Reprocessing practice in digestive endoscopy units of district hospitals: results of a Portuguese National Survey

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Background and aim **An inadequate disinfection of endoscopes and associated accessories can result in the transmission of infections to patients. The aim of this study was to access reprocessing practice in the endoscopy units of Portuguese district general hospitals.**

Methods **An anonymous questionnaire on cleaning and disinfection methods was sent to all endoscopy units of Portuguese district general hospitals.**

Results **A total of 25 units responded (93%). All endoscopy units performed manual cleaning (including brushing of accessible channels) before disinfection. Automated endoscope reprocessing machines were available in all units. Manual disinfection was performed in only one unit. In 48% of the surveyed units, endoscopes were systematically disinfected before each session, whereas in 16% this was performed only occasionally. The most commonly used disinfectant was peracetic acid (32%). Disposable papillotomes, biopsy forceps, and polipectomy snares were used in nine (36%), six (24%), and 14 (56%) units, respectively. Disposable papillotomes, forceps, and snares were reused in three (12%), two (8%), and three (12%) units, respectively, always after sterilization. Most units did not perform regular evaluation of reprocessing staff competence (60%), regular microbiological inspection (56%), or registry of reprocessing (56%).**

Conclusion **The data collected suggest that there is a good compliance with standard guidelines. Nevertheless, there is still room for improvement mainly in quality assurance.** ***Eur J Gastroenterol Hepatol*** **23:1064–1068** © **2011 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Inadequate cleaning and disinfection practices in digestive endoscopy may place patients at risk of infection. The real incidence of cross-infection caused by contaminated endoscopes is unknown, as there is no prospective study on this issue. However, such transmission is considered as a rare event, with the frequency estimated to be 1 in 1.8 million cases [1]. This infection rate may, however, be an underestimation due to factors such as incomplete surveillance, underreporting, asymptomatic infections, and infections with a long incubation period. A review article published in 1993, cited 281 cases of transmission of microorganisms by digestive endoscopy [2]. Since 1993, only five more cases were reported (one case of *Trichosporon* infection and four cases of HCV infection) [1]. Despite the wide range of microorganisms and procedures reported involving endoscopes, the pathways of contamination are very similar and almost always involve some failure in the cleaning and disinfection procedures.

The recognition of the cross-infection risk associated with an inadequate reprocessing practice in digestive endoscopy has led several scientific societies to recommend guidelines to minimize this risk and to ensure maximum safety [3–6]. These guidelines reinforce the importance of strict adherence to reprocessing guidelines and periodic surveillance of quality of reprocessing.

There have been few recent surveys examining the reprocessing practices for digestive endoscopes and their accessories. They have been performed in Spain [7], USA [8], Romania [9], Lombardy [10], and China [11]. No survey has been undertaken in Portugal. This study aimed to assess cleaning and disinfection practice in digestive endoscopy units of district hospitals of Portugal.

Materials and methods

Nucleus of Gastroenterology of District Hospitals (NGHD) is a national association that represents 27 digestive endoscopy units of Portuguese district hospitals. These units cover the entire continental and insular territory of Portugal. In April 2010, the scientific committee of NGHD elaborated a questionnaire with 35 questions regarding six topics (endoscopic activity and

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equipment, local of reprocessing, reprocessing staff, reprocessing procedure, accessories reprocessing, and quality assurance) of reprocessing practice (see SDC). The questionnaire was based on earlier surveys in Italy, the USA, and Spain, and on guidelines of main digestive endoscopy societies. It was sent by mail to all members of NGHD. All data were entered in a computer database and rendered anonymous for analysis. Responses were tabulated and are presented as percentages of those responding. For analysis, digestive endoscopy units were divided into two types according to the sort and the number of digestive endoscopic procedures performed monthly, including ecoendoscopy, endoscopic retrograde cholangiopancreatography, and upper and lower gastrointestinal (GI) endoscopy. Units were classified under each type when two of the following criteria for each category were met:

(i) type 1 units: 15 or more endoscopic retrograde cholangiopancreatography, 15 or more ecoendoscopy, 250 or more upper GI endoscopy, 150 or more lower GI endoscopy.
(ii) type 2 units: less than 15 endoscopic retrograde cholangiopancreatography, less than 15 ecoendoscopy, less than 250 upper GI endoscopy, less 150 lower GI endoscopy.

Statistical Package for Social Sciences (SPSS 18.0 Package Facility; SPSS Inc., Chicago, Illinois, USA) was used for data support and analysis. The χ^2-test or Fisher's exact test (when < 5 observations) were used for comparisons. Statistical significance was set at a P value of less than 0.05.

The data of this study were orally presented and discussed at the 25th annual meeting of NGHD that took place in Leiria (Portugal), from 12 November to 13 November 2010.

Results

We received data from 25 of 27 (93%) endoscopy units.

Endoscopic activity and equipment

The characteristics of the different types of digestive endoscopy units are shown in Table 1.

Table 1 Classification of digestive endoscopy units: availability of instruments and mean number of endoscopic procedures performed monthly

Type of unit	Units	Upper gastrointestinal endoscopy	Lower gastrointestinal endoscopy	Endoscopic retrograde cholangiopancreatography	Ecoendoscopy	Gastroscopes	Colonoscopes	Duodenoscopes	Ecoendoscopes	Endoscopy rooms	Reprocessing rooms
I	14	256	268	21	9	3–9	4–10	2–3	0–2	2–4	1–2
II	11	168	148	4	2	2–6	3–7	0–2	0–1	1–3	0–1

Local of reprocessing

In 23 (92%) units, there were specific areas for reprocessing endoscopic material, whereas in the remainder this was carried out in the examination room. In 17 (68%) units, the reprocessing room was exclusive for digestive endoscopic material, whereas in 21 (84%) units the room had adequate ventilation or exhaustion system. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of reprocessing facilities.

Reprocessing staff

The reprocessing was carried out by nurses, technicians, or both in 12 (48%), 11 (44%), and two (8%) units,

respectively. In all units, reprocessing staff had received specific training on handling of endoscopic equipment, automated endoscope reprocessing machines, and detergents/disinfectants. Adequate personal protective equipment (gown + mask + gloves + eye protection) was used by the reprocessing staff in 15 (60%) units. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of reprocessing staff.

Reprocessing procedure: precleaning

A precleaning in the endoscopy room was performed in 22 (88%) units. The endoscopic material was systematically transported to reprocessing room in a closed recipient in 11 (44%) units. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of precleaning.

Reprocessing procedure: cleaning

All units manually cleaned endoscopes before disinfecting them. For manual cleaning, 13 (52%) units used an enzymatic detergent, 10 (40%) used a nonenzymatic detergent, and two units used (8%) enzymatic and nonenzymatic detergents. Selective cleaning of the internal channels by brushing was systematically performed in all units. Rinsing between cleaning and disinfection was performed in 22 (88%) units. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of manual cleaning.

Reprocessing procedure: disinfection

All units had automated endoscope reprocessing machines. Only one (4%) unit performed manual disinfection. Table 2 sets out the disinfectants used. The most commonly used disinfectant was peracetic acid (32%). In 12 (48%) units, endoscopes were systematically disinfected before each session, whereas in four (16%) units this was performed only occasionally. In all units, disinfection was followed by rinsing, which was performed automatically in 21 (84%) units. Sterile water was used for disinfection in 19 (76%) units. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of disinfection.

Reprocessing procedure: drying

In 21 (84%) units, endoscopes were systematically dried before usage or storage, whereas in two (8%) units this was performed only occasionally. In the units that performed drying before usage or storage (23 units), this was done automatically in only 11 (48%) units, manually in only four (17%) units, and automatically and manually in eight (35%) units. In the units that performed manual drying (12 units), this was performed with compressed air in eight (67%) units and with 70% alcohol in four (33%) units. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of drying.

Table 2 Disinfectants used

Disinfectant	Number of units
Peracetic acid	8
Electrolyzed acid water	7
Peracetic acid/hydrogen peroxide	6
Orthophthalaldehyde	6
Glutaraldehyde	5

Reprocessing procedure: storage

Endoscopes were stored in ventilated cabinets in 22 (88%) units and in a closed box in the remaining. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of storage.

Accessories reprocessing

Table 3 presents data regarding the reprocessing of endoscopic accessories. Disposable papillotomes, biopsy forceps, and polipectomy snares were used in nine (36%), six (24%), and 14 (56%) units, respectively. Disposable papillotomes, forceps, and snares were reused in three (12%), two (8%), and three (12%) units, respectively, always after sterilization. Ultrasonic cleaning of accessories was performed systematically in 15 (60%) units, and occasionally in three (12%) units. Critic reusable accessories were sterilized in 23 (92%) units. Water bottles were sterilized and high-level disinfection was performed systematically in 15 (60%) units and occasionally in six (24%) units, at the end of each session. In 19 (76%) units, water bottles were filled with sterile water. Rubber biopsy port caps were changed systematically in six (24%) units and occasionally in 17 (68%) units, after passage of biopsy forceps, guidewires, or other accessories. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of accessories reprocessing.

Quality assurance

Competence of reprocessing staff was evaluated regularly in 10 (40%) units, mostly once a year. Regular microbiological inspection was performed in 11 (44%) units, mostly once a month. In 11 (44%) units, there was a

Table 3 Reprocessing of endoscopic accessories

Endoscopic accessory	Reusable/disposable (number of units)	Type of reprocessing (number of units)
Papillotomes	11 NE/NR	NA
	5 reusable	3 sterilization/ 2 high-level disinfection
	9 disposable	3 sterilization
Biopsy forceps	3 NR	NA
	16 reusable	14 Sterilization/ 2 high-level disinfection
	6 disposable	2 sterilization
Polipectomy snares	3 NR	NA
	8 reusable	6 sterilization/ 2 high-level disinfection
	14 disposable	3 sterilization

NA, not applicable; NE, not existing; NR, not responded.

Table 4 Cases of positive microbiological inspection

Unit code	Unit type	Year	Isolated agents	Local of isolation
11	II	2009	Gram-positive *bacillus*	Air/water valve
15	II	2008	*Bacillus* spp	Storage cupboard
15	II	2008	*Staphylococcus*	Washing machine
15	II	2008	Coagulase-positive *Staphylococcus* *Bacillus* spp	Colonoscope
15	II	2009	Gram-positive *bacillus* *Sphingomonas*	Washing machine
24	II	2010	*Stenotrophomonas maltophilia* *Candida albicans*	Not reported

procedure for tracing instruments (the possibility of following the instrument's history throughout its lifespan recorded as a paper 'logbook' or by computer). Three units, all of type 2, reported six cases of positive microbiological inspection (Table 4). None of the units reported any case of cross-infection transmitted by the endoscope. There was no significant difference between type 1 and type 2 units ($P > 0.05$) in terms of quality assurance.

Discussion

The response rate in this survey was quite high (93%), making these results very representative of the current reprocessing practices in digestive units of Portuguese district hospitals.

All guidelines on digestive equipment reprocessing consider manual cleaning before disinfection as the critical step in endoscope reprocessing [3–6]. All units that replied to the questionnaire performed manual cleaning (including brushing of accessible channels) of endoscopes before disinfection.

Automated endoscope reprocessing machines have numerous advantages: reduce staff contact with chemicals and contaminated equipment, reduce contamination of the environment, ensure a validated and standardized reprocessing cycle, and provide highly reliable reprocessing. European Society of Gastrointestinal Endoscopy (ESGE), European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGNA), and British Society of Gastroenterology (BSG) strongly recommend the use of automated endoscope reprocessing machines [3,6]. In this survey, all units reported to have automated endoscope reprocessing machines, with only one unit performing manual disinfection. In previous similar surveys, the rate of availability of automated endoscope reprocessing machines ranged from 22% in China to 84% in Lombardy [7–11].

There is some controversy regarding the need for endoscopes disinfection before each session. The US Multisociety Guidelines do not recommend this disinfection procedure [4], whereas ESGE, ESGNA, and BSG recommend this procedure before the next use [3,6]. In 48% of the surveyed endoscopy units, endoscopes were systematically disinfected before each session, whereas in 16% of the units this was performed only occasionally. These data are comparable with those from previous surveys [7–11].

There is no consensus regarding the best disinfectant. Nevertheless, BSG recommends that units should move away from using aldehyde-based and alcohol-based disinfectants because of their fixative properties, which in theory could anchor prion and other protein within endoscope channels [6]. This survey found that units favor the use of peracetic acid or electrolysed acid water instead of aldehydes. This is in contrast with previous similar surveys, in which glutaraldeyde was the most commonly used disinfectant [7–11].

Uncertainty still exists regarding the relative costs and the clinical effectiveness of disposable versus reusable endoscopic accessories [12]. Intuitively, disposable devices do not pose a risk for transmission of infection, but properly maintained and reprocessed reusable devices remain safe and effective. Both single-use and reusable accessories function well. American Society for Gastrointestinal Endoscopy states that the selection of one or another class of devices must be based on local purchase costs, reprocessing costs and abilities, storage and disposal facilities, and personal preferences [12]. ESGE and ESGNA make no recommendation [3], whereas BSG states that disposable accessories should always be used in preference to reusable accessories and that reusable accessories should only be used in situations in which no single use-equivalent accessory exists [6]. This survey found a significant use of disposable papillotomes (36%), biopsy forceps (24%), and polipectomy snares (56%).

Despite the information in the Medical Devices Agency Bulletin (DB 2006 - 04) on the potential clinical and legal risks related to reprocessing and reuse of disposable medical devices [13], reuse of disposable accessories is not rare in many endoscopy units, mainly due to economic considerations, ranging from 23% in Lombardy to 71% in China [10,11]. In this survey, approximately one-third of the units that used disposable accessories claimed to reuse them, always after sterilization.

In our study, most units have adequate reprocessing rooms, that is, rooms dedicated to reprocessing of digestive endoscopic equipment and with proper ventilation or exhaustion system.

Most guidelines reinforce the importance of reprocessing quality assurance, which involves several aspects such as regular evaluation reprocessing staff competence, regular microbiological inspection, and registry of reprocessing [3–6]. With regard to this topic, in our study, most units did not perform regular evaluation of reprocessing staff competence (60%), regular microbiological inspection (56%), or registry of reprocessing (56%).

Importantly, we found no significant difference between type 1 and type 2 units in terms of reprocessing. Nevertheless, all positive cases of microbiological inspection were from type 2 units.

Despite the high rate of response, this survey has some limitations, such as with any survey it is impossible to know whether the units that did not reply to the questionnaire apply the same methods for digestive equipment reprocessing, and we cannot assess the truth of the replies received. In addition, the survey only covered public district hospitals. This obviously limits the general applicability of the results.

In conclusion, this survey found a good level of awareness of the importance of reprocessing in digestive units of Portuguese district hospitals and good adherence to the current guidelines. Nevertheless, there is still room for improvement, mainly in quality assurance through regular evaluation of reprocessing staff competence, regular microbiological inspection, and registry of reprocessing.

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Conflicts of interest

There are no conflicts of interest.

References

1 Nelson DB, Barkun AN, Block KP, Burdick JS, Ginsberg GG, Greenwald DA, *et al*. Technology status evaluation report: transmission of infection by gastrointestinal endoscopy. *Gastrointest Endosc* 2001; **54**:824–828.
2 Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993; **118**:117–128.
3 Beilenhoff U, Neumann CS, Rey JF, Biering H, Blum R, Cimbro M, *et al*. ESGE-ESGENA guideline: cleaning and disinfection in gastrointestinal endoscopy. *Endoscopy* 2008; **40**:939–957.
4 Nelson DB, Jarvis WR, Rutala WA, Foxx-Orenstein AE, Isenberg G, Dash GP, *et al*. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Dis Colon Rectum* 2004; **47**:413–420.
5 WGO-OMGE/OMED Practice Guideline: Endoscope Disinfection. 2005. Available from: *http://www.omed.org/downloads/pdf/guidelines/wgo_omed_endoscope_disinfection.pdf*.
6 BSG guidelines for decontamination of equipment for gastrointestinal endoscopy. Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee. 2008. Available from: *http://www.bsg.org.uk/images/stories/docs/clinical/guidelines/endoscopy/decontamination_2008.pdf*.
7 Brullet E, Ramirez-Armengol JA, Campo R. Cleaning and disinfection practices in digestive endoscopy in Spain: results of a national survey. *Endoscopy* 2001; **33**:864–868.
8 Moses FM, Lee JS. Current GI endoscope disinfection and QA practices. *Dig Dis Sci* 2004; **49**:1791–1797.
9 Fratila O, Tantau M. Cleaning and disinfection in gastrointestinal endoscopy: current status in Romania. *J Gastrointestin Liver Dis* 2006; **15**:89–93.
10 Spinzi G, Fasoli R, Centenaro R, Minoli G. Reprocessing in digestive endoscopy units in Lombardy: results of a regional survey. *Dig Liver Dis* 2008; **40**:890–896.
11 Zhang X, Kong J, Tang P, Wang S, Hyder Q, Sun G, *et al*. Current status of cleaning and disinfection for gastrointestinal endoscopy in China: a survey of 122 endoscopy units. *Dig Liver Dis* 2011; **43**:305–308.
12 Croffie J, Carpenter S, Chuttani R, DiSario J, Hussain N, Liu J, *et al*. ASGE technology status evaluation report: disposable endoscopic accessories. *Gastrointest Endosc* 2005; **62**:477–479.
13 Medicines and Healthcare products Regulatory Agency. Single-use medical devices: implications and consequences of reuse. DB 2006 (04). 2006. Available from: *http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2024995*.