Venting vs Ventilating*
A Danger of Manual Resuscitation Bags

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A pressure relief valve, a standard safety feature on many hand held resuscitation bags, prevented the bag from developing sufficient pressure for ventilation during resuscitation of a patient. Many conditions for which cardiopulmonary resuscitation is needed require ventilation pressures higher than the pressure relief valve setting. Despite this, the venting of the "safety" valve is often unrecognized. Knowledge of this problem and of simple methods for overriding the valve need to be disseminated and the equipment designed for safer use.

Hazards and malfunctions of manually operated resuscitation bags have been reported by laboratory testing and clinical use. Most complications arose from excessively high ventilating pressure and include pneumothorax,1-5 pneumomediastinum,6 pneumocephalus,6 and gastric rupture,7 and resulted in modifications designed to limit high pressures.4

In this report we note an important hazard of these bags caused by one such modification, describe circumstances in which the hazard may arise, and suggest methods for its correction.

CASE REPORT

A two-year-old boy was brought to the emergency room after a fall from a 4th story window. He had severe multiple injuries and within minutes suffered cardiorespiratory arrest. Endotracheal intubation was performed, ventilation was begun by an anesthesiologist with a pediatric Hope II (Ohio Medical Products) resuscitation bag, and external cardiac massage was started. While being ventilated with oxygen, arterial blood gas values were pH, 7.08; P O2, 20 mm Hg; P CO2, 71 mm Hg. These were not improved by more vigorous bagging.

We then arrived and noted that only minimal chest excursions were being produced and that the pressure relief valve of the bag was venting on each squeeze. This venting was unrecognized by those performing CPR. When the pressure relief valve hole (Fig 1) was occluded with a finger, considerable force was required to ventilate the patient, but there was an immediate increase in effective ventilation indicated by chest movement and breath sounds. It was then determined that the patient had unilateral pneumothorax and intrapulmonary hemorrhage causing this decrease in chest compliance, and appropriate therapeutic measures were taken. The severity of the patient's head injuries and his lack of response to therapy caused us to terminate resuscitative efforts at this point.

DISCUSSION

We reported this equipment hazard to the manufacturer and to the U.S. Pharmacopeia. Through the Bureau of Medical Devices of the U.S. Food and Drug Administration, testing of the pressure relief valve of this bag and another involved in a similar clinical situation was arranged. The valves released at the rated level of 40 cm H2O.

Hand-operated resuscitator bags are frequently used either with masks or endotracheal tubes, in virtually every respiratory arrest, for elective intubations, and for ventilation before and after endotracheal tube suctioning. They are available in a variety of shapes and sizes compatible with prematurity through adulthood and reviews of these devices have been published.8-11 Many models have a pressure relief valve available as an optional "safety" feature designed to limit the maximum pressure that can be provided, thus reducing the

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Figure 1. Diagram of a resuscitation bag, showing pressure relief valve.
risk of overinflation of compliant lungs and the production of pneumothorax, especially at the hands of an operator inexperienced in gauging the "feel" of bagged ventilation. Laboratory testing of a similar model showed that the relief valve frequently vented during the test procedure.

This feature, however, places an entire class of patients at risk of inadequate ventilation. A wide variety of clinical situations can result in increased resistance to artificial ventilation and require higher pressures than the preset maximum, including intrinsic lung disease, pulmonary edema, pneumothorax, and chest wall injury. Cardiopulmonary resuscitation itself often produces this situation, particularly since the National Conference on Cardiopulmonary Resuscitation and Emergency Cardiac Care of 1979 now recommends that external cardiac massage not be stopped to allow for ventilation, but that the breaths be given quickly between cardiac compressions, requiring higher pressures. In fact, they recommend that resuscitation bags should not be equipped with a pressure relief valve and suggest that a manometer be placed in line in equipment designed for neonates. In addition, a resuscitation bag may be defective or become so after repeated use and sterilization, thus failing to deliver even the specified maximum pressure.

We have attempted to make this problem more widely known in our institution by informal discussion and formal teaching. The need for additional knowledge in this area was documented recently at a course in cardiopulmonary resuscitation for physicians, at which only two of 18 participants were able to recognize this inappropriate venting when it was demonstrated as part of a test.

The relief valve may be inactivated by occluding the outlet with a finger, but in doing so, the operator must either change his grip on the bag, making it less securely held, or he must use his other hand, losing the ability to stabilize the mask or endotracheal tube. A pressure relief valve is an optional feature in resuscitation bags and should not be purchased casually. If a resuscitation bag containing a pressure relief valve is desired, we suggest that bags with a valve more noticeable to the operator and more easily occluded without interference with bag function be used. A bag so designed (manufactured by A. Laerdal, Stavenger, Norway) was found particularly safe and effective.

Anyone using a resuscitation bag should be aware that inadequate ventilation, despite vigorous squeezing of the bag, may be due to inappropriate venting of the pressure relief valve. This can be recognized by the sound made when the valve vents to the air; occluding the relief valve while bagging may be life-saving. We have since seen a number of similar situations in which ventilation was impossible until the relief valve was occluded.

Malfunctions and hazards of medical devices should be dealt with diligently. A new mechanism has been set up for reporting hazards or malfunctions of medical equipment. The United States Pharmacopeia has established a toll-free telephone number for filing such reports. Any problems experienced with products, including unclear labeling, poor packaging, product breakdown, malfunctioning equipment, inaccurate results, inadequate design, etc may be reported by calling toll-free (800) 638-6725 or by writing The Medical Device and Laboratory Product Problem Reporting Program in care of: Dr. Joseph C. Valentino, The U.S. Pharmacopeial Convention, Inc., 12001 Twinbrook Parkway, Rockville, Maryland 20852. The details are then referred to both the manufacturer and the Bureau for Medical Devices of the Food and Drug Administration. In this way, information may be disseminated, and if necessary, faulty or hazardous medical equipment can be recalled from the market.

Although we reported this hazard in the above manner, no corrective action has been deemed necessary by the FDA or the manufacturer because the device functioned according to the manufacturer's specifications. Therefore, it has been left to the individual to recognize and correct a commonly occurring but little recognized equipment deficiency.

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