

QUESTION 2: Does the use of forced air warming (FAW) during orthopaedic procedures increase the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: There is no evidence to definitively link FAW to an increased risk of SSIs/PJIs. Alternative methods of warming can be effective and may be used.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 93%, Disagree: 2%, Abstain: 5% (Super Majority, Strong Consensus)

RATIONALE

Maintaining intraoperative normothermia has been shown to reduce perioperative complications including SSI. FAW represents one of the most widely-used methods to prevent hypothermia and maintain intraoperative normothermia. Intraoperative hypothermia has been linked to increased mortalities and morbidities, longer hospital stays, increased requirements for blood transfusion and increased SSI rates. The SSI prevention effects have not been demonstrated in implant surgery, such as total knee arthroplasty (TKA), total hip arthroplasty (THA) and total shoulder arthroplasty (TSA). There has been a concern in the literature about possible contamination of the operating room (OR) air and surgical field with these devices, and subsequent potential increased risk of SSI, especially PJI. Conductive fabric blankets (CFBs) have been suggested as an alternative for intraoperative warming.

Several experimental studies raised a concern for the possibility of intraoperative contamination caused by FAW. McGovern et al. compared FAW and conductive fabric warming (CFW) devices in a simulation of hip and spine surgery with a mannequin used as a patient [1]. They used bubbles generated at the floor and at the mannequin's head to monitor flow of air in the simulated theater and detected significantly increased bubbles close to the surgical field with the use of the FAW devices. They also conducted a clinical review of their infection data between a twenty-month period when FAW devices were used vs. a seven-month period where CFW devices were used, and found a statistically higher rate of deep SSI with the use of the FAW device. The authors noted, however, that their observational study did not account for infection control procedures that changed over the study period or account for several possible differences in patient risk factors, such as obesity and fitness for surgery. Other studies of the same cohorts by these researchers revealed potential impacts unrelated to the change in warming modality, including thromboprophylaxis [2] and methicillin-sensitive *Staphylococcus aureus* screening [3]. Legg et al. measured changes in temperature and air particles at the surgical site in a simulated OR setup with a volunteer patient simulator [4]. They found statistically significant increases in temperature and particle counts with the use of FAW compared to controls or radiant warming devices. In a follow-up study on a simulated TKA set-up, the authors used a bubble generator with a digital camera to actually visualize airflow disruptions caused by FAW [5].

Similar to the prior study, they showed a significant increase in particle counts at the surgical site and in drape temperatures. They also identified a substantial disruption in the unidirectional airflow when FAW was used. Dasari et al. conducted an experiment where a mannequin was used as a patient and temperature was measured at multiple different heights and locations with the use of FAW, a conductive blanket or a resistive mattress [6]. They found significantly greater temperature increases caused by FAW at patient height locations, whereas, temperatures measured at other heights (floor, head and ceiling) were similar among the three warming devices. They concluded that FAW generates convection current activity in the vicinity of the surgical site which may disrupt laminar air flow. Belani et al. conducted a study with a mannequin draped for a TKA in an orthopaedic room and a bubble generator placed at the head to visualize air currents [7]. Bubbles were counted on sequential photographs at the surgical field and compared between FAW and CFW. The authors found significantly increased bubble counts over the surgical site with FAW and time-lapse photography identified convection currents mobilizing air from the mannequin's head over the drapes and into the surgical field. A recent predictive fluid flow simulation conducted by He et al. on a computer aided design OR showed significant disruption in airflow caused by FAW with a displacement of squames from the floor into the surgical field [8].

Tumia et al. quantified bacterial counts in air samples taken in empty ORs, during normal surgical operations prior to turning the FAW device on, and 15 minutes after turning the warmer on [9]. They had low study numbers to reach statistical significance, but they observed an increase in bacterial counts during regular surgical operations with the warmer off compared to the empty OR and a further increase after turning the warmer on. They concluded that most of the contamination of OR air is secondary to the presence of surgical staff and OR traffic, and that FAW increases contamination to a lesser extent, but this is likely not of clinical significance given that the counts seen were still well below recommendations for ultra-clean air theaters. Albrecht et al. evaluated filter efficiency in the air blower of FAW devices and 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 [10,11]. They cultured organisms such as *Staphylococcus aureus* and coagulase-negative *Staphylococcus*, which are known to be the major pathogens in total joint arthroplasty. Avidan et al. sampled air coming out of blowers and also found positive cultures in 4 out of 10 devices [12]. However, after connecting the perforated blanket to the air blower and sampling the air coming out underneath the blankets, no organisms grew.

On the other hand, several studies have failed to demonstrate any increased contamination with the use of FAW. Sharp et al. performed a surgical simulation using patients with psoriasis, who are known to have increased shedding of skin [13]. They utilized slit-air sampling and simulated regular OR activity. No bacterial colonies were grown, leading the authors to conclude that FAW did not result in the contamination of the surgical site. Sessler et al. evaluated the effect of FAW on operative room air in laminar airflow conditions using volunteer subjects in an OR with simulated surgical set-up and heated mannequins to simulate OR personnel [14]. A smoke plume was used to visualize airflow and revealed that FAW did not induce any upward draft or any disruption in the normal downward movement of sterile air. A particle counter was used to evaluate changes in particle concentrations near a theoretical incision site. No significant differences were found between having the FAW device off, on ambient air or on warm air. All scenarios had particle counts below stringenter criteria established in Europe for the evaluation of adequate function of laminar flow in operating rooms.

Moretti et al. evaluated the effect of FAW on air quality during THA procedures with the use of an air-sampling device with agar plates [15]. No differences in bacterial loads were noted at several positions of the surgical field with or without the use of FAW. Memarzadeh et al. reported

computational fluid dynamics and particle tracking studies conducted by the National Institutes of Health to assess whether FAW devices lead to contamination of the surgical site [16]. They found no increased squame deposition from potential contaminant sources due to the FAW device in laminar flow theater situations in their models. Zink et al. evaluated air quality in rooms with volunteers lying down covered by surgical drapes with culture plates placed on their abdomen while FAW was turned on for two hours [17]. Results were compared to a two-hour period where the warmer was turned off. No statistically significant difference was identified between the two situations. Shirozu et al. looked at the effect of FAW on airflow in a simulated operative setting with the use of an ultrasonic anemometer, smoke and laser light [18]. The authors found that downward laminar flow efficiently counteracted the upward airflow caused by FAW blankets and concluded that contamination of the surgical field is not likely in the presence of adequate laminar flow. In a study from the veterinarian literature, two groups of surgical patients were compared (one with use of FAW blankets and one without) [19]. Surgical drapes were swabbed and aerobic cultures were obtained. No difference in positive cultures was noted.

Oguz et al. recently conducted a prospective study where orthopaedic patients were randomized to receive either a FAW blanket or a CFW [20]. They performed a multivariate analysis looking at the effect of multiple factors on the number of bacteria in the OR air and on the field as measured by agar plates positioned at different locations in the room, and nitrocellulose plates placed on the instrument table. These factors included the type of warming device in addition to the presence of laminar airflow, the number of operating room personnel and the operative time. While increased surgical time and absence of laminar flow significantly affected bacterial counts, the type of warming device used did not.

Sikka and Prielipp published a focused review of the literature in the *Journal of Bone and Joint Surgery* and concluded that there is not enough evidence to support or disprove a link between FAW and PJI [21]. They did list recommendations that need to be followed for proper use of the devices including frequent filter changes, calibration and always using the device with the accompanying blanket. Kellam et al. in a comprehensive review for the Association of Perioperative Registered Nurses (AORN) failed to identify conclusive evidence for an increased risk of SSI with the use of FAW and recommended continued use of these devices [22]. Wood et al. conducted a similar review and concluded that FAW does contaminate ultra-clean air in the operating room, but found no definite link to an increased rate of SSIs [23]. They recommended considering alternative warming systems when contamination of the surgical field is deemed to be critical. In a more recent systematic review that encompassed a total of 1,965 patients and 8 studies, Haerberle et al. concluded that there was an absence of evidence to support an increased rate of SSI with the use of FAW blankets [24].

Sandoval et al. compared FAW vs. CFW in its ability to prevent hypothermia in 120 THA and TKA surgeries [25]. There were 60 patients in each group and they concluded that FAW and CFB were equally as effective at maintaining core temperatures during and after surgery. There were no reported SSIs in either group. This study was a quality improvement project and not powered to show a clinically significant difference in infection rates.

In conclusion, the literature is conflicting and there is still a lack of strong evidence linking FAW to increased risk of SSI. In light of this, while we recognize the theoretical risk posed by FAW, we cannot recommend discontinuing the use of these devices at this time. We do, however, recommend following the manufacturer's instructions and frequently changing the filters, making sure the devices are calibrated and most importantly using the devices only with the appropriate perforated blanket. Other alternative warming methods can be used. We recommend a randomized prospective trial to answer the index question, and a pilot is underway. (ISRCTN 74612906)

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