Journal of Hospital Infection 83 (2013) 22–29

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Current limitations about the cleaning of luminal endoscopes

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ARTICLE INFO

Article history:
Received 1 September 2011
Accepted 22 August 2012
Available online 23 October 2012

Keywords:
Luminal endoscope
Decontamination
Prion
CJD

SUMMARY

Background: The presence and potential build-up of patient material such as proteins in endoscope lumens can have significant implications, including toxic reactions, device damage, inadequate disinfection/sterilization, increased risk of biofilm development and potential transmission of pathogens.

Aim: To evaluate potential protein deposition and removal in the channels of flexible luminal endoscopes during a simple contamination/cleaning cycle.

Methods: The level of contamination present on disposable endoscopy forceps which come into contact with the lumen of biopsy channels was evaluated. Following observations in endoscopy units, factors influencing protein adsorption inside luminal endoscope channels and the action of current initial cleaning techniques were evaluated using a proteinaceous test soil and very sensitive fluorescence epimicroscopy.

Findings: Disposable endoscope accessories appear to be likely to contribute to the contamination of lumens, and were useful indicators of the amount of proteinaceous soil transiting through the channels of luminal endoscopes. Enzymatic cleaning according to the manufacturer's recommendations and brushing of the channels were ineffective at removing all proteinaceous residues from new endoscope channels after a single contamination. Rinsing immediately after contamination only led to a slight improvement in decontamination outcome.

Conclusion: Limited action of current decontamination procedures and the lack of applicable quality control methods to assess the cleanliness of channels between patients contribute to increasing the risk of cross-infection of potentially harmful micro-organisms and molecules during endoscopy procedures.

Introduction

Complex instruments such as flexible luminal endoscopes present various materials, cavities and hinges allowing the deposition of contaminants. The adsorption and aggregation of patient tissue proteins in endoscope lumens could have significant implications. Such contamination may lead to toxic reactions and device damage, provide a favourable background for colonization by micro-organisms and biofilm formation, and subsequently increase the risk of inadequate disinfection/sterilization.[1] Protein contamination has emerged as a potential threat with identification of the misfolded prion protein (PrP^{Sc}) as the most likely 'non-conventional' infectious agent of transmissible spongiform encephalopathies (TSEs).[2] Identified from sheep scrapie, PrP^{Sc} is also found in TSEs affecting humans, including the variant and sporadic forms of Creutzfeldt-Jakob

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http://dx.doi.org/10.1016/j.jhin.2012.08.008

disease (vCJD and sCJD, respectively). Variant CJD is characterized by a lengthy incubation period and wide tissue distribution of infectivity in asymptomatic carriers. It is therefore difficult, at present, to quantify the risk of re-using surgical devices that have been used on patients at risk of CJD.[3–6]

Endoscopes are fragile, expensive pieces of equipment. They cannot be autoclaved at temperatures sufficient to destroy micro-organisms or eliminate the infectivity of potentially adsorbed prions. Despite presenting difficulties to clean, endoscopes are subjected to repetitive use and rapid turnaround. This involves manual cleaning, leak testing and washing in automatic endoscope reprocessors (AERs). Current methods available to clinical settings for the rapid assessment of instrument cleanliness lack sensitivity and are not applicable to endoscope channels.[7] Most microbiological contamination tests still rely on sufficient recovery after swabbing.[8]

Manufacturers give specific recommendations for the decontamination of flexible endoscopes. Current evidence suggests that the prevalence of vCJD is low; nevertheless, there is a thriving market for AERs and associated chemistries, some designed to eliminate prion infectivity where this is a concern.[9] However, there is a lack of independent scientific evidence about the action of these products on protein removal or the 'inactivation' of human prion strains. Recommended 'best practices' for the reprocessing of flexible endoscopes (such as ISO 15883 Parts 1 and 4) are based on current evidence and available technologies.[10,11] Due to the limited follow-up of elective patients, variable incubation periods and potential lack of reports from patients, it is impossible to maintain a comprehensive record of iatrogenic infections through endoscopy procedures. Most cross-infections will remain unnoticed because they involve common innocuous commensals. However, it is well documented that endoscope channels represent ideal niches for a range of micro-organisms, which may include occasional pathogens with serious consequences in immunocompromised patients.[12] Proteinaceous contaminants are likely to offer the basic substrate for adhesion and embedding of bacteria, viruses and, in extreme cases, parasites, and should therefore be a prime target during endoscope reprocessing.

Episcopic differential interference contrast/epi-fluorescence (EDIC/EF) microscopy is a very sensitive technique developed in the authors' laboratory for the rapid quantification of microbial and proteinaceous contamination on surfaces.[13,14] Based on observations in local endoscopy units, this study applied EDIC/EF microscopy to evaluate the protein adsorption inside working channels of flexible endoscopes.

Methods

Endoscope channels and accessories

Endoscope channels were kindly provided by a manufacturer. Single-use endoscope biopsy forceps and single-use brushes for manual cleaning of the particular channels examined were a kind gift from various endoscopy units.

Soil

Edinburgh soil (Medisafe; Bishops Stortford, UK) was resuspended in reverse-osmosis (RO) distilled water and stored at 4 °C, following the manufacturer's recommendations. The suspension was further diluted (10% or 1% v/v) in RO water as required. A protein assay (Bradford method, Bio-Rad, Hemel Hempstead, UK) was performed using a range of test soil dilutions (in triplicate) to determine the protein concentration.

Contamination of endoscope channels

New endoscope biopsy and air/water channels were cut into short sections (20 cm) and sealed to a syringe. Test soil was pumped through the whole length of the tubing, followed by air to remove excess soil, to simulate the passage of tissues. Adsorbed soil was then left in contact with the luminal surface while the channel was placed in a dry incubator at 37 °C for 10 min (according to the test soil manufacturer's recommendations — identified as 'dry condition' later in the text); alternatively, the channel was filled with de-ionized water ('wet condition') until further cleaning.

Decontamination

An enzymatic cleaner used in a number of endoscopy units was employed for the decontamination of soiled channels, following the manufacturer's recommendations. Volumes were measured accurately and temperature (37 °C) was monitored. Contact time was 5 min for all channels (including brushing when applied).

Disposable single-use endoscope brushes were also used according to current practice. With the channel immersed in the enzymatic solution, the brush head was inserted at one end, pushed and pulled several times through the whole length of the channel, then pushed completely out at the other end. Channels were finally rinsed by flushing de-ionized water, and excess water was removed by flushing air through the channel (using new syringes for each stage) based on standard practice.

Staining and microscopy

Proteinaceous deposits on endoscope accessories and inside channel lumens were detected using SYPRO Ruby (excitation: 470 nm; emission: 618 nm; Molecular Probes, Eugene, OR, USA) and an EDIC/EF microscope (Best Scientific, Wroughton, UK) as described elsewhere.[14] After cleaning, a new syringe was sealed to the channel to allow gentle injection of the dye inside the lumen. After 15 min, the syringe was replaced by a new syringe containing de-ionized water, and the unbound dye inside the channel was washed off by gentle flushing. Air was then pumped through once to remove excess water. The tubing was cut in half longitudinally (using a new scalpel blade for each channel) and left to dry for up to 1 h (in the dark) before examining the lumen. Staining was quantified from 10 representative fields of view for each channel examined, using Image Pro software (MediaCybernetics, Silver Spring, MD, USA).

Statistics

Quantitative data were expressed as mean ± standard error of the mean from a least five separate experiments, and differences in contamination were assessed using analysis of variance and *t*-test. A value of $P \leq 0.05$ was considered to indicate significance.