

Retrospective Study

Comparison of the diagnostic yield and outcomes between standard 8 h capsule endoscopy and the new 12 h capsule endoscopy for investigating small bowel pathology

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Abstract

AIM: To evaluate the completion rate and diagnostic yield of the PillCam SB2-ex in comparison to the PillCam SB2.

METHODS: Two hundred cases using the 8-h PillCam SB2 were retrospectively compared to 200 cases using the 12 h PillCam SB2-ex at a tertiary academic center. Endoscopically placed capsules were excluded from the study. Demographic information, indications for capsule endoscopy, capsule type, study length, completion of exam, clinically significant findings, timestamp of most distant finding, and significant findings beyond 8 h were recorded.

RESULTS: The 8 and 12 h capsule groups were well matched respectively for both age (70.90 ± 14.19 vs 71.93 ± 13.80 , $P = 0.46$) and gender (45.5% vs 48% male, $P = 0.69$). The most common indications for the procedure in both groups were anemia and obscure gastrointestinal bleeding. PillCam SB2-ex had a significantly higher completion rate than PillCam SB2 (88% vs 79.5%, $P = 0.03$). Overall, the diagnostic yield was greater for the 8 h capsule (48.5% for SB2 vs 35% for SB2-ex, $P = 0.01$). In 4/70 (5.7%) of abnormal SB2-ex exams the clinically significant finding

was noted in the small bowel beyond the 8 h mark.

CONCLUSION: In our study, we found the PillCam SB2-ex to have a significantly increased completion rate, though without any improvement in diagnostic yield compared to the PillCam SB2.

Key words: PillCam SB2; Capsule endoscopy; Obscure gastrointestinal bleeding

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Core tip: The PillCam SB2-ex and the PillCam SB2 have the same size and specifications, except the PillCam SB2-ex offers 12 h of operation, 4 more hours than the original PillCam SB2. There has been no evaluation regarding the completion rate and diagnostic yield between these two capsules. We examined 200 cases using the 8-h PillCam SB2 and compared it to 200 cases using the 12 h PillCam SB2-ex. We found the PillCam SB2-ex to have a significantly increased completion rate, though without any improvement in the diagnostic yield compared to the PillCam SB2.

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INTRODUCTION

Capsule endoscopy has proven to be an effective method to investigate small bowel pathology including Crohn's disease, unexplained abdominal pain, diarrhea, and obscure gastrointestinal (GI) bleeding^[1,2]. Of these indications, capsule endoscopy has become the first-line option for evaluation of obscure GI bleeding which is defined as "overt bleeding and/or anemia with a negative endoscopic workup including complete colonoscopy and gastroscopy"^[3]. The PillCam SB (previously known as the M2A; Given Imaging, Yokneam, Israel) which was introduced in 2001^[1,4,5] began the era of capsule endoscopy for day to day clinical use^[3,4].

The MiroCam (IntroCam, Seoul, South Korea) has a 12 h operating time as compared to 8 h of the Olympus Endo Capsule and PillCam SB2^[3]. Longer operating time can reduce incomplete examination and may increase diagnostic yield^[4]. Pioche *et al*^[3] found the MiroCam to have comparable efficacy to the PillCam SB2. The MiroCam uses human body communication for image transmission as opposed to radiofrequency as does the PillCam SB2^[3]. In 2010, Given imaging introduced

the PillCam SB2-ex which differs from its predecessor (PillCam SB2) in that it offers a 12 h operating time similar to the MiroCam. The PillCam SB2 and the PillCam SB2-ex have the same size and specifications except for the recording time^[6].

While a longer operating time may increase the rate of complete examinations, defined by passage of the capsule into the colon during its operating time, it is still unknown whether the additional 4 h of recording time will increase diagnostic yield or clinical outcomes. To answer these questions we investigated the completion rate and diagnostic yield of the new 12 h PillCam SB2-ex in comparison to the 8 h PillCam SB2.

MATERIALS AND METHODS

The study was conducted at North Shore University Hospital after obtaining institutional review board approval. There was no external financial support. Capsules that were placed endoscopically in the stomach or duodenum were excluded from consideration. We conducted a retrospective review of four hundred consecutive inpatients, 200 of whom had undergone 8-h PillCam SB2 from 2009 to 2011 and 200 consecutive 12 h PillCam SB2-ex inpatient exams from 2011 to 2013. No inpatient studies using the 8-h PillCam SB2 were performed following the introduction of the 12 h PillCam SB2-ex in our practice. Demographic information, indications for capsule endoscopy, capsule type, study length, completion or incomplete exam (completion defined as capsule passage into the cecum during the recording), abnormal capsule findings divided into, bleeding, Arteriovenous malformation (AVM) (arteriovenous malformation), erosive disease, polyps/mass, and miscellaneous, timestamp of most distant finding, and findings beyond 8 h were recorded. All procedures were read by one of two experienced gastroenterologists. Standard protocol for inpatients prior to capsule endoscopy required that each patient receive nothing but clear liquids by mouth from at least noon the day before capsule ingestion, and that they receive nothing by mouth other than medication and sips of water after midnight the night before ingestion. There was no standard purgative bowel prep used at our institution before capsule ingestion. Two hours after capsule ingestion, the patients were permitted to have clears and then two hours later a regular diet if deemed medically appropriate by the gastroenterology consultant. The primary study endpoint was the completion rate, defined by passage of the capsule into the cecum during its operating time. The secondary endpoint was diagnostic yield, defined by any finding considered abnormal by the interpreting gastroenterologist.

Statistical analysis

For the comparison of baseline characteristics and

Table 1 Demographics and indications for capsule endoscopy in each capsule group *n* (%)

	PillCam SB2 cases	PillCam SB2-ex cases	<i>P</i> value (< 0.05)
Age (mean ± SD)	70.90 ± 14.19	71.93 ± 13.80	0.46
Male	91 (45.5)	96 (48)	0.69
Obscure GI bleed	131 (65.5)	146 (73)	0.13
Anemia	47 (23.5)	36 (18)	0.22
Anemia or obscure GI bleed	178 (89)	182 (91)	0.62
AVM	11 (5.5)	9 (4.5)	0.82
Other	11 (5.5)	9 (4.5)	0.82

GI: Gastrointestinal; AVM: Arteriovenous malformation.

Table 2 Characteristics and small bowel findings¹ for each capsule group *n* (%)

	PillCam SB2 cases	PillCam SB2-ex cases	<i>P</i> value (< 0.05)
Complete studies	159 (79.5)	176 (88)	0.03
Average completed study duration	4:15:56	4:51:27	
Abnormal finding total	97 (48.5)	70 (35)	0.01
Bleeding	21 (10.5)	20 (10)	1.00
AVM	35 (17.5)	19 (9.5)	0.03
Erosive disease	32 (16)	26 (13)	0.45
Polyp/mass (see text)	9 (4.5)	4 (2)	0.26
Miscellaneous	0	1 (1)	1.00

¹Some cases had multiple findings. AVM: Arteriovenous malformation.**Table 3** Clinically significant findings beyond the 8 h mark in the SB2-ex capsule group

Findings outside of the small bowel	Time	Findings in the small bowel	Time
Bleeding in colon	8:59:18; 14:09:59; 15:08:22	Bleeding in duodenal bulb due to AVM	8:57:24
AVM in colon	8:59:34	AVM	9:34:04
Portal gastropathy	10:38:06	Denuded mucosa in SB Jejunitis	11:15:22 13:02:13

AVM: Arteriovenous malformation.

outcome variables between the PillCam SB2 and PillCam SB2-ex capsule groups, two sample unpaired *t*-test for continuous variables and Fischer's exact test for categorical values were used. *P* value < 0.05 was considered significant. GraphPad software was used for all analysis. The statistical methods of this study were reviewed by Meredith Akerman.

RESULTS

A total of 400 cases were reviewed. The two groups were well matched for both age and gender as well

as for indications for capsule endoscopy as shown in Table 1. There were four categories of indications for capsule endoscopy: anemia, obscure GI bleed, known history of AVM, and "other". The "other" category included Crohn's/ileitis, chronic nausea and vomiting, abdominal pain, diarrhea, weight loss, evaluation for carcinoid tumor, follow up of ileal intussusception, history of small bowel polyp, and history of small bowel obstruction.

The PillCam SB2-ex had a significantly higher completion rate than the PillCam SB2 (88% vs 79.5%, *P* = 0.03). The diagnostic yield was greater for PillCam SB2 than PillCam SB2-ex, (48.5% vs 35%, *P* = 0.01), with a greater rate of detection of AVMs (17.5% vs 9.5%, *P* = 0.03). Other findings were similar between the two groups. The mean study lengths were 4:15:56 and 4:51:27 for PillCam SB2 and PillCam SB2-ex, respectively. The most distal timestamp of a positive finding for the PillCam SB2-ex (15:08:22) was longer than that of the PillCam SB2 (7:24:21). For the PillCam SB2, six cases found small bowel polyps and three cases described a soft tissue lesion. In the PillCam SB2-ex, two cases identified a duodenal mass, one case a polypoid lesion in the jejunum, and one case a duodenal polyp (Table 2).

Nine cases from the total SB2-ex capsule group (200) had clinical significant findings beyond the 8 h mark. These findings are summarized in Table 3. Of these 9 cases, 4/70 (5.7%) of abnormal PillCam SB2-ex small bowel findings occurred beyond 8 h.

DISCUSSION

Since the introduction in 2003 of the M2A capsule, capsule endoscopy has become a first line modality for the evaluation of obscure GI bleed^[3,4]. The advancement of longer operating times is expected to offer the potential of both increasing the rate of completed studies and detecting more clinically significant findings. Our findings do confirm that the extra 4 h of operating time provided by the 12 h SB2-ex resulted in a significantly higher rate of complete studies over the 8 h SB2 capsule for an inpatient population, 88% vs 79.5%, *P* = 0.03 respectively. Two retrospective studies on 8- hour capsule performed in Thailand and New Zealand demonstrated similar completion rates as our PillCam SB2 group^[7,8]. Unfortunately the authors of the Thai study did not delineate whether the population of patients involved in the study were strictly inpatient-based, and the patients included in the New Zealand study were a mixed population of inpatients and outpatient. Additionally, all patients received bowel preparations, and some may have been given pro-motility agents. This highlights a difference from our own study which was performed exclusively in the inpatient population, and was done without routine use of bowel prep or pro-motility agents. Previously reported data have

found incompleteness rates for 8 h capsule endoscopy to be as high as 25% of all cases^[4,6]. These previous results suggest that the difference we observed was real, and not related to an abnormally low completion rate in the SB2 group. Incomplete studies may be due to battery/system failure before reaching the cecum, though this was not the case in either the SB2 or SB2-ex group. Other factors more commonly affecting completion rate such as variable bowel motility, delayed gastric emptying, capsule retention, previous SB surgery, and poor bowel cleansing^[2,9] likely accounted for the incomplete examinations in both groups.

Despite the significantly higher study completion rate, we were unable to demonstrate a superior diagnostic yield for SB2-ex over SB2. In fact the diagnostic yield between PillCam SB2 and PillCam SB2-ex was 48.5% vs 35% (P value = 0.01), favoring improved diagnostic yield for the 8 h PillCam SB2. This unexpected finding would appear to challenge the notion that a longer operating time translates into an improvement in diagnostic yield. We suspect however that the difference in diagnostic yield found in the present study is related to the advancing/changing expertise of the interpreting gastroenterologists over time. As noted, the PillCam SB2 examinations all occurred in the years 2009 to 2011 prior to the PillCam SB2-ex examinations 2011 to 2013. It is possible that over the time period studied that the standards by which each of the gastroenterologists qualified a finding as "positive" may have changed. It is particularly notable that the largest classification of significant finding by SB2 was AVMs, found in 17.5% of studies, compared to 9.5% for the SB2-ex. Since there is no gold standard for labeling a finding as an AVM by capsule endoscopy it is possible that with more practice, the reporters' threshold to interpret AVMs as a significant finding increased leading to less AVMs reported, and a decreased diagnostic yield overall.

Though even if we accept a similar diagnostic yield between the two capsule systems, there is still a potential for improved cost effectiveness with the 12 h system. Since extending the operating life of the capsule resulted in more complete studies, this would seem to offer a cost benefit by avoiding repeating those studies which were incomplete, by not prolonging the patient's hospital admission to repeat incomplete studies, and by limiting the need for diagnostic imaging to confirm capsule passage which is often required when visualization of the cecum is not achieved during capsule recording.

While ours is the largest study to date, it is not the first to address diagnostic yield of an 8 h vs a 12 h capsule^[3,4]. Kim *et al*^[4] found a nonsignificant increased diagnostic yield with the 12 h MiroCam capsule compared with the 8 h PillCam SB2 in 24 patients (45.8% vs 41.7%), with a completion rate to the cecum which was higher. However, it should be noted that the completion was rate for standard

PillCam SB in his study was very low at 58.3%. Pioche *et al*^[3] performed a larger, multicentered, prospective, randomized study also comparing the diagnostic yield of the PillCam SB2 and MiroCam capsules in 83 patients. In patients having both examinations completed, the MiroCam identified significantly more findings than the PillCam SB2 capsules. However, a more recently published study performed by Choi *et al*^[10], performed in a similar fashion with 105 patients, was unable to show an improvement in diagnostic yield for the MiroCam in comparison to the PillCam SB2, and only showed a positive trend but not a statistical difference in completion rates.

In our study, significant SB findings beyond 8 h were identified in four cases by PillCam SB2-ex, 5.7% of the total "positive" studies. While this yield beyond 8 h did not contribute to a significantly increased study yield overall for the 12 h system, it is notable that such a large percentage of significant findings occurred beyond the standard 8 h window.

One issue that can occur particularly often in hospitalized patients, is slowed or altered gastric motility. A potential weakness of our study was the lack of any control for this variable, as well as a lack of data regarding potential prokinetic use by the study population. Conversely we do know that prokinetic use is not routine in our institution for capsule studies. Given the overall demographic similarities between the two groups it seems unlikely that prokinetic use effected the study results if it was in fact utilized. In two of the eight cases mentioned above, despite the capsule retention in the stomach for a portion of time equivalent to the complete battery life of the PillCam-SB2, the additional battery life of the PillCam SB2-EX allowed the capsule enough time to locate a finding of clinical interest. Prokinetics have been used to shorten small bowel transit time and possibly improve completion rates^[11]. In a meta-analysis by Koulaouzidis *et al*^[11], a statistically higher completion rate was found in patient who ingested the capsule with metoclopramide vs control [OR (95%CI): 2.8 (1.35-3.21)]. In addition, a prospective study comparing metoclopramide ingestion prior to capsule endoscopy vs control found statistically significant higher completion rates in the former group (97% vs 76%)^[12]. These studies were both performed using the 8-h capsules.

Additionally, bowel preparation can affect the degree of visualization of the small bowel^[13]. Currently, European guidelines advocate the use of a PEG preparation for capsule endoscopy^[14]. It has been shown that using a bowel prep in addition to a prokinetic agent can increase completion rate, as shown in a meta-analysis published by Koulaouzidis *et al*^[11]. In Pioche's study, polyethylene glycol (PEG) was used for bowel cleanliness in patients receiving the MiroCam or the PillCam SB2^[3]. The diagnostic yield was higher for the MiroCam when compared to PillCam SB2. Our institution capsule protocol required each

patient to have nothing but clear liquids from noon the day before the examination and to receive “nothing by mouth” the night prior to capsule ingestion. While no specific purgative bowel preparation was required for capsule examination, we know from standard practice in the institution that many of these patients had their study performed soon after a negative colonoscopy which itself involved a bowel cleanse. As it was not standard to address bowel purgative use prior to capsule study in the capsule reports, it is unknown how purgative use may have been a potential confounding factor.

An additional limitation of our study is its non-randomized nature, notably with the pre-procedure indication of obscure GI bleeding differing between the two groups. When including both obscure GI bleed and anemia together as an indication, there was no longer a statistical difference between the study groups. There was also no control for the timing of capsule endoscopy in these cases of obscure GI bleeding. Prior studies have shown that capsule endoscopy performed within the first few days of obscure GI bleed increases the diagnostic yield^[15-17].

In our study, obscure GI bleeding was the major indication for both PillCam SB2 (65.5%) and PillCam SB2-ex (73%) capsule studies. In the PillCam SB2-ex group, the most common findings were active small bowel bleeding, erosive disease, and AVM with rates of 10%, 13%, and 9.5%, respectively. Our findings are similar to prior reports. In a large meta-analysis involving 22840 capsule endoscopies, AVM was the most common diagnosis for obscure GI bleed followed by small bowel inflammation/ulcers^[9].

In conclusion we have demonstrated superior completion rates for the PillCam SB2-ex 12 h capsule as compared to the 8 h PillCam SB2. We were unable to demonstrate a superior overall diagnostic yield of the 12 h system despite a notable number of clinically significant findings detected beyond the 8 h mark, including active bleeding, in the SB2-ex group. Further prospective randomized studies will be needed to confirm the advantage of PillCam SB2-ex over PillCam SB2.

COMMENTS

Background

Wireless capsule endoscopy, which requires the patient to ingest a small digital camera which transmits pictures of the bowel, is an effective method to investigate small bowel disease. A longer battery life, leading to longer operating times are expected to reduce incomplete examinations and may increase diagnostic yield. The new PillCam SB2-ex and the PillCam SB2 have the same size and specifications, except the PillCam SB2-ex offers 12 h of operation, 4 more hours than the original PillCam SB2. To date, there has been no evaluation regarding the completion rate and diagnostic yield between these two capsules.

Research frontiers

Capsule endoscopy systems are being created with longer operating time. The current research hotspot is to evaluate whether these longer operating capsules truly have better diagnostic yield.

Innovations and breakthroughs

Prior studies have compared 12 h operating time capsules to 8 h capsules but the capsules systems uses different image transmission system. The PillCam SB2 and the PillCam SB2-ex have the same size and specifications except for the recording time. The authors found the PillCam SB2-ex to have a significantly increased completion rate, though without any improvement in the diagnostic yield compared to the PillCam SB2.

Applications

Despite these findings, there were a small number of patients who had clinically significant findings beyond the 8 h mark, implying a role for the longer-length examination in a selected population. Additionally, the significantly increased rate of successful, completed studies for the longer operating capsule should offer a cost benefit over the older system.

Terminology

Capsule endoscopy refers to a miniature capsule shaped camera that takes multiple pictures as it passes through the small intestine. Images are wirelessly transmitted to a recording device which is attached to the patient. There are different capsule endoscopy systems. PillCam SB2 is the older capsule with an 8 h operating time, and PillCam SB2-ex is the newer capsule with a 12 h operating time.

Peer-review

In this well written study the authors compared 12 h to 8 h camera and identified that the 12 h camera was associated with higher completion rate and 6% findings that were distal to the 8 h camera reach. Surprisingly, the diagnostic yield of the 8 h camera was significantly higher. This is the largest cohort to date and the results are certainly interesting.

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