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Randomized Control Trials

A randomised trial of post-discharge enteral feeding following surgical resection of an upper gastrointestinal malignancy

Farid Froghi^{a,*}, Grant Sanders^a, Richard Berrisford^a, Tim Wheatley^a, Paul Peyser^a, Jo Rahamim^a, Stephen Lewis^b^a Department of Surgery, Plymouth Hospitals NHS Trust, Derriford Hospital, Plymouth, Devon, UK^b Department of Gastroenterology, Plymouth Hospitals NHS Trust, Derriford Hospital, Plymouth, Devon, UK

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SUMMARY

Background: Patients undergoing upper gastrointestinal surgery often eat poorly post-operatively, despite dietetic input. A pilot study was conducted to examine the benefit of a 6 week nutritional supplementation via a feeding jejunostomy on fatigue, quality of life and independent living.

Methods: A feeding jejunostomy was placed routinely at oesophagectomy or total gastrectomy for cancer. At discharge, patients were randomised to nutritional supplementation (600 kcal/day) via their feeding jejunostomies or no jejunal supplement. Patients were assessed at discharge and 3, 6, 12 and 24 weeks following discharge for fatigue (MFI-20), quality of life (QLQ-OES18), health economic analysis (EQ5D) as well as completing a two-day dietary diary.

Results: 44 patients (M:F, 29:15) were randomised, 23 received jejunal supplements. There were no differences between the groups. Percentage of calculated energy requirement received was greater in the supplemented group at weeks 3 and 6 ($p < 0.0001$). Oral energy intake was not different between the groups at any time period. After hospital discharge, there were no differences in MFI-20, EQ5D and QLQ-OES18 scores at any time point. From hospital discharge fatigue improved and plateaued at 6 weeks ($p < 0.05$ for both groups), independence at 12 weeks ($p < 0.05$ for both groups). No improvement was seen in quality of life until 24 weeks in the active group alone ($p < 0.02$) and not at all in the control group.

Conclusions: Addition of jejunal feeding is effective in providing patients with an adequate energy intake. Increased energy intake however, produced no obvious improvement in measures of fatigue, quality of life or health economics.

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1. Introduction

Despite dietetic input, patients often eat poorly immediately following upper gastrointestinal surgery, with patients losing up to 10% of their preoperative weight [1,2]. The mechanics of the surgery leads to a loss of gastric reservoir function, lack of appetite, altered intestinal motility and gastro-oesophageal reflux which usually results in reduced dietary intake and further weight loss following hospital discharge [1,3]. Feeding jejunostomies are often placed during gastroesophageal surgery, however, practice is varied across

centres in the UK. Timing of discontinuation of jejunal feeding is also variable.

There are no studies showing any clinical benefit or improvement in quality of life from nutritional supplementation following hospital discharge after surgery [4]. Also, despite these patients being 'at higher risk' nutritionally than other surgical patients, there have been no studies of nutritional supplementation post hospital discharge in patients who have undergone upper gastrointestinal resections. Under nutrition seen post hospital discharge after upper gastrointestinal surgery may exacerbate the reduced quality of life and fatigue patients' already experience. However, the process of enteral feeding itself may also contribute to a reduced quality of life for these patients.

The authors hypothesise that improving patients' nutritional intake following hospital discharge will improve their fatigue levels and quality of life. There is little evidence on which to base sample

* Corresponding author. Department of Upper GI Surgery, Level 7, Derriford Hospital, Derriford Road, Plymouth, PL68DH, UK. Tel.: 01752 517649; fax: +44 01752 792240.

E-mail address: farid.froghi@nhs.net (F. Froghi).

size calculations. We hereby present the results of a pilot prospective single-centre randomised trial of six-week post discharge jejunal supplementation in patients undergoing upper gastrointestinal surgery for cancer.

2. Methods

2.1. Patients

Consecutive patients referred for an elective 'curative' upper gastrointestinal surgery (oesophagectomy or total gastrectomy) for malignancy at a tertiary referral centre (Peninsula Oesophago-Gastric Unit, Derriford Hospital, Devon, UK) were approached and given information about the study preoperatively.

All patients were operated upon by their attending surgeon, had standard postoperative care according to local protocols and had a feeding jejunostomy placed at the time of surgery as per unit 'routine practice'. Patients in whom the jejunostomy feed was used postoperatively without complication, were approached one to two days before hospital discharge. Consenting patients were then randomly allocated to either the study 'control' or 'interventional' group. Patients were excluded if they were participating in another trial, age <18, oral intake at hospital discharge of >90% of requirements, or it is felt that they or their carers would not cope with home tube feeding and those unable to give written informed consent. Patients with very low (<18) or high (>35) pre-operative BMIs required specialist dietetic input and were excluded from the trial.

All patients received dietician review during hospital stay and just prior to hospital discharge and were offered oral nutritional supplements to take at home.

The study was approved by the Southwest Research Ethics Committee (UKCRN 7704).

2.2. Intervention

Patients allocated to jejunal feeds were given 600 kcal/day of enteral feed (Fresubin® original) to be taken via their jejunostomy for 6 weeks post hospital discharge as per standard practice in our institution. Appropriate education and consumables were supplied.

The 'control' group received no jejunal feed post hospital discharge, but retained their feeding jejunostomy. The feeding jejunostomies were removed in clinic at six weeks post hospital discharge.

2.3. Data collection

The primary outcome was chosen as improvement in fatigue as measured by the multidimensional fatigue inventory (MFI-20) score [5,6]. The MFI-20 is divided into five scales: general fatigue, physical fatigue, reduced activity, reduced motivation and mental fatigue. The QLQ-OES18 scale [6]; a disease specific Health Related Quality of Life (HRQL) questionnaire, designed to examine the influence of upper gastrointestinal pathology on patients following treatment was also used. Health economic analysis was based on the EQ-5D scale [7]; this scale defines health in terms of five dimensions: mobility, self-care, usual activities, pain and anxiety.

Demographic, clinical, operative and postoperative data were recorded. At hospital discharge patients completed a two-day dietary diary, MFI-20, QLQ-OES18 and EQ5D scales. At 3, 6, 12 and 24 weeks following discharge all these were completed again. In addition, patients were asked about any complications relating to their surgery or jejunostomy feeding.

Data from the two-day dietary diaries were entered into Dietplan 7 (Forestfield software, Horsham, UK) from which a mean

daily energy intake value (Kcal) was calculated. Patient calculated energy requirements using the Harris-Benedict formula [8].

2.4. Randomisation and statistical analysis

A Microsoft Access® based computer randomisation software was used to allocate patients randomly to one of the two study groups stratified by operation site (gastric and oesophageal). Results were analysed non-parametrically (Mann-Whitney) and data presented as medians with interquartile ranges (IBM SPSS v17.0).

2.5. Power calculation and sample size

A power calculation performed prior to start of the trial demonstrated that two groups of 64 patients would give a power of 80% for detecting an effect size of 0.5 (This represents a change of two in one of the (five) MFI-20 scores (scales), with standard deviation 4.0 which was felt to be a clinically significant change in other surgical studies [9,10]). Due to the uncertainty in the size of effect, and the potential for 'drop outs' post-surgery we felt a 'full sized' study would need to recruit a total of 160 patients (80 in each group). We decided a pilot study of 44 patients would give us enough information on the size of effect and recruitment rate to plan an adequately powered study. Overall one hundred upper gastrointestinal resections are done per year for cancer in our centre.

3. Results

Between December 2012 and July 2014, a total of 44 patients (M:F, 29:15) were randomised (Fig. 1). Twenty-three patients received jejunal supplements and twenty-one received no supplementary jejunal feeding. The patients' baseline demographics and operative data are presented in Table 1. No difference between the groups were noted.

The percentage of calculated energy requirement received was greater in the supplemented group at weeks 3 and 6 ($p < 0.0001$) than the control group (Fig. 2). The 600 kcal supplementation was well tolerated and boosted patient's daily energy intake to a desirable amount (percentage of calculated requirements at 3

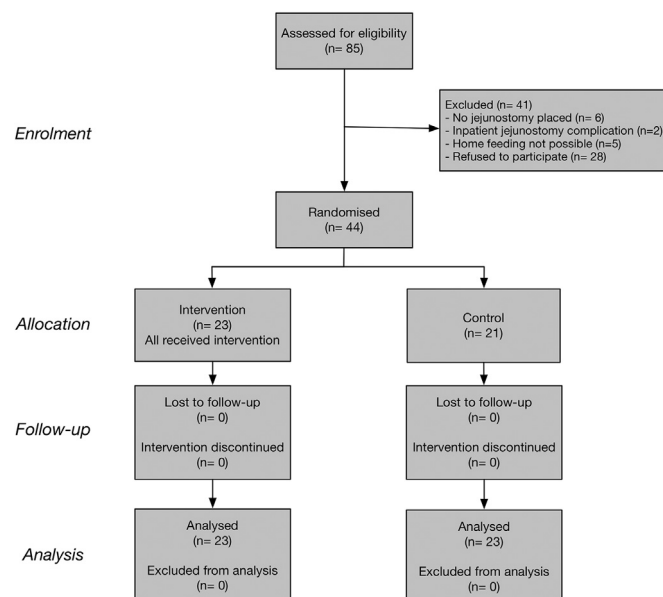


Fig. 1. Consort diagram.

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