The effect of unselected post-operative nutritional supplementation on nutritional status and clinical outcome of orthopaedic patients

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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
The routine use of unselected oral nutritional supplements for the postoperative management of orthopaedic patients was examined. Supplements were either juice- or milk-based, according to preference. The milk-based drinks contained 300 kcal and 10 g protein per carton, while the juice-based drinks contained 300 kcal and 9.5 g protein per carton.

Type of intervention
Other: Supportive care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients undergoing elective or emergency orthopaedic surgery. The exclusion criteria included a predicted length of stay of less than 7 days, severe renal, liver or malignant disease, obesity (body mass index greater than 30). Other exclusion criteria were pregnancy, nutritional support already being given, malabsorption, uncontrolled endocrine disease, barbiturates, and the prescription of drugs that could interfere with metabolism. Patients with psychopathology such as dementia, Alzheimer's disease or schizophrenia, that was sufficient to impair cooperation or consent, were also excluded.

Setting
The setting was a hospital. The economic study was conducted in the UK.

Dates to which data relate
The dates when the effectiveness and resource use data were gathered were not reported. The price year was not reported. The authors stated only that the data were collected for a period of 18 months.

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

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

Study sample
Power calculations, if performed, were not reported. All eligible patients identified at the authors' institution during an
18-month period of data collection were enrolled in the study. Of an initial group of 231 potentially eligible patients, 55 did not consent. Of these, 33 did not give any explanation, 7 patients felt they were not well enough, 2 feared the possible weight gain due to supplements, 5 did not want additional blood tests, 2 did not like sweet drinks, and one patient was unable to participate because English was not their first language. Therefore, a final group of 181 patients was included in the analysis. There were 84 patients in the intervention group and 97 patients in the control group. The patients in the intervention group had a mean age of 71.3 years (age range: 48 - 88) and 67.9% were female. The patients in the control group had a mean age of 72.9 years (age range: 37 - 90) and 62.9% were female. Food intake was analysed in a sub-group of patients who were randomly identified. This sub-group comprised 20 patients from the intervention group and 28 patients from the control group.

Study design
This was a prospective cohort study that was carried out in two wards of the North Tyneside General Hospital in Sheffield, UK. The patients were allocated to the control or intervention group according to the ward to which they were admitted. A crossover design was employed to remove any potential bias caused by differences in nursing staff. A single observer measured all clinical end points. The patients appear to have been followed until they were discharged from the hospital. No patient appears to have been lost to the follow-up assessment, although some outcomes were available only for the sub-groups of patients.

Analysis of effectiveness
All of the patients included in the initial study sample were accounted for in the effectiveness study. The primary outcome measures were:

- compliance rates;
- food intake analysis (energy intake and protein intake) in the sub-group of patients;
- major complications (wound infections, significant anaemia, pressure sores, bone fusion failure, pneumonia, deep vein thrombosis, pulmonary embolus and septicaemia);
- minor complications (urinary tract infections, transient cough or breathlessness, phlebitis, pressure area erythema, and transient pyrexia with no established diagnosis);
- any changes in medication, additional treatments (e.g. transfusions), specialised radiological investigations, and the number and type of biochemical and haematological assays;
- nutritional parameters (change in body mass index, grip strength and mid-arm-muscle circumference); and
- biochemical parameters (haemoglobin, C reactive protein, transferrin and albumin).

The two groups were comparable in terms of their demographics, clinical characteristics, and the type and frequency of orthopaedic surgery. The authors also stated that the sample of patients was representative of the whole orthopaedic inpatient population.

Effectiveness results
One hundred per cent compliance (taking the full intended number of supplements for the duration of the patient’s hospital stay) was achieved in 14.9% of the patients.

The supplements were taken for a median of 4 days (range: 1 - 55) and the median number of supplements taken was 4 (range: 0 - 79).

Twenty per cent of patients were unable to comply at any level, but were included in the outcome analysis.

Almost 40% of the patients discontinued supplements at some point during the hospital admission. A similar 40% of
patients continued supplements at reduced levels.

In the sub-group analysis (20 patients in the supplemented group and 28 in the control group), the median energy intake was 1,527 kcal/day in the intervention group and 1,289 kcal/day in the control group, (p=0.02). No statistically significant differences were observed for median protein intake. The analysis revealed that those patients in the intervention group who did not receive any supplement had significantly lower energy intake than those who received full supplements.

The total number of major complications was 22 in the intervention group and 55 in the control group, (p=0.0002).

The most frequent complication was wound and joint infections (13.1% in the supplemented group and 21.6% in the control group). However, 11 of 14 patients in the supplemented group who developed major complications had taken less than five supplements in total.

The proportion of patients who developed major complications was 16.6% in the intervention group versus 35.1% in the control group, (p=0.005).

The rate of complications among planned admissions was 19% in the intervention group versus 28% in the control group, (p=0.273).

The rate of complications among emergency admissions was 9.5% in the intervention group versus 51% in the control group, (p=0.0016).

The difference in minor complications was not statistically significant.

Fewer additional treatments were required among the intervention patients. Only differences in the number of ultrasound scans (3 versus 12), antibiotics (35 versus 88 days), urea and electrolyte requests, and units of whole blood (41 versus 77) were statistically significant.

The median length of stay was 9 days (range: 7 - 101) in the intervention group and 10 days (range: 7 - 49) in the control group. The difference was not statistically significant.

The difference in nutritional parameters from baseline to 1-week post-admission did not reach statistical significance.

Among biochemical parameters, only the changes in mean haemoglobin (from 11.7 to 10.9 g/dL in the intervention group and from 12 to 10.9 g/dL in the control group) and transferrin (from 27.7 to 26.3 microg/L in the intervention group and from 28.8 to 26.5 microg/L in the control group) reached statistical significance.

Clinical conclusions
The effectiveness analysis showed that patients in the supplemented group achieved a significantly greater mean energy intake than patients in the non-supplemented group. Other clinical end points (in particular, the reduction in major complications) favoured the routine use of nutritional supplements.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

Direct costs
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were not reported, but the quantities of resources used were. The health services included in the economic evaluation were inpatient days and all additional treatments required in both groups. Surgery costs were not considered because they were comparable between groups. The cost/resource boundary of the study was not explicitly stated, but it could have been that of the hospital. Resource use was estimated using patient-level data that were derived from the sample of patients included in
the effectiveness study. The source of the costs was not explicitly reported. The price year was not given.

**Statistical analysis of costs**
The costs were presented as mean and median values. No statistical analysis, to test the statistical significance of differences in the estimated costs, was conducted.

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

**Currency**
UK pounds sterling (£).

**Sensitivity analysis**
Sensitivity analyses were not carried out.

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

**Cost results**
The total costs for additional treatments were 2,533.99 in the intervention group (84 patients) and 4,484.53 in the control group (97 patients). Therefore, the mean (median) cost per patient was 30.16 (1.26) in the intervention group and 46.23 (5.97) in the control group. Thus, nutritional supplements led to mean (median) cost-savings of 16.07 (4.71).

When the cost of hospital stay was considered, the median cost per patient was 2,068.47 in the intervention group and 2,198.68 in the control group.

At the authors’ institution there would have been a sample of 868 patients eligible for nutritional supplements, which would have generated potential annual savings of 13,949.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

**Authors’ conclusions**
Compared with no nutritional supplements, the routine use of unselected oral nutritional supplements led to an improvement in energy intake, fewer complications, and a reduction in the cost of additional treatments for patients who had undergone orthopaedic surgery.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator (no nutritional supplements) was clear. It permitted the actual value of the intervention to be evaluated. You should decide whether this represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a cohort study. This was appropriate for the study question since the two study groups were comparable at baseline and the authors reduced the impact of possible bias and confounding factors. The method used to select the sample was reported, as was the approach used to assess the clinical outcomes. Statistical tests
to determine the statistical significance of differences in the estimated clinical end points were conducted. The study sample appears to have been representative of the patient population. These issues tend to enhance the external validity of the analysis. However, there was no evidence of the appropriateness of the sample size and power calculations were not carried out. Some clinical outcomes were assessed in sub-groups consisting of small numbers of patients.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The authors did not explicitly state the perspective adopted in the study, but it appears to have been that of the hospital that provided the services. The unit costs and the price year were not presented, which limits the possibility of replicating and reflating the results of the analysis in other settings. Details of the resource use data were reported. The costs were treated deterministically and were specific to the study setting. Caution is therefore required when extrapolating the economic results to other contexts.

**Other issues**
The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not carried out, which limits the external validity of the analysis. The study referred to patients who had undergone orthopaedic surgery and this was reflected in the authors’ conclusions.

**Implications of the study**
Since some problems with compliance were observed, the authors noted that the type and amount of supplementation, and its mode of administration, should be carefully considered to maximise compliance.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
12553948

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Aged; Aged, 80 and over; Arm /physiology; Blood Proteins /analysis /drug effects; Body Mass Index; Dietary Proteins /administration & dosage; Dietary Supplements /economics /statistics & numerical data; Energy Intake
AccessionNumber
22003000383

Date bibliographic record published
31/03/2005

Date abstract record published
31/03/2005