



Outpatient facility volume, facility type, and the risk of serious colonoscopy-related adverse events in patients with comorbid conditions: a population-based study

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Abstract

Purpose Patients with a chronic comorbidity or multiple comorbidities are at much greater risk of serious colonoscopy-related gastrointestinal (GI) adverse events relative to patients with no comorbidity. It is important to identify outpatient facilities that can effectively and safely provide colonoscopy to complex patients. To address this need, the association between outpatient facilities' complex care volume and type (ambulatory surgery center (ASC) and hospital outpatient department (HOPD)) and the risks of serious GI adverse events in colonoscopy patients with single and multiple chronic comorbidities were examined.

Methods Outpatient colonoscopies of 1,020,372 patients with single and multiple comorbidities were investigated, using a retrospective cohort study. Thirty-day hospitalizations due to colonic perforations and GI bleeding were examined. Ambulatory surgery and hospital discharge datasets from California, Florida, and New York for 2006–2009 were used.

Results Higher complex care volume was associated with lower risks of adverse events in patients with comorbidities (OR 1.69; 95% CI [1.13, 2.54]). ASCs had higher risks of adverse events in patients with comorbidities relative to HOPDs (OR 2.85; 95% CI [2.40, 3.38]). Patients with single and multiple comorbid conditions, patients with systemic diseases, and complex patients of advanced age had higher risks of adverse events.

Conclusions Referring patients with single and multiple chronic comorbidities to facilities experienced in treating complex patients, or HOPDs, may reduce colonoscopy-related adverse events.

Keywords Outpatient colonoscopy · Chronic comorbid conditions · Adverse events · Freestanding ambulatory surgery centers · Hospital-based outpatient departments

Introduction

Cancer screening may prevent an onset of cancer with an estimated 1.73 million new cases diagnosed in the USA in 2018 [1]. Outpatient colonoscopy is the preferred method of colorectal cancer (CRC) screening and prevention [2], as 15 million colonoscopies were provided in 2015 in the USA [3].

With increasing patient complexity and aging population, it is expected that more patients with chronic comorbidities will undergo colonoscopy in the USA. Outpatient colonoscopy is considered a safe procedure, but patients with a chronic comorbidity [4] or multiple comorbidities [5] are at much greater risks of serious colonoscopy-related gastrointestinal (GI) adverse events relative to patients with no comorbidity. It is important to identify outpatient facilities that can effectively and safely provide colonoscopy to clinically complex patients, i.e., those with multiple comorbidities.

Prior research finds that patients treated in high-volume hospitals for surgical and therapeutic services have better outcomes [6]. In addition, high-volume providers of outpatient colonoscopy are associated with lower rates of adverse events in comparison with low-volume providers in a general patient population [7]. In this study, we rank outpatient facilities according to their annual complex care volume of colonoscopy procedures to identify whether

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volume is associated with reduced adverse events in patients with comorbidities. We hypothesize that increases in an outpatient facility's colonoscopy volume are associated with lower risks of serious colonoscopy-related adverse events in patients with comorbid conditions.

In addition, it is largely unknown which outpatient facility type may be best suited for patients with comorbidities undergoing colonoscopy. Comparative effectiveness research reports mixed findings of colonoscopy outcomes for freestanding ambulatory surgery centers (ASCs) and hospital-based outpatient departments (HOPDs) [8–10]. ASCs, sometimes described as highly specialized “focused factories,” may follow evidence-based clinical pathways and improve patient outcomes, regardless of the volume of services [6, 11]. HOPDs, in contrast, provide a wide array of services, possess capabilities and resources, including intensive care, surgical consult, health information technology (HIT), and additional staff that may improve patient outcomes [8]. As both ASCs and HOPDs may improve outpatient care processes and subsequent colonoscopy outcomes for clinically complex patients, we hypothesize that there is a difference in the risks of serious colonoscopy-related adverse events in patients with comorbid conditions treated at either ASCs or HOPDs. We rely on empirical analyses of large claims data to identify an effective type of outpatient colonoscopy provider for complex patients.

Materials and methods

Healthcare Cost and Utilization Project's (HCUP) State Ambulatory Surgery and Services Databases (SASD) and State Inpatient Databases (SID) from California, Florida, and New York for 2006–2009 were used. These datasets provide all-payer, encounter-level, and discharge data that include encrypted patient identifiers, primary and secondary diagnoses as classified by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), dates of outpatient procedures and inpatient admissions, primary and secondary procedure codes based on Current Procedural Terminology (CPT), facility types, and other patient demographic characteristics. We describe exclusions and inclusion criteria in Fig. 1. The analytical sample of 1,020,372 procedures was derived.

Patient outcomes

Thirty-day unplanned hospital admissions due to serious gastrointestinal adverse events

Thirty-day unplanned hospitalizations due to colonic perforations and serious GI bleeding were the outcomes of interest and a common colonoscopy-specific measure of quality.

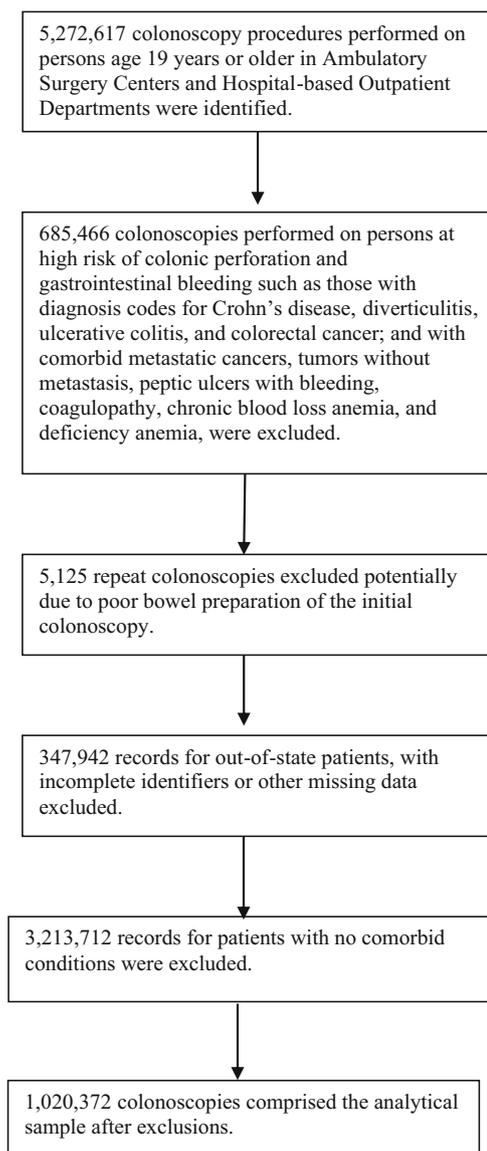


Fig. 1 Analytic sample of outpatient colonoscopy in California, Florida, and New York, 2006–2009

These serious adverse events (SAEs) are rare, but significant contributors to patient morbidity, mortality, and high cost of care [12]. Primary diagnosis codes in the hospital discharge datasets were used for colonic perforations (ICD-9-CM: 569.83, 998.2), GI bleeding (ICD-9-CM: 578, 578.1, 578.9, 998.1) that also included acute post-hemorrhagic anemia (ICD-9-CM: 285.1) and blood transfusion (ICD-9-CM: 280–284.9, 285.2–285.9, 99.03, 99.04) [13]. We also excluded observations with primary diagnoses of Crohn's disease, ulcerative colitis, colorectal cancer, and other serious GI conditions. These exclusions are likely to result in an underestimate of the incidence of serious adverse events; however, they are warranted as colonic perforations and GI bleeding may be complications of the excluded diagnoses and confound adverse events due to colonoscopy.

Comorbid conditions

We applied Elixhauser's methodology [14] to identify 29 comorbid conditions using all secondary ICD-9-CM codes available in outpatient and inpatient datasets. Metastatic cancers, tumors without metastasis, peptic ulcers with bleeding, coagulopathy, chronic blood loss anemia, and deficiency anemia were excluded as these conditions were potentially correlated with increased risks of colonic perforations or GI bleeding. We also excluded all patients without a comorbidity from the analysis.

Patients with seven common, single comorbidities—hypertension, diabetes without chronic complications, chronic pulmonary disease, hypothyroidism, obesity, depression, and fluid and electrolyte disorders—were identified in both—ASC and HOPD—facility types. We developed indicator variables for each of these comorbidities.

Patients with 17 uncommon (i.e., having less than 1% prevalence in the study population), single comorbid conditions—valvular disease, weight loss, neurological disorders, peripheral vascular disease, liver disease, renal failure, congestive heart failure, rheumatoid arthritis/collagen vascular disease, psychoses, diabetes with chronic complications, alcohol abuse, drug abuse, paralysis, pulmonary circulation disease, lymphoma, acquired immune deficiency syndrome (AIDS)—were aggregated as a single indicator variable—rare comorbidities. We then identified each patient with two or more comorbidities and developed an indicator for multiple chronic conditions (MCC) or multimorbidity. These indicators—seven single comorbid conditions, rare comorbidities, and multiple chronic conditions [4]—were used as control variables, where the MCC was the reference category.

Outpatient facility characteristics

Facility type We categorized the outpatient facilities as ASC and HOPD. An indicator variable was created to designate the type of outpatient facility where the patient received the colonoscopy procedure.

Facility volume of multiple chronic conditions Annual outpatient facility volume was calculated as the total number of complex care patients with multiple chronic comorbidities undergoing outpatient colonoscopy. The quartiles of the outpatient facility volumes were calculated for each year. A high total complex care (TCC) volume quartile was the reference category. Each facility was then assigned to one of four TCC volume quartiles that were allowed to vary from year to year for the study period (2006–2009). Volume measures are commonly used as proxies of health care facility and provider experience and ability to improve quality of care and patient outcomes [6].

Colonoscopy procedures

Six colonoscopy procedure categories were identified as (1) simple colonoscopy—colonoscopy without polypectomy (reference), which included diagnostic colonoscopy (CPT 45378); (2) colonoscopy with the cold biopsy forceps used for single or multiple biopsies (CPT 45380); (3) polypectomy by ablation (CPT 45383); (4) polypectomy by hot biopsy forceps or bipolar cautery forceps (CPT 45384); (5) polypectomy by snaring (CPT 45385); (6) multiple colonoscopy procedures or those with any form of cautery (e.g., CPT 45380, 45383, 45384, and 45385) that were performed during the same episode [13]. We defined complex colonoscopy procedures as polypectomies in categories 4–6 (i.e., hot forceps, snaring, and multiple procedures) relative to categories 1–3 (i.e., simple colonoscopy, cold forceps, and ablations). These measures were used to control for complexity of colonoscopy that was potentially correlated with a severity of the index disease, multiplicity, and type of polyps removed using different colonoscopy techniques [13].

Patient characteristics

Prior research reported variations in outpatient quality of care by patient age, race/ethnicity, sex, and health insurance types [13, 15]. We categorized patient age as 19–49 (reference), 50–64, 65–74, 75–84, and ≥ 85 years old. Clinical recommendations and health policy relevance informed age categories for this study. Outpatient colonoscopy for colorectal cancer screening, among other methods, is recommended in adults, beginning at age 50 years and continuing until age 75 years. Medicare covers outpatient colonoscopy in adults at age 65 years and older. Screening colonoscopy is usually not recommended at age 75 years and should be avoided in those older than 85 years. We also included adults younger than 50 years for whom colonoscopy may be recommended due to symptoms, a family history of colorectal cancer, and other reasons. We included race/ethnicity variables as white (reference), Hispanic, black or African American, or other (including unknowns). Sex was a binary variable (male as the reference). Indicator variables for Medicare (reference), Medicaid, private, selfpay or charity, and other insurance-represented health insurance types were included. We also included a set of dummy variables for each study year (2006 (reference)–2009) and state (California (reference), Florida, and New York).

Statistical analysis

In descriptive analyses, patient characteristics and facility types were examined for each volume TCC quartiles. Unadjusted rates for serious adverse events were calculated by dividing the total numbers of adverse events in patients with MCC by the total number of colonoscopies

in patients with any comorbidity per 10,000 outpatient procedures. Unadjusted rates of SAEs were estimated for outpatient facilities.

The critical parameters of interest were the odds ratio for 30-day unplanned hospital admissions due to serious gastrointestinal (GI) adverse events for the different levels of facility volume (TCC quartiles) and to compare these estimates in ASC and HOPD facilities.

Univariate analyses were conducted to evaluate differences between all independent variables and differences in rates of adverse events, and facility volume quartiles. We then applied a logistic regression model to estimate the odds ratios on the full sample that included both facility types and stratified by the facility type (i.e., ASC or HOPD). Stratified analyses were conducted to account for the effect modification of facility volume and types. The logistic regression models assume a linear relation between the logit function of the probability of the 30-day unplanned hospital admissions due to serious GI adverse events and the covariates on the right-hand side of the equation. We controlled for the potential effect state level policies by adding the state fixed effects and used the generalized estimating equations (GEE) model with repeated measurements to account for clustering of patients within facilities.

Odds ratios were estimated to evaluate the magnitude and direction of the effect for the key parameters of interest as the exponents of the parameter coefficients. All models detected associations among key independent variables (facility volume and organizational types) with the serious adverse events (SAE), after adjusting for differences in comorbidities, colonoscopy procedure types, patient characteristics, insurance types, and other statistical controls. For individual statistical tests, a *p* value less than 0.01 was considered statistically significant given the large sample size. The study was approved by the Virginia Commonwealth University's institutional review board. We applied the Firth penalized likelihood logistic regressions to reduce small sample bias in the maximum likelihood estimation of the probabilities of rare events [16].

Results

Descriptive analyses

HOPDs provided colonoscopies to about 72% of patients with any—single and multiple—comorbidities (Table 1). HOPDs treated more patients with MCC relative to ASCs in all TCC volume categories from 56.56% in the lowest quartile to 77.62% in the highest volume quartile for HOPDs. The percent of patients with single comorbidities treated at facilities in different volume categories was relatively similar. More complex colonoscopy procedures (9.42%), snares (14.15%), and cold biopsies (21.87) were provided by high-TCC volume

relative to low-TCC volume facilities (7.88%, 13.29%, and 19.06%, respectively) and more simple colonoscopies (47.3%), ablations (2.03%), and hot biopsies (10.44%) were provided by low-TCC-volume relative facilities (46.09%, 1.18%, and 7.52%, respectively). High-TCC volume facilities cared for more patients in 50–64 age category (45.76%) in comparison with low-volume facilities (41.94%).

Hypertension (4.00%), diabetes (3.70%), chronic pulmonary disease (2.98%), obesity, depression, and fluid and electrolyte disorders (6.68%) were common single conditions. Over 45% of patients had single, but rare chronic conditions. Over 34% of patients had two of more chronic conditions. Similar patterns were observed by volume quartiles.

Fewer patients in 19–49 age category (9.94%) and elderly patients in 75–84 (15.35%) and > 85 (2.22%) categories were treated by high-TCC volume providers relative to low-volume facilities (12.34%, 16.16%, and 3.10%, respectively). More female, White, and Hispanic patients received colonoscopies at low-TCC volume facilities. Low-TCC volume facilities provided colonoscopy to a higher proportion of Medicare beneficiaries; while high-TCC volume providers treated more patients with indemnity insurance (Table 1). More Floridians received colonoscopies in low-TCC volume facilities; residents of California and New York were more likely to be treated in high-TCC volume facilities (Table 1).

The unadjusted rates of SAEs per 10,000 were 19.89 in low-volume facilities and 9.44 in high-volume facilities in both ASCs and HOPDs (Table 2). For HOPDs, the SAE rates were 15.18 in low-volume and 5.57 in high-volume, facilities. For ASCs, they were 26.01 and 22.85, respectively (Table 2). The rates of SAEs were lower for those of HOPDs relative to ASCs in all volume quartiles. In addition, HOPDs provided a greater number of colonoscopies to complex patients than ASCs in all volume quartiles (Table 2).

Multivariate analyses

Table 3 presents results for patients with comorbidities treated in both HOPDs and ASCs (Model 1), as well as stratified analyses by ASC or HOPD types. The odds of SAEs in ASC patients with comorbidities were greater than that in HOPD patients with comorbidities (OR 2.85; 95% CI [2.40, 3.38]). When comparing odds of SAEs by volume quartiles for patients in both HOPDs and ASCs, we observe consistent, statistically significant pattern of higher odds of SAEs for lower volume quartiles in comparison with the referent highest volume quartile: for quartile 3 (OR 1.33; 95% CI [1.12, 1.58]), quartile 2 (OR 1.39; 95% CI [1.10, 1.75]), and quartile 1 (OR 1.69; 95% CI [1.13, 2.54]), respectively. A similar pattern was observed for HOPDs in a stratified analysis, where higher odds of SAEs were statistically significant by quartile (quartile 3 (OR 1.75; 95% CI [1.32, 2.33]), quartile 2

Table 1 Characteristics of colonoscopy patients with comorbidities by facility's total complex care volume quartiles in California, Florida, and New York, 2006–2009

	Volume quartile 1	Volume quartile 2	Volume quartile 3	Volume quartile 4	Total
Complex cases	22,127	95,131	234,334	668,780	1,020,372
HOPD (%)	56.56	57.94	63.92	77.62	72.18
ASC (%)	43.44	42.06	36.08	22.38	27.82
Hypertension (%)	4.09	3.80	3.88	4.06	4.00
Diabetes w/o chronic complications (%)	3.66	3.45	3.57	3.79	3.70
Chronic pulmonary disease (%)	2.40	2.52	2.70	3.17	2.98
Hypothyroidism (%)	1.42	1.19	1.14	1.27	1.24
Obesity (%)	1.38	1.47	1.49	1.71	1.63
Depression (%)	1.09	0.93	0.76	0.48	0.60
Fluid and electrolyte disorders (%)	8.12	7.90	7.49	6.18	6.68
Rare comorbidities (%)	46.26	48.07	47.35	43.95	45.17
Two or More Comorbidities (%)	31.58	30.67	31.61	35.39	34.00
Simple procedure (%)	47.30	44.90	46.48	46.09	46.10
Cold biopsy by forceps (%)	19.06	22.11	21.01	21.87	21.63
Ablation (%)	2.03	1.78	1.46	0.97	1.18
Hot biopsy/cautery by forceps (%)	10.44	8.42	7.84	7.18	7.52
Snare (%)	13.29	13.59	14.3	14.21	14.15
Complex Colonoscopy (%)	7.88	9.20	8.91	9.68	9.42
Ages 19–49 (%)	12.31	10.60	10.19	9.94	10.11
Ages 50–64 (%)	41.94	41.25	42.40	45.76	44.48
Ages 65–74 (%)	26.49	27.8	27.68	26.73	27.05
Ages 75–84 (%)	16.16	17.53	17.00	15.35	15.95
Ages > 85 (%)	3.10	2.82	2.73	2.22	2.41
Male (%)	45.51	46.18	46.6	46.25	46.31
Female (%)	54.49	53.82	53.4	53.75	53.69
White (%)	74.07	73.46	73.16	71.21	71.94
Hispanic (%)	10.32	9.48	8.46	9.56	9.31
Black/African American (%)	9.22	9.85	10.99	12.25	11.67
Other/unknown (%)	6.39	7.21	7.39	6.98	7.08
Medicare (%)	46.03	46.71	45.8	41.56	43.11
Medicaid (%)	5.44	6.46	7.11	5.73	6.11
Indemnity (%)	43.04	41.39	42.76	47.84	45.97
Self-pay/charity (%)	1.94	2.11	1.62	2.02	1.93
Other payers (%)	3.55	3.33	2.71	2.85	2.88
California (%)	17.81	22.14	25.20	30.90	28.50
Florida (%)	70.14	56.04	45.83	40.64	43.90
New York (%)	12.05	21.82	28.97	28.46	27.60

ASC ambulatory surgery centers, HOPD hospital-based outpatient departments. In univariate analyses, we evaluated associations between all independent variables, facility volume categories, or rates of serious adverse events. All the differences were statistically significant at the p value > 0.001

(OR 1.90; 95% CI [1.28, 2.83]), and quartile 1 (OR 2.70; 95% CI [1.50, 4.86])). As for ASCs, volume quartiles had no statistically significant associations with the odds of SAE in a stratified analysis.

In addition, the odds of SAEs in patients with seven single comorbid conditions were significantly lower than those relative to patients with MCC. However, the odds ratio in patients

with fluid and electrolyte disorders was statistically significantly greater than those in patients with MCC treated at both facility types (OR 2.99; 95% CI [1.94, 4.74]), HOPDs (OR 6.45; 95% CI [3.46, 12.02]), and ASCs (OR 1.92; 95% CI [1.05, 3.66]), respectively. In addition, there was no statistically significant difference in the odds of SAEs for patients with obesity relative to patients with MCC.

Table 2 Serious adverse events in patients with comorbidities by facility's total complex care volume quartiles at ASCs and HOPDs in California, Florida, and New York, 2006–2009

		Volume quartile 1	Volume quartile 2	Volume quartile 3	Volume quartile 4
HOPD and ASC (<i>n</i> = 90)*	Patients with comorbidities	22,127	95,131	234,334	668,780
	Serious adverse events	44	161	363	631
	Rate of SAE per 10,000	19.89	16.92	15.49	9.44
HOPD (<i>n</i> = 58)*	Patients with comorbidities	12,516	55,122	149,777	519,087
	Serious adverse events	19	61	153	289
	Rate of SAE per 10,000	15.18	11.07	10.22	5.57
ASC (<i>n</i> = 32)*	Patients with comorbidities	9611	40,009	84,557	149,693
	Serious adverse events	25	100	210	342
	Rate of SAE per 10,000	26.01	24.99	24.84	22.85

*Average number of facilities (providers of colonoscopy to patients with comorbidities) in operation per year; ASC ambulatory surgery centers, HOPD hospital-based outpatient departments. In univariate analyses, we evaluated associations between facility volume categories and rates of serious adverse events. All the differences were statistically significant at the *p* value > 0.001

The odds of SAEs were greater for patients undergoing more complex procedures relative to simple colonoscopy (Table 3). Cold biopsy with forceps was identified as a safe procedure provided in all facility types. Finally, the odds of SAEs were significantly greater in clinically complex patients of advanced age (Table 3).

Discussion and conclusion

Even though chronic comorbidities present serious health and health care issues to patients and health care providers, limited research is available on quality performance of outpatient facilities providing colonoscopy to clinically complex patients. We assessed risks of SAEs in patients with comorbidities treated at HOPDs and ASCs that may employ a generalist or a specialist strategy, respectively. This study also evaluated the risks of serious gastrointestinal bleeding and colonic perforations in patients with comorbidities undergoing outpatient colonoscopy at high-volume and low-volume facilities that may be related to provider experience in managing complex patients. We found a consistent pattern, where high complex care volume facilities were associated with decreased odds of SAEs. Our data demonstrated that HOPDs provided colonoscopy to the majority of patients with comorbidities (72%). In a stratified analysis, a positive volume-outcome association was reported for HOPDs. Moreover, lower odds of SAEs were reported for patients with comorbidities treated at HOPDs relative to ASCs. Finally, having multiple comorbid conditions was associated with higher odds of SAEs in comparison with having a single comorbidity. The exceptions were single comorbidity for fluid electrolyte disorders that were associated with greater odds and obesity that had comparable odds of SAEs, relative to MCC.

Outpatient facilities experienced in managing high volume of patients with comorbidities may serve as referral centers for the clinically complex population in need of colonoscopy. Experienced providers may have developed effective clinical processes to prevent SAEs or resolve SAEs in complex patients. HOPDs may serve as referral centers for patients with comorbidities. HOPDs are an integral part of health systems that may have capacity, resources, and staff to reduce risks of colonoscopy associated with patient severity. Hospital-wide, innovative complex care programs may benefit patients with comorbidities receiving colonoscopy at HOPDs. Effective referral strategies to other inpatient units may be employed at HOPDs on a timely basis for patients experiencing adverse episodes during colonoscopy. Our findings also suggest that patients without comorbidities may be effectively treated at ASCs.

Our study provides additional evidence of risks associated with specific comorbidities for clinically complex patient populations. Comorbid conditions contribute to patient frailty and increase adverse drug events due to polypharmacy, as well as patients' poorer physical and social functioning [17, 18] may prevent them from adhering to pre- and post-colonoscopy recommendations. Some comorbidities may contribute to manifestation of clinical GI symptoms, such as advanced polyposis, that require complex polypectomies prone to adverse events. In addition, patients with single, but systemic disease or condition—fluid and electrolyte disorder and obesity—had either increased or equitable risks of adverse events relative to patients with multimorbidity. Fluid and electrolyte disorders and obesity may indirectly increase the likelihood of post-colonoscopy SAEs due to unmeasured patient severity and potential difficulties in performing colonoscopy [19]. In addition, elderly patients with comorbidities were at much greater risks of SAEs. Perhaps, colonoscopy risks in patients with multimorbidity, elderly patients with comorbidities, and in frail and obese patients should be weighed against

Table 3 Logistic model predicting serious adverse events following colonoscopy in patients with comorbidities in California, Florida, and New York, 2006–2009

Parameter	Value	HOPD and ASC	HOPD	ASC
Number of complex cases		1,020,372	736,502	283,870
Facility	ASC	2.85*** (2.40, 3.38)	–	–
	HOPD	REF	–	–
Volume of TCC	Volume quartile 1 (lowest)	1.69*** (1.13, 2.54)	2.70*** (1.50, 4.86)	1.24 (0.67, 2.29)
	Volume quartile 2	1.39*** (1.10, 1.75)	1.90*** (1.28, 2.83)	1.13 (0.77, 1.66)
	Volume quartile 3	1.33*** (1.12, 1.58)	1.75*** (1.32, 2.33)	1.08 (0.78, 1.49)
	Volume quartile 4 (highest)	REF	REF	REF
Comorbidity	Hypertension	0.42*** (0.35, 0.51)	0.37*** (0.28, 0.49)	0.48*** (0.36, 0.65)
	Diabetes w/o chronic complications	0.33*** (0.19, 0.61)	0.24*** (0.09, 0.65)	0.45 (0.20, 1.02)
	Chronic pulmonary disease	0.58*** (0.37, 0.94)	0.46*** (0.23, 0.95)	0.70 (0.36, 1.38)
	Hypothyroidism	0.55** (0.33, 0.96)	0.33*** (0.13, 0.86)	0.79 (0.38, 1.66)
	Obesity	0.61 (0.29, 1.42)	0.53 (0.15, 1.85)	0.66 (0.11, 1.28)
	Depression	0.35** (0.14, 0.95)	0.30 (0.07, 1.40)	0.39 (0.10, 1.39)
	Fluid and electrolyte disorders	2.99*** (1.94, 4.74)	6.45*** (3.46, 12.02)	1.92** (1.05, 3.66)
	Rare comorbidities	0.35*** (0.23, 0.53)	0.34*** (0.16, 0.70)	0.35*** (0.21, 0.59)
	Two or more Comorbidities	REF	REF	REF
Procedure	Cold biopsy by forceps	0.70*** (0.55, 0.90)	1.03 (0.70, 1.54)	0.54*** (0.38, 0.75)
	Ablation	1.69** (0.94, 3.06)	3.66*** (1.84, 7.26)	0.66 (0.21, 2.02)
	Hot biopsy/cautery by forceps	1.88*** (1.46, 2.43)	3.28*** (2.20, 4.89)	1.29 (0.90, 1.84)
	Snare	1.92*** (1.57, 2.36)	3.20*** (2.28, 4.49)	1.30 (0.97, 1.73)
	Complex colonoscopy	2.28*** (1.84, 2.85)	3.15*** (2.15, 4.62)	1.87*** (1.37, 2.54)
	Simple procedure	REF	REF	REF
Age	50–64	1.60*** (1.10, 2.34)	1.27 (0.74, 2.18)	2.04*** (1.16, 3.57)
	65–74	2.26*** (1.51, 3.38)	1.76 (0.98, 3.15)	2.88*** (1.61, 5.17)
	75–84	3.06*** (2.02, 4.62)	2.37*** (1.34, 4.21)	3.89*** (2.14, 7.08)
	> 85	4.22*** (2.56, 6.97)	3.77*** (1.84, 7.71)	4.84*** (2.32, 10.01)
	19–49	REF	REF	REF

All models control for patient race/ethnicity, sex, insurance status, state of residence, and a year when colonoscopy was delivered

TCC total complex case, ASC ambulatory surgery centers, HOPD hospital-based outpatient departments; *** $p < 0.01$. All models include indicators for each state and study-years

its benefits, especially when less invasive CRC screening options are available.

Limitations inherent in administrative data may have constrained the study. We used administrative data that lacked clinical information to fully adjust for the quality of bowel preparation or previous use of medications (e.g., anticoagulants or antibiotics) that may be correlated with colonoscopy-related adverse events. There was also no information on lesion type, polyp size, and multiplicity in the dataset. We used several different types of colonoscopy and polypectomy procedures and their combination, which may provide some control for differences in polyp type, size, and multiple polyps. Further, we had no information on endoscopists' volume, which may potentially correlate with facility volume and affected the rate of adverse events. In addition, we had no access to data on adverse events resulting in emergency department visits and colonoscopies provided in physician offices. Our

data did not capture patients with colonoscopy-related adverse events who were hospitalized outside California, Florida, and New York; thus, records of out-of-state patients were excluded from the analysis. Our study is restricted to the three states, which may not be fully generalizable to the entire USA. However, we controlled for state-specific fixed effects and patient clustering within facilities. In addition, our dataset is one of the largest population-based datasets available on patients with chronic conditions who receive outpatient colonoscopy in the USA. Thus, our findings may have a broader generalizability to patients with comorbidities who may benefit from outpatient colonoscopy referrals to high-volume, or hospital-based, outpatient facilities. Nevertheless, more research potentially utilizing electronic medical records and data from other states is needed to better understand whether clinical factors and endoscopists' characteristics are correlated with adverse events in patients with chronic conditions.

The US population is aging and becoming clinically complex, pressuring the health care delivery system, facilities, and providers to switch from treating a single disease to managing multiple chronic conditions. Our study suggests that HOPDs and ASCs treat different patient populations and that HOPDs, as high-intensity setting, may be better positioned to provide colonoscopy to patients with comorbidities. ASCs, by design, are low-intensity settings that focus on treating a healthier patient population. As such, selective referral of clinically complex patients to HOPDs and patients without comorbidities to ASCs may improve colonoscopy outcomes. HOPDs may reduce SAEs in clinically complex patients, as well as decrease costs associated with reversing SAEs. The Centers for Medicare and Medicaid Services (CMS) are harmonizing payments that would reimburse providers identically for comparable services provided in different settings [20, 21]. Without adjusting for clinical complexity, outpatient facilities serving patients with comorbidities may be disproportionately affected by lower payments. Finally, to ensure safe CRC screening for elderly patients with comorbidities, patients with multiple chronic conditions, patients with systemic diseases or conditions, primary care physicians and gastroenterologists may consider less invasive options for CRC screening.

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