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endoNEWS INTERNATIONAL

Dear Readers,

Hospital-acquired infections are still an issue of significance, and patient infections related to endoscopic procedures have been repeatedly reported in the past. The debate about the causes for this problem is a broad one, as is the range of suggestions to prevent it. One central aspect of prevention is the aspect of optimal cleaning of endoscopes. Several guidelines on the topic have been published in various countries, considering factors such as competent personnel, detailed instructions, equipment, storage, and documentation.

When it comes to the topic of infections from thermolabile endoscopes, one important question is the following: In the presence of remaining residues in thermolabile endoscopes, do the currently available sterilization methods ensure a sufficient reduction of microbial contamination?

In the article at hand, Dr. H. Biering attempts to answer that question.

I wish you an insightful read!

Kind regards

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INFECTIONS FROM THERMOLABILE ENDOSCOPES: IS STERILISATION A SOLUTION?

Patient infections associated with endoscopic procedures have been reported in a series of publications in the professional literature as well as public media in recent years. Within professional associations, regulatory authorities, and standards organisations, these publications of both individual cases and outbreaks of infections with multidrug-resistant organisms associated with endoscopic retrograde cholangiopancreatography (ERCP) in the USA, France, the Netherlands, and Germany[4-5] have led to a broad-based debate about the root causes as well as suggestions of preventive actions.

The European position

In 2016, the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) published a joint position statement on the "Prevention of multidrug-resistant infections from contaminated duodenoscopes".[6] In addition to providing advice about informing patients on the benefits and risks of ERCP, the visual inspection and maintenance of endoscopes as well as outbreak management, the position statement particularly supplies recommendations on the optimal cleaning of duodenoscopes, such as the following:

- Use of specially trained and competent personnel
- Provision of detailed reprocessing instructions by endoscope manufacturers
- Generation of reprocessing protocols that lay out each reprocessing step in detail for each endoscope model based on the manufacturer's specifications
- Use of cleaning equipment specified by the manufacturer
- Use of endoscope type-specific, single-use cleaning brushes whose material, diameter, and length has been defined by the manufacturer

Endoscope cleaning should start immediately after withdrawal from the patient in the examination room and be followed by leak testing, thorough manual cleaning steps, and automated reprocessing in the endoscope washer disinfector (EWD).[6]

Hence, the ESGE/ESGENA position statement emphasises measures to ensure the optimal cleaning of endoscopes before the subsequent reprocessing steps of disinfection and/or sterilisation, drying and storage.

The discussion in the US

In addition to improved cleaning, the debate in the US includes the fundamental question of whether the disinfection of thermolabile endoscopes is sufficient for eliminating the microbial contamination arising during use of the devices. An alternative recommendation is the routine sterilisation of thermolabile endoscopes since the "overkill process" of this procedure offers a higher margin of safety than does disinfection.[7] In September 2017, the US standards organisation for reprocessing medical devices, the Association for the Advancement of Medical Instrumentation (AAMI), held a meeting on reprocessing thermolabile endoscopes, which was attended by experts from practice, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) as well as testing laboratories.

During this event, W. A. Rutalla suggested changing the SPAULDING Classification (a risk classification scheme for medical devices) for thermolabile endoscopes as follows:

- Semicritical instruments: endoscopes used for diagnostics
- Critical instruments: endoscopes used therapeutically (e.g., for biopsy) and endoscopes that may directly or indirectly come into contact with mucous membranes or skin that is not intact[8]

Semicritical instruments may be disinfected, while critical instruments must be sterilised. The following were discussed as risk factors for sufficient endoscope decontamination through disinfection:

- High microbial load after use on the patient
- Complex design of thermolabile endoscopes
- Risk of biofilm formation

As a result of the event, a gradual move from routine disinfection to routine sterilisation of thermolabile endoscopes and the incorporation of this move into corresponding guidelines and standards was suggested.[8] In accordance with this modified SPAULDING Classification, the majority of endoscopes used in gastroenterology would have to undergo routine sterilisation after each use on a patient.

The central question

The listed risk factors can lead to inorganic and/or organic residues remaining on and in endoscopes following cleaning. Therefore, the question is whether in the presence of such residues, the currently available sterilisation methods for thermolabile endoscopes ensure a better reduction of microbial contamination and therefore offer a greater margin of safety than disinfection procedures performed under comparable conditions.

Assessment of the efficacy of disinfection methods

A disinfectant is suitable for the final disinfection of thermolabile endoscopes if it has been proven to possess at least bactericidal, mycobactericidal, fungicidal, and virucidal (against enveloped and non-enveloped viruses) effectiveness.[9] Disinfectant efficacy testing is conducted in quantitative suspension tests and in carrier tests at a low protein load using water of standardised hardness, that is, inorganic and organic loads are taken into account in the testing. In Europe, the efficacy testing for instrument disinfectants is conducted in accordance with the standard DIN EN 14885[10], which defines the test methods to prove efficacy. For use in EWDs for the automatic reprocessing of thermolabile endoscopes, as part of type testing, the disinfectant is first tested as described above, but also under consideration of the carry-over of residues from the preceding process stages (processing chemicals and contaminants). Furthermore, the disinfectant is tested in combination with the EWD

- In the disinfection stage in accordance with the standard EN ISO 15883-4: Annex B[11] and
- In the overall process (cleaning and disinfection step) in accordance with DIN ISO/TS 15883-5: Annex I[12]

Testing of the overall process employs test specimens (PTFE tubing, length 2 m, diameters 2 mm and 1 mm) as well as endoscopes. The test specimens and the working channel of the endoscopes are contaminated with heparinised sheep blood using *Enterococcus faecium* as the test germ. As a result, 9-log reduction of the test germ must be achieved in the overall process, and the test specimens must be clean on visual inspection.[13]

In the automated reprocessing of endoscopes in the EWD, tested according to the EN ISO 15883 standards, processes are therefore used that have been successfully tested in the presence of inorganic and considerable organic loads as part of type testing.

Sterilisation procedures

Due to their design and materials, most of the flexible endoscopes currently used are not resistant to higher temperatures. Therefore, they cannot be reprocessed with steam sterilisation methods at higher temperatures. The following low-temperature methods are available:

- Low-temperature steam and formaldehyde sterilisation (LTSF)
- Ethylene oxide sterilisation
- Hydrogen peroxide sterilisation with and without plasma

In most cases, these sterilisation methods are tested at low organic and inorganic loads. In the discussions taking place in the US, higher safety is assumed to be achieved with sterilisation particularly at the contaminant loads for which no comprehensive test results are available.

Due to the design of multiple endoscopes (number and length of channels and channel diameter), not all internal surfaces come into contact with the sterilisation agent. These sterilisation procedures may therefore be used only in endoscopes that have been tested and approved by the manufacturer of the endoscopes and/or sterilisers. Experts also discuss a massive loss in efficacy of these low-temperature methods in the presence of inorganic and/or organic materials. Older studies in which such efficacy losses have arisen are reportedly available.

Summary

In the author's opinion, current data do not support changing the SPAULDING Classification of thermolabile endoscopes in an effort to increase the margin of safety during reprocessing at this time. The following recommendations are suggested:

- Thorough cleaning, taking into account the recommendations listed in the ESGE/ESGENA position statement[6], is the prerequisite for the successful reprocessing of thermolabile endoscopes.
- Sterilisation is required for critical medical devices in accordance with the current SPAULDING Classification, which is defined by their medical application.
- For semicritical instruments, the recommended procedure for the inactivation of microbial contamination is disinfection, preferably performed in an EWD that has been tested in accordance with the standards DIN EN ISO 15883.

Outlook

To reduce the potential risk of incomplete cleaning, low-temperature sterilisation methods could make a significant contribution in the routine reprocessing of thermolabile endoscopes provided that

- Type testing of the processes demonstrates that better efficacy is achieved in the presence of inorganic and organic loads under conditions comparable to disinfectant testing
- It is ensured that all internal and external surfaces come into contact with the sterilisation agent.

Author:
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