EVALUATION OF CLEANING AND DISINFECTION PERFORMANCE OF AUTOMATIC WASHER DISINFECTORS MACHINES IN PROGRAMS PRESENTING DIFFERENT CYCLE TIMES AND TEMPERATURES[1]

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Thermal washer-disinfectors represent a technology that brought about great advantages such as, establishment of protocols, standard operating procedures, reduction in occupational risk of a biological and environmental nature. The efficacy of the cleaning and disinfection obtained by automatic washer disinfectors machines in running programs with different times and temperatures determined by the different official agencies was validated according to recommendations from ISO Standards 15883-1/1999 and HTM2030 (NHS Estates, 1997) for the determining of the Minimum Lethality and DAL both theoretically and through the use with thermocouples. In order to determine the cleaning efficacy, the Soil Test, Biotrace Pro-tect and the Protein Test Kit were used. The procedure to verify the CFU count of viable microorganisms was performed before and after the thermal disinfection. This article shows that the results are in compliance with the ISO and HTM Standards. The validation steps confirmed the high efficacy level of the Medical Washer-Disinfectors. This protocol enabled the evaluation of the procedure based on evidence supported by scientific research, aiming at the support of the Supply Center multi-professional personnel with information and the possibility of developing further research.

DESCRIPTORS: disinfection, validation studies [publication type], colony count, microbial, technology/instrumentation

EVALUACIÓN DEL DESEMPEÑO DE LA LIMPIEZA Y DESINFECCIÓN DE LAS MÁQUINAS LAVADORAS DESINFECTADORAS AUTOMÁTICAS EN PROGRAMAS CON DIFERENTES TIEMPOS Y TEMPERATURAS

La lavadora termo-desinfectadora es una tecnología que ha traído grandes ventajas, como los protocolos, la standardización de procedimientos, la documentación del proceso, la reducción del riesgo ocupacional biológico y ambiental. El desempeño de la limpieza y desinfección realizado por máquinas lavadoras desinfectadoras automáticas en programas con diferentes tiempos y temperaturas recomendados por distintos órganos oficiales ha sido validado conforme las recomendaciones de las Normas ISO 15883-1/1999 y HTM 2030 (NHS Estates, 1997) para el cálculo teórico y con termopares de Letalidad Mínima y DAL. Para evaluar el resultado de la limpieza se utilizó Soil Test, test Biotrace Pro-tect y Test Kit Proteina. El procedimiento de contabilidad de UFC de microorganismos viables ha sido realizado antes y después de la termo-desinfección. Este artículo demuestra que los resultados están en conformidad con las Normas ISO y HTM. Las etapas validadas comprueban el excelente desempeño de las lavadoras desinfectadoras como instrumentos de desinfección de alto nivel. Este protocolo ha permitido evaluar la práctica basada en la evidencia y fundada en la pesquisa científica, para que la equipe de profesionales del Centro de Materiales pueda ser subsidiada con informaciones y desarrollar nuevas pesquisas.

DESCRIPTORES: desinfección; estudios de validación [tipo de publicación]; recuento de colonia microbiana; tecnología/instrumentación

AVALIAÇÃO DO DESEMPENHO DA LIMPEZA E DESINFECÇÃO DAS MÁQUINAS LAVADORAS DESINFECTADORAS AUTOMÁTICAS EM PROGRAMAS COM DIFERENTES TEMPO E TEMPERATURA

A lavadora termodesinfectadora é uma tecnologia que trouxe grandes vantagens como protocolos, padronização dos procedimentos, documentação do processo, redução do risco ocupacional de ordem biológica e ambiental. O desempenho da limpeza e desinfecção das máquinas lavadoras desinfectadoras automáticas, em programas com diferentes tempos e temperaturas preconizados por distintos órgãos oficiais, foi validado, conforme as recomendações das Normas ISO 15.883-1/1999 e HTM2030 (NHS Estates, 1997) para cálculo teórico e com termopares da Letalidade Mínima e DAL. Para avaliação do resultado da limpeza, foram utilizados Soil Test, teste Biotrace Pro-tect e o Teste Kit Proteína. O procedimento de contagem de UFC de microrganismos viáveis foi realizado antes e após termodesinfecção. Este artigo mostra que os resultados estão em conformidade com a Norma ISO e HTM. As etapas validadas comprovam desempenho excelente das Máquinas Lavadoras Desinfectadoras como desinfecção de alto nível. Este protocolo permitiu avaliação da prática baseada na evidência e fundamentada na pesquisa científica, para que a equipe multiprofissional do Centro de Material possa ser subsidiada com informações e desenvolver novas investigações.

DESCRITORES: desinfecção; estudos de validação [tipo de publicação]; contagem de colônia microbiana; tecnologia/instrumentação

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INTRODUCTION

Changes in health care have occurred at an unprecedented speed, including, for example: emergence of infections by recently-identified pathogens, introduction of more complex equipment and technologies and care tendencies. As a consequence of this change, hospital care is increasingly concentrated on care for seriously-ill patients and, therefore, susceptible to hospital infections.

Infection prevention and control is complex and depends on scientific knowledge and evidence and technical skills. Each care-related action requires the application of relevant knowledge, including specific topics in microbiology, immunology, epidemiology, engineering and personal and environmental hygiene.

Different hospital device cleaning and disinfection procedures are used on a large scale. This gave rise to the opportunity to study the efficacy of washer-disinfector machines for cleaning and disinfection, due to concerns about contamination risks caused by handling articles without the use of protection equipment and without correct standardization, as well as about environmental contamination by waste after cleaning[1].

The cleaning of work environment and devices is a factor of utmost importance, as its incorrect realization entails serious problems in subsequent steps[2-3]. In this area, there has been considerable technological evolution, with various types of washing machines, such as: ultrasonic, disinfecting, pasteurizing and sterilizing, besides the technological development of materials like enzymatic detergents, dirt residue tests and protein residue detection tests[4-6]. In the European Community, thermal washer-disinfectors operate with different running times and temperatures, determined by official organs in different countries, causing difficulties in our context to choose the program selection[1-6]. In Brazil, there are neither operating standards nor guidelines to assess these washer-disinfectors. Therefore, we use standards adopted in the countries of origin and manufacturer guidelines.

This research was carried out to make it easier for Supply Center nurses to safely choose different cleaning and disinfection programs in automatic washer-disinfector machines, as a foundation for evidence-based practice.

OBJECTIVES

The general study objective was to assess the efficacy of the cleaning and disinfection obtained by automatic washer-disinfector machines in running programs with different times and temperatures, determined by different official agencies. Specific objectives were: to assess the efficacy of mechanical cleaning and thermal disinfection by automatic washer-disinfector machines in running programs with different times and temperatures; to calculate and analyze Minimum Lethality - A0 levels and Disinfection Assurance Level - DAL in the washer-disinfector equipment in view of different disinfection programs, comparing them with theoretical calculations.

MATERIAL AND METHOD

We carried out a quantitative applied evaluation study in two different laboratories. The methodological framework consisted of the ISO 15.883-1-4/1999 and HTM 2030 (NHS Estates, 1997) standards[2,7]. The operational phase was realized with thermal washer-disinfector devices in the Supply and Sterilization Central of a private hospital in the city of São Paulo, Brazil.

Microbiological analyses were performed at the Bromatology and Chemistry Division, Sterility Control Section of the Adolfo Lutz Institute, under the responsibility of a pharmacist, using a Miele® thermal washer-disinfector, model G7736-CD MCU - Microcomputer-controlled Unit. The equipment offers 15 programs of broad application which can neither be modified nor deleted; programs 16 and further can be created, installed or deleted by specialized technical assistance. Before starting the study, the equipment was subject to maintenance by specialized technical assistance, and the programs to be assessed were revised. The inserted programs contained three cleaning programs. Mechanical cleaning time was set at one minute with detergent, followed by a one-minute rinsing phase, with disinfection time and temperature according to established standards. In all programs, the cleaning phase was assessed using Endozime A W Plus detergent, manufactured by Ruhof®, dispensing a total of 18 ml in each of the three cleaning process phases.

In the validation process, performance was qualified by a specialized company, under the responsibility of an engineer who was accompanied

by the researcher, in line with ISO 15.883-1-2-3-4/ 1999 and HTM 2030 recommendations and requirements.

Three resources were used to assess cleaning efficacy: the Residue Test Soil Test®, Biotrace Pro-tect® Protein Residue Test and the Miele Merck® Protein Test Kit; the chosen instruments were used in routine surgical procedures, such as: acetabular broach, femoral broach, Crile forceps, Kelly forceps, Hartman forceps, Debakey forceps, Kerrison, Glover Vascular clamps and others. Standard HTM 2030 was taken as the base to choose and determine the quantity of instruments for the test.

The Cleaning Assessment Phase occurred in the same way in all programs. The Soil and Biotrace Pro-tect Tests was assessed in three mechanical cleaning cycles. The Soil Test was applied to 313 instruments. Five of these presented Soil Test residues after visual evaluation. Due to their complex structure, they were also submitted to the Biotrace Pro-tect protein residue test. This test was applied to 65 instruments, assessing 20 in each cycle. A control test was used in each assessment.

The protein residue test - Miele Protein Test Kit was separately applied in three consecutive mechanical cleaning cycles, assessing 141 instruments, 47 in each cycle. A control test was used in each assessment.

To qualify performance, cycles had to be carried out for three consecutive times, in accordance with ISO 15.883. Thus, each cycle consisted of 20 contaminated instruments, submitted to three cycles in each assessed protocol. After the thermal disinfection process, the test instruments were sent to the Bromatology and Chemistry Division, Sterility Control Section of the Adolfo Lutz Institute for the Identification of Initial and Final Viable Microorganisms.

For this phase, 60 instruments were intentionally contaminated with placenta blood after normal birth, maintaining contact with the placenta for one hour. This time was chosen based on real data about intraoperative time, time to dismount the surgical room, time to receive the purification and preparation of instruments for the cleaning and disinfection procedure.

After contamination, excess residues were taken away with a jet of cold water under pressure and placed between the second and third support shelves of the thermal washer-disinfector. The other shelves were filled with contaminated material from the service under study. After the thermal disinfection cycle, the instruments were removed with the help of gloves and two gamma-irradiated polyethylene bags. The devices were placed in the packing using an aseptic technique and sealed; next, they were identified and externally packed in resistant polyethylene.

RESULTS

Results of the Dirt and Protein Residue Tests to Assess the Mechanical Cleaning Process.

Table 1 - Residue Frequency Distribution assessed by Soil Test, Biotrace Pro-tect and the Miele® Protein Test Kit. São Paulo, 2003

Detection method	Visual Inspection		Colorimé trico		Colorimé trico			
Mechanical cleaning performance	Soil Test	%	Pro-tect Biotrace	%	Teste Kit Proteína Miele	%	Total	%
Presence of protein dirt	5	1,6	5	8	0	0	10	1,9
Absence of protein dirt	308	98,4	60	92	141	100	509	98,1
Total	**313**	**100**	**65**	**100**	**141**	**100**	**519**	**100**

According to data in Table 1, Soil Test residues were found in five (1.6%) assessed instruments. The absence of Soil Test residues was found in 308 (98.4%) cases, totaling 313 instruments.

The Soil Test residues were observed on the following instruments: one Ruskin Rongeur, one Leksell Gouge, one Luer Stille Gouge, one Stille Liston Rongeur, one Kerrison. In some devices, the central link was dismounted to permit opening and access for mechanical cleaning; however, other manufacturing models and brands did not offer this possibility.

Sixty instruments (92.0%) presented negative results on the Protein Residue test - Biotrace Pro-tect. The same test was applied to the five (8.0%) instruments that showed residues on the Soil Test, and the results confirmed protein presence.

For the sake of control, the Protein Residue Test - Biotrace Pro-tect was applied to an instrument with organic matter. The color evolved to purple, demonstrating test functionality. The tests performed with the Miele® Protein Test Kit produced negative results on all 141 (100%) tested instruments.

In total, we assessed 519 instruments, and found absence of dirt and protein in 509 (98.1%). In 10 (1.9%) instruments, the presence of dirt and protein residues could have been different if the critical structure of these instruments had been rigorously observed, dismounted and submitting these devices to manual or mechanical cleaning before the thermal disinfection process.

Result of the Thermal Qualification of Washer-Disinfector Machines, according to the BGA, HTM, RIVM, SIS Standards and in running cycles with Pasteurization Time and Temperature.

This step was performed by an engineer responsible for a specialized validation company and the researcher. Tests were performed in empty and loaded cycles. According to the protocol, the following recommendations and requirements were adopted: GMP/FDA 21 CFR Part. II, GHTF Study Group 3 - Quality Systems - Process Validation Guide, ISO 15.883:1999 and HTM 2030.

Table 2 - Result of Thermal Distribution Study in Thermal Disinfector in Empty and Loaded Cycles, according to BGA, DHSS/HTM, RIVM, SPRI/SIS standards and Cycle with Pasteurization Time and Temperature. São Paulo, 2003

Cycle Time	BGA 10 minutes	Great-Britain 1 second	Great-Britain 2 minutes	Pasteurization 30 minutes	Holland 5 minutes	Sweden 1 minute	Sweden 3 minutes
			Temperature				
Set-Point	95,0ºC	90,0ºC	82,0ºC	70,0ºC	90,0ºC	85,0ºC	85,0ºC
Max. Empty C.	95,7ºC	90,5ºC	83,2ºC	71,6ºC	91,1ºC	86,2ºC	86,0ºC
Mean Empty C.	94,5ºC	89,8ºC	82,8ºC	70,7ºC	90,8ºC	85,9ºC	85,4ºC
Min. Empty C.	92,9ºC	87,6ºC	81,9ºC	69,5ºC	90,3ºC	85,4ºC	84,9ºC
Max. Load C.	95,1ºC	90,3ºC	83,4ºC	72,8ºC	91,5ºC	86,5ºC	86,7ºC
Mean Load C.	94,5ºC	89,9ºC	82,9ºC	71,0ºC	91,1ºC	86,0ºC	86,3ºC
Min. Load C.	93,4ºC	88,5ºC	82,3ºC	70,4ºC	90,5ºC	84,6ºC	85,4ºC
Same Sensor	< ± 1ºC	< ± 1ºC	< ± 1ºC	< ± 1ºC	< ± 1ºC	< ± 1ºC	< ± 1ºC
Between Sensors	< ± 2ºC	< ± 2ºC	< ± 2ºC	< ± 2ºC	< ± 2ºC	< ± 2ºC	< ± 2ºC
Situation	Approved	Approved	Approved	Approved	Approved	Approved	Approved

The performance qualification of the thermal washer-disinfector was carried out in the empty and loaded cycles. Twelve thermocouples were used. All protocols presented a variation of < ± 2ºC between sensors and < ± 1ºC between the same sensor, below levels determined by ISO15883-1/1999 and HTM 2030 (NHS Estates, 1997). In all cycles, sensor 7 demonstrated a variation superior to ± 1ºC, during exposure, due to its placement close to the water heating reservoir. Therefore, its results were ignored in the final result interpretation. Distribution studies were repeated for each type of protocol we mentioned, without any changes outside established standards, so that all cycles were considered approved.

Result of Mean Count of Viable CFU found after the Thermal Disinfection Cycles, Calculation of required Minimum Lethality and Disinfection Assurance Level according to ISO 15883-1/1999, obtained Theoretically and with Thermocouples, in line with BGA, HTM, RIVM, SIS Standards, for running cycles with Pasteurization Time and Temperature.

Table 3 - Comparison between Mean Count of Viable CFU, Calculation of required Lethality and DAL according to ISO standard, results obtained theoretically and with Thermocouples, according to BGA, HTM, RIVM, SIS standards and Cycle with Pasteurization Time and Temperature. São Paulo, 2003

Standard	BGA	Great-Britain	Great-Britain	Pasteurization	Holland	Sweden	Sweden
Temperature	94ºC	90ºC	82ºC	70ºC	90ºC	85ºC	85ºC
Exposure Time	10.00 min	1.00 Sec	2.00 min	30.00 min	5.00 min	1.00 min	3.00 min
			Required Minimum Lethality and DAL				
Lethality	10,00 min	10,00 min	10,00 min	10,00 min	10,00 min	10,00 min	10,00 min
DAL	> 10^{-2}	> 10^{-2}	> 10^{-2}	> 10^{-2}	> 10^{-2}	> 10^{-2}	> 10^{-2}
			Mean Count of Viable CFU				
Initial CFU	10^{8}	10^{8}	10^{8}	10^{8}	10^{8}	10^{8}	10^{8}
Final CFU	<10^{2}	<10^{2}	<10^{2}	<10^{2}	<10^{2}	<10^{2}	<10^{2}
			Minimum Lethality and DAL Obtained with Thermocouples				
Minimum Lethality	318,2 min	26,42 min	7,76 min	3,88 min	85,76 min	12,09 min	20,17 min
DAL	1 x 10^{-307}	3,8 x 10^{-19}	1,7 x 100	1,3 x 10^{+4}	1,7 x 10^{-78}	8,1 x 10^{-5}	6,7 x 10^{-13}
Situation	Approved	Approved	Rejected	Rejected	Approved	Approved	Approved
			Theoretical Minimum Lethality and DAL				
Minimum Lethality	251,00min	0,17 min	3,17 min	3,00 min	50,00 min	3,16 min	9,48 min**
DAL	1 x 10^{-243}	6,76 x 10^{+7}	6,76 x 10^{+4}	1 x 10^{+5}	1 x 10^{-42}	6,92 x 10^{+4}	3,31 x 10^{-2}*
Situation	Approved	Rejected	Rejected	Rejected	Approved	Rejected	** Rejected * Approved

Data in Table 3 show the importance of assessing all theoretical and thermocouple parameters for A_0, DAL and initial and final CFU. Although this study has demonstrated a reduction of CFU below $<10^2$ in all protocols, this does not mean that they are approved. In the theoretical calculation of Lethality and DAL, two protocols were approved and five rejected, because they showed lower levels than those found during validation with thermocouples. In the validation with thermocouples, the approved protocols were: German Standard, BGA - time 10 minutes and temperature 94ºC, British Standard, HTM - time 1 second and temperature 90ºC, Dutch Standard, RIVM - time 5 minutes and temperature 90ºC and Swedish Standards, SIS - times 1 and 3 minutes and temperature 85ºC. The rejected protocols were: British Standard, HTM - time 2 minutes and temperature 82ºC, cycle of 30 minutes and temperature 70ºC used for pasteurization, which did not reach the levels set by ISO 15.883.

DISCUSSION

The Supply Center is one of the most important areas in the hospital environment, including the management, technical and human resource areas. In recent years, great changes have occurred in this field, reflecting on the professionals working there and on new cleaning, disinfection and sterilization technologies[2,7-8]. Thus, a critical and detailed assessment of the physical area is important with a view to promoting a safe work environment for professionals and procedures.

The detailed planning of equipment, accessories, materials and adequate instruments and other devices is needed for effective planning in surgery and other hospital areas. Cleaning and disinfection procedures in this context should follow the protocols and guidelines of material and equipment manufacturers[9-10]. Cleaning agents need to be tested before their approval. Adequate resources have to be assured for professionals, equipment and the work environment[9-11].

Professional qualification in this area is important. Therefore, training and constant verification of process knowledge and performance are both relevant and paramount. Equipment working in a closed system is safer for professionals, as it impedes the dissemination of aerosols in the area and decrease accident risks. The use of individual and environmental protection equipment should be required. Purification is considered a potentially contaminated area in the hospital environment[9,11]. HTM 2030 and ISO15883 Standards need to be used to validate thermal washer-disinfectors. In order to guarantee consistent results, a validation project should be established in accordance with the standards, which indicate the use of thermocouples for performance qualification. The Residue Soil Test and the Protein Residue Test are indicated to assess cleaning effectiveness in thermal disinfection. Viable microorganism counts are one value for nurses to calculate and obtain A_0 and DAL levels during the validation.

The comparison between the mean initial viable microbial load in the assessed instruments (10^8 CFU) and the viable microbial load during the assessment, after the thermal disinfection processes guided by different times and temperatures, in accordance with BGA, HTM, SIS, RIVM Standards and using running cycles with pasteurization time and temperature ($<10^2$ CFU) demonstrated no growth. Viable CFU counts are also important to get to know and assess the criticality of the instruments and establish the necessary cleaning processes the instrument needs to be subject to before the thermal disinfection process.

The performance qualification of the thermal washer-disinfector was realized on the basis of the BGA, HTM, RIVM, SIS Standards and using the cycle with Pasteurization time and temperature, using 12 thermocouples for the thermal distribution study, in the three empty and in the three loaded cycles. All protocols were considered approved. Minimum lethality calculations with thermocouples presented higher results than in theoretical calculations because, in the thermal disinfection process, minimum lethality starts to be accumulated as temperature increases, before the start of the disinfection phase.

The measurements with thermocouples can reveal both the insufficiency and the excess of the time-temperature relation. Thermocouples allow for measurements with high-precision wires, and results are available during and immediately after the end of the validation. Actual heat quantities can be directly compared by calculating A - Lethality and supply technical details about the procedures. An excessive time-temperature relation can be equally determined, as well as totally inadequate heating[6].

It needs to be certified whether these obtained theoretical values are in accordance with data obtained in the thermometric validation.

Important variables need to be taken into account in this process, such as: time, temperature, water quality and volume, types of detergents, dosage, lubricants and the washer model itself[4-12]. In order to certify these values, theoretical data need to be compared with the thermocouples and data obtained in the microorganism counts[6].

In performance qualification, the results of Minimum Lethality and DAL calculations need to be studied, assessed and applied. According to ISO 15883 and HTM2030, the recommended time for Minimum Lethality - A_0 was 10 minutes. The Disinfection Assurance Level - DAL was calculated on the basis of the initial known population 10^8. In order to guarantee an A_0 equaling 10 minutes, a = 10^{-2} reduction is needed[2,7].

The following protocols reached the established Minimum Lethality and DAL levels during thermal qualification with thermocouples: German Standard, BGA (94ºC/10 minutes); Dutch Standard, RIVM (90ºC/5 minutes); Swedish Standard, SIS (85ºC/1 minute); Swedish Standard, SIS (85ºC/3 minutes); British Standard, HTM (90ºC/1 second)

The protocols that did not reach the recommended Minimum Lethality and DAL during thermal qualification with thermocouples were: Pasteurization Time and Temperature (70ºC/30 minutes); British Standard, DHSS/HTM (82ºC/2 minutes).

The standards from different countries validated in thermal disinfector machines by means of thermocouples demonstrate that it is possible to achieve a reduction of the microbial load of Minimum Lethality and DAL superior to theoretical calculations when performing High-Level Disinfection. This provides foundations for our actions to follow scientific and technological evolutions at a Supply Center, supporting nurses with information. The importance of multiprofessional teamwork at the Supply Center needs to be disseminated and applied, so that the acquired knowledge can generate benefits for nursing care and professionals.

CONCLUSION

This study allows us to conclude that all established objectives were reached. The organizational structure of the Supply Center should evolve. A careful assessment of its physical area is needed with a view to improvements and the installation of adequate resources to carry out techniques in material traceability and professional and environmental safety. Protocols, procedures and written routines need to be validated in terms of applicability and to be readily available in each area, depending on its specific characteristics. Their results should be critically assessed to the benefit of patients, guaranteeing competence with accountability and high-quality practice.

In line with ISO 15883 and HTM2030 recommendations for cleaning efficacy assessment, the Soil Test, the Biotrace Pro-tect and the Protein Test Kit were used. Minimum Lethality and DAL concepts were applied during performance qualification to obtain results and compare theoretical calculations with results achieved through thermocouples. CFU counts of viable microorganisms were realized to assess thermal disinfection.

In each protocol, all assessments carried out before and after thermal disinfection indicate quality, according to our research results and literature reports proving that High-Level Disinfection is performed by means of thermal washer-disinfector machines. Minimum Lethality and DAL results above recommended standards guarantee the security and quality of this process.

ISO 15883-1-2-3-4/1999 and HTM 2030 standards permit the assessment of evidence and scientific research-based practice, allowing multiprofessional teams at sterilization units to act in infection prevention, carry out new studies and apply them in their reality, in accordance with available resources.

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