Randomized clinical trial of the effects of preoperative and postoperative oral nutritional supplements on clinical course and cost of care


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 pre- and postoperative oral nutritional supplementation (ONS) among patients undergoing lower gastrointestinal tract surgery. Four groups (CC, SS, CS and SC) were compared. CC received no nutritional supplement. SS received supplements both before and after surgery. CS received postoperative supplements only. SC received supplements only before surgery. Fortisip, a drink containing 1.5 kcal and 0.05 g protein per mL, was used for ONS.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing elective moderate to major lower gastrointestinal tract surgery. The exclusion criteria included age younger than 18 years, pregnancy, overt dementia, and emergency or laparoscopic surgery. Other exclusion were the receipt of other forms of preoperative nutritional support and the inability to take ONS for at least 7 days before the operation. Patients were also not included if they refused to participate in the study.

Setting
The setting was primary and secondary care. The economic study was carried out across three sites in England (two in London and one in Stoke-on-Trent).

Dates to which data relate
The study was published in 2004, but the dates to which the data related were not given. No price year was stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were used to determine the sample size. These showed that 31 patients in each arm were required to achieve 95% power. Of the 532 eligible patients presenting at the participating centres, 179 (34%) met the inclusion criteria and agreed to be randomised into the study. Forty-two were allocated to the SS group, 48 to the SC group, 39 to
the CS group, and 50 to the CC group. The mean age of the participants was 55 years (range: 26 - 81) in the SS group, 61 years (range: 23 - 84) in the SC group, 62 years in the CS group (range: 22 - 83), and 63 years (range: 25 - 88) in the CC group.

**Study design**
This was a multi-centred, stratified, randomised controlled trial. Patients from three hospitals participated in the study. The patients were stratified according to nutritional status prior to randomisation, using a combination of body mass index and history of weight loss and age, to ensure an even distribution of poorly nourished individuals. The patient were randomised to the groups by means of sealed envelopes. All participants were aware of the intervention, as it was not feasible to blind them to the treatment.

Data were collected at recruitment, at hospital admission, on the day of resumption of free fluids or light diet, at hospital discharge, and 2 and 4 weeks after discharge. Twenty-seven patients were withdrawn from the study, leaving 152 patients that completed the treatment. Of these, 32 were in the SS group, 41 in the SC group, 35 in the CS group, and 44 in the CS group. A single dietician at each centre collected the data to minimise inter-observer variation. Questionnaires to assess quality of life were self-completed with the intention of minimising bias.

**Analysis of effectiveness**
The analysis of effectiveness was conducted on the basis of treatment completers only. The primary outcome was the postoperative change in bodyweight. The secondary outcomes were clinical complications, length of hospital stay, nutritional status, and quality of life. Quality of life was assessed using the SF36 and EuroQol instruments. The groups were comparable in age, gender, nutritional status and risk, diagnosis and operation performed, although there was a difference in body mass index between the SS and CC groups. The authors noted the difference, but no adjustment was made.

**Effectiveness results**
There was significantly less postoperative weight loss in the SS group than in the CC and CS groups, (p<0.050, Bonferroni adjusted test). Only patients in the SS group gained weight before surgery.

There were no differences between the groups in any other anthropometric variable measured, or in fatigue and quality of life scores.

There were significantly fewer minor complications in the SS and CS groups than in the CC group, (p<0.050), although the rate of major complications in the four groups was similar.

There were no significant differences in energy consumed between the groups at any time point.

**Clinical conclusions**
The authors concluded that perioperative ONS, started before hospital admission for lower gastrointestinal tract surgery, significantly diminished the degree of weight loss and incidence of minor complications.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was used in the analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
Discounting was not undertaken, which was appropriate given the short timeframe of the study. The quantity/cost boundary adopted was that of the health service. The details of the resource and cost data collected were limited, as the authors stated that further details of the costing methodology would be presented elsewhere. They asserted that "all resource elements in both primary and secondary care" were costed, which included the use of consumables, staff time,
ward costs and specific ward-based tasks. The resource quantities were derived using actual data from the trial and were collected from the beginning of the hospital stay until 28 days after discharge. The costs were obtained from the University Hospital of North Staffordshire and/or national sources. The cost of surgery was excluded from the analysis as it was common to all groups. No price year was stated.

**Statistical analysis of costs**
The costs were treated stochastically, with mean costs and standard deviations being provided. No statistical tests were carried out.

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

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
No sensitivity analysis was undertaken.

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

**Cost results**
The mean cost per patient was 2,289 (95% confidence interval, CI: 2,034 - 2,717) in the SS group, 2,286 (95% CI: 2,050 - 2,566) in the SC group, 2,324 (95% CI: 2,018 - 2,661) in the CS group, and 2,618 (95% CI: 2,272 - 3,181) in the CC group.

Differences in the costs were not statistically significant.

**Synthesis of costs and benefits**
The study was, in effect, a cost-consequences analysis. Therefore, the costs and benefits were not combined.

**Authors' conclusions**
Perioperative oral nutritional supplementation (ONS), started before hospital admission for lower gastrointestinal tract surgery, significantly diminished the degree of weight loss and incidence of major complications. It was also cost-effective.

**CRD COMMENTARY - Selection of comparators**
ONS was compared with no treatment. This allowed the actual effect of ONS to be observed. Groups receiving ONS at different stages of treatment were also compared.

**Validity of estimate of measure of effectiveness**
The basis of the analysis was a randomised controlled trial, which is the 'gold' standard method for an analysis of effectiveness. The study sample appears to have been representative of the study population. The patient groups were shown to be comparable at analysis. No further statistical tests, to account for potential biases and confounding factors, were undertaken and the outcomes were analysed for treatment completers only.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. Therefore, the study was, in effect, a cost-consequences analysis. The lack of a generic benefit measure means that the results cannot be compared with those from studies of other health technologies.

Validity of estimate of costs
The perspective adopted in the economic analysis was that of the health service. It is unclear whether all the categories of cost relevant to this perspective were included in the analysis, as the authors provided little detail. The authors stated that the full costing methodology would be presented elsewhere. The quantities of resources used were also not reported, which restricts the generalisability of the results. A statistical analysis of the prices was not conducted. The date to which the costs referred was not reported, which hinders the reproducibility of the results. Discounting was not carried out, which was appropriate since the costs were incurred during a short timeframe. Overall, the reporting of the costing was poor, so it is hard to judge the validity of the results.

Other issues
The authors made appropriate comparisons of their results with those of other studies. However, the issue of generalisability to other settings was not addressed. The authors might have presented their results selectively as they did not report data for all the outcomes assessed, including quality of life and fatigue. The authors' conclusions reflected the scope of the analysis.

Implications of the study
The study found that the benefit of postoperative ONS was independent of nutritional status. The authors believe this raises questions about the reliability of recently published guidelines, which recommend that elective surgical patients should receive artificial nutritional support only if a preoperative weight loss of 10% or more is observed, or if adequate oral food intake is expected later than 10 days after surgery. The authors suggested further research on whether supplements should be given for longer periods before the operation, and whether there are specific patient groups that might gain greater benefit from ONS.

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