Comparison of the safety of early enteral vs parenteral nutrition in mild acute pancreatitis

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
Using early total enteral nutrition (TEN) administered via jejunal feedings or early total parenteral nutrition (TPN) in acute pancreatitis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients suffering from acute pancreatitis or an acute flare of chronic pancreatitis, as characterised by abdominal pain with elevated amylase and lipase. The study patients were set to be able to start TEN or TPN within 48 hours of hospital admission, without having any evidence of short bowel syndrome, Crohn’s disease or major pancreatic resection.

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

Dates to which data relate
The dates associated with the effectiveness and resource use data and the price year were not stated.

Source of effectiveness data
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 study.

Study sample
The sample size (20 patients for each group) was determined based on power calculations to detect inter-group differences in terms of clinical outcomes. The initial sample size consisted of 38 patients. After the exclusion of 8 patients (20%) the two study groups each consisted of 16 randomised hospital admissions, giving a total of 32 admissions for 30 patients.

Study design
The study was a randomized controlled trial carried out in two centres. The duration of follow-up was until hospital
discharge.

**Analysis of effectiveness**
The analysis was based on treatment completers only. The primary health outcome measure was the percentage achievement of goal calories. Patient health outcomes were also measured in terms of days to normalization of amylase, and days to diet by mouth, as well as serial mean pain scores per day and length of hospitalisation (LOH). The groups were shown to be comparable in terms of age, sex, etiology of pancreatitis, initial Ranson criteria, APACHE III, and multiple organ failure (MOF) scores. The latter three measures were also recorded during the study period (within 48 hours of admission and then repeated twice every two to three days).

**Effectiveness results**
At day four of hospitalisation (usually the third day of feeding) the mean percentage of the feeding target achieved was 72% in the TEN and 85% in the TPN group, (p>0.05). The mean serial pain scores were reported as having no difference at any point in time (measured daily) with a p value greater than 0.05. The number of days to normalization of amylase was 4.8 (+/- 0.6) for the TEN group and 6.8 (+/- 1.5) for the TPN group, (p>0.05). The corresponding figures for the number of days to diet by mouth were 5.6 (+/- 0.8) and 7.1 (+/- 1.1), (p>0.05). LOH was 9.7 days (+/-1.3) for TEN group versus 11.9 days (+/- 2.6) for TPN group (P>0.05). The mean serial Ranson criteria (measured three times every 48 hours), the APACHE III, and MOF scores decreased in the TEN group, as well as in the TPN group, with the third Ranson criteria being the only one with a p value <0.05 (2.8 for TPN group versus 0.5 for TEN group, p=0.002).

**Clinical conclusions**
Although both groups on entry to the study had a similar degree of severity of pancreatitis, the TPN group appeared to develop less stress-induced hyperglycaemia and was slower to resolve the stress response associated with pancreatitis (as evidenced by the difference in the pattern of serial Ranson criteria) compared with the TEN group.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis and only separate clinical outcomes were reported.

**Direct costs**
Although some quantities of resource use were reported (length of hospital stay, and length of ICU stay), only the resource utilisation associated with nutrition support (endoscopic tube or IV line placement and volume of nutritional hyperalimentation infused) was considered in the cost analysis. The unit costs were derived from mean charges to patients at the two study institutions. The cost analysis (charge to the patient) was performed from the patient=s perspective. The price year was not reported.

**Statistical analysis of costs**
Mann-Whitney U tests were used test differences in costs and length of ICU stay. The difference in terms of length of hospital stay was analysed by means of a Student’s t test. Standard deviations were reported.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean cost of nutrition support was $761 (+/- 50.3) for the TEN group and $3294 (+/- 551.9) for the TPN group, (p<0.005). The length of hospital stay was 9.7 (+/-1.3) and 11.9 (+/-2.6) in the TEN and TPN groups, respectively (p>0.05). The length of ICU stay was in turn 1.3 (+/-0.9) and 2.8 (+/-1.3), (p>0.05).

Synthesis of costs and benefits
Since the TEN option turned out to be weakly dominant, the costs and benefits were not combined.

Authors’ conclusions
TEN for acute pancreatitis is as safe and effective as, but significantly less costly than, TPN. Compared with TPN, TEN may promote more rapid resolution of the toxicity and stress response to pancreatitis. TEN via jejunal feeding should be used preferentially in this disease setting.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator which was the standard of practice for providing exogenous nutrients in pancreatic patients. You should consider whether this a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the study results is questionable due to the small sample size and the fact that the analysis of the results was based on the principle of treatment completers, after the post-randomization exclusion of those patients who did not comply with the protocols.

Validity of estimate of costs
The cost analysis was based on charges as proxies of true costs. The quantities associated with length of hospital and ICU stay were comparable between groups and that appears to be the reason for their exclusion from costing. The price date was not reported.

Other issues
Since the study population was composed of patients with mild, predominantly alcoholic, pancreatitis, the results may not be generalisable to severe acute pancreatitis patients

Source of funding
Supported by a research grant from Clintec Nutrition Company, Deerfield, Illinois.

Bibliographic details