Risk on bacterial contamination of duodenoscopes and linear echoendoscopes is not age or wear and tear dependent: outcomes of two Dutch prevalence studies

Arjan W. Rauwers1, Anne F. Voor in ‘t Holl2, Ron de Groof2, Jolanda G. Buijj3, Nicole H. Ester1, Marco J. Bruno1, Margreet C. Vos2
1Gastroenterology and Hepatology, 2Medical Microbiology and Infectious Diseases, 3Staff Office Medical Devices, Erasmus MC, Rotterdam, The Netherlands

d.a.ruuwers@erasmusmc.nl a.rauwers@erasmusmc.nl
m.vos@erasmusmc.nl

AIMS
• To assess the contamination prevalence of duodenoscopes and linear echoendoscopes (DLE)
• To assess risk factors for bacterial contamination of DLE

BACKGROUND
• Rising number of duodenoscope-associated outbreaks of MDRO worldwide. ≥41 outbreaks, ≥ 350 patient infections, ≥ 20 deaths, between 2012-2015.
• Duodenoscopes (USF and ERCP) and linear echoendoscopes (used for EUS) have a similar contamination-prone design.
• During the studies, microbial surveillance was not mandatory.
• 2015 Dutch prevalence PROCESS 1 study: 15% of duodenoscopes are contaminated with gut / oral flora
• Predicted probability decreased during the study. Possibly due to effect of alerts on reprocessing adherence
• PROCESS 2 nationwide prevalence study was conducted. Data of both studies were merged to assess the aims.

STUDY FLOWCHART

PROCESS 1: June 2015 – March 2016
66/74 (89%) responding centers
150 Duodenoscopes (701 samples)

PROCESS 2: October 2016 - May 2017
61/73 (84%) responding centers
64 Linear Echoendoscopes (371 samples)
159 Duodenoscopes (797 samples)

PROCESS 1 & 2 combined: 72/74 (97%) responding centers
373 DLE (1869 samples)
64 Linear echoendoscopes
309 Duodenoscopes: 81 sampled once in PROCESS 1
90 sampled once in PROCESS 2
69 sampled twice in both studies

METHODS
• Two cross-sectional prevalence studies:
  PROCESS 1: ≥2 duodenoscopes per center
  PROCESS 2: all DLE of each center
• Local sampling according a strict and uniform sampling protocol explained by video instructions
• Central culturing of all samples at the Erasmus MC
  Flushes filtrated over 0.22 µm filter, filtrate on R2A agar
  Incubation: 3 days on 35°C
  Swabs vortexed in E-swab medium, 0.75ml on blood agar

ESGE and Dutch guideline contamination definitions
• AMO2: Any microorganism with ≥20 colony forming units
• MGO: Microorganisms with gastrointestinal or oral origin
• Analysis 1: Age & usage (number of procedures)
• Analysis 2: PROCESS 2 only: Age & usage reset if biopsy channel was replaced.

REFERENCES

CONCLUSIONS
• Similar high contamination prevalence for D & LE of ~15%
• Similar contamination risk for older & heavy used DLE as for new DLE
• Similar high contamination prevalence during PROCESS 1 & 2 studies

IMPLICATIONS
• No need for standard depreciation of older DLE, if maintained correctly
• Microbiological surveillance & control methods for cleaning
• Redesign of complex flexible endoscopes is needed

ANALYSIS 1: Contamination is independent of age and usage

<table>
<thead>
<tr>
<th></th>
<th>N=227 Duodenoscopes</th>
<th>OR*</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AM20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (per each year)</td>
<td>1.04</td>
<td>0.79-1.38</td>
<td></td>
</tr>
<tr>
<td>Usage (per 100 proc.)</td>
<td>1.02</td>
<td>0.77-1.32</td>
<td></td>
</tr>
<tr>
<td>MGO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (per each year)</td>
<td>1.07</td>
<td>0.78-1.44</td>
<td></td>
</tr>
<tr>
<td>Usage (per 100 proc.)</td>
<td>0.98</td>
<td>0.69-1.30</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LE (N=50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AM20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (per each year)</td>
<td>1.83</td>
<td>0.82-3.56</td>
<td></td>
</tr>
<tr>
<td>Usage (per 100 proc.)</td>
<td>0.46</td>
<td>0.11-1.84</td>
<td></td>
</tr>
<tr>
<td>MGO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (per each year)</td>
<td>0.91</td>
<td>0.35-2.19</td>
<td></td>
</tr>
<tr>
<td>Usage (per 100 proc.)</td>
<td>0.86</td>
<td>0.32-1.96</td>
<td></td>
</tr>
</tbody>
</table>

* Adjusted for multiple samples of each DLE and for correlated outcomes within centers

ANALYSIS 2: Channel replacement does not ‘reset’ endoscope

<table>
<thead>
<tr>
<th></th>
<th>N=109 Duodenoscopes</th>
<th>OR*</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AM20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (per each year)</td>
<td>1.07</td>
<td>0.50-2.01</td>
<td></td>
</tr>
<tr>
<td>Usage (per 100 proc.)</td>
<td>0.91</td>
<td>0.43-1.65</td>
<td></td>
</tr>
<tr>
<td>MGO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (per each year)</td>
<td>1.13</td>
<td>0.57-2.09</td>
<td></td>
</tr>
<tr>
<td>Usage (per 100 proc.)</td>
<td>0.88</td>
<td>0.40-1.53</td>
<td></td>
</tr>
</tbody>
</table>

BASELINE: 55/373 (15%) DLE contaminated with MGO

<table>
<thead>
<tr>
<th></th>
<th>AM20</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

METHODS – Sampling sites

All DLE
• Swab forcesps elevator
• Flush suction channel
• Flush biopsy channel
• Brush biopsy/suction ch.

Type dependent
• Swab protection cap
• Flush forcesps elevator
• Flush air/water channel
• Brush air/water channel
• Brush balloon channel

* MGO: Microorganisms with gastrointestinal or oral origin

P-values
≥ 0.27
≥ 0.66

Lower odds on contamination
Higher odds on contamination