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Heating, ventilation and air conditioning (HVAC) system, microbial air contamination and surgical site infection in hip and knee arthroplasties: the GISIO-SItI ISChIA study

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Key words: Operating theatre, Arthroplasty, Heating, ventilation and air conditioning system, HVAC, air microbial contamination, surgical site infections

Parole chiave: Sala operatoria, artroprotesi, impianto di ventilazione e condizionamento a contaminazione controllata, VCCC, contaminazione microbica dell'aria, infezioni sito chirurgico

Abstract

Background. *Recent studies have questioned the role of unidirectional airflow ventilation system in reducing surgical site infection (SSI) in prosthetic implant surgery. The aim of the ISChIA study ("Infezioni del Sito Chirurgico in Interventi di Artroprotesi" which means "Surgical site infections in arthroplasty surgery") was to evaluate, as a contribution to this debate, the association between heating, ventilation and air conditioning systems, microbial air contamination and surgical site infection in hip and knee arthroplasty.*

Methods. *The study was performed from March 2010 to February 2012 in 14 hospitals, for a total of 28 operating theatres: 16 were equipped with vertical unidirectional airflow ventilation (U-OTs), 6 with mixed airflow ventilation (M-OTs), 6 with turbulent airflow ventilation (T-OTs). Microbial air contamination in the operating theatre was evaluated by means of passive (Index of Microbial Air contamination, IMA) and active (Colony Forming Units per cubic metre, cfu/m^3) sampling. SSI surveillance was carried out according to the Hospitals in Europe Link for Infection Control through Surveillance protocol.*

Results. *A total of 1,285 elective prosthesis procedures (61.1% hip and 38.9% knee) were included in the study. The results showed a wide variability of the air microbial contamination in operating theatres*

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equipped with unidirectional airflow. The recommended values of ≤2 IMA and ≤10 cfu/m³ were exceeded, respectively, by 58.9% and 46.4% of samples from U-OTs and by 87.6% and 100% of samples from M-OTs. No significant difference was observed between SSI cumulative incidence in surgical procedures performed in U-OTs compared with those performed in T-OTs. A lower risk of SSI, even though not statistically significant, was shown in surgical procedures performed in U-OTs with a microbial air contamination within the recommended values (≤2 IMA and ≤10 cfu/m³) compared with those performed in U-OTs where these limits were exceeded, and compared with those performed in T-OTs with microbial air contamination within the recommended values for this type of OTs (≤25 IMA, ≤180 cfu/m³).

Conclusions. *ISChIA study did not show a protective effect of unidirectional airflow compared with turbulent airflow in arthroplasty surgery. However, the frequent exceeding of recommended air microbial contamination values in OTs equipped with unidirectional airflow, and the lower SSI risk in surgical procedures performed in compliant U-OTs compared with those performed in non-compliant U-OTs and with those performed in compliant T-OTs, suggest the need of further studies, which should consider air microbial contamination and other aspects of SSI prevention that may negate the potential benefits of the ventilation system; differences in intrinsic and extrinsic risk factors, medical treatment and surgical technique are also to be considered. Training interventions aimed at improving the behaviour of operators are essential.*

Introduction

Surgical site infection (SSI) following total joint replacement surgery is the most feared complication, associated with longer post-operative stay, additional surgical procedures, higher mortality and additional costs (1, 2). Many factors can increase the risk of SSI, including patient-related and procedural-related factors (1, 2). Microbial contamination of the surgical site is a necessary precursor of SSI, and air is a potential vehicle of infection (3). It has been demonstrated that the majority of the microorganisms found in the wound at the end of the operations come from the air; airborne microorganisms can fall directly into the wound or can land on exposed surfaces and subsequently be transferred to the wound (4). The Medical Research Council (MRC) study found, in hip and knee replacements, an association between heating, ventilation and air conditioning (HVAC) system, the level of bacterial air contamination, the wound bacterial count and the incidence of deep postoperative SSI (5, 6). Since then the use of ultraclean ventilated operating theatres with unidirectional airflow, also called laminar airflow, have been recommended in orthopaedic implant surgery, with maximum air microbial contamination values during operation of 10 colony-forming units per cubic metre (cfu/m^3) when measured by active sampling and 2 cfu/9-cm plate/h or 350 cfu/m^2/h when measured by passive sampling (7-13).

In 2008, a German retrospective study unexpectedly showed significantly higher SSIs rates after hip prosthesis implantation when using unidirectional airflow ventilation compared with turbulent ventilation (14), and a subsequent systematic review demonstrated that unidirectional airflow ventilation was a risk factor for developing severe SSIs in hip prosthesis operations (15). A later meta-analysis comparing unidirectional airflow ventilation with turbulent ventilation showed no difference in risk for SSIs following total hip and knee arthroplasty (16). However, none of the studies included in the meta-analysis contained an assessment of air microbial contamination, and it was not considered a possibility that, despite unidirectional airflow ventilation, the microbial air contamination could have exceeded the recommended threshold values, negating the effect of this ventilation system.

The aim of the ISChIA project proposed by GISIO (Italian Study Group of Hospital Hygiene), belonging to SItI (Italian Society

of Hygiene, Preventive Medicine and Public Health) was to evaluate the association between the HVAC system, microbial air contamination and risk of SSI in hip and knee prosthesis, in order to contribute to the debate on the protective role of unidirectional airflow on the incidence of SSI. Results of the ISChIA study relative to the microbial air contamination (17), the surveillance of SSI (18) and the perioperative antibiotic prophylaxis (19) had been already published. This paper, preceded by a short paper published in this same journal (20), summarizes the whole study, and expands preliminary data on microbial air contamination and on the association between HVAC system, microbial air contamination and risk of SSI.

Methods

The study was carried out from March 2010 to February 2012 in 14 hospitals (7 in Northern Italy, 3 in Central Italy and 4 in Southern Italy and islands). Hospitals' participation in the study was voluntary. A total of 28 operating theatres (OTs) were included in the study: 16 (57.14%) were equipped with vertical unidirectional airflow ventilation (U-OTs); 6 (21.43%) with mixed airflow ventilation (M-OTs), only the patient area being ventilated by vertical unidirectional airflow; 6 (21.43%) with turbulent airflow ventilation (T-OTs). OTs size ranged from 30 to 60 m^2 (mean: 39.3 m^2; SD: 6.7 m^2; median: 39.2 m^2) and from 90 m^3 to 180 m^3 (mean: 116 m^3; SD: 20.4 m^3; median: 111 m^3). The mean number of air changes per hour was 18 (SD: 4.5). The HVAC systems were equipped with high-efficiency particulate air filters ≥ 99.97% for particles ≥ 0.3 μm. For each surgical procedure the information regarding the type of HVAC system of OT was collected. The compliance to perioperative antibiotic prophylaxis guidelines was assessed, and the patient was followed-up for one year after surgery for SSI surveillance (18, 19). SSI surveillance was conducted according to the Hospitals in Europe Link for Infection Control through Surveillance (HELICS)-SSI protocol (21). Microbial air contamination in operating theatres was evaluated in the patient area, once at rest and, subsequently, during surgical procedure, starting at the time of surgical incision. Samples were collected by passive sampling (Index of Microbial Air contamination, IMA) (12, 22), and - where an active sampler was available - by active sampling (colony-forming units per cubic metre, cfu/m^3), as previously reported (17).

SSIs cumulative incidence in procedures performed in the different types of OTs considered was calculated as described elsewhere (18). Moreover, cumulative incidence of operations performed in compliant U-OTs was compared with the cumulative incidence of procedures performed in non-compliant U-OTs; as for IMA, the H+ target and alert values, respectively 2 IMA and 5 IMA, were considered (10); as for cfu/m^3, the HTM 03-01 and ISPESL 2009 threshold values, respectively ≤10 cfu/m^3 and ≤20 cfu/m^3, were considered (8, 23). Cumulative incidence value of procedures performed in compliant U-OTs was also compared with the cumulative incidence of procedures performed in compliant T-OTs (≤25 IMA, ≤180 cfu/m^3) (8, 10, 23).

Data collection was carried out by using the web-based SPSS Data Entry Enterprise Server (SPSS Inc.) at the LAPOSS, Laboratory for Planning, Experimentation and Analysis of Public Policies and Service for People, University of Catania.

Statistical Package for the Social Sciences Versions 14.0 and 22.0 (SPSS Inc., Chicago, IL, USA) was used for statistical evaluation. Continuous variables were described as mean, standard deviation (SD), medians, percentiles, ranges. Categorical variables were compared using Chi-squared test,

and continuous variables were compared using Student's *t*-test. P-values <0.05 were considered to indicate significance.

Results

A total of 1,285 surgical procedures (61.1% hip – No 785 - and 38.9% knee – No. 500) performed in the 28 operating theatres (OTs) were included in the study: 548 (42.6%) were performed in U-OTs, 136 (10.6%) in M-OTs, 247 (19.2%) in T-OTs, and 354 (27.6%) were performed in TH-OTs, (with T-OTs' surgical team wearing Steri Shield Turbo Helmets from Stryker, Newbury, UK).

Microbial air contamination was evaluated for 1,228 surgical procedures. Table 1 shows IMA and cfu/m^3 values, by type of HVAC system; mean and standard deviation, median and 10^{th}, 25^{th}, 75^{th}, 90^{th} percentiles, minimum and maximum values, are reported. In U-OTs, as expected, both IMA and cfu/m^3 values were significantly lower than in T-OTs. However, in U-OTs both IMA mean and median values (mean±SD = 5.39 ± 6.70, median = 3), exceeded the recommended threshold value of 2 IMA (10), and a maximum value of 64 IMA was reached. As for cfu/m^3, the mean value exceeded the recommended value of 10 cfu/m^3 (8) which corresponded to the median value obtained. A wide variability of microbial

Table 1 - Microbial air contamination (IMA and cfu/m^3) of operating theatres by type of heating, ventilation and air conditioning (HVAC) system

All operations	HVAC system			
	U-OT	M-OT	T-OT	TH-OT
IMA				
No.	528	105	245	350
Mean ± SD	5.39±6.70	17.40±19.89	9.73±13.77	4.34±4.34
Median	3	9	7	3
Minimum - Maximum	0-64	0-94	0-156	0-30
10^{th} percentile	0	2	3	0
25^{th} percentile	1	5	4	1
50^{th} percentile	3	9	7	3
75^{th} percentile	8	23.5	11	6
90^{th} percentile	12	51	17	9
CFU/m^3				
No.	252	23	64	0
Mean ± SD	22.07±34.61	255.87±145.47	60.69±45.18	
Median	10	251	54	
Minimum - Maximum	0-290	2-466	0-249	
10^{th} percentile	0	17.80	18	
25^{th} percentile	5	154	31.5	
50^{th} percentile	10	251	54	
75^{th} percentile	25	387	76.75	
90^{th} percentile	53.7	436.40	112.5	

IMA, index of microbial air contamination; cfu, colony-forming units; U-OT, unidirectional airflow operating theatre; M-OT, mixed airflow operating theatre; T-OT, turbulent airflow operating theatre; TH-OT, turbulent airflow operating theatre with surgical team wearing Steri-Shield Turbo Helmets.

contamination was observed, with IMA and cfu/m^3 values ranging respectively from 0 to 64 IMA and from 0 to 290 cfu/m^3. In M-OTs, the highest IMA and cfu/m^3 mean and median values were observed, significantly higher than those in U-OTs, T-OTs and TH-OTs; a great variability of microbial contamination values was observed, even wider than it was in U-OTs, with IMA and cfu/m^3 values ranging respectively from 0 to 94 IMA and from 2 to 466 cfu/m^3. The recommended values of 2 IMA and 10 cfu/m^3 were exceeded, respectively, by 58.9% and 46.4% of samples from U-OTs and by 87.6% and 100% of samples from M-OTs. In T-OTs median values of 7 IMA and 54 cfu/m^3 were recorded, ranging respectively from 0 to 156 IMA and from 0 to 249 cfu/m^3; the 90th percentile of 17 IMA and 112.5 cfu/m^3 were lower than the current standard of 25 IMA and 180 cfu/m^3 (8, 10, 23). The lowest IMA mean microbial contamination values were observed in TH-OTs, significantly lower compared with U-OTs, M-OTs and T-OTs; the median value of 3 IMA was equal to U-OTs, with the 75th (6 IMA) and 90th (9 IMA) percentiles lower than the ones observed in U-OTs, 8 IMA and 12 IMA respectively.

Table 2 shows the cumulative incidence of SSIs per 100 operations by type of procedure and HVAC system. A wide variability was observed; the lowest incidence values were recorded in arthroplasties performed in TH-OT (0.8%), even considering separately hip and knee surgical procedures, respectively 0% and 1.2%. The highest values were recorded in operations performed in M-OTs for hip procedures (3%) and in T-OTs for knee procedures (6.6%). A statistically significant difference was observed only for the SSI cumulative incidence between interventions of knee arthroplasty carried out in T-OTs and those in TH-OTs (p=0.014).

Considering only the severe SSIs (deep incisional and organ/space) (Table 3), the lowest SSI cumulative incidence was observed in operations performed in U-OTs and M-OTs (0.7%), the highest in operations performed in T-OTs (1.2%). As for hip procedures, the lowest SSIs cumulative incidence value was recorded in operations performed in TH-OTs, where no SSI were recorded; the highest values were observed in surgical procedures performed in M-OTs (1%) and U-OTs (0.8%), where the lowest incidence values were recorded for knee procedures, respectively 0% and 0.6%. The highest SSI cumulative incidence value for knee procedures was recorded in operations performed in T-OTs (3.3%).

Tables 4 and 5 show SSI cumulative incidences in procedures performed in U-OTs with microbial air contamination compliant with the IMA and cfu/m^3 recommended threshold values (≤ 2 IMA and ≤ 5 IMA; ≤

Table 2 - Surgical site infection cumulative incidence (per 100 operations) by type of heating, ventilation and air conditioning (HVAC) system

	Cumulative incidence per 100 operations								
	All operations			Hip arthroplasties			Knee arthroplasties		
HVAC system	No. SSI	Total operations	%	No. SSI	Total operations	%	No. SSI	Total operations	%
Turbulent airflow	5	247	2	1	186	0.5	4	61	6.6*
Unidirectional airflow	10	548	1.8	6	387	1.6	4	161	2.5
Mixed airflow	4	136	2.9	3	99	3	1	37	2.7
Turbulent + helmet	3	354	0.8	0	113	0	3	241	1.2*
Total	22	1,285	1.7	10	785	1.3	12	500	2.4

*p = 0.014

Table 3 - Severe surgical site infection (deep and organ/space) cumulative incidence (per 100 operations) by type of heating, ventilation and air conditioning (HVAC) system

HVAC system	Cumulative incidence per 100 operations								
	All operations			Hip arthroplasties			Knee arthroplasties		
	No. SSI	Total operations	%	No. SSI	Total operations	%	No. SSI	Total operations	%
Turbulent airflow	3	247	1.2	1	186	0.5	2	61	3.3
Unidirectional airflow	4	548	0.7	3	387	0.8	1	161	0.6
Mixed airflow	1	136	0.7	1	99	1	0	37	0
Turbulent + helmet	3	354	0.8	0	113	0	3	241	1.2
Total	11	1,285	0.9	5	785	0.6	6	500	1.2

$p > 0.05$

Table 4 - Comparison of surgical site infection cumulative incidence (per 100 operations) between operations performed in unidirectional airflow operating theatres (U-OT) with IMA values below and above the recommended values (10)

IMA values	≤ 2[a]	> 2	≤ 5[b]	> 5	All IMA values
Total operations	217	311	340	188	528
No. SSI	3	7	4	6	10
Cumulative incidence	1.4	2.3	1.2	3.2	1.9
p-value	p=0.471		p=0.104		

IMA, Index of microbial air contamination; [a]IMA target values; [b]IMA alert value

Table 5 - Comparison of surgical site infection cumulative incidence (per 100 operations) between operations performed in unidirectional airflow operating theatres (U-OT) with cfu/m^3 values below and above the recommended values (8, 23)

Cfu/m^3 values	≤ 10	> 10	≤ 20	> 20	All cfu/m^3 values
Total operations	135	117	181	71	252
No. SSI	1	1	1	1	2
Cumulative incidence	0.7	0.9	0.6	1.4	0.8
p-value	$p = 0.919$		$p = 0.491$		

cfu/m^3, colony-forming units per cubic metre

Table 6 - Comparison of surgical site infections cumulative incidence (per 100 operations) between operations performed in unidirectional airflow operating theatres (U-OT) and turbulent airflow operating theatres with IMA and cfu/m^3 values below the recommended values (8, 10, 23)

	A		B		C	
	U-OT ≤ 2 IMA	T-OT ≤ 25 IMA	U-OT ≤ 10 cfu/m^3	T-OT ≤ 180 cfu/m^3	U-OT ≤ 2 IMA and ≤ 10 cfu/m^3	T-OT ≤ 25 IMA and ≤ 180 cfu/m^3
Total operations	217	236	135	60	108	58
No. SSI	3	5	1	1	1	1
Cumulative incidence	1.4	2.1	0.7	1.7	0.9	1.7
p-value	$p = 0.552$		$p = 0.554$		$p = 0.653$	

10 cfu/m^3 and ≤ 20 cfu/m^3) (8, 10, 23), and the ones performed in U-OTs with microbial air contamination values above these limits. Lower SSI cumulative incidences were observed in operations performed in compliant U-OTs, even though the difference was not statistically significant.

Lower values of SSI cumulative incidence were observed in operations performed in U-OTs with microbial air contamination ≤2 IMA (incidence: 1.4%) and ≤10 cfu/m^3 (incidence: 0.7%), compared with the incidences in operations performed in compliant T-OTs, ≤25 IMA and ≤180 cfu/m^3, where SSI incidences of 2.1% and 1.7% respectively were recorded (Table 6, A and B). Considering the U-OTs with both IMA and cfu/m^3 values within the recommended limits, a SSI cumulative incidence of 0.9% was observed, which was lower than the incidence observed in T-OTs with ≤25 IMA and ≤180 cfu/m^3 (incidence: 1.7%) (Table 6, C). The SSI cumulative incidence differences were not statistically significant.

Discussion and conclusions

Since the studies of Charnley, the father of the modern total hip replacement (24-26), the need for the unidirectional air flow ventilation system where hip and knee replacement surgery is performed has been a subject of great interest and debate (1-3, 6, 14-17, 27-52).

MRC clinical trial (5, 6) performed between 1974 and 1979, which considered 8,052 knee and hip arthroplasties, strongly supported the benefit of the unidirectional airflow ventilation system in reducing SSI in arthroplasties, and since then this kind of technology has been recommended for orthopedic implant operations. The study by Brandt et al. (14) and subsequent meta-analyses (15, 16) suggested that unidirectional airflow system confers no advantage in terms of incidence of SSIs when compared with the use of turbulent ventilation. In particular, the meta-analysis by Bischoff et al. (16), performed within the framework of developing World Health Organization (WHO) Global Guidelines for the Prevention of Surgical Site Infections issued in 2016 (1), included ten studies focusing on total hip or knee arthroplasty, and found that laminar air flow ventilation did not reduce deep SSI when compared with conventional ventilation. On the basis of this meta-analysis, the WHO Guidelines suggest that laminar airflow ventilation systems should not be used to reduce the risk of SSI for patients undergoing total arthroplasty surgery; however, the strength of this recommendation was considered to be conditional, considering the very low quality of the supporting evidence (1). Actually, some criticisms have been aimed at the studies included in the meta-analysis (17, 27, 33, 36-38, 49). None of the studies had a randomized study design; most of the studies were based on large surveillance or national registry databases which may not have collected information on relevant confounders, such as patient characteristics, operative environment and the type and the performance of the ventilation systems; information on the ventilation technology installed in operating theatres was obtained by a questionnaire from the infection control team, so that the reliability of the answers might be questionable, introducing a potential responder bias; data derived from arthroplasty registry studies underestimate the percentage of periprosthetic joint infection by up to 40%; data on air microbial contamination was not considered. This latter point is a fundamental weakness of these studies; in this respect, Brandt et al. (14) affirmed that it can be assumed that the installed ventilation technique was functional in the enrolled hospitals because in Germany this is subject to regular controls by the health authorities. However, it should be considered that the mere presence of

laminar air ventilation does not guarantee its proper function; in particular, the crowding in the operating theatres and the movement of the operators, as well as the opening of the doors, can alter the flow and create turbulences, determining an increase in the air microbial contamination undermining the potential benefits of the unidirectional airflow ventilation (17, 53-63). Other hypotheses have been formulated, that can explain the lack of protective effect of unidirectional airflow: several obstacles (e.g. scialitic lamps, personnel) can disrupt the airflow; the area covered by the unidirectoral airflow may fail to extend to the instrument table, leaving the uncovered instruments outside the ultraclean area; the false sense of security can lead to lapses in the compliance to other basic infection prevention practices, the use of unidirectional airflow is a risk factor for hypothermia (16, 37, 42, 64, 65, 68). A focus of discussion has been the role of the forced-air warming systems aimed at avoiding the patient hypothermia which may alter the vertical unidirectional flow, and also may directly distribute microorganisms originating from the environment or the inside of the device into the sterile field (66-69); a recent systematic review concludes that there is not current evidence in the orthopaedic literature that forced-air warming devices translate into increased SSIs (69).

Apart from the MRC study, although not designed as a clinical trial, the ISChIA project is the only multicentre study including the evaluation of OT air quality, and we consider this as the main strength point of our study. A wide variability in the air microbial contamination in OTs equiped with unidirectional airflow (U-OTs and M-OTs) was observed, with values often higher than expected, and in particular in M-OTs frequently higher than the values recorded in T-OTs, suggesting a bad management of these operating theatres. As already pointed out as a limit of air sampling evaluation in M-OTs, air samples could have be taken outside the ventilation plenum of unidirectional airflow; however, in some cases, the microbial air contamination values were so high that there should be no doubt about the poor management of these OTs (17). Up to 100 door openings were recorded in U-OTs, and a positive correlation was found between both the number of people and the number of door openings with microbial air contamination (17). These findings support the position that a correct assessment of the impact of the unidirectional airflow system should take into consideration the air microbial contamination levels, which can increase due to a poor maintenance of the ventilation system and/or the incorrect behaviour of the surgical team. It is interesting to note that the "2017 European Centre for Disease Prevention and Control protocol for surveillance of surgical site infections and prevention indicators in European hospitals" (70) includes, among the data to be collected, the number of operating room door openings during the operation, measured from the opening of the sterile equipment until the closure of the surgical wound; it is recommended to be collected only if an automated system for operating room door openings is in place.

In our study the lowest level of microbial air contamination was observed in TH-OTs, where the lowest number of people and the lowest number of door openings were registered, and where the lowest cumulative incidence of SSI, considering all surgical procedures, was also observed. Analyzing in detail the data related to U-OT for which a larger number of surgical procedures were included, the overall cumulative incidence of SSI was lower in operations performed in U-OTs with IMA and cfu/m^3 values below the recommended values, compared with the incidence obtained in operations performed in U-OTs with microbial air contamination values above the threshold limits. SSI cumulative incidence

in operations performed in compliant U-OTs were also lower than SSI cumulative incidence observed in operations performed in compliant T-OTs (8, 10, 23). However, none of the differences were statistically significant. A limit of our study was the low number of recruited patients; a very large sample size, approximately 10,000 patients in each group, should be recruited in order to have enough power to detect significant differences in deep SSIs (16).

We observed in OTs, with the same kind of HVAC system, a high variability in microbial air contamination and a difference in SSI cumulative incidence. Having an unidirectional airflow ventilation system in place will not automatically provide low airborne counts in the surgical area.

Brandt et al. (31) underlined the fact that evidence-based medicine distinguishes between *efficacy*, under study conditions, and *effectiveness*, under conditions of routine patient care, and interventions showing an effect in study conditions may fail in the daily practice. However, it is unacceptable that this failure is due to avoidable risk factors, which are demonstrated to be correlated with the increase of microbial air contamination (e.g. the high traffic in operating theatres). There is a strong consensus that the numbers of microorganisms in the operating theatre environment correlate directly with the probability of surgical site infection (3) and the unidirectional air flow decreases the number of airborne microorganisms in the OT (6, 17, 53, 66, 71), as long as the ventilation system is designed and planned correctly, and regularly maintained, and the recommended behaviour is respected. It should not be permitted that a bad management of the ventilation system and a poor behaviour of the operators undermine the efforts to reduce the microbial contamination, and this is valid for both U-OTs and T-OTs. A surprising finding of this study was that 8.6% of T-OTs had microbial contamination values below the recommended values for U-OTs (17), and the median value were 7 IMA and 54 cfu/m^3, much lower than the recommended values of 25 IMA and 180 cfu/m^3 (8, 10, 23). Actually, other studies have shown that in well managed, conventionally ventilated operating theatres, the airborne microbial load was well below the current standard values (72-74). In particular, in a study by Cristina et al (72), which included 255 total hip and knee replacements, in 63.01% of total hip replacement, and in 73.39% of total knee replacement procedures, the mean values of airborne bacterial load were below 10 cfu/m^3. On the other hand, it should be considered that very critical situations have been recorded in conventional operating theaters. An Italian multicentre study, performed by the GISIO-SItI, on the microbial contamination of air coming out of ventilation systems, showed microbial charges of up to 700 cfu/m^3 (75); in an other study, in some operating blocks, no statistically significant differences were observed between bacterial contamination inside the theatre and that in the adjacent corridor, suggesting that air from the two environments had been mixed, and high levels of fungal contamination were found (73). In both cases, preventive measures, including air microbial monitoring, were shown to improve the air quality significantly (73, 76). These findings are of paramount importance considering that, according to the current guidelines (1-3), arthroplasty surgery may be performed in conventional operating theatres.

However, in the light of the debate on the unidirectional airflow ventilation system as a preventive measure to reduce SSI risk, and considering the ISChIA study results, we believe it is premature to discontinue the use of unidirectional airflow for arthroplasty surgery, given the clinical importance of the issue and the associated costs of SSIs that are well defined (77-79), whereas those due to the use of unidirectional airflow ventilation are still controversial (30, 32, 36, 38).

In agreement with other authors (14, 16, 33, 36-38, 42), we support the need for further research and evaluation about the effect of unidirectional airflow ventilation on SSIs. As Evans affirmed, the absence of high level of evidence from randomized trials is not proof of ineffectiveness (36, 44). It would be desirable to carry out a randomized clinical trial, including the evaluation of microbial air contamination and other known and avoidable variables which can undermine the effectiveness of the unidirectional airflow system; relevant differences in intrinsic and extrinsic risk factors, medical treatment and surgical technique should also be considered. In particular, the SSI Risk Index should be considered, which after multivariate analyses taking into account several risk factors including the perioperative antibiotic prophylaxis, in our study turned to be the only single independent risk factor associated with SSI (18).

However, although it appears that unidirectional airflow may not be necessary, the role of positive ventilation systems and the efforts to reduce the microbial air contamination in OT cannot be questioned (3, 44). It is essential to spend every effort to ensure that air cleanliness levels are consistent with the expected values; in this context, air microbiological control can be a useful tool to assess air quality, test the effectiveness of preventive measures and identify hazardous situations, having also an important educational role (73, 80-82). It is essential to increase healthcare workers' awareness of the risk associated with incorrect behaviour and implement targeted training interventions.

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Riassunto

Impianto di ventilazione e condizionamento a contaminazione controllata, contaminazione microbica dell'aria e infezione del sito chirurgico in interventi di artroprotesi di anca e ginocchio: lo studio ISChIA del GISIO-SItI

Introduzione. Recenti studi hanno messo in discussione il ruolo protettivo dei sistemi di sistemi di ventilazione e condizionamento a contaminazione controllata (VCCC) a flusso d'aria unidirezionale nel ridurre le infezioni del sito chirurgico (ISC) nella chirurgia ortopedica protesica. Scopo dello studio ISChIA (Infezioni del Sito Chirurgico in Interventi di Artroprotesi) è stato quello di valutare, come contributo a questo dibattito, l'associazione tra impianto VCCC, contaminazione microbica dell'aria e infezioni del sito chirurgico in interventi di artroprotesi di anca e ginocchio.

Metodi. Lo studio è stato effettuato nel periodo marzo 2010 – febbraio 2012 in 14 ospedali per un totale di 28 sale operatorie (SO): 16 con impianto VCCC a flusso d'aria unidirezionale (SO-U), 6 con flusso d'aria misto (SO-M) e 6 con flusso d'aria turbolento (SO-T). La contaminazione microbica dell'aria è stata valutata mediante campionamento passivo (Indice Microbico Aria, IMA) e campionamento attivo (unità formanti colonia per metro cubo, ufc/m^3). Per la sorveglianza delle ISC è stato adottato il protocollo HELICS (Hospitals in Europe Link for Infection Control through Surveillance).

Risultati. Nello studio sono stati inclusi 1.285 interventi di artroprotesi (61,1% di anca e 38,9% di ginocchio). I risultati hanno mostrato un'ampia variabilità nella contaminazione microbica nelle sale operatorie con impianto VCCC a flusso unidirezionale. I valori raccomandati (≤2 IMA e ≤10 ufc/m^3) sono stati superati, rispettivamente, nel 58,9% e nel 46,4% dei campioni nelle SO-U e nell'87,6% e nel 100% dei campioni nelle SO-M. Nessuna differenza statisticamente significativa è stata osservata tra l'incidenza cumulativa di ISC nelle procedure chirurgiche eseguite in SO-U rispetto a quelle eseguite in SO-T. Un rischio più basso di ISC, anche se non statisticamente significativo, è stato rilevato negli interventi eseguiti in SO-U con una contaminazione microbica dell'aria al di sotto dei valori raccomandati (≤2 IMA e ≤10 ufc/m^3) rispetto a quelli eseguiti in SO-U in cui tali valori venivano superati, e anche rispetto a quelli eseguiti in SO-T con valori al di sotto di quelli raccomandati (≤25 IMA, ≤180 ufc/m^3).

Conclusioni. Lo studio ISChIA non ha evidenziato un effetto protettivo dei sistemi VCCC a flusso unidirezionale rispetto a quelli a flusso turbolento. Tuttavia, il frequente superamento dei valori raccomandati di contaminazione microbica dell'aria nelle SO con impianto a flusso unidirezionale e il più basso rischio di ISC nelle

procedure chirurgiche eseguite nelle SO-U con qualità dell'aria conforme ai requisiti rispetto a quelle eseguite nelle SO-U non conformi e rispetto a quelle eseguite nelle SO-T con valori di contaminazione microbica dell'aria nei limiti raccomandati, suggeriscono la necessità di ulteriori studi che considerino la contaminazione microbica dell'aria e altri aspetti della prevenzione delle ISC che possono compromettere l'efficacia dei sistemi di ventilazione, oltre a fattori di rischio intrinseci ed estrinseci, trattamenti medici e tecnica chirurgica. Interventi di formazione tesi a migliorare il comportamento degli operatori sono essenziali.

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