Cost effectiveness analysis of improved blood pressure control in hypertensive patients with type 2 diabetes: UKPDS 40

UK Prospective Diabetes Study Group

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
Blood pressure control in hypertensive patients with type 2 diabetes.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Hypertensive patients with type 2 diabetes. The mean (SD) age of patients was 56.4(8.1) years.

Setting
The setting was secondary care. The study took place in 20 hospital based clinics in England, Scotland, and Northern Ireland. The economic study was carried out by the UK Prospective Diabetes Study Group in Oxford, UK.

Dates to which data relate
The data for the effectiveness analysis were collected between 1987 and 1997. 1997 prices were used.

Source of effectiveness data
The effectiveness data were extracted from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample and unit costs of resources used by trial patients were obtained from national statistics and from centres participating in the trial. Data on use of non-inpatient health care resources were collected retrospectively by means of a questionnaire.

Study sample
A total of 1,148 hypertensive patients with type 2 diabetes (54% male) were recruited from the UK Prospective Diabetes Study patient population. Power calculations were not used to determine the sample size.

Study design
The study was a randomized controlled trial. The study was multi-centred involving 20 hospital based clinics in the United Kingdom. Median duration of follow up was 8.4 years (1 to 10). The method of randomization was not
Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes used in the analysis were mortality rate and development of diabetic complications (coronary heart disease, cerebrovascular disease, amputations, laser treatment for retinopathy, cataract extraction and renal failure). There were no significant differences between the patients assigned to the two groups in terms of other drug treatments or trial visits to clinics.

Effectiveness results
Mortality and complication rates were reported in another publication.

Clinical conclusions
Tight control of blood pressure for hypertensive patients with type 2 diabetes reduced the risk of complications and improves health.

Modelling
A simulation model was used in order to estimate life expectancy beyond the end of the trial. The model parameters were estimated from data from the hypertension in diabetes study conducted by the same group and were fitted to the entire cohort. Multiple regression was used to estimate, for each patient, the annual use of non-hospital resources standardised for age, sex, body mass index, duration of diabetes, and time from a non-fatal end-point related to diabetes.

Measure of benefits used in the economic analysis
The outcome measures used in the analysis were time free from diabetes related end points and life years gained. A simulation model was used in order to estimate life expectancy beyond the end of the trial.

Direct costs
The direct health service costs were considered and included treatment costs, visits to and tests at diabetic clinics and costs of treating diabetic complications. Costs were discounted at 6%, and 3% discount rates, and were also reported undiscounted. Costs were reported separately. The estimation of quantities was based on actual data from the trial (1987-1997); use of non-hospital resources was estimated using a questionnaire and multiple regression techniques. Estimation of costs was based both on actual data and national statistics. 1997 price data were used. Adjustments were made to the observed costs to correct for protocol driven costs.

Statistical analysis of costs
All results were reported as mean values with standard deviations, and mean differences in costs and effects, with 95% Confidence Interval (CI). Fieller's method was used for estimating means and 95% CI for the incremental cost-effectiveness ratios. When data were skewed, 1,000 bootstrap replications of the original data were performed to test the robustness of the parametric assumptions concerning mean differences in costs.

Indirect Costs
The indirect costs were not considered.

Currency
UK pounds sterling (£).
**Sensitivity analysis**

One-way simple sensitivity analysis was carried out on the number of visits (at a 6% discount rate for both costs and effects), and on the discount rate.

**Estimated benefits used in the economic analysis**

The mean time in years (SD in parentheses) to a diabetic related end point (at 0%, 6% and 3% discount rates respectively) was:

less tight control group: 7.61(3.61), 4.63(1.78) and 5.88(2.55)

tight control group: 8.16(3.52), 4.85(1.73) and 6.24(2.48)

mean difference: 0.54, 0.23 and 0.35

The modelled mean life years gained were:

less tight control group: 19.07(8.40), 10.30(3.39) and 13.60(5.14)

tight control group: 19.88(8.10), 10.63(3.17) and 14.10(4.87)

mean difference: 0.81, 0.33 and 0.50.

**Cost results**

The total costs per patient for the two groups were not significantly different, means were:

less tight control group: 9,085 (0% discount rate), 7,156 (6%) and 8,024 (3%)

tight control group: 8,875 (0% discount rate) 7,081 (6%) and 7,891 (3%)

Adjusted for the protocol driven costs the mean total costs were:

less tight control group: 7,869 (0% discount rate), 6,145 (6%) and 6,920 (3%)

tight control group: 8,048 (0% discount rate), 6,381 (6%) and 7,132 (3%)

**Synthesis of costs and benefits**

The estimated costs and benefits were combined using incremental cost-effectiveness ratios. Incremental cost-effectiveness ratios were calculated using Fieller's method. The cost per extra year free from diabetes related end-points was 1,049 (-4,635 to 52,373) at 6% discount rate and 599 (-3,400 to 13,226) at 3% discount rate for both costs and health effects. When protocol driven costs were considered the results were -333 (-10,767 to 23,882) at 6% discount rate. The incremental cost-effectiveness ratios for life years gained were 720 (6%) and 422 (3%), and after adjusting for the protocol driven costs was -229 (6%).

**Authors' conclusions**

The authors concluded that tight control of blood pressure for hypertensive patients with type 2 diabetes offers a cost-effective means of reducing the risk of complications and improving health.

**CRD COMMENTARY - Selection of comparators**

The reason for the choice of comparator is clear.

Validity of estimate of benefits:
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The data were not used selectively to prove a particular point.

**Validity of estimate of costs**
The authors did not report quantities separately. Adequate details of estimation of quantities and costs were given. As the authors used both statistical analysis of costs and also undertook sensitivity analyses the cost results are likely to be valid.

**Other issues**
The study sample-size differences between the two groups should be noted. Also, the study did not consider quality of life.

**Source of funding**
Grants for the health economics study were received from: UK Department of Health, GlaxoWellcome, SmithKline Beecham, Pfizer, Zeneca, Pharmacia and Upjohn, Novo Nordisk, Bayer and Roche.

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