Faecal calprotectin testing for differentiating amongst inflammatory and non-inflammatory bowel diseases: systematic review and economic evaluation

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 evaluated the cost-effectiveness of faecal calprotectin testing to decide on referral of patients for colonoscopy to distinguish inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS). The authors concluded that calprotectin testing could reduce the number of referrals from primary care, and the number of colonoscopies in secondary care, saving costs. The study methods were appropriate and well reported, and the authors' conclusions appear to be valid.

Type of economic evaluation
Cost-utility analysis

Study objective
The aim was to evaluate the cost-effectiveness of faecal calprotectin testing to decide on referral of patients for colonoscopy to distinguish inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS).

Interventions
The intervention differed depending on the context in which the test was provided or ordered: adults in primary care or children in secondary care.

For adults, faecal calprotectin testing was compared with clinical history alone, to decide on referral. A rapid point-of-care test, CalDetect, was assessed, as well as the Enzyme-Linked Immunosorbent Assay (ELISA). The cutoff was 15 micrograms (μg)/g for CalDetect and 50μg/g for the ELISA.

For children, the ELISA with a cutoff of 50μg/g and with a cutoff of 100μg/g, were compared with direct referral to colonoscopy.

Location/setting
UK/primary care for adults, and secondary care for children.

Methods
Analytical approach:
A Markov model was used to combine published evidence for the diagnostic strategies. Treatment for ulcerative colitis, Crohn's disease, and IBS was based on published models. The outcomes for true and false negative results for IBD were modelled; those for false positives were not. The time horizon was 10 years. The authors stated that the perspective of the patient benefits and NHS and Personal Social Services costs was adopted.

Effectiveness data:
Test accuracy data were from a systematic review of the literature. The estimates for the ELISA were from a meta-analysis. Those for CalDetect were from one study. Optimal cutoff points were chosen. Colonoscopy was assumed to have 100% specificity. The effectiveness of treatment for ulcerative colitis, Crohn's disease and IBS was from the published models, using the most cost-effective treatments in these models. The delay in correctly identifying patients with false negative results was estimated by clinical experts.

Monetary benefit and utility valuations:
Utilities were applied for the Crohn's disease, ulcerative colitis and IBS health states. The estimates were from publications identified by a review of the literature. The authors selected those estimates that had the most relevance to the population and to the UK.

Measure of benefit:
The measure of benefit was the quality-adjusted life-year gained. Benefits were discounted at an annual rate of 3.5%.

Cost data:
The costs included the provision of the tests, consultations, and treatment including medication and surgery. They were from NHS Reference Costs, the British National Formulary, and the Personal Social Services Research Unit. Staff time for the tests was estimated by experts. All costs were reported in UK £. The price year was 2011. Costs were inflated to 2011, where necessary, using the Hospital and Community Services Costs price index. They were discounted at an annual rate of 3.5%.

Analysis of uncertainty:
Probabilistic sensitivity analysis was conducted by varying all model parameters simultaneously. The results were presented in cost-effectiveness acceptability frontiers. One-way sensitivity analysis was conducted on the key parameters, including the whether calprotectin testing increased the number of patients being tested in general practice.

Results
For adults in primary care, clinical history resulted in an average of 6.2637 QALYs, CalDetect resulted in 6.2646 QALYs, and the ELISA resulted in 6.2643 QALYs. Clinical history cost an average of £3,312, CalDetect cost £3,230, and the ELISA cost £3,230.

The cost savings with calprotectin testing were almost eliminated if the test doubled the number of people being tested. If the specificity of specialist assessment increased to 95%, the cost savings from calprotectin fell to £10.

For children in secondary care, colonoscopy resulted in an average of 6.6809 QALYs, ELISA 50μg/g resulted in 6.6824 QALYs, and ELISA 100μg/g resulted in 6.6814 QALYs. Colonoscopy cost an average of £8,696, ELISA 50μg/g cost £8,491, and ELISA 100μg/g cost £8,456.

Authors' conclusions
The authors concluded that calprotectin testing could reduce the number of referrals from primary care, and the number of colonoscopies in secondary care, saving costs.

CRD commentary
Interventions:
The interventions were adequately reported and current practice was included, which was good for local decision making.

Effectiveness/benefits:
The sensitivity and specificity estimates were from a systematic review. The methods of this review were appropriate and comprehensive. It was not specifically stated why only one study was used for CalDetect at a 15μg/g cutoff, but it may have been the only study found. The time horizon was 10 years. If any benefits were gained after 10 years then the benefits of calprotectin were underestimated. The detrimental effects of false positives were not modelled for simplicity, which suggests that the benefit of testing may have been underestimated. The sources for the utility estimates were well described.

Costs:
The study perspective was clearly stated. The relevant costs appear to have been included and the cost estimates were applicable for the setting and population. The cost methods and data were well reported. The costs were appropriately discounted and adjusted for inflation.

Analysis and results:
The analysis was well reported and appropriate. The results were also well reported. The uncertainty in the cost-
effectiveness estimates was appropriately evaluated. The authors provided a comprehensive discussion on the limitations of their study, the uncertainties surrounding some key parameters and future research needs.

Concluding remarks:
The study methods were appropriate and well reported, and the authors’ conclusions appear to be valid.

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