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ENDOSCOPE REPROCESSING USING GLUTARALDEHYDE IN ENDOSCOPY SERVICES OF GOIÂNIA, BRAZIL

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ABSTRACT – ***Context*** - The endoscopic procedure safety depends on the use of an adequately reprocessed device which quality is related to each of its operational steps. ***Objective*** - To characterize the reprocessing of endoscopes using glutaraldehyde in endoscopy services ***Methods*** - Study was conducted by observing the reprocessing of 60 endoscopes from 20 medical practices of the municipality of Goiânia, GO, central area of Brazil. ***Results*** - This study showed failure in all reprocessing steps. The pre-washing was performed in 24 (40.0%) of the endoscope. In the cleaning steps, was identify the improper use of enzymatic detergent, and in 27 (45.0%) cases, the brushing of internal channels was not performed. All 60 endoscopes were submitted to this disinfectant. However, for 33 (55.0%) of the cases the internal channels was not filled. The total immersion of endoscope in the glutaraldehyde was not performed in 39 (65.0%) cases. The recommended minimum total immersion time for exposure to 2% glutaraldehyde solution was followed only for 12 (20.0%) endoscopes. There was no filter for water treatment used in the rinse of most endoscopes 54 (90.0%) and to dry the internal channels only 6 (10.0%) of them used compressed air. Adequate storing conditions were identified. ***Conclusion*** - Considering the particularities of the endoscope and its reprocessing, it is imperative to establish protocols to ensure the quality of the disinfection and the prevention of cross-contamination.

HEADINGS - Endoscopes, gastrointestinal. Disinfection. Equipment contamination. Glutaral.

INTRODUCTION

Endoscopic reprocessing is a multi-step process that renders a contaminated endoscope safe for reuse[18]. In the US, it is estimated that flexible endoscopes are used for diagnosis and treatment of gastrointestinal diseases in more than 10 million cases per year[17, 20].

Endoscopes are considered semi-critical items because they are designed to come into contact with the mucosa without penetrating the tissue[11]. The safety of endoscopic procedures has been an important issue in the last decade due to the possibility of transmission of microorganisms[6, 24]. The incidence of infection associated with the use of the endoscope is low and estimated to occur in approximately 1 of 1.8 million procedures, making it a rare event[10]. Most documented cases of microorganism transmission are mediated by bacteria. The published episodes of pathogen transmission have been associated with failure to follow established cleaning and disinfection guidelines[17, 24].

The risk of transmission of potential pathogens depends on three major factors: exposure of the endoscope to the microorganism, inadequate cleaning and disinfection procedures, and the intricate design of the endoscopes, which feature narrow, long lumens and are made of delicate material[19]. The risk of infection for patients undergoing these procedures has been progressively reduced by the implementation of increased policies to control hospital infection and adequate training of personnel[3].

In 1999, the first step of national standardization for the cleaning and disinfection of endoscopes and accessories in Brazil was established for nurses. The Brazilian Society of Digestive Nursing Endoscopy (SOBEEG) with Brazilian Society of Digestive Endoscopy (SOBED) support published protocol for reprocessing of cleaning and disinfection of endoscopic devices and accessories[8].

Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. The endoscopes have a high bioburden of microorganisms after use, and cleaning can dramatically reduce this. The reprocess method chosen in most services is high-level disinfection. However, there should be a specific time allocated for the reprocessing of the endoscope, and all chemical and physical stages should be performed by a skilled professional.

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This article aimed to discuss compliance with reprocessing protocols, the structure of endoscopy units and the recommendation of nursing conditions in the pursuit of quality in endoscopy reprocessing. This provides security for the entire medical team as well as the patient.

Here we characterize the reprocessing of endoscopes using glutaraldehyde in endoscopy services.

METHODS

A descriptive study was conducted by observing the reprocessing of 60 endoscopes from 20 medical practices (municipality of Goiânia, GO, central area of Brazil) that agreed to participate in the investigation. Of these, 16 were private services and 4 were contained in public hospitals. The project was approved by the Ethics Committee in Human and Animal Medical Research of Hospital das Clínicas, Federal University of Goias (protocol no. 064/07).

The samples consisted of endoscopes used in medical procedures and the personnel involved in reprocessing. Data were collected by direct observation in a checklist[16] and recorded. The glutaraldehyde concentration and pH was measured by a strip test (Glutaraldehyde Comply™ Cold SteriLog™ 3987®; universal indicator pH paper, J. Prolab®) placed in the solutions that were in used for reprocessing.

The database was structured and processed in the program Statistical Package for the Social Sciences (SPSS), version 13.0. Data were tabulated and analyzed using descriptive statistics and arranged on tables.

RESULTS

Three endoscope reprocessing observations were made in each reprocessing service (60 endoscopes total).

The professionals responsible for the reprocessing operations were healthcare workers in 57 (95.0%) services, especially nursing technical (42.6%). However, it was observed that 3 (5.0%) of the reprocessing procedures were completed by workers outside the healthcare (e.g., secretaries).

Tables 1-6 show the distribution of data according to the three phases: pre-washing, cleaning and disinfection.

TABLE 1. Characterization of pre-washing of endoscopes (n = 24). Goiânia, 2007

Pré-wash	n	%
Cleaning the tube insertion		
Yes	05	20.8
No	19	79.2
Triggers channel air/water		
Yes	24	100.0
Number of times		
Twice	03	12.5
Three times	21	87.5
Use of detergent enzymatic		
Yes	24	100.0

In the first stage, the cleaning is initiated by pre-washing of the endoscope at the examination. This was performed in 24 (40.0%) of the reprocessing procedures observed. In 19 (79.2%) instances, the cleaning tube insertion was not performed in the pre-wash.

In 24 (100.0%) observations, the workers alternated between the air and water channel with use of an enzymatic detergent either 2 (12.5%) or 3 times (87.5%) in order to prevent obstructions of the channel. In 24 (40.0%) of the cases in which the pre-wash was performed, only 1 (1.7%) carried the endoscope in an adequate container. The sealing test was performed in only 3 (5.0%) of the endoscopes during the reprocessing.

Tables 2 and 3 present the characterization of chemical and manual cleaning of the endoscopes. In chemical cleaning (Table 2), it was observed that the majority of cases (33 [55.0%]) did not remove all the channel valves (air, water and suction) of the endoscope. The enzymatic detergent was used for cleaning in 40 (66.7%) endoscopes. However, it is emphasized that in 25 (41.7%) cleanings there was no complete endoscope immersion in the detergent. The internal channels were not completed in 22 (36.7%) cases, and in 28 (46.7%) situations, the recommended exposure time for the enzymatic detergent was not followed.

TABLE 2. Chemical cleaning of endoscopes in endoscopy services. Goiânia, 2007

Chemical cleaning	n	%
Removal of valves for cleaning		
Yes	27	45.0
No	33	55.0
Use of enzymatic detergent		
Yes	40	66.7
No	20	33.3
Total immersion of the endoscope in detergent		
Yes	15	25.0
No	25	41.7
Did not use enzymatic detergent	20	33.3
Filling of lumens with the detergent		
Yes	18	30.0
No	22	36.7
Did not use enzymatic detergent	20	33.3
Followed recommended exposure time for enzymatic detergent		
Yes	12	20.0
No	28	46.7
Did not use enzymatic detergent	20	33.3

Table 3 shows that external manual cleaning of the endoscopes was completed in 51 (85.0%) reprocessing procedures and that the internal channel cleaning was not accomplished in 27 (45.0%) endoscopes.

TABLE 3. - Manual cleaning of endoscopes in endoscopy departments. Goiânia, 2007

Manual cleaning	n	%
Rubbed the outside of the endoscope		
Yes	51	85.0
No	09	15.0
Applied friction to the region distal and valves		
Yes	33	55.0
No	27	45.0
Brushed and cleaned internal channels		
Yes	30	50.0
Biopsy channel only	03	5.0
No	27	45.0
Irrigated channels with enzymatic detergent		
Yes	15	25.0
No	18	30.0
Did not perform cleaning of internal channels	27	45.0
Used adapters for irrigation		
Yes	12	20.0
No	03	5.0
Did not perform the irrigation of channels	18	30.0
Did not perform cleaning of the internal channels	27	45.0

The rinsing of endoscopes after manual cleaning and after disinfection is shown in Table 4. The endoscope external rinse was more frequent than that of the internal channels, and, when performed, the internal channel rinse was conducted only for the biopsy channel without the use of adapters. The rinse of the endoscopes was not done with filtered water in 54 (90.0%) cases, and in the 6 (10.0%) others, water was obtained from an urban service with a filter adaptation for the tap.

TABLE 4. Rinse of endoscopes after manual cleaning and disinfection in endoscopy services. Goiânia, 2007

Rinse	After cleaning		After disinfection	
	n	%	n	%
Washed outside				
Yes	57	95.0	57	95.0
No	3	5.0	3	5.0
Rinsed internal channels				
Yes	21	35.0	21	35.0
No	21	35.0	24	40.0
Only biopsy channel without adapter	18	30.0	15	25.0
Used the adapter for the rinse				
Yes	12	20.0	12	20.0
No	27	45.0	24	40.0
No rinse of internal channels	21	35.0	24	40.0

The disinfection of endoscopes using glutaraldehyde is shown in Table 5. All 60 endoscopes were submitted to this disinfectant. However, for 33 (55.0%) of the cases the internal channels was no filled. The recommended minimum total immersion time for exposure to disinfectant in a 2% glutaraldehyde solution was followed only for 12 (20.0%) endoscopes.

TABLE 5. – Procedures used for the disinfection of endoscopes in glutaraldehyde in endoscopy services. Goiânia, 2007

Disinfection	n	%
Filled internal channels		
Yes	24	40.0
Only for biopsy channel	03	5.0
No	33	55.0
Total immersion of endoscope		
Yes	21	35.0
No	39	65.0
Time of immersion (minutes)		
30'	12	20.0
20'	15	25.0
15'	03	5.0
10'	03	5.0
5'	21	35.0
No standardized time	06	10.0

Table 6 shows the data of endoscope drying after cleaning and disinfection. External drying procedures were performed after cleaning in 49 (81.7%) cases, and in 36 (60.0%) drying was completed after disinfection. However, in 24 (40.0%) and 18 (30.0%) cases, respectively, the drying was done improperly. Internal channel drying was not performed for most endoscopes, as in 44 (73.3%) cases after cleaning and 45 (75.0%) after disinfection. Drying internal channels with compressed air was done only for 9 (15.0%) pre-disinfection endoscopes and 6 (10.0%) post-disinfection.

TABLE 6. – Drying of endoscopes before and after disinfection. Goiânia, 2007

Drying	Before disinfection		After disinfection	
	n	%	n	%
External drying				
Yes	49	81.7	36	60.0
No	11	18.3	24	40.0
Conditions of tissue used for drying				
Appropriate	25	41.7	18	30.0
Improper	24	40.0	18	30.0
Did not dry	11	18.3	24	40.0
Internal drying				
Yes	16	26.7	15	25.0
No	44	73.3	45	75.0
Use of compressed air				
Yes	09	15.0	06	10.0
No	51	85.0	54	90.0

The recommended rinse was not performed in 21 (35.0%) after cleaning and disinfection of the endoscopes (Table 4). In 3 (5.0%) it was not performed after the reprocessing, while in 15 (25.0%) the rinse occurred the end of the process only biopsy channel without adapter.

Proper glutaraldehyde maintenance, according to the manufacturer's instructions, was followed by 54 (95.0%) reprocessing procedures (14 or 28 days) after activation. The monitoring of the glutaraldehyde concentration was performed in only 9 (15.0%) of the reprocessing procedures. Lower concentrations glutaraldehyde were observed in 18 (30.0%) endoscopes solutions and an alkaline pH was observed in 30 (50.0%).

The majority of endoscopes (58 [96.6%]) were stored in a vertical position with parts removed or disconnected in 51 (85.0%) cases and in 45 (75.0%) was used in the valve aeration cabinets.

DISCUSSION

Monitoring of the reprocessing of 60 endoscopes in 20 medical services permitted to participate in this study was completed in Goiânia, Brazil.

Personnel responsible for the reprocessing were majors in Health Care Work, but three (5.0%) workers without any knowledge were also involved in that reprocessing. Nursing performance is recognized as a fundamental factor in the effectiveness of decontamination of the endoscope and is widely recognized as essential to the specific qualifications of health professionals who work in endoscopy services[1, 3, 4, 7, 15, 17, 18, 19, 21].

Endoscope pre-washing was not a commonly observed practice. During the pre-washing, it was verified that the air/water and biopsy channels were submitted to the enzymatic detergent 3 times, as recommended. However, the removal of excess secretions on the insertion tube was neglected by the majority of workers (19 [79.2%]).

Of all 24 endoscopes moved to a specific area for reprocessing, only 1 (1.7%) was carried using a container for support. Similar data have been found in other studies: 61.0% of centers surveyed in the US reported that endoscopes were carried by hand and that only 26.0% used a container for transport to the reprocessing area[14].

Sealing the endoscope is recommended prior to the cleaning procedure in order to observe any leakage or escape of air from the endoscope and because the immersion in water or cleaning solution may damage the meter[16, 17, 23]. This preventative care was observed in only three (5%) reprocessing procedures.

Manual reprocessing procedures were observed in all cases. The enzymatic detergent was used for 40 (66.7%) endoscopes in reprocessing (Table 2), but was used incorrectly due to incomplete immersion of the entire endoscope, inadequate filling of internal channels and shorter than recommended incubation times for action of the enzymatic detergent.

Care with the endoscope is necessary for the action of the enzymatic detergent. Disconnecting the air-water and suction valves air-water allows for access to the internal channels of the endoscope. The total immersion of the endoscope allows the entire surface (external and internal) to have contact with the enzymatic detergent[23]. Another important point is to observe is the time recommended by the manufacturer for proper action of the enzymatic detergent[2]. Inadequate household detergent was used for cleaning 20 (33.3%) endoscopes.

Chemical cleaning is appropriate for internal surfaces of the endoscope but was neglected for internal channels as observed by inadequate irrigation by detergent and brushing of only the biopsy channel during the manual cleaning.

Organic matter not removed during the cleaning process is fixed on the surface of the endoscope by the action of glutaraldehyde hindering or even preventing the reprocessing and promoting blockage of the channels within the endoscope[9, 13]. Rinsing only external surfaces in endoscope reprocessing (Table 4) allows organic matter (blood, mucus, pus and secretions) to remain on the equipment. Furthermore, enzymatic detergent residue and glutaraldehyde can remain in the internal channels after cleaning and disinfection. A jet of water at low pressure and syringe adapter should be used to ensure that the entire length of the internal channels is rinsed, and it is recommended that the rinsing be repeated 5 times[16]. However, the frequency of rinsing for all endoscopes after cleaning was only 3 times so as to finish the disinfection procedure.

Poor chemical rinses can also pose a risk to the patient[25]. Another important point to consider is the quality of the water used in the rinse. There was no filter for water treatment used in the rinse of most endoscopes. The reprocessing area should contain a water source filtered by a 0.2 micron filter or water of equivalent quality (suitable for human consumption)[19].

Improper use of glutaraldehyde was also observed through incomplete filling of most of the endoscopes reprocessed (Table 5), as well as incomplete immersion of the endoscope in the glutaraldehyde solution and a breach of the minimum time of exposure to the cleaning product. Adequate disinfection is achieved when parameters such as prior cleaning of the equipment, use of germicides in appropriate concentrations and pH, and direct contact between the germicide and the endoscope according to the time period recommended by the manufacturer are strictly observed[19, 22].

Studies performed in endoscopy units in Brazil have also observed contact times of glutaraldehyde and endoscopes at less than 30 minutes [7, 12]. It is worth mentioning that the Brazilian legislation recommends at least 30 minutes for the disinfection[5].

Results concerning the observed concentration and pH indicate the need for constant monitoring of the solution in use to ensure a germicide concentration equal to 2% and pH between 7.5 and 8.5. The expiration date set by the manufacturer should also be strictly observed. Additionally, after 14 or 28 days, the antimicrobial activity of glutaraldehyde is not always stable and therefore depends not only on the printed expiration date, but also on conditions such as dilution and content of organic material[5].

External drying, prior to and after disinfection, was performed in most endoscopes. However, the inadequate conditions of the materials used for drying should be noted. The use of a previously utilized area or cotton towel after cleaning and disinfection allows recontamination, since even the clean endoscopes have a microbial load.

The internal drying of endoscopes by compressed air prior to and after disinfection was carried out in a minority of endoscope reprocessings. Drying maintains the concentration of glutaraldehyde during disinfection. At the end of the disinfection, after rinsing, incomplete drying and the presence of moisture in the internal channels allow microbial growth, especially if the endoscope is stored.

Most endoscopes are stored in proper conditions in vertical position with the appropriate parts removed and the valve disconnected for aeration.

This study observed that many procedures require the use of an endoscope, although there are often insufficient devices available and a limited number of qualified professionals for the reprocessing of the endoscope. Also, there is a high cost associated with the procedure, and in the services analyzed there are inadequate protocols for reprocessing.

CONCLUSION

The reprocessing of endoscopes using glutaraldehyde is a multi-step process. This study shows failure in many different reprocessing steps: pre-wash, chemical and mechanical cleaning, and the rinsing and drying of the endoscope, all of which can compromise the quality of the disinfection.

For all the endoscopes, disinfection was performed by using glutaraldehyde, but the recommendations for proper disinfection were not followed. Quality control for the glutaraldehyde solution in use was done only by observing the expiration date set by the manufacturer. Important quality parameters such as pH and concentration of the solution were not monitored in most reprocessing settings. Considering the particularities of the endoscope and its reprocessing, it is imperative to establish protocols to ensure the quality of the disinfection and the prevention of cross-contamination. Given its complexity, the physical, chemical and biological parameters of endoscopic reprocessing and disinfection should be concerns not only for nursing personnel but also for the patient and the medical team.

Barbosa JM, Souza ACS, Tipple AFV, Pimenta FC, Leão LSNO, Silva SRMC. O reprocessamento de endoscópios pelo uso do glutaraldeído: a realidade em serviços de endoscopia de Goiânia, GO. Arq Gatroenterol. 2010;47(3):219-24.

RESUMO – ***Contexto*** - A segurança do procedimento endoscópico depende do uso de um aparelho adequadamente reprocessado e a qualidade do reprocessamento está relacionada a cada uma das etapas operacionais desse processo. ***Objetivo*** - Caracterizar o reprocessamento de endoscópios pelo uso do glutaraldeído em serviços de endoscopia. ***Métodos*** - Estudo conduzido em 20 serviços de endoscopia digestiva do município de Goiânia, GO. A amostra se constituiu de endoscópios utilizados para endoscopia digestiva alta. Os dados foram obtidos mediante observação direta de 60 reprocessamentos de endoscópios. ***Resultado*** - Foram observadas falhas em todas as etapas do reprocessamento. Em 24 (40,0%) endoscópios foi realizada a pré-lavagem. Na etapa da limpeza, foi identificado o uso inadequado do detergente enzimático e em 27 (45,0%) não foi realizada a escovação dos canais internos. Todos os 60 endoscópios foram submetidos ao desinfetante, entretanto para 33 (55,0%) não foi aspirado o produto nos canais internos. O tempo de exposição ao glutaraldeído foi observado apenas para 12 (20%) dos endoscópios. O enxágue de 54 (90,0%) dos endoscópios ocorreu com o uso de água não-filtrada e, para a secagem dos canais internos, apenas 6 (10,0%) utilizaram o ar comprimido. Foram identificadas condições adequadas para o armazenamento. ***Conclusão*** - Considerando as particularidades do reprocessamento dos endoscópios é imperativo estabelecer protocolos para assegurar a qualidade da desinfecção e a prevenção da contaminação cruzada.

DESCRITORES – Endoscópios gastrointestinais. Desinfecção. Contaminação de equipamentos. Glutaral.

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