

# Popular Anesthetic Safe

Halothane, widely used as an anesthetic because it is nonflammable, has been exonerated of charges of causing liver damage—By Faye Marley

► FEAR that the popular anesthetic halothane might be the cause of fatal liver damage is almost groundless, a three-year study has shown.

Instead of being dangerous, halothane had a safety record reflected in an overall death rate of 1.87% compared to an average for all anesthetics of 1.93%. Nitrous oxide-barbiturate had a similar death rate, whereas cyclopropane and "other" anesthetics were linked to 2.5% death rates.

Ether had the lowest death rate following its use, but the committee said it "deserves more systematic study." The result recorded in the present findings is unreliable because so few hospitals in the study used it extensively, and no further conclusions can be drawn now.

A summary report of the huge study was released in the Journal of the American Medical Association, 197:

775, 1966. A special committee of the National Academy of Sciences-National Research Council took three years to analyze anesthetic administrations given to more than 856,000 patients in 34 hospitals during the four-year period 1959 through 1962.

The study covered approximately three-quarter million separate administrations of the general anesthetics used. There were 16,840 deaths from various causes, and 60.4% cases were autopsied, with special attention paid to the abdomen.

Dr. John P. Bunker of Stanford University School of Medicine, Palo Alto, Calif., was chairman of the national halothane study, which began in June 1963 after a drug warning was issued by the manufacturer, Ayerst Laboratories, New York.

The warning stated that 12 new cases of fatal hepatic necrosis had followed surgical procedures in which

halothane was used. Several of these deaths followed gallbladder operations, 27,000 of which were studied in a separate analysis.

In the gallbladder surgery study, death rates were found to be lowest following the use of halothane in spite of the caution by Ayerst that "the administration of halothane to patients with known liver or biliary tract disease is not recommended."

The committee reported on the side of caution, however, stating that although the study "failed to establish a causal relationship between halothane and hepatic necrosis, no study of this type could completely exclude the possibility of rare causation."

Thus, according to the report, unexplained fever and jaundice in a specific patient who had been given halothane would indicate that this anesthetic should not be repeated in that patient.

Dr. Bunker said one of the most important findings of the study is that there are no systematic methods for appraising new therapeutic techniques.

"It is doubtful whether any drug was ever more extensively studied both before and after its introduction than halothane," Dr. Bunker said. "Yet after halothane had been given to patients perhaps 10 million times it was impossible to give firm reliable answers to many basic questions about its effects."

The committee recommended "the establishment of a cooperating group of institutions to serve as a panel-laboratory for the acquisition of trustworthy information on new drugs as they come into use."

The U.S. Food and Drug Administration is withdrawing many drugs, or causing them to be labeled dangerous on the basis of poorly designed studies and insufficient clinical evidence, Dr. Bunker said.

The summary report will be followed by a full report by NAS-NRC in the next six months with computer procedures and tabulations of data assembled at Stanford's computer center.

Halothane, whose trade name is Fluothane, is discussed in the 1965 edition of New Drugs, evaluated by the AMA Council on Drugs. It has been used widely because of its nonflammability and nonexplosiveness, the evaluation stated.

"Inhalation of halothane vapor does not irritate the mucus membranes, excitement is relatively brief, and pharyngeal and laryngeal reflexes are rapidly depressed." This means that coughing and vomiting are limited and consciousness returns quickly.

Among the 34 institutions that took part in the study were Peter Bent Brigham Hospital, Boston, the Mayo Clinic, Rochester, Minn., and hospitals associated with the universities of Michigan, Miami, California, Iowa, Columbia, Duke and of California at Los Angeles.

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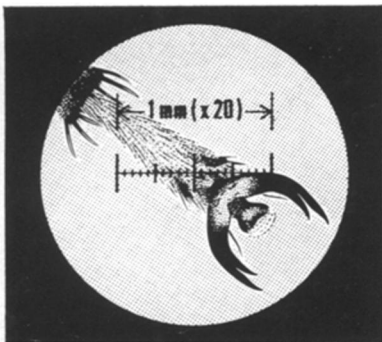
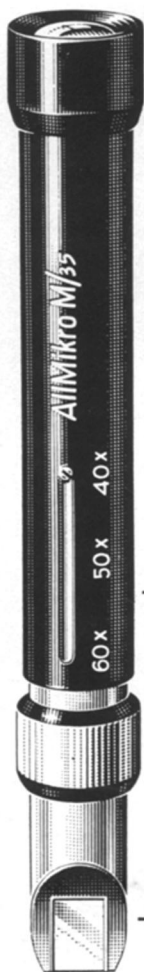
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