Contraindications and Complications

Capsule endoscopy (CE) has proved to be an extraordinary safe device to use. Over 300.000 capsules have been deployed worldwide with no reported deaths and with few side-effects. Careful selection of the patients to be subjected to CE is however required to avoid the occurrence of complications. As in the case with any diagnostic procedure there are patients who are appropriate for study with this device and others who are not.

Contraindications

Suspected or known gastrointestinal obstruction is listed as a contraindication, due to the risk of capsule retention (1), *(Table 1)*. This is becoming a common indication for a difficult group of patients who present to surgeons with recurrent small-bowel obstruction and negative investigations. It is also unwise to use CE in patients with known motility disorders or intestinal pseudo-obstruction. Swallowing disorders and patients with pacemakers (CPs) or with implanted cardiac defibrillators (ICDs) are relative contraindications. Swallowing disorders may result in ineffective swallowing with misplacement of the capsule in or around the pyriform sinuses or in the trachea. They should be carefully investigated before capsule ingestion. Another concern is that CE signals could cause electromagnetic interference and alter pacemaker or defibrillator function. Evidence is accumulating about the safety of CE in patients with CPs and ICDs implanted in the chest (2,3) However, until more data is available, it is recommended that these procedures be done in the hospital under continuous monitoring, with support from the patient's cardiologist. No data is available on patients undergoing esophageal CE or in patients with CPs or ICDs implanted in the abdomen. These patients should undergo CE in a monitored environment. The safety of CE in pregnancy has not been established.

Patients should not undergo magnetic resonance imaging after having completed a CE until they have passed the capsule. The capsule can be easily identified on plain radiographs, and this should be performed if there is any question. Informed consent before any capsule study should include mention of possible capsule retention requiring surgery, potential complications related to swallowing of the capsule, potential risks for electromagnetic interference and the possibility of an incomplete study that might necessitate its repetition.

Complications

1. Capsule Retention

The main complication is that the capsule may become impacted in intestinal strictures. Capsule retention is defined as capsule present and confirmed by abdominal X-ray at 2 weeks post ingestion (4). This means that capsule is retained indefinitely in the small bowel unless an intervention of any sort is initiated. Capsule retention is distinct from slow and incomplete transit without anatomic abnormality, which may occur in up to 20% of examinations. Preliminary studies with very strict exclusion criteria reported a retention rate of 0.75% (5). It is now clear that the rate of indefinite retention appears to be dependent on the indication for the examination (4). High risk of retention occurs in patients with prolonged NSAID use *(Figure 1)*, abdominal radiation injury *(Figure 2)*, extensive Crohn's enteritis, and prior major abdominal surgery or small-bowel resection, (6-7) *(Table 2)*. The highest rate of intestinal retention in patients with obscure bleeding is around 5%, while in known Crohn's disease it can reach 7%. In suspected Crohn's disease the average retention rate is around 1%. A retention rate of 21% has been reported when CE was used in patients with suspected small-bowel obstruction (4). No retention was reported in 773 capsule ingestions by healthy volunteers (8) *(Table 3)*. In a recent large multicenter study of 733 capsule examinations performed for different clinical reasons an intestinal retention rate of 1.9% has been reported (9). Patients undergoing esophageal capsule studies should also be informed of the potential risk for small intestinal retention. If the risk of capsule retention is dependent on the indication for the exam, it is expected that the intestinal retention rate will be much lower for esophageal studies in light of such patients not having small-bowel disease (1).

There is no accepted method of completely avoiding capsule retention. A complete knowledge of the patient's clinical picture is the most effective approach to minimize unexpected failure of capsule passage (10). It has been recommended that a radiological examination, preferably with enteroclysis, should be carried out to exclude adhesive or inflammatory obstruction before CE (11). Unfortunately, imaging studies such as barium studies only provide very limited information for predicting capsule passage. CT or MRI enteroclysis are promising but published studies are still limited. The patency capsule (a inert capsule identical in size to the actual endoscopic capsule, which dissolves in 2-3 days if not excreted, designed precisely to test the permeability of the small bowel prior to the real examination) has been used as a screening test to assess the passage of an endoscopic capsule in patients at risk for small-bowel strictures.

TABLES

Table 1: Contraindications to capsule endoscopy.

Patients with known or suspected GI obstruction, strictures, based on the clinical picture or procedure testing
Patients with cardiac pacemakers or other implanted electro-material devices
Patients with swallowing disorders
Pregnancy

Table 2: Groups of patients at higher risk of capsule retention.

Chronic NSAID use
Extensive Crohn´s enteritis
Abdominal radiation injury
Prior major abdominal surgery
Prior small-bowel resection

Table 3: Frequency of capsule retention.

Healthy Volunteers	0%
Suspected Crohn´s disease	1%
Known Crohn´s disease	5%
Obscure gastrointestinal bleeding	1.5%
Suspected small-bowel obstruction	21%

FIGURES

Figure 1: NSAID-induced small-bowel stricture.

Figure 2: Radiation induced small-bowel stricture.

Figure 10: Same patient as in fig.9. Plain radiograph of the abdomen showing retained capsule.

Figure 11a: Same patient as in fig.9 at surgery.

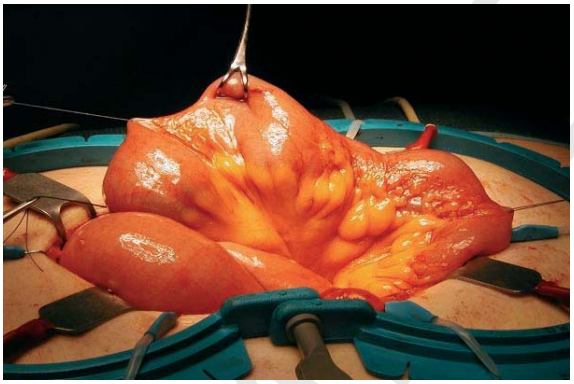

Figure 11b: Same patient as in fig.9 at surgery.

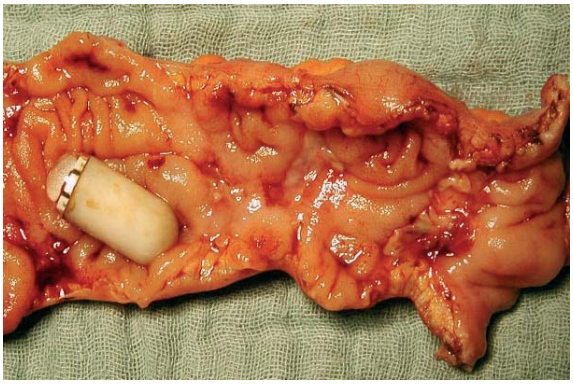

Figure 12: Capsule endoscope image showing airways (courtesy of Prof. R. de Franchis).

Figure 13: Capsule endoscope image showing vocal cords (courtesy of Prof. R. de Franchis).