Gastrointestinal endoscope contamination rates – elevators are not only to blame: a systematic review and meta-analysis

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🌐 Supplementary material is available under https://doi.org/10.1055/a-1795-8883

ABSTRACT

Background and study aims Duodenoscopes that are contaminated due to inadequate reprocessing are well-documented. However, studies have demonstrated poor reprocessing of other kinds of endoscopes as well, including echoendoscopes, gastroscopes, and colonoscopes. We estimated the contamination rate beyond the elevator of gastrointestinal endoscopes based on available data.

Methods We searched PubMed and Embase from January 1, 2010 to October 10, 2020, for studies investigating contamination rates of reprocessed gastrointestinal endoscopes. A random-effects model was used to calculate the contamination rate of patient-ready gastrointestinal endoscopes. Subgroup analyses were conducted to investigate differences among endoscope types, countries, and colony-forming unit (CFU) thresholds.

Results Twenty studies fulfilled the inclusion criteria, including 1,059 positive cultures from 7,903 samples. The total contamination rate was 19.98 % ± 0.024 (95 % confidence interval [CI]: 15.29 %–24.68 %; I^2 = 98.6 %). The contamination rates of colonoscope and gastroscope channels were 31.95 % ± 0.084 and 28.22 % ± 0.076, respectively. Duodenoscope channels showed a contamination rate of 14.41 % ± 0.029. The contamination rates among studies conducted in North America and Europe were 6.01 % ± 0.011 and 18.16 % ± 0.053 %, respectively. The contamination rate among studies using a CFU threshold > 20 showed contamination of 30.36 % ± 0.094, whereas studies using a CFU threshold < 20 showed a contamination rate of 11 % ± 0.026.

Conclusions On average, 19.98 % of reprocessed gastrointestinal endoscopes may be contaminated when used in patients and varies between different geographies. These findings highlight that the elevator mechanism is not the only obstacle when reprocessing reusable endoscopes; therefore, guidelines should recommend more surveillance of the endoscope channels as well.

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Introduction

In recent years, reusable duodenoscopes have become an area of interest because of numerous reports of infection transmission by contaminated duodenoscopes following ERCP [1–4]. Duodenoscopes are prone to reprocessing errors because of their complex designs, especially around the elevator mechanism. Many studies found that microbes harbor in the instrument channel and other places in the endoscope as well. In addition, the channels of the endoscopes are prone to scratches when tools are inserted, which can create additional areas for the microbes to harbor [5,6]. Microbiological testing is standard at most endoscopy units; however, sampling methods and requirements vary across countries.

Adenosine triphosphate (ATP) testing is an established and inexpensive indicator for washing efficacy [7]. Nevertheless, this test should not replace routine microbiologic methods because of their low sensitivity and specificity [8]. ATP tests poorly correlate with microbiologic standards for assessing endoscope contamination [9]. Visual inspection using a borescope has been suggested as a quality assurance step in reprocessing to detect scratches and other irregularities within endoscope channels. Several studies identified internal defects of instrument channels to be more frequent than anticipated, increasing their microbiological contamination susceptibility [6,10, 11]. Inconsistencies in recommended quality measures to detect microbiological debris in endoscope channels may also pose safety risks.

In July 2019, the United States Food and Drug Administration (FDA) was made aware of a hospital in Oklahoma that had used contaminated gastroscopes on almost 1,000 patients. However, no patient-related infections were allegedly reported or detected [12]. Several studies investigating duodenoscope contamination rates sampled both the elevator and the working channel and detected microbiological organisms in both parts [9,13–15]. Duodenoscopes with disposable endcaps have been introduced as an attempt to overcome the challenges of duodenoscopes being vectors for patient cross-infections [16]. However, studies showed that even single-use endcap duodenoscopes remain contaminated after reprocessing [17,18]. Bronchoscopes have been implicated in multiple outbreaks and associated with high contamination rates, even without the elevator [18–21]. The fact that positive microbiological samples have been identified in various non-elevator endoscopes may indicate that contamination issues due to inadequate reprocessing are not limited to duodenoscopes. Previous studies investigated contamination rates in endoscope channels and areas beyond the elevator mechanism; nevertheless, no studies estimated the overall contamination rate associated with patient-ready gastrointestinal endoscopes unrelated to the elevator mechanism. We aimed to assess the contamination rate beyond the elevator of patient-ready gastrointestinal endoscopes based on the data from 2010 to 2020.
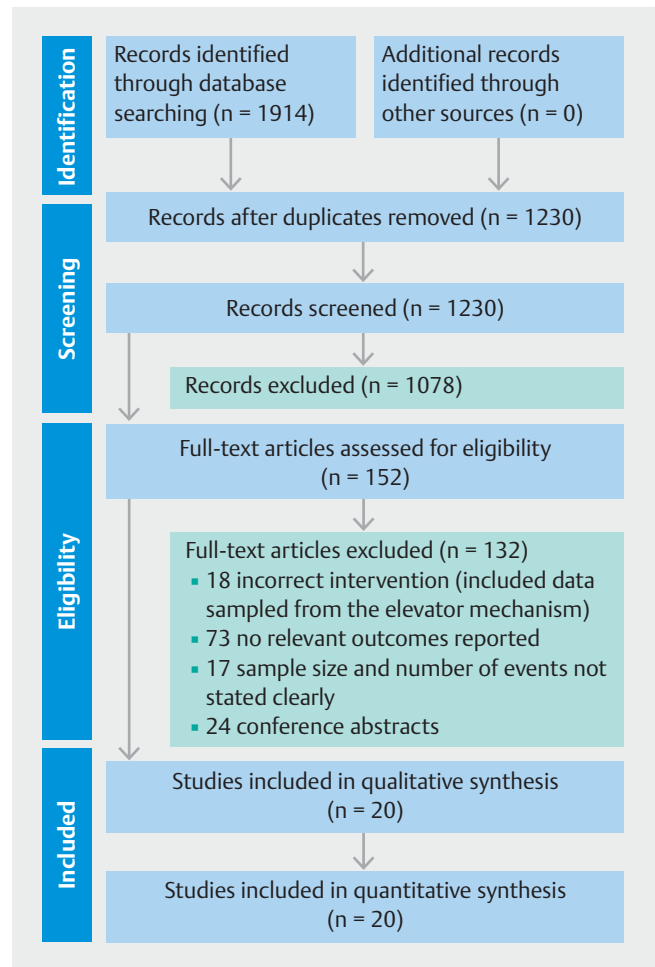
▶ **Fig. 1** Flowchart illustrating the study process and the selection of included publications. From *Moher D, Liberati A, Tetzlaff J* et al. The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses; The PRISMA Statement. PLoS Med 6; e1000097

Methods
Study selection

We conducted a systematic literature review to identify full-text studies published in English, investigating contamination rates associated with all types of gastrointestinal endoscopes. Studies concerning duodenoscopes and linear echoendoscopes, which are both endoscope types with an elevator, were included if data were available for any channels sampled. The comprehensive literature search is presented in ▶ **Fig. 1**. The analysis and inclusion criteria were based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Guideline [22].

Studies were identified through a systematic literature search from January 1, 2010 until October 10, 2020 in the electronic databases PubMed, Web of Science, and Embase. To identify relevant studies, we conducted the search using the following medical subject headings (MeSH) and keywords: (duodenoscope* [MeSH Terms]) OR (gastroscope* [MeSH

Terms])) OR (colonoscope* [MeSH Terms])) OR (endoscope [MeSH Terms])) OR (endoscopic ultrasonography [MeSH Terms])) OR (endoscopic ultrasonographies [MeSH Terms])) OR (cholangiopancreatographies, endoscopic retrograde [MeSH Terms])) OR (double balloon enteroscopies [MeSH Terms])) OR (double balloon enteroscopy [MeSH Terms])) OR (enteroscopies, double balloon [MeSH Terms])) OR (enteroscopy, double balloon [MeSH Terms])) OR (cholangiographies [MeSH Terms])) OR (cholangiography [MeSH Terms])) OR (Spyglass) AND ((contamination, equipment [MeSH Terms]) OR (cross-contamination)) OR (bacterial infections [MeSH Terms])) OR (disinfection [MeSH Terms])) OR (disinfectants [MeSH Terms])) OR (reprocessing)) OR (equipment reusability [MeSH Terms])). Truncation was deployed after some keywords to include different variations of the term and thereby broaden the search.

Inclusion and exclusion criteria

The search was conducted to identify relevant randomized controlled trials, surveillance studies, and prospective or retrospective cohort studies investigating contamination rates associated with reprocessed gastrointestinal endoscopes. The search was limited to studies published after 2010, as microbiological surveillance testing in endoscopy and was recommended in both European and US guidelines in this period followed by varies updates in reprocessing guidelines [23–27] because a time horizon of 10 years was considered reasonable due to various updates in endoscope reprocessing guidelines in last 10 years. For inclusion, the total number of microbiological samples (N) and the number of positive cultures (n) needed to be reported. It was imperative that all samples were acquired from a gastrointestinal endoscope excluding samples taken from the elevator mechanism and not from any patients or other medical equipment. Exclusion criteria included all types of studies performed on animals or in vitro models, as well as conference abstracts, editorials, letters, and gray literature that did not report any original findings. We assumed high heterogeneity between studies due to varying study design and definitions of positivity. To account for the heterogeneity, studies with sample size of less than 50 were excluded to avoid bias in the random-effects model [28].

Titles and abstracts of all identified studies were independently reviewed by two authors (SL and NBL). Studies that did not fulfill the inclusion criteria were excluded, and the full texts of the remaining publications were independently reviewed by three authors (SL, NBL, and SA). Any disagreements related to the inclusion or exclusion of studies were resolved by consensus.

Data extraction

All included studies were assessed for eligibility by three independent reviewers (SL, NBL, and SA). The authors were not blinded to any information within the studies. For each included study, we extracted the following baseline characteristics: First author, year, study design, country, hospital, endoscope type(s), sampled channels/areas, positive cultures, sample size, type of microorganism, reprocessing method, and CFU threshold.
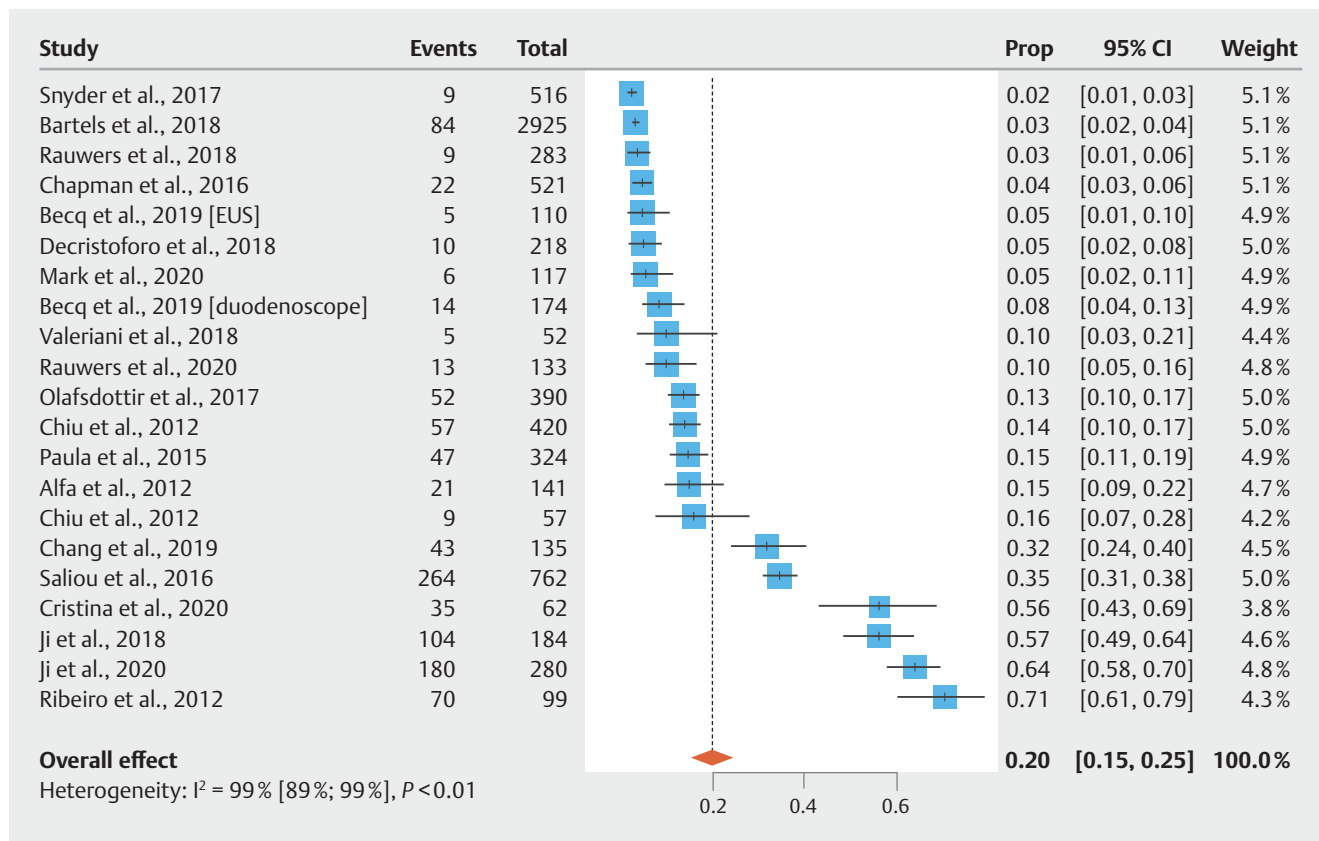
Outcomes

The primary outcome of the meta-analysis was the total weighted contamination rate beyond the elevator, based on the number of positive microbiological sample cultures (n) relative to the number of samples in total (N). Three subgroup analyses were carried out to assess potential significant differences between countries and applied CFU thresholds. The first subgroup analysis was conducted for studies only including samples from gastroscope channels and colonoscope channels both individually and combined. The second subgroup analysis was conducted for studies only, including samples taken from duodenoscope channels and areas beyond the elevator. The third subgroup analysis was conducted for studies that originated in North America, Europe, and the rest of the world (RoW). The fourth subgroup analysis was conducted among studies with a CFU threshold > 20 and those with a CFU threshold < 20.

No patient-specific data were assessed because the analysis only focused on gastrointestinal endoscopes. There were no missing data for any of the data points used to calculate the weighted contamination rates.

Data analysis and statistical methods

A meta-analysis was conducted based on data from studies where contamination rates of gastrointestinal endoscope channels, insertion cord, and all other surface areas beyond the elevator mechanism were assessed. The primary objective of the meta-analysis was to calculate the total contamination rate beyond the elevator of reprocessed patient-ready gastrointestinal endoscopes. Four subgroup analyses were carried out to do the following: 1) investigate the contamination rate among samples from gastroscope and colonoscope channels both separately and combined; 2) investigate the contamination rate among samples from duodenoscope channels; 3) assess the contamination rate in various countries (North America, European countries, and RoW); and 4) assess the contamination rate among studies using a CFU threshold > 20 and studies using a CFU threshold < 20.

We used the meta-package (metafor) in RStudio version 3.6.2 to conduct the statistical analyses. All data were pooled using a random-effects model based on proportions (prop). The random-effects model was applied because we anticipated heterogeneity, predominantly arising from variations in both sample size (N) and outcome (positive samples, n). We used the inconsistency index (I^2) test to estimate the level of heterogeneity between the included studies. I^2 indicates the proportion (%) of variation between the studies linked to heterogeneity rather than a coincidence [29, 30]. Heterogeneity values below 50% indicated low to moderate heterogeneity levels [30]. Publication bias was assessed using funnel plots. To avoid drawing any subjective conclusions based solely on the funnel plot, we evaluated the asymmetry of the funnel using Egger's regression. All study outcomes were presented in forest plots (▶ Fig. 2).

Study	Events	Total		Prop	95% CI	Weight
Snyder et al., 2017	9	516		0.02	[0.01, 0.03]	5.1%
Bartels et al., 2018	84	2925		0.03	[0.02, 0.04]	5.1%
Rauwers et al., 2018	9	283		0.03	[0.01, 0.06]	5.1%
Chapman et al., 2016	22	521		0.04	[0.03, 0.06]	5.1%
Becq et al., 2019 [EUS]	5	110		0.05	[0.01, 0.10]	4.9%
Decristoforo et al., 2018	10	218		0.05	[0.02, 0.08]	5.0%
Mark et al., 2020	6	117		0.05	[0.02, 0.11]	4.9%
Becq et al., 2019 [duodenoscope]	14	174		0.08	[0.04, 0.13]	4.9%
Valeriani et al., 2018	5	52		0.10	[0.03, 0.21]	4.4%
Rauwers et al., 2020	13	133		0.10	[0.05, 0.16]	4.8%
Olafsdottir et al., 2017	52	390		0.13	[0.10, 0.17]	5.0%
Chiu et al., 2012	57	420		0.14	[0.10, 0.17]	5.0%
Paula et al., 2015	47	324		0.15	[0.11, 0.19]	4.9%
Alfa et al., 2012	21	141		0.15	[0.09, 0.22]	4.7%
Chiu et al., 2012	9	57		0.16	[0.07, 0.28]	4.2%
Chang et al., 2019	43	135		0.32	[0.24, 0.40]	4.5%
Saliou et al., 2016	264	762		0.35	[0.31, 0.38]	5.0%
Cristina et al., 2020	35	62		0.56	[0.43, 0.69]	3.8%
Ji et al., 2018	104	184		0.57	[0.49, 0.64]	4.6%
Ji et al., 2020	180	280		0.64	[0.58, 0.70]	4.8%
Ribeiro et al., 2012	70	99		0.71	[0.61, 0.79]	4.3%
Overall effect				**0.20**	**[0.15, 0.25]**	**100.0%**
Heterogeneity: I^2 = 99% [89%; 99%], P < 0.01						

▶ **Fig. 2** Pooled estimates of contamination rates beyond the elevator. CI, confidence interval; EUS, endoscopic ultrasound.

Results

Characteristics of included studies

We identified a total of 1,914 peer-reviewed studies. After duplicates were removed, a total of 1,230 studies were screened based on title and abstract. After applying our inclusion and exclusion criteria, the number of studies was narrowed to 152 studies that were assessed in full text for eligibility. After the full-text assessment, 20 studies fulfilled all inclusion criteria and were included in the final meta-analysis. ▶ **Fig. 1** shows the PRISMA flowchart illustrating the study selection process.

All 20 studies included in the final analysis were published between January 1, 2010, and October 10, 2020. The included studies yielded a sample size of 7,903 cultures sampled from various gastrointestinal endoscope channels and areas beyond the elevator. There were a total of 1,059 positive samples. One study (Becq et al., 2019 [31]) provided complete data for both echoendoscopes and duodenoscopes and, therefore, was included in the analysis twice (i. e., 21 data points were included in the random-effects model).

Baseline characteristics of all included studies (n = 20) in the primary analysis are provided in ▶ **Table 1**. Of the included studies, six studies (30%) were conducted in the United States, seven (35%) were conducted in Europe, including studies from the Netherlands (n = 2), Italy (n = 2), France (n = 1), and Austria (n = 2). Five studies (25%) were conducted in Asia, including studies from Taiwan (n = 3) and China (n = 2). Finally, one study

(5%) was conducted in Canada, and one study (5%) was conducted in Brazil. ▶ **Table 2** shows the total sample size and number of positive samples taken from gastroscopes and colonoscopes separately and combined.

The majority of the studies (17 of 20, 85%) reported using high-level disinfection (HLD) as the reprocessing method used to clean the gastrointestinal endoscopes. Two studies (10%) tested a combination of both HLD, double HLD (dHLD), and ethylene oxide (EtO) sterilization, and one study compared dHLD and HLD (5%). Thirteen of 20 studies (65%) reported a CFU threshold, six studies (30%) reported a CFU threshold >20, and seven studies (35%) reported a CFU threshold <20.

Analysis of primary outcomes

Meta-analysis of the included studies demonstrated a pooled contamination rate beyond the elevator of 19.98% ± 0.024% (95% confidence interval [CI]: 15.29%–24.68%; I^2 = 98.6%; ▶ **Fig. 2**). Heterogeneity between the included data points (n = 21) was considered to be high. Funnel plot analysis and Egger's regression test indicated no significant publication bias (*P* = 0.0531).

Subgroup analyses

Meta-analysis of studies only including samples from colonoscopes (n = 7) showed a contamination rate of 31.95% ± 0.084 (95% CI: 15.55%–48.36%; I^2 = 95.2%;) (▶ **Fig. 3**). Egger's regression test indicated significant publication bias (*P* =

▶ **Table 1** Characteristics of included studies.

First author, year	Study design	Country	Hospital	Endoscopes type(s)	Sampled channels/ areas	Positive cultures, n	Sample size, N	Type of microorganism	Reprocessing method	CFU threshold
Saliou, 2016 [32]	Descriptive study	France	Brest Teaching Hospital	Gastroscopes, colonoscopes, duodenoscopes, echoendoscopes, transnasal gastroscopes, enteroscopes, choledoscope	Working channel, air/water channel, elevator-guidewire channel, waterjet channel	264	762	Coagulase-negative staphylococci, Bacillus spp., Micrococcus spp., Corynebacterium spp., Enterococcus spp., Actinomyces spp., Brevibacterium spp., Staphylococcus aureus, Streptococcus spp., Streptomyces spp., Pseudomonas aeruginosa, Stenotrophomonas spp., Klebsiella spp., Rhizobium radiobacter, Acinetobacter spp., Enterobacter spp., Sphingomonas spp., Escherichia coli, Methylobacterium spp., Brevundimonas spp., Citrobacter spp., Moraxella spp., Morganella morganii, Candida spp., Rhodotorula spp., Cladosporium spp., other fungi and yeasts	HLD	>25 CFU
Snyder, 2017 [33]	Parallel group randomized study	United States	Beth Israel Deaconess Medical Center	Duodenoscopes	Working channel	9	516	N/A	HLD, dHLD, HLD/EtO	>0 CFU
Rauwers, 2018 [34]	Prospective nationwide cross-sectional study	Netherlands	67 Dutch ERCP centers	Duodenoscopes	Biopsy channel, suction channel	9	283	Yeasts, Moraxella spp., Klebsiella pneumoniae, Streptococcus salivarius, Enterobacter cloacae, Moraxella osloensis, Escherichia coli, Streptococcus mitis, Klebsiella oxytoca, Neisseria flavescens, Enterococcus faecium, Rothia spp., Enterococcus faecalis, Streptococcus mutans, Pseudomonas aeruginosa, Streptococcus oralis, Staphylococcus aureus, Streptococcus spp. Bacillus spp., Stenotrophomonas maltophilia, Micrococcus luteus, Acinetobacter spp., Staphylococcus epidermidis, Agrobacterium radiobacter, Kocuria spp., Paracoccus yeeii, Staphylococcus hominis, Achromobacter xylosoxidans, Staphylococcus warneri, Alternaria spp., Kocuria rhizophila, Pseudomonas monteilii, Micrococcus spp. Pseudomonas putida, Staphylococcus auricularis, Sphingomonas paucimobilis, Staphylococcus spp. (CNS), Rhizobium spp. Or Sphingobium spp.	HLD	≥20 CFU
Olafsdottir, 2017 [9]	Parallel group randomized study	United States	Beth Israel Deaconess Medical Center	Duodenoscopes	Working channel	52	390	N/A	HLD	>0 CFU

▶Table 1 (Continuation)

First author, year	Study design	Country	Hospital	Endoscopes type(s)	Sampled channels/areas	Positive cultures, n	Sample size, N	Type of microorganism	Reprocessing method	CFU threshold
Paula, 2015 [35]	Descriptive study	Austria	Vienna University Hospital	Duodenoscopes	Air, water, suction, and biopsy channel	47	412	Unspecified skin bacteria and aerobe spore-forming bacilli	HLD	>100 CFU
Mark, 2020 [13]	Descriptive study	United States	Children's Hospital Colorado	Duodenoscopes	Working channel	6	117	Pseudomonas aeruginosa, fungal organisms, Staphylococcus aureus, Coagulase-negative staphylococcus, Streptococcus viridans	HLD	>10 CFU
Alfa, 2012 [36]	Descriptive study	Canada	St Boniface General Hospital	Colonoscopes, gastroscopes, duodenoscopes	All channels	21	141	gram-positive Bacilli, gram-positive Cocci	HLD	N/A
Cristina, 2020 [15]	Descriptive study	Italy	N/A	Duodenoscopes	Distal end, instrument channel	35	62	Pseudomonas aeruginosa, Klebsiella pneumoniae, Acinetobacter baumannii, Klebsiella oxytoca, Stenotrophomonas maltophilia, Escherichia coli, Citrobacter freundii, Enterobacter spp	HLD	>10 CFU
Ji, 2018 [37]	Descriptive study	China	Unspecified, all endoscopy units in Tianjin, China	Colonoscopes, gastroscopes	Biopsy channel	104	184	Pseudomonas aeruginosa, Escherichia coli, Acinetobacter lwoffii, Stenotrophomonas maltophilia, Malodorous mononeurosis, Enterococcus faecalis, Testicular pseudomonas, Burkholderia cepacia	HLD	>20 CFU
Chang, 2019 [38]	Descriptive study	Taiwan	Unspecified, 14 major tertiary care teaching hospitals	Duodenoscopes	Distal end outer surface, distal attachment cap, elevator wire channel, suction biopsy channel	43	135	N/A	HLD, dHLD, EtO	N/A
Chapman, 2016 [39]	Descriptive study	United States	N/A	Echoendoscopes	Suction channel	22	521	Klebsiella pneumoniae, Citrobacter freundii, Escherichia coli, Pseudomonas aeruginosa, Klebsiella oxytoca, Sphingomonas paucimobilis, Acinetobacter baumanii, Hafnia alvei, Enterobacter cloacae, Pseudomonas putida, Stenotrophomonas maltophilia	HLD	N/A

▶ Table 1 (Continuation)

First author, year	Study design	Country	Hospital	Endoscope type(s)	Sampled channels/areas	Positive cultures, n	Sample size, N	Type of microorganism	Reprocessing method	CFU threshold
Chiu, 2012 [40]	Prospective surveillance study	Taiwan	Chang Gung Memorial Hospital, Kaohsiung Medical Center	Colonoscopes, gastroscopes	Biopsy channel	57	420	GNGN bacteria, Klebsiella pneumoniae, Acinetobacter baumanni, Enterococcus spp., Comamonas testosterone, Chryseobacterium indologenes, Sphingomonas paucimobilis, Pseudomonas putida, Viridans Streptococcus, Stomatococcus spp., Prevotella bivia, Escherichia coli, Pseudomonas aeruginosa, Enterococcus faecium, Bacteroides fragilis, Bacteroides vulgatus, Bacteroides distasonis, Clostridium perfringens, Proteus mirabilis, Moraxella osloensis, Candida glabrata	HLD	10^3 CFU/mL
Valeriani, 2018 [41]	Descriptive study	Italy	Unspecified, 10 Italian hospitals	Colonoscopes	Unspecified, inner channels	5	52	B. vulgatus 16S amplicon, B. vulgatus OmpA, Enterococcus faecalis, Escherichia coli, B. fragilis, S. aureus	HLD	N/A
Becq, 2019 [31]	Prospective single-center study	United States	N/A	Echoendoscopes	Working channel	5	110	N/A	HLD	>0 CFU
				Duodenoscopes		14	174			
Chiu, 2012 [42]	Descriptive study	Taiwan	N/A	Enteroscopes (DBE)	Suction channel	9	57	Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, E. aerogenes, A. baumannii, Enterococcus sp., Gm (+) bacilli glucose-nonfermenting gp., Proteus vulgaris, Staphylococcus epidermidis, Bacteroides caccae, Prevotella melaninogenica	HLD	N/A
Decristoforo, 2018 [43]	Descriptive study	Austria	Unspecified, 29 endoscopy centers	Colonoscopes, gastroscopes, duodenoscopes	Biopsy/suction channel	10	218	Sphingomonas parasanguinis, Streptococcus viridans, Moraxella osloensis, Pseudomonas pseudoalcaligenes, Pseudomonas oleovorans, Pseudomonas luteola, Streptococcus mitis, Moraxella osloensis, Staphylococcus aureus	HLD	≤ 10 CFU
Ribeiro, 2012 [44]	Descriptive study	Brazil	Unspecified, gastrointestinal endoscopy units in Belo Horizonte	Colonoscopes, gastroscopes	Air/water channel	70	99	Pseudomonas aeruginosa, Escherichia coli, Acinetobacter baumannii, Klebsiella pneumoniae	HLD	N/A

▶ **Table 1** (Continuation)

First author, year	Study design	Country	Hospital	Endoscopes type(s)	Sampled channels/areas	Positive cultures, n	Sample size, N	Type of microorganism	Reprocessing method	CFU threshold
Rauwers, 2020 [45]	Prospective nationwide cross-sectional study	Netherlands	61 Dutch ERCP centers	Duodenoscopes, echoendoscopes[1]	Balloon channel, biopsy channel, suction channel	13	133	N/A	HLD	≥20 CFU
Ji, 2020 [46]	Descriptive study	China	Unspecified, 59 Endoscopy units in Tianjin	Colonoscopes, gastroscopes	Biopsy channel	180	280	N/A	HLD	>20 CFU
Bartles, 2018 [47]	Controlled randomized study	United States	Unspecified, four facilities with endoscopy labs	Echoendoscopes and duodenoscopes	Suction and working channel	84	2,925	*Enterococcus* spp, *Enterobacter cloacae*, *Aeromonas* spp, *E. coli* (ESBL+), *E. coli* (ESBL-), *Enterococcus faecium*[2]	dHLD, HLD	N/A

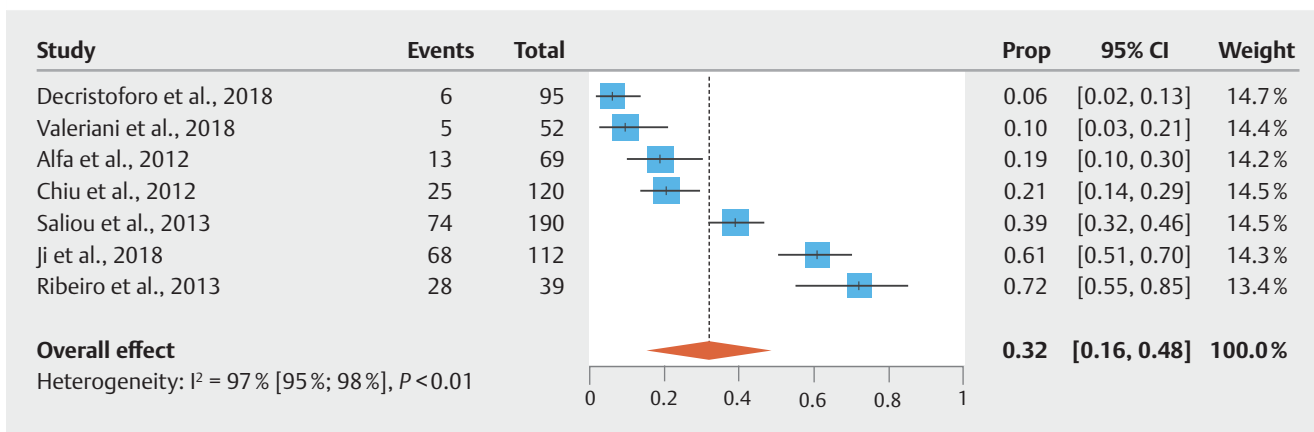The study was conducted in the main hospitals of different Italian regions (Campania, Emilia Romagna, Lazio, Liguria, Marche, Molise, Tuscany, Veneto, Sardinia, and Sicily) involving ten endoscopy units that reprocess approximately 50–100 endoscopes per business day.

[1] Samples from the original biopsy channels for both duodenoscopes and echoendoscopes.

[2] Only high-concern pathogens were specified in study.

▶ **Table 2** Characteristics of studies that included samples from colonoscopes and gastroscopes.

First author, year	Country	Endoscopes type(s)	Positive cultures, n	Sample size, N
Saliou, 2016 [32]	France	Gastroscopes	86	274
		Colonoscopes	74	190
Alfa, 2012 [36]	Canada	Gastroscopes	3	29
		Colonoscopes	13	69
Ji, 2018 [37]	China	Gastroscopes	36	72
		Colonoscopes	68	112
Chiu, 2012 [40]	Taiwan	Gastroscopes	32	300
		Colonoscopes	25	120
Valeriani, 2018 [41]	Italy	Colonoscopes	5	52
Decristoforo, 2018 [43]	Austria	Gastroscopes	3	107
		Colonoscopes	6	95
Ribeiro, 2012 [44]	Brazil	Gastroscopes	42	60
		Colonoscopes	28	39
Ji, 2020 [46]	China	Gastroscopes & colonoscopes	180	280

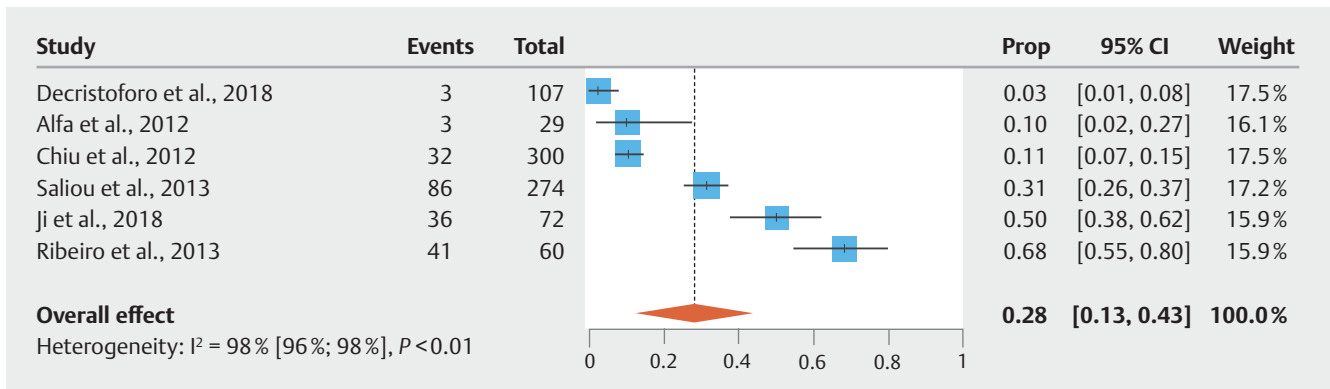| Study	Events	Total		Prop	95% CI	Weight
Decristoforo et al., 2018	6	95		0.06	[0.02, 0.13]	14.7%
Valeriani et al., 2018	5	52		0.10	[0.03, 0.21]	14.4%
Alfa et al., 2012	13	69		0.19	[0.10, 0.30]	14.2%
Chiu et al., 2012	25	120		0.21	[0.14, 0.29]	14.5%
Saliou et al., 2013	74	190		0.39	[0.32, 0.46]	14.5%
Ji et al., 2018	68	112		0.61	[0.51, 0.70]	14.3%
Ribeiro et al., 2013	28	39		0.72	[0.55, 0.85]	13.4%
Overall effect				**0.32**	**[0.16, 0.48]**	**100.0%**
Heterogeneity: I^2 = 97% [95%; 98%], P < 0.01						

▶ **Fig. 3** Pooled estimates of contamination rates for studies that included samples only from colonoscopes. CI, confidence interval; prop, proportion.
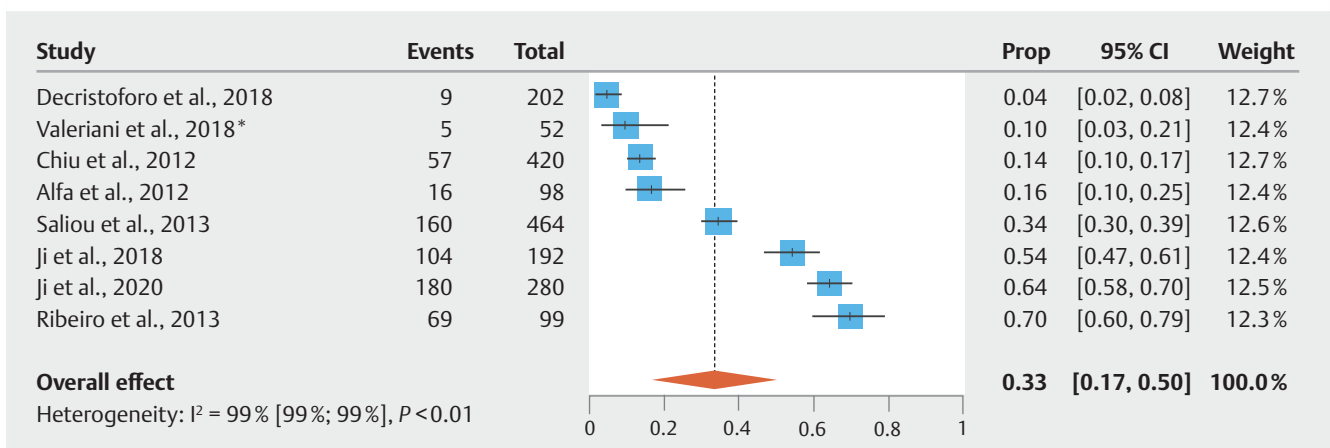
0.0469). Meta-analysis of studies with gastroscope-specific samples (n=6) showed a contamination rate of 28.22%± 0.076 (95% CI: 13.35%–43.10%; I^2=96.4%) (▶ **Fig. 4**). Egger's regression test indicated no significant publication bias (P= 0.1293). Meta-analysis of studies including samples from both gastroscopes and colonoscopes (n=8) showed a contamination rate of 33.20%±0.084 (95% CI: 16.80%–49.60%; I^2=98.9%) (▶ **Fig. 5**). Egger's regression test indicated significant publication bias (P=0.0434). Meta-analysis of studies with duodenoscope channel-specific samples (n=8) showed a contamination rate of 14.41%±0.029% (95% CI: 8.70%–20.13%; I^2=96.4%) (▶ **Fig. 6**). Egger's regression test indicated no significant publication bias (P=0.9919).

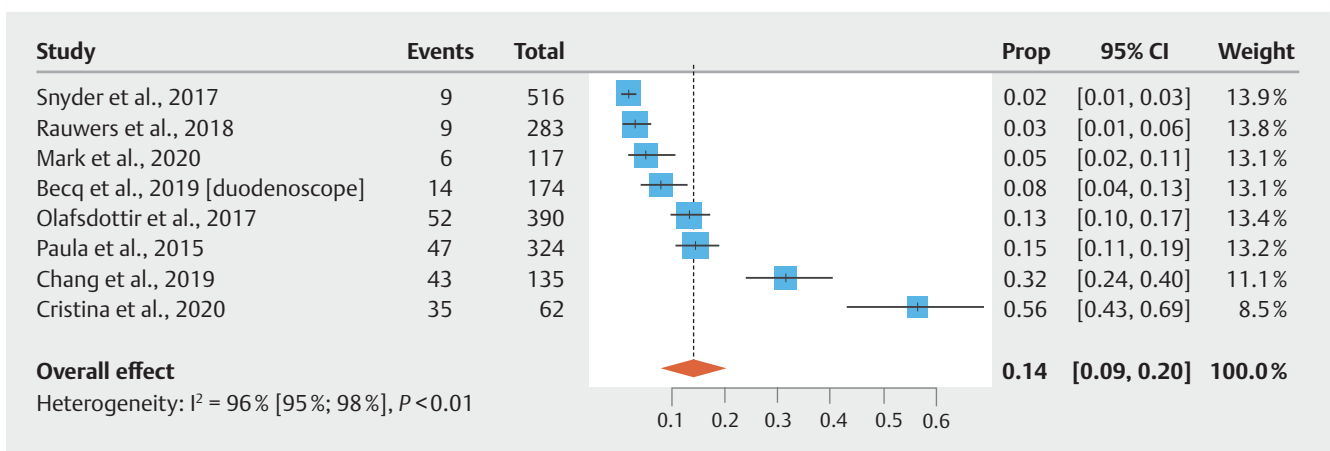Meta-analysis of studies conducted in North America (USA and Canada) (n=7) showed a pooled contamination rate of 6.01%±0.011% (95% CI: 3.88%–8.15%; I^2=89.3%; **Supplementary Fig. 1**). The pooled contamination rate among studies conducted in European countries (n=7) was 18.16%±0.053% (95% CI: 7.75%–28.57%; I^2=98.1%; **Supplementary Fig. 2**). Studies defined as RoW (n=6) demonstrated a contamination rate of 42.10%±0.011% (95% CI: 19.78%–64.41%; I^2=98.7%; **Supplementary Fig. 3**). Egger's regression test indicated significant publication bias (P=0.0025) for studies conducted in Europe. Egger's regression test did not indicate significant publication bias for studies conducted in North America and RoW (P=0.0655 and P=0.2231). Finally. meta-analysis of studies using a CFU threshold >20 (n=6) showed a pooled contamination rate beyond the elevator of 30.36%±0.094% (95% CI: 11.96%–48.75%; I^2=99.3%), whereas studies using a CFU threshold<20 (n=8) showed a contamination rate of 11%±

Study	Events	Total		Prop	95% CI	Weight
Decristoforo et al., 2018	3	107		0.03	[0.01, 0.08]	17.5%
Alfa et al., 2012	3	29		0.10	[0.02, 0.27]	16.1%
Chiu et al., 2012	32	300		0.11	[0.07, 0.15]	17.5%
Saliou et al., 2013	86	274		0.31	[0.26, 0.37]	17.2%
Ji et al., 2018	36	72		0.50	[0.38, 0.62]	15.9%
Ribeiro et al., 2013	41	60		0.68	[0.55, 0.80]	15.9%
Overall effect				**0.28**	**[0.13, 0.43]**	**100.0%**
Heterogeneity: I^2 = 98% [96%; 98%], $P < 0.01$						

▶ **Fig. 4** Pooled estimates of contamination rates for studies that included samples only from gastroscopes. CI, confidence interval; prop, proportion.

Study	Events	Total		Prop	95% CI	Weight
Decristoforo et al., 2018	9	202		0.04	[0.02, 0.08]	12.7%
Valeriani et al., 2018*	5	52		0.10	[0.03, 0.21]	12.4%
Chiu et al., 2012	57	420		0.14	[0.10, 0.17]	12.7%
Alfa et al., 2012	16	98		0.16	[0.10, 0.25]	12.4%
Saliou et al., 2013	160	464		0.34	[0.30, 0.39]	12.6%
Ji et al., 2018	104	192		0.54	[0.47, 0.61]	12.4%
Ji et al., 2020	180	280		0.64	[0.58, 0.70]	12.5%
Ribeiro et al., 2013	69	99		0.70	[0.60, 0.79]	12.3%
Overall effect				**0.33**	**[0.17, 0.50]**	**100.0%**
Heterogeneity: I^2 = 99% [99%; 99%], $P < 0.01$						

▶ **Fig. 5** Pooled estimates of contamination rates for studies that included samples from both gastroscopes and colonoscopes. CI, confidence interval; prop, proportion.

Study	Events	Total		Prop	95% CI	Weight
Snyder et al., 2017	9	516		0.02	[0.01, 0.03]	13.9%
Rauwers et al., 2018	9	283		0.03	[0.01, 0.06]	13.8%
Mark et al., 2020	6	117		0.05	[0.02, 0.11]	13.1%
Becq et al., 2019 [duodenoscope]	14	174		0.08	[0.04, 0.13]	13.1%
Olafsdottir et al., 2017	52	390		0.13	[0.10, 0.17]	13.4%
Paula et al., 2015	47	324		0.15	[0.11, 0.19]	13.2%
Chang et al., 2019	43	135		0.32	[0.24, 0.40]	11.1%
Cristina et al., 2020	35	62		0.56	[0.43, 0.69]	8.5%
Overall effect				**0.14**	**[0.09, 0.20]**	**100.0%**
Heterogeneity: I^2 = 96% [95%; 98%], $P < 0.01$						

▶ **Fig. 6** Pooled estimates of contamination rates beyond the elevator for studies that included only samples from duodenoscopes. CI, confidence interval; prop, proportion.

0.026% (95% CI: 5.94%–16.06%; I^2 = 95.3%) (**Supplementary Fig. 4** and **Supplementary Fig. 5**). Egger's regression test only indicated significant publication bias for studies using a CFU threshold > 20 ($P = 0.026$). Heterogeneity was considered high for all subgroup analyses.

Discussion

We performed a meta-analysis to estimate contamination rates unrelated to the elevator mechanism among patient-ready gastrointestinal endoscopes. Our findings suggest that the overall

reported contamination rate beyond the elevator of patient-ready gastrointestinal endoscopes is 19.98%. Subgroup analyses found different contamination rates depending on the type of endoscope. Studies only including samples from colonoscopes showed a contamination rate of 31.95%±0.084% compared to studies only including samples from gastroscopes where the contamination rate was 28.22%±0.076%. The endoscope type with the lowest contamination rate was duodenoscopes (14.41%±0.01%). Additionally, subgroup analyses found different contamination rates across countries, with the highest contamination rate among studies conducted in what was defined as "RoW," including studies from China, Taiwan, and Brazil (42.10%±0.011%). The contamination rates in studies originating from Europe and North America were 18.16%± 0.053% and 6.01%±0.011%, respectively. Finally, studies using a CFU threshold>20 revealed contamination rates of 30.36%± 0.094%. In contrast to these findings, studies using a CFU threshold <20 showed a significantly lower contamination rate of 11%±0.026%. However, we should also note that these conclusions could also be impacted by differences in study design, definitions of positivity, and apparent neglect to categorize any sample with a pathogen as a positive, high-risk finding.

Our subgroup analysis indicated the lowest contamination rate among studies carried out in North America. These findings might reflect the increasing awareness of the risk of contaminated endoscopes and development of FDA guidelines leading to stricter adherence to reprocessing guidelines. However, most of the communications related to endoscope reprocessing has concerned duodenoscopes with a special focus on the elevator, which does not explain why the contamination rate beyond the elevator channel was lower than that of other countries as well. We found the contamination rate beyond the elevator was 18.16% in Europe, significantly higher than the contamination rate in North America. Despite very limited communications regarding contaminated endoscopes and reprocessing in European countries, these findings may indicate that contamination issues are not limited to the United States. Our previous study on duodenoscope contamination rates found an overall contamination rate of 15.25%, whereas only four studies were conducted in European countries [32]. Rauwers et al. invited 74 Dutch endoscopy centers to sample duodenoscopes and linear echoendoscopes and found that ~15% of the endoscopes were contaminated [33]. Our findings suggest a higher contamination rate for colonoscopes and gastroscopes compared to duodenoscopes. This might be due to the fact that most of the samples included in these analyses originated from "RoW" where an overall higher contamination rate was found compared to North America and Europe. These studies may have skewed the data toward higher contamination rates for both colonoscopes and gastroscopes. We also would like to stress on the impact of various culture methods on microbial growth. It is important to note that most studies conducted prior to 2018 did not utilize a neutralizer to counteract the effect of residual reprocessing chemicals on microbial growth, and most of the earlier studies incubated samples for only 48 hours. However, the study by Saliou et al. notes the importance of longer incubation times to grow viable slow-growing mi-

crobes. Therefore, the positivity rate in their study was far higher than almost any of the other included studies (35%). Later in 2018, the US FDA/CDC released new guidance recommending that flush-brush-flush sampling methods be used to harvest samples; neutralizers be used to counteract reprocessing chemicals; and samples be incubated for at least 72 hours.

Very limited evidence exists on the attributable infection risk associated with contaminated gastroscopes and colonoscopes. Wang et al. estimated the post-endoscopic infection per 1,000 procedures within seven days for colonoscopy (screening and non-screening) and gastroscopy. The infection risk for screening colonoscopy was 1.1/1,000, and for non-screening colonoscopy, it was 1.6/1,000. The infection risk for gastroscopy was 3/ 1,000, which was almost twice as high as that of colonoscopy [34]. Lin et al. compared the incidence of infection within 30 days after colonoscopy and sigmoidoscopy. Following colonoscopy, the overall infection risk was 0.37%, which was significantly higher than that of the contro group (0.04%; $P<0.001$) [35]. Few cases of gastroscope-associated cross-infections have been published [36–39]. Naas et al. reported an outbreak where two patients developed carbapenem- and colistin-resistant *Klebsiella pneumoniae* due to a contaminated gastroscope [37]. The bacteria mutated to 17 different isolates over 4.5 years in one of the infected patients, and the patient died due to sepsis with intestinal bacteria, including the original carbapenem- and colistin-resistant *Klebsiella pneumoniae* [39].

However, the lack of evidence linking contaminated gastrointestinal endoscopes other than duodenoscopes to infections could indicate a smaller risk associated with non-endoscopic retrograde cholangiopancreatography procedures. Nevertheless, the discrepancy could be due to lesser degrees of awareness about infection risk from the endoscope parts beyond the elevator mechanism.

In recent years, contaminated duodenoscopes have gained much attention due to their complex design [2, 16]. However, duodenoscopes are not the only types of endoscope with complex designs; linear echoendoscopes also have similar designs. Sun et al. stated that there is a significant overlap between the indications for endoscopic ultrasound (EUS) and ERCP, and recommended that similar reprocessing FDA recommendations should be applied for all endoscopes with elevator mechanisms. [40] Despite similarities between duodenoscopes and echoendoscopes, few studies report contamination data or infection related to EUS. Chapman et al. found that 21 of 521 cultures (4.1%) obtained from echoendoscopes were positive following HLD. [41] Rauwers et al. investigated contamination rates of both duodenoscopes and echoendoscopes and found that 13 of 133 samples (9.8%) taken from the balloon, biopsy, and suction channels were positive for microbiological growth [33]. This suggests that the elevator may not be the only obstacle when reprocessing elevator-containing endoscopes. Additionally, Olympus recently issued an 'urgent field safety notice' concerning the use of EUS endoscopes. Olympus has revised instructions for use for various EUS endoscopes after an investigation indicated a potential risk of infection due to residue in the air/water channel. To further mitigate this risk, Olympus has updated the instructions for use for 23 affected EUS endo-

scope models by adding an inspection step before reprocessing [42].

Gastrointestinal endoscope channels are prone to scratches and their long, narrow channels make them difficult to properly investigate for microbiological debris [5, 41, 43]. Our analysis casts doubt on the suggestion that disposable endcaps are the answer to contamination issues; several studies reported high contamination rates in the channels and areas beyond the elevator. Ridtitid et al. compared bacterial contamination and organic residue using rapid ATP testing and cultures from duodenoscopes with detachable versus fixed distal caps after HLD. The authors found that, after HLD, the proportion of bacterial contamination and the organic residue was significantly lower in the group with detachable end caps than in the group of duodenoscopes with fixed end caps (37.0% vs. 75.9%; $P<0.001$; relative risk 0.49, 95% Cl 0.33–0.71). However, even with a significant reduction in the contamination levels, the duodenoscopes were still not completely free of bacterial residues. Our subgroup analysis demonstrated a 14.41% contamination rate among studies only including samples from duodenoscope channels.

Contaminated endoscopes remain a challenge, and until the potential harmful effects of this are fully investigated, these issues should be taken seriously. The US Centers for Disease Control and Prevention recommends surveillance culture for bacterial contamination from both the elevator and the working channel. Nevertheless, one should keep in mind that stricter recommendations related to meticulous surveillance sampling and microbiological culturing have both practical and financial impacts [17]. However, contamination rates have been shown to drop following the implementation of microbiological surveillance [15]. Microbiologic testing of endoscopes is costly and requires 72 hours for culture; it may be difficult for some endoscopy facilities to achieve this if their budgets are limited [17,44]. On the other hand, endoscope-related infections caused by contaminated endoscopes are also costly to treat, especially as most endoscope-related infections are caused by multidrug-resistant organisms [45–47]. Regardless, we should strive for best patient care while keeping the rate of infection transmission as low as possible.

We believe that the findings of this study are informative and relevant for decision-making in infection control and future clinical guidelines. Nevertheless, when concluding on these results important limitations must be considered. One of the main limitations is the high heterogeneity among included studies. The high heterogeneity could indicate that there is no "real" true effect behind the data included in the analysis because there is no consensus regarding the outcomes from the included studies [48]. On the other hand, despite being widely used, I^2 is not always an adequate measure for heterogeneity because it is exquisitely dependent on precision of the included studies and because I^2 tends to be 100% if the single studies have substantial sample sizes [29,48]. Another limitation is the inconsistency regarding how each study tested the level of contamination and the choice of CFU threshold. Some studies did not state which CFU threshold they applied to determine whether the endoscopes were considered contaminated. A

third limitation is the indication of publication bias that may be resulted from the lack of published negative results. Finally, limitations exist with respect to the channels and areas sampled beyond the elevator mechanism and samples pooled from different institutions. Data were derived from studies not directly investigating the contamination rate of a specific area in the endoscope and potentially with varying methodology between institutes, which would increase the risk of confounding factors affecting the findings.

Conclusions

Despite the abovementioned limitations, we believe that the findings of this study are highly important and may help overcome issues related to contaminated endoscopes, not only related to the elevator mechanism and duodenoscopes.

Our findings support the notion that contamination issues due to inadequate reprocessing are not only limited to duodenoscopes and the elevator mechanism. We found a 19.98% contamination rate unrelated to the elevator in several gastrointestinal endoscopes. Meta-analyses found variations in contamination rates among countries, with the highest pooled contamination rate among studies conducted in Asia and Brazil (42.10%) and in Europe (18.16%). The lowest pooled contamination rate was found among studies conducted in North America (6.01%).

Competing interests

References

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