Flexible spectral imaging color enhancement and indigo carmine in neoplasia diagnosis during colonoscopy: a large prospective UK series

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study assessed the accuracy and economic impact of a national bowel cancer screening programme, to diagnose colorectal polyps of less than 10mm, using white light, with flexible spectral imaging colour enhancement (FICE), and with indigo carmine dye spray. The authors concluded that FICE with or without indigo carmine improved the accuracy of diagnosis for small polyps and could produce significant cost savings, compared with white light alone. There were some limitations that might affect the validity of these conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study assessed the accuracy and economic impact of a national bowel cancer screening programme, to diagnose colorectal polyps of less than 10mm, using white light and flexible spectral imaging colour enhancement (FICE) in vivo, without optical magnification, and considering the advantages of applying indigo carmine dye spray.

Interventions
The interventions were white light, with the addition of FICE, and then indigo carmine, for the diagnosis of polyps of less than 10mm, during endoscopy to determine whether or not to remove them. This was compared with standard histology on the removed polyps.

Three protocols were compared: traditional, Portsmouth, and futuristic. The traditional protocol was to retrieve and send all polyps of less than 10mm for histological assessment. The Portsmouth protocol was to retrieve and send suspected adenomas and cancers, but not hyperplastic polyps for histological assessment. The futuristic protocol was to leave all adenomas and hyperplastic polyps and only send suspected cancers for histological assessment.

Location/setting
UK/primary care.

Methods
Analytical approach:
The analysis was based on a single study over a short period. The authors stated that it took the perspective of the UK NHS.

Effectiveness data:
The clinical evidence came from a within-group comparison study, in which each patient underwent all screening procedures. This included 232 consecutive polyps of less than 10mm, in 89 patients (mean age 65 years; 70 men and 19 women), who underwent colonoscopy between September 2009 and 2010. All assessments were performed by one endoscopist. The key endpoints were the accuracy, sensitivity, specificity, positive predictive value, and negative predictive value for each additional intervention. A subgroup of patients with polyps of less than 5mm was analysed.

Monetary benefit and utility valuations:
Not considered.
Measure of benefit:
The accuracy of the diagnostic procedures was the main endpoint.

Cost data:
The analysis assessed the cost of histological diagnosis for the three protocols, which included the costs of tissue fixation, processing, staining, and pathology reporting. The quantities of resources were from the clinical study and their unit costs were the official NHS rates. All costs were in UK pounds sterling (£) and Euros (EUR).

Analysis of uncertainty:
Not considered.

Results
Compared with standard histology, the accuracy was 71% with white light, 86% with the addition of FICE, and 91% with the addition of indigo carmine. The sensitivity was 75% for white light, 88% with FICE, and 94% with indigo carmine. The specificity was 64% with white light, 82% with FICE, and 84% with indigo carmine. The positive predictive value was 81% with white light, 91% with FICE, and 92% with indigo carmine. The negative predictive value was 56% with white light, 78% with FICE, and 88% with indigo carmine.

The differences between white light and the addition of FICE, and the addition of FICE then indigo carmine were statistically significant. The differences between FICE and the addition of indigo carmine were not statistically significant. In the subgroup of polyps of less than 5mm, indigo carmine after FICE was significantly more sensitive for neoplasias than FICE alone.

In the study cohort, for any of the three diagnostic methods, compared with the traditional protocol (sending all polyps for standard histology), the Portsmouth protocol saved £4,397 or EUR 4,945 (a 32% reduction in costs), and the futuristic protocol saved £13,468 or EUR 15,146 (a 99% reduction). Considering all patients undergoing colonoscopy in the UK Bowel Cancer Screening Programme these savings were £365,553 (EUR 411,102) with the Portsmouth protocol, and £678,253 (EUR 762,767) with the futuristic protocol.

Authors' conclusions
The authors concluded that FICE improved the accuracy of in vivo histological diagnosis for small polyps, compared with white light alone. The addition of indigo carmine dye spray after FICE could improve diagnosis, especially for polyps of less than 5mm. This improved accuracy could produce significant cost savings for the UK Bowel Cancer Screening Programme.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as the analysis considered the usual care and the proposed strategies for the UK Bowel Cancer Screening Programme.

Effectiveness/benefits:
The within-group comparison had the advantage of not requiring an external comparison group, which would need to be appropriate and comparable. All procedures were performed in the same group of patients, but the authors acknowledged that the sequence of procedures could be important. To avoid the potential confounding factor of multiple endoscopists, with different skills in in vivo diagnosis, all procedures were performed by one endoscopist. The appropriate size of the sample was estimated using prospective power calculations. A potential limitation of the analysis was the fact that all the evidence came from one institution, which might not have been representative of other medical centres. Appropriate endpoints were used to assess the impact of the procedures on the patients' health, but the effect on final outcomes, such as mortality, was not evaluated.

Costs:
The analysis only included the cost of histology. The unit cost was reported and was equivalent to costs observed in similar laboratories across Europe and North America. The authors stated that the estimated costs for each protocol were unaffected by the diagnostic method, which affected only the acceptability of each protocol in terms of missed...
neoplasia. The resource use was directly from the clinical study and should be representative of the authors’ context. The costs were presented in pounds sterling and Euros, but the price year was not reported. The costs were treated deterministically and no sensitivity analysis was conducted.

Analysis and results:
The results were clearly reported. The costs and benefits of the various strategies were not synthesised; a cost-consequences analysis was carried out. The uncertainty was not investigated, but confidence intervals around the mean values were reported. The authors compared their results with those of other published studies and explained the similarities and differences. The results appear to be specific to the authors’ setting and their transferability was not discussed.

Concluding remarks:
This analysis had some methodological limitations that might affect the validity of the authors’ conclusions.

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