

Serious events in older Ontario residents receiving bowel preparations for outpatient colonoscopy with various comorbidity profiles: A descriptive, population-based study

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BACKGROUND: Polyethylene glycol-based bowel preparations (PEGBPs) and sodium picosulfate (NaPS) are commonly used for bowel cleansing before colonoscopy. Little is known about adverse events associated with these preparations, particularly in older patients or patients with medical comorbidities.

OBJECTIVE: To characterize the incidence of serious events following outpatient colonoscopy in patients using PEGBPs or NaPS.

METHODS: The present population-based retrospective cohort study examined data from Ontario health care databases between April 1, 2005 and December 31, 2007, including patients ≥ 66 years of age who received either PEGBP or NaPS for an outpatient colonoscopy. Patients with cardiac or renal disease, long-term care residents or patients receiving concurrent diuretic therapy were identified as high risk for adverse events. The primary outcome was a serious event (SE) defined as a composite of nonelective hospitalization, emergency department visit or death within seven days of the colonoscopy.

RESULTS: Of the 50,660 outpatients ≥ 66 years of age who underwent a colonoscopy, SEs were observed in 675 (2.4%) and 543 (2.4%) patients in the PEGBP and NaPS groups, respectively. Among high-risk patients ($n=30,168$), SEs occurred in 481 (2.8%) and 367 (2.8%) of patients receiving PEGBP and NaPS, respectively.

CONCLUSIONS: The SE rate within seven days of outpatient colonoscopy was 24 per 1000 procedures, and among high-risk patients was 28 per 1000 procedures. The rates were similar for PEGBP and NaPS. Clinicians should be aware of the risks associated with colonoscopy in older patients with comorbidities.

Key Words: Adverse events; Bowel preparations; Colonoscopy; Older patient

Colonoscopy is a commonly performed diagnostic and therapeutic procedure. In 2001, approximately 172,000 colonoscopies were performed in Ontario (1) and more than one-third of these were performed on individuals ≥ 65 years of age (2). In the United States, approximately 13% of all colonoscopies were performed in patients ≥ 80 years of age (3) and the number of colonoscopies will likely increase as colorectal cancer screening programs become more widely adopted.

Des événements graves chez des habitants âgés de l'Ontario présentant des comorbidités et qui prenaient une préparation intestinale en vue d'une coloscopie sans hospitalisation : une étude descriptive en population

HISTORIQUE : Les préparations intestinales à base de polyéthylène glycol (PBPEG) et de picosulfate sodique (PSNa) sont souvent utilisées pour l'irrigation intestinale avant une coloscopie. On ne sait pas grand-chose des effets indésirables de ces préparations, notamment chez les patients âgés présentant des comorbidités.

OBJECTIF : Caractériser l'incidence d'événements graves (ÉG) après une coloscopie sans hospitalisation chez des patients qui utilisent des PBPEG ou du PSNa.

MÉTHODOLOGIE : La présente étude de cohorte rétrospective en population portait sur des données tirées de bases de données ontariennes sur les soins de santé entre le 1^{er} avril 2005 et le 31 décembre 2007, incluant les patients de 66 ans ou plus qui avaient pris soit une PBPEG, soit du PSNa en vue d'une coloscopie sans hospitalisation. Les patients atteints d'une maladie cardiaque ou rénale, les patients en soins de longue durée et ceux qui recevaient un traitement diurétique concomitant étaient considérés comme très vulnérables à des effets indésirables. Des ÉG, définis comme un ensemble composite d'hospitalisation urgente, de consultation à l'urgence ou de décès dans les sept jours suivant la coloscopie, constituaient la mesure de résultats primaire.

RÉSULTATS : On a observé des ÉG chez 675 (2,4 %) et 543 (2,4 %) des 50 660 patients ambulatoires de 66 ans ou plus qui ont subi une coloscopie et avaient pris du PBPEG ou du PSNa, respectivement, ainsi que chez 481 (2,8 %) et 367 (2,8 %) des patients très vulnérables ($n=30 168$) qui avaient pris du PBPEG ou du PSNa, respectivement.

CONCLUSIONS : Le taux d'ÉG dans les sept jours suivant la coloscopie sans hospitalisation correspondait à 24 cas pour 1 000 interventions, et chez les patients très vulnérables, à 28 cas pour 1 000 interventions. Les taux étaient similaires avec l'utilisation de PBPEG ou de PSNa. Les cliniciens devraient connaître les risques liés à la coloscopie chez les patients âgés qui présentent des comorbidités.

Polyethylene glycol-based bowel preparations (PEGBPs) are effective, generally well tolerated and perceived as safer than oral sodium phosphate preparations (4-12). However, studies of PEGBPs suggesting a lack of influence on serum electrolytes or volume status often excluded older patients or those with cardiac or renal disease (4-6,13). Among case reports and case series of older individuals, however, electrolyte disturbances, specifically hypokalemia, have been described

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(14-16). Although patients with hypokalemia may be asymptomatic, they may also present with life-threatening cardiac arrhythmias. Therefore, we conducted the present population-based retrospective cohort study to describe the rate of serious events (SEs) associated with PEGBPs in older Ontario patients who underwent an outpatient colonoscopy. We also sought to describe the SE rate among patients with comorbidities predisposing them to hypokalemia and subsequent adverse events.

METHODS

Setting

The present study used health administrative data from the province of Ontario. Ontario has a universal insurance plan for prescription medications for all provincial residents ≥ 65 years of age, and universal coverage for physician and hospital services for all residents.

Data sources

Seven health care administrative databases were linked using unique encrypted identifiers. The Ontario Drug Benefit database consists of all claims for prescriptions filled in outpatient pharmacies for medications covered under the provincial insurance program for individuals ≥ 65 years of age. The Canadian Institute for Health Information Discharge Abstract Database and National Ambulatory Care Reporting System are standardized records of all inpatient hospitalization and ambulatory care (including emergency department [ED]) episodes, respectively. The Ontario Health Insurance Plan contains physician claims for inpatient and outpatient services. The Ontario Diabetes Database and Ontario Cancer Registry were used to identify patients with diabetes or cancer diagnoses, respectively. The Registered Persons Database contains information regarding the date of death for all patients who have been issued a health card. These databases were linked to perform the present study and patient anonymity was preserved with encrypted health card numbers. The study was approved by the Research Ethics Board at Sunnybrook Health Sciences Centre (Toronto, Ontario).

Study design and sample

The present study was a retrospective cohort analysis. Using the administrative data described above, a cohort of all Ontario residents ≥ 66 years of age, who filled a prescription for either PEGPB or sodium picosulphate (NaPS) between April 1, 2005 and December 31, 2007, and who underwent an outpatient colonoscopy performed within three months of filling the prescription were identified. This observation window was based on a pilot study that found that 75% of individuals who filled a PEGBP prescription underwent a colonoscopy within 15 days of filling the prescription. Cohort inclusion was restricted to the first prescription for either bowel preparation during the study period. This excluded patients with complicated gastrointestinal disease who required frequent colonoscopies ($n=21,727$) and who would be predisposed to the outcome. Also excluded were patients who underwent a colonoscopy during a hospital admission ($n=16,433$) because their prescriptions would not be captured in the administrative databases. Finally, due to the substantial heterogeneity of individuals who did not undergo a colonoscopy within three months of filling a PEGBP or NaPS script, or who underwent a colonoscopy without filling a PEGBP or NaPS script in the preceding three months ($n=178,347$), were also excluded from the present study.

Individuals were stratified into two groups based on their potential risk for an adverse event following PEGBP use. The high-risk group was defined as patients with pre-existing cardiac or renal disease, those receiving diuretic therapy or those who resided in a long-term care facility (in Ontario, this exclusively refers to nursing homes). Individuals with cardiac or renal comorbidities, or who are on diuretics, are predisposed to volume disturbances, electrolyte disturbances and subsequent adverse events. Long-term care facility residents tend to be frail with a high burden of multimorbidity including dementia (17). All other patients were considered to be at lower risk for an adverse event.

All cohort subjects were followed for up to seven days from the date of the colonoscopy. The colonoscopy date, rather than the prescription fill date, was used as the start of follow-up because PEGBP administration would have occurred within the preceding 24 h.

Exposure

The two cohorts were defined by the administered bowel preparation. Patients were exposed to either PEGBP or to the alternative bowel preparation NaPS, both of which are covered by the Ontario Drug Benefit program. Patients who took any nonformulary bowel preparation were not included in the study.

Outcome

The primary outcome was an SE, described as a composite of death from any cause, a nonelective admission to hospital or visit to an ED within the seven-day follow-up period. Only the first of any of these events to occur in the follow-up period were counted. Each of the above outcomes was also analyzed separately as a secondary outcome. Other secondary outcomes included a physician diagnosis of electrolyte disturbances, congestive heart failure, syncope, dehydration or falls within seven days of the colonoscopy. Patients who were seen in the ED and then admitted to hospital were only counted as a hospital admission.

Analysis

Descriptive statistics were used to characterize baseline demographic and clinical variables of the cohorts according to exposure status. Baseline characteristics such as age, sex and long-term care residence between the two exposure groups were compared. Also examined were comorbidities that would increase the risk of the outcome; the stratified PEGBP and NaPS cohorts were based on these risk categories. For example, cardiac and renal diseases increase the risk of congestive heart failure and, therefore, the primary outcome. Patients with inflammatory bowel disease or postgastric surgical syndromes would be prone to electrolyte disturbances and dehydration and, subsequently, the primary outcome. The number of medications was recorded because a higher number has been associated with increased health care services use, mortality and hospitalizations (18). Medications that increase potassium levels, such as potassium-sparing diuretics, angiotensin converting enzyme inhibitors or angiotensin receptor blockers, and electrolyte supplementation, and those that decrease potassium levels such as nonpotassium-sparing diuretics or other laxatives, were recorded. Also recorded were medications that would be affected by electrolyte disturbances and result in a bias toward the primary and secondary outcomes. These drugs included antiarrhythmics and negative chronotropic cardiac medications. Finally, drugs that could be associated with the reason for a colonoscopy, such as antiplatelets, anticoagulants, nonsteroidal anti-inflammatory drugs, bisphosphonates, proton pump inhibitors and prescription antihistamine 2 receptor antagonists were recorded.

Other variables that were associated with the primary outcomes, such as the Charlson comorbidity index, number of medications and a hospital admission within the preceding 12 months, were also recorded.

Because the main objective of the present study was descriptive in nature, formal statistical tests were not performed.

RESULTS

During the study period, a total of 50,660 patients filled a prescription for either a PEGBP ($n=28,071$ [55.4%]) or NaPS ($n=22,589$ [44.6%]), and underwent a colonoscopy within three months (Table 1). The characteristics of both groups were similar, with one-third having a diagnosis of inflammatory bowel disease. Patients in the PEGBP group, however, were slightly more likely to have a gastrointestinal malignancy, have undergone a colonoscopy within the preceding four years, a biopsy during the colonoscopy, and same-day gastroscopy and colonoscopy. Interestingly, 7% of NaPS patients had renal disease, a known contraindication to this agent.

TABLE 1
Characteristics of older patients receiving either a polyethylene glycol-based (PEG) or sodium picosulfate (NaPS) bowel preparation for an outpatient colonoscopy

Characteristic	PEG (n=28,071)	NaPS (n=22,589)
Age, years, median (IQR)	73 (69–78)	73 (69–77)
66–75	17,812 (63.5)	15,095 (66.8)
76–85	9346 (33.3)	6842 (30.3)
≥86	913 (3.3)	652 (2.9)
Female	14,279 (50.9)	11,918 (52.8)
Charlson Index		
Missing	16,537 (58.9)	13,887 (61.5)
0	5386 (19.2)	4601 (20.4)
1	2370 (8.4)	1834 (8.1)
2	2050 (7.3)	1267 (5.6)
≥3	1728 (6.2)	1000 (4.4)
Medications, median (IQR)	10 (6–15)	9 (6–14)
Hospitalized within past 12 months	4126 (14.7)	2885 (12.8)
Underlying bowel disease		
Inflammatory bowel disease	8955 (31.9)	6611 (29.3)
Postgastric surgery syndrome	19 (0.1)	8 (0.0)
Gastrointestinal malignancy	2052 (7.3)	1102 (4.9)
Colonoscopy description		
Full colonoscopy	26,551 (94.6)	21,353 (94.5)
Incomplete colonoscopy	1520 (5.4)	1236 (5.5)
Colonoscopy interval, years		
≥10	16,224 (57.8)	13,654 (60.4)
5–9	5135 (18.3)	4838 (21.4)
≤4	6712 (23.9)	4097 (18.1)
Biopsy during colonoscopy	18,232 (64.9)	13,397 (59.3)
Same day gastroscopy and colonoscopy	7577 (27.0)	5096 (22.6)
High-risk group		
Long-term care facility*	243 (0.9)	200 (0.9)
Cardiac disease*	13,150 (46.8)	10,189 (45.1)
Renal disease*	2456 (8.7)	1581 (7.0)
Diuretics (K and non-K sparing)*	7382 (26.3)	5790 (25.6)
K-sparing diuretics	1139 (4.1)	961 (4.3)
Non-K-sparing diuretics	7236 (25.8)	5681 (25.1)
Medications that affect electrolyte levels		
Electrolyte supplementation	36 (0.1)	19 (0.1)
Other laxatives	622 (2.2)	511 (2.3)
Simultaneous administration of bisacodyl or magnesium citrate	3282 (11.7)	3222 (14.3)
Medications affected by electrolyte disturbances		
Antiarrhythmics	530 (1.9)	422 (1.9)
Negative chronotropes, rate controlling	8236 (29.3)	6257 (27.7)
Medications associated with reason for colonoscopy		
Protein pump inhibitors	12,312 (43.9)	9267 (41.0)
Antiplatelets, anticoagulants, NSAIDs, bisphosphonates	15,338 (54.6)	11,921 (52.8)
Other medications		
Antipsychotics	596 (2.1)	500 (2.2)
Antidepressants, cholinesterase inhibitors	5252 (18.7)	4217 (18.7)

Data presented as n (%) unless otherwise indicated. *High-risk group criteria. IQR Interquartile range; K Potassium; NSAIDs Nonsteroidal anti-inflammatory drugs

In the seven days following the colonoscopy, 675 patients (2.4%) in the PEGBP group and 543 patients (2.4%) in the NaPS group experienced an SE (Table 2). Death was rare among both groups. The

groups were similar in ED visits (1.3% PEGBP versus 1.4% NaPS) and nonelective hospital admissions (1.1% PEGBP versus 1.0% NaPS). There was also no apparent difference between the cohorts in the secondary outcome (1.3% PEGBP versus 1.3% NaPS), a composite of electrolyte disturbances, congestive heart failure, syncope, dehydration and falls.

In both the PEGBP and NaPS groups, patients identified in the high-risk group exhibited a slightly higher frequency of SEs (2.8%) compared with the low risk patients (1.7% and 1.9%, respectively). (Table 2).

DISCUSSION

Among outpatients ≥66 years of age living in Ontario who received an outpatient colonoscopy, the SE rate within seven days of the procedure was 24 per 1000 procedures. This outcome occurred with similar frequency in patients receiving the saline laxative, NaPS or PEGBP.

Patients in the high-risk group experienced a higher incidence of SEs compared with those in the low-risk cohort. To our knowledge, the present analysis is the first descriptive study of SEs in older patients (ie, >65 years of age) within seven days of an outpatient colonoscopy, which examined different bowel preparations and populations with different comorbidity burdens.

Although the adverse effects of oral sodium phosphate have been recognized, PEGBPs are designed to be iso-osmotic and are marketed as having no influence on volume status or electrolytes; they are, therefore, generally presumed to be safe (7-9,12). However nausea, abdominal cramping and significant adverse events have been reported for these agents. These include hemodynamic changes in 20% to 35% of patients (11) and a 3.3% incidence of renal insufficiency (19). Case reports of aspiration with PEGBPs administered via nasogastric tube in cognitively impaired patients (20) and severe hyponatremia causing seizures have also been described (14). In older hospitalized patients with comorbidities, hypokalemia associated with PEGBPs has been demonstrated in observational and prospective randomized studies (6,15,16). This is believed to be a result of increased colonic potassium secretion through vasoactive intestinal peptide and cholinergic pathways (21-24). In addition, potassium secretion through the large bowel is increased in patients with chronic renal insufficiency (25) and also by aldosterone (26). Older patients often have impaired renal function (27) and are at risk for volume depletion and aldosterone excess resulting from several factors including decreased thirst reflex (28) and concomitant diuretic therapy. Although more attention has been devoted to the risks of oral sodium phosphate, NaPS – also a saline laxative – is not without its risks. Electrolyte disturbances such as hyponatremia, hypokalemia and volume disturbances following NaPS have been described in case reports (29,30). Our study did not find a difference in SEs between bowel preparations. While this rate was low, health care professionals should still consider these risks when prescribing these medications to older individuals, particularly those who may be in a higher risk group for such complications as a result of their comorbid conditions.

Previous population-based studies of patients undergoing outpatient colonoscopies have documented lower rates of adverse events, or focused on bleeding and perforation with observational windows of 30 days (31-33). Despite a shorter observational window of seven days postcolonoscopy, our SE rate following the procedure was 24 per 1000 procedures, and among high-risk patients, 28 per 1000 procedures, corresponding to one per 36 colonoscopies. This is likely due to the fact that our study population was older and had more comorbidities. Warren et al (31) found that among a random sample of Medicare beneficiaries 66 to 95 years of age, the risk of hospitalization or an ED visit was 38 per 1000 in the 30 days following colonoscopy; however, their study did not account for different bowel preparations and included oral sodium phosphate. Our shorter observation window provides a more robust, temporal association between the bowel preparation and colonoscopy and the primary outcome. Our study also provides insight into bowel preparations by excluding

TABLE 2
Serious events in older patients for outpatient colonoscopy

Outcome	Polyethylene glycol-based bowel preparation			Sodium picosulphate		
	Total (n=28,071)	Low risk (n=11,184)	High risk (n=16,887)	Total (n=22,589)	Low risk (n=9308)	High risk (n=13,281)
Serious event*	675 (2.4)	194 (1.7)	481 (2.8)	543 (2.4)	176 (1.9)	367 (2.8)
Death†	8 (0.03)	≤5 (0.0)	7 (0.04)	≤5 (0.0)	0 (0.0)	≤5 (0.0)
ED visit	360 (1.3)	106 (0.9)	254 (1.5)	322 (1.4)	104 (1.1)	218 (1.6)
Nonelective hospital admission	313 (1.1)	88 (0.8)	225 (1.3)	221 (1.0)	72 (0.8)	149 (1.1)
Additional secondary outcomes‡	371 (1.3)	107 (1.0)	264 (1.6)	292 (1.3)	80 (0.9)	212 (1.6)

Data presented as n (%). *Composite of death, emergency department visit or nonelective hospital admission; †Due to the Institute for Clinical Evaluative Sciences' privacy policy, outcomes of ≤5 cannot be reported; ‡Composite of diagnoses of electrolyte disturbances, congestive heart failure, syncope, dehydration and falls. ED Emergency department

those who exclusively used oral sodium phosphate, and by studying the commonly assumed 'safer' agents PEGBP and NaPS. Given the significant proportion of individuals >65 years of age with comorbidities undergoing colonoscopies, our study provides valuable information to clinicians as they counsel their patients about the risks and benefits of outpatient colonoscopy and bowel preparations.

Our study has limitations. First, we only captured patients who filled their bowel preparation prescription and who underwent colonoscopy; therefore, we were unable to identify individuals who took the bowel preparation but did not attend the procedure. If a substantial proportion of these 'colonoscopy no shows' did not attend because of an SE, this would result in an underestimation of the SE rate in this population. Second, we were unable to capture bowel preparations that were not covered by the provincial formulary. Therefore, patients receiving other formulations of these bowel preparations, or who received oral sodium phosphate (which is available over the counter), were not included in the present study; and a more complete comparison between bowel preparations could not be performed. Third, our primary outcome only captured adverse events severe enough to result in hospital contact or death. Patients who experienced mild hypokalemia following their bowel preparation may have recovered after resuming a normal diet. The frequency of mild adverse events is still unknown but potentially more common than the severe outcomes reported here.

In our population-based study of patients >65 years of age receiving either NaPS or PEGBP for an outpatient colonoscopy, the SE rate within seven days of the procedure was similar between bowel preparations. This rate was higher in the high-risk group and, furthermore, is an underestimation of the overall SE rate. Clinicians should appreciate these clinically relevant risks and monitor patients closely, especially if they have cardiac or renal disease, reside in a long-term care facility or are on diuretic therapy. In this way, patients can be properly informed of the risks of a procedure that has therapeutic intent.

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