THE ANAESTHETIC MACHINE –THE NEXT GENERATION

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In the last 10 to 15 years we have seen a move from pneumatically controlled, mechanical anaesthetic machines and ventilators, to electronic control of gas flow, gas mixing, vapour delivery and ventilation. Closed loop control of end tidal concentration of oxygen, nitrous oxide and anaesthetic agent has become a practical reality, and software is available to predict the future. Closed loop control of other aspects of patient physiology using actual and surrogate markers has also been trialled.

In parallel, there have been aviation accidents where it appears that a contributing factor has been the level of automated control of the aircraft and the suppositions and algorithms which drive the response of the machine to the control inputs from the aviator in unusual or abnormal conditions.

The presentation will cover –

- The origins of anaesthetic machines
- Where we are now in terms of technology
- Closed loop control of anaesthesia and its limitations
- The regulatory environment now and in the future

Where Have We Come From?

The earliest anaesthesia administration system was the so called “rag and bottle” technique where ether or chloroform was dripped into a handkerchief held over the patient’s nose and mouth. One of the early attempts to produce a machine to deliver gases and vapours with an integrated ventilator was described by Sykes in 1962.

Early Electronic Machines

The PhysioFlex machine was introduced into clinical practice in the late 1980s. It was a fully closed circuit anaesthesia machine with electronic gas flow control, direct injection of anaesthetic agent into the circuit with closed loop control of end tidal agent, inspired oxygen concentration and circuit volume. While it was a revolutionary concept, it apparently had problems with the stability of end tidal agent control system with a degree of wobble. The control of nitrous oxide levels was said to be inadequate.

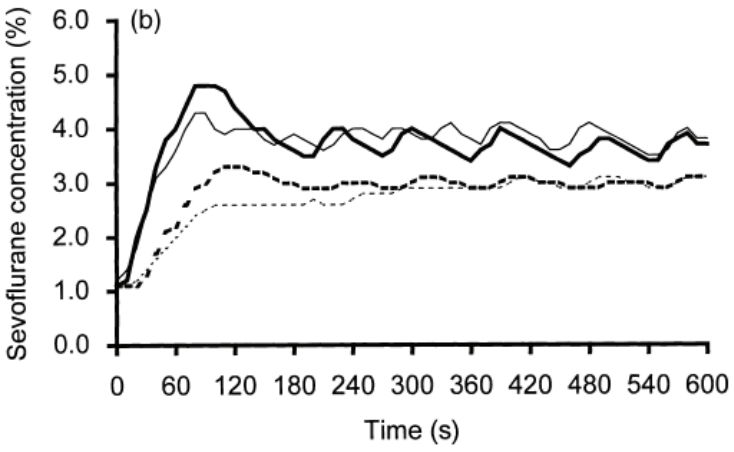

Figure 1. Change of inspired (solid line) and end-tidal (dashed line) sevoflurane in a PhysioFlex

closed circuit in seven patients when the end-tidal sevoflurane setting was changed from 1.0 to 3.0% during maintenance of inhalational anaesthesia. Patients showing the slowest change indicated by the light lines, patients showing the fastest change indicated by the heavy lines.[2]

In the 1990s the Datex ADU was introduced with mechanical control of fresh gas flow, but with electronic measurement of flow, and electronic control of agent delivery using the Aladdin Cassette. The availability of the gas flow and vaporiser setting data, along with inspired and end tidal agent concentrations in the breathing system, resulted in the development of a system which estimated the current effect site volatile concentration, and provided predictions of future end tidal and effect site volatile concentrations.

Where Are We Now?

In parts of the third world, anaesthesia is administered using halothane delivered from draw over halothane vaporisers with supplemental oxygen from oxygen concentrators, using ventilators designed to be driven by the compressor of the concentrator. Volatile concentrations and anaesthetic depth is estimated using surrogate markers such as pulse, blood pressure, movement and tearing.

In the developed world, anaesthesia is moving to automated control of a number of variables, including end tidal agent concentration, inspired oxygen concentration, depth of anaesthesia, muscle relaxation, mean arterial pressure (MAP).

Closed Loop Control in Anaesthesia

In open loop control of the anaesthetic agent or other variable, the anaesthetist takes information (variables) from various monitors, and based on knowledge, experience and a mental model, adjusts the actuator (the vaporiser), observes the results, and readjusts the actuator to bring the value(s) closer to the desired value, the set point.

In contrast to open loop systems, a closed loop controller (eg of end tidal agent) consists of a number of parts –

1. The system which is controlled (the patient)
2. A sensor which measures the controlled variable (vapour analyser and end tidal agent)
3. A set point for the variable (the desired end tidal concentration, chosen and set by the anaesthetist)
4. An actuator which controls the administration of the agent (the vaporiser)
5. A controller (the brain), which contains an algorithm which converts the information received from the sensor(s), the entered set point, and alters the actuator
6. A user interface, which allows input from the anaesthetist, and displays the controlled variable(s) and possibly actuator setting
7. Some models may include an adaptor, which updates the model based on the response of the system to initial control inputs

Examples of controller types –

1. Proportional integral derivative (PID) controller
   a. The difference between the set point and the measured variable is calculated. The output of the controller is proportional to the difference, to the integral of the difference against time, and to the rate of change of the difference (the differential)
   b. These are commonly used in industry to control relatively simple systems
   c. PID controller can be made to adapt to specific patient characteristics
2. Model based
   a. Using knowledge of the pharmacokinetics and pharmacodynamics of a drug, a mathematical model can be constructed which predicts physiological responses
   b. Because of inter-patient variation, these models need to be designed to adapt to patient responses
3. Knowledge based – using fuzzy logic or neural networks

Limitations of closed loop controllers –

1. The variable controlled may be –
   a. Direct – end tidal agent

   b. Surrogate marker - BIS for depth of anaesthesia
2. The controller needs to be stable under extreme conditions
3. There needs to be an ability to reject signal artefacts or noise in the monitored variable signal
4. The controller needs to be stable and not cause the variable controlled to oscillate around the set point, or deviate from the set point
5. There must be limits to the output of the actuator to prevent over dosage

Advantages of closed loop control –

1. Reduced anaesthetist work load
2. Better control of physiological variables
3. Decreased agent consumption using end tidal control
4. Possibly more rapid recovery

Disadvantages –

1. Over reliance on automation and decreased vigilance
2. Unexpected and unusual response of the controller to unusual circumstances
3. There is a need for those using these automated systems to understand fully –
   a. The functional logic of the controller
   b. Its limitations
   c. Its behaviour in unusual or extreme circumstances
   d. The need to maintain vigilance in spite of being "on auto pilot"

Current examples of closed loop control in anaesthesia –

1. GE Aisys with control of end tidal agent and inspired oxygen – as it relatively new in clinical use there is relatively little in the literature on the Aisys. Intuitively it should decrease agent concentration in the hands of those not used to closed circuit or very low flow anaesthesia, but in its present iteration it has a mandatory minimum flow of 500ml, which is not true closed circuit anaesthesia
2. Drager Zeus with control of end tidal agent and inspired oxygen – there is more literature on the Zeus, and some studies suggest that its use in closed loop mode decreases agent consumption

Where Are We Going?

1. In the literature there are examples of the use of closed loop control for –
   a. Depth of anaesthesia including sedation
   b. Analgesia
   c. Muscle relaxation
   d. Arterial pressure
   e. Ventilation
2. Integrated Automated Control – McSleepy is an experimental closed loop control system that monitors depth of anaesthesia, nocioception and muscle relaxation, and administers doses of the appropriate drugs as necessary
3. Predicting the future. Many of you will be aware of the work of Ross Kennedy and Richard French of Christchurch in developing a system to guide volatile agent administration. Using data from the ADU of fresh gas flow and vaporiser setting, and inspired and end tidal agent from the gas analyser of the S/5 monitor, it estimates effect site agent concentration and predicts end tidal agent concentrations for the next 10 to 20 minutes. The introduction of the model has coincided with significant reductions in fresh gas flow settings. It has also proved useful in teaching the practice of inhalational kinetics and low flow

The Regulatory Environment

The "Government"

Those of you who deal with the purchase of equipment will be aware of the necessity for WAND and TGA certification. WAND is the "Web Assisted Notification of Devices" program run by Medsafe which requires all

"medical devices" to be notified. TGA is the Australian Therapeutic Goods Administration which serves a similar function across the Tasman.

Recently our government and their Australian counterparts have announced a joint scheme for the regulation of therapeutic goods (medicines, medical devices), the Australia New Zealand Therapeutic Products Agency, which will absorb the current regulators – Australia's Therapeutic Goods Administration and New Zealand's Medsafe (ANZTPA; yet another MLA to remember). The aim is to create, over time, a "joint regulatory scheme across both countries [which] will safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries" which will be absorb the two current regulators, Medsafe and the Australian TGA. Whether this will make matters simpler remains to be seen.

The Australian and New Zealand College of Anaesthetists (ANZCA)

The College has published a new document "Minimum Safety Requirements for Anaesthetic Machines for Clinical Practice" 2011 T3 (2011). It has recognised the hazards inherent in electronic anaesthetic machines in adding point 4.3.1 –

> 4.3 An "on/off" switch, if present, must be protected from unintended activation.
> 4.3.1 Switching "off" an electronic anaesthetic machine during normal operation should require a confirmatory step and/or the machine should display a warning of imminent shut-down.

The provisions with regard to machine obsolescence are also powerful tools in dealing with management who are reluctant to replace aging and failing equipment.

Conclusion

We are in a time of interesting developments in the technology of anaesthesia delivery, and it is unclear which of the innovations will become accepted into clinical practice. Some of these innovations may not add safety or efficacy in proportion to their costs. We may well be developing more and more expensive ways of doing what we do, and we need to retain a degree of scepticism with regard to innovations being presented to us, and avoid the view that everything new is necessarily a good thing.

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