting, the output flow of the flow generator remains relatively stable (Fig. 2b). There exists a strong correlation (0.99) between total oxygen flow and FiO_2 (%) of the output flow (Fig. 2c). The device operation chart was developed based on the one-to-one mapping of the oxygen supplied and the FiO_2 (%) of the output flow of the device at each PEEP settings (5, 10, and 15 cmH_2O) (Fig. 2c, Fig. S3). Users can adjust the FiO_2 in steps of 5% by controlling the secondary oxygen flow following this device operation chart (Fig. S3).

Analysis of the validation study

After laboratory evaluation, the OxyJet system was initially tested on five healthy volunteers. Figure 2d presents a participant's expiratory flow and pressure over time at 5 and 10 cmH_2O PEEP settings. We observed that pressures recorded at the patient interface exceeded the set PEEP. This occurred because the adjustable PEEP valve is a spring-based mechanical device whose pressure varies with gas flow. During exhalation, the increased flow temporarily elevates the pressure, while inhalation decreases it. This fluctuation in pressure throughout the respiratory cycle is typical for such devices.

Measurements showed that participants using both interfaces (CPAP mask and helmet) maintained a pressure close to the set PEEP value and had adequate flow during both inhalation and exhalation (Table S8). There were no significant changes in the participants' physiological parameters (heart rate, respiratory rate, body temperature, blood pressure, and SpO_2) during the administration of the OxyJet CPAP (Table S9). Figure 2e and f present the computed work of breathing (J/L) and tidal volume (L), respectively, illustrating the effort associated with each interface. Both metrics remained within normal physiological ranges. We present the summary statistics of the results in the *Supplementary Information*. We further compared the participant's comfort level on both interfaces and found that the CPAP helmet was more comfortable compared to the non-vented CPAP mask using a numerical rating scale (Fig. S7, Table S10). However, both interfaces provided a tight seal and were equally effective in delivering CPAP therapy to the participants. Based on the findings, we concluded that OxyJet CPAP could administer effective CPAP therapy by maintaining a pre-specified PEEP.

Following the successful test on healthy volunteers, the OxyJet system was applied to five adult hypoxemic patients in a clinical setting to assess its efficacy in improving oxygenation. Measurements showed that a significant improvement ($p = 0.0001$; paired t-test) in the peripheral oxygen saturation (SpO_2) by 11.2 (± 2.59)% was observed, while other physiological measurements remained stable (heart rate, respiratory rate, and blood pressure) during the administration of the OxyJet CPAP (Fig. 3b, Table S12). Figure 3b shows a rapid improvement in SpO_2 (%) of the patients within the first 15 min of administering OxyJet CPAP, which remained stable for the rest of the study duration. We compared the patient comfort level on both interfaces. Contrary to the findings of the healthy volunteer study, we found that patients preferred the non-vented CPAP mask over the CPAP helmet (Fig. S7, Table S13). Some patients reported anxiety while on the CPAP helmet due to claustrophobia and the inability to communicate with others. CPAP

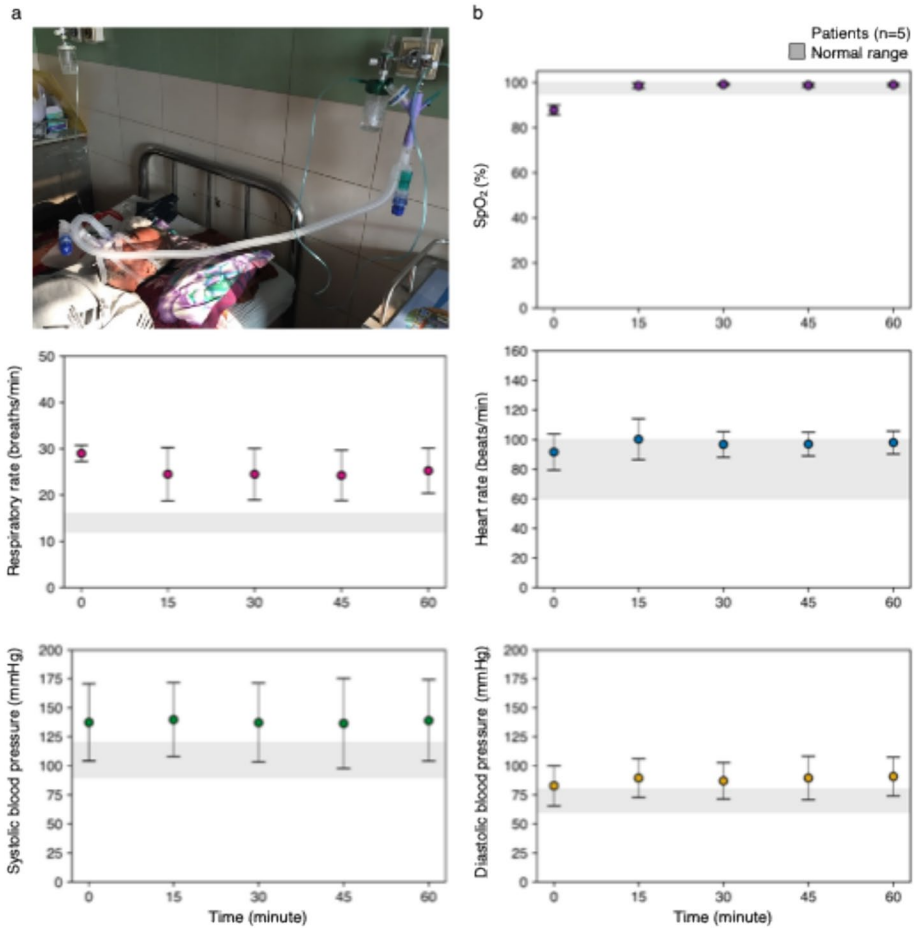


Fig. 3 Device Validation on Hypoxemic Patients. **a.** Delivering OxyJet CPAP to a hypoxemic patient via a CPAP mask. **b.** Scatter plots with mean ± standard deviation, showing the changes in peripheral oxygen saturation (SpO_2), respiratory rate, heart rate, and blood pressure (systolic and diastolic) measured at 15-min intervals from five adult hypoxemic patients. The region shaded in grey represents the normal physiological range for adults. The '0' in the timeline represents the patient's condition in room air, measured just before administering the CPAP

helmet was thus discontinued in the pilot study. However, overall, the findings demonstrated the clinical feasibility of the OxyJet CPAP system in general ward settings.

Pilot study in Dhaka, Bangladesh

Results of the pilot study demonstrated a significant improvement in peripheral oxygen saturation (SpO_2) in both groups following the intervention ($p < 0.05$; Paired t-test), while other physiological measurements showed no significant changes (Fig. 4, Table S15). In the OxyJet CPAP group, the mean improvement of the SpO_2 was 12.0% (95% CI 10.79, 13.21), whereas in the standard CPAP group, it was 11.54% (95% CI 9.33, 13.76) (Tables S16, and S17). However, comparing the SpO_2 improvements between patients in the two groups showed no significant difference ($p = 0.695$; Independent t-test). Similarly, the changes in other physiological measurements between the groups were also insignificant (Table S18). We present the summary statistics of the results in the *Supplementary Information*. No technical difficulties or aborted sessions occurred, and no

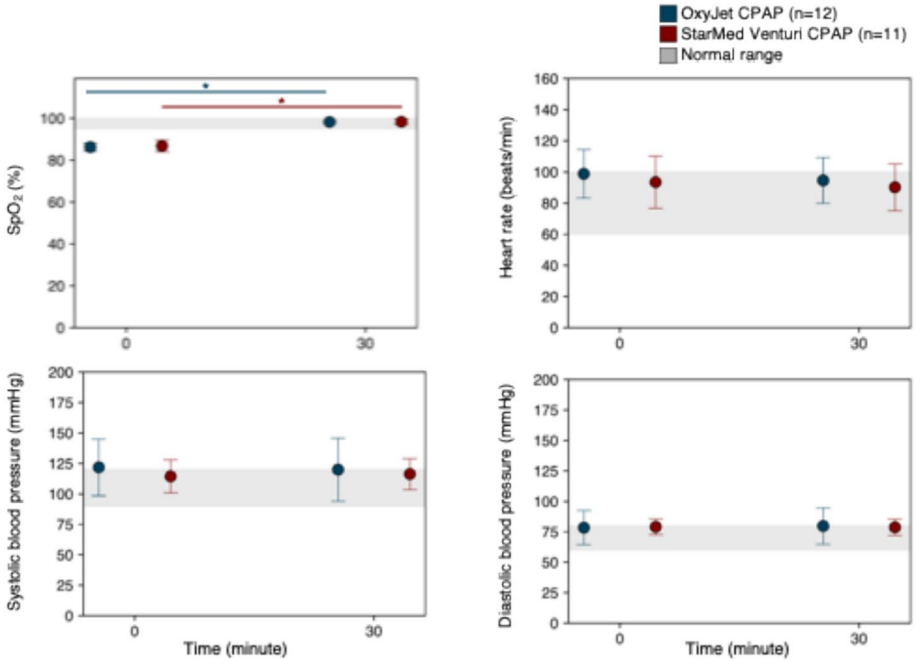


Fig. 4 Findings of the pilot study. Scatter plots with mean ± standard deviation, showing the changes in physiological measurements, including peripheral oxygen saturation (SpO_2), heart rate, and blood pressure (systolic and diastolic) of the adult hypoxemic patients during the pilot study. Measurements were recorded before and at the last minute of the intervention. The region shaded in grey represents the normal physiological range for adults. * denotes significant improvement (p-value < 0.05) of the physiological level of patients before and after the intervention. The '0' in the timeline represents the patient's condition in room air, measured just before administering the CPAP

adverse effects were observed. None of the patients required intubation or ICU transfer immediately following the CPAP session. Both groups had comparable short-term physiological effects, and the devices helped improve the patient's condition. Thus, the findings support the feasibility of the device in providing emergency respiratory support to hypoxemic patients in general wards/pre-ICU settings.

Discussion

In this article, we present the design and development of OxyJet, a low-cost, portable, electricity-free, 3D-printed continuous positive airway pressure (CPAP) device for providing noninvasive respiratory support to hypoxemic patients in general wards. Benchtop testing and performance evaluations have demonstrated that OxyJet CPAP meets the UK-MHRA RMCPAP standards [19] and offers specifications comparable to those of existing devices (Table S2). We present the comparison in the *Supplementary Information*. Regarding performance and risk minimization from aerosolization, the OxyJet CPAP provides features comparable to the UCL Ventura system for less than 10% of the cost. Our innovative approach of repurposing off-the-shelf precision needles and 3D printing-based manufacturing achieves this significant cost–benefit. Our design and benchtop testing also confirm that the device delivers at least 50 L/min of oxygenated air flow, sufficient to provide emergency support to hypoxemic patients [19]. The device validation stage on five

healthy volunteers has shown that the device can adequately maintain positive pressure and flow required for a CPAP device. Although an 11% reduction in heart rate (Δ10 beats/min; $p = 0.083$) was observed, this effect is consistent with known CPAP physiology: by raising intrathoracic pressure in systole (reducing venous return/preload) and in diastole (increasing pericardial pressure and lowering transmural pressure/afterload), and by lung inflation–mediated vagal activation, CPAP reliably slows the heart rate (Table S9) [28]. One practical consideration is the use of spring-loaded adjustable PEEP valves. Their pressure stability can vary due to mechanical tolerances and gas flow, a behavior typical for such devices. Although these valves may show modest fluctuations around the set PEEP, they are widely available and common in hospitals, making them a practical and accessible option for LMICs. Testing on hypoxemic patients has revealed its ability to significantly improve oxygenation within a short period while retaining other physiological parameters stable.

Findings from the pilot study support the feasibility of OxyJet as an emergency therapy for hypoxemic patients in a low-resource healthcare setting. Results showed a significant improvement in peripheral oxygen saturation (SpO_2), with no notable changes in other vitals. Moreover, the short-term physiological effects of OxyJet CPAP were comparable to those of standard CPAP. Nonetheless, the study was limited by the absence of arterial blood gas analysis, as well as its small sample size and short duration.

This study has several limitations. First, the sample size for both validation and pilot studies was small, which limits the statistical power of our findings. Second, the duration of patient monitoring was short, preventing long-term outcome assessments. Third, the study was conducted in a single geographical location, which may limit the applicability of our findings to varying healthcare contexts in other LMICs. These factors highlight the need for larger, multi-center trials with extended follow-up to establish efficacy, safety, and real-world usability.

The experimental validation and pilot study suggest that the OxyJet CPAP may be a feasible option for short-term emergency respiratory support outside the ICU in low-resource healthcare settings. Additionally, in LMICs, when ICU beds are unavailable, patients may suffer while being transported to a higher-level facility since high-flow devices are not available within traditional ambulances. Given that the Oxyjet device can operate from a portable oxygen cylinder, it may be well-suited for use in ambulances (Fig. S8). However, this application requires further testing and validation. The device is not intended to replace low-flow CPAP systems such as the Boussignac or O-two models, which remain essential when oxygen availability is extremely limited. Rather, it is designed to address an important clinical need for patients who do not respond adequately to low-flow CPAP and require a higher level of respiratory support. Future work should include larger-scale piloting with extended follow-up to better assess the efficacy and safety of the device. Nonetheless, the OxyJet CPAP has immense potential to make non-invasive respiratory support more accessible and affordable in LMICs. While conventional care remains ideal, using OxyJet CPAP as an emergency non-invasive respiratory support while awaiting resource availability can sustain life and reduce critical care burden.

Methods

We designed the OxyJet CPAP specifically to provide non-invasive respiratory support in resource-limited settings. This low-cost device easily connects with existing medical gas outlets and is powered by a pressurized oxygen source without electricity. This makes it ideal for use in settings where expert personnel and uninterrupted power supplies are unavailable. An overall schematic diagram of the proposed innovative CPAP system is shown in Fig. 1b. We designed the flow generator (Fig. 1c) by adapting the basic principle of a gas ejector [29]. Oxygen from an external source is accelerated through a converging nozzle, generating a high-velocity oxygen jet (Fig. 1d; O_2 jet). This jet creates a low-pressure zone within the flow generator (Fig. 1d; Suction chamber), drawing in room air through the air inlet. The entrained air mixes with the oxygen jet to produce an oxygen-rich high-flow (Fig. 1d; Mixing chamber).

Theory

The OxyJet flow generator operates on the principle of a gas ejector, a well-established technique for fluid entrainment that dates to the mid-twentieth century [30, 31]. In our application, this principle is used to create an electricity-free continuous positive airway pressure (CPAP) device suitable for low-resource healthcare settings. The theoretical behavior of the flow generator can be described using a quasi-one-dimensional compressible flow theory under isentropic assumptions, which allows for analytical estimation of critical performance parameters such as mass flow rate and pressure ratios.

The primary driving component is a repurposed stainless-steel dispensing needle, acting as a converging nozzle. The mass flow rate through the nozzle can be defined by the following relation:

$$\dot{m} = \frac{p_0 A^*}{\sqrt{RT_0}} \sqrt{\gamma} \cdot M \cdot \left(1 + \frac{\gamma - 1}{2} M^2\right)^{-\frac{\gamma+1}{2(\gamma-1)}} \tag{1}$$

where $\dot{m}$ is the mass flow rate, p_0 is the stagnation pressure, T_0 is the operating temperature, A^* is the critical cross-sectional area of needle, R is the specific gas constant, M is the Mach number and γ is the heat capacity ratio. The corresponding pressure ratio between the upstream (source) and downstream (nozzle exit) flow is defined as:

$$\frac{p_0}{p} = \left(1 + \frac{\gamma - 1}{2} M^2\right)^{\frac{\gamma}{\gamma-1}} \tag{2}$$

where p denotes the back pressure at nozzle exit. While these equations provide valuable one-dimensional approximations for design optimization, the inherently complex nature of the flow generator—particularly the interaction between entrained ambient air and oxygen flow—necessitates a more detailed analysis through simulation and experimentation.

Design and fabrication of the OxyJet flow generator

The OxyJet flow generator consists of four main components: the OxyJet body, a double-sided connector, a converging nozzle (needle), and a Diameter-Index Safety System (DISS) female adapter (Fig. 1c). The OxyJet body (150 mm × 30 mm × 70 mm) designed using 3D computer-aided design (CAD) software (SolidWorks®, 2019), was fabricated with fused deposition modeling (FDM)-based 3D printing using polylactic acid (PLA). The air inlet and outlet ports have a standard outer diameter of 22 mm and are angled at 50° to direct gas flow efficiently into the mixing chamber and

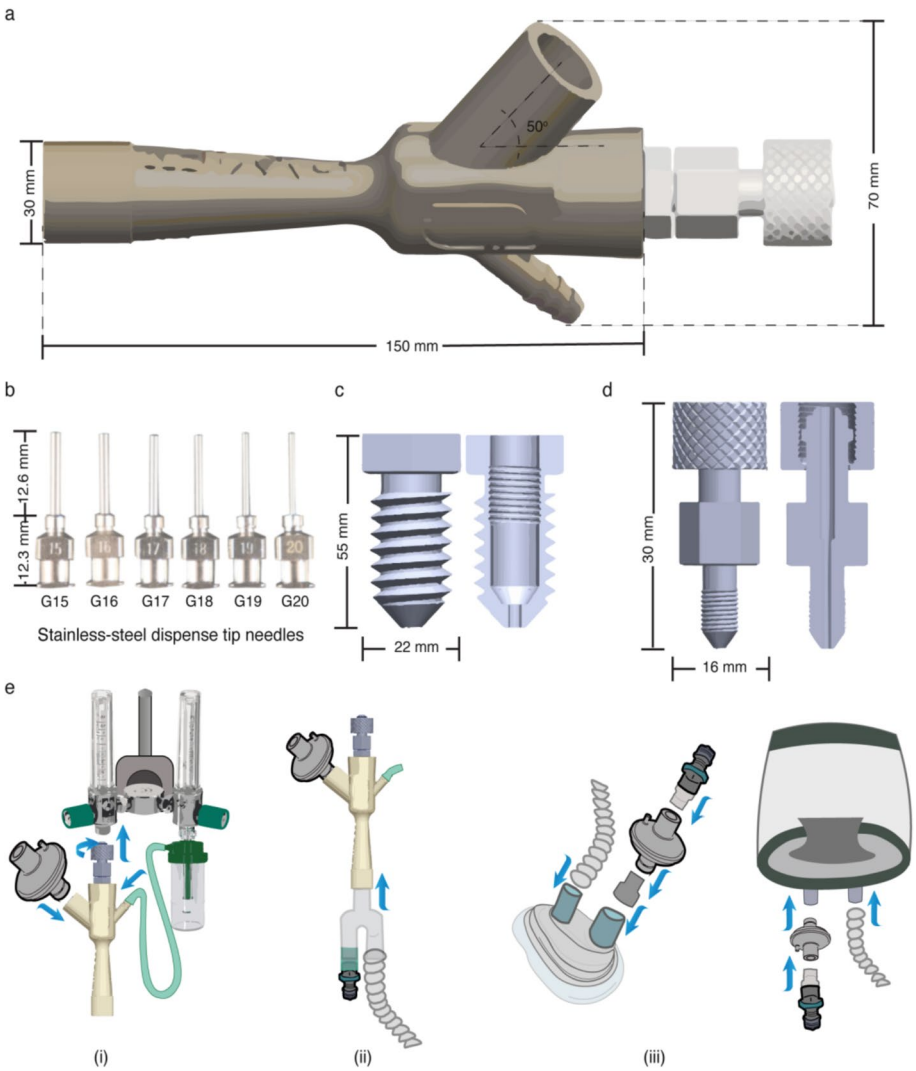


Fig. 5 Design and Assembly of the OxyJet CPAP. **a.** Isometric view of the OxyJet flow generator. **b.** Stainless steel dispense tip needles used as flow generator nozzles. **c.** Cross-sectional view of the double-sided connector. **d.** Cross-sectional view of the DISS female adapter. **e.** Step-by-step assembly of the OxyJet CPAP system. (i) The OxyJet flow generator is connected to a primary flowmeter via the DISS adapter. A second flowmeter with a bubble humidifier is attached to the secondary oxygen inlet via an oxygen tube. A viral/HEPA filter is attached to the air inlet port. (ii) One end of the breathing circuit is connected to the outlet port of the flow generator. (iii) The other end of the breathing circuit is connected to the inhalation port of the CPAP mask/helmet. Finally, a viral/ HEPA filter followed by an adjustable PEEP valve is attached to the exhalation port of the CPAP mask/helmet

facilitate 3D printing (Fig. 5a). As the nozzle, we repurposed off-the-shelf stainless steel (SS) dispensing needles (Fig. 5b) capable of withstanding high pressure (~ 100 psi). The nozzle is the most critical component of the device requires high precision, and thus, using an off-the-shelf needle significantly reduces manufacturing complexity. The metal components—a double-sided connector (55 mm × 22 mm) and a DISS female adapter (30 mm × 16 mm) (Fig. 5c, d)—were custom-made from nickel-plated brass using CNC machining to meet the necessary specifications for hospital oxygen systems (as per CGA V-1 or ISO 5359 standards).

Assembly and operation of the OxyJet CPAP system

Figure 5e illustrates a schematic diagram of the step-by-step assembly of the OxyJet CPAP system. The OxyJet flow-generator readily attaches to a high-pressure (3.5 bar) oxygen source such as an oxygen cylinder or centralized oxygen supply via a standard oxygen flowmeter (primary oxygen flow). The flowmeter regulates the source pressure and flow of oxygen delivered to the flow generator. A high-efficiency particulate air (HEPA) filter at the air entrainment port protects the flow generator and the patient from environmental pathogens and dust particles. A second flowmeter with a bubble humidifier is connected to the secondary oxygen port, supplying additional humidified oxygen (secondary oxygen flow) to the flow generator, enabling the device to increase the FiO_2 up to 100% (Fig. 5e). The flow generator outlet is attached to a long breathing circuit, then to the inhalation port of a non-vented CPAP mask or a CPAP helmet/hood. The setup also includes a safety valve to ensure that the pressure within the system does not exceed 25 cmH_2O. The exhalation port of the CPAP mask/helmet includes a HEPA filter followed by an adjustable PEEP valve (5–15 cmH_2O) (Video S1; OxyJet CPAP setup). The compliance of the breathing circuit was measured at 6.53 mL/cmH_2O, which is insignificant, ensuring accurate delivery of pressure and volume. Flow resistance across the complete system remained low (≤ 0.03 $cmH_2O/L/min$), producing a pressure drop of < 1.8 cmH_2O at peak flow (65 L/min), which is negligible compared to the delivered PEEP (5–15 cmH_2O). As CPAP is an aerosol-generating procedure [32] and poses a risk of aerosolizing virus particles and environmental contamination in the general wards. We minimize this risk using viral/HEPA filters and the non-vented CPAP mask (or CPAP helmet/hood) [33].

The OxyJet CPAP is turned on by setting the primary oxygen flow to 15–16 L/min (approx.). The device will generate a high flow of 65 L/min with an initial FiO_2 of 40% at 5 cmH_2O PEEP. To adjust the FiO_2 of the flow, additional oxygen is supplied using a secondary flowmeter via the secondary O_2 port of the OxyJet flow generator. Desired FiO_2 (%) can be set in 5% increments by adjusting the secondary flowmeter's flow (L/min) following a device operation chart (Fig. S3), as shown in the *Supplementary Information*. This chart is developed based on the device flow characteristics, which are detailed in the results section. In a similar fashion, the PEEP settings of the CPAP can be changed by turning the PEEP valve knob. The device is turned off by simply turning off the flowmeters. Clinicians and hospital staff in the general wards are familiar with adjusting the standard flow meters and valves. Thus, the unique design of OxyJet CPAP allows a straightforward operation requiring minimal to no training (Video S1; OxyJet CPAP operation).

OxyJet is compatible with existing hospital facilities and can be plugged into a medical gas outlet or used with an oxygen cylinder. Although our system includes an integrated bubble humidifier, it is also compatible with an external heated humidifier with temperature control (Fig. S4), as shown in the *Supplementary Information*. However, per the MHRA guidelines [19], we consider this optional. An external heated humidifier introduces more complexity, increases costs, and makes it less suitable for resource-limited settings, requiring an uninterrupted power supply.

The estimated material cost of the OxyJet flow generator is about US$20. The entire CPAP system, including all accessories, can cost up to US$56.81 (Fig. S6, Table S3), which may be reduced if mass-produced. In contrast, a full UCL Ventura setup costs $1221 (Table S1). We have presented the breakdown of the cost in the *Supplementary Information*.

Characterization of the OxyJet flow generator

The OxyJet flow generator was characterized using the IMTAnalytics FlowAnalyser PF-300 (Fig. S2b), as shown in the experimental setup in Fig. S2 in the *Supplementary Information*. A total of 75 OxyJet devices (Fig. S1) were developed and used to evaluate its dynamic range. The QC-passed devices were used in the pilot study. The OxyJet flow generator was connected to the gas flow analyzer via a corrugated tube. An adjustable PEEP valve (5–15 cmH_2O) was set at the outlet port of the analyzer. Data were recorded at the flow generator outlet with a sampling rate of 200 s^{-1}. The analysis was done on various data points, including flow (L/min), FiO_2 (%), PEEP (cmH_2O), humidity, and temperature. Device optimization and the analysis of pressure, flow, and FiO_2 (%) characteristics are detailed in the results section (Fig. 2a–c).

Device validation study

The OxyJet CPAP system was validated in two steps after completing the laboratory evaluation. First, the device was tested on five healthy volunteers (Fig. 2d, Table S7) for a short duration of 15 min. CPAP was administered to each participant using two patient interfaces: a CPAP mask and a CPAP helmet, each tested at two PEEP settings (5 and 10 cmH_2O). Expiratory flow and pressure were continuously measured and recorded at the patient interfaces for the entire duration. Additionally, the physiological measurements of the participants were recorded before and at the last minute of CPAP administration. Second, the device was applied to five adult hypoxemic patients (SpO_2 between 85 and 93% in room air) for a short duration of one hour in the general wards at Dhaka Medical College Hospital (DMCH) (Table S11). Each patient received two consecutive 30-min CPAP sessions—first with a non-vented CPAP mask, followed by a CPAP helmet (Fig. 2d). The physicians adjusted the FiO_2 and PEEP according to each patient's needs. Patients were monitored at 15-min intervals, and their physiological parameters were recorded. Both steps were approved by the National Research Ethics Committee (NREC) of the Bangladesh Medical Research Council (BMRC), Dhaka, Bangladesh (Ref: BMRC/NREC/2019-2022/1110). Physicians conducted all procedures following the approved clinical guidelines and regulations. Informed written consent was obtained from all participants for enrollment. Additionally, informed consent was obtained from a participant to publish his identifying images in an online open-access publication.

Pilot study design

The pilot study was designed to assess the feasibility of a locally made OxyJet CPAP device in providing respiratory support to patients with acute hypoxemic respiratory failure in the general ward settings. A standard CPAP device (StarMed Venturi-CPAP; Fig. S5) was used as a positive control for comparison, as shown in the *Supplementary Information*. The pilot study was conducted by the study physicians under the supervision of the co-investigators in the general wards of the National Institute of Diseases of the Chest and Hospital (NIDCH), Dhaka, Bangladesh. This study was approved by the Directorate General of Drug Administration (DGDA), Dhaka, Bangladesh (Ref: DGDA/CTP-04/2016/10056).

Patients were eligible for enrollment if they were aged between 18 and 65 years and hypoxemic with an SpO_2 (%) between 85 and 93% in room air. Informed written consent (Bengali and English) was obtained from the patients before enrollment. Patients with a low respiratory drive or requiring cardiopulmonary resuscitation, contraindications for CPAP, and pregnant women were excluded.

This was a pilot feasibility study; therefore, no formal power analysis was conducted. Instead, the sample size was determined following Julious et al. [34], which recommend a minimum of 12 participants per group to reliably estimate variability and evaluate the practicality of study procedures. A sample size of 24 was selected for the study with 12 patients in each arm, i.e., OxyJet CPAP and standard CPAP (StarMed).

Eligible patients were randomly assigned (1:1) to one of two groups: OxyJet CPAP or StarMed CPAP therapy. The patients were assigned using block randomization (block size of 10) with an internet-based system with allocation concealment. The randomization sequence was secured in a sealed envelope with one of the co-investigators on site, who was not responsible for enrolling patients. Only the study physicians who performed the patient screening were unblinded after the patient had signed the informed consent form. Between 18 June and 10 October 2023, a total of 24 adult hypoxemic patients were enrolled in the study. However, one patient from the standard CPAP treatment group was excluded from the final analysis due to missing data.

At enrollment, we collected the demographic information (including age, sex, weight, height, and BMI), comorbid state, and physiological measurements (including blood pressure, heart rate, respiratory rate, and oxygen saturation) of the patients. The baseline characteristics of the patients in the two groups were comparable in terms of age, gender, BMI, history of illness, physiological measurements, and comorbidities (Table S14), as presented in the *Supplementary Information*. In both cases, the intervention was administered to each patient using a non-vented CPAP mask with a 5 cmH_2O PEEP for a duration of 30 min. The study physicians ensured that patients in both groups received treatment according to the standard management protocol. Patients were followed up during the intervention, and their physiological measurements were monitored. Heart rate, blood pressure, and SpO_2 (%) measurements were recorded before and at the last minute of the intervention. Blood pressure was measured using an Omron 5 Series Digital blood pressure monitor (USA) device. Peripheral oxygen saturation was measured using an iMDK Fingertip pulse oximeter (Model C101A3). Manufactured OxyJet units were inspected for damage and irregularities and assessed through quality control (QC) tests (Fig. S1). The passed devices were then sterilized using Ethylene Oxide (EtO) and

sealed. The administration of a new device was carried out solely by the attending physicians (Fig. S6). The disposable components, including- the CPAP mask, HEPA filters, and PEEP valve, were replaced after use. The OxyJet CPAP was assembled on-site by study physicians using off-the-shelf components supplied by the investigators, following a standardized step-by-step protocol (see Video S1). After each intervention, patients were reverted to their standard treatment protocol.

Statistical analysis

Data were reported as means (SD). Normality was assessed using the Shapiro–Wilk test. Comparisons between groups were expressed as mean differences (95% CI). The paired Student's t-test was used to compare the physiological parameters before and after the intervention, and the Independent Student's t-test was used to compare the physiological measurements of patients between the two groups. All the analyses were performed using Minitab® and Microsoft Excel® software.

Abbreviations

CPAP	Continuous Positive Airway Pressure
NIV	Non-Invasive Ventilation
BiPAP	Bilevel Positive Airway Pressure
HFNC	High-Flow Nasal Cannula
COVID-19	Coronavirus Disease 2019
COPD	Chronic Obstructive Pulmonary Disease
FiO_2	Fraction of Inspired Oxygen
ICU	Intensive Care Unit
LMIC	Low- and Middle-Income Countries
UK-MHRA	United Kingdom Medicines and Healthcare Products Regulatory Agency
DMCH	Dhaka Medical College and Hospital
NIDCH	National Institute of Diseases of the Chest and Hospital
HEPA	High-Efficiency Particulate Air
BMRC	Bangladesh Medical Research Council
NHS	National Health Service (UK)
RMCPAP	Rapidly Manufactured CPAP System
WHO	World Health Organization
UNOSSC	United Nations Office for South-South Cooperation
NREC	National Research Ethics Committee
DGDA	Directorate General of Drug Administration
EtO	Ethylene Oxide
DISS	Diameter-Index Safety System
FDM	Fused Deposition Modeling
BMI	Body Mass Index
PEEP	Positive End-Expiratory Pressure
CNC	Computer Numerical Control (Machining)
SpO_2	Peripheral Oxygen Saturation
G	Gauge (for needle sizes)

Supplementary Information

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Additional file1 (PDF 3376 KB)

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Author contributions

M.K.A., K.A.A., M.R., F.M. and T.H. developed the OxyJet CPAP device design and performed experiments. T.H., N.N., R.A., M.K.I., F.U.H.C., M.M.S., M.N.A., N.R., K.N.I., M.S.S.S., and M.S.I. conceived the study and developed its design. R.H.R., S.J., M.M.S., F.U.H.C., M.N.A., N.R., K.N.I., M.S.S.S., and M.S.I. recruited patients. T.H., N.N., and K.A.A. uploaded Case Report Forms and conducted quality assurance checks on the database. M.K.A. and T.H. analyzed the data and wrote the initial

manuscript. Y.K., S.R., A.B.L., S.A., M.K.A., and M.T.M. provided advisory support, and manuscript editing. All authors contributed to the writing of the final version.

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Data availability
The primary data supporting the findings in this study are available within the paper and its Supplementary information. Data requests for academic research purposes should be submitted to the corresponding author. Anonymized data will be provided by the corresponding author only for academic research purposes.

Declarations

Ethics approval and consent to participate
The device validation studies (on five healthy volunteers and five hypoxemic patients) and the subsequent pilot comparative study were conducted under full ethical oversight. The validation study was approved by the National Research Ethics Committee (NREC) of the Bangladesh Medical Research Council (BMRC), Dhaka, Bangladesh (Ref: BMRC/NREC/2019-2022/1110), and the pilot study by the Directorate General of Drug Administration (DGDA), Dhaka, Bangladesh (Ref: DGDA/CTP-04/2016/10056). All procedures were carried out in accordance with the approved clinical guidelines and regulations. Written informed consent was obtained from every participant prior to enrollment.

Consent for publication
Informed consent was obtained from each of the participants. In addition, separate consent was secured from one volunteer whose identifying images appear in an online open-access format.

Competing interests
T.H., M.K.A., K.A.A., M.R., and F.M. are inventors of a US patent (US 11793958, Oct. 24, 2023). All other authors declare no competing interests.

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OxyJet CPAP: An electricity-free low-cost emergency respiratory support device – Supplementary Information

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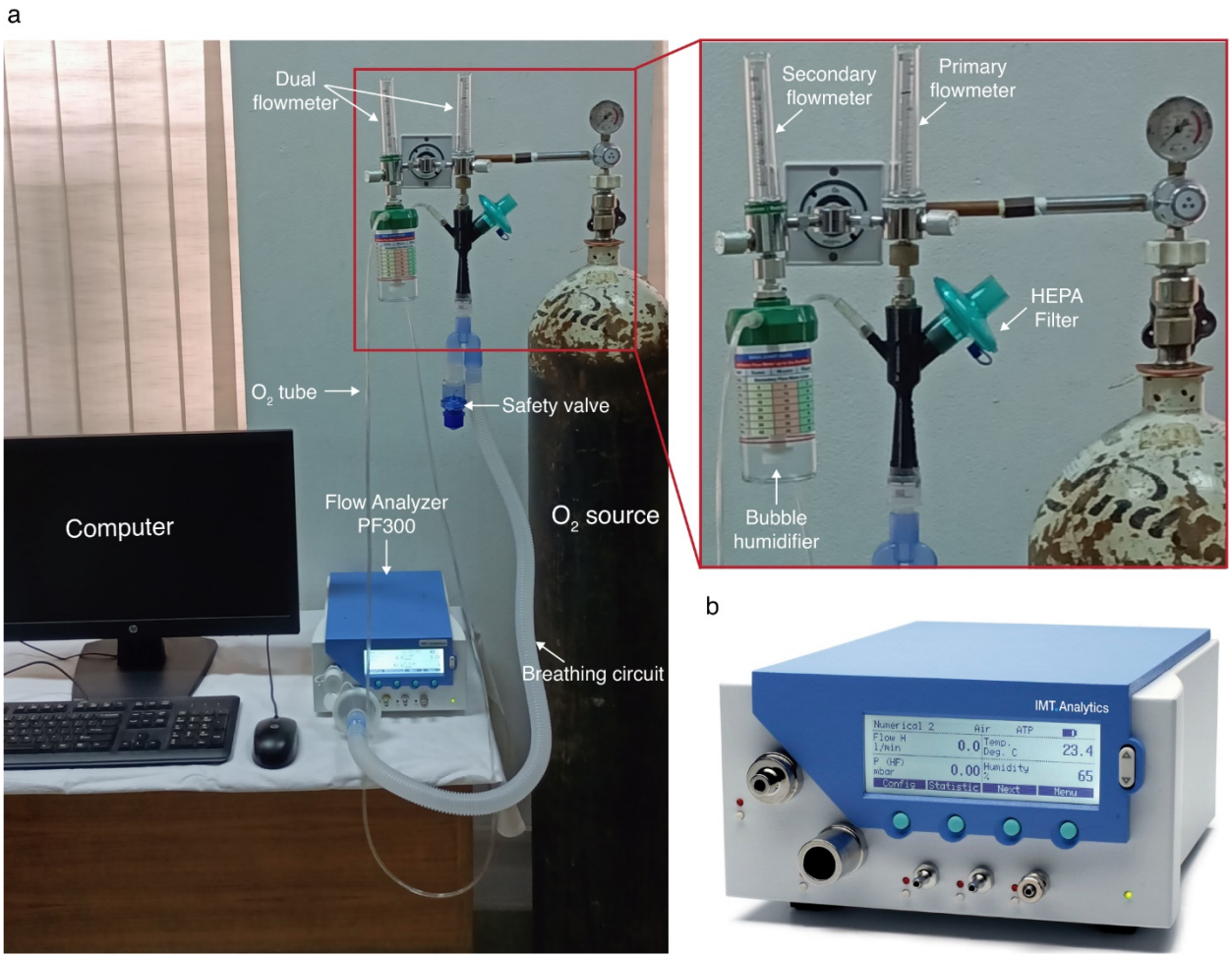
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Supplementary Figure 1. Photograph of locally made OxyJet devices.
The devices were rapidly manufactured during the second wave of the COVID-19 pandemic (July 2021) with an intention to provide emergency respiratory support to hypoxemic COVID patients in the general hospital ward while awaiting critical care availability.



Supplementary Figure 2. Device characterization setup for OxyJet CPAP.

(a) Setup for device characterization. OxyJet CPAP was installed, and the output port of the flow generator was connected to a flow analyzer via a breathing circuit. The output flow (L/min), FiO_2 (%), PEEP (cmH_2O), humidity, and temperature of the system were measured, as described in **Methods**. (b) Photograph of the IMTAnalytics FlowAnalyser PF-300 (https://www.imtanalytics.com/en/Analyser/FlowAnalyser). All the data were acquired using it.

OPERATION CHART			
Set primary flowmeter to 15 (L/min)			
PEEP	**5** cmH_2O	**10** cmH_2O	**15** cmH_2O
$\%FiO_2$	**Secondary flowmeter** (L/min)		
>40%	0	0	0
>60%	14	14	10
>65%	18	16	14
>75%	24	22	16
>80%	28	26	18
>85%	30	28	20
>90%	36	32	24
>95%	40	36	26

Supplementary Figure 3. OxyJet CPAP operation chart.

The operation chart of OxyJet CPAP system is given to manually control the FiO_2 (%) of the generated high-flow delivered to the patient.

a



b

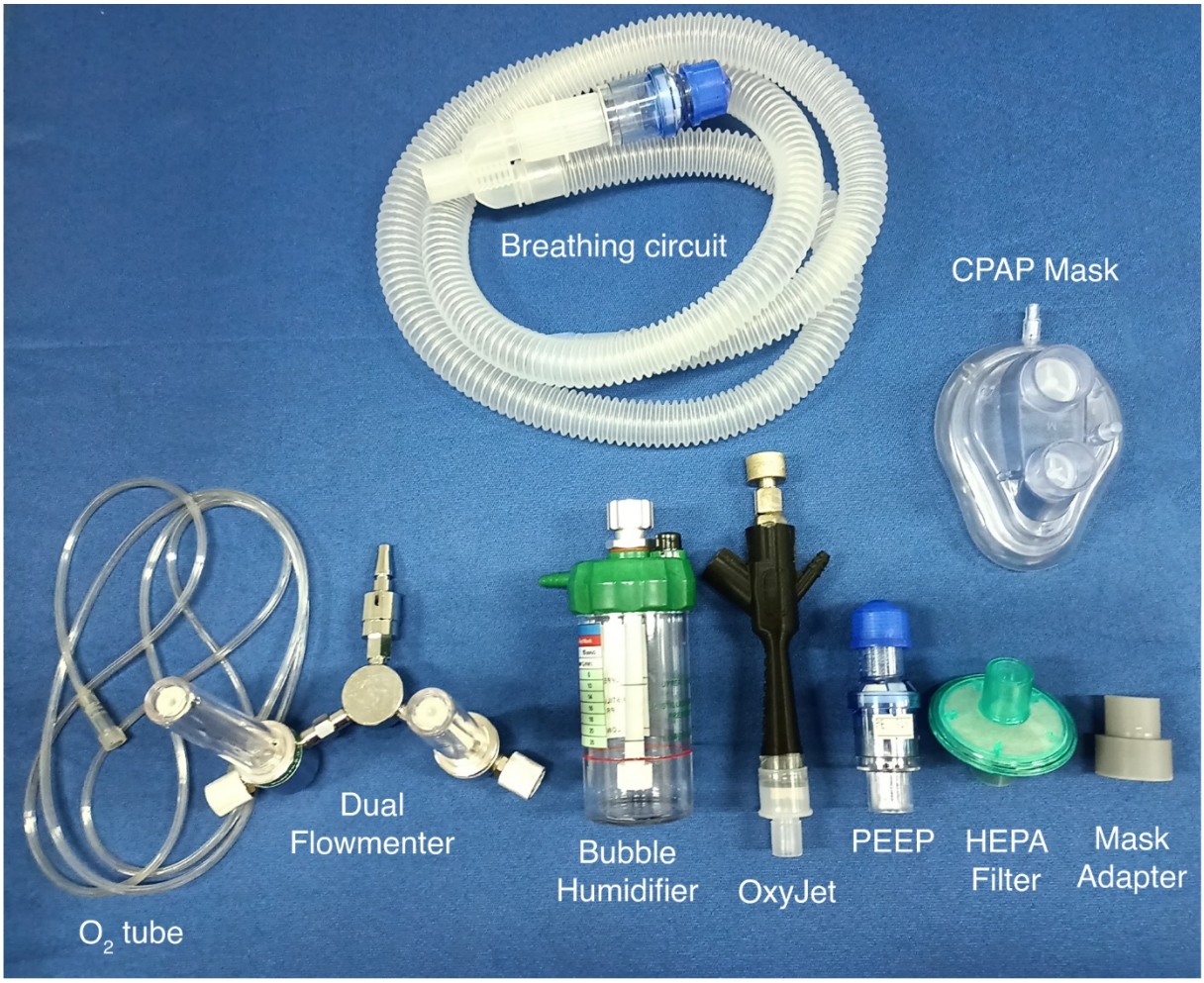


Supplementary Figure 4. Setup for testing OxyJet CPAP with an external heated humidifier.
(a) Setup for testing OxyJet CPAP with an external heated humidifier. (b) Photograph of the heated humidifier PN-2000FC850 (https://www.pigeon-medical.com/products/pn-2000fc850-respiratory-humidifier).



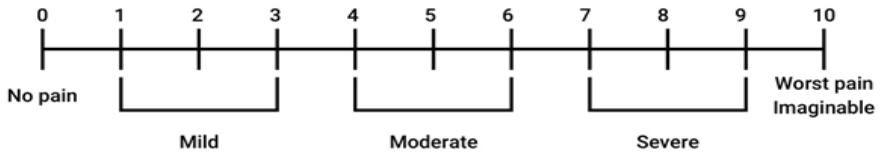
Supplementary Figure 5. StarMed Venturi CPAP device

The StarMed venture CPAP device (https://www.intersurgical.com/products/critical-care/starmed-ventumask-with-venturi-flow-driver-for-cpap-therapy) was used in the control arm for adult hypoxemic patients in the pilot study. It can deliver an adjustable PEEP (at 5, 7.5, 10 and 12.5 cmH_2O) and an adjustable FiO_2 (%) (from 40% - 100%).



Supplementary Figure 6. OxyJet CPAP kit used for clinical trials.

OxyJet CPAP kit consists of a breathing circuit, an oxygen tube, two viral/HEPA filters, one adjustable PEEP valve (5-15 cmH_2O), CPAP masks (S/M/L), a dual flowmeter, a bubble humidifier, and OxyJet flow generator.



Supplementary Figure 7. Numerical Rating Scale (NRS) of patient discomfort level.

The NRS was used to measure the patient discomfort level of two interfaces (CPAP mask and CPAP helmet).



Supplementary Figure 8. Testing OxyJet CPAP on a healthy volunteer in ambulance setting.

Supplementary Tables

Supplementary Table 1. Comparison of OxyJet CPAP with the most competing CPAP system.

Category	OxyJet CPAP	UCL Ventura[1]
Affordable	Estimated material cost of the OxyJet flow generator is $20. The whole CPAP system with all the accessories can cost around $56.81.	Cost of the UCL Ventura CPAP with all the accessories is around $1221.
Dependency on global supply chain	Can be produced from locally available raw materials.	Requires imported raw materials.
Design innovation and manufacturability	OxyJet CPAP has a novel design. It can be produced using off-the-shelf components, 3D printing and CNC machining. Does not require a complex manufacturing infrastructure.	Device is produced by reverse-engineering an FDA approved device (Whispherflow CPAP)[1]. It requires a high-precision manufacturing infrastructure.
Clinical evaluation	Pilot study was conducted to prove the efficacy of the system.	As the device is reverse engineered from an FDA approved device, its clinical trial was exempted.
Usability	The device directly fits a standard flowmeter and is operated by regulating the flow of the flowmeters following a device operation chart. Requires minimal training.	The device attaches to a wall-mount oxygen port. It can be operated by regulating the flow and the FiO_2 knobs (no dial scale). However, it needs electronic sensors to measure and display the flow (L/min) and the FiO_2 (%).
Power requirement	OxyJet is completely electricity free, pressure driven CPAP system.	UCL Ventura is pressure driven but not completely electricity free. It requires electricity to power the sensors.
Sensitive and specific	Performance is similar to other predicate devices. It provides a high flow up to 65 L/min with a FiO_2 (%) ranges within 40-100% and can be controlled in steps of 5%. The PEEP can be set between 5-15 cmH_2O.	It can provide a high flow of 0-120 L/min with a FiO_2 (%) between 30-100%. These can be precisely controlled by turning knobs and with visual feedback from the sensors. The PEEP can be set between 5-15 cmH_2O.
Oxygen consumption (L/min)	As the operating flow is limited to 65 (L/min), it can deliver higher level of FiO_2 (%) consuming less oxygen. To deliver a FiO_2 (%) of 60% to patients it draws an oxygen flow of 32 (L/min).	The device specification suggests, to deliver a FiO_2 (%) of 60% to patients with higher work of breathing, it draws an oxygen flow of 46.7 (L/min)[2]. However, it can draw much higher flow of oxygen reaching up to 116 L/min when all valves are fully opened[3].

Supplementary Table 2. Specifications comparison with existing devices

Aspect of CPAP device	OxyJet CPAP	StarMed CPAP	UCL Ventura
Maximum flowrate	65 L/min (approx.) at 5 cmH_2O PEEP	60 L/min (approx.) at 5 cmH_2O PEEP	0-120 L/min
PEEP settings	5, 10, 15 cm H_2O	5 - 7.5 - 10 - 12.5 cm H_2O	5, 10, 15 cm H_2O
PEEP mechanism	Standard adjustable PEEP valve	Standard adjustable PEEP valve	Standard adjustable PEEP valve
FiO_2 (%)	40% - 100%	40% - 100%	30% - 100%
Compatible masks	Non-vented cpap mask, or CPAP helmet	Non-vented cpap mask, or CPAP helmet	Non-vented cpap mask, or CPAP helmet
Oxygen port	Standard DISS connector	Standard DISS connector	Standard DISS connector
Requirements	Oxygen cylinders or central oxygen lines	Oxygen cylinders or central oxygen lines	Oxygen cylinders or central oxygen lines
Negative-pressure room	Not required	Not required	Not required
Aerosol generation	Risk is minimized by HEPA filter	Risk is high	Risk is minimized by HEPA filter
Risk of high pressure	Minimized by pressure-relief valve (at 25 cm H_2O)	Not known	Minimized by pressure-relief valve (at 25 cm H_2O)

Supplementary Table 3. Material cost estimate of an OxyJet CPAP system.

Description	Supplier	OxyJet CPAP kit		
		Quantity	Unit cost (USD)	Cost (USD)
OxyJet flow generator	Fully assembled device[a]			
i. OxyJet 3D printed body	3D Printed	1	4.80	4.80
ii. Needle[b]		1	0.20	0.20
iii. Double-sided connector	Local workshop	1	5.00	5.00
iv. DISS female adapter	Local workshop	1	10.00	10.00
Dual Flowmeter with Humidifier	Amcaremed Technology Co. Ltd, China[c]	1	16.00	16.00
Breathing Circuit	Evereast Medical Products Group Co. Ltd, China[d]	1	2.13	2.13
Viral Filter	Shandong Zhenfu Medical Device Co. Ltd, China[e]	2	0.65	1.30
Secondary Tube	Ningbo Greetmed Medical Instruments Co. Ltd, China[f]	1	0.36	0.36
Peep Valve with Peep Adaptors	Ningbo Finer Medical Instruments Co. Ltd, China[g]	2	1.50	3.00
CPAP Mask	Evereast Medical Products Group Co. Ltd[h]	3	4.11	12.33
Connectors (JS029-6105, JS029-6103)	Shaoxing Jenston Medical Co. Ltd[i]	1	0.06	0.06
Mask Adaptor	3D Printed[j]	1	2.00	2.00
Estimated total material cost for a fully equipped OxyJet CPAP system[k]				56.81

a. The cost is estimated for producing a fully assembled OxyJet flow generator using in lab-scale fabrication. It's subjected to reduce when scaled.
b. https://www.amazon.in/12-Pack-Dispensing-Stainless-18G-25mm-12pcs/dp/B07JRFVV3S
c. https://www.alibaba.com/product-detail/AmcareMed-Aluminum-Body-Oxygen-Flowmeter-with_62007802170.html
Company Link: https://www.amcaremed.com/
d. http://en.changdongjituan.com/our-product/our-product6.html
e. https://www.alibaba.com/product-detail/Disposable-Bacteria-Viral-Filter-for-CPAP_1600519478099.html?spm=a2700.shop_plgr.41413.39.6d546737ujHnTt
Company Link: http://m.zhenfumedical.cn/product/30.html
f. https://greetmed1.en.alibaba.com/search/product?SearchText=medical%20pvc%20oxygen%20connection%20tubing
Company Link: https://www.china-greetmed.com/En/product_d/id/182.html
g. https://www.alibaba.com/product-detail/medical-ambu-bag-peep-valve_60741014807.html?spm=a2700.7724857.0.0.6e8a3461AdeHYj
Company Link: http://www.finermed.com/e_products/?big_id=3&small_id=371
h. https://www.alibaba.com/product-detail/Disposable-medical-Nasal-CPAP-Face-Mask_62303863868.html
Company Link: https://www.evereastmedical.com/cpap-pvc-mask.html
i. Company Link: http://www.jstmed.com/
j. Mask Adaptors have been printed in our lab facility with 3d printer (Formlabs SLA Printer) and the cost is estimated according to the material used for each adaptor manufacturing.
k. The estimated cost only covers the raw materials used at the time of submission, which may vary depending on the market. The final estimate for commercialization should include the overall costs comprising transportation cost, vat & tax for importing, human resources, manufacturing cost and miscellaneous items.

Supplementary Table 4. Comparison of the flow produced by the OxyJet flow generator using different needle gauges vs PEEP.

Needle Gauge	PEEP Settings		
	5 cmH_2O	10 cmH_2O	15 cmH_2O
	Mean output flow (L/min)		
G20	115	107	100
G19	105	99	91
G18	96	91	84
G17	81	75	66
G16	67	60	50
G15	52	44	35

* Primary input flow of oxygen was set to 15-16 (L/min).

Supplementary Table 5. The maximum output flow and the minimum FiO_2 generated by the G16 based fixed OxyJet flow generator (n=75) for different PEEP settings.

G16 based OxyJet flow generator	PEEP Settings		
	5 cmH_2O	10 cmH_2O	15 cmH_2O
Flow (L/min) (mean±std)	65.30±3.74	56.11±3.26	46.50±2.74
FiO_2 (%) (mean±std)	40.05±0.63	43.00±0.79	46.42±0.83

* The primary input flow was set to 15-16 L/min of oxygen and the secondary input flow was kept zero.

Supplementary Table 6. Total oxygen supplied versus FiO_2 of the output flow generated by the G16 based fixed OxyJet flow generator (n=75) for different PEEP settings.

PEEP Settings	Supply oxygen (L/min)	Measured FiO_2 (%) (mean±std)
5 cmH_2O	16	40.05±0.62
	50	81.93±1.51
	61	97.77±0.80
10 cmH_2O	16	42.96±0.79
	36	70.20±2.22
	52	97.90±0.65
15 cmH_2O	16	46.42±0.83
	35	80.67±2.14
	43	96.80±1.07

* The primary input flow was set to 15-16 L/min of oxygen and additional oxygen was supplied through the secondary inlet.

Supplementary Table 7. Summary of the demographic information of the healthy volunteers (n=5).

Characteristic		No (%) / Value (mean±std)
Age (years)		27.6±5.32
Gender	Male	5 (100%)
	Female	0 (0%)
Weight (kg)		76.54±14.7
Height (cm)		169.78±2.99
BMI		26.45±4.28
Respiratory Difficulty	Yes	0 (0%)
	No	5 (100%)
History of acute Illness	Yes	0 (0%)
	No	5 (100%)
Chronic diseases	Yes	0 (0%)
	No	5 (100%)
Hospitalized in last one month	Yes	0 (0%)
	No	5 (100%)
Comorbidity	Yes	0 (0%)
	No	5 (100%)
Appearance (Well alert)	Yes	5 (100%)
	No	0 (0%)

Supplementary Table 8. Summary of the expiratory pressure and flow (during inhalation and exhalation) of healthy volunteers (n=5) on two interfaces.

Set PEEP (cmH_2O)	Interface type	Pressure (cm H_2O) (mean±std)		Expiratory flow (L/m) (mean±std)	
		Inhalation	Exhalation	Inhalation	Exhalation
5	CPAP mask	4.93±0.34	6.95±0.10	35.91±3.10	62.19±2.18
5	CPAP helmet	6.32±0.19	7.84±0.09	56.68±2.00	73.40±1.75
10	CPAP mask	12.19±0.31	13.50±0.12	21.16±3.37	41.40±1.54
10	CPAP helmet	13.40±0.12	14.42±0.14	45.54±1.85	64.19±0.81

Supplementary Table 9. Summary of comparison of the physiological levels of healthy volunteers (n=5) before and after administering OxyJet CPAP

Physiological parameter	Before (mean±std)	After (mean±std)	p value* (2-sided t-test)	Significant (p<0.05)
Heat Rate (beats/min)	88.4±7.27	78.8±12.77	0.083	No
Respiratory rate (breaths/min)	19.6±3.85	17.6±2.61	0.189	No
Temperature (°F)	97.6±0.55	97.92±0.18	0.195	No
SpO_2 (%)	99±0.00	99±0.00	1.000	No
Systolic blood pressure (mm Hg)	130±12.25	131.6±14.06	0.444	No
Diastolic blood pressure (mm Hg)	82±13.04	82.2±14.72	0.906	No

* Using “Paired t-test”.

Supplementary Table 10. Summary of comparison of the comfort level of healthy volunteers (n=5) on two types of interfaces.

Interface type	Discomfort level* (mean±std)
CPAP Mask	4.20±1.30
CPAP Helmet	2.60±0.89

* The patient's discomfort level was rated based on the numerical rating scale (NRS) shown in Supplementary Fig. 7

Supplementary Table 11. Summary of the demographic information of the adult hypoxemic patients (n=5).

Characteristic		No (%) / Value (mean±std)
Age (years)		52.6±2.51
Gender	Male	2 (40%)
	Female	3 (60%)
Weight (kg)		55.2±10.26
Height (cm)		161.44±5.99
BMI		21.11±3.27
COVID-19 test result	Positive	0 (0%)
	Negative	5 (100%)
Disease during admission	Severe pneumonia	1 (20%)
	Pneumonia	4 (80%)
Cyanosis	Present	0 (0%)
	Absent	5 (100%)
Antibiotics started	Yes	5 (100%)
	No	0 (0%)
Oxygenation method	Low flow	1 (20%)
	Non-rebreather mask	4 (80%)
Duration of cough (days)		3.2±2.49
Duration of fever (days)		2.2±3.03
Duration of respiratory difficulty (days)		3.4±2.07
Duration of hospitalization (days)		3.2±1.79

Supplementary Table 12. Summary of comparison of the physiological levels of patients (n=5) before and after administering OxyJet CPAP.

Physiological parameter	Before (mean±std)	After [a] (mean±std)	Difference (mean±std)	p value[*] (2-sided t-test)	Significant (p<0.05)
Heart Rate (beats/min)	91.6±12.20	91±17.00	-0.6±8.76	0.8860	No
Respiratory rate (breaths/min)	29±1.73	25.4±4.22	-3.6±3.51	0.0830	No
SpO_2 (%)	87.8±2.17	99±0.71	11.2±2.59	0.0001	Yes
Systolic blood pressure (mm Hg)	137.4±29.13	141.2±30.77	3.8±13.29	0.5570	No
Diastolic blood pressure (mm Hg)	82.8±17.22	91.6±14.62	8.8±7.40	0.0560	No

[*] Using "Paired t-test".

[a] After refers to – Measurements were recorded during the last minute of administering the CPAP intervention.

Supplementary Table 13. Summary of comparison of the comfort-level of patients (n=5) on two interfaces.

Interface type	Discomfort level* (mean±std)
CPAP mask	1.20±1.10
CPAP helmet	2.00±1.22

* The patient's discomfort level was rated based on the numerical rating scale (NRS) shown in Supplementary Fig. 7

Supplementary Table 14. Summary of the baseline characteristics of patients enrolled in the pilot study.

Category	Total (n = 23)	OxyJet CPAP (n = 12)	Standard CPAP (n = 11)
Sex			
Male	13 (56.5%)	6 (50%)	7 (63.6%)
Female	10 (43.5%)	6 (50%)	4 (36.4%)
Age	50.40±10.22	51.3±11.5	49.45±9.15
Weight (Kg)	49.85±12.11	51.1±15.7	48.6±7.81
Height (cm)	159.39±4.35	160.27±4.71	158.50±4.01
BMI	19.6±4.56	19.83±5.80	19.37±3.81
Duration of cough (days)	32.47±27.14	36.9±33.1	27.6±19.1
Duration of fever (days)	13.10±22.91	16.3±28.4	10.2±17.5
Duration of respiratory difficulty (days)	30.13±27.16	38.9±31.9	20.5±17.6
Physiological parameters on enrollment			
Pulse (BPM)	96.26 ± 16.00	98.8 ± 15.6	93.5 ± 16.7
SpO_2 (%)	86.52 ± 2.33	86.25 ± 1.96	86.82 ± 2.75
Systolic Blood Pressure (mmHg)	118.21 ± 19.17	121.8 ± 23.3	114.4 ± 13.5
Diastolic Blood Pressure (mmHg)	78.74 ± 10.90	78.4 ± 14.1	79.1 ± 6.52
Appearance			
Well Alert	16 (69.5%)	8 (66.6%)	8 (72.7%)
Lethargic	7 (30.5%)	4 (33.4%)	3 (27.3%)
Comorbidity (%)			
None	18 (78.3%)	9 (75%)	9 (81.8%)
Hypertension	2 (8.7%)	1 (8.3%)	1 (9.1%)
Diabetes Mellitus	3 (13%)	2 (16.7%)	1 (9.1%)

* Data are n (%) or mean ± std. BMI=body-mass index.

Supplementary Table 15. Summary of comparison of the physiological levels before and after administering intervention to hypoxemic patients (n=23) in the pilot study.

Physiological level	Before (mean±std)	After [a] (mean±std)	Difference mean (95% CI)	p value* (2-sided)	Significant (p<0.05)
Heart Rate (beats/min)	96.26 ± 16.00	92.48 ± 14.70	-3.78 (-7.29, 0.28)	0.036	Yes
SpO_2 (%)	86.5 ± 2.33	98.30 ± 1.020	11.8 (10.65, 12.91)	0.000	Yes
Systolic blood pressure (mm Hg)	118.21 ± 19.17	118.22 ± 20.30	0.00 (-3.57, 3.57)	1.000	No
Diastolic blood pressure (mm Hg)	78.74 ± 10.90	79.26 ± 11.46	0.52 (-1.66, 2.70)	0.624	No

* Using “Paired t-test”.

[a] After refers to – Measurements were recorded during the last minute of administering the intervention.

Supplementary Table 16. Summary of comparison of the physiological levels before and after administering OxyJet CPAP to hypoxemic patients (n=12) in the pilot study.

Physiological level	Before (mean±std)	After [a] (mean±std)	Difference mean (95% CI)	p value* (2-sided)	Significant (p<0.05)
Heart Rate (beats/min)	98.8 ± 15.6	94.58 ± 14.68	-4.17 (-9.06, 0.72)	0.088	No
SpO_2 (%)	86.25 ± 1.96	98.25 ± 0.754	12.0 (10.79, 13.21)	0.000	Yes
Systolic blood pressure (mm Hg)	121.8 ± 23.3	119.92 ± 25.91	-1.83 (-7.94, 4.28)	0.523	No
Diastolic blood pressure (mm Hg)	78.4 ± 14.1	79.75 ± 14.92	1.33 (-3.06, 5.73)	0.518	No

* Using “Paired t-test”.

[a] After refers to – Measurements were recorded during the last minute of administering the CPAP intervention.

Supplementary Table 17. Summary of comparison of the physiological levels before and after administering Standard CPAP (StarMed) to hypoxemic patients (n=11) in the pilot study.

Physiological level	Before (mean±std)	After [a] (mean±std)	Difference mean (95% CI)	p value* (2-sided)	Significant (p<0.05)
Heart Rate (beats/min)	93.5 ± 16.7	90.18 ± 15.08	-3.36 (-9.33, 2.60)	0.238	No
SpO_2 (%)	86.82 ± 2.75	98.36 ± 1.286	11.54 (9.33, 13.76)	0.000	Yes
Systolic blood pressure (mm Hg)	114.4 ± 13.5	116.36 ± 12.71	2.00 (-2.24, 6.24)	0.318	No
Diastolic blood pressure (mm Hg)	79.1 ± 6.52	78.73 ± 6.60	-0.364 (-1.174, 0.45)	0.341	No

* Using "Paired t-test".

[a] After refers to – Measurements were recorded during the last minute of administering the CPAP intervention.

Supplementary Table 18. Summary of comparison of the change in physiological levels of the hypoxemic patients treated with OxyJet CPAP and Standard CPAP (StarMed) in the pilot study.

Change in physiological level	OxyJet (n=12) (mean±std)	StarMed (n=11) (mean±std)	Difference mean (95% CI)	p value* (2-sided)	Significant (p<0.05)
Heart Rate (beats/min)	-4.17 ± 7.70	-3.36 ± 8.88	0.80 (-6.48, 8.09)	0.820	No
SpO_2 (%)	12.00 ± 1.91	11.55 ± 3.30	-0.45 (-2.88, 1.97)	0.695	No
Systolic blood pressure (mm Hg)	-1.83 ± 9.62	2.00 ± 6.31	3.83 (-3.21, 10.88)	0.269	No
Diastolic blood pressure (mm Hg)	1.33 ± 6.92	-0.36 ± 1.21	-1.70 (-6.17, 2.77)	0.421	No

Using “Two sample t-test”.

Supplementary Videos



Supplementary Video. OxyJet CPAP setup and operation

Demonstration of the step-by-step assembly of the OxyJet CPAP. First, OxyJet flow generator is attached to a standard flowmeter (primary). Next, the secondary O_2 inlet of the flow generator is connected to a second flowmeter with integrated bubble humidifier via an oxygen tube. Next, a viral / HEPA filter is attached to the air inlet port of the flow generator. A breathing circuit is attached to the outlet port of the flow generator. The other end of the breathing circuit is attached to the inhalation port of a CPAP mask. A mask adapter followed by a viral / HEPA filter is attached to the exhalation port of the CPAP mask. Finally, an adjustable PEEP valve (5-15 cmH_2O) with specified PEEP is attached after the filter at the exhalation port to complete the setup.

Demonstration of the OxyJet CPAP system on a healthy participant. OxyJet CPAP is turned on by setting the primary flowmeter's flow to 15-16 (L/min) approximately. The FiO_2 (%) of the generated high flow is adjusted by supplying an additional amount of oxygen flow (L/min) via a second flowmeter with humidifier following the device operation chart (Supplementary Fig. 3). CPAP therapy is being administered.

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