Following extensive laboratory investigation, halothane (Fluothane), 1,1,1-trifluoro-2,2-bromochloroethane, was introduced to clinical anesthesia in England in 1956 and in the United States in 1958. Studies of hepatic function in the experimental animal and in man gave no indication of halothane-induced hepatic damage, but isolated reports of massive hepatic necrosis following halothane anesthesia soon appeared and suggested the need for further investigation. In December 1961, the Committee on Anesthesia of the National Academy of Sciences-National Research Council (NAS-NRC) designated a study group to report periodically on all clinical aspects of halothane anesthesia and to give special attention to any evidence of association with fatal postoperative hepatic necrosis. In October 1962, a subcommittee of three was appointed to make recommendations on the need for and the feasibility of a clinical study of the relationship of halothane anesthesia to hepatic necrosis.

The subcommittee found the evidence insufficient to establish or refute a causal relationship between halothane and postoperative hepatic damage.

"In May 1963, a drug warning was issued by the manufacturer on the basis of 12 new cases of fatal hepatic necrosis that followed surgical procedures in which halothane was used; several of the deaths followed cholecystectomy.

Considerations of feasibility and effort, however, strongly favored the retrospective survey as a first step and one that could possibly make a large clinical trial unnecessary. The plans for a clinical trial were discontinued in favor of a survey of experience in the years before the issue of hepatotoxicity had been seriously raised.

Fifty-four medical centers volunteered to participate in the collaborative retrospective study. When provided the exacting requirements of the proposed protocol, 16 of them, in view of limitations of personnel and problems in record retrieval, decided against participation. The protocol was tested and refined in a pilot study of the December 1962 records of the remaining 38 institutions. Three withdrew, and 35 [institutions] contributed data on the four-year period from 1959 through 1962; 34 met the requirements of the protocol and their data constitute the basis of the subcommittee's report.

Special attention was paid to a comparison of halothane and other commonly used anesthetics with respect to hepatic necrosis and postoperative death generally. The main conclusions are:
1. Fatal postoperative massive hepatic necrosis was a rare occurrence. It could usually be explained on the basis of circulatory shock, sepsis, or previous hepatic disease. The possible rare occurrence of halothane-induced hepatic necrosis following single or multiple administrations could not be ruled out.

2. Halothane, rather than being a dangerous anesthetic, had a record of safety as reflected in an overall mortality of 1.87%, compared to an average for all anesthetic practices of 1.93%. This overall parity of halothane holds up when imbalances in patient populations are taken into account by detailed statistical adjustments. No evidence was found to support the imputed risk of halothane in operations performed on the gall-bladder or bile ducts, or in craniotomies.

3. In the middle-death-rate operations cyclopropane and 'other' were associated with reliably higher mortality than were halothane and nitrous oxide-barbiturate; in terms of crude death rates there was a nearly two-fold contrast. After statistical adjustment to compensate for differences in the populations exposed to the various agents, cyclopropane and 'other' had death rates 2.5% or more, compared to approximately 2% for halothane and nitrous oxide-barbiturate, roughly 25% greater.

4. Ether deserves more systematic study; although the death rate following ether administration was lowest of all, the result is unreliable because so few hospitals in the study used it extensively, and so no further conclusions can now be drawn.

5. Of special interest and concern were the large differences in postoperative mortality occurring among the participating institutions. These differences could not be accounted for by the variations among hospital populations by any of the criteria measured in this study. This matter is discussed further in the full report.

Recommendations of the Committee on Anesthesia and the Subcommittee on the National Halothane Study, National Research Council.

1. We recommend that consideration be given to the initiation of limited randomized studies of death rates associated with anesthesia agents. ... 

2. We recommend the establishment of a cooperating group of institutions to serve as a panel-laboratory for the acquisition of trustworthy information on new drugs (not merely anesthetics) as they come into use. ...

3. We recommend consideration of the establishment of a registry for the collection of clinical, laboratory, and pathological findings in cases of hepatic necrosis.”


“The patient with impaired muscle function presents a special problem to the anesthesiologist. At the end of general anesthesia, muscular relaxation must be reversed as quickly and as completely as possible, and for this reason halothane has been a frequent choice as the inhalational anesthetic. ... The present study of halothane deals with two questions: (1) Does this volatile anesthetic, halothane, have an appreciable effect on neuromuscular transmission? (2) At what site or sites does halothane act? ...
"All our experiments were performed on the frog. . . . Halothane, even in moderate concentrations, gives evidence of blocking action on neuromuscular transmission . . . .

"When halothane was studied in the amphibian nerve-muscle preparation, the blocking concentrations of halothane were found to be 1.5% for the nerve-stimulated twitch, 4% for axonal conduction, and 4% for the directly stimulated muscle. From these results, it was concluded that the peripheral blockade produced by halothane occurs at the neuromuscular junction. By the use of microelectrode penetration of single fibers, it was demonstrated that, at the neuromuscular junction, the postjunctional membrane is the synaptic structure most sensitive to the action of halothane."


"A study was . . . undertaken to define certain effects of halothane on hepatic function tests in patients in whom liver function had been assessed previously by clinical, biochemical, and histologic examinations and to compare these effects with those that followed the administration of diethyl ether. . . .

"A random sample of 100 patients was selected, prior to elective abdominal surgery. . . . Patients known to have malignant disease or disorders of the liver and biliary tract were excluded. The anesthesia sequence in each group was similar except for the primary agent. . . .

"Liver-function tests were performed before and after operation. . . . Fifty patients had received an anesthetic sequence with halothane as the principal agent, and 50 had received a similar sequence with diethyl ether.

"Although clinical unsuspected, trivial abnormalities in test results were found in 14% of patients prior to operation and abnormal liver histologic findings were noted at the time of operation in 13.3%. The combination of abnormal results of liver-function tests and of abnormal liver histologic findings was seen in only two patients.

"Minor but significant alterations in liver function occurred after operation in 30 patients — 17 following halothane anesthesia and 13 after diethyl ether. The incidence and degree of these changes were similar regardless of the primary anesthetic agent, but the pattern of changes differed significantly.

"Evidence of more serious impairment of liver function was noted in three patients after operation; two of these otherwise appeared and felt well. Two of the three had received diethyl ether and one, halothane."


"Methoxyflurane (Penthrane) is a short-chain halogenated ether which was developed as a general anesthetic by Van Poznak and Artusio and has been in clinical use since 1959. Although chemically an ether, this compound has organic chloride and fluoride substituents similar to that of halothane.

"In view of this structural similarity it might be expected that in-
creasing use of methoxyflurane will be associated with rare reports of drug-induced hepatic injury. To our knowledge, this is the first nonfatal case of suspected methoxyflurane hepatotoxicity with documented hepatic cellular necrosis.

"In June 1965, a 58-year-old Negro woman was seen in the outpatient department complaining of a persistent vaginal discharge. A friable lesion, which on biopsy proved to be a squamous-cell carcinoma was noted in the vaginal vault.

"She received two 30-hour radium implants into the tumor. The first was performed on July 13 under thiopental sodium-cyclopropane anesthesia and the second on July 29 under thiopental-methoxyflurane anesthesia. In both instances, the preanesthetic medications were pentobarbital and atropine. These procedures were uneventful and lasted about 45 minutes each. Within two days of the second procedure the patient complained of fatigue with anorexia and nausea, and a temperature elevation. On Aug. 7 she noted dark urine and on Aug. 10 she had light stools and was jaundiced. On that day her liver was palpable 8 cm beneath the right costal margin in the midclavicular line and liver-function tests were markedly abnormal.

"A percutaneous liver biopsy was performed on Sept. 1, four weeks after the onset of symptoms. Sections showed centrilobular dropout of parenchymal cells with disruption of cell cords and focal reticulin collapse. There were large multinucleated liver cells, mononuclear cells, and Kupffer cells containing yellow pigment in these central areas. She was asymptomatic when she was admitted on Oct. 19 for a repeat liver biopsy and liver-function tests. Biopsy showed a return of liver structure towards normal.

"In the evaluation of the hepatotoxicity of an anesthetic agent many factors must be considered."


"The purpose of the present investigation was to determine (1) whether depression of myoneural transmission in peripheral muscle could be related to abdominal muscle relaxation, (2) the magnitude of peripheral myoneural block required to produce profound abdominal relaxation, and (3) the feasibility of application of results to clinical monitoring of muscle-relaxant administration.

"Twenty-five unselected adult surgical patients scheduled for intra-abdominal operations requiring profound relaxation of the abdominal-wall muscles were studied. The evoked muscle action potential of the hypothenar muscles in the hand or the medial plantar muscles of the foot was recorded with either surface electromyographic disks or an intramuscular coaxial electrode. Supramaximal stimulation of the ulnar nerve at the wrist or the posterior tibial nerve at the ankle was with two subcutaneous 26-gauge steel hypodermic needles placed along the course of the nerve.

"Anesthesia was maintained with endotracheal nitrous oxide-oxygen-halothane, following thiopental and succinylcholine induction. Depth of anesthesia was sufficient for skin incision and was maintained at moderate to light surgical levels."
Amplitude of the muscle action potential in millivolts was measured directly from calibrated Polaroid photographs. Depression of neuromuscular transmission, evidenced by reduction in amplitude of the experimental EMG, was expressed as percent change from control (100%). Estimated abdominal muscle relaxation (poor, adequate, good) was tabulated for four levels of myoneural transmission block (76% to 100%, 51% to 75%, 26% to 50%, and 1% to 25% EMG amplitude).

The association between abdominal relaxation and myoneural transmission block is statistically significant (PL 0.001; chi-square test)....

A profound transmission block... provided—in this group with halothane anesthesia—uniformly profound abdominal relaxation, independent of the muscle relaxant used.

This investigation was initiated to determine the feasibility of employing quantitative changes in neuromuscular transmission in small muscles of the hand and foot as indices of abdominal muscle relaxation during administration of muscle relaxants....

Results from this study make it clear that total paralysis is not a necessary prerequisite to profound abdominal relaxation. Thus dosage of muscle relaxant may be titrated to a definite endpoint which varies as the surgical requirements demand....

Present results show clearly that profound relaxation is obtainable shortly before neuromuscular transmission is entirely abolished."


The purpose of this paper is to describe a simple technique of monitoring neuromuscular transmission....

A peripheral motor nerve is selected for stimulation according to its accessibility during the surgical procedure. When the upper extremity can be placed on an arm board, the ulnar nerve is stimulated at the medial aspect of the wrist. When the arm is inaccessible as in upper extremity or head and neck operations, the posterior tibial nerve is stimulated at the medial malleolus. If the extremities are out of reach, the facial nerve may be stimulated by placing electrodes between the mastoid process and the neck of the mandible....

Any stimulator capable of delivering pulses lasting 0.1 to 0.5 msec and at least 75 v in amplitude is suitable for supramaximal excitation of the motor nerve through needle electrodes. Recently several battery-operated economical and simple stimulators have become commercially available for use in the operating room....

Battery-operated stimulators are desirable since the stimulus is isolated from ground.... Sufficient information to titrate muscle relaxant dosage is obtained from the peripheral muscle response to single stimuli....

Sixty-five adult patients scheduled for surgical procedures requiring abdominal muscular relaxation were studied.... The decrease in contractile twitch strength of small muscles of the hand, foot, or face to electrical stimulation of the appropriate motor nerve was estimated visually or by palpation. Abdominal muscle relaxation was satisfactory in 63 of 65 subjects without resorting to total paralysis of small peripheral muscles.

Profound muscular relaxation—in the adequately anesthetized patient—could be achieved by maintaining
a flicker of muscle activity (corresponding to an EMG amplitude of 5% to 10% of control). By this means, the administration of muscle relaxants could be titrated to obtain optimal drug efficacy at lowest drug dosage. Nevertheless, evidence of residual drug action on neuromuscular transmission was detected in 36 of 65 patients at termination of anesthesia. Muscle-relaxant action could be reversed with neostigmine in 31 of 33 patients who exhibited muscle fatigue during nerve stimulation at tetanic rates. In five patients, drug action was not or could not be reversed by neostigmine.

"Testing of neuromuscular transmission during muscle-relaxant administration is a useful and practical clinical technique which provides minute-to-minute information about drug action. Furthermore, it assures that patients are not returned to the recovery area until adequate neuromuscular function has returned."


"The importance of spinal and epidural analgesia in reducing peripheral venous and arteriolar tone is well appreciated. A less well-known but important additional factor is the hemodynamic effect produced by sympathetic denervation of the heart. . . ."

"It is technically feasible to reduce the interference from the peripheral circulation and thus isolate the cardiac component by introducing an in-dwelling catheter into the epidural space at the upper thoracic level, then by selecting a proper mass of local analgesic to restrict the analgesia to the upper four or five thoracic nerves that contain the cardiac sympathetic fibres. This method of cardiac sympathetic blockade without gross denervation of the peripheral circulation provides a convenient method of studying the role of reduced cardiac sympathetic tone on myocardial function in humans. Accordingly, the present investigation was undertaken to isolate and identify the extent of cardiocirculatory changes to be expected following upper thoracic epidural sympathetic blockage. . . .

"The investigations were carried out on six fit, non-sedated adult patients before operation. . . . Cardiocirculatory dynamics were assessed by measuring arterial and central venous pressures, heart rate, and cardiac output (Indocyanine dilution) and calculating total systemic vascular resistance and left ventricular work.

"Following epidural blockade there was a significant reduction in cardiac index (16%) and in heart rate, whereas the stroke volume remained constant in spite of a significant rise in central venous pressure (1.9 cm H\textsubscript{2}O). A decline in arterial pressure (7%) paralleled the reduction to minute flow. It is concluded that upper thoracic epidural analgesia reduces cardiac performance by interfering with fundamental cardiac mechanisms in two ways: first, by slowing the heart rate, and second, by reducing the myocardial response to its filling pressure."


"External direct-current and alternating-current countershock has proved effective in terminating ventricular tachycardia. Various medica-
tions have also been used to control this arrhythmia. . . .

"Only recently has ventricular tachycardia of nonsurgical origin been reported as successfully treated by lidocaine, but there has been no reference to its prolonged intermittent, intravenous use (i.e., more than eight repeated doses). It has been used for prolonged epidural analgesia. Continuous intravenous infusion with a 1% or 2% solution has not been reported, although infusion with concentrations of 0.1% to 0.2% have not been considered effective in prevention or treatment of ventricular arrhythmias. The duration of antiarrhythmic action of intravenous doses of 1 mg/kg is 10 to 20 minutes; therefore, it has been recommended that each dose be administered rapidly intravenously.

"Toxic effects include somnolence, cerebral irritation, medullary depression, restlessness, and convulsions; intravenous doses of 1 mg/kg repeated at 5 to 30 minute intervals have not been associated with toxicity in previous reports. Lidocaine also produced less systemic hypotension than procainamide.

"The initial trial of lidocaine hydrochloride in this patient consisted of two doses of 50 mg each at 15-minute intervals and was unsuccessful. However, when doses of 20 mg each were given rapidly every three to five minutes totaling 240 to 400 mg per hour, the arrhythmia was controlled. These total amounts were much larger than any previously reported for intravenous administration. . . .

"Lidocaine may have cumulative toxicity in experimental animals. Because of this possibility it was withdrawn abruptly at the end of 24 hours, after beginning intravenous sedation. . . .

"Recurrent ventricular tachycardia arising in an otherwise healthy, 31-year-old white woman was unresponsive to various antiarrhythmic agents. The arrhythmia was controlled with a combination of direct-current countershock and intermittent, intravenous lidocaine hydrochloride administration."


"The muscular activity in the diaphragm under conditions interfering with respiratory physiology seems to the authors to be an important object for studies with regard to the demands of modern anaesthesiology.

"As life is always threatened by a sudden occlusion or an extensive obstruction of the airways, and as the most important task for the anaesthetist is to avoid and take care of this complication, the authors considered that it would be of great interest to study — by means of electromyography — the activity of the diaphragm during obstruction or occlusion of the airways in light and deep anaesthesia and after vagotomy. . . . The experiments were performed on cats. . . .

"Light anaesthesia: — With increasing obstruction the respiratory frequency was markedly reduced. The electrical activity, however, was most pronounced during total occlusion, which shows that the most vivid motor-unit activity was built up during an extreme alarm situation.
“Deep anaesthesia:—Deep anaesthesia reduced the range of activity of the respiratory regulation under exposures to respiratory distress of the same magnitude as used in light anaesthesia.

“After vagotomy:—After division of the vagal nerves the frequency of breathing and the increase in the amplitude of the electromyographic pattern were very low with no apparent change when the animals were exposed to obstruction or occlusion of the airway. The conditions described in deep anaesthesia, and especially after vagotomy, may very well be the result of a depression of vagal reflex activity.”


“When regional anaesthesia is performed, the most important aim is to attain good analgesia. This can be achieved by intravenous regional anaesthesia. . . . In addition to analgesia, muscle relaxation is often desirable. Good muscle relaxation is usually accompanied by good analgesia. . . . With respect to regional intravenous anaesthesia, certain factors must be taken into consideration. The procedure is carried out with the extremity in question cut off from the general circulation, and this in itself affects muscle function. . . .

“Investigations of muscle power have been carried out: — 1. under anoxic conditions, 2. when a 0.5% Citanest solution is injected simultaneously with the production of an anoxic state, and 3. when the anoxic state precedes the injection of the anaesthetic agent by 20 minutes.

“It has been shown that muscle power is diminished or abolished by this form of anaesthesia. Muscle relaxation is more quickly produced if a period of arterial occlusion precedes the injection of the anaesthetic by 20 minutes. Intravenous regional anaesthesia is thus suitable for surgery of the extremities, even when muscle relaxation is desired.”


“Physiotherapists who treat thoracic surgical patients are well aware of the difficulty in obtaining the best results postoperatively because of pain, which so often limits the ability of the patient to carry out exercises. . . . Relief of pain is therefore of primary importance. . . . The method described below has been designed to overcome these difficulties, at least in part. . . . Analgesia is provided by the inhalation of 0.5% trichlorethylene delivered from an inhaler approved by the Central Midwives Board for use by midwives. . . . It was found that 8 to 12 breaths of 0.5% trichlorethylene were sufficient to give a beneficial effect for about two minutes. . . . These inhalations were used in conjunction with . . . injections of pethidine or papaveretum. . . .

“One hundred and twenty-three patients who had undergone thoracic surgery received 0.5% trichlorethylene/air inhalations to provide analgesia for postoperative physiotherapy. The results were gauged subjectively and by measurements of peak flow before and after treatment. The re-
suits were encouraging, and with only a 5% failure rate it is thought that this procedure could well be applied to any patient whose postoperative pain might restrict respiratory or limb movements."


"The problem for this study was . . . How do blood pressure readings obtained in the clinical setting by palpation of the brachial artery compare with readings obtained by auscultation of the same vessel?

"The study was a direct comparison of two methods of blood pressure reading obtained by simultaneous independent readings by two observers according to a predetermined pattern. The sample consisted of 50 adult medical-surgical patients selected in sequence from the census of a medical and a surgical unit of a 430-bed general hospital. . . .

"A comparison of blood pressure readings obtained simultaneously on 50 patients by two independent observers utilizing an interchanging pattern of palpation and auscultation of the brachial artery yielded a range of mean difference from 5.74 to 7.00 mm. of mercury. These figures are well within the mean error of 8.00 mm. of mercury that the American Heart Association states may be expected for individual readings of systolic and diastolic pressures in normal persons. . . . The findings indicate that the technique of palpation deserves further study."


"Because of the geographical size of the United States, the rapidly growing population and the relative shortage of medical doctors, it is impossible to consider replacing all nurse anesthetists with medical anesthesiologists; neither is it economically practical to do such a thing. Furthermore, the ordinary training of a medical practitioner does not fit him for the role of an anesthesiologist. The anesthesiologist requires special training just as the nurse anesthetist requires much additional training in addition to her basic tuition.

"The title of this paper should, therefore, be 'The value of the well trained anesthesiologist and the well trained nurse anesthetist.'

"Enormous changes have occurred in the last 25 years in surgery and anesthesia which have made it impossible for a partly trained doctor or nurse successfully to carry out the administration of modern anesthetics for modern operations. . . .

"Mention must be made of the vitally important auxiliary services performed by the anesthesia department outside the operating room. In two areas, resuscitation and inhalation therapy, the anesthetist's particular knowledge of cardiovascular and pulmonary problems makes him a great asset, especially in smaller hospitals where there are no specialized departments to cover such patient requirements."
MEDICARE REIMBURSEMENT

Here is the long-awaited statement concerning reimbursement of non-hospital employed anesthetists. This statement is reproduced with the permission of Arthur E. Hess, Director, Bureau of Health Insurance, Department of Health, Education and Welfare, Social Security Administration, Baltimore, Maryland.

COVERAGE OF SERVICES OF NONPHYSICIAN ANESTHETISTS

Similarities between services performed by nonphysician anesthetists, particularly Certified Registered Nurse Anesthetists, and some services performed by anesthesiologists and physician-anesthetists have led to questions regarding the coverage under both Part A and Part B of the services of the nonphysician anesthetist. The following summary discusses the situations in which such services are reimbursable on a cost basis as provider services or on a charge basis under the medical and other health services provisions of Part B.

ANESTHETISTS' SERVICES AS HOSPITAL SERVICES

When a nonphysician is a salaried member of the staff of a hospital, the services furnished by such an individual in connection with the administration of anesthetic agents are covered in the same manner as the services of other nonphysician hospital employees. Such services to hospital inpatients would be covered under Part A as inpatient hospital services. When provided for outpatients, these services would be covered under Part B as hospital services incident to a physician’s services to outpatients. In either situation, reimbursement for the services furnished would be made to the hospital on a reasonable cost basis.

When a nonphysician anesthetist who is not a salaried member of the hospital staff provides services to the hospital’s inpatients on a fee-for-service basis, such services will be covered in the same manner as the services of a salaried nonphysician anesthetist, providing the nonphysician anesthetist is legally authorized to furnish such services and her services are made available under arrangements by which payment to the hospital for the service discharges the liability of the patient or any other individual to pay for the services. It is not necessary, however, that the billing arrangements entered into with the hospital by the nonphysician anesthetist be identical for all patients handled by the anesthetist in order for her services to be covered in those cases in which the arrangement does provide that the hospital bill for the services. Reimbursement for anesthesia services provided “under arrangements” by which the
hospital bills for the services will be made to the hospital on a reasonable cost basis.

ANESTHETISTS' SERVICES INCIDENT TO A PHYSICIAN'S SERVICES

In addition to coverage as an outpatient hospital service, a nonphysician anesthetist's services are covered under Part B when provided as an incident to a physician's professional services. Generally, the nonphysician anesthetist's services will meet this definition in two situations:

1. The nonphysician anesthetist is an employee of an anesthesiologist, performs the services under the direct, personal, and continuous supervision of the anesthesiologist and the anesthesiologist includes the charges for the service in his bill. To be rendering direct, personal, and continuous supervision, the anesthesiologist need not be in the operating room at all times but must be close by and available to provide immediate personal assistance and direction. Availability of the anesthesiologist by telephone would not constitute direct, personal, and continuous supervision.

   Charges attributable to the nonphysician anesthetist's services would be taken into account by the Part B carrier when determining the anesthesiologist's reasonable charges. If a nonphysician anesthetist in the employ of an anesthesiologist performs services which are not under his direct personal supervision, the services are not covered even if billed by the anesthesiologist.

2. The nonphysician anesthetist is an employee of, or her services are engaged by a surgeon who is participating in the operative procedure and supervising the services of the nonphysician anesthetist in connection with the administration of anesthetic agents, and that surgeon includes the charges for the nonphysician anesthetist's services in his bill. The Part B carrier would take into account the charges for the nonphysician anesthetist's services when determining the surgeon's total reasonable charge for the operative procedure.

The services of a nonphysician anesthetist are not included among those services which are specifically covered as medical and other health services under Part B. Therefore, coverage of a nonphysician anesthetist's services on a reasonable charge basis is limited to the situations described above in which the services are incident to a physician's services. Services billed directly by a nonphysician anesthetist to an individual patient are not covered under Part A or Part B.
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