Malfunction of an adjustable pressure limit valve

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EDITOR:

We report the malfunction of an adjustable pressure limit (APL) valve on a KION (Siemens, Siemens-Elema AB, Solna, Stockholm, Sweden) anaesthesia workstation which occurred twice. The first time, the malfunction was detected during the pre-use manual check, but not by the automatic self-check. The second time, the malfunction occurred intermittently during ventilation of a patient but it was rapidly discovered by the anaesthesiologist and no harm came to the patient. After the second incident, visible rust was found on the exit of the APL valve as the cause of the malfunction.

The KION anaesthesia machine is an electronic anaesthesia workstation, which incorporates an anaesthesia circle breathing system with a bag-inbottle ventilator and an integrated patient and machine monitor. In the morning before the beginning of the operating list the anaesthesia machine was switched on and the pre-use automatic function check was faultlessly performed. Afterwards the anaesthesiologist performed a manual check according to departmental protocol (check for leakage in the breathing system and check for correct function of the APL valve). For that purpose, the circle system was short-circuited by connecting the Y-piece to a manual breathing bag, the APL valve was set at 30 mbar and fresh gas flow was turned on until the pressure in the circuit reached 30 mbar. Then the fresh gas flow was turned down to the lowest possible flow this anaesthesia machine can allow, i.e. $0.1 \, \text{Lmin}^{-1}$. According to European Standard EN 740, the maximum acceptable fresh gas flow during the leakage test to sustain a pressure of 30 mbar must be 0.15 Lmin^{-1} [1]. With these settings, if the APL valve functions correctly, a pressure of 30 mbar should not be exceeded. However, the pressure in the breathing system increased

to 70 mbar. Further pressure rise was limited by the additional electronic safety control, which was set (upper pressure limit) at 70 mbar. The anaesthesia machine was switched off and then switched on again. The pre-use automatic function check was performed again without a failure indication. The manual function check was repeated with the previous settings and again showed the same problem. In addition, the standard test for the correct function of the APL valve was performed with settings of the APL valve at 0 or 20 mbar, and with high fresh gas flows of 10 L min⁻¹. This test also did not result in release of the system pressure. The anaesthesia machine was rejected and replaced by another to continue with the operating list.

Afterwards, the APL valve was removed and replaced by a different one and this new one functioned as expected. Although the originally malfunctioning APL valve could be turned, without any obvious difficulty, to any position between 90 and 0 mbar, it displayed the same malfunction when it was connected to the anaesthesia machine. Finally, it was removed from the anaesthesia machine to be checked by a Siemens service technician. In the meantime, the spring mechanism at the lower end of the valve was pressed several times by another anaesthesiologist without apparent problems. The valve was again placed into the anaesthesia machine to be photographed, and, surprisingly, it worked correctly. The Siemens technicians could not find any malfunction of the valve in the subsequent testing.

Three months later, the same malfunction of the same APL valve occurred. This time, both the pre-use automatic and the manual function checks were passed correctly. When the patients' lungs were ventilated manually with the APL valve set at 20 mbar, the airway pressure rose quickly to 55 mbar. Further pressure rise was prevented by the electronic safety control function. Although the APL valve was immediately rotated to the fully open (spontaneous) position, the valve did not release the system pressure. Without delay, the patient' circuit was disconnected from the patient and the anaesthesia machine was exchanged with

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Figure 1.

Visible rust on the lower end of the adjustable pressure limit valve, which led to an intermittent blockage of the valve. The loss of the gas-release ability caused an excessive build-up of the gas pressure in the breathing circuit.

another one. No harm came to the patient. On subsequent inspection of the APL valve, its lower end appeared to be rusty (Fig. 1).

It is important to note that according to the KION Operation Manual, the pre-use automatic function check only tests the following: device leakage, flow transducer, bellow level detectors and alarm detectors. A manual function test is explicitly required for gas supply hoses, correct assembly of the circle system and patient tubing, state of the vaporizer, inspiratory and expiratory valve and the APL valve. In the operation manual it is stated: 'Before the KION system is connected to a patient, or at least once a day, the [manual] function check below must be followed to ensure correct status...' [2].

The cause of the malfunction of the APL valve was finally found by the Siemens technicians after the second malfunction incident. Excessive humidity in the breathing system had led to rust on the spring mechanism of the APL valve (Fig. 1), which itself caused the valve to stick. Possible sources for the humidity might be the sterilization process or the patient's expiratory gases accumulating in the patient cassette. In the latter case, a special dehydration filter placed on the connection of the expiratory patient tubing with the patient cassette is required. These filters have been ordered with the intention to be used routinely from now on in our department. Furthermore, increased attention is paid so that no humidity remains in the breathing system following the sterilization process. The Siemens technicians subsequently acknowledged that a similar incident had already occurred in another hospital in Greece.

This apparatus report emphasizes two main points: first, the need to continue to check manually the breathing system of even the up-to-date electronic anaesthesia workstations immediately before their use for leakage of the respiratory circuit and for correct function of the APL valve [3,4]. This check must be performed even if the automatic function test is completed successfully. This is also underlined by Fasting and Gisvold [5] in their analysis of the intraoperative problems of more than 80 000 consecutive anaesthesia cases during a 5-yr-period. Their advice regarding equipment problems is to improve and intensify routine preoperative equipment checks. In a recently published cohort study by Arbous and colleagues [6] on severe perioperative morbidity and mortality, the equipment check according to protocol and checklist and also the documentation of the equipment check were among the anaesthesia management factors that were associated with a decreased risk of death or coma.

The second lesson from this report is that the anaesthesiologist must be prepared to expect, even after successful completion of all advised anaesthesia machine checks, spontaneous malfunctions of ventilation equipment to occur at any time during the course of manual or mechanical ventilation. Lehmann and colleagues [7] have reported an intermittent malfunction of the inspiratory valve of the anaesthesia machine Sulla 808 V (Dräger, Lübeck, Germany) after borderline damage. Harper [8] described the case of an intermittent potentially hazardous problem with the APL valve of a Cato (Dräger) anaesthesia machine which caused, as in this report, a rapid built up of gas pressure in the breathing circuit. These various reports of intermittent valve malfunctions indicate that we must stop thinking that an anaesthesia machine that is functioning normally cannot present a sudden failure.

The application of only light pressure on the lower end of the valve screw was sufficient to loosen the blockage of the valve. The unpredictability and especially, as in this report, the lack of reproducibility of intermittent malfunctions of parts of ventilatory equipment can lead under special circumstances not only to injury to the patient, but to medicolegal consequences for the anaesthesiologist in charge, if in a subsequent investigation, the malfunction cannot be verified. This case report also emphasizes the fact that physicians should not self-investigate the faulty equipment during a critical incident. It is wiser to leave it to specialists who will check later. Testing in a hurry during an emergency situation could change the original problem without realizing it, so that the malfunction cannot be detected and proved afterwards.

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ProSeal LMA: a potentially dangerous modification

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EDITOR:

We would like to report a potential critical incident resulting from an unauthorized unconventional modification of anaesthetic equipment. The ProSeal laryngeal mask airway (LMA) is a modification of the classic LMA [1], designed to enable separate respiratory and gastrointestinal tracts. A gastric drain tube is incorporated, which can vent gas leakage during ventilation, thus preventing gastric insufflation. It also enables aspiration of gastric contents intraoperatively by insertion of an orogastric tube and has been used to detect malposition of the mask.

A ProSeal LMA was used to secure an airway after induction of general anaesthesia. After cuff inflation, the anaesthetic assistant picked up the anaesthetic breathing circuit to connect it to the ProSeal LMA, and encountered two possible connector choices at the distal end of the LMA. We then noticed that the drain tube of the LMA also had a 7 mm endotracheal tube connector securely attached to its distal end (Fig. 1). The breathing circuit was

Accepted for publication 16 May 2007 EJA 4368 First published online 20 June 2007 connected to the appropriate airway connector, avoiding the unintended oesophageal ventilation and insufflation. The unnecessary connector was removed from the drain tube to avoid future incident.

Modification of anaesthetic equipment is well known and in the past has played an important part



Figure 1.

ProSeal LMA with two airway connectors, one at the distal end of reinforced LMA tube and the other unexpected connector attached to the drain tube. LMA: laryngeal mask airway.

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