Impact of pancreatic head resection on direct medical costs in patients with chronic pancreatitis

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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
Two surgical procedures for pancreas head resection were examined in patients with chronic small duct pancreatitis and an inflammatory mass (>30 mm diameter) in the head of the pancreas. The procedures were pylorus-preserving pancreaticoduodenectomy (PPPD) and duodenal-preserving pancreatic head resection (DPPHR).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with chronic small duct pancreatitis and an inflammatory mass (>30 mm diameter) in the head of the pancreas. Histopathologic confirmation of chronic pancreatitis was required.

Setting
The setting was secondary care. The economic study was carried out at the Department of Surgery and Gastroenterology of the Indiana University School of Medicine at Indianapolis (IN), USA.

Dates to which data relate
The effectiveness evidence and resource use data were gathered between 1992 and 1997. The price year was 1996.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not reported. Of an initial group of 74 consecutive eligible patients, only 34 were enrolled. This was because their complete medical care and hospital stay for at least 12 months before and at least 12 months after surgery were carried out exclusively at the study hospital, and follow-up data were available. It was not stated whether any of the patients refused to participate or were excluded for any reason from the initial study sample. There were 13 patients in the PPPD group and 21 in the DPPHR group. The mean age in the PPPD group was 50 (+/- 11) years and 54% of the patients were men. In the DPPHR group, the mean age was 37 (+/-
10) years and 52% were men.

**Study design**
This was a prospective cohort study that was conducted in a single centre. The patients were allocated to the study groups on the basis of patient preferences, after a thorough discussion of the risks and benefits of each procedure. The pre-operative mean follow-up was 26 months (range: 12 - 36) and the post-operative mean follow-up was 41 months (range: 12 - 73). The loss to follow-up from the initial group of 74 patients was not reported.

**Analysis of effectiveness**
All of the patients included in the initial study sample were considered in the effectiveness analysis. The primary health outcomes were:

- pain severity, estimated using a visual analogue scale ranging from 0 (no pain) to 10 (most severe pain imaginable) at 6, 12, 24, 36, 48, 60 and 72 months;
- both early and late post-operative complications;
- the use of analgesics;
- the rate of pain-free patients; and the occupational rehabilitation rates.

The study groups were comparable at baseline in terms of gender distribution and clinical characteristics, such as etiology of pancreatitis, indication for resection, and co-morbidities. However, those in the DPPHR group were significantly younger.

**Effectiveness results**
The pre-operative pain severity in the DPPHR group was 8.3 (+/- 2.1) at baseline. It decreased to 2.1 at 6 months, then deteriorated slightly to 3.4 at 24 months, although it remained significantly improved compared with pre-operative values, (p<0.001).

Likewise, the pre-operative pain severity in the PPPD group was 7.8 (+/- 1.9) at baseline, decreasing to 1.7 at 6 months, and then deteriorating slightly at 24 months (3.1). However, the difference compared with pre-operative values remained statistically significant, (p<0.001).

Early and late post-operative complications, the use of analgesics and the rate of pain-free patients did not differ statistically between the groups.

The occupation rehabilitation rates were 74% in the DPPHR group and 60% in the PPPD group.

**Clinical conclusions**
The effectiveness study showed that the two procedures were equally effective and safe for the surgical treatment of patients with chronic duct pancreatitis.

**Measure of benefits used in the economic analysis**
The two interventions were shown to have been comparable with respect to efficacy and safety. A cost-minimisation analysis was therefore performed.

**Direct costs**
Discounting was not carried out, but it would have been relevant since the costs per patient were incurred during more than two years. The unit costs were only reported separately from the quantities of resources for inpatient stay. The
health services included in the economic evaluation were hospital and physician services. The analysis considered all the interventions used to treat chronic pancreatitis directly, and abdominal surgery directly related to pancreatitis or that was necessary to treat a complication of surgery or recurrent pain. The direct treatments for chronic pancreatitis were, for example, celiac plexus blocks, endoscopic retrograde cholangiopancreatography with or without sphincterectomy, and pancreatic duct stent placement.

The cost/resource boundary adopted in the study was unclear, despite the fact that the authors stated that a societal perspective was adopted. Resource use was estimated using actual data coming from the sample of patients included in the effectiveness study from 1992 to 1997. The unit costs were estimated from the hospital accounting database for inpatient procedures and from the relative value units multiplied by the 1996 Medicare conversion factor for ambulatory services (physician fees). All the costs were inflated to 1996 values using the medical care consumer price index.

**Statistical analysis of costs**
Statistical tests were conducted to test the statistical significance of differences in the total estimated costs. Normally distributed costs were analysed using analysis of variance, while non-normally distributed data were analysed using the Wilcoxon signed-rank test.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not conducted.

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

**Cost results**
The average disease-specific medical costs per patient were $23,381 (+/- 16,496) in the DPPHR group and $27,295 (+/- 14,702) in the PPPD group, (p=0.018).

The pre-operative costs per patient per year were $9,818 (+/- 9,903) in the DPPHR group and $9,673 (+/- 7,245) in the PPPD group.

The post-operative costs per patient per year were $4,245 (+/- 6,245) in the DPPHR group and $4,387 (+/- 7,135) in the PPPD group.

The costs declined significantly in each group from the pre- to post-operative period, but there was no statistically significant difference between the two groups.

**Synthesis of costs and benefits**
The costs and benefits were not combined and, in effect, a cost-minimisation analysis was performed.

**Authors' conclusions**
Pylorus-preserving pancreaticoduodenectomy (PPPD) and duodenal-preserving pancreatic head resection (DPPHR) were equally effective and safe, although the authors noted that a small cohort of patients was used. Both procedures were associated with a decrease in disease-specific hospital costs, while DPPHR was a little less expensive than PPPD.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was appropriate, as the authors stated that PPPD and DPPHR represented two widely used techniques for patients requiring pancreas head resection. You should decide whether they represent widely used approaches in your own setting.

Validity of estimate of measure of effectiveness
The analysis of the effectiveness used a prospective cohort study, although a randomised design would have been more appropriate. The patients themselves selected their treatment on the basis of information provided by the surgeons. This could have introduced some bias into the process of allocation to the study groups. Indeed, the two groups were not well balanced at baseline because of significant differences in the age of the participants. The authors stated that strict inclusion criteria were used and the study sample may not have been representative of the overall study population. The length of follow-up was reported. The method used to select the sample was not described satisfactorily, in that the reasons for excluding a substantial group of patients were not reported. The greatest limitations to the internal validity of the analysis was the small sample size and the lack of power calculations. The authors noted that a more appropriate measure for assessing pain severity would have been useful.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis and, in effect, a cost-minimisation analysis was conducted.

Validity of estimate of costs
The authors did not identify appropriately the perspective adopted in the study, in that they stated that a societal point of view had been adopted. However, as they noted later in the article, neither the indirect nor outpatient costs were considered due to the lack of high-quality data. The unit costs were not reported separately from the quantities of resource use for all cost items. The sources of the cost and resource use data were reported. The price year was provided, thus simplifying reflation exercises in other settings. Statistical tests of the quantities and resource use were performed, using the appropriate test according to the distribution of the costs. Discounting was not conducted, although it would have been relevant given the long period during which the costs were collected.

Other issues
The authors compared their findings with those obtained from other published studies and found similar results. The issue of the generalisability of the study results was not explicitly addressed, as sensitivity analyses were not conducted and the clinical and economic estimates came from a single centre. However, the authors stated that the conclusions of the analysis should not be extrapolated outside the narrow population considered in the study.

Implications of the study
The study results suggested that both PPPD and DPPHR may be used for the surgical treatment of patients requiring pancreas head resection. Some savings may be obtained with DPPHR, but caution is required when interpreting the study results due to the small sample size considered in the analysis.

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