

Retention of endoscopic capsules in diverticula: Literature review of a capsule endoscopy rarity



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ABSTRACT

Background and study aims This review aimed to provide an updated and comprehensive review of capsule retention within diverticula, shedding light on the characteristics and management of this rare event in capsule endoscopy.

Methods A systematic literature search was conducted across multiple databases. All observational studies that reported capsule retention in a diverticulum among complication and outcomes, as well as case reports and series, were included. Manual cross-checking of references was also performed. Two extractors performed abstract and full-text reviews, as well as data-extraction.

Results We found 167 references from Pubmed, Embase, and Web Of Science. Sixty-five duplicates were removed and another 71 references were excluded. Crosschecking of references found additional two articles. In total, 32 articles were included, resulting in a total of 34 cases of retained capsules in diverticula. The median age was 69 and the majority of the patients were male (76.5%). The most common retention occurred in Meckel's diverticulum (32.4%) followed by Zenker's diverticulum (20.6%). Investigation of capsule retention was done with x-ray (50%) and computed tomography (CT) scan (44.1%). Seventeen cases (50%) were asymptomatic. Resolution of the retention happened with endoscopy (35.3%) and surgical management (32.4%), as well as self-resolution (20.6%).

Conclusions Due to the small number of cases, diverticula are not a risk factor for incomplete capsule endoscopy examination. It affects mainly elderly, male, asymptomatic patients, and typically is diagnosed with x-rays and CT scans. The most common type is Meckel's diverticulum, and endoscopy is the primary management. Capsule endoscopy retentions are extremely rare, with only 34 cases reported since the technology's introduction.

Introduction

Capsule endoscopy (CE) is widely accepted as a noninvasive way to evaluate the gastrointestinal tract and is the leading modality for investigation of occult gastrointestinal bleeding (OGIB), and other small bowel (SB) diseases [1]. The safety profile of CE has been thoroughly examined in the past, and many researchers have investigated adverse events (AEs) associated with it, the most common being capsule retention [2, 3]. Retention of the capsule is defined as presence of the capsule in the gastrointestinal tract for at least 2 weeks after ingestion, or indefinite retention unless endoscopic or surgical intervention has been done [4]. Capsule retention within the SB or colonic diverticula was a complication postulated when CE was introduced but was shown to be very infrequent and/or without clinically relevant consequences [5, 6]. A proportion of capsules are retained, usually due to Crohn's disease or strictures from use of nonsteroidal anti-inflammatory drug (NSAID) use [1, 7, 8], but retention has also been linked to tumors in the SB and previous gastrointestinal surgery [2, 3]. SB diverticula can occur anywhere in the SB but are most often found in the duodenum. A retrospective review of 208 patients with symptomatic SB diverticulosis reported diverticula in the duodenum in 79% of the patients, in the jejunum or ileum in 18%, and in all three segments in 3% of the patients [9]. Jejunoileal diverticula are rare and reported to affect 0.5% to 2.3% of individuals in radiographic series [10]. Colonic diverticula disease prevalence in western patients was found to be 15% to 35% [11].

The aim of this review was to compile the available data about retention after CE in diverticula to provide an overview and characteristics of this AE.

Methods

A systematic literature search was conducted in the PubMed, Embase, and Web of Science databases. Three groups of search terms were defined: investigation, comparator, and outcome. These three groups each included relevant terms using the Boolean expression "OR" within the groups and the Boolean expression "AND" for combining the groups. The investigation group was used to identify papers on CE. The comparator groups were used to limit results to references that included diverticula. Finally, the outcome groups were to restrict results to papers reporting on retention of capsules. The search strategy is provided in **Appendix A**. There was no limit on publication year. Cohort studies and case reports/series were included if they described individuals with capsule retention in any type of diverticula. No exclusions were made for language.

The final literature search was conducted on May 4, 2023. Specific search strings are provided in **Appendix A**. Two authors (C.T. and O.S.) screened titles and abstracts independently. Papers that met the inclusion criteria were included in full-text screening, which was also done in detail by two independent authors (C.T. and O.S.) In case of discrepancies, the authors would re-read and discuss the article. In the case of an unknown language, help was sought from other authors. To ensure the search was adequate, crosschecking was done to

screen the reference lists of the included papers for further possible relevant articles. From each included reference, two authors independently extracted data needed for analysis. The outcome data extracted were study type, sex and age of patients, reported reason for undergoing CE, investigation modalities used before CE, capsule modality, type of diverticulum, retention investigation process, how long the retention lasted, whether the patient had symptoms, and the course of treatment for retention. When appropriate, data extraction and statistical analyses were done using Microsoft Excel 2010 (Microsoft Corp., Redmond, Washington, United States). Numerical results are reported as percentages.

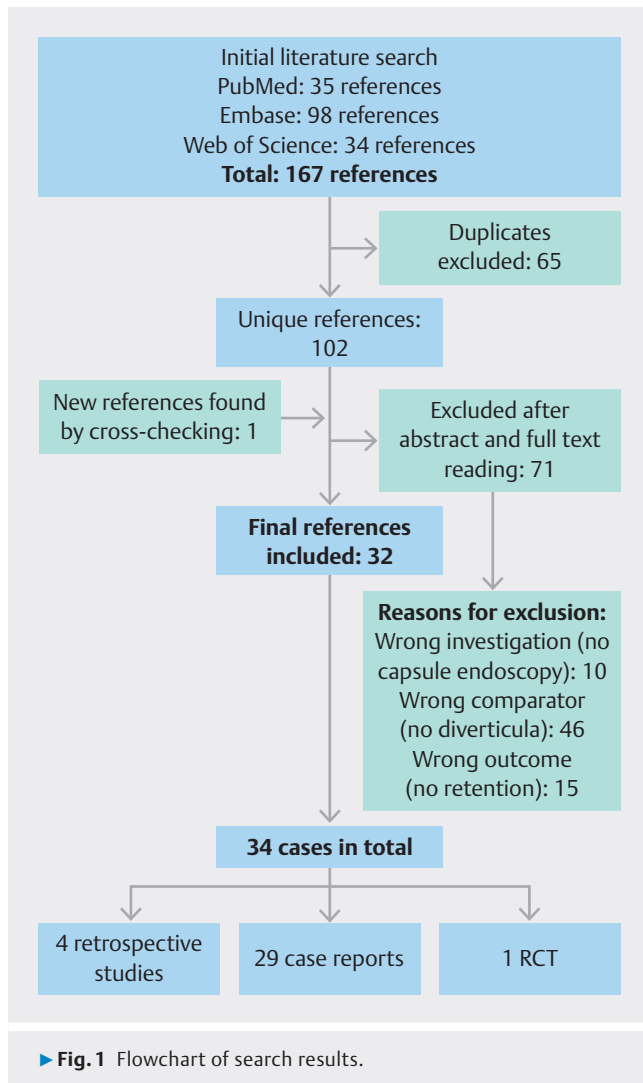
Results

The initial literature search resulted in 167 references from PubMed, Embase, and Web of Science, 65 duplicates were removed, and 71 references did not meet the inclusion criteria for retention in a diverticulum and were excluded, with reasons categorized by investigation (10/71), comparator (46/71), and outcome (15/71) as defined in the methods section. Thorough crosschecking of references found one additional article.

In total, 32 articles were included, resulting in a total of 34 cases of retained capsules in diverticula [1, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42]. An overview of the specific search results is provided in ► **Fig. 1** and an overview of the included articles is provided in ► **Table 1**.

Patient details

Of the 34 cases, eight (23.5%) were female and the age of individuals ranged from 12 to 87 years, with a median age of 69 years. Reasons for undergoing CE varied; 10 patients (29.4%) experienced OGIB, seven (20.6%) had hematochezia, and another seven (20.6%) described melena. Only one (2.9%) reported loose stools [30]. In 17 cases (50%), anemia was reported as the reason for undergoing CE including 10 (58.8%) with iron-deficiency anemia, three (17.6%) with microcytic anemia, three (17.6%) with unspecified anemia, and the last one with an acute drop in hemoglobin. This patient also experienced acute melena, hallucinations, and cough for 2 days prior [28]. Four patients (11.8%) had pain as the reason for undergoing CE. Three were described as abdominal pain and the fourth was specifically intermittent periumbilical pain. One patient experienced syncope [21] and another patient had a positive fecal occult blood test [36]. The investigation modalities used before the patients underwent CE was primarily gastroscopy (27 cases, 79.4%) and colonoscopy (26 cases, 76.5%). Other modalities were computed tomography (CT) scan (4, 11.8%), push enteroscopy (3, 8.8%), CT enterography (3, 8.8%), CT angiography (2, 5.9%), technetium-99m pertechnetate scan (2, 5.9%), SB radiology (2, 5.9%), SB follow-through (1, 2.9%), arteriography (1, 2.9%), x-ray (1, 2.9%), and gastric lavage using a nasogastric tube (1, 2.9%). In five cases (14.7%), no prior investigations were reported.



Capsule specifications

In 16 cases (47%), the company and model of CE were not specified. Thirteen patients (38.2%) were examined using capsules from Given Imaging Ltd (now Medtronic, Minneapolis, Minnesota, United States): six used M2A capsules, one used PillCam SB, three used PillCam SB2, one used PillCam SB3, and the remaining two were non-specific. Two cases used MiroCam, IntroMedic. One used Olympus and one used CapsoRetire (possibly CapsoCam, CapsoVision). In 31 cases (91.2%), the capsule modality was reported and all of were for SB investigation.

Presentation of diverticula retention

Among the 34 cases in total, the most common retention was within Meckel's diverticulum (32.4%), in 11 cases. Seven patients (20.6%) experienced capsule retention in Zenker's diverticula. Four (11.8%) were in the jejunum and four (11.8%) capsule retentions happened in the colon. Three retentions (8.8%) happened in the duodenum and two (5.8%) were in esophageal diverticula; one was described as epiphrenic [26]. Two (5.8%) had a non-specific SB location in proximal and distal, respectively, and the patient with capsule retention in distal SB diver-

tacula had two separate diverticula [16]. One capsule retention (2.9%) was in a gastric diverticulum. In 17 cases (50%), capsule retention was investigated with x-rays and in 15 cases (44.1%), CT scans were used. In 14 cases (41.2%), the capsule videos were reviewed as part of the standard investigation process after the video upload, and in two cases (5.8%), a real-time viewer was used. In five patients (14.7%), the capsule was not excreted, which led to suspected capsule retention. In three patients (8.8%), the first sign of retention was either discomfort in the cervical region [22], pain in the lower abdomen [17], or a sensation in the esophagus [14]. In total, nine patients (26.5%) had symptoms of retention, 17 cases (50%) asymptomatic, and in eight cases (23.5%), there was no information about whether the patients were symptomatic. One patient experienced dysphagia 2 years after ingestion of the capsule, which was lodged in a Zenker's diverticulum [39]. One patient brought in a delayed expelled capsule 34 days after ingestion, and the capsule video showed capsule retention in a Zenker's diverticulum [29]. Retention rates exhibited significant variation over time, ranging from the longest case, which lasted 7.5 years within a Meckel's diverticulum of a young man [31], to the shortest case lasting only 1 hour in a Zenker's diverticulum [14].

Management of capsule retention in diverticula

The retention was self-resolved in seven patients (20.6%). Twelve patients (35.3%) had endoscopic treatment, of whom six underwent gastroscopy, two had a double-balloon enteroscopy (DBE), and in the remainder, the procedure was not specified. A polypectomy snare to retrieve the capsule was used on two occasions, Roth Net in five, and in one case, an unspecified retrieval basket. Surgical management was used in 11 cases (32.4%), in eight of them resection of the diverticular segment was performed, two did not specify resection, and in one case, the surgical procedure was not specified. Five patients underwent laparoscopy, and one of those procedures was converted to a laparotomy [33]. Even though surgery was pursued due to actual retention in all 11 cases, only three of those reports offered a clear explanation for the choice of surgical management. In one case, an attempted endoscopic retrieval via a colonoscopy failed [12]. In another case, both upper and lower endoscopies were attempted but failed [33], and in the third case, an attempt to retrieve the capsule via flexible sigmoidoscopy failed due to epithelialization of the mucosa around the capsule [37]. There was no clear pattern in management of the nine patients with symptoms; however, in four of those cases, surgery with resection was performed [17, 33, 37, 41] four patients underwent endoscopy [14, 22, 30, 39], and in the last case, the retention was resolved on its own [29].

Discussion

This comprehensive literature review reveals the rarity of capsule retention within diverticula. It predominantly affects elderly male patients, with Meckel's diverticulum being the most common cause. Diagnostics were primarily conducted using x-rays and CT scans; in most cases, the patients were asymptomatic. Resolution was primarily achieved through endoscopy,

Table 1 Overview of cases.												
References	Study type	Sex	Age	Investigation modalities used before CE	Reported reason for CE	Capsule brand	Capsule modality	Diverticulum type	Retention investigation process	Retention duration	Symptoms	Retention management
Gortzak et al. [12]	CR	M	55	Gas, Colo, PE, CT scan, AG, SB radio, Tc99m	OGIB	NR	SB	Meckel's	No excreted capsule, abdominal x-ray, explorative laparotomy	> 4 months	No	Surgical (laparotomy, resection)
Ford et al. [13]	CR	F	73	Gas, Colo, SB, F-T	Melena, anemia	GIVEN	SB	Zenker's	Viewing capsule data, Neck x-ray	8 hours	No	Endoscopic
Simmons et al. [14]	CR	M	73	PE, SB radio	Melena	GIVEN	SB	Zenker's	Sensation in proximal esophagus, x-ray	1 hour	Yes	Endoscopic (polypectomy snare)
Knapp et al. [15]	CR	M	79	Gas, Colo	Anemia	NR	SB	Zenker's	Precautionary x-ray	NR	No	Endoscopic (gastroscopy, polypectomy snare)
Gaba et al. [16]	CR	F	60	Gas, Colo	IDA	M2A GIVEN	SB	Distal SB (2 separate)	No excreted capsule, CT scan	> 2 months	No	NR
Yu et al. [17]	CR	F	69	Gas, Colo, PE	OGIB	M2A GIVEN	SB	Meckel's	Lower quadrant abdominal pain, CT scan	> 4 months	Yes	Surgical (laparoscopy, resection)
Wei et al. [18]	Re.	NR	NR	NR	NR for specific case	M2A GIVEN	SB	Duodenal	Viewing capsule data	40 hours	No	Self-resolved
Ordubadi et al. [19]	CR	F	74	Gas, Colo	Microcytic anemia	M2A GIVEN	SB	Duodenal	abdominal x-ray	3 weeks	No	Endoscopic (gastroscopy, Roth Net)
Giday et al. [20]	CR	M	82	Gas, Colo	OGIB	M2A GIVEN	SB	Proximal SB	Viewing capsule data, abdominal x-ray	16 days	No	Self-resolved
Tanaka et al. [21]	CR	M	20	Gas, Colo	Hematochezia, syncope	PillCam SB2	SB	Meckel's	Viewing capsule data, DBE	1 day	No	Endoscopic (DBE, polypectomy snare)
Horiuchi et al. [22]	CR	M	66	Gas, Colo, x-ray	Melena, slight IDA	Olympus	SB	Zenker's	Discomfort in cervical region, real-time viewer	< 1 day	Yes	Endoscopic (Roth Net)
Sonpal et al. [23]	Re.	NR	NR	NR	NR	NR	NR	Colonic	NR	NR	NR	Endoscopic (DBE, Roth Net)
Ziachehabi et al. [24]	CR	M	71	Gas, Colo	OGIB	M2A GIVEN	SB	Zenker's	Viewing capsule data, Contrast swallow x-ray	NR	No	Endoscopic (gastroscopy, Roth Net)

▶ **Table 1** (Continuation)

References	Study type	Sex	Age	Investigation modalities used before CE	Reported reason for CE	Capsule brand	Capsule modality	Diverticulum type	Retention investigation process	Retention duration	Symptoms	Retention management
Courcoutsakis et al. [25]	CR	M	58	Gas, Colo	Abdominal pain, melena, IDA	PillCam SB2	SB	Meckel's	Viewing capsule data, CT scan	NR	No	Surgical (non-specific operation)
Ekanayake et al. [26]	CR	F	73	NR	IDA, OGIB	PillCam SB	SB	Esophageal epiphrenic	Viewing capsule data, Esophagram, second VCE	> 8 hours, but not specified	No	Self-resolved
Verma et al. [27]	Re.	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Anderson et al. [28]	CR	M	55	Gas, Colo, CT EG	Hallucinations and cough for 2 days, acute drop in hemoglobin, melena	NR	SB	Colonic	No excreted capsule, Abdominal x-ray	5 days	No	Self-resolved
Garcia et al. [29]	CR	M	80	Gas, Colo	IDA	MiroCam MCT1000	SB	Zenker's	Viewing capsule data, patient brings in expelled capsule	34 days	Yes	Self-resolved
Kim et al. [30]	CR	M	69	CT scan, Colo	Hematochezia, loose stools	MiroCam IntroMedic	SB	Duodenal	Viewing capsule data, CT scan, x-ray	1 day	Yes	Endoscopic (gas-troscopy, retrieval basket)
Ling et al. [31]	CR	M	32	Gas, Colo, CT AG	OGIB 7.5 years earlier led to CE, pt. lost to follow-up, now melena, IDA	OMOM	NR	Meckel's	X-ray, CT scan	7.5 years	No	Surgical (non-specific operation)
Nemeth et al. [1]	CR	F	75	Gas	OGIB	NR	SB	Esophagus	NR	NR	NR	Endoscopic (gas-troscopy)
García-Compean et al. [32]	CR	M	18	Gas, Colo, CT EG	Hematochezia, anemia	NR	SB	Meckel's	Viewing capsule data, abdominal x-ray, CT scan	7 days	NR	Surgical (laparoscopy)
Cano-Valderrama et al. [33]	CR	M	44	Gas, Colo	IDA	PillCam SB3	SB	Meckel's	Viewing capsule data, abdominal x-ray, CT scan	NR	Yes	Surgical (laparoscopy, laparotomy, resection)

▶ Table 1 (Continuation)												
References	Study type	Sex	Age	Investigation modalities used before CE	Reported reason for CE	Capsule brand	Capsule modality	Diverticulum type	Retention investigation process	Retention duration	Symptoms	Retention management
Lin et al. [34]	CR	M	19	Gas, Colo, CT scan	Intermittent periumbilical pain	PillCam SB2	SB	Meckel's	Viewing capsule data	2 hours	No	No treatment
Ostrowski et al. [35]	RCT	NR	NR	Gas	OGIB	NR	SB	Jejunal	NR	NR	NR	NR
Kang et al. [36]	CR	M	12	Gas, Colo, Tc99m, CT AG, CT EG	Hematochezia, abdominal pain, FOBT+	NR	SB	Meckel's	NR	NR	NR	Surgical (laparoscopy, diverticulectomy)
D'Souza et al. [37]	CR	F	65	Gas, Colo	IDA	NR	SB	Colonic (sigmoid)	CT scan	> 4 years	Yes	Surgical (sigmoid colectomy)
Saad et al. [38]	CR	F	80	Gas, Colo	Microcytic anemia, hematochezia	CapsoRetire	SB	Gastric	No excreted capsule, x-ray, CT scan	2 weeks	No	Endoscopic (gastroscopy)
Saad et al. [38]	CR	M	84	Gastric lavage	Microcytic anemia, recurrent melena	NR	SB	Jejunal	No excreted capsule, x-ray, CT scan	21 days	NR	Surgical (laparoscopy, resection)
Rey et al. [39]	CR	M	75	NR	OGIB	NR	SB	Zenker's	2 x-rays negative, dysphagia 2 years later led to CT scan	2 years	Yes	Endoscopic (Endoscopy, Roth Net)
Noujaim et al. [40]	CR	M	59	Gas, Colo	Chronic IDA, OGIB	NR	SB	Meckel's	Viewing capsule data, CT scan	< 6 months	No	Self-resolved
Diaz-Alcazar et al. [41]	CR	M	71	Gas, Colo	Melena	NR	SB	Jejunal	Viewing capsule data, x-ray, CT scan	5 days	Yes	Surgical (laparoscopy, resection)
Diaz-Alcazar et al. [41]	CR	M	87	Gas, Colo	Hematochezia	NR	SB	Jejunal	Real-time video, CT	19 hours	No	Self-resolved
Cheah et al. [42]	CR	M	32	Gas, Colo, CT scan	IDA, hematochezia, abdominal pain	NR	SB	Meckel's	CT scan, abdominal x-ray, diagnostic laparotomy	NR	NR	Surgical (laparoscopy, resection)

AG, angiography; CLD, chronic lung disease; Colo, colonoscopy; CR, case report; CT scan, computer tomography scan; DBE, Double-balloon enteroscopy; EG, enterography; F, Female; FOBT+, fecal occult blood test positive; Gas, gastroscopy; GE reflux, gastroesophageal reflux; GI, gastrointestinal; IDA, iron-deficiency anemia; M, male; NR, not reported; OGIB, obscure gastrointestinal bleeding; PE, push enteroscopy; radio, radiology; Re, retrospective; SB, small bowel; Tc99m, technetium-99m pertechnetate scan; VCE, video capsule endoscopy; F-T, follow-through.

but occasionally a laparoscopic approach became necessary, and some cases resolved spontaneously.

Careful and meticulous patient selection for CE is essential. The rate of capsule retention is low in most studies due to careful selection of study populations, excluding patients who are at risk of SB obstruction or intestinal stricture [8]. However, the patients included in this review had undiagnosed diverticula, and for apparent reasons, they could not be excluded. This reflects the challenges encountered in real-world situations.

Given the low percentage of retention cases, identifying high-risk patients is challenging. Perhaps it is more important to direct our focus toward optimizing capsule retention management techniques and outcomes when capsule retention in diverticula arises. A case report proposed to perform ingestion under visual guidance via gastroscopy in patients with known gastric diverticulum, adding new dimensions to enhancing procedure precision [38]. In another case, the capsule was secured to a conventional endoscope using a snare and released directly into the stomach of a patient with a Zenker's diverticulum, thereby bypassing the diverticulum [43].

Within the well-established yet limited landscape of AEs in CE, this review sheds light on the potential complication associated with previously documented retention rates in the range of 0.73% to 2% [2, 3, 44]. Most capsule retentions are attributed to strictures secondary to conditions such as inflammatory bowel disease or use of NSAIDs [44], and retention within diverticula is scarce, which is supported by our review with only five studies (1 RCT and 4 retrospective studies) mentioning this particular occurrence. However, capsule retention within Meckel's diverticulum is infrequent and there is a possibility that spontaneous passage will occur in such cases, particularly if the patient is asymptomatic [40]. When it comes to management of capsule retention, the prospect of a capsule eventually passing after several months further accentuates the need for balanced consideration between symptomatic and asymptomatic scenarios. Notably, capsule retention stands out as a significant concern due to the potential complication of gastrointestinal obstruction. In a review, it was evident that only a minority of patients experienced obstructive symptoms, leading to the conclusion that capsule retention rarely results in serious obstructive symptoms [44]. However, in the analysis by those authors, 57% of patients with retention underwent surgical management, although not all because of obstructive symptoms. The authors speculate about whether the reason for surgical management was availability of surgical at the study center and lack of availability of endoscopic options, or the rationale was prevention of future AEs from retained capsules, particularly when repeated capsule procedures were anticipated [44].

Optimal management of capsule retention remains the subject of debate, and surgical intervention is not the recommended primary standard of care [1, 8, 38]. According to European Society of Gastrointestinal Endoscopy (ESGE) guidelines on SB CE and device-assisted endoscopy, in cases of capsule retention, the first line should be conservative treatment. An endoscopic retrieval attempt should be considered when medical therapy proves ineffective [45]. Surgical management is only

indicated in patients with obstructive symptoms, an occurrence that is not typically expected in cases of capsule retention within the diverticula.

As presented in our review, surgery was chosen as the primary approach to address capsule retention. However, this approach may have been overly aggressive, and primarily driven by fear of bowel obstruction from the retained capsule, because it was apparent that a limited number of surgeons attempted alternative modalities first. Furthermore, it is reasonable to wonder whether surgery could have been avoided in patients with retained capsules and known Crohn's disease or NSAID strictures by optimizing medical treatment [46].

A prominent concern emerges from the fact that 12 of 25 cases fail to align with the established criteria mandating a 14-day retention period within the gastrointestinal tract. This discrepancy prompts an exploration of whether the same yardstick should be applied to capsule retention within diverticula. If not, this raises the question of how to navigate and address this issue. The inadvertent presence of a capsule within a diverticulum, although undesirable, also raises the question of whether a distinction should be drawn between a capsule incidentally entering a diverticulum during its journey through the gastrointestinal tract, irrespective of a specific time threshold, and genuine retention that extends for a full 14-day period. Addressing this differentiation is essential for a more nuanced understanding of CE outcomes and has implications for clinical practice.

This review aimed to present an updated and thorough analysis of available evidence regarding capsule retention in diverticula. Among the 34 cases included in this review, 29 were derived from case reports. It is important to note that not all instances of capsule retention in diverticula are reported or published. One of the limitations of our search lies in the possibility of missing cases due to language and accessibility limitations, potentially introducing bias in the selection process and leading to an underestimation of the true incidence. Furthermore, only five studies reported retention as a complication or outcome, suggesting potential underreporting of and missing data about this occurrence. Nevertheless, despite the retrospective nature of case reports without statistical calculations, the included articles have been deemed appropriate for the purpose of this review, indicating their adequacy in terms of quality. While we acknowledge the possibility of undetected or unreported cases, this review is a current and comprehensive compilation of relevant information, facilitating a more accurate estimation of the rate of capsule retention in diverticula.

Conclusions

In conclusion, it appears that, due to the small number of cases, diverticula are not a risk factor for incomplete CE examination. Retention affects mainly elderly male patients who are mostly asymptomatic. X-rays and CT scans emerged as the predominant diagnostic modalities. The most common cause was Meckel's diverticulum and endoscopy was the primary management. Retention is very rare and only reported anecdotally, because only 34 cases have documented in the literature since the

introduction of CE. When considering capsule retention in diverticula, there have been no reports of severe clinical consequences or symptoms, and the probability of such occurrences is low.

Conflict of Interest

A.K.: Co-founder and shareholder of A.J.M. Medicaps; co-director and shareholder of iCERV Ltd.; consultancy fees (Jinshan Ltd.); travel support (Jinshan, Aquilant, and Dr Falk Pharma); research support (grant) from ESGE/Given Imaging Ltd. And (material) IntroMedic/SynMed; honoraria (Dr Falk Pharma UK, Ferring, Jinshan, Medtronic). Member of Advisory board meetings (Dr Falk Pharma UK, Tillots, ANKON). SS: Affiliation with Ovesco. The remaining authors have no conflict of interest to declare.

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