FACTORS RELATED TO EXCHANGE OF DISINFECTION SOLUTIONS OF ENDOSCOPIC DEVICES

Fatores relacionados à troca das soluções de desinfecção dos aparelhos endoscópicos

Factores relacionados con el intercambio de soluciones de desinfección de endoscópios dispositivos

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ABSTRACT: Objective: To identify the factors related to the replacement of disinfection solutions of endoscopes devices. **Method:** A quantitative study carried out at an endoscopy service in the city of Belo Horizonte, belonging to the Brazilian National Health System, in the period from March 28, 2012 to March 20, 2013. It was carried out a documentary analysis of test records for daily monitoring of chemical disinfection processes in that particular sector. Descriptive statistics were used with frequency distribution and central trend measurements. **Results:** The following factors related to the replacement of the disinfecting solution of peracetic acid were identified: minimum solution concentration inferior to the required (75%), volume below the ideal amount (15%), presence of deposits and accidental solution spillage, both at 5%. The extra cost estimated on the unnecessary exchanges reached 66.6%. **Conclusion:** There is a prior need to review the planning and protocols of the service.

KEYWORDS: Endoscopy, gastrointestinal. Disinfection. Peracetic acid. Sanitizing products.

RESUMO: Objetivo: Identificar os fatores relacionados à substituição das soluções de desinfecção dos aparelhos endoscópicos. **Método:** Estudo quantitativo, realizado em um serviço de endoscopia digestiva alta de Belo Horizonte pertencente ao Sistema Único de Saúde, entre 28 de março de 2012 e 20 de março de 2013. Fez-se uma análise documental dos registros de testes realizados para monitorização diária dos processos de desinfecção química no setor citado. Foi utilizada estatística descritiva com distribuição de frequência e medidas de tendência central. **Resultados:** Como fatores relacionados à substituição da solução de desinfecção de ácido peracético, identificou-se a concentração mínima da solução inferior à necessária (75%), volume abaixo da quantidade ideal (15%), presença de depósitos e derramamento acidental da solução, ambos com 5%. O custo extra estimado com as trocas desnecessárias foi de 66,6%. **Conclusão:** Observou-se a necessidade de revisão do planejamento e protocolos do serviço de forma prioritária.

PALAVRAS-CHAVE: Endoscopia gastrointestinal. Desinfecção. Ácido peracético. Saneantes.

RESUMEN: Objetivo: Identificar los factores relacionados con la sustitución de soluciones de desinfección de endoscopios dispositivos. **Método:** Estudio cuantitativo, realizado en un alto de servicio de endoscopia en la ciudad de Belo Horizonte perteneciente al Sistema Nacional de Salud de Brasil, (SUS) entre el 28 de marzo de 2012 y 20 de marzo de 2013. Hubo un análisis documental de entradas de prueba realizados para el seguimiento diario de los procesos de desinfección químicos enese sector. Se utilizó estadística descriptiva con la distribución y medidas de tendencia central frecuencia. **Resultados:** Factores relacionados con la sustitución de la solución desinfectante de ácido peracético: concentración mínima requerida para bajar la solución (75%),volumen por debajo de la cantidad ideal (15%), presencia de los depósitos y derrame accidental de lasolución, tanto con 5%. El costo adicional estimado intercambios innecesarios fue de 66,6%.**Conclusión:** Hay una necesidad de revisar la planificación y protocolos de un servicio prioritario.

PALABRAS CLAVE: Endoscopía gastrointestinal. Desinfección. Ácido peracético. Saneantes.

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INTRODUCTION

Digestive endoscopy is a procedure carried out with the assistance of an endoscopic device for the diagnosis and treatment of several gastrointestinal diseases[1]. The demand for this procedure has grown in the past few years due to the increasing complaints of dyspepsia and the prevention and screening of cancer[2].

Endoscopic devices are expensive and consist of long channels, with complex design. They are made out of delicate material, which makes it more difficult to clean them; however, they are more easily damageable[3]. At use, the external and internal surfaces of these devices are exposed to several micro-organisms, which requires proper decontamination after each procedure to prevent cross-contamination, to increase the device's lifecycle, to protect the team that reprocesses it against infections and to prevent diagnostic errors, once fragments of biopsy could remain inside the device and be mixed with those of other patients[2,4].

It is recommended that, after use, endoscopic devices be submitted to high-level disinfection through liquid disinfectants, considering these are semi-critical and thermosensitive items[5,6]. This process leads to a minimum 6-log reduction in mycobacteria, and to the destruction of all other micro-organisms, except for prions and bacterial spores[7,8].

Working as high-level disinfectants, peracetic acid, glutaraldehyde and ortho-phthalaldehyde are usually used to reprocess endoscopes in Brazil. Its records are authorized by the Brazilian Health Surveillance Agency[9]. During reprocessing, the endoscopic device must be submerged in a high-level disinfectant right after the cleaning stage. The duration of the exposure of the device to each one of these solutions, as well as the expiration date proposed for the product and the prepared solution, is defined according to antimicrobial efficacy tests conducted by the manufacturers[10].

However, the effective disinfection of these devices is directly related to the quality of the use of disinfecting solutions. Many external factors can affect the efficacy of these solutions, like inefficient cleaning, which can compromise the sanitizing action, since the action of many solutions can be reduced or annulled when in contact with organic matter; the temperature of the used solution; the immersion of the endoscopic device, still wet, in the solution, leading to hyper dilution and the consequent change in the product's pH and concentration; and the time of exposure of the device to the disinfecting solution, besides the characteristics related to the device's washing and drying process[5].

Therefore, it has been recommended to monitor the disinfecting solutions in order to ensure its efficacy[10]. Then, with a chemical indicator, it is possible to assess the conditions of the solution regarding the minimum effective concentration (MEC) established by the manufacturer so that these solutions can have the proper effect. If the monitor shows, though changing colors, that the chemical solution is not in the established MEC, it should be discarded, even if prior to the expiration date. The solution must be monitored at least once a day before the beginning of activities[10]. Therefore, the use of high-level disinfectants in non-ideal conditions, causing flaws in the reprocessing stages of the endoscopic device, can be prevented[1].

Flaws in the reprocessing stages of endoscopic devices represent one of the main causes of cross-transmission of micro-organisms and formation of biofilm, which can be detached and contaminate the patient[11]. It is estimated that the rate of infection in gastrointestinal endoscopic procedures is of 1 in 1.8 million. However, these data may be underestimated, considering the sub-notification of cases, lack of surveillance from health services and long period of incubation of some infections[4].

It is expected that the results found can contribute with the establishment of protocols regarding the control of the chemical solution to plan for actions and to promote improvements in endoscopic services.

GENERAL OBJECTIVE

To identify the factors related to the replacement of disinfecting solutions for endoscopic devices.

METHOD

This was a quantitative study conducted in a high digestive endoscopy service of Belo Horizonte, belonging to a secondary reference unit of the Unified Health System (SUS). This service assists the State of Minas Gerais, and provides approximately 360 diagnostic digestive endoscopies per month.

In the referred service, a documentary analysis of records was conducted regarding the daily monitoring tests for the processes of chemical disinfection in the aforementioned

sector, from March 28, 2012, to March 20, 2013. If necessary, complementary records from the nursing service were consulted, such as the occurrence book in the digestive endoscopy service.

The solution control is registered in a document, and the MEC test strips for the peracetic acid solution are attached. Dates and reasons for the disposal/replacement of the peracetic acid solution were extracted from these documents to reach the results. A total of 216 MEC strips were analyzed in the study period. For the treatment of data, descriptive statistics with distribution of frequency and central tendency measurements were used. The collected data were typed and then statistically described, by calculating the percentages and being presented in a spread sheet.

Since this study does not involve the participation of human beings, it does not require the approval from the Research Ethics Committee of the institution, according to resolution 466/12. Therefore, a formal authorization to use the records was obtained from the service coordination.

RESULTS

The analyzed service has four endoscopic devices. Two of these devices are exclusively used in a solution of peraceltic acid and the two others, in a solution of glutaraldehyde, being submitted to high-level disinfection in their respective solutions since the first use.

The endoscopes processed in glutaraldehyde are only used when those processed in peracetic acid require maintenance, replacing them. That is, devices of preferential use are those processed in paracetic acid; therefore, the use of devices submitted to high-level disinfection with glutaraldehyde is reduced. Some of the reasons that limit the use of these devices are based on the reduced quality of the images provided by the equipment, besides the difficulty of the service to acquire the referred solution.

During the week, about 95 endoscopies are conducted and involve 2 work shifts: morning and afternoon. During the study period, 2,720 digestive endoscopy examinations were performed.

To monitor the solutions, 216 MEC strips used in the period were analyzed.

As to the solutions, during this period, peracetic acid supplied by the same manufacturer was prevalently used. Glutaraldehyde was only used four times, while the device processed in peracetic acid was under maintenance. Because of the little use of this solution, the strips monitoring it were not analyzed in this study.

To meet the objective of the study, of identifying the factors related to the replacement of disinfecting solutions for endoscopic devices, results will be presented according to the analysis of estimated and real time to replace the disinfecting solution in endoscopic devices, to the factors related to the solution exchange, and to the cost estimated for the solution exchange in the estimated and real time.

The exchange of the peracetic acid solution at use has been proposed for every 30 days, according to the manufacturer. Therefore, for the study period, it is estimated that this solution was exchanged 12 times; however, we observed it was replaced 20 times.

By analyzing the reasons that determined why the solution had to be discarded/replaced, the fact that in 75% of the cases the MEC strip indicated minimum concentration lower than the requirement to work efficiently as a high-level disinfectant stood out.

Another reason to replace the solution in 15% of the cases was owed to the fact that the mean volume of the solution in the recipient was inferior to the established one, to ensure the complete immersion of the whole surface of the endoscopic device.

It was also possible to observe, in 5% of the replacements, the presence of deposits in the solution, as well as the accidental spillage of the product in a similar percentage (Table 1).

Regarding the estimated cost for the exchange of the solution in the estimated and in the real time, it was observed that the replacement of the solution of peracetic acid was used 66.6% more often than predicted in the studied period. Concerning the economic impact of this use, we analyzed this extra cost for the replacement of solution for different reasons.

Table 1. Causes for the replacement of the peracetic acid solution before the predicted time. Belo Horizonte, 2014.

Causes to replace the sanitizing solution	Frequency (%)
Concentration below the established levels	75
Lower quantity than necessary	15
Dirt/residue	5
Spillage	5
Total	100

Therefore, considering the mean value of the 5 L container of peracetic acid to the value of R$ 400.00 used for every solution exchange, it is estimated that R$ 80,000 were spent on the product, whereas R$ 48,000 could have been spent, generating an impact on the system with an extra cost of R$ 32,000, according to table of costs of a supplier, with the current price of the market.

DISCUSSION

The peracetic acid is an efficient high-level disinfectant formed by the mixture of acetic acid (CH_3COOH) and hydrogen peroxide (H_2O_2) in an aqueous solution. It is found in several formulations with pH, ranging between 3 and 8.5, with a broad spectrum of activity and inactivation of gram-positive and gram-negative bacteria, fungi and yeast[1,12].

Little is known about its mechanism of action, but it is believed to work similarly to other oxidants. It denatures proteins, alters the permeability of the membrane and oxidizes the sulfhydryl radical and the sulfur bonds in proteins, enzymes and metabolites[7]. Depending on the composition, the products are used at room temperature or up to 56°C[1].

When compared to the glutaraldehyde, peracetic acid is safer for the manipulator, and its action is faster and less aggressive for the environment due to the low toxicity of its products of decomposition (acetic acid, water, oxygen, hydrogen and peroxide)[1,12].

In spite of that, peracetic acid is less stable. Depending on the storage conditions, the liquid form of the product is valid from 12 to 18 months, and the powder form, for three years, whereas glutaraldehyde is valid for 24 months[1]. Disadvantages include the strong vinegar smell and the incompatibility with some materials (bronze, copper, straight steel, and galvanized iron), presenting a corrosive action on them[7]. Before use, it is necessary to add an anticorrosive agent, which is sold with the product. There are records of irritation on skin, eyes and airways among people manipulating it[13,14].

The efficiency of the peracetic acid solution is directly associated with its pH[1]. Therefore, it is necessary to control the solution with a MEC strip. The MEC strip is an acid-base indicator, or pH indicator, presenting different colors according to the pH of the solution it is inserted in.

The use of pH indicators was introduced in the XVII century by Robert Boyle[15] and, ever since then, it has been used to measure the pH of different substances. In Brazil, the use of the strip to monitor peracetic solutions is recommended[10]. The use of a chemical indicator allows to assess, by reading the pH, the conditions of the solutions regarding the minimum effective concentration established by the manufacturer so it can have the desired effect.

In the analyzed service, the peracetic acid solution is stored in plastic containers with lids, and big enough for an endoscopic device. It can be controlled with a MEC strip every day, before the activities begin. Nursing assistants can do that, supervised by the nurse in charge of the sector. When necessary, the solution can be replaced by the nurse or by the nursing assistants who were trained to do that safely.

For the extra costs with the solution, whose volume exceeded the predicted exchanges in 66.6%, a high financial investment was observed. Considering this is a health service, and because of the precariousness of investments in it, especially for being a public service (SUS), this extra cost means a huge waste of money. In a scenario of difficulties related to investments in health, this amount could be used in other actions and benefit the users of the public health service.

Regarding the potential causes for the need to use a new peracetic acid solution, some analyses can be carried out.

The fact that, 75% of the time, the solution was discarded because the concentration was lower to the minimum established value for an effective high-level disinfection indicates an error while drying the device, between the stages of cleaning and disinfection. This finding leads us to infer that these devices were immersed still wet to be processed. The minimum established concentration for the product to be efficient ranges according to its formulation, informed by the manufacturer. The chemical disinfectant at use in the analyzed service has a 0.2% concentration of peracetic acid, and, at lower concentrations, the MEC strip needed to be changed.

Immersing the endoscopic device in sanitizing solution without drying it properly is against the guidelines of the institutional protocol and the norms established by the Brazilian Society of Nursing in Digestive Endoscopy and by the American Society for Gastrointestinal Endoscopy. The general protocol to process endoscopic devices consists of 5 stages:

1. pre-cleaning of the insertion tube,
2. leak test,
3. manual cleaning of the internal and external surfaces of the device, including the use of brushes and enzymatic detergent,

4. immersion of the device in high-level disinfecting solution for the time proposed by the manufacturer and washing,
5. drying and storage[16,17].

It is established that, after washing, and before the stage in which the device will be submitted to high-level disinfection, it is important to dry the endoscope externally and let dry as much as possible before placing it in the solution, in order to prevent the product from changing[16]. Therefore, alterations in the concentration and in the pH of the solution would be minimized/prevented.

It is also important to mention that, in case the endoscope is properly processed and stored according to the current guidelines, there is no evidence showing that a cycle of additional reprocessing immediately before use in the beginning of the day is necessary[16].

Another additional aspect refer to the fact that, by immerging the device in the high-level disinfectant, it is important to introduce the solution in all channels to prevent air bubbles, and to make sure the product is in touch with the entire internal and external surface of the equipment[17,18]. However, in case the solution inside the device is not removed before taking it out of the container with the sanitizing agent, it will be lost when the washing phase begins, which is the second most prevalent reason for the exchange of solutions, similarly to the reduced quantity of sanitizing agent in the container. In this case, when the complete immersion of the endoscopic device in the solution is not possible, its use is not recommended because the solution will not be in touch with all external and internal surfaces of the equipment[3].

The deposits found in the solution, which encouraged the exchange in 5% of the cases, such as glue residue at the extremity of the tube, according to the analysis of the maintenance of endoscopic devices, bring up a new discussion about the damage that can be caused by peracetic acid on endoscopic devices. It is known that the peracetic acid is incompatible with some materials, such as steel, copper and bronze, however, no reports of damage to the glue used in the device have been found in the literature[18].

Intercurrences causing the spillage of the solution represent 5% of the cases and indicate flaws in the actions of professionals regarding the use of the disinfectant.

Professionals working in endoscopy services, at the moment of admission and afterwards, should be trained in relation to the process of cleaning, disinfecting, sterilizing, storing and transporting endoscopic devices. They should also know about the mechanisms of action of the different solutions, expiration dates, norms for use, care regarding the risks for the operator/manipulator, besides the control of the efficacy of sanitizing agents[17,19].

In the analyzed service, all employees are trained at admission by the nurse in charge. However, the direct supervision during the activity is limited, once it does not occur during the entire work shift because of the lack of a nurse that can exclusively supervise the high-digestive endoscopy service during the working hours of the sector.

It is important to mention the different shifts of the nursing professionals, who change sectors every three months, from endoscopy to other departments, and the coordination is in charge of defining this sector.

CONCLUSION

The control of disinfecting solutions for endoscopic devices by strips that indicate the minimum effective concentration of sanitizing solutions is an important ally for the professional practice. It aims at ensuring a safe parameter for the processing of these devices, providing minimum objective conditions that indicate if the solution is adequate to work effectively.

From the identification of factors related to the replacement of disinfecting solutions of endoscopic devices, it is possible to establish measurements that aim at the improvement of the health sector.

The factors found for the replacement/disposal of the solution to disinfect endoscopes point out to the review of the service planning and protocols. Essential actions, such as the training of the nursing team regarding the stages of processing of endoscopic devices and its direct supervision as possibilities to minimize behaviors that interfere in the effectiveness of solutions, will also reduce the unnecessary exchanges and, therefore, save money and avoid extra costs.

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