Operating room ventilation systems and microbial air contamination in total joint replacement surgery: results of the GISIO-ISChIA study

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Running Head: Air microbial contamination in total joint replacement surgery.

Key Words: Air microbial contamination, Total joint replacement, Operating room, HVAC

Structured Abstract

Objective. To evaluate microbial contamination in operating rooms (ORs) during hip and knee replacement surgery and compare the findings with expected values based on the type of ventilation system installed.

Summary Background Data. Recent studies have shown a higher rate of Surgical Site Infections (SSIs) in hip prosthesis implantation using unidirectional airflow ventilation (UAF) compared to turbulent ventilation. However, those studies did not measure the air microbial quality of ORs, and simply assumed it to be consistent with the existing Heating, Ventilation and Air Conditioning (HVAC) system.

Methods. Microbial air samplings were performed in the patient area of 28 ORs supplied with unidirectional, turbulent and mixed airflow ventilation, both at rest and during surgical activity. Samples were collected using passive sampling methods and the Index of Microbial Air contamination (IMA) was determined. In some of the ORs active sampling was also performed to measure colony forming units per cubic metre (cfu/m^3). The average number of persons in ORs and the number of door openings during the exposure of the settle plates were also recorded.

Results. 1228 elective hip (60.1%) and knee (39.9%) prosthesis procedures were included in the study. A total of 43.0% of procedures were performed in UAF ORs (U-OR), 8.6% in mixed airflow ORs (M-OR), 20% in turbulent airflow ORs (T-OR), and 28.5% in turbulent ORs with the surgical team wearing a Turbo Helmet Steri Shield (TH-OR). 58.9% of passive samplings performed in U-ORs and 87.6% of those in M-ORs yielded air microbial contamination values >2 IMA. The highest compliance (60%) with IMA recommended values for ultraclean ORs was observed in TH-ORs. 8.6% of IMA values recorded in T-ORs were ≤2 IMA.

Conclusions Our findings undermine the idea that unidirectional systems always provide acceptable bacterial counts. Furthermore, the number of door openings and the number of persons inside the OT during surgical activity can be regarded as a positive predictor of higher bacterial counts.

INTRODUCTION

Since the Medical Research Council (MRC) study demonstrated an association between air microbial contamination and deep surgical site infection (SSI) in hip and knee arthroprosthesis (1), the recommendation is to perform total joint replacement surgery in ultraclean operating rooms (ORs) with maximum air microbial contamination values of 10 colony forming units (cfu/m^3) when measured by active sampling (2-5), and 350 cfu/m^2/h (6) or 2 cfu/plate 9 cm Ø/h (7) when measured by passive sampling. However, in 2008 a German retrospective study (8) unexpectedly showed significantly higher SSI rates after hip prosthesis implantation when using unidirectional airflow ventilation (UAF) compared to turbulent ventilation. Nevertheless, this study did not evaluate the air microbial quality of ORs, assuming it to be consistent with the room's Heating, Ventilation and Air Conditioning (HVAC) system, since UAF ORs in Germany are subject to periodic controls by health authorities. A subsequent meta-analysis demonstrated that the presence of UAF was a risk factor for developing severe SSIs in hip and knee prosthesis (9). None of the studies included in the meta-analysis contained an assessement of air microbial contamination.

Since it is not correct to assume that an ultraclean air system will always provide low bacterial air counts, even when functioning correctly, we measured the microbial contamination in ultraclean ORs where hip and knee replacement were performed, compared the findings with the expected values and checked the compliance with recommended air quality standards (4,7). Microbial contamination was also measured in turbulent ORs that were used for implant prosthesis. Two variables were also investigated for a possible association with microbial air contamination: the number of persons in an OT during surgical activity and the number of door openings.

This study is part of the multicentre ISChIA (*Infezioni del Sito Chirurgico in Interventi di Artroprotesi*) – GISIO-SItI (Italian Study Group of Hospital Hygiene of the Italian Society of Hygiene, Preventive Medicine and Public Health) project, which relies on a multiple active surveillance of SSIs, antibiotic prophylaxis and OT air microbial contamination.

METHODS

The study was performed between March 2010 and February 2011 in 14 hospitals (7 in the North, 3 in the Center and 4 in the South/Islands of Italy). Hospitals were invited to join the ISChIA project and participation was voluntary. Accepting Operative Units (OUs) were invited to attend a meeting to involve the key stakeholders as representatives of the final users of the project (hospital managers, epidemiologists, surgeons, nurses, microbiologists). Participation was voluntary.

Microbial air sampling was performed in the patient area of ORs, once at rest, before the surgical activity began, and then during the surgical procedure, starting at the time of the surgical incision. Samples were collected using passive sampling methods and, where an air sampler was available, active method. Settle plates (9-cm diameter) were left open to the air according to the 1/1/1 scheme (for 1 hour, 1 m from the floor, about 1 m from any obstacles) to determine the Index of Microbial Air contamination (IMA) (10). Active sampling was performed using the Surface Air System Sampler (SAS, International Pbi, Milan, Italy), with 55-mm diameter RODAC plates, a flow rate of 180 L/min, and the suction volume set to 1000 L (five consecutive samplings of 200 L each during the 1-hour exposure of the settle plate). The active sampler was positioned at a height of 1 m beside the settle plate. The number of colony-forming units (cfu) was adjusted using the conversion table provided by the manufacturer, and the results were expressed as cfu/m^3. Tryptic soy agar was used for the total aerobic bacterial count, with incubation at 36°±1°C for 48 h.

For surgical procedures lasting less than one hour, the air sampling was stopped when the first gauze was placed on the wound. Values measured in the sampling time were proportioned to one hour.

The H+ Swiss guidelines for IMA (7) and the HTM 0301 for cfu/m^3 (4) were used to interpret the results.

The average number of persons in the OR and the number of door openings during the 1-hour exposure of the settle plates were also recorded.

Statistical analyses

Statistical analyses were performed using the SPSS 14.0 statistical package (SPSS Inc., Chicago, IL, USA). Descriptive analyses consisted essentially of frequency tables. Continuous variables were described by mean, standard deviation (SD), median and range.

Categorical variables were compared using the chi-squared test, and continuous variables by Student's t-test. Correlation between variables was evaluated using Spearman's correlation coefficient. A $p<0.05$ was considered significant.

RESULTS

A total of 28 ORs were included: 16 (57.1%) supplied with UAF, 6 (21.4%) with turbulent airflow ventilation, and 6 (21.4%) with mixed air flow ventilation.

The OR size ranged from 90 m^3 to 180 m^3 (mean: 116 m^3±20.4 m^3). The mean number of air changes per hour was 18.0 (± 4.5). The HVAC systems were equipped with particulate air filters with an efficiency ≥ 99.97%.

A total of 1228 elective hip (60.1%) and knee (39.9%) prosthesis procedures were included in the study. 43.0% of procedures were performed in unidirectional airflow ORs (U-OR), 8.6% in mixed airflow ORs (M-OR), 20% in turbulent airflow ORs (T-OR), and 28.5% in turbulent ORs with the surgical team wearing a Turbo Helmet Steri Shield (Stryker) (TH-OR).

In empty U-ORs a value of 0 IMA was recorded in all passive samplings; a median value of 3 cfu/m^3 (range 0-5) was recorded with active sampling. A median IMA value of 0 was recorded in M-ORs, with a maximum value of 8 IMA, while the only active sampling gave a value of 18 cfu/m^3. In T-ORs median values of 1 IMA and 11.75 cfu/m^3 were recorded, with maximum values of 4 IMA and 23.5 cfu/m^3.

Table 1 shows the descriptive statistics of air microbial contamination during surgical activity. Median IMA values ranged from 3 IMA, observed in U-ORs and TH-ORs, to 9 IMA, recorded in

M-ORs. Cfu/m^3 values ranged from 10 cfu/m^3 in U-ORs to 277 cfu/m^3 in M-ORs. The minimum value observed by passive sampling was 0 IMA and was recorded at least once in every OR type. The minimum value observed by active sampling was also 0 cfu/m^3 and was recorded in U-ORs and T-ORs, but never in M-ORs. In U-ORs the maximum values were 64 IMA and 290 cfu/m^3, while in M-ORs maximums were 94 IMA and 466 cfu/m^3.

Mean air microbial values were significantly lower in U-ORs compared to M-ORs and T-ORs ($p<0.001$), both for IMA and cfu/m^3, even when considering hip and knee prosthesis separately. The lowest IMA mean value (4.3 IMA) was observed in TH-ORs and was significantly lower than U-ORs (5.4 IMA; $p<0.001$).

Table 2 shows IMA values by OR and type of HVAC system. A high variability in microbial air contamination was observed among the ORs supplied with the same type of HVAC and among operations performed in the same OR. M-ORs showed the highest level of variability (median values between 5.5 and 40 IMA). T-OR n. 23 showed the widest range (153 IMA).

Most of the air samplings collected in UAF ORs showed a microbial contamination higher than the recommended threshold values of 2 IMA (7) and 10 cfu/m^3 (4). 58.9% (311/528) of passive samplings and 46.4% (17/252) of active samplings performed in U-ORs yielded air microbial contamination values higher than 2 IMA and 10 cfu/m^3 respectively (4,7). A total of 87.6% of IMA values recorded in M-ORs exceeded the recommended values (4,7). The best compliance (210/350) with IMA recommended values for hip and knee replacement was recorded in TH-ORs (60.0%). 8.6% of IMA values recorded in T-ORs were ≤2 IMA. In the majority of ORs (13/15 U-OR; 3/6 M-OR; 3/6 T-OR; 2/2 TH-OR) a microbial contamination value compliant with the recommended values for hip and knee replacement was recorded at least once (3,4,7).

Door openings median values during the sampling time ranged from 3 for TH-ORs to 50.5 for T-ORs. In U-ORs a maximum value of 100 was reached, while a value of 173 was recorded in a T-OR (Table 3). A significantly higher mean number of door openings was observed during hip prosthesis compared with knee prosthesis (28.4 *vs* 15.1) ($p<0.001$).

During the surgical activity the number of persons in ORs ranged from 4 in TH-ORs, to 19 in U-ORs. The lowest median value (5 persons) was observed in TH-ORs, while the highest (10 persons) in M-ORs (Table 3). A significantly higher mean number of people was recorded during hip prosthesis compared with knee prosthesis (7.8 *vs* 6.6) ($p<0.001$).

IMA values positively correlated both with the number of persons in ORs (Spearman's correlation coefficient = 0.377; $p<0.001$) and with the number of door openings (Spearman's correlation coefficient = 0.345; $p<0.001$).

DISCUSSION

Our study, based on a large number of ORs in different Italian regions, reveals that during surgical activity a high proportion of ORs showed high microbial air contamination values despite UAF, and exceeded the expected values for this kind of technology. Even worst was the situation for mixed ORs, where air microbial contamination values where higher than in turbulent ORs.

The air samplings performed in ORs at rest show the efficiency of UAF, even though in one OR supplied with a mixed ventilation system the air was contaminated already before the surgical activity had begun.

Our findings support the idea that it is not correct to assume that a unidirectional system would always provide acceptable bacterial counts (4,7), even when properly engineered and monitored, and correctly functioning. Therefore, only procedures in which the air quality complies with the achievable standard for this type of airflow should be considered in order to evaluate the SSI-reducing efficacy of UAF systems.

Assadian et al (11) had already criticized the assumption by Brandt et al (8) that OR ventilation systems installed in enrolled hospitals would be effective as a result of UAFs routine control by health authorities. Afterward, a study (12) was conducted to assess the impact of UAF on bacterial counts. It included a limited number of surgical procedures performed in UAF ORs (21 large

laminar air flow and 19 small laminar air flow): the results indicated that just having a UAF system in place will not automatically provide bacteria-free conditions in the surgical area.

The installation and management of ultraclean ORs is very expensive (13). It is therefore an ethical duty to ensure that cleanliness levels match the ventilation system and the economic investment is not undermined. This statement is also valid where turbulent ventilation systems are in place.

As for T-ORs, it came as a surprise that 8.6% of them showed values ≤ 2 IMA and their median microbial contamination was 7 IMA, the same value observed in a recent study performed on T-ORs at the University Hospital in Parma (14). With reference to EC GMP (15), 7 IMA would correspond to less than 100 cfu/m^3. In light of this, the recommended value for working T-ORs (4), dating back to the 1980s (16), appears too high for modern T-ORs and could lead to underestimate the risk.

We also included TH-ORs, which were supplied with turbulent airflow with the surgical team wearing a Turbo Helmet Shield. In these ORs the lowest number of door openings and persons were observed, and the same air quality was achieved as with UAF.

Our study, including a high number of surgical procedures, was a further confirmation that the frequency of door openings and the number of persons inside an OR during surgical activity can be regarded as a positive predictor of increased bacterial counts. The Centers for Disease Control and Prevention (CDC) guidelines for prevention of SSIs (5) recommend that doors should be kept closed except as needed for passage of equipment, personnel and the patient; the number of personnel entering the ORs should be limited to necessary personnel.

The high degree of variability in microbial air contamination observed in the different ORs with similar forms of ventilation, with very low microbial air contamination levels in some surgical operations, suggests that it is possible to achieve a strict control of the factors affecting the quality of air.

The high number of ORs with contamination values exceeding recommended thresholds needs to be commented. These values were identified in the course of a specific project that exposed a situation

that otherwise might not have been brought to light. As already observed in our previous study (17), we believe that it is essential to increase health workers' awareness on the risks deriving from incorrect behaviors. Moreover, people responsible for infection control should promote periodic audits to ensure that ORs are properly managed (e.g. through microbiological monitoring) and that procedures are followed correctly.

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