Malfunction of the Siaretron 1000 Iper™ hyperbaric ventilator

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Key words
Ventilators, equipment, hypoxia, barotrauma, safety, hyperbaric facilities

Abstract
(Bothma PA, Brodbeck A, Bapat U. Malfunction of the Siaretron 1000 Iper™ hyperbaric ventilator. *Diving and Hyperbaric Medicine*. 2009;39:45-7.)
Introduction: Patient ventilators for use in the hyperbaric chamber need to be of special design; any malfunction could have disastrous consequences. We report two serious problems with a recently purchased Siaretron 1000 Iper™ ventilator.
Methods: The ventilator was tested with a Biotek VT-Plus™ gas flow analyzer, which also measures O_2 concentration. The changes in fraction of inspiratory oxygen (FiO_2) were verified with a Teledyne Electronic Devices™ O_2 analyzer.
Results: In volume control ventilation (VCV) mode: excessively large tidal volumes were delivered when the fraction of inspiratory oxygen (FiO_2) was changed.
In pressure control ventilation (PCV) mode: changing the FiO_2 setting did not change the FiO_2 delivered by the ventilator. The ventilator also exhibited an irregular flow pattern in PCV.
Conclusions: These problems may cause serious diagnostic and clinical consequences if not identified as equipment malfunction issues. A malfunction of the integrated memory in the microchip on the main board was said to cause the PCV malfunction. The manufacturer replaced the main board, which corrected the problem. The solution offered for the VCV problem was to change FiO_2 in steps of 0.1 per breath, which eliminates the tidal volume surges. We feel it is extremely important that all users of the Siaretron 1000 Iper™ are made aware of these problems as they are not described in the user manual or elsewhere.

Introduction

The design of equipment for critically ill patients in the hyperbaric environment tests engineers and manufacturers to the limit.[1,2] For a long time, existing transport or intensive care ventilators (or modified versions thereof) have been used with reasonable success. These are all affected variously by the hyperbaric environment and many are no longer supported technically and or spare parts are no longer available.[3] One such earlier generation ventilator, the Iper 60VF, has been developed further and is one of only two CE (Conformité Européenne or European Conformity) certified hyperbaric ventilators on the market as the Siaretron 1000 Iper™ (Figure 1).[4] It is described as "*an electropneumatic ventilator which has automatic compensation of the volume delivered up to pressure of 7 ATA measured by a special absolute pressure transducer. The ventilator can operate in IPPV, PSV, SIMV and CPAP modes and it has alarms for high and low airway pressure. The user can set the oxygen concentration (between 21% and 99%) as well as I:E ratio. The ventilator is supplied by the air and oxygen having pressure at 3.5 bar higher than pressure in the chamber. The electronic circuit is powered by low voltage batteries (2x6V) granting autonomy of about 3 hours*".[5]

As this ventilator has received a lot of interest internationally, we report here initial experiences with a recently purchased

unit that did not perform satisfactorily. We recognised there were problems when an Ohmeda 5410™ volume monitor was used during testing prior to putting the ventilator into service. It was noticed that the tidal volume increased by up to 100% when changing FiO_2 from 1.0 to 0.21. It was realized that more thorough testing was required.

Methods

We tested the ventilator with a Siemens™ test lung 190, 1L and then with a Biotek VT-Plus™ gas flow analyzer. This apparatus also measures O_2 concentration after an automatic calibration in room air and 100% O_2. In addition, a Teledyne Electronic Devices™ O_2 analyzer (calibrated manually at FiO_2 0.21 and 1.0) was incorporated into the circuit to confirm the findings (see Results). All measurements were done at atmospheric pressure as none of this equipment is certified as safe under hyperbaric conditions.

Results

VOLUME CONTROL VENTILATION (VCV)

It was found that, on changing the FiO_2 setting, the ventilator delivered one or two large tidal volume breaths. The magnitude of this increase varied from 30% to 100% above the set volume and occurred both when increasing and decreasing the FiO_2. This could lead to volutrauma or barotrauma unless the high airway pressure limit has been set to safe levels, which in our practice is 20% above baseline.

PRESSURE CONTROL VENTILATION (PCV)

Changing FiO_2

Changing the FiO_2 setting did not change the FiO_2 delivered by the ventilator while in PCV mode. Attempting to decrease it was extremely slow, lasting 5 to 10 minutes to decrease from 1.0 to 0.9 and inadequate to be of practical use. Changing the FiO_2 setting from 0.21 to 1.0 did not change the delivered FiO_2 at all. Both these malfunctions pose serious clinical problems, with the latter obviously a major risk to the patient.

Because we were initially concerned that the O_2 analysis was erroneous, the circuit was interrupted to add the Teledyne O_2 analyzer. On reconnecting the circuit, the FiO_2 immediately changed in the appropriate fashion. This was reproduced repeatedly, i.e., with the circuit closed the FiO_2 would not change, but interrupting the circuit for a few seconds would correct the problem.

Irregular flow pattern

It was also found that the flow pattern in PCV was irregular, and particularly bad with the FiO_2 in the 0.21 to 0.5 range. A saw-tooth pattern was seen throughout the ventilator cycle, but most prominent during the plateau phase. We termed this 'sobbing' ventilation: when connected to the test lung it resembled the breathing pattern of a sobbing child. In VCV the pattern was smooth and acceptable.

We tested a second unit of the same model ventilator from another UK-based hyperbaric unit and found the same problems, except a slightly less irregular, 'sobbing' flow pattern was observed.

Discussion

RESOLUTION OF PCV PROBLEMS

The ventilator was returned to the manufacturer and we reported the problem to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. A malfunction of the integrated memory in the microchip on the main board was diagnosed and the main board was replaced. On its return, the ventilator was re-tested as before. Both the problems in PCV had been eliminated.

The failure of FiO_2 to revert back to 1.0 at the end of an air break could lead to hypoxia in certain patients with impaired oxygenation, and or negate the beneficial effects of hyperbaric oxygen therapy. If this problem is not identified, the resulting decreased oxygenation could be ascribed to patient factors with increasing positive end expiratory pressure (PEEP) being introduced or a pneumothorax being suspected.

RESOLUTION OF VCV PROBLEMS

The manufacturing company, Siare, based in Italy, advised us not to change the FiO_2 setting in steps of more than 0.1.

Figure 1
Siaretron 1000 Iper™ ventilator

We have found that changing FiO_2 in steps of 0.1 (and even 0.2) per breath, is well tolerated by the ventilator and avoids surges in tidal volume. Thus, switches in FiO_2 should be achieved over four to eight breaths to avoid this problem. Hopefully the company will have a better solution in time.

In the meantime, training is very important to make all staff aware of the importance of setting the high airway pressure limit to 20% above baseline pressure and of changing FiO_2 in steps of 0.1 or 0.2 at most. Careful monitoring of ventilation should also be used, as for example in the measurement of end tidal carbon dioxide, spirometry, or transcutaneous pO_2 and pCO_2 and, of course, monitoring of the cardiovascular system. We have attached a laminated warning notice to the ventilator.

We made enquiries from colleagues elsewhere, known to use this model of ventilator, but nobody had noticed similar problems. Given that a loaned second unit demonstrated the same problems, this may not be an isolated finding. All hyperbaric facilities using the Siaretron, (or indeed, any other make or model of mechanical patient ventilator) should fully test their ventilator(s) before placing one into clinical service.

Further testing under hyperbaric conditions is required.

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