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Original article

High-quality endoscope reprocessing decreases endoscope contamination

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ABSTRACT

Objectives: Several outbreaks of severe infections due to contamination of gastrointestinal (GI) endoscopes, mainly duodenoscopes, have been described. The rate of microbial endoscope contamination varies dramatically in literature. The aim of this multicentre prospective study was to evaluate the hygiene quality of endoscopes and automated endoscope reprocessors (AERs) in Tyrol/Austria.
Methods: In 2015 and 2016, a total of 463 GI endoscopes and 105 AERs from 29 endoscopy centres were analysed by a routine (R) and a combined routine and advanced (CRA) sampling procedure and investigated for microbial contamination by culture-based and molecular-based analyses.
Results: The contamination rate of GI endoscopes was 1.3%–4.6% according to the national guideline, suggesting that 1.3–4.6 patients out of 100 could have had contacts with hygiene-relevant microorganisms through an endoscopic intervention. Comparison of R and CRA sampling showed 1.8% of R versus 4.6% of CRA failing the acceptance criteria in phase I and 1.3% of R versus 3.0% of CRA samples failing in phase II. The most commonly identified indicator organism was *Pseudomonas* spp., mainly *Pseudomonas oleovorans*. None of the tested viruses were detected in 40 samples. While AERs in phase I failed ($n = 9$, 17.6%) mainly due to technical faults, phase II revealed lapses ($n = 6$, 11.5%) only on account of microbial contamination of the last rinsing water, mainly with *Pseudomonas* spp.
Conclusions: In the present study the contamination rate of endoscopes was low compared with results from other European countries, possibly due to the high quality of endoscope reprocessing, drying and storage. **P. Decristoforo, Clin Microbiol Infect 2018;▪:1**

Introduction

Several outbreaks of endoscopy-related infections have been reported in literature in recent years mainly associated with duodenoscopic interventions [1–3]. The US Food and Drug Administration received notification of 142 cases of patient infection or exposure from reprocessed duodenoscopes since 2010 [4]. In 2015 the US Food and Drug Administration issued a safety alert and ascertained concerns of an association between multidrug-resistant bacterial infections in patients who had undergone a duodenoscopic investigation [5].

Leffler et al. evaluated 6383 oesophagogastroduodenoscopies and 11 632 colonoscopies (including 7392 for screening) for the occurrence of procedure-related hospital visits with an electronic medical record-based system within 14 days after endoscopy. Hospital visits were recorded in 1.07%, 0.84% and 0.95% of all oesophagogastroduodenoscopies, colonoscopies and screening colonoscopies, respectively and in 0.4% if only signs of infection are considered [6].

Reprocessing of flexible endoscopes by sterilization is difficult due to heat-labile components, and duodenoscopes are probably

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most challenging due to their complex design [7]. Cleaning and disinfection regimens are complicated by narrow lumina and multiple internal channels [8]. Therefore, multiple steps of pre-cleaning, cleaning, high-level disinfection with automated endoscope reprocessors (AERs), rinsing, drying and storage are required within the reprocessing chain to avoid transmission of microorganisms from one patient to another [9]. However, the existing guidelines are inconsistent concerning the frequency and method of the microbiological monitoring [10–12]. The aim of the present study was to evaluate the hygiene level of ready-to-use gastrointestinal (GI) endoscopes and reprocessing quality of AERs in a multicentre prospective study. A further aim of this study was to assess whether a combined routine and advanced (CRA) sampling procedure has an impact on microbial detection, compared with the recommended endoscope routine (R) sampling.

Material and methods

Study participants and design

As this study did not have any influence on the treatment of patients, an institutional review board approval was not required at the Medical University Innsbruck.

Tyrol is one of nine Austrian federal districts with 728 000 inhabitants and approximately 90 000 endoscopic procedures per year. The hygiene status of all available reprocessed endoscopes and AERs was evaluated in two consecutive years (phase I June–December 2015 and phase II June–December 2016). For sampling, an appointment with the study members was fixed in advance. At this time-point all available reprocessed endoscopes and AERs of the respective centre were checked except those out of service or just in use (each endoscope and each AER was checked only once per phase). In phase II the procedure was repeated with the same centres and so, on the whole, the same endoscopes and AERs as in phase I were checked again. The routine (R) sampling procedure was compared with the combined routine and advanced (CRA) sampling procedure, which consisted of the routine (R) and an advanced (A) sample (see Supplementary material, Fig. S1). Samples were analysed in a central microbiological laboratory, which is accredited according to DIN EN ISO 17025 by using culture-based and molecular-based methods including detection of GI viruses. Samples, that were identified as being part of an outbreak (due to the occurrence of the same pathogen in more endoscopes and AERs than expected), were excluded from further data analyses to minimize the influence of extreme results on the overall data set.

All participating centres reprocessed the endoscopes adhering to the complete reprocessing chain (pre-cleaning, manual cleaning, AER, storing) recommended by the Austrian Society for Sterile Supply (ÖGSV) guidelines [10]. Reprocessing of endoscopes was done directly after the GI procedure, enzymatic agents were used for pre-cleaning in 83% of study centres. In six of 52 AERs (11.5%), no regular thermal self-disinfection was performed. The disinfectant used in AERs of all study members was exclusively based on glutaraldehyde.

Samples

All samples were obtained by two hygiene experts and processed under highly aseptic conditions. All specimens were stored on ice and immediately transferred for further analyses. Maximum time from sampling to analyses of the samples was 5 h according to the quality standards in microbiology/infection diagnostics by the German Society for Hygiene and Microbiology [13]. For routine investigation (R sample) of ready-to-use endoscopes, 20 mL of sterile 0.9% NaCl solution was flushed through the biopsy/suction channel from the proximal inlet to the distal end and collected in a 50-mL aseptic microbiological container without any adjuvant. In the case of a duodenoscope, the Albarran lever was moved into the central position and the recess behind and before was investigated with a sterile cotton swab after the flushing of R sampling. For A samples, the same ready-to-use endoscopes were immediately thereafter investigated by steering a sterilized 2.8–5.0 mm id synthetic disc brush PULL THRU™ (Galantai Manufacturing Co. Ltd, Auckland City, New Zealand) in one direction (proximal to distal end) through the biopsy/suction channel with the leading end in first to abrade the inner lumen, including possible biofilms. Once the leading end of the brush appeared at the distal end of the scope, the brush was pulled completely through the endoscope, removed and finally the disc component was cut off and placed into a 50-mL aseptic microbiological container. This procedure was followed by flushing the biopsy/suction channel with 20 mL of 0.9% NaCl and collection of the liquid sample in the same 50-mL aseptic microbiological container (A sample) (see Supplementary material, Fig. S1).

To check reprocessing quality of AERs after a completed cycle of cleaning and high level disinfection, 500 mL of final rinsing water was collected. Technical AER check consisted of check of cleanliness and disinfection performance and examination of temperature and retention time with six temperature data loggers according to the ÖGSV guidelines [10] (Table 1).

Laboratory analyses

R and A samples were vortexed and the disc-brush from A samples was removed under sterile conditions. The samples (R and A samples) were centrifuged at 4600 *g* for 10 min. The virtual pellets were resuspended to a volume of 10 mL with 0.9% NaCl each and used for culture-based and molecular-based analyses. The supernatant was used for molecular-based analyses only.

For molecular-based diagnostics, 5 mL of the resuspended pellet of the A sample was centrifuged again (4600 *g* for 10 min). In addition, the supernatants of R and A samples were pooled and decanted to a 38.5-mL thin wall, Ultra-Clear™ ultra-centrifugation tube (Beckman Coulter, Brea, CA, USA) and ultra-centrifuged at 84 600 *g* at 4°C for 90 min. Both pellets were resuspended in 200 µL of 0.9% NaCl and pooled for further molecular analyses. Fig. 1 shows the flowchart of sample preparation.

For culture-based analyses, the samples were inoculated on blood agar and liquid trypticase soy broth. The final rinsing water of the AER was analysed according to the microbiological requirements of the Austrian drinking water regulations [14]. Bacterial identification was done by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (Bruker, Vienna, Austria), antimicrobial resistance testing was not performed. Culture results of R samples were compared with those of CRA samples consisting of R and A samples (A samples were not evaluated separately as the latter are dependent on the R samples due to the sampling procedure) and for interpretation, the guidelines of the ÖGSV, were followed as detailed in Table 1 [10].

Molecular-based analyses were performed in a total of 40 randomly selected (by random number function of Microsoft Excel) samples, including 20 culture-positive and 20 culture-negative samples and analysed in duplicates. Detection of rotavirus, adenovirus, astrovirus, sapovirus, norovirus (genotype I and II), poliovirus, echovirus, coxsackievirus and human enterovirus 70/71, *Helicobacter pylori* and *Clostridium difficile* was performed using different Rida®Gene RT-PCR assays (R-Biopharm AG, Darmstadt, Germany). More detailed information on the laboratory analyses are given in the Supplementary material (Appendix S1).

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