

Factors associated with incomplete small bowel capsule endoscopy studies

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Abstract

AIM: To identify patient risk factors associated with incomplete small bowel capsule endoscopy (CE) studies.

METHODS: Data from all CE procedures performed at St. Paul's Hospital in Vancouver, British Columbia, Canada, between December 2001 and June 2008 were collected and analyzed on a retrospective basis. Data collection for complete and incomplete CE study groups included patient demographics as well as a number of potential risk factors for incomplete CE including indication for the procedure, hospitalization, diabetes mellitus with or without end organ damage, limitations in mobility, renal insufficiency, past history of bowel obstruction, abdominal surgery, abdominal radiation therapy and opiate use. Risk factors were analyzed using a univariable and multivariable logistic regression model.

RESULTS: From a total of 535 CE procedures performed, 158 were incomplete (29.5%). The univariable analysis showed that CE procedures performed for overt gastrointestinal bleeding ($P = 0.002$), and for patients with a prior history of abdominal surgery ($P = 0.023$) or bowel obstruction ($P = 0.023$) were significantly associated with incomplete CE studies. Patients on opiate medications ($P = 0.094$) as well as hospitalized patients ($P = 0.054$) were not statistically significant, but did show a trend towards incomplete CE. The multivariable analysis showed that independent risk factors for an incomplete CE procedure include prior history of bowel obstruction [odds ratios (OR) 2.77, $P = 0.02$, 95% confidence intervals (CI): 1.17-6.56] and procedures performed for gastrointestinal bleeding (Occult OR 2.04, $P = 0.037$, 95% CI: 1.04-4.02 and Overt OR 2.69, $P = 0.002$, 95% CI: 1.44-5.05). Patients with a prior history of abdominal surgery (OR 1.46, $P = 0.068$, 95% CI: 0.97-2.19), those taking opiate medications (OR 1.54, $P = 0.15$, 95% CI: 0.86-2.76) and hospitalized patients (OR 1.82, $P = 0.124$, 95% CI: 0.85-3.93) showed a trend towards statistical significance.

CONCLUSION: We have identified a number of risk factors for incomplete CE procedures that can be used to risk-stratify patients and guide interventions to improve completion rates.

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Key words: Capsule; Capsule endoscopy; Incomplete endoscopy

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INTRODUCTION

Capsule endoscopy (CE) is a novel and non-invasive imaging modality for the small bowel initially described in 2000^[1,2]. The procedure utilizes a battery-powered wireless capsule to transmit images of the gastrointestinal tract as it traverses through the intestine. These transmitted images are sent to a recorder worn on the abdominal wall of the patient. The images are later downloaded to a computer and interpreted by a trained physician.

There are a number of indications for the use of CE in small bowel diseases. One of the most common indications for a CE study is to investigate obscure gastrointestinal bleeding, but other indications include inflammatory bowel disease, small bowel tumors, familial polyposis syndromes and celiac disease^[1,3-8]. Various studies have shown favorable results in using CE in the aforementioned small bowel diseases^[3-10]. Furthermore, studies have also shown that CE has better diagnostic yield when compared to other modalities of imaging the small bowel such as push-enteroscopy or computed tomography angiography in the diagnosis of obscure gastrointestinal bleeding^[9,10].

However, it is important to note that CE is not without limitations. There are, albeit rare, reports of capsule retention in the gastrointestinal tract as well as aspiration of capsule devices^[11,12]. Furthermore, a retrospective study carried out in 2005 revealed a technical limitation/failure rate of 8.5% which was due to factors such as downloading or transmitting failures, insufficient battery life, or signal interference of the devices^[13]. A relatively common limitation is the issue of incomplete CE studies, which can be due to the capsule not reaching the cecum and/or poor visualization of a significant portion of the small bowel due to factors such as poor preparation or excess debris. A number of studies have shown rates of incomplete CE procedures to be greater than 13%^[13-15].

CE studies that are incomplete or difficult to interpret due to poor visualization potentially lead to delays in the diagnosis of small bowel pathology. Further investigative tests such as repeat CE studies, radiologic exams, or endoscopic interventions are often required to help delineate the diagnosis. Ultimately, there are increased costs to the medical system and inconvenience to the patient with delays in diagnosis.

The aim of this study is to determine demographic and procedure process related risk factors associated with incomplete CE studies. A number of small studies have identified factors such as diabetes mellitus, hospitalization, slowed gastric transit, previous small bowel surgery, and poor bowel cleansing^[14,16,17]. Data for this study are drawn from the capsule endoscopies performed at St. Paul's Hospital, a quaternary referral center for gastroenterology services and the only referral center for CE in the province of British Columbia, Canada.

MATERIALS AND METHODS

CE procedure

All CE procedures were performed at St. Paul's Hospital in Vancouver, British Columbia, Canada. Prior to the procedure, informed consent was obtained and all patients were given a standardized set of instructions. The instructions included an overnight fast beginning at midnight before the procedure, as well as a bowel-cleansing regimen consisting of a single bottle (300 mL) of Magnesium citrate. Motility agents were not routinely used during the procedure; however, if patients were already taking these medications, they were permitted to continue taking them. All CE procedures began at 7 am and were completed by 3 pm on the same day, at which time the data recorders would be returned. The images were subsequently downloaded to a computer and reviewed within 24 h by a single gastroenterologist (RE). Patients were permitted to drink within 2 h and eat within 4 h following ingestion of the capsule. All CE procedures were performed using the PillCam produced by Given Imaging (Yoqneam, Israel). Incomplete CE studies were defined as those that did not reach the cecum or had incomplete visualization of the small bowel due to debris or incomplete cleansing (involving > 25% of the study). We included incomplete visualization of the small bowel to our definition of an incomplete CE study to provide an estimate of incomplete capsules in a real-world clinical setting.

Data collection

Data from all CE studies performed between December 2001 and June 2008 were reviewed and analyzed on a retrospective basis. An incomplete CE study was defined as: (1) the capsule did not reach the cecum by the end of battery life; and (2) poor visualization of > 25% of the mucosa. To determine potential risk factors for incomplete CE studies using univariable and multivariable statistical analysis, data on a number of potential factors were collected: (1) The indication for the CE (iron deficiency, abdominal pain, change in bowel habits, active GI bleed, occult GI bleeding, recurrent GI bleed); (2) Whether the study was performed on a hospitalized patient; (3) Diabetes mellitus with or without end organ damage (defined as diabetic nephropathy, retinopathy, neuropathy or diabetes-associated peripheral vascular disease); (4) Limitations in mobility (i.e. post stroke, hemiplegia), (5) Renal insufficiency; (6) Patient demographics (age, gender); (7) Past history of abdominal surgery, bowel obstruction, or abdominal radiation therapy; and (8) Opiate use.

Statistical analysis

All statistical analyses were performed using STATA 10.0 (College Station, TX). Descriptive statistics were used to characterize the demographics of the patient population. Patients with incomplete studies were compared to those with completed studies and risk factors for an incomplete CE were compared using a univariable and then multivariable logistic regression. Hemiplegia and diabetes with end organ damage were risk factors that occurred in a low

Table 1 Patient demographics (%)

	Complete CE	Incomplete CE	Total
<i>n</i>	377	158	535
Gender (F)	50.9	50.0	50.7
Age (yr)	58.1 (13.2-92.9)	60.6 (12.8-90.7)	58.8 (12.8-92.9)
Hospitalized	4.5	8.8	5.8
Diabetes	12.7	16.5	13.8
Hemiplegia	0.27	1.3	0.56
Renal disease	6.6	8.2	7.1
DM with EOD	2.7	2.5	2.6
No bleed	22.3	18.4	19.3
Occult bleed	30.9	26.0	30.0
Overt bleed	46.8	55.6	50.7
Change in BM	17.5	17.7	17.6
Bowel obstruction	3.4	8.2	4.9
Abdominal surgery	34.5	44.9	37.6
Abdominal radiation	1.9	1.9	1.9
Opiate use	8.8	14.8	10.7

CE: Capsule endoscopy; DM: Diabetes mellitus; EOD: End organ damage; BM: Bowel movement.

number of patients and were therefore excluded. From the multivariable regression analysis, odds ratios (OR) and corresponding 95% confidence intervals (CI) were generated on all significant variables (P -value < 0.05). Patients excluded from statistical analysis include those with evidence of mass lesion or stricture that was responsible for delaying transit through the small bowel.

RESULTS

A total of 653 CE procedures were reviewed in total. However, 118 studies were excluded, as there was evidence of a mass lesion or stricture that clearly delayed transit through the small bowel and was felt to be primarily responsible for the incomplete study. Therefore, statistical analysis was performed on a total of 535 CE procedures. Of those 535 CE procedures, 158 CE were found to be incomplete (29.5%).

Patient demographics

Patient demographic information for complete and incomplete CE studies is seen in Table 1. The mean age of the patients was 58.8 years, and 50.9% of patients were female. There was no significant difference in the demographics as well as the indication for performing the CE procedure between complete and incomplete CE study groups.

Univariable analysis

Results of the univariable analysis are listed in Table 2 for all investigated potential risk factors for incomplete CE studies listed in Table 1. The analysis reveals that factors strongly associated with incomplete CE studies include overt GI bleeding ($P = 0.002$, OR 2.39, 95% CI: 1.36-4.16), as well as prior history of bowel surgery ($P = 0.023$, OR 1.55, 95% CI: 1.06-2.26) and bowel obstruction ($P = 0.023$, OR 2.51, 95% CI: 1.13-5.55). Patients on opiate medications ($P = 0.094$, OR 1.61, 95% CI: 0.92-2.82) as well as

Table 2 Univariable analysis

	B coefficient	<i>P</i> value	OR	95% CI	Pseudo R-squared
Gender (F)	-0.0371	0.845	0.96	0.66-1.39	0.0001
Age	0.00759	0.152	1.01	0.99-1.02	0.0032
Hospitalized	0.722	0.054	2.06	0.99-4.29	0.0055
Diabetes	0.3	0.256	1.35	0.80-2.27	0.0019
Hemiplegia	1.57	0.200	4.82	0.43-53.5	0.0027
Renal disease	0.233	0.513	1.26	0.63-2.54	0.0007
DM with EOD	-0.048	0.936	0.95	0.29-3.09	0.00001
No bleed	Reference				0.0167
Occult bleed	0.517	0.095	1.68	0.91-3.07	
Overt bleed	0.87	0.002	2.39	1.36-4.16	
Change in BM	0.0148	0.952	1.01	0.62-1.65	0.00001
Bowel obstruction	0.92	0.023	2.51	1.13-5.55	0.0078
Abdominal surgery	0.439	0.023	1.55	1.06-2.26	0.0079
Abdominal radiation	0.0228	0.974	1.02	0.26-4.00	0.00001
Opiate use	0.479	0.094	1.61	0.92-2.82	0.0042

DM: Diabetes mellitus; EOD: End organ damage; BM: Bowel movement; OR: Odds ratio; CI: Confidence interval.

Table 3 Multivariable analysis

	OR	<i>P</i> value	95% CI
Sex	0.99	0.975	0.68-1.46
Age	0.99	0.995	0.99-1.01
Hospitalized	1.82	0.124	0.85-3.93
Diabetes	1.25	0.411	0.73-2.17
Renal disease	1.03	0.926	0.50-2.16
Occult bleeding	2.04	0.037	1.04-4.02
Overt bleeding	2.69	0.002	1.44-5.05
PMHx bowel obstruction	2.77	0.020	1.17-6.56
PMHx abdo surgery	1.46	0.068	0.97-2.19
PMHx abdo radiation	0.91	0.890	0.22-3.71
Opiate use	1.54	0.150	0.86-2.76

PMHx: Past medical history; OR: Odds ratio; CI: Confidence interval.

those admitted to hospital ($P = 0.054$, OR 2.06, 95% CI: 0.99-4.29) were not statistically significant risk factors, but clearly showed a trend towards significance.

Multivariable analysis

Results of the multivariate analysis, shown in Table 3, using significant risk factors determined from the univariable analysis, show a statistically significant independent risk of incomplete CE study in patients who completed the study for a history of overt (OR 2.69, $P = 0.002$, 95% CI: 1.44-5.05) or occult (OR 2.04, $P = 0.037$, 95% CI: 1.04-4.02) gastrointestinal bleeding as well as patients with a previous history of bowel obstruction (OR 2.77, $P = 0.02$, 95% CI: 1.17-6.56). A prior history of abdominal surgery (OR 1.46, $P = 0.068$, 95% CI: 0.97-2.19) lacked statistical significance, but did show a trend towards an incomplete CE study. Patients on opiate medications (OR 1.54, $P = 0.15$, 95% CI: 0.86-2.76, 130/377 in the complete group, 71/158 in incomplete group) and those who were hospitalized (OR 1.82, $P = 0.124$, 95% CI: 0.85-3.93, 33/377 in the complete group, 23/158 in the incomplete group) also showed a trend towards statistical significance.

DISCUSSION

Our study intended to determine risk factors associated with incomplete small bowel CE studies due to poor visualization or failure of the capsule to reach the cecum. In order to accomplish this task, we have reviewed all CE studies performed at our center over a seven-year period. We identified 158 incomplete studies from a total of 535 eligible capsules (29.5%), showing that our incomplete CE study rate is higher than reports from other papers^[13-15]. This is likely because we were more inclusive in the definition of an incomplete CE study compared to previous studies, as we have included poor visualization of > 25% of the mucosa into the definition rather than only counting capsules that did not reach the cecum^[13-15]. We added both aforementioned scenarios into our definition to provide a real-world clinical estimate of the rate of incomplete capsule endoscopies.

A number of prior studies have already identified risk factors associated with incomplete CE studies such as hospitalization, diabetes mellitus, prolonged gastric transit times, and poor bowel cleansing^[14,16,17]. Our results have largely added to this list of established risk factors. The result of our univariable analysis showed that factors strongly associated with incomplete studies include a past history of bowel obstruction or abdominal surgery, as well as studies done for overt gastrointestinal bleeding. Hospitalized patients and those on opiates showed a trend towards significance for incomplete CE studies. Furthermore, the multivariable analysis revealed that a prior history of bowel obstruction and studies performed for gastrointestinal bleeding (both overt and occult) were independent risk factors for incomplete studies, with a past history of abdominal surgery, hospitalization and opiate use showing a trend towards significance.

Given that there are a number of studies that have investigated risk factors for incomplete CE procedures, including a recent article published by Westerhof *et al.*^[14,16,17] in 2009 that, like our paper, provided a retrospective univariable and multivariable analysis of factors associated with incomplete small bowel CE procedures, we feel that our study contributes to the literature in a number of ways. Firstly, our study provides a systematic analysis of risk factors for small bowel CE procedures with the largest patient population available in the literature at the present time. Secondly, we have included a variety of potential risk factors such as hospitalization, opiate use, mobility limitations and systemic illness into our statistical model. And thirdly, we have included a functional definition of an incomplete study, being more inclusive than other studies to give a better real-world estimate of the proportion of CE studies that are incomplete or difficult to interpret.

In terms of how this data affects our practice, we have used this information to risk-stratify patients undergoing CE studies to determine if they are indeed at high risk for an incomplete study. If a patient is deemed to be at high risk, we have made changes to our practice such as utilizing the MiRo capsule (IntroMedic Co., Ltd., Seoul, Korea), a device that is capable of a longer battery life

compared to other capsules, in order to continue filming the gastrointestinal tract in those with slowed intestinal motility. We also utilize a stronger bowel-cleansing regimen in those who are deemed to be at high risk for an incomplete study, which includes 4 L of Go-Lytely on the day prior to the procedure rather than a standard single bottle of Magnesium citrate.

There have been limited numbers of published studies that have investigated the use of prokinetic agents such as metoclopramide and erythromycin to improve completion rates in CE studies^[17-20]. However, because of the paucity of data and heterogeneity of results seen in the literature surrounding prokinetic agents in CE, its routine use has remained controversial^[20]. Because of this controversy, we do not routinely use prokinetic agents during CE studies, nor do we use them in patients deemed to be at high risk for an incomplete study. However, we feel that this would be an interesting area of research in the future to see if the routine use of prokinetic agents in a large patient population can improve completion rates.

Finally, it is important to note that our study includes a large patient population where we have retrospectively looked at numerous risk factors for incomplete CE studies. We acknowledge that there are limitations to a retrospective statistical analysis, and as a result, we feel that larger scale studies performed on a prospective basis are required to further delineate the risk factors identified. We hope that further studies can shed light on a number of issues, such as determining optimal preparations for capsule studies since there is much heterogeneity between centers, analyzing the cost-effectiveness of CE given the high incompleteness rates quoted in papers, and finally, determining positive predictors of diagnostic yield in CE to aid clinicians in determining appropriate patient selection for this procedure.

COMMENTS

Background

Capsule endoscopy (CE) is a relatively new imaging modality for the small bowel initially described in 2000. It utilizes a pill-shaped camera to image the small bowel as it traverses through. CE is currently being used to diagnose and follow patients with a variety of conditions such as gastrointestinal bleeding, small bowel tumors, inflammatory bowel diseases, and celiac disease. This study focuses on determining risk factors that lead to incomplete CE procedures (i.e. capsules which fail to traverse the entire small bowel or do so but encounter so much debris that the images cannot be interpreted). This study determined that there is an incomplete rate of 29.5% in CE procedures.

Research frontiers

Future areas of research will include determining optimal preparations to be used in patients prior to undergoing a CE procedure. In addition, given the relatively high rate of incomplete procedures, studies that determine cost-effectiveness of the procedure and that determine which groups to offer the procedure to (i.e. which groups of patients will have the greatest yield by completing this procedure) will constitute future areas of research.

Innovations and breakthroughs

Prior studies have already established a number of risk factors for incomplete CE studies. These include patients with a history of diabetes mellitus, procedures performed on hospitalized patients, patients with poor bowel cleansing prior to the procedure, and those with delayed gastric emptying. The authors have added to this list of risk factors patients with a history of bowel obstruction or abdominal surgery, those taking opiate medications, hospitalized patients,

as well as studies performed for gastrointestinal bleeding. To accomplish this, they have collected data and performed statistical analysis on a large patient population at a Canadian academic teaching hospital.

Applications

Once specific risk factors can be determined for incomplete CE studies, one can use this information to provide patients with interventions to modify the risk factors (i.e. different bowel cleansing regimens, prokinetic agents, using capsules with longer battery life) in the hopes of improving CE study completion rates.

Terminology

Capsule endoscopy: A procedure that utilizes a pill-shaped camera that is swallowed by patients and is used to image the gastrointestinal tract as it traverses through. Capsules have a limited battery life and are expected to reach the end of the small bowel before time runs out. Prokinetic agent: A medication given to speed the emptying of stomach contents. Bowel cleansing regimen: A medication given to patients prior to undergoing a CE procedure to clean out the bowels such that improved visualization of the mucosa can be achieved.

Peer review

The paper is well designed and structured for both the aims and results. The discussion is too large and redundant and should be shortened.

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