Colonic Capsule Endoscopy

C.T.Streba (1), C.C. Vere (1), Corina Lavinia Gruia (2), F.Sima (1), M.C.Sergiu (1), A.G. Ionescu (1)

(1) Department of Internal Medicine, County Emergency University Hospital, University of Medicine and Pharmacy, Craiova; (2) Department of Pathology, County Emergency University Hospital

ABSTRACT Colonic capsule endoscopy represents a novel technique used to identify colon lesions. Being a non-invasive procedure, with a high patient compliance and minimal side-effects, it can safely be administered to large population groups with different pathologies. When used in conjunction with a self-absorbing patency capsule, it becomes a safe procedure even if obstruction is present, thus eliminating one of the most important risk factors. On the other hand, colonoscopy currently represents the "gold standard" for colon diagnosis and therapy. The technology has not notably evolved in recent years, as its technique remains basically unchanged. Being an invasive procedure, dependent on the experience of the operator, it puts patients under a considerable amount of stress, thus having low patient compliance. Recent studies advanced the possibility of using colonic capsule endoscopy in colorectal cancer screenings as an alternative or a complementary method to standard colonoscopy. We reviewed such literature trying to present accurate data regarding the safety, feasibility and performance of colonic capsule endoscopy when compared with standard colonoscopy.

KEY WORDS Colonic capsule endoscopy; Colonoscopy; Colorectal cancer screening; Colon Cancer; Colonic polyps

Introduction

Clinical utilization of the endoscopic videocapsule received the approval of the FDA in 2001, and it shortly became a modern and efficient imagistic approach in the exploration of the intestine. [1] Recently, small bowel capsule endoscopy emerged as an extremely useful tool to acquire images in the areas of the small bowel that are inaccessible through upper or lower endoscopy. Further developments in the technology have resulted in products that are designed for use in imaging of the small bowel and colon. [2,3]

Colonoscopy currently represents the "gold standard" for colon diagnosis and therapy. It has an overall risk of complications of 0.3%, rising to 2% when including a therapeutic procedure. [4–6]

Conventional colonoscopy represents an invasive, expensive procedure, with a number of contraindications and a small acceptance rate. It needs conscious or deep sedation, thus associating a degree of procedural risk. [7] Patient fear, procedural discomfort, embarrassment, decrease the feasibility of colonoscopy in colorectal cancer (CRC). [7–9]

The ideal screening method for CRC should be non-invasive, safe, not operator-dependent, well accepted by the target population, cost-effective and of high diagnostic accuracy. [10] The cost/efficiency factor being taken into consideration, the use of capsule endoscopy in the colon has also been proposed as an alternative colorectal cancer screening test and as a device to investigate patients for other forms of colorectal pathology. [2]

Technical characteristics

The Pillcam™ Colon is a disposable capsule measuring 11 mm * 32 mm (about the size of a large vitamin pill), which has dual cameras, optics with a wide coverage area (more than twice the coverage area of the current PillCam Small Bowel capsule), automatic light control and a frame rate of four frames per second. The cameras captures four images per second or 144,000 images over a 10-hour period, which represents the time period necessary for the capsule to travel through the gastrointestinal tract. The images are transmitted to a recorder placed on the patient’s belt. The physician downloads the transmitted data to a computer workstation to analyse the images. As with other types of virtual colonoscopy (computed tomography colonography), if pathological findings are present, further diagnostic workup (conventional colonoscopy) is needed to allow therapeutic procedures and/or biopsies. [11]

Indications.

The main indications for the use of colon capsule are:

- contraindications for conventional colonoscopy
- monitoring non-specific inflammatory bowel disease
- incomplete colonoscopy
Incomplete conventional colonoscopy may represent a controvered indication for colon capsule. Triantafyllou et al. in a retrospective case series of patients with incomplete colonoscopy found that Pilcam Colon Capsule endoscopy did not always satisfactorily examined the entire length of the colon. [12]

**Contraindications.**

Contraindications for capsule endoscopy include:
- pregnancy
- swallowing disorders
- bowel obstruction [11]
- implantable medical devices (cardiac pacemakers or defibrillators) [13]

**Advantages.**
- sedation is not required
- higher compliance than colonoscopy [3,12,14,15]
- non-operator dependent
- can be performed in an outpatient environment
- cost-efficiency is similar to colonoscopy [14,16]

**Limitations.**

The technology has a number of limitations, deriving both from the patient and from the device itself:
- colon preparation may not be fully completed, it is patient-dependent thus subject to error
- the battery lifespan varies depending on colon length and motility
- high refinement is needed in order to accurately locate lesions.

**Examination technique**

The preparation for the procedure is similar with that for conventional colonoscopy. The patient is allowed to ingest only clear liquids one day prior to the investigation and a polyethylene glycol (PEG) solution is administered the morning of the examination and the day before. A modified regimen has been developed, including an additional low residue diet on days -5 to -2, 4 senna tablets on day -2, clear liquid diet and 3 liters of PEG on day -1, and PEG instead of Sodium Phosphate (NaP) prokinetic on the procedure day. [17] A four point grading scale that evaluates cleansing degree was recently developed by Italian researchers. [18] The capsule is ingested orally with a glass of water. In one study patients were also given a 6 mg dose of Tegaserod before capsule ingestion. Sodium phosphate may also be used to enhance capsule excretion. [19]

After ingestion the capsule remains active for only 5 minutes. In this short period the capsule passes through the esophagus and reaches the stomach. After the initial activation, the capsule transitions into a sleep mode for 2 hours. This is the estimated time for the device to transit the majority of the small bowel and to reach, approximately the level of terminal ileum. After reactivation, the capsule records images for approximately 10 hours, 2 hours longer than the small-bowel device. Data are transmitted to a recording device via an antenna– lead array similar to that used in the small bowel capsule. [2]

A patency capsule was developed, which helps verify the continuity of the digestive tract. [20] The capsule contains a RFID (radio frequency identification) tag which makes exact detection of the stricture possible. The capsule is self-resorbing after approximately 30 hours, thus it poses no threat to the patient. This new way of control augments the efficacy of the regular capsule system, supplementing its diagnostic abilities at the same time. [20,21]

**Literature Clinical data.**

In a recent study [19] conventional colonoscopy was compared with capsule endoscopy of the colon in order to determine if the two methods have similar detection rates for colonic lesions, including colorectal polyps. The primary objective of this study was to evaluate the detection rates of pathological colonic conditions using the Pill Cam followed by conventional colonoscopy. The study found similar results in specificity, sensitivity and positive predictive value but a higher negative predictive value of conventional colonoscopy over colonic capsule.

A second study [22] reported on the use of PillCam Colon in patients who were suspected to have either colon polyps or colorectal cancer, followed by conventional colonoscopy. A number of 36 patients were subjected to both procedures. The capsule had a 17% rate of excretion failure in a 10 hour period. CE successfully identified polyps in 19 of the 25 patients (76%) with prior positive findings after conventional colonoscopy. It was also able to positively identify 10 out of 13 polyps larger than 6 mm (77%). The study found a sensitivity of 77%, specificity of 70%, positive predictive value of 59% and a negative predictive value of 85%.

In a small proof-of-concept study [23] of 25 patients who were undergoing screening with
capsule colonoscopy, CT colonography, and conventional colonoscopy. 44% of these patients had findings that were thought to be significant; however, PillCam Colon and CT colonography were both inferior to standard colonoscopy in this study.

Another study [16] was undertaken in order to assess the cost and effectiveness of population-based screening for CRC using capsule endoscopy compared with that of a standard colonoscopy screening program. A Markov mathematical model (theoretical model designed to simulate real life events and scenarios) was constructed to simulate a comparison of CRC screening scenarios comparing PillCam COLON with standard colonoscopy. Model parameters were varied to simulate alterations in cost, thresholds for treatments, sensitivities and specificities, and screening adherence rates. Through pooled analyses, it was determined that a threshold ≥ 6 mm for polypectomy referral substantially reduced costs while only minimally impacting efficacy. This study concluded that colon capsule represents an efficient strategy for CRC prevention, with cost-effectiveness potentially superior to colonoscopy.

Deviere et al. [24] compared the accuracy of PillCam COLON in detecting polyps with that of conventional colonoscopy. The trial was conducted in eight centres and enrolled 320 elderly patients (mean age of 59 years). Patients were subjected to prior to capsule ingestion, patients underwent traditional preparation, including a one-day liquid diet and the use of prokinetic tablets. An independent physician performed traditional colonoscopy. CE had a specificity, sensitivity, negative predictive value and positive predictive value of 66%, 82%, 72% and 77%, respectively. As in the previously cited study, significant findings were defined as one polyp over 6 mm in size, or three polyps of any size. In this case, CE had a sensitivity of 64% and 60% and a specificity of 84% and 98% respectively.

In one study J. J. Y. Sung et al. [25] evaluated the accuracy CE with the PillCam COLON has in monitoring colon inflammation and ulcerative colitis, when compared to colonoscopy. The study included 42 patients aged 18 to 70 with suspected inflammatory lesions or other colonic affects. CE and colonoscopy were performed by independent physicians. The study reported no adverse effects related to CE ingestion and passage. PillCam had a sensitivity of 77% and a specificity of 78%. Colonoscopy identified active ulcerative colitis in 22 patients. M. Opezzi et al. [14] assed the diagnostic yield of colon CE in a 12-patients study aged 21 to 72, with potential inflammatory colon pathology. Test subjects were also submitted to the AGILE Patency Capsule Test. Pan-colonoscopy was performed the day prior to the investigation. They concluded that colon capsule is suitable for colonoscopic examination in terms of effectiveness and acceptance but needs improvement for complete visualisation.

In one case presentation Samuel Giday et al. [26] evidenced a cecal mass in a patient with recurrent episodes of melena and hematochezia using small bowel CE. The procedure was followed by conventional colonoscopy. The biopsies taken revealed a moderately differentiated adenocarcinoma.

Discussions and Conclusions
Colon capsule endoscopy is an emerging form of colon imaging that may be useful to improve compliance with colorectal cancer screening, but published experience with this device is extremely limited. Because the technology is currently only diagnostic, any positive findings require conventional colonoscopy for tissue sampling or polypectomy. There is currently no video capsule device cleared by the Food and Drug Administration for dedicated colon imaging. Significant research on this topic is required, and many fundamental questions regarding this technology remain unanswered. [2]

Further meta-analyses and large-scale studies should be carried out in order to accurately establish the diagnostic yield and efficiency of colon capsule endoscopy. Small numbers of involved subjects and a short timeframe currently represent the principal issues encountered in almost all reviewed research studies above. A lot of data is only available in abstract form, being presented at several conferences but not in full-text. We found conflicting data between several studies regarding the sensitivity and predictive values colonic capsule has.

Despite disadvantages, given the less-invasive nature of capsule endoscopy, the procedure may increase participation in colorectal cancer screening. [7–10,27]

References


11. Tran K. Capsule colonoscopy: PillCam Colon [Issues in emerging health technologies issue 106], Ottawa: Canadian Agency for Drugs and Technologies in Health; 2007.


