Cost-effectiveness of intensive insulin therapy for type 2 diabetes: a 10-year follow-up of the Kumamoto study

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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.

Health technology
Intensive insulin therapy for type 2 diabetes in Japan.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of Japanese patients with type 2 diabetes.

Setting
The setting was a hospital. The economic study was conducted in Japan.

Dates to which data relate
Effectiveness, resource use and cost data were collected between 1988 and 1998. The price year was 1998.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was conducted retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
110 patients with insulin-requiring type 2 diabetes were assigned to the MIT group (n=55) or the CIT group (n=55). No power calculations in the determination of sample size, or patient inclusion/exclusion criteria were reported.

Study design
The study took the form of a prospective randomised controlled trial carried out at a single centre. Patients were followed up for 10 years. After 10 years, 97 patients remained in the study.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcome used was the frequency of complications, including progression of retinopathy, preproliferative or proliferative retinopathy, photocoagulation, progression of nephropathy, clinical neuropathy, macrovascular complications, and diabetes-related death. There were no significant differences between groups in terms of age, gender, duration of diabetes, or body mass index at the start of the trial.

**Effectiveness results**

Compared with CIT, MIT resulted in the following risk reductions:

- Progression of retinopathy, 67% (95% CI: 49 - 79%);
- Preproliferative or proliferative retinopathy, 69% (95% CI: 34 - 86%);
- Photocoagulation, 77% (95% CI: 47 - 90%);
- Progression of nephropathy, 66% (95% CI: 42 - 80%);
- Albuminuria, clinical neuropathy, 100%, 64% (95% CI: 45 - 76%);
- Macrovascular complications, 54% (95% CI: 2 - 78%); and
- Diabetes-related death, 81% (95% CI: 28 - 95%).

Compared with CIT and discounted at 3% and 5% rates, intensive insulin therapy prolonged the free period by 1.4 and 1.1 years for progression of retinopathy, 0.2 and 0.1 years for photocoagulation, 1.1 and 0.8 years for progression of nephropathy, and 1.5 and 1.1 years for clinical neuropathy.

**Clinical conclusions**

Intensive insulin therapy could significantly reduce the risk of diabetic microvascular complications and prolong the period in which the patient is free from endpoint complications in Japanese patients with type 2 diabetes.

**Measure of benefits used in the economic analysis**

The frequency of complications was used as the measure of benefits, as indicated in the effectiveness results reported above. Hence, the analysis was of cost-consequences design. Benefits were discounted at rates of 3% and 5%.

**Direct costs**

Direct costs were discounted at rates of 3% and 5%. Quantities and costs were reported separately. Direct costs included all direct medical costs related to diabetes such as those associated with inpatient care, outpatient care, medications, medical equipment, and laboratory tests. The quantity/cost boundary adopted was that of a third-party payer. The estimation of quantities and costs was based on the medical records of the authors' institution. Costs of medical services were based on the reimbursement fee schedule of the Japanese National Health Insurance. The price year was 1998.

**Statistical analysis of costs**

The authors reported mean total costs per patient. Student's t-tests were used to compare costs between the two groups.

**Indirect Costs**

Indirect costs were not included.
Currency
US dollars ($) with $1 = Yen120.

Sensitivity analysis
Sensitivity analyses were conducted on the discount rate and the risk reduction rate of each incidence of major complications.

Estimated benefits used in the economic analysis
As the analysis was based on a cost-consequences approach, see the effectiveness results reported above.

Cost results
Treatment costs per patient were $27,201 in the MIT group and $21,121 in the CIT group, (p<0.001). Complications costs per patient were $7,591 in the MIT group and $15,565 in the CIT group, (p<0.001). Discounted at a rate of 3%, total costs of treatment and complications per patient were $30,310 in the MIT group and $31,525 in the CIT group, (not significant). Discounted at a rate of 5%, the total costs of treatment and complications per patient were $27,822 in the MIT group and $28,675 in the CIT group, (not significant).

Synthesis of costs and benefits
Given that the total costs were not significantly different between the two groups, intensive insulin therapy was the most cost-effective therapy: costs were similar but MIT is more beneficial in terms of health outcomes.

Authors' conclusions
MIT is more beneficial than CIT in terms of both cost and effectiveness. Therefore, MIT is recommended for the treatment of type 2 diabetic patients who require insulin therapy as early as possible from the perspective of both patients and health policy.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely that it represented a current treatment alternative. You, as a user of the database, should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. Patient groups were shown to be comparable at analysis.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study. The clinical consequences assessed were appropriately compared in the context of a randomised controlled trial over a long period of follow-up. The validity of the results is therefore likely to be high.

Validity of estimate of costs
Good features of the cost analysis were that all relevant direct cost categories were included: quantities and costs were reported separately and the price year was stated. However, capital costs, costs borne by patients and their families, and production losses associated with lost or impaired ability to work were not considered. No sensitivity analyses were conducted on costs, which limits the generalisability of the results. Charges were not converted into costs and, hence, true opportunity costs were not estimated. These latter features, however, may reflect the Japanese system which determines costs and reimbursements centrally.
Other issues
The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors did not present their results selectively. The study enrolled Japanese patients with type 2 diabetes and this was reflected in the authors' conclusions.

Implications of the study
MIT is more beneficial than CIT in terms of both cost and effectiveness. Therefore, MIT is recommended for the treatment of type 2 diabetic patients who require insulin therapy as early as possible from the perspective of both patients and health policy.

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