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Risk factors for infections after endoscopic retrograde cholangiopancreatography (ERCP): a retrospective cohort analysis of US Medicare Fee-For-Service claims, 2015–2021

Susan Hutfless ,[1] Yasutoshi Shiratori,[2] Daniel Chu,[1] Simon Liu ,[1] Anthony Kalloo[3]

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[1]Johns Hopkins University, Baltimore, Maryland, USA
[2]Sherbrooke University Hospital, Sherbrooke, Quebec, Canada
[3]Maimonides Medical Center, Brooklyn, New York, USA

Correspondence to
Dr Susan Hutfless;
shutfle1@jhmi.edu

ABSTRACT

Objective Contaminated reprocessed duodenoscopes pose a serious threat to patients in the endoscopy unit. Despite manufacturer changes to reprocessing guidelines, 20% of reprocessed duodenoscopes meet criteria for quarantine-level contamination based on microbiological or ATP testing. We aimed to examine risk factors for postendoscopic retrograde cholangiopancreatography (ERCP) infection.

Design Retrospective cohort analysis.

Setting US Medicare Fee-For-Service claims (2015–2021) and all-payer data (2017).

Participants In the Medicare data, 823 575 ERCP procedures were included. The all-payer five-state data, 16 609 procedures were included.

Interventions ERCP was identified by Current Procedural Terminology and International Classification of Disease (ICD) procedure codes. We identified inpatient infections using ICD diagnosis codes.

Outcome measures A logistic regression model predicted risk factors for infections occurring within 7-day and 30-day periods following ERCP. 7-day and 30-day all-cause hospitalisations and post-ERCP pancreatitis were also examined.

Results Post-ERCP infection occurred within 3.5% of 7-day and 7.7% of 30-day periods in Medicare. Disposable duodenoscopes were billed in 711 procedures, with 1.4% (n=10, 7-day) and 3.5% (n=25, 30-day) post-ERCP infections. Urgent ERCPs were the strongest risk factor for infections in the 7-day period (OR 3.3, 95% CI 3.2 to 3.4). Chronic conditions, sex (male), age (older) and race (non-white) were also risk factors. In the all-payer five-state data, fewer infections (2.4%, 7 days) were observed. No difference arose between Medicare and other payers for 7-day period infections (OR 1.0, 95% CI 0.7 to 1.3).

Conclusions Urgent ERCPs, patient chronic conditions and patient demographics are post-ERCP infection risk factors. Patients with infection risk factors should be targeted for specialised infection control prevention measures, including disposable duodenoscopes.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We reviewed data from over 800 000 qualifying endoscopic retrograde cholangiopancreatography (ERCP) procedures performed in US Fee-for-Service Medicare between January 2015 and December 2021, making this one of the largest studies to examine infections after ERCP (disposable duodenoscopes were used in a small number of the procedures).
⇒ The generalisability of the findings was examined by performing a similar analysis in all-payer data from five states in 2017.
⇒ Charts of patients with infections could not be manually reviewed for specific details on tests performed and outcomes related to specific pathogens.
⇒ Duodenoscopes could not be individually examined or tracked for defects or contamination because claims data do not track the serial numbers of specific devices used during patient procedures.

INTRODUCTION

Contaminated reprocessed duodenoscopes pose a serious threat to patients in the endoscopy unit. In 2013, the US Centers for Disease Control and Prevention notified the Food and Drug Administration (FDA) of a potential association between duodenoscopes and antibiotic-resistant infections.[1] The notification followed a history of gastrointestinal endoscopes (including duodenoscopes) being associated with infectious transmission since the 1970s.[2–5] For example, in 1997, patient-to-patient transmission of hepatitis C after colonoscopy was confirmed (using genetic sequencing) in three patients whose procedures were performed using the same colonoscope but different biopsy forceps on the same day. The biopsy-suction channel

was not mechanically cleaned, which did not adhere with guidelines.[6] In 2019, the Emergency Care Research Institute—a patient-safety organisation that conducts independent medical device evaluations—specifically listed mishandling flexible endoscopes as a top 10 health technology hazard[7]; in 2020 the language addressing the hazard is generalised to all disinfection process failures.[8]

The FDA has instigated numerous investigations and recommendations for duodenoscopes since 2013.[1] These include manufacturer guidance changes, postmarketing surveillance studies and recommendations to use disposable components or duodenoscopes that 'facilitate or eliminate the need for reprocessing.'[1] These recommendations are reinforced by studies that sampled patient-ready reprocessed duodenoscopes for contaminants. In the Netherlands, 22% of reprocessed duodenoscopes had micro-organism growth with ≥20 colony-forming units/20 mL. The Netherlands requires devices with this level of contamination to be quarantined and investigated prior to further patient use.[9] In a US study testing multiple types of endoscopes with ATP, 22% were considered 'highly contaminated' with ATP>200 24 hours after reprocessing.[10]

Despite the high rates of endoscopic contamination after reprocessing, infections after endoscopic retrograde cholangiopancreatography (ERCP) range between 0.01% and 1.4% of procedures.[11–15] However, infections arising after inpatient ERCP were as high as 8% in a tertiary-care hospital in China.[16] In a national US study, 9% of ERCP inpatients subsequently developed sepsis.[16] These discrepancies indicate that more large, representative studies of post-ERCP infection are needed to understand associated risk factors.

We aimed to calculate patient risk factors for infection after inpatient and outpatient ERCPs performed in the USA.

METHODS

Data sources and linkage

This study analyses Fee-for-Service Medicare patients undergoing ERCP between January 2015 and December 2021. All Fee-for-Service Medicare Inpatient, Outpatient and Carrier files for patients undergoing ERCP at US hospitals and ambulatory surgery centres (ASCs) were eligible. Inpatient and outpatient procedures were included. Medicare is a federal programme that provides health insurance to all Americans aged 65 years and older and individuals with disabilities.

Generalisability of the Medicare results was estimated by including all-payer information from five states (ie, Florida, Georgia, Iowa, Maryland and Wisconsin) in 2017. State data were made available through Agency for Healthcare Research and Quality and Healthcare Cost and Utilisation Project.[17] These states were selected because they make links available between hospital outpatient, hospital-affiliated ASC and inpatient records using individual patient identifiers that are consistent across the files. The states provide scrambled service utilisation dates. The unique encrypted patient identifiers are valid during a single calendar year.

Identification of ERCP procedures

ERCP was identified by Current Procedural Terminology (CPT) codes (43 260–43265, 43 273–43278) and International Classification for Diseases, 9th and 10th Revisions (ICD-9 and ICD-10) procedure codes (5110, 0FJB8ZZ, 0FJD8ZZ, BF110ZZ, BF111ZZ, BF11YZZ). These are the core CPT and ICD codes to identify ERCP, which we confirmed by cross-tabulating potential ERCP code combinations. We excluded procedures missing age, sex, patient identifier or procedure date information (0 deleted from Medicare; 187 deleted from all-payer data). For Carrier and Outpatient ERCPs, we categorised procedures as having infection at time of ERCP if a diagnosis code for infection was present on the claim. For Inpatient ERCPs, we categorised procedures as having infection at time of ERCP if infection was listed as an admitting diagnosis or was recorded as present on admission. Urgent ERCPs were identified by a variable indicating admission to an emergency department (all-payer data), CPT codes for emergency department (Medicare data) or the reason for admission listed as urgent or emergent (all-payer and Medicare data).

In Medicare data, the same procedure can be recorded by the facility (Inpatient and Outpatient settings) and proceduralist (Carrier setting). In order to limit double-counting, procedures were included based on a hierarchy to keep inpatient procedures, followed by outpatient, then by carrier for the same patient on the same day. This hierarchisation was not necessary for the all-payer data because information is aggregated to the patient date of service instead of the line item.

Identification of infections, non-elective hospitalisations and post-ERCP pancreatitis

Infections were identified by ICD-9 and ICD-10 Revisions, ICD-Clinical Modification diagnosis codes (ICD-9-CM and ICD-10-CM). The previously used ICD-9-CM codes were updated to include the ICD-10-CM equivalents; ICD-10-CM codes for infections were primarily identified using the first diagnosis code position of 'A' or 'B' (see the publicly available code in the GitHub repository for further details on this substringing).[18] Cholangitis and sepsis were not included as infections unless they were recorded simultaneously with a specific infection code. New infections recorded during hospitalisations within 7-day and 30-day periods following ERCP were included as post-ERCP infections. For inpatient ERCP, the hospitalisation had to occur at least 1 day after the ERCP admission date (ie, the patient had to be discharged following the procedure and then readmitted). All-cause hospitalisations included non-elective hospitalisations for any reason within 7 and 30 days following the procedure. Hospitalisation for post-ERCP pancreatitis (ICD-10-CM K9189) was also evaluated.

Risk factors

Characteristics of interest included: age; sex; race/ethnicity; history of hospitalisation for any reason in the 30 days prior to the ERCP; and non-elective procedure, infection, cancer, pancreatitis or biliary condition, and comorbidities recorded on the ERCP claim. Comorbidities were identified differently in the two data sources. In Medicare, comorbidities were categorised according to the Medicare chronic conditions list.[19] In the state data, the database-derived Elixhauser comorbidity index was used.[20]

Statistical analyses

We calculated the percentage of infections occurring within 7 days after the qualifying ERCP. We used logistic regression models to examine the relationship between the risk factors and infection using the OR. Infection ORs for each risk factor were adjusted for all other factors in the model. The same methodology was used for the other outcomes: 30-day period infections; 7-day and 30-day period non-elective hospitalisations; and post-ERCP pancreatitis. All analyses were performed using SAS V.9.4.

Patient and public involvement

None.

RESULTS

We identified 823 575 qualifying ERCP procedures in the Medicare setting (see table 1), of which 3.5% were hospitalised for infection within the 7-day period post-ERCP (see table 2). Urgent ERCP (OR 3.3, 95% CI 3.2 to 3.4) and chronic conditions were the strongest risk factors for postendoscopic infection. Infection at time of ERCP, sex (male), age (older) and race (non-white) were also risk factors. Odds of infection were lower in each year compared with 2015 despite increasing infections and decreasing ERCP volume in 2020 (see figure 1). Hospitalisations in the 30 days prior to the procedure were associated with fewer infections when the inpatient, outpatient and carrier bill settings were combined. However, when each setting was considered separately, hospitalisations prior to the procedure were an infection risk factor in the inpatient and outpatient settings only (see online supplemental appendix table 1 and online supplemental appendix table 2). Similar risk factors were observed for 30-day period infections, non-elective hospitalisations falling within 7-day and 30-day periods post-ERCP, and post-ERCP pancreatitis (see table 2 and online supplemental appendix table 3). Disposable duodenoscopes were billed in 711 procedures, with 1.4% (n=10, 7-day) and 3.5% (n=25, 30-day) post-ERCP infections.

Fewer infections were observed in the all-payer state data (see table 1). Of the 16 609 procedures, 2.4% were hospitalised for infection within 7 days of ERCP. The all-payer population was younger (50% under age 65) with fewer comorbidities (28% of patients had none). The strongest risk factors for postendoscopic infection were

Table 1 Characteristics of Medicare and all-payer beneficiaries with and without 7-day hospitalisation for infection after ERCP, January 2015 to December 2021

	Medicare N=823 575		All-payer N=16 609	
	Infection after ERCP	No infection	Infection after ERCP	No infection
No ERCP	29 090	794 485	403	16 206
Year of ERCP, %				
2015	14.7	14.6	0	0
2016	14.5	15.1	0	0
2017	15.1	14.9	100	100
2018	14.9	14.7	0	0
2019	15.0	14.7	0	0
2020*	12.9	13.1	0	0
2021*	12.9	13.1	0	0
Age at ERCP, %				
<65	12.8	13.6	45.7	50.4
65–74	35.9	38.8	24.8	24.0
75–84	32.3	31.4	20.1	18.2
85–94	17.3	15.0	9.4	7.0
95–105	1.7	1.2	0	0.5
Female, %	48.3	52.8	52.1	57.2
Race/ethnicity, %				
White	81.7	83.5	63.8	75.2
Black	7.0	7.0	18.4	11.7
Asian/Pacific Islander	3.8	2.7	11.7	8.7
Hispanic	2.7	2.5	3.2	1.7
North American Native/Native American	0.8	0.8	1.0	0.5
Other	4.0	3.5	2.0	2.3
Elective/Non-emergency department, %	80.2	92.1	45.4	73.6
Hospitalised 30 days prior to ERCP, %	33.5	54.0	20.1	13.9
Cancer at time of ERCP, %	11.9	11.5	16.8	13.4
Pancreatitis or biliary condition at the time of ERCP, %	81.6	80.6	86.9	88.2
PEP at time of ERCP, %	1.7	1.8	7.7	2.9
Infection at time of ERCP, %	5.7	4.0	6.7	7.3
Comorbidities, %				

Continued

Table 1 Continued

	Medicare N=823 575		All-payer N=16 609	
	Infection after ERCP	No infection	Infection after ERCP	No infection
0	2.3	2.7	27.1	27.5
1–5	23.8	28.6	67.1	67.2
6–10	46.7	46.1	5.7	5.3
11–15	25.1	21.2	0.1	0.1
16+	2.1	1.5	<0.1	<0.1
Disposable duodenoscope, %	0.03	0.1	–	–
Medicare, %	100	100	56.6	52.4
Setting, %				
Carrier†	80.0	53.4	–	–
Inpatient Hospital	6.2	7.7	62.5	25.6
Outpatient Hospital	13.8	38.9	37.5	74.4

*The decreases in 2020–2021 reflect incomplete claims processing as final action claims are available 2 years after the end of the calendar year. The 2020 decrease may also reflect decreased volume due to COVID-19.
†The Carrier file includes professional service fees and free-standing facilities billed using CMS-1500 form. Inpatient and outpatient institutional services are billed using the CMS-1450 form which is also known as UB-04.
ERCP, endoscopic retrograde cholangiopancreatography.

non-elective procedure and multiple chronic conditions (see table 2). To examine the generalisability of the Medicare population to all patients, we examined the effect of Medicare as primary payer vs other payers. Data indicated no difference between Medicare and other payers for 7-day period infections (OR 1.0, 95% CI 0.7 to 1.3).

DISCUSSION

Hospitalisation for infection within 7 days of ERCP occurs in 3.5% of Medicare patients and 2.4% of all patients. Multiple risk factors for post-ERCP infection exist. High-risk patients include those who: present urgently for ERCP; have infection at the time of ERCP; have chronic conditions and are older, non-white or male. Disposable duodenoscopes were rarely used (<1% of procedures) but were associated with decreased hospitalisations for infection.

These risk factors could help prioritise which patients should be considered for use of duodenoscopes that are either fully disposable or have disposable components.[21 22] Published data showed disposable duodenoscopes provide similar performance with reusable duodenoscopes.[23] Reprocessing procedures might not eliminate the risk of infections because of complicated factors such as intricate structure of duodenoscope (elevator channel endoscope), systematic monitoring of contamination and repair issues.[23] Disposable devices did not fully eliminate post-ERCP infections in our study. However, disposable duodenoscopes were related to lower rates of post-ERCP infection and decreased the rate of all-cause hospitalisation. The Transitional Pass-Through Treatment (TPT C1748) code introduced in July 2020 allows supplemental payment for disposable duodenoscope billed in the Medicare Outpatient file.[24] However, this code was used only 711 times (and was associated with 10 infections occurring within the 7-day period following ERCP), which limits comparison of infection rates by scope type. Although the statistically significant ORs of 0.32 and 0.47 for 7-day and 30-day infections are compelling, these likely remain confounded by calendar year since disposable duodenoscopes were not available during the entire time period and infection events decreased with time. More widespread recording of TPT C1748 will facilitate research on how effectively these novel devices might reduce post-ERCP infection rates.

We included patients whose ERCP took place during a hospitalisation in addition to outpatient ERCP procedures. An undercounting of post-ERCP inpatient outcomes is likely because we defined events by the requirement that patients be discharged. In previous inpatient-only studies, sepsis was recorded as not present on admission in 9% of procedures[16] and pathology-confirmed infections were present in 8% of patients[25] compared with our infection rate of 3%. This discharge and readmission requirement may also explain our lower-than-expected finding of post-ERCP pancreatitis (1% compared with 3%–10% in trials).[12] However, underuse of the post-ERCP pancreatitis ICD diagnosis code (relative to the clinical assessments performed in trials) may have contributed to this finding. Based on these observations, our estimates should be considered conservative; they may represent the lower bound of post-ERCP infection event rates.

The major strengths of this study were the large number of ERCP procedures and the ability to examine outcomes after disposable duodenoscopes. Furthermore, we investigated the generalisability of the findings by performing a similar analysis in all-payer data from five states in 2017, close to the midpoint of the 2015–2021 study period. This sensitivity analysis of all-payer data found no association between infection and Medicare versus other payers after accounting for demographics and other potential confounders.

There are several limitations. The definition of an urgent ERCP procedure was limited to indicators in the data for ‘urgent’ or ‘elective’ procedures and CPT codes indicating that the patient had emergency department utilisation at the time of the procedure. These indicators are likely to capture urgent procedures performed in an inpatient setting, but many patients are seen in outpatient settings urgently that may have been fit into a busy schedule without being labelled as urgent in the claims.

Table 2 OR of hospitalisation for infection after ERCP in Medicare and all-payer populations, January 2015 to December 2021

	Medicare	Medicare	All-payer	All-payer
	7-day infection	30-day infection	7-day infection	30-day infection
Event, %	3.5%	7.7%	2.4%	5.5%
Age at ERCP vs 65–74				
0–64	1.01 (0.97–1.05)	1.08 (1.05–1.11)	0.96 (0.68–1.35)	1.00 (0.80–1.25)
75–84	1.06 (1.03–1.09)	0.94 (0.92–0.95)	1.01 (0.75–1.37)	0.96 (0.78–1.17)
85–94	1.20 (1.16–1.25)	0.90 (0.88–0.92)	1.19 (0.80–1.76)	1.02 (0.78–1.33)
95–105	1.51 (1.38–1.67)	0.98 (0.91–1.06)	<0.001 (<0.001->999)	0.19 (0.03–1.40)
Race vs white				
Other/unknown	1.16 (1.09–1.23)	1.13 (1.09–1.18)	1.53 (1.17–2.02)	1.38 (1.14–1.67)
Black	1.10 (1.05–1.15)	1.16 (1.13–1.20)	1.48 (1.07–2.05)	1.21 (0.96–1.53)
Asian/Pacific Islander	1.39 (1.31–1.48)	1.35 (1.29–1.41)	2.62 (1.47–4.68)	1.34 (0.81–2.23)
Hispanic	1.08 (1.00–1.16)	1.12 (1.06–1.18)	2.91 (1.03–8.20)	1.17 (0.42–3.24)
North American Native/Native American	1.02 (0.89–1.16)	0.92 (0.84–1.01)	1.23 (0.60–2.52)	0.85 (0.49–1.47)
Male vs female	1.26 (1.23–1.29)	1.26 (1.24–1.28)	1.18 (0.96–1.44)	1.23 (1.08–1.42)
Year of ERCP vs 2015				
2016	0.87 (0.83–0.92)	0.92 (0.89–0.96)	–	–
2017	0.91 (0.87–0.96)	0.96 (0.93–0.99)	–	–
2018	0.91 (0.87–0.96)	0.96 (0.93–1.00)	–	–
2019	0.91 (0.86–0.96)	0.94 (0.91–0.97)	–	–
2020	0.88 (0.84–0.93)	0.94 (0.91–0.97)	–	–
2021	0.89 (0.84–0.93)	0.91 (0.87–0.94)	–	–
Hospitalised 30 days prior to ERCP	0.37 (0.36–0.38)	0.94 (0.93–0.96)	1.46 (1.13–1.89)	1.70 (1.44–2.01)
Chronic conditions vs 0				
1–5	1.02 (0.94–1.10)	1.08 (1.02–1.15)	1.85 (1.33–2.56)	1.90 (1.52–2.36)
6–10	1.27 (1.17–1.37)	1.35 (1.27–1.43)	6.29 (4.13–9.59)	4.23 (3.14–5.71)
11–15	1.54 (1.42–1.68)	1.72 (1.62–1.82)	16.09 (4.71–54.95)	4.18 (1.29–13.51)
16+	1.88 (1.68–2.12)	2.29 (2.12–2.48)	<0.001 (<0.001->999)	<0.001 (<0.001->999)
Cancer at time of ERCP	1.02 (0.98–1.06)	1.55 (1.52–1.59)	1.28 (1.00–1.64)	1.88 (1.60–2.21)
Pancreatitis or biliary condition at time of ERCP	1.13 (1.09–1.18)	0.97 (0.94–0.99)	0.78 (0.58–1.05)	0.89 (0.72–1.09)
Infection at time of ERCP	1.13 (1.07–1.19)	1.18 (1.14–1.23)	0.35 (0.23–0.53)	1.16 (0.93–1.44)
Urgent ERCP	3.30 (3.20–3.40)	1.79 (1.75–1.84)	2.42 (1.93–3.04)	1.59 (1.36–1.85)
Disposable duodenoscope	0.32 (0.17–0.60)	0.47 (0.31–0.69)	–	–
Primary payer Medicare vs other	NA	NA	0.96 (0.70–1.32)	1.16 (0.94–1.43)

ERCP, endoscopic retrograde cholangiopancreatography; NA, not available.

The strength of the association between urgent procedures not labelled as such and infection outcomes may differ from the reported OR; knowing the true 'urgency' of all procedures could change the current estimate. Another limitation is the inability to identify the specific duodenoscopes used in patients by a serial number or other manufacturer-specified tracking number. If such a tracking number was recorded in the claims, a duodenoscope associated with infection in one patient could be track longitudinally to examine if the same instrument was associated with subsequent infections. Despite the FDA requiring postmarket device tracking of manufacturers, this information is not included in Medicare or all-payer claims to perform large-scale surveillance of dangerous or defective devices.[26] Because this was a claims-based study, we were not able to inspect any of the duodenoscopes associated with infections nor the detailed medical charts of patients with infections. Because medical charts

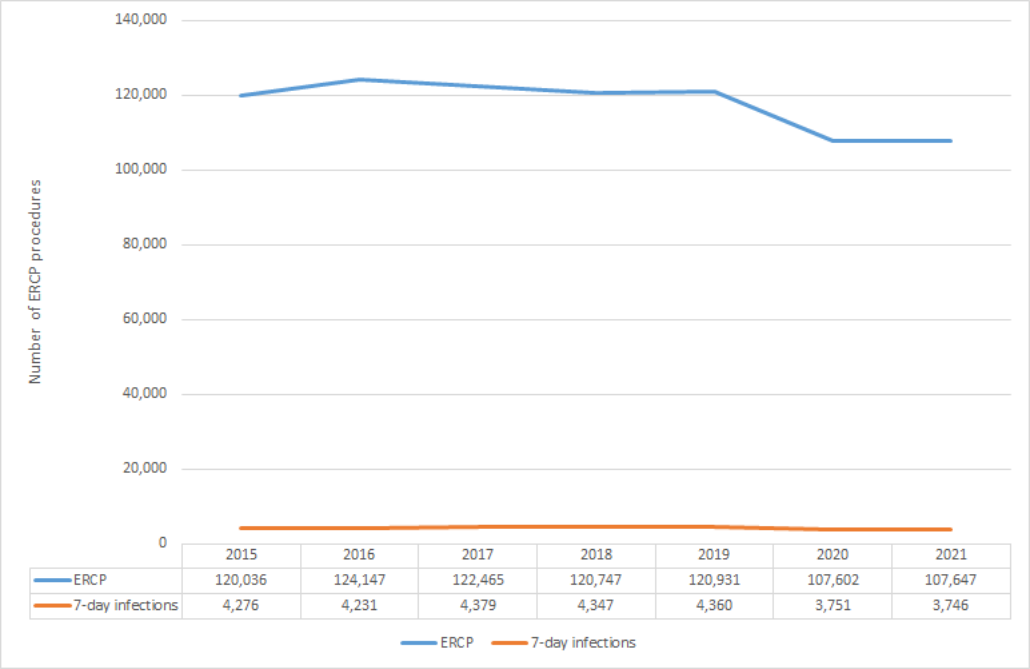

Figure 1 Number of ERCP procedures and 7-day infections in Medicare, by year. ERCP, endoscopic retrograde cholangiopancreatography.

were not available, we were not able to calculate the diagnostic accuracy of the procedure codes used to identify ERCP. The need for such a diagnostic accuracy study is especially important as additional duodenoscope technologies, that may not have dedicated codes, are made available to prevent post-ERCP infections.

In summary, infections after ERCP are common, especially in the elderly population. High-risk patients should be targeted for specialised infection control prevention measures, including use of duodenoscopes that are either fully disposable or have disposable components.

Contributors Guarantor (SH); Design (SH and AK); Analysis (DC, SH and SL); Drafting and revisions (DC, SH, AK, SL and YS); Approval for submission (DC, SH, AK, SL and YS). All authors approved the final version of the manuscript.

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Patient consent for publication Not applicable.

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Data availability statement Data may be obtained from a third party and are not publicly available. Medicare data are available through ResDAC (https://resdac.org/). Code available under create commons licence at https://github.com/susanmhutfless/playground/tree/master/ercp infections.

ORCID iDs
Susan Hutfless http://orcid.org/0000-0002-6311-2611
Simon Liu http://orcid.org/0000-0002-1182-5492

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Appendix Table 1. Characteristics and Outcomes of Medicare Beneficiaries By Setting, January 2015 – December 2021

	All	Carrier Setting	Outpatient Setting	Inpatient Setting
N	823,575	447,499	313,175	62,901
ERCP Year, %				
2015	14.57	14.9	13.99	15.14
2016	15.07	15.23	14.62	16.27
2017	14.87	14.9	14.68	15.61
2018	14.66	14.61	14.69	14.87
2019	14.68	14.67	14.84	14.05
2020	13.07	12.95	13.41	12.19
2021	13.07	12.74	13.79	11.89
Age at ERCP, %				
0-64	13.62	13.02	14.39	13.97
65-74	38.70	36.36	42.15	38.17
75-84	31.40	31.79	30.89	31.26
85-94	15.06	17.26	11.86	15.32
95-105	1.22	1.57	0.71	1.28
Female, %	52.65	52.34	53.09	52.71
Race, %				
Unknown/ Missing	3.54	3.52	3.62	3.34
White	83.44	82.72	84.85	81.57
Black	6.95	7.2	6.18	9.01
Asian	2.69	2.84	2.52	2.44
Hispanic	2.53	2.8	2.12	2.76
North American Native	0.83	0.91	0.71	0.88

	All	Carrier Setting	Outpatient Setting	Inpatient Setting
Emergency Department / Urgent ERCP, %	8.32	3.88	2.5	68.89
Hospitalized 30 days prior to ERCP	53.31	75.49	12.75	97.46
Cancer at ERCP	11.48	7.84	13.98	24.96
Pancreatitis or biliary infection at the time of ERCP	80.61	81.16	79.34	83.06
Infection at time of ERCP	4.02	1.62	2.72	27.54
Post-ERCP pancreatitis at the time of ERCP	1.78	1.48	1.77	3.97
Chronic conditions, %				
0	2.63	2.85	2.46	1.95
1-5	28.38	26.79	30.93	27.03
6-10	46.13	45.24	47.5	45.6
11-15	21.36	23.3	18.13	23.6
16+	1.50	1.81	0.98	1.82
Setting, %				
Carrier	54.34	100	0	0
Inpatient	7.64	0	0	100
Outpatient	38.03	0	100	0
Disposable scope	0.09	0	0.22	0.02
Outcomes, %				
Infection within 7 days of ERCP	3.53	5.2	1.29	2.85
Infection within 30 days of ERCP	7.71	10.09	4.15	8.42
Non-elective hospitalization within 7 days of ERCP	8.94	13.13	3.41	6.67

	All	**Carrier Setting**	**Outpatient Setting**	**Inpatient Setting**
Non-elective hospitalization within 30 days of ERCP	16.85	22.25	9.04	17.29
Post-ERCP pancreatitis within 7 days of ERCP	0.46	0.63	0.25	0.3

Appendix Table 2. Odds Ratio of 7-day Infection after ERCP by Medicare Setting

	All (same OR as main manuscript)	Inpatient	Outpatient	Carrier
Event, %	3.5%	2.9%	1.3%	5.2%
Age at ERCP vs 65-74				
0-64	1.01 (0.97 - 1.05)	1.28 (1.11 - 1.47)	1.03 (0.93 - 1.14)	0.98 (0.94 - 1.03)
75-84	1.06 (1.03 - 1.09)	0.88 (0.78 - 0.99)	0.95 (0.88 - 1.03)	1.04 (1.01 - 1.08)
85-94	1.20 (1.16 - 1.25)	0.71 (0.60 - 0.83)	0.99 (0.89 - 1.10)	1.12 (1.08 - 1.17)
95-105	1.51 (1.38 - 1.67)	0.68 (0.42 - 1.10)	0.90 (0.62 - 1.32)	1.31 (1.18 - 1.46)
Race vs White				
Other/Unknown	1.16 (1.09 - 1.23)	1.15 (0.90 - 1.48)	1.14 (0.97 - 1.33)	1.08 (1.00 - 1.16)
Black	1.10 (1.05 - 1.15)	1.30 (1.13 - 1.51)	1.13 (1.00 - 1.28)	1.02 (0.97 - 1.08)
Asian/Pacific Islander	1.39 (1.31 - 1.48)	1.50 (1.16 - 1.95)	1.42 (1.20 - 1.68)	1.20 (1.12 - 1.30)
Hispanic	1.08 (1.00 - 1.16)	1.00 (0.74 - 1.33)	1.30 (1.07 - 1.58)	0.92 (0.84 - 1.00)
North American Native/Native American	1.02 (0.89 - 1.16)	1.28 (0.80 - 2.03)	0.80 (0.52 - 1.23)	0.84 (0.72 - 0.98)
Male vs Female	1.26 (1.23 - 1.29)	1.19 (1.08 - 1.31)	1.26 (1.18 - 1.34)	1.27 (1.23 - 1.30)
Year of ERCP vs 2015				
2016	0.87 (0.83 - 0.92)	0.94 (0.77 - 1.14)	0.88 (0.77 - 1.01)	0.85 (0.80 - 0.91)
2017	0.91 (0.87 - 0.96)	0.82 (0.67 - 1.00)	0.96 (0.85 - 1.10)	0.91 (0.86 - 0.97)
2018	0.91 (0.87 - 0.96)	0.92 (0.75 - 1.12)	0.90 (0.79 - 1.03)	0.92 (0.86 - 0.97)
2019	0.91 (0.86 - 0.96)	1.01 (0.83 - 1.23)	0.94 (0.83 - 1.07)	0.90 (0.85 - 0.96)
2020	0.88 (0.84 - 0.93)	0.89 (0.73 - 1.10)	0.87 (0.76 - 1.00)	0.91 (0.86 - 0.97)
2021 (Jan-Apr)	0.89 (0.84 - 0.93)	0.85 (0.69 - 1.06)	0.91 (0.79 - 1.04)	0.93 (0.87 - 0.99)
Hospitalized 30 days prior to ERCP	0.37 (0.36 - 0.38)	0.74 (0.58 - 0.95)	1.76 (1.64 - 1.90)	0.14 (0.13 - 0.14)
Chronic Conditions vs 0				
1-5	1.02 (0.94 - 1.10)	1.26 (0.82 - 1.93)	1.06 (0.84 - 1.34)	1.31 (1.20 - 1.44)
6-10	1.27 (1.17 - 1.37)	1.60 (1.04 - 2.45)	1.32 (1.05 - 1.67)	1.77 (1.62 - 1.94)
11-15	1.54 (1.42 - 1.68)	2.01 (1.30 - 3.11)	1.73 (1.36 - 2.20)	2.17 (1.97 - 2.38)
16+	1.88 (1.68 - 2.12)	2.29 (1.35 - 3.90)	2.39 (1.71 - 3.35)	2.65 (2.32 - 3.02)
Cancer at time of ERCP	1.02 (0.98 - 1.06)	1.56 (1.40 - 1.73)	2.25 (2.09 - 2.42)	1.13 (1.07 - 1.19)
Pancreatitis or biliary condition at time of ERCP	1.13 (1.09 - 1.18)	0.81 (0.70 - 0.94)	0.99 (0.91 - 1.09)	1.16 (1.11 - 1.21)
Infection at time of ERCP	1.13 (1.07 - 1.19)	1.48 (1.34 - 1.63)	1.93 (1.67 - 2.21)	2.84 (2.62 - 3.08)
Urgent* ERCP	3.30 (3.20 - 3.40)	1.03 (0.93 - 1.14)	1.24 (1.03 - 1.48)	2.75 (2.65 - 2.87)
Disposable duodenoscope	0.32 (0.17 - 0.60)	2.38 (0.31 - 18.60)	1.02 (0.53 - 1.98)	NA**

*Emergency department claim on the same claim as the ERCP

**NA, not applicable because no disposable scopes used in this setting

Appendix Table 3. Odds of All cause Hospitalizations and Post-ERCP pancreatitis after ERCP in Medicare, 2015-2021

	7-day All cause hospitalization	30-day All cause hospitalization	Post-ERCP pancreatitis within 7 days
Event, %	8.9%	16.8%	0.5%
Age at ERCP vs 65-74			
0-64	1.03 (1.00 - 1.05)	1.16 (1.14 - 1.19)	1.16 (1.14 - 1.19)
75-84	1.04 (1.02 - 1.06)	0.94 (0.93 - 0.95)	0.94 (0.93 - 0.95)
85-94	1.12 (1.10 - 1.15)	0.91 (0.89 - 0.92)	0.91 (0.89 - 0.92)
95-105	1.30 (1.21 - 1.39)	0.97 (0.92 - 1.02)	0.97 (0.92 - 1.02)
Race vs White			
Other/Unknown	1.07 (1.02 - 1.11)	1.06 (1.03 - 1.10)	1.06 (1.03 - 1.10)
Black	1.01 (0.98 - 1.04)	1.14 (1.11 - 1.16)	1.14 (1.11 - 1.16)
Asian/Pacific Islander	1.06 (1.01 - 1.11)	1.07 (1.03 - 1.11)	1.07 (1.03 - 1.11)
Hispanic	0.94 (0.89 - 0.99)	0.98 (0.95 - 1.02)	0.98 (0.95 - 1.02)
North American Native/Native American	0.89 (0.82 - 0.98)	0.89 (0.83 - 0.95)	0.89 (0.83 - 0.95)
Male vs Female	1.07 (1.06 - 1.09)	1.11 (1.10 - 1.13)	1.11 (1.10 - 1.13)
Year of ERCP vs 2015			
2016	0.94 (0.91 - 0.97)	0.97 (0.95 - 1.00)	0.97 (0.95 - 1.00)
2017	0.95 (0.92 - 0.99)	0.99 (0.96 - 1.01)	0.99 (0.96 - 1.01)
2018	0.97 (0.94 - 1.00)	0.99 (0.96 - 1.01)	0.99 (0.96 - 1.01)
2019	0.98 (0.95 - 1.02)	0.99 (0.97 - 1.02)	0.99 (0.97 - 1.02)
2020	0.94 (0.91 - 0.97)	0.97 (0.94 - 0.99)	0.97 (0.94 - 0.99)
2021 (Jan-Apr)	0.95 (0.92 - 0.98)	0.96 (0.94 - 0.99)	0.96 (0.94 - 0.99)
Hospitalized 30 days prior to ERCP	0.32 (0.31 - 0.32)	0.82 (0.81 - 0.83)	0.82 (0.81 - 0.83)
Chronic Conditions vs 0			
1-5	0.98 (0.93 - 1.03)	1.08 (1.03 - 1.12)	1.08 (1.03 - 1.12)
6-10	1.03 (0.98 - 1.08)	1.25 (1.20 - 1.30)	1.25 (1.20 - 1.30)
11-15	1.14 (1.08 - 1.20)	1.52 (1.46 - 1.58)	1.52 (1.46 - 1.58)
16+	1.27 (1.17 - 1.38)	1.89 (1.79 - 2.01)	1.89 (1.79 - 2.01)
Cancer at time of ERCP	0.92 (0.90 - 0.94)	1.37 (1.34 - 1.39)	1.37 (1.34 - 1.39)
Pancreatitis or biliary condition at time of ERCP	1.11 (1.08 - 1.14)	1.00 (0.98 - 1.01)	1.00 (0.98 - 1.01)
Infection at time of ERCP	0.52 (0.49 - 0.54)	0.67 (0.64 - 0.69)	0.67 (0.64 - 0.69)
Urgent ERCP	5.22 (5.11 - 5.33)	2.75 (2.70 - 2.80)	2.75 (2.70 - 2.80)
Disposable duodenoscope	0.23 (0.15 - 0.36)	0.51 (0.40 - 0.66)	0.51 (0.40 - 0.66)

*Emergency department claim on the same claim as the ERCP