A Quality Control Program to Evaluate and Improve Procedures for Cleaning and Disinfection of Flexible Endoscopes

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Introduction

The water channel is used as check-point for cleaning and disinfection of flexible endoscopes (FE) in a Danish quality control program.

After careful manual cleaning of the gastroscopes without proliferation of bacteria, we earlier detected the mean of CFU from water channel samples at 5 CFU per ml, range 0–20 CFU (a clean endoscope).

FE with more than 250 CFU per ml are called risk endoscopes.

Materials and Methods

Extensive laboratory evaluations of the washer-disinfectors (WD) and the used products are available. They indicate an effective reduction of microorganisms.

Ten endoscopy departments in seven different hospitals took samples from FE immediately before performing gastro-intestinal endoscopies.

Cold-chemical WD (2% glutaraldehyde (GA) at 25 C°) and Thermo-chemical WD (0,24% GA at 59 C°) were used.

Process benchmarking was carried out on best and worst cases, and the risk factors were determined.

Risk factors were divided into generel risks and WD-related risks.

After the elimination of risk factors a continuous quality control was established.

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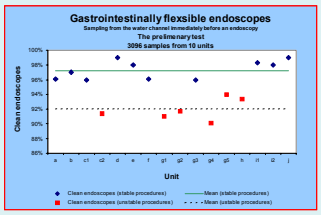
Figure 1. The preliminary test with sam-pling from the water channel of gastro-intestinal endoscopes immediately before an endoscopy. In a unit 100 – 430 samples were carried out during a test period. C1, c2: Test period 1 and 2 in a unit.



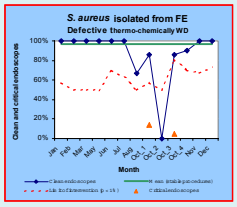


Figure 2. Failure of the decontamination of flexible endoscopes October month in an Olympus EDT WD. The process temperature was one degree lower than recommended, and intake of detergent failed. *S. aureus* were isolated from the water channels.

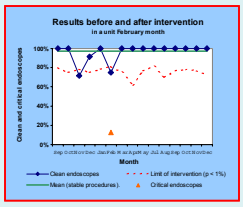


Figure 3. Sampling before and after check and change of the procedure for manual cleaning and disinfection of the endoscopes in a unit February 2001.
WD: Olympus ETD 2. The figure shows change from an unstable to a stable procedure.

Results

A total of 3096 samples were obtained immediately before endoscopy. The numbers of clean endoscopes were distributed within two means (*Figure 1*).

- Endoscopy units with **stable procedures** held a mean of 97 % for clean endoscopes (Range 95 – 99 %) with no risk endoscopes.
- Endoscopy units with **unstable procedures** held a mean of 92% for clean endoscopes (range 90 –94%) and with risk endoscopes.

General risks

- An unsuitable connection between WD and the endoscope.
- Reuse of wash water in the manual cleaning.
- Recontamination from another endoscope in the WD.
- Proliferation of bacteria in FE.
- No alcohol flush through the channels of FE before storage.
- Missing corelation between laboratory evaluations and in-use test.

WD-related risks

Cold-chemical WD

- Use of ineffective detergents.
- Disinfection without a preceding wash procedure in the WD.

Thermo-chemical WD

- Process temperature < 58 °C (*Figure 2*)
- Use of detergents that do not increase the heat sensitivity of micro-organisms.
- Failure of intake of detergent. (*Figure 2*)
- Lack of maintenance.

Continuous Quality Control

- After elimination of the risk factors, 1272 samples showed stable procedures with 97-100% clean endoscopes (*Figure 3*) in all endoscopy units.

Conclusion

- The numbers of “clean endoscopes” are a useful parameter to evaluated and improve procedures for decontamination of FE in a endoscopy unit.
- Clinically in-use evaluation and control of procedures for cleaning and disinfection of FE are necessary.

Layout: Zofia Kruszona, AV-046, Hvidovre Hospital, Denmark