Therapy conversion to biphasic insulin aspart 30 improves long-term outcomes and reduces the costs of type 2 diabetes in Saudi Arabia

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 estimate the cost-effectiveness of biphasic insulin aspart 30 (BIAsp 30) compared with human insulin in patients with type 2 diabetes. The authors concluded that conversion to BIAsp 30 from human insulin improved quality-adjusted life expectancy and reduced medical costs. The methodology was satisfactory and the methods and results were adequately reported. The authors' conclusions appear to be appropriate, but should be treated with caution due to the use of non-randomised effectiveness evidence.

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

Study objective
The objective was to estimate the long-term clinical and cost outcomes of moving patients with poorly controlled type 2 diabetes from their current treatment with human insulin to adequate treatment with biphasic insulin aspart 30 (BIAsp 30).

Interventions
The study compared therapy with BIAsp 30 with human insulin.

Location/setting
Saudi Arabia/primary care.

Methods
Analytical approach:
A published Markov model was used to assess the long-term clinical and cost outcomes of the two interventions (Palmer, et al. 2004, see 'Other Publications of Related Interest' below for bibliographic details). The time horizon was 40 years and the authors reported that a third party payer perspective was adopted.

Effectiveness data:
The clinical and effectiveness data were derived from published studies. Most of the data used to populate the model were derived from the Saudi Arabian subgroup of the Physicians' Routine Evaluation of Safety and Efficacy of NovoMix 30 Therapy (PRESENT) study (Shestakova, et al. 2008, see 'Other Publications of Related Interest' below for bibliographic details). This was a six-month, single-arm, observational study conducted in 15 countries including Saudi Arabia, which participated with 598 patients. The main parameter was the effectiveness of treatment, measured by the reductions in haemoglobin A1c and hypoglycaemic events. These data were derived from the PRESENT study.

Monetary benefit and utility valuations:
Diabetes-related health state utility values were derived from Palmer, et al. 2004. The disutility values associated with hypoglycaemia were derived from another published study.

Measure of benefit:
Quality-adjusted life-years (QALYs) gained and life-years were the measures of benefit. As benefits could be generated over the lifetime of the patient, future benefits were discounted at an annual rate of 3%.
Cost data:
The direct costs were those relating to: treatment; patient management and concomitant medication, such as screening, statins, aspirin, and ACE inhibitors; and medical complications, such as cardiovascular disease, renal complications, acute events, eye disease, and amputation. It was assumed that the costs of self-management would be the same for both interventions and so they were not included. The annual costs of treatment were from the study sponsor and manufacturer of the drugs. To ascertain the costs of diabetes-related complications, 50 physicians were surveyed and asked for the costs of procedures, resource use, and medications given for each of the complications. The price year was 2007. As costs could be incurred over a 40-year period, future costs were discounted at an annual rate of 3%. All costs were reported in Saudi Arabian riyals (SAR).

Analysis of uncertainty:
A series of one-way sensitivity analyses was performed to assess the uncertainty around the data and the impact of changing the model parameters. The following parameters were varied: the complication costs, costs of hypoglycaemic events, discount rate, time horizon, hypoglycaemic event rates, and the reduction in haemoglobin A1c associated with BIAsp 30. A Monte Carlo simulation, with 1,000 patients analysed 1,000 times for each simulation, was performed to obtain the mean values and standard deviations (SDs) using a non-parametric bootstrapping approach.

Results
Treatment with BIAsp 30 generated on average 11.77 (SD 0.20) life-years and 7.03 (SD 0.12) QALYs, compared with 11.15 (SD 0.19) life-years and 6.07 (SD 0.11) QALYs with human insulin treatment. The costs per patient for treatment with BIAsp 30 were SAR 84,761 (SD 3,102) and for treatment with human insulin they were SAR 138,640 (SD 4,102). This was a cost saving of SAR 53,879 with BIAsp 30.

The costs and benefits were not combined as BIAsp 30 was dominant, which means it was both more effective and less costly than human insulin.

The sensitivity analyses showed that these results were most sensitive to changes in hypoglycaemic event rates for BIAsp 30 and reductions in haemoglobin A1c with BIAsp 30.

Authors’ conclusions
The authors concluded that conversion to BIAsp 30 from human insulin improved quality-adjusted life expectancy and reduced the lifetime medical costs.

CRD commentary
Interventions:
The interventions were reported clearly and in detail. They included the current practice in the study setting.

Effectiveness/benefits:
The main effectiveness and clinical parameters were derived from a non-randomised observational study; the PRESENT study. Adequate details of this study were reported and the reference was given. As it was non-randomised the results of this study could have been biased due to differences in the baseline characteristics between the treatment and control groups. Differences were not reported, but the authors did report that the lack of randomisation was a limitation to their study.

Costs:
The perspective was reported and all the cost categories and costs, relevant to the third-party payer perspective, appear to have been included. The derivation of the resource use and cost data, mainly from the expert opinions of 50 physicians, was adequately reported. The price year, discount rate and time horizon were all reported.

Analysis and results:
The evidence was synthesised using a Markov model, based on a published model. Adequate details were provided, but no diagram was given. The uncertainty in the results was investigated using Monte Carlo simulation and a series of one-way sensitivity analyses. These methods explore some of the impact of uncertainty, but probabilistic sensitivity analyses would have been more thorough in evaluating the overall model uncertainty. The authors reported the limitations of
their study.

Concluding remarks:
The methodology was satisfactory and both the methods and results were adequately reported. The authors’ conclusions appear to be appropriate, but should be treated with caution due to the use of non-randomised effectiveness evidence.

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