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Cross-contamination in Gastrointestinal Endoscopy: Why is Less Attention Paid in Europe than the US?

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Abstract

Multiple published studies provide evidence that gastrointestinal endoscopes can be contaminated even after proper reprocessing and that highly contaminated endoscopes increase the risk of patient-to-patient infections. However, attention on cross-contamination and post-ERCP infections has mainly been limited to the US, despite relevant studies being published in Europe and other parts of the world. Why is this major problem being acknowledged in the US but not in most European countries? We present data from the literature illustrating that the problem is also present in Europe, thus increased focus and transition to innovative technologies and designs is recommended.

Keywords: Endoscopy • Contamination • Cross-contamination • Infections • Gastroenterology

Abbreviations: CDC: Centers for Disease Control and Prevention; CFU: Colony-forming Unit; ERCP: Endoscopic Retrograde Cholangiopancreatography; FDA: Food and Drug Administration; HLD: High-level Disinfection; MRKP: Multidrug-resistant Klebsiella Pneumoniae

Gastrointestinal endoscopes are used for both therapeutic and diagnostic purposes. During the procedures, the endoscope is in close contact with the gastrointestinal tract's mucous membranes [1]. If the endoscope is contaminated, the risk of patient-to-patient contamination increases, which can lead to hospitalization [2-4]. The multiple benefits associated with endoscopic procedures outweigh the potential risks. However, contaminated reusable endoscopes have been linked to more patient infections and outbreaks than any other reusable medical device [1].

To achieve adequate cleaning of medical devices, the Spaulding classification was developed, which categorizes medical devices as either critical (high risk), semi-critical, or non-critical (low risk), based on the risk related to their use, and ranks the cleaning methods from simple disinfection to sterilization [5]. Endoscopes are categorized as semi-critical in this classification system [3]. Semi-critical devices only require high-level disinfection (HLD) after each procedure, and sterilization is unnecessary [1]. HLD usually eliminates all bacteria colony-forming units (CFUs), though a few bacterial spores may survive if the device was originally highly contaminated [5]. Despite the existence of comprehensive reprocessing guidelines, endoscope contamination is not uncommon. A meta-analysis of 15 studies found a contamination rate of 15% among patient-ready duodenoscopes [6]. In 2013, the US Centers for Disease Control and Prevention (CDC) alerted the US Food and Drug Administration (FDA) about a potential link between endoscopic retrograde cholangiopancreatography (ERCP) and outbreaks of multidrug-resistant bacterial infections. Following further investigation, it was discovered that these outbreaks seemed to have occurred despite proper manufacturer reprocessing instructions being followed [7]. This resulted in a series of Safety Communications from the FDA and the initiation of postmarket surveillance studies. The final results of these studies were made public in April 2020; they showed a 6.8% contamination rate associated with reprocessed duodenoscopes [8]. The majority (5%) of the total contamination rate involved high-concern organisms. Following this, the FDA recommended transition to duodenoscopes with innovative designs that make reprocessing easier or more effective or even unnecessary (based on using single-use endoscopes). Alongside the Safety Communications from the FDA, the US Senate published a comprehensive report of more than 300 pages that described and analyzed the problem of antibiotic-resistant infections due to contaminated duodenoscopes [9]. The report stated that these duodenoscopes had been linked to at least 25 outbreaks involving at least 250 patients between 2012 and the spring of 2015. Multiple published studies provide evidence that gastrointestinal endoscopes can be contaminated even after proper reprocessing and that highly contaminated endoscopes increase the risk of patient-to-patient infections [10,11]. However, attention on cross-contamination and post-ERCP infections has mainly been limited to the US, despite relevant studies being published in Europe and other parts of the world. Why is this major problem being acknowledged in the US but not in most European countries?

Although major influencers in the US such as the FDA and the US Senate are paying attention to contaminated duodenoscopes and cross-infections, it seems that most European countries have chosen to focus less on these issues. There has been a lack of communication from European healthcare bodies, compared to the corresponding US bodies, concerning infections caused by contaminated gastrointestinal endoscopes. If there is more consistent adherence to reprocessing guidelines in European countries, they may experience lower contamination rates. However, several multidrug-resistant bacterial outbreaks have been reported to have occurred despite appropriate reprocessing. Therefore, it seems unlikely that there is a difference in the rate of post-endoscopy infections between Europe and the US. As post-ERCP outbreaks of multidrug-resistant microorganisms have been reported in Europe, it is highly unlikely that gastrointestinal endoscopes in Europe are completely clean and contamination-free [12]. This was exemplified in an Italian study by Christina et al. in 2020, as initial surveillance revealed that 75% of the samples from duodenoscopes were positive for high-concern microorganisms [13]. In general, individual research groups in Europe have focused on the problem of contaminated endoscopes and possible accompanying infections. In the Netherlands, Rauwers et al. [14] investigated an outbreak of multidrug-resistant Klebsiella pneumoniae (MRKP) from two contaminated duodenoscopes. Cultures were available from 81 patients who had undergone an ERCP with one of the two contaminated endoscopes, and 27 of these patients were positive for MRKP. Ten of these patients developed an active MRKP infection, most of them presenting with sepsis. A Spanish study by Blázquez-Garrido et al. [15]

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states that "It seems likely that the problem is being underestimated and that cross-contamination with another, more common, type of microorganism may go unnoticed".

Despite these concerning findings from Europe, the number of studies focusing on contaminated endoscopes seems to be considerably lower in Europe than the US. In the meta-analysis by Larsen et al. [6] only four of the 15 studies were conducted in European countries, while nine were conducted in the US. Nevertheless, multiple post-ERCP infection outbreaks have been reported in European countries. A literature review by Rubin et al. [16] reported that nine of 32 post-ERCP infection outbreaks in 2000–2017 occurred in European countries. The authors conclude that many outbreaks occurred despite adherence to reprocessing guidelines, and that either device redesign or altered reprocessing techniques are needed. In addition, the Mannheim University Hospital in Germany was subject to negative public attention in 2014 when an anonymous insider reported that dirty duodenoscopes were being used [16]. This led to an investigation, which discovered non-compliance regarding endoscope reprocessing, along with underqualified personnel and ineffective automated endoscope reprocessors that had not been officially validated. Communication of these findings to the public was limited to reports in German newspapers, with very little information being provided.

Although it could be speculated that issues of contaminated gastrointestinal endoscopes are more critical in the US than Europe, the issue seems to occur in both the US and Europe. Contaminated endoscopes can lead to post-endoscopic infections, compromising patient safety, so this issue should not be ignored. Therefore, we recommend an increased focus on post-endoscopy infections in European countries and transition to innovative designs that make reprocessing easier or more effective or even unnecessary in accordance with the FDA recommendations. If patient safety is compromised due to the current design of gastrointestinal endoscopes, it is necessary to take action, including in Europe.

Disclosure

SL and SA are employed by Ambu A/S. NBL declares no conflict of interest.

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