

Retrospective Study

Effect of longer battery life on small bowel capsule endoscopy

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METHODS: A retrospective study was performed at a tertiary, university-affiliated hospital in Vancouver, Canada. Patients who underwent CE with either PillCam™ SB2 or SB2U between 01/2010 and 12/2013 were considered for inclusion. SB2 and SB2U share identical physical dimensions but differ in their battery lives (8 h vs 12 h). Exclusion criteria included history of gastric or small bowel surgery, endoscopic placement of CE, interrupted view of major landmarks due to technical difficulty or significant amount of debris, and repeat CE using same system. Basic demographics, comorbidities, medications, baseline bowel habits, and previous surgeries were reviewed. Timing of major landmarks in CE were recorded, and used to calculate gastric transit time, small bowel transit time, and total recording time. A complete CE study was defined as visualization of cecum. Transit times and completion rates were compared.

RESULTS: Four hundred and eight patients, including 208 (51.0%) males, were included for analysis. The mean age was 55.5 ± 19.3 years. The most common indication for CE was gastrointestinal bleeding ($n = 254$, 62.3%), followed by inflammatory bowel disease ($n = 86$, 21.1%). There was no difference in gastric transit times (group difference 0.90, 95%CI: 0.72-1.13, $P = 0.352$) and small bowel transit times (group difference 1.07, 95%CI: 0.95-1.19, $P = 0.261$) between SB2U and SB2, but total recording time was about 14% longer in the SB2U group (95%CI: 10%-18%, $P < 0.001$) and there was a corresponding trend toward higher completion rate (88.2% vs 93.2%, OR = 1.78, 95%CI 0.88-3.63, $P = 0.111$). There was no statistically significant difference in the rates of positive findings (OR = 0.98, 95%CI: 0.64-1.51, $P = 0.918$).

CONCLUSION: Extending the operating time of CE may be a simple method to improve completion rate although it does not affect the rate of positive findings.

Key words: Capsule endoscopy; Battery life; Completion

Abstract

AIM: To determine if longer battery life improves capsule endoscopy (CE) completion rates.

rate; Positive finding; Transit time

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Core tip: This is the first study, to our knowledge, to specifically examine the effect of battery life on capsule endoscopy completion rate (*i.e.*, complete visualization of the entire small bowel). Capsule endoscopies performed using SB2U had longer recording time and a corresponding trend toward higher completion rate than the older-generation SB2. As the two systems are identical in dimensions, there was no difference in the transit times. There was no difference in the rates of positive findings. A randomized controlled trial would be necessary to confirm the diagnostic advantage of longer battery life in capsule endoscopy.

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INTRODUCTION

Small bowel capsule endoscopy (CE) is non-invasive means of assessing the small bowel mucosa for numerous indications such as obscure gastrointestinal bleeding, small bowel Crohn's disease, celiac disease, and polyposis syndrome^[1-5]. While it offers excellent diagnostic utility compared to other imaging modalities^[6-10], a major limitation of the technology is the finite battery life, which ranges from 8 to 12 h depending on the system used^[2,4]. CE is incomplete in approximately 16.5% of the cases, defined as the failure of capsule entry into the cecum prior to cessation of battery life, which thus leaves a segment of the distal small bowel unexamined^[3].

As CE lacks a means of self-propulsion and relies primarily on bowel motility for transit, previous studies have evaluated various methods to enhance bowel motility in an attempt to improve completion rate; however, purgatives^[11], prokinetics^[12,13], and chewing gum^[14,15] have shown mixed results, and thus currently there is no recommendation for the routine use of any of these measures to improve CE completion rate^[1,16]. In fact, enhancing bowel motility may not be the optimal approach because shorter bowel examination time by the CE may potentially be associated with reduced diagnostic yield^[17].

Fortunately, with the advances in technology, newer generations of CE promise longer battery life without sacrificing image quality^[4,18-20]. PillCam™ SB2U is a newer generation CE that promises 12 h of operating time compared to 8 h of its predecessor, SB2. The extended battery life is accomplished while maintaining

identical physical dimensions (26 mm × 11 mm). It is conceivable that completion rate would improve with longer CE operating time, but to date there has not been any study that examined specifically the impact of battery life on CE completion rate. We therefore sought to determine the clinical impact of longer battery life on CE in terms of completion rate and rate of positive findings.

MATERIALS AND METHODS

Design and patient population

This is a retrospective analysis of patients who underwent small bowel capsule endoscopy at a university-affiliated tertiary care centre (St. Paul's Hospital, Vancouver, British Columbia, Canada) between January 2010 and September 2013. Inclusion criteria: Patients who underwent CE using either PillCam™ SB2 or SB2U (Given Imaging, Yoqneam, Israel), which are identical in terms of dimensions and image quality. SB2U is also known as SB2EX in some markets. Our institution switched from SB2 to SB2U in July 2011. Exclusion criteria: History of gastric or small bowel surgery, endoscopic placement of capsule endoscope, interrupted view of major landmarks due to technical difficulty or significant amount of debris, and repeat CE using same system (*i.e.*, only the first CE was included if the patient underwent repeat CE using the same system, but if two CEs had been performed using different systems then both were included). This study was approved by University of British Columbia Providence Health Care Research Ethics Board.

Small bowel capsule endoscopy procedure

As per standard protocol at our institution, all patients are asked to stop any oral iron supplementation five days prior to the procedure, and to undergo bowel preparation with clear liquid-only diet and 2 L polyethylene glycol plus electrolyte solution the day before the procedure. Following capsule endoscope ingestion, patients were permitted to resume clear fluids after 2 h and solid food after 4 h. Motility-altering agents were not used during the procedure unless patients were previously taking these medications. Each CE was reviewed on real-time viewer after 7-8 h of recording to determine the progress if the battery had not ceased to function. If the capsule endoscope was felt to be in the colon, then the study was terminated; otherwise it was allowed to continue until the battery runs out or at the next assessment if deemed complete. Data images were downloaded and independently reviewed by a single experienced gastroenterologist and the gastrointestinal therapeutics fellow/research assistant. If discrepancy existed among the reviewers, a consensus was reached.

Data extraction

Data collected included demographics, indications

Table 1 Exclusions

Other capsule endoscopy system	140
History of gastrointestinal surgery proximal to ileocecal valve	101
Endoscopic placement	7
Repeat procedure with same system	6
Aborted procedure due to inability to swallow	2
Technical difficulty with data transmission gap	3
Debris obscuring identification of landmarks	2

for CE, medical comorbidities and prior abdominal/pelvic surgery, use of agents that alter bowel motility, any significant bowel habit changes at the time of procedure, inpatient/outpatient status, type of capsule endoscope, small bowel transit time (SBTT), gastric transit time (GTT) and total recording time. GTT is defined as the time between first gastric image and first duodenal image. Similarly, SBTT is defined as the time between the first duodenal image and the first cecal image. In cases of incomplete small bowel examination, the SBTT is censored at the time of last recorded image. Total recording time is defined as the entire length of video recording until either the capsule camera's battery runs out, or the study was terminated based on real-time finding that the capsule camera likely had entered the colon and thus concluded the small bowel examination. Capsule completion rates, rates of positive findings, SBTT, GTT, and total recording time were compared between the two groups.

Primary outcome was CE completion rate to the cecum. Secondary outcome was the rate of positive findings, defined as any culprit lesion felt to explain the signs/symptoms for which the procedure was indicated (e.g., vascular lesion for gastrointestinal bleeding, ulcerated lesion for inflammatory bowel disease).

Statistical analysis

Baseline characteristics were summarized as mean and standard deviation, or median and quantiles, for continuous variables; whereas categorical values were described as frequency and percentage. Comparisons of the baseline characteristics between SB2 and SB2U groups were conducted using Wilcoxon rank-sum test, Chi-square test, or Fisher's exact test as appropriate.

Linear regression analysis was used to compare the SB2 and SB2U groups in terms of transit time and battery life. GTT, SBTT and total recorded time were log transformed to satisfy the required normality assumption of linear regression. The comparison was adjusted for age, gender, indications, inpatient status, use of narcotics, previous abdominal/pelvic surgery, bowel habit, diabetes and connective tissue disease. To compare the completion rate between groups, logistic regression adjusted for the same set of variables as above was considered. To compare the rates of positive findings, logistic regression adjusted for age, gender, Charlson comorbidity index^[21] and indications was employed.

Statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC, United States). Statistical significance was defined as *p*-value less than 0.05.

RESULTS

Between January 2010 and September 2013, 668 small bowel CEs were performed, of which 528 were performed using either PillCam™ SB2 or SB2U; 120 were excluded due to meeting exclusion criteria and 408 were included for analysis (Table 1). This group of patients consisted of 208 (51.0%) males, and the mean age was 55.5 ± 19.3 years. Two patients in the SB2 group retained the CE in the stomach during the duration of the study but eventually passed the capsule endoscope; these two patients were excluded from analyses of bowel transit times. None of the included patients in the SB2U group experienced any adverse event. The most common indication for CE was gastrointestinal bleeding ($n = 254$, 62.3%), followed by inflammatory bowel disease (IBD) ($n = 86$, 21.1%). The mean Charlson comorbidity index, unadjusted for age, was 1.0 ± 1.6 . Twenty CEs (4.9%) were performed on an inpatient basis. There was no statistically significant difference between the SB2 and SB2U groups in terms of baseline characteristics and comorbidities, although there was a trend toward higher proportion of IBD cases in the SB2U group (25.7% vs 15.6%, $P = 0.051$) (Table 2).

In the unadjusted analysis, there was no statistically significant difference between SB2 and SB2U in terms of median GTT ($P = 0.794$) or median SBTT ($P = 0.669$). Total recording time was significantly longer in the SB2U group ($P < 0.001$) and there was a trend toward higher completion rates in the SB2U group ($P = 0.076$). However, rates of positive findings on CE were not statistically different ($P = 0.905$) (Table 3).

In the adjusted analysis, there was again no difference in terms of GTT ($P = 0.352$) and SBTT ($P = 0.261$), or positive findings rates ($P = 0.918$). However, total recording time was estimated to be 14% longer in the SB2U group (95%CI: 10%-18%, $P < 0.001$), and there was a corresponding trend toward higher completion rate in the SB2U group (OR = 1.78, 95%CI: 0.88-3.63, $P = 0.111$) (Table 4).

DISCUSSION

Small bowel CE is an excellent non-invasive means of assessing for small bowel pathology, but approximately 16.5% of CEs are incomplete^[3]. Finite battery life poses a major limitation to its clinical use, as incomplete examination of the small bowel results in diagnostic uncertainty, particularly in cases without significant findings on CE^[22,23]. This often necessitates further investigations to examine the distal portion of the small bowel that was not visualized.

In theory there are two ways to improve CE completion rates: increasing bowel motility and hence

Table 2 Basic Information *n* (%)

Variable	All (<i>n</i> = 408)	SB2 (<i>n</i> = 186)	SB2U (<i>n</i> = 222)	<i>P</i> value
Male	208 (51.0)	93 (50.0)	115 (51.8)	0.717
Age				0.602
Mean ± SD	55.5 ± 19.3	56.6 ± 17.3	54.6 ± 20.9	
Median (IQR)	60.0 (44.0, 70.0)	59.5 (47.0, 69.0)	60.0 (41.0, 70.0)	
Range	(9.0, 90.0)	(15.0, 90.0)	(9.0, 88.0)	
Indication				0.051
Gastrointestinal bleeding	254 (62.3)	121 (65.1)	133 (59.9)	
Inflammatory bowel disease	86 (21.1)	29 (15.6)	57 (25.7)	
Abdominal pain, radiological abnormality, history of obstruction	47 (11.5)	23 (12.4)	24 (10.8)	
Others ¹	21 (5.1)	13 (7.0)	8 (3.6)	
Inpatient	20 (4.9)	8 (4.3)	12 (5.4)	0.607
Previous abdominal/pelvic surgery	171 (41.9)	83 (44.6)	88 (39.6)	0.310
Use of narcotics or prokinetics				0.641
None	371 (90.9)	168 (90.3)	203 (91.4)	
Narcotics	33 (8.1)	17 (9.1)	16 (7.2)	
Prokinetics	4 (1.0)	1 (0.5)	3 (1.4)	
Bowel habit				0.848
Normal	342 (83.8)	154 (82.8)	188 (84.7)	
Constipation	14 (3.4)	8 (4.3)	6 (2.7)	
Diarrhea	41 (10.0)	19 (10.2)	22 (9.9)	
Alternating	11 (2.7)	5 (2.7)	6 (2.7)	
Connective tissue disease	16 (3.9)	9 (4.8)	7 (3.2)	0.382
Diabetes mellitus	73 (17.9)	28 (15.1)	45 (20.3)	0.171
Charlson index score (unadjusted for age)				0.819
Mean ± SD	1.0 ± 1.6	1.0 ± 1.5	1.1 ± 1.7	
Median (IQR)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	
Range	(0.0, 10.0)	(0.0, 7.0)	(0.0, 10.0)	

¹Polyposis syndrome, cancer/lymphoma screening/surveillance, abnormal bowel movement, reflux, pancytopenia, refractory celiac disease, recurrent vomiting. IQR: Interquartile range; SD: Standard deviation.

Table 3 Unadjusted analysis

Variable	All (<i>n</i> = 408)	SB2 (<i>n</i> = 186)	SB2U (<i>n</i> = 222)	<i>P</i> value
GTT, minutes				0.794
Mean ± SD	35.4 ± 44.5	35.0 ± 41.5	35.7 ± 47.0	
Median (IQR)	19.5 (10.7, 41.9)	19.5 (10.6, 42.7)	19.5 (10.9, 41.8)	
Range	(0.1, 417.2)	(0.1, 262.8)	(0.4, 417.2)	
SBTT, hours				0.669
Mean ± SD	4.1 ± 2.2	3.9 ± 1.6	4.3 ± 2.6	
Median (IQR)	3.9 (2.7, 4.8)	3.9 (2.8, 4.5)	3.9 (2.5, 4.9)	
Range	(0.3, 14.5)	(0.3, 7.8)	(0.5, 14.5)	
Total recorded time, h				< 0.001
Mean ± SD	8.4 ± 1.8	7.7 ± 0.5	9.0 ± 2.2	
Median (IQR)	7.9 (7.9, 8.2)	7.9 (7.8, 7.9)	8.2 (8.0, 8.6)	
Range	(3.6, 16.1)	(3.8, 8.0)	(3.6, 16.1)	
Completion				0.076
No	37 (9.1)	22 (11.8)	15 (6.8)	
Yes	371 (90.9)	164 (88.2)	207 (93.2)	
Result				0.905
Negative	279 (68.7)	127 (69.0)	152 (68.5)	
Positive	127 (31.3)	57 (31.0)	70 (31.5)	

IQR: Interquartile range; GTT: Gastric transit time; SBTT: Small bowel transit time; SD: Standard deviation.

the speed of CE transit, or increasing the recording time. Even though motility-enhancing agents have not shown convincing benefit, we now have CE systems that are capable of longer recording times. In fact, previous studies have demonstrated that

Table 4 Adjusted analyses

Variable	Group difference (95%CI)	<i>P</i> value
GTT	0.90 (0.72-1.13)	0.352
SBTT	1.07 (0.95-1.19)	0.261
Total recorded time	1.14 (1.10-1.18)	< 0.001
	Odds ratio (95%CI)	
Completion	1.78 (0.88-3.63)	0.111
Positive findings	0.98 (0.64-1.51)	0.918

GTT: Gastric transit time; SBTT: Small bowel transit time.

MiroCam (IntroMedic, Seoul, South Korea), a CE system capable of 11-h recording time, may have higher completion rates compared to the 8-h PillCam SB2 (Given Imaging, Yoqneam, Israel)^[18,19]. However, MiroCam also differed from PillCam SB2 in its physical dimensions, which certainly could have had an impact on CE transit. To our knowledge, our study is the first to assess solely the effect of battery life on CE completion rate.

The results of our study suggest that utilizing a capsule endoscope with longer operating time may be a simple yet effective way of improving completion rates. Although our results did not reach statistical significance, there was a clear trend towards higher completion rate by extending the mean operating time by one hour with the help of real-time viewer to determine if the cecum had been reached.

Of the 15 CEs that were not complete in the SB2U group, 6 were disconnected between 8 h and 9 h either per patient preference or based on real-time identification of features suggestive of colonic mucosa by the research assistant/gastrointestinal therapeutics fellow; the remaining 9 were disconnected by the patients at home late at night after at least 10 h of recording, usually before bed time or after the recorder has powered down due to loss of signal (*i.e.*, battery outage). It is possible that a statistically significant difference in the completion rates between SB2U and SB2 may have been detected had the CEs not been disconnected prematurely. Assuming the 6 CEs would have been complete with extended recording times, the completion rate of SB2U could have been as high as 95.9% ($P = 0.004$). However, the optimal recording duration remains to be determined, as premature disconnections confound this study's ability to draw such conclusion.

While the real-time viewer is a valuable tool, the ability to distinguish small bowel mucosa from that of the cecum may be limited as was the case with the 6 CEs that were disconnected before reaching cecum. The combination of slow transit and single-frame viewing, as well as debris obscuring the view can make distinction between ileal mucosa from cecal mucosa difficult at times. An alternative approach would be recording until the battery runs out. This is particularly important in patients at risk of slower bowel motility, such as those with history of abdominal/pelvic surgery, diabetes mellitus, altered bowel anatomy, and inpatients^[24-27]. Subgroup analyses of completion rates among patients at risk of slower bowel motility was not performed due to small sample sizes. Further studies are needed to confirm this.

There was a trend towards employing CE more frequently in the investigation of IBD after the transition to SB2U, due to CE's high sensitivity and specificity for small bowel Crohn's disease^[6-8]. However, this did not appear to affect the CE completion rates. The percentages of patients with "narrowing and regional transit abnormality", which can be seen in stricturing Crohn's disease, were also not significantly different between SB2 and SB2U (9.7% vs 6.3%, $P = 0.607$). This is not surprising as CE is usually reserved for those with subtle findings that may not be easily detected on other imaging modalities.

There was no difference between the two groups in terms of positive findings rates despite the longer recording time in the SB2U group. Given that SB2U's main advantage over SB2 is the ability to identify potential lesions in distal ileum, a larger sample size would be necessary to detect any difference. In addition, the value of a complete CE study lies in the ability to exclude lesions without needing further investigation to assess the distal small bowel that would otherwise be unexamined in an incomplete study. This has significant implications in resource utilization.

Our study has a number of limitations in addition to not assessing the full potential of the SB2U CE system as described above. The study is retrospective in nature and reflects single-centre experience. We also did not include patients with altered bowel anatomy as it was not possible to determine the extent of anatomical changes in these patients. In addition, we did not include those who had endoscopic placement of capsule endoscope based on anticipated bowel dysmotility in the referral history or previously failed CE. It is possible that these patient populations would benefit most from the extended recording time of the SB2U. Randomized controlled trials are necessary to assess for this. Finally, this study did not assess the impact that longer battery life has on the endoscopist's CE reading time. However, anecdotally the 14% increase in average recording time did not increase the reviewing time significantly. This is partly due to slower motility in the distal bowel, which frequently results in identical images that are filtered by the CE software.

In summary, our study demonstrates a trend towards increased completion rates using CE with a longer battery life in patients without altered bowel anatomy. Extending the operating time of CE may be a simple method to improve completion rates. A randomized controlled trial may be necessary to confirm this. In the meanwhile, efforts to increase the operating efficiency of CE should be encouraged. When given two CE systems with identical physical dimensions, use of the CE with longer battery life should be considered (*e.g.*, 12-h SB2U vs 8-h SB2; 12-h SB3 vs 8-h SB3EX).

COMMENTS

Background

Capsule endoscopy does not completely visualize the small bowel approximately 16.5% of the time, primarily due to limited battery life. Incomplete examination may require additional investigations.

Research frontiers

As technology advances, newer capsule technology such as PillCam™ SB2U offers a longer battery life without sacrificing image quality or physical size compared to its predecessor, SB2. This provides a unique opportunity to examine the effect of battery life on capsule completion rate.

Innovations and breakthroughs

SB2U has longer battery life than SB2 while maintaining identical size and image quality. With longer operating time, SB2U showed a trend toward higher rate of visualizing the entire length of small bowel. There was no difference in the rates of positive findings, but further investigations can potentially be avoided.

Applications

Using capsule endoscopy with longer battery life may be a simple way to improve study completion rate.

Terminology

Capsule endoscopy is a non-invasive means of visualizing the small bowel with high diagnostic value. It utilizes a wireless capsule camera that captures images of the inside of the small bowel and transmits the data to a recorder, which can then be downloaded to a workstation to be reviewed by an endoscopist.

Peer-review

This is a retrospective study evaluating the effect of longer battery life on small bowel capsule endoscopy. Authors conclude that there was a trend toward higher completion rate with longer battery life without affecting the diagnostic yield.

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