Are CRNAs Inadvertently Contributing to Post-operative Wound Infections?

The Potential Contamination of skin

By the use of a

Forced Air Warming Device

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April 22, 2016

Presented to the Faculty at the University of Michigan-Flint
In partial fulfillment of the requirements for the
Doctor of Anesthesia Practice Program

Winter/2016

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Abstract

Purpose

The purpose of this study was to examine the use of 3M Corporation's Bair Hugger® forced air warming (FAW) device and the transfer of potentially infectious material to the patient's skin.

Methods

After receiving approval from 2 IRBs, 31 patients undergoing surgical procedures that would benefit from active warming were consented for this study. Per the study protocol, 3 samples were obtained from each subject using contact agar plate sampling. After cleansing the skin and preparing it as for a surgical incision, the first sample was taken directly underneath the nozzle connection for the FAW prior to blanket application. At the termination of the procedure a second sample was taken from the same area and the third sample was taken from the interior of the blanket prior to removing it from the patient. The agar plates were incubated for 48 hours and the plates were inspected for any growth. All plates were examined for any colony forming units (CFUs). The numbers of CFUs were counted for comparison between all 3 samples.

Results

Of the 30 patients included in the study, three (10%) had contamination of the skin following removal of the FAW blanket, and the remaining 27 (90%) had no skin contamination. Colony growth was present on the interior of 14 (47%) of the FAW blankets postoperatively. No patient had any postoperative surgical site infections after a 30 day follow up.

Conclusion

This study concluded that despite the potential for contamination of the patient's skin the risk of warming each patient with a FAW may outweigh the risks associated with hypothermia.

Data Sources

PubMed, CINNAHL, Medline and the Cochrane Collaboration.

Keywords

Forced air warming, convective warming, surgical site infection, and skin contamination.

Introduction and Background

It is the responsibility of the anesthesia provider to determine whether or not to actively warm surgical patients for the duration of their operative procedure. Forced air warming (FAW) has proven to be one of the most cost effective and efficient means for reducing the loss of core body temperature during general anesthesia. The warm air supplied by these devices is gathered from the environment of the operating theatre, generally on or very near the floor, thus the warm air supplied can only be as clean as the operating room (OR) environment itself, and the filters provided by the manufacturer. The filters are designed to significantly reduce or eliminate harmful material that could be distributed about the operating room or transferred to the patient during use. These filters are meant to be replaced on a regular basis (every 12 months or 500 hours of use) as recommended by the manufacturer.[1] This may or may not occur according to the manufacturer's suggested schedule depending upon the designated performer of maintenance, or the knowledge of said performer concerning the proposed change schedule. The potential for transmission of infection could possibly be increased if the filters are dirty or allowed to be used beyond the recommended period of replacement. Prior to beginning a surgical procedure, the patient's skin surrounding the proposed incision site is cleansed with a bactericidal solution to prevent the possible transfer of infectious material from the patient's skin into the incision. The patient is then draped extensively to cover any other unprepared and exposed skin to further prevent transfer of infectious material.

Problem Statement/Objectives

Post-operative surgical wound infections are typically thought to be the result of poor skin preparation, inadequate draping, unsatisfactory instrument sterilization, or a general lack of the required level of care. Certified Registered Nurse Anesthetists (CRNAs) are typically meticulous about preventing blood borne infections by utilizing strict aseptic technique during injections, as well as universal-type precautions such as adhering to the "One and Only" campaign directive from the United States Centers for Disease Control that states providers and patients together must insist upon "One Needle, One Syringe,

Only One Time" for each and every injection.[2] The reduction or prevention of post-surgical infections is a critical indicator of surgical quality and post-operative care. In the current healthcare environment of exploding costs and the existence of agencies that stress the importance of the *quality* of care over the *quantity* of care, post-operative infections will likely affect Medicare and Medicaid payments or reimbursements to hospitals in the near future. It is foreseeable that the transfer of potentially infectious material to the skin of the patient may result in an increased incidence of post-operative surgical infections. This leads to the research question this project sought to answer:

Do FAW devices used by anesthesia providers to prevent hypothermia during surgical procedures lead to an increase of bacteria present on the skin of the patient?

Review of Literature

Search Parameters

Focused searches of PubMed, CINAHL, MedLine and the Cochrane Collaboration collection were conducted using various combinations of the following key words; "forced air warming (warmers)", "infection", "surgical site (infection) contamination", "intra-operative hypothermia", "perioperative hypothermia" and "prevention" in multiple combinations. In total, prior to any search restrictions, 1467 articles were identified as being at least obliquely related to the search terms. Following implementation of a twenty year time limit and a human species restriction the search terms returned 315 items for review. Once a preliminary viewing of titles and abstracts for relevance to the proposed topic was complete, 69 were selected for full review. After a full reading of the material in addition to examining the references lists for other relevant material, 29 articles were used in this review, including 5 literature reviews and a single systematic review. Inclusion criteria included full text articles published or translated into English. Access to the abstract alone gave sufficient cause to exclude the reference.

Definition of Hypothermia

Many definitions of perioperative hypothermia exist,[3] the current globally accepted standard is the one defined by the Surgical Care Improvement Project (SCIP) initiated by the United States (U.S.) Centers for Medicare and Medicaid Services (CMS). The SCIP became effective on 1 July 2006 and since that time perioperative hypothermia has been defined as a core body temperature below 36° Celsius (96.8° F) or a single degree Celsius below the universally accepted normal of 37° (98.6°F). The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) adopted this definition some time later and included it in their National Patient Safety Goals for 2010; it has become an item of interest to hospitals seeking to ensure and/or maintain Joint Commission accreditation.[3]

Normal Human Thermoregulation

Typically, the human thermoregulatory system maintains the core body temperature within 0.2° Celsius of the normal 37°C.[4] The hypothalamus responds to upper and lower temperature thresholds by reducing environmental heat loss via vasoconstriction or increasing metabolic heat production by way of energy use or shivering, respectively.[4] These responses allow typical individuals under ordinary circumstances to maintain their core body temperature very close to normal regardless of external temperature variations. Unfortunately, surgical patients are rarely under ordinary circumstances; they are generally hungry, thirsty, anxious and severely under-dressed for their environment. Perioperative hypothermia commonly results in the presence of cold operating rooms, room temperature skin preparation solutions and various anesthetic techniques that reduce or eliminate the ability of the thermoregulatory center to operate efficiently.[4] Specifically, volatile anesthetic agents have been shown to produce significant decreases in the upper and lower temperature thresholds for vasoconstriction and shivering.[5]

Consequences of intraoperative hypothermia

Something as seemingly innocuous as the loss of a single degree Celsius of body heat can translate into a myriad of problems for the patient; thus the reasons to keep surgical patients warm are multiple and

diverse. Hypothermia experienced during surgery increases surgical blood loss and transfusion requirements; it also interferes with the electrical conduction of the heart, sometimes causing arrhythmias or even cardiac arrest.[6] Unintended hypothermia is expensive; adding between $2500 and $7000 to inpatient hospital bills per patient.[6] Hypothermia has been shown to delay discharge from the post-anesthesia care unit, to increase the sensation of postoperative pain and to impair immune function by interfering with neutrophil function and promoting vasoconstriction; which leads to tissue hypoxia and an increased incidence of surgical site infections.[7] A study by Kurz, et. al. published in 1996 found that the patients that experienced unintentional intraoperative hypothermia had three times as many culture-positive surgical wound infections as the patients who were actively warmed and had normothermia maintained.[8] Lastly, the prevention of perioperative hypothermia has been theorized to be at least as important as, if not more so, than preoperative antibiotic administration in the prevention of surgical site infections.[9]

Methods of warming surgical patients

As soon as a patient is brought into a chilly operating room, the inevitable loss of body heat begins. The heat of the body is exchanged with the environment primarily by radiation, accounting for 60% of the heat exchange that occurs, but also by conduction and vaporization.[10] Anesthesia providers attempt to prevent these losses perioperatively by various methods of patient warming. In general, attempts at warming patients fall into two categories; passive and active. Passive methods of heating consist of covering the patient with warm blankets and the unheated surgical drapes, thereby isolating the patient from the environment. Occasionally a heat/moisture exchanger (HME) within the breathing circuit of the anesthesia machine is utilized.[10] The initial rapid loss of body heat after the induction of anesthesia is secondary to the redistribution of blood from the warmer core of the body to the cooler periphery by vasodilation. For this reason passive heating alone is usually insufficient.[10]

Actively warming the patient has been shown to be more effective than passive warming alone[11] and thus has become one of the preferred methods to prevent intraoperative hypothermia. Active warming is

achieved primarily through the use of convection, which is the movement of heat through fluids (including air);[12] this is the basis of forced air warming technology. Anesthesia providers also use intracorporeal heating, or the intravenous infusion of warm fluids.[13] Another method of active warming is conduction, which is the transfer of heat energy down a temperature gradient from a warm object to a cooler object. In this category are circulating water mattress pads/blankets or electrically warmed mattresses or blankets. Forced air warmers must be used with the appropriate warming blanket supplied by the manufacturer so that warmed air may circulate through it when placed in direct contact with the patient's body. Forced air warmers have demonstrated efficacy in preventing intraoperative hypothermia if the appropriate sized and shaped blanket is used, that it is placed on the body correctly, and a sufficiently high temperature is selected.[10]

Problems associated with active warming

As beneficial as forced air warming has proven to be over the past several decades, it has not been without controversy. Conflicting reports have arisen from a variety of sources concerning the safety and efficacy of forced air warmers and whether or not their use should be continued or halted in specific circumstances. Interestingly, one of the biggest and most vocal opponents of forced air warmers is the inventor of the Bair Hugger® Convective warming system, Scott Augustine, MD.[14]

Anesthesia providers may assume the warmed air circulating around patients is clean because each patient gets a clean, fresh, and brand-new out of the package blanket. The cleanliness of the air supplied to the warming blanket can be determined (at least partially) by where it comes from (usually close to the floor), the cleanliness of that surface, and the efficiency of the filter used to clean the air prior to it leaving the warming device.[15,16]

Source of warmed air

Surgical suites are cleaned several times every day; typically before the first case, between each subsequent case, and then a final, thorough 'terminal cleaning' at the end of each day's cases. The evidence

clearly shows that those responsible for this cleaning need to do a better job to ensure a clean operating environment for the protection of the patients; even the best cleaned surfaces in the OR (the door, the field lights and the telephone) are truly clean only about 35% of the time, and the other surfaces only 25% of the time.[15] Environmental contamination of surfaces in operating rooms plays a significant role in the spread of methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE) and *Clostridium difficile (C. diff)*.[15] These virulent bacteria can wreak havoc on the health of patients and the state of the economy: Hospital acquired infections cost the U.S. health care system almost $10 billion per year; *C.diff* accounts for more than 15% of that total.[17]

Surface contaminants have the ability to spread rapidly and exponentially from a variety of different surfaces. Cell phones have become an invaluable tool in health care, having essentially replaced the pager as a means of instant contact, and as a source of rapid information retrieval when necessary. They are not, however without cause for worry. A study published in 2015 checked the bacterial contamination of cell phones of orthopedic surgeons and found that 83% were contaminated with pathogenic bacteria when tested prior to any cleaning.[18] Even though cleaning brought that number down to 8%, within a week 75% were again contaminated, suggesting that they should be left out of the operating room if they are not routinely cleaned and disinfected.[18]

An experiment of transmission modeling further demonstrates the ability of bacterial contamination to spread at an exponential pace. In one 'pod' of a six pod neonatal intensive care unit (each pod contained eight cribs); a *single* telephone handset was inoculated with simulated bacteria consisting of plant DNA. Within four hours the "bacteria" was identified on staff's hands and other environmental surfaces in *all six* pods.[19] While this experiment, in and of itself is not proof positive of the virulence and speed of bacterial spread, it does plainly illustrate how quickly bacterial contamination can find itself far from its original source, as well as the critical nature of operating room disinfection and overall cleanliness.

Filtration efficiency

With adequate filtration, clean air should still be able to be supplied to a surgical patient even if the OR surfaces are not as clean as they should be. Adequate filtration though has proven to be an issue. A seminal study in this area of inquiry was published in 1997; a time when multiple drug resistant pathogens were emerging.[20] The investigation determined that when warmed air was sampled directly from the distal hose end, without the benefit of the intended blanket, microbial pathogens were detectable in almost half of the units tested (n = 10).[20] These findings were replicated during a study by Reed, et.al. from 2013, that examined the intake filtration of 23 devices in Austria and found an efficiency rating of only 63.8% at the 0.2μm size.[21] This lack of efficiency led to a significant buildup of internal microbial contamination within inaccessible air pathways that prevented decontamination, or even modest cleaning by the end user.[21]

Reed's study was a logical complement to a study conducted in the U.S. in 2011. This study looked at 52 FAW blowers from 38 individual operating rooms and 11 different hospitals. An even poorer efficiency rating of 61.3% was demonstrated with subsequent internal microbial contamination by *Staphylococcus aureus*, coagulase-negative *Staphylococcus* and methicillin-resistant *S. aureus*.[16] This study more closely replicated the experiments of Avidan, et.al. by also examining the air from the distal hose end for particle emissions that theoretically should have been trapped by the filter. The findings are at the very least disconcerting – 58% of the FAW blowers examined generated up to 35 000 particles/ft^3 in a size greater than 0.3μm.[16] Following these results the authors went on to proclaim that "*popular FAW devices in current use are of questionable design with regard to preventing airborne contamination emissions into the OR and possibly the surgical field.*"[16] While these results appear potentially damning, it should be disclosed that this study was funded by Augustine Medical and Design of Eden Prairie, MN – the company of the original inventor of forced air warming, Dr. Scott Augustine. Even when taking that into consideration it does not explain the multitude of evidence-based literature questioning the safety and efficacy of FAW.

The Skin Microbiome

It has been established that the source of the warmed air at its origin may not be as clean as is desirous before it is propelled down upon a patient. The filtration efficiency of some machines is not optimal. Assuming that the warmed air was obtained from a clean source, and that the filters are proficient at removing potential pathogens, is that enough to prevent further contamination of the patient's skin? Consider the skin itself and the pathogens that could be distributed about the OR environment when warm air is blown over it at high velocity.

The skin is the largest organ and an effective barrier to foreign pathogens; but that is not to say that the skin itself does not harbor its own pathogens.[22] There are approximately 1 X 10^9 bacteria on every square centimeter of human skin, including hair follicles and the sebaceous glands.[23] The bacterial count is primarily dependent upon the location sampled. The skin of the body can be divided into three different categories; moist, sebaceous and dry.[22] The moist sites include primary surgical entry points such as the navel and the groin, as well as the axilla, the soles of the feet and the antecubital and popliteal fossas.[22] Moist sites are host to the greatest number of bacteria, harboring as many as 1 X 10^7 aerobic bacteria/cm^2.[23] Most of the microbes found in the moist areas consist of the staphylococcus and Corynebacterium species[22] with *S. epidermis* - a gram-positive bacterium - accounting for 90% of the aerobic flora.[23] The skin is also frequently inhabited by other pathogens including viruses, fungi and parasites.[22] While the majority of microbes present on the skin are typically considered relatively harmless, they can (and often do) cause serious infections during periods of immune suppression.[22] A frequent causative agent of nosocomial infection is *S. epidermis*, which is a close family relative of *S. aureus*, and the skin literally teems with *S. epidermis*.[22] In a surgical setting many diabetic patients present with slow or non-healing wounds. Immobile patients with decubitus ulcers are frequently seen in an operating room. It is these populations that are frequent victims of normally harmless skin flora.[22]

Knowledge that skin carries multiple types of potentially infectious pathogens is the impetus for the pre-surgical cleansing of the skin; it is an attempt to rid or immobilize bacteria on the skin to protect the surgical site from infection. Thoroughness of surgical skin preparation is affected by the acuity of the patient. Preparation time is frequently different between scheduled versus emergency cases. A study was conducted in 2013 to inspect the impact of differing methods of skin preparation on patients undergoing hip replacement surgery. Patients scheduled for surgery were given a Betadine® scrub solution to use as shower soap the night before surgery, whereas the emergency cases were not afforded this option.[24] Following the induction of anesthesia another Betadine® scrub was conducted, followed by two applications of an alcohol antiseptic dermal polyvidone-iodine solution (Betadine® alcohol 5%). Samples were obtained from both groups from the trochanter area and the inguinal area. Researchers discovered that initial bacterial levels obtained were three times more abundant in the emergency cases.[24]

The skin plays host to multitudes of potentially infectious pathogens. In addition, it has been demonstrated that the epidermis continually sheds keratinocytes into the environment that are rich in microbes clinging to their surface.[23] These shed epidermal cells then become part of the operating room environment, to be tossed about the room on unpredictable air currents. Many operating rooms are designed considering this, and the ventilation systems are engineered specifically to reduce various airborne contaminants from settling on the patient. Whether or not they are successful may enforce the argument against the use of forced air warmers.

Unintended air currents

Many operating rooms, especially those specifically designed for use as orthopedic surgical suites, are equipped with a ventilation system that utilizes a laminar flow pattern. The airflow is unidirectional, moving through the room in one direction only. It can flow either vertically or horizontally, but vertical flow is customarily preferred because it decreases the incidence of infection by nearly 37% by consistently directing airborne and human-shed bacteria away from the patient.[25] This type of ventilation system is

favored for orthopedic surgery because the implantation of foreign materials (such as artificial joints) drastically reduces the number of bacteria required to instigate an infection.[26] In some cases with certain materials, as much as a 10 000 fold *decrease* is possible, meaning that in some orthopedic cases a single *S. aureus* bacterium may be sufficient to cause an infection.[26]

Despite attempts by hospital designers and ventilation architects to keep the air in operating rooms as clean as possible, the truth is an overabundance of airborne contaminants exists everywhere; including operating theatres equipped with what is termed ultra-clean ventilation (UCV).[27] Contaminants consist of particulate matter suspended in the air including dust, lint, respiratory droplets, and skin squames shed from staff and patients.[26] Use of UCV has been shown to reduce the airborne bacterial count from 5.4/ft^3 in a standard operating room, to 0.45/ft^3 in an OR equipped with UCV.[28] However, these reduced counts are dependent upon the uninterrupted downward airflow from the ventilation system. Air released from forced air warmers is approximately 20°C warmer than the surrounding air in the operating room. This warmer air creates turbulence and rising air currents that interfere with the effectiveness of the laminar airflow system, and may potentially lead to surgical site contamination.[28] It takes very little movement of the air to disturb the downward laminar airflow. Turbulence significant enough to be of concern is created simply by movement of the staff and opening the OR door.[25] As a case in point, Moretti, et.al. demonstrated a statistically significant increase in airborne bacterial load simply by bringing the patient into the room.[29]

The concern about interruption of the downward airflow by rising currents of warm air is the warm air that is rising over the surgical field originated from the potentially non-sterile air very close to the floor. The drawing of that air up and into the area of the operation may compromise the sterile field.[27] The decision to use a FAW, particularly during orthopedic implant surgery, should therefore not be taken lightly.

Effects of warm air surrounding open surgical wounds

It has been hypothesized that the warm air that rises from under the blankets of FAWs competes with the downward airflow in laminar flow rooms and may increase the bacterial count in the area directly

above the surgical site.[30] To test this theory, an experiment was conducted that measured the airflow around the surgical site, the temperature on both sides of the surgical drapes and the particle counts directly above the surgical incision. What was discovered is that the temperature on the surgical side of the drape was 5°C warmer than on the anesthesia side, which caused turbulence of the air and convection currents over the surgical area.[30] The convection currents created then drew simulated contaminants into the surgical field and increased the particle count more than 1000-fold from 2000 particles/m^3 to 2.174 X 10^3 particles/m^3.[30]

Deposition of potentially infectious material

In a study from 1992 researchers placed an agar plate on the abdomen of eight un-anesthetized male volunteers for four hours – two with the FAW working and two with it off, serving as the control.[31] They were unable to confirm a statistically significant difference between the numbers of bacteria noted in either group and therefore reached the conclusion that FAW therapy does not increase the incidence of airborne contaminants over the surgical site.[31] Aside from this single study, the majority of studies concerning FAWs and their potential for causing infection focused on the air measured directly from the hose end, air distal to the intake filter, on internal air paths that were inaccessible, or the perturbation of air currents. No studies were located that measured the bacterial colony count on the skin directly underlying the FAW blanket before and after the surgical procedure. This study serves to address this gap in the literature.

Methods

Over the course of 63 days, 31 patients consented to participate in the study. During the course of their admission to the facility for a surgical procedure, the research protocol was thoroughly explained and informed consent was obtained from all 31 individuals (informed consent document available in appendix A). Inclusion criteria consisted of adult patients that could read, speak and understand the English language who were undergoing a surgical procedure that would benefit from active warming in the operating room. Patients that did not speak English, children, and the mentally handicapped were excluded from this study, as were any individuals who were unable to personally provide consent. Additional exclusion criteria

included refusal to participate and/or the presence of a skin condition (rash, infection) in the area of skin that was to be sampled.

After informed consent was obtained, the patient was transferred into the operating theatre and a standard intravenous induction of general anesthesia was initiated. Following anesthesia induction but prior to surgical skin preparation, the area of skin to be sampled was cleansed with ChloraPrep® solution for 30 seconds according to the manufacturer's instructions. A commercially prepared sterile agar plate designed specifically for contact sampling was used to sample the skin of the patient that would lie directly beneath the distal hose end of the FAW where it connects to the blanket. This area was either on the right or left shoulder for those being warmed with an upper body blanket, or on the right or left anterior lower leg for those that were warmed with a lower body blanket.

Sampling occurred by pressing the sterile agar plate directly to the patient's cleansed skin. After the sample was procured, the sterile agar plate was immediately covered with the supplied cover, and labeled for identification. Surgical skin preparation was completed, followed by placement of the surgical drapes and the surgery commenced. Following the surgical procedure, after skin closure but prior to anesthesia emergence, another sampling of the skin was completed in the same area as the previous sample using the same technique as previously described. A third sample was obtained from the interior of the blanket directly under the hose end. Each sample was identified with the number of the patient in the sequence (1 – 31) and the current time so that pre-, post-, and blanket samples could be differentiated. Subsequent to the surgery and transfer of the patient to the post-anesthesia care unit, each sample was transported to the laboratory where specimens were examined by trained lab personnel, then incubated for 48 hours at 37° C. Following incubation the samples were examined by the laboratory personnel; any colony forming units (CFU) were counted and compared between the pre- post- and blanket samples.

Project Study Design

This study was conceived by the principal researcher after noting the buildup of foreign material on the filter of the forced air warmers in long term use at the local community hospital. It was this author's

hope to conduct the study prior to the scheduled cleaning and/or replacement of the FAW filters so as to gain a better understanding of the relationship between time of use on the filter and the potential contamination of the patient's skin. This became impractical when the filters were changed or cleaned prior to the start of the study. This study design demonstrates whether or not foreign material was left on the patient's skin by the forced air warmer.

The idea of measuring additional foreign material deposited on the skin by a FAW was presented to a statistical adviser for consultation and feasibility testing. After explaining the purpose and intent – which was to sample un-prepared skin, place the FAW, re-sample following surgery and compare the number of colony forming units – it was determined that to obtain adequate power utilizing the Wilcoxon Signed Rank Test for matched pairs that a minimum of 28 subjects would be required. After considering the time and logistics required to enroll the minimum number of patients, it was decided that 30 subjects would be enrolled in the event that any subjects would be excluded.

Having determined the required numbers for statistical significance, IRB approval was sought and obtained from both sponsoring facilities (Mercy St. Vincent's Medical Center in Toledo, Ohio and the University of Michigan – Flint). Prior to beginning data collection the principal researcher consulted with the laboratory personnel that would be examining the numerous agar plates (93) to be used in the study. When this experiment was first discussed with them they suggested that skin that had not been specifically cleaned or prepared for surgery could potentially grow numerous colonies of various strains, making the differentiation of only a few colonies between the pre- and post-tests problematic at best. They suggested rather than attempting to merely determine whether or not the colony count had increased following surgery that the skin be physically cleansed prior to the first sample and placement of the FAW blanket. They surmised that this should provide adequate proof of whether or not anything was being deposited upon the skin of the patient solely by the FAW without the attendant problems associated with trying to differentiate between potentially very small differences between the samples.

Prior to beginning data collection, preliminary experiments were conducted to determine the feasibility of distinguishing between before and after skin samples without prior skin cleansing. To demonstrate the presence of microorganisms on un-prepared skin capable of colonization, a small trial with 10 subjects was conducted. Ten volunteers submitted themselves for skin sampling with direct contact agar plates. Following 48 hours of incubation at 37°C, 40% displayed greater than 100 colonies – enough to make differentiation between the before and after samples difficult, if not impossible according to the laboratory. See Appendix B for results of preliminary experiment #1. It was determined that another experiment should be conducted, this time to see actual pre-post samplings after using a skin preparation solution.

It has been theorized that combination solutions of chlorhexidine and alcohol are superior to povidone-iodine solutions for surgical skin cleansing.[32] A combination solution was selected (ChloraPrep® solution, CareFusion Corp.) to clean the skin prior to the 2nd preliminary experiment. Five operating room personnel volunteered for this test. In the morning before patient contact commenced, each individual had the skin of the outer aspect of their upper arm cleaned and scrubbed for 30 seconds with the ChloraPrep® solution following the manufacturer's instructions. This was allowed to dry for an additional 30 seconds. The skin was then sampled with a Direct Surface Agar Plate (DSAP). These plates (Remel Corp. Lenexa, KS) include specific ingredients (Lecithin and Polysorbate 80) to neutralize the residual microbial action of the chlorhexidine in the cleaning solution and allow for subsequent samplings following disinfection. After completion of a full eight hour shift, the same area of skin was sampled again with a fresh DSAP without prior cleaning. This experiment confirmed that growth could be realized after surgical skin preparation; each of the five volunteers displayed zero colonies on the pretest agar plates and three of the five (60%) posttest agar plates grew only one or more easily counted colonies. See Appendix C for the results of preliminary experiment #2.

Setting and Resources

This investigation was conducted at the Mercy Defiance Hospital in Defiance, Ohio; a small, 25 bed community hospital. The following items were required to perform this study: Bair Hugger® forced air warming machines as well as the appropriate upper and lower body blankets, ChloraPrep® skin cleansing solution, direct contact agar plates and skin markers. These items were supplied by the hospital at no charge to the researcher. The hospital also provided the following services to the researcher without cost; laboratory time and employee effort for incubation, reading and reporting of any observed colony growth.

Study Population

The patient population for this study was acquired from Defiance, Ohio and surrounding areas. The patients were approached for inclusion randomly based upon the principal researcher's case assignments for each day the study was to be conducted. Thirty of the 31 patients consented were included in the study. One patient was excluded for displaying contaminated skin in the preoperative specimen. Demographic data collected included sex, age, height, weight, and total body surface area. Other pertinent data collected included the surgical procedure, FAW machine used (#1or #2), total time on the FAW filter at the beginning of the procedure, and length of contact time between the patient and the FAW blanket. See Appendix D for a sample of the information collected and Appendix E for a complete table of collated study information. Demographic data is displayed below in Table 1 and Table 2 for females and males respectively:

Table 1. Females (n = 17)

	Age (yrs.)	**Height (cm)**	**Weight (kg)**	**Total BSA (m^2)**	**Time (min)**
Mean	52.24	163.62	82.16	1.91	76.18
St. Deviation	17.93	6.37	23.89	0.29	46.07
Range	18 – 80	153.70 – 177.80	49 – 138.30	1.45 – 2.56	36 - 195

Table 2. Males (n = 13)

	Age (yrs.)	Height (cm)	Weight (kg)	Total BSA (m^2)	Time (min)
Mean	52.69	179.57	93.42	2.14	83.38
St. Deviation	17.76	6.42	26.34	0.29	52.77
Range	23 – 73	172.70 – 190.50	62.60 – 147.80	1.77 – 2.68	30 - 191

Data Analysis

The second preliminary experiment convinced the researcher that cleansing the skin prior to initial sampling was the correct way to conduct this experiment. The statistician was not consulted prior to making this change to the study. After data collection and 30 day patient follow-up was completed however, the statistician was consulted again for post data collection analysis. The researcher was informed that when the data to be collected was changed from nominal (yes or no, did new colonies appear?) to ordinal (actual counting of the colonies), the planned statistical test (Wilcoxon Signed Rank Test for Matched Pairs) was rendered ineffective for this experiment; to produce meaningful analysis many more subjects would be required. As the anticipated amount of data collection had already been completed, this presented the researcher with a quandary – either report collected data or reopen the study to enrollment. It was decided due to time constraints to report what was discovered. Statistical significance of the findings was unable to be determined. This project can convincingly report the descriptive statistics noted in Tables 1 and 2 above and on page 18 as well as report correlations for several different parameters. See table 3 below on page 20 for correlations. While this study is strongly suggestive of relative safety to the patient it lacks the statistical significance to support this.

Several unanticipated correlations were determined from the collected data. Three different pairings displayed a moderate, positive, linear relationship, two of which demonstrated statistical significance. Each pairing relating to the patient's body habitus (height, weight or body surface area) and the colony count

within the warming blanket displayed a positive, linear correlation. Below in table 3 are the Pearson's product moment correlation coefficients (r_p) of all the pairings that were determined and their p value determining statistical significance:

Table 3. Correlations

Pearson's Product moment correlation coefficient (r_p)			
	Pairings	r_p	*p value*
Hours on Filter	Post-op Colony Count	-0.1189	> .50
Hours on Filter	Blanket Colony Count	-0.2824	< .20
Total Contact Time	Post-op Colony Count	0.2182	< .30
Total Contact Time	Blanket Colony Count	-0.0517	> .50
Body Surface Area	Post-op Colony Count	-0.0177	> .50
Body Surface Area	Blanket Colony Count	**0.3793**	**< .05**
Weight	Post-op Colony Count	-0.0485	> .50
Weight	Blanket Colony Count	0.3323	< .10
Height	Post-op Colony Count	0.0497	> .50
Height	Blanket Colony Count	**0.3915**	**< .05**

Ethics and Human Subjects Protection

This study was approved by the Institutional Review Board (IRB) of Mercy St. Vincent's Medical Center in Toledo, Ohio and assigned IRB # 0815102. It was also reviewed and approved by the IRB of the University of Michigan – Flint and the Hurley Medical Center in Flint, Michigan.

Strengths and Weaknesses of Study

This was a small study conducted at a single facility with the two existing FAWs that had been in use since their acquisition over 10 years prior. Although elegant in the simplicity of its design this study did not lend itself to meaningful statistical analysis. Regrettably this occurred as a result of the change from nominal to ordinal data prior to the start of data collection. An important lesson was learned however; always consult with a statistician following any change to methodology that may impact the data, even if it does not appear that it will have an impact at first glance. Although a few interesting correlations were noted within the data, only two of these proved to be statistically significant. Further trials with larger

groups should be considered and conducted to confirm these findings. Future studies may consider separating subjects by size, in order to confirm or refute the findings that blanket colony count is positively correlated to body habitus. This study did not attempt to identify the organisms that colonized the agar plates, only to verify their existence and their ability to colonize. Identification of the actual organisms colonized could prove to be an impetus for improving filter efficiency, development of special disinfectant techniques in terminal cleaning of the interior of the machines, or modifying the design of the machines to permit access to the air pathways for the purpose of cleaning and disinfection.

Conclusion

Lay people may view the conduct of an anesthetic as successful when a loved one wakes up at the end of the case. For anesthesia providers who spend careers attempting to perfect the practice, it is a balancing act of competing thoughts and the subsequent decisions; sedated or unconscious? Laryngeal Mask Airway (LMA) or intubate the trachea? Muscle paralysis or not? An attempt is made daily to balance everything based on the needs of the patient as well as considering the needs of the surgeon and their requirements for surgical exposure.

Among the many decisions providers make for each case, whether or not to actively warm the patient is an important consideration. The consequences of not warming the patient are considerable and well documented; but if practitioners warm the patient with a FAW, does this intervention contribute to the incidence of postoperative or surgical site infections? This question is particularly important when the proposed surgical procedure includes the implantation of foreign devices such as those used during joint replacement surgery. There is an extensive body of research that implies the use of a FAW device is tantamount to malpractice; that their use is dangerous to the health of patients due to the increased risk of surgical site infections. This claim is made in the face of the evidence that the sequelae of even mild intra-operative hypothermia is equally as harmful to the patient, if not more so.

There exists a plethora of literature that supports the use of forced air warming as safe, effective and inexpensive. Having been in routine use for almost three decades, forced air warming has proven to be effective in the prevention of perioperative hypothermia for a variety of surgical cases, including joint replacement surgery. This study, while not emphatically proving that FAW use is safe, contributes to the body of knowledge that demonstrates they are primarily safe. Ten percent (3) of the subjects in this study were undergoing joint replacement surgery and no post-operative complications were identified; no one participating in this study experienced surgical site or post-operative infections. All subjects except one were contacted to confirm the lack of complications; one individual could not be reached, therefore had his/her medical records reviewed for any evidence of infection at post-surgical follow up appointments, and no evidence was identified.

Forced air warming devices may not be an optimal choice for preventing perioperative hypothermia; additionally they are not the only option for warming patients intraoperatively. Until a superior method of intraoperative warming is developed that is as effective, economical and available to be placed in wide use, practitioners should thoughtfully consider if FAWs should continue to be utilized. The ongoing research and currently available evidence continue to support the use of FAWs in delivering safe care. When the decision is whether or not to warm a patient and the only way to do so is with a FAW, the preponderance of the evidence agrees that their use is justified and safe.

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Appendices A - F:

Appendix A: Informed Consent Document

Mercy St. Vincent Medical Center

2213 Cherry Street

Toledo, Ohio 43608-2691

Informed Consent Form
And
Authorization to Use and Disclose Protected Health Information for Research

[Protocol Title: Transfer of potentially infectious material to patient skin by use of a forced air warming device]

IRB No.: **0815102**

Research Personnel

Kevin R. Hamilton, CRNA (419) 956-2050
Jane Motz, CRNA, DrAP (Faculty Advisor) (810) 762-0058
Donna Carnahan, CRNA, DrAP (Faculty Advisor) (810) 762-0058

1. Purpose of the Research

You have been invited to take part in a research trial. The purpose of the research is to determine whether or not foreign material is being deposited on your skin by a device that is used to maintain your body temperature while you are under general anesthesia. This research is being conducted to determine if the use of forced air warming devices should be continued. This research is the basis of a doctoral project through the University of Michigan - Flint
There will be 30 persons in this research from Mercy St. Vincent Medical Center/Defiance Mercy Hospital and none nationally.

2. Procedures of the Research

During your surgical procedure today we will be using a forced air warming device to maintain your body temperature while you are under general anesthesia. Should you consent to participate in this research study two swabbings of your skin will be performed; one before the standard skin preparation and cleansing that occurs prior to every surgery, and one following closure of the surgical incision. These swabbings will consist of your skin being rubbed in a back and forth fashion with a sterile swab or Q-tip® type device. These specimens will be obtained from the area of your skin that lies directly under the warmer blanket. If you are scheduled for abdominal or lower limb surgery the swabs will be taken from your upper left chest. If you are scheduled for surgery on your upper limbs, shoulders, head or neck, the swabs will be taken from your left lower leg. Should you choose not to participate in the research study, nothing will change except that the swabbings will not be taken – you will still be kept warm for the duration of the surgery as is our standard. The duration of this research is very short – the duration of your surgical procedure. The

specimens obtained will be incubated for a period of time then viewed under a microscope to determine if anything ended up on your skin during surgery that wasn't there previously. Regardless of what we find, the specimens will be destroyed following examination.

3. Risks of the Research.

There is very little risk to you if you agree to participate in this study. While it is possible that your skin could become irritated if the rubbing of the swab is especially vigorous but this is unlikely. If this does occur some mild discomfort may be experienced, but it should be self-limiting and disappear shortly. Portions of your body will be exposed to the researcher for the purpose of obtaining the specimens – your privacy and dignity will be maintained at all times regardless of whether or not you choose to participate. There are no financial risks associated with participating in this study.

There may also be unexpected risks that are currently not known, but these are also extremely unlikely. Please tell the person explaining this research about any medical problems or concerns you have.

4. Benefits of the Research

There is no payment, nor any immediate benefit to you as a patient for participating in this study. The information gained by the researcher may change the standard of care for surgical warming, or possibly change the types of devices used for perioperative warming. This will result in a benefit to society as a whole, and may benefit you or your loved ones in the future if this occurs.

5. Confidentiality

Mr. Hamilton, Dr. Motz, Dr. Carnahan, Mercy St. Vincent's Medical Center and The Mercy Defiance Hospital will treat your personal information with professional standards of confidentiality. Information that identifies you by name will be confidential, to the extent permitted by Federal, State, and Local law. Authorized representatives of regulatory and oversight agencies such as the St. Vincent's Institutional Review Board may be granted access to and copy records containing your personal information when necessary for them to perform their official duties. The results of the research may be published, but you will not be mentioned by name.

6. Information about the Research

You may contact Kevin Hamilton, CRNA; Jane Motz, CRNA, DrAP or Donna Carnahan, CRNA, DrAP at the phone numbers listed below if you have more questions or concerns.

Kevin R. Hamilton, CRNA (419) 956-2050
Jane Motz, CRNA, DrAP (810) 762-0058
Donna Carnahan, CRNA, DrAP (810) 762-0058

7. Stopping the Research

You can stop being in this research at any time. If you choose to stop, this decision will not affect your current or future medical care with Mercy St. Vincent Medical Center, Mercy Defiance Hospital or any of their affiliates.

If you decide to withdraw from the research you must contact Kevin Hamilton, CRNA (the Principal Investigator) so that he may destroy the specimens associated with your surgical case. There will be no direct or indirect consequences to you if you choose to withdraw from the study. The investigator, the University of Michigan – Flint, Mercy St. Vincent's Medical Center or Mercy Defiance Hospital may decide to stop your participation in this research without your consent, or to cancel the research. If the principal investigator discovers that you suffer from any skin condition that may interfere with the findings you may be excluded from the research study.

You will be told of any new findings that may change your willingness to continue taking part in this research.

8. Alternative to Participation
There are no alternatives to participation.

9. Voluntary Participation
You do not have to be in this research. Your participation is completely voluntary. If you refuse to participate, this decision will not affect your current or future medical care by the investigator*(s)*, Mercy St. Vincent Medical Center, Mercy Defiance Hospital or any of their affiliates.

10. Costs to You
There will be no additional costs to you or your insurance company for participating in this research.

11. Payments to You
There will be no payments made to you for your voluntary participation in this research.

12. Payments to Investigators
None of the investigators involved in this research receive any payment of any kind for conducting this research study.

13. Research-Related Injuries
If an injury happens because of your taking part in this research (which is extremely unlikely), medical treatment is available.
Neither Mercy St. Vincent Medical Center, Mercy Defiance Hospital, nor the investigators, has set aside any money for payment of medical costs, lost wages, and/or direct or indirect losses. However, by signing this form you are not giving up any legal rights to seek compensation for injury.

14. Research Subject's Rights
If you have any questions about your rights as a research subject, you may contact the Chair of the Mercy St. Vincent Medical Center Adult Institutional Review Board through the Research Oversight & Education Department at (419) 251-3585.

15. Authorization for Release of Protected Health Information
Federal law requires that persons participating in research must give specific permission before their identity and/or any health information about them (protected health information or PHI) can be used and/or disclosed.
By signing below, you are giving permission to Mercy St. Vincent Medical Center, Mercy Defiance Hospital and all others involved in the Research Study the right to use and disclose your PHI for the purposes of the Research Study as explained to you in this Informed Consent Form.
You understand that information to be used and/or disclosed may include information relating to sexual diseases, AIDS, HIV, mental illness, or alcohol or drug abuse. If your PHI might show any of this, you acknowledge that researchers might become aware of this information.

You can revoke this permission to use and disclose your PHI at any time. To do so, you must do so in writing and give it to Kevin Hamilton, CRNA and he will ensure that the revocation is handled appropriately. If not revoked, your permission will remain in effect until the end (completion) of the Research Study.
Your decision to allow use and disclosure of PHI during the Research Study is voluntary but if you don't allow it you cannot be in the Research Study. You may inspect or copy the PHI that is used or disclosed. There is always a risk that your PHI may be improperly used or disclosed. If you have any privacy concerns related to the use and/or disclosure of your PHI related to this Research Study, please contact the Privacy Officer, Heather Doll-Hinton at (419) 696-5375.

You may be asked by the Research Study sponsor for permission to use your PHI for matters beyond the Research Study. If you give the sponsor this kind of permission, that is between you and the sponsor and you are bound by what you agree to with the sponsor.

16. Signatures

- By signing this form, you do not give up any legal rights.
- A copy of this consent form will be given to you.

_____

Name of Subject: (Print Name)

_____ _____am /pm

Signature of Subject Date Time

_____

Name of Person Obtaining/Explaining Consent: (Print Name)

_____ _____am /pm

Signature of Person Obtaining/Explaining Consent Date Time

_____ _____*am /pm*

Signature of Investigator *Date* *Time*

Appendix B: Preliminary Experiment #1

Contact Plate Trial #1

Specimen ID	Date & Time	CFUs 24hrs	CFUs 48hrs
TF	8/31/15 1110	3	6
MR	8/31/15 1111	18	23
AI	8/31/15 1112	82	108
TF	8/31/15 1113	317	962
LP	8/31/15 1114	62	97
KT	8/31/15 1114	12	20
MB	8/31/15 1115	20	77
AN	8/31/15 1115	18	20
JK	8/31/15 1116	197	224
KR	8/31/15 1116	159	397

Appendix C: Preliminary Experiment #2

Contact Plate Trial #2

Specimen ID	Date	"Pre" CFUs	"Post" CFUs
LP	9/1/2015	0	1
JK	9/1/2015	0	3
AI	9/1/2015	0	0
TF	9/1/2015	0	0
MB	9/1/2015	0	1

Appendix D: Data Collection Sheet

Subject # _____

Age _____

Height _____

Weight _____

BSA _____

Surgical Procedure _____

Pre-op Betadine shower _____

Upper or Lower blanket _____

Hour Meter Reading _____

Time of Pre-procedure specimen _____

Time of Post-Procedure specimen _____

Time of Blanket specimen _____

Temperature Setting _____

Total Contact Time _____

Appendix E: Table of Collated information

Subject	Age	Ht[1]	Wt[2]	BSA[3]	Procedure[4]	U or L[5]	FAW#	Hours[6]	Pre CC[7]	Post CC[8]	Blanket CC[9]	Fan	Temp	Contact Time[10]
1	56	162.6	111.0	2.12	Sigmoid Colectomy	Upper	1	108.6	0	0	1	Hi	43	161 minutes
2	34	157.5	63.2	1.63	Lap Cholecystectomy	Upper	1	111.3	0	0	1	Hi	43	44 minutes
3	52	170.2	76.6	1.88	Total Hip Arthroplasty	Upper	2	205.5	0	0	0	HI	43	58 minutes
4	54	170.2	112.0	2.3	Lap Cholecystectomy	Upper	1	115.5	0	0	4	Hi	43	58 minutes
5	23	175.3	141.9	2.63	Inguinal Hernia repair	Upper	1	116.2	0	0	2	Hi	43	43 minutes
6*	51	165.1	102.0	2.07	Wound Debridement	Upper	1	116.8	3	5	5	Hi	43	45 minutes
7	61	161.3	67.9	1.74	Breast Biopsy	Lower	2	222.4	0	0	2	Hi	43	37 minutes
8	50	162.6	76.3	1.86	A&P Repair	Upper	2	224.0	0	0	0	Hi	43	84 minutes
9	68	175.3	76.8	1.93	Total Knee Arthroplasty	Upper	1	118.2	0	2	2	Hi	43	191 minutes
10	37	175.3	147.8	2.68	Umbilical Hernia	Upper	1	121.7	0	0	2	Hi	43	63 minutes
11	75	154.9	80.7	1.86	Ventral Hernia	Upper	1	123.1	0	0	0	Hi	43	87 minutes
12	66	172.7	71.7	1.85	Inguinal Hernia repair	Upper	1	124.6	0	0	0	Hi	43	36 minutes
13	68	188.0	91.0	2.18	Inguinal Hernia repair	Upper	2	227.5	0	0	2	Hi	43	118 minutes
14	66	157.5	73.4	1.79	Lap Cholecystectomy	Upper	2	229.4	0	0	0	Hi	43	117 minutes
15	71	182.9	91.4	2.15	Inguinal Hernia repair	Upper	2	235.4	0	0	0	Hi	43	70 minutes
16	48	175.3	91.6	2.11	Knee Scope	Upper	2	237.2	0	1	1	Hi	43	30 minutes
17	75	170.2	138.3	2.56	Total Knee Arthroplasty	Upper	1	125.1	0	0	4	Hi	43	74 minutes
18	64	172.7	65.9	1.78	Shoulder Arthroscopy	Lower	1	126.8	0	0	0	Hi	43	113 minutes
19	36	190.5	104.8	2.35	Shoulder Arthroscopy	Lower	1	128.4	0	0	0	Hi	43	181 minutes
20	30	177.8	104.3	2.27	Inguinal Hernia repair	Upper	1	131.3	0	0	0	Hi	43	46 minutes
21	61	167.6	93.9	2.09	Breast Biopsy	Lower	1	132.1	0	0	0	Hi	43	110 minutes
22	48	165.1	50.7	1.52	Bilateral Mastectomy	Lower	2	244.1	0	0	0	Hi	43	195 minutes
23	41	165.1	71.7	1.81	Lap Cholecystectomy	Upper	2	249.9	0	0	0	Hi	43	64 minutes
24	63	177.8	77.1	1.95	Lap Cholecystectomy	Upper	2	251.0	0	0	0	Hi	43	69 minutes
25	28	177.8	108.9	2.32	Lap Cholecystectomy	Upper	1	138.7	0	0	1	Hi	43	36 minutes
26	18	162.6	87.6	1.99	Lap Cholecystectomy	Upper	1	139.6	0	1	1	Hi	43	38 minutes
27	27	157.5	62.6	1.67	Lap Cholecystectomy	Upper	1	140.2	0	0	0	Hi	43	37 minutes
28	38	190.5	87.5	2.15	Inguinal Hernia Repair	Upper	1	140.9	0	0	10	Hi	43	76 minutes
29	73	180.3	62.6	1.77	Inguinal Hernia Repair	Upper	2	262.7	0	0	1	Hi	43	48 minutes
30	80	153.7	49.0	1.45	Left Mastectomy	Lower	2	265.7	0	0	0	Hi	43	51 minutes
31	62	165.1	73.0	1.83	Lap Cholecystectomy	Lower	2	267.6	0	0	0	Hi	43	44 minutes

Notes: 1 – Height in centimeters; 2 – weight in kilograms; 3 – Body Surface Area calculated by the Dubois and Dubois method; 4 – Surgical Procedure; 5 – U = Upper Body Bair Hugger ® Blanket, L = Lower Body Bair Hugger® Blanket; 6 – Total hours noted on FAW device at time of procedure start; 7 – Colony count on skin prior to blanket placement noted after 48 hours incubation; 8 – Colony count on skin after procedure noted after 48 hours incubation; 9 - Colony count from interior of blanket noted after 48 hours incubation; 10 – Total time the FAW was used with the blanket attached, rounded to the nearest minute. *This subject was excluded from the study and all calculations in correlations secondary to the inability to obtain a clean preoperative skin sample.

Appendix F: Acknowledgements

The author of this study would like to offer sincere thanks to all those who assisted in its completion. Extraordinary thanks go to the Administration and OR staff of Mercy Defiance Hospital for graciously offering the materials and supplies needed to conduct this study without charge to the researcher. Many thanks also to Mercy St. Vincent's Medical Center in Toledo, Ohio for serving as the primary institutional review board for this project. Special thanks to Mercy Defiance laboratory technicians Ms. Amanda Mick and Mr. Joseph Lewis for their invaluable assistance with laboratory operations, procedures and conducting or supervising the incubations and colony counts. Much gratitude is offered to Professor Barbara Saltzman, PhD of the University of Toledo for her assistance and counseling concerning statistical analysis before and after data collection.

Finally, the principal researcher and primary author would like to thank Dr. Donna Carnahan, CRNA, DrAP for her support, motivation and role as primary reader and editor of this manuscript. Thanks also to Dr. Jane Motz, CRNA, DrAP for her role as mentor, instructor, reviewer and second reader.