Comparison of a multiple daily insulin injection regimen (basal once-daily glargine plus mealtime lispro) and continuous subcutaneous insulin infusion (lispro) in type 1 diabetes: a randomized open parallel multicenter study

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 compare the clinical outcomes and costs associated with multiple daily injection (MDI) of insulin and continuous subcutaneous insulin infusion (CSII) in people with type 1 diabetes. The authors concluded that glycaemic control was no better with the more expensive CSII therapy than with MDI therapy. The cost-effectiveness of MDI was unclear, given the limited reporting of the statistical results of adverse events and the limitations of the trial.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to compare the clinical outcomes and costs associated with multiple daily injection (MDI) of insulin and continuous subcutaneous insulin infusion (CSII) in people with type 1 diabetes.

Interventions
The two interventions were: MDIs with insulin glargine once a day in the evening and mealtime insulin lispro; and CSII using insulin lispro in a MiniMed 508 pump.

Location/setting
UK, France, and Italy/home.

Methods
Analytical approach:
The effectiveness and cost data were derived from a single, randomised controlled trial (RCT). The time horizon of the study was 24 weeks. The authors did not report the study perspective.

Effectiveness data:
The effectiveness data were derived from an equivalence (new treatment versus standard treatment rather than placebo) multi-centre RCT performed in three European countries. Fifty-eight diabetic patients were randomised, with 30 in the MDI group and 28 in the CSII group. Fifty of these patients (26 in the MDI group and 24 in the CSII group) were analysed. The demographic and clinical characteristics of the patients in each group were shown to be comparable at baseline. Patients were followed-up at eight, 16 and 24 weeks. The primary outcome was glycaemic control (measured by haemoglobin A1c). Secondary outcomes included other measures of blood glucose control, hypoglycaemia, adverse events, and treatment satisfaction.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The primary measure of benefit was glycaemic control (A1c).

Cost data:
The treatment costs were included in the analysis. Some of the resource use estimates were obtained during the clinical trial. All costs were in Euros (EUR).

Analysis of uncertainty:
The analysis of uncertainty involved confidence intervals for clinical events.

Results
The percentage of A1c decreased from 7.7 at baseline to 7.0 at the end point (24 weeks) in the CSII group, and from 7.8 to 7.2 in the MDI group. The adjusted difference in change (which favoured CSII) was -0.1 (95% CI -0.5 to 0.3). There were small differences between the two groups for the other clinical estimates. Treatment satisfaction increased from 22.8 at baseline to 31.5 at the end point for those in the CSII group, and from 24.0 to 28.8 in the MDI group. This treatment difference was 3.1 (95% CI 0.1 to 6.1).

The average cost per treatment was EUR 3,020 in the CSII group and EUR 778 in the MDI group.

Authors’ conclusions
The authors concluded that MDI resulted in similar improvement in A1c levels and was cheaper than CSII.

CRD commentary
Interventions:
The two interventions were clearly described and appear to have been relevant comparators in the authors’ setting.

Effectiveness/benefits:
The analysis was based on a multi-centre randomised controlled trial, which is potentially high quality data source. The authors stated that this was the best clinical evidence available for this treatment effect. The analysis was per protocol, which was appropriate for an equivalence trial. The target sample size was set to power the trial appropriately, but the actual sample was smaller and the study was not powered to detect the specified adverse event equivalence. No statistical test results for adverse events were reported. The authors acknowledged that the sample should ideally have been larger and the time horizon longer.

Costs:
The authors did not report the perspective, so it is not clear if the appropriate cost categories were included. Some cost details were not reported. The unit costs were reported in an online table. The price year was not reported, so it will not be possible to re-value the estimates in future years.

Analysis and results:
No synthesis of the effectiveness and cost data was conducted so, in effect, a cost-consequence analysis was performed. While the results of the study were clearly reported, the impact of uncertainty on the parameters was not investigated, which makes it difficult to assess whether the study results were robust. The authors did not state that equivalence had been demonstrated for all the relevant outcomes. They referred to non-inferiority in their discussion, when equivalence would have been more appropriate. The authors noted some limitations to their results.

Concluding remarks:
The cost-effectiveness of MDI was not completely clear, given the limited reporting of the statistical results of adverse events and the limitations of the trial.

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Bibliographic details