

Analyzing the risk factors influencing surgical site infections: the site of environmental factors

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Accepted Sept. 21, 2016; Early-released
 Feb. 1, 2017

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DOI: 10.1503/cjs.017916

Background: Addressing surgical site infection (SSI) is accomplished, in part, through studies that attempt to clarify the nature of many essential factors in the control of SSI. We sought to examine the link between multiple risk factors, including environmental factors, and SSI for prevention management.

Methods: We conducted a longitudinal prospective study to identify SSIs in all patients who underwent interventions in 2014 in 8 selected hospitals on the Mediterranean coast of Spain. Risk factors related to the operating theatre included level of fungi and bacterial contamination, temperature and humidity, air renewal and differential air pressure. Patient-related variables included age, sex, comorbidity, nutrition level and transfusion. Other factors were antibiotic prophylaxis, electric versus manual shaving, American Society of Anaesthesiologists physical status classification, type of intervention, duration of the intervention and preoperative stay.

Results: Superficial SSI was most often associated with environmental factors, such as environmental contamination by fungi (from 2 colony-forming units) and bacteria as well as surface contamination. When there was no contamination in the operating room, no SSI was detected. Factors that determined deep and organ/space SSI were more often associated with patient characteristics (age, sex, transfusion, nasogastric feeding and nutrition, as measured by the level of albumin in the blood), type of intervention and preoperative stay. Antibiotic prophylaxis and shaving with electric razor were protective factors for both types of infection, whereas the duration of the intervention and the classification of the intervention as “dirty” were shared risk factors.

Conclusion: Our results suggest the importance of environmental and surface contamination control to prevent SSI.

Contexte : La lutte contre les infections du site opératoire (ISO) passe entre autres par des études visant à clarifier la nature de nombreux facteurs essentiels de contrôle. Nous avons donc cherché à examiner le lien entre divers facteurs de risque, notamment de nature environnementale, et les ISO, dans une optique de prévention.

Méthodes : Nous avons mené une étude longitudinale prospective afin de recenser les ISO parmi tous les patients ayant subi une intervention chirurgicale en 2014 dans 8 hôpitaux de la côte méditerranéenne de l'Espagne. Nous nous sommes penchés sur les facteurs de risque liés au bloc opératoire, soit le degré de contamination fongique et bactérienne, la température et l'humidité ambiantes, le renouvellement de l'air et la pression d'air différentielle, et sur les variables liées aux patients, soit l'âge, le sexe, la comorbidité, l'état nutritionnel et le fait d'avoir reçu ou non une transfusion. Les autres facteurs pris en compte ont été l'antibioprophylaxie, le type de rasage (électrique ou manuel), la santé physique d'après la classification de l'American Society of Anesthesiologists, le type et la durée d'intervention et le séjour préopératoire.

Résultats : Les ISO superficielles étaient le plus souvent associées à des facteurs environnementaux, comme la contamination fongique (par 2 unités formant colonies) et bactérienne ou la contamination de surface. En absence de contamination du bloc opératoire, il n'y a eu aucune ISO. Les facteurs déterminants d'une ISO profonde ou touchant un organe ou une cavité étaient plus souvent associés aux caractéristiques du patient (âge, sexe, transfusion, alimentation par sonde nasogastrique et état nutritionnel mesuré par la concentration sanguine d'albumine), au type d'intervention et au séjour préopératoire. Enfin, l'antibioprophylaxie et le rasage électrique étaient des facteurs de protection contre les 2 types d'infection, tandis que la durée de l'intervention et la catégorisation de l'intervention comme étant « sale » étaient des facteurs de risques communs.

Conclusion : Nos résultats indiquent que le contrôle de la contamination environnementale et de surface est important pour prévenir les ISO.

Most authors accept that surgical site infection (SSI) is one of the worst complications that a patient can experience after an intervention. Many important aspects are affected by these infections, including mortality, morbidity, changes in prostheses, functional dependence and lawsuits as well as the associated costs of a prolonged hospital stay and increased total health care, social and labour costs. A multitude of studies worldwide focus on this issue from different scientific perspectives, refining the definitions of SSI parameters and risk factors as well as increasing our knowledge of what factors are important contributors to SSIs and how to control them at a clinical level.¹⁻³

In the past few years, important advances have been achieved in the field that may have had an impact on the reduction of SSIs.⁴ These include more effective surgical sterilization procedures, laminar flow, high-efficiency particulate absorbing (HEPA) filters, ultraviolet radiation, air renewal, humidity control, differential temperature and air pressure, particle count, surface colony count and antibiotic prophylaxis.⁵⁻⁸ However, other factors, such as decreased length of hospital stay, and more aggressive interventions performed on patients with worse clinical conditions, probably contribute to an increased incidence of SSIs.

The influence of all these factors is not clear given that, to our knowledge, no studies have examined the link between multiple factors, especially environmental control, and SSI. The goal of pursuing more effective systems of SSI vigilance and control is accomplished, in part, through studies such as this one, which attempt (within the current hospital dynamic) to clarify the nature of many essential aspects in the control of SSI. The main objective of our study was to analyze the relative importance of factors associated with the operating theatre and environmental biosafety as well as patient-related factors that contribute to the incidence of superficial, deep and organ/space SSI.

METHODS

The study was carried out in 8 hospitals of similar size (350–600 beds) on the Mediterranean coast of Spain. These hospitals serve a population of about 2 million people with a Mediterranean diet and lifestyle. In addition, to be included in our study, hospitals had to be public, use similar software and have had an almost identical incidence of SSIs during the previous year (2%–3%).

The study was an epidemiologic, longitudinal, prospective study carried out over the course of 1 year (2014). Services and pathologies studied were cardiac surgery, vascular surgery, general surgery, digestive surgery, neurosurgery, thoracic surgery, trauma surgery and orthopedic surgery. Patients were classified as cases (SSI) or controls (no SSI).

To be included in the study, patients had to have undergone an intervention in an operating room with laminar flow and had to have been admitted to hospital in 2014.

We excluded those who were operated on in outpatient services or the short-stay surgical unit, or in an operating theatre without laminar flow.

Our institutional review boards approved the study, and we obtained informed consent from all participants.

All patients had surgery in operating rooms with HEPA filters with minimum efficiency reporting values (MERV) and laminar flow (unidirectional air moving at a steady speed along parallel lines). We reviewed the conditions of the operating room according to the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) standards on a weekly basis.⁹

For the definition and classification of SSI, we strictly followed the criteria set out by the Centers for Disease Control in 1999. We classified the events as superficial or deep and organ/space SSIs.¹⁰

In each hospital, a selected surgeon and 1 of 2 trained nurse epidemiologists inspected all patients and evaluated the wounds daily during the hospital stay; staff differed in each hospital. They were blind to other patient characteristics. All patients were prospectively followed up, either in hospital or as an outpatient, for 30 days after surgery for the development of an SSI or other postoperative complications. Follow-up visits occurred at 15 and 30 days after the intervention in all patients, and a single team at each hospital conducted all the follow-up visits in order to avoid use of different SSI assessment criteria.

Variables associated with the operating theatre were obtained in the middle of each operation and included environmental contamination of fungi and bacteria measured in colony-forming units (CFU) and surface contamination of fungi and bacteria (number). Other variables were monitored daily in the operating room: air renewal rate per hour, differential air pressure measured in pascals, humidity as a percentage of saturation and temperature.

Patient-related variables previous to surgery, and considering only the time passed since admission, were age; sex; number of any comorbidities, including chronic renal failure, diabetes, cancer, chronic obstructive pulmonary disease, hepatic cirrhosis and smoking; immunosuppression (no. of days preceding intervention); nutrition, as measured by the albumin level in blood 1 or 2 days before the intervention (reference range 3.5–5.4 g/100 mL); number of days of nasogastric tube feeding; transfusion (yes v. no); and length of preoperative stay.

Variables associated with the operation and recorded during each surgery were prophylaxis (appropriate antibiotic prophylaxis was defined as correct antibiotic, dosage and time of administration); depilation (electric shaving v. manual razor); American Society of Anaesthesiologists (ASA) class;¹¹ type of intervention according to US National Research Council group in 1964 (clean, clean-contaminated, contaminated, dirty);⁵ and duration of intervention.

Environmental controls (fungi and bacteria) were carried out using an active volumetric sampler. The controls

were performed by extraction of 1 m³ of air in each sample, aspirated for 10 min and resulting in an expression of CFU/1000 L. The extraction ratio was approximately 1 m³ per 100 of circulating air.

The contact pressure method was used to carry out surface sampling in the area near the foot of the operating table at the time of the surgery, and it was performed with 2 different samples — 1 for fungi (agar extract with chloramphenicol) and 1 for bacteria — using one-plate Rodac contact plates (size 60 × 60 mm²) per sample. The total fungal concentration was determined after 72–120 h of incubation at 37°C, and all were identified at a species level based on macroscopic and microscopic morphology. Data from the operating room were gathered in the middle of every intervention (1 environmental and 2 surface samples). All samples were identified with a code and cultured in the microbiology service, which is accredited by a national accreditation organism in all the hospitals. We used the Velocicalc Plus tool (model 8386A, TSI Inc.) for the other parameters (air temperature, air velocity, pressure and relative humidity).

Statistical analysis

Statistical analysis was performed using SPSS software version 16.0 (SPSS Inc.). We tested the univariate association between each independent factor and SSI using the Student *t* test for continuous variables and the χ^2 test for categorical variables. Results are expressed as means \pm standard deviation, and we considered results to be significant at $p < 0.05$. To test the independence of the risk factors for

SSI, the significant variables in the univariate analyses were entered into a multiple logistic regression model with likelihood ratio forward selection. We then obtained the relative risk (RR) and the 95% confidence intervals (CI).

RESULTS

The total study sample comprised 18 910 patients, 1267 of whom experienced an SSI, for a total incidence of 6.7%.

Table 1 shows the association between SSI and the type of intervention. The incidence of SSI was 2.1% for a clean intervention, 5.1% for a clean–contaminated intervention, 12.9% for a contaminated intervention and 21.7% for a dirty intervention ($p < 0.001$).

Table 2 shows the risk of SSI associated with the ASA class. The rates were 2.7% for ASA class 1, 6.7% for class 2, 9.1% for class 3, 16.4% for class 4 and 19.9% for class 5. These differences were also significant ($p = 0.001$).

A contrast of averages was carried out (Table 3) and analyzed using the Student *t* test, and we found significant differences with regard to the appearance of an SSI in association with the following factors: surface contamination of fungi and bacteria, environmental contamination of fungi and bacteria, temperature, humidity, air renewal, age and comorbidity of the patient, duration of the intervention, nasogastric tube, serum albumin and immunosuppression. The differential pressure in the operating room was not found to be a significant factor. The SSI rate was minimal (0.34%) in the absence of CFU, environmental, or surface contamination and when surgery was not considered dirty owing to bacteria or fungi.

Table 1. Rate of surgical site infection by intervention type*

Variable	Intervention type; no (%)†				Total
	Clean	Clean–contaminated	Contaminated	Dirty	
No SSI	6072 (31.68)	7677 (40.05)	2745 (14.32)	1149 (5.99)	17 643 (92.05)
SSI	129 (0.67)	413 (3.01)	407 (2.3)	318 (1.97)	1267 (7.95)
Total	6201 (32.35)	8090 (43.06)	3152 (16.62)	1467 (7.97)	18 910 (100)
Infection rate	2.1	5.1	12.9	21.7	6.7

SSI = surgical site infection.
 * χ^2 : 80.112, $p < 0.001$
 †Unless indicated otherwise.

Table 2. Rate of surgical site infection by patient ASA class*

Variable	ASA class; no (%)†					Total
	1	2	3	4	5	
No SSI	8061 (42.06)	3585 (18.7)	4158 (21.69)	1629 (8.5)	210 (1.1)	17 643 (92.05)
SSI	221 (1.67)	258 (1.66)	417 (2.55)	319 (1.77)	52 (0.3)	1267 (7.95)
Total	8282 (43.73)	3843 (20.36)	4575 (24.24)	1948 (10.27)	262 (1.4)	18 910 (100)
Infection rate, %	2.7	6.7	9.1	16.4	19.9	

ASA = American Society of Anaesthesiologists; SSI = surgical site infection.
 * χ^2 : 98.135, $p < 0.001$.
 †Unless indicated otherwise.

Finally, we performed a multiple logistic regression (Table 4), from which we extracted the following information. Significant risk factors in superficial SSIs were environmental contamination by fungi (≥ 6 CFU, RR 6.2) and bacteria as well as surface contamination by both fungi and bacteria. Also important were humidity, differential pressure and temperature. The factors that were associated with the onset of deep and organ/space SSI were ASA class, patient-related factors (age, sex, nutrition), transfusion, type of intervention and days of preoperative stay. Some factors were common to both superficial and deep organ/space SSIs: antibiotic prophylaxis, shaving with electric razor, duration of the intervention and dirty intervention type.

DISCUSSION

The SSI rate in our study was rather high at 6.7%, but it should be noted that we included somewhat aggressive interventions in our analysis. Rates of SSI can vary significantly in the literature depending on several factors. There may be a combination of different interventions and surgical services with different SSI rates, or the study

design might be retrospective or prospective. Above all, the rates oscillate depending on whether follow-up is carried out after patient discharge. For example, a study reported an SSI rate of 3.1%, but the study design was retrospective and did not include postdischarge follow-up.¹² Another study reported a rate of just 1.0%, but it was carried out by analyzing administrative discharge registers and included only 7 surgical procedures. Another multi-centre study, which reported a rate of 5.0%, was carried out over a period of just 1 month.¹³ Moreover, there can be variations in the definition of the term “surgical infection.”^{14–16} In broad strokes, reviews have reported SSI rates ranging from 1.5% to 20.0%.¹⁵ Therefore, in order to optimize the comparability of the results, it is necessary to define the parameters of SSI studies.¹⁷

We found that older age and female sex were significant risk factors for deep organ/space SSIs, which is in line with the findings of previous studies on postcolorectal infections¹⁸ and cardiac surgery.¹⁹ The mean age of patients with SSIs in our study was 67.5 years, which is very close to the mean reported in other studies.² However, the effect of the age variable is more nuanced; Mintjes-de Groot and colleagues²⁰ found age to be a risk factor, and in our study, it approached the threshold for statistical significance. On the other hand, its effect may decrease when associated with more clear-cut factors, such as comorbidity and nutrition level.²⁰

With regards to the type of intervention, we observed a higher risk for SSI for operations classified as dirty. The results were statistically significant (OR 1.71, $p = 0.032$ for superficial SSI and OR 5.16, $p < 0.001$ for deep organ/space SSI).

Correct antibiotic prophylaxis was one of the most important factors in avoiding SSI. We studied both the choice of the antibiotic and the time of administration, which have been shown to be relevant.²¹ Appropriate use of the antibiotic can be even more important in specific interventions, such as colorectal surgery; Hrivnak and colleagues²² go so far as to suggest local administration. Furthermore, antibiotics protect the patient even when — as is frequent — surgical gloves are torn during the procedure.²³

For many years, it has been known that the use of manual razors before surgery increases the incidence of wound infection compared with clipping, depilatory use, or no hair removal at all.²⁴ In our study, the use of electric razors compared with manual razors was very important, resulting in an OR of 0.15.

Some studies have shown that preoperative hospital stay is associated with an increased risk of SSI, but this is masked because infections occurred in patients with greater severity or comorbidity. Our study shows that both length of preoperative stay and comorbidity increase the risk for SSI.⁵

Despite the fact that in some randomized controlled trials, preoperative nutritional therapy did not reduce incisional and organ/space SSI risk, our results corroborated

Table 3. Contrast of averages between the SSI and No SSI groups

Factor	SSI	Mean \pm SD
EC fungi, no. CFU*	No	0.85 \pm 1.147
	Yes	2.47 \pm 1.883
EC bacteria, no. CFU*	No	1.11 \pm 1.316
	Yes	3.05 \pm 2.004
SC fungi, no. CFU*	No	0.64 \pm 0.864
	Yes	1.57 \pm 1.430
SC bacteria, no. CFU*	No	1.22 \pm 1.118
	Yes	1.79 \pm 1.027
Temperature, °C*	No	24.15 \pm 1.807
	Yes	24.44 \pm 2.532
Humidity, %*	No	48.76 \pm 3.560
	Yes	54.71 \pm 5.055
Differential pressure, Pa	No	4.21 \pm 5.675
	Yes	4.12 \pm 5.228
Air renewal rate, no./h*	No	22.88 \pm 1.857
	Yes	21.66 \pm 5.810
Age, yr*	No	64.41 \pm 15.971
	Yes	67.55 \pm 14.237
Duration of intervention, min*	No	141.69 \pm 24.719
	Yes	184.12 \pm 15.870
Comorbidity, no*	No	0.81 \pm 0.773
	Yes	2.26 \pm 1.526
Nasogastric tube, d*	No	1.66 \pm 1.893
	Yes	2.67 \pm 3.329
Immunosuppression, d*	No	1.16 \pm 2.083
	Yes	1.32 \pm 1.281
Albumin level, g/100 mL*	No	4.347 \pm 0.753
	Yes	3.805 \pm 0.499

CFU = colony-forming units; EC = environmental contamination; SC = surface contamination; SD = standard deviation; SSI = surgical site infection.
* $p < 0.05$.

others showing that the hypoalbumin level of the patient was a significant factor.^{12,13,17}

Environmental biosafety factors

When analyzing the environmental biosafety factors, it is worth remembering that many standards have been proposed to better control infections, but we could not identify any studies in the scientific literature anywhere in the world that contained an exhaustive recounting of all of the interrelated factors included in the present study.^{1,2,7} The scientific community generally accepts that laminar flow of ultraclean air and the use of HEPA filters over a relatively large area creates a field of air intended to isolate the surgical area and team and that these factors help prevent the development of SSIs.^{25,26} All of the interventions carried out in our study met these basic conditions to prevent SSIs. Some investigators, such as Brandt and colleagues,²⁷ propose turbulent flow; however, their study was retrospective, based on routine surveillance data in 63 departments in Germany and limited in terms of the procedures included. It has been suggested that the measurement of air particle concentration could be used as an indicator of microbiological contamination,²⁸ but studies by Friberg and colleagues²⁹ and Landrin and colleagues³⁰ could not find a statistical correlation, and they recommend continuing to measure the microbiological contamination. Recently other authors have carried out similar studies, concluding that further research is still necessary to identify substitutes for these procedures.³¹

Our study highlights the importance of contamination, mainly environmental, by fungi (≥ 6 CFU, OR 6.2). It also supports the statement that various measures for the control of the superficial SSI can be highly effective.³² Like other authors,³³ we observed seasonal variations in the frequency of fungi, with lower levels in autumn and winter; however, the most common fungus in our study was *Penicillium* rather than the previously reported *Aspergillus*. With regard to the number of CFU found in our study, these were quite low compared with the levels published elsewhere³⁴ in studies that observed the lowest levels of CFU in operating rooms with 12 ± 14 CFU/m³. Even so, the level of contamination was much lower than that observed outside. Moreover, some authors attest that the best way to measure the level of contamination in an operating room is through the use of a dusting cloth or

DC pads, a simple flan tampon (\varnothing 4.5 cm) prepared by covering a cotton disk that can be sewn to any type of surface and will detect more than twice the CFU as the standard Rodac contact.³⁵

Although they are equipped with air conditioning systems that use HEPA filters, most of the operating rooms were found to contain airborne fungi, albeit at lower concentrations than those found in the other environments monitored.³⁵ Furthermore, such contamination may be caused or exacerbated by a range of factors, such as non-compliance with procedural norms (e.g., the frequent opening of doors between the operating room and the outer environment) and inefficient operation or inadequate maintenance of the air conditioning system.³¹ Our study supports all efforts of recent technological advances in this field that aim to reduce environmental contamination,

Table 4. Logistic regression of surgical infections and environmental factors

Factor	Superficial SSI		Deep organ/space SSI	
	OR (95% CI)*	p value	OR (95% CI)*	p value
ASA class*				
2			1.86 (1.01–3.42)	0.041
3			1.96 (1.15–3.34)	0.018
4			3.74 (1.45–9.62)	< 0.001
5			5.83 (2.03–16.69)	< 0.001
Low albumin			1.93 (1.09–3.41)	0.023
EC bacteria	1.75 (1.52–2.02)	< 0.001		
EC fungi				
1				
2–5	3.41 (1.02–11.39)	0.04		
≥ 6	6.23 (2.02–19.13)	< 0.001		
SC bacteria	1.96 (1.49–2.16)	< 0.001		
SC fungi	1.61 (1.22–2.58)	< 0.001		
Comorbidity			1.85 (1.48–2.31)	< 0.001
Age			1.03 (1.01–1.05)	< 0.001
Preoperative stay			1.22 (1.01–1.49)	0.041
Humidity	1.35 (1.28–1.43)	< 0.001		
Immunosuppression				
Differential air pressure	1.31 (1.22–1.42)	< 0.001		
Prophylaxis†	0.29 (0.12–0.66)	< 0.001	0.29 (0.12–0.66)	< 0.001
Depilation‡	0.15 (0.06–0.36)	< 0.001	0.15 (0.06–0.36)	< 0.001
Air renewal rate				
Sex§			2.28 (1.19–4.36)	0.016
Nasogastric tube			1.12 (1.02–1.23)	0.027
Temperature	1.27 (1.09–1.47)	< 0.001		
Duration of intervention	2.05 (1.64–2.57)	< 0.001	6.56 (1.5–28.62)	0.015
Intervention type¶				
Clean-contaminated			3.22 (1.47–7.02)	< 0.001
Contaminated			3.87 (1.58–9.44)	< 0.001
Dirty	1.71 (1.03–2.83)	0.03	5.16 (1.75–15.2)	< 0.001
Transfusion			3.11 (1.4–6.91)	< 0.001

ASA = American Society of Anaesthesiologists; CI = confidence interval; EC = environmental contamination; OR = odds ratio; SC = surface contamination; SSI = surgical site infection.

*ASA class 1 is the reference group.

†Yes is the reference group.

‡Manual razor is the reference group.

§ Men are the reference group.

¶Clean is the reference group.

such as using a high-intensity narrow-spectrum light environmental decontamination system (HINS-light EDS)³⁶ or ultraclean airflow mobile units.³⁷

Our study also shows that when contamination levels were virtually zero, almost no SSIs occurred for a total of 17 643 interventions, providing a large margin from which to safely draw our conclusions. The zero contamination level may be a reflection of many factors associated with the surgical activity and therefore can be considered a global or outcome index of many others (e.g., professional interest, patient preparation). Unlike the results found by other researchers, such as Humphreys,³⁸ the results of our study did not show the air renewal rate to be a significant factor affecting SSIs. However, it should be kept in mind that the operating rooms were kept in adequate conditions practically at all times and that the ventilation system was on all day.³⁹

We found that there were different risk factors associated with each type of surgical infection. Superficial SSIs were associated with environmental factors, such as environmental contamination by fungi (≥ 2 or more CFU) and bacteria, surface contamination, humidity, differential pressure and temperature of the operating room. However, the factors that determined the deep organ/space SSIs were more often associated with patient characteristics (age, sex, transfusion, nasogastric feeding and nutrition), type of intervention and preoperative stay.

Other studies reported associations between SSIs and some of these factors, but they reported on SSIs in general rather than on superficial and deep organ/space SSIs separately.⁷ Another possible factor is the fact that the operative attire of the staff was limited to the operating room.

Regarding all of these aspects of environmental control, we, like other authors, consider that those elements denominated as factors of environmental biosafety should be comprehensively standardized and monitored, a process that is already beginning to take place for the factors associated with patient preparation.⁴⁰ Considering the severity of the consequences, the establishment of international operating standards of reference for environmental biosafety is an urgent challenge.

Limitations

Important limitations of this study should be emphasized. First, because there are marked differences in surgeons' tendencies to diagnose SSIs, we did not allow a surgeon's diagnosis alone to identify SSI cases.⁴¹ We could not minimize interhospital variations, including observer differences, different patient groups and operating room discipline. We could have misclassified variables in this study, but this was probably nondifferential, so this misclassification likely weakened the association between SSI and different risk factors.

CONCLUSION

Our results suggest the importance of environmental and surface contamination control to prevent SSIs.

Acknowledgements: This work was funded by the Spanish National Health Institute, grant 013/2145.

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Competing interests: None declared.

Contributors: J.L. Alfonso-Sanchez and J.M. Martín-Moreno designed the study. J.L. Alfonso-Sanchez, I.M. Martínez, R.S. González and F. Botía acquired the data, which all authors analyzed. J.L. Alfonso-Sanchez, I.M. Martínez, R.S. González and F. Botía wrote the article, which all authors reviewed and approved for publication.

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