Economic Evaluation of Second-Generation Colon Capsule Endoscopy for Investigation of the Colon Through Direct Visualisation

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INTRODUCTION

Colonoscopy (COL) is the gold standard diagnostic test for individuals with symptoms suggestive of colorectal cancer (CRC). Waiting times for COL can be long and the procedure can be unpleasant. Colon capsule endoscopy (CCE) is a less invasive test which may be an alternative option to rule out polyps or CRC.

OBJECTIVES

We aimed to evaluate the cost-effectiveness of second-generation CCE (CCE-2) for detecting colorectal polyps and CRC from the perspective of the NHS and Personal Social Services (PSS).

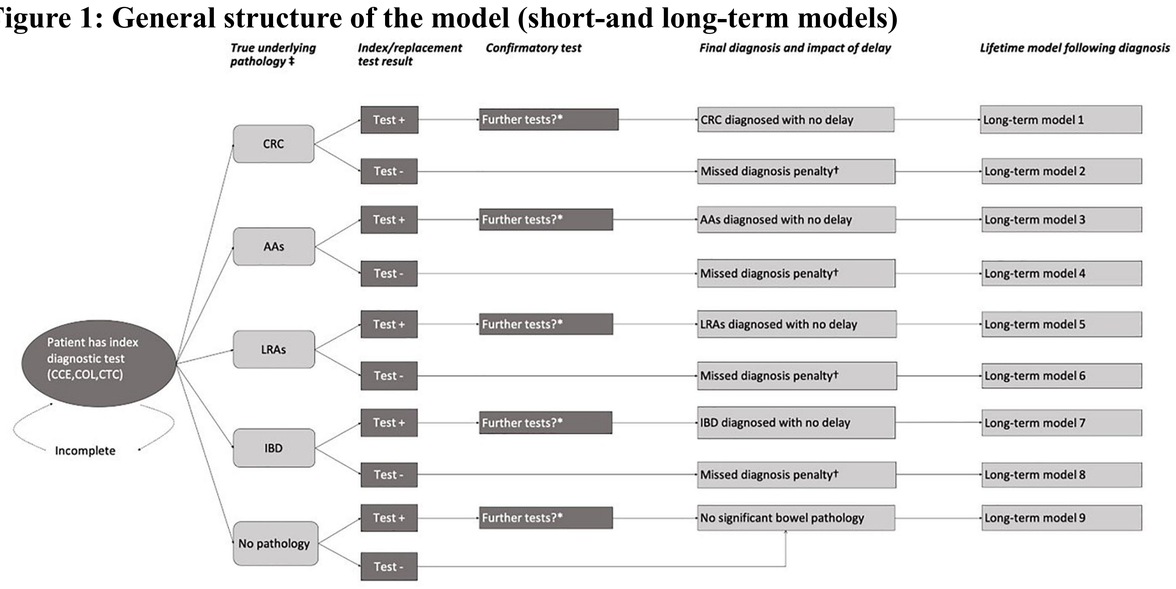
METHODS

We conducted a systematic review and meta-analysis of diagnostic accuracy studies of CCE-2 for detecting colorectal polyps or CRC. A *de novo* economic model was developed, which consisted of a short-term decision tree for the diagnostic pathways and outcomes followed by a long-term model for expected lifetime outcomes and costs (Figure 1). The incremental cost-effectiveness of CCE-2 was assessed against COL and computed tomography colonography (CTC) across three populations:

1. People with symptoms suggestive of CRC with a faecal immunochemical test (FIT) score of 10-100 micrograms per gram of faeces (µg/g)
2. People with symptoms suggestive of CRC with a FIT of <10µg/g; and
3. People undergoing 3-year post-polypectomy surveillance.

For each population, subgroup analyses were conducted for COL-eligible and COL-ineligible patients. The diagnostic pathways in the decision-tree model were informed by clinical input. Long-term model outcomes and costs were taken from the re-analyses of the Microsimulation Model in Cancer of the Bowel (MiMiC-Bowel) screening model.[1-2] Key model parameters were informed by the NHS England CCE Pilot Study,[3] diagnostic accuracy meta-analyses, systematic reviews, routine costing sources, published literature and assumptions. A fully incremental analysis was used to evaluate the incremental cost-effectiveness of CCE versus COL and CTC. Net monetary benefits (NMBs) were estimated assuming willingness-to-pay (WTP) threshold of £30,000 per QALY gained. Uncertainty was assessed using probabilistic sensitivity analysis (PSA) and deterministic scenario analyses. Intermediate outcomes were estimated in terms of the number of COLs/flexible sigmoidoscopies (FSIGs) required, pathology detected/missed and complications for each diagnostic test.

Figure 1: General structure of the model (short-and long-term models)



COL - colonoscopy; CTC - computed tomography colonography; CCE - colon capsule endoscopy; CRC - colorectal cancer; LRA - low-risk adenomas; AAs - advanced adenomas; IBD - inflammatory bowel disease
** Following a positive index test, the further tests required will depend on the acceptability of COL and the pathology detected. This may include diagnostic or therapeutic COL (or in some patients, FSIG).*
† For patients with underlying CRC, this penalty is estimated as a potential worsening shift in cancer stage. For people with AAs and LRAs, a penalty is applied to reflect an increased risk of polyp growth or progression to CRC. For people with IBD, a penalty is applied to reflect potential worsening of disease severity at the point of later diagnosis.
‡ The prevalence of each bowel pathology differs between populations.

Table 1: Central estimates of cost-effectiveness – CCE vs COL and/or CTC, probabilistic, ranked by QALYs

Option	LYGs	QALYs	Costs	Inc. LYGs	Inc. QALYs	Inc. costs	Incremental cost per QALY gained
Population 1a: Symptomatic, FIT 10-100µg/g, COL-eligible							
COL	14.52	11.3517	£5,090	0.00	0.0023	£324	£142,565
CCE	14.51	11.3501	£5,413	-	-	-	Dominated
CTC	14.52	11.3494	£4,766	-	-	-	-
Population 1b: Symptomatic, FIT 10-100µg/g, COL-ineligible							
CTC	14.52	11.3494	£4,771	0.00	0.0001	-£576	Dominating
CCE	14.51	11.3493	£5,347	-	-	-	Dominated
Population 2a: Symptomatic, FIT <10µg/g, COL-eligible							
COL	14.60	11.4689	£2,283	0.00	0.0019	£376	£200,840
CCE	14.60	11.4685	£2,559	-	-	-	Dominated
CTC	14.60	11.4671	£1,907	-	-	-	-
Population 2b: Symptomatic, FIT <10µg/g, COL-ineligible							
CCE	14.60	11.4678	£2,476	0.00	0.0008	£566	£713,959
CTC	14.60	11.4670	£1,910	-	-	-	-
Population 3a: Surveillance (post-polypectomy), COL-eligible							
COL	14.01	10.8882	£2,028	0.01	0.0061	£84	£13,788
CTC	14.00	10.8821	£1,944	-	-	-	-
CCE	14.00	10.8797	£2,573	-	-	-	Dominated
Population 3b: Surveillance (post-polypectomy), COL-ineligible							
CTC	14.00	10.8818	£1,955	0.01	0.0041	-£626	Dominating
CCE	14.00	10.8777	£2,581	-	-	-	Dominated

CCE - colon capsule endoscopy; COL - colonoscopy; CTC - computed tomography colonography; FIT - faecal immunochemical test; LYG - life year gained; QALY - quality-adjusted life year; Inc. - incremental

RESULTS

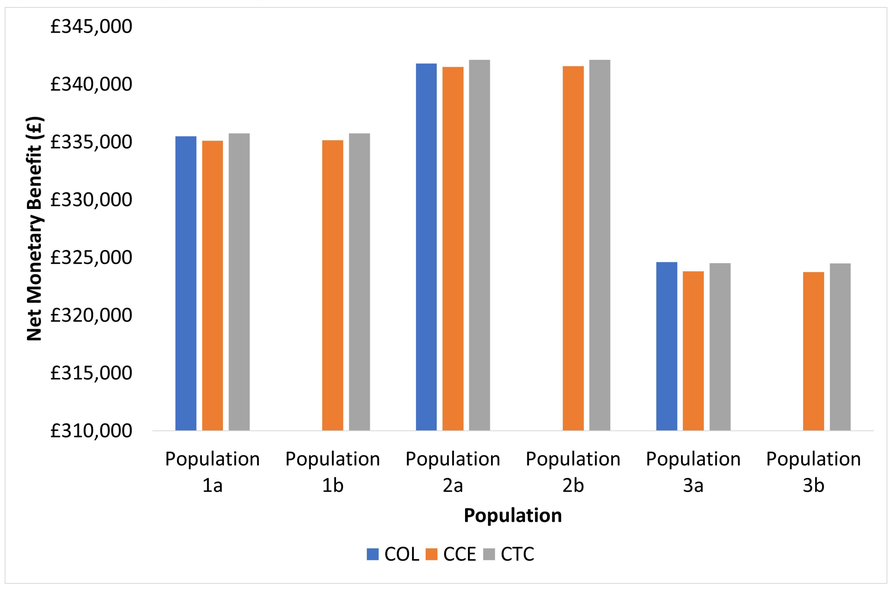
Cost-effectiveness and uncertainty analysis

For COL-eligible patients, CCE is expected to be dominated by COL. For COL-ineligible patients, CCE is either dominated by CTC or has an incremental cost-effectiveness ratio (ICER) which is markedly higher than £30,000 per QALY gained (Table 1 and Figure 2). These findings are driven by four key factors: (i) COL and CTC are assumed to have higher sensitivity than CCE for detecting high-risk polyps and CRC (which leads to slightly fewer QALYs for CCE); (ii) a large proportion of CCE procedures are incomplete requiring further replacement tests (which leads to increased costs); (iii) CTC procedures incur lower costs than CCE and (iv) the detection of significant bowel pathology with CCE necessitates confirmatory testing (which leads to increased costs). The base case findings were consistent across scenario analyses, with ICERs ranging from dominated to in excess of £389,000 per QALY gained. The cost-effectiveness acceptability curves (CEACs) indicate that the probability that CCE generates more net benefit than COL and CTC at a WTP threshold of £30,000 per QALY gained is approximately zero across all three populations.

Model-predicted COL sparing (intermediate outcomes)

In COL-eligible patients, CCE is expected to lead to substantial reductions in the number of COLs/FSIGs required: approximately 46%, 50% and 32% in symptomatic FIT 10-100µg/g, symptomatic FIT <10µg/g and surveillance populations, respectively. In COL-ineligible patients, expected reductions in the number of COL/FSIG referrals are smaller: approximately 8%, 10% and 2%, respectively. This may help to release capacity in constrained endoscopy services.

Figure 2: Net monetary benefits of CCE, COL and CTC, at the WTP of £30,000 per QALY gained, probabilistic



CCE - colon capsule endoscopy; COL - colonoscopy; CTC - computed tomography colonography

LIMITATIONS AND UNCERTAINTIES

- There are some inconsistencies in the definitions of polyp risk groups between evidence sources used to inform the model.
- Assumptions were required to estimate prevalence from the NHS England CCE Pilot Study data.
- There is uncertainty in the estimates of diagnostic test accuracy of CCE and its comparators.
- Older/frail patients were excluded from the economic analyses.

CONCLUSIONS

CCE is expected to be less effective and more costly than COL. However, CCE may help to release capacity in currently constrained endoscopy services. Further research is required to reduce uncertainty around the diagnostic accuracy of CCE, as well as on the optimal CCE delivery setting, CCE bowel preparation methods and patient experience.

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