Pancreas transplantation in Ohio: a 15-year outcomes analysis
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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
The health intervention examined in the study was the gaining of experience in pancreas transplantation, either performed alone (PTx) or with kidney transplantation (KPTx).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients eligible for PTx or KPTx procedures. The inclusion criteria were type I or type II diabetic patients with diabetic sequelae or life-threatening problems with management of their diabetes. Patients were excluded on the basis of substance abuse, active infection, end-stage cardiac, pulmonary, cerebrovascular, or haematologic disease, inability to understand the potential outcomes of the procedure, or uncontrolled malignancy.

Setting
The setting was a hospital. The economic study was carried out in four OSOTC member hospitals in Ohio, USA. These were the Ohio State University Hospitals, University Hospitals of Cleveland, University of Cincinnati Medical Center, and the Cleveland Clinic Foundation.

Dates to which data relate
The effectiveness evidence and resource use data were gathered from 1984 to 1999. The price year was 1985.

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

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

Study sample
No power calculations to determine the sample size were reported. A total of 824 patients undergoing PTx or KPTx at the study hospitals from 1984 to 1999 were included in the sample. The mean age in the sample was 38 years (range: 20 - 60) and 60% were men. Of the 841 transplantations performed, 765 (91%) were KPTx and 76 (9%) were PTx. The number of transplants was 102 in era 1, 381 in era 2, and 358 in era 3. No patient was excluded from the initial sample.
Study design
The study was based on a longitudinal observational design, which was intended to assess the improvements in health outcomes occurring over 15 years. No control group was defined and the comparisons were carried out between patients in each of the three eras considered. This multi-centred study was carried out in four hospitals in Ohio. The length of follow-up was 3 years. Follow-up data were available for all patients who underwent PTx. Twenty-one patients who underwent KPTx were lost to follow-up (3 in era 1, 13 in era 2, and 5 in era 3).

Analysis of effectiveness
The analysis of effectiveness was limited to those patients who completed the follow-up. The primary health outcomes assessed in the analysis were:

- the patient and graft survival rates, as calculated using the Kaplan-Meier method;
- the mean waiting times for patients listed at the OSOTC centres;
- the length of hospitalisation; and
- the mean number of readmissions during the first and second years of transplantation.

The comparability of the study groups in the three eras was not reported.

Effectiveness results
The 1-year patient survival rates were 100% in the three eras in the PTx group. The corresponding rates in the KPTx group were 87% in era 1, 92% in era 2, and 94% in era 3.

The 1-year graft survival rates were 21% for era 1, 50% for era 2, and 85% for era 3 in the PTx group, (p<0.01). The corresponding rates in the KPTx group were 68% for era 1, 80% for era 2, and 85% for era 3.

The 3-year survival results were not presented according to era.

The mean waiting times for patients listed at the OSOTC centres were 132 days in era 1, 161 days in era 2, and 318 days in era 3.

The mean lengths of hospitalisation were 34 days in era 1, 21 days in era 2, and 18 days in era 3.

The mean number of readmissions was not presented according to era.

Clinical conclusions
The effectiveness analysis showed that the effectiveness of pancreas transplantation improved from 1984 to 1999 in terms of the 1-year survival (with kidney transplantation only), graft survival (statistically significantly without kidney transplantation) and length of hospitalisation.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore carried out.

Direct costs
No discounting was carried out as the costs for each patients were incurred over a time period of less than 2 years. The unit costs and the quantities of resources were not reported separately. A breakdown of the cost categories was not given. The cost/resource boundary adopted in the analysis was that of the hospital transplantation centre. Hospital charges were used to derive the costs, but the source of the cost data was unclear. The quantities of resources were
obtained using actual data derived from the patients’ charts during the period 1984 to 1999. All of the costs were reported in 1985 values, using the appropriate inflation factor based on the Consumer Price Index.

**Statistical analysis of costs**
Statistical analyses of the total costs were carried out to test for statistical significance of the results. The Wilcoxon rank sum test and Spearman correlation were used to analyse the charges and length of hospital stay.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
There was a statistically significant decrease in the mean hospital charges over time. The mean hospital charges expressed in year of transplant were $74,000 in era 1, $83,000 in era 2, and $92,000 in era 3. When expressed in 1985 values, the mean hospital charges were $64,000 in era 1, $53,000 in era 2, and $46,000 in era 3. The statistical analysis showed a statistically negative correlation (r) between the mean hospital charges and the age of the patient, (p=0.007; r=-0.0928) at the time of transplantation. It also showed a significantly strong correlation between the mean hospital charges and the length of hospitalisation (p<0.0001; r=0.7716).

**Synthesis of costs and benefits**
Not relevant.

**Authors’ conclusions**
The Ohio Solid Organ Transplantation Consortium (OSOTC) experience proved that pancreas transplantation was a cost-effective procedure for patients with insulin-dependent diabetes, with or without end-stage renal disease.

**CRD COMMENTARY - Selection of comparators**
No comparator was explicitly considered in the study. The progress of the intervention (pancreas transplantation) was observed over time, and the comparison was carried out across the three eras considered in the study. It might be considered reasonable to consider the choice to continue with the status quo, i.e. the same treatment essentially for more years, in order to gain by improved experience in the technique. This can be contrasted with the choice to implement an entirely new technology.

**Validity of estimate of measure of effectiveness**
The analysis of the effectiveness used a longitudinal study, which was carried out in four centres. Details of the study populations in the three study periods were not reported. Thus, it is not possible to assess whether the study groups in the three eras were comparable, or whether the study sample was representative of the study population. In addition, it
was unclear whether the authors took into account the impact of possible factors unrelated to the intervention on the procedure outcomes. A final threat to the internal validity of the analysis was the lack of statistical analyses. These are necessary to take account of potential biases and confounding factors, due to the lack of randomisation and blinding.

**Validity of estimate of measure of benefit**
No summary benefit measure was used and a cost-consequences analysis was therefore carried out. It would have been interesting had the authors used the estimated data on the patients' survival and carried out an appropriate cost-effectiveness analysis.

**Validity of estimate of costs**
The overall costs of the procedure, from the perspective of the hospital, were included in the analysis. However, a breakdown of the resources and the unit costs was not reported. The costs were estimated using charges, which may not reflect true opportunity costs. Finally, sensitivity analyses were not carried out, although some statistical analyses were performed to compare the total costs.

**Other issues**
The authors made some comparisons of their findings with those from other studies, but the issue of the generalisability of the study results to other settings was not addressed. In addition, sensitivity analyses were not carried out. Thus, the external validity of the analysis is low. A specific sample of patients requiring pancreas transplantation was enrolled in the study, and this was reflected in the conclusions of the study. The authors reported the results of the analysis in detail.

**Implications of the study**
The authors suggested that the OSOTC experience was positive, the only exception being longer waiting times, due to the reduced availability of organ donors in relation to the increasing demand.

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