

Comparison of Methods for the Sterilization of Instruments Used for Laparoscopic Surgery

Estudo Comparativo de Métodos de Esterilização de Material de Uso em Cirurgias Laparoscópicas

EDUARDO CREMA¹; EVA CLÁUDIA VENÂNCIO DE SENNE²; DANIELE FOSSALUSSA NESPOLO³; ADRIANA GONÇALVES DE OLIVEIRA⁴; CELSO JÚNIOR OLIVEIRA TELES⁵; ALEX AUGUSTO SILVA⁶

¹ Professor and Chair of Gastrointestinal Surgery, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; ² Nurse, Nosocomial Infection Control Service (SCIH), Hospital de Clínicas, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; ³ Student, School of Medicine, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; ⁴ Adjunct Professor of Microbiology, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba-MG, Brazil; ⁵ Student, School of Medicine, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; ⁶ Adjunct Professor of Gastrointestinal Surgery, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil.

ABSTRACT

INTRODUCTION: Technological advancements have led to the development of various novelties that contribute to better health care. Among these new developments are “single-use” or disposable devices made of noble materials and designed for specific purposes in medical-surgical procedures. Various countries have adopted reuse to reduce costs. In the United States, reprocessing of single-use devices is performed by subcontractors that are regulated by the FDA (Graziano, 2006). **MATERIAL AND METHODS:** All instruments (trocars, forceps and ultrasonic scalpel) were processed at the Central Material and Sterilization Facility (CME) of HC-UFTM. After mechanical washing, the instruments underwent ultrasonic cleaning, were dried with compressed air, and sterilized with hydrogen peroxide in the Sterrad® system. Each instrument was then placed in a sterile plastic bag containing 100 mL 0.9% saline for 5 minutes. The fluid was collected and sent to two different laboratories of UFTM for culture. **RESULTS:** A total of 1016 cultures were performed, including 227 on blood agar, 227 on MacConkey agar, 227 on Sabouraud agar, 227 in Löwenstein medium, and 108 in Middlebrook medium. No microbial growth was detected in any of the 1016 cultures using different media. **CONCLUSION:** The results showed that the standard technique used for the processing and sterilization of surgical instruments at the University Hospital of UFTM is effective and safe and might be used for the reprocessing of medical instruments for laparoscopic surgery.

Key words: single use, laparoscopy, tuberculous mycobacteria, reprocessing.

Bras. J. Video-Sur, 2010, v. 3, n. 3: 134-138

Accepted after revision: February, 11, 2010.

INTRODUCTION

Due to technological advances, there have been various new developments that have contributed to better healthcare. One of these innovations are disposable devices classified as “single use,” many manufactured with expensive materials for specific purposes in medical and surgical procedures. This is especially true in video-assisted surgeries that have adopted dissecting forceps, grabbing forceps, cutting instruments, trocars, and staplers intended to be used once. However, the technology increasingly makes

these newly developed items more expensive. The products are frequently more expensive than the reimbursement provided by public and private payers. Thus individuals responsible for purchasing do not buy all the devices needed to perform the procedures¹. This has led to a search for an alternative to moderate such outlays; the solution encountered is the reprocessing of these items, one way of controlling the cost factor while maintaining the benefit of a new product. Several countries – including Brazil – have adopted this approach to reduce the costs of utilizing technology.

Norms for the reutilization of “single use” devices have been discussed by the Ministry of Health and by the *Agência Nacional de Vigilância Sanitária* (ANVISA) [National Agency for Public Health Surveillance] since 1985². Due to the great variety of these devices in medical and hospital care, in 2001, Public Notice No. 98 was published, which established procedures for the reuse of products, generating great debate in the scientific community and among health institutions. After five years of discussion, in February 2006, ANVISA published Resolution 515, which established a list of single use materials for which reprocessing was prohibited. Among the 78 elements on the list were various instruments used in different areas of medicine, such as forceps, scissors, needles and trocars used routinely in video laparoscopic surgery. This resolution was based on safety criteria that reflected impossibility of sterilizing the instruments using methods available at the time.

Although they were not consulted and considering the use of some “single use” materials (ultrasonic scalpels, esophageal staplers), it is known that these are indispensable for performing advanced laparoscopic surgery. Furthermore, it should be noted that comparable permanent devices to substitute the disposables don't exist, since the prices were raised by multinational companies.

With regard to sterilization, the first stage is fundamental for the cleaning of surgical material, because it reduces the initial microbial burden by 99.99%, or in other words, four logarithmic cycles of the *bioburden* present on the device³. Therefore, whatever method used, the presence of organic material impedes the action of the physical or chemical agent during the sterilization and can impede the elimination of microorganisms capable of transmitting infections. The importance of cleaning is so great, that it appears as the first item in the regulations of the U.S. Centers for Disease Control (CDC) governing the reutilization of medical instruments. In addition, there is the question of damaging the material due to repeated use, and methods used in cleaning and sterilization that can lead to stiffening of the articulations, loss of cutting quality, among others. Still, the quality of the reprocessed device should be comparable to that offered by a new item, especially with regard to its functionality, lack of toxicity, and sterility.

The advantage of reprocessing, for healthcare institutions, was to increase the availability of materials, as well as resolve a work overload and the monitoring of the *performance* of permanent devices⁴. Reuse is a reality in this country and globally and there is no expectation that the situation will change, at least in the short to medium term in Brazil. The practice of reuse is very common, without standardization of the products and processes, and without monitoring of the impact on clinical outcomes. Given the lightness, ease of manipulation, and greater functionality of “single use” devices, surgeons prefer to use reprocessed rather than permanent devices¹. In this context, the issue is: what is the best way to work without compromising the key qualities of the product.

Statistics from studies demonstrate that even though the practice is very common, few adverse events have been registered. The methodology of the few studies that have been carried out in this area is questionable. Although there's no evidence that reuse causes harm, there also is no proof that it doesn't cause harm. Moreover, many publications do not present any standards for products used for cleaning.

Brazil is not the only country to consider reprocessing. In the United States, reprocessing of “single use” devices is outsourced to companies regulated by the FDA⁴. In Canada, a study carried out with 421 hospitals revealed that only 20% of them had a Committee on the re-use of materials, and of these, only 30% had written protocols. In 1996, the Canadian Healthcare Association Guidelines were published with recommendations on reuse practices. In this country, critical devices are not reused (except some institutions that reuse hemodynamic/Swan-Ganz catheters). Semi-critical devices, however, are reused with greater frequency. Currently, it is the healthcare services that carry out the reprocessing, but due to the complexity of the protocols for validation, the great majority of health care services will be unable to continue this practice.

According to Graziano⁴, various studies have been published in Germany about the cost-effectiveness of reuse. Although it is considered a common practice, reprocessing is subject to surveillance of the public-health officials of the country. In Australia, reuse is frequently practiced, and policies similar to those of the United States were adopted, namely that the hospitals that

reprocess are treated as re-manufacturers. England – where the greatest concern is *prions* – permits reuse in certain circumstances. Spain does not authorize reuse and hospitals that practice reuse will be held responsible for any risks experienced by the patient. Whereas Sweden permits reuse, as long as quality control standards are met, France effectively prohibits reuse.

Due to biotechnology advances in the medical and hospital equipment industry, there has been a significant replacement of permanent items with disposable items, as well as the addition of new devices. At a conference of these changes, many companies, that until the 1970s had products that were called “reusable,” simply changed their labels for “single use,” even though they made no changes in the composition of the product. In the United States of America, there was an increase in the number of legal actions due to this change that occurred when the manufacturer defined its product as reusable and limited the number of possible reuses. This is the way to make reprocessing safe.

As a consequence of these transformations, thousands of patients can not benefit from this important technological advance, especially those in public hospitals, whose financing is almost exclusively from the *Sistema Único de Saúde* (SUS).

The move to some permanent instruments also caused an increase in the prices of materials that are manufactured exclusively for single use and/or our reusable. At no time was any consideration given to the experience with thousands of reprocessings already carried out in a safe manner around the world. For example, we can cite the experience of the *Hospital de Clínicas of Universidade Federal do Triângulo Mineiro* (UFTM), which had at one point performed more than 12,000 laparoscopic procedures without ever having any outbreak of infection.

With disposable devices becoming increasingly complex and expensive, and with hospitals possessing and applying low temperature sterilization technologies, the application of its sterilization technologies to disposable materials, in order to reuse them, was a truly natural evolution. Another explanation for the reutilization is the limited availability of these devices in the marketplace, especially those that must be imported. One cannot forget, however, that there is a certain need for special care in the reprocessing of these items, so

that one attains a standard of quality. The labeling of a device undergoing reutilization should contain information that permits the traceability of the material: name and location of the reprocessor, complete address, nomenclature of the device, reprocessing number, details of the reprocessing, and indications for use.

According to the manufacturer's (Johnson & Johnson) manual, the STERRAD® is a sterilizer for dental/medical/hospital materials based on hydrogen peroxide plasma technology ⁵. The equipment is comprised of an aluminum circular chamber, and is totally automated and computerized and operates in 55 or 72 minute cycles. Sterilization parameters are recorded for each process in order to guarantee safety and reliability. The mechanism has a frontal opening with an optical sensor for the insertion of cassettes and barcodes for the operation of the system (10 ampoules/cassette, with two ampoules used per cycle). Each ampoule contains 1.8 ml of 58% hydrogen peroxide. The retrieval of used cassettes is performed by an internal system using a collection box. The material that is to be sterilized it is placed in the chamber. A guillotine-like door closes automatically and the chamber is subjected to a vacuum. After this, eight steps are performed: vacuum, injection, diffusion, plasma, injection, diffusion, plasma and ventilation. Each of these steps can be monitored on a liquid crystal display that, by means of a built-in printer, assure the registry of each phase of the sterilization cycle. The equipment is automatic and thus does not need human monitoring. If there are variations in the load conditions of sterilization, the system detects the failure, cancels the cycle and emitting an alarm sound/beep. In addition a report indicates the cancellation and its probable cause.

According to the information above, it is essential to carry out studies aimed at the sterilization of single-use devices that are being reprocessed, in order to assess whether there are risks or not in the reuse of these materials and which is the most efficient method for performing this procedure ^(6, 7, 8, 9). Given that the reprocessing of “single use” devices in laparoscopy is a common practice, it is important to analyze the efficiency of processing methods and sterilization of materials, since these devices can serve as a source of acquisition of microorganisms by patients undergoing surgery. Therefore, standardization of the methods of sterilization is necessary, as there is no standard for this procedure in Brazil.

SPECIFIC OBJECTIVES

Verify the feasibility of reusing “single use” laparoscopic materials after reprocessing, evaluating the risk of the patient acquiring any pathogens coming from the reprocessed material. For this, cultures in *Blood agar*, *Sabouraud agar*, *MacConkey agar*, *Middlebrook* culture media and *Löwestein* media will be carried out to verify if there is bacterial or fungal growth after reprocessing employing sterilization of devices using the Sterrad® method.

MATERIALS AND METHODS

In order to describe the steps and components of the process, we first prepared a flowchart of the steps in the reprocessing of “single use” 5 and 10 mm trocars, forceps and cutting forceps used in videosurgery. The material used was: 5 trocars (two 10 mm and three 5 mm), and two laparoscopic forceps (scissors, scalpel, and endostaplers).

The pieces used were new and sterilized upon manufacture. First they were placed in sterilized plastic bags, and individually and totally immersed in 100 ml saline for 10 minutes. After this, the liquid was collected and centrifuged at 3,000 rpm for another 10 minutes. After centrifugation, the supernatant was aspirated and discarded, and the residue was seeded on culture plates that were placed in an incubator at 37.5° C with 5% CO₂.

The cultures were performed by two laboratories, the Microbiology Laboratory of *Hospital de Clínicas* of the *Universidade Federal do Triângulo Mineiro* (UFTM) and the Microbiology Research Lab of the UFTM. The media used were *Blood agar* (used to isolate non-fastidious microorganisms, for verification of hemolysis by *Streptococcus spp.* and *Staphylococcus spp.* and presumptive identification of *Haemophilus spp.*); *Sabouraud Agar* (used for the cultivation and growth of species of *Candida* and filamentous yeast, especially those associated with superficial infections); *MacConkey agar* (for the isolation of gram negative bacilli – enterobacteria and non-fermentors – and verification of the presence or absence of fermentation of lactose); *Middlebrook* media (for the isolation of rapidly growing mycobacteria) and *Löwestein* media (for the primary isolation of mycobacteria). Incubation times for each type of plate are: *Blood agar* 24 hours; *Sabouraud agar* for 40 days; *MacConkey agar* for

24 hours (if there was no growth, plate would be incubated for an additional 24 hours); *Middlebrook* media for 60 days; *Löwestein media* for 60 days.

Immediately after the gastrointestinal surgeries were performed, the trocars and the forceps are subjected to the same technical procedures described above, and the liquid was plated for culture.

The processing of the trocars, forceps and ultrasonic bisturis was carried out by the Material and Sterilization Center of HC-UFTM. Instruments were received immersed in sterile water, taken apart and, soon thereafter, immersed in enzymatic detergent for 2 to 5 minutes, in accordance with the recommendations of the manufacturer (with injection of the detergent into the lumen of the instrument using a syringe). The trocars and the forceps scalpel were scrubbed with special brushes for two minutes and immediately flushed with pressurized water, and then passed under compressed air for five minutes. Cannulas were sent to an ultrasonic washer, and were subsequently inspected under a magnifying glass. When they were found to be in accordance, they were dried with compressed air and then subjected to a process of sterilization with hydrogen peroxide in the STERRAD® equipment. After this process was completed, specimens were again collected for culture following the same sequence of procedures described above.

RESULTS

A total of 1016 cultures were carried out, 227 on blood agar media, 227 on *MacConkey agar*, 227 on *Sabouraud agar*, 227 on *Lowenstein* culture media, and 108 on *Middlebrook* media. Half of the samples were processed at the Central Laboratory of the *Hospital de Clínicas* of UFTM and the rest at the Microbiology Research Laboratory of UFTM. Even with various media used, and each specimen cultured at two different laboratories, in none of the 1016 cultures was the growth of microorganisms – either bacteria or tuberculous mycobacteria – detected.

CONCLUSION

Based on the material evaluated, it can be concluded that the processing and sterilization of trocars, forceps and endostaplers utilized in laparoscopic surgeries carried out at the *Universidade Federal do Triângulo Mineiro* (UFTM) are effective and safe.

RESUMO

INTRODUÇÃO: Devido ao avanço tecnológico surgiram várias novidades que vieram para dar maior assistência à saúde. Uma dessas novidades são os artigos classificados como de uso único (ou descartáveis), muitos deles construídos com materiais nobres para finalidades específicas em procedimentos médico-cirúrgicos. Vários países têm adotado medidas de reutilização para reduzir os custos. Nos Estados Unidos, o reprocessamento de artigos de uso único é realizado por empresas terceirizadas regulamentadas pelo FDA (Graziano, 2006). **MATERIAL E MÉTODOS:** Todo o material (trocâteres, pinças e bisturi ultrassônico) foi processado pela Central de Materiais e Esterilização (CME) do HC-UFTM. Após lavagem mecânica, os instrumentos foram encaminhados para lavadora ultrassônica, secagem com ar comprimido, e posteriormente submetidos à esterilização com peróxido de hidrogênio pelo aparelho STERRAD®. Em seguida, cada instrumento foi colocado em saco plástico estéril com 100 ml de soro fisiológico 0,9% durante 5 minutos. Realizou-se culturas em dois laboratórios distintos da UFTM. **RESULTADOS:** Foram realizados um total de 1016 culturas, sendo 227 culturas no meio Ágar Sangue, 227 Ágar MC Conkey, 227 Ágar Sabouraud, 227 Lowenstein e 108 Middlebrook. Em nenhuma das 1016 culturas com os diversos meios utilizados detectou-se o crescimento de microorganismos. **CONCLUSÃO:** Com base neste material pode-se concluir que o processamento e a esterilização destes instrumentos através da técnica padronizada no HC da UFTM são eficazes e seguros, e podem ser empregados no reprocessamento dos materiais de uso em cirurgias laparoscópicas.

Palavras-chaves: uso único, laparoscopia, micobactéria tuberculose, reprocessamento.

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Correspondence Address:

DR. EDUARDO CREMA
Rua Marcos Lombardi, 305
Bairro Santos Dumont
Uberaba, MG, Brazil 38050-170
E-mail: cremauftm@mednet.com.br