Risk simplifies to $3/n^4$. Then finding zero events in seven observations as in Liu’s study, and zero events in 13 observations as in LaMantia’s study means that the maximum long-run risks (with 95% confidence) of observing these events in the entire population would be no greater than 34.8% and 20.6%, respectively. In other words, even though the authors observed zero events in seven and 13 observations, the chances of observing these events in the population remains substantial up to 34.8% and 20.6%, respectively. To predict a maximum long-run risk of 5% (with 95% confidence), one needs to observe zero events in 60 observations.

Even though zero events were observed in these two studies, the maximum long-run risk remains substantial because the sample sizes were small. In order to reduce the maximum long-run risk when zero events are observed, we must design our studies with larger sample sizes. If we allow observations from small sample sizes to guide our clinical practice, we may, in fact, be misled.

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REFERENCES


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Flowmeter Malfunction: Effect on Delivered Anesthetic Concentration

To the Editor—We would like to report an unusual malfunction of a flowmeter (Ohio Medical Products Sid- arm Anesthetic Vaporizer, Vernitrol®) that could cause complications, confusion, and hazard during the delivery of an anesthetic.

A two-month-old child scheduled for elective repair of a cleft lip was taken to the operating room for an inhalational anesthetic induction using halothane, nitrous oxide, and oxygen. Despite a thorough routine preoperative check of the anesthesia machine, a defect in the flowmeter portion of the Vernitrol® was not detected. The defect was missed primarily because of the lack of contrast of the broken part and the white scale background (fig. 1, left panel). The problem was detected only at the beginning of the induction partly by abnormal “feel” of the control knob and partly by visual inspection. It was noted that the movement of the float seemed sluggish when the flowmeter control knob was turned. The anesthetic induction was delayed, another machine was substituted, and the case proceeded uneventfully. Closer inspection of the defective anesthesia machine postoperatively revealed that part of the small, white, plastic device (the float stop) had become dislodged from the top of the flowmeter and was resting on top of and inside the black float (fig. 1, upper right panel). The bottom right panel (fig. 1) allows comparison of an intact float stop and the broken part removed from the machine.

An Ohio Medical Products representative measured the delivered halothane concentrations with and without the broken float stop resting on the float at 3,000 and 5,000 ml·min⁻¹ oxygen flows using a Riken Analyzer® #180iH. The Riken Analyzer is an optical refractometer that is used by the manufacturer for field calibration. The presence of the broken float stop on the float, because of the additional weight and/or altered gas physics within the tube, caused errors in the delivered halothane concentrations, as both oxygen flows tested, from 19 to 100% above the calculated (expected) values (table 1).

In the case of the inhalational induction of the child discussed above, errors in the range of 30–100% in the halothane concentration could have resulted in complications with the induction or caused confusion. In the
FIG. 1. Ohio Medical Products Sidearm Anesthetic Vaporizer, Vernitrol®. The left panel demonstrates the broken float stop resting on top of and inside the black float. The white float stop is difficult to see against the white calibrated background at the zero flow (bottom) but is seen more easily in the middle of the flowmeter (upper right panel). The bottom right panel shows the intact and broken float stops for comparison. The broken float stop caused the delivery of higher than expected halothane concentrations.

As seen in the left panel of fig. 1, the broken white float stop on the white background is difficult to see. It is also difficult to see in the middle of the flowmeter tube.

TABLE 1. Calculated and Measured Halothane Concentrations for Ohio Medical Products Sidearm Anesthetic Vaporizer (Vernitrol®) with and without Obstruction to Flow at Two Levels of Oxygen Flow Rates

<table>
<thead>
<tr>
<th>Oxygen flow 3 l·min⁻¹</th>
<th>20</th>
<th>0.40</th>
<th>0.46 (15)%</th>
<th>0.69 (73)%;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50</td>
<td>0.88</td>
<td>1.06 (20);</td>
<td>1.58 (80);</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>1.75</td>
<td>1.89 (8);</td>
<td>2.02 (61);</td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>3.30</td>
<td>3.46 (5);</td>
<td>4.07 (51);</td>
</tr>
<tr>
<td></td>
<td>300</td>
<td>4.80</td>
<td>4.66 (3);</td>
<td>&gt;6.00 (--;)</td>
</tr>
<tr>
<td>Oxygen flow 5 l·min⁻¹</td>
<td>20</td>
<td>0.25</td>
<td>0.28 (12);</td>
<td>0.45 (80);</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>0.54</td>
<td>0.64 (19);</td>
<td>1.08 (100);</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>1.05</td>
<td>1.15 (10);</td>
<td>1.76 (68);</td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>2.05</td>
<td>2.02 (--;</td>
<td>2.96 (44);</td>
</tr>
<tr>
<td></td>
<td>300</td>
<td>3.00</td>
<td>2.97 (--;</td>
<td>3.91 (30);</td>
</tr>
<tr>
<td></td>
<td>400</td>
<td>3.85</td>
<td>3.64 (--;</td>
<td>4.99 (50);</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>4.70</td>
<td>4.36 (--;</td>
<td>5.60 (19);</td>
</tr>
</tbody>
</table>

* Corrected for temperatures between 21 and 23.5°C.
† Nature of obstruction to flow described in text.
‡ Per cent increase above calculated values.
It was not noticed by the anesthesiologist during the routine preanesthetic check of the machine. Routine service by the manufacturer was accomplished 1 month prior to the equipment failure.

We have discussed the problem with the manufacturer's Manager of Product Safety. We recommended the possibility of incorporating color contrast in the materials used and suggested that the float stop be replaced periodically during routine servicing to prevent a mishap in the future. In addition, we recommend to our colleagues that if this malfunction is detected, the machine should be taken out of service and repaired.

In reply.—We thank Drs. Dobler and Hinkle for bringing their experience to us as soon as it had happened. We speculate that breakage may be the result of individuals, during servicing, bending the float stop to straighten it; thus, causing a fracture at the stem's base. The service kits include a replacement float stop, the intent being that the float stop should be replaced with each servicing. The servicing instruction sheets have been modified to emphasize that this float stop should be changed every time, not only when it appears to be required. The part number for ordering the float stop is 216-1874-100.

The Paradox of Paradoxic Air Embolism—PEEP, Valsalva, and Patent Foramen Ovale. Should the Sitting Position be Abandoned?

To the Editor.—The recent letter by Fischler et al., demonstrating the identification of a patent foramen ovale (PFO) using an echo contrast technique during normal respiration or with the Valsalva maneuver or coughing, deserves further comments. These authors recommend performing contrast echocardiography to screen patients for a PFO who then would not be placed in the sitting position for surgery. This important information by Fischler and co-workers coincides with other findings that have been generated but recently. Hagen et al. just have published a postmortem study of the incidence and size of PFO during the first 10 decades of life in 965 normal hearts. They found an overall PFO incidence of 27.3%, with a mean diameter of 4.9 mm.

Reversal of the normal transatrial pressure gradient enhancing the movement of air from right to left heart across a PFO has been described in the sitting position, with positive end-expiratory pressure (PEEP) and during the Valsalva maneuver. Cucchiara, recently reported the use of transesophageal echocardiography (TEE) for detecting and tracking air in the right heart chamber and when it passes from the right atrium to left atrium via a PFO. Conventional Doppler verification was equivocal in two cases and, of course, unable to identify the air crossing into the left side of heart.

In January 1984 we had the opportunity to anesthetize a patient in the sitting position for a deep-seated posterior fossa tumor. This procedure was uneventful, with no changes in vital signs, Doppler, blood gases, or positive yield for air on intermittent aspiration of a five-hole catheter whose tip was located near the SVC-RA junction.