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Evaluation of Agent-Specific and Universal PAC™ Drawover Anesthesia Devices Using a Procine Model

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In the austere medical environment, inhalational anesthetic agents can be delivered using a drawover vaporizer anesthesia device. This small, lightweight, rugged unit can operate independently of a powered ventilator or pressurized gas cylinder. Two devices are available commercially: the Oxford Miniature Vaporizer™ and the PAC™ Portable Anesthesia System™. Data in this report compare the operating characteristics of PAC™ agent-specific vaporizers with a Universal PAC™ vaporizer that is capable of delivering a variety of inhalational agents. Using a porcine model, we determined that the universal unit performed as well as agent-specific units; and overall performance was within the manufacturer's specifications. In the course of our study, some problems or limitations inherent to the design of the vaporizer were observed, one of which was corrected by the manufacturer. However, in the hands of a trained health care provider, both the agent-specific and the Universal PAC™ vaporizers fulfill the requirements for a safe and effective anesthesia delivery system.

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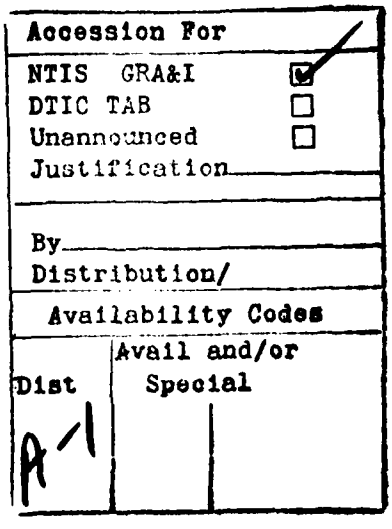


INTRODUCTION

The idea of drawover anesthesia has existed since the discovery of inhalational anesthetic agents. The Schimmelbusch mask, the Flagg can and the Ombredanne mask are examples of early devices that relied on the patient's inspiratory effort to draw anesthetic vapor mixed with room air into the lungs (Schimmelbusch 1890; Ombredanne, 1908; Flagg, 1939). John Snow (1847) designed the first true drawover vaporizer to administer chloroform. It was heated with warm water and contained a series of baffles to improve vaporization of the agent, and it had a valve to prevent rebreathing.

Administration of a single anesthetic agent lost favor with the advent of the Boyle-type machine in the early 1900's. This unit, a forerunner of modern anesthesia machines, used compressed oxygen and nitrous oxide to provide a continuous flow of mixed anesthetic gases and oxygen to the patient.

Interest in drawover anesthesia was renewed with the experiences of Sir Robert Macintosh, a British anesthesiologist serving in the Spanish Civil War. In the absence of adequate anesthesia equipment, he treated casualties using a crude drawover vaporizer fashioned from an empty ether can (a Flagg can). Recognizing that anesthesia care could be compromised by inadequate supplies of oxygen and nitrous oxide, he worked with colleagues in England to develop a vaporizer for effectively administering ether in room air (Calverly, personal communication). The result was the Epstein, Macintosh, and Oxford (EMO) ether inhaler.

Major advantages of this device were a calibrated dial to regulate the concentration of agent, a water jacket to promote heat exchange for agent vaporization, a thermal compensation mechanism to stabilize agent concentration at different temperatures, and a large capacity (Epstein and Macintosh, 1956). This vaporizer with the Oxford Inflating

Bellows for assisted ventilation comprised a complete drawover anesthesia device (Macintosh, 1955).

When halothane became available for widespread use, the vaporizer was redesigned to use more potent but less volatile agents. The resulting device, the Oxford Miniature Vaporizer (OMV®), was smaller than the EMO inhaler; it was thermally stabilized with an antifreeze solution; and it had no thermal compensation mechanism.

The British military modified the OMV® by dulling the finish and adding retracting legs for stability. The vaporizer with hoses, a self-inflating bag, a non-rebreathing valve, regulators, and a Sanders tee for supplemental oxygen comprise the Triservice Anesthesia Apparatus (Epstein and Sanders, 1980), which currently is used by British forces for field anesthesia. It has been used extensively throughout the world, most recently during the Falklands campaign (Carmichael, 1981; Knight and Houghton, 1981; Jowitt and Knight, 1983; Jowitt, 1984).

Other vaporizers were also developed that met requirements for drawover anesthesia; i.e., delivered reliable concentrations of agent at varying flow rates and demonstrated minimal resistance to flow. The United States military evaluated several of these devices and used them in field hospitals during the Vietnam conflict. The AE Inhaler®, the Fluoxaire®, the Portablease System®, and the Fluotec Mark II® vaporizer were all shown to be suitable for use under these conditions (Coursey and Wilson, 1965; Vacanti et al., 1968; Joyce et al., 1969; Ramagnoli and Tousignant, 1970; Counts et al., 1973). Some of these devices also enjoyed wide popularity as dental anesthesia machines during the 1960's and 70's.

There are two drawover vaporizer anesthesia devices available commercially: the OMV® which was described previously and the PAC Portable Anesthesia System®, marketed by the OHMEDA Division of the British Oxygen Corporation. The PAC® system incorporates a low resistance vaporizer with hoses and valves for a complete

anesthesia delivery system. Integral to the vaporizer is a port for supplemental oxygen, a non-rebreathing valve, a stabilizing stand, and a thermal compensation device. A unique safety feature of this vaporizer is its ability to be tipped or inverted without releasing liquid agent into the breathing circuit.

A number of publications support the safety and efficacy of the OMV® and PAC® systems (Houghton, 1981; Borland et al., 1983; Kocan, 1987; Yoganthan and Houghton, 1988). The United States Food and Drug Administration (FDA) has given a 510(k) exemption to PAC® agent-specific devices; i.e., those units which can dispense only one specific anesthetic agent such as halothane, enflurane, or isoflurane. In this study we used a porcine model to evaluate the performance of the Universal PAC® vaporizer and compare it to agent specific vaporizers. The universal vaporizer is designed to accommodate most inhalational anesthetic agents and would have the broadest application in providing field anesthesia. Data reported herein was submitted by OHMEDA to the FDA in seeking a 510(k) exemption for the Universal PAC® "For Battlefield Use Only." This exemption was granted in September 1990.

MATERIALS AND METHODS

For this study, young Yorkshire swine (17-26 kg) were obtained commercially and housed with food and water ad libitum, except for a 24 h period of fasting prior to anesthesia. Use of animals in these studies was approved by the Animal Use and Care Committee, Brooke Army Medical Center.

Fifteen animals were assigned randomly to three treatment groups corresponding to the anesthetic agents tested: halothane, enflurane, or isoflurane. To induce anesthesia, a technician held the unmedicated animal while it inhaled agent through a mask. Following intubation and instrumentation, the animal was subjected to increasing levels of agent delivered either by an agent-specific vaporizer (PAC-halothane®, -enflurane®, -isoflurane®, OHMEDA a Division of BOC, Madison, WI) or the universal vaporizer (Universal PAC®, OMHEDA). Controlled ventilation was provided by a Model V5-A® ventilator (OHMEDA) with descending bellows which was placed in the breathing circuit between the vaporizer and the subject. It was adjusted to maintain an end-tidal carbon dioxide (CO_2) concentration of 35-40 mm of Hg. Supplemental oxygen (O_2) was provided by connecting bottled gas through a flow meter to a connector on the vaporizer. The flow rate was adjusted to 1.0 liter/min.

Blood pressure, temperature, and ECG were monitored continuously. Oxygen saturation (SaO_2) was measured using a pulse oximeter (Model 3700®, OHMEDA) with the sensing unit attached to the subject's tail. Connected to the breathing circuit were a mass spectrometer (MGM 6000, OHMEDA) to measure inspired and expired respiratory gas concentrations and a volume monitor (Model 5420®, OHMEDA). A capnograph and O_2 analyzer also were added to the circuit to confirm CO_2 and O_2 measurements made by the spectrometer. All equipment was calibrated according to manufacturer's instructions prior to use. Animals were removed from study, whenever they demonstrated an

inadequate depth (low concentrations) of anesthesia or the instruments indicated an O_2 saturation < 85% by pulse oximetry, a systolic blood pressure < 60 mm of Hg, or a CO_2 level > 65 mm of Hg. Data reported in this communication are the mean responses (± S.D.) of 5 animals measured for 5.0 min after a steady state of anesthesia was reached as determined by the end-tidal concentration of agent.

RESULTS

Vaporizer performance with spontaneous or controlled ventilation. Performance of the universal vaporizer was evaluated by filling the unit with one of three agents: halothane, enflurane, or isoflurane and measuring the delivery of the agent during spontaneous and controlled ventilation. These data were compared with the delivery of the same agent by the agent-specific vaporizer. Data in Figs. 1, 2, and 3 illustrate the performance of the different vaporizers; and data in Tables I, II, and III list the results of regression analyses of the same data.

During spontaneous and controlled ventilation, all vaporizers delivered mean end-tidal concentrations of agent that approached dial settings on the unit. There was considerable variability in the measurements as reflected by large standard deviations and moderate R^2 values. Variability appeared to be related to limitations of the mass spectrometer which required a large sample size relative to the small tidal volume and minute ventilation of the swine model.

Another problem with the swine model was its greater anesthetic requirements. Whereas the minimum alveolar concentration (MAC) for halothane in humans is 0.76%, the MAC for pigs is 1.2%. As a result, at low dial settings the rapid induction of anesthesia was difficult to achieve. With enflurane the lowest effective setting on the universal vaporizer was 1.8%.

During data analysis, we noted that both the agent-specific and universal vaporizers connected to the ventilator released higher concentrations agent than expected. Results in Fig. 1 dramatically illustrate that during administration of halothane with controlled ventilation, outputs by both vaporizers were consistently higher than their corresponding dial settings and higher than the outputs of the same units using spontaneous ventilation.

Examination of the vaporizers during controlled ventilation revealed that the valve in the vaporizer outflow port that prevented backflow did not seal consistently during ventilation. The odor of agent was detected in the reservoir (inlet). When a volume monitor was connected to the reservoir tube, we measured a retrograde flow of approximately 40 cc per breath.

The halothane-specific vaporizer was returned to the manufacturer for evaluation and modification. The mica disk in the non-return valve was replaced with a more compliant teflon disk that eliminated the leak. Data in Figure 4 illustrate the outputs of the halothane vaporizer with controlled ventilation before and after modification. Regression analyses of these data show that modification of the vaporizer reduced the output and improved the performance of the unit (slope = 0.92, *y* intercept = 0.44, $R^2 = 0.96$) in comparison to the unmodified unit (slope = 0.6, *y* intercept = 1.5, $R^2 = 0.85$). Moreover, performance of the modified unit using the porcine model compared very favorably with calibration data provided by the manufacturer and data obtained from a bench test of the unit in our laboratory using the Model V5-A® ventilator (see Fig. 5).

Effect of controlled ventilation and supplemental O_2 on O_2 saturation during anesthesia. Mahla (see Appendix A) reported in his study on the OMV®, that dogs anesthetized with 2 to 3% halothane and breathing spontaneously demonstrated a drop in arterial O_2 levels and required supplemental O_2. Similarly, in our study there was an inverse relationship between agent concentration and O_2 levels. Animals anesthetized with low concentrations of agent (1 to 2%) using spontaneous ventilation had SaO_2 levels that averaged around 90% (Figs. 6, 7, and 8). With increasing concentrations of agent, SaO_2 levels fell lower. In particular, halothane or isoflurane administered at vaporizer settings of 3% or 4%, effected a reduction in SaO_2 levels to about 85%, which in humans would be considered inadequate oxygenation.

Oxygen saturation increased to safe levels (>92%, Borland et al., 1983), when the animals were maintained on a respirator. The most improvement occurred when animals received supplemental O_2. Irrespective of whether the animal was maintained on a ventilator or not, SaO_2 exceeded 95% when O_2 at 1.0 liter/min was introduced through a port in the vaporizer.

DISCUSSION

Under conditions of spontaneous ventilation, the Universal PAC® performed like the agent-specific units and reliably dispensed halothane, enflurane, and isoflurane. This was to be expected since the agent-specific and the universal vaporizers are identical, except for two modifications to the latter. The filling port was redesigned with a funnel mouth; and dial settings for the different agents were stamped on metal plates, which are fastened to the top of the unit with a special dial screw. The drain cap in the bottom of the vaporizer serves as a wrench to remove this dial screw and prompts the user to drain the unit before introducing a different agent.

During our study we discovered that the non-return valve on both agent-specific and universal vaporizers leaked when animals were maintained on a ventilator. As a result, agent concentrations received by the experimental subjects were variable and higher than expected. Whereas this defect probably would not pose a dangerous risk to patients, the manufacturer corrected the problem by replacing the rigid valve with a more compliant one, as discussed previously. Not only did we measure an improvement in the performance of the vaporizer, the manufacturer reported that the unit was easier to calibrate (personal communication).

We observed that other physical characteristics of the PAC® units met the manufacturer's specifications. All vaporizers tolerated extended usage and shipping without damage or a change in calibration. Inversion of the vaporizer during use resulted in a transient increase in agent concentration of $<0.5\%$ which returned to the set value with continued use. No liquid was spilled during inversion. Finally, we found that the Universal PAC® could be cleared of all traces of agent by draining the reservoir, turning the dial fully open, and passing air through the vaporizer for 5 min using an AMBU® bag.

The need for drawover anesthesia today is the same as that which inspired Sir Robert Macintosh to revive the concept over 50 years ago. The austere medical environment which currently exists in underdeveloped nations can rapidly evolve elsewhere in times of natural disaster and war. In the absence of compressed oxygen and nitrous oxide, modern anesthesia machines, including the M885-A field anesthesia machine, will not function. The drawover vaporizer can operate independently of these resources; and it is lightweight, rugged, compact, and portable. The Universal PAC® also can dispense all inhalational agents currently in use.

The PAC® and OMV® units were designed to administer agents safely and accurately under conditions of spontaneous ventilation, which may predominate when the unit is employed in the field. Mahla (Appendix A) reported that in the canine model the output from the OMV® during spontaneous ventilation was about 75% of the dial setting. With the PAC-halothane® vaporizer, modified with a new valve, there was very close correlation between agent output and dial settings in both laboratory tests and in the porcine model.

Our results and those of Mahla demonstrate that with spontaneous ventilation, animals become dangerously hypoxic with higher concentrations of halothane, isoflurane, or enflurane. Published reports also suggest that patients anesthetized with drawover in conjunction with spontaneous ventilation may exhibit reduced blood O_2 levels. However, investigators developed and employed techniques to minimize this problem.

Coursey and Wilson (1965), using the A.E. Inhaler® (a forerunner of the PAC®), reported on the response of patients anesthetized with halothane or with a halothane-ether azeotrope. Patients breathing room air spontaneously or with controlled ventilation had an average pO_2 of 80 mm of Hg; whereas those receiving supplemental O_2 had a pO_2 of 110 to 150 mm of Hg. They concluded, " While the 0.5 liter per minute flow rate was sufficient to maintain an adequate arterial pO_2, those patients allowed to breathe room air alone

also did well and had pO_2 values equal to those observed on nitrous oxide-oxygen. Use of an endotracheal tube greatly enhanced the effectiveness of the unit; without airway obstruction, none of the patients developed any discernible cyanosis or other evidence of respiratory difficulty."

Joyce et al. (1969) tested the Fluoxair® (the immediate predecessor of the PAC®) on surgery patients using halothane and spontaneous ventilation. To facilitate induction they increased the concentration of halothane to 4 or 5% as rapidly as tolerated by the patients, and measured the depth of anesthesia by observing for central fixation of the eye and constriction of the pupil. At that point they immediately reduced the concentration of halothane to 1 or 2%. They observed that failure to reduce agent concentration at this point resulted in profound respiratory depression with the paO_2 as low as 40 torr. However, if the anesthetic concentration was reduced, the paO_2 averaged 83 torr; and during the operative period, the paO_2 remained at or slightly above preoperative levels.

Finally, Borland et al. (1983) field-tested PAC® agent-specific units and observed that when halothane was used, supplemental oxygen was required to ensure an adequate SaO_2. Whereas these results would appear to be contradictory to earlier observations, the investigators evaluated only 11 patients; and they did not describe how the anesthesia was administered or at what altitude. Some of the field trials reported in this study were done at an altitude of 1676 m (barometric pressure = 619 mm of Hg).

Use of the drawover anesthesia device is subject to the limitations imposed by the alveolar gas equation: $\mathbf{PaO_2 = (Pbar\text{-}47)(FiO_2) - PaCO_2/RQ}$

Where PaO_2 = alveolar oxygen tension

Pbar = barometric pressure

FiO_2 = fractional inspired oxygen concentration

$PaCO_2$ = arterial carbon dioxide tension

RQ = respiratory quotient (0.8)

This equation demonstrates that the alveolar oxygen tension is increased with increasing barometric pressure and fractional inspired oxygen concentration; whereas it is decreased by increased arterial carbon dioxide tension. Therefore, it follows that the SaO_2 would improve in patients receiving supplemental oxygen or under controlled respiration (Wakai, 1963; Mackie, 1987; Nunn, 1987)

Supplemental oxygen is the preferred method for ensuring that a patient is adequately oxygenated. Our data and reports by others show that a good SaO_2 levels may be maintained by introducing low flows of O_2 into the breathing circuit. In our study the O_2 was obtained from a compressed gas cylinder. At the flow rates used (1.0 liter/min) sufficient O_2 also could have been generated with an O_2 concentrator.

The use of controlled ventilation to improve oxygenation involves significant problems. Currently, there is no mechanical ventilator in the U.S. military inventory, except the AMBU® bag, that will support drawover anesthesia. Ventilating patients by physically squeezing a bag during long surgical procedures would burden operating room personnel and could subject the patient to an overdose of agent. Joyce et al (1969) reported that "early attempts at controlled ventilation rapidly produced a deterioration in the patient's cardiorespiratory status, due to anesthetic overdose secondary to tidal volumes between 1 and 2 L(iters)." This problem was corrected as the anesthesiologist learned to correlate bellows movement with tidal volumes of 0.4 to 0.9 liters.

Controlled ventilation overrides an inherent safety feature of drawover anesthesia. During spontaneous ventilation, respiratory depression limits anesthetic uptake and prevents overdose. With controlled ventilation, the operator needs to recognize that the efficiency of the machine has improved; and calibration curves may be necessary to preclude overdose.

CONCLUSIONS AND RECOMMENDATIONS

The Universal PAC® unit is elegantly simple:

a. It can accommodate all inhalational anesthetic agents in the U.S. field medical inventory.

b. It is rugged and performs to published specifications without additional logistical requirements, such as compressed gas.

c. It has two important safety features, temperature compensation and tippability, which are lacking on the OMV®.

This vaporizer is ideally suited for use by U.S. medical units in the absence of conventional anesthesia devices and it should be added to the field medical inventory as soon as possible.

Whereas drawover anesthesia can be administered without pressurized gas or supplemental oxygen, data from animal studies and clinical trials indicate that SaO_2 may drop significantly when modern halogenated anesthetic agents are used. This problem may be alleviated by

a. Intubating patients.

b. Rapidly inducing patients with a high concentration of agent followed by a rapid reduction in agent delivery.

c. Administering supplemental O_2.

d. Using controlled ventilation.

In this report only the efficacy of the last two procedures has been demonstrated, and supplemental oxygen is the best method for minimizing the risks of hypoxemia and hypercarbia.

The FDA, in granting a 510(k) exemption for the Universal PAC®, has specified that it is intended for use only in military battlefield situations where conventional

anesthesia systems are not available. This precludes the use of this device for routine patient care, training, or experimental protocols involving human subjects in medical treatment facilities in or outside of the continental United States.

Awareness of performance characteristics of the Universal PAC® is important to those providing anesthesia support in the field, however, inhalational techniques with air/oxygen mixtures such as are used in drawover anesthesia can easily be practiced with conventional machines. Experience with these techniques and the patient response to them is a critical element of good anesthesia care, and is not necessarily a function of the delivery system used. As with all inhalational agents, anesthetic concentration is based on assessment of patient responses and is delivered to effect. In the absence of safety devices and monitoring equipment, vigilance, technical skills, and clinical experience become key elements in the successful use of drawover anesthesia units.

Figure 1. Output of a PAC-halothane® drawover vaporizer at various settings during spontaneous (○——○) or controlled (△——△)ventilation compared to the Universal PAC® drawover vaporizer using halothane during spontaneous (●——●) or controlled (▲——▲) ventilation. Each data point represents the average concentration of agent inspired by 5 swine over a 5.0 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.

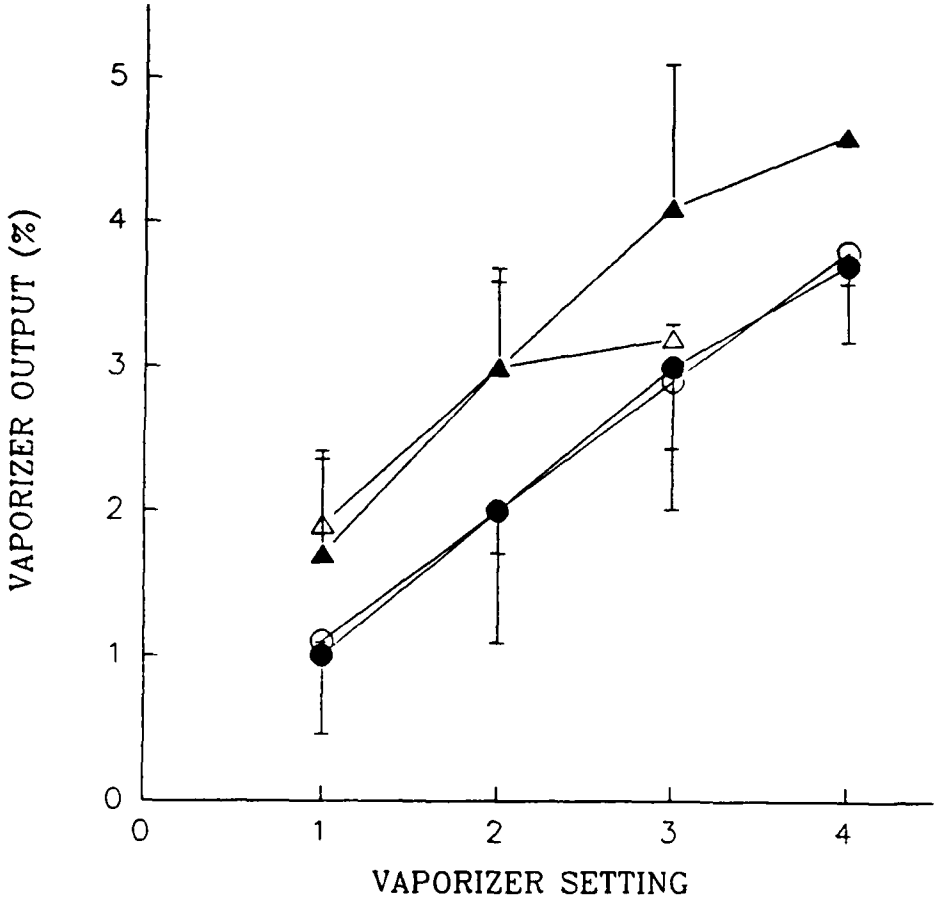


Table I. Results of regression analyses of data illustrated in Figure 1.

Vaporizer	Means of Ventilation	Slope	Intercept	R^2
Halothane-specific	spontaneous	0.94	0.14	0.71
Universal	spontaneous	0.91	0.13	0.31
Halothane-specific	controlled	0.75	1.35	0.32
Universal	controlled	1.20	-0.39	0.49

Figure 2. Output of a PAC-enflurane® drawover vaporizer at various settings during spontaneous (○——○) or controlled (△——△)ventilation compared to the Universal PAC® drawover vaporizer using enflurane during spontaneous (●——●) or controlled (▲——▲) ventilation. Each data point represents the average concentration of agent inspired by 5 swine over a 5.0 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.

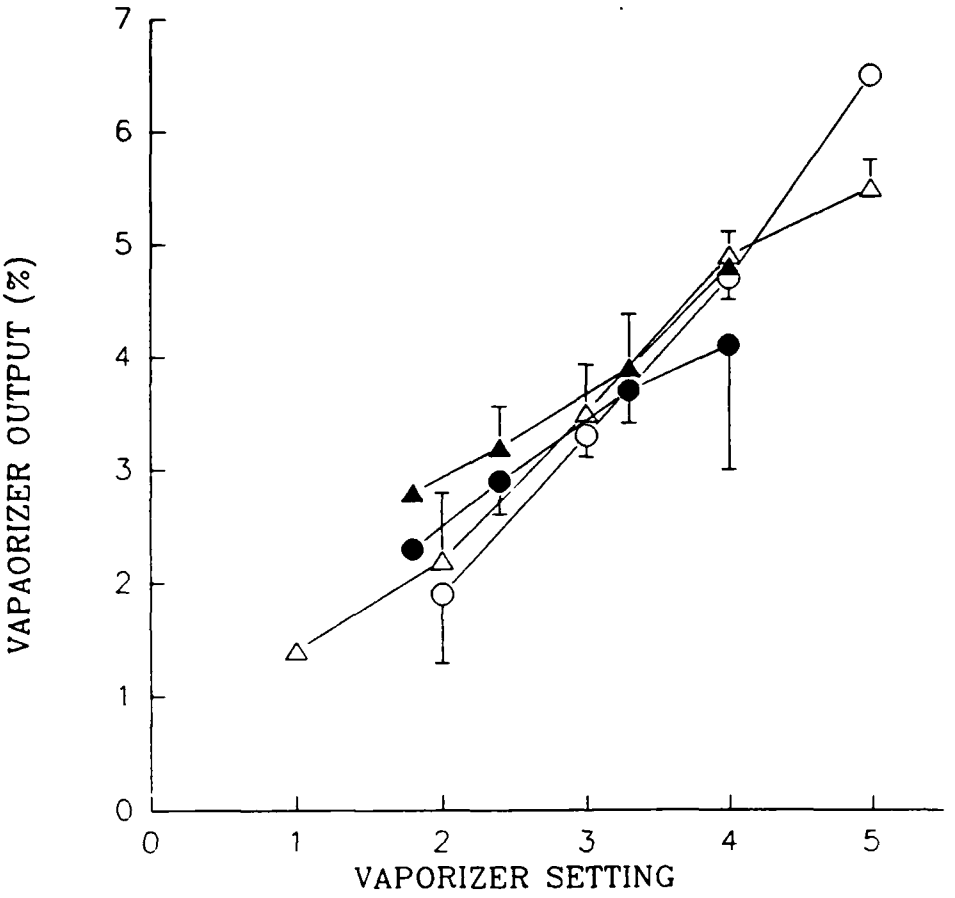


Table II. Results of regression analyses of data illustrated in Figure 2.

Vaporizer	Means of Ventilation	Slope	Intercept	R^2
Enflurane-specific	spontaneous	1.50	-1.20	0.88
Universal	spontaneous	1.20	-0.20	0.66
Enflurane-specific	controlled	1.10	0.15	0.85
Universal	controlled	0.91	0.99	0.64

Figure 3. Output of a PAC-isoflurane® drawover vaporizer at various settings during spontaneous (○——○) or controlled (△——△)ventilation compared to the Universal PAC® drawover vaporizer using isoflurane during spontaneous (●——●) or controlled (▲——▲) ventilation. Each data point represents the average concentration of agent inspired by 5 swine over a 5.0 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.

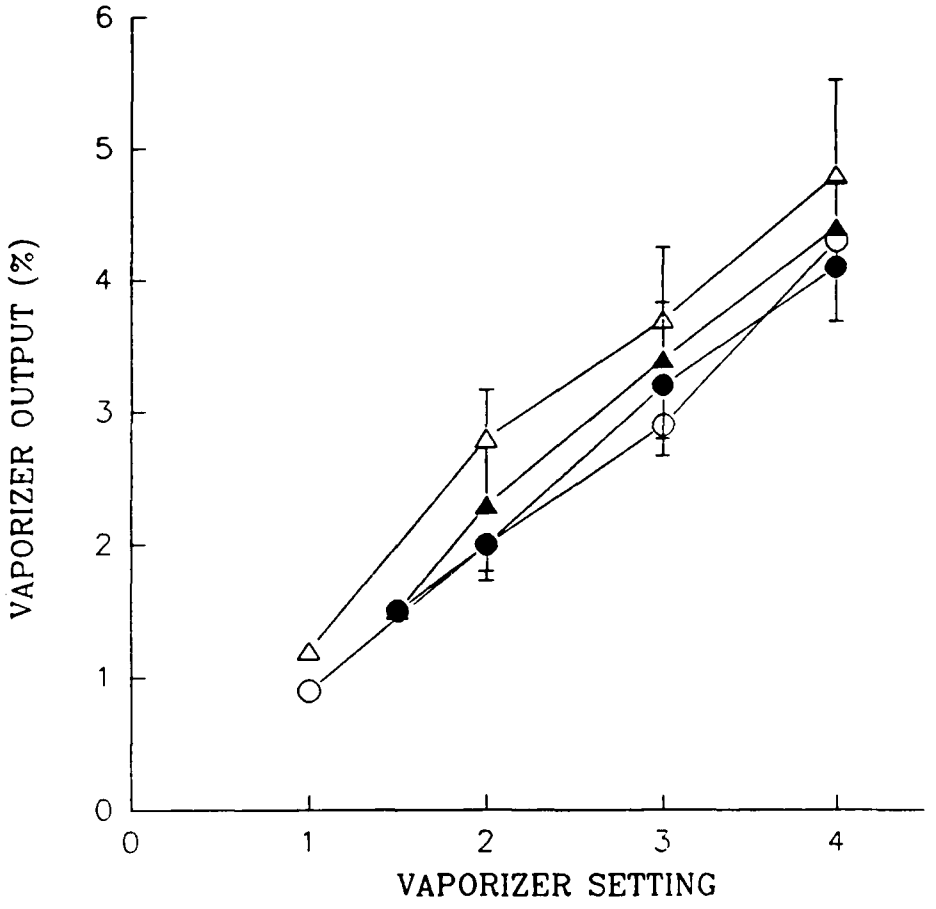


Table III. Results of regression analyses of data illustrated in Figure 3.

Vaporizer	Means of Ventilation	Slope	Intercept	R^2
Isoflurane-specific	spontaneous	1.20	-0.39	0.88
Universal	spontaneous	1.20	-0.46	0.85
Isoflurane-specific	controlled	1.10	0.53	0.55
Universal	controlled	1.20	-0.11	0.79

Figure 4. Output of a PAC-halothane® drawover vaporizer at various settings using controlled ventilation with a mica disk (○——○) or a Teflon disk (●——●) in the non-return valve. Each data point represents the average concentration of agent inspired by 5 swine over a 5.0 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.

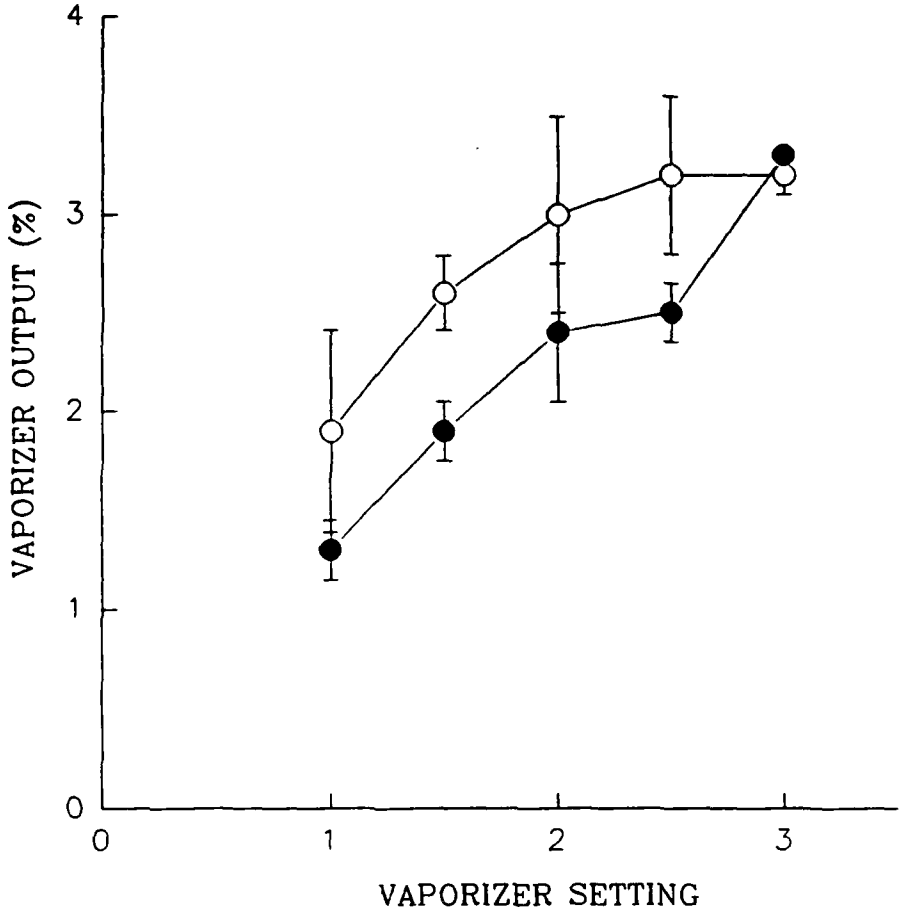


Figure 5. Output of a PAC-halothane® drawover vaporizer, modified with a Teflon disk in the non-return valve: calibration data obtained from the manufacturer (●——●), data from a bench test of the unit using a Model V5-A® ventilator (▲——▲), and data from the porcine model using spontaneous ventilation (■——■).

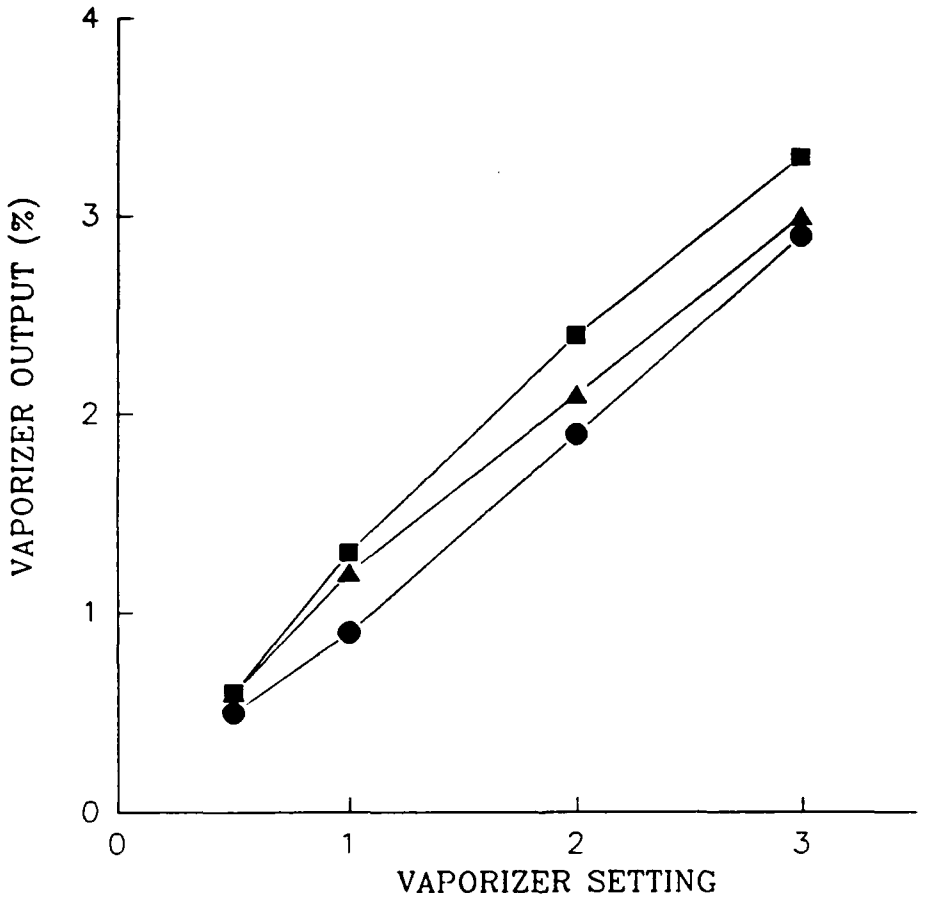


Figure 6. Oxygen saturation of arterial blood from swine anesthetized with the PAC-halothane® drawover vaporizer. Subjects inhaled various concentrations of halothane while breathing spontaneously (○——○), breathing spontaneously with supplemental O_2 (●——●), breathing with a ventilator (△——△), or breathing with a ventilator and supplemental O_2 (▲——▲). Oxygen saturation was measured using a pulse oximeter attached to the tail, and each data point represents the mean value obtained from 5 animals measured over a 5 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.

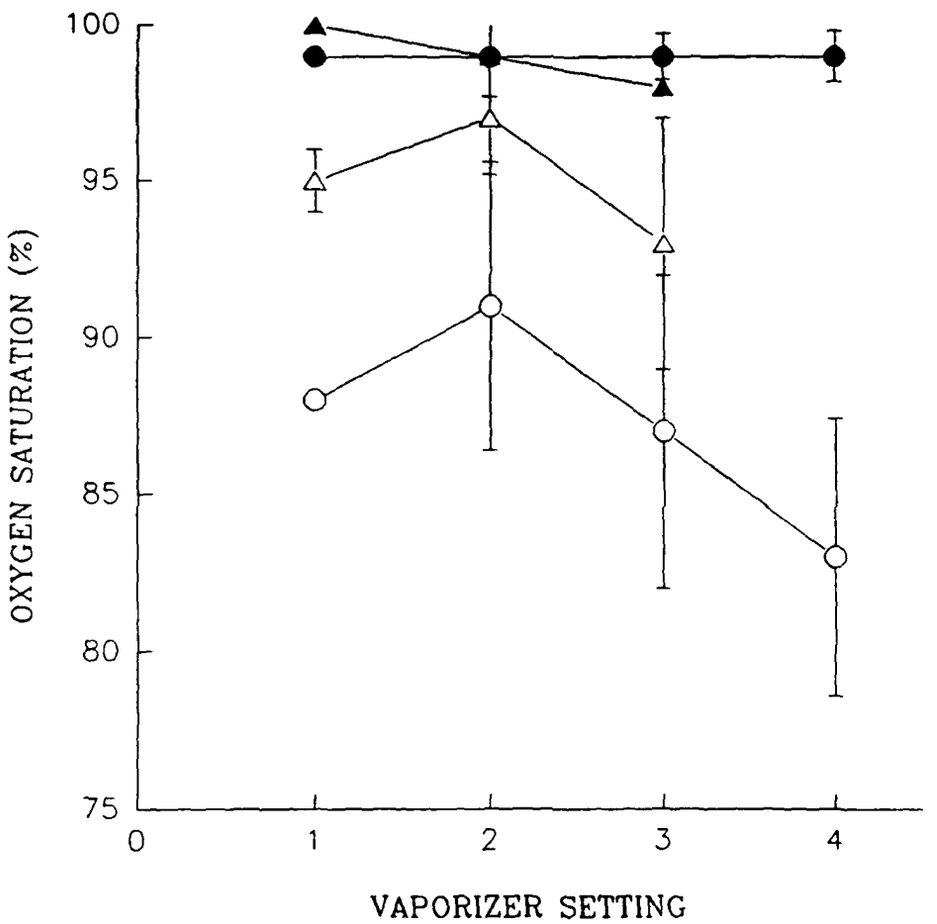


Figure 7. Oxygen saturation of arterial blood from swine anesthetized with the PAC-enflurane® drawover vaporizer. Subjects inhaled various concentrations of enflurane while breathing spontaneously (○——○), breathing spontaneously with supplemental O_2 (●——●), breathing with a ventilator (△——△), or breathing with a ventilator and supplemental O_2 (▲——▲). Oxygen saturation was measured using a pulse oximeter attached to the tail, and each data point represents the mean value obtained from 5 animals measured over a 5 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.

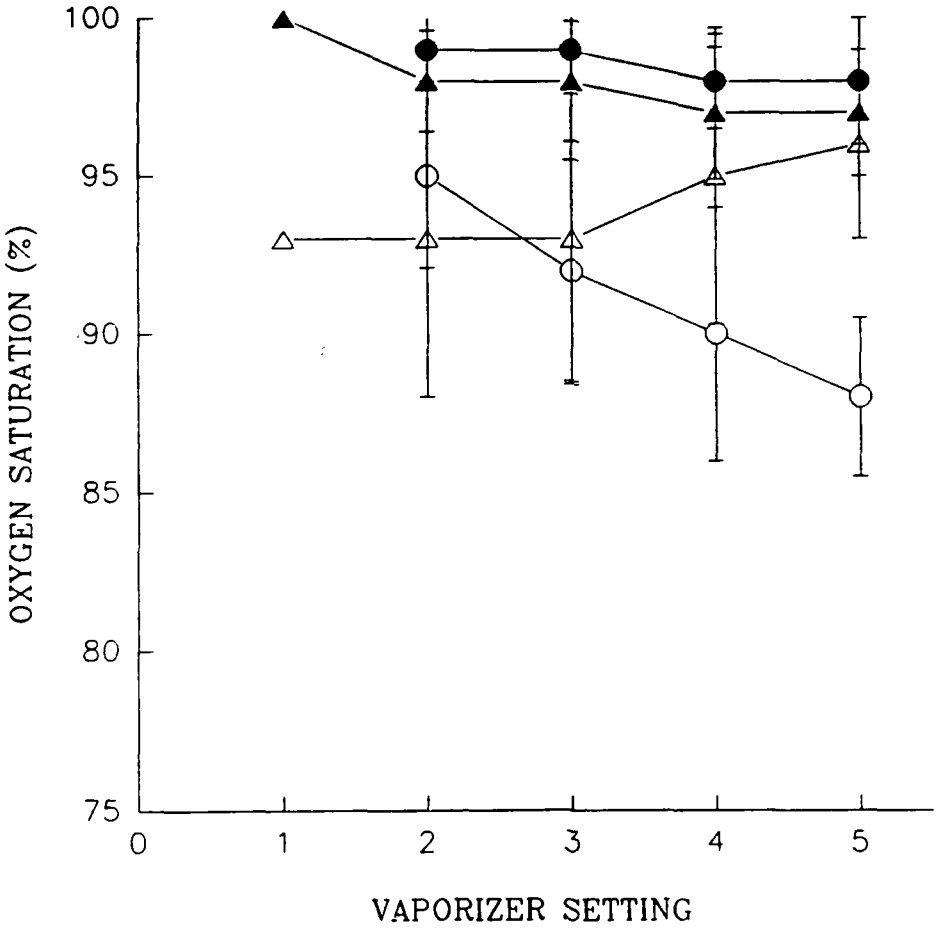
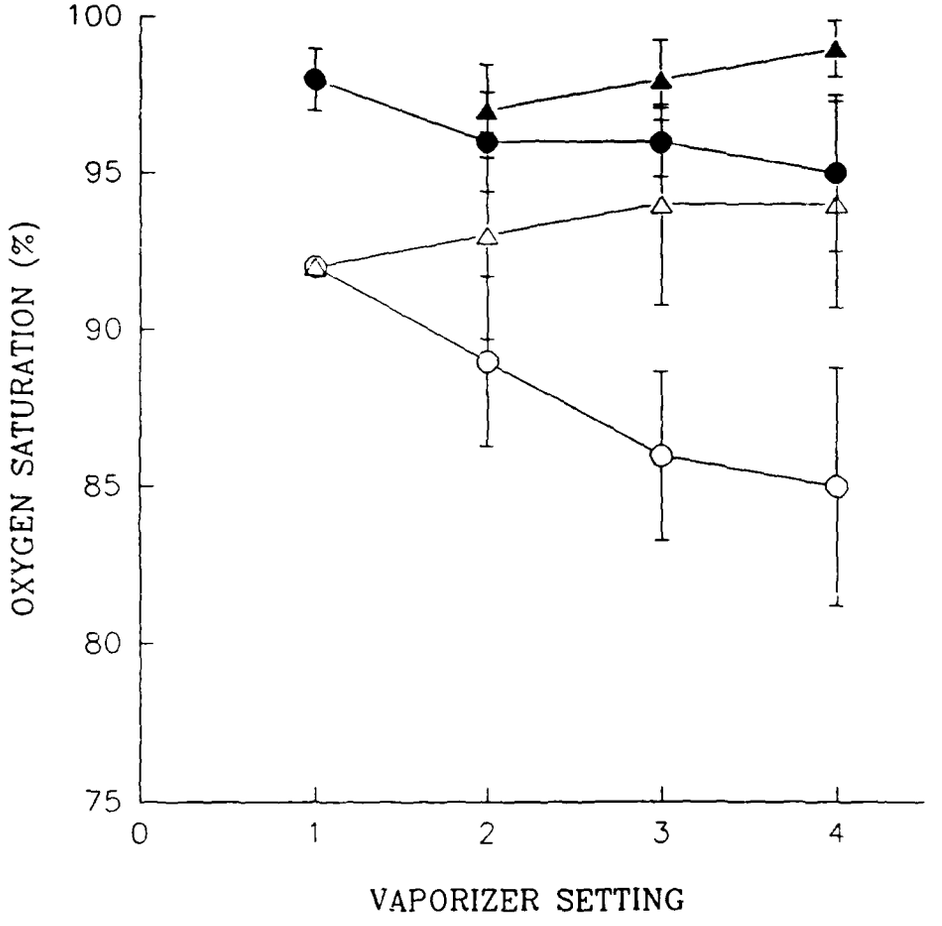


Figure 8. Oxygen saturation of arterial blood from swine anesthetized with the PAC-isoflurane® drawover va rizer. Subjects inhaled various concentrations of isoflurane while breathing spontaneously (○——○), breathing spontaneously with supplemental O_2 (●——●), breathing with a ventilator (△——△), or breathing with a ventilator and supplemental O_2 (▲——▲). Oxygen saturation was measured using a pulse oximeter attached to the tail, and each data point represents the mean value obtained from 5 animals measured over a 5 minute interval after reaching a steady state of anesthesia. Error bars represent the standard deviation.



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APPENDIX A

HSHL-SAO .18 March 1986

SUBJECT: Report on Animal Experiments Utilizing the Triservice Anesthesia Machine (TSA)

To: COL Robert McClain
Deployable Medical Systems
The Pentagon
Washington, DC

From: MAJ Michael E. Mahla, M.D.
Jane McCarthy, CRNA, PhD
LTC Peter P. Price, M.D.

1. In order to evaluate the performance of the Triservice Anesthesia apparatus and Oxford Miniature Vaporizer in vivo, the following animal experiments were done:

Thirteen animals were anesthetized with sodium surital, 15 mg/kg IV. The trachea was intubated and the animals were allowed to breath spontaneously. Ventilation was assisted, if necessary, until redistribution of the barbiturate allowed resumption of adequate spontaneous respiration. An arterial line was placed in the femoral artery for direct measurement of blood pressure and sampling of blood gases. End-tidal carbon dioxide levels were measured using a Hewlett-Packard 14590C Infrared Capnometer which was calibrated daily after warmup using optical calibration. Measurement of inspired and end-tidal Halothane levels was accomplished with a Beckman Infrared Gas Analyzer. This analyzer was calibrated using room (0.0%) and 1% Halothane (+/- .05% manufacturer's specification). Maintenance IV fluid consisting of Lactated Ringer's solution was given at a rate of 4cc/kg/hr. After a baseline arterial gas was drawn without halothane, the following experiments were done. With the dog breathing room air spontaneously, halothane was added in 0.5% increments. At each level of halothane, the vaporizer output and the inspired concentration of halothane were measured. In addition, blood pressure pulse (as measured by EKG), minute ventilation, end-tidal CO_2 and arterial blood gases were recorded. Halothane concentration was increased in 0.5% increments to a maximum of 3%. This part of the experiment was discontinued if the dog demonstrated inadequate respiration (pCO_2 > 60 torr) or hypotension (systolic BP less than 80 torr) secondary to deep anesthesia. Oxygen was added to the inspired mixture if the dog's PaO_2 dropped below 50 torr breathing room air. After completion of this part of the experiment, the dogs were placed on a Harvard pump volume ventilator and ventilation controlled to maintain a normal $PaCO_2$ and end-tidal CO_2. Halothane was discontinued until end-tidal concentration dropped below 0.1%. If needed, the dogs were given increments of 3 mg/kg of surital for light anesthesia. Halothane was then added in 0.5% increments with the dog's respirations controlled by the Harvard ventilator. Room air was used as the carrier gas. The same measurements were made as in the previous experiments at each increment of halothane up to 3%. Oxygen was added if the PaO_2 on room air dropped below 50 torr. The experiment was discontinued if the

systolic BP dropped below 80 torr.

RESULTS:

The performance of the Oxford Miniature Vaporizer (OMV) was analyzed and is summarized in Tables one and two below.

Table 1: Dogs Breathing Spontaneously

N (Number of Dogs)	Vaporizer Setting (% Halothane)	Mean+ Peak Vaporizer Output*	Mean++ Peak Inspired Concentration*
13	0.5	0.57 (.11)	.42 (.08)
13	1.0	1.07 (.14)	.87 (.15)
13	1.5	1.55 (.14)	1.13 (.15)
13	2.0	2.06 (.20)	1.72 (.17)
12	2.5	2.62 (.29)	2.02 (.17)
10	3.0	3.08 (.17)	2.36 (.21)

*numbers in parentheses represent standard deviation.
+ measured at outflow limb of vaporizer
++measured in the endotracheal tube

Table 2: Dogs with Ventilation Controlled

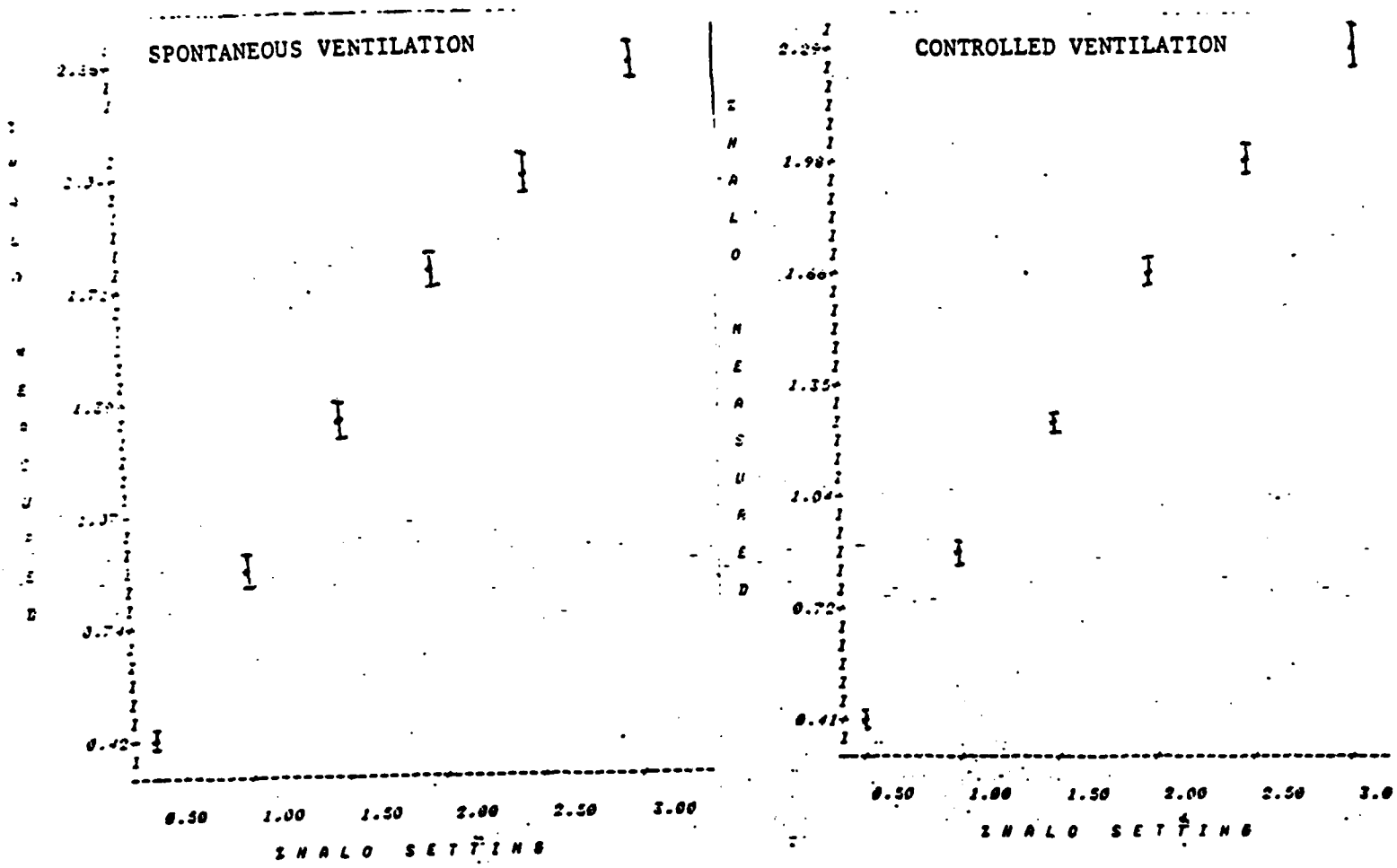
N (Number of Dogs)	Vaporizer Setting (% Halothane)	Mean+ Peak Vaporizer Output*	Mean++ Peak Inspired Concentration*
13	0.5	.51 (.09)	.41 (.08)
13	1.0	.97 (.06)	.86 (.09)
13	1.5	1.35 (.05)	1.24 (.06)
13	2.0	1.89 (.11)	1.66 (.10)
13	2.5	2.10 (.10)	1.95 (.14)
11	3.0	2.50 (.22)	2.29 (.17)

*numbers in parentheses represent standard deviation
+measured at outflow limb of vaporizer
++measured in endotracheal tube

Using two-way analysis of variance, the performance of the OMV was compared with the dogs breathing spontaneously versus controlled ventilation. There was no statistically significant difference in halothane output at any level measured.

Using linear regression analysis, the vaporizer setting versus measured inspired concentration was plotted for both spontaneous and controlled ventilation and may be seen in Figures 1 and 2. For spontaneous ventilation the

slope of the regression line is 0.77 and the correlation coefficient is 0.997. For controlled ventilation, the slope of the regression line is 0.75 and the correlation coefficient is 0.998.



In order to assess the impact of omitting oxygen from the anesthetic mixture used, arterial blood gases were drawn at each level of halothane both with the dog breathing spontaneously and with controlled ventilation. The results are summarized in Table 3 and 4 below. Dogs who required supplemental oxygen (PaO_2 less than 50 torr) were omitted from the data. However, the total number of dogs needing supplemental oxygen was recorded.

Table 3: Arterial Blood Gas Measurements
Spontaneously Breathing Animals

Blood gas values are mean values in torr. Standard deviation is shown in parentheses.

N (Number of Animals)	% Halothane (Dial Setting)	pH	pO_2	pCO2	# Animals Needing Oxygen
13	0 (baseline)	7.34(.04)	65.0(15.8)	40.7(5.4)	NA
13	0.5	7.34(.04)	73.8(7.9)	41.3(5.9)	0
13	1.0	7.32(.03)	76.9(11.3)	42.3(4.8)	0
13	1.5	7.29(.04)	71.5(10.3)	48.0(7.2)	1
13	2.0	7.27(.04)	67.6(10.6)	50.3(8.5)	4
12	2.5	7.27(.03)	66.0(11.0)	49.0(5.5)	5
10	3.0	7.26(.02)	60.0(10.4)	58.6(10.2)	5

Table 4: Arterial Blood Gas Measurements
Controlled Ventilation

N (Number of Animals	% Halothane (Dial Setting)	pH	pO_2	pCO_2	# Animals Needing Oxygen
13	0	7.31(.05)	77.9(15.0)	43.1(8.2)	0
13	0.5	7.36(.04)	83.4(11.2)	36.4(5.5)	0
13	1.0	7.36(.04)	78.4(13.0)	36.7(4.2)	0
13	1.5	7.36(.04)	78.6(9.5)	35.7(3.6)	0
13	2.0	7.36(.04)	76.7(8.3)	37.8(4.6)	0
13	2.5	7.34(.04)	75.0(12.3)	37.7(2.2)	0
11*	3.0	7.34(.05)	73.7(6.0)	37.4(3.6)	0

*animals eliminated because syst BP < 80.

To compare oxygenation with controlled ventilation versus spontaneous ventilation, a two-way analysis of variance was done at each level of halothane. Significant differences were indicated by a p value of < .05. Oxygenation was significantly improved by controlled ventilation at levels of 0.5, 2.0 and 3.0% halothane. Oxygenation improved at all levels but was only statistically significant at these levels. Significantly more animals required oxygen to maintain pO_2 >50 torr when breathing spontaneously than

when ventilation was controlled. As has been shown in multiple other studies, oxygenation decreased and CO_2 increased with increasing halothane levels in spontaneously breathing animals.

Discussion and Recommendations:

The Oxford Miniature Vaporizer (OMV)

Prior evaluations of the OMV were performed in vitro in the laboratory. This in vivo study showed that vaporizer output length in the spontaneous and controlled mode was approximately 75% of the dial setting. This error was predictable and reliable at all levels of halothane. Prior studies in vitro showed significantly better vaporizer output accuracy than this in vivo study. This discrepancy must be explained. This type of vaporizer is a "draw-over" type (Fig. 3).

Fig. 3

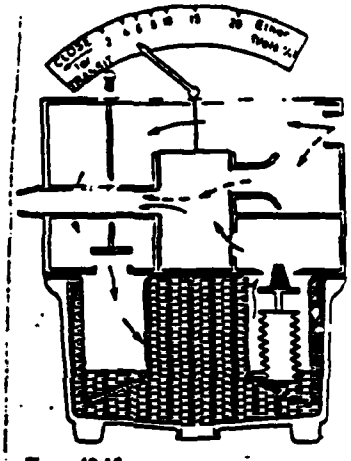
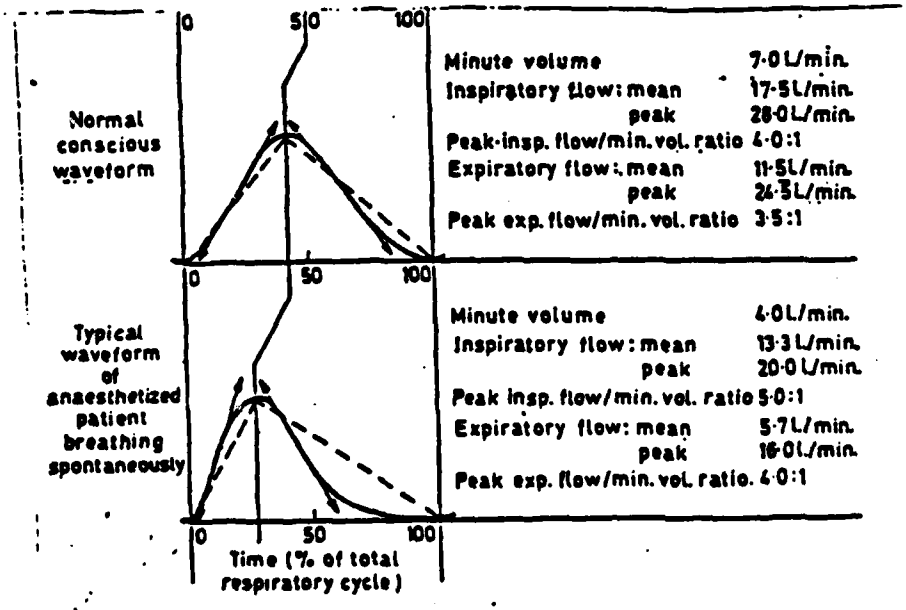


Figure 49.13
EMO Vaporizer. (From Ward, 1975, by courtesy of the author and Bailliere Tindall)

Efficiency of vaporization depends on the surface area of the gas/liquid interface and the velocity of the vaporizing gas passing over the liquid. Bench testing of the vaporizer was done at flow rates not exceeding 12L/min. Inspiratory flow rates during the respiratory cycle (Fig. 4) are continuously variable ranging from 0 to in excess of 100L/min depending on the state of the patient (resting vs. exercise).

Fig. 4



During normal tidal breathing in the dog and man, flow rates of 30L/min would not be uncommon. Thus vaporizer efficiency would be very low for part of the inspiratory cycle. This could easily account for the drop off in inspired concentration of gas from the peak measured at the vaporizer to the peak measured at the dog. In addition, it would explain why the vaporizer did not perform as well in vivo as in vitro.

To test this hypothesis, the OMV was tested in the lab using continuous flows up to 25L/min at concentrations ranging from 0.5% to 2%. At all concentrations tested, the OMV vaporizer delivered, delivered concentrations most closely agreed with the dial setting in the range of 5-10L/min. With higher flows, the concentration of halothane delivered dropped off rapidly reaching the following values @ 25L/min flows:

Table 5: Delivered Halothane at 25 Liters/Minute Gas Flow

Dial Setting	Measured Concentration (% Halothane)*
0.5	0.26 (.02)
1.0	0.66 (.03)
1.5	0.74 (.05)
2.0	0.89 (.09)

*values in parentheses are standard deviations.

Thus, in summary:

1) The OMV vaporizer reliably delivers a known concentration of the anesthetic gas halothane.

2) The delivered concentration is roughly 75% of the dial setting.

3) There is no difference in performance between controlled and spontaneous ventilation.

4) Differences in performance betwen this study and other evaluations may be explained by the flow rates encountered in normal tidal breathing.

Regarding the use of room air with this vaporizer:

There are several things to be noted from this data which have a bearing on military anesthesia.

1) A significant number of animals were hypoxemic when allowed to spontaneously breathe therapeutic concentrations of halothane in room air.

2) Controlling ventilation significantly improved oxygenation at several levels of halothane.

While the dog lung is not a good model for human pulmonary function, data al-

ready available in man breathing halothane is compatible with this data. No anesthetic technique improves pulmonary function. Our human study will test the safety of using room air with halothane on healthy patients using a pulse oximeter to continuously assess oxygen saturation. The pulse oximeter may allow the use of oxygen to be minimized, but without that monitor, there is no way to guarantee adequacy of oxygenation other than gross clinical signs. Vital signs may be misleading in that clinical decompensation with hypoxemia may not occur until very late.

Overall Recommendations:

1) The TSA machine can safely deliver a known concentration of anesthesia in an in vivo system and would thus appear to be a useful addition to the military anesthetists armamentarium in delivering anesthesia in an unfavorable environment.

2) While final recommendations must await completion of a human study, there is no theoretical reason to expect the results to change.

3) Oxygen supplementation must be available.