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Device failures and patient-related adverse events with small bowel capsule endoscopy: a 20-year MAUDE database analysis

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Abstract

Background Small bowel capsule endoscopy (SBCE) is a critical tool in the evaluation of small bowel bleeding, detection of small bowel neoplasms and diagnosing Crohn's disease. The object of this study was to examine device failures (DF) and patient-related adverse events (PRAE) in SBCE, including those involving the patency capsule system, using user-generated reports from the US Food and Drug Administration's (FDA) Manufacturer and User facility Device Experience (MAUDE) database.

Methods We analyzed post marketing surveillance data for SBCE data for all of the SBCE systems from the FDA's MAUDE database from January 2000 until December 2023.

Results A total of 352 reports were obtained during the study period, pertaining to the following SBCE systems, in descending order of frequency: Pillcam SB® system, Pillcam® Patency Capsule, Endocapsule®, CapsoCam® and MiroCam®. The vast majority pertained to the Pillcam® and Pillcam® Patency system: a total of 307 medical device reports with 398 DFs and 569 PRAEs. The most reported DFs were entrapment of the device (n=212, 53.2%), failure to transmit record (n=38, 9.5%), and failure to record (n=35, 8.7%). The most commonly reported PRAEs were a foreign body retained in the patient (n=140, 24.6%), unintentional exposure to radiation (n=104, 18.2%), and unintended exposure to anesthesia (n=58, 10.2%).

Conclusions Findings from the MAUDE database regarding SBCE devices provide valuable information on DFs and PRAEs. This knowledge can help operators optimize patient selection and reduce patient risk.

Keywords Adverse events, FDA MAUDE database, post-marketing surveillance, small bowel capsule endoscopy, video capsule endoscopy

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Introduction

In 2000, Iddan *et al*, in conjunction with Given Imaging®, published a landmark article in *Nature* describing the first wireless capsule endoscopy with a 6-h battery life in 10 healthy volunteers [1]. Now, 24 years and hundreds of thousands of video capsule endoscopies later, the data compiled are substantial, the variations of the original design are numerous, and the battery life has doubled, yet the principles and clinical utility of small bowel capsule endoscopy (SBCE) have remained the same.

SBCE is a valuable tool in the evaluation of suspected small bowel bleeding, diagnosis of suspected Crohn's disease (CD) and detection of small bowel neoplasms. Quality indicators have recently been established to streamline the diagnostic interpretation of these studies [2]. Much literature has been published on the utility of SBCE and its favorable safety profile over more invasive endoscopic imaging techniques, such as single- or double-balloon enteroscopy [3-8]. The safety profile

of SBCE has been examined by many studies, including several meta-analyses, which have contributed to the examination of clinical adverse events [9-12]. Capsule retention is a patient-related adverse event (PRAE) of significant relevance, as SBCE is often employed in the diagnosis or monitoring of CD and may require surgical intervention for retrieval. Capsule aspiration during ingestion, another significant PRAE, is reportedly uncommon, with a meta-analysis showing only 63 reported cases across 57 studies involving approximately 14,522 capsule endoscopy exams from the years 1996-2022 [13].

Since the US Food and Drug Administration's (FDA) approval of the first video capsule endoscopic devices in the early 2000s, multiple models have come on the market. There are currently many SBCE systems available, with the PillcamSB® (Medtronic) system appearing to dominate the US market [14,15].

While PRAEs in SBCE are well-documented, data focused specifically on device failures (DFs) remain scarce, despite the introduction of numerous video capsule endoscopy (VCE) models since the early 2000s. The Manufacturer and User facility Device Experience (MAUDE) database is a well-known and reputable source of voluntary user reporting of FDA-approved devices. We used this database to analyze the reports of SBCE-related DFs and PRAEs over the past 24 years, from January 01, 2000, to December 31, 2023.

Materials and methods

The MAUDE database

The FDA's MAUDE database is a free, downloadable public database that is composed of voluntary user reports since 1993 and manufacturer reports since August 1996. The MAUDE database collects major adverse reports involving medical devices after FDA approval. It is publicly accessible (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). Reporting is on a mandatory (manufacturers, importers, and device-user facilities) or voluntary (healthcare professionals, patients, and consumers) basis.

The database is updated monthly with reports containing information on the specific device, event data, whether the device was returned to the manufacturer, and narratives from the user and/or the manufacturer. Events are classified based on severity into 4 categories: death, injury, malfunction, or other. If a device is deemed defective, the FDA can issue safety alerts or recalls. Although this surveillance system cannot be used to establish definitive event rates or causal relationships, it can provide important insights into the most commonly encountered clinical adverse events and into potential mechanisms of medical device failures, as evidenced by the over 500 MAUDE database studies that have been published at the time of writing [16].

Technical aspects of SBCE

In a study focused on DFs and PRAEs, a brief overview of the components of the endoscopic capsule system is in order. The most commonly used capsule endoscopy systems currently consist of 3 basic parts: the ingested capsule, an externally worn recorder with antenna for wireless data transmission/collection, and a method to download the recorded data to a computer for software to interpret the findings. A typical endoscopic capsule consists of a battery, transmitter, CCD/CMOS sensor, LED lights and antenna, all housed in a translucent casing for disposable 1-time use [14,17].

For instance, the PillCam® SB capsule measures 11.4mm × 26.4mm, with the SB generation having 1 video camera delivering 2 fps (frames per sec), while the Pillcam® SB3 is a third-generation device that differs from its predecessors in having an adaptive frame rate that can auto-adjust from 2 images/sec to 6 images/sec as it detects peristaltic acceleration in conjunction with its external data recorder. This change was made to theoretically improve its diagnostic sensitivity in areas of the small bowel that historically have lesions that are "missed", such as the duodenal sweep [18].

SBCE devices examined

We obtained and analyzed post marketing surveillance data from the FDA's MAUDE database over a 24-year period pertaining to the SBCE devices on the market. To provide an accurate description of the events, the text of each individual adverse event report was analyzed. The reports overwhelmingly involved the Medtronic Pillcam® SB system, which consisted of 1 or more of the following components over the period analyzed: Pillcam®, Pillcam® SB 2 Capsule, Pillcam® SB 3 Capsule, Pillcam® Endoscopy System, Pillcam®Recorder Belt DR2C, Pillcam® Recorder DR3. Although there were far fewer reports available for the other capsule devices available on the market, including Pillcam® Patency capsule (Medtronic), EndoCapsule 10® (Olympus), CapsoCam SV 1® (CapsoVision), and MiroCam® (IntroMedic), these additional devices were included in this analysis for completeness. The following capsule devices were not included in this study, since there were no reports available: OMOM Capsule2® (Jinshan Science and Technology) and NaviCam SB® system (AnX Robotic Corp).

Results

Pillcam® SB system

There were 279 total reports identified and analyzed individually during the study period for the Medtronic Pillcam® SB capsule system. When plotted as a function of time, the report frequency over the studied period appears somewhat bell-shaped, with the number of reports peaking in 2018 (n=158, Fig. 1).

Device failures (Pillcam®)

A total of 398 DFs were identified (Table 1). The 10 most common DF events reported were, in descending order of

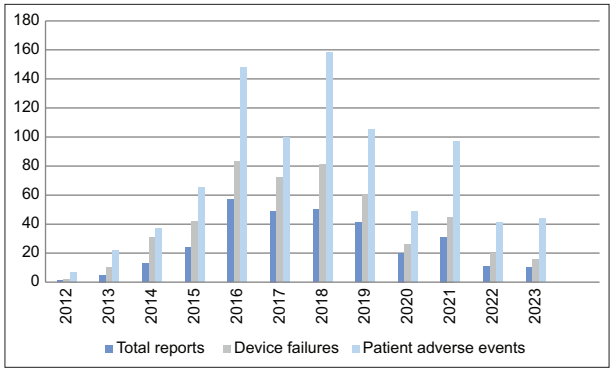

Figure 1 Device report frequency, by year (all Pillcam® devices*, MAUDE database Jan 2000 to Dec 2023)
* SB, SB2, SB3, Patency capsule system

frequency: entrapment of device (n=212, 53.2%), failure to transmit record (n=38, 9.5%), failure to record (n=35, 8.7%), loss of power of device (n=22, 5.5%), endocapsule fragmentation (n=17, 4.2%), adverse event without identified device or use problem (n=13, 3.2%), signal of device lost/external interference (n=8, 2.0%), device operated differently than expected (n=7, 1.7%), video data corruption (n=5, 1.2%), and inability to retrieve data (n=5, 1.2%).

PRAEs (Pillcam®)

A total of 569 PRAEs were identified (Table 2). The 10 most common PRAEs were, in descending order of frequency (with percentages of reported cases): foreign body retained in patient (n=140, 24.6%), unintended exposure to radiation (X-ray, computed tomography [CT], or both [n=104, 18.2%]), unintended exposure to anesthesia (n=58, 10.2%), Minor/miscellaneous events with no known impact or consequence to patient (n=48, 8.4%), abdominal pain (n=30, 5.2%), unintended exposure to surgery (n=27, 4.7%), small intestinal obstruction (n=16, 2.8%), vomiting (n=16, 2.8%), unintended exposure to enteroscopy (n=13, 2.2%), and dysphagia (n=10, 1.7%). Other serious and less-intuitive PRAEs were reported, such as stroke, cardiac arrest and pancreatitis. In these data entries, the manufacturer narrative in the reports stated that these severe AEs were unrelated to the capsule study. However, they have been included in order to preserve internal validity and not exclude any reported complications.

Pillcam® patency system

A query of the MAUDE database for the Pillcam® Patency Capsule® System yielded 28 reports that included 104 PRAEs and 42 DFs. The 5 most common PRAEs, in descending order of frequency, were: unintended exposure to radiation (n=18, 17.3%), unintended exposure to anesthesia (n=14, 13.4%), foreign body in patient (n=14, 13.4%), abdominal pain (n=11, 10.6%), and unintended exposure to surgery (n=10, 10.4%; Table 3). The 5 most common DFs, in descending order of frequency, were: entrapment of device (n=24, 57.1%), failure of patency capsule to dissolve (n=9, 21.4%), adverse event without identified device or use problem (n=3, 7.1%), device operated differently than expected (n=2, 4.7%), and endocapsule fragmentation (n=2, 4.7%) (Table 3). Although the Pillcam® Patency Capsule system is designed to dissolve, 2 reports described capsule obstruction leading to mesenteric

Table 1 Device failure frequency (Pillcam® devices*, MAUDE database Jan 2000 - Dec 2023)

Device failures reported	Frequency
Entrapment of device	212
Failure to transmit record	38
Failure to record	35
Loss of power of device	22
Endocapsule fragmentation	17
Adverse event without identified device or use problem	13
Signal of device lost/external interference	8
Device operates differently than expected	7
Video data corruption	5
Unable to retrieve data	5
Premature discharge of battery	5
Failure of patency capsule to dissolve	4
Short-circuit of electrical component	4
Device markings/labeling problem	2
Computer operating system problem	2
No display/image	1
Display malfunction	1
Missing device component	1
Failure to read input signal	1
Defective device component (sensor belt)	1
Poor quality video data	1
Failure to download data	1
Display/image freezing	1
Device displays incorrect message	1
Shortage of electrical component (power cable)	1
Physical resistance/sticking	1
Device dislodged or dislocated	1
Device or device fragments location unknown	1
User mishandling of device	1
Prematurely terminated study	1
Failure to connect recorder to device;	1
Loss of data	1
Misassembly by users	1
Malposition of device	1
Total	398

* SB, SB2, SB3

Table 2 Patient-related adverse events (Pillcam® devices*, MAUDE database Jan 2000 - Dec 2023)

Adverse events	Frequency
Foreign body in patient	140
Unintended exposure to radiation (X-ray, CT)	104
Unintended exposure to anesthesia	58
Minor/miscellaneous events with no known impact or consequence to patient	48
Abdominal pain	30
Unintended exposure to surgery	27
Small-intestinal obstruction	16
Vomiting	16
Unintended exposure to enteroscopy	13
Dysphagia	10
Aspiration of capsule/airway obstruction	9
Death	9
Delay of hospital discharge	8
Unable to swallow device	8
Intestinal perforation	6
Device embedded in tissue without associated bleeding	6
Unintended exposure to repeat capsule endoscopy	6
Unintended exposure to bronchoscopy	5
Diarrhea	5
Unintended exposure to colonoscopy	5
Unintended exposure to exploratory laparotomy	5
Foreign body sensation in esophagus	4
Peritonitis	2
Rash, generalized	2
Respiratory failure	2
Device embedded in tissue with associated bleeding	2
Intestinal obstruction, abdominal hernia	1
Odynophagia	1
Unintended exposure to laryngoscopy	1
Low blood pressure/hypotension	1
Weight loss	1
Device retention in fistulous tract	1
Seizures	1
Hyponatremia	1
Dizziness	1
Nosocomial infectious disease transmission (*C. diff*)	1
Pancreatitis	1
Cardiac arrest	1
Ventricular tachycardia	1
Intubation	1
Abscess	1
Sepsis	1
Capsule entrapment in metallic colon stent	1
Capsule entrapment in appendiceal orifice	1
Infarction, cerebral**	1
Stroke**	1
Indefinite entrapment (surgical removal deferred)	1
Capsule entrapment in Zenker's diverticulum	1
Thermal injury to intestine	1
Total	569

(*Contd...*)

Table 2 (*Continued*)

* SB, SB2, SB3

Table 3 Adverse events (Pillcam® patency capsule device, MAUDE database Jan 2000 - Dec 2023)

Adverse events	Frequency
Patient-related adverse events	
Unintended exposure to radiation	18
Unintended exposure to anesthesia	14
Foreign body in patient	14
Abdominal pain	11
Unintended exposure to surgery	11
Small intestinal obstruction	10
Vomiting	6
Unintended exposure to bronchoscopy	2
Intestinal perforation	2
Aspiration of capsule/airway obstruction	2
Capsule obstruction with mesenteric ischemia; intestinal resection required	2
Diarrhea	1
Hypoxia	1
Unintended exposure to upper endoscopy	1
Nausea	1
Foreign body reaction	1
Peritonitis	1
Rash, generalized	1
Delay of hospital discharge	1
Dysphagia	1
Unintended exposure to enteroscopy	1
Dyspnea	1
Small intestinal ileus	1
Total	104
Device related failures	
Entrapment of device	24
Failure of patency capsule to dissolve	9
Adverse event without identified device or use problem	3
Device operates differently than expected	2
Endocapsule fragmentation	2
Human–device interface problem	1
Difficult to remove device	1
Total	42

ischemia and small bowel perforation, with surgical intestinal resection required. The manufacturer narrative alleged that in this case, the capsule was not the cause of the obstruction.

Other video capsule systems

An additional 46 reports of less frequently reported devices were analyzed (Endocapsule®, n=37; CapsoCam®, n=8; MiroCam®, n=1), with a combined total of 31 PRAEs and 54 DFs. The OMOM Capsule 2® (n=0), and Navicam® (n=0) were not included in the study, as no reports were retrieved. The 3 most commonly reported PRAEs were as follows, in descending order of frequency: unintended exposure to radiation (n=8, 25.8%), unintended exposure to endoscopy (n=4, 12.9%), to surgery (n=4, 12.9%) and to anesthesia (n=4, 12.9%; Table 4). Rare PRAEs reported for these VCE systems included generalized rash and unspecified chest pain, which the manufacturer stated were unlikely to be attributable to the capsule ingredients or capsule study. The 3 most common DFs were as follows, in descending order of frequency: adverse event without identified device or use problem (n=28, 51.9%), entrapment of device (n=15, 27.8%), and inability to retrieve data (n=4, 7.4%; Table 4).

Table 4 Device failures and patient related adverse events of other video capsule endoscopy devices, combined*

Adverse events and device failures	Frequency
Patient related adverse events	
Unintended exposure to radiation	8
Unintended exposure to endoscopy	4
Unintended exposure to surgery	4
Unintended exposure to anesthesia	4
Abdominal pain	3
Unintended exposure to enteroscopy	2
Small bowel resection	1
Diarrhea	1
Generalized rash	1
Minor/misc. events with no known impact or consequence to patient	1
Unintended exposure to colonoscopy	1
Unspecified chest pain	1
Total	31
Device related failures	
Adverse event without identified device or use problem	28
Entrapment of device	15
Unable to retrieve data	4
Failure to transmit record	2
Endocapsule fragmentation	1
Failure to record	1
No display/image	1
Premature discharge of battery	1
Signal of device lost/external interference	1
Total	54

*Additional devices: 46 reports total (Endocapsule®, n = 37; CapsoCam®, n = 8; MiroCam®, n = 1)

Unusual PRAEs

Multiple AEs were mentioned that appear to be unusual in the setting of an SBCE exam. Stroke was a listed AE, and in the event description for this solitary report of stroke, it reads, "post-operatively, the patient suffered a stroke, believed to be unrelated to the capsule study." Systemic rashes were reported as well. Three reports were identified with a specified "generalized rash". Two were of an allergic/urticarial nature, whereas the other reported bullous pemphigoid. One of the Endocapsule® reports describes in detail a patient who had retained a capsule for at least 18 days, and reported a severe allergy to "iodotrotynyl butylcarbamate", which she believed must have coated the capsule, resulting in blisters and inflammation, and reported her "stomach is on fire and aching 24/7" with 11 lbs. of weight loss. As per the manufacturer's narrative, "… it was confirmed the substances associated with the patient's allergy were not included in the list of ingredients." Acute pancreatitis is mentioned as an AE in the CT findings, and the report mentions it was probably an incidental finding. Cardiac arrest was mentioned as an AE. In this specific case, the reporter stated the patient was already high-risk from a cardiac standpoint before a triple procedure (colonoscopy, endoscopy, and endoscopically placed Pillcam®). It is mentioned that the patient had a significant history of heart-related issues and previous open-heart surgeries, and the narrative concluded that his cardiac arrest was most likely attributable to this history. The AE of intubation was mentioned in conjunction with this patient, and was probably performed for resuscitation. The solitary AE of abscess formation was in a patient with active CD. The healthcare team proposed that, shortly after the introduction of the capsule, the device became lodged in a previously existing uracho-vesical fistula, thereby forming an abscess. This complication of an abscess is the only one of the above AEs that was most probably linked to the passage of the capsule.

Discussion

We performed an analysis of the FDA MAUDE database for DFs and PRAEs reported in the most commonly used capsule endoscopy systems available in the US over a period of 24 years. To the authors' knowledge, this study represents the first description of PRAEs and DFs pertaining to SBCE using the MAUDE database. Although these data are publicly available on the FDA website, each individual report is listed under ambiguous search terms and can involve tedious descriptions, making the ability to guide clinical decisions based on this data a challenge without a summary analysis.

A key quality marker in SBCE is reaching the cecum, e.g., completion rate. This is especially important in CD, where SBCE can provide vital information to determine the need for treatment escalation regarding anatomic extent of disease

and monitoring mucosal healing [19]. Despite stricturing and stenosing disease being a risk factor for capsule retention, the data on completion rate in CD varies significantly. Some series show the Pillcam® Crohn's Capsule with completion up to 100% [20]. Although obscure gastrointestinal bleeding has a higher completion rate than CD, 1 meta-analysis comprising over 86,000 patients undergoing capsule endoscopy showed a pooled completion rate of 89.6%, with 90.6% for obscure bleeding and 86.5% for CD, with no significant differences detected in the indication for VCE exam or the capsule device used [12].

Although capsule retention leading to operative intervention is rare [21,22], Du *et al*, in a retrospective analysis of 204 Crohn's patients undergoing capsule endoscopy, found that 8.3% had retention, defined as the device remaining for at least 2 weeks in the bowel, or the need for intervention. They subdivided the patients and performed a subgroup analysis based on various factors, including sex, age, disease course and passage time: an older age and a longer disease course differed significantly between groups. Time with retained capsules varied from 16 months to as long as 4 years, but while 17 had obstruction, only 4 of those required surgical intervention. In addition, multi-factor regression showed that abdominal distention before the examination was a significant predictor for retention (odds ratio 8.45, 95% confidence interval 1.85, 38.56 [23].

Although capsule retention is uncommon, the exact frequency is unknown. The generally accepted rate of 0.75% comes from a study by Barkin *et al* of a series of 900 patients with occult gastrointestinal bleeding [24]. International consensus guidelines concluded that the rates of this complication varied by as much as from 0% to up to 13% in different series [25]. Several predisposing risk factors have been established: e.g., prior major abdominal surgery, previous bowel obstruction, chronic use of non-steroidal anti-inflammatory drugs, known or suspect CD, small bowel neoplasm, and prior irradiation of the bowel [26,27]. Notably, there is no universal concordance recommending a patency capsule in suspected CD, as the European guidelines differ from the American guidelines with regard to the perceived risk of retention in patients with CD, with the former guidelines in 2022 recommending a patency capsule in suspected Crohn's and the presence of obstructive symptoms [28,29]. In our study, the most common DFs and PRAEs pertained to entrapment of the capsule device and retention of a foreign body, which could entail any component of the capsule system. This presents a potential limitation, as incomplete exploration (e.g., capsule does not reach cecum), is a key quality indicator in SBCE, which could be underreported in this dataset, as it is likely that not all cases of the SBCE failing to reach the cecum were labeled as "retained capsule".

Many of the serious PRAEs reported seem strange to report in the context of a VCE procedure and require clarification. Although most of these complications can arguably be discarded, and realizing that subjectivity is an inherent flaw in any MAUDE study, we believe their inclusion is essential to preserve the integrity and internal validity of a study based on reported complications.

Aimed at the subset of patients who merit capsule endoscopy yet have a higher risk of retention, the Given® Patency System (now known as the PillCam® Patency Capsule) was developed in 2006 by Medtronic®. This capsule is of the same dimensions as the SB capsule. It is composed of a radio-frequency tag surrounded by a cellophane exterior with barium-laced lactose walls to enable it to be digestible, radiopaque, and detectable by an external scanner. Early studies with the patency capsule suggest that PRAEs are rare and mild. Signorelli *et al* reported that 2 of their 32-patient cohort (6.2%) experienced mild abdominal pain [30]. In a retrospective study of 30 patients undergoing patency capsule evaluation, 20% had mild, self-limited abdominal pain [31]. Similar results have been demonstrated in a large, multicenter case series describing 1615 patency capsule tests [32].

Serious PRAEs related to patency capsule are scarce. Rasmussen *et al* reported a case series of 2 patients with symptomatic capsule retention, 1 of whom had the patency capsule, and cited erosion into the intestinal wall, leading to an ileocecal valve perforation requiring surgery [33]. In 2018, a comprehensive review of the reported complications associated with patency capsule use was published, citing a single instance of intestinal perforation and a single case of intestinal ischemia [34]. Our present study revealed 16 reports involving serious small bowel complications: e.g., obstruction, perforation, and/or intestinal ischemia requiring surgical intervention and/or endoscopic retrieval. Several reports also described patency capsule aspiration requiring bronchoscopy for retrieval. It is unclear how a diagnostic test as seemingly harmless as a patency capsule could be associated such severe complications. We emphasize that the purpose of this study is not to report causality; nevertheless, to the authors' knowledge, our study represents the largest report in the literature of such serious PRAEs related to the patency capsule system.

There are several limitations to our study. First, although there are multiple SBCE devices available, the Medtronic's Pillcam® SB1, SB2, SB3, and Patency Capsule systems represented the vast majority of data points. Although there is no way of determining whether the lack of reports is due to the manufacturer's reluctance to report, or to the absence of malfunctions, a potential explanation of the scarcity of reports pertaining to the other models apart from the Pillcam SB® system could be a question of market share and/or the time the device has been on the market.

Additional limitations are that the Medtronic Pillcam® SB capsule system is a multi-component system, with several steps involved in the setup, deployment and transmission of video capsule data. Any number of these crucial steps could have been tainted by user error and potentially misrepresented as device failure. Thus, the concept of a reported "device failure" in any MAUDE study can be interpreted by the manufacturer as user error. This ambiguity in "device failure" definition and subjective bias via voluntary reporting is inherent to all MAUDE studies. Although this bias cannot be mitigated, we feel these reports still offer valuable insight, as the operators have a unique perspective on these devices' patterns of failure. Finally, regarding the true frequency of complications, we are unable to calculate the incidence of events in MAUDE studies

because manufacturers are not required to disclose the number of devices in circulation.

One thing that remains certain is that, despite SBCE having several pitfalls regarding missed diagnostic lesions, potential adverse events and technical challenges, it remains a vital tool for gastroenterologists. Tawheed *et al* contend that the value of SBCE has outweighed its potential pitfalls, and because of this it has remained on the market for 24 years. They suggest that the future of VCE could be enhanced with advanced technological improvements, such as artificial intelligence models to reduce the missed lesions, and potential therapeutic interventions controlled by physicians remotely [35].

In conclusion, although serious adverse events with SBCE and patency capsule systems are rare, DFs and PRAEs remain important aspects of informed consent for these procedures. Our analysis of over 20 years of the FDA MAUDE database provides valuable insights regarding PRAEs and DFs, especially regarding the Pillcam® Patency capsule system, to assist endoscopists in appropriate patient selection and effective utilization of the various SBCE systems.

Summary Box

What is already known:

- Small bowel capsule endoscopy (SBCE) is a valuable tool in the evaluation of suspected small bowel bleeding, diagnosis of suspected Crohn's disease and detection of small bowel neoplasms
- There are currently multiple SBCE systems available, with Pillcam SB® (Medtronic) appearing to dominate the US market

What the new findings are:

- A query of the FDA MAUDE database spanning 20 years was performed to obtain reports pertaining to all SBCE devices. This yielded 352 total reports, in which 492 device failures and 696 patient-related adverse events were identified
- The devices comprised the Pillcam® SB system (Medronic), Pillcam® Patency capsule, Endocapsule® (Olympus), CapsoCam® (Capsovision), and MiroCam® (IntroMedic)
- The most common adverse events pertained to capsule retention and/or more serious unintended exposures to radiation, endoscopy or surgery
- The most common device failures pertained to entrapment of the device or failure to transmit data

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