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Water quality in endoscopy … clean, pure, sterile?

DEGEA Online Seminar for endoscopy personnel in collaboration with the Endoscopy Campus, sponsored by Chemische Fabrik Dr. Weigert, 14 April 2021

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The online seminar of the General Society of Endoscopy Nurses and Associates (DEGEA) held on 14 April focused exclusively on the water quality used to reprocess flexible endoscopes. Ulrike Beilenhoff, DEGEA chairman, introduced the topic by asking: Why is water of an appropriate quality needed for effective reprocessing in endoscopy?

She began by explaining that the first step in everyday practice when reprocessing flexible endoscopes consisted of manual pre-cleaning, followed by cleaning and disinfection in the endoscope washer-disinfector (EWD) and then the endoscopes were dried, if this was not already done in the EWD, stored or reused.

Water of impeccable microbiological quality must be used for the final rinse when cleaning and disinfecting endoscopes in the EWD as well as for manual cleaning and disinfection in order to prevent endoscope recontamination.

Reprocessing mistakes could lead to infection of the next patient, in particular those mistakes resulting from a combination of inadequate cleaning/drying and inappropriate storage. Beilenhoff demonstrated this by citing a case report involving clusters of infection after ERCP – it emerged that infection was always observed in the first patients undergoing endoscopy in the morning. This was caused by contamination of the drinking water, thus also of the EWD, with pseudomonads. It also became clear that all factors had to be investigated: the endoscopes, EWDs and water supply.

Daniela Schricker, Chemische Fabrik Dr. Weigert, spoke about water constituents and water qualities.

During endoscope reprocessing the water dissolved contaminant particles and transferred the processing chemical substances to the endoscope surfaces and then rinsed them off again. The water quality impacted the cleaning efficacy and, through possible foam formation, also the circulation pump pressure in the EWD.

Since the quality of municipal water varied greatly from one region to another, treated water was normally used for endoscope reprocessing.

In principle, a distinction must be made between municipal water and softened water/demineralized water.

In the case of softened water, the calcium and magnesium salts responsible for water hardness had been removed by cation exchangers. This prevented calcium deposits and also had a positive effect on the cleaning results.

> *Water softening reduces deposits and also has a positive effect on the cleaning results. The use of demineralized water is recommended.*

The speaker explained that demineralized water produced by ion exchangers or reverse osmosis systems was characterized by an overall very low water constituent content, hence when using demineralized water there was no evidence of staining once water residues had dried. The low chloride content in demineralized water also helped to prevent chloride-induced pitting corrosion.

The Guideline for Validation of Automated Endoscope Reprocessing Processes recommended the use of at least softened water for pre-cleaning and intermediate rinse as well as for the cleaning steps, and demineralized water for the final rinse – indeed, the use of demineralized water was advisable for all reprocessing steps.

Verona Schmidt, Chemische Fabrik Dr. Weigert, reported on the microbiological requirements to be met by the water used for reprocessing flexible endoscopes. She gave an overview of the most important waterborne bacteria, e.g. *Pseudomonas aeruginosa*, a widespread bacterium that grew in humid environments and could cause wound infections, urinary tract infections or pneumonia. Atypical Mycobacteria also caused pneumonia. Legionellae grew especially in water pipes, causing pneumonia if inhaled. Escherichia coli and enterococci, as intestinal bacteria, could enter the drinking via the surface water. The German Drinking Water Regulation had set threshold values in particular for faecal indicators such as *E. coli* (0 CFU/100 ml); tests for *Pseudomonas aeruginosa* were also carried out for samples delivered in closed containers. The threshold value was 0 CFU/250ml. The water utility companies also checked the total microbial count (max. 100 CFU/ml).

She went on to explain that drinking water thus had a low microbial count and did not contain pathogens of relevant concentrations. However, the water covered a long distance before being used for endoscope reprocessing; this meant that the microbiological quality of the water may have been negatively impacted again by dead spaces, biofilm, etc.

Biofilms were bacterial communities found on almost all moist surfaces; they were composed of the microorganisms themselves and of extracellular polymeric substances (EPS) and could also contain pathogenic microorganisms.

Ms Schmidt pointed out that microorganisms could also quickly grow on inadequately dried endoscopes; exponential growth then resulted in appreciable contamination.

If endoscopes are to be stored, they should be dry once reprocessed – otherwise there is a risk of bacterial growth.

Next, Ms Schmidt spoke about the microbiological requirements to be met by the water used in the final rinse. It should be of impeccable microbiological quality – but what did that mean? Here, the requirements addressed to the final rinse water in various directives were applied: the ESGENA (European Society of Gastroenterology and Endoscopy Nurses and Associates) Position Statement called for drinking water quality, but recommended using sterile water. Schmidt stated that the requirements set out in EN ISO 15883-4 were essentially clearer, specifying a microbial count of max. 10 CFU/100 ml rather than drinking water quality – samples should be taken at the water inlet pipe into the EWD chamber and not from, for example, the pump well. Only in that way was it possible to draw conclusions regarding the quality of the water used for the final rinse. If the water sample was taken before the EWD, the water in the EWD could still be contaminated e.g. by any biofilm present. That meant that the endoscopes, too, would become contaminated in the final rinse. The KRINKO (Commission for Hygiene and Infection Prevention at the Robert Koch Institute) called for drinking water quality, but explained that tap water or unsterile distilled water often did not suffice because drinking water quality was frequently not available anymore at the reprocessing site; water disinfection, sterile filtration or UV irradiation in the EWD were recommended. And finally there was the guideline compiled by the DEGEA, DGKH (German Society of Hospital hygiene), DGSV (German Society of Sterile Supply) and AKI (Working Group Instrument Preparation): this was based on the standard EN ISO 15883-4 (max. 10 CFU/100 ml). In general, no pathogenic microorganisms should be present in 100 ml (pseudomonads, atypical mycobacteria, possibly legionellae). What was important was to apply the requirements to the water at the point of use: the incoming water pipe to the EWD or before the manual final rinse.

The water should be analysed during validation, first at short intervals, then in accordance with the water quality at the respective site (risk analysis).

Marcus Arnold, Hartmann Pure Water Technologies, spoke about water treatment systems, in particular for EWDs. He stated that there was no single standard regulating the water quality, but the topic was touched upon in several standards, e.g. in EN 15883-1 and -4 and in EN 285 (Water quality for sterilization processes).

Citing EN 15883-1, Arnold explained that the criteria were specified separately for the process and the final rinse step. For example, demineralized water had to be used in the final rinse step; the water conductivity should be below 15 μS/cm. The water hardness varied greatly locally. At least water of microbiological drinking water quality was needed.

There is a risk of pitting corrosion if untreated water is used.

What happens if untreated water was used? Deposits, calcium water stains may be found in the cleaning chamber as well as on the instruments. Arnold stressed that silicate deposits were difficult to remove in the cleaning chamber. Pitting corrosion was another risk.

Arnold presented various types of water softening systems. In softening systems the salt content and conductivity value even rose slightly after softening, hence this water was not suitable for the final rinse.

In mixed-bed ion exchanger systems all the salt constituents were removed and water released. Thanks to the low conductivity value this water could also be used for the final rinse.

In reverse osmosis water was pressed under pressure through a membrane, removing 99% of all particles (salts, bacteria, other contaminants). In electrodeionization (EDI), comprising electrodialysis and ion exchange, the conductivity value in the diluate was reduced to below 1 μS/cm in an electrochemical process.

Arnold explained the design of a complete water treatment system and its components. These systems were also available in relatively space-saving designs.

The procurement costs for reverse osmosis systems, with or without EDI, were high, while they were low for mixed-bed ion exchanger systems. The opposite was the case for the operating costs, hence an amortization schedule was entirely reasonable.

Patricia Müller, Aqua free, reported on the provision of water of impeccable microbiological quality when reprocessing endoscopes. The water quality used for the final rinse was particularly important – if this led to recontamination, the reprocessing results were jeopardized. Based on the KRINKO-BfArM Recommendation*, the water used for the final rinse

must be of drinking water quality and free of facultative pathogenic microorganisms. The Recommendation states that this could be achieved with sterile filtration.

Müller explained how sterile water filters worked. They were able to effectively filter out waterborne bacteria, such as pseudomonads, by passing them through a membrane with a pore size of 0.2 μm and reduce the microbial count by 7 log levels.

Protection against retrograde contamination is needed when using terminal sterile filters.

Where can such filters be used in endoscope reprocessing? For the final rinse in manual reprocessing, a terminal sterile filter can be used at the sampling point or fitted to a water spray device. It was important to note the service life of these filters. Furthermore, they should not be immersed in the cleaning solution or become contaminated through contact with splash water. The filter outlet should be disinfected daily.

For automated reprocessing the final rinse water was disinfected through heating or UV irradiation or also sterile filtration. In this case sterile filters should be installed between ion exchangers and EWD; the filter service life depended on the flow volume. In the case of EWDs it should be noted that there were possibly several water inlets, each of which had to be protected with a filter.

Following questions from the audience, a number of additional practical tips were given: Verona Schmidt explained that sampling should always be carried out at the water inlet into the EWD chamber rather than e.g. from the pump well. While testing water taken from the pump well would test the EWD water, it would additionally pick up any effects caused by the reprocessing cycle itself as well as the EWD. When taking this sample, as commonly done in practice, it was important when interpreting the results that all potential sources of contamination in the EWD and inadequate reprocessing were considered.

Ulrike Beilenhoff stressed that the optics cleaning bottle should also be filled with sterile water since otherwise rapid bacterial growth was possible – that was also true for pump systems left idle for a prolonged period.

* Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)