A pilot study to evaluate the safety and efficacy of automated mechanical Respiratory Aid device "RespirAID R20" in post operative care patients

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Abstract

Background: High burden of morbidity and mortality due to respiratory illnesses was witnessed during the COVID-19 pandemic. We developed a portable automated mechanical respiratory assist device (RespirAID R20) that delivers Intermittent Positive Pressure Ventilation by mechanically compressing a Bag Valve Mask. The objective of the study is to evaluate the safety and efficacy of the RespirAID R20, a mechanical ventilation device in post-operative care patients.
Method: This pilot study enrolled five subjects at Yenepoya Medical College Hospital, India. Post-operative subjects were transferred from the Mindray Synovent E3 (standard ventilator) to the RespirAID R20 for 3 hours. Ventilator and physiologic parameters were recorded and compared.
Result: All patients maintained normal blood pressure, heart rate, and heart rhythm. The delivered mean tidal volume (V_T) and peak inspiratory pressure (PIP) was 419.64 +/- 11 ml and 20 +/- 2 cmH_2O, which remained within the initial set range of 428 +/- 12 ml and 24 +/- 2 cmH_2O throughout the study duration. Arterial blood gas (ABG) parameters during RespirAID R20, except PaO_2, were within the normal range. PaO_2 levels were greater than 300 mm Hg during the first four hours (323 +/- 163 mmHg and 344 +/- 97 mmHg).
Conclusion: The findings of this study suggests that RespirAID R20 may be an alternative device in providing respiratory assistance to sedated and intubated adult patients in the postoperative period. Additional studies are required to evaluate other possible applications of the RespirAID R20.

Keywords: RespirAID R20, ABG parameters, mechanical ventilation, respiratory assist

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Introduction

Respiratory illnesses are one of the most common causes of death around the world. [1,2] It is the highest contributor to the disease burden in the world equaling 1 in 10 disability-adjusted life years (DALY) losses. [2] Respiratory illnesses are responsible for 20-40% of hospital admissions. A majority of the population in developing and underdeveloped countries still live in rural areas where they lack access to mechanical ventilators. [3] A severe shortage of ventilators exists in government hospitals which lead to about 2,625 deaths per day in India. [4] Shortage situations often require patients to be shuttled between hospitals, during which many people die due to their critical conditions. [4]

Existing manual resuscitation bags (MRBs) MRB are commonly being used for shorter duration of ventilation, but it prevents clinical interventions and holds patients to the risks of volutrauma, barotrauma, and hyperventilation. [5,6] In contrast, finding enough mechanical ventilators in rural settings is also challenging because of the logistics, training, and environmental conditions. [7] The mechanical ventilator, a life-support system which can be adjusted according to the lungs of the patients, receiving general anesthesia [8] may also cause lung damage. [9] Similar technologies developed in recent past and present consist of electronic devices and analog systems, but there are certain drawbacks such as excessive cost, maintenance, and resource demands. [5,10]

For the patients requiring emergency ventilation where a transport ventilator is not available, MRBs is used to provide ventilation, even for patients transported in aeromedical units. But the standard adult MRB delivers high-volume, low-Positive End Expiratory Pressure (PEEP) ventilation contrary to current recommendations for lung-protective ventilation. [11] Hyperventilation can be caused using MRB [12] and even experienced clinicians have delivered higher peak pressure with MRB in simulated resuscitation scenarios. [13] This can be prevented by the application of monitoring tools that can display ventilation performance and values for the clinician in charge. [14] Along with that, adjustable PEEP valves are recommended. [15,16] To control such scenarios, a portable ventilator with a simple set up with disposable circuits can be used. [17] Oxygen should be available for bias flow through the circuit and to control the ventilation cycle. [18,19]

RespirAID R20 is a portable automated mechanical respiratory assist device that delivers Intermittent Positive Pressure Ventilation (IPPV) by mechanically compressing a MRB at clinician-set parameters.

RespirAID R20 (Figure 1) is built with software to compress the MRB and deliver tidal volumes (V_T). The purpose of the device is to be a safe, reliable, and affordable ventilator for critical patients in smaller hospitals with low resources and skills. The frequency of ventilation can be set by a trained medical professional and oxygen supplementation can also be provided. The mechanical motion of the MRB compression mechanism is synthesized to deliver end values of pressure and breath frequency.

In simple terms, the RespirAID device simulates the effects of hand compression of a trained professional during ventilation.

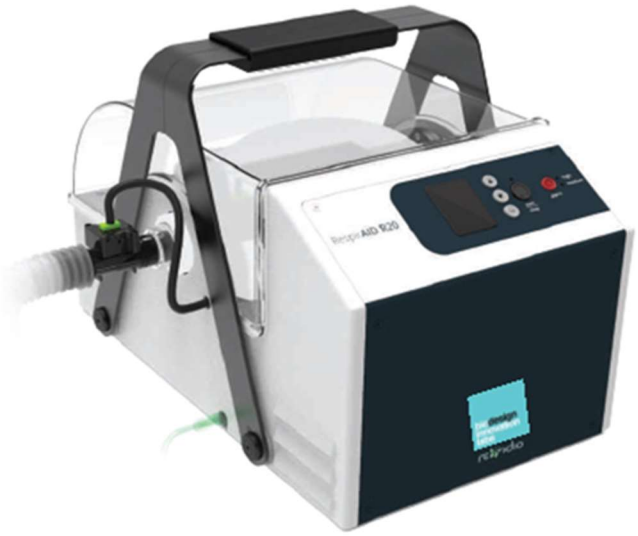

Figure 1. RespirAID R20.

The drive gas enters the MRB, where the oxygen regulator regulates the flow of oxygen. The MRB is compressed by the contact arms provided in the device thereby, automating the process of manual bagging. Here, the drive gas pressure builds up to the PIP as set by the user and the gas is forced out into the breathing system. If the pressure falls below the required PEEP value, the exhaust valve will close and the fresh gas supplied will increase the pressure maintaining the PEEP. The ventilation flow cycle is shown in Figure 2.

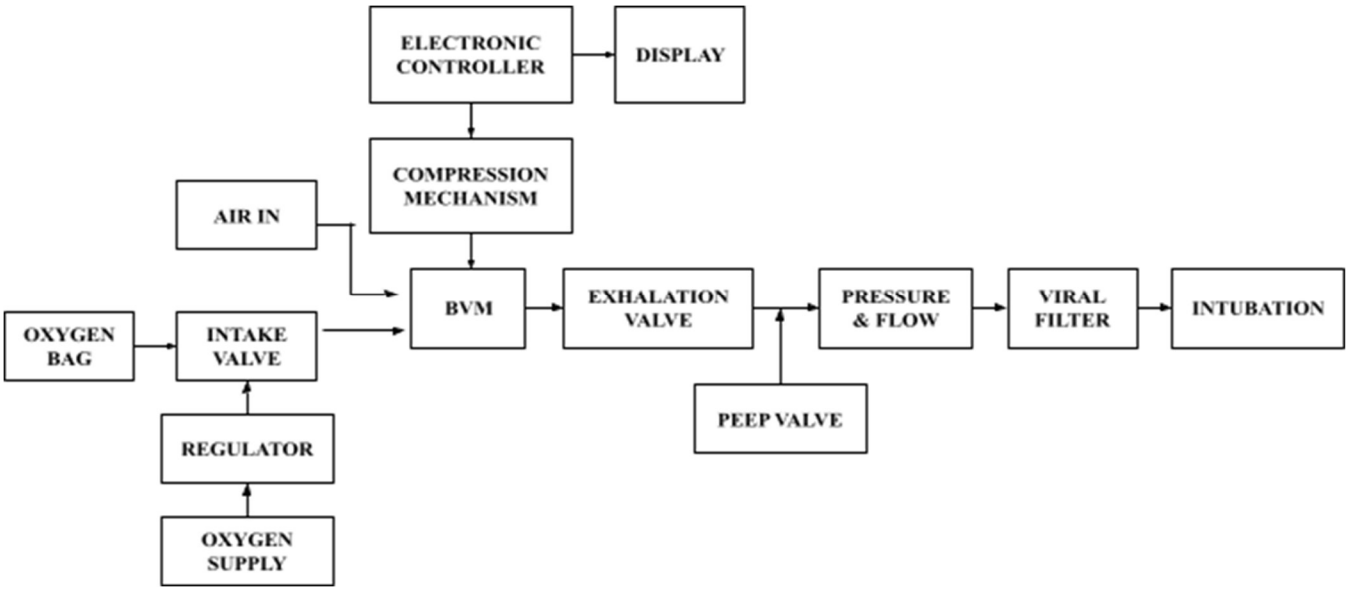

Figure 2: Ventilation flow cycle of RespirAID R20

The RespirAID R20 includes alarms to alert clinicians of any abnormality in the device's function or change in patient condition. Its simple interface makes it suitable to be used in a limited resource setting by less trained operators and during transport. It can as well be employed in a tertiary care hospital when there is a shortage of ventilators to tide over the crisis. The objective of this study is to test the safety and efficacy of RespirAID R20 in the post operative care patients.

The device uses a MRB and the system is significantly cheaper than commercial ventilators. that have the capability to provide other modes of ventilation. MRB are widely used for their well-established systems in place for procurement, sterilization, and disposal, even in the low-resource settings. Primary control in the device is that of the frequency of breaths delivered per minute, which is set by the medical professional using the device's intuitive interface. Power for the operation of the device can be drawn from a standard wall power supply, or the battery pack in the device can be charged for a wireless operation during transit and power outages.

Control Settings			
Parameter	**Range**	**Accuracy**	**Default**
VT (ml)	200 - 600	+/- (5 ml + 10% of set value)	200
Respiratory Rate (RR) (BPM)	8 - 30	+/- 1	8
PIP (cmH_2O)	10 - 80	+/- (2 cm H_2O + 4% of target)	40
PEEP (cmH_2O)	5 - 20	+/- (2 cm H_2O + 4% of target)	10
Inspiratory Expiratory ratio (I:E)	1:1, 1:2, 1:3, 1:4	NA	1:2

Table 1: Operational Characteristics of RespirAID R20

Study Design

This was an open-label trial conducted in the department of Anesthesia and Pulmonary medicine at Yenepoya Medical College Hospital, India, to determine the efficacy of RespirAID R20, to ventilate patients in the postoperative period after getting written consent from the subjects. This study was conducted with the approval from Yenepoya Ethics Committee - 1, (Protocol No. YEC-1/2020/049), Mangalore. Subjects under the age of 18 and over the age of 60, as well as those with hemodynamic instability and pre-existing respiratory conditions were excluded from the trial, while those between the age of 18 and 60 years, with a requirement for mechanical ventilation in post-operative care were included. Study design scheme summarized in figures 3.

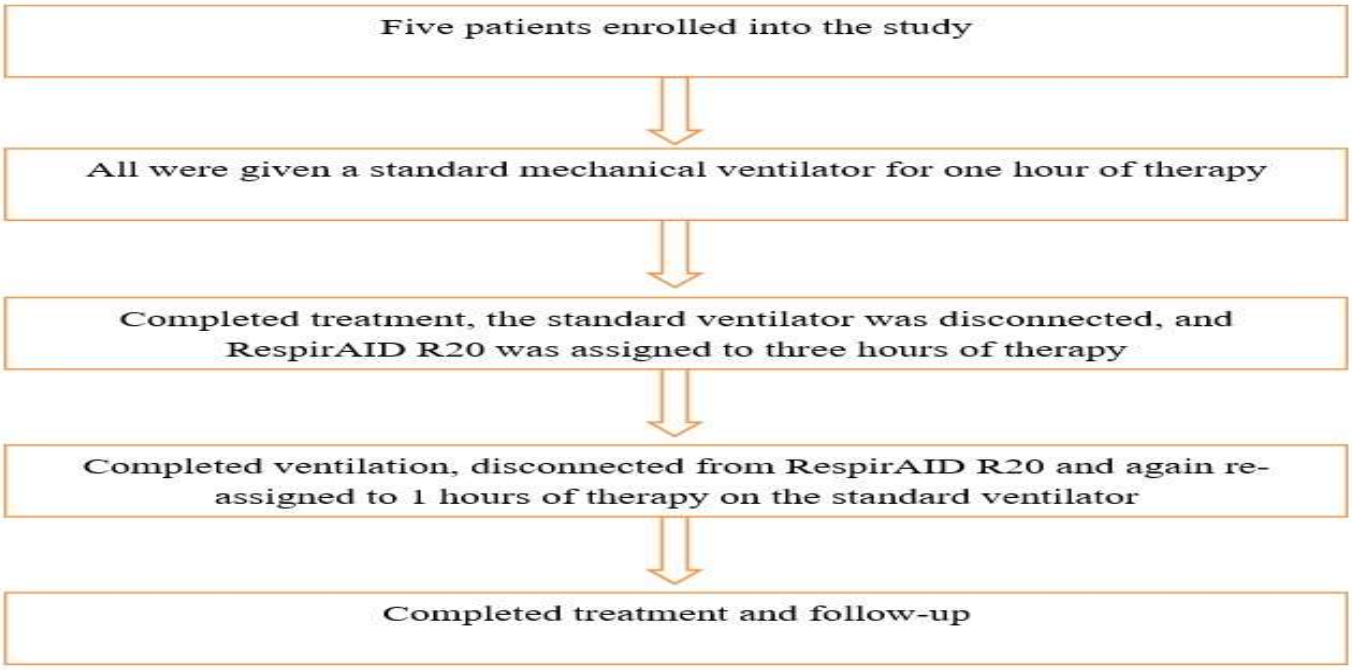

Figure 3: Flow diagram of the study

This study involved a total of 5 subjects who required surgery under general anesthesia. Age ranged from 27 to 53 years and all were men. All 5 subjects met the inclusion criteria and provided informed consent. All were diagnosed with carcinoma in the upper and lower airways and were undergoing different kinds of surgical procedures (Table 2).

Subject	Age (years)	Gender	Diagnosis	Procedure
1	33	M	carcinoma tongue	Flap reconstruction
2	27	M	Buccal mucosa carcinoma	Radial artery forearm flap
3	53	M	carcinoma alveolus	Free fibular flap
4	48	M	Right lower gingivo labial sulcus carcinoma	composite resection and free fibular flap
5	47	M	Carcinoma buccal mucosa	Composite resection and free flap

Table 2: Characteristics of study subjects

Materials & Methods

Methodology

Initially, subjects were connected to a standard ventilator (Mindray Synovent E3) andwere continuously monitored for their heart rate, SpO_2, noninvasive blood pressure (NIBP) and ECG every 15 minutes for 1 hour, as well as other respiratory parameters including V_T, RR, PIP, and PEEP. Then, RespirAID R20 was used with the same ventilator settings as the standard ventilator for 3 hours and monitored in a similar way. After 3 hours on RespirAID R20, subjects were connected again to the standard ventilator for 1 hour and were monitored for all relevant parameters every 15 minutes. Arterial blood gas (ABG) levels were also measured based on clinical need. ABG was performed after 1 hour of standard ventilator and 3 hours of RespirAID R20.

Results

The data collected include PIP, RR, V_T, and PEEP. The standard ventilator was used to measure these respiratory parameters both before and after RespirAID R20 therapy. The pressure gradient between the start and end of inspiration was determined by PIP.

The average set PIP was 24 +/- 2 cmH_2O, during RespirAID R20, the recorded mean PIP was 20 +/- 2 cmH_2O. After four hours of ventilation, the mean PIP reordered with the standard ventilator was 17 +/- 2 cmH_2O. The average V_T delivered during RespirAID R20 was 419 +/- 11 compared to the initial set range of 428 +/- 12. Results are summarized in table 3.

ECG was taken every 15 minutes, and all patients had a normal sinus rhythm. Similarly, under both RespirAID R20 and standard ventilator, all patients maintained normal blood pressure and heart rate. The median PEEP administered was 6 cmH2O. A PEEP of 4, 5, or 6 cmH2O was applied during RespirAID R20. For both the standard ventilator and the RespirAID R20, the set and measured PEEP were comparable.

	Pre		During RespirAID		Post	
	Set Value	**Measured Value**	**Set Value**	**Measured Value**	**Set Value**	**Measured Value**
V_T (ml)	414 +/- 11	392 +/- 16	428 +/- 12	419 +/- 11	420 +/- 12	394 +/- 19
PIP (cmH_2O)	16 +/- 2	20	24 +/- 2	20+/- 2	20 +/- 2	17 +/- 2
PEEP (cmH_2O)	4 +/- 0	5	5 +/- 1	5 +/- 0	5 +/- 0	5 +/- 1

Table 3: V_T, PIP, and PEEP of the five subjects before, during, and after the RespirAID R20 ventilation.

Blood gases: ABG was performed after 1 hour of standard ventilation in this study. The second ABG sample was taken after 3 hours of RespirAID R20 ventilation. After that, the patient was put back on the standard ventilator for an hour, another ABG sample was taken. The results of blood gas analysis before and after RespirAID R20 are shown in Table 4.

	Pre	During RespirAID R20	Post
pH	7.37 +/- 0.03	7.39 +/- 0.035	7.39 +/- 0.02
Partial pressure of carbon dioxide ($PaCO_2$) (mmHg)	44 +/- 2	43 +/- 4	47 +/- 3
Partial pressure of oxygen (PaO_2) (mmHg)	323 +/- 163	344 +/- 97	204 +/- 60
Bicarbonate (HCO_3) (mEq/L)	26 +/- 2	25 +/- 3	25 +/- 3
BE (mEq/L)	1+/- 3	1 +/- 2	-0.45 +/- 2

Table 4: Mean ABG parameters of five subjects before, during and after RespirAID R20

Discussion

RespirAID R20 is not a full featured mechanical ventilator, but a device that provides automated compression of a MRB. These devices, which are referred to as "emergency resuscitators" and typically offer controlled breathing with an adjustable RR and V_T, manual PEEP valve, and simple alarms. [20] The lack of actual V_T delivery measurement is one of the limitations of the existing MRB. There is no automated inspiratory or expiratory pause feature in the RespirAID R20 to assess inspiratory plateau pressure. [21,22]

An immediate mechanical ventilation support is necessary for the postoperative period provide ventilatory support. In most cases, patients who do not have complex respiratory problems can usually be extubated within a day.

RespirAID R20 provided IPPV to support patients in the postoperative care with similar ventilation as a standard device. During the study, the RR was adjusted based on the metabolic demands. All subjects maintained the initial set RR throughout the study, even though a higher RR is frequently needed to keep CO_2 levels within the acceptable ranges.

Pulse oximetry was used to measure oxygen saturation continuously and non-invasively. The mean oxygen saturation of 99.7% was observed during RespirAID R20 as well as in a standard ventilator. In general, during the immediate postoperative period, oxygen saturation may change due to multiple factors e.g. atelectasis, aspiration, ventilation/perfusion mismatch, pulmonary edema, or pulmonary embolism. [24,25] Hypoxemia may occur in those who had a surgical procedure under general anesthesia. [26] No such observation was found in this study. Figure 4 shows the mean SpO_2 of the five subjects during the whole study.

This supports the feasibility of RespirAID R20 as a ventilation support device for those who require mechanical ventilation for a short period. The delivered V_T is directly related to the peak pressure within the breathing circuit at the end of inspiration.

All ABG parameters, except PaO_2, were within the normal range (pH: 7.35 to 7.45; $PaCO_2$: 35 to 45 mmHg; HCO_3^-: 22 to 28 mEq/L; BE: -2 to +2 mEq/L). Increase in PaO_2 was observed in patients with 5 cmH_2O PEEP. This could be due to maintaining the same flow rate and thus FiO_2 throughout the therapy, as well as the duration of RespirAID R20, which may be the reason for hyperoxemia (i.e. arterial PaO_2 > 120 mmHg). 0.41 FiO_2 was observed before and after RespirAID R20. To reduce the risk of surgical site infection in patients during surgery and for up to six hours afterward, the World Health Organization (WHO) recommends a fractional inspired oxygen concentration of 0.8 for all intubated patients. [27,28] Even anesthetists have already widely criticized this recommendation. [29,30,31] During the first four hours of RespirAID R20, PaO_2 levels were greater than 300 mmHg (323 +/- 163 mmHg and 344 +/- 97 mmHg). Then after one hour of standard ventilation, a gradual decrease in PaO_2 was observed (204 +/- 60 mmHg).

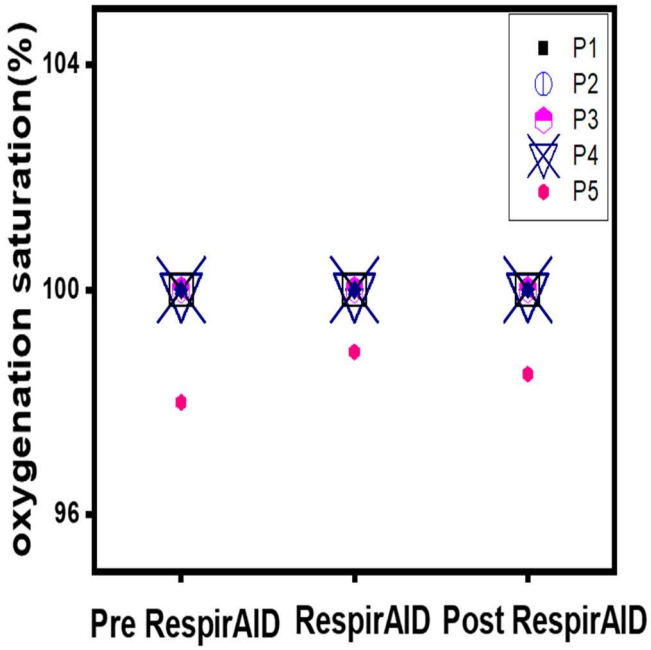

Figure 4: Mean oxygen saturation of five volunteers during RespirAID R20, pre and post-RespirAID R20 at different time periods.

The study has some limitations, mostly inherent the shortcomings of existing MRB such as lack of FiO2 and end-tidal CO2 analyzer. The study involved a small number of subjects who required surgery under general anesthesia. All these subjects were treated for a short time period (3 hours) using RespirAID R20. Further larger studies are needed to evaluate the feasibility of expanding the applications in other critical care departments as a supportive device for acute hypoxemic lung failure or diseased respiratory state. In case of electrical or motor failure, an additional portable uninterrupted power supply (UPS) support can assist the functioning of the RespirAID R20. The small number of subjects enrolled in this pilot safety trial study make statistical analysis difficult. Larger and sufficiently powered studies are required to accurately demonstrate differences in devices or strategies.

Conclusions

RespirAID R20 was successfully applied for 3 hours to the subjects in this study. Further studies are needed to evaluate its efficacy in diseased lung states or acute hypoxemic respiratory failure. RespirAID R20 potentially could be used during the shortage of ventilators as a means to stabilize the patients replacing the manual bagging.

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