Concomitant radiochemotherapy in unresectable carcinoma of the exocrine pancreas: cost-effectiveness analysis

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 use of concomitant radiochemotherapy for patients with advanced pancreatic cancer.

Type of intervention
Palliative treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with unresectable pancreatic carcinoma who were sensitive to radiochemotherapy. Patients were included if they were aged no more than 75 years, had an unresectable tumour, had free distant metastases, or had an ECOG score of 0 to 2. Patients who died within 30 days after biliary drainage were excluded.

Setting
The setting for the study was unclear. The economic study was conducted in Italy.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not reported. The price year was not explicitly reported.

Source of effectiveness data
The effectiveness evidence was 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 were performed to determine the sample size. The method used to select the sample was not reported. Overall, 40 patients (22 males and 18 females) were included in group 1 and 45 (27 males and 18 females) in group 2. The mean age of the patients was 63 years in both groups.

Study design
This was a retrospective cohort study. The centres in which the study was conducted were not reported clearly. The length of follow-up was unclear. The methods used to assess the outcomes were not reported.

**Analysis of effectiveness**
It appears that all the patients included in the study were accounted for in the analysis. The primary health outcomes considered were the median survival and the 1- and 2-year survival. These were calculated using the Kaplan-Meier test. No statistical analyses were conducted to show the comparability of the groups.

**Effectiveness results**
The median survival was 4.5 months in group 1 and 10 months in group 2, (logrank p=0.0046). As a result, the incremental survival with concomitant radiochemotherapy over strategy 1 was 5.5 months (0.46 years). The 1-year survival rate was 8% in group 1 and 32% in group 2. The 2-year survival rate was 0% in group 1 and 3% in group 2.

**Clinical conclusions**
Concomitant radiochemotherapy (strategy 2) was statistically significantly more effective than biliary drainage plus observation (strategy 1) in extending survival in the patients included in the study.

**Measure of benefits used in the economic analysis**
The benefit measure used in the economic analysis was the increased survival of concomitant radiochemotherapy over strategy 1. This was expressed as the extra years of life saved (LYS), and was derived directly from the effectiveness analysis.

**Direct costs**
Discounting was irrelevant due to the low survival rate after 2 years. The cost/resource boundary adopted was that of the health care payer. The unit costs and the quantities of resources used were not reported. The analysis of the costs was incremental, in that the extra costs of concomitant radiochemotherapy over strategy 1 were reported. The health service costs included in the costing analysis referred only to the concomitant radiochemotherapy protocol, since the cost of diagnosis and staging were similar in the two groups. The costs were derived from actual data, based on the Italian DRG for hospitalisation and outpatient services in 1998. The quantities of resources used were estimated from a retrospective review of the patients' charts. However, the timeframe of the resource analysis was not reported. The price year was not reported.

**Statistical analysis of costs**
Statistical analyses of the costs were not conducted.

**Indirect Costs**
The indirect costs were not included.

**Currency**
Italian lira (L). These were converted to US dollars ($) using the exchange rate $1 = L 1,800.

**Sensitivity analysis**
To take into account different clinical situations, sensitivity analyses were conducted in which both the costs and the survival associated with the two interventions were varied. Increased survival was varied using the estimated survival +/- 1.5 months. The costs were varied on the basis of a "minimum" or "maximum" treatment protocol. The type of analysis conducted was not explicitly stated.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The incremental cost of concomitant radiochemotherapy was $4,755. The incremental cost was $4,410 for the minimum treatment protocol and $8,375 for the maximum treatment protocol.

Synthesis of costs and benefits
The costs and the benefits were combined through an incremental cost-effectiveness analysis. The incremental cost per LYS of concomitant radiochemotherapy over strategy 1 was $10,337. When varying the survival gains and incremental costs in the sensitivity analyses, the incremental cost per LYS ranged from $7,603 to $25,379.

Authors' conclusions
The analysis showed that concomitant radiochemotherapy was a cost-effective strategy in the treatment of patients with advanced pancreatic carcinoma. The calculated cost per LYS was far below the widely accepted threshold of $50,000.

CRD COMMENTARY - Selection of comparators
The authors did not provide any rationale for the selection of the comparator. The strategy based on biliary drainage plus observation (strategy 1) represented a feasible alternative for the treatment of the patients considered in the study. However, it was unclear whether other treatment protocols were available, but were not considered as possible comparators. You should assess whether strategy 1 represents a widely used health intervention in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a retrospective cohort study, a type of study that is prone to selection bias. Also, the comparability of the groups was not reported. Power calculations were not carried out to determine the sample size, and there was no evidence to suggest that the initial sample size was appropriate for the clinical study question. In addition, the number of centres in which the study was conducted was not reported. The dates during which the effectiveness evidence was gathered were not indicated. The length of follow-up was not reported.

Validity of estimate of measure of benefit
The benefit measure was derived directly from the effectiveness analysis. It would have been interesting to have derived a benefit measure reflecting not only survival, but also the quality of life (such as quality-adjusted life-year), as the authors reported that concomitant radiochemotherapy also improved pain levels, compared with strategy 1.

Validity of estimate of costs
Only the costs of concomitant radiochemotherapy were included in the analysis, since other relevant costs were similar in the two groups. The cost estimations appear to have been quite specific to the study setting, but sensitivity analyses were conducted to assess the cost of different treatment protocols. The price year, and the dates during which the data on resources used were gathered, were not reported. Appropriate currency conversions were reported. However, the resource quantities and the unit costs were not provided, thus hindering the generalisability of the study.

Other issues
The authors did not compare their findings with those from other studies. The issue of the generalisability of the study to other settings was partially addressed through sensitivity analyses on estimates around survival and costs, as different treatment scenarios were assumed. Thus, the external validity of the study was partially enhanced. The results were reported in full for the effectiveness, but selectively for the costs. The authors' conclusions should be considered in the
context of the study population, which might be quite specific, and the lack of sample information.

**Implications of the study**
The authors report that concomitant radiochemotherapy was more effective in relation to strategy 1, not only in terms of longer survival, but also in relation to greater pain reduction and improvements in weight gain. However, no evidence was presented in terms of pain and weight. The other conclusions should be viewed in the light of the caveats outlined, particularly in terms of possible bias or confounding.

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