FLEXIBLE ENDOSCOPES REPROCESSING

Retrospective analysis of 7818 endoscope samples
INTRODUCTION

MATERIAL AND METHOD

• Sampling method
• Sampling solution
• Interpretation criteria

RESULTS

• Endoscope brand,
• Sampling circumstances,
• Endoscope type,
• Manual vs. automatic reprocessing procedure
• Nature of the microorganisms isolated
• Evolution of the results through the test period.

CONCLUSION
INTRODUCTION

- Since 30 years a lot of progress have been made regarding endoscope reprocessing,
- Automatic endoscope reprocessors compliant to ISO 15883-1 and 4 have become the best standard reprocessing procedure and are widely used,
- Unfortunately, only few studies have been published on the microbiological quality of endoscopes in real use conditions.
INTRODUCTION

Published data

Number of positive bacterial cultures obtained from biopsy channels of gastroscopes and colonoscopes after reprocessing in an AER:

<table>
<thead>
<tr>
<th>Category</th>
<th>BC No. (%)</th>
<th>AER No. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroscope, n = 300</td>
<td>32 (10.7)*</td>
<td>6 (2.0)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Colonoscope, n = 120</td>
<td>25 (20.8)*</td>
<td>1 (0.8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total, n = 420</td>
<td>57 (13.6)</td>
<td>7 (1.7)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

BC, biopsy channel; AER, automated endoscope reprocessor.

Samples were collected by flushing the biopsy channel with sterile distilled water,

INTRODUCTION
Aim of the study

The objective of this retrospective study was to analyse the results of 7818 endoscopes samples performed between January 2004 and December 2011 in 94 private or public hospitals in France:

- By our trained laboratory technicians,
- Using a validated sampling solution/method.
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MATERIAL AND METHOD

Study details

• 94 public or private hospitals
• From January 2004 to December 2011
• 7818 endoscope samples:
  • 3446 coloscopes
  • 2509 gastrosopes
  • 1017 bronchoscopes
  • 345 duodenoscopes
  • 256 echoendoscopes
  • 5 Enteroscopes
• All samples were performed by Biotech-Germande’s trained technicians.
MATERIAL AND METHOD

Endoscopes sampling method

The sampling method was based upon the method described in the French guidelines regarding microbiological monitoring of endoscope and traceability in endoscopy published in 2007\(^{(1)}\).

MATERIAL AND METHOD
Endoscope sampling method

- All endoscope channels were flushed with T+ Thio recovering solution (50 ml per channel) using the “flush-suction-flush” method.
- Collection of the sampling solution and analysis of the sample by membrane filtration.
- Incubation 5 days at 30°C on PCA agar (+ 7H10 for 21 days if mycobacteria need to be detected)
- Expression of the results as the total number of CFU/endoscope.

CFU= Colony Forming Unit
MATERIAL AND METHOD

Sampling solution

Different sampling solutions are described in the literature for endoscope sampling:

- **Sterile distilled water**, **Not recommended**
- **Saline solution**\(^{(1)}\) [NaCl (0.9%)],
- **FHM**\(^{(1,2)}\) [Peptone (0.01%), Tween 80 (0.1%), NaCl (0.043%), Phosphate (0.095%)],
- **DNP**\(^{(3)}\) [Peptone (0.01%), Tween 80 (0.3%), Lecithin (0.01%), Histidin chloride (0.01%) NaCl (0.043%), KH\(_2\)PO\(_4\) (0.036%), Na\(_2\)HPO\(_4\), 2H\(_2\)O (0.072%)],
- **T+Thio**\(^{(4)}\) [Tween 80 (0.3%), Lecithin (0.03%), L-Histidin (0.01%) Sodium thiosulfate (0.05%)].

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\(^{(2)}\) NF EN ISO 11737-1

\(^{(3)}\) DNP: Neutralizing Pharmacopoeia Diluent.

\(^{(4)}\) Sampling solution recommended by Biotech-Germande
MATERIAL AND METHOD
Validation of the sampling solution (1)

The recovery ratio of the sampling method was determined by repeated rounds of sample collection according to ISO 11737-1 annex C1.(2, 3)

![Graph showing recovery ratios for different sampling solutions]


(2) ISO = International Organization for Standardization.

MATERIAL AND METHOD

Validation of the sampling solution

“The Tween 80-Lecithin based solution is more efficient than NaCl in:

- Detecting biofilm contamination,
- Detecting contaminated endoscopes (8/25 vs. 1/25 for NaCl),
- Recovering bacterial flora from endoscopes (281 CFU vs. 19 CFU/100 ml for NaCl).

“There was no significant difference between NaCl 0.9% and sterile water”

MATERIAL AND METHOD
Standard reprocessing procedure

AUTOMATIC

Bedside pre-treatment
Manual cleaning
Cleaning (1)
Rinsing (1)
Cleaning (2)
Rinsing (2)
Disinfection
Rinsing +/- air blowing

MANUAL

Bedside pre-treatment
Cleaning 1 (10 min)
Rinsing (1)
Cleaning (2) 5 min
Rinsing (2)
Disinfection
Rinsing +/- air blowing
# MATERIAL AND METHOD

Interpretation criteria (1)

<table>
<thead>
<tr>
<th>DISINFECTION LEVEL</th>
<th>TARGET LEVEL</th>
<th>ALERT LEVEL</th>
<th>ACTION LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>High level disinfection + rinsing with sterile water</td>
<td>Total aerobic flora &lt;1 CFU</td>
<td></td>
<td>Total aerobic flora &gt;1 CFU or presence of indicator microorganisms (2)</td>
</tr>
<tr>
<td>Intermediate level of disinfection + rinsing with bacteriologically controlled water (3)</td>
<td>Total aerobic flora &lt;5 CFU and no indicator microorganisms</td>
<td>Total aerobic flora between 5 and 25 CFU and no indicator microorganisms</td>
<td>Total aerobic flora &gt;25 CFU or presence of indicator microorganisms</td>
</tr>
<tr>
<td>Intermediate level of disinfection + rinsing with potable water (4)</td>
<td>Total aerobic flora &lt;25 CFU and no indicator microorganisms</td>
<td>Total aerobic flora between 25 and 100 CFU and no indicator microorganisms</td>
<td>Total aerobic flora &gt;100 CFU or presence of indicator microorganisms</td>
</tr>
</tbody>
</table>


(2) Indicator microorganisms: *Staphylococcus aureus*, Enterobacteriaceae, *Pseudomonas aeruginosa* and other *Pseudomonas*, *Stenotrophomonas maltophilia*, *Acinetobacter sp*, *Candida sp*.

(3) < 10 CFU/100 ml at 22°C and no *Pseudomonas aeruginosa* for 100 ml

(4) <100 CFU/ml at 22°C and <10 CFU/ml at 37°C, no *Pseudomonas aeruginosa* for 100 ml and no *Coliforms* for 100 ml
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CONCLUSION
RESULTS

Samples distribution according to the endoscope brand

Endoscopes sampled are Olympus (56%), Fujinon (28%) and Pentax (13%) endoscopes.
## RESULTS
Samples distribution according to sampling circumstances

<table>
<thead>
<tr>
<th>SAMPLING CIRCUMSTANCES</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine sampling</td>
<td>5745</td>
<td>73</td>
</tr>
<tr>
<td>(After reprocessing, after storage,…)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After contamination</td>
<td>922</td>
<td>12</td>
</tr>
<tr>
<td>(Second or third sampling performed on endoscopes found to be contaminated during routine sampling,…)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New endoscopes</td>
<td>106</td>
<td>1</td>
</tr>
<tr>
<td>(Sampling performed on new endoscopes before the first use on patient,…)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After maintenance</td>
<td>826</td>
<td>11</td>
</tr>
<tr>
<td>Not specified</td>
<td>219</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>7818</td>
<td>100</td>
</tr>
</tbody>
</table>


RESULTS

Ratio of contaminated endoscopes (at or exceeding the action level) for each hospital (whatever sampling circumstances and for the full test period)

Mean: 21%
RESULTS

Hospitals distribution according to the ratio of samples at or exceeding the action level (whatever sampling circumstances for the full test period)
Endoscopes sampled are Olympus (56%), Fujinon (28%) and Pentax (13%) endoscopes.

Most of the samples are part of a quality monitoring process in which endoscopes are tested periodically (routine sampling 73%),

Between 2004 and 2011, the mean ratio of endoscopes at or exceeding the action level (whatever sampling circumstances) per hospitals is 21%,

Only 28% of the hospitals present a mean ratio of endoscopes at or exceeding the action level (whatever sampling circumstances) lower than 10%.
RESULTS

Results distribution according to the nature of the endoscope (whatever sampling circumstances for the full test period)
RESULTS
Automated vs manual (whatever sampling circumstances and for the full test period)

<table>
<thead>
<tr>
<th>Level</th>
<th>Total (n=7818)</th>
<th>Automatic (n=5351)</th>
<th>Manual (n=2362)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Level</td>
<td>77% (n=6002)</td>
<td>79% (n=4248)</td>
<td>71% (n=1668)</td>
</tr>
<tr>
<td>Action Level</td>
<td>6% (n=433)</td>
<td>6% (n=301)</td>
<td>5% (n=128)</td>
</tr>
<tr>
<td>Alert Level</td>
<td>18% (n=1383)</td>
<td>15% (n=802)</td>
<td>24% (n=566)</td>
</tr>
</tbody>
</table>
RESULTS
Automated vs manual (routine sampling for the full test period)

- **Total (n=5745)**: 79% (n=4518), 5% (n=298)
- **Automatic (n=4374)**: 78% (n=3418), 6% (n=244)
- **Manual (n=1329)**: 80% (n=1064), 4% (n=53)

Target Level
Alert Level
Action Level
## RESULTS

Results distribution according to sampling circumstances

<table>
<thead>
<tr>
<th>SAMPLING CIRCUMSTANCES</th>
<th>TARGET LEVEL</th>
<th>ALERT LEVEL</th>
<th>ACTION LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine sampling (after reprocessing, after storage,...)</td>
<td>79% (n=4518)</td>
<td>5% (n=298)</td>
<td>16% (n=929)</td>
</tr>
<tr>
<td>After contamination (Second or third sampling performed on endoscopes found to be contaminated during routine sampling,...)</td>
<td>58% (n=533)</td>
<td>7% (n=65)</td>
<td>35% (n=324)</td>
</tr>
<tr>
<td>New endoscope</td>
<td>89% (n=94)</td>
<td>7% (n=7)</td>
<td>5% (n=5)</td>
</tr>
<tr>
<td>After maintenance</td>
<td>81% (n=673)</td>
<td>6% (n=53)</td>
<td>12% (n=100)</td>
</tr>
<tr>
<td>Not specified</td>
<td>84% (n=184)</td>
<td>5% (n=10)</td>
<td>11% (n=24)</td>
</tr>
<tr>
<td>Total</td>
<td>77% (n=6002)</td>
<td>6% (n=433)</td>
<td>18% (n=1383)</td>
</tr>
</tbody>
</table>
RESULTS
Summary

- Colonoscopes present the highest ratio of endoscopes at or exceeding the action level (25% whatever sampling circumstances).

- Cystoscopes present the lowest ratio of endoscopes at or exceeding the action level (4% whatever sampling circumstances).

- Whatever sampling circumstances is considered the automatic reprocessing procedure gives the best results (15% of the samples at or exceeding the action level against 24% for manual reprocessing).

- For routine sampling, the automatic and the manual reprocessing procedure yield to the same results (16% of the samples at or exceed the action level).
# RESULTS

Nature of the microorganisms isolated

<table>
<thead>
<tr>
<th>MICROORGANIMS</th>
<th>n</th>
<th>% (1)</th>
<th>Contamination source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fungi</strong></td>
<td>352</td>
<td>11</td>
<td>Environment</td>
</tr>
<tr>
<td><strong>Bacillus sp.</strong></td>
<td>1101</td>
<td>35</td>
<td>Environment</td>
</tr>
<tr>
<td><strong>Coagulase-negative staphylococcus, Micrococcus sp.</strong></td>
<td>1083</td>
<td>35</td>
<td>Human</td>
</tr>
<tr>
<td><strong>Other Gram-positif cocci</strong> (Staphylococcus aureus, Strpetococcus sp,...)</td>
<td>30</td>
<td>1</td>
<td>Human</td>
</tr>
<tr>
<td><strong>Corynebacterium sp.</strong></td>
<td>47</td>
<td>2</td>
<td>Human</td>
</tr>
<tr>
<td><strong>Yeast</strong> (Candida sp., Cryptococcus sp., Rhodotorula sp,...)</td>
<td>90</td>
<td>3</td>
<td>Human</td>
</tr>
<tr>
<td><strong>Neisseria sp.</strong></td>
<td>82</td>
<td>3</td>
<td>Human</td>
</tr>
<tr>
<td><strong>Enterobacteriaceae</strong> (Enterobacter sp., Escherichia coli, Klebsiella sp., Proteus sp., Serratia sp.....)</td>
<td>416</td>
<td>13</td>
<td>Human</td>
</tr>
<tr>
<td><strong>Pseudomonas aeruginosa</strong></td>
<td>400</td>
<td>13</td>
<td>Water</td>
</tr>
<tr>
<td><strong>Pseudomonas sp.</strong></td>
<td>195</td>
<td>6</td>
<td>Water</td>
</tr>
<tr>
<td><strong>Other Gram-negative rod</strong> (Burkholderia sp., Stenotrophomonas sp., Sphinghomonas sp., Aeromonas sp., Brevundimonas sp,...)</td>
<td>567</td>
<td>18</td>
<td>Water</td>
</tr>
</tbody>
</table>

(1) The same sample may contain several microorganisms
RESULTS
Evolution of the ratio of endoscopes at or exceeding the action level (whatever sampling circumstances)
RESULTS

Evolution of the ratio of endoscopes at or exceeding the action level (only routine sampling)

% of samples at or exceeding the action level

- Automatic reprocessing procedures
- Manual reprocessing procedures
- Total (i.e. all reprocessing procedures)

Years: 2003-2012
RESULTS

Summary

46% of the microorganisms isolated from endoscope channels are environmental microorganisms (i.e. fungi, *Bacillus sp.*.) and 37% waterborne bacteria.

Among all bacteria found in endoscope channels, 13% are identified as Enterobacteriaceae and their presence reflects a flaw in the reprocessing procedure.

With a prevalence of 13%, *Pseudomonas aeruginosa* remains one of the major endoscope contaminant.

For endoscopes reprocessed in an AER, the ratio of endoscopes at or exceeding the action level decreases from 22% in 2004 to 12% (routine sampling) in 2011. On the opposite for endoscopes reprocessed manually it remains stable (from 17% in 2004 to 15% in 2011).
CONCLUSIONS

The results of this study demonstrate that:

- Although it decreases, the mean ratio of endoscopes at or exceeding the action level remains high (13%),
- Automatic endoscopes reprocessors lead to better results (84% of the samples are below the target level in 2011 against only 70% for manual reprocessing procedure),
- Even if washer-disinfectors helps to improve the overall quality of endoscopes, further efforts should be made (i.e. during validation to demonstrate the efficacy of the process against all endoscopes intended to be reprocessed).
THANKS YOU VERY MUCH