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BILVIP: PROTOTYPE LUNG VENTILATOR TO TREAT TWO PATIENTS WITHOUT RISK OF CROSS-CONTAMINATION

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Abstract: State of the art: The recent COVID-19 pandemic that has been devastating the world had its first cases detected in December 2019 in Wuhan, China (HUANG et al., 2020). The causative virus, called SARS--CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), quickly spread throughout the country and then around the world, with the number of cases increasing 13-fold in two weeks (GORBALENYA et al., 2020). This increase in the number of cases led the WHO (World Health Organization) to declare a global pandemic on March 11, 2020 (BRAZIL, 2020). **Objectives:** Design, development, and testing of a versatile mechanical ventilator capable of ventilating two patients simultaneously without the risk of gas mixing and enabling the monitoring of independent parameters (i.e., tidal volume, FiO2, respiratory rate, inspiratory pressure, and PEEP) for the treatment of patients with respiratory diseases. **Methods: The** methodology used to design the ventilator was based on systems engineering and, therefore, guided by the various complex requirements and functional challenges demanded by medicine in order to achieve a non-traditional design. Thus, the BILVIP (BI-Lung Ventilator with Independent Parameters) ventilator was conceived as a single piece of equipment, but with a versatile design that includes portability and two independent systems with the following elements: 12V electric motor, pulley and belt assembly, crank-crankcase, connecting rod-piston plate assembly, bellows assembly-bellows with inspired volume regulator and air flow regulator, intake valve with oxygen blender, inspiratory pressure adjustment valve (VAP), one-way valve with PEEP (VUP), IRPM counter, HME filters, and connections necessary for a complete breathing circuit. **Results:** During laboratory tests, the ventilator prototype was able to supply two Dräger test lungs with a resistance of 20 mbar/L/s and a complian-

ce of 25 mL/mbar simultaneously with independent ventilation parameters and, due to its new design, avoiding any risk of cross-contamination. **Conclusions:** Although the scientific community does not recommend the use of a single device to ventilate more than one patient, this consensus is naturally still based on the technology and design of traditional ventilators available to date. The BILVIP was designed to try to break this paradigm and overcome the main flaws of the co-ventilation method pointed out in the literature. Thus, the prototype model developed and presented in this article demonstrated, through a new design, that it is possible to ventilate two distinct lungs without the risk of gas mixing and with independent parameter monitoring, thus respecting the individuality of each patient.
Keywords: Mechanical ventilator; Respiratory diseases; ICU; Invasive ventilation.

INTRODUCTION

The recent COVID-19 pandemic that has been devastating the world had its first cases detected in December 2019 in Wuhan, China (HUANG et al., 2020). The causative virus, called SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), quickly spread throughout the country and then around the world, with the number of cases increasing 13-fold in two weeks (GORBALENYA et al., 2020). This increase in the number of cases led the World Health Organization (WHO) to declare a global pandemic on March 11, 2020 (BRAZIL, 2020).

Upon arriving in Brazil on February 26 of the same year, the pathogen spread rapidly, prompting the Ministry of Health to declare a state of community transmission one month later (BRAZIL, 2020, p. 1; Ministry of Health, 2020). With the rapid spread of the virus and the high rate of patients admitted to hospitals requiring respiratory assistance, around 72% (RANZANI et al., 2021), studies estimated the need for support to the public health system to prevent collapse, given that the number of mechanical ventilators in the country was already insufficient in some regions before the pandemic (Institute for Health Policy Studies, 2020).

Even after the warnings, the collapse happened (LEMOS et al., 2020), because of the basic law of the market: Supply vs. Demand. the increase in global demand for hospital supplies caused prices to rise and the market was unable to meet the need, leading to a dispute between countries over equipment and overburdening companies, which were often unable to deliver what they had promised, leading the government to invest in the domestic market for the production of machinery (MINISTRY OF HEALTH, 2021).

Despite investment initiatives, there was a need for more ventilators to meet demand, and therefore the idea of using a single ventilator to serve two or more patients was revived (U.S. PUBLIC HEALTH SERVICE COMMISSIONED CORPS, 2021), as did Greg Neyman and Charlene Irvin in 2006, who attempted to overcome several associated problems. Thus, in a laboratory study, they attempted to demonstrate the feasibility of modifying the circuits to address the problems (NEYMAN; IRVIN, 2006), and the method was subsequently tested on animals (PALADINO et al., 2007).

However, the concept has significant limitations, namely: equivalent ventilation only when there is identical compliance in the patients' lungs, ineffectiveness in individual patient monitoring and control, inability to provide assistance according to each patient's individual pathology, and the imminent risk of cross-contamination (BRANSON ET AL., 2012).

Given this scenario, it is important to study and develop a mechanical ventilator that can simultaneously serve two (2) patients and, even in its design phase, already contempla-

te the possibility of independently controlling various individual parameters to contribute to the treatment of patients with respiratory diseases.

METHOD

For the design of the BILVIP (BI-Lung Ventilator with Independent Parameters), concepts from systems engineering were used, which are based on a methodical and multidisciplinary approach to the design, implementation, technical management, operations, and even disposal of complex systems (PAHL, 2007). The complex system described in this article corresponds to a unique type of mechanical ventilator, which was designed to meet the medical needs arising from the COVID-19 pandemic. To this end, design requirements from both medicine/physiotherapy and engineering were considered.

Several medical questions published by the American Society of Anesthesiologists (ASA), in conjunction with other associations (PAHL, 2007), were established as a guiding mechanism for analyzing the proper functioning of this complex system, addressing mainly the difficulties and problems of the co-ventilation method with traditional ventilators. In addition to these questions, which will be addressed in more detail in the discussions, two engineering variables were also established: low production cost and portability for use in ambulances and mobile ICUs.

After defining the problems to be solved, the steps of the systems engineering methodology proposed in the literature by Gerhard Pahl in 2007 were strictly followed. Thus, some possible solutions were studied, analyses were carried out on the best solutions according to the requirements imposed, optimization of the solutions was sought, a prototype of the final solution was manufactured, and finally, a plan was drawn up for the implementation of the BILVIP system.

BILVIP: DESIGN AND OPERATION.

CONCEPT:

The BILVIP (BI-Lung Ventilator with Independent Parameters) device was designed to overcome the main scientifically proven problems inherent in the procedure of ventilating two patients with traditional ventilators available on the market at the time of publication of this article. In fact, BILVIP differs from traditional ventilators in several ways. For example, its design prevents any possibility of cross-contamination.

As the acronym itself indicates, each patient's individuality and parameters are controlled independently and, consequently, there is no danger of cross-contamination. It was designed with a unique layout to eliminate any possibility of mixing or even minimal contact between the air masses supplied to each patient. Aware of the fact that each patient is unique and may be affected with greater or lesser severity, the overriding design requirement in the conception of BILVIP was full respect for this individuality.

This feature makes it possible to respect the different approaches required in the specific pathological treatment of each patient. Thus, there is no need for similarity between the pulmonary compliance of the two patients being treated. However, the BILVIP has the limitation that it was designed for the treatment of COVID-19. For other uses, some adaptations are necessary.

OPERATION:

BILVIP also features the basic operating principles of a mechanical ventilator, but the prototype developed in the laboratory operates only in the controlled volume ventilation mode, where the operating parameter is the volume of air delivered to the patient. As one of the objectives is also portability, the venti-

lator is powered by a 12V electric motor |Fig. 1a|, which can easily be powered by a vehicle charger. When the operator turns on the motor, they set the RR (respiratory rate) with an RPM controller (similar to the IRPM) on the motor, fig. 1b, activating the piston-plate system |Fig. 1c - highlighted in red at the bottom|, which in turn moves the bellows |Fig. 1d|, delivering air to the patient's lungs.

In conjunction with the RR (Respiratory Rate) setting, the operator must adjust the volume of the bellows, which is set to 1000 ml by default, in order to adapt the TV (Tidal Volume) according to the patient's needs and characteristics. To do this, it is necessary to adjust the volume regulator of the bellows, Fig. 2 – highlighted in red at the top| which, when rotated, changes the initial volume of the bellows, decreasing or increasing the volume of air administered to the patient. For greater precision in adjusting the VT, there is also a flow regulator that controls part of the mixture contained in the bellows, releasing or not releasing part of the volume into the atmosphere.

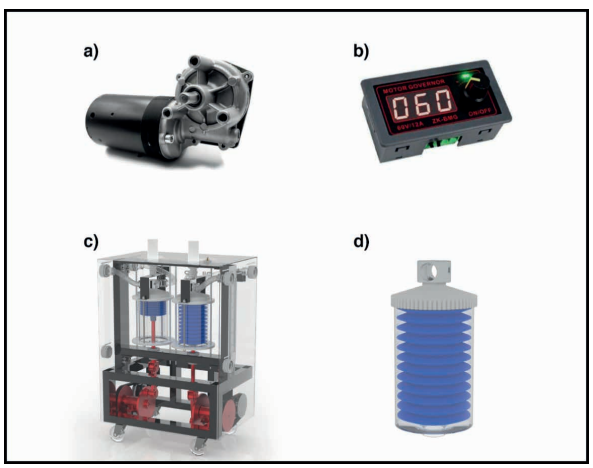

Figure 1 - Ventilator parts

Source: Own work.

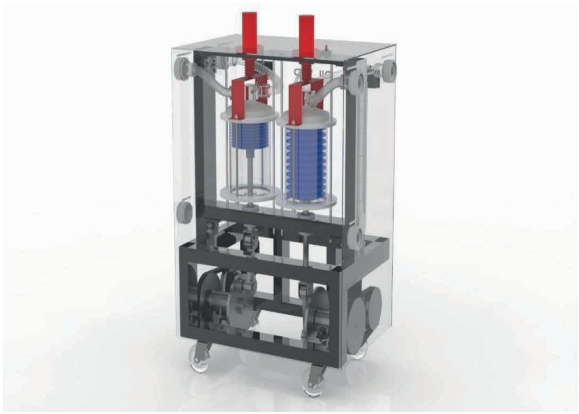

Figure 2 – Bellows volume regulator.

Source: Own work.

Once the tidal volume has been set, a mixture with the appropriate oxygen concentration from the cylinder enters through the intake valve |Fig. 3a|. This valve is equipped with manual FIO2 (Inspired Oxygen Fraction) controllers that act as a blender |Fig. 3b|, where each controller has a pre-set fixed percentage of FIO2, ranging from 24 to 100%. Immediately after admission, the mixture goes to the bellows and is sent to the patient's inspiratory circuit, but first passes through the VAP (inspiratory pressure adjustment valve) |Fig. 3c|, ensuring safety during the patient's inspiration process and preventing barotrauma.

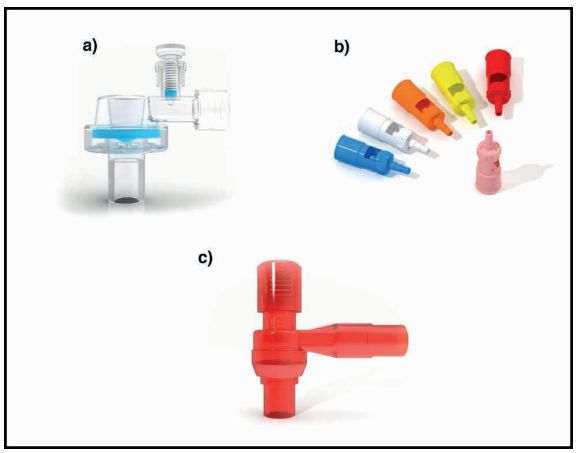

Figure 3 - Oxygen flow valves and controllers

Source: Own work.

In the expiratory circuit, a VUP (unidirectional valve with PEEP) |Fig. 4| is used to meet specific needs for longer or shorter retention times and air pressure within the alveoli. Then, once the PEEP has expired, the exhaled air is expelled via a filter and channeled to an external area. BILVIP has two subsets of similar elements, but the operation described above applies equally to the two independent systems, which are customized for each patient.

Figure 4 - One-way valve with PEEP

Source: Own work

ETHICAL AND CIVIL LIABILITY ISSUES IN THE PRODUCTION AND DISTRIBUTION OF BILVIP

The development and eventual commercialization of the BILVIP ventilator impose a series of ethical and civil responsibilities on its manufacturer and distributor. As this is a life-support medical device, it is imperative that production strictly follows the technical standards established by the Brazilian Health Regulatory Agency (ANVISA), ensuring the safety, efficacy, and traceability of the devices sold (BRAZIL, RDC No. 546, 2021). The civil liability of the manufacturer stems from the obligation to provide safe and functional products, governed by the Consumer Protection Code (Law No. 8,078/1990) and the Civil Code (Law No. 10,406/2002), which provide for full compensation in cases of damage caused by product failure, regardless of fault. From an ethical standpoint, manufacturers must respect human dignity and the principle of beneficence, ensuring that the equipment meets the clinical needs of patients in an equitable manner (CONSELHO FEDERAL DE MEDICINA, 2013). The commercialization of BILVIP also requires transparency regarding its limits of use, as well as shared responsibility with healthcare professionals for adequate training and technic tion and safe handling of the device. In addition, the implementation of post-marketing surveillance systems and risk management plans is recommended, in accordance with ISO 14971:2019, with a view to the continuous reduction of adverse events.

Thus, when innovating to overcome technical challenges associated with BILVIP, there is a demand from those responsible for it to have a robust ethical commitment, combined with regulatory compliance and full legal responsibility for its clinical use in public and private hospital environments.

RESULTS

To validate the project, power and continuity tests were performed using two Dräger test lungs with a resistance of 20 mbar/L/s and a compliance of 25mL/mbar. In the initial power supply tests, the ventilator was connected to a vehicle outlet for 3 hours, while in the continuity test, the equipment was connected to a 220V outlet via its 12V power supply for 720 hours. In both tests, the ventilator was able to supply the two lungs simultaneously and uninterruptedly with independent ventilation parameters and, due to its new design, avoiding any risk of cross-contamination.

DISCUSSIONS

Given the shortage of ventilators caused by the pandemic, gyms were motivated to seek quick and practical solutions, such as the production of low-cost and quick-production ventilators. However, these ventilators only served one patient, and hospitals continued

to face high patient demand, returning to the problems already pointed out in this article. The scientific literature has also made it clear that the use of traditional ventilators to treat two or more patients should not be recommended, mainly due to the proven risk of cross-contamination.

In view of this, the American Society of Anesthesiologists (ASA), in conjunction with other associations, published a statement (American Society of Anesthesiologists, 2021) clarifying all the problems with this method of using traditional ventilators, which are listed below:

- A greater volume of air would go to the patient with the more compliant lung, causing an imbalance;
- Positive end-expiratory pressure (PEEP), which is critically important for intubated patients, would be impossible to manage;
- Monitoring patients and assessing lung mechanics would be challenging, if not impossible;
- Monitoring and managing alarms would not be feasible, as the parameters of the two patients would not be treated independently;
- Individualized management of clinical improvements or worsening would be impossible for the same reason mentioned in the previous item;
- In cases of heart attack, ventilation of all patients would need to be stopped to allow switching to manual ventilation without aerosolizing the virus and exposing healthcare professionals;
- In these circumstances, the second patient would be totally disadvantaged, as the
- breathing dynamics of the other patient would be altered;
- The volume of added breathing circuits makes self-testing (failure testing) impossible. Thus, the operator will be forced to operate the ventilator without a successful test, increasing errors in device measurements;
- Additional external monitoring would be necessary. The ventilator monitors average pressure and volume;
- Even if all patients connected to a single ventilator had exactly the same clinical parameters at the beginning, they could worsen or recover at different stages;
- Air distribution to each patient would be uneven and unmonitored. The most deteriorated patient would receive a lower tidal volume, while the improving patient would receive the highest tidal volume;
- The greatest risks occur with the sudden deterioration of one of the patients (e.g., pneumothorax, kinked endotracheal tube), with the ventilation balance distributed to the other patients;
- Finally, there are ethical issues. If the ventilator can save the life of a single patient, using it on more than one patient at the same time carries the risk of life-threatening treatment failure for all of them;

Considering the undoubted problems listed by the ASA and also the cost and portability requirements, the BILVIP project was designed to overcome the main challenges presented above in order to mitigate the various issues as illustrated in the table in Fig. 5 below:

CONCLUSIONS

Although the scientific community does not recommend the use of a single device to ventilate more than one patient, this consensus is naturally still based on the technology and design of traditional ventilators available to date. The BILVIP was designed to try to break

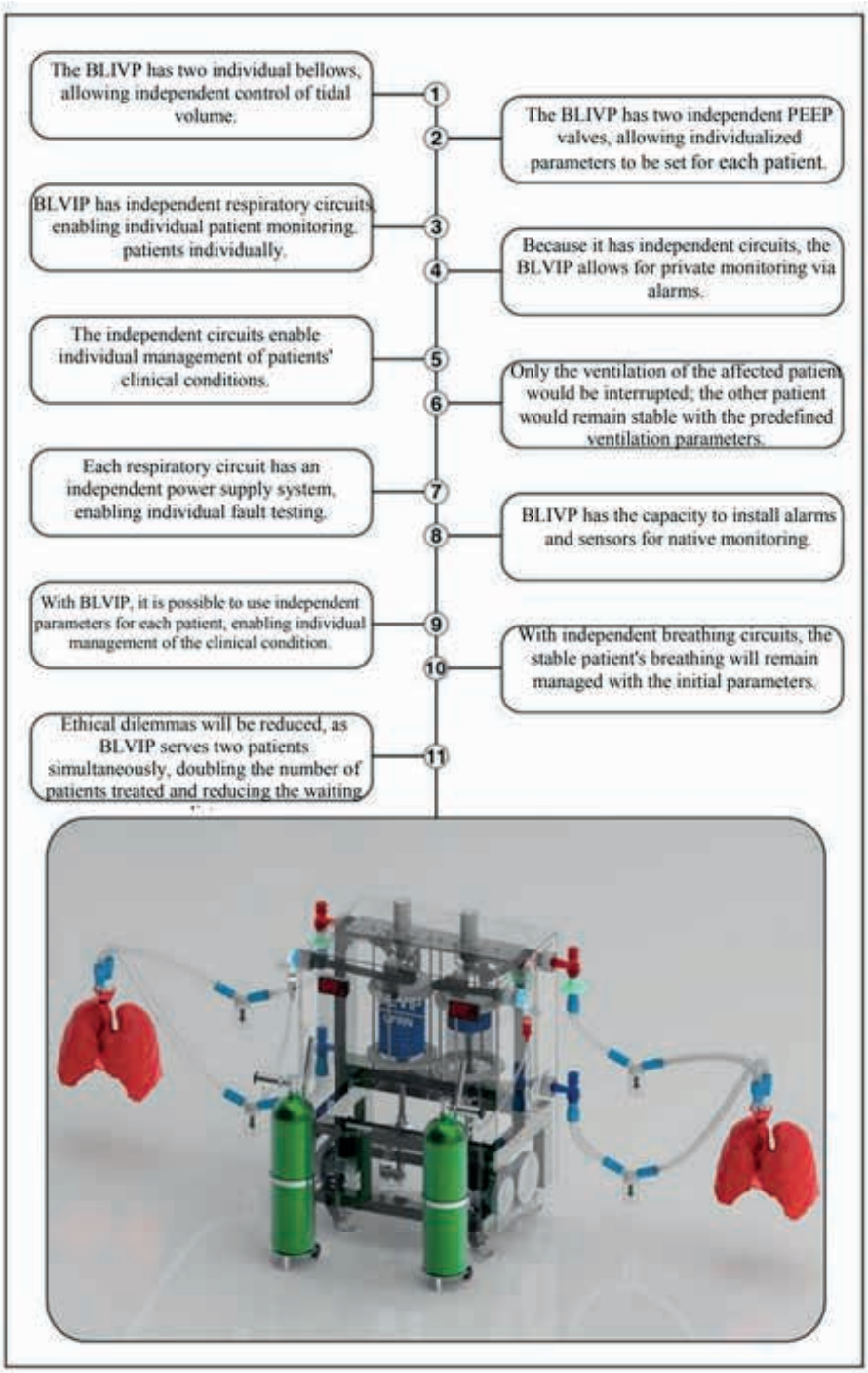

Figure 5 – Advantages of using BILVIP in the co-ventilation method.

Source: Own work.

this paradigm and overcome the main flaws of the co-ventilation method pointed out in the literature. Thus, the prototype model developed and presented in this article demonstrated, through a new design, that it is possible to ventilate two distinct lungs without the risk of gas mixing and with independent parameter monitoring, thus respecting the individuality of each patient. Naturally, the laboratory prototype presented can still be refined through upgrades to easily include a higher degree of automation, as well as improved quality of the alarms implemented at the time of submission of this article. This work to upgrade the BILVIP is already underway at the LAIS laboratory at UFRN. However, as a contribution, the feasibility of manufacturing a non-traditional ventilator that can overcome several of the challenges posed by the co-ventilation method has been clearly demonstrated and tested.

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