Clinical Evaluation of the Innovative OxyJet CPAP Compared to a Standard CPAP for Treating Hypoxemic Patients in General Wards: A Randomized Control Trial

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Phase 3-Extended Trial

- The phase-3 extended randomized controlled trial aims to **compare the OxyJet CPAP with a standard CE-certified CPAP** device in the general ward setting.
- Aimed to recruit **non-COVID hypoxemic patients** in the general wards.
- The study was conducted at the **respiratory units of NIDCH, Dhaka.**

We had Bruises…
Not Only in our Nose/Face,
But also deep in our Heart!

Image Source: Reuters

In order to rise from its own ashes, a phoenix first must burn

OCTAVIA BUTLER

KITESANDROSES.COM

We Succeeded to Manage the Severity of Situation And Hold Back the Death Race…

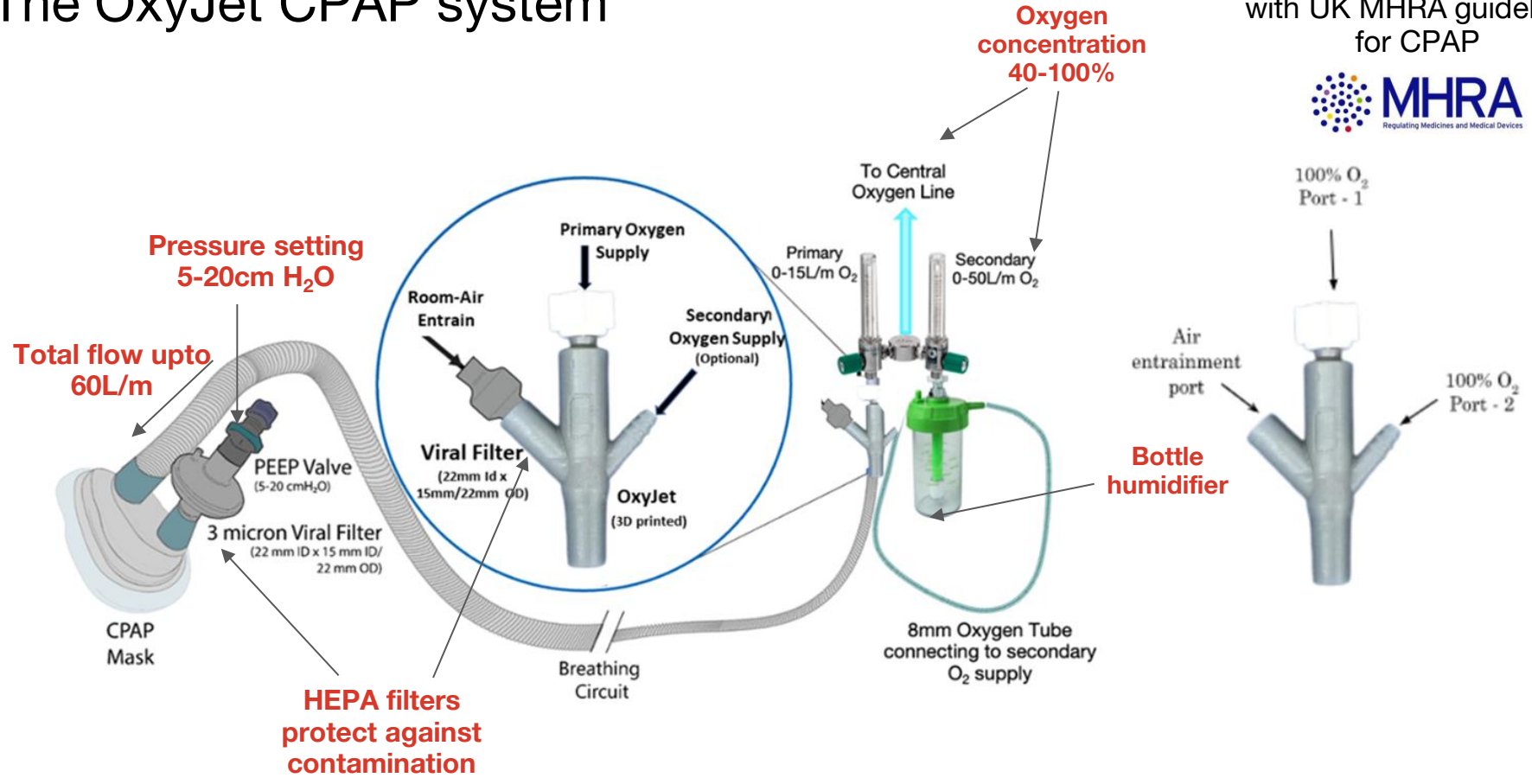
Our Solution: The OxyJet CPAP

Main Features and Benefits

- **Non-Invasive ventilator (5-20cm PEEP)**
- **Upto 60L/min flow**
- **No electricity required**
- **%FiO2 controllable (40-100%)**
- **Low-cost**
- **Connects to existing flow-meters**
- **Simple operation**

The OxyJet CPAP system

Overall system complies with UK MHRA guidelines for CPAP



Phase 1: Healthy Volunteer Trial (BUET)

Phase 1: Findings

- **Study design:**
  - Total 5 healthy subjects were recruited (n = 5).
  - They were administered CPAP on the mask and hood for about 15 minutes each.
  - Pressure and flow values inside the mask were measured.
  - Patient vitals (Pulse, RR, %SpO2, BP, HR, etc.) measured before and after the trial.

- **Main findings:**
  - OxyJet performs **similar to a traditional CPAP** and provides positive end expiratory pressure (**PEEP**).
  - Adequate flow was generated and provided to the subject.
  - There were **no significant changes in the vitals** of the subjects before and after trial.

Phase 2: Clinical Feasibility Study (DMCH)

Phase 2: Findings (DMCH)

- **Study design:**
  - A total of 5 hypoxemic non-Covid patients were recruited (%SpO2 85 - 93).
  - CPAP was administered for 1 hour using CPAP mask and hood for 30 minutes each.
  - Physiological parameters before and after the trial, and pressure values were measured.

- **Main findings:**
  - OxyJet significantly **increases the oxygen saturation by 11.2%** within 30 minutes.
  - **Other physiological parameters** except oxygen saturation are **relatively unchanged**.
  - The device is able to sustain the required positive pressure during inhalation and exhalation
  - The patients are not in serious discomfort during or after the trial
  - The device is sufficiently user friendly in a clinical setting

Phase 3: Randomized Controlled Trial - CPAP vs HFNO

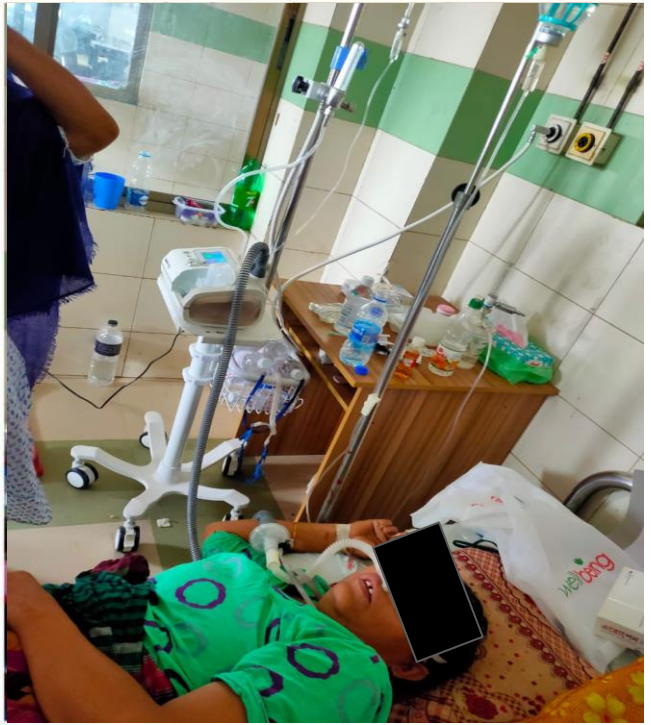


Photo: Patients undergoing treatment using Oxyjet CPAP (left) and HFNO (right) at DMCH Covid-19 and suspected wards

Phase 3: Findings (DMCH)

- **Study design:**
  - A total of 45 hypoxemic COVID confirmed/suspected patients were enrolled.
  - Age: 18 - 65 years. Oxygen saturation between 85 - 90% on 15L/min of 100% oxygen.
  - Primary outcome was the number of ventilator-free days up to 10 days (efficacy).

- **Main findings:**
  - The phase-3 randomized controlled trial findings show that the OxyJet CPAP treatment is **non-inferior compared to HFNO treatment**.
  - The clinical trial data also shows that OxyJet CPAP uses about **30% less oxygen** compared to HFNO treatment.

Phase 3-Extended Study (NIDCH)

- **Rationale:**
  - The OxyJet CPAP device was not thoroughly evaluated on non-COVID hypoxemic patients during the pandemic.
  - The performance of the device compared to a standard CPAP in the general ward setting was not previously studied

Phase 3-Extended: Study Design

- **Primary outcome/endpoint**
  - Difference in oxygen saturation (%SpO2) before and after the trial.

- **Secondary outcomes/endpoint**
  - Difference in blood pressure before and after the trial.
  - Difference in paCO2 before and after the trial.
  - Difference in heart rate before and after the trial.
  - Difference in respiratory rate before and after the trial.
  - Grade of adverse events according to CTCAE scale (if any).

Phase 3-Extended: Study Design

- **Inclusion/exclusion criteria**
  - Age ≥ 18 years
  - Adult hypoxemic patients (SpO2 ≤93% in room air) treated with low-flow oxygen
  - Patient is hemodynamically stable

- **Sample size calculation:**
  - Significance level of 5% (α = 0.05)
  - 90% confidence interval (1 − β = 0.90)
  - Equivalence margin 5%

$$N \geq \frac{2\,\sigma^2 (Z_{1-\beta} + Z_{1-\alpha})^2}{d^2}$$

N = 10 for each arm

Total sample size = 20

N	=	Required sample size for the non-inferiority trial
σ^2	=	Estimated variance of the primary outcome
α	=	Significance level
$1-\beta$	=	Confidence interval (power)
$Z_{1-\alpha}$	=	The Z-score for the confidence level α
$Z_{1-\beta/2}$	=	The Z-score for the confidence interval $\beta/2$
d	=	Equivalence margin

Study Procedure

- **Enrollment and Randomization**
  - We recruited subjects based on the inclusion/exclusion criteria.
  - Patients were allocated to the two arms of the study based on a predefined randomization sequence.
  - The randomization was done by a separate researcher who was not involved in enrollment of patients for this trial.

- **Treatment Procedure and Data collection**
  - Patient data were collected during enrollment as per protocol
  - The allocated treatment using OxyJet CPAP, or standard CPAP was administered for 30 minutes as per the protocol.
  - The patients were returned to the standard treatment after trial.

Baseline Characteristics

Description		Total (n = 20)	OxyJet CPAP (n = 10)	Standard CPAP (n = 10)
Gender	Male (%)	10 (50%)	4 (40%)	6 (60%)
	Female (%)	10 (50%)	6 (60%)	4 (40%)
Age (mean±std)		48.75±9.95	49.3±11.6	48.2±8.6
Weight (Kg) (mean±std)		49.85±12.11	51.1±15.7	48.6±7.81
Height (cm) (mean±std)		159.39±4.35	160.27±4.71	158.50±4.01
BMI (mean±std)		19.6±4.56	19.83±5.80	19.37±3.81
Duration of cough (days) (mean±std)		33.5±27.41	42.6±33.5	24.4±16.6
Duration of fever (days) (mean±std)		14.89±24.33	19.5±31.2	11.2±18.1
Dur. of resp. difficulty (days) (mean±std)		33.80±27.29	45.7±30.6	21.9±18.0

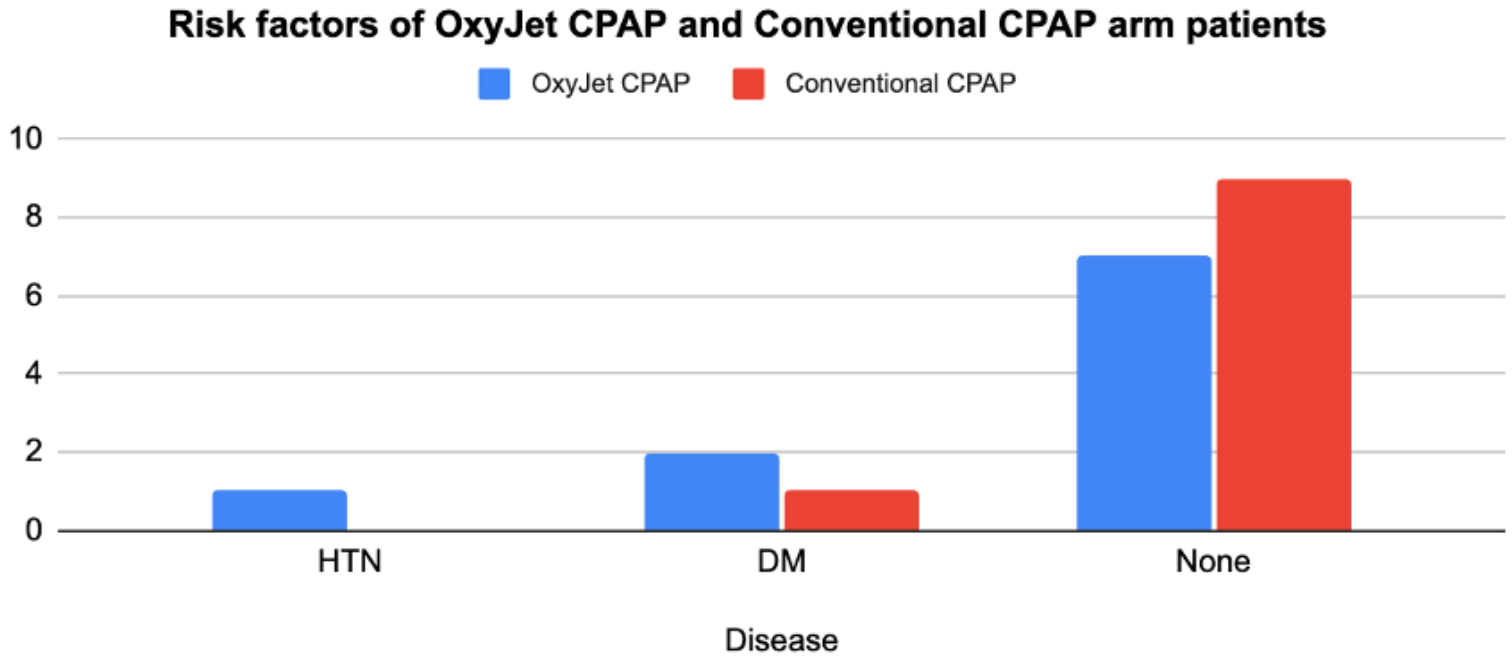
Baseline Characteristics (cont.)

Description		Total (n = 20)	OxyJet CPAP (n = 10)	Standard CPAP (n = 10)
Physiological parameters (during enrollment)	Pulse (BPM) (mean±std)	95.20 ± 16.82	98.2 ± 17.03	92.20 ± 16.95
	Resp. rate (breaths/min)	17.55±3.33	17.80±3.29	17.30±3.53
	SpO2 (%)	86.55 ± 2.46	86.2 ± 2.044	86.90 ± 2.885
	Blood Pressure (Systolic)	119.90 ± 18.92	124.10 ± 23.15	115.70 ± 13.42
	Blood Pressure (Diastolic)	80.05 ± 10.63	80.10 ± 14.20	80.0 ± 6.09
Appearance	Well Alert	14 (70%)	7 (70%)	7 (70%)
	Lethargic	6 (30%)	3 (30%)	3 (30%)
	Irritable	0 (0%)	0 (0%)	0 (0%)
	Confused	0 (0%)	0 (0%)	0 (0%)
	Unconscious	0 (0%)	0 (0%)	0 (0%)

Statistical analysis of patient parameters

Patient Parameters	OxyJet (n=10)	Standard CPAP (n=10)	Difference (95% CI)	P-value (2-sided t-test)	Significant (p < 0.05)
Age (mean±std)	49.3±11.6	48.2±8.6	1.1 (-8.5, 10.7)	0.8120	No
Gender Proportion (male) (mean±std)	0.4	0.6	-0.2 (-0.63, 0.23)	0.6560	No
Gender Proportion (female) (mean±std)	0.6	0.4	-0.2 (-0.63, 0.23)	0.6560	No
Weight (Kg) (mean±std)	51.1±15.7	48.6±7.81	2.50 (-9.12, 14.12)	0.657	No
Height (cm) (mean±std)	160.27±4.71	158.50±4.01	1.78 (-2.33, 5.88)	0.375	No
BMI (mean±std)	19.83±5.80	19.37±3.18	0.47 (-3.93, 4.86)	0.826	No

Patient Risk Factors



- **Patients in two groups are similar in demographics, baseline conditions and risk factors**

Clinical examination before and after trial (All 20 patients)

Physiological parameter		Before Enrollment	After 30 mins of Enrollment	Difference	P-value (2-sided t-test)	Significant ($p < 0.05$)
Pulse (BPM)		95.20 ± 16.82	91.75 ± 15.55	3.45 (-0.60, 7.50)	0.0910	No
SpO_2		86.55 ± 2.46	98.30 ± 1.031	-11.75 (-13.00, -10.5)	0.0000	Yes
Blood Pressure (Systolic)		119.90 ± 18.92	119.90 ± 20.24	0.00 (-4.16, 4.16)	1.0000	No
Blood Pressure (Diastolic)		80.05 ± 10.63	80.65 ± 11.23	-0.60 (-3.13, 1.93)	0.6260	No
AbGT	PCO_2 (mm Hg)	43.81 ± 14.52	43.56 ± 15.08	0.25 (-2.35, 2.86)	0.84	No
	PO_2 (mm Hg)	55.85 ± 12.70	54.10 ± 19.64	1.75 (-5.11, 8.61)	0.599	No

Clinical examination before and after trial (OxyJet CPAP)

Physiological parameter		Before Enrollment	After 30 mins of Enrollment	Difference	P-value (2-sided t-test)	Significant ($p < 0.05$)
Pulse (BPM)		98.2 ± 17.03	94.30 ± 15.97	3.90 (-2.16, 9.96)	0.1800	No
SpO_2		86.2 ± 2.044	98.3 ± 0.213	-12.1 (-13.34,-10.86)	0.0000	Yes
Blood Pressure (Systolic)		124.10 ± 23.15	121.90 ± 26.56	2.20 (-5.38, 9.78)	0.5280	No
Blood Pressure (Diastolic)		80.10 ± 14.20	81.70 ± 14.98	-1.60 (-7.05, 3.85)	0.5230	No
AbGT	PCO_2 (mm Hg)	40.19 ± 11.72	38.44 ± 13.79	1.75 (-2.24, 5.74)	0.347	No
	PO_2 (mm Hg)	53.70 ± 9.66	53.30 ± 15.84	0.40 (-11.97, 12.77)	0.943	No

Clinical examination before and after trial (Standard CPAP)

Physiological parameter		Before Enrollment	After 30 mins of Enrollment	Difference	P-value (2-sided t-test)	Significant ($p < 0.05$)
Pulse (BPM)		92.20 ± 16.95	89.20 ± 15.52	3.00 (-3.63, 9.63)	0.3330	No
SpO_2		86.90 ± 2.885	98.30 ± 1.337	-11.40 (-13.86, -8.94)	0.0000	Yes
Blood Pressure (Systolic)		115.70 ± 13.42	117.90 ± 12.27	-2.20 (-6.93, 2.53)	0.3200	No
Blood Pressure (Diastolic)		80.0 ± 6.09	79.60 ± 6.26	0.400 (-0.505, 1.305)	0.3430	No
AbGT	PCO_2 (mm Hg)	47.44 ± 16.68	48.70 ± 15.2	-1.24 (-5.12, 2.64)	0.488	No
	PO_2 (mm Hg)	58.00 ± 15.40	54.90 ± 23.71	3.10 (-5.66, 11.86)	0.444	No

Analysis of the Primary Outcome

- We perform analysis of primary outcome for equivalence test comparing OxyJet CPAP and standard CPAP using an equivalence limit of (-5,+5)
- The difference in the primary outcome between the two groups was 0.7 (95% CI: -1.41, 2.81) which is within the equivalence limit with a p-value of 0.001
- The OxyJet CPAP device can be claimed to be equivalent to the standard CPAP device.

Primary outcome	OxyJet CPAP (n=10)	Standard CPAP (n=10)	Difference (95% CI)	p-value (for equivalence test)	Significant ($p < 0.05$)
Difference in SpO2 (%)	12.1 ± 1.73	11.4 ± 3.44	0.7 (-1.41, 2.81)	0.001	Yes

Analysis of the Secondary Outcomes

- Secondary analysis shows that BP systolic and pCO2 had slightly reduced after using OxyJet CPAP compared to standard CPAP.

Secondary outcomes	OxyJet CPAP (n=10)	Standard CPAP (n=10)	Difference (95% CI)	p-value	Significant (p < 0.05)
Difference in Pulse (BPM)	3.90 (-2.16, 9.96)	3.00 (-3.63, 9.63)	0.9 (-1.94, 3.74)	0.542	No
Difference in BP (Systolic)	2.20 (-5.38, 9.78)	-2.20 (-6.93, 2.53)	4.4 (1.57, 7.23)	0.008	Yes
Difference in BP (Diastolic)	-1.60 (-7.05, 3.85)	0.40 (-0.505, 1.305)	-2 (-3.75, -0.25)	0.051	No
Difference in pCO2 (mmHg)	1.75 (-2.24, 5.74)	-1.24 (-5.12, 2.64)	2.99 (1.23, 4.75)	0.004	Yes
Difference in pO2 (mmHg)	0.40 (-11.97, 12.77)	3.10 (-5.66, 11.86)	-2.7 (-7.49, 2.09)	0.286	No

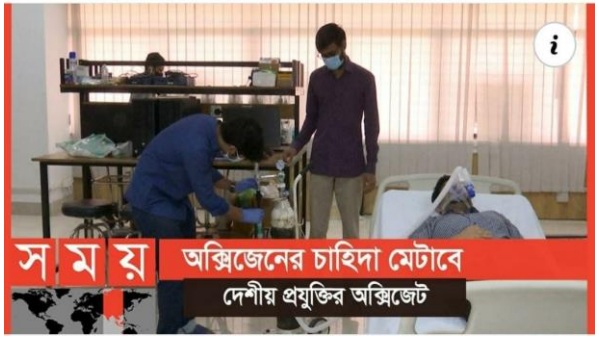
Summary of Findings

- Treatment using the developed **OxyJet CPAP device is equivalent compared to the standard CPAP** device based on the primary outcome of the study. The primary outcome was defined as the difference in %SpO2 before and after the trial.
- Trial outcomes also showed that patients of both arms showed steadily declining but stayed at normal levels of BP and pulse as expected. Overall, both CPAP devices helped improve the patient's condition.
- There was no statistically significant difference with respect to the physiological parameters, BP, pulse, pCO2, and pO2, before and after the trial for both groups of patients.
- There were no adverse events observed during the study period.

Conclusions

- The OxyJet project demonstrates how local medical innovation can effective in solving the unique problems in low-resource settings.
- The study shows that this innovative device can be used for respiratory disease patients even beyond the Covid-19 pandemic
- The OxyJet CPAP device can be a valuable low-cost device in the general wards to strengthen the hospital systems of Bangladesh

Media Coverage



Speedboats unregulated for decades

SAJAD HOSSAIN and SUZIT KUMAR DAS

Right under the authorities' noses, unskilled drivers have been operating unregistered speedboats on the Padma's Shimulia-Bangla Bazar route for over a decade.

The issue has come into the limelight after one such motorboat crashed into a sand-laden bulk carrier near Bangla Bazar Ferry Ghat in Madaripur's Shibchar upazila on Monday morning, leaving 26 passengers, including women and children, dead.

Sources in the Shimulia Ferry Terminal

SEE PAGE 10 COL 3

A breath of fresh air in Covid crisis

Buet researchers develop low-cost portable device to provide Oxygen to critical coronavirus patients

MOHAMMAD AL-MASUM MOLLA

As the demand for oxygen increased at hospitals amid this second wave of the pandemic, a group of Buet researchers has developed a low-cost portable ventilator that can deliver oxygen to patients efficiently without electricity.

The non-invasive device, which requires a connection with an cylinder or medical oxygen supply, is designed to help severe coronavirus patients with low oxygen levels, according to the researchers.

Named OxyJet CPAP by the researchers from Buet's Department of Biomedical Engineering, it has already been field-tested and approved for clinical trials.

This device can be used in remote villages or ambulances -- wherever it is possible to carry cylinders -- as an alternative to the high-flow nasal oxygen (HFNO) support.

"We've developed a non-invasive CPAP ventilator that runs without electricity. The main goal of the device is to provide oxygen treatment to patients of general wards and prevent ICU admission," Dr

SEE PAGE 2 COL 3

dailyobserver Wednesday, May 12, 2021, Baishakh 29, 1428 BS, Ramadan 29, 1442 Hijri

BUET launches clinical trials of 'OxyJet'

This non-electric and low-cost ventilator to meet oxygen need of corona patients

Tausiful Islam,
DU Correspondent

Bangladesh University of Engineering and Technology on Tuesday started clinical trial of 'OxyJet', a low-cost C-PAP ventilator device to meet the oxygen needs and high-speed ventilation of corona affected people.

This device can be used without any kind of electrical power by connecting it to an oxygen cylinder or a medical oxygen line.

Patients with Covid-19 disease are first given low doses of oxygen (low-flow oxygen therapy, 0-15 L/min). But if this small dose does not improve the patient's condition, high-flow oxygen is required which can prevent the patient from deteriorating.

At a time when the corona outbreak is at its peak, hospitals in our country

SEE PAGE 2 COL 1

A patient being administered oxygen using the gadget made by a team of BUET students. [Inset] The team leader holds the oxygen cylinder specially designed to aid patients with severe breathing problem. PHOTO: OBSERVER

Awards and Recognition

Featured in United Nations Report by UNCDF

IEEE Idea Contest Winner (2020)

Bangabandhu Innovation Grant 2021 (Top 26)

Winner - Biomedical Engineering Society (BMES) Design Competition 2021

Imagine IF Global Winner (2021)

EO GSEA 1st Prize 2022-23 (Bangladesh Chapter)

Current Activities

- Devices distributed in 15+ reputed hospitals within and outside Dhaka.
- Device successfully tested in ambulances.

OxyJet Clinical Trial Team

Dr. Taufiq Hasan,
Associate Professor, BME, BUET.
Team Lead & Principal Investigator

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Director, National Institute of Diseases of The Chest & Hospital (NIDCH) and National Asthma Centre.

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Popular Medical College
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Kaisar Ahmed Alman
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Thank
you!