Monitoring the physical processes of sterilization in hospitals in the state of Goiás*

O MONITORAMENTO DE PROCESSOS FÍSICOS DE ESTERILIZAÇÃO EM HOSPITAIS DO INTERIOR DO ESTADO DE GOIÁS

MONITOREO DE PROCESOS FÍSICOS DE ESTERILIZACIÓN EN HOSPITALES DEL INTERIOR DEL ESTADO DE GOIÁS

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ABSTRACT

The objective of this descriptive study was to identify the physical, chemical and biological controls of the sterilization process by saturated steam in Pasteur autoclaves at Material and Sterilization Centers (MSC). The data was obtained by interviewing the worker responsible for the MSC of the largest hospital in every city in the interior of Goiás that had population of at least 20,000, in the period from August 2005 to June 2006. A total 44 municipalities participated. The analysis was performed using SPSS software. In 31 (94.0%) hospitals there were no nurses exclusive to the MSC, the workers responsible for the center were nursing aides and technicians. Most did not perform any physical, chemical and biological control of the sterilization process, and, in one case only these controls were performed simultaneously. Failing to monitor the sterilization cycles, and thus not ensuring the quality of the processes, is a risk to the population being assisted.

DESCRIPTORS

Sterilization
Cross infection
Quality control
Central Supply, Hospital
Nursing

RESUMO

Estudo descritivo com o objetivo de identificar a realização de controles físicos, químicos e biológicos dos processos de esterilização pelo vapor saturado sob pressão e em estufas de Pasteur em Centros de Material e Esterilização - CME. Os dados foram obtidos por meio de entrevista ao responsável pelo CME do maior hospital de todas as cidades do interior do Estado de Goiás, com número de habitantes igual ou superior a 20.000, no período de agosto de 2005 a junho de 2006. Participaram 44 municípios. Foi utilizado o programa SPSS, para análise. Em 31 (94,0%) hospitais não havia enfermeiros exclusivos no CME, os responsáveis eram técnicos e auxiliares de enfermagem. A maioria não realizava os controles físicos, químicos e biológicos dos processos de esterilização e, em apenas um, esses eram realizados simultaneamente. O descumprimento da monitorização dos ciclos de esterilização, impedindo a garantia da qualidade dos processos, representa risco à população assistida.

DESCRITORES

Esterilização
Infecção hospitalar
Controle de qualidade
Almoxarifado Central Hospitalar
Enfermagem

RESUMEN

Estudio descriptivo que objetivó identificar la realización de controles físicos, químicos y biológicos de procesos de esterilización por vapor saturado bajo presión y en estufas de Pasteur en Centros de Material y Esterilización - CME. Datos obtenidos mediante entrevistas a responsables de CME del mayor hospital de todas las ciudades del interior del estado de Goiás, con número de habitantes mayor a 20.000, en período de agosto 2005 a junio 2006. Participaron 44 municipios. Se utilizó el programa SPSS para el análisis. En 31 (94%) hospitales no había enfermeros exclusivos en el CME, los responsables eran técnicos y auxiliares de enfermería. La mayoría no realizaba controles físicos, químicos y biológicos de los procesos de esterilización y, en apenas uno, estos eran realizados simultáneamente. El incumplimiento del monitoreo de los ciclos de esterilización, impidiendo la garantía de calidad de procesos, representa un riesgo para la población atendida.

DESCRIPTORES

Esterilización
Infección hospitalaria
Control de calidad
Central de Suministros en Hospital
Enfermería

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INTRODUCTION

Infections related to health delivery are complications that arise from diagnostic and therapeutic procedures and represent one of the main problems in quality of care. These can be classified as endogenous when the causative agents are present in the individual him/herself and as exogenous when microorganisms come from the external environment[1].

Controlling exogenous infections related to health services depends on the prevention practice of professionals in the field in relation to a series of measures such as the reprocessing of dental-medical-hospital material, which is an important measure of anti-infectious protection and includes validation and monitoring of all stages[1].

The validation of sterilization depends on a set of various stages called 'qualification', with certification of the suitability of these parameters. Among these is the validation of the performance of the sterilizing device that is accomplished by physical, chemical and biological controls, the purpose of which is to ensure that the probability of survival of microorganisms is below 10^{-6}[2-3].

The survival of microorganisms after sterilization can result from human and/or mechanical failure. The regular monitoring of the process is an integral part of the factors that avoid such failures that can interfere in sterilization efficiency[3].

All dental-medical-hospital material should be in a safe condition (be reprocessed before the next use) and be free of viable microorganisms, minimizing the risk of infectious iatrogenies[1-3].

The type of reprocessing depends on the potential risk of transmission of microorganisms to the patient through the material used. Material considered critical is that which comes into direct contact by invasive procedures with sites considered sterile. Sterilization is recommended for critical material[2-4].

Sterilization is the process by which all forms of microbial life are destroyed such as fungus, viruses, and bacteria in vegetative and spore forms and can be performed by physical, chemical and physical-chemical means. The physical processes include sterilization by saturated steam under pressure and dry heat – Pasteur's oven[2-3].

Sterilization by saturated steam under pressure is performed in autoclaves and its principle of destroying microorganisms includes the combined action of time, temperature, pressure and humidity, which promotes thermo-coagulation and denaturation of proteins from their cellular genetic structure. There are also gravity and pre-vacuum autoclaves[5].

Dry heat sterilization is performed by a gravity or mechanical convection oven. An oven is an electrical apparatus that propagates dry heat, has low penetrating power, where sterilization occurs in an irregular and slow manner. Destruction of microorganisms occurs through cellular oxidation and desiccation[2,4].

Ensuring safety while reprocessing dental-medical-hospital material is an important measure in controlling infections associated with health care. The chain of transmission of microorganisms can be interrupted through sterilization. However, for sterilization to be effective one needs to have knowledge and properly perform each phase of this reprocessing: cleansing, drying, preparation, sterilization itself and storage[6-8]. From this perspective, efforts have been made toward the construction of quality indicators concerning the structure, process and results of sterilization, seeking to measure each of these stages[3,6].

Since the infectious process depends on various factors, specifically identifying failures in the sterilization of material as the causal factor of infections is difficult, however, there are mechanisms to rule out this potential source through quality control of each stage from cleansing to ensuring the efficiency of the sterilization cycle[1-3,6].

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Sterilization monitoring should encompass physical, chemical and biological evaluations of the sterilization process. Physical control includes the monitoring of critical parameters of each process through manual recording or by a printer connected to the sterilizer. Different indicators and integrators of chemical control are available on the market in different presentations. Biological indicators are characterized by a standardized preparation of bacterial spores designed to produce suspensions with 10^5 to 10^6 spores per unit of paper filter. Bacterial species differ according to the sterilization process. There are first, second and third generations of indicators[1-3].

Considering the complexity and importance of controls to ensure the quality of the sterilization processes as well as its contribution to prevent and control infections, this study intends to provide a situational diagnosis concerning these indicators. Identifying the status of this context will ensure the quality of the processes both at an institutional level and in terms of health inspection.

OBJECTIVE

To identify the physical, chemical and biological controls performed in sterilization by saturated steam under pressure and dry heat (Pasteur's oven) in the Sterilization and Supply Centers (SSC) of hospitals in the cities in the interior of Goias, Brazil.

METHOD

This descriptive study was carried out in all the cities in the interior of Goias, GO, Brazil with a population equal to or greater than 20,000 inhabitants. A total of 45 cities were considered eligible according to data provided by the Brazilian Institute of Geography and Statistics (IBGE)[9]. One hospital was selected in each city, the one with the greatest number of beds.

The project was approved by the Ethics Committee for Medical Human and Animal Research of the General Hospital of Goiania, protocol nº 110/05. The population was composed of the technical supervisors of the SSC of the hospitals registered in the DATASUS[10]. Data were collected through interviews following a structured script, which was held with the technical supervisors of each SSC from August 2005 to June 2006. The facilities' directors and technical supervisors signed free and informed consent forms according to Resolution 196/96[11]. Data collection was carried out by one of the researchers in each city.

The script contained data characterizing the institutions, technical supervisors and information on the physical methods of sterilization and physical, chemical and biological tests for control quality used by the hospitals concerning types, periodicity and records forms.

The Statistical Package for Social Sciences (SPSS) version 16.0 was used for data analysis. Data were presented in tables and figures and descriptive statistics was used to present measures of simple frequency.

RESULTS AND DISCUSSION

Of the 45 eligible hospitals, 44 were included in the study. The hospital in one city was being re-built. No nurses were available in 11 (25.0%) facilities; 31 (94.0%) out of the 33 (75.0%) facilities that had nurses available, did not have exclusive nurses for the SSC and nursing technicians and auxiliaries were those responsible for the unit; only two (6.0%) facilities had nurses assigned exclusively to the SSC.

Reprocessing of material performed by non-qualified personnel may compromise its quality. The responsibility for the SSC, its maintenance, validation and control of the routine of sterilization methods should be designated to a properly qualified person[2]. Hence, the presence of a nurse exclusively dedicated to the SSC is extremely important[2]. It is worth noting that the SSC is essentially composed of the nursing team workforce, with the exception of workers for administrative support, hygiene and cleansing. Therefore, according to the Federal Council of Nursing, law Lei n° 7.498[12], nurses should supervise the staff.

A study performed in 74 public and private hospitals, from medium to large, in the city of São Paulo, SP, Brazil, identified that there was a nurse responsible for the SSC[13] in 95.9% of the cases. An inverse situation of that found in this study. The validation of sterilization methods also depends on the human element, which should be trained to properly perform the stages of material reprocessing[2,4,14]. Professionals who graduated from high school are apt for the technical activities inherent to the process but it is recommended they be under the direct coordination and supervision of a nurse who should respond quality control issues[1,2].

Table 1 – Physical methods of sterilization used for reprocessing material in hospitals in the cities of the interior of Goias, GO, Brazil – 2006

Sterilization methods	N	%
Autoclave	29	66.0
Autoclave and oven	14	31.8
Oven	01	2.2
Total	44	100.0

Note: (n = 44)

The sterilization methods adopted in the hospitals are described in Table 1. Most (97.8%) used sterilization in autoclaves, the method of choice for critical material because it fills in the operational requirements of suitability, time, cost and safety. However, Pasteur's oven was also adopted in 15 hospitals and it is a method that tends to disappear given technical advancements and operational difficulties, aspects that should be observed since they interfere in the material's final quality[2-4,].

Table 2 shows the characterization of autoclaves and the monitoring methods used for this equipment.

Table 2 – Characterization of the sterilization process by saturated steam under pressure in hospitals in cities of the interior of Goias, Go, Brazil – 2006

Variables	N	%
Type of autoclave in use		
Gravity	34	77.2
Prevacuum	08	18.2
Does not have autoclave	01	2.3
No information	01	2.3
Total	44	100.0
Monitoring method		
Physical, chemical and biological	01	2.3
Physical and chemical	01	2.3
Chemical and biological	05	11.6
Chemical	36	83.8
Total	43*	100.0

*One hospital had no autoclave.
Note: (n = 44)

There was a predominance of gravity autoclaves (77.2%), with the pre-vacuum type found in only eight (18.2%) hospitals. One hospital did not have an autoclave and the in-

formation was not reported in another. A gravity autoclave removes oxygen by gravity because the steam injection in the chamber forces cold air to exit through a valve located in its low portion. Time of sterilization is longer and there is a greater chance of the formation of bulbs inside the package, interfering with the quality of sterilization[1-2].

Pre-vacuum steam autoclaves have a vacuum pump that removes air from the chamber and from the material through one or three pulsating cycles, which better allows steam to penetrate into the packages. Time of exposure, sterilization and drying are reduced when compared to the gravity autoclave[2-4]. The pre-steam system is recommended given the improved conditions it offers for the sterilization cycles, and, consequently, for the final process.

In relation to monitoring, data found in this study are of concern, since only one (2.3%) hospital simultaneously performed physical, chemical and biological controls. Most (36/83.8%) used only chemical controls.

Physical, chemical and biological controls are part of the qualification and monitoring of performance, to check whether the conditions of a given sterilization process actually ensure the method's effectiveness and efficiency[1]. Isolated chemical control (different classes) is not satisfactory to ensure the sterilization process's effectiveness. Similar data were found in a study investigating Health Units in Goiania, GO, Brazil, which also found a predominance of a class 1 chemical indicator in the autoclaves of dental services[15]. Another study showed that 96.0% of the hospitals in the Southeast of São Paulo used biological indicators and 47.3% also used chemical indicators[13].

In relation to physical monitoring, only one (2.3%) service properly performed it; records were sent to the equipment's printer (Table 3).

Table 3 – Physical indicators used in the reprocessing of material by saturated steam under pressure in hospitals of cities in the interior of Goias, GO, Brazil – 2006

Variables	N	%
Monitoring of physical parameters		
Yes	01	2.3
No	42	97.7
Total	43	100.0
Autoclave maintenance		
Corrective	30	69.7
Preventive and corrective	13	30.3
Total	43	100.0
Frequency of preventive maintenance		
Monthly	06	46.2
Biannual	03	23.0
Biweekly	01	7.7
Bimonthly	01	7.7
Quarterly	01	7.7
Occasionally	01	7.7
Total	13	100.0

Note: (n = 43)

Records concerning the required parameters for the sterilizing method should be kept. Saturated steam under pressure includes temperature, time and pressure (preferably automatically taken). If the sterilizer has no printer connected, this record should be manually noted every minute and is a document used for legal purposes[1-4]. It is worth keeping in mind that mechanical failures that prevent the process may occur during the cycle and these can be verified by simply systematically consulting these parameters. The costs incurred for the hospital are linked to human resources, which reiterates the importance of monitoring physical parameters during cycles.

Periodical preventive and/or corrective maintenance is also recommended and the problem and solution adopted should be recorded[2]. Only 13 (30.3%) facilities performed preventive and corrective maintenance and most (69.7%) performed only corrective maintenance, indicating that maintenance on equipment was only performed when the equipment was no longer working.

There are however different preventive procedures to be performed daily, weekly, and biweekly, varying according to the procedure. Preventive maintenance should occur daily, weekly, and biweekly such as concurrent cleaning of the chamber, lubricating the trim, cleaning the chamber with a product for rust removal, respectively, according to the manufacturer's recommendations. These tasks can be performed by a nursing technician qualified for the task while monthly and annual procedures should be performed by a specific and able professional[4]. Monthly preventive maintenance was reported by six (46.2%) hospitals.

Table 4 presents the chemical and biological indicators used in autoclaves and steam by the hospitals.

Table 4 – Chemical and biological indicators used by hospitals in the cities of the interior of Goiás to evaluate the saturated steam under pressure sterilization – Goiania, GO, Brazil - 2006

Variables	N	%
Chemical indicators		
Class I – thermochromic tape	43	100.0
Class II – Bowie-Dick* test (n=8)		
Yes	03	37.5
No	05	62.5
Biological Indicators		
Yes	07	16.3
No	36	83.7
Frequency		
Monthly	04	57.1
Weekly	01	14.3
4 to 6 months	01	14.3
Monthly and when there is a surgery with infection	01	14.3

* Eight hospitals had prevacuum autoclave
Note: (n = 43)

Chemical monitoring should be performed by indicators and integrators that undergo chemical and physical changes when exposed to a sterilization process, evaluating one or more parameters of the process, aiming to internally and externally control the package to be sterilized. These are essential to monitor failures and constitute an instrument to ensure the quality of the process[1-4].

Six classes of chemical indicators are currently available: Class I (process indicators) whose function is to identify and differentiate the material to be processed from those that were not processed (thermochromic tape); Class II – the Bowie & Dick test (indicator for use in a specific test) the purpose of which is to test the efficacy of the vacuum system in the pre-vacuum autoclave, detecting failures in the vacuum pump's functioning and consequently the presence of residual air; Class III (single parameter indicators) is designate to react to a specific parameter; Class IV (multiparametric indicators) responds to one or more critical parameters; Class V (integrator indicators) reacts to all critical parameters in the sterilization process; Class VI (simulation/emulator indicators) monitors all the critical parameters of the sterilization process, and does not react until approximately 94% of the cycle is concluded. To use this integrator, the user has to associate the parameters of the sterilizer to the specifications of a given Class VI integrator[1-4].

The use of thermochronic tape (class I) was reported by all the services that had an autoclave. The tape's function is to discriminate between reprocessed and non-reprocessed material, though its isolated use is inefficient to ensure the quality of saturated steam under pressure. The Bowie and Dick test (class II) was used in three hospitals, that is, less than half used pre-vacuum autoclaves. Of those using it, two adopted the daily frequency recommended by the Ministry of Health[4]. This test presents a very positive cost-benefit relation and is extremely important as an indicator in the steam sterilization process. The test, recommended to be used in the first load in the morning after the equipment is heated, shows the presence of residual air in the chamber. The equipment should not be used when the test indicates positive, because air is a barrier to steam[1-3].

Most (83.7%) of the hospitals did not use a biological indicator and among those (16.3%) that did, the second-generation test was used and only one hospital adopted the recommended minimum weekly frequency. The test should be performed with every load containing implantable material[2-4].

The biological indicator consists of one standardized preparation of bacterial spores engineered to produce suspensions containing 10^6 spores per unit of filter paper. The method ensures that the set of all sterilization critical parameters is appropriate, because the microorganisms are directly tested for growth after the application of the process[1-3]. Thus, the data found in this study are of concern, since a minority of hospitals performed biological monitoring

The Pasteur's oven is not a first-choice piece of equipment for the physical sterilization of dental-medical-hospital material[2-4]. The parameters that determine the quality of sterilization in this method are: relationship between time/temperature, use of adjunct thermometer, putting a small quantity of material inside the wrappers, not surpassing 2/3 of the chamber's capacity, correctly disposing of boxes inside the chamber, keeping the door close during the entire cycle, performing chemical and biological monitoring with *Bacillus atrophaeus* and, preventive maintenance[1-2,4,6]. Data concerning the use of this equipment are described in Table 5.

Table 5 – Variables of the sterilization process in ovens in hospitals in cities in the interior of Goias, GO, Brazil - 2006

Variables	N	%
Relation time/temperature		
Indicated	04	26.7
Not indicated	10	66.6
Did not inform	01	6.7
Monitoring by adjunct thermometer		
Yes	06	40.0
Not	09	60.0
Chemical control, class I		
Yes	11	73.4
Not	04	26.6
Biological control		
Yes	01	6.6
Not	14	93.4

Note: (n = 15)

Non-recommended practices predominated in relation to time/temperature. The values recommended by the Ministry of Health for dry heat sterilization are 170°C for one hour of exposure or 160°C for two hours[7]. This relation is essential for ensuring efficacy of the cycle, noting that timing of exposure should begin only when a given temperature is reached; time spent to heat the equipment should not be taken into account[1,7]. A study conducted in 101 dental offices in the central region of Goiania concluded that intervenient factors with greater significance related to sterilization failures were: not complying with the time/temperature ratio recommended for the sterilization cycle and the absence of an adjunct thermometer to control the temperature of the cycles, aspects ratified in microbiological tests that were positive in 46 (45.5%) of the evaluated cycles[16]. Similar data were found in other studies that evaluated sterilization in Pasteur's ovens in dental offices[17-18].

The use of an adjunct thermometer is essential to determine the temperature, which in this study was used only by a minority (40.0%). Temperatures taken from two different thermometers diverge because the thermometer in the device shows a temperature higher than that reached within the load; the reason is that the device's thermometer is closer to the equipment's electrical circuits[1,7]. These findings also coincide with those of other studies[15-18].

A study carried out in Canoas, RS, Brazil in 27 dental offices revealed that an adjunct thermometer was used in 24 (88.9%) offices, which shows better sterilization control when compared to data from this investigation[19].

Chemical indicators specific for monitoring the Pasteur's oven are: Class I (thermo-chromic tape for external use) and class IV (tape indicating the internal use turning after five minutes after reaching temperature of 170°C). These indicators do not prove sterilization occurred but provide evidence as to functioning problems in the equipment[1-4]. The use of a chemical indicator (class I) predominates in the use of ovens.

Bacillus atrophaeus are used for monitoring the biological process of dry heat sterilization. These indicators should be used in ovens at the time they are installed, weekly and after each corrective and preventive maintenance task. The indicators check whether the materials were successfully sterilized, which is indicated by the death of all spores in the biological indicator used to test[1-4].

The biological indicators available in the market specific for Pasteur's oven are paper strips inoculated with spores – first generation indicators with a definitive reading after seven days[1]. In this study, only one service performed biological monitoring in the ovens weekly. Studies show a low level of adherence to chemical and biological monitoring methods in the process of oven sterilization[16-17,20].

CONCLUSION

This study leads to the conclusion that most of the hospitals did not follow physical, chemical and biological control of the sterilization cycles in autoclaves by saturated steam under pressure. Class I chemical indicators were predominant in Pasteur's ovens. Only one hospital performed physical, chemical and biological control simultaneously.

The low valorization of physical parameters draws one's attention. Such parameters can be considered *primary* for monitoring the equipment functioning both in relation to the maintenance of equipment and to parameters of sterilization cycles. Only one hospital recorded the physical monitoring (temperature, pressure, time) in all the cycles and verified the performance of only corrective maintenance of autoclaves. For the ovens, the monitoring conditions are even worse, since most hospitals adopted a non-recommended relation between time and temperature and there was a low level of use of adjunct thermometers to measure the temperature.

Despite all the technology available for quality control in reprocessing material, human resources are those responsible for appropriate compliance of all the operational stages. Some situations, such as performing physical control by monitoring sterilization parameters, depend exclusively on human resources for successful completion, both at the managerial and care levels. Hence, the importance of having an exclusive nurse for the SSC who is responsible for monitoring reprocessing quality becomes apparent. A nurse assigned exclusively to the SSC, though, was found in only two hospitals. Moreover, it shows the need for nurses to be appropriately qualified to deal with the complexity of an SSC.

The absence of a nurse in 25% of the hospitals means that technical supervisors (nursing technicians and auxiliaries) worked without even an indirect supervision of nurses. The lack of a qualified nurse to coordinate SSC is evidenced throughout this study when technical supervisors were not able to provide information requested, revealing a lack of knowledge, which actually became a limitation of this study. It is worth noting that failures in sterilization control can reflect on the quality of care delivery; these failures represent a risk factor for infections.

The results of this study are expected to support educational and surveillance actions for safe practice in reprocessing materials, while the greatest recipients of such quality are the clients and then, by extension, medical professionals and facilities.

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