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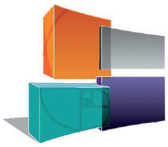

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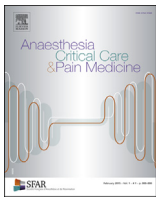

Short communication

Serious adverse events and deaths linked to poor ventilator use: A report of four closed claims

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ABSTRACT

Through this series of four closed claims, we highlight examples of accidents stemming from poor ventilator use. We then review the main issues in this regard as reported in the literature and by learned societies. This case series has led us to emphasise the need for safety procedures involving systematic checks prior to use, declaration and analysis of the risk, as well as feedback and teaching regarding ventilation systems.

1. Introduction

Through this series of four closed claims, we highlight examples of accidents stemming from poor ventilator use, and we review the main issues in this regard. These cases were filed with the French insurer SHAM (*Société Hospitalière d'Assurance Mutuelle*) following a request for damages consequent to an anaesthesia incident. They were the subject of a ruling by a court or by the Commission for Conciliation and Compensation for medical accidents (CCC).

2. Description of the four cases

2.1. Clinical case 1: connection of the patient to the exhalation valve of the transport ventilator

The patient in this case had suffered a crushed lower limb with infectious cellulitis.

During a session of hyperbaric oxygen therapy, the patient was not fitted to the ventilator. The anaesthesia resident administered them a bolus of midazolam. In order to transport the patient to their bed, the monitoring device had been disconnected, and upon being reconnected a bradycardia (30/min) was noted, followed by cardiac arrest. The patient ultimately died of anoxic encephalopathy.

Analysis of the underlying causes for this accident showed that a mistake was made when connecting the transport ventilator (OSIRIS 2) while exiting the chamber, associated with the absence of monitoring by capnography. The patient was connected to the expiratory valve and not to the inspiratory valve (a mouthpiece supplied by the ventilator): see Fig. 1. Although the alarms were set properly, they failed to be triggered.

This accident stemmed from erroneous connection to the transport ventilator, and it was exacerbated by the absence of an error-proof system between the inspiratory and the expiratory valve. Furthermore, the lack of monitoring by capnography was an exacerbating factor.

2.2. Clinical case 2: ventilator not turned on during transfer of a patient to the recovery room

A patient was undergoing treatment at home for coma. In the emergency unit, the intubated patient was connected to the emergency ventilator by the nurse. The monitoring device was set-up without capnography. Subsequent to this, a bradycardia and cardiac arrest occurred. The medical team noted the lack of effective mechanical ventilation due to the failure to turn on the emergency ventilator. The patient's coma became a vegetative state.

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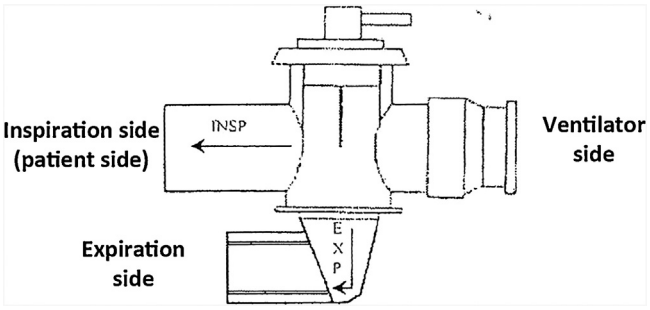

Fig. 1. Connector for coupling the transport respirator with the inspiratory valve and the expiratory valve.

In this case, the cause of the AE was a human error (forgetting to turn on the device and failure to check that there was effective mechanical ventilation), which was exacerbated by a substantial workload in the emergency unit and the simultaneous presence of several other patients. The absence of capnography was a factor that did not allow the problem to be diagnosed in a timely manner.

2.3. Clinical case 3: Error with assembling the anaesthesia system, thereby making it impossible to provide ventilation after the induction

An asthmatic patient required surgery for a thyroidectomy. The anaesthetic induction was performed without pre-oxygenation and without curare. Since manual ventilation with the internal circuit of the ventilator was not possible at the start of the procedure, intubation was performed in an emergency. As ventilation was still not possible in controlled ventilation mode, obstruction of the endotracheal tube and bronchospasm were considered to be the possible underlying causes for this issue, thus leading to a reintubation and the administration of salbutamol, methylpredisolone, and adrenalin. In light of the inefficacy of these treatments, more than 15 minutes after the start of the induction, the intubation tube was finally connected to the accessory system. Ventilation then became possible but a hypoxic cardiac arrest occurred that led to the patient's death.

Several shortcomings underlie the occurrence of this accident:

- the pre-operative check of the ventilator of the anaesthesia system upon opening the operating theatre was incomplete (lack of a visual check of the configuration);
- The parameters displayed on the screen of the ventilator were not taken into account during the pre-oxygenation (the fraction of inspired oxygen = 21% and the fraction of expired oxygen < 21%);
- an anomaly of the mechanical circuit was not considered, and there was a delay in connecting to the backup accessory circuit;
- lastly, an error in the assembly of the patient circuit (ventilation tubes), secondary to a maintenance operation that was not completed, was uncovered. The tests at the end of the operation are meant to occlude the patient circuit (ventilation tubes) by occlusion of the Y-shaped part (see Fig. 2). It is possible to obtain the same result by connecting the inspiratory socket and the expiratory socket of the ventilator with a piece of circuit folded into a loop (see Fig. 2A). This is a procedure aimed at testing only the airtightness of the ventilator. It is employed for maintenance but never for anaesthesia use. Having noted a leak in the system of tubes in place, the engineer created a simple loop between the inspiratory socket and the expiratory socket (see Fig. 2B). As the engineer was interrupted while they were in the process of doing this, they left the operating room, leaving in place this configuration that was incompatible with ventilation of a patient. The rest of the anaesthesia circuit that was not connected to the ventilator was left suspended from the tubing support arm and masked the abnormal configuration. The nurse anaesthetist who was present during the maintenance operation did not notice the unusual connection of the circuit. The self-test before the room was opened was normal.

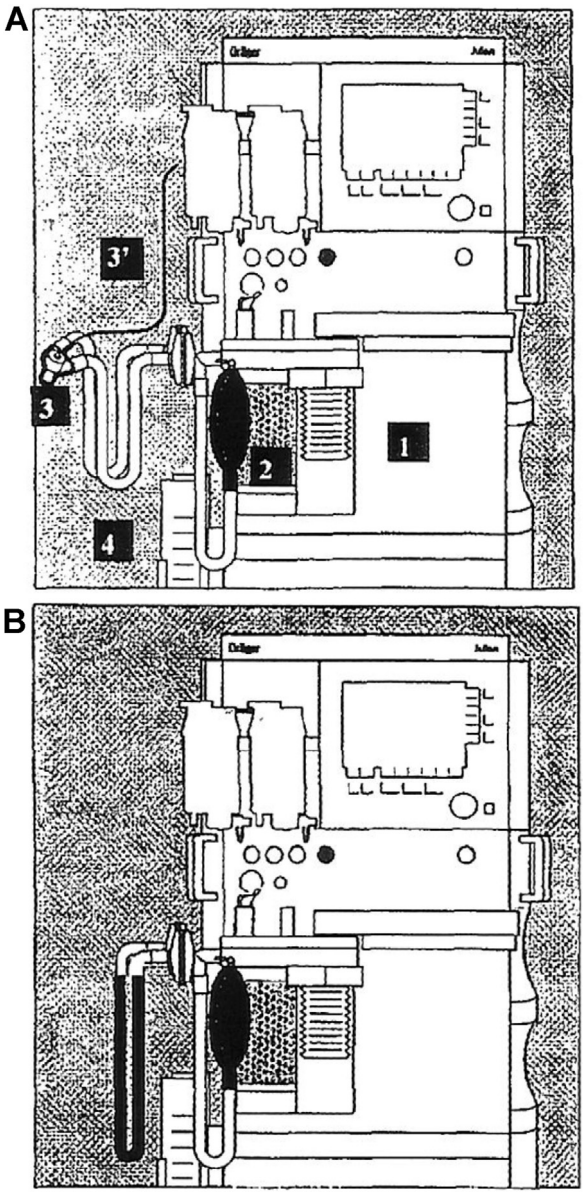

Fig. 2. a: respirator with its patient circuit. Legend: 1 = respirator, 2 = soda lime tray, 3 = Y-shaped device with the sampling line (3') for analysis of the gas, 4 = patient circuit; b: short-circuited assembly carried out during the maintenance procedure. For clarity of the diagram, the rest of the patient circuit that was not connected to the respirator is not shown.

2.4. Clinical case 4: connection of the patient to a ventilator operating in self-test mode in the intensive care unit

In this case, the patient had undergone heart bypass surgery.

The transfer from the operating theatre to the intensive care unit (several stories above) involved use of a transport ventilator. Upon arrival, the patient was connected to the resuscitation ventilator. The team noticed the inability to measure the invasive arterial pressure, which became the focus of their attention.

Several minutes later, the nurse noted a lack of SpO_2 signal and rapid onset of bradycardia. As no carotid pulse was detected, external cardiac massage was performed. A bedside transthoracic echocardiogram identified an electromechanical dissociation. The doctor then noticed that the ventilator was not working. They reconnected the patient to the transport ventilator.

The medical surgical team opted for renewed surgery in order to investigate the possible surgical cause for the cardiac arrest. The exploration did not identify the cause for the cardiac arrest. Upon awakening, the patient exhibited a hypoxic coma and their condition deteriorated to the point that they died.

Analysis of the information regarding the intensive care ventilator by the biomedical engineers and the manufacturer revealed that at the time of arrival in the intensive care unit, self-test procedures were implemented and no ventilation mode was programmed and validated. The cardiac arrest was therefore probably related to hypoxia due to the lack of ventilation.

The accident was linked to the ventilator not being checked when the patient was set up in the intensive care unit, and the failure to check the efficacy of the ventilation.

3. Discussion

The experts raised three main factors: the lack of verification prior to use, the failure to check the efficacy of the ventilation (lack of capnography), and delayed recourse to a backup ventilation system in case of an incident.

The analysis of these four observations underscores the importance of environmental factors that promote the occurrence of AE, obstacles to the detection, or also barriers to recovery. In these cases, there was not a primary failure of the mechanical system, but instead poor use of the ventilator.

With an AE in which the equipment is implicated, a declaration of materiovigilance has been mandatory since 1996 (“Materiovigilance” decree). AEs have been reported to be severe in 10% to 12% of cases and fatal in 2% of cases. In the Anglo-Saxon register, the 1021

incidents recorded were classified as either minor (43% of cases), moderate (35% of cases), or serious (22% of cases). In anaesthesia, analysis of the literature revealed that while in the 1980s 10% of anaesthesia AE were due to the ventilator, this rate is currently below 5%. The latest report from Closed Claims even reports a frequency of about 1% [1].

It appears to be essential that the possibly defective equipment is no longer handled after an incident and that it is placed under seal, so that it can be analysed, if necessary, by independent experts and in a contradictory way. While genuine technical breakdowns are rare, all of the incident reviews show that the causes were linked with the users and mainly to a human error. The majority of these accidents are therefore avoidable (35% to 43%, depending on the study) [1].

Monitoring of capnography is a major safety element that in these at-risk situations (a switch from the ventilator and starting a new ventilator) allows for identification of a fault or lack of ventilation. In a more general manner, monitoring of capnography is mandatory with anaesthesia, as specified by the decree of December 5, 1994 or the guidelines of the American Society of Anesthesiologists [2]. The guidelines of the European Society of Anaesthesia stipulate that the capnograph monitor needs to be connected to the ventilator during the transport of patients who are intubated or who have a supraglottic device [3].

With the aim of contributing to optimal patient safety, the French Society of Anaesthesia and Intensive care (SFAR) has established guidelines regarding anaesthesia devices and their verification prior to use [4].

Within a unit, the availability of equipment training should promote the development of safe attitudes in this respect.

4. Conclusion

This case series has led us to emphasize safety procedures by systematic checks prior to ventilator use, declaration and analysis of the risk, as well as feedback and teaching regarding ventilation systems.

The SFAR, the French Intensive Care Society (SRLF), the French Association of Biomedical Engineers (AFIB), and the National Association for the Medical Technology Industry (SNITEM) have joined forces to improve user training and the organisation of the use

of ventilators. A common knowledge base has been drafted [5], equipment training is regularly organized by the SFAR and the SRLF, and the notion of “equipment training” has been defined.

Disclosure of interest

F.F. and M.A. are SHAM employees. The other authors declare that they have no competing interest.

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