The cost-effectiveness of macrogol 3350 compared to lactulose in the treatment of adults suffering from chronic constipation in the UK

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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 aim was to estimate the cost-effectiveness of macrogol 3350, compared with lactulose, for the treatment of chronic constipation in adults. The authors concluded that macrogol 3350 was cost-effective. The methods and the reporting of the results were good. The results appear to be reliable, but the small difference in health-related quality-of-life and the uncertainty around the mean estimates should be considered.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The objective was to estimate the cost-effectiveness of macrogol 3350 for the treatment of chronic constipation in adults, compared with lactulose, in clinical practice within the UK.

Interventions
Treatment with macrogol 3350 for constipation with any cause was compared with treatment with lactulose. Both treatments were osmotic laxatives, the mean dose of macrogol 3350 was 1.5 sachets per day (95% CI 1.4 to 1.6) and the mean dose of lactulose was 20.8 mL per day (95% CI 19.9 to 21.7).

Location/setting
UK/primary care.

Methods
Analytical approach:
A decision-tree model was used to compare the short-term cost and effectiveness data for the treatment of constipation in a clinical setting. The time horizon was six months and the authors stated that the perspective was that of the UK NHS.

Effectiveness data:
The evidence came from The Health Independent Network (THIN) database of medical records from UK primary care consultations. The efficacy of macrogol had been demonstrated in clinical trials and the authors wanted to evaluate it for a real clinical setting. The data for 1,000 patients, aged 18 years or older and treated with macrogol, were randomly selected from the database. The inclusion criteria for the population were clearly reported. These patients were matched, to 1,000 patients treated with lactulose, for age, gender and time between starting treatment and the previous laxative. Patients were not matched for co-morbidities, but these were on the whole comparable. The main clinical parameter was the percentage of patients who were successfully treated, defined by the discontinuation of laxative treatment by six months following commencement of treatment.

Monetary benefit and utility valuations:
The utility estimates were based on the preferences of a sample of the UK general public, collected using the standard gamble method (Guest, et al. 2008, see 'Other Publications of Related Interest' below for bibliographic details).

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs) gained.
Cost data:
The direct costs and resource consumption included laxative prescriptions, clinic visits, admissions to hospital, accident and emergency attendances, laboratory tests, and diagnostic procedures. The constipation-related resource use was from the 2,000 patient records in THIN database, which were used for the effectiveness estimates. The unit costs for resources were provided in UK pounds sterling (£) and in 2007 to 2008 prices. They were from the Drug Tariff and the British National Formulary.

Analysis of uncertainty:
Probabilistic sensitivity analyses were conducted, by simultaneously varying the key outcome probabilities, the unit costs, the use of resources, and the utility estimates. One-way deterministic sensitivity analyses were conducted.

Results
The percentage of successfully treated patients was higher for macrogol 3350 (68%) than for lactulose (60%, p<0.0001). Patients treated with macrogol 3350 were estimated to have 0.458 QALYs (95% CI 0.429 to 0.486) at six months compared with 0.454 (95% CI 0.427 to 0.482) for those treated with lactulose, a gain of 0.004 QALYs or 1%.

The total cost to the NHS for macrogol 3350 was estimated to be £420 compared with £419 for lactulose.

Over six months, the incremental cost-effectiveness of macrogol 3350 compared with lactulose was estimated to be £250 per QALY gained. At a willingness-to-pay of £20,000 per QALY the probability of macrogol 3350 being cost-effective was estimated to be 0.78. The probability of macrogol being cost-effective increased as the threshold increased.

Authors’ conclusions
The authors concluded that macrogol 3350 was a cost-effective treatment for chronic constipation.

CRD commentary
Interventions:
The interventions appear to have been appropriate comparators, given the usual care in the UK. These strategies are likely to be relevant in other settings.

Effectiveness/benefits:
The effectiveness data were from a database of UK primary care consultation information. This was relevant to the study setting and the objectives. The authors provided details of the database, including the reference, and the process used to extract the data. This type of data has limitations, which were highlighted by the authors, but it enabled the authors to reflect clinical practice rather than an artificial protocol-driven trial. It is clear that bias could be present and this needs to be considered when assessing the results. The methods used to derive the utility estimates were provided and the preferences were from the general public, but they were not obtained using the European Quality of life (EQ-5D) questionnaire, as recommended by the National Institute for Health and Clinical Excellence (NICE) in the UK. The six-month time horizon appears to have been appropriate for capturing the relevant costs and effectiveness of the two treatments, but it might not have been sufficient.

Costs:
The authors defined the study perspective and they appear to have included all the relevant costs. These estimates were also relevant to the study population and setting. The authors reported the price year and the currency, and all sources of data were referenced. The resource use was reported in detail, with the costs. The database recorded clinical practice, but the resource use was not collected prospectively and the data might have limitations.

Analysis and results:
The analytic approach was clearly described and a diagram of the decision-tree model was given. The results were reported clearly and in full, and their sensitivity to variations in the key parameters of the model was assessed, using probabilistic sensitivity analysis. The reporting was good, with estimates of the effectiveness in terms of successful treatment and QALYs, and the cost data presented. The authors acknowledged and discussed some limitations of their study, such as the non-random allocation to treatment.
Concluding remarks:

The methods and reporting of the results were good. The results appear to be reliable, but the small difference in health-related quality-of-life and the uncertainty around the mean estimates should be considered.

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