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CLINICAL REVIEW

Colon capsule endoscopy: toward the future

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Abstract Colon capsule endoscopy is a wireless and minimally invasive technique for visualization of the whole colon. With recent improvements of technical features in second-generation systems, a more important role for colon capsule endoscopy is rapidly emerging. Although several limitations and drawbacks are yet to be resolved, its usefulness as a tool for colorectal cancer screening and monitoring disease activity in inflammatory bowel diseases has become more apparent with increased use. Further investigations, including multicenter trials, are required to evaluate the substantial role of the colon capsule in managing colorectal diseases.

Keywords Capsule endoscopy · Colonoscopy · Colorectal cancer · Polyp · IBD

Introduction

Colorectal cancer (CRC) is one of the leading causes of cancer-related death in both men and women in Western [1] and Asian countries, including Japan [2, 3]. In Japan, CRC screening programs organized by the national government for colorectal cancer based on fecal occult blood testing (FOBT) started in 1992, and the incidence of CRC halted its increase shortly thereafter. Japanese population-based CRC screening is offered to those aged 40 years and over, and total colonoscopy is performed for those with positive fecal immunochemical test (FIT) result [4]. Although use of FOBT or FIT has been demonstrated to reduce mortality from CRC in randomized controlled trials [5], the specificity and sensitivity of fecal occult blood screening are substantially limited. Colonoscopy is the gold-standard modality for early detection of adenoma, the colorectal premalignant lesion, thereby leading to prevention of CRC [6]. However, the acceptance rate for CRC screening is still low in most Western countries [7] as well as Japan. This is probably due to the invasive nature of colonoscopy, unpleasant perceptions, and complications such as bleeding or perforation [8].

Colon capsule endoscopy (CCE) was introduced in 2006 as a minimally invasive and wireless technique for imaging the colon [9]. To increase the accuracy of CCE, second-generation CCE was developed and eventually introduced in 2009. This modality is a novel and promising technology that can be useful for screening and monitoring of colorectal diseases [10]. In this review article, we comprehensively analyze recent reports and discuss the potential roles and future perspectives of CCE.

Technical features

The PillCam colon capsule endoscope (Covidien–Medtronic, Dublin, Ireland) is now available in its second-generation form (CCE-2). There are three main components to this system: (1) an ingestible capsule endoscope (11.6×31.5 mm^2 in size, equipped with two head cameras with 172° angle of view), (2) a sensing system with sensing pads or a sensing belt to attach to the patient, a data recorder, and a battery pack, and (3) a personal computer workstation with software (RAPID 8; Fig. 1a–c). Compared with the first-generation CCE with 156° angle view, the new model allows for almost 360° visual coverage of

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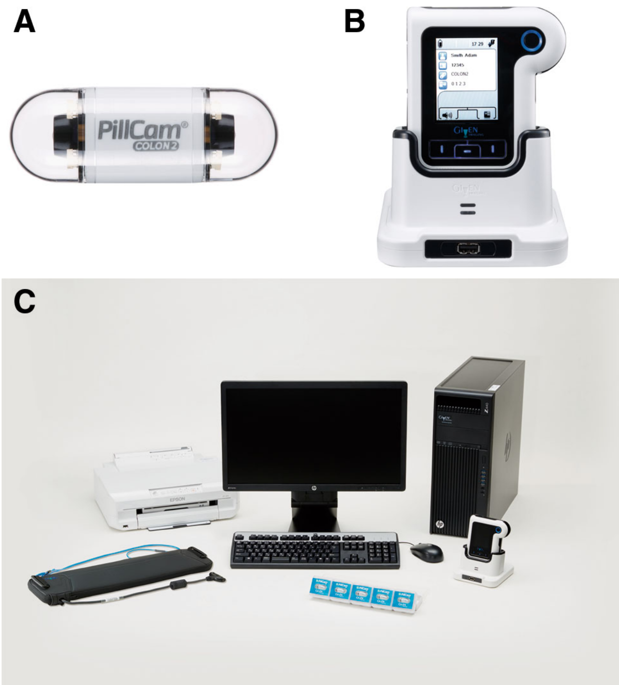

Fig. 1 Second-generation colon capsule endoscopy system: **a** capsule with two cameras incorporated, **b** data recorder with real-time viewer, and **c** workstation (RAPID 8)

the colon. The data recorder is incorporated within handheld viewers that allow real-time review of images during examinations. It also has the unique feature of an adaptive frame rate (AFR). The AFR function is activated using a bidirectional communication system between the capsule and data recorder. It automatically determines the frame rate, which ranges from 4 per second when stable to 35 per second while in rapid motion. This function not only improves battery life, but also reduces "skipped" visualization of the colon. The resolution of the CCE-2 image is below 0.1 mm, with magnification range of about 1–8 (Fig. 2a). The latest RAPID software includes a graphical interface tool for polyp size estimation (Fig. 2b), as well as image enhancement, including flexible spectral imaging color enhancement (FICE; Fig. 2c, d). Moreover, the capsule is capable of giving feedback to the patient regarding its location via vibrations, and displays instructions when small bowel mucosa is detected [11].

Indications and contraindications

Current indications for CCE in Japan are (1) incomplete colonoscopy due to technical difficulties such as scope looping, and (2) presumed difficulty in conventional colonoscopy because of colonic adhesion due to previous abdominal surgery. Contraindications for CCE are comparable to those for small bowel capsule endoscopy [12]. However, CCE examinations should not be performed in patients (1) with known or suspected gastrointestinal obstruction, stricture, or fistula, because of the risk of CCE retention, (2) with cardiac pacemakers or other implanted electromedical devices because of the microwaves transmitted by the CCE, (3) with swallowing disorders because of risk of aspiration, and (4) who are pregnant [13, 14].

Preparation

Accurate diagnosis can only be achieved when the colon is completely free of stool during the colonic examination. Unlike conventional colonoscopy, adequate bowel preparation is crucial to achieve successful CCE because additional cleaning maneuvers, such as washing and suctioning during the procedure, are not available [13]. In addition, the capsule transit time, which allows its excretion from the rectum within the capsule's battery life, is also important [15, 16]. There is an apparently positive correlation between examination sensitivity for colonic lesions and the degree of cleansing of the colon [17]. Subjects are encouraged to start a low-residue diet 2 days before CCE and a clear liquid diet the day before CCE. There are various diet protocols in place for CCE, depending on the institution, mainly consisting of polyethylene glycol (PEG) solution and boosters with sodium phosphate [17, 18]. Sodium phosphate can accelerate the bowel transit time of the capsule but may cause serious complications such as acute renal failure and electrolyte imbalance. Patients who are at risk of sodium phosphate toxicity need to undergo alternative booster preparations such as magnesium citrate [19–21]. Gastrografin, which is a contrast medium for the digestive tract, is an alternative to sodium phosphate in the bowel preparation regimen for CCE [22]. Additional agents may also be used: emptying prokinetics for gastric motility and a bisacodyl suppository [23]. Aromatic castor oil, a vegetable oil obtained by pressing the seeds of the plant, may also act as a booster (personal communication). Patient tolerance of the bowel preparation used is a substantial concern, because reluctance to repeat such intensive preparation has been widely reported [24]. Unfortunately, the optimal preparation method that is both effective in cleansing for successful CCE and tolerable by patients has yet to be determined.

CCE for detection of colon polyps

Since the introduction of the CCE-2 with improved performance as described above, the accuracy of CCE for polyp detection has increased [10, 13, 25, 26]. To date, five studies have been published on polyp detection by CCE-2

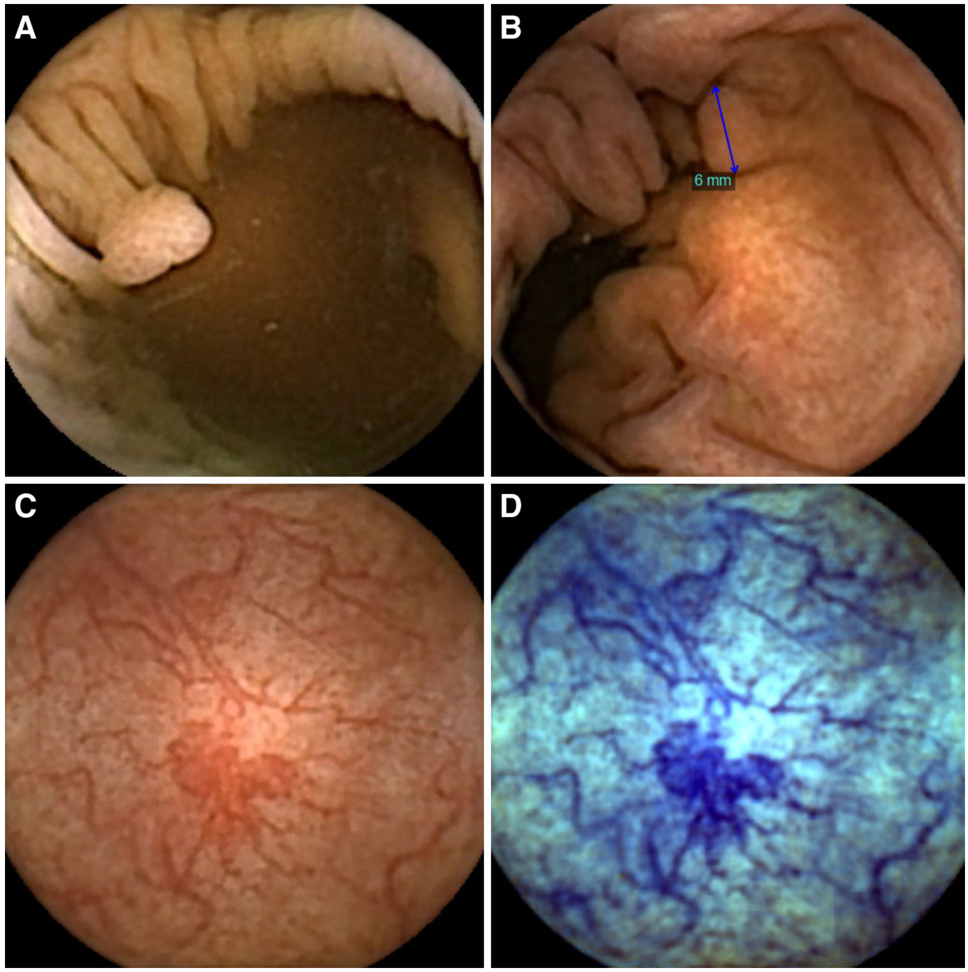

Fig. 2 **a** High-resolution image of a colon polyp captured by CCE-2. **b** Polyp size estimated with graphics tool software. **c** Image of angioectasia detected under white light. **d** Enhanced image using flexible spectral imaging color enhancement (FICE)

Table 1 Diagnostic accuracy of CCE-2 versus colonoscopy for detecting colon polyps

Author [Ref.]	Year	No.	Completion (%)	≥6 mm		≥10 mm	
				Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Eliakim [27]	2009	98	81	89	76	88	89
Spada [28]	2011	109	81	84	64	88	95
Rex [31]	2015	695	91	88	82	92	95

compared with conventional colonoscopy [27–31]. These studies highlighted the considerably high sensitivity and specificity of CCE-2. Three landmark studies that recruited more than 100 patients reported sensitivity and specificity ranging from 84 to 89 and 64 to 95 %, respectively (Table 1). The relatively low specificity was mainly due to size discrepancy rather than false positives. However, there were a few adverse effects, usually related to bowel preparation. A metaanalysis of over 2400 subjects revealed sensitivity for 6 mm and larger polyps of 58 % for the first-generation CE and 86 % for the CCE-2 [32]. Based on these results, combined with its safety profile, it was concluded that the colon capsule may be a suitable alternative to colonoscopy for colon polyps, particularly in patients unwilling to undergo colonoscopy or for those in whom it is technically not feasible.

CCE in IBD

Recently, several studies on surveillance of inflammatory bowel diseases (IBD) have been published, mainly on ulcerative colitis (UC) [33–37]. However, data regarding use of CCE in patients with IBD are insufficient because histological verification is required for diagnosis of IBD. A possible role for CCE in the field of IBD is for evaluation of mucosal healing while monitoring disease activity [13]. In a large study conducted by Sung and colleagues using first-generation CCE [33], the sensitivity and specificity of CCE for detection of active ulcerative colitis was 89 and 75 %, respectively, when compared with conventional colonoscopy. In a recent study of pediatric patients using CCE-2 [36], the sensitivity and specificity for disease activity were 96 and 100 %, respectively. However, whether CCE is superior to conventional colonoscopy for assessment of disease activity and extent in UC remains controversial [34].

Although literature on use of CCE in Crohn's disease (CD) is sparse due to the concern of capsule retention caused by strictures, more recent studies demonstrate the safety and feasibility of use of CE in this disease [38–42]. In a multicenter pilot study, CCE-2 detected colonic ulcerations with 86 % sensitivity and 40 % specificity, and no adverse events were observed. As capsule use in evaluating the small bowel of patients with CD has become well established, once a small bowel stenosis is reliably excluded by preceding patency capsule ingestion, CCE can be used as a panenteroscopic test in this disease [43].

Complications

CCE has been shown to be a safe procedure so far, with complications mostly due to bowel cleansing. In an analysis of over 1600 reported cases involving both first- and second-generation CEs, the minor complication rate was 4.1 %, while the major complication rate was 0.49 %, not being directly related to CCE [25]. Reports stated that the major complication of perforation was derived from the particular performance of the colonoscopy, including the therapeutic interventions undertaken [44–46] (Table 2). Some case reports raised the possibility of capsule aspiration [47] and retention in a diverticulum [48]. In any case, endoscopic or surgical interventions may be necessary to address any complications such as retention or aspiration. After ingesting the CCE and until it is successfully excreted, the patient should not approach any source of powerful electromagnetic fields such as magnetic resonance imaging scanners, as instructed by the provider.

Future perspectives

CCE examination has been estimated to cost approximately $950 in the USA, €700 in Europe, and ¥120,000 (without medical insurance) in Japan. Cost–performance issues underlie when this novel technology will be introduced into CRC screening [49]. For polyp detection, CT colonography (CTC) has also been recommended as an imaging modality of choice in the case of incomplete colonoscopy in the USA [50]. One recent clinical trial demonstrated that both CCE-2 and CTC detected polyps 6 mm and larger with high levels of accuracy; CCE-2 seemed to be better tolerated than CTC [51]. Another prospective study for patients with incomplete colonoscopy demonstrated that the diagnostic yield of CCE was superior to that of CTC [23]. However, the advantages and disadvantages of CCE should be discussed compared with those of CTC, which seems to be a cost-effective option in CRC screening.

During conventional colonoscopy, the colon is distended by air or carbon dioxide, but during CCE, it is naturally distended by water, ensuring lesions are not so stretched in the colonic wall [52]. Flat or sessile lesions require special attention by endoscopists because they have higher risk of cancer than polypoid lesions. It is often difficult to detect sessile serrated adenoma/polyps (SSA/Ps) with conventional colonoscopy because the form of the lesion is typically flat and the color is similar to the background mucosa or more faded [53]. Image enhancement techniques have been reported to be useful in detecting serrated lesions [54]. Importantly, prospective trials evaluating the accuracy of CCE-2, with or without spectral image color enhancement, in the detection of flat and sessile lesions are greatly needed.

Training systems for CCE also need to be developed. Several training programs have been established for small bowel CE, but the method of reading and interpretation of

Table 2 Complication rates from reported studies involving over 100 cases

Author [Ref.]	Year	No.	Complication rate		Cause of major complication
			Major (%)	Minor (%)	
Van Gossum [17]	2009	320	0	2.9	
Eliakim [27]	2009	104	0.96	7.7	Urinary retention
Gay [44]	2010	128	0	0	
Sacher-Huvelin [45]	2010	545	0.5	3.5	Cardiac failure, colonic perforation[a], bleeding after mucosectomy
Spada [28]	2011	109	0.85	6.8	Perforation after colon polypectomy
Herrerías-Gutiérrez [46]	2011	144	0	0	

[a] Potentially related to bowel preparation

results in CCE is totally different from that in small bowel CE because of its characteristic functions, double cameras, and AFR. A pilot study using an electric learning system for CCE (ELCCE) has been reported to be effective for improving reading competence for CCE. Hands-on training for trainees also seems useful to shorten the learning curve in achieving CE competency [55–57]. Apart from this, with CCE, the entire gastrointestinal tract is visualized with potential extracolonic findings and pathology. This may be beneficial for patients receiving CCE as a panendoluminal examination but impose an excessive burden on interpreters.

The human colon is a relatively large-sized organ whose complete visualization using a passive capsule is quite difficult. A capsule maneuvered with an external magnetic field, a so-called magnetically controlled capsule (MCC), has recently been developed, and several trials have reported promising results, mainly for gastric lesions [58]. This novel MCC has shown high diagnostic accuracy compared with conventional gastroscopy and has a very low complication rate. In the colon, the maneuverability and safety of MCC have also been demonstrated [59], and increased accuracy in detecting and monitoring colorectal lesions can be expected in the near future.

Conclusions

Although several issues such as cost–performance, practical implementation, training programs, and patient preference remain to be resolved, the technical performance of second-generation CCE has markedly improved. Given the expectation of further evolution in medical device technology, CCE appears to be a novel, promising technique that is noninvasive and painless and therefore suitable for evaluation of colorectal diseases. Further investigations, such as prospective randomized trials with a large number of subjects, are required to establish the firm inclusion of CCE in diagnostic algorithms for colorectal diseases.

Compliance with ethical standards

Conflict of interest: All authors declare that they have no conflict of interest

Human Rights: All procedures followed have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Informed Consent: No informed consent.

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