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A case series

Ann Ital Chir, 2021 92, 5: 505-508
pii: S0003469X21036587
Online ahead of print 2021 - Sept. 10
free reading: www.annitalchir.com

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Operating room environment assessment and biofilm risk for breast implants. A case series

AIM: *Breast implant-associated anaplastic large cell lymphoma, is a rare cancer. Several theories are speculated that may constitute its etiological factors. None of them has been clearly proven. The case report we present is intended to indicate the leading cause of this disease entity.*
CASE PRESENTATION: *Air samples taken in varying conditions at appropriate intervals by the MicroFlow Alfa 90 device in the operating room during five breast implant surgery were analyzed. Samples were taken four times during each operation. After the air was taken and delivered to the laboratory, the plates were immediately incubated under aerobic conditions. The incubation was carried out for up to 7 days. It has been shown that there is a significant difference between the total number of microorganisms during air intake carried out without and with the supply of air to purify the area in a given area by air recirculation of the operating block and cleaning it from bacteria and particles. No air colony-forming units were grown from air samples taken in the supply. However, from air samples taken without blowing, they were raised in various quantities.*
CONCLUSION: *Laminar free airflow used in operating room conditions significantly reduces the risk of infection of the surgical site, and thus may reduce the risk of developing breast implant-associated anaplastic large cell lymphoma.*

KEY WORDS: BIA-ALCL ethiological factors, Biofilm, Breast implants, Laminar air flow, Surgical site infections

Introduction

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), or anaplastic large cell lymphoma, is a rare cancer associated with breast implants. This topic is being discussed more and more widely in the group of mainly surgical and oncological ones. As of February 21, 2020, the American Society of Plastic Surgeons recognizes 888 cases worldwide. There are several theories that may be related to BIA-ALCL - implant surface type, genetic factors, biofilm, inflammatory factors and implant micro-damage. Until now, none of them has been unambiguously confirmed, but it is probably a combination of related events [1]. In this report, we present the results of the demonstration supporting the theory of biofilm as the leading trigger stimulating the onset of ALCL.

Case series

The demonstration was conducted in the Clinical Department of General and Oncological Surgery of the University Hospital of Karol Marcinkowski in Zielona Gora, during the five operations of implanting breast prosthesis in the period from 10.12.2019 to 13.1.2020 by the Polish-German Center of Microbiology EnviScence. Two of these tests were conducted during

Pervenuto in Redazione Maggio 2021. Accettato per la pubblicazione Giugno 2021
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ABBREVIATIONS

BIA-ALCL: Breast implant-associated anaplastic large cell lymphoma
ALCL: anaplastic large cell lymphoma
CFU: colony forming units

surgical procedures, which were attended by ten people for training reasons (surgical workshops). There were six people in the operating room during the rest of the procedures. Air samples were taken at appropriate intervals by the MicroFlow Alfa 90 device in the operating room from above the table where the breast implant is located (Fig. 1). Collections were made on agar plates using a MicroFlow Alfa 90 device (Fig. 2) and subjected to microbiological analysis. Air intake samples were taken four times during each operation: the first - without airflow before the operation, the second - in the airflow, at the operating table during the operation, the third - in the airflow, at the operating table after the operation, the fourth - without airflow after the operation. The Operio sterile air zone module was used, which is equipped with integrated air supply for cleaning the air in a given area through air recirculation of the operating block and cleaning it from bacteria and particles. Air circulation through mechanical filters (HEPA filters) causes air purification. The resulting ultra-clean air is directed as laminar flow (free of turbulence) over the surgical table. The polluted air is pushed into the area of the room, where it can be absorbed by a conventional ventilation system, which is supposed to reduce pollution and infection. The air content of a given plate was applied to Tryptone-Soy 1.6% Agar + Neutraliser No 4 microbiological medium. After the air was taken and delivered to the Enviscience laboratory, the plates were immediately incubated at 25 ± 2°C under aerobic conditions in accordance with PN-EN standards 13098. As the control applies to air under typical conditions, the incubation is carried out for up to 7 days, i.e., the period indicated by the norm for mesophilic bacteria. After incubation, colonies are counted as the total number of mesophilic aerobic microorganisms (in addition, the number of mold fungi is given). The air samples were collected by the collision method using the MicroFlow Alfa 90 sieve sampler; therefore, the number of counted colonies is corrected according to the conversion table (UNICHEM method no 1962-2 ed. 2006). For samples smaller than 1000 liters (in our case 500 liters - 100l / min for 5 minutes), the corrected number of colonies (read from conversion tables) is multiplied accordingly so that the final result is expressed in colony-forming units (CFU) (JTK) - colony-forming units in 1 m^3 air. Our results show a definite difference between the total number of microorganisms during withdrawals made with the laminar mobile flow and without its use (Tables I-III). From air samples taken in the abovementioned CFU was not grown. On the other hand, microorganisms such as *Micrococcus luteus, Staphylococcus hominis, Staphylococcus saprophyticus, Bacillus sp., Micrococcus sp.*, and *Staphylococcus epidermidis* were grown in varying amounts from air samples taken without blowing.

Fig. 1: Mobile laminar flow in operating room conditions.

Fig. 2: MicroFlow Alfa 90 air sampler.

Discussion and Comment

The benefits of using laminar flow in the operating room conditions have been demonstrated in the scientific literature. Jain and Reed, in their work [2], note that the operating room environment plays a crucial role in preventing surgical site infections (SSI). Microorganisms present in the operating room come from many sources - skin, surgical instruments, clothing, dust, droplets formed during speaking, sneezing coughs, and are responsible for 98% of SSI. Early studies have shown lower rates of infection with laminar airflow, which justifies its use. In turn, Vogelsang, et al. [3] conclude that the use of an additional mobile laminar airflow effectively reduces CFU during neurosurgical operations to the level of ultra-clean air. The central ventilation system in the operating room is not able to do this at the same level, even considering different surgical procedures: in patients undergoing sternotomy [4], gastric surgery [5], vascular procedures [6] or orthopedic surgery [7]. However, taken together, these studies demonstrated the relationship between the presence of bacterial biofilm and BIA-ALCL [4-7]. Walker J. et al [8] performed microbiological analysis of the breast, skin, implant, and capsule among patients with BIA-ALCL (n = 7) and control group by methods of culture, 16S rRNA sequencing, and immunohistochemistry. *Staphylococcus spp.* was the most frequently obtained bacterium in both the test group and the control group. Patients affected by BIA-ALCL do not appear to have a specific microbiome [9]. It should be noted that chronic bacterial infections have long been recognized as a factor contributing to the carcinogenesis process [10].

Occasionally, it may be responsible for the occurrence of blood infection associated with earlier implantation of prostheses [11]. Bearing in mind that chronic bacterial infection is one of the alleged factors of BIA-ALCL development, and mobile laminar flow significantly reduces the amount of bacterial biofilm in patients undergoing breast implant surgery, it can be assumed with high probability that the use of mobile laminar flow in the above-mentioned type of surgery can significantly reduce the risk of developing a disease such as BIA-ALCL.

In conclusion, laminar free airflow used in operating room conditions significantly reduces the risk of infec-

TABLE I - *Air samples taken on 10/07/2019.*

No.	Test sample	Total number of microorganisms	Presence found
1	Intake without airflow at 09.20	49 CFU on plate i.e. 108 CFU in 1m3	Among others: Micrococcus luteus, Staphylococcus hominis Staphylococcus saprophyticus
2	Intake with airflow at 09.40	0 CFU on plate i.e. less than 1 CFU in 1m3	Not applicable
3	Intake with airflow at 10.15	0 CFU on plate i.e. less than 1 CFU in 1m3	Not applicable
4	Intake without airflow at 10.25	4 CFU on plate tj. 8 CFU w 1 m3	Among others: Bacillus sp., Staphylococcus saprophyticus
5	Control plate	0 CFU	Not applicable

CFU: Colony Forming Units.

TABLE II - *Air samples taken on 19/09/2019 (1) - first surgery, (2) - second surgery - operations with more people present in the operating room.*

No.	Test sample	Total number of microorganisms	Presence found
1	Control plate	0 CFU on plate i.e. 0 CFU in 1 m3	
2	(1) Without airflow before surgery at 09.26	91 CFU on platei.e. 126 CFU in 1 m3	Among others:Micrococcus sp. Staphylococcus saprophyticus Staphylococcus hominis
3	(1) With airflow at 10.10	5 CFU on platei.e. 5 CFU in 1 m3	
4	(1) After burgery without airflow at 12.02	25 CFU on plate i.e. 26 CFU in 1 m3	
5	(2) Without airflow before surgery, at 12.55	71 CFU on plate i.e. 78 CFU in 1 m3	
6	(2) With airflow, implant, at 14.05	12 CFU on platei.e. 12 CFU in 1 m3	
7	(1) After surgery without airflow at 15.20	103 CFU on platei.e. 139 CFU in 1 m3	

CFU: Colony Forming Units.

TABLE III - *Air samples taken on 03.01.2020 (1) - first surgery, (2) - second surgery.*

No.	Test sample	Total number of microorganisms	Presence found
1	(1) Without airflow at 08.00	8 CFU on plate i.e. 16 CFU in 1 m3	Staphylococcus hominis
2	(1) With airflow at 08.30	0 CFU on plate i.e. < 2 CFU in 1 m3	Not applicable
3	(1) With airflow at 09.10	0 CFU on plate i.e. < 2 CFU in 1 m3	Not applicable
4	(1) Without airflow at 09.30	8 CFU on plate i.e. 16 CFU in 1 m3	Micrococcus sp.Staphylococcus epidermidis
5	(1) Control plate	0 CFU on plate	Not applicable
6	(2) Without airflow at 08.00	9 CFU on plate i.e. 18 CFU in 1 m3	Micrococcus sp.Staphylococcus epidermidis
7	(2) With airflow at 08.30	0 CFU on plate i.e. < 2 CFU in 1 m3	Not applicable
8	(2) With airflow at 09.10	0 CFU on plate i.e. < 2 CFU in 1 m3	Not applicable
9	(2) Without airflow at 09.30	4 CFU on plate i.e. 8 CFU in 1 m3	Staphylococcus epidermidis
10	(2) Control plate	0 CFU on plate	Not applicable

CFU: Colony Forming Units.

tion of the surgical site, and thus may contribute to reduce the risk of developing anaplastic large cell lymphoma in patients undergoing plastic-reconstructive surgeries within the mammary gland, whose occurrence may be due to the presence of a chronic inflammatory process caused by bacterial contamination of the operated site.

Acknowledgement

The Polish-German Center of Microbiology EnviScence has made substantive contributions to this manuscript. The Center organized the demonstration, the results of which the authors of this manuscript decided to use to create a retrospective scientific paper.

Riassunto

L'articolo descrive il potenziale rischio di contaminazione delle protesi mammarie quale fattore di rischio per lo sviluppo del linfoma anaplastico a grandi cellule. Durante la procedura chirurgica di impianto protesico mammario, sono stati prelevati, a intervalli prestabiliti, numerosi campioni di aria che successivamente sono stati sottoposti ad analisi microbiologica. I campioni sono stati prelevati prima dell'intervento chirurgico, in un ambiente senza ricircolo di aria, al tavolo operatorio durante l'intervento chirurgico e immediatamente dopo l'intervento chirurgico, in presenza di ricircolo di aria, e infine al termine dell'intervento senza ricircolo. I campioni di aria prelevati sono stati immediatamente incubati in ambiente aerobico, e l'incubazione è durata fino a 7 giorni. Le analisi microbiologiche hanno dimostrato che c'era una differenza significativa nel numero di microorganismi presenti nei campioni di aria prelevati in assenza di ricircolo con quelli prelevati in presenza di ricircolo, suggerendo che il flusso laminare utilizzato in sala operatoria riduce significativamente il rischio di infezioni del sito chirurgico e quindi può ridurre il rischio di linfoma anaplastico a cellule larghe.

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