



Effectiveness of downflow ultraclean air in operating theatres: a correlation study between heating, ventilation and air conditioning (HVAC) systems and surgical site infections

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SUMMARY

Background: Air quality in operating theatres (OTs) is crucial for preventing surgical site infections (SSIs). HVAC systems should ensure high air quality, minimizing microbial contamination. Recently, the effectiveness of downflow ultraclean air (UCA) systems in preventing SSIs has been debated.

Aim: To analyse the correlation between OT HVAC systems and SSI incidence using data from 12 hospitals in the Marche Region (2018–2019).

Methods: The data were correlated with the incidence of SSIs following 899 surgical procedures. Logistic regression analysis showed that UCA systems were associated with a reduced risk of SSI (odds ratio: 0.37; 95% confidence interval (CI): 0.15–0.92).

Findings: Thirty-eight SSIs were observed, yielding a total incidence of 4.2% (95% CI: 3.0–5.8). Of these, 29 occurred under non-UCA systems (5.17%; 95% CI: 3.5–7.4), and nine occurred in UCA environments (2.66%; 95% CI: 1.2–5.0). Technical data were collected from validation tests in each OT, focusing on UCA HVAC systems with unidirectional airflow meeting ISO 5 class standards.

Conclusion: These data suggest the potential effectiveness of UCA in reducing microbial air contamination, thus improving air quality and decreasing the risk of SSIs compared to non-UCA ventilation systems.

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Introduction

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Surgical site infections (SSIs) refer to infections that are located in the patient's wound after surgical activity. They are among the most common healthcare-associated infections. SSIs involve longer postoperative hospital stays, may lead to

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additional surgical procedures, may require intensive care, and result in higher attributable morbidity and mortality [1].

Operating theatres (OTs) are particularly complex systems in which multiple risk factors facilitate the occurrence of SSIs. These include the behaviour of the surgical team, the health of the patient, the type of surgical procedure, and the quality of the air and ventilation system. Several studies have shown that air can facilitate the transmission of pathogens, and it is considered a major cause of SSIs [2–7]. Debate on this topic continues since there is a general lack of understanding of how airborne microbial populations pose a significant risk to patients undergoing specific surgery scenario, such as device implant surgery [8].

Despite this, operating theatres are equipped with heating, ventilation and air conditioning (HVAC) systems, aimed at minimizing airborne contamination through high air-exchange rates and high-efficiency particulate air (HEPA) filtration.

Two main strategies are used for OT air conditioning: mixing ventilation airflow (MAF) and unidirectional airflow, also known as downflow ultraclean air (UCA).

MAF systems mix contaminated room air with clean air supplied by terminal diffusers, while UCA systems direct clean air downwards through a filter ceiling above the operating field, at least $3 \times 3 \text{ m}^2$ in size, supplying filtered air directly to the surgical area. Both systems use HEPA filters (H13 or H14), compliant with the EN 1822 standard. The question of which of the two systems is the most effective in reducing the incidence of SSIs has been a matter of controversy and contradiction for many years; a 2017 meta-analysis concluded that there was no benefit for laminar airflow compared with conventional turbulent ventilation of the operating room in reducing the risk of SSIs in specific surgery scenarios such as total hip and knee arthroplasties, and abdominal surgery [9–11]. However, the largest dataset used in this study, the Norwegian registry data, was subsequently shown to be inaccurate as the ventilation systems were not checked. A subsequent data analysis demonstrated that infection rates were lower in UCA systems [12].

One of the reasons for these contradictory results may be an incorrect classification of what is intended by UCA. Some inaccuracies in data collection regarding environmental variables may have led to a confused classification of proper UCA surgical rooms versus non-UCA surgical rooms. This aspect could have biased the results. Conclusions based on national registries and epidemiological studies should not be interpreted without considering some inaccuracy of the data [13]. One of the weaknesses of these studies concerns the classification of ventilation systems into MAF and UCA:

- UCA can mean quite different techniques in different countries (e.g. USA vs European Union (EU)), so the results of studies that do not take this into account may not be comparable.
- The size of the UCA ceiling in many studies is not specified or is too small compared to the relevant technical requirements. Frequently, OTs are classified as UCA with a filter ceiling smaller than $3 \times 3 \text{ m}^2$ or with insufficient air flow to ensure unidirectional flow under operating conditions. Romano *et al.* demonstrate that this type of filter ceiling has lower performance than adequately sized ceilings with high flowrates [14]. This type of OT does not fit the ISO 5 cleanliness level.

However, even more recent studies have not yet demonstrated a correlation between the type of ventilation and the risk of infection [15]. Moreover, other studies, such as that by Surial *et al.*, suggest that beyond microbial and particle concentration, other aspects of airflow dynamics – including flow directionality and turbulence – may influence the risk of SSI [16].

Considering the level of total airborne contamination according to the ISO 14644-1 standard, OTs with UCA systems achieve a higher air cleanliness level, such as ISO 5 or less, compared to rooms with MAF systems, which reach at most ISO 6 class [4].

Also, when considering airborne microbial contamination, several studies show that UCAs appear to have better performances than MAFs in terms of the number of colony-forming units (cfu) [14,17].

However, several clinical registry studies carried out in recent years have suggested that the risk of SSI after surgery with UCA systems is the same as or even higher than with MAF [18,19]. This lack of scientific evidence led the World Health Organization (WHO) in 2018 to issue a conditional recommendation against the use of UCA to reduce the risk of SSI for patients undergoing some orthopaedic surgeries [20]. However, the WHO relied principally on the registry data, and other regulatory authorities, such as the National Institute for Health and Care Excellence (NICE) in the UK and the Deutsche Gesellschaft für Krankenhaushygiene e.V (DGKH) in Germany, recommend the use of UCA systems [13,21].

The present regional, multicentre observational study investigates whether the use of UCA ventilation systems in OT is associated with a lower incidence of SSIs compared to non-UCA systems. To this end, we analysed a cohort of 899 surgical procedures performed in 12 hospitals using a standardized data collection protocol. The association between ventilation system type and SSI occurrence was assessed through multivariable logistic regression, adjusting for relevant clinical and procedural confounders. This study aims to contribute real-world evidence to a longstanding and unresolved debate in surgical infection prevention.

Methods

The present historical cohort study is based on data collected in 2018 and 2019 from 12 hospitals in the Marche Region.

Population sample

Data were collected on 899 surgical procedures of patients from November 29th, 2017 to September 25th, 2019 across 12 hospitals in the Marche Region. For each record, we collected several variables including patient's age, surgery duration in minutes, type of surgery (laparoscopic/not laparoscopic), ASA (American Society of Anesthesiologists) class (1–5), contamination class (clean, clean-contaminated, contaminated, dirty, not known), presence of sSSI (yes/no), type of air flow (non-UCA vs UCA). The prospective surveillance of SSI followed the European Centre for Disease Prevention and Control (ECDC) methodology [22]. All procedures were grouped into seven major surgical groups based on the textual content of the surgical procedure description field: implant-related orthopaedic surgery, minor orthopaedic/trauma, abdominal surgery,

general soft-tissue surgery, gynecology, head/thorax/ENT, and neurosurgery.

Personnel involved in the study used a standardized methodology and a questionnaire designed to collect data following an educational session. The questionnaire included sections on demographic characteristics including patient's national identity code, sex, and age; dates of admission and discharge; outcome (i.e. discharge, transfer, or death); surgical intervention, specified according to the ICD-9-CM code; surgery date, duration, and urgency (i.e. elective or urgent); use of endoscopy; wound contamination class; and American Society of Anesthesiologists score. The infection section included details on the onset date and anatomic site (i.e. superficial incisional, deep incisional, or organ/space). Post-discharge surveillance of SSIs was conducted by the referring surgeons through two complementary methods: either via direct inspection of the surgical wound during scheduled outpatient follow-up visits, or through telephone contact at 30 days post operation. In both instances, the final diagnosis of SSI was made by the surgeon in charge of the patient's post-discharge care, based on clinical evaluation. This approach ensured a consistent methodology across all participating centres and minimized potential variability associated with self-reported symptoms. All data collectors were healthcare professionals (infection control practitioners or designated hospital staff) who received specific training in the use of the standardized surveillance form, based on ECDC protocols. An initial educational session was held at the regional level to ensure consistent data collection practices across all sites. Regular communication and centralized oversight were provided throughout the study to ensure data completeness and uniform interpretation of variables. The use of a standardized form and centralized coordination contributed to ensuring the validity and reliability of the collected data.

Operating room characteristics and ultraclean air definition

This study included 65 OT. Technical data on contamination control performance were obtained from validation tests routinely conducted in each OT according to the Italian INAIL guidelines [23]. To classify a room as UCA, ceiling size, airflow

state, and performance were assessed in terms of particulate and microbiological airborne contamination. It was hypothesized that non-UCA rooms are an independent risk factor for SSI, whereas UCA systems have a preventive effect, resulting in a lower incidence of wound infection. The parameters used to assess OT performance are described in Table I, while Table II specifies the criteria applied to classify OTs as UCA or non-UCA.

Among the 65 OTs, 21 are supplied with a UCA ventilation system, 42 with a mixed airflow (MAF) system, and two OTs with filter ceiling smaller than 3×3 m² that do not meet the requirements summarized in Table II are classified as non-UCA rooms.

Airborne particle contamination

The concentration of airborne particles of diameter ≥0.5 µm is measured using an optical particle counter (Climet 450t, Climet, Redlands, CA, USA; Rigel, Instambul, Turkey; suction rate 50 L/min). The method is described in EN 14644-3 and enables determination of the ISO cleanliness level of the operating room [24]. Results are expressed in number of particles/m³. Table I shows the average value for UCA system to be 191.26 counts/m³, corresponding to an ISO 4 class, while the average value for non-UCA systems is 26,057.18 counts/m³, corresponding to an ISO 6 class.

Recovery time

Recovery time is a parameter suggesting the ability of the ventilation system to remove suspended particles from the air. Evaluating the recovery performance after a particle generation event represents a test of the efficiency and effectiveness of the system. For each OT, the 100:1 recovery time, defined as the time required to reduce the initial concentration by a factor of 100, is determined. The recovery test is performed in at-rest condition as described in ISO 14644-3 [24]: the room is contaminated with aerosol, and the particle concentration is measured over time by means of the optical particle counter (Climet 450t; suction rate 50 L/min).

The particle decay curve is evaluated at the centre of the room, in the position of the operating table. In the case of OTs served by mixing airflow systems, the recovery time is

Table I

Main technical parameters indicating airborne contamination of the ultraclean air (UCA) and non-UCA operating theatres considered in the study

Ventilation type	Downflow UCA	Non-downflow non-UCA	P-value
No. of operating rooms	21	44	
Airborne particle concentration (no. of particles ≤0.5 µm/m ³) in at-rest condition			
Mean	191.26	26,057.18	<0.05
SD	436.08	35,383.04	
Recovery time (min)			
Mean	1.38	22.24	<0.05
SD	0.68	12.73	
Viable particle concentration (cfu/m ³) in at-rest condition			
Mean	2.11	9.04	<0.05
SD	3.75	11.39	
Viable particle concentration (cfu/m ³) in operational condition			
Mean	6.52	40.63	<0.05
SD	5.89	36.69	

Table II
Classification criteria for ultraclean air (UCA) operating theatres

Parameter	UCA requirement	References
Ceiling size	$\geq 9 \text{ m}^2$	Italian ISPEL guideline; UNI 11425
ISO 14644 class (particle size $\geq 0.5 \mu\text{m}/\text{m}^3$) in at-rest condition	$\leq \text{ISO } 5$	Italian ISPEL guideline; UNI 11425
Recovery time (min) in at-rest condition	≤ 10	Historical data
Viable particle concentration (cfu/m^3)		
At-rest condition	≤ 10	Historical data
Operational condition	≤ 20	Italian ISPEL guideline

generally representative of the entire room; whereas in the case of the OTs served by UCA systems, the recovery time is representative only of the measurement point (surgical area under the unidirectional air flow).

Table I shows that the recovery time of a UCA room is typically <2 min, compared to an average recovery time of >20 min for a non-UCA room.

Microbial air contamination

For each OT, viable particle contamination is evaluated through active sampling to measure the concentration of micro-organisms in the air. A surface air sampling (SAS Super 100, PBI International, Houston, TX, USA; suction rate 100 L/min) is used for active sampling while the microbial load was evaluated using 24 cm^2 RODAC plates containing plate count agar. Results are expressed as cfu/m^3 .

Microbial contamination is evaluated both at rest and in operation during surgical activity, in the following way: (i) at rest: 600 L air sampling is taken in the middle of the room, in the position of the operating table; (ii) in operation: air sampling is taken after the surgical incision, then repeated every 5–10 min depending on the surgery time duration, for a total of 1000–1400 L of air sampled.

The variable is expressed as viable particle concentration in at-rest/operational condition (cfu/m^3).

General airborne particle concentration was also measured in at-rest condition (no. of particles $\leq 0.5 \mu\text{m}/\text{m}^3$) and recovery time in minutes intended as the time required for the air in the room to be completely renewed and for contaminants such as aerosols, particles, or micro-organisms to be removed.

Statistical analysis

Patient sample characteristics were grouped according to the type of airflow used during the surgical procedure (UCA/non-UCA). Differences among the various characteristics were explored using the Mann–Whitney test for continuous variables due to the non-normal distribution of the data, and the χ^2 -test for categorical variables, as appropriate. To investigate the possible association between the exposure to UCA and the risk of SSI, logistic regression was performed. The model was adjusted for the following variables: wound contamination class (clean, clean-contaminated, contaminated, dirty, not known), laparoscopic surgery (yes/no), ASA class (1–5), age class (20–54, 55–70, 71–80, >80 years), sex, and whether the duration of

surgery exceeded the 75th percentile (yes/no), according to the ECDC method. Covariates were selected for multivariable logistic regression based on the results of bivariate analyses ($P < 0.10$), supplemented by clinical and epidemiological reasoning.

In this cohort study, odds ratios (ORs) were used to assess the relationship between specific variables, such as the type of HVAC system, surgical procedure, and patient characteristics, and the occurrence of SSIs, as logistic regression is ideal for binary outcomes such as SSIs. Due to the low incidence of SSIs in both UCA and non-UCA environments, 2.66% in UCA and 5.17% in non-UCA, the OR is an effective measure. With low incidence, the OR closely approximates the RR, making it appropriate for evaluating the effect of UCA systems on reducing SSIs. The OR allows a clear comparison of the likelihood of SSIs between the two environments, with a lower OR in the UCA group indicating a reduced risk. This approach also accounts for confounding factors such as surgery type, patient characteristics, and comorbidities, providing insights into the effectiveness of UCA environments in minimizing SSI risk. Logistic regression is widely adopted in studies examining SSI risk and the impact of ventilation systems in operating rooms, including recent investigations in cardiac surgery, orthopaedic trauma and arthroplasty, and vascular surgery [15,25,26].

Air data for the operational rooms showed a non-normal distribution. Consequently, the Mann–Whitney *U*-test was employed to evaluate differences between the UCA and non-UCA groups for the following variables: mean airborne particle concentration ($\geq 0.5 \mu\text{m}/\text{m}^3$) at rest, recovery time in the patient area (minutes), viable airborne microbial contamination (cfu/m^3) in operational conditions, and viable airborne microbial contamination (cfu/m^3) at rest.

For all analyses, the level of significance was set at $P \leq 0.05$.

All analyses were performed using Stata/SE version 15.1 (StataCorp LLC, College Station, TX, USA).

Results

The difference between UCA and non-UCA OTs is shown in Table I: microbial contamination of UCA rooms is more than four times lower at rest and more than six times lower in operation compared to non-UCA rooms.

Table I presents air quality and recovery times results for two types of surgical environments: 21 UCA OTs and 44 non-UCA OTs. The results show that UCA rooms have significantly lower airborne particle concentration ($\leq 0.5 \mu\text{m}/\text{m}^3$) in at-rest conditions (191.26 vs 26,057.18 particles/ m^3 in non-UCA rooms, $P < 0.05$).

UCA rooms also have a significantly shorter recovery time (1.38 vs 22.24 min in non-UCA rooms, $P < 0.05$). In addition, UCA rooms show lower viable particle concentrations (cfu/m^3) both in at-rest (2.11 vs 9.04 cfu/m^3 in non-UCA rooms, $P < 0.05$) and in operational conditions (6.52 vs 40.63 cfu/m^3 in non-UCA rooms, $P < 0.05$). These results indicate that UCA systems reduce airborne particles and microbiological contamination both in at-rest conditions and operational conditions.

Table II shows the criteria we used to classify operating theatres as UCA or non-UCA. There are no requirements for UCA systems in the Italian regulations for recovery time and airborne contamination in at-rest conditions, so we based our analysis on historical data [22].

Table III

Distribution of our sample characteristic grouped by type of air flow during surgery

Characteristic	Non-UCA N = 561	UCA N = 338	P-value
Age (years), mean (SD)	69.3 (17.6)	60.8 (18.5)	<0.05
Surgery duration (min), mean (SD)	107.4 (76.5)	137.9 (113.7)	<0.05
Laparoscopic			<0.05
Yes	75 (13.37%)	23 (6.8%)	
No	454 (80.93%)	313 (92.6%)	
Not applicable	13 (2.32%)	1 (0.3%)	
Not reported	19 (3.39%)	1 (0.3%)	
ASA class			<0.05
1	75 (13.37%)	82 (24.26%)	
2	251 (44.74%)	158 (46.75%)	
3	191 (34.05%)	84 (24.85%)	
4	21 (3.74%)	3 (0.89%)	
5	0	1 (0.3%)	
Not reported	23 (4.1%)	10 (2.96%)	
Contamination class			<0.05
Clean	318 (56.68%)	73 (21.6%)	
Clean-contaminated	137 (24.42%)	202 (59.76%)	
Contaminated	61 (10.87%)	25 (7.4%)	
Dirty	37 (6.6%)	35 (10.36%)	
Not known	8 (1.43%)	3 (0.89%)	
Percentile >75 th			<0.05
Yes	171 (31.15%)	150 (45.59%)	
No	378 (68.85%)	179 (54.41%)	
Surgical site infection			0.07
Yes	29 (5.17%)	9 (2.66%)	
No	532 (94.83%)	329 (97.34%)	
Sex			<0.05
Male	317 (66.04%)	163 (33.96%)	
Female	237 (57.52%)	175 (42.48%)	

UCA, ultraclean air; ASA, American Society of Anesthesiologists.

Table III shows patient characteristics grouped by the type of air flow (non-UCA vs UCA) used during surgery. Patients in the non-UCA system were older (mean age: 69.31 years) compared to those in the UCA group (mean age: 60.79 years, $P < 0.05$). The average surgery duration was shorter in the non-UCA group (107.41 min) compared to those in the UCA group (137.88 min, $P < 0.05$). Gender distribution differed significantly, with more females in the non-UCA group (56.61%) and more males in the UCA group (51.78%, $P < 0.05$). Laparoscopic surgery was less common in the UCA group (6.8% vs 13.37%, $P < 0.05$). The UCA group had a higher proportion of patients in ASA classes 1 and 2 (24.26% and 46.75%, respectively) compared to the non-UCA group (13.37% and 44.74%, respectively). The contamination class data showed a higher percentage of 'clean-contaminated' procedures in the UCA group (59.76%) compared to the non-UCA group (24.42%), and 56.68% of procedures in the non-UCA group were 'clean' compared to 21.6% in the UCA group. The UCA group had a higher percentage of patients with surgery durations above the 75th percentile (45.59% vs 31.15%, $P < 0.05$). Finally, the SSI rate was lower in the UCA group (2.66% vs 5.17%) but did not show statistical significance.

Surgical procedures were grouped into seven major categories to explore potential differences in infection risk across clinical contexts (**Table IV**). Among the 899 procedures analysed, infection rates varied by group: 7.61% in general/

soft-tissue surgery, 5.77% in abdominal surgery, 5.56% in neurosurgery, 3.55% in minor orthopaedic and trauma procedures, 2.56% in gynaecological and urological surgery, 2.08% in implant-related orthopaedic surgery, and 1.92% in head/neck/thoracic/ENT surgery. However, no statistically significant difference in infection rates was observed between groups ($P = 0.245$).

Table V presents the results of the multivariate logistic regression analysis. UCA is significantly associated with a lower likelihood of infection (OR: 0.37; 95% CI: 0.15–0.92; $P = 0.03$). The third contamination class (contaminated) shows a higher likelihood of infection compared to the clean class (4.47; 1.51–13.18; $P = 0.01$). Laparoscopic surgery is associated with a reduced likelihood of infection (0.11; 0.01–0.86; $P = 0.04$). ASA class 3 increases the likelihood of infection (9.64; 1.80–51.56; $P = 0.01$), also if the surgical operation time is above the 75th percentile (4.05; 1.85–8.86; $P = 0.01$).

Discussion

The results of this study show a possible association between the type of HVAC system of the operating theatre and the development of SSIs. In particular, the presence of laminar flow is a protective factor for the risk of infection (OR: 0.37; 95% CI: 0.15–0.92; $P = 0.03$). This means that the presence of

Table IV

Infections are stratified by surgical procedure

Surgical procedures	Infection		Total	P-value
	No	Yes		
Abdominal surgery	245 (94.23%)	15 (5.77%)	260	0.245
General/soft-tissue surgery	85 (92.39%)	7 (7.61%)	92	
Gynaecological and urological surgery	152 (97.44%)	4 (2.56%)	156	
Neurosurgery	51 (94.44%)	3 (5.56%)	54	
Implant-related orthopaedic surgery	141 (97.92%)	3 (2.08%)	144	
Orthopaedic and minor trauma procedures	136 (96.45%)	5 (3.55%)	141	
Head–neck/thoracic/ENT surgery	51 (98.08%)	1 (1.92%)	52	
Total	861 (95.77%)	38 (4.23%)	899	

ENT, ear–nose–throat.

laminar flow reduces the risk of infection by >60%, all other risk factors being equal. This result agrees with previous studies that found an increased risk of SSI when surgery was performed under non-laminar flow conditions [27,28]. It has been shown that UCA systems are extremely useful for maintaining sterile conditions in the OT because their microbial sedimentation plates produce a continuous flow of micro-organism-free air, improving air quality by reducing the presence of microbes [7]. Other authors also suggest how this

system can guarantee additional ultraclean space during surgery [29]. James *et al.* found that UCA theatres reduced micro-organisms in OT air even though there was no significant reduction of the rates of infection in joint replacements [30].

Despite this evidence, there is not yet a consensus on the use of laminar flow since numerous studies have found UCA to be ineffective at lowering infection rates while others suggest that installation of UCA is not suitable in operating theatres as it increases the chance of SSIs and increases the financial burden at the same time due to its high installation cost [11,31]. Our results offer an important perspective on the ongoing debate regarding the role of ultraclean UCA in surgical settings [32,33]. Consistent with the literature, orthopaedic procedures involving large implants showed a relatively low infection rate (2.08%). However, comparable or even higher rates were observed in non-implant surgeries, such as abdominal (5.77%) and general soft-tissue procedures (7.61%), with no statistically significant difference across surgical categories. These findings align with the study by Stauning *et al.*, which documented a 9.5% infection rate in clean and clean-contaminated elective surgeries without implants in a major teaching hospital in Ghana [34]. Notably, Stauning *et al.* identified a genetic match between airborne bacterial contamination and an SSI isolate, underscoring the potential relevance of airborne transmission even outside the context of implant surgery. Although our study did not perform microbial sampling or sequencing, the observed distribution of infections supports the hypothesis that air quality may play a protective role across a broader range of surgical procedures.

In our study, we guaranteed a rigorous classification of surgical rooms operating under a UCA vs non-UCA by analysing the OT performance in terms of airborne particle concentration, microbial air contamination, and cleanliness recovery time. The fact that we carefully classify the types of operating rooms is a key strength as demonstrated by Langvatn *et al.*, who showed that the classification of operating rooms may lead to faulty analysis [35]. Another strength of the paper is that the OTs were assessed microbiologically, so they were properly classified as either ultraclean or as turbulently ventilated.

The robustness of this result is confirmed by adjusting for several variables that commonly influence the potential occurrence of SSIs, such as age, contamination class, ASA class, surgery time, and use of laparoscopic surgery [36].

However, we recognize some important limitations in our study. First, the cohort size is modest and includes a

Table V

Multivariate logistic regression analysis of factors influencing surgical site infections.

Variables	OR	95% CI	P-value
UCA			
No	1		
Yes	0.37	0.15–0.92	0.03
Wound contamination class			
Clean	1		
Clean-contaminated	1.5	0.58–3.88	0.40
Contaminated	4.47	1.51–13.18	0.01
Dirty/infected	1.40	0.39–5.00	0.60
Laparoscopic surgery			
No	1		
Yes	0.11	0.01–0.86	0.04
ASA class			
1	1		
2	2.81	0.57–13.98	0.21
3	9.64	1.80–51.56	0.01
4	4.16	0.28–60.85	0.30
Surgery time over 75 th percentile			
No	1		
Yes	4.05	1.85–8.86	0.00
Age class (years)			
20–54	1		
55–70	0.49	0.15–1.56	0.24
71–80	0.39	0.12–1.28	0.12
>80	0.38	0.11–1.32	0.13
Sex			
F	1		
M	1.18	0.56–2.50	0.67

OR, odds ratio; CI, confidence interval; UCA, ultraclean air; ASA, American Society of Anesthesiologists.

heterogeneous mix of procedures not limited to class I (clean) surgeries. Second, we lacked data on some important confounding variables, such as antibiotic prophylaxis. Third, while post-discharge surveillance was performed by trained surgeons for up to 30 days, this period may not capture all SSIs related to prosthetic or cardiac surgeries, as shown by previous studies [37]. Fourth, we did not have microbiological data to differentiate endogenous from exogenous (airborne) sources of infection. Despite these limitations, we found a statistically significant association between laminar airflow and reduced SSI risk. These findings support the potential protective role of LAF in the OT, although causality cannot be definitively established.

Further studies can be undertaken to investigate the correlation between SSIs and OT performance characteristics, such as air changes, recovery time, and airborne contamination. This would help predict the risk of infection connected to a specific OT based on its environmental contamination parameters.

In conclusion, the findings support a potential protective role of LAF systems of UCA in reducing microbial air contamination, thus improving air quality and decreasing the risk of SSIs compared to non-UCA ventilation systems.

However, it is important to emphasize that in order to classify an operating theatre as a true UCA, it is essential to verify its performance in terms of airborne contamination and recovery time. Therefore, this result highlights the need to carefully consider the technical characteristics of the operating theatre, from design to environmental validation measurements. Based on these considerations, it is important in this kind of study to collect the proper and updated documentation of ventilation systems to properly distinguish between UCA vs non-UCA OTs.

Our study provided a rigorous classification of UCA versus non-UCA operating rooms, contributing to more robust data. There is solid evidence that attention to multiple patient- and procedure-related risk factors leads to a reduction in the risk of SSIs in various clinical settings. Our results should be interpreted with caution and do not allow for definitive conclusions on causality. Future studies should explore additional parameters related to surgical techniques used and to the environmental performance of OTs, such as air exchange rates and aerobiological contamination, to improve the prediction of surgical infection risk. Although our classification was based on established microbiological and physical parameters, future studies may benefit from incorporating ventilation indices that capture more complex features of air distribution in the operating room.

Furthermore, while our results support the potential protective role of LAF systems, we acknowledge that the broader evidence remains controversial and context-dependent. Therefore, LAF should be considered part of a comprehensive bundle of preventive strategies. The correct implementation of other evidence-based measures – such as timely antibiotic prophylaxis, aseptic surgical technique, and patient optimization – remains fundamental to reducing SSI risk.

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Author contributions

J. Dolcini: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Validation,

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Conflict of interest statement

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