Clinical White Paper

Reduced prosthetic joint infection rates with use of supplemental intraoperative air decontamination: A retrospective cohort study.

Background Periprosthetic joint infection (PJI) is a common complication after joint arthroplasty surgery with significant economic and human costs. Air contamination is a common but underappreciated source of bacteria etiologic to PJI.

Objective To determine whether supplemental intraoperative air decontamination reduced the rate of PJI in arthroplasty surgery.

Methods This is a retrospective observation study which analyzed the incidence of postoperative PJI following a consecutive series of 508 hip, knee and shoulder arthroplasty operations performed at a single institution between the dates of January 2016 and August 2017. Patients with surgeries between January 2016 and February 2017 received standard institutional surgical site infection measures, including antibiotic prophylaxis. Patients between March 2016 and August 2017 underwent an identical protocol with the addition of supplemental intraoperative air decontamination. There we no significant differences in the groups regarding age, BMI, diabetes diagnosis, smoking status, length of surgery, or revision status.

Results A total of five cases met the criteria for PJI (1.0%). All five cases were recorded during the study period when standard air treatment was used. No further cases of PJI were observed after the institution of the supplemental air decontamination. This was statistically significant overall ($p < 0.045$).

Conclusions Although PJI etiology is multifactorial in nature, this study found that the use of intraoperative air decontamination significantly reduced overall rates of PJI.

Approximately 1.2 million arthroplasties are performed in the United States each year and this number is anticipated to increase in part because of aging of the U.S. population, exceeding 3.8 million annually by the year 2030.[1] Documented rates of periprosthetic joint infection (PJI) range from 2.0-2.4%. The general estimate for the cost of a PJI in the United States is approximately $100,000. In addition, multiple studies have documented that PJI is associated with a mortality rate between 2% and 7%.[2,3] It has been suggested that in selective patients the 5-year survival rate with a PJI is worse than with many cancers.[4] Using current metrics, the projected (total) cost burden associated with PJI in the United States will approach $1.6 billion by the year 2020.[4]

Over the last two decades several peer-reviewed publications have shown evidence that airborne microbial populations play a significant role in the etiology of surgical site infection (SSI), especially in procedures involving implantable biomedical devices, such as prosthetic joints. Surgical procedures involving an implant are at significant risk after intraoperative contamination from even a minimal

microbial inoculum.[5,6] The air within an OR can spread airborne particles, posing a potential risk for postoperative infection. These airborne particles include dust, textile fibers, skin scales, and respiratory aerosols, carrying viable microorganisms (including *Staphylococcus aureus*) originating from the surgical team members and patient into the surrounding air. These particles have been shown to settle onto surfaces including the surgical wound and instruments.[7-13] A study supporting this assertion documented the recovery of the same molecular strains of coagulase-negative staphylococci and *S aureus* recovered from OR air samples, originating from nasopharyngeal shedding by members of the surgical team during the same surgical cases.[14] Dalstrom et al documented using a standard culture technique a time-dependent contamination of opened sterile OR trays, and found that "Culture positivity correlated directly with the duration of open exposure of the uncovered operating-room trays." [15]

Recently, the HEPA-Ultraviolet Air Recirculation System (HUAIRS) has been introduced which provides supplemental air decontamination within the OR. Designed for use during surgical procedures, the mobile unit removes bacterial contamination in the peripheral segments of the operating room, near the vulnerable surgical trays described by Dalstrom. The unit delivers 450 cubic feet (12.7 m^3) per minute of non-turbulent ultraclean air. The efficacy of this innovative system has been recently evaluated for reducing airborne microorganisms present within active operating rooms. The system incorporates C-band UV light focused on a photolytic chamber filled with cylindrical silicate quartz segments to decrease bacteria counts in the airstream. In the study, an air sampling impactor and agar media plates were placed in multiple locations in the OR and used to measure the number of colony forming units (CFU) per cubic meter of bacteria in the air before and after use of the system. From the cultured samples obtained, there was a 53.4% (p = .0163) reduction in CFU count overall.[16]

In this clinical study, The HUAIRS system was utilized in a controlled single center retrospective review of 508 consecutive patients over a two year period to determine if supplemental air decontamination was associated with reduced rates of PJI.

Methods

Figure 1. HUAIRS unit, in operating room.

This is a retrospective observation study which analyzed the incidence of postoperative PJI following a consecutive series of 508 hip, knee and shoulder arthroplasty operations performed at a single institution between the dates of January 2016 and August 2017. Patients with surgeries between January 2016 and February 2017 received standard institutional surgical site infection prevention measures, including antibiotic prophylaxis. Patients between March 2016 and August 2017 underwent an identical protocol with the addition of supplemental intraoperative air decontamination (Figure 1), using the HUAIRS system (Aerobiotix Illuvia ®, West Carrollton, OH). There were no significant differences in the groups regarding age, BMI, diabetes diagnosis, smoking status, length of surgery, or revision status. The study was performed at Medical Center at Elizabeth Place, a community acute care hospital located in Dayton, Ohio USA. The operating rooms used for the study were approximately 500 square feet (46.5 m^2), and used standard vertical turbulent (non-laminar) flow arrays with

20 air exchanges per hour (ACH) and positive pressure. Statistical analysis was performed using a Fisher Exact Probability Test, with an acceptance criteria of <0.05.

Results

There were a total of 508 consecutive patients who underwent joint arthroplasty procedures at a single center with a single surgeon between January 2016 and August 2017 (Table 1). Four months of follow up data was obtained through review of electronic medical records through the two year study period ending December 2017. The control group consisted of 275 patients and the experimental group consisted of 233 patients. The patients underwent, in descending order of frequency, primary knee replacement (n=223), primary hip replacement (n=134), revision knee replacement (n=54), bilateral primary knee replacement (n=39), primary shoulder replacement (n=24), revision hip replacement (n=18), incision and drainage of total joint with revision (n=7), and open reduction internal fixation of fracture with joint replacement revision shoulder replacement (n=4) and bilateral primary hip replacement (n=3).

	Control Goup (n=275)		ABX Group (n=233)	
Male	98 (35.6%)		78 (33.5%)	
Mean age	62.7		63.1	
Mean BMI	33.4		33.2	
Revision	42 (15.3%)		40 (17.1%)	
DM dx	58 (21.1%)		61 (26.2%)	
Smoker	48 (17.5%)		36 (15.4%)	
Mean OR time	63.5		60.4	
Procedures		PJI		PJI
Primary hip	65 (23.6%)	3	69 (29.6%)	0
Primary knee	132 (48%)	0	91 (39%)	0
Primary Shoulder	5 (1.8%)	0	19 (8.1%)	0
Revision hip	9 (3.3%)	1	9 (3.9%)	0
Revision knee	24 (8.7%)	1	30 (12.9%)	0
Revision shoulder	1 (0.3%)	0	0 (0%)	0
Bilateral hip	3 (1.1%)	0	0 (0%)	0
Bilateral knee	26 (9.5%)	0	13 (5.6%)	0
I&D	7 (2.5%)	0	1 (0.4%)	0
ORIF	3 (1.1%)	0	1 (0.4%)	0
16 wk Infection Rate		5		0
		5/275 1.8%		0/233 0%

Table 1. Results of retrospective review of 508 consecutive patients with control group (n=275) and supplemental air (ABX) group (n=233)

Between the control and experimental groups, there was no significant difference gender, mean age, BMI, revision status, diabetes diagnosis, smoking status, or operative time. There was a trend towards more primary knee procedures in the control group (48% vs. 39%) and primary shoulder procedures in the experimental group (1.8% vs 8.1%). However, none of the reported infections occurred in these groups, so the impact on the results should be negligible.

Five PJIs occurred during the study period. These consisted of primary hip (n=3), revision hip (n=1) and revision knee (n=1). All PJIs occurred in the control group prior to placement of the supplemental air system. There were no PJIs in the experimental group during the study period. The total infection rate in the control group was 1.8%, versus 0% for the experimental group (p=0.045).

Discussion

Microbial contamination of air in the OR is an underappreciated factor in the etiology of PJIs. Traditional infection control strategies such as limiting OR traffic has had a marginal impact in reducing intraoperative microbial aerosols or the risk of implant-associated infections. Even with compliant room engineering

standards, there are numerous reports and studies linking airborne contamination directly to device-related procedures and specifically, orthopedic SSIs[17-20]. Current engineering controls and practice requirements for limiting traffic during cases have thus far resulted in failure to reduce the risk of microbial aerosols or intraoperative contamination of implantable devices during arthroplasty surgery. Future consideration should be given to institutional investment in innovative air purification technologies as an adjunctive strategy to enhance current engineering controls, in an effort to reduce the risk of PJIs.

In the practice of orthopedic joint replacement, multiple strategies have been used or proposed to reduce the risk of PJI. In this controlled study, supplemental air decontamination uniting the HUAIRS device has demonstrated a statistically significant reduction in PJI rates when used during joint arthroplasty procedures. Ongoing research shall continue to further define this outcome.

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