

Short communication

Reprocessing practices for gastrointestinal endoscopes: a multicentre study in Egyptian university hospitals

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ممارسات إعادة معالجة منظار الجهاز الهضمي: دراسة متعددة المراكز في مستشفيات جامعية مصرية رحاب السكري، أحمد وجدان، أحمد مسعد، رشا بسيوني، وائل عوض

الخلاصة: تمثل الهدف من هذه الدراسة في تقييم ممارسات العاملين في مجال الرعاية الصحية أثناء إعادة معالجة منظار الجهاز الهضمي، وتقييم معلوماتهم بشأن إعادة المعالجة، والتحقق من الامتثال في المختبرات والاختبارات الميكروبيولوجية في وحدات المناظير في مستشفيات جامعتي الزقازيق والفيوم. وأدرج جميع أفراد هيئة التمريض المناوبين من 10 وحدات للمناظير تحتوي على مناظير مرنة. وقُيِّمت المعلومات والممارسات بواسطة استبيان وقائمة مرجعية. وجاء متوسط درجة المعرفة 7.5 (بانحراف معياري 1.9). في حين سجل الامتثال 90% بالنسبة للتعقيم و74% لتجهيز المنظار بعد التطهير. وقبل إعادة استخدام المناظير بعد تنظيفها، لم تكتشف أي كائنات حية في خمسة مناظير، في حين اكتُشفت 8 وحدات مكونة لمستعمرات في منظارين. وكانت الزائفة الزنجارية الكائن الأكثر شيوعاً الذي تم عزله. خلصت الدراسة إلى وجود حاجة ماسة لتطبيق المعايير الخاصة بإعادة معالجة المناظير بشكل صارم، لا سيما في مرحلة ما قبل التنظيف وفي اختبار التسريب. ويجب تكرار التطهير عالي المستوى بعد التخزين وقبل الاستخدام.

ABSTRACT The aim of this study was to assess the practices of health care workers during gastrointestinal endoscope reprocessing, evaluate their knowledge about reprocessing, and verify their compliance with laboratory and microbiological tests in endoscopy units at Zagazig University and Fayoum University hospitals. All nursing staff on duty from 10 endoscopy units, with 16 flexible endoscopes, were included. Knowledge and practice were assessed by a questionnaire and a checklist. The mean knowledge score was 7.5 (SD 1.9), which was poor. Compliance was 90% for disinfection and 74% for endoscope processing after disinfection. Before reuse after cleaning, no organisms were detected in 5 endoscopes, while 8 colony forming units were found in 2. *Pseudomonas aeruginosa* was the most common organism isolated. Strict implementation of the reprocessing guidelines are needed, especially the pre-cleaning stage and leak testing. Repeating high level disinfection after storage and before use must be followed.

Pratiques de traitement des endoscopes gastro-intestinaux : étude multicentrique dans des hôpitaux universitaires en Égypte

RÉSUMÉ La présente étude avait pour objectif d'évaluer les pratiques des agents de soins de santé lors du traitement des endoscopes gastro-intestinaux, de mesurer leur connaissance du traitement, et de vérifier leur bonne exécution des tests de laboratoire et des tests microbiologiques dans les unités d'endoscopie des hôpitaux universitaires de Zagazig et de Fayoum. Toutes les équipes de personnels infirmiers issues de 10 unités d'endoscopie, avec 16 endoscopes souples, ont été incluses dans l'étude. Les connaissances et les pratiques ont été évaluées par un questionnaire et une liste de contrôle. Le score de connaissance moyen était de 7,5 (ET 1,9). La conformité était de 90 % pour la désinfection, et de 74 % pour le traitement des endoscopes après désinfection. Après nettoyage et avant réutilisation, aucun organisme n'a été détecté pour cinq endoscopes, et huit unités formant des colonies ont été trouvées dans deux autres endoscopes. *Pseudomonas aeruginosa* était l'organisme le plus couramment isolé. Une application stricte des directives de traitement est requise, notamment à l'étape du pré-nettoyage et des essais d'étanchéité. Il est important d'effectuer une désinfection de haut niveau répétée après entreposage et avant utilisation.

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Introduction

Appropriate reprocessing of endoscopes and their accessories is essential to safeguard patients and staff. Reprocessing flexible endoscopes involves multiple steps (cleaning, disinfection and sterilization) and adherence to the guidelines on reprocessing is essential (1). In Egypt, rules for this process have been figured out in the national guide for infection prevention and control (2), which is the standard for the country.

Information about staff practices in endoscopy units regarding reprocessing and their adherence to guidelines is needed to support the development of effective performance improvement (3). To our knowledge there have been no previous studies that have assessed these practices. Therefore, the objectives of this study were to: evaluate the practices of nursing staff during gastrointestinal endoscope reprocessing, assess their knowledge about reprocessing, and verify their compliance by laboratory and microbiological tests.

Methods

A cross-sectional multicentre study was carried out at the endoscopy units of Zagazig University Hospitals and Fayoum University Hospitals from March 2015 to September 2015. The study was approved by the institutional review boards of the Zagazig and Fayoum universities.

All functioning endoscopes were included—16 flexible endoscopes from 10 endoscopy units. A total of 59 nursing staff in the units, who were responsible for cleaning and storage of the endoscopes, were enrolled. We excluded staff members who were on leave during the study period. No staff declined to participate and all gave their written consent.

The study was conducted in 2 phases: in phase one, the knowledge and compliance of health care workers

were assessed and in phase two, laboratory and microbiological verification of compliance was determined.

Knowledge of the health care workers was assessed by a 21-question questionnaire (4,5) in Arabic. It was prepared in Arabic for better understanding and to get more reliable results. The questionnaire was pilot tested on a sample of 15 nurses to determine its acceptability and the clarity of the questions, and to confirm its face validity; it was then modified accordingly. These staff were excluded from the final analysis. The questionnaire included 7 questions about personal and job-related variables (age, sex, place of work, duration of work in general, duration of work in endoscopy units, and training on endoscope reprocessing and awareness of reprocessing guidelines) and 13 scored questions about the reprocessing procedures at the facility. A correct answer was assigned a score of 1, an incorrect answer was assigned a score of 0. The total knowledge score was calculated by adding the number of correct answers. A mean score equal to and above the median was considered satisfactory knowledge, and a score below the median was considered unsatisfactory knowledge. The survey was distributed to and self-completed by all participants. All surveys were anonymous.

Evaluation of the compliance of health care workers was done using another 49-point self-completed questionnaire, adapted from the national guidelines (2), which were grouped under 7 areas. All criteria were marked as: compliant, not compliant or not applicable, and the percentage of compliance was calculated (6).

Laboratory verification of cleaning processes by protein assay was done as follows: 10 mL of rinse solution were collected after cleaning of the endoscope and before high level disinfection. Protein assay was done by the biuret method. The permissible level for organic and bioburden residuals is less

than 6.4 µg/mL protein as described in a previous study (7).

Microbiological examination of endoscopes was done after storage and before being used again. Using aseptic technique, 10 mL of rinse solution were collected (7) from reprocessed endoscopes and a culture was done. Colony count and identification to species level was performed (8).

After bacterial culture and isolation, the bioburden level was estimated as follows: counts were reported as the number of colony forming units (cfu) per mL (9). Quantification of bacterial growth was done: no growth = 0 cfu, sparse growth = <5 cfu/mL, moderate growth = 5–20 cfu/mL and heavy growth = > 20 cfu/mL (10).

Statistical analysis was done using SPSS, version 15. Quantitative data are presented as ranges, means and standard deviations (SD). For qualitative data, numbers and percentages are presented. The Pearson correlation coefficient (*r*) was used to assess the significance of association between protein and bioburden levels. A *P*-value less than 0.05 was considered statistically significant.

Results

A total of 46 health care workers were present at the time of the study and were enrolled: 43 were women. Their ages ranged from 25 to 53 years with a mean of 35.3 (SD 5.6) years. Duration of work in endoscopy units ranged from 3 months to 30 years. Most of the staff (78%) were aware that there were reprocessing instructions available in the unit and 44% had had training courses on endoscope reprocessing (Table 1).

The knowledge and compliance of health care workers are shown in Tables 2 and 3. The mean knowledge score about all reprocessing steps was 7.5 (SD 1.9), with a maximum of 13. The median score was 8.3. The mean score for cleaning processes was 2.9

Table 1 Personal and job-related variables

Variable	Values
Sex (No.)	
Male	3
Female	43
Age (years)	
Range	25–53
Mean (SD)	35.3 (5.6)
Duration of work in nursing (years)	
Range	10–35
Mean (SD)	17.5 (6.3)
Duration of work in endoscopy units (range)	3 months–30 years
Previous experience in an endoscopy unit [(No. (%))]	
Only one unit	2 (4.3)
More than one unit	44 (95.7)
Aware of available instructions about reprocessing? [(No. (%))]	
Yes	35 (77.8)
No	10 (22.2)
Had training courses on endoscope reprocessing [(No. (%))]	
Yes	20 (43.5)
No	25 (54.3)

(SD 0.75). All participants thought that after mechanical cleaning, immersible equipment should be thoroughly rinsed with water. On the other hand, only 47% of participants thought that endoscope should be checked by inspection and a leak test. The mean score for disinfection steps was 2.1 (SD 0.08): 98% of the participants knew that repeated entry into any chemical disinfectant and retained water on equipment can lower the concentration over time. On the other hand, 67% of participants knew that internal and external surfaces of the endoscope should be in contact with disinfectant for 20 minutes. The mean score for storage processes was 1.5 (SD 0.08). Only 6% of participants knew that control valves, distal hoods, caps, etc. should be removed prior to storage of the endoscope.

Table 2 Knowledge of endoscope reprocessing among health care workers

Reprocessing step	Percentage who answered the question correctly
Cleaning	
The cleaning brushes should be disposable/thoroughly cleaned and receive a high-level disinfection or sterilization after each use	49
All channels should be brushed and irrigated with large amounts of enzymatic presoak solution or detergent and tap water	50
After mechanical cleaning, immersible equipment should be thoroughly rinsed with water	100
The endoscope should be checked by inspection and leak test	47
All detachable parts should be removed and soaked in an enzymatic presoak solution	67
Disinfection	
Internal and external surfaces and channels must be in contact with the disinfecting agent for at least 20 minutes	67
Repeated dipping into any chemical disinfectant and retained water on equipment can lower the concentration over time	98
All containers with glutaraldehyde solutions should be sealed or covered	85
Treatment after disinfection	
Rinsing should be done with sterile water. If sterile water is not available, then potable tap water should be used with a rinse of the internal lumens with alcohol	62
Drying with alcohol and compressed air should be done between each patient when tap water is being used to rinse the endoscope channels	67
Drying with alcohol and compressed air should be done before storage whether tap water or sterile water is used	79
Endoscopes should be stored vertically in a cabinet	72
Control valves, distal hoods, caps, etc. should be removed before storage of the endoscope	6

Table 3 Compliance with specific policies, procedures and practices

Reprocessing step	Rate ¹ (%)
Cleaning of endoscope	67
Disinfection of endoscope	90
Treatment of the endoscope after disinfection	74
Processing endoscopic accessory equipment	44
Hazardous materials' management	0
Endoscopy personnel occupational health issues ²	61
Environmental factors (storage) and design issues for the endoscopy unit	58

¹Minimal compliance = $\leq 75\%$, partial compliance = 76–84% and satisfactory compliance = $\geq 85\%$ (7).

²Such as thorough hand hygiene before and after each procedure, use of personal protective equipment as needed, accessible personal protective equipment, vaccination against hepatitis B.

The results of the laboratory and microbiological verification of compliance are shown in Table 4. Protein levels ranged from 4.6 to 32.8 $\mu\text{g}/\text{mL}$ with a mean of 14.8 (SD 8.9) $\mu\text{g}/\text{mL}$. The highest level of protein (32.8 $\mu\text{g}/\text{mL}$) was detected from endoscope numbers 5 and 15. Three endoscopes showed protein levels below the permissible level (i.e. $< 6.4 \mu\text{g}/\text{mL}$), indicating the cleaning process was effective. The number of cfu ranged from 0 to 8, with a mean of 2 (SD 5.8). Endoscope numbers 5 and 15 had the highest number of cfu (8 each), while no growth was detected from endoscope numbers 4, 7, 8, 13 and 14. There was a statistically significant positive correlation between protein and bioburden levels ($r = 0.589$, $P = 0.03$).

While, endoscope numbers 4 and 14 showed no bacterial growth, the protein level was higher than the permissible level ($< 6.4 \mu\text{g}/\text{mL}$). Only endoscopes numbers 7, 8 and 13 showed no bacterial growth and permissible protein levels.

Pseudomonas aeruginosa was the most common isolated organism (30.8%), followed by micrococcus (15.4%), *Serratia* spp. (7.7%), *Staphylococcus saprophyticus* (7.7%) and diphtheroids (7.7%). No growth was detected in 30.7% of samples.

Discussion

In the current study, more than three quarters of the staff were familiar with existing reprocessing policies. A study in the United States of America (USA) reported that only 35% of bronchoscopists and 45% of medical directors in bronchoscope units were familiar with any national reprocessing rules (4). Only about half of our study participants had received training on endoscope reprocessing. Continuous medical education is important for all staff members and should be considered in the planning of training programmes in the units studied. Guidelines might be valuable for detailing proper practices, however they are not necessarily effective in changing behaviour (11).

The participants in the current study had a poor mean knowledge score of 7.5 (SD 1.9). Similar results have been reported previously (4). A similar knowledge score about cleaning procedures was recorded in a study in the USA (3), except for the leak test step; 90% of staff in their study (3) versus 47% in our study knew the endoscope should be checked by inspection and leak test. Compliance with national guidelines was achieved for disinfection steps with partial compliance for treatment of the endoscope after disinfection. Another study found that most practitioners complied with the established disinfection guidelines

(12), while Seoane-Vazquez and colleagues reported that the primary cause of endoscopy-related infections was poor reprocessing practices (13).

Despite the importance of the cleaning process, minimal compliance was reported for this area in the current study. Inadequate cleaning can leave excess biomaterial on the surface of an endoscope, even after multiple reprocessing. Appropriate cleaning reduces the amount of organic debris (14) that can interfere with high level disinfection. Missing or rushing through key steps is a common problem (15). In the present study, nearly half of the study participants knew that leak testing is a required step; this is much lower than a previous study (77%) (3). The failure to perform a proper leak test could also have serious implications. This test detects any physical breaks to the exterior or interior of the endoscope. These physical breaks compromise the integrity of the endoscope and will damage the internal structures (i.e. electrical wires, light bundle, manipulation cables) of the endoscope, which are not designed to be in contact with fluids. These breaks may also create a reservoir for microorganisms to grow. Continuing to use a damaged endoscope could result in further damage and be costly (3).

The rates of compliance with guidelines for reprocessing were 27% and 50% in 2 separate studies (16). The present

Table 4 Results of the microbiological and protein assays¹

Endoscope no.	Bioburden estimation (cfu)	Protein level ($\mu\text{g}/\text{mL}$) ²	<i>P</i> -value	<i>r</i>
1	5	16.3	0.03	0.58
2	3	15.6		
3	2	28.6		
4	0	10		
5	8	32.8		
6	4	12.3		
7	0	4.9		
8	0	5.1		
9	5	22.2		
10	2	8.1		
11	3	12		
12	1	15.6		
13	0	4.6		
14	0	9.1		
15	8	32.8		
16	3	28.6		
Total level				
Range	0–8	4.6–32.8		
Mean (SD)	2 (5.8)	14.8 (8.9)		

¹Results are the average of 3 repeated experiments.

²The proposed standard for permissible level is 6.4 $\mu\text{g}/\text{mL}$.

P < 0.05 was considered as statistically significant.

r = Pearson correlation coefficient; cfu = colony forming units.

study results showed that there was minimal compliance for processing of endoscopic accessory equipment. This agrees with the results of another study which found that a third of respondents reported that they reused disposable accessories (12). Reuse of disposable accessories should be avoided so as to limit the likelihood of cross-infection between patients and staff (17). A lack of financial resources may lead to reuse so it is essential that an adequate budget is allocated to prevent reuse.

In the current study, there was minimal compliance with endoscopy personnel occupational health issues, including thorough hand hygiene before and after each procedure, use of personal protective equipment, accessible personal protective equipment and vaccination against hepatitis B. A study in Korea found that although most respondents reported having experienced occupational hazards, the

majority (78%) did not wear protective eyewear (17).

Unfortunately, no responses were recorded for dealing with hazardous materials. This suggests that occupational safety programmes are not properly implemented in the hospitals studied.

Visual inspection could be used to check for adequate cleaning. However, compliance with cleaning of flexible endoscope channels cannot be confirmed using visual inspection (7). Therefore, in our study, verification of efficient cleaning was done by estimating protein levels on the endoscope. A considerable amount of residual protein was detected, which exceeded a proposed standard for permissible levels (6.4 $\mu\text{g}/\text{mL}$) (7). A much lower result was obtained in a previous study, 0.1 and 0.22 $\mu\text{g}/\text{mL}$ after total cleaning (7). This could be explained by poor adherence of the health care workers to the

cleaning steps. This is supported by the low compliance rate for this step (67%).

According to the national guidelines, repeating high level disinfection after storage and before use is highly recommended, yet it is often not done. Checking for storage efficacy by microbiological testing of the endoscope fluid wash was performed to confirm the importance of conducting this step. Our study showed that, on 4 out of 16 occasions, the reprocessing steps and storage conditions were sufficient to avoid bacterial contamination. In contrast, on 2 out of 16 occasions, the process was inadequate with moderate growth (8 cfu/mL) and in 10 out of 16 occasions there was sparse growth.

Given the sparse growth and the nature of the organisms, most probably the cleaning protocols were not followed and/or monitored on a regular basis (18). Our laboratory and microbiological findings confirmed the results

about knowledge and compliance from the questionnaire, which showed deficiencies in the cleaning process. On the other hand, the moderate bacterial growth found and the organisms isolated indicate breaches in the reprocessing steps and/or storage conditions in some cases. This is an alarming sign which needs close monitoring to ensure that the reprocessing guidelines are implemented and closely adhered to. In the current study, detection of *Pseudomonas* spp. (especially *P. aeruginosa*) and other

non-fermenting rods indicates insufficient final rinsing and incomplete drying of the endoscope or contaminated flushing equipment for the air/water-channel (19).

Conclusion

Strict regulations are still needed for the endoscope cleaning process, especially the pre-cleaning stage and leak testing. Repeating high level disinfection

after storage and before use should be strictly followed. An occupational safety programme is needed for staff working in endoscope units. Efforts are needed to overcome knowledge barriers and financial constraints so as to ensure proper reprocessing of endoscopes and avoid adverse health effects on patients and staff.

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