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SWALLOWABLE WIRELESS CAPSULAR ENDOSCOPY: A NOVEL BREAKTHROUGH IN THE BIOMEDICAL INDUSTRY AND FUTURE PROGRESS

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Keywords:

Wireless Capsule endoscopy (WCE), Components of Capsule Endoscope, Mechanism of CE, Indications of CE

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ABSTRACT: Wireless capsule endoscopy (WCE) is a medical procedure which has revolutionized for the first time a painless inspection of the small intestine. It is a simple, safe, non-invasive, reliable technique, well accepted and tolerated by the patients, which allows complete exploration of the small intestine. WCE has vitamin size pill which captures images of the digestive tract and entire small bowel, transported passively by peristalsis. WCE is a novel breakthrough in the biomedical industry and future progresses in key technologies, expected to drive the development of the next generation of such devices. WCE became an essential component in the management of several clinical conditions. WCE offers diagnostic tool for diseases like small bowel, gastrointestinal bleeding, Crohn's disease, localization of small bowel tumor, colon cancer screening, assessment of esophageal disorders and diagnosis of coeliac disease. However, compared with wired endoscopies, the limited working time, the low frame rate and the low image resolution limit the wider application. The progress of this new technology is reviewed in this paper and the evolution tendencies are analyzed to be high image resolution, high frame rate, long working time and also current indications of capsule endoscopy.

INTRODUCTION: Modern endoscopic techniques revolutionized the diagnosis and treatment of diseases of the upper gastrointestinal tract (esophagus, stomach, and duodenum) and the colon. The last remaining frontier has been the small intestine. The small intestine has been a difficult organ in which to make diagnosis and treatment without performing surgery.

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Radiological procedures, specifically the upper GI series with small bowel follow-through which involves following swallowed barium as it passes through the intestine with x-ray films, have been available for diagnosis but these radiological procedures are time-consuming and are not accurate in identifying small tumors and other subtle abnormalities of the small intestine.

The demand for improved capabilities in the small intestine has been less because a minority of intestinal diseases involves the small intestine beyond the reach of the upper gastrointestinal endoscope and the colonscope. Nevertheless, improved diagnostic and therapeutic capabilities in the small intestine would be very useful

particularly in uncovering the causes of abdominal pain, diarrhea and anemia due to intestinal loss of blood and diagnosing diseases that may involve only the small intestine, for example, Crohn's disease. One of the newer technologies that expand the diagnostic capabilities in the small intestine is capsule endoscopy also known as wireless capsule endoscopy.

Small bowel capsule endoscopy uses a wireless miniature encapsulated video camera designed to image the entire small bowel. It was developed in the mid-1990s, received FDA approval for use in 2001 and was FDA approved as a first line small bowel imaging device in 2003. It is noninvasive, painless and disposable. It can be used in an ambulatory or hospital setting. The camera takes 50000-60000 digital images per study. The system consists of an ingestible pill camera (26 x 11 mm), a data recorder and computer software for interpretation.

The procedure takes about eight hours, but the patient can go to work or perform routine activities during the study. The most frequent indications are evaluation of obscure gastrointestinal bleeding and the diagnosis of suspected Crohn's Disease. Other indications may include diagnoses or suspicion of small bowel tumors, coeliac disease, polyposis syndromes, abdominal pain, and malabsorption. Capsule endoscopy should not be performed when small bowel obstruction is present.

Care must be used in patients with swallowing disorders. Patients with implantable cardiac devices must consult with their physician. Risks include capsule retention which is usually transient but may require endoscopic retrieval or rarely surgical resection. It is a diagnostic tool and cannot be used to biopsy or treat findings.

The best way to detect GI diseases and uncover the inner works is directly viewing the GI tract so the endoscopy is a direct and effective diagnostic technology. The invention of wired endoscopy made it possible to view the entire stomach, the upper small intestine, and colon. Because of the ability of allowing clinicians to directly view the GI tract, endoscopy has become the standard method and the criteria for diagnosing GI diseases in clinic. However, limited by physical reasons, the traditional invasive wired endoscopy cannot examine the whole GI tract, leaving the small intestine as a dead zone. They are inconvenient and cause intense pain for patients. Furthermore, they can increase the risk of intestine perforation and the chances of cross-contamination.

History [2, 4, 6]: The first capsule was developed in the mid-1990 and was given FDA approval for use in the U.S. in 2001. It was approved as a first line small bowel imaging modality in 2003. Since that time, there have been over 500000 ingestions of the capsule and nearly 1000 scientific articles about its clinical use.

The initial capsule endoscope was developed by Given Imaging (Yoqneam, Israel) and approved in Europe by the European Medicines Agency and in the United States by the Food and Drug Administration in 2001. This technique is available in over 4500 gastrointestinal centers throughout the world.

Capsule Endoscope [4, 5, 6, 7, 8]: Capsule endoscopy is a technology that uses a swallowed video capsule to take photographs of the inside of the esophagus, stomach, and small intestine. For capsule endoscopy, the intestines are first cleared of residual food and bacterial debris with the use of laxatives and/or purges very similar to the laxatives and purges used before colonoscopy. A large capsule-larger than the largest pill-is swallowed by the patient. The capsule contains one or two video chips (cameras), a light bulb, a battery and a radio transmitter.

As the capsule travels through the esophagus, stomach and small intestine, it takes photographs rapidly. The photographs are transmitted by the radio transmitter to a small receiver that is worn on the waist of the patient who is undergoing the capsule endoscopy. At the end of the procedure approximately 24 hours later, the photographs are downloaded from the receiver into a computer and the images are reviewed by a physician. The capsule is passed by the patient into the toilet and flushed away.

Wireless capsule endoscopy is a technique designed to allow doctors to visualize the most inaccessible parts of the gastrointestinal (GI) tract. The small bowel capsule is an ingestible camera in a pill, approximately the size of a large vitamin

which passes through the patient's GI tract, taking about 50000-60000 digital images for the doctor's review. The vast majority of capsule endoscopy studies are for visualization of the small bowel (intestine). There are also capsule devices for use in the esophagus and the colon. This technique evaluates endoscopically with high resolution images, the whole small bowel, avoiding any sedation, surgery or radiation exposure.

Also many studies have established with a growing body of evidence that this technique is cost-effective in other clinical situations such as detection of small bowel lesions in Crohn's disease in patients in which other methods have failed to provide a diagnosis, non-steroidal anti-inflammatory drug enteropathies, coeliac disease, small bowel polyposis syndromes and small bowel tumors.

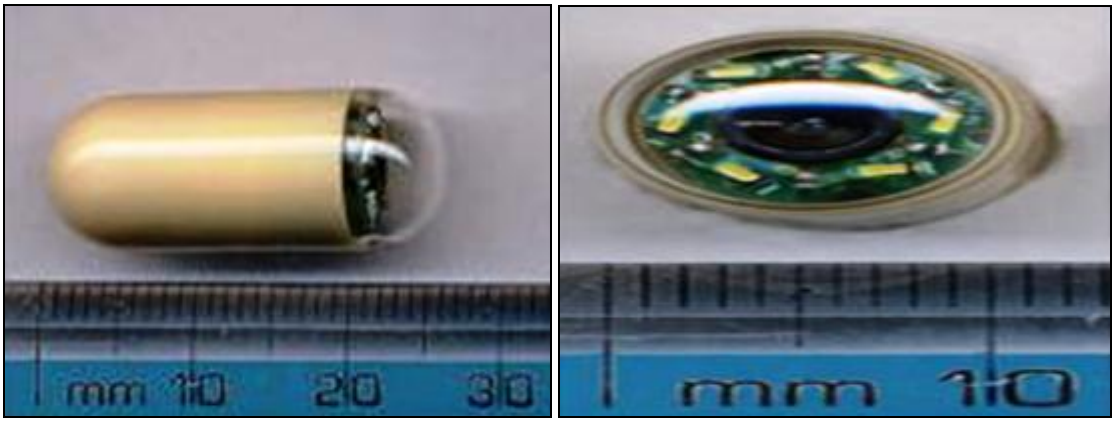

FIGURE 1: SIZE AND DIAMETER OF CAPSULE (11 mm × 26 mm)

The capsule endoscope is a disposable, small, swallowable, wireless, miniature camera which allows us to get a direct visualization of the gastrointestinal mucosa. The capsule which measures only 11 mm × 26 mm and weighs 4 g (As shown in **figure 1**) holds a metal oxide semiconductor imaging-chip video camera, 6 white light-emitting diode illumination sources, 2 silver-oxide batteries and a radio telemetry transmitter. The image filed is 140 degrees, magnification is × 8 and the depth of view is 1 to 30 mm.

There are two types of capsules are present as follows,

A. Esophageal Capsule [11, 12, 20]: The esophageal capsule is the same size as the small bowel capsule but has lenses on both ends of the 'pill.' It is designed for imaging the esophagus to evaluate for Barrett's mucosa and esophageal varices (**Figure 2 & 3**). Its role is currently under investigation. Insurance coverage for this procedure varies regionally.

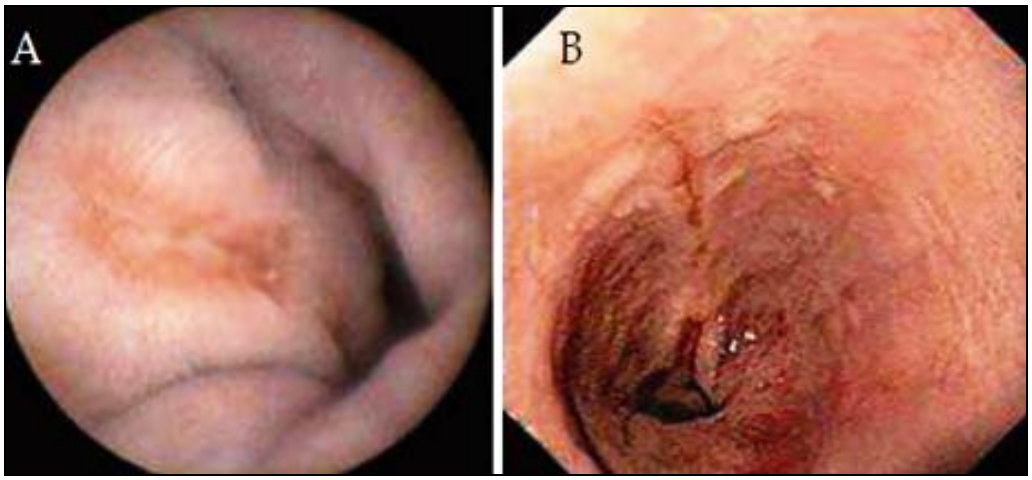

FIGURE 2: A: PILLCAM™ ESO IMAGE OF EROSIVE ESOPHAGITIS; B: ENDOSCOPY IMAGE OF DISTAL ESOPHAGUS IN THE SAME PATIENT

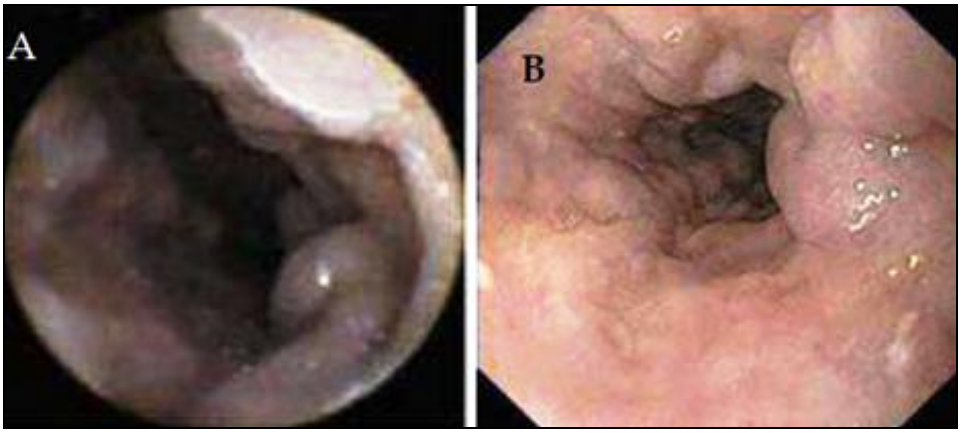

FIGURE 3: A: PILLCAM ESO™ IMAGE SHOWING ESOPHAGEAL VARICES; B: UPPER ENDOSCOPY IMAGE OF DISTAL ESOPHAGUS IN THE SAME PATIENT.

CE has been extended to examine the esophagus. Capsule transit time via the esophagus is significantly faster than the transit time in the small bowel. For this reason, two cameras transmitting images at a high rate (14 frames per second) have been placed at each end of the esophageal capsule camera. This camera with high transmission screens the esophagus well. The esophageal capsule has a very high diagnostic sensitivity for diseases such as reflux esophagitis, Barrett's esophagus and esophageal varices.

The advantages of using CE are the lack of need for sedation, noninvasiveness, and the possibility of performing the procedure at the first office visit. The disadvantage is that the esophageal capsule is competing with a very good, albeit invasive device, the gastroscope which is in most places cheaper.

B. Colon Capsule [12, 13]: A wireless capsule for visualizing the colon for screening purposes has been developed, but is not currently FDA approved for use in the U.S.

a. The small bowel is narrow. As the capsule camera enters the small bowel, it remains by and large oriented in the same direction, either camera first or transmitter first. The capsule will not flip around its own axis. The capsule will remain oriented in the given position as it entered the small bowel along its journey through the small bowel. For this reason, the single camera will screen the entire small bowel mucosa. This is not true for the colon. In the large bowel, with its wide diameter, the capsule can tumble backward and forward. A capsule with a single camera would film certain areas twice and other areas not at all.

The solution to this challenge is a colon capsule that has two cameras, one camera at each end (**figure 4**). The colonic mucosa is visualized from both directions simultaneously and thus complete visual coverage of the entire colon is guaranteed.

FIGURE 4: COLON CAPSULE WITH TWO VIDEO CAMERAS, ONE AT EACH END OF THE CAPSULE

b. The capsule transit time to reach the end of the colon is much longer than the time required for the capsule to reach the cecum, and the colon capsule consumes more energy than the small bowel capsule since it transmits images from two cameras. To reduce the energy requirements, the colon capsule is put to sleep for an hour and a half, 5 min after ingestion. Images captured by the Pillcam™ Colon and conventional colonoscopy as shown in **figure 5**.

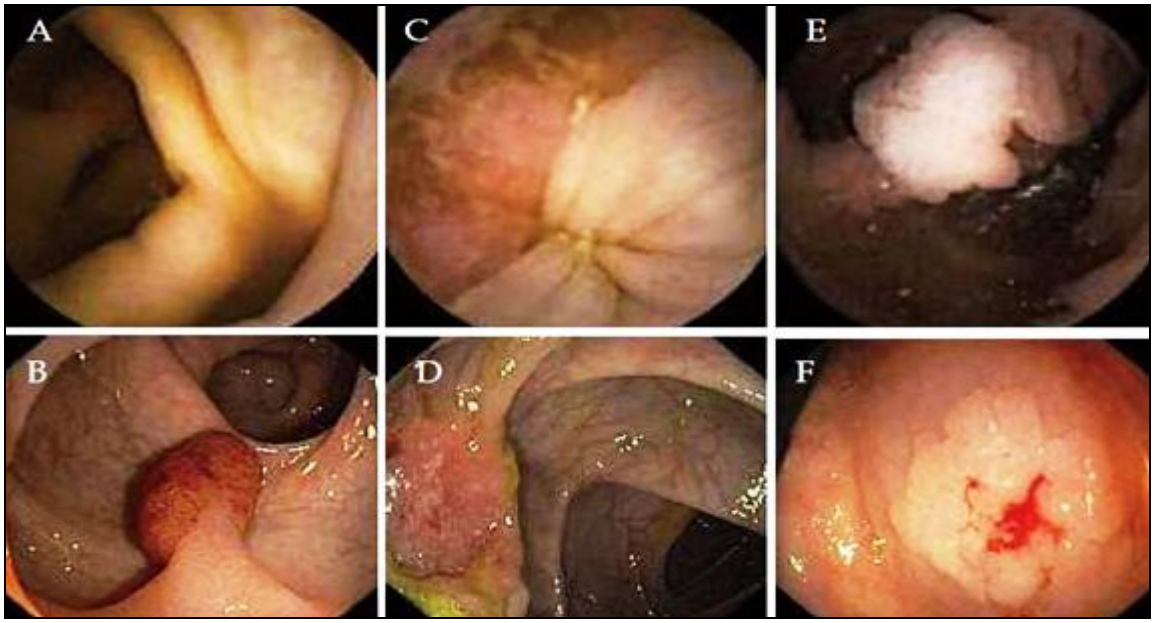

FIGURE 5: IMAGES CAPTURED BY THE PILLCAM™ COLON AND CONVENTIONAL COLONOSCOPY. A AND B: PEDUNCULATED POLYP IN THE SIGMOID COLON; C AND D: ULCERATED TUMOR IN THE TRANSVERSE COLON; E AND F: FLAT ADENOMA IN THE ASCENDING COLON.

c. The third hurdle is bowel cleansing. In standard colonoscopy, some minimal amount of liquid debris can be aspirated, yet minimal amount of debris may compromise the capsule's ability to identify pathological changes. A more vigorous bowel preparation had to be offered to patients to assure proper cleansing for colon capsule examinations.

Components of Capsular Endoscope [3, 13]: The capsule, which is swallowed by the patient, is 26mm x 11mm in size and consists of;

a) An optical dome
b) A lens
c) Several light emitting diodes
d) A semiconductor
e) Transmitter, and
f) An antenna

The system also consists of a sensor array or electrodes which are attached to the patient's abdomen much like EKG leads or a Sensor Belt worn around the abdominal area (**figure 6**). These are connected to a data recorder which is worn by the patient during the study. The M2A capsule consists of following properties as shown in **figure 7**.

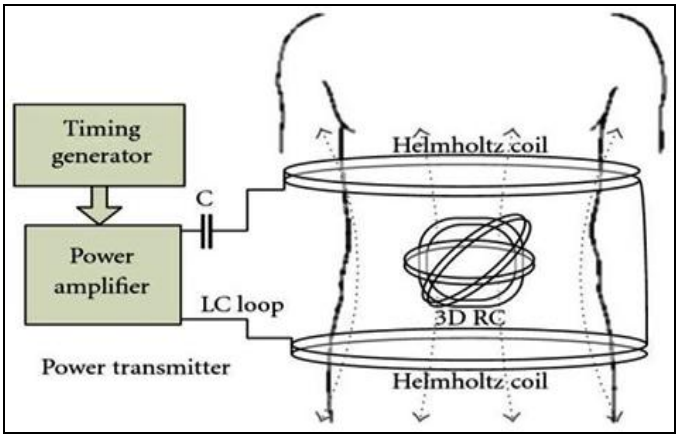

FIGURE 6: THE ILLUSTRATION OF THE POWER SUPPLY SYSTEM

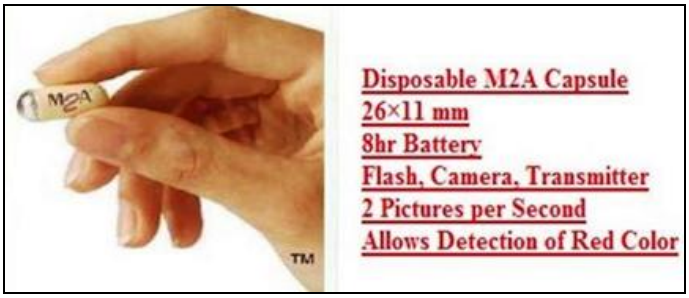

FIGURE 7: M2A CAPSULE

The disposable capsule is propelled physiologically through the entire GI tract, taking its most accurate images in the small bowel. Images recorded by the capsule camera are transmitted and stored on a data recorder worn by the patient. After the study, the images are downloaded onto a computer where the images are then viewed and interpreted by a specially trained gastroenterologist.

A typical wireless capsule endoscopy (WCE) system contains main four parts: capsule endoscope (CE), receiving box, image working station and software application, as shown in **Figure 8**. The CE is an electronic microsystem, which can be ingested to image the GI tract and transmit the images outside of the patient's body.

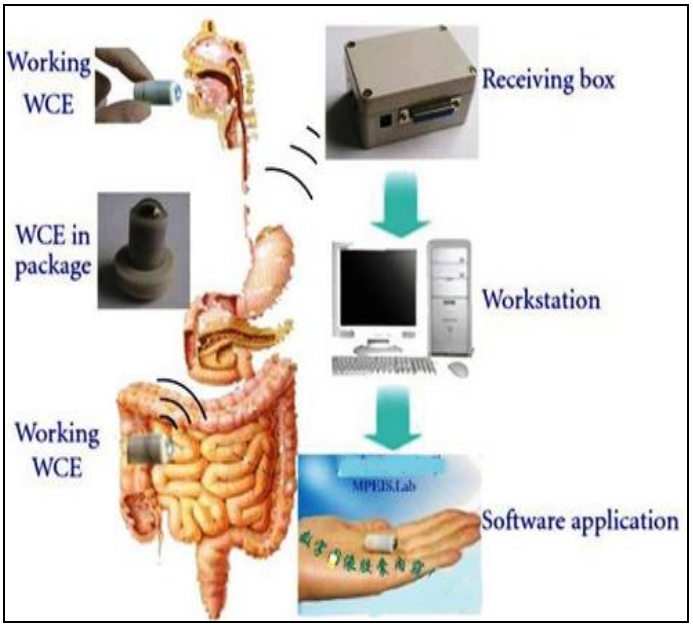

FIGURE 8: A TYPICAL WCE SYSTEM

Cost:
1. Single Capsule: $450.00
2. GIVEN (Gastro Intestinal Video Endoscopy) Data Recorder Set with belt pack and batteries: $5,400.00
3. RAPID workstation and software: $14,500

After reporting the first WCE system in 2000, the Given Image Company released the first commercial WCE product system M2A in Yoqneam, Israel. The CE of the system is 11 mm in diameter and 26 mm in length, which is small enough to be swallowed by the patient. The CE is composed of 8 main models including,

1. Optical dome
2. Lens holder
3. Lens
4. LED (light emission diode) lighting
5. CMOS (complementary metal oxide semiconductor) image sensor
6. Cell battery
7. ASIC (Application specific integrated circuit) transmitter
8. Antenna, as shown in **Figure 9**.

After the CE is swallowed by patients, it will go through the entire GI tract with the natural peristalsis. During this course, the optical dome can plump up the intestine wall without requiring air inflation.

In the meantime, the micro CMOS image sensor images the GI tract, and the RF model transmits the images outside of patient's body at the frame rate of 2 f/s (frames per second). The images are received by the receiving box outside and showed in PC workstation. After the examination, the CE is vented out naturally.

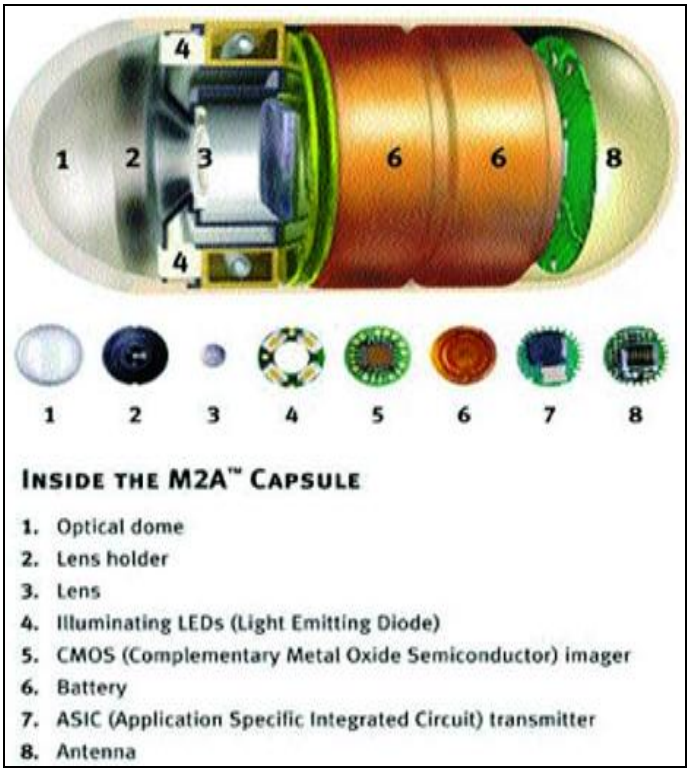

FIGURE 9: THE EIGHT MAIN COMPONENTS OF THE M2A CAPSULE

The name of M2A was changed to PillCam (means Pill and Camera) later. In 2005, Given Imaging developed two distinct WCE systems: PillCam ESO especially for the esophagus and PillCam SB especially for the small intestine as discussed in above in capsule endoscopy, as shown in **figure 10**.

FIGURE10: PILLCAM SB AND PILLCAM ESO

Procedure [2]: A bowel prep to clean the intestine, similar to that used for colonoscopy, may be recommended by your doctor to take the night before undergoing a capsule endoscopy. The exam is usually done in an office setting. Sensors are placed on the patient's abdomen and the data recorder is attached to a large belt worn by the patient. The capsule is then activated and swallowed with a sip of water. The patient may leave the doctor's office and continue with routine daily activities, including eating a light meal after several hours. Later, the patient returns for removal of the equipment, and then returns home. There is no sedation needed for the procedure and it is completely painless. The capsule is disposable and usually passes out of the GI tract unnoticed. The results are discussed in a follow up appointment with the patient's doctor. Capsule endoscopy can also be performed in hospitalized patients and in children as young as 2 years old in special circumstances.

Mechanism of Capsule Endoscopy [4, 9, 10]: Before the capsule is swallowed, 8 skin antennas are taped to the patient's anterior abdominal wall and connected to the hard drive. After an overnight fast, the patient swallows the capsule with a few sips of water and then the capsule is passively moved along by peristalsis. Two hours after ingestion, the patient is allowed to drink while eating is allowed after 4 h. During the procedure the patient may carry on with his daily activities.

The camera is activated by removal of the capsule from its magnetic holder and takes 2 images per second and transmits these by means of radio frequency to a sensor array placed on the patient's abdomen and from here to a recording device in a belt that the patient wears for the duration of the battery life (8 h). The use of the real time viewer may shorten procedures, as the patient can be disconnected once the cecum is visualized.

The journey of the capsule through the gut is shown in **figure 11**.

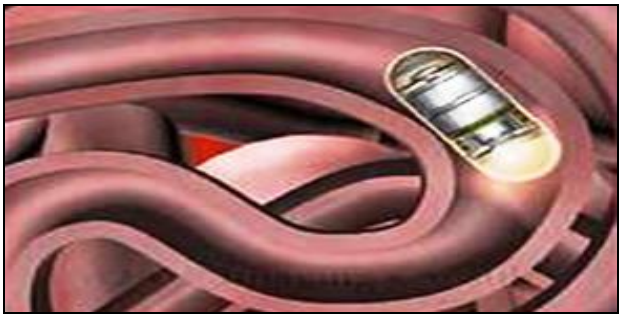

FIGURE 11: A JOURNEY OF THE CAPSULE THROUGH THE GUT

After those 8 h, the sensor array and recorded data are removed and the recorded images are downloaded to the computer. It takes on average 40-60 min to read these images and since it is very time-consuming, one possible cost-effective strategy could be the use of expert nurse endoscopists to select images. Some studies have shown that highly motivated nurses and gastrointestinal residents trained to read CE can detect clinically significant lesions at a similar rate to physicians. Since its development, additional support systems have been added to the software to assist the reader, such as localization capability, suspected blood indicator, a multiviewing feature and quick view modality.

The capsule is excreted with the feces; usually within 24 to 48 hr. CE is usually performed as an outpatient procedure. The presence of intestinal contents or a motility disorder may cause the incomplete visualization of the intestinal mucosa. Several studies have examined the possibilities of improving bowel cleanliness and shortening transit time by means of different medications and different fasting periods. Nevertheless, small bowel preparation is still a controversial issue. We have participated in a prospective multicenter randomized trial which has shown that bowel preparation with different laxatives does not improve the visualization of the small intestine.

Uses of Capsule Endoscopy: Capsule endoscopy provides images of digestive system that cannot be captured with conventional X-rays. It is the only imaging method that can provide color images of the lower small intestine painlessly. Furthermore, not considering the cost, patients prefer WCE to traditional push endoscopy.

Gastroenterologist will use the images transmitted by the capsule to diagnose and evaluate a variety of conditions, including:

- Gastro Esophageal Reflux Disease (GERD)
- Diarrhea
- Polyps
- Anemia and bleeding
- Bowel function
- Malabsorption
- Abdominal pain
- Small intestinal tumors such as lymphoma, carcinoid tumor and small intestinal cancer.
- Coeliac sprue
- Crohn's disease of the small intestine
- Angiodysplasias (collections of small blood vessels located just beneath the inner intestinal lining that can bleed intermittently and cause anemia)

Gastroenterologist may also use capsule endoscopy to monitor the progress of treatment plans for these conditions. If doctor detects a serious problem in esophagus, may need to undergo a conventional endoscopy to confirm diagnosis and possibly to receive treatment.

Indications [2, 14, 20]: Capsule endoscopy is mainly indicated for the evaluation of Small Bowel (SB) diseases, particularly for the diagnosis of Obscure Gastro Intestinal Bleeding (OGIB). The numbers of small bowel and esophagus indications are as follows;

a) Small Bowel

- Obscure gastrointestinal bleeding
- Occult (positive FOBT)
- Evaluation of iron deficiency anemia
- Crohn's disease
- Suspected Crohn's disease
- Indeterminate colitis
- Assessment of mucosal healing
- Abdominal pain
- Craft-versus-host disease
- Surveillance of polyposis syndromes
- Coeliac disease
- Suspected small bowel tumors
- Follow up of small intestine Transplantation
- Evaluation of abnormal SB Imaging
- Evaluation of drug induced injury

b) Esophagus

- Barrett's esophagus
- Esophagitis
- Variceal evaluation

1. **Obscure Gastrointestinal Bleeding:** The most frequent indication for performing a capsule endoscopy is the evaluation of obscure GI bleeding. Patients who have unexplained iron deficiency anemia or are losing blood from an unknown source in the GI tract are first evaluated with a colonoscopy and upper endoscopy (EGD). However, if these exams show no identifiable source of blood loss, then a wireless capsule endoscopy study is the next step in trying to find the cause of the bleeding.

   About five percent of all obscure GI bleeding emanates from the small bowel, most often from small vascular lesions (**figure 13 A**) called angioectasias. These are small blood vessels with thin walls that may be found throughout the GI tract and may bleed profusely or very subtlety over an extended time. Other causes of bleeding from the small bowel include ulcerations, erosions, inflammation, tumors, masses or rare hereditary conditions. Various Capsular Endoscopy (VCE) images of lesions found in patients with obscure-overt GI bleeding is shown in **figure 12**.

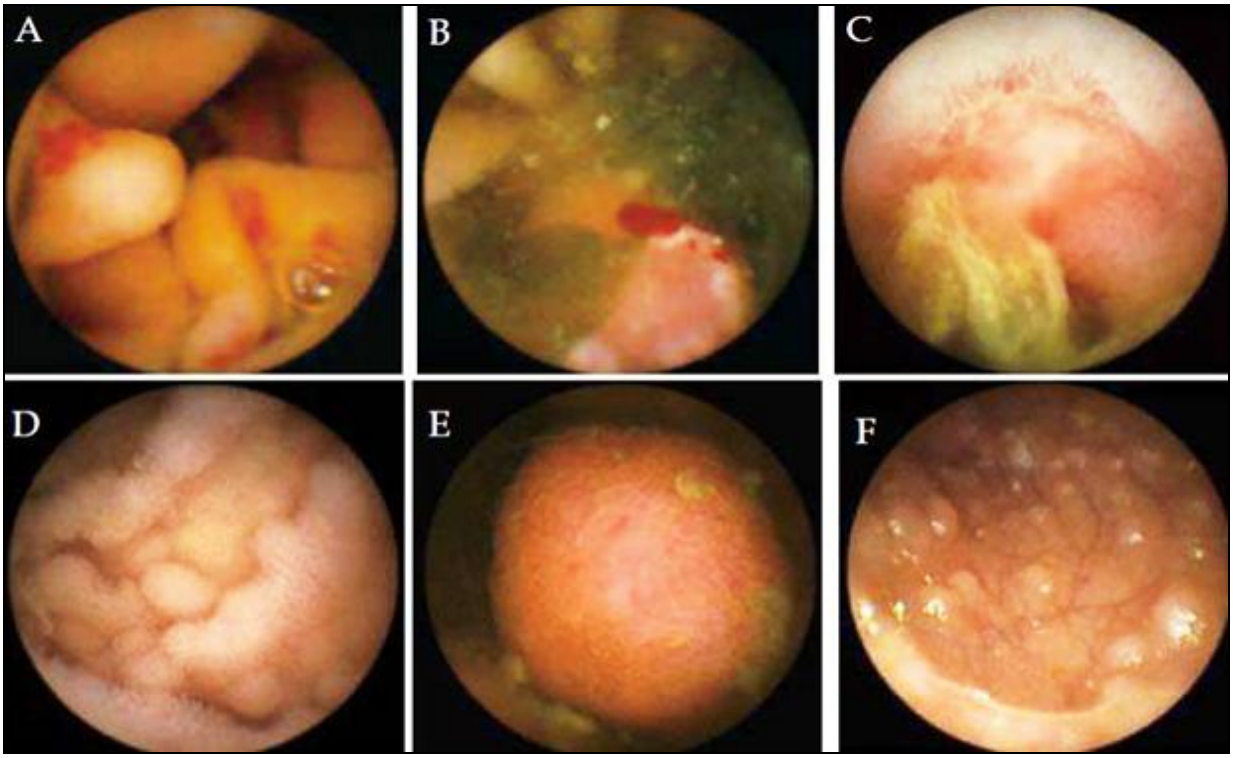

FIGURE 12: VCE IMAGES OF LESIONS FOUND IN PATIENTS WITH OBSCURE-OVERT GI BLEEDING. A: Multiple angiodysplasias in the jejunum; B: A jejunal mass with active bleeding; C: An ileal ulcer in a patient with newly diagnosed Crohn's disease. D: Benign lymphoid hyperplasia located diffusely through the GI tract in a patient with CVID; E: A jejunal polyp in a patient with peutz-jeghers disease; F: Multiple small polyps in the ileum.

2. **Small bowel Crohn's disease [1, 18, 20]:** Another common indication for capsule endoscopy is evaluation for Crohn's Disease. Crohn's disease is a chronic, inflammatory disorder affecting any part of the gastrointestinal tract, but frequently involves the small and large bowel. The etiology of Crohn's disease is unknown. Capsule endoscopy is the gold-standard examination for the diagnosis of Crohn's disease (CD) of the small intestine. Crohn's is an inflammatory bowel disease which can affect the small intestine causing pain, inflammation, ulceration (**figure 13 B)** and bleeding.

A range of diagnostic tools can be used to determine the presence of Crohn's disease, including radiology, endoscopy and serum antibody tests. Unfortunately, these diagnostic tools are often associated with low diagnostic yields and may require repeated testing before a diagnosis is even established. Small bowel capsule endoscopy is also a useful tool in evaluation of the small bowel for tumors such as lymphoma, carcinomas or carcinoids. This technology can be beneficial as an adjunctive diagnostic study in patients with coeliac sprue and for surveillance in patients with hereditary polyposis syndromes.

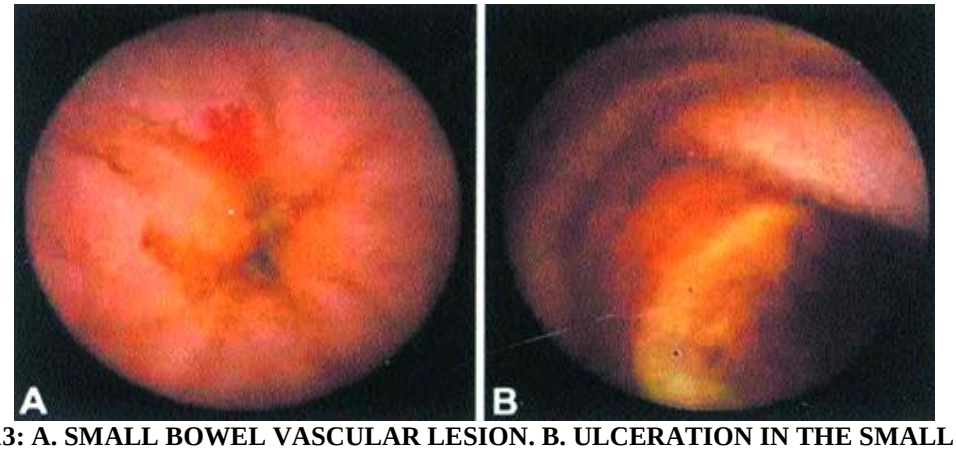

FIGURE 13: A. SMALL BOWEL VASCULAR LESION. B. ULCERATION IN THE SMALL BOWEL.

Other potential indications for capsule endoscopy are under consideration and may include the evaluation of certain types of abdominal pain, refractory diarrheas or malabsorption

Limitation of Capsule Endoscopy [13]:

1. Abnormalities in some areas of the intestine are missed because of rapid transit of the capsule and blurred, uninterruptable photographs.

2. If there are narrow areas due to scarring (strictures) or tumors in the small intestine, the capsule can get stuck in the narrow area and cause an obstruction of the intestine that requires surgical removal of the capsule.

3. The capsule endoscopy system is purely diagnostic and is not used to biopsy or treats any conditions.

4. The picture quality is not as good as the best quality of flexible wired video endoscopy.

5. The frame rate with the capsule is lower (2–18 v 25 f/s).

6. The image resolution of 256 × 256 is not satisfied, and the light intensity cannot yet respond to altering requirements.

7. Most of these existing CEs are powered by cell batteries because of the limited power supply, and few of these CEs can keep working for more than 8 hours. Nevertheless, for a patient with GI tract disease, it needs greatly more than 8 h for diagnosing; otherwise, the small intestine is still not examined when the cell battery runs out of power.

8. Finally, reviewing the tens of thousands of photographs is very time consuming for the conscientious physician.

Risk [2]: The main risk with capsule endoscopy is possible retention of the device in the small bowel. In patients who undergo the test to evaluate for bleeding, the risk is very low, approximately one to two percent. For patients with Crohn's Disease, the risk may increase to four to five percent.

Most cases of retention resolve spontaneously after a short delay in the passage of the capsule and most patients have no symptoms whatsoever. Occasionally, medications are given to help facilitate passage. In rare instances, there is an abnormality in the small bowel which blocks the passage. In such a case, the capsule can be retrieved during an endoscopic procedure called a double balloon enteroscopy, or in unusual instances, by surgical resection. If the doctor is concerned about a possible blockage in the small bowel, a patency (or 'dummy') capsule can be ingested as a test beforehand to insure that no blockages exist.

Contraindication: Known small bowel obstruction is a contraindication for capsule endoscopy. Patients who are at risk for obstruction, have swallowing disorders, or have pacemakers or other implanted cardiac devices should have careful evaluation by a specialist before undergoing a capsule endoscopy.

Absolute contraindications include;

1. Bowel obstruction
2. Extensive and active Crohn's
3. Disease ± strictures
4. Intestinal pseudo-obstruction
5. Young children (<10 years)

Relative contraindications include;

1. A history of a gastrointestinal motility disorder such as gastroparesis

2. A history of intestinal strictures or fistula, pregnancy, presence of cardiac pacemaker or defibrillator

3. A known history of multiple small bowel diverticula

4. A history of Zenker's diverticulum

5. A history of extensive abdominal surgeries or radiation, and an active swallowing disorder or dysphasia

6. Pregnancy

CONCLUSION: Capsule endoscopy is a simple and well tolerated and safe examination of the small bowel with a diagnostic yield superior to radiological investigations. This capsular endoscopy technique is very much so important in the diagnosis of the gastrointestinal disease by using capturing color images which should diagnose with doctors or physicians. The Complete exploration of the small intestine is done by the Wireless Capsule Endoscopy so the capsule endoscopy is most important in the diagnosis and the number of diseases as small bowel diseases, gastrointestinal bleeding, Crohn's disease and small bowel tumors, assessment of esophageal disorders and diagnosis of coeliac disease. Capsule retention is the major complication. Care must be taken in patients with symptoms suggesting partial obstruction and Crohn's Disease.

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