Endoscopy reprocessing: then and now

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Endoscopes

- **Flexible** fiber endoscopes: soft, synthetic materials, *long and narrow lumen.*

  Routine  > rapid turnaround between endoscopic examination with a comparably small instrument pool

- **Rigid** endoscopes and **MIC**-Instruments: long and narrow lumen, joints

  > sterile instruments needed

Quelle: [http://www.wolf-endoskope.de/starre-endoskope.html](http://www.wolf-endoskope.de/starre-endoskope.html)
Weaknesses of endoscopes

1.) multiple channels
2.) narrow lumens (1-4 mm)
3.) difficult to access

Biofilm-formation if
- Insufficient reprocessing
- Insufficient drying
- Inappropriate storage
Natural bioburden detected on endoscopes - gut microbiota („intestinal microbiome“)

Colonization sites: intestinal lumen, mucin layer, mucosal surface

→ Small intestine: $10^4$ to $10^8$ microorganisms per mL gut content
→ Large intestine: $10^{10}$ to $10^{12}$ microorganisms per mL gut content

anaerobe bacteria > aerobe bacteria

• High bioburden on endoscopes after intestinal endoscopy (up to $10^{10}$ CFU per instrument)*

* Chu NS et al. Gastrointest Endosc 2000
Risk assessment - endoscopes

• Semi-critical device with increased requirements for reprocessing

• Cleaning + Disinfection + Drying

• „high-level disinfection“ in AEWD
Infections due to endoscopy

- Transmission from patient to patient through endoscopes or endoscopic accessories
- **94% due to insufficient reprocessing***
- Contamination through unsterile rinse water
- Insufficient drying and/or storage

Infections due to endoscopy

MEDIZIN

Keime im Kanal

Von Hackenbroch, Veronika

Bei Darmspiegelungen können lebensgefährliche Erreger wie Hepatitis- oder AIDSviren übertragen werden. Seit neuestem gibt es Kontrollen. Doch reichen sie aus?

Erst eine S-förmige Biegung, dann links und weiter geradewegs; hinter gefurchten scharfen Linkskurve an der Milz gleich noch mal links, dr weiter bis zum Blinddarm - das ist der Weg, den Ärzte mit dem Endoskop zurücklegen, wenn sie im Darm auf Tumorsuche gehen.


Keine Frage, die Früherkennung kann Leben retten. Doch sie birgt auch Gefahren: Denn das Endoskop kann gefährliche Keime, etwa Hepatitis oder HIV-Viren, von einem Patienten auf den anderen übertragen.

Wie sauber also sind die Endoskope? In den nächsten Wochen will die kassenärztliche Vereinigung Bayerns (KVB) eine Studie vorlegen, bei der Geräte zur Magen-, Darm-, Blasen- und Bronchienleitung aus 600 Praxen auf Keimrückstände nach der Desinfektion untersucht werden. Das Fazit des betreuenden Mediziners Lutz Bader von der Klinikiren-Universitätsklinik: "Es besteht dringender Handlungsbedarf."

KVB-Chef Axel Munte befürchtet sogar, die Ergebnisse könnten Vorsicht vor Patienten verlangen. So warnt Heinz-Peter Werner, der in Schwierigkeiten der Prüflabor für Medizinprodukte betreibt, bereits: "Ich wurde mich nicht mehr nur von der Qualität der Geräte auf KVB-Kontrolle abhängig machen."
Blood-borne viruses: HCV

• Married couple: blood donation since 20 years
• Routine testing: both suddenly show hepatitis C positive tests
• Both of them underwent endoscopy a few month earlier (same physician)
• Genotyping: Virus originated from a patient that underwent endoscopy before them on the same day

>> Publication in the NEJM 1997: Bronowicki et al.
Carbapenemase producing enterobacteriaceae (Klebsiella pneumoniae)

2008 2010 2014
January – December 2013: 135 cases of CRE transmissions after ERCP in the United States

44 cases were from Illinois during an outbreak

Between 2012 and 2015: at least 250 more patients worldwide affected (Fr, NL, D, GB)

In the US no reporting of these incidents to the authorities (FDA) by the affected hospitals.

In 2013 reports of 2 independent laboratories in Europe > duodenoscopes remain contaminated, even after reprocessing affected (Fr, NL, D, GB)

Dutch report details European superbug outbreak linked to faulty scopes
Multi-drug resistant bacteria in endoscopy

- Alrabaa SF et al. Early identification and control of **carbapenemase-producing Klebsiella pneumoniae**, originating from contaminated endoscopic equipment. *Infect Control* 2013 Jun
- Epstein L et al. **New Delhi Metallo-β-Lactamase-Producing Carbapenem-Resistant Escherichia coli** Associated With Exposure to Duodenoscopes. *JAMA* 2014
- Verfaillie C et al. Withdrawal of a novel-design duodenoscope ends outbreak of a **VIM-2-producing P. aeruginosa**. *Endoscopy* 2015
Carbapenemase producing bacteria in endoscopy

• **KPC**- producing *Klebsiella pneumoniae*

• **OXA 48**-producing *Klebsiella pneumonia*

• **NDM1**- producing *Escherichia coli*

• **VIM2**-producing *Pseudomonas aeruginosa*
Transmission paths

• Aumeran C et al. MDR Klebsiella pneumonieae outbreak after endoscopic retrograde cholangiopancreatography. *Endoscopy* 2010 Nov

• Kola A et al. An outbreak of carbapenem-resistant OXA 48-producing Klebsiella pneumonia associated to duodenoscopy. *ARIC* 2015
  > insufficient endoscope reprocessing
  > End of the outbreak after additional training in reprocessing

  > Endoscope model?
  > > End of the outbreak after removal of concerned models
Background

Reports in the literature describe transmission of multiresistant enterobacteriacae in connection with endoscopic procedures\(^1,2,3\), especially duodenoscopy


Duodenoscope diagram

Image Source: FDA/CDRH Webinar
Albarran mechanism

older models

newer models

Differences

• The conventional elevator wire channel had an open end and required flushing. It was sealed off by an O-Ring in newer models > no more flushing required: the O-ring might not seal the forceps elevator axis sufficiently?

• The fixed distal cap of the TJF Q 180V model hampered cleaning and disinfection > the dismantling of the duodenoscope tip revealed multi-drug resistant enterobacteriaceae (Verfaillie C et al. Endoscopy 2015)

>> Periodic replacement of O-ring now recommended by manufacturer
Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*

**Background and study aims:** Infections are a recognized risk of endoscopic retrograde cholangiopancreatography (ERCP). This paper reports on a large outbreak of VIM-2-producing *Pseudomonas aeruginosa* that was linked to the use of a recently introduced duodenoscope with a specific modified design (Olympus TJF-Q180V).
FDA warning March 2015:

- Duodenoscope design not optimal
- Reprocessing very difficult
- Manufacturers were asked for statements
Endoscope models in routine use during 2004 until today

<table>
<thead>
<tr>
<th>Type of endoscope</th>
<th>Manufacturer</th>
<th>Model</th>
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<tbody>
<tr>
<td>Duodenoscope</td>
<td>Olympus</td>
<td>TJF-180 V</td>
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<tr>
<td>Duodenoscope</td>
<td>Olympus</td>
<td>TJF-160 VR</td>
</tr>
<tr>
<td>Duodenoscope</td>
<td>Olympus</td>
<td>JF-130</td>
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<tr>
<td>Choledoscope</td>
<td>Olympus</td>
<td>CHF-P 20</td>
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<tr>
<td>Baby endoscope</td>
<td>Olympus</td>
<td>CHF-BP 30</td>
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<tr>
<td>Endoscopic ultrasound (EUS)</td>
<td>Olympus</td>
<td>GF-UE 160</td>
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<tr>
<td>Endoscopic ultrasound (EUS)</td>
<td>Olympus</td>
<td>GF-UMQ 130</td>
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</tbody>
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Validated reprocessing

**Validation** of the whole process of endoscope reprocessing:

- Reprocessing done by trained staff
- purpose-designed reprocessing areas (clean/dirty)
- Validated AEWDs
- Annual revalidation of AEWD
- Qualiy control through monitoring - **periodic microbiologic surveillance cultures** according to Austrian authorities
Microbiologic surveillance cultures of duodenoscope reprocessing at the Vienna University Hospital 2004 – 2015 ICHE 2015
Major Article

Prospective microbiologic evaluation of the forceps elevator in closed-channel duodenoscopes after reprocessing

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Prospective study

• Study period: 09/2015 bis 02/2016

• Sampling of all duodenoscopes in routine use at the Division of Gastroenterology and Hepatology during the study period

• ESwab™ collection system (COPAN Diag. Inc.)

• Columbia blood agar with 5% sheep blood and MacConkey agar plates > 37°C for 48 hours
Results

No growth at the site of the Albarran lever (100% of samples)
Quality in endoscopy

Maintenance care bundle to prevent infection transmission

1.) Validated reprocessing – Overall process validation
   - Endoscope washer
   - Reprocessing facilities and processes
   - qualified, trained and skilled staff

2.) Duodenoscope-design: complicated, but possible?
   - Manufacturers needed to come up with new ideas

3.) Quality Control – ongoing monitoring
   Infection control and authorities – microbiological sampling
Manufacturer’s responsibility

• Balance between introduction of innovative new medical devices and patient safety

• Manufacturer is responsible for the reprocessability of his complex medical devices

• Vigilance & market surveillance „Post Market Surveillance“ of complex medical devices
Weak spot - reprocessing

“Since almost all outbreaks are related to breaches in reprocessing techniques, it is crucial that endoscope cleaning, disinfection, and drying are performed according to a strict protocol.”

Standards and guidelines

• **ESGE (Europ. Society of Gastrointestinal Endoscopy) and ESGENA (European Society of Gastroenterology Nurses and Associates)** - Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement – Update 2018

• **Standard EN 15883-4** - Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
Endoscopy procedure room

Bedside cleaning

Transport to reprocessing area

Reprocessing room

Leakage test, Manual cleaning (incl. brushing)

Cleaning & disinfection (AEWD)
Manual versus automated
Endoscope reprocesssing

„Then“
Between „then“ and „now“...
Endoscope reprocessing
„Now“
Automates reprocessing of flexible endoscopes in AEWD

Chemo-thermal process in an AEWD

Storage of endoscopes

- suspended
- dust-protected
- with opened valves
- near the workplace
- in closed closet for endoscope storage

In case of recontamination need for renewed reprocessing before use!
Monitoring in endoscopy

• Monitoring of endoscopes

• Monitoring of the performance of AEWD
Infection control - endoscopes

Ongoing periodic test schedules for endoscopes:

- Visual inspection after reprocessing
- Weekly protein tests (Residual protein levels)
- Annual microbiologic surveillance cultures: the aim is to sample each endoscope in use at least once a year (Austrian health authority requirements)
- In case of problems: control sampling until the problem is solved
Infection control – performance qualification tests of AEWD

- Installation tests (performance test before initial use)
- Exchange of critical/process-relevant parts of the AEWD
- Modification of chemistry or program configuration
- Doubts about performance efficiency
- After repair work
- Annual revalidation test
Postmarket surveillance

Vigilance & market surveillance

„Postmarket Surveillance“ *of complex medical devices

*October 2015: FDA requires „postmarket surveillance“ from the 3 main endoscope manufacturers
Lessons learned

"Swiss cheese model",
James Reason

Need for multibarrier-strategies
Infections due to insufficiently reprocessed endoscopes:

do we need to sterilize our endoscopes?
Discussion