

Intelligent ventilator safety valve prevents accidental ventilator induced lung injury

J Mulier, K Braem, M Crombach, A Sels

Citation

J Mulier, K Braem, M Crombach, A Sels. *Intelligent ventilator safety valve prevents accidental ventilator induced lung injury*. The Internet Journal of Anesthesiology. 2009 Volume 22 Number 2.

Abstract

A ventilator safety valve (VSV) is developed by Medsafetec, It opens the airway circuit if airway pressure stays above 20 cmH₂O, but allows ventilation with high airway pressures. In a first experiment a test lung and VSV were connected to a ventilator with a fresh gas flow of 12 liter/minute in the breathing bag mode without manual compression and a closed adjusted pressure limiting (APL) valve. The VSV opened the circuit after 6 seconds of a pressure above 20 cmH₂O. In a second test the airway pressure during lung recruitment was measured. In a third test the VSV never opened. at 19 cmH₂O, but opened at 21 cmH₂O after 6 seconds. In the fourth test the best VSV position found was the inspiratory circuit at the ventilator or the patient connector. The safety frog allows to ventilate at high pressures but prevent any sustained elevation of the airway pressures.

FINANCIAL SUPPORT

Medsafetec nv constructed the test model analyzed in this study. Personal funding was used for analysis.

CONFLICT OF INTEREST

This device will be constructed under the name safety frog and will be sold by. Medsafetec nv. Royalties will be paid to K Braem and J Mulier

ETHICAL COMMITTEE

No animals were used in this study.

The ethical committee approval was asked to measure the airway pressure during normal lung recruitment maneuvers in 10 patients after extracorporeal circulation and in 10 other patients during bariatric surgery when lung recruitment was needed. All the other test were performed without a patient.

MEETINGS AT WHICH THE WORK HAS BEEN PRESENTED

NYSSA 59th Annual Postgraduate Assembly, 9-13 December 2005, New York, NY. Poster and scientific exhibit presentation: Mulier JPJ New ventilator safety valve. Price for best scientific exhibit.

ESA, Munchen, Germany, 8 June 2007. Abstract W 000101: Mulier JPJ Correct position of ventilator safety valve

BACKGROUND AND GOAL OF STUDY

The adjustable pressure limiting (APL) valve exists for a long time and allows manual inflation of the lungs in the breathing bag mode. The pressure at which the valve opens can be varied from zero to 70 cmH₂O. It might prevent the occurrence of high airway pressures when it is continuously adapted. Anaesthetists frequently choose a high APL setting to allow manual ventilation with a mask but they reduce the safety function at the same time. It is this breathing bag mode with a high APL setting that is dangerous when no manual compression is given. The anaesthetist might forget to open the APL valve when patient is breathing spontaneously or to switch to mechanical ventilation when patient stops breathing.

Technical failures as an occluded expiration circuit, blocked expiration valve or failure to start mechanical ventilation create the same danger. Patient get a volutrauma with or without an airway pressure alarm. Most ventilators have an airway pressure monitor that gives an alarm when pressure exceeds a preset value. No ventilator has an alarm that opens the circuit at the alarm level neither will any ventilator drop the pressure to zero allowing total lung deflation. Therefore every ventilator remains at risk certainly in young healthy patients with compliant lungs.

M Weinger (1) suggested a new approach to improve the safety. He asked why the APL valve was never investigated to improve its safety. In a previous study J P Mulier (2)

found that all ventilators used today are at risk. It was suggested that a safety valve with a memory could open at a lower pressure if this pressure exists longer than the longest possible inspiratory time. This intelligent ventilator safety valve (VSV) should be mounted close to the patient to protect him in all conditions. Such a VSV, the safety frog, is now constructed by Medsafetec nv as shown in figure 1. MedecBenelux uses this valve now in all their ventilators to protect them from inducing accidental volutrauma.

First goal of this study was to analyse the characteristics of the VSV when put in the breathing circuit of a ventilator connected to an artificial lung and set in the breathing bag mode with closed APL and without manual compression.

Second goal was to search for clinical situations where the VSV would open while there was no need for it. The need of lung recruitment manoeuvres remains questionable (3) This manoeuvre create prolonged periods of elevated airway pressures. Lung recruitment is performed in the operating room by manual compressing a breathing bag with an almost closed APL valve in contrast with intensive care where ventilator induced lung recruitment is done. The manual technique used in the operating room is used to evaluate possible inappropriate effects of the VSV.

Third goal was to test the VSV in its accuracy of pressure and time measurement in a closed circuit.

Fourth goal was to search for the best VSV position on the anaesthesia ventilator to protect against different induced technical and human errors.

MATERIALS AND METHODS

In the first experiment the active VSV is compared with the inactive VSV. An S/5 aespire ventilator from General electric inc is connected to an artificial lung. The artificial lung consists of a "Pulmo-Sim" test lung from Blease with a maximum capacity of 1,2 litre. The compliance is variable and set at 23 ml/cmH₂O a common value in healthy patients during anaesthesia. The resistance and leakage of the artificial lung are set to zero. A latex free disposable breathing bag of 2 liter from Vital signs, Inc is connected as American breathing bag. The circuit pressure is measured with and without the VSV in the breathing bag circuit.

The APL valve and the pressure alarm are set at their maximum level. The airway pressure is recorded with a pressure transducer connected close to the artificial lung and converted to cmH₂O. Most experiments are done with an

artificial lung and didn't require acceptance of the ethical committee.

In the second experiment three different situations are measured regarding circuit pressure and time to predict opening of the device when not needed. First the ventilator is varied in ventilation frequency till the VSV opens at an I/E ratio of 1/1 and with an artificial lung compliance of 11 ml/cmH₂O in the volume controlled ventilation mode with a tidal volume of 750 ml. Second the ventilator air leakage is tested before its use with and without the VSV. In the third part of the second experiment the airway pressure is measured during manual recruitment manoeuvres in 10 patients before discontinuation of cardio pulmonary bypass. Lungs were manually inflated until visible atelectasis disappeared. An other recruitment manoeuvre is performed in 10 morbid obese patients during laparoscopy when saturation drops below 90% and a recruitment manoeuvre is normally required. No VSV is connected or used. Approval of the ethical hospital committee is obtained. Only the time the airway pressure stays elevated above 20 cmH₂O is noted.

In the third experiment the accuracy of the VSV is analysed in vitro again. Are the pressure and the time accurately measured? This means that the VSV should open when the pressure is 21 cmH₂O during 6 seconds and shouldn't open when the pressure is 19 cmH₂O for a period longer than 6 seconds or 21 cmH₂O for a period of maximum 5 seconds.

In the fourth experiment four positions of the VSV on a ventilator with a fresh gas flow of 12 liter/min connected to an artificial lung are compared. The different positions are the inspiratory limb, the expiratory limb, the breathing bag and the patient connection. Following errors are tested each time, no manual ventilation of the breathing bag in breathing bag mode with closed APL and 12 l/min fresh gas flow, occlusion of the expiratory limb between artificial lung and ventilator in mechanical ventilation mode and occlusion of expiratory valve in mechanical ventilation mode.

RESULTS

Figure 1

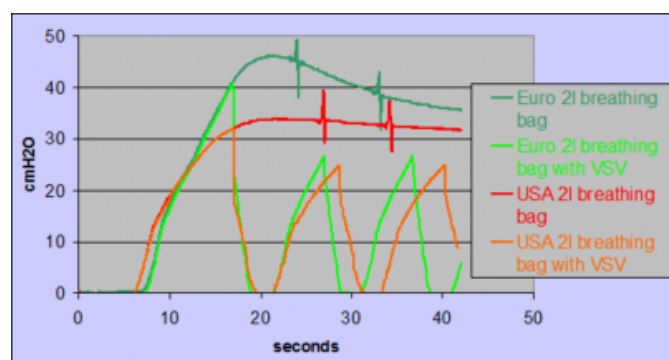
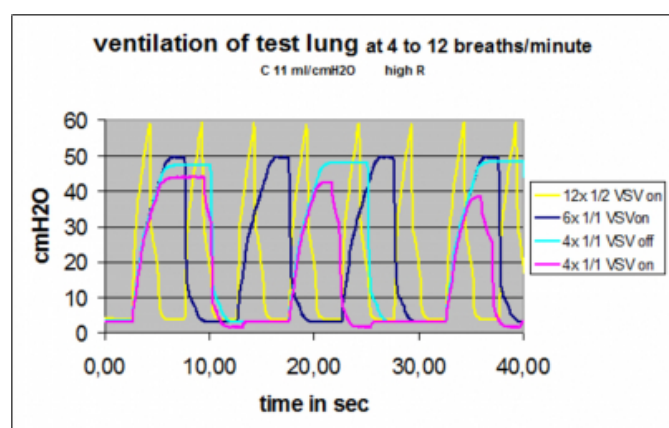


Figure 2 gives the results of the first experiment with the fresh gas flow at 12 liter per minute while the VSV is first not connected and secondly connected.

Figure 2



Without VSV the pressure in the circuit rises according to the compliance of the breathing bag. This was shown in a previous study by J P Mulier (1) where the impact of the ventilator type was less important than the compliance of breathing bag and lung. With the VSV active the pressure never stays long elevated but drops to zero if no respiration cycle is sensed.

Figure 3 gives the results of the second experiment with a decreasing ventilation frequency in the volume controlled mode. The artificial lung was ventilated at 12, 6 and 4 cycles per minute in controlled volume mode with an I/E ratio of 1/1. Each time the airway pressure is given with the VSV connected. The VSV was only activated when frequency was at 4 breaths per minute as shown with the extra trace without VSV connected at 4 cycles per minute.

Table 1 shows how long the airway pressure was above 20 cm H₂O during manual recruitment maneuvers. Manual recruitment maneuvers were on average 0,5 second at 20 cmH₂O in the post extra corporeal circulation group and 1,5

seconds above 20 cmH₂O in the laparoscopy group because the manual balloon needs refilling. The maximum time was 4 seconds in one patient, still below 6 seconds. The VSV will not be activated unless abnormal long recruitments with closed APL are performed. Mechanical recruitment is only possible on intensive care ventilators where the VSV is not needed. Peep levels above 20 cmH₂O activate the VSV but are never used in the operating room. The leak test procedure in the morning requires a constant airway pressure above 20 cmH₂O and activates the VSV. It allows to test the VSV on its performance if performed first without VSV connected and then with VSV connected

The third experiment with the APL first below 20 cmH₂O and then above 20 cmH₂O gave the following results as shown in figure 4. At a constant pressure of 19 cmH₂O the VSV did not open after 6 seconds. At a constant pressure of 21 cmH₂O it opened when the airway pressure was exactly 6 seconds. The pressure and time is accurately measured.

Table 2 gives the results of the fourth experiment. The different failures were combined with different VSV positions. Only the inspiratory position and the patient position give full protection for all tested failures. Inspiratory limb position is simple compared to the patient position and should therefore be recommended.

DISCUSSION

One can discuss the safety of the 20 cmH₂O limit and the 6 seconds limit. Many patients will sustain higher pressures for a longer time, certainly when lung and thorax compliance is small. In pediatric and adolescent patients with high compliant lungs 20 cm H₂O during 6 seconds gives hyperinflation and is certainly dangerous. No investigation is therefore needed to find out if higher airway pressures for a longer period are never deleterious in all patients. Adapting the limits for every patient creates the inherent risk of not adapting the setting or using a setting too low that disturbs normal ventilation. It is clear that a compromise is necessary to go as low as possible without disturbing normal ventilation needs. The proposed 20 cm H₂O and 6 seconds is in this regard a good and safe choice and will certainly be better than no protection at all.

A large compliant breathing bag will also limit the maximum pressure. (5) The American breathing bag should keep pressure below 35 cmH₂O. Modern European breathing bags still go above 45 cmH₂O. The curves shown are dependent on the fresh gas flow and the lung compliance. At high gas flow or large lung volumes pressure

will not come back to zero and the repetitive frequency will change.

Recruitment maneuvers after extra corporeal circulation are done under direct vision of the lung. These lungs are slowly and gently opened manual. A long period of high pressures is not needed and with an APL not totally closed the manual balloon needs refill after several seconds of recruitment. This is different from the intensive care where recruitment of ARDS lungs is done without direct vision of the lung with the ventilator making very long still disputable recruitment maneuvers. (3,4) The leak test done in some ventilators uses a longer period with pressures above 20 cmH₂O.

The inspiratory limb position will protect every patient for accidental volutrauma. Anesthetists should be warned that expiratory tubing occlusion will hyperinflate the lungs but not the breathing bag during spontaneous breathing with an open APL valve. When the alarm sensor of the ventilator is connected to the expiratory circuit as in the ADU ventilator no airway pressure alarm is possible. Occlusion of the inspiratory tubing will never hyper inflate the lungs. Not every type of lungtrauma by ventilators is however prevented (6).

CONCLUSION

The VSV performs as described and protects against

accidental volutrauma. At 12 liter per minute fresh gas flow with a closed APL valve the VSV protection drops the pressure in the circuit to zero. If no immediate correction takes place the VSV repeats its action and performs an escape ventilation. During mechanical ventilation no interference takes place except at an abnormal ventilation frequency below 6 breaths per minute in patients with a very large tidal volume and a non compliant lung. The test procedure should be performed without VSV to test the ventilator and with VSV to test the VSV. No interference with a manual recruitment of the lungs is seen. The best position is close to the ventilator at the inspiratory circuit.

References

1. Matthew B. Weinger. User-Centered Design: A Clinician's Perspective MDDI, Jan 2000, p. 80 Weinger
2. Mulier J, Deckmyn Thomas, Cnudde S. Are ventilators safe to prevent accidental lung trauma? Submitted for publication at the same moment as this article.
3. Kacmarek RM, Kallet RH. Should recruitment maneuvers be used in the management of ALI and ARDS? *Respir Care* 2007; 52:461-75
4. Celebi S, Koner O, Menda F, Korkut K, Suzer K, Cakar N. The pulmonary and hemodynamic effects of two different recruitment maneuvers after cardiac surgery. *Anesth Analg* 2007;104:384-90
5. Johnstone RE, Smith TC. Rebreathing bags as pressure-limiting devices. *Anesthesiology* 1973;38:192-4
6. Kolobow T. The mechanical ventilator: a potentially dangerous tool. *Minerva Anestesiologica* 2001;67:210-4

Author Information

Jan Paul J. Mulier, M.D., PhD.

Department of Anaesthesiology, AZ sint jan AV Brugge

Kristof Braem, BME.

Medsafetec nv

Mark Crombach, M.D

Department of Anesthesiology, University Hospitals Leuven

Annabel Sels, MBA, PhD

Center for economics and management, Hogeschool-Universiteit Brussel