LOW-TEMPERATURE STERILIZATION AND NEW TECHNOLOGIES

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The new low-temperature sterilization technologies are presented as an alternative to the use of ethylene oxide. This review was performed in order to identify evidences of the antimicrobial activity, toxicity, adverse events and the applicability of these technologies. The research was carried through the electronic databases MEDLINE and LILACS up to 2005. The authors analyzed 10 articles in this survey. The studies about the efficacy of these sterilization methods constitute experimental and comparative research that showed the influence of the extension and diameter of the lumen, besides the presence of crystal salts. Thus, choosing the correct equipment is essential, as well as the assurance of the cleansing of the devices, which interfere with the effectiveness of the low-temperature sterilization. These technologies present limitations regarding the sterilization of graft bone and affect the materials properties.

DESCRIPTORS: sterilization; ethylene oxide; hydrogen peroxide

MÉTODOS DE ESTERILIZACIÓN POR BAJA TEMPERATURA Y NUEVAS TECNOLOGÍAS

Nuevos métodos de esterilización a baja temperatura son una alternativa frente al óxido de etileno. El artículo tiene por objetivo identificar evidencias de actividad antimicrobiana, toxicidad, efectos colaterales y la aplicación de tecnologías por bajas temperaturas. La investigación fue realizada mediante consulta en los bancos de datos MEDLINE y LILACS hasta 2005. Fueron analizados en su totalidad 10 artículos, cuyos resultados demostraron que: a) los estudios sobre la eficacia de la esterilización se constituyen en investigaciones básicas y comparativas que muestran la influencia de la extensión y diámetro del lumen y la presencia de sales de cristal, b) la selección del equipo es tan fundamental como el garantizar la limpieza de los materiales que influyen en la eficacia de los procesos y en la toxicidad, c) la esterilización a bajas temperaturas muestra limitaciones para el caso de esterilización de injerto óseo, así como deteriora las propiedades de los materiales.

DESCRIPTORES: esterilización; óxido de etileno; peróxido de hidrógeno

MÉTODOS DE ESTERILIZAÇÃO POR BAIXA-TEMPERATURA E NOVAS TECNOLOGIAS

Novos métodos de esterilização à baixa temperatura são apresentados como alternativa ao óxido de etileno. Este artigo tem como objetivo identificar evidências da atividade antimicrobiana, toxicidade, eventos adversos e aplicabilidade das tecnologias de baixa temperatura. A pesquisa foi realizada mediante consulta nas bases de dados MEDLINE e LILACS até 2005. Foram analisados 10 artigos na íntegra, nesse levantamento, cujo resultado demostrou que: a) os estudos sobre a eficácia da esterilização constituem pesquisas básicas e comparativas que demonstram a influência da extensão e diâmetro do lúmen e a presença de cristais de sais, b) a seleção do equipamento é fundamental, assim como a garantia da limpeza dos materiais, que interfere na eficácia dos processos e na toxicidade, c) a esterilização à baixa temperatura apresenta limitação para esterilizar osso para enxerto e efeitos deletérios sobre as propriedades dos materiais.

DESCRITORES: esterilização; óxido de etileno; peróxido de hidrogênio

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INTRODUCTION

Ethylene oxide is the eldest low temperature sterilization method and has been used since the 1950's to reprocess heat-sensitive medical-hospital materials. Different factors have influenced professionals and health institutions to look for new sterilization technologies. Rutala and Weber identify the reasons for this search among health professionals in the United States, such as complying with environmental legislation that establishes the elimination of CFC (chlorofluorocarbons) gas use, which is a better thinner than ethylene oxide, which affects the ozone layer, and regulating acceptable exposure levels to ethylene oxide, established by the public occupational health body[1-2].

In our context, the search for new low temperature sterilization technologies is justified by the same motives as in the USA, besides the need for faster reprocessing than when using ethylene oxide. The challenge for hospital infection control and material center professionals in health institutions is to assess available new technologies in terms of microbiological safety, cost-effectiveness and the absence of adverse effects for patients and professionals. Thus, the user's choice should be based on scientific evidence.

This bibliographic review aims to identify, in scientific literature, evidences of antimicrobial activity, toxicity, adverse effects and applicability of low temperature sterilization technologies.

METHODOLOGY

The bibliographic research was carried out by consulting the electronic databases MEDLINE and LILACS until 2005, on the portals of BIREME and the US National Library of Medicine. Free and controlled keywords were used in Portuguese and English, in combination with the Boolean operator AND for specificity. Initially, the controlled keywords were defined in Portuguese by means of the *Descritores em Ciências da Saúde* - DeCS on the Bireme portal (www.bireme.br), and in English by using the Medical Subject Heading - MeSH on the portal of the US National Library of Medicine - NLM (www.pubmed.com). Next, the bibliographic survey was carried out.

The following descriptors were located: *esterilização*/sterilization; *óxido de etileno*/ethylene oxide and *peróxido de hidrogênio*/hydrogen peroxide. However, no controlled keywords were located for: *esterilização baixa temperatura*/low temperature sterilization; *plasma de peróxido de hidrogênio*/ hydrogen peroxide plasma, which were used in the search as free keywords.

RESULTS

Table 1 presents the results obtained through the application of the described search strategy.

Table 1 - Results of the bibliographic search until 2005, carried out in the BIREME and NLM portals, According to the controlled or free keywords used. São Paulo, 2006

Keywords			BIREME		PUBMED
	Controlled	Free	Medline	Lilacs	Medline
Sterilization*	X	-	9792	774	17.796
Sterilization and ETO** and HP***	X	-	29	2	18
Low temperature sterilization	-	X	124	1	344
Low temperature sterilization and Sterilization and ETO** and HP***	X	X	11	0	4

*The results of the search with the controlled keyword sterilization were not accessed
** Ethylene oxide = ETO
*** Hydrogen peroxide = HP

The abstracts of all publications located in the databases were read, except for the results of the exclusive search with the descriptor *sterilization*, due to the large number of publications found and the lack of specificity. The abstracts were analyzed and those that addressed at least one of the following items were selected: antimicrobial activity, toxicity, adverse events and applicability of low temperature sterilization technologies. Only ten publications from the research universe complied with the inclusion criteria.

In the adopted search system, only one Brazilian study was located which did not attend to the inclusion criterion, as it presented the methodology for validating the low temperature formaldehyde sterilization technology.

Next, we will present a synthesis of the publications, according to the theme and the chronological order of publication.

Efficacy: Comparative studies of low temperature sterilization methods

In 1996, a Canadian study assessed the sterilization efficacy of four low temperature sterilization technologies: 100% ethylene oxide (ETO), 12/88 mixture of ETO (12% of ETO and 88% of CFC), hydrogen peroxide plasma and hydrogen peroxide vapor. All methods were effective in reducing the used test strains to $6\log_{10}$, except when 10% of serum and 0.65% of salt were present. In this condition, 12/88 ETO showed the best performance, reaching the secure sterility level[3].

Another study from 1998 assess the sterilization efficacy of four low temperature sterilization technologies: ETO, containing hydrochlorofluorocarbons (ETO-HCFC), STERIS® system, containing peracetic acid and hydrogen peroxide, and the Sterrad 100® and 100S® system, containing hydrogen peroxide plasma, 40-centimeter-long materials and lumens with a diameter of 1-3mm. Narrower lumens compromised the efficacy of the sterilization processes by the Sterrad 100® and STERIS® systems, while the other methods displayed satisfactory results[4].

Another publication from 1998 assessed the STERIS® system, 100% ETO and ETO-HCFC, for materials of 125cm and lumens with a diameter of 3mm. Differently from the results of the above study, the STERIS® system was significantly more efficient in comparison with the other processes to reduce the microbial load, although it did not achieve sterility. It should be observed that, in this situation, the material was longer, but with a less narrow lumen[5].

The comparative analysis of these studies is limited by the fact that each of them presents different challenges to assess the performance of these technologies in terms of sterilization efficacy.

Adverse events: cornea destruction epidemic - 1998

In 1998, the Centers for Disease Control and Prevention (CDC) interrupted the use of a new sterilization technology in the United States, which sterilizes through peracetic acid and hydrogen peroxide vapor, due to the occurrence of a cornea destruction epidemic among patients submitted to intraocular ophthalmological surgery. At that time, this technology had not been approved by the Food and Drug Administration (FDA) to sterilize surgical instruments with lumens or hinges. Nevertheless, it was introduced at the Hospital and the investigation of the epidemic concluded that the sterilization method degrade the metal of cannulated copper and zinc surgical instruments, resulting in the destruction of endothelial cornea cells[6-7].

Cost analysis of low temperature sterilization - 1998

In general, the choice of the sterilization technology is based on cost and compared with available technologies. A German study compared the costs of hydrogen peroxide plasma (Sterrad 100®), ETO and formaldehyde sterilizations. The authors included vapor sterilization and all related direct and indirect costs. Plasma sterilization is faster and cheaper than ETO and does not require sparging, thus needing a smaller inventory of instruments; formaldehyde sterilization takes three times longer than plasma, but, in comparison with ETO, the time was shorter, which implies lower costs. However, a larger inventory was needed. Vapor was considered the fastest and cheapest method and was chosen for small and medium-sized institutions, although it causes greater damage to instruments in the long term[8].

Application: reuse of electrophysiology catheters - 1998

The reuse of highly complex and high-cost single-use products has been assessed, and the reprocessing of electrophysiology catheters has revealed to be feasible, from the perspective of security as well as efficacy. In this American study, the authors assessed electrophysiology catheter (without lumen), reprocessed five times each, and ablation catheters, reprocessed twenty times each and sterilized in hydrogen peroxide plasma, with satisfactory results. Cost economy is significant when each catheter is used five times. The authors appoint the following study limitations: absence of clinical results in terms of safety, although sterility tests revealed to be satisfactory; and the fact that the tests were not realized with catheters from all commercially available brands[9].

Limitations: bone graft sterilization - 2001

Bone grafts have been widely used in orthopedic surgeries, despite the risk of transmitting infectious agents from the donor, although bone banks carry out serological tests. Nowadays, there does not exist any sterilization technology without adverse

effects on the biological properties of the bone graft. A trial study assessed the effect of hydrogen peroxide plasma sterilization on the osteoinductive capacity of the demineralized human bone matrix, which resulted in a negative effect on the osteoinduction capacity. Therefore, this technology cannot be applied to sterilize bone grafts[10].

Limitations: Effects of sterilization on tensile force of single-use product materials - 2002

The study was conducted by researchers from the FDA, who assessed the effect of sterilization processes on the materials used for manufacturing the articles: latex, silicone, two types of polyurethane, nylon, high-density polyethylene. The samples were previously assessed for tensile force, submitted to different disinfection and low temperature sterilization technologies and then reassessed. The final results show that silicone is the least affected, while the tensile force of latex, polyethylene and nylon was reduced. Depending on the formulation, polyurethane presented alterations, strengthening or weakening its tensile force. The authors of that study highlighted that there exists little scientific evidence about the effects of different sterilization methods on material properties[11].

CONCLUSIONS

This bibliographic review on new low temperature sterilization technologies allowed for the following conclusions:

- a small number of scientific publications exist, reporting on basic lab research with overdimensioned challenges, which do not always reflect clinical practice;
- in some experiments, ETO, considered the gold standard as a low temperature sterilization method, did not achieve the desired sterility affect and has been surpassed by new methods;
- presence of serum and salt in tested material presented protective action against microorganisms in the sterilization process;
- when using low temperature sterilization methods, materials with narrow lumens are more challenging for successful sterilization than long materials;
- currently available literature is insufficient to select the low temperature method to replace ETO.

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