Treatment strategies for insulin-dependent diabetics with ESRD: a cost-effectiveness decision analysis model

Douzdjian V, Ferrara D, Silvestri G

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
Treatment of end stage renal disease either by dialysis, kidney transplant from either a cadaver or living donor, or simultaneous pancreas/kidney transplantation.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
Patients with Type I diabetes and ESRD.

Setting
Hospital. The economic analysis was conducted in Charleston, South Carolina, USA.

Dates to which data relate
Effectiveness data were taken from studies published between 1993 and 1995. Resource data were estimated based on data from published sources and personal communications between 1988 and 1997. 1996 price years were used in the analysis.

Source of effectiveness data
Effectiveness data were derived from a review of previously completed studies.

Modelling
A decision analysis model was used to combine information on clinical probabilities, cost data and quality of life weights in order to determine costs per quality-adjusted year for the four possible treatment options: dialysis alone, kidney transplantation from cadaver only, kidney transplantation from living donor and simultaneous pancreas/kidney transplantation. The model was constructed using the Data 3.0 Package from TreeAge Software Inc, Williamstown, Massachusetts, USA. The duration of the model was 5 years.

Outcomes assessed in the review
Renal dialysis, and kidney and pancreas transplantation survival rates were assessed in the review.
Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
5 primary studies were included in the review.

Methods of combining primary studies
Not combined.

Investigation of differences between primary studies
Not conducted.

Results of the review
The following probabilities were identified:

5 year survival rates:
- diabetics and non diabetics on dialysis aged 20-44, 0.34 and 0.51;
- patients receiving kidney transplantation from cadaver or living donor, 0.73 and 0.80;
- patients receiving simultaneous kidney/pancreas transplantation 0.80.

5 year kidney graft survival rates:
- patients receiving kidney transplantation from cadaver or living donor, 0.54 and 0.68;
- patients receiving simultaneous kidney/pancreas transplantation, 0.68.

5 year pancreatic graft survival rate was 0.62.

The 6 month probability of dying during the operation or due to complications for patients receiving kidney transplantation from either cadaver or living donor was 0.08 compared with 0.09 for patients receiving simultaneous kidney/pancreas transplantation.

Measure of benefits used in the economic analysis
The benefit measure was quality-adjusted life years gained (QALYs). A decision analysis model was used for the different treatment options. Utility weights were determined using the standard gamble method. Interviews were conducted with 17 patients with diabetic retinopathy and neuropathy prior to transplantation who had undergone
simultaneous kidney/pancreas transplantation at the authors’ institution between 1990 and 1996. It is not clear whether the interviews were conducted on a face to face basis or over the telephone by the transplant surgeon or co-ordinator. Subjects had to consider 5 scenarios:

(1) death from operation or complications,
(2) kidney fails/pancreas works,
(3) pancreas fails/ kidney works,
(4) both organs fail, and
(5) both organs work.

In this analysis, preferences elicited for states from best to worst (1 - 0) were estimated as:

1 - dialysis free, insulin free,
0.6 - dialysis free, insulin dependent,
0.5 - dialysis dependent, insulin free,
0.4 dialysis dependent, insulin dependent,
0.0 - and death.

**Direct costs**
The costs of diabetes management, dialysis, kidney and pancreas transplantation and annual transplantation follow-up were identified. In addition, the costs of dealing with adverse events such as failed transplantations were estimated. It was assumed in the base case scenario that any graft failures would occur during year 3. Charges rather than costs were reported in the model. Dialysis and kidney transplantation estimates were taken from 1990 Medicare expenditures. Charges for simultaneous kidney/pancreas transplantation were based on 1988 data from the US National Co-operative Transplantation Study. This estimate was then compared with other, more recent, published estimates and personal communication with a university transplant centre. Discounting does not appear to have been incorporated into the model. Costs were determined from the perspective of a third party payer and 1996 price years were used.

**Statistical analysis of costs**
Not conducted.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
One way sensitivity analyses were conducted varying costs, survival probability and quality of life values within a 10% range of baseline values.

**Estimated benefits used in the economic analysis**
In the 5 year model, expected quality-adjusted life years gained for each of the four strategies were:

dialysis 0.68,

kidney transplant from cadaver 1.38,

kidney transplant from living donor 1.70,

simultaneous kidney/pancreas transplant 2.36.

Incremental QALYs gained using simultaneous transplantation, compared with each of the three other treatment options respectively, were:

dialysis 1.68;

kidney transplant from cadaver 0.98,

and kidney transplant from living donor 0.66.

These estimates took account of possible adverse events and complications resulting from treatment.

**Cost results**

The expected five year costs per patient in the model for each of the treatment options were:

dialysis $216,068;

kidney transplant from cadaver $214,678;

kidney transplant from living donor $210,872;

simultaneous kidney/pancreas transplant $241,207.

Incremental cost of simultaneous transplantation, compared with each of the three other treatment options respectively, were:

dialysis $25,139;

kidney transplant from cadaver $26,529;

kidney transplant from living donor $30,355.

The costs of adverse events and complications were included in the analysis.

**Synthesis of costs and benefits**

In the base case scenario, where it was assumed that any graft failure would occur in year 3, the incremental cost per QALY gained using simultaneous kidney/pancreas transplantation in comparison with the next most effective option (kidney transplantation from a living donor) was $45,962. This appears to have been incorrectly reported in the paper as $15,009. The strategy was dominant over the other two treatment options. The average cost per quality-adjusted life year for the four treatment options were: dialysis $317,746; kidney transplant from cadaver $156,042; kidney transplant from living donor $123,923 and simultaneous kidney/pancreas transplant $102,422. The results remained robust in sensitivity analysis.

**Authors' conclusions**

In assessing options for transplantation in patients with end stage renal disease it is important to consider quality of life.
outcomes. From the decision analysis model simultaneous kidney pancreas transplant is a cost-effective option compared with dialysis and kidney only transplantation.

**CRD COMMENTARY - Selection of comparators**
A justification was provided by the authors for the comparators used, as kidney transplantation and dialysis are well accepted treatment options for patients with Type I diabetes and end stage renal disease.

**Validity of estimate of measure of benefit**
An estimate of benefits was based on a review of registry data on transplantation and dialysis. It is not clear how this data was identified, and this may bias the conclusions of the analysis. Utilities were determined using a well defined technique, the standard gamble, and a sample of patients who had undergone kidney/pancreas transplantation and who were no longer insulin dependent.

**Validity of estimate of costs**
An estimate of costs was determined from previously published sources. As noted by the authors, charges rather than costs were reported. Only direct costs were included in the analysis and future studies may wish to consider other costs to society, patients and care givers. The duration of the model used in the analysis was five years, but neither costs nor benefits appear to have been discounted. Discounting is often appropriate in studies where the duration of costs and benefits is greater than one year.

**Other issues**
The results of the analysis may not be generalisable to other settings and countries. In reporting the results of the cost-utility analysis the authors appear to have incorrectly placed too much emphasis on the average cost-utility ratios rather than the incremental ratios. Simultaneous kidney/pancreas transplantation yields more QALYs, but at a higher cost, than the next best option, kidney transplantation only from a living donor. It was concluded that simultaneous transplantation was the most cost-effective option, but decision makers must determine whether the incremental cost per QALY of this treatment option is within acceptable parameters. It should also be noted that the calculation of the incremental cost-utility ratio appears to be mistyped in the paper at approximately $15,000 rather than $45,000.

**Implications of the study**
As the authors noted, prospective randomised trials comparing these four options have not been conducted. Such studies, if ethically permissible, should be conducted alongside well designed economic evaluations for different patient populations and institutional settings.

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