ORIGINAL ARTICLE

Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA

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ABSTRACT

Objective Over 15 million colonoscopies and 7 million osophagogastroduodenoscopies (OGDs) are performed annually in the USA. We aimed to estimate the rates of infections after colonoscopy and OGD performed in ambulatory surgery centres (ASCs).

Design We identified colonoscopy and OGD procedures performed at ASCs in 2014 all-payer claims data from six states in the USA. Screening mammography, prostate cancer screening, bronchoscopy and cystoscopy procedures were comparators. We tracked infection-related emergency department visits and unplanned in-patient admissions within 7 and 30 days after the procedures, examined infection sites and organisms and analysed predictors of infections. We investigated case-mix adjusted variation in infection rates by ASC.

Results The rates of postendoscopic infection per 1000 procedures within 7 days were 1.1 for screening colonoscopy, 1.6 for non-screening colonoscopy and 3.0 for OGD; all higher than screening mammography (0.6) but lower than bronchoscopy (15.6) and cystoscopy (4.4) (p<0.0001). Predictors of postendoscopic infection included recent history of hospitalisation or endoscopic procedure; concurrence with another endoscopic procedure; low procedure volume or non-freestanding ASC; younger or older age; black or Native American race and male sex. Rates of 7-day postendoscopic infections varied widely by ASC, ranging from 0 to 115 per 1000 procedures for screening colonoscopy, 0 to 132 for non-screening colonoscopy and 0 to 62 for OGD.

Conclusion We found that postendoscopic infections are more common than previously thought and vary widely by facility. Although screening colonoscopy is not without risk, the risk is lower than diagnostic endoscopic procedures.

INTRODUCTION

On 19 February 2015, the Food & Drug Administration (FDA) published a Safety Communication relating to possible transmission of microorganisms from reprocessed duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP).[1] Between January 2013 and December 2014, the FDA received 75 Medical Device Reports encompassing infections of approximately 135 patients in the USA. These infectious agents included multidrug-resistant bacteria such as *Escherichia coli* and *Klebsiella* species. The infections were originally thought to be due to design flaws, but an outbreak occurred in a facility that used the redesigned duodenoscope and revised cleaning protocol.[2] Other mechanisms might play a role to contribute to postendoscopic infections.[3] If facility factors play a role in infection transmission, we expect that procedures using colonoscopes and upper endoscopes without elevator mechanisms might also be associated with postendoscopic infections.

While about 500 000 ERCP procedures are performed in the USA each year, there are over 15 million colonoscopies and 7 million osophagogastroduodenoscopies (OGDs) performed annually.[1 4 5] About 40% (6.3 million) of colonoscopies are performed for colorectal cancer screening among individuals who are completely asymptomatic. Rates of colonoscopy-associated complications such as bleeding and perforation have been studied.[6–9] A meta-analysis of 21 studies published between 2001 and 2015 estimated incidences for postcolonoscopy perforation, bleeding and mortality to be 0.5/1000, 2.6/1000 and 2.9/100 000 procedures.[10] Case reports have described infections after colonoscopy and OGD performed in hospitals, which tend to have sicker patients than ambulatory surgery centres (ASCs) and infection control units monitoring for outbreaks. No study has examined the rate of infections after colonoscopy or OGD. In particular, no study or case report has examined rates of infections after screening colonoscopy, non-screening colonoscopy or OGD performed in ASCs. Over 50% of endoscopic procedures are now performed in ASCs in the USA.[11] Healthcare reform has led to a shift in endoscopic procedures from hospitals to ASCs to reduce costs of care.[12]

We aimed to examine the variation in rates of infections after screening and non-screening colonoscopy and OGD performed in ASCs in 2014. We used all-payer information from six geographically and racially diverse states representing 31% of the US population. We also examined the infections by site and organism and analysed patient, procedure and facility predictors of infection.

METHODS

Data sources and linkage

We identified colonoscopy and OGD procedures performed in ASCs and tracked patients' emergency

department (ED) visits and hospitalisations within 7 and 30 days after the endoscopic procedures. We obtained statewide ASC, ED and in-patient claims data from six states that varied in population size and race. For Florida, New York, Georgia, Nebraska and Vermont, we used Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP) data. For California, we used data collected by the Office of Statewide Health Planning and Development (OSHPD). Information from both hospital-owned and freestanding ASCs was available in California, Florida and New York. Only hospital-owned ASC information was available from Nebraska, Vermont and Georgia. The variables in HCUP and OSHPD data were sufficiently uniform to be merged for analysis, including variables on patient characteristics and service utilisation information. ED visits and hospitalisations were linked to eligible endoscopic procedures using unique encrypted patient identifiers and deidentified service utilisation dates.

Endoscopic procedures

We included colonoscopy and OGD procedures based on Current Procedural Terminology (CPT) codes (online supplementary appendix tables 1 and 2). We excluded procedures where information was missing for age (n=10), sex (n=79), patient identifier (n=135 997) or procedure date (n=28) and where an infection diagnosis code was present at the time of the procedure (online supplementary appendix table 3; n=50 928) and during which the patient died (n=13). Screening colonoscopy was identified using CPT codes G0105 and G0121. For New York, Nebraska and Vermont where CPT modifiers were reported, if the modifier '33' or 'PT' was appended to any colonoscopy CPT code (online supplementary appendix tables 1),[13] we classified this procedure as screening colonoscopy. These modifiers identify colorectal cancer screening tests that were converted to diagnostic or therapeutic procedures. For California, Florida and Georgia where no CPT modifiers were reported, the CPT code 45 378 was considered a screening colonoscopy in addition to G0105 and G0121.

Comparator groups to calculate the background infection rates and comparison to other endoscopic procedures

Considering that the population is at risk for infection-related visits even without undergoing a colonoscopy or OGD, we selected patients undergoing screening mammography and prostate cancer screening (CPT codes given in online supplementary appendix table 3) as non-endoscopic comparator groups that do not involve sedation. Screening mammography was selected as the primary comparator as most prostate cancer screenings do not occur in ASCs. As a non-invasive examination often performed on a healthy population, these screening tests provided the opportunity to estimate the background rate of infection that would occur stochastically after a visit at an ASC, which was helpful for understanding the net influence of colonoscopy and OGD on infection outcomes. We then compared the rates with bronchoscopy and cystoscopy (online supplementary appendix table 3). These procedures are common endoscopic procedures that involve sedation and often occur in the same ASC as gastrointestinal endoscopic procedures.

Unplanned visits

All-cause unplanned visits within 7 and 30 days after procedures were defined according to the Centers of Medicare and Medicaid Services (CMS) colonoscopy quality measure (ID 2086: *Facility 7 Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy*) (online supplementary appendix figure 1).[14 15] All ED visits and the hospitalisations with evidence of observational stay service utilisation were considered unplanned visits. For hospitalisations without an observational stay, CMS's Planned Readmission Algorithm, V.4.0 was used to remove the planned admissions.[15]

Infections

Our analyses focused on unplanned visits associated with infections (online supplementary appendix table 4). Our primary outcome was 7-day infection-related unplanned visit rates. Thirty-day rates were also calculated. We examined infections by the sites involved, including gastrointestinal, respiratory, genitourinary and central nervous systems as well as septicaemia and infectious endocarditis. We also investigated infections by the

Significance of this study

What is already known on this subject?

- Previous studies estimated rates of colonoscopy-associated complications such as bleeding, perforation and aspiration pneumonia, but not infectious complications.
- Case reports have described infection outbreaks after colonoscopy and osophagogastroduodenoscopy (OGD) performed in hospitals.
- No study has comprehensively examined the rates of infections after colonoscopy or OGD in ambulatory surgery centres (ASCs). Unlike hospitals, ASCs often do not have infection control units and do not have linked electronic medical records to local emergency departments and hospitals to identify postprocedural events.

What are the new findings?

- This study aimed to estimate the rates of infection after colonoscopy and OGD and compare those rates with screening mammography, prostate cancer screening, bronchoscopy and cystoscopy.
- Although patients are routinely told that common endoscopic procedures are entirely safe, we found that postendoscopic infections (those present within 7 or 30 days after the procedure) are more common than previously thought and vary widely by the ASC facility.
- The observed postendoscopic infection rates at some ASCs are over 100 times higher than their expected rates that account for patient severity and procedure complexity.
- Overall and site-specific infection rates are 2–10 times higher for colonoscopy and OGD compared with screening mammography.
- Infection rates after colonoscopy and OGD were lower compared with bronchoscopy and cystoscopy.

How might it impact on clinical practice in the foreseeable future?

- Patients should be informed of the infectious risk associated with screening colonoscopy and all endoscopic procedures.
- This study provides comparative rates to common non-endoscopic and endoscopic procedures to inform those patient-provider conversations.
- This study also highlights that the facility that a patient undergoes their procedure impacts their risk of infection.
- Patient-accessible public reporting of facility-level procedure volumes and infection rates may be valuable to patients seeking quality of care information.

responsible organism, namely drug-resistant microorganisms such as *E. coli*, *Klebsiella pneumoniae*, *Clostridium difficile*, *Pseudomonas*, *Staphylococci*, *Streptococci*, gram-negative and anaerobic bacteria.

Aspiration pneumonia

We investigated unplanned visits related to aspiration pneumonia (online supplementary appendix table 5), because it is a potential complication due to the anaesthesia or sedation used for colonoscopy and OGD and could be miscoded as infectious pneumonia. The definition of aspiration pneumonia using The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes included two possible case definitions in previous publications.[16–18] For completeness, we examined all ICD-9-CM codes that could potentially be coded for aspiration pneumonia and calculated the rates for two case definitions: (1) 507.0 or (2) 507.0, 507.8, 482.89, 482.9 or 483.8. The case definition of 507.0 for aspiration pneumonia was confirmed in 91% of patients during chart review.[18] For the state of New York where method of anaesthesia was reported, we compared the rates of infectious and aspiration pneumonia between procedures performed under general anaesthesia versus those not associated with general anaesthesia.

Patient predictors

We examined patient, procedure and facility predictors of postendoscopic infection-related unplanned visits. Patient characteristics that may impact the risk of infections included age; sex; race; history of hospitalisation and gastrointestinal endoscopic procedure within 30 days prior to procedure; conditions present at the procedural visit that were identified by the Elixhauser comorbidity index[19] and inflammatory bowel disease (ICD-9-CM codes 555 and 556). Elixhauser comorbidities were categorised by the number of patient conditions (0, 1 or 2–14 (the maximum number observed)). We imputed the race of all patients in Nebraska to white as 96% of the population is white and no race information was available.

Procedure predictors

Procedure characteristics included invasiveness and concurrence with other gastrointestinal endoscopic procedures on the same day. We determined a procedure's invasiveness according to whether gastrointestinal mucosa was likely disrupted during the procedure (online supplementary appendix tables 1 and 2). For example, screening and diagnostic procedures where no biopsy was taken were categorised as non-invasive. However, diagnostic procedures where biopsies were taken or therapeutic procedures like polypectomy and lesion ablation occurred were categorised as invasive. Concurrence with other gastrointestinal endoscopic procedures was determined by examining whether another endoscopic procedure was coded on the same visit. For example, if a colonoscopy and an OGD occurred on the same visit, then both procedures contributed to the analyses and were considered as having concurred with another gastrointestinal endoscopic procedure.

Facility predictors

Facility characteristics of interest included the state where the ASC was located; annual procedure volume; hospital-owned or freestanding; multispecialty or gastroenterology-specific endoscopy unit and the proportion of gastrointestinal endoscopic procedures that were performed on patients with an infection coded on the day of the procedure. We calculated the 2014 colonoscopy and OGD volumes for each ASC and categorised the volumes into tertiles. We examined whether non-gastrointestinal endoscopic procedures (bronchoscopy and cystoscopy) were performed at each ASC and defined facilities that performed both gastrointestinal and non-gastrointestinal endoscopic procedures as multispecialty. Multispecialty facilities are likely to share procedural suites and cleaning rooms for all scopes, which could lead to cross-contamination. Although procedures with infection diagnoses coded on the day of the procedure were excluded from the analyses, we calculated the annual cumulative proportion of procedures performed on infectious cases for each ASC as a predictor.

Statistical analyses

Six-state outcome rates

We calculated the unadjusted rates of 7-day postendoscopic infection-related unplanned visits for screening and non-screening colonoscopy, OGD, screening mammography, bronchoscopy and cystoscopy. Thirty-day infection and all-cause unplanned visit rates were calculated for screening and non-screening colonoscopy, OGD and the primary comparator, screening mammography. The denominator was the eligible screening or non-screening colonoscopy; OGD procedures or comparator procedures in all six states. The numerator was the number of procedures that were followed by an ED visit or unplanned hospitalisation where at least one infection was coded within 7 or 30 days. Because planned hospitalisations were not considered outcome events, procedures followed by planned hospitalisations that included an infection code were not included in the numerator but they were part of the denominator. The proportion of infection-related unplanned visits that resulted in hospitalisation and the associated length of stay and mortality were calculated for the gastrointestinal endoscopic procedures.

Patient, procedure and facility predictors of infection-related unplanned visits

To analyse the predictors of 7-day infection-related unplanned visits, we used multivariable logistic regression models with patient, procedure and facility characteristics as predictors. We also used the same models to analyse the predictors of 7-day unplanned visits specifically related to infections.

Variation in infection-related unplanned visit rates by ASC

We used multivariable logistic regression models with patient and procedure predictors to compare the observed versus expected number of events by centre. We summed the model-based expected probabilities of infection-related unplanned visits for all procedures performed at each ASC to get the expected number of events. We then calculated the ratio of the observed number of events over the expected for each ASC. Adjusted outcome rates were calculated by multiplying the observed over expected ratio by the six-state unadjusted outcome rates. We plotted the ASC variation in 7-day infection rates after screening colonoscopy, non-screening colonoscopy and OGD procedures for ASCs that performed at least 10 of the procedures in 2014. We conducted statistical analyses using SAS software, V.9.4 (Cary, North Carolina, USA) and Stata V.13 (College Station, Texas, USA).

RESULTS

There were 462 068 screening colonoscopies performed at 1157 ASCs and 914 140 non-screening colonoscopies performed at 1202 ASCs (table 1). There were 873 138 OGDs performed

Table 1 Infection-related and all-cause unplanned visit rates after colonoscopy, OGD and the comparator tests and procedures

Rate per 1000 procedures	Screening colonoscopy (n=462 068)	Non-screening colonoscopy (n=914 140)	OGD (n=873 138)	Screening mammography (n=647 212)	Prostate cancer screening (n=26 428)	Bronchoscopy (n=30 116)	Cystoscopy (n=68 432)
All-cause visits	11.613	16.414	34.606	6.435	13.735	51.036	37.906
Infection-related visits	1.128	1.566	3.038	0.609	1.551	16.536	4.413
Infections of gastrointestinal system	0.160	0.290	0.354	0.039	0.076	0.299	0.321
Infections of genitourinary system	0.045	0.048	0.087	0.025	0.038	0.033	0.789
Infections of respiratory system	0.524	0.602	1.260	0.351	0.908	12.385	0.950
Pneumonia	0.299	0.286	0.688	0.104	0.341	11.223	0.555
Aspiration pneumonia	0.087	0.097	0.333	0.015	0	1.527	0.088
Infections outside the treated organ system	0.968*	1.276*	2.684*	0.609†	1.551†	4.151‡	3.624§

*Non-gastrointestinal infections for colonoscopy and OGD (all infections minus gastrointestinal infections).
†All infections for screening mammography.
‡Non-respiratory infections for bronchoscopy (all infections minus respiratory infections).
§Non-genitourinary infections for cystoscopy (all infections minus genitourinary infections).
OGD, osophagogastroduodenoscopy.

at 1212 ASCs. The comparator groups consisted of 647 212 screening mammographies at 338 ASCs; 26 428 prostate cancer screenings at 209 ASCs; 30 116 bronchoscopies at 665 ASCs and 68 432 cystoscopies at 912 ASCs. The number of ASCs, maximum procedure volume and patient characteristics such as race varied by state as was expected given the diversity of the states selected (online supplementary appendix table 6).

Infection-related unplanned visits rates

The rates of 7-day infection-related unplanned visits were 1.1 per 1000 procedures for screening colonoscopy, 1.6 for non-screening colonoscopy and 3.0 for OGD, which were twofold to fivefold higher compared with the rate of 0.6 for screening mammography and similar to twofold higher compared with the rate of 1.6 for prostate screening (table 1). The rates of 30-day infection-related unplanned visits per 1000 procedures were 4.0 for screening colonoscopy, 5.4 for non-screening colonoscopy and 10.8 for OGD, compared with 2.9 for screening mammography (table 2). The proportion of infection-related unplanned visits that resulted in hospitalisation was 61.8% for screening, 60.5% for non-screening colonoscopy and 64.2% for OGD. Infection-related hospitalisations required a mean length of stay of 8 days (range: 0–54, median 5) for screening colonoscopy, 7 days (range: 0–98, median 5) for non-screening colonoscopy and 8 days for OGD procedures (range: 0–148, median 5). Death occurred during 0.4%, 1.7% and 2.6% of the infection-related unplanned visits after screening colonoscopy, non-screening colonoscopy and OGD procedures.

Infections by site and by organism

The rates of gastrointestinal infections were 0.2 per 1000 procedures for screening colonoscopy, 0.3 for non-screening colonoscopy and 0.4 for OGD, 5–10 times higher than the rate of 0.04 per 1000 procedures for screening mammography (table 2). The rates of septicaemia and infections of respiratory and genitourinary systems were also higher for screening and non-screening colonoscopy and OGD compared with screening mammography. *E. coli*, *C. difficile* and *Staphylococci* were the most common organisms for screening and non-screening colonoscopy and OGD, with infection rates 3–30 times higher compared with screening mammography. The most common infections within 30 days after procedures were similar to those within 7 days.

We examined the rates of acute and subacute bacterial or infective endocarditis for comparison with the prior case reports (table 2). We identified 7 and 21 unplanned visits for acute and subacute bacterial or infective endocarditis within 7 and 30 days after non-screening colonoscopy (7 day rate: 0.008 per 1000 procedures; 30 day rate: 0.023) and 6 and 38 after OGD (7 day rate: 0.007; 30 day rate: 0.044). There was no visit for bacterial/infective endocarditis after screening colonoscopy within 7 days and 5 visits within 30 days (30 day rate: 0.011). There was no visit for bacterial/infective endocarditis after screening mammography within 7 or 30 days.

Aspiration pneumonia after gastrointestinal endoscopic procedures, bronchoscopy and cystoscopy

The aspiration pneumonia rate was lowest after screening colonoscopy and highest after bronchoscopy (screening colonoscopy 0.087; cystoscopy 0.088; non-screening colonoscopy 0.097; OGD 0.333 and bronchoscopy 1.527) (table 1). When infections of the treated organ system (ie, infections that could possibly be indications) were excluded, the infection rates were still lower for colonoscopy and OGD than bronchoscopy and cystoscopy. The majority of the codes for aspiration pneumonia were 507.0 (online supplementary appendix table 7).

Influence of general anaesthesia

New York was the only state that reported the anaesthesia method used for endoscopic procedures (online supplementary appendix table 8). The rates of infections after procedures performed under general anaesthesia were largely similar to those not performed under general anaesthesia. The rates of respiratory system infection per 1000 procedures with versus without general anaesthesia were 0.377 vs 0.347 for screening colonoscopy (p=0.86), 0.405 vs 0.516 for non-screening colonoscopy (p=0.34) and 1.071 vs 0.790 for OGD (p=0.07). For colonoscopy, the rates of aspiration pneumonia were similar regardless of the use of general anaesthesia (rates per 1000 procedures and p values (general anaesthesia vs not): screening colonoscopy: 0 vs 0.053, p=0.40; non-screening colonoscopy: 0.119 vs 0.058, p=0.15). For OGD, the rates of aspiration pneumonia was about twofold higher with the use of general anaesthesia (rates per 1000 procedures and p value (general anaesthesia vs not): 0.341 vs 0.179, p=0.03).

Table 2 Seven-day infection-related unplanned visit rates (by major infection sites and organisms) after colonoscopy, OGD or screening mammography at an ambulatory surgery centre, 2014

	Screening colonoscopy (n=462 068)		Non-screening colonoscopy (n=914 140)		OGD (n=873 138)		Screening mammography (n=647 212)	
Infection (ICD-9-CM codes)	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures
By infection site								
Infections of gastrointestinal system (001–009, 566–567)	74	0.160	265	0.290	309	0.354	25	0.039
Intestinal infectious diseases (001–009)	24	0.052	130	0.142	182	0.208	20	0.031
Abscess of anal and rectal regions (566)	4	0.009	13	0.014	5	0.006	3	0.005
Peritonitis and retroperitoneal infections (567)	47	0.102	125	0.137	126	0.144	2	0.003
Infections of respiratory system (460–466, 480–488, 511.1)	242	0.524	550	0.602	1100	1.260	227	0.351
Acute respiratory infections (460-466)	97	0.210	265	0.290	482	0.552	152	0.235
Pneumonia (480–486)	138	0.299	261	0.286	601	0.688	67	0.104
Influenza (487–488)	14	0.030	34	0.037	43	0.049	13	0.020
Pleurisy with effusion, with mention of a bacterial cause other than tuberculosis (511.1)	0	0	0	0	1	0.001	0	0
Septicaemia (038)	88	0.190	235	0.257	568	0.651	25	0.039
Infections of genitourinary system (590)	21	0.045	44	0.048	76	0.087	16	0.025
Bacterial/infective endocarditis (421.0, 421.1)	0	0	7	0.008	6	0.007	0	0
Infections of central nervous system (320, 321, 323.0–323.2, 323.4, 323.61)	0	0	2	0.002	1	0.001	1	0.002
By organism								
Infection with drug-resistant microorganisms (V09)	1	0.002	4	0.004	22	0.025	0	0
Escherichia coli (038.42, 041.4, 482.82)	39	0.084	102	0.112	174	0.199	21	0.032
Klebsiella pneumoniae (041.3, 482.0)	10	0.022	20	0.022	56	0.064	5	0.008
Clostridium difficile (008.45)	16	0.035	80	0.088	113	0.129	2	0.003
Pseudomonas (038.43, 041.7, 482.1)	6	0.013	7	0.008	41	0.047	1	0.002
Staphylococcus (038.1, 041.1, 482.4)	22	0.048	45	0.049	112	0.128	9	0.014
Streptococcus (038.0, 038.2, 041.0, 041.2, 481, 482.3)	12	0.026	33	0.036	95	0.109	4	0.006
Gram-negative bacteria (038.4, 482.83)	14	0.030	41	0.045	109	0.125	3	0.005
Anaerobes (038.3, 482.81)	0	0	5	0.005	5	0.006	0	0
Human papillomavirus (079.4)	0	0	3	0.003	0	0	0	0

ICD-9-CM, The International Classification of Diseases, Ninth Revision, Clinical Modification; OGD, osophagogastroduodenoscopy .

Predictors of 7-day postendoscopic infection-related unplanned visits

Patient predictors

Age, sex, race, comorbidities and 30-day hospitalisation and endoscopic procedure history had statistically significant associations with 7-day postendoscopic infections (tables 3 and 4). History of hospitalisation within 30 days prior to the procedure was the strongest patient risk factor for postendoscopic infections followed by history of a gastrointestinal endoscopic procedure in the prior 30 days. For screening colonoscopy, patients 70 years and older had higher infection rates compared with those aged 50–59 years old. For non-screening colonoscopy and OGD, both younger and older age groups had higher infection rates than those aged 50–59 years old. Sex did not have any statistically significant associations with postendoscopic infections after screening or non-screening colonoscopy, although female patients were less likely to have an infection after OGD compared with male patients. Black race had higher infection rates compared with the white after screening and non-screening colonoscopy and OGD. Native American had higher rates of infection after screening colonoscopy compared with the white. Number of comorbidities and inflammatory bowel disease were also associated with higher odds of postendoscopic infections.

Procedure predictors

Invasiveness (eg, polyp removal) did not alter the risk of infection after screening colonoscopy (aOR (95% CI): 1.16 (0.82 to 1.65)) or non-screening colonoscopy (aOR (95% CI): 1.03 (0.87 to 1.22)), but lowered the risk of infections after OGD (aOR (95% CI): 0.82 (0.74 to 0.91)) (table 4). Concurrence with another gastrointestinal endoscopic procedure on the same day increased the odds of infections after screening colonoscopy (aOR (95% CI): 1.40 (1.14 to 1.71)) and non-screening colonoscopy (aOR (95% CI): 1.62 (1.44 to 1.82)), but decreased odds of infections after OGD (aOR (95% CI): 0.78 (0.72 to 0.85)).

Facility predictors

Procedure volume was the strongest predictor of postendoscopic infections (table 4). ASCs with higher volume had the lowest rates of postendoscopic infections. ASCs in New York had lower infection rates compared with those in Florida. ASCs that treated patients with active infection at the time of the procedure did not have statistically significant higher rates of postendoscopic infections.

The patient, procedure and facility predictors of site-specific infections, such as gastrointestinal and respiratory system

Table 3 Stratified infection-related and all-cause unplanned visit rates after colonoscopy, OGD or screening mammography at an ambulatory surgery centre stratified by prior hospitalisations and procedures, 2014

		Colonoscopy (n=1 376 208)						Mammography (n=647 212)	
		Screening (n=462 068)		Non-screening (n=914 140)		OGD (n=873 138)		Screening (n=647 212)	
		N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures
All eligible patients									
Infection-related unplanned visits	7-day	521	1.128	1432	1.566	2653	3.038	394	0.609
	30-day	1841	3.984	4933	5.396	9415	10.783	1884	2.911
All-cause unplanned visits	7-day	5366	11.613	15 005	16.414	30 216	34.606	4165	6.435
	30-day	14 637	31.677	38 382	41.987	66 301	75.934	15 392	23.782
Patients with history of hospitalisation within 30 days prior to procedure		Colonoscopy (n=11 088)						Mammography (n=2219)	
		Screening (n=2887)		Non-screening (n=8201)		OGD (n=18 924)		Screening (n=2219)	
		N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures
Infection-related unplanned visits	7-day	44	15.241	92	11.218	347	18.337	5	2.253
	30-day	129	44.683	297	36.215	1122	59.290	34	15.322
All-cause unplanned visits	7-day	242	83.824	660	80.478	2248	118.791	83	37.404
	30-day	567	196.398	1608	196.074	4880	257.874	284	127.986
Patients without history of hospitalisation within 30 days prior to procedure		Colonoscopy (n=1 365 120)						Mammography (n=644 993)	
		Screening (n=459 181)		Non-screening (n=905 939)		OGD (n=854 214)		Screening (n=644 993)	
		N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures
Infection-related unplanned visits	7-day	477	1.039	1340	1.479	2306	2.700	389	0.603
	30-day	1712	3.728	4636	5.117	8293	9.708	1850	2.868
All-cause unplanned visits	7-day	5124	11.159	14 345	15.834	27 968	32.741	4082	6.329
	30-day	14 070	30.642	36 774	40.592	61 421	71.904	15 108	23.424
Patients with history of gastrointestinal endoscopic procedure within 30 days prior to procedure		Colonoscopy (n=28 849)						Mammography (n=2311)	
		Screening (n=7241)		Non-screening (n=21 608)		OGD (n=28 080)		Screening (n=2311)	
		N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures
Infection-related unplanned visits	7-day	22	3.038	64	2.962	133	4.736	7	3.029
	30-day	66	9.115	232	10.737	460	16.382	17	7.356
All-cause unplanned visits	7-day	180	24.858	588	27.212	1117	39.779	28	12.116
	30-day	484	66.842	1516	70.159	2694	95.940	86	37.213
Patients without history of gastrointestinal endoscopic procedure within 30 days prior to procedure		Colonoscopy (n=1 347 359)						Mammography (n=644 901)	
		Screening (n=454 827)		Non-screening (n=892 532)		OGD (n=845 058)		Screening (n=644 901)	
		N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures	N of visits	Rate/1000 procedures
Infection-related unplanned visits	7-day	499	1.097	1368	1.533	2520	2.982	387	0.600
	30-day	1775	3.903	4701	5.267	8955	10.597	1867	2.895
All-cause unplanned visits	7-day	5186	11.402	14 417	16.153	29 099	34.434	4137	6.415
	30-day	14 153	31.117	36 866	41.305	63 607	75.269	15 306	23.734

OGD, osophagogastroduodenoscopy.

infections, were similar in direction and magnitude to the all infection results, except with wider CI (data not shown).

Variation in postendoscopic infection-related unplanned visits

ASCs with lower procedure volume had higher infection-related unplanned visit rates even after accounting for patient and procedure complexity (figure 1). There was wide variation in the adjusted rates of postendoscopic infections. For the 1047 ASCs that performed 10 or more screening colonoscopies in 2014, their facility-level case-mix adjusted rates of infection-related unplanned visits ranged from 0 to 115 per 1000 procedures. For the 1140 ASCs that performed 10 or more non-screening colonoscopies, their adjusted infection rates ranged from 0 to 132 per 1000 procedures. Adjusted rates for the 1151 ASCs that

Table 4 Patient, procedure and facility predictors of infection within 7 days after colonoscopy or OGD performed at an ambulatory surgery centre, 2014

		Screening colonoscopy (n=462 068)			Non-screening colonoscopy (n=914 140)			OGD (n=873 138)		
		% of all procedures	Infection-related unplanned visit rate/1000 procedures	Adjusted OR (95% CI)	% of all procedures	Infection-related unplanned visit rate/1000 procedures	Adjusted OR (95% CI)	% of all procedures	Infection-related unplanned visit rate/1000 procedures	Adjusted OR (95% CI)
Patient predictors										
Age*	0–9	Not applicable			0.2	4.5	2.63 (1.29 to 5.35)	1.1	8.8	3.18 (2.50 to 4.05)
	10–19				1.0	4.7	2.62 (1.89 to 3.65)	2.3	3.1	1.20 (0.92 to 1.56)
	20–29				3.0	2.4	1.76 (1.34 to 2.31)	4.6	3.4	1.43 (1.18 to 1.74)
	30–39				5.3	2.3	1.70 (1.36 to 2.12)	7.4	2.9	1.15 (0.97 to 1.36)
	40–49	7.6	1.4	1.28 (0.93 to 1.76)	8.9	1.7	1.29 (1.06 to 1.58)	12.6	2.7	1.02 (0.88 to 1.18)
	50–59	39.8	0.9	Reference	31.1	1.2	Reference	21.9	2.6	Reference
	60–69	32.1	1.0	1.09 (0.88 to 1.37)	28.9	1.3	1.05 (0.90 to 1.22)	24.2	2.7	0.96 (0.85 to 1.09)
	70–79	16.8	1.4	1.40 (1.09 to 1.78)	17.1	1.7	1.28 (1.09 to 1.51)	18.0	2.9	1.00(0.88 to 1.13)
	80–100	3.8	2.5	1.96 (1.39 to 2.76)	4.4	3.3	2.27 (1.85 to 2.78)	7.8	5.3	1.54 (1.35 to 1.77)
Sex	Male	42.6	1.1	Reference	47.1	1.5	Reference	40.7	3.3	Reference
	Female	57.4	1.1	0.94 (0.79 to 1.11)	52.9	1.6	1.06 (0.95 to 1.18)	59.3	2.8	0.89 (0.83 to 0.97)
Race	White	66.3	1.1	Reference	67.7	1.5	Reference	67.2	3.0	Reference
	Black	10.1	1.8	1.57 (1.22 to 2.01)	9.2	2.0	1.32 (1.11 to 1.56)	8.2	4.4	1.41 (1.25 to 1.60)
	Hispanic	15.0	1.3	1.11 (0.87 to 1.42)	14.1	1.6	1.04 (0.89 to 1.22)	15.4	2.9	0.99 (0.88 to 1.11)
	Asian or Pacific Islander	4.0	0.5	0.50 (0.27 to 0.96)	3.8	1.2	0.77 (0.57 to 1.07)	3.8	2.5	0.84 (0.67 to 1.05)
	Native American	0.3	4.1	3.68 (1.51 to 8.98)	0.3	2.4	1.64 (0.78 to 3.45)	0.3	3.3	1.09 (0.57 to 2.11)
	Other race	4.3	0.6	0.70 (0.39 to 1.25)	4.8	1.9	1.46 (1.16 to 1.83)	5.1	2.6	1.10 (0.57 to 2.11)
Hospitalisation within 30 days prior to procedure	Yes	0.6	15.2	9.41 (6.82 to 12.99)	0.9	11.2	5.34 (4.31 to 6.63)	2.2	18.3	5.11 (4.55 to 5.74)
	No	99.4	1.0	Reference	99.1	1.5	Reference	97.8	2.7	Reference
Gastrointestinal endoscopic procedure in an ASC within 30 days prior to procedure	Yes	1.6	3.0	2.64 (1.71 to 4.07)	2.4	3.0	2.20 (1.70 to 2.84)	3.2	4.7	1.45 (1.22 to 1.73)
	No	98.4	1.1	Reference	97.6	1.5	Reference	96.8	3.0	Reference
Inflammatory bowel disease coded on day of procedure †	Yes	Not applicable			3.9	2.9	1.72 (1.40 to 2.13)	1.0	4.4	1.51 (1.09 to 2.09)
	No				96.1	1.5	Reference	99.0	3.0	Reference
Elixhauser comorbidities	0	74.6	0.9	Reference	73.5	1.3	Reference	63.2	2.1	Reference
	1	14.5	1.4	1.23 (0.96 to 1.58)	15.0	2.2	1.40 (1.21 to 1.62)	20.3	3.8	1.45 (1.31 to 1.60)
	2–14	10.9	2.3	1.70 (1.32 to 2.19)	11.5	2.8	1.70 (1.46 to 1.99)	16.5	5.6	1.82 (1.63 to 2.02)
Procedure predictors										
Invasiveness‡	Yes	16.6	0.8	1.16 (0.82 to 1.65)	83.5	1.6	1.03 (0.87 to 1.22)	89.0	2.9	0.82 (0.74 to 0.91)
	No	83.4	1.2	Reference	16.5%	1.3	Reference	11.0%	4.3	Reference
Concurrence with another gastrointestinal endoscopic procedure	Yes	18.0	1.7	1.40 (1.14 to 1.71)	20.9	2.5	1.62 (1.44 to 1.82)	35.3	2.5	0.78 (0.72 to 0.85)
	No	82.0	1.0	Reference	79.1	1.3	Reference	64.7	3.3	Reference
Facility predictors										

Continued

Table 4 Continued

		Screening colonoscopy (n=462 068)			Non-screening colonoscopy (n=914 140)			OGD (n=873 138)		
		% of all procedures	Infection-related unplanned visit rate/1000 procedures	Adjusted OR (95% CI)	% of all procedures	Infection-related unplanned visit rate/1000 procedures	Adjusted OR (95% CI)	% of all procedures	Infection-related unplanned visit rate/1000 procedures	Adjusted OR (95% CI)
ASC state	Florida	40.4	1.4	Reference	39.8	1.7	Reference	42.4	3.0	Reference
	California	20.3	1.2	0.83 (0.64 to 1.07)	18.0	2.0	0.96 (0.82 to 1.12)	17.4	4.4	1.03 (0.92 to 1.14)
	Georgia	5.1	1.6	0.78 (0.53 to 1.13)	3.7	2.0	0.88 (0.68 to 1.15)	4.7	4.3	0.81 (0.68 to 0.95)
	New York	31.5	0.7	0.52 (0.38 to 0.71)	34.9	1.2	0.67 (0.58 to 0.78)	32.8	2.1	0.63 (0.57 to 0.70)
	Nebraska	1.6	1.8	1.18 (0.64 to 2.18)	2.1	1.4	0.67 (0.44 to 1.00)	2.0	3.9	0.82 (0.64 to 1.06)
	Vermont	1.1	0.2	0.16 (0.02 to 1.13)	1.6	0.9	0.58 (0.33 to 1.02)	0.7	2.5	0.62 (0.38 to 1.01)
Annual procedure volume (tertile)§	Low	2.8	2.2	Reference	2.8	2.6	Reference	2.8	5.7	Reference
	Middle	16.7	1.2	0.86 (0.57 to 1.31)	17.7	1.9	0.83 (0.63 to 1.08)	18.2	3.8	0.69 (0.58 to 0.84)
	High	80.5	1.0	0.77 (0.51 to 1.16)	79.5	1.4	0.82 (0.63 to 1.06)	79.0	2.8	0.69 (0.58 to 0.82)
Freestanding	Yes	46.2	0.9	0.67 (0.48 to 0.92)	44.1	1.2	0.84 (0.69 to 1.02)	41.5	1.8	0.76 (0.65 to 0.89)
	No	53.8	1.3	Reference	55.9	1.8	Reference	58.5	3.9	Reference
Multispecialty	Yes	63.6	1.2	0.77 (0.58 to 1.02)	64.2	1.8	1.07 (0.90 to 1.28)	65.8	3.7	1.16 (1.00 to 1.36)
	No	36.4	1.0	Reference	35.8	1.2	Reference	34.2	1.8	Reference
Proportion of procedures performed on patients with infection coded on day of procedure	0%	1.2	1.5	Reference	1.6	1.5	Reference	1.3	2.0	Reference
	>0%–5%	80.9	1.0	0.72 (0.35 to 1.48)	79.6	1.4	0.76 (0.50 to 1.16)	76.7	2.7	1.15 (0.75 to 1.74)
	>5%–50%	17.9	1.6	0.80 (0.38 to 1.68)	18.7	2.3	0.86 (0.55 to 1.34)	22.0	4.4	1.24 (0.81 to 1.89)

NA: not applicable. Adjust ORs were calculated from multivariable models adjusting patient, procedural and facility predictors.
*Screening colonoscopies coded for patients younger than 40 years old were reclassified as non-screening colonoscopies.
†Screening colonoscopies coded for patients with inflammatory bowel disease were reclassified as non-screening colonoscopies.
‡A procedure was defined as invasive if gastrointestinal mucosa was likely disrupted during the procedure.
§Screening colonoscopy volume tertiles: lowest 1–90, middle 91–370, highest 371–6645. Non-screening colonoscopy volume tertiles: 1–165, 166–730, 731–7597. OGD volume tertiles: 1–163, 164–693, 694–5944.
ASC, ambulatory surgery centre; OGD, osophagogastroduodenoscopy.

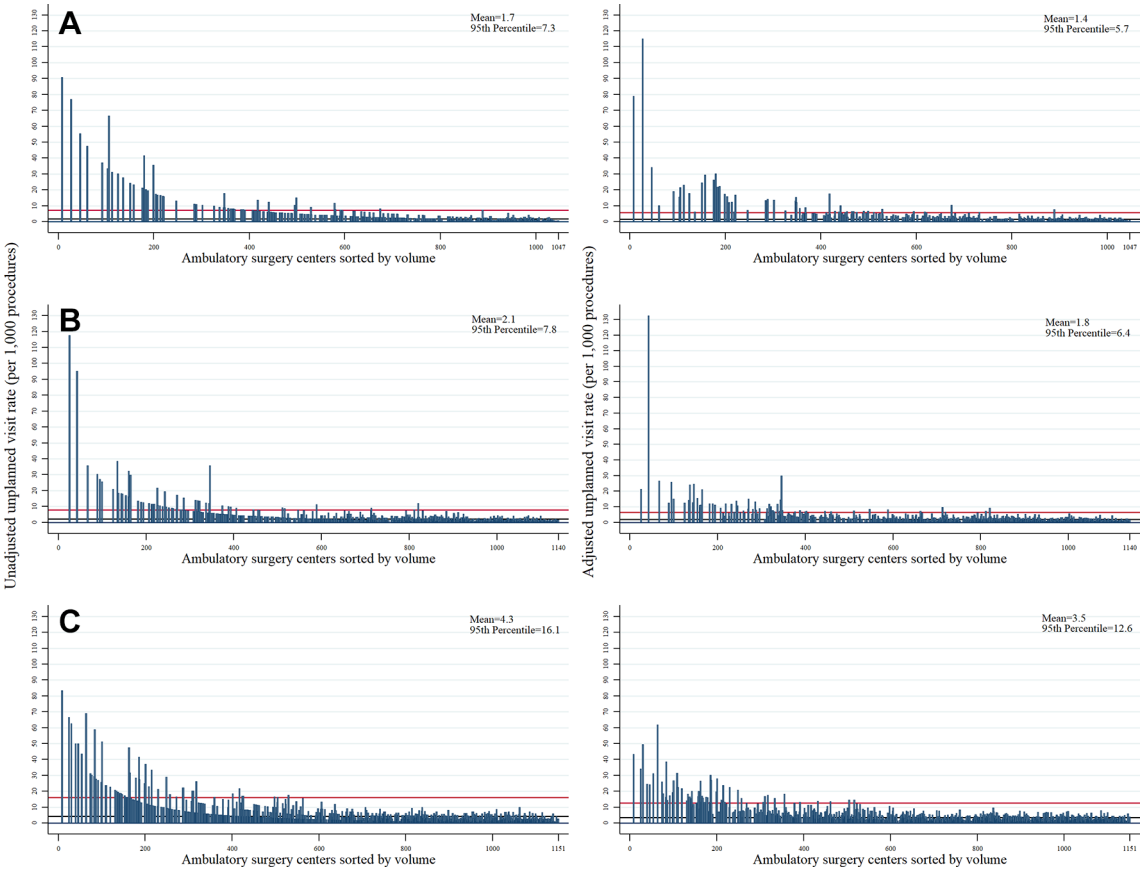

Figure 1 Volume-driven variation in the rates of infection-related unplanned visits within 7 days after colonoscopy or OGD among ASCs performing 10 or more procedures in 2014. (A) Screening colonoscopy (number of ASCs=1047). (B) Non-screening colonoscopy (number of ASCs=1140). (C) OGD (number of ASCs=1151). The graph on the left shows the unadjusted unplanned visit rates. The graph on the right shows the adjusted unplanned visit rates, adjusting for patient and procedure predictors listed in table 4. Each vertical navy bar in the graph represents an ASC. The horizontal black line indicates the mean rate. The horizontal red line indicates the 95th percentile. ASC, ambulatory surgery centre; OGD, osophagogastroduodenoscopy.

performed 10 or more OGDs ranged from 0 to 62 per 1000 procedures. In contrast, we observed small variation in the adjusted infection rates after screening mammography, ranging from 0 to 8 per 1000 examinations for the 220 ASCs with examination volume of 10 or greater.

DISCUSSION

Postendoscopic infections occur in more than 1 out of 1000 procedures for screening colonoscopy and more than 3 out of 1000 for OGD. These rates are twofold to fivefold higher than the infection rate after a screening mammography, but lower than bronchoscopy and cystoscopy. About 1 out of 5 postcolonoscopic infections and 1 out of 8 post-OGD infections involve the gastrointestinal system, 5–10 times higher than the rate of gastrointestinal infections after screening mammography. The rate of postendoscopic infections varies widely by ASC with a range of 0%–12.3% for screening colonoscopy, 0%–12.8% for non-screening colonoscopy and 0%–4.7% for OGD. ASC annual procedure volume is the strongest facility factor associated with risk of infection with the lowest relative risk after procedures performed in high-volume ASCs. Patients who were hospitalised within 30 days prior to a procedure have a greater than fivefold risk of postendoscopic infection compared with non-hospitalised patients. These findings have implications for the choice of facility to undergo an endoscopic procedure. The timing of procedures after hospitalisation should be carefully considered to prevent postendoscopic infections among recently hospitalised patients.

Despite the millions of endoscopic procedures performed annually in the USA, prior studies have not comprehensively examined postendoscopic infections. One study based on all-payer claims of California between 2005 and 2011 investigated the rate of pneumonia and bacteraemia after colonoscopy.[20] They identified a 7-day pneumonia rate of 2.7–4.4 per 10 000 procedures that was comparable with our estimate of 2.9–3.0 in 2014. Their 7-day bacteraemia (ICD-9-CM 790.7) rate estimate of 0.2–0.3 per 10 000 procedures was lower than our estimate of 1.9–2.6 for septicaemia (ICD-9-CM 038). We also calculated rates for a larger group of infections and comparison groups in our comprehensive examination.

Other studies mainly focused on cases of specific infections identified in outbreak investigations. Case reports published between 1981 and 1999 documented four cases of hepatitis C and two cases of hepatitis B after flexible sigmoidoscopy or colonoscopy and attributed to inadequate device cleaning.[21–24] Between 1974 and 2001, 138 *Pseudomonas aeruginosa* infection cases and 3 hepatitis B cases were reported after OGD and also attributed to inadequate cleaning.[25–32] According to a systematic review, there were only seven identified cases of endocarditis between 1966 and 2002 associated with OGD in the USA.[33 34] However, we identified six endocarditis cases within 7 days after OGD in a single year in a 31% sample of the US population.

Our findings suggest that postendoscopic infections are occurring without being detected by existing surveillance systems. Although the rates of infection after colonoscopy and OGD are higher than previously thought, they are still relatively low compared with other endoscopic procedures such as bronchoscopy and cystoscopy. The comorbidities and indications across the endoscopic procedures likely drive these rate differences. Prior encounters with the healthcare system were strong predictors of infections after gastrointestinal procedures.

Microorganisms thought to be most closely related to gastrointestinal endoscopic procedures include *E. coli*, *Klebsiella* spp., *P. aeruginosa* and *Salmonella* spp.[34] We did observe relatively high rates of infections due to these organisms in the 2014 administrative claims data. For colonoscopy and OGD, the 7-day postendoscopic infection rate ranged from 0.084 to 0.199 per 1000 procedures for *E. coli* infection, 0.022–0.064 for *K. pneumoniae* and 0.008–0.047 for *Pseudomonas*, 3-fold to 24-fold higher compared with postmammography. This might also suggest that claims data have value for evaluating postendoscopic infection outcomes. While focusing on infections within 7 days maximised the specificity, infections with longer incubation periods were likely underestimated. For example, it was possible that we underestimated the rate of human papillomavirus infection. A lab-based study suggested human papillomavirus was not adequately killed by the disinfectants used for high-level disinfection.[35]

Hospitalisation for infectious pneumonia was common among the infections. We evaluated the infectious pneumonia codes (ICD-9-CM codes: 482.89, 482.9 and 483.8) that could represent misclassified aspiration pneumonia.[16] Our results showed that these three codes only consisted a small fraction of all infectious pneumonia (2.8%–3.7%), suggesting that very few of the infectious pneumonia cases we identified were potentially misclassified aspiration pneumonia. In addition, the twofold higher rates of infectious pneumonia after colonoscopy or OGD compared with screening mammography suggests that endoscopy is associated with greater rates than the background occurrence of pneumonia. Our estimates of 7-day respiratory infection rates after screening mammography and prostate screening were 0.4 and 0.9 per 1000, lower than the estimates reported for another background comparison group, healthcare workers. Two Chinese studies of 223 and 481 healthcare workers in emergency or respiratory wards reported the weekly incidence of clinical respiratory infection to be around 18/1000 for viral or bacterial infection.[35 36]

We found no significant difference in the risk of infections or aspiration pneumonia between colonoscopy procedures performed with and without general anaesthesia. Our estimates of aspiration pneumonia rate were 0, 0.119 and 0.341 per 1000 procedures for screening, non-screening colonoscopy and OGD. These estimates were comparable with a prospective multicentre study (ProSed2) that observed an aspiration event rate of 0.23 per 1000 gastrointestinal endoscopy procedures performed under sedation.[37]

Our findings are of particular importance for ASCs, which usually do not have their own infection control units and to which patients are unlikely to come back to seek care for their postendoscopic infections. These factors greatly impede the identification of infection-related complications at ASCs and can result in undetected infectious outbreaks that can profoundly harm many patients. Our study shows that ASCs had great variation in the rate of infection-related complications even after accounting for patient and procedure complexity. The infection rates observed at some low-procedure-volume ASCs were over 100 times more than the rates we would expect to see had patients received procedures at an average ASC. Therefore it is critically important for providers and patients to know the ASC-specific risks of postendoscopic infections for informed decision making about colorectal cancer screening and the most appropriate approach to diagnose and treat symptomatic conditions. Individuals with average risk of colorectal cancer should consider receiving non-invasive tests such as faecal occult blood test and faecal immunochemical test annually or biannually or a combination of colonoscopy and non-invasive tests at appropriate intervals as recommended by their national health policies.[38 39] Similarly, judicious use of endoscopic procedures shortly after hospitalisation or increased vigilance or prophylaxis for infection should be considered as these patients had the highest risk of postendoscopic infections. Disposable endoscopes could be considered for patients at high risk of acquiring or transmitting infections.[40 41]

Our all-cause unplanned visit findings were similar to the estimate of 16.3 all-cause unplanned visits within 7 days per 1000 colonoscopies in the 20% sample of 2010 Medicare data used to create the CMS measure.[9] However, the CMS colonoscopy quality measure (ID 2086) has been questioned by experts in the gastroenterology community due to concerns that it might disincentivise endoscopic resection of precancerous lesions. Biopsies are associated with perforation and bleeding and may increase the all-cause unplanned visit rate, despite the benefit of biopsies for patients. Focusing on all-cause visits may also disincentivise providers to treat the most challenging patients at higher risk of a procedure-associated complication.[36 37] In contrast, our facility-level adjusted infection-related unplanned visit rate specifically reflects the real quality of care, as the rate of postendoscopic infections should be zero, especially for screening colonoscopy.

The infection rates in this study can serve as a baseline estimate of the current burden of postendoscopic infection-related complications. Our findings can also serve as the scientific foundation for decision makers to identify if targeted interventions are needed in endoscopy units at ASCs to prevent the incidence of postendoscopic infections, similar to the interventions targeted to surgical and intensive care units to prevent the healthcare-associated infections in those settings.

Our study has a few limitations. We used all-payer claims data from six states in the USA because linkable all-payer data are not available nationally. Our results are likely generalisable to the whole country because together these six states have similar sex, racial and age composition as the national population and make up 31% of the US population. Although we examined the history of hospitalisation and endoscopic procedure within 30 days prior to the procedure as predictors and analysed unplanned visits within 7 days after the procedure as the outcome, we did not wash out procedures performed during the first 30 days and the last 7 days in 2014 due to lack of real service utilisation dates and months in the claims data of some states. This could result in an underestimation of the infection rates because we were not able to capture all possible outcomes for procedures performed during the last 7 days of 2014 and were not able to adjust for all hospitalisations that occurred 30 days prior. Our study shares the general limitations of claims-based research, such as flaws in billing codes and limited clinical details to determine causality. The procedure codes for sedation (CPT codes: 00810, 99 143–99145, 99 148–99150) was only coded in 1.0% of colonoscopy and 0.9% of OGD cases, so we were not able to study the impact of sedation on infection rates in most states, a limitation shared by another study using the same database.[20] It is difficult to prove a definite causal relationship between the

endoscopic procedures and infections without individual case investigation and microbiological testing of the endoscopes and facility environment. However, we tried to maximise the specificity of our outcome definition by excluding patients with a diagnosis of infection at the time of procedure and restricting the timeframe of infections to 7 days after procedures for the primary analyses. Because only 2014 data were available in this claims database, we were not able to compare the long-term risks and benefits between colonoscopy, OGD and non-invasive alternatives.

CONCLUSION

Our results suggest that infection-related complications after colonoscopy and OGD were much more common than previously thought and that the adjusted infection rates varied widely by ASC. Quality reporting may prevent ASC-specific postendoscopic infections. In addition, these data could inform shared decision making.

Contributors PW participated in study design, data analysis and wrote the first draft of the manuscript. SH conceived the study idea, oversaw the research project and participated in study design, data analysis and manuscript drafting and editing. SN and AK contributed to study design and manuscript editing. TX and MAM contributed to manuscript editing.

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