

Operating room environment and surgical site infections in arthroplasty procedures

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Keywords

Operating room • surgical site infection • surveillance • arthroplasty procedures

Summary

Background. *The rate of surgical site infections (SSI) is strongly influenced by operating room quality, which is determined by the structural features of the facility and its systems and by the management and behavior of healthcare workers. The aim of the present study was to assess microbial contamination in the operating room during hip- and knee-replacement procedures, the behavior of operating room staff and the incidence of SSI through post-discharge surveillance.*

Methods. *Microbial contamination was evaluated by active and passive sampling at rest and in operating conditions. Organizational and behavioral characteristics were collected through observational assessment. The incidence of SSI was evaluated in 255 patients, and follow-up examinations were carried out 30 and 365 days after the procedure.*

Results. *The mean values of the airborne and sedimenting microbial loads were 12.90 CFU/m³ and 0.02 CFU/cm²/h, respectively. With regard to outcome, the infection rate proved to be 0.89% and was associated with knee-replacement procedures. The microorganism responsible for this superficial infection was *Staphylococcus aureus*.*

Conclusions. *Clinical outcomes proved to be satisfactory, owing to the limited microbial load (in both at-rest and operating conditions), the appropriate behavior of the staff, compliance with the guidelines on preoperative antibiotic prophylaxis, and efficient management of the ventilation system.*

Introduction

The rate of surgical wound infections is strongly influenced by operating room quality, which is determined by the structural features of the facility and its systems and by the management and behavior of healthcare workers [1, 2]. It has been suggested that the main sources of contamination, especially in clean surgical procedures, are the patient's skin and airborne particles from operating room personnel [2, 3]. In this regard, a study conducted by the Medical Research Council showed a correlation between microbial air contamination and the incidence of surgical site infections (SSI) in prosthetic joint surgery [4]. Hip- and knee-replacement operations are common procedures and are performed to improve quality of life in individuals with end-stage joint degeneration. However, SSI can give rise to very severe complications which nullify the efficacy of the procedure. Infection rates after primary total knee arthroplasty reported in the literature range from 0.39% to 2.5%; total hip infection rates are approximately 0.2%-2.2% for primary procedures [5]. In addition to the devastating consequences for the patient, such infections have an enormous economic impact on the treating hospital, since they substantially prolong hospitalization and increase costs [6]. Approximately 12,000 joint infections occur annually in the United States, with an estimated cost of \$600 million a year [5].

A number of host factors increase the risk of treatment failure, including male sex, advanced age, rheumatoid arthritis, an American Society of Anesthesiologists (ASA) risk score > 2, diabetes mellitus, morbid obesity, immuno-compromission and previous revision arthroplasty [7, 8]. Other factors related to the risk of infection concern the pathogen involved, medical therapy and surgical techniques [9-11]. The aim of the present study was to assess microbial contamination in the operating room during hip- and knee-replacement procedures, the behavior of staff and the incidence of SSI through post-discharge surveillance.

Materials and methods

The study started on 1st October 2014 and was concluded on 31st January 2016. The study evaluated microbial contamination in the operating room during 255 operations (hip- and knee-replacement surgery; ICD9-CM 81.51 and 81.54), and microbial contamination in at-rest conditions at the beginning of each operating session.

The operating room is devoted exclusively to prosthetic surgery and situated within a hospital facility in the north-west of Italy.

The incidence of SSI was evaluated in the patients, and follow-up examinations were carried out 30 and 365

days after the procedure. For each of the 255 procedures monitored, the following patient characteristics were recorded: age, sex, ASA score, type of prosthesis implanted and antibiotic therapy. With regard to the surgical teams ($n = 2$) involved in the procedures, several behavioral features were monitored.

FEATURES OF THE OPERATING ROOM AND THE VENTILATION SYSTEM

The design of the operating suite provides adequate space for reception, anesthesia, surgery, recovery, and observation of patients. The operating room has a turbulent-flow ventilation system equipped with High Efficiency Particulate Air filter (HEPA) filters, which are 99.97% efficient in removing airborne particles of 0.3 μm or larger; the filters are replaced every 6 months and maintenance work on the system is carried out periodically in accordance with a predetermined schedule. The operating room is under positive pressure in relation to the adjacent rooms (≥ 5 Pa).

ENVIRONMENTAL FEATURES

Airborne bacterial contamination in the center of the room in operating conditions

To determine the total airborne bacterial load, we used an SAS SUPER 100 (PBI International[®]) impactor equipped with RODAC plates ($\varnothing = 55$ mm). In order to sample the air in the center of the room, the instrument was positioned in the immediate vicinity of the operating table, at a height of 1.5 m. During each procedure, a 1000 L volume of air was aspirated by means of a multi-aspiration modality; the impactor was switched on by remote control just as the skin was incised, and was switched off on completion of suturing. In addition, passive air sampling was carried out during each procedure. Settle plates (9 cm in diameter) were left open to the air according to the 1/1/1 scheme (for 1 h, 1 m from the floor, about 1 m from any obstacles) to determine the index of microbial air contamination (IMA).

Airborne bacterial contamination in at-rest conditions

In order to assess the efficacy of the ventilation system used in the operating room, contamination of the air emerging from the inlet ports was evaluated by means of an SAS SUPER 100 (PBI International[®]) impactor equipped with RODAC plates ($\varnothing = 55$ mm) before the beginning of each session of operations. A total volume of 1000 L of air was aspirated at each inlet port.

In order to sample the air in the center of the room in at-rest conditions, we used an SAS SUPER 100 (PBI International[®]) impactor equipped with RODAC plates ($\varnothing = 55$ mm). The instrument was positioned in the center of the operating room, at a height of 1.5 m. A total volume of 1000 L of air was aspirated.

To measure the total airborne bacterial count, γ -irradiated tryptic soy agar (TSA) (Biotest Italia s.r.l.) was used. Plates were incubated at 37°C for 48 h before the total bacterial count was measured [12]. Microbiological results were expressed as CFU (colony forming units)/

m^3 and CFU/ m^2/h for active samplers and settle plates, respectively.

Surface bacterial contamination

Microbial measurements of surfaces were conducted with RODAC contact plates ($\varnothing = 55$ mm) containing Columbia blood agar culture medium (Biotest Italia s.r.l.). Sampling was carried out after sanitization of the operating room as indicated by ISPEL and by the French guidelines [13, 14].

Plates were incubated at 37°C for 48 h before the total aerobic bacterial count was measured. Microbiological results are expressed as CFU (Colony Forming Units)/plates.

Microclimatic parameters

With regard to the detection of microclimatic parameters (temperature; relative humidity; air speed) we used a portable microclimatic BABUC (LSI[®]) device equipped with psychrometric probes, a black-globe thermometer and a hot-wire anemometer; the device was positioned in the vicinity of the operating table. A sufficient time was allowed for the probes to acclimatize; the instrument then recorded microclimatic parameters for the entire duration of the surgical activity.

The comfort indexes Predicted Mean Vote (PMV) and Predicted Percentage of Dissatisfied (PPD) were calculated by means of Bruel & Kjaer software by entering the data of M (metabolism), Icl (clothing), ETA (mechanical efficiency) relative to the surgical staff and environmental parameters (temperature, relative humidity, air speed, etc.).

Number of efficacious air exchanges

The efficacy of the air-conditioning system was assessed in at-rest conditions by measuring the decay of the concentration of tracer gas by means of a portable GA301 meter (Eco-CONTROL, Milan) connected to a computer for the collection and analysis of data, as described by Sartini et al. [15].

ORGANIZATIONAL AND BEHAVIORAL CHARACTERISTICS

During each operation, we collected detailed information on the surgical procedure, including the duration of the procedure (skin-skin), the number of staff members in the room at the time of the incision, and the door-opening rate. For each surgical team, we also recorded the adherence to dress regulations and preoperative antibiotic prophylaxis protocol, behavioral aspects, etc.

FOLLOW-UP

In order to detect any surgical site infections, surveillance examinations were carried out 30 and 365 days post-operatively. The extended period of ascertainment of nosocomial SSI of up to 1 year was set in accordance with the Centers for Disease Control and Prevention (CDC) for operative procedures such as replacement of the hip and the knee by artificial joint prostheses [16]. The first control (day 30) involved an outpatient examination; subsequently, telephone interviews were conducted

by trained healthcare personnel, who utilized a standard data-collection form that had already been validated in previous studies on SSI [17]. Patients had been informed of the postoperative epidemiological surveillance that they were to undergo 365 days post-operatively.

SSI detection was carried out in accordance with the definition laid down by the National Nosocomial Infections Surveillance (NNIS), which has also been adopted by Hospitals in Europe Link for Infection Control through Surveillance (HELICS) [18]. SSI are defined as infections occurring within 30 days after a surgical operation (or within one year if an implant is left in place after the procedure) and affecting either the incision or deep tissue at the operation site [19].

STATISTICAL METHODS

Statistical analysis was carried out by means of the STATA SE14™ software (StataCorp LP - USA). As the data did not display a normal distribution, every possible numerical transformation of the data was evaluated. As none of these was able to reduce the effect of skewness, the data were analyzed by means of non-parametric tests. The results were analyzed in terms of descriptive statistics, and the relationships between data were examined by means of the non-parametric Mann-Whitney-Wilcoxon ranksum test and Pearson's Chi-square test.

ETHICS STATEMENT

As the study was carried out as part of routine control tests that we conduct in the operating rooms of the hospital, no ethics approval was needed. As is the case of all studies conducted in the hospital environment, the

General Management of the hospital approved the study protocol. The General Management is responsible for ensuring the ethical aspects of all activities of the hospital. Furthermore, the entire study was organized in accordance with a protocol agreed upon with the operating room teams. On entering the hospital, all patients sign an informed consent form regarding treatments in the hospital and the conditions of those treatments. Finally, the research was carried out in full respect of the Italian law on the privacy (Legislative Decree N. 196 of 30th June 2003).

Results

Of the 255 procedures monitored, 49.0% involved total hip replacement (ICD9-CM:81.51) and 51.0% total knee replacement (ICD9-CM:81.54). Regarding the duration of total hip replacement and total knee replacement procedures, the median values were 35 (range 17-126) and 39 minutes (range 19-102), respectively; the difference between these values did not prove statistically significant ($z = -1.28$, $p = 0.20$). Concerning the characteristics of the prostheses implanted, 80% were metal-polyethylene, 7.5% metal-metal, 5.1% ceramic-ceramic, 3.5% metal-ceramic, 3.1% ceramic-polyethylene, 0.39% ceramic-metal and 0.39% Titanium. In 38.4% of cases, the prosthesis was fixed by means of cement, and in 86.7% tobramycin was added. For what concerns the environmental features of the operating room, the values of the airborne and sedimenting bacterial loads and microclimate parameters are reported in Table I.

Tab. I. Mean values, standard deviation and range of airborne and sedimenting bacterial load (during procedures), of microclimate parameters and microclimate indexes in the operating room.

	Procedures	Mean±SD	Min-Max
Airborne bacterial load, center of room (CFU/m ³)	All procedures	12.90±17.00	0-85
	Total hip replacement	12.18±12.97	0-80
	Total knee replacement	13.58±20.16	0-85
Sedimenting bacterial load (CFU/cm ² /h)	All procedures	0.02±0.03	0-0.13
	Total hip replacement	0.02±0.03	0-0.13
	Total knee replacement	0.02±0.02	0-0.09
Microclimate Environmental parameters	All procedures	18.94±1.16* 50.65±14.37^ 0.06±0.02°	16.38-20.45* 21.3-73.6^ 0.03-0.11°
	Total hip replacement	18.48±1.60* 45.72±17.93^ 0.06±0.01°	16.38-20.11* 21.3-62.2^ 0.05-0.07°
	Total knee replacement	19.24±0.81* 53.93±12.11^ 0.07±0.03°	18.19-20.45* 36.4-73.6^ 0.03-0.11°
Microclimate Indexes	All procedures	0.21±0.13** 6.3±1.5°°	0.03-0.44** 5-9°°
	Total hip replacement	0.20±0.08** 5.7±0.5°°	0.07-0.25** 5-6°°
	Total knee replacement	0.22±0.17** 6.7±1.9°°	0.03-0.44** 5-9°°

*Air temperature (°C); ^relative humidity (%); °air speed (m/s); **PMV surgical staff, °°PPD surgical staff (%)

As can be seen, the highest mean values of the airborne bacterial load (13.6 ± 20.2 CFU/m³) were recorded during total knee replacement procedures, while the mean values recorded during total hip replacement proved to be lower (12.2 ± 13.0 CFU/m³). In 63.01% of total hip replacement procedures, mean values of airborne bacterial load below 10 CFU/m³ were recorded; in total knee replacement procedures, the corresponding percentage was 73.39%.

The mean values of the sedimenting bacterial load did not differ between the two types of procedure. The surface bacterial load was always 0 CFU/plate.

With regard to microclimatic parameters, considering the total number of procedures, the mean values of air temperature, relative humidity and air velocity were: $18.94 \pm 1.16^\circ\text{C}$; $50.65 \pm 14.37\%$ and 0.06 ± 0.02 m/s, respectively. No statistically significant difference emerged between the two types of procedures ($p > 0.05$). With regard to the characteristics of the air-conditioning system, 19 efficacious air exchanges were carried out per hour.

On visual inspection carried out at the beginning of each surgical session, the overhead light and the grills of the inlet ports of the air-conditioning system were free from visible dust. For all operating sessions the microbial load of the airflow through the inlet ports and in the air (at-rest conditions) proved to be <1 CFU/m³ and 4 ± 2 CFU/m³, respectively.

Concerning the organizational and behavioral features of the staff during the procedures, surgeons wore highly effective isolation helmet systems and the instrument-keeper wore headwear and a semi-integral mask; anesthesiologists and circulating nurses wore surgical masks and hair covering. The surgical technique utilized in all the procedures monitored involved the use of the ultrasonic scalpel.

The doors communicating with the rooms adjacent to the operating room were kept closed; the door-opening rate was 0.24 times per minute. The mean number of persons present in the operating room was 5 ± 1 .

With regard to patient characteristics, 39.61% were males and 60.39% females; the mean age of the overall patient population was 68.55 ± 10.61 years (range 42-91): 70.79 ± 8.27 for women and 65.14 ± 12.71 for men. ASA scores were: 1 in 10.20% of patients, 2 in 62.35% and 3 in 27.45%. The difference between the distribution of ASA scores in the two types of procedure (hip and knee replacement) did not prove statistically significant ($X^2 = 2.2530$, $p = 0.336$).

All of the patients examined had received preoperative antibiotic therapy 30-60 minutes prior to skin incision. Table 2 shows the drugs used and their doses. A further dose of antibiotic was administered to 48.84% of patients within 24 hours after surgery.

With regard to follow-up, 255 patients were examined in the hospital 30 days after the procedure. After 365 days, 84.71% responded to follow-up. Within the first 30 days of follow-up, 3.53% of patients had taken additional antibiotic therapy for 1 week. However, this was for reasons unconnected with the procedure (infections of the

Tab. II. Percentage use of antibiotics for preoperative prophylaxis.

Antibiotic used	%
Vancomycin 1 g associated to Pefloxacin 400 mg	96.08
Cefazolin 2 g associated to Amikacin 500 mg	3.14
Cefazolin 2 g associated to Pefloxacin 400 mg	0.78

respiratory and/or urinary tracts). Only one patient, who had undergone a knee-replacement procedure, presented with a superficial *S. aureus* infection of the wound; this resolved rapidly.

Discussion and conclusions

An incidence of surgical site infections of 0.3-2.5% after arthroplasty procedures of knee and hip has been reported [20]. In our study, only one case of superficial infection was recorded; this was in a patient who had undergone knee-replacement surgery. The infection rate in knee-replacement procedures therefore proved to be 0.89% when calculated on the number of responders at 365 days. The microorganism responsible for this superficial infection was *S. aureus*, one of the most common infecting organisms after periprosthetic joint surgery [18, 21]. This infection rate is in line with that reported in the literature [6, 22].

No postoperative infections were recorded in the sample of responders who had undergone hip-replacement procedures.

The clinical outcome recorded may have been influenced by a number of factors, including the microbiological characteristics of the operating room.

In the present study, the mean values of the airborne microbial load (12.90 ± 17.00 CFU/m³) during all procedures proved to be below the standard values (180 CFU/m³) for conventionally-ventilated operating rooms in Italy [13]. Moreover, during most replacement procedures, the airborne microbial load was below the limit of 10 CFU/m³ indicated by United Kingdom's National Health Service (NHS) for ultra-clean operating rooms with unidirectional airflows, which is recommended for arthroplasty procedures [23].

In this regard, it has been shown [24] that there is a progressive fall in the incidence of joint sepsis, especially when air contamination is below 10 CFU/m³. The mean value of the sedimenting bacterial load was 0.02 CFU/cm²/h, corresponding to 1 IMA/h; this is below the 2 IMA/h threshold indicated by the Association of Swiss Hospitals for operating rooms in which orthopedic prosthetic surgery is performed [25].

The good levels of airborne microbial contamination were achieved despite the fact that the ventilation system provided turbulent, not laminar, airflow. This can probably be attributed to several factors.

The fact that the technical department carefully scheduled cleaning operations (both of the conduits of the ventilation system and of the grills of the inlet ports) and the replacement of filters may have played an important role in abating the microbial load of the air supplied. The use of a laminar-flow system should improve the microbiological quality of the air, thereby further reducing the risk of SSI in prosthetic orthopedic surgery.

The results regarding surface bacterial contamination highlight the fact that the efficacy of sanitation procedures reduces the risk of cross-infections [26].

The clinical outcomes reported could have been partially affected by the thermal comfort of the surgical staff, as emerged from PMV and PPD values, which were within the reference values indicated by Fanger; indeed, thermal comfort improves concentration, reducing mistakes and accidents [27].

Providing proper ventilation is only one aspect of a complex strategy to minimize the risk of infection during surgical operations [28-30]; procedural and behavioral factors can also have a negative impact on the surgical outcome, including the risk of SSI.

A behavioral approach aims to reduce the number of airborne particles in the operating room through disciplinary measures. Some authors have observed that simple and cheap measures, such as limiting the number of staff members in the operating room and restricting their movements to a minimum, can reduce the dispersion of microbes in the air [31]. During the present study, operating room staff kept their movements to a minimum and were always properly attired.

Knobben et al. [32] observed that the combination of systemic and behavioral measures in the operating room, such as wearing proper attire and limiting needless activity, led to a reduction in the incidence of intra-operative bacterial contamination and, consequently, of prolonged wound discharge and superficial SSI. Moreover, after one-year follow-up, fewer deep periprosthetic infections were recorded. While it is difficult to determine the relative influence of each individual measure on the final result, the combination of all these parameters evidently creates the most effective weapon against infections.

We cannot rule out the possibility that appropriate behavior on the part of surgical teams during the study might have been influenced by the so-called "Hawthorne effect", i.e. the notion that performance improves when subjects are aware that they are being observed.

The clinical outcomes achieved seem to be explained by the microbial load (in both at-rest and operating conditions), the appropriate behavior of the staff, compliance with the guidelines on preoperative antibiotic prophylaxis, and efficient management of the ventilation system.

In this regard many studies have shown that various methods can be adopted in order to minimize postoperative infection [20, 33, 34]; these include using antibiotic-impregnated cement and laminar air flow, and minimizing operating room traffic. However, one of the most effective ways to prevent infection has proved to be the administration of prophylactic antibiotics within 1 hour

of surgical incision and continuation of its use during the immediate postoperative period [35, 36]. The importance of timing the first dose correctly is now underlined in the official recommendations for good clinical practice, so much so that in the United States this concept has been incorporated into "pay-for-performance" measures [37]. It is currently estimated that antibiotic prophylaxis in prosthetic surgery is able to prevent one infection for every 13 patients to whom it is administered [38]. The unequivocal evidence of the efficacy of perioperative antibiotic prophylaxis has led to this practice being adopted as standard treatment in these categories of patients, and great efforts have been made to raise awareness of this issue among all the health-care workers involved, with a view to ensuring efficacious administration [39]. Various international bodies [17, 33, 40, 41] recommend the use of glycopeptides for prophylaxis in high-risk procedures involving the implantation of prosthetic material whenever SSI due to MRSA are seen to be particularly frequent. In the hospital facility that we monitored, the decision to use Vancomycin in such a high percentage of cases was driven by the epidemiological assessment of the spread of MRSA in the hospital and/or by the risk factors for MRSA colonization in these patients.

The surveillance of postoperative infections is an essential tool in the management of infective risk. Published data suggest that as many as 20% to 70% of SSI are detected during the post-discharge period, although post-discharge SSI data are reportedly difficult for many medical centers to collect comprehensively [42].

The department of orthopedic surgery where the present study was carried out is a center of excellence for hip and knee-replacement surgery; as such, it also receives patients from outside the region in which it is situated. In such cases, the post-discharge course (apart from the outpatient examination 30 days after the procedure) and rehabilitation are often monitored by facilities situated close to the patient's place of residence. It is therefore difficult, especially for hospital facilities with such a large catchment area, to keep track of any postoperative infections that may arise. Consequently, there is a risk of underestimating the real rate of surgical site infections. It was this consideration that prompted us to institute a system of post-discharge surveillance which would, at least in part, fill this gap. The good response obtained from patients through telephone interviews, even a year after the surgical procedure (84.71% of responders), can be ascribed to the fact that, before surgery, patients were carefully informed of the importance of complying with follow-up, the time schedule of telephone contacts, the nature of the questions that would be asked and the purpose behind them.

Thus, the surveillance of SSI requires a systematic approach, with attention to multiple risk factors related to the patient, the procedures, including proper antibiotic prophylaxis, and the hospital environment [43]. While it is difficult to determine the relative influence of each individual measure on the final result, the combination of all these parameters evidently creates the most effective weapon against infections.

Acknowledgements

The authors declare no conflict of interest.

Authors' contributions

MLC conceived, designed and coordinated the research. GO and ES collected data and performed the data quality control. MS and ES optimized the informatics database. MS performed the statistical analyses. AMS evaluated the results. MLC and AMS wrote the manuscript. All Authors revised the manuscript and contributed to improving the paper. All authors read and approved the final manuscript.

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■ Received on May 29, 2016. Accepted on August 29, 2016.

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