THE PREVALENCE OF BACTERIAL CONTAMINATION IN THE VENTILATOR BELLOWS OF ANESTHESIA MACHINES

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SIMMONS

THE PREVALENCE OF BACTERIAL CONTAMINATION IN THE VENTILATOR BELLOWS OF ANESTHESIA MACHINES

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ABSTRACT

The anesthesia breathing circuit has been inconclusively implicated as a source of postoperative, hospital-acquired respiratory infections that follow surgery. Little investigation of the prevalence of bacterial contamination in the anesthesia ventilator bellows has been done. The purpose of this study was to determine the prevalence of bacterial contamination in the ventilator bellows of anesthesia machines. A prospective study of 12 anesthesia machines at a major medical facility was conducted to determine whether ventilator bellows are bacterially contaminated and to quantify and identify any bacterial organisms present. Two sets of samples were collected. Twelve machines were sampled in the morning and 10 machines were sampled in the afternoon after surgery was completed. Using sterile culturette bacterial swabs and aseptic technique, samples were collected by swabbing the internal diameter of the ventilator bellows. All of the morning samples and 80% of the afternoon samples were negative for bacterial growth. Two (20%) of the afternoon samples had 3+ growth or greater than 100 colony forming units of *Staphylococcus epidermidis* indicating external contamination during collection or laboratory processing. From these findings, the ventilator bellows does not appear to harbor pathogenic microorganisms. These data support that the present methodology of cleaning and sterilization of the anesthesia machine at this facility is effective.

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DEDICATION

To my husband and children I dedicate the creation of this thesis. Without their love, encouragement, and support the attainment of a dream and the creation of this thesis would not have been possible.

To my mother and father, I dedicate this paper and thank you for instilling within me a strong work ethic and the desire for knowledge and for your many years of encouragement and support.

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CHAPTER ONE: INTRODUCTION

The prevalence of bacterial contamination in various components of the anesthesia machine may be related to hospital-acquired infections. The anesthesia ventilator bellows is a reservoir that receives the exhaled gases from the patient via the exhalation chamber. At the completion of exhalation, it redirects those same gases through the carbon dioxide absorber which are mixed with gases from the common gas outlet, and ultimately back to the patient via the inhalation chamber and the patient's breathing circuit. The ventilator bellows portion of the anesthesia machine was studied because it is a major component of the anesthesia breathing circuit and is often overlooked.

Nosocomial infections are major sources of morbidity and mortality among hospitalized patients. "Nosocomial" is a medical term for "hospital-associated" and is used to describe infections that arise during hospitalization as a complication of another illness (Ryan, 1994). As a result of these infections, hospital costs are increased, hospital stays are prolonged, and patients are thereby placed at higher risk for morbidity and mortality. Nosocomial infections are reputed to extend hospitalization an average of 4 days per infection, and nearly 4% of all nosocomial infections resulted in death (Smith, et al, 1996). The rates of nosocomial infections for most hospitals in the United States are estimated to range between 3 and 5%. These percentages represent millions of hospital-acquired cases annually since more than 40 million persons are hospitalized in the United States each year (Ryan, 1994).

Infectious hazards appear to be inherent in the hospital environment. The infectious agents responsible for nosocomial infections arise from various sources

including the patents' own normal bacterial flora. In addition to any immunocompromising disease or therapy, the hospital may impose additional risks by treatments that breach the normal defense barriers. Surgery, urinary or intravenous catheters, and invasive diagnostic procedures all may provide normal nonpathogenic bacterial or viral flora with access to usually sterile sites (Ryan, 1994). Once introduced to these protected or immunological privileged areas the normal barriers are breached and acute infection may result.

In conjunction with these hospital generated risks, more opportunistic infections are occurring due to the increasing elderly patient component of the population. The modern practice of medicine is keeping individuals alive longer through surgical procedures and powerful drugs that affect immune status. As a consequence, organisms that were once considered harmless are now feared as opportunistic pathogens. The geriatric population and patients who are immunocompromised therefore are specifically at risk.

Nosocomial infections are also known to result from the phenomenon of cross-infection, or "the transmission from one patient to another" (Ryan, 1994, p. 824). Transmission is usually by direct contact, by hospital personnel for example, but, airborne transmission is also possible. Much of the success of modern medicine is related to medical devices that support or monitor basic body functions. Nevertheless, by their very nature, invasive devices such as catheters and ventilators carry the risk of nosocomial infections because they bypass normal defense barriers, providing organisms access to normally sterile fluids and tissues. The risk of infection is associated with the degree of patient debilitation and various factors concerning the design and management

of these devices.

Medical devices that are most frequently associated with nosocomial infections are urinary and vascular catheters, and ventilators (Ryan, 1994). According to Ryan (1994, p. 825), "machines that assist or control respiration by pumping air directly into the trachea have a great potential for infection if the aerosol they deliver becomes contaminated." Lower respiratory tract infections account for 14 to 18% of all nosocomial infections, the third largest type of such infections.

Infection control is paramount to the prevention of nosocomial infections and the problems associated with them. Asepsis, the central concept of infection control, is defined by Ryan (1994, p. 827) as the "prevention of contact between microorganisms and susceptible sites" using methods of sterilization and disinfection. Ryan (1994, p. 827) also states that "The surgical suite and operating room represent the most controlled and rigid application of aseptic principles."

Inhalational anesthesia equipment has been suspect since the 1950s as a potential source for organisms that cause nosocomial infections. This primary concern of the risk of cross-infection has led to the evolution of modern anesthesia practice and equipment over the past 40 years. Disposable endotracheal tubes and circuits, bacterial filters, and a variety of standard infection control practices are in use today as the result of ongoing attempts to reduce or eliminate the potential risk of transmission of organisms to patients.

Numerous studies have been reported which attempt to clearly establish or refute any connection between anesthesia equipment and postoperative nosocomial infections. It is quite difficult to prove any direct cause and effect relationship between anesthesia machines and subsequent nosocomial infections. Although new methods and equipment

were consequently developed and have become the standard of practice, the controversy as to anesthesia's role in nosocomial infections continues to be debated. The possible introduction of bacteria from the anesthesia circle system may undoubtedly increase the patient's risk for developing a lower respiratory tract infection. According to Smith, Wygant, McGrory and Silka (1996, p. 153), "A relationship between contamination of anesthesia equipment and infection of the patient must be considered because as many as 40 out of 10,000 patients receiving general anesthesia may suffer postoperatively from hospital-acquired pneumonia." However, most anesthesia providers have been reluctant in recognizing that contaminated anesthesia equipment and ventilators may be a significant source of cross-infection because of the difficulty in pinpointing the actual source of postoperative pulmonary infections (Shiotani, Nicholes, Ballinger, and Shaw, 1971). This may be due in part to the difficulty in recognizing and tracing the actual epidemiology and fomites involved in the nosocomial infection. Clinical reports which attribute postoperative infection to contaminated anesthesia equipment are rare and often inconclusive (Garibaldi, Britt, Webster, and Pace, 1981).

Carbon dioxide absorbers, inspiratory and expiratory valves, and ventilator bellows are integral components of the anesthesia machine and complete the connection to the patient's breathing circuit. Because bacterial filters and disposable circuits are in routine use, these components of the anesthesia machine which are located more distant from the patient, and yet previously identified to be potential sources of organisms, receive less attention in routine cleaning and decontamination practices performed by most anesthesia departments (Dryden, 1975). These areas are often not routinely cleaned or decontaminated between uses on patients because they pose mechanical problems in

handling and may not readily tolerate the usual decontamination methods available (Dryden, 1975). The typical busy operating room schedule does not usually allow for the time necessary to perform this level of cleaning between cases. The prevailing attitude appears to be that these areas pose little threat to the patient (Dryden, 1975). Some studies have shown that organisms can travel from the expiratory limb, through the carbon dioxide absorber and to the ventilator. Organisms have been cultured from these machines although most of these studies predate the advent and routine use of disposable equipment.

Statement of the Problem

Little investigation of the prevalence of bacterial contamination in the anesthesia ventilator bellows has been reported. The primary focus of infection control in anesthesia appears to center around the patient's breathing circuit. However, most patients receiving general anesthesia are routinely ventilated mechanically using anesthesia ventilators. Now that disposable equipment is in routine use, the potential risk of infection from sites within the anesthesia machine that are more distant from the patient needs to be fully assessed to determine whether the anesthesia machine still remains a potential threat to the patient or whether it can be assumed to be safe for patient use.

Some nosocomial infections are suspected to be related to bacterial organisms that may be present within the anesthesia machine. Sterilization/disinfection procedures for anesthesia equipment are established to minimize the potential transfer of these organisms to patients. The anesthesia ventilator bellows, which is considered to be a major component of the patient's breathing circuit, has not been clearly examined for its

potential risk in harboring organisms that may be involved in cross-infection. Therefore, the prevalence of bacterial contamination in the ventilator bellows of anesthesia machines considered to ready for patient use is the focus of this study.

Data obtained from this study will hopefully heighten the awareness among anesthesia providers of the prevalence of bacterial contamination in the anesthesia ventilator bellows. This study will further document the presence of bacterial organisms and evaluate the current infection control practices utilized within the anesthesia profession. Ultimately, changes may be made that will reduce post-operative morbidity and mortality related to nosocomial pulmonary infections and, thereby, reduce health care costs.

Research Questions

1. Is the anesthesia ventilator bellows contaminated?
2. What is the quantity of bacterial organisms present in the anesthesia bellows?
3. What are the major bacterial organisms identified within the anesthesia ventilator bellows?

Definition of Terms

Nosocomial Infection: Medical term for "hospital-acquired" used to describe infections that arise during hospitalization (Ryan, 1994).

Cross-Infection: The transmission of an infection from one patient to another (Ryan, 1994).

Asepsis: The prevention of contact between microorganisms and susceptible sites

through infection control methods such as sterilization and disinfection (Ryan, 1994).

Sterilization: "The complete killing, or removal, of all living organisms..." (Ryan, 1994, p. 171).

Disinfection: "The destruction of pathogenic microorganisms by processes that fail to meet the criteria for sterilization" (Ryan, 1994, p. 171).

Pasteurization: "The use of heat at a temperature sufficient to inactivate important pathogenic organisms..., but at a temperature below that needed to ensure sterilization" (Ryan, 1994, p. 171).

Normal Bacterial Flora: Nonpathogenic organisms that usually reside in or on the human body without causing disease (Ryan, 1994).

Opportunistic Pathogens: Normal bacterial flora that become pathogenic when given the opportunity during altered physiological states of the host (Ryan, 1994).

Anesthesia Ventilator Bellows: A component of the anesthesia machine that acts as a reservoir for expired air and mechanically provides ventilation for the patient (Ehrenwerth & Eisenkraft, 1993).

Anesthesia Breathing Circuit: The interface between the patient and the anesthesia machine which provides the gas pathway. The basic components of a circle system consist of an inspiratory and expiratory limb, each with a unidirectional valve, and a reservoir bag or counterlung moving reciprocally with the patient's lungs. Other components include a carbon dioxide absorber, a fresh-gas inflow site, and a pop-off valve for venting excess gas (Ehrenwerth & Eisenkraft, 1993).

Thioglycolate "Thio" Broth Tubes: A general-purpose liquid culture media containing

nutrients designed to satisfy the growth requirements of bacteria to permit isolation and propagation. Specimens may be added directly to the media and the presence of bacteria is detected by the appearance of turbidity within the media after an incubation period (Ryan, 1994).

Limitations of the Study

The samples for this study were collected at one institution for ease in specimen collection and submission to the laboratory. The sample size was limited by the number of anesthesia machines available at this facility. Viral and fungal contamination were excluded to narrow the focus on bacterial contamination of the anesthesia ventilator bellows.

Since the number and length of the scheduled surgeries varied, the amount of time that elapsed after surgery ended and specimens were collected also varied. Consequently, every effort was made to collect the evening samples as soon after surgery ended as was possible. Another related limitation was that the number of general anesthetics delivered in each of the operating rooms varied depending on the type of surgery and the type of anesthesia chosen by the anesthesia provider. Also, anesthesia machines in use at the time of specimen collection were excluded in order to maintain the integrity of the other samples collected.

CHAPTER TWO: THEORETICAL FRAMEWORK

The approach to infection control has been examined for decades with the goal in hospitals of eliminating or reducing the incidence of nosocomial infection. The central concept in infection control is to prevent or remove threatening microbes before they can reach the patient. Aseptic techniques, standardized medical and nursing procedures, as well as disinfection and sterilization methods have been developed and are performed with infection control as one of the primary goals.

Some types of medical equipment are routinely reused from patient to patient and pose a threat as a vehicle for nosocomial infections. Spaulding, Cundy and Turner, recognizing this threat, developed a framework that divided medical devices into three categories based on the risk of infection associated with their clinical use. Subsequently, sterilization or disinfection procedures were established for each category (as cited in Rendell-Baker, 1993).

This classification system for medical devices is currently recognized as the cleaning guidelines for a variety of medical equipment, including that used to provide anesthesia. The first category consists of "critical items" which include devices that penetrate the skin or are in contact with sterile areas of the body, such as spinal needles or surgical instruments, and require sterilization. Next are the "semicritical items" which include devices that are in contact with mucous membranes, such as endoscopes or tracheal tubes, and require high-level disinfection or may be sterilized. The third category, "noncritical items", includes devices that are in contact with intact skin and body surfaces, such as blood pressure cuffs, and require intermediate or low-leveldisinfection (Rendell-Baker, 1993).

Antiseptics and disinfectants are chemicals used to kill germs. Antiseptics, however, can be used on living tissues where as disinfectants can not. Disinfection is further subdivided into three levels based on the degree of its bacterial kill ability. High-level disinfection kills bacteria, fungi, and viruses, but large numbers of endospores may not be killed. If sufficient contact time is allowed, most of these disinfectants can produce sterilization. Intermediate-level disinfection kills bacteria, tuberculosis organisms, fungi, and most viruses, but not bacteria endospores. Low-level disinfection kills most bacteria and some fungi and viruses, but does not kill tuberculosis organisms or endospores (Rendell-Baker, 1993).

Sterilization kills all bacteria, including endospores, fungi, and viruses. It can be accomplished by steam or gas autoclaving. Steam is the preferred method for equipment that can tolerate the heat and steam such as laryngoscope blades, and has the quickest turn-around time. Ethylene oxide gas is useful for items that cannot tolerate high temperatures and steam such as items made of plastic or rubber. This method requires at least a 24-hour turn-around time to eliminate any residual ethylene oxide gas (Rendell-Baker, 1993).

Most pieces of anesthesia equipment do not need to be sterile. The majority of items used in anesthesia fall into the semicritical category and require high-level disinfection. They include fiberoptic endoscopes and certain reusable items, such as rubber face masks, breathing circuits, tracheal tubes and temperature probes. Hard surfaces that become contaminated need an intermediate-level disinfection (Rendell-Baker, 1993).

Pasteurization, now widely used to disinfect plastic and rubber anesthesia and

respiratory equipment, kills most organisms, including mycobacteria, but does not destroy spores. It can be used when clean rather than sterile equipment is acceptable. After blood, secretions, and other contaminants are removed, the equipment is subjected to hot water at 77 degrees Centigrade for 30 minutes. The anesthesia ventilator bellows, for example, can be effectively cleaned by this method (Rendell-Baker, 1993).

Prior to choosing any of these methods, all reusable anesthesia items must first be cleaned and decontaminated by washing them with a detergent or disinfectant to remove all blood, mucus, and foreign material. Next, they are rinsed and dried, and are then considered to be decontaminated. Since these items are reasonably free of transmitting infection, they are rendered safe to handle (Rendell-Baker, 1993).

The Association of Operating Room Nurses (AORN) has published recommended practices for the cleaning and processing of anesthesia equipment. In 1985, the AORN stated, "Any apparatus that harbors microorganisms,...is a hazard in the operating room (p. 627)." They recognize that anesthesia equipment has the potential to be a vector in the transmission of microorganisms and that when patients are anesthetized or ventilated, the risk of cross-infection can be minimized by proper and regular cleaning, disinfection or sterilization (AORN, 1985, 1991 & 1994). According to the AORN (1985, p. 625), "Anesthesia ventilators should be considered an extension of the breathing bag in the anesthesia circuit and can become contaminated." Their specific recommendation for the ventilator is that the ventilator bellows should be cleaned followed by high-level disinfection or sterilization according to an established routine since patient exposure causes microbial buildup (AORN, 1991).

The American Association of Nurse Anesthetists (AANA) has also developed

infection control guidelines for anesthesia (1989). No specific guideline was listed for the cleaning or disinfection of the ventilator bellows. The Association did address external cleaning of the anesthesia ventilator and the use of bacterial filters for the protection against inadvertent contamination. The AANA (1989, p. 301) also made a generalized statement stating that, "Special consideration should be given to manufacturer's instructions, especially concerning the appropriate time interval for effective disinfection or sterilization."

Spalding et al's framework for categorizing medical equipment and its cleaning guidelines are clearly delineated. Consequently, adherence to these guidelines should result in the near elimination of nosocomial infections associated with all types of medical equipment. However, the incidence of nosocomial infections, including those potentially related to inhalational anesthesia equipment, continues to persist.

Literature Review

The relationship of anesthesia to the hazards of nosocomial infections is complicated and varied. The design and construction of much of the equipment used in anesthesia is such that many items are not readily cleaned or sterilized. While the anesthesia techniques employed provide obvious and often invaluable benefits, they nevertheless increase the risk of infection for patients.

In the past, a perfunctory rinse of the breathing tube and mask was the extent of the anesthesia providers' attempt at cleanliness. There was little interest in routine sterilization of the breathing system because there had been few reports of cross contamination related to anesthesia equipment (Thomas, 1968). It was not until the late

1960s, when cardiac and other surgeons reported outbreaks of postoperative chest infections arising from sources in the anesthesia ventilator or breathing bag and tubing, that it was realized that a real problem might exist.

Disposable breathing circuits were introduced into routine practice throughout many of the developed countries in 1968. Prior to their use and eventual replacement of reusable rubber breathing circuits, several studies concluded that microorganisms pass from the patient to other parts of the anesthesia system such as the mask, endotracheal tube, breathing circuit, and reservoir bag. These studies also suggested that without proper sanitization of the anesthesia breathing system, that organisms may be disseminated to subsequent patients (Joseph, 1952; Gross, 1955; Stark, Green, & Pask, 1962; Pandit, Mehta, & Agarwal, 1967).

Russell (1968) actually determined the route of travel of specific bacteria in the anesthesia machine and the disease-producing potential of the organisms isolated. Not only did he culture the breathing circuit and soda lime canister, he also included the ventilator. Bacterial contamination was found in all areas, with the greatest degree and incidence in those portions nearest the patient.

A second part of Russell's study involved sterilizing the removable parts of the anesthesia machine with ethylene oxide followed by the routine administration of anesthesia. Afterwards, several parts were again found to be colonized with the same organisms isolated from the patient's upper respiratory tract such as *Staphylococcus aureus* and *Pseudomonas aeruginosa*. He concluded that most parts of the anesthesia system do become contaminated with microorganisms.

Another similar study performed by Thomas (1968) supported the opinion that

organisms contaminating the anesthesia system originate from the patient. He was also able to demonstrate the movement of organisms found in the unsterilized ventilator used in his study to other areas of the system that had been sterilized, the reservoir bag and expiratory tubing. This finding further increased the concern about the risks of cross-infection to the patient.

The soda-lime used in the carbon dioxide absorber has been thought to potentially offer protection from cross-infection for the patient during the administration of anesthesia. However, this too is controversial. According to a study performed by Dryden (1969, p. 942), "not all organisms are stopped by the mechanical or chemical action of the absorbent." Murphy, Fitzgeorge, and Barrett (1991) predicted and demonstrated that soda-lime does exert a potent bacteriocidal effect on nonsporing organisms. They did state, however, that spores may be more resistant to the highly alkaline medium than the parent organism and, subsequently, advocated the continuation of the policy for sterilization or disinfection of non-disposable anesthesia components.

Another device designed to reduce the risk of cross-infection is the bacterial filter which is placed in the anesthesia breathing circuit. The purpose of this filter is to protect the patient from the organisms that may be present within the anesthesia machine and, sometimes, to protect the machine from the organisms in the patient's airway, depending on its placement within the breathing circuit. Currently, at least one bacterial filter is placed in the patient's breathing circuit and on the inspiratory side to protect the patient.

In 1981, there were two studies performed with similar outcomes to evaluate whether bacterial filters reduce and/or prevent postoperative pulmonary infections. Feeley, Hamilton, Xavier, Moyers, and Eger (1981) examined whether the sterile

disposable breathing circuit with a bacterial filter over the clean reusable breathing circuit without a bacterial filter would reduce the incidence of postoperative pulmonary infection. They found the overall infection rate to be 3.5% with no significant difference in the infection rates between the two groups.

Garibaldi, Britt, Webster, and Pace (1981) performed their study by comparing the incidence rate of postoperative pneumonia between groups using disposable breathing circuits with bacterial filters and disposable breathing circuits without bacterial filters. The study showed an infection rate of 17% and concluded that the bacterial filters did not reduce the incidence of infection rates. They reported in their study that the routine use of bacterial filters for this purpose is not cost-effective.

Albrecht and Dryden (1974) reported a retrospective study of 220 patient charts after an extensive five-year cleanup regimen was instituted at their facility. After obtaining positive cultures from all parts of the breathing circuit, they instituted the cleaning of endotracheal tubes, masks, breathing tubes and bags with disinfectants. Later, they began to gas sterilize the breathing circuits between every case using ethylene oxide, but this still left the soda-lime canister and valve assembly contaminated.

The next step in Albrecht and Dryden's cleanup regimen included the use of disposable absorber and valve systems while the rest of the circuit was sterilized. This insured clean circuits and absorbers for every patent. Finally, anesthesia ventilators and laryngoscopes were added.

A random review of the charts of patients who had had noninfected abdominal surgical procedures during the institution of the total cleanup regimen revealed a dramatic drop in postoperative pulmonary infections from 23% before the cleanup to 6% after.

The infection rate remained high (26%) until the disposable absorber was employed. Albrecht and Dryden (1974) acknowledged that not all variables of their study were amenable to control, but claimed that the only change was in the complete cleaning of the breathing circuit between each anesthetic case.

Dryden reported in 1989 that an additional step in his facility's cleanup regimen had been added. Along with single-use absorbers and breathing circuits, they were using ventilators that allow simple mechanical separation of the bellows from the ventilator drive system and patient ventilator components that tolerate flash steam autoclaving. The rubber ventilator bellows were now being cleaned by flash sterilization.

Effective sterilization of the bellows required that the bellow folds be separated to permit an effective bacteria kill. Through trial and error, Dryden was able to determine an appropriate exposure time which provided for an effective bacteria kill without damage to the ventilator components. After adding the ventilator to the cleanup regimen, Dryden (1989) reported an incidence of nosocomial pulmonary infections at zero percent.

Details of Dryden's study were not given in his 1989 report. He did however describe the events that occurred after an unplanned lapse in the cleanup protocol for several days. According to Dryden, "Seven of eight ventilator units became contaminated with organisms that included *Pseudomonas*, *Staphylococcus aureus*, mold, yeast, fungus, and *Flavobacterium* (1989, p. 1123)." There was also a suspected relationship between a *Pseudomonas* organism found on a ventilator and a burn patient. The only sources of this organism identified by the laboratory during this time were from the burn patient and the ventilator bellows used during the patient's surgery.

In summary, the literature review is inconclusive as to whether contaminated

anesthesia systems are potential sources of bacteria that lead to postoperative nosocomial infections. For the most part, the studies clearly report that organisms are present throughout the anesthesia circle system and that the contamination may often originate from the anesthetized patient. The controversy continues as to the pathogenicity of these organisms found within the anesthesia system and exposed to subsequent patients.

Use of disposable breathing circuits and bacterial filters has not produced any notable difference in the overt percentage of postoperative infection rates. It is accepted that the bacteriocidal effects of soda-lime does not appear to guarantee protection from cross-infection from patient to patient. Cleaning, disinfection, and sterilization procedures were developed to minimize organisms on reusable anesthesia equipment. Lack of adherence to these protocols was reported by some authors and was suspected by others.

Whether the anesthesia ventilator bellows is a source of bacterial contamination to anesthetized patients has not been clearly documented. Studies have focused on the anesthesia breathing circuit, including the carbon dioxide absorber. Albrecht and Dryden did discuss the ventilator bellows as a source of contamination, but studies have not been done. The purpose of this study was to identify the prevalence of bacterial growth in the ventilator bellows of anesthesia machines considered to be safe for patient use. In addition, the prevalence of bacterial organisms present in the morning prior to the start of the day was compared with the prevalence in the evening after anesthesia had been repeatedly administered to determine if repeated use correlated with the level of contamination.

CHAPTER THREE: METHODOLOGY

A major medical facility located in the state of Maryland was chosen as the study site. This facility has a busy operating room schedule five days a week and is open to perform surgical procedures 24 hours a day, seven days a week. There are 14 operating rooms located in the main operating room suite and two additional operating rooms located in labor and delivery. Permission from the facility was obtained prior to specimen collection. Actual patient consent was not required since the protocols for protection of human rights were not affected in this study.

The study sample consisted of 10 - 12 anesthesia machines routinely used by this facility. The anesthesia machines located in labor and delivery and in two of the rooms in the main operating room suite were automatically excluded from the study due to the infrequency of general anesthesia being administered there. Two sets of samples were collected on the same day during the normal work week from the same anesthesia machines. These samples were collected at different times.

The first set of samples was collected in the early morning hours prior to the beginning of the work day for ease of collection and to prevent any interruption to the operating room schedule. Samples collected at this time were reflective of anesthesia machines that are in their best "ready for patient use" status. A second set was collected from the same anesthesia machines as soon as possible after the last case of the day was finished. These samples were reflective of anesthesia machines that have been repeatedly used throughout the day on multiple patients. Aside from the usual replacement of the disposable breathing circuit between patients, no other cleaning or disinfection of the anesthesia machine was performed.

Using sterile culturette bacterial swabs, the anesthesia machine bellows was disassembled, exposed and sampled. The culture samples were collected aseptically and transported to the microbiology laboratory at the Uniformed Services University of the Health Sciences within the allowable two-four hours of specimen collection. All cultures were collected by the investigator to eliminate any variation in sample collection. The external housing of the ventilator was removed, and then using aseptic technique, the entire circumference of the internal lip at the base of the ventilator bellows was swabbed two times in one continuous motion. For identification purposes, each swab was assigned a number between 1 and 12 that corresponded to the identification numbers assigned to the anesthesia machines. Each specimen also received the letter "A" or the letter "P" to further differentiate the morning from the evening samples.

At the laboratory, all swabs were immediately placed into thioglycolate broth tubes by laboratory personnel. The thioglycolate tubes were assigned identification numbers and letters to allow tracing to those given to the corresponding swabs. The tubes were incubated for 24 hours in 5-10% carbon dioxide and 90-95% oxygen at 35-37 degrees centigrade.

The thioglycollate tubes were visually checked for the presence of bacterial growth by observing for turbidity at the end of 24 hours of incubation. If growth was visible in the thioglycollate tubes, subcultures from the tubes onto blood agar plates were performed and incubated under aerobic and anaerobic conditions. A count of the number of bacterial colony forming units (CFUs) after incubation was completed and recorded by the microbiology technicians. Colony counts were ranked according to the following scheme used by duMoulin and Saubermann (1977): 1 to 9 CFUs was designated 1+;

10 to 99 CFUs was designated 2+; more than 100 CFUs was designated 3+. If no growth was noted within the thioglycollate tubes, the tubes were reincubated for an additional 24 and/or 48 hours and reassessed for growth after each additional 24 hours of incubation. Any growth observed was further worked-up to identify the major organisms present. An unused sterile culturette swab, blood agar plate and thioglycollate tube was incubated along with the samples to test for contamination and to act as controls.

Statistical summarization of these data showed the prevalence of bacterial contamination within the anesthesia machines considered to be ready for patient use. The prevalence of contamination in the morning was compared with that in the evening to determine the effect of repeated use on the level of contamination present. The extent of the growth was evaluated based on the colony counts. Finally, all cultures exhibiting growth were further tested to identify the bacterial organisms present.

CHAPTER FOUR: RESULTS

The 22 samples in this study were all collected from Ohmeda Modulus II Plus anesthesia machines that were used to provide general inhalational anesthesia on the day of sample collection. Twelve anesthesia machines were sampled in the morning before the start of any cases, and 10 of those same machines were sampled again later that same day after the cases were finished. Two anesthesia machines had to be excluded from the afternoon sampling because surgery was still in progress at the time of sample collection.

All samples were collected by the investigator using aseptic technique as previously described. Less than one hour was required to collect each set of samples, and all samples were promptly delivered to the microbiology laboratory at the Uniformed Services University of the Health Sciences within two hours of their collection. Upon arrival at the laboratory, qualified, experienced laboratory personnel immediately placed the samples in thioglycollate broth tubes that were labelled with each sample's corresponding identification number, and then incubated. Negative controls for contaminants were simultaneously processed and incubated with the samples. The samples were evaluated after 24, 48, and 72 hours of incubation for any signs of bacterial growth. Appropriate subsequent tests were performed as needed to isolate and identify any organisms that exhibited growth.

Of the 12 samples collected in the morning, 100% of them were reported to have no visible evidence of bacterial growth. Of the 10 afternoon samples, two or 20% of them were later reported positive for bacterial growth (Figure 1). The index indicated that 3+ or greater than 100 colony forming units (CFUs) were counted for each of these positive samples. After additional tests were performed for identification, the only

organism present in either of the positive samples was *Staphylococcus epidermidis*. No other bacterial species were grown from any of the samples or from the negative controls.

The standard error for the 20% positive results reported in this study was calculated to be 12.6% using the following formula: $\sqrt{P_1(1-P_1)/n}$. The 95% confidence interval for the 20% positive results was then calculated to have a range of -26% to 46%. Therefore, this investigator accepts from these statistics that the reported 20% positive results are not significant and are due to sampling error. Of course, the Type II error is quite high due to the small sample size.

An additional observation about each of the ventilator bellows was made by the investigator on the day the samples were collected. Each of the ventilator bellows was tagged with a label that showed when the last time each ventilator bellows had been replaced. It was noted that these dates ranged from six to twelve months before the day of sample collection (Figure 2). Of the two positive samples, one of the ventilator bellows had been changed approximately six months before and the other 12 months before the day of collection.

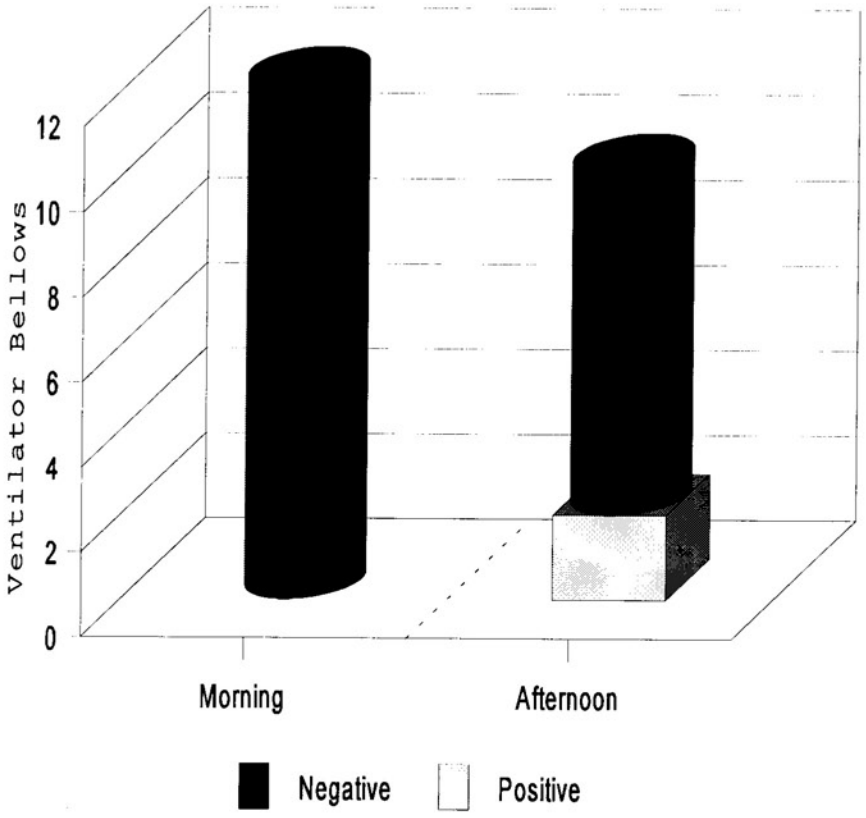

Figure 1. The number of morning and afternoon samples that were positive and negative for bacterial growth in 12 anesthesia ventilator bellows.

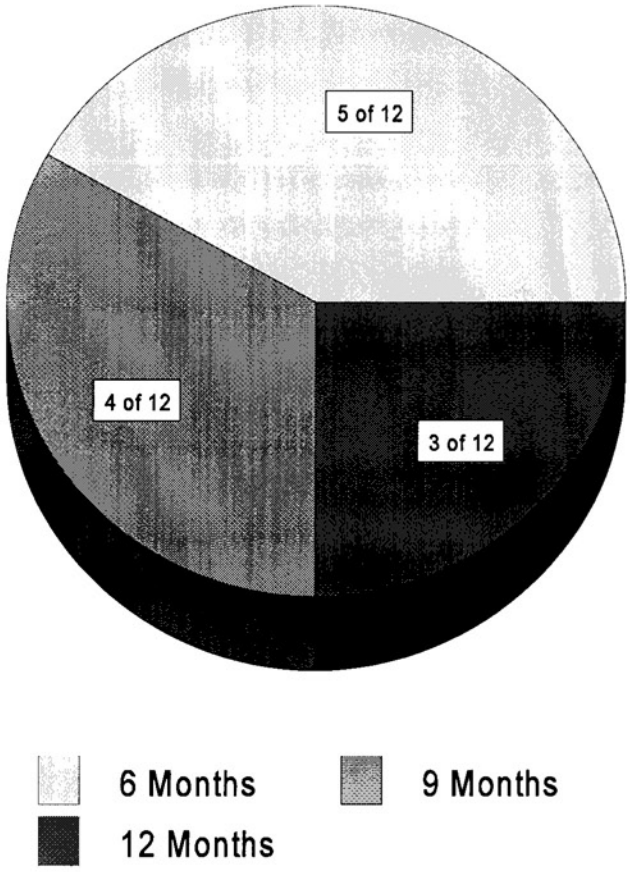

Figure 2. The age in months of the 12 anesthesia ventilator bellows that were sampled in this study.

CHAPTER FIVE: CONCLUSION

The findings of this study support the opinion that the ventilator bellows does not harbor microorganisms and does not present as a loci for nosocomial agents. No pathogenic organisms as measured by turbidity were grown from the 22 samples that were collected. The two samples which were positive for growth of *Staphylococcus epidermidis* indicates that some external contamination of the samples may have occurred during sample collection by the investigator or during the placement of the culturette swabs into the thioglycollate broth by laboratory personnel. *Staphylococcus epidermidis* is a known skin contaminant and not a normal flora found in the respiratory tract, and it is unlikely that it would be found in the ventilator bellows. These data support that the anesthesia ventilator bellows in this study were protected from patient to patient respiratory contamination.

The focus of this study was to identify whether the ventilator bellows of anesthesia machines may contribute to postoperative nosocomial infections by serving as a potential source for bacterial contamination to patients. This study supports the work of Murphy, et al (1991) who stated that soda lime exerts a bacteriocidal effect on nonsporing organisms. This study implies that sterilization of the ventilator bellows, an important component of the cleanup regimen instituted by Dryden (1989), may not be a necessary step in precluding the risk of cross contamination. Finally, these data support that the present methodology of cleaning and sterilization of anesthesia machines at this facility is effective.

Generalization of these findings is limited by the collection of the samples at one institution and the diminutive size of the sample. Recommendations from this study to

fully document the potential risks of cross contamination from anesthesia circle systems include repeating this study with a larger sample size collected at multiple institutions. Another recommendation is to expand the number of sites sampled within each anesthesia circle system to include the carbon dioxide absorber, the inspiratory and expiratory valves, as well as the ventilator bellows at multiple institutions. Ways to identify and eliminate the risks of cross-infection between anesthesia systems and surgical patients must be further investigated to reduce patient morbidity and mortality and to avoid unnecessary hospital costs.

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