Cost-effectiveness of quantitative fecal lactoferrin assay for diagnosis of symptomatic patients with ileal pouch-anal anastomosis

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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
The objective was to determine the cost-effectiveness of faecal lactoferrin assay for the initial diagnosis of patients with symptoms of ileal pouch-anal anastomosis. Compared with empiric metronidazole therapy, faecal lactoferrin assay before treatment with metronidazole was less costly and only marginally less effective. It also involved less exposure to antibiotics and less need for endoscopy. The study was based on valid methodology, but the clinical data sources were only partially described. In general, the authors’ conclusions appear to be robust.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to determine the cost-effectiveness of faecal lactoferrin for the initial diagnosis of symptomatic patients with ileal pouch-anal anastomosis (IPAA) compared with other diagnostic strategies.

Interventions
Four strategies were compared. In the treatment strategy, metronidazole was given to all patients at a dose of 500mg orally three times a day for 14 days. In the biopsy strategy, a pouch endoscopy with biopsy was performed. In the assay strategy, the faecal lactoferrin assay was followed by metronidazole therapy for those with elevated lactoferrin and amitriptyline for those without. In the assay and biopsy strategy, the faecal lactoferrin assay was followed by pouch endoscopy with biopsy for those with elevated lactoferrin and amitriptyline for those without. Biopsies produced definitive diagnoses and were followed by appropriate treatment.

Location/setting
USA/secondary care and hospital.

Methods
Analytical approach:
The analysis was based on a decision tree with a 30-day time horizon. The authors stated that the perspective of the third-party payer was adopted.

Effectiveness data:
The clinical data appear to have been derived from a selection of known, relevant studies, which were not identified by means of a literature review. Little information on the design and other characteristics of these studies was given, except for two diagnostic studies that were used to determine the sensitivity and specificity of the faecal lactoferrin assay. Some expert opinions were required. The key clinical input was the accuracy of the faecal lactoferrin assay.

Monetary benefit and utility valuations:
Not included.

Measure of benefit:
The summary benefit measure was the number of days of correct diagnosis and response to treatment, from the initial presentation of a patient with symptoms of IPAA (30 days minus the number of days until correct treatment).
Cost data:
The economic analysis included the costs of medications, pouch endoscopy, biopsy, histologic evaluation, and faecal lactoferrin assay. Drug costs were based on average wholesale prices. The cost of faecal lactoferrin assay was based on verbal communication with a laboratory. Other costs were derived from allowable Medicare reimbursements. The source of data on resource consumption was not clearly reported. All costs were in US dollars ($) and the price year was not explicitly stated.

Analysis of uncertainty:
A Monte Carlo simulation of 1,000 patients was undertaken using arbitrary ranges of values for the economic inputs (±50%) and published ranges for the clinical inputs. The key assumptions for the two most favourable strategies were identified.

Results
The expected costs were $241.20 with assay, $250.80 with treatment, $404.80 with assay and biopsy, and $431.00 with biopsy. The benefits were 17.17 with assay, 17.95 with treatment, 17.23 with assay and biopsy, and 19.09 with biopsy.

In comparison with the next less costly non-dominated strategy, the incremental cost per day of correct diagnosis and response to treatment was $12.31 with treatment over assay, and $158.07 with biopsy over treatment. Assay and biopsy was dominated, which means it was more costly and less effective.

The probabilistic sensitivity analysis showed that the assay strategy was the best overall. The cost of the assay and the diagnostic delay with it were the most influential model inputs. In general, the treatment and assay strategies had similar costs and effectiveness, but the assay strategy was associated with a reduction of 31% in antibiotic exposure compared with the treatment strategy.

Authors’ conclusions
The authors concluded that compared with empiric metronidazole therapy, faecal lactoferrin assay before treatment with metronidazole was less costly and only marginally less effective. It also produced less exposure to antibiotics and less need for endoscopy.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear. The authors justified their choice of the comparators, with the biopsy and the treatment strategies being the two commonly used for this patient population. The two assay strategies were the new diagnostic options. Faecal lactoferrin qualitative tests were excluded due to a lack of valid data.

Effectiveness/benefits:
The approach used to select the data may have missed relevant sources of information. The two diagnostic studies used to determine the accuracy of faecal lactoferrin were described, but the remaining data sources were only partially described, with few details on their study design, patient characteristics, and follow-up. This makes it difficult to judge the validity of the clinical estimates. The authors stated that the benefit measure was of clinical relevance, but it was disease-specific and in natural units, which may not be comparable with the benefits of other health care interventions.

Costs:
The analysis of costs was consistent with the perspective in terms of the cost items and the data sources. The unit costs were presented for some items, while others were reported as macro-categories due to the Medicare accounting system. The price year was not explicitly reported, but most of the costs were derived from sources published in 2003. The costs were treated deterministically in the base case, but were varied in the sensitivity analysis.

Analysis and results:
The analytic approach used to synthesise the costs and benefits was appropriate as both incremental and average ratios were calculated. The issue of uncertainty was appropriately and comprehensively investigated. The results were clearly presented and discussed. The authors stated that this was the first study to evaluate the cost-effectiveness of several diagnostic and treatment strategies for symptomatic patients with IPAA.
Concluding remarks:
The study was based on valid methodology, but the clinical data sources were only partially described. In general, the authors’ conclusions appear to be robust.

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