Comparison of different insulin regimens in elderly patients with NIDDM

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.

Health technology
The use of twice daily subcutaneous injections of a mixture of fast-acting and NPH insulin 30 minutes before breakfast and dinner, in elderly patients with poorly controlled non insulin dependent diabetes mellitus (NIDDM).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Elderly NIDDM patients, whose disease state was poorly controlled by diet and oral antihyperglycemic agents. The patients were aged 68 (+

Setting
The practice setting was an outpatient department. The economic analysis was performed in Maastricht, The Netherlands.

Dates to which data relate
The dates to which data relate were not given.

Source of effectiveness data
Evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
Costs were derived prospectively from the same source as the effectiveness data.

Study sample
102 patients, who were eligible and from whom consent was obtained, were consecutively randomised to one of three insulin regimens for the treatment of poorly controlled NIDDM: Regimen A (34 patients), regimen B (28 patients) and regimen C (33 patients). Power calculations were not used to determine sample size.

Study design
The study was a randomised controlled trial. Patients were followed up for six months. Loss to follow up was 6.9%, due mainly to cardiovascular problems. The regimens from which withdrawals came were not specified.
Analysis of effectiveness
The analysis was conducted on the basis of treatment completers. The primary health outcomes included metabolic control (measured by fasting blood glucose levels and HbA(1c) levels) and also the side effects of weight gain and hyperglycaemia. At analysis, groups were not shown to be comparable in terms of demographic characteristics. Statistically significant differences between the groups were found in total cholesterol levels and residual beta-cell function.

Effectiveness results
9 (32%) of the patients in group B and 11 (33%) of those in regimen C needed a second insulin injection. One episode of serious hypoglycaemia was observed.

Under regimen A:
fasting blood glucose fell from 14.5 (+/- 1.9) to 8.5 (+/- 2.0) P<0.05;
HbA(1c) decreased from 11.2 (+/- 1.3) to 8.2 (+/- 1.2%);
Body weight (kgs) rose from 67.4 (+/- 11.8) to 71.4 (+/- 12.8) P<0.05.

Under regimen B:
fasting blood glucose fell from 14.4 (+/- 1.9) to 8.4 (+/- 1.9) P<0.05;
HbA(1c) decreased from 10.5 (+/- 1.2) to 8.1 (+/- 1.1%);
Body weight (kgs) rose from 76.1 (+/- 16.4) to 80.5 (+/- 16.8) P<0.05.

Under regimen C:
fasting blood glucose fell from 13.5 (+/- 2.7) to 8.1 (+/- 2.2) P<0.05;
HbA(1c) decreased from 11.1 (+/- 1.3) to 8.5 (+/- 1.1%);
Body weight rose from 69.2 (+/- 10.3) to 72.6 (+/- 10.7) P<0.05.

The authors found no differences in the outcomes between regimens, but did not report the statistical significance of these findings.

Clinical conclusions
The three regimens were equally effective in the treatment of poorly controlled NIDDM in elderly patients. Weight gain was a side effect of all the insulin regimens considered in the study.

Measure of benefits used in the economic analysis
Since the effectiveness analysis showed no difference in effectiveness between groups the economic analysis was based on differences in costs only.

Direct costs
Resource quantities were reported separately. The cost dates were not given and costs were not discounted. The costs estimated included drug costs and the cost of needles. Costs were reported for regimen A (insulin alone) and regimens B and C combined (insulin plus sulfonylureas). Prices and dates for prices were not given. The cost boundary adopted was that of the hospital pharmacy.
Statistical analysis of costs
A statistical analysis of costs was not performed.

Indirect Costs
Indirect costs were not considered.

Currency
Dutch guilders (Dfl) converted to US dollars ($) at the rate of $1 = Dfl1.60.

Sensitivity analysis
A sensitivity analysis was not performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The average estimated monthly per patient cost of regimen A was Dfl94.39 ($59.00). The average estimated monthly per patient cost of regimens B and C combined was Dfl111.85 ($70.00).

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
Treatment of poorly controlled NIDDM in elderly patients with twice daily injections of insulin was cost-effective, relative to treatment with insulin plus sulfonylureas.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used. The authors referred to the frequency with which regimens with insulin plus sulfonylurea are advocated in the medical literature. You, the user of this database, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
Oral antihyperglycemic therapy was continued for patients, who were transferred from a once daily to a twice daily insulin injection. Since the latter was shown by the study to be an effective treatment for metabolic control, the continuation of oral therapy would appear to be unnecessary in practice. By including the costs of the oral therapy in the economic analysis, the cost-effectiveness of twice daily insulin relative to insulin plus sulfonylurea may have been over-estimated.

Validity of estimate of costs
Costs were not analysed statistically and only drug costs were included in the analysis. Separate costs for each comparator were not estimated. It is therefore not possible to determine the relative cost-effectiveness of the insulin regimens considered in the study.
Other issues
A statistical analysis of costs was not performed. No sensitivity analysis was carried out. It is therefore unlikely that the authors' conclusions concerning cost effectiveness are justified.

Implications of the study
A more comprehensive analysis of costs would give a more accurate estimate of the cost effectiveness of different insulin regimens.

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