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Original Article

Assessment of the Efficacy of an Automated AMBU Bag Operating Device (RC Device) in Patients Requiring Mechanical Ventilation: A Pilot Study

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Abstract

Background Providing efficient mechanical ventilation using artificial manual breathing unit is a tiring and laborious task for healthcare providers. The current pilot study was planned to assess the efficacy of an automated artificial mechanical breathing unit (respiration control [RC] device) in patients requiring mechanical ventilation in a tertiary care hospital in North India. RC device is an automated bag valve mask ventilator developed in collaboration with Gyrodrive Machineries (P) Ltd. India and Postgraduate Institute of Medical Education and Research, Chandigarh.

Methods Ten adult patients from the emergency and trauma section requiring mechanical ventilation who were unable to obtain ventilators in the intensive care unit were enrolled in the study. The vital parameters of the patients and the respiratory parameters from arterial blood gas were recorded at given time periods.

Results All 10 patients recruited in the study were ventilated using the RC device for at least 24 hours. The mean age of the patients was 32.3 ± 4.3 years. The mean Glasgow coma scale was 7.2 ± 2.0 (range: 3–10). The heart rate, systolic blood pressure, and diastolic blood pressure remained within normal limits. There were no episodes of desaturation in any of the patients. The patients' care provider rated their satisfaction with the device as excellent in two patients and good in eight patients.

Conclusion RC device has shown a promising result in providing satisfactory care among trauma patients and may be used in providing routine mechanical ventilation among these patients.

Keywords
- RC device
- AMBU
- mechanical ventilation
- efficacy
- ventilators

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Introduction

Obtaining the goal of high-quality healthcare within a resource-constrained environment is desirable in developing countries, but it is fraught with many challenges. Critical care is still in its nascent stages in many developing countries, where healthcare technology is limited and high cost is a major constraint to the availability of ventilators in hospitals.[1] There is a lack of reliable epidemiological data, and there is a significant disparity in the quality of care across developing countries.[2] In such countries, obtaining a ventilator upon arrival of a patient in an emergency or trauma center is a true struggle. As a result, many potentially savable patients are unable to obtain the best possible care and capitulate to their illness.[3] If the mechanical ventilators are provided thoughtfully, the high burden of the patients and mortality because of respiratory failure can be reduced. The use of artificial manual breathing unit (AMBU) ventilation by patient attendants for ventilating sick patients remains a common sight in many hospitals in developing countries due to the unavailability of mechanical ventilators.[4,5] These manual mechanical resuscitators are in use since the late 1950s and act as good means of short-term ventilation in both out-of-hospital and in-hospital environments.[6] It is a self-inflating handheld device that must be compressed manually to deliver air or oxygen to the patient's lungs. Although AMBU ventilation can act as life-saving in acute settings, providing continuous ventilation through AMBU has certain inherent drawbacks; maintenance of required respiratory rate (R.R.), volume, and regularity of manual breaths, and the ratio of oxygen/air cannot be ensured. It is very laborious and grueling for operators. It also exposes both patients' attendants and hospital staff to infections. Hence, developing a low-cost, simple-to-use mechanical device that operates AMBU mechanically and eliminates the need for manual labor is a pressing need.

The proposed respiration control device (RC device) is an attempt to provide survival chances to patients requiring ventilation in the face of the paucity of ventilators (►**Fig. 1**). This low-cost mechanical device intended to operate AMBU can provide efficient positive pressure ventilation to patients who are not able to obtain ventilators upon admission at emergency or trauma centers, hence reducing the anguish of the patients and their attendants.

RC device is an automated bag valve mask ventilator developed in collaboration with Gyrodrive Machineries (P) Ltd. India and Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh. It is powered by a 12v-4 ampere D.C. Supply switched mode power supply and a lithium polymer (Lipo) battery backup provision for power failure. In the RC device actuation of the bag valve mask (BVM) is achieved symmetrically by two linear actuators working in tandem. The RC device has been designed to work in the assist control mode. A device patent for RC device was filed and has been published.[7] This pilot study was planned to assess the efficacy of RC device in patients requiring mechanical ventilation.

Materials and Methods

After institutional ethical committee approval (NK/6127/Study/079) and obtaining Clinical Trials Registration- India registration (CTRI/2020/09/027819), this observational pilot study was carried out at the emergency/ trauma bay, PGIMER, Chandigarh. Ten adult patients aged between 18 and 65 years requiring mechanical ventilation who were unable to obtain ventilators in the intensive care unit (ICU) setup and requiring manual ventilation were recruited in the study. Written informed consent was taken from all the patients' attendants before enrolling them in the study. Patients having severe emphysema/pre-existing lung pathology, adult respiratory distress syndrome, history of liver failure/chronic kidney disease, and pregnant patients were excluded from the study. After recruiting patients in the study, their age, gender, Glasgow coma scale (GCS), and chest X-ray findings were noted. A baseline arterial blood gas (ABG) was done in all patients. The automated AMBU device was attached to the patient after obtaining baseline ABG.

The patients were started on sedation with a bolus of morphine 0.05 mg/kg and 0.04 mg/kg of midazolam followed

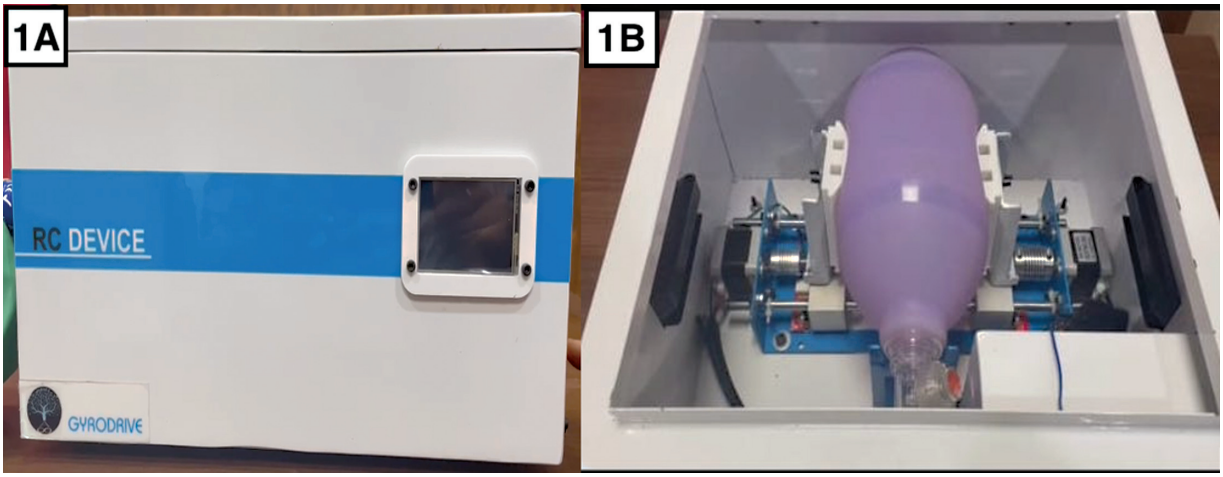

Fig. 1 (A) The respiration control (RC) device. (B) The interior and mechanism of functioning of the RC device.

by infusion of a 1:1 ratio of morphine and midazolam at a rate of 1 to 2 mL/hour targeting Richmond Agitation Sedation Score of mild-to-moderate sedation (−2 to −3) before putting on to automated AMBU bag device. Oxygen supplementation at fraction of inspired oxygen of 0.40 to 0.60 was given via oxygen connected to AMBU in the machine at a flow rate of 8 to 10 L per minute to each patient. The ventilatory parameters (tidal volume [TV], RR, inspiratory:expiratory [I:E] ratio) were set in accordance with baseline ABG and thereafter following serial ABGs and were recorded for the first 24 hours. After 20 minutes of initiation of ventilation by RC device, another ABG was taken. The arterial saturation levels of the patients were measured using a pulse oximeter. Serial ABGs were done at 2 hours and then every 4 hours thereafter, till the first 24 hours. The respiratory parameters from ABG including the potential of hydrogen, partial pressure of oxygen, partial pressure of carbon dioxide, arterial oxygen saturation, bicarbonate levels, and base deficit/excess were recorded. The vital parameters of the patients were continuously measured and were recorded at the baseline, 20 minutes, 2 hours, 4 hours, 8 hours, 16 hours, 20 hours, and 24 hours.

The patients were ventilated using the RC device till they received definitive ventilators in ICU or the patient was weaned from the ventilator. Throughout the period of mechanical ventilation, patients were monitored and the above-mentioned parameters were entered by one of the investigators. The complications such as disconnection, desaturation, and device failure alarm were noted. The satisfaction rating was done by the patients' care provider and recorded as excellent/good/poor.

Statistical Analysis

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, Illinois, United States, version 25.0 for Windows). The continuous data were checked for normal distribution using Shapiro–Wilk test. The continuous data was presented as mean, standard deviation, median, and interquartile range. The categorical data was presented as frequencies and percentages. Repeated measured analysis of variance was used to compare the hemodynamic parameters measured over a period of time.

Table 1 Demographic characteristics of the patients

Sl. no.	Characteristics	*n*
1.	Total patients	10
2.	Age (y)	32.3 ± 4.3
3.	Gender (male/female)	7/3
4.	Mechanism of injury (fall from height/road traffic accident)	3/7
5.	Glasgow coma scale	7.2 ± 2.0

Results

All 10 patients enrolled in the study were on mechanical ventilation with an RC device for at least 24 hours. There were seven males and three females in the study group and the mean age of the patients was 32.3 ± 4.3 years. All the patients were cases of traumatic brain injury; three patients had a history of falls, while seven patients were road traffic accident patients. The GCS of patients varied from 3 to 10 and the mean GCS was 7.2 ± 2.0 (►**Table 1**).

The chest X-rays of all the patients were grossly normal. The initial ventilatory settings were as follows: seven patients were started with a TV of 450 mL and three patients were put on a TV of 400 mL; the RR was kept at 12 in all patients and I:E ratio was kept 1:2 in all patients. Throughout mechanical ventilation, the heart rate, systolic blood pressure, and diastolic blood pressure remained within normal limits in all 10 patients. The heart rate, systolic and diastolic blood pressures of the patient were measured at different time points (►**Fig. 2A–C**) There were no episodes of desaturation below 90% in any of the patients. The serial ABGs were obtained periodically as described in ►**Table 2**. The satisfaction rating as given by the patients' care provider was excellent in two patients and good in eight patients.

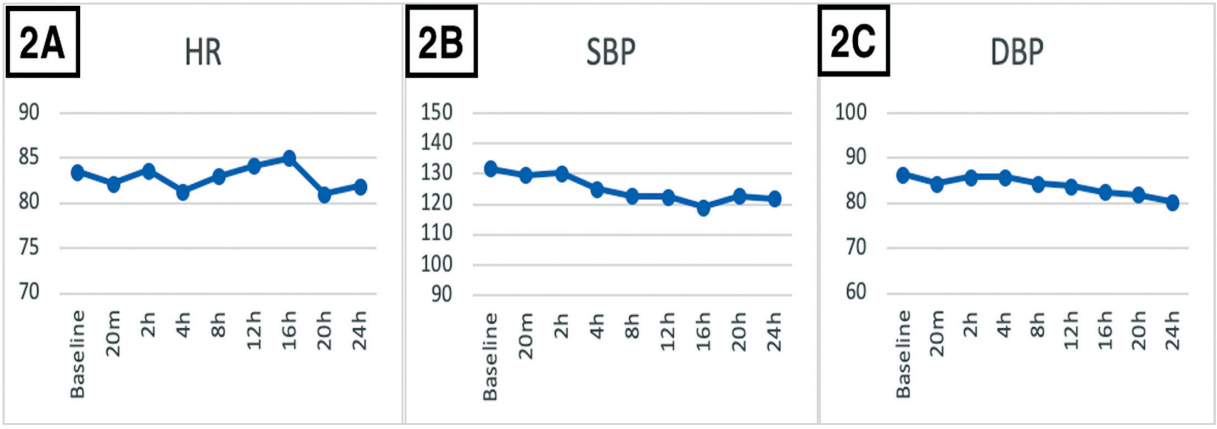

Fig. 2 (**A**) The heart rate (HR), (**B**) the systolic blood pressure (SBP), and (**C**) the systolic blood pressure (SBP) of the patients at various time points.

Table 2 The arterial blood gas parameters (pH, PaO_2, $PaCO_2$, HCO_3) of the study participants

Parameters	Pt-1	Pt-2	Pt-3	Pt-4	Pt-5	Pt-6	Pt-7	Pt-8	Pt-9	Pt- 10
pH	7.32–7.44	7.27–7.44	7.26–7.34	7.40–7.51	7.36–7.44	7.34–7.42	7.35–7.49	7.29–7.43	7.35–7.44	7.40–7.47
PaO_2	136–187	178–201	202–267	210–250	223–256	183–224	192–210	190–221	182–219	191–232
$PaCO_2$	32–44	31–44	38–42	40–44	42–47	28–33	31–39	34–47	26–30	31–34
HCO_3	21–22	19–23	17–21	27–29	24–27	23–25	23–26	19–22	22–25	21–23

Abbreviations: $PaCO_2$, partial pressure of carbon dioxide; PaO_2, partial pressure of oxygen; pH, potential of hydrogen; Pt, patient; HCO_3, bicarbonate levels.

Discussion

Providing quality medical care for all patients remains an arduous task, especially in resource-constrained settings. Postsurgical management, trauma, infectious diseases, peripartum stage, and maternal and neonatal complications are among the common medical ailments requiring mechanical ventilation.[8] Most of these illnesses are recoverable and may only require brief periods of mechanical ventilation. AMBU ventilation has been demonstrated to be highly helpful in circumstances requiring short-term respiratory support.[9] However, AMBU ventilation has its shortcomings. It does not ensure consistent air/oxygen delivery to the patient because of the operator's fatigue and lack of knowledge. There are numerous cases of hyperventilation and volutrauma, both of which are harmful to the patients.

We conducted this study to evaluate the ability of RC devices to deliver adequate mechanical ventilation to patients of the age group 18 to 65 years requiring mechanical ventilation in emergency or trauma areas. The RC device was found to be effective in providing adequate mechanical ventilation to all patients with no known respiratory disease who were unable to be admitted to the ICU due to a scarcity of beds and ventilators.

In the RC device, two linear actuators work in tandem to compress the BVM to generate the desired TV at the set respiratory settings. These linear actuators are made up of a lead screw-lead nut mechanism that is powered by National Electrical Manufacturers Association (NEMA) 17 stepper motors, which enable very precise motions. The motion of the actuators is supervised by a microprocessor that can regulate the speed of linear motion from 0 to 36 mm/s (depending on the set RR) and stroke length from 0 to 80 mm (depending on the set TV). The RC device was designed to work in the assist control mode where the clinician sets a predefined TV and RR to achieve the desired minute ventilation. The controller reads the RR and TV settings and calculates the parameters for the required motor rotation. For squeezing the BVM, the rotary motion of the electric motor has to be converted to linear motion. The linear motion of these two actuators is transmitted to the AMBU bag via the pressure plates connected to the lead nut body hence achieving the set TV and RR. The buzzer alarm is for disconnection, abnormal airway pressures, and power failure. Volume and pressure microsensors are placed at the patient end to ensure the safety of the device.

All the patients enrolled in our study were ventilated by the RC device for a minimum of 24 hours. The patients maintained normal vital parameters and ABG parameters during this period. Further, there was no episode of accidental disconnection, extubation, or device failure in any of the patients. The care providers were also fairly satisfied with the working of the RC device.

A major shortcoming of this study is the small number of recruited patients. Also, none of our patients suffered from any respiratory pathology or sepsis. Hence, the results cannot be extrapolated to the patients with respiratory or severe systemic involvement. However, we are presenting this as a pilot study, and further studies are needed to further

understand the potential as well as limitations of RC device. Nonetheless, RC device can prove to be a boon for overloaded hospitals in resource-constrained settings.

Conflict of Interest

None declared.

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