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ORIGINAL

Survival of patients with advanced cancer in Enteral Nutritional Therapy: a comparison between caloric estimates

Sobrevida de pacientes com câncer avançado em Terapia Nutricional Enteral: um comparativo entre estimativas calóricas

Brenda Domingues WANDERLEY[1] 0000-0002-3679-0871
Rosane de Souza SANTOS[1] 0000-0002-9081-3501
Mariana Fernandes COSTA[1] 0000-0002-7702-1841

ABSTRACT

Objective

To assess factors related to the achievement of the caloric estimates of enteral nutritional therapy and the survival of patients with advanced cancer in exclusively palliative care.

Methods

Retrospective study, where patients using enteral nutrition admitted from March 2019 to February 2020 were divided into two groups: Group 1 included patients who reached 75% of the estimated caloric goals, and Group 2 included those who did not. The data were extracted from the patients' electronic medical records. Logistic regression analyzes were performed to assess associations between the studied sociodemographic, clinical, and nutritional variables, and the Kaplan-Meier curve and Cox regression were used to assess the survival of the groups.

Results

A total of 158 patients participated in the study, with a median age of 63 (IIQ: 55-70) years. 57% reached the caloric goal (Group 1). In the logistic regression, the functional capacity (OR: 5.82; CI: 2.28-14.84; p<0.001) and symptoms of

[1] Instituto Nacional de Câncer José Alencar Gomes da Silva, Hospital do Câncer IV, Setor de Nutrição Clínica. R. Visconde de Santa Isabel, 274, Vila Isabel, 20560-121, Rio de Janeiro, RJ, Brasil. Correspondence to: RS SANTOS. E-mail: <rosanerssoli@gmail.com>.

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nausea or vomiting (OR: 0.050; CI: 0.005-0.455; *p*=0.008) were independent variables for achieving the caloric goal. Cox regression showed Karnofsky Performance Status as an independent predictor for survival (HR: 1.85; CI: 1.13-3.04).

Conclusion

Patients with better functionality have longer survival and are potential candidates for reaching the caloric goals proposed by national and international guidelines for cancer patients.

Keywords: Enteral nutrition. Neoplasms. Palliative care. Quality indicators, health care. Survival.

RESUMO

Objetivo

Avaliar os fatores relacionados ao alcance das estimativas calóricas da terapia nutricional enteral e a sobrevida dos pacientes com câncer avançado em cuidados paliativos exclusivos.

Métodos

Estudo retrospectivo no qual pacientes em uso de nutrição enteral internados no período de março de 2019 a fevereiro de 2020 foram divididos em dois grupos: Grupo 1, composto por pacientes que atingiram 75% das metas calóricas estimadas, e Grupo 2, composto por aqueles que não atingiram. Os dados foram extraídos do prontuário eletrônico dos pacientes. Análises de regressão logística foram realizadas para avaliar associações entre as variáveis sociodemográficas, clínicas e nutricionais estudadas, e a curva de Kaplan-Meier e regressão de Cox foram usadas para avaliar a sobrevida dos grupos.

Resultados

Participaram do estudo 158 pacientes, com mediana de idade de 63 (IIQ:55-70) anos. Cinquenta e sete por cento dos pacientes atingiram a meta calórica (Grupo 1). Na regressão logística, a capacidade funcional (OR:5,82; IC: 2,28-14,84; p<0,001) e os sintomas náuseas ou vômitos (OR:0,050; IC:0,005-0,455; p=0,008) se mostraram variáveis independentes para o alcance da meta calórica. A regressão de Cox mostrou o Karnofsky Performance Status como preditor independente para sobrevida (HR: 1,85; IC: 1,13-3,04).

Conclusão

Pacientes com melhor funcionalidade possuem sobrevida maior e são potenciais candidatos ao alcance das metas calóricas propostas por diretrizes nacionais e internacionais para pacientes com câncer em terapia nutricional enteral.

Palavras-chave: *Nutrição enteral. Neoplasia. Cuidados paliativos. Indicadores de qualidade em assistência à saúde. Sobrevida.*

INTRODUCTION

Patients with advanced cancer usually present nutritional deficiencies and metabolic syndromes that lead to poor life qualities. These are related either to the treatment, the progression of the disease, or even depression, all of which hinder adequate oral intake [1,2]. Nutrition is central in these patients' lives, going beyond the function of energy supply and allowing a better quality of life and comfort [2,3]. In this context, Enteral Nutritional Therapy (ENT) is a clinical tool when patients cannot ingest food orally or when their intake capacities have been below 60% for a period of two weeks [4].

Recommending ENT for advanced cancer patients in exclusively palliative care is not an easy decision and should not be done in isolation. It requires a reflection from both clinical and bioethical points of view and consideration of the patient's nutritional status and functional ability [3]. Its prescription and continuity in palliative care is a complex and controversial theme [5]. Thus, adequate criteria are needed to identify eligible patients for nutritional enteral nutrition, avoiding therapeutical futility [6].

Patients with advanced cancer present intense and systemic inflammatory responses relevant to the progression of the disease and symptoms. These may lead to worsened functional abilities such as the

reduction of the individual's autonomy and self-care. Thus, observing these patients' inflammatory markers is important for prognostic evaluation [7,8].

To improve life quality and reduce the severity of symptoms, ENT may be monitored in hospital environments. The International Life Sciences Institute of Brazil, ILSI – suggested 32 quality indicators of ENT, the Indicators of Quality in Nutritional Therapy (IQTNs), which constitute quantitative criteria to help health professionals manage the patient's clinical and nutritional status, avoiding complications and making adaptation to the treatments easier. So far, few studies used IQTNs in monitoring the nutritional therapy in patients with advanced cancer [9-11].

Thus, the goal of this study is to evaluate the factors related to reaching caloric estimates in enteral nutritional therapy and the survival of advanced cancer patients in exclusively palliative care.

METHODS

This is a longitudinal retrospective study carried out in the unit of exclusive palliative care of the national center of reference for the control of cancer, located in *Rio de Janeiro*, Brazil.

The study included patients admitted in the hospital from March 2019 to February 2020 with advanced malignant tumors in any location in the body, from both sexes, who were 18 years old or older, and who had nasoenteric or nasogastric tubes, gastrostomy, or jejunostomy for the infusion of enteral diets. The criteria for exclusion were patients with associated oral nutrition for complementing the energy intake and/or within less than 72 hours of ENT administration. From the patients' records, we collected their age, sex, anthropometric variables (body weight and related stature or the last measured values), the volume of prescribed and administered diets, route of administration, and complications during the administration of the diet.

At the beginning of the ENT, the Karnofsky Performance Status (KPS) was used to evaluate the patients' functional capacity, varying from 0 to 100% with 10% increments in between. Each increment describes how much the patient can carry out daily activities independently. For instance, a 30% punctuation indicates a patient who is very unable in that sense and with hospitalization needs [12]. The Modified Glasgow Prognostic Score (mGPS) evaluated the patients' inflammatory status with the serum values of Albumin and C-Reactive Proteins (CRP) until 15 days before the beginning of ENT. The mGPS result was 2 when the Albumin and CRP values were <3.5mg/dL and >10mg/L; 1 for concentration of albumin ≥3.5mg/dL and CRP>10mg/L; and the mGPS was 0 if the CRP was ≤10mg/L. Thus, the larger the mGPS values, the greater the inflammatory response [13]. When the patients' serum values of albumin and CRP were not available, they were excluded from the analysis.

The outcomes of release or death were analyzed, and the survival was calculated in days after the ENT patient's inclusion in the study until his or her death or end of follow-up within 60 days. Five IQTNs proposed by ILSI – Brazil were selected from a preliminary study with patients in exclusively palliative cancer care (Chart 1) [14].

To calculate the adequacy of nutritional needs (caloric and protein), we considered the recommendations for cancer patients of 25 to 30Kcal/kg/day and 1.2 to 1.5g of protein/kg of body weight [4,15]. Patients were divided into two groups: Group 1: patients who reached an average of 75% of these estimated caloric needs during the hospital stay; and Group 2: patients who reached less than 75% of energy adequation, according to what ILSI – Brazil understands as an adequate caloric administration [11].

Chart 1 – Indicators used to evaluate the quality of the enteral nutrition therapy. *Rio de Janeiro* (RJ), Brazil, 2020.

Indicators	Formula	Goal	Results
Frequency of measurement or estimation of energy expenditure and protein need	Number of patients in ENT who had their energetic and protein expenditure evaluated X 100/Total patients in ENT	80%	58%
Frequency (in days) of adequate administration of the prescribed X infused volumes*	Number of days with adequate ENT volume X 100/Total number of days in ENT	≥80%	89%
Frequency (in days) of inadequate administration of protein	Number of days with protein intake <100% of the prescription X 100/Total number of days in ENT	≤10%	84%
Frequency (in days) of inadequate administration of energy	Number of days with caloric intake below 25% of 25Kcal/kg or above 25% of 30Kcal/kg x 100/ Total number of days in ENT	<20%	45%
Frequency of episodes of abdominal distension	Number of patients in ENT who presented abdominal distension X 100/Total patients in ENT	<15%	8%

Note: *Adapted formula. ENT: Enteral Nutrition Therapy.

The data were analyzed in IBM SPSS Statistics (version 2.0). The Kolmogorov-Smirnov was applied for the distribution of variables. The descriptive analysis was presented in percentages for the categorical variables and median and interquartile range for continuous variables.

We applied a logistic regression model to identify the factors associated with obtaining the energy needs estimated by ENT. The variables with $p \leq 0.20$ in univariate analysis were included in the multivariate analysis. The final model was obtained with the Backward procedure and considered $p<0.05$ statistically significant.

The analysis of survival was carried out with the Kaplan-Meier curve and the log-rank test was used to compare the survival curves according to the reach of caloric goals (or lack thereof). Besides, univariate and multivariate Cox regressions were used to verify the factors associated with death in the group that reached 75% of the caloric estimated goal.

This work was elaborated with respect to the Guidelines for Research with Human Beings (CNS resolution 466/12) and approved by the Ethics Committee in Research of the *Instituto Nacional de Câncer José Alencar Gomes da Silva* (INCA, National Institute of Cancer) (CAAE: 32114620.9.0000.5274).

RESULTS

We evaluated 158 patients with an average age of 63 (IIQ:55-70) years old, 73.4% of whom were male. The mGPS was calculated for 101 patients and presented a score of 1 or 2 in 54.5% of them. Regarding the patients' functional ability, 72 (45.6%) of them presented a KPS between 40-50%. We observed that 57% (n=90) of the patients reached the proposed calorie needs (Group 1) and that head and neck tumors were predominant in the study (69%), with total dysphagia, found in 58.2% of the patients, being the most common cause for prescribing ENT.

Enteral Nutritional Therapy was administered for 7 days (IQR:4-14), supplying 45g of protein (IIQ:38-59) and 20Kcal/kg/day (IIQ:14-24) in a daily diet volume of 833ml (IIQ:667-959). Among the possible complications during ENT that may lead to its interruption, only 13 patients presented abdominal distensions, and 13 presented nausea or vomits. The deliberation of "end-of-life care" was the factor of diet suspension for 55 patients (Table 1).

Chart 1 contains the results of the IQTNs used in the study and their formulas and respective goals. As can be seen, the adequate frequency of administration of the prescribed volume versus the infused volume and the frequency of episodes of abdominal distension among those who reached the goals (>80%

Table 1 – Clinical and pathological characteristics of patients in enteral nutrition therapy with advanced cancer in exclusively palliative care. *Rio de Janeiro* (RJ), Brazil, 2020.

Variables	N	%	Median	IQR
Sex				
Male	116	73.4		
Female	42	26.6		
Age			63	55-70
<60 years	60	38		
≥60 years	98	62		
Caloric goals				
Yes	90	57		
No	68	43		
mGPS (n=101)				
0	46	45.5		
1 e 2	55	54.5		
KPS			40	30-50
≤30%	69	43.7		
40-50%	72	45.6		
≥60%	17	10.7		
Tumoral location				
Head and neck	109	69		
Gastro-intestinal tract	20	12.7		
Neurologic	10	6.3		
Breasts	4	2.5		
Other	15	9.5		
Reason for ENT				
Total dysphagia	92	58.2		
Partial dysphagia	50	31.6		
Gastric or bowel Obstruction	7	4.4		
Lowering of the level of consciousness	9	5.7		
Administration				
Naso-entheric catheter	100	63.3		
Gastrostomy	57	36.1		
Jejunostomy	1	0.6		
ENT Complications (n=96)				
Abdominal distension	13	13.5		
Tube obstruction	7	7.3		
Tube exit	8	8.3		
Nausea or vomit	13	13.5		
End-life care	55	57.3		
ENT Characteristics				
Duration of ENT (days)			7	4-14
Administered volume (mL/day)			833	667-959
Administered protein (g/day)			45	38-59
Administered Calories /weight (Kcal/kg/day)			20	15-24
Survival (days)			19	8-45

Note: ENT: Enteral Nutrition Therapy; IQR: Interquartile Range; KPS: Karnofsky Performance Status; mGPS: Modified Glasgow Prognosis Score.

and <15%, respectively). However, the frequencies of inadequate protein and energy administration in days disagreed with the goals proposed for these indicators, as did the frequency with which the energetic expenditure and protein needs were estimated.

In the multivariate analysis, only KPS (OR:5.82; CI:2.28-154.84; p<0.001) and the symptoms of nausea and vomit (OR:0.050; CI:0.005-0.455; p=0.008) appeared as independent variables for reaching the proposed caloric goal (Table 2).

Table 2 – Univariate and multivariate analysis of caloric adequation in ENT, estimated with the reach of 75% of the caloric goals and variables of study. *Rio de Janeiro* (RJ), Brazil, 2020.

Variables	Univariate (n=90)			Multivariate (n=90)		
	OR	95%CI	*p*-value	OR	95%CI	*p*-value
Age ≥60 years	0.91	0.48-1.75	0.785	–		–
Female	0.77	0.38-1.57	0.776	–		–
KPS ≥40%	2.69	1.40-5.15	0.003	5.82	2.28-14.84	<0.001
mGPS ≥1	0.61	0.28-1.29	0.2	–		–
Survival ≤20 days	0.46	0.24-0.88	0.02	–		–
Abdominal distension	0.30	0.90-1.04	0.057	–		–
Catheter obstruction	0.55	0.12-2.55	0.447	–		–
Unintended cateter exit	0.23	0.05-1.20	0.082	–		–
Nausea or vomit	0.20	0.05-0.76	0.018	0.05	0.01-0.45	0.008

Note: CI: Confidence Interval; KPS: Karnofsky Performance Status; mGPS: Modified Glasgow Prognosis Score.

The survival of the sample was of 19 (3-45) days. Analyzing the 60-day survival of patients who received at least 75% of their estimated caloric needs (Group 1), we notice the larger survival of these patients when compared to Group 2, as shown in Figure 1. After the exclusion of confounding factors, Cox multivariate regression suggested that KPS may act as an independent predictor for survival (HR:1,85; CI:1,13-3,04) (Table 3).

Table 3 – Cox's regression model for survival. *Rio de Janeiro* (RJ), Brazil, 2020.

Variables	Univariate (n=90)			Multivariate (n=90)		
	HR	95%CI	*p*-value	HR	95%CI	*p*-value
Age ≥ 60	1.11	0.74-1.67	0.600	–		–
Female	1.16	0.76-1.78	0.485	–		–
KPS ≥ 40	1.68	1.13-2.49	0.010	1.85	1.13-3.04	0.015
mGPS ≥ 1	1.45	0.90-2.35	0.125	–		–
Abdominal distension	0.87	0.44-1.75	0.710	–		–
Catheter obstruction	0.57	0.21-1.56	0.274	–		–
Unintended catheter exit	1.23	0.57-2.69	0.600	–		–
Nausea or vomits	1.19	0.62-2.28	0.590	–		–

Note: HR: Hazard Ratio; KPS: Karnofsky Performance Status; mGPS: modified Glasgow Prognosis Score.

DISCUSSION

The present study evaluated the survival rates of advanced cancer patients with ENT and the factors related to the reach of estimated caloric needs. Our findings show that patients with caloric adaptation in ENT present improved survival rates, and KPS ≥ 40% was associated with that outcome.

Thus, the decision-making for starting ENT must be precocious, respecting the functionality of the gastrointestinal tract, but also the patient's clinical condition, functional ability, life expectancy, and reflecting on bioethical principles of autonomy, beneficence, non-maleficence, and justice for the patient [16].

According to the European Society for Clinical Nutrition and Metabolism (ESPEN, 2017), if the expected survival is of several months or years, ENT is suggested to ensure the adequate intake of energy and protein and maintain an adequate performance state and quality of life [17]. For patients with shorter

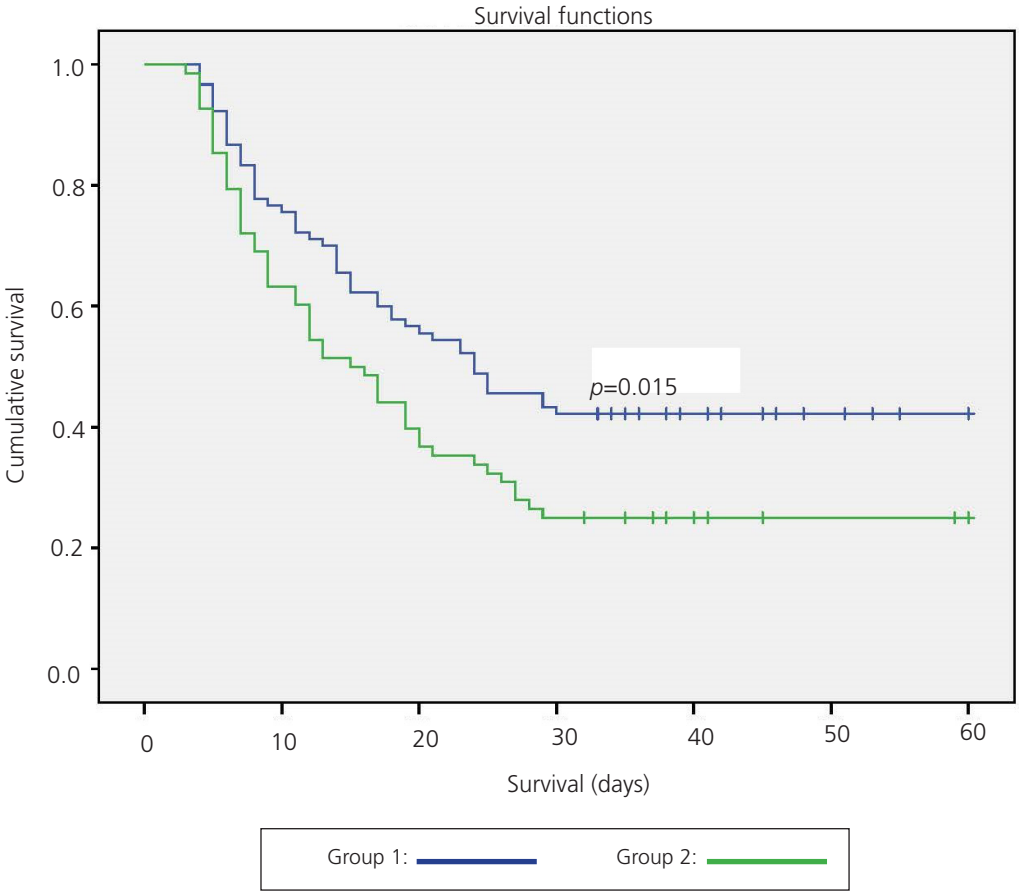

Figure 1 – Survival curve in 60 days according to the reach of the caloric goal. *Rio de Janeiro* (RJ), Brazil, 2020.
Note: Group 1: ≥75% of the caloric goal; Group 2: <75%.

life expectancies, relieving symptoms with nutritional impact might mitigate suffering. In these cases, ENT may be a measure of comfort – and no longer of nutritional support. Consequently, the goals, pros and cons of nutritional treatment must be explained to patients, families, and overseeing teams. Suspending ENT in patients in palliative care is to be evaluated, especially when there are complications and in end-of-life processes, as the hypometabolism characteristic of terminality may make the regular quantities of energy and substrates excessive, inducing metabolic stress – as our essay on suspending ENT in "end-of-life care" patients (imminent risk of death) shows [17].

In this perspective, patients with advanced cancer must receive nutritional interventions if the expected positive outcomes overweight the harmful ones and provided that the patient accepts it [4,18]. However, the biggest challenge is to identify patients within performance and staging states of the disease that allow them to survive for more than three months [19]. The patient's prognosis is determinant for clinical decision-making in advanced-stage and progressing disease [20]. It usually includes factors related to the patient like functional ability, dyspnea, delirium, anorexia/cancer cachexia, and may be evaluated with clinical abnormalities using markers of inflammatory response, like high C-reactive protein [21].

Karnofsky Performance Status assesses the patients' functionality through a function of capacity scale ranging from 10 to 100% [12]. Its lowest scores are related to a worse prognosis; thus, it is less likely that these patients benefit from more aggressive nutritional support [17,22]. As this study shows, most

patients with KPS≥40% were able to obtain the estimated caloric needs and presented longer survival periods. Consequently, they benefited more from ENT. Ruggeri *et al.* [6] also found patients with more elevated KPS to have longer survival rates during ENT. Thus, controlling symptoms and providing adequate nutritional interventions to improve these patients' life expectancy and quality is extremely relevant [8].

The systemic inflammation that may occur in these patients is estimated by measuring the serum values of C-reactive protein and albumin. The classification of the inflammatory response with mGPS is a strong predictor of morbidity and death in patients with cancer [17]. However, it was not considered decisive for survival or caloric expectation outreach in our study.

Among the evaluated patients, 69% presented tumors in the head and neck. It is known that these patients frequently present nutritional status depletion and found it difficult to ingest food even before the oncologic treatment due to the tumor's anatomic location. This makes them easily eligible for ENT [23]. Also, about 10% of the people in this group require a permanent or long-term accessory route for consuming food [24]. Finally, 58.2% of the sample had total dysphasia as the reason for starting ENT.

Among the five IQTNs selected for the study, the frequency of administration of the prescribed versus the infused volume was above the 80% goal. However, regarding the inadequacy of energy and protein, our results were below the goals, like those of Lee *et al.* [10], who identified a deficit of 363.3±214.1Kcal, and 14.2±8.41g of protein in patients with cancer in nutritional risk. In their study of the intensive care unit in *Campo Grande*, State of *Mato Grosso do Sul*, Rosa *et al.* [25] also found different results for IQTNs related to energy and protein support, obtaining a larger index of nonconformity (20.0%) than the goal established by ILSI-Brazil. Previous research carried out in the same Hospital Unit also presented inadequate frequencies of administration (in days) of energy (57.4%) and protein (25.5%) [14].

Energy-protein deficiencies in ENT may contribute to worsening the nutritional state and life quality of patients, showing the importance of applying IQTNs and their controls in clinical practice to evaluate, intervene, and improve ENT's adequation [26]. Our findings corroborate that the IQTNs proposed by ILSI – Brazil may certify the efficacy of hospital attention, reduce costs, improve the capacity of process analysis, and lead to better clinical results [27].

Patients with cancer are not always able to tolerate the amount of enteral nutrition infusion required to meet their nutritional needs, usually due to peritoneal carcinomatosis and/or intra-abdominal recurrences, besides the complications of ENT itself like precocious satiety, retarded gastric emptying, abdominal distension, nausea, and vomits, which occur in about 20% of the patients receiving ENT [4,18,28]. In our study, patients with nausea or vomiting received nutritional inputs below the estimated, and these symptoms have been correlated with ENT's complications as one of the main causes for its interruption or suspension.

The study's limitations are its inclusion of only one care center, its type (retrospective), the sample's heterogeneity, and the secondary data collection. Nevertheless, we presented the scenario of ENT for this group of patients and identified aspects to be refashioned.

CONCLUSION

Our findings show that more functional patients have longer life expectancies and are potential candidates for reaching the caloric goals proposed by national and international guidelines for patients with

cancer and in ENT. A longitudinal approach that considers the psychosocial issues in nutrition and life quality is necessary for handling the nutritional support in advanced cancer patients in palliative care.

CONTRIBUTORS

The study was conceived and planned by BD WANDERLEY, RS SANTOS, and MF COSTA. WANDERLEY and SANTOS collected and analyzed the data. The three authors worked in the interpretation, writing, and critical review of the manuscript's content.

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