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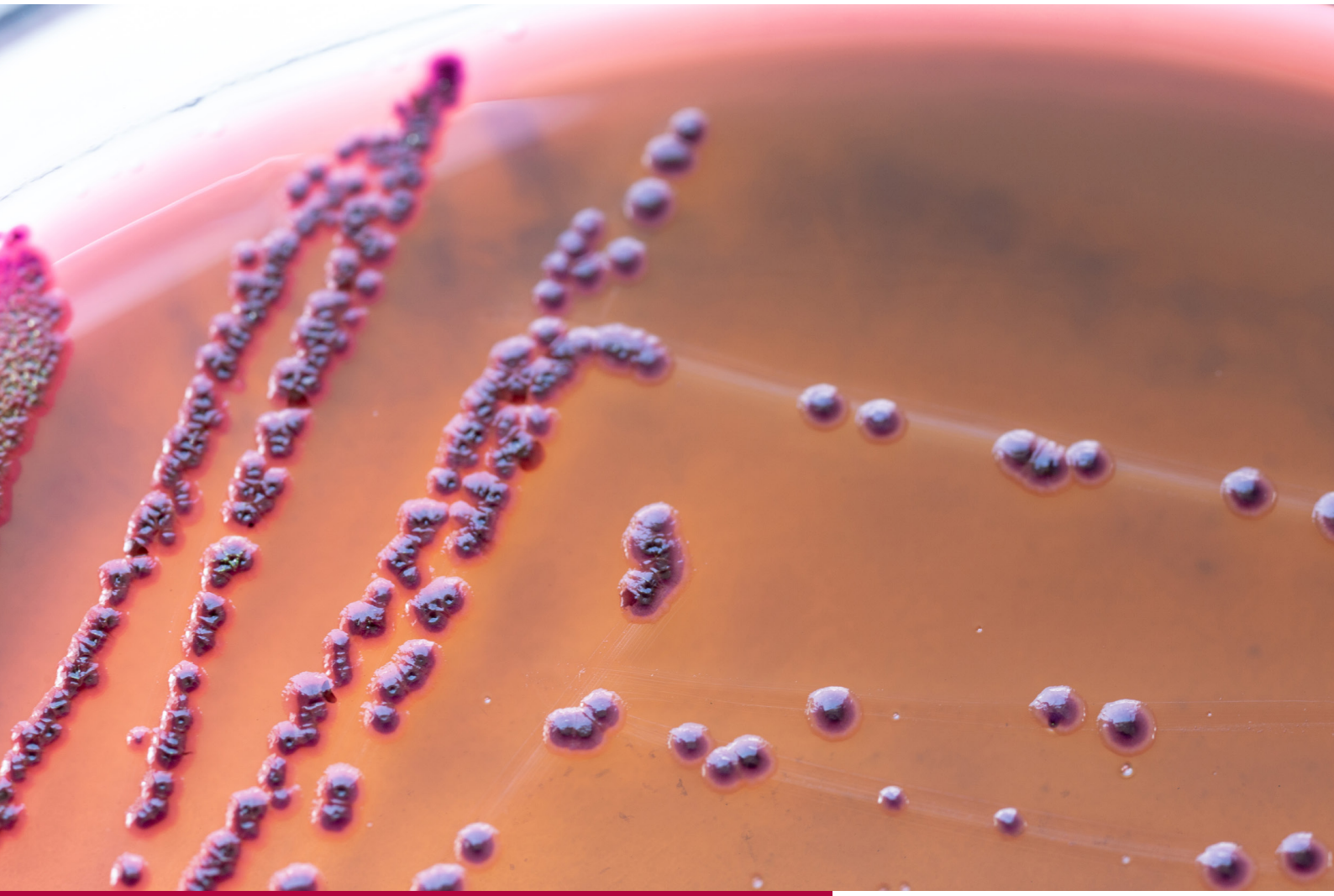


e-Booklet

Summaries of five cross-contamination studies related to duodenoscopes

Results of duodenoscope culture and quarantine after manufacturer-recommended cleaning process

Mark J, Underberg K, Kramer R. Gastrointest Endosc. 2020 Jan 13.

Summary

This is a prospective case-series study in which an institution adopted high-level disinfection and quarantine practices over several years in a pediatric hospital setting performing a low volume of ERCPs. The study results suggest that standard culture and quarantine of duodenoscopes is feasible in clinical practice at a centre performing a low volume of ERCP's. Culture and quarantine is more difficult at a higher volume site unless a major investment in additional equipment is made to accommodate a quarantine period of up to 72 hours. The study supplements others that have found that neither SHLD nor DHLD eliminates bacterial contamination, which is primarily due to the design of the duodenoscope. Additionally, damaged duodenoscopes are known to be at risk of inadequate cleaning, biofilm formation, and subsequent infection transmission.

Methods

- Institution adopted all manufacturer recommendations and the CDC's recommendations for culture and quarantine.
- Two culture specimens were taken using a sterile brush from the distal tip, including elevator mechanism, and by flushing sterile water through the working channel.
- Positive cultures were defined as greater than 10 colony forming units (CFU's) of low-concern organisms, or any CFU of high-concern organisms according to CDC recommendations. If either culture specimen was positive, the process was repeated until cultures were negative.

Key results

- 18% of duodenoscopes had a positive culture after initial HLD. There was no difference in rates of positive cultures among the three duodenoscope models studied (all Olympus Models).
- HLD cleaning has been shown to not eliminate risks of bacterial transmission even when there have not been breaches in protocols.
- A repeated HLD was 86% effective at eliminating contaminations. The third cleaning was 75% effective at eliminating initial and repeat positive cultures respectively. There was one instance of positive cultures after a third clearing. This scope was sent to the manufacturer and was found to have cracks in the distal tip casing. The scope was repaired and no longer had consistently positive cultures after repair.

Key conclusions

- Contamination rates continue to exist despite the use of a second HLD cycle. This provides further concern that standard practices are inefficient in removing contaminates.
- Without a culture and quarantine process, contaminates residing in defective scopes, which otherwise seem normal in appearance, can go undetected.
- The lack of available equipment compelled the facility to remove scopes from quarantine earlier than expected. Facilities with low volumes of procedures and a low inventory of scopes may not be able to adequately culture and quarantine.
- Study suggests that facilities should take additional precautions beyond what manufacturers recommend.

Duodenoscope-associated infections beyond the elevator channel: Alternative causes for difficult reprocessing

Balan GG, Rosca I, Ursu EL, Fifere A, Varganici CD, Doroftei F, Turin-Moleavin IA, Sandru V, Constantinescu G, Timofte D, Stefanescu G, Trifan A, Sfarti CV. Molecules. 2019 Jun 25;24(12).

Summary

Post ERCP, numerous outbreaks of multidrug-resistant organisms (MDRO) infections have been reported prompting extensive research of overall duodenoscope design for their possible causes. This study aims to search for possible duodenoscope surface damages that could provide an alternative and plausible source of infections (beyond the elevator). The FDA advises to strictly follow manufacturer reprocessing protocols emphasizing the need for double reprocessing cycles backed by surveillance protocols like the "culture and hold" policy prior to use. Manufacturers are addressing this issue by redesigning duodenoscopes focusing on proper sealing of the elevator channel or by introducing a detachable/single-use distal tip/elevator.

Methods

- Selected One (1) duodenoscope from a high-volume tertiary hospital that was previously used in up to 500 ERCP procedures.
- The scope was dismantled, and samples were taken from the external resin polymer and inside the air/water, elevator, and working (biopsy) channels.
- Assessment of the samples were performed via a litany of advanced imaging approaches.

Key results

- Current studies and FDA protocols suggest challenges with reprocessing due to the difficult-to-clean design of the distal tip. However, this study illustrates that surface alterations (specifically the inner channels) are also harboring resistant bacteria that persist even after extensive cleaning.
- Average roughness value varied from 12.8 nm to 70.2 nm suggesting the intense usage of the proximal part of the duodenoscope caused more extensive polymer damage in the proximal segments of the scope.
- While the outside polymers on the scope showed amorphous and irregular patterns of deterioration, the inside (air/water and working) channels showed parallel micro-recess formation, mainly due to the repeated passage of instruments through the working channel and the methods used to clean these channels.

Key conclusions

- The study provides new evidence about how micro-abrasions to coating materials that directly (external) and indirectly (internal channels) contact living tissues increase the risk of a scope's ability to harbor MDROs even after HLD reprocessing.
- Repeated reprocessing and routine procedural use (including passing/handling routine ERCP instruments through working channel) create patterns of deterioration that make a duodenoscope more susceptible to bacterial contamination and MDRO biofilm formation.

Use of ethylene-oxide gas sterilization to terminate multidrug-resistant bacterial outbreaks linked to duodenoscopes

Muscarella L. BMJ Open Gastroenterol. 2019 Aug 5;6(1):e000282.

Summary

This review shows how current reprocessing practices are insufficient in preventing duodenoscopes from transmitting of carbapenem-resistant Enterobacteriaceae (CRE) and related multi-drug resistant organisms (MDRO's). The authors reviewed all publications (23) describing a duodenoscope-related CRE outbreak beginning in 2012. The primary focus was to evaluate the affected apostrphe institutions' reprocessing methods, level of compliance with recommended guidelines, and to discuss corrective actions taken to prevent further infections/outbreaks. While it was not the main objective, the review found that Ethylene-Oxide (EO) gas terminated CRE outbreaks when used as a sterilizing agent.

Methods

- A systematic-review and meta-analysis of available publications related to confirmed cases of CRE and MDRO infections coming from duodenoscopes since 2012.
- The author used MEDLINE/PubMed database, internet searches for news articles, and the FDA's MAUDE database to identify 23 publications describing instances of duodenoscope related CRE outbreaks.
- The review aimed to assess: a) the reprocessing method used at time of infection (e.g., HLD), b) whether the facility was compliant with manufacturer reprocessing instructions, and c) the corrective actions implemented to prevent additional infections.

Key results

A) What reprocessing methods were used at time of infection?

- 12 of 23 centres reported that the duodenoscopes were being high-level disinfected (HLD) at time of infection, consistent with guidelines.

- >50% of duodenoscopes following standard reprocessing guidelines still became infected.

B) Was the facility compliant with manufactuerer reprocessing guidelines?

- 8 of 23 infections occurred despite no identifiable breach in the reprocessing procedure

- Only 35% of centres were following manufacturer IFU (in accordance with professional guidelines).

C) What corrective actions were implemented to prevent further infection?

- 6 centres reported adopting ethylene-oxide (EO) gas sterilization with at least 3 reporting this measure impeded the outbreak.

- Other measures to prevent additional infections included:

- Removing the implicated duodenoscope from use
- Retraining staff about proper cleaning
- Microbiological culturing
- Reprocessing the duodenoscope twice

Key conclusions

- The FDA classifies duodenoscopes and most other flexible endoscopes as semi-critical devices, meaning they are required to be cleaned by high-level disinfection or sterilization.
- HLD has become the standard because sterilization chemicals tend to cause devices to deteriorate too quickly.
- Current reprocessing practices may not always be sufficiently effective to prevent a duodenoscope from transmitting CRE and related MDROs.

Independent root-cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to investigate an outbreak of multidrug-resistant Klebsiella pneumoniae

Rauwers AW, Troelstra A, Fluit AC, Wissink C, Loeve AJ, Vleggaar FP, Bruno MJ, Vos MC, Bode LG, Monkelbaan JF. Gastrointest Endosc. 2019 Nov;90(5):793-804.

Summary

Multidrug-resistant Klebsiella pneumoniae (MRKP) is a serious issue in the healthcare system. Worldwide, an increasing number of duodenoscope associated outbreaks are reported. The high prevalence rate of contaminated duodenoscopes puts patients undergoing ERCP at risk of exogenous transmission of microorganisms. The aim of this article is to further understand the duodenoscope design as it relates to contamination.

Methods

- Conducted at single-centre site that had an outbreak of MRKP.
- Retrospective analysis that acquired samples of patients thought to be exposed to two contaminated duodenoscopes between 01/23/2015 and 08/13/2015.
- A contact investigation was initiated, consisting of screening of patients and a microbiological laboratory database search.

Key results

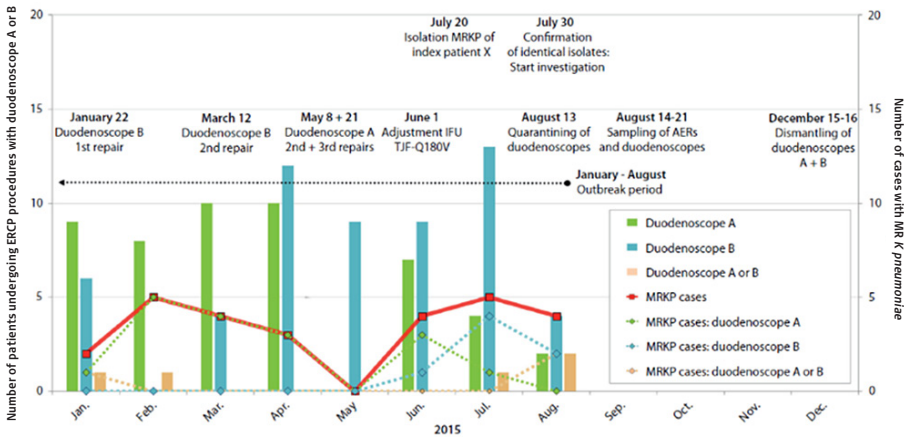
81 patients yielded culture results.

Scope A – (17/49 patients) 35% attack rate.

Scope B – (7/24 patients) 29% attack rate.

Culturing of duodenoscopes A and B showed persistent contamination of the channels with identical MRKP isolates.

*Attack rate is the number of infected or colonized cases/number of exposed persons.



Key conclusions

Outbreaks are associated with a combination of factors, including, duodenoscope design issues, repair issues, improper cleaning, and systemic monitoring of contamination. All of these factors involve human error.

- The paper concluded that new duodenoscope designs were needed to reduce risk factors.
- Biopsy channels of all types of endoscopes are frequently damaged, even as early as after 4 weeks of use, which may add to the risk of contamination.
- The American Society for Gastrointestinal Endoscopy warns that endoscope durability is incompletely understood.

Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using hydrogen peroxide-ozone sterilizer

Molloy-Simard V, Lemyre JL, Martel K, Catalone BJ. Am J Infect Control. 2019 Mar;47(3):243-250.

Summary

There are many processing challenges and infection risks associated with duodenoscopes. Studies have demonstrated that the current practices are inadequate for producing endoscopes that are patient-ready. Alternatively, terminal sterilization would offer a greater margin of safety and potentially reduce the risk of patient infection(s). The study was performed to evaluate the microbicidal efficacy of a hydrogen peroxide-ozone sterilizer with regulatory clearance for terminal sterilization of duodenoscopes.

Methods

- The study was conducted using three separate methods: overkill, simulated use, and a clinical in-use validation. The tests were performed both under simulated worst-case laboratory conditions and in-use clinical conditions.
- The sterilizer used in this study was the STERIZONE VP4 (TSO3 Inc.). The duodenoscope model used for the study was the Olympus EVIS EXERA II TJF-Q180V (AIZU OLYMPUS CO.).
- The sampling methods for all test sites were validated by direct inoculation of the sites with 10 CFU-100 CFU of the G stearothermophilus spore solution. The tested sites were inoculated, left to dry overnight, tested in triplicate, and sampled.

Key results

- No growth (sterile) using the overkill and simulated-use methods in all sampled sites
- Clinical in-use contamination levels before sterilization showed (microorganism contamination types: aerobic, anaerobic, yeasts and molds). Aerobic-only shown below:

Sampled site	Pre-cleaning samples 1 2 3	Post-cleaning samples 4 5 6 7 8
Instrument/suction channel group	+ +++ +++	++ + ++ + +
Air/water channel group	++ ++ +++	+ + - + +
Elevator mechanism	++ +++ +++	+++ ++ +++ ++ ++
Insertion tube surface	++ +++ ++	+ - - + -

-: No growth (sterile) +: <10CFU ++: 10 to 200 CFU +++: >200 CFU. CFU, Colony-forming unit.

Key conclusions

- Hydrogen peroxide-ozone sterilization was just recently introduced in 2014, and just recently gained regulatory clearance.
- The sterilization method is not currently listed as a validated processing method in the duodenoscope manufacturers' instructions for use (IFU).
- The study only looked at challenges faced by the Olympus 180 scope, which is the market-leader and most-used scope. This raises questions as to whether issues related to the many other scopes on the market are under-reported and/or not yet known.