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 examined the cost-effectiveness of oral mesalazine plus topical mesalazine enema in comparison with oral mesalazine alone in patients with mild-to-moderately active ulcerative colitis. The authors concluded that the addition of topical mesalazine was the preferred option because it was less expensive and slightly more effective than oral mesalazine alone. The methodology was valid, but more detailed reporting of the sources of the clinical inputs would have been useful. The authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of oral mesalazine plus topical mesalazine enema in comparison with oral mesalazine alone in patients with mild-to-moderately active extensive ulcerative colitis.

Interventions
Topical mesalazine 1mg plus oral mesalazine 4g was compared with oral mesalazine 4g alone. Treatments were given for a maximum of 32 weeks.

Location/setting
UK/out-patient.

Methods
Analytical approach:
A Markov model was developed to determine the cost-effectiveness of the two alternatives over a short time horizon, which was a maximum of four, eight-week cycles. The authors stated that the perspective of the National Health Service (NHS) was used.

Effectiveness data:
The clinical data came from a selection of known, relevant studies. The data on the treatment effect were from a published randomised controlled trial (RCT), which compared topical and oral mesalazine against oral mesalazine alone in patients with mild-to-moderate exacerbations of ulcerative colitis. The other transition probabilities were from published evidence, the details of which were not reported. The primary endpoint was the rate of remission, which was based on the Ulcerative Colitis Disease Activity Index.

Monetary benefit and utility valuations:
The utility valuations were from the same RCT that supplied the clinical effectiveness data. These patients completed the European Quality of life (EQ-5D) questionnaire.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure.

Cost data:
The economic analysis included the costs of drugs, clinical consultations, and diagnostic examinations. A breakdown of the cost items was given. Those costs associated with scheduled follow-up visits and with colectomy were not included. The quantities of resources used were based on published studies and guidelines published by the British Society for Gastroenterology and the European Crohn's and Colitis Organisation. All costs were from official NHS sources, such as the British National Formulary, NHS National Tariffs, and the Personal Social Services Research Unit. They were in UK pounds sterling (£) and the price year was 2008.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken by assigning probability distributions to the model inputs. The net health benefit was also calculated and cost-effectiveness acceptability curves were generated for various willingness-to-pay thresholds.

Results
In the base case, where infliximab was used to treat steroid-refractory patients, the expected costs were £1,812 (SD 358) with combination therapy and £2,390 (SD 533) with monotherapy. The QALYs were 0.56 (SD 0.01) with oral and topical mesalazine and 0.55 (SD 0.01) with oral alone (placebo topical). The combination therapy was dominant as it was more effective and cheaper than oral mesalazine alone.

The combination therapy remained dominant when the model was projected only over 16 weeks and infliximab was not used to treat steroid-refractory patients (the National Institute for Health and Clinical Excellence recommended no use of infliximab).

The probabilistic analysis showed that, even at a maximum willingness-to-pay threshold of £20,000 per QALY, the addition of the mesalazine enema consistently produced a higher probability of being more cost-effective than oral mesalazine alone.

Authors' conclusions
The authors concluded that the addition of topical mesalazine was the preferred option because it was less expensive and slightly more effective than oral mesalazine alone.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear. The choice of the two strategies was appropriate and was based on clinical guidelines.

Effectiveness/benefits:
Little information on the sources of evidence was reported. The treatment effect was from a head-to-head clinical trial that used an intention-to-treat approach, but no other details, such as the methods, patient populations, and results, of this RCT nor the other sources were provided. The authors did not address issues of the use of mixed sources, such as the heterogeneity of patient populations. This means it is not possible to objectively assess the validity of the clinical estimates. QALYs are an appropriate measure for this patient population given the impact of the disease on patients’ quality of life. The utility weights were from the same patients used in the clinical analysis and the authors stated that the EQ-5D was a reliable evaluation tool for patients with inflammatory bowel disease.

Costs:
The categories of costs and their sources were consistent with the perspective. The authors justified their exclusion of some cost categories. In general, the economic analysis was well reported, including the unit costs, quantities of resources used for some items, and the price year. The means, standard deviations, and confidence intervals were calculated for the costs in the base case.

Analysis and results:
The costs and benefits were clearly presented. The analytic approach was appropriate as the incremental analysis allowed the identification of the most cost-effective strategy. The calculation of a cost-utility ratio was not required given the superior profile of combination therapy. The issue of uncertainty was appropriately investigated in the
probabilistic sensitivity analysis.

Concluding remarks:
The methodology was valid, but more detailed reporting of the sources of the clinical inputs would have been useful. The authors’ conclusions appear to be valid.

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