Advice Statement

Colon capsule endoscopy (CCE-2) for the detection of colorectal polyps and cancer in adults with signs or symptoms of colorectal cancer or at increased risk of colorectal cancer

Advice for NHSScotland

Colon capsule endoscopy (CCE-2) is not recommended for routine use in NHSScotland for the detection of colorectal polyps and cancer. The clinical effectiveness evidence is currently limited, no relevant published evidence on the cost effectiveness of the technology was identified, and its place in the patient care pathway has still to be established.

CCE-2 may however be considered as an additional testing option in patients who are able to undergo the intensive bowel cleansing needed for CCE-2 and who have contraindications for optical colonoscopy or CT colonography.

CCE-2 has the potential to be delivered in community settings which could benefit patients who currently travel long distances to access optical colonoscopy or CT colonography hospitals services.

Research into improving levels of adequate bowel preparation and CCE-2 procedure completion rates is required prior to considering more widespread use of this technology. The ScotCap programme is exploring using CCE-2 to triage patients presenting with gastrointestinal symptoms.

*NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) advice.*

Why is SHTG looking at this topic?

In 2016/17 a feasibility study on community-based colon capsule endoscopy (CCE-2) was conducted in the Scottish Highlands. Following completion of this pilot study, the Scaling
Digital Innovation Service approached the Scottish Government about exploring national adoption of CCE-2. The subsequently created ScotCap group felt it was important that the published evidence on CCE-2 was reviewed prior to making any decision about rolling out this technology. The topic was prioritised for inclusion on the SHTG programme following a referral from the Scaling Digital Innovation Service.

Evidence Note 86 was produced by Healthcare Improvement Scotland in response to this request.

Background

Colorectal cancer is the third most common cancer in Scotland with 3,671 new diagnoses in 2015. Colorectal cancer often begins as a growth on the inner lining of the colon, called a polyp. Early detection and removal of precancerous polyps is very effective for preventing colorectal cancer.

People in Scotland with suspected colorectal polyps/cancer are currently referred for an optical colonoscopy or CT colonography if optical colonoscopy is not clinically appropriate. Colon capsule endoscopy (CCE-2) is a new technique for examining the colon using an ingestible capsule containing one or more cameras.

Health technology

Optical colonoscopy, CT colonography and CCE-2 all require patients to undergo a period of bowel cleansing which varies in composition and intensity between imaging modalities. The most intensive bowel cleansing is used for CCE-2 and the least intensive for CT colonography.

During optical colonoscopy the bowel can be irrigated to improve visualisation of the colon wall and suspicious polyps removed; this is not possible with CCE-2. If polyps are identified on CCE-2, an optical colonoscopy is required to remove the polyps. However, CCE-2 is a less invasive procedure than optical colonoscopy and does not involve exposure to ionising radiation as occurs in CT colonography.

Images from CCE-2 require detailed and extensive examination and interpretation by an expert, which may require out-sourcing to a specialist organisation. If out-sourced a report of the findings is usually sent to the clinician within five working days.

Clinical effectiveness

Diagnostic accuracy general points

- The studies identified recruited patients from a screening population or included a mix of participants with symptoms or positive screening tests. The mean age of study participants was between 50 and 64 years (range 18 to 87) and the majority were male.
Diagnostic accuracy estimates for CCE-2 are likely to be affected by the adequacy of bowel cleansing, the proportion of complete bowel examinations, and the expertise of staff interpreting CCE-2 images.

Tests with high sensitivity for detecting colorectal polyps are desirable as they are less likely to miss clinically relevant polyps (≥6mm).

Optical colonoscopy is the reference standard for diagnosing colorectal polyps and cancer. Calculation of sensitivity and specificity for CCE-2 therefore requires patients to undergo both CCE-2 and optical colonoscopy.

Prospective diagnostic cohort studies in patients with prior incomplete optical colonoscopy, unable for clinical reasons to have an optical colonoscopy, or unwilling to undergo optical colonoscopy, were restricted to reporting detection rates or proportion of patients with clinically significant lesions. This is because participants could not receive the reference standard (optical colonoscopy) required for calculating diagnostic accuracy. For this reason the evidence base for these groups is unlikely to improve in future.

**Diagnostic accuracy of CCE-2 compared with reference standard optical colonoscopy**

In a systematic review of five studies (n=361) in patients scheduled to undergo optical colonoscopy for known or suspected colonic disease, CCE-2 had sensitivity of 87% (95% confidence interval (CI) 77% to 93%) and specificity of 76% (95% CI 60% to 87%) for detecting clinically significant polyps ≥6mm. Included studies may have overestimated the diagnostic accuracy of CCE-2 due to selection and elimination bias.

**Diagnostic accuracy of CCE-2 compared with CT colonography**

A prospective diagnostic study included in the systematic review compared CCE-2 with CT colonography in patients with a positive screening test (FOBT) who were offered optical colonoscopy (n=54). No statistically significant differences in sensitivity or specificity were reported for detection of clinically significant polyps ≥6mm. This study was at high risk of selection, incorporation and elimination bias.

In another prospective cohort study (n=97; 54 symptomatic) there was a statistically significant two-fold increase in relative sensitivity for CCE-2 compared with CT colonography for detection of clinically significant polyps ≥6mm in patients with prior incomplete optical colonoscopy: odds ratio (OR) 2.0, 95% CI 1.4 to 2.98, p<0.05.

**Safety**

Studies reported colon capsule retention in 0.8% (95% CI 0.2% to 2.4%), and capsule aspiration in 0.1%, of people tested.

There are contraindications to the use of CCE-2 in patients with known or suspected gastrointestinal obstruction, stricture or fistulas; patients with implanted electronic medical devices; patients with swallowing disorders; and pregnant women. Some or all of these contraindications may also apply to optical colonoscopy and CT colonography.
CCE-2 may not be suitable for use in patients with physical disabilities affecting their ability to swallow or quickly access a toilet, or in patients with cognitive impairments that affect their ability to complete the procedure.

Mild/moderate adverse effects relating to bowel cleansing, such as nausea or abdominal discomfort, are more common than adverse events associated with the CCE-2 technology. Adverse effects relating to bowel cleansing appear to be most common with CCE-2 and least common with CT colonography.

Safety issues relating to the CCE-2 bowel cleansing regimen include electrolyte imbalance in people with existing renal impairment and tolerability in the frail elderly.

Cost effectiveness

A Canadian economic analysis was identified but not reported in detail as the results were not generalisable to Scotland.

The University of Strathclyde (Glasgow) is conducting a cost comparison of the current patient pathway versus a new patient pathway where CCE-2, along with the FIT screening test, is used as an initial test to guide referrals to optical colonoscopy.

Patient and social aspects

A cross-sectional study undertaken in the UK reported that:

- Patients undergoing CCE-2 (n=56), CT colonography (n=158) or optical colonoscopy (n=253), 73% of whom were symptomatic, rated CCE-2 and CT colonography more highly than optical colonoscopy for overall tolerability. CT colonography was also rated more highly than CCE-2.
- 94% (n=234) of people undergoing optical colonoscopy and 96% (n=152) receiving CT colonography were willing to undergo the same test in future, compared with 86% (n=48) of patients willing to undergo CCE-2 in future.
- Among members of the public (n=100) provided with information on colorectal imaging tests, 45% stated they would choose optical colonoscopy, 37% CT colonography and 18% CCE-2, for investigating bowel symptoms.

Key considerations for patients choosing between colon imaging tests include invasiveness of the procedure, the intensity of the bowel cleansing regimen, and the need for a second procedure following a positive CCE-2 or CT colonography finding.

Context (includes organisational issues)

In March 2018, 37% of patients were waiting longer than six weeks (national waiting time standard) to receive an optical colonoscopy in Scotland.

Performing CCE-2 at home was feasible for patients living in remote areas and detected clinically significant lesions that were confirmed by optical colonoscopy.

Interpretation of images from CCE-2 requires expert knowledge, skills and time. It is unlikely to be practical for individual colonoscopists within the NHS to interpret images from multiple CCE-2 examinations due to the volume of images involved.
Further research

CCE-2 for detection of colorectal polyps and cancer appears to be at stage 3 ‘assessment via randomised controlled trials or alternatives’ of the IDEAL-D framework for medical devices.

- Cost-effectiveness studies are needed that compare CCE-2 with optical colonoscopy or CT colonography from an NHS or UK societal perspective.
- Qualitative studies comparing patient experiences of CCE-2, optical colonoscopy and CT colonography are desirable.
- Appendix 3 of the associated evidence note outlines current research on CCE-2 in Scotland. The ScotCap project aims to evaluate bowel cleansing rates, CCE-2 procedure completion rates, and pathology findings from CCE-2 and subsequent diagnostic procedures in NHS Highland, NHS Western Isles and NHS Grampian.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

SHTG Advice Statements will be considered for review if new evidence becomes available which is likely to materially change the advice. Stakeholders may submit a request, highlighting new evidence to shtg.hcis@nhs.net.
Acknowledgements

SHTG would like to thank the following individuals and organisations who provided comments on the draft Advice Statement:

- Ms. Claire Donaghy Bowel Cancer UK
- Ms. Catherine Leonard, Health Economics Manager, Medtronic UK & Ireland
- Dr. Keith Moffat, GP, Medical Advisor NSS
- Prof. Robert Steele, Research Professor, University of Dundee
- Prof. Frank Sullivan, Professor of Primary Care Medicine, University of St Andrews
- Ms. Diana Yung, Clinical Research Fellow, Centre for Liver and Digestive Disorders, Edinburgh Royal Infirmary

Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by the SHTG’s Evidence Review Committee. However, reviewers had no role in authorship or editorial control and the views expressed are those of SHTG. Details of SHTG membership are available on the Healthcare Improvement Scotland website.

Chair

Scottish Health Technologies Group

NICE has accredited the process used by Healthcare Improvement Scotland to produce its evidence review products. Accreditation is valid for 5 years from January 2013. More information on accreditation can be viewed at www.nice.org.uk/accreditation