Hypocaloric jejunal feeding is better than total parenteral nutrition in acute pancreatitis: results of a randomized comparative study

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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 methods of nutritional support were studied among patients with acute pancreatitis (AP). The two approaches were total parenteral nutrition (TPN) and nasojejunal feeding (enteral, EN). TPN was delivered via central vein catheters in patients in the intensive care unit and by peripheral catheter in floor patients. Jejunal tubes were placed by fluoroscopy or endoscopy. For both types of feeding, the goal feeding rates were the provision of 1.5 g protein/kg per day and 25 to 30 kcal/kg per day.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with acute abdominal pain and a 3-fold evaluation of serum pancreatic enzymes, amylase and lipase, with a primary diagnosis of AP.

Setting
The setting was a hospital. The economic study appears to have been carried out at the Division of Gastroenterology of the Medical College of Virginia, Virginia Commonwealth University in Richmond (VA), USA.

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

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 were performed in the preliminary phase of the study on the basis of prior studies. They suggested that 50 patients were required in the overall sample to ensure the detection of statistically significant differences in nutritional outcomes and complications, with 80% power. All 156 eligible patients presenting at the study hospital during a 12-month period were given an initial 48-hour treatment with intravenous fluids and electrolytes in addition to

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analgesics. The mean age was 46 (+/- 1) years and 56 (34%) were women. The average body mass index was 25.5 kg/m². In all, 117 patients (75%) showed improvements and were restarted on a soft oral diet (group O), while the remaining 39 patients were allocated to the two treatment groups (19 to TPN and 20 to EN). To reach the target study sample of 50 patients, 14 more patients were enrolled in the following 3 months (8 to TPN and 6 to EN). Thus, the final sample included 27 patients in the TPN group and 26 in the EN group. The mean age in the TPN group was 50 (+/- 3) years and 14 were women. The mean age in the EN group was 48 (+/- 3) years and 10 were women. The mean body mass index was 26.6 kg/m² in the EN group and 25.7 kg/m² in the TPN group.

Study design
This was a prospective, randomised clinical trial, which appears to have been conducted in a single centre (the Medical College of Virginia). The unit of randomisation was the patient. The method of randomisation was not described. The patients were followed until discharged from hospital. No loss to follow-up appears to have occurred. Two TPN patients required conversion to EN, while two EN patients were given TPN due to complications. The outcome assessment was not blinded.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The health outcomes used in the analysis were:

the average length of stay (LOS),

the duration of nutrition,

the overall one-year recurrence rate,

the daily quantity of nutrients,

the tolerance profile of subsequent oral feeding, and

nutrition-associated complications (hyperglycaemia, line infections, deaths, multiple organ failure, pancreatic necrosis, adult respiratory distress syndrome, and pseudocyst).

A sub-group analysis was conducted, which analysed only those patients with more than three Ranson's criteria (severity of disease). The study groups were shown to have been comparable at baseline in terms of their demographics and clinical characteristics.

Effectiveness results
The LOS was 14.2 (+/- 1.9) days in the EN group and 18.4 (+/- 1.9) days in the TPN group, (p not significant).

The duration of nutrition was 6.7 (+/- 1.1) days (range: 2 - 21) in the EN group and 10.8 (+/- 1.7) days (range: 2 - 43) in the TPN group, (p=0.03).

The overall one-year recurrence rate was 11%.

The daily quantity of nutrients (energy and proteins) given to EN patients was lower than that provided to TPN patients, (p<0.005). Thus, EN was less effective in reaching the estimated nutritional requirements.

After disease resolution, oral feeding was better tolerated in the EN group than in the TPN group. A total of 80% of the EN patients advanced to an oral diet without any problem, compared with 63% of those in the TPN group, (p<0.05).

With respect to nutrition-associated complications, hyperglycaemia and line infections were significantly more frequent in the TPN group than in the EN group, (p<0.05).
The occurrence of the other complications was comparable across the study groups. The results were generally comparable in the sub-group analysis. The exception was the duration of nutrition, which was significantly lower for patients in the EN group, (p=0.03).

**Clinical conclusions**

The effectiveness analysis showed that EN was effective in reducing the duration of feeding and the occurrence of nutrition-related complications, but TPN was faster in reaching the target nutritional requirements.

**Measure of benefits used in the economic analysis**

The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. A cost-consequences analysis was therefore conducted.

**Direct costs**

Discounting was irrelevant since the costs per patient were incurred during a short time. The unit costs were not analysed separately from the quantities of resources used. A detailed breakdown of the costs was not provided. The economic analysis only included the costs for hospitalisation. The cost/resource boundary was that of the hospital that provided the nutritional treatment. Resource used was estimated using data coming from the same patients as those involved in the effectiveness study. The costs were estimated from the study hospital, but no details were provided. The price year was not reported.

**Statistical analysis of costs**

Standard statistical analyses were conducted to test the statistical significance of the difference in the total estimated costs. The authors stated that the power calculations carried out in the effectiveness study were also valid for the cost analysis. The impact of severity of disease on LOS and hospital costs was also evaluated.

**Indirect Costs**

The indirect costs were not included.

**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 estimated average nutritional cost per patient was $394 in the EN group and $2,756 in the TPN group, (p=0.0004).

Severity of disease was strongly associated with total hospital costs. The average hospitalisation costs were $6,794 in patients with no Ranson's criteria and $39,597 in patients with four criteria. Also, for more sickly patients needing nutritional support, those given EN feeding had lower total average hospitalisation costs than those receiving TPN ($26,464 versus $34,530).
Synthesis of costs and benefits
The costs and benefits were not combined because a cost-consequences analysis was conducted.

Authors' conclusions
Jejunal feeding (enteral, EN) was associated with lower complications and reduced costs in comparison with total parenteral nutrition (TPN), which in turn was more effective in reaching the target nutritional requirements. The authors highlighted that most patients settled within 48 hours if treated with bowel rest, thus did not require special nutritional treatment.

CRD COMMENTARY - Selection of comparators
The authors discussed the choice of the comparators. They stated that conventional treatment was to place patients on strict bowel rest and use intravenous feeding (O group) or TPN until the serum enzyme normalised. EN represented the alternative treatment evaluated in the study. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a randomised study, which was highly appropriate for the study question. The internal validity of the analysis was further enhanced by power calculations and the use of intention to treat as the basis for the analysis of the clinical study. The sample selection process was carefully described. Statistical analyses were performed to compare the two groups at baseline and to investigate the significance of differences in the outcome results. The study sample was unselected, and thus is likely to have been representative of the study population. A sub-group analysis was also conducted. However, the method of randomisation was not described and some patients were switched to the alternative treatment due to complications.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences analysis.

Validity of estimate of costs
The perspective adopted in the study was not explicitly stated, but is likely to have been that of the hospital. A breakdown of the cost categories was not provided and the unit costs were not reported separately from the quantities of resources used. The price year was not mentioned. Statistical tests were conducted to compare the estimated costs and to evaluate the impact of disease severity on the economic results. However, the cost estimates were specific to the study setting and no sensitivity analyses were conducted.

Other issues
The authors made extensive comparisons of their findings with those from other studies and discussed the conclusions reached by other authors. However, the issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted. Thus, the overall external validity of the analysis is low. The study referred to patients with AP and this was reflected in the conclusions of the analysis.

Implications of the study
The study results suggested that EN is safer and less expensive than TPN and enables oral feeding to be resumed earlier. The authors stated that further studies should determine whether "EN at normocaloric infusion is as effective as feeding at the hypocaloric rates used in usual daily practice". Also, whether a better control of blood sugar with current insulin infusions improves the outcome in parenteral fed patients. Thus, the actual recommendation is to give a trial of EN to patients who do not improve after bowel rest and intravenous fluids for 48 hours. The switch to TPN should only be considered for those who do not receive any benefit from EN.
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