

EVALUATION OF THE STERILIZATION EFFICACY OF DOMESTIC ELECTRIC DRILLS USED IN ORTHOPAEDIC SURGERIES

Vania Regina Goveia¹; Flavia Morais Gomes Pinto¹; Irene Alexeevna Machoshvili²; Thereza Christina Vessoni Penna²;
Kazuko Uchikawa Graziano¹

¹Escola de Enfermagem, Universidade de São Paulo, São Paulo, SP, Brasil; ²Faculdade de Ciências Farmacêuticas, Universidade de São Paulo, São Paulo, SP, Brasil

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ABSTRACT

It is estimated that electric drills (ED) have been used in orthopaedic surgeries for bone drilling for more than 50 years in Brazilian hospitals. It is an electric, thermosensitive equipment, not indicated for surgical use, which has not been previously evaluated regarding the sterilization efficacy, being suspect of infection risk. This study evaluated the efficacy of sterilization by ethylene oxide (EtO) of new drills that were intentionally contaminated with *Bacillus atrophaeus* spores. An experimental, laboratory, randomized applied research was developed, where 16 electric drills were analyzed, in addition to positive and negative controls. All the previously cleaned and sterilized equipment were submitted to contamination by spores. The experimental group was submitted to cleaning and sterilization by EtO and test of sterility by filtration through a 0.45 µm membrane. The membranes were cultivated and Gram and Wirtz-Conklin staining were carried out in positive results for spore visualization. An efficacy of 99.999981% of the process of sterilization by EtO was confirmed, with a probability of survival of 1.19×10^{-8} . Under the development conditions of the experiment, the efficacy of the sterilization of ED by EtO was confirmed.

Key words: Sterilization. Orthopaedic surgery. Surgical wound infection. Orthopaedic equipment. Ethylene oxide.

INTRODUCTION

The increasing technological development in the surgical area had resulted in more interventions with fewer risks;

however, the healthcare-associated infections comprise a great concern for the health professionals.

The surgical site infection is the third more frequent one

*Corresponding Author. Mailing address: Rua Cláudio, 213/153, Vila Romana, 05043-000 São Paulo/SP, Brasil.; E-mail: vaniagoveia@uol.com.br

among the healthcare-associated infections in the United States (3). In a prospective study that lasted a decade, Cruse and Foord (6) found 1.9% of infection in total hip prostheses, although the surgeries were performed in rooms without laminar flow and HEPA (high efficiency particulate air) filtration system. The incidence of infection in total hip arthroplasty in a specialized Brazilian university hospital was 13%, whereas in total knee arthroplasty, it has remained around 3% (7, 9, 10). Infections in orthopaedic surgeries can be severe and osteomyelitis is considered the most serious complication that can persist and lead to the functional deficiency of the extremities (8).

Considering that the instruments and equipment used during a surgical procedure must be microorganism-free, sterilization constitutes an important measure of infection control. Although the term “sterile” means “absolute absence of microorganisms”, in practice the sterile condition is expressed by the probability of microorganism absence (1).

The first step to guarantee the sterilization process is the effective cleaning performed with soap and water, either manually or by machines. Rutala and Weber (16) affirm that the manual cleaning requires two basic and essential components: the friction exercised by the abrasion of the dirty area and the fluidification that consists in applying an under-pressure fluid in the internal area of the object, applicable to objects with a lumen in order to remove the dirt. Materials used in surgical procedures, in sterile body sites, have a low microbial load, between 10^2 and 10^3 colony-forming units (CFU) per material (4, 15).

Orthopaedic surgeries require electric or pneumatic drills for bone drilling. The specific drills for medical-surgical use can generally be subjected to adequate cleaning in order to guarantee sterilization; however, it is estimated that the Brazilian hospitals have used, for more than 50 years, domestic use electric drills in orthopaedic surgeries.

This type of equipment has openings for the ventilation of the motor, through which there is risk of contamination by blood and residues. Considering that the post-surgical cleaning is performed externally, due to the impossibility of immersing the equipment in a detergent solution, the organic material probably remains in the internal part of the equipment and can impair the sterilization.

In a study carried out at the end of the 80s, the risk of organic contamination of the domestic use electric drill was evaluated microbiologically through a swab culture, raising doubts about the efficacy of sterilization (14). Another author describes how he adapted a domestic use electric drill for surgical use, in addition to reporting on the sterilization by formalin tablets in non-validated conditions (11).

The national publications on infections of the surgical site in orthopaedic surgeries have not identified the use of domestic use electric drills as a risk factor, despite the concerns of the healthcare professionals with the improvised and inadequate use of the equipment (7, 9, 10).

The practice in hospitals probably occurs due to the high costs of the specific equipment; however, the lack of research evaluating the risk of using such equipment, as well as the absence of recommendations or standardizations for the processing generate uncertainties regarding the efficacy of sterilization.

The aim of this study was to evaluate the efficacy of sterilization by ethylene oxide (EtO) in new domestic use electric drills, submitted to challenge contamination.

MATERIAL AND METHODS

An experimental, laboratory, randomized applied study was carried out to evaluate the efficacy of sterilization by EtO of new electric drills. This study was developed at the laboratory of experimental research of the Department of Medical-Surgical Nursing of the Nursing School of the

University of São Paulo (EE-USP), where 16 new electric drills were intentionally contaminated with 30 mL of a solution containing defibrinated sheep blood, which was sterilized and inoculated with bacterial spores of *Bacillus atrophaeus* (ATCC 9372™) 2.8×10^6 UFC/mL. The drills were sequentially submitted to the cleaning and sterilization processes by EtO and to a sterility test by membrane filtration. Six electric drills (ED) were used for the positive control and 3 bone drills (BD) specific for surgical use were the negative control, totaling 22 ED and 3 BD. The randomization was carried out to intentionally contaminate ED or BD and when the ED was drawn, the second draw was carried out to determine whether it would belong to the experimental or positive control group, proceeding with the cleaning, sterilization and analysis or the immediate analysis, respectively.

The sterility tests were carried out in the interior of a laminar flow hood and the aseptic technique was thoroughly adopted. The sterilized equipment were individually submitted to the washing of the internal and external areas by sonication (USC-2800, Enge Solutions®, 40 kHz frequency, 30W power, Brazil) in 3 liters of sterile water for 10 minutes. The content referring to 1,000 mL of the lavage was filtrated through a membrane with a porosity of $0.45 \mu\text{m}$ (Sterifil Holder®, Millipore) and that was cultivated in Petri dishes containing Tryptic (Trypticase) Soy Agar – TSA (Difco™ Agar medium with enzymatic digests of casein and soybean, USP, BD), incubated in a culture incubator (Orion®, model 502, Fanem, Brazil) at 37°C for 14 days.

The result was considered positive when there was a microbial growth of colonies, which were counted and submitted to Gram and Wirtz-Conklin staining for spore visualization. The colonies identified as Gram-positive bacilli without the presence of spores were transferred to a new

culture medium on a Petri dish containing TSA and incubated for 96 hours at 37°C .

After this period, the culture was submitted to a new Wirtz-Conklin staining for spore visualization. The cultures from dishes that did not present spores were submitted to thermal shock at 80°C for 10 minutes, and again, incubated at 37°C for 48 hours, for the final determination of the presence or absence of spores.

The sample size was calculated considering as successful result, an efficiency of 99.9% of the sterilization procedure by EtO and as unsuccessful result, a chance of 50%. In order to do that, the sample size was estimated in 16 units excluding the positive and negative control group. For the positive and negative control, six ED and 3 BD, which were specific for medical surgical use, were utilized, respectively.

The efficiency of the sterilization process by EtO of the ED from the experimental group was calculated by the formulas presented below:

Efficiency of the sterilization process by EtO

$$\text{Efficiency (\%)} = \frac{N_0 - N_t}{N_0} \times 100 \quad (1)$$

N_0 = initial concentration = initial number of living cells = 2.8×10^6 UFC/mL x 30 mL = 84×10^6 CFU

N_t = final concentration = number of living cells at the end of the processes

Probability of survival

$$\text{Survival index} = \frac{N_t}{N_0} \quad (2)$$

N_0 = initial concentration = initial number of living cells = 2.8×10^6 UFC/mL x 30 mL = 84×10^6 UFC

N_t = final concentration = number of living cells at the end of processes.

RESULTS

All six membranes cultivated from the ED of the positive control presented growth of innumerable CFU of *Bacillus atrophaeus* after 24 hours of incubation at 37 °C. After 3-4 days of incubation, a smear was made and the Wirtz-Conklin staining confirmed the presence of spores, which demonstrated the capacity of adherence of the contaminant to the ED.

Of the 16 ED from the experimental group, 4 presented microbial growth on the cultivated filter of 1-2 CFU/dish, being only one with bacilli; however, the spores were not clearly visualized at the first Wirtz-Conklin staining, in spite of the suspicion.

The four dishes that presented microbial growth were Gram-staining positive, with coccus colonies in three dishes and bacillus colonies in one dish. The Wirtz-Conklin staining for the dish with growth of Gram-positive bacilli presented a doubtful result, so it was transferred to a new culture medium on a Petri dish containing TSA and kept at the incubator for 96 hours at 37 °C, to attain nutrient depletion, development of spores and posterior visualization through a new Wirtz-Conklin staining. Although the second microscopy confirmed the presence of spores, the colonies from this dish were prepared, submitted to thermal shock and again incubated for 48 hours, at 37 °C. A new smear was made as well as a new Wirtz-Conklin staining for microscopy and visualization of the spores and confirmation of the recovery of *Bacillus atrophaeus*. After the third Wirtz-Conklin staining, the recovery of 1 CFU of spores in the culture of the filter of the lavage of one ED was confirmed.

None of the three BD from the negative control presented growth from the membrane culture. Of the 16 ED from the experimental group, only one presented the recovery of 1 CFU of spores in the filter sample. The efficiency of the

sterilization process by EtO was 99.9999881%, with a survival index of 1.19×10^{-8} for the ED that presented 1 CFU at the membrane culture.

DISCUSSION

The electric drills have openings for motor ventilation that allow the internal contamination by blood and residues during the surgical use, as it is not possible to immerse this electric equipment in a cleaning solution in order to clean it internally. The importance of cleaning materials used in medical-surgical settings to guarantee the efficacy of the sterilization processes is well known. As mentioned before, researchers have confirmed the low microbial load in surgical material after its use, before the cleaning as well as after it, on average, 10^2 CFU/material (4, 5, 15).

The infection of the surgical wound can occur due to the microbial contamination of surgical site, depending on factors such as the amount of inoculated microorganisms, their virulence and the immunological status of the patient. The risk of infection is high when the local is contaminated with microorganisms at a concentration $>10^5$ per tissue gram, although the inoculum that is necessary to cause infection can be much lower when accompanied by some material, such as, for instance, 10^2 microorganisms introduced with suture thread (3). However, the infections related to orthopaedic implants are different from infections at the surgical site, due to the presence of prostheses. The space around the prosthesis represents a region with depressed immunity, susceptible to microbial colonization and presents a higher risk for infection. Thus, experimental studies have demonstrated that the inoculum amount that is necessary to cause infection is smaller in situations where there is no prosthesis (2).

It is considered that clean materials have low microbial load, which results in the success of the sterilization process. The condition for the material to be sterilized or free of viable

microorganisms is considered a probability of sterility for each material submitted to sterilization. This probability is called the sterility assurance level - SAL - and is defined as the probability of survival of viable microorganisms after the sterilization or the probability of failure during the sterilization process.

The FDA (Food and Drug Administration) establishes a SAL of 10^{-6} for sterilization processes; therefore, for an initial population of 1,000,000, there must be a reduction of 12 logarithmic cycles to attain the sterilization (12, 13).

In the present study, each one of the 16 ED was intentionally contaminated with a high microbial load: 30 mL of spore suspension of *Bacillus atrophaeus* 2.8×10^6 UFC/mL, which means 84×10^6 UFC/FE or 84,000,000 CFU/ED. After the contamination and the time of exposure of 60 minutes, simulating the approximate time of the ED use in an orthopaedic surgery, each one of them was submitted to external manual cleaning with enzymatic detergent and sterilization by EtO. The results of this experiment show that the efficiency of the sterilization process by EtO for each one of the 16 ED was 99.9999881% and $>99.9999881\%$ for the others. Even considering the recovery of cells in this experiment, the SAL was $\leq 1.19 \times 10^{-8}$, higher than the SAL established by the competent organs that regulate and standardize the sterilization of materials for medical-surgical use, which is 1×10^{-6} .

In spite of the concerns raised by the professionals that work with control of hospital infections and sterilization of medical-surgical materials regarding the efficacy of the sterilization process of ED, there is no evidence of the association of ED use and the occurrence of infections at the surgical site, or even related to orthopaedic implants, a fact that was supported by the results of this investigation. Although the difficulties to perform the cleaning of ED are known, the sterilization with EtO was effective to eliminate

the inoculated microbial load.

It must be considered that the variables involved were controlled, as this was a laboratory experimental study. There is no intention to support the improvised use of domestic ED in surgeries, although these results have confirmed the efficacy of sterilization by EtO.

It is noteworthy the fact that this study does not validate the use of re-use of ED for surgical procedures, especially because there are commercially available appropriate equipment for this purpose. This study only evaluated the risk of a frequent practice in Brazilian hospitals, confirming the efficacy of the sterilization process by EtO. It is not safe to extrapolate these results to other automated methods of sterilization that use low temperature, i.e., hydrogen peroxide plasma (HPP) and low-temperature steam and formaldehyde (LTSF), which have a lower capacity of diffusion.

We expect that the present study can contribute to the decision-making by health professionals that seek assistance improvement.

RESUMO

AVALIAÇÃO DA EFICÁCIA DA ESTERILIZAÇÃO DE FURADEIRAS ELÉTRICAS DOMÉSTICAS UTILIZADAS EM CIRURGIAS ORTOPÉDICAS

Estima-se que há mais de 50 anos, as furadeiras elétricas têm sido empregadas em cirurgias ortopédicas nos hospitais brasileiros para a perfuração óssea. Trata-se de equipamento elétrico, termossensível, não indicado para uso cirúrgico, não avaliado anteriormente quanto à eficácia da esterilização, suspeitando-se de risco para infecções. Esse estudo avaliou a eficácia da esterilização por óxido de etileno (ETO) de furadeiras novas intencionalmente contaminadas com esporos de *Bacillus atrophaeus*. Foi desenvolvida pesquisa

experimental, laboratorial, randomizada e aplicada onde foram analisadas 16 furadeiras elétricas, além de controle positivo e negativo. Todos os equipamentos previamente limpos e esterilizados foram submetidos à contaminação com esporos. O grupo experimental foi submetido à limpeza e esterilização por ETO e teste de esterilidade por filtração por membrana de 0,45 µm. As membranas foram cultivadas e para resultados positivos foram realizadas coloração de Gram e Wirtz-Conklin para visualização dos esporos. Foi comprovada a eficiência de 99,9999881% do processo de esterilização por ETO, com a probabilidade de sobrevivência de $1,19 \times 10^{-8}$. Nas condições do desenvolvimento do experimento, a eficácia da esterilização das FE por ETO foi comprovada.

Palavras-chave: Esterilização. Cirurgia ortopédica. Infecção da ferida operatória. Equipamentos ortopédicos. Óxido de etileno.

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