Do Forced-Air Warming Blankets Increase Surgical Site Infections?

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Over the last year or so, orthopaedic surgeons and anesthesiologists have been reaching out to me asking the question: "Do forced-air warming blankets cause an increase in surgical site infections?" The impetus behind this question may be a recent publication in the literature and the subsequent publicity that followed condemning forced-air warming (FAW) blankets [1]. We, therefore, decided to perform an analysis of all the available data to provide a "scientific" response to the aforementioned question.

Why Use Warming Blankets in the First Place?

FAW blankets have been used in the operating room (OR) for decades with the main rationale behind their use being maintenance of normothermia during surgery. The benefits of perioperative normothermia are numerous. In fact, one of the main benefits of perioperative normothermia demonstrated by randomized studies, relates to its ability to reduce surgical site infection (SSI) as well as several postoperative complications [2-5]. These benefits of normothermia have been demonstrated in many surgical procedures including orthopedic surgery. In a few randomized studies involving patients undergoing total hip arthroplasty (THA), the use of FAW led to decreased blood loss and transfusion needs, as well as quicker post-anesthesia recovery [6-8]. These high level studies have demonstrated the benefits of normothermia maintained with the use of FAW blankets [2-8]; and this has been the rationale behind the widespread use of FAW worldwide over the last few decades.

Should We Be Concerned?

If the benefits of FAW are so undisputable, why would any orthopedic surgeon or anesthesiologist begin to pose questions related to its "safety"? A recent article by McGovern et al. [1] has raised potential issues with the use of FAW in ultra-clean operating rooms. In that study, investigators used a bubble generator to visualize air currents and compared FAW to conductive fabric warming in simulated THA and spine surgery performed in laminar airflow equipped operating rooms. For THA, upper body warming blankets were used and bubbles were introduced at the head/neck of the manikin simulating the patient. The main outcome consisted of bubble counts at the surgical site in a sequence of serial photographs. There was a statistically significant difference in bubble counts between the two groups when the vertical drape (anesthesia screen) was laid down or at half height, but not with full vertical draping (drape to ceiling). This drove the authors to the conclusion that FAW, and not the conductive fabric warming, mobilized under-drape air into the surgical site. In the spine surgery setting, lower-body blankets were used and bubbles were introduced at floor level. With FAW, bubble movement was observed from floor level to the surgical field through time-lapse photography. No such aberrant airflow was observed with fabric warming. To further support their position, the authors studied SSI incidence data and compared a period when FAW was used versus a period when conductive fabric warming was utilized. They found a statistically significant decrease in the incidence of SSI when conductive warming was utilized. With all these findings at hand, the authors concluded that FAW was incompatible with ultraclean operating rooms.

The above study suffers many shortfalls, and in my opinion fatal flaws. First, there appeared to be other factors affecting the air current around their simulated OR. Based on the authors' own admission, there was an airflow imbalance in the setting of the experimental OR "owing to the location of the theatre preparation room", which could have contributed to disrupted air currents and confounded the observed results. Second, the conclusions of the study are based on bubble counts monitored with five sequential photographs taken at 10 seconds intervals. It is not specified at what time point the photographs were taken, and if they were consistently taken at the same time in all cases. Furthermore, better results were found when the vertical drape was at half height compared to the drape laid down, which is not consistent with the hypothesis of the study. In most cases of total joint arthroplasty performed in laminar airflow equipped ORs, the vertical drape is usually stuck on the laminar flow box (drape to ceiling) and this position has yielded no statistically significant difference in air quality according to this study. The clinical data, which was based on retrospective data, had many limitations also. The study did not control for important confounding variables that influence SSI. In fact, the reverse is true as the two periods were not comparable. There was a change in the type of prophylactic antibiotic administered to the patients during each period, which is known to be one of the most important factors for prevention of SSI [9]. Patients subjected to FAW received gentamycin as prophylaxis, which

most authorities would argue is ineffective against most common organisms causing SSI after joint replacement. Thus, this study, in my opinion, is overstretching the data to condemn FAW when no such definitive conclusion could be formulated.

Is there Any Evidence That Forced-Air Warming Blankets Are Safe?

The study by McGovern et al. is not by any means the first study pertinent to FAW. In fact, many previous studies have evaluated the potential of forced-air to cause increased bacterial counts at the surgical site. In this brief document we will not discuss all studies. We will highlight studies that are pertinent to the use of implants, as well as those relating to laminar flow equipped ORs.

A study by Sessler et al., tested the air quality in laminar flow equipped operating rooms [10]. The investigators tested the air quality in laminar flow equipped ORs with a FAW device under three settings: device turned off, device delivering ambient air and device delivering warm air. The study was conducted using volunteers acting as patients and heat-generating manikins mimicking surgeons, and was done for both upper body and lower body FAW blankets. Air quality was objectively evaluated through quantitative standards used in Germany to assess the adequacy of laminar flow in ORs (DIN 1946-4:2008-12). An aerosol generator was used and aerosolized particle concentrations directly above the abdomen (near a theoretical abdominal incision) were measured. The study found that there was no deterioration in the air quality with the use of FAW blankets with ambient or warm air. There was no statistically significant difference in particle concentration between having the machine turned off or on. However, a trend towards decreased protective effect was observed in the subgroup using the lower body blanket. The authors also introduced smoke to visualize airflow within the laminar airflow area and found that FAW did not induce any upward draft or any disruption in the normal downward movement of sterile air. The investigators concluded that FAW was safe to use in laminar airflow equipped ORs.

Other investigators have resorted to air sampling (aerobiology) to evaluate the effect of FAW on OR air quality. Moretti et al. used air samplers during THA to compare air quality in empty ORs to that immediately following placement of patients and during the use of Bair Hugger [11]. The air samples around the operating table demonstrated an increase in bacterial colonies (CFU) immediately after placing the patient compared to empty rooms. An increase was also observed after the use of Bair Hugger, but to a lesser extent than after patient placement, which drove the authors to the conclusion that the medical staff themselves represent the main source of bacteria in the OR. Sampling around patient axillae was also performed and reported, however, this was done only in cases where the Bair Hugger was used and thus was not compared to a control group. Furthermore, there was no sampling during the surgical procedure in cases not using Bair Hugger, except for the point immediately following the placement of the patient on the operating table. In a letter to the editor commenting on Moretti et al.'s paper, Memarzadeh further confirmed their conclusions [12]. The National Institute of Health (NIH) has also engaged in evaluating the safety of FAW blankets. Using "computational fluid dynamics and particle-tracking technology", the NIH found negligible disruption of laminar flow air by FAW, as well as no increased deposition of squames or particles that would originate from the healthcare personnel present in the OR during surgery. However, this study relied on theoretical models and many confounding parameters present in the clinical setting were not taken into consideration.

There are some studies showing that the use of FAW may result in a reduction of bacterial count in the OR [13, 14]. The study by Huang et al. conducted on 16 consecutive patients undergoing aortic surgery with graft insertion, found that there was a reduction in the bacterial count in the OR air at completion of surgery performed with the use of FAW blankets [13]. Sampling around the axillae evaluating exhaust air coming from the patient's skin beneath the drapes also showed a reduction in CFUs, although to a lesser extent than the air in the OR. Sampling from the wound showed consistent negative cultures both at the start and at the completion of operation when FAW was used. The higher counts observed at the start of the procedure were postulated to result from increased OR traffic around that time. The use of a control group without FAW, as well as sampling during the course of operation, would have brought more insight into the issue.

In another study on a limited number of patients (three THA and one shoulder surgery) and two control cases, air around the middle of the operating table in laminar airflow equipped OR was found to have a lower bacteria count when the warmer was turned on versus when it was off [14]. The investigators did find a consistent rise, though not statistically significant, in bacterial counts as surgery progressed. The bacterial counts, however, remained well below the threshold recommended for the assessment of ultraclean air, and thus the rise attributed to the warming device, even if it were found statistically significant, would still have been clinically irrelevant.

Sharp et al. also performed air sampling in laminar flow equipped ORs to study the effect of FAW on air quality [15]. They resorted to volunteer patients with varying severity of psoriasis that have increased shedding of skin cells, and thus would increase the risk of air contamination if the FAW device did in fact mobilize skin squames into the OR air. Air 30cm far from a theoretical operating site was sampled and there were no positive cultures. A smoke test used to visually assess airflow found no disturbance by the FAW device. Even though the authors assessed the influence of personnel activity outside the airflow region on the air quality inside, no sampling was performed with medical personnel inside the laminar flow area, which is usually the case during real procedures. An important point to mention in this study is the use of the "Warm Touch" device for FAW, which is equipped with a high efficiency particulate air (HEPA) filter. Other FAW devices carry different filters and thus the results of this study cannot be fully extrapolated to all FAW devices. Indeed, Albrecht et al. addressed the specific issue of filter efficiency in the air blower of FAW devices [16, 17]. In their most recent work, they found that the intake filters used in air blowers were far from optimal efficiency, which resulted in colonization of the internal parts of the device [16]. 92% of the devices they tested resulted in positive bacterial growth after sampling their internal air path with swabs. Cultured organisms included *Staphylococcus aureus* (both methicillin-sensitive and methicillin resistant) and coagulase-negative *Staphylococcus*, which are known to be the major pathogens in total joint arthroplasty. The authors concluded that the design of the devices should be improved in

order to decrease air contamination. They suggested providing means to decontaminate the internal air path (which is currently not accessible for decontamination), using a more efficient intake filter, and installing an additional filter at the output of the tube that connects the blower to the blanket. It is worth mentioning that throughout the study, the authors evaluated the blowers without the blankets. In another study Avidan et al. sampled air coming out of blowers and found positive cultures in four out of 10 devices [18]. However, after connecting the perforated blanket to the air blower and sampling the air coming out underneath the blankets, no organisms could be isolated. They also found that some of the machines were colonized in several locations (internal microbial filter and inside the tube). In those colonized devices, applying a microbial filter to the distal end of the tube connected to the blower yielded negative culture results when sampling the air blowing out of those machines. The authors concluded that using FAW devices with the appropriate matching perforated blankets and regular change of microbial filters as indicated by manufacturers should prevent a possible contamination of OR air.

An interesting report worth mentioning in the context of this review concerns an outbreak of multi-drug resistant *Acinetobacter baumannii* in a Dutch hospital [19]. After extensive sampling of medical equipment in the ICU, FAW dust filters were among the sources of positive cultures, and thus were incriminated, along with other medical devices, in contributing to this outbreak by air contamination. In the study, positive cultures were found in other equipment, including the patient ventilators. After thoroughly cleaning the environment and all equipment, the outbreak subsided. The cause was never traced to the FAW units. Additionally, it is not surprising that pathogens from the environment were also found on the FAW air filter. It is fulfilling its function of trapping particles and preventing them from reaching the patient.

Air quality assessment without resorting to air sampling devices has also been performed. In one study, eight volunteers were positioned supine on an operating table [20]. Culture plates were placed over the abdomen at the site of a theoretical incision. The skin was not disinfected, making this a worst case scenario. The culture results after placement of plates on the abdomen for two hours with the FAW turned on versus off were compared. Plates collected from the control period (FAW turned off) grew more coagulase-negative *Staphylococcus* than plates when FAW was on. However, with the given number of subjects, the total number of bacterial colonies isolated between the two groups was not statistically significant.

Conclusion

At this point, and with the available evidence present, there is no scientific proof that the use of FAW blankets leads to an increase in SSI, regardless of the type of surgical procedure and the type of operating room. Maintenance of perioperative normothermia plays a critical role in minimizing complications following any surgical procedure and should be exercised whenever possible. We continue to use FAW blankets at our institution in patients undergoing total joint arthroplasty in laminar flow equipped ORs.

Dr. Parvizi is a member of the Scientific Advisory Board of 3M's Infection Prevention Division and is a paid consultant for the company.

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