Review Article

Safety Features in Anaesthesia Machine

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ABSTRACT

Anaesthesia is one of the few sub-specialties of medicine, which has quickly adapted technology to improve patient safety. This application of technology can be seen in patient monitoring, advances in anaesthesia machines, intubating devices, ultrasound for visualisation of nerves and vessels, etc., Anaesthesia machines have come a long way in the last 100 years, the improvements being driven both by patient safety as well as functionality and economy of use. Incorporation of safety features in anaesthesia machines and ensuring that a proper check of the machine is done before use on a patient ensures patient safety. This review will trace all the present safety features in the machine and their evolution.

Key words: Anaesthesia machine, hypoxia prevention, safety features

INTRODUCTION

WTG Morton, in 1846, first publicly demonstrated 'general anaesthesia', at Masschussets General Hospital, preserved for posterity as the 'ether dome'. Several improvements in drugs, apparatus and techniques have made anaesthesia safe over the years. H.E.G Boyle, a British anaesthetist developed a new continuous flow anaesthesia machine in 1917, which was eventually patented by British Oxygen Company as 'Boyle's Machine'.[1] There were several features in the simple machine, which made anaesthesia easier to administer and safer, compared to earlier methods. Several advances were incorporated in Boyle's machines also over the years from the earlier Boyle Basic to Boyle E, Boyle F, Boyle G, Boyle H, Boyle M, Boyle major and Boyle International models.

Subsequent developments in the machine were dictated by convenience, functionality, mobility and safety, leading to Boyle's Machine being replaced by the anaesthesia delivery unit' also called the 'Anaesthesia Workstation' since the 1990s. These machines delivered gases and inhalational agents, had facility for patient monitoring as well as incorporating advanced ventilation modes and patient monitoring and safety features.[2]

Safety features were incorporated sequentially over this huge time span of nearly 100 years of evolution of the anaesthesia machine (since 1917), with more and more safety systems being added as realisation of the problems and mishaps surfaced.[3,4] In the present milieu of patient litigation related to anaesthesia mishaps, steadily on the rise in India also, it is imperative that we understand these features and incorporate them for better outcomes and improved safety standards in our departments.

THE SAFETY FEATURES IN AN ANAESTHESIA MACHINE

Safety features can be further sub-divided into the following categories:

1. Gas supplies: From the central pipeline to the machine as well as cylinders.
2. Flow meters.
3. Vaporizers.
4. Fresh gas delivery: Breathing systems and ventilators.
5. Scavenging.
6. Monitoring.

We shall examine in detail the safety features in each of the categories described above apart from patient monitoring, which is not directly related to the anaesthesia machine.

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Various national associations of Anaesthesiologists have recommended the minimum safety features for machines used in their countries or by their members. Many international standards exist for the anaesthesia machines (or workstations as they are called) specifying the safety features that are absolutely required and those that are relative/desirable.[5,6] Anaesthesia machines are covered by the American Society for Testing and Materials (ASTM) Standard.[5,6] The most popular ones are those from the American Society of Anesthesiologists (ASA), Canadian Society of Anaesthesiologists (CAS), Australian and New-Zealand College of Anaesthetists (ANZCA).[7,8]

Most professional associations e.g., Association of Anaesthetists of Great Britain and Ireland (AAGBI) and ASA also recommend pre-anaesthesia checkout procedures that check the proper functioning of all the safety features incorporated in the machine.[9,10]

Newer electronic machines have a computerised check out, but most of them do allow for a conscious bypass of this to be made in case of emergencies when a quick start up may be required, sometimes leading to errors.[11] Some machines do also limit the number of times this bypass feature can be used, after which a mandatory full checkout has to be performed.

In a review conducted over the years 1962-1991 by ASA, 72 of 3791 (ASA closed claims Project) malpractice claims were related to gas delivery equipment. Death and permanent brain damage accounted for a majority of the claims (76%). Misuse of equipment was 3 times more common than equipment failure, highlighting the necessity of proper equipment check and training before use.[12]

This article is only intended to help the reader understand the minimum safety features needed in an anaesthetic machine; however, this list is not exhaustive. There are many other safety features, which are not discussed here such as electrical safety, monitoring capability, reliability or reproducibility of results/performance under different working conditions. The ultimate responsibility for the safe use of the machine rests with the end user – the anaesthesia provider.

In most new machines pneumatic systems can be divided into the high, intermediate and low-pressure systems [Figure 1]. Safety features are incorporated into every single component of the machine.[13,14]

HIGH-PRESURE SYSTEM

The high-pressure system consists of cylinders and their yoke assemblies, cylinder pressure indicators, pressure regulators.

Many mishaps have happened because of the wrong cylinder or the wrong gas being filled in the intended cylinder.[15,16] Hence, the cylinder colour coding and PIN index systems were developed but still accidents do happen.[17-19]

The hanger yokes of the machine, which support the cylinder, have the Pin Index safety systems, which prevent the attachment of the wrong cylinder to the yokes [Figure 2]. Pins, which are 4 mm in diameter and 6 mm long, are placed as an arc on the circumference of a circle, which has got a radius of 9/16 inches. The pins are on the yoke assembly and the cylinders have corresponding holes. The pin positions of the commonly used gases are Oxygen 2, 5, Nitrous oxide 3, 5 and for Air 1, 5. Presence and integrity of pins should be visually checked before installing cylinders as defects could make the feature useless.[20]

The other safety features in the cylinders are the colour-coding schemes, which are used on all

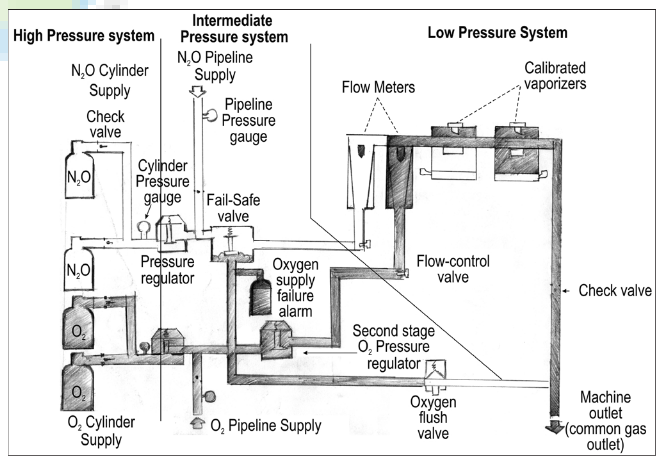

Figure 1: The high, intermediate and low-pressure systems of the anaesthesia machine

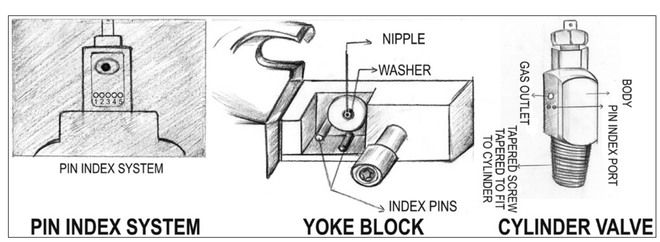

Figure 2: The pin index system and its components

caps, hoses, connectors, knobs and pressure gauges concerned with the said gas.

Oxygen has a black body with white shoulders, medical grade air is coded grey with white and black shoulders, nitrous oxide is blue, entonox is blue and white in colour. Different countries (for e.g., the US) have different national colour-coding systems, which may not be in conformity with international coding. This may lead to confusion for personnel working across different geographic areas.

Pressure relief device

Cylinders have exploded because of over-pressure in them either due to over filling or mis-filling.[21] To prevent this, ASTM standards[5] require all cylinders to have pressure relief devices, which vent the contents of the cylinder to the atmosphere should dangerous pressures develop inside the cylinder [Figure 3]. They are of two types: Rupture disc, where, when a predetermined pressure is reached a disc guarding an orifice ruptures releasing the contents or the fusible plug, which is a thermally operated plug providing protection against high temperatures, but not pressure. A combination of these two is sometimes used as well. Further newer modifications are the pressure relief valves which re-close after the dangerous pressures have been vented, thus saving the contents and not entirely discharging the cylinder.

Pressure regulators

Anaesthesia standards require that each gas be provided with a separate pressure regulator for providing a constant low pressure suitable for the machine from the variable high-pressure cylinders.[5] Some machines use two regulators whereby the second regulator delivers the gas at slightly above atmospheric pressure to the downstream components e.g., flow meters. This helps in providing a smooth constant flow of gas irrespective of fluctuations in pipeline pressures due to peak/trough demands in the system. Some manufacturers adjust the output from the cylinder regulators to be lower than that of the pipeline pressure, so that preferentially the pipeline gas is used, thus saving the cylinder contents even if the cylinder be left open inadvertently.[22]

INTERMEDIATE PRESSURE SYSTEM

The intermediate pressure system consists of the pipeline inlet connections, master switch (present in newer machines), pipeline pressure indicators, second stage pressure regulators, auxiliary gas outlets for ventilators, oxygen failure devices, oxygen pressure failure devices, oxygen flush and the flow control valves.

Cross over of gas pipelines,[23] filling of cylinders with wrong gases,[17] wrong connectors,[24] incorrect tanks from the central manifolds,[25] accidents during installation or routine maintenance of pipelines,[26] may all compromise patient safety.

Connectors that can be fitted to the wrong gas terminals have caused patient dangers[27,28] and led to the development of safety features such as non-interchangeable screw thread (NIST), diameter index safety system (DISS), etc.

Schrader probe

The probe for each gas supply has a protruding indexing collar with a unique diameter, which fits the Schrader socket assembly for the same gas only [Figure 4].

Hose pipes

These are flexible, colour-coded and have built in reinforcements in the wall to make them kink proof.

Pipeline attachments

Each terminal unit that connects to the main pipeline system is equipped with the DISS [Figure 4]. Non-interchangeability of connections is achieved by differing diameters of the shoulders that surround the nipple. Properly engaged parts allow the thread to

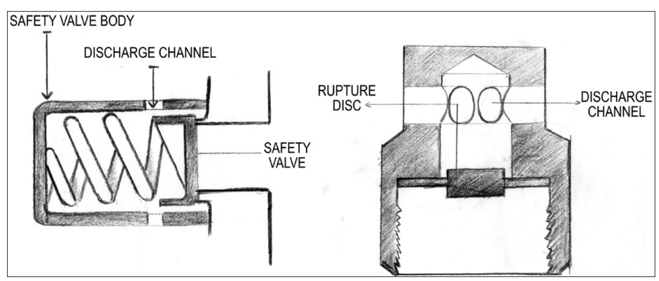

Figure 3: Safety valves

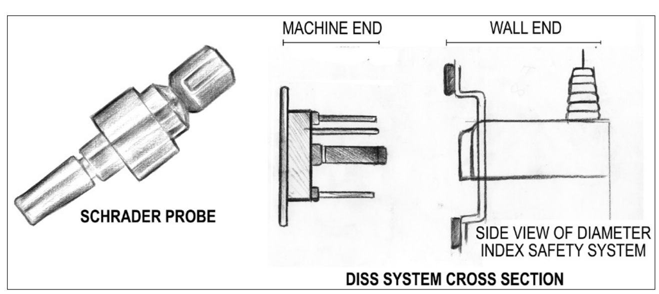

Figure 4: Different connectors and their safety mechanisms

connect to each other so that gas starts to flow. Quick connectors are other safety devices, which allow correct attachments by using varying combinations of shapes and spacing of the different portions of the components that couple with each other. Each gas inlet also contains a unidirectional check valve that prevents leakage into the pipeline system when cylinders are being used as the main source.

Machine end of gas pipelines

NIST connection to the anaesthetic machine [Figure 5]: Each flexible hose ends in a unique fitting of nut and probe. This ensures a hose connection specific to each gas service. It comprises of a nut and probe. The probe has a unique profile for each gas, which fits only the union on the machine for that gas. The nut has the same diameter and thread for all gas services, but can only be attached to the machine when the probe is engaged. The term NIST is in fact misleading; the screw thread does not determine the unique fit. A one-way valve ensures unidirectional flow.

Pipeline pressure indicators

Indicators are required for each gas.[5] They usually have a colour-coded dial and in some indicators satisfactory working pressures zones have a special colour for easier identification.

To decrease the chances of damage/leaks some of the components such as regulators, yokes, NIST, pressure gauges are made into one single block in some types of machines.[22]

Oxygen pressure failure system

Several catastrophes have resulted when the oxygen supply had depleted allowing the administration of hypoxic gas mixtures.

Anaesthesia workstation standards require that whenever oxygen supply pressure is reduced, the delivered oxygen concentration at the common gas outlet (CGO) does not fall below 21%.[5] The older anaesthesia machines employed the Ritchie whistle, which is an audible alarm and cuts off all other gas supplies.[29]

Anaesthesia machine standards also specify that when oxygen pressure falls below a safe threshold an audible alarm [Figure 6] be sounded within 5 seconds and that this cannot be muted.[5]

The failure devices may decrease the supply of all other gases in proportion to the fall in oxygen supply pressure or may totally cutoff other gases, which might include air as well [Figure 6].

The oxygen failure safety device and the oxygen supply failure alarm both depend and detect failure based on pressure and not on flow. These mechanisms work on supply connections upstream of the machine. Hence they do not protect against hypoxic gas delivery, which may occur because of empty cylinders or misconnected pipelines or the wrong proportion of gases being dialled on the flow meters.

Second stage pressure regulator

Some machines incorporate an additional regulator just upstream of the flow meters so that flow is constant at the meters even if there are fluctuations in the pipeline pressure. These reduce the pressure to approximately 14 psig for oxygen and 26 psig for N_2O.

Oxygen flush

Named as flush or emergency oxygen or by other numerous names, this switch directs a highpressure flow of oxygen direct to the CGO from the source, either pipeline or cylinder, bypassing all intermediate meters and vaporizers. Barotrauma and awareness may result from inappropriate activation of this switch.[30,31] To prevent accidental activation these are usually placed in a recessed setting and will deactivate as soon as the finger activating the switch is removed.

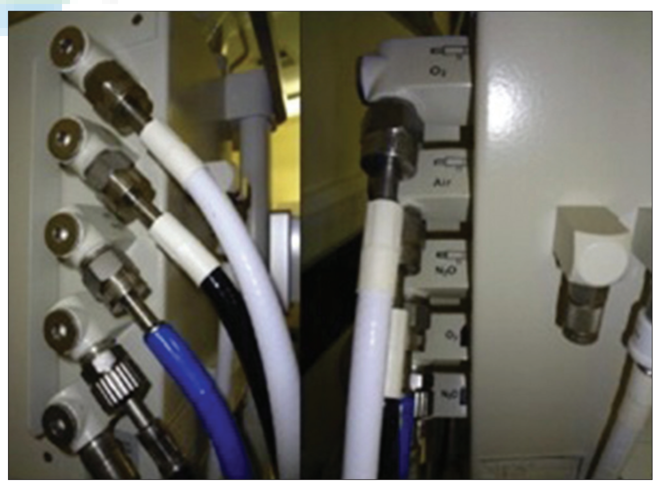

Figure 5: Non-interchangeable screw thread

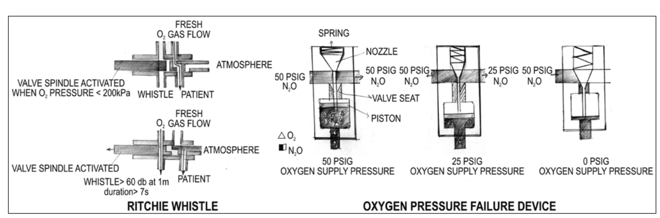

Figure 6: Oxygen failure warning devices

LOW-PRESSURE SYSTEM

Flow in this part of the machine is slightly above the atmospheric pressure. This part contains the flow meters, hypoxia prevention devices, vaporizers, unidirectional valves and pressure relief devices.

Flow meter assembly

Potential or actual oxygen loss because of oxygen flow meter being positioned upstream of all other gases have been reported.[32-34] Hence in the modern machines, oxygen flow meter is always positioned downstream or last in a sequence of flow meters [Figure 7], so that if there is a leakage anywhere upstream of any other gas, still oxygen will be delivered in a sufficient concentration to the CGO. The flow control knob for oxygen is the largest, most protruding and has tactile differentiating features like a fluted profile for additional and easy identification.[5,22]

Flow meters

Anaesthesia workstation standards require that only one flow control be provided for each gas and it be placed near the corresponding flow meter.[5] The various safety features built into the flow meters/control valves are:

1. Providing stops at the full ON or OFF position, so that excessive pressure may not damage either the valve seat or get disengaged at the full ON position so that gas escapes out of the meters.
2. Control knob: Oxygen flow control knob is the largest and fluted for easy identification. A protective barrier around the control minimises accidental changes in settings.
3. Tubes, which measure flow, have different lengths and diameters. Some machines have a pin-index system at each end.
4. Tubes are made leak-proof with neoprene washers (O-rings) at both ends of the flow meter assembly.
5. The tubes have an antistatic coating on both surfaces, preventing the bobbin from sticking.
6. The bobbin is visible throughout the length of the tube.

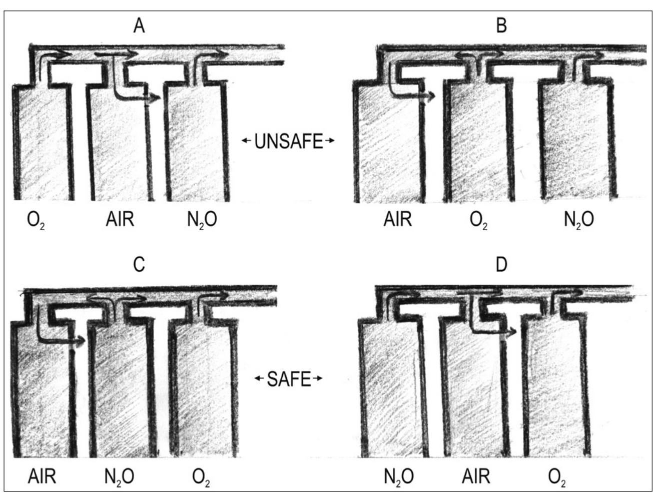

Figure 7: Potential unsafe and safe arrangements of flow meter tubes

Hypoxia prevention devices

Mandatory minimum oxygen flow

Most modern machines have a minimum pre-set oxygen flow, which will automatically start once the machine is powered on. In a few machines this base flow is needed before other gases can be tuned in, thus assuring a minimum supply of oxygen. This flow is variable between 50-250 ml/min depending upon the manufacturer and the machine.[13]

Minimum oxygen ratio

Anaesthesia workstation standards require that a device be provided that protects against a user selection of a gas mixture with an O_2 concentration below 21%.[5] Hypoxic injuries have happened in the past with older machines where it had been possible to set oxygen and nitrous oxide flows independently.[35,36]

In November 2000, a 3-year-old girl died in the Accident and Emergency Department of Newham Hospital, London. She was mistakenly given pure nitrous oxide gas instead of oxygen. In the urgency of the moment and the need to resuscitate a seriously ill child; a doctor mistakenly administered nitrous oxide only. It was a classic human error in an already unsafe system. It need not have happened, had the anaesthetic machine been fitted with a safety guard or an alarm warning of the administration of a low level of oxygen.[37]

Mechanical linkage

Mechanically linking the oxygen and nitrous oxide flow control valves can ensure that at a certain set percentage of concentration (of oxygen) both flows either increase or decrease in proportion to the oxygen [Figure 8]. Above the set percentage, the gases can be altered independent of each other. Usually, these devices only link O_2 and Nitrous oxide. Air is not linked into this safety device.[22]

Electronic linkage

An electronic proportioning valve controls the oxygen concentration to a pre-set minimum, depending on the feedback it receives from a computer that constantly

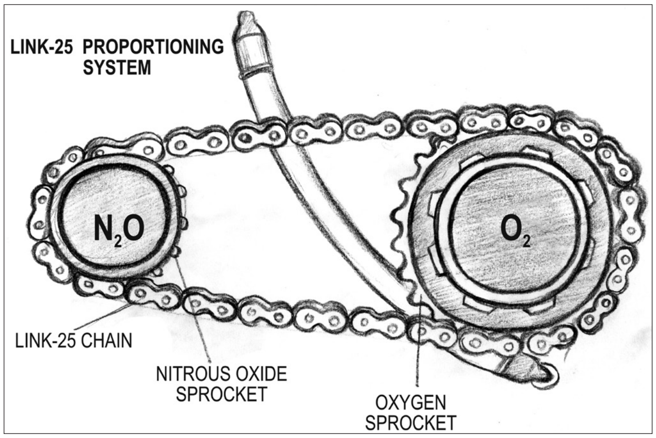

Figure 8: Mechanical linkage of oxygen and nitrous flow meters, to prevent hypoxic mixture delivery

calculates the maximum safe limit of other gases that can be delivered.[22]

Alarms

Some machines also activate an alarm when a user tries to set a flow with a lower than desired O_2 concentration.

Pressure relief devices

Modern machines have a pressure relief device between the vaporizer and the CGO which vents to the atmosphere in case dangerous pressures develop downstream due to occlusions, thus protecting the machine.

CGO

This has a standard 15 mm female slip joint fitting with 22 mm coaxial connector. Machine standards dictate that accidental disconnection of the breathing hoses at this point be prevented or made difficult.[1,2]

Some newer machines have more than one CGO, thus causing potential confusion. Machine standards also dictate that when more than one CGO is provided, only one is functional at any given time.[38,39]

Alternate oxygen flow meter

Many newer machines have the facility of a separate, stand-alone mechanical flow meter e.g., Datex-Ohmeda Avance S5, which has to be consciously activated in the rare instance of electronics in the machine failing to provide a gas flow to the CGO. This flow usually may or may not pass through the vaporizers.

Vaporizers

Several errors regarding the use of vaporizers have been known; wrong installation leading to loss of fresh gas flow,[40,41] wrong agent being filled,[42,43] multiple vaporizers being used simultaneously, gas channels being filled with liquid agent due to inappropriate transport arrangements[44] etc., All these kind of errors have led to addition of multitude of safety mechanisms for vaporizers as mandated by the ISO and ASTM.[45] These include:

1. Most vaporizers have a push (release) button to be activated before the dial can be turned on. This push button cannot be used until the vaporizer is seated firmly on the back bar, ensuring that the vapour is not delivered if installation is incorrect.
2. All modern vaporizers come equipped with an interlock mechanism, which prevent from more than one vaporizer being put to use at the same time, thus causing an accidental overdose. Checking the proper working of interlock mechanism is part of the recommended machine check algorithm. When the control dial is turned on, this releases a rod on either side of the vaporizer which then engage on the control dial of the adjacent vaporizer when present, thus immobilising the dial. When machines have more than 2 slots for vaporizers putting vaporizers at either end (with a vacant slot in the middle) will not allow effective functioning of the interlock system.
3. Some vaporizers have two different mechanisms of interlock; e.g., Drager Vapor, so that they can be used on different types of machines. For permanently mounted vaporizers, there is a lever that engages on a groove in the rear portion of the dial. For removable vaporizers, a slide lever makes a shaft engage a hole on the dial of the unused vaporizer and immobilises it.
4. Newer modern vaporizers have a separate transport setting, which prevents spillage of the liquid agent into the bypass channel, which may cause potential overdosing when the vaporizers are used [Figure 9]. Some models also incorporate an automatic lock in the fully off position (blease) making the vaporizer suitable for transport.
5. All newer vaporizers have keyed/funnel filling systems with unique sizing of the fillers/funnels that are agent specific [Figure 10]. Specific changes are also made on the bottle end of the filling adaptors. The bottle end of the connector has got slots that match the projections on the agent bottle's collar. In the case of desflurane, the bottle comes with an attached filling adaptor and a spring-loaded mechanism that engages only when fitted to

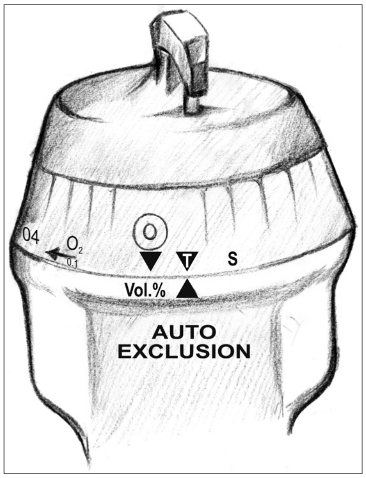

Figure 9: Transport setting in a vapourizer

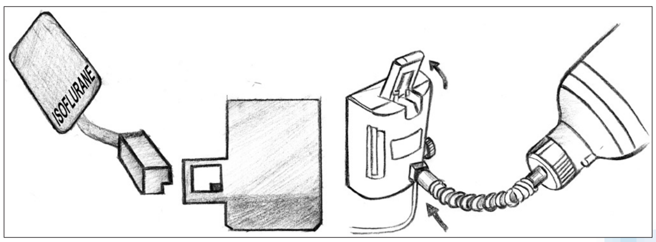

Figure 10: Keyed and colour coded vaporiser filling systems

the correct desflurane vaporizer in the correct position. The colour coding of the anaesthetic agent is usually applied to the concentration dial, filling port and in some vaporizers on the front of the body as well. The ASTM machine standard recommends that every vaporizer have a specific permanently attached device that prevents filling of a wrong agent.

The internationally accepted colours are halothane-red, enflurane-orange, isoflurane-purple, sevoflurane-yellow and desflurane-blue.

6. Very few models of vaporizers have a safety mechanism whereby they work properly despite reversal of gas flow through them. These are usually stand-alone vaporizers and are hardly ever used in modern anaesthesia.
7. Despite all the safety features described, some vaporizers leak gas into the outflow channel even when the vaporizer is in the fully OFF/Lock position.[46] The small amounts do not produce a clinical effect, but may cause problems when patients with malignant hyperthermia are being anaesthetised. Hence, these vaporizers may need to be removed from the machine before use in these cases.

Scavenging systems

Due to various reasons such as cost, ignorance, lack of health safety checks etc., scavenging is an ignored item in respect to the anaesthesia machine in India. Nevertheless, we must make an effort to change and be aware of the standards and safety.

Scavenging systems are governed both by ASTM and international standards.[47,48]

All connections in the scavenging system are of 30 mm diameter, which is distinctly different from the airway accessories (15/22 mm) making misconnections improbable.[49,50] Some older versions may have 19 mm or 22 mm fittings, which may allow accidental/mistaken connections with breathing components. Transfer tubings in the system are different by colour and configuration to that of breathing gases, resistant to kinking and are occlusion proof.

Scavenging systems also incorporate negative and positive pressure relief valves to make sure no dangerous pressures are transmitted into the breathing system in the event of malfunction of the system. Negative pressure relief valve and a reservoir are needed in active scavenging systems, whereas a positive pressure valve is needed in a passive system.

Monitoring

General anaesthesia should never be administered without an oxygen analyser in the breathing circuit. This is because, despite all the safety features of the machine, the final confirmation is the percentage of oxygen delivered to the patient as intended. There are many types of oxygen analysers, the commonest one used on most of the machines being the galvanic cell type. The other types are paramagnetic analysers, and the polarographic (Clark's electrode) type. Oxygen analysers have to be calibrated at regular intervals, most often as part of the machine start-up check procedure. ASTM standards do require that low oxygen alarm level cannot be set below 21%.[5]

Gas volume monitoring is performed with spirometers, which may be of the rotating vane type, hot wire anemometer or the ultrasonic variety. This monitoring gives us a measure of the tidal volume and minute volume, as well as disconnection.

Airway pressure monitoring in most of the machines is now electronic using flow transducers, which can then be displayed as wave forms on the machine monitors.

Some older machines still use a mechanical pressure gauge. The purpose of airway pressure monitors is to prevent either high (to prevent barotraumas) or low pressures (leaks or disconnection). Although, it is simple to set a high-pressure alarm, the low-pressure alarm threshold should be set just below the minimum peak pressure expected during inspiration. The machines normally allow about 15 s for this pressure to be reached and then the alarm goes off if not reached. For best results the airway sampling should be just before the endotracheal tube. Most of the airway alarms do not work in spontaneous breathing.

Disconnection monitors are an integral component of newer anaesthesia machines.[51] They can be based on the gas flows (volume measurements), pressure in the circuit, or gas detection like capnography.

Criteria to determine obsolescence of anaesthesia machines

Anaesthesia machines may be considered obsolete (to be discarded) if they do not offer the following mandatory safety features:

Lack of certain safety features

1. Minimum oxygen ratio device in a machine, which can provide nitrous oxide as well.
2. Oxygen failure safety device.
3. Oxygen supply pressure failure alarm.
4. Vaporizer interlock device (may be waived off if machine is capable of accepting only one vaporizer).
5. Pin index safety system and Non-interchangeable gas connectors like DISS.

Presence of unacceptable features

1. Measured flow (flow meter-controlled) vaporizers. (e.g., Copper Kettle, Verni-trol).
2. More than one flow control knob for a single gas delivered to the CGO of the machine.
3. Vaporizer with rotary concentration dials such that the anaesthetic vapour concentration increases when the dial is turned clockwise.
4. Connection (s) in scavenging system of the same (i.e., 15-mm or 22-mm) diameter as a breathing system connection.

Lack of certain desirable features to be considered

1. Means to isolate the adjustable pressure-limiting valve during mechanical ventilation.
2. Oxygen flow control knob that is fluted and larger than the other flow control knobs.
3. Oxygen flush control protected from accidental activation.
4. Main on/off switch for electrical power to integral monitors and alarms.
5. Anti-disconnection device at the fresh gas outlet.
6. Airway pressure alarm (for detecting sustained positive pressure, negative pressure and high peak pressure).

SUMMARY

As anaesthesia machines or workstations as they are called these days, develop in complexity, newer problems might crop up. The only way to stay ahead of dangers is to be on a constant vigil. “User errors, quality control, problems during production of the device and design faults were the three main causes of a total of 1004 incidents reported in the French health system in the year 1998. The problems identified during the study period enabled the faulty medical devices to be improved in 12-44% of the cases. We conclude that post-marketing surveillance is a useful way of improving the quality of medical devices”.[11] New solutions to old problems might raise new problems. We must remain educated, prepared and vigilant.[14] An oxygen analyser and a vigilant anaesthetist is the minimum mandatory requirement for providing safe anaesthesia.

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