American Journal of Infection Control 43 (2015) 1092-5

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Biologic monitoring and causes of failure in cycles of sterilization in dental care offices in Mexico

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Key Words:
Autoclave
Biologic indicators
Dry heat
Infection

Background: Biologic indicator tests (BIs) are considered the most meaningful way to verify sterilization.
Objective: To monitor the cycles of sterilization using BIs in dry heat sterilizers and steam autoclaves and to identify the causes of failures in the cycles of sterilization in dental offices in San Luis Potosí, México.
Methods: An invitation to participate was sent to 400 dental offices, and 206 practitioners of 200 dental offices were included. A questionnaire was given to each of the participants, asking for the following information: sterilizer type, operational parameters used (eg, temperature, pressure, and length of exposure), frequency of sterilization cycles per day, use of BIs, and maintenance procedures of the sterilizer. Two hundred thirty sterilizers were monitored using BIs. The sterilizers with positive results were monitored a second and third time to identify the cause of the failure.
Results: Twenty-two percent of practitioners (n = 46) used BIs, and 17% (n = 39) of the sterilizers reported positive results (bacterial growth). The detected failures were a mistake in the procedure (eg, temperature, time, or pressure), an absence of supervision of the procedure performed by the assistant, and improper maintenance.
Conclusions: There are opportunities to increase information on infection control, to improve the adoption of standard quality control methods for sterilization as a routine process, to improve training on proper testing, and standardize processes.

The sterilizing methods used in dental practice include steam autoclave and dry heat.[1-4] Procedures used for monitoring the effectiveness of sterilization are external indicators (physical), internal chemical indicators, and biologic indicator tests (BIs).[5,6] The BIs area considered the most meaningful way to verify sterilization because they measure whether highly resistant bacterial spores are killed (ie, lethality). If the spores are killed, it may be assumed that all other microbes on dental instruments are also killed.[2,7-10] The difference between the chemical indicators (ie, multiparameter indicators and integrating indicators) and the BIs is that chemical indicators cannot measure lethality.[3-6] In Mexico, the monitoring of the sterilizers with BIs is not a routine procedure; however, health authorities recommend this method. Therefore, the objectives of our study were to monitor the cycles of sterilization using BIs in dry heat sterilizers and steam autoclaves and identify the causes of failures in the cycles of sterilization of the dental care offices in San Luis Potosí, Mexico.

MATERIALS AND METHODS

A transversal study from December 2012-December 2014 was performed. Three hundred eighty-five dental offices registered in the National Institute of Statistics, Geography, and Information Technology in the city of San Luis Potosí (State of San Luis Potosí), Mexico, were invited to participate. In addition, an invitation was personally given to universities, dental associations, and private dental offices not registered by the National Institute of Statistics, Geography, and Information Technology (n = 15). Two hundred six practitioners at 200 dental offices with a total of 230 sterilizing instruments (ie, dry heat and/or autoclave) accepted the invitation

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Conflicts of interest: None to report.

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http://dx.doi.org/10.1016/j.ajic.2015.05.034

to participate in the study. According to the ethical principles of the Declaration of Helsinki, informed and voluntary written consent was obtained from the participants before the beginning of the study. Practitioners of any sex and age owning sterilizing equipment (ie, dry heat, autoclave, or both) were included. Exclusion criteria were practitioners who did not send written acceptance to participate and sterilizers that did not perform the sterilizing cycle. Elimination criteria were questionnaires that were not delivered or incomplete and samples that were contaminated. The participants received a questionnaire for each sterilizer, requesting information about the type of sterilizer, operational parameters used (eg, temperature, pressure, and length of exposure), frequency of sterilization cycles per day, the person responsible for its use, use of BIs, and maintenance procedures.

Monitoring of the sterilization cycles

Preparation of the samples

The indicators used in the study were spores of *Bacillus Stearothermophilis* and *Bacillus subtilis* variety *níger*. The spore tests used were SGM strip and Bacterial Spore Sterilization Strip (SGM Biotech, Inc, Lakewood, CO).[4] The samples were prepared by introducing a spore strip test in a culture tube with a screw top. The samples were marked with a code and randomly assigned to the participants who received 1 sample per equipment item. The participants received the spore tube samples with instructions for their use and were asked to place them in the center of the middle tray of the equipment during a normal sterilization cycle.

Processing of the samples

The samples were processed in the Laboratory of Clinical Investigation, Dental Medicine Faculty, Autonomous University of San Luis Potosí, San Luis Potosí, México. The culture medium used to identify the presence or absence of bacterial growth was Soy Trypticase (BD and BBL, Becton Dickinson and Company, Franklin Lakes, NJ) with 0.25% of anhydrous dextrose (Hycel de México, S.A de C.V., México D.F., Roma Norte, México). Three milliliters of the culture medium were placed in each tube (sample) and the tubes were incubated at 37°C for 7 days to test the dry heat sterilization cycles and at 57°C for 7 days to test the autoclaves. For each sample, a positive control (bacterial growth), a negative control (absence of bacterial growth), and a culture medium control were used.[4]

Interpretation of the results

The procedure detects the presence or the absence of bacterial growth in a cultivated spore sample. The presence of bacterial growth is considered a positive result and therefore a malfunction of the equipment. The absence of bacterial growth is a negative result and therefore proof of correct functioning of the sterilizer. The test was performed blind to the identity of the practitioner, the equipment, and the procedure. The results were delivered to the participants.

Identification of the causes of sterilization failure

In the study, 3 monitoring experiments were performed. First monitoring: If the result was negative, there was correct functioning of the sterilizer. If the result was positive, the questionnaire variables were modified (with recommendations to a correct functioning of the sterilizer) to identify the cause of the bacterial growth in a second monitoring. Second monitoring: With the variables modified in the first monitoring with positive result, a second monitoring was performed. If the result was negative, there was correct functioning. If the result was positive, the questionnaire variables were modified for a second occasion to identify the cause of the bacterial growth in a third monitoring. Third monitoring: With the variables modified in the second monitoring of a positive result, the presence (result positive) or absence (result negative) of bacterial growth was identified (Fig 1).

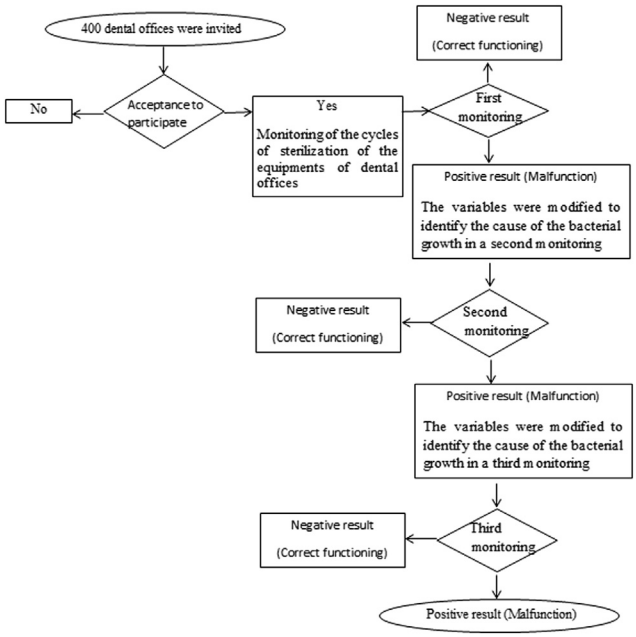

Fig 1. Identification of the causes of sterilization failure.

Statistical analysis

The kappa simple test was performed to standardize the investigators in the variable of presence or absence of bacterial growth. The categorical variables were reported with frequencies and percentages; the continuous variables were reported with means, standard deviations, and ranges. A binary logistic regression multivariate analysis was performed to estimate the association among the variables of the study. In the analysis, the presence or absence of bacterial growth was established as a dependent dichotomous variable. The independent variables were a correct or incorrect procedure, the frequency of the sterilizing cycles per day, the use of BIs, and the maintenance of the equipment in the first monitoring. The analysis was performed with JMP version 10.0 (SAS Institute, Cary, NC) and Stata version 11.0 (Stata Corp LP, College Station, TX).

RESULTS

Four hundred dental care offices in the city of San Luis Potosí (State of San Luis Potosí, Mexico) were contacted and invited to participate, and 200 (50%) responded to the survey. A total of 230 equipment items (ie, dry heat sterilizer and/or autoclave) were included in the study.

Two hundred dental care offices did not participate because of the following reasons: in 9% (n = 18), the practitioner did not answer the questionnaire; in 73% (n = 146), the practitioners could not be located; and in 18% (n = 36) the practitioner decided not to participate because of lack of time. Two hundred six practitioners participated in the study (51%, n = 105 women) within an age range of 23-68 years (mean age, 40 ± 9.9 years).

A total of 230 sterilizers were included, 62 autoclaves (55%; n = 34 of foreign origin) and 168 dry heat (93%; n = 156 of Mexican