10-2021

Continued Aspirin Use and Bleeding Risk After Endoscopic Submucosal Dissection of Gastric Neoplasms: A Meta-Analysis

Hermant Goyal MD

Sonali Sachdeva MBBS

Abhilash Perisetti MD

Mark M. Aloysius MD

Saurabh Chandan MD

See next page for additional authors

Authors

Hermant Goyal MD, Sonali Sachdeva MBBS, Abhilash Perisetti MD, Mark M. Aloysius MD, Saurabh Chandan MD, Benjamin Tharian MD, and Nirav Thosani MD

studies have documented microbes in the channels of reprocessed gastrointestinal (GI) endoscopes, including duodenoscopes and linear echoendoscopes. Our aim is to estimate the channel contamination rate of patient-ready reprocessed GI endoscopes based on the currently available data.

Methods: We searched PubMed, Web of Science, and Embase from January 1, 2010, until October 10, 2020, for studies investigating contamination rates of channels of patient-ready flexible GI endoscopes by following the PRISMA guidelines. A random-effects model based on the proportion distribution was used to calculate pooled total contamination rate. A subgroup analysis was carried out for studies originating from North America (USA and Canada). We used the meta-package (*metafor*) in RStudio version 3.6.2 to conduct the statistical analyses. 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 tests.

Results: We identified 1,230 peer-reviewed studies after duplicates were removed. Finally, 20 studies fulfilled the inclusion criteria, including 1,059 positive cultures from 7,903 samples. The total weighted contamination rate was 19.98% ± 0.024 (95% CI: 15.29%-24.68%; I^2=98.6%) (figure 1a). Subgroup analysis amongst studies from North America (n=7) showed a contamination rate of 6.01% ± 0.011 (95% CI: 3.88%-8.15%; I^2=89.3%) (figure 1b). I^2 indicated high heterogeneity. Egger's regression test indicated no significant publication bias for both groups (Egger's test of publication bias: p=0.0531 and p=0.0655).

Conclusion: Our analysis demonstrates that 19.98% of reprocessed patient-ready GI endoscopes may be contaminated. The contamination rate was lower amongst US studies, which may be attributed to the actions taken in the US to overcome this issue. However, our findings highlight that the elevator mechanism is not the only obstacle when reprocessing endoscopes. More studies are needed to fully determine the role of contaminated endoscope channels in the cross-transmission between the patients.

S992

Don't Blame the Duodenoscope Elevator, the Channels Are Contaminated as Well: A Systematic Review and Meta-Analysis

Hemant Goyal, MD, PGDCA (MBA)[1], Sara Larsen, MSc[2], Abhilash Perisetti, MD[3], Aman Ali, MD[4], Jiannis Anastasiou, MD, DMSc, FEBGH[3], Nikolaj B. Larsen, MSc[5], Lotte Ockert[6], Sven Adamsen, MD[7], Benjamin Tharian, MD, MRCP, FRACP[3], Nirav Thosani, MD, MHA[8].
[1]Wright Center for Graduate Medical Education, Scranton, PA; [2]Ambu A/S, Ballerup, Hovedstaden, Denmark; [3]University of Arkansas for Medical Sciences, Little Rock, AR; [4]The Commonwealth Medical College, Wilkes-Barre, PA; [5]Ambu A/S, Frederiksberg, Hovedstaden, Denmark; [6]Ambu, Ballerup, Hovedstaden, Denmark; [7]Copenhagen University Hospital, Bispebjerg, Copenhagen, Hovedstaden, Denmark; [8]University of Texas Health Science Center, Houston, TX.

Introduction: The elevator mechanism has been suggested as the main reason for multiple outbreaks associated with contaminated reusable patient-ready duodenoscopes. The elevator is difficult to clean even with all precautions, and specially designed brushes are recommended for proper cleaning. However, the narrow channels of the duodenoscope might pose a risk of contamination since they are prone to scratches by the insertion of various accessories creating space for microbes to hide. Our aim is to estimate the contamination rate beyond the elevator of duodenoscopes based on currently available literature.

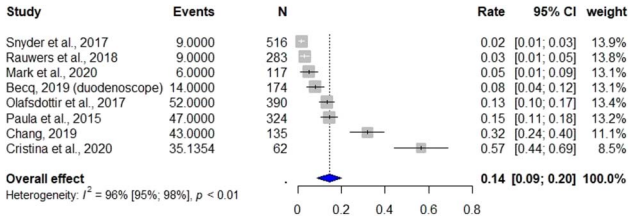
Methods: We searched PubMed, Web of Science, and Embase from January 1, 2010, until October 10, 2020, for studies investigating contamination rates of reprocessed duodenoscope channels and areas beyond the elevator. A random-effects model (REM) based on the proportion distribution was used to calculate the pooled total contamination rate beyond the elevator of reprocessed duodenoscopes. The meta-package (*metafor*) in RStudio version 3.6.2 was used to conduct the statistical analyses. Heterogeneity between the included studies was analyzed using the inconsistency index (I^2) statistics. Publication bias was assessed using the funnel plot and Egger's regression test.

Results: Eight studies including 215 positive cultures from 2,001 samples fulfilled the inclusion criteria. Four studies (50%) originated from the US, 3 studies (37.5%) originated from Europe (Italy, Netherlands, and Austria), and 1 study (12.5%) was conducted in Taiwan. See table 1 for baseline characteristics of the included studies. The total weighted contamination rate was 14.41% ± 0.029 (95% confidence interval [CI]: 8.70% - 20.13%), see figure 1. I^2 was 96.4% indicating high heterogeneity. Egger's regression test indicated no significant publication bias (Egger's test of publication bias: p=0.9919).

Conclusion: Our analysis indicates that 14.41% of reprocessed patient-ready duodenoscopes may be contaminated unrelated to the elevator. These findings highlight that the elevator mechanism is not the only part of the duodenoscope, which could remain contaminated even after reprocessing. Despite the role of contaminated channels has been studied, more evidence is needed to fully determine the consequences and potential link to patient-to-patient infections. Additionally, guidelines for disinfection units should recommend thorough surveillance of the endoscope channels to minimize endoscope-related infections.

[0992] **Table 1. Study characteristics of included studies.**

First author, year	Study design	Country	Sampled channels/areas	Positive cultures, n	Sample size, N	Type of microorganism
Snyder, 2017	Parallel group randomized study	USA	Working channel	9	516	N/A
Rauwers, 2018	Prospective nationwide cross-sectional study	Netherlands	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.
Olafsdottir, 2017	Parallel group randomized study	USA	Working channel	52	390	N/A
Paula, 2015	Descriptive study	Austria	Air, water, suction, and biopsy channel	47	412	Unspecified skin bacteria and aerobe spore-forming bacilli
Mark, 2020	Descriptive study	USA	Working channel	6	117	Pseudomonas aeruginosa, fungal organisms, Staphylococcus aureus, Coagulase negative staphylococcus, Viridans streptococcus
Cristina, 2020	Descriptive study	Italy	Distal end, instrument channel	35	62	Pseudomonas aeruginosa, Klebsiella pneumoniae, Acinetobacter baumannii, Klebsiella oxytoca, Stenotrophomonas maltophilia, Escherichia coli, Citrobacter freundii, Enterobacter spp
Chang, 2019	Descriptive study	Taiwan	Distal end outer surface, distal attachment cap, elevator wire channel, suction biopsy channel	43	135	N/A
Becq, 2019	Prospective single-center study	USA	Working channel	14	174	N/A



[0992] **Figure 1.** Pooled estimates of contamination rates beyond the elevator of patient-ready duodenoscope. CI: confidence interval; prop: proportion.

S993

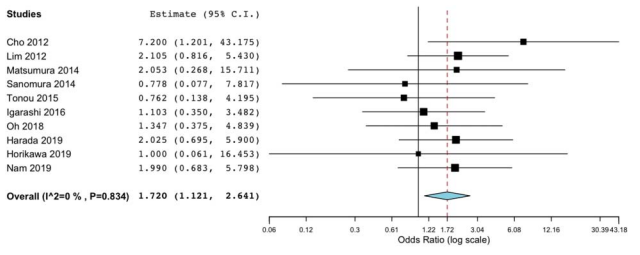
Continued Aspirin Use and Bleeding Risk After Endoscopic Submucosal Dissection of Gastric Neoplasms: A Meta-Analysis

Hemant Goyal, MD, PGDCA (MBA)[1], Sonali Sachdeva, MBBS[2], Abhilash Perisetti, MD[3], Mark M. Aloysius, MD, PhD[1], Saurabh Chandan, MD[4], Benjamin Tharian, MD, MRCP, FRACP[3], Nirav Thosani, MD, MHA[5].
[1]Wright Center for Graduate Medical Education, Scranton, PA; [2]Boston University Medical Center, Boston, MA; [3]University of Arkansas for Medical Sciences, Little Rock, AR; [4]Creighton University School of Medicine, Omaha, NE; [5]University of Texas Health Science Center, Houston, TX.

Introduction: With the development of endoscopic technologies, the detection rate of early gastric cancer (EGC) and precancerous lesions is gradually increasing. As an effective minimally invasive therapy, endoscopic submucosal dissection (ESD) has been accepted as a standard treatment for EGC and dysplasia. However, postprocedural bleeding is one of the most common complications of ESD, with a reported incidence of 5.1%. Moreover, the effect of continued low-dose aspirin (LDA) on bleeding during the peri-ESD period is not clear.

Methods: We searched the OVID/Medline and Google Scholar databases through June 2021 to find studies relating to continued LDA use in patients undergoing ESD. Studies reporting bleeding rates in patients undergoing ESD with and without continued LDA were included. Postoperative bleeding rates were compared between those who continued LDA during the procedure and those who did not; a random-effects model was used to calculate pooled odds ratio for bleeding risk with continued LDA use. A p-value < 0.05 was considered statistically significant.

Results: The initial search identified 2023 studies; after excluding duplicates, review articles, and studies not meeting inclusion criteria, 9 studies (all were retrospective observational studies) were finally included in the analysis. The total number of patients undergoing ESD procedure was 7978, out of which 703 continued LDA during the procedure. Pooled analysis comparing the post-operative bleeding rates between people with and without continued use of LDA revealed that aspirin use during ESD translated into higher postoperative bleeding rates compared to those who did not. (Pooled OR 1.720 , 95%CI: 1.121-2.641, P= 0.01). No interstudy heterogeneity was observed (I^2=0).



[0993] **Figure 1.** Forest plot of gastric neoplasm studies with and without continuation of low-dose aspirin.

[0993] **Table 1. Baseline Characteristics of Included Studies.**

Author	Year	Country/Region	Study Design	Sample size	Continued LDA use
Cho	2012	South Korea	Retrospective Cohort study	514	19
Lim	2012	South Korea	Retrospective Cohort Study	1503	172
Matsumura	2014	Japan	Retrospective Cohort Study	425	21
Sanomura	2014	Japan	Retrospective Cohort Study	78	28
Tonou	2015	Japan	Retrospective Cohort Study	385	14
Igarashi	2016	Japan	Retrospective observational Study	2104	33
Oh	2018	South Korea	Retrospective Observational study	215	57
Harada	2019	Japan	Retrospective observational study	597	95
Horikawa	2019	Japan	Retrospective observational study	293	52
Nam	2019	South Korea	Retrospective Observational Study	1864	212

Conclusion: The results of our meta-analysis demonstrated that LDA continuation significantly increased the risk of post-ESD bleeding. Therefore, the physicians should individualize the decision of continuing LDA in patients undergoing ESD based on their thrombotic risk.

S994

Medical Device Safety in Gastroenterology: FDA Recalls of Duodenoscopes, 2015-2020

Rushi K. Talati, MD[1], Adam Goodman, MD[2], Mark B. Pochapin, MD[1].
[1]New York University School of Medicine, New York, NY; [2]New York University Langone Medical Center, New York, NY.

Introduction: Duodenoscopes are used in more than 500,000 procedures annually in the US as a minimally invasive diagnostic and therapeutic modality for hepatobiliary and pancreatic diseases. Traditionally, these devices have been intended for re-use after undergoing strict cleaning and disinfection protocols to reduce the risk of infection between patients. However, since 2008, several major outbreaks of infections linked to duodenoscopes have resulted in devices recalled from the market. Understanding what occurred in instances of device failure leading to recalls is important to improve the safety and efficacy of these devices.
Methods: This institution review board-exempt study reviewed the FDA Center for Devices and Radiologic Health database for all duodenoscope-related recall events from November 1, 2002 through December 31, 2020. Market entry data, recall characteristics, and adverse reports were collected for each device.
Results: Seventeen class II duodenoscope-related recall events were identified, affecting at least 24,611 units in distribution. 12 out of the 17 (70%) recall events were for duodenoscopes, 3 out of 17 (18%) recalls were for operation manuals, and 2 out of 17 (12%) recalls were for reprocessors. 15 out of 17 recalled devices (88%) had at least 1 documented occurrence of an adverse event at the time of recall. All recall events were approved via the 510k pathway, however postmarket-related issues accounted for 88% of recalls.
Conclusion: Given the wide utilization of duodenoscopes in treating pancreaticobiliary diseases, an understanding of their recall events and associated public health impact are important for endoscopists to have a greater awareness of potential safety concerns. Recalls by three duodenoscope manufacturers and one scope reprocessor manufacturer highlight the need for innovation in design and improved post-marketing surveillance mechanisms.

S995

Endoscopic Ultrasound-Guided Celiac Plexus Block for Pain Relief in Chronic Pancreatitis Is an Effective Procedure When Used Judiciously

Nikhil Sonthalia, MD, DM, Mahesh K. Goenka, MD, DM, FACG, Vikram Patil, MD, Bhavik Shah, MD, Shivaraj Afzalpulkar, MD.
Institute of Gastrosciences, Apollo Gleneagles Hospital, Kolkata, West Bengal, India.

Introduction: There is not enough data available for the effectiveness of Endoscopic ultrasound guided celiac plexus block (EUS-CPB) for pain relief in chronic pancreatitis (CP) among Indian patients where the aetiology and phenotype of CP are different from the western population. The aim of the current study was to find out the efficacy of EUS-CPB in CP irrespective of whether the patients have undergone Endoscopic Retrograde Cholangiopancreatography (ERCP) or not.
Methods: A prospectively maintained data base of patients undergoing EUS-CPB was analyzed. EUS-CPB was done by injecting mixture of 0.25% bupivacaine and triamcinolone acetate as per the institutional protocol. Both central and bilateral techniques were used depending upon the feasibility. The main outcome measures were, 1) response to Celiac plexus block which was defined as more then 50% reduction in visual analogue scale (VAS) pain score after the procedure, 2) VAS pain score recorded at 4,12, 24 weeks after the procedure, 3) adverse event attributed to the procedure and 4) duration of response. In addition, factors among responders and non-responders were compared.
Results: In total 22 patients of CP underwent EUS-CPB between 2018 and 2021 for refractory pain .The mean age of patients was 40.2 years, among which males were 63.6%. Disease duration was classified as Short duration ($\leq$ 2 years) of CP which was seen in 36.4 % and long duration ($>$2 years) of CP which was seen in 63.6 %. Overall 18/22 (81.8 %) patients had response to EUS-CPB . Among responders, mean duration of response was 8 months (Standard deviation-4.73). Mean VAS score at 4,12 weeks and 24 weeks after procedure were significantly lower among those who had short duration of CP as compared to those with longer duration (Figure 1). Males had significantly better response as compared to females (100% vs 50%, p-0.01). Among responders significant proportion of patients discontinued the use of pain killer or used them occasionally. There was no significant difference in response to EUS-CPB according to the ERCP status of the patients. Total five adverse events- hypotension in 3 and diarrhoea in 2 patients were encountered. No major or serious adverse events occurred.
Conclusion: In our population, EUS-CPB is a safe and effective procedure in select group of chronic pancreatitis patients when used judiciously. Males had better response than females in our study. EUS-CPB may have a better result when used early in course of CP irrespective of ERCP status.

[0994] **Table 1. Product Recalls for Duodenoscopes and Accessories.**

Product	Manufacturer	Year	Classification	Recall Class	Manufacturer Self-Reported Reason	FDA-Determined Cause	Pre- or Post-market	Market Entry	Quantity	Distribution	Adverse Events?
Pentax Video Duodenoscope (ED-3490TK)	Pentax	2018	Duodenoscope	2	The duodenoscopes are being recalled in order to replace the forceps elevator mechanism, the O-rings, and the distal end covering to be consistent with the updated design as well as provide an updated periodic inspection as part of the Operation	Device Design	Postmarket	510(k)	559	Nationwide	Reported
					Manual in order to mitigate the potential risk of infection in flexible endoscopy.						
Olympus Duodenoscopes (JF-140F/160F)	Olympus	2018	Duodenoscope	2	Issuance of validated, new reprocessing procedures. This corrective action is being undertaken as a result of ongoing manufacturer and FDA activities relating to reported patient infections associated with duodenoscopes. The new cleaning procedure requires additional recess flushing and forceps elevator raising/lowering steps during precleaning, manual cleaning and manual disinfection.	Under Investigation by Firm	Postmarket	510(k)	1062	Nationwide	Reported
Olympus Duodenoscopes (TJF-Q180V, GF-UCT180, PCF-Q180AC, GIF-H180J)	Olympus	2018	Duodenoscope	2	The adhesive used in the repair of the endoscope was incorrectly prepared. It is unknown what effect the nonconforming adhesive mixture would have on the durability or effectiveness of the gluing operation for the endoscope repair.	Under Investigation by Firm	Postmarket	510(k)	6	Nationwide	None reported to date
Pentax Video Duodenoscope (ED-3490TK and ED-3270K)	Pentax	2017	Duodenoscope	2	Pentax initiated a field correction/safety alert for two (2) models of the Video Duodenoscope to determine how soiling may have occurred on the surface of the suction cylinder and under the distal cap during testing.	Device Design	Postmarket	510(k)	2015	Worldwide	Reported
Fujifilm Duodenoscope (FUJINON ED-530XT)	Fujifilm	2017	Duodenoscope	2	An update to the design and labeling was implemented to help reduce patient risk associated with inadequate reprocessing	Device Design	Postmarket	510(k)	362	Nationwide	Reported
					of the device. The action includes replacement of the forceps elevator mechanism, the O-ring seal, the distal end cap and issuance of a new Operation Manual.						
Olympus TJF-Q180V Duodenoscope	Olympus	2016	Duodenoscope	2	Olympus America Inc is conducting a voluntary removal/corrective action of all TJF-Q180V duodenoscopes in order to replace the forceps elevator mechanism. Olympus is replacing the forceps elevator mechanism with a new forceps elevator design consistent with the design specification in the recently cleared TJF-Q180V 510k.	No Marketing Application	Postmarket	None	4436	Nationwide	Reported
Olympus TJF-Q160F	Olympus (Distr: Integrated Medical Systems Inc)	2016	Duodenoscope	2	If excessive pressure is applied to the distal end of the endoscope, the internal coil pipe assembly at the distal end of the endoscope can become detached and angulation may not operate as intended.	Nonconforming Material/Component	Premarket	510(k)	16	Worldwide	Reported
Pentax Video Duodenoscope (Multiple Models)	Pentax	2016	Duodenoscope	2	Pentax Medical learned of reports of carbapenem-resistant Enterobacteriaceae (CRE) infection at a medical facility	Other	Postmarket	510(k)	423	Nationwide	Reported
Olympus TJF-160F/VF Duodenoscope	Olympus	2016	Duodenoscope	2	New reprocessing instructions for the Olympus TJF-160/VF duodenoscopes, consisting of revised manual cleaning and high level disinfection procedures [the firm] plan[s] to implement as well as a new cleaning brush (MAJ-1534), which is enclosed with	Under Investigation by Firm	Postmarket	510(k)	Unspecified	Nationwide	Reported