

Are ventilators safe to prevent accidental lung trauma?

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Citation

J Mulie, T Deckmyn, S Cnudde. *Are ventilators safe to prevent accidental lung trauma?*. The Internet Journal of Anesthesiology. 2009 Volume 22 Number 2.

Abstract

It is well recognised that sometimes an anaesthetist forget to switch from breathing bag mode to mechanical ventilation. Technical valve errors, occluded expiratory tubing can happen also. The goal of this study was to evaluate the performance of eight ventilators in the breathing bag mode without compressing the breathing bag with an APL valve and an alarm set at their maximum value. The airway pressure and the time it took for the alarm to sound were measured. An American breathing bag was connected. Fresh gas flow was set at 12 litres per minute. Each ventilator was connected to an artificial lung. And a compliance of 23 ml/cmH₂O. A ventilator was considered at risk if the artificial lung inflated above 20 cmH₂O for more than 5 seconds. It was considered dangerous if no alarm did go off in that time. All ventilators were considered at risk and most considered dangerous.

MEETINGS AT WHICH THE WORK HAS BEEN PRESENTED

NYSSA 59th Annual Postgraduate Assembly, 9-13 December 2005, New York, NY. Poster Presentation: Are ventilators safe to prevent accidental lung trauma? J. P. Mulier.

ESA, Madrid, Spain, 6 June 2006. Abstract W 000101: Why is accidental lung trauma possible? J.P. Mulier.

INTRODUCTION

The adjustable pressure limiting (APL) valve on a ventilator has existed for a long time. The APL valve protects against high airway pressures if adjusted properly but not against volutrauma. Volutrauma is a prolonged state of moderately increased airway pressure causing hyperinflation with edema of the lungs (1,2,3) and biotrauma, which is the release of cytokinines from the lungs causing damage to other organs (4). The pressure at which the APL valve opens can be varied from 0 to 75 cmH₂O. Frequently, the APL is turned to its maximum to facilitate manual ventilation. However, having the APL valve turned to the maximum value can reduce safety of the ventilator and increases the risk of volutrauma and barotrauma. All modern ventilators have a required internal pressure limit of 75 cmH₂O, but this is too high to even prevent barotrauma.

At induction of anaesthesia, the fresh gas flow is set to a high flow to further improve face mask ventilation. This

manual mode, using a high fresh gas flow and an almost closed APL valve, is dangerous after connecting the ventilator to the endotracheal tube if the anesthetist is disturbed in giving further manual compression or in starting the ventilator in an automatic ventilation mode.

The risk of barotrauma with ventilators is well-known but not specific to the APL valve only. Previous publications describe the danger of high pressures during normal ventilation (5,6,7) or during mechanical problems that cause high airway pressures (8,9,10,11,12,13,14,15).

Most ventilators have an airway pressure monitor that gives an alarm when the pressure exceeds a preset value. Some have also a high peep alarm or a high-sustained pressure alarm. The monitor can have also an extra high-pressure alarm. However, these alarms do not open a safety valve. Airway pressure can rise very fast depending on the fresh gas flow, the size of the breathing balloon and its compliance, and the size of the lungs and their compliance. Insufflating the lung above its lung capacity causes volutrauma. At pressure above 30 cmH₂O, the alveoli might get a barotrauma. High airway resistance can initially protect the alveoli but pressure will rapidly equalize. Low total lung compliance will protect the lungs from hyperinflation.

Lungs of children and healthy ASA I and II patients, however, have a high compliance and will be already hyperinflated with an airway pressure of 20 cmH₂O. A prolonged period of increased intra-thoracic pressure

obstructs venous return and can be very deleterious for the hemodynamic output and the organ perfusion.

These situations are rarely reported but occur frequently. Cases of barotrauma are not frequent but are reported in the closed claims database when patients have died. Most anesthetists have seen a breathing bag being inflated to a large volume with an increased airway pressure before action was taken to correct the problem. The lungs are always overinflated in this situation unless the lungs have a very low compliance. A high airway resistance protects the alveoli during high inspiratory flow ventilation but is less active during a relatively slow lung inflation of 12 litres per minute. As the breathing bag is distending, alveolar distension and damage is taking place. A human mistake or a technical error is always possible.

High-workload, high-stress, and high-risk environments, such as operating rooms increase the risk of human error. Human factor engineering (HFE) is the application of knowledge about human characteristics and abilities (physical, emotional, and intellectual) to the design and the development of medical devices and would improve patient safety. HFE reveals that at the induction of anesthesia, a dangerous combination exists. The anesthetist must change the ventilation mode from manual to mechanical ventilation in a stressful moment of the induction, while the fresh gas flow is high and the APL valve almost closed. This change can be made in some ventilators by turning one heavy knob. Some ventilators, like the Aestiva 5 from Ohmeda, do not start if this knob is turned on before the electric power is switched on. In this situation, good design keeps the manual system open preventing volutrauma. Other ventilators require pressing one or two switches twice. On these machines, double clicking too fast can result in no action. Older ventilators require the operator to change two knobs, one mechanical and one starting the electric circuit. The human risk factor in all these situations is that the user might assume that the correct mode was started, while the ventilator may have remained in the breathing bag mode without manual compression.

A second human risk factor exists when two anesthetists work together during induction. One anesthetist may connect the endotracheal tube to the ventilator, assuming that the other would start the correct ventilation mode. Rigorous rules might be set that would require the person who connects a patient to the ventilator to set the ventilator to the correct mode.

A third human risk factor exists when the anesthetist forgets to change the ventilation from breathing bag mode to mechanical ventilation. It is possible that after a difficult intubation or other distracting event, the anesthetist might forget that the ventilation mode had not yet been changed. If alarms were to go off immediately, the anesthetist will be warned. When the alarms are set to high values, no alarm may warn the anesthetist in time.

A last human risk factor exists when the anesthetist cannot see the ventilator while performing the intubation. The ventilator may be out of the line of vision of the anesthetist during induction, drapes may be hanging over the ventilator, the anesthetist may be standing between patient and the ventilator, or surgical procedures on the head may require the ventilator to face the opposite direction. In any of these situations, the anesthetist cannot immediately verify the ventilator settings. This increases the danger of staying in breathing bag mode without an operator compressing the manual breathing bag.

The goal of this study was to evaluate the behaviour of commonly used ventilators in the breathing bag mode. Ventilators were tested without manual compression using a standardized fresh gas flow, APL setting, breathing bag and artificial lung. We investigated the following questions: what airway pressure would the patient experience, and what would the ventilator do? Would an alarm go off in time?

MATERIALS AND METHODS

Eight different ventilators were evaluated with an artificial lung. The airway pressure was measured and the time at which an alarm went off. The artificial lung consisted of a “Pulmo-Sim” test lung from Blease with a maximum capacity of 1.2 L. The compliance was variable and was set at 23 ml/cmH₂O, which is a common value for healthy adults during anaesthesia. The resistance and leakage were set to zero. A latex-free disposable American breathing bag (2 L volume; Vital Signs, Inc.) was connected to all ventilators.

First, the compliance of the American breathing bag was measured and compared with the compliance of a latex-free autoclavable, reusable European breathing bag (2 and 3 L volume; C.H. Medical Ltd.). Compliance of standard black rubber breathing balloons (2 and 3 L volume) were also measured.

Next, each ventilator was tested with the American (2 L) breathing bag and the Pulmo test lung. The fresh gas flow was set at 12 liters per minute, which is the maximum flow

in modern anaesthesia ventilators. Mechanical fresh gas flow valves allow very high gas flow more than 30 L, which would increase the risk further.

The 2 L breathing bag filled in 10 seconds without a rise in pressure. Then the Pulmo test lung filled in 6 seconds, with a pressure change according to the compliance of the test lung. When the test lung was maximally filled, the total compliance became very small. The pressure rapidly increased above the peak inflation pressure. It was difficult to measure when total lung capacity was reached. This pressure point depends on the lung compliance. With a high compliance, a pressure of 20 cmH₂O might indicate a maximum lung filling or hyperinflation. After 5 seconds, an extra 1000 ml was blown in the breathing bag and into the lungs, causing an over-distension of the lungs. This distension would certainly damage the lungs.

Therefore a ventilator was assumed to be at risk if no alarm went off or no valve opened within 5 seconds after reaching a pressure of 20 cmH₂O. An alarm in the first 5 seconds after the pressure reached 20 cmH₂O should be ideal to prevent this damage.

The APL valve and the pressure alarm were set at their maximum level. The same American breathing bag was connected to the manual system of the different ventilators. The pressure was recorded with a pressure transducer and a Datex-Ohmeda Inc monitor S/5 connected to the artificial lung and converted to cmH₂O.

The following ventilators from Datex-Ohmeda Inc. were evaluated: The Excel 210 SE, The Excel 410, the Datex ADU and the Aestiva 5. The following ventilators from Drägerwerk AG were also evaluated: the Dräger Titus, the Dräger Cato and the Dräger Julian. The following ventilator from Medec was evaluated: The Neptune. These ventilators do not allow the setting of a peep in the manual or in the spontaneous mode. Therefore peep was always kept at the zero level.

Each ventilator was switched on and set in the breathing bag mode. The fresh gas flow was closed. The APL valve and the airway pressure alarm were set to their maximum level. The artificial lung was connected to the ventilator. The manual breathing bag was always emptied before the start of each experiment. At time zero the fresh gas flow was opened to 12 L per minute. A high frequency pulse was given on the pressure transducer at the same time to note the exact zero time. The airway pressure was continuously monitored, and

a high frequency pulse on the pressure transducer noted the times at which the alarms went off. The type of alarm was noted in the records. The recording was stopped after 60 seconds.

A ventilator was considered at risk if the airway pressure was more than 20 cmH₂O for more than 5 seconds; the ventilator was considered dangerous if no alarm went off during that time.

RESULTS

Figure 1 shows the compliance of the 2 L American type breathing bag, the 2 and 3 L European type breathing bags and the standard black rubber 2 and 3 L breathing bags as pressure versus volume. The maximum pressure in the ventilator circuit was determined by the compliance of the breathing bag. The European 2 L breathing bag had a maximum pressure of 55 cmH₂O at 5 L. The American 2 L breathing bag had a maximum pressure of 33 cmH₂O at 5.5 L.

Figure 1

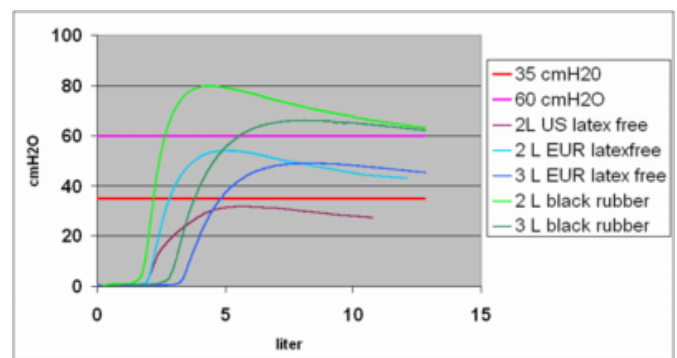


Figure 2 shows the results of a ventilator with a maximum number of alarms, the Aestiva, and the results of a ventilator with the least number of alarms, the Julian. Airway pressure in cmH₂O was traced against time in seconds. All traces start at time zero. The first pulse at time zero was eliminated from the figure to improve clarity. Note the moment of an alarm indicated by a pressure pulse.

Figure 2

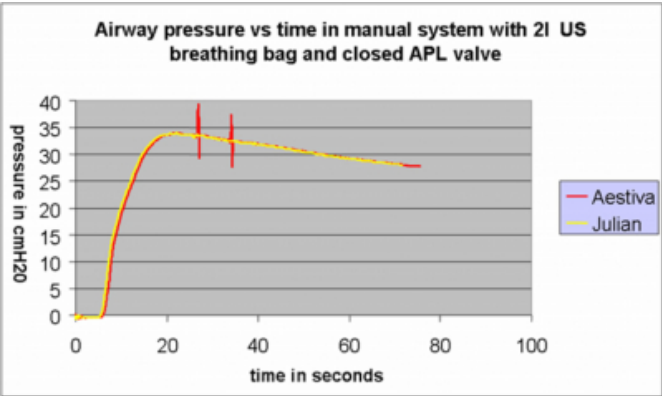


Table 1 shows the results for all ventilators analyzed. The APL and the alarm settings are given in columns 2 and 3. The first alarm that went off is noted in column 4, while the time between the moment the airway pressure reached 20 cmH₂O and the first alarm is given in column 5. Later alarms are noted in column 6 without time indication. The last column describes the risk profile for every ventilator.

Figure 3

Ventilator type	APL valve setting	alarm setting	first alarm	time to first alarm	later alarms	Risk profile
excel 210 SE	75 cmH ₂ O	100 cmH ₂ O	sustained pressure	17 sec	apnoe	dangerous
excel 410	75 cmH ₂ O	100 cmH ₂ O	sustained pressure	18 sec		dangerous
datex as3	80 cmH ₂ O	80 cmH ₂ O	high peep	5 sec		At risk
aestiva 5	70 cmH ₂ O	99 cmH ₂ O	apnoe	17 sec	sustained pressure	dangerous
dräger titus	70 cmH ₂ O	98 cmH ₂ O	no alarm			dangerous
dräger calo	70 cmH ₂ O	98 cmH ₂ O	no alarm			dangerous
Medec neptune	70 cmH ₂ O	70 cmH ₂ O	high pressure	3 sec		At risk
dräger julian	70 cmH ₂ O	98 cmH ₂ O	no alarm			dangerous

Every ventilator was considered at risk, and most are dangerous. No ventilator opened a valve, even late, to protect the patient. Most ventilators had an alarm that sounded very late and some ventilators had even never an alarm.

Other ventilators that were not investigated here are comparable in structure to those studied here and are therefore likely also not safe. Ventilators used at intensive care units have no manual system and are therefore safer but are not investigated here.

DISCUSSION

Real lungs will react differently than the artificial lung. The artificial lung was small and has a fixed compliance. However when pressure reaches 20 cmH₂O the reactions of different ventilators will not be different. The size of the breathing bag of the manual system and its compliance are

more important. Breathing bags with different size and compliance can be used. Johnstone(16) stated in 1973 that breathing bags can act as pressure-limiting devices. The American National Standard for Anesthetic equipment-Reservoir Bags ANSI Z79.4 of 1983 (17) states that each bag with a volume greater than 1.5 L should not exceed a pressure of 35 cmH₂O when expanded to twice its volume, and at six times its volume the pressure should not exceed 60 cmH₂O. As a result, in the USA, very compliant breathing bags are used.

Volutrauma is still possible in very compliant lungs with a low airway resistance when pressure is continuously above 20 cmH₂O. In Europe, where no standard for reservoir bags exists, most anesthetists prefer less compliant breathing bags, provided by the ventilator company or by third parties like those from C.H. Medical Ltd. These European latex-free balloons are more compliant than the older black rubber balloons, where pressure can rise easily above 60 cmH₂O. The 2 and 3 L European balloons do not comply with the ANSI requirement. At twice their uninflated volume, the 2 L balloon from C.H.Medical Ltd reaches a pressure of 46 cmH₂O, while the 3 L balloon reaches a pressure of 52 cmH₂O, far above the 42 cmH₂O limit.

Every anesthetist is aware of the risks of connecting a patient to a ventilator without using the appropriate ventilation mode. When an alarm goes off, the anesthetist can react to correct the problem. Many anesthetists use their own safety precautions to prevent both volutrauma and barotrauma. Some anesthetists always use a very large balloon while others use a balloon with a hole requiring fingertip occlusion to increase pressure, and thus will never create unattended rises in pressure. Balloons with a hole are no longer produced because of problems connecting a scavenging system to it. Some anesthetists will never change personnel during the induction of anesthesia and patient positioning, preferring to have the same person connect the patient to the ventilator and start the ventilator. Correct alarm and APL settings may provide earlier warnings but can not prevent volutrauma. Below 20 cm H₂O, manual face mask ventilation is frequently insufficient, and correct alarms will go off continuously during face mask ventilation.

Only continuous vigilance, not only a correct alarm or APL setting, can prevent volutrauma. Continuous vigilance by an anesthetist in direct contact with the patient is mandatory in most countries. However, better precautions should still be taken if possible.

In 2000, Weinger (18) suggested the use of HFE for the design and development of medical tools and devices. Weinger stated that many anesthetists forgot to coordinate the settings of the manual 'bag/ventilator' selector switch and the APL, which determines whether a mechanical ventilator is attached to the breathing circuit or if the clinician must continue to manually ventilate the patient. As a result, the patient would not receive any breaths and might get a volutrauma of his lungs.

One can discuss the artificial limit of 20 cmH₂O and 5 seconds as being dangerous. No clear answer exists regarding an acceptable pressure and time that would not be deleterious for the lungs. No exact pressure exists under which no lung trauma will occur. The old ANSI standard of 1983 took 35 cmH₂O at two times the balloon volume, allowing still higher pressures at larger volumes. The ventilator is known to be potentially dangerous under many circumstances as mentioned by Kolobow (2) in 2001. Volutrauma, however, is more important than barotrauma today. Inflation above the total lung capacity is more dangerous than inflation to a high pressure with a small lung volume as first mentioned by Dreyfuss (19) in 1992. In patients with adult respiratory distress syndrome or those with a stiff thorax or stiff lungs, prolonged pressures of 20 cmH₂O might not be dangerous. Most healthy lungs have peak pressures during ventilation far below 20 cmH₂O, suggesting that inflation above 20 cmH₂O might hyperinflate and damage the lungs. If we take the risk of biotrauma (4) into account, then every pressure increase during ventilation can be damaging.

In children, it is clear that airway pressures or lung volumes above normal physiologic values are always bad for the lungs. A new safety system should not only limit the pressure rise after a certain time, it should certainly limit the volume expansion of the lungs by allowing a total deflation. The actual proposed limit in the ventilators of 75 cmH₂O and in the American breathing bags of 35 cmH₂O is far too high and certainly dangerous in many patients.

Z Fu and JB West found in anesthetized rabbits that the capillary permeability increased significant at high states of lung inflation. The number of endothelial and epithelium breaks per millimeter cell lining increased significant from 0.7 and 0.9 to 7.1 and 8.5 when they increased the longvolume by increasing the transpulmonary pressure from 5 to 20 cmH₂O for the same transmural capillary pressure. (20)

More reports of barotraumas exist in animal anesthesia because of lower equipment quality, less training required, fewer legal restrictions or legal consequences of reporting problems. Reluctance to publish adverse events restricts human examples. In Belgium, two closed claims exist of patient death due to barotrauma by the ventilator.

There are many ventilators that are not evaluated, although no indication exists that their construction has a safer design. There was no difference in safety between the older and the newer ventilators other than an improvement of the knob design to change from manual to automatic. Since 1983, the USA has required more compliant breathing bags while the rest of the world has continued to use breathing bags with compliance ranging between that of the American and the older black rubber balloons.

No investigated ventilator with the American breathing bag meets the safe conditions regarding the reached pressure and the alarms. They all, therefore, can be considered at risk or dangerous. If a better safety valve existed, these dangerous situations might never occur. A safety valve with a memory could open at a lower pressure than the APL valve if the dangerous pressure exists longer than the maximum possible inspiratory time. Ventilation frequency below 6 breaths per minute and PEEP above 20 cmH₂O are rarely used. Manual ventilation with a balloon can never give continuously high pressure. When a breathing bag is almost empty, one needs to release the pressure for a short period to refill the breathing bag.

We end with the suggestion that such a safety device should be built and should be used on every ventilator. This system should be mounted in the breathing circuit or in the manual circuit connecting to the breathing bag, but preferable close to the patient to protect him or her in all conditions. Ideally, it must work in all conditions and positions, and it must not interfere with all normal manual and automatic ventilation modes. It should always be active or should switch on and off automatically.

Future studies with such a device could determine whether prolonged airway pressure restrictions would be beneficial, but such studies would be very difficult to set up. Animal studies would be extremely useful, assuming lung physiology is comparable. A system that lowers pressure over the time and still allows for manual and mechanical ventilation would be an improvement for all anaesthesia ventilators.

CONCLUSION

A ventilator was considered at risk if the artificial lung was inflated over its maximum volume or has a pressure above 20 cmH₂O for more than 5 seconds. Ventilators were considered dangerous if no alarm went off during that time. All ventilators analyzed were at risk. Correct alarm settings and vigilance remain the cornerstones of safety. Changing the alarms is not enough to improve the safety. If possible, every ventilator, certainly those with a manual breathing bag should be technically protected using human factor analysis to prevent these dangerous situations.

ACKNOWLEDGMENTS

AZ-St-Jan-AV Brugge and A.Z. St-Lucas Brugge for the use of their ventilators in the operating room.

Rene Heylen M.D.,Ph.D. for the reference of two closed claims in Belgium.

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