**Forced-air warming linked to periprosthetic total joint replacement infections.**

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**Background:** It is well-established that a single airborne bacterium can cause a periprosthetic joint infection (PJI) following total joint replacement surgery. Several studies have shown that the waste heat from forced-air warming (FAW) escapes near the floor and warms the contaminated air resident near the floor, causing it to form into convection currents that rise up into the sterile field above the surgical table.

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**Methods:** To investigate whether the rising contaminates from the waste FAW heat are linked to PJIs, we retrospectively collected joint implant infection data from three hospitals. We compared PJI rates during a period of forced-air warming to PJI rates during a period of air-free conductive fabric warming. Surgical and antibiotic protocols were held constant.

**Results:** The pooled multicenter data showed a decreased PJI rate of 75% following the discontinuation of FAW and a switch to air-free CFW (n=2,034; p=0.002).

**Conclusions:** The 75% reduction in joint implant infections noted in this observational study when FAW was discontinued and CFW implemented, strongly suggests that there is a link between the waste FAW heat and PJIs. These results also suggest that FAW should not be used in joint replacement surgery until it is proven to be safe.

It is now generally recognized that in the absence of active warming, most surgical patients will become clinically hypothermic.1,2 It has also been shown that mild perioperative hypothermia is detrimental to a variety of outcomes including: increased soft tissue infections (SSI),3,4 increased bleeding and transfusion requirements,5-7 increased risk of morbid cardiac events,8 prolonged recovery and prolonged hospital stays.3,7,9 As a result of these studies, forced-air warming (FAW) has become a Standard of Care for most surgical procedures.10

In 2009, Augustine et al. reported the results of their laboratory research showing that the waste air from FAW is not simply benign waste air but is in fact 1000 watts of waste *heat*. The waste heat and air escapes from under the surgical drapes near the floor. Then the waste heat warms the contaminated air normally resident near the floor, causing it to form convection currents that rise along the sides of the surgical table, mobilizing the floor bacteria into the sterile surgical field above the patient.11

This initial research showing the rising waste FAW heat has since been corroborated by six peer-reviewed, published studies.12-17 One study by Legg et al. for example, showed that there are 2000 times more contaminating particles above the surgical site when FAW is used than with air-free, conductive fabric warming (CFW).12

It has been shown that the concentration of contaminates in the air of the sterile surgical field correlates positively with the risk of periprosthetic joint infections (PJI) during total joint replacement surgery.18-29 It is also known that in contrast to soft tissue SSIs which require an inoculum of more than 1 million bacteria,30 a single bacterium can cause a catastrophic PJI and that it is usually an airborne contaminate.21-23 Therefore, it is only logical to suspect that the contamination from the rising waste FAW heat could be increasing the risk of PJIs.

A large retrospective outcome study by McGovern et al*,* has linked the rising waste FAW heat to the majority of deep joint infections in total joint replacement surgery.13 The investigators reported a 74% reduction in periprosthetic joint infections when they discontinued the use of FAW and switched to air-free CFW warming. “[FAW] Patient warming ventilation disruption was associated with a significant increase in deep joint infections…”

Many clinicians want to see dramatic results like McGovern’s, corroborated by additional studies.

**Methods**

This study is designed to investigate periprosthetic joint infection (PJI) rates while using FAW (Bair Hugger®, 3M, St. Paul, MN or Mistral®, Stryker, Kalamazoo, MI) compared with air-free CFW (HotDog®, Augustine Temperature Management, Eden Prairie, MN). The measured outcome in each of these studies is periprosthetic joint infection (PJI). This multicenter retrospective outcome study consists of data reported by three hospitals.

Each hospital report shares a similar study design to the McGovern study. In each study, a baseline PJI rate is determined for the forced-air warming control group, over a one year period of time (t baseline). FAW is then discontinued and the hospital switches to air-free CFW warming. Any infections occurring during the first two months after the switch in warming technologies were disregarded. Given that PJIs do not necessarily occur in the immediate postoperative period, it would be impossible to know if an infection occurring during the “washout period,” came from the FAW or CFW time period. Starting with month three of the CFW period, the PJI rate is determined during the following 6-24 months of data collection (tstudy). The changes in PJI rates from tbaseline totstudy are then determined.

Only hospitals that could verify that no other significant changes were made to their surgical and antibiotic prophylaxis protocols during the study period qualify. No effort was made to standardize surgical protocols with the assumption that the averaging of the multicenter data would offset minor variations in protocols. No effort was made to control for demographic variables, with the assumption that the average patient population using a given hospital for total joint replacement surgery does not change appreciably from year to year.

Model selection and parameter significance tests were performed by comparing differences in model deviance to the expectation value under the χ2 distribution (likelihood ratio test). Statistical calculations were performed by a paid, independent statistician.

**Results**

As shown in Table 1, each of the three hospitals reported in this study show significant decreases in the PJI rates (34%, 81% and 100%) when FAW was discontinued in orthopedic surgery. In each case, the lower PJI rate was achieved using air-free CFW. The pooled multicenter data showed a decreased PJI rate of 75% following the discontinuation of FAW and a switch to air-free CFW (n=2,034; p=0.002).

Each hospital verified that no other significant changes were made to their surgical and antibiotic prophylaxis protocols during the study period. No effort was made to control for the unlikely possibility of year-to-year demographic variables within each hospital.

The three hospitals reported in this study were the first three that the authors contacted. No hospitals were omitted from the study due to poor infection results (“cherry picking”).

Table 1

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| --- | --- | --- | --- | --- |
|  | No. (%) Developing Infection | No. (%) Not Developing Infection | Odds Ratio (95% Confidence Interval) | P value |
| Center #1  Patient Warming Device  Conductive Fabric  Forced Air | 2 (0.3)  6 (1.5) | 675 (99.7)  382 (98.5) | 1.0  4.59 (1.06, 19.85) | 0.029a |
| Center #2  Patient Warming Device  Conductive Fabric  Forced Air | 0 (0.0)  4 (2.3) | 218 (100)  171 (97.7) | 1.0  11.47 (0.61, 214.43) | 0.031a |
| Center #3  Patient Warming Device  Conductive Fabric  Forced Air | 2 (1.0)  6 (1.6) | 192 (99.0)  376 (98.4) | 1.0  1.33 (0.31, 5.78) | 0.70a |
| Multicenter pooled results  Patient Warming Device  Conductive Fabric  Forced Air | 4 (0.4)  16 (1.7) | 1085 (99.6)  929 (98.3) | 1.0  4.28 (1.50, 12.19) | 0.002a |

Abbreviations: No., Number of Patients

aType III (deleted parameter) Likelihood Ratio χ2 Test with 0.5 added to each cell using Haldane correction for sparse observations

**Discussion**

This is a multicenter observational outcome study investigating the relationship between forced-air warming and periprosthetic joint infections (PJI) in hip and knee total joint replacement surgery. The data were collected retrospectively at three hospitals. The switch from forced-air warming (FAW) to air-free conductive fabric warming (CFW) is the only independent variable noted during the study period. Assuming that there were no other unreported significant changes in the surgical or antibiotic protocols during the study period, changes in the PJI rates can reasonably be attributed to the change in warming technology.

The pooled multicenter data from the three hospitals reported in this study showed a decreased PJI rate of 75% following the discontinuation of FAW and a switch to air-free CFW. This pooled result corroborates the findings of the McGovern study, which reported a 74% decrease in PJI rates when FAW was discontinued and CFW was initiated.13

The McGovern study13 has been criticized because the antibiotic protocol was changed half way through the FAW data collection period. Although antibiotics have never been shown to have a significant influence on periprosthetic joint infection (PJI) rates much less a 74% influence, critics have used the mid-study antibiotic change to dismiss the McGovern research.31

In order to answer this criticism, McGovern and his co-authors revisited the PJI infection data of their institution. The FAW patients who received the first antibiotic were dropped from the results. This left 677 patients with 22 PJIs in the FAW group receiving the second antibiotic (3.2% PJI rate). Then 14 more months of CFW patients were added for a total of 1097 CFW patients, which included 10 PJIs, all of whom received the second antibiotic (0.9% PJI rate). These new data show that the PJI rates decreased 72% when FAW was discontinued and CFW initiated (1774 patients, OR=3.55 (1.70, 7.44); p=0.0004). This 72% reduction compares favorably with the previously reported 74% reduction, indicating that the switch in antibiotics was not a significant variable. These over-lapping data sets have not been submitted for publication because of the prohibition against such submissions. Nonetheless, this author (PM) hopes that these additional data points will put the antibiotic criticism of the prior study to rest.

The idea that FAW could be causing periprosthetic joint infections while reducing soft tissue infections seems to be an oxymoron. However, this apparent contradiction is explained by the presence or absence of biofilm.32 Biofilm is a coating of exopolysaccharide material that protects the bacterium from antibodies and antibiotics, effectively allowing it to hibernate for up to one year before sprouting into a full infection.

Many bacteria can form biofilm coatings in the presence of implanted foreign materials but cannot form effective biofilm in soft tissue.32 The result is that the infectious process is fundamentally different in joint replacement surgery where a single bacterium can cause an infection, compared to soft tissue surgery where an inoculum of more than one million bacteria are usually required to cause an infection.21-23 Patients receiving implants, especially orthopedic implants, are especially susceptible to infection because bacteria can form biofilm on the implant.

The often-referenced studies showing FAW reducing surgical site infections were looking at *soft tissue* surgery (colon, breast and hernia), where effective biofilm cannot be formed.3,4 With soft tissue surgery, normothermia by any means of warming, seems to lower the infection rate. This is likely due to the fact that even heavily contaminated air cannot introduce the more than one million bacteria into a wound that are the required inoculum for a soft tissue infection. However, the results of this study indicate that FAW should not be used during total joint replacement surgery where a single bacterium is adequate to cause the PJI.21-23

In summary, six published studies have documented the contamination of the sterile surgical field by the rising waste FAW heat.12-17 Now there are two published outcome studies investigating the linkage between the rising waste FAW heat and deep joint infections (PJI) in total joint replacement surgery. Both of these studies show dramatic decreases in PJI rates when the use of FAW is discontinued. Discontinuing the use of FAW in this multicenter retrospective trial resulted in a reduction of the PJI rates of 75%, which is consistent with the 74% reduction reported by McGovern et al.13 In both of these studies, the lower infection rates were achieved while using air-free, conductive fabric warming (CFW). Based on these data it is only prudent that hospitals and clinicians avoid using FAW to warm patients during surgeries involving implanted materials, especially total joint replacements, until it is proven to be safe. Conductive fabric warming has been shown to be both safe and effective.

Given the mass tort litigation that is currently directed at the leading FAW manufacturer alleging that the waste FAW heat is causing PJIs,33 it seems unlikely that a randomized controlled trial (RCT) will ever be done. Therefore, retrospective outcome studies are the most robust clinical information that is likely to be available on this topic and additional studies should be encouraged.

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