European Journal of Cancer 64 (2016) 107–112

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejcancer.com

Original Research

Impact of home enteral nutrition in malnourished patients with upper gastrointestinal cancer: A multicentre randomised clinical trial

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Received 1 February 2016; received in revised form 11 May 2016; accepted 20 May 2016

KEYWORDS
Gastrointestinal cancer;
Malnutrition;
Home enteral nutrition;
Nutritional counselling

Abstract ***Background:*** Weight loss is frequent in patients with gastrointestinal (GI) cancer. Nutritional status deteriorates throughout anti-cancer treatment, mostly after major surgery, increasing complications, reducing tolerance and worsening the final prognosis. Enteral nutrition is safe and effective in malnourished patients undergoing major GI surgery. Randomised trials aimed at investigating the effects of home enteral nutrition (HEN) in post-surgical patients with GI cancer are lacking. This study compares HEN and counselling in limiting weight loss during oncologic treatment.

Patients and methods: Patients with upper GI cancer and candidate to major surgery were included in the protocol when the nutritional risk screening (NRS 2002) score was $\geq$3. All patients were supported with enteral nutrition through a jejunostomy after surgery and randomly assigned to continue enteral nutrition or receiving nutritional counselling after discharge. Nutritional and performance status, quality of life (QoL) and tolerance to cancer treatment have been evaluated at 2 and 6 months after discharge.

Results: Seventy-nine patients were randomised; 38 continued enteral nutrition at home and 41 patients received nutritional counselling only. After 2 months, patients on HEN maintained their mean body weight, while patients in the nutritional counselling group showed a weight loss of 3.6 kg. Patients supported on HEN had a higher chance to complete chemotherapy as planned (48% versus 34%). QoL was not worsened by HEN. No complications were reported.

Conclusions: HEN is a simple and feasible treatment to support malnourished patients with

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http://dx.doi.org/10.1016/j.ejca.2016.05.032
0959-8049/Published by Elsevier Ltd.

upper GI cancer after major surgery and during chemotherapy in order to limit further weight loss.
Published by Elsevier Ltd.

1. Introduction

Malnutrition in gastrointestinal (GI) cancer patients negatively affects all different phases of oncologic treatment and represents an independent prognostic factor for worse clinical outcomes [1,2]. In more detail, malnutrition increases surgical morbidity and mortality, enhances the incidence and severity of chemo- or radiotherapy-associated toxicities, prolongs hospital staying and decreases performance status and quality of life (QoL) [2].

Weight loss is the most frequent sign of malnutrition, often present since diagnosis [3], with a prevalence in GI cancer patients ranging from 49.5% to 69.2% [4,5]. It is associated with shorter survival [6,7]. Of note, standard treatment approaches for GI cancer such as surgery and chemoradiotherapy further deteriorates nutritional status [8,9]. In order to maintain an adequate nutritional status over the oncological treatment period, regular assessment of nutritional indicators and specific nutrition interventions should be instituted from diagnosis [10–12]. Body mass index, recent weight loss and change in food intake correlate with impaired organ function and clinical outcome; these parameters, together with assessment of clinical conditions, are used to calculate the nutritional risk score with the NRS 2002 tool and therefore to identify patients who are more likely to benefit from nutritional intervention [13].

Enteral nutrition is safe and effective in malnourished patients undergoing major GI surgery [12,14–16]. After hospital discharge, the continuation of home enteral nutrition (HEN) and regular monitoring of nutritional status might prevent further deterioration of nutritional status and allow patients to complete scheduled anticancer treatment [17,18]. However, to our knowledge, prospective evidence specifically aimed at investigating the effects of HEN in post-surgical patients with GI cancer is lacking.

This randomised study evaluates the impact of HEN on nutritional status, QoL and chemotherapy feasibility in malnourished patients affected by upper GI cancer who underwent major surgery.

2. Patients and methods

2.1. Design

This was a multicentre, controlled, open-label, two-parallel groups, randomised clinical trial conducted at the Fondazione IRCCS Istituto Nazionale dei Tumori (Milan, Italy) and at the European Institute of Oncology (Milan, Italy). Patients were randomly assigned – by a computer-generated list – in a 1:1 ratio stratified according to centre by following a random permuted block design to receive either HEN (treatment group) or nutritional counselling only (control group). Each row of the list contained the randomisation number (progressive number) and the randomisation arm. One interim and one final efficacy analyses were planned, with the interim analysis to be performed when half of the patients had been followed for at least 6 months.

The study was conducted in line with the Helsinki declaration; its design was approved by the local Ethical Committees and all patients signed an informed consent before inclusion.

During the study, the patients will not be blinded as to which random arm they are in. The trial was registered at clinicaltrials.gov (registration number NCT02664974).

2.2. Patients

Adult (>18 years) patients with documented cancer of the upper GI tract (oesophagus, stomach, pancreas, biliary tract) who were candidate for major elective surgery and presented a preoperative nutritional risk score ≥3 according to the NRS 2002 tool [13] were eligible. Exclusion criteria were as follows: Karnofsky index <60, renal insufficiency (ongoing haemodialysis or plasma creatinine >3 mg/dl), respiratory insufficiency (arterial blood PaO_2 <70 mmHg), American Society of Anaesthesiology score 4–5, Child–Pugh liver function class C, short bowel syndrome, pregnancy or need for emergency or palliative surgery. Patients with foreign residence, residents in an Italian region with no specific regulation for HEN or those unable to be regularly followed-up were excluded as well from accrual.

Patients were free to leave the study at any time. The investigators also could withdraw subjects from the study in case of administrative issues related to HEN product delivery or repeated absence to planned follow-up controls.

2.3. Interventions

The study was conducted from December 2008 to June 2011; the minimum treatment period was 2 months. All patients continued observation until 6 months after discharge.