guidance
ARTICLE

Note: This article has been the subject of recent press releases, e-mail blasts, and blog entries from Augustine Temperature Management. ECRI Institute states that it did not participate in or approve of the above-mentioned materials, and warns that they should not be construed as representing our opinion or judgment. Our views on forced-air warming are explained in this article, and we recommend that readers refer to it—and nothing else—to learn what we think.

FORCED-AIR WARMING AND SURGICAL SITE INFECTIONS

Our Review Finds Insufficient Evidence to Support Changes in Current Practice

Maintaining normothermia during surgery is an important measure in preventing surgical site infections (SSIs). Several technologies are available to accomplish this during surgery, including the popular method of forced-air warming (FAW). Recently, however, some member hospitals have asked us about FAW and whether it might actually contribute to SSIs. Specifically, their questions were focused on whether the use of FAW during surgery (including orthopedic implant surgery) leads to an increased rate of SSIs as compared to the use of other methods of patient warming and, if so, whether such concerns merited discontinuing the use of FAW during surgery. In response to these questions, ECRI Institute has conducted an assessment of the published literature to determine whether the evidence supports a decision not to use FAW.

Based on our assessment, we do not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. This article explains our reason for this judgment.

THE IMPORTANCE OF MAINTAINING NORMOTHERMIA DURING SURGERY

Maintaining normothermia in surgery patients has been reported to significantly lower the risk of postoperative surgical wound infections (Kurz et al. 1996, Melling et al. 2001). Hypothermia triggers vasoconstriction, ultimately resulting in a reduction of the partial pressure of oxygen in tissue. This in turn impairs the body's ability both to fight infection at the wound site and to promote wound healing. Maintenance of body temperature during and after surgery is recommended in practice guidelines by a variety of organizations, including the Centers for Disease Control and Prevention, Guideline for Prevention of Surgical Site Infection, 1999; the American Society of Anesthesiologists, Practice Guidelines for Postanesthetic Care, 2002; the American College of Cardiology/American Heart Association, ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery, 2007; and the National Collaborating Centre for Nursing and Supportive Care, The Management of Inadvertent Perioperative Hypothermia in Adults, 2008.

FORCED-AIR WARMING MAY DISTURB AIR PATTERNS IN THE OPERATING ROOM

FAW is a popular method to maintain normothermia during surgery. FAW systems (warming units and blankets) are designed to warm patients by gently blowing warm air onto the skin of the patient via an air blanket. But there are other methods to warm patients during surgery, such as conductive-fabric warmers and water-circulating warmers. The theoretical concern raised with the use of FAW is that air currents created by the system may carry microbes that might contaminate the surgical site.

Some studies have investigated this concern, looking at the impact of FAW on laminar airflow systems—especially the potential disruption of the downward airflow patterns. For example, five studies (Belani et al. 2012, Dasari et al. 2012, Legg et al. 2012, Legg and Hamer 2013, McGovern et al. 2011) demonstrate that the exhaust from FAW units results in thermal currents that rise into the downward ventilation airflow of the laminar airflow systems studied. The disruption of airflow patterns is particularly worrisome in laminar-flow and ultraclean ORs, in which a wide variety of implant surgeries are performed. The argument is that mobilization of contaminated air near the floor or decreased effectiveness of the downward laminar airflow pattern could contribute to an increased rate of SSIs, including prosthetic joint infections (PJIs), compared to when other methods of patient warming are used. This is especially concerning during orthopedic surgeries because contamination of the surgical site may present a greater risk of developing a PJI, which is

UMDNS terms. Warming Units, Patient [17-570] ■ Warming Units, Patient, Circulating-Fluid [17-648] ■ Warming Units, Patient, Conductive Layer [25-785] ■ Warming Units, Patient, Forced-Air [17-950] ■ Warming Units, Patient, Radiant [13-248] ■ Warming Units, Patient, Radiant, Adult [13-249]

harder to treat and resolve than would be the case with SSIs in general. These studies, however, only raise questions about airflow disruptions. Demonstrating that airflow patterns change when FAW is used does not establish that it results in increased bacterial contamination or increased rates of SSI and PJI as compared to use of other methods of patient warming.

WHAT THE EVIDENCE SHOWS

The literature review process we used involves articulating a specific question to answer, creating search strategies for a comprehensive and objective literature search, and identifying inclusion and exclusion criteria that are applied to each study. The studies that meet the inclusion criteria are evaluated for their design and the potential for study bias—specifically, study features that could impact whether the treatment being studied is responsible for the outcomes observed. Studies are then analyzed for the information they contain.

The question we asked was: Do surgical patients whose body temperatures were controlled with FAW systems (when used as intended) have an increased risk of SSIs compared to patients whose body temperatures were controlled by another method? Our inclusion criteria required that the study include a comparison of SSI rates and that it have at least two arms (FAW compared to at least one alternative warming technology), with a minimum of 10 patients (per arm) undergoing surgery. We also required that studies include documentation of body temperature maintenance for all methods and that they report all infections that occurred within a follow-up period of at least 30 days. (Our complete inclusion criteria and the reasoning behind them can be found in "Study Inclusion Criteria" on this page.)

Our search of the published literature identified over 180 studies potentially related to our question. These studies were all eliminated for a variety of reasons. Any study that was not clinical in nature—that is, that did not involve human surgical patients—was excluded. We also eliminated studies that looked at OR contamination when FAW units were used but did not examine SSIs. Granted, some of these studies report increased microbial contamination within FAW units (e.g., Albrecht et al. 2011) or increased particle counts (particles injected into the air, not bacteria) at monitored OR locations when FAW units were being used (Legg et al. 2012, Legg and Hamer 2013). But while studies like these raise questions, they don't establish that an increased risk of SSI exists with FAW compared to other warming technologies. For similar reasons, we excluded studies that solely examined air current patterns that may affect the distribution of microbes.

While we did not find any studies that met all our inclusion criteria, we did identify four studies that came close to meeting our criteria and that examined SSI rates following clinical procedures:

- Two studies—one by Huang et al. (2003) and one by Moretti et al. (2009)—primarily involved assessment of bacterial counts in different locations of the OR and at the surgical wound edges. These studies used slightly different approaches: Huang did cultures at the start and finish of surgery with use of an Augustine Medical Bair Hugger FAW system; Moretti did cultures with and without use of the Bair Hugger FAW system. The authors of the studies reported that no SSIs occurred in any patient in the studies (total of 46 patients combined). *Reason for exclusion:* These studies lacked a comparison of FAW to an alternative warming system.
- A study by Melling et al. (2001) looked at SSI rates in a total of 421 patients who underwent breast, varicose vein, or hernia surgeries. Patients were randomized into three groups: 138 patients with localized warming before surgery, 139 patients with whole-body FAW before surgery, and 139 patients with no warming before surgery

STUDY INCLUSION CRITERIA

The following are the inclusion criteria we used when determining which studies would be included in our analysis. These criteria were developed before the clinical literature review.

- Studies must have enrolled human subjects who underwent surgery involving the creation of a surgical wound. Studies without human subjects do not provide generalizable conclusions.
- Studies must evaluate a forced-air warming system and at least one other means of maintaining a patient's body temperature (with devices used as intended) during surgery. Such comparison studies are needed to determine the extent to which the FAW system is responsible for altering the infection risk compared to other means of maintaining a patient's body temperature, while all other factors in promoting or reducing infection risk are held constant.
- Studies must have data showing that the body temperature of the patient was maintained by both the FAW system and the comparison technology. If the comparison technology or the FAW system was not effective at maintaining body temperature, then this failure rather than other technology differences may be responsible for any differences in infection rate.
- Studies must be randomized controlled trials or nonrandomized comparison studies with at least two treatment arms.
- Studies must have at least 10 patients enrolled per study arm.
- Studies must report the number or rate of surgical site wound infections within 30 days of the surgery.
- Studies must be published in English.
- Studies must be published as full articles in a peer-reviewed journal.

LAWSUIT ALLEGES CONTAMINATION BY FORCED-AIR WARMER

ECRI Institute has learned that in March 2013, a lawsuit was filed against 3M Corporation alleging that a patient sustained a periprosthetic infection while undergoing hip replacement surgery as a result of contaminants being deposited in the surgical site by a 3M Bair Hugger forced-air warmer.

We have reviewed the plaintiff's petition. It does not present any new information that would alter the conclusions we have drawn in this article based on our review of the published literature.

Case information can be found in the press release from the plaintiff's attorneys at www.prweb.com/releases/2013/3/prweb10554160.htm.

(control group). This study compared the Augustine Medical Bair Hugger FAW system to the Augustine Medical Warm-Up. The Warm-Up (which is no longer available for purchase) was a noncontact normothermic wound therapy system designed to provide warmth and humidity in the wound area and was therefore not intended to maintain a patient's body temperature during surgery. The patient warming occurred for a minimum of 30 minutes before surgery. The SSI rate was not significantly different between warming systems (3.6% for Warm-Up, 5.8% for Bair Hugger, $p = 0.4$), but was significantly lower in warmed patients (5%) versus nonwarmed (14%, $p = 0.001$). *Reason for exclusion:* There was no comparison of whole-body warming methods used during surgery to maintain normothermia.

- A study by McGovern et al. (2011) that examined effects of warming devices on OR ventilation also provided data on PJIs in patients treated by different technologies for maintaining body temperature during surgery. The study reports on 1,437 patients who underwent joint replacement surgery; 1,066 patients had surgery during a period when the hospital used FAW, and 371 had surgery during a period when the hospital switched to using conductive fabric for warming. Data was collected retrospectively. The study reported PJI rates of 3.1% for FAW versus 0.8% for conductive-fabric warming, which was a significant difference ($p = 0.024$, Wald test) when data was combined for hip and knee surgeries. Based on the study's findings, the authors recommend that FAW not be used in orthopedic surgeries. *Reasons for exclusion:* This study lacked documentation of normothermia during surgery. In addition, the authors reported that both the prophylactic antibiotic regimen and thromboprophylaxis regimens were altered during the study period. Since the two types of warming treatment were not applied concurrently, other treatment differences or changes during the two different time periods may have influenced PJI rates. Other notable limitations of the study are that data was collected retrospectively rather than from a prospective study; the data was from only one hospital; and the authors did not state whether the data was collected from all patients who underwent primary hip and knee replacement surgery during the reported time periods.

  Note that no information was provided on what model warming devices were used on patients in the SSI portion of the study, only whether the devices were conductive fabric or FAW. However, in the operating-theater-ventilation portion of the study, a Bair Hugger warming unit with a Model 540 FAW blanket and a Hot Dog brand Model B110 conductive-fabric blanket were used.

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

REFERENCES

Albrecht M, Gauthier RL, Belani K, et al. Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011 May;39(4):321-8.

American College of Cardiology (ACC)/American Heart Association (AHA) Task Force on Practice Guidelines. ACC/AHA 2007 guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery. *J Am Coll Cardiol* 2007 Oct 23;50(17):e159-242. Also available: http://content.onlinejacc.org/article.aspx?articleid=1138596.

American Society of Anesthesiologists (ASA) Task Force on Postanesthetic Care. Practice guidelines for postanesthetic care. *Anesthesiology* 2002;96(3):742-52. Also available: http://journals.lww.com/anesthesiology/Fulltext/2002/03000/Practice_Guidelines_for_Postanesthetic_Care.33.aspx.

Belani KG, Albrecht M, McGovern PD, et al. Patient warming excess heat: the effects on orthopedic operating room ventilation performance. *Anesth Analg* 2012 Jul 19. [Epub ahead of print.]

Centers for Disease Control and Prevention (CDC). Guideline for prevention of surgical site infection. 1999. *Infect Control Hosp Epidemiol* 1999 Apr;20(4):250-78. Also available: www.cdc.gov/hicpac/pdf/SSIguidelines.pdf.

Dasari KB, Albrecht M, Harper M. Effect of forced-air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012 Mar;76(3):244-9.

ECRI Institute. HotDog (Augustine Temperature Management) compared with Bair Hugger (Arizant Healthcare, Inc.) for maintaining body temperature during surgery [custom product brief]. Custom Hotline Service. 2012.

Huang JK, Shah EF, Vinodkumar N, et al. The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk? *Crit Care* 2003 Jun;7(3):R13-6.

Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. Study of Wound Infection and Temperature Group. *N Engl J Med* 1996 May 9;334(19):1209-15.

Legg AJ, Cannon T, Hamer AJ. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone Joint Surg Br* 2012 Feb;94(2):254-6.

Legg AJ, Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J* 2013 Mar;95-B(3):407-10.

McGovern PD, Albrecht M, G Belani K, et al. Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. *J Bone Joint Surg Br* 2011 Nov;93(11):1537-44.

Melling AC, Ali B, Scott EM, et al. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial. *Lancet* 2001 Sep 15;358(9285):876-80.

Moretti B, Larocca AM, Napoli C, et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J Hosp Infect* 2009 Sep;73(1):58-63.

National Collaborating Centre for Nursing and Supportive Care. Inadvertent perioperative hypothermia: the management of inadvertent perioperative hypothermia in adults. Clinical guideline; no. 65. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Apr. Also available: http://guidance.nice.org.uk/CG65.

WE'RE SEEKING YOUR INPUT

Complete our CT user experience survey. We want your thoughts on your CT system's ease of use, functionality, and reliability. Take a few minutes to fill out our survey, available through your member home page or at https://survey.ecri.org/Survey.aspx?s=c35088ec1d80459cbb4fff432f0a5a8e. When done, you'll be automatically entered to win an **iPad Mini.**

Do you use CMMS apps? Are you using mobile phones and/or tablets to provide computerized maintenance management system functions? If so, how are they being used, and how is this approach working for you? ECRI Institute would like to hear from you. Please send your responses to healthdevices@ecri.org. We appreciate your help.