Temperature and humidity in the storage area of sterile materials: a literature review

TEMPERATURA E UMIDADE NO ARMAZENAMENTO DE MATERIAIS AUTOCLAVADOS: REVISÃO INTEGRATIVA

TEMPERATURA Y HUMEDAD EN EL ALMACENAMIENTO DE MATERIALES AUTOCLAVADOS: REVISIÓN INTEGRATIVA

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ABSTRACT

The recommendations for temperature (T°) and relative humidity (RU) for the storage of sterilized materials in Sterilization Central Supply (SCS) vary according to different sources, and are not based on theoretical frameworks or experiments. The practice shows difficulties in controlling these parameters, leading to doubts regarding the maintenance of the sterility of these materials. This article proposed, through a literature review, to identify and analyze the recommendations for T° and RU for the sterile storage area. We did not find any literature that justifies the referred recommendations. Seven articles were included which analyzed the variables T° and RU in the storage area as factors that could affect the sterility of the materials, and showed contradictory results regarding these factors' interference in maintaining the sterility of the materials.

DESCRIPTORS

Materials
Temperature
Humidity
Sterilization
Materials management, hospital

RESUMO

São diversificadas as recomendações referentes à temperatura (T°) e umidade relativa do ar (UR) no armazenamento de materiais esterilizados em Centrais de Material e Esterilização (CME), sem que essas recomendações estejam embasadas em referenciais teóricos ou experimentos. A prática mostra dificuldades em controlar esses parâmetros, suscitando dúvidas quanto ao risco para a manutenção da esterilidade dos materiais. Este artigo propôs, por meio de uma revisão bibliográfica integrativa, identificar e analisar as recomendações referentes à T° e UR indicadas para o setor de guarda dos materiais na CME. Não foi encontrada literatura que justifique tais recomendações. Foram incluídas sete publicações que analisaram as variáveis T° e UR da área de armazenagem como fatores que podem afetar a manutenção do material esterilizado, e apresentaram resultados contraditórios quanto à interferência desses fatores na manutenção da esterilidade dos materiais.

DESCRITORES

Materiais
Temperatura ambiente
Umidade
Esterilização
Administração de materiais no hospital

RESUMEN

Bien diversas son las recomendaciones referentes a la temperatura (T°) y humedad relativa del aire (UR) en el almacenamiento de materiales esterilizados en Centrales de Materiales y Esterilización (CME), sin que tales recomendaciones estén basadas en referenciales teóricos o experimentos. La práctica muestra dificultad para controlar estos parámetros, generando dudas en cuanto al riesgo para el mantenimiento de la esterilidad de estos materiales. Este artículo propuso, a partir de una revisión bibliográfica integrativa, identificar y analizar las recomendaciones referentes a la T° y UR indicadas para el sector de guardado de materiales en la CME. No se encontró literatura que justifique tales recomendaciones. Fueron incluidas siete publicaciones que analizaron las variables T° y UR del área de almacenamiento como factores que pueden afectar el mantenimiento del material esterilizado y presentaron resultados contradictorios en cuanto a la injerencia de dichos factores en el mantenimiento de la esterilidad de los materiales.

DESCRIPTORES

Materiales
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INTRODUCTION

The Central Sterile Supply (CSS) Depaetment has the ability to receive, clean, disinfect, repair, sterilize, store and distribute materials used in health care[1].

The storage of materials is one of the critical points in maintaining their sterility, and there are recommendations regarding environmental conditions that must be met in the storage areas. Among them, we highlight the control of temperature (T°) and relative humidity (RH)[2-8].

The Collegiate Board Resolution (Resolução da Diretoria Colegiada - RDC) No. 50 regulates the necessity of air conditioning in storage and distribution rooms holding sterile materials and clothing[9], although practice shows that not all CSS are capable of meeting these regulations, either due to technical, structural or financial issues.

There are also some recommendations made both by associations and by independent authors which aim to standardize the T° and RH of the storage environment.

Summary of recommendations as to temperature and humidity in the storage of materials sterilized in a CSS (Chart 1)

Chart 1 - Comparison of temperature (T°C) and relative humidity (RH%) recommendations regarding the storage location of sterilized materials according to different authors - São Paulo, 2011

AUTHOR/YEAR	T°C	RH%
APECIH, 2010	18-22	35-70
SOBECC, 2009	25	30-60
AORN, 2008	24	≤ 70
AIA, 2006	-------	MAX 70
AAMI, 2006	MAX 24	30-60
CARDO & DRAKE, 1996	18-22	30-70
JAPP, 1997	18-22	35-50

The sterilization manual of the Paulista Association for the Study and Control of Hospital Infection (APECIH) recommends that the storage area has a relative air humidity between 35% - 70% and temperature between 18ºC - 22°C. The recommendations justify the belief that these conditions are unfavorable to microbial growth and favorable to packaging, despite the fact that there is an absence of scientific evidence to confirm the recontamination of the sterilized items when these conditions are not present. In these recommendations the interval proposed for the RH draws our attention[2].

The Brazilian Society of Operating Room Nurses, Anesthetic Recovery and Central Sterile Supply (*Sociedade Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Central de Materiais e Esterilização* - SOBECC) recommends keeping control of T° around 25°C and RH between 30% - 60%, not showing a justification for either guideline[3].

The Association of Perioperative Registered Nurses (AORN) recommends T° less than or equal to 24°C and RH less than or equal to 70%[4]. It does not detail the reasons for the choice of these values.

The American Institute of Architects (AIA) recommended a RH of a maximum value of 70% and does not specify the desired T°, nor are justifications mentioned[5].

The Association for the Advancement of Medical Instrumentation (AAMI) recommends that the T° should not exceed a maximum of 24°C, citing comfort for employees, in addition to affirming that bacteria thrive at higher temperatures, and suggests that low temperatures can reduce bacterial growth in general, including on the surface of packages [13]. It further recommends that the RH should not exceed 70%, affirming that high humidity promotes microbial growth. No references are made to studies justifying these assertions[6].

Renowned American authors[7] suggest that T° must be maintained between 18°C and 22°C and RH between 35% and 70%, without mentioning any theoretical basis to justify these recommendations.

Another author[8] suggests values of T° between 18°C to 22°C and RH between 35% - 50%, arguing that the maintenance of optimal conditions minimizes the potential for contamination of sterile products and justifying that the RH established prevents premature damage to materials and sealing of the packages, although the author does not list the scientific studies substantiating these claims.

Storage and supply rooms of sterilized materials are often adjacent to the sterilization area where the autoclaves are located, which eliminates steam at the end of the process, constantly elevating both the RH and the T° of the environment.

Based on the above, the question is: Would all articles be subjected to the risk of contamination when the T° and the RH of the storage area are outside the standards specified?

If the objective of the packages is to keep the goods sterilized until they are used, including storage and transport[10], would the qualified packages not also serve the purpose of protecting the sterilized contents in the many variations of T° and relative humidity of the environment?

As an example, for the qualification of surgical grade paper for the purpose of obtaining registration with the National Health Surveillance Agency in Brazil (ANVISA), an accelerated aging test must be performed at 37°C, 50°C and at standard temperature inside a refrigerator (4°C) in order to determine that the package does not undergo any change in physical properties, including the microbial barrier, even after 6 months' exposure at these temperatures [11].

Given that internal questions must seek answers based on scientific evidence[12], this research has as its objective to

identify and analyze the theoretical foundations that led to the establishment of parameters for T° and RH of the environment of the storage sector of sterilized materials as possible sources of contamination of stored materials.

METHOD

We performed an integrative review of the scientific literature in order to answer the question: What are the theoretical foundations that guide the definition of the values of T° and RH in the storage area of sterilized materials?

We used the databases MEDLINE, PUBMED and LILACS, with the following keywords of the Medical Subject Headings (*MESH*): time factors, surgical instruments, sterilization, product packaging, temperature and humidity. By analyzing the title and abstract, we selected the articles that included recommendations for conditions of T° and/or relative humidity in the storage of autoclaved health products. The publications that met the inclusion criteria were included in full. We excluded articles that did not refer to storage of sterile materials, articles not characterized as primary studies, that did not report conditions of T° and RH in the storage area of autoclaved materials and/or that did not refer to health products.

As complementary strategies we consulted manuals and guides of associations responsible for making recommendations for actions developed at CSS, as well as existing laws, and manually consulted the collections of libraries at the University of São Paulo School of Nursing (EE-USP), Central Library of the Federal University of São Paulo (UNIFESP) and the local collection of the Infection Control Commission of the São Paulo Hospital, connected to UNIFESP, as well as the Brazilian Society of Surgical Center Nurses, Anesthesia Recovery, Sterilization and Material Storage Center (SOBECC). We also conducted a search in order to find the primary references cited by the articles selected.

There were no restrictions on the languages of the works found, and although the bibliographic research does not present any time restrictions for the search of the publications, the oldest study found dates back to 1971.

RESULTS

Contrary to expectations, no studies were found that assessed only the influence of T° and RH in maintaining the sterility of items stored in a Material and Sterilization Center. The articles found report experiments performed with the aim of assessing the validity period of the sterility of materials stored in different types of packaging. In these experiments, the control inclusion of Tº and UT of the environment was justified as controlling external or secondary variables and were included in the study because they allowed the analysis of interference of these factors in maintaining the sterility of materials.

We found 109 articles; of these, only four met the inclusion criteria (Chart 2) and three articles were selected through the search in tree. The repeated articles were discarded.

Chart 2 - Distribution of scientific articles according to the database consulted - São Paulo, 2011

DATABASE	ARTICLES FOUND	ARTICLES EXCLUDED	ARTICLES INCLUDED
MEDLINE	44	40	4
PUBMED	67	64	3*
LILACS	38	35	3*

*Already cited in MEDLINE

Summary of experiments that included the evaluation of the control impact of temperature and humidity on the maintenance of materials sterility

A comparative research performed at two hospitals in order to determine how long materials would remain sterile when stored under different climate conditions, open or closed (covered) shelves, and different types of packages observed contamination of the contents related primarily to the type of shelf used, but did not relate the contamination found with the variations of T° and RH because these did not vary significantly in the hot and cold months. The T° averaged 25°C and the RH ranged between 35% and 48%, leading the authors to conclude that no evidence was found to correlate the contamination directly with atmospheric changes[14].

The same authors[15] conducted another experiment, in addition to the previous study, to compare the maintenance of the sterility of materials when they were prepared and stored under the most adverse conditions of packaging and shelving observed in the previous experiment. The values of T° were maintained between 21.1°C and 26.7°C and RH between 30% and 55%. The results also showed contamination unrelated to the climate conditions of the material storage environment.

Another study[16] performed with the aim of analyzing the maintenance of sterility of packages during different periods and storage conditions, including various packages, type of shelves and controlled places versus sites without environmental control and handling, showed no statistical significance regarding the contaminations found.

An experiment[17] was conducted to compare the shelf life of sterilized materials with the "event-related" control. This paradigm assumes that the sterilized and suitably packaged material remains in this condition until the package is damaged, which may occur due to humidity, tears, dents or breakage of the seal[18]. The sterilized samples were distributed into five areas of a hospital; some with control of T° by means of air conditioning, and others without. None of the samples analyzed showed contamination.

Chart 3 - Summary of published experiments involving the study of environmental temperature and humidity in the storage of sterilized materials – São Paulo, 2011

Author	Year/Place	Journal	Type of Study	Methodology	Result
Standard et al.	1971 USA	Applied Microbiology	Experimental laboratorial	Storage in different packages, in two different hospitals; open and closed shelves. Daily microbiological analysis up to the 6th day and then weekly. Controlled environment.	No evidence was found to relate the contaminations found with atmospheric changes.
Standard et al.	1973 USA	Applied Microbiology	Experimental laboratorial	Storage in different packages, on open and closed shelves up to 77 days. Controlled environment. Microbiological analysis.	The conclusions of the previous experiment were confirmed.
Mayworm D.	1984 USA	Journal of hospital supply	Field exploratory	Materials abandoned on site with no environmental control, probably for 43 years, microbiologically analyzed.	No contamination was observed in the materials found.
Klapes et al.	1987 USA	Infection Control	Field exploratory	Storage at CSS, in controlled environment and Emergency Ward, in uncontrolled environment, on open and closed shelves for a period of one year. Each month, a sample was collected and analyzed.	The contaminations found were considered accidental, occurring at the time of sample incubation and not caused by factors of the environment and/or manipulation.
Webster et al.	2003 Austrália	Infection Control an Hospital Epidemiology	Field exploratory	Storage in five different areas of a hospital, in different conditions of environmental control, for the period of 2 years. Each month, samples were analyzed.	No contamination was found in any of the samples analyzed.
Bhumisirikul W, Bhumisirikul P, Pongchairerks	2003 Thailand	Asian Journal os Surgery	Field exploratory	Storage in operating rooms with humidity control. Samples were analyzed for up to 96 weeks.	No contamination was found in any of the samples.
Neves et al.	2004 Brazil	Revista Brasileira de enfermagem	Field exploratory	Storage at two CSS of different hospitals on open and closed shelves, one with environmental control and another without control, for a period of up to 25 days. At the end of the period, a microbiological analysis was performed.	The contaminations found were considered accidental. The authors recommended studies to evaluate the importance of To and RH in storage.

A group of researchers interested in confirming the possibility of a long sterility validity period stored small instruments packed and sterilized in an operating room with controlled humidity, and evaluated them microbiologically for a period of up to 96 weeks. A group of instruments was stored in the same environment, but without packaging, constituting the positive control group. None of the samples packaged showed contamination, while the unpackaged group showed contamination of all samples, except for the first two analyzed[19].

In order to validate the sterilization period of two hospitals, one with temperature control in the storage area of sterilized materials and the other without, samples were stored at the CSS and analyzed as to microbiological contamination for different storage periods. The contamination found was considered accidental and the authors concluded by recommending the performance of studies to evaluate the effect of RH and T° on storage of sterilized materials, since in the experiment they conducted there was no acclimation of the samples in the areas of storage of the material[20].

In a 1977 report, boxes of surgical instruments found stored for 43 years in the basement of a hospital without any environmental control were found to have no viable microorganisms[21].

DISCUSSION

There are recommendations from official organizations in the health care field regarding parameters of T° and RH for the storage environment of sterilized materials at CSS. The recommended values for temperature range from 18°C to 25°C, while the RH range from 30% to 70%[2-8].

Although the recommendations are from official bodies, none presented research proving the impact of environmental factors, T° and RH, on the maintenance of sterility of the stored materials; some presented no justification at all for the recommendations made.

The experimental research publications found through this literature review were carried out primarily to evaluate the storage conditions of materials, in order to endorse or change the validity date of sterility, or to evaluate the microbial barrier properties of the packages, and not with the main purpose of evaluating the impact of T° and RH on the contamination of the stored articles.

In view of this major gap in knowledge, it was possible to realize the fragility of CBR No. 50 requirements, as well as the recommendations mentioned, since one can say with confidence that there are no data that can elucidate the importance of controlling these variables in the storage room.

The analysis of poor influence of T° and RH shown by the articles found revealed contamination in experimental situations under controlled conditions within the parameters established in the literature, and absence of contamination when these parameters were not controlled, minimizing the importance of such controls in the maintenance of sterility of materials during their storage.

CONCLUSION

In spite of the many methodologies employed in the research, the contradictions found in the results raise doubts regarding the importance of these controls, which reinforces the thesis that the T° and RH of the environment has little or no impact on the maintenance of sterility of materials which have been properly packaged.

The gap in the literature pointed out by this review indicates the need for the development of well-designed experimental research that can definitively determine the relevance or (non-relevance) of the control of T° and RH in the environment where sterilized materials are stored, from the belief that qualified packaging protects its contents from adverse environmental conditions, including therein variations of T° and RH.

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