

Anesthesiology
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A Potentially Serious Anesthesia System Malfunction

To the Editor:—We wish to alert readers who use anesthesia machines with Ohmeda GMS CO₂ absorbers about a potentially serious malfunction. This malfunction can occur only in GMS absorbers with adjustable-height breathing bag arms. The following clinical case describes this problem.

Prior to anesthetizing a patient with a year-old Ohmeda Modulus II® anesthesia machine, a routine equipment and circle system breathing circuit precheck was performed. No problems were detected. After an uneventful intravenous induction and tracheal intubation, the adjustable-height breathing bag arm was lowered. The breathing circuit was attached to the endotracheal tube, and it was discovered that manual ventilation of the patient's lungs was impossible. Squeezing the breathing bag produced no gas flow from the bag. It seemed that a total block in gas flow existed somewhere in the inspiratory side of the circle system. No obvious source of the block could be detected but, oddly enough, it was quickly noted that only manual ventilation was impossible. Turning the GMS switch from "Bag-APL" to "Ventilator" produced normal gas flow when the ventilator was operated. It was then discovered that only when the adjustable bag arm was lowered did manual ventilation become impossible. The patient experienced no significant period of apnea and was uneventfully anesthetized for the remainder of the case.

Later, with the cooperation of Ohmeda service personnel, it was determined that the normal gas flow (fig. 1 A, B, and C) in the GMS adjustable bag arm "tube-in-a-tube" was blocked due to the absence of a locking C-ring, which keeps the lower rubber gasket in place below the gas inlet holes. The lack of the C-ring resulted in the eventual upward migration of the gasket above the inlet holes. Then, when the bag arm was lowered, gas flow from the bag was totally blocked (fig. 1D). This did not cause any problem with the ventilator mode.

We recommend that any remaining GMS absorbers with adjustable bag arms be either modified or replaced with fixed-height bag arms to prevent this serious malfunction from occurring.

Anesthesiology
65:563-564, 1986

In reply:—Ohmeda wishes to take this opportunity to respond to the letter by Dr. Springman and Mr. Malischke. The authors describe an extremely unusual oc-

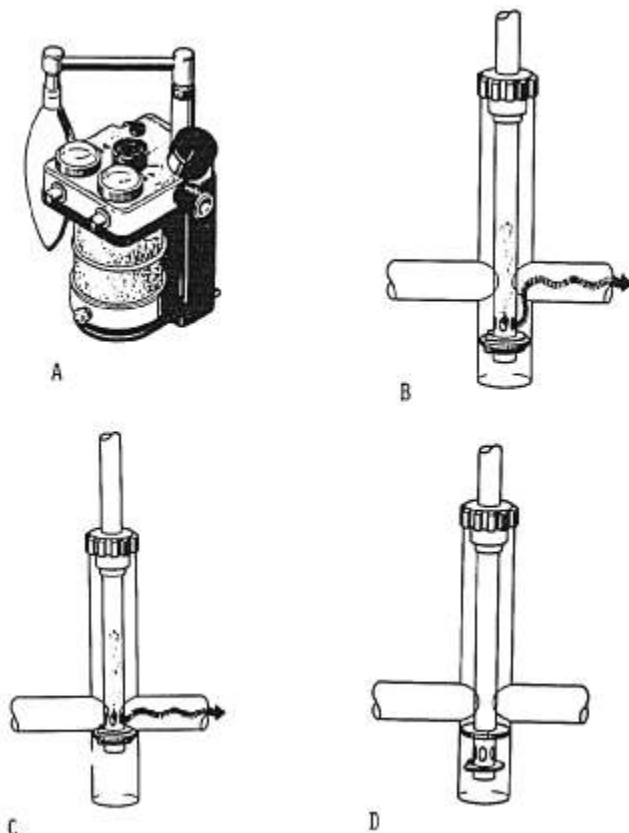


FIG. 1. A. GMS Absorber. B. Down position of bag arm, proper function with bidirectional gas flow. C. Up position, proper function. D. Down position. Migration of gasket with blocked gas flow due to missing C-ring.

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currence with an Ohmeda GMS Absorber with an adjustable height bag arm that lacked a locking ring.

This appears to be an isolated incident. Ohmeda has

not received similar reports of this type of occurrence. Furthermore, a result of this incident, a field investigation involving a number of GMS absorbers with adjustable-height bag arms did not detect any missing locking rings. Routine service and preventive maintenance procedures conducted by Ohmeda do not require the removal of the locking ring. Thus, the reason why this particular GMS absorber lacked the locking ring is not definitely known.

The GMS absorber with an adjustable-height bag arm contained a locking ring designed to retain a plastic gasket below the gas outlets. Ohmeda discontinued the manufacture of GMS absorbers with adjustable-height bag arms in mid-1985 as part of a design simplification program. Since that time, GMS absorbers have been supplied with

fixed-height bag arms. An occurrence such as described in the letter is not possible with the newer designed bag arm.

For additional information, contact the local Ohmeda representative or contact Ohmeda in Madison, Wisconsin, at (608)221-1551.

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Lethal/Toxic Injection of 20% Lidocaine: A Well-known Complication of an Unnecessary Preparation?

To the Editor:—The continuing availability of 20% lidocaine concentrates “for dilution only” has provoked eight case reports in peer review journals since 1979.¹⁻⁸ These reports document the danger that these preparations are likely to be mistaken for the more frequently used and familiar 2% solutions for iv injection. The injection of 1 or 2 g of lidocaine directly iv generally produces a life-threatening situation or often death.* In one case report two cases occurred in one institution, in another, two 1-g unit doses were injected into one person’s circulation.^{2,3} An average of two reports of such accidental toxic injection with 20% lidocaine are received at the Food and Drug Administration (FDA) yearly, with as many as six reports in 1979. Most frequently, preparations in syringes have been implicated, with a mortality rate of 75%.* My personal activities in this field have uncovered two recent cases of toxic injection in the United States that were never formally reported to a federal agency for tabulation, so nonreporting of such events certainly can be stated to exist. The scope of this problem is clearly greater than cases reported to the FDA alone, and misadventures continue to occur in spite of all previously instituted packaging improvements.

A review of 30 reports filed at the FDA led to the unanimous decision of the Anesthesia Life Support Advisory Committee to restrict the unit dosage of prefilled syringes to 100 mg in April 1985.* One- and two-gram

syringes remain on the market, and the contents are easily injected into infusion tubing Y-ports in spite of “protective needle housings.” Persons unfamiliar with these preparations are at greatest risk for making this mistake, and all medical personnel should be made familiar with them. Elimination of these preparations from hospital stocks is a viable alternative in precluding morbidity, mortality, and liability on a local scale. Safer alternatives for constituting iv infusions are currently available, and premixed bags for infusion or 4% concentrates can be recommended at this time.

Most important is that any previously unreported or newly occurring misadventures, as well as any perceived packaging complaints regarding lidocaine (or any drug) be reported directly to the FDA offices as such and with as much detail as possible. This reporting will increase appreciation of drug-related problems at the federal agency responsible for protecting the patient from unsafe products. This could hopefully induce the elimination of 20% lidocaine from the market at the soonest possible date. The use of FDA Form #1639 will guarantee confidentiality in the reporting of events. “Packaging Complaint” is not a solicited item on this form, and the individual reporter should emphasize any perceived packaging problem in using this form. Reporting of aborted or “near-miss” events to the FDA also is desirable.

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* Graham CF: Report to the Anesthesia and Life Support Advisory Committee, October 24, 1984. Food and Drug Administration, Rockville, Maryland 20857.