Primary enteric drainage of the pancreas allograft revisited

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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
Primary enteric drainage (ED) of exocrine secretions in pancreas allografts versus bladder drainage (BD) in simultaneous pancreas-kidney transplantations.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients who underwent simultaneous pancreas-kidney transplantations. No further details were given.

Setting
Hospital. The economic study was carried out in South Carolina, USA.

Dates to which data relate
The main effectiveness data were taken from a study conducted between October 1990 and September 1996. Resources and costs data were obtained from 1990-96 sources. The price year was 1996.

Source of effectiveness data
The estimates of length of stay for transplantation, total number of readmissions, length of hospital stay in the first 6 months after discharge, complications, duration of the operative procedure, reoperation, actuarial patient survival rates, kidney survival rates and technically successful pancreas survival rates were obtained 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 study.

Study sample
The study sample comprised 42 patients who underwent simultaneous pancreas-kidney transplantations: 26 patients (62%) had transplantation between October 1990 and September 1995 and underwent BD of exocrine secretions, and 16 patients (38%) had transplantations between September 1995 and October 1996 and underwent ED of exocrine secretions. The average age of recipient patients in the BD group was 34.4 years (+/- 8.9) and the average age of donor patients was 26.8 years (+/- 11.9). The corresponding figures in the ED group were 36.6 years (+/- 5.9) and 25.9 years (+/- 9.4). The percentage of female patients was 42% in the BD recipient group and 27% in the BD donor group. The corresponding figures for the ED group were 38% and 25%. The AB and DR match in the BD group were 0.6 (+/- 0.7)
and 0.6 (+/- 0.6), respectively. The corresponding figures in the ED group were 0.3 (+/-0.5) and 0.13 (+/- 0.3). Power calculations to determine the sample size were not undertaken.

**Study design**
The study was a non-randomized controlled trial. The duration of the follow-up was not given.

**Analysis of effectiveness**
The analysis of the clinical study was based on treatment completers only. The primary outcomes were length of stay for the transplantation, total number of readmissions, length of hospital stay in the first 6 months after discharge, complications, duration of the operative procedure, reoperation, actuarial patient survival rates, kidney survival rates and technically successful pancreas survival rates. The patient groups were shown to be comparable with respect to donor and recipient characteristics.

**Effectiveness results**
The length of stay for the transplantation was 12.9 (+/- 5.6) days with ED versus 20.4 (+/- 9.6) days with BD, (p=0.2). The total number of readmissions was 1.7 (+/- 1.5) days with ED versus 1.2 (+/- 1.2) days with BD, (p=0.2). The length of hospital stay in the first 6 months after discharge was 13.7 (+/- 16.2) days with ED versus 10 (+/- 11.3) days with BD, (p=0.4). Complications were distributed as follows in BD and ED patients: recurrent/persistent urinary complications (46% versus 6%, p=0.01), dehydration (27% versus 6%, p=0.05), symptomatic graft pancreatitis (8% versus 6%, p=0.9), gastrointestinal disturbance (27% versus 12%, p=0.1) and wound infection (12% versus 9%, p=0.5). The duration of the operative procedure was 4.3 hours (+/- 0.9) against 5.4 hours (+/- 0.8) in the ED and in the BD group, respectively. Reoperation was necessary in 23% of the BD patients compared with none in the ED group, (p=0.04). Actuarial patient survival rates (96% versus 94%, p=0.6), kidney survival rates (85% versus 87%, p=0.9) and technically successful pancreas (90% versus 85%, p=0.6) survival rates were similar in the BD and in the ED group.

**Clinical conclusions**
When compared with BD, ED was associated with less morbidity and shorter hospitalisation without compromising outcome. Primary ED is therefore a viable alternative to BD in simultaneous pancreas-kidney transplantation.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the analysis and as such the benefits are considered to be the same as the outcome measures. The principal benefits relate, however, to the reduction in morbidity and reduced hospitalisation.

**Direct costs**
Cost figures represent charges rather than true cost. Charges were based on the transplantation admission only and included hospital and organ acquisition charges. All charges were adjusted for inflation. Quantities were reported separately from costs. The quantity/cost boundary adopted was the hospital. Discounting was not undertaken. The price year was 1996.

**Statistical analysis of costs**
Mean values +/- standard deviation were provided. The statistical test mentioned in the study was the student’s t test but it is not clear if this was used in the analysis of costs.

**Indirect Costs**
Not considered.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The length of stay for the transplantation was 12.9 (± 5.6) days with ED versus 20.4 (± 9.6) days with BD, (p=0.2). The total number of readmissions was 1.7 (± 1.5) days with ED versus 1.2 (± 1.2) days with BD, (p=0.2). The length of hospital stay in the first 6 months after discharge was 13.7 (± 16.2) days with ED versus 10 (± 11.3) days with BD, (p=0.4). Complications were distributed as follows in BD and ED patients: recurrent/persistent urinary complications (46% versus 6%, p=0.01), dehydration (27% versus 6%, p=0.05), symptomatic graft pancreatitis (8% versus 6%, p=0.9), gastrointestinal disturbance (27% versus 12%, p=0.1) and wound infection (12% versus 9%, p=0.5). The duration of the operative procedure was 4.3 hours (± 0.9) against 5.4 hours (± 0.8) in the ED and in the BD group, respectively. Reoperation was necessary in 23% of the BD patients compared with none in the ED group, (p=0.04). Actuarial patient survival rates (96% versus 94%, p=0.6), kidney survival rates (85% versus 87%, p=0.9) and technically successful pancreas (90% versus 85%, p=0.6) survival rates were similar in the BD and in the ED group.

Cost results
Hospital charges were $73,458 (± 17,103) and $107,193 (± 32,965) in the ED and BD group, respectively, (p=0.001).

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
When compared with BD, ED is associated with less morbidity and shorter hospitalisation without compromising outcome. Primary ED is a viable alternative to BD simultaneous pancreas-kidney transplantations.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear. ED of exocrine secretion was associated with a poor outcome mostly as a result of infectious complications. This led to the adoption of BD as the primary method of drainage of exocrine secretions. BD, however, can be associated with considerable morbidity, mostly as a result of recurrent urologic complications as well as dehydration and metabolic acidosis which lead to longer hospital stays and increased cost. You, as a user of this database, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis although the validity of reduced morbidity and hospitalisation would appear to be well founded. The data have not been used selectively, but a full economic evaluation using one benefit measure would be required to assure greater validity.

Validity of estimate of costs
Resource quantities were reported separately from the prices and adequate details of methods of quantity/cost estimation were given. Important cost items do not appear to have been omitted.
Other issues
As noted by the authors, the validity of the study results is questionable on the grounds that the study is retrospective and non-randomized and involved small patient samples. Furthermore, ED and BD groups encompassed transplantations performed during two successive periods. As such, differences in management between the time periods include the type of antimicrobial prophylaxis and the type of maintenance immunosuppression. Additionally, only patients with ED benefited from the transplant outpatient units, as patients with BD had transplantation before the introduction of this unit. However, adequate comparisons with other studies were given with respect to the safety, efficacy and resource utilisation of ED.

Implications of the study
Further research is needed to analyse ED and BD groups undergoing transplantations performed during the same time period.

Source of funding
None stated.

Bibliographic details

PubMedID
9358092

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Antibiotic Prophylaxis; Drainage /economics /methods; Exudates and Transudates; Female; Humans; Imunosuppression; Intestines; Kidney Transplantation; Length of Stay; Male; Pancreas Transplantation /economics /methods; Retrospective Studies; Urinary Bladder

AccessionNumber
21997001459

Date bibliographic record published
30/04/1999

Date abstract record published
30/04/1999