Clinical guide for using Colon Capsule Endoscopy in the lower gastrointestinal pathway

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Scope

In June 2020, clinical guidance on triaging patients with lower gastrointestinal (GI) symptoms was published. This guidance supported the use of Colon Capsule Endoscopy (CCE) in patients with NG12 specified symptoms and a Faecal Immunochemical Test (FIT) result of between 10-100 ug/gm. This guidance document updates and sets out further information on use of CCE in the lower GI pathway and the patient cohort that this procedure can be offered to.

The National Cancer Team has allocated funding to support Cancer Alliances to establish pilot CCE clinics to test and develop the evidence base for this technology, and to support restoration of endoscopy services during the COVID-19 pandemic.

Clinical evidence and data on CCE

Second-generation colon capsule endoscopy (CCE-2) has shown promising accuracy for the diagnosis of overall neoplasia.

A meta-analysis that looked at 14 studies and provided data from 2420 patients concluded that CCE-2 detected polyps >6 mm with 86% sensitivity and 88.1% specificity. CCE-2 detected polyps >10 mm with 87% sensitivity and 95.3% specificity. CCE-2 identified all 11 invasive cancers detected by colonoscopy.[1]

A second meta-analysis demonstrated that mean sensitivity, specificity and diagnostic odds ratio was 0.85, 0.85 and 30.5, respectively for polyps of any size, 0.87, 0.95 and 136.0, respectively for polyps ≥ 10mm and 0.87, 0.88 and 51.1, respectively for polyps ≥ 6mm. This meta-analysis identified a complete examination (capsule excreted) in between 57-100%

[1] https://www.cghjournal.org/article/S1542-3565(16)30151-3/fulltext

patients.[2] A study within the meta-analysis found the mean capsule transit time was 4 hours and 4 minutes, and ≥70% of patients excreted the capsule within 5 hours.[3]

The evidence is sufficient to support a national pilot on the use of this technology as a diagnostic tool in lower risk patients.

Target population and exclusions

This guidance permits the use of CCE in patients referred on an urgent cancer pathway in the **symptomatic endoscopy service** in the following patient populations:

- Those with a FIT score between 10-100 ug/gm
- Those with a FIT score of <10 ug/gm who have been referred on an urgent cancer pathway due to concerning symptoms

CCE should be performed safely with the aim of achieving a high quality, complete colonic examination. The following do not necessarily preclude CCE, but are risk factors for complications of capsule endoscopy, adverse reactions to purgatives and an inadequate examination. Although many are as applicable to conventional colonoscopy, CCE does not have a cleansing facility and therefore thorough bowel preparation is critical.

Therefore, patients in these categories may be more suitable for an alternative investigation:

- with dysphagia
- with Crohn's disease
- with strictures
- long term daily use of non-steroidal anti-inflammatory drugs
- with abdominopelvic irradiation
- during pregnancy

Risk of capsule retention can be minimised by luminal pre-assessment using radiological imaging or the Agile Patency Device.

Concomitant medication

Patients should generally continue to take their existing medicines or follow existing pre-assessment guidance of colonoscopy. Those taking antiplatelet therapy, warfarin, heparin or a DOAC should continue these medicines. Patients with diabetes should follow existing guidelines.

Bowel Preparation

Effective and complete bowel preparation is an important prerequisite for CCE helping to ensure conclusive imaging and smooth expulsion of the capsule.

[2] https://pubmed.ncbi.nlm.nih.gov/32858753/
[3] https://www.sciencedirect.com/science/article/abs/pii/S0016510719323363

Bowel preparation for colon capsule involves dietary manipulation, cleansing and, after capsule ingestion, a “boost” to accelerate passage through the small intestine, aiming for 90-95% excretion rates.

The following bowel preparation regime is recommended:

- Low residue diet 3-5 days before the procedure
- Clear liquid diet the day before the procedure
- 2L PEG solution the evening before, and on the morning of, the procedure, before swallowing the capsule at about 10am (1L+1L split dose PEG + Ascorbate is an option for units currently using this bowel preparation for colonoscopy)
- On arrival for the procedure, administer 1mg of prucalopride (or 2mg to patients with treatment dependent chronic constipation or those with a past history of poor bowel cleansing for colonoscopy)
- Once capsule enters small bowel or as soon as patient has returned home, administer first booster
- Wait three hours and if capsule not excreted, administer second booster

  European Society of Gastroenterology guidelines (2012) recommend the use of sodium phosphate:
  booster 1: sodium phosphate (Fleet phosphosoda) 30ml with 1L water
  booster 2: sodium phosphate (Fleet phosphosoda) 15ml with 0.5L water

  Recent studies reporting high capsule excretion rates incorporate 50ml Gastrografin into both boosters.

  For either regimen, bisacodyl suppository 10mg is recommended for all patients if the capsule is not excreted 2 hours after the second booster.

- Sodium phosphate should be used with caution in patients with renal and cardiac disease, hypovolaemia and those taking diuretics or ACE inhibitors.

Factors which predict poor bowel preparation include a history of cirrhosis, diabetes, stroke, cognitive impairment and the use of opioid or tricyclic antidepressant medication.

Reduced tolerance of laxatives and impaired mobility may explain poorer response in elderly patients. Those who do not have sufficient flexibility and dexterity to self-administer the bisacodyl suppository may be at risk of an incomplete CCE.

Referral to colonoscopy

In line with European guidance:

- patients found to have a polyp ≥6mm and those with ≥3 polyps, irrespective of size, should be sent for post-CCE colonoscopy for polypectomy. The urgency of this colonoscopy should be dictated by the responsible clinician using factors such as polyp size, morphology, and image quality. Patients can be taken off an urgent

pathway if the clinician is satisfied that cancer has been ruled out and has communicated this to the patient.

- If polyps found on the reading are deemed to be hyperplastic, teams should use their clinical judgment to decide if a referral to colonoscopy is appropriate.
- For polyps detected by CCE but then not on the subsequent colonoscopy a repeat colonoscopy, or other appropriate investigation, is recommended at an interval dictated by the responsible clinician, based on the extent of the pathology identified at CCE. It may be appropriate for the responsible clinician to re-read the original CCE video to assess the extent of the pathology missed.

Procedural factors

- **Incomplete CCE**
  - An incomplete examination should ordinarily prompt a completion investigation to ensure that the whole of the colon has been visualised. It is anticipated that, in most cases, this will be a flexible sigmoidoscopy because the battery life of the CCE may not have be sufficient to permit adequate views of the rectosigmoid.
  - Sometimes views may be insufficient to fully satisfy the reporter that there is or is not significant pathology present. Here a clinical judgement will have to be made as to whether further investigation is required.

- **Inadequate CCE bowel prep**
  - A validated bowel prep score for CCE, CC-CLEAR has been introduced for this pilot.
  - A CCE examination judged to be inadequate (0-5 points on the CC-CLEAR scale) should prompt a further investigation of the colon, either a colonoscopy or CTC, rather than a repeat CCE.
  - Beyond this, and as with existing practice in colonoscopy and CTC, an assessment of the adequacy of bowel prep will need to be made by the reporting clinician and responsible clinician dependent upon the composite of any other clinical risks.

- **Capsule retention**
  - Capsule retention is generally defined as the presence of the capsule in the digestive tract for a minimum of two weeks.
  - If the recording shows that the capsule has not reached the caecum then a plain abdominal X-ray should be performed to see if has been retained in the small bowel. If retention is confirmed, consider CT scan to investigate why and escalate to the National Cancer Team.
  - If the recording shows that the capsule has entered the caecum but not exited the patient or visualised the anorectal verge, the patient will need further endoscopy (flexible sigmoidoscopy or colonoscopy) to complete the examination and exclude the possibility of capsule retention.
  - If capsule retention is confirmed, further management will be dictated by the diagnosis and location of the capsule.

Patient specific factors

- The age, symptoms, performance status, family history, co-morbidity and the views of the patient should all be considered when coming to a clinical decision about the patient's management after CCE. In particular these factors should influence clinical decision making with regard to judgements around the adequacy of the bowel prep and the need to perform a further colonic evaluation.
- Patient specific considerations are most important in deciding whether pursuing diminutive polyps are in the patient's best interests.
- On-going symptoms, such as diarrhoea, might prompt the need to obtain histology in order to exclude microscopic colitis.

Extracolonic findings

Extracolonic findings should also be reported when clinically meaningful prompting an appropriate management plan.

After care/onward referral/discharge and safety netting

- Patients judged to have a negative CCE or benign disease requiring no further secondary care management should be discharged from the 2ww pathway.
- Some patients may continue within secondary care but the majority will return to primary care. This decision will need to be communicated clearly to the patient, GP and practice.
- All patients discharged to primary care will require a formal review at 6 weeks to ensure that their symptoms have resolved or are adequately treated or, if still symptomatic, that they are re-referred to secondary care.

Training for staff

Clinical leads in each pilot clinic are responsible for ensuring endoscopy professionals with sufficient experience are nominated to undertake training. This can include gastroenterology trainees, consultants, experienced endoscopy nurses, nurse endoscopists, IBD nurses, colorectal surgeons and staff redeployed from the bowel scope screening programme.

All staff reading and interpreting colon capsule endoscopy must have completed and passed the IMIGe advanced (BSG approved) reader training.

Evaluation

Hospitals participating in the pilot will be expected to collect a minimum dataset for each procedure including patient outcomes which will feed into a national evaluation delivered by the National Cancer Programme Team. All Trusts must nominate a Data Collection Lead to lead this process.