

# Contamination rate of reusable patient-ready duodenoscopes used for endoscopic retrograde cholangio-pancreatography (ERCP): a systematic review and meta-analysis

Larsen, Sara<sup>1</sup>; Russell, Rasmus V.<sup>1</sup>; Mærkedahl, Anders<sup>2</sup>; Travis, Helena S.<sup>3</sup>; Ockert, Lotte K.<sup>1</sup>; Ehlers, Lars H.<sup>3</sup>

<sup>1</sup>Ambu A/S, Ballerup, Denmark • <sup>2</sup>Nordic HTA, Copenhagen, Denmark • <sup>3</sup>Aalborg University, Aalborg, Denmark.

**AIM: TO ESTIMATE THE CONTAMINATION RATE OF REUSABLE PATIENT-READY DUODENOSCOPES USED FOR ERCP.**

## BACKGROUND

Multiple infection outbreaks have been linked to contaminated reusable patient-ready duodenoscopes used in patients undergoing endoscopic retrograde cholangio-pancreatography (ERCP). Due to a complex design the duodenoscopes are difficult to clean properly, especially the elevator mechanism and working channel. Since 2015, 1 out of 5 Medical Device Safety Communications published by the Food and Drug Administration (FDA) has been endoscope-related, primarily concerning duodenoscopes. Interim results from postmarket surveillance studies initiated by the FDA recently revealed a 9% contamination rate associated with reusable duodenoscopes. The results were higher than expected compared to an anticipated contamination rate of 0.4%.

## METHOD

We searched PubMed and Embase from January 2013 to June 3, 2019 to identify studies in which duodenoscopes have been sampled for microbiological culturing before use. Methods of analysis and inclusion criteria were based on the PRISMA guideline. Studies with less than 10 samples were excluded to avoid bias in the random effects model due to small sample sizes. The primary outcome was a pooled contamination rate. A random effects model was used to calculate the pooled estimates from each included study. Heterogeneity between the included studies was analyzed using the inconsistency index ( $I^2$ ) statistics. Publication bias was assessed using funnel plots and Egger's regression test.

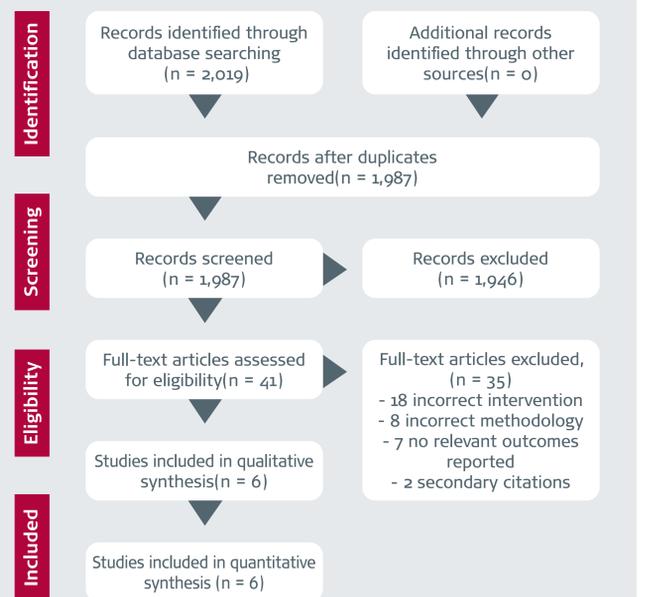
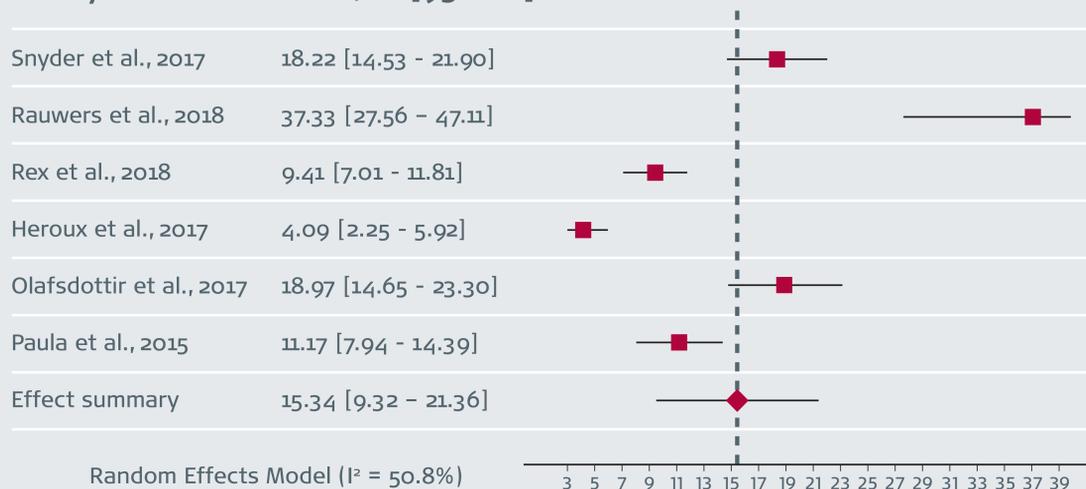
## RESULTS

The literature search yielded 2,019 studies. After applying our inclusion and exclusion criteria, the search was narrowed down to 41 studies, which were reviewed in full detail. Six studies fulfilled all inclusion criteria and included a total of 348 contaminated duodenoscopes from 2,560 samples. Four studies were conducted in the United States, one study was conducted in the Netherlands, and one study was conducted in Austria. The pooled contamination rate was 15.34% ± 0.0307 (95% CI: 0.0932 - 0.2136).  $I^2$  was 50.8% indicating moderate heterogeneity. The Egger test was significant ( $p < 0.01$ ) for publication bias.

## CONCLUSION

We found that 15.34% of reusable patient-ready duodenoscopes are contaminated. The result is consistent with contamination rates of other endoscopes (e.g., bronchoscopes, gastroscopes, and colonoscopes), but higher than the interim results posted by FDA. However, the significant publication bias should be considered. More high-evidence studies should be conducted to address issues with contaminated reusable duodenoscopes potentially leading to cross-infections and patient harm following ERCP.

## Study Rate, % [95% CI]



Item	Country	Hospital	Annual ERCPs	Contaminated duodenoscopes, n*	Cultures, n	Type of microorganism	Reprocessing method	CFU threshold
Snyder, 2017 [23]	USA	Beth Israel Deaconess Medical Center	1,500	94	516	N/A	HLD, dHLD, HLD/Eto	>0 CFU
Rauwers, 2018 [24]	Netherlands	67 Dutch ERCP centers	N/A	56	150	Yeasts, Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus spp. Bacillus*	HLD	> 20 CFU
Rex, 2018 [25]	USA	N/A	3,000	59	627	Enterococcus spp., Candida spp., Zygomycete, Micrococcus spp., Staphylococcus (CNS), Bacillus spp. Corynebacterium spp.	dHLD	N/A
Heroux, 2017 [26]	USA	Beth Israel Deaconess Medical Center	1,500	19	465	N/A	HLD, dHLD, Eto	>10 CFU
Olafsdottir, 2017 [27]	USA	Beth Israel Deaconess Medical Center	1,500	74	390	N/A	HLD	>0 CFU
Paula, 2015 [28]	Austria	Vienna University Hospital	700	46	412	Unspecified skin bacteria and aerobic spore-forming bacilli	HLD	>100 CFU

\*Only a proportion of the microorganisms found in this study are presented in this table