



EVOLUTION OF INVASIVE LUNG RESPIRATORS FOR THE COVID-19 PANDEMIC SCENARIO

Freire AB; §; Galdeano GMK§; Moreira LD§; DelMonaco ADM§;

§ *University Center of Americas, São Paulo, Brazil.*

Abstract. The COVID-19 pandemic scenario brought to countless patients the need to use a pulmonary ventilator, which was highlighted as one of the most important resources in combating the coronavirus pandemic to support the lives of thousands of people. This study sought to present a historical-scientific overview of the mechanical ventilator and its importance for intensive care processes, especially with the advent of Coronavirus. A search was carried out in the databases of Scielo, Bireme, Medline, Lilacs, Academic Google, HBSCO, published in the period 2000 to 2021 and in the NCBI database within the central PubMed for the period from March 2020 to March 2021. Studies have shown that many ventilators have emerged over time with different interfaces that provide pulmonary support to critically ill patients. In view of these studies, several types and forms of ventilation were discovered, such as invasive and non-invasive ventilation, in addition to the types of ventilation cycles and some ventilation modalities. Patients who had severe pulmonary complications required this type of intensive care, however with the high demand for these respirators, rising dollar and logistical problems, biomedical engineering departments of institutions, research centers and universities developed and designed pulmonary support equipment. It could be observed that the pandemic brought a need for acceleration in the manufacturing processes of mechanical ventilators, and greater concern in producing this technology in national territory. The conclusion of this study was that there is a demand throughout the market's production chain for this type of technology, which brings the need for greater investment in research, innovation and infrastructure for the hospital technology segment.

Keywords: Mechanical ventilator, mechanical ventilation, exhalation valve, respiratory assistance, intubation, life support, ICU, breathing cycle, coronavirus.



Introduction. The first artificial ventilations were performed through differential pressure chambers, a method known as the “steel lung”. However, over time, it was observed that the use of positive pressure artificial ventilation brought more benefits and easier monitoring of patients, which resulted in an assessment that positive pressure artificial ventilation had some advantages over the method known as "steel lung". Through positive pressure artificial ventilation, it was found that it could increase airway resistance [1,2].

The first automatic intermittent positive pressure equipment was developed by Frenkner and the AGA company, with its entry into the commercial market in the year 1940, from these experiments other equipment began to be developed and began to enter the market.

Nowadays, we have several companies producing and distributing these life support equipment, which has become something very necessary and essential, especially after the arrival of the virus called COVID-19. some respiratory pathology that prevents the gas exchange from being carried out in a natural way, then the mechanical ventilator performs the function of assisting the patient in their inspiration and expiration, ensuring that the patient's oximetry remains regulated.

Mechanical ventilator

The mechanism became known in the 12th century, with it the evolution and study of the subject grew, in 1660, it was discovered that the lungs did not expand because they inflate on their own, but that they are inflated by air and therefore expand; in 1820, the elasticity of the lungs was studied; in 1864, the “steel lung” was created, which was based on the use of negative pressure to expand the lungs; in 1928, the first steel lung was widely used, where changes in pressure in the rotary ventilator occurred through electrical impulses; in 1952, modern mechanical ventilation began, and in 1968, a prototype was used for the study of mechanical ventilation. With this, we can observe that the evolution of the studies grew and the milestones of discoveries began to get closer to each other, which has not changed nowadays, as the aim has always been to improve and comfort the use of patients who have some pathology where it prevents gas exchange from being carried out in a natural way [2,3,4].



With the advancement of studies, several forms and types of ventilators were created, with two forms of application, invasive and non-invasive. Invasive ventilation consists of ventilation that requires the use of an endotracheal tube or a tracheostomy tube, whereas non-invasive ventilation involves the use of a ventilator through a mask [5,6]. The current article will focus on the use of the ventilator through invasive ventilation. In addition to the ways in which the ventilator is used, we have the classification by types of respiratory cycles, which we will see in more detail below in Table 1.

Table 1: Types of ventilation cycles

Types of cycles	How it works
Controlled cycle	All phases are carried out by the ventilator.
Assisted cycle	The patient starts the cycle, but is controlled and terminated by the ventilator.
Spontaneous cycle	The patient is responsible for the trigger, directly influencing the flow received, that is, the beginning, control and end of the cycle is performed by the ventilator.

Source: own authorship



Below we will talk a little about the ventilation modalities and how they are used in Table 2.

Table 2: Ventilation Mode

Ventilation Mode	How it works
(CMV) Controlled ventilation	The ventilator performs all phases of the cycle, being programmed in the equipment each time of the cycle.
(AMV) Assisted ventilation	The ventilator will not perform the cycle alone, but through the patient's inspiration, the ventilator, upon perceiving the reduction in chest pressure, makes the airway pressure drop, thus determining the respiratory rate.
(A/C) Controlled assisted ventilation	This modality has a predetermined respiratory rate, where when the patient has an apnea or drop in respiratory rate, the equipment comes in as a breathing aid.
(SIMV) Synchronized intermittent mandatory ventilation	In this modality, there is a combination of controlled ventilation and spontaneous ventilation, for this to occur, there is a maintenance of the air flow in the circuit through an injection of air.
	This modality is assisted ventilation, where there is constant positive pressure levels in the airway in the inspiratory phase, this flow is only interrupted when the inspiratory flow drops and



(PSV) Pressure support ventilation	the expiratory valve opens. The greater the pressure support, the greater the ventilator's work and the lesser the patient's work.
(PVC) Pressure controlled ventilation	This modality allows the expiratory pressure peak limit. The pressure value is quickly reached and is maintained throughout the patient's inspiratory period.

Source: own authorship

Medicine together with technology has always been growing and developing to bring benefits in all ways and to treat various pathologies, some of which are even incurable, but with the help of some equipment, it manages to reduce symptoms and help our body to fight it. of the pathology. With the Mechanical Ventilator it is no different, especially nowadays where we are facing a virus that especially attacks our lungs, causing fibrosis. Always bearing in mind that the lung is an organ that does not regenerate, which increases caution with the fibrosis generated in it. The ventilator's function is to assist the patient's gas exchange, thus providing life support, as many severe cases of hospitalized patients with COVID-19 are unable to perform this type of "simple" function, which is so necessary to keep us alive [7,8,9,10].

The virus acts as if it were a thrombosis in our lungs, leaving them weak, and often unable to perform their function, with this, the Mechanical Ventilator enters, making the patient able to breathe even if the lung is not supplying their need. vital. What happens is that the oxygen in our organism is a main element for all our vital functions, being extremely important, and if we cannot breathe, our organism will turn off, thus functioning as a fuel [11,12].

With the growth of positive cases of corona virus, the demand for this equipment in the intensive care units (ICU) of all hospitals has increased, but as it is imported equipment and without its own Brazilian manufacture, it generated a lot of despair for professionals in the matter having many patients needing a Mechanical Ventilator and not being able to find the equipment to meet the



health market, with that, many faculties began to study a way to produce equipment that did the same function and to pay for it so that it could meet the necessary demand. , however, many international companies began to develop several models and were gradually meeting the demand of hospitals in beds that still did not have all the necessary equipment for the treatment of a patient tested positive [13].

Types of occurrences [14,15,16,17]:

Around 20% of patients diagnosed with COVID-19 develop the severe form of the disease and may acquire ARDS (acute respiratory distress syndrome) and with this the patient ends up manifesting acute hypoxemic respiratory failure and around 42% to 100% these patients need respiratory assistance.

- Patients with $\leq 93\%$ oxygen saturation or with rapid disease progression or with signs of respiratory distress should be intubated and ventilated for two weeks or more.
- Severe conditions meet the ventilation criteria as the patient starts to present hypoxia (oxygen saturation $\leq 93\%$), tachypnea (≥ 30 breaths/min) or respiratory failure and involvement of more than 50% of the lung parenchyma.
- In the critical stage of the disease, it is possible to visualize ARDS, and even shock and failure of other organs may occur, 30% to 100% of patients in this phase require mechanical ventilation.
- For patients with mild respiratory discomfort, the use of a nasal catheter with low oxygen flow is recommended. Non-invasive mechanical ventilation can be performed when nasal cannula and mask oxygen therapy are ineffective.

With these questions, we decided to show the rapid evolution of the development of these equipments at such a complicated time as the arrival of the COVID-19 virus.

Materials and methods.

This study is an explanatory research, through a literature review. A literature search was carried out in the databases of Scielo, Birene, Medline, Lilacs, Academic Google, HBSCO, published from 2000 to 2021. For the period from March 2020 to March 2021, searches were performed in



the database. NCBI within the central PUBmed. Using the following descriptors: respirators, monitoring, covid-19, history of ventilation, mechanical ventilator, low-cost pulmonary ventilator. In English: respirators, monitoring, covid-19, history of ventilation, low-cost mechanical ventilator. For selection, bibliographies that addressed monitoring of patients, respirators, ventilators, the Covid-19 protocol were considered as inclusion criteria, and all those that did not meet the thematic approach were excluded.

Results and discussion.

Mechanical ventilation over the years has proven its effectiveness and relationship with ICUs. It has been advocated as a highly important strategy for saving and sustaining lives in acute and serious conditions. And after approximately 70 years, this technological resource was highlighted as one of the most important resources in combating the coronavirus pandemic precisely because it is a resource aimed at maintaining the respiratory conditions that were so affected by the lesions of the lung parenchyma caused by Covid-19.

The high demand for ventilators caused by the pandemic context has led to a growing technological, economic and political interest in the acquisition of these equipment. The industry had been improving for some decades on new models with smarter interfaces, touch screens, security mechanisms and integrated monitoring parameters. Another factor that directly contributed to the increase in the supply of this equipment was the initiative and promotion of research centers, universities and companies in the development of respirators, which through research and projects managed to generate low-cost equipment, leaving it open to companies that interested in reproducing these projects for free. It is also worth mentioning that, given this scenario, the National Health Surveillance Agency (ANVISA) issued exceptional guidelines on an urgent basis for regularization of respiratory equipment.

For the technical development of this equipment, several interconnected and codependent steps are necessary. Initially, a company or institution must have its records made with ANVISA, as well as the registration of the product and its sanitary identification upon request, in accordance



with RDC 185/2021. After the legal validations, the testing phases begin in an animal model prepared with validated models of lung lesions. Models that show good reproducibility are generally swine and sheep and must be conducted in accordance with animal research ethics. The final step in the development of the equipment is the execution of clinical tests on humans with prior approval by the Research Ethics Committee and in accordance with Good Clinical Practice in Clinical Research.

The need and urgency of lung respirators in the pandemic context led to the development of several models with very different characteristics, functionalities and costs. Departments of Biomedical Engineering at universities have worked in this direction and further consolidated this professional area in technological development in national and international health. As this is a training that encompasses from fundamentals of physiology to health technology, biomedical engineering has been a central area in times of pandemic, mainly in the production of Personal Protective Equipment (PPE) and low-cost ventilators.

Price comparison

Due to the high demand for respirators to supply Covid-19 cases at the beginning of the pandemic, along with cases that already needed respirators, there was a great demand for the equipment, which led to shortages in several suppliers. With the increase of the dollar and with the borders closed to importation, the products had prices above the market value and with a delivery time much longer than normal. With this, Brazilian universities began to look for ways to develop the equipment, with the aim of lowering production costs and time to meet the necessary demand in the ICUs.

Below we can see a table with the market price comparison in Table 3:

**Table 3:** Price comparison

Period compared	Price	Delivery/Manufacturing Time
Start of pandemic	R\$ 24.320,00 a R\$ 160.00,00	3 to 180 business days
Current period	R\$ 11.400,00 a R\$ 120.000,00	1 to 30 business days
Low cost ventilators	R\$ 1.000,00 a R\$ 3.000,00	2 hours to 5 hours

Source: own authorship

As we can see in the table above, there was a huge drop in relation to the values and times available on the market for supplying ventilators. If there was greater support for research and project financing, as there was in this period when universities sought to develop equipment within Brazil, we could have greater manufacture of other equipment that is imported. Because, as has already been proven, Brazil has all the technology and professionals with sufficient capacity to develop and manufacture the necessary equipment. With that, there would be a drop in the values and time of supply of these equipments, which would also help in the value of the national GDP.

Conclusion.

It was possible to observe that despite the technology in the health area being something that is always in evolution and development, there is still a great delay and lack of resources for research and projects, with the arrival of the pandemic. We can see an acceleration in the development and costing of equipment, which should have happened long before any type of occurrence, which shows us that we would have to predict and be more prepared so that this type of embezzlement of equipment does not happen again in the market, as we have all the technology and competent professionals for these developments national.

Disclosure. The authors report no conflicts of interest in this work.



References.

1. HOLSBAH, L. R. et al. Abordagem de Vigilância Sanitária de Produtos para Saúde Comercializados no Brasil: Sistema de Anestesia. Boletim Informativo de Tecnovigilância, v. ISSN 2178, n. 1, 2012.
2. MARK, B. et al. Bird Mark 7: Avaliação e Evolução Clínica durante sua Utilização*. n. 11, p. 94–97, 2005.
3. MEDEIROS, J. K. B. Weaning from mechanical ventilation in pediatrics Resumo Introdução. ASSOBRAFIR Ciência 2011 Jun;2(1):57-64, v. 2, n. Vm, p. 57–64, 2009.
4. SANTOS, F. R. A. DOS et al. Efeitos da compressão torácica manual versus a manobra de PEEP-ZEEP na complacência do sistema respiratório e na oxigenação de pacientes submetidos à ventilação mecânica invasiva. Revista Brasileira de Terapia Intensiva, v. 21, n. 2, p. 155–161, 2009.
5. NARDELLI, Liliane M. et al. Entendendo os mecanismos determinantes da lesão pulmonar induzida pela ventilação mecânica. Rev. bras. ter. intensiva, São Paulo, v.19, n.4, p.469-474, Dec. 2007. Available from <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0103507X2007000400011&lng=en&nrm=iso>. Access on 23 May 2021. <https://doi.org/10.1590/S0103-507X2007000400011>.
6. Amato MB, Barbas CS, Medeiros DM, Magaldi RB, Schettino GP, Lorenzi-Filho G, et al. Effect of a protective-ventilation strategy on mortality in the acute respiratory distress syndrome. N Engl J Med. 1998;338(6):347-354. <https://doi.org/10.1056/NEJM199802053380602>
7. Amato MB, Meade MO, Slutsky AS, Brochard L, Costa EL, Schoenfeld DA, Stewart TE, Briel M, Talmor D, Mercat A, Richard JC, Carvalho CR, Brower RG. Driving pressure and survival in the acute respiratory distress syndrome. N Engl J Med. 2015 Feb 19;372(8):747-55. doi: 10.1056/NEJMsa1410639. PMID: 25693014.
8. Equipamentos Médico-Hospitalares e o Gerenciamento da Manutenção: capacitação a distância / Ministério da Saúde, Secretaria de Gestão de Investimentos em Saúde, Projeto REFORSUS. – Brasília, DF: Ministério da Saúde, 2002.
9. Electronic Document Format(ABNT)
10. SUZUMURA, Erica Aranha et al . Desafios para o desenvolvimento de ventiladores alternativos de baixo custo durante a pandemia de COVID-19 no Brasil. Rev. bras. ter. intensiva, São Paulo , v. 32, n. 3, p. 444-457, Sept. 2020 . Available from <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0103-



507X2020000300444&lng=en&nrm=iso>. access on 24 May 2021. Epub Oct 12, 2020. <https://doi.org/10.5935/0103-507x.20200075>.

11. Holanda MA, Pinheiro BV. COVID-19 pandemic and mechanical ventilation: facing the present, designing the future. *J Bras Pneumol*. 2020;46(4):e20200282. Disponível em: <http://www.jornaldepneumologia.com.br/how-to-cite/3383/pt-BR>. Acesso em outubro 2021.

12. Suzumura EA, Zazula AD, Moriya HT, Fais CQ, Alvarado AL, Cavalcanti AB, et al. Desafios para o desenvolvimento de ventiladores alternativos de baixo custo. *Rev Bras Ter Intensiva*. 2020;32(3):444-457. Disponível em: <https://doi.org/10.5935/0103-507X.20200075>. Acesso em outubro de 2021

13. Brasil. Agência Nacional de Vigilância Sanitária. Gerência Geral de Tecnologia em Produtos para a Saúde. Coordenação de Pesquisa Clínica em Produtos para a Saúde. Manual para Submissão de Dossiê de Investigação Clínica de Dispositivos Médicos (DICD), Dossiê Específico de Ensaio Clínico e Notificações de Ensaio Clínico. 3a ed. Brasília: Anvisa; 2018. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/plano_acao_pesquisa_clinica_brasil.pdf. Acesso em outubro de 2021

14. SILVA, O. L.; et al. Contribuições da engenharia biomédica da UFABC no combate à COVID. *R. Tecnol. Soc., Curitiba*, v. 16, n. 44, p. 12-22, ed. esp. 2020. Disponível em: <https://periodicos.utfpr.edu.br/rts/article/view/12377>. Acesso em outubro 2021.

15. Três meses depois de anunciar projeto de respirador mais barato, USP diz que faz ultimo teste nesse final de semana. 2020. Disponível em: <https://g1.globo.com/sp/sao-paulo/noticia/2020/06/25/tres-meses-depois-de-anunciar-projeto-de-respirador-mais-barato-usp-diz-que-faz-ultimo-teste-nesse-final-de-semana.ghtml> . Acesso em novembro de 21.

16. Mapa comparativo de preços de ventiladores pulmonares no inicio da pandemia. 2020. Disponível em: <http://www.compras.mg.gov.br/images/stories/arquivoslicitacoes/2020/SEPLAG/07-05-2020/precos-ktk.pdf> . Acesso em novembro 2021.

17. Barbosa LD, Zanatta G, Campiolo EL. O uso de ventiladores na pandemia do COVID-19 The use of ventilators in COVID-19 pandemic Uso de ventiladores na pandemia. *Interam J Med Health* 2020;3:e202003052. 2020. Disponível em: <https://iajmh.emnuvens.com.br/iajmh/article/download/141/171/>. Acesso em novembro 2021.