Cleaning and Disinfection in Gastrointestinal Endoscopy: Current Status in Romania*

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Abstract

Background. Today, endoscopic procedures have become an important tool in the diagnosis and treatment of gastrointestinal diseases. In order to prevent cross infections, the cleaning and disinfection/sterilisation procedures of the endoscopes and accessories are primordial. **The goal of** this paper was to assess the way and the conditions in which endoscopic disinfection is achieved in our country. **Methods.** A study-type questionnaire with eighteen questions, about reprocessing of flexible endoscopes and accessories, was addressed to 37 centres from Romania known to perform digestive endoscopy. **Results.** Twenty-nine centres (78.37%) answered the questionnaire. In all the cases, the reprocessing is based on pre-established protocols and the endoscopy nurse has the principal responsibility (62.06%). Enzymatic type detergents are available in 75.86% and glutaraldehyde is the most used disinfector (55.17%). The costs (41.38%) and the financial resources (27.6%) are considered when selecting a product. Despite their advantages, automatic-disinfectors are available in only 34.48% of the cases. All the participants in the study (100%) reused endoscopic instruments, but only 31.03% used them after sterilization by steam autoclaving or ethylene oxide. Adequate facilities for manipulating potential toxic solutions are assured in 48.27%, but separate purpose-designed rooms are available in only 27.58%. Most centres (86.20%) regularly control the quality of the cleaning and disinfection by sampling. **Conclusions.** In general, the disinfection and sterilization of the endoscopes and accessories are carried out in good conditions. With regard to European Union integration, adequate facilities and funds are required to improve the reprocessing activity.

Key words

Cleaning - disinfection/ sterilization – gastrointestinal endoscopy

Rezumat

Premize. Procedurile endoscopice joacă astăzi un rol important în diagnosticul şi tratamentul afecțiunilor gastrointestinale. În scopul prevenirii transmiterii infecțiilor, procedurile de dezinfecție şi sterilizare a endoscoapelor şi instrumentarului joacă un rol primordial. **Scopul** acestei lucrări este aprecierea modului şi a condițiilor în care se realizează dezinfecția endoscopică în unitățile de profil din țara noastră. **Metodă.** Studiul de tip chestionar a vizat 37 de centre cu activitate de endoscopie digestivă din România şi a cuprins optsprezece întrebări referitoare la operațiunea de procesare a endoscoapelor şi a instrumentarului de endoscopie. **Rezultate şi discuții.** Au răspuns întrebărilor noastre 29 de centre (78,37%). În toate cazurile, reprocesarea se desfăşoară pe baza unui protcocol prestabilit, iar responsabilitatea acestei activități revine în principal (62,06%) asistentei de edoscopie. Detergenții enzimatici sunt folosiți în 75,86%, iar glutaraldehida este cea mai utilizată substanță dezinfectantă (55,17%). Costul (41,38%) şi disponibilitățile financiare (27,6%) sunt frecvent invocate în selectarea produsului. Deşi oferă avantaje certe, maşinile automate de spălat şi dezinfectat endoscoape sunt disponibile în doar 34,48% din unități. Toți cei chestionați (100%) reutilizează instrumentarul, dar numai 31,03% după o prealabilă sterilizare prin autoclavare sau etilenoxid. Condiții specifice pentru manipularea soluțiilor potențial toxice sunt asigurate în 48,27%, dar camere speciale în acest scop există doar în 27,58%. Majoritatea centrelor (86,20%) controlează periodic eficiența dezinfecției prin prelevare de probe. **Concluzii.** În general, procedurile de dezinfecție şi sterilizare a endoscoapelor şi instrumentarului se realizează în condiții corespunzătoare. În perspectiva integrării

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europene, sunt necesare fonduri şi condiții specifice care să permită îmbunătățirea acestei activități.

Introduction

Today, endoscopic procedures have become an important tool in the diagnosis and treatment of patients with gastrointestinal and pancreatico-biliary disorders.

In the last years, the risk of infection has increased due to the increasingly invasive character of the endoscopic procedures, to the increased number of elderly patients, with multiple diseases and with immune system deficiencies investigated (1). Patients should be examined and treated without risk of transmission of infection or side effects that may result from inadequately reprocessed endoscopic equipment (e.g. harm from residual chemicals or inadequately rinsed accessories) (2).

During the last decade, the cleaning and disinfection/ sterilisation procedures of the endoscopes and accessories have become more and more standardised. This was facilitated by the increasing number of protocols established by international committees including physicians, endoscopy nurses, industrial representatives and microbiologists – e.g. British Society of Gastroenterology 1998 (3), Society of Gastroenterology Nurses and Associates, 2000 , European Society of Gastrointestinal Endoscopy, 2000 (2), Multi-Society Guideline, 11 professional organizations, 2003 (4), Centers for Disease Control and Prevention, 2004 (5).

All reprocessing should be carried out by specifically trained staff in purpose-designed environment. It is the responsibility of the healthcare provider to ensure that adequate facilities for reprocessing are available. Regular quality control and an institution's adherence to validated reprocessing procedures is the responsibility of both endoscopic and healthcare provider and should be to monitored (6).

The goal of this paper was to assess the mode and the conditions in which endoscopic disinfection is achieved in our country and to find out if this activity meets the actual international recommendations.

Material and method

We included in our study 37 centers in Romania known to perform digestive endoscopy, from university or non-university hospitals, private or public ambulatory units. Our questionnaire comprised 18 questions about reprocessing of flexible endoscopes and endoscopic accessories. We requested data concerning: the procedure of disinfection, the existence of pre-established protocols for this activity, the responsibility of processing the equipment, the chemical products available, the obligation in use of the irrigative system, the respect of disinfection time, rinsing procedures, the reusability of endoscopic instruments and the disinfection method used for this purpose, the availability of adequate facilities for reprocessing, the periodic quality control of the disinfection by sampling.

Fig.1 Endoscopy units in different regions of Romania (green) involved in the study.

Results

Twenty-nine (78.37%) from 37 centers performing endoscopy responded to the questionnaire, from various geographical regions (Fig.1).

Our data revealed that in all the centers, the reprocessing of flexible endoscopes and endoscopic accessories is based on pre-established protocols. The responsibility for this activity belongs mainly to the endoscopy nurses (62.06%), in 13.79% to the physicians and in 24.14% to both. Brushing all the accessible channels and the use of the irrigative system for disinfection are mandatory in 96.55% of the cases. Only 75.86% from those questioned are using enzymatic type detergent solutions. Among the available chemical disinfectors, glutaraldehyde is currently the most widely used (55.17%), followed by peracetic acid (48.27%) and ortho-phthalaldehyde (24.13%). The cost (41.38%) and the financial resources of the healthcare provider (27.6%) are frequently stated among the reasons for selecting a certain product, while criteria as effects for medical staff and environment are mentioned in only 10.34%. The contact time recommended by the manufacturers for high quality disinfection is respected by all the centers. For the final rinsing of the instruments, sterile water is used in only 20.69% of the cases and ethyl alcohol after the final rinsing in 17.24% of the cases. The washer-disinfectors, high cost automatic machines, are available in only 34.48% of the centers, despite their efficiency. All the participants in the study reuse the endoscopic instruments, but only 31.03% used them after having been chemically disinfected and sterilised by steam autoclaving or ethylene oxide. Adequate facilities for manipulating chemical solutions with potential toxicity are assured in 48.27%, but separate purpose-designed rooms for cleaning and disinfection are available in only 27.58%. Finally, most centers (86.20%) regularly control the quality of the cleaning and disinfection methods by sampling.

Discussion

Endoscopes are frequently used for the diagnosis and therapy of medical disorders. For example, only in the United States, more than 10 million gastrointestinal endoscopic procedures are performed annually (4).

Flexible endoscopes, by virtue of the site of use, have a high bioburden of microorganisms after use. The bioburden found on flexible gastrointestinal endoscopes following use has ranged from 10^5 to 10^{10} CFU/ml, with the highest levels being found in the suction channels (3).

To date, all published episodes of pathogen transmission related to gastrointestinal endoscopy have been associated with failure to follow established cleaning and disinfection/ sterilization guidelines or use of defective equipment (7).

In order to prevent transmission of infection, endoscope reprocessing requires high level disinfection. There are three steps in reprocessing: mechanical cleaning, disinfection and then rinsing and drying.

The most critical step is mechanical cleaning. Cleaning should be done immediately after each use of an endoscope to prevent drying of secretions, to allow removal of organic material and to decrease the number of microbial pathogens. Several investigators have shown a mean log(10) reduction factor of 4 (99.99%) in the microbial contaminants with cleaning alone (8). Improper cleaning can overwhelm high-level disinfection, regardless of subsequent steps and is the most susceptible to error. Adenosine triphosphate (ATP) bioluminescence provided a rapid means of assessing the efficacy of cleaning steps prior to terminal disinfection (9).

High-level disinfection refers to the use of a disinfectant (e.g., FDA-cleared chemical sterilant or high-level disinfectant) that inactivates all microorganisms (i.e. bacteria, viruses, fungi, mycobacteria) but not high levels of bacterial spores (10). The disinfection process requires immersion of the endoscope in the high-level disinfectant and ensuring all channels are perfused for the approved contact time (11).

The endoscopes may be disinfected manually or automatically in washer disinfectors, according to specification. Following disinfection, the endoscope and channels are rinsed with sterile water, filtered water or tapwater. The channels are then flushed with alcohol and dried using forced air. The endoscope should be stored in a manner that prevents recontamination (12).

The endoscopic accessories should be reprocessed in a similar manner and sterilised, according to the manufacturer's recommendations by steam autoclaving or ethylene oxide (2). A protocol that describes the meticulous manual cleaning process, the appropriate training and evaluation of the reprocessing personnel and a quality assurance program for endoscopes should be adopted and enforced by each unit performing endoscopic reprocessing (13).

Regarding our study, in all the centers, the reprocessing activity is based on pre-established protocols, including rules of handling and guidelines for cleaning and disinfection/sterilisation. It is mandatory to ensure that protocols are equivalent to the current international guidelines available from professional organizations. The implementation of such guidelines has therefore economic implications, increasing the cost of endoscopic procedures, but it is necessary in order to protect both patient and endoscopy personnel. The staff who reprocesses the endoscope should be specifically trained for the purpose and their competency tested at least annually (14).

Meticulous manual cleaning of the endoscope is largely considered (96.55%) in our study, providing a good defence against person-to-person transmission. However**,** enzymatic detergents, which are superior to other detergents in endoscope decontamination and strongly recommended by the international guidelines (4,6) are used in only 75% of the units.

In Romania, glutaraldehyde is currently the most widely used chemical disinfector, followed by peracetic acid and ortho-phthalaldehyde, all of them being accepted in the view of efficiency (Table I). In the selection of a certain product, criteria as the effects on medical staff and environment are rarely mentioned.

Table I High level disinfection- cleared chemical sterilants (14)

Exposure Time ≥ 12 min-30 min, 20°C

Germicide	Concentration
Glutaraldehyde	1 ≥ 2.0%
Ortho-phthalaldehyde (12 min)	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **Efficacy not verified

Two percent glutaraldehyde has historically been the most commonly used disinfectant in endoscopy units worldwide. Unfortunately this agent is irritant and sensitising, with common adverse effects among endoscopy staff. A further problem with glutaraldehyde-based disinfectants is their potential to cross-link residual protein material. The resulting amalgam is very difficult to remove from working channels of endoscopes that have been repeatedly flushed with aldehydes. The manufacturers of a widely-used glutaraldehyde-based product have now withdrawn this disinfectant largely due to health and safety concerns (3). Ortho-phthalaldehyde (OPA) is odourless and does not emit noxious fumes. OPA is a potential skin and respiratory sensitiser and thus can aggravate pre-existing asthma, bronchitis or dermatitis (15). It does not appear to damage instrument components, but like other aldehydes it can stain and cross-link protein material. Peracetic acid is a powerful disinfectant, more effective than glutaraldehyde at removing organic matter, but can cause discolouration and peeling of electroplated components and rubber (16). Electrolyzed acid water is an emerging liquid chemical germicide that may be equivalent to currently accepted disinfectants (7).

Research for the ideal chemical sterilisant are still in progress. Its properties include: a rapid high level disinfection ($\leq$ 10 min), no disinfectant residue after rinsing, excellent material compatibility, long shelf-life, nontoxic (no odor or irritation issues), no disposal problems and acceptable cost (14).

Because of their high cost, the washer-disinfectors are available in only about one third of our centers. International guidelines recommend that automated endoscope reprocessing machines should be used for all endoscope decontamination following manual precleaning (17). These machines are recommended both because they reliably expose all external and internal components of the endoscope to thorough disinfection and rinsing, and because they help prevent atmospheric pollution by the disinfectant (18).

Even if all the participants in the study reused the endoscopic instruments, only about one third used them after chemical disinfection and steam autoclaving or ethylene oxide sterilisation. Because sterilising facilities are not widely available and sometimes they are expensive, Endoscopy Units should work towards a policy of employing single-use accessories, whenever possible, as the only practical way of minimising the risk from accessories (19).

In our study, adequate facilities for manipulating chemical solutions are assured in less than a half of the centers and separate rooms for cleaning and disinfection are available in less than one third. The objective control of cleaning and disinfection is achived by sampling in a satisfactory percent (86.20% of the cases).

In a similar study-questionnaire completed by 230 endoscopy units in USA, the results showed the existence of a separate cleaning room in 85%. Sixty-seven percent had an active unit infection control (IC) service and 98% had a quality assurance (QA) program. While most units claim to have ongoing QA programs, few use objective criteria to monitor effective disinfection or lapses in technique (20).

New, secure and efficient methods to enhance endoscope reprocessing could be important to retain public confidence.

Conclusions

In general**,** the cleaning and disinfection procedures of the endoscopes and accessories are carried out in Romania in good conditions, based on pre-established protocols and local economic possibilities. Compliance with accepted guidelines for the reprocessing of gastrointestinal endoscopes between examinations is critical to the safety and success of their use. When these guidelines are followed, pathogen transmission can be effectively prevented. In consideration of European Union integration, we also require sustained efforts to ensure adequate facilities and funds, which will permit a better and generalised reprocessing activity at the highest standard.

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