EDITORS’ NOTE
Augustine Temperature Management recently published press releases, e-mail blasts, and blog entries on this article, which appeared in the April 2013 issue of ECRI Institute’s Health Devices journal and is titled “Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice.”

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 our article, and we recommend that readers go here—and nowhere else—to learn what we think.
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 compared to the use of other methods of patient warming and, if so, whether such concerns merit 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.

**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 compared to the use of other methods of patient warming and, if so, whether such concerns merit 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.

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**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 (PJs), 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
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.
LAW SUIT 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.

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 PJIs 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


This report appears in the April 2013 issue of ECRI Institute’s monthly Health Devices journal, which is provided to members of ECRI Institute’s Health Devices System, Health Devices Gold, and SELECTplus™ programs. Health Devices features comparative, brand-name evaluations of medical devices and systems based on extensive laboratory testing and clinical studies. ECRI Institute’s evaluations focus on the safety, performance, efficacy, and human factors design of specific medical devices and technologies.

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