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Submission Date: 2023-05-25
Accepted Date: 2023-10-17
Accepted Manuscript online: 2023-10-17

Endoscopy

Effect of novel endoscope cleaning brush on duodenoscope contamination

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DOI: 10.1055/a-2193-4481

Please cite this article as: van der Ploeg K, Haanappel C P, Voor in 't holt A F et al. Effect of novel endoscope cleaning brush on duodenoscope contamination. Endoscopy 2023. doi: 10.1055/a-2193-4481

Conflict of Interest: KvdP, CPH, AFV, WG, AJCB, NSE, BCGCS and JAS have no conflicts of interest to disclose. MCV has received research support from Boston Scientific, 3M and Pentax Medical. MJB has received research support from Boston Scientific, Cook Medical, Pentax Medical, Mylan, ChiRoStim and acted as a consultant/lecturer for Boston Scientific, Cook Medical, Pentax Medical and AMBU. The authors declare that the Endoss firm had no relation with the authors in this study and was not involved in this research financially or otherwise.

Abstract:

Background and aims

Current duodenoscope reprocessing protocols are insufficient to prevent contamination and require adaptations to prevent endoscopy-associated infections (EAI). This study aimed to investigate the effect of a new endoscope cleaning brush on the contamination rate of ready-to-use duodenoscopes.

Methods

This retrospective before-and-after intervention study collected duodenoscope surveillance culture results from March 2018 to June 2022. Contamination was defined as ≥1 colony-forming units of gastrointestinal or oral microorganisms (MGO). In December 2020, an endoscope cleaning brush with a sweeper design was introduced as the intervention in the manual cleaning of duodenoscopes. A logistic mixed effects model was used to study the effects of the intervention.

Results

Data were collected from 176 culture sets before the new brush's introduction and 81 culture sets after. Pre-introduction, culture sets positive with MGO comprised 45.5% (95% CI: 38.3%-52.8%, 80/176), decreasing to 17.3% (95% CI: 10.6%-26.9%, 14/81) after implementing the new brush. Compared to the former brush, duodenoscopes cleaned with the new brush had lower odds of contamination with MGO (aOR=0.25, 95% CI: 0.11-0.58, p=0.001).

Conclusions

Use of the new brush in manual cleaning reduced contamination with MGO and is expected to prevent EAIs. These findings should be confirmed in future prospective randomized studies.

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Thieme

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Abstract word count: 200

Main text word count: 2000

Tables: 1

Figures: 3

Keywords: Cholangiopancreatography, Endoscopic Retrograde; Cross Infection; Disinfection; Duodenoscopes; Endoscopes, Gastrointestinal; Equipment Contamination; Humans; Netherlands; Prevalence; Pseudomonas aeruginosa; Risk Assessment

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Conclusions

Use of the new brush in manual cleaning reduced contamination with MGO and is expected to prevent EAIs. These findings should be confirmed in future prospective randomized studies.

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Introduction

Infection is a potential (severe) complication of endoscopic retrograde cholangiopancreatography (ERCP), occurring in 1.4% to 7.7% of patients, with a mortality rate of 7.8% [1, 2]. Infectious complications post-ERCP can result from the translocation of endogenous intestinal flora during the procedure or the introduction of exogenous microorganisms via contaminated equipment. Contaminated duodenoscopes have caused multiple nosocomial outbreaks, mainly involving multidrug-resistant organisms, resulting in cases of illness and death [3]. Studies on duodenoscope contamination rates show significant variation. A recent meta-analysis reports a contamination rate of 21.5% (95% CI: 15.4%-27.6%) in non-outbreak-initiated studies [4].

A major factor responsible for duodenoscope contamination is biofilm formation. Risk factors for biofilm formation include reprocessing lapses, delays before reprocessing, endoscope damage and insufficient drying [5]. Biofilms can reduce the efficacy of high-level disinfection (HLD) and may cause false-negative culture results [5-7]. Once a biofilm has formed in the endoscope channels it is difficult to remove and may require channel replacement [8].

Manual cleaning of duodenoscopes is considered a critical step in achieving adequate reprocessing and involves flushing and brushing endoscope channels [9]. Currently, the duodenoscope channel cleaning brushes advised by the duodenoscope manufacturers consist of a wire with a single cleaning brush. However, an *in vitro* study demonstrated that the Endoss® Push and Pull brush (EPP; Endoss BV), a cleaning brush with a sweeper design, might be more efficient in cleaning duodenoscope channels [10]. In this study, we aimed to evaluate the effect of EPP introduction on the contamination rate of Pentax ED34-i10T2 duodenoscopes.

Methods

<u>Setting</u>

This retrospective before-and-after intervention study was performed in a large tertiary care center, the Erasmus MC University Medical Center Rotterdam, The Netherlands (Erasmus MC). Approximately 750 ERCP procedures are performed on adult patients annually. We included culture sets collected from eight Pentax ED34-i10T2 duodenoscopes (with disposable caps) from March 2018 until June 2022. Reprocessing was performed by dedicated reprocessing staff according to the manufacturer's instructions.

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Intervention

On December 15, 2020, the EPP (JPP50) was introduced for manual cleaning of the Pentax ED34-i10T2 duodenoscopes and replaced the Pentax Single-Use Brush (CS5522A).

Sampling

The duodenoscope culture sets consisted of five sample sites. First, the distal tip of the duodenoscope was swabbed using Copan Liquid Amies Elution Swab (eSwab, Copan). Then 20 mL of sterile saline (0.9%) was flushed through the suction channel, biopsy channel and air water channel separately and collected in sterile containers. Subsequently, a single-use endoscope cleaning brush (Pentax CS5522A) was pulled through the suction and biopsy channels. The distal tip of the brush was cut using disinfected pliers and placed in an eSwab container. Starting in April 2021, sterile water was used as the flushing fluid instead of saline. Routine surveillance cultures were taken approximately monthly. Data on the exact timing of sampling and errors in the sampling process were not available.

Microbiological methods and interpretation

The Eswab containers were vortexed and poured over a sheep blood agar plate (Becton Dickinson). The flushing fluid was filtered through a 0.22 µm filter (Milliflex Plus Test System) after which the filter was placed on Reasoners2A agar (Becton Dickinson). Plates were incubated for three days at 35°C. All morphologically distinct microorganisms were identified; colony-forming units (CFU) were counted. Identification was performed using the Matrix Assisted Laser Desorption/Ionization Time-Of-Flight analyzer (Bruker). Contamination was divided into two categories: ≥1 CFU of microorganisms of gut and oral origin (MGO) or ≥20 CFU/20mL of microorganisms of water and skin origin (AM20) [11-13]. Once a duodenoscope tested positive for MGO, it was quarantined and repeatedly sampled until tested negative. If the duodenoscope still tested positive after three attempts, it was sent to the manufacturer for inspection and possible channel replacement. From November 2020, MGO-positive duodenoscopes underwent routine borescope inspections for channel damage and, if necessary, were sent to the manufacturer for repair. Subgroup analysis distinguished primary contamination from persistent contamination. Primary contamination included cases with preceding negative culture sets or emergence of other microorganisms. Persistent contamination involved the same microorganisms at species level across consecutive culture sets. Subgroup analysis excluded culture sets from duodenoscopes with no patient exposure between sets.

Data collection

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A sample size was not calculated as this study involved retrospectively retrieved data and was not designed to detect a predefined difference. Duodenoscope usage data were extracted from the endoscopic documentation system Endobase (Olympus) and the electronic patient records. All available culture set data of Pentax ED34-i10T2 duodenoscopes were extracted from the electronic laboratory information system of the Department of Medical Microbiology and Infectious Diseases. The culture set result was determined by combining the five duodenoscope sample sites results. Additionally, the duodenoscopes' repair history and maintenance records were obtained from the manufacturer.

Statistical analyses

All analyses were performed using R version 4.1.3 [14]. Categorical variables are presented as absolute or relative frequencies (%), while continuous variables are expressed as the median with the first and third quartile (Q1, Q3) or as the mean and standard deviation (SD). Point estimates of contamination are accompanied by Wilson score confidence intervals (CI, 95% confidence level). To analyze the effect of EPP on contamination with MGO or AM20, logistic mixed-effects regression models were employed, with endoscope-specific random intercepts incorporated to account for potential correlation between observations of the same duodenoscope [15]. The following covariates, were included: duodenoscope usage since the preceding culture set, preceding culture set positive for MGO, preceding culture set positive for AM20, and duodenoscope usage since the last biopsy channel replacement. The covariates were selected based on existing literature and clinical expertise. To facilitate model estimation, duodenoscope usage since the preceding culture was divided by 10, and duodenoscope usage since the last biopsy channel replacement was divided by 30. A subgroup analysis was conducted to assess the impact of EPP specifically on primary contamination. Additionally, we used mixed model analyses to compare the odds of contamination per sample site. To adjust for the increased risk of type-I errors due to multiple testing, we applied the Bonferroni correction and set the significance threshold to $p < 0.004$.

Results

Culture characteristics

A total of 257 culture sets were collected from eight Pentax ED34-i10T2 duodenoscopes. Pre-intervention (March, 2018 - December 15, 2020), 176 (68.5%) culture sets were collected, and during the intervention (December 15, 2020 - June 2022), 81 (31.5%) culture sets were collected. Table 1 presents an overview of the culture characteristics. The cultured MGO are listed in Supplementary Appendix (SA) Tables S1-S2, and the AM20 in Tables S3-S4.

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Contamination with MGO

The introduction of the EPP statistically significantly reduced the odds of contamination with MGO (aOR = 0.25, 95% CI: 0.11-0.58, $p = 0.001$) (Figure 1). We did not find a statistically significant association between the odds of contamination with MGO and duodenoscope usage since the preceding culture set (aOR = 1.10, 95% CI:0.91-1.32, $p = 0.33$) or biopsy channel replacement (aOR = 1.01, 95% CI: 0.89, 1.16, $p = 0.84$). Although not statistically significant, a preceding culture set positive with MGO seemed to increase the odds of contamination with MGO in the subsequent culture set (Figure 1). This effect was similar in our subgroup analysis studying only primary contamination (SA Figure S2). During the period the Pentax single-use brush was utilized, the distal tip (aOR = 0.08, 95% CI: 0.03-0.20, $p < 0.001$) and air/water channel (aOR = 0.11, 95% CI: 0.05-0.24, $p < 0.001$) were associated with lower odds of contamination with MGO compared to the biopsy channel (Figure 2). In the EPP period, the brush pulled through the biopsy and suction channels had higher odds of being contaminated, although this effect was not statistically significant (aOR = 3.25, 95% CI: 0.81 – 13.01, $p = 0.10$).

Contamination with AM20

The use of the EPP increased the odds of a positive culture set with AM20 (aOR = 4.43, 95% CI: 1.57-12.48, $p = 0.005$), but did not reach statistical significance after correction for multiple testing (Figure 1). This effect was also slightly reduced in the subgroup analysis (aOR = 3.05, 95% CI: 1.03- 9.04, $p = 0.04$) (SA Figure S2). Duodenoscope usage was not statistically significantly associated with increased odds of contamination with AM20 (Figure 1). Although not statistically significant, a preceding culture set positive with AM20 was associated with higher odds of contamination in the subsequent culture set (aOR = 1.86, 95% CI: 0.94-3.69, $p = 0.08$). Irrespective of the cleaning brush, the distal tip, air/water channel, and culture of the brush were associated with lower odds of contamination with AM20 compared to the biopsy channel (Figure 3).

Discussion

After the introduction of the EPP for manual cleaning, we observed a 28.2% reduction in contamination with MGO in Pentax ED34-i10T2 duodenoscopes. This is a remarkable finding, which bares important clinical relevance. Literature reports on outbreaks highlight the risks associated with contaminated duodenoscopes. Balan et al. documented 24 outbreaks, involving 490 patients and resulting in over 30 deaths [3]. The minimum base risk of exogenous duodenoscope infections per ERCP procedure has been estimated to be 0.01% [16]. Contamination with MGO indicates

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inadequate reprocessing and can occur even in the absence of identified reprocessing breaches [17]. These findings highlight the importance of innovative approaches to improve reprocessing outcomes.

In our study, *P. aeruginosa* was the most commonly identified MGO, accounting for 14.4% (37/257 culture sets). *P. aeruginosa* is notorious for its ability to form biofilms in challenging environments, which demonstrate a certain level of tolerance to commonly used disinfectants in HLD.
Before the intervention, the duodenoscope contamination rate was 45.4%, significantly higher than the 22.5% reported in a recent meta-analysis [4]. We hypothesize that multiple duodenoscopes harbored a robust *P. aeruginosa* biofilm, contributing to the elevated contamination rate. The introduction of the EPP may have eliminated the biofilm, as only one culture set tested positive for *P. aeruginosa* after its implementation. The EPP's design, incorporating an additional sweeper, likely improves circumferential sealing of the duodenoscope channels. This could disrupt biofilm formation and allow the disinfecting agents used during HLD to reach and eliminate the embedded bacteria.

Although not statistically significant after correcting for multiple testing, the introduction of the EPP led to an increase of culture sets contaminated with AM20, up to 90%. Even though the clinical significance of AM20 contamination is likely low, the bio-matrix of environmental flora may protect MGO during HLD [5]. The increase in AM20 contamination is observed specifically in sample sites treated with the EPP, namely the biopsy and suction channels. We suggest that the sweeper of the EPP becomes contaminated with AM20 during the manual cleaning process and subsequently contaminates the duodenoscope channels.

Duodenoscope usage or biopsy channel replacement did not seem to influence the odds of contamination with MGO and AM20. This is in line with the findings of Rauwers et al. [13]. Borescope studies have shown that endoscope biopsy channels are often damaged, which increases with use and has been associated with higher bacterial attachment [18, 19]. However, the risk of channel damage may depend less on the frequency of use and more on ERCP-characteristics such as used instruments.

This study has limitations associated with its before-and-after design [20]. Firstly, the order in which the brushes were used was not randomized, and no control group was available. Therefore, we cannot establish a causal relationship between the reduction in MGO contamination and the implementation of the EPP. Additionally, as this study was retrospective, important information such as the drying time after reprocessing, the surveillance methods employed, and adherence to reprocessing and sampling protocols, was not recorded. This may have led to biased estimates of the

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impact of using the EPP. Furthermore, it is a single site study and the EPP was only used with one type of duodenoscope, limiting the generalizability of our findings to other settings, types or brands.

Conclusion

In this study, the introduction of the EPP was associated with significantly lower odds of contamination with MGO in Pentax ED34-i10T2 duodenoscopes. Therefore, this seems a promising intervention to reduce contamination rates of ready-to-use duodenoscopes and improve prevention of duodenoscope-associated infections. Future prospective multicenter studies in multiple duodenoscope brands should be performed to confirm these observations.

Acknowledgments:

The authors would like to thank T. Korteland – Vogel and S. van den Oever, the endoscopy staff responsible for collecting duodenoscope samples in the Erasmus MC.

Contributors:

KvdP: conceptualization; data acquisition; analysis and interpretation of data; drafting the manuscript; critical revision. CPH: analysis and interpretation of data; critical revision. AFV: analysis and interpretation of data; critical revision. WG: data acquisition; critical revision. AJCB: data acquisition; critical revision. NSE: analysis and interpretation of data; critical revision. BCGCMS: analysis and interpretation of data; critical revision. MCV: acquisition of data; analysis and interpretation of data; critical revision. MJB: conceptualization; analysis and interpretation of data; critical revision of the manuscript for important intellectual content; study supervision. JAS: conceptualization; analysis and interpretation of data; critical revision; study supervision

Funding

This study received no funding

Competing interest

KvdP, CPH, AFV, WG, AJCB, NSE, BCGCS and JAS have no conflicts of interest to disclose. MCV has received research support from Boston Scientific, 3M and Pentax Medical. MJB has received research support from Boston Scientific, Cook Medical, Pentax Medical, Mylan, ChiRoStim and acted as a consultant/lecturer for Boston Scientific, Cook Medical, Pentax Medical and AMBU. The authors declare that the Endoss firm had no relation with the authors in this study and was not involved in this research financially or otherwise.

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References

1. Andriulli A, Loperfido S, Napolitano G et al. Incidence Rates of Post-ERCP Complications: A Systematic Survey of Prospective Studies. Official journal of the American College of Gastroenterology | ACG 2007; 102: 1781-1788.
2. Hutfless S, Shiratori Y, Chu D et al. Risk factors for infections after endoscopic retrograde cholangiopancreatography (ERCP): a retrospective cohort analysis of US Medicare Fee-For-Service claims, 2015–2021. BMJ Open 2022; 12: e065077. doi:10.1136/bmjopen-2022-065077
3. Balan GG, Sfarti CV, Chiriac SA et al. Duodenoscope-associated infections: a review. Eur J Clin Microbiol Infect Dis 2019; 38: 2205-2213. doi:10.1007/s10096-019-03671-3
4. Larsen S, Russell RV, Ockert LK et al. Rate and impact of duodenoscope contamination: A systematic review and meta-analysis. EClinicalMedicine 2020; 25. doi:10.1016/j.eclinm.2020.100451
5. Alfa MJ, Singh H. Impact of wet storage and other factors on biofilm formation and contamination of patient-ready endoscopes: a narrative review. Gastrointest Endosc 2020; 91: 236-247. doi:S0016-5107(19)32219-9 [pii] 10.1016/j.gie.2019.08.043
6. Alfa M, Olson N, DeGagne P et al. 270 Prevention of Biofilm Accumulation in Duodenoscopes Varies With the Method of Reprocessing...Digestive Disease Week (DDW) 2017 American Society for Gastrointestinal Endoscopy (ASGE) Program and Abstracts, Chicago, Illinois, 6–9 May 2017. GASTROINTEST ENDOSC 2017; 85: AB67-AB68. doi:10.1016/j.gie.2017.03.081
7. Bridier A, Sanchez-Vizuete Mdel P, Le Coq D et al. Biofilms of a Bacillus subtilis hospital isolate protect Staphylococcus aureus from biocide action. PLoS One 2012; 7: e44506. doi:PONE-D-12-06272 [pii] 10.1371/journal.pone.0044506
8. da Costa Luciano C, Olson N, DeGagne P et al. A new buildup biofilm model that mimics accumulation of material in flexible endoscope channels. J Microbiol Methods 2016; 127: 224-229. doi:S0167-7012(16)30152-X [pii] 10.1016/j.mimet.2016.06.022
9. The U.S. Food and Drug Administration (FDA) tCfDCaP, (CDC) ASfMA. Guideline Duodenoscope Surveillance Sampling-and Culturing Protocols. 2018.
10. Colman S, Vanzieleghem T, Leroux-Roels I. In vitro comparison of 3 different brushes for manual cleaning of endoscopes. Infect Control Hosp Epidemiol 2022; 43: 1076-1078. doi:S0899823X21001707 [pii] 10.1017/ice.2021.170
11. Nederlandse Vereniging voor Medische Microbiologie. Richtlijn controle op microbiologische veiligheid van thermolabiele flexibele hoog-risico gastrointestinale endoscopen. 2018.
12. Rauwers AW, Voor In 'T Holt AF, Buijs JG et al. High prevalence rate of digestive tract bacteria in duodenoscopes: A nationwide study. Gut 2018; 67: 1637-1645. doi:10.1136/gutjnl-2017-315082

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13. Rauwers AW, Voor in 't holt AF, Buijs JG et al. Nationwide risk analysis of duodenoscope and linear echoendoscope contamination. Gastrointest Endosc 2020; 92: 681-691.e681. doi:10.1016/j.gie.2020.05.030
14. R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. . In: 2022:
15. Dimitris Rizopoulos. GLMMadaptive: Generalized Linear Mixed Models using Adaptive Gaussian Quadrature. R package version 0.8-5. In: 2022:
16. Kwakman JA, Erler NS, Vos MC et al. Risk evaluation of duodenoscope-associated infections in the Netherlands calls for a heightened awareness of device-related infections: A systematic review. Endoscopy 2021. doi:10.1055/a-1467-6294
17. Ofstead CL, Buro BL, Hopkins KM et al. Duodenoscope-associated infection prevention: A call for evidence-based decision making. Endosc Int Open 2020; 8: E1769-E1781. doi:10.1055/a-1264-7173
18. Visrodia K, Petersen BT. Borescope examination: Is there value in visual assessment of endoscope channels? Gastrointest Endosc 2018; 88: 620-623. doi:S0016-5107(18)32846-3 [pii]
10.1016/j.gie.2018.07.005
19. Santos LCS, Parvin F, Huizer-Pajkos A et al. Contribution of usage to endoscope working channel damage and bacterial contamination. J Hosp Infect 2020; 105: 176-182. doi:S0195-6701(20)30106-7 [pii]
10.1016/j.jhin.2020.03.007
20. Schweizer ML, Braun BI, Milstone AM. Research Methods in Healthcare Epidemiology and Antimicrobial Stewardship-Quasi-Experimental Designs. Infect Control Hosp Epidemiol 2016; 37: 1135-1140. doi:S0899823X16001173 [pii]
10.1017/ice.2016.117

Figure legends

Figure 1 Forrest plot with results of mixed model analysis of duodenoscope culture sets by contamination definition. AM20, microbial growth with ≥20 CFU/20 mL of water or skin type microorganisms; CFU, colony forming units; CI, Confidence interval; MGO, presence of microorganisms of gut or oral origin; OR, odds ratio

Figure 2 Forrest plot with results of mixed model analysis of duodenoscope sample site contamination with MGO by type of brush used during manual cleaning. MGO, microorganisms of gut or oral origin; OR, odds ratio

Figure 3 Forrest plot with results of mixed model analysis of duodenoscope sample site contamination with AM20 by type of brush used during manual cleaning. AM20, microbial growth with ≥20 CFU/20 mL of water or skin type microorganisms; CFU, colony forming units; OR, odds ratio

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Supplementary appendix

Table S1 Gastrointestinal microorganisms identified in culture sets using the different cleaning brushes

Gastrointestinal microorganisms independent of CFU	**Total no. of culture sets (n=257)**	**Pentax single-use brush (n= 176)**	**Endoss Push and Pull brush (n= 81)**
Pseudomonas aeruginosa	37 (14.4%)	36 (20.5%)	1 (1.2%)
Staphylococcus aureus	11 (4.3%)	8 (4.5%)	3 (3.7%)
Stenotrophomonas maltophilia	11 (4.3%)	11 (6.2%)	0 (0%)
Enterobacter cloacae complex	10 (3.9%)	9 (5.1%)	1 (1.2%)
Klebsiella pneumoniae	4 (1.6%)	3 (1.7%)	1 (1.2%)
Enterobacter aerogenes	2 (0.8%)	2 (1.1%)	0 (0%)
Enterococcus faecalis	2 (0.8%)	2 (1.1%)	0 (0%)
Acinetobacter pitii	1 (0.4%)	1 (0.6%)	0 (0%)
Citrobacter braakii	1 (0.4%)	1 (0.6%)	0 (0%)
Citrobacter freundii	1 (0.4%)	1 (0.6%)	0 (0%)
Enterobacter spp.	1 (0.4%)	1 (0.6%)	0 (0%)
Enterococcus faecium	1 (0.4%)	1 (0.6%)	0 (0%)
Escherichia coli	1 (0.4%)	1 (0.6%)	0 (0%)
Yeast and molds			
Candida parapsilosis	3 (1.2%)	3 (1.7%)	0 (0.0%)
Yeast NFI	1 (0.4%)	1 (0.6%)	0 (0.0%)
Aspergillus fumigatus	1 (0.4%)	1 (0.6%)	0 (0.0%)
Aspergillus niger complex	1 (0.4%)	0 (0.0%)	1 (1.2%)
Candida orthopsilosis	1 (0.4%)	0 (0.0%)	1 (1.2%)
Number of culture sets positive with gastrointestinal microorganisms	75 (29.2%)	68 (38.6%)	7 (8.6%)

Culture sets can contain multiple gastrointestinal microorganisms; therefore, the number of positive culture sets is not necessarily equal to the sum of individual microorganisms identified. CFU, Colony Forming Units; NFI, not further identified; no., Number; spp., species.

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Table S2 Oral microorganisms identified in culture sets using the different cleaning brushes

Oral microorganisms independent of CFU	Total no. of culture sets (n=257)	Pentax single-use brush (n= 176)	Endoss Push and Pull brush (n= 81)
Moraxella spp.	5 (1.9%)	5 (2.8%)	0 (0%)
Moraxella osloensis	4 (1.6%)	3 (1.7%)	1 (1.2%)
Neisseria spp.	4 (1.6%)	2 (0.8%)	2 (2.5%)
Gram negative cocci NFI	3 (1.2%)	1 (0.6%)	2 (2.5%)
Rothia dentocariosa	3 (1.2%)	2 (0.8%)	1 (1.2%)
Rothia mucilaginosa	3 (1.2%)	2 (0.8%)	1 (1.2%)
Actinomyces oris	2 (0.8%)	1 (0.6%)	1 (1.2%)
Neisseria subflava	2 (0.8%)	1 (0.6%)	1 (1.2%)
Gemella haemolysans	1 (0.4%)	0 (0%)	1 (1.2%)
Haemophilus parainfluenzae	1 (0.4%)	1 (0.6%)	0 (0%)
Neisseria flavescens	1 (0.4%)	1 (0.6%)	0 (0%)
Neisseria mucosa	1 (0.4%)	0 (0%)	1 (1.2%)
Rothia amarae	1 (0.4%)	1 (0.6%)	0 (0%)
Rothia spp.	1 (0.4%)	0 (0%)	1 (1.2%)
Streptococcus gordonii	1 (0.4%)	1 (0.6%)	0 (0%)
Streptococcus mitis	1 (0.4%)	1 (0.6%)	0 (0%)
Streptococcus parasanguinis	1 (0.4%)	1 (0.6%)	0 (0%)
Streptococcus spp.	1 (0.4%)	1 (0.6%)	0 (0%)
Streptococcus vestibularis	1 (0.4%)	1 (0.6%)	0 (0%)
Number of culture sets positive with oral microorganisms	26 (10.1%)	19 (10.8%)	7 (8.6%)

Culture sets can contain multiple oral microorganisms; therefore, the number of positive culture sets is not necessarily equal to the sum of individual microorganisms identified. A microorganism was considered NFI when MALDI-TOF identification was not possible. CFU, Colony Forming Units; NFI, Not further identified; no., Number; spp., species

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Table S3 Water type microorganisms identified in culture sets using the different cleaning brushes

Water microorganisms ≥20CFU/20mL	Total. of culture sets (n=257)	Pentax single use brush (n= 176)	Endoss Push and Pull brush (n= 81)
Achromobacter xylosoxidans	8 (3.1%)	6 (3.4%)	2 (2.5%)
Aeromicrobium spp.	2 (0.8%)	2 (1.1%)	0 (0.0%)
Agrobacterium radiobacter	12 (4.7%)	8 (4.5%)	4 (4.9%)
Agrobacterium spp.	3 (1.2%)	2 (1.1%)	1 (1.2%)
Arthrobacter spp.	1 (0.4%)	1 (0.6%)	0 (0.0%)
Brevundimonas diminuta	0 (0.0%)	0 (0.0%)	0 (0.0%)
Brevundimonas spp.	2 (0.8%)	1 (0.6%)	1 (1.2%)
Chryseobacterium spp.	26 (10.1%)	13 (7.4%)	13 (16.0%)
Cupriavidus spp.	7 (2.7%)	2 (1.1%)	5 (6.2%)
Delftia acidovorans	3 (1.2%)	3 (1.7%)	0 (0.0%)
Gram negative rods	48 (18.7%)	22 (12.5%)	26 (32.1%)
Methylobacterium spp.	70 (27.2%)	39 (22.2%)	31 (38.3%)
Microbacterium oxydans	6 (2.3%)	4 (2.3%)	2 (2.5%)
Microbacterium spp.	25 (9.7%)	8 (4.5%)	17 (21.0%)
Ochrobactrum anthropi	23 (8.9%)	22 (12.5%)	1 (1.2%)
Ochrobactrum spp.	1 (0.4%)	1 (0.6%)	0 (0.0%)
Paracoccus spp.	3 (1.2%)	1 (0.6%)	2 (2.5%)
Paracoccus yeei	36 (14.0%)	11 (6.2%)	25 (30.9%)
Pseudoarthrobacter spp.	2 (0.8%)	2 (1.1%)	0 (0.0%)
Pseudomonas alcaligenes	2 (0.8%)	2 (1.1%)	0 (0.0%)
Pseudomonas stutzeri	11 (4.3%)	10 (5.7%)	1 (1.2%)
Pseudoxanthomonas mexicana	37 (14.4%)	7 (4.0%)	30 (37.0%)
Pseudoxanthomonas spp.	4 (1.6%)	0 (0.0%)	4 (4.9%)
Sphingobacterium spiritivorum	4 (1.6%)	2 (1.1%)	2 (2.5%)
Sphingomonas koreensis	17 (6.6%)	9 (5.1%)	8 (9.9%)
Sphingomonas parapaucimobilis	1 (0.4%)	1 (0.6%)	0 (0.0%)
Sphingomonas paucimobilis	3 (1.2%)	3 (1.7%)	0 (0.0%)
Sphingomonas spp.	5 (1.9%)	3 (1.7%)	2 (2.5%)
Sphingopyxis terrae	2 (0.8%)	2 (1.1%)	0 (0.0%)

AM20, microbial growth with ≥20 CFU/20 mL of water or skin type microorganisms; CFU, colony forming units; spp., species

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Table S4 Skin type microorganisms identified in culture sets using the different cleaning brushes

Skin microorganisms ≥20CFU/20mL	Total. of culture sets (n=257)	Pentax single use brush (n= 176)	Endoss Push and Pull brush (n= 81)
Bacillus cereus	27 (10.5%)	18 (10.2%)	9 (11.1%)
Bacillus spp.	3 (1.2%)	1 (0.6%)	2 (2.5%)
Brevibacterium casei	22 (8.6%)	18 (10.2%)	4 (4.9%)
Brevibacterium spp.	2 (0.8%)	1 (0.6%)	1 (1.2%)
Cellulosimicrobium cellulans	9 (3.5%)	2 (1.1%)	7 (8.6%)
Gram positive cocci	7 (2.7%)	3 (1.7%)	4 (4.9%)
Gram positive rods	27 (10.5%)	14 (8.0%)	13 (16.0%)
Gram unstable rods	7 (2.7%)	3 (1.7%)	4 (4.9%)
Micrococcus luteus	6 (2.3%)	6 (3.4%)	0 (0.0%)
Staphylococcus epidermidis	7 (2.7%)	4 (2.3%)	3 (3.7%)
Staphylococcus hominis	2 (0.8%)	2 (1.1%)	0 (0.0%)
Staphylococcus lugdunensis	2 (0.8%)	1 (0.6%)	1 (1.2%)
Staphylococcus spp.	5 (1.9%)	5 (2.8%)	0 (0.0%)
Staphylococcus warneri	21 (8.2%)	9 (5.1%)	12 (14.8%)

AM20, microbial growth with ≥20 CFU/20 mL of water or skin type microorganisms; CFU, colony forming units; spp., species

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Table 1 Contamination of duodenoscopes before and after introduction of the Endoss Push and Pull brush

	Pentax single use brush (CS5522A) N = 176 culture sets				Endoss Push and Pull brush (JPP50) N = 81 culture sets			
	MGO		AM20		MGO		AM20	
	Not contam.	Contam.	Not contam.	Contam.	Not contam.	Contam.	Not contam.	Contam.
Pentax ED34-i10T2 culture sets (n= 257) (n (%, 95% CI))	96 (54.5%, 47.2%-61.7%)	80 (45.5%, 38.3%-52.8%)	59 (33.5%, 27.0%-40.8%)	117 (66.5%, 59.2%-73.0%)	67 (82.7%, 73.1%-89.4%)	14 (17.3%, 10.6%-26.9%)	6 (7.4%, 3.4%-15.2%)	75 (92.6%, 84.8%-96.6%)
Sample sites (n= 1285) (n (%, 95% CI))	710 (80.7%, 77.9%-83.2%)	170 (19.3%, 16.8%-22.1%)	628 (71.4%, 68.3%-74.3%)	252 (28.6%, 25.7%-31.7%)	390 (96.4%, 94.0%-97.7%)	15 (3.6%, 2.3%-6.0%)	218 (53.8%, 49.0%-58.6%)	187 (46.2%, 41.4%-51.0%)
Air/water channel (n= 257) (n (%, 95% CI))	169 (96.0%, 92.0%-98.1%)	7 (4.0%, 1.9%-8.0%)	161 (91.5%, 86.4%-94.8%)	15 (8.5%, 5.2%-13.6%)	79 (97.5%, 91.4%-99.3%)	2 (2.5%, 0.7%-8.6%)	79 (97.5%, 91.4%-99.3%)	2 (2.5%, 0.7%-8.6%)
Biopsy channel (n= 257) (n (%, 95% CI))	125 (71.0%, 63.9%-77.2%)	51 (29.0%, 22.8%-36.1%)	90 (51.2%, 43.8%-58.4%)	86 (48.8%, 41.2%-56.2%)	78 (96.3%, 89.7%-98.7%)	3 (3.7%, 1.3%-10.3%)	8 (9.9%, 5.1%-18.3%)	73 (90.1%, 81.7%-94.9%)
Brush (n= 257) (n (%, 95% CI))	122 (69.3%, 62.2%-75.7%)	54 (30.7%, 24.3%-37.8%)	113 (64.2%, 56.9%-70.9%)	63 (35.8%, 29.1%-43.1%)	72 (89.9%, 80.2%-94.0%)	9 (11.1%, 6.0%-19.8%)	38 (46.9%, 36.4%-57.7%)	43 (53.1%, 42.3%-63.6%)
Forceps elevator (n= 257) (n (%, 95% CI))	171 (97.1%, 93.5%-98.8%)	5 (2.9%, 1.2%-6.5%)	169 (96.5%, 92.0%-98.1%)	7 (3.5%, 1.9%-8.0%)	80 (98.8%, 93.3%-99.9%)	1 (1.2%, 0.1%-6.7%)	79 (97.5%, 91.4%-99.3%)	2 (2.5%, 0.7%-8.6%)
Suction channel (n= 257) (n (%, 95% CI))	123 (69.9%, 62.7%-76.2%)	53 (30.1%, 23.8%-37.3%)	95 (54.0%, 46.6%-61.2%)	81 (46.0%, 38.8%-53.4%)	79 (97.5%, 91.4%-99.3%)	2 (2.5%, 0.7%-8.6%)	14 (17.3%, 10.1%-26.9%)	67 (82.7%, 73.1%-89.4%)
Number of MGO identified per culture set (median [Q1, Q3])		1.00 [1.00, 2.00]	1.00 [1.00, 2.00]	1.00 [1.00, 2.00]		1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	1.00 [1.00, 1.75]
Number of AM20 identified per culture set (median [Q1, Q3])	2.00 [1.00, 4.00]	2.00 [1.00, 3.00]		2.00 [1.00, 3.00]	3.00 [2.00, 4.00]	4.00 [2.75, 5.00]		3.00 [2.00, 5.00]
Preceding culture set positive with MGO (n= 91)	36 (45.6%)	43 (54.4%)	31 (39.2%)	48 (60.8%)	12 (85.7%)	2 (14.3%)	2 (14.3%)	12 (85.7%)
Preceding culture set positive with AM20 (n= 192)	59 (50.9%)	57 (49.1%)	32 (27.6%)	84 (72.4%)	63 (82.9%)	13 (17.1%)	6 (7.9%)	70 (92.1%)
Days since last culture set (median [Q1, Q3])	22.00 [13.00, 42.00]	15.00 [9.00, 36.00]	21.00 [12.00, 39.50]	20.00 [12.00, 37.00]	29.00 [19.00, 71.00]	71.00 [25.75, 89.00]	69.00 [43.00, 85.25]	29.00 [19.00, 71.00]
Number of uses since preceding culture set (median [Q1, Q3])	3.00 [0.00, 10.00]	6.00 [0.00, 12.25]	1.00 [0.00, 8.50]	6.00 [1.00, 14.00]	7.00 [2.50, 14.00]	11.00 [3.75, 19.75]	16.50 [1.75, 29.00]	7.00 [3.00, 13.50]
Number of uses since biopsy channel replacement (median [Q1, Q3])	48.00 [19.50, 95.00]	65.00 [23.50, 91.50]	48.00 [22.00, 75.00]	56.00 [21.00, 112.00]	78.00 [12.50, 121.00]	31.50 [6.75, 151.25]	55.50 [7.25, 115.75]	76.00 [11.50, 134.00]
Days since last biopsy channel replacement (median [Q1, Q3])	185.50 [67.75, 350.00]	178.00 [85.50, 287.25]	173.00 [92.50, 274.00]	202.00 [64.00, 353.00]	279.00 [138.00, 462.00]	231.00 [77.50, 554.50]	224.50 [39.75, 350.00]	270.00 [131.00, 506.50]

AM20, microbial growth with ≥20 CFU/20 mL of water or skin type microorganism; CFU, colony forming units; Contam., contaminated; MGO, presence of ≥1 CFU of gastrointestinal or oral microorganism; Not contam., not contaminated.

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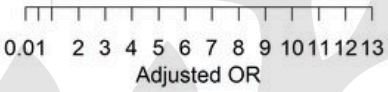
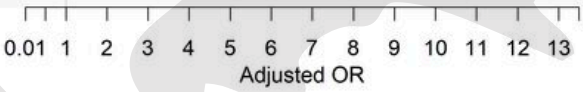
	adjusted OR (95% CI)	P-value
MGO		
Number of uses since preceding culture set	1.10 (0.91 to 1.32)	0.33
Number of uses since last biopsy channel replacement	1.01 (0.89 to 1.16)	0.84
Preceding culture set positive with MGO	1.81 (0.98 to 3.33)	0.06
Preceding culture set positive with AM20	1.50 (0.79 to 2.86)	0.22
Endoss Push and Pull brush used	0.25 (0.11 to 0.58)	0.001
AM20		
Number of uses since preceding culture set	1.17 (0.91 to 1.51)	0.23
Number of uses since last biopsy channel replacement	1.08 (0.91 to 1.29)	0.36
Preceding culture set positive with MGO	0.66 (0.35 to 1.24)	0.20
Preceding culture set positive with AM20	1.86 (0.94 to 3.69)	0.08
Endoss Push and Pull brush used	4.43 (1.57 to 12.48)	0.005



Sample sites	adjusted OR (95% CI)	P-value
Biopsy channel	Reference	
Pentax single-use brush		
Suction channel	1.05 (0.70 to 1.60)	0.81
Brush (sample site)	1.08 (0.72 to 1.64)	0.71
Distal tip	0.08 (0.03 to 0.20)	<0.001
Air/water channel	0.11 (0.05 to 0.24)	<0.001
Endoss push and pull brush		
Suction channel	0.66 (0.13 to 3.35)	0.62
Brush (sample site)	3.25 (0.81 to 13.01)	0.10
Distal tip	0.33 (0.03 to 3.27)	0.34
Air/water channel	0.66 (0.12 to 3.53)	0.63



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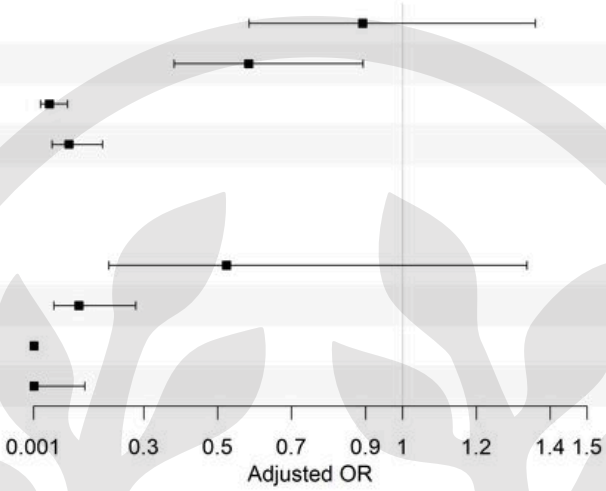
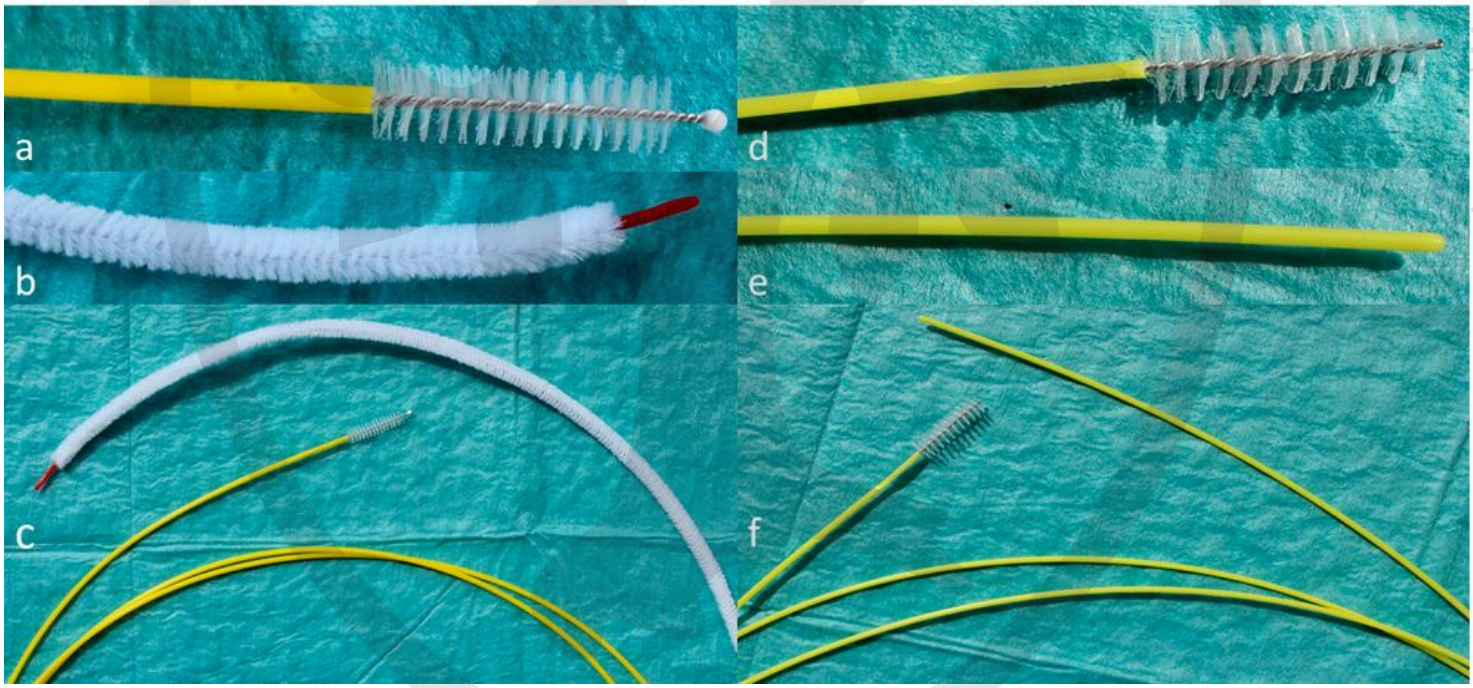
Sample sites	adjusted OR (95% CI)	P-value
Biopsy channel	Reference	
Pentax single-use brush		
Suction channel	0.89 (0.59 to 1.36)	0.60
Brush (sample site)	0.58 (0.38 to 0.89)	0.01
Distal tip	0.04 (0.02 to 0.09)	<0.001
Air/water channel	0.10 (0.05 to 0.19)	<0.001
Endoss push and pull brush		
Suction channel	0.52 (0.21 to 1.34)	0.18
Brush (sample site)	0.12 (0.06 to 0.28)	<0.001
Distal tip	0.003 (0.001 to 0.013)	<0.001
Air/water channel	0.003 (0.001 to 0.14)	<0.001





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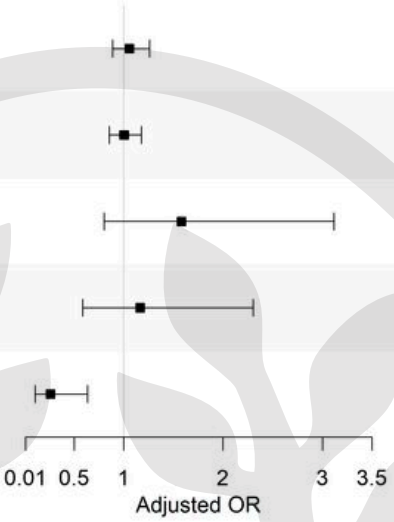
MGO	adjusted OR (95% CI)	P-value
Number of uses since preceding culture set	1.06 (0.89 to 1.26)	0.53
Number of uses since last biopsy channel replacement	1.00 (0.85 to 1.18)	0.97
Preceding culture set positive with MGO	1.58 (0.80 to 3.12)	0.19
Preceding culture set positive with AM20	1.17 (0.59 to 2.30)	0.66
Endoss Push and Pull brush used	0.26 (0.11 to 0.64)	0.003



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