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Evolution and Characteristics of Bag-Valve-Mask Ventilation During Pandemic: A Review of the Literature

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Abstract*—Mass casualty incidents such as those that are being experienced during the novel coronavirus disease (COVID-19) pandemic can overwhelm local healthcare systems, where the number of casualties exceeds local resources and capabilities in a short period of time. The introduction of patients with worsening lung function as a result of COVID-19 has strained traditional ventilator supplies. To bridge the gap during ventilator shortages and to help clinicians triage patients, manual resuscitator devices can be used to deliver respirations to a patient requiring breathing support. For patients who require ventilatory support, manual ventilation is a vital procedure. It has to be performed by experienced healthcare providers that are regularly trained for the use of bag-valve-mask (BVM) in emergency situations. We will present, a historical view on manual ventilation's evolution throughout the last decades. Artificial ventilation has developed progressively and research is still going on to improve the actual devices used. Throughout the past years, a brand-new generation of ventilators was developed, but little was done for manual ventilation. Manual ventilation through BVM can be replaced by automatic ventilation which illustrates that the Tidal Volume vs. Time graph of the automated system is similar to the graph produced by manual operation of the BVM and to the graph produced by a human subject. The use of an automatic manually operated device may improve ventilation efficiency and decrease the risk of pulmonary overdistention, while decreasing the ventilation rate.

***Keywords*—Mechanical Ventilator, Automated BVM, BPM, COVID-19, Ventilator design**

I. INTRODUCTION

Coronavirus disease 2019 (COVID-19) is increasing mortality rates by overwhelming medical infrastructure at the regional level [1-4]. Ventilation is an important treatment which is usually utilized to ventilate patients who cannot breathe adequately on their own. Patients with underlying lung disease may develop respiratory failure under a variety of challenges and can be supported by mechanical ventilators. These are machines which mechanically assist patients inspire and exhale, allowing the exchange of oxygen and carbon-dioxide to occur in the lungs, a process referred to as artificial respiration [2]. There are many techniques and methods of artificial ventilation, both manual and mechanical. Bag-valve mask (BVM) devices are ubiquitous in ambulances and healthcare environments, however require a medical professional to be present and constantly applying compression to provide the patient with respirations. While modern ventilators are computerized machines, patients can be ventilated with a simple, hand-operated bag valve mask (BVM) also [3]. Mechanical ventilators, which are essential for treating both influenza and COVID-19 patients in severe acute respiratory failure [5], are in critical short supply in some locations [6, 7]. During pandemics intensive care units (ICUs) do not have sufficient ventilators to treat all the patients requiring them, which forces triage and rationing [8]. This is despite national stockpiles of proprietary, mass-manufactured ventilators, which are simply not numerous enough due to prohibitive costs to service society during an extreme pandemic.

A. History of Artificial Ventilation

Ventilation with BVM is the commonly used technique to provide manual positive pressure ventilation to respiratory failing patients. From the mid-1500s until the early 1900s, artificial ventilation techniques reported in the literature recall only mouth-to-mouth and the use of bellows. Indeed, in 1472, Paulus Bagellardus published the first known book on childhood diseases and described mouth-to-mouth resuscitation by recommending to midwives to blow into the newborn's mouth if there is no respiration [9-11]. This shows that mouth-to-mouth ventilation was already considered at that time. In 1543, after further investigations on a porcine trachea with a reed for increasing animal's survival. This practice was taken over in 1559 by an Italian professor of anatomy Matteo Realdo Colombo who also described the tracheotomy's method. One century later, Robert Hooke, one of the greatest experimental scientists of the seventeenth century, repeated the Vesalius's experimentation using a strangled chicken model, which was ventilated by bellows. He demonstrated with this model that it was only the fresh air leak which caused death. In 1732, the first mouth-to-mouth ventilation case was reported on a coal miner. This latter revival was performed by the surgeon William Fossach [12]. He presented in 1744 at Edinburgh the case study of his mouth-to-mouth

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rescue [13]. In 1787, Baron Antoine Portal proposed, for respiratory insufficiency cases, to inflate the lungs of the new-born with air. The Scottish surgeon John Hunter, advocate of the experimental method in Medicine, who developed human bellows with pressure relief valve, recommended to the Royal Human Society in 1776 the need to apply artificial ventilation immediately for revival [11, 13]. Furthermore, in order to reduce stomach inflation, the major problem with bellows ventilation, he suggested pressing gently the larynx against the vertebrae [9, 14]. The bellows ventilation was condemned by the Royal Human Society and the French Academy of Medicine for lack of safety due to their first adverse effects. In 1745, John Fothergill listed singular advantages of mouth-to-mouth expired air ventilation compared to the bellows ventilation during recovery [9, 13]. He said that "the warmth and moisture of the breath would be more likely to promote the circulation than the chilling air forced out of a pair of bellows and that the lungs of one man may bear, without injury, as great a force as those of another can exert, which by the bellows cannot always be determined" [9]. Indeed, with mouth-to-mouth ventilation, it is impossible to increase pressure to be higher than that the human is able to generate. Nevertheless, an example of successful bellows ventilation has been reported by Fell in 1891 in a clinical trial. James Leroy d'Etiolles emphasized the need for early use of the bellows and recommended in 1828 a graduated bellows according to the patient size to reduce hyperventilation with high volumes which may induce barotrauma. In 1958, Peter Josef Safar, "the father of modern recovery," demonstrated the superiority of mouth-to-mouth ventilation over other methods of manual ventilation in a clinical study [15, 16].

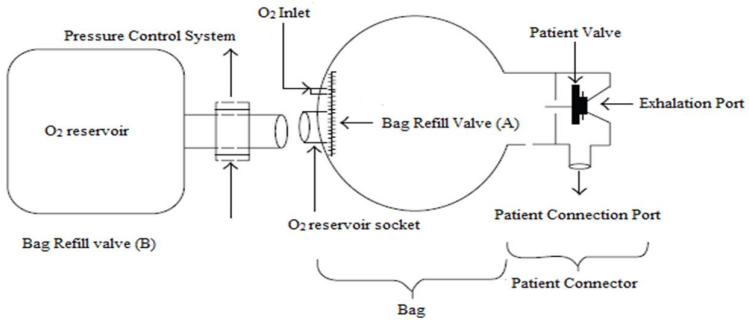


Fig. 1 Basic components of the BVM system (De Godoy et al. [11])

At the middle of the 20th century, several unidirectional valves were developed with different technical characteristics. The original bag-valve-mask concept was developed in 1953 by the German doctor Holger Hesse and his partner Danish anesthetist Henning Ruben, following their initial work on a suction pump. Their resuscitator, named "Ambu" (Artificial Manual Breathing Unit), was manufactured and marketed in 1956 by their company [17].

II. THEORIES AND PRINCIPLES

The theoretical background and principle of the operation of mechanical ventilators and Ambu bag are presented below.

A. Principle of Operation of Mechanical Ventilators

The ventilator is connected to the patient through a tube (endotracheal or ET tube) that is placed into the mouth or nose and down into the windpipe. When the doctor places the ET tube into the patient's windpipe, it is called intubation. Some patients have a surgical hole placed in their neck and a tube (tracheostomy or "trach" tube) is connected through that hole. The trach tube is able to stay in as long as needed and is more secure than an ET tube. At times a person can talk with a trach tube in place by using a special adapter called a speaking valve.

The ventilator blows gas (air plus oxygen as needed) into a person's lungs. It can help a person by doing all of the breathing or just assisting the patient's breathing. The ventilator can deliver higher levels of oxygen than delivered by a mask or other devices. The ventilator can provide a pressure (PEEP pressure) which helps hold the lungs open so the air sacs don't collapse. The tube in the windpipe makes it easier to remove mucus if someone has a weak cough.

The ventilator should stop delivering air into the lungs with external force as soon as the patient starts to breathe itself. If it operates while the respiratory system of the patient is active it may cause damage to the lungs and vomiting of the patient may occur. So, there is a system to monitor when the patient starts to breathe himself and stop the operation of the ventilator. Also, mechanical ventilators are much more expensive than BVM devices and require an oxygen source. BVM can be performed with room air.

B. Operation of Ambu Bag

In Fig. 1 the various parts of an Ambu bag are identified. Manual resuscitators cause the gas inside the inflatable bag portion to be force-fed to the patient via a one-way valve when compressed by the rescuer; the gas is then ideally delivered through a mask

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and into the patient's trachea, bronchus and into the lungs. The tidal volume and respiratory rate have to be maintained as per the conditions of the patients by the rescuer.

Typical tidal volume is 500 to 800 mL of air and typical respiratory rate is 10 to 12 respiration per minute for adults and 20 respirations per minute for infants. Professional rescuers are taught to ensure that the mask portion of the BVM is properly sealed around the patient's face. The main drawback with BVMs is their manual operation requiring continuous operator engagement to hold the mask on the patient and squeeze the bag. This operating procedure induces fatigue during long operations, and effectively limits the usefulness of these bags to temporary relief. Moreover, an untrained operator can easily damage a patient's lungs by over compression of the bag.

III. LITERATURE REVIEW

There are currently many open-source solutions that seek to disseminate manual resuscitator (bag-valve mask; BVM) ventilator designs with the hope of bridging the gap during the COVID-19 pandemic [18]. First, the design should ensure that the device does not degrade the BVM performance with regard to pressure V_T, and flow waveforms from repetitive device motion. Durability testing has to be performed not only on the mechanical system but also on the BVM device. Secondly, even with a fixed BVM compression setting, the V_T delivered is dependent on the resistance of the airway and the compliance of the lungs. The only respiratory parameter that can be controlled by most devices is the respiratory rate, and while the Central Drug Standard Control Organization has issued emergency use authorizations for devices in which V_T can be selected, designs with a fixed stroke length (compression setting) lead to inconsistent V_T delivered as pulmonary parameters change. Ventilator designs should measure expired volumes or predict V_T across ventilator settings for specific pulmonary resistance and compliance parameters.

For this work, automated BVM-based device could consistently deliver mechanical respirations with a variety of widely commercially-available BVMs. The automated BVM operation can be successfully implemented by completing following parameters 1) rapidly design and develop a volume-controlled automated manual resuscitator, 2) evaluate the parameters of V_T rate, and mean airway pressure over different resistance and compliance settings that would be representative of patients with varying lungs states, and 3) establish longevity and implementation of the device across multiple BVM models.

The design of the proposed automated BVM for adult patients can be considered on the basis of following assumptions: -

- Tidal volume to be delivered = 200 to 750 mL
- Breath rate to be maintained = 10 to 20 BPM
- Maximum power required by the motor = 30 W
- Maximum torque to be delivered by the motor = 1.5 N.m

The design assumptions are based on the work by Husseini et al. [19], as they determined the assumptions after necessary experiments taking the mechanical properties and dimensions of the Ambu bag into considerations. So, there assumptions can be taken without further experimentations. To automate the operation of Ambu bag, the mechanical system developed to compress the bag must be synchronized with the ideal motion that is maintained by a professional rescuer.

Under the Drugs and Cosmetics Act and Medical Device Rules, companies generally need a license to make items listed as Essential Medical Equipment. However, considering the medical urgency (due to Covid-19) at hand, this rule was waived for manufacturers who had partnered with a licensed firm. Some of these companies listed below are developing the low-cost ventilator for mass production [20].

Nocca Robotics: It has developed an ICU-grade ventilator customized for handling coronavirus patients which will cost less than one-tenth of a high-end imported ventilator. The ventilator can be used both in ICU as well as ported out to handle patients in other locations like trains etc. It is said to work for 4 hours on battery as well.

Alpha Design Technology: The primary design of these ventilators leverageselectro- mechanical modules in the form of Printed Circuit Board (PCB) assemblies, display units, controllers and signal processing, with built-in firmware including solenoids, valves etc. The entire architecture is enclosed in a robust mechanical structure and all connectivity is through electronically activated circuits.

Prana-Vayu: The ventilators' first version worked on the controlled operation of the prime mover to deliver the required amount of air to the patient and had automated the process to control pressure and flow rates in the inhalation and exhalation lines. The ventilator also had feedback that could control tidal volume and breathe per minute.

Ethereal Machines: A simple ventilator splitter is used on the frontlines to help provide oxygen to two patients, instead of one. The splitter would supply in a 50:50 ratio, but this may not be ideal because patients generally require differential ventilation. Depending on individual recovery rates, the ratio is either 30:70 or 40:60. Cross- contamination between two patients using the same ventilator posed an additional problem.

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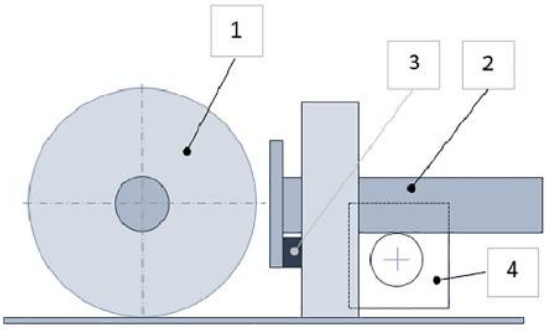


Fig. 2 The process of compression of a self-inflating bag: A) initial homing position of the pusher, B) compression stage, 1) self-inflating bag, 2) pushing rod, 3) limit switch, and 4) stepper motor [21].

The developed system should have three control inputs for the variables: tidal volume (V_T), breathing rate per minute (BPM), and inspiratory-to-expiratory ratio (I/E). BPM and I/E will be controlled by rotary potentiometers, and BPM with a rotary encoder. The self-inflating bag compression process is shown in Fig. 2. At the beginning of the operation, the pusher will reach the home position by hitting the limit switch. From this point, the tidal volume can be adjusted by the amplitude of the movement of the pusher (dL), and the breathing rate can be adjusted by a pusher frequency.

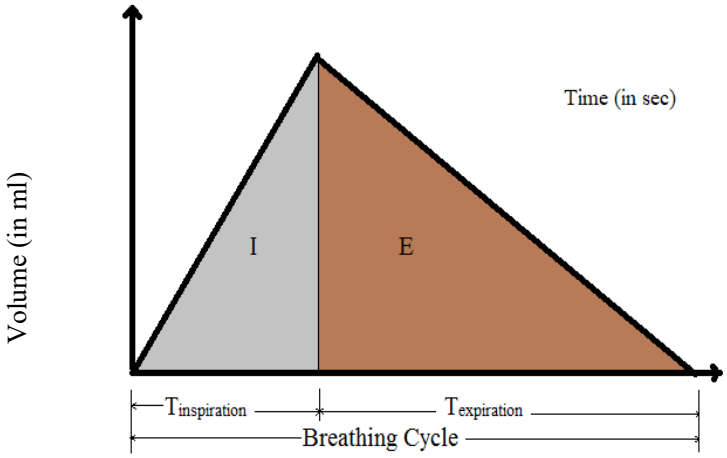


Fig. 3 Breathing control diagram: the tidal volume depends on the length of extension of the pusher, and the timings for the inspiratory and expiratory phases – are functions of stepper motor delays between its successive steps [21].

As can be seen from Fig. 3, V_T, BPM, and I/E are functions of the number of steps and the speed of the stepper motor. To provide the desired breathing parameters, the number of motor steps should be calculated as follows:

$$n = \frac{dL \cdot N}{\Pi \cdot D}$$

where D is the gear diameter in millimeters, dL is the desired pusher length in millimeters, and N is the number of steps per one full revolution. Thus, a balance was experimentally found between the number of motor steps and the permissible vibration of the bag support system with a micro-stepping coefficient of 4, which corresponds to ~800 steps per single revolution of the shaft [21].

A. Bag-Valve-Mask Ventilation Difficulty

Besides these technical incidents, BVM ventilation is quite not easy to perform in order to deliver adequate insufflations. Healthcare providers have no information on insufflated tidal volumes, ventilatory rates, gastric insufflation volumes, airway pressures, and leaks. These parameters are very important to appreciate helping the rescuer to adequately ventilate the patient. However, many studies have demonstrated that healthcare professionals trained in airway management provide to cardiac and/or

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respiratory arrest patient high ventilatory rates and inadequate ventilation volumes [22]. A study by Aufderheide et al. showed that experienced emergency medical personnel hyperventilated all patients with 37 ± 4 breaths/min (twice the recommendations) and none of them survived [22]. Furthermore, a recent bench study showed that hyperventilation occurred in simulated pediatric recovery with 40.6±11.8 breaths/min compared to the recommended rate from 8 to 20 breaths/min by the Pediatric Advanced Life Support guidelines [23]. Problem is the rapidly refilling bag and the emergency stressful situation which can induce a reflex in which rescuers tend to squeeze and deliver breath as soon as the bag reinflates. These difficulties to perform adequate ventilation may lead to excessive insufflated volume and pressure. These reports have pointed out the negative outcomes of human errors, which are usually the result of lack of experience and/or infrequent training. This leads to inadequate and inefficient ventilation according to the International Liaison Committee on Recovery (ILCOR) guideline.

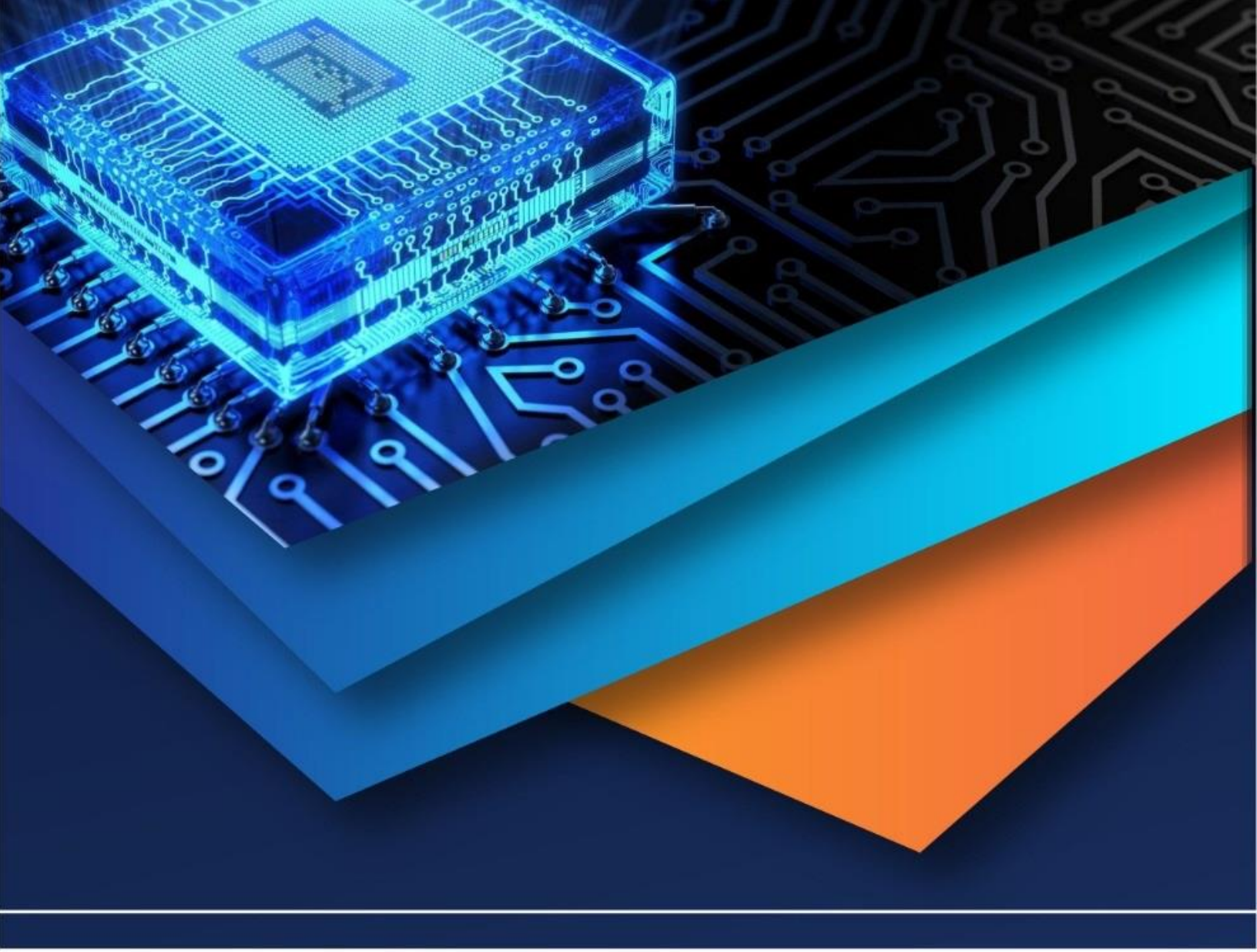
IV. CONCLUSION

The use of an automatic, manually triggered ventilation devices for recovery may present valuable advantages over the standard manual BVM ventilation. Such devices may improve ventilation efficiency and decrease the risk of pulmonary overdistention. Clinicians should, however, be aware that the performance of such devices depends strongly on each patient's pathology and on the user's individual experience. As the COVID-19 crisis is overwhelming health care systems, leaving some institutions without an adequate supply of ventilators, the concept of automating the Ambu bag or BVM can be used for developing a low-cost portable mechanical ventilator for actual emergency cases where existing sophisticated devices are not present. The challenge is to develop devices and technologies that improve and secure the quality of manual ventilation.

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