Rev. Latino-Am. Enfermagem
Jan-Feb 2010; 18(1):81-6
www.eerp.usp.br/rlae

Original Article

The Sterilization Efficacy of Reprocessed single Use Diathermy Pencils

Simone Batista Neto[1]
Kazuko Uchikawa Graziano[2]
Maria Clara Padoveze[3]
Júlia Yaeko Kawagoe[4]

In Brazil, single use diathermy pencils (SUDP) are among the most common reused devices. This study assesses the sterilization efficacy of reprocessing SUDP using two cleansing methods (manual or automated), followed by one of three of the low-temperature sterilization methods: Hydrogen Peroxide Plasma (HPP), Ethylene Oxide (ETO) or Low-Temperature Steam Formaldehyde (LTSF). The sample was composed of 360 SUDP after their first use. The probability of sterilization failure was estimated considering the number of positive microbiological results obtained by cultures of the studied devices. The overall sterilization failure probability for SUDP was 0.26. The sterilization method, which presented the lowest failure probability was the LTSF (0.01), followed by ETO (0.21) and HPP (0.56). Automated cleansing obtained a better result than manual cleansing. This trial demonstrated that the probability of sterilization in reprocessed SUDP is highly dependent on both the type of cleansing and the sterilization method applied.

Descriptors: Equipment Reuse; Equipment and Supplies / Microbiology; Sterilization / Methods.

[1] RN, M.Sc., Material and Sterilization Center, Instituto do Câncer do Estado de São Paulo, Brazil, e-mail: sibane@uol.com.br.
[2] RN, Ph.D, Full Professor, Escola de Enfermagem, Universidade de São Paulo, Brazil, e-mail: kugrazia@usp.br.
[3] RN, Ph.D. Faculty, Escola de Enfermagem, Universidade de São Paulo, Brazil, e-mail: padoveze@usp.br.
[4] RN, Ph.D., Hospital Albert Einstein, Brazil, e-mail: julyaeka@uol.com.br.

Corresponding Author:
Maria Clara Padoveze
Departamento de Enfermagem em Saúde Coletiva. Escola de Enfermagem.
Universidade de São Paulo
Av. Dr. Enéas de Carvalho Aguiar, 419
Bairro Cerqueira César
CEP: 05403-000 São Paulo, SP, Brasil
E-mail: padoveze@usp.br

Eficácia da esterilização de canetas de bisturi elétrico de uso único reprocessadas

No Brasil, a caneta de bisturi elétrico de uso único (CBEUU) é um dos artigos mais comumente reutilizados. O presente estudo avaliou a eficácia da esterilização de CBEUUs reprocessadas, utilizando dois métodos de limpeza (manual ou automatizado), seguidos de um dos seguintes métodos de esterilização: plasma de peróxido de hidrogênio (PPH), óxido de etileno (OE) ou vapor de baixa temperatura de formaldeído (VBTF). Foram analisadas 360 CBEUUs após sua primeira utilização. A probabilidade de falha de esterilização foi estimada considerando o número de resultados positivos de cultura dos dispositivos estudados. A probabilidade geral de falha de esterilização das CBEUUs foi de 0,26. A menor probabilidade de falha foi obtida com o VBTF (0,01), seguida do OE (0,21) e do PPH (0,56). A limpeza automatizada obteve melhores resultados quando comparada à limpeza manual. O presente estudo demonstrou que a probabilidade de esterilização das CBEUUs reprocessadas é altamente dependente dos métodos de limpeza ou esterilização aplicados.

Descritores: Reutilização de Equipamento; Equipamentos e Provisões / Microbiologia; Esterilização / Métodos.

La eficacia de la esterilización del bisturí eléctrico tipo lápiz de uso único reprocesados

En Brasil, el bisturí eléctrico tipo lápiz de uso único (BETLUU) es uno de los artículos más comúnmente reutilizados. El presente estudio evaluó la eficacia de la esterilización de BETLUUs reprocesados, utilizando dos métodos de limpieza (manual y automatizado), seguidos de uno de los siguientes métodos de esterilización: plasma de peróxido de hidrogeno (PPH), óxido de etileno (OE) o vapor de baja temperatura de formaldehído (VBTF). Fueron analizadas 360 BETLUUs después de su primera utilización. La probabilidad de falla de esterilización fue estimada considerando el número de resultados positivos de cultura de los dispositivos estudiados. La probabilidad general de falla de esterilización de los BETLUUs fue de 0,26. La menor probabilidad de falla fue obtenida con el VBTF (0,01), seguida del OE (0,21) y del PPH (0,56). La limpieza automatizada obtuvo mejores resultados cuando comparada a la limpieza manual. El presente estudio demostró que la probabilidad de esterilización de los BETLUUs reprocesados es altamente dependiente de los métodos de limpieza o esterilización aplicados.

Descriptores: Equipo Reutilizado; Equipos y Suministros / Microbiología; Esterilización / Métodos.

Introduction

The evolution of healthcare technologies has led to the increasing development of medical devices identified by their producers as single use. This raises the costs of healthcare assistance and makes access to health services more difficult for the economically less favored.

Reprocessing and reusing single use medical devices is a common practice in developing countries (Africa, Asia, Eastern Europe, Central and South America), where there is a shortage of medical and financial resources[1-2]. A national survey conducted in Brazil from 1999 to 2001 demonstrated that 97% of 119 institutions reported reuse of single-use devices during hemodynamic procedures[3].

The cost involved in the process of reusing devices is not usually acknowledged by healthcare workers. A

Brazilian study developed and proposed a methodology for reuse cost analysis. The authors demonstrated that once the reuse is carried out following the best procedures, the costs are considerable, and can even be high if the risk of adverse events is increased by the number of times any device is reused[4]. Although costs were analyzed, there are no conclusive studies regarding sterilization safety in the practice of reusing single use medical devices[5-7].

Among the medical devices reused in many hospitals in Brazil, it is common practice to reuse the Single Use Diathermy Pencil (SUDP), an instrument suitable for cutting and cauterizing tissues in surgery. However, there is not enough scientific evidence to guarantee the safety of this practice. This study assesses the sterilization efficacy of reprocessing diathermy pencils, using two different cleansing methods (manual or automated) followed by sterilization by means of the low-temperature methods currently available in hospitals: Hydrogen Peroxide Plasma (HPP), Ethylene Oxide (ETO) and Low-Temperature Steam Formaldehyde (LTSF).

Methods

SUDP Sample selection

Sample size was determined estimating a 2% interval for the event (Hypothesis H1) and a 95% interval for the null hypothesis (Hypothesis H0), considering a 5% alpha risk ($p \leq 0.05$).

The present study used 1,816 units of SUDP (Valleylab®) which were donated by a hospital after their first use; they were cleansed manually using an enzymatic detergent solution, dried and subsequently sterilized with Ethylene Oxide (ETO). A sample of 360 units was randomly obtained from this SUDP universe through systematic probability sampling, selecting multiples of eight pencils.

SUDP Preparation

Intentional microbial contamination of the SUDP was performed at the Microbial Laboratory of the College of Nursing at the Universidade de São Paulo, using *Bacillus subtilis* 10^6 spores U.F.C./mL. Each SUDP was submitted to manual and unidirectional contamination across its entire external length, including the electric wire and using gauzes drenched in this inoculum broth by way of 10 consecutive movements and followed by natural drying to allow the adherence of microorganisms.

SUDP Cleansing and wrapping

One hundred and eighty units of SUDP were automatically cleansed and another 180 units were cleansed manually. Automated cleansing was performed by a machine with devices for pulsed jet cleansing of narrow lumens (Medisafe SI Digital Cannulated Instrument Cleaner™) and was carried out for approximately 5 minutes at 38º to 40ºC. The pencils were then rinsed under running tap water.

The manual cleansing was performed by friction using a towel soaked in an enzymatic detergent solution along the length of the SUDP including its electric wire. The detergent was removed using a sponge moistened with tap water.

All SUDP had their external parts dried with a clean dry sponge and the internal parts with a clean air jet. The SUDP were wrapped and labeled according to the sterilization method used. Medical grade paper bags were used for both ETO and LTSF methods and Tyvek™ wrapping was used for HPP. A class 6 chemical emulator (Browne™) compatible with each sterilization process was placed inside every package.

SUDP Sterilization

Following both of the cleansing procedures each of the three different sterilization methods was used to reprocess the SUDP: 120 SUDP were submitted to HPP (Sterrad 100 S, Johnson & Johnson™); 120 SUDP were submitted to ETO (Quiminox AF 961™) and 120 SUDP were submitted to LTSF (Cisa SN6415™). The LTSF equipment used paraformaldehyde tablets as a source of formaldehyde. The LTSF and HPP equipment were located in two hospitals and the ETO in a sterilization company. Performance of all the equipment had been previously validated and they were routinely monitored in their respective institutions.

Sterility evaluation

After sterilization, all samples were sent for evaluation of their sterilization by direct inoculation in the Pharmacy Department laboratory of the School of Pharmaceutical Sciences at the University of São Paulo. Using aseptic techniques and an ultra-clean environment, the electric wires were cut off and only the pencil bodies were inoculated in Tryptic Soy Broth (TSB) and incubated at 37º C for 72 hours.

Controls

As a control for the reprocessing methods, we chose to use 36 new diathermy pencils labeled by the manufacturer as "reusable" (Conmed™), and therefore should achieve the best results in terms of sterility efficacy. All procedures for the intentional contamination, cleansing, drying, packaging and sterilization were performed on these items in exactly the same way as described for the SUDP. Manual cleansing was used on 18 Reusable Diathermy Pencils (RDP) followed by LTSF, ETO and PPH. Automated cleansing was applied to 18 RDP followed by LTSF, ETO and PPH, as well. Figure 1 shows the sample distribution scheme for each method.

Statistical analysis

The probability of failure in the sterilization process was estimated taking into consideration the results of microbial growth, where the probability of failure is the number of samples with positive results divided by the total amount of samples. The difference between the results of the two cleansing methods was analyzed via the Chi square test and a *P* value of less than 0.05 was considered significant (Epi-info for Windows v3.2, Centres for Disease Control and Prevention).

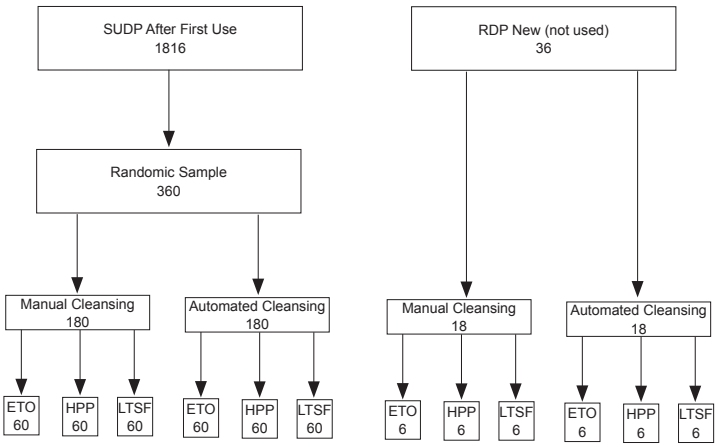

Figure 1 - Distribution of the number of samples of Single Use Diathermy Pencils (SUDP) and Reusable Diathermy Pencils (RDP) according to the type of cleansing and sterilization methods evaluated (ETO=Ethylene Oxide, HPP=Hydrogen Peroxide Plasma, LTSF= Low-Temperature Steam Formaldehyde). Sao Paulo, 2005

Results

Eight SUDP were lost due to technical problems, reducing the total number of samples to 352 items. SUDP sterility evaluation results are shown on Table 1. The overall probability of failure in the SUDP sterilization process was 0.26 (90/352). The sterilization method which presented the lowest probability of failure was the LSTF (0.01), followed by ETO (0.21) and HPP (0.56).

Microbiological results showed that the use of automated cleansing obtained a better result than manual cleansing in sterilization analysis (p< 0.0001; RR=0.16, IC=0.09-0.28). When using manual cleansing, the overall failure probability in the process was 0.44. Compared to automated cleansing, the use of manual cleansing increased the probability of sterilization failure in both the ETO and HPP methods. The probability of failure for ETO and HPP was 0.05 and 0.14 using automated cleansing versus 0.36 and 0.97 using manual cleansing.

Table 1 – Sterility evaluation of single use diathermy pencils (SUDP) reprocessed after the first use and sterility failure probability, according to cleansing and sterilization methods. São Paulo, 2005

Cleansing method	Sterilization method	Microbial growth		Total of samples	Sterility failure probability
		Positive	Negative		
Manual	ETO	21	38	59	0.36
	HPP	57	2	59	0.97
	LTSF	0	59	59	0
Automated	ETO	3	55	58	0.05
	HPP	8	50	58	0.14
	LTSF	1	58	59	0.02
Total		90	262	352	0.26

The probability of sterilization failure for RDP was 0.36 and statistical analysis showed no difference in positive results between SUDP and RDP (*P* = 0.24) (Table 2). Neither cleansing method showed any significant difference in the sterility evaluation of RDP (*P* = 1.00)

nor when the sterilization process was performed by using LSTF (P >0.05).

Table 2 – Results of the sterility evaluation of single use diathermy pencils (SUDP) and reusable diathermy pencils (RDP), and sterility failure probability according to cleansing methods. São Paulo, 2005

Cleansing methods	SUDP Microbial growth		RDP Microbial growth	
	Positive	Negative	Positive	Negative
Manual	78	99	6	12
Automated	12	163	7	11
Sterility failure probability	0.26		0.36	

Discussion

Scientific evidence has demonstrated that cleansing is the cornerstone of reprocessing and is responsible for an important reduction in microbiological burden[8]. In our trial, the automated method provided the best results in terms of sterility efficacy when compared to manual cleansing. Despite strictly following manufacturer recommendations (temperature and concentration of enzymatic detergent) in both methods, it was only possible to aggregate accessories for internal lumen cleansing when applying the automated method. These combined factors improve cleansing, as shown in another research project, which compared the efficacy of manual and automated cleansing for video laparoscopy lumened instruments[9]. However, the influence of cleansing methods proved to be insignificant when LTSF was used, as demonstrated by the results of both SUDP and RDP. As a limitation of the present study, we did not assess the level of cleanliness before sterilization, which could have offered some insights into the subject.

The present study showed HPP sterilization to be ineffective in eliminating *Bacillus subtilis* spores in SUDP and RDP. This result was expected to a certain extent, as HPP sterilization possesses a low diffusion power and is significantly inactive in the presence of organic material. According to Schneider, when compared with ETO, HPP has a diffusion power of 10:1000[10]. Therefore, ETO sterilization would have been expected to give much better results than PPH which was not confirmed by the probability of sterilization failure comparing these two methods. Furthermore, although ETO sterilization (12/88 blend with HCFC) is considered to be the "gold standard" among low-temperature sterilization methods, it did not appear as the most effective method in our study.

Low-Temperature Steam Formaldehyde sterilization performed best in achieving the sterilization of SUDP and RDP via manual and automated cleansing. The study on LTSF demonstrated effective elimination of bacterial spores after sterilization of lumened devices with complex designs[11]. These authors applied LTSF sterilization with a 37% formaline solution as a source of formaldehyde. In our study, we used the LTSF equipment with 336g paraformaldehyde tablets and achieved successful sterilization for SUDP and RDP. Both liquid and solid formulations are currently adopted as sources of formaldehyde gas in sterilization equipment.

The most intriguing point in our study is the absence of significant difference in the probability of sterilization failure between the SUDP and RDP. These results raise some concern regarding the criteria used for the classification of products as "single use" or "reusable". It seems that the 'single use' label on health products is determined by manufacturers, based mainly on the properties of the material of which they are made (non-noble plastic or some other type of elastomer)[12]. In fact, worldwide labeling of the product as 'single use' or "reusable" has been determined exclusively by manufacturers, without the need to demonstrate scientific proof for their choice. Some studies have highlighted the fact that complex design makes adequate cleansing more difficult, and may allow organic material and mineral salts to remain in the material, exerting a protective effect on microorganisms when submitted to sterilization[6,8,13-14]. However, in many situations there was a minimal difference, if any, in design between reusable and single use medical devices. Nevertheless, the costs of acquiring reusable or single use versions are quite different. These results are relevant to discuss classifications of single use and reusable devices from the perspective of hospital infection control. Therefore, we suggest a review of the criteria used for attributing "single use" labels in health care materials.

From the microbiological point of view, our findings indicate that reusable diathermy pencils present the same problems as single use models when being reused, except when the choice of cleansing and sterilization methods is considered. The microbiological results in this trial demonstrated that the effectiveness of SUDP sterilization is highly dependent on both the type of cleansing and the sterilization method applied. It was found that automated cleansing and LTSF were the most effective methods. According to the theoretical and methodological frameworks used, the main contribution of our research is to provide support for reviewing the

concept of single use materials and to demystify the idea that reprocessing reusable materials is always safe in microbiological terms.

The present study is focused only on sterilization analysis. However, other potential risks can still be present on the devices, such as prions, biofilms, endotoxins, blood protein residues, toxic residues from the cleansing and sterilization processes, etc. These risks should be studied in the future in order to better explore the complex reuse problem.

Conclusions

Our findings indicate that after the first use, reusable diathermy pencils presented the same probability of sterilization failure as single use models, except when the choice of cleansing and sterilization methods was considered. Due to the finding of no difference between devices intended by the manufactures for reuse or single use, there are reasons for reviewing the concept of single use materials and demystifying the idea that reprocessing reusable materials is always safe in microbiological terms.

In the present trial, the method utilized for cleansing (manual or automated) showed interference in the sterilization results. It was demonstrated that automated cleansing is better than manual cleansing. Some sterilization methods can be more affected by residual dirt than others, particularly low temperature methods. In this trial, the LTSF proved to be less affected by residual dirt than other methods applied.

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Received: Oct. 28th 2008
Accepted: Oct. 6th 2009