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 economic evaluation assessed the cost-effectiveness of adding granulocyte and monocyte adsorption (GMA) apheresis to traditional treatment, for steroid-dependent patients with moderate-to-severe ulcerative colitis. The authors concluded that adding GMA apheresis was affordable for the Spanish Health System. The methods and validity of the data syntheses and analyses of uncertainty were unclear. The cost data were from 2007, and the effectiveness evidence was poor, making it difficult to have confidence in the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This economic evaluation assessed the cost-effectiveness of adding granulocyte and monocyte adsorption (GMA) apheresis (Adacolumn) to traditional treatment, for steroid-dependent patients with moderate-to-severe ulcerative colitis.

Interventions
Traditional treatment was compared with GMA apheresis added to the same treatment. Steroid-dependent patients on traditional treatment received azathioprine for a new flare-up of ulcerative colitis. In the GMA apheresis arm, they received apheresis according to an estimate of its market penetration (40% of patients), or azathioprine. If remission was not achieved, surgery was considered.

Location/setting
Spain/out-patient and in-patient care.

Methods
Analytical approach:
A one-year decision-tree model was constructed, using published evidence. The authors stated that a third-party payer perspective was adopted.

Effectiveness data:
The primary effectiveness measure was the probability of remission within one year of follow-up. This probability of remission, for patients on traditional treatment, was derived by synthesising data from published studies of patients with ulcerative colitis, and an ulcerative colitis guideline. The probability of remission, for GMA apheresis patients, was a weighted average of remission for patients in five published uncontrolled trials of GMA apheresis. The probability of patients having surgery, after unsuccessful treatment, was the expert opinion of a panel of seven Spanish gastroenterologists.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measure of benefit was the number of patients achieving remission.

Cost data:
The data on medications, blood tests, other diagnostic procedures, and hospital stay were based on a questionnaire...
given to the panel of seven experts. This included the dosing regimens, the numbers of patients undergoing procedures, the numbers of medical visits, and the average hospital stay. The costs of adverse events were from the literature, and validated by the expert panel. The unit costs were official Spanish data, and the adverse event costs were from Spanish diagnosis-related groups. All costs were in Euros (EUR) and the price year was 2004.

Analysis of uncertainty:
Univariate sensitivity analyses were undertaken, using plausible ranges of values based on expert opinion.

Results
The total costs of traditional treatment were EUR 6,059, and those of GMA apheresis were EUR 11,436, resulting in an incremental cost of EUR 5,377. The percentage of patients in remission with traditional treatment was 38.5, while the percentage in remission with GMA apheresis was 61.

The incremental cost-effectiveness ratio of GMA apheresis, compared with traditional treatment, was EUR 23,898 per extra remission achieved.

Varying the costs of azathioprine and of azathioprine-related adverse events did not cause much variation in the total costs.

Authors' conclusions
The authors concluded that adding GMA apheresis to the management of patients with ulcerative colitis was affordable for the Spanish Health System.

CRD commentary
Interventions:
The interventions were well reported, with details on the timing of drug administration, and the drugs administered. Infliximab was not considered as it was not part of any guidelines when the analysis was conducted, in 2007, but it may be relevant now, meaning that not all valid comparators were analysed.

Effectiveness/benefits:
The source of the effectiveness data was clear, and the authors acknowledged some limitations. The authors did not reveal how the studies were identified and selected, so it is not clear whether the best available evidence was used. An expert panel validated the trial data and provided estimates of effectiveness, where no trial data were available, but how this panel was selected was not reported. It appears that data from uncontrolled studies were pooled, but it was not clear how this was done. As acknowledged by the authors, uncontrolled studies have a risk of bias and may overestimate effectiveness.

Costs:
The unit costs were from appropriate sources and used diagnosis-related group data, which should allow their generalisation to other health care systems that use these codes, such as the UK. The resource use was estimated by a panel of seven experts. It is not clear whether these estimates were appropriate. All costs were clearly reported, but they were for 2007 and are likely to underestimate the current costs. The cost data should be updated and validated for the setting before use. As the model time horizon was only one year, no discounting was needed.

Analysis and results:
The results of the economic evaluation were clearly reported. One-way sensitivity analysis results were reported for two cost variables; it was not clear if other variables were tested. The analysis of uncertainty appears to have been insufficient, especially as many inputs were estimated by experts. It was not clear if the time frame of the analysis was appropriate, as ulcerative colitis is a chronic condition. A lifetime horizon would have more accurately reflected the costs and benefits of treatment.

Concluding remarks:
The model parameters were clearly reported, but the methods and validity of the data synthesis and analyses of uncertainty were unclear. The cost data were from 2007, and the effectiveness evidence was poor, making it difficult to have confidence the authors' conclusions.
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