

Recent advances in epidemiology and prevention of gastrointestinal endoscopy related infections

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Purpose of review

This article reviews recent publications relevant to endoscope reprocessing and the potential for transmission of infection during gastrointestinal endoscopy.

Recent findings

There have been a number of established reprocessing failures of gastrointestinal endoscopes at various healthcare facilities across the US resulting in patient notifications. These episodes have been associated with user errors and reprocessing equipment failures, highlighting the need for increased compliance with established guidelines. Surveillance cultures may be useful to monitor the outcome of reprocessing, although their use is controversial. New technology to allow point-of-use monitoring is promising. Biofilm accumulation may be an issue when reprocessing gastrointestinal endoscopes. Although peracetic acid has been promoted as superior to aldehyde-type liquid chemical germicides with regard to soil fixation, it may only be a modest improvement. Electrolyzed acid water is an emerging liquid chemical germicide that may be equivalent to currently accepted disinfectants. There appears to be no benefit to an additional reprocessing cycle before use for endoscopes that have been appropriately cleaned, disinfected, and stored.

Summary

With the recent media attention on gastrointestinal endoscope reprocessing failures, despite the absence of documented transmission of infection, increased compliance with existing guidelines and new initiatives to enhance endoscope reprocessing are increasingly important to maintain public confidence.

Keywords

disinfection, endoscopy, reprocessing

Introduction

With the rapid and exciting advances in gastrointestinal endoscopy, it is perhaps not surprising that the relatively mundane topic of infection control in gastrointestinal endoscopy is taken for granted. While the established risk of infection is remote (and, when accepted reprocessing protocols are followed, virtually eliminated) [1], the well established benefits of endoscopy are rarely mentioned. As one example, the average person faces a 6% lifetime risk of developing colorectal cancer (147 000 new cases, 57 000 deaths per year in the US) [2], which is largely preventable by colonoscopy. A recent comprehensive review of the medical literature suggests that transmission of infection resulting from gastrointestinal endoscopy is an extremely rare event, and has invariably been associated with a breach in cleaning protocols or defective equipment. This is not an excuse for inadequate cleaning and disinfection, nor should it relieve endoscope manufacturers from improving the materials and design of endoscopes to facilitate both function as well as the cleaning and disinfection process.

Review

In the past year there have been several reports in the lay media regarding reprocessing failures of endoscopes in the US. These media reports have generally appeared after notification letters have been sent from the healthcare facility to potentially affected patients [3–7]. In California, the state department of health received reports from 10 institutions in which over 5000 endoscopy patients were notified of a reprocessing failure (J. Rosenberg, personal communication). These reprocessing breaches can be grouped into technician errors (most notably failure to clean an auxiliary channel on certain models of endoscopes; equipment compatibility issues (usually between the endoscope and the automatic endoscope reprocessor (AER), resulting in inadequate perfusion of the liquid chemical germicide (LCG); and AER malfunction/failure. Although there have been no documented episodes of transmission of infection resulting from these reprocessing breaches, they do highlight the need for improved compliance with existing guidelines [8], and innovative strategies to help monitor this process.

Monitoring the outcome of endoscope cleaning and disinfection

There is currently no generally accepted mechanism for verifying the adequacy of high-level disinfection at the

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Abbreviations

AER automatic endoscope reprocessor
EAW electrolyzed acid water
LCG liquid chemical germicide

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point of use. Although aspects of the process can be tested (e.g. checking the minimum inhibitory concentration of the germicidal chemical bath), in the event of cleaning/disinfection failure there is little (other than grossly visible contamination) to indicate to the health-care professional at the time that a given endoscope has failed high-level disinfection. As noted in the episodes above, a system failure can be missed for a prolonged time period, resulting in a significant pool of patients with a potential exposure. One possible approach has been to conduct random microbial surveillance cultures. Some have argued that routine environmental sampling is expensive and of little value, and that it should be reserved for investigation of outbreaks [9]. However, others have proposed surveillance cultures as a mechanism for quality assurance [10,11,12^{*}]. In one recent study [13^{*}], surveillance cultures led to the identification of an automatic endoscope reprocessing unit contaminated with *Pseudomonas* species, which has been previously reported [14].

Routine surveillance cultures require standardized protocols which can be complex, are time-consuming, expensive, may not detect atypical organisms, and the results are not available until after the potential exposure has occurred. The results also need to be interpreted with caution; after high-level disinfection, endoscopes are not handled in a sterile fashion, and thus skin and environmental contaminants can be expected (and should not be interpreted as a failure of disinfection).

Although not accepted as a standard practice, Moses *et al.* [12^{*}] used a survey instrument to evaluate the current use of surveillance cultures as a quality assurance measure, and found that these were used at 17% of responding centers. Highlighting the underlying controversy regarding surveillance cultures, the authors found that the testing was not standardized and varied widely between centers. However, the most disturbing aspect of this survey was the claim that nearly 10% of centers performed mechanical cleaning as the only reprocessing step. The survey does not distinguish between manual mechanical cleaning and manual disinfection, which are two separate processes, and probably led to confusion among respondents. This more likely represents the fraction of centers still using manual high-level disinfection, as opposed to the use of an AER (and not failure to disinfect as suggested by the authors). Another claim is that 30% of the centers surveyed do not perform manual cleaning prior to using an AER for reprocessing (which is required). The survey actually asks whether the center performs both manual disinfection followed by automated disinfection, implying two cycles of disinfection (which is not required). This finding would be at odds with another large survey that found that

mechanical cleaning was performed appropriately in over 90% of the centers responding [15].

A novel approach to monitoring the effectiveness of cleaning and disinfection using a portable luminometer system has been reported. The LUM-T system uses an enzyme detection assay for adenosine triphosphate, which is present in all microbial organisms except viruses and prions [16^{*}]. The advantage of the system is that surveillance samples can be taken at any time, and results are available within 5 min. A disadvantage of the system is that, by definition, it cannot assess for the presence of viruses and prions, nor does it necessarily measure infectivity (i.e. it is not clear that the assay can discriminate between viable and nonviable organisms, or between environmental contaminants and pathogenic organisms). It is also relatively insensitive, as the LUM-T system cannot detect fewer than 105–106 CFU. This may provide a false sense of security in the face of actual contamination with a pathogen.

The importance of biofilm in endoscope reprocessing

The importance of biofilm in endoscopy has largely centered around its role in biliary stent occlusion. Two studies from the same group addressed the issues of biofilm as it relates to endoscope cleaning and disinfection. The first study attempted to evaluate the utility of enzymatic detergents in the removal of biofilm during the mechanical cleaning phase of endoscope reprocessing [17^{*}]. The endpoint was the amount of biofilm seen on scanning electron microscopy (SEM) after incubating a carrier sample with biofilm in a test bath containing a detergent with or without enzymes. The authors found that a detergent without enzymes performed better than those with enzymes, although they did not speculate why the addition of enzymes would be detrimental. While the intent of the study was to simulate 'in-use' testing, it is not clear whether the results can be generalized to clinical practice. Biofilm growth was allowed to proceed for 6 days on a carrier tube prior to evaluation (most endoscopes are mechanically cleaned multiple times daily). The test carrier was simply immersed in detergent for a specified time period, which does not accurately simulate the shearing action of mechanical cleaning that accompanies the use of a detergent. The use of a qualitative, unblinded endpoint (SEM estimation of biofilm reduction) makes the results difficult to interpret reliably. The fact the sponsor of the study was also the manufacturer of the only detergent without enzymes is also problematic.

The second study also used electron microscopy to determine the presence of bacteria, biofilm, and residual soil on the surface of endoscope tubing (internal

channels) that had been recovered from endoscopes sent to a repair facility in Australia [18[•]]. The key assumption of the study was that the discarded endoscope channels obtained from a repair facility were representative of those found in patient-ready endoscopes, and reflect the efficacy of routine high-level disinfection used in practice. From the outset, this assumption is severely flawed. The authors readily admit that absolutely no history regarding these instruments was available. The age, frequency of use, or reason for repair of these instruments was not known. In fact, it was not known whether these were bronchoscopes or gastrointestinal endoscopes, or whether they were fully immersible instruments. Since biopsy, air, and water channels are not routinely replaced during endoscope repair unless failure of the internal channels was the reason for repair, it is precisely because these channels were damaged that they were available for the study. It is not clear how these particular channels were selected or obtained, thus selection bias could further impair the limited generalizability of these results. As the authors also point out, the high-resolution imaging (electron microscopy) of the study material also prohibited comprehensive sampling, and only a 1 cm section from each specimen was examined, raising the potential for sampling error.

The most egregious error was the assumption that any organic deposits and biofilm found on these tubing samples directly reflected the adequacy of cleaning and disinfection on a patient-ready endoscope. It is more likely that these organic residues are the results of multiple cleaning and disinfection cycles over the life of the instrument, and we do not know whether these were appropriately performed. There is evidence to suggest that in Australia, where the study was performed, there may have been significant lapses in appropriate cleaning and disinfection protocols that would be considered unacceptable by US standards [19,20]. Although this has undoubtedly improved since these early reports, there is still concern that not all endoscopy centers follow current guidelines [21]. Furthermore, because Australian standards recommend a 10 min glutaraldehyde exposure, rather than the 20 min exposure recommended in the US, even if guidelines were followed the results may not be applicable to the US. It is stated that all of the endoscopes sent for servicing had documented evidence of decontamination. Assuming that this was actually done for an instrument being sent in for repair (which is a major assumption in and of itself), the definition of decontamination is simply a process that renders a device safe to handle. Specifically, a decontamination process does not necessarily mean that the item is safe for patient reuse [22]. Furthermore, if the instruments were not fully dried prior to being sent to the repair facility (which might not be necessary for 'decontamination'), growth of *Pseudomonas aeruginosa* and its associated biofilm would

be expected, and the study findings again would not represent patient-ready endoscopes. Details of the handling and storage of the tubing after removal (prior to the study) are also unknown. Thus the findings on biofilm in the study have little clinical relevance.

Although these studies do raise the possibility that biofilm might be an issue in gastrointestinal endoscope reprocessing, their methodologic flaws make it difficult to determine the clinical relevance of the findings.

Mechanism of action of liquid chemical germicides

In discussing the properties of various LCGs used for high-level disinfection, fixation of organic soils and proteins is often listed as a disadvantage of glutaraldehyde [23], due to its known mechanism of action of cross-linking proteins [24]. Peracetic acid has been proposed as a superior alternative because it does not result in soil fixation [23,25[•]], although this has not been systematically investigated. One study [25[•]] evaluated the degree of surface fixation of dried blood by glutaraldehyde, peracetic acid, quaternary ammonium compounds (QACs), and phenol. Surprisingly, phenol and QACs, considered to be low-level disinfectants inadequate for endoscope reprocessing [26], performed the best with regard to removal of blood and fixation to the test carrier. The rate of blood fixation to the test carrier after exposure to glutaraldehyde ranged from 76.9 to 102.5%, whereas the rate for peracetic acid ranged from 19.2 to 78.1%. Although somewhat reduced, soil fixation was an issue for peracetic acid as well, again highlighting the importance of mechanical cleaning to remove organic soils that can protect microorganisms from the effects of LCGs.

Alternative technologies for endoscope disinfection

Although most LCGs have been associated with contact toxicity (most commonly in patients due to residual disinfectant left on the endoscope from inadequate rinsing, or exposure of the healthcare worker due to spills, etc.), glutaraldehyde has a prominent vapor component, which has been associated with ocular, nasal, and respiratory problems [27,28]. In many areas, glutaraldehyde is being replaced by LCGs that are faster acting and, to date, have been associated with fewer issues with vapor toxicity. Electrolyzed acid water (EAW), also called super-oxidized water, is a novel LCG generated from tap water and salt (sodium chloride) in an electrolysis tank through which current is passed [29]. This generates hypochlorous acid, hydrochloric acid, and chlorine and a significant oxidation–reduction (redox) potential. The antimicrobial effect of the resulting solution is postulated to result from the synergistic effects of low pH, high redox potential, and free chlorine [30]. Lee *et al.* [31[•]] performed in-use testing on the efficacy of EAW and 2%

alkaline glutaraldehyde during reprocessing of upper gastrointestinal endoscopes. The authors collected samples from four parts of each test endoscope: the operating channel, the tip of the insertion tube, the surface of the umbilical cord, and the surface of one of the control knobs. The results are somewhat difficult to interpret because the reprocessing protocols were not directly comparable. While the glutaraldehyde reprocessing unit exposed the entire endoscope to the LCG, the EAW reprocessor exposed only the insertion tube and the operating channel to the disinfectant; the remainder of the instrument was disinfected with 75% ethanol spray/scrub. In general, the rate of positive microbial cultures was greater in the EAW group at all sampling sites, although not statistically significant. The 27.0% contamination rate of the angulation knobs in the EAW is problematic, although perhaps not unexpected as they were treated with a low-level disinfectant (rather than a high-level disinfectant/sterilant). However, it should be noted that the contamination rate for the control knobs undergoing disinfection with glutaraldehyde, while less than that for EAW, also had a high rate of contamination (17.7%). Because the vast majority of the organisms recovered in the study in general were not pathogens and were present in low concentration (1 CFU), the significance of these findings is unclear, and the culture results in many cases may represent environmental contaminants. This may have been an artifact of the collection method. In clinical use, endoscopes are not handled with sterile gloves after disinfection, and we are not told whether the endoscopes were handled in an aseptic fashion for the study.

Reprocessing endoscopes after storage

There has been some controversy regarding the need for endoscope reprocessing immediately before the first procedure of the day in an endoscope that has been appropriately reprocessed and stored previously. Although there are little or no data supporting this practice, the British Society of Gastroenterology, the European Society of Gastrointestinal Endoscopy, and the Association of Perioperative Registered Nurses all recommend that endoscopes undergo a reprocessing cycle before the first patient of the day [32–34]. The US Multi-Society guidelines, based on current evidence (or more accurately, the lack of evidence that this practice provides a clinical benefit), do not recommend this practice for endoscopes that have undergone appropriate cleaning, disinfection, and storage [8]. In one of the few studies performed specifically to address this issue, Rejchrt *et al.* [35[•]] cultured a variety of endoscopes immediately after disinfection and storage, and subsequently every other day for 5 days, and found only four out of 135 cultures were positive, all of which were skin contaminants. To minimize the possibility that this contamination was an artifact introduced by the repeated

sampling procedure, in the second part of the study, 10 endoscopes were cultured after storage for 5 days; all cultures were negative. Although a small study, it does suggest that endoscopes that have been appropriately reprocessed and stored do not need an additional reprocessing cycle prior to use. This confirms the findings of an earlier study [36] suggesting that an additional reprocessing cycle for endoscopes is unnecessary even after storage for up to 1 week.

Conclusion

With the recent media attention on gastrointestinal endoscope reprocessing failures, despite the absence of documented transmission of infection, increased compliance with existing guidelines and new initiatives to enhance endoscope reprocessing are increasingly important to maintain public confidence.

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