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ORIGINAL ARTICLE

Experimental study on the analysis of sterility in the reuse of harmonic scalpels

Estudo experimental de análise da esterilidade na reutilização de bisturi harmônico

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ABSTRACT

The harmonic scalpel is an instrument used in videosurgery for cutting and coagulating tissues. In an attempt to reduce costs related to the use of single-use articles, many institutions from different countries have adopted the reuse of harmonic scalpels. The objective of this study was to evaluate the effectiveness of the sterilization process in the reuse of harmonic scalpels. The study sample was composed of 30 harmonic scalpels from two different manufacturers. The inoculum used for contamination was a spore (a) Geobacillus stearothermophilus suspension and (b) Bacillus atrophaeus var. niger suspension, plus sterile defibrinated sheep blood. Both groups were subjected to the disassembling process, an essential phase in the cleaning process. Under the conditions of this experiment, the remaining samples negate the initial hypothesis of this study that the reuse of harmonic scalpels is safe, because bacterial adhesion was detected, which represents an imminent risk of surgical site infection.

Keywords: Sterilization; Equipment Reuse; Focal Infection

RESUMO

O bisturi harmônico é um instrumento utilizado em videocirurgia, que realiza o corte e a coagulação de tecidos. Na tentativa de reduzir custos relacionados ao emprego de artigos de uso único, várias instituições, de distintos países, têm adotado a reutilização desse item. O objetivo deste estudo foi avaliar a eficácia do processo de esterilização na reutilização do bisturi harmônico. O corpo amostral partiu de 30 unidades de bisturis harmônicos de dois fabricantes distintos. O inóculo utilizado para a contaminação constitui-se de suspensão (a) Geobacillus stearothermophilus e (b) Bacillus atrophaeus var. niger, na forma esporulada, acrescido de sangue de carneiro desfibrinado estéril. Os dois grupos foram submetidos ao processo de desmontagem, fase essencial para o processo de limpeza. As amostras remanescentes mostraram que, nas condições desse experimento, refutaram a hipótese inicial da pesquisa, quanto à segurança na reutilização de bisturis harmônicos, pois detectou-se a presença de adesão bacteriana, a qual remete ao risco eminente de infecção de sítio cirúrgico.

Keywords: Esterilização; Reutilização de Equipamento; Infecção Focal

INTRODUCTION

Electrosurgery with different electrical currents is used for protein denaturation and coagulation. This technique has been contributing to intraoperative safety. The electrical energy originates from an electrosurgical generator and is applied by an active electrode to the tissue. This active electrode is a cautery pen - used in conventional surgery - or a harmonic scalpel - used in minimally invasive surgery, also known as videolaparoscopic surgery.[1]

A constantly evolving concept that is being incorporated by many medical specialties is minimally invasive surgery, because it causes less damage to the tissue during surgery. That is, the length of incisions made to reach the organs that need to be repaired is reduced due to improvements brought about by this surgical technique and its use results in fewer incisions and steps. These devices allow the performance of surgery through holes using videolaparoscopy[2].

Pressure exerted on tissue with the blade surface causes the coagulation of blood vessels, which are coapted by tamponading and sealed with a denatured protein coagulum[3]. Although it has a high added value and is a disposable device, studies show that the use of harmonic scalpels for cutting and coagulating tissue reduces surgery time, on average by one hour. Given the amount of time saved, the benefits produced outweigh the additional cost of the device.[4]

There are many benefits to patients when harmonic scalpels are used. Nevertheless, the increase of health care costs is causing concern to hospital administrators, health professionals and third-party payers, such as the Unified Health System (SUS) or private health insurance operators. In an attempt to reduce costs related to the use of single-use articles, many institutions from different countries have adopted the reuse of harmonic scalpels.[5]

In the United States, a study conducted in 2005 analyzed the cost-benefit of harmonic scalpels from different manufacturers. The conclusion from this analysis was favorable for the reuse of this biomedical device (for 20 reprocessing cycles).[6]

The extent of devices reuse in hospital settings has remained unknown for many years. Nevertheless, the increasing complexity of surgical procedures and the need for use of (often costly) disposable biomedical items, are making the reuse of devices an attractive option for health services.[6] Regulations on the manufacture of medical articles address the reuse of single-use articles, highlighting definitions and raising reflections on the “safety” of surgical patients.[7]

It is noteworthy that there is currently a global trivialization of the risks involving the reuse of single-use devices. There are countless instances of surgical site infection outbreaks which evidence the reuse of disposable articles.

High morbidity and mortality rates related to surgical site hospital infections evidence a worldwide public health problem. Such problem is discussed in many countries to seek justification for an ethically and economically questionable method.[8,9]

In recent decades, awareness-raising - of professionals working in all internal hospital departments and especially in the materials sterilization departments - has started to show a significant contribution to the reduction of hospital infections. Theincidence of surgical site infections is increasingly becoming an institutional marker of quality assurance.

Surgical Site Infections (SSI) are characterized by the penetration and multiplication of microorganisms in the surgical incision, due to the use of contaminated surgical instruments.[9] Serious surgical site infections cases - caused by rapidly growing mycobacteria - have alarmed inspection agencies across the country. The Brazilian National Health Surveillance Agency (ANVISA) has developed actions to reduce the incidence of cases strongly related to failures in the cleaning, disinfection and sterilization processes of medical products. In most of the investigated health services, surgical instruments were only submitted to disinfection, but not to sterilization, as required by Resolution RE2606/06.[10]

Given the above, it is concluded that all items used during surgery should be sterilized before use so as not to cause adverse events. Any failure in the cleaning or sterilizing process may result in the transmission of highly infectious agents. Therefore, the safety of surgical items that come into contact with the vascular system is of paramount importance.

There are countless devices used in surgical sites that may be linked to SSI. When improperly processed, these devices cause infections due to the transmission of infectious agents.[11,12]

The reuse of harmonic scalpels in Brazil is controversial, because they are not allowed to be reprocessed in this country. Nevertheless, harmonic scalpels reuse is widely practiced in hospitals, often even according to the manufacturer’s guidance.

The need for further research on this controversial topic - so common in hospital practice - is obvious. This study aimed to evaluate the effectiveness of the sterilization process for reusable harmonic scalpels.

METHODS

This experimental, applied, comparative, controlled study was carried out between 2012 and 2013 in the laboratory of microbiology of the Pontifical Catholic University of Paraná (PUCPR) and in the Institute of Technology of Parana (TECPAR).

The parameter set for this research is globally accepted, because there is strong methodological evidence about "challenge" contamination through inoculation of blood sterilization-resistant microorganisms.

The inocula used for incubation were purchased at the Reference Microbiology Laboratory, National Institute of Quality Control in Health, Oswaldo Cruz Foundation (FIOCRUZ). For incubation, we used two 100-ml bags of sterile defibrinated sheep blood, which was chosen because it is the most similar to human blood. The strains used in this study were:

- spore *Geobacillus stearothermophilus* (ATCC 7953), at a concentration of 10^6colony-forming units per milliliter (CFU / ml), used for monitoring the efficacy of steam sterilization cycles.
- *Bacillus atrophaeus var. niger* (ATCC 9372), used for assessing microbial death by sterilization by ethylene oxide[13,14].

Samples selection

The sample size was calculated using a statistical power of 99% (likelihood of detecting the expected difference in each group) and the following assumptions: 50% incidence of adverse events in the manual cleaning process and 5% incidence of adverse events in the mechanical cleaning process. Thus, 12 harmonic scalpels constituted group A and 12 harmonic scalpels constituted group B. Three new tweezers - 3 units from each manufacturer - were used for microbial count and constituted the control group (approximately 20% of the sample size - 30 units).[15]

Group A was composed of harmonic scalpels reused according to manufacturer's instructions. Group B was composed of harmonic scalpels labelled as single-use only.

In order to ensure the presence of microorganisms, tests to measure cleaning and sterilization effectiveness were carried out in two phases: Phase 1 - artificial contamination; and Phase 2 - evaluation of the manufacturer's data.

Inclusion criterion was: harmonic scalpels only used once. Exclusion criterion were: damaged tweezers and scalpels used in contaminated surgeries.

Samples preparation

Sample preparation began with the organization of the environment and the materials being used. Hand antisepsis was performed with aid of a 0.5% chlorhexidine scrub (aseptic technique). The researchers were dressed in disposable surgical scrub suits. Next, the table where the experiments were to be performed was set with disposable sterile waterproof fields.

The first preparation phase consisted in the contamination of 100 ml of sterile defibrinated sheep blood with *Geobacillus stearothermophilus* (ATCC 7953). The second phase, performed on a second table, consisted in the contamination of 100 ml of sterile defibrinated sheep blood with Bacillus atrophaeus var. niger (ATCC 9372).

New samples were washed with sterile water and enzymatic detergent, and dried with medical compressed air. Then we prepared the inoculum that would be used to confirm the load of inoculated microorganisms.

Microbial Load adherence

In the second phase, three 200-ml samples of sheep blood were contaminated with 10^6 colony-forming units per milliliter (CFU/ml):

- 03 samples contaminated with *Bacillus atrophaeus var. níger;*
- 03 samples contaminated with *Geobacillus stearothermophilus*.

This control was essential to detect adherence of the microorganism to the sample for one hour, average duration of a videolaparoscopic surgical procedure. The study was continued only after inoculum adherence to the instruments was confirmed.[15]

Control group contamination

After microorganisms count was determined for the control group, the internal rods and lumens of the harmonic scalpels which constituted the experimental group were contaminated by injecting 20 ml of microbial suspension with blood and inoculum. With the aid of a syringe, 20 ml of the inoculum were injected into the lumens every 20 minutes for one hour. This procedure simulated the handling of the harmonic scalpel by the surgeon. The handles and flanges of the tweezers were also pressed every 20 minutes for one hour.

Cleaning, packaging and sterilization

In the next phase, the samples were submitted to processing, i.e., disassembly, cleaning, disinfection and sterilization. They were first disassembled, then immersed for 5 minutes in a solution of sterile water heated at about 40°C and enzymatic detergent stored in a sterile stainless steel container, as per the manufacturer's instructions. Manual cleaning was performed with the aid of disposable brushes of 1-mm to 3-mm internal diameter for internal washing of the lumens. Other brushes with soft bristles were used for cleaning the outer parts. The rinse was done with sterile water and the samples were dried with medical compressed air. Automated cleaning was performed by means of a 35.3-liter ultrasonic washer with 38 kHz ultrasound frequency. Finally, rinsing was done with sterile water and the samples were dried with medical compressed air. Five samples of each group were individually wrapped in surgical paper and exposed to different sterilization methods. Samples from Group A were sterilized by an outsourced service provider using ethylene oxide at low temperatures. These sample were individually stored in zip lock plastic bags and packed in rigid, closed plastic boxes. The other samples (Group B) were sterilized (according to the manufacturer's data) in a steam autoclave for 5 minutes at 134°C.[16]

Sterility assessment

With the aim of reducing costs without losing generality, three representative units were removed from each test body in order to be subjected to microbial count testing and sterility testing using the direct inoculation method at the Institute of Technology of Parana (TECPAR).

Analysis of the criteria for making decisions about the reuse

To properly apply the criteria for reuse of biomedical devices it is important to understand the current regulations and the instructions provided by the manufacturer, even before the purchase of the article. In order to obtain a better understanding of the device, an evaluation form was developed for each harmonic scalpel. For mapping these data, a protocol containing the following items was created:[17]

- *Technical product description*: Data on the manufacturer, brand and approximate cost of the device;
- *Product criticality rating;*
- *Device Specifications;*
- *Acceptability of the cleaning process;*
- *Disruption of the physical integrity of the device after reuse;*
- *Presence or absence of the device in the negative list of the current legislation;*
- *Product labeling by the Brazilian National Health Surveillance Agency (ANVISA);*
- *Occupational accident risks during the reuse process;*
- *Traceability of reuse.*

RESULTS

Our findings, derived from the analysis of the scalpels, are in agreement with the results of the literature concerning the reuse of disposable scalpels. Our results indicate that the disassembling of the harmonic scalpel usually causes irreparable damage to its physical structure. This difficulty in disassembly was associated with the recovery of microbial load. It should be noted that disposable articles are generally manufactured from raw materials that are not resistant to abrasive materials, which compromises disassembly and may alter the manufacturer›s features.[17,18]

The following physical alterations occurred during disassembly: breakage of the white rod, swivel base and shirt rod of the tweezers in Group A; and breakage of the locking arm, torque wrench and trigger of the tweezers in Group B.

All samples infected with microbial load were processed according to the following steps:

- Disassembling of the samples;
- Immersion in enzymatic detergent;
- Manual cleaning;
- Rinse;
- Mechanical cleaning;
- Rinse;
- Drying;
- Storage

The results obtained from the simulated challenge with microbial strains of Geobacillus stearothermophilus and Bacillus atrophaeus in new harmonic scalpels are presented in Table I.

Table I - *Evaluation of the microbial recovery in the control group of new harmonic scalpels. Curitiba, Brazil, 2012.*

Materials used in the control group			*Bacillus atrophaeus*	*Geobacillus stearothermophilus*
Harmonic scalpels (Reused)	GROUP A	A1	03/3	00/3
		A2	02/3	00/3
		A3	05/3	00/3
Harmonic scalpels (Single Use)	GROUP B	B1	00/3	02/3
		B2	00/3	03/3
		B3	00/3	02/3

Number of microorganisms found (CFU)/Total sample unit.

The results shown in Table I attest to the adherence of the inoculum and blood to the samples, validating the process of contamination measured by colony-forming units per milliliter.

The results of the experimental group sample are presented in Table II.

Table II - *Sterility Test by direct inoculation of specimens with the microbial strain of the experimental group. Curitiba, Brazil, 2012.*

Materials used in the experimental group			*Bacillus atrophaeus*	*Geobacillus stearothermophilus*
Harmonic scalpels (Reused)	GROUP A	A1	01/5	00/5
		A2	02/5	00/5
		A3	01/5	00/5
Harmonic scalpels (Single Use)	GROUP B	B1	00/5	01/5
		B2	00/5	01/5
		B3	00/5	01/5

Number of microorganisms found (CFU)/Total sample unit.

The analysis of the data distributed by the manufacturer for marketing purposes and for ensuring reuse are shown in Table III.

Table III - *Results of the analysis of the checklist applied to the harmonic scalpels samples from different brands. Curitiba, Brazil, 2012.*

Criteria for making decisions about the reuse	Group A	Group B
Technical product description	YES	YES
Manufacturer's data	YES	YES
Can be disassembled	NO	NO
Product is listed in the RDC 2605/ANVISA	YES	YES
Existence of occupational risks during disassembly	YES	YES
Reuse can be controlled	YES	YES
Removal of dirt during the cleaning process	NO	NO
May pose risks to the patient if there are failures in use	YES	YES
Its integrity is compromised after reuse	YES	YES
Can be reused	NO	NO

In studies such as this one, the completion of preliminary microbial counts is indispensable. We highlight the importance of disassembly for cleaning, because this is the first and most important step in the processing of articles. All samples from both groups showed the presence of microorganisms (as measured by CFU). Thermal or chemical disinfection as well as sterilization are not possible if all visible and invisible organic matters are not completed removed from the articles. If the scalpel is not clean, it cannot be sterilized, let alone be used in a second patient.

DISCUSSION

The practice of reuse without due processing is merely a belief. However, it has been performed since the 80s, compromising the quality of care to patients. The idea of investigating the effectiveness of sterilization of harmonic scalpels used in surgical procedures aimed to ensure the understanding of health professionals about the imminent risk of infection associated with it.

Currently, disposable articles are becoming a pandemic and the risk associated with their reuse is made commonplace. This is the case of both of the harmonic scalpels analyzed in this study. After analyzing the samples according to the current laws and to the information provided by the manufacturers, we found that both scalpels have similar functions, features, criticality rating and, most importantly, they are both not demountable, a crucial factor on which depends the safety of this practice.

According to the findings of this study, the two harmonic scalpels tested cannot be reused, because they cannot be easily disassembled and thus, the cleaning process is compromised. The impossibility of disassembly led to the presence of organic material in the laboratory results.

This is in line with the results obtained by Greene 2004, who concluded that the functionality of harmonic scalpels is compromised after their use, which impedes their reuse.[20]

The processing of medical devices in health care is complex. Primary goal is always the avoidance of adverse events related to reuse. Thus, reduction of microbial load through disassembly and cleaning is essential to avoid cross infection.

The story of complications associated with the reuse of biomedical articles begins in the 70s, before disposable devicesstarted being manufactured. Most medical devices were made of glass, metal, rubber. Materials considered easy to clean and reprocess. With the advancement of technology, however, instruments with smaller and more complex lumens were developed and made the cleaning process more difficult. This consequently resulted in a high rate of pathogens, leading many patients to be affected bycross-contamination.

The advent of HIV transmission revolutionized the industry's ability to manufacture single-use articles,giving birth to the "disposable mentality". The convenience of disposable products was initially a relief for hospitals, because they no longer had to worry about product lifetime, breakage and malfunction, which had been the case for permanent biomedical articles until then.[21]

In this period, European hospitals began to experience surgical site infections which had been considered unusual until then. As a result, they started to discard permanent products used in patients exposed to the so-called prions (Creutzfeldt-Jakob disease), a protein resistant to several sterilization methods.[22]

Several countries are reviewing their laws in order to curb or prohibit the practice of reuse. In Germany and Sweden, contractors and hospitals are allowed to reuse single-use articles as long as they follow a regulation similar to that applied to manufacturers. A study conducted in the United States has shown that 30% of American hospitals reused single-use articles. However, in France, the UK, Italy, Spain and Switzerland, the reuse of disposable health products is strictly prohibited.[23,24]

Specific legislations in Brazil, such as the RDC 2605 and RDC 2606 of August 11th 2006, restrain the reuse of invasive devices which come into contact with the vascular system.[25]

It is important to note the role played by suppliers and operators in the reuse of health products. Purely economic decisions, with no technical or scientific support, end up being part of hospital practice. A Decision of the Brazilian Supreme Court of Justice (STJ) does not allow health insurance operators to make changes in treatments suggested by physicians, because the patient (or health insurance consumer) cannot be prevented from receiving treatment with the latest techniques available on the market, even if these techniques are costly single-use devices.[26]

There is a civil suit in progress in the Public Prosecutor's Office of the State of São Paulo against a health insurance operator which was accused of abusive practices in public health. According to the complaint, the aforementioned operator imposes the reuse of single-use shaver blades on cooperating doctors and hospitals, by threatening to exclude them in case of non-compliance. The operator passes on only one third of the value of the product to the cooperating parties and forces them as well as their distributors to reprocess the blades at least three times[27].

CONCLUSION

Most harmonic scalpels showed physical damage after disassembly. Moreover, recovery of the microorganisms Geobacillus stearothermophilus and Bacillus atrophaeus was evidenced in all samples, which indicates that neither sterilization nor high or low temperatures were effective under experimental conditions.

The incidence of contamination found in this study indicates that (both manual and mechanized) cleaning processes within reprocessing are prone to failures. This may be due to the difficulty generated by the physical structure of medical products, since many of them had narrow lumens, which hinders the elimination of biological waste. When cleaning does not achieve the desired effect, the sterilization process is also compromised, because the remaining residues somehow "protect" the microbial load from the sterilizing agent.

Based on the facts presented here, it may be concluded that further studies on the reuse of harmonic scalpels and other biomedical devices should be conducted, especially in conjunction with functionality tests. Finally, this study also shows that this topic is associated with an issue of market regulation and involves the practices adopted by health insurance operators. This problem, therefore, transcends health aspects and asks for a broad discussion with regulatory agencies, health care institutions, health insurance operators, medical products distributors, health associations and even consumer protection agencies.

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