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Original article

Design and construction of a simplified, gas-driven, pressure-controlled emergency ventilator

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ABSTRACT

Introduction: Due to the COVID-19 crisis or any other mass casualty situation it might be necessary to give artificial ventilation to many affected patients. Contrarily, the worldwide availability of emergency ventilators is still a shortage, especially in developing countries.
Methods: Modes of artificial ventilation were compared and the most safe, easy to use, and lung protecting principle was optimized to fit all requirements of both emergency ventilation and cost-effective mass production.
Results: The presented research results describe a simplified device for a pressure-controlled ventilation which works without electricity according to a known principle. Just pressurized gas and a patient connection is required. The device enables the control of basic ventilator parameters such as peak inspiratory pressure, positive end-expiratory pressure and the ventilation frequency. Further, the device is semiadaptive to the patient's lung stiffness and automatically maintains minute volume through frequency adjustment. The machine can be manufactured by turning, milling and drilling and needs purchased components with costs less than 100 USD. A sterilization and thus a reuse is possible.
Discussion: The presented development does not describe a ready-to-purchase ventilator, it rather outlines a refined working principle for emergency ventilation and its easiest methods of production with a minimum of requirements. The presented research aims on providing an open-source guideline for production of an emergency ventilator using worldwide available methods and thus should inspire local researchers to do a reverse engineering and eventually to put it into operation following country-specific regulations. For long-term ventilation exceeding emergency purposes, a monitoring of alarms for disconnection and violation of desired ventilator parameters should be established. The ventilator is limited to a fixed ratio between PIP and PEEP. Moreover, the ventilation frequency depends on two parameters, which needs some training. Nevertheless, the ventilator provides basic features to enable an emergency ventilation with minimal prerequisites.

African relevance

- Due to the COVID-19 crisis it might be necessary to give artificial ventilation to many affected patients
- We describe a simplified gas-driven, fully mechanical, pressure-controlled emergency ventilator with semiautomatic adjustment of PIP-controlled tidal volume and frequency
- In comparison to existing ventilators, the devised ventilator can be self-manufactured and is hence independent from the availability of purchased ventilators.

Introduction

The COVID19 virus is spread in nearly all countries all over the world [1] with an increasing number of patients at the point of writing (June 2020). Around 5% of those patients develop such severe symptoms, that the impaired pulmonary gas exchange finally leads to the need for external ventilation [2]. Depending on the local resources and the number of severe patients, the number of available intensive care unit respirators and even emergency ventilators could be too low [3] to serve all and thus lose lives due to local technical limits. Motivated by this issue, the authors started research for ventilation principles [4] and

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finally identified a gas-driven, pressure-controlled automatic cycling ventilator as the most robust principle for emergency ventilation in environments with limited resources. The aim of our research was the development of a semiautomatic, easy to use emergency ventilator, that can be produced with a minimum of machines, material and technical knowledge, is robust and works with a driving pressure of compressed oxygen or air for both assisted spontaneous breathing and mandatory ventilation only. Compressed gas (oxygen, air or its mixture) can easily be generated by portable air compressors or provided by pressurized tanks and e.g. a Venturi injector. The paper describes the functionality of the developed emergency ventilator, its potential and limitations. The authors like to stimulate physicians as well as engineers to take this idea, to replicate and to enhance it by e.g. attaching alarms and monitoring devices.

Currently, many emergency ventilators are available on the market [5]. A comprehensive comparison of various transport ventilators is presented by Chipman et al. [6]. Most of modern emergency ventilators are advanced developments that require high-end production methods and end up in costs of 5-digit USD amounts. However, there are a few products that utilize very simple working principles and operate without electricity. The product Go2Vent (Vortran Medical, Sacramento, USA) is a pressure-controlled emergency ventilator made of injection molded plastic. It is intended for single use with a fixed ratio of peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP). The detailed function and evaluation are described by Babic et al. [7]. Go2vent uses a similar principal like the devised ventilator. Instead of the piston used in this paper, Go2vent uses a membrane as control unit. This makes the manufacturing and assembly much more complicated.

Another pressure-controlled ventilator is the Oxylator (CPR Medicial Inc., Canada). This device requires advanced production methods and provides a very low PEEP of 2–4 mbar only [8]. The emergency ventilator Ambu Matic (Ambu GmbH, Bad Nauheim, Germany) provides a volume-controlled ventilation. An external valve must adjust the PEEP.

In the background of the COVID19 pandemic, Pearce provides a review of existing open-source ventilators [9]. Many of the described concepts are based on electrical motors and electronics, cf. [10–14]. Furthermore, many solutions use 3D-printed components, cf. [15,16].

All referred ventilators are either purchased products or open-source products which require some deeper knowledge in electronics or use some high advanced manufacturing methods.

The aim of the present research is to develop a ventilator which is independent of special purchased products, which works without electricity and can be manufactured and assembled with conventional machines. Therefore, various emergency ventilator concepts were analyzed with the focus on manufacturing and operating resources. For this reason, a gas-driven, automatic pressure-controlled ventilator was rated as the most convenient principle, since it automatically adapts the tidal volume to the lung compliance and maintains minute volume through frequency adjustment within given limits. The Vortran Go2Vent already takes advantage of this principle, but requires expensive manufacturing methods of injection molding and the usage of a membrane, which is not available everywhere, hard to assemble and for single-use only.

Methods

Functional principle

Fig. 1 depicts the major components of the device and the functionality during spontaneous and forced inhalation and exhalation. All components which move by themselves are marked red and all springs are green. The pressurized air must be connected to the air interface . The patient is connected to the device via the patient interface ②. The PIP and PEEP can be measured by a manometer ③. The piston ④ is the core of the novel development and the key component of the device. Together with a prestressed spring, the piston controls the pressure during inhalation and exhalation of the patient. Component ⑤ represents the outlet, where a screw controls the number of open holes and thus the volume flow. To protect the patient in case of excessive pressure during adjustment of the device an overpressure valve ⑥ is included. A spontaneous breathing of the patient with continuous positive airway pressure (CPAP) enables valve ⑦.

During inhalation, pressurized air from the bottle (tank) or pressure line can enter the ventilator. A constant flow rate is necessary and realized by integrating a standard oxygen flowmeter in front of the inlet. During inspiration, the pressure increases as long as the prestressed spring with the piston at the end can seal the outlet. As soon as the pneumatic pressure acting on the piston exceeds the prestress of the spring, the piston opens the outlet to allow expiration. The maximum pressure just before outlet opening represents the Peak Inspiratory Pressure (PIP). After the piston releases the outlet, all gas from both sources (supply and patient) can exhaust through the outlet. The exhaust flow rate can be controlled by a screw which clears outflow openings.

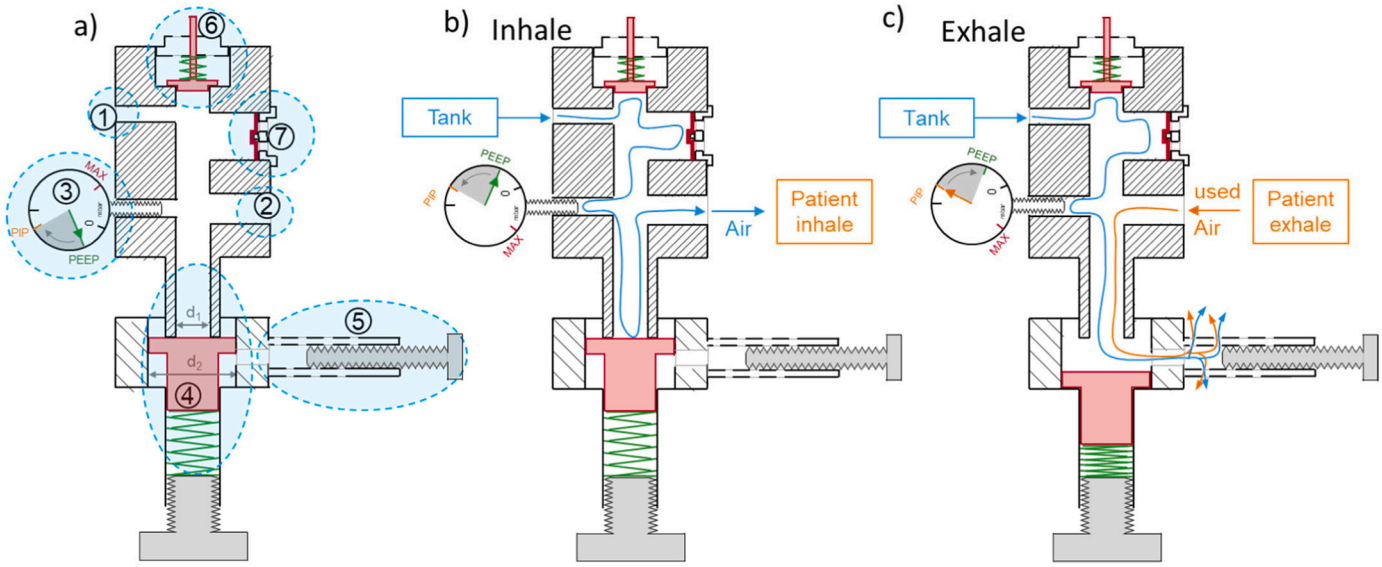

Fig. 1. Components and functional principle of the ventilator, a) pressurized air interface, ② patient interface, ③ manometer, ④ piston, ⑤ outlet, ⑥ overpressure valve, ⑦ spontaneous inhalation valve, b) air flow during inhalation, c) air flow during exhalation.

Due to the movement of the piston, the pressure acting area changes from the diameter d_1 to d_2, see Fig. 1a. The acting force is the product of the pressure and the acting area. If the acting area increases, the force will simultaneously increase. Consequently, a pressure lower than the PIP with a larger area d_2 will lead to the equal force acting on the piston. This hysteresis behavior is used to realize the expiration. The pressure inside the ventilator decreases during expiration. However, the piston will leave the outlet open until the force of the spring and the lowered pressure with the increased area are in balance. At this moment, the piston seals the outlet and the process automatically repeats.

Given this functional principle, it is possible to modify the PIP through prestressing the piston spring. This can be done by the screw at the bottom end. The PEEP can be controlled by the ratio of d_1 to d_2. The screw in the outlet controls the output flow rate and thus the exhalation time and ventilation frequency.

Due to the importance of the piston, it is mandatory to enable a proper function of this component. This means that the piston does not stick in the upper or lower position and is guided with a minimum tolerance to prevent tilting.

Materials

From the mechanical view it is possible to manufacture all components out of plastics or metals. The material must be biocompatible, non-corrosive, oxygen resistant and temperature resistant up to 130 °C for sterilization. Plastics should have a medical grade and should be free from additives such as plasticizer, antioxidants or stabilizers. Possible plastics are polyethylene (PE), polypropylene (PP), polyethylene terephthalate (PET), polyvinylchloride (PVC), polycarbonate (PC), polytetrafluoroethylene (PTFE) or polyoxymethylene (POM). In case of metals it is suitable to use stainless steel like 1.4301 or 1.4401.

Features

Additional to the ventilation as basic function, the device also enables auxiliary features. Fig. 2 depicts these two functions. The first feature is a protection in case of a dysfunction of the device or the attached tubes. Therefore, an overpressure valve is included. This valve opens if the pressure reaches a maximum value. The pressure will decrease after the opening of the valve. A pretension of a spring adjusts the maximum pressure. In the second feature, a simple membrane allows spontaneous breathing through opening with any outflow (suction) that exceeds the gas supply flow and is permanently closed if the patient does not breath spontaneously. This means that the patient can inhale at a higher flow rate than provided by the gas interface and thus receives inspirational support comparable to Assisted Spontaneous Breathing or Pressure Support Ventilation. During exhalation, the membrane closes and the patient exhales through the resistance of the adjustable outlet.

It is possible to disassemble the ventilator and to sterilize all components. Afterwards, the device can be reused.

Manufacturing

The entire ventilator can be manufactured by hand-driven turning, milling and drilling machines. Additionally, it is necessary to drill some bore holes and to thread. The key point in manufacturing is the sliding guide of the piston. First, it is crucial to ensure the gap between the piston and the guide is large enough to enable a nearly frictionless movement of the piston. Second, the gap should be as small as possible to prevent a tilting of the piston. A tilting of the piston will lead to leakage and hence to a dysfunction of the ventilator.

Test procedure

Fig. 3 shows in subfigure a) a CAD-Model of the ventilator and in subfigure b) the test setup. The manufactured prototype has the dimensions 300 mm × 200 mm × 60 mm and a weight of 1.04 kg (including manometer).

During testing, the pressure in the system was measured by an electronical pressure sensor (Model 239, Setra Systems, Inc., USA). The aim of the test series was to measure the pressures PIP and PEEP and the ventilation frequencies using different input air flow rates and different diameters d_1. The pressurized air was provided by a tank and the input air flow rate was controlled by a flowmeter with included pressure regulator (model Ergo SELECT, VTI Ventil Technik GmbH, Menden, Germany). The patient was simulated by a lung dummy with a volume of 600 ml, a compliance of 50 ml/cmH_2O and a resistance of 20 cmH_2O/L/S (model head Star, Taipei, Taiwan).

The test series were done under an ambient pressure of 978 mbar, room temperature of 20 °C and using a diameter d_2 of 34.9 mm.

Two test series were performed. The first series analyzed the range of the frequency under a set PIP of 20 mbar. The frequency was modified by the screw in the outlet. This was done for different flow rates and diameters d_1. A second test series analyzed the range of minimum and

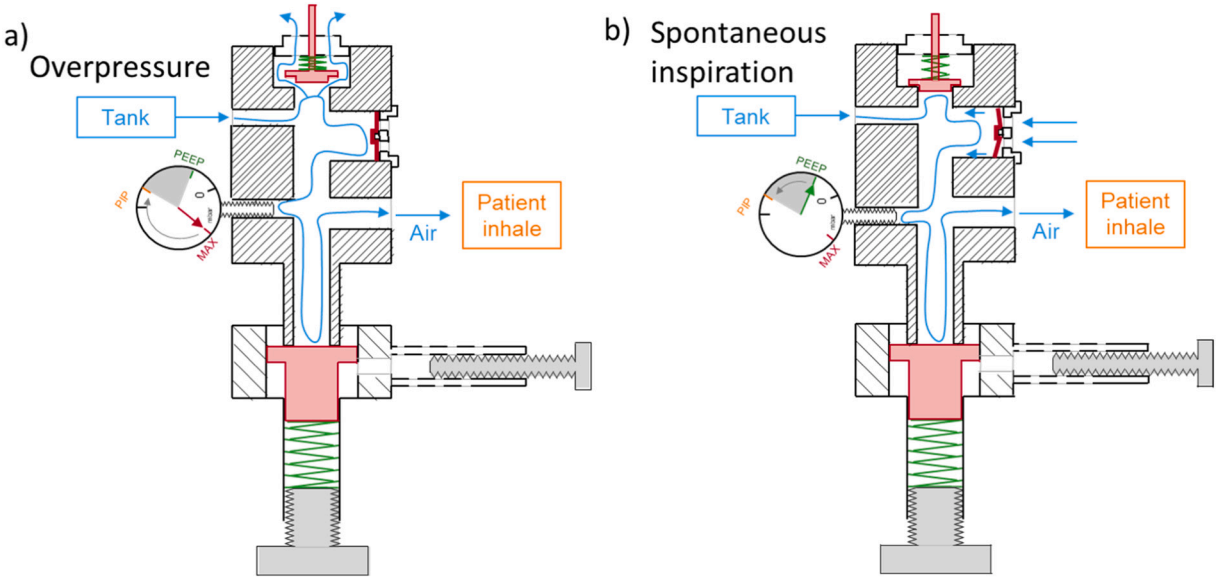

Fig. 2. Additional features of the ventilator a) function of the overpressure valve, b) function of the spontaneous inhalation valve.

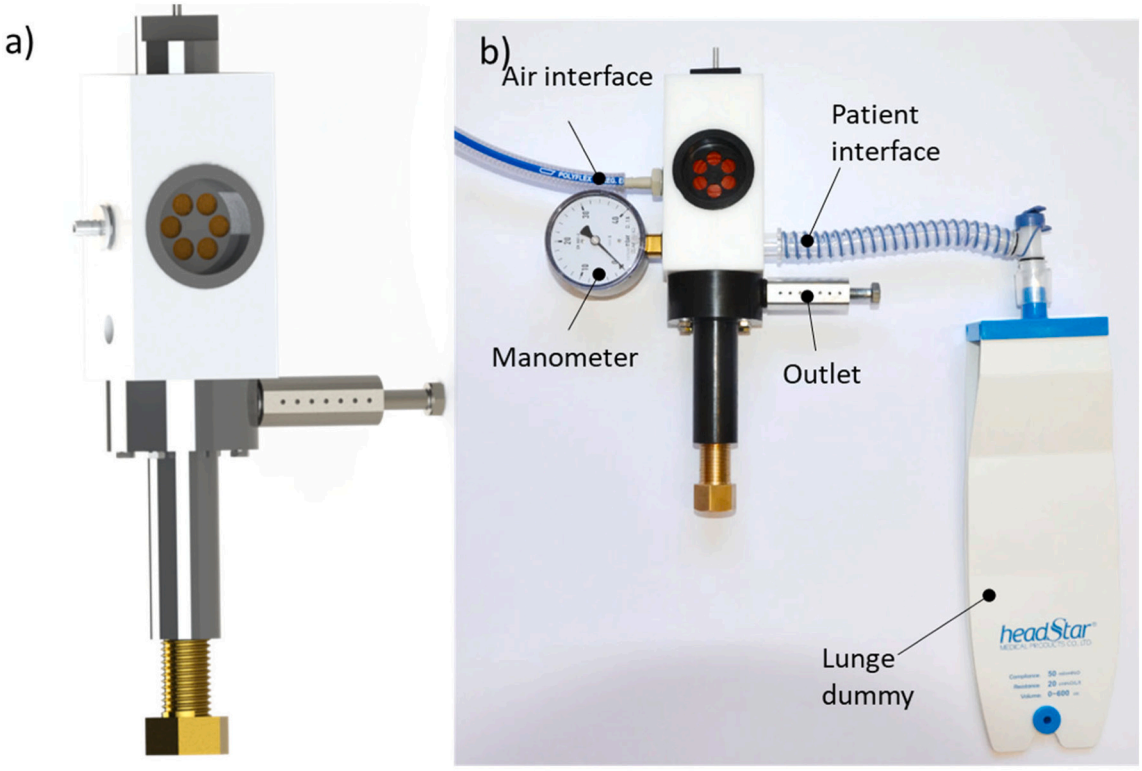

Fig. 3. a) CAD-model, b) ventilator with assembled air and patient interface.

maximum PIP values. The frequency was adjusted to reach the minimum and maximum PIP limits. Only useful PIP values less than 45 mbar were adjusted. This was also performed for different flow rates and diameters d_1. The test duration was 60 s for determining the frequency and the mean values for PIP and PEEP.

Results

Fig. 4 shows three measurements with three different diameters d_1. Each measurement was adjusted to the same PIP value of nearly 21 mbar. All curves depict almost a triangular shape. The plateau during inspiration and expiration results from the pleats of the used lung dummy. The results indicate that the PEEP value increases with an increasing diameter d_1. This means, if the ratio of the diameters d_1/d_2 and hence of the areas A_1/A_2 increase, then the ratio of the pressures PEEP/PIP also increases. In this example, the diameter $d_1 = 6.8$ mm shows a PEEP of 4 mbar, the diameter $d_1 = 8.5$ mm leads to a PEEP of around 5 mbar and the diameter $d_1 = 11$ mm to a PEEP of 6.5 mbar. The change of d_1 also modifies the ventilation frequency at fixed outlet screw position. With an increasing diameter, the frequency rises as well. From 7.5 breaths per minute (bpm) ($d_1 = 6.8$ mm) to 10.3 bpm ($d_1 = 8.5$ mm) and to 10.8 bpm ($d_1 = 11$ mm).

Table 1 sums up the major test results of the two test series. The influencing parameters are the diameter d_1 and the input air flow rate. Each of the three input diameters was tested with four input flow rates between 8 l/min and 25 l/min. Every combination was adjusted to a PIP of 20 mbar and the minimal and maximal ventilation frequency was measured. This is shown in column three and four. For the smallest

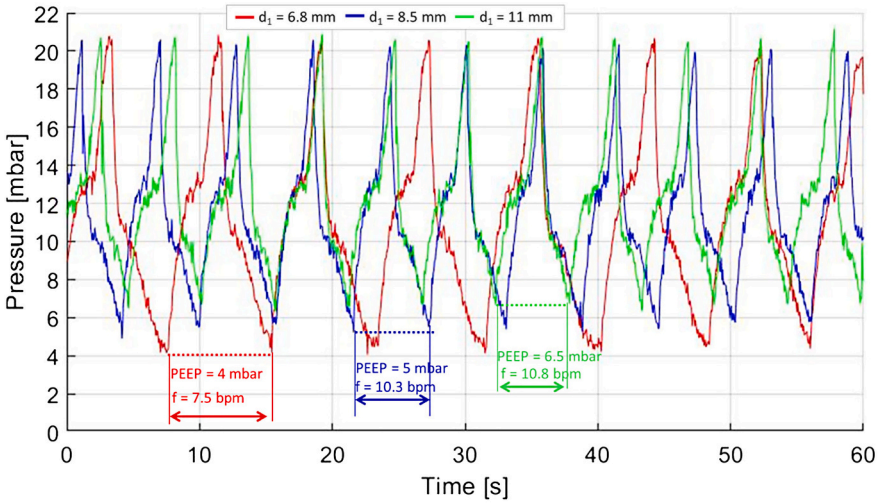

Fig. 4. Pressure vs. time diagram of three representative modifications.

Table 1
Overview over the main test results.

Parameters		Test series 1		Test series 2		Sensitivity
d_1 [mm]	Flow rate [l/min]	PIP = 20 mbar		PEEP:PIP [mbar]		PIP by piston screw [mbar/rotation]
		f_{min} [bpm]	f_{max} [bpm]	Min	Max	
6.8	8	4.8	7	3:10.5 f = 16 [bpm]	3:10.5 f = 17 [bpm]	4.55
	12	6	7.5	4:20 f = 7.5 [bpm]	10:36 f = 12.3	3.85
	15	7	7.8	6:20 f = 7.8 [bpm]	10:37 f = 9.9 [bpm]	5
	25	Not possible to reach 20 mbar		8:38 f = 10.5 [bpm]	8:38 f = 10.5 [bpm]	Not possible to calculate
8.5	8	7	7	3:11 f = 14 [bpm]	12:37 f = 16 [bpm]	3.7
	12	7	10.5	3:12 f = 15.3 [bpm]	12:36 f = 16 [bpm]	3.33
	15	9	11.5	4:13 f = 12.5 [bpm]	12:40 f = 16 [bpm]	3.7
	25	12	12	5:18 f = 13 [bpm]	12:42 f = 11 [bpm]	5
11	8	4.5	7.2	3:9 f = 17.3 [bpm]	14:33 f = 5 [bpm]	2.44
	12	7.3	10.9	4:13 f = 14 [bpm]	13:37 f = 14.5 [bpm]	3.45
	15	9	13	5:14 f = 11.5 [bpm]	14:40 f = 19 [bpm]	3.57
	25	14	14	6:20 f = 14 [bpm]	15:38 f = 16 [bpm]	3.12

diameter d_1 = 6.8 mm it was not possible to reach a PIP less than 38 mbar. Overall, the frequency increases with an increasing flow rate and an increasing acting pressure diameter d_1. A healthy adult breathing rate under normal conditions is between 12 bpm and 20 bpm [17–20]. The last two columns show the minimum and maximum PEEP and PIP and the corresponding frequency. Thus, the adjustment range is shown. In reference to [21] the PIP should be less than 30 mbar. The position of the piston screw was also documented to calculate the sensitivity to regulate the PIP. This is shown in the last column. Sensitivities between 2.5 mbar/rotation and 5 mbar/rotation were measured.

Discussion

The experiments show that the emergency ventilator enables frequencies as well as PIP and PEEP values which are in the target range for a ventilation [22]. A d_1 of 11 mm and a flow rate of 15 l/min provides the most suitable setting for a broad range of emergency ventilation requirements for adults. The mean value of the PIP sensitivity is about 3.8 mbar/rotation. The used prototype has a pitch of 1.5 mm/rotation for the screw. Thus, the value can be decreased by using a lower pitch.

Comparison to other low-cost ventilators

Mertz describes in [23] some low-cost ventilators with similar functions. The Illinois RapidVent ventilator represents a low-cost emergency ventilator [24]. The working principle has the same main idea like the devised ventilator and is quite analogue to the Go2vent ventilator [7]. Additionally, the Illinois RapidVent provides some pressure sensors to control PIP and PEEP. The main difference is that our developed ventilator uses a piston instead of a membrane and that it is made by common manufacturing processes. The Go2vent as well as the Illinois RapidVent are assembled out of injection molding components respectively 3D-printed parts. Thus, expensive molds and an injection molding machine or 3D-pinters are mandatory. In conclusion, the Go2vent and the Illinois RapidVent are nearly equal commercial devices and require much more effort in manufacturing and assembly by providing the same functions and nearly equal limitations as the devised ventilator. In contrast, our more rugged piston-driven model is an open-source development for most easy production worldwide.

Limitations

The simplicity of the ventilator comes along with some limitations. These are limitations compared to current high-end ventilators. The ratio between PEEP and PIP is a fixed value of the devised ventilator. A modification of this ratio during ventilation is not possible in the current design. The ratio can be changed by emerging the insert for d_1. A set of e. g. two to maximum three inserts with different diameters could be produced and assembled. Different ventilation pressures required during longer emergency use (until an intensive care ventilator is available) could be addressed through quickly exchanging the whole ventilator against another one with alternative diameters d_1, since exchanging the insert requires a bit more time. To speed-up the substitution of the insert, it could be useful to use a kind of turret. Another limitation is the manageability of the ventilator frequency. The frequency must be adjusted by the input air flow and the screw in the outlet. It is necessary to adjust both to get the desired frequency which needs some training. This challenge can easily be solved by defining a fixed air flow rate and establishing frequency marks at the outlet screw. Another characteristic is that the air flow continues during inhalation and exhalation. Hence, compressed gas is also consumed during exhalation.

Improvements

The presented device is a most basic version for an emergency ventilator with semiautomatic adjustment of pressure-frequency relation towards an almost constant minute ventilation. In case successful mass production can be ensured, multiple options for improvements can be added: The use of oxygen can be reduced by using a Venturi injector at the gas inlet interface [25,26]. Simultaneously, the oxygen ratio could be reduced to a value below 100%, e. g. 50%. Another helpful component would be a disposable Heat and Moisture Exchange (HME) filter

between the ventilator and the patient which separates water from expired gas. This prevents dehydration of the patient and adds hygienic safety. For a long-time ventilation it is useful to integrate alarms. For example, the overpressure valve could be combined with a whistle to give an acoustic signal in case of a dysfunction.

Purchased components

Significant additional value is added by completing the ventilator with some purchased components. In the air and patient interface some nozzles should be mounted. Here it is meaningful to use threads according to the available nozzles. A manometer should monitor the PIP and PEEP. Therefore, a manometer with a measurement range from 0 mbar to 40 mbar is recommended. Further, two springs, six screws and a simple membrane are needed. The supplementary material describes necessary technical parameters of purchased components. Thus, it is possible to use similar components, which are locally available. Overall, the purchased components cost less than 100 USD.

Conclusion

Our research results describe a simplified gas-driven, fully mechanical, pressure-controlled emergency ventilator with semiautomatic adjustment of PIP-controlled tidal volume and frequency. The operating power comes from pressurized breathing gas. Lack of electronics and the developed piston-driven principle add endurance and thus safety in remote areas. Another characteristic is the easy manufacturing process. The device can be manufactured by hand-driven milling, turning and drilling machines. The detailed design should be adapted to the manufacturing machines, materials and purchased components which are locally available. Exemplarily, the dimensions of the housing or the threads should always be adapted in a way that the manufacturing can be done easy and repeatable. The functionality is independent of the used material.

In comparison to existing ventilators, the devised ventilator can be self-manufactured and is hence independent from the availability of purchased ventilators. The manufacturing and assembly can be done with some basic machines and a basic experience in engineering.

Overall, the paper describes the functionality and the basic influencing parameters of the ventilator. To adjust the device to the local needs and infrastructure, comprehensive supplementary material is provided.

Dissemination of results

The achievements of this research were presented to medical scientists in the field of emergency medicine and artificial ventilation. Simultaneously, the device was presented to scholarship holders from all over the world to learn about the conditions in hospitals in their countries.

CRediT authorship contribution statement

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: RS contributed 20%; RT 20%; AW 30%; and AF, FR and MK contributed 10% each. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Declaration of competing interest

The authors declared no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.afjem.2020.09.018.

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