

Infection Prevention News

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HotDogs, Bair Huggers, and Lawsuits, Oh My! A brief review of the controversy surrounding perioperative warming methods.

Maintenance of Perioperative Normothermia: Background and Rationale

A 2-degree Celsius decrease in body temperature in patients undergoing general anesthesia can triple the rate of a postoperative wound infection. The benefits of maintaining normothermia in surgical patients have been extensively studied. These benefits include: 1) reduction of risk of surgical site infection, 2) better coagulation, and 3) faster discharge from the post-anaesthesia care unit. (1, 2)

Maintenance of normothermia is now a standard of care and a key component of the Surgical Care Improvement Project (SCIP). Also, adherence to normothermia protocol is a current requirement for receipt of full reimbursement from CMS. (3)

Most operating rooms, including ours, rely on forced air warming (FAW) devices, such as the Bair Hugger, to ensure normothermia during surgery. FAW warming devices circulate warmed air in a hose connected to a disposable and inflatable blanket. All clinical trials that documented the benefit of maintaining normothermia during surgery have used FAW devices. (1,2)

Resistive Polymer Warming (RPW), FAW's competition:

RPW devices (HotDog) warm patients by passing an electric current through a resistive polymer which in turn is encased in a reusable blanket. In contrast to FAW devices, RPW devices require direct contact with a patient's skin. The warming capacity of RPW devices was compared to that of FAW devices in a 2011 study by Kimberger et al. This study showed that RPW warmed anaesthetized ENT patients at a slower rate. (4)

Current controversies:

Most operating rooms typically utilize "ultraclean air ventilation" during joint replacement procedures. "Ultraclean air ventilation" relies on constant and unidirectional filtered air flow, known as laminar flow, to protect the surgical site from airborne contamination.

A few investigators have speculated that use of FAW devices disrupts laminar flow thus potentially increasing the risk of contamination of the operative site. (5-7) Most studies that reached these conclusions were funded by the manufacturer of a single RPW device. This same company currently

sponsors “informative websites” that emphasize their claims of an increased risk of developing a surgical site infection due to the use of FAW warming devices while simultaneously promoting their alternative RPW product.

A single study done by McGovern et al is the primary source and most commonly quoted evidence for the claim that FAW warming devices are unsafe. (8) These authors evaluated ventilation airflow patterns using a machine that emitted “neutrally buoyant detergent bubbles” during a simulated hip arthroplasty and a lumbar spinal surgical procedure done on mannequins in order determine if laminar airflow was differentially and adversely disrupted by the use of a FAW warming device compared to the use of a RPW warming device. Photographs were used to provide data on “bubble counts” over the operative site during these mock surgical procedures. Bubble counts on operative site over mannequins were higher when FAW devices were used. No actual microbiologic data was collected during this portion of the experiment. (8)

McGovern et al also examined rates of surgical site infection (SSI) after use of either a FAW or RPW warming device in a total of 1,437 patients undergoing knee and hip replacements over a 2.5-year period. They concluded that the risk developing a SSI was higher in patients undergoing arthroplasty procedures when FAW warming devices were used than when RPW warming devices were used (OR 3.8, 95% CI (1.2-12.5), $p=0.024$). Curiously the risk of developing a SSI was remarkably higher in patients undergoing hip replacement procedures with the use of FAW warming devices than in patients undergoing knee replacements warmed with the same FAW devices (OR 4.1, 95% CI (1.9-8.6), $p < 0.001$). (8)

We and others (3) believe that the preceding widely quoted study by McGovern et al has significant limitations: 1) infection control practices and perioperative antibiotics were not standardized in the two study groups, and 2) the authors did not adjust their outcomes for age or other important patient-related comorbidities. Moreover, the authors failed to discuss what these important details: 1) no mention was made of whether the FAW devices used in this study had proper maintenance including appropriately timed changing of filters in their tubing (see table); 2) they did not provide sufficient supporting data to document that the use of “neutrally buoyant detergent bubbles” are a valid proxy for bacterial contamination, and 3) they did not discuss or explain why patients undergoing hip arthroplasty procedures had such high rates of SSI in their study.

Our take:

The body of evidence describing the link between FAW and increased operative site infections is weak. To the best of our knowledge, no adequately powered, properly controlled, statistically significant, reproducible study has been published that demonstrates an increased risk of SSI due to the use of FAW warming devices. We do not believe that experimental studies using machines that emit bubbles in mock surgical procedures is a proven or standardized method to assess the risk of operative site contamination. Finally, we believe it is important and notable that no studies performed by independent investigators have been published that confirm the findings of the study by McGovern et al. Until such data are published, we believe that it is reasonable and appropriate to continue the use of FAW warming devices in patients. Indeed, our data and that collected by the NHSN suggest that

approximately 99% of patients undergoing joint replacement procedures do not develop a SSI despite the fact that FAW warming devices continue to be widely and appropriately used.

Conclusions:

- We continue to believe that it is reasonable and appropriate to use FAW warming devices to maintain normothermia as these devices are the only devices proven to decrease the risk of developing a post-operative infection.
- FAW warming devices have a >20-year track record of safety in >200 million surgical patients.
- FAW devices should be regularly undergo maintenance as outlined by manufacturer's guidelines, see attached table for recommendations.

References:

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Warming Unit Information and Table

“The repair, calibration, and servicing of the warming unit requires the skill of a qualified medical equipment service technician who is familiar with good practice for medical device repair” —3M Bair Hugger Manual (<http://multimedia.3m.com/mws/media/7983990/service-manual-english.pdf>)

Refer to your model manual for exact specifications. The table below is a general guide, and should not replace model specific guidelines.

TABLE I

Proper Maintenance and Use of Forced Air Warmers

Recommendations
1. The filter should be changed every 6 months or 500 hours. A counter is available on some devices (e.g., Bair Hugger 700 series) to indicate the total hours of use.
2. Calibration testing should occur every six months by biomedical engineering staff at the user’s institution. The manufacturer should check or replace devices that fail calibration testing.
3. Do not warm patients with the warming unit’s hose alone, as severe thermal injury may occur. Always connect the hose to a new, manufacturer-approved warming gown for each patient.
4. Do not continue warming if the red over-temperature indicator light illuminates or an audible alarm sounds, as thermal injury may result. Turn the warming unit off immediately and check the patient’s skin.
5. Do not use a forced air warming device over transdermal medications; increased drug delivery and patient death or injury may result.
6. Do not allow the patient to lie on the warming unit hose or allow the hose to contact the patient’s skin during patient warming.
7. Equipment is not suitable for use in the presence of a flammable anesthetic mixture (e.g., containing air, oxygen, or nitrous oxide).
8. Do not place the non-perforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (the side with small holes) toward the patient.

Recommendations
<p>9. The warming device should be disconnected from the power source before cleaning. Between patients, the outside of the hose should be cleaned with a damp, soft cloth and a mild detergent or antimicrobial spray and then dried with a separate cloth.</p>
<p>10. If a fault occurs in the unit, unplug the temperature management unit and wait for five minutes. Reconnect the temperature management unit to a grounded power source. The unit will perform the normal power-on-reset sequence and then enter the standby mode. If the unit does not return to normal operation, contact a service technician.</p>
<p>11. Temperature and calibration testing should be performed every 6 months or 500 hours of use.</p>

Taken from Sikka, RS *J Bone Joint Surg Am*, 2014 Dec 17; 96 (24): e200 .
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