An economic evaluation comparing once daily with twice daily mesalazine for maintaining remission based on results from a randomised controlled clinical trial

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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 examined the cost-effectiveness of once daily versus twice daily dosing of mesalazine therapy for the maintenance of remission in patients with mild to moderate ulcerative colitis. The authors concluded that mesalazine once daily was more cost-effective than conventional twice daily dosing, from the perspective of the UK National Health Service. The study was well conducted and was clearly presented. The authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of once daily versus twice daily dosing of mesalazine therapy to maintain remission in patients with mild to moderate ulcerative colitis (UC).

Interventions
Mesalazine 2g once daily was compared with mesalazine 1g twice daily.

Location/setting
UK/secondary care.

Methods
Analytical approach:
This economic evaluation was based on a decision analytic model that used data from a single study. The time horizon was one year. The authors stated that the analysis was conducted from the perspective of the UK National Health Service (NHS).

Effectiveness data:
The clinical data came from a multi-centre, single-blind, randomised controlled trial (RCT); the Pentasa™ Once Daily in UC Maintenance (PODIUM) trial. Patients who were in remission and who had experienced a relapse, which required adjustments to their maintenance therapy, were randomised to receive mesalazine either 2g once daily or 1g twice daily. The details on the sample size were not provided. The length of follow-up was one year. The key clinical endpoint was the change, from baseline at four, eight, and 12 months, in the ulcerative colitis disease activity index (UCDAI).

Monetary benefit and utility valuations:
The utility valuations were estimated in the sample of patients, who were enrolled in the RCT and completed the UCDAI. These values were then converted to health utilities using 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 following items: mesalazine treatment and other drugs, gastroenterologist and general practitioner consultations, and various diagnostic examinations. The resource quantities were based on the
actual patterns of consumption in the RCT, excluding protocol-driven visits or procedures. These costs were derived from official UK sources such as NHS tariffs and the British National Formulary. They were in UK pounds sterling (£) and the price year was 2007.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken, by assigning probability distributions to the model inputs, and cost-effectiveness acceptability curves were generated, using the net benefit method. In a separate analysis, the cost of initial sigmoidoscopy, which was performed at the first sign of relapse, was excluded.

Results
The annual treatment costs were £815 (95% confidence interval, CI: 677 to 949) in the once daily group and £971 (95% CI: 620 to 860) in the twice daily group. When disaggregated, all cost categories were lower for once daily compared with twice daily mesalazine.

The expected QALYs were 0.935 (95% CI: 0.932 to 0.936) in the once daily group and 0.931 (95% CI: 0.929 to 0.934) in the twice daily group. Thus, under base-case assumptions, once daily mesalazine was dominant because it was less costly and more effective than twice daily.

Similar results were observed in the scenario excluding the initial costs of sigmoidoscopy. The probabilistic sensitivity analysis indicated that the probability of once daily mesalazine being cost-effective was 0.94 at a willingness to pay of £0 per QALY and 0.98 at a threshold of £20,000 per QALY.

Authors’ conclusions
The authors concluded that mesalazine once daily was more cost-effective than conventional twice daily treatment for maintaining remission in patients with UC, from the perspective of the UK NHS.

CRD commentary
Interventions:
The two regimens were appropriately selected as twice daily mesalazine was the conventional approach while once daily mesalazine was proposed to improve treatment adherence due to the single administration pattern.

Effectiveness/benefits:
The use of a RCT to derive the clinical data was appropriate given the strengths of its design, and this enhances the validity of the clinical estimates. The multi-centre and single-blind design further improves the reliability of the effectiveness evidence. Little information on the methods and results of the RCT was provided because this was published elsewhere. For example, the sample size was not reported. The authors stated that previous studies had shown the EQ-5D to be a valid and reliable tool for use in this patient population. QALYs are an appropriate benefit measure, not only because they capture the impact of disease on a patient’s quality of life, but also because they allow cross-disease comparisons to be made.

Costs:
The analysis of costs reflected the perspective in terms of both cost categories and the sources of data. The economic information was clearly reported. Unit costs, sources of data, and the price year were explicitly reported, which improves the external validity. Confidence intervals around the total costs were calculated, using a probabilistic approach, to investigate the uncertainty around the economic inputs. The authors stated that the treatment patterns after relapses were those recommended by both the British Society of Gastroenterology and the European Crohn’s and Colitis Organisation. They also noted that the adoption of a societal perspective, and the subsequent inclusion of productivity costs, would have further favoured the once daily mesalazine.

Analysis and results:
The methods used to synthesise the costs and benefits were appropriate. The issue of uncertainty was investigated using a validated approach, which allows the global assessment of uncertainty. The findings were clearly presented. They should be considered to be specific to patients suffering from mild to moderate UC and should not be generalised to more severe cases.
Concluding remarks:
The study was well conducted and was clearly presented. The authors’ conclusions appear to be valid.

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