**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 of the study was to compare the long-term costs and outcomes of treatment with biphasic insulin aspart 30 (BIAsp 70/30) compared with insulin glargine. The authors concluded that long-term treatment with BIAsp 70/30 was projected to be cost-effective for patients with Type 2 diabetes. Overall, the quality of the methodology was good and both the methods and results, with a few exceptions, were well reported. The authors’ conclusions appear to reflect the scope of their analysis.

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

**Study objective**
The objective of the study was to compare and project the long-term costs and clinical outcomes of treatment with biphasic insulin aspart 30, compared with insulin glargine, in insulin-naive Type 2 diabetes patients failing to achieve glycaemic control with oral antidiabetic agents alone.

**Interventions**
The study compared the use of biphasic insulin aspart 30 (BIAsp 70/30; 30% soluble and 70% protaminated insulin aspart) with insulin glargine.

**Location/setting**
USA/outpatient secondary care.

**Methods**

**Analytical approach:**
The authors reported that the analysis was based on a non product-specific, comprehensive and interactive computer-based Markov/Monte-Carlo model designed to calculate the long-term clinical and economic outcomes of treatment options and strategies in patients with Type 1 or Type 2 diabetes. The model, known as the CORE diabetes model, has been described and published elsewhere (Palmer et al. 2004, see ‘Other Publications of Related Interest’ below for bibliographic details). The time horizon of the study was 35 years. The authors reported that the perspective adopted in the economic study was that of a third-party payer.

**Effectiveness data:**
Short term-treatment effects were derived from the INITIATE trial, a randomised controlled trial (RCT) involving 233 insulin naive patients with Type 2 diabetes. The authors did not report the duration of follow-up in the INITIATE trial. Short-term effectiveness measures were extrapolated using the authors’ own assumptions, which were based on reports of long-term follow-up studies of patients such as the United Kingdom Prospective Diabetes Study (UKPDS) and NHANES II. The main clinical estimate, derived from the INITIATE trial, was the change from baseline in haemoglobin A1c (HbA1C) levels.

**Monetary benefit and utility valuations:**
The authors did not report the source used to obtain utility valuations for the generation of quality-adjusted life-years (QALYs).
Measure of benefit:
The measures of benefits used were the QALYs gained and the life-years gained.

Cost data:
The direct costs used in the analysis were for screening for retinopathy, study drugs, other drugs in the treatment of diabetes or its complications, and the treatment and management of events due to diabetes complications (e.g. myocardial infarction, angina, stroke, congestive heart failure, renal disease, peripheral vascular disease, vision loss, ulcer and amputation). The costs of study drugs were derived from US pharmacy costs. The costs of complications caused by diabetes were derived from published studies. The price year was 2004. All costs were reported in US dollars ($). Since the costs were incurred over 35 years, discounting was performed at an annual rate of 3.0%.

Analysis of uncertainty:
A series of one-way sensitivity analyses were undertaken in which change in HbA1c, time horizon, discount rate, baseline age and duration of treatment were varied. A Monte-Carlo simulation was also undertaken in which 1,000 patients were simulated through the model 1,000 times. The results were presented by means of an acceptability curve, which measured the probability of each treatment being cost-effective given a cost-effectiveness threshold.

Results
Treatment with BIAsp 70/30 generated 13.47 life-years and 9.40 QALYs per patient, compared with 13.29 life-years and 9.21 QALYs per patient for treatment with glargine.

Treatment with BIAsp 70/30 over 35 years generated average lifetime costs per patient of $107,393, compared with lifetime costs per patient of $98,569 for patients treated with glargine.

Overall, the additional cost per QALY gained when BIAsp was compared with glargine was $46,533 per QALY gained. The results of the Monte Carlo simulation showed that, at a threshold of $50,000 per QALY gained, the probability that BIAsp 70/30 was cost-effective in comparison with glargine was 60%.

The results of the one-way sensitivity analyses showed that variations in changes in HbA1C were the main drivers of long-term cost-effectiveness. The results also showed that the shorter the time horizon the worse the cost-effectiveness of BIAsp 70/30 in comparison with glargine.

Authors' conclusions
The authors concluded that long-term treatment with BIAsp 70/30 was projected to be cost-effective for patients with Type 2 diabetes compared with glargine.

CRD commentary
Interventions:
The interventions were reported clearly. Although, no clear justification was given for using insulin glargine as the comparator, it would appear to represent a valid comparator as it was used as a comparator in a recent RCT.

Effectiveness/benefits:
The short-term effectiveness data were derived from a single RCT. The authors provided adequate details of the methods used in this trial and its main results, but did not report the duration of follow-up in the trial. They also did not report why evidence from other trials was not used. Consequently, it is not clear if all the available effectiveness evidence was used. The long-term effectiveness was extrapolated using the authors' own assumptions, although these assumptions were backed up by the findings of large long-term cohort studies. The authors did not report how utility valuations used to generate QALYs were obtained. However, as the authors used a published model, it might be that these valuation have been reported elsewhere.

Costs:
The costs included would appear to reflect the authors' stated perspective. Furthermore, all the relevant costs appear to have been included in the analysis. The cost data were well reported, along with adjustments, including both discounting and the price year. All costs used in the analysis were reported in detail, as were the results of the cost analysis.
Analysis and results:
The authors used a published and validated diabetes model to estimate the cost-effectiveness of BIAsp 70/30. They also conducted an appropriate incremental analysis and presented the results in full. The results of both the Monte-Carlo simulation and one-way sensitivity analyses were also reported in full. However, although these are valid methods of dealing with uncertainty within a model, the use of a probabilistic analysis would have been a more thorough method of capturing full model uncertainty. The time horizon used, 35 years, would appear to capture all the relevant outcomes and costs of the two interventions being investigated.

Concluding remarks:
Overall, the quality of the methodology was good and the methods and results, with a few exceptions, were well reported. The authors’ conclusions appear to reflect the scope of the analysis.

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Bibliographic details

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Oral; Adult; Aged; Cost-Benefit Analysis; Diabetes Complications /economics /prevention & control; Diabetes Mellitus, Type 2 /blood /complications /drug therapy /economics; Epidemiologic Methods; Female; Health Care Costs /statistics & numerical data; Hemoglobin A, Glycosylated /metabolism; Humans; Hypoglycemic Agents /economics /therapeutic use; Insulin /analogs & derivatives /economics /therapeutic use; Male; Middle Aged; Treatment Failure; Treatment Outcome

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