



A Descriptive Analysis of Capsule Endoscopy Events in the FDA Manufacturer and User Facility Device Experience (MAUDE) Database

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Abstract

Introduction The malfunction of capsule endoscopy (CE) devices is a significant reason for the failure of CE procedures, which could hinder and prevent diagnosis. Unfortunately, malfunction-related adverse events (AEs) caused by CE devices are rarely reported in publications. Although most malfunction-related AEs could not lead to physical harm, they could reduce the efficiency of medical care and increase medical costs. The manufacturer and user facility device experience (MAUDE) database, a publicly accessible resource for patient safety, contains not only the common complications of CE but also valuable malfunction-related AEs, which have been underutilized. Therefore, the study aims to discover and analyze the possible AEs associated with CE and demonstrate the utility of the MAUDE reports to promote patient safety.

Materials and Methods We acquired MAUDE reports of CE systems from January 01, 2008, to July 31, 2020, through a systematic search strategy. We utilized the manufacturers, brand names, and product codes as search terms from which medical device reports including structured data and narrative texts were extracted, followed by a manual review of the narrative texts, reporter occupation, device involved, event type and the phase of the event; finally, patient outcomes were recorded and analyzed as per CE categories and characteristics.

Results A total of 377 CEs medical device reports were retrieved, and 342 reports were included after reviewing. There were 327 mandatory reports (96%) and 15 voluntary reports (4%). These reports referred to capsule endoscope ($n = 213$), sensing system ($n = 66$), patency capsule ($n = 38$), and capsule delivery device ($n = 26$). A total of 349 CE-related AEs were identified, including complications ($n = 228$), malfunction-related AEs ($n = 109$), and other events ($n = 12$). The composition of AEs was not the same for the CE devices. Complications were major AEs of capsule endoscope and patency capsule, but malfunction-related AEs were the most common in AEs of sensing systems and capsule delivery devices.

Conclusion MAUDE serves as an invaluable data source for investigating malfunction-related AEs. In addition to common complications, malfunction of CE devices could threaten patient safety in CE procedures. Improving awareness of the malfunction of CE devices and raising adequate training for staff working in gastrointestinal (GI) endoscopic units could be critical and beneficial in preventing malfunction-related AEs.

Keywords

- adverse events
- capsule endoscopy
- patient safety

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Introduction

Adverse event (AE) is an undesirable incident associated with the use of a medical product in a patient and is also referred to harms from medical care rather than an underlying disease.^{1,2} Each year, approximately 42.7 million AEs occur in hospitalization, which represent the main cause of morbidity and mortality throughout the world.^{3,4} Medical devices that are indispensable to medical care account for more than 1 million AEs annually in the US, at a rate of 6.3 events per 1000 patient-days.^{4,5} AEs of medical devices are complex, since the errors are usually associated with manufacturers, users, and use.⁴ The primary reporters of AEs are health care providers who often focus on technical procedural outcomes. As a result, severe or rare events may be reported more often than minor but frequent events.⁶ Nevertheless, health care providers must raise their awareness of AEs as a consequence of device malfunction, in terms of a fuller spectrum, which may occur in their routine practice.⁷

Capsule endoscopy (CE) provides visual images of the gastrointestinal tract (GIT) with noninvasive examination,^{8,9} which has been regarded as a safe and primary investigative method of small bowel diseases.^{10,11} CE is also a feasible alternative to esophagogastroduodenoscopy (EGD) for screening and surveillance of GI bleeding.¹² Although an overall complication rate of CE is reported to be as low as between 1 to 3%, its AEs and complications have drawn global attention.¹³⁻¹⁵ Common AEs include capsule retention, obstruction, perforation, and capsule aspiration.¹⁶⁻¹⁹ In addition, malfunction of any component of CE and human errors could lead to failure of a CE procedure.⁶ Although the occurrence of AEs in GI endoscopic unit's daily practices is not unknown, the reports regarding AEs and malfunctions of CE devices are not adequately utilized by health care providers for promoting patient safety.

The manufacturer and user facility device experience (MAUDE), an open-access database maintained by the Food and Drug Administration (FDA), represents reports of AEs involving all FDA-approved medical devices. Since 1991, MAUDE has grown a collection of over 4 million medical device AEs and product problem reports.²⁰ Manufacturers are mandated to report any suspected device-associated deaths, serious injuries, or malfunctions to the FDA.²¹ Each year, several hundred thousand medical device reports (MDRs) are submitted by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters (health care professionals, patients, and consumers). The MDRs include initial AEs and published case reports. The manufacturers could analyze these reports and attempt to investigate root causes, categorizing them as either an operator error or device malfunction.⁷ So far, efforts have been made by utilizing data in MAUDE to understand the reported dangers and malfunctions of medical devices.^{20,22-26} MAUDE serves as an important data source for monitoring and investigating safety incidents of medical devices, and helping the users and even government officials to recall the potentially dangerous materials from the market.^{20,27} Although reports

combined with severe AEs of CE and routine instrument failures are available in MAUDE, little has been investigated in this regard.

Therefore, we aim to identify and analyze potential threats to patients undergoing CE toward enhanced understanding and management strategies of causes or harms of CE-related AEs. By studying the contextual issues and insights, this work was intended to raise the awareness of CE-related AEs and help health care providers improve patient outcomes.²⁸

Materials and Methods

We initiated a systematic search of the MAUDE database on the FDA website between January 1, 2008, and July 31, 2020, by applying a search strategy for identifying MDRs of the CE system. We utilized the fields of manufacturers, brand names of products, and product codes as search terms to sort and filter the data records. Multiple capsule systems were available worldwide. Four manufacturers and their devices were certificated by FDA. There were Giving Imaging Israel, Olympus Japan, Capso Vision USA, and US Endoscopy USA. Brand names included PillCam, EndoCapsule, CapsoCam, Patency capsule, AdvanceCE, and delivery device. Three product codes were used as search terms. They were NEZ, NSI, and PGD. NEZ and NSI mean ingestible telemetric gastrointestinal capsule imaging system. PGD means colon capsule endoscopy system.

The CE system consists of the following three components: (1) a capsule endoscope; (2) a sensing system with a sensing belt, a data recorder, and a battery pack; (3) a personal computer workstation with proprietary software.⁹ MDRs of all devices of the three components were included to analyze the categories of CE-related AEs. Additionally, we collected MDRs of patency capsules and capsule delivery systems, since they have been widely used as assists of CE procedures.

The MDRs comprise structured data and narrative texts. First, we extracted the fields of report source, reporter occupation, and event type from the structured data. Then, all the corresponding narrative texts describing AEs were reviewed manually. Duplicated reports were excluded. Some short texts providing little information to identify the categories of AEs were also excluded. For each report, we recorded the phase of the event, the device involved, and the outcome of the patient. In the study, we applied three phases, that is, before, during, and after the CE procedure. The defined phase of duration covers from the beginning, when a patient swallows a capsule, to the end, when the capsule is excreted. We also collected information regarding the possibility devices associated with malfunction being returned to manufacturers for investigation. Finally, we summarized the categories of CE-related AEs and investigated the causes and potential management strategies. All death reports were extracted and analyzed. Two physicians independently performed reviews of all the identified cases. In case of discrepancies, the first authors used an adjudication process and team discussions to reach an agreement.

Results

We retrieved all MDRs from MAUDE between January 1, 2008, and July 31, 2020. Generally, the number of CE-related MDRs has shown an increasing trend over the past 12 years (►Fig. 1). The annual reporting trend of CE-related MDRs was in line with the overall trends of total MDRs (►Fig. 2). In the study, a total of 377 CE-related MDRs were retrieved. Our manual review identified 27 duplicated cases, 5 cases with insufficient information, and 3 reports extracted from the literature of clinical studies, which were excluded on the basis of our inclusion criteria. As a result, 342 reports were included, among which 327 were mandatory reports (96%) and 15 were voluntary reports (4%).

Devices Associated with CE-related AEs

Four types of devices were identified in the study. Among the 342 reports, 213 (62.3%) were associated with capsule endoscope, 66 (19.0%) with sensing system (sensing belt, recorder, and battery), 38 (11.1%) with patency capsule, and 26 (7.6%) with capsule delivery device (►Fig. 3). One report involved two devices. In all reports, only 48 (14.0%) devices were returned to the manufacturers for investigation.

Categories of CE-related AEs

Currently, there is no standard taxonomy for categorizing CE-related AEs. Based on the grounded theory and the sociotechnical model,²⁹ we categorized these events into

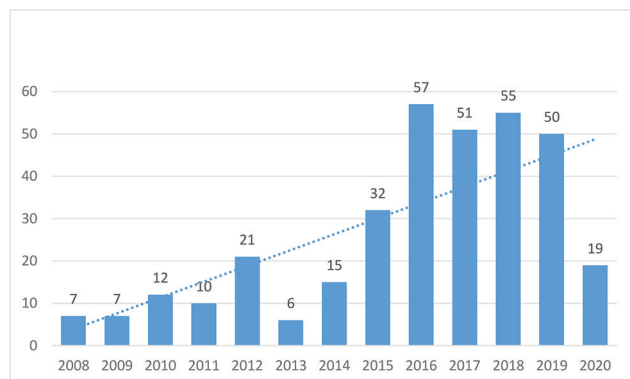


Fig. 1 Capsule endoscopy's (CE's) medical device reports (MDRs) in manufacturer and user facility device experience (MAUDE).

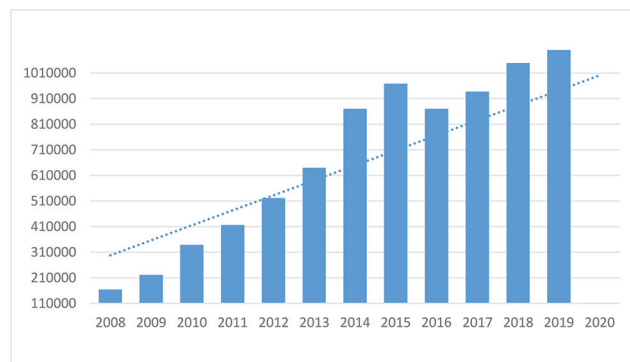


Fig. 2 Total records of medical device data in manufacturer and user facility device experience (MAUDE).

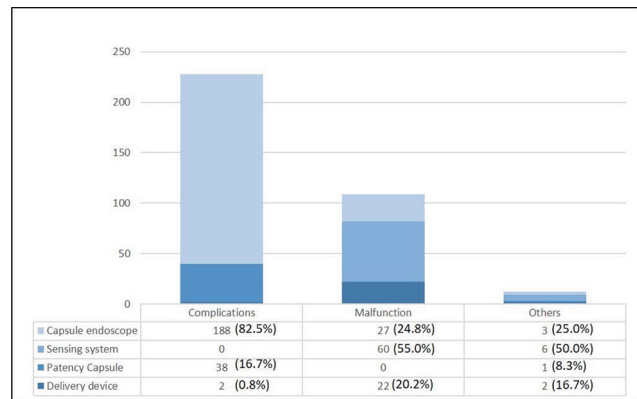


Fig. 3 Categories of capsule endoscopy (CE)-related adverse events (AEs).

three types by literature review: suspected complications, malfunction, and other events (►Fig. 3).^{28,29} First, a complication is a clinical unfavorable consequence of the CE procedure. Suspected complications (65.3%, $n = 228$) were the most common category of CE-related AEs in the study. Second, CE devices were reportedly failed to function normally and such events were classified as a malfunction (31.2%, $n = 109$). Third, other events (3.4%, $n = 12$) were recognized as results of user errors. Complications were the major AEs of capsule endoscopes and patency capsules, and malfunction was common in sensing systems and capsule delivery devices.

AEs of Capsule Endoscopes

A total of 213 reports of CE were retrieved including 218 AEs. There were 188 suspected complications, 27 malfunction events, and 3 other events. Among 188 suspected complications, capsule retention ($n = 154$) accounts for the majority, followed by capsule aspiration ($n = 20$), and other suspected complications ($n = 14$). Capsule retention and aspiration are recognized complications of capsule endoscopes. Capsule retention occurs when the capsule remains in the digestive tract for 2 weeks or more, requiring directed medical, endoscopic, or surgical intervention.³⁰⁻³² Most capsule retentions were asymptomatic in the study. Twenty events were combined with obstruction or perforation, and one combined with appendicitis. For asymptomatic patients, some retained capsules passed after conservative treatment or were managed by prompt endoscopic intervention. However, surgery was planned when capsule retention was combined with acute intestinal obstruction or perforation. Aspiration is referred to as an accidental aspiration of a capsule endoscope into the upper respiratory tract.³³ Most identified aspiration events ($n = 19$) were asymptomatic or accompanied by a slight cough, which was resolved safely by bronchoscopy. Additionally, some events that occurred during or after CE procedures were not recognized complications, since no evidence to prove the causal link between the events and CE procedures. We called them other events (►Table 1), including cardiac events, stroke, pneumonia, and so on.

Malfunctions of capsule endoscope included capsule break ($n = 15$), signal loss ($n = 8$), and failure to pair the recorder ($n = 4$). A capsule endoscope broken into two or more pieces

Table 1 AEs of CE systems

CE		
Complications (n = 188)	Retention (n = 154)	
	Aspiration (n = 20)	
	Cardiac event (n = 6)	Myocardial infarct, cardiac arrest, heart attack, ventricular tachycardia, other cardiac events.
	Others (n = 8)	Abdominal pain, stroke, pneumonia, allergic reaction, urticarial bullous pemphigoid, infected urachal cyst with enterourachal and vesicourachal fistulas, vasovagal reaction, regurgitated the capsule
Malfunction (n = 27)	Break (n = 15)	
	Signal loss (n = 8)	
	Failure to pair the recorder (n = 4)	
Others (n = 3)	A new hired medical assistant made a mistake to use ESO2 capsule as patency capsule.	
	A procedure was ongoing when the capsule was not found anymore. The patient swallowed the capsule along with the magnet.	
Sensing system		
Malfunction (n = 60)	Incomplete or no video (n = 29)	
	Recorder failure (n = 22)	
	Failure of downloading (n = 9)	
Others (n = 6)	The wrong cable was connected to the cradle.	
	The spider was removed before the end of the procedure, and resulted in a short video.	
	Patient fell. Then the recorder dropped into water, and failed. There was no raw data found on the SD card. It is likely that the data was deleted when trying to perform a new check-in.	
	The patient spit out the capsule case and just the outer layer of the capsule. An incomplete video liked caused by using an expired battery.	
Patency capsule		
Complications (n = 38)	Retention (n = 36)	
	Aspiration (n = 2)	
Others (n = 1)	The agile capsule used was past its expiration date.	
Delivery device		
Malfunction (n = 22)	Inappropriate detach (n = 9)	
	Failed to deploy (n = 13)	
Complications (n = 2)		Trauma to the mucosa in the duodenum The device stuck in patient's larynx.
Others (n = 2)	The tip-protector was pushed into the lumen of the patient.	
	The RN attached the Pillcam capsule cup incorrectly.	

Abbreviations: AE, adverse event; CE, capsule endoscopy; RN, registered nurse; SD, secure digital.

is defined as a capsule break. Sometimes, it would not be identified until the patient excreted the broken capsule. A signal loss means that the recorder could not receive a signal of the capsule during a CE procedure. Without the manufacturer's evaluation, it was difficult to identify the reason for these devices' malfunction.

AEs of Sensing Systems

A total of 66 sensing system-related AEs were identified, including 60 malfunctions and 6 other events. No complication was reported. The types of malfunction included incomplete video (n = 29), recorder failure (n = 22), and download

failure (n = 9). Incomplete video means the images recorded were incomplete, discontinuous, or even no recording at all. Recorder failure included recorder frozen, power off, belt short out, cable bent, and failed to receive images from the capsule endoscope. The reasons for the malfunction of sensing systems remained unknown, as no feedback was provided by the manufacturers.

AEs of Patency Capsules

Thirty-eight reports of patency capsules were identified, including 39 AEs. There were 38 complications and 1 other event (►Table 1). Among 38 complications, 36 involved

patency capsule retention, and 17 of them combined with intestinal obstruction or perforation. Another two complications concerned capsule aspiration. The management of patency capsule retention and aspiration was identical to that of capsule endoscopes.

AEs of Capsule Delivery Systems

A capsule delivery system allows for direct endoscopic placement of capsule endoscopes in patients who are unable to swallow or pass the capsule through the pylorus. A total of 26 AEs of capsule delivery systems were identified, including 22 events of malfunction, 2 complications, and 2 other events caused by user errors (►Table 1). Among the 22 events of malfunction, 13 events were due to physicians failing to deploy capsules. Another 9 events were because of components detached from the delivery devices inappropriately. The components involved holder, tip protector, and capsule cup. For example, a capsule was separated from the device because the holder was broken. Two complications were suspected duodenal mucosal trauma and the device stuck in the patient's larynx.

Other Events

There were 12 other events in the study, which were caused by preventable user errors (►Table 1). Most of the events were caused by a lack of training or communication. For instance, a newly hired medical assistant mistakenly used ESO2 capsules as patency capsules. Likewise, a wrong cable was connected to the cradle when using a recorder.

Death Reports

There were 11 death reports identified. Ten cases were associated with small bowel capsules, and 1 with patency capsules. Four patients died during CE procedures, and the cause was probably sudden cardiac death (SCD). These patients had a history of severe heart disease. However, there was no evidence to prove that SCD was related to the CE procedure. Five patients died after capsule retention. Three of them died after undergoing surgery to take out the trapped capsule. The cause of death was surgery complications. One patient died after capsule retention due to carcinoma. Another patient with retention died without a reported reason. Among the remaining two patients, one reportedly died from an acute ischemic stroke, a day after the patient swallowed a capsule endoscope, without proven evidence related to the CE procedure. The last patient died of aspiration pneumonia a few months after a successful CE procedure. The death cases were significant; however, it appeared that the MAUDE reports did not provide sufficient information to determine the relations between death and CE procedures.

Discussion

Patient safety is the highest priority in the performance of GI endoscopy to ensure the completion of a high-quality, cost-efficient endoscopic examination.³⁴ Our effort was focused on the analysis of the possible AEs and their causes, risks, and management strategies associated with the CE

systems in the MAUDE database. Then, we attempted to demonstrate the utility of the MAUDE reports, in order to promote patient safety. MAUDE contains not only the common complications of CE but also malfunction-related AEs and user errors, which have been underutilized for informing frontline practitioners and enhancing patient safety. Clinical practice guideline recommends health care providers and patients should be aware of the potential risks of CE, including failed procedures.³⁵ Despite malfunctions and other events that may not result in physical harm, they reduce the efficiency of medical care and increase medical costs. Human rather than technical failures represent the greatest threat to the complex and potentially hazardous systems, including health care systems.³⁶ The malfunction was a significant cause of the failed procedures in the study. Malfunction-related AEs are often labeled as technical limitations and failures, which could hinder and prevent diagnosis in CE procedures.^{15,32} The incidence of malfunction-related events of CE accounts for 8.59%, and they prevent or hamper diagnosis by 2.9%.³⁷ Although the events can lead to the failure of CE procedures, they are rarely reported in publications. The reason might be that they may not lead to physical harm directly, and physicians tend to report only unexpected or severe AEs as opposed to the commonly observed side effects.⁷

We are interested in analyzing root causes and management strategies of CE-related AEs, especially for malfunction-related events and other events. First, some reports in MAUDE provide insufficient information to conduct root causes analysis, because most devices are not returned to the manufacturers. The causes of these incidents are not definitively determined. Therefore, it is necessary to collect and return the questionable devices to the manufacturers besides reporting these events. Meanwhile, the reports are expected to contain the results of root cause analysis.³⁸ As an ever-growing database of postmarket surveillance of medical devices, MAUDE holds the potential for manufacturers to improve their devices. Second, about how to manage malfunction-related AEs, some reports mentioned that physicians can use a spare device for further operation. The majority of malfunction-related AEs reportedly occurred in the early phase of capsule use, when the first generation of CE was placed for use, which was probably related to the infancy of the technique.³⁷ Health care providers such as physicians, nurses, and assistants, may be involved in malfunction-related events. To improve the patient safety of CE procedures, it is essential to examine the device before use. Besides, all working in GI endoscopic units should be provided adequate knowledge of malfunction of CE devices and offered sufficient training. Third, other events identified in MAUDE result from user errors. Human errors and unsafe acts arise primarily from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness.³⁹ Training and using a checklist could help prevent human errors in CE procedures.

MAUDE collects some reports about potential, but perhaps unseen, risks to patients.³⁸ Although we cannot infer the causal relationship between these events and CE devices due

to insufficient evidence, continuing tracking and reporting these incidents are necessary. For example, six cardiac events identified in the study accounted for four death reports. These events occurred during or after CE procedures, but no information was provided in regard to whether the patients were placed with cardiac pacemakers or other implanted electromedical devices. The CE manufacturers list the presence of an implanted cardiac device as a relative contraindication to the use of CE. Even CE reportedly does not affect the function of the cardiac devices.⁴⁰⁻⁴² Furthermore, the FDA is reluctant to advocate the use of this technology in this cohort of patients.¹⁵ Therefore, collecting CE cases related to severe heart disease would help clear up the potential relationship. Case reports are valuable resources to study rare AEs. The greater the number of reports, the more likely is the confirmation of the causal relationship between AEs and medical devices.

There are some limitations to MAUDE when using the data for further investigation. First, it is not appropriate to calculate or derive the incidence of an AE from the database and estimate the frequency of device use. Second, it is difficult to verify the causal relationship between an event and the device due to incomplete and inaccurate reports. Third, the management strategies of these events cannot be confirmed by investigating MAUDE merely. Finally, MAUDE may not include all categories of CE-related AEs.

Despite the abovementioned limitations, MAUDE represents an objective source of reported failures of medical devices. Searching the database is invaluable in maintaining and growing knowledge of AEs, which is not yet or rarely reported in publications and especially critical to inform the clinicians who consider the use of a new medical device.⁴³ Knowledge of adverse medical device events is critical for us to enhance patient safety in CE procedures.

Conclusion

To the best of our knowledge, it is the first study to summarize and analyze the categories and characteristics of CE-related AEs in the MAUDE database. The present study demonstrates that in addition to common complications, malfunction of CE devices could threaten patient safety in CE procedures. Although malfunction is the primary reason for failure CE procedures, AEs due to malfunction might be underreported as most of them could not lead to physical injuries to patients. Considering these findings, it is highly recommended that clinicians and manufacturers should submit high-quality MDRs, incorporating complete and accurate information, to investigate root causes and management strategies. Meanwhile, it is demanded that in daily operations of CE, all providers in GI endoscopic units should constantly improve their awareness of malfunction of CE devices via education or training on a regular basis.

Finally, utilizing MAUDE by the manufacturers could help analysis of root causes and identification of potential harms of medical devices and keep the community informed of the challenges, risks, and solutions.

Conflict of Interest

None.

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