

Adapted ice cream as a nutritional supplement in cancer patients: impact on quality of life and nutritional status

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Abstract

Aims The aim of this study was to assess the impact of adapted ice cream as a dietary supplement on the quality of life (QLQ) of malnourished patients with cancer.

Material and methods We present an exploratory prospective observational study comparing two patterns of nutrition in cancer patients admitted during the study period who presented malnutrition disorders: adapted ice cream (Group I: 39 patients) and nutritional supplements (Group II: 31 patients). Patients were selected from two different hospitals from the same Oncologic Institute. QLQ was evaluated with the Hospital Anxiety and Depression Scale (HADS) and QLQ of the European Organization for Research and Treatment of Cancer (EORTC QLQ C30). Nutrition was determined by the PG-SGA test.

Results HADS showed significant differences in anxiety ($p=0.023$) and depression ($p=0.011$) at the end of the study only in Group I. QLQ-C30 revealed statistically significant differences in baseline measures of global dimension between the two groups (Group I: 40.64–56.36 CI; Group II: 25.70–43.11 CI; $p=0.017$). Differences were also present in the social dimension (Group I: 77.42–93.51 CI; Group II: 55.85–82.85 CI; $p=0.039$). Statistically significant differences were observed between the two groups at the end of the study in the global scale: Group I had 49.36–63.88 CI and Group II had 33.05–51.88 CI ($p=0.016$), and in the fatigue scale: Group I had 36.19–53.83 CI and Group II had mean=65.87, 52.50–79.23 CI ($p=0.007$).

Conclusions The administration of ice cream could cover, in part, the social aspect of food and improve QLQ in malnourished cancer patients. These results are encouraging and deserve further confirmation.

Keywords Advanced cancer · PG-SGA test · HADS test · QLQ C30 · Malnutrition · Ice cream · Quality of life

Introduction

The primary aim of cancer treatment is to cure the disease; it is assessed by tumour control and patient survival. Adverse effects of cancer treatment occur at different levels (vomiting, anosmia, dysgeusia, dysphagia, etc.), and may interfere with the process of feeding. Furthermore, cancer patients present a risk of malnutrition for different reasons [1]: (a) release of substances that reduce appetite and nutrient intake (TNF-alpha, IL-6 and interferon-gamma); (b) increase of nutrient consumption via gluconeogenesis at the expense of muscle protein reserves and lipolysis in adipose tissue leading to cancer cachexia; and (c) some tumours, such as head and neck, oesophagus, stomach or lung, may interfere with the processes related to food, digestion and food absorption.

These factors cause varying degrees of malnutrition, decreased tolerance and effectiveness of treatment, with reduced tumour control and decreased survival. Dietary status has an important impact on treatment response and/or survival in the case of lung, digestive system, colon, breast, head and neck tumours [2]. Besides, malnutrition is associated with a greater incidence of complications (infections, fistulas, etc.) and mortality. Fifty per cent of patients with advanced cancer present malnutrition problems that require intervention [3]. Early identification of malnutrition and optimal treatment allow greater therapeutic efficacy, fewer complications and increased quality of life (QLQ). In cases where the normal oral diet is inadequate, the ingestion of nutritional supplements (NS) is useful to increase nutrient intake and to maintain or improve the nutritional status and functional capacity in cancer patients. No ideal supplement is available, but a standard polymeric diet in the form of a hypercaloric hyperproteic diet with or without fibre administered as liquid or cream is recommended. These pharmacological NS include the series of fatty acids omega 3 (eicosapentaenoic acid), arginine or leucine, which appear to have beneficial anabolic effects, although their level of evidence has not been demonstrated in systematic reviews [4]. Nonetheless, although these NS help restore nutritional status, they do not address the socio-cultural and fun aspects of food as they exclude the sensory pleasures, and social and cultural habits associated with food and eating.

This is a prospective comparative study that assesses the impact of adapted ice cream as a dietary supplement and traditional NS on the QLQ of malnourished patients with advanced cancer. The cost of implementing this intervention is also presented in our study.

Material and methods

We present an exploratory prospective observational study comparing two patterns of nutrition: adapted ice cream (Group I) and NS (Group II). Patients were selected from the Inpatient Units of the Medical Oncology Services of

the Consorci Sanitari de Terrassa and Hospital Parc Taulí in Sabadell from December 2005 to July 2008. The study was approved by the Ethics Committee and the Clinical Research Centre of Consorci Sanitari de Terrassa.

Inclusion criteria:

1. Cancer patients admitted for any reason during the study period who presented with a malnutrition disorder detected by biochemical parameters (levels of albumin <34 mg/l, protein <60 mg/l and cholesterol <3.9 mmol/l) and by validated tests.
2. Patients who agreed to participate in the study and provided signed informed consent.
3. Patients with a Karnofsky Performance Status index (KPS) $\geq 40\%$.

Exclusion criteria:

1. Patients with KPS <40%.
2. Readmitted patients included in the study.
3. Patients with physical or cognitive deficit impeding questionnaire completion.
4. Lactose intolerance.
5. Insulin dependence or difficulty controlling diabetes.

Intervention groups:

- Group I: Nutritional intervention with tailored ice cream.
- Group II: Intervention with traditional NS.

Intervention

Assignment to a group (I vs. II) was conducted by the hospital to avoid bias in the study. Ice cream was administered in the Consorci Sanitari de Terrassa and NS in the Hospital Parc Taulí of Sabadell. As both hospitals are part of the IOV, they share the same organisational structure in diagnostic procedures, treatment protocols and guidelines of cancer follow-up. Given the difficulty in recruiting patients, once patients were included in Group I, intervention, both hospitals recruited patients who were administered NS.

Patients who met the inclusion criteria were selected by two physicians from the oncology departments of the two participating hospitals. A nurse was trained as an outside observer to confirm inclusion criteria, obtain informed consent and collect clinical data, and to administer the various tests for evaluating the intervention. A new observer was included in the last months of data collection, after the nurse withdrew from the study.

Group I was administered two 90-g servings of ice cream per day, from a selection of seven flavours (cream, vanilla, nougat, cinnamon, chocolate, coffee and hazelnut), with a known composition of immediate-release active principles and a higher fat intake of lactic origin.

Group II was given nutritional supplements in the form of 2 or 3 shots per day of 200 ml (Fortisiv® and Clinutren®),

Table 1 Mean values for ice cream and NS

Type of nutrition	Ice cream (90 g)	NS (100 ml)
Quantity per day	2–3/day	2–3/day
Energy	149–255 kcal	150–250 kcal
Proteins	3.5–5 g	3–5.5 g
Carbohydrates	23.4–27.5 g	20.5–27 g
Lactose	4.3–6.2 g	3.5–6 g
Fats	4.8–15 g	5–14 g

also with a known composition of immediate-release active principles (Table 1).

A total of 115 patients who met the inclusion criteria were included in the study. Of these, 39 were in the intervention arm with specially adapted ice cream (Group I) and 31 in the NS group (Group II). A total of 45 patients were excluded from the analysis despite fulfilling the inclusion criteria, as they were unable to complete the questionnaires due to severe worsening (13) or death (29), and 3 did not undergo the final laboratory test. The mean age of the subjects excluded was 68 years (95% CI: 65–71), 51.1% (23) had metastasis, and the most frequent tumour location was the lung, in 29% (13).

Measurements

Signed informed consent was obtained from all the subjects selected for participation in the study. Complete sociodemographic and clinical data were collected including age, gender, date of diagnosis, stage of disease, Karnofsky score (KPS), Barthel, Body Mass Index (BMI) and treatment received. The following questionnaires were administered to measure the patients' emotional state: the Hospital Anxiety and Depression Scale (HADS) and the QLQ of the European Organization for Research and Treatment of Cancer (EORTC QLQ C30). Nutritional status was determined by the Ovesen test [5] (Table 2) to determine the type of disturbance and its intensity and by the Patient-Generated Subjective Global Assessment [6] (PG-SGA). The results of the PG-SGA were categorised in two groups, to reflect slight malnutrition (level A in PG-SGA) or moderate-severe malnutrition (level B+C in PG-SGA).

Tools

HADS [7] is a 14-item questionnaire developed to screen for clinically significant anxiety and depression in general medical patients. This scale was adapted and validated in a Spanish population [8]. Each item was scored from 0 to 3, the latter indicating the highest values and a greater tendency to anxiety and depression. The Spanish version of the HADS has shown consistency and external validity [9].

EORTC QLQ C30 has 30 items that use 5 functional scales (physical, role, emotional, cognitive and social functioning), 3 symptoms scales (fatigue, pain, and nausea

Table 2 Ovesen test

TI	Have you noticed a change in taste?
II	Have you noticed a change in smell?
III	Do you have difficulty chewing or swallowing?
IV	Do you have a dry mouth?
V	Do you vomiting or nausea?
VI	Have you lost your appetite?
VII	Do you have diarrhoea or constipation?
VIII	Do you feel full fast after eating?
IX	Have you gone off any food?
X	Do you feel pain?

and vomiting), global QOL and 6 questions about common symptoms [10]. The EORTC QLQ C30 has been validated for use in Spain [11].

To evaluate nutritional status we used the Scored Patient-Generated Subjective Global Assessment (PG-SGA) in its Spanish translated version. The Spanish version was revised by its author and has not had any subsequent modifications. The PG-SGA identifies patients who require and may benefit from intensive nutritional support. It looks into the interrelationship of weight loss, current dietary intake in relation to the usual intake of the patient, digestive symptoms in the last 2 weeks, functional capacity and metabolic requirements. Each parameter is assessed as mild (A), moderate (B) or severe (C) [12, 13].

Statistical analysis

SPSS for Windows (Version 13.0) was used for statistical analysis. We performed a descriptive analysis of the variables presenting the results in absolute and relative frequency for qualitative variables and average confidence interval for the quantitative variables. The ANOVA and Kruskal-Wallis tests were used for statistical comparison before and after nutritional intervention, with Group II as a control group. The KPS questionnaire was analysed as a qualitative variable with three intervals (40–50, 60 and 70). Statistical significance was established at 5%.

Results

The mean age of the subjects, the most common site of cancer, the distribution of each KPS value and stages III or IV allocated in each group (I or II) are shown in Table 3.

There was no statistically significant difference in KPS between groups ($p=0.132$) or in median Barthel scores.

The two groups were homogeneous and comparable in age, gender, anxiety and depression (HADS test) at baseline, BMI, KPS, Barthel, PG-SGA and disease staging (Table 3). Statistically significant differences were observed in one of the items of the Ovesen test ("Do you feel full fast after eating?") (Table 4).

Table 3 Characteristics of the results by group

	Ice cream	NS
Age	63 (CI95: 59–67)	62 (CI95: 58–66)
Gender (M/F)	56.4%/43.6%	53%/47%
Tumour location		
Lung	33.3%	25.8%
KPS		
40–50	41%	29%
60	20.5%	45.2%
70	30.8%	25.8%
Tumour stage		
III	23.1%	35.5%
IV	76.9%	64.5%

NS, nutritional supplement; CI, confidence interval; M, male; F, female; KPS, Karnofsky Performance Status index

There were no statistically significant differences in biochemical objective parameters of nutritional status at baseline in the two groups with respect to cholesterol ($p=0.390$) or protein ($p=0.715$). A difference was found in values of albumin ($p=0.04$) (Table 5).

In Group I, 48% (19) had one altered biochemical factor, 38.5% (15) had two and 12.8% (5) had three altered factors. In Group II, 45.2% (14) had one altered biochemical factor, 41.9% (13) had two and 12.9% (4) had three altered factors. No statistically significant differences were found between the two groups ($p=0.952$). This biochemical distribution was maintained in the first week of admission,

while the blood test at discharge revealed a lower rate of malnutrition in both groups, but no statistically significant difference.

In relation to HADS, significant differences were found at the end of the study in Group I in anxiety ($p=0.023$) and depression ($p=0.011$), but not in Group II ($p=0.410$ and $p=0.891$ respectively).

The baseline PG-SGA scores in Group I were: 28.2% (11 patients) were mildly malnourished (Group A) and 71.8% (28) were moderately or very badly malnourished (Group B+C). With respect to the final score obtained in the PG-SGA evaluation, 25.8% (8) belonged to Group A and 74.2% (23) to Group B+C, with a statistically significant improvement between the two measurements after admission ($p=0.000$) (Table 6).

In Group II, 9.7% (3) belonged to group A and 90.3% (28) to Group B+C. The measurement of the final PG-SGA after admission showed that 25.8% (8) belonged to Group A and 74.2% (23) Group B+C, with a statistically significant difference between the two measurements ($p=0.012$).

The average length of stay of subjects in Group I with a PG-SGA of A was 6 days (CI=2.3–9.8), whereas the average length of stay for patients with worse SGA (B+C) was 10 days (CI=7.5–11.9). In intervention Group II, the average stay was 20.6 days (CI=5.2–35.9) for the better nourished Group (A) and 16.9 days (CI=12.8–20.9) for the worst prognosis Group (B+C).

While the intervention group with NS showed no statistically significant difference in relation to malnutrition (A

Table 4 Baseline characteristics per group

	Ice cream (n=39)	NS (n=31)	p
HADS A1	8.71 (7.37–10.06)	7.83 (5.95–9.71)	0.430
HADS D1	7.66 (6.22–9.10)	9.09 (7.37–10.81)	0.196
Barthel	15.02 (13.66–16.38)	13.74 (12.36–15.12)	0.189
Age	63.31 (58.99–67.62)	62.45 (58.35–66.56)	0.775
Nutritional study			
Cholesterol	4.51 (3.72–5.30)	3.99 (3.09–4.88)	0.390
Albumin	n=33, 30.92 (29.53–32.31)	n=23, 28.52 (26.55–30.49)	0.040
Proteins	58.21 (56.41–60.01)	n=30, 57.42 (52.97–61.87)	0.715
Metastasis	30 (76.9%)	20 (64.5%)	0.520 unilateral

Table 5 Ovesen test results

		Group A %	Group B %
I	Have you noticed a change in taste?	56.4	68.8
II	Have you noticed a change in smell?	38.5	40.6
III	Do you have difficulty chewing/swallowing?	43.6	56.3
IV	Do you have a dry mouth?	89.7	90.6
V	Do you have vomiting or nausea?	25.6	31.3
VI	Have you lost your appetite?	76.9	87.6
VII	Do you have diarrhoea or constipation?	59	68.8
VIII	Do you feel full fast after eating?	61.5	84.4
IX	Have you gone off any food?	35.9	53.1
X	Do you feel pain?	41	40.6

Table 6 PG-SGA evolution after intervention in each group

	Ice cream			NS		
	Baseline	Endpoint	<i>p</i>	Baseline	Endpoint	<i>p</i>
SGA-A	28.2%	25.8%	0.000	9.7%	25.8%	0.012
SGA-B+C	71.8%	74.2%		90.3%	74.2%	

Table 7 QLQ-C30 measures in baseline and endpoint analysis

	Ice cream (n=39)	NS (n=31)	<i>p</i> value
Baseline			
Physical	44.78 (36.17–53.40)	38.06 (27.51–48.61)	0.311
Role	27.77 (16.94–38.60)	12.90 (5.54–20.25)	0.104
Emotional	58.33 (49.14–67.52)	58.33 (47.14–69.52)	1.000
Cognitive	70.08 (61.04–79.12)	75.80 (67.93–83.67)	0.350
Global	48.50 (40.64–56.36)	34.40 (25.70–43.11)	0.017
Social	85.47 (77.42–93.51)	69.35 (55.85–82.85)	0.039
Fatigue	59.82 (50.45–69.20)	68.81 (59.14–78.48)	0.184
Nausea	17.09 (9.11–25.07)	23.65 (11.45–35.85)	0.346
Pain	47.43 (36.45–58.42)	54.83 (41.42–68.25)	0.384
Dyspnoea	41.02 (27.80–54.5)	26.88 (14.89–38.86)	0.182
Insomnia	40.17 (27.01–53.33)	50.53 (35.11–65.96)	0.300
Appetite	53.84 (39.90–67.78)	73.11 (60.32–85.91)	0.065
Constipation	40.17 (27.73–52.61)	36.55 (20.97–52.13)	0.710
Diarrhoea	17.09 (7.21–26.96)	32.25 (16.32–48.19)	0.137
Financial	17.09 (7.21–26.96)	18.27 (6.53–30.02)	0.875
Endpoint			
Physical	45.98 (36.47–55.49)	36.22 (24.08–48.35)	0.196
Role	21.79 (11.71–31.87)	22.58 (12.78–32.38)	0.911
Emotional	68.16 (59.48–76.83)	71.11 (61.31–80.90)	0.649
Cognitive	72.64 (66.03–79.26)	74.73 (66.10–83.35)	0.693
Global	56.62 (49.36–63.88)	42.47 (33.05–51.88)	0.016
Social	85.47 (78.01–92.92)	79.44 (67.58–91.30)	0.364
Fatigue	45.01 (36.19–53.83)	65.87 (52.50–79.23)	0.007
Nausea	14.52 (6.48–22.57)	21.50 (10.21–32.79)	0.298
Pain	36.32 (26.34–46.30)	47.31 (35.28–59.34)	0.154
Dyspnoea	35.04 (23.42–46.65)	21.50 (10.77–32.23)	0.094
Insomnia	27.35 (16.58–38.11)	39.78 (25.87–53.69)	0.149
Appetite	50.42 (36.65–64.20)	60.21 (44.93–75.49)	0.338
Constipation	35.89 (23.90–47.88)	34.40 (19.77–49.04)	0.872
Diarrhoea	15.38 (6.49–24.26)	27.95 (14.90–41.01)	0.099
Financial	12.82 (4.37–21.26)	18.27 (7.88–28.67)	0.405

vs. B+C) and duration of admission ($p=0.464$), there was a trend towards significance in the intervention group in relation to the same parameters ($p=0.085$).

QLQ-C30 analysis (Table 7) revealed statistically significant differences in baseline measures of global dimension between the two groups (Group I: 40.64–56.36 CI; Group II: 25.70–43.11 CI; $p=0.017$). Differences were also present in the social dimension (Group I: 77.42–93.51 CI; Group II: 55.85–82.85 CI; $p=0.039$). Statistically significant differences were observed between the two groups at the end of the study on the global scale (Group I had 49.36–63.88 CI and Group II had 33.05–51.88 CI, $p=0.016$) and on the fatigue scale (Group I had 36.19–53.83 CI and Group II had mean=65.87, 52.50–79.23 CI, $p=0.007$). It is worth highlighting that there was no statis-

tically significant difference in baseline levels of fatigue between groups.

The patients' assessment of the ice cream flavours in order of preference was: cream 31% (12), vanilla 17% (6), nougat 13% (5) and cinnamon and chocolate 11% (4 each).

The cost of the intervention with ice cream was 3 euros per day of admission for an average length of hospital stay of 9 days. The cost of the intervention with NS was 8 euros per day for an average hospital stay of 16 days.

Conclusions

An opportunistic nutritional intervention was carried out in a homogeneous population of patients with no significant

differences in any of the items analysed (Table 5). All patients were diagnosed, treated and followed at two different hospitals that act as a single functional unit. Both hospitals share the same criteria for the detection of malnutrition in admitted patients. The intervention consisted in the administration of classical NS and adapted ice cream to two groups of patients. Both groups showed a similar, albeit not significant, improvement in objective parameters of malnutrition such as albumin, cholesterol and triglycerides. These parameters were chosen because they were automatically registered in the haemogram performed upon admission and in order to avoid unnecessary test repetition. A statistically significant improvement in HADS test for anxiety and depression was observed in Group I with respect to the NS group.

The intensity of malnutrition measured by the PG-SGA before and after the nutritional intervention also showed a statistically significant improvement in both groups. Nonetheless, it should be stressed that the trend toward significance in improving the outcome of G-SGA after intervention with adapted ice cream was associated with fewer days of hospitalisation. This could be a factor to evaluate in further studies with larger numbers of patients.

Statistically significant improvements were observed in global QLQ and fatigue in Group I, but a baseline difference was already present in the global dimension. Nevertheless, in an interim analysis conducted with the final sample of Group I (N=39) and Group II (N=19), the global dimension of QLQ showed no statistical differences between the two groups, and homogeneity was maintained. However, at the end of the study period (Group II: NS=31), differences were found in global dimensions, as stated in the Results. The wide confidence intervals in Group II suggest that a possible explanation for this discrepancy may be the change of observer, as although the nurse had been trained in data collection, observer bias may have been introduced.

There is a strong link between cancer and malnutrition resulting in a common syndrome, cancer cachexia, which produces a lack of energy intake with the metabolic disturbances associated with cancer. Furthermore, malnutrition affects the course of cancer, increasing morbidity and mortality, implying a poor QOL [14] and increased health-care costs.

We should bear in mind that food not only fulfils a physiological function, but is also associated with culture and pleasure. Anthropologists and sociologists consider these functions basic to man as a social being. Hence, any positive nutritional intervention, especially in cancer patients, adds a benefit that is measurable with objective tests [15]. The ingestion of food not only nourishes us, but also activates a complex set of sensory messages that make up what we understand as the taste of food. In addition to the properties captured by taste and smell, the taste sensations of food integrate visual, somatoaesthetic (temperature, texture, etc.) and even hearing sensations. We speak of the taste of food as a biological condition which connects with

the cultural and psychological dimensions of eating. If we are offered two foods with the same calorific value, we will always choose the one that provides a greater sensory pleasure, as food is not limited to energy requirements. The sensations associated with the ingestion of ice cream include a perception of taste, cold on the tongue and oral cavity, different aromas, creamy texture or consistency while it melts in the mouth, producing a sensation of freshness and satiation and even a symbolic sense of happiness. This euphoriant effect has been associated with that produced by chocolate [16], although the chocolate flavour was only in the fifth place in the preferences of the patients in our intervention.

Although the administration of ice cream is a highly widespread empirical practice in the continuous care of advanced or terminal patients, to our knowledge, no studies published to date have prospectively and experimentally analysed the potential benefits of such an intervention. Our encouraging results in different dimensions associated with QLQ highlight the need for further scientific research in this field.

Nonetheless, despite the improvement such an intervention provides in various aspects of QLQ (including a reduction in anxiety and depression) in a population with advanced neoplastic disease, which no other active treatment seems to achieve, our study has several limitations. First, this was not a randomised study. Moreover, the number of patients was limited and the intervention and measurement of the improvement were performed over a short period of time. The latter two limitations were due to the fact that, in the planning of the study, we considered it essential for patients to be in an environment (a hospital inpatient ward) where control of administration and consumption of NS and ice cream could be adequately achieved. Admission also facilitated easy administration of tests. The fourth and final limitation of our study may be due to the advanced state of the vast majority of patients with stage IV cancer. Although the patients received the appropriate monitoring and support in both hospital outpatient clinics, it was expected that patients were admitted mainly because of symptoms associated with disease progression. This fact was probably not sufficiently taken into account in the planning of the study. Hence a significant proportion of the patients who agreed to participate, met the criteria and had signed the informed consent were only able to perform the test at baseline and were lost to follow-up.

These limitations should lead us to consider the good results obtained as exploratory or as a starting point for further studies with larger samples. Furthermore, increasing the follow-up period by several weeks would enable assessment of the validity of the data already obtained, or to extend the administration of the adapted ice cream to a group of patients with less advanced disease stages, without criteria of malnutrition, but whose treatment involves a high risk. NS would not be indicated in such patients as they are considered as “drugs” to be administered only in cases of objectively measured nutritional deficiencies. The

administration of ice cream would partly cover the fun and social aspect of food, improve the quality of life in cancer patients prior to the first signs of nutritional deficiency and may even delay its onset.

The secondary objective of this study was to estimate the cost of the intervention with adapted ice cream. Al-

though all the ice cream, transport and storage (refrigerator) were ceded to us free of charge, the cost-minimisation study was clearly positive.

Conflict of interest The authors declare that they have no conflict of interest relating to the publication of this manuscript.

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