

SAFETY AND EFFICACY EVALUATION OF THE OXYJET CPAP DEVICE COMPARED TO HIGH-FLOW NASAL OXYGEN FOR TREATING HYPOXEMIC COVID-19 PATIENTS IN GENERAL HOSPITAL WARDS: A RANDOMIZED CONTROLLED TRIAL

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Background: During the COVID-19 pandemic, general wards generally were capable of providing up to 15L/min of oxygen. Shortage of Intensive Care Unit (ICU) beds, High-Flow Nasal Oxygen (HFNO), and other intermediary devices have caused many premature deaths during the pandemic. During this period, we have developed OxyJet CPAP, a locally-made 3D printed continuous positive airway pressure (CPAP) device that can provide up to 60 liters/min of oxygen without electric power. This study assessed whether the OxyJet CPAP could be a non-inferior alternative to an HFNO device in COVID-19 wards. **Methods:** We performed an open-label, parallel-assignment, randomized controlled trial in 45 patients admitted to the general COVID-19/suspected wards of Dhaka Medical College Hospital (DMCH), Bangladesh, between April 17, 2021, and July 9, 2021. Eligible patients were confirmed/suspected COVID-19 aged between 18–65 with oxygen saturation (SpO₂) between 85–90% while being treated with a non-rebreather mask at 15L/min of 100% oxygen. We used a computerized pseudorandom sequence generator for randomization. The sample size was calculated based on a non-inferiority margin of 1.5 days. Analysis was intention-to-treat. **Results:** The primary outcome of the trial was ventilator-free days (VFDs) within a 10-day period assessed after study completion. A total of 180 patients were screened, and 45 eligible patients were enrolled. We randomly assigned 23 (51.11%) patients to receive CPAP and 22 (48.89%) patients to receive HFNO. For the CPAP and HFNO arms, the mean value of the primary outcome was found to be 7.41 (STD 3.68) and 6.6 (STD 3.69) days, respectively. The mean difference in the primary outcome was 0.81 (95% CI -1.41–3.03), with the lower bound above the non-inferiority margin, thus, establishing the non-inferiority hypothesis ($p = 0.021$). Adverse events (AE) were recorded according to the Common Terminology Criteria for Adverse Events (CTCAE) scale (1–5). In the CPAP and HFNO arms, the mean CTCAE scale was found to be 1.39 (STD 0.499) and 1.59 (STD 0.503), respectively, showing no significant difference ($p = 0.189$). In Post Hoc analysis, we found that, on average, the OxyJet CPAP requires significantly less oxygen per patient compared to HFNO with a median difference of -16.11 L/min (95% CI -24.63–-6.67, $p=0.001$). **Conclusion:** The results show that the OxyJet CPAP treatment was non-inferior compared to the HFNO treatment. In the context of many hospitals in Bangladesh, especially in rural areas, using the locally made OxyJet CPAP could provide significant benefits due to its lower cost and usability. This device can be used as an effective bridging therapy reducing ICU admissions in the general ward settings or preserving life while awaiting resource availability. In addition, the device can also be used in emergencies and ambulances. The Directorate General of Drug Administration (DGDA) has provided limited approval of the device for hospital use. Currently, we are using the device in different hospitals for hypoxemic patients.

Keywords: Safety and efficacy OxyJet CPAP device, High-Flow Nasal Oxygen, hypoxemic COVID-19 patients,

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